USER MANUAL

Valid for ref code: SI R10-PN
with all Versions of Software 5.00X

Quantitative Capillary Photometry for the Erythrocyte-Sedimentation Rate (ESR)

In Vitro Diagnostic Medical Device for professional use

INDEX

In this instrument we have developed a new type of analysis sensor called CPS MC. This sensor have a more longer duration and does not require of maintenance. For easiness in this manual we will call it CPS.

Note: The paragraphs written with the italic characters (as on this note), have been added or modified respect to the previous version of the manual; the same is true in case the chapter appears in blue in the index, this means the chapter has been added or there changes done inside this chapter.

We reserve the right to make changes in the course of technical development without previous notice.

TYPOGRAPHICAL CONVENTIONS

The warnings, notes and symbols described hereafter are used in the current manual, on the instrument and on its packaging.

DISPLAY of WARNINGS and NOTES

The signal word "Danger" and a relating symbol point to imminent dangers.
The non-observance of a danger warning can result in death or at least serious irreversible injury. A damage of the system or an adverse effect on the system function cannot be excluded.

The signal word "Warning" and a relating symbol points to potential dangers.
The non-observance of a warning can result in death or at least serious irreversible injury. A damage of the system or an adverse effect on the system function cannot be excluded.

The signal word "Caution" and a relating symbol point to potential dangers/ problems.
The non-observance of safety instructions can result in minor injuries. A damage of the system or an adverse effect on the system function cannot be excluded.

The signal word "Caution" points to potential problems.
The non-observance of a safety instruction can result in damage of the system or an adverse effect on the system function.

The signal word "Note" points to potential problems.
The non-observance of notes can result in an adverse effect on the system function (result deterioration).

USED WARNINGS SYMBOLS

Caution, risk of danger to person or damage to equipment!
Consult instructions for use!

Biohazard!

Caution, moving parts inside!

Electrical hazard!

Mechanical hazard!

Laser hazard!

Cut injury / sharp hazard!

Ground!

Automatic start-up!

Consult instructions for use

OTHER SYMBOLS

Manufactured by

Lot number

Expiration date

Temperature limitations

RoHS2 Compliant

CE mark

Mains in AC voltage

ID number

Weight

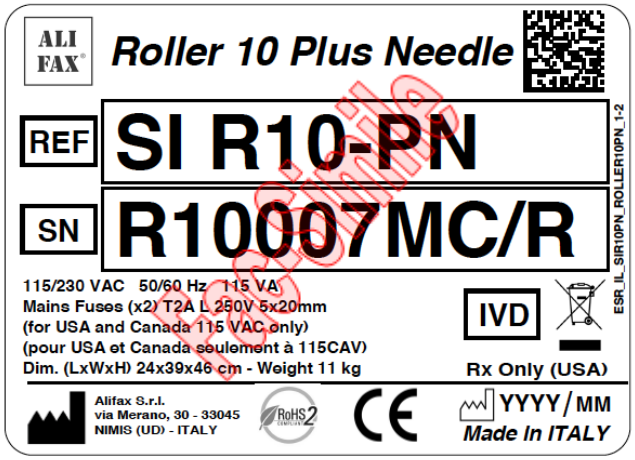
Serial number

Fuse

Disposal of Electrical and Electronic Equipment
In the European Union, electrical and electronic equipment must not be disposed of with other household-type waste. It must be collected separately. Please observe the relevant legal regulations effective in your country.

Size, [L] Length, [W] Width, [H] Height

NOTE Following labels refers to Roller 10-PN and contains between others the reference serial number of the instruments



Rx Only (USA) Explanation:
Caution: U.S. Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device

ROLLER 10-PN INTRODUCTION

Dear Valued Customer,

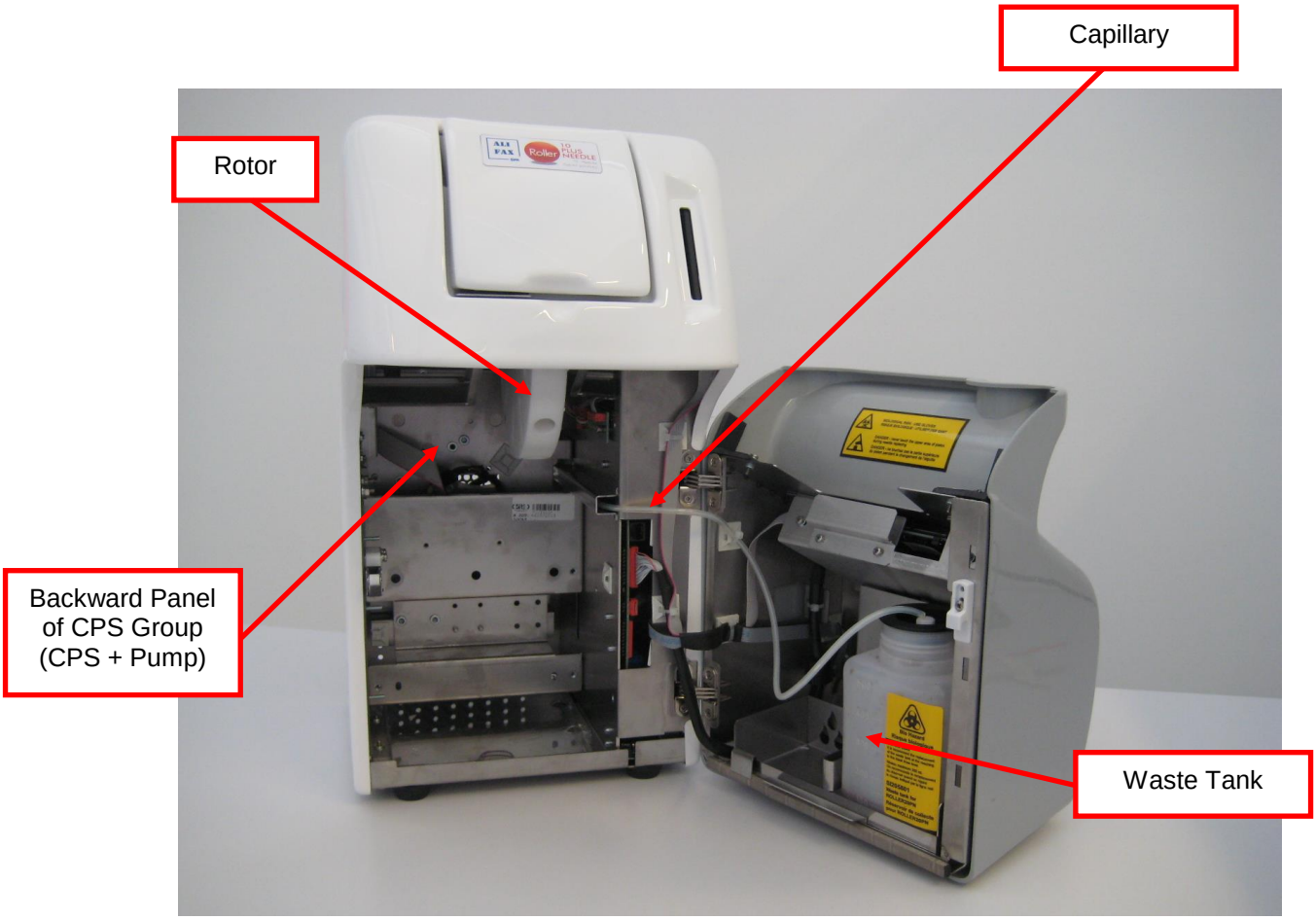
Just few words to present the Roller 10PN instrument (code SI R10-PN) the most recent of the Alifax ESR analyzers, expressly conceived to process minimal amounts of blood (only 30 microliters) that are usually collected from pediatric and normal samples.

Being part of the Roller family instruments, Roller 10PN shares the same shape and design of its predecessors and its software has been adjusted to the new purposes; its simplified design, with mixer and without automatic withdrawal syringe, has been studied to process capillary or pediatric tubes that requires manual opening and analysis through an external withdrawing probe.

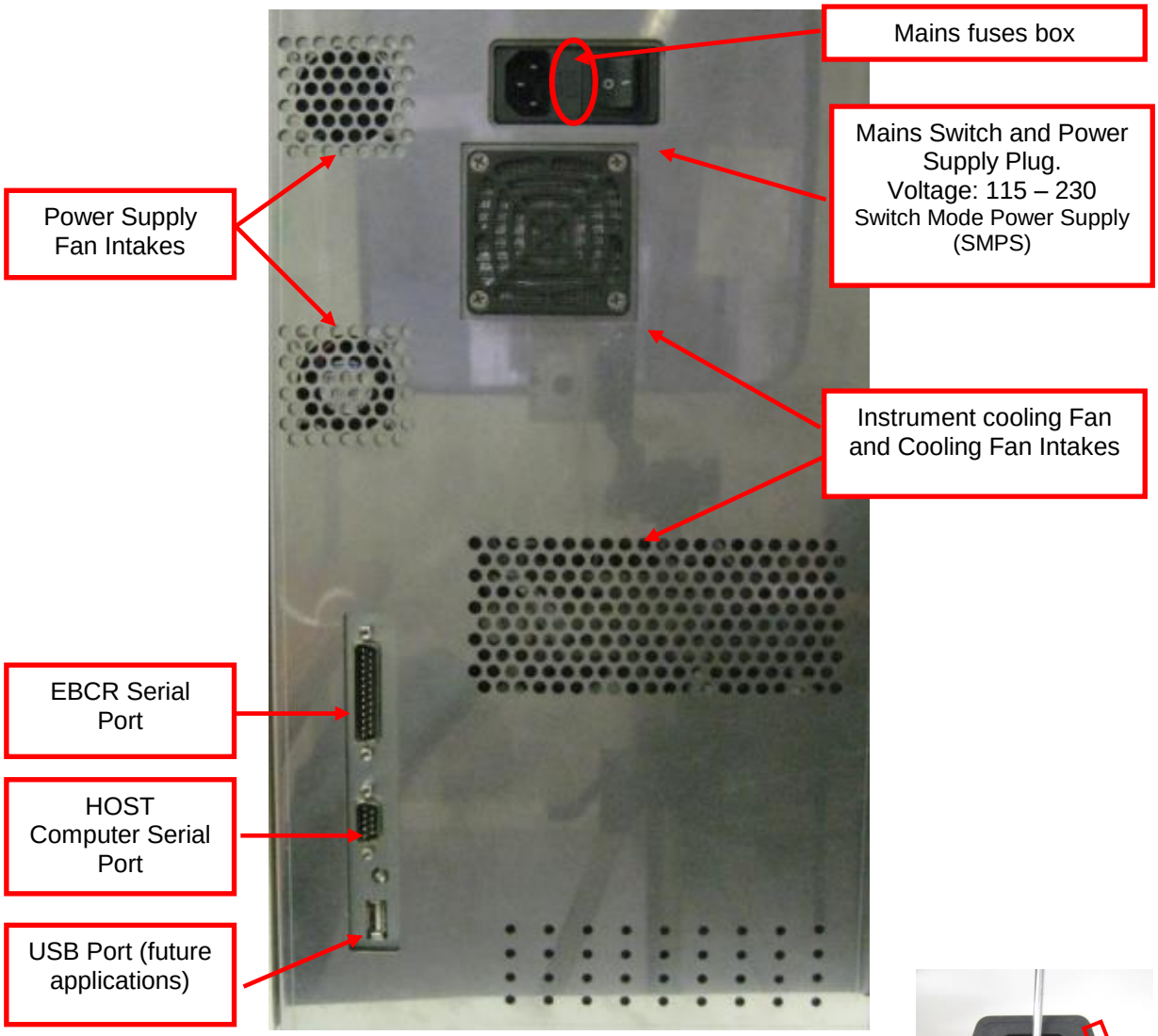
With Roller 10PN Alifax keeps working to ensure reliability and functionality to its instruments, which is at the basis of 20-years of experience in the determination of ESR.

The Alifax R&D Team.

ROLLER R10-PN INTERNAL / EXTERNAL VIEW



ROLLER R10-PN REAR SIDE VIEW and MAINS FUSE REPLACEMENT



To replace the fuses use the following procedure:

- Locate the fuses' box →
- Using a flat screwdriver push down the small tongue that keeps the box inside the switch block and pull it using a small pliers (if necessary).
- Remove the fuse box
- Remove the fuse box and replace BOTH fuses (*)
  - Insert again the fuse box inside the Main Switch block pressing it firmly to assure the box's tongue
  - fits on the hook.

(*)
The fuse which is placed in appliance inlet shall be replaced only by a T2A L 250 V dimensions 5x20 mm
The 2 Ampere fuses are suitable for both 115 and 230 Vac.

INSTRUMENT PLASTIC COVER REMOVING

To remove instrument's plastic cover proceed as follows:

Remove the 4 screws using a Phillips screwdriver and then unthread the cover form the instrument pulling a bit both sides and then lifting up the whole plastic cover.

Remove the 2 screws located at the instrument's upper rear side using a Phillips screwdriver, there are also two screws located below the loading door, these also must be removed, then unthread the metallic cover pulling toward you and then lifting up.

INSTRUMENT TECHNICAL DATASHEET ESR_PTDS_SIR10-PN_ROLLER10PN_2-0_EN

NAME: **Roller 10 Plus Needle**

REF Code: **SI R10-PN**

INTEDED USE: Automatic analyzer for Erythrocyte Sedimentation Rate (ESR) determination.

DESCRIPTION: Model a mixing rotor with a capacity of 10 samples, equipped with manual external withdrawal tip for pediatric test-tubes and for test tubes that can be uncapped.

ANALYSIS PRINCIPLE: Quantitative Capillary Photometry for the Erythrocyte-Sedimentation Rate (ESR)

- At the first daily switch ON wait 3 minutes before starting an analysis cycle to allow the thermal stabilization.
- Instrument uses a technology that allows the measurement of the ESR at a stabilized temperature of 37°C (±0.5°C)

RESULTS: Given in mm/h in the range from 2 to 120 mm/h.

SAMPLE REQUIREMENTS: In case of use of sample coming from patients affected by an oncological pathology, we remark that ESR result of those samples could be eventually NOT reliable as explained in section "method limitations" paragraph 2.

- the sample must be of whole blood collected in EDTA anti-coagulant.
- the blood sample must be neither coagulated nor hemolyzed.
- Samples mixing is done at the beginning of the analysis with the purpose of disaggregating erythrocytes. A possible ineffective disaggregation could affect the results given by the instrument which measures system is based on the detection of the kinetics of aggregation of the red cells.
- The use of sample tubes with different volumes could affect the performance of the instrument

Manual withdrawal:

- the minimum blood working volume required for the analysis is about 100 microliters, except for the first sample from which supplementary 100 microliters are approximately withdrawn for priming.
- samples separation inside the capillary by air bubble.

TUBE REQUIREMENTS: Test-tubes 13x75 mm like BD Vacutainer® or BD Microtainer® or Greiner Bio-one or with 13 mm diameter and from 75 to 83 mm high, cap included (like for example the Sarstedt tubes that measure 11,5x66 mm without cap).

- It is possible to use "BD Microtainer MAP®" tubes directly (also in conjunction with other 13x75 tubes)
- It is possible to use "Sarstedt S-Monovette EDTA®", "Tapval® pediatric tube", "BD Vacutainer® pediatric tube" tubes; for these models of test tubes it is required the use of specific test tube adapters

PEDIATRIC TUBE COMPATIBILITY **For tubes not listed here, please contact you Alifax Distributor**	**Roller20PN2** With mixer, internal and external withdraw	**Roller20MC** Without mixer, external withdrawn only	**Roller10PN** With mixer, external withdraw only
			

	Sarstedt S-Monovette EDTA 1.2 ml pediatric tube and SI195595 Tube Adapter	Internal mixing Internal withdraw External withdraw also	External mixing External withdraw only	Internal mixing External withdraw only
	Tapval pediatric tube and SI195590 Tube Adapter	Internal mixing Internal withdraw External withdraw	External mixing External withdraw only	Internal mixing External withdraw only
	BD Vacutainer pediatric tube and SI195593 Tube Adapter	Internal mixing Internal withdraw External withdraw	External mixing External withdraw only	Internal mixing External withdraw only
	BD Microtainer MAP from 250 to 500 uL pediatric cuvette into 13x75mm tube with pierceable cap No tube adapter required	Can be used together with other 13x75mm test-tubes if the blood volume is at least 250uL and the following shrewdness: turn upside down each tube and give a flip to the cap for bring down the blood towards the cap just before loading the tube into the rotor	External mixing External withdraw only	Internal mixing (use centrifuged mixing) External withdraw only
	Sarstedt Microvette 500 K3E Code 20.1341.100 Capillary pediatric test tube for 500uL and SI205052 Tube Adapter	Internal mixing (use centrifuged mixing) **Internal withdraw (minimum 300uL)** External withdraw (less than 300 uL)	External mixing External withdraw only	Internal mixing (use centrifuged mixing) External withdraw only
	Sarstedt Microvette 200 K3E Code 20.1288.100 Capillary pediatric Test tube for 200uL and SI205052 Tube Adapter	Internal mixing (use centrifuged mixing) **No internal withdraw (too few blood 200uL)** External withdraw (200 uL is enough)	External mixing External withdraw only	Internal mixing (use centrifuged mixing) External withdraw

Please notice all above tubes, have been tested mechanically to check compatibility with the instrument rotor and piercing system. There is not available any specific comparative performance information about them.

OPERATIVE PERFORMANCES

- Could be used 30 uL of blood for analysis, suitable for pediatric samples
- Results available in 18 seconds after starting manual withdrawal
- Thermoplastic cover with lid for protecting withdrawal probe.
- New Smart Card with divisible credit enabled by codes.
- Photometer check after each washing, to ensure continuous control of the instrument.
- New photometer with two detectors for ESR analysis and blood flow management.
- Automatic washing request programmable at the end of each cycle
- Management of Latex Controls kits for TEST1 family analyzers **(Ord. code SI 305.100-A/SI 305.102-A and SI 305.300-A/ SI 305.302-A).**
- In the event customer uses collecting tubes with 4ml capacity, it is possible to obtain good correlation with the method used into the laboratory with the following tips:

  1. Using the gain of the instrument during correlation with lab reference method
  2. Increasing the mixing time (on R20-MC the mixing MUST BE DONE only externally).
  3. If the CBC has the venting function, possibly execute first the CBC analysis and then the ESR analysis

Manual withdrawal:

- Start the analysis within 2-4 hours from vein-puncture, otherwise keep the samples in refrigerator at +4÷8 °C for a maximum of 24 hours. If the samples have been conserved in refrigerator at +4÷8 °C, it is necessary to leave them at room temperature at least for 30 minutes before their analysis, even if it is in any case suggested to let the samples remain at room temperature preferably for about 60 minutes, after that, test should be executed within 4 hours.

- Minimum volume required is 100 uL except for the first sample from which supplementary 100 microliters are approximately withdrawn for priming.
- verify that the sample volume should in any case not exceed the 50-60% of the total volume of the test-tube in order to optimise the blood homogenization.
- To mix the samples, configure the instrument at 32 rpms and 140 cycles of mixing to allow a suitable homogenization of the samples.

- In the event customer uses collecting tubes with 4ml capacity, it is possible to obtain good correlation with the method used into the laboratory with the following tips:
  1. Using the gain of the instrument during correlation with lab reference method
  2. Increasing the mixing time (this can be obtained using an external mixer before the ESR analysis or/and increasing the mixing time of the ESR analyzer).
  3. If the CBC has the venting function, possibly execute first the CBC analysis and then the ESR analysis.

Error notice:
The instrument in case of error or malfunction, reports this situation with a specific message on the screen plus with an acoustic intermittent signal of 62,5 dBA.

CAPACITY: Max. 10 samples / session.

ANALYTICAL PERFORMANCES (obtained with 3 ml test-tubes):

Agreement with TEST1: **R^2 = 0.91**

Repeatability: mean CV% = 5.7% on the whole range 2 - 120 mm/h
Reproducibility: mean CV% = 5.1% on the whole range 2 - 120 mm/h

Stability of samples stored for 24 h at room temperature:
In order to view the effects of different methods of storage on the ESR value, 272 K_3EDTA-anticoagulated whole blood samples, some of which have been stored at 4 °C and some others at room temperature, have been analysed after 4 hrs and after 24 hrs on TEST1 device. Good correlation was found between the results taken at 4 hrs and those taken at 24 hrs on the samples stored at 4 °C (r=0.980). Those stored at room temperature did not correlate quite as well as those stored at 4 °C, but still had very good correlation (r=0.917)[(1)].

METHOD LIMITATIONS: **1.** The erythrocyte sedimentation rate is a phenomenon confined to fresh blood and transient[(2)], not a hematic matrix component (at corpuscular / molecular level). The procedures used to determine the ESR cannot be calibrated as they are susceptible to a variety of errors (temperature, hematocrit, erythrocyte mean corpuscular volume, plasma viscosity, etc.)[(2)]. Based on the acquired experience,TEST1 family instruments (TEST1, MicroTEST1, Roller20LC,

Roller20PN, Roller20MC, Roller10PN and JO-PLUS), are limitedly affected by these variables. For this reason it is possible to observe instrument performances deviations compared to other procedures if the above variables are not taken into account.

2. Erythrocyte sedimentation remains an only partly understood phenomenon….is a nonspecific reaction (from a clinical point of view)… [(2)] that is affected by several technical aspects [(3)]. The ESR is often normal in patients with cancer...[(3)]**.**
International guidelines for diagnosis and management of multiple myeloma do not mention the Erythrocyte Sedimentation Rate [(4)]. It is then necessary to point out that even though TEST1 analytical performances have been confirmed in patients affected by multiple myeloma [(5,6)]**,** there have been some cases of patients affected by multiple myeloma in which TEST1 has reported clinically negative ESR values in comparison to other methods. Based on this experience there could be cases in which Roller gives low ESR results likewise TEST1 in presence of Multiple Myeloma.

Furthermore in presence of this disease and/or other oncological pathologies it is possible to observe deviations form other methods since other phenomena in addition to the rouleaux formation can contribute to the sedimentation like for example amorphous aggregates formation (crystallization of paraproteins or mineral materials like calcium) resulting from bone tissue alteration.

It is then highly recommended to perform other tests together with the ESR in the diagnosis of cancer since a normal ESR value is not enough to exclude that the patient is not affected by this pathology.

