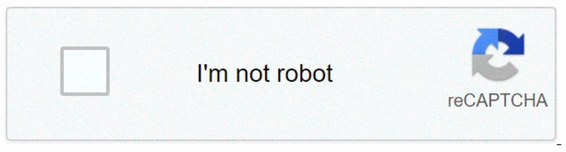

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Manual book sysmex xn 1000

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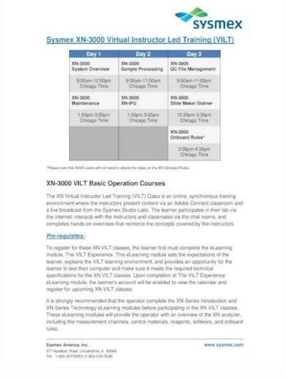

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2-1 Installation. . . . . .
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XN-1000 Instructions for Use Revised August 2012 Chapter 1 Introduction Chapter 1 Introduction Thank you for purchasing the XN series automated hematology analyzer. Please read this manual carefully before operating this product. Keep this manual in a safe place for future reference. Note: • Data generated by the XN series is not intended to replace professional judgment in the determination of a diagnosis or in monitoring patient therapy. • Operate the instrument as instructed. Reliability of test results cannot be guaranteed if there are any deviations from the instructions in this manual. If the instrument fails to function properly as a result of either the user's operation not specified in the manual or the user's utilization of a program not specified by Sysmex, the product warranty would not apply. Contact Address Manufacturer SYSMEX CORPORATION 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan Authorized Representative European Representative SYSMEX EUROPE GmbH EC REP Bornbarch 1, 22848 Norderstedt, Germany Phone: +49 40 5 27 26-0 / Fax: +49 40 5 27 26-100 Americas SYSMEX AMERICA, Inc. 577 Aptakisic Road, Lincolnshire, IL 60069, U.S.A. Phone: +1-224-543-9500 / Fax: +1-224-543-9505 Asia-Pacific SYSMEX ASIA PACIFIC PTE LTD. 9 Tampines Grande #06-18 Singapore 528735 Phone: +65-6221-3629 / Fax: +65-6221-3687 Ordering of Supplies and Replacement Parts If you need to order supplies or replacement parts, please contact your local Sysmex representative. Service and Maintenance Please contact the Service Department of local Sysmex representative. CE-mark The IVD-system described in this manual is marked with a CE-mark which confirms the observance of the essential requirements of the following European directive: 98/79/EC IVD Directive 1-1 XN-1000 Instructions for Use Revised August 2013 Chapter 1 1.1 Introduction Intended use The XN series is an automated hematology analyzer for in vitro diagnostic use in clinical laboratories. Only human blood, human body fluids or control blood should be run. Any other use is regarded as non-specified. Use only the reagents and cleaning fluids mentioned in this manual. If the instrument fails to function properly as a result of either the user's operation not specified in the manual or the user's utilization of a program not specified by Sysmex, the product warranty would not apply. 1.2 Overview of the system This instrument is a blood count analyzer for in vitro diagnostic use in screening patient populations found in clinical laboratories. This instrument enables quantitative, identification, and existence ratio analysis and flagging of tangible components of blood and body fluid (red blood cells, white blood cells, platelets and other cells) by means of electrical impedance, laser light scattering, and dye bonding. The analysis data appears on the screen of the IPU (Information Processing Unit)*. * This manual refers to the Information Processing Unit as IPU. The XN series consists of the components and options below, which are used in a suitable combination. The components and options may be sold as individual units. • Analyzer (XN-10/20) • Sampler section (SA-10/SA-01/SA-20/SA-30) • IPU • Pneumatic unit • SP-10 • Additional components Analyzers are classified into 6 types depending on differences in the included channels. • XN-10: XN-10[B1], XN-10[B2], XN-10[B3], XN-10[B4] • XN-20: XN-20[A1], XN-20[A2] Analyzer Type Channels XN-20 [A1] XN-10 [A2] [B1] WNR ✓ RBC / PLT ✓ HGB ✓ WDF ✓ [B2] [B3] [B4] WPC ✓ ✓ — — — — RET ✓ ✓ ✓ — ✓ — PLT-F ✓ — ✓ ✓ — — 1-2 XN-1000 Instructions for Use Revised August 2012 Chapter 1 1.2.1 Introduction Configuration description System expansion is possible by combining components and options. The system name varies depending on the combination. This manual explains the system configuration below (XN-1000). XN-1000 System including 1 analyzer (XN-10/XN-20) and a sampler (SA-10/SA-01). This will be one of the configurations below, depending on your sampler type.

Analyzer (XN-10/XN-20) Sampler section (SA-10) Sampler section (SA-01) * IPU and pneumatic unit are omitted in this figure. External view of XN-1000 1-3 XN-1000 Instructions for Use Revised August 2012 Chapter 1 1.3 Introduction Analysis parameters This instrument analyzes the following parameters. [Whole Blood]/[Low WBC]/[Pre-Dilution] mode XN-20 XN-10 Parameters [A1] [A2] [B1] [B2] WBC White blood cell (leukocyte) count ✓ RBC Red blood cell (erythrocyte) count ✓ HGB Hemoglobin concentration ✓ HCT Hematocrit ✓ MCV Mean corpuscular volume ✓ MCH Mean corpuscular hemoglobin ✓ MCHC Mean corpuscular hemoglobin concentration ✓ PLT Platelet count ✓ RDW-SD Red cell distribution width (standard deviation) ✓ RDW-CV Red cell distribution width (coefficient of variation) ✓ PDW Platelet distribution width ✓ MPV Mean platelet volume ✓ P-LCR Platelet-large cell ratio ✓ PCT Plateletcrit ✓ NRBC# Nucleated red blood cell count ✓ NRBC% Nucleated red blood cell percent ✓ NEUT# Neutrophil count ✓ LYMPH# Lymphocyte count ✓ MONO# Monocyte count ✓ EO# Eosinophil count ✓ BASO# Basophil count ✓ NEUT% Neutrophil percent ✓ LYMPH% Lymphocyte percent ✓ MONO% Monocyte percent ✓ EO% Eosinophil percent ✓ BASO% Basophil percent ✓ IG# Immature granulocyte count ✓ IG% Immature granulocyte percent ✓ [B3] [B4] 1-4 XN-1000 Instructions for Use Revised May 2014 Chapter 1 XN-20 Introduction XN-10 Parameters [A1] [A2] [B1] [B2] [B3] [B4] NEUT-RI* Neutrophil reactivity intensity ✓ NEUT-GI* Neutrophil granularity intensity ✓ RET% Reticulocyte percent ✓ ✓ ✓ — ✓ — RET# Reticulocyte count ✓ ✓ ✓ — ✓ — IRF Immature reticulocyte fraction ✓ ✓ ✓ — ✓ — LFR Low fluorescence ratio ✓ ✓ ✓ — ✓ — MFR Medium fluorescence ratio ✓ ✓ ✓ — ✓ — HFR High fluorescence ratio ✓ ✓ ✓ — ✓ — RET-He Reticulocyte hemoglobin equivalent ✓ ✓ ✓ — ✓ — RBC-He Mature RBC hemoglobin equivalent ✓ ✓ ✓ — ✓ — Delta-He Parameter calculated by an equation of RET-He - RBC-He ✓ ✓ ✓ — ✓ — IPF Immature platelet fraction ✓ — ✓ ✓ — — [B3] [B4] * The availability of these functions depends on your system configuration. [Body Fluid] mode XN-20 XN-10 Parameters [A1] [A2] [B1] [B2] WBC-BF White blood cell (leukocyte) count ✓ RBC-BF Red blood cell (erythrocyte) count ✓ MN# Mononuclear count ✓ PMN# Polymorphonuclear count ✓ MN% Mononuclear percent ✓ PMN% Polymorphonuclear percent ✓ TC-BF# Total nucleated cell count ✓ * The body fluid analysis can only be performed if the instrument offers the body fluid analysis mode. [HPC] mode XN-20 XN-10 Parameters HPC# [A1] [A2] [B1] [B2] [B3] [B4] ✓ ✓ — — — — Hematopoietic progenitor cell count Other parameters are the same as in [Whole Blood] mode. * HPC analysis can only be performed if the instrument offers the HPC analysis mode. 1-5 XN-1000 Instructions for Use Revised May 2014 Chapter 1 1.4 Introduction About the manuals 1.4.1 List of manuals The following manuals are provided with this instrument. Each manual is bound and included in the product; however, a manual with the same content is also built into the IPU.

For procedures on viewing the manual, see Chapter 6. (➤P.6-21 "Chapter 6: 6.8 On-line manuals") • Instructions for Use (this manual) This manual explains how to operate the instrument, focusing primarily on routine work. • Administrator's Guide This manual explains the operations such as configuration of the instrument. 1.4.2 Structure of this manual This manual consists of the following chapters. Chapter Description Chapter 1: Introduction Explains an overview of this manual and of the instrument. Chapter 2: Safety Information Explains precautions to be observed for safe use of the instrument, and also explains the meaning of the safety symbols that appear on the instrument. Chapter 3: Before using the system Explains information you should know before using the system. Chapter 4: Part Names and Functions Explains external views, names and functions of each of the devices connected to the instrument. Chapter 5: Reagents Explains the reagents to be used in the instrument. Chapter 6: Basic Operation Explains how to perform basic operations, such as start-up, shut-down of the system. Chapter 7: Preparing for analysis (registering information) Explains how to register and manage analysis orders, patient information, doctor information, and ward information. Chapter 8: Performing Quality Control Explains how to perform regular administrative tasks to ensure reliable analysis results.

Chapter 9: Analyzing samples Explains how to analyze samples. Chapter 10: Checking analysis data (Sample Explorer) Explains the Sample Explorer function used to check and manage the analysis data in list format. Chapter 11: Checking detailed analysis information (Data Browser) Explains the Data Browser function used to check and manage the detailed information of the analysis data. Chapter 12: Performing Calibration Explains the calibration function used to ensure the accuracy of the instrument. Chapter 13: Performing maintenance of instrument and replacing supply parts Explains an overview of the maintenance tasks for the instrument and explains how to perform those tasks, including the replacement of reagents and supply parts. 1-6 XN-1000 Instructions for Use Revised August 2012 Chapter 1 Chapter Introduction Description Chapter 14: Troubleshooting Explains the errors that may occur in the system and how to troubleshoot them. Chapter 15: Technical Information Explains technical information such as specifications and principles. 1.4.3 Points to note about this manual • You may not reprint the contents of this manual in whole or in part without permission. • The names of patients, doctors, etc., mentioned in this manual do not represent actual people in any way. • Images and certain details related to product are for illustration purposes only and may not exactly match with what is indicated within this manual. • The screens used in this manual are for Windows 7. 1.5 Symbols used in this manual Note, Information, Caution and Warning statements are presented throughout this manual to call attention to important safety and operational information.

Non-compliance with this information compromises the safety features incorporated in the analyzer. Risk of infection Indicates the presence of a biohazardous material or condition. Warning! High risk. Ignoring this warning could result in personal injury to the operator. Caution! Average risk. Ignoring this warning could result in property damage. To avoid damage and incorrect measuring results. Information Minor risk.

Considerations that should be observed when operating this instrument. Note: Background information and practical tips. 1-7 XN-1000 Instructions for Use Revised May 2014 Chapter 1 Introduction Indicates that the operation supports the touchscreen. 1.6 Trademarks • Sysmex is a registered trademark of SYSMEX CORPORATION, Japan.

• CELLPACK, CELLCLEAN, Fluorocell, SULFOLYSER, and Lysercell are trademarks of SYSMEX CORPORATION. • ISBT128 (International Society of Blood Transfusion) is copyrighted by and is used under License Agreement with ICCBBA, Inc. • Windows is a trademark or registered trademark of Microsoft Corporation in the United States and other countries.

Other company names and product names in this manual are the trademarks or registered trademarks of their respective owners. The fact that a trademark is not explicitly indicated in this manual does not authorize its use. TM and ® are not explicitly indicated in this manual. 1-8 XN-1000 Instructions for Use Revised August 2012 Chapter 2 Safety Information Chapter 2 Safety Information This chapter explains precautions for safe use of this instrument.

2.1 General information Warning! • Keep your hair, fingers and pieces of your clothing away from the instrument while it is running. You may get injured by getting them caught in the instrument. • Do not spill blood samples or reagents into the instrument, or get any metals, such as staples and clips, inside the instrument. Doing so could cause a short-circuit. • The operator should not touch any electrical circuitry inside the cover. In particular, the risk of electrical shock is especially high when one's hands are wet. • Avoid damage to the power cable: do not place any heavy object on the power cable or pull on it. Doing so may cause a fire or shock due to an electrical short or a break in the wiring. • In the unlikely event that the instrument emits an unusual odor or smoke, immediately turn OFF the main switch and unplug the power cable. Then contact Sysmex service representative. Continued use of the instrument in such conditions could result in fire, electrical shock or personal injury. Caution! • Never touch the sample rack while the instrument is working. Touching a rack or a sample tube especially when the rack is moving could cause sample spillage. • Do not lean against the instrument. The resulting impact could damage the instrument or cause it to tip over. 2.2 Installation Warning! • The unpacking, setup and confirmation of correct initial operation is performed under the direction of Sysmex technical service. • This instrument must not be connected to a power outlet rated at anything other than specified in the rated plate. Please note that the instrument must be grounded. Failure to do so may cause a fire or electrical shock. • Switch OFF the power supply before connecting any peripheral devices (host computer, printer, etc.). This is to prevent electrical shock hazard. If a peripheral device is connected after the instrument is started up, the instrument may stop abnormally. 2-1 XN-1000 Instructions for Use Revised August 2012 Chapter 2 Safety Information Caution! • Install the instrument in a place protected from water splashes. • Install in a place where the instrument will be protected from high temperature, humidity, dust and direct sunlight. • Install the instrument in a location that is free from any strong shock or vibration. • Install the instrument in a well ventilated place. • Avoid installation of the instrument near devices that emit electrical interference, such as radio, centrifuge, etc. • Do not use this instrument in any operating environment which has electroconductive or flammable gases, including oxygen, hydrogen, and anesthesia. 2.3 Electromagnetic compatibility (EMC) This instrument complies with the following IEC (EN) standards: • IEC61326-2-6:2005 (EN61326-2-6:2006) Electrical equipment for measurement, control and laboratory use - EMC requirements • EMI (Electromagnetic Interference) For this standard the requirements of class A are fulfilled.

• EMS (Electromagnetic Susceptibility) For this standard the minimum requirements with regards to immunity are fulfilled. • This equipment has been designed and tested to CISPR11 Class A. In a domestic environment it may cause a radio interference, in which case, you may need to take measures to mitigate the interference. The electromagnetic environment should be evaluated prior to operation of the device. Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation. This instrument includes an RFID(Radio-Frequency Identification Device) module. • RFID device: TR3-C202-A0-8 • Intended use: This RFID module is an electromagnetic induction type non-contact IC can read and write RFID tag data. • This instrument complies with IDA Standards. • The compliance mark indicates that the product complies with the applicable standard and establishes a traceable link between the equipment and the manufacturer, importer or their agent responsible for compliance and for placing it on the Australian and New Zealand market. Caution! This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment.

This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense. 2-2 XN-1000 Instructions for Use Revised August 2012 Chapter 2 2.4 Safety Information Avoiding infections Risk of infection • When performing any task on the instrument, such as testing, maintenance, preparation, or post processing, be sure to wear protective garments and gloves.

Also, wash your hands after completing the process. There is a risk of infection.

• Never touch waste, or parts that have come in contact with waste, with your bare hands. If you inadvertently come in contact with potentially infectious materials or surfaces, immediately rinse the skin with large amounts of water, then follow your laboratory's prescribed cleaning and decontamination procedures. • Use appropriate care when handling samples and quality control materials. In the unlikely event that some infectious material gets in the eyes or an open wound, rinse with large amounts of water and seek immediate medical attention. 2.5 Handling of reagents and quality control materials Warning! • CELLPACK diluent is a good electrical conductor. If diluent is spilled inadvertently near electrical cables or appliances, there is a risk of electrical shock.

Switch the instrument off, unplug it and wipe-up the liquid. • CELLCLEAN AUTO contains sodium hypochlorite.

If CELLCLEAN AUTO comes in contact with the instrument's surface, it may corrode its finish. Immediately wipe off CELLCLEAN AUTO with a damp cloth. Caution! Follow directions on QC material labeling. For other cautionary points, see Chapter 5. (➤P.5-1"Chapter 5: Reagents") 2.6 Laser Warning! The analyzers have a semiconductor laser unit that is located inside the instrument. To avoid physical risk of injury from the laser, access is limited to authorized Sysmex technical representative. 2-3 XN-1000 Instructions for Use Revised August 2012 Chapter 2 2.7 Safety Information Maintenance Information When performing maintenance, use only the tools specially authorized by Sysmex. 2.8 Disposal of materials 2.8.1 Waste Disposal Risk of infection After becoming waste at end-of-life, this instrument and its accessories are regarded as infectious. They are therefore exempted from EU directive 2012/19/EU (Waste Electrical and Electronic Equipment Directive) and may not be collected by public recycling to prevent possible risk of infection of personnel working at those recycling facilities. Warning! • Do not dispose the instrument, accessories and consumables via public recycling! • Incineration of contaminated parts is recommended! • Contact your local Sysmex service representative and receive further instructions for disposal! Follow local legal requirements at all times. Caution! Waste effluents from the instrument may contain dangerous substances in it and decision about disposal only has to be made by local water authority.

2.8.2 Decontamination Warning! Before decontaminating the instrument, be sure to turn off the power supply and unplug the power cord. This is necessary to avoid the risk of electric shock. When cleaning the instrument, always wear protective gloves and gown. Also, wash hands after decontamination carefully with antiseptic solution first and with soap afterwards. Do not open the instrument for decontamination inside. This is executed only by Service Technician. 2-4 XN-1000 Instructions for Use Revised February 2013 Chapter 2 Safety Information Information • To ensure decontamination of the instrument outer surfaces, clean the instrument surface at the end of the daily work. This has to be executed in the following three situations; - Regularly, at the end of a daily work, - Immediately, during contamination with potentially infectious material, and - In advance of repair or maintenance by the field technical service representative. • Wipe off the instrument surfaces using a cloth soaked with a suitable decontamination solution. Please use one-way cloths, e.g. made of paper or cellulose. The cloth may be moistened in a way only that no wetness may reach the inside of the instrument. • The indicated residence time of the decontamination solution shall be observed. • If required, you may afterwards remove normal contaminations with commercial neutral detergent, in case these could not be removed by the decontaminant. • As a last step the instrument shall be dried with a dry one-way cloth. 2.9 Markings on the system Interior of the Analyzer (1) (3) (2) Front view Left view (1) Caution! Do not perform analysis while cover is open as outside noise will affect the data. 2-5 XN-1000 Instructions for Use Revised February 2013 Chapter 2 Safety Information (2) Risk of infection In principle, all parts and surfaces of the instrument must be regarded as infective. (3) Warning! To avoid electrical shock, unplug the cord before servicing. Rear of the Analyzer (1) (2) (1) Risk of infection In principle, all parts and surfaces of the instrument must be regarded as infective. (2) Warning!

• To avoid electrical shock, unplug the cord before servicing.

• Replace only with fuses of the specified type and current rating. 2-6 XN-1000 Instructions for Use Revised February 2013 Chapter 2 Safety Information Sampler section SA-10 SA-01 Top view Top view (1) (2) Front interior (3) Rear view (1) Risk of infection In principle, all parts and surfaces of the instrument must be regarded as infective. (2) Warning! To avoid electrical shock, unplug the cord before servicing. 2-7 XN-1000 Instructions for Use Revised August 2012 Chapter 2 Safety Information (3) Warning! • To avoid electrical shock, unplug the cord before servicing. • Replace only with fuses of the specified type and current rating.

Pneumatic unit (2) (3) (1) Front view Rear view (1) Risk of infection In principle, all parts and surfaces of the instrument must be regarded as infective. (2) Caution! Do not block the exhaust opening. (3) Warning! • To avoid electrical shock, unplug the cord before servicing. • Replace only with fuses of the specified type and current rating. 2-8 XN-1000 Instructions for Use Revised August 2012 Chapter 2 2.10 Safety Information Operators Caution! • Only properly trained personnel shall use instrument. • In the event that a malfunction of the instrument occurs, take the measures indicated in the Instructions for Use manual. Further resolution should be referred to your Sysmex technical representative. 2.11 Computer viruses Warning! Although our software has already been checked for computer viruses, the configuration of a specific user environment may make it prone to computer virus infections via the Internet or a network. We recommend that our customers consider computer virus countermeasures that suits their computer operating environment. Customers that use antivirus software in their operating environment should take the following precautions. 1. Use the antivirus software to periodically check for viruses. (1) Use antivirus software designed for your operating system to periodically check for viruses. (2) Disable the antivirus software during instrument software operation as it may adversely affect instrument operation. (3) Disable functions that check file access. (4) Disable firewalls and any other functions that protect or control data transfers. 2. Do not install any software other than the antivirus software. 3. USB memory sticks, CD-Rs and other external memory devices should be checked for viruses before use. 4. Do not open files attached to email or files of unknown origin without first performing a virus check. 5. Do not download files from the Internet or other sources that are not required for instrument operation. However, the virus definition files used by the antivirus software are not subject to this restriction.

6. Always check for viruses before accessing files in a folder shared with other computers. 7. Check effectiveness of computer virus countermeasures used on other computer systems in your laboratory, and select the most effective for use on this instrument. 8. The customer must take sole responsibility when connecting to an external network (for example, the Internet). 2-9 XN-1000 Instructions for Use Revised August 2012 Chapter 2 2.12 Safety Information Use of other software Warning! • Do not install any software other than that preinstalled on the instrument. And do not run any other software on the instrument. However, this restriction does not include the installation of antivirus software. • Note that we will accept no liability whatsoever for any malfunctions arising from use of other software.

2-10 XN-1000 Instructions for Use Revised August 2012 Chapter 3 Before using the system Chapter 3 Before using the system This chapter explains information about proper use of the system. 3.1 Preparing for installation This instrument is installed/moved by Sysmex service representatives. The following is a list of things to do beforehand to prepare for the installation/move. • Secure ample space for installation, with safety considerations. For details, see Chapter 15. (➤P.15-34 "Chapter 15: 15.6.4 Installation space") • Note the weight of this instrument. Make sure that the floor and/or the equipment on which the instrument is to be installed can withstand the weight. • The power cable for this instrument is 2.0 m long.

Use a nearby outlet that is designed for it. • Once this instrument is delivered, check the condition of its packaging as soon as possible. Information If the packaging has been damaged in any way, contact Sysmex representative as soon as possible. • Until the installation is ready, store this instrument as packaged in a dry place.

Store upright. 3.2 Basic settings of the system After the instrument has been installed, the administrator must check the basic settings. For the details on the instrument's settings, see "Administrator's Guide". (➤Administrator's Guide, "Chapter 4: Instrument Setup") ● Check the time. Make sure that the time displayed on the IPU matches the current time. ● Check the Auto Output settings. If Auto Output is necessary, check that the instrument is set for automatic transmission/printing before starting analysis. ● Set the alarm sound. When an error occurs in the instrument, the IPU notifies you with an alarm. There are three types of alarm sounds as indicated below. • Alarm sound triggered when a warning error occurs • Alarm sound for any error that stops the sampler analysis • Alarm sound for emergency stop errors such as an instrument failure (the setting cannot be changed) The alarm sound below will come from the analyzer. Moreover, these alarm sounds cannot be changed in the configuration. Short beep When loading the dye cassette, When the next samples can be analyzed Long beep An error is in progress Long beep (continuous) When the dye cartridge is installed incorrectly 3-1 XN-1000 Instructions for Use Revised February 2013 Chapter 3 3.3 Before using the system Terms used in analysis 3.3.1 Sample No. A sample number is a number and text string up to 22 digits in length that is assigned to a sample. Sample numbers are used to identify samples. Sample numbers can be acquired by any one of the following methods: • Manual input • Reading sample tube barcodes with a barcode reader • Automatic assignment (when a barcode read error occurs, etc.) • Inquiry to host computer When the auto increment function is on, the number is automatically incremented by one and assigned to each subsequent sample after the first sample number is set (during manual analysis).

3.3.2 Rack No./tube position A rack number is a 6-digit number that identifies a rack. Rack numbers can be acquired by any one of the following methods: • Manual input • Reading rack barcodes with a barcode reader • Automatic assignment (when a barcode read error occurs, etc.) The sample tube position is a two-digit number that defines the sample tube position in a rack. There are 10 sample tube positions in a rack. Sample tube positions are assigned from the right side in the order "01, 02, 03, ...". 3.4 Supported sample tubes and racks This section explains the sample tubes and racks you can use with this instrument. 3.4.1 Supported sample tubes Regular sample tubes d Diameter (a) φ11 to 15 mm Length (b) At least 57 mm Length including the cap (c) 70 to 85 mm Cap diameter (d) φ18 mm or less c b * Except for when performing micro analysis, use the tube with the cap on. a 3-2 XN-1000 Instructions for Use Revised August 2012 Chapter 3 Before using the system e.g. Tubes verified for proper operation • • • • VENOJECT II (Terumo)* Hemoguard (BD) VACUETTE (greiner) Monovette (SARSTEDT) * Reusable caps cannot be used Information When performing sampler analysis using the VENOJECT II (Terumo), fold the film seal so that it does not protrude horizontally and then place in the rack. Otherwise, there is a risk that the seal will interfere with an adjacent sample tube and cause it to fall from the rack. Micro collection sample tubes Typical shapes of micro collection tubes are shown below. Acceptable dimensions vary depending on the shape of the micro collection tube.

The following are guidelines. Verification using the actual micro collection tube is necessary. Type B φ7.4 to 7.8 mm φ9.8 to 10.8 mm 8.5 mm φ8 mm or less 36 to 46 mm φ13 mm or less 20 mm At least 27 mm 28 to 48 mm φ13 mm or less 36 to 50 mm At least 35 mm 20 mm φ13 mm or less Type C At least 35 mm Type A φ10.0 to 11.0 mm * Cap not included in dimensions. Open the cap during analysis. e.g. Tubes verified for proper operation • CAPIJECT (Terumo) • Microtainer 365973 (BD) Raised Bottom Tube (RBT) A microtube that can be used in sampler analysis. Compatible dimensions are the same as regular sample tubes. e.g. Tubes verified for proper operation • Microtainer Map 363706 (BD) Note: For information on using sample tubes not described here, consult your local Sysmex representative.

3-3 XN-1000 Instructions for Use Revised August 2013 Chapter 3 Before using the system 3.4.2 Supported racks Only Sysmex 10-tube racks can be used with normal sample tubes. If the diameter of the tube is φ14 mm or less, attach a dedicated adapter onto the rack. A dedicated adapter is included with the instrument. 55 mm 200 mm 25 mm Caution! To use Raised Bottom Tubes, place the tubes in a dedicated Raised Bottom Tube rack. Do not place regular sample tubes in the RBT rack. 3.5 Sample tube and rack barcode labels In order to achieve optimum performance levels of the system, laboratory must ensure that barcode labels are properly applied to the sample tube as well as rack labels. This section will provide the necessary information related to their application onto the sample tube and system rack.

For the specific information about barcode types, see "Administrator's Guide". (➤Administrator's Guide, "Chapter 5: 5.3 ID Barcode Specifications") Caution! During the attachment of the barcode labels pay attention to prevent misreading of barcodes or mix-up of samples.

• Affix the label so that the lines of the barcode are run horizontally.

• Do not affix multiple labels. • Label surfaces must not be wrinkled. • Make sure that the label does not extend past the bottom of the sample tube.

• Make sure that no part of the barcode label is peeled off. • Make sure that the labeled sample tubes can be inserted into and removed from the rack with ease. • Do not write any text in the margins of a barcode label. 3-4 XN-1000 Instructions for Use Revised August 2013 Chapter 3 3.5.1 Before using the system Sample tube barcode labels (sample numbers) Apply barcode label to the sample tube so that its within the indicated distance shown in the figure on the right. At least 5 mm 48 mm or less At least 21 mm 3.5.2 At least 5 mm At least 16 mm Barcodes for tube racks (rack numbers) 2 labels with same barcode number will accompany your system. Affix the label with printed text to the side of the rack for verification purposes. 9.5 mm 16 mm 3 mm 39 mm Barcode area 45 mm Label area 3-5 XN-1000 Instructions for Use Revised August 2012 Chapter 3 3.6 Before using the system Additional components This instrument can be combined with various additional components to configure a system that better serves your purpose. 3.6.1 List of additional components Item name Description Dedicated wagon (WG-10) A wagon for installing the analyzer. You can house reagents, pneumatic unit, and IPU. Reservoir tank A tank to store hemolytic agents and diluents. RU-20 A reagent unit prepares (dilutes) concentrated reagent using RO water and feeds it to connected analyzers. Touchscreen display A display unit for the IPU. You can use the touchscreen to perform some of the operations. Data printer Prints analysis data in the ticket format. Graphic printer List printer Prints lists of analysis information and results. Prints hardcopies of analysis results and screenshots of histograms, scattergrams, etc. Waste tank full sensor Detects when the waste tank is full. External indicator light (SI-10) Indicator light that enables you to check the current instrument status from a distance. External indicator light (Lamp_Assy No.7) 3-6 XN-1000 Instructions for Use Revised August 2012 Chapter 4 Part Names and Functions Chapter 4 Part Names and Functions This chapter provides an external view and a summary of each device that makes up this instrument. 4.1 Analyzer Analyzes patient and control samples. Front view 1 Front top cover Opens upward. Open this cover to inspect the interior of the analyzer, or to perform cleaning or maintenance tasks. 1 2 Front bottom cover This is a protective cover. Open this cover to inspect the interior of the analyzer, or to perform cleaning or maintenance tasks.

3 Tube holder 6 2 4 5 3 Used to load the sample tubes for manual analysis. 4 Start switch Press to start manual analysis. 5 Mode switch Press to switch between manual analysis and sampler analysis. Pressing it opens and closes the tube holder. When the tube holder is open: Manual analysis When the tube holder is closed: Sampler analysis 6 Status indicator LED Indicates the status of the device by LED. Green/orange* Ready (Analysis possible) Flashing green/ orange* Starting up / Analysis in progress / Mode switching in progress / Shutting down Green Waiting to execute maintenance Flashing green Maintenance in progress Red Error (without alarm) / Initializing system / Error stop / Stopped Flashing red Error (with alarm) Not lit Powered OFF * Green during normal operation, orange when an error has occurred that allows operation to continue. 4-1 XN-1000 Instructions for Use Revised August 2012 Chapter 4 Part Names and Functions ● When using the optional external indicator light The indicator light is linked to the instrument status, and indicates the status as follows. Priority levels Low High Status indicator LED Indicator light Analyzer Ready / Analysis in progress / Starting up / Shutting down Green Sampler Ready / Analysis in progress / Starting up Analyzer Error / Initializing system / Stopped Sampler Analysis not possible Red (Flashes in red if an alarm is sounding) Analyzer Power off / Error stop Not lit The external indicator light is also linked to the sampler status LED*. The external indicator light indicates the status that has the higher priority of the analyzer and sampler statuses. The indicator light lights green regardless of the above priority levels during switching of the analysis mode and while running maintenance.

*When the sampler (SA-01) is used, only the analyzer status LED is indicated. Rear view 1 Various tubes/cables Hydraulic tubes and electrical cables to be connected to the different devices.

The tubes and cables will be connected by Sysmex service representative. 2 Waste Fluid Outlet Nipple Waste fluid is discharged via this nipple.

Connect this to the drain or the waste container. 3 Fuse holder 1 3 2 4 Use a 250V 10A (Time Lag low breaking capacity) fuse. 4 AC power inlet Supplies power using the provided power cable. 4-2 XN-1000 Instructions for Use Revised August 2012 Chapter 4 Part Names and Functions Front interior 1 2 3 4 8 5 6 7 1 Pneumatic trap chamber Prevents the reagent from flowing back into the pneumatic unit, when the instrument malfunctions. 2 0.16 MPa regulator Regulates the pressure at 0.16 MPa. 3 Main power switch Turns the main power of the device ON/OFF. Caution! Do not turn this switch ON/OFF repeatedly within a short time. This will overload the fuse and may cause it to blow. 4 0.07 MPa regulator Regulates the pressure at 0.07 MPa. 5 RBC/PLT detector section Equipped with a RBC/PLT detector. 6 Tube grabber Removes the sample tube from the rack and mixes it.

Then after the analysis is complete, places the sample tube back in the rack. 7 Tube rotation mechanism Rotates the sample tube to read its barcode label. 8 Dye cartridge holder Holds the dye reagent. 4-3 XN-1000 Instructions for Use Revised August 2012 Chapter 4 4.2 Part Names and Functions Pneumatic unit Supplies vacuum and pressures to the device. Front view Rear view 1 3 4 2 5 6 7 1 0.25 MPa regulator Regulates the pressure supplied to the analyzer at 0.25 MPa. 2 Pilot lamp Lights up when the pneumatic unit's power is ON. 3 Pressure outlet nipple Pressure is supplied to the analyzer from this nipple. Connect this nipple with the pressure supply nipple on the analyzer. 4 Vacuum outlet nipple Vacuum is supplied to the analyzer from this nipple. Connect this nipple with the vacuum supply nipple on the analyzer. 5 Fuse Use only with fuses of the specified type and current rating. 100 -117 VAC: Fuse 250V 4A (Time Lag) 220 - 240 VAC: Fuse 250V 3.15A (Time Lag) 6 Power connector Supplies power using the provided power cable. 7 Pneumatic control input connector An input connector for turning the pneumatic unit ON/OFF. Connect this to the pneumatic control output connector on the analyzer. 4-4 XN-1000 Instructions for Use Revised August 2012 Chapter 4 4.3 Part Names and Functions IPU (Information processing unit) Processes and displays data generated by the analyzer. This is also where you operate the analyzer and specify various settings.

1 2 4 3 1 Display You can also use a touchscreen display (optional). 2 Keyboard 3 Mouse 4 Main unit Information The above diagram is for reference only. Refer to the computer's manual for current operation, the layout of connection ports and other details. For more information, please contact your local dealer or Sysmex Representative. 4-5 XN-1000 Instructions for Use Revised August 2012 Chapter 4 4.4 Part Names and Functions Sampler section Automatically supplies the samples to the analyzer. SA-10: Top view 7 8 9 4 1 5 2 3 6 1 Analysis line A maximum of two racks are automatically transported laterally. In this line, the sample number barcode labels are read, and the samples are mixed and aspirated. 2 Right sampler pool Place the racks in this pool. A maximum of 5 racks can be placed at a time. Once the sampler analysis starts, the racks are automatically fed to the analysis line. 3 Status indicator LED Indicates the status of the device by LED. Green Ready (Analysis possible) / Sampler analysis screen is open / Waiting to execute maintenance Flashing green Starting up / Sampler analysis in progress / Maintenance in progress Orange Sampler analysis is stopped / Sampler analysis is not possible Red Error (without alarm) / Initializing system Flashing red Error (with alarm) Not lit Powered OFF ● When using the optional external indicator light The external indicator light is linked to and indicates the status indicated on the instrument status LED. See the following for details: (➤P.4-2 "●When using the optional external indicator light") The external indicator light is also linked to the analyzer status LED*.

The external indicator light indicates the status that has the higher priority of the analyzer and sampler statuses. * When the sampler (SA-01) is used, only the analyzer status LED is indicated. 4-6 XN-1000 Instructions for Use Revised August 2012 Chapter 4 4 Part Names and Functions Rack feed-out lever Feeds the finished racks from the analysis line to the left sampler pool. 5 Left sampler pool The racks are fed from the analysis line to this pool. Up to 5 analyzed racks can be pooled.

6 7 Protective cover Main power switch Turns the main power of the device ON/OFF. 8 Fuse holder Use a 250V 3.15A (Time Lag low breaking capacity) fuse. 9 AC power inlet Supplies power using the provided power cable. SA-01: Top view 3 1 4 2 5 1 Analysis line Racks are automatically transported. In this line, the sample number barcode labels are read, and the samples are mixed and aspirated. 2 Right sampler pool Place the racks in this pool. A maximum of 5 racks can be placed at a time. 3 Rack feed-out lever Feeds the finished racks from the analysis line to the left sampler pool. 4 Left sampler pool The racks are fed from the analysis line to this pool. Up to 5 analyzed racks can be pooled. 5 Protective cover 4-7 XN-1000 Instructions for Use Revised August 2012 Chapter 4 Part Names and Functions 4-8 XN-1000 Instructions for Use Revised August 2012 Chapter 5 Reagents Chapter 5 Reagents This chapter explains the reagents to be used with this instrument. 5.1 General information All reagents used in this instrument are exclusively for use with Sysmex equipment. Do not use them for any other purpose. Please follow the warnings for handling and using each of the reagents correctly. 5.2 CELLPACK DCL General name Whole blood diluent for use in hematology analyzers Intended use CELLPACK DCL is a reagent for measuring the numbers and sizes of RBC and platelets by the hydro dynamic focusing (DC Detection). With the addition of the specified lyse reagent for hemoglobin concentration determination, it can also be used to analyze hemoglobin concentration. Also it can be used as a sheath fluid for FCM detector. This reagent is to be used by connecting to an automatic hematology analyzer specified by Sysmex. Warnings and precautions (for in vitro diagnostic use only) Caution! 1. The reliability of the analysis values cannot be guaranteed if the reagent is used outside of the written intended use, or not according to the written directions for use. 2.

When replacing the reagent, do not refill and use the same container. 3. Handle the reagent with care to prevent air bubbles from forming. If air bubbles form, the analysis may not be performed normally. 4.

Do not use expired reagents, as the reliability of the analysis values cannot be guaranteed. 5. If the reagent is removed after it has been connected (i.e. opened), it may become contaminated with bacteria and other particles, causing its performance to deteriorate. Therefore, reconnecting an open reagent is not recommended. 6. NEVER use this reagent on human body.

Avoid contact with skin and eyes, and avoid ingestion. If it comes in contact with the skin, rinse skin thoroughly. If it gets in the eye, rinse with large amounts of water, and seek immediate medical attention. In the unlikely event that it was ingested, seek immediate medical attention. Examination procedure Use CELLPACK DCL at 15 - 30°C. If an analysis is performed at a temperature over 30°C or under 15°C, you may not be able to obtain accurate results. Connect the CELLPACK DCL container to the designated place on the instrument. For details, see Chapter 13. (➤P.13-30 "Chapter 13: 13.4 Replace reagents") 5-1 XN-1000 Instructions for Use Revised August 2012 Chapter 5 Reagents Storage and shelf life after first opening Store CELLPACK DCL at 2 - 35°C, away from direct sunlight. If the reagent has not been opened, it can be kept until the expiration date printed on the reagent container. For shelf life after opening (connecting to the instrument), refer to the expiration date printed on the reagent container or reagents specifications. (➤P.5-17 "5.18 Table of reagent specifications") Replace the reagent if it is showing signs of contamination or instability, such as cloudiness or discoloration. If frozen, thaw and mix thoroughly before use. Disposal procedures 1. If crushing the container when disposing of fluid, make sure that any remaining fluid has been completely removed from the container before crushing. 2. Disposal procedures should meet requirements of applicable local regulations. 5.3 CELLPACK DST General name Concentrated diluent of reagent unit for use in hematology analyzers Intended use CELLPACK DST is a reagent for measuring the numbers and sizes of RBC and platelets by the hydro dynamic focusing (DC Detection).

With the addition of the specified lyse reagent for hemoglobin concentration determination, it can also be used to analyze hemoglobin concentration. Also it can be used as a sheath fluid for FCM detector. This reagent is to be used by connecting to a reagent preparation device specified by Sysmex. Warnings and precautions (for in vitro diagnostic use only) Caution! 1. This reagent is a concentrated reagent. Use this reagent by connecting to a reagent preparation device specified by Sysmex. 2. The reliability of the analysis values cannot be guaranteed if the reagent is used outside of the written intended use, or not according to the written directions for use. 3. When replacing the reagent, do not refill and use the same container. 4. Handle the reagent with care to prevent air bubbles from forming.

If air bubbles form, the analysis may not be performed normally.

5.

Do not use expired reagents, as the reliability of the analysis values cannot be guaranteed.

6. If the reagent is removed after it has been connected (i.e. opened), it may become contaminated with bacteria and other particles, causing its performance to deteriorate. Therefore, reconnecting an open reagent is not recommended. 7. NEVER use this reagent on human body. Avoid contact with skin and eyes, and avoid ingestion. If it comes in contact with the skin, rinse skin thoroughly. If it gets in the eye, rinse with large amounts of water, and seek immediate medical attention. In the unlikely event that it was ingested, seek immediate medical attention. Examination procedure Use CELLPACK DST at 15 - 30°C. If an analysis is performed at a temperature over 30°C or under 15°C, you may not be able to obtain accurate results. Connect the CELLPACK DST container to the designated place on the reagent preparation device. For details, see Chapter 13. (➤P.13-30 "Chapter 13: 13.4 Replace reagents") 5-2 XN-1000 Instructions for Use Revised August 2012 Chapter 5 Reagents Storage and shelf life after first opening Store CELLPACK DST at 2 - 35°C, away from direct sunlight. If the reagent has not been opened, it can be kept until the expiration date printed on the reagent container. For shelf life after opening (connecting to the instrument), refer to the expiration date printed on the reagent container or reagents specifications.

(➤P.5-17 "5.18 Table of reagent specifications") Replace the reagent if it is showing signs of contamination or instability, such as cloudiness or discoloration. Do not use a reagent that is suspected to have frozen. Disposal procedures 1. If crushing the container when disposing of fluid, make sure that any remaining fluid has been completely removed from the container before crushing. 2. Disposal procedures should meet requirements of applicable local regulations. 5.4 CELLPACK DFL General name Whole blood diluent for use in hematology analyzers Intended use CELLPACK DFL is a reagent used in combination with Fluorocell RET for the analysis of reticulocytes or with Fluorocell PLT for the analysis of platelets by flow cytometry method using a semiconductor laser. This reagent is to be used by connecting to an automatic hematology analyzer specified by Sysmex.

Warnings and precautions (for in vitro diagnostic use only) Caution! 1. The reliability of the analysis values cannot be guaranteed if the reagent is used outside of the written intended use, or not according to the written directions for use. 2. This reagent is to be combined and used with Fluorocell RET or Fluorocell PLT. When replacing this reagent, do not refill and use the same container. 3. Handle the reagent with care to prevent air bubbles from forming. If air bubbles form, the analysis may not be performed normally. 4. Do not use expired reagents, as the reliability of the analysis values cannot be guaranteed. 5. If the reagent is removed after it has been connected (i.e. opened), it may become contaminated with bacteria and other particles, causing its performance to deteriorate. Therefore, reconnecting an open reagent is not recommended. 6. NEVER use this reagent on human body. Avoid contact with skin and eyes, and avoid ingestion. If it comes in contact with the skin, rinse skin thoroughly. If it gets in the eye, rinse with large amounts of water, and seek immediate medical attention. In the unlikely event that it was ingested, seek immediate medical attention. Examination procedure Use CELLPACK DFL at 15 - 30°C. If an analysis is performed at a temperature over 30°C or under 15°C, you may not be able to obtain an accurate count of reticulocytes and platelets. Connect the CELLPACK DFL container to the designated place on the instrument.

For details, see Chapter 13. (➤P.13-30 "Chapter 13: 13.4 Replace reagents") 5-3 XN-1000 Instructions for Use Revised August 2012 Chapter 5 Reagents Storage and shelf life after first opening Store CELLPACK DFL at 2 - 35°C, away from direct sunlight. If the reagent has not been opened, it can be kept until the expiration date printed on the reagent container. For shelf life after opening (connecting to the instrument), refer to the expiration date printed on the reagent container or reagents specifications. (➤P.5-17 "5.18 Table of reagent specifications") Replace the reagent if it is showing signs of contamination or instability, such as cloudiness or discoloration. Do not use a reagent that is suspected to have frozen. Disposal procedures 1. If crushing the container when disposing of fluid, make sure that any remaining fluid has been completely removed from the container before crushing. 2. Disposal procedures should meet requirements of applicable local regulations. 5-4 XN-1000 Instructions for Use Revised August 2012 Chapter 5 5.5 Reagents SULFOLYSER General name A reagent for the automated determination of hemoglobin concentration of blood Intended use SULFOLYSER is a reagent for the automated determination of hemoglobin concentration of blood. SULFOLYSER is manufactured for use on all Sysmex automated hematology analyzers. SULFOLYSER cannot be used on semi-automated instruments. Warnings and precautions (for in vitro diagnostic use only) Caution! Avoid contact with skin and eyes. In case of skin contact, flush the area with water. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. If swallowed, seek medical advice immediately. Examination procedure 1.

Allow the container of SULFOLYSER to equilibrate to environmental temperature (15 - 30°C). 2. Loosen and remove the cap on the SULFOLYSER container.

3. Attach the Dispenser Kit to the SULFOLYSER container. Tighten the cap. Connect the SULFOLYSER line from the instrument to the Dispenser Kit. 4. Prime the SULFOLYSER through the hydraulic system of the instrument by cycling the instrument several times in the whole blood mode to fill all SULFOLYSER tubing with reagent and to remove air bubbles in the lines. For details, see Chapter 13. (➤P.13-30 "Chapter 13: 13.4 Replace reagents") Storage and shelf life after first opening Store SULFOLYSER at 1 - 30°C, away from direct sunlight. If the reagent has not been opened, it can be kept until the expiration date printed on the reagent container. For shelf life after opening (connecting to the instrument), refer to the expiration date printed on the reagent container or reagents specifications. (➤P.5-17 "5.18 Table of reagent specifications") Replace the reagent if it is showing signs of contamination or instability, such as cloudiness or discoloration. Do not use a reagent that is suspected to have frozen.

Disposal procedures 1. If crushing the container when disposing of fluid, make sure that any remaining fluid has been completely removed from the container before crushing.

2. Disposal procedures should meet requirements of applicable local regulations. 5-5 XN-1000 Instructions for Use Revised August 2012 Chapter 5 5.6 Reagents Lysercell WNR General name A lysing reagent for hematology analyzers Intended use Lysercell WNR is a reagent product to be combined and used with Fluorocell WNR. By hemolyzing red blood cells with Lysercell WNR and by differentiating white blood cells (non-basophil), basophils, and nucleated red blood cells with Lysercell WNR and Fluorocell WNR, the white blood cell count, basophil count, basophil percentage, nucleated red blood cell count, and nucleated red blood cell percentage are analyzed. This reagent is to be used by connecting to an automatic hematology analyzer specified by Sysmex.

Warnings and precautions (for in vitro diagnostic use only) Caution! 1.

The reliability of the analysis values cannot be guaranteed if the reagent is used outside of the written intended use, or not according to the written directions for use. 2.

This reagent is to be combined and used with Fluorocell WNR.

When replacing this reagent, do not refill and use the same container. 3. Handle the reagent with care to prevent air bubbles from forming. If air bubbles form, the analysis may not be performed normally. 4. Do not use expired reagents, as the reliability of the analysis values cannot be guaranteed. 5. If the reagent is removed after it has been connected (i.e. opened), it may become contaminated with bacteria and other particles, causing its performance to deteriorate. Therefore, reconnecting an open reagent is not recommended. 6. NEVER use this reagent on human body. Avoid contact with skin and eyes, and avoid ingestion. If it comes in contact with the skin, rinse skin thoroughly. If it gets in the eye, rinse with large amounts of water, and seek immediate medical attention. In the unlikely event that it was ingested, seek immediate medical attention.

Examination procedure Use Lysercell WNR at 15 - 30°C. If an analysis is performed at a temperature over 30°C or under 15°C, you may not be able to obtain accurate white blood cell count, basophil count, basophil percentage, nucleated red blood cell count, and nucleated red blood cell percentage. Connect the Lysercell WNR container to the designated place on the instrument. For details, see Chapter 13.

(➤P.13-30 "Chapter 13: 13.4 Replace reagents") Storage and shelf life after first opening Store Lysercell WNR at 2 - 35°C, away from direct sunlight. If the reagent has not been opened, it can be kept until the expiration date printed on the reagent container. For shelf life after opening (connecting to the instrument), refer to the expiration date printed on the reagent container or reagents specifications.

(➤P.5-17 "5.18 Table of reagent specifications") Replace the reagent if it is showing signs of contamination or instability, such as cloudiness or discoloration. Do not use a reagent that is suspected to have frozen. Disposal procedures 1. If crushing the container when disposing of fluid, make sure that any remaining fluid has been completely removed from the container before crushing. 2. Disposal procedures should meet requirements of applicable local regulations. 5-6 XN-1000 Instructions for Use Revised August 2012 Chapter 5 5.7 Reagents Lysercell WDF General name A lysing reagent for hematology analyzers Intended use Lysercell WDF is a reagent product to be combined and used with Fluorocell WDF. By hemolyzing red blood cells with Lysercell WDF and dyeing the white blood cell component with Fluorocell WDF, the counts and percentages of neutrophils, lymphocytes, monocytes, and eosinophils are analyzed. This reagent is to be used by connecting to an automatic hematology analyzer specified by Sysmex. Warnings and precautions (for in vitro diagnostic use only) Caution! 1. The reliability of the analysis values cannot be guaranteed if the reagent is used outside of the written intended use, or not according to the written directions for use. 2. This reagent is to be combined and used with Fluorocell WDF. When replacing this reagent, do not refill and use the same container. 3. Handle the reagent with care to prevent air bubbles from forming. If air bubbles form, the analysis may not be performed normally. 4. Do not use expired reagents, as the reliability of the analysis values cannot be guaranteed. 5.

If the reagent is removed after it has been connected (i.e. opened), it may become contaminated with bacteria and other particles, causing its performance to deteriorate. Therefore, reconnecting an open reagent is not recommended. 6. NEVER use this reagent on human body. Avoid contact with skin and eyes, and avoid ingestion. If it comes in contact with the skin, rinse skin thoroughly. If it gets in the eye, rinse with large amounts of water, and seek immediate medical attention. In the unlikely event that it was ingested, seek immediate medical attention. Examination procedure Use Lysercell WDF at 15 - 30°C. If an analysis is performed at a temperature over 30°C or under 15°C, you may not be able to obtain accurate counts and percentages of neutrophils, lymphocytes, monocytes, and eosinophils. Connect the Lysercell WDF container to the designated place on the instrument. For details, see Chapter 13. (➤P.13-30 "Chapter 13: 13.4 Replace reagents") Storage and shelf life after first opening Store Lysercell WDF at 2 - 35°C, away from direct sunlight. If the reagent has not been opened, it can be kept until the expiration date printed on the reagent container. For shelf life after opening (connecting to the instrument), refer to the expiration date printed on the reagent container or reagents specifications. (➤P.5-17 "5.18 Table of reagent specifications") Replace the reagent if it is showing signs of contamination or instability, such as cloudiness or discoloration. Do not use a reagent that is suspected to have frozen. Disposal procedures 1. If crushing the container when disposing of fluid, make sure that any remaining fluid has been completely removed from the container before crushing. 2. Disposal procedures should meet requirements of applicable local regulations. 5-7 XN-1000 Instructions for Use Revised August 2012 Chapter 5 5.8 Reagents Lysercell WPC General name A lysing reagent for hematology analyzers Intended use Lysercell WPC is a reagent product to be combined and used with Fluorocell WPC.

Lysercell WPC hemolyzes red blood cells, and Lysercell WPC and Fluorocell WPC detect any presence of abnormal or immature cells. This reagent is to be used by connecting to an automatic hematology analyzer specified by Sysmex. Warnings and precautions (for in vitro diagnostic use only) Caution! 1.

The reliability of the analysis values cannot be guaranteed if the reagent is used outside of the written intended use, or not according to the written directions for use.

2. This reagent is to be combined and used with Fluorocell WPC. When replacing this reagent, do not refill and use the same container.

3. Handle the reagent with care to prevent air bubbles from forming. If air bubbles form, the analysis may not be performed normally. 4.

Do not use expired reagents, as the reliability of the analysis values cannot be guaranteed.

5. If the reagent is removed after it has been connected (i.e. opened), it may become contaminated with bacteria and other particles, causing its performance to deteriorate. Therefore, reconnecting an open reagent is not recommended.

6. NEVER use this reagent on human body. Avoid contact with skin and eyes, and avoid ingestion. If it comes in contact with the skin, rinse skin thoroughly. If it gets in the eye, rinse with large amounts of water, and seek immediate medical attention. In the unlikely event that it was ingested, seek immediate medical attention. Examination procedure Use Lysercell WPC at 15 - 30°C. If an analysis is performed at a temperature over 30°C or under 15°C, you may not be able to accurately detect the presence of abnormal or immature cells. Connect the Lysercell WPC container to the designated place on the instrument. For details, see Chapter 13. (➤P.13-30 "Chapter 13: 13.4 Replace reagents") Storage and shelf life after first opening Store Lysercell WPC at 2 - 35°C, away from direct sunlight. If the reagent has not been opened, it can be kept until the expiration date printed on the reagent container.

For shelf life after opening (connecting to the instrument), refer to the expiration date printed on the reagent container or reagents specifications.

(➤P.5-17 "5.18 Table of reagent specifications") Replace the reagent if it is showing signs of contamination or instability, such as cloudiness or discoloration. Do not use a reagent that is suspected to have frozen. Disposal procedures 1. If crushing the container when disposing of fluid, make sure that any remaining fluid has been completely removed from the container before crushing. 2. Disposal procedures should meet requirements of applicable local regulations. 5-8 XN-1000 Instructions for Use Revised August 2012 Chapter 5 5.9 Reagents Fluorocell WNR General name A staining reagent for hematology analyzers Intended use Fluorocell WNR is to be used to stain the nucleated cells in diluted and lysed blood samples for determination of white blood cell count, nucleated red blood cell count and basophil count in blood with Sysmex automated hematology analyzers. Warnings and precautions (for in vitro diagnostic use only) Caution! 1. Wear gloves and a lab coat for protection. Avoid contact with skin and eyes. 2. In case of skin contact, rinse immediately with plenty of soap and water. 3.

In case of contact with eyes, rinse immediately with water or normal saline, occasionally lifting upper and lower lids until no evidence of dye remains.

Obtain medical attention.

4. If swallowed, seek medical advice immediately. 5.

In case of accident or you feel unwell, seek medical advice immediately (show the label where possible).

R22: Harmful if swallowed.

Sysmex products are labeled with Hazard Symbol and Risk and Safety Phrases in compliance with the European Community Directive. Examination procedure 1. Put a Fluorocell WNR cartridge in the prescribed position and then connect the Fluorocell WNR line. 2. Do not remove the IC tag until disposal. All the product information is managed by the IC tag on the label. 3. After setting, reset of the package is not recommended. Removing the reagent cartridge from the analyzer may cause deterioration of the reagent by contamination and opening in a sealing film. For details, see Chapter 13. (➤P.13-30 "Chapter 13: 13.4 Replace reagents") Storage and shelf life after first opening Store Fluorocell WNR in a dark place at 2 - 35°C.

If the reagent has not been opened, it can be kept until the expiration date printed on the reagent container. For shelf life after opening (connecting to the instrument), refer to the expiration date printed on the package insert or reagents specifications. (➤P.5-17 "5.18 Table of reagent specifications") Do not use a reagent that is suspected to have frozen. Disposal procedures 1. Tightly seal the spout of a cartridge before disposing to prevent residual reagent solution leaks. You may use tape to secure the spout. 2. Disposal procedures should meet requirements of applicable local regulations. 5-9 XN-1000 Instructions for Use Revised August 2012 Chapter 5 5.10 Reagents Fluorocell WDF General name A staining reagent for hematology analyzers Intended use Fluorocell WDF is to be used to stain the leukocytes in diluted and lysed blood samples for determination of 4-part differential count in blood with Sysmex automated hematology analyzers. Warnings and precautions (for in vitro diagnostic use only) Caution! 1. Wear gloves and a lab coat for protection. Avoid contact with skin and eyes. 2. In case of skin contact, rinse immediately with plenty of soap and water. 3. In case of contact with eyes, rinse immediately with water or normal saline, occasionally lifting upper and lower lids until no evidence of dye remains. Obtain medical attention. 4. If swallowed, seek medical advice immediately. 5. Do not breathe vapor. In case of accident or you feel unwell, seek medical advice immediately (show the label where possible). R20/21/22: Harmful by inhalation, in contact with skin and if swallowed. R68/20/21/22: Harmful: possible risk of irreversible effects through inhalation, in contact with skin and if swallowed. S23: Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer). S24/25: Avoid contact with skin and eyes. S37/39: Wear suitable gloves and eye/face protection.

S45: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Sysmex products are labeled with Hazard Symbol and Risk and Safety Phrases in compliance with the European Community Directive. Examination procedure 1. Put a Fluorocell WDF cartridge in the prescribed position and then connect the Fluorocell WDF line.

2. Do not remove the IC tag until disposal. All the product information is managed by the IC tag on the label. 3. After setting, reset of the package is not recommended.

Removing the reagent cartridge from the analyzer may cause deterioration of the reagent by contamination and opening in a sealing film. For details, see Chapter 13. (➤P.13-30 "Chapter 13: 13.4 Replace reagents") Storage and shelf life after first opening Store Fluorocell WDF in a dark place at 2 - 35°C. If the reagent has not been opened, it can be kept until the expiration date printed on the package insert. For shelf life after opening (connecting to the instrument), refer to the expiration date printed on the package insert or reagents specifications. (➤P.5-17 "5.18 Table of reagent specifications") Do not use a reagent that is suspected to have frozen.

Disposal procedures 1. Tightly seal the spout of a cartridge before disposing to prevent residual reagent solution leaks. You may use tape to secure the spout. 2. Disposal procedures should meet requirements of applicable local regulations. 5-10 XN-1000 Instructions for Use Revised August 2012 Chapter 5 5.11 Reagents Fluorocell RET General name A staining reagent for hematology analyzers Intended use Fluorocell RET is to be used to stain the reticulocytes in diluted blood sample for the assay of reticulocyte count, reticulocyte percent and platelet count in blood with Sysmex automated hematology analyzers. Warnings and precautions (for in vitro diagnostic use only) Caution! 1. Wear gloves and a lab coat for protection.

Avoid contact with skin and eyes. 2. In case of skin contact, rinse immediately with plenty of soap and water. 3. In case of contact with eyes, rinse immediately with water or normal saline, occasionally lifting upper and lower lids until no evidence of dye remains. Obtain medical attention.

4. If swallowed, seek medical advice immediately. 5.

Do not breathe vapor. In case of accident or you feel unwell, seek medical advice immediately (show the label where possible). R10: Flammable. R20/21/22: Harmful by inhalation, in contact with skin and if swallowed.

R68/20/21/22: Harmful: possible risk of irreversible effects through inhalation, in contact with skin and if swallowed.

R16: Keep away from sources of ignition – No smoking. S23: Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer). S24/25: Avoid contact with skin and eyes. S37/39: Wear suitable gloves and eye/face protection. S45: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Sysmex products are labeled with Hazard Symbol and Risk and Safety Phrases in compliance with the European Community Directive. Examination procedure 1. Put a Fluorocell RET cartridge in the prescribed position and then connect the Fluorocell RET line. 2.

Do not remove the IC tag until disposal. All the product information is managed by the IC tag on the label. 3. After setting, reset of the package is not recommended.

Removing the reagent cartridge from the analyzer may cause deterioration of the reagent by contamination and opening in a sealing film. For details, see Chapter 13. (➤P.13-30 "Chapter 13: 13.4 Replace reagents") Storage and shelf life after first opening Store Fluorocell RET in a dark place at 2 - 35°C. If the reagent has not been opened, it can be kept until the expiration date printed on the package insert. For shelf life after opening (connecting to the instrument), refer to the expiration date printed on the package insert or reagents specifications. (➤P.5-17 "5.18 Table of reagent specifications") Do not use a reagent that is suspected to have frozen. Disposal procedures 1. Tightly seal the spout of a cartridge before disposing to prevent residual reagent solution leaks. You may use tape to secure the spout.

2. Disposal procedures should meet requirements of applicable local regulations. 5-11 XN-1000 Instructions for Use Revised August 2012 Chapter 5 5.12 Reagents Fluorocell PLT General name A staining reagent for hematology analyzers Intended use Fluorocell PLT is to be used to stain the platelet in diluted blood sample for the assay of platelet count in blood with Sysmex automated hematology analyzers.

Warnings and precautions (for in vitro diagnostic use only) Caution! 1. Wear gloves and a lab coat for protection. Avoid contact with skin and eyes. 2. In case of skin contact, rinse immediately with plenty of soap and water. 3. In case of contact with eyes, rinse immediately with water or normal saline, occasionally lifting upper and lower lids until no evidence of dye remains. Obtain medical attention. 4. If swallowed, seek medical advice immediately. 5. In case of accident or you feel unwell, seek medical advice immediately (show the label where possible). R22: Harmful if swallowed. Sysmex products are labeled with Hazard Symbol and Risk and Safety Phrases in compliance with the European Community Directive. Examination procedure 1. Put a Fluorocell PLT cartridge in the prescribed position and then connect the Fluorocell PLT line. 2. Do not remove the IC tag until disposal. All the product information is managed by the IC tag on the label. 3.

After setting, reset of the package is not recommended. Removing the reagent package from the analyzer may cause deterioration of the reagent by contamination and opening in a sealing film. For details, see Chapter 13. (➤P.13-30 "Chapter 13: 13.4 Replace reagents") Storage and shelf life after first opening Store Fluorocell PLT in a dark place at 2 - 35°C.

If the reagent has not been opened, it can be kept until the expiration date printed on the package insert. For shelf life after opening (connecting to the instrument), refer to the expiration date printed on the package insert or reagents specifications. (➤P.5-17 "5.18 Table of reagent specifications") Do not use a reagent that is suspected to have frozen. Disposal procedures 1. Tightly seal the spout of a cartridge before disposing to prevent residual reagent solution leaks. You may use tape to secure the spout. 2. Disposal procedures should meet requirements of applicable local regulations. 5-12 XN-1000 Instructions for Use Revised August 2012 Chapter 5 5.13 Reagents Fluorocell WPC General name A staining reagent for hematology analyzers Intended use Fluorocell WPC is to be used to stain the leukocytes in diluted and lysed blood samples for detection of various immature cells in blood with Sysmex automated hematology analyzers. Warnings and precautions (for in vitro diagnostic use only) Caution! 1. Wear gloves and a lab coat for protection. Avoid contact with skin and eyes. 2. In case of skin contact, rinse immediately with plenty of soap and water. 3.

In case of contact with eyes, rinse immediately with water or normal saline, occasionally lifting upper and lower lids until no evidence of dye remains.

Obtain medical attention. 4. If swallowed, seek medical advice immediately. 5.

Do not breathe vapor.

In case of accident or you feel unwell, seek medical advice immediately (show the label where possible). R10: Flammable. R22: Harmful if swallowed. S16: Keep away from sources of ignition – No smoking. S24/25: Avoid contact with skin and eyes. S37: Wear suitable gloves. S45: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Sysmex products are labeled with Hazard Symbol and Risk and Safety Phrases in compliance with the European Community Directive. Examination procedure 1. Put a Fluorocell WPC cartridge in the prescribed position and then connect the Fluorocell WPC line.

2. Do not remove the IC tag until disposal. All the product information is managed by the IC tag on the label. 3. After setting, reset of the package is not recommended. Removing the reagent cartridge from the analyzer may cause deterioration of the reagent by contamination and opening in a sealing film. For details, see Chapter 13. (➤P.13-30 "Chapter 13: 13.4 Replace reagents") Storage and shelf life after first opening Store Fluorocell WPC in a dark place at 2 - 35°C.

