User manual DYNABLOT Automatic

DYNEX



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1 Introduction

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Welcome to Dynablot Automatic. The application enables you to manage all processes of Dynablot Automatic, an instrument for automatic preparation of immunoblot strips.

This document describes how to work with the Dynablot Automatic application. It enables the Dynablot Automatic user to gather information about the instrument's use from two different perspectives:

1) According to application structure - this chapter describes in detail individual application screens, how to manage them and the instrument's functions related to these screens and managed from them.

2) According to the standard instrument's procedures - the chapter contains work procedures, which are usually performed when working with the instrument. The procedures are described in detail step by step and guide the user through the whole process.

1.1 System requirements

To be able to use the application it is necessary to meet the system requirements of the controlling computer.

Basic requirements:

- PC with a CPU of minimum 600 MHz, 128 MB RAM and 500 MB free disc space
- Windows 7 (and higher)
- optimized for SVGA 1600 x 900 monitor

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1.2 Glossary

Glossary

Instrument run

Execution of all steps of the given assay.

Assay editor

The Assay editor is a tool for creating operation procedures (assay files) for the instrument to prepare strips via a certain method.

Assay

Assay is a procedure for strip preparation. The assay is created by the user according to guidelines in diagnostic kits. The assay describes the types of used reagents and the order in which they are filled and aspired from the strip wells, the incubation duration with individual reagents etc. The assays are structured into steps according to the filling of the reagents and the subsequent incubation.

Calibration

A process for setting up parameters of a certain part of the instrument so that it works as intended (e.g. finding and saving calibration constants of peristaltic pumps).

External system

A software for the results evaluation from the strip pictures

Manual step

An action of an assay step, which requires stopping the instrument, the action is performed by the user.

Multi shot

Multiple pipetting of one sample into the reagent wells.

Pipetting

Pipetting is a transfer of the tested sample from the primary tube into the reagent well.

Strip tray

A strip tray is a plastic part inserted into the rack in the instrument. The tray contains reagent wells for strip insertion (as many as 44 wells in one strip tray). During the test the wells with the strip are being filled, incubated and emptied according to the assay procedure.

Protocol

Protocol is a procedure, which assigns individual wells (1 - 44) on the strip plate an identification number of the patient's sample. It is created based on the worklist and one instrument run is executed according to it.

Reagent

Reagent is an agent (liquid) used during the strip processing

Assay group

Grouped assays have an identical structure of steps. They can differ only in the type and volume of reagent and the filling activity, in the sample volume and pipetting activity.

Status bar

Information field in the lower part of the application screen.

Test

The test is a type of sample examination (e.g. discovering the presence of specific antibodies). Several tests from one manufacturer may use a common assay for sample processing.

Worklist

Worklist is a list of instructions assigning individual positions on the primary sample tube rack an identification number of the patient's sample and test(s), which shall be performed on the sample.



2 Application description

This chapter describes in detail the individual application screens, how to manage these screens and the functions related to these screens and managed from them.

The introductory screen is divided into the workspace and the upper, lower and side command bar. The upper bar contains the menus for the instrument control and work with application. The lower bar contains information about the current state of the instrument and facilitates its fluent use.

The side bar contains icons for quick launch of basic functions.

Some options in the command bars are available only to users with higher role Service or Administrator.

The application is divided into the following parts (screens):

• Run protocol

New Imported Imported protocol - screens

• Instrument maintenance

System preparation Pump priming Automatic calibration Weekly maintenance Monthly maintenance Run Self-test

• History

Self-tests Maintenance Communication with external system Protocols

• Editing

Assays	(Administrator, Service - limited)
Tests	(Administrator, Service - limited))
Reagent	(Administrator, Service - limited))
Tube types	(Administrator, Service - limited))

Application administration

Logging in	
Change password	
List of users	(Administrator, Service)
Logging off	
Application setup	(Administrator, Service)
Removing unnecessary data	(Administrator, Service)
About	

2.1 Run protocol

The process of preparing and running the protocol performs sample processing in accordance with a prescribed method.

The menu Run protocol offers two possibilities:

- New creating, preparation and processing of a new protocol per the worklist within application
- Imported preparation and processing of a protocol which was imported from the external system. The imported protocol can also be performed without a preparation and whole process only by the strip pictures taking.

It is possible to enter the menus directly by using the buttons

or in the side bar.

2.1.1 New protocol

The whole process consists of several steps, which will guide the user to the end of the protocol:

<u>Step 1</u> - Creating a worklist

By creating a new worklist the user defines the samples ID, their position in the tube rack and tests for the samples processing.

Filling the worklist items:

Protocol name - entered by user, not a required field, the name serves to identify the protocol by the user. If the application settings require its pre-filling, the system will pre-fill it according to the required structure in the settings (Application settings). The pre-filled protocol name can be edited by the user. .

Author - the system pre-fills it with the name and surname of the logged user or the user fills it. Not a required field, can be edited.

Entering samples ID into the worklist:

The samples can be entered in two ways:

A) If the bar code reader is used:

Scanning with the reader:

In new worklist the system pre-fills the field **Last tube position for BCR scanning** with the value 44, which is the maximum amount of positions in the tube rack. If the user doesn't require to scan the maximum number of samples, he can edit the field in two ways:

By clicking on the field Last tube position for BCR scanning he will overwrite the required value
 By selecting the last sample position to be scanned in the sample map

В	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	D			
•	0	0	ο	ο	ο	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	٠			
Α	1	3	5	7	9	11	13	15	17	19	21	23	25	27	29	31	33	35	37	39	41	43	с			
•	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	•	and	pressing	the

arrow swill fill the change in the field Last tube position for BCR scanning.

The user will press the button "Use BCR for sample ID". The system will display a prompt to enter



the samples into the instrument

The tubes are then inserted into the rack and the rack is inserted into the instrument. The user may confirm (select "Yes") to continue by scanning the sample codes (if he doesn't confirm, the system will remove the prompt window).

The reader will scan sample codes on the tubes, which are located in the numbered positions of the rack (the reader doesn't scan positions A, B, C and D). The system will write and highlight in green the successfully scanned codes in the field "Sample ID". The position which ID bar code could not be scanned are highlighted in red. These position can be filled manually.

B) If the bar code reader is not used:

Loading from a file:

The user selects the button "**Sample ID file**". The system displays a window for selecting a file from the user's computer in a "txt" format (each row in the document contains the ID of one sample). The user selects the file and presses "**Open**". The system fills the field "**Sample ID**" with the values from the file and highlights them green.

The tubes are then inserted into the rack and the rack is inserted into the instrument. **The order of sample ID in the tube rack must correspond with the entry in the application!**

Manual entry:

The tubes are then inserted into the rack. The user enters the sample codes into the field "Sample ID" in the worklist according to the actual order of the samples in the rack. Then he inserts the rack into the instrument. The order and sample ID in the tube rack must correspond with the entry in the application!

Assigning tube types to samples :

The system presets a default tube type for each sample (for postions 1-44 standard tubes, positions A, B, C and D have control tubes). The user may change the preset tube type. The user clicks on the arrow in the field "Tube type" and the system will display the offer of registered tubes. The selected type must correspond with the tube in the instrument (otherwise it will be impossible to perform correct pipetting of the sample. For more details about tube types see editing\Tube types).

Entering tests into worklists

If the user scanned/entered samples into the worklist, he continues by entering tests to the samples.

EUROBlotOne - Protocol run _ P X														
Back Workl	ist													Next Cancel
Protocol name	2014_10_2	23_1	B 2 4 6	8 10 12	14 16 18	20 22 24 2	26 28	30 32	34 36	38 4	0 42	44	D	
Written by			• • • •	000	000	0000	00	00	0 0	0 0	0 0	Ο	•	
Use BCR			A 1 3 5	7 9 11	13 15 17	19 21 23 2	25 27	29 31	33 35	37 3	9 41	43	с	
Last tube position for BCR so	canning 6	<<	• • • •	000	000	0000	0 0	0 0	0 0	0 0	0 0	0	•	
Use BCR for sample ID	Position	Sample ID	Tube type	BorrEL_IgG	Ana16 😑	Ana15 😑								
	A		Control											A
Open WL template	в		Control											
Save WL template	С		Control											
Test	D		Control											
	1	Sample 1	Standard											
ANA MK 🛛 🛕	2	Sample 2	Standard											
Ana17 O	3	Sample 3	Standard											
Ana18 O	4	Sample 4	Standard		\checkmark									U.
Ana1b 💿	▶ 5	Sample 5	Standard											
Ana3b 🗿	6	Sample 6	Standard											
Ana5 📀	7		Standard											
B. afzelii IgG 🛛 🗿	8		Standard											
B. afzelii IgM 🛛 🥥	9		Standard											
B. burg US IgG 🛛 🔾	10		Standard											
B. burg US IgM 🛛 🔾	11		Standard											
B. burg. IgG 🛛 🔾	12		Standard											
B. burg. IgM 🛛 🔾	13		Standard											
B. garinii IgG 🛛 🗿	14		Standard											
B. garinii IgM 🛛 🔍 🗸	15		Standard											
4 🏶 📩 🔌	3 ×													BlotAutomat ver. 4.36

The test is entered by pressing the button in the list of tests registered in the application

(see Editing\tests). Wrong selected test can be removed by button 🧧 . For each sample the user selects the 🔽 field, if the given test should be performed on the given sample.

To select a test for more samples at once the user presses the left mouse button and drags the mouse cursor over multiple rows.

The selection of tests for the worklist is influenced by the first selected test. After the first test is selected the selection is limited only to the tests from the same assay group. They can be done in one protocol run.

Creating a worklist template

The user may create a new template when processing the worklist. The template sets the combination of tests in the worklist. To create a template press button "**Save WL template**". The system will save the template (currently selected set of tests) into the template list.

Loading a template

The user may load a test combination saved in a template by pressing the **"Load WL template"** button. The saved template may be removed from the list by the eraser icon **2**.

After the selection of the tests it is possible to continue with the protocol processing by pressing " **Next**". The system will check whether the number of tests doesn't exceed the number of wells in the strip tray and whether for each inserted test there s at least one sample for processing. A test without any scanned/entered sample for processing must be removed by the user before continuing.

By pressing the "**Cancel**" button the protocol creation will be aborted without an option to save the progress.

<u>Step 2</u> - Processing a protocol

Individual rows of the protocol represent the wells in the strip tray in order from the left. Each well is

assigned a sample ID, test type and possibly a manufacturing lot of the strip that is being used. The user checks whether the protocol has filled items "**Protocol name**", "**Author**", "**Sample ID**" and "**Test**". The fields "**Protocol name**" and "**Writte n by**" can be changed.

EUROBlotOne - Protocol run								
Back Protocol								
Protocol name 2012_12_12_1								
Written by								
Strip o	rder 🔺	Sample ID	Test	Lot				
Strip o	rder 📤 1	Sample ID Sample 1	Test B. afzelii IgG	Lot				
Strip o	rder 🔺 1 2	Sample ID Sample 1 Sample 2	Test B. afzelii IgG B. afzelii IgG	Lot				
Strip o	rder ^ 1 2 3	Sample ID Sample 1 Sample 2 Sample 3	Test B. afzelii IgG B. afzelii IgG B. afzelii IgG	Lot				
Strip or	rder - 1 2 3 4	Sample ID Sample 1 Sample 2 Sample 3 Sample 4	Test B. afzelii 1gG B. afzelii 1gG B. afzelii 1gG B. afzelii 1gG	Lot				

Sample test lot - by clicking into the field "**Lot**" the user may assign a lot number to the test or he may let the entry of the lot to the instrument run itself. (see step 7 - Instrument run).

By pressing "Next" it is possible to continue with the processing of the protocol. By pressing "**Back**" the system shows the previous page of protocol processing (step 2 - Processing a protocol). By pressing the "**Cancel**" button the protocol creation will be aborted without an option to save the progress.

<u>Step 3</u> - Preparation of the system solution

If there is no system solution prepared in the instrument (Its status is "Not ready" - icon in the lowe bar) and the protocol includes tests, the assay of which contains the pipetting action, the user must prepare it now. The user inserts the attached system solution bottle into its holder and clicks on the pump icon. After pumping the application changes the status of the system solution to

"Primed" and the system solution icon will change to





By pressing "**Next**" it is possible to continue with the processing of the protocol. By pressing "**Back**" the system shows the previous page of protocol processing (step 2 - Processing a protocol). By pressing the "**Cancel**" button the protocol creation will be aborted without an option to save the progress.

<u>Step 4</u> - Inserting the tray and selecting the starting well

The user is prompted to inserts the tray with wells for strips into the instrument.





By clicking into the strip field the starting position, from which the sample testing will begin (in case that a previously partially used tray is inserted). The user may select only such starting position, which is followed by a sufficient number of empty wells for all sample tests.

By pressing "Next" it is possible to continue with the processing of the protocol. By pressing "**Back**" the system shows the previous page of protocol processing (step 3 - Preparation of system solution). By pressing the "**Cancel**" button the protocol creation will be aborted without an option to save the progress.

Step 5 - Waste bottle check

The user checks whether the waste bottle is attached and has sufficient free space for waste liquid from the sample processing. If the bottle isn't empty, it is advisable to empty it so that the instrument has a sufficient reserve for waste liquid storage.



Note:

During sample processing or another activity (e.g. maintenance) the waste bottle may be filled. Such situation is reported by a sound signal and a change in the color of the icon in the lower bar. If the

waste bottle status is suitable for the instrument's operation, it is signalized by a blue icon 🔲 . If

the waste bottle is starting to fill, the icon changes to yellow _____. The instrument's operation isn't limited in this case, but it is advisable to empty the bottle. If the waste bottle is near owerfilled the

icon changes to red . In this situation the instrument stops running of activities, which require the use the aspiration to the waste bottle.

By pressing "**Next**" it is possible to confirm attachment of an empty waste bottle and continue in processing of the protocol with preparation and loading of reagents (step 6).

If the assays of the selected tests don't use any reagents, the next step is skipped.

By pressing "**Back**" the system shows the previous page of protocol processing (Step 3). By pressing the "**Cancel**" button the protocol creation will be aborted without an option to save the progress.

<u>Step 6</u> - Assigning and priming of reagents

If the test assays require the use of reagents, the user has to assign individual reagents to specific pumps and load them into the instrument's tubing. At the beginning the system assigns reagents to individual pumps according to the preferentially recommended pairing. (see editing\Reagents).

Assigning reagents to a pump - if the user doesn't agree with the implicit assignment, he clicks into the pump field, presses left mouse button and transfers the reagent to another pump. The system transfers the original reagent from the target pump to the place where the transferred reagent came from.



and the system loads the reagent into the

tubing. If the user sees the reagent pouring from the appropriate tube, he can confirm the loading by



Postpone reagent - reagents, which are unstable in time, can be postponed by the user. Instead of

loading he presses **1**. The system will alert the user to the need to load the postponed reagent 5 minutes before the reagent is used in the instrument run. (see step 7 - Instrument run).



