

# User manual DYNABLOT Automatic

DYNEX





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**Part**



# 1 Introduction



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

## 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 aspirated 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.

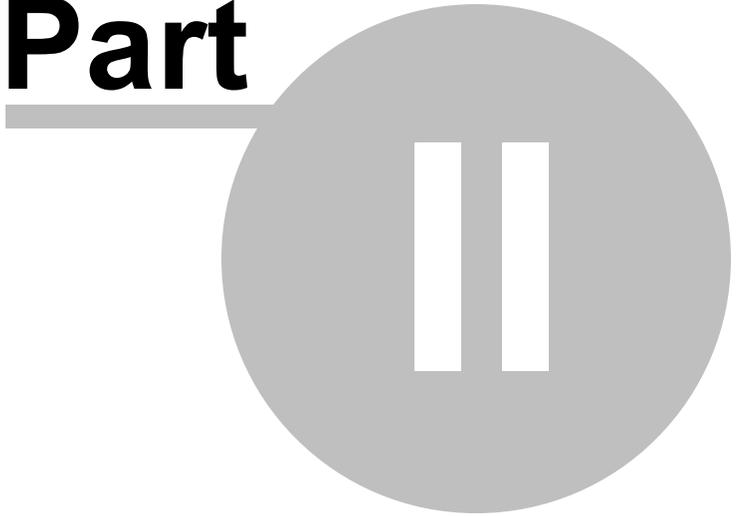
**Test**

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. ,

**Part**



## 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:

#### Step 1 - 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:

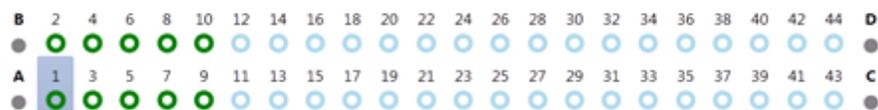
The samples can be entered in two ways:

#### **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:

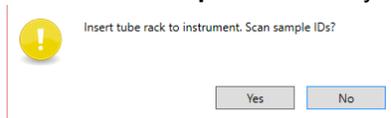
1. By clicking on the field **Last tube position for BCR scanning** he will overwrite the required value
2. By selecting the last sample position to be scanned in the sample map



and pressing the

arrow  will 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:

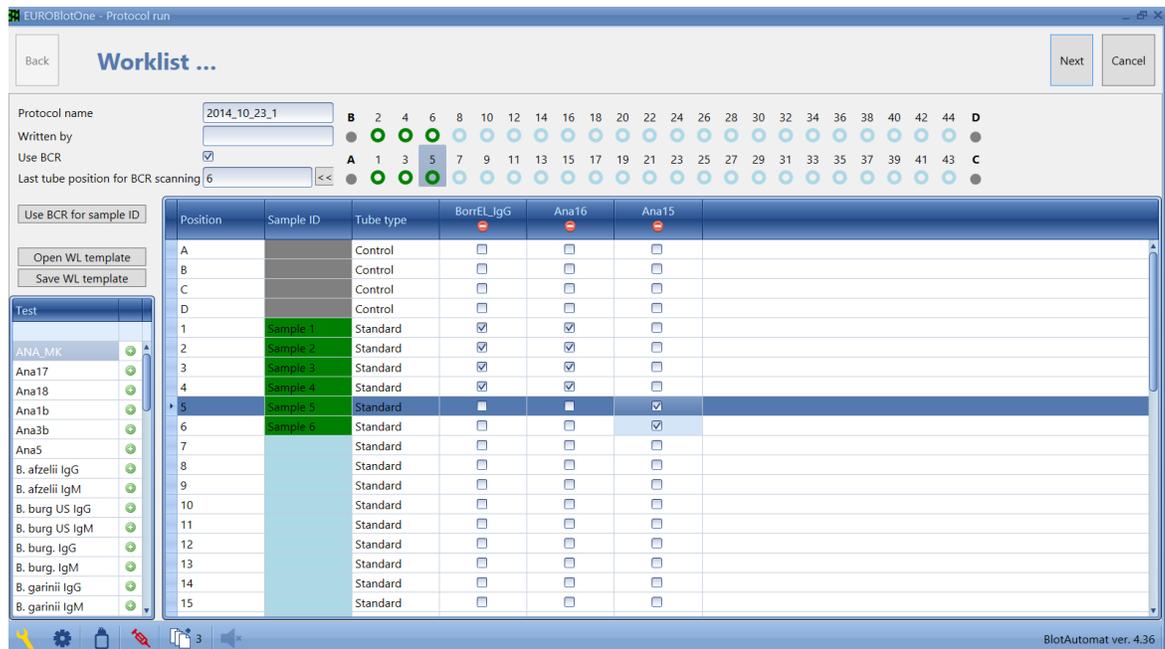
The tubes are then inserted into the rack. The user enters the sample codes into the field **"Sample ID"** in the worklist according to the actual order of the samples in the rack. Then he inserts the rack into the instrument. **The order and sample ID in the tube rack must correspond with the entry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

#### **Assigning tube types to samples :**

The system presets a default tube type for each sample (for positions 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.



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 .

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 is 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.

## Step 2 - 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 "**Written by**" can be changed.



Strip order	Sample ID	Test	Lot
1	Sample 1	B. afzelii IgG	
2	Sample 2	B. afzelii IgG	
3	Sample 3	B. afzelii IgG	
4	Sample 4	B. afzelii IgG	
5	Sample 5	B. afzelii IgG	