If the reagent has not been opened, it can be kept until the expiration date printed on the package insert. For shelf life after opening (connecting to the instrument), refer to the expiration date printed on the package insert or reagents specifications. (➤P.5-17 "5.18 Table of reagent specifications") Do not use a reagent that is suspected to have frozen. Disposal procedures 1. Tightly seal the spout of a cartridge before disposing to prevent residual reagent solution leaks. You may use tape to secure the spout. 2. Disposal procedures should meet requirements of applicable local regulations. 5-13 XN-1000 Instructions for Use Revised August 2012 Chapter 5 5.14 Reagents CELLCLEAN AUTO General name Detergent for fully automated hematology analyzer Intended use CELLCLEAN AUTO is to be used as a strong alkaline detergent to remove SYSMEX lysing reagent, cellular residuals and blood proteins remaining in the hydraulics of XN series automated hematology analyzer and SP-10 automated hematology slide preparation unit. Warnings and precautions (for in vitro diagnostic use only) Warning! Avoid contact with skin and eyes. In case of skin contact, flush the area with water. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice immediately. R31: Contact with acids liberates toxic gas. R36/38: Irritating to eyes and skin. S2: Keep out of the reach of children. S25: Avoid contact with eyes.

Sysmex products are labeled with Hazard Symbol and Risk and Safety Phrases in compliance with the European Community Directive. Storage and shelf life after first opening Store CELLCLEAN AUTO at 1 - 30°C, away from direct sunlight. Do not use a reagent that is suspected to have frozen. Disposal procedures 1. After use, there will be a hole in the film that seals the top of the tube. Exercise caution, as residual fluid may leak from the hole. 2. Disposal procedures should meet requirements of applicable local regulations. 5-14 XN-1000 Instructions for Use Revised August 2013 Chapter 5 5.15 Reagents Control blood (XN CHECK/XN CHECK BF) Intended use Used to controlling the quality of hematology analyzers. Warnings and precautions (for in vitro diagnostic use only) Risk of infection Always wear protective garments and gloves when using control blood. Also, wash your hands after completing the process. The basic blood used in the control blood has tested negative for HBs antigen, HCV/HIV-1/HIV-2 antibodies, and serologic tests for syphilis. However, there are no tests that can completely rule out any infections. In addition, it has not been tested for other viruses. Therefore, handle it with the same level of care you would use when handling other blood samples that may be infectious. Storage and shelf life after first opening Store the control blood in a dark refrigerated place at 2 - 8°C. If it has not been opened, you can keep it until the expiration date printed on the vial label and outer box. For shelf life after opening, refer to the expiration date printed on the package insert or reagents specifications.

(➤P.5-17 "5.18 Table of reagent specifications") 5.16 Calibrator (XN CAL/XN CAL PF) Intended use Use the XN CAL for the calibration of the instrument for WBC, RBC, HGB, HCT, PLT, and RET. Use the XN CAL PF for the calibration of the instrument for PLT-F (platelet count obtained from the PLT-F channel). Warnings and precautions (for in vitro diagnostic use only) Risk of infection Always wear protective garments and gloves when using control blood.

Also, wash your hands after completing the process. The basic blood used in the calibrator has tested negative for HBs antigen, HCV/HIV-1/HIV-2 antibodies, and serologic tests for syphilis. However, there are no tests that can completely rule out any infections. In addition, it has not been tested for other viruses. Therefore, handle it with the same level of care you would use when handling other blood samples that may be infectious. Storage and shelf life after first opening Store the calibrator in a dark refrigerated place at 2 - 8°C. If it has not been opened, you can keep it until the expiration date printed on the vial label and outer box. For shelf life after opening, refer to the expiration date printed on the package insert or reagents specifications. (➤P.5-17 "5.18 Table of reagent specifications") 5-15 XN-1000 Instructions for Use Revised August 2012 Chapter 5 5.17 Reagents Symbols used on the labels Signs and symbols used on reagent containers and packages are as follows: Caution! Important information about the handling of reagents is noted on their containers or the package insert. Use the reagents after fully understanding the descriptions.

Xn Harmful (Hazardous class in the EU) Catalogue number Corrosive (Hazardous class in the EU) Concentrated reagent In vitro diagnostic medical device Keep away from sunlight Manufacturer Use no hooks Authorised Representative in the European Community This way up Consult instructions for use Keep away from rain Temperature limitation Stacking limit by number Biological risks Fragile; handle with care Use by Corrugated recycles Batch code The design of the symbols may differ from the actual product. 5-16 XN-1000 Instructions for Use Revised August 2012 Chapter 5 5.18 Reagents Table of reagent specifications 5.18.1 Table of reagent specifications Brand name Volume CELLPACK DCL 20 L CELLPACK DST 20 L Shelf life after opening Storage temp. Usage temp. 2 - 35°C 15 - 30°C 60 days Sodium chloride 0.7% Tris buffer 0.2% EDTA-2K 0.02% 60 days Sodium chloride 15.7% Tris buffer 4.3% EDTA-2K 0.4% 60 days Tricine buffer 0.17% 60 days Sodium lauryl sulfate 1.8 g/L 10 L 10 L 4L CELLPACK DFL 1.5 L SULFOLYSER* 1.5 L 1 - 30°C 4L Composition 90 days 5L Lysercell WNR 4L Lysercell WDF Lysercell WPC 60 days Organic quaternary ammonium salts 0.20% Nonionic surfactant 0.10% 4L 90 days Organic quaternary ammonium salts 0.07% Nonionic surfactant 0.17% 1.5 L 90 days Anionic surfactant 0.03% Nonionic surfactant 0.12% Fluorocell WNR 82 mL 90 days Polymethine dye 0.005% Ethylene glycol 99.9% Fluorocell WDF 42 mL 90 days Polymethine dye 0.002% Methanol 3.0% Ethylene glycol 96.9% Fluorocell RET 12 mL 90 days Polymethine dye 0.03% Methanol 7.9% Ethylene glycol 92.0% Fluorocell PLT 12 mL 90 days Oxazine dye 0.003% Ethylene glycol 99.9% Fluorocell WPC 12 mL 90 days Polymethine dye 0.004% Ethanol 15.1% Ethylene glycol 84.8% - Sodium Hypochlorite (available chlorine concentration 5.0%) CELLCLEAN AUTO 4 mL 2 - 35°C 1 - 30°C * Available reagent package sizes may vary in some regions. For more details please contact your local Sysmex representative. 5-17 XN-1000 Instructions for Use Revised August 2013 Chapter 5 Reagents 5.18.2 Table of control blood/calibrator specifications Brand name XN CHECK Volume 3.0 mL Storage temp. 2 - 8°C Usage temp. 15 - 30°C Shelf life after opening 7 days XN CHECK BF 3.0 mL 30 days XN CAL 3.0 mL 4 hours XN CAL PF 3.0 mL 5-18 XN-1000 Instructions for Use Revised August 2012 Chapter 6 Basic Operation Chapter 6 Basic Operation This chapter explains the basic operation of this instrument. 6.1 Operation of the IPU The operation of the IPU is based on Windows. For information on how to perform Windows, see the user's manual or the help system of the operating system. The commonly used functions of the IPU are accessible via the touchscreen. If you are using a touchscreen display (optional), you can operate the IPU by directly touching the display. Caution! The IPU is a dedicated PC for the instrument, and cannot be used as a generic PC. 6.1.1 Main screen layout The basic screen layout of the IPU is as follows Toolbar (fixed) Toolbar (changeable) Window (view) Control menu Toolbar (fixed) The following frequently-used function buttons are displayed: [Menu] Click to return from each function screen to the Menu screen. [QC File] Click to display the QC File screen. [Work List] Click to display the Work List screen. [Rule] Click to display the Rule screen. 6-1 XN-1000 Instructions for Use Revised August 2012 Chapter 6 Basic Operation [Explorer] Click to display the Sample Explorer. [Browser] Click to display the Data Browser. Toolbar (changeable) Buttons are displayed according to the displayed function of the window. While performing each function, clicking the [Close] button displayed on the right edge closes each function screen displayed on in the window. Window (view) Area for performing various types of processes and operations. By default, the Menu screen is displayed. Click the desired icon to execute its function. (➤P.6-7 "6.1.3 List of menu items") You can change the icons to be displayed in the Menu screen. Click the [Settings] button on the toolbar to select the icons to be displayed.

Icons that are hidden in the menu screen are also hidden on the toolbar. Control menu Displays the status of each device connected to the IPU. In addition, you can perform operations on each device, such as analysis and maintenance. 6.1.2 Control menu The layout of the Control menu is as follows: Analyzer area RU area Printer area Sampler area Host computer area Analyzer area Displays information about the analyzers. Sampler area Displays information about the sampler. RU area Displayed when the RU-20 is connected. Printer area Displays information about the printer.

Host computer area Displays information about the host computer. 6-2 XN-1000 Instructions for Use Revised August 2013 Chapter 6 Basic Operation ● Analyzer area The following items are displayed in the analyzer area: Change Analysis Mode button Manual Analysis button Analyzer information Help button Sampler Analysis button Analyzer menu button Reagent remaining volume indicator Error message Device status Sample information Analyzer information Displays the name of the analyzer and its settings. The meaning of each icon is as follows: : This is displayed when the X-barM function is ON. : This is displayed when the blood aspiration sensor is ON.

: This is displayed when [Cap Open] is ON. Help button This is displayed when there is an error. Click to display the Help dialog box. Change Analysis Mode button This is displayed when performing manual analysis.

Click to select an analysis mode. Manual Analysis button This is displayed when performing manual analysis.

Click to define the settings for the sample. The displayed icon depends on the [Cap Open] setting. : This is displayed when [Cap Open] is OFF. : Blinks when [Cap Open] is ON.

Sampler Analysis button This is displayed when performing sampler analysis. Click to define the settings for the sample. In addition, if you click during sample analysis, a dialog box for aborting the sample analysis is displayed (SA-10 only). Analyzer menu button Click to run various types of maintenance functions. Clicking this button opens and closes the Analyzer menu. (➤P.6-7 "6.1.3 List of menu items") Reagent remaining volume indicator Displays visually how much reagent is remaining. The colors indicate the color of each reagent's package. The reagents are, from left to right in the figure below: DCL, SULFOLYSER, WNR, WDF, DFL, RET, PLT, WPC.

The thick bars indicate dilution/hemolytic agent, and thin bars indicate dye. Amount remaining Click the reagent level display to open the reagent replacement dialog. 6-3 XN-1000 Instructions for Use Revised August 2012 Chapter 6 Basic Operation Error message Displays the highest priority error among all current errors. The displayed error is categorized as one of the following error types: Orange background / black text: Caution Red background / white text: Warning Non-urgent information such as notices appear in normal background / white text. Device status Indicates the status of the analyzer. The meaning of each displayed color is the same as the Status indicator LED on the device. (➤P.4-1 "Chapter 4: 4.1 Analyzer") Sample information Displays the information about the sample to be analyzed. Sample number: Displays the sample number. If [>] appears at the beginning of the sample number, this indicates that the next sample can be aspirated. If the sample number is not read, or if it has not been entered manually, a message is displayed to prompt the input of the number. Analysis mode: The selected analysis mode is displayed from the following: WB: Whole blood, LW: Low WBC, PD: Pre-Dilution, BF: Body Fluid, HPC: HPC, hsA: hsA Discrete: Displays the selected discrete test. This is not displayed when the analysis mode is BF/HPC. Sample number Discrete Analysis mode Note: Clicking other places in the screen while the dialog box is displayed will minimize the dialog box, as shown below.

Because the dialog box is still internally open in this state, you may not be able to perform other operations. Minimized dialog 6-4 XN-1000 Instructions for Use Revised December 2012 Chapter 6 Basic Operation ● Sampler area The following items are displayed in the sampler area: Device status Error message Device status Indicates the status of the sampler. The meaning of each displayed color is the same as the Status indicator LED on the device. (➤P.4-6 "Chapter 4: 4.4 Sampler section") Error message* Displays the highest priority error among all current errors. The displayed error is categorized as one of the following error types: Orange background / black text: Caution Red background / white text: Warning * The error message does not appear when the sampler (SA-01) is used.

● RU area The following items are displayed in the RU area: RU menu button Reagent remaining volume indicator RU status RU menu button Opens and closes the RU help dialog. When an error occurs on the RU-20, a help icon appears in the button part. For details on the RU help dialog, see Chapter 14. (➤P.14-1 "Chapter 14: 14.1.1 Help dialog box") Reagent remaining volume indicator Displays visually how much reagent is remaining in the RU-20. RU status Indicates the status of the RU-20. The meaning of each displayed color is as follows: Green: Ready Flashing green: Starting up / Maintenance in progress / Reagent preparation in progress / Automatic operation (draining / RO water refilling) / Shutting down Orange: Warning Red: Error 6-5 XN-1000 Instructions for Use Revised August 2012 Chapter 6 Basic Operation ● Printer area The following items are displayed in the printer area: Printer menu button Number of print jobs Printer status Printer menu button Opens and closes the printer's menu. Printing can be stopped from the printer menu. Number of print jobs Shows the number of jobs spooled to the printer. Printer status Displays the status of connection with the printer. The meaning of each displayed color is as follows: Not lit: No connection setting Green: Connected* Red: Error in progress * Displays the printer connection status in the IPU settings. Lights green when the printer power is OFF, and also when the printer driver is not installed.

● Host computer area The following items are displayed in the host computer area: Host menu button Host setting Host status Host menu button Opens and closes the host computer's menu. The items displayed in this menu are synchronized with the setting in [Host Computer]. For details, see "Administrator's Guide". (➤Administrator's Guide, "Chapter 4: 4.3.4 Connection settings") Host setting Displays the name of the connected host computer. Host status Displays the status of connection with the host computer. The meaning of each displayed color is as follows: Not lit: No connection setting Green: Connected Flashing green: Communicating Red: Cannot connect 6-6 XN-1000 Instructions for Use Revised August 2013 Chapter 6 6.1.3 Basic Operation List of menu items The layout of the items displayed in the basic screen of the IPU are as follows: Menu QC File Patient Information Work List Ward Name Patient List Doctor Name Rule Sample Explorer Repeat Rule Data Browser Rerun/Reflex/Comment Rule Instructions for Use Validation Rule LOGOFF Output Rule Exit IPU History Audit Log Precision Check Error Log Calibration Reagent Replace Log Analyzer Setting Maintenance Log IPU Setting Version Information RU Log GP Customize Analyzer menu QC Analysis Precision Check X-barM Setting Calibrator Calibration Calibration Calibrator Calibration (PLT-F) Maintenance Auto Rinse Cleaning Shutdown Drain Waste Fluid Chamber Reagent Replacement Rinse Waste Fluid Chamber Remove Flowcell Air Bubbles Rinse Flowcell Drain Reaction Chamber Drain RBC Isolation Chamber Remove RBC Detector Clogs Counter Pressure Adjustment WB Aspiration Motor Test Sheath Motor Test Aspiration Unit Motor Test Tube Holder Motor Test Hand Test Reagent Replenishment Analyzer BR Test Analyzer Sensor Display Sampler Operation Test Sampler BR Test Sampler Sensor Display Replace Piercer 6-7 XN-1000 Instructions for Use Revised August 2012 Chapter 6 6.2 Basic Operation Overall flow of operation The flow chart below is a general representation of the operation of this instrument. Once you understand the overall flow, see each operation explained in detail in the following sections. Power ON ➤P.6-9 "Chapter 6: 6.3 Start up" Execute QC analysis ➤P.8-1 "Chapter 8: Performing Quality Control" Process samples ➤P.9-4 "Chapter 9: 9.2 Prepare the sample" Analyze Manual analysis ➤P.9-7 "Chapter 9: 9.3 Manual analysis" Sampler analysis ➤P.9-18 "Chapter 9: 9.6 Sampler analysis" Display/output analysis results ➤P.10-1 "Chapter 10: Checking analysis data (Sample Explorer)" Shutdown ➤P.6-16 "Chapter 6: 6.6 Shutdown" 6-8 XN-1000 Instructions for Use Revised August 2013 Chapter 6 6.3 Basic Operation Start up 6.3.1 Checks prior to turning power ON Before turning ON the instrument's power, check the following. Instrument inspection • • • • • • Check the connection of tubes and cables. Check if there are any bent tubes. Check if there is any object on top of the instrument. Check for any misplaced racks. Make sure that the network devices (hubs and network converters) are all powered ON. Discard any waste fluid in the waste container (if applicable). For the details on discarding waste fluid, see Chapter 13. (➤P.13-5 "Chapter 13: 13.3.1 Replace the waste container") Reagent inspection Make sure there are extra supplies of reagents for the number of samples to be processed on the day of analysis. The amount of reagent needed varies with analysis mode. Therefore, check if enough reagent is available for the daily routine analyses. If a reagent runs out during the analysis, the instrument automatically stops. Replace the reagent at this time. The analysis cannot resume until the replacement is complete. Volume of reagent per box For reagent volumes, refer to Chapter 5. (➤P.5-17 "Chapter 5: 5.18 Table of reagent specifications") Volume of reagent used per analyzed sample (in continuous analysis) * The following are examples. For more information, please contact your local dealer or Sysmex Representative. Discrete mode Reagent CBC CBC+WDF+WPC+RET+PLT-F Total reagent volume Approx.

29.9 mL Approx. 62.8 mL CELLPACK DCL Approx. 27.9 mL Approx.

53.7 mL SULFOLYSER Approx. 0.5 mL Approx. 0.5 mL Lysercell WNR Approx. 1.5 mL Approx.

2.5 mL Fluorocell WNR Approx. 20 μL Approx. 20 μL Lysercell WDF - Approx. 1.5 mL Fluorocell WDF - Approx. 20 μL Lysercell WPC - Approx. 1.5 mL Fluorocell WPC - Approx.

20 μL CELLPACK DFL - Approx. 3.0 mL Fluorocell RET - Approx. 20 μL Fluorocell PLT - Approx. 20 μL 6-9 XN-1000 Instructions for Use Revised December 2012 Chapter 6 Basic Operation Volume of reagent used on instrument startup Volume of reagent used for rinsing Total reagent volume Approx. 313.8 mL Total reagent volume Approx. 272.6 mL CELLPACK DCL Approx. 286.5 mL CELLPACK DCL Approx. 236.2 mL SULFOLYSER Approx. 1.5 mL SULFOLYSER Approx. 2 mL Lysercell WNR Approx. 7.5 mL Lysercell WNR Approx. 10 mL Fluorocell WNR Approx. 60 μL Fluorocell WNR Approx. 80 μL Lysercell WDF Approx. 4.5 mL Lysercell WDF Approx. 6 mL Fluorocell WDF Approx.

60 μL Fluorocell WDF Approx. 80 μL Lysercell WPC Approx.

4.5 mL Lysercell WPC Approx. 6 mL Fluorocell WPC Approx. 60 μL Fluorocell WPC Approx. 80 μL CELLPACK DFL Approx. 9 mL CELLPACK DFL Approx. 12 mL Fluorocell RET Approx. 60 μL Fluorocell RET Approx.

80 μL Fluorocell PLT Approx. 60 μL Fluorocell PLT Approx. 80 μL * Analysis conditions: At least 1 hour and no more than 24 hours after shutdown/cleaning.

Volume of reagent used on shutdown process 6.3.2 Total reagent volume Approx. 75.9 mL CELLPACK DCL Approx.

71.9 mL CELLCLEAN AUTO Approx.

4 mL (1 vial) Turn power ON Follow the steps below to turn ON the instrument's power. 1 Make sure that the main power of each device connected to the instrument is ON. Check the power for the following devices. The power of the sampler and the analyzer is controlled by the IPU. Therefore, you can keep the main power switches in the "ON" position at all times. • Analyzer (➤P.4-3 "Chapter 4: Front interior") • Sampler (➤P.4-6 "Chapter 4: 4.4 Sampler section") • Display unit • Printer (optional) 6-10 XN-1000 Instructions for Use Revised August 2013 Chapter 6 Basic Operation Information Do not restart only the IPU (by restarting Windows) or log off (log off from Windows) while the main power switch of the connected equipment is ON. After Windows restarts or you log off, the equipment may not be able to reconnect with the IPU. If you need to restart or off from Windows, also switch off the main power switch of the equipment. Make sure that the IPU has finished restarting before switching the main power switch back on.

2 Turn ON the IPU. The power to the instrument turns ON, and the analyzer runs a self-check. Wait until the self-check is complete. (➤P.6-13 "6.3.4 Execution of analyzer self-check") If the IPU Logon setting is set to ON, the Logon dialog box appears. (➤P.6-12 "6.3.3 Log on to the IPU") Note: If an error occurs (e.g. if a reagent runs out) during startup, the operator must log on to the IPU to resolve the error. 6-11 XN-1000 Instructions for Use Revised August 2012 Chapter 6 Basic Operation 6.3.3 Log on to the IPU When turning ON the instrument's power, the following logon dialog box appears in the IPU*. Enter the required information, then click [OK] to log on to the instrument. If you click [Abort], logon is not performed, and the IPU program exits. * If Auto Logon is enabled in the IPU, the Logon dialog does not appear.

Contact your administrator for your logon name and password. Information Immediately after logging on, the administrator should reset the default logon name and password.

Also, add users and set their permissions for this instrument. For details, see "Administrator's Guide". (➤Administrator's Guide, "Chapter 4: 4.3.2 System settings") 6-12 XN-1000 Instructions for Use Revised August 2012 Chapter 6 6.3.4 Basic Operation Execution of analyzer self-check Once the power on the instrument turns ON, a self-test automatically runs for approximately 10 minutes, to determine if there is any error in the analyzer. The self-check consists of the following tasks. ● Initialization of the mechanical parts The mechanical parts move to their initial positions, and initialize/check the hydraulic parts. ● Rinse Rinses the analyzer one to three times, depending on how long it has been since the last rinse. ● Waiting for temperature stabilization* The dialog box on the right appears, and the system waits until the temperatures are stable. Once the temperatures are stable, the dialog box closes automatically. Current Temperature (°C) Displays the current temperatures of each device. Target (°C) Displays the target temperatures. * Depending on the analyzer type, the following items do not appear in the dialog box. 34-deg. Reaction Chamber, 34-deg. Liquid Heater ● Background check Performs analysis without aspirating the samples to verify the effects of the auto rinse.

This is repeated up to 3 times.

The analysis results can be checked in the Sample Explorer screen. Any item whose result is not within the acceptable range is marked with a [!]. Parameters analyzed in background check and their acceptable values Checked Parameter Acceptable Value Explanation WBC-N 0.10 x 103/μL or less WBC counted in the WNR channel WBC-D 0.10 x 103/μL or less WBC counted in the WDF channel WBC-P*1 0.10 x 103/μL or less WBC counted in the WPC channel RBC 0.02 x 106/μL or less - HGB 0.1 g/dL or less*2 - PLT-I 10 x 103/μL or less PLT counted in the RBC/PLT channel (PLT particle size distribution) PLT-O*1 10 x 103/μL or less PLT counted in the RET channel PLT-F*1 3 x 103/μL or less PLT counted in the PLT-F channel *1 These items do not appear with all analyzer types. *2 In the case of Netherlands SI units, 0.1 mmol/L. 6-13 XN-1000 Instructions for Use Revised August 2012 Chapter 6 Basic Operation If the results are still not within the acceptable range after 3 analyses, it will be considered a background check error. Click [Execute] in the Help dialog box to execute Auto Rinse and Background Check again. If the results are still not within the acceptable range, see Chapter 14. (➤P.14-4 "Chapter 14: 14.2 Error message list") Caution! When the results are not within the acceptable range, you can still finish the check by clicking [Close] on the Help dialog box. However, please note that the analysis results may be unreliable. Clicking [Close] does not clear the error.

Note: The sample number for the background check data is [BACKGROUNDCHECK]. 6.4 Log off from the IPU To switch between users, follow the steps below to log off. 1 Click the [LOGOFF] icon in the Menu screen. The dialog box on the right appears. 2 Click [Yes]. The user is logged off from the IPU. After the logoff, the Logon dialog box appears. (➤P.6-12 "6.3.3 Log on to the IPU") Note: You cannot log off while the analyzer or the sampler is running. 6-14 XN-1000 Instructions for Use Revised August 2012 Chapter 6 6.5 Basic Operation Operation lock function (IPU Screen Lock) When an operator needs to step away from the instrument, the IPU can be locked. The operation lock is turned ON in the following cases. However, if a dialog or control menu appears, the operation lock function will not operate.

• When the instrument has not been operated for a set length of time* • When the operator turns ON the operation lock function directly by pressing Ctrl + L. * You can set this between 15 to 60 minutes. For the details on the instrument's settings, see "Administrator's Guide". (➤Administrator's Guide, "Chapter 4: 4.3.2 System Settings") The following dialog box appears while the operation lock is enabled. [Logon Name] Displays the user name currently logged on. [Password] Enter the password here to unlock. [OK] Click this button after entering the password to unlock the operation lock. [Log on as a different user] Log off the current user, and then click when logging on as a different user. 6-15 XN-1000 Instructions for Use Revised August 2012 Chapter 6 6.6 Basic Operation Shutdown This section describes the procedure for shutting down the instrument. Be sure to perform shutdown after finishing analysis for the day. 6.6.1 Automatically shutting down the entire system The power of the entire system can be turned off automatically by placing a rack with CELLCLEAN AUTO. Follow the steps below to shut down the entire system. 1 Make sure that the analyzer and the sampler are in the READY state. If the status LED is not lit green, wait until it does. Status LED e.g. Sampler (SA-10) 2 Make sure that the tube holder is retracted into the analyzer.

If the tube holder is ejected out, press the mode button on the analyzer. Tube holder 3 Place CELLCLEAN AUTO in the rack. Place CELLCLEAN AUTO into the 10th position of the rack. 1 2 3 4 5 6 7 8 9 10 6-16 XN-1000 Instructions for Use Revised August 2012 Chapter 6 4 Basic Operation Place the rack in the right sampler pool. Slide the groove on the rack onto the protrusion on the right side (when you face the analyzer), and start sampler analysis. If the sampler auto-start function is ON on the SA-10 Conveying automatically starts when the rack is placed. If the SA-01 is used, or if the sampler auto start function is OFF on the SA-10 Protrusion Click the sampler analysis button in the control menu and then click [Start]. 5 Shutdown is performed automatically. CELLCLEAN AUTO is aspirated and rinsing begins. Shutdown takes about 15 minutes. When all operations are finished, the instrument power turns OFF. Caution! • Use 1 vial of CELLCLEAN AUTO for each analyzer. CELLCLEAN AUTO that has already been used cannot be reused. • During the transition to shutdown, other sample tubes are not accepted. • Do not mix regular sample tubes together with CELLCLEAN AUTO. 6-17 XN-1000 Instructions for Use Revised August 2012 Chapter 6 6.6.2 Basic Operation Shutting down the analyzer manually If needed, you can shut down only the analyzer. Follow the steps below to shut down the analyzer. 1 Check the Status indicator LED on the analyzer. If the Status indicator LED is not lit green, wait until it does. Status indicator LED 2 Click the Analyzer menu button on the control menu. The menu on the right appears. 3 Click [Shutdown]. The window on the right appears. If retracted, the tube holder slides out forward. 6-18 XN-1000 Instructions for Use Revised August 2012 Chapter 6 4 Basic Operation Place CELLCLEAN AUTO in the tube holder. Place it in the front holder, when you face the analyzer. 5 Press the start switch on the analyzer. The tube holder retracts into the analyzer and aspiration begins. When aspiration finishes, the tube holder automatically eject out. Note: • When [IPU Shutdown] is set to ON, the IPU shuts down automatically after all analyzers connected to the IPU have shut down. (➤Administrator's Guide, "Chapter 4: 4.3.2 System Settings") • About 15 minutes is required for shutdown. Progress is shown in a progress bar on the screen. When shutdown finishes, the tube holder automatically retracts into the analyzer. • If the CELLCLEAN AUTO is not removed before shutdown finishes, a notice indicating that a sample tube remains in the tube holder will appear at the next startup.

6-19 XN-1000 Instructions for Use Revised December 2012 Chapter 6 6.6.3 Basic Operation Shutting down the IPU manually If needed, you can shut down the IPU. Follow the procedure below to turn off the power of the IPU. 1 Click [Exit IPU] in the menu screen. A dialog box appears. 2 Click [Yes]. The IPU shuts down. 3 Shutdown Windows. Your computer shuts down. 6.7 Restart the analyzer If [IPU Shutdown] is set to OFF, you can restart the analyzer by following the steps below. If [IPU Shutdown] is set to ON, the IPU shuts down automatically after all analyzers connected to the IPU have shut down. Therefore, the analyzers cannot be restarted. (➤Administrator's Guide, "Chapter 4: 4.3.2 System settings") 1 Shutdown all analyzers connected to the IPU. A dialog box appears. 2 Click [Restart] in the dialog. The power to the analyzer turns ON, and the analyzer runs a self-check. Wait until the self-check is complete. (➤P.6-13 "6.3.4 Execution of analyzer self-check") 6-20 XN-1000 Instructions for Use Revised August 2012 Chapter 6 Basic Operation 6.8 On-line manuals For rapid access, the manual will be accessible through the IPU. The following screen appears when [Instructions for Use] is clicked in the menu screen.

Manual selection buttons Acrobat Reader toolbar Bookmark display area Manual display area Magnification button Previous/next buttons First page/last page buttons Manual selection buttons Click to change manuals. The manuals that appear vary depending on the configuration of your instrument. Acrobat Reader toolbar Acrobat Reader toolbar area.

Enter a page number in the box on the left to display that page. Enter a text string in the box on the right to search the manual for that text. Manual display area Displays the manual. Bookmark display area Table of contents of the manual. Click a chapter title to display the topics in that chapter. Click a topic to display that topic in the screen. [Back] Click to return the bookmark area to the list of chapter titles. [Zoom] Changes the zoom [+] Click to enlarge the view of the manual. [-] Click to reduce the view of the manual. Magnification button Select any magnification to change the view of the manual to that magnification.

[Fit] Click to fit the view of the manual to the manual display area. 6-21 XN-1000 Instructions for Use Revised August 2012 Chapter 6 Basic Operation [Move Page] First page/last page buttons Use to move through the pages. Click to move to the first page or the last page of the displayed manual. Previous/next buttons Click to move back to the previous page or forward to the next page. [Toolbar] You can select whether the Acrobat Reader toolbar is displayed. 6-22 XN-1000 Instructions for Use Revised August 2012 Chapter 7 Preparing for analysis (registering information) Chapter 7 Preparing for analysis (registering information) This chapter explains how to manually register the analysis order and the patient information before performing an analysis.

7.1 Work List functions The Work List functions allow you to display, register, modify and delete analysis orders. You can register analysis information for up to 2,000 orders. You can sort, filter, search, save and restore analysis order. 7.1.1 Work List screen Clicking the [Work List] icon in the Menu screen displays the screen shown below.Alternatively, you can also click the [Work List] button on the toolbar. A maximum of 2,000 analysis orders can be stored. Toolbar Font size button Order properties Filter/sort description Order list Patient information [Work List] screen Display switching button ● Toolbar The button of the following functions are displayed. [Regist.] Click to display the [Regist Order] dialog box. [Modify] Click to display the [Modify Order] dialog box for the selected analysis order. [Download] Click to download analysis orders from the host computer. [Filter] Click to display a dialog box that allows you to set conditions for the data displayed in the order list. [Sort] Click to display a dialog box that allows you to set the sorting order for the data displayed in the order list. [Output] Click to output the data of the selected analysis order. [Upper] Click to move the selection up by one row. [Lower] Click to move the selection down by one row. 7-1 XN-1000 Instructions for Use Revised August 2012 Chapter 7 Preparing for analysis (registering information) [FIND] Click to display a dialog box that allows you to search data. [Pending] Click to switch the display between pending orders only and all analysis orders.

[File] Click to display a submenu. This can be used to save and restore data. [Delete] Click to display a dialog box that allows you to delete the selected analysis order. ● Order list The main screen of the Work List screen. [Status] Displays the status of the order. [PEND.] Indicates that the order has been registered. [COMP.] Indicates that the analysis has completed. [ERR.] Indicates that an error has occurred. [Date] Displays the date and time at which the order was registered.

[Rack] Displays the rack number. [Position] Displays the sample tube position number when the sampler analysis was performed. [Sample No.] Displays the sample number. The column to the right of the [Sample No.] column indicates how the sample number was obtained. [B] : Hand-held barcode reader input [M] : Manually entered [C] : Host computer queried If you modify a sample number, an [M] is displayed. [Discrete] Displays the discrete tests for the analysis parameters you specified in the [Work List] screen or the host computer. [Patient ID] Displays the patient ID. [Patient Name] Displays the name of the patient (first name, last name).

[Sample Comment] Displays the status of the sample entered by the user and other information. ● Order properties Displays the details of the analysis order selected in the order list.

It appears on the sub screen. [ITEM] All analysis items are displayed. [Order] The analysis parameters for the order selected in the list pane are marked with a check mark ([V]). 7-2 XN-1000 Instructions for Use Revised August 2012 Chapter 7 Preparing for analysis (registering information) ● Patient information Displays the patient information of the analysis order selected in the order list. It appears on the sub screen. Patient Name Patient Comment Patient ID Ward Name Date of birth, sex and age Doctor Name Patient Name Displays the name of the patient (first name, last name). Patient ID Displays the patient ID. Date of birth, sex and age Displays the date of birth, gender, and age of the patient. Ward Name Displays the patient's ward name or the name of the clinical service. Doctor Name Displays the name of the doctor assigned to the patient. Patient Comment Displays comments about the patient. Note: • For the details on registering each items, see below. - Patient Name, Patient ID, Date of birth, sex and age: (➤P.7-20 "7.2.2 Registering and modifying patient information") - Ward Name: (➤P.7-27 "7.2.7 Registering and modifying ward names") - Doctor Name: (➤P.7-29 "7.2.9 Registering and modifying doctor names") • Items that have not been filled will not be displayed. ● Filter/sort description Shows what conditions were used to display the analysis orders. These are the conditions you specified in the filter and sort settings. For the details on the settings, see below. (➤P.7-10 "7.1.3 Sorting analysis orders") (➤P.7-11 "7.1.4 Specifying data display conditions (filter)") The following symbols are used. Symbol Analysis Method [] Brackets The condition inside [ ] is considered one grouping. If there is a defined name, it is shown in front of the brackets.

e.g. A filter called "Weekly Retests" that restricts by [Date]: Weekly Retests[Date[2010/05/05~2010/06/06]] , Comma The conditions before and after the comma are combined with a logical AND. e.g. Orders restricted by [Date] AND [Order Type]: [Date[2010/05/05~2010/06/06],Order Type[Rerun]] 7-3 XN-1000 Instructions for Use Revised August 2012 Chapter 7 Preparing for analysis (registering information) Symbol Analysis Method | Pipe The conditions before and after the pipe are combined with a logical OR. e.g. All orders whose [Order Type] is either [Rerun] OR [Reflex]: [Order Type[Rerun|Reflex]] : Colon Used between a setting and its value. e.g. All orders whose [Print Graphic] setting under [Output Results] is [Outputted]: [Output Results[Print Graphic:Outputted]] () Parentheses Indicates [Asc.] or [Desc.]. e.g. All orders sorted by [Analysis Date] in ascending order: [Analysis Date(Asc.)] > Greater-than symbol Indicates priorities between sort conditions. e.g. [Date] has higher priority than [Time]: [Date(Desc.)]>[Time(Asc.)] ● Display switching button You can click the display switching button to open/close the sub screens. Click to switch through the 4 patterns in the order "sub-screen (right and bottom)" → "sub-screen (bottom)" → "no sub-screen" → "sub-screen (right)". ● Font size button To change the size of the characters and the line height in the sample list, click the character size button. When you change the size setting of the characters, see "Administrator's Guide".

(➤Administrator's Guide,"Chapter 4: 4.3.3 Display settings") Note: Multiple data can be selected as follows: • Drag multiple consecutive rows while holding down the left button on the mouse or. • While pressing Ctrl, click on the row that you want to select. 7-4 XN-1000 Instructions for Use Revised August 2012 Chapter 7 7.1.2 Preparing for analysis (registering information) Registering and modifying analysis orders This section explains how to register and modify an analysis order from the [Work List] screen. Registering an analysis order Click the [Regist.] button on the toolbar to display the dialog box below. Order selection area [Regist Order] dialog Modifying an analysis order When you double-click on the table of orders in the [Regist Order] dialog, the [Modify Order] dialog appears. Alternatively, you can also select the order you want to modify, and then click the [Modify] button on the toolbar. The fields in the [Modify Order] dialog box are the same as those of the above*. Please refer to it. * [Rack unit registration] does not appear. Note: • If 2,000 analysis orders have been registered, the [Regist.] button on the toolbar is grayed out and cannot be clicked.

Delete old orders and then register a new analysis order. • Analysis orders for which analysis has been completed cannot be modified. • When registering an analysis order, if an order with the same entries for the items below has already been registered, a dialog box will appear to confirm overwriting of the previous order.

- [Sample No.] - [Rack No.] and [Tube Pos.] 7-5 XN-1000 Instructions for Use Revised February 2013 Chapter 7 Preparing for analysis (registering information) Follow the steps below to register or modify an analysis order.

1 Populate the displayed fields. [Sample No.] For new registrations, a sample number is automatically generated. Alternatively, you can also assign an arbitrary sample number. You can enter up to 22 characters. An order can only be modified if analysis ordering is set to [Rack No./Tube Pos.]*. [Rack No.] For new registrations, a rack number is automatically generated. Alternatively, you can also assign an arbitrary number. You can enter up to 6 characters. Entry is only possible when analysis ordering is set to [Rack No./Tube Pos.]*. In the Modify dialog box, [Rack No.] is grayed out and cannot be clicked. [Tube Pos.] For new registrations, a tube position number is automatically generated. Alternatively, you can also assign an arbitrary number. Any number between 1 and 10 can be entered.

Entry is only possible when analysis ordering is set to [Rack No./Tube Pos.]*. In the Modify dialog box, [Tube Pos.] is grayed out and cannot be clicked. [Rack unit registration] This can be selected to register orders by rack. If less than 10 orders can be registered, this is grayed out and cannot be selected. Entry is only possible when analysis ordering is set to [Rack No./Tube Pos.]*. [Discrete] Select the discrete test. For the parameters included in each discrete test, see below. (➤P.7-9 "Table of discrete tests and their corresponding analysis parameters") A selection button is displayed on the right side of [Discrete].

Clicking the button displays the order selection area on the right side of the dialog box. [Sample Comment] Enter comments about the sample. You can enter up to 40 characters. [Patient ID] Enter the patient ID. You can enter up to 16 characters. When you enter a [Patient ID], a corresponding [Patient Information] is automatically searched. If there is a match, the information is displayed. This is displayed only if the user who is logged in has the privileges to display and modify patient info. For details on privileges to display and modify patient info, see the "Administrator's Guide". (➤Administrator's Guide,"Chapter 4: 4.3.2 System settings") * For the analysis ordering setting, see the "Administrator's Guide". (➤Administrator's Guide, "Chapter 4: 4.3.5 Auto Processing Settings") 7-6 XN-1000 Instructions for Use Revised February 2013 Chapter 7 Preparing for analysis (registering information) ● [Patient Information] The analysis order can be registered without entering any patient information.

* This is displayed only if the user who is logged in has the privileges to display and modify patient info. For details on privileges to display and modify patient info, see the "Administrator's Guide". (➤Administrator's Guide,"Chapter 4: 4.3.2 System settings") [Last Name] Enter the last name of the patient. You can enter up to 20 characters. [First Name] Enter the first name of the patient. You can enter up to 20 characters. [Birth] Enter the patient's date of birth. Enter it in the format "Year (4 digits)/Month (2 digits)/Date (2 digits)". If you click the button on the right edge of the input field, a calendar appears. You can also enter the date by selecting from this calendar. A delete button is displayed on the right side of [Birth] field. Clicking it will clear the patient's date of birth. [Age] Enter the patient's age. This is automatically displayed when [Birth] is entered. [Sex] Select the patient's gender. [Ward Name] Select the name of the patient's ward. [Doctor Name] Select the name of the doctor assigned to the patient. [Patient Comment] Enter any comment about the patient. You can enter up to 100 characters. Information If a patient ID has not been entered, patient information cannot be entered. Order selection area ● [Order] Select the check boxes to specify the parameters to analyze. The displayed analysis parameters vary depending on the configuration of the connected analyzer. If you have selected a [Discrete], the check boxes for the corresponding parameters are selected. If the selected parameter combination does not exist under [Discrete], [FREE SELECT] is displayed in the [Discrete] field. For discrete tests and analysis parameters, see below. (➤P.7-9 "Table of discrete tests and their corresponding analysis parameters") ● [Channel] [Analyze PLT-F Channel] Select this check box to enable the analysis of the PLT-F channel. You can select this check box only when the order includes the PLT parameter. [Analyze WPC Channel] Select this check box to enable the analysis of the WPC channel. You can select this check box only when the order includes the DIFF parameter. 7-7 XN-1000 Instructions for Use Revised August 2012 Chapter 7 2 Preparing for analysis (registering information) Click [OK]. The dialog box closes, and the analysis order is registered (or modified). To register continuously, click [Continuous Registration]. * In the Modify dialog box, [Continuous Registration] does not appear.

[Continuous Registration] When [Rack unit registration] is not selected The entered analysis order is registered and the next analysis order can be registered. When [Rack unit registration] is selected The entered analysis order is registered as a [Tube Pos.] 1. Repeat to register tube positions to [Tube Pos.] 10. If tube positions are registered to [Tube Pos.] 10, the next [Regist Order] dialog box appears. Note: If a discrete test in not selected under [Discrete], or if the [Sample No.] field is blank or set to "0", the [OK] button and [Continuous Registration] button are grayed out and cannot be clicked. 7-8 XN-1000 Instructions for Use Revised August 2012 XN-1000 Instructions for Use ✓ ✓ CBC+DIFF+RET+PLT-F*2,3 Revised August 2012 ✓ NRBC# NRBC% ✓ ✓ ✓ ✓ - ✓ ✓ - - ✓ ✓ - NEUT%/LYMPH%/ MONO%/EO%/BASO%/ NEUT#/LYMPH#/ MONO#/EO# / BASO# ✓ - ✓ - ✓ ✓ - - ✓ ✓ - - RET%/RET#/ IRF/LFR/ MFR/HFR *1 In addition, depending on the specified analysis conditions, the analysis results from [RBC/PLT], [PLT-F], or a combination of [RBC/PLT] and [RET] channel will be used.

*2 During [Pre-Dilution] mode, you can use only these discrete tests. [RET] and [PLT-F] do not appear with all analyzer types. *3 Cannot be used depending on the analyzer type.

This is displayed when the condition for [FREE SELECT] is met, and the [Analyze WPC Channel] and the [Analyze PLT-F Channel] check boxes are both selected. ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ RDW-SD/ RDW-CV/ PDW/MPV/ P-LCR/PCT FREE SELECT+PLT-F+WPC ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ PLT*1 This is displayed when the condition for [FREE SELECT] is met, and the [Analyze PLT-F Channel] check box is selected. ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ MCHC FREE SELECT+PLT-F ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ MCH This is displayed when the condition for [FREE SELECT] is met, and the [Analyze WPC Channel] check box is selected. ✓ CBC+DIFF+RET+PLT-F+WPC*3 ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ MCV FREE SELECT+WPC ✓ CBC+DIFF+PLT-F+WPC*3 ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ HCT If a combination other than the above default discrete tests is selected, [FREE SELECT] is displayed. ✓ CBC+DIFF+RET+WPC*3 ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ HGB FREE SELECT ✓ CBC+DIFF+WPC*3 ✓ ✓ CBC+DIFF+PLT-F*3 CBC+RET+PLT-F*3 ✓ CBC+PLT-F*3 ✓ CBC+RET*3 CBC+DIFF+RET* ✓ CBC+DIFF*2 3 ✓ WBC RBC CBC*2 Default Discrete Tests Analysis parameters Table of discrete tests and their corresponding analysis parameters Chapter 7 Preparing for analysis (registering information) 7-9 Chapter 7 7.1.3 Preparing for analysis (registering information) Sorting analysis orders You can sort analysis orders by the conditions that you specify. Follow the steps below to sort analysis orders. 1 Click the [Sort] button on the toolbar.

The dialog box on the right appears. 2 Populate the displayed fields. In fields [1st Key] through [4th Key], specify the sort conditions. The sort conditions are prioritized from [1st Key] to [4th Key]. After selecting the keys, sort the alphanumeric in [Asc.] (0 to 9, A to Z) or [Desc.] (9 to 0, Z to A) order. 3 [Date] Sorts by date and time of registration. [Sample No.] Sorts by sample number. [Rack No.] Sorts by rack number. [Tube Pos.] Sorts by sample tube position number. [None] Condition not specified. Click [OK]. The dialog box closes, and sorting is applied. 7-10 XN-1000 Instructions for Use Revised August 2012 Chapter 7 7.1.4 Preparing for analysis (registering information) Specifying data display conditions (filter) You can specify conditions for the data you want displayed. Follow the steps below to specify conditions for the data you want displayed. 1 Click the [Filter] button on the toolbar. The dialog box on the right appears. If a pending order is displayed, the [Filter] button is grayed out and cannot be clicked. 2 Populate the displayed fields. The following items appear in the dialog box.

[Use Filter] [Specify Date] [Starting Day] / [Ending Day] [Specify Status] 3 Selecting this check box will display only the orders that match the specified conditions. If you clear the check box, the settings will be grayed out and cannot be selected. Select this check box to restrict the data to display by date. Click to select [Today], [Yesterday] or [Specify]. Selecting [Specify] allows you to specify the date. In the field below [Specify], enter the date in the format "Year (4 digits)/Month (2 digits)/Date (2 digits)". If you click the button on the right edge of the input field, a calendar appears. You can also enter the date by selecting from this calendar. Select this check box to specify the status of the analysis order you want displayed. [PEND.] Select this check box to display orders that have not been analyzed.

[COMP.] Select this check box to display orders whose analysis have been completed. [ERR.] Select this check box to display orders in which an analysis error has occurred. Click [OK]. The dialog box closes and the specified data appear. 7-11 XN-1000 Instructions for Use Revised August 2012 Chapter 7 Preparing for analysis (registering information) 7.1.5 Searching analysis orders You can search for a specific analysis order. Follow the steps below to search for an analysis order. 1 Click the [FIND] button on the toolbar. The dialog box on the right appears. When the dialog box is started, the ward name / doctor name selection field is not displayed. Ward name input field Ward selection area List of ward names Select button When the Ward selection area is displayed Note: The doctor selection area is similar to the above dialog box. Please refer to it.

2 Populate the displayed fields. The following items appear in the dialog box. ● [Find Conditions] [Sample No.] Enter the patient's sample number. You can enter up to 22 characters. [Patient ID] Enter the patient's ID.

You can enter up to 16 characters. [Last Name] Enter the patient's last name. You can enter up to 20 characters.

[First Name] Enter the patient's first name.

You can enter up to 20 characters. [Ward Name] Displays the selected ward name. Select button [Doctor Name] Select button Clicking the button displays the ward selection area on the right side of the dialog box. Displays the selected doctor for the patient. Click to cancel the ward name / doctor name filter. 7-12 XN-1000 Instructions for Use Revised August 2012 Chapter 7 Preparing for analysis (registering information) ● Ward / Doctor selection area Ward name / Doctor name input field Enter a condition to narrow down the ward names / doctor names. You can enter up to 20 characters. List of ward names / doctor names Displays the ward names / doctor names that contain the condition that you entered. Click to select the ward name / doctor name. You can only select one ward name / doctor name. [Clear] Click to clear the selected ward name / doctor name. Note: You can enter "?" and "*" as substitution characters in your search. "?": A "?" is used in place of any one character. e.g. If you search for "99?99", "99099", "99999", and "99A99" are all selected. "*": A "*" is used in place of zero or more characters. e.g. If you search for "9*9", "909", "9119", and "99A99" are all selected. 3 Specify the search condition. If you want to find orders that match the specified conditions exactly, select the [Find exact matches] check box. If you clear the check box, it will also find orders that partially match the specified conditions. 4 Click [PREV.] / [NEXT]. An order that matches the search conditions is selected in the list pane. 5 [PREV.] Click to search up from the analysis order selected in the list pane. [NEXT] Click to search down from the analysis order selected in the list pane. Click [Close]. The dialog box closes. 7-13 XN-1000 Instructions for Use Revised December 2012 Chapter 7 Preparing for analysis (registering information) 7.1.6 Saving pending order (backup) You can save all of the registered pending orders in one file. Follow the steps below to save pending analysis orders. 1 Click the [File] button - [Backup] on the toolbar. The dialog box on the right appears. Note: If there are no pending orders, [Backup] is grayed out and cannot be clicked. 2 Click [OK]. The [Save As] dialog box appears. 3 Specify the save folder. 4 Enter the file name. The file extension is ".odr". Note: The default file name is in the format [XN][Software version][Order][Date of save_Time of save].odr. e.g. [XN][00-01][Order][20100505_080808].odr 5 Click [Save]. All registered pending orders are saved.

Information In the patient information that is associated with the order, only [Patient ID] is backed up regardless of the setting. To back up other patient information, back up from patient registration. 7-14 XN-1000 Instructions for Use Revised August 2012 Chapter 7 7.1.7 Preparing for analysis (registering information) Restoring saved pending orders You can restore saved pending orders. Follow the steps below to restore saved pending orders. 1 Click the [File] button - [Restore] on the toolbar. The [Open] dialog box appears.

2 Select the name of the file you want to restore. The file extension is ".odr". 3 Click [Open]. Pending orders are restored. Note: • Once the number of registered orders exceeds 2,000, any subsequent new registration will overwrite the oldest registered order. • If a registered data already exists with the same value for the items below, a dialog box appears to confirm overwriting. - [Sample No.] - [Rack No.] and [Tube Pos.] • Because of the analyzer's structure, the orders which cannot be registered are deleted when the orders including the items that cannot be analyzed are restored. 7.1.8 Displaying only the pending orders Displaying only pending analysis orders in the order list is possible. Click the [Pending] button on the toolbar to display pending orders. 7-15 XN-1000 Instructions for Use Revised February 2013 Chapter 7 Preparing for analysis (registering information) 7.1.9 Downloading analysis orders Analysis orders can be downloaded from the host computer. Follow the steps below to download analysis orders. 1 Click the [Download] button on the toolbar. The dialog box on the right appears. 2 Enter the [Rack No.]. Enter the rack number of the analysis order you want to download. You can enter up to 6 characters. You can query up to 10 orders.

3 Click [OK]. The analysis orders are downloaded from the host computer using the rack number that you entered. Note: • If the host computer is not connected, if the order request item is set to [Sample No.], [OK] is grayed out and cannot be clicked. • Once the number of registered orders exceeds 2,000, any subsequent new orders will overwrite the oldest registered order. • If the [Patient ID], [Ward Name] and/or [Doctor Name] of a downloaded analysis order are the same as an already registered order, they are overwritten. • If a communication error occurs while downloading, the downloaded orders are registered. The orders which does not finish downloaded are not registered. • If the downloaded analysis order and the already registered pending order have the same [Rack No.] and [Tube Pos.], a dialog box appears to confirm overwriting.

• Because of the analyzer's structure, the orders which cannot be registered are deleted when the orders including the items that cannot be analyzed are restored. 7-16 XN-1000 Instructions for Use Revised February 2013 Chapter 7 7.1.10 Preparing for analysis (registering information) Deleting analysis orders Follow the steps below to delete analysis orders selected in the order list. 1 In the list pane, click the order you want to delete. The order is selected. You can select multiple items. 2 Click the [Delete] button on the toolbar. The dialog box on the right appears. 3 Click [OK].

The dialog box closes, and the order is deleted. 7-17 XN-1000 Instructions for Use Revised August 2012 Chapter 7 7.2 Preparing for analysis (registering information) Patient List functions Use the Patient List functions to display, register, modify, save, restore and delete patient information, ward names, and doctor names. Opening / switching to [Patient List] screen Clicking the [Patient List] icon in the Menu screen displays the [Patient List] screen. Clicking the tab switches the view.

* The procedures for using the functions in the [Patient List] screen are same as the [Work List] screen. For information on saving, restoring, and deleting patient information, see the procedures for using the [Work List] screen. ● Saving [Patient Information] You can back up all of [Patient Information], [Ward Name], and [Doctor Name] into a single file. The file extension is ".pat".

Refer to the following procedures in the [Work List] screen. (➤P.7-14 "7.1.6 Saving pending order (backup)") Note: The default file name is in the format [XN][Software version][Patient][Date of save_Time of save].pat e.g. [XN][00-01][Patient][20100505_080808].pat Information If [Include patient information] is selected in [Security Settings], patient information is output to the backup file. If [Output patient information] is selected, patient information is output to a CSV file. For the details on the security settings, see "Administrator's Guide". (➤Administrator's Guide, "Chapter 4: 4.3.2 System settings") ● Restoring saved [Patient Information] You can restore the [Patient Information], the [Ward Name], or the [Doctor Name] from the backup patient information. The file extension is ".pat". Refer to the following procedures in the [Work List] screen. (➤P.7-15 "7.1.7 Restoring saved pending orders") ● Deleting [Patient Information], [Ward Name], and/or [Doctor Name] Perform this operation while the screen corresponding to the item to be deleted is displayed. Refer to the following procedures in the [Work List] screen. (➤P.7-17 "7.1.10 Deleting analysis orders") 7-18 XN-1000 Instructions for Use Revised August 2012 Chapter 7 7.2.1 Preparing for analysis (registering information) Patient Information screen Clicking the [Patient Information] tab displays the following screen. In the [Patient Information] screen, you can sort, filter, search, save and restore patient information. You can register patient information for up to 10,000 patients. Toolbar Patient information list [Patient Information] screen ● Toolbar The button of the following functions are displayed. [Regist.] Click to display the [Register Patient Information] dialog box. [Modify] Click to display the [Modify Patient Information] dialog box for the selected patient information. [Filter] Click to display the dialog box that allows you to set the conditions for the data to be displayed in the patient information list. [Sort] Click to display the dialog box that allows you to set the sort order for the data to be displayed in the patient information list. [Upper] Click to move the selection up by one row. [Lower] Click to move the selection down by one row. [FIND] Click to display a dialog box that allows you to search data. [File] Click to display a submenu. This can be used to save and restore data. [Delete] Click to display a dialog box that allows you to delete the selected patient information. 7-19 XN-1000 Instructions for Use Revised August 2012 Chapter 7 Preparing for analysis (registering information) ● Patient information list Displays the registered patient information. [Patient ID] Displays the patient's ID. [Patient Name] Displays the name of the patient (first name, last name). [Sex] Displays the patient's gender. [Birth] Displays the patient's date of birth. [Age] Displays the patient's age. [Ward Name] Displays the patient's ward name or the name of the clinical service. [Doctor Name] Displays the name of the doctor assigned to the patient. [Patient Comment] Displays comments about the patient. 7.2.2 Registering and modifying patient information This section explains how to register and modify patient information. Registering patient information Click the [Regist.] button on the toolbar to display the following dialog box. [Register Patient Information] dialog Modifying patient information From the list pane, double-click the patient information you want to modify.

The [Modify Patient Information] dialog box appears. Alternatively, you can also select the patient information you want to modify, and then click the [Modify] button on the toolbar. The fields in the [Modify Patient Information] dialog box are the same as those in the [Register Patient Information] dialog box*. Please refer to it. Follow the steps below to register or modify patient information. * [Continuous Registration] does not appear. 7-20 XN-1000 Instructions for Use Revised August 2012 Chapter 7 1 2 Preparing for analysis (registering information) Populate the displayed fields. [Patient ID] For new registrations, you can enter the patient ID. You can enter up to 16 characters. You cannot modify it. The patient ID cannot be changed when modifying information. [Last Name] Enter the patient's last name. You can enter up to 20 characters. [First Name] Enter the patient's first name. You can enter up to 20 characters. [Birth] Enter the patient's date of birth. Enter it in the format "Year (4 digits)/Month (2 digits)/ Date (2 digits)". If you click the button on the right edge of the input field, a calendar appears. You can also enter the date by selecting from this calendar. A delete button is displayed on the right side of [Birth] field. Clicking it will clear the [Birth] field. [Age] Enter the patient's age. This is automatically displayed once the date of birth is entered. [Sex] Select the patient's gender. [Ward Name] Select the patient's ward name or the name of the clinical service.

[Doctor Name] Select the doctor assigned to the patient.

[Patient Comment] Input comments about the patient. You can enter up to 100 characters. Click [OK]. The dialog box closes, and the patient information is registered (or modified).

Clicking [Continuous Registration] registers the [Patient Information] that you just entered, and allows you to register the next [Patient Information]*. * In the Modify dialog box, [Continuous Registration] does not appear. Note: Once the number of registered orders exceeds 10,000, any subsequent new registration will overwrite the oldest registered order. 7-21 XN-1000 Instructions for Use Revised August 2012 Chapter 7 Preparing for analysis (registering information) 7.2.3 Sorting patient information You can sort patient information by the condition that you specify. Follow the steps below to sort patient information. 1 Click the [Sort] button on the toolbar. The dialog box on the right appears. 2 Populate the displayed fields. In fields [1st Key] through [5th Key], specify the sort keywords. The sort conditions are prioritized from [1st Key] to [5th Key]. After selecting the keys, sort the alphanumeric in [Asc.] (0 to 9, A to Z) or [Desc.] (9 to 0, Z to A) order. 3 [Patient ID] Sorts by patient's ID. [Last Name] Sorts by patient's last name. [First Name] Sorts by patient's first name. [Age] Sorts by patient's age. [Sex] Sorts by patient's gender. [None] Condition not specified. Click [OK]. The dialog box closes, and sorting is applied. 7-22 XN-1000 Instructions for Use Revised August 2012 Chapter 7 7.2.4 Preparing for analysis (registering information) Specify conditions for the patient information to display (filter) You can specify conditions for the data you want displayed in the patient information list. Follow the steps below to specify conditions for the data you want displayed. 1 Click the [Filter] button on the toolbar. The following dialog box appears. * When the dialog box is started, the ward name / doctor name selection field is not displayed. Select button Ward name input field Ward selection area When the Ward name is displayed List of ward names Note: The doctor selection area is similar to the above dialog box. Please refer to it. 2 Populate the displayed fields. The following items appear in the dialog box.

[Use Filter] Selecting this check box will display only the orders that match the specified conditions. If you clear the check box, the following settings will be grayed out and cannot be selected. [Specify Sex] Selecting this check box enables you to specify the patient's gender. [Specify Ward] Selecting this check box enables you to specify the patient's ward. Select button Clicking the button displays the ward selection area on the right side of the dialog box. [Specify Doctor Name] Select button Selecting this check box enables you to specify the name of the patient's doctor. Clicking the button displays the doctor selection area on the right side of the dialog box. 7-23 XN-1000 Instructions for Use Revised August 2012 Chapter 7 Preparing for analysis (registering information) ● Ward / Doctor selection area 3 Ward name / Doctor name input field Enter a condition to narrow down the ward names / doctor names. You can enter up to 20 characters. List of ward names / doctor names Displays the ward names / doctor names that contain the condition that you entered.

Click to select the ward name / doctor name. You can only select one ward name / doctor name. [Clear] Click to cancel the ward name / doctor name filter. Click [OK]. The dialog box closes. Only the patient information that match all of the specified criteria are displayed. 7.2.5 Searching for patient information You can search for specific patient information. Follow the steps below to search for patient information. 1 Click the [FIND] button on the toolbar. The dialog box on the right appears. 2 Populate the displayed fields. [Patient ID] Enter the patient ID. You can enter up to 16 characters. [Last Name] Enter the patient's last name. You can enter up to 20 characters.

[First Name] Enter the patient's first name. You can enter up to 20 characters.

7-24 XN-1000 Instructions for Use Revised August 2012 Chapter 7 Preparing for analysis (registering information) Note: You can enter "*" and "?" as substitution characters in your search. "?": A "?" is used in place of any one character. e.g. If you search for "99?99", "99099", "99999" and "99A99" are all selected. "*": A "*" is used in place of zero or more characters. e.g. If you search for "9*9", "909", "9119" and "99A99" are all selected. 3 Specify the search condition. If you want to find patient informations that match the specified conditions exactly, select the [Find exact matches] check box. If you clear the check box, it will also find patient informations that partially match the specified conditions. 4 Click [PREV.] / [NEXT]. An patient information that matches the search conditions is selected in the list pane. 5 [PREV.] Click to search upward from the ward name selected in the list. [NEXT] Click to search downward from the ward name selected in the list. Click [Close]. The dialog box closes. 7-25 XN-1000 Instructions for Use Revised August 2012 Chapter 7 Preparing for analysis (registering information) 7.2.6 Ward Name screen Clicking the [Ward Name] tab displays the following screen. In the [Ward Name] screen, you can sort and search ward names. You can register up to 200 ward names. Toolbar List of ward names ● Toolbar The button of the following functions are displayed. [Regist.] Click to display the [Register Ward Name] dialog box. [Modify] Click to display the [Modify Ward Name] dialog box for the selected ward name. [Sort] Click to display the dialog box that allows you to set the conditions for the data to be displayed in the ward name list. [Upper] Click to move the selection up by one row. [Lower] Click to move the selection down by one row. [FIND] Click to display a dialog box that allows you to search data. [Delete] Click to display a dialog box that allows you to delete the selected ward name. ● List of ward names [No.] Displays the ward number. [Ward Name] Displays the name of the ward. Note: For instructions on the following tasks in the [Ward Name] screen, see the procedures for the [Patient Information] screen. • Sorting ward names (➤P.7-22 "7.2.3 Sorting patient information") • Searching for a ward name (➤P.7-24 "7.2.5 Searching for patient information") • Deleting ward names (➤P.7-17 "7.1.10 Deleting analysis orders") 7-26 XN-1000 Instructions for Use Revised August 2012 Chapter 7 7.2.7 Preparing for analysis (registering information) Registering and modifying ward names You can register and modify ward names from the [Ward Name] screen. Registering a ward name Click the [Regist.] button on the toolbar to display the dialog box on the right.

[Register Ward Name] dialog Modifying a ward name From the list pane, double-click the ward name you want to modify. The [Modify Ward Name] dialog box appears. Alternatively, you can also select the ward name you want to modify, and then click the [Modify] button on the toolbar. The fields in the [Modify Ward Name] dialog box are the same as those in the [Register Ward Name] dialog box. Please refer to it. Follow the steps below to register or modify a ward name. 1 2 Populate the displayed fields. [No.] For new registrations, the minimum number that has not been registered is automatically generated. You can change the displayed number. Any number between 0 and 200 can be entered. The number cannot be changed when modifying information. [Ward Name] Enter the name of the ward. You can enter up to 20 characters. Click [OK]. The dialog box closes, and the ward name is registered (or modified). Clicking [Continuous Registration] registers the [Ward Name] that you just entered, and allows you to register the next [Ward Name]*. * In the Modify dialog box, [Continuous Registration] does not appear. Note: If 200 records have been registered, the [Regist.] button on the toolbar is grayed out and cannot be clicked. 7-27 XN-1000 Instructions for Use Revised August 2012 Chapter 7 Preparing for analysis (registering information) 7.2.8 Doctor Name screen Clicking the [Doctor Name] tab displays the following screen. In the [Doctor Name] screen, you can sort and search for doctor names. You can register up to 200 doctor names. Toolbar Doctor name list ● Toolbar The button of the following functions are displayed. [Regist.] Click to display the doctor name registration dialog box. [Modify] Click to display the Modify dialog box for the selected doctor name.

[Sort] Click to display the dialog box that allows you to set the conditions for the data to be displayed in the doctor name. [Upper] Click to move the selection up by one row.

[Lower] Click to move the selection down by one row. [FIND] Click to display a dialog box that allows you to search data.