3. Samples mixing is programmed at the beginning of the analysis with the purpose of disaggregating erythrocytes. An inefficient disaggregation could affect the results given by the instrument that in fact measures erythrocytes aggregation kinetics.

4. The above instrument performances have been obtained using test tubes with a capacity of 3 ml and 13x75 mm size with K_3EDTA anticoagulant. The use of such tubes optimizes the mixing phase and consequently the results reproducibility.

ENVIRONMENTAL AND PHYSICAL SPECIFICATIONS

Permissible environment conditions for operation:

Temp.: from 10 to +30°C
Humidity: from 15% to 85% - no dew

Permissible environment conditions for transportation and storage:

Temp.: from -20 to +70°C
Humidity : from 5% to 95% - no dew

Size and weight:

[L] Length: 24 cm
[W] Width: 39 cm
[H] Height: 46 cm
Weight: 11 Kg

Packaging: Cardboard box

[L] Length: 65 cm
[W] Width: 34 cm
[H] Height: 50 cm
Gross Weight: 15 Kg
Volume: 0,1105 m^3
Pallet: No

ELECTRICAL SPECIFICATIONS

Voltage: 115 - 230 Vac
Switch Mode Power Supply (SMPS)
Frequency: 50/60 Hz
Classification: Class I (EN61010-1 – IEC 1010-1 – CEI 66-5)

Power consumption: 40 VA

OTHER OPERATIVE SPECIFICATIONS:

Heat dissipation in the environment: about 136 BTU/hour

Noise:
39,5 dB(A) standby
53.4 dB(A) printing
50.2 dB(A) working/washing

Maximum rated altitude: 3000 mt asl

Communication: 2 serial RS232 ports located on the rear side of the instrument:
Port 1 (DB25) is dedicated to connect an external scanner
Port 2 (DB) is dedicated to connect the instrument to an Host Computer
1 USB serial ports (for future applications)

Functioning: The instrument is designed to remain switched ON 24 hours a day, it is however suggested to switch it off at the end of the working day, applying previously a washing procedure using 3 washing tube (distillate water, chlorine, distillate water) to ensure a long capillary's and sensors' life.

Restrictions: Indoor user appliance

Rated pollution degree: Grade 2

Working life of the instrument: 10 years (if maintenance is done correctly)

INTERNAL QUALITY CONTROL

Latex Controls: With the purpose of guarantee an always optimum performance of the instrument, the daily use of the latex control kit is recommended.
Latex Controls (or Calibrators), once extracted from the refrigerator (keep in refrigerator to + 4÷8 °Cs) must remain at room temperature for at least 30 minutes before the use; once used the latexes must be returned in the refrigerator within maximum 1 hour after their use.
Latex Controls for TEST1 family analyzers allow the control of the calibration stability of TEST1, MicroTEST1; Roller10, Roller20LC, Roller20PN, Roller20MC, Roller10PN and JO-PLUS.

They are available in two kinds of test tubes:
- ♦ 13x75 mm Greiner: **Latex Controls (6 tests) - code SI 305.100-A;** **Latex Controls (30 tests) – code SI 305.300-A**
- ♦ 11,5x66 mm Sarstedt: **Latex Controls (6 tests) - code SI 305.102-A;** **Latex Controls (30 tests) - code SI 305.302-A**

CONSUMABLES

Printer Paper: Thermal roller paper 58 +0/-1 mm x Max 32 mm external diameter

Smart Card: Conform to ISO 7816-1 specifications – 85.6 x 54 x 0.8 mm
Coded using Alifax proprietary algorithm.
Available for 1,000 (Ord. code SI 195.901) - 4,000 (Ord. code SI 195.904) - 10,000 (Ord. code SI 195.910) - 20,000 (Ord. code SI 195.920) tests / Universal Card; furthermore from Sw. version 5.00 it is available also the 5,000 test (SI 195.950) Multicode Card for TEST1 family analysers (TEST1, MicroTEST1, Roller20LC, Roller20PN, Roller20MC, Roller10PN

Waste Tank: 500 ml plastic waste tank with screw cap.

Wash Tank: 500 ml plastic waste tank with screw cap (Available only on SI R20 PN Model)

OPTIONAL AVAILABLE TOOLS

Patient identification: External CCD bar-code reader (**SI195820**)

INFORMAZIONI REGOLATORIE:

Classificazione	IVD	
Codice EAN13	805604014449	
Codice CND	W02029001	Not Applicable
Codice FDA-CFR	Product code: GKB	Regulation Number: 864.5800 Automated sedimentation rate device
Codice EDMA	23091001	Other_HHIHC Hardware + accessories + consumables + software
Codice GMDN	35488	An automatic or semi-automatic instrument used to measure the sedimentation (sinking) velocity of red blood cells in a sample of whole blood using photometry. This is also called, erythrocyte sedimentation rate (ESR).
RoHS2 2011/65/EU	Conforme	
Repertorio Alifax	1301770	

BIBLIOGRAFIA:

(1) Nicoli M. et All. Lab. Analisi Chimico-Cliniche ed Ematologiche Osp. Civile Verona: “Roller T1: Una nuova generazione di analizzatori per la Velocità di Eritrosedimentazione” , Biochimica Clinica, 2004, Vol 28, pg 203

(2) Kagawa Yuko[1], Nobuko Ikeda[1], Shingo Ito[1], Makino Sahei[2], Miyake Noriko[3]: Clinical Test Section of Eiju Hospital[1], Finggal Link Co. Ltd[2], Dept. of Clinical Pathology of Juntendo Univeristy[3]: “Evaluation for ESR automated measuring instrument with EDTA” 36th Japan Society for Clinical Laboratory Automation, 30 September 2004, Japan.

(3) E. Heverin (Galway-Mayo Institute of Technology, Ireland): ”Comparison of the Westergren method versus the TEST1 technique for determining the Erythrocyte Sedimentation Rate”, May 2002, private communication

(4) NCCLS “Reference and Selected procedure for the Erythrocyte Sedimentation rate (ESR) Test; Approved Standard-Fourth Edition”, Vol. 20 No. 27

(5) Sox HC, Liang MH: “The Erythrocyte Sedimentation Rate”, Annals of Internal Medicine 1986; 105:515-523.

(6) NCCN (National Comprehensive Cancer Network) Clinical Practice Guidelines in Oncology “Multiple Myeloma” (V.I.2007)

(7) Ajubi et al.: “Determination of the lenght of sedimentation reaction in blood using the TEST1 system: comparison with the Sedimatic 100 method, turbidimetric fibrinogen levels, and the influence of M-proteins”, Clin Chem Lab Med 2006; 44 (7): 904-906

(8) Mercurio S. et al.: “Confronto tra due metodi per la determinazione della VES in pazienti con mieloma”, 37° Congresso Nazionale SIBioC, 11-14 ottobre 2005 Roma

1.0 METHIOD LIMITATIONS

METHOD LIMITATIONS:

1. The erythrocyte sedimentation rate is a phenomenon confined to fresh blood and transient[(2)], not a hematic matrix component (at corpuscular / molecular level). The procedures used to determine the ESR cannot be calibrated as they are susceptible to a variety of errors (temperature, hematocrit, erythrocyte mean corpuscular volume, plasma viscosity, etc.)[(2)]. Based on the acquired experience,TEST1 family instruments (TEST1, MicroTEST1, Roller20LC, Roller20PN, Roller20MC, Roller10PN and JO-PLUS), are limitedly affected by these variables. For this reason it is possible to observe instrument performances deviations compared to other procedures if the above variables are not taken into account.

2. Erythrocyte sedimentation remains an only partly understood phenomenon….is a nonspecific reaction (from a clinical point of view)… [(2)] that is affected by several technical aspects [(3)]. The ESR is often normal in patients with cancer...[(3)].

International guidelines for diagnosis and management of multiple myeloma do not mention the Erythrocyte Sedimentation Rate [(4)]. It is then necessary to point out that even though TEST1 analytical performances have been confirmed in patients affected by multiple myeloma [(5,6)], there have been some cases of patients affected by multiple myeloma in which TEST1 has reported clinically negative ESR values in comparison to other methods. Based on this experience there could be cases in which Roller gives low ESR results likewise TEST1 in presence of Multiple Myeloma.

Furthermore in presence of this disease and/or other oncological pathologies it is possible to observe deviations form other methods since other phenomena in addition to the rouleaux formation can contribute to the sedimentation like for example amorphous aggregates formation (crystallization of paraproteins or mineral materials like calcium) resulting from bone tissue alteration.

It is then highly recommended to perform other tests together with the ESR in the diagnosis of cancer since a normal ESR value is not enough to exclude that the patient is not affected by this pathology.

3. Samples mixing is programmed at the beginning of the analysis with the purpose of disaggregating erythrocytes. An inefficient disaggregation could affect the results given by the instrument that in fact measures erythrocytes aggregation kinetics.

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4. The above instrument performances have been obtained using test tubes with a capacity of 3 ml and 13x75 mm size with K_3EDTA anticoagulant. The use of such tubes optimizes the mixing phase and consequently the results reproducibility.

REFERENCES:

1. E. Heverin (Galway-Mayo Institute of Technology, Ireland): ”Comparison of the Westergren method versus the TEST1 technique for determining the Erythrocyte Sedimentation Rate”, May 2002, private communication
2. NCCLS “Reference and Selected procedure for the Erythrocyte Sedimentation rate (ESR) Test; Approved Standard-Fourth Edition”, Vol. 20 No. 27
3. Sox HC, Liang MH: “The Erythrocyte Sedimentation Rate”, Annals of Internal Medicine 1986; 105:515-523.
4. NCCN (National Comprehensive Cancer Network) Clinical Practice Guidelines in Oncology “Multiple Myeloma” (V.I.2007)
5. Ajubi et al.: “Determination of the lenght of sedimentation reaction in blood using the TEST1 system: comparison with the Sedimatic 100 method, turbidimetric fibrinogen levels, and the influence of M-proteins”, Clin Chem Lab Med 2006; 44 (7): 904-906
6. Mercurio S. et al.: “Comparison between two methods for ESR measure in patients affected by myeloma”, 37° SIBioC National Congress, 11-14 October 2005 Rome.
7. H02-A5 vol 31 No.11 PROCEDURES FOR THE ERYTHROCYTE SEDIMENTATION RATE TEST; APPROVED STANDARD – FIFTH EDITION

2.0 - WARNINGS FOR A CORRECT USE OF THE INSTRUMENT

The following safety instructions must be observed at all times, both before and during operation and during maintenance.

WARNING

Handling of Instructions for use Manual

the instructions for use manual is provided for your safety and gives important instructions for the handling of the system described.

- Read all instructions!
- Keep the instructions for use manual nearby the system.
- he instructions for use manual must be accessible to the user at any time.

Roller 10PN system is designed and manufactured in accordance with the safety requirements for electronic and medical systems. If the law issues regulations concerning the installation and/or operation of the instrument, then it is the operator's responsibility to adhere to them.

The manufacturer have done everything possible to guarantee that the equipment functions safely, both electrically and mechanically. The systems are tested by the manufacturer and supplied in a condition that allows safe and reliable operation.

GENERAL SAFETY

WARNING

Non-Observance of Warnings

The non-observance of warnings can result in serious personal injury and material damages.

- Follow all warnings included in this manual.
- Follow all warnings marked on the instrument.
- If the instrument has been stored in cold places, wait at least 30 minutes before switching ON the instrument for the first time in order to avoid eventual damages due to dew presence on internal parts of the instrument.

WARNING

Use of the System according to Intended Use only

Improper use of the instrument, not in compliance with the manufacturer specifications, could lead protection impairment and damages to both operator and/or instrument as well as can result in wrong results, damage of the system and personal injury.

- The handling and maintenance of the system must only be performed by trained and authorized personnel.
- Before the operation of the system, the Instruction for use manual must have been read and understood.
- The instrument must only be used in accordance with its intended use.
- The instrument is designed for indoor uses only.
- For professional in vitro medical diagnostic use only. The English language knowledge is required in those countries where neither Italian nor French nor Spanish nor German nor Russian is spoken.
- Use only the consumables and accessories described herein
- Keep away any kind of objects, liquids, or substances not required for the instrument's use from the instrument.
- The manufacturer assumes no liability for any damages, including those to third parties, caused by improper use or handling of the system, installation not in compliance with the manufacturer's specifications, use of the instrument not in security, use of not suitable materials regarding those specified in the user's manual, use of the instrument for various scopes different from those for which it has been designed and built, use of the instrument by not expert staff person or however non-authorized to the use of the instrument and/or in case the sanitization procedure will not be carried out if required.
- **This instrument is not intended for use by persons with reduced physical, mental and sensorial capabilities or lack of experience and knowledge, unless**

they have been given supervision or preliminary instructions for the use of the analyzer by a person responsible for their safety.

NOTE

IN CASE UNAUTHORIZED SOFTWARE IS INSTALLED ON THE INSTRUMENT, THIS MIGHT GENERATE MALFUNCTIONING OF THE INSTRUMENT AND/OR EVENTUALLY UNRELIABLE ANALYTICAL RESULTS; FURTHERMORE INSTALLING UNAUTHORIZED SOFTWARE INVALIDATE THE WARRANTY OF THE INSTRUMENT.

OPERATIVE SAFETY

WARNING

Mobile Phones

Do not use a mobile phone next to a running system. It is possible to affect the correct function of the system.

WARNING

Instrument use in routine

- At the first daily switch ON wait 3 minutes before starting an analysis cycle to allow the thermal stabilization.
- Instrument uses a technology that allows the measurement of the ESR at a stabilized temperature of 37°C (±0.5°C)
- Before starting a new session, the instrument visualizes a control check-list, is mandatory to verify all check that all the parameters in the check-list are as expected, otherwise contact the Technical Service
- For professional in vitro medical diagnostic use only. The English language knowledge is required in those countries where neither Italian nor French nor Spanish nor German nor Russian is spoken.
- Check the waste tank level before starting the measures. Empty or replace it, if filled to security level; for the disposal of waste tank content, follow the standard safety procedures in use in the laboratory.
- Carry-out appropriate "WASHING PROCEDURES" to a good instrument maintenance
- Keep away any kind of objects, liquids, or substances not required for the instrument's use from the instrument.
- Check if the tube contains at least 800 uL of blood and verify that the blood is not neither hemolysis nor coagulated. Use exclusively blood samples withdrawn in EDTA anticoagulant (K_2 or K_3).
- Use preferably tubes with a capacity of 3 ml verifying that the sample volume should in any case not exceed the 50-60% of the total volume of the test-tube in order to optimise the blood homogenization.
- The use of sample tubes with different volumes could affect the performance of the instrument
- Instrument offers three mixing speeds (60 rpm, 32 rpm, 24 rpm); it is recommended to configure a speed of 32 rpm and 140 cycles for an adequate homogenization of the samples.
- Samples mixing is done at the beginning of the analysis with the purpose of disaggregating erythrocytes. A possible ineffective disaggregation could affect the results given by the instrument which measures system is based on the detection of the kinetics of aggregation of the red cells.
- In the event customer uses collecting tubes with 4ml capacity, it is possible to obtain good correlation with the method used into the laboratory with the following tips:
  1. Using the gain of the instrument during correlation with lab reference method
  2. Increasing the mixing time (this can be obtained using an external mixer before the ESR analysis or/and increasing the mixing time of the ESR analyzer).
  3. If the CBC has the venting function, possibly execute first the CBC analysis and then the ESR analysis

- In case of use of sample coming from patients affected by an oncological pathology, we remark that ESR result of those samples could be eventually NOT reliable as explained in section “method limitations” paragraph 2.
- In case of external mixing of the samples, use a rotating wheel or a tilting bed set at speed of 32 rpms and 140 cycles of mixing to allow a suitable homogenization of the samples.
- Start the analysis within 2-4 hours from vein-puncture, otherwise keep the samples in refrigerator at +4÷8 °C for a maximum of 24 hours. If the samples have been conserved in refrigerator at +4÷8 °C, it is necessary to leave them at room temperature at least for 30 minutes before their analysis, even if it is in any case suggested to let the samples remain at room temperature preferably for about 60 minutes, after that, test should be executed within 4 hours.
- Latex Controls (or Calibrators), once extracted from the refrigerator (keep in refrigerator to + 4÷8 °Cs) must remain at room temperature for at least 30 minutes before the use; once used the latexes must be returned in the refrigerator within maximum 1 hour after their use.
- Do not pour liquids or leave to fall anything inside the refrigerator and thermostat units. In such case, switch OFF **IMMEDIATELY** the instrument and call the Technical Service. Do not try to remove any object, even if visible, when the unit is switched ON.
- In case of a vial is broken inside the instrument, it is mandatory to call the Technical Service
- An acoustic signal will be activated when the loading door remains opened. Close the door to allow the system to progress with the analysis.

MECHANICAL SAFETY

Danger of Electrocution or Mechanical Injury by Missing or Opened Protective Covers
To avoid serious injury with lethal consequences due to electrocution or injury by the system (e.g. contusion, cuts etc.), protective covers must not be opened or removed by no reason by **user**; only authorized Technical Service Engineers or manufacturer Engineers can remove protective covers.

- Do not remove the panels neither camper the reading sensor.
- The internal carriage moves over a sliding guide which is an “auto lubricating” guide, so it is not necessary to lubricate or add any kind of oil or grease along the rails of the carriage guides.
- Switch off the system, separate it from the mains supply and protect it against restarting.
- For your safety, if any part should be damaged, ask for the immediate replacing with original spare parts, specially for the parts connected to mains (power cord, fuse-holder and mains switch …)
- In order to avoid possible mistakes in the Query-Host communication and/or the transmission of patient ID to the Host computer, it is recommended the use of bar-code codification which includes the “check-digit” option in its protocol.
- Use only original spare parts supplied by the manufacturer.
- Use only peripherals authorized by the Manufacturer

Maintenance must be carried out only by qualified Technical Engineers authorized by the manufacturer

- Use only original spare parts supplied by the manufacturer.
- Use only peripherals authorized by the Manufacturer
- Is absolutely forbidden exchanging any electronic board from one instrument to another instrument.
- Make sure that nobody works on the system and that all covers are attached and closed before you reconnect the system to the mains supply.
- Perform maintenance works with highest caution.
- Only perform maintenance works described in this manual.
- The unit shall be inspected and maintained each 30 000 analyses.

ELECTRICAL SAFETY

Electrocution/Fire Hazard!
Non-observance of rules and regulations can cause serious personal injury with lethal consequences and material damage.
National rules and legal regulations for the safe electrical operation of the system must be observed.

During Installation please be sure

- Avoid improper connection of the system and the peripheral devices to mains supply can cause serious personal injury with lethal consequences and material damage (e.g. fire).
- Use only connection and extension cables with a protective conductor and sufficient capacity (performance, power) to connect the system and the peripheral devices to the mains supply.
- Never interrupt the grounding contacts.
- Grounding of the system and its peripheral devices to the same protective earth potential must be ensured and it is connected to a mains socket with a Protective Earth terminal before its use
- The use of a multi plug is not allowed!
- Use a Smart Ups with at least 1500 VA capacity.
- Damaged connecting cables can cause serious personal injury with lethal consequences. Damaged connecting cables must be replaced immediately!
- No objects may be placed on the connecting cables.
- Connecting cables must be laid so that they cannot be squeezed or damaged.
- Connecting cables must be laid so that they do not lay in accessible or drivable areas.
- Switch OFF the instrument before connecting any external peripheral as external bar code readers, printer cables and/or RS232 serial cables

Danger due to Improper Place of Installation
Improper place of installation of the system can cause accidents with serious injuries with lethal consequences, fire or serious system damages because the system cannot be switched off or be separated from the mains supply.

- Ensure the place of installation of the system is so that the power supply and mains switch are easily accessible.
- The instrument has to be installed on a dry surface sheltered from sun light to avoid sun rays hit the door sensor when the door is open generating unplanned consequences.
- The manufacturer does not assume any responsibility for eventual damages to persons or things due to improper, installation not in compliance with the manufacturer's specifications.

Electrocution/Fire Hazard!
During the normal routine working please:

- Keep away any kind of objects, liquids, or substances not required for the instrument's use.
- Do not pour liquids or leave to fall anything inside the refrigerator and thermostat units. In such case, switch OFF **IMMEDIATELY** the instrument and call the Technical Service. Do not try to remove any object, even if visible, when the unit is switched ON.

Electrocution/Fire Hazard!
During Maintenance/ Technical Service activities be sure to:

- Immediately separate the defective system from the mains supply, if a safe usage is no longer possible.
- Secure the defective system against reconnection.
- Label the defective system clearly as being defective.

WARNING

Battery Handling

The product may contain an internal lithium manganese dioxide, vanadium pentoxide, or alkaline battery or battery pack. There is risk of fire and burns if the battery pack is not handled properly. To reduce the risk of personal injury:

- Do not attempt to recharge the battery.
- Do not expose to temperatures higher than 60°C (140°F).
- Do not disassemble, crush, puncture, short external contacts, or dispose of in fire or water.
- Risk of explosion if battery is replaced by an incorrect type. Dispose of used batteries according to the instructions.
- Replace only with the spare designated for this product.
  Battery for Unit Interface board SI205001 (S25.001x) is Kinetic #MH60B3AL3; Ni MH; 3,6V 60 mAh.

NOTE

Transient Emissions and Interference Resistance

The instrument meets the requirements described in standard IEC 61326 and IEC61326-2 on transient emissions and interference resistance.

- This instrument can cause radio interference in domestic environment. In this case it may be required to take action to eliminate such interference.
- Before setup and operation of the instrument, the electromagnetic environment should be evaluated.
- Do not use the instrument in the vicinity of sources with excessive electromagnetic radiation (e.g. unshielded, deliberately operated high frequency sources) since they could interfere with the proper operation of the instrument
- Avoid if possible the connection to mains through plug adapters and choose an electrical outlet far from any strong impulsive voltages, usually generated from centrifuges, refrigerators, elevators and freight elevators.
- Avoid the use of the instrument near electromagnetic sources like for example cellular phones, CB's, radio transmitting units and similar
- This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference

BIOLOLGICAL SAFETY

DANGER

Risk of infection!

The instrument, can be exposed to potentially infective materials; system therefore must be treated as being potentially infectious, is thus indispensable to adopt all the precautions and warnings necessary apt to avoid the contact (mandatory the use of gloves and glasses during vial manipulation) in accordance with national laws.
Improper handling of infectious parts can cause skin irritations, illnesses and possibly to death.