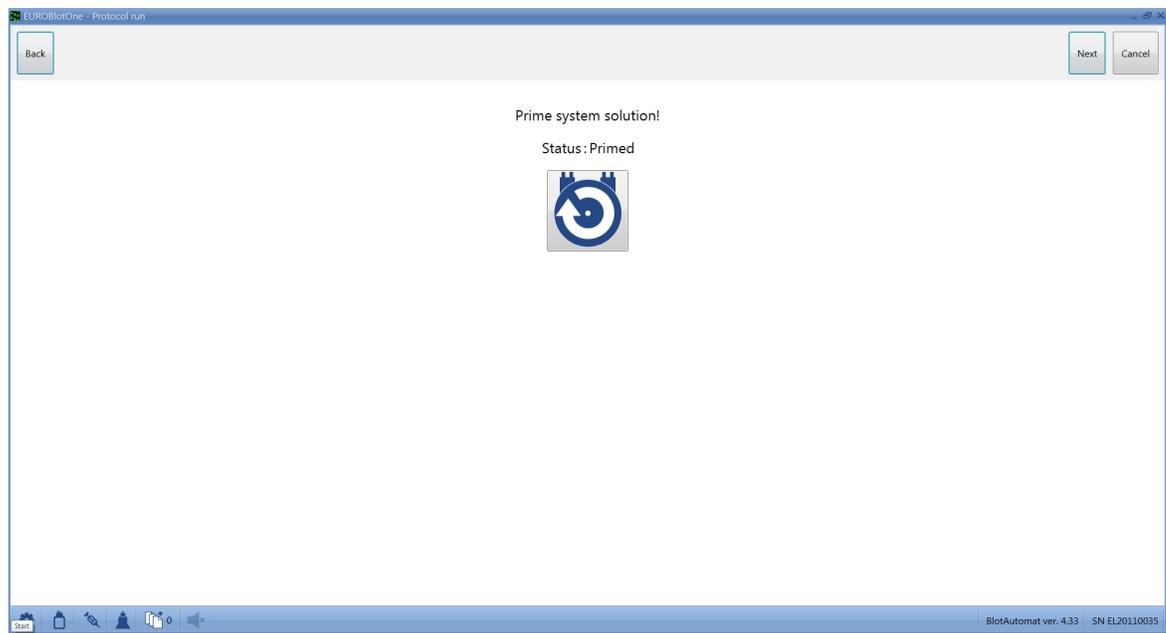
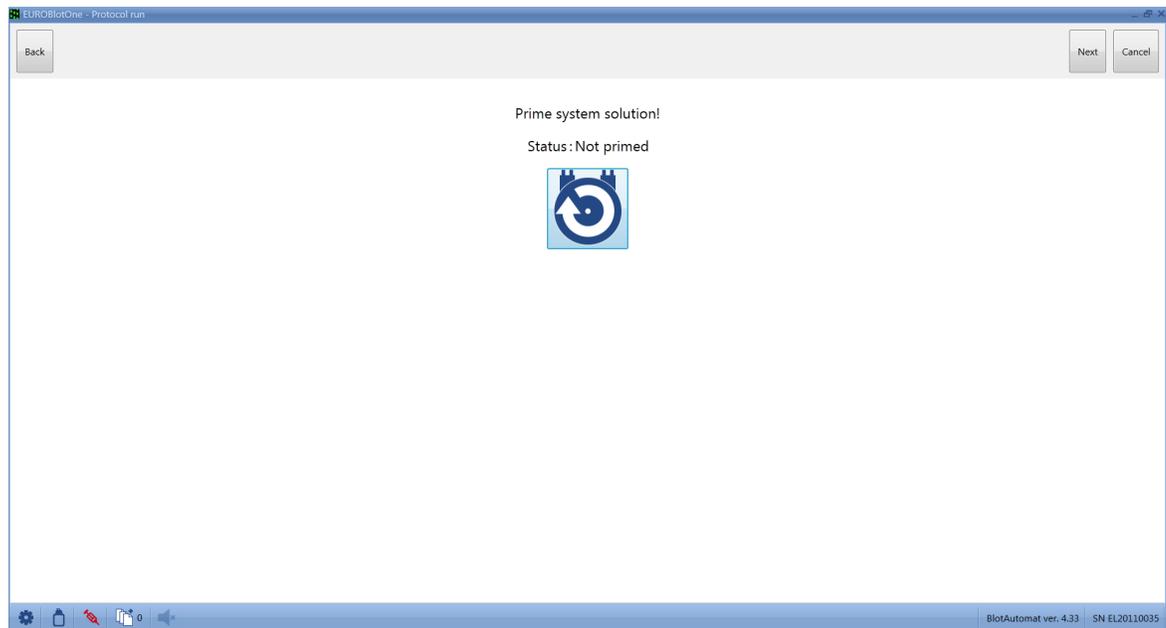
**Sample test lot** - by clicking into the field "**Lot**" the user may assign a lot number to the test or he may let the entry of the lot to the instrument run itself. (see step 7 - Instrument run).

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.

### Step 3 - Preparation of the system solution

If there is no system solution prepared in the instrument (Its status is "Not ready" - icon  in the lower 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

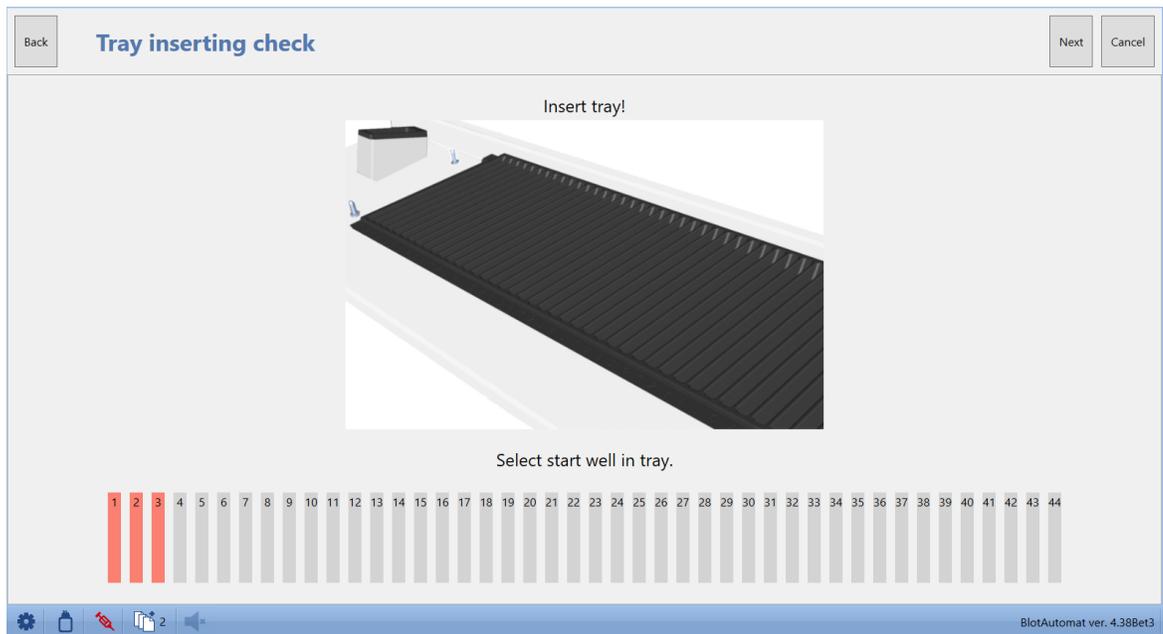
"**Primed**" and the system solution icon will change to .



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.