Back	One - Protocol run Reagents preparation									N	lext Cancel
				Assign or postpo	one each using re	agent!					
	Reagent Required volume Time to the first Pump position	1.position Wash buffer 76.0 ml	2.position	3.position IgG conjugate 8.5 ml	4.position 4.position IgM conjugate 8.5 ml	5.position IgA conjugate 8.5 ml	6.position	7.position Subtrate 20.5 ml 09:34 7	8.position DI H2O 20.5 ml 8		
* 1	1 🔌 🛕 🛅 0 🛶									BlotAutomat ver. 4.33	SN EL20110035

If the user confirmed the loading of all necessary reagents (or postponed it), he can continue with the processing

of the protocol by pressing "Next". The system displays a query, whether the user agrees with the running of the instrument. If he does, the system starts the run, i.e. begins the gradual execution of planned assay steps.

🚆 EUROBlotOne - Proto	ol run			_ 8 >
Back	gents preparat	ion		Next Cancel
	Reagent Required volume Time until the first usage Pump position	1.position Universalbuffer 18.0 ml	Asign or postpone each used reagent!	
🏶 📩 🔌 ,	🛕 📑 1 🛋		ds	BlotAutomat ver. 4.36
		開	Confirmation	
			Start of instrument run.	

By checking the box Pause

the protocol run is started in Pause. Then there is possibility to start the protocol run from another then the first step.

If the user doesn't agree with the run, he selects "No". In that case the regent preparation screen will remain active and the user may change the loading of reagents including the pump positions.

Yes

By pressing "Back" the system shows the previous page of protocol processing. By pressing the " Cancel" button the protocol creation will be aborted without an option to save the progress.

<u>Step 7</u> - Instrument run

After the run is started the system will display a timeline with basic data on the progress of sample tests:

Time until end of step	00:14:59 Time until end of protocol	02:26:07 Expected finish time	12:47:06
Time until manual operation	02:26:07	Time in pause	00:00:50

• Time until end of step - time remaining to the finish of the actual step

• Time until manual operation - time remaining until the start of next action which requires user input

• Time until end of protocol - estimated time until completion of all assay activities

• Expected finish time - time calculated by the system as a sum of the duration of all assay steps

• **Time in pause** - total time during which the instrument is paused. It is the sum of times of pauses caused by the user, times necessry for manual sample pipetting (e.g. if the sample isn't found in the primary tube) and times of individual manual steps

The screen contains the Steps time line. The line in it shows the progres of the protocol run.

Back Run			Com	plete with pump priming Complete	Cancel
Step Strips preparation	Time until end of step	00:14:47 Time until end of protocol 02:25:56 Expected fini 02:25:56 Time in paus	sh time 13:00:50	1 2 3 4 5 6 7	8
Display : Tests Samples Lot	Lot :	Сору to		Order : 1 Test : Ana15 Sample :	1 - Sample
Ana15 1 Ana15 7 Ana16 8 Ana16 9 Ana16 9	Amaile CMV 196 CMV 196	13 14 15 16 17 18 19 20 21 22 23	24 25 26 27 28 29 30	31 32 33 34 35 36 37	38 39
Display : Steps timeline Actions t	imeline			0/72.45	01405
00:00:00 Strips preparation	Samples	01:05:43 01:2 Wash 1 Con	ugates	01:52:48 02:09:22 Wash 2 Substrate	02:19:5 Stop
Step Strips	preparation				
Time until end of protocol 02:25:5	6				
103462 - End of Pause 102008 - Start of pause 101937 - Bys Instead - Ships preparation 10:1936 - Run started - Protocol 201610_17_1,	Assay group: EURO 01,02				
<					>
A A A	Ö			BlotAutomat ver	. 4.38Bet3

The log of a protocol run is recorded and on-line view is displayed bellow the time line. Log contains the protocol name and time marked records of steps, pauses and errors.

```
12:03:14 - Pause start

12:03:11 - Sample pipetting error - 1020 - Sample level not found (Well; 3, Sample: 523)

12:02:49 - Pause end

12:02:48 - Pause start

12:02:48 - Error -

#1028 - Cleaning bowl filling error

12:02:17 - Pause end

12:02:15 - Pause start

12:02:15 - Error -

#1028 - Cleaning bowl filling error

12:01:45 - Pause end

12:01:45 - Pause start

12:01:42 - Pause start

12:01:42 - Error -

#1028 - Cleaning bowl filling error
```

By pressing Actions timeline button the more detailed protocol run timeline is displayed.

Back Run			Complete with pump priming Complete Cancel
Step Tir Strips preparation	ne until end of step 00:11:57 Time until end o ne until manual operation 02:23:06	of protocol 02:23:06 Expected finish time 13:00:50 Time in pause 00:14:34	
Lot Lot :	Copy to	Order : 1 Test :	Ana15 Sample : 1 - Sample 16 Assay : EURO01 IgG
6 7 8 9 10 11 12 1 9 9 9 10 11 12 1 9 9 7 8 9 10 11 12 1 9 9 7 7 7 7 1 12 1 9 9 7 7 7 7 7 1 9 9 7 7 7 7 7 9 9 7 7 7 7 1 9 9 7 7 7 7 7 9 9 7 7 7 7 7 9 9 7 7 7 7 7 9 9 7 7 7 7 7 9 9 7 7 7 7 7 9 9 7 7 7 7 7 9 9 7 7 7 7 7 9 7 7 7 7 7 7 9 7 7 7 7 7 7 9	3 14 15 16 17 18 19 20 21 22 Sample pipetting Dispensing Drying	23 24 25 26 27 28 29 30 31 32 33 34 Pause Cother Error E	35 36 37 38 39 40 41 42 43 44
<			
🏶 👌 🔌 🛓 🛅 1 🙋) •		BlotAutomat ver. 4.38Bet3

Each activity of an assay step is displayed in a different color:

Incubation 📃 Shooting 📕 Manual operation 📕 Aspiration 📒 Sample pipetting 🔲 Dispensing 🔳 Drying 📕 Pause 📕 Other 📗 Error 🗬

After moving the mouse over th field of the tested sample the timeline shows the following information:

- sample position in the tray
- sample ID
- test
- assay
- assay step

In the center of the screen a map of the tray is displayed. Groups of wells with the same tests are displayed in a common color. According to the button Tests, Display or Lot the field of each well displays the appropriate information.

If the user didn't enter the lot for tests during the protocol preparation, he can click clicks the button **"Lot"**. The system displays a field for entering the lot value.



The user then clicks on the position of the sample, for which he needs to enter the lot value and he enters the value in the free text field above the map of samples. If he requires to enter the same lot for the following tests as well, he presses the button **"Copy to".** The system enters the given value into the same tests (same tests are displayed in the same color).

Displ	ay :	Tests	Sam	ples	Lot		Lot		: S	-5891	4		Col	oy to
S-56897 L	S-56897 N	S-56897 w	S-58914 &	S-58914 G	S-58914 o	S-58914 A	8	9	10	11	12	13	14	15

The lot value is not required.

The meaning of icons of the instrument run, which are displayed in the upper right corner next to the panel with indicators of pumps filled with reagents:



instrument is performing an operation (user information)



repeated start of an interrupted run

Cancel	

- irreversible abortion of the run

instrument is paused. When the instrument is paused the red field with information appears. The time of the protocol run is interrupted. In the case when the Pause is activated during the incubation, the time of the run is not interrupted and the rocking continues. The the protocol time interruption is done after the incubation finishing. The rocking and the run time can be stopped immediatelly by the button "Stop incubation"

- skip to step. When the protocol run is paused it is possible to restart the run from any step of the assay. By pressing this button in the right side of the red file the line Skip to step appears.

Skip to step	Restart

. Any step can be selected in the side

menu of the line offers all steps. The check question appears after the button Restart pressing. After confirmation the window for reagents preparation is opened and then a new run is started.

Loading of postponed reagents - If the user preparation, the system will change the icon of the	didn't pum	loa p in	d a the	ll rea	age us	nts bar	durir to ye	ng the ellow 5	protoc 5 minute	ol s
before the use of a postponed reagent o . After cl	icking	on	this	icon	or	the	pane	l with	indicato	S
of pumps filled with reagents in the upper right corner.	1	2 3	4	5	6	7 09:07	8	The sy	vstem w	ill
display a dislama fastla landing of the gesta and a	+	15 16		ام م م						

display a dialogue for the loading of the postponed reagent. If the user doesn't load the reagent until

the time of its planned use, the system will pause the run and displays a dialogue with icons for automatic loading (see step 6). For the run to continue, the user must load the reagent. The time of the pause is then included in the time in pause.



Instrument run error - during the run an error in processing might occur, which is signalled by a short interrupted sound signal. The error is then reported to the user by a prompt window with a numerical and written description of the error.

A E	Fror •
	Unexpected instrument error #1002 - Aspiration arm is not at sensor
	Operations can continue after successful self-test Run self-test Continue Cancel

In relation to the mistake type the system offers the user solution options. If the user chooses the self-test, which then runs successfully, it is possible to continue in the interrupted run.



During a manual assay step a text is displayed, according to which the user proceeds. The text has been entered during the assay creation (see editing\Assay groups)



Manual pipetting - during the assay operation "Pipetting" a situation might occur, where the sample level cannot be found in the primary tube. In that case th application will prompt the user after the end of automatic pipetting to manually pippete the samples, where the automatic pipetting failed. The user pipettes the required amount of the sample, displayed in the red field above the appropriate sample in the well map. The pipetting time is included in the time in pause.

Info																								
Sample pipetting incorrect. Pipette	selected sa	mples manuall	y (volume i	n µl is sho	wn above	each str	rip). The	en press	Contin	ue. Co	ontinu	e												۰
splay : Tests Samples Lot Lot : S-58914 Copy to Order : 8 Test : CMV IgG Sample : 5 - San																								
1 - Sample 16 2 - Sample 2 N 3 - Sample 8 N 1 - Sample 2 S 2 - Sample 8 N 3 - Sample 2 S 3 - Sample 8 S	5 - Sample 5 0 6 - Sample 6 0	10 11	12 13	14 15	16 1	7 18	19	20 21	22	23	24	25	26 2	28	29	30	31	32 3	3 3	4 3	5 36	37	38	39

Succesfull completion of the run is displayed by a text message in a green field.

Back Run					Complete with pump priming	Complete Cancel
Shooting	Time until end of step Time until manual operation	00:00:00 Time until end of protocol 00:00:00	00:00:00 Expected finish Time in pause	time 11:25:49 00:00:00	1 2 3 4	4 5 6 7 8
Info Protocol run was finished successf	ully.					Ø
Display : Tests Samples Lot	Lot : S-58914	Copy to			Order : 8 Test : Cl	MV IgG Sample : 5 - San
1 2 3 4 5 6 Signature Signature Signature Signature Signature Signature Display : Steps timeline Actions timeline Actions timeline	7 8 9 10 11 12 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	13 14 15 16 17 18 19	20 21 22 23 2	4 25 26 27 28 2	29 30 31 32 33 34	35 36 37 38 39
Incubation Shooting Man	ual operation Aspiration	Sample pipetting Dispensing	Drying Pause	Other Error		00:15:00
						v
 1 1						BlotAutomat ver. 4.38Bet3

If the run is unsuccessful (for example after a error which could not be recoveded), the message appears in red.



Stopping the run - at any time the user can press the "Cancel" button. The system definitively ends the run - this ending is irreversible. The time of stopping is entered in the protocol and the protocol is assigned a status of "Not processed - error".

After the run is completed (all assay actions are successfully completed or they are interrupted by an error or user action) the user continues by voluntary pump priming.

<u>Step 8</u> - Pump priming

If the user doesn't require pump priming after the run is completed, he presses the "**Complete**" button and the system finishes the protocol.

If the user requires the pumps to be cleaned from the used reagents, he presses **"Complete with priming"**. The system displays an icon of the pump with the amount of the priming liquid and selects pumps used during the run to be primed. The preset liquid volume for priming (5 ml) as well as the set of pumps for priming can be changed by the user.



on Starts

The user puts the reagent tubing to the bottle with destilled water. The button cleaning pump by pump. The cleaning can be arbitrarily repeated.

After the priming the user may finish the protocol by pressing "Complete".

The system records the finished protocol run into the protocol register (History\Protocols). The protocol status is set according to the success of the protocol run to "Processed" or "Not processed - error".

2.1.2 Imported protocol

The application may communicate with the external system, from which it can receive protocols for testing. The results from the performed protocol are transfered back into the external system, which then evaluates them. (see History\Communication with the external system).

The user is notified about the received protocol on the bar below. The imported protocol icon (imported

protocol = protocol received from the external system) has the displayed number of protocols waiting for processing. The imported protocol may be processed by testing the sample tests. (see below "Complete processing of the imported protocol") or just by creating of strips pictures (see below "Imported protocol-screens").

Rur	n protocol Instrument maintenance History Edit	Application administration			
	Protocol list				
	KClose Sefresh ≤				
	Identifier	Name	Date of creation	•	
				-	
	46	ANA_161003_1	10/10/2016 11:47 AM	Run protocol	Shoot according to protoc
	45	ALD_161002_1	10/10/2016 11:46 AM	Run protocol	Shoot according to protoc

Protocol can be deleted by the bubber icon 2 on its line.

To begin the run of the imported protocol the user selects the protocol from the list and presses the " **Run protocol**" button.

Complete processing of the imported protocol:

<u>Step 1</u> - Display protocol

The user is shown the detail of the imported protocol with these items: **Protocol name** - identification of the protocol from the external system **Written by** - name of the author from the external system For each sample: **Strip order** - number showing the order of the strip in the tray **Sample ID** - unique identification of the sample **Test** - is a type of the test, several tests from one manufacturer can use the same assay for sample processing **Lot** - lot ot the strip number - production batch identification

Back	Proto	col		Next	Cancel
Protocol name	e ANA_16100	3_1			
Witten by	LONOBIOLO				
Strip order	 Sample ID 	Test	Lot		
• 1	1 785	Ana15	def_Ana15		^
2	2 785	Ana16	def_Ana16		
3	3 785	Ana17	def_Ana17		
* 0	10	2 ×		BlotAutomat v	er. 4.38Bet3

If the instrument uses the bar code reader and the user requests to continue with the protocol, he presses the "Next" button and the system displays a prompt to insert the sample rack into the instrument with a query to continue with the sample scanning.

The tubes are then inserted into the rack in any order; however from position 1 without position skipping, and the rack is inserted into the instrument. The user may confirm (select "Yes") to continue by scanning the sample codes (if he doesn't confirm, the system will remove the prompt window). The number of scanned positions is corresponding with number of the samples which are contained in the imported protocol. See step 2 for further steps.

If the instrument doesn't use the bar code reader and the user requests to continue with the protocol he presses the "Next" button and the system displays a worklist window with ID samples prefilled acccording to the imported protocol.

Step 2 - Worklist display

If the instrument uses the bar code reader the system displays the worklist detail with scanned bar codes of the samples (Sample ID) entered into the instrument.

Scanned samples ID are compared with values in the imported protocol.