[Delete] Click to display a dialog box that allows you to delete the selected doctor name information. ● Doctor name list [No.] Displays the doctor number. [Doctor Name] Displays the doctor's name. Note: For instructions on the following tasks in the [Doctor Name] screen, see the procedures for the [Patient Information] screen. • Sorting doctor names (➤P.7-22 "7.2.3 Sorting patient information") • Searching for a doctor name (➤P.7-24 "7.2.5 Searching for patient information") • Deleting doctor names (➤P.7-17 "7.1.10 Deleting analysis orders") 7-28 XN-1000 Instructions for Use Revised August 2012 Chapter 7 7.2.9 Preparing for analysis (registering information) Registering and modifying doctor names You can register and modify doctor names from the [Doctor Name] screen. Note: The steps for registering and modifying a doctor name are the same as those for registering and modifying a ward name. (➤P.7-27 "7.2.7 Registering and modifying ward names") 7-29 XN-1000 Instructions for Use Revised August 2012 Chapter 7 Preparing for analysis (registering information) 7-30 XN-1000 Instructions for Use Revised August 2012 Chapter 8 Performing Quality Control Chapter 8 Performing Quality Control This chapter explains how to perform quality control tasks. 8.1 Introduction Quality control is the routine monitoring of performance using commercial or patient controls. Controls with known characteristics are analyzed and compared to the known characteristics using statistical methods. This allows changes to performance to be detected and then action can be taken if these changes are significant. 8.1.1 Quality control workflow Follow the steps below to perform quality control. Configure quality control settings ➤P.8-3 "Chapter 8: 8.2 settings" Configure quality control Create QC file (input lot information)* ➤P.8-4 "Chapter 8: 8.3 Registering and modifying a QC file (lot information input)" QC File screen ➤P.8-16 "Chapter 8: 8.5.1 screen" QC File Perform QC analysis ➤P.8-11 "Chapter 8: 8.4.1 Performing QC analysis using manual analysis" Check QC results ➤P.8-16 "Chapter 8: 8.5 results" Check quality control ➤P.8-15 "Chapter 8: 8.4.2 Performing QC analysis using sampler analysis" QC File screen ➤P.8-16 "Chapter 8: 8.5.1 screen" QC File QC Chart screen Troubleshoot any error that occurred ➤P.8-26 "Chapter 8: 8.6 control errors" ➤P.8-18 "Chapter 8: 8.5.2 screen" QC Chart Troubleshoot quality Repeat QC analysis and check results * This step is not necessary if you are using the automatic lot registration function. 8-1 XN-1000 Instructions for Use Revised August 2012 Chapter 8 Performing Quality Control 8.1.2 Types of quality control The following types of quality control methods exist. Use the appropriate method according to your needs. QC methods using control material • X-bar Control: The control blood is analyzed twice in succession, and the average of the 2 results is used as the control data. • L-J Control: Takes the data from a single analysis of control blood and uses it as the control data. QC using normal samples X-barM Control: This program calculates a weighted average of batches of normal patient samples (usually 20) and plots the resulting value as control data.

The number of samples can be set to any number. 8.1.3 About the timing of QC analysis Quality control is performed in order to monitor an instrument's performance over time. XN CHECK is the quality control material used to monitor the performance of the XN analyzer. Quality control should be run according to licensing agency regulations.

It should be noted that for troubleshooting purposes, additional control runs may be necessary. Note: You can periodically display a message to prompt the user to perform quality control tasks (quality control alarm). 8.1.4 Quality control materials When performing X-bar control or L-J control, use dedicated control blood. ● Types of control blood XN CHECK Level 1 XN CHECK Level 2 XN CHECK Level 3 XN CHECK BF Level1 XN CHECK BF Level2 Information • Only use the specified control blood. Control blood is specially designed to the analysis technology of the instrument.

• To execute the quality control using an external QC sample or a residual sample (pooled blood), set the [Material] to [Other]. 8-2 XN-1000 Instructions for Use Revised August 2012 Chapter 8 8.2 Performing Quality Control Configure quality control settings Before performing quality control tasks, configure the following settings. • Method of quality control (X-bar Control or L-J Control) • Settings related to limits • X-barM batch setting For explanation on how to configure these settings, see "Administrator's Guide". (➤Administrator's Guide, "Chapter 4: 4.3.8 QC settings") 8.2.1 Activating / deactivating X-barM Control X-barM control is executed each time the analyzer is started.

You can temporarily change this setting to not execute control. Follow the steps below to configure X-barM control settings.

1 Click the Analyzer menu button on the control menu. The menu on the right appears. 8-3 XN-1000 Instructions for Use Revised August 2012 Chapter 8 2 Performing Quality Control Click [X-barM Setting]. The dialog box on the right appears. Click [Execute] to perform X-barM Control, or [Cancel] to cancel X-barM Control. 3 Click [OK]. 8.3 Registering and modifying a QC file (lot information input) To perform quality control tasks, QC files must be registered. You can register up to 94 QC files per analyzer. Register lot information using one of the methods below. • Manual lot registration (➤P.8-4 "8.3.1 Performing lot registration manually") • Automatic lot registration (➤P.8-10 "8.3.2 Performing lot registration automatically") • Modifying lot information (➤P.8-10 "8.3.3 Modifying lot information") 8.3.1 Performing lot registration manually Follow the steps below to perform lot registration. 1 Click the [QC File] icon in the Menu screen. The [QC File] screen appears. 8-4 XN-1000 Instructions for Use Revised August 2012 Chapter 8 2 Performing Quality Control Click the [Regist.] button on the toolbar. The following dialog appears. Clear Date button [Input Lot Information] dialog 3 Enter lot information. ● [Lot Information] This section explains lot information settings.

[Material] Select the type of control blood. [Lot No.] Enter the lot number. You can enter up to 8 alphanumeric characters.

[Exp.

Date] Displays the currently set date. You can also click and directly enter the date. Clear Date button: Click to clear the displayed date. Information If you modify the [Material], the values in the list of setting parameters in step 4 are reset to the values that appear when the [Input Lot Information] dialog box is opened. 8-5 XN-1000 Instructions for Use Revised August 2012 Chapter 8 Performing Quality Control ● [Read Assay File] Reads the lot information from the CD-ROM that came with the control blood, or from the specified folder. Clicking [Read Assay File] will display the following dialog box. Source directory field List of files Source directory field Displays the folder from which the file list will be imported. You can also specify the import destination by manual entry. [Browse] Click to display the dialog box for specifying the folder. [Select Lot] Displays the list of files on the CD-ROM.

Select the file that you want to register. [Read Target / Limit] Select this check box if you want to read the target / limit of the selected QC item. If the check box is not checked, the target/limit values are reset to their default values which are shown when the dialog box is opened. Note: The lot number is registered as shown below in the assay file*. • XN CHECK Level1: QC-XXXX1101 • XN CHECK Level2: QC-XXXX1102 • XN CHECK Level3: QC-XXXX1103 • XN CHECK BF Level1: QC-XXXX1301 • XN CHECK BF Level2: QC-XXXX1302 *A number for each lot appears in XXXX. 8-6 XN-1000 Instructions for Use Revised August 2012 Chapter 8 4 Performing Quality Control Set target and limit values. List of setting parameters ● List of setting parameters This section explains how to edit target values and limit values.

[Item] The QC item name is displayed. [Lower Limit] The lower limit value is displayed. [Target] You can enter the target value. If left blank, a variable target is used, same as when you enter "0". [Upper Limit] The upper limit value is displayed. [Unit] The units of the QC item are displayed. ● [Manual Settings] You can manually set the target and limit values for the selected QC item. [Item] Displays the name of the item currently selected in the list. [Target] Click to enter the target value of the item that is selected in the list. [Limit Range (#)] / [Limit Range (%)] Click to enter the limit value of the item that is selected in the list. Depending of the configuration, this is displayed as a numerical value (#), or a ratio (%). ● [Variable Target] Specify this to quality control the QC files with arbitrary target values. A function that automatically calculates the target values using the control data in the file. This function activates when the targets are set to blank for X-bar Control, L-J Control, and X-barM Control.

Click to designate the target value of the selected item as a variable.

Nothing will be displayed in the [Target] field of the applicable item. If a "0" is entered in the [Target], or if it is left blank, it will be processed as a variable target. 8-7 XN-1000 Instructions for Use Revised August 2012 Chapter 8 Performing Quality Control Note: The average of the plots, excluding the latest plot, is set as the variable target. The target values are calculated as follows: If the number of plots is zero: 0* If the number of plots is 1: value of the plot. If the number of plots is 2 or more: Average value (excluding the latest plot) *If the limit setting is ratio, the limit range will be 100% and the minimum number of digits will be displayed on the grid for each QC item. ● [Auto Setting] Automatically sets the target and limit values for the selected QC item. Clicking [Auto Setting] will display the dialog box on the right. [Select Data] When the respective check box(es) is selected, the value for [Target] and/or [Limit] fields will be automatically calculated. [Lot Information] Displays the lot information. Information If the QC data or the selected range of plots contains less than 3 plots, statistical data cannot be calculated for the limit, therefore the limit cannot be automatically set. ● [Read Assay Items] Reads the assay targets and limits from the CD-ROM that came with the control blood, or from the specified folder. The file extension is ".qxn" or ".qbf".

Clicking [Read Assay Items] will display the dialog box on the right. [Browse] Click to display the dialog box for specifying the folder. [Select Data] When the respective check box(es) is selected, the value for [Target] and/or [Limit] fields will be read. [Lot Information] Displays the lot information. 8-8 XN-1000 Instructions for Use Revised August 2012 Chapter 8 Performing Quality Control ● [Backup] The [Save As] dialog box is displayed to let you save a target/limit backup file. Note: The Target/Limit values are saved as follows. [Analyzer ID][Software version][QCTargetLimit][File No.][Material][Lot No.].tlf ● [Restore] The [Open] dialog is displayed to let you restore a target/limit backup file. 5 Click [OK]. The lot information is registered and the dialog closes. Information If lot information with a same number already exists in the analyzer for which you are registering the lot information, registration cannot be performed. 8-9 XN-1000 Instructions for Use Revised August 2012 Chapter 8 Performing Quality Control 8.3.2 Performing lot registration automatically When sampler analysis is performed, lot information is acquired immediately before analysis and registered in the QC file. The assay value file is read from the CD-ROM included with the control blood and the lot information is registered in the QC file. Lot information (expiration date, target/limit values) is acquired from the lot number. If 94 QC files are already saved, saving a new file deletes the oldest file from the data base. If the oldest file is in use, the next oldest file that is not in use is deleted. Note: • A backup is kept of the deleted file as shown below. [Analyzer ID][Software version][QCFile][Date of save_Time of save][Material][Lot No.].qcf • If the lot number after "QC-" is more than 8 digits long, registration will not be performed. 8.3.3 Modifying lot information Follow the procedure below to modify lot information. 1 Click the [QC File] icon in the Menu screen. The QC File screen appears. For QC file, see below. (➤P.8-16 "8.5.1 QC File screen") 2 Select the QC file to be modified and click the [Modify] button on the toolbar. The [Input Lot Information] dialog box appears. For information on the [Input Lot Information] dialog box, see below. (➤P.8-4 "8.3.1 Performing lot registration manually") The following items can be modified. • Lot No • Exp. Date. • Target/Limit Note: [Material] cannot be modified, and thus the [Read File] button is grayed out and cannot be clicked. 8-10 XN-1000 Instructions for Use Revised August 2012 Chapter 8 8.4 Performing Quality Control Perform QC analysis This section explains how to perform QC analysis. 8.4.1 Performing QC analysis using manual analysis To perform body fluid analysis QC or QC using an external QC sample or remaining sample (pooled blood), perform manual analysis.To perform QC using an external QC sample or remaining sample (pooled blood), set [Material] to [Other]. Follow the steps below to perform QC analysis using manual analysis. 1 Check the Status indicator LED on the analyzer. If the Status indicator LED is not lit green, wait until it does. Status indicator LED 2 If the tube holder has not ejected out, press the mode switch. The tube holder slides out forward. 8-11 XN-1000 Instructions for Use Revised August 2012 Chapter 8 3 Performing Quality Control Click the Change Analysis Mode button on the control menu. The dialog box on the right appears. If the sample is whole blood, select [Whole Blood] mode. For body fluid, select [Body Fluid] mode. 4 Click [OK].

The dialog box closes. 5 Click the Analyzer menu button on the control menu. The menu on the right appears. 8-12 XN-1000 Instructions for Use Revised December 2012 Chapter 8 6 Performing Quality Control Click [QC Analysis]. The dialog box on the right appears. List of QC files 7 From the list of QC files, click the file you want to analyze. The dialog box on the right appears. [Execute L-J] dialog 8 Analyze the sample using manual analysis. For the details on analysis, see Chapter 9. (➤P.9-7 "Chapter 9: 9.3 Manual analysis" Step 5 and following steps) For the procedure for analyzing body fluid, see Chapter 9. (➤P.9-11 "Chapter 9: 9.4 Body fluid analysis" Step 5 and following steps) 8-13 XN-1000 Instructions for Use Revised August 2013 Chapter 8 9 Performing Quality Control Check the analysis results. When the analysis finishes, the analysis results are displayed in the [Execute L-J] dialog box. File information Error message Shortcut button Analysis results Next button Back button File information The information about the analyzed QC file is displayed. Error Message A message is displayed when there is an anomaly in the analysis results.

[Check control chart]: Indicates that the analysis data exceeds the QC limit. [Data error, repeat test]: Indicates that the analysis data exceeds the QC limit by over three times. This is displayed in white font on red background. Shortcut button Click to display item screens that are not currently displayed. If the data in a screen includes a warning, a warning mark appears. Analysis results Displays the analysis results*. For L-J Control, data will be displayed for 1 analysis only. For X-bar Control, the sample is analyzed twice, and an average value is displayed. If there was an abnormality in the analysis results, the corresponding cells are highlighted in red. * The dialog box above is for L-J Control. Back button Click to display the previous screen. Next button Click to display the next screen.

[Accept] Click to close the dialog and plot the analysis data onto QC charts. For the details on checking your analysis results, see below. (➤P.8-16 "8.5 Check quality control results") 8-14 XN-1000 Instructions for Use Revised August 2012 Chapter 8 8.4.2 Performing Quality Control Performing QC analysis using sampler analysis Follow the steps below to perform QC analysis using sampler analysis. 1 Place the vial containing control blood in the rack. When using a new lot of control blood, you can automatically import QC data obtained from the server. If the instrument is not configured to allow connection with the server, or if no network connection is available, insert the CD-ROM that came with the control blood into the IPU before analyzing, import the assay values, and register the lot information. For importing assay values, see below. (➤P.8-4 "8.3 Registering and modifying a QC file (lot information input)") 2 Analyze the sample using sampler analysis. For procedures on analysis, see Chapter 9. (➤P.9-18 "Chapter 9: 9.6 Sampler analysis") Once the analysis is finished, the QC results are displayed on the IPU's screen. For procedures on checking the results, see below. (➤P.8-16 "8.5 Check quality control results") 8-15 XN-1000 Instructions for Use Revised August 2013 Chapter 8 8.5 Performing Quality Control Check quality control results This section explains how to check the results from QC analysis. 8.5.1 QC File screen In the [QC File] screen, you can check the latest QC results for the QC file that is selected in the list. Clicking the [QC File] button on the toolbar, or the [QC File] icon on the Menu screen displays the following screen. Toolbar Radar charts QC file list Tabs [QC File] screen Display switching button ● Toolbar The buttons of the following functions are displayed. [Regist.] Click to display the [Input Lot Information] dialog box. [Modify] Click to display the [Input Lot Information] dialog box in edit mode. The displayed controls and fields are the same as when manually registering a new QC file. [QC Chart] Click to display the [QC Chart] screen. [Filter] Click to display the submenu. Select either [All Files] or [Lot registration exists]. [Sort] Sort the QC file list. Click to display the submenu. [File No.] Click to sort by file number in ascending order.

[Analysis Date] Each time this is clicked, the sorting method changes in the following order: analysis date/time descending order – registration date descending order – file number ascending order. [Sort]* Click to sort by the sorting condition set in [Modify Settings]. * The name of [Sort] in the sub-menu can be changed using [Sort Name] in [Modify Settings]. [Modify Settings] Click to open a dialog that lets you set the sorting condition. Select from [File No.], [Lot No.], [Regist. Date], or [Analysis Date]. 8-16 XN-1000 Instructions for Use Revised August 2012 Chapter 8 Performing Quality Control [Upper] Click to move the selection up by one row.

[Lower] Click to move the selection down by one row. [File] Click to display a submenu. This can be used to save and restore data. The submenus are not displayed when the X-barM chart is displayed. [Delete] Click to display a dialog box that allows you to delete the selected QC file. ● QC file list Displays a list of registered QC files. If there is a problem with a QC data, "[Error]" is displayed in white font on red background, on the left side of the list of QC files. ● Radar charts Displays the latest plot data from the selected QC file on the radar charts. If there is not a single plot in the selected QC file, only the frame and the item name are displayed. Any point exceeding the upper or lower limit is marked with a red "X". Upper Limit Target Lower Limit Plot data Title Displays the name of the analysis parameter (QC item). The displayed parameters vary with the QC method used. Any parameter exceeding the QC limit (upper or lower) will be highlighted in red. Lower Limit Indicates the lower QC limit. Upper Limit Indicates the upper QC limit. Target Indicates the target value. Plot data Indicates the plot data from the selected QC file. ● Display switching button You can click the display switching button to open/close the Radar charts (sub screens). 8-17 XN-1000 Instructions for Use Revised August 2012 Chapter 8 Performing Quality Control 8.5.2 QC Chart screen The [QC Chart] screen allows you to view detailed graph data of the QC file.

Clicking the [QC Chart] on the [QC File] screen's toolbar displays the following screen. QC file information (main) Chart display area (Left) Toolbar QC file information (reference) Chart display area (Center) Chart display area (Right) [QC Chart] screen ● Toolbar The buttons of the following functions are displayed.

[Regist.] Click to display the [Input Lot Information] dialog box. The QC chart is not displayed if the lot information has already been registered. [Modify] Click to display the [Input Lot Information] dialog box in edit mode. The displayed controls and fields are the same as when manually registering a new QC chart. [Manage] Click to display the [Cursor Data Management] dialog box, which allows you to set the cursor data. (➤P.8-22 "8.5.3 Configuring cursor data settings") [Shift] You can set up a maximum of 3 work shifts. This button switches the display between charts for each shift. To apply display by shift, select any shift between [Shift 1] to [Shift 3]. Selecting [Shift All] displays all shifts. [Sort] Click to display the sort dialog box. You can change the order of quality control items.

[Output] Print the selected chart to various printers or a host computer. Click the [Output] button to select [Host Computer (HC)], [Report (GP)] or [Ledger (LP)]. [Upper] Click to move the selection up by one row. [Lower] Click to move the selection down by one row. 8-18 XN-1000 Instructions for Use Revised August 2012 Chapter 8 Performing Quality Control [Vial] You can display a vial line to indicate replacing of a vial with a new one. While the analysis data from the new vial is selected, click [Vial] to draw the vial line. Repeat the same procedure to delete the line. This button cannot be used in X-barM control. (➤P.8-23 "8.5.4 Displaying the vial line") [Range] Click to display the QC chart in select range mode. When the number of plots on the QC chart is 1 and a lot has not been registered on the QC chart, the [Range] button cannot be selected. (➤P.8-23 "8.5.5 Select range mode") [Ref.] Click to display the submenu. [None] Select this check box to cancel the reference function.

[Compare QC Files] QC charts registered to the same analyzer are overlaid on top of each other for comparison. Compares the new lot with the current lot. (➤P.8-25 "8.5.6 Compare QC Files") [File] Click to display a submenu. This can be used to save and restore data. [Delete] Click to display a dialog box that allows you to delete the selected data point. ● QC file information Apart from the main QC file, you can compare its information with two additional QC files. The information from each QC file is displayed in different colors. [Nickname] Displays the name of the analyzer for the QC chart. [Material] Displays the material registered for the QC file. [Regist. Date]* Displays the registration date of the material registered in the QC file. [File No.] Displays the QC file number. [Lot No.]* Displays the lot number registered for the QC file. [Exp. Date]* Displays the expiration date of the control blood for the QC file. When it has expired, it is displayed in white font on red background. * Not displayed if [File No.] is X-barM. ● Chart display area (Left) [Item] Displays the name of the QC item.

[UL] Displays the upper control limit. [Target] Displays the control target value. [LL] Displays the Lower control limit. 8-19 XN-1000 Instructions for Use Revised August 2012 Chapter 8 Performing Quality Control ● Chart display area (Center) The analysis data are plotted cumulatively and displayed in the chart area as a line graph. When comparing QC files, the line graphs are displayed in different colors for each QC file. Comment display area Comment mark Plot Vial line Calibration-executed line Main cursor Analysis Date Comment display area Displays comments. Comment mark Displayed when a comment exists for a QC chart. For the procedure for entering comments, see below. (➤P.8-22 "8.5.3 Configuring cursor data settings") Indicates a comment for the cursor data.

The comment is displayed in the comment display area. Indicates a comment for data other than the cursor data. Plot Displayed when the analysis data is within the range between the upper and lower limits. Displayed when the analysis data is outside the range between the upper and lower limits. Displayed when the analysis data is not managed.

A plot for a data that is not managed is not connected by lines, as shown on the figure on the right. A data that is not managed is displayed in this way even if it is outside the range between the upper and lower limits. For details on data that is not managed, see below. (➤P.8-22 "8.5.3 Configuring cursor data settings") Vial line Indicates that the vial was switched to a new one. Calibration-executed line A calibration-executed line (a line to indicate that a calibration was performed) is displayed to the left of the first plot after the calibration. The calibration-executed line cannot be erased. 8-20 XN-1000 Instructions for Use Revised August 2012 Chapter 8 Performing Quality Control Main cursor Indicated the currently selected data.

Analysis Date Displays the date and time of analysis for the data selected by the cursor. ● Chart display area (Right) [n=xx] Displays the total number of all managed plots that appear in the chart display area. [Data] Displays the data specified by the main cursor. Values exceeding the [UL] value in the chart display area (right) are indicated by a [+], and values that are under the [LL] value are indicated by a [-]. [SD] Displays the standard deviation calculated from all managed plots that appear in the chart display area. [Mean] Displays the average value calculated from all managed plots that appear in the chart display area. [CV] Displays the coefficient of variation calculated from all managed plots that appear in the chart display area. Note: • When the [QC Chart] screen is not in the range-selecting mode (when the only cursor displayed is the main cursor), this is called single-cursor mode. • Once the number of datapoints exceeds 300, any subsequent new plot will overwrite the oldest data.

• If the displayed range of the QC chart contains plots that are not managed, the plots do not connect to the plots outside the displayed range. Current display range Lines are not connected Lines are not connected Current display range Lines are not connected • The plots of data for which the data mask [- - - -] (this means non-analyzable) appears are not joined by the line. For the data masks, see below. (➤P.10-9 "Chapter 10: 10.1.4 Numerical data of the analysis results") 8-21 XN-1000 Instructions for Use Revised August 2013 Chapter 8 8.5.3 Performing Quality Control Configuring cursor data settings You can exclude the QC data selected by the cursor or add comments to it. Follow the steps below to configure the cursor data settings. 1 Click the [Manage] button on the toolbar. The following dialog box appears. [Cursor Data Management] dialog box [Specify Excluded] Specify whether a QC data should be excluded from quality control. Use the cursor to select the QC data in question, and select whether or not they are to be managed*. If [Not Managed] is selected, the excluded data is not managed by the functions below. • Statistical computations (SD, Mean, CV) • Automatic limit computation • Variable target computation • Number of data points n * In X-barM control, this is always managed. [Comments Settings] A comment can be added to the QC data selected by the cursor. [None] Select this if you are not including any comment for the selected data. [Input Any Comment] Select this if you want to type a comment. [Fixed Comments] Select this if you want to use a comment from a list of preset comments. You can preset up to 10 user-defined comments. (➤Administrator's Guide, "Chapter 4: 4.3.8 QC settings") [Any Comments] 2 Select this when [Input Any Comment] is selected in [Comments Settings]. You can enter up to 100 characters. Click [OK]. The selected settings become reflected in each QC item.

8-22 XN-1000 Instructions for Use Revised August 2012 Chapter 8 8.5.4 Performing Quality Control Displaying the vial line The display of the vial line changes depending on the existence of a plot. The relationship between the vial line and the plot is as follows. If all plots before the vial line are deleted If all plots between the vial lines are deleted (1) (2) Delete Delete (2) The vial line is hidden 8.5.5 If plots on both sides of the vial line are deleted The old vial line is hidden The plots on both sides of the deleted plots are connected by a line. Delete Select range mode A main cursor and sub-cursor can be displayed on the QC chart, and the data between the two cursors can be manipulated. You can compare the analysis results at the start point indicated by the sub-cursor, with the statistics over any selected range.

When modifying lot information in select range mode, you can automatically configure target/limit settings for the plot of the selected range. When you click on [Range] in the [QC Chart] screen, a sub-cursor appears.

The sub-cursor is fixed at the position where the main cursor was located. The main cursor is used for scrolling to select a range, and can be moved by clicking on the end point of the range you want to select in the [QC Chart] screen. Sub-cursor Displayed in range-selecting mode. It indicates the start point of the selection. Sub-cursor 8-23 XN-1000 Instructions for Use Revised August 2012 Chapter 8 Performing Quality Control In the range-selecting mode, the functions of some buttons on the toolbar and the layout of the [QC Chart] screen are different from the single-cursor mode. ● Toolbar The buttons whose functions change are as follows. [Shift] If [Shift] is changed, range selection mode is canceled. [Sort] Sorts the displayed items. [Manage] The [Manage] button cannot be used. [Ref.] The range-selecting mode is automatically cancelled. [Output] The selected range of data can be output to an output destination. [Delete] The selected range of data can be deleted (only main chart data is deleted). Range selection mode is cancelled. ● Chart display area (Right) [n=xx] Displays the number of managed plots within the range selected by the cursors. [Data] The data at the sub-cursor (the original position) data is displayed.

[SD] Displays the standard deviation calculated from the managed plots within the range selected by the cursors. [Mean] Displays the average value calculated from the managed plots within the range selected by the cursors. [CV] Displays the coefficient of variation calculated from the managed plots within the range selected by the cursors. Note: • To cancel select range mode, press the [Range] button on the toolbar again. • When the QC charts are hidden, the range-selecting mode is automatically cancelled. 8-24 XN-1000 Instructions for Use Revised August 2012 Chapter 8 8.5.6 Performing Quality Control Compare QC Files QC charts registered to the same analyzer are overlaid on top of each other for comparison. Compares the new lot with the current lot. X-barM data cannot be compared with other data. Follow the steps below to compare QC files. 1 In the [QC Chart] screen, click the [Ref.] button on the toolbar. The submenu on the right appears. 2 Click [Compare QC Files].

The dialog box on the right appears. [Show Level Difference] 3 Not selected Only files with the same material and same level as the main chart are shown in the dialog box. Selected All files with the same material as the main chart are shown in the dialog box. Select the QC files you want to overlay, and then click [OK]. The selected QC files are compared and displayed. Only one QC file can be superimposed.

8-25 XN-1000 Instructions for Use Revised August 2012 Chapter 8 8.6 Performing Quality Control Troubleshoot quality control errors This section explains how to troubleshoot errors that occur during quality control analysis. ● If a data exceeds the QC limit, and is highlighted in red, check the analysis data in the Data Browser screen. ● Check parameters which have recorded errors on the radar chart. ● Check detailed data from the line graph. Note: When performing manual QC analysis, if you click the [Cancel] button on the analysis screen, the data will not be plotted to the QC file. 8-26 XN-1000 Instructions for Use Revised August 2012 Chapter 8 8.7 Performing Quality Control Manage QC files This section explains how to manage QC files.

Follow the steps below to modify, delete, save and restore QC files. 1 Click the [QC File] icon menu. The [QC File] screen appears. 2 Select the QC file you want to manage. Modify Click the [Modify] button on the toolbar to display the [Input Lot Information] dialog box. The displayed controls and fields are the same as when manually registering a new QC file. (➤P.8-4 "8.3 Registering and modifying a QC file (lot information input)") Delete Click the [Delete] button on the toolbar to delete the selected file. Save QC file data Click the [File] button - [Backup] on the toolbar to display the dialog box for confirming the file name and save directory. Note: The following file is saved. [Analyzer ID][Software version][QCFile][Date of save_Time of save][Material][Lot No.].qcf Restoring saved data Click the [File] button - [Restore] on the toolbar to display the dialog box for specifying the file to read. 8-27 XN-1000 Instructions for Use Revised August 2012 Chapter 8 Performing Quality Control 8-28 XN-1000 Instructions for Use Revised August 2012 Chapter 9 Analyzing samples Chapter 9 Analyzing samples This chapter explains the preparation of analysis samples and the different analysis modes. Caution! • Please ensure that samples are mixed sufficiently before being placed on the analyzer. This is especially important for samples from patients prone to high degrees of sedimentation or for samples that have been refrigerated/transported in a cool environment. • The instrument is equipped with a Blood Aspiration Sensor. However, there is a possibility that correct results may not be obtained if the sample volume is lower than that stated in the Instructions for Use. • During analysis, do not turn OFF the main power switch of the instrument. Risk of corrupting the information that is written to the reagent cartridge. 9.1 Types of analysis This instrument supports the following analysis mode. Manual analysis In this analysis, the operator loads the sample tubes individually by hand. The operator also mixes the samples by hand. Use this analysis for STAT sample analysis, or for analyzing special samples. Micro analysis This is a type of manual analysis. The analysis is performed without a cap on the sample tube, to reduce dead volume. The conditions for micro analysis are as follows: • When [Cap Open] is turned ON in the Manual Analysis menu • When an analysis is performed in [Pre-Dilution] mode • When a micro collection tube is used RBT analysis This is a type of manual analysis. The analysis is performed using Raised Bottom Tubes, to reduce dead volume. Body fluid analysis*1 This is a type of manual analysis. Use this analysis to measure body fluid. HPC analysis*1 This is a type of manual analysis.

Use this for the analysis of HPC-related parameters. hsA analysis*1,2 This is a type of manual analysis.

Use this for the analysis of low-concentration blood cell samples for research. *1 The availability of these functions depends on your system configuration.

2 For information on hsA analysis, see the "Administrator's Guide". (➤Administrator's Guide, "Chapter 3: 3.3 hsA analysis") Caution! In manual analysis, Raised Bottom Tubes can only be used for RBT analysis. Risk of instrument failure. 9-1 XN-1000 Instructions for Use Revised August 2013 Chapter 9 Analyzing samples Sampler analysis In this analysis, the operator loads the sample tubes into a rack, which is then automatically transported and analyzed by the instrument. You can place up to 50 samples at a time. To use Raised Bottom Tubes in sampler analysis, place the tubes in a rack for Raised Bottom Tubes (RBT rack). Caution! When the SA-01 is used, Raised Bottom Tubes and RBT racks cannot be used. Risk of instrument failure. Note: Except when performing micro analysis, use the sample tube with the cap on. 9-2 XN-1000 Instructions for Use Revised August 2013 Chapter 9 9.1.1 Analyzing samples Analysis modes In this instrument, you can select the analysis mode according to the different samples. The following are characteristics of each analysis mode: Analysis mode Description Remarks [Whole blood] mode Used for analyzing whole blood. • Anticoagulant added • Manual analysis/Sampler analysis • This mode is automatically selected when performing a Sampler analysis. [Low WBC] mode Used for analyzing low WBC using whole blood. The count time of the WDF channel is set to 3 times that of [Whole blood] mode to increase white blood cell measurement accuracy. • Anticoagulant added • Manual analysis • Sampler analysis (only for retesting and querying host) [Pre-Dilution] mode Used for analyzing a minute amount • 1:7 dilution of blood collected from the earlobe • Manual analysis (micro analysis) only or fingertip. • Blood aspiration sensor not used [Body Fluid] mode • Manual analysis only Used for analyzing body fluid • Blood aspiration sensor not used (cerebrospinal fluid, serous (peritoneal and pleural), synovial fluid, CAPD (Continuous ambulatory peritoneal dialysis) fluid). [HPC] mode* Used for the analysis of HPCrelated parameters using whole blood. [hsA] mode* Used for the analysis of parameters • Manual analysis only of low-concentration blood cells for • Blood aspiration sensor not used research. • Anticoagulant added • Manual analysis only • Blood aspiration sensor not used * The availability of these functions depends on your system configuration. Information The parameters in the hsA analysis results are for research purpose only. Do not use the analysis results of these parameters for the diagnosis of patients. 9-3 XN-1000 Instructions for Use Revised August 2013 Chapter 9 9.2 Analyzing samples Prepare the sample This section will explain how to prepare the sample for analysis. 9.2.1 Sample types and handling Samples analyzed in each analysis mode are as follows: • [Whole blood]/[Low WBC]/[HPC] mode: Whole blood • [Pre-Dilution] mode: Diluted blood such as capillary blood that has been diluted • [Body Fluid] mode: Body fluid (cerebrospinal fluid, serous (peritoneal and pleural), synovial fluid, CAPD (Continuous ambulatory peritoneal dialysis) fluid) Handling whole blood Collect venous blood with anticoagulant (EDTA-2K, EDTA-3K, or EDTA-2Na). Draw the specified amount of blood as per the package insert of the tube used. The sample should be analyzed within 4 hours after collection. If it is not possible to analyze the sample within 4 hours, store it in a refrigerator at 2 to 8°C until it can be analyzed.

When analyzing a refrigerated sample, take it out of the refrigerator at least 15 minutes prior to analysis, to bring it back to room temperature. Once restored to room temperature, mix the blood sufficiently before performing analysis.

Caution! • Please ensure that samples are mixed sufficiently before being placed on the analyzer.

Any delay in processing after mixing may lead to the production of incorrect results. This is especially important for samples from patients prone to high degrees of sedimentation or for samples that have been refrigerated/transported in a cool environment.

• If analyzing in [HPC] mode, mix the sample gently and analyze promptly. Mixing with excessive force may cause cellular degradation and or activation of the sample and should be avoided. • Use only the specified anticoagulant.

Using a non-specified anticoagulant may result in hemolysis or platelet aggregation, preventing correct analysis results. • Please ensure that sample tubes are filled and used in accordance with the manufacturer's package insert. If a sample tube is filled in excess of the specified volume, accurate analysis cannot be guaranteed. Over filling can lead to insufficient mixing or inadequate sample anticoagulation. Sample tubes are designed such that the normal filling allows an air gap at the top of the tube. This air gap is crucial to mixing as without this the blood does not move when the tube is inverted. 9-4 XN-1000 Instructions for Use Revised August 2013 Chapter 9 Analyzing samples Handling diluted blood For diluted blood, dilute capillary or venous blood by a factor of 7. In the case of capillary blood, dilute by a factor of 7 after collection by dispensing the blood directly into the diluent. Do not use any anticoagulants. Alternatively, you can collect the blood in a micro collection tube, and dilute it later. e.g. 1 2 3 4 Pour CELLPACK DCL into the diluent-dispensing container. Dispense 120 µL of CELLPACK DCL into the micro collection tube. Add 20 µL blood to the micro collection tube containing 120 µL CELLPACK DCL (dilution ration 1:7). Cap the sample, mix well and analyze Caution! • The sample should be analyzed immediately after dilution, as platelet aggregation can easily occur in diluted samples. In addition, the dispensed diluent can cause a margin of error in the analysis data due to evaporation or contamination. Therefore, a new diluted blood sample should be prepared for each analysis. • After diluting the sample, mix gently and analyze promptly. If the sample is mixed excessively after dilution, the results may not be accurate. • It is OK to apply light pressure to collect the capillary blood sample. However, too much pressure will squeeze out body fluid with the blood, which lowers the reliability of the analysis results.

Handling body fluids Upon the collection of body fluid, add an anticoagulant such as EDTA or heparin as needed. Analyze as soon as possible after collecting the sample. Particularly in the case of cerebrospinal fluid (CSF), it has been indicated that cell breakdown starts to occur within one hour after collection*. * CLSI H56-A: Clinical and Laboratory Standards Institute H56-A Caution! Excessive mixing of a body fluid sample may cause false WBC-BF and TC-BF# values. Mix as gently as possible. 9-5 XN-1000 Instructions for Use Revised August 2013 Chapter 9 Analyzing samples Sample volume This section explains the required sample volume. Type of analysis Sampler analysis Specimen Tube type Whole blood Closed tube Sample Setting Position Sampler rack Raised Bottom RBT rack Tube (closed) Whole blood Closed tube Diluted blood Manual analysis Body fluid*1 Manual Analysis Menu [Cap Open] - Aspirated sample volume 88 µL - Required sample volume 1 mL 250 µL OFF Open tube Normal tube holder ON 300 µL Open micro tube Micro tube holder - 160 µL Raised Bottom Normal tube Tube (closed) holder OFF 250 µL Open tube Normal tube holder ON Open micro tube Micro tube holder - Closed tube Normal tube holder OFF Open tube ON 300 µL Open micro tube Micro tube holder - 160 µL Normal tube holder OFF ON 400 µL Micro tube holder - 260 µL Whole blood Closed tube (HPC)*2 Open tube Open micro tube 88 µL 70 µL 1 mL 300 µL 140 µL 88 µL 190 µL 1 mL 1 mL *1 The body fluid analysis can only be performed if the instrument offers the body fluid analysis mode. *2 HPC analysis can only be performed if the instrument offers the HPC analysis mode.

(1) Normal sample tube holder (2) Micro collection tube holder (2) (1) Analyzer Front side Direction of movement of the tube holder 9-6 XN-1000 Instructions for Use Revised August 2013 Chapter 9 9.3 Analyzing samples Manual analysis This section explains how to analyze whole blood and diluted blood in manual analysis. The method for analyzing a STAT sample is the same as the method for manual analysis. Caution! • Samples measured in the manual mode are not mixed by the instrument and therefore must be mixed manually. • A Raised Bottom Tube cannot be used in [Pre-Dilution] mode. Follow the steps below to perform manual mode analysis. 1 Check the Status indicator LED on the analyzer. If the Status indicator LED is not lit green, wait until it does.

This step is not necessary when analyzing a STAT sample. Proceed to the next step. Status indicator LED 2 If the tube holder has not ejected out, press the mode switch. The tube holder slides out forward.

9-7 XN-1000 Instructions for Use Revised August 2013 Chapter 9 3 Analyzing samples Click the Change Analysis Mode button on the control menu. The dialog box on the right appears. ● Specifying the analysis mode [Whole blood] Select this when using whole blood as the sample. [Low WBC] Select this to perform low WBC analysis when using the whole blood as the sample. [Pre-Dilution]* Select this when using 1:7 diluted blood as the sample. * When changing to [Pre-Dilution] from a different mode, the switching will takes some time. Please wait a while. 4 Click [OK]. The dialog box closes. 5 Click on the Manual Analysis button on the control menu. A dialog box corresponding to the selected mode appears. ● In [Whole blood] mode / [Low WBC] mode: [Sample No.]* Input is not necessary if the [Read ID] checkbox is selected. If you will not scan a barcode, enter the sample number manually in the input field. [Read ID] Select this checkbox if barcode labels on sample tubes will be scanned using the analyzer's builtin barcode reader. This cannot be selected if sample tube barcode reading is not enabled in the analyzer settings. [Patient ID] Enter the patient ID in the input field. [Discrete] Select the check marks for the discrete tests you want performed. In [Low WBC] mode, [DIFF] cannot be changed. [Cap Open] Select the check mark to perform a micro blood analysis. This enables you to analyze the sample without a cap on the sample tube, to minimize dead volume. [Query to Host] This only appears if real-time query is set to ON in the analyzer settings. Select this checkbox to query the host for analysis information. This cannot be selected when the [Read ID] checkbox is selected. [Aspiration Sensor] Enables/disables the Blood Aspiration Sensor. [Raised Bottom Tube] Select the check mark to perform RBT analysis. This enables you to analyze the sample by using a Raised Bottom Tube, to minimize dead volume. This enables you to analyze the sample with the cap on the sample tube. * You can also use the hand-held barcode reader to input the sample number. 9-8 XN-1000 Instructions for Use Revised August 2013 Chapter 9 Analyzing samples ● In [Pre-Dilution] mode: [Cap Open], [Aspiration Sensor] and [Raised Bottom Tube] are not displayed. In addition, the discrete tests are different. Other settings are the same as the [Whole blood] mode. Note: • The instrument is equipped with a Blood Aspiration Sensor. However, there is a possibility that correct results may not be obtained if the sample volume is low and the sensor could not detect a "Short Sample" or "Sample Not Asp Error". • If you know in advance that the blood sample has a very low hemoglobin (e.g. blood from a dialysis patient), disable the Blood Aspiration Sensor. (➤Administrator's Guide, "Chapter 4: 4.2.9 Analyzer settings") 6 Click [OK]. The dialog box closes. 7 Mix the sample tube as shown. e.g. Normal sample tube 9-9 XN-1000 Instructions for Use Revised August 2013 Chapter 9 8 Analyzing samples Place the sample tube in the tube holder. There are 2 sample tube holders. When inserting a micro collection tube, insert the tube all the way in so that the bottom of the tube contacts the base of the holder.

(1) Normal sample tube holder (2) Micro collection tube holder (2) (1) Analyzer Front side Direction of movement of the tube holder ● When performing micro analysis Place the sample tubes after removing the cap. When removing the cap, use caution to prevent the sample from splattering. ● When performing RBT analysis Place the Raised Bottom Tube in the normal sample tube holder.

9 Press the start switch on the analyzer. The tube holder slides in, and the aspiration of the sample begins.

Once the analysis finishes, the tube holder slides out. e.g. When a normal tube is set 10 Remove the sample. To analyze another sample, repeat steps 3 through 10. 11 Press the mode switch on the analyzer. The tube holder slides into the analyzer.

For the details on checking the analysis results, see Chapter 10. (➤P.10-1 "Chapter 10: 10.1 Sample Explorer functions") Information If a message appears during analysis to ask for reagent replacement, replace the reagent concerned. If the reagent is replaced when the reagent level is low, bubbling could occur, which would raise the blank value. 9-10 XN-1000 Instructions for Use Revised August 2013 Chapter 9 9.4 Analyzing samples Body fluid analysis This section explains samples and analysis items for body fluid analysis. * The availability of this function depends on your system configuration. Caution! A Raised Bottom Tube cannot be used for body fluid analysis. Follow the steps below to perform body fluid analysis. 1 Check the Status indicator LED on the analyzer. If the Status indicator LED is not lit green, wait until it does. Status indicator LED 2 If the tube holder has not ejected out, press the mode switch. The tube holder slides out forward. 9-11 XN-1000 Instructions for Use Revised August 2013 Chapter 9 3 Analyzing samples Click the Change Analysis Mode button on the control menu. The dialog box on the right appears. 4 Click [Body Fluid]. 5 Click [OK]. The instrument will automatically perform a background check after body fluid analysis is accessed. If the background values that result from the background check are under the allowable values, the Status indicator LED lights green and the analyzer enters the body fluid analysis preparation done state. Checked Parameter Acceptable Value 3/µL or less WBC-BF 0.001 x 10 RBC-BF 0.003 x 106/µL or less Explanation White blood cell count in body fluid obtained from the WDF channel. Red blood cell count in body fluid obtained from the RBC/PLT channel. For information on background check, see Chapter 6. (➤P.6-13 "Chapter 6: 6.3.4 Execution of analyzer self-check") 6 Click on the Manual Analysis button on the control menu. A dialog box corresponding to the selected mode appears. [Sample No.]* Input is not necessary if the [Read ID] checkbox is selected. If you will not scan a barcode, enter the sample number manually in the input field.

[Read ID] Select this checkbox if barcode labels on sample tubes will be scanned using the analyzer's built-in barcode reader.

This cannot be selected if sample tube barcode reading is not enabled in the analyzer settings. [Patient ID] Enter the patient ID in the input field. [Cap Open] Select the check mark to perform a micro blood analysis.

This enables you to analyze the sample without a cap on the sample tube, to minimize dead volume.

[Query to Host] This only appears if real-time query is set to ON in the analyzer settings. Select this checkbox to query the host for analysis information. This cannot be selected when the [Read ID] checkbox is selected. * You can also use the hand-held barcode reader to input the sample number. 9-12 XN-1000 Instructions for Use Revised August 2013 Chapter 9 Analyzing samples Note: Immediately after the analysis type is changed to [Body Fluid], [Cap Open] is in the selected state. If you will perform closed analysis using regular sample tubes, remove the [Cap Open] checkmark. 7 Click [OK]. The dialog box closes. 8 Mix the sample tube as shown. e.g. Normal sample tube 9 Place the sample tube in the tube holder. There are 2 sample tube holders. When inserting a micro collection tube, insert the tube all the way in so that the bottom of the tube contacts the base of the holder. (1) Normal sample tube holder (2) Micro collection tube holder (2) (1) Analyzer Front side Direction of movement of the tube holder ● When performing micro analysis Place the sample tubes after removing the cap. When removing the cap, use caution to prevent the sample from splattering. 9-13 XN-1000 Instructions for Use Revised August 2013 Chapter 9 Analyzing samples 10 Press the start switch on the analyzer. The tube holder slides in, and the aspiration of the sample begins. Once the analysis finishes, the tube holder slides out. e.g. When a normal tube is set 11 Remove the sample. To analyze another sample, repeat steps 3 through 10. 12 Press the mode switch. The tube holder slides into the analyzer. For the details on checking the analysis results, see Chapter 10. (➤P.10-1 "Chapter 10: 10.1 Sample Explorer functions") Information If a message appears during analysis to ask for reagent replacement, replace the reagent concerned.

If the reagent is replaced when the reagent level is low, bubbling could occur, which would raise the blank value. 9.5 HPC analysis This section explains the procedure for performing HPC analysis. * The availability of this function depends on your system configuration. Caution! A Raised Bottom Tube cannot be used for HPC analysis. 9-14 XN-1000 Instructions for Use Revised August 2013 Chapter 9 Analyzing samples Follow the steps below to perform HPC analysis. 1 Check the Status indicator LED on the analyzer. If the Status indicator LED is not lit green, wait until it does. Status indicator LED 2 If the tube holder has not ejected out, press the mode switch. The tube holder slides out forward. 3 Click the Change Analysis Mode button on the control menu. The dialog box on the right appears. 4 Click [HPC]. 9-15 XN-1000 Instructions for Use Revised August 2013 Chapter 9 Analyzing samples 5 Click [OK]. 6 Click on the Manual Analysis button on the control menu. A dialog box corresponding to the selected mode appears. [Sample No.]* Input is not necessary if the [Read ID] checkbox is selected. If you will not scan a barcode, enter the sample number manually in the input field. [Read ID] Select this checkbox if barcode labels on sample tubes will be scanned using the analyzer's built-in barcode reader. This cannot be selected if sample tube barcode reading is not enabled in the analyzer settings. [Patient ID] Enter the patient ID in the input field.

[Cap Open] Select the check mark to perform a micro blood analysis. This enables you to analyze the sample without a cap on the sample tube, to minimize dead volume. [Query to Host] This only appears if real-time query is set to ON in the analyzer settings. Select this checkbox to query the host for analysis information. This cannot be selected when the [Read ID] checkbox is selected. * You can also use the hand-held barcode reader to input the sample number. 7 Click [OK]. The dialog box closes. 8 Mix the sample tube as shown. e.g. Normal sample tube 9-16 XN-1000 Instructions for Use Revised August 2013 Chapter 9 9 Analyzing samples Place the sample tube in the tube holder.

There are 2 sample tube holders. When inserting a micro collection tube, insert the tube all the way in so that the bottom of the tube contacts the base of the holder. (1) Normal sample tube holder (2) Micro collection tube holder (2) (1) Analyzer Front side Direction of movement of the tube holder ● When performing micro analysis Place the sample tubes after removing the cap. When removing the cap, use caution to prevent the sample from splattering. 10 Press the start switch on the analyzer. The tube holder slides in, and the aspiration of the sample begins.

Once the analysis finishes, the tube holder slides out.

e.g. When a normal tube is set 11 Remove the sample. To analyze another sample, repeat steps 3 through 10. 12 Press the mode switch. The tube holder slides into the analyzer. For the details on checking the analysis results, see Chapter 10. (➤P.10-1 "Chapter 10: 10.1 Sample Explorer functions") Information If a message appears during analysis to ask for reagent replacement, replace the reagent concerned. If the reagent is replaced when the reagent level is low, bubbling could occur, which would raise the blank value.

9-17 XN-1000 Instructions for Use Revised August 2013 Chapter 9 9.6 Analyzing samples Sampler analysis Sampler analysis can be started in 2 ways. • Automatically start the analysis when a rack is placed on the sampler (sampler auto-start function)*. • Start the analysis from the information processing unit. * Only when using the sampler (SA-10) Caution! • Correct analysis results may not be obtained due to insufficient mixing if the sample is left for more than 4 hours and the cells/plasma have separated. Therefore, in case of analyzing such samples, make sure to mix the samples thoroughly before setting them on the sampler. • Please ensure that sample tubes are filled and used in accordance with the manufacturer's package insert. If a sample tube is filled in excess of the specified volume, accurate analysis cannot be guaranteed.

Over filling can lead to insufficient mixing or inadequate sample anticoagulation. • Sample tubes are designed such that the normal filling allows an air gap at the top of the tube. This air gap is crucial to mixing as without this the blood does not move when the tube is inverted. 9.6.1 If the sampler auto-start function is ON (SA-10 only) If the sampler auto-start function is turned on in the sampler (SA-10), follow the steps below to perform sampler analysis. 1 Make sure that the analyzer and the sampler are in READY state. If the Status indicator LED is not lit green, wait until it does. Status indicator LED 9-18 XN-1000 Instructions for Use Revised August 2013 Chapter 9 2 Analyzing samples Check that the tube holder is retracted into the analyzer. If the tube holder is retracted, it means that the sampler analysis is enabled. If the tube holder is ejected out, press the mode switching button on the analyzer. Tube holder 3 Click on the Sampler Analysis button on the control menu.

The dialog box on the right appears. Check the settings.

This step is not required if you are using barcodes. Proceed to the next step. [Sample No.]* Enter the sample number in the input field. [Rack No.]* Enter the rack number in the input field. [Starting Tube Position] Specify the position of the sample tube where analysis should start. [Discrete] Select the check marks for the discrete tests you want performed. * You can also use the hand-held barcode reader to input the sample and rack numbers. 4 Click [OK]. The dialog box closes. 5 Place the rack in the right sampler pool. Slide the groove on the rack into the protrusion on the right side (when you face the analyzer). A maximum of 5 racks can be placed. Once the rack is set in place, the sampler analysis automatically starts. ● To abort the sampler analysis before it is finished: Click the sampler analysis button in the control menu, and then click [Yes] in the dialog that appears. Protrusion 9-19 XN-1000 Instructions for Use Revised August 2013 Chapter 9 Analyzing samples Caution! • If it is necessary to use a Raised Bottom Tube, insert the tube in the RBT rack, please note the following.

- Do not insert a Raised Bottom Tube in anything other than a RBT rack. - Do not insert a sample tube other than a Raised Bottom Tube in a RBT rack.

• Set the racks horizontally as far to the left edge and towards the front as possible. Correct operation is not guaranteed if the racks are set diagonally. Note: If the instrument has been set to perform a retest on a sample, it will automatically perform the analysis(es) on the sample. 6 Remove the rack after the analysis is finished. The finished racks are transported to the left sampler pool. Check that the protrusion has cleared the groove, and then remove the rack. For procedures on checking the analysis results, see Chapter 10. (➤P.10-1 "Chapter 10: 10.1 Sample Explorer functions") 9-20 XN-1000 Instructions for Use Revised August 2013 Chapter 9 9.6.2 Analyzing samples Start sampler analysis manually If the sampler auto-start function is turned OFF in the sampler (SA-10), or if the sampler (SA-01) is used, follow the steps below to perform sampler analysis. The sampler (SA-10) is used as an example in the following procedure. 1 Make sure that the analyzer and the sampler are in READY state. If the Status indicator LED is not lit green, wait until it does. Status indicator LED e.g. Sampler (SA-10) 2 Check that the tube holder is retracted into the analyzer. If the tube holder is retracted, it means that the sampler analysis is enabled.

If the tube holder is ejected out, press the mode switching button on the analyzer. Tube holder 3 Place the rack in the right sampler pool. Slide the groove on the rack into the protrusion on the right side (when you face the analyzer). A maximum of 5 racks can be placed. Protrusion 9-21 XN-1000 Instructions for Use Revised August 2013 Chapter 9 Analyzing samples Caution! • If it is necessary to use a Raised Bottom Tube, insert the tube in the RBT rack, please note the following. - Do not insert a Raised Bottom Tube in anything other than a RBT rack. - Do not insert a sample tube other than a Raised Bottom Tube in a RBT rack. • Set the racks horizontally as far to the left edge and towards the front as possible.

Correct operation is not guaranteed if the racks are set diagonally. 4 Click on the Sampler Analysis button on the control menu. The dialog box on the right appears. Check the settings. The setting below is not required if you are using barcodes. Proceed to the next step.

[Sample No.]* Enter the sample number in the input field. [Rack No.]* Enter the rack number in the input field. [Starting Tube Position] Specify the position of the sample tube where analysis should start. [Discrete] Select the check marks for the discrete tests you want performed. [Start] Click to start the analysis of the sample. * You can also use the hand-held barcode reader to input the sample and rack numbers. 5 Click [Start]. The dialog box closes, and the sampler analysis starts. ● To abort the sampler analysis before it is finished (SA-10 only): Click the sampler analysis button in the control menu, and then click [Yes] in the dialog that appears. Note: If the instrument has been set to perform a retest on a sample, it will automatically perform the analysis multiple times on the sample (Only when using the sampler (SA-10)). 9-22 XN-1000 Instructions for Use Revised August 2013 Chapter 9 6 Analyzing samples Remove the rack after the analysis is finished. The finished racks are transported to the left sampler pool. Check that the protrusion has cleared the groove, and then remove the rack. For procedures on checking the analysis results, see Chapter 10. (➤P.10-1 "Chapter 10: 10.1 Sample Explorer functions") 9-23 XN-1000 Instructions for Use Revised August 2013 Chapter 9 Analyzing samples 9-24 XN-1000 Instructions for Use Revised August 2013 Chapter 10 Checking analysis data (Sample Explorer) Chapter 10 Checking analysis data (Sample Explorer) This section explains how to check the analysis data. 10.1 Sample Explorer functions The Sample Explorer's functions allow you to display, delete, validate, and output analysis data that are saved on the IPU.

You can display the analysis data for up to 100,000 samples. In addition, you can sort, filter, search, save, and restore analysis results. 10.1.1 Sample Explorer screen Clicking the [Sample Explorer] icon in the Menu screen displays the following screen. Alternatively, you can also click the [Explorer] button on the toolbar. Toolbar Font size button Analysis data Filter/sort description Analysis data list Tab Patient information Display switching button [Sample Explorer] screen Toolbar The button of the following functions are displayed. [Modify] Click to display the dialog box for modifying the selected data in the analysis data list. [Validate] Click to validate the selected analysis data in the analysis data list. If the list was already validated, clicking in the list reset the validation status. [Filter] Click to display the submenu that allows you to set the conditions for the data to be displayed in the analysis data list. [Sort] Click to display the submenu that allows you to set the sort order for the data to be displayed in the analysis data list.

[Output] Click to display the submenu for selecting the output destinations.

[Upper] Click to move the selection up by 1 row. 10-1 XN-1000 Instructions for Use Revised August 2012 Chapter 10 Checking analysis data (Sample Explorer) [Lower] Click to move the selection down by 1 row. [FIND] Click to display a dialog box that allows you to search data. [Last20] Click to display the analysis data for the last 20 samples in the analysis data list window. In the filter/sort description box, [Last 20] is displayed. The analysis data are sorted by analysis date in descending order. Toggle off the [Last 20] view to return to the original setting. When a new analysis data is saved, the list is automatically updated.

If the list was already filtered, clicking in the list displays all samples. [File] Click to display the submenu that allows you to save and restore data.

[Delete] Click to display the dialog box for deleting the selected data in the analysis data list. Analysis data list Displays the analysis data selected in the analysis data list. It appears on the sub screen. For details, see the following. (➤P.10-9 "10.1.4 Numerical data of the analysis results") Tab You can switch between the screens by clicking the tab. Patient information Displays the information on the patient selected in the analysis data list. It appears on the sub screen. Patient category icon Patient Comment Patient category icon Patient Name Patient ID Ward Name Date of birth, sex and age Doctor Name Displays an icon. Below the icon is the category number of the patient. If there is no corresponding category, no number is displayed. Category number Patient Name Displays the name of the patient (first name, last name). Patient ID Displays the patient ID. Date of birth, sex and age Displays the date of birth, gender, and age of the patient. Doctor Name Displays the name of the doctor assigned to the patient. Ward Name Displays the patient's ward name or the name of the clinical service.

Patient Comment Displays comments about the patient. 10-2 XN-1000 Instructions for Use Revised August 2012 Chapter 10 Checking analysis data (Sample Explorer) Note: • Items that have not been filled will not be displayed. • If the currently logged on user does not have privileges to display patient information, only the patient category icon is displayed. Filter/sort description Shows what conditions were used to display the analysis data list. These are the conditions you specified in the filter and sort settings. For the details on how to read the symbols, see Chapter 7. (➤P.7-1 "7.1.1 Work List screen" (●Filter/sort description)) Display switching button You can click the display switching button to open/close the sub screens. A sub-screen is a screen that is displayed to the right or below the list of analysis data, that can be opened and closed. Click to switch through the 4 patterns in the order "sub-screen (right and bottom)" → "sub-screen (bottom)"→"no sub-screen" → "sub-screen (right)". Font size button To change the size of the characters and the line height in the analysis data list, click the character size button. When you change the size setting of the characters, see "Administrator's Guide". (➤Administrator's Guide, "Chapter 4: 4.3.3 Display settings") Changing the screen layout For the details on changing the displayed items, see Chapter 10.

(➤P.10-31 "10.11 Change layout of analysis data list") Note: Multiple data can be selected as follows: • Drag multiple consecutive rows while holding down the left button on the mouse or. • While pressing Ctrl, click on the row that you want to select.

10-3 XN-1000 Instructions for Use Revised August 2012 Chapter 10 10.1.2 Checking analysis data (Sample Explorer) Analysis data list The analysis data list displays common items and selection-based items. Common items are items displayed on all tabs. Selection-based items differ depending on the tab that is selected. Once the number of stored items exceeds 100,000, each new item that is stored overwrites the item with the oldest analysis date and time. Information Analysis results of research parameters are indicated by a gray background to distinguish them from report analysis results.

Research items are the parameter for research. Analysis results for these parameters must not be used for diagnosis of patients. Common items Common items are displayed in the left section of the analysis data list. [V] (Validate) A [V] will appear for validated samples. If a sample has not been validated, nothing is displayed. [Sample No.] Displays the sample number.

(Analysis mode) The column to the left of the [Sample No.] column shows the analysis mode for each sample. [WB]: Whole blood [LW]: Low WBC [PD]: Pre-Dilution [BF]*: Body fluid [HPC]*: HPC [hsA]*: hsA * The availability of these functions depends on your system configuration. If body fluid analysis is performed without clearing the error after an [Analysis result is high] error message is displayed, the background appears in red.

For information on [hsA] mode, see the "Administrator's Guide". (➤Administrator's Guide, "Chapter 3: 3.3.2 Checking analysis data") (Sample information) The column to the right of the [Sample No.] column indicates how the sample number was obtained. [A]: Automatically incremented [B]: ID barcode scanned [M]: Manually entered [C]: Host computer queried [Output] Displays the output status of the analysis results. [D]: Indicates that the analysis results have not been output to Ticket printer (DP).

[G]: Indicates that the analysis results have not been output to Graphic printer (GP). [H]: Indicates that the analysis results have not been output to Host computer (HC). It takes a maximum of 40 seconds for an output result to be reflected. [P/N] Displays whether an analysis result is Positive or Negative.

[D]: Diff. Positive [M]: Morph. Positive [C]: Count Positive On Negative samples no (D), (M), or (C) are indicated at all. 10-4 XN-1000 Instructions for Use Revised December 2012 Chapter 10 Checking analysis data (Sample Explorer) [Action] Displays an action message, if one exists. [Check] Displayed when the sample needs to be checked.

[Review] Displayed when channel difference has occurs, for example, and the analysis results need to be reviewed. [Retest] Displayed when the analysis mode, the order and the status of the sample need to be reviewed, and then need to be re-analyzed.

[Order Type]* Displays the type of order of the analyzed sample. [Initial] Analysis order processed for the first time.

[Initial/Repeat] An order that resulted in an error on the first test for sample analysis and was reanalyzed. [Rerun] An order that is automatically triggered to rerun a sample with the same discrete test profile as the initial analysis. [Reflex] An order that is automatically triggered to rerun a sample with additional discrete test profiles. [Rerun/Repeat] An order that was re-analyzed after the [Rerun] resulted in an error. [Reflex/Repeat] An order that was re-analyzed after the [Reflex] resulted in an error. [Manual] An order that was analyzed manually. [Manual (Open)] An order that was analyzed by cap open analysis. [Error] Displays the errors that occurred during the analysis. [Result] One of the following errors has occurred: [Blood cannot be aspirated.], [Insufficient blood volume], [Low count error].

[Func.] An error other than [Result] and Barcode Reader errors has occurred. * When a sampler (SA-01) is used, this does not appear. 10-5 XN-1000 Instructions for Use Revised February 2014 Chapter 10 Checking analysis data (Sample Explorer) Selection-based item Selection-based items are displayed in the right section of the analysis data list.

● [Sample Info] display screens If a pending analysis, not all items are displayed. [Date] Displays the date when the analysis result was made available. [Time] Displays the time when the analysis result was made available. [Seq.] A serial number appears for each analyzer used the day of analysis when the IPU was turned on. [Reception Date] Displays the date and time when the first test was received for the sample. [Rack] Displays the rack number of the sample (for sampler analysis). For all except sampler analysis, nothing is displayed. [Position] Displays the sample tube position number of the sample (for sampler analysis). For all except sampler analysis, nothing is displayed. [Distribution] Displays abnormal distribution. [R]: Abnormal RBC distribution [P]: Abnormal PLT distribution [IP (WBC)] Displays the flag number of the WBC IP message. For details, see Chapter 11. (➤P.11-33 "Chapter 11: 11.7.2 Table of IP message details") [IP (RBC)] Displays the flag number of the RBC/RET IP message. For details, see Chapter 11. (➤P.11-33 "Chapter 11: 11.7.2 Table of IP message details") [IP (PLT)] Displays the flag number of the PLT IP message. For details, see Chapter 11. (➤P.11-33 "Chapter 11: 11.7.2 Table of IP message details") [Discrete] Displays the test profile.

For the details on discrete tests, see Chapter 7. (➤P.7-9 "Chapter 7: Table of discrete tests and their corresponding analysis parameters") [Rule Result]* Displays the results of the first test, determined according to the rules. Some rules will display the number of comments in parentheses after the determined result. e.g.) [Reflex] with 1 comment: [Reflex (1)] [Repeat] The analysis must be repeated due to an error in the first test. [Rerun] Analysis must be repeated for the same item as in the first test. [Reflex] Analysis must be performed with additional items.

[Query to HOST] A host inquiry is necessary. [None] It is not necessary to make a host inquiry or repeat analysis. [Sample Comment] Displays the comment entered when the sample was registered. [Validator] If validation was done manually, this field displays the login name of the user. For auto validation, [(Auto Validate)] is displayed. [Analyzer Nickname] Displays the name of the analyzer that was used for the analysis of the sample.