#### **Step 4** - Inserting the tray and selecting the starting well

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



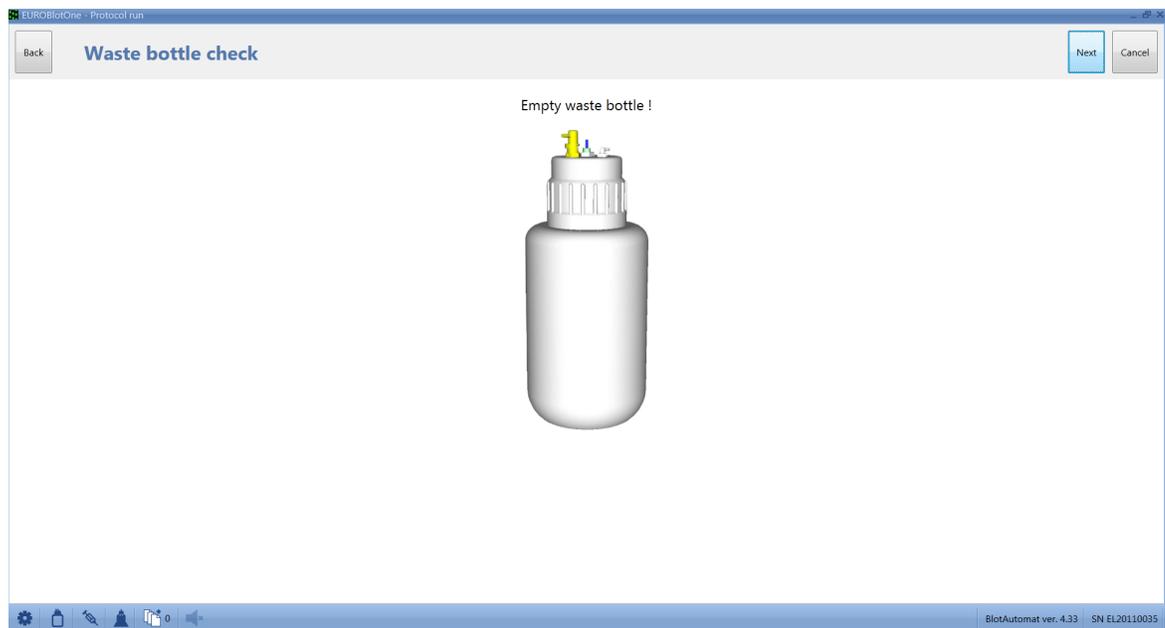
By clicking into the strip field he can to select the starting position, from which the sample testing will begin (in case that a previously partially used tray is inserted). The user may select only such starting position, which is followed by a sufficient number of empty wells for all sample tests.

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 signaled 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 overfilled 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.

### **Step 6 - Assigning and priming of reagents**

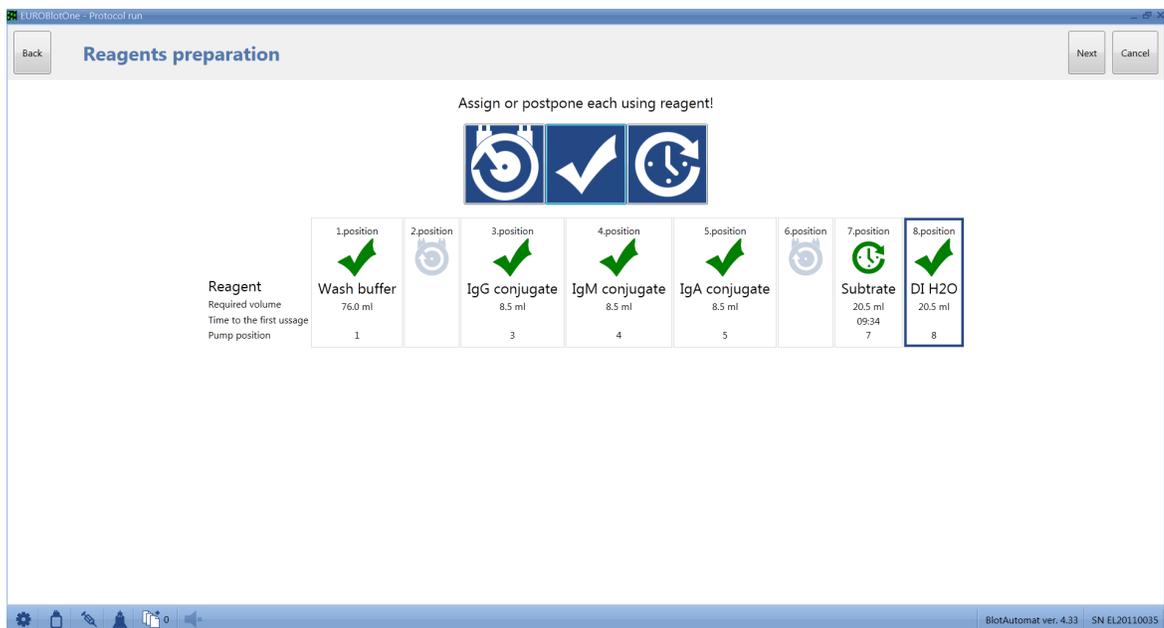
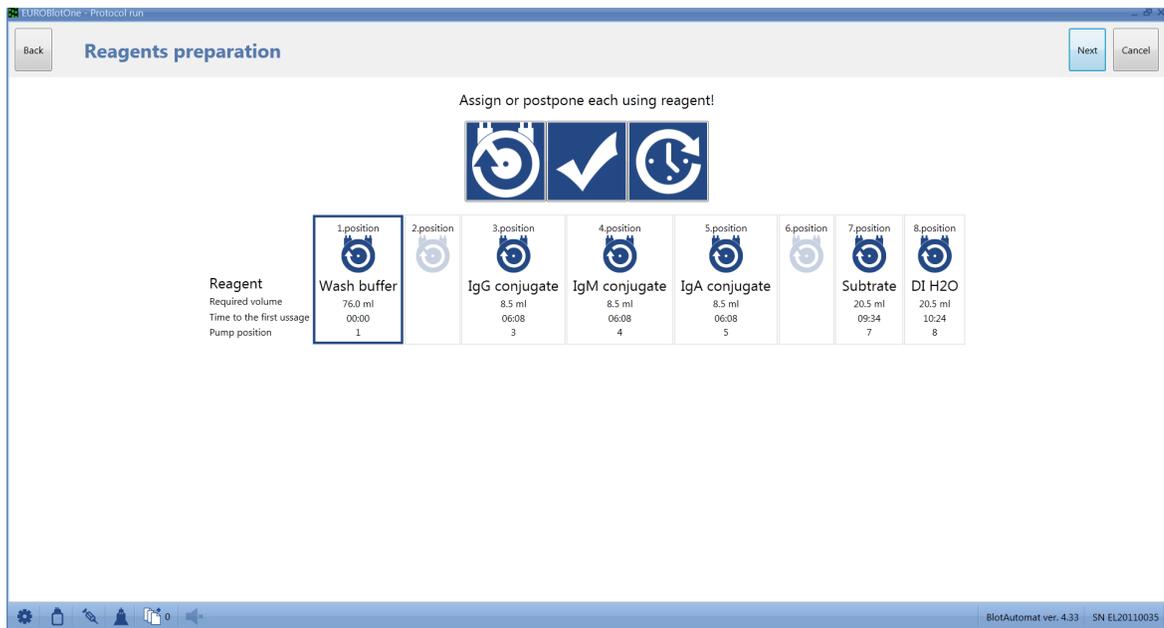
If the test assays require the use of reagents, the user has to assign individual reagents to specific pumps and load them into the instrument's tubing. At the beginning the system assigns reagents to individual pumps according to the preferentially recommended pairing. (see editing\Reagents).

**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.

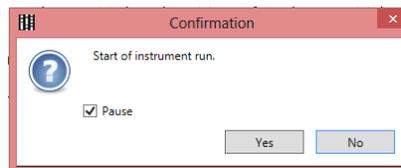
**Priming of reagents** - then the user presses  and the system loads the reagent into the

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

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



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.



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 reagent preparation screen will remain active and the user may change the loading of reagents including the pump positions.

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..