- If the scanned sample ID:
- is contained by the protocol , its line is green highlighted
- is not contained by the protocol or scanning was unsuccesseful, its line is orange highlighted

If some sample ID contained by protocol are not found by BCR the window with their list appears. The user may enter the sample ID in orange fields manually.

The system displays a tube type for each worklist position, which may be changed by the user according to the actual tube type registered in the application (see editing\Tube types). Positions 1 - 44 are intended for the standard tube types, A, B, C and D for the control tube types.

Ba	ck W	orklist .																										Next	Cano	cel
Prot	ocol name		Ana 161017_1	R	2 4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	п				
Writ	ten by		FUROBIOT One		ō ċ	ŏ	ŏ	Ő	Õ	0	0	0	0	0	Ö	0	0	0	0	0	0	0	Ő	Õ	Ö					
lise	BCR				1 3	-	7		11	12	15	17	10	21	22	25	27	20	21	22	25	27	20	41	42	~				
Lact	tube position f	or RCR scapping	2	 -	ດ່ ດໍ	ó	ó	ő	ö	0	0	ő	0	0	0	0	0	0	0	0	0	0	59	0	45	-				
Last	tube position i	or beit scanning	5		<u> </u>		<u> </u>																							
P	osition	Sample ID	Tube type	_			_		_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_			
► A			Control																											
B			Control																											
0			Control																											
0)		Control																											
1		Sample 16	Barnsted 5 ml																											
2		Sample 2	Barnsted 5 ml																											
3		Sample 8	Barnsted 5 ml																											
4			Barnsted 5 ml																											
5			Barnsted 5 ml																											
6			Barnsted 5 ml																											
7			Barnsted 5 ml																											
8			Barnsted 5 ml																											
9			Barnsted 5 ml																											
1	0		Barnsted 5 ml																											
1	1		Barnsted 5 ml																											
1	2		Barnsted 5 ml																											
1	3		Barnsted 5 ml																											
1	4		Barnsted 5 ml																											
1	5		Barnsted 5 ml																											
1	6		Barnsted 5 ml																											-
\$		🛕 📑 2	×																								Blot	Automat	er. 4.38	Bet3

30

Back	orklist .	•••																											Next	Ca	incel
Protocol name		Ana 161017_1		в	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	D				
Written by		EUROBlot One			Ō	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
Use BCR				Α	1	3	5	7	9	11	13	15	17	19	21	23	25	27	29	31	33	35	37	39	41	43	с				
Last tube position f	for BCR scanning	3	< <	•	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	•				
Position	Sample ID	Tube type																													
▶ A		Control																													- î
В		Control																													
С		Control						_										_													
D		Control						EUF	OBlot	One)	×													
1	Sample 16	Barnsted 5 ml								Sample	is not fe	ound in	rack:																		
2		Barnsted 5 ml						•		Sample	2																				
3	Sample 8	Barnsted 5 ml																													
4		Barnsted 5 ml														0	K														
5		Barnsted 5 ml																													
6		Barnsted 5 ml																													
7		Barnsted 5 ml																													
8		Barnsted 5 ml																													
9		Barnsted 5 ml																													
10		Barnsted 5 ml																													
11		Barnsted 5 ml																													
12		Barnsted 5 ml																													
13		Barnsted 5 ml																													
14		Barnsted 5 ml																													
15		Barnsted 5 ml																													
16		Barnsted 5 ml																													
		2																										Blot	Automat	ver. 4.3	88Bet3

If the instrument does not use the bar code reader - the system fills the sample IDs into the worklist according to the imported protocol. The user inserts tubes with samples into the rack according to the positions in the worklist. If it isn't possible, the user ends the editing of the imported protocol by pressing "Cancel", because the sample ID cannot be edited.

If the user requests to continue with the editing of the imported protocol, he presses "Next". The system performs a check, whether the worklis sample IDs match the imported protocol sample IDs. If their range and ID don't match, the system alerts the user, that the detected samples in the instrument must match. Until these are marched it isn't possible to continue with the protocol. If the samples match, the system continues with the next step.

By pressing the **"Cancel"** button the protocol creation will be aborted without an option to save the progress .

The process from Step 3 is identical to the process for a New protocol

2.1.3 Imported protocol - images

The user may process the imported protocol just by creating shots of the sample test strips. To begin to create the screens select the protocol and press "**Shoot according to protocol**".

Run	protocol Instrument maintenance History Edi Protocol list	t Application administration			
	🗱 Close 🛛 🦈 Refresh				
	Identifier	Name	Date of creation	•	
				·	
	47	Ana 161017_1	10/17/2016 12:40 PM	Run protocol	Shoot according to protoc
	45	ALD_161002_1	10/10/2016 11:46 AM	Run protocol	Shoot according to protoc

Procedure to create sample test screens of the imported protocol:

Step 1 - Protocol display

The system displays details of the imported protocol

Back	Proto	col		Next	Cancel	
Protocol nam	Protocol name Ana 161017_1					
Written by	EUROBIot C	Ine				
Strip order	 Sample ID 	Test	Lot			
•	1 Sample 2	Ana15	def_Ana15		A	
	2 Sample 8	Ana15	def_Ana15			
	3 Sample 16	Ana15	def_Ana15			
					v	
* 0	N	2 🛋 🛪	Bio	tAutomat	er. 4.38Bet3	

with non-editable items:

Protocol name - identification of the protocol from the external system
Written by - name of the author from the external system
For each sample:
Strip order - number showing the order of the strip in the tray
Sample ID - unique identification of the sample
Test - is a type of the test, several tests from one manufacturer can use the same assay for sample processing

Lot - lot of the strip number - production batch identification

If the user requests to continue with the shooting of sample test strips of the imported protocol, he presses the "**Next**" button (see Step 2).

The user may finish the protocol processing by pressing the "**Cancel**" button without the option to save the progress.

<u>Step 2</u> - Inserting the strip tray and selecting the starting position

The system prompts the user to insert the strip tray into the instrument. The user inserts the tray and continues by selecting the starting strip.





starting position from which the shooting of the sample test strips will start

The user may select only such starting position, which is followed by a sufficient number of free strips for all sample tests.

If the user requests to continue with the shooting of the strips of the imported protocol, he presses the "**Next**" button (see Step 3)

<u>Step 3</u> - Strip shooting

The system starts shooting the strips in the tray from the starting position given by the user and informs the user about the currently shot position in the tray.

	Cancel
Shooting in progress	
Shooting of strip no. 1	

After the shooting is finished, the system informs the user about the result. If the shooting was successful, the strips pictures are saved onto the hard disc and the user may view them from the detail of the performed protocol (see History\Protocols)

Back	Shooting according to protocol	Complete	Cancel
Shooting su	ccessfully finished.		
		PlotAutomativ	or 4 20Pot2

2.2 Edit

The Edit menu enables the to an Administrator role user to create assay groups with specific assays. The user also has to register reagents, which are then selected during the assay creation. For the worklist creation it is necessary to enter tests, which are assigned assays with a prescribed procedure of sample processing and the list of tube types of the standard and control variety, which are used by

the laboratory.

The Edit menu includes the following items :

- Assays
- Tests
- Reagents
- Tube types.

2.2.1 Assays

Assay groups contain individual assays, which describe the procedure of individual assays during sample processing. Creation and change of an essay group can be done only by a user with the Administrator role.

A common user with the User role has only a limited read-only access.

Run p	tun protocol Instrument maintenance History Edit Application administration					
n 🗌	Assay group list					
	Close New assay group Miselect all/nothing Discourse in the second secon					
	Name - Export					
	🖻 EURO 01/02			02		
	EURO 01/02 Demo			D 2		
	🖻 EURO 03			D 2		
	🖻 EURO 04			D 2		
	EURO 11 Allergy EL60			D 2		
	🖻 EURO 12 Allergy 16h			D 2		
	EURO 13 Allergy 2h					
	EURO Check		—	D 2		
	Pictures			42		
	Pipetting clot detection			- La / L		
		d s	BlotAutomat ver.	4.38Bet3		

Creation of a new assay group can be done by an Administrator in the assay group list by pressing " **New assay group**". The system displays the detail of a new assay group, where the user enters the assay group name, which is unique and required, then the assay name(s) and enters individual tasks, which are the same for all its assays. In accordance with the kit handbooks it is possible to link individual structures into a step structure. The step names are later displayed during the protocol run. They help the user to orientate in the protocol processing procedure.

To edit an assay group or display an assay group - the user clicks on the folder icon displays of the relevant assay group and the system displays its detail, describing individual steps and register list of the relevant assays.

Run p	protocol Instrument maintenance History Edit Application administration Assay group		.
H	Close 🗄 Save		
	Assay group name	ssays	
	0		📧 Open template
	Steps	Name	
	Name		
\$		d s	BlotAutomat ver. 4.38Bet3

The user creates a new assays step by pressing the document icon \square .

Run	protocol Instrument maintenance History Edit Application administration Assay group	
	Sclose 🗟 Save	
	Assay group name Group II Steps A V Name	Assays
	Step Order : 1 Name Strips praparation OK Cancel	
•		d s BlotAutomat ver. 4.38Bet3

If he has selected a row with the step and presses the the "**Open template**" button in the upper right corner of the application, he can create a new step from the individual actions.By dragging the step

activity icon (aspiration 🛄, dispensing 💁, pipette samples 🛄, incubation 🛄, manual
operation, drying, action binding, cycle), to the arrow displayed in the step row,
the user creates the requested step. The user then may enter the values of volume and type of reagent
which is offered in the range appropriate to reagents, which are registered in the application. He then

sets the number of repeats or changes the implicit speed of the strip tray swinging during incubation.

Wrongly defined actions can be removed by dragging the appropriate icon into the trash bin

Run	protocol Instrument maintenance History	Edit Application administration		
	Assay group			
	Close El Save			
	Assay group name		Actions	Assays
	Group II	Strips praparation		🗋 🖶 🖺 Open template
	Steps	4		Name
				·
	Name	Message Insert strips!		
	🖻 1 Strips praparation 🧷			
		Define step structure by drawing icons to these arrows.		
				8
				2
			Ŏ	
				ā
				/
				1
•	💧 🍬 🖺 1 🛶			d s BlotAutomat ver. 4.38Bet3

After creating an assay group the user creates individual assays by pressing icon in windows Assays. The asssays can differ in parameters of some operations - volumes and types of reagents for dispensing and the volume for sample pipetting. The change is made by selecting the required assay and then selecting the activities in the step, where the change of parameters is required. These assays will be offered to be assigned with tests.

Run protocol Instrument maintenance History	Edit Application administration	-						
Close Save								
Assay group name EURO 01/02 Steps	Strips preparation	Assays Assays						
Steps	Volume 15 • 0.1 ml Reagent Sample buffer Blocking buffer Blocking buffer Conjugate IgA Conjugate IgG AAB Conjugate IgG Inf Conjugate IgG ABB Conjugate IgG Mater Sample buffer Notking Sample buffer Stop rod Substrate Volume Volume Volume Volume Stop rod Substrate Volume Volume Volume	P EURO_02 IgG 2 P EURO_02 IgA 2 P EURO_02 IgG 2 P EURO_02 IgG 2 P EURO_02 IgM 2						
🏶 📩 🔌 🖺 1 🛶		d s BlotAutomat ver. 4.38Bet3						
Run p	rotocol Instrument maintenance History	Preview				- c	x נ	
-------	--	-----------------------	--	------------------	----------------------------------	----------------	-----	---
	Assay group	<u>File View B</u> ac	tkground				-	
	X Close Save	i M 🗁 🗎 8	88 ▷ 🗄 🖓 🖓 🖓 🔍 🔍 10 ▾ 🗏 ଏ ଏ ▷ 🗵 🗄 🖗 🖗 🕼 🖓 ▾ 😂 ▾					
	Assay group name EURO 01/02 Stans						Î	Assays
	Name ■ 1 Strips preparation		Group : EURO 01/02 Assay : EURO_01 IgG					 ➢ EURO_02 IgG ➢ EURO_02 IgA ➢ EURO_02 IgG ➢ EURO_02 IgG ➢ EURO_02 IgM
	🖻 2 Samples 🖉		Step	Action	Parameter	Value		
	🖻 3 Wash 1 🖉		Strips preparation	Dispensing	Volume	15.00 * 0.1 ml		
	🖻 4 Conjugates 🖉				Reagent	Sample buffer		
	🖻 5 Wash 2 🖉		Strips preparation	Manual operation	Message	Insert strips!		
	🖻 6 Substrate 🖉		Strips preparation	Incubation	Rocking speed	2		
	🖻 7 Stop 🖉				Incubation time	00:15:00		
	🖻 8 Shooting 🖉				Stop rocking after incubation	Yes		
			Samples	Aspiration	Extra aspiration	No		
			Samples	Dispensing	Volume	15.00 * 0.1 ml		
					Reagent	Sample buffer		
			Samples	Sample pipetting	Volume	15.00 µl		
					Disable multiple shots	Yes		
					Extra needle cleaning	Yes		
					Clot detection	Yes		
			Samples	Incubation	Rocking speed	2		
					Incubation time	00:30:00		
		4			Stop rocking after incubation	Yes		
-	A & A .	Page 1 of 3				100% 🖂 📃	•	d s BlotAutomat ver. 4.38Bet3

In the assay group detail the user may select the required assay and print it.

The user (with the Service or Administrator role) may export required assay groups into a file, which is saved outside of the application. To export it he selects the required assay groups in the assay group list in the "**Export**" column (or by the button "**Select all/nothing**") and by pressing the "**Export**" button he initiates the data export from the application in the "XML" format. The system will offer the user a selection of the location for saving the file and after confirmation the file is saved.

2.2.2 Tests

Test contains the assay name and the shutter time for the strip picture taking. Tests are allocated samples during the worklist creation.

The test register must contains all test which will be used by user for worklist creation or which will be contaned in protocols imported from the external system.

Run p	Run protocol Instrument maintenance History Edit Application administration						
	Tests register				-		
	KClose □ New Select all/nothing □ Export □ Impo	ort					
	Name	Assay	Shutter time (ms)	Export			
	😂 1111 Pipetting clot	Pipetting clot detection	50		2 🐴		
	🗁 AEA Food	EURO_11 IgE	20		2		
	🗁 AEA Inhalation	EURO_11 IgE	20		2		
	aEA Insects	EURO_11 IgE	20		2		
	🗁 AEA Pediatry/Atopy	EURO_11 IgE	20		2		
	😂 AEA SPAC Ins.v.1	EURO_11 IgE	20		2		
	😂 AEA SPAC Pollen1	EURO_11 IgE	20		2		
	😂 ALD	EURO_01 IgG Demo	20		2		
	😂 ANA_MK	EURO_01 IgG	20		2		
	ana15	EURO_01 IgG	20		2		
	😂 Ana16	EURO_01 IgG	20		2		
	😂 Ana17	EURO_01 IgG	20		2		
	😂 Ana18	EURO_01 IgG	20		2		
	😂 Ana1b	EURO_01 IgG	20		2		
	😂 Ana3b	EURO_01 IgG	20		2		
	😂 Ana5	EURO_01 IgG	20		2		
	😂 ANCA	EURO_04 IgG	20		2		
	😂 B. afzelii IgG	EURO_02 IgG	20		2		
	🖻 B. afzelii IgM	EURO_02 IgM	20		Q		
	😂 B. burg US IgG	EURO_02 IgG	20		Q		
	😂 B. burg US IgM	EURO_02 IgM	20		2		
	🖻 B. burg. IgG	EURO_02 IgG	20		Q		
	🖻 B. burg. IgM	EURO_02 IgM	20		2		
	🖻 B. garinii IgG	EURO_02 IgG	20		<u>a</u>		
	🖻 B. garinii IgM	EURO_02 IgM	20		2,		
\$	t d s BlotAutomat ver. 4.388et3						

Creating a new test

A user with the Administrator role may create new tests in the application. By pressing on the "**New**" button he displays the screen for test creation.