[Analyzer ID] Displays the ID number of the analyzer that was used for the analysis of the sample. * When the sampler (SA-01) is used, [Comment] will appear when a rule judgment is made. The number of comments is indicated in parentheses at the end. 10-6 XN-1000 Instructions for Use Revised August 2012 Chapter 10 Checking analysis data (Sample Explorer) ● [CBC], [DIFF], [RET]*, [PLT-F]* display screens Displays the data relevant to the selected tab. Some data may have a mark in the next column. For the details, see the following. (➤P.10-9 "10.1.4 Numerical data of the analysis results") * These items do not appear with all analyzer types. Screen and display items Screen Display items [CBC] WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, RDW-SD, RDW-CV, PDW, MPV, P-LCR, PCT, NRBC#, NRBC% [DIFF] NEUT#, LYMPH#, MONO#, EO#, BASO#, NEUT%, LYMPH%, MONO%, EO%, BASO%, NEUT-RI*, NEUT-GI*, IG#, IG% [RET] RET%, RET#, IRF, LFR, MFR, HFR, RET-He, RBC-He, Delta-He [PLT-F] IPF * The availability of these functions depends on your system configuration. ● [Patient Information] display screen Displays the patient information registered for the analyzed sample. Patient ID, patient name, gender, date of birth, ward, doctor, and comments are displayed. ● [Reagent] display screen Displays the lot number of the reagent that was used at the time the sample was analyzed. If the lot number is not registered, nothing is displayed. The name of the reagent connected to the leftmost instrument connected to the IPU is displayed*. * If the RU-20 is not connected, CELLPACK DST does not appear. If all analyzers are connected to the RU, CELLPACK DCL does not appear. For the details on reagents, see Chapter 5. (➤P.5-1 "Chapter 5: Reagents") 10-7 XN-1000 Instructions for Use Revised May 2014 Chapter 10 Checking analysis data (Sample Explorer) 10.1.3 Check Body fluid analysis data in Sample explorer Click the [Body Fluid] tab* in the [Sample Explorer] screen to view a list of the body fluid analysis data. The sub screen shows the items analyzed ([ITEM]), numerical data ([DATA]), marks, and the units ([UNIT]) of the sample selected in the analysis data list. * The body fluid analysis can only be performed if the instrument offers the body fluid analysis mode. The following items are displayed in the [Body Fluid] display screen.

Some data may have a mark in the next column. For the details, see the following. (➤P.10-9 "10.1.4 Numerical data of the analysis results") Screen and display items* Screen [Body Fluid] Display items WBC-BF, RBC-BF, MN#, PMN#, MN%, PMN%, TC-BF# * For details on items for research, see "Administrator's Guide". (➤Administrator's Guide, "Chapter 3: 3.2 Check items for research") 10-8 XN-1000 Instructions for Use Revised August 2012 Chapter 10 Checking analysis data (Sample Explorer) 10.1.4 Numerical data of the analysis results The analysis data pane of the [Sample Explorer] screen displays the analysis parameters ([ITEM]), their numerical values ([DATA]), marks, and the units ([UNIT]) for the sample that is currently selected in the analysis data list. It appears on the sub screen. Notations for abnormal data If there is an abnormality in the analysis data, it is represented by the following masks and marks. Data masks Notation Meaning Description [----] Analysis impossible Indicates that an analysis error or a parsing error has occurred and the value cannot be displayed. [++++] Out of range Indicates that the data cannot be displayed because the value exceeds the display limit. [No order Indicates that the analysis order does not exist.] Marks* Notation Meaning Description [*] Low reliability Indicates that the reliability of the data is low. [@] Out of range Indicates that the data is outside the linearity limits. [!] Exceeds upper panic limit /Below lower panic limit Exceeds upper acceptable background check value limit Indicates that the value is higher than or less than the clinical panic value. Also indicates that the value is higher than the allowed value for a background check. [+] Exceeds upper limit Indicates that the value is higher than the reference interval. [-] Exceeds lower limit Indicates that the value is less than the reference interval. * Only 1 mark can be appended per data value. If multiple abnormalities apply to an analysis result, whichever abnormality has the highest priority is notated. Priorities are assigned to the marks in the order they appear in the table above ([*]). 10-9 XN-1000 Instructions for Use Revised August 2012 Chapter 10 10.2 Checking analysis data (Sample Explorer) Validate analysis results To validate analysis results means to accept them so that they can be output externally for reporting purposes*. * You cannot validate any results while the last 20 samples are displayed. Follow the steps below to validate the analysis results. 1 In the list pane, click the analysis result you want to validate. The analysis result is selected. You can select multiple items. 2 Click the [Validate] button on the toolbar. A [V] appears on the left end of the analysis data list. If multiple lines of analysis results are selected, the validation state of the active (reverse-displayed) line of analysis result is applied to the entire selection.

For example, when you validate the active (reverse-displayed) analysis results, other analysis results in the selection also become validate. Note: After validating, you cannot change any sample information, such as the sample number. If you need to change any information, click [Validate] to reset the validation status. 10-10 XN-1000 Instructions for Use Revised August 2012 Chapter 10 Checking analysis data (Sample Explorer) 10.3 Sort analysis data list You can sort the analysis data list by the conditions that you specify*. The specified conditions are displayed in the filter/sort description box. * You can sort the results by [Asc.] or [Desc.] of [Analysis Date] only, while the last 20 samples are displayed.

Follow the steps below to sort the list. 1 Click the [Sort] button on the toolbar.

The submenu on the right appears.

2 Click the conditions by which you want to sort the list. The submenu closes, and the list is sorted. [Analysis Date] Click to sort first by [Date], then by [Time]. You can select between [Asc.] and [Desc.] using the button on the right. The ascending order/descending order setting is applied to both [Date] and [Time]. [Reception Date] Click to sort first by [Reception Date], then by [Analysis Date]. You can select between [Asc.] and [Desc.] using the button on the right. The ascending order/descending order setting is applied to both [Reception Date] and [Analysis Date]. [Sample No.] Click to sort first by [Sample No.], then by [Date] in [Desc.] order, then by [Time] in [Desc.] order. You can select between [Asc.] and [Desc.] using the button on the right. The ascending order/descending order setting is applied to [Sample No.].

Regardless of the setting, [Date] and [Time] is always descending order. [Sort 01], [Sort 02] Click to sort by the criteria specified in [Sort 01] or [Sort 02]. [Modify Settings] Click to change the settings for [Sort 01] or [Sort 02]. 10-11 XN-1000 Instructions for Use Revised August 2012 Chapter 10 Checking analysis data (Sample Explorer) Modify Settings You can change the settings for [Sort 01] and [Sort 02]. Follow the steps below to change the settings. 1 Click [Modify Settings]. The dialog box on the right appears. 2 Populate the displayed fields. You can specify a [Sort Name]. You can enter up to 20 characters. In fields [1st Key] through [5th Key], specify the sort conditions.

The sort conditions are prioritized from [1st Key] to [5th Key]. After selecting the keys, sort the alphanumeric in [Asc.] (0 to 9, A to Z) or [Desc.] (9 to 0, Z to A) order. 3 [Date] Sorts by date of analysis. [Time] Sorts by time of analysis. [Sample No.] Sorts by sample number. [Rack No.] Sorts by rack number. [Tube Pos.] Sorts by sample tube position number.

[Sequence No.] Sort by the serial number, incremented the analysis day. [Reception Date] Sort by the date and time when the sample's first test was received. [None] Conditions not specified.

Click [OK]. The dialog box closes, and sorting is applied. 10-12 XN-1000 Instructions for Use Revised August 2012 Chapter 10 Checking analysis data (Sample Explorer) 10.4 Specify data display conditions You can specify conditions for the samples you want displayed in the analysis data list*. * You cannot specify any conditions while the last 20 samples are displayed. Follow the steps below to specify conditions for the data you want displayed. 1 Click the [Filter] button on the toolbar. The submenu on the right appears. 2 Click the display conditions.

The submenu closes, and the samples that match the conditions are displayed in the list. [No filter] Click to display all sample information.

If the filter was applied, this removes the filter. [Filter 01] to [Filter 05] Click to display samples that match the conditions set in the corresponding filter. [Modify Settings] Click to change the setting for the corresponding filter. Note: If the data is selected with display conditions specified and a condition is no longer satisfied due to the date being changed or other reason, the selected state cannot be maintained.

A dialog that notifies you of the change of selection range appears. 10-13 XN-1000 Instructions for Use Revised August 2012 Chapter 10 Checking analysis data (Sample Explorer) Modify settings You can change the settings for [Filter 01] through [Filter 05]. Follow the steps below to change the settings. 1 Click [Modify Settings]. The following dialog box appears.

2 Populate the displayed fields. [Filter Name] You can change the filter name. You can enter up to 20 characters. ● Date [Date] [Modify] Select this check box to specify the samples you want displayed by their dates of analysis. The setting appears on the right side of the button. Click to display the dialog box on the right. Click to select [Today], [Yesterday] or [Specify]. Selecting [Specify] allows you to specify the date. In the field below [Specify], enter the date in the format "Year (4 digits)/Month (2 digits)/Date (2 digits)". If you click the button on the right edge of the input field, a calendar appears. You can also enter the date by selecting from this calendar. 10-14 XN-1000 Instructions for Use Revised August 2012 Chapter 10 Checking analysis data (Sample Explorer) ● Validate [Validate] [Modify] Select this check box to specify the samples you want displayed by whether or not they have been validated. The setting appears on the right side of the button. Click to display the dialog box on the right. Select [Validated] or [Not Validated]. ● Error [Error] [Modify] Select this check box to specify the samples you want displayed by their error statuses. The setting appears on the right side of the button. Click to display the dialog box on the right. Select [Error Occurred], [Error Did Not Occur], or [Set separately].

If you select [Set separately], specify [ID Read Error] and/or [Analysis Error] by selecting the corresponding check box(es). Select [Occurred] or [Not Occurred] for the error(s) you specified. ● Positive/Negative [Judgment] [Modify] Select this check box to specify the samples you want displayed by their Positive/ Negative results. The setting appears on the right side of the button.

Click to display the dialog box on the right. You can select [Positive], [Negative], or [Set separately]. If you select [Set separately], specify [Diff.], [Count], and/or [Morph.] by selecting the corresponding check box(es).

Select [Positive] or [Negative] for the items you specified. 10-15 XN-1000 Instructions for Use Revised August 2012 Chapter 10 Checking analysis data (Sample Explorer) ● Output [Output] [Modify] Select this check box to specify the samples you want displayed by their output destinations. The setting appears on the right side of the button. Click to display the dialog box on the right. You can specify [Host Computer (HC)], [Report (GP)], and/or [Ticket (DP)] by selecting the corresponding check boxes, and select [Not Output] or [Outputted] for each item. ● Reference Interval [Reference Interval] [Modify] Select this check box to specify the samples you want displayed by whether or not they are within the reference interval. The setting appears on the right side of the button. Click to display the dialog box on the right. Select [Inside Reference Interval] or [Outside Reference Interval]. 10-16 XN-1000 Instructions for Use Revised August 2012 Chapter 10 Checking analysis data (Sample Explorer) ● QC [QC Sample] [Modify] Select this check box to specify the samples you want displayed by their QC status. The setting appears on the right side of the button. Click to display the dialog box on the right. Select [QC Displayed] or [QC Not Displayed].

● Patient ID* [Patient ID] [Modify] Select this check box to specify the samples you want displayed by their patient IDs. The setting appears on the right side of the button. Click to display the dialog box on the right. Enter the [Patient ID].

You can enter up to 16 characters.

Enter the [Patient ID] and click [OK] to display samples that partially match the entered Patient ID. To display samples that match the entered Patient ID exactly, select the check box [Filter exact matches]. * This is displayed only if the user who is logged in has the privileges to display and modify patient info.

For details on privileges to display and modify patient info, see the "Administrator's Guide". (➤Administrator's Guide,"Chapter 4: 4.3.2 System settings") 10-17 XN-1000 Instructions for Use Revised August 2012 Chapter 10 Checking analysis data (Sample Explorer) ● Discrete [Discrete] [Modify] Select this check box to specify the samples you want displayed by the status of their discrete tests. The setting appears on the right side of the button.

Click to display the dialog box on the right. Specify the discrete tests by selecting the corresponding check box(es)*.

When you select the [Specify discretes] check box, the filter will include the selected discrete test. If you select [Other], the selectable discrete tests will be filtered out. When you select the [Filter using conditions that include the selected discrete test] check box, the filter will include any discrete tests that partially match the selected discrete test. For details on discrete tests, see Chapter 7.

(➤P.7-9 "Chapter 7: Table of discrete tests and their corresponding analysis parameters") * These items do not appear with all analyzer types. ● Analysis mode [Measurement Mode] [Modify] Select this check box to specify the samples you want displayed by their analysis modes. The setting appears on the right side of the button.

Click to display the dialog box on the right. Select the checkbox to set [WB] ([Whole Blood] mode), [LW] ([Low WBC] mode), [PD] ([Pre-Dilution] mode), [BF] ([Body Fluid] mode)*, [HPC] ([HPC] mode)*, and [hsA] ([hsA] mode)*. * The availability of these functions depends on your system configuration. 10-18 XN-1000 Instructions for Use Revised December 2012 Chapter 10 Checking analysis data (Sample Explorer) ● Order type* [Order Type] [Modify] Select this check box to specify the samples you want displayed by their order types. The setting appears on the right side of the button. Click to display the dialog box on the right. You can specify [Initial], [Initial / Repeat], [Rerun], [Rerun /Repeat], [Reflex], [Reflex / Repeat], [Manual], and/or [Manual (Open)] by selecting the corresponding check box(es). * When a sampler (SA-01) is used, this does not appear. ● Background check [Background check] [Modify] 3 Select this check box to specify the samples you want displayed by their background check status. The setting appears on the right side of the button. Click to display the dialog box on the right. Select [Background check displayed] or [Background check not displayed]. Click [OK]. The dialog box closes, and the filter settings change. 10-19 XN-1000 Instructions for Use Revised August 2012 Chapter 10 10.5 Checking analysis data (Sample Explorer) Search for a sample You can search the analysis data list for a specific sample*. * You cannot search for any samples while the last 20 samples are displayed. Follow the steps below to search for a sample. 1 Click the [FIND] button on the toolbar. The following dialog box appears. In the following dialog box, the ward selection area appears*. * In the default setting, ward selection area does not appear. Ward name input field Ward selection area List of ward names Select button Note: The doctor selection area is similar to the ward selection area. Use the above dialog box as a reference for the doctor selection area. 10-20 XN-1000 Instructions for Use Revised August 2012 Chapter 10 Checking analysis data (Sample Explorer) 2 Populate the displayed fields. ● [Search Conditions] The specified items are used as search conditions. [Sample No.] Enter the sample number. You can enter up to 22 characters.

[Patient ID] Enter the patient's ID. You can enter up to 16 characters. [Last Name] Enter the patient's last name. You can enter up to 20 characters. [First Name] Enter the patient's first name. You can enter up to 20 characters. [Ward Name] Displays the selected ward name. Select button [Doctor] Clicking the button displays the ward selection area on the right side of the dialog box. Displays the selected doctor for the patient. Select button Clicking the button displays the doctor selection area on the right side of the dialog box. ● Ward/Doctor selection area Ward name/ Doctor input field Enter a conditions to narrow down the ward names/doctors. You can enter up to 20 characters. List of ward names/doctors Displays the ward names/doctors that contain the conditions that you entered. Click to select the ward name/doctor. You can only select 1 ward name/doctor.

[Clear] Click to clear the narrowed down ward name/doctor. Note: You can enter "*" and "?" as substitution characters in your search. "?": A "?" is used in place of any 1 character. e.g. If you search for "99?99", "99099", "99999" and "99A99" are all selected. "*": A "*" is used in place of 0 or more characters. e.g. If you search for "9*9", "909", "9119" and "99A99" are all selected. 10-21 XN-1000 Instructions for Use Revised August 2012 Chapter 10 3 Checking analysis data (Sample Explorer) Set the search conditions for a match. If you want to find analysis data that match the specified conditions exactly, select the [Find exact matches] check box. If you clear the check box, it will also find samples

that partially match the specified conditions. 4 Click [PREV.] / [NEXT]. A sample that matches the search conditions is selected in the list pane. 5 [PREV.] Click to search up from the analysis result selected in the list pane. [NEXT] Click to search down from the analysis result selected in the list pane. Click [Close]. The dialog box closes. 10.6 Modify sample information You can modify the sample information from the analysis data list*. When sample information is modified, the identification of analysis data changes. Exercise this operation very carefully. * If the selected sample in the analysis data list is validated, or if the analysis data list for the last 20 samples is displayed, you cannot modify any sample information. Follow the steps below to modify sample information. 1 In the list pane, click the sample you want to modify. The sample information is selected. 2 Click the [Modify] button on the toolbar. The dialog box on the right appears. 10-22 XN-1000 Instructions for Use Revised August 2012 Chapter 10 Checking analysis data (Sample Explorer) 3 Populate the displayed fields. [Sample No.] Displays the sample number. You cannot modify the rule without entering the sample NO. You can enter up to 22 characters. [P/N] Displays the Positive/Negative result of the sample. You can modify a Positive result to Negative. If the result is Negative, the setting is grayed out and cannot be modified.

However, if it is a Negative result with [DIFF], [MORPH], or [COUNT], then the setting can be modified. [Sample Inf.] Displays the sample number attribute. You can select from [Manual Setting (M)], [Auto Increment (A)], [ID Barcode Reader (B)], or [Host Setting (C)]. [Patient ID]* Displays the [Patient ID]. You can enter up to 16 characters. [Patient Name] Displays the patient name retrieved by [Patient ID]. You cannot modify it. [Sample Comment] Displays comments about the sample. You can enter up to 40 characters. * If the patient ID was changed, delta check is performed.

4 Click [OK]. The modified sample information is saved. 10-23 XN-1000 Instructions for Use Revised August 2012 Chapter 10 10.7 Checking analysis data (Sample Explorer) Print analysis data From the analysis data list in the [Sample Explorer] screen, you can print the analysis data for the selected sample to various output destinations*. Up to 300 samples can be output at once. * The analysis data cannot be printed in the following cases. • If the sample has not been validated.

• If the analysis data list for the last 20 samples is displayed. • If you are not connected to any host computer or printers. 10.7.1 Output to host computer or printer Follow the steps below to output to the host computer or the printer. 1 In the list pane, click the sample you want to output. The sample information is selected.

You can select multiple items. 2 Click the output destination from the [Output] button on the toolbar. The analysis data is output to the specified destination*. * Destinations that are not connected are grayed out and cannot be clicked. [Host Computer (HC)] Outputs to the host computer. [Ticket (DP)] Prints to a ticket printer. [Report (GP)] Prints to a graphic printer in report format. [Ledger (LP)] Prints to a ledger printer. [Report for Lab Use Only] Prints to a graphic printer for laboratory use only.

10-24 XN-1000 Instructions for Use Revised August 2012 Chapter 10 Checking analysis data (Sample Explorer) 10.7.2 Save in CSV/FCS format You can select any analysis data in the [Sample Explorer] or [Data Browser] screens, and save it in CSV*1/ FCS*1,2 format. *1 You cannot save while the last 20 samples are displayed. *2 Analysis data from program versions prior to 00-12 and restored analysis data cannot be saved. Information When saving in CSV format, use caution on the following: • IP messages are intended for use only in the clinical laboratory and are not for patient diagnosis. IP messages provide notification of the possibility of a specific sample abnormality based on examination of the analysis data. • Do not use analysis results of any research parameter for the patient diagnosis.

Note: When saving in CSV format, use caution on the following: • The order of the saved parameters cannot be changed. • Headers of research parameters are enclosed in [ ]. • Scattergrams and particle size distributions are saved individually as image files*. • If the analysis data exceeds 256 parameters, 256 columns of data are saved as 1 file*. * Depends on the configuration of IPU. Follow the steps below to save the analysis data in CSV/FCS format. 1 In the analysis data list pane, click the sample you want to save. The sample information is selected. You can select multiple items. 2 Click the [File] button - [Output in CSV Format]/[Output in FCS Format] on the toolbar. The [Save As] dialog box appears. 3 Specify or create the folder to save the sample data into. 10-25 XN-1000 Instructions for Use Revised December 2012 Chapter 10 4 Checking analysis data (Sample Explorer) Enter a file name. ● CSV Format The file extension is ".csv".

The extension for scattergrams and other image files is ".bmp" or ".png". ● FCS Format The file extension is ".fcs". Note: • The default file name of CSV format is set to [XN][software version][SAMPLE].csv e.g. [XN][00-01][SAMPLE].csv • The default name of CSV format for the image file is set to [Analyzer ID][software version][analysis date_analysis time][sample number] [image name].png (or bmp). e.g. [XN][00-01][20100505_080808][1234][RBC].png • The default file name of FCS format is set to [Analyzer ID][software version][Fcs][analysis date_analysis time][sample number][Channels].fcs e.g. [XN-20^11001][00-01][Fcs][20100505_080808][123456789][WNR].fcs • If a character that cannot be used in a file name in Windows (\/:*?”<>|) is included in a sample number, the character is automatically converted to a space. 5 Click [Save].

The data is saved in the specified format. Note: If you selected multiple data for save, the data will be saved in order from the top of list. 10-26 XN-1000 Instructions for Use Revised May 2014 Chapter 10 Checking analysis data (Sample Explorer) 10.8 Save analysis data You can save analysis data*. Up to 1,000 entries of analysis data can be saved. * You cannot save any analysis data while the last 20 samples are displayed. Follow the steps below to save analysis data to a file.

1 In the list pane, click the sample you want to save. The sample information is selected. You can select multiple items. 2 Click the [File] button - [Backup] on the toolbar. The [Open] dialog box appears. 3 Specify or create the folder to save the sample data into.

4 Check the file name. The file extension is ".smp". Note: • The file name is set to [Analyzer ID][software version][Sample][analysis date_analysis time][sample number].smp. e.g. [XN][00-01][Sample][20100505_080808][1234].smp • If a character that cannot be used in a file name in Windows (\/:*?”<>|) is included in a sample number, the character is automatically converted to a space. 5 Click [Save]. A dialog that allows you to check progress appears. When the save is finished, the dialog box closes. The data are saved to the specified file*. * Whether or not the backup data includes patient information depends on the IPU security settings.

For information on security, see the "Administrator's Guide". (➤Administrator's Guide,"Chapter 4: 4.3.2 System settings") Note: If you selected multiple samples, all selected data are backed up to multiple single smp files. 10-27 XN-1000 Instructions for Use Revised May 2014 Chapter 10 10.9 Checking analysis data (Sample Explorer) Restore saved analysis data You can restore saved analysis data*. Up to 1,000 entries of analysis data can be restored. * You cannot restore any analysis data while the last 20 samples are displayed. Follow the steps below to restore saved analysis data. 1 Click [File] - [Restore] on the toolbar. The [Open] dialog box appears. 2 Select the name of the file you want to restore. The file you can open is ".smp". You can select multiple items. 3 Click [Open].

A dialog that allows you to check progress appears. When restoring is finished, the dialog closes. The analysis data is restored*. * If the user who is logged in does not have the privileges to display and modify patient info, a dialog box appears to warn the user that patient info cannot be restored. For details on privileges to display and modify patient info, see the "Administrator's Guide". (➤Administrator's Guide,"Chapter 4: 4.3.2 System settings") 10-28 XN-1000 Instructions for Use Revised August 2012 Chapter 10 Checking analysis data (Sample Explorer) ● If a data entry with the same [Patient ID] already exists If the same [Patient ID] as the data you are restoring has already been registered in patient registration, the following dialog box is displayed*. * If the patient informations matches to the registered informations exactly, this dialog does not appear. Follow the steps below to specify the patient's ID and information. 1 Specify patient ID. Select [Overwrite] or [Register in different ID]. You can enter up to 16 characters in the [Register in different ID] field. 2 Specify patient information. Select which items of the patient information you want to use. If you want to select all items in [Registered patient information] or [Patient information in file], click [Always use registered patient information] or [Always use patient information in file].

3 Click [Overwrite with above settings]. The patient ID and the patient information are overwritten. 10-29 XN-1000 Instructions for Use Revised August 2012 Chapter 10 10.10 Checking analysis data (Sample Explorer) Delete analysis data You can delete the selected analysis data from the analysis data list*. * You cannot delete any analysis data while the last 20 samples are displayed. Follow the steps below to delete analysis data. 1 In the list pane, click the analysis data you want to delete. The sample information is selected. You can select multiple items.

2 Click the [Delete] button on the toolbar. The dialog box on the right appears. 3 Click [Yes]. The selected analysis data is deleted from the analysis data list. 10-30 XN-1000 Instructions for Use Revised August 2012 Chapter 10 Checking analysis data (Sample Explorer) 10.11 Change layout of analysis data list You can change the layout of the analysis data list in the [Sample Explorer] screen.

Follow the steps below to change the layout of the analysis data list. 1 Right click on the tab or the analysis data list of the [Sample Explorer] screen. A context menu opens. 2 Click the item you wish to change. You can populate the displayed fields. ● [Property] The following dialog box appears. Select tabs Common Displayed Items list Displayed Items list 10-31 XN-1000 Instructions for Use Revised August 2012 Chapter 10 Checking analysis data (Sample Explorer) Common Displayed Item Settings [Selectable Items] Displays the items that can be set as common items and all items for research*. [Selected Item(s)] The items in this list will be displayed in the analysis data list as common displayed items. [Insert] Click to move the selected item from Common Displayed Items list to the Items list, above the selected item. [Add] Click to move the item you selected in the Common Displayed Items list to the bottom of the Displayed Items list. [Move Up] Click to move up the selection in the Displayed Items list by 1 item.

[Move Down] Click to move down the selection in the Displayed Items list by 1 item. [Delete] Click to move the item you selected in the Displayed Items list to the bottom of the Common Displayed Items list. * To display the items for research, the IPU setting is required. For details, see "Administrator's Guide". (➤Administrator's Guide "Chapter 4: 4.3.2 System settings") And, the items for research are displayed on gray background. Tab Item Setting* [Add Tab] Click to add a new tab to the right of the rightmost tab in the select tabs.

The name of the new tab is "Tab", and nothing is displayed in the Displayed Items list. If there are maximum number of tabs (20 tabs), this button is grayed out and cannot be clicked. [Delete Tab] Click to delete the tab that is currently displayed in the analysis data list. Select tabs Allows you to change the individual items for the tab you clicked. [Tab Caption] Allows you to change the caption displayed on the tab.

You can enter up to 20 characters. [Move Left] Click to move the tab selection to the left by 1 tab. [Move Right] Click to move the tab selection to the right by 1 tab. * The functions of the [Insert], [Add], [Move Up], [Move Down], [Delete] buttons are the same as described in the "Common Displayed Item Settings" section. 10-32 XN-1000 Instructions for Use Revised August 2012 Chapter 10 Checking analysis data (Sample Explorer) ● [Backup] Click to display the [Save As] dialog box. Enter a file name and click [OK] to save the layout. The file extension is ".elf". Note: The default file name is set to [XN][software version][ExplorerLayout].elf. ● [Restore] Click to display the dialog box. Select a file name and click [OK] to restore a layout. The file extension is ".elf". ● [Initialize] Click to display the dialog box for confirming reset the layout to factory setting. Click [Yes] to have the layout initialized. 3 Click [OK]. The dialog box closes, and the layout of the analysis data list changes.

10-33 XN-1000 Instructions for Use Revised August 2012 Chapter 10 Checking analysis data (Sample Explorer) 10-34 XN-1000 Instructions for Use Revised August 2012 Chapter 11 Checking detailed analysis information (Data Browser) Chapter 11 Checking detailed analysis information (Data Browser) This section explains how to check detailed information on analysis data. 11.1 Data Browser screen In the [Sample Explorer] screen, double-clicking a sample data displays the [Data Browser] screen. Alternatively, you can also display the screen by selecting the sample you want to display, and clicking the [Data Browser] icon on the Menu screen, or the [Browser] button on the toolbar. Action Error Rule result Sample information Toolbar Patient information Sample link Positive/ Negative Validation Tabs Analysis data [Data Browser] screen Toolbar The buttons below only appear in the [Data Browser] screen. [Output] - [Cumulative Report] Click to output cumulative data from the graphic printer. For the output procedure, see Chapter 10. (➤P.10-24 "Chapter 10: 10.7.1 Output to host computer or printer") * Only appears in the following cases: • A graphic printer (GP) is connected. • The user has permission to display and edit patient information. • The user has permission to display and output research items. • The user has permission to perform external output. • There is data to be printed. • The most recent 20 samples are not displayed. • Analysis data of [Whole Blood] / [Low WBC] / [Pre-Dilution] / [HPC] mode are shown. For details on permission to display and edit patient information, permission to display and output research items, and permission to perform external output, see the "Administrator's Guide". (➤Administrator's Guide,"Chapter 4: 4.3.2 System settings") The functions in the toolbar of Data Browser are similar to the toolbar of Sample Explorer. For details, see Chapter 10. (➤P.10-1 "Chapter 10: 10.1.1 Sample Explorer screen" (Toolbar)) However, the function of [File] is only [Output in CSV Format]. You cannot backup and restore the file. 11-1 XN-1000 Instructions for Use Revised August 2012 Chapter 11 Checking detailed analysis information (Data Browser) Navigating in the screen You can switch the screen by clicking the display-switching tab. 11.1.1 Common displayed items This section explains the common items that are displayed on all tabs, in the top section of the [Data Browser] screen. Tabs Click to switch to a different analysis data display. When the analysis data is from [Body Fluid], [HPC] or [hsA] mode, the contents of the displayed tabs change.

* The availability of these functions depends on your system configuration. For information on [hsA] mode, see the "Administrator's Guide". (➤Administrator's Guide, "Chapter 3: 3.3.2 Checking analysis data") When the analysis data is from [HPC] mode, the [HPC] tab appears in place of the [Cumulative] tab. Positive/Negative, Validation Displays the Positive/Negative result, and validation status. Positive/Negative result If the Positive/Negative result cannot be determined, the background becomes gray and nothing is displayed. If there are no samples, or if the Positive/Negative result has not been determined, nothing is displayed. [Positive] This is displayed in white letters on red background, if there were any abnormalities in the blood cell count or blood cell morphology.

The following Positive results are displayed on the right side. [Diff.] Indicates an abnormal blood cell differentiation value. [Morph.] Indicates an abnormal cell morphology. [Count] Indicates an abnormal blood cell count. [Negative] [Negative] is displayed if the sample had no errors. Validation If there are no samples, nothing is displayed. [Validated] This is displayed to indicate that the analysis data has been validated.

[Not Validated] This is displayed to indicate that the analysis data has not been validated. 11-2 XN-1000 Instructions for Use Revised December 2012 Chapter 11 Checking detailed analysis information (Data Browser) Action, Error, Rule result Displays the determined actions, errors, and rules. Action Nothing is displayed if there are no action messages or no samples. The details of the action message are displayed in the [Action] field in the analysis data pane. [Action]* If there is an action message, it is displayed in white letters on red background. The details appear on the below.

[Check] There may be a mix-up of samples. Otherwise, there is a significant difference in the analysis results. Check the sample. [Review] Channel difference has occurred. Check the analysis results. [Retest] Check the analysis mode, the order and the status of the sample, and then re-analyze. * Use the analysis results only for testing in the clinical laboratory. They are not intended for patient diagnosis. Error If an analysis error occurred, [Error] is displayed in white letters on red background. Nothing is displayed if there are no errors. The details of the error message are displayed in the [Error/Rule Comments] field in the analysis data pane. [Func.] An analysis error other than the ID barcode read error or [Result] has occurred. [Result] One of the following analysis errors has occurred: [Blood cannot be aspirated.], [Insufficient blood volume], [Low count error]. Rule result Nothing is displayed if there are no samples. If there are any comments, the comment icon and the number of comments are displayed on the right side of [Rule Result]. The details of the comment are displayed in the [Error/Rule Comments] field in the analysis data pane. * When the sampler (SA-01) is used, only the number of comments is displayed. The background color varies depending on the judgment result. When there are multiple comments, the background color of the most important comment appears. • Black Low importance • Orange Medium importance • Red High importance [Repeat] The analysis must be repeated due to an error in the first test. [Rerun] Analysis must be repeated for the same item as in the first test. [Same] Analysis is performed using the same analyzer as the first test. [Reflex] Due to the results from the first test, analysis must be performed with additional items. The discrete test to be added is displayed on the right. If [LW_DIFF] was added, [LW] and [DIFF] are displayed. [Query to HOST] A host inquiry is necessary. [None] The result is that it is not necessary to make a host inquiry or repeat analysis.

11-3 XN-1000 Instructions for Use Revised February 2014 Chapter 11 Checking detailed analysis information (Data Browser) Sample information Displays the sample information of the analysis data. Analysis sample icon Sample No. Comments Analysis Date Rack No. Sample tube Analysis sample icon An icon is displayed to indicate the analysis sample. [WB] (Whole Blood sample) / [LW] (Low WBC sample) / [PD] (Pre-diluted sample) / [BF] (Body Fluid sample)* / [HPC] (HPC analysis sample)* / [hsA] (hsA analysis sample)* are displayed. Sample No. Displays the sample number. Analysis Date Displays the date when the analysis result was made available. Rack No. Displays the rack number of the analyzed sample. Sample tube Displays the sample tube position number of the analyzed sample. Comments Displays comments about the sample. * The availability of these functions depends on your system configuration. If you performed body fluid analysis without clearing a [Analysis result is high], "BF" will be displayed in white on a red background and the body fluid icon will appear darker. Patient information Displays the patient information of the analysis data. Sample link The order type of the displayed analysis sample and the analyzer used for analysis are displayed in buttons in the selected state. If the sample has [Initial], [Repeat], [Rerun], or [Reflex] information, corresponding buttons appear. Information on the same analyzer appears. Click the sample link button to display the applicable analysis data in the [Data Browser] screen. 11-4 XN-1000 Instructions for Use Revised December 2012 Chapter 11 Checking detailed analysis information (Data Browser) 11.1.2 Display analysis data The analysis data pane displays the details of the data selected in the analysis data list. The method of displaying the data differs depending on the selected tab. Information Analysis results of research parameters are indicated by a gray background to distinguish them from report analysis results. Research items are the parameter for research. Analysis results for these parameters must not be used for diagnosis of patients. Notations for abnormal data If there is an abnormality in the analysis data, it is represented by the following masks and marks.

For the details on masks and marks, see Chapter 10. (➤P.10-9 "Chapter 10: 10.1.4 Numerical data of the analysis results") 11.2 Check all information You can check all information about the analysis data in the [Main] and [Graph] screens. 11.2.1 Main screen Clicking the [Main] tab displays the following screen. [Whole Blood] / [Low WBC] / [Pre-Dilution] / [HPC]* mode When displaying analysis data, the following items are displayed in the main screen: Analysis parameters, all reportable numerical data, flag information, SD Bar, action, rule comment and error message. * The availability of the HPC analysis function depends on your system configuration. When the analysis data is [HPC] mode data, the [HPC] tab appears. [Main] screen 11-5 XN-1000 Instructions for Use Revised August 2012 Chapter 11 Checking detailed analysis information (Data Browser) [Item]*1,2 Displays analysis parameters. [Data]*2 Displays the numerical data for each parameter. If there is an abnormality in the data, [*] will appear after the value. [Unit]*2 Displays the unit of each parameter. [LL UL]*2 For each parameter, the SD Bar displays its deviation from the normal range. A green dot in the SD Bar turns red if the upper or lower limit is exceeded. However, if the analysis result is not applicable for a reference interval judgment, or the lower limit is set higher than the higher limit, nothing is displayed. Normal range: A green dot is displayed inside the upper/lower limits. Abnormal range: Red dots are displayed at the upper/lower limits.

[WBC Flag(s)] Displays WBC IP messages, if one exists. The messages are displayed in the order of abnormal messages, then suspect messages. [RBC Flag(s)] Displays RBC IP messages, if one exists. The messages are displayed in the order of abnormal messages, then suspect messages. [PLT Flag(s)] Displays PLT IP messages, if one exists. The messages are displayed in the order of abnormal messages, then suspect messages. [Action] Displays an action message, if one exists. [Error/Rule Comments] Displays the error message and/or rule comment, if one exists. The rule comments are sorted by priority with the highest priority on top, and then by rule number in ascending order. *1 These items do not appear with all analyzer types. *2 The items for research are displayed on gray background. Note: The action message [Suspect sample, check the sample.] appears when it is suspected that the sample was not sufficiently mixed before being placed in the analyzer. This message may also appear when there is an extended time between mixing and analysis, when the sample has a high degree of sedimentation, when the sample has been refrigerated/transported in a cool environment, or when the sample has a high RBC count or high HCT value. If this message appears, check the sample. 11-6 XN-1000 Instructions for Use Revised May 2014 Chapter 11 Checking detailed analysis information (Data Browser) [Body Fluid] mode* When displaying analysis data, the following items are displayed in the main screen: Analysis parameters, all numerical data, flag information, action, rule comment and error message. * The body fluid analysis can only be performed if the instrument offers the body fluid analysis mode. [Main] screen [Item]* Displays analysis parameters. [Data]* Displays the numerical data for each parameter. If there is an abnormality in the data, [*] will appear after the value. [Unit]* Displays the unit of each parameter. [WBC Flag(s)] The WBC IP messages are displayed in the order of suspect messages, then abnormal messages.

[Action] Displays an action message, if one exists. [Error/Rule Comments] Displays the error message or rule comment, if one exists. The rule comments are sorted by priority with the highest priority on top, and then by rule number in ascending order. * The items for research are displayed on gray background. 11-7 XN-1000 Instructions for Use Revised August 2012 Chapter 11 11.2.2 Checking detailed analysis information (Data Browser) Graph screen Clicking the [Graph] tab displays the following screen. [Whole Blood] / [Low WBC] / [Pre-Dilution] / [HPC]* mode When displaying analysis data, the following items are displayed in the [Graph] screen: Analysis parameters, all reportable numerical data, flag information, distribution data, and scattergram. * The availability of the HPC analysis function depends on your system configuration. When the analysis data is [HPC] mode data, the [HPC] tab appears. Distribution data display area Scattergram display area [Graph] screen The display of [Item], [Data], [Unit] and flag informations are same to the [Main] screen. See the [Main] screen explanation of whole blood or diluted sample as a reference for the [Graph] screen. (➤P.11-5 "11.2.1 Main screen") Distribution data Displays the distributions for [RBC] and [PLT]. Double-click to display an enlarged view display area in a new window. Scattergram display area Displays 2-dimensional distributions (scattergrams) for [WDF], [WNR], [WPC]*1,2, [RET]*1, [PLT-F]*1 and [PLT-O]*1. Double-click to display an enlarged view in a new window. *1 These items do not appear with all analyzer types. *2 For HPC analysis, [WPC(SSC-FSC)] is displayed. 11-8 XN-1000 Instructions for Use Revised August 2012 Chapter 11 Checking detailed analysis information (Data Browser) [Body Fluid] mode* When displaying analysis data, the following items are displayed in the graph screen: Analysis parameters, all reportable numerical data, flag information, distribution data, and scattergram. * The body fluid analysis can only be performed if the instrument offers the body fluid analysis mode. Distribution data display area Scattergram display area [Graph] screen The display of [Item], [Data], [Unit] and flag informations are same to the [Main] screen. See the [Main] screen explanation of body fluid sample as a reference for the [Graph] screen. (➤P.11-7 "[Body Fluid] mode*") Distribution data display area Displays the distributions for [RBC]. Double-click to display an enlarged view in a new window. Scattergram display area Displays 2-dimensional distributions (scattergrams) for [WDF]. Double-click to display an enlarged view in a new window. 11-9 XN-1000 Instructions for Use Revised August 2012 Chapter 11 11.3 Checking detailed analysis information (Data Browser) Check data by time ([Whole Blood] / [Low WBC] / [Pre-Dilution] mode) The [Cumulative] screen displays the change in the analysis data over time*. The analysis data for a specific patient is restored by [Patient ID], and displayed cumulatively on the screen.

[Displayed Items] and [Display Method] can be selected. * The analysis results below are not shown. • [Body Fluid] mode analysis, [HPC] mode analysis • Analysis error • [Patient ID] is not registered If there are multiple analysis results with the same reception date, only the result with the most recent analysis date and time is displayed. Clicking the [Cumulative] tab displays the following screen. The [Cumulative] screen only appears if the user who is logged in has permission to display and modify patient information. For details on privileges to display and modify patient info, see the "Administrator's Guide". (➤Administrator's Guide,"Chapter 4: 4.3.2 System settings") Analysis date [Cumulative] screen Note: The displayed data is that which is older than the specified data. Data of newer samples will not be displayed even if they are included in the analysis data list of the [Sample Explorer] screen. Common Displayed Items This section explains the common items displayed in the [Cumulative] screen. In the above screen, [Numerical] is selected.

The common displayed items are the same when [Graph] or [Scattergram] is selected. ● [Displayed Items] For the discrete tests and their corresponding analysis parameters, see Chapter 7. (➤P.7-9 "Chapter 7: Table of discrete tests and their corresponding analysis parameters") [CBC] Click to display the report analysis item corresponding to the [CBC] discrete. [DIFF] Click to display the report analysis items corresponding to WBC and [DIFF] discrete. [RET/PLT-F]* Click to display the report analysis items corresponding to RBC, PLT, and [RET] discrete. * These items do not appear with all analyzer types. Either [RET] or [PLT-F] only appears. 11-10 XN-1000 Instructions for Use Revised August 2012 Chapter 11 Checking detailed analysis information (Data Browser) ● [Display Method] [Numerical] Click to display the numerical data cumulatively. [Graph] Click to display cumulative line graphs. [Scattergram] Click to display scattergrams and distributions cumulatively. ● Analysis date [Date] Displays the date on which the data was analyzed. [Hour(s)] Displays the time at which the data was analyzed.

11.3.1 Cumulative numerical display Clicking [Numerical] displays the following screen. The analysis data of 7 past analyses, with the selected analysis data as the most recent data, are displayed as a numerical list. Analysis parameters Analysis data ● Analysis data Analysis parameters Displays analysis parameters of the selected [Displayed Items]. Analysis data Displays the analysis parameter data in numerical values.

11-11 XN-1000 Instructions for Use Revised February 2013 Chapter 11 Checking detailed analysis information (Data Browser) 11.3.2 Cumulative graph display Clicking [Graph] displays the following screen. The analysis data of 7 past analyses, with the selected analysis data as the most recent data, are displayed as a line graph. Analysis parameters Analysis data ● Analysis data Analysis parameters Displays analysis parameters of the selected [Displayed Items]. Analysis data Displays the analysis parameter data as line graphs. ● Maximum and minimum values [Max] Displays the maximum value of each parameter. [Min] Displays the minimum value of each parameter. 11-12 XN-1000 Instructions for Use Revised December 2012 Chapter 11 Checking detailed analysis information (Data Browser) 11.3.3 Cumulative scattergram display Clicking [Scattergram] displays the following screen. The analysis data of 7 past analyses, with the selected analysis data as the most recent data, are displayed as a scattergram and distribution. Analysis parameters Analysis data ● Analysis data Analysis parameters Displays the channels of the selected [Displayed Items]. Analysis data Displays the analysis parameter data as scattergrams and distributions. The displayed channels in the scattergrams and distributions change according to the selected [Displayed Items]. Information • The scattergram in the [Cumulative] screen is shown at low resolution. • The scattergram does not display enlarged view by double-clicking. ● [Displayed Items] and Scattergram Displayed Items Scattergram [CBC] [WNR], [RBC] (histograms) , [PLT] (histograms) [DIFF] [WDF], [WNR], [WPC]* [RET/PLT-F] [RET], [PLT-F]* / [PLT-O]* * These items do not appear with all analyzer types. 11-13 XN-1000 Instructions for Use Revised December 2012 Chapter 11 11.4 Checking detailed analysis information (Data Browser) Check data by time ([HPC] mode) The [HPC] screen displays the change in the analysis data over time*.

Only appears for an analysis sample in [HPC] mode. The analysis data for a specific patient is restored by [Patient ID], and displayed cumulatively on the screen. [Display Method] can be selected. * The analysis results below are not shown. • [Whole Blood] / [Low WBC] / [Pre-Dilution] / [Body Fluid] mode analysis • Analysis error • [Patient ID] is not registered If there are multiple analysis results with the same reception date, all are shown. Clicking the [HPC] tab displays the following screen. The [HPC] screen only appears if the user who is logged in has permission to display and modify patient information. For details on privileges to display and modify patient info, see the "Administrator's Guide". (➤Administrator's Guide,"Chapter 4: 4.3.2 System settings") Information Analysis date [HPC] screen Common Displayed Items This section explains the common items displayed in the [HPC] screen. In the above screen, [Numerical] is selected.

The common displayed items are the same when [Graph] or [Scattergram] is selected. • Numerical value / graph display: HPC#, WBC, NEUT#, PLT are displayed. • Scattergram display: WPC(SSC-FSC), WDF are displayed. ● [Display Method] [Numerical] Click to display the numerical data cumulatively. [Graph] Click to display cumulative line graphs. [Scattergram] Click to display scattergrams and distributions cumulatively. ● Information [Latest] Indicates the most recent data. [Selecting] Indicates the currently displayed data. ● Analysis date [Date] Displays the date on which the data was analyzed. [Hour(s)] Displays the time at which the data was analyzed. 11-14 XN-1000 Instructions for Use Revised February 2013 Chapter 11 Checking detailed analysis information (Data Browser) 11.4.1 Cumulative numerical display ([HPC]) Clicking [Numerical] displays the following screen. The analysis data from the most recent 7 analyses, including the selected analysis data, are displayed as a numerical list. Analysis parameters Analysis data ● Analysis data Analysis parameters Displays analysis parameters. Analysis data Displays the analysis parameter data in numerical values. 11-15 XN-1000 Instructions for Use Revised August 2012 Chapter 11 Checking detailed analysis information (Data Browser) 11.4.2 Cumulative graph display ([HPC]) Clicking [Graph] displays the following screen. The analysis data from the most recent 7 analyses, including the selected analysis data, are displayed as a line graph. Analysis parameters Analysis data ● Analysis data Analysis parameters Displays analysis parameters. Analysis data Displays the analysis parameter data as line graphs. ● Maximum and minimum values [Max] Displays the maximum value of each parameter. [Min] Displays the minimum value of each parameter. 11-16 XN-1000 Instructions for Use Revised December 2012 Chapter 11 Checking detailed analysis information (Data Browser) 11.4.3 Cumulative scattergram display ([HPC]) Clicking [Scattergram] displays the following screen. The analysis data from the most recent 7 analyses, including the selected analysis data, are displayed as a scattergram and distribution. Analysis parameters Analysis data ● Analysis data Analysis parameters The tests are displayed. Analysis data Displays the analysis parameter data as scattergrams and distributions. Information • The scattergram in the [Cumulative] screen is shown at low resolution. • The scattergram does not display enlarged view by double-clicking. 11-17 XN-1000 Instructions for Use Revised August 2012 Chapter 11 11.4.4 Checking detailed analysis information (Data Browser) Change layout of HPC screen You can change the layout of the analysis data list in the [HPC] screen. Follow the steps below to change the layout of the analysis data list. 1 Right click on the tab or the analysis data list of the [HPC] screen. A context menu opens. 2 Click the item you wish to change.

You can populate the displayed fields. ● [Property] The following dialog box appears.

Row Displayed Items list Displayed Items list 11-18 XN-1000 Instructions for Use Revised August 2012 Chapter 11 Checking detailed analysis information (Data Browser) Displayed Item Settings [Selectable Items] Displays the items that can be set as row items and all items for research*. [Selected Item(s)] The items in this list will be displayed in the analysis data list as row displayed items. [Insert] Click to move the selected item from Row Displayed Items list to the Items list, above the selected item. [Add] Click to move the item you selected in the Row Displayed Items list to the bottom of the Displayed Items list. [Move Up] Click to move up the selection in the Displayed Items list by 1 item. [Move Down] Click to move down the selection in the Displayed Items list by 1 item. [Delete] Click to move the item you selected in the Displayed Items list to the bottom of the Row Displayed Items list. * To display the items for research, the IPU setting is required. For details, see "Administrator's Guide". (➤Administrator's Guide "Chapter 4: 4.3.2 System settings") And, the items for research are displayed on gray background. ● [Backup] Click to display the [Open] dialog box. Enter a file name and click [OK] to save the layout. The file extension is ".hlf".

Note: The default file name is set to [XN][software version][HPC Layout Files].hlf. ● [Restore] Click to display the dialog box. Select a file name and click [OK] to restore a layout. The file extension is ".hlf". ● [Initialize] Click to display the dialog box for confirming reset the layout to factory setting. Click [Yes] to have the layout initialized. 3 Click [OK]. The dialog box closes, and the layout of the analysis data list changes. 11-19 XN-1000 Instructions for Use Revised August 2012 Chapter 11 11.5 Checking detailed analysis information (Data Browser) Check data by Q-Flag The [Q-Flag] screen displays the Positive/Negative levels for 10 types of suspect IP messages, as histograms. The displayed information corresponds to the sample you selected in the analysis data list of the [Sample Explorer] screen. Clicking the [Q-Flag] tab displays the following screen. ● Suspect IP messages For the details on IP message judgment conditions and judgment methods, see the following. (➤P.11-29 "11.7.1 IP message judgment conditions and judgment methods") Q-Flag WBC type RBC type PLT type *1 *2 *3 *4 Message Meaning [Blasts/Abn Lympho?] Possibility of blasts or abnormal lymphocytes [Blasts?]*1 Possibility that blasts are present [Left Shift?] Possibility of left shift [Abn Lympho?]*1 Possibility abnormal lymphocytes [Atypical Lympho?] Possibility of atypical lymphocytes [RBC Agglutination?] Possibility of RBC agglutination [Turbidity/HGB Interf?] Possibility of HGB interference by chylemia [Iron Deficiency?] Possibility of iron deficiency anemia [HGB Defect?] Possibility of HGB abnormality [Fragments?] Possibility of fragmented RBCs [pRBC?]*2 Possibility of parasite-infected RBCs*4 [PLT Clumps?]*3 Possibility of PLT clumps These items do not appear with all analyzer types. The availability of this function depends on your system configuration. The judged channel (WNR/WDF/PLT-F) is appended to the IP message. The flag indicates that red blood cell may be infected with either P. vivax or P. malariae – trophozoite, schizont and gametocyte stages. This is only a suspect flag and NOT definitive or specific for malaria infection. 11-20 XN-1000 Instructions for Use Revised February 2014 Chapter 11 Checking detailed analysis information (Data Browser) ● [Q-Flag] In the histogram, Negative results of the sample are displayed in green, and Positive results are displayed in red. The values are displayed below the histogram. These values range from 0 to 300, in increments of 10. Values over 100 are determined as Positive. In addition, the following may appear in the judgment value position. Nothing is displayed on the bar graph. [Discrete]: Displayed in gray text. If the parameter used for judgment has not been analyzed. [Error]: If judgment impossible. Blank: If prerequisite for judgment was not met.

Also, if the suspect judgment was not performed due to blank data, etc. 11.6 Boundary between Positive and Negative Above this line: Positive Below this line: Negative Change layout of screen You can change the layout for [User] and [Lab Use Only] screens. [User] screen This screen allows the user to set any layout. Items that can be set are reportable items on your analyzer. This appears when the [User] tab is clicked. [Lab Use Only] screen This screen allows the user to set any layout. Items that can be set are reportable items on your analyzer and research items*. This appears when the [Lab Use Only] tab is clicked. * Research items only appear when the user has permission for [Display and Output of Research Items]. For details on permission for [Display and Output of Research Items], see the "Administrator's Guide". (➤Administrator's Guide, "Chapter 4: 4.3.2 System settings") 11-21 XN-1000 Instructions for Use Revised August 2012 Chapter 11 Checking detailed analysis information (Data Browser) When you right-click on the screen, a menu is displayed, allowing you to change the settings. The items you can configure change according to what part of the screen you right-click. Right-clicking on the desired display-switching button: The following context menus are displayed. [Change Name] Click to display the dialog for renaming the button. Up to 12 characters can be entered. [Layout backup] Clicking this item opens the [Save As] dialog box. Enter a file name and click [Save] to save the screen layout that is currently displayed. The file extension is ".blf". The default file name is set to [XN][software version][BrowserLayout].blf. [Layout restore] Clicking this item opens the [Open] dialog box. You can restore a screen layout. The file extension is ".blf". Select a file and click [Open] to display the overwrite confirmation dialog box. Clicking [OK] overwrites the screen layout and the dialog box closes. [Layout initialize] Click to display the dialog box for confirming reset the layout of the screens to factory setting. Click [Yes], you can reset the layout of the screens that is currently displayed to factory setting. Right-clicking inside the desired screen: [Add Item] Click to display the dialog box on the right. Clicking a button places the item on the screen. A table, a scattergram, a list box, a distribution, or a pie chart can be placed. Simultaneously, a setting dialog box for each item is displayed. Displayed item, name, color, types of scattergram and distribution, and types of IP message, error/rule comment and action can be set. 11-22 XN-1000 Instructions for Use Revised August 2012 Chapter 11 Checking detailed analysis information (Data Browser) Right-clicking on an item in the screen: [Move] Click this menu selects the right-clicked item, and its coordinates appear on the top right corner of the screen. In this state, you can drag to move the item to any position. Moreover, you can resize the item by dragging its vertex or one of the four corners. Displayed Item of coordinates [X]: The horizontal coordinate of the top left corner of the item, with the top left corner of the screen as the origin. [Y]: The vertical coordinate of the top left corner of the item, with the top left corner of the screen as the origin. [W]: The length of the item. [H]: The height of the item. [x]: The horizontal coordinate of cursor, with the top left corner of the screen as the origin. [y]: The vertical coordinate of cursor, with the top left corner of the screen as the origin. [Delete] Click to delete the selected item. [Properties] Click to display the Property dialog box for the selected item. You can configure its advanced settings of following items from this dialog box.

[Grid] You can set items ([Item], [Data], [Unit] and [LL UL]) and analysis items to display in a table. The items for research can be set to display*. [Text Box] You can specify the analysis parameters, units, and display data to display. In addition, you can set the font and background colors for entering free text. The items for research can be set to display*. [Scattergram] You can specify the type of scattergram you want to display. [List Box] You can specify the type of IP messages, the list of Error / Rule comment and the display of action comment you want to display. [Distribution] You can specify the type of distribution and normal range you want to display. [Pie Chart] You can set the analysis items you want to display in the pie chart and their colors. [Group] You can specify the group name for each item you want to display. * To display the items for research, the IPU setting is required. For details, see "Administrator's Guide". (➤Administrator's Guide, "Chapter 4: 4.3.2 System settings") And, the items for research are displayed on gray background. 11-23 XN-1000 Instructions for Use Revised August 2012 Chapter 11 11.7 Checking detailed analysis information (Data Browser) IP Messages When analysis data is analyzed in the IPU, information that supplements the Positive/Negative sample judgment appears in the [Data Browser] screen. Results without an error messages are classified into Positive/Negative based on the preset criteria.

The system bases its judgments on comprehensive surveys of numerical data, particle size distributions, scattergrams, and provides easily-to-understand flags/messages indicating the instruments findings. These flags/messages are referred to as "IP (Interpretive Program) messages." IP messages appear on the sample information tab of the [Sample Explorer] screen, on the main tab of the [Data Browser] screen, and the flag display area of the graph tab. Caution! • A "Positive" or "Error" judgment indicates the possibility of an abnormality. It is not a diagnosis of the patient. If a "Positive" or "Error" judgment occurs, check the data and repeat the test or examine carefully in accordance with the protocol of your laboratory. • IP Messages are only intended for use in the clinical laboratory and are not for patient diagnosis. IP messages provide notification of the possibility of a specific sample abnormality based on examination of the analysis data. Positive/Negative judgment Flag display area The main tab of [Data Browser] screen ● Flag categories [WBC Flag(s)] Shows IP message(s) for WBC. [NRBC Present] flag are also shown in here [WBC Flag(s)]. [RBC Flag(s)] Shows IP message(s) for RBC/RET.

[PLT Flag(s)] Shows IP message(s) for PLT. 11-24 XN-1000 Instructions for Use Revised August 2012 Chapter 11 Checking detailed analysis information (Data Browser) ● Message types There are 2 types of IP messages, abnormal message and suspect message, that may be displayed for each of WBC, RBC/RET, and PLT. Abnormal message Indicates that the sample is clearly abnormal. With some exceptions, the criteria for abnormal message judgment can be preset. Suspect message Indicates a possibility that the sample is abnormal. ● Positive/Negative judgment [Positive] Indicates that an analysis value or cell morphology exceeds the preset criteria for the IP message (abnormal sample). Displayed on a red background. A Positive judgment is classified into the 3 types shown below. The type appears to the right of [Positive]. [Diff.] Indicates an abnormal blood cell differentiation value. [Morph.] Indicates abnormal cell morphology. [Count] Indicates an abnormal blood cell count.

[Negative] Indicates that there was no analysis error or abnormality, and that there is no IP message (normal sample).

Displayed on a green background. Note: Only "Positive" judgment is performed for analysis in [Pre-Dilution] / [Body Fluid] / [HPC] mode. 11-25 XN-1000 Instructions for Use Revised August 2012 Chapter 11 Checking detailed analysis information (Data Browser) With respect to the following IP messages, when a sample judgment is Positive, the analysis results are regarded as having low reliability due to the abnormality and "*" (or "----") appears to the right of the data. WBC IP messages NRBC# NEUT# LYMPH# MONO# WBC NRBC% NEUT% LYMPH% MONO% EO# BASO# EO% BASO% IG# IG% WBC-BF TC-BF# PMN#, PMN% MN#, MN% WBC Abn Scattergram ∗ Lymph, Mono(WDF) Neut, Eo(WDF) ∗ Lymph, Neut(WDF) ∗ Neut, Mono(WDF) ∗ Lymph, Baso(WDF) ∗ ∗ ∗ ∗ ∗ ∗ ∗ ∗ ∗ Mono, Eo(WDF) ∗ Mono, Baso(WDF) Ghost, Neut(WDF) ∗*2 ∗*2 Ghost, Baso(WDF) ∗*2 ∗*2 Ghost, Lymph(WDF) ∗*2 ∗*2 Ghost, Eo(WDF) ∗*2 ∗*2 ∗ ∗ ∗ ∗ ∗ ∗ ∗ Lymph, Eo(WDF) ∗ ∗ ∗ ∗ ∗ ∗ ∗ ∗ ∗ ∗ ∗ ∗ ∗*2 ∗ ∗ ∗*2 ∗ ∗ ∗*2 ∗ ∗ ∗*2 ∗ Ghost, WBC(BF)*3 Ghost or other interference with WBC in body fluid analysis ∗ ∗ 4DIFF, Baso(WNR) ∗ ∗ ∗ ∗ ∗ ∗ ∗ ∗ ∗ 4DIFF, Nrbc(WNR) ∗*1 ∗ ∗ ∗ ∗ Ghost, 4DIFF(WNR) ∗*1 ∗ ∗ ∗ 1 Ghost, Nrbc(WNR) ∗* ∗ ∗ ∗ ∗ ∗ ∗ ∗ WBC calculation not possible(WNR) ----*1 ---- ----*1 ----*1 ----*1 ----*1 ----*1 ----*1 ---- ---- ---- ---- ---- ---- 5DIFF data calculation not possible ∗ IG fraction HF-BF high value NRBC Present Blasts/Abn Lympho? ∗ ∗ ∗ Blasts?*4 ∗ ∗ ∗ ∗ ∗ ∗ Abn Lympho?* 4 Left Shift? ∗ Atypical Lympho? ∗ *1 *2 *3 *4 ∗ ∗ ∗ WBC in the WNR channel. WBC in the WDF channel. The body fluid analysis can only be performed if the instrument offers the body fluid analysis mode. These messages do not appear with all analyzer types.

11-26 XN-1000 Instructions for Use Revised August 2013 Chapter 11 Checking detailed analysis information (Data Browser) RBC/RET IP messages RBC RET# HCT MCV MCH MCHC RET# RET% IRF HGB LFR MCH MFR MCHC RDW-SD RDW-CV HFR PLT RET-He ∗*2 ∗ RBC Abn Distribution MP-Flag ∗ ---- ---- Abnormal RDW-SD ∗ ---- ∗ Other abnormal distribution ∗ ∗ ∗ ---- ---- Dimorphic Population RET Abn Scattergram*1 RET abnormal fraction (Deformation) ∗ Other than above (RET zone error) ∗ ∗ Foreign particles mixed in PLT zone (High impact) ----*2 Foreign particles mixed in PLT zone ∗*2 RBC Agglutination? Turbidity/HGB Interf? ∗ ∗ Iron Deficiency? HGB Defect? Fragments? pRBC?*3 *1 This message does not appear with all analyzer types. *2 PLT in the RET channel. *3 The availability of this function depends on your system configuration. 11-27 XN-1000 Instructions for Use Revised February 2014 Chapter 11 Checking detailed analysis information (Data Browser) PLT IP messages PLT PDW MPV P-LCR PCT IPF PLT Abn Distribution Abnormal PDW ---∗ Other abnormal distribution PLT Abn Scattergram* 4 3 ∗* ∗ PLT Clumps? PLT-F not analyzed PLT-F analyzed *1 *2 *3 *4 ∗*1, 2 ∗ ∗*3 ∗ ∗ PLT in the PLT channel. PLT in the RET channel. PLT in the PLT-F channel. This message does not appear with all analyzer types. 11-28 XN-1000 Instructions for Use Revised August 2012 Chapter 11 Checking detailed analysis information (Data Browser) 11.7.1 IP message judgment conditions and judgment methods In the following cases, IP message judgment are not performed. • QC analysis data • Blank data • Background check data • Insufficient blood volume • Adjustment ● Blank data Blank data is data that meets all of the following conditions: • WBC < 1.00 x 103/μL • RBC < 0.30 x 106/μL • HGB < 1.0 g/dL • PLT < 20 x 103/μL ● Judgment method WBC < 0.50 x 103/μL The judgment for WBC suspect message ([Left Shift?]) is not performed.

(In [PreDilution] mode, when WBC < 0.20 x 103/μL) RBC < 0.50 x 106/μL IP message judgment for RBC other than [RBC Abn Distribution] is not performed. This is displayed as [RBC Abn Distribution], even if the analysis of RBC was not indicated. • • If an error or other condition prevents an analysis item necessary for judgment from being calculated ("----" or "++++" appears), judgments that include that analysis item will not be performed. Items for which the user has not specified that analysis be performed (blank " ") are not used for judgment. ● [Pre-Dilution] / [Body Fluid]* / [HPC]* mode For IP messages judged in analysis of [Pre-Dilution] / [Body Fluid] / [HPC]* mode, see the following. (➤P.11-33 "11.7.2 Table of IP message details") Only Positive judgment is performed; Negative judgment is not performed. * The availability of these functions depends on your system configuration. 11-29 XN-1000 Instructions for Use Revised August 2013 Chapter 11 Checking detailed analysis information (Data Browser) IP message types, meanings, and judgment methods You can change the judgment values of the IP message in the setting. For details, see "Administrator's Guide".

(➤Administrator's Guide, "Chapter 4: 4.2.6 Flag settings") WBC IP messages Message Meaning Judgment method/equation Abnormal messages WBC Abn Scattergram Abnormal WBC scattergram Based on clustering in WNR and WDF scattergrams. For body fluid analysis, based on clustering in the WDF scattergram and the HF-BF value. Neutropenia Low neutrophil count NEUT# < 1.00 x 103/μL or NEUT% < 0.0 % Neutrophilia High neutrophil count NEUT# > 11.00 x 103/μL or NEUT% > 100.0 % Lymphopenia Low lymphocyte count LYMPH# < 0.80 x 103/μL or LYMPH%< 0.0 % Lymphocytosis High lymphocyte count LYMPH# > 4.00 x 103/μL or LYMPH% > 100.0 % Monocytosis High monocyte count MONO# > 1.00 x 103/μL or MONO% > 100.0 % Eosinophilia High eosinophil count EO# > 0.70 x 103/μL or EO% > 100.0 % Basophilia High basophil count BASO# > 0.20 x 103/μL or BASO% > 100.0 % Leukocytopenia Low leukocyte count WBC < 2.50 x 103/μL Leukocytosis High leukocyte count WBC > 18.00 x 103/μL NRBC Present High nucleated RBC count NRBC% > 2.0 % IG Present Increased immature granulocyte IG# > 0.10 x 103/μL or IG% > 100.0 % Suspect messages Blasts/Abn Lympho? Possibility that blasts are present/ Possibility of abnormal lymphocytes Judged from the presence of Blasts/ Abn Lympho on the WDF scattergram. Blasts?* Possibility that blasts are present Judged from the presence of Blasts on the WDF and WPC scattergrams. Abn Lympho?* Possibility of abnormal lymphocytes Judged from the presence of Abn Lympho on the WDF and WPC scattergrams. Left Shift? Possibility of left shift Based on the distribution state of the upper right area of the NEUT in the WDF scattergram. 11-30 XN-1000 Instructions for Use Revised February 2013 Chapter 11 Checking detailed analysis information (Data Browser) Message Meaning Atypical Lympho? Possibility of atypical lymphocytes Judgment method/equation Based on the distribution state of the upper area of the lymphocytes in the WDF scattergram. * WPC+WDF channel only. These messages do not appear with all analyzer types. RBC/RET IP messages Message Meaning Judgment method/equation Abnormal messages RBC Abn Distribution Abnormal RBC distribution Judged from RBC distribution.