### Step 7 - Instrument run

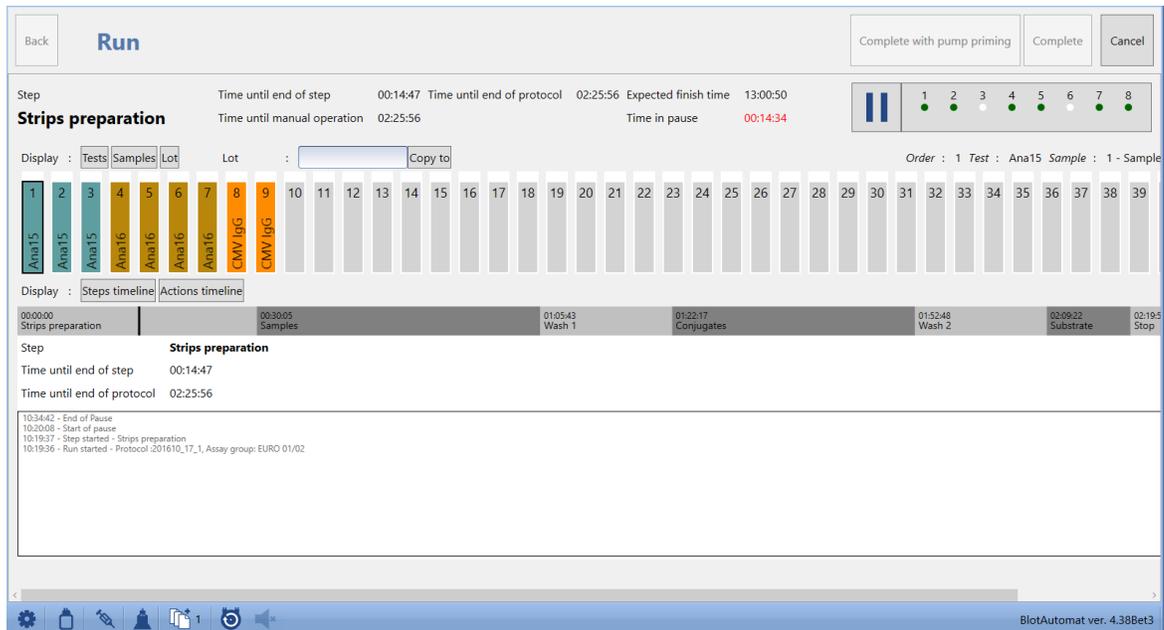
After the run is started the system will display a timeline with basic data on the progress of sample tests:

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 necessary 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.



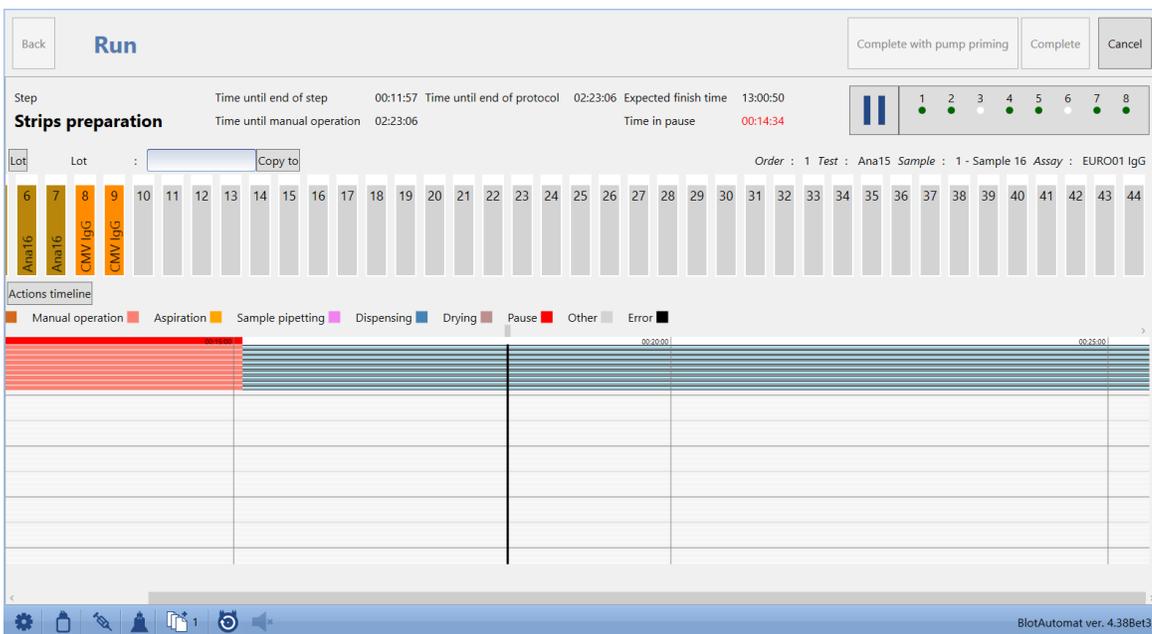
The log of a protocol run is recorded and on-line view is displayed bellow the time line. Log contains the protocol name and time marked records of steps, pauses and errors.

```

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
12:01:42 - Pause start
12:01:42 - Error -
#1028 - Cleaning bowl filling error

```

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



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

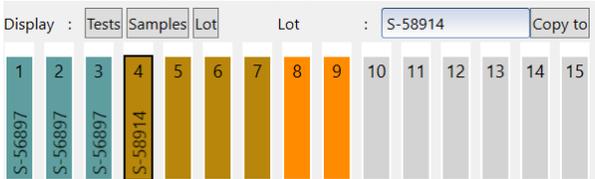


After moving the mouse over the field of the tested sample the timeline shows the following information:

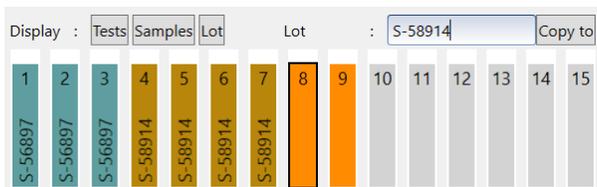
- sample position in the tray
- sample ID
- test
- assay
- assay step

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 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).



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



- 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 immediately by the button **"Stop incubation"**



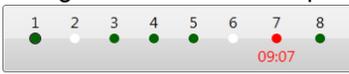
- **skip to step**. When the protocol run is paused it is possible to restart the run from any step of the assay. By pressing this button in the right side of the red file the line Skip to step appears.