Nam	ne	New test	
Assa	iy		
S	hutter tim		
		EUKO_01 IgG	
		EURO_01 IgG Demo	
	•	EURO_02 IgA	ns) 50 Camera start
		EURO_02 IgA Demo	
		EURO_02 IgG	
		EURO_02 IgG Demo	
		EURO_02 IgM	
		EURO_02 IgM Demo	
		EURO_03 IgG	
		EURO_03 IgM v	OK Cancel

When **creating a new test** the user enters the test **Name**, which must be unique within the application. Then he chooses an assay which is already registered in the application. If the application has an option set to use the camera and the assay associated with the test contains the activity "Shooting", the user has to enter the times of the camera **Shutter time** entered in milliseconds. It is possible to enter up to 10 shutter times by adding lines to shutter time table.. During the protocol run picture of each strip is made and saved several times according to number lines in the table. The camera shutter time can be enteed as a numeric value or by pressing the button "**Camera start**".

Name Assay	New test EURO_01 IgG
Shutter	time (ms)
	OK Cancel

The instrument will move the arm with the camera above the first well in the strip tray. The system displays a window with the real camera view, the user can the move the time slider of the shutter and select the slider position with the best display of the actual camera view. This way he sets the shutter time.

For a test which is assigned with an assay without Shootin activity set the Shutter time 0.

If all test parameters are selected, the user confirms their setting by pressing "**OK**". The system will create a new test in the test list. If the user doesn't agree with the entered items of doesn't require the test to be saved, he selects "**Cancel**".

Test deletion

A user with an Adminstrator role may remove tests from the register. He presses the 🕍 icon in the line of the test to be removed. The system then displays a query to remove the test.



If the user agrees, he selects "Yes" and the system removes the test from the list.

Importing tests

A user with the Administrator or Service role may import tests created in another application.

The user presses the "**Import**" button. The system displays a Windows Explorer window and the user selects a XML document with the test definition. He confirms the selection of the document by pressing "**Open**". The system the checks, whether the data in the file have the correct structure. If they do, it then proceeds with importing the test(s) into the test list. If the tests are already included in the test list, the system will alert the user; the user may confirm the overwriting of current tests in the application with imported tests. Imported tests are then entered in the test list. If the imported test includes information about the link to an essay, which is currently registered in the application, the system then with the user's confirmation imports the test with this link. A test without a registered assay link will be assigned an assay registered in the application. Only a test with a link to an assay can be inserted into the worklist when creating a new protocol.

Exporting tests

A user with an Administrator role may export tests outside the application.

The user will press the "Export" button. The system displays the Windows Explorer window, the user

selects a location to save the file in XML format with the exported test data and selects the location and name of the file. The user then confirms the saving of the file by pressing "Save".

2.2.3 Reagents

The items of the reagents register are used during the assay creation as a parameter of the Dispensing action.

Reagent register

Each user may display the reagent list by using the menu "Edit/Reagents register".

Respent v							
Reagent	 Antidrop 	Reagent saving	Prime before run	Pumps assignment			
Blocking buffer				2			
😂 Conjugate IgA				3			
😂 Conjugate IgE				3			
😂 Conjugate IgG AAB				4 2			
😂 Conjugate IgG Inf				5 2			
😂 Conjugate IgM				6 2			
😂 Dist. Water				8			
😂 SamBu IgM				2			
😂 Sample buffer				2			
😂 Substrate				7 2			
😂 Universalbuffer				1 2			

For each edited reagent there are attributes "Antidrop", "Reagent saving", "Prime before run" a "Pumps assignment", which make the work with reagents more accurate during sample testing.

- Reagent unique identifier
- Antidrop after each reagent dosage to the well the pump turn back slightly to remove the drop at the dispensing arm
- Reagent saving the reagent from tubing is saved back to its bottle after last dispensing
- **Prime before run** a small amount of reagent is splahhed to the priming bowl before every Dispensing action. Then even the first strip has a fresh reagent every time.
- **Pumps assignment** number of pump (1 8) which will be used for the reagent during the protocol run. If the value is not fullfilled the reagent is assigned with pump casually.

Entering new reagent

A user with an Administrator role may enter new reagent in the reagent list by pressing "**New**". The system displays a window with the items of the new reagent.

Name	0
Antidrop	
Reagent saving	
Prime before run	
Pumps assignment	
O	Cancel

If the user entered all items of the new reagent, he presses the "**OK**" button and the system will save the new reagent in the list. After pressing "**Cancel**" the window for entering new reagents will be closed.

Removing a reagent.

The user selects a reagent from the list, which he wants to remove and presses the eraser icon . The system displays a query whether the user really wants to remove it. If yes, the reagent is removed from the list.

Confirmation						
?	Really delete record?					
	Yes					

2.2.4 Tube types

The tube register contains the tube names which can be used during the worklist creation.

n protocol Instrument maintenance History Edit Application administration						
Tubes register						
Close	e 🗋 New tube type 💭 Import 🗹 Export					
Ord	der 🔺 Name					
Pe						
	2 Control	2				
6	5 nova	2				
6	3 Small	<u>a</u>				
8	1 Standard	Q				
		v				
	* *			dia PlatAutomativar 4		
U				d s BlotAutomat ver. 4.		

The type differ by the tube dimensions and their insertion to the sample tubes rack. From the insertion wiew there are 44 positions for standard tubes



which can differ by their diameter and height because they are fixed in position by the spring mechanism. They can be provided by the bar code label with the sample ID.

Control tubes are smaller and enable to detect levels and load samples from small volumes. They can be placed in positions A, B, C, D.



Their dimensions are limited by the holes dimensions. The bar code reading is not possible in the control tubes position.

Entering a new tube type

A Service or Administrator level user may enter a new tube type. The entry of a new type is done in several steps, during which the instrument moves the arm and records its positions, confirmed by the user, to determine the parameters of the given tube type. Tube type setup wizard is opened by the button "**New tube type**".

<u>Step 1</u> - Determining the tube type

Back	Tube type			Next Cancel
	₽	Inner tube Name Control tube Tube inner diameter	diameter Standard I	

The user enters the **Name** of the tube type (text field) and selects whether this is a **Control tube** type. The user measures the tube for **Tube inner diameter** (in millimeters). This value is necessary for the correct function of the level following during sample taking.

<u>Step 2</u> - Inserting the tube into the instrument

Back	Insert tube to rack position 1.	Next	Cancel

The user inserts the tube into the position marked by the arrow (standard - position 1, control - position "A").

The "**Next**" button continues to next step. The "**Cancel**" button ends the entry of the new tube type

! Pay attention - in this point the arm starts to move. Make sure there is no obstacle in the arm working area.

<u>Step 3</u> - Setting the upper edge of the tube System moves the arm above appropriate position of the tube rack.

Back Center of tube top edge		Next Cancel
	Set tube center	

By pressing the control arrows the user moves the lower end of the needle above the center of the upper edge of the tube. This point is the start point for the level detection before the loading of the sample.



The "**Next**" button continues to next step. The "**Cancel**" button ends the entry of the new tube type

<u>Step 4</u> - Setting the bottom of the tube

Back	Tube bottom	Complete Cancel
	Set tube bottom	

By pressing the control arrows the user moves the tip just above the bottom of the tube. This point is final for the sample level detection.

When searching for the position it is possible to orientate according to the displayed Z coordinate

The lowest needle position is limited by the maximal Z coordinate and it is fixed by the system (8200).

By pressing "Complete" the new tube type is saved.

The "**Cancel**" button will end the entry of the new tube type without saving the progress and the arm returns to default position.

Checking the new tube settings

The User (with user role or not logged) may check the settings of the tube. He presses the folder icon

at the tube line. The system displays individual steps of the setting of tube parameters (see Entering a new tube type) so that the user may check the settings. The value of parameters can not be changed.

Removing a tube type

An Administrator or Service level user may choose a tube type from the list and by using the eraser

icon $\overset{\checkmark}{=}$ remove the tube from the list.

Exporting tubes

An Administrator or Service level user may **Export** tube types registered in the tube type list.



The system displays a Windows Explorer window, where the user selects a location to save the file with exported tube types. He selects the file name and click on the "**Save**" button. The system saves all tube types, registered in the application, in an XML file. The exported file can be imported into an application located at a different place.

Importing tubes

An Administrator or Service level user may import tube type lists into his application so that he doesn't have to manually set each one of them. The user presses the "**Import**" button.

Run p	Tub	ol Instrument maintena es register	ance History	Edit Application ad	dministration				
	×с	lose 🛛 🗋 New tube type	🖾 Import 🛛 🗹	Export					
		Tube import						×	<
		\leftrightarrow \rightarrow \checkmark \uparrow \square \rightarrow This P	C > Documents >	Tube types	~ (5 Search Tube ty	/pes	P	
		Organize 👻 New folder					8== •		
		zmena_hesla ^	Name	^	Date modified	Туре	Size		
	6	Zobrazeni_chyb	Tubes 161018.xm	l .	18/10/2016 12:07	XML File		3 KB	
	6	ConeDrive							
		This PC							
		Documents							
		Downloads							
		👌 Music							
		Pictures							
		Videos							
		Windows8_OS ((
		A Makanali Filo name	Tub 1610101			Val files (* ve	-D		
		File name	E Tubes to to taxmi			V Ami files (*.xn	ni)	· ·	
						Open	6	ancel	

System displays the Windows Explorer window to select an XML file with the exported tube types. The user selects "**Open**" and the system imports the data from the file as records of tube types. The system then informs about the success of the importing. If it isn't possible to carry out the import, the systems alert the user. The reason may be a damaged file or an incorrect file format.

2.3 History

The user may check the records about the instrument's performance in history.

The history records are non-editable data, which can be printed in some cases (self-test records, protocol including shots).

The History menu includes these items:

- Self-tests
- Maintenance
- Communication with the external system
- Protocols

2.3.1 Self-tests

The list of self-tests includes all records about performed self-tests.

Self-test list

The system shows an overview of all performed self-tests together with the date and time and result of the self-test. If the user needs to find a record from a certain day, he can use the filter. After clicking into the light blue field in the header of the list he writes the requested date and the system finds the wanted record. If he clicks the arrow, the system shows a calendar where the user can select the date of the requested record.



Self-test details

and

The user may select a self test record from the list.

× .

Icons 🧹

mean successful self-test and self-test with some error.



Run	protocol Instrument maintenance H	listory Edit Application adminis	tration	
	Self-tests register			
	Ӿ Close 🛛 🦈 Refresh			
	Self-test	Cover sensor testing	Rocking motor	
	10/17/2016 4:18 PM ♀ ♥ 🖶 10/17/2016 12:01 PM ♀ ♥ 🖶	Z Motor	Vacuum 😯	
	10/17/2016 10:13 AM	Y Motor	Needle washing station asp. valve	
	10/13/2016 10:48 AM 🛛 🖌 😸 10/13/2016 10:02 AM 🖓 🗲 🚍	X Motor	Aspiration arm valve	
	10/13/2016 10:00 AM S & S & S 10/13/2016 10:00 AM S & S & S & S & S & S & S & S & S & S	Aspiration arm	BCR	
	10/12/2016 2:51 PM	Plunger pump	Camera	
	10/12/2016 2:35 PM 10/12/2016 2:25 PM 10/12/2016 9:44 AM ▼ ◆ ⊜	#1015 - BCR error - incorrect rea	ad in self-test	
	10/11/2016 4:41 PM 10/11/2016 4:40 PM ■ ★ ●			
	10/11/2016 4:39 PM 10/11/2016 3:58 PM 10/11/2016 9:37 AM ↓ ↓			
	10/10/2016 2:50 PM 10/10/2016 2:28 PM ✓ ♥ ⊕			
-	10/10/2016 1:51 PM	<u>]</u>		s Blotáutomat ver 4 388et3
		•		

Icons Not and Real mean successful part of self-test and some part with some error.

Printing the self-test result

The user selects a self-test record in the list and after pressing the print icon the self-test record may be printed or saved to the computer.