Dimorphic Population Double-peak RBC distribution Gap between the high and low points and shape of distribution peak. RET Abn Scattergram*1 Abnormal RET scattergram Clustering in the RET scattergram Reticulocytosis*1 Reticulocytosis RET% > 5.00% or RET# > 0.2000 x 106/μL Anisocytosis Anisocytosis RDW-SD > 65.0 fL or RDW-CV > 20.0% Microcytosis Microcytosis MCV < 70.0 fL Macrocytosis Macrocytosis MCV > 110.0 fL Hypochromia Hypochromia MCHC < 29.0 g/dL Anemia Anemia HGB < 10.0 g/dL Erythrocytosis Erythrocytosis RBC > 6.50 x 106/μL Suspect messages RBC Agglutination? Possibility of RBC agglutination Judged from RBC and RBC distribution. Turbidity/HGB Interf?

Possibility of effect on HGB by chylemia Judged from hemoglobin related parameters. Iron Deficiency? Possibility of iron deficiency Judged from RBC distribution and hemoglobin related parameters. HGB Defect? Possibility of HGB abnormality Judged from RBC distribution related parameters. Fragments? Possibility of fragmented red blood cells Judged from RBC distribution, PLT distribution and RET scattergram.

pRBC?*2 Possibility of parasite-infected RBCs Judged from the WNR and WDF scattergrams.

*1 These messages do not appear with all analyzer types. *2 The availability of this function depends on your system configuration. 11-31 XN-1000 Instructions for Use Revised February 2014 Chapter 11 Checking detailed analysis information (Data Browser) PLT IP messages Message Meaning Judgment method/equation Abnormal messages PLT Abn Distribution Abnormal PLT distribution Judged from PLT distribution. PLT Abn Scattergram* Abnormal PLT scattergram PLT clustering in the PLT scattergram Thrombocytopenia Thrombocytopenia PLT# < 60 x 103/μL Thrombocytosis Thrombocytosis PLT# > 600 x 103/μL Suspect messages PLT Clumps? Possibility of PLT clumps Judged from the presence of PLT Clumps on the WNR, WDF and PLT-F scattergrams. * These messages do not appear with all analyzer types. 11-32 XN-1000 Instructions for Use Revised December 2012 Abnormal messages XN-1000 Instructions for Use Suspect messages Abnormal messages WBC RBC/RET Revised February 2014 Suspect messages Abnormal messages Suspect message WNR, WDF WDF WDF WDF WDF WDF WDF WNR WNR, WDF WNR, WDF WNR WDF WDF WDF+WPC WDF+WPC WDF WDF, WDF+WPC RBC RBC RET RET RBC RBC RBC RBC+HGB HGB RBC RBC+HGB RBC+HGB RBC+HGB RBC RBC, PLT, RET WNR, WDF PLT PLT-F PLT, RET, PLT-F PLT, RET, PLT-F WNR, WDF, PLT-F Morph. Diff. Diff. Diff. Diff. Diff. Diff. Diff. Count. Count. Morph.+Count. Morph.+Count. Morph. Morph. Morph. Morph. Morph. Morph. Morph. Count. Count. Morph. Morph. Morph. Morph. Count. Count. Count. Count. Morph. Morph. Morph. Morph. Morph. Count. Count. Count. Count. Detection channel Flag category of Positive/Negative judgment [Body Fluid]*2 ○ × ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ × × × × × Δ × × ○ ○ ○ ○ ○ ○ ○ ○ × × × × ○ × ○ ○ ○ × ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ × × ○ [HPC]*2 Analysis Mode [PreDilution] Δ × × × × × × × ○ ○ ○ × × × × × × ○ ○ × × ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ Δ ○ ○ × ○ ○ Δ CBC ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ × × ○ Δ ○ ○ × × ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ Δ ○ ○ × ○ ○ Δ CBC+DIFF ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ × × ○ Δ ○ × ○ ○ Δ CBC+DIFF +RET Δ × × × × × × × ○ ○ ○ × × × × × × ○ × ○ ○ Δ CBC+RET ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ × ○ ○ ○ ○ ○ ○ ○ × × ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ Δ ○ ○ × ○ ○ Δ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ × ○ × ○ ○ Δ CBC+DIFF CBC+DIFF +RET+WPC +WPC Target table of flag judgment to discrete test Judgment enabled.

(For WBC Abn Scattergram, body fluid mode and other modes are judged with different rules.) Partial judgment enabled. (Rules that use channels that are not analyzed are not judged.) Judgment disabled. *1 Message in the Explorer screen (Flag No.) *2 The availability of these functions depends on your system configuration. *3 These messages do not appear with all analyzer types. ○: Δ: ×: 1 1 2 3 4 5 6 7 8 9 A E F 7 1 A 3 4 1 2 9 A 3 4 5 6 7 8 1 2 3 4 5 6 1 4 2 3 No.*1 --○ ○ ○ Δ +PLT-F 11.7.2 Microcytosis Macrocytosis Hypochromia Anemia Erythrocytosis RBC Agglutination? Turbidity/HGB Interf? Iron Deficiency? HGB Defect? Fragments? pRBC?*2 PLT Abn Distribution PLT Abn Scattergram*3 Thrombocytopenia Thrombocytosis PLT Clumps? Neutropenia Neutrophilia Lymphopenia Lymphocytosis Monocytosis Eosinophilia Basophilia Leukocytopenia Leukocytosis NRBC Present IG Present Blasts/Abn Lympho? Blasts?*3 Abn Lympho?*3 Left Shift? Atypical Lympho? RBC Abn Distribution Dimorphic Population RET Abn Scattergram*3 Reticulocytosis*3 Anisocytosis WBC Abn Scattergram Message Chapter 11 Checking detailed analysis information (Data Browser) Table of IP message details PLT 11-33 Chapter 11 Checking detailed analysis information (Data Browser) 11-34 XN-1000 Instructions for Use Revised August 2012 Chapter 12 Chapter 12 Performing Calibration Performing Calibration This chapter explains how to perform calibration. 12.1 Introduction Calibration is performed to ensure accuracy of the system.

About calibration For this instrument, you can use a dedicated calibrator to calibrate the instrument (calibrator calibration). The instrument automatically analyzes the same calibrator 11 times consecutively, and the repeatability and accuracy of the analysis parameters are checked. At the same time, the compensation rate can be updated. There are 2 types of calibrator calibration, as follows. • Calibrator calibration: Calibration of parameters other than PLT-F • Calibrator calibration (PLT-F)*: Calibration of PLT-F The calibrator used for each calibration is different.

* Calibration cannot be used with all analyzer types. In addition, precision check function is available for checking only the instrument's repeatability by using a normal sample. Note: For calibrator calibration and precision check, please note the following.

• Repeat, Rerun, and Reflex are not performed. (➤Administrator's Guide, "Chapter 2: 2.1 Types of rules") • Identification of samples by barcode reader is not performed. The following sample numbers are automatically assigned by the analyzer. - Calibrator calibration: CAL-CAL-01 to CAL-CAL-11 - Calibrator calibration (PLT-F): PF-CAL-CAL-01 to PF-CAL-CAL-11 - Precision check: PRE-CHK-01 to PRE-CHK-11 Before Performing Calibration Before performing calibration, check the remaining amount of the reagent connected to the instrument. If the reagent runs out, the calibration stops. If it stops, cancel the calibration. After replacing the reagent, restart the operation from the beginning. 12-1 XN-1000 Instructions for Use Revised August 2012 Chapter 12 12.1.1 Performing Calibration Calibration practice standards The initial calibration is done by your Sysmex technical representative, at the time of installation. Perform calibration as needed, e.g., when the QC data is fluctuating. However, if the abnormality in the QC analysis data was caused by an error in the analyzer, degradation of the reagent, or degeneration of the control blood, do not perform calibration. 12.1.2 Calibrators and samples to be used Use the following calibrators and samples for calibrator calibration and precision check. Calibrator calibration XN CAL: Use for the calibration of the analyzer for WBC, RBC, HGB, HCT, PLT, and RET. Calibrator calibration (PLT-F) XN CAL PF: Use for the calibration of the analyzer for PLT-F (Platelet count analyzed by the PLT-F channel). Precision check For precision check, use one sample of fresh normal blood per analyzer that meets the following requirements.

• Blood of a healthy person who is not taking any medicine; • Blood added with an appropriate amount of anticoagulant; • Whole blood volume in each sample is at least 2.5 mL.

Information Control blood is not suitable for calibrator calibration. Control blood is intended for quality control, not for calibration. 12-2 XN-1000 Instructions for Use Revised August 2012 Chapter 12 12.2 Performing Calibration About Calibrator Calibration Calibrator calibration is performed by manual analysis. The discrete tests to be analyzed are specified automatically, and cannot be changed. In addition, different discrete tests are specified depending on the type of analyzer that is connected.

See below for details: Discrete test Discrete test Analyzer Calibrator calibration Calibrator calibration (PLT-F) XN-20[A1] CBC+DIFF+RET+WPC CBC+PLT-F XN-20[A2] CBC+DIFF+RET+WPC - XN-10[B1] CBC+DIFF+RET CBC+PLT-F XN-10[B2] CBC+DIFF CBC+PLT-F XN-10[B3] CBC+DIFF+RET - XN-10[B4] CBC+DIFF - 12.2.1 Performing Calibrator Calibration Follow the steps below to perform calibrator calibration for parameters other than PLT-F. 1 Check the Status indicator LED on the analyzer. If the Status indicator LED is not lit green, wait until it does.

Status indicator LED 12-3 XN-1000 Instructions for Use Revised August 2012 Chapter 12 2 Performing Calibration If the tube holder has not ejected out, press the mode switch. The tube holder slides out forward. 3 Click the Change Analysis Mode button on the control menu. The dialog box on the right appears. In calibrator calibration, select [Whole Blood] mode. 4 Click [OK]. The dialog box closes. 5 Click the Analyzer menu button on the control menu. The menu on the right appears. 12-4 XN-1000 Instructions for Use Revised December 2012 Chapter 12 6 Performing Calibration Click [Calibration] - [Calibrator Calibration]. The dialog box on the right appears. Shortcut button Calibration parameters Data display area Back button Next button [Calibrator Calibration] analysis dialog box Shortcut button Click to display calibration item screens that are not currently displayed. If the data in a screen includes a warning, a warning mark appears. Data display area Calibration parameters The analysis parameters to be calibrated are displayed. Different parameters are displayed depending on the type of analyzer that is connected. [No. 1] [No. 11] For each calibration parameter, the analysis results are displayed for the 11 repeated analysis cycles. A strike-through is displayed for the results for [No. 1] since it is not reflected in [Mean Value], [SD], and [CV(%)].

[Mean Value] For each calibration parameter, the mean value of the analyzed values from [No.2] to [No.11] is displayed. [SD] For each calibration parameter, the standard deviation for the analyzed values from [No.2] to [No.11] are displayed. If the [Mean Value] is 0, [----] is displayed. [CV (%)] Displays the coefficient of variation for the analysis result for each calibration parameter. After the 11th analysis is complete, if the coefficient of variation is greater than the [Limit (%)], then it is displayed in white font on red background. [Limit (%)] Displays the standard value (acceptable value) for the coefficient of variation of each calibration parameter. Back button Click to display the previous screen. Next button Click to display the next screen. [Calibration] When clicked, the [Calibrator Calibration] data confirmation dialog box is displayed. 12-5 XN-1000 Instructions for Use Revised August 2012 Chapter 12 Performing Calibration 7 Mix the vial containing the calibrator as shown. 8 Place the vial in the sample tube holder. 9 Press the start switch on the analyzer. Once the manual analysis starts, the analysis is performed 11 times consecutively, with the tube holder pulled into the analyzer. Once the analysis finishes, the tube holder slides out. Wait until all analyses are complete. Information If an error occurs during an analysis, and the analysis can no longer continue, stop the calibrator calibration. Once the error is cleared, redo the manual analysis.

10 Redo the manual analysis. The results from the analysis in step 9 are displayed in the [Calibrator Calibration] analysis dialog box. When the analysis results do not satisfy the conditions below, the test numbers of tests that must be repeated are displayed in the [Calibrator Calibration] analysis dialog box. Select and redo the manual analysis. • All analysis results are normal.

• All calibration parameters are below the [Limit (%)] value. When the analysis results satisfy the conditions, [Calibration] can be clicked in the [Calibrator Calibration] analysis dialog box. Proceed to the next step. 12-6 XN-1000 Instructions for Use Revised May 2014 Chapter 12 Performing Calibration 11 Click [Calibration] on the [Calibrator Calibration] analysis dialog box. The dialog box on the right appears.

Shortcut button Data display area Back button Next button [Calibrator Calibration] data confirmation dialog box [Analysis Result] When clicked, the [Calibrator Calibration] analysis dialog box is displayed. [Read Target] Use this to read the target value for each calibration parameter from the server. [Lot No.] Enter and search the lot number of the calibrator (XN CAL).

[Read] When clicked, the target value is read. Shortcut button Click to display calibration item screens that are not currently displayed. If the data in a screen includes a warning, a warning mark appears. Data display area [Target] Enter the target value for each calibration parameter. The input methods are as follows. • Referring to the target sheet supplied with the XN CAL, enter the values manually. • Read the target values from the medium supplied with the calibrator. [Range Value] Displays the difference between the maximum and the minimum values for each calibration parameter. If this is greater than the maximum range, it is displayed in white font on red background. [Max Range] When the target value is entered, a value that is equal to "Target value x Fixed ratio for each calibration parameter" is displayed. [Mean Value] Displays the average value of the analysis data. [Delta Percent (%)] When the target value is entered, a value that is equal to "|Target value - Mean Value|/Mean Value x 100 (%)" is displayed. If this value is greater than the Acceptable Limit and less than the Service Limit, the background is displayed in yellow. If this is greater than the Service Limit, it is displayed in white font on red background. [Acceptable Limit (%)] Displays a numeric value for determining whether calibration is necessary. If the Delta Percent is less than this value, no calibration is necessary. 12-7 XN-1000 Instructions for Use Revised May 2014 Chapter 12 Performing Calibration [Service Limit (%)] Displays the maximum Delta Percent when performing calibrator calibration.

If the Delta Percent is greater than this value, calibration cannot be performed for that parameter.

[Current Rate (%)] Displays the compensation rate for each calibration parameter before calibrator calibration. [New Rate (%)] Displays the new compensation rate, which is calculated from "Target value x Current Rate/Mean Value". This value is displayed once [Target] and [Mean Value] are displayed. Back button Click to display the previous screen.

Next button Click to display the next screen. 12 Click [OK]. The dialog box on the right appears*.

* The display will vary depending on the type of analyzer that is connected. Calibrator parameter check box Modify check box Back button Next button [Calibrator Calibration] execution dialog box Calibrator parameter check box Select the check box to include the calibration parameter in the calibrator calibration. Clear the check box to exclude it from calibrator calibration. If a calibration parameter meets all of the conditions below, the check box for that parameter is automatically selected when the screen appears. In addition, you can select or clear the check boxes manually. 1) 80% ≤ New Rate ≤ 120% 2) New Rate - Current Rate ≤ ±5%* 3) Range Value ≤ Max Range 4) Acceptable Limit ≤ Delta Percent ≤ Service Limit If a calibration parameter meets all of the conditions from 1) to 3), and the Delta Percent is less than the Acceptable Limit, it is excluded from calibration, as there is no need for calibration. If a calibration parameter does not meet all of the conditions from 1) to 3) and the Delta Percent is greater than the Acceptable Limit, calibration cannot be performed.

Calibration is performed with this calibration parameter excluded. * When the RBC checkbox is selected, condition 2) of PLT changes to "New Rate Current Rate ≤ ±12.5%". 12-8 XN-1000 Instructions for Use Revised May 2014 Chapter 12 Performing Calibration [Current Rate (%)] Displays the compensation rate for each calibration parameter before calibrator calibration. [New Rate (%)] Displays the new compensation rate calculated by the system. Modify check box Selecting the check box enables you to manually enter a value in [New Rate (%)]. You can enter a value within the range of 80 to 120%. However, the check box cannot be selected for any calibration parameter with "Delta Percent > Acceptable Limit". In addition, calibration parameters with manually entered values will be displayed with an asterisk (∗) in the calibrator calibration history.

When the check box is cleared, you will not be able to manually enter a value in [New Rate (%)]. Any values that were manually entered prior to clearing the check box will revert to the system-calculated values. Back button Click to display the previous screen. Next button Click to display the next screen.

13 Click Next button.

The dialog box on the right appears. The contents of the dialog box are the same as in step 12. Calibrator parameter check box Modify check box Back button Next button 14 Click [OK].

The compensation rates are updated, and this calibration process is logged in the calibrator calibration history. For details on calibration history, see below. (➤P.12-16 "12.3 Manage Calibration History") 12-9 XN-1000 Instructions for Use Revised May 2014 Chapter 12 12.2.2 Performing Calibration Performing calibrator calibration (PLT-F) Follow the steps below to perform calibrator calibration for PLT-F. This function may not be available depending on the configuration of the instrument you are using. 1 Check the Status indicator LED on the analyzer. If the Status indicator LED is not lit green, wait until it does. Status indicator LED 2 If the tube holder has not ejected out, press the mode switch. The tube holder slides out forward. 3 Click the Change Analysis Mode button on the control menu. The dialog box on the right appears. In calibrator calibration (PLT-F), select [Whole Blood] mode.

12-10 XN-1000 Instructions for Use Revised December 2012 Chapter 12 4 Performing Calibration Click [OK]. The dialog box closes. 5 Click the Analyzer menu button in the Control menu. The menu on the right appears. 6 Select [Calibration] - [Calibrator Calibration (PLT-F)]. The dialog box on the right appears. Data display area [Calibrator Calibration (PLT-F)] analysis dialog box Data display area [No. 1] [No. 11] The analysis results for PLT-F are displayed for the 11 repeated analysis cycles. A strike-through is displayed for the results for [No. 1] since it is not reflected in [Mean Value], [SD], and [CV(%)]. [Mean Value] The mean value of the analyzed data from [No.2] to [No.11] is displayed. 12-11 XN-1000 Instructions for Use Revised August 2012 Chapter 12 Performing Calibration [SD] The standard deviation of the analyzed data from [No.2] to [No.11] is displayed. If the [Mean Value] is 0, "[----]" is displayed. [CV (%)] Displays the coefficient of variation for the analysis result. After the 11th analysis is complete, if the coefficient of variation is greater than the [Limit (%)], then it is displayed in white font on red background. [Limit (%)] Displays the standard value (acceptable value) for the coefficient of variation of PLT-F. [Calibration] When clicked, the [Calibrator Calibration (PLT-F)] data confirmation dialog box is displayed. 7 Mix the vial containing the calibrator as shown. 8 Place the vial in the sample tube holder. 9 Press the start switch on the analyzer.

Once the manual analysis starts, the analysis is performed 11 times consecutively, with the tube holder pulled into the analyzer.

Once the analysis finishes, the tube holder slides out. Wait until all analyses are complete. 12-12 XN-1000 Instructions for Use Revised August 2012 Chapter 12 Performing Calibration Information If an error occurs during an analysis, and the analysis can no longer continue, stop the calibrator calibration (PLT-F).

Once the error is cleared, redo the manual analysis. 10 Redo the manual analysis. The results from the analysis in step 9 are displayed in the [Calibrator Calibration (PLT-F)] analysis dialog box. When the analysis results do not satisfy the conditions below, the test numbers of tests that must be repeated are displayed in the [Calibrator Calibration (PLT-F)] analysis dialog box. Select and redo the manual analysis. • All analysis results are normal. • All calibration parameters are below the [Limit (%)] value. When the analysis results satisfy the conditions, [Calibration] can be clicked in the [Calibrator Calibration (PLTF)] analysis dialog box. Proceed to the next step. 11 Click [Calibration] in the [Calibrator Calibration (PLT-F)] analysis dialog box. The dialog box on the right appears. Data display area [Calibrator Calibration (PLT-F)] data confirmation dialog box [Analysis Result] When clicked, the [Calibrator Calibration (PLT-F)] analysis dialog box is displayed. [Read Target] Use this to read the PLT-F target value from the server.

[Lot No.] Enter and search the lot number of the calibrator (XN CAL PF). [Read] When clicked, the target value is read. 12-13 XN-1000 Instructions for Use Revised August 2012 Chapter 12 Performing Calibration Data display area [Target] Enter the target value for PLT-F.

The input methods are as follows. • Referring to the target sheet supplied with the XN CAL PF, enter the values manually.

• Read the target values from the medium supplied with the calibrator. [Range Value] Displays the difference between the maximum and the minimum values of PLT-F. If this is greater than the maximum range, it is displayed in white font on red background. [Max Range] When the target value is entered, a value that is equal to "Target value x Fixed ratio for PLT-F" is displayed. [Mean Value] Displays the average value of the analysis data. [Delta Percent (%)] When the target value is entered, a value that is equal to "|Target value - Mean Value|/Mean Value x 100 (%)" is displayed.

If this value is greater than the Acceptable Limit and less than the Service Limit, the background is displayed in yellow. If this is greater than the Service Limit, it is displayed in white font on red background. [Acceptable Limit (%)] Displays a numeric value for determining whether calibration is necessary. If the Delta Percent is less than this value, no calibration is necessary. [Service Limit (%)] Displays the maximum Delta Percent when performing calibrator calibration (PLT-F). If the Delta Percent is greater than this value, calibration cannot be performed for that parameter. [Current Rate (%)] Displays the compensation rate for PLT-F before the calibrator calibration (PLT-F). [New Rate (%)] Displays the new compensation rate, which is calculated from "Target value x Current Rate/Mean Value". This value is displayed once [Target] and [Mean Value] are displayed. 12-14 XN-1000 Instructions for Use Revised August 2012 Chapter 12 Performing Calibration 12 Click [OK]. The dialog box on the right appears. Calibrator parameter check boxes Modify check boxes [Calibrator Calibration (PLT-F)] execution dialog box Calibrator parameter check boxes Select the check box to include the calibration parameter in the calibrator calibration (PLT-F). Clear the check box to exclude it from calibrator calibration (PLT-F).

If the conditions below are met, the check box for PLT-F is automatically selected when the screen appears. In addition, you can select or clear the check boxes manually. 1) 80% ≤ New Rate ≤ 120% 2) New Rate - Current Rate ≤ ±5% 3) Range Value ≤ Max Range 4) Acceptable Limit ≤ Delta Percent ≤ Service Limit If all of the conditions from 1) to 3) are met, and the Delta Percent is less than the Acceptable Limit, it is excluded from calibration, as there is no need for calibration. If not all of the conditions from 1) to 3) are not met and the Delta Percent is greater than the Acceptable Limit, calibration cannot be performed. [Current Rate (%)] Displays the compensation rate for PLT-F before the calibrator calibration (PLT-F). [New Rate (%)] Displays the new compensation rate calculated by the system. Modify check boxes Selecting the check box enables you to manually enter a value in [New Rate (%)].

You can enter a value within the range of 80 to 120%. However, the check box cannot be selected if "Delta Percent > Acceptable Limit". In addition, manually entered values will be displayed with an asterisk (∗) in the Calibrator Calibration History. When the check box is cleared, you will not be able to manually enter a value in [New Rate (%)]. Any values that were manually entered prior to clearing the check box will revert to the system-calculated values. 12-15 XN-1000 Instructions for Use Revised August 2012 Chapter 12 Performing Calibration 13 Click [OK]. The compensation rates are updated, and this calibration process is logged in the calibrator calibration history. For details on calibration history, see below.

(➤P.12-16 "12.3 Manage Calibration History") 12.3 Manage Calibration History Up to 20 records can be saved in the calibrator calibration history, and any record after the 20th record overwrites the existing records, starting from the oldest. A calibration history can be displayed, output, saved, restored, and deleted. 12.3.1 Calibration screen Clicking the [Calibration] icon in the Menu screen displays the following screen. Data display area Toolbar Calibration parameters Text size button Common Items Tab [Calibration] screen Display switching button Toolbar Displays buttons with the following functions. [Output] When clicked, the selected calibration history data is output. [Upper] Click to move the selection up by one row. [Lower] Click to move the selection down by one row. [File] Click to display a submenu that allows you to save and restore data. [Delete] When clicked, a dialog box appears that allows you to delete the selected calibration history. 12-16 XN-1000 Instructions for Use Revised August 2012 Chapter 12 Performing Calibration Common Items [Analyzer Nickname] Displays the name of the analyzer for which calibration was performed. [Calibration Date] Displays the date and time when the calibration was performed. [Logon Name] Displays the name of the user who was logged on to the IPU, at the time of calibration. Data display area The content displayed depends on the type of calibration history. Clicking on a displayed history data switches it. [Material] Displays the name of the calibrator. (XN CAL, XN CAL PF) [Lot No.] Displays the lot number of the calibrator. Calibration parameters The analysis parameters to be calibrated are displayed. Different parameters names are displayed depending on the type of analyzer that is connected. ● Calibrator calibration history When you click the display switching button, the following screen is displayed. This is the same as parameters displayed in the calibrator calibration (PLT-F) history. Calibration parameter units Calibration parameters Calibration parameters* The analysis parameters to be calibrated are displayed. Calibration parameter units* Displays the units of the calibration parameters. [Target] Displays target values for the calibrator. [No. 2] - [No. 11] For each calibration parameter, the analysis results are displayed for the 11 repeated analysis cycles.

[Range Value] Displays the difference between the maximum and the minimum values of the analysis data. If this is greater than the maximum range, it is displayed on red background. [Max Range] Displays a value calculated from the [Target] that was entered. [Mean Value] Displays the average value of the analysis data. 12-17 XN-1000 Instructions for Use Revised August 2012 Chapter 12 Performing Calibration [Delta Percent (%)] A value that is equal to "|Target value - Mean Value|/Mean Value x 100 (%)" is displayed. If this value is greater than the allowed error rate and less than the maximum allowed error rate, the background is displayed in yellow. If this is greater than the maximum allowed error rate, it is displayed on red background. [Acceptable Limit (%)] Displays a numeric value for determining whether calibration is necessary. [Service Limit (%)] Displays the maximum Delta Percent that allows calibration. [Current Rate (%)] Displays the compensation rate for each analysis parameter before calibration. [New Rate (%)] Displays the compensation rate for each analysis parameter after calibration. Analysis parameters with an asterisk (∗) next to its value are parameters that were manually entered in calibrator calibration. * The display will vary depending on the type of analyzer that is connected. Display switching button Click the display switching button to open and close the sub-screens. A sub-screen is a screen that is displayed to the right of the list of analysis data, that can be opened and closed. Text size button Click the text size button to change the size and the line height of the text displayed in the list samples. To change the text size, see the "Administrator's Guide". (➤Administrator's Guide, "Chapter 4: 4.3.3 Display settings") Note: You can select multiple data as follows: • Drag multiple consecutive rows while holding down the left button on the mouse or. • While pressing Ctrl, click on the row that you want to select. 12-18 XN-1000 Instructions for Use Revised August 2012 Chapter 12 12.3.2 Performing Calibration Outputting calibration history You can save and output the data of the selected calibration history as a CSV file, or print to a connected printer as a list (ledger printing). Follow the steps below to output calibration history. 1 Click the [Calibration] icon in the Menu screen. The [Calibration] screen appears. 2 Select the calibration history to output. 3 Select the format and output. ● Outputting in CSV format On the toolbar, click the [File] button - [Output in CSV Format], then name and save the file. The file extension is ".csv".

● Printing to a Ledger On the toolbar, click the [Output] button, and then [Ledger (LP)]. 12.3.3 Saving a calibration history (backup) You can save the calibration history as a file. Follow the steps below to save the calibration history. 1 Click the [Calibration] icon in the Menu screen. The [Calibration] screen appears. 2 Select the history you want to save. 3 On the toolbar, click on the [File] button, then click [Backup]. A folder selection dialog box appears, for specifying the folder to which you want to save the file. 4 Select the folder to which you want to save the file. The file extension is ".cad".

You cannot change the file name. 12-19 XN-1000 Instructions for Use Revised August 2012 Chapter 12 12.3.4 Performing Calibration Restoring a saved calibration history (Restore) You can restore saved calibration history. Follow the steps below to restore a saved calibration history. 1 Click the [Calibration] icon in the Menu screen.

The [Calibration] screen appears.

2 On the toolbar, click on the [File] button, then click [Restore]. A dialog box for selecting the file to restore is displayed. 3 Select to open the file you want to restore. The file extension is ".cad". Information In the following cases, the saved history cannot be restored.

• If the history is for a parameter that cannot be analyzed with the analyzer that is connected. • If a history exists with the same date and time as the history being restored. 12.3.5 Deleting a calibration history You can delete a calibration history. Follow the steps below to delete calibration history. 1 Click the [Calibration] icon in the Menu screen. The [Calibration] screen appears. 2 Select the calibration history to delete. 3 Click the [Delete] button on the toolbar. The dialog box on the right appears. 4 Click [Yes].

The selected history is deleted. 12-20 XN-1000 Instructions for Use Revised August 2012 Chapter 12 12.4 Performing Calibration Perform a precision check The precision check is performed by manual analysis. The discrete tests to be analyzed are specified automatically by the system, and cannot be changed.

In addition, different discrete tests are specified depending on the type of analyzer that is connected. See below for details: Discrete test Analyzer Discrete test XN-20[A1] CBC+DIFF+RET+PLT-F+WPC XN-20[A2] CBC+DIFF+RET+WPC XN-10[B1] CBC+DIFF+RET+PLT-F XN-10[B2] CBC+DIFF+PLT-F XN-10[B3] CBC+DIFF+RET XN-10[B4] CBC+DIFF Follow the steps below to perform precision calibration. 1 Check the Status indicator LED on the analyzer. If the Status indicator LED is not lit green, wait until it does. Status indicator LED 2 If the tube holder has not ejected out, press the mode switch. The tube holder slides out forward. 12-21 XN-1000 Instructions for Use Revised August 2012 Chapter 12 3 Performing Calibration Click the Change Analysis Mode button on the control menu.

The dialog box on the right appears. In precision check, select [Whole Blood] mode. 4 Click [OK]. The dialog box closes. 5 Click the Analyzer menu button on the control menu. The menu on the right appears. 12-22 XN-1000 Instructions for Use Revised December 2012 Chapter 12 6 Performing Calibration Click [Calibration] - [Precision Check].

The dialog box on the right appears. Shortcut button Calibration parameters Data display area Back button Next button [Precision Check] analysis dialog box Shortcut button Click to display calibration item screens that are not currently displayed. If the data in a screen includes a warning, a warning mark appears. Data display area Calibration parameters The analysis parameters to be calibrated are displayed. Different parameters are displayed depending on the type of analyzer that is connected. [No. 1] - [No. 11] For each calibration parameter, the analysis results are displayed for the 11 repeated analysis cycles. A strike-through is displayed for the results for [No. 1] since it is not reflected in [Mean Value], [SD], and [CV (%)].

[Mean Value] For each calibration parameter, the mean value of the analyzed values from [No.2] to [No.11] is displayed. [SD] For each calibration parameter, the standard deviation of the analyzed values from [No. 2] to [No. 11] is displayed. If the [Mean Value] is 0, "[----]" is displayed. [CV(%)] Displays the coefficient of variation for the analysis result for each calibration parameter. After the 11th analysis is complete, if the coefficient of variation is greater than the [Limit (%)], then it is displayed in white font on red background.

[Limit (%)] Displays the standard value (acceptable value) for the coefficient of variation of each calibration parameter. Back button Click to display the previous screen. Next button Click to display the next screen. 12-23 XN-1000 Instructions for Use Revised August 2012 Chapter 12 Performing Calibration 7 Mix the vial containing the sample as shown. 8 Place the vial in the sample tube holder. 9 Press the start switch on the analyzer. Once the manual analysis starts, the analysis is performed 11 times consecutively, with the tube holder pulled into the analyzer. Once the analysis finishes, the tube holder slides out. Wait until all analyses are complete.

Information If an error occurs during an analysis, and the analysis can no longer continue, stop precision check. Once the error is cleared, redo the manual analysis. 12-24 XN-1000 Instructions for Use Revised August 2012 Chapter 12 Performing Calibration 10 Redo the manual analysis. The results from the analysis in step 9 are displayed in the [Precision Check] analysis dialog box. When the analysis results do not satisfy the conditions below, the test numbers of tests that must be repeated are displayed in the [Precision Check] analysis dialog box. Select and redo the manual analysis. • All analysis results are normal. • All calibration parameters are below the [Limit (%)] value. When the analysis results satisfy the conditions, [OK] can be clicked in the [Precision Check] analysis dialog box.

Proceed to the next step. 11 Click [OK] on the [Precision Check] analysis dialog box. The dialog box on the right appears. 12 Click [Yes]. The results are added to the precision check history. For details on precision check history, see below. (➤P.12-26 "12.5.1 Precision Check screen") 12-25 XN-1000 Instructions for Use Revised August 2012 Chapter 12 12.5 Performing Calibration Manage the Precision Check History Up to 20 records can be saved in the precision check history, and any record after the 20th record overwrites the existing records, starting from the oldest. Each history can be output, saved, restored, and deleted. 12.5.1 Precision Check screen Clicking the [Precision Check] icon in the Menu screen displays the following screen.

Data display area Toolbar Calibration parameters Text size button Common items Tab Display switching button [Precision Check] screen Toolbar Displays buttons with the following functions.

[Output] When clicked, the selected precision check history data is output. [Upper] Click to move the selection up by one row. [Lower] Click to move the selection down by one row. [File] Click to display a submenu that allows you to save and restore data.

[Delete] When clicked, a dialog box appears that allows you to delete the selected precision check history. Common items [Analyzer Nickname] Displays the name of the analyzer for which precision check was performed. [Execution Date] Displays the date and time that the result of the precision check was recorded.

[Logon Name] Displays the name of the user who was logged on to IPU, at the time of precision check. 12-26 XN-1000 Instructions for Use Revised August 2012 Chapter 12 Performing Calibration Data display area When you click the display switching button, the following screen is displayed. Calibration parameter units Calibration parameters Calibration parameters* The analysis parameters to be calibrated are displayed. Calibration parameter units* Displays the units of the calibration parameters. [No. 2] - [No. 11] For each calibration parameter, the analysis results are displayed for the 11 repeated analysis cycles. [Mean Value] Displays the average analyzed value for each calibration parameter. [SD] Displays the standard deviation of the analyzed values for each calibration parameter. [CV (%)] Displays the coefficient of variation for each calibration result. [Limit (%)] Displays the standard repeatability value for each calibration parameter. * The display will vary depending on the type of analyzer that is connected. Note: The [Precision Check] screen has similar functions as the [Calibration] screen. For the operation of the following, see the procedures for the [Calibration]. (➤P.12-16 "12.3.1 Calibration screen") • Display switching button • Text size button • Selecting multiple precision check history data 12-27 XN-1000 Instructions for Use Revised August 2012 Chapter 12 12.5.2 Performing Calibration Outputting precision check history You can save the selected precision check history as a CSV file, or print to a connected printer as a list (ledger printing). Follow the steps below to output the precision check history. 1 Click the [Precision Check] icon in the Menu screen. The [Precision Check] screen appears. 2 Select the precision check history to output. 3 Select the format and output. ● Outputting in CSV format On the toolbar, click the [File] button - [Output in CSV Format], then name and save the file. The file extension is ".csv". ● Printing to a Ledger On the toolbar, click the [Output] button, and then [Ledger (LP)]. 12.5.3 Saving a precision check history (backup) You can save a precision check history as a file. Follow the steps below to save a precision check history. 1 Click the [Precision Check] icon in the Menu screen. The [Precision Check] screen appears.

2 Select the history you want to save.

3 On the toolbar, click on the [File] button, then click [Backup]. A folder selection dialog box appears, for specifying the folder to which you want to save the file. 4 Select the folder to which you want to save the file. The file extension is ".pre". You cannot change the file name. 12-28 XN-1000 Instructions for Use Revised August 2012 Chapter 12 12.5.4 Performing Calibration Restoring a saved precision check history (Restore) You can restore saved history. Follow the steps below to restore a saved precision check history. 1 Click the [Precision Check] icon in the Menu screen. The [Precision Check] screen appears. 2 On the toolbar, click on the [File] button, then click [Restore]. A dialog box for selecting the file to restore is displayed. 3 Select to open the file you want to restore. The file extension is ".pre". Information In the following cases, the saved history cannot be restored. • If the history is for a parameter that cannot be analyzed with the analyzer that is connected. • If a history exists with the same date and time as the history being restored. 12-29 XN-1000 Instructions for Use Revised August 2012 Chapter 12 12.5.5 Performing Calibration Deleting a precision check history You can delete a precision check history.

Follow the steps below to delete a precision check history. 1 Click the [Precision Check] icon in the Menu screen.

The [Precision Check] screen appears. 2 Select the precision check history to delete. 3 Click the [Delete] button on the toolbar. The dialog box on the right appears.

4 Click [Yes]. The selected history is deleted. 12-30 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts Chapter 13 Performing maintenance of instrument and replacing supply parts This chapter explains an overview of the maintenance tasks for the instrument and explains how to perform those tasks, including the replacement of reagents and supply parts. 13.1 Introduction Regular maintenance of the analyzers is necessary to keep the instrument in the most optimal condition. Please perform the appropriate maintenance tasks according to this chapter.

In addition, whenever you perform a maintenance task, log it in the maintenance inspection checklist. (➤P.13-78 "13.8 Maintenance inspection checklist") To perform maintenance, the analyzer and the sampler must be in READY state. Otherwise, maintenance cannot be performed. In addition, analysis is not possible during maintenance. 13.1.1 List of maintenance items Maintenance tasks can be categorized into daily tasks, and tasks that are performed on an as need-basis. Below is a list of maintenance tasks. Daily maintenance tasks • Shutdown (➤P.13-5 "13.2.1 Shutting down the instrument") Maintenance tasks performed as needed • • • • • • • • • • • • • • Replacing waste container (➤P.13-5 "13.3.1 Replace the waste container") Automatic rinsing (➤P.13-7 "13.3.2 Perform auto rinse") Cleaning (➤P.13-9 "13.3.3 Perform cleaning") Remove an RBC detector clog (➤P.13-11 "13.3.4 Clog removal from the RBC detector") Cleaning RBC detector aperture (➤P.13-12 "13.3.5 Rinse the RBC detector aperture") Draining the waste chamber (➤P.13-14 "13.3.6 Drain the waste chamber") Rinsing the waste chamber (➤P.13-15 "13.3.7 Rinse the waste chamber") Removing flowcell air bubbles (➤P.13-17 "13.3.8 Remove air bubbles from flowcell") Rinsing flowcell (➤P.13-18 "13.3.9 Rinse flowcell") Draining reaction chamber (➤P.13-20 "13.3.10 Drain the reagent from the reaction chamber") Draining RBC isolation chamber (➤P.13-20 "13.3.11 Drain the reagent from the RBC isolation chamber") Adjusting the pressure (0.25 MPa) (➤P.13-21 "13.3.12 Adjust the pressure (0.25 MPa)") Adjusting the pressure (0.16 MPa) (➤P.13-23 "13.3.13 Adjust the pressure (0.16 MPa)") Adjusting the pressure (0.07 MPa) (➤P.13-25 "13.3.14 Adjust the pressure (0.07 MPa)") Draining the pneumatic trap chamber (➤P.13-28 "13.3.15 Drain the pneumatic trap chamber") 13-1 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts Replacing reagents and supply parts • Replacing reagents (➤P.13-30 "13.4.1 List of reagents", P.13-30 "13.4.2 About [Reagent Replacement] dialog box") • Replacing a new dilution/hemolytic agent (➤P.13-32 "13.4.3 Replace a new dilution/hemolytic agent", P.13-35 "13.4.4 Replace with new CELLPACK DST") • Replacing a new dye (➤P.13-38 "13.4.5 Replace a new dye") • Replenishing reagents (➤P.13-41 "13.4.6 Replenish reagents") • Draining the reagent (➤P.13-43 "13.4.7 Drain the reagent") • Reagent replacement history (➤P.13-45 "13.4.8 Check the reagent replacement history") • Replacing supply parts (➤P.13-45 "13.5.1 Replace supply parts") • Replacing piercer (➤P.13-46 "13.5.2 Replace the piercer") • Replacing fuse (➤P.13-58 "13.5.3 Replace the fuse") Time required (per analyzer) The time guidelines for the procedure of maintenance are as shown below. Maintenance Task Time Shutdown About 15 minutes Cleaning About 20 minutes Rinsing the waste chamber About 15 minutes Rinsing flowcell About 10 minutes 13.1.2 Maintenance menu Analyzer Maintenance menu You can perform specific maintenance tasks, operation checks, and operation test, using the Maintenance menu. Follow the steps below to display the Maintenance menu. 1 Click the Analyzer menu button on the control menu. The menu on the right appears. 13-2 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 2 Click [Maintenance]. The submenu on the right appears. Note: • For the details on operation checks, see Chapter 14. (➤P.14-47 "Chapter 14: 14.5 Check the status of the device") • For the details on operation test, see Chapter 14. (➤P.14-53 "Chapter 14: 14.6 Test proper operation of the device") 13-3 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts RU-20 Maintenance menu When the RU-20 is used, special maintenance and settings can be performed in the RU-20 Maintenance menu. Follow the steps below to display the RU-20 Maintenance menu. 1 Click the RU menu button on the control menu. The dialog box on the right appears. Submenu button 2 Click the submenu button. The submenu on the right appears. Note: For information on the settings, see the "Administrator's Guide". (➤Administrator's Guide, "Chapter 4: 4.6 Reagent unit settings (RU-20)") 13-4 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 13.2 Daily maintenance tasks 13.2.1 Shutting down the instrument Turn OFF the power after rinsing each instrument. When you finish analysis work for the day, always perform shutdown and then turn off the power. If analysis work will continue for more than one day, perform a shutdown once a day.

For details, see Chapter 6. (➤P.6-16 "Chapter 6: 6.6 Shutdown") 13.3 Maintenance tasks performed as needed If an error occurs that requires maintenance, the help dialog box appears in the IPU screen. Perform the necessary maintenance tasks according to the message shown in the [Action] field in the help dialog box. For the details on the help dialog box, see Chapter 14. (➤P.14-1 "Chapter 14: 14.1.1 Help dialog box") 13.3.1 Replace the waste container If you are using waste tank full sensor and waste container becomes full, the help dialog box appears in the IPU screen. Risk of infection Use caution to prevent waste from splattering. Caution! Install the waste tank below the bottom of the analyzer. 13-5 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts Follow the steps below to replace the waste container. 1 Prepare an empty waste container and remove the cap. 2 Loosen the cap on the full waste container by turning it in the direction of the arrow. 3 Lift the cap straight up with the tube connected. For disposing a full waste container, see Chapter 2. (➤P.2-4 "Chapter 2: 2.8 Disposal of materials") 4 Insert the cap straight into the new waste container, with the tube connected. 5 Close the cap by turning it in the direction that is opposite of the direction in step 2. 6 Click [Accept] in the help dialog box. 13-6 XN-1000 Instructions for Use Revised February 2013 Chapter 13 Performing maintenance of instrument and replacing supply parts 13.3.2 Perform auto rinse Automatic analyzer rinse You can automatically perform rinsing of the analyzer and the post-rinse background check. If a background check error occurs, a help dialog will appear on the IPU screen. Follow the procedure below to perform automatic rinsing. 1 Click the Analyzer menu button on the control menu.

The menu on the right appears.

2 Click [Auto Rinse]. The menu automatically closes, [Auto Rinse] appears in the control menu and auto rinse starts. Progress is shown as a progress bar in the control menu. Wait until it is complete. Once complete, [Auto Rinse] disappears and the background check begins. For the details on background check, see Chapter 6. (Background check ➤P.6-13 "Chapter 6: 6.3.4 Execution of analyzer self-check") In [Body Fluid] mode, the background check for body fluid analysis starts*. For the details on background check of body fluid mode, see Chapter 9. (➤P.9-11 "Chapter 9: 9.4 Body fluid analysis") * The body fluid analysis can only be performed if the instrument offers the body fluid analysis mode. 13-7 XN-1000 Instructions for Use Revised August 2013 Chapter 13 Performing maintenance of instrument and replacing supply parts Automatic RU-20 rinse When using the RU-20, follow the steps below to perform automatic rinsing. In the event that a reagent preparation problem occurs, the partially prepared reagent can be drained and the interior of the RU-20 automatically rinsed. When automatic rinsing is performed, the prepared reagent in the supply tank is not drained. Follow the procedure below to perform automatic rinsing. 1 Display the RU-20 Maintenance menu. (➤P.13-4 "RU-20 Maintenance menu") 2 Click [Auto Rinse].

The dialog box on the right appears. 3 Click [Execute]. The dialog box automatically closes, [Maintenance in progress] appears in the operation status display area of the help dialog box, and automatic rinsing begins.

For the operation status display area, see Chapter 14. (➤P.14-1 "Chapter 14: 14.1.1 Help dialog box") Wait until it is complete. When it is complete, [Maintenance in progress] disappears. 4 Click [Cancel]. The dialog box closes. 13-8 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 13.3.3 Perform cleaning If the error is not cleared after automatic rinsing is performed, perform cleaning. In addition, when the required time for cleaning arrives, a help dialog will appear on the IPU screen. You can clean the optical detector block and hydraulic circuit with CELLCLEAN AUTO. Follow the steps below to perform cleaning. 1 Check the Status indicator LED on the analyzer. If the Status indicator LED is not lit green, wait until it does. Status indicator LED 2 Display the Maintenance menu. (➤P.13-2 "13.1.2 Maintenance menu") 3 Click [Cleaning]. The window on the right appears. 13-9 XN-1000 Instructions for Use Revised August 2012 Chapter 13 4 Performing maintenance of instrument and replacing supply parts If the tube holder is not ejected, press the mode switch on the analyzer. The tube holder slides out forward. 5 Place the CELLCLEAN AUTO in the sample tube holder. Set it into the front holder, when you face the analyzer. 6 Press the start switch on the analyzer. The sample tube holder retracts into the analyzer and aspiration begins. Wait until this process is finished.

When the process ends, cleaning starts and the tube holder is ejected. Cleaning takes about 20 minutes. Progress is shown as a progress bar on the screen. Wait until this process is finished. 7 Remove the CELLCLEAN AUTO. 8 Press the mode switch. The tube holder slides into the analyzer. Once cleaning is complete, auto rinse starts automatically. (➤P.13-7 "13.3.2 Perform auto rinse") Wait until it is complete. When it is complete, the window closes automatically. 13-10 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 13.3.4 Clog removal from the RBC detector If the RBC detector is clogged or air bubbles have formed, a help dialog will appear on the IPU screen. Follow the procedure below to remove the clog from the RBC detector. 1 Display the Maintenance menu. (➤P.13-2 "13.1.2 Maintenance menu") 2 Click [Remove RBC Detector Clog]. The window appears, and the removal of the clog starts.

Progress is shown as a progress bar on the screen. Wait until it is complete. When it is complete, the window closes automatically. Note: If the clog cannot be removed with this operation, see below. (➤P.13-12 "13.3.5 Rinse the RBC detector aperture") 13-11 XN-1000 Instructions for Use Revised August 2012 Chapter 13 13.3.5 Performing maintenance of instrument and replacing supply parts Rinse the RBC detector aperture If the removing the clog from the RBC detector does not remove all the clog or clear the error, rinse the RBC detector aperture. Warning! Never touch the detector when the power of the Main Unit is turned ON. An electrical shock could occur. Caution! • Be sure to use CELLCLEAN AUTO only. • When closing the detector cover, take care not to kink the tube. Otherwise, it may lead to incorrect analysis. • When rinsing the detector aperture, use the supplied unclogging brush and lightly tap on the detector aperture. Excessive force will damage the detector aperture. Follow the steps below to rinse the RBC detector aperture. 1 Open CELLCLEAN AUTO with the special CELLCLEAN AUTO opener.

With CELLCLEAN AUTO held straight as shown, press down the opener until you hear a "pop" sound. Keep the opener attached, and remove immediately before you use CELLCLEAN AUTO. Opener Caution! • Always wear rubber gloves when opening CELLCLEAN AUTO. • Press down slowly so that the content fluid does not splash. • Store opened CELLCLEAN AUTO standing on the rack with the opener attached. If CELLCLEAN AUTO is tilted, the content fluid may leak even when the opener is attached. 13-12 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 2 Shutting down analyzer for maintenance. Shut down the instrument and switch off the main power switch. For analyzer shutdown procedures, see Chapter 6. (➤P.6-18 "Chapter 6: 6.6.2 Shutting down the analyzer manually") Note: When [IPU Shutdown] is set to ON, the IPU shuts down automatically after all analyzers connected to the IPU have shut down. If you do not want to shut down the IPU, set [IPU Shutdown] to OFF before executing shutdown. 3 Open the top front cover.

Open to the highest point. It may move down. 4 Loosen the screw that is holding the detector cover in place. 5 Remove the detector cover. Lift it temporarily, and pull it out toward you. 6 Pull out the lid of the detector chamber by turning it in the direction of the arrow. 7 Soak the supplied unclogging brush in the content fluid of CELLCLEAN AUTO, and wash the detector aperture by lightly tapping it. Note: If fluid spills, wipe off the spilled fluid with a piece of tissue paper. 8 Insert the detector chamber cap straight in, and turn in the direction of the arrow. Insert the detector chamber cap all the way in to attach. Caution! If the detector chamber cover is not properly attached, correct analysis results will not be obtained. There is also a risk of instrument damage due to fluid leakage. 9 Attach the detector cover and secure with the screw. 10 Close the top front cover. 13-13 XN-1000 Instructions for Use Revised August 2013 Chapter 13 Performing maintenance of instrument and replacing supply parts 11 Turn ON the analyzer's power. For procedures to restart the analyzer, see Chapter 6. (➤P.6-20 "Chapter 6: 6.7 Restart the analyzer") Note: • Wash the brush and opener well and store in a clean state. Risk of instrument malfunctioning if there are small particles or other contaminants on the brush or opener. • CELLCLEAN AUTO used for rinsing can be used for shutdown that day. To do so, remove the opener from the CELLCLEAN AUTO, place in the sample tube holder, and shut down manually. For details, see Chapter 6. (➤P.6-18 "Chapter 6: 6.6.2 Shutting down the analyzer manually") 13.3.6 Drain the waste chamber If the waste tube from the waste chamber is clogged, a help dialog will appear on the IPU screen. Follow the procedure below to drain waste fluid that has collected in the waste chamber. 1 Display the Maintenance menu. (➤P.13-2 "13.1.2 Maintenance menu") 2 Click [Drain Waste Fluid Chamber]. The menu closes automatically, [Drain Waste Fluid Chamber] appears in the control menu, and draining begins.

Wait until it is complete. When it is complete, [Drain Waste Fluid Chamber] disappears. Note: If the error cannot be cleared with this operation, see below. (➤P.13-15 "13.3.7 Rinse the waste chamber") 13-14 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 13.3.7 Rinse the waste chamber If the error is not cleared after waste fluid is drained from the waste chamber, rinse the waste chamber.

You can clean the waste chamber with CELLCLEAN AUTO. Follow the steps below to rinse the inside of the waste chamber. 1 Check the Status indicator LED on the analyzer. If the Status indicator LED is not lit green, wait until it does. Status indicator LED 2 Display the Maintenance menu. (➤P.13-2 "13.1.2 Maintenance menu") 3 Click [Rinse Waste Fluid Chamber]. The window on the right appears. 13-15 XN-1000 Instructions for Use Revised August 2012 Chapter 13 4 Performing maintenance of instrument and replacing supply parts If the tube holder is not ejected, press the mode switch on the analyzer. The tube holder slides out forward. 5 Place the CELLCLEAN AUTO in the sample tube holder. Set it into the front holder, when you face the analyzer. 6 Press the start switch on the analyzer. The tube holder retracts into the analyzer and rinsing starts. Rinsing takes about 15 minutes. Progress is shown as a progress bar on the screen. Wait until this process is finished. When the process ends, the tube holder is ejected. 7 Remove the CELLCLEAN AUTO. 8 Press the mode switch.

The tube holder slides into the analyzer. 13-16 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 13.3.8 Remove air bubbles from flowcell If air bubbles have formed in the Flowcell, a help dialog will appear on the IPU screen. Follow the procedure below to remove the air bubbles from the inside of the Flowcell. 1 Display the Maintenance menu. (➤P.13-2 "13.1.2 Maintenance menu") 2 Click [Remove Flowcell Air Bubbles]. The window appears, and the removal of air bubbles starts. Wait until it is complete. Progress is shown as a progress bar on the screen. When it is complete, the window closes automatically. 13-17 XN-1000 Instructions for Use Revised August 2012 Chapter 13 13.3.9 Performing maintenance of instrument and replacing supply parts Rinse flowcell If the Flowcell is clogged or dirty, a help dialog will appear on the IPU screen. Follow the procedure below to rinse the inside of the Flowcell. 1 Check the Status indicator LED on the analyzer. If the Status indicator LED is not lit green, wait until it does. Status indicator LED 2 Display the Maintenance menu. (➤P.13-2 "13.1.2 Maintenance menu") 3 Click [Rinse Flowcell]. The window on the right appears. 13-18 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 4 If the tube holder is not ejected, press the mode switch on the analyzer. The tube holder slides out forward. 5 Place the CELLCLEAN AUTO in the sample tube holder. Set it into the front holder, when you face the analyzer. 6 Press the start switch on the analyzer. The tube holder retracts into the analyzer and rinsing starts. Rinsing takes about 10 minutes. Progress is shown as a progress bar on the screen. Wait until this process is finished. When the process ends, the tube holder is ejected. 7 Remove the CELLCLEAN AUTO. 8 Press the mode switch.

The tube holder slides into the analyzer. 13-19 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 13.3.10 Drain the reagent from the reaction chamber If the drain tubing in the RBC/HGB reaction chamber is clogged, the help dialog box appears in the IPU screen. Follow the procedure below to drain reagent that has collected in the reaction chamber. 1 Display the Maintenance menu. (➤P.13-2 "13.1.2 Maintenance menu") 2 Click [Drain Reaction Chamber]. The window appears, and draining starts. Wait until it is complete. When it is complete, the window closes automatically. 13.3.11 Drain the reagent from the RBC isolation chamber If the density of the reagent is inconsistent, [PLT sampling error] appears on a help dialog of the IPU screen. If the error appears after clear it, drain the reagent from the RBC isolation chamber. Follow the steps below to drain the reagents that have accumulated in the RBC isolation chamber. 1 Display the Maintenance menu. (➤P.13-2 "13.1.2 Maintenance menu") 2 Click [Drain RBC Isolation Chamber].

The window appears, and draining starts. Wait until it is complete. Progress is shown as a progress bar on the screen.

When it is complete, the window closes automatically. 13-20 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 13.3.12 Adjust the pressure (0.25 MPa) A 0.25 MPa pressure is applied to operate the master valves. If an error message for pressure abnormality is displayed, first check the tubes to see if there is any air leakage. If there is no abnormality in the tube, display the [Pressure Adjustment] window and adjust the pressure by checking the numeric values. Information If the pressure is too high, first decrease it below the specified value, and then increase to adjust it.

Follow the steps below to adjust the 0.25 MPa pressure. The adjustment is done in the pneumatic unit. 1 Display the Maintenance menu. (➤P.13-2 "13.1.2 Maintenance menu") 2 Click [Pressure Adjustment]. The window on the right appears. Each monitored pressure and its current value are displayed.

[0.25MPa] Shows the value read for 0.25 MPa. [0.16MPa] Shows the value read for 0.16 MPa. [0.07MPa] Shows the value read for 0.07 MPa. [-0.04MPa] Shows the value read for -0.04 MPa. This cannot be adjusted. [Pressure Adjustment] window 13-21 XN-1000 Instructions for Use Revised August 2012 Chapter 13 3 Performing maintenance of instrument and replacing supply parts Loosen the fastening screw for the 0.25 MPa regulator on the front of the pneumatic unit. For the location of the regulator, see Chapter 4. (➤P.4-4 "Chapter 4: 4.2 Pneumatic unit") Loosen Fastening screw 4 Adjust the pressure by turning the knob on the 0.25 MPa regulator. While checking the pressure displayed in the [Pressure Adjustment] window, adjust the pressure to the specified value (0.25 ± 0.04 MPa). Turn the knob clockwise to increase the pressure, and counter-clockwise to decrease the pressure.

Low High Adjustment knob Note: When using the RU-20, you can also check the pressure indication in the [Show Status] window while adjusting the pressure. (➤P.13-27 "Adjust the pressure of the RU-20") 5 Tighten the fastening screw of the 0.25 MPa regulator, without turning the adjustment knob.

6 Click [Close] in the [Pressure Adjustment] window. The window closes. 13-22 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 13.3.13 Adjust the pressure (0.16 MPa) A 0.16 MPa pressure is applied to the optical detection block to supply the sheath fluid. If an error message for pressure abnormality is displayed, first check the tubes to see if there is any air leakage. If there is no abnormality in the tube, display the [Pressure Adjustment] window and adjust the pressure by checking the numeric values. Information If the pressure is too high, first decrease it below the specified value, and then increase to adjust it. Follow the steps below to adjust the 0.16 MPa pressure. The adjustment is done in the main unit. 1 Display the Maintenance menu. (➤P.13-2 "13.1.2 Maintenance menu") 2 Click [Pressure Adjustment]. The [Pressure Adjustment] window appears. ([Pressure Adjustment] window ➤P.13-21 "13.3.12 Adjust the pressure (0.25 MPa)") 3 Open the top front cover.

Open to the highest point.

It may move down. Caution! During analysis and other times when the analyzer is in operation, never open the top front cover. 13-23 XN-1000 Instructions for Use Revised August 2012 Chapter 13 4 Performing maintenance of instrument and replacing supply parts Pull out the adjustment knob on the 0.16 MPa regulator to unlock it. For the location of the regulator, see Chapter 4. (➤P.4-1 "Chapter 4: 4.1 Analyzer") Adjustment knob 5 Adjust the pressure by turning the knob on the 0.16 MPa regulator. While checking the pressure displayed in the [Pressure Adjustment] window, adjust the pressure to the specified value (0.16 ± 0.016 MPa). Turn the knob clockwise to increase the pressure, and counter-clockwise to decrease the pressure. Low 6 Push the adjustment knob on the 0.16 MPa regulator to lock it. 7 Close the top front cover.

8 Click [Close] in the [Pressure Adjustment] window. High The window closes. 13-24 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 13.3.14 Adjust the pressure (0.07 MPa) A 0.07 MPa pressure is applied to drain waste and mix the samples. If an error message for pressure abnormality is displayed, first check the tubes to see if there is any air leakage. If there is no abnormality in the tube, display the [Pressure Adjustment] window and adjust the pressure by checking the numeric values. Information If the pressure is too high, first decrease it below the specified value, and then increase to adjust it. Adjust the pressure of the analyzer Follow the steps below to adjust the 0.07 MPa pressure. The adjustment is done in the main unit. 1 Display the Maintenance menu. (➤P.13-2 "13.1.2 Maintenance menu") 2 Click [Pressure Adjustment].

The [Pressure Adjustment] window appears. ([Pressure Adjustment] window ➤P.13-21 "13.3.12 Adjust the pressure (0.25 MPa)") 3 Open the top front cover. Open to the highest point. It may move down. Caution! During analysis and other times when the analyzer is in operation, never open the top front cover. 13-25 XN-1000 Instructions for Use Revised August 2012 Chapter 13 4 Performing maintenance of instrument and replacing supply parts Pull out the adjustment knob on the 0.07 MPa regulator to unlock it. For the location of the regulator, see Chapter 4. (➤P.4-1 "Chapter 4: 4.1 Analyzer") Adjustment knob 5 Adjust the pressure by turning the knob on the 0.07 MPa regulator. While checking the pressure displayed in the [Pressure Adjustment] window, adjust the pressure to the specified value (0.07 ± 0.01 MPa).

Turn the knob clockwise to increase the pressure, and counter-clockwise to decrease the pressure.

Low 6 Push the adjustment knob on the 0.07 MPa regulator to lock it. 7 Close the top front cover. 8 Click [Close] in the [Pressure Adjustment] window.

High The window closes. 13-26 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts Adjust the pressure of the RU-20 Follow the steps below to adjust the 0.07 MPa pressure. The adjustment is done on the RU-20. 1 Display the RU-20 Maintenance menu. (➤P.13-4 "RU-20 Maintenance menu") 2 Click [Show Status]. The window on the right appears. Each monitored pressure and its current value are displayed. [0.25MPa] Displays the source pressure of the pneumatic unit. [0.07MPa] Displays the pressure value inside the instrument. [-0.04MPa] Displays the vacuum value inside the instrument. [Show Status] window 3 Adjust the pressure. For the detailed procedure, see the RU-20 "Instructions For Use". (➤RU-20 Instructions for Use, "Chapter 6: 6.2.2 Adjusting the air pressure" Step 2 and following steps) 4 Click [Close] in the [Show Status] window. The window closes. 13-27 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 13.3.15 Drain the pneumatic trap chamber If the pneumatic trap chamber becomes full of water, a help dialog will appear on the IPU screen. Check if the trap chamber is full of water, and drain as needed. Caution! If water accumulates daily, the analyzer may have malfunctioned. Contact your Sysmex technical representative. Follow the steps below to drain the pneumatic trap chamber. 1 Open the top front cover.

Open to the highest point. It may move down. Caution! During analysis and other times when the analyzer is in operation, never open the top front cover. 13-28 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 2 Remove the pneumatic trap chamber by rotating it in the direction of the arrow. Pneumatic trap chamber Loosen 3 Discard water that has collected in the chamber. 4 Remove the float, and place it in the pneumatic trap chamber. Hold the removed float in the same orientation and put it straight into the pneumatic trap chamber. Float 5 Attach the pneumatic trap chamber by turning it in the direction that is opposite from step 2. 6 Close the top front cover.

13.3.16 View the maintenance log The maintenance log can be viewed. The log data shows maintenance execution information, and comments can be entered.

The log can be printed or output as a file in CSV format. For details, see below. (➤P.13-64 "13.6 About the history screen", P.13-72 "13.7 About the RU history screen") 13-29 XN-1000 Instructions for Use Revised August 2012 Chapter 13 13.4 Performing maintenance of instrument and replacing supply parts Replace reagents This section explains how to replace reagents. 13.4.1 List of reagents The following reagents are used in this device.