- Use appropriate gloves!
- Use an appropriate lab coat!
- Avoid contact between skin/mucous membrane and samples/test reagents or parts of the instrument.
- Clean, disinfect and decontaminate the system immediately if potentially infectious material has been spilled.
- Do not use broken or chipped tubes or bottles.
- Observe the instructions in the package inserts for a correct use of the reagents.

DANGER

Waste and Disposable procedures

- Observe local and national provisions, legislation and laboratory regulations.
- Observe the legal regulations for the handling of infectious material.
- **Dispose used vials, following the standard safety procedures in use in the laboratory.**

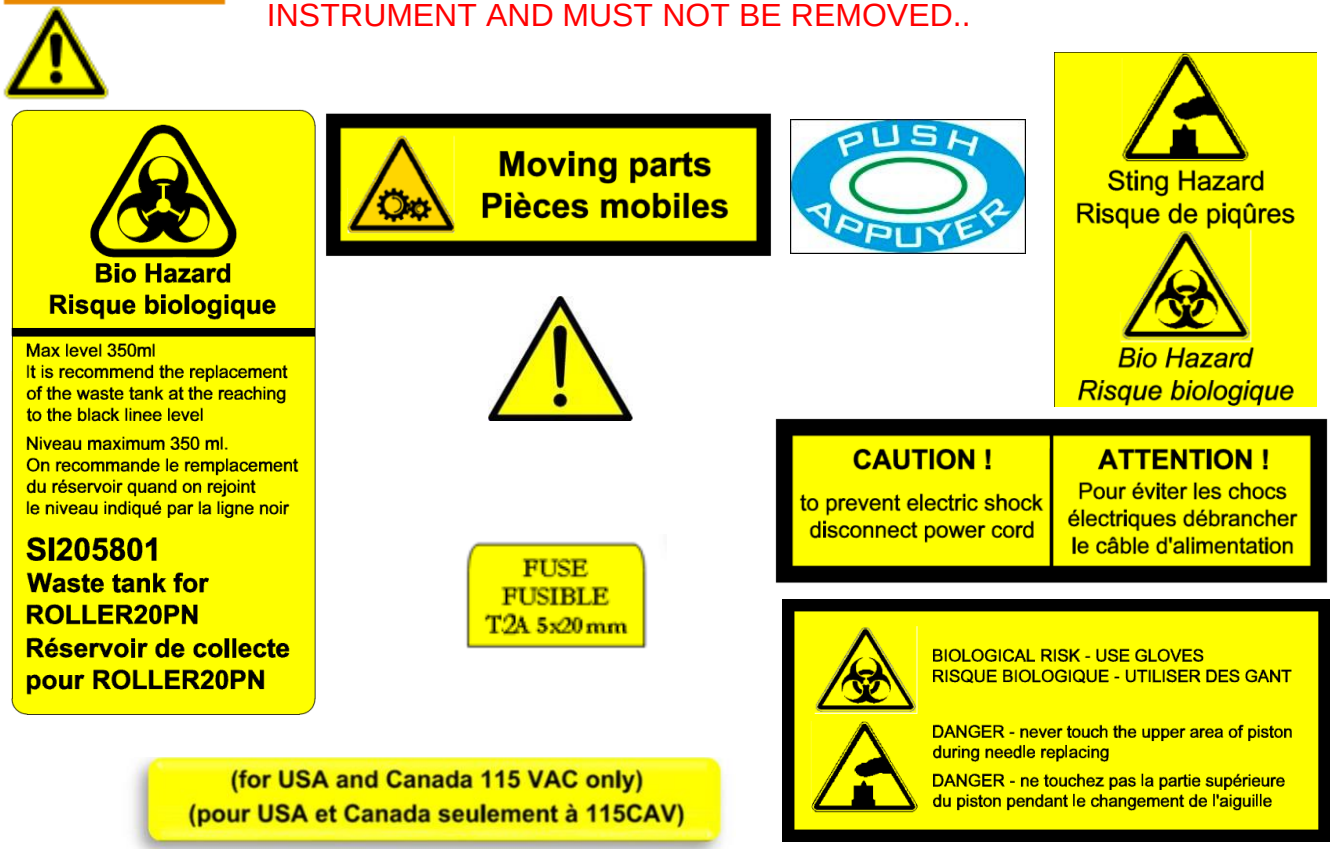
Maintenance
During Maintenance/ Technical Service activities be sure to:

- **use gloves to protect agains any possible accidental contact with infectious materials presents inside instrument .**
- if during maintenance the instrument has been stored /moved to a cold places, wait at least 30 minutes before switching ON again the instrument for the first time in order to avoid eventual damages due to dew presence on internal parts of the instrument.
- It is mandatory to do the sanitization (use gloves and protective glasses) and locking drawers procedure before maintenance or before send back to the manufacturer

Roller 10-PN SAFETY LABELS

WARNING

THE FOLLOWING LABELS ARE STUCK AS WARNINGS ON THE INSTRUMENT AND MUST NOT BE REMOVED..



PROCEDURE OF INSTRUMENT WASTE AT THE END OF ITS OPERATIONAL LIFE

As stated in the European directive 2002/ 96/CE related on waste of electrical and electronic equipment (WEEE), appropriate measures should be adopted to minimize the disposal of the instrument as unsorted municipal waste and to achieve a high level of separate collection of WEEE, according to the applicable local laws and rules.
The crossed-out wheeled bin symbol on side, placed also close to the plate of the apparatus, points out the necessity of the separate collection of the electrical and electronic equipment (WEEE).
The separate collection of this instrument at the end of its life is organized and managed by your distributor. The user who is going to get rid of it will therefore contact his distributor and follow the system that he has adopted in order to dispose the separate collection of the equipment that has reached the end of its working life.
The unauthorized disposal will be pursued according to the local laws and the rules in the nation of use. Fines will be effective, proportionate and dissuasive.

3.0 – UNPACKING AND INSTALLATION

NOTE The unpacking of the instrument is done directly by Alifax (or local Distributor) Field Service Engineer

4.0 – INSTRUMENT START-UP

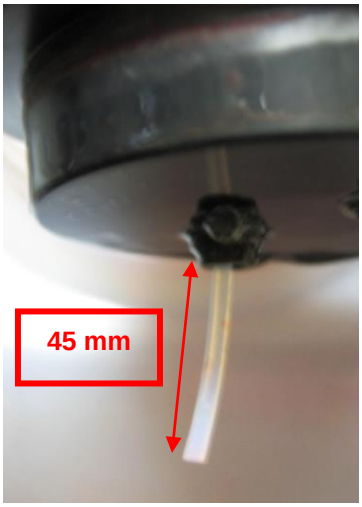
INSTRUMENT DESCRIPTION and start-up

NOTE The installation and instrument Start-up is done directly by Alifax (or local Distributor) Field Service Engineer

5.0 – WASTE TANK REPLACE / EMPTY

Roller family uses an internal control system to check the level of waste tank:

- at every switch ON of the instrument
- at every washing procedure start-up
- at the ending of every cycle of analysis the instrument controls the level of liquid inside the waste tank, using the peristaltic pump to aspire from the tank. If the pump aspires material, the reading unit detects the presence of the material and blocks the operation of the instrument, informing via display that the waste tank needs to be emptied/replaced.
- It is important to NOT REMOVE/CUT waste tank discharge tube because the length is designed specifically for measure safely the level of the waste tank and advise the operator to empty the tank.
- **The safe length MUST BE AT LEAST 45 mm**



For the disposal of the waste tank content follow the standard safety procedures in use in the laboratory.

6.0 – INCREASE AVAILABILITY TEST USING THE SMART CARD

All Alifax instruments need a personalized smart card in order to enable the analysis of blood for the ESR determination. The instrument is supplied with 200 test for first demos and first analysis, but a warning message is displayed at the begin of each analysis session alerting the user that test availability increase is required.

WARNING!! If during the analytical cycle there is no test availability, the instrument will set itself in idle and will not allow any kind of activities up when the availability will be increased using the specific smart card.

To increase availability, it is necessary to have a personalized smart card (the sizes are from 1.000, 4.000, 10.000 and 20.000 test plus the new Multicode card of 5.000 test that can enable 500 test a time using some card codes as described on **chapter 17.1**).

From Main Screen (if the card is inserted while the display shows a different menu, it will not consider it…) insert the appropriate smart card in the reading slot, facing the card with the contacts toward the right side, as displayed on the following picture:

The instrument will printout and display the current availability, only for the credits enabled, then it will check the personalization, the number of credits and which type of credit are enabled:

The instrument will printout and display the current availability, only for the credits enabled:

then will check the personalization, the number of credits and which type of credit are enabled:

- If the instrument's personalization is different from the one programmed in the card it will reject the card. Then after pressed "**OK**" the instrument asks to remove the card and comes back to Main Menu. In this case the credits don't increase.

- If the instrument have no personalization, it will acquire the one set in the smart card. Then after pressed "**OK**" the instrument asks to remove the card and comes back to Main Menu. In this case the credits increase as is possible to see in the printout.

- If the personalization is the same as the one stored in the card, the instrument, after pressed "**OK**", asks to remove the card and comes back to Main Menu. In this case the credits increase as is possible to see in the printout.

If, for some reason, the card inserted is defective the instrument will show a message informing about that, then after pressed "**OK**", the instrument asks to remove the card and comes back to **MAIN MENU**.

- In case of not properly card loading: possibly malfunction causes are explained in the follow **chapter 6.1.**

Please refer to **chapter 17.1.2** to see the complete and detailed explication and procedures to set the warning level and to see the availability.

Starting from April 2019 a smart card with a new graphical layout is available on the market; below example refers to the 10000 test.

6.1 - SMART CARD ERRORS

The possible malfunction causes usually are:

1. The smart card is not properly inserted, the card contact plate must stay on the right side when inserted (upside-down) or the Card contact plaque wouldn't be in the lower position faced to the instrument.

2. The reader contacts don't allow the Card to be read.

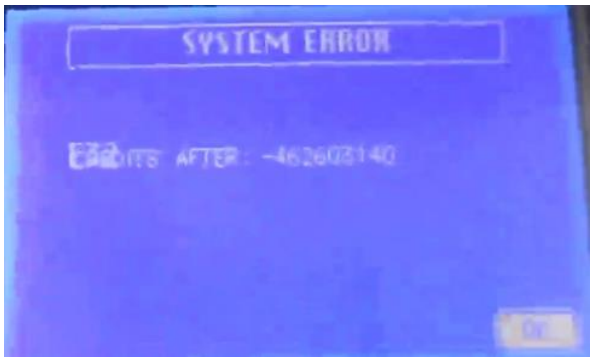
3. **Out Std error** means the card has a number of tests that is outside the normal ranges: 1.000 - 4.000 - 5.000 - 10.000 - 20.000

4. **Not valid Card** means the card has already been previously downloaded, so the instrument is not able to load again, or the card is not personalized for this instrument.

If the instrument displays error OUT STD 24384 means the card has been inserted upside down or with the contacts facing the left side instead the right side

Please refer to **chapter 17.1.2** to see the complete and detailed explication and procedures to set the warning level and to see the availability.

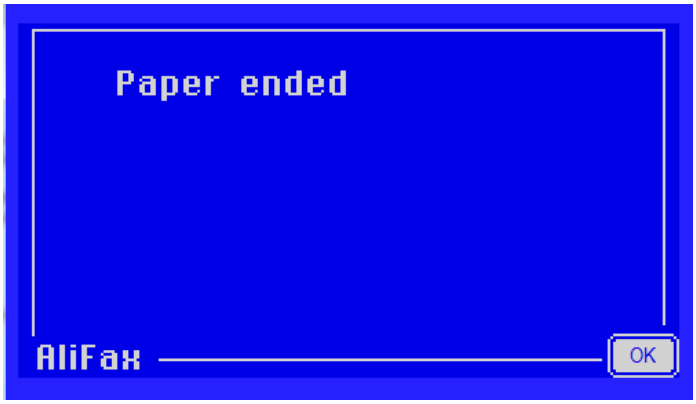
Please notice, with new Software 5.00A, in case during the smart card insertion or during the downloading of the credits from smart card to instrument, one or more of the following error happens:



Refer to troubleshooting at chapter 22, errors 31, 32 and 33

7.0 – PAPER ROLL LOADING - REPLACEMENT

In the event the paper ends, instrument shows on screen a message informing paper has ended:

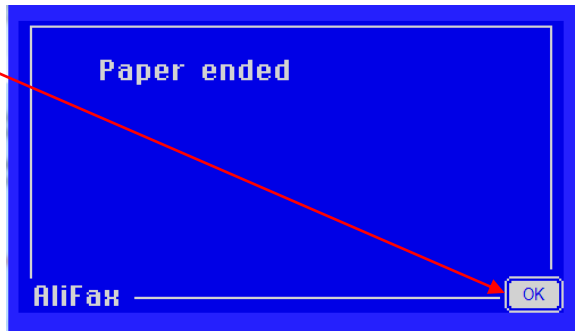


Replace the roll is simple and quick:

Pull the plastic lever of the printer, lift up the plastic cover and remove the plastic core (if present) of the old roll

Keep the plastic cover up and insert the new roll of paper being sure to pull it a bit in order to allow paper being captured and pressed by printer's rubber roll.

Close the plastic cover and press the "advance paper" button to check if paper is coming out correctly; after that press OK on the display



Wait while instrument finish the internal checks.

8.0 –SWITCH ON AND MAIN MENU

Start the instrument by pressing the switch on upper backside; at the first daily switch ON wait 3 minutes before starting an analysis cycle to allow the thermal stabilization.
Instrument uses a technology that allows the measurement of the ESR at a stabilized temperature of 37°C (±0.5°C)
The instrument automatically will start the internal check up and then display will show the following image:

This instrument is controlled using the “Touch Screen”, each option, function, process will be activated/deactivated simply touching the screen in the corresponding “button”.

To be even more user friendly, as you can see, the main screen sets up ready to uses highlighting the **4 main buttons** in order to allow the operator begin analysis without necessity to **“look around”** for the operative buttons.
Available buttons are displayed in the upper screen side:

- **Main:** allows accessing to common use functions like measure, wash, standard and Q.C.;
- **Setup:** allows accessing to some common use functions like Date and Time, Flag List, Settings and also to specific functions protected by passwords (accessible only to technical service);
- **Availability:** allows accessing to set the test credit warning alarm, to printout the availability of credits and for use the blocks of the card with divisible credit;
- **Comm:** allows accessing to communication functions protected by passwords (accessible only to technical service);
- **Tech:** allows accessing to the whole Technical Menu, protected by passwords (accessible only to technical service);
- **More:** allows accessing to some info, like useful information and technical phone numbers, or to the data of the last session.

8.1 - MENU DESCRIPTION

In the next pages will be explained the functionality of each menu.

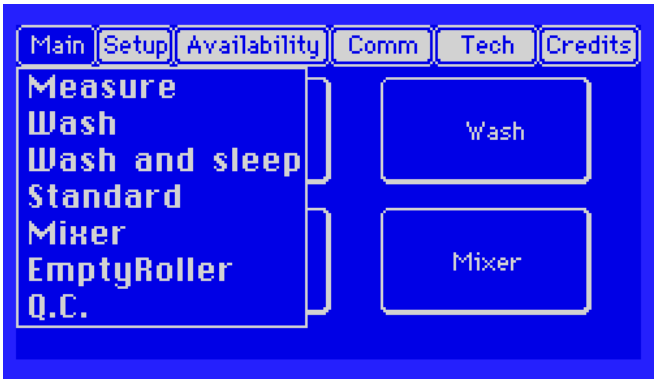
WARNING!! Remember that not all the functions inside each one of the menus are freely accessible; the instrument has three levels of access:

Level 1 Operator Access:	free without password can access only some functions like date & time
Level 2 Coordinator:	require password can access Level 1 and the Setup functions
Level 3 Technical Service:	require a password, allow access to all functions; this password is **ONLY for Technical Service and Alifax Manufacturing dept**.

For more details on the three level access, please refer to chapter 16.1.

9.0 – MAIN MENU

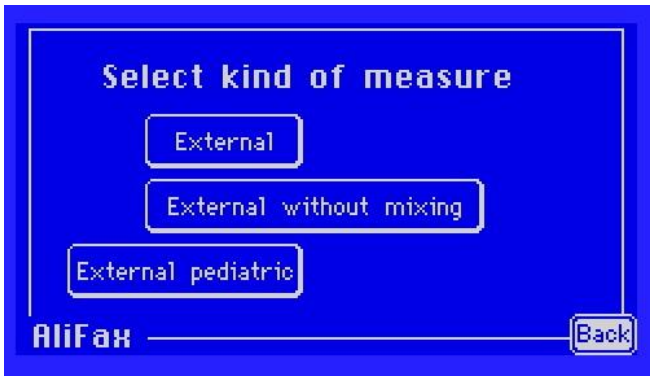
Main Menu:
Pressing "**Main**" in the **MAIN SCREEN,** the instrument shows the following options



9.1 - MEASURE MENU

Measure:
Pressing the option **"Measure"**, the instrument, offers these possible options:

- External normal withdrawing;
- External withdrawing without mixing.
- External pediatric withdrawing (only if pediatric flag is enabled);



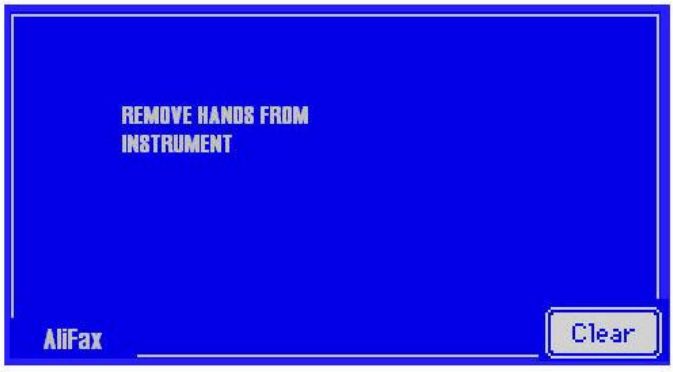
Then, independently from the option previously chosen, the instrument checks the state of the rotor, controls the level of the waste tank, controls the availability of credits and requires to identify and load the samples to be analysed.

9.2 – PATIENT IDENTIFICATION BY EXTERNAL BARCODE READER

If the sample is identified by a BCR, read it using the external scanner. The instrument will show the read ID number on the screen and after that will move ahead 1 position the rotor in order to allow the sample insertion.

WARNING!! The tube MUST be inserted **ONLY AFTER** the instrument shows on the display the read ID as in the following example:

If by mistake has been read the wrong patient ID, just pressing "**Back**" is possible to read again the correct one.
To insert the tube open the tilting door, insert the tube in the available tube holder; the instrument **has two sensors** to detect the presence of the tube's cap and also to detect the presence of fingers. If after few seconds the outer sensor still detect the fingers, the instrument will show on the display the following message:



Otherwise this one:

as is possible to observe, after the loading of the first sample, the instrument shows the "**Start**" button; pressing it the instrument start the analysis.
If more samples are required to be analyzed just repeat the procedure or reading ID using the EBCR.

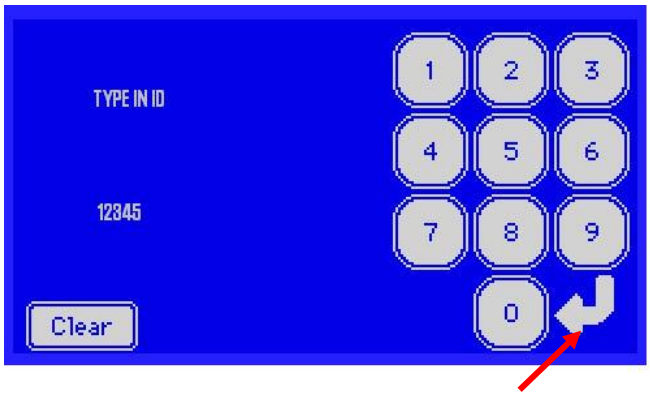
This means that the instrument is ready to read the next sample's ID by EBCR or, by **pressing**:

Start: The instrument will start the analysis cycle
Back: Will ask to remove all the previous inserted tubes, checking one by one they has been removed.

9.3 – MANUAL INSERTION OF THE PATIENT ID

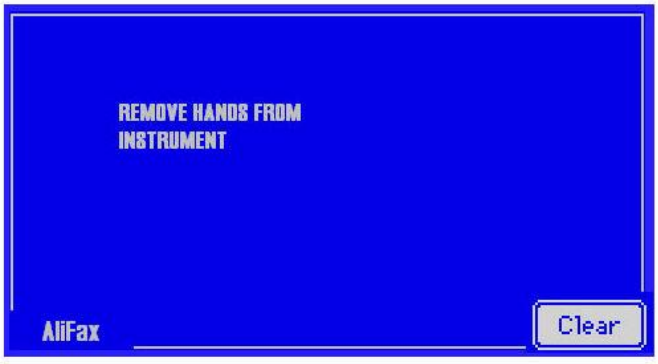
If the instrument doesn't have an external bar code reader (EBCR) but in any case the sample is identified by a barcode label, it is possible to load sample's ID by "keyboard" as explained in this chapter.

After have pressed "**Measure**" in the Main Menu, the instrument shows the following message:



now pressing **"Manual ID"** the instrument allow to type manually the sample's ID then, pressing "**ENTER**" (in this case the left arrow) the instrument will ask to insert the tube, then pressing "**OK**" the instrument shows this message and moves the rotor to the corresponding position to allow the operator insert the tube.

If by mistake the wrong patient ID was entered, just pressing "**Back**" it is possible to enter the correct one.
To insert the tube open the tilting door, insert the tube in the available tube holder; the instrument **has two sensors** to detect the presence of the tube's cap and also to detect the presence of fingers. If after few seconds the outer sensor still detect the fingers, the instrument will show on the display the following message:



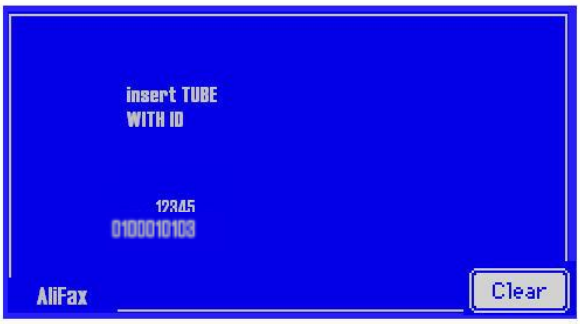
as is possible to observe, after the loading of the first sample, the instrument shows the "**Start**" button; pressing it the instrument start the analysis.
If more samples are required to be analyzed just repeat the procedure.