<section-header><section-header><section-header></section-header></section-header></section-header>	Test result	Self-test Date : 10/18/2016 8:30: Test result : OK Self-test Cover sensortesting Z Motor
Stiffersts Date Ite 2018/2016 8:30:02 AM. Test result Test result Test result OK Motor OK Motor OK Apiration amn OK Acking motor OK Vacum OK Aspiration amn valve OK BCR OK Carmaa OK Error OK	Test result	Date : 10/18/2016 8:30: Test result : OK Self-test Cover sensortesting Z Motor
Date • 10/10/2010 0.5.0/02 AM Test result : OK Self-test Test result Óver sensor testing OK Z Motor OK Y Motor OK Aspiration am OK Runger pump OK Rocking motor OK Vacuam OK BCR OK Camea OK Error	Test result	Test result : OK Self-test Cover sensor testing Z Motor
Self-test Test result Cover sensortesting OK Z Motor OK Y Motor OK Appiration am OK Runger pump OK Rocking motor OK Needle washing station asp. valve OK BCR OK Camera OK Error N	Test result	Self-test Cover sensortesting Z Motor
Series Feat result Cover sensortesting OK Z Motor OK Y Motor OK Apiration am OK Plunger pump OK Rocking motor OK Vacuam OK Needle washing station asp. valve OK BCR OK Camera OK Error Intervention		Cover sensor testing Z Motor
Z Motor OK Y Motor OK X Motor OK Aspiration am OK Plunger pump OK Rocking motor OK Vacuam OK Aspiration any valve OK Aspiration arm valve OK BCR OK Camera OK Error Image: Common state		Z Motor
Y Motor OK X Motor OK Aspiration am OK Phunger pump OK Rocking motor OK Vacuam OK Aspiration asp. valve OK Aspiration arm valve OK BCR OK Camea OK Error Image: Common state		
X Motor OK Aspiration am OK Phanger pump OK Rocking motor OK Vacuam OK Needle washing station asp. valve OK BCR OK Camera OK Error Image: Comparison of the co		Y Motor
Pignaro pump OK Pinnger pump OK Rocking motor OK Vacuam OK Aspiration am valve OK BCR OK Camea OK Error Image: Comparison of the second seco		X Motor
Rocking motor OK Vacuarn OK Needle washing station asp. valve OK Aspiration arm valve OK BCR OK Camera OK Error Image: Comparison of the second s		Plunger pump
Vacuam OK Needle washing station asp. valve OK Aspiration arm valve OK BCR OK Camera OK Error		Rocking motor
Needle washing station asp. valve OK Aspiration arm valve OK BCR OK Camera OK Error		Vacuum
Aspiration am valve OK BCR OK Camera OK Error		Needle washing station asp. valve
Camea OK Error		Aspiration arm valve
Error 1 of 1 100% —		Camera
1 of 1 100% ⊙		Error
Self-test Date : 10/14/2016 11:50:16 AM		Self-test Date : 10/14/2016 11:50
Test result : Error		Test result : Error
Self-test Test result	Test result	Self-test
Cover sensortesting OK		Cover sensor testing
Y Motor OK		Y Motor
X Motor OK		X Motor
Aspiration am OK		Aspiration am
Plunger pump OK		Plunger pump
Rocking motor OK		Rocking motor
		Vacuum
Vacuum OK Needla washing station asp when OK		ineedle washing station are wake
Vacuam OK Needle washing station asp. valve OK Assiration app. valve OK		weedle washing station asp. valve
Vacuam OK Needle washing station asp. valve OK Aspiration amv valve OK BCR Emor	r	veedle washing station asp. valve Aspiration am valve BCR
Vacuam OK Needle washing station asp. valve OK Aspiration am valve OK BCR Enror Camera Not tested	r tested	veedle washing station asp. valve Aspiration ami valve BCR Camera
Date : 10/14/2016 11:50:16 AM Test result : Error Self-test Test result Cover sensortesting OK Z Motor OK Y Motor OK Aupitation aum OK	Test result	Date : 10/14/2016 11:50 Test result : Error Self-test Cover sensor testing Z Motor Y Motor X Motor Aspiration am

2.3.2 Maintenance

The user may display an overview of the performed maintenance operation.

protocol Instrument maint	enance History Edit Application a	administration	
Close Sefresh	Print		
Date from 10/18/2015 12	100 AM	04.4	
Date Ironi 10/18/2013 12	2.00 AM Date to 10/18/2010 11.39	PIN	
Date of maintenance	 Maintenance task 	Maintenance status	
10/12/2016 10:26 AM	Dumps cleaning		
10/12/2016 10:30 AM	Monthly maintenance	Finished	
10/13/2016 10:24 AM	Monthly maintenance	Canceled	
10/12/2016 2:04 PM	Monthly maintenance	Einished	
10/12/2016 1:57 PM	Monthly maintenance	Canceled	
10/12/2016 9:53 AM	Autocalibration	Finished	
10/11/2016 9:56 AM	Weekly maintenance	Finished	
10/3/2016 9:46 AM	Monthly maintenance	Canceled	
10/3/2016 9:41 AM	Monthly maintenance	Canceled	
10/3/2016 9:02 AM	Monthly maintenance	Canceled	
			_
	-4		
🗭 🖸 🍳 U_ 1	×		

It is possible to select the period of records by the time setting in the fields *Date from* and *Date to*. The default setting is 1 year from the current date.

The list includes records about next types of maintenance :

- Pumps cleaning
- Autocalibration of the pumps
- Weekly maintenance
- Monthly maintenance

The column *Maintenence status* contains information about the maintenance process completnes - " *Finished*" or "*Canceled*"

The records can be filtered by date, type and completion status of the maintenance (filter text can be inserted to the free line above the table header)

The records of the autocalibration and monthly maintenance contain details about each pump calibration. It appears in the right part of the window after the record selection.

Run protocol	Instrument maintenance ance history	History Edit Application admi	nistration				
Close	🗇 Refresh 🛛 🖶 Print						
Date fro	m 10/18/2015 12:00 AM	Date to 10/18/2016 11:59 PM	•				
Date of n	maintenance -	Maintenance task	Maintenance status	Pump nu 🔶 Flow	(ml/min) Calibration status Error		
10/13/20	16 10:36 AM	Pumps cleaning	Finished	1	80 OK		
10/13/20	016 10:33 AM	Monthly maintenance	Finished	2	85 OK		
10/13/20	016 10:24 AM	Monthly maintenance	Canceled	4	82 OK		
10/12/20	016 2:04 PM	Monthly maintenance	Finished	5	0 Not calibrated		
10/12/20	016 1:57 PM	Monthly maintenance	Canceled	6	0 Not calibrated		
10/12/20	016 9:53 AM	Autocalibration	Finished	7	0 Not calibrated		
10/11/20	016 9:56 AM	Weekly maintenance	Finished	8	0 Not calibrated		
10/3/201	16 9:46 AM	Monthly maintenance	Canceled				
10/3/201	16 9:41 AM	Monthly maintenance	Canceled				
10/3/201	16 9:02 AM	Monthly maintenance	Canceled				
*	%			c		d	s BlotAutomat ver. 4.38Ber

Maintenance history printing

Maintenance history database content can be printed -

		Prev	view		
<u>File View Background</u>					
೫ 🗁 🖬 🗳 🗳 🖏 🎝 🔍 🔍 10 ▪ 🔍 🖂 🕨	N 🕑 🐴 🔯 🗋 - 🖂	- 🔞 -			
	1				
	Instrument ma	intenance			
	E				
	To date	· 10/22/2010 12:50 PM			
	10 uate	. 10/22/2014 11.39 FM			
	Date and time of comple	ti Maintenance task	Maintenance status		
	10/15/2014 10:38:10 AM	Weekly maintenance	Finished		
	10/15/2014 10:44:45 AM	Autocalibration	Finished		
	Pum	ps autocalibration			
	Order	numbe Calibration status	Flow (ml/min)	Error	
	1	OK	77		
	2	OK	82		
	3	Error	0	#1018 - Pump flow under range	
	4	Not calibrated	0		
	5	Not calibrated	0		
	0	Not calibrated	0		
	8	OK	80	_	
		I			
	10/15/2014 10:56:18 AM	Monthly maintenance	Finished		
	Pum	ps autocalibration			
	Order	numbe Calibration status	Flow (ml/min)	Error	
	1	OK	80		
	2	OK	76		
	3	OK	80		
	4	Not calibrated	0		
	P	Not cambrated	v	1	

The record from the selected period are ready for printing.

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2.3.3 Communication with the external system

The application may communicate with the external system via services, which can transfer data for protocol processing (see imported protocol). The data are transferred in the XML format via the Internet interface with on-line data exchange. The data transfer protocol is the HTTP. For the transfer to be performed it is necessary to launch the application and to be connected to the Internet, or to install SW using the application services on a common PC.

Communication with the external system is logged; the overview of the communication with the external system contains items:

- Date date of accepting a query from the external system
- Service name of the query from the external system
- Protocol identification of the protocol, which had been the subject of the query
- **Response** status of the query from the external system

Run p	protocol Instrument maintenanc	e History Edit Appli	cation administration	
	Communication register			-
	Ӿ Close 🛛 🗇 Refresh			
	Date	 Service 	Protocol	Response
				· · · · · · · · · · · · · · · · · · ·
	10/17/2016 12:41 PM	Protocol receiving		ОК
	10/17/2016 12:41 PM	Instrument status		Waiting
	10/17/2016 12:02 PM	Protocol receiving	45	ОК
	10/17/2016 12:02 PM	Instrument status		Waiting
	10/12/2016 10:09 AM	Protocol receiving	46	ОК
	10/12/2016 10:09 AM	Delete protocol	46	ОК
	10/12/2016 10:09 AM	Protocol receiving	46	_199ProtocolCreationError
	10/12/2016 10:09 AM	Instrument status		Waiting
	10/10/2016 11:48 AM	Protocol receiving	46	ОК
	10/10/2016 11:48 AM	Instrument status		Waiting
	10/10/2016 11:46 AM	Protocol receiving	45	ОК
	10/10/2016 11:46 AM	Instrument status		Waiting
	9/27/2016 4:45 PM	Protocol receiving	44	ОК
	9/27/2016 4:45 PM	Instrument status		Waiting
	9/27/2016 4:44 PM	Protocol receiving	44	_103IncompatibleTest
	9/27/2016 4:44 PM	Delete protocol	44	302
	9/27/2016 4:44 PM	Protocol receiving	44	_103IncompatibleTest
	9/27/2016 4:44 PM	Instrument status		Waiting
	9/27/2016 4:44 PM	Protocol receiving	44	_106TestNotFound
	9/27/2016 4:44 PM	Delete protocol	44	302
	9/27/2016 4:44 PM	Protocol receiving	44	_106TestNotFound
	9/27/2016 4:44 PM	Instrument status		Waiting
	9/27/2016 4:38 PM	Protocol receiving	44	ОК
	9/27/2016 4:38 PM	Instrument status		Waiting
•	📩 🔌 📑 1 🛋			d s BlotAutomat ver. 4.38Bet3

The user may monitor messages from the external system and replies sent to the external system in the overview

More information about the communication with the external system can be found in the part How to.../ Description of communication with the external system.

2.3.4 Protocols

The application user may display processed protocols. These are protocols for which the instrument run has begun and they finished either successfully or with an error or the user ended them during processing. The user may filter the lists in the usual way by using the first row.

B

Run p	protocol Instrument maintenance History Edit	Application administration				
ן	Close SRefresh Schriving					
6	Identifier	Name	Date of creation	 Date and time of completion 	- Status	
					•	
	8 47	Ana 161017_1 2016_10_17_2	10/17/2016 12:40 PM	10/17/2016 4:30 PM	Processed Not processed	d - error
		2016_10_17_1	10/17/2016 10:18 AM	10/17/2016 11:25 AM	 Processed 	
	l					v
4	n 👌 💊 📑 1 🛋				d s	BlotAutomat ver. 4.38Bet3

The list of protocols contains protocol items:

• **Identifier** - unique protocol identifier under which the protocol is identified in the external system. Newly created protocol in the application doesn't include this identifier

• Name - name of the protocol, which serves the user to identify the protocol

• **Date of creation**- date when the protocol was created or received from external system (imported protocol)

• Date and time of completion - date and time of completion of the protocol processing

• State - indication of the processing result, can have values of "Processed" - when all planned assay activities are finished correctly, "Not processed - error" - if the instrument run in ended by the user or if there is a processing error, due to which it isn't possible to complete the run according to the planeed activities of the assay.

To display protocol detail the user selects a protocol from the list and presses the folder icon The system displays the protocol details with items:



• **Protocol name** - name of the protocol, which serves the user to identify a protocol in the application

• Written by - the person who created the protocol

• Status - indication of the processing result, can have values of "Processed" - when all planned assay activities are finished correctly, "Not processed - error" - if the instrument run in ended by the user or if there is a processing error, due to which it isn't possible to complete the run according to the planeed activities of the assay.

• Date and time of creation - date when the protocol was created or received from external system (imported protocol)

• Date and time of completion - date and time of completion of the protocol processing

Following items are displayed for individual samples:

• Strip order - order of the sample in the protocol

• **Sample ID** - unique identifier of the sample; identifier under which the protocol is identified in the external system. Newly created protocol in the application doesn't include this identifier

• Test - name of the sample test

• Lot - the strips lot number

• **Image** - image of the strip with the shutter time. Number of the pictures depends on the appropriate test setting.

Printing the test document

In the protocol detail as well as from the protocol list the user can display and print the generated

protocol document by pressing the print icon . If the assay includes the "Shooting" activity the images of strips are displayed as well



The protocol document may be printed **or** saved **i**. The document includes the name, identifier, date and time of the completion and the name of the author. For each sample there is a strip order number, sample ID, test name, lot and image (if required in the assay).

The protocol run log can be opened by the icon 0 . The protocol run log contains next time marked information :

- the protocol name

-date and time of protocol start

-starts of steps

- mistakes during pipetting (no level detection, clot detection with sample name and position in the tray)

-pauses

-errors

-run end status (OK, Protocol cancelled,...)

-time of pauses during the run

Birchew	-		×
<u>F</u> ile <u>V</u> iew <u>I</u>	2ackground		
8 🖻 🗄	" " " " " " " " " " " " " " " " " " "		
	10:19:36 - Run started - Protocol :2016_10_17_1, Assay group: EURO 01/02		
	10:19:37 - Step started - Strips preparation		
	10:20:08 - Start of pause		
	10:34:42 - End of Pause		
	10:35:51 - Start of pause		
	10:37:43 - End of Pause		
	10:49:28 - Start of pause		
	10:49:36 - End of Pause		
	10:49:43 - Step started - Samples		
	10:51:34 - Sample pipetting error - 1029 - Clot detection (Well; 3, Sample: Sample 8)		
	10:51:43 - Error -		
	#1028 - Cleaning bowl filling error		
	10:51:43 - Start of pause		
	10:51:47 - End of Pause		
	10:52:32 - Sample pipetting error - 1029 - Clot detection (Well; 5, Sample: Sample 2)		
	10:54:02 - Start of pause		
	10:59:22 - End of Pause		
	10:59:27 - Start of pause		
	11:02:09 - End of Pause		
	11:02:19 - Start of pause		
	11:03:04 - End of Pause		
	11:03:06 - Start of pause		
	11:05:23 - Run restarted - Protocol :2016_10_17_1, Assay group: EURO 01/02, Starting step: Strips preparation	n	
	11:05:23 - Step started - Strips preparation		
	11:05:30 - Start of pause		
	11:05:42 - End of Pause		
	11:06:13 - Start of pause		

Protocol archiving - by pressing the archiving icon **Archiving** in the protocol list the user can archive the protocols. Archiving serves to transfer the old unused data from the application so that the user could further use (display) them.

Creating protocol archive - the user clicks on the arrow in the row with preset date for archiving. The system displays a calendar, from which the user selects a date, by which he requires the archiving of the protocols. Then he presses the "**Archive protocols**" button and the system creates an archive of protocols, which have their date of completion earlier or equal to the set date for archiving.

ni eui			_ 문 ×
Run	protocol Instrument maintenance History Edit Application administratio	1	
	Protocol archive Archiving		-
	× Close		
-6			
		Performed protocol archivation	
		Select the final date (include) for protocol archiving 12/12/2012 Archive protocols	
	Archived in • Date of cre	ation Created by Na	me
	12/11/2012 12/11/2013	20	12-12-11
•			BlotAutomat ver. 4.33 SN EL20110035

After the archive is saved the system notifies the user with a message displaying the path to the saved file.

Information	
Í	Successful archiv. Protocol were saved to directory c:\Dynex\EUROBlot\Archives\2012-12-12.
	Ok

The system creates an archive file with the appropriate protocols in the XML format, which are then saved into a folder e.g. "2012-10-26" with path: c:\Dynex\EUROBIot\Archives\2012-10-26. The folder created for storage of archived protocols is named after the date of archive creation in the format Year (4)-Month(2)-Day(2). The user can view the archived protocols outside the application with an internet browser.