For details on each reagent, see Chapter 5. (➤P.5-1 "Chapter 5: Reagents") Product Code Description Volume Product Code Description Volume DCL-300A CELLPACK DCL 20 L WNR-200A Lysercell WNR 4L DCL-310A CELLPACK DCL 10 L WDF-200A Lysercell WDF 4L DST-300A CELLPACK DST 20 L WPC-200A Lysercell WPC 1.5 L DST-310A CELLPACK DST 10 L WNR-800A Fluorocell WNR 82 mL DST-320A CELLPACK DST 4L WDF-800A Fluorocell WDF 42 mL DFL-300A CELLPACK DFL 1.5 L WPC-800A Fluorocell WPC 12 mL SLS-240A SULFOLYSER* 1.5 L RET-800A Fluorocell RET 12 mL SLS-250A SULFOLYSER* 4L PLT-800A Fluorocell PLT 12 mL SLS-220A SULFOLYSER* 5L * Available reagent package sizes may vary in some regions. For more details please contact your local Sysmex representative. 13.4.2 About [Reagent Replacement] dialog box The [Reagent Replacement] dialog box allows you to check the remaining volume for reagents and replace them. If a reagent runs out during an analysis, the analysis is paused, and an error message appears in the analyzer area of the Control menu. Display the [Reagent Replacement] dialog box to replace the reagent. When using the RU-20, a help dialog box appears when CELLPACK DST runs low. See below for the procedure for replacing CELLPACK DST. (➤P.13-35 "13.4.4 Replace with new CELLPACK DST") Note: Even when an error message does not appear, the steps below can be used to open the [Reagent Replacement] dialog box. • Click the analyzer menu button in the control menu, and click [Reagent Replacement]. • Click the reagent level display in the control menu. 13-30 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts Follow the steps below to display the [Reagent Replacement] dialog box. 1 Click the help button on the control menu. Help dialog box appears. (➤P.14-1 "Chapter 14: 14.1.1 2 Help dialog box") Click [Execute]. The following dialog box appears, and the reagent remaining volume indicator appears. Shelf life after opening Lot No. Remaining volume graph Reagent state Reagent name Shelf life after Display the shelf life of the reagent after opening. This is not displayed if the reagent has not opening been registered.

When the shelf life after opening has expired, it displayed in white letter on a red background. Lot No. Displays the lot number of the reagent. Reagent state Displays the remaining number of tests for the reagent.

(Only the remaining level of [CELLPACK DCL] reagent will be displayed.) The remaining number of tests is only an approximation. It can change with use conditions. This is not displayed if the reagent has not been registered. When the reagent runs low, the background becomes yellow. During diluent or hemolytic agent replacement, progress is indicated as "0 to 100%". Reagent name Displays the reagent name. Remaining volume graph Displays the remaining volume of the reagent as a graph. This is not displayed if the reagent has not been registered, or if the reagent has run out. 13-31 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 13.4.3 Replace a new dilution/hemolytic agent This section explains how to replace the following reagents.

• CELLPACK DCL, CELLPACK DFL • SULFOLYSER • Lysercell WNR, Lysercell WDF, Lysercell WPC See below for the procedure for replacing CELLPACK DST. (➤P.13-35 "13.4.4 Replace with new CELLPACK DST") For cautions while replacing reagents, see Chapter 5. (➤P.5-1 "Chapter 5: Reagents") Caution! • Install the reagent at a height no more than 1 meter above or below the bottom of the analyzer. Do not put reagents on top of the instrument. • The new reagent must to be left for at 24 hours at room temperature (15 to 30°C). • If reagent spills, immediately wipe it off using wet cloth or the like. If a dedicated wagon is used, the reagent for the analyzer is stored in the area below. When replacing the reagent pull out the reagent storage slowly. SULFOLYSER, Lysercell WPC, CELLPACK DFL Reagent storage CELLPACK DCL Lysercell WNR, Lysercell WDF * The above diagram is an example. The installation locations of the reagents may vary depending on your conditions of use. Warning! • Open and close the storage using the handle on the dedicated wagon. • When opening or closing the storage, watch your finger. • Because the dedicated wagon is carrying the reagent, it is very heavy. When pulling out and pushing in the storage, do so slowly with care. 13-32 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts Follow the steps below to replace the reagent. 1 Display the [Reagent Replacement] dialog box. (➤P.13-30 "13.4.2 About [Reagent Replacement] dialog box") 2 Remove the cap from the new reagent container. Check that the reagent has not expired. 3 Input the reagent code (barcode). Input by barcode scanning Scan the reagent code (barcode) on the outer box of the new reagent with hand-held barcode reader. Reagent Code (barcode) is as shown the right illustration. Manual input Click the name of the reagent to be replaced in the [Reagent Replacement] dialog box. Enter the reagent code (barcode) and click [OK]. Note: In case the reagent outer box label shows a "XN Reagent Code" barcode, please scan this barcode. 4 Remove the cap from the old reagent container. e.g.) Lysercell WNR (4 L) 13-33 XN-1000 Instructions for Use Revised August 2013 Chapter 13 Performing maintenance of instrument and replacing supply parts 5 Pull out the dispensing set straight up. 6 Insert the dispensing set straight into the new reagent container. 7 Close the cap. 8 Click [Execute]. The replacement of the reagent starts.

Wait until it is complete. When it is complete, the dialog box closes automatically. The time guidelines for replacement of the reagent are as shown below. Reagent name Time CELLPACK DCL About 1 and a half minutes SULFOLYSER About 2 minutes CELLPACK DFL Time* Maximum 7 and a half minutes About 1 minute Lysercell WPC About 3 minutes Lysercell WDF About 1 and a half minutes Lysercell WNR * When using the reservoir tank. 13-34 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 13.4.4 Replace with new CELLPACK DST This section explains the procedure for replacing the CELLPACK DST when using the RU-20. For cautions while replacing reagents, see Chapter 5. (➤P.5-1 "Chapter 5: Reagents") Caution! • Install the reagent at a height no more than 1 meter above or below the bottom of the analyzer. Do not put reagents on top of the instrument. • The new reagent must to be left for at 24 hours at room temperature (15 to 30°C). • If reagent spills, immediately wipe it off using wet cloth or the like. If a dedicated wagon is used, the CELLPACK DST is stored in the area below. When replacing the CELLPACK DST pull out the reagent storage slowly. CELLPACK DST Reagent storage * The above diagram is an example. The installation locations of the reagents may vary depending on your conditions of use. Warning! • Open and close the storage using the handle on the dedicated wagon. • When opening or closing the storage, watch your finger. • Because the dedicated wagon is carrying the reagent, it is very heavy. When pulling out and pushing in the storage, do so slowly with care. 13-35 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts Follow the steps below to replace the reagent. 1 Display the RU-20 Maintenance menu. (➤P.13-4 "RU-20 Maintenance menu") 2 Click [Replace Reagent]. The following dialog box appears and displays the remaining level of CELLPACK DST reagent. Shelf life after opening Lot No. Reagent state Remaining volume graph RU-20 [Replace Reagent] dialog box Shelf life after opening Display the shelf life of the reagent after opening.

This is not displayed if the reagent has not been registered. When the shelf life after opening has expired, it displayed in white letter on a red background. 3 Lot No. Displays the lot number of the reagent. Reagent state Displays the remaining reagent as a percentage.

When the reagent runs low, the background becomes yellow. Remaining volume graph Displays the remaining volume of the reagent as a graph. This is not displayed if the reagent has not been registered, or if the reagent has run out. Remove the cap from the new reagent container. Check that the reagent has not expired. 4 Input the reagent code (barcode). Input by barcode scanning Scan the reagent code (barcode) on the outer box of the new reagent with hand-held barcode reader. Reagent Code (barcode) is as shown the right illustration. Manual input Click the name of the reagent to be replaced in the [Reagent Replacement] dialog box. Enter the reagent code (barcode) and click [OK]. Note: In case the reagent outer box label shows a "XN Reagent Code" barcode, please scan this barcode.

13-36 XN-1000 Instructions for Use Revised August 2013 Chapter 13 Performing maintenance of instrument and replacing supply parts 5 Remove the cap from the old reagent container. 6 Pull out the dispensing set straight up. 7 Insert the dispensing set straight into the new reagent container. 8 Close the cap.

9 Click [Execute]. The replacement of the reagent starts. Wait until it is complete. When it is complete, the dialog box closes automatically. Note: The RU-20 [Replace Reagent] dialog box can also be displayed by the method below. • Click [OK] in the Help dialog that appears when insufficient CELLPACK DST remains. • Click the reagent level display in the RU area of the control menu. 13-37 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 13.4.5 Replace a new dye This section explains how to replace the following reagents. • Fluorocell WNR, Fluorocell WDF, Fluorocell WPC • Fluorocell RET • Fluorocell PLT For cautions while replacing reagents, see Chapter 5. (➤P.5-1 "Chapter 5: Reagents") Install the dye cartridge in its corresponding dye cartridge holder. The dye cartridge holder that can be install will vary depending on the analyzer types. The position of each dye cartridge holder is shown below. WNR WDF RET PLT WPC WNR WDF XN-20 RET PLT XN-10 Follow the steps below to replace the reagent. 1 Display the [Reagent Replacement] dialog box. (➤P.13-30 "13.4.2 About [Reagent Replacement] dialog box") 2 Prepare the new reagent cartridge.

Check that the reagent has not expired. For the details on new reagent cartridge, see below.

(➤P.13-30 "13.4.1 List of reagents") e.g.) Fluorocell WDF 13-38 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 3 Open the top front cover. Open to the highest point. It may move down. Caution! During analysis and other times when the analyzer is in operation, never open the top front cover. 4 Pull up the cover from the reagent that is to be replaced.

Pull firmly until all the way up. e.g.) XN-20 Note: When the dye solution cover is pulled up, a Help dialog box appears in the IPU screen. Proceed to the next step. When the dye solution cover is pushed down in step 7, the Help dialog box closes. 13-39 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 5 Remove the old reagent cartridge from its holder. 6 Install the new reagent cartridge into the holder. Make sure that the color of the label on the new reagent cartridge matches the color of the dye cover, and install as shown at right. The analyzer beeps. Caution! • If you install a different reagent, the analyzer beeps repeatedly and Help dialog box appears in the IPU screen. • If dye solution spills, immediately wipe it off using wet cloth or the like. Otherwise, the coated surface of the instrument could be stained. 7 Pull down the cover on the reagent. Pull down until you hear a "click" sound. The ID of the new reagent is read automatically, and the information is registered. 8 Close the top front cover. The replacement of the reagent starts. Wait until it is complete. When it is complete, the window closes automatically. 13-40 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 13.4.6 Replenish reagents Replenish analyzer reagents If you encounter an error with the dye solution, or if you set the wrong reagent, you can replenish the reagent. Follow the steps below to replenish the reagent. 1 Make sure that the reagent you want to replace is connected. 2 Display the Maintenance menu. (➤P.13-2 "13.1.2 Maintenance menu") 3 Click [Reagent Replenishment]. The dialog box on the right appears. 4 Click the name of the reagent to replenish, and click [Execute]. The replenishing of the reagent begins. Progress is shown as a progress bar on the screen. Wait until it is complete. When it is complete, the dialog box closes automatically. Note: Multiple reagents can be replaced at once.

13-41 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts Replenish the reagent in the RU-20 (Replacing the reagent in the RU-20 instrument and supply tank) When using the RU-20, follow the steps below to replace the reagent in the RU-20. Perform this procedure if the concentrated reagent in the RU-20 has expired or the wrong reagent was accidentally connected. This procedure can be used to drain the concentrated reagent from the RU-20 and replace it with new CELLPACK DST, and drain the prepared reagent from the supply tank and replace it with reagent prepared using new CELLPACK DST. Follow the steps below to replenish the reagent. 1 Make sure that the reagent you want to replace is connected. 2 Display the RU-20 Maintenance menu. (➤P.13-4 "RU-20 Maintenance menu") 3 Click [Reagent Replenishment]. The dialog box appears.

4 Click [Execute]. The dialog box automatically closes, [Maintenance in progress] appears in the operation status display area of the help dialog box, and reagent replacement begins. For the operation status display area, see Chapter 14.

(➤P.14-1 "Chapter 14: 14.1.1 Help dialog box") Wait until it is complete. Reagent replacement takes about 4 to 6 hours. When it is complete, [Maintenance in progress] disappears. 5 Click [Cancel]. The dialog box closes. 13-42 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 13.4.7 Drain the reagent Draining analyzer reagent If the reservoir tank is being used, reagent can be drained and the reservoir tank automatically cleaned in the event that the reagent in the tank has expired or the wrong reagent was taken in. Follow the procedure below to drain the reagent. 1 Make sure that the reagent you want to reconnect is connected. 2 Display the Maintenance menu. (➤P.13-2 "13.1.2 Maintenance menu") 3 Click [Drain Reagent]. The dialog box on the right appears. 4 Click the name of the reagent that you wish to drain and click [Execute]. Draining starts. Progress is shown as a progress bar on the screen. Wait until it is complete. When it is complete, the dialog box closes automatically. Note: Multiple reagents can be drained at once. 13-43 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts RU-20 reagent draining (Replacing the reagent in the RU-20 instrument) When using the RU-20, follow the steps below to replace the reagent from in the RU-20. If the concentrated reagent in the RU-20 has expired or the wrong reagent was accidentally connected, the concentrated reagent in the RU-20 can be drained and replaced with new CELLPACK DST. Follow the procedure below to drain the reagent. 1 Make sure that the reagent you want to reconnect is connected. 2 Display the Maintenance menu. (➤P.13-4 "RU-20 Maintenance menu") 3 Click [Drain Reagent]. The dialog box appears. 4 Click [Execute]. The dialog box automatically closes, [Maintenance in progress] appears in the operation status display area of the help dialog box, and reagent draining begins. For the operation status display area, see Chapter 14. (➤P.14-1 "Chapter 14: 14.1.1 Help dialog box") Wait until it is complete. Reagent draining takes about 1 hour. When it is complete, [Maintenance in progress] disappears. 5 Click [Cancel]. The dialog box closes. 13-44 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 13.4.8 Check the reagent replacement history The history of reagent replacements can be viewed. The log data shows the information entered at the time of replacement, and comments can be entered.

The log can be printed or output as a file in CSV format. For the details, see the following. (➤P.13-64 "13.6 About the history screen", P.13-72 "13.7 About the RU history screen") 13.5 Replace supply parts This section explains how to replace supply parts. 13.5.1 Replace supply parts This section explains how to replace the supply parts below. Part Number Description AN965961 ASP_Assy (PM) No.8 266-7768-1 Fuse 50T100H (Main Unit, 100- 240V Specifications / 250V 10A, Time Lag, Low breaking capacity) 266-5011-3 Fuse STA-4A-N1 (Pneumatic Unit, 100-117V Specifications / 250V 4A, Time Lag) 266-5293-0 Fuse No. 19195 (Pneumatic Unit, 220-240V Specifications / 250V 3.15A, Time Lag) AX880901 Fuse 50T032H (Sampler, 250V 3.15A, Time Lag, Low breaking capacity) Reference ➤P.13-46 "13.5.2 Replace the piercer" ➤P.13-58 "13.5.3 Replace the fuse" 13-45 XN-1000 Instructions for Use Revised August 2013 Chapter 13 13.5.2 Performing maintenance of instrument and replacing supply parts Replace the piercer When the number of piercing actions exceeds 120,000, the help dialog box appears in the IPU. Continue use without replacing the piercer will cause the tip of the needle to wear and break. Therefore, replace the piercer according to the steps below. Note: Depending on the condition in which the device is used, the piercer may wear down before 120,000 counts of piercing. If the piercer is damaged in any way, replace it immediately. Removing the old piercer Follow the steps below to remove the old piercer. 1 Display the Maintenance menu. (➤P.13-2 "13.1.2 Maintenance menu") 2 Click [Replace Piercer]. The dialog box on the right appears. 3 Click [Yes]. The piercer operation count is reset and the piercer moves to the replacement position. Wait until it is complete. When it is complete, the dialog box closes automatically. 13-46 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 4 Open the top front cover. Open to the highest point. It may move down. 5 Turn OFF the Main power switch. OFF 6 Remove the screws of the bottom front cover. 13-47 XN-1000 Instructions for Use Revised August 2012 Chapter 13 7 Performing maintenance of instrument and replacing supply parts Remove the bottom front cover. 1 Tilt forward and down the front cover. 2 Lift up the front cover, and remove it. (1) (2) 8 Loosen the screws (x3) on the switch cover. 9 Pull down the switch cover. Pull out and then pull down. Switch cover 13-48 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 10 Make sure that the piercer moves. Check that the piercer has moved to a replaceable position (see right illustration).

Piercer 11 Cut the tie wrap holding the tube protruding from the top of the piercer and remove the tube. Tie wrap Information 2 layers of tubes are used in some places. Remove both layers at once. 13-49 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 12 Disconnect the rinse cup (bottom of piercer) tube.

Rinse cup 13 Remove the screw on the right side of the rinse cup. 14 Install the replacement metal plate. Place so that the slit in the metal plate is aligned with the center hole in the rinse cup and the upper hole in the piercer.

13-50 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 15 Tighten the screw on the lower part of the metal plate. 16 Tighten the screw on the upper part of the metal plate. 17 Remove the screws on the piercer (2 places). 2 screws 13-51 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 18 Remove the screw on the rinse cup. 19 Remove the piercer. For disposing a piercer that has been removed, see Chapter 2. (➤P.2-4 "Chapter 2: 2.8 Disposal of materials") 13-52 XN-1000 Instructions for Use Revised February 2013 Chapter 13 Performing maintenance of instrument and replacing supply parts Attaching a new piercer Follow the steps below to attach the new piercer. 1 Set the new piercer. 2 Loosely fasten the rinse cup with a screw. Keep the screw loose.

Rinse cup 3 Tighten the screws on the piercer (2 places). 2 screws 13-53 XN-1000 Instructions for Use Revised August 2012 Chapter 13 4 Performing maintenance of instrument and replacing supply parts Tighten the loose screw from step 2.

Tighten the screw by holding up the rinse cup, so that there is not gap (A). 5 Remove the screw from the upper part of the metal plate. 6 Remove the screw from the lower part of the metal plate. A 13-54 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 7 Remove the metal plate. 8 Tighten the screw on the right side of the rinse cup. 9 Attach the 2 tubes to the rinse cup. 13-55 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 10 Attach the tube above the piercer and fasten with a tie wrap. Be careful not to block the tube when binding the tie wraps. Cut off the excess tie wrap. Tie wrap 11 Set the switch cover. Pull firmly until all the way up and tuck into the rear. 12 Tighten the screws (x3) on the switch cover. 13-56 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 13 Set the bottom front cover. 1 Align the lower protrusion on the analyzer with the protrusion on the front cover. 2 Tilt down toward the analyzer to attach. (2) (1) 14 Tighten the screws of the bottom front cover. 15 Turn ON the Main power switch.

ON 16 Close the top front cover. 17 Turn ON the analyzer's power. For procedures to restart the analyzer, see Chapter 6. (➤P.6-20 "Chapter 6: 6.7 Restart the analyzer") 13-57 XN-1000 Instructions for Use Revised August 2012 Chapter 13 13.5.3 Performing maintenance of instrument and replacing supply parts Replace the fuse If a fuse blows, replace the fuse. The replacement procedure varies depending on the device. Warning! • Make sure to unplug the power cable when replacing a fuse. This is to avoid the risk of electrical shock. • Make sure to only use a fuse of the specified type and rating. This is to avoid the risk of fire. To replace the fuse for an analyzer Follow the steps below to replace the fuse in the analyzer. 1 Turn OFF the power to the entire device. For shutdown procedures, see Chapter 6. (➤P.6-16 "Chapter 6: 6.6 Shutdown") 2 Open the top front cover.

Open to the highest point. It may move down. 3 Turn OFF the Main power switch of the analyzer. OFF 13-58 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 4 Unplug the power cable from the rear side of the main unit. For locations of the power cable plug and the fuse on each device, see Chapter 4. (➤P.4-1 "Chapter 4: 4.1 Analyzer") 5 Remove the old fuse. 1 On the rear of the unit, pinch the tabs of the fuse holder and pull out forward. 2 Remove the old fuse from the fuse holder. Fuse Fuse holder Tab 6 Set the new fuse into the fuse holder, and insert it into the unit. 7 Plug in the power cable. 13-59 XN-1000 Instructions for Use Revised August 2012 Chapter 13 8 Performing maintenance of instrument and replacing supply parts Turn ON the Main power switch of the analyzer. ON 9 Close the top front cover. 10 Turn ON the power to the device. For the details on starting the device, see Chapter 6. (➤P.6-9 "Chapter 6: 6.3 Start up") 13-60 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts To replace the fuse for a pneumatic unit Follow the steps below to replace the fuse in the pneumatic unit. 1 Turn OFF the power to the entire device. For shutdown procedures, see Chapter 6. (➤P.6-16 "Chapter 6: 6.6 Shutdown") 2 Unplug the power cable from the rear side of the main unit. For locations of the power cable plug and the fuse on each device, see Chapter 4. (➤P.4-4 "Chapter 4: 4.2 Pneumatic unit") 3 Remove the old fuse. 1 On the rear of the unit, pull out the fuse holder forward. Use a flathead screwdriver to push up on the hook part of the fuse holder, and withdraw the fuse holder. Fuse Fuse holder 2 Remove the old fuse from the fuse holder. Tab 4 Set the new fuse into the fuse holder, and insert it into the unit. 5 Plug in the power cable. 6 Turn ON the power to the device. For the details on starting the device, see Chapter 6. (➤P.6-9 "Chapter 6: 6.3 Start up") 13-61 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts To replace fuse for a sampler (SA-10) Follow the steps below to replace the fuse in the sampler (SA-10). 1 Turn OFF the power to the entire device. For shutdown procedures, see Chapter 6. (➤P.6-16 "Chapter 6: 6.6 Shutdown") 2 Turn OFF the Main power switch of the sampler.

For the location of the main power switch, see Chapter 4. (➤P.4-6 "Chapter 4: 4.4 Sampler section") 3 Unplug the power cable from the rear side of the main unit. For locations of the the power cable plug and the fuse on each device, see Chapter 4. (➤P.4-6 "Chapter 4: 4.4 Sampler section") 4 Remove the old fuse. 1 On the rear of the unit, pinch the tabs of the fuse holder and pull out forward. 2 Remove the old fuse from the fuse holder. Fuse Fuse holder Tab 13-62 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 5 Set the new fuse into the fuse holder, and insert it into the unit. 6 Plug in the power cable. 7 Turn ON the Main power switch of the sampler. 8 Turn ON the power to the device. For the details on starting the device, see Chapter 6. (➤P.6-9 "Chapter 6: 6.3 Start up") 13-63 XN-1000 Instructions for Use Revised August 2012 Chapter 13 13.6 Performing maintenance of instrument and replacing supply parts About the history screen Clicking the [History] icon in the Menu screen displays the following screen. In the following screen, the error log tab appears.

Toolbar Font size button History list Display-switching tabs [History] screen Toolbar [Input] Click to display a dialog box that allows you to enter a comment. You can enter up to 50 characters. Once the comment is entered, it cannot be edited or deleted. If there is an existing comment, any new comments entered are appended after the previously entered comment. [Filter] Click to display a dialog that allows you to specify the conditions for the data you want displayed in the history list. [Output] Click to display a submenu that allows you to specify the output destination. [Upper] Click to move up one data. [Lower] Click to move down one data. [File] Click to display a submenu that allows you to save and restore data. [Close] Click to close the [History] screen.

Font size button To change the size of the characters and the line height in the sample list, click the character size button. When you change the size setting of the characters, see "Administrator's Guide". (➤Administrator's Guide, "Chapter 4: 4.3.3 Display settings") Navigating the screen You can switch between the screens by clicking the display-switching tab. 13-64 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 13.6.1 About the history list The items in the history list change depending on which tab is selected. ● Operation history screen Displays a history of operations performed in the device. A maximum of 5000 entries are stored and displayed in the operation history.

The operation history tab is similar to the error log tab.

For the details on the display of the error log tab, see below. (➤P.13-64 "13.6 About the history screen") [Date] Displays the date and time at which the history data was registered. [Logon Name] Displays the user name that was logged in when the history data was registered. [Operation Name] Displays the name of the operation performed. [Details] Displays the details of the operation performed. [Comments] Click to display a dialog box that allows you to enter a comment. You can enter up to 50 characters. Once the comment is entered, it cannot be edited or deleted. If there is an existing comment, any new comments entered are appended after the previously entered comment. The history list displays the following operators under respective conditions. Operator Display condition [Logon] When a user logs on. [Logoff] When a user logs off. [Modify Sample No.] When the sample number of an analysis data is modified. [Modify Pos. -> Neg.] When the judgment of an analysis data is changed from Positive to Negative. [Modify Neg. -> Pos.] When the judgment of an analysis data is changed from Negative to Positive. [Modify Sample Inf.] When the sample information of an analysis data is modified. [Modify Patient ID] When the patient ID of an analysis data is modified. [Delete Analysis Data] When an analysis data is deleted*1. [Register QC File] When a QC file is registered. [Modify QC Lot] When QC lot attributes (expiration date and lot number) are changed. [Modify QC Target/ Limit] When a QC target is changed. [Delete QC File] When a QC file is deleted. [Delete QC Plot] When a QC plot is deleted. [Delete Analysis Registration] When an analysis order is deleted*1. [Execute Calibration] When a compensation rate is changed. [Change Settings] When a setting is changed in the [IPU Setting] or [Analyzer Setting] dialog box. [Restore Setting] When a saved setting is restored in the [IPU Setting] or [Analyzer Setting] dialog box. 13-65 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts Operator Display condition [Initialize Setting] When a setting is initialized in the [IPU Setting] or [Analyzer Setting] dialog box.

[Register Rule] When a rule is registered in the rules screen. [Modify Rule] When a rule is modified in the rules screen. [Delete Rule] When a rule is deleted in the rules screen. [Restore Rule] When a saved rule is restored in the rules screen*2. [Initialize Rule] When a rule is initialized in the rules screen. [Enable Rule Setting] When a setting for a rule is enabled. [Disable Rule Setting] When a setting for a rule is disabled. *1 A deletion is not logged if a data was automatically deleted because the maximum number of registered data was exceeded. *2 The history is displayed by rule type. ● Error Log screen A history of errors that occurred is displayed with information at the time of occurrence and clearance. A maximum of 5000 entries are stored and displayed in the error log. For the details on the display of the error log tab, see below. (➤P.13-64 "13.6 About the history screen") [Date] Displays the date and time at which the history data was registered. [Logon Name] Displays the user name that was logged in when the history data was registered. [Status] Displays the status of the error that occurred. [Occurred]: Error [Clear]: Error cleared [Error] Displays the message of the error that occurred. [Error Code] Displays the error code of the error that occurred.

[Parameter1]/ [Parameter2] Displays parameter 1 and parameter 2 of the error that occurred. Depending on the type of error, this field may be blank. [Location] Displays the name of location where the error occurred.

[Comments] Click to display a dialog box that allows you to enter a comment. You can enter up to 50 characters. Once the comment is entered, it cannot be edited or deleted. If there is an existing comment, any new comments entered are appended after the previously entered comment. For details on errors, see Chapter 14. (➤P.14-1 "Chapter 14: Troubleshooting") 13-66 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts ● Reagent Replacement Log screen Displays a history of reagent replacement, and any information that was entered at the time of replacement. A maximum of 5000 entries are stored and displayed in the reagent replacement log. The reagent replacement log tab is similar to the error log tab. For the details on the display of the error log tab, see below.

(➤P.13-64 "13.6 About the history screen") [Date] Displays the date and time at which the history data was registered. [Logon Name] Displays the user name that was logged in when the history data was registered. [Analyzer Nickname] Displays the name of the analyzer for which the reagent was replaced. [Reagent] Displays the name of the replaced reagent.

[Lot No.] Displays the lot number of the replaced reagent. [Serial No.] The serial number within the lot of the replaced reagent appears. [Exp. Date] Displays the expiration date of the replaced reagent. [Exp. date after opening] Displays the shelf life of the replaced reagent after it has been opened. [Amounts] If a diluent or a hemolytic agent was replaced, the amount of the replaced reagent is displayed. If a dye was replaced, the number of tests for the replaced reagent is displayed. [Entry Type] Displays the method of input for the replaced reagent. [Manual]: Manual [Barcode]: Barcode reader [RFID]: ID reader of the dye [ProductCode] Displays the entered part code.

[Manufacturer] Displays the entered manufacturer. [Address] Displays the entered manufacturer's address. [Comments] Click to display a dialog box that allows you to enter a comment.

You can enter up to 50 characters. Once the comment is entered, it cannot be edited or deleted. If there is an existing comment, any new comments entered are appended after the previously entered comment. For details on replacing reagents, see the following: (➤P.13-30 "13.4 Replace reagents") 13-67 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts ● Maintenance Log screen Displays a history of maintenance tasks executed with information at the time of execution. A maximum of 5000 entries are stored and displayed in the maintenance log. The maintenance log tab is similar to the error log tab. For the details on the display of the error log tab, see below. (➤P.13-64 "13.6 About the history screen") [Date] Displays the date and time at which the history data was registered. [Logon Name] Displays the user name that was logged in when the history data was registered. [Nickname] Displays the name of the analyzer for which the maintenance task was executed.

[Maintenance] Displays the name of the maintenance task executed. [Maintenance Property] Displays the attributes of the maintenance task executed.

[Comments] Click to display a dialog box that allows you to enter a comment.

You can enter up to 50 characters. Once the comment is entered, it cannot be edited or deleted. If there is an existing comment, any new comments entered are appended after the previously entered comment. A maintenance log entry is registered when the following maintenance task is performed. The following are the maintenance tasks and attributes displayed. Maintenance Task Maintenance Attributes Auto Rinse As needed Cleaning As needed Shutdown Daily Drain Waste Chamber As needed Rinse Waste Chamber As needed Remove Air Bubbles As needed Rinse Flowcell As needed Drain Reaction Chamber As needed Drain RBC Isolation Chamber As needed Remove Clogs As needed Reagent Replenishment As needed Drain Reagent As needed Reset Piercer Operation Cycle Count Replace Parts Adjust Pressure As needed Replace Piercer Replace Parts For details on maintenance, see the following: (➤P.13-1 "13.1.1 List of maintenance items") 13-68 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 13.6.2 Specify conditions for the history to display (filter) You can specify conditions for the log entries you want displayed in the history list. Follow the steps below to specify conditions for the log entries you want displayed. 1 Click the [Filter] button on the toolbar. The following dialog box appears. Condition specification area e.g.) Filter of Error log 2 Populate the displayed fields. The following items are displayed in the dialog box. [Use Filter] Selecting this check box will display only the log entries that match the specified conditions. If you clear the check box, the settings will be grayed out and cannot be selected. [Specify Date] Select this check box to restrict the data to display by date. [Starting Day]/ [Ending Day] Click to select [Today], [Yesterday] or [Specify]. Selecting [Specify] allows you to specify the date. In the field below [Specify], enter the date in the format "Year (four digits)/Month (two digits)/Date (two digits)". You cannot enter double-byte characters. If you click the button on the right edge of the input field, a calendar appears. You can also enter the date by selecting from this calendar. [Specify Logon Name] Select this check box to specify the data to display by logon name. Click to select the logon name to display.

You can only select one user. Condition specification area The displayed buttons are different depending on the displayed screen. By selecting the check box displayed at the top, you can use the condition displayed on the button. Below each button, items that can be selected by each condition are displayed. [Specify Operation] Displayed when the operation history screen is open. Select this check box to restrict the data to display by operation name. Selecting the check box below the button displays the selected operation name. You can select multiple operators. 13-69 XN-1000 Instructions for Use Revised August 2012 Chapter 13 3 Performing maintenance of instrument and replacing supply parts [Specify Location] Displayed when the error history screen is open. Select this check box to restrict the data to display by location. Selecting the check box below the button displays the selected location. You can select multiple locations. [Specify Error] Displayed when the error history screen is open.

Select this check box to restrict the data to display by error type. Selecting the check box below the button displays the selected error type. You can select multiple error types. [Specify Analyzer] Displayed when the reagent replacement screen or maintenance log screen is open. Select this check box to restrict the data to display by analyzer. Selecting the check box below the button displays the selected analyzer. You can select multiple analyzers. [Specify Reagent] Displayed when the Reagent Replacement Log screen is open.

Select this check box to restrict the data to display by reagent. Selecting the check box below the button displays the selected reagent. You can select multiple reagents. [Specify Maintenance] Displayed when the Maintenance Log screen is open. Select this check box to restrict the data to display by maintenance type. Selecting the check box below the button displays the selected maintenance type. You can select multiple maintenance types.

Click [OK]. The dialog box closes. The log entries that match the specified conditions are displayed in the history list.

13-70 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 13.6.3 Output history to a printer You can output the history list to a connected printer. Click the [Output] button - [Ledger (LP)] on the toolbar. The history list is output from the ledger printer.

13.6.4 Save history in CSV format. You can save the history list as a CSV file. Follow the steps below to save the history in CSV format. 1 Click the [File] button - [Output in CSV Format] on the toolbar.

The [Save As] dialog box appears. 2 Specify the folder to save to, or create a new folder. 3 Enter a file name. The file extension is ".csv". 4 Click [Save]. The CSV data is saved. Note: When the dialog box opens, the files names are pre-entered as follows: • XN_SoftwareVersion_AUDITLOG.csv (Operation history) • XN_SoftwareVersion_ERRORLOG.csv (Error Log) • XN_SoftwareVersion_REAGENTLOG.csv (Reagent Replacement Log) • XN_SoftwareVersion_MAINTENANCELOG.csv (Maintenance Log) 13-71 XN-1000 Instructions for Use Revised August 2012 Chapter 13 13.7 Performing maintenance of instrument and replacing supply parts About the RU history screen Clicking the [RU history] icon in the Menu screen displays the following screen. In the following screen, the error log tab appears.

Toolbar Font size button RU history list Display-switching tabs [RU history] screen Toolbar [Filter] Click to display a dialog that allows you to specify the conditions for the data you want displayed in the RU history list. [Output] Click to display a submenu that allows you to specify the output destination. [Upper] Click to move up one data.

[Lower] Click to move down one data. [File] Click to display a submenu that allows you to save and restore data. [Close] Click to close the [RU history] screen. Font size button To change the size of the characters and the line height in the sample list, click the character size button. When you change the size setting of the characters, see "Administrator's Guide". (➤Administrator's Guide, "Chapter 4: 4.3.3 Display settings") Navigating the screen You can switch between the screens by clicking the display-switching tab. 13-72 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 13.7.1 About the RU history list The items in the RU history list change depending on which tab is selected.

● Preparation history screen Displays a history of reagent preparation performed on the RU and related information. A maximum of 2000 entries are stored and displayed in the preparation history. The preparation history log tab is similar to the error log tab. For the details on the display of the error log tab, see below. (➤P.13-72 "13.7 About the RU history screen") [RU Name] Name of the RU for which the history was stored. Either [RU-1] or [RU-2] appears. [Result] Shows the result of reagent preparation as [OK] or [NG]. [Temperature] Temperature when reagent preparation was completed. [Conductivity] Conductance when reagent preparation was completed. [Reference Value] AD value of the reference voltage when reagent preparation was completed. [Electrode Value] AD value of the electrode voltage when reagent preparation was completed. [Thermistor Value] AD value of the thermistor voltage when reagent preparation was completed.

[Date] Date when the history was stored. [Time] Time when the history was stored. ● RO water history screen Displays a history of reagent preparation performed on the RU and related information. A maximum of 2000 entries are stored and displayed in the RO water history. The RO water history log tab is similar to the error log tab.

For the details on the display of the error log tab, see below. (➤P.13-72 "13.7 About the RU history screen") [RU Name] Name of the RU for which the history was stored. Either [RU-1] or [RU-2] appears. [Result] Result of RO water preparation. [OK]: Normal [WA]: Warning value [NG]: Abnormal value [Temperature] Temperature when the history was stored. [Conductivity] Conductance when the history was stored. [Reference Value] AD value of the reference voltage when the history was stored. [Electrode Value] AD value of the electrode voltage when the history was stored.

[Thermistor Value] AD value of the thermistor voltage when the history was stored. 13-73 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts [Type] Conditions when the history was stored. [Supply Start]: First measurement value when supply to RO water chamber started (the valve was switched).

[End Supply]: Last measurement value when supply to RO water chamber ended (the valve was switched). [Fixed Period]: Measurement values every 5 minutes when the time from start to end of supply exceeds 5 minutes. [Range Error]: First measurement value outside the monitor level (two types: abnormal range / warning range) during supply.

[Restore]: First measurement value that returned to the monitor level (two types: abnormal range / warning range) during supply. [Supply Direction] RO water supply direction when the history was stored. [Chamber]: Measurement value during supply to RO water chamber. [Drain]: Measurement value during draining from RO water chamber.

[Supply Direction] is shown as [---] when the [Result] is [NG] or [WA] and the [Type] is [Range Error]. [Date] Date when the history was stored. [Time] Time when the history was stored. ● Error Log screen A RU history of errors that occurred is displayed with information at the time of occurrence and clearance. A maximum of 2000 entries are stored and displayed in the error log. For the details on the display of the error log tab, see below.

(➤P.13-72 "13.7 About the RU history screen") [RU Name] Name of the RU for which the history was stored. Either [RU-1] or [RU-2] appears. [Error] Displays the description of the error. [Status] Displays the status of an error that occurred. [Error]: Error has occurred. [Restore]: Error cleared. [Date] Date when the history was stored. [Time] Time when the history was stored. For details on errors, see Chapter 14 or the RU-20 "Instructions For Use". (➤P.14-1 "Chapter 14: Troubleshooting", RU-20 Instructions for Use "Chapter 7 Troubleshooting") 13-74 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts ● Reagent Replacement Log screen Displays a history of reagent replacement, and any information that was entered at the time of replacement. A maximum of 200 entries are stored and displayed in the reagent replacement log. The reagent replacement log tab is similar to the error log tab. For the details on the display of the error log tab, see below. (➤P.13-72 "13.7 About the RU history screen") [RU Name] Name of the RU for which the history was stored. Either [RU-1] or [RU-2] appears. [Reagent] Displays the name of the replaced reagent.

[Lot No.] Displays the lot number of the replaced reagent. [Serial No.] The serial number within the lot of the replaced reagent appears. [Exp. Date] Displays the expiration date of the replaced reagent. [Exp. date after opening] Displays the shelf life of the replaced reagent after it has been opened. [Amounts] The amount of the replaced reagent is displayed. [Entry Type] Displays the method of input for the replaced reagent. [Manual]: Manual [Barcode]: Barcode reader [ProductCode] Displays the entered part code. [Manufacturer] Displays the entered manufacturer. [Address] Displays the entered manufacturer's address.

[Date] Date when the history was stored.

[Time] Time when the history was stored. For details on replacing reagents, see the following: (➤P.13-35 "13.4.4 Replace with new CELLPACK DST") ● Part Replacement Log screen This displays the part replacement log. A maximum of 200 entries are stored and displayed in the part replacement history.

The part replacement history tab is similar to the error log tab. For the details on the display of the error log tab, see below. (➤P.13-72 "13.7 About the RU history screen") [RU Name] Name of the RU for which the history was stored. Either [RU-1] or [RU-2] appears. [Description] Information on replaced parts appears. [Filter], [DP1], [DP2], and [Reagent Conductivity Calibration] appear. [Date] Date when the history was stored. [Time] Time when the history was stored. For details on part replacement, see the RU "Instructions for Use". (➤RU-20 Instructions for Use "Chapter 6: 6.4.2 Replacing a maintenance part") 13-75 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 13.7.2 Specifying RU log display conditions (filter) Conditions can be specified for which RU logs are displayed in the RU log list. Follow the steps below to specify conditions for the RU logs to be displayed. 1 Click the [Filter] button on the toolbar. The submenu on the right appears. 2 Click the display conditions. The submenu closes, and the samples that match the conditions are displayed in the list. [All] Click to display all data recorded as logs in the displayed screen. [RU-1] Click to display only the data in the logs in the displayed screen that occurred in [RU-1]. [RU-2] Click to display only the data in the logs in the displayed screen that occurred in [RU-2]. 13-76 XN-1000 Instructions for Use Revised August 2012 Chapter 13 Performing maintenance of instrument and replacing supply parts 13.7.3 Output RU history to a printer You can output the RU history list to a connected printer. Click the [Output] button - [Ledger (LP)] on the toolbar. The RU history list is output from the ledger printer. 13.7.4 Save RU history in CSV format. You can save the RU history list as a CSV file. Follow the steps below to save the RU history in CSV format. 1 Click the [File] button - [Output in CSV Format] on the toolbar. The [Save As] dialog box appears. 2 Specify the folder to save to, or create a new folder. 3 Enter a file name. The file extension is ".csv". 4 Click [Save]. The CSV data is saved. Note: When the dialog box opens, the files names are pre-entered as follows: • XN_SoftwareVersion_RU_QUALITYLOG.csv (Preparation Log) • XN_SoftwareVersion_RU_ROWATERLOG.csv (RO water Log) • XN_SoftwareVersion_RU_ERRORLOG.csv (Error Log) • XN_SoftwareVersion_RU_REAGENTLOG.csv (Reagent Replacement Log) • XN_SoftwareVersion_RU_PARTSLOG.csv (Part Replacement Log) 13-77 XN-1000 Instructions for Use Revised August 2012 Day XN-1000 Instructions for Use Replacing reagents (Fluorocell WNR) Replacing reagents (Fluorocell WDF) Replacing reagents (Fluorocell WPC) Replacing reagents (Fluorocell RET) Replacing reagents (Fluorocell PLT) Draining the reagent Replacing piercer Replace fuses Remove Air Bubbles Rinse Flowcell Draining reaction chamber Drain RBC isolation chamber Adjusting the pressure (0.25 MPa) Adjusting the pressure (0.16 MPa) Adjusting the pressure (0.07 MPa) Draining chamber * We recommend that our customers prepare a checklist that suits their operating environment. Replacing reagents (Lysercell WPC) Replacing reagents (Lysercell WNR) Remove Clog Rinsing waste chamber Replacing reagents (SULFOLYSER) Draining waste chamber Replacing reagents (Lysercell WDF) Replacing reagents (CELLPACK DFL) Replacing waste container RBC detector aperture cleaning Replacing reagents (CELLPACK DST) Maintenance task Cleaning M/D Signed Replacing reagents (CELLPACK DCL) M/D Signed Auto Rinse Maintenance task Month M/D Signed M/D Signed 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 Maintenance Tasks to Be Performed as Needed Replacing reagents and supply parts Signed Maintenance task Shutdown Yr. 13.8 Daily Maintenance Tasks e.g.) Chapter 13 Performing maintenance of instrument and replacing supply parts Maintenance inspection checklist 13-78 Revised August 2012 Chapter 14 Troubleshooting Chapter 14 Troubleshooting This chapter explains the errors that may occur in the instrument and how to troubleshoot them. 14.1 Introduction 14.1.1 Help dialog box When a specific error occurs, or a maintenance task or cleaning becomes necessary, the following help dialog box appears on the IPU. Respond to the error message according to the message shown the [Action] field. (➤P.14-14 "14.3 Causes of errors and remedial actions") [Reset Alarm] Click to stop the alarm. [Error Message List] Displays a list of current errors. If multiple errors exist, errors that have higher priority are displayed at the top. [Action] Displays the troubleshooting action(s) for the selected error. Depending on the type of error, this field may be blank. [Detailed procedure] Click to display a section of the "Instructions for Use" manual that explains the procedure for troubleshooting the selected error.

This button cannot be selected if there are no relevant sections. [Instruction manual] Click to display a section of the "Instructions for Use" manual that explains the selected error. This button cannot be selected if there are no relevant sections. [Execute]/[Accept] Depending on the error type, either the [Execute] button or the [Accept] button appears. Clicking the [Execute] button performs the action displayed in the Action field. Clicking the [Accept] button clears the error. [Close] Click to close the help dialog box. 14-1 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Note: • When there is an error, the help dialog box can be displayed. Click the help button on the control menu.

• All alarms sounding on the IPU will stop when you click any button in the Help dialog box or press any key on the keyboard. When using the RU-20, if a specific error occurs on the RU-20 or a maintenance task or cleaning task becomes necessary, the help dialog box below appears on the IPU.

Respond to the error message according to the message shown the [Action] field. (➤RU-20 Instructions for Use "Chapter 7: 7.3 Causes of errors and remedial action") Operation status display area Submenu button Operation status display area The status of the RU-20 appears. [Resetting in progress]: The RU-20 unit is resetting. [Maintenance in progress]: The RU-20 unit is executing maintenance operation. [Stop Alarm] Click to stop the alarm. [Error Message List] Displays a list of current errors.

If multiple errors exist, errors that have higher priority are displayed at the top. [Action] The corrective action for the highest priority error appears. Depending on the type of error, this field may be blank. [Show Manual] Click to display a section of the "Instructions for Use" manual that explains the selected error.

This button cannot be selected if there are no relevant sections. [Show Detailed Procedure] Click to display a section of the "Instructions for Use" manual that explains the procedure for troubleshooting the selected error. This button cannot be selected if there are no relevant sections. Submenu button Click to display a submenu for RU-20 maintenance operations and settings. For details on maintenance, see Chapter 13. (➤P.13-2 "Chapter 13: 13.1.2 Maintenance menu") For information on the settings, see the "Administrator's Guide". (➤Administrator's Guide, "Chapter 4: Section 4.6 RU-20 Reagent Unit Settings") 14-2 XN-1000 Instructions for Use Revised December 2012 Chapter 14 Troubleshooting [OK] Click to execute the action or clear the error displayed in the action field. [Cancel] Click to close the help dialog box. Note: • The RU menu button in the control menu can be clicked to display the help dialog box. • All alarms sounding on the IPU will stop when you click any button in the Help dialog box or press any key on the keyboard. 14-3 XN-1000 Instructions for Use Revised August 2012 Chapter 14 14.2 Troubleshooting Error message list 14.2.1 Error message list (in alphabetical order) The following is an alphabetical list of error messages related to the analyzer/sampler. -0.04 MPa pressure error. . . . .

. . . . .
. . . .
. . . . . 34°C reagent heater temperature is high. .
. . . . . .
. . . . . .
. .
. . . . . 34°C reagent heater temperature is low . . . . . .
. . . . . .
. . . . . .
. . . . 34°C reagent heater thermistor error. . . . . .
. . . . .
. . . . . 41°C FCM reaction chamber temperature is high . . . . . .
. . . . . .
. .
. 41°C FCM reaction chamber temperature is low. . . . . .
41°C FCM reaction chamber thermistor error . . . . . .
. . 41°C reagent heater temperature is high. . .
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. . .
. .
. . . . . .
. . . . . 41°C reagent heater temperature is low . . .
. . . . . .
. . .
. . . . . 41°C reagent heater thermistor error. . . . . .
. . .
. . . . . .
. . . . . .
. . . . . .
. A sample other than CELLCLEAN AUTO has been placed. . . . . .
. . . . . Abnormal pressure loss . . . . . .
. . . . . .
. . . . . .
. . .
. . .
. . . . Analysis item not specified . . . . .
. . . . . .
. .
. . . . . Analysis result is high . . . . . .
. . . . . .
. . . . . .
. .
. . .
. . Analyzer barcode reader communication error . . . . . .
.
. . . . . APD thermistor error . . . . . .
. . . . . .
. . .
. . . . . .
. . . .
. . Aspiration Sensor error . . . . . .
. . . . . .
. . .
. . .
. . . . .
. Aspiration unit left-right motor error . . . . . .
. . . . . .
. . . . . Aspiration unit up-down motor error . . . . . .
. . . . . Background check error. . . . . .
. .
. . . . . .
. . . . . .
. .
. . . . Blood cannot be aspirated. . . . . .
. . . . . .
. . . .
. . . . . Bubbles in RBC detector . . . . . .
. . . . . .
. . . . .
. .
. . . . . Cannot recognize CELLCLEAN AUTO . .
. . . . . .
. . . . .
. . . . .
. . .
. . .
. . . Cannot recognize Fluorocell PLT information . . . . . .
. . . . . .
. . . . Cannot recognize Fluorocell RET information . . . . . .
. . . . .
.
. Cannot recognize Fluorocell WDF information . . . . . .
. . .
. . . Cannot recognize Fluorocell WNR information . . . . . .
. . . . .
Cannot recognize Fluorocell WPC information . . . . . .
. . .
. .
. . . . . .
. . . CELLCLEAN AUTO has already been used. . . . . CELLCLEAN AUTO has expired. . . . . .
. . . .
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. . . . . .
.
. . . . . .
. . CELLCLEAN AUTO is not placed correctly . . . . . .
. . . . . CELLPACK DCL aspiration error. . . . . .
. . . . .
.
. . . . . .
. . . . . CELLPACK DCL has expired . . . . . .
. . . . . .
. . . . . .
. . . . . CELLPACK DFL has expired.
. . . . . .
. . . . . .
. . . . .
. . . . . .
. . . CELLPACK DST has expired . . . . . .
. . . . . .
. .
. . . . . .
. . . . . Check Measurement Mode . . . . . .
. . . . . .
. . . . . Cleaning is required (warning). . . . . .
. . . . . .
. . . . . .
. . . . . Cleaning is required. . . . . .
.
. . . . . .
. Communication error during sampler analysis.
. . .
. .
. . . . . .
. . . . . .
Completed sampler analysis stop . . . . . .
. . . . .
. . . . . .
. . . . . Control has expired.. . . . . .
. . . . . .
. . . . . .
. . . . . Control is not entered. . . . .
. . . . . .
. . . .
. . . .
. . . . . Data Errors . . .
. . . . . .
. . . . . .
. . .
. . . . . .
. . . . . .
. . Ejection table is full . . . . . .
. . . . . .
. . . .
. . . . . .
Ejection table is full . . . . . .
. . . . .
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. . . . .
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. . . . . .
. . . .
. . . . . Ejection table stopper position error . .
. . . . . .
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. . .
. . .
. . . .
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. . . . . .
. . 14-14 14-14 14-14 14-14 14-15 14-15 14-16 14-15 14-15 14-16 14-15 14-15 14-16 14-15 14-15 14-16 14-43 14-15 14-32 14-36 14-39 14-16 14-22 14-21 14-21 14-36 14-22 14-35 14-44 14-46 14-46 14-46 14-46 14-46 14-44 14-44 14-43 14-17 14-42 14-42 14-42 14-41 14-42 14-41 14-39 14-24 14-40 14-40 14-35 14-25 14-29 14-25 14-4 XN-1000
Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Environment temperature is high . . . . . .
. . . . .
. . . . . Environment temperature is low . . . .
.
.
. . .
. . . . . .
. . . . . .
. . . . . Environment temperature thermistor error . . . . . .
. . . . . Failed to read rack number. . .
. .
. . . . . .
. . . . .
. . . .
. . Failed to read sample number.. . . . .
. . . . . .
. . . .
. .
. . . . . .
. . Failed to read sample number (analyzer). . . . . .
. . . .
. . . . . Failed to read sample number (sampler).. . . . . .
.
. . . . . .
. .
.
. . FCM detector cover is open. . . .
. . .
. . . . .
. . . . . .
. . . . . FCM detector temperature is high . . .
. . .
. . . . .
.
. . . . . FCM detector temperature is low .
. . . . . .
. . .
. . . . . .
.
. . . . . FCM detector thermistor error . . . . . .
. . . . . .
. . .
. . . . .
. FCM sheath aspiration error. . . .
. . . . .
. . . . . .
. . . . . FCM sheath motor error . . . . . .
. . . . . .
. FCM sheath temperature is high . .
. . . . . .
. . . . .
. . . . . .
. . . . . FCM sheath temperature is low . . . . . .
. . . . . .

. . .
. . . . . FCM sheath thermistor error . . . . . .
. . . .
. . . . . Feed-in table stopper position error . . .
. . . . . .
. . . . . Fluorocell PLT aspiration error .
. . . . . .
. . . . . Fluorocell PLT cover is open . . . . . .
. . . . . .
. . . . .
. . . . . .
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. . .
. .
Fluorocell PLT has already been used . . . . . .
. . . . . .
. . . . . Fluorocell PLT has expired. . . . . .
. . . . . .
. . .
. . . . . Fluorocell PLT is not installed. . . . . .
. . . . . .
. . . . . Fluorocell PLT RFID tag error . . .
. . . . . .
. . . . . .
. . . . . .
. . .
. .
. . Fluorocell RET aspiration error. . . . . .
. . . . . .
. . . . . Fluorocell RET cover is open . .
. .
. . . . . .
. . . . . .
.
. . . . . .
. Fluorocell RET has already been used . . . . . .
. . . . . .
. . . . . Fluorocell RET has expired . . . . . .
.
. . . .
. . Fluorocell RET is not installed . . .
. . . . .
. .
. . . . . .
. . . . . .
. . . . .
Fluorocell RET RFID tag error . . .
. . . .
. . . . . .
. . . . .
. . . . . .
. . . . . Fluorocell WDF aspiration error . . . . . .
. . . . . .
. .
. . . . . Fluorocell WDF cover is open .
. . . . . .
. . . . . Fluorocell WDF has already been used . . . . . Fluorocell WDF has expired . . . . . .
. . . . . .
.
. . . . .
. . . .
.
. . . . . Fluorocell WDF is not installed . . . . . .
. . . .
. . . .
. . . Fluorocell WDF RFID tag error. . . . . .
. . . . . Fluorocell WNR aspiration error . . . . . .
. . . . . .
. . . . . .
. . . . . .
. . . . .
Fluorocell WNR cover is open . . .
. . . . . .
. . . . . .
. . . . . .
. . . . . .
Fluorocell WNR has already been used . . . . . .
.
. . . . . .
. . . .
. . . Fluorocell WNR has expired. . . . . .
. . . . . .
. . . .
. . . .
. . . .
. . . . . .
. Fluorocell WNR is not installed. . . . . .
. .
. . . . . Fluorocell WNR RFID tag error .
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. . . . . .
. . . . . .
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. . Fluorocell WPC aspiration error . . . . . .
. . . . . .
. . . Fluorocell WPC cover is open . . .
. .
. . . . . .
. . . . . .
. . . .
. . . . . Fluorocell WPC has already been used . . . . .
. . . . . .
. . . . . Fluorocell WPC has expired . . . . . .
. .
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. . . . . .
. . . . . .
. . . . .
.
. . . Fluorocell WPC is not installed. .
. . .
. . . . . .
. . . . Fluorocell WPC RFID tag error. . . . . .
.
. . . . . .
. . . . . .
. . . . . Front cover is open. . . . . .
. . .
. . . . . .
. . . . . .
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. . . . .
. . .
. .
. . Front cover open error . . .
. . . .
. . . . . .
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. . . . .
. . .
. . .
.
. Hand open/close error . . . . . .
. . . . . .
. . . . . .
. . . . . Hand up-down error . . .
. . . . . .
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. . .
. . . . . .
. . . . . .
. HGB error . . . . . .
. . . . . .
. . . . . .
. . . . . .
. . . . . Instrument communication error. . . . . .
. . . . . Insufficient blood volume . . . . . .
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. . . . . .
. . .
. . . . . Insufficient blood volume (short sample) . . . . . .
. . . . . .
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. . .
. . . . Internal Error .
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. . . .
. . . . . .
. . .
. . Invalid analysis item is specified. . . . . .
. . . . . .
. . . . . .
. Invalid analysis item is specified (sampler analysis) . . . .
. . . . . .
. Laser life . . . . .
.
. . . . . Laser output error . . . . . .
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14-16 14-16 14-16 14-32 14-31 14-31 14-31 14-37 14-15 14-15 14-16 14-17 14-21 14-15 14-15 14-16 14-24 14-17 14-38 14-45 14-42 14-45 14-46 14-17 14-38 14-45 14-42 14-45 14-46 14-17 14-38 14-45 14-42 14-45 14-46 14-17 14-38 14-45 14-42 14-45 14-46 14-17 14-38 14-45 14-42 14-45 14-46 14-37 14-37 14-31 14-31 14-35 14-39 14-23 14-23 14-40
14-32 14-32 14-38 14-38 14-5 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting L-J Control Error .
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. . . . . .
. . . . . .
.
. . . . . Low count error . . . . . .
. . .
. . . . . .
. . . . . Lysercell WDF has expired . .
. . . . . .
. . .
. . . . . .
. . . . . .
. .
. . . . . Lysercell WNR has expired . . . . . .
. . . .
.
. . . . . Lysercell WPC has expired . . . . . Mixing error . .
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. . . . . .
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. . . . . .
. . Out of CELLPACK DCL . . . .
. . . . . .
. . . . . Out of CELLPACK DFL . . . .
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. . . . . .
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. . . . . Out of diluted CELLPACK DST .
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. . . . . .
. . . .
. . . . . .
. . . . . Out of Fluorocell PLT. . . . . .
. . . . . .
. . . Out of Fluorocell RET . . . . . .
. . . . . .
. . .
. . . . . .
. . Out of Fluorocell WDF . . . . . .
.
. . . . . Out of Fluorocell WNR. . . . . .
. . . . . .
. . .
. . . . . .
. . . . . Out of Fluorocell WPC .
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. . . . . .
. . . . . .
. . . . . Out of Lysercell WDF.
. . . . . .
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. . . .
. . . . . .
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. . . . . Out of Lysercell WNR . . . . . .
. . . . . .
. . . . . Out of Lysercell WPC . . . . . .
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. . . . . .
. . . . . .
. Out of SULFOLYSER . . . . . .
. . Piercer replacement is required. . . . . .
. . .
. . . . . .
. . . . . .
. . . . . PLT channel error . . . .
. . . .
. . . . . .
. . . . . PLT sampling error . . . . . .
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. . . .
. . . . . PLT-F channel error. . . . . .
. . . . . .
. . . . . .
. . . . . .
. PLT-F sampling error. . . . . .
. . . . . .
. . . . . .
PLT-F Scattergram sensitivity error . . . . . .
. . . . . .
. . Positive ID check error. . . . .
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. . . . . .
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. . . . . .
. . . . .
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. . . . . .
. .
Press Start SW .
. .
. . . . . .
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. . . . . .
. .
. . . . .
.
. . . . . .
. . QC not executed.. .
. .
. . . .
. . . . . .
. .
. .
. . . . . .
. .
. . . . . Rack ejection error. . . . . .
. . . . . .
. . . . . .
. . . . . Rack ejection error. . . . . .
. . .
. . .
. . . . . .
. . . . .
.
. . . . . .
. Rack ejection home position error . . . .
. . . . . .
. . . . . .
. . . . . .
. Rack ejection home position error . . . . . .
. . . . . .
. . . . . Rack feed-in error . . . . . .
. . . . . .
. . . . . .
. . . . . Rack feed-in error . . . . . .
. . .
. . . . . .
. . . .
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. . . . . .
Rack feed-in home position error. . . .
. . . . .
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. . . .
. . . . . Rack feed-in home position error. . . . . .
. . .
. . . . . Rack move error . . . . . .
. . .
. . . . . .
. . Rack move error (back belt) . . . .
. . . . . .
. . . . . Rack move error (front belt). . .
. . . . . .
. . . . . .
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. . . . . Rack move home position error. . . .
. .
. . . . . .
. . . . . .
. . .
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. . . .
. . Rack move mechanism initialization error (back belt) . .
. . . .
. . . . .
. . . . . Rack move mechanism initialization error (front belt) . . . . . .
. . . .
. . . . . .
. . .
Rack not placed on feed-in table .
. . . . . .
. . .
. . .
. . . . . .
. . . .
.
Rack not placed on feed-in table . . . . . .
. . . . . Rack removed . . . . . .
.
. . . . .
. . . . . .
. . . . . RBC channel error . . . . . .
. . . . . .
. . . .
. . . . . .
. . . . . RBC detector clog . . .
. . . . . .
.
.
. . .
. . . . . .
. . . . . RBC detector cover is open. . . . .
. . . . . .
. . . . . RBC sampling error . . .
. . . . . .
. . . . . .
RBC sheath fluid aspiration error. . . . . .
. . . . . .
. . . . . .
. . . . . .
RBC sheath motor error. . . . . .
. . . . . .
.
. . . . . .
. . . . . .
. RBC/HGB chamber not draining . . . . . .
. . . . . .
. . Reservoir tank is empty (CELLPACK DCL). . . . . .
. . . . . .
. . . . . .
Reservoir tank is empty (CELLPACK DFL) . . . . .
. . . . . .
. .
. . .
. . . . . Reservoir tank is empty (Lysercell WDF) . . . . . .
. . . . . .
. . . . . .
Reservoir tank is empty (Lysercell WNR) . . . . . .
. . . . . Reservoir tank is empty (Lysercell WPC) . . . . . Reservoir tank is empty (SULFOLYSER) .
.
. . .
.
. . . . . .
. . . .
. . . . . RET channel error . . . . . .
. . . . . .
. . . . . .
. . . . RET sampling error . . .
. .
. . . . . .
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.
. RET Scattergram sensitivity error . . . . . .
. . . . . .
. . . . . 14-40 14-35 14-42 14-42 14-42 14-30 14-18 14-18 14-19 14-18 14-18 14-18 14-18 14-18 14-18 14-18 14-18 14-18 14-18 14-43 14-34 14-33 14-34 14-33 14-41 14-31 14-43 14-41 14-26 14-28 14-26 14-28 14-25 14-27 14-25 14-27 14-28 14-26 14-26 14-28 14-26 14-26 14-25 14-29 14-29 14-34 14-35 14-37 14-33 14-17 14-21 14-19 14-19 14-19 14-19 14-19 14-19 14-19 14-19 14-34 14-33 14-41 14-6 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting RFID communication error . .

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. . . . . .
. . . . . .
RU has stopped supplying reagent. .
. . . .
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. . . . . .
.
Sample number not input . .
. . . . . .
. . . . . Sampler analysis stop error has occurred. . . . . .
. . . . . .
. . . .
. . . . . Sampler barcode reader communication error .
. . .
. . . . . .
. . . . . Sampler belt error. . . . . .
. . . . . .
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.
. . . . . Sampler belt error.
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. . .
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. .
. . . . . SULFOLYSER has expired . . . . . .
. . . . . Temperature stabilizing error . . . . . .
. . . .
. . . . . The sample must be remixed. . . . . .
. . . . . .
. . .
. . . . . .
Tube holder move error . . . . . .
.
.
. . . . . .
.
. . . . . Tube pickup error . . . . . .
. . . . . .
. . . . . .
.
.
.
. . . . . Tube presence verification home position error . . . . . .
. . . Tube remains in tube holder. . . . . .
. . . . . Tube return error . . . . . .
. . . . . .
. .
.
. . . . . Two tubes are in tube holder . .
. . . . . .
. . .
. . . . . .
. . . . . Unable to correctly detect CELLCLEAN AUTO.. . . . . .
. . . .
. . . . .
. . . . . Waste chamber 1 not draining . . . . .
. . . . . .
. . . . . .
. Waste chamber 2 not draining . . . .
. . . . . .
. . . .
. . . . . .
. . . . . Waste container is full . . . . .
. . . . . Water leak detected . .
. . . . . .
. . . . .
. . . . . .
. . .
. .
. . . . . Water leak detected (analysis not possible) .
. . . .
. . . . . .
. . . . .
. . . .
. . . . . Water leak sns error . . . . .
. . .
. . . . . .
. . . . . .
. . . WB aspiration motor error . . . . . .
. . . . . WDF channel error . . . . . .
. . . . . .
. . . . . .
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. . . . . .
. . .
. WDF sampling error . . .
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. . . . . .
. . . . WDF Scattergram sensitivity error . . . .
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. . . .
. . . . . .
. . . .
. WNR channel error.
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. . . . . .
. . . . . WNR sampling error . . . . . .
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. . . . . .
. . .
.
. . . . .
. . . . . WNR Scattergram sensitivity error . .
. . . . . .
.
. . . . . WPC channel error . . . . . .
. . . . . .
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. . . . . .
. . .
. . WPC sampling error . . . . . .
. . . . . .
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. . . .
. . . . . WPC Scattergram sensitivity error . . . . . .
. . . .
. . . . .
. . .
. . . . . .
. .
. Wrong reagent installed in Fluorocell PLT holder. . . . . .
. . . .
. . . .
. . . . . Wrong reagent installed in Fluorocell RET holder . . . . . .
. . . . Wrong reagent installed in Fluorocell WDF holder . . . .
. . . .
. .
.
. . . . . .
. . . . . Wrong reagent installed in Fluorocell WNR holder. . . . . .
. Wrong reagent installed in Fluorocell WPC holder. . . . . .
. . .
. . . . . X-bar control error . . . . . .
. .
. .
. . . . .
. . . . . .
. . . . . X-barM control error . . . . . .
.
. . . . . .
. . . . . 14-39 14-19 14-32 14-26 14-39 14-24 14-28 14-42 14-16 14-31 14-30 14-30 14-24 14-30 14-30 14-30 14-44 14-20 14-20 14-20 14-20 14-20 14-20 14-21 14-34 14-33 14-41 14-34 14-33 14-41 14-34 14-33 14-41 14-45 14-45 14-45 14-45 14-45 14-40 14-40 14-7 XN-1000 Instructions for Use Revised August 2012 Chapter 14 14.2.2 Troubleshooting
Error message list by function Analyzer/sampler Errors related to pressure -0.04 MPa pressure error. .
. . . . . .
. . . . . .
. 0.07 MPa pressure error . .
. . . . . .
. . . .
. . . . . .
. . . . . .
. 0.16 MPa pressure error . . . . . .
.
. . . . . .
. . . . . .
. . . . 0.25 MPa pressure error . . . . . .
. . . . . .
. . . . . .
. . . . .
. . . .
. . . . . Abnormal pressure loss . . . . . .
. .
. . . . . .
. . . . . .
. . . . . 14-14 14-14 14-14 14-14 14-14 14-15 Errors related to temperature 34°C reagent heater temperature is high. . . .
. . . . . .
. . . . . .
. . . . . .
.
. . . 34°C reagent heater temperature is low . . . .
. . . . . .
. . . . . .
. . . . . 34°C FCM reaction chamber temperature is high . . . . . .
. . . . . 34°C FCM reaction chamber temperature is low. . .
.
. . . . . .
. . . . . .
. 41°C reagent heater temperature is high. . . . . .
41°C reagent heater temperature is low . . . . . .
. . . . . 41°C FCM reaction chamber temperature is high .
. . . . . 41°C FCM reaction chamber temperature is low. . . . . FCM detector temperature is high . . .
. . . . . .
. . . . .
. . . . . FCM detector temperature is low. . . . . .
.
. . .
. . . . . .
. .
. . . . . FCM sheath temperature is high .
. . . .
. . . . . .
. . . . . FCM sheath temperature is low. . .
. .
. . . .
. . . . . .
. .
. . . . . .
. . . . . .
. . . 34°C reagent heater thermistor error. . . . . .
. . . . . .