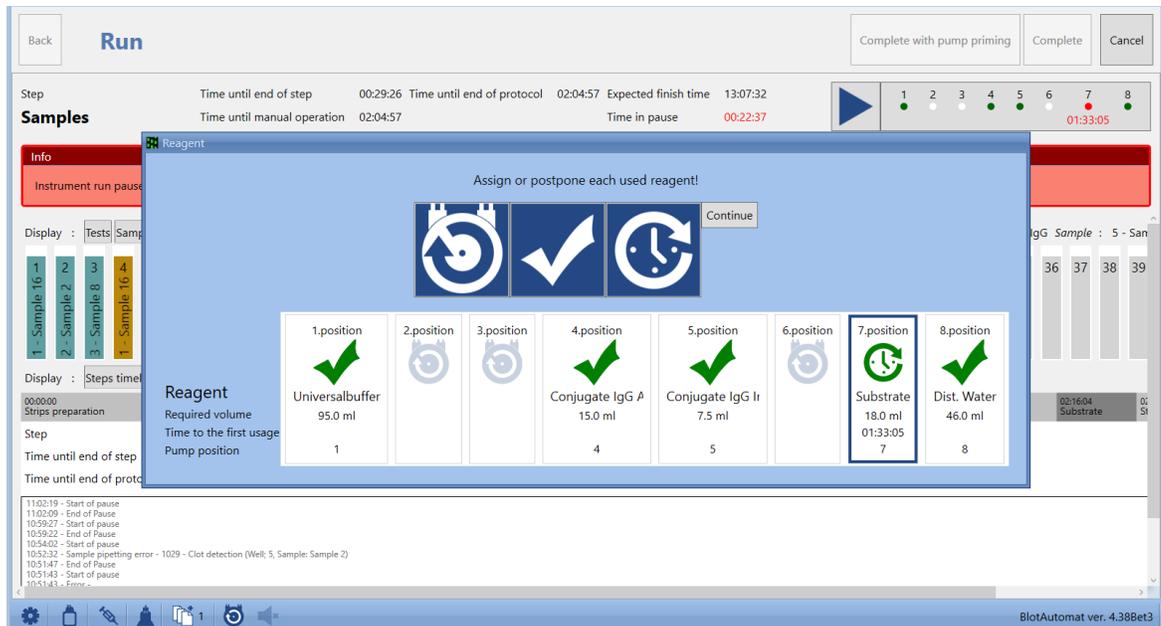
. Any step can be selected in the side menu of the line offers all steps. The check question appears after the button Restart pressing. After confirmation the window for reagents preparation is opened and then a new run is started.

**Loading of postponed reagents** - If the user didn't load all reagents during the protocol preparation, the system will change the icon of the pump in the status bar to yellow 5 minutes

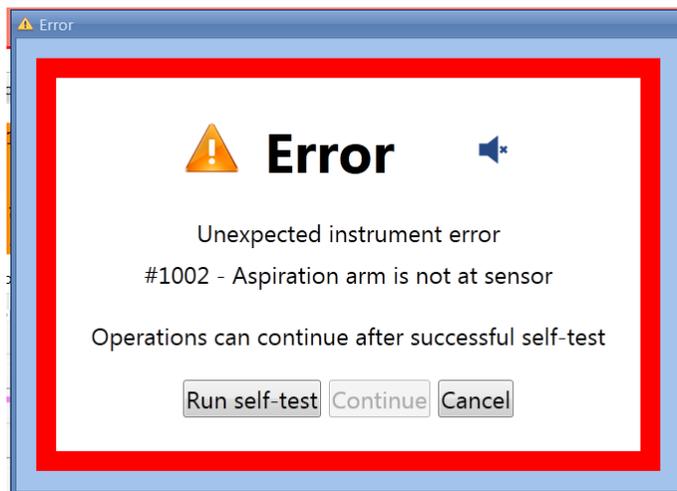
before the use of a postponed reagent . After clicking on this icon or the panel with indicators

of pumps filled with reagents in the upper right corner  The system will display a dialogue for the loading of the postponed reagent. If the user doesn't load the reagent until

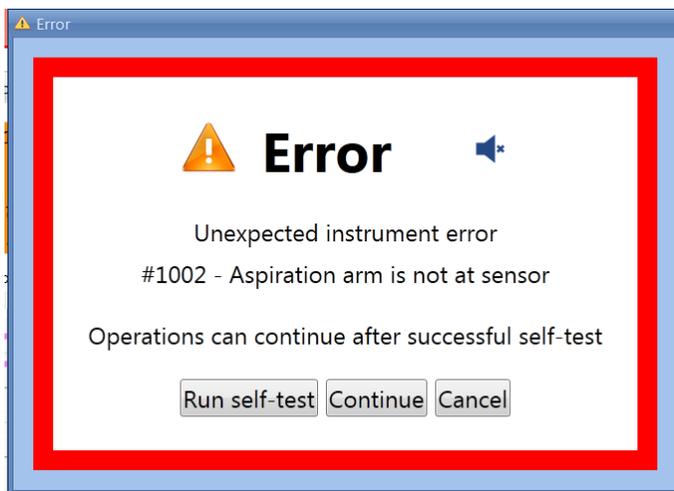
the time of its planned use, the system will pause the run and displays a dialogue with icons for automatic loading (see step 6). For the run to continue, the user must load the reagent. The time of the pause is then included in the time in pause.



**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.



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)

Back **Run** Cancel

Step Time until end of step 00:14:59 Time until end of protocol 02:26:08 Expected finish time 13:32:29  
**Strips preparation** Time until manual operation 02:26:08 Time in pause 00:00:20

Info  
 Insert strips: Continue

Display : Tests Samples Lot Lot : S-58914 Copy to Order : 8 Test : CMV IgG Sample : 5 - San

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	
Ana15	Ana15	Ana15	Ana16	Ana16	Ana16	Ana16	CMV IgG	CMV IgG																															

Display : Steps timeline Actions timeline

Step	Time until end of step	Time until end of protocol
00:00:00 Strips preparation	00:14:59	02:26:08
00:15:57 Samples		
00:51:35 Wash 1		
01:08:09 Conjugates		
01:38:40 Wash 2		
01:55:14 Substrate		
02:05:46 Stop		

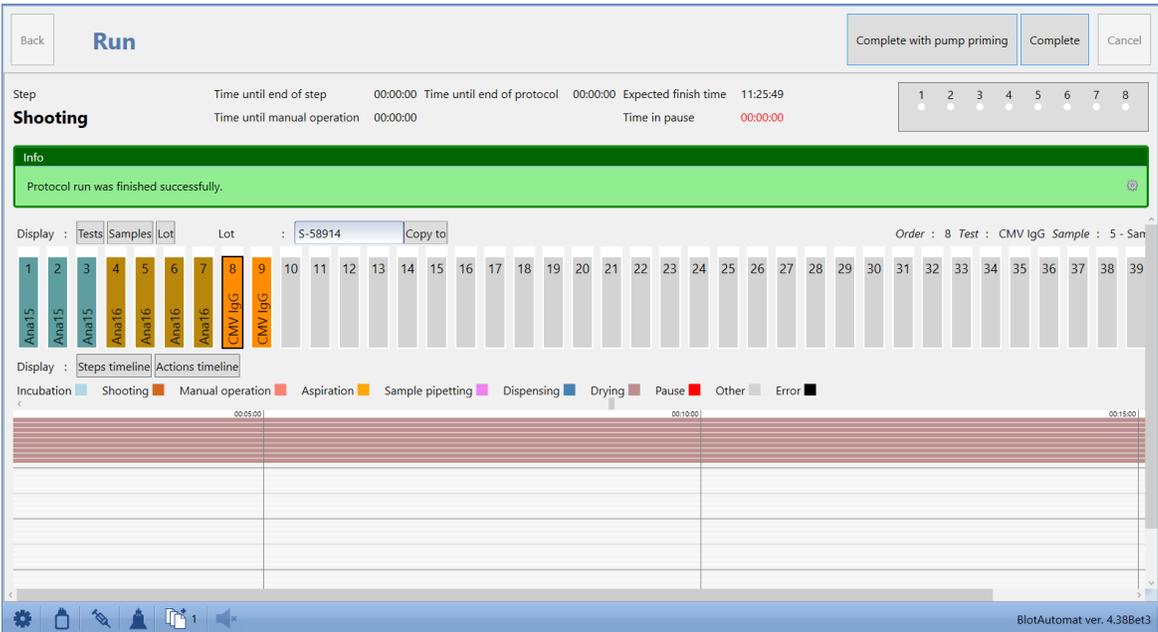
11:06:13 - Start of pause  
 11:05:42 - End of Pause  
 11:05:30 - Start of pause  
 11:05:23 - Step started - Strips preparation  
 11:05:23 - Run restarted - Protocol 201610\_17\_1, Assay group: EURO 01/02, Starting step: Strips preparation  
 11:03:06 - Start of pause  
 11:03:04 - End of Pause  
 11:02:19 - Start of pause  
 11:02:09 - End of Pause  
 10:59:27 - Start of pause