This means that the instrument is ready to read the next sample's ID by EBCR or, by **pressing**:
Start: The instrument will start the analysis cycle
Back: Will ask to remove all the previous inserted tubes, checking one by one they has been removed

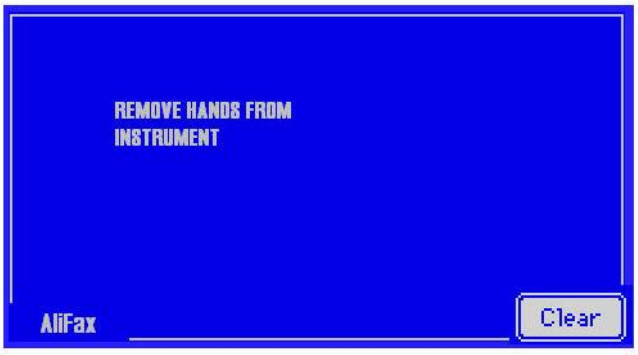
9.4 – AUTOGENERATED ID

If the instrument doesn't have an external bar code reader (EBCR) and/or the sample tube doesn't have a Bar Code Label, it is possible to insert the tube allowing the instrument to autogenerate a progressive ID .
After have pressed "**Measure**" in the Main Menu, the instrument shows the following message:

now pressing **"Auto"** the instrument will self-generate the sample's ID and then, pressing **OK**, the instrument shows this message and moves the rotor to the corresponding position to allow the operator insert the tube



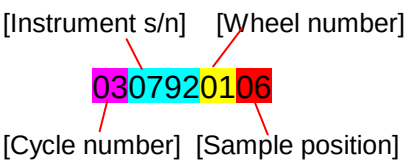
To insert the tube, open the tilting door, insert the tube in the available tube holder; the instrument **has two sensors** to detect the presence of the tube's cap and also to detect the presence of fingers. If after few seconds the outer sensor still detect the fingers, the instrument will show on the display the following message:



as is possible to observe, after the loading of the first sample, the instrument shows the "**Start**" button; pressing it the instrument start the analysis. If more samples are required to be analyzed just repeat the procedure.
This means that the instrument is ready to self-generate next sample's ID or, by **pressing**:

Start: The instrument will start the analysis cycle
Back: Will ask to remove all the previous inserted tubes, checking one by one they has been removed

The auto-generated code is a numeric code that is generated from instrument with the following fields: cycle number, instrument serial number (s/n), wheel number and sample position into the wheel (see right side example)…

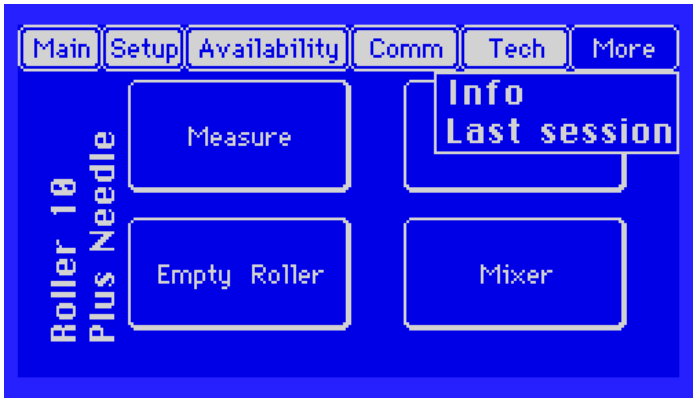


9.5 – RESTORE LAST SESSION

This function allows to restore the last session, in case of the instrument is switched off for mistake, for an error or for a black out. **Notice that this function doesn't work for external withdrawing without mixing.**
When this occurs, after switched on the instrument again, it after few second asks this question: "Restore last session?"

Then, is possible to choose if restore the session or no, in fact, pressing "**YES**" button, the instrument starts to mixing the samples and after continues with the interrupted session analysing the remaining samples.
Otherwise, pressing "**NO**" or "**Back**" button, the instrument definitively aborts the current session, asks to remove the samples and comes back to main menu.

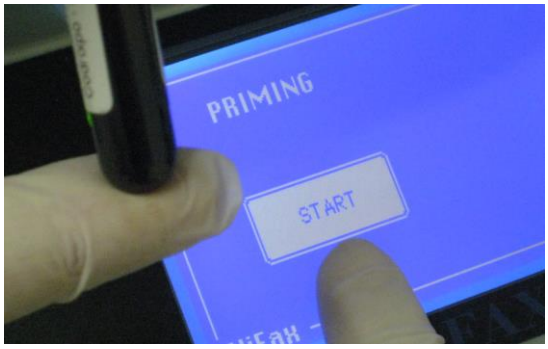
In any case, when the instrument comes back to main menu, it is possible to see the results of the last session, pressing "**Last session**", inside menu **More**.



9.5 – EXTERNAL PEDIATRIC SAMPLING PROCEDURES, USING INTERNAL MIXING

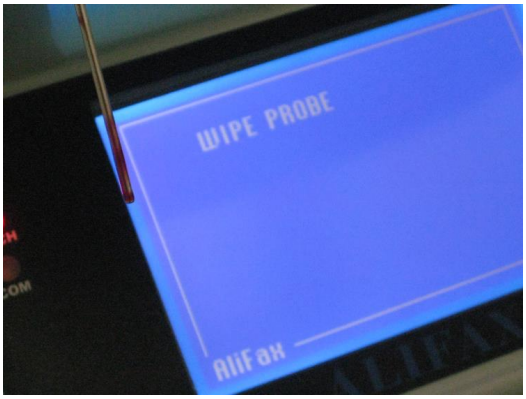
When using the external withdrawal procedure, it is mandatory to use gloves and all the others protective tools, precautions and warnings necessary to avoid the contact with biological materials in accordance with national laws.

In case the option chosen is external sampling normal or paediatric (with internal mixing), the instrument will ask to load the samples and will mix them; then (after the mixing cycles have been executed) the instrument will require to remove one by one the samples from the rotor.
Note: ONLY if the analysis is done after a washing procedure, the instrument will execute a "Priming procedure".

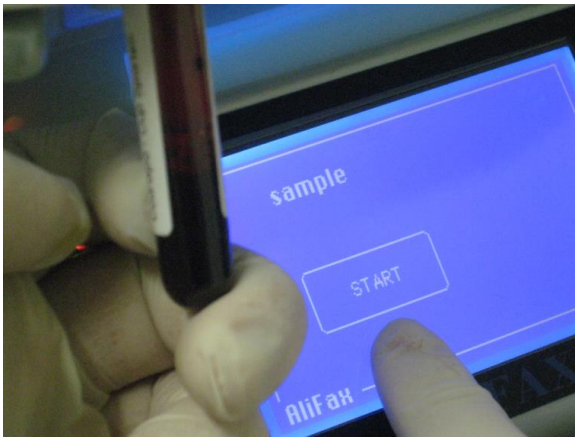


For the priming procedure, instrument will mix the blood loaded for the half of the total mixing cycles (in any case the minimum number of cycles done for mixing is not lower than 10), then the instrument asks to remove tube 1 and withdraw a small quantity of blood for the priming.
Take out tube from position 1, uncap it and insert inside the external probe and press START. Instrument will take a small amount of blood form the tube**, then it will issue 3 beeps, this means the tube MUST be removed from the probe.**
Next the blood is moved inside the reading unit to prepare the capillary receive the blood. Meanwhile instrument asks to reload tube in position 1 and continues with the mixing cycles till reaches the programmed mixing cycles.
Note: Only with pediatric session, is possible to do priming with pediatric samples, with normal session, is mandatory to use a normal sample (adult sample) for the priming, in order to don't waste pediatric samples.

To clean the external tip, use simple paper without adding any kind of detergent. Clean gently the tip moving from the top to the bottom, do not pull too hardly in order to avoid to damage the tip. At the end of the priming procedure, the tip come back to home position.



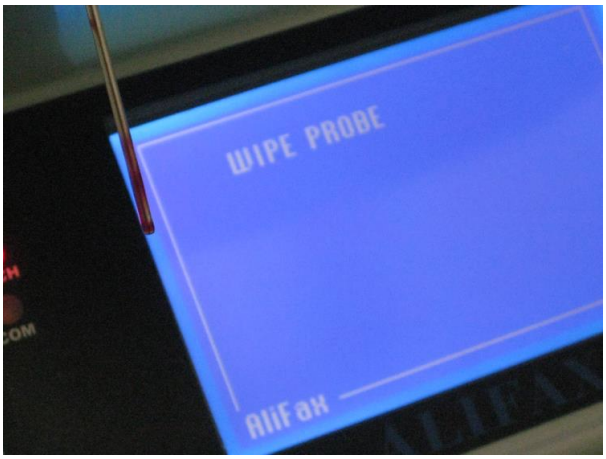
After the instrument has finished the mixing, will ask to remove from rotor the tube, then the probe will be moved out and (after having uncapped) insert the tube over the probe all the way down. Next just press START.

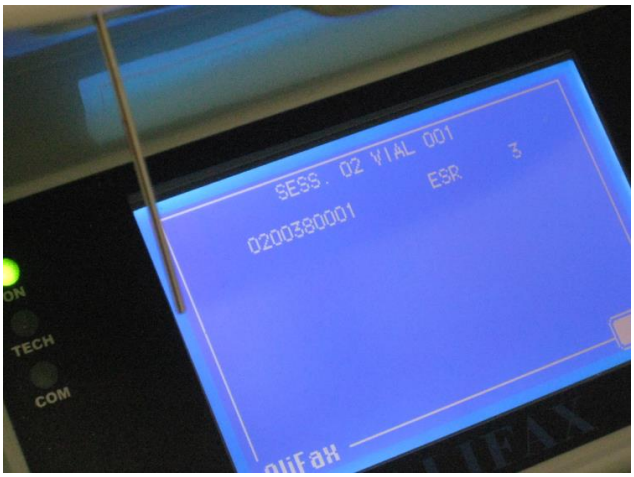


Note: when the aspiration is finished, instrument will beep 3 times, this means the tube must be removed from the external tip and recapped.

The tube can be reloaded on the rotor or left outside the instrument (external rack) for other eventual analysis.

During the analysis, the instrument will ask to clean the external tip. To clean the external tip, use simple paper without adding any kind of detergent. Clean gently the tip moving from the top to the bottom, do not pull too hardly in order to avoid to damage the tip.





Then the instrument will move the rotor to the next position and will ask to pick the next sample to be analyzed.

During the session the instrument will display on the screen the results obtained. Based on the printer setup, the printer will printout the results in “real time” (that means after each single analysis) or globally at the end of the analysis cycle.

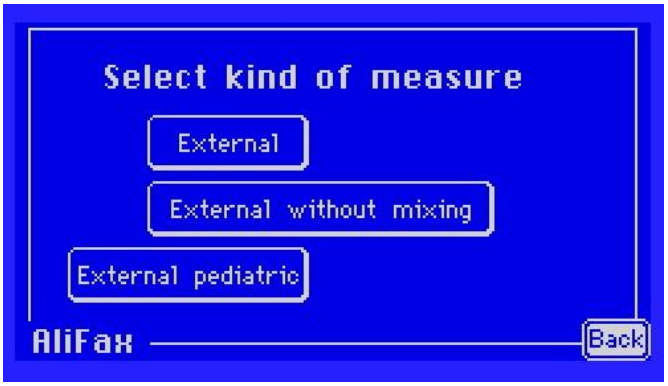
IMPORTANT:

Using external withdrawing tip, it is **mandatory** to clean it following the washing procedure in order to avoid blood dries inside the tip causing the formation of blood clogs inside it. The tip must be washed within 10 minutes after last sample analysis.

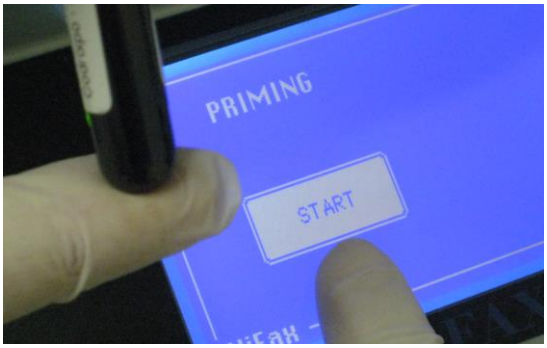
9.7 – EXTERNAL SAMPLING WITHOUT INTERNAL MIXING

When using the external withdrawal procedure, it is mandatory to use gloves and all the others protective tools, precautions and warnings necessary apt to avoid the contact in accordance with national laws.

In case the option chosen is external sampling **WITHOUT MIXING**, it is mandatory to mix samples by means of a rotating wheel or a tilting bed set at 32 rpm and 140 mixing cycles to allow a suitable homogeneization of the samples prior to the analysis.

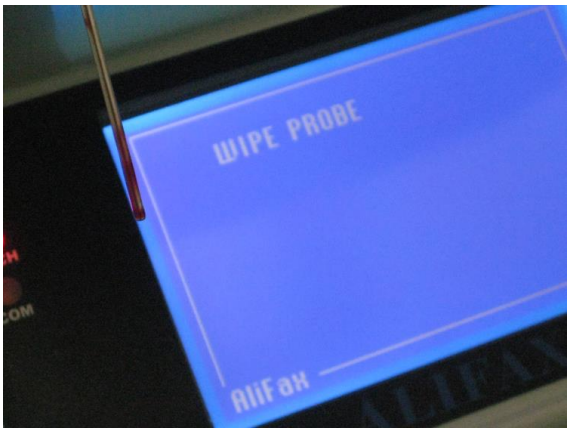


Then, ONLY if the analysis is done after a washing procedure, the instrument will execute a "Priming procedure".



For the priming procedure, take a tube well filled of blood, uncap it, insert it inside the external probe and press START. Instrument will take a small amount of blood form the tube**, then it will issue 3 beeps, this means the tube MUST be removed from the probe.**
Next the blood is moved inside the reading unit to prepare the capillary receive the blood. Meanwhile instrument asks to reload tube in position 1 and continues with the mixing cycles till reaches the programmed mixing cycles.
Note: in case of pediatric samples that normally contain few blood, in order not to waste them, the withdrawal for the priming can be done using a previous analyzed sample or blood belonging to an adult)

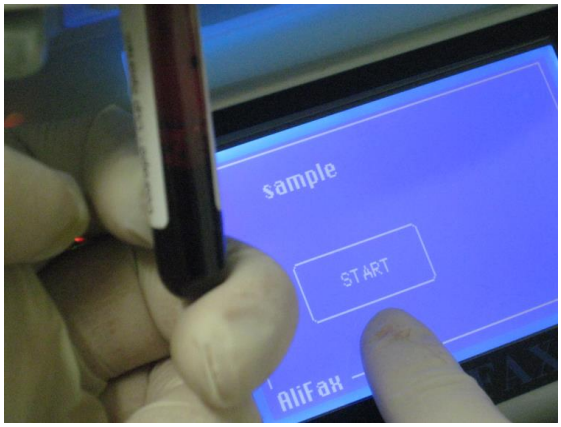
To clean the external tip, use simple paper without adding any kind of detergent. Clean gently the tip moving from the top to the bottom, do not pull too hardly in order to avoid to damage the tip.



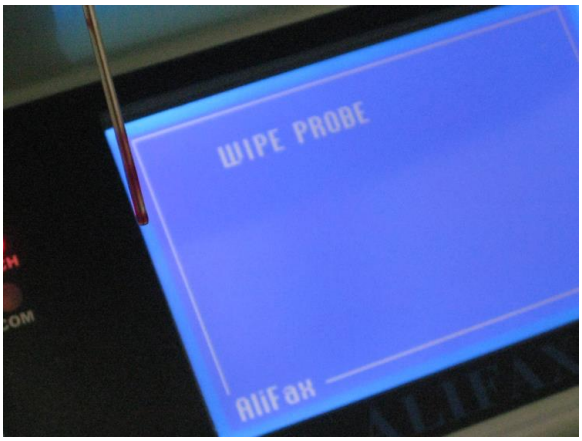
After the priming, instrument asks to identify the sample to be analyzed; as for the previous cases, the options are:

- Autogenerated ID
- Manual ID (typed manually)
- EBCR

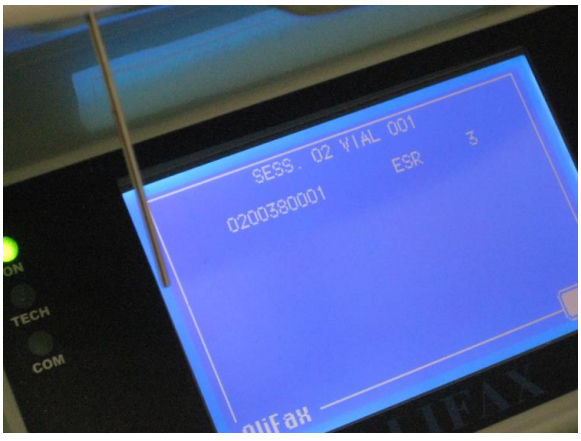
Once pressed OK instrument asks to withdraw the tube just identified previously; after pressing START the instrument will aspire the blood. In case of mistake, pressing the “BACK” button (not visible in the photo here displayed) instrument returns to previous screen were user can re-insert the ID.



Note: when the aspiration is finished, instrument will beep 3 times, this means the tube must be removed from the external tip and recapped.



During the analysis, the instrument will ask to clean the external tip. To clean the external tip, use simple paper without adding any kind of detergent. Clean gently the tip moving from the top to the bottom, do not pull too hardly in order to avoid to damage the tip.



At the end of the analysis, instrument show on the screen the result (and also print it if the flag “print in run” is enable), than after press OK button, reappears the ID insertion screen and so you can choose if analyse another sample, or pressing BACK button, to end the session.

IMPORTANT:

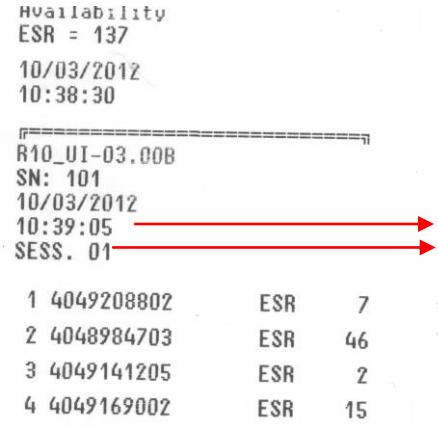
Using the external withdrawing tip, it is **mandatory** to clean it following the washing procedure in order to avoid blood dries inside the tip causing the formation of blood clogs inside it. The tip must be washed within 10 minutes after last sample analysis.

9.8 – ANALYSIS RESULTS (Display and Printouts)

After the sample analysis the instrument will show on display results and also printout each sample analysis's result.

During the analysis the instrument will display on the screen the result obtained. Based on the printer setup, the printer will printout the results in "real time" (that means after each single analysis).

The printout result looks like the one showed here:



For each session is reported:
Date and time of analysis
Session number (01 = first session of day)

Then for each sample are printed, in order:
The patient's ID and the ESR results expressed in (mm/h)

NF message generated because of missing blood flow into the capillary or a clot could be present inside the cell of measurement or there could eventually be an insufficient quantity of blood in the test-tube or eventually air bubbles thus the instrument is not able to identify presence of blood inside reading unit.
Details in APPENDIX A on page **70**

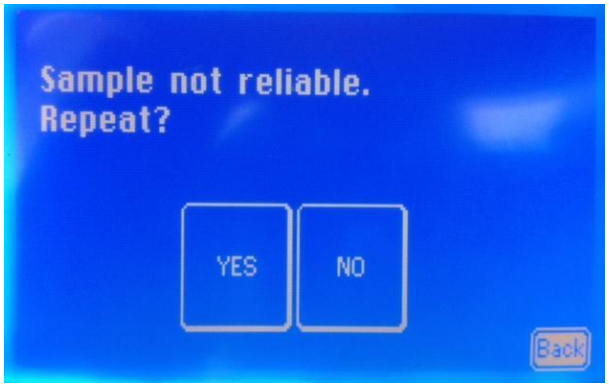
NR (**N**o **R**eliable) message generated because even if blood is inside reading unit, no aggregation is detected or a clot could be present inside the cell of measurement or there could eventually be an insufficient quantity of blood in the test-tube It is suggested to repeat the analysis indeed a second mixing sequence in some cases helps the blood desegregate well. Details in APPENDIX B on page **70**

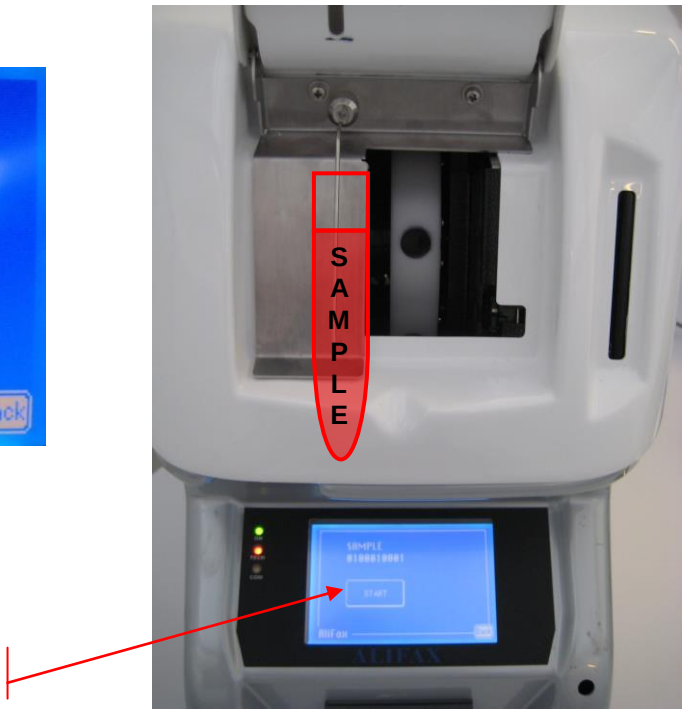
Attention, if the waste tank is full (the control is executed automatically by the instrument before beginning a new session), is necessary to empty the waste tank before starting a new session; otherwise, the instrument remains in standby until the waste tank is emptied.