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.
. . .
. . . Rack feed-in error . .
. .
. .
. . . . . .
. . . . . .
. . . . Rack not placed on feed-in table . . .
. .
. . . . . .
. . . . . .
. .
. . . . Rack ejection error. . . .
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. . . .
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. . . . . .
. .
.
. . .
. . . . Rack ejection home position error . .
. . . . . .
. . .
. . . . . .
. . . . Rack move mechanism initialization error (front belt) . . . . . .
. .
. . .
. . . . . Rack move mechanism initialization error (back belt) . . . . . .
. . . . . Rack move error (front belt). . . . . .
.
. . . . . .
. . . . . .
Rack move error (back belt) . . . . . .
. . . Sampler analysis stop error has occurred. . . . . .
. . . . . .
. . . . . .
. 14-24 14-24 14-24 14-24 14-25 14-25 14-25 14-25 14-25 14-26 14-26 14-26 14-26 14-26 14-26 14-26 Errors related to sampler analysis (SA-01) Rack feed-in error . . . . . .
. . . . . .
. . . . . .
.
. . . . . Rack feed-in home position error. . . . . .
.
. . . . . .
. . . . .
.
. . . . . Rack move error . . . . . .
. . .
. . . . . .
. . .
. . . . .
. . . . Rack move home position error. . . . . .
. .
. . Rack ejection error.
. . . . . .
. . . . .
. . . . . .
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. . .
. . . . .
. . . . . .
. Rack ejection home position error . . . . . .
.
. . . . . .
. . . . . Sampler belt error . . . . . .
. . . . . .
. . . . . .
. .
. . . . . .
. . . Rack removed . .
. .
. . .
. . . . . .
. .
. . . . . .
. . . . . Rack not placed on feed-in table . . . . . .
. . . . . .
. . . . . .
. .
Ejection table is full .
.
. . . . . .
. . .
. . . . . .
. . . .
. . . .
. . . . . .
. . . 14-27 14-27 14-28 14-28 14-28 14-28 14-28 14-29 14-29 14-29 Errors related to the tube grabber and tube holder Mixing error . . . . . .
. . . . . .
. . . . . .
. . . . . .
. . . .
. . . . . Two tubes are in tube holder . . . . . .
. . . . . Tube remains in tube holder . .
. . . . . .
. . .
. .
. . . . . .
. . . . Tube pickup error. . . . . .
. . .
. . . . . .
. . . . . Tube holder move error . . . . . .
.
. . . . . .
. . . . . Tube return error . . . . .
. . . . . .
. . . . . Hand up-down error. . .
. . . . . .
. . . . . Hand open/close error . . . .
. . . . . .
. . .
. . . . .
. . . . . .
. . . . . The sample must be remixed. . . .
. . . . . .
. . . .
. . . . . 14-30 14-30 14-30 14-30 14-30 14-30 14-31 14-31 14-31 Errors related to sample number and rack number Failed to read sample number (sampler). .
. .
. . . . . .
. . . . . Failed to read sample number (analyzer).
. . . . . .
.
. . . . Failed to read sample number.
. . . . . .
. . . .
. . Positive ID check error. . . . . .
. . . .
. . . . . Failed to read rack number . . . . . .
.
. . . . . .
. . . . . Sample number not input. .
. . .
. . . . . .
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. . . . . .
. . .
. 14-31 14-31 14-31 14-31 14-32 14-32 14-10 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Errors related to orders Analysis item not specified . . . .
. . . . . .
. . . . . 14-32 Invalid analysis item is specified. . . . . .
. . . . . 14-32 Invalid analysis item is specified (sampler analysis) . .
. . . . . .
. . . . . .
. 14-32 Errors related to analysis PLT sampling error . . . .
. . . . . .
. . . . . .
. . . . . .
. . . . . RBC sampling error . . .
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. . . .
. . . .
. . . . .
. . . . . .
. . . . . PLT-F sampling error .
. . . . . .
.
. . . . . RET sampling error . . . . . .
. . . . . .
. . . . . .
. . . . . WDF sampling error . . . . . .
. . .
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. . . . . WNR sampling error . . .
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. . . . . .
. . . . . .
. . . . . WPC sampling error . .
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. . . . . .
. . . . . WDF channel error . . . .
. . . . . .
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. . . . . .
PLT-F channel error . . . . . .
. . . . . .
. . .
. . . . . .
. . . WNR channel error. . .
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. . . . . .
. . . . . .
. WPC channel error . . . . .
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. . . . . .
. . . . . PLT channel error. . . . .
. . . . .
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. . . . . .
. . . .
. .
. . . . . RBC channel error . . .
. . . . . .
. . . . . .
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RET channel error . . . . . .
. . . . . .
. . . . . HGB error . . . . . .
. . . . . .
. . . . . .
. . . . . .
. . . .
. . .
. . . . . RBC detector clog . . . . . .
. . . . . .
. . . . . .
. . . . . .
.
. . . . . Bubbles in RBC detector . .
. . . .
.
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. . . . . .
. . . . . Low count error . . . .
. . . .
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. . . .
. . . .
. . . . . .
. . . . . Data Errors . .
.
. . . . . .
. . . . . .
. . . . . .
. . . . . Analysis result is high . . . . . .
. . . . .
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. . . . . .
. . . . . .
. . .
. . .
. . . .
. Background check error . . . . . .
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. . . 14-33 14-33 14-33 14-33 14-33 14-33 14-33 14-33 14-34 14-34 14-34 14-34 14-34 14-34 14-34 14-35 14-35 14-35 14-35 14-35 14-36 14-36 Errors related to covers Front cover open error . . . .
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. . . . . .
. . . . .
. . . . . .
. .
. . . . . Front cover is open. . . . . .
. . .
. . . . . .
. . . . . .
FCM detector cover is open. . . . . .
. .
. . . . .
. .
. . . . . .
. . . . . RBC detector cover is open.. . .
. . . . .
. .
.
.
. . . . . Fluorocell WNR cover is open . . . . . .
. . . . . .
. . . .
. . . . . Fluorocell WDF cover is open . . .
. . . . . .
. . . . . .
. . . . . .
. . . . . Fluorocell WPC cover is open . . . . .
. . . .
. . . . . .
. . .
. .
. . . . . Fluorocell RET cover is open . . . . . .
. . . . . .
. . . . . Fluorocell PLT cover is open . . .
. . . . . .
. . .
. . .
. . . . . 14-37 14-37 14-37 14-37 14-38 14-38 14-38 14-38 14-38 Errors related to the laser Laser output error .
. .
. . . . . .
. . . . . .
. . . . . .
. . .
. 14-38 Laser life . . . . . .
. . .
. . . . . .
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. . . . .
. . . . . 14-38 14-11 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Errors related to the system Analyzer barcode reader communication error . . . . . .
.
. .
. . . . . .
. . .
. .
. . Sampler barcode reader communication error . .
. . . . . .
. . . . . .
.
. . . . . Communication error during sampler analysis. . . . . .
. . . . . RFID communication error. . . . . .
. . . . . Instrument communication error . . . . . .
. . . . . .
. . . . . Internal Error . . . . .
. . . . . .
. . . . . .
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. . . . . 14-39 14-39 14-39 14-39 14-39 14-40 Errors related to quality control L-J Control Error . . . . . .
. . . . . .
. . . . . .
. . . . . .
. . . X-barM control error. . . . . .
. . . . . .
.
.
. . . . . X-bar control error . . . . . .
. .
. . . . . .
. . .
. . . . . Control has expired.. . .
. . .
. . . . . .
. . . . . Control is not entered. . . . . .
. . . . . .
. . . . . .
. . . . . .
. . . QC not executed.. . . . . .
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WNR Scattergram sensitivity error . . . . . .
. .
WDF Scattergram sensitivity error. . . . . .
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WPC Scattergram sensitivity error. . . . . .
. . . . . .
. . . . . .
. . . . . RET Scattergram sensitivity error . . . . . .
. . . . . .
. . . . . .
. . . PLT-F Scattergram sensitivity error . . .
. . . .
. .
. . . . . Check Measurement Mode . . . . . .
. . . . .
. . .
. . . . . .
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. . . .
. . . . 14-40 14-40 14-40 14-40 14-40 14-41 14-41 14-41 14-41 14-41 14-41 14-41 Errors related to user maintenance and warnings Cleaning is required.
.
. . . . . .
.
. . . . . .
. . . . . Cleaning is required (warning). . . . . .
. . . . . CELLPACK DCL has expired .
. .
. . .
.
. . . . . .
. . . . . SULFOLYSER has expired .
. . . . . .
. . . . . .
. . . .
. .
. . . . . .
. . . . . Lysercell WNR has expired . . . . . .
. . . . . .
. . . . Lysercell WDF has expired . . .
. . . . . .
. . . . . .
. . . . . .
. . .
. .
. . . Lysercell WPC has expired . . . . . .
. .
. . . . . .
. . . . . .
. . . . . .
. CELLPACK DFL has expired. . . . . .
. . . . . .
. Fluorocell WNR has expired .
. . . . .
. . . . . .
. . . . . .
. .
. . . . . .
. . Fluorocell WDF has expired . . . . . .
. . . . . .
. . . Fluorocell WPC has expired . . . .
. . . . . .
. . . . . .
. . Fluorocell RET has expired . . . . . .
. . . . . Fluorocell PLT has expired . . . . . .
. . . . . .
. . . .
. . . . . CELLPACK DST has expired .
. .
. . . . . .
. . . . .
. . . . . Piercer replacement is required. . . . . .
. . . . . .

. . . . . Press Start SW . . . . .
. . . . .
. . .
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. . . .
. . .
. . . .
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. . . . . .
. . .
. . .
. . . . . CELLCLEAN AUTO is not placed correctly . . . . . .
. .
. . . . . .
. . . . . A sample other than CELLCLEAN AUTO has been placed.
. . . .
. . . . . Unable to correctly detect CELLCLEAN AUTO. . . . . .
. . .
CELLCLEAN AUTO has already been used.
. . . . . .
. .
. . .
. . . . . Cannot recognize CELLCLEAN AUTO . . . . . .
. . . . . CELLCLEAN AUTO has expired. . .
. . . . . .
. . .
. . . . . 14-41 14-42 14-42 14-42 14-42 14-42 14-42 14-42 14-42 14-42 14-42 14-42 14-42 14-42 14-42 14-43 14-43 14-43 14-43 14-44 14-44 14-44 14-44 14-12 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Errors related to the dye cartridge holder Wrong reagent installed in Fluorocell WNR holder. . .
. . . . . .
. . . .
. . . . . Wrong reagent installed in Fluorocell WDF holder . . .
. . . . .
. . . . .
. . . .
. . . .
. .
Wrong reagent installed in Fluorocell WPC holder. .
. .
. . . . . .
Wrong reagent installed in Fluorocell RET holder . . . . . .
. . . . . Wrong reagent installed in Fluorocell PLT holder. . . . . .
.
. . . . .
.
. . .
. . Fluorocell WNR is not installed. .
. . . .
. .
. . . . . .
. . . . . .
. Fluorocell WDF is not installed . . . . . .
. . . . . .
. . .
. . . . . Fluorocell WPC is not installed. . . . . .
. . . . . Fluorocell RET is not installed . . . . . .
.
. . . . .
. . .
. . . Fluorocell PLT is not installed. . . . . .
. . . . . .
. . . . . Fluorocell WNR has already been used . . . . . .
. . . . . .
. . . . . Fluorocell WDF has already been used . . . . . .
. . . . . .
. . . . . .
. Fluorocell WPC has already been used . . . . . .
. . . . . .
. . . . . Fluorocell RET has already been used . . . . . .
. . . . . Fluorocell PLT has already been used . . . . . .
. . . . . Cannot recognize Fluorocell WNR information .
. . . . . .
. . . . . .
. . . . . Cannot recognize Fluorocell WDF information. . . . . .
. . . . . .
.
. . . . . Cannot recognize Fluorocell WPC information. . . . . .
Cannot recognize Fluorocell RET information .
. . . . . .
. . . . . Cannot recognize Fluorocell PLT information . . . . . .
. . . . .
. . . . . .
. . . . . Fluorocell WNR RFID tag error .
. .
. . . . . .
. . . . . .
. . . .
. . . . Fluorocell WDF RFID tag error. . . .
. . . . .
. . . . . .
. . . . . .
Fluorocell WPC RFID tag error. . . .
. . . . .
. . . . . .
. . . . . Fluorocell RET RFID tag error . . . .
. . . . . .
. . .
. . . . . Fluorocell PLT RFID tag error . .
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14-45 14-45 14-45 14-45 14-45 14-45 14-45 14-45 14-45 14-45 14-45 14-45 14-45 14-45 14-45 14-46 14-46 14-46 14-46 14-46 14-46 14-46 14-46 14-46 14-46 14-13 XN-1000 Instructions for Use Revised August 2012 Chapter 14 14.3 Troubleshooting Causes of errors and remedial actions If an error occurred, refer to the causes and actions below and take appropriate action. If the error persists after taking the suggested action, or if a malfunction or any other damage occurs, contact your Sysmex service representative. 14.3.1 Analyzer/sampler Errors related to pressure Error Messages -0.04 MPa pressure error Probable Cause 1) There is a foreign object pressing on the tubing connected to the pneumatic unit, or there is a kink in the tubing. 2) The nipple on the pneumatic unit is loose.
3) Water has accumulated in the anti-backflow chamber. Actions 1) Remove the object that is pressing on the tubing, and straighten the tubing. 2) Connect the nipple securely. 3) Drain water from the pneumatic trap chamber. For the details on draining water from the pneumatic trap chamber, see Chapter 13. (➤P.13-28 "Chapter 13: 13.3.15 Drain the pneumatic trap chamber") Error recovery condition The pressure returns within the monitored range. Error Messages 0.07 MPa pressure error 0.16 MPa pressure error 0.25 MPa pressure error Probable Cause 1) The pressure value has fallen out of the monitored range. 2) The power to the pneumatic unit is OFF. 3) There is a foreign object pressing on the tubing connected to the pneumatic unit, or there is a kink in the tubing. 4) The nipple on the pneumatic unit is loose. 5) There is an abnormality in the regulator. Actions 1) Click [Execute] in the help dialog box. While checking the displayed [Pressure Adjustment] dialog box, adjust the pressure. For the details on adjusting the pressure, see Chapter 13.
(➤P.13-21 "Chapter 13: 13.3.12 Adjust the pressure (0.25 MPa)") 2) Securely plug in the power cable of the pneumatic unit, and then turn ON the power switch. 3) Remove the object that is pressing on the tubing, and straighten the tubing. 4) Connect the nipple securely. 5) The device needs to be serviced. Contact your Sysmex service representative. Error recovery condition The pressure returns within the monitored range. 14-14 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Error messages Abnormal pressure loss Probable Cause The power to the pneumatic unit shut OFF while running. Actions Securely plug in the power cable of the pneumatic unit, and then turn ON the power switch. Remove the sample tubes from the device, and then click [Execute] in the help dialog box. Restart the device.
Error recovery condition Restart the device. Errors related to temperature Error messages 34°C reagent heater temperature is high 34°C reagent heater temperature is low 34°C FCM reaction chamber temperature is high 34°C FCM reaction chamber temperature is low 41°C reagent heater temperature is high 41°C reagent heater temperature is low 41°C FCM reaction chamber temperature is high 41°C FCM reaction chamber temperature is low FCM detector temperature is high FCM detector temperature is low FCM sheath temperature is high FCM sheath temperature is low Probable Cause The temperature of the unit has fallen out of the monitored range. Actions Click [Execute] in the help dialog box. While checking the displayed [Sensor 1] dialog box, wait for the temperature to return within the monitored range. Click [Cancel] to close the dialog box. For details on the [Sensor 1] dialog box, see the following.
(➤P.14-47 "14.5.1 Test proper operation of the device (sensor)") If the error has not cleared after 30 minutes, contact your Sysmex service representative. Error recovery condition The temperature returns within the monitored range.
14-15 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Error messages 34°C reagent heater thermistor error 34°C FCM reaction chamber thermistor error 41°C reagent heater thermistor error 41°C FCM reaction chamber thermistor error APD thermistor error FCM detector thermistor error FCM sheath thermistor error Environment temperature thermistor error Probable Cause The thermistor in the unit has malfunctioned, or there is a break in its connection. Actions Remove the sample tubes and racks from the device, and then turn OFF the main power. The device needs to be serviced. Contact your Sysmex service representative. Error recovery condition - Error messages Environment temperature is high Environment temperature is low Probable Cause The ambient temperature of the device has fallen out of the usable range. Actions Click [Execute] in the help dialog box. While checking the displayed [Sensor 1] dialog box, wait for the temperature to return within the monitored range. Click [Cancel] to close the dialog box. For details on the [Sensor 1] dialog box, see below. (➤P.14-47 "14.5.1 Test proper operation of the device (sensor)") Error recovery condition The temperature returns within the monitored range. Error messages Temperature stabilizing error Probable Cause The temperature of the unit is not stabilizing. Actions Remove the sample tubes and racks from the device, and then turn OFF the main power. The device needs to be serviced. Contact your Sysmex service representative.
Error recovery condition - 14-16 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Errors related to reagents and chambers Error messages CELLPACK DCL aspiration error FCM sheath aspiration error RBC sheath fluid aspiration error Probable Cause 1) The tubing connected to the reagent container is clogged. 2) There is a foreign object pressing on the tubing connected to the reagent container, or there is a kink in the tubing.
Actions 1) Click [Execute] in the help dialog box, and then replenish the reagent. For the details on replenishing a reagent, see Chapter 13. (➤P.13-41 "Chapter 13: 13.4.6 Replenish reagents") 2) Remove the object that is pressing on the tubing, and straighten the tubing. Error recovery condition Replenish the reagent. Error messages Fluorocell WNR aspiration error Fluorocell WDF aspiration error Fluorocell WPC aspiration error Fluorocell RET aspiration error Fluorocell PLT aspiration error Probable Cause 1) Air bubbles have formed in the tubing connected to the reagent container.
2) The dye cover opened. Actions 1) Click [Execute] in the help dialog box, and then replenish the reagent. For the details on replenishing a reagent, see Chapter 13. (➤P.13-41 "Chapter 13: 13.4.6 Replenish reagents") 2) Close the dye cover.
Error recovery condition 1) Replenish the reagent.
2) Close the dye cover. 14-17 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Error messages Out of CELLPACK DCL Out of SULFOLYSER Out of Lysercell WNR Out of Lysercell WDF Out of Lysercell WPC Out of CELLPACK DFL Probable Cause 1) The remainder of the reagent has run out. 2) There is a foreign object pressing on the tubing connected to the reagent container, or there is a kink in the tubing. Actions 1) Click [Execute] in the help dialog box, and then replace the reagent with a new one.
For the details on replacing a reagent, see Chapter 13. (➤P.13-32 "Chapter 13: 13.4.3 Replace a new dilution/hemolytic agent"). 2) Remove the object that is pressing on the tubing, and straighten the tubing. Error recovery condition Replace the reagent. Error messages Out of Fluorocell WNR Out of Fluorocell WDF Out of Fluorocell WPC Out of Fluorocell RET Out of Fluorocell PLT Probable Cause The remainder of the reagent has run out. Actions Replace the reagent with a new one. For the details on replacing a reagent, see Chapter 13. (➤P.13-38 "Chapter 13: 13.4.5 Replace a new dye") Error recovery condition Replace the reagent. 14-18 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Error messages Reservoir tank is empty (CELLPACK DCL) Reservoir tank is empty (SULFOLYSER) Reservoir tank is empty (Lysercell WNR) Reservoir tank is empty (Lysercell WDF) Reservoir tank is empty (Lysercell WPC) Reservoir tank is empty (CELLPACK DFL) Probable Cause 1) The remainder of the reagent has run out. 2) There is a foreign object pressing on the tubing connected to the reagent container, or there is a kink in the tubing. Actions 1) Click [Execute] in the help dialog box, and then replace the reagent with a new one. For the details on replacing a reagent, see Chapter 13. (➤P.13-32 "Chapter 13: 13.4.3 Replace a new dilution/hemolytic agent").
2) Remove the object that is pressing on the tubing, and straighten the tubing. Error recovery condition Replace the reagent. Error messages Out of diluted CELLPACK DST RU has stopped supplying reagent. Probable Cause The CELLPACK DST has run out. Actions Click [Execute] in the help dialog box of the RU menu, and replace CELLPACK DST. For the procedure for replacing CELLPACK DST, see Chapter 13. (➤P.13-35 "Chapter 13: 13.4.4 Replace with new CELLPACK DST") Error recovery condition Replace the CELLPACK DST. Error messages RBC/HGB chamber not draining Probable Cause The drain tubing of RBC/HGB is clogged. Actions Click [Execute] in the help dialog box and drain the reagent from the reaction chamber. For the procedure for draining reagent from the reaction chamber, refer to Chapter 13. (➤P.13-20 "Chapter 13: 13.3.10 Drain the reagent from the reaction chamber") Error recovery condition The draining by the device finishes successfully. 14-19 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Error messages Waste chamber 1 not draining Waste chamber 2 not draining Probable Cause The drain tubing is clogged. Actions Click [Execute] in the help dialog box and drain waste fluid from the waste chamber. For the procedure for draining waste fluid from the waste chamber, refer to Chapter 13. (➤P.13-14 "Chapter 13: 13.3.6 Drain the waste chamber") Error recovery condition The draining by the device finishes successfully. Error messages Waste container is full Probable Cause The waste container is full. Actions Replace the waste container, and then click [Accept] in the help dialog box. For the details on replacing the waste container, see Chapter 13. (➤P.13-5 "Chapter 13: 13.3.1 Replace the waste container") Error recovery condition Click [Accept] in the help dialog box. Error messages Water leak detected Water leak detected (analysis not possible) Probable Cause There is a water leak inside the analyzer. Actions Turn OFF the main power. The device needs to be serviced. Contact your Sysmex service representative. Error recovery condition - Error messages Water leak sns error Probable Cause The water leak sensor has malfunctioned.
Actions Remove the sample tubes from the device, and then turn OFF the main power. The device needs to be serviced. Contact your Sysmex service representative.
Error recovery condition - 14-20 XN-1000 Instructions for Use Revised August 2013 Chapter 14 Troubleshooting Errors related to motors Error messages FCM sheath motor error RBC sheath motor error Probable Cause A piece of tubing or another object is touching the FCM (or RBC) sheath injector piston. Actions Separate any tubing that is touching the piston, and click [Execute] on the help dialog box. The motor operation test begins. Error recovery condition The test operation by the device finishes successfully. Error messages Aspiration unit up-down motor error Probable Cause A piece of tubing or another object is touching the aspirator. Actions Remove the sample tubes from the device, and then click [Execute] in the help dialog box. Restart the device. Error recovery condition Restart the device. Error messages Aspiration unit left-right motor error Probable Cause A piece of tubing or another object is touching the aspirator. Actions Separate any tubing that is touching the piston, and click [Execute] on the help dialog box. The motor operation test begins. Error recovery condition The test operation by the device finishes successfully. Error messages WB aspiration motor error Probable Cause A piece of tubing or another object is touching the WB aspiration pump. Actions Separate any tubing that is touching the piston, and click [Execute] on the help dialog box. The motor operation test begins. Error recovery condition The test operation by the device finishes successfully. 14-21 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Errors related to blood aspiration Error messages Blood cannot be aspirated. Probable Cause 1) The density of the sample is inconsistent. 2) The piercer or the tubing of the WB aspiration line is clogged.
3) The blood aspiration sensor has malfunctioned. Actions 1) Click [Accept] in the help dialog box, mix the sample well, and then re-analyze. 2) Click [Accept] in the help dialog box. Once the device is in READY state, perform an auto rinse. If the error persists, perform cleaning. If the error still persists, replace the piercer. For the details on auto rinse, see Chapter 13. (➤P.13-7 "Chapter 13: 13.3.2 Perform auto rinse") For the details on cleaning, see Chapter 13. (➤P.13-9 "Chapter 13: 13.3.3 Perform cleaning") For the details on replacing the piercer, see Chapter 13. (➤P.13-46 "Chapter 13: 13.5.2 Replace the piercer") 3) The device needs to be serviced. Contact your Sysmex service representative. Error recovery condition Click [Accept] in the help dialog box. Error messages Aspiration Sensor error Probable Cause The blood aspiration sensor has malfunctioned. Actions The device needs to be serviced.
Contact your Sysmex service representative. Error recovery condition Click [Accept] in the help dialog box. 14-22 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Error messages Insufficient blood volume Insufficient blood volume (short sample) Probable Cause 1) The sensor could not detect the specified amount of blood. 2) Blood volume is insufficient.
3) The piercer or the tubing of the WB aspiration line is clogged. Actions 1) Repeat the analysis by manual or micro analysis. 2) Repeat the analysis by manual or micro analysis. 3) Click [Accept] in the help dialog box. Once the device is in READY state, perform an auto rinse.
If the error persists, perform cleaning. If the error still persists, replace the piercer. For the details on auto rinse, see Chapter 13. (➤P.13-7 "Chapter 13: 13.3.2 Perform auto rinse") For the details on cleaning, see Chapter 13. (➤P.13-9 "Chapter 13: 13.3.3 Perform cleaning") For the details on replacing the piercer, see Chapter 13. (➤P.13-46 "Chapter 13: 13.5.2 Replace the piercer") Error recovery condition Click [Accept] in the help dialog box. Errors related to sampler analysis (SA-10) The names and positions of the sensors attached to the sampler (SA-10) are shown below. Sample tube monitoring sensor Tube rotation mechanism Analysis line termination monitoring sensor Analysis line (Rack horizontal-feed unit) Blood monitoring sensor Left sampler pool return prevention stopper Right sampler pool (Rack feed-in table) Left sampler pool Left sampler pool rack full sensor Rack feed-in arrival monitoring sensor Right sampler pool return prevention stopper Right sampler pool rack detecting sensor The structure of a sampler 14-23 XN-1000 Instructions for Use Revised February 2013 Chapter 14 Troubleshooting Error messages Feed-in table stopper position error Probable Cause There is a foreign object in the movement path of the return prevention stopper in the right sampler pool. Actions Remove the foreign object away from the return prevention stopper. Error recovery condition Click [Accept] in the help dialog box. Error messages Completed sampler analysis stop Probable Cause When aborting sampler analysis, this message appears after the abort operation has completed. Actions - Error recovery condition Click [Accept] in the help dialog box. Error messages Tube presence verification home position error Probable Cause 1) There is a foreign object in the movement path of the tube rotation mechanism. 2) The sample tube monitoring sensor is not operating correctly due to dust and/or other particles. Actions 1) Remove the foreign object away from the tube rotation mechanism. 2) Remove the dust and/or other particles. Error recovery condition Click [Accept] in the help dialog box. Error messages Sampler belt error Probable Cause A rack was detected on the analysis line while initializing the analysis line.
Actions Remove the rack from the analysis line. Error recovery condition Click [Accept] in the help dialog box. 14-24 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Error messages Ejection table is full Probable Cause 1) The left sampler pool is full with racks. 2) There is a foreign object in the movement path of the racks in the left sampler pool.
3) The left sampler pool rack full sensor is not operating correctly due to dust and/or other particles. Actions 1) Remove the racks. 2) Remove the foreign object from the left sampler pool.
3) Remove the dust and/or other particles. Error recovery condition Perform the above actions. (Automatically cleared) Error messages Ejection table stopper position error Probable Cause There is a foreign object in the movement path of the return prevention stopper in the left sampler pool. Actions Remove the foreign object away from the return prevention stopper. Error recovery condition Click [Accept] in the help dialog box. Error messages Rack feed-in home position error Rack feed-in error Probable Cause 1) There is a foreign object in the movement path of the racks in the right sampler pool. 2) The rack is not placed properly. 3) The rack detecting sensor in the right sampler pool is not operating correctly due to dust and/or other particles. Actions 1) Remove the foreign object from the right sampler pool. 2) Reposition the rack, and then perform sampler analysis. 3) Remove the dust and/or other particles. Error recovery condition Click [Accept] in the help dialog box. Error messages Rack not placed on feed-in table Probable Cause 1) The rack is not placed properly. 2) The rack detecting sensor in the right sampler pool is not operating correctly due to dust and/or other particles. Actions 1) Reposition the rack, and then perform sampler analysis. 2) Remove the dust and/or other particles. Error recovery condition Click [Accept] in the help dialog box. 14-25 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Error messages Rack ejection error Rack ejection home position error Probable Cause 1) 2) 3) 4) There is a foreign object in the movement path of the rack feed-out lever. There is a foreign object in the movement path of the racks in the left sampler pool. The feed-out movement of the rack was blocked. The rack is not moving properly because the table surface of the left sampler pool is dirty. Actions 1) 2) 3) 4) Remove the foreign object from the rack feed-out lever. Remove the foreign object from the left sampler pool. Reposition the rack, and then perform sampler analysis. Clean the table surface of the left sampler pool. Error recovery condition Click [Accept] in the help dialog box. Error messages Rack move mechanism initialization error (front belt) Rack move mechanism initialization error (back belt) Rack move error (front belt) Rack move error (back belt) Probable Cause 1) There is a foreign object in the movement path of the rack on the sampler's analysis line. 2) The rack is not placed properly.
Actions 1) Remove the foreign object from the analysis line. 2) Reposition the rack, and then perform sampler analysis. Error recovery condition Click [Accept] in the help dialog box. Error messages Sampler analysis stop error has occurred. Probable Cause An interruption error occurred during sampler analysis. Actions Clear all errors and then click [Accept] in the help dialog box. Error recovery condition Click [Accept] in the help dialog box. 14-26 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Errors related to sampler analysis (SA-01) The names and positions of the sensors attached to the sampler (SA-01) are shown below.
Rack feed-out initial position sensor Analysis line (Rack horizontal-feed unit) Sample tube monitoring sensor Blood monitoring sensor Rack shift initial position sensor Right sampler pool rack feed-in end sensor Right sampler pool rack feed-in position sensor Right sampler pool (Rack feed-in table) Left sampler pool Left sampler pool rack full sensor Rack shift monitor sensor Right sampler pool rack feed-in initial position sensor The structure of a sampler Error messages Rack feed-in error Rack feed-in home position error Probable Cause 1) There is a foreign object in the movement path of the racks in the right sampler pool. 2) The rack is not placed properly. Actions 1) Remove the foreign object from the right sampler pool. 2) Reposition the rack, and then perform sampler analysis. Error recovery condition Click [Execute] in the help dialog box. 14-27 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Error messages Rack move error Rack move home position error Probable Cause 1) There is a foreign object in the movement path of the rack on the sampler's analysis line. 2) The rack is not placed properly. Actions 1) Remove the foreign object from the analysis line. 2) Reposition the rack, and then perform sampler analysis. Error recovery condition Click [Execute] in the help dialog box. Error messages Rack ejection error Rack ejection home position error Probable Cause 1) 2) 3) 4) There is a foreign object in the movement path of the rack feed-out lever. There is a foreign object in the movement path of the racks in the left sampler pool. The feed-out movement of the rack was blocked. The rack is not moving properly because the table surface of the left sampler pool is dirty. Actions 1) 2) 3) 4) Remove the foreign object from the rack feed-out lever. Remove the foreign object from the left sampler pool. Reposition the rack, and then perform sampler analysis. Clean the table surface of the left sampler pool. Error recovery condition Click [Execute] in the help dialog box. Error messages Sampler belt error Probable Cause A rack was detected on the analysis line while initializing the analysis line. Actions Remove the rack from the analysis line. Error recovery condition Click [Accept] in the help dialog box. 14-28 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Error messages Rack removed Probable Cause When the hand unit was holding a sample tube during sampler analysis, the rack was removed from the analysis line. Actions Remove the sample tube from the hand unit and return it to the rack. Reset the rack and perform sampler analysis. Error recovery condition Click [Accept] in the help dialog box. Error messages Rack not placed on feed-in table Probable Cause 1) The rack is not placed properly. 2) The rack feed-in position sensor in the right sampler pool has malfunctioned due to dust or other particulate matter. Actions 1) Reposition the rack, and then perform sampler analysis. 2) Remove the dust and/or other particles. Error recovery condition Click [Accept] in the help dialog box. Error messages Ejection table is full Probable Cause 1) The left sampler pool is full with racks. 2) There is a foreign object in the movement path of the racks in the left sampler pool. 3) The left sampler pool rack full sensor is not operating correctly due to dust and/or other particles. Actions 1) Remove the racks. 2) Remove the foreign object from the left sampler pool. 3) Remove the dust and/or other particles. Error recovery condition Perform the above actions. (Automatically cleared) 14-29 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Errors related to the tube grabber and tube holder Error messages Mixing error Probable Cause 1) There is a foreign object in the movement path of the tube grabber in the sampler. 2) The sample tube is not set properly.
Actions 1) Remove the foreign object from the movement path of the tube grabber. 2) Reposition the sample tube, and then perform sampler analysis. Error recovery condition The test operation by the device finishes successfully. Error messages Two tubes are in tube holder Probable Cause Both the normal sample tube and the micro collection sample tubes were set for manual analysis. Actions Remove the sample tube that does not need to be analyzed. Error recovery condition Click [Accept] in the help dialog box.
Error messages Tube remains in tube holder Probable Cause When the analysis was switched from manual to sampler, a sample tube was found left in the tube holder. Actions Remove the sample tube from the tube holder. Error recovery condition Click [Accept] in the help dialog box. Error messages Tube pickup error Tube holder move error Tube return error Probable Cause 1) There is a foreign object in the movement path of the tube holder. 2) The sample tube is not set properly.
Actions 1) Remove the foreign object from the tube holder. 2) Reposition the sample tube, and then perform sampler analysis. Error recovery condition The test operation by the device finishes successfully. 14-30 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Error messages Hand up-down error Hand open/close error Probable Cause 1) There is a foreign object in the movement path of the tube grabber in the sampler. 2) The sample tube is not set properly. Actions 1) Remove the foreign object from the movement path of the tube grabber.
2) Reposition the sample tube, and then perform sampler analysis. Error recovery condition The test operation by the device finishes successfully.
Error messages The sample must be remixed. Probable Cause The set time (60 seconds) elapsed after an analysis information query was sent to the host computer during manual analysis. Actions Re-agitate the sample. Click [Accept] in the help dialog box and then repeat analysis. Error recovery condition Click [Accept] in the help dialog box. Errors related to sample number and rack number Error messages Failed to read sample number (sampler). Failed to read sample number (analyzer). Failed to read sample number. Probable Cause 1) The barcode label on the sample is dirty. 2) The print quality of the barcode label on the sample is poor. 3) The position of the barcode label on the sample is off. Actions Check the position and cleanliness of the barcode label. Error recovery condition Click [Accept] in the help dialog box. Error messages Positive ID check error Probable Cause 1) The barcode read by the sampler was different from that read by the analyzer. 2) There is a foreign object in the device. Actions 1) Reposition the sample, and then perform sampler analysis. 2) Remove the foreign object from the device. Error recovery condition Click [Accept] in the help dialog box. 14-31 XN-1000 Instructions for Use Revised December 2012 Chapter 14 Troubleshooting Error messages Failed to read rack number Probable Cause 1) The barcode label on the rack is dirty. 2) The print quality of the barcode label on the rack is poor. 3) The position of the barcode label on the rack is off. Actions Check the position and cleanliness of the barcode label. Error recovery condition Click [Accept] in the help dialog box. Error messages Sample number not input Probable Cause No sample number was specified at the time of manual analysis. Actions Enter the sample number, and then perform the analysis. Error recovery condition Click [Accept] in the help dialog box. Errors related to orders Error messages Analysis item not specified Probable Cause No analysis parameter was specified at the time of manual analysis. Actions Enter the analysis parameter, and then perform the analysis. Error recovery condition Click [Accept] in the help dialog box. Error messages Invalid analysis item is specified Probable Cause An analysis parameter was specified that cannot be analyzed in manual analysis. Actions Change the analysis parameter, and then perform the analysis. Error recovery condition Click [Accept] in the help dialog box. Error messages Invalid analysis item is specified (sampler analysis) Probable Cause An analysis parameter was specified that cannot be analyzed in sampler analysis. Actions Check the analysis parameter and click [Accept] in the help dialog box. The analysis of the sample is skipped, and the sampler analysis continues. Error recovery condition Click [Accept] in the help dialog box. 14-32 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Errors related to analysis Error messages PLT sampling error RBC sampling error Probable Cause 1) The density of the sample is inconsistent. 2) The detector suddenly became clogged. Actions 1) Click [Accept] in the help dialog box, mix the sample well, and then re-analyze. 2) Click [Accept] in the help dialog box. Once the device is in READY state, remove the clog from the RBC detector. For the details on removing a clog from the RBC detector, see Chapter 13. (➤P.13-11 "Chapter 13: 13.3.4 Clog removal from the RBC detector") Error recovery condition Click [Accept] in the help dialog box.
Error messages PLT-F sampling error RET sampling error WDF sampling error WNR sampling error WPC sampling error Probable Cause 1) The density of the sample is inconsistent. 2) The flowcell has suddenly become clogged. Actions 1) Click [Accept] in the help dialog box, mix the sample well, and then re-analyze. 2) Click [Accept] in the help dialog box. Once the device is in READY state, rinse the flowcell. For the details on rinsing the flowcell, see Chapter 13.
(➤P.13-18 "Chapter 13: 13.3.9 Rinse flowcell") Error recovery condition Click [Accept] in the help dialog box. 14-33 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Error messages WDF channel error PLT-F channel error WNR channel error WPC channel error PLT channel error RBC channel error Probable Cause 1) The density of the sample is inconsistent. 2) Because of external noise, the number of particles has exceeded the limit of display range.
Actions 1) Click [Accept] in the help dialog box, mix the sample well, and then re-analyze. 2) Keep the noise source away from the Main Unit. Click [Accept] in the help dialog box, and then re-analyze. Error recovery condition Click [Accept] in the help dialog box. Error messages RET channel error Probable Cause 1) 2) 3) 4) Actions 1) Click [Accept] in the help dialog box, mix the sample well, and then re-analyze. 2) Click [Accept] in the help dialog box. Once the device is in READY state, rinse the flowcell. For the details on rinsing the flowcell, see Chapter 13. (➤P.13-18 "Chapter 13: 13.3.9 Rinse flowcell") 3) Click [Accept] in the help dialog box. Once the device is in READY state, rinse the flowcell. For the details on rinsing the flowcell, see Chapter 13. (➤P.13-18 "Chapter 13: 13.3.9 Rinse flowcell") 4) Click [Accept] in the help dialog box. Once the device is in READY state, remove the air bubbles from the flowcell. For the details on removing air bubbles from the flowcell, see Chapter 13. (➤P.13-17 "Chapter 13: 13.3.8 Remove air bubbles from flowcell") The density of the sample is inconsistent.
The flowcell is clogged.
The flowcell is dirty. Air bubbles have formed in the flowcell.
Error recovery condition Click [Accept] in the help dialog box. 14-34 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Error messages HGB error Probable Cause The HGB background value or the HGB sample value has fallen out of the specified range. Actions Click [Accept] in the help dialog box, and then re-analyze.
Error recovery condition Click [Accept] in the help dialog box. Error messages RBC detector clog Bubbles in RBC detector Probable Cause 1) The detector is clogged. 2) Air bubbles have formed in the detector. Actions Click [Execute] in the help dialog box, and then remove the clog from the RBC detector. For the details on removing a clog from the

RBC detector, see Chapter 13. (➤P.13-11 "Chapter 13: 13.3.4 Clog removal from the RBC detector") Error recovery condition The clog is successfully removed from the RBC detector. Error messages Low count error Probable Cause The piercer or the tubing of the WB aspiration line is clogged. Actions Click [Accept] in the help dialog box. Once the device is in READY state, perform an auto rinse. If the error persists, perform cleaning. If the error still persists, replace the piercer. For the details on auto rinse, see Chapter 13. (➤P.13-7 "Chapter 13: 13.3.2 Perform auto rinse") For the details on cleaning, see Chapter 13. (➤P.13-9 "Chapter 13: 13.3.3 Perform cleaning") For the details on replacing the piercer, see Chapter 13. (➤P.13-46 "Chapter 13: 13.5.2 Replace the piercer") Error recovery condition Click [Accept] in the help dialog box. Error messages Data Errors Probable Cause The analyzed value has fallen out of the specified range of upper/lower limits. Actions Check the analyzed data, and revise the specified upper and lower limits. Error recovery condition Click [Accept] in the help dialog box. 14-35 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Error messages Analysis result is high Probable Cause When body fluid analysis was performed, analysis data with high values that may affect the next analysis results were obtained*. * The availability of this function depends on your system configuration. Actions Remove the sample tube from the device. Click [Execute] in the help dialog box to perform a background check. For the details on background check of body fluid mode, see Chapter 9. (➤P.9-11 "Chapter 9: 9.4 Body fluid analysis") Error recovery condition The background check completes successfully.

Error messages Background check error Probable Cause 1) 2) 3) 4) Actions 1) Click [Execute] in the help dialog box, and then perform an auto rinse. For the details on auto rinse, see Chapter 13. (➤P.13-7 "Chapter 13: 13.3.2 Perform auto rinse") 2) Click [Execute] in the help dialog box, and then perform an auto rinse. For the details on auto rinse, see Chapter 13. (➤P.13-7 "Chapter 13: 13.3.2 Perform auto rinse") 3) Click [Execute] in the help dialog box, and then perform an auto rinse. For the details on auto rinse, see Chapter 13. (➤P.13-7 "Chapter 13: 13.3.2 Perform auto rinse") 4) Replace the reagent with a new one. For the details on replacing a reagent, see Chapter 13. (➤P.13-30 "Chapter 13: 13.4 Replace reagents") Air bubbles have formed in the detector. The detector is clogged. The detector is dirty.

The reagent is defective. Error recovery condition The value of the background check is within the acceptable range. 14-36 XN-1000 Instructions for Use Revised August 2013 Chapter 14 Troubleshooting Errors related to covers Error messages Front cover open error Probable Cause The top bottom cover opened during analysis. Actions Remove the sample tubes from the device, and then close the bottom front cover. Click [Execute] in the help dialog box. Restart the device. Error recovery condition Restart the device. Error messages Front cover is open Probable Cause 1) The bottom front cover opened. 2) The sensor on the bottom front cover is malfunctioned. Actions 1) Close bottom front cover. 2) The device needs to be serviced.

Contact your Sysmex service representative. Error recovery condition 1) Close the bottom front cover. 2) - Error messages FCM detector cover is open.

Probable Cause 1) The FCM cover is open. 2) The sensor on the FCM cover is malfunctioned. Actions Contact your Sysmex service representative. Error recovery condition - Error messages RBC detector cover is open. Probable Cause 1) The RBC cover is open. 2) The sensor on the RBC cover is malfunctioned. Actions 1) Close the RBC cover. 2) The device needs to be serviced. Contact your Sysmex service representative. Error recovery condition 1) Close the RBC cover. 2) - 14-37 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Error messages Fluorocell WNR cover is open Fluorocell WDF cover is open Fluorocell WPC cover is open Fluorocell RET cover is open Fluorocell PLT cover is open Probable Cause 1) The dye cover opened during analysis. 2) The sensor on the dye cover is malfunctioned. Actions 1) Close the dye cover. 2) The device needs to be serviced. Contact your Sysmex service representative. Error recovery condition 1) Close the dye cover. 2) - Errors related to the laser Error messages Laser output error Probable Cause The laser output has exceeded the control range. Actions Remove the sample tubes and racks from the device, and then turn OFF and ON the main power to the system. The laser needs to be replaced. Contact your Sysmex service representative. Error recovery condition - Error messages Laser life Probable Cause It is time to replace the laser. Actions The laser needs to be replaced. Contact your Sysmex service representative. Error recovery condition - 14-38 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Errors related to the system Error messages Analyzer barcode reader communication error Probable Cause There was a communication error between the analyzer and the barcode reader. Actions Remove the sample tubes and racks from the device, and then turn OFF and ON the main power to the system. If the error persists, contact your Sysmex service representative. Error recovery condition - Error messages Sampler barcode reader communication error Probable Cause There was a communication error between the sampler and the barcode reader. Actions Remove the sample tubes and racks from the device, and then turn OFF and ON the main power to the system. If the error persists, contact your Sysmex service representative. Error recovery condition - Error messages Communication error during sampler analysis. Probable Cause Communication with the analyzer has been disconnected in sampler analysis. Actions Remove the sample tubes and racks from the device, check the connection with the analyzer. Error recovery condition Click [Accept] in the help dialog box.

Error messages RFID communication error Probable Cause Communication with the RFID unit has been disconnected. Actions Remove the sample tubes and racks from the device, and then turn OFF and ON the main power to the system.

If the error persists, contact your Sysmex service representative. Error recovery condition - Error messages Instrument communication error Probable Cause There was a communication error between the device and the IPU. Actions Remove the sample tubes and racks from the device, and then turn OFF and ON the main power to the system.

Error recovery condition Power OFF 14-39 XN-1000 Instructions for Use Revised December 2012 Chapter 14 Troubleshooting Error messages Internal Error Probable Cause An error occurred in the operation of the program. Actions Turn OFF the main power. Contact your Sysmex service representative. Error recovery condition - Errors related to quality control Error messages L-J Control Error X-barM control error X-bar control error Probable Cause An abnormality was detected in the quality control data.

Actions In the QC chart, check the parameter that exceeded the QC limits, and then click [Accept]. Perform calibration as necessary. For details on QC charts, see Chapter 8. (➤P.8-18 "Chapter 8: 8.5.2 QC Chart screen") Error recovery condition Click [Accept] in the help dialog box. Error messages Control has expired. Probable Cause The control blood has expired.

Actions Replace the control blood by a new lot. Register the lot information, and then click [Accept] in the help dialog box. For the details on registering lot information, see Chapter 8. (➤P.8-4 "Chapter 8: 8.3 Registering and modifying a QC file (lot information input)") Error recovery condition Click [Accept] in the help dialog box. Error messages Control is not entered. Probable Cause Control blood with an unregistered lot number was used. Actions Register the lot information of the control blood, and then click [Accept] in the help dialog box. For the details on registering lot information, see Chapter 8. (➤P.8-4 "Chapter 8: 8.3 Registering and modifying a QC file (lot information input)") Error recovery condition Click [Accept] in the help dialog box. 14-40 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Error messages QC not executed. Probable Cause It is time to perform QC analysis. Actions Perform QC analysis, and then click [Accept] in the help dialog box.

For the details on quality control, see Chapter 8. (➤P.8-11 "Chapter 8: 8.4 Perform QC analysis") Error recovery condition Click [Accept] in the help dialog box. Error messages WNR Scattergram sensitivity error WDF Scattergram sensitivity error WPC Scattergram sensitivity error RET Scattergram sensitivity error PLT-F Scattergram sensitivity error Probable Cause A numerical value for a parameter in the scattergram is outside the specified range. Actions Check the scattergram. Error recovery condition Click [Accept] in the help dialog box. Error messages Check Measurement Mode Probable Cause The analysis mode and the type of control blood are not compatible. Actions Check the type of analysis mode and control blood.

Error recovery condition Click [Accept] in the help dialog box. Errors related to user maintenance and warnings Error messages Cleaning is required. Probable Cause It is time to perform cleaning. Actions Perform cleaning, and then click [Accept] in the help dialog box. For the details on cleaning, see Chapter 13. (➤P.13-9 "Chapter 13: 13.3.3 Perform cleaning") Error recovery condition Click [Accept] in the help dialog box. 14-41 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Error messages Cleaning is required (warning) Probable Cause Cleaning needs to be performed. Actions Click [Execute] in the help dialog box, and then perform cleaning. For the details on cleaning, see Chapter 13. (➤P.13-9 "Chapter 13: 13.3.3 Perform cleaning") Error recovery condition Cleaning completes successfully. Error messages CELLPACK DCL has expired SULFOLYSER has expired Lysercell WNR has expired Lysercell WDF has expired Lysercell WPC has expired CELLPACK DFL has expired Probable Cause The reagent has expired. Actions Click [Execute] in the help dialog box, and then replace the reagent with a new one. For the details on replacing a reagent, see Chapter 13. (➤P.13-32 "Chapter 13: 13.4.3 Replace a new dilution/hemolytic agent"). Error recovery condition Replace the reagent. Error messages Fluorocell WNR has expired Fluorocell WDF has expired Fluorocell WPC has expired Fluorocell RET has expired Fluorocell PLT has expired Probable Cause The reagent has expired. Actions Replace the reagent with a new one. For the details on replacing a reagent, see Chapter 13.

(➤P.13-38 "Chapter 13: 13.4.5 Replace a new dye") Error recovery condition Replace the reagent.

Error messages CELLPACK DST has expired Probable Cause The CELLPACK DST has expired. Actions Replace the CELLPACK DST with a new one. For the details on replacing a CELLPACK DST, see Chapter 13. (➤P.13-35 "Chapter 13: 13.4.4 Replace with new CELLPACK DST") Error recovery condition Replace the CELLPACK DST. 14-42 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Error messages Piercer replacement is required. Probable Cause It is time to replace the piercer. Actions Turn OFF the main power to the analyzer, and then replace the piercer.

For the details on replacing the piercer, see Chapter 13. (➤P.13-46 "Chapter 13: 13.5.2 Replace the piercer") Error recovery condition Replace the piercer.

Error messages Press Start SW Probable Cause The set time (5 hours) has elapsed since the analyzer entered the standby state. Actions Press the start switch. Error recovery condition Press the start switch. Error messages CELLCLEAN AUTO is not placed correctly Probable Cause The CELLCLEAN AUTO is not placed correctly. Actions Place the CELLCLEAN AUTO in the specified position again. (➤P.6-16 "Chapter 6: 6.6 Shutdown") Error recovery condition Click [Accept] in the help dialog box.

Error messages A sample other than CELLCLEAN AUTO has been placed. Probable Cause A sample other than CELLCLEAN AUTO is placed in a rack in which CELLCLEAN AUTO is placed in the specified position. Actions Remove sample tubes that are not CELLCLEAN AUTO from the rack and place the rack again. (➤P.6-16 "Chapter 6: 6.6 Shutdown") Error recovery condition Click [Accept] in the help dialog box. 14-43 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Error messages Unable to correctly detect CELLCLEAN AUTO. Probable Cause The CELLCLEAN AUTO information read by the sampler does not match the CELLCLEAN AUTO information read by the analyzer. Actions Place the CELLCLEAN AUTO again. (➤P.6-16 "Chapter 6: 6.6 Shutdown") Error recovery condition Click [Accept] in the help dialog box. Error messages CELLCLEAN AUTO has already been used. Probable Cause A used CELLCLEAN AUTO has been installed. Actions Replace the CELLCLEAN AUTO with a new one. Error recovery condition Click [Accept] in the help dialog box. Error messages Cannot recognize CELLCLEAN AUTO Probable Cause 1) The barcode label on the CELLCLEAN AUTO is dirty. 2) The position of the barcode label on the CELLCLEAN AUTO is off. Actions Check the position and cleanliness of the barcode label. Error recovery condition Click [Accept] in the help dialog box. Error messages CELLCLEAN AUTO has expired. Probable Cause The CELLCLEAN AUTO has expired. Actions Replace the CELLCLEAN AUTO with a new one. Error recovery condition Click [Accept] in the help dialog box. 14-44 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Errors related to the dye cartridge holder Error messages Wrong reagent installed in Fluorocell WNR holder Wrong reagent installed in Fluorocell WDF holder Wrong reagent installed in Fluorocell WPC holder Wrong reagent installed in Fluorocell RET holder Wrong reagent installed in Fluorocell PLT holder Probable Cause The dye cartridge holder and the dye that was installed are different. Actions Set a correct reagent. For the details on setting a reagent, see Chapter 13. (➤P.13-38 "Chapter 13: 13.4.5 Replace a new dye") Error recovery condition Set a correct reagent. Error messages Fluorocell WNR is not installed Fluorocell WDF is not installed Fluorocell WPC is not installed Fluorocell RET is not installed Fluorocell PLT is not installed Probable Cause The dye has not been installed in the dye cartridge holders. Actions Set a reagent. For the details on setting a reagent, see Chapter 13. (➤P.13-38 "Chapter 13: 13.4.5 Replace a new dye") Error recovery condition Set a reagent. Error messages Fluorocell WNR has already been used Fluorocell WDF has already been used Fluorocell WPC has already been used Fluorocell RET has already been used Fluorocell PLT has already been used Probable Cause A used dye has been installed. Actions Replace the reagent with a new one. For the details on replacing a reagent, see Chapter 13.

(➤P.13-38 "Chapter 13: 13.4.5 Replace a new dye") Error recovery condition Set a new reagent. 14-45 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Error messages Cannot recognize Fluorocell WNR information Cannot recognize Fluorocell WDF information Cannot recognize Fluorocell WPC information Cannot recognize Fluorocell RET information Cannot recognize Fluorocell PLT information Probable Cause The ID of the dye is damaged. Actions Click [Execute] in the help dialog box, click the reagent name, and register the reagent information.

Error recovery condition Register reagent information. Error messages Fluorocell WNR RFID tag error Fluorocell WDF RFID tag error Fluorocell WPC RFID tag error Fluorocell RET RFID tag error Fluorocell PLT RFID tag error Probable Cause Cannot write any data to the dye ID. Actions Replace the reagent that has the correct ID. For the details on replacing a reagent, see Chapter 13. (➤P.13-38 "Chapter 13: 13.4.5 Replace a new dye") Error recovery condition Set the reagent that has the correct ID. 14.4 Check the error log 14.4.1 Display the error log The history of error occurrences can be viewed. The log data shows the information regarding the occurrence and the clearing of each error, and comments can be entered. The log can be printed or output as a file in CSV format.

For details, see Chapter 13.

(➤P.13-64 "Chapter 13: 13.6 About the history screen", P.13-72 "Chapter 13: 13.7 About the RU history screen") 14-46 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting 14.5 Check the status of the device You can check the operation or the operation count of each unit.

14.5.1 Test proper operation of the device (sensor) You can verify the temperature, pressure, and the operation status of each unit. The data display is updated every 0.5 seconds. Sensor screen for the analyzer Follow the steps below to display the sensor screen for the analyzer. 1 Display the Maintenance menu. (➤P.13-2 "Chapter 13: 13.1.2 2 Maintenance menu") Click [Analyzer Sensor Display]. The dialog box on the right appears. Shortcut buttons The buttons of the dialogs that appear in the analyzer sensor display screen are displayed. Click a button of a dialog that does not currently appear to display the dialog. [Pressure (units: Mpa)] Displays the pressure for each unit. [Temperature (units: °C)] Displays the temperatures of each unit within the instrument as well as the ambient temperature. The items that are displayed vary depending on the analyzer that is connected. [HGB] Displays the conversion value for hemoglobin.

Nothing is displayed during analysis. [Aspiration Sensor] Displays the conversion value for the blood aspiration sensor. Nothing is displayed during analysis. [Laser Current] Displays the output current of the laser. Next button Click to display the [Sensor 2] dialog box. Shortcut buttons Next button [Sensor 1] dialog box 14-47 XN-1000 Instructions for Use Revised August 2012 Chapter 14 3 Troubleshooting Click Next button. The dialog box on the right appears. Shortcut buttons Sensor operation status display area Back button [Sensor 2] dialog box Shortcut buttons The buttons of the dialogs that appear in the analyzer sensor display screen are displayed. Click a button of a dialog that does not currently appear to display the dialog. Sensor operation status display area Displays the operation status of each sensor. Sensors that are ON are displayed in red, and those that are OFF are displayed in white. The following is a list of sensor numbers and sensor names. Sensor Number Sensor Name [01] Float switch 1 status (WC1) [02] Float switch 2 status (WC2) [03] Float switch 3 status (FCM) [04] Float switch 4 status (DIL) [05] Float switch 5 status (RBC) [06] Float switch 6 status [07] Start switch [08] Mode switch [09] FCM cover [10] Front cover sensor 1 [11] Front cover sensor 2 [12] RBC detector cover sensor [13] Water leak detecting sensor 1 [14] Water leak detecting sensor 2 [15] Water leak detecting sensor 3 [16] Waste tank sensor [17] Dye cartridge holder monitor 1 (WNR) [18] Dye cartridge holder monitor 2 (WDF) 14-48 XN-1000 Instructions for Use Revised February 2013 Chapter 14 Troubleshooting Back button [19] Dye cartridge holder monitor 3 (WPC) [20] Dye cartridge holder monitor 4 (RET) [21] Dye cartridge holder monitor 5 (PLT) [25] Sample tube identification sensor [26] Hand Z-axis tube holder catch position [27] Hand Z-axis sampler catch position [28] Tube presence sensor [29] Sample tube stabilizing unit initial position [38] Water leak sensor error monitor 1 [39] Water leak sensor error monitor 2 [40] Water leak sensor error monitor 3 [41] Prism sensor (CELLPACK DCL) [43] Prism sensor (SULFOLYSER) [44] Prism sensor (Lysercell WNR) [45] Prism sensor (Lysercell WDF) [46] Prism sensor (CELLPACK DFL) [47] Prism sensor (Lysercell WPC) [49] Prism sensor (Fluorocell WNR) [50] Prism sensor (Fluorocell WDF) [51] Prism sensor (Fluorocell WPC) [52] Prism sensor (Fluorocell DFL) [53] Prism sensor (Fluorocell PLT) [61] Micro collection tube monitor [62]* Blood presence monitor [65] Reservoir tank: Float switch 1 status (CELLPACK DCL high) [66] Reservoir tank: Float switch 2 status (CELLPACK DCL low) [67] Reservoir tank: Float switch 3 status (CELLPACK DFL) [68] Reservoir tank: Float switch 4 status (Lysercell WPC) [69] Reservoir tank: Float switch 5 status (SULFOLYSER) [70] Reservoir tank: Float switch 6 status (Lysercell WDF) [71] Reservoir tank: Float switch 7 status (Lysercell WNR) [75] Reservoir tank: Prism sensor (CELLPACK DCL1) [81] Reservoir tank: Prism sensor (CELLPACK DCL2) Click to display the [Sensor 1] dialog box. * Only when using the sampler (SA-01) 14-49 XN-1000 Instructions for Use Revised May 2014 Chapter 14 Troubleshooting Sensor screen for the sampler When using the sampler (SA-10), follow the steps below to display the sampler sensor screen. 1 Display the Maintenance menu.

(➤P.13-2 "Chapter 13: 13.1.2 Maintenance menu") 2 Click [Sampler Sensor Display].

The dialog box on the right appears. Sensor operation status display area Sensor operation status display area Displays the operation status of each sensor. Sensors that are ON are displayed in red, and those that are OFF are displayed in white. The following is a list of sensor numbers and sensor names. Sensor Number Sensor Name [03] Sample tube monitoring sensor [04] Left sampler pool rack full sensor [05] Return prevention stopper monitoring sensor [06] Rack feed-in arrival monitoring sensor [07] Blood monitoring sensor [08] Right sampler pool rack detecting sensor [09] Analysis line termination monitoring sensor 14-50 XN-1000 Instructions for Use Revised February 2013 Chapter 14 Troubleshooting 14.5.2 Check operation count (counter) You can check the analysis count for each analysis mode/channel, or the operation count of each unit (or oscillation time of the laser). For some units, you can reset or save the operation count. To reset the operation count, the analyzer and the sampler must be in READY state. Otherwise, the operation count cannot be reset. Note: Other than the piercing count, all operation/analysis counts are for reference only. They cannot be reset. Follow the steps below to check the counters. 1 Display the Maintenance menu. (➤P.13-2 "Chapter 13: 13.1.2 2 Maintenance menu") Click [Counter]. The dialog box on the right appears. Shortcut buttons The buttons of the dialogs that appear in the operation counter screen are displayed. Click a button of a dialog that does not currently appear to display the dialog. [Mode] Displays the name of the analysis mode. [WB]: Whole blood analysis [PD]: Dilution analysis [BF]*: Body fluid analysis [HPC]*: HPC Analysis [hsA]*: hsA Analysis [QC]: Quality control analysis [Maintenance Measurement]: Background check (Includes a background check for body fluid and hsA analysis*) [Total]: All analysis [Counter] Displays the analysis count by analysis mode. [Test] Displays the name of the test. [Total] Displays the total analysis count by discrete test. [Rerun] Displays for each discrete test the number of reruns of an analysis with the same parameters as the first test. [Reflex] Displays for each discrete test the number of analysis with additional parameters after the first test. [Repeat] Displays for each discrete test the number of retries of an analysis due to an error in the first test. Next button Click to display the [Pump Counter] dialog box. Shortcut buttons Next button [Analysis Mode Counter] dialog box * The availability of these functions depends on your system configuration. 14-51 XN-1000 Instructions for Use Revised December 2012 Chapter 14 3 Troubleshooting Click Next button. The dialog box on the right appears. Shortcut buttons The buttons of the dialogs that appear in the operation counter screen are displayed.

Click a button of a dialog that does not currently appear to display the dialog. [Pump] Displays the name of the pump. [Counter] Displays the operation count by pump. Back button Click to display the [Analysis Mode Counter] dialog box. Next button Click to display the [Unit Counter] dialog box. Shortcut buttons Next button Back button [Pump Counter] dialog box 4 Click Next button. The dialog box on the right appears.

5 Shortcut buttons The buttons of the dialogs that appear in the operation counter screen are displayed. Click a button of a dialog that does not currently appear to display the dialog. [Unit] Displays the unit name for which the operation count is being taken. [Counter] Displays the operation count of each unit (for laser, displays the oscillation time).

[Reset Piercer] Click to set the piercer counter value to zero. Back button Click to display the [Pump Counter] dialog box.