					1	
÷)⊕l€	C:\Dynex\EUROBlot	\Archives\2012-12-12\archiv.htm J	O ▼ C:\Dynex\EUROBlot\	Archiv ×		
• • •	🖃 🖶 🔻 Stránk	ka 👻 Zabezpečení 👻 Nástroje 👻	0 •			
Archive	ed protocol	s				
	•					
Date of crea	ation: 12/12/2012	5-34-31 PM				
Archived in	12/12/2012	2 12:00:00 AM				
User:						
	-					
Identifier	Name	Date and time of creation	Date and time of completion	State		
	2012_12_12_3	12/12/2012 5:29:55 PM	<u>12/12/2012 5:30:09 PM</u>	Processed		
39	asas	12/12/2012 4:14:46 PM	<u>12/12/2012 5:24:58 PM</u>	Processed		
38	121212_ana3b	12/12/2012 3:22:01 PM	12/12/2012 3:50:16 PM	Not processed - error		
	2012_12_12_2	12/12/2012 12:00:33 PM	12/12/2012 12:05:25 PM	Not processed - error		
	2012_12_12_1	12/12/2012 11:25:17 AM	12/12/2012 11:57:13 AM	Processed		
	2012_12_11_1	12/11/2012 2:27:16 PM	12/11/2012 2:27:57 PM	Processed		

By double clicking on the protocol record in the archive file the user can display the details of the specific protocol including images, if they are a part of it.



2.4 Maintenance

The Instrument maintenance menu contains items for the preparative operations before the protocol running and the maintenance operations.

The maintenance menu contains these items:

- System liquid
- the system liquid preparation before the protocol running
- the pump and tubing cleaning by the flush or their emptying
- Pumps priming Pumps autocalibration - the peristaltic pumps calibration to achieve their dispensing accuracy
- Weekly maintenance
- Monthly maintenance
- -starting of the regular weekly maintenence -starting of the regular monthly maintenence
- Run self-test checking
- starting of the exceptional self-test for the instrument parts function

2.4.1 System liquid

The system liquid is necessary for the pipetting action. Prior to the protocol run the user should pump the system liquid into the pipettor hydraulic system. The default status of the system solution after the

in the lower bar. application starts is "Not primed" and is signalized by an icon



The user places the system liquid bottle to its holder, puts the lid with connection to the SYSTEM pump

and selects the priming button



After successful priming next window appears



After the system liquid priming its icon is displayed in the lower bar as blue and the icon of the

level status in the system liquid bottle appears as well ______. If the depletion of the system solution is

near, the icon changes to yellow **Least**. The instrument's operation is not influenced, but it is advisable to add system solution. If there is a critical shortage of the system solution in the tubes, the icon



system solution volume by a sound signal, which is can be silenced by the icon **the lower** bar. If the user adds system solution, the icon changes back to blue and the sound signal ends.

If the user doesn't prime the system liquid before the protocol run preparation, he will be prompted during the protocol run.

To empty the hydraulic circuits of the system solution remove the lid from the bottle and press the



right - less distinctive - icon

2.4.2 Pumps priming

Anytime outside the instrument's run the user may perform a priming of the pumps. The system presets the volume of the priming liquid to 5 ml. The user may change the volume. The user changes the pump designation according to the current need for priming. The priming is started by clicking on the pump icon.



2.4.3 Pumps autocalibration

Calibration of the peristaltic pumps sets the system parameters so that the dispensing of reagents during the protocol run corresponded with values in the assays. This way the current status of the mechanical parts of the pumps is taken into account, as it can gradually change during the instrument's operation. If the user doesn't perform autocalibration according to current need, it will be performed as a part of the monthly maintenance. The records of the performed maintenances are entered in the Maintenance list.

Autocalibration consists of several steps:

Back	Tubes exercise		Next	Cancel
	Select pumps for new tubes exercise!			
	Exercise time (min):			
* 0		d s BlotA	utomat ve	r. 4.38Bet3

<u>Step 1</u> - New cassettes running-in

The autocalibration may include the tubes running-in. It is recommended to run-in the new pump cassettes before their first calibration. The time stability of the calibration will be higher. The user selects the pump with new cassette and sets time of the required run-in (default value is 5 min). The run-in isn't mandatory. If the user doesn't want to perform it, he cancels the preset pump designation and continues by pressing "**Next**".

The user may press "Cancel" to end the autocalibration process. This won't be entered into the

maintenance list.

Step 2 - Pump selection

Back	Selection of p	oumps fo	r autocali	bration						Next Cancel
	Select pumps for autocalibration, insert the tubes into a container with dist. water and prime them. One pump needs about 50 ml.								50 ml.	
				3	\checkmark	$\overline{0}$				
	Kalibrovat:	1.position	2.position	3.position	4.position	5.position	6.position	7.position	8.position	
		-		0	0	0	0	0	0	
			V							
* Č) 🔌 🛕 🖺 🖬								d s Blo	tAutomat ver. 4.38Bet3

To perform autocalibration the user selects the pump, which he wants to calibrate. Then he inserts the tubing of the selected pump(s) into a bottle with DI water and then select the pump with the



mouse cursor and primes it with the button. By pressing the priming button he can repeat the priming. If he checks the water flow from the dispensing arm he marks the pump as



primed by pressing

If all pumps needed for the autocalibration are marked as primed, the user may continue by pressing "**Next**". By pressing "**Back**" he displays the previous screen. The user may press "**Cancel**" to end the autocalibration process.

Step 3 - Autocalibration cuvette inserting

Back	Autocalibration cuvette inserting	Next	Cancel
	Insert autocalibration cuvette and connect it to waste bottle!		
* 0	🗞 🛕 👫 1 🛶 ds	BlotAutomat v	er. 4.38Bet3

The user places the calibration cuvette on the upper case of the instrument according to the picture and connects the cuvette tube to the waste bottle with a self-closing clutch.

If the cuvette is connected the user may continue by pressing "Next".

Back			Next
	4		
		Cancel	
😄 👌 🐁 🛔 🕅 1	×		d s BlotAutomat ver. 4.38Bet

<u>Step 4</u> - The process of autocalibration

The process itself proceeds individually for each pump. The first required pump starts filling the cuvette until it's full and the tip signals that the level of primed liquid has been reached. The liquid is then pumped into the waste bottle.

<u>Step 5</u> - Autocalibration results

Back				Next
Pump number	 Flow (ml/min) 	Calibration status	Error	
	1	82 OK		A
	2	76 OK		
	3	0 Not calibrated		
	4	0 Not calibrated		
	5	0 Not calibrated		
	6	0 Not calibrated		
	7	0 Not calibrated		
		Pump autocalibration finished.		
			d s	r BlotAutomat ver. 4.38Bet3

If the autocalibration is error-free and the value of the given pump is found in the requested range the pump status is set to "**OK**".

If the calibration is not possible to do because some fault or bad pump condition, the status is set to " **Error**".

If the autocalibration is cancelled by pressing "**Cancel**", the running calibration will be stopped, the calibration of the following pumps won't start and all the following pumps selected for autocalibration will have their status set to "**Cancelled**".

<u>Step 6</u> - Finishing the pump autocalibration

Back Pumps autocalibration finished	Complete
Remove autocalibration cuvette and disconnect it from waste bottle!	
	d s BlotAutomat ver. 4.38Bet3

If the system performed autocalibration of the selected pumps, the user removes the cuvette from the instrument and disconnects it from the waste bottle.

To end the autocalibration the user selects the "Complete" button.

The autocalibration record can be found in the Maintenance history.

2.4.4 Weekly maintenance

Weekly maintenance is performed to sanitize the instrument's tubing from the used reagents. It is performed by the user regularly 7 days from the previous successful weekly maintenance or monthly maintenance, which substitutes the weekly one.

After 7 calendar days have passed the user will be notified about the need to perform the weekly

maintenance, which the system signalizes by the icon in the lower bar.

Weekly maintenance consists of several steps:

<u>Step 1</u> - Tubing sanitation

Back	Т	ubing sanitation	Next	Cancel
		Insert tubes of reagents and system liquid to cleaning solution!		
*		🛓 👫 1 📲 dis Blot	Automat ve	er. 4.38Bet3

The user inserts the system solution and reagent pump tubing into a bottle with the cleaning solution. By pressing the "**Next**" button the system flushes tubes with a cleaning solution. The volume for the flush is set by *Pumps cleaning volume* in the menu *Application administration / Settings*.

A period of sanitizing of the tubes with the cleaning solution follows. During this period the remaining

time till completion is displayed	Sanitation will finish in: 0:18	and after it expires a sound
signal is activated and	the message appers	
Sanitation time comp	leted.	
	0 <u>K</u>	

The time is set in by Pumps sanitation time in the menu Application administration / Settings .

Step 2 - Cleaning with DI water

Back	Cleaning with dist. water	Next Cancel
	Insert tubes of reagents and system liquid to dist. water!	
* () 🔌 🖺 1 📲* ds	BlotAutomat ver. 4.38Bet3

The user inserts system the system solution and reagent pump tubing into a bottle with DI water. By pressing "**Next**" the system flush the tubes.

By pressing "Cancel" he may cancel the maintenance process.

Step 3 - Tubing voiding



The user takes out the reagent and system solution pump tubing from the bottle and continues to complete the weekly maintenance by pressing "**Complete**". The system empties the tubes so that there won't be any remaining liquid. By pressing "**Cancel**" the user may cancel the weekly maintenance process.

The performed weekly maintenance will be recorded in the maintenance list, including the overall result (see also "History", "Maintenance").

2.4.5 Monthly maintenance

Monthly maintenance is performed to thoroughly sanitize the instrument's tubing, during the maintenance the peristaltic pumps are being calibrated as well. The monthly maintenance is performed regularly by the user after a calendar month passes since the previous successful monthly maintenance or an extraordinary monthly maintenance.

After the calendar month has passed, the user will be notified about the need to perform the monthly

maintenance, which the system signalizes by the icon **i** in the status bar.

Monthly maintenance consists of several steps:

Step 1 - Tubing sanitation

Back	Tubing sanitation		Next Cancel
		Insert tubes of reagents and system liquid to cleaning solution!	
* () 🔌 🗓 1 🛋	d s	BlotAutomat ver. 4.38Bet3

The user inserts the system solution and reagent pump tubing into a bottle with the cleaning solution. By pressing the "**Next**" button the system flushes tubes with a cleaning solution. The volume for the flush is set by *Pumps cleaning volume* in the menu *Application administration / Settings*.

A period of sanitizing of the tubes with the cleaning solution follows. During this period the remaining



The time is set in by Pumps sanitation time in the menu Application administration / Settings .

Step 2 - Cleaning with DI water



The user inserts system the system solution and reagent pump tubing into a bottle with DI water. By pressing "**Next**" the system flush the tubes.

By pressing "Cancel" he may cancel the maintenance process.

Step 3 - Pumps selection

The system implicitly presets all pumps for autocalibration. This status can be changed by the user by cancelling the selection of the given pump. If the user removes all pumps, the monthly maintenance process will continue without performing autocalibration. When selecting at least one pump the maintenance will be performed and the autocalibration record will be entered into the maintenance overview, including the result and details of the autocalibration.



The system selects all pumps for calibration but user can change it by deselecting some of them.

Then he selects the pump with the mouse cursor and primes it with the button. By pressing the priming button he can repeat the priming. If he checks the water flow from the

dispensing arm he marks the pump as primed by pressing

If all pumps needed for the autocalibration are marked as primed, the user may continue by pressing "Next".

By pressing "**CanceI**" the user may cancel the monthly maintenance process. The record of the cancellation will be entered in the "Maintenance" overview. By pressing "**Back**" the user may display the previous 2nd step of the monthly maintenance with tube priming with DI water and can repeat the priming.

Step 4 - Autocalibration cuvette inserting



The user places the calibration cuvette on the upper case of the instrument according to the picture and connects the cuvette tube to the waste bottle with a self-closing clutch.

If the cuvette is connected the user may continue by pressing "Next".

<u>Step 5</u> - The process of autocalibration

The system performs the calibration of selected pumps in the given order and informs about the currently calibrated pump in the information window.



Back				Next
				·
	4			
		Autocalibration of pump no. 1 (1/2).		
🏶 👌 🔌 🛓 📫 📲			d s	BlotAutomat ver. 4.38Bet3

The process itself proceeds individually for each pump. The first required pump starts filling the cuvette until it's full and the tip signals that the level of primed liquid has been reached. The liquid is then pumped into the waste bottle.

Back Pump number Ever (m/min) Calibration status Ever 1 2 7 0 Next 1 2 7 0 1 2 7 0 1 2 7 0 1 1 2 7 1 1 2 7 1 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 1 2 1 2 1 2 1 2 1 2 1 2 2 2 2 <

Calibration results

If the autocalibration is error-free and the value of the given pump is found in the requested range the pump status is set to "**OK**".

If the calibration is not possible to do because some fault or bad pump condition, the status is set to "**Error**".

By pressing "**Next**" the user may continue with the monthly maintenance. By pressing "**Cancel**" the user may cancel the monthly maintenance process. The record of the cancellation will be entered in the "Maintenance" overview.



<u>Step 6</u> - Pumps autocalibration finishing

If the system performed autocalibration of the selected pumps, the user removes the cuvette from the instrument and disconnects it from the waste bottle.

By pressing "**Next**" the user may continue with the monthly maintenance. By pressing "**Cancel**" the user may cancel the monthly maintenance process. The record of the cancellation will be entered in the "Maintenance" overview.

<u>Step 7</u> - Tubing voiding


The user takes out the reagent and system solution pump tubing from the bottle and continues to complete the monthly maintenance by pressing "**Complete**". The system empties the tubes so that there won't be any remaining liquid. By pressing "**Cancel**" the user may cancel the monthly maintenance process.

The system enters the record of the monthly maintenance into the maintenance list, including the overall result (see "Maintenance").

2.4.6 Run self-test

The aim of the self-test is to set the default positions of movements and ensure functionality of individual functional parts of the instrument. The self-test is performed automatically after the instrument switch on or manually in menu *Instrument maintenance / Run self-test* or by button *Run self-test* in the error window which appears after instrument faults.

The self-test tests the following:

Cover sensor testing - sensor of the closed position of the working area lid

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Z Motor	 motor for vertical movement of the needle
Y Motor	- motor for forward and backward movement of the pipettor module
X Motor	 motor for left right movement of the working arm
 Aspiration arm 	- the aspiration arm top position sensor (arm movement is done by the
pipettor module)	
Syringe	 motor for the piston of plunger pump movement
 Incubation motor 	 motor for the tray holder rocking movement
 Cleaning bowl valve 	 test of the pinch valve for the needle cleaning bowl aspiration
 Aspiration arm valve 	 test of the pinch valve for the wells content aspiration
• BCR	- test of the bar code reader
Camera	- test of the camera system

A successful self-test is a prerequisite for the use of the instrument!

Cover sensor testing	Rocking motor
Z Motor	Vacuum
Y Motor	Needle washing station asp. valve
X Motor	Aspiration arm valve
Aspiration arm	BCR
Plunger pump	Camera
0x80002091 - X shift error	
	Close Self-test restart

- test successful

The self-test process is shown in the window

Meaning of the icons :



- error during the test. The error number and description are in red text in the window

error.