9.9 - ANALYSIS RESULTS DURING SECOND TAKE OF SAMPLE

This function allows, in case of the sample value is not detectable, e.g. NF or NR (see Note 2), to try a second taking.

With this function, the instrument asks to following a specific procedure.
When the value of one sample is not detectable, the instrument shows this screen:





Then, is possible to choose if analyse again the sample or not, in fact, pressing "**YES**" button, the instrument asks to analyse again the sample and after pressing "**START**" button, is executed again the analysis procedure. Otherwise, pressing "**NO**" or "**Back**" button, the instrument doesn't analyse again the sample and then shows, prints and sends to host (if is present) the value NF (-4) or NR (-2).

NOTE 1: Every failed attempt, is saved inside the "Error Log" (visible only with technical password) in this way:

1ST NF EXT = failed first take, not detected continuous blood flow;
2ND NF EXT = failed second take, not detected continuous blood flow;
1ST NR EXT = failed first take, sample not detectable;
2ND NR EXT = failed second take, sample not detectable;

NOTE 2: The meaning of messages NF (sent to LIS as -4) and NR (sent to LIS as -2) is the following:

NF (-4) means that No blood Flux was detected from the instrument, usually because
a. the test-tube was removed before the three beeps or
b. there wasn't enough blood or
c. a clot is obstructing the withdrawal tip (in this case a washing will solve the error)

NR (-2) means sample Not Reliable because the instrument detected the blood stream but there wasn't any red cells aggregation kinetics on this blood. In this case, try to repeat the sample and if NR message again appears, verify the patients' blood profile for possible pathologies.

10.0 – WASH MENU

This procedure is designed to guarantee the capillary and all the hydraulic circuitries are maintained clean and free of blood residuals.

Considering the instrument uses a capillary tube in which blood, water and latex flows, it is normal that the internal walls of the capillary tend to become opaque, and also to remain dirty because some blood residual parts remain inside the capillary.

Washing options:

- Washing using 1 test tube with distilled water (standard washing);
- Maintenance washing (using 1 test tube with distilled water and one test-tube with chorine);
- End of working day washing procedure (wash and sleep).

At the end of every washing procedure the software, with the attempt to reach the original value (called **white value**) which is an absolute number **3800**, updates an internal compensator factor value according to the read water value (e.g. **Wt. 3796**).

To every incorrect washing procedure, (water value >4095 or water value <2100 due to water mixed with bubbles, anomalous water flow, etc.) the instrument will generate a **PHOTOMETER NOT OK error** and a new washing procedure will be requested.

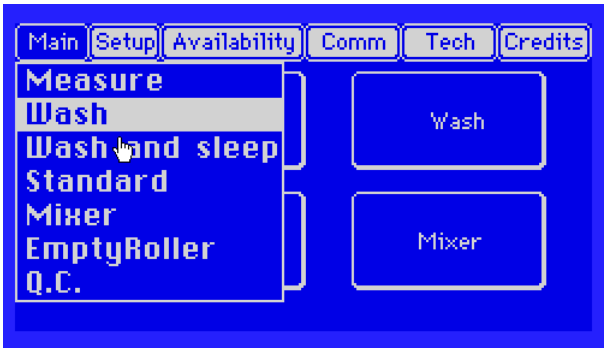
10.1 – WASHING USING 1 TEST TUBE (STANDARD WASHING)

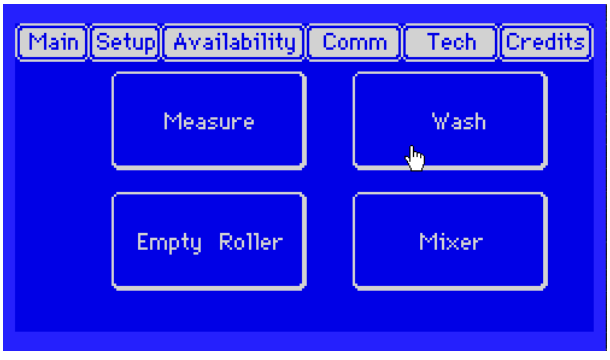
This option is used when **the instrument requires or needs to be washed** in a "normal" way (e.g. when the instrument asks by itself for a washing after three successive NF messages).

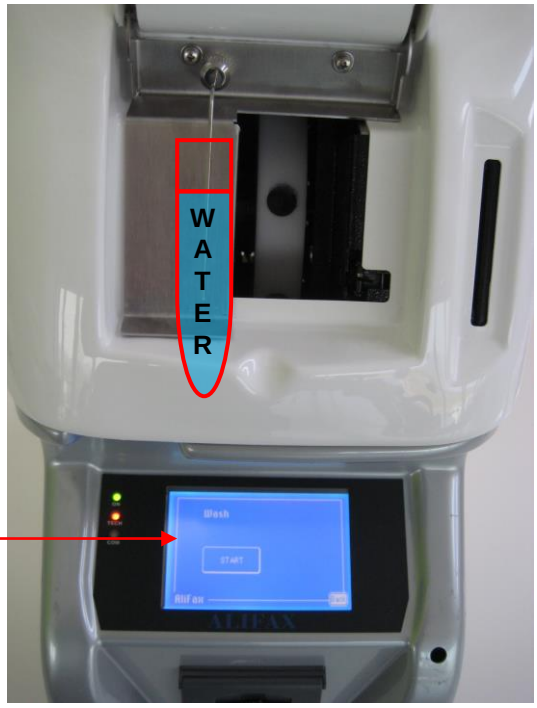
After this washing has ended the instrument is ready to continue working, but if not, try with washing for maintenance (chapter 10.1.2)

This procedure requires to **1 test tube** filled 3/4 with **distilled water**;

Wash:
Pressing “Wash” (from Main Menu or Main Screen) the instrument will set itself to be ready to perform a wash cycle







At this point, the instrument shows these screens:

Now the operator, after pressing "**OK**" on the first screen, and after inserting the washing tube inside the probe, can press "**START**" button to start the washing procedure. Otherwise if "**Back**" button is pressed, the instrument comes back to Main Menu.

At the end of the washing cycle, the instrument will printout a report in which it shows the parameters of the photometer.

If the procedure was successful, so without any type of error, the instrument will report "**PHOTOMETER OK**".

Otherwise, if for any reason the washing procedure reports "**PHOTOMETER NOT OK**" this means that the washing cycle has not been executed correctly. **In this case, try to proceed with Washing Procedure for Maintenance described on the next chapter 10.1.2.**

Now pressing "**OK**"; the instrument will display the previous message that suggest to repeat the washing procedure.

In both case, at the end of the washing procedure, the instrument asks to close the front door:

Then, after press "**OK**" button, the instrument comes back to Main Screen.

Attention, if the waste tank is full (the control is executed automatically by the instrument every 19 cycles of analysis), it is necessary to empty the waste tank before starting a new session; otherwise, the instrument remains in standby until when the waste tank is emptied.

10.2 – WASHING PROCEDURE FOR MAINTENANCE

For a good maintenance of the instrument and in case the needle and/or capillary are obstructed, carry-out this procedure using distilled water and Sodium Hypochlorite (5% of dilution).
This procedure should be done on a daily basis; in any case it is mandatory before the quality control procedure using the Latex Controls or just before powering off the instrument or if the instrument will be left idle for some hours (e.g. more than 2 hours).

- Execute the first washing, selecting "**Wash**" and using **1** test-tube filled ¾ with distilled water.
- Execute a second washing, selecting "**Wash**" and using a test-tube filled up ¾ with sodium hypochlorite (diluted at 5%).
- Execute a third washing (rinse) selecting "**Wash**" and using **1** test-tube filled ¾ with distilled water.
- **This procedure can be carried out also for capillary and/or probe obstructed**

10.3 - WASHING PROCEDURE IN CASE OF USE OF LATEX CONTROLS

The washing procedure in case of LATEX CONTROLS, is the same of the previous procedure described (**washing procedure for maintenance**). It must be used every time before starting with the control process in order to carry-out quality control of the instrument.

If the instrument is controlled using Latex Control Kit, this procedure MUST be done every time latex controls are used.

At the beginning of each Latex Controls session:

- Execute one first washing, selecting **"Wash",** then option **"Internal**", load 2 test-tube filled ¾ with distilled water in positions 1 and 2 of the rotor
- Execute a second washing selecting **"Wash"** then option **"Internal** " and to load in position a 1 test-tube filled up ¾ with sodium hypochlorite (diluted at 5%), while in position 2, a test-tube filled up ¾ with distilled water.
- Now is possible to execute the Latex Control session. Choose the option **"Standard"** located inside **"Main"** menu. Load in position a 1 test-tube filled up ¾ with distilled water, then the three latex-tubes and the others two tests-tube filled up for ¾ with distilled water following the instructions indicated on the screen.

10.4 - END OF WORKING DAY WASHING PROCEDURE (Wash and Sleep)

This option is used at the **end of the working day** and offers the possibility to maintain the capillary moist overnight. This is useful because all the hydraulic circuitry remains filled with water.
The advantage of this procedure is that all residual blood particles that eventually have remained inside the capillary, are kept moist avoiding them to remain stuck over the internal capillary walls.

Attention: before to launch this Wash and Sleep procedure, we recommend a first standard Washing with a test-tube filled ¾ with distillate water, a second standard Washing with a tube filled ¾ with chlorine and finally the following Wash and Sleep procedure:

Wash and Sleep:
To activate the procedure select "**Wash and Sleep"** from the Main Menu:

Then, the instrument requires 1 test-tubes filled up 3/4 with distilled water and then active the washing procedure. (like in the **chapter 10.1.1**).

At the end of the washing cycle, the instrument after having printed out the result of the first wash, requires to use a further test-tube always with distilled water. From this test-tube it will withdraw approximately 1/3 of the content, then the instrument will stop the pump leaving the liquid inside the capillary and **it will ask to switch OFF the instrument**.

This system maintains all the hydraulic circuit filled with water and avoids that eventual residual particles of blood dries and stick to the inner wall of the capillary.
At the next **switch ON** the instrument will empty the residual water from the capillary.

This procedure of washing **MUST BE EXECUTED** at the end of each working day in order to guarantee a good and efficient maintenance of the instrument.

10.5 - WASHING ERRORS

If for any reason the washing procedure reports **"PHOTOMETER NOT OK"** means that the washing cycle has not been executed correctly or has been found anomalies in the system.

The possible causes of malfunctioning could be:

- It has been used an empty WASH tube,
- Washing reference level lower than 2100
- Washing reference level inside the range (2100 – 4095) but not detected sample's end
- Washing reference level higher than 4095
- Detected air bubbles during the washing procedure

11.0 - STANDARD (Latex control / calibration)

With the purpose of guarantee an always optimum performance of the instrument, the daily use of the latex control kit is recommended.

Latex Controls kit is a valid check tool to monitor the reliability of the analyser during its working life. The kit is supplied in a box. It can contain three test tubes filled with Latex that allow executing a total of 6 controls (sale code **SI 305.100-A**) or it can contain five test tubes filled with Latex that allow executing a total of 30 controls (sale code **SI 305.300-A**). Before starting the Control process, the analyser can require a washing procedure. In this case, the operator should carry-out a washing procedure as "WASHING USING 2 TEST TUBES", chapter, explains. At the end of the Control process, the printed out results are three ESR values: the first one can be closed to 9 mm/h, the intermediate one to 20 mm/h and a high level to 60mm/h. The obtained results should be compared with the values reported on the label, second table, applied on the kit package. If the obtained results are into to the expected ranges, reported on the label, it means that the analyser is calibrated correctly. On the contrary, if one or more results are out of the expected ranges, it is recommended to call the Technical Service to carry out a functional verification of the analyser and a new calibration of it.

Latex Controls (or Calibrators), once extracted from the refrigerator (keep in refrigerator to +4÷8 °Cs) must remain at room temperature for at least 30 minutes before the use; once used the latexes must be returned in the refrigerator within maximum 1 hour after their use.

PRINCIPLE OF METHOD
The Latex Controls kit is based on the use of three samples with known turbidity values, on which the analyzer performs transmittance measurements related to ESR values. The results obtained should fit the expected ranges. Otherwise the calibration of the instrument shall be verified.
Please refer to **chapter 14.0** for quality control and statistical tools.

At the beginning of each Latex Controls session:

- Execute one first washing, selecting **"Wash",** then load 2 test-tube filled ¾ with distilled water in positions 1 and 2 of the rotor (or in case of external circuit, wash it using 1 tube)
- Execute a second washing selecting **"Wash"** then option **"Internal** " and to load in position a 1 test-tube filled up ¾ with sodium hypochlorite (diluted at 5%), while in position 2, a test-tube filled up ¾ with distilled water.
- Now is possible to execute the Latex Control session. Choose the option **"Standard"** located inside **"Main"** menu. Load in position a 1 test-tube filled up ¾ with distilled water, then the three latex-tubes and the others two tests-tube filled up for ¾ with distilled water following the instructions indicated on the screen.

IMPORTANT: Remember that in case you choose of don't use the internal rotor for the mixing, you will must use an external system for mixing the vials. Then for the mixing, is advised to mixing manually the latex tubes (it is enough 5-10 top-down inversions) or to use a Vortex or an external mixer rotor for 5-10 seconds to re-suspend the latex.

Material:

- 1 tube "**Tube 1**" filled ¾ with distilled water;
- 3 tubes "**Tube 2**" , "**Tube 3**" and "**Tube 4**" of Latex control;
- 2 more tubes "**Tube 5**" and **"Tube 6**" filled ¾ with distillated water.

Checks:

- If the Latex expiration date has been passed, the instrument will abort the procedure without performing the control;

- If the three tubes don't belong to the same kit, if not will tell the inserted codes are inconsistent, in that case press "**Exit**" and the instrument will return to Main Menu;
- If more than 6 weeks has passed after the first piercing date of the inserted triplet, the instrument will abort the procedure without performing the control;
- If the loaded triplet has been used more than 6 times, the instrument will abort the procedure without performing the control;
- If the hydraulic circuit is dirty (not washed after last analytical session), the instrument asks to make a wash.

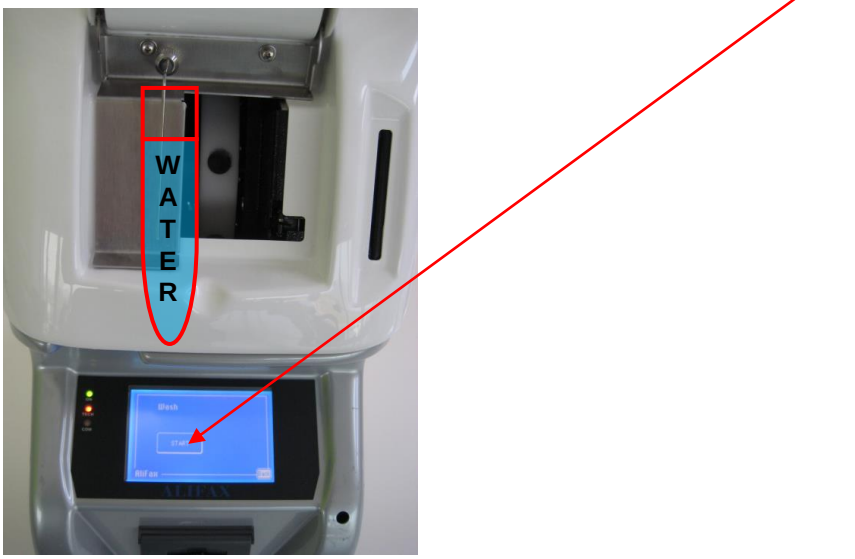
If all checks are ok, the instrument will begin the control procedure.

Sequence:

1) Instrument asks to open the front door, then after pressing "**OK**" asks to read the three codes of the latex's triplet:

Remember to insert the codes in this order: "**Tube 2**", "**Tube 3**", "**Tube 4**", and also in this case, is possible to insert the code **Manually**, pressing the Manual ID button and typing the number with the keyboard, or using the **Memo** button in order to recall a previously memorized code, or using the **EBCR** (External Barcode Reader) to read the bar codes on Latex Control tubes #2, #3 and #4.

2) After the codes insertion, take the first water tube ("**Tube 1**"), insert it inside the probe and press "**START**"

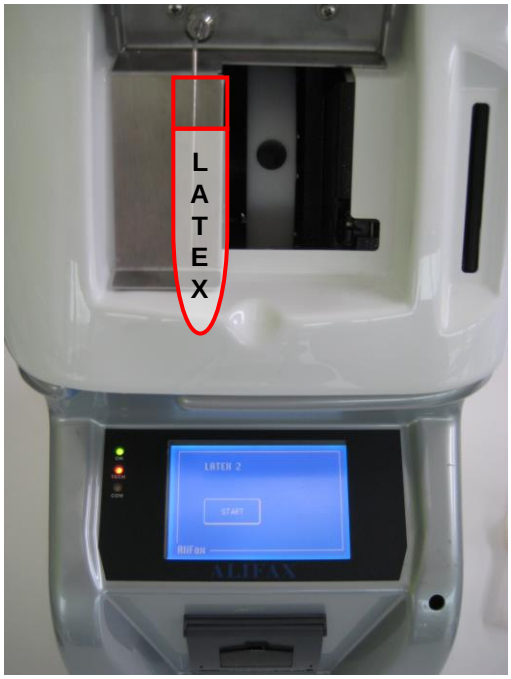


Otherwise if "**Back**" button is pressed, the instrument comes back to Main Screen

3) After wash, Instrument asks to perform the **Priming**, then after **mixing** the tube ("**Tube 2**") insert it inside the probe and press "**START**", instrument will perform a PRIMING procedure aspiring a small quantity of latex and then will issue 3 beeps, this means the tube MUST BE REMOVED FORM THE PROBE, and meanwhile the instrument does the priming it asks to **wipe the probe**

IMPORTANT: Remember to mixing the tubes with the internal rotor or with an external rotor or manually by reverting smoothly each single latex tube for at least 30 seconds.

4) After priming, the instrument asks again the "**Tube 2**", so after **mixing** the tube, reinsert it in the probe and pressing "**START**", the instrument aspires the prefixed aliquot of latex, then will issue 3 beeps, this means the tube MUST BE REMOVED FORM THE PROBE, and meanwhile the instrument does the priming it asks to **wipe the probe**

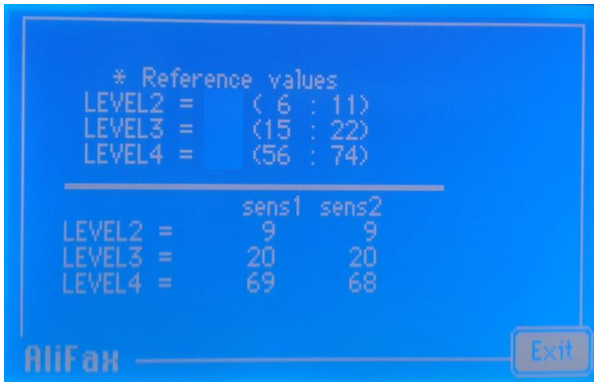


The same procedure will be repeated for "**Tube 3**" and "**Tube 4**" of latex.

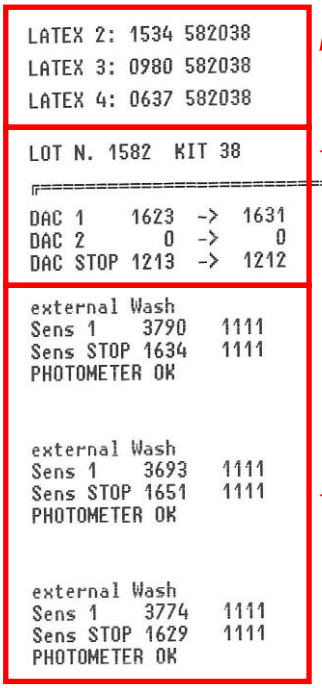
IMPORTANT: Remember to mixing well the tubes with the internal rotor or an external rotor or manually by reverting smoothly each single latex tube for at least 10 seconds.

5) After latex, take the second water tube ("**Tube 5**") to run first washing after latex, followed by another washing with the third wash tube ("**Tube 6**")

6) Finished the washing procedures, instrument will display and print the expected values and the obtained values, the after pressing "**Exit**" it comes back to Main Screen.


* Reference values
LEVEL2 = (6 : 11)
LEVEL3 = (15 : 22)
LEVEL4 = (56 : 74)
sens1 sens2
LEVEL2 = 9 9
LEVEL3 = 20 20
LEVEL4 = 69 68
AliFax
Exit

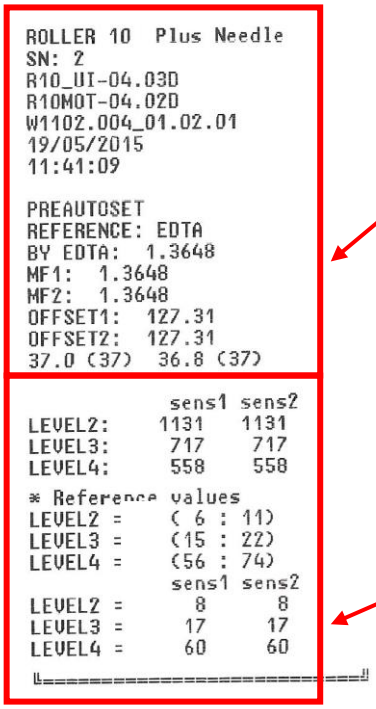
11.1 – LATEX CONTROL PRINTOUT



Part 1:
Barcodes of latex inserted:
Latex 2: first code of latex read
Latex 3: second code of latex read
Latex 4: third code of latex read

Part 2:
Latex lot number and progressive number of the lot.
Values of the DAC before and after washing

Part 3:
Washing sequence, here instrument prints out the water values of the three tubes (1st before latex and then last 2 after latex)
Also report if Photometer is OK or NOT OK

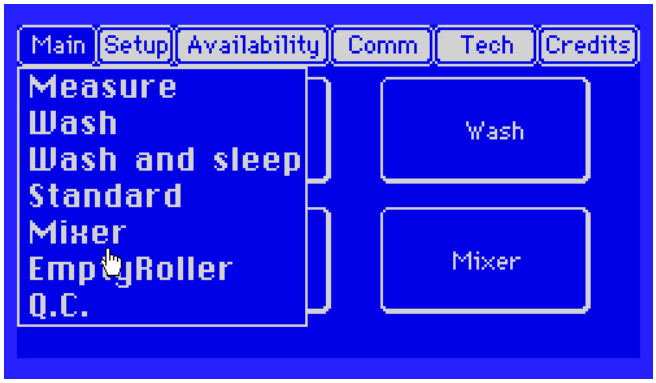


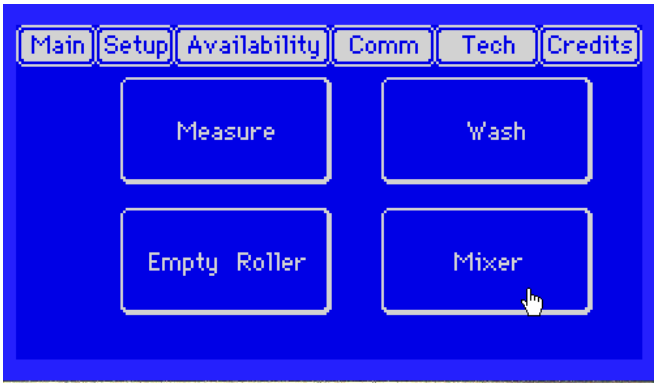
Part 4:
Operative parameters set to the Reading Unit:
Type of reference (EDTA or Citrate)
BoosterY (EDTA or Citrate, in base to the reference chosen)
MFact 1
MFact 2 (the same value of MFact 1)
Offset 1
Offset 2 (the same value of Offset 1)
Temperature of both CPS parts (Led + Photometer)

Part 5:
In this part the instrument printout the result get after the Control procedure
Expected values
Measured values.