[Save] Click to store the counter value before it is reset to zero in the analyzer memory. Shortcut buttons Back button [Unit Counter] dialog box Click [Close]. The dialog box closes. 14-52 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting 14.6 Test proper operation of the device You can perform various tests to verify proper operation of each unit, or to identify the cause of an error that occurred in the analyzer. To perform the tests, the analyzer and sampler must be in READY state. Otherwise, the tests cannot be performed. Analysis is not possible during the test process. If the test did not complete successfully, the help dialog box appears in the IPU. Troubleshoot according to the message displayed in the [Action] field in the help dialog box. 14.6.1 An operation test on the barcode reader You can perform an operation test on the barcode reader on the analyzer or the sampler. Analyzer barcode reader operation test Follow the procedure below to test the operation of the analyzer barcode reader. 1 Display the Maintenance menu. (➤P.13-2 "Chapter 13: 13.1.2 2 Maintenance menu") Click [Analyzer BR Test]. The dialog box on the right appears. [Sample No.] Displays the sample number that was read from the barcode. [CD] Displays the check digit of the barcode. [Type] Displays the type of barcode. Read result display area Displays the result from the read operation. One of the following symbols is displayed, depending on the result. If there was no problem with reading, nothing is displayed. [E]: Barcode reader reading error or invalid check digit. [+]: A value that is longer than the specified number of digits was read. [-]: A value that is shorter than the specified number of digits was read. Read result display area 3 Set the sample tube into the tube holder, with the barcode affixed. 4 Click [Start]. The read test starts.

If a previous test result was displayed, it is cleared when the test begins. Wait until it is complete. Once the read operation completes, the result is displayed. 14-53 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting Sampler barcode reader operation test When using the sampler (SA-10), follow the steps below to test the operation of the sampler barcode reader.

1 Display the Maintenance menu. (➤P.13-2 "Chapter 13: 13.1.2 Maintenance menu") 2 Click [Sampler BR Test]. The dialog box on the right appears. Read result display area [Sample No.] Displays the sample number that was read from the barcode. [CD] Displays the check digit of the barcode. [Type] Displays the type of barcode.

Read result display area Displays the result from the read operation.

One of the following symbols is displayed, depending on the result. If there was no problem with reading, nothing is displayed. [E]: Barcode reader reading error or invalid check digit. [+]: A value that is longer than the specified number of digits was read. [-]: A value that is shorter than the specified number of digits was read. 3 Insert the sample tubes into the rack, with the bar codes affixed. Place the rack on the analysis line. 4 Click [Start]. The read test starts. If a previous test result was displayed, it is cleared when the test begins. Wait until it is complete. Once the read operation completes, the result is displayed. 14-54 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting 14.6.2 An operation test on the WB aspiration motor Follow the steps below to perform an operation test on the WB aspiration motor. 1 Display the Maintenance menu.

(➤P.13-2 "Chapter 13: 13.1.2 2 Maintenance menu") Click [WB Aspiration Motor Test]. The window appears, and the WB aspiration motor test begins.

Wait until it is complete. Once the test complete successfully, the window closes automatically. 14.6.3 An operation test on the sheath motor Follow the steps below to perform an operation test on the sheath motor. 1 Display the Maintenance menu. (➤P.13-2 "Chapter 13: 13.1.2 2 Maintenance menu") Click [Sheath Motor Test]. The window appears, and the sheath motor test begins. Wait until it is complete. Once the test complete successfully, the window closes automatically. 14-55 XN-1000 Instructions for Use Revised August 2012 Chapter 14 14.6.4 Troubleshooting An operation test on the aspiration unit motor Follow the steps below to perform an operation test on the aspiration unit motor.

1 Display the Maintenance menu. (➤P.13-2 "Chapter 13: 13.1.2 Maintenance menu") 2 Click [Aspiration Unit Motor Test]. The window appears, and the aspiration unit motor test begins. Wait until it is complete. Once the test complete successfully, the window closes automatically. 14.6.5 An operation test on the tube holder motor Follow the steps below to perform an operation test on the tube holder motor. 1 Display the Maintenance menu. (➤P.13-2 "Chapter 13: 13.1.2 Maintenance menu") 2 Click [Tube Holder Motor Test]. The window appears, and the tube holder motor test begins.

Wait until it is complete. Once the test complete successfully, the window closes automatically. 14-56 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting 14.6.6 An operation test on the sampler Operation tests vary depending on the type of sampler. When using the sampler (SA-10) You can test the operation of the two belts that transport the racks horizontally on the analysis line.

Facing the sampler, the belt that is closer to the sampler is the front belt, and the belt that is furthest out from the sampler is the back belt. Follow the steps below to perform an operation test on the sampler. 1 Display the Maintenance menu. (➤P.13-2 "Chapter 13: 13.1.2 2 Maintenance menu") Click [Sampler Operation Test]. The dialog box on the right appears. 3 Set the rack on the analysis line. 4 Click [Front Belt Sampler Operation Test Start] or [Back Belt Sampler Operation Test Start]. A window appears, and the test for the clicked belt begins.

Wait until it is complete. Once the test complete successfully, the window closes automatically. 14-57 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting When using the sampler (SA-01) You can test rack feed-in from the sampler to the analysis line, rack shifting on the analysis line, and rack feedout from the analysis line to the sampler. Follow the steps below to perform an operation test on the sampler. 1 Display the Maintenance menu. (➤P.13-2 "Chapter 13: 13.1.2 Maintenance menu") 2 Click [Sampler Operation Test]. The dialog box on the right appears. 3 Place the rack in the sampler or on the analysis line. To test [Rack feed-in], place the rack in the sampler. To test [Rack shift] or [Rack feed-out], place the rack on the analysis line. 4 Click [Front Belt Sampler Operation Test Start] or [Back Belt Sampler Operation Test Start]. A window appears, and the test for the clicked belt begins. Wait until it is complete. Once the test complete successfully, the window closes automatically. 14-58 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting 14.6.7 An operation test on the tube grabber Follow the steps below to perform an operation test on the tube grabber. 1 Display the Maintenance menu. (➤P.13-2 "Chapter 13: 13.1.2 2 Maintenance menu") Click [Hand Test]. The window appears, and the operation test of the tube grabber begins.

Wait until it is complete. Once the test complete successfully, the window closes automatically. 14-59 XN-1000 Instructions for Use Revised August 2012 Chapter 14 Troubleshooting 14-60 XN-1000 Instructions for Use Revised August 2012 Chapter 15 Technical Information Chapter 15 Technical Information This chapter explains technical information such as specifications and principles. 15.1 Performance/specifications Note: Channels and analysis parameters are specified depending on the connected analyzer.

For details, see Chapter 1. (➤P.1-4 "Chapter 1: 1.3 Analysis parameters") Operating Environment (Ambient temperature) 15 to 30°C (same with the temperature of the supplied reagent) Operating Environment (Relative humidity) 30 to 85% Storage Condition (Transportation) Ambient temperature: -10 to 60°C Relative humidity: 30 to 95% (no condensation) Atmospheric pressure: 70 to 106 kPa Dimensions (including the sampler) Width: Height: Depth: Total weight (including the sampler) 645 mm (SA-10), 520 mm (SA-01) 855 mm (SA-10), 840 mm (SA-01) 755 mm (SA-10), 680 mm (SA-01) Approx. 78 kg (SA-10), Approx. 70 kg (SA-01) Pneumatic unit dimensions Width: Height: Depth: 280 mm 400 mm 355 mm Pneumatic unit weight Approx. 17 kg Power supply Analyzer (XN-10, XN-20) AC100 to 240V (50 / 60 Hz) Sampler (SA-10) AC100 to 240V (50 / 60 Hz) Pneumatic unit AC100 to 117V (50 / 60 Hz) AC220 to 240V (50 / 60 Hz) Power consumption Analyzer (XN-10, XN-20) 270 VA or less Sampler (SA-10) 110 VA or less Pneumatic unit 50 Hz: 230 VA or less (100 - 117V), 220 VA or less (220 - 240V) 60 Hz: 280 VA or less (100 - 117V), 250 VA or less (220 - 240V) Laser class Class I (IEC60825-1:2007) Protection type Class I Safety standard IEC61010-1:2001, IEC61010-2-081:2001+A1, IEC61010-2-101:2002 15-1 XN-1000 Instructions for Use Revised August 2012 Chapter 15 Technical Information Throughput [Whole blood] mode*1 [Low WBC] mode Values of the analyzer as a standalone unit are indicated below. CBC 100 samples/hour CBC+DIFF 100 samples/hour (88 samples/hour*1) 2 CBC+DIFF+WPC* 88 samples/hour (68 samples/hour*1) 2 CBC+DIFF+RET* 83 samples/hour (65 samples/hour*1) 2 83 samples/hour CBC+RET* CBC+DIFF+WPC+RET*2 71 samples/hour (57 samples/hour*1) 2 68 samples/hour CBC+PLT-F* CBC+DIFF+PLT-F*2 68 samples/hour (55 samples/hour*1) 2 CBC+DIFF+WPC+PLT-F* 53 samples/hour (45 samples/hour*1) 2 47 samples/hour (41 samples/hour*1) CBC+DIFF+RET+PLT-F* 2 CBC+RET+PLT-F* 47 samples/hour 47 samples/hour (41 samples/hour*1) CBC+DIFF+WPC+RET+PLT-F*2 *1 [Low WBC] mode. *2 These items do not appear with all analyzer types.

Throughput [Pre-Dilution] mode Values of the analyzer as a standalone unit are indicated below.

CBC 90 samples/hour CBC+DIFF 90 samples/hour CBC+DIFF+RET* 53 samples/hour CBC+DIFF+PLT-F* 52 samples/hour CBC+DIFF+RET+PLT-F* 39 samples/hour * These items do not appear with all analyzer types. Throughput [Body Fluid] mode*2 Values of the analyzer as a standalone unit are indicated below. 40 samples/hour Throughput [HPC] mode*3 Values of the analyzer as a standalone unit are indicated below. CBC+DIFF+RET+PLT-F+WPC* 16 samples/hour CBC+DIFF+RET+WPC* 18 samples/hour * These items do not appear with all analyzer types. Sample Volume Required [Whole blood] mode [Low WBC] mode Sampler analysis: 88 µL Manual analysis: 88 µL Micro analysis: 88 µL Micro analysis*: 88 µL RBT analysis: 88 µL * Analysis using a micro collection tube. Sample Volume Required [Pre-Dilution] mode Micro analysis: 70 µL (The blood volume required for dilution is 20 µL.) Micro analysis*: 70 µL (The blood volume required for dilution is 20 µL.) * Analysis using a micro collection tube. Sample Volume Required [Body Fluid] mode*2 Manual analysis: 88 µL Micro analysis: 88 µL Micro analysis*: 88 µL * Analysis using a micro collection tube.

Sample Volume Required [HPC] mode*3 Manual analysis: 190 µL Micro analysis: 190 µL Micro analysis*: 190 µL * Analysis using a micro collection tube. *1 When a Raised Bottom Tube is used, processing throughput decreases.

*2 The body fluid analysis can only be performed if the instrument offers the body fluid analysis mode.

3 The HPC analysis can only be performed if the instrument offers the HPC analysis mode. 15-2 XN-1000 Instructions for Use Revised May 2014 Chapter 15 Technical Information Analysis parameters For details on analysis parameters, see Chapter 1. (➤P.1-6 "Chapter 1: 1.3 Analysis parameters") Display range WBC: 0.00 to 999.99 x 103/µL RBC: 0.00 to 99.99 x 106/µL HGB: 0.0 to 30.0 g/dL HCT: 0.0 to 100.0% PLT: 0 to 9999 x 103/µL NRBC#: 0.00 to 999.99 x 103/µL NRBC%: 0.0 to 9999.9 / 100WBC 1 0.00 to 99.99% RET% : 0.0000 to 0.9999 x 106/µL RET#*1: 1: 0.0 to 100.0% IRF* 0.0 to 100.0% LFR*1: 1: 0.0 to 100.0% MFR* 0.0 to 100.0% HFR*1: 0.0 to 999.9 pg RBC-He*1 -999.9 to 999 pg Delta-He*1 2 NEUT-RI* 0.0 to 999.9 FI 0.0 to 999.9 SI NEUT-GI*2 WBC-BF: 0.000 to 999.999 x 103/µL RBC-BF: 0.000 to 99.999 x 106/µL MN#: 0.000 to 999.999 x 103/µL PMN#: 0.000 to 999.999 x 103/µL MN%: 0.0 to 100.0% PMN%: 0.0 to 100.0% *1 These items do not appear with all analyzer types.

*2 The availability of these functions depends on your system configuration. Background limits WBC 0.10 x 103/µL or less RBC 0.02 x 106/µL or less HGB 0.1 g/dL or less 10 x 103/µL or less 10 x 103/µL or less PLT*1 10 x 103/µL or less PLT*2,4 3,4 PLT* 3 x 103/µL or less WBC-BF 0.001 x 103/µL or less RBC-BF 0.003 x 106/µL or less *1 PLT counted in the RBC/PLT channels (PLT particle size distribution). *2 PLT counted in the RET channels. *3 PLT counted in the PLT-F channels. *4 These items do not appear with all analyzer types. 15-3 XN-1000 Instructions for Use Revised May 2014 Chapter 15 Technical Information Analysis range [Whole blood] mode [HPC] mode*1 WBC RBC HGB HCT PLT NRBC# NRBC% RET% RET# 0.00 to 440.00 x 103/µL 0.00 to 8.60 x 106/µL 0.0 to 26.0 g/dL, 0.0 to 16.14 mmol/L 0.0 to 75.0% 0 to 5000 x 103/µL 0.00 to 20.00 x 103/µL 0.0 to 600.0 / 100WBC 0.00 to 30.00% 0.0000 to 0.7200 x 106/µL Analysis range [Pre-Dilution] mode WBC RBC HGB HCT PLT 0.00 to 100.00 x 103/µL 0.00 to 8.60 x 106/µL 0.0 to 26.0 g/dL, 0.0 to 16.14 mmol/L 0.0 to 75.0% 0 to 1000 x 103/µL Analysis range [Body Fluid] mode*2 WBC-BF RBC-BF TC-BF# 0.000 to 10.000 x 103/µL 0.000 to 5.000 x 106/µL 0.000 to 10.000 x 103/µL *1 The HPC analysis can only be performed if the instrument offers the HPC analysis mode. *2 The body fluid analysis can only be performed if the instrument offers the body fluid analysis mode.

15-4 XN-1000 Instructions for Use Revised August 2012 Chapter 15 Technical Information Precision (repeatability) [Whole blood] mode [HPC] mode*1 Indicated as coefficients of variation (95% reliability) when analysis of peripheral blood (samples with nucleated RBC for NRBC, samples with immature granulocyte for IG (same-day blood), diluted peripheral blood for PLT*2,4 and samples with at least RET# 0.020 × 106/µL for RET-He (same-day blood)) or control blood is repeated at least 10 times. (For NRBC and IG, abnormal samples of peripheral blood (samples with nucleated RBC for NRBC, samples with immature granulocyte for IG (same-day blood)) repeatedly analyzed at least 5 times.) WBC 3.0% or less (4.00 x 103/µL or more) RBC 1.5% or less (4.00 x 106/µL or more) HGB 1.0% or less HCT 1.5% or less MCV 1.0% or less MCH 2.0% or less MCHC 2.0% or less 1 4.0% or less (100 x 103/µL or more) PLT* 2,3 6.0% or less (100 x 103/µL or more) PLT* 2,4 PLT* 2.5% or less (PLT 100 x 103/µL or more) 5.0% or less (PLT 20 x 103/µL or more) RDW-SD 2.0% or less RDW-CV 2.0% or less PDW 10.0% or less MPV 4.0% or less P-LCR 15.0% or less PCT 6.0% or less NRBC# 25.0% or less, or within ±0.12 x 103/µL NRBC% 25.0% or less, or within ±1.5 NRBC% (WBC 4.00 x 103/µL or more) NEUT# 8.0% or less (1.20 x 103/µL or more) LYMPH# 8.0% or less (0.60 x 103/µL or more) MONO# 20.0% or less (0.20 x 103/µL or more) EO# 25.0% or less, or within ±0.12 x 103/µL BASO# 40.0% or less, or within ±0.06 x 103/µL NEUT% 8.0% or less (30.0 NEUT% or more, WBC 4.00 x 103/µL or more) LYMPH% 8.0% or less (15.0 LYMPH% or more, WBC 4.00 x 103/µL or more) MONO% 20.0% or less (5.0 MONO% or more, WBC 4.00 x 103/µL or more) EO% 25.0% or less, or within ±1.5 EO% (WBC 4.00 x 103/µL or more) BASO% 40.0% or less, or within ±1.0 BASO% (WBC 4.00 x 103/µL or more) IG# 25.0% or less or within ±0.12 x 103/µL (IG# 0.10 x 103/µL or more) IG% 25.0% or less or within ±1.5 IG% (IG% 2.0% or more, WBC 4.00 x 103/µL or more) 15-5 XN-1000 Instructions for Use Revised August 2012 Chapter 15 Technical Information Precision (repeatability) [Whole blood] mode [HPC] mode*1 RET%*2 RET#*2 IRF*2 15.0% or less (RBC 3.00 x 106/µL or more, RET% 1.00 to 4.00%) 15.0% or less (RBC 3.00 x 106/µL or more, RET% 1.00 to 4.00%) 30.0% or less (RBC 3.00 x 106/µL or more, RET% 1.00 to 4.00%, IRF 20.0% or more) 2 30.0% or less (RBC 3.00 x 106/µL or more, RET% 1.00 to 4.00%, LFR LFR* 20.0% or more) 50.0% or less (RBC 3.00 x 106/µL or more, RET% 1.00 to 4.00%, LFR MFR*2 20.0% or more) 2 100.0% or less or within ±2.0 HFR HFR* (RBC 3.00 x 106/µL or more, RET% 1.00 to 4.00%) 2 5.0% or less (RET# 0.0200 x 106/µL or more) RET-He* 2 5.0% or less RBC-He* 2 RET-He 5.0% or less, RBC-He 5.0% or less Delta-He* 3.0% or less (1.20 NEUT# x 103/µL or more) NEUT-RI*5 5 3.0% or less (1.20 NEUT# x 103/µL or more) NEUT-GI* IPF 25.0% or less (PLT 50 x 103/µL or more, IPF 3.0% or more) 20.0% or less (PLT 10 to 50 x 103/µL, IPF 10.0% or more) Indicates the coefficient of variation when peripheral blood (sample with HPC) is analyzed at least 5 times in succession, or the range of variation from the average value. 30.0% or less, or within ±15/µL HPC#*6 *1 PLT counted in the RBC/PLT channels (PLT particle size distribution). *2 These items do not appear with all analyzer types. *3 PLT counted in the RET channels.

*4 PLT counted in the PLT-F channels.

*5 The availability of these functions depends on your system configuration. *6 [HPC] mode. Precision (repeatability) [Pre-Dilution] mode Indicated as coefficients of variation (95% reliability) when analysis of diluted peripheral blood (samples with nucleated RBC for NRBC, samples with immature granulocyte for IG (same-day blood), and samples with at least RET# 0.020 × 106/µL for RET-He (same-day blood)) or control blood is repeated at least 10 times. (For NRBC and IG, abnormal samples of diluted peripheral blood (samples with nucleated RBC for NRBC, samples with immature granulocyte for IG (same-day blood)) repeatedly analyzed at least 5 times.) WBC 5.0% or less (4.00 x 103/µL or more) RBC 4.5% or less (4.00 x 106/µL or more) HGB 3.0% or less HCT 4.5% or less MCV 4.5% or less MCH 4.5% or less MCHC 6.0% or less 15-6 XN-1000 Instructions for Use Revised May 2014 Chapter 15 Technical Information Precision (repeatability) [Pre-Dilution] mode PLT*1 PLT*2,3 PLT*2,4 12.0% or less (100 x 103/µL or more) 13.0% or less (100 x 103/µL or more) 5.0% or less (PLT 100 x 103/µL or more) 10.0% or less (PLT 20 x 103/µL or more) RDW-SD 6.0% or less RDW-CV 6.0% or less PDW 20.0% or less MPV 8.0% or less P-LCR 36.0% or less PCT 12.0% or less NRBC# 50.0% or less, or within ±0.25 x 103/µL NRBC% 50.0% or less, or within ±3.0 NRBC% (WBC 4.00 x 103/µL or more) NEUT# 16.0% or less (1.20 x 103/µL or more) LYMPH# 16.0% or less (0.60 x 103/µL or more) MONO# 40.0% or less (0.20 x 103/µL or more) EO# 40.0% or less BASO# 50.0% or less, or within ±0.06 x 103/µL NEUT% 16.0% or less (30.0 NEUT% or more, WBC 4.00 x 103/µL or more) LYMPH% 16.0% or less (15.0 LYMPH% or more, WBC 4.00 x 103/µL or more) MONO% 40.0% or less (5.0 MONO% or more, WBC 4.00 x 103/µL or more) EO% 40.0% or less (WBC 4.00 x 103/µL or more) BASO% 50.0% or less, or within ±1.5 BASO% (WBC 4.00 x 103/µL or more) IG# 75.0% or less, or within ±0.36 x 103/µL (IG# 0.10 x 103/µL or more) IG% 75.0% or less, or within ±4.5 IG% (IG% 2.0% or more, WBC 4.00 x 103/µL or more) 2 35.0% or less (RBC 3.00 x 106/µL or more, RET% 1.00 to 4.00%) RET%* 2 RET#* 35.0% or less (RBC 3.00 x 106/µL or more, RET% 1.00 to 4.00%) 5 6.0% or less (1.20 NEUT# x 103/µL or more) NEUT-RI* 6.0% or less (1.20 NEUT# x 103/µL or more) NEUT-GI*5 IPF 40.0% or less (PLT 50 x 103/µL or more, IPF 3.0% or more) *1 PLT counted in the RBC/PLT channels (PLT particle size distribution). *2 These items do not appear with all analyzer types. *3 PLT counted in the RET channels. *4 PLT counted in the PLT-F channels. *5 The availability of these functions depends on your system configuration. Precision (repeatability) [Body Fluid] mode*2 Indicated as coefficients of variation when analysis of diluted samples of peripheral blood or control blood is repeated at least 10 times. WBC-BF 30.0% or less (0.005 to 0.015 x 103/µL) 15.0% or less (0.016 to 0.030 x 103/µL) 10.0% or less (0.031 to 0.050 x 103/µL) RBC-BF 40.0% or Max - Min ≤ 0.007 x 106/µL (0.003 to 0.050 x 106/µL) TC-BF# 30.0% or less (0.005 to 0.015 x 103/µL) 15.0% or less (0.016 to 0.030 x 103/µL) 10.0% or less (0.031 to 0.050 x 103/µL) *1 The HPC analysis can only be performed if the instrument offers the HPC analysis mode. *2 The body fluid analysis can only be performed if the instrument offers the body fluid analysis mode. 15-7 XN-1000 Instructions for Use Revised May 2014 Chapter 15 Technical Information Accuracy (blood cell count) [Whole blood] mode [HPC] mode*1 Indicated as the average value of the difference between the measured values of at least 100 samples of peripheral blood and values measured on a standard instrument or international standard methods*1 (HGB and HCT only). WBC within ±3% or ±0.20 x 103/µL RBC within ±2% or ±0.03 x 106/µL HGB within ±2% or ±0.2 g/dL HCT within ±3% or ±1.0 HCT MCV within ±3% or ±2.0 fL Indicated as a correlation factor with the reference data when at least 100 samples of peripheral blood are analyzed. The reference data are obtained by the standard analysis method or standard instrument method (IPF only) by the flow cytometry method based on the international standards.

within ±5% or ±10 x 103/µL PLT*2 3,5 within ±7% or ±10 x 103/µL PLT* 4,5 within ±5% or ±10 x 103/µL PLT* MPV within ±5% or ±1.0 fL (PLT 100 x 103/µL or more) PCT within ±5% or ±0.03 PCT (PLT 100 x 103/µL or more) 5 IPF* r = 0.8 or more Indicated as a tolerance with respect to the average value reference data when at least 20 samples of peripheral blood are analyzed. The reference data are obtained by the standard analysis method using the flow cytometry method based on the CD34 positive cell analysis method. within ±30.0%, or ±10/µL HPC#*6 *1 In the case of HGB, the hemoglobin analysis method using the cyanmethemoglobin (HiCN) method in accordance with the recommendations of the ICSH (International Council for Standardization in Haematology). In the case of HCT, the standard analysis method in accordance with the recommendations of the ICSH (International Council for Standardization in Haematology). *2 PLT counted in the RBC/PLT channels (PLT particle size distribution). *3 PLT counted in the RET channels. *4 PLT counted in the PLT-F channels. *5 These items do not appear with all analyzer types. *6 [HPC] mode. 15-8 XN-1000 Instructions for Use Revised August 2012 Chapter 15 Technical Information Accuracy (blood cell count) [Pre-Dilution] mode Indicated as the average value of the difference between the measured values of at least 100 samples of diluted peripheral blood and values measured on a standard instrument or international standard methods*1 (HGB and HCT only). WBC within ±10% RBC within ±8% HGB within ±5% HCT within ±4% or ±2.0HCT MCV within ±4% or ±3.0 fL Indicated as a correlation factor with the reference data when at least 100 samples of diluted peripheral blood are analyzed. The reference data are obtained by the standard analysis method or standard instrument method (IPF only) by the flow cytometry method based on the international standards. within ±10% PLT*2 within ±15% PLT*3,5 within ±10% PLT*4,5 MPV within ±7% or ±1.5 fL (PLT 100 x 103/µL or more) PCT within ±7% or ±0.04 PCT (PLT 100 x 103/µL or more) 5 r = 0.5 or more IPF* *1 In the case of HGB, the hemoglobin analysis method using the cyanmethemoglobin (HiCN) method in accordance with the recommendations of the ICSH (International Council for Standardization in Haematology). In the case of HCT, the standard analysis method in accordance with the recommendations of the ICSH (International Council for Standardization in Haematology). *2 PLT counted in the RBC/PLT channels (PLT particle size distribution). *3 PLT counted in the RET channels. *4 PLT counted in the PLT-F channels. *5 These items do not appear with all analyzer types. Accuracy (blood cell count) [Body Fluid] mode*2 Indicates the correlation with the reference method and the slope of the regression line when 50 or more body fluid samples are analyzed. The reference data are obtained by the visual observation method. WBC-BF r=0.9 or more, and within slope=1 ±0.3 RBC-BF r=0.8 or more, and within slope=1 ±0.3 TC-BF# r=0.9 or more, and within slope=1 ±0.3 *1 The HPC analysis can only be performed if the instrument offers the HPC analysis mode. *2 The body fluid analysis can only be performed if the instrument offers the body fluid analysis mode. 15-9 XN-1000 Instructions for Use Revised August 2012 Chapter 15 Technical Information Accuracy (differential blood count) [Whole blood] mode [HPC] mode*1 Indicated as a correlation factor with the reference data when at least 100 samples (at least 20 samples for NRBC and IG) of peripheral blood (samples with nucleated RBC for NRBC, samples with immature granulocyte for IG) are analyzed. The reference data is obtained by a standard analysis method that uses the flow cytometry method, based on the standard instrument, standard 5-category white blood cell analysis method, standard NRBC analysis method, or standard immature granulocyte analysis method. NRBC% r = 0.80 or more NEUT% r = 0.90 or more LYMPH% r = 0.90 or more MONO% r = 0.75 or more EO% r = 0.80 or more BASO% r = 0.50 or more IG% r = 0.80 or more Indicated as the average value of the difference between the measured values of at least 100 samples (at least 20 samples for NRBC and IG) of peripheral blood (samples with nucleated RBC for NRBC, samples with immature granulocyte for IG) and values measured on a standard instrument. NEUT% within ±3.0 NEUT% LYMPH% within ±3.0 LYMPH% MONO% within ±2.0 MONO% EO% within ±1.0 EO% BASO% within ±1.0 BASO% IG% within ±1.5 IG% 15-10 XN-1000 Instructions for Use Revised August 2012 Chapter 15 Technical Information Accuracy (differential blood count) [Pre-Dilution] mode Indicated as a correlation factor with the reference data when at least 100 samples (at least 20 samples for NRBC and IG) of diluted peripheral blood (samples with nucleated RBC for NRBC, samples with immature granulocyte for IG) are analyzed. The reference data is obtained by a standard analysis method that uses the flow cytometry method, based on the standard instrument, standard 5-category white blood cell analysis method, standard NRBC analysis method, or standard immature granulocyte analysis method. NRBC% r = 0.70 or more NEUT% r = 0.70 or more LYMPH% r = 0.70 or more MONO% r = 0.60 or more EO% r = 0.60 or more BASO% r = 0.50 or more Indicated as the average value of the difference between the measured values of at least 100 samples (at least 20 samples for NRBC and IG) of diluted peripheral blood (samples with nucleated RBC for NRBC, samples with immature granulocyte for IG) and values measured on a standard instrument. NEUT% within ±3.0 NEUT% LYMPH% within ±3.0 LYMPH% MONO% within ±2.0 MONO% EO% within ±1.0 EO% BASO% within ±1.0 BASO% Accuracy (differential blood count) [Body Fluid] mode*2 Indicates the correlation with the reference method and the slope of the regression line when 50 or more body fluid samples are analyzed. The reference data are obtained by a method in which slides created by sight spin method are visually classified. MN# r = 0.9 or more, and within slope=1 ±0.5 PMN# r = 0.9 or more, and within slope=1 ±0.5 MN% r = 0.7 or more, and within slope=1 ±0.5 PMN% r = 0.7 or more, and within slope=1 ±0.5 *1 The HPC analysis can only be performed if the instrument offers the HPC analysis mode. *2 The body fluid analysis can only be performed if the instrument offers the body fluid analysis mode. 15-11 XN-1000 Instructions for Use Revised August 2012 Chapter 15 Technical Information Accuracy (reticulocyte parameters*1) [Whole blood] mode [HPC] mode*2 Indicated as a correlation factor with the reference data when at least 100 samples of peripheral blood are analyzed. The reference data are obtained by the standard instrument method or the visual observation method. RET% r = 0.90 or more RET# r = 0.90 or more RET-He r = 0.9 or more (More than the half of the samples are RET# 0.020 x 106/µL or more) RBC-He r = 0.9 or more Delta-He RET-He r = 0.9 or more, RBC-He r = 0.9 or more Indicated as the average value of the difference between the measured values of at least 100 samples of peripheral blood and values measured on a standard instrument. RET% within ±20% or ±0.30 RET% RET# within ±20% or ±0.0150 x 106/µL IRF within ±30% or ±10.0 IRF (within 40.0 IRF*) LFR within ±30% or ±10.0 LFR (within 35.0 LFR*) MFR within ±30% or ±10.0 MFR (within 30.0 MFR*) HFR within ±30% or ±5.0 HFR (within 15.0 HFR*) * Control blood or calibrator Accuracy (reticulocyte parameters*1) [Pre-Dilution] mode Indicated as a correlation factor with the reference data when at least 100 samples of diluted peripheral blood are analyzed. The reference data are obtained by the standard instrument method or the visual observation method. RET% r = 0.80 or more RET# r = 0.80 or more RET-He r = 0.7 or more RBC-He r = 0.7 or more Delta-He RET-He r = 0.7 or more, RBC-He r = 0.7 or more Indicated as the average value of the difference between the measured values of at least 100 samples of diluted peripheral blood and values measured on a standard instrument. RET% within ±30% or ±0.50 RET% RET# within ±30% or ±0.020 x 106/µL IRF within ±50% or ±10.0 IRF LFR within ±50% or ±10.0 LFR MFR within ±50% or ±10.0 MFR HFR within ±50% or ±5.0 HFR *1 These items do not appear with all analyzer types. *2 The HPC analysis can only be performed if the instrument offers the HPC analysis mode. 15-12 XN-1000 Instructions for Use Revised May 2014 Chapter 15 Technical Information Linearity [Whole blood] mode [HPC] mode* Indicated as a logical value or a residual or residual rate with respect to the value measured on a standard instrument. WBC within ±3% or ±0.20 x 103/µL (0.00 to 100.00 x 103/µL) within ±6% (100.01 to 310.00 x 103/µL) within ±11% (310.01 to 440.00 x 103/µL) RBC within ±2% or ±0.03 x 106/µL (0.00 to 8.00 x 106/µL) within ±4% or ±0.06 x 106/µL (8.01 to 8.60 x 106/µL) HGB within ±2% or ±0.2 g/dL (0.0 to 25.0 g/dL, 0.00 to 15.52 mmol/L) within ±5% or ±0.5 g/dL (25.1 to 26.0 g/dL, 15.53 to 16.14 mmol/L) HCT within ±3% or ±1.0 HCT (0.0 to 75.0%) within ±5% or ±10 x 103/µL (0 to 1000 x 103/µL) PLT*1 within ±6% (1001 to 5000 x 103/µL) 2,4 within ±7% or ±10 x 103/µL (0 to 5000 x 103/µL) PLT* 3,4 within ±5% or ±10 x 103/µL (0 to 1000 x 103/µL) PLT* within ±6% (1001 to 5000 x 103/µL) NRBC# within ±10% or ±0.20 x 103/µL (0.00 to 20.00 x 103/µL) NRBC% within ±20% or ±2.0 NRBC% (0.0 to 600.0/100WBC) within ±20% or ±0.30 RET% (0.00 to 30.00%) RET%*4 within ±20% or ±0.0150 x 106/µL (0.0000 to 0.7200 x 106/µL) RET#*4 *1 PLT counted in the RBC/PLT channels (PLT particle size distribution). *2 PLT counted in the RET channels. *3 PLT counted in the PLT-F channels. *4 These items do not appear with all analyzer types. Linearity [Body Fluid] mode* Indicated as a logical value or a residual or residual rate with respect to the value measured on a standard instrument. This specification is based on the verification using control blood. WBC-BF within ±0.010 x 103/µL (0.000 to 0.050 x 103/µL, RBC < 1.000 x 106/µL) within ±20% (0.051 to 10.000 x 103/µL, RBC < 1.000 x 106/µL) RBC-BF within ±2% or ±0.010 x 106/µL (0.000 to 5.000 x 106/µL) TC-BF# within ±0.010 x 103/µL (0.000 to 0.050 x 103/µL, RBC < 1.000 x 106/µL) within ±20% (0.051 to 10.000 x 103/µL, RBC < 1.000 x 106/µL) * The availability of these functions depends on your system configuration. 15-13 XN-1000 Instructions for Use Revised February 2013 Chapter 15 Technical Information Carryover [Whole blood] mode [Pre-Dilution] mode [HPC] mode*1 WBC RBC HGB HCT PLT NRBC# NEUT# LYMPH# MONO# EO# BASO# 1.0% or less 1.0% or less 1.0% or less 1.0% or less 1.0% or less 2.0% or 0.02 x 103/µL or less 2.0% or 0.05 x 103/µL or less 2.0% or 0.05 x 103/µL or less 2.0% or 0.03 x 103/µL or less 2.0% or 0.03 x 103/µL or less 2.0% or 0.03 x 103/µL or less Carryover [Body Fluid] mode*2 WBC-BF RBC-BF TC-BF# 0.3 % or 0.001 x 103/µL or less 0.3 % or 0.003 x 106/µL or less 0.3 % or 0.001 x 103/µL or less *1 The HPC analysis can only be performed if the instrument offers the HPC analysis mode. *2 The body fluid analysis can only be performed if the instrument offers the body fluid analysis mode. 15-14 XN-1000 Instructions for Use Revised December 2012 Chapter 15 Technical Information Sample Stability with Time after Blood Collection 8 hours Changes after blood is taken are shown below. HCT MCV within +5.0% within +5.0% 24 hours HCT MCV NRBC% IG% RET%*1 RET#*1 IRF*1 LFR*1 MFR*1 HFR*1 RET-He*1 RBC-He*1 Delta-He*1 NEUT-RI*2 NEUT-GI*2 IPF within +8.0% (in a refrigerator), within +15.0% (stored at 18 to 26°C) within +8.0% (in a refrigerator), within +15.0% (stored at 18 to 26°C) within ±10.0% or ± 3.0 / 100 WBC within ±2.0 IG% within ± 20.0% or ±0.3 RET% within ± 20.0% or ±0.015 x 106/µL within ± 30.0% or ±10.0 IRF within ± 30.0% or ±10.0 LFR within ± 30.0% or ±10.0 MFR within ± 30.0% or ±5.0 HFR within ± 8.0% (RET# 0.0100 x 106/µL or more) within ± 8.0% RET-He, RBC-He within ± 8.0% (RET# 0.0100 x 106/µL or more) within ±8.0% within ±8.0% within ± 30.0% or ±2.0 IPF% (PLT 100 x 103/µL or more, IPF 2.0% or more) 36 hours NEUT% LYMPH% MONO% EO% BASO% within ±8.0 NEUT% within ±7.0 LYMPH% within ±3.0 MONO% within ±3.0 EO% within ±1.0 BASO% 48 hours PLT*3 PLT*1,4 PLT*1,5 NEUT% LYMPH% MONO% EO% BASO% within ±10% or ± 30 x 103/µL within ±15.0% within ±10.0% or ± 30 x 103/µL within ±8.0 NEUT% within ±7.0 LYMPH% within ±4.0 MONO% within ±3.0 EO% within ±1.0 BASO% 72 hours WBC RBC HGB within ±10.0% within ±5.0% within ±5.0% *1 *2 *3 *4 *5 These items do not appear with all analyzer types. The availability of these functions depends on your system configuration. PLT counted in the RBC/PLT channels (PLT particle size distribution). PLT counted in the RET channels. PLT counted in the PLT-F channels.

Note: The data are the values when analyzing the samples stored at 18 to 26°C or in a refrigerator (2 to 8°C). If the samples were refrigerated, they were restored to room temperature before analyzing. Depending on how the samples were stored, the values may not fall within the above range. 15-15 XN-1000 Instructions for Use Revised May 2014 Chapter 15 Technical Information Data Storage Capacity Samples stored: Patient information: Wards registered: Doctor names registered: Analysis registration function: QC files: Reagent replacement history: Maintenance history: 100,000 samples 10,000 records 200 wards 200 names 2,000 records 99 files per analyzer (300 plots per file) 5,000 records 5,000 records Quality Control X-bar control (L-J control): 300 plots x 94 files X-barM control: 300 plots x 5 files 15-16 XN-1000 Instructions for Use Revised August 2012 Chapter 15 Technical Information 15.2 System limits 15.2.1 Possible sample interferences WBC If any of the following is present, the system may erroneously report a low white blood cell count. • Leukocyte aggregation If any of the following is present, the system may erroneously report a high white blood cell count. • Possibility of PLT clumps • Cryoprotein • Cryoglobulin • Fibrin • Giant platelets (Platelets > 1,000,000/µL) RBC Where the following are present, the system may erroneously report a low red blood cell count. • Erythrocyte aggregation (Cold agglutinin) • Microerythrocytes • Possibility of fragmented RBCs If any of the following is present, the system may erroneously report a high red blood cell count. • Leukocytosis (> 100,000/µL) • Giant platelets (Platelets > 1,000,000/µL) HGB If any of the following is present, the system may erroneously report a high hemoglobin concentration. • Leukocytosis (> 100,000/µL) • Lipemia • Abnormal protein 15-17 XN-1000 Instructions for Use Revised August 2013 Chapter 15 Technical Information HCT If any of the following is present, the system may erroneously report a low hematocrit value. • Erythrocyte aggregation (Cold agglutinin) • Microerythrocytes • Possibility of fragmented RBCs If any of the following is present, the system may erroneously report a high hematocrit value. • Leukocytosis (> 100,000/µL) • Severe diabetes • Uremia • Spherocytosis PLT If any of the following is present, the system may erroneously report a low platelet count. • Possibility of PLT clumps • Pseudothrombocytopenia • Giant platelets If any of the following is present, the system may erroneously report a high platelet count.

• Microerythrocytes • Possibility of fragmented RBCs • Fragmented leukocytes • Cryoprotein • Cryoglobulin RET If any of the following is present, the system may erroneously report a high reticulocyte count. • Erythrocyte aggregation (Cold agglutinin) • Giant platelets • Possibility of PLT clumps • Fragmented leukocytes • Malaria • Howell-Jolly body 15-18 XN-1000 Instructions for Use Revised August 2012 Chapter 15 Technical Information 15.3 Program version • To find out the version of your current program of the IPU, click the [Version Information] icon in the Menu screen. • When using the RU-20, the current RU-20 program version can be checked by clicking the [Show Status] button in the RU menu. 15-19 XN-1000 Instructions for Use Revised August 2012 Chapter 15 15.4 Technical Information Functional descriptions This device performs hematology analyses according to the Hydro Dynamic Focusing (DC Detection), flow cytometry method (using a semiconductor laser), and SLS-hemoglobin method. 15.4.1 Analysis principles Hydro Dynamic Focusing (DC Detection) The RBC detector counts the RBC and PLT via the Front sheath Hydro Dynamic Focusing (DC Detection). At the same time, Recovery tube reagent the hematocrit (HCT) is calculated via the RBC pulse height detection method. Inside the detector, the sample nozzle is positioned in front of the aperture and in line with the center. After diluted sample is forced from the sample nozzle into the conical chamber, it is surrounded by front sheath reagent and passes through the aperture center. After passing through the aperture, the diluted sample is sent to the catcher tube.

This prevents the blood cells in this area Sample Aperture nozzle from drifting back, and prevents the generation of false platelet pulses. The Hydro Dynamic Focusing method improves blood count accuracy and repeatability. And because the blood cells pass through the aperture in a line, it also prevents the generation of abnormal blood cell pulses.

Flow cytometry method using semiconductor laser Cytometry is used to analyze physiological and chemical Blood cell characteristics of cells and other biological particles. Flow cytometry is used to analyze those cells and particles as they are passed through extremely small flow cells. Sheath reagent A blood sample is aspirated and measured,

diluted to the specified Flowcell ratio, and stained. The sample is then fed into the flow cells. Sample nozzle This Hydro Dynamic Focusing mechanism improves cell count accuracy and repeatability. And since the blood cell particles pass in a line through the center of the flow cell, the generation of abnormal blood pulses is prevented and flow cell contamination is reduced. 15-20 XN-1000 Instructions for Use Revised August 2012 Chapter 15 Technical Information A semiconductor laser beam (wavelength: 633 nm) is emitted to the blood cells passing through the flow cell. The forward scattered light and side scattered light is captured by the photodiode, and the side fluorescent light is captured by the avalanche photodiode. This light is converted into electrical pulses, thus making it possible to obtain blood cell information. Side Fluorescent Light System Avalanche photodiode Spectral filter Dichroic mirror Side Scattered Light System Photodiode Lateral light condensing Semiconductor laser Beam stopper Photodiode Collimator lens Condenser lens Beam Spot Generator System Flow cell System Beam stopper Forward Scattered Light System • Forward Scattered Light and Side Scattered Light When obstacles pass through a light path, the light beam scatters from each obstacle in various directions. This phenomenon is called light scattering. By detecting the scattered light, it is possible to obtain information on cell size and material properties. Likewise, when a laser beam is emitted to blood cell particles, light scattering occurs. The intensity of the scattered light depends on factors such as the particle diameter and viewing angle. This device detects forward scattered light, which provides information on blood cell size; and side scattered light, which provides information on the cell interior (such as the size of the nucleus). • Side Fluorescent Light When light is emitted to fluorescent material, such as stained blood cells, light of longer wavelength than the original light is produced. The intensity of the fluorescent light increases as the concentration of the stain becomes higher. By measuring the intensity of the fluorescence emitted, you can obtain information on the degree of blood cell staining. Fluorescent light is emitted in all directions; this device detects the fluorescent light that is emitted sideways. 15-21 XN-1000 Instructions for Use Revised August 2012 Chapter 15 Technical Information SLS-Hemoglobin Method In the past, the mainstream methods for automatically measuring hemoglobin were the cyanmethemoglobin method and oxyhemoglobin method. But these methods have both advantages and disadvantages when they are used with a large, fully automatic instrument such as this instrument. The cyanmethemoglobin method was recommended by the International Committee for Standardization in Hematology (ICSH) in 1966 as an international standard method. But since its hemoglobin conversion speed is slow and multiple-sample processing is an assumed requirement, this method is not really appropriate for automatic analysis. Moreover, since it uses cyanide compounds, which are poisonous as reagents, the liquid waste must be treated, making the method undesirable from an environmental perspective. Currently, this is not an appropriate analysis method, particularly as a large fully automatic instrument that discharges large amounts of liquid waste. In contrast, the hemoglobin conversion speed of the oxyhemoglobin method is fast, as blood hemoglobin is instantly converted into oxyhemoglobin. And since it does not use poisonous substances such as cyanide, it is a suitable method for performing automatic analysis. It cannot, however, convert methemoglobin into oxyhemoglobin, which is not a problem for normal human blood, but will result in values that are lower than the true values for samples that contain large amounts of methemoglobin, such as control blood samples. The SLS-hemoglobin method is an analysis method that makes use of the advantages of the two aforementioned methods. As with the oxyhemoglobin method, the hemoglobin conversion speed of the SLS-hemoglobin method is fast and the method does not use poisonous substances, making it a suitable method for automation. Further, since methemoglobin can be analyzed, control samples such as blood containing methemoglobin can also be accurately analyzed.
15.4.2 Analysis parameters and channels WBC analysis WNR channel The WNR channel is primarily a channel to count the white blood cells and nucleated red blood cells. By flow cytometry method using a semiconductor laser, a two-dimensional scattergram is plotted, with the X-axis representing the intensity of the side fluorescent light (SFL), and the Y-axis representing the intensity of the forward scattered light (FSC). This scattergram displays groups of nucleated red blood cells, basophil, non-basophil white blood cells, and debris (hemolyzed red blood cells and platelets). FSC Basophils Nucleated red blood cells Debris Lymphocytes+Monocytes+ Neutrophils+Eosinophils SFL 15-22 XN-1000 Instructions for Use Revised August 2012 Chapter 15 Technical Information WDF channel The WDF channel is primarily a channel for classifying white blood cells. By flow cytometry method using a semiconductor laser, a two-dimensional scattergram is plotted, with the X-axis representing the intensity of the side scattered light (SSC) and the Y-axis representing the intensity of the side fluorescent light (SFL). This scattergram displays groups of lymphocytes, monocytes, eosinophils, basophils + neutrophils, and debris. SFL Lymphocytes Monocytes Basophils + Neutrophils Eosinophils SSC Debris WPC channel The WPC channel is a channel for detecting immature cells such as myeloblasts, and abnormal lymphocytes. By flow cytometry method using a semiconductor laser, a two-dimensional scattergram is plotted, with the X-axis representing the intensity of the side scattered light (SSC) and the Y-axis representing the intensity of the side fluorescent light (SFL). This scattergram displays groups of immature cells, abnormal cells, and mature white blood cells. Mature white blood cells SFL Immature cells, Abnormal cells SSC RBC/PLT analysis Calculation of RBC constants The red blood cell constants (mean cell volume, mean cell hemoglobin, and mean cell hemoglobin concentration) are calculated from the RBC, HGB, and HCT. ● MCV (Mean cell volume) The MCV is calculated from the RBC and HCT, using the following equation: HCT (%) MCV (fL) = RBC (x 106/µL) x 10 ● MCH (Mean cell hemoglobin) The MCH is calculated from the RBC and HGB, using the following equation: HGB (g/dL) MCH (pg) = RBC (x 106/µL) x 10 ● MCHC (Mean cell hemoglobin concentration) The MCHC is calculated from the HCT and HGB, using the following equation: HGB (g/dL) MCHC (g/dL) = HCT (%) x 100 15-23 XN-1000 Instructions for Use Revised May 2014 Chapter 15 Technical Information RBC particle size distribution The RBC (red blood count) is calculated as a particle count between two discriminators (lower discriminator (LD) and upper discriminator (UD)), which are automatically set up in the ranges of 25 - 75 fL and 200 - 250 fL, respectively.
The particle size distribution is checked for abnormal relative frequencies at each discriminator level, existence of more than one peaks, and abnormal distribution width. In this instrument, the RBC distribution width (RDW) is expressed in the following two ways. ● RDW-SD With the peak height assumed to be 100%, the distribution width at the 20% frequency level is RDW-SD. The unit used is femtoliter (fL) (1 fL = 10-15 L). 100% 20% RDW ● RDW-CV With points L1 and L2 found at a frequency of 68.26% of the total distribution area, RDW-CV is calculated from the following equation: 68.26% of total distribution area L2 - L1 RDW-CV (%) = L2 + L1 x 100 (L1) (L2) PLT particle size distribution The PLT (platelet count) is calculated as a particle count between two discriminators (lower discriminator (LD) and upper discriminator (UD)), which are automatically set up in the ranges of 2 - 6 fL and 12 - 30 fL, respectively. PLT particle size distributions are checked for abnormalities, including abnormal relative frequencies at the lower discriminator, abnormal distribution widths, and the existence of more than one peak. ● PDW (Calculated distribution width of platelets) With the peak height assumed to be 100%, the distribution width at the 20% frequency level is PDW. The unit used is femtoliter (fL) (1 fL = 10-15 L).
100% P-LCR ● P-LCR (Platelet-Large Cell Ratio) The P-LCR is the ratio of large platelets from the 12 fL discriminator or larger. It is calculated as a ratio comparing the number of particles between the fixed discriminator and UD, to the number of particles between LD and UD. 20% (LD) (12 fL) PDW (UD) ● MPV (Mean Platelet Volume) The MPV is calculated from the following equation: PCT (%) MPV (fL) = PLT (x 103/µL) x 10000 PCT: PCT is called the platelet hematocrit or platelet volume ratio, and is weighted toward the PLT frequency. 15-24 XN-1000 Instructions for Use Revised May 2014 Chapter 15 Technical Information Particle size distribution expression The impression one receives of a particle size distribution can vary greatly, depending on the way in which it is expressed. The width of a particle size distribution requires particular attention, because it can appear completely different, depending on the expression used for the distribution. The instrument utilizes a conventional particle size distribution expression (normal expression) and a particle size distribution expression method that enables the user to obtain a large amount of information from the particle size distribution intuitively (normal cell size range expression). ● Normal expression With the peak of the particle size distribution set as full scale (maximum height when the particle size distribution is displayed), this method of expression normalizes and expresses the distribution. • Features: Patterns of particle size distributions whose counts are different can be viewed on the same scale. Widths of particle size distributions can be compared intuitively. • Displays Supported area: RBC and PLT particle size distributions RBC PLT ● Normal cell size range expression This method of expression does not consider the peak of the particle size distribution as the full scale (maximum height when the particle size distribution is displayed). Instead, it normalizes the distribution, with the peak of the normal cell size range, which was calculated empirically, set as the full scale. At the same time, this method overplays the normal range of the particle size distribution.
If, however, the peak of the particle size distribution is higher than the peak of the normal cell size range, the expression is made with the distribution peak set as full scale. In this case, the normal cell size range is proportionally smaller than the height of the particle size distribution peak.
A normal cell size range can be obtained by superposing the particle size distributions of a large number of healthy people and then utilizing the region from the 10th percentile to the 90th percentile. • Features: The viewer can intuitively see the size of the particle count from the particle size distribution. If the particle size distribution strays from the normal range, the viewer knows instantly that the particle size distribution pattern is abnormal. • Displays Supported area: RBC and PLT particle size distributions if settings are preset to normal range RBC PLT 15-25 XN-1000 Instructions for Use Revised August 2012 Chapter 15 Technical Information PLT-F channel* The PLT-F channel is for accurately measuring platelets, especially for low platelet counts. By flow cytometry method using a semiconductor laser, a two-dimensional scattergram is plotted, with the X-axis representing the intensity of the side fluorescent light (SFL), and the Y-axis representing the intensity of the forward scattered light (FSC). This scattergram displays groups of platelets, part of red blood cells, part of white blood cells, and debris. The IPF is obtained as a ratio of platelet count in the area with strong fluorescent light intensity in the PLT-F scattergram (IPF zone), to the total platelet count.
Red blood cells White blood cells FSC Debris IPF Platelets SFL IPF(Immature Platelet Fraction): Particle count in IPF zone IPF= Particle count in the platelet zone x 100 * Cannot be used depending on the analyzer type.
RET analysis RET channel* By flow cytometry method using a semiconductor laser, a two-dimensional scattergram is plotted, with the X-axis representing the intensity of the side fluorescent light (SFL), and the Y-axis representing the intensity of the forward scattered light (FSC). This scattergram displays groups of reticulocytes, mature red blood cells and platelets. Mature red blood cells FSC Reticulocytes Platelets SFL The scattergram is divided into three RET zones based on the intensity of the fluorescent light, and the ratio of the reticulocytes in each zone to the total number of reticulocytes is calculated. FSC LFR MFR * Cannot be used depending on the analyzer type. HFR SFL 15-26 XN-1000 Instructions for Use Revised August 2012 Chapter 15 Technical Information Reticulocyte Ratio: Particle count in reticulocyte zone RET% = Particle count in mature RBC zone + Particle count in reticulocyte zone x 100 Reticulocyte Count: RET% x RBC RET# = 100 Low Fluorescence Ratio: LFR = 100 - HFR - MFR Middle Fluorescence Ratio: Particle count in MFR zone MFR = x 100 Particle count in reticulocyte zone High Fluorescence Ratio: Particle count in HFR zone HFR = x 100 Particle count in reticulocyte zone Immature Reticulocyte Fraction: IRF = MFR + HFR LFR: MFR: HFR: IRF: Low Fluorescence Ratio Middle Fluorescence Ratio High Fluorescence Ratio Immature Reticulocyte Fraction RET-He (Reticulocyte Hemoglobin equivalent) : The RET-He is a unique parameter developed by Sysmex that is derived using the reticulocyte scattered light signals and a proprietary Sysmex calculation equation. 15-27 XN-1000 Instructions for Use Revised December 2012 Chapter 15 15.4.3 Technical Information Electrical system of the analyzer The control unit in the analyzer controls solenoid valves and master valves in the hydraulic system, thus, it controls the flow of the sample, reagents, and waste fluid in the hydraulic system. The electrical signals received from each detector are processed (waveform processing) in the analog unit, and sent to the control unit. In the control unit, the analog signals are converted to digital signals, and arithmetic processing is performed.
RBC and PLT cell signals are sent to the applicable waveform processing circuits of the analog unit, where noise is eliminated and the required blood cell signals are picked up. The microcomputer unit converts the analog-todigital-converted cell signals into particle size distribution data and sends the data to the IPU. HGB is calculated by subtracting the light absorbance of the diluent (background count) from the light absorbance of the sample. As for this light absorbance, light that is passed through the liquid is received by the photodiode, where it is photoelectrically converted. It is then converted from analog to digital signals, and sent to the IPU. The blood cell signals from the optical detector block (which analyzes WDF, WNR, WPC, PLT-F, and RET channel) can be obtained by sending signals from the forward scattered light, side scattered light, and side fluorescent light to the applicable waveform processing circuits of the analog unit, where noise is eliminated and the required blood cell signals are picked up. The control unit converts the analog-to-digital-converted cell signals into scattergram data and sends the data to the IPU. 15-28 XN-1000 Instructions for Use Revised August 2012 Chapter 15 Technical Information 15.5 Unpacking checklist XN-1000 packages Part Number AK369883 Names Quantity Intake Tube_Assy No. 12 1 BG329981 Intake Tube_Assy No. 13 1 923-8092-8 Power Cord No. 15 2*1,3 1*1,4 265-7153-5 Power Cord TA-6P(A)+TA-5(A) H05VV-F 2*1,2,3 1*1,2,4 424-3332-1 Sample Rack No.5-1 6 XN series Software (1XN1X) * Make sure that the label "1XN1X" is affixed to the disk. BC324723 1 Cover No.2032 1*3 BK729343 Cover_Assy No.195 1*3 266-7768-1 Fuse 50T100H (250V 10A, Time Lag, Low breaking capacity) 2 15-29 XN-1000 Instructions for Use Revised August 2013 Chapter 15 Technical Information Part Number AX880901 Names Fuse 50T32H (250V 3.15A, Time Lag, Low breaking capacity) 462-2381-8 Screwdriver Phillips No.1300#2 462-3520-5 Transducer Brush Quantity 2*3 1 1 442-4486-8 Tube Joint PD-ML 1 442-5343-6 Tube Polyurethane 10 mm x 14 mm 10 m 1 442-5340-5 Tube Polyurethane 6 mmID x 9 mmOD 1m 1 442-5338-7 Tube Polyurethane 4 mmID x 6 mmOD 5 m 1 442-5055-4 Tube Polyurethane 1.8 mm x 3.4 mm 2 m 1 266-4461-8 Tie Wrap CV-100 10 266-4462-1 Tie Wrap CV-250 5 15-30 XN-1000 Instructions for Use Revised August 2012 Chapter 15 Technical Information Part Number BD562985 Names Quantity XN-1000 Instructions for Use 1 AQ113796 XN series Administrator's Guide 1 BR650149 Adapter No.208 60 BK393670 Cover No.2858 1*4 CC769227 Cover No.2857 1*4 348-4101-5 Washer built-in screw (sheet t0.5) M3 x 8 4*4 266-7108-4 SS-4 300 mm 1*4 BT850247 Cap No.559 1 442-1657-0 PipeNo.27 1 15-31 XN-1000 Instructions for Use Revised August 2013 Chapter 15 Technical Information Part Number BG807462 Names Quantity Plug No.110 10 *1 *2 *3 *4 for Asia-Pacific for Europe When using the sampler (SA-10) When using the sampler (SA-01) Analyzer (XN-20) Part Number CG049669 Names Quantity XN-20 Main Complete 1 Analyzer (XN-10) Part Number CN889554 Names Quantity XN-10 Main Complete 1 Pneumatic Unit (PU-17) Quantity Part Number Names 100 - 117 V 220 - 240 V 013-3015-4 PU-17 Main Complete (100 - 117 V) (White) 1 - 013-3016-8 PU-17 Main Complete (220 - 240 V) (White) - 1 923-8092-8 Power Cord No. 15 1 - 265-7153-5 Power Cord TA-6P(A)+TA-5(A) H05VV-F - 1 266-5011-3 Fuse STA-4A-N1 (250V4A, Time Lag) 2 - AY579418 Fuse 02183.15MXP (250V3.15A) - 2 Sampler (SA-10) Part Number Names Quantity BK186773 SA-10 Main Complete 1 BS483827 Table_Assy No.23 1 Sampler (SA-01) Part Number Names Quantity BY618122 SA-01 Main Complete 1 BJ595320 Table_Assy No.64 1 15-32 XN-1000 Instructions for Use Revised December 2012 Chapter 15 Technical Information 15.6 Installation 15.6.1 Cautions on installation The instrument and associated equipment is installed by your Sysmex technical representative. In case relocation becomes necessary after installation, contact your Sysmex technical representative. Problems resulting from moving of the equipment by anyone other than a Sysmex technical representative are not covered by the Warranty even within the warranty period. 15.6.2 Grounding The instrument power supply cord uses a 3-prong plug. When the power supply socket is provided with grounding, simply plug it to the socket. If the socket does not provide grounding, use an adapter to ground the power supply safely. Warning! • Be sure to ground this instrument. Improper grounding may cause electrical shock. • Be sure not to exceed socket capacity. Failure to do so may cause a fire.
Caution! Use the power cord that comes with the instrument. Also, do not use it with any other instrument. 15.6.3 Installation environment • Use the instrument in an ambient temperature within the range of 15 to 30°C. • Relative humidity should be within the range of 30 to 85%. • If ambient temperature and relative humidity are not within the suggested range, air-condition the environment. • Avoid places of extremely high or low temperatures. • Avoid a place that is exposed to direct sunlight. • Choose a well ventilated place. • Avoid places with wireless communication devices or other equipment that can generate high frequency waves, as radio interferences can occur. 15-33 XN-1000 Instructions for Use Revised August 2012 Chapter 15 15.6.4 Technical Information Installation space To secure the space required for maintenance, install the IPU on the right side of the analyzer.
Secure a distance of at least 30 cm behind the device. Component Width (mm) Depth (mm) Height (mm) Weight (kg) Analyzer (including the sampler (SA-10)) 645 755 855 approx. 78 Analyzer (including the sampler (SA-01)) 520 680 840 approx.
70 Pneumatic Unit 280 355 400 approx. 17 840 855 645 755 When using the sampler (SA-10) 15.7 520 680 When using the sampler (SA-01) Warranty All Sysmex instruments are warranted against defective material or workmanship for a period of one year, commencing on date of installation at the customer's premises. This warranty does not however cover any defect, malfunction or damage due to: • Accident, neglect or willful mistreatment of the product. • Failure to use, operate, service or maintain the product in accordance with the applicable Sysmex Instruction for Use. • Failure to use the appropriate reagents and supply parts specified for the product. Information If the customer moves the instrument or operates it at a different location, the warranty expires. Contact your Sysmex technical representative before moving. 15-34 XN-1000 Instructions for Use Revised August 2012 Index Index A D About Calibrator Calibration .....12-3 Calibrator calibration .....12-3 Calibrator calibration (PLT-F) .....12-10 About the history list .....13-65 About the RU history list .....13-73 Additional components .....3-6 Adjust air pressure .....13-21 Analysis data list .....10-4 Analysis in manual mode .....9-7 Analysis in sampler mode .....9-18 Analysis methods .....9-1 Analysis parameters .....1-4 Analyzer .....4-1 Auto rinse .....13-7 Avoiding Infection .....2-3 Data browser .....11-1 Change layout .....11-21 Cumulative screen .....11-10 Display analysis data .....11-5 Main screen .....11-5 Disposal of materials .....2-4 Doctor Name Registering and modifying .....7-29 Screen .....7-28 Drain the pneumatic trap chamber .....13-28 Drain the reagent from the RBC isolation chamber .....13-20 Drain the reagent from the reaction chamber .....13-20 Drain the waste chamber .....13-14 B Electromagnetic compatibility (EMC) .....2-2 Error log .....14-46 Error message list (in alphabetical order) .....14-4 Error message list by function .....14-8 Barcode labels .....3-4 Body fluid analysis .....9-11 C Calibration .....12-1 Introduction .....12-1 Practice standards .....12-2 Calibrator (XN CAL/XN CAL PF) .. 5-15, 12-2 Calibrator calibration Back up .....12-19 Delete .....12-20 Manage .....12-16 Output .....12-19 Restore .....12-20 Screen .....12-16 Causes of errors and remedial actions .....14-14 CELLCLEAN AUTO .....5-14 CELLPACK DCL .....5-1 CELLPACK DFL .....5-3 CELLPACK DST .....5-2 Cleaning .....13-9 Clog removal from the RBC detector ....13-11 Common displayed items .....11-2 Computer viruses .....2-9 Control blood (XN CHECK) .....5-15 E F Fluorocell PLT .....5-12 Fluorocell RET .....5-11 Fluorocell WDF .....5-10 Fluorocell WNR .....5-9 Fluorocell WPC .....5-13 Functional descriptions .....15-20 H Hazard information .....1-7 HPC analysis .....9-14 I Installation .....15-33 Introduction .....1-1 IP message judgment conditions and judgment methods .....11-29 IP message types, meanings, and judgment methods .....11-30 IP messages .....11-24 IPU .....4-5 Main screen .....6-1 Operation .....6-1 IPU Screen Lock .....6-15 i XN-1000 Instructions for Use Revised August 2013 Index L Q Laser .....2-3 List of maintenance items .....13-1 List of menu items .....6-7 Logging off .....6-14 Logging on .....6-12 Lot information Automatic lot registration .....8-10 Manual lot registration .....8-4 Modify .....8-10 Overview .....8-4 Lysercell WDF .....5-7 Lysercell WNR .....5-6 Lysercell WPC .....5-8 QC analysis Manual analysis ..... 8-11 Sampler analysis ..... 8-15 Q-Flag .....
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Reagent management is simple too – if you want we can integrate your reagents in an analyser wagon. The XN-1000 can be equipped with all the available diagnostic applications. Depending on what is installed, the XN Rerun & Reflex performs a range of rule-based tests. The samples in question are fed into extended measurement automatically. Extended measurement is only performed if it adds additional diagnostic value. While the XN-1000 is a standalone system, optional software can still make it uniquely flexible. It can be networked with other XN concepts at other locations.
Think of individual systems for measuring body fluids on neurology wards. Or transfusion centres. And thanks to our remote services, we can together define levels of support quality, guaranteed service response times and ensure maximum system uptime.