- The Cover sensor testing was skipped by the user .This status isn't considered an

During the camera test the arm moves above the testing label with *Camera test* text and the live feed window is displayed.



If the image of a strip is displayed, the user confirms the correct function by pressing OK. Otherwise he presses the *Error* button.

Only after a correctly performed self-test the user may start the protocol run and perform maintenance.

Cover sensor testing	Rocking motor
Z Motor	Vacuum 😯
Y Motor	Needle washing station asp. valve
X Motor	Aspiration arm valve
Aspiration arm	BCR
Plunger pump	Camera
	Close Self-test restart

The button *Close* finishes the self-test procedure. The self-test can be repeated by button *Self-test* restart.

Records of performed self tests is stored in history (Self-test)

Self-test indication - the icons in the lower bar inform the user about the self-test status







2.5 Application administration

The menu *Application administration* is ordinarily used for users login. The menu content is changed according to a role of the user and it can be used for the application settings too.

The menu contains the following items:

- Login nobody logged, user, service, administrator
- Password change user, service, administrator
- List of users service, administrator

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- Logout user, service, administrator
- Settings service, administrator
- BCR settings service, administrator
- Segments import service, administrator **! ATTENTION. Only authorized service technician** is allowed to perform the this operation.
- Old data deleting service, administrator
- About application nobody logged, user, service, administrator

2.5.1 Login

A common user may work with the application either after logging in or without logging in. Login is required, if the "Login required" option is checked in the application settings.

Application login - the user enters his user name and password. After pressing "**Login**" the system logs the user into the application.

User scł	midt	
Password		
	Login	Close

The name of the user logged into the application is displayed in the lower bar on the right.

When an incorrect user name or password is entered, the system notifies the user with an error message.

User shmid	User schmidt
Password	Password
User was not found.	Invalid password.
Login Close	Login Close

The name of the user, who is logged in, is transferred to the document of the protocol to the "Written by" field.

2.5.2 Password change

The logged in user may change his password. In the menu select "**Change password**"; the system displays a window, where the password may be changed.

Cancel

Original password	
New password	•••
Confirm password	•••
	OK Cancel
	OK Cancel

The user enters the original password, the new password and confirmation of the new password. By pressing "**OK**" the system registers the changed data for the given user.

If the user fills wrongly some of the fields, the system will alert him.

Original password	Original password
New password	New password
Confirm password	Confirm password
Passwords are not identical	Invalid original password.
OK Cancel	ОК

2.5.3 List of users

An Administrator or Service level user may open List of users.

Run	Run protocol Instrument maintenance History Edit Application administration							
	Close New user				Ť			
	Surname	Name	User name	_				
	😂 Polak	Karel	Polak	2	2			
	🗁 Urban	Josef	Urban	2	2			
	🖻 s	d	ds	2	2			
	😂 Schmidt	Johan	schmidt	2	2			
	🖻 Salavova	Jana	Salavova	2	2			
The The	The user information can be changed after pressing the icon at his line.							
	User Johan Schmidt New password Confirm password							
Pre	OK Cancel	n user line deletes his record.						

The button New user openes window for a new user data entering.

User name	baker
Title	
Name	Anna
Surname	Baker
Title	
Assigned r	oles Unassigned user profile
	Save

After a new user is created the following fields must be filled:

- User name the name which the user uses to login into the application
- Front title title of the user (e.g. BA) not required
- Name the first name of the registered user (eg. Anna)
- **Surname** surname of the registered user (eg. Baker)
- Rear title title after the name of the registered user (eg. CSc.) not required
- Role type of rights to use the application, which contains a certain range of the application's

and 🗹

functions. The role is selected by using of buttons

Roles description :

Administrator (admin)

Full access.

Service

Full access except the assays, tests and reagents registers changing.

User

No access to the application settings and the assays, tests and reagents registers changing.

2.5.4 Logout

The logged in user may log out of the application. After choosing "Log out" the system displays a query, whether the user is sure he wants to log out. If the user presses "Yes", the system logs out the user from the application and updates the lower bar. If the user selects "No", the system ends the process of logging out.

User query



2.5.5 Settings

An user with Administrator and Service role may change the application settings.

Language	English
Use BCR	\checkmark
Use camera	\checkmark
Default standard tube	Barnsted 5 ml
Default control tube	Control
Laboratory name	
Login required	
Minimal space on HDD (MB)	500
Dead volume (ml)	4
Pumps cleaning volume (x 0.1 ml)	50
Tubes sanitation time	15 🗧 m 🛛 🗧 s
Protocol name	%D%_%N%
	OK Close

Language - the user may change the language version of the application

Use BCR - by selecting this setting the user will enable the use of a bar code reader during protocol processing. If not selected, the protocol will use manual entry of samples, loading samples from a file or import of samples from the external system.

Use camera - by selecting this setting the user will enable the use of a camera during protocol processing

Default standard tube type - the user selects the default standard tube type from the list of standard tube types entered in the application. This selected type will be preset in a new worklist for positions 1-44 in the tube rack.

Default control tube type - the user selects the default control tube type from the list of control tube types entered in the application. This selected type will be preset in a new worklist for positions A, B, C and D in the tube rack.

Laboratory name - name of the lab that uses the instrument. The name is transferred to the instrument protocol template.

Login required - select whether login is required for users to use the application

Minimal space on HDD - the amount of disc space, which is necessary for the application's operation

(data saving)

Dead volume (ml) - volume added to calculated reagent needed volume which is displayed during the reagents priming. Default value is 4 ml.

Pumps cleaning volume (x 0,1 ml) - the volume of the solution for pump priming during the weekly and monthly maintenance

Tube sanitation time - time for the sanitation of tubes and pumps with a cleaning solution during the weekly and monthly maintenance

Protocol name - preset protocol name, displayed in the protocol template (%D%_%N% means automatic creation of the protocol name with the actual date and protocol order number in this day).

2.5.6 BCR settings

An user with Administrator and Service role may change the barcode reader settings in the case when Use BCR is checked.

Next type of bar code can be enabled by checking its box:

- Code 39
- Interleaved 2 of 5
- Code 128
- Industrial 2 of 5
- UPC/EAN
- Codabar

User can select only code types used in laboratory. It brings the highest reliability of the code reading.



2.5.7 Old data deleting

An Administrator or Service level user may remove unnecessary data from the application, which would otherwise use the computer's memory. Removal of the data is an irreversible process. The records with date in field *Select the final date for data deleting* and older are deleted. The system presets the date for data removal 1 month back (e.g. on 1. 11. 2012 the date for data removal will be set to 1. 10. 2012)

The records can be deleted selectively accordint to their type by buttons :

•	Self-tests	- self-test history
•	Maintenance	- maintenance history
•	Communication	- communication with external system history
•	Application log	-special service files saved out of the application, they are accessible directly
	on PC	

Archiving - protocol archiving history

All - all types of records

Run	un protocol Instrument maintenance History Edit Application administration							
	Close							
	Old data deleting							
	Select the final date for data deleting 9/19/2016							
	Delete: Self-tests Maintenance							
	Communication Application Log							
	Archiving							
\$	d s BlotAutomat ver. 4.38Bet3							

The calendar window can be opened for date selection :

Select the final date for data deleting	11/:	12/20	12	•					
				12 De	cembe	r 2012			
Delete	Delete			November 2012					٠
	_	Su	Мо	Tu	We	Th	Fr	Sa	_
			29			1	2	3	
		4	5	6	7	8	9	10	
		11	12	13	14	15	16	17	
		18	19	20	21	22	23	24	
		25	26	27	28	29	30	1	
		2		4		6	7	8	
					Clear				

Old data deleting

The selected data will be removed after confirmation :



2.5.8 About application

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The user may find more information about the application in the following areas:

Application name - Dynablot Automatic Supplier - DYNEX TECHNOLOGIES Version - e.g. 1.0.0.0 Segment version - the segment version is determined by the numbering of segments imported into the application Application author - ASD Software, s.r.o. with a link to the website Name of laboratory - name of the lab, which uses this application Help - link to the application help

III About application 🛛 🕹 🗙					
Dynablot	t Automatic				
DYNEX TE	CHNOLOGIES				
Version of application:	1.2.0.0				
Version of segments:	1.2.0.0				
Application author:	ASD Software, s.r.o.				
Name of laboratory: <u>Help</u>	http://www.asd-software.cz				



3 How to ...

The below listed common work processes will make it easier for you to orientate in the application, if you need to use the instrument for one of the routine activities. Select the specific procedure from the routine activities list and proceed according to the instructions.

Routine activities of the instrument:

- Starting the application
- · Changing the default settings
- Principle of the protocol run
- Creation of assays and test
- · Preparation of the instrument for testing
- Sample testing
- Shooting of the imported protocol
- Monitoring the instrument's status
- Maintenance
- Ending the instrument's operation
- · Description of the communication with the external system

3.1 Starting the application

• Run the application by pressing



, which is located on your desktop or in the Start menu.



- The system displays the application starting icon
- The system displays the introductory screen of the Dynablot Automatic application.



- Switch on the Dynablot Automatic instrument.
- The system checks the instrument's activity; if the instrument is active, the application will display the firmware version of the instrument control board (BlotAutomat ver. 4.38). on the right of the lower bar.
- The system automatically runs a self-test. The self-test checks the instrument's readiness for use and checks the functionality of individual parts.

Now the application and the instrument (if the self-test was successful) are ready for work .

3.2 Changing the default settings

During the installation of the application the system sets up default settings for some variable application functions. The user can change the default settings according to the following procedure:

• Log in to the application as and Administrator (admin) or Service in the menu Application administration\Login.

- In the application menu click on Application administration \Settings to change the default settings.
- Change the required options.

• Confirm changes by pressing "OK".

3.3 Principle of the protocol run

During the planning of the instrument run tests are assigned to the individual samples, which set in what way the sample has to be processed. The test is usually created for each parameter, which will be examined. An assay is assigned to each test and camera shutter time for shooting the strip images. Assays describe the process during which the instrument carries out the sample testing according to some procedure given by the used method. The shutter time enables to get images of the strip in adequate quality for processing in the evaluating SW.

Assays are a part of an assay group. If various tests have assays assigned to them, which are from the same group, they can be used in the protocol run together at once. Assays from one group have the same structure of activities; however they can differ in the type and volume of reagents in the dispensing activity (used particularly for testing of a parameter in various classes - IgG, IgM...) and the volume of transferred sample and pipetting.

When creating an assay a reagent is selected for the dispensing action. The list of reagents with necessary parameters can be created in the reagents database, which can be created and updated before the creation of an assay or during its editing.

When planning a protocol run it is possible to choose a tube type in the worklist, from which the sample is loaded during pipetting. Tube types are saved in the tube types database and differ in the values of inner radius and coordinates of the edge and bottom. Setting the tube type is important for correct level detection.

3.4 Creation of assays and tests

Prior to the running of the protocols the application must contain registered assays with reagents and tests. Only an Administrator can create assays, reagents and tests according to the following procedure:

- Log in as an Administrator (admin)in the menu Application administration\Login.
- Register all reagents used by the instrument (e.g. H₂0, Buffer, conjugate IgA, conjugate IgG) in the reagent list in *Edit**Reagents*
- In the item Edit/Assay groups create the needed assay groups with their assays.
- Register all tests, which you will use to process the samples (see Edit\Tests).

3.5 Before the protocol run

Prior the worklist preparation and the protocol run the application must contain :

- tests with assignes assays, which specify the sample processes (See *Edit / Assay group list*, *Edit / Test registr*).
- the tube types which will be inserted to the tube rack (See Edit\Tube types).

 selection of the *Default standard tube* and *Standard control tube* in menu *Application administration Settings*, primarilly before the protocol import from the external system. Otherwise the imported protocol is rejected by the system.

The successfully performed self-test is a precondition for the protocol run. If the self-test is not

performed self-test or to switch the instrument OFF and ON.

Before a worklist creation or the imported protocol run the system liquid should be primed by menu

*Maintenance**System solution.* The system solution readiness is indicated by the icon in the lower bar. But the run preparation is not conditioned by it. If the system solution is not primed its priming is part of procedure before the protocol run (*Run protocol / New protocol ,* Step 3).

3.6 **Protocol run**

For the preparation of the protocol start the conditions described in the capture **Before protocol run** must be met.

The protocol can be prepared in the application via the worklist in the menu *Run protocol / New* or by selection of the protocol from protocol list imported from the external system - menu *Run protocol* \ *Imported*

After the preparation (reagents, tray, waste bottle) the run is started by the user and it will continue automatically.

After the protocol run finish the record is done in the list of menu *History / Protocols*. The record contains the status *Processed* or *Not processed - Error.*

If the strips images are transferred to the external system there is possibility of deletion the protocol record by the external system command.

3.7 Shooting according to the imported protocol

The protocols received from the external system can be also proceeded by the strips images shooting only. This function could be used in case of any fault during the results evaluation caused by bad image quality (strip position in the well, a water drop on the strip surface, ...).

- Send the protocol from the external system again
- Select it from the list of imported protocols (Run protocol / Imported)
- Presse the button *Shoot according to protocol* in the appropriate line and continues in Imported protocol-images procedure.

3.8 Monitoring of the current status of the instrument

The lower bar contains a set of icons, which show the instrument and application status. The right side of the bar contains an indicator of the connected instrument and its firmware version. The left side contains icons of the instrument maintenance and some parts operating status.

Maintenance notice

If the time from last maintenance expires the icon appears. When the cursor is placed on this icon tooltip with maintenance type -Weekly or Monthly- appears. The icon double clicking starts

appropriate type of the maintenance. The maintenance requirement does not block the instrument using. The maintenance history can be checked in menu *History / Maintenance history*.

The instrument readiness

The icon of the instrument readiness to run could have two colors. The red 🔅 means the instrument

is not ready. After the successful self-test color is change to blue . , it means that the protocol run is enabled.

The self-test is started :

- · automatically after the instrument switch on
- manually by menu Instrument maintenance\Run self-test
- by button *Run self-test* in error window

	Error
	Unexpected instrument error. #1005 - Aspiration arm error
	Operations can continue after successful Self-test Run Self-test Continue Cancel
• ^	1 1 1

Waste bottle level

The liquid level in the waste bottle is watched by the sensors and it is displayed by the icon color.

low level. The instrument operation is not limited.

warning. The liquid is at the level when the waste bottle should be emptied. The instrument operation is not limited.

alarm. The liquid level is at a critical level. If the instrument starts with an operation which requires the aspiration to the waste bottle the operation is interrupted by the error message.

System liquid readiness

The instrument records the status whether the system liquid was primed. It is displayed by the icon color.



system liquid is not primed

system liquid is primed

System liquid level

This icon is displayed only during the system liquid is primed. The liquid level in the bottle is watched by the sensors and it is displayed by the icon color.



high level. The instrument operation is not limited.

warning. The liquid is at the level when the bottle should be refilled. The instrument operation is not limited.

alarm. The liquid level is at a critical level. If the instrument starts with an operation which requirs the system liquid (pipetting) the operation is interrupted by the error message.