12.0 - MIXER

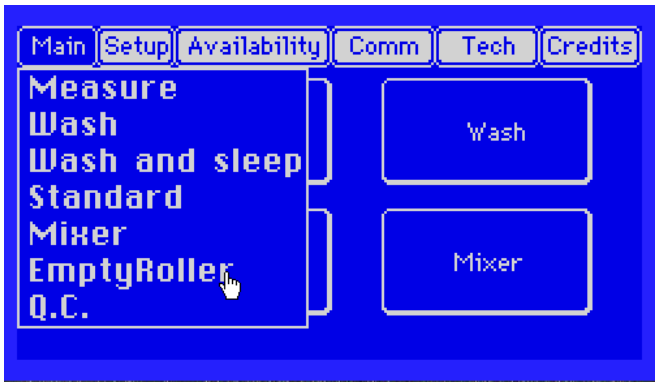
- By pressing **"Mixer"**, (from Main Menu or Main Screen), The display will visualize the message: **OPEN FRONT DOOR.**
- Now the instrument wait the insertion of the vials. (After the insertion of every vial, the rotor will rotate by one step until to reach the next vial position).
- **BEFORE TO INSERT THE VIALS IN TO THE ROTOR, CHECK THAT THEY ARE CAPPED VERY WELL TO AVOID LEAKS OF BLOOD AND PROBLEMS AT THE PROPERLY FUNCTIONS OF THE INSTRUMENT.**
- When you have finished to insert the vials, close the front door and press **MIXING.**
- The instrument will start to mixing the vials until to reach the number of rotation preset cycles.
- When the vials are ready be analyzed, the display will visualize the written **MIXING DONE.**
- The rotor will continue to mixing the vials for maintain the blood mixed until the analysis.

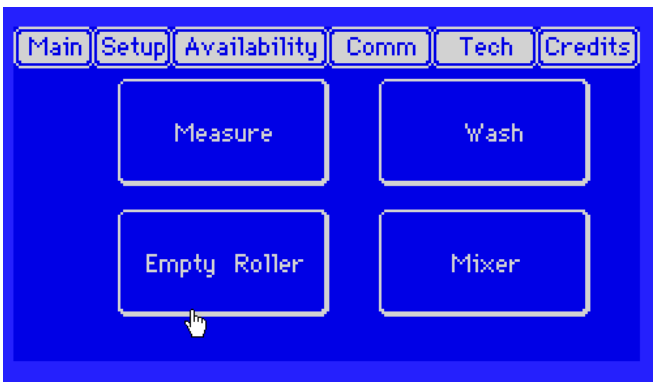




13.0 - EMPTY ROLLER

- By pressing **"Empty Roller",** (from Main Menu or Main Screen) the instrument will start to rotate to check the presence and the number of vials inserted.
- The display will visualize the message: **OPEN FRONT DOOR.**
- Now the instruments is ready to extract the vials and will displaying the written **EXTRACT VIAL**. (After the extraction of every vial, the rotor will rotate of one step until to reach the next vial position).





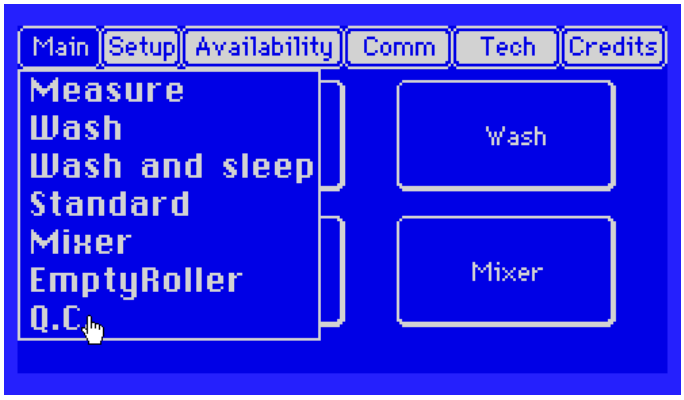
14.0 - STATISTICS

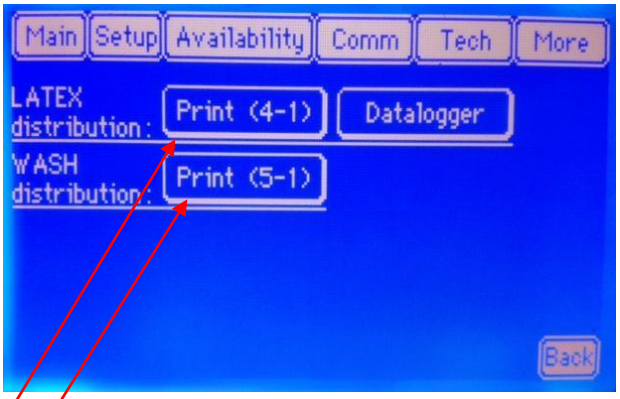
ROLLER family analyser provides a series of control tools for an effective product performances monitoring; such control tools are the following:

1. Photometrical check done during each washing.

2. For laboratory quality control it is then important to have at disposal a control system reproducible, reliable and easy to handle.
   This system is available using the **Latex Control kit** (**Ord. code SI 305.100-A / SI 305.102-A or SI 305.300-A / SI 305.302-A**) that was designed expressly for TEST1 family (TEST1, MicroTEST1, Roller). Please refer to **chapter 11.0** for latex control procedures.

Pressing **"Q.C."** from Main Menu, the instrument displays the Statistical Main Menu:





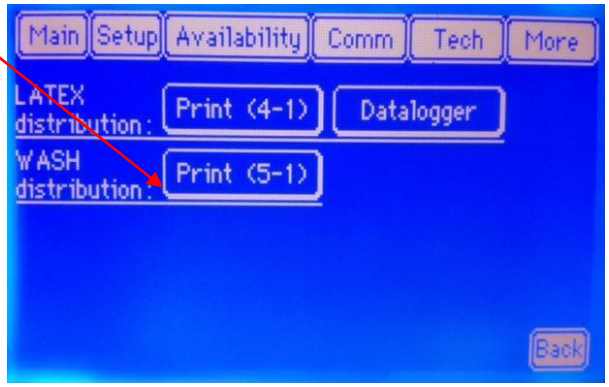
The instrument collects data from:

- Latex Control results
- Washing results

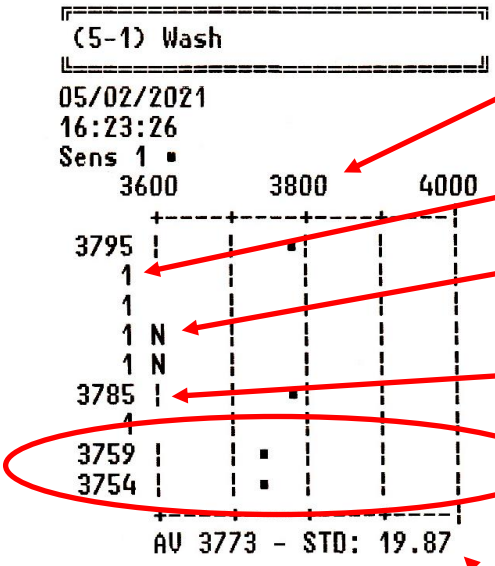
14.1 - WASHING QUALITY CONTROL PRINTOUT - Graph meaning

This function allows to printout statistical data about the washings executed on the instrument:
The printout of the washing control allows to estimate the efficiency of the photometer. The diagram visualizes the trend of washing values detected by the two sensors which are directly correlated to the photometric signal. Normally, the instruments are regulated automatically around to an absolute value of 3800 during the washing with distilled water. This value tends to move down during the time, because of the residues of biological material inside the capillary.

Pressing **"Print (5-1)"** activates the printout that represents the behaviour and the tendency of the photometric values correspondents to the values of the water.



How can see from the graph below, the instrument shows the trend of the last 30 days, from which is easy to identify any possible drift or abnormal values.
Explanation and interpretation of the diagram:



References of the sensors: 1, and stop (only 1 and stop for instruments with CPS mounted)
Lower and Upper limits of water acceptability, ideal reference is 3800 for the sensor.

This indication that identify the instrument has been switched ON, <u>not used</u> and switched OFF

This indication identify that the instrument has been switched ON, <u>used</u> and then switched OFF <u>without have been washed or every time Photometer NOK is issued</u>

This indication means that the instrument has been washed and the three sensors have detected a water value included within the lower and higher limits:

- sensor 1: 3785

On the graphical print out, the instrument prints always the last washing executed in the day, independently from how many had been effectively executed. In case more washings had been done during the same day, the data is overwritten. At midnight (change of the day), the instrument memorizes definitively the data of the last wash; that data is the one printed out.

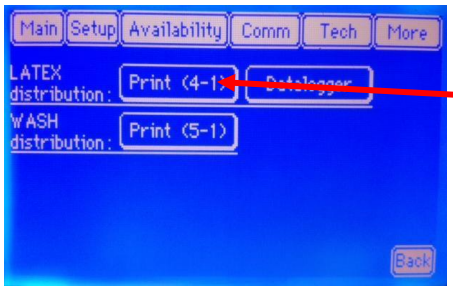
In the lower part of the report is printed out the statistical data about the last 30 days; this means, for every sensor: the average and the SD of the period. The most important thing is that the first two averages remain as close as possible to 3800 which is the reference value.

14.2 – INSTRUMENT VERIFICATION USING THE LATEX CONTROL KIT

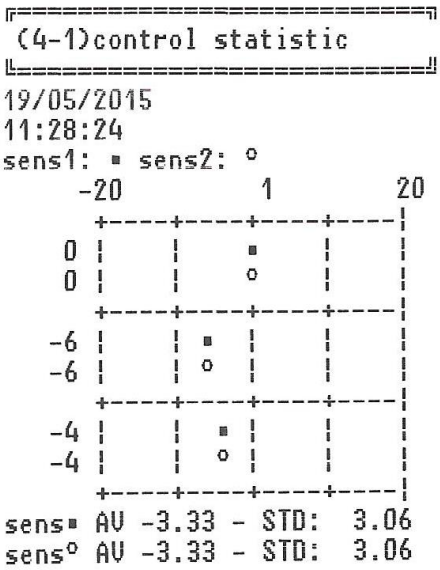
With the purpose of guarantee an always optimum performance of the instrument, the daily use of the latex control kit is recommended

The Latex Controls kit (**Ord. code SI 305.100-A / SI 305.102-A or SI 305.300-A / SI 305.302-A**) is a valid tool for the functional verification of the analyser Roller 10 PN. The results of the control simulate three ESR values, a first level (around 9 mm/h), one intermediate level (around 19 mm/h) and a high level (around 65 mm/h). By comparing the results obtained from the analyser with those reported on the kit package it will be very easy to control if the instrument is reporting reliable results or not. In this way, the instrument can be kept monitored during its whole operational life.

It is necessary to **strictly follow** the instructions for use included into the Latex Controls kit and at the end of the procedure compare the printed results from the analyser against the values reported in Table 2 on the package kit box: if the results obtained by analyser fits the expected range reported on Table 2 , it means that the analyser is calibrated.
On the contrary, if one or more results are different from the ones reported on the kit package, it is recommended to call the Technical Service for a functional verification and calibration of the apparatus.
Below are reported all the menus and printouts, where the user can check the data regarding the Latex Control kit



Results obtained during the latex control procedure are stored by the instrument; it is therefore possible to print out a report pressing the key **"Print (4-1)".** With this option it is possible to visualize the tendency of the instrument and being able to find eventual drifts that will require an accurate control of the instrument. The graphical printout cover the last 30 days.



The trend of the latex must be interpreted as a tendency pointer.
The starting reference are the values obtained during the calibration and then, for every control executed with the Latex Kit, the trend will show how much the read latex values drifts from the reference values printed on the box and also on the printout report generated during each control procedure.

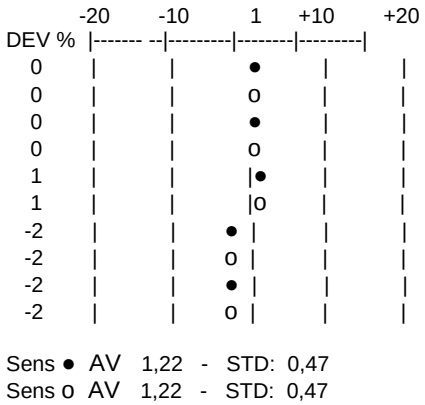
Analysing the diagram it is possible to observe that:

The sensors (that have the same value) show the reference marker which represents the drift from the reference (**1**) obtained from the analyser against the reference values.

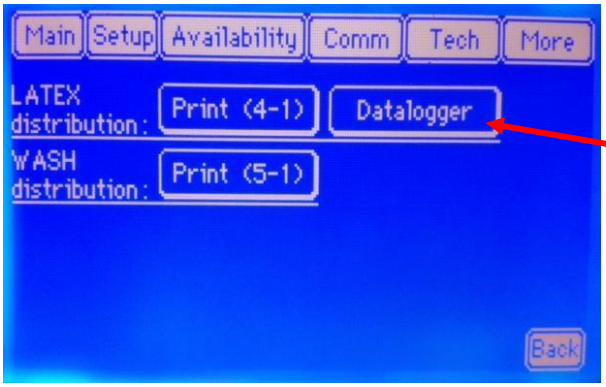
This trend, when is completely full, **represents a maximum of 30 days of analysis,** therefore anomalous tendency in the daily values, against the reference is easily identifiable. Consequently the customer is able to understand if there is systematic error or an instrument error. Data are shown from the oldest (lower part) to the most recent (upper part of the diagram).

Note: In this trend is shown a second value same to the first, this for maintain the compatibility to the old our sensor. This value is completely irrelevant from the point of view of measurement, and will be disabled in to the our next software release.

Explication of the printout report:

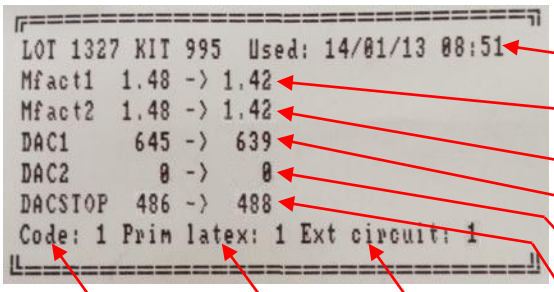


In order to better understand the meaning of the results printed out, imagine a series of three controls with values of 9, 19 and 65 mm/h (values of reference). Executing the control of the analyser, if the values will be identical (9, 19 and 65 that is the ideal case), there won't be a shift (y=1.00*x) and the dots symbol will printed exactly on the column 1, as on the first line on the aside graph. On the contrary, if for example the shift is +1,00% (y=1.01*x) the dots will be positioned between column 1 and column +10%, like the fourth white dot in the graph aside.
At the bottom are printed out the Average of DEV% values (AV) and the Standard Deviation (STD).



Results obtained during the latex calibration procedure are stored by the instrument; it is therefore possible to print out a report pressing the key "**Datalogger**". With this option it is possible to visualize precise information about all calibrations done, like the LOT and the KIT of the triplet, the date of withdrawal, old and new Model Fact, the type of withdrawal and the priming latex flag.

Printout explanation:



LOT number, **KIT** number, **date** of withdrawal

Mfact1 **old** -> **new** (value of Model Fact1 pre and post calibration)

Mfact2 **old** -> **new** (same value of Model Fact1)

DAC1 **old** -> **new** (value of DAC1 pre and post calibration)

DAC2 **old** -> **new** (always '0')

DACSTOP **old** -> **new** (value of DACSTOP pre and post calibration)

Ext circuit: **1** (1 = calibration done with external withdrawal)

Prim latex: **1** (1 = calibration done with priming latex enable)

Code: **1** or **2** or **3** (1 = ID inserted manually)
(2 = ID inserted with "Memo" button)
(3 = ID inserted with External Barcode Reader)

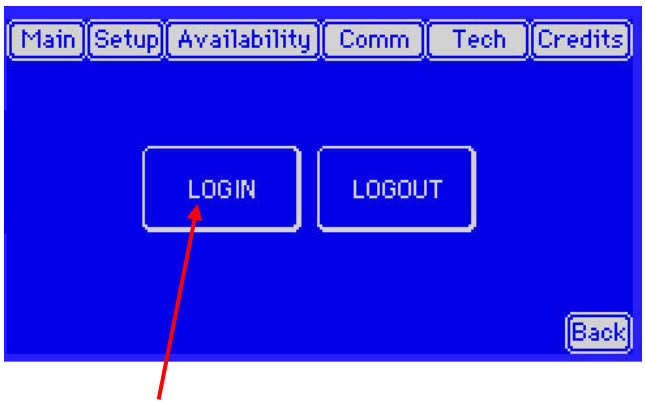
15.0 - SETUP MENU

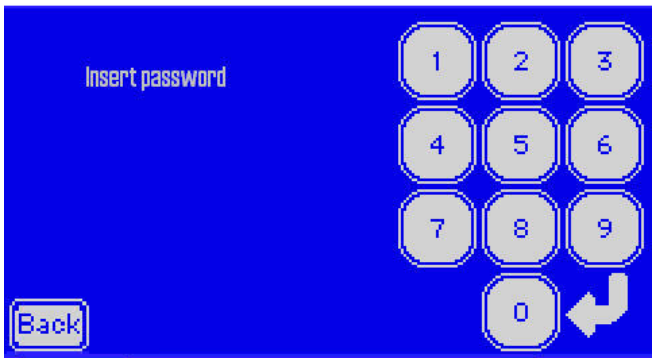
Setup Menu:
Pressing "**Setup**" from the Main Screen, the instrument shows the following options

15.1 - LOG IN-OUT

With the Menu "**Log In-Out**" in Setup Menu, the instrument allows the user to log in or out with the appropriate passwords.

After pressing "**Log In-Out**", the instrument will display:





pressing **"LOGIN"** the instrument will display a keyboard to type the password, type the proper password (see table in the next page), then press the **"left arrow"** to confirm or "**Back**" to exit without change anything, in both cases, the instrument will display again the previous screen, then press "**Back**" to return in Main Screen.

To Logout, access again to this function, press **"Log In - Out"** (in the Setup Menu), this time press **"LOGOUT"** and the instrument will return to **level 1**. Pressing "**Back**" is possible to go back to Main Screen.

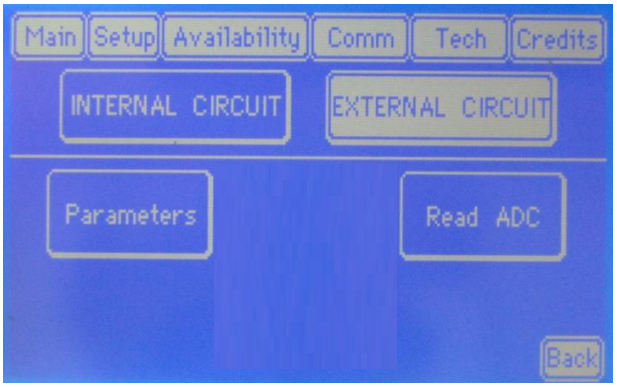
Password levels:

level	access
1	No password required, allow access only to the elementary functions
2	"LOGIN - USER LEVEL" (Typing the password "**1010**"): allow access to the elementary setup functions. When the instrument is switched off, the instrument loose this password, so next time the instrument is switched on it will be setup as **level 1 (base level)**.
3	"LOGIN - TECH LEVEL" (Typing the password "**xxxx**" – not given on this manual): this level is only for Technical Service Personnel.

15.2 - CPS MENU

CPS:
This function's accessibility **is linked to a password level**.

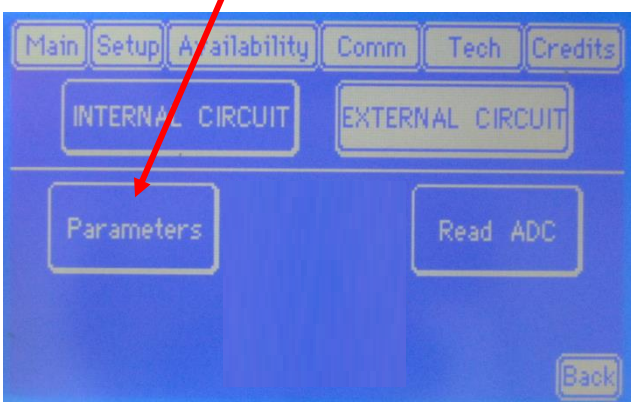
Pressing **"CPS"** (in the Setup Menu) without any password level activated, the instrument will display:

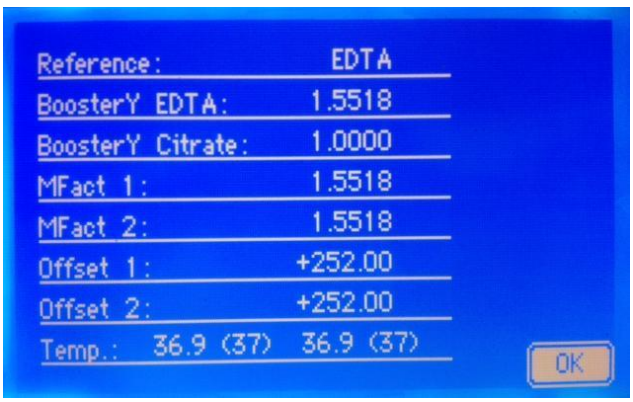


Pressing **"Back"** the instrument comes back to the Main Screen.