BlotAutomat ver. 4.38Bet3

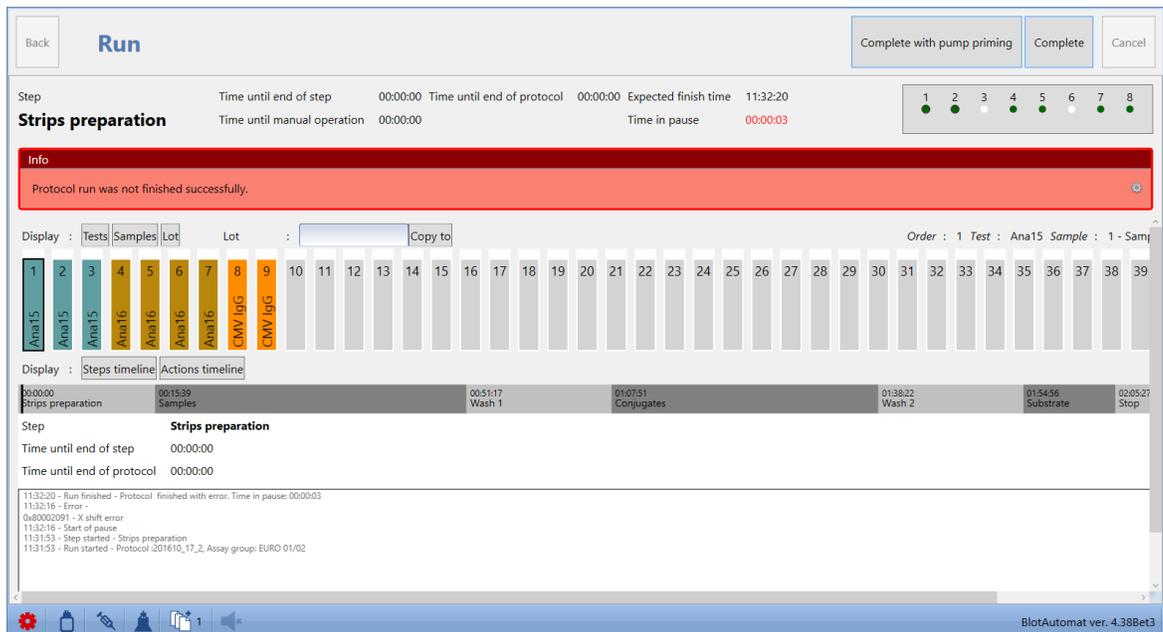
**Manual pipetting** - during the assay operation "Pipetting" a situation might occur, where the sample level cannot be found in the primary tube. In that case the application will prompt the user after the end of automatic pipetting to manually pipette the samples, where the automatic pipetting failed. 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.



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



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



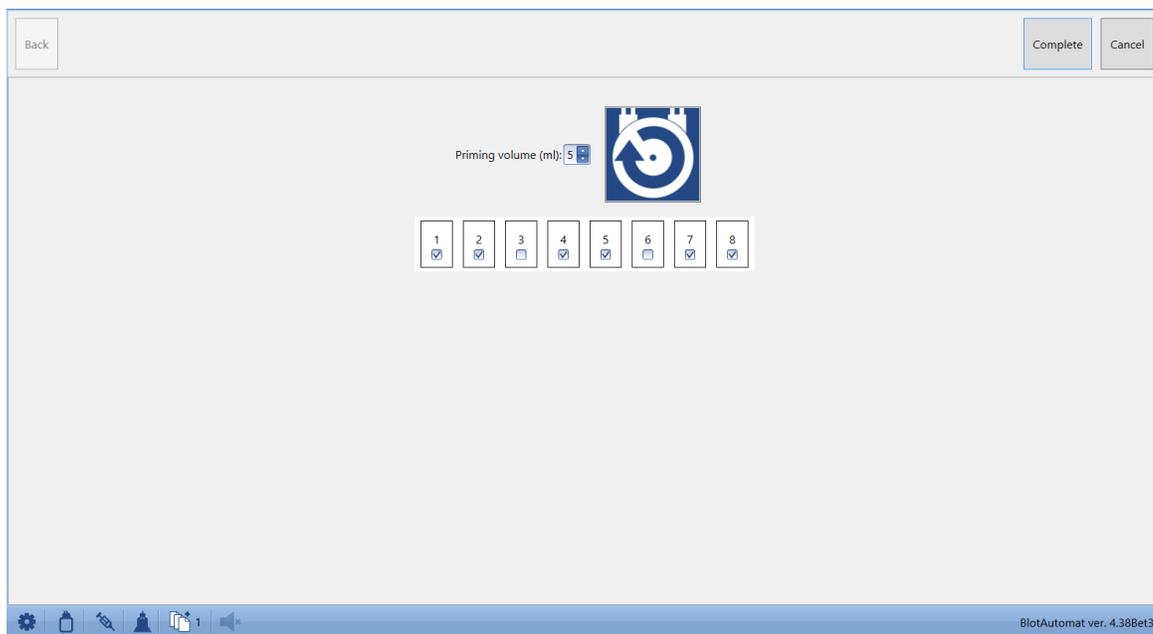
**Stopping the run** - at any time the user can press the "Cancel" button. The system definitively ends the run - this ending is irreversible. The time of stopping is entered in the protocol and the protocol is assigned a status of "Not processed - error".

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.

### Step 8 - 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.



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

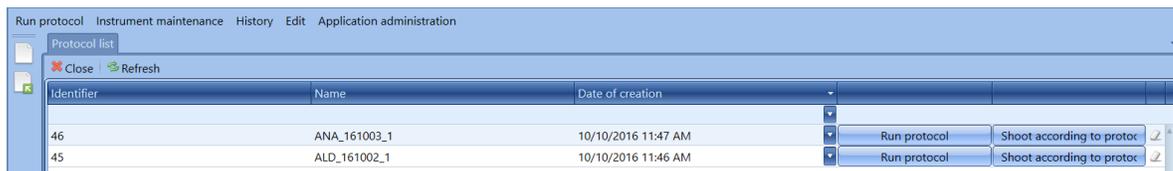
After the priming the user may finish the protocol by pressing "**Complete**".

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 transferred 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").