Imported protocol

Protocols sent from the external system, which await processing by the instrument, are indicated by

the **under** icon. The number shows the number of protocols in the queue.

Sound signal

Sound signal is activated when the instrument needs the user treatment. It is displayed by its icon intensity.



signal is active. By clicking on the iconit is possible to mute it.

3.9 Maintenance of the instrument

The operations of the instrument maintenance are controlled from the menu Instrument maintenance.

The items from this menu could be used for example with next reasons :

• System liquid

If the samples pipetting is used in a protocol the system liquid must be primed before the running. This operation is a part of the protocol run preparation procedure. But it is possible to prime the system liquid a bit earlier by this menu. The function for the liguid emptying is used after the instrument working or it can be used for the system cleaning.

• Pumps priming

The tubes and pumps cleaning is part of the protocol run. This menu can be used for an extra cleaning or a tube voiding.

• Pumps autocalibration

The pumps autocalibration is part of the monthly maintenance. This menu can be used for extra calibration all or some pumps for example after the pump casette replacement or if the user suspects that the dispensing precision of some pumps is bad.

• Weekly maintenance

The user runs the weekly maintenance process after notice by the icon need, for example if the user suspects that the tubing is contaminated.

or extra according to a

• Monthly maintenance

The user runs the weekly maintenance process after notice by the icon or extra according to a need, for example if the user suspects that the tubing is contaminated or the reagent dispensing has bad precision

• Run self-test

The self-test is started automatically after the instrument switch on or manually by the user after the instrument error messages. This menu can be used rot an extra self-test run before the protocol preparation if the user suspects that some part doe not work well.

3.10 Ending the instrument's operation

If the instrument run is finished next operation are suitable to do :

Cleaning the reagent tubes by distilled water (if it is not already done during finishing of last protocol)

- · Insert the reagents tubes to bottle with DI water
- Perform Pumps priming

The reagent tubing voiding

- · dry the reagent tubes and let them free on the pad
- Perform Pumps priming with volume 10 ml

The system tubing voiding

- · remove the lid from the system liquid bottle
- void the system from menu Instrument maintenance / System liquid

Emptying and cleaning the waste bottle.

Switching off the instrument

- Close the application by pressing the cross in the upper right corner of the application 🗵.
- Turn the instrument off with a switch on its back side

3.11 Description of the communication with the external system

The application can communicate with the external system. The main reason of the import of readied protocols, which the external system user processes. The processed protocol can be transferred back to the external system by the external system or it can be removed. The user cannot influence the communication in any way; however he can monitor the communication records in the overview History/Communication with the external system.

The communication process:

- the communication is performed by means of queries and answers, the external system sends queries and the application replies.

Service 1. - Device status report

<u>Query</u> - external system sends query into the application about the instrument status <u>Reply</u> - application transfers the reply about the instrument status, which can be positive (instrument si ready) or negative (instrument isn't ready) - if it's positive, the system can continue with the communication

Service 2. - Protocol receiving

<u>Query</u> - external system sends a protocol into the application to be processed, the application system performs a check of the protocol for uniqueness of ID samples, known tests and number of tests (maximum of 44)

<u>Reply</u> - system answer whether it could or couldn't receive the protocol. If it did receive the protocol, it is displayed in the protocol list and the status bar shows the number of imported protocols awaiting



which is one more than before.

Service 3. - Protocol status report

processing

<u>Query</u> - external system queries the status of the specific protocol <u>Reply</u> - the protocol can be processed, awaiting processing or unprocessed with an error (the run has ended unsuccessfully)

If the protocol is processed (status "Processed"/"Unprocessed - error"), the external system can carry on with the communication.

Service 4. - Strip image transmitting

<u>Query</u> - external system requires results of protocol processing (protocol ID and the order number of the strip), which is processed in the application (status "Processed"/"Unprocessed - error") <u>Reply</u> - the system of the application transfers the protocol strip image into the external system

Service 5. - Protocol deletion

<u>Query</u> - the external system requests the deletion of the protocol from the application, if the protocol can be found in the application, the system deletes it

<u>Reply</u> - the application system sends a message about the deletion of the protocol or that the deletion cannot be performed (e.g. the protocol wasn't found)



4 Error messages

The application displays error messages and after the error is successfully removed, it enables to continue in the activity, during which the error occurred.

Error display

Error list

4.1 Error display

Errors are displayed in several ways according to the current activity of the instrument. The error type is identified by a number and description of the current activity.

Error display during a self-test

Cover sensor testing	Rocking motor
Z Motor	Vacuum
Y Motor	Needle washing station asp. valve
X Motor	Aspiration arm valve
Aspiration arm	BCR
Plunger pump	Camera
#1005 - Aspiration arm error	
	Close Self-test restart

The number and error description are displayed by red text in the lower left corner. After the error is removed it is possible to repeat the self-test by pressing *Self-test restart*

In a dialogue window of one of the instrument's activities

•	Sample ID scanning error #1012 - Rear control code not found. Repeat scanning?
	Yes No

The relevant dialogue window then offers options how to continue with the instrument operation after the error is removed

Error display in its own window

A Error
🔺 Error 🔹
Unexpected instrument error. 0x80002091 - X shift error
Operations can continue after successful Self-test
Run Self-test Continue Cancel

The windows contains the error number and description.

The icon **t** can be used to mute the sound signal.

It is possible to continue with the instrument's operation, if the button *Continue* is active. In the other case the activation of the *Continue* button is dependent on the successful self-test - after pressing the *Run self-test* button.

In case it isn't possible to continue in the activity, during which the error occurred or the user doesn't require it, it is possible to return to the starting screen by pressing *Cancel*. In this case the self-test

has a not ready status

4.2 Error list

Nu mb er.	Name	Description	Corrective action
100 1	Z doesn't leave home	The referential sensor of z movement is unexpectedly constantly switch on	Probable movement hindrance, remove obstacle - run self-test. Referential position sensor or motor error - service required
100 2	Aspiration arm is not at sensor	The aspiration arm sensor isn't switch on as it should be according to the upper position of the arm	Aspiration arm probably stuck in the reclined position, remove obstacle - run self-test. Upper position sensor error

			- service required
100	Y doesn't leave	The referential sensor of v	Probable movement
3	home	movement is unexpectedly	hindrance, remove obstacle
Ũ	nomo	constantly switch on	- run self-test
			Referential position sensor
			or motor error - service
			required
100	X doesn't leave home	The referential sensor of x	Probable movement
4		movement is unexpectedly	hindrance, remove obstacle
		constantly switch on	- run self-test.
			Referential position sensor
			or motor error - service
			required.
100	Aspiration arm error	The aspiration arm sensor	Probable hindrance of aspiration
5		is unexpectedly constantly	arm movement or the Y-
		switch on	movement, remove obstacle - run
			self-test
100	Syringe doesn't leave	The referential position	Probable syringe or the system
6	home	sensor of the syringe is	solution hydraulic circuits, run
		unexpectedly constantly	self-test.
		switch on	If the self-test is unsuccessful -
			service required
100	Rocking doesn't	The referential position	Probable movement
7	leave home	rocking sensor is	hindrance, remove obstacle
		unexpectedly constantly	- run self-test.
		switch on	Referential position sensor
			or motor error - service
			required.
100	Vacuum switch error	Vacuum switch in the waste bottle	Impassible aspiration tubing,
8		unexpectedly switch on during	remove obstacles - run self-test.
		self-test	vacuum sensor - service required
100	Vacuum low	Insufficient vacuum in the waste	Check the waste bottle seal after
9		bottle	previous emptying of the bottle -
			continue with the activity or run
			self-test
			Waste tubes wrongly inserted in
			pinch valves in the rear of the
			instrument. Insert the tubes
			properly into the valve slots -
			continue with the activity or run
			vacuum pump, regulator or
			vacuum sensor enor - service
101	Cleaning hows	The pressure in the waste bottle	Impassible aspiration tubing
0	asniration value error	didn't decrease when opening the	remove obstacles - run self-test
0		ninch-value of the assiration of the	Pinch valve error - service
		cleaning needle cuvette	necessary
101	Strip aspiration value	The pressure in the waste bottle	Impassible aspiration tubing
1	error	didn't decrease when opening the	remove obstacles - run self-test
	0.101	pinch-valve of the aspiration of	Pinch valve error - service
		wells	necessarv

101 2	Rear control code not found	The control code placed before the back tube row wasn't read prior to the reading of the sample tubes' bar codes	The tube rack isn't inserted in the instrument or is inserted backwards - insert the rack correctly and repeat reading Mirror dirty - clean the mirror and repeat reading Bar code reader or mirror turning mechanism fault - service required
101 3	Front control code not found	The control code placed before the front tube row wasn't read during the reading of the sample tubes' bar codes	Bar code reader or mirror turning mechanism fault - service required
101 4	BCR error - self-test no read	The control code placed in the instrument wasn't read during the self-test	Mirror dirty - clean the mirror and repeat reading Bar code reader or mirror turning mechanism fault - service required
101 5	BCR error - self-test incorrect read	The control code placed in the instrument wast read incorrectly during the self-test	Mirror dirty - clean the mirror and repeat reading Bar code reader or mirror turning mechanism fault - service required
101 6	Pump failure during autocalibration	No level detected during the autocalibration of the peristaltic pump even after reaching the maximum number of repeats	Poor state of the pump cartridge - change the cartridge and after its run-in repeat calibration. Pump motor or needle level detection error (the cuvette would overflow at the same time) - service required
101 7	Autocalibration - level not found	After finishing dispensation the needle didn't detect level in the neck of the calibration cuvette.	Level detection error - service required
101 8	Pump flow below range	The pump cartridge parameter is below the allowed flow range - 65 ml/min	Poor state of the pump cartridge - change the cartridge and after its run-in repeat calibration.
101 9	Pump flow above range	The pump cartridge parameter is above the allowed flow range - 95 ml/min	Poor state of the pump cartridge - change the cartridge and after its run-in repeat calibration.
102 0	Sample not found	No sample level detected in the primary tube during pipetting.	Low sample volume - perform manual pipetting. Incorrectly set tube type - perform manual pipetting, use the correctly set tube type in the next run Level detection error - service required.
102 1	Insufficient volume in needle for dispensing	The needle contains insufficient volume for dispensing sample into wells.	Protocol processing error - report the error to the manufacturer.
102 2	System solution cleaning bowl priming error	During the preparation of the system solution the solution hasn't been primed into the	Cap with aspiration tube isn't inserted into the system solution bottle - insert the cap into the

102	Suringe 3-way value	cleaning bowl	bottle and repeat preparation Poor state of the pump cartridge - change the cartridge and after its run-in repeat calibration. Peristaltic pump motor error or needle level detection error - service required
3	error	system solution the 3-way valve wasn't switched and the system solution flows into the cleaning bowl through the syringe.	5-way valve entit - service required
102 4	System solution needle priming error	During the preparation of the system solution the syringe circuits and needle haven't been primed with the solution	Hydraulic circuits error - service required
102 5	Case not closed	The case closed sensor not pressed during the shooting of strip images	Case open - close the case and continue with the activity Case sensor error - service required.
102 6	System solution bottle level low	The level in the system solution bottle is below the minimum allowed level.	Insufficient sample volume in bottle - add sample and continue with the activity The system solution bottle isn't in its holder or the holder's cable isn't connected to the connector at the back of the instrument - insert bottle or connect the connector and continue with the activity Level detection in the system solution bottle error - service required
102 7	Waste bottle level high	The level in the waste bottle is above the maximum allowed level.	High volume of solution in the bottle - empty the bottle and continue with the activity Waste bottle cable isn't connected to the connector at the back of the instrument - connect the connector and continue with the activity Float or bottle level sensor error - service required
102 8	Cleaning bowl filling error	The needle cleaning bowl filling was not detected during the extra needle cleaning.	Check the system solution (correct concentration of the Setup clean) and try to Continue. Problem can be in bad closing of the cleaning bowl aspitarion pinch valve too. Needle level detection function can be faulty too.
102 9	Clot detection	Clot detection during sample taking from primary tube. The sample was not dispensed to tray.	Pipette the sample manually.

0x8 000 209 1	X shift error	Steps of the X motor have been lost during the run, resulting in the wrong position of the arm (movement left or right)	Probable movement hindrance, remove obstacle - run self-test. Incremental sensor or motor error - service required
0x8 000 209 2	Y shift error	Steps of the Y motor have been lost during the run, resulting in the wrong position of the arm (movement back and forward)	Probable movement hindrance, remove obstacle - run self-test. Referential position sensor or motor error - service required.
0x8 000 209 3	Z shift error	Steps of the X motor have been lost during the run, resulting in the wrong vertical position of the needle (movement up or down)	Probable movement hindrance, remove obstacle - run self-test. Referential position sensor or motor error - service required.
0x8 000 209 4	Syringe error	Steps of the syringe motor have been lost during the run, resulting in the wrong position of the valve and unreliable sample transfer	Probable syringe or system solution hydraulic circuits error - run self-test Referential position sensor or motor error - service required.
0x8 000 209 5	Rocking error	Steps of the rocking motor have been lost during the run, resulting in the wrong position of the tray holders when stopped	Probable movement hindrance, remove obstacle - run self-test. Referential position sensor or motor error - service required.
0x8 000 219 1	Home X timeout	The request for movement to the referential X position timed out, sensor not pressed	Probable movement hindrance, remove obstacle - run self-test. Referential position sensor or motor error - service required.
0x8 000 219 2	Home Y timeout	The request for movement to the referential Y position timed out, sensor not pressed.	Probable movement hindrance, remove obstacle - run self-test. Referential position sensor or motor error - service required.
0x8 000 219 3	Home Z timeout	The request for movement to the referential Z position timed out, sensor not pressed	Probable movement hindrance, remove obstacle - run self-test. Referential position sensor or motor error - service required.
0x8 000 219 4	Home syringe timeout	The request for movement to the referential syringe position timed out, sensor not pressed.	Probable movement hindrance, remove obstacle - run self-test. Referential position sensor

			or motor error - service
0x8 000 219 5	Home rocking timeout	The request for movement to the referential rocking position timed out, sensor not pressed.	Probable movement hindrance, remove obstacle - run self-test. Referential position sensor or motor error - service required.
100 000	Status timeout error		
100 008	Status timeout error		
100 016	Blok_Uk sequence error		
100 032	Blok_Uk recurrence		
100 064	Not treated data overwrite		
100 128	Command error		
131 073	USB status time		
131 074	Device not found		
131	Constants motor/		
075	valve error	Communication and system	Call the service
076	recognised	commands errors	
131	Command code		
131	Bad command code		
078	parameter		
131	Constants serialize		
079	error		
131	Dictionary argument		
080	error		
131	USB get data page		
081	timeout		
131	Property datatype		
082	not accept		
131	Errors buffer overflow		
121	LISP act data failed		
098	USD yel uala ialleu		