15.3 – CPS PARAMETERS

Then pressing "**Parameters**" will be displayed CPS's parameter but without the possibility to modify anything as showed in the next image:



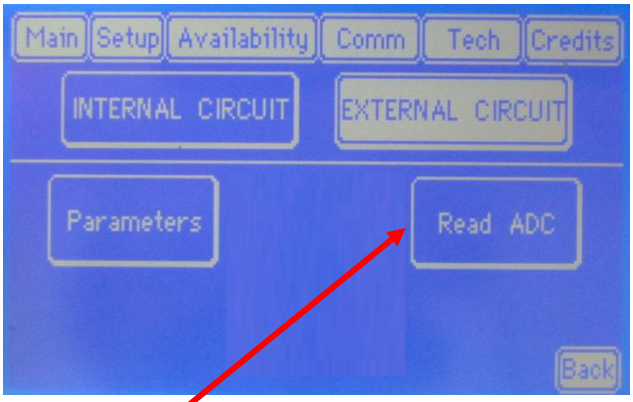


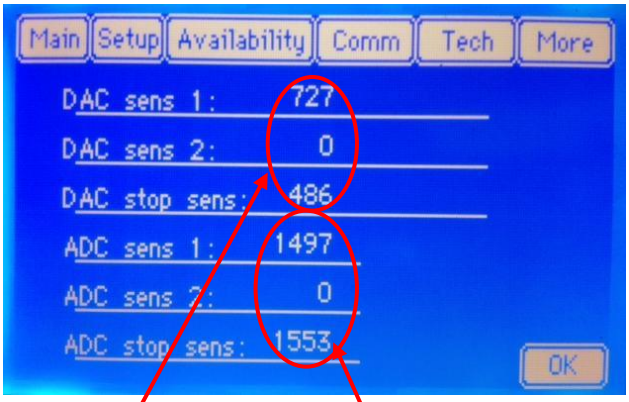
Pressing **"OK"** the instrument comes back to the CPS Menu.

15.4 – CPS Read ADC

This function allow technician to verify CPS's Analog-Digital Converters reference (without the possibility to modify anything if not logged as technical service).

Note: In this instrument the field INTERNAL CIRCUIT is not available.





Pressing "**Read ADC**" will be displayed CPS's Analog-Digital Converters reference, in particular:

DAC: which is changeable refers to the power emitted by the LED inside the reading unit. This value changes every time a latex procedure is done and the change is adjusted in order to obtain a value of DAC which guarantees a water value as close as possible to the reference value of 3800 (printed out during washing procedure). DAC reference number goes from 0 to 1023; normal working range goes **from 500 to 850**.

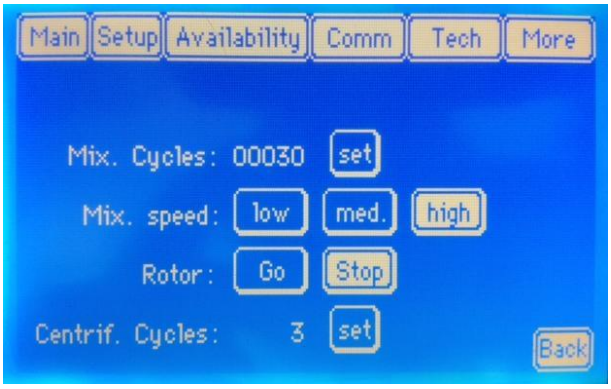
ADC: refers to the effective value that each sensor reads (in other words is the sensibility of the sensor) , in this case this value changes continuously and each value is independent from the others. **ADC reference number goes from 0 to 4095. There is no specific working range even if the normal value should be around 1300 - 1800**

Pressing **"OK"** the instrument comes back to the CPS Menu.

Remember that to modify DAC's values is mandatory a technical password.

15.5 - MIX MENU

Pressing **"Mix"** (in the Setup Menu), the instrument will display:



this function allows the user to set:

- The desired number of rotations: pressing **"set"** the instrument will display a keyboard where the operator can type the desired number of rotations (from 2 up to 1000), then pressing the **"left arrow"** confirm the new value.
- The desired mixing speed: **"low"**, **"med"** or **"high"**; just press the desired speed "button"

- The desired number of Cycles Centrifugations (for pediatric mode): pressing "**set**" the instrument will display a keyboard where the operator can type the desired number of cycles (from 2 up to 100), then pressing the "**left arrow"** confirm the new value.
- **by default the instrument is set up at medium speed, 140 cycles and 30 centrifugation cycles.**

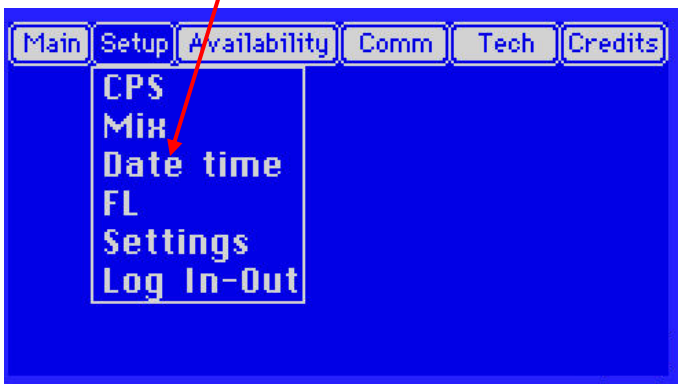
Finally the operator can check practically the rotor speed, by pressing "**Go**", in this case the rotor being to rotate and will still rotate up when the "**Stop**" is pressed.

Pressing **"Back"** the instrument will go back and will display the Main Screen.

15.6 - DATE TIME MENU

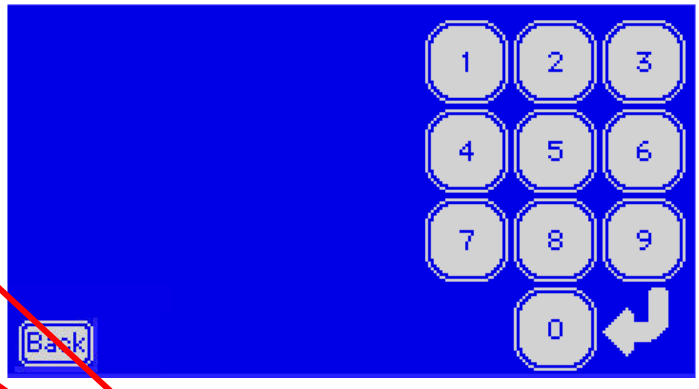
This function's accessibility **is linked to a password level**.

Without a password:
Pressing **"Date time"** (in the Setup Menu), the instrument will display:



Pressing "**Back**" the instrument comes back to Main Screen.

With a User Password (after logged, please see **chapter 15.1**):
Pressing **"Date time"** (in the Setup Menu), this time the instrument will display:



Now, pressing **"SET"** the instrument allow to modify TIME or DATE values;

- If the change is applied to **DATE**, the instrument will ask to modify in the following order: **Year**, **Month** and **Day,** to modify these parameters, just type the desired value;
- If the change is applied to **TIME**, the instrument will ask to modify in the following order: **Hour**, and **Minute**, to modify these parameters, just type the desired value.

Then press the **"left arrow"** to confirm or "**Back**" to exit without change anything, then the instrument will display again the previous image with the DATE or TIME new value. Pressing "**Back**" is possible to go back to Main Screen.

15.7 - FL (Flag List) MENU

Pressing **"FL"** (in the Setup Menu), the instrument will printout the Flag List

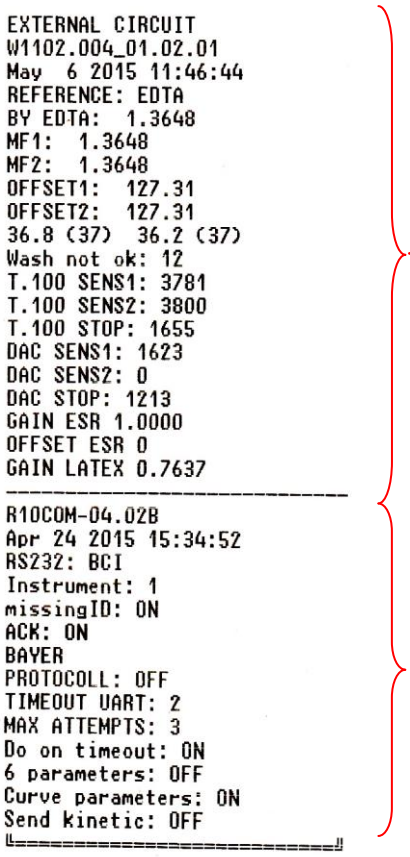
In the Flag List are printed out all the operational parameters of the instrument, in particular:

```
╔═══════════════════════════╗
19/05/2015
11:27:33
ROLLER 10  Plus Needle
R10-04.03D.00
---------------------------
R10_UI-04.03D
# Apr 24 2015 15:28:58
# SN: 2
DEBUG: ON
MAINTENANCE
WARNING: 30000
MAINTENANCE COUNTER: 1002
washing time: 20
PRINT DURING ANALYSIS: OFF
PRINT EXPANDED TEXT: ON
2 CPS: OFF
Pump on CPS: ON
Pediatric samples: ON
Test Mode: OFF
---------------------------
# Availability Enabled Print
# ESR =   9920     On    On
# AGF =      0     Off   Off
#  AF =   3000     Off   Off
#  VF =      0     Off   Off
# HCT =      0     Off   Off
#  HB =      0     Off   Off
# Global count ESR: 978
# Global count AGF: 0
# Global count  AF: 0
# Global count  VF: 0
# Global count HCT: 0
# Global count  HB: 0
SMART WARNING: 2000
# ALIFAX SPA
---------------------------
R10MOT-04.02D
Apr 24 2015 15:33:27
Mixing cycles: 110
Mixing speed: high
Manual sample ul: 30
Steps UP: 3700
Tube offset: 0
Syr fast: OFF
Centrifugation cycles: 20
```

UNIT INTERFACE
Date and time of the software compilation
Instrument serial number
Debug (ON or OFF) **(Only Technical Service)**
Threshold level for Maintenance intervention requesting. **(Only Technical Service)** reference value: 30000
Maintenance counter, counts the number of analyses
Threshold (in minutes) for automatic washing. **(Only Technical Service)** reference value 60
patient ID and ESR results printing on real time (ON or OFF)
IDs and ESR results on double height printing (ON or OFF)
Specify if 1 or 2 CPS are installed on the instrument **(Not available)**
Specify if the pump home sensor is mounted on the CPS (MC) board or not **(Only Technical Service)**
Specify if pediatric samples are enabled or not
Specify if test mode is enable or not

Test availability for the ESR and other parameters analysis
ESR and other parameters counter of executed test
Smart warning **(Only Technical Service)** reference value 1000
Smart personalization (distributor name)

MOTOR BOARD
Motor Board Software version.
Date and time of the Motor Board software compilation.
Number of mixing revolutions, from 2 to 1000
Mixing speed, 1=60 RPM (default), 2=32 RPM and 3=26 RPM
Withdrawal volume of blood, **(Only Technical Service)** reference value 30 µL
Upward steps done by syringe in automatic sampling **(Not available)**
Tube offset,
Syr Fast, define if the syringe moves up-down slow or fast **(Not available)**
Centrifugation cycles, number of cycles for pediatric samples, from 2 to 100



CPS BOARD (EXTERNAL)
Analogical Board Software version.
Date and time of the CPS Board software compilation.
Instrument BoosterY reference (EDTA or Sodium Citrate) **(Only Technical Service)**
Instrument Gain (BY EDTA or CITRATE) in base to the reference chosen **(Only Technical Service)**
Latex gain factor Sensor 1, values accepted between 0,6000 to 2,0000 **(Only Technical Service)**
Latex gain factor Sensor 2, same value of Sensor 1
Compensator factor to instrument calibration for Sensor 1 **(Only Technical Service)**
Compensator factor to instrument calibration for Sensor 2, same value of Sensor 1
Led and Photometer temperature, values accepted between 20 to 40 **(Only Technical Service)**
Instrument switching off counter without washing procedure
Value of washing water read and memorized for Sensor 1
Value of washing water read and memorized for Sensor 2, always with value '3800'
Value of washing water read and memorized for Stop Sensor
Analogical Reference for Sensor 1 **(Only Technical Service)**
Analogical Reference for Sensor 2, always with value '0'
Analogical Reference for Stop Sensor **(Only Technical Service)**
Gain of ESR (blood) value **(Only Technical Service)**
Offset of ESR (blood) value **(Only Technical Service)**
Gain of Latex value **(Only Technical Service)**

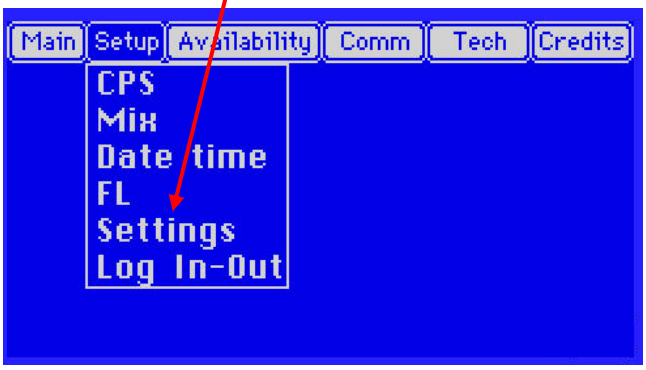
COMMUNICATION BOARD
Communication Board Software version.
Date and time of the Communication Board software compilation.
Serial communication protocol **(Only Technical Service)**
Instrument number, if there is more than one instrument in series **(Only Technical Service)**
Analysis enabling for samples with patient ID not recognised **(Only Technical Service)**
Enable the extended waiting time to receiving "**T**" messages from Host **(Only Technical Service)**
Enable (disable) Bayer protocol compatibility **(Only Technical Service)**
Timeout for Host waiting in serial interface **(Only Technical Service)**
Max number of attempts if the host don't receive the ACK **(Only Technical Service)**
The instrument will/will not do the analysis if TIMEOUT event happens **(Only Technical Service)**

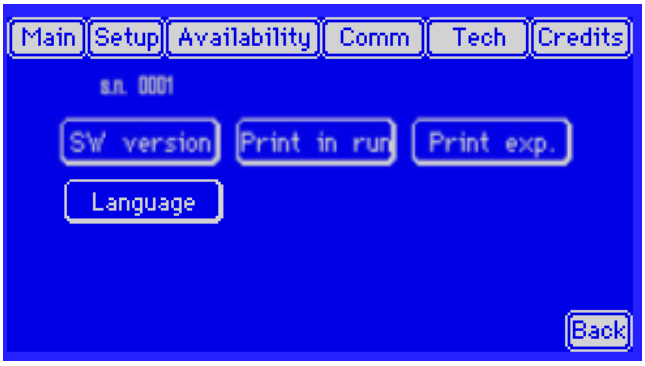
15.8 - SETTINGS MENU

This function's accessibility **is linked to a password level**.

Without a password is possible to access only few functions

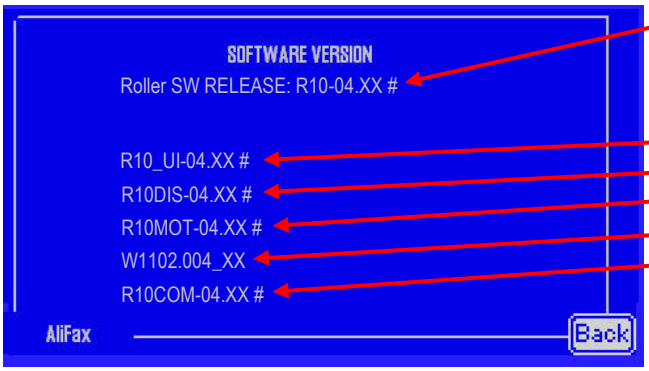
Pressing **"Settings"** (in the Setup Menu), the instrument will display:





15.8.1 - SOFTWARE VERSION

This instrument uses 5 different processors to work, this means that not all of them necessarily have the same or last version installed; to know which software version is installed in each processor press "**SW version**" the instrument will display software version's installed.



Where **X** is the version (expressed in numbers, eg: 4.01#) and the **#** is the release (expressed by a letter from A up to Z, eg: 4.01A)

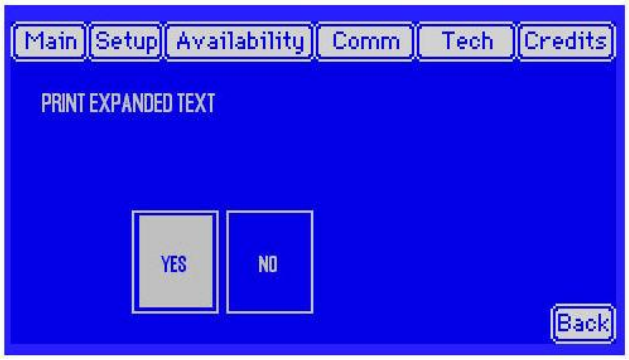
Interface Unit Board Software Version
Display Software Version
Motor Board Software Version
Analogical Board Software Version
Communication Board Software Version

Pressing "**Back**" the instrument will display again the **Setting Menu** screen.

15.8.2 - PRINT EXPANDED

This function, if activated, allow to printout the IDs and ESR results on double height; to access the function press "**Print exp.**" the instrument will display:

In this example the function is set to "**YES**"



Pressing "**Back**" the instrument will display again the **Setting Menu** screen.

15.8.3 - PRINT IN RUN

This function, if activated, allow to printout the IDs and ESR results after the corresponding sample analysis (in "real time"); to access the function press "**Print in run.**" the instrument will display:

In this example the function is set to "**YES**"

Pressing "**Back**" the instrument will display again the **Setting Menu** screen.

15.8.4 - LANGUAGE SETUP

This function, if activated, allows to setup the language in which will be displayed messages and warnings; to access the function press "**Language**" the instrument will display:

Available languages are:

- English
- Italian
- Spanish
- French
- Russian

Just press the desired language, in this case English to setup the instrument in **English** language

Pressing "**Back**" the instrument will display again the **Setting Menu** screen.

15.8.5 - SETTINGS MENU with "USER LEVEL" PASSWORD LEVEL ACCESS

As stated before, to have the possibility to modify these parameters it is necessary to be logged as "**user level**" (**see chapter 15.1**) otherwise the instrument will not allow to access the function.

After logged with User password, the instrument will show this screen (inside the Setting Menu):

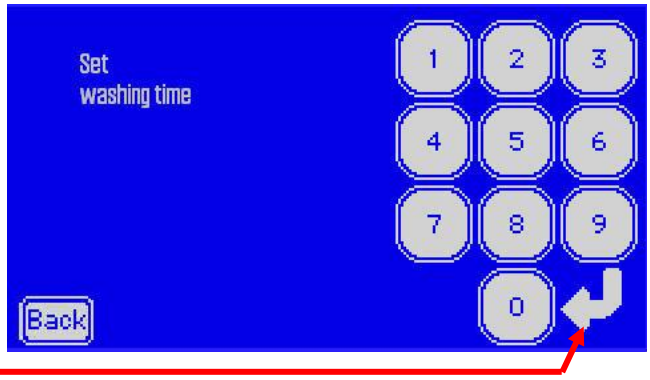
Pressing "**Back**" the instrument comes back to the Main Screen:

15.8.6 - WASH TIME

This option allows to modify the delay of time (in minutes) for the alarm activation for a washing procedure requesting. The counter's countdown starts at the end of the analysis cycle.

To access this function, press **"Wash Time"** (in the Setup Menu after a user login), the instrument will display:

To modify the waiting time, just type the desired value (from 1 minute to 240 minutes).



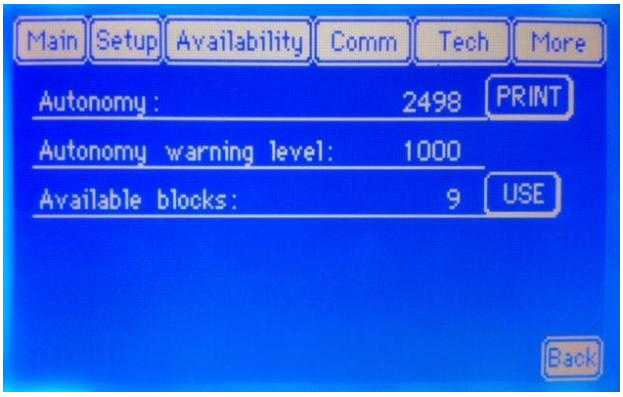
then press the **"left arrow"** to confirm or "**Back**" to exit without change anything, the instrument will display again the previous screen (Setup Menu). Pressing "**Back**" is possible to go back to Main Screen.

16.0 - AVAILABILITY MENU

Pressing "**Availability**" from Main Screen, the instrument shows the following options :

16.1 - SHOW AVAILABILITY CREDITS

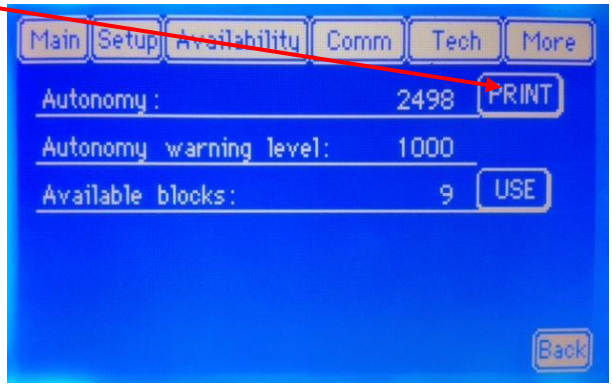
Pressing "**Show**" in Availability menu, the instrument will show this screen:



Press "**Back**" to come back to Main Screen.