Protocol can be deleted by the bubble icon  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:

#### Step 1 - 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 of the strip number - production batch identification

The screenshot shows a software window titled "Protocol ...". At the top left is a "Back" button, and at the top right are "Next" and "Cancel" buttons. Below the title bar, there are two input fields: "Protocol name" with the value "ANA\_161003\_1" and "Written by" with the value "EUROBlot One". Below these fields is a table with the following data:

Strip order	Sample ID	Test	Lot
1	785	Ana15	def_Ana15
2	785	Ana16	def_Ana16
3	785	Ana17	def_Ana17

At the bottom of the window, there is a taskbar with several icons and the text "BlotAutomat ver. 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 according 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.

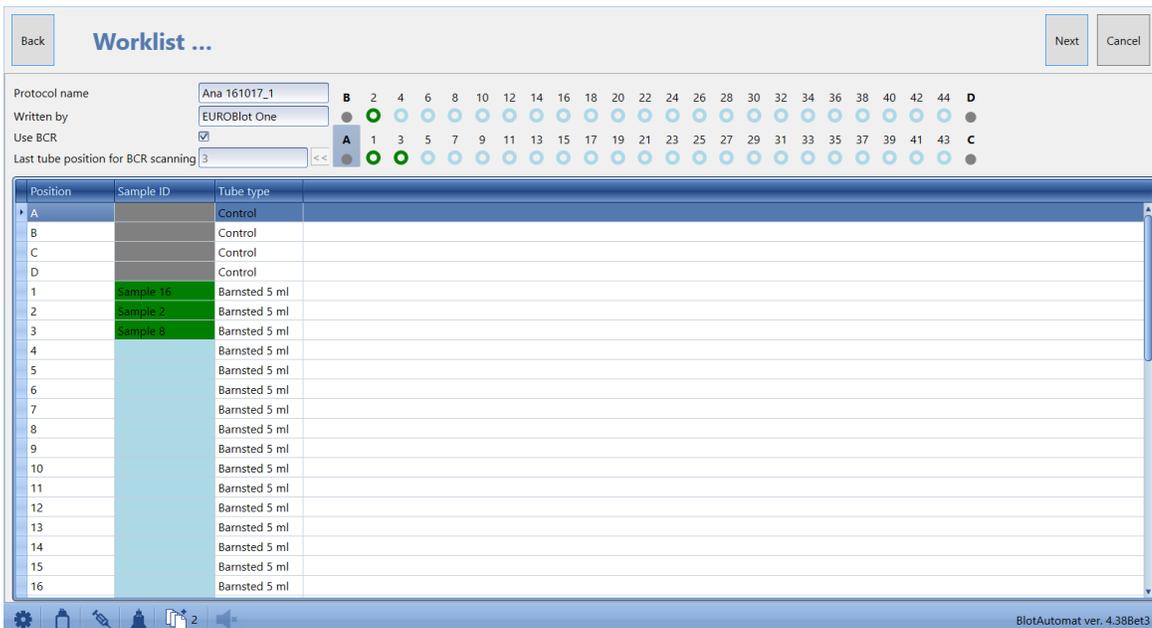
Scanned samples ID are compared with values in the imported protocol.

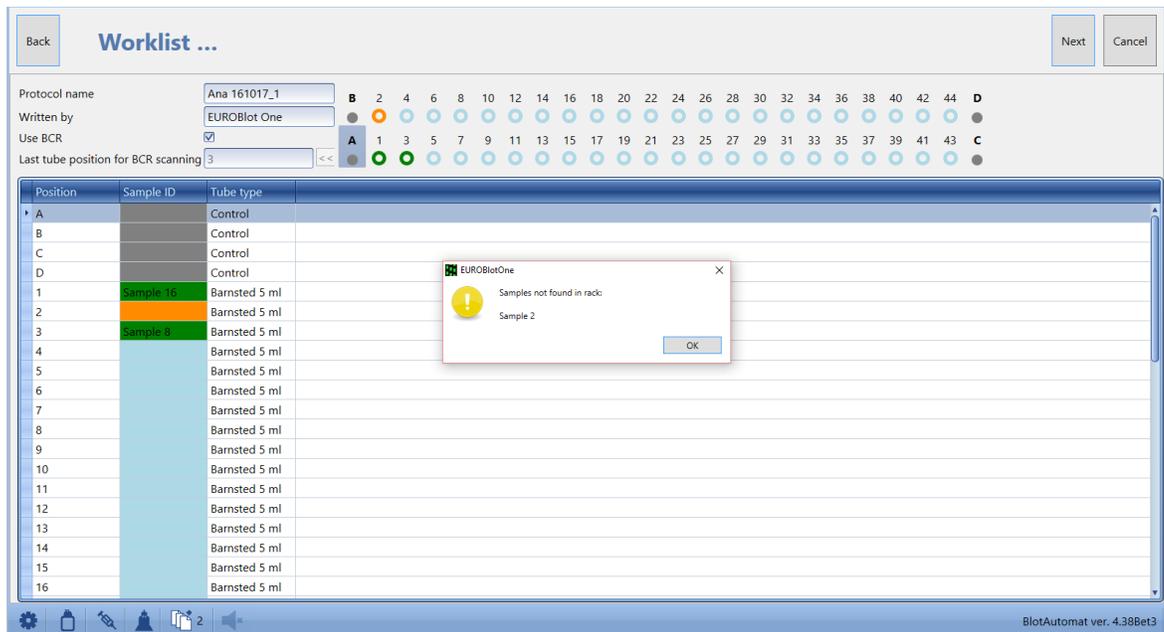
If the scanned sample ID:

- is contained by the protocol , its line is green highlighted
- is not contained by the protocol or scanning was unsuccessesful , 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.





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.

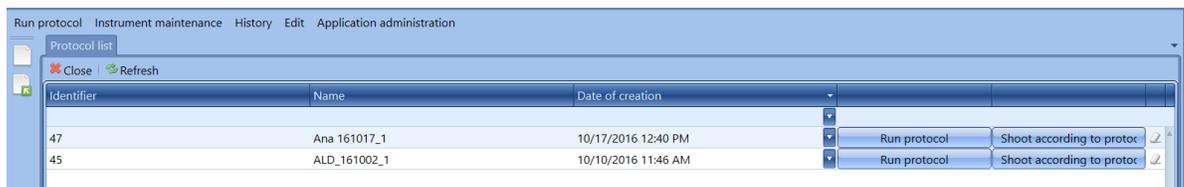
If the user requests to continue with the editing of the imported protocol, he presses "Next". The system performs a check, whether the worklist sample IDs match the imported protocol sample IDs. If their range and ID don't match, the system alerts the user, that the detected samples in the instrument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