16.1.1 - PRINT AUTONOMY

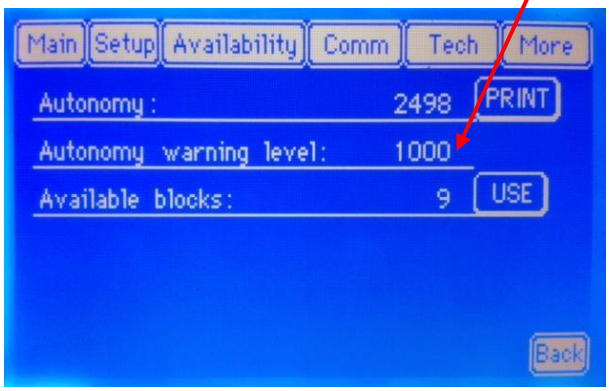
Pressing "**PRINT**", the instrument will print out the remaining number of credits for each active parameters.



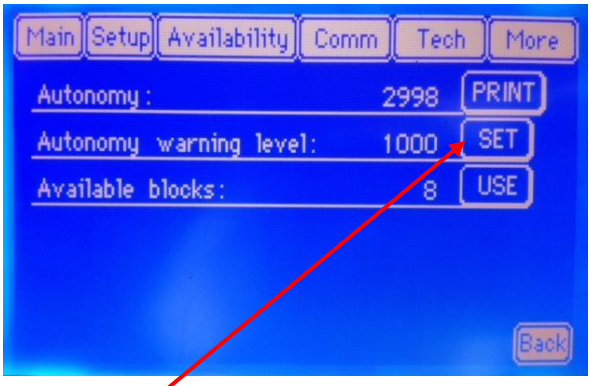
Press "**Back**" to come back to Main Screen.

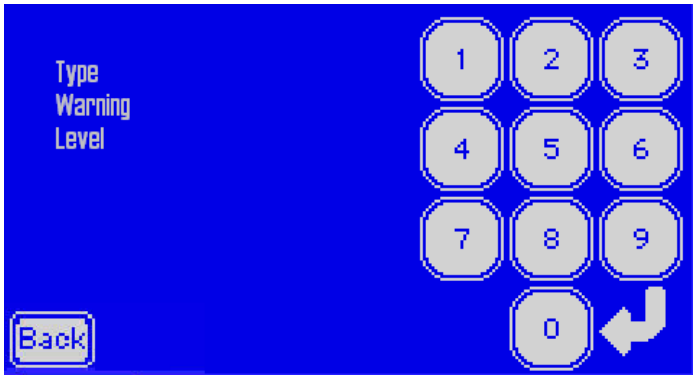
16.1.2 – CREDITS WARNING LEVEL

Without a password:
The instrument only shows the actual value of the credits Warning Level (1000 by default):



With a User Password (after logged, please see **chapter 15.1**):
The instrument will display:

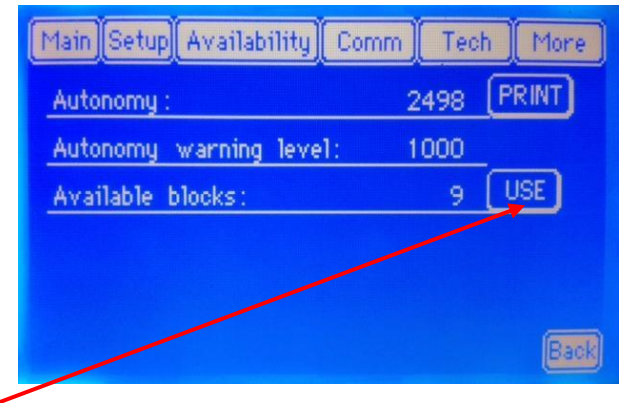




Pressing "**SET"** the instrument allows to modify threshold level (from 5 to 63000) using the keyboard, so to increase availability type the desired warning value, then press the "**Left Arrow**" to confirm or "**Back**" to exit without change anything, in both cases, the instrument will display again the previous screen with the new warning reference. Then press "**Back**" to go back to Main Screen.

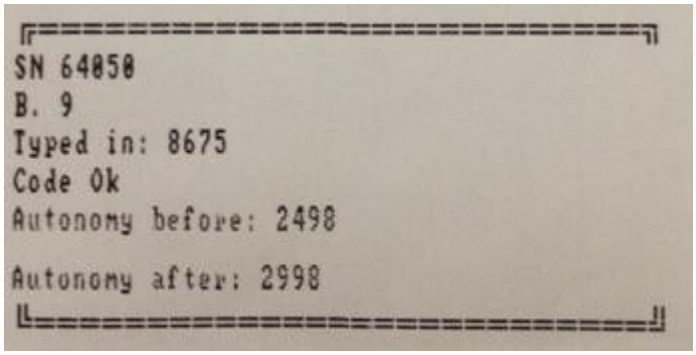
16.1.3 - CARD WITH DIVISIBLE CREDIT

If a card with divisible credit has been loaded, pressing "**USE**" it is possible to use one by one the special codes, for increase the availability in blocks of 500 credits (till to 4500 credits for each card).



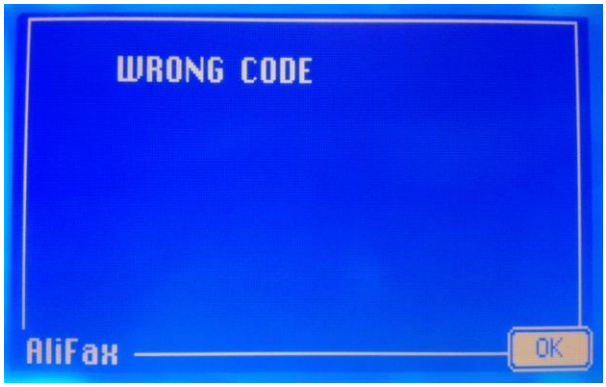
After pressing "**USE**" button, the instrument will show this screen:

Where in base of the Serial Number (**SN**) of the card and the number of the block (**B.**), typing the correct code is possible to load the 500 credits. Then after typed the code, press "**Left Arrow**" to confirm or "**Back**" to exit without change anything. The instrument controls the code and if is correct, it loads the 500 credits and prints this:



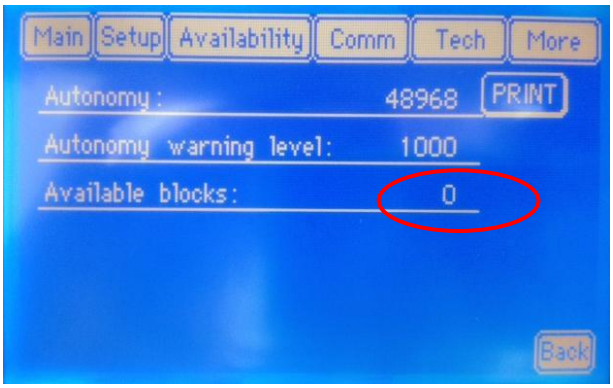
Then it comes back to Availability Menu.

Otherwise, if the code is wrong the instrument shows this:



Then press "**OK**" to come back to Availability Menu, and try again to type the code.

When the number of blocks become '0' (zero), the button "**USE**" become invisible, and is no longer possible to load the credits, until a new card with divisible credit is loaded.



Pressing "**Back**" it is possible to go back to Main Screen.

17.0 - COMM MENU (Technical password required)

Under this menu resides all the functions and options related with the communication between Roller 10 and a Host Computer. To modify the whole parameters' values is **MANDATORY to login using the Technical Service password (see chapter 15.1)**.

Without a password

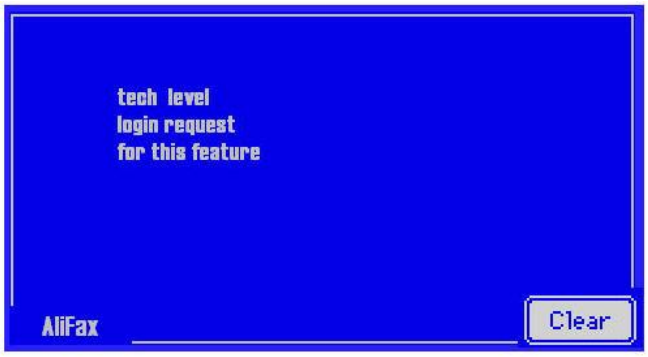
This function does not work without a password level and the instrument will display the following message:

18.0 -TECH MENU (Technical password required)

Under this menu resides all the functions and options related with the **TECHNICAL CONFIGURATION** of Roller 10. To modify the whole parameters' values is **MANDATORY to login using the Technical Service password (see chapter 15.1)**.

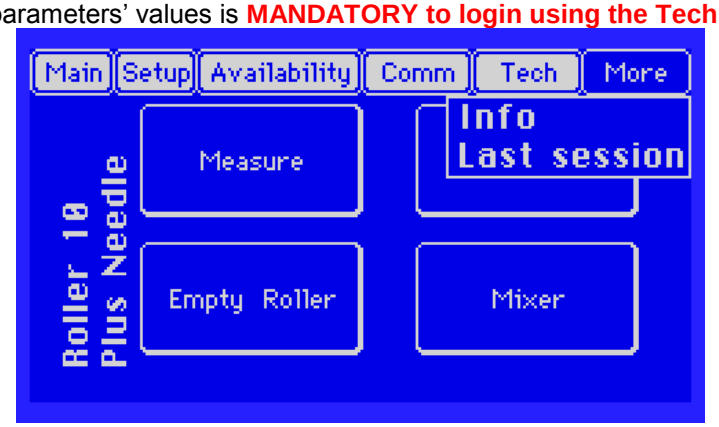
Without a password

This function does not work without a password level and the instrument will display the following message:



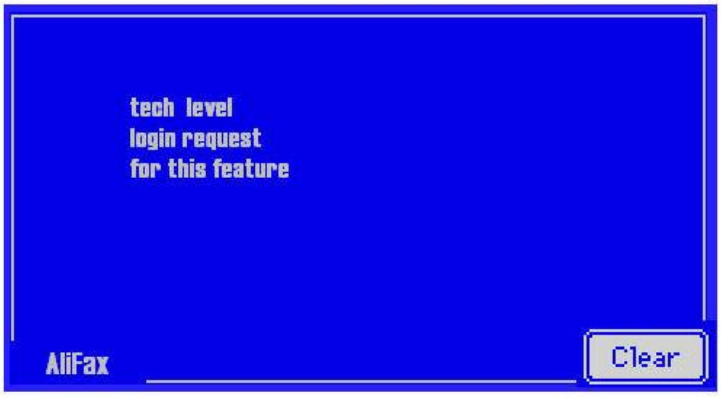
19.0 - MORE MENU

Under this menu resides all the functions and options related with the **TECHNICAL CONFIGURATION** of Roller 10. To modify the whole parameters' values is **MANDATORY to login using the Technical Service password.**



Without a password

This function does not work without a password level and the instrument will display the following message:



19.1 – INFO MENU

Pressing "**Info**" from More Menu, the instrument will show this screen:

Where are written some information and references about the Technical Assistance for the instrument, then press "**Back**" for return to Main Screen.

19.2 - LAST SESSION MENU

Pressing **"Last Session**" from More Menu, the instrument shows:

Because with this kind of Roller, this function is not available, so the instrument will always display this screen, then press "**OK**" for return to Main Screen.

20.0 - SWITCHING OFF

Before switching OFF the instrument it is mandatory to use the WASHING procedure (see chapter 9.0).

Then the instrument can be switched OFF using the back side push-button.

When the instrument is switched ON if the washing was done previously, the instrument is immediately ready for work, on the contrary it warns the user that is advised to run a washing procedure. These messages are useful to start correctly the analytical cycle only if the washing procedure was performed.

21.0 - SANITIZATION PROCEDURE

The following procedure must be executed before:

1) Collection/shipment of the instrument from laboratory after a demo or for replacement/reparations.
2) Technical service repair or check inside the instrument.

Protection tools and suggested materials to be used:

1) Glasses.
2) Latex gloves.
3) Absorbing paper towels.
4) Plastic bag for waste disposal .

For the description of sanitization procedures of a working instrument: refer to the Sanitization Form (**Appendix D**)

The Sanitization Form MUST be filled up and accompany the instrument.
In case the sanitization cannot be executed due to a failure of the washing system, contact your Local Technical Service.
Note: we suggest to make a copy of the **Appendix D** at each sanitization and to fill it according to the sanitization procedure.

22.0 - ERROR LIST

ERRORS THAT CAUSE INSTRUMENT'S BLOCKAGE:

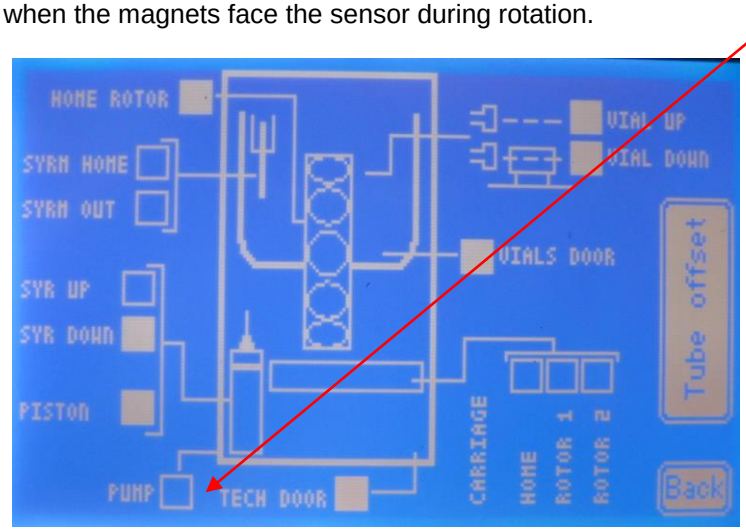
MAJOR ERROR 1ST LINE	MINOR ERROR 2ND LINE	Note
E00	Debugging parameters	**MOT** – Motor board disconnected or error during the transmission of the data. Switch off the instrument, wait 10 seconds and switch on again
E14	Debugging parameters	**CPS** – Internal Serial Communication Protocol error, switch off the instrument, wait 10 seconds and switch on again
E15	Debugging parameters	**EXT_Eeprom** – Error during external eeprom access, switch off the instrument, wait 10 seconds and switch on again
E16	Debugging parameters	**RTC** – Error during internal communication, switch off the instrument, wait 10 seconds and switch on again
E18	Debugging parameters	**COMM** – Error during internal data transmission, switch off the instrument, wait 10 seconds and switch on again
E20	Debugging parameters	**MOT** – The same of Error 'E00', command START movement OK, but not received command of END movement. Switch off the instrument, wait 10 seconds and switch on again
E21	Debugging parameters	**PUMP** – Not detected home sensor for peristaltic pump even after three complete rotations, check if square magnet is present on the pump's rotor.
E30	Debugging parameters	CPS.: Error E30 refers to a problem of missing communication between CPS and UI board during initial start-up. **In the event this error is issued CPS must be replaced** board
E26 **E01**	Debugging parameters	**E26** - (Generic error) Mechanical movimentation. **E01** - (Specific error) Stall Rotor.
E31		MOTOR. (*peristaltic pump*) During movement of the pump there are detected motor stalls. (limited to CPS-MC Module), switch off the instrument, wait 10 seconds and switch on again board
E32		COMM Error in the internal communication with the cryptographic module; switch off the instrument, wait 10 seconds and switch on again
E33		COMM Error timeout in the internal communicating with the cryptographic module, switch off the instrument, wait 10 seconds and switch on again
E34		COMM Error in the decreasing of availability of tests inside the cryptographic ,module in the internal communicating with the cryptographic module, switch off the instrument, wait 10 seconds and switch on again

In case one of the mentioned errors is reported, for don't lose the current session, press the "**OK**" button, then the instrument automatically tries again the last operation (move again the motor) and if this time the error not occurred, it will continue with the analysis.

The voices: **MOT, COMM, CPS, RTC, EXT_Eeprom** belongs to the electronic board that compose the instrument. This electronic boards contains parts and electronics components that **CAN NOT BE ADJUSTED BY THE LOCAL FIELD ENGINEER.** It is possible just to check the presence/absence of the square magnets on the syringe, carriage and peristaltic pump.

23.0 PROGRAMMED MAINTENANCE PROCEDURE

Frequency	Part to check	Description of checks (please fill in the checks done)
30.000 TEST		
	External Probe	□ Check for any damage or obstruction of the probe (In case of damages, to replace the probe, contact the Technical Assistance)
	Pump tube	□ Replace it, even if it seems not damaged.
	PTFE tubing	□ Check the status of PTFE tubing from probe to the reading block (CPS) and from this one to pump, and from pump to waste tank, replace the tubing if deformed or damaged . □ Check if blood flow is normal and regular.
	Pump	□ Check the rotation of pump, pay attention to rolls are regularly rolling. □ Verify the regularity of pressure of rolls due to springs. If some squeaking is heard while the rolls operate, lubricate the rolls spraying them with a bit of silicon oil. □ Check if the magnets stuck on the head of pump are present, check the sensor, and look if the sensor, on the commands panel, is lighted when the magnets face the sensor during rotation.
	CPS module	□ Check its calibration as described in the chapter 9.1.3 □ The calibration can be adjusted using the calibration kit SI 305.400, composed by a series of optical filters and the calibration procedure.
	Reset of counters	□ When all the described checks are performed at the level of 30.000 test, reset the Maintenance Counter (Only Technical Service). When reset, the instrument will alert the operator when other 30.000 test are performed, to call technical service. To reset the counter, enter in RESET MENU
60.000 TEST	**Perform all checks reported for the 30.000 test as above described and also:**	
	Pump speed reducer	□ Check the oscillation of the reduction gear shaft into the bearings. If the oscillation is higher than 0,5 mm evidencing also a grease leakage, replace the reduction gear.
	Repeatability check	□ Execute this test loading a certain number of samples available (max 60), repeat the analysis three cycles consecutively. □ Compare the results to verify the instrument repeatability.



24.0 - ROLLER – REFERENCES

Manufacturer: **ALIFAX S.r.l.**

Production Site:
Via Merano 30 33045 Nimis (UD) Italy
Tel +39 0432 547454
Fax +39 0432 547378

Legal Site:
via F. Petrarca 2
Isola dell'Abbà
35020 Polverara (PD)
Tel. +39-049-0992000
e-mail info@alifax.com
web **www.alifax.com**
VAT: IT04337640280

The instrument is CE certified
According to directive 98/79/EC relative to In Vitro Diagnostic Medical Devices

The instrument is MET certified for the North American market by MET Laboratories Inc.

MET E114263 COMPLIES WITH UL 61010-1 CSA C22.2 NO. 61010-1

APPENDIX A (NF meaning)

It appears when the system is not able to aspirate blood.
It could be possible:

- The excursion of the needle is not enough and accordingly the needle cannot aspirate blood. If this is true, you should call the technical service in order to increase the excursion of the needle inside the test tube:

Too low

- The excursion of the needle is too high and accordingly the needle cannot aspirate blood because its tip is over the blood level. If this is true, you should call the technical service in order to reduce the excursion of the needle inside the test tube:

OK

- Air access into the capillary during aspiration.
If this is true, the terminal part of the capillary which touches the needle base could be ruined.
The capillary, therefore, has to be replaced and the analogical board adjusted. To do that, call the technical service.

Too high

- The needle is obstructed partially for a limited flow. The photometer, therefore, reads blood mixed with air. Check or replace the needle.

- The pump rubber tube is not able to aspirate blood correctly. The technical service should be called in order to replace the tube.

APPENDIX B (NR meaning)

NR is a printed out message which warns the operator that the result is no reliable.
It means that the specimen has been recognised in the reading cell at the beginning of the measuring phase but no cells aggregation was detected. A possible cause could be due to the blood not well mixed, suspected clots in the capillary or in the reading cell or eventually not enough blood inside the sample tube. As a consequence of previous causes, sample analysed is reported as NR because not reliable. A possible solution is in the pre-mixing of the specimen (refer to page **37**) and the successive analysis cycle.

APPENDIX C - IMPROVEMENTS ON SOFTWARE VERSIONS from 5.00A

Version 5.00A

- Universal Software for R20-PN, R10-PN and R20-MC.
- Handling of the new smart card reader

APPENDIX D – SANITIZATION FORM

This module must be filled by the Laboratory / Technical Service Engineer before shipping the instrument.

This document MUST be attached to the instrument.

Description of sanitization procedures to be done by the Laboratory:

Switch ON the instrument:

	OK	NOK
➢ Execute the washing procedure		
1. Perform a first wash using two tubes filled with distilled water	☐	☐
2. Perform a second wash using one tube filled with sodium hypochlorite and one tube filled with water	☐	☐
➢ Empty and clean very well the Waste tank avoiding to leave blood residual inside For the disposal of the waste tank content follow the standard safety procedures in use in the laboratory.	☐	☐

If due to a failure, the instrument cannot be switched ON, mark as NOK .

Description of sanitization procedures to be done by the Technical Service Engineer:

Wear protection tools (glove and glasses) and remove the cover of the instrument.

If Laboratory Operator marked the washing procedure as **NOK**, verify if it is possible to make in some way the washing procedures.

	OK	NOK
➢ Execute the washing procedure		
1. Perform a first wash using two tubes filled with distilled water	☐	☐
2. Perform a second wash using one tube filled with sodium hypochlorite and one tube filled with water	☐	☐
➢ Empty and clean very well the Waste tank avoiding to leave blood residual inside For the disposal of the waste tank content follow the standard safety procedures in use in the laboratory.	☐	☐

If due to a failure, the instrument cannot be switched ON, mark as NOK .

To continue with the sanitization procedure, switch OFF the instrument and unplug it from the power supply cable.

➢ If some part inside the instrument are contaminated with blood:		
1. Spray the parts with a disinfectant (cationic surfactants).	☐	☐
2. Collect liquid from the sprayed parts with absorbing paper towels.	☐	☐
3. Wash with water and dry with paper	☐	☐

For the disposal of the contaminated stuff and Waste Tank content, follow the standard safety procedures in use in the laboratory.

➢ If there are no parts contaminated with blood: Wash with water and dry with absorbing paper	☐	☐

For the disposal of the contaminated stuff and Waste Tank content, follow the standard safety procedures in use in the laboratory

In the event contaminated material is penetrated inside the instrument (thermostated plate) IT IS MANDATORY TO INDICATE ON the INSTRUMENT and on the SANITIZATION SHEET that contaminated material has percolated inside the instrument and it has not been possible eliminate using the external sanitization procedure.

MANDATORY:
If the sanitization was carried on, please cut the lover right side of the page (or make a photocopy) and include the tag in the shipping documents.

SANITIZED