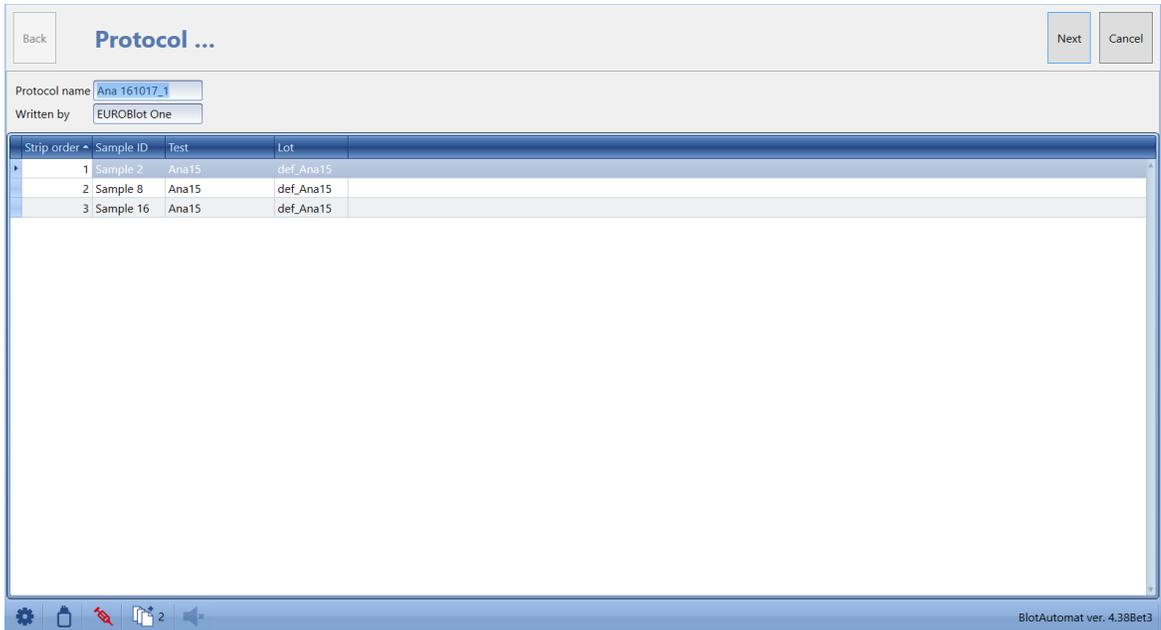
The user may process the imported protocol just by creating shots of the sample test strips. To begin to create the screens select the protocol and press "**Shoot according to protocol**".



**Procedure to create sample test screens of the imported protocol:**

### Step 1 - Protocol display

The system displays details of the imported protocol



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

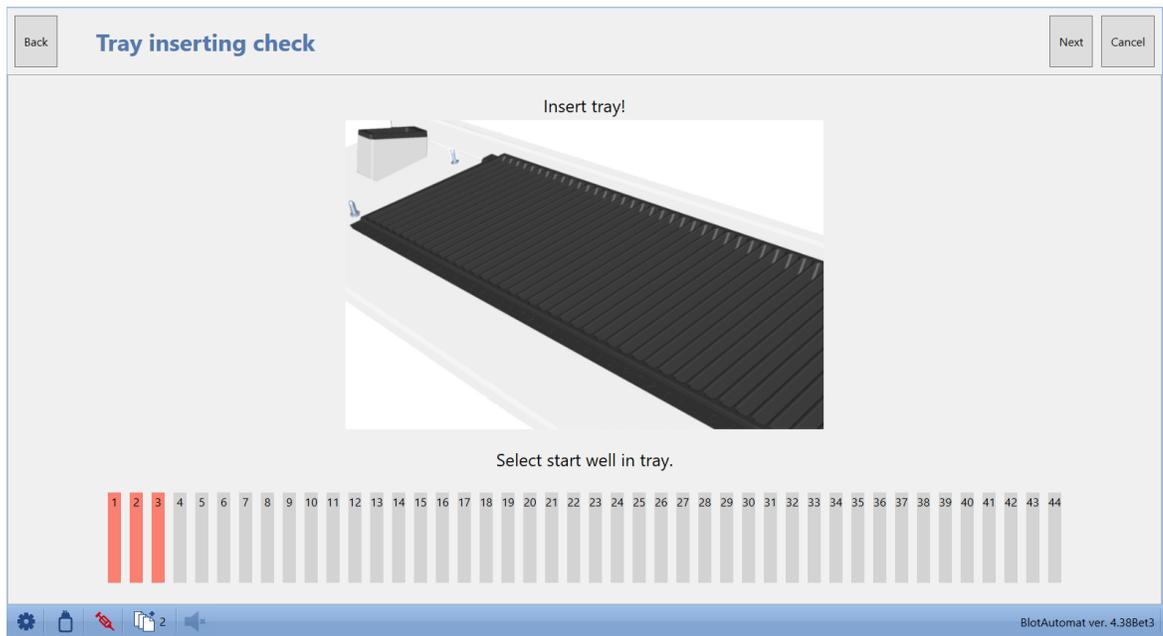
**Lot** - lot of the strip number - production batch identification

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.

### Step 2 - 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.



By clicking on the strip field  the user selects the 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.

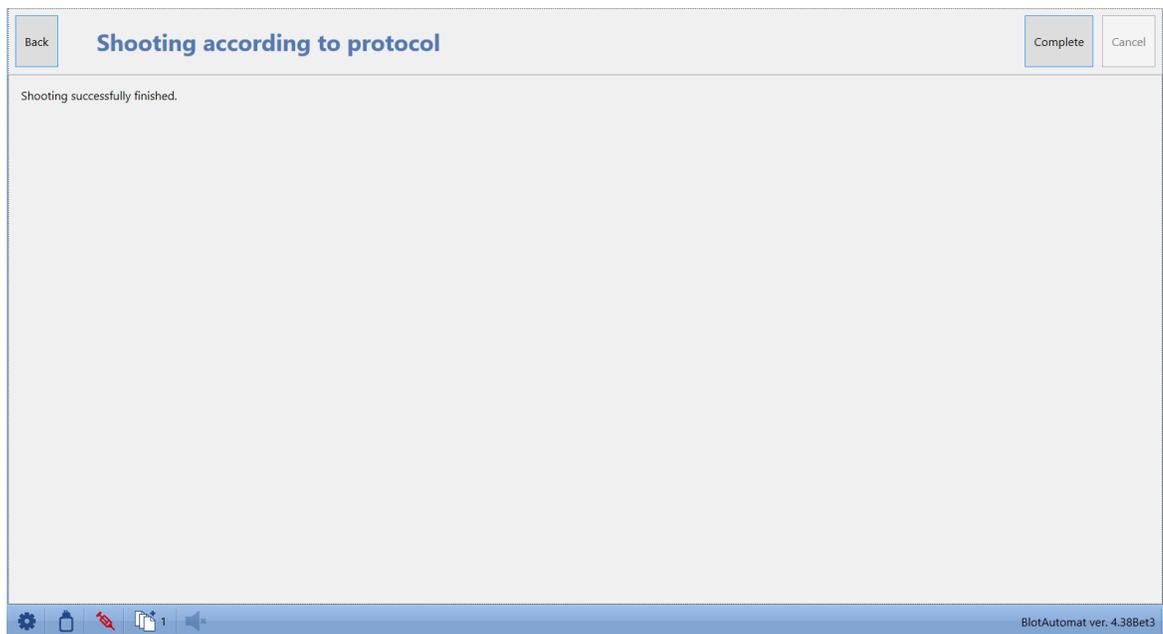
If the user requests to continue with the shooting of the strips of the imported protocol, he presses the "Next" button (see Step 3)

### **Step 3 - 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.



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 )



## 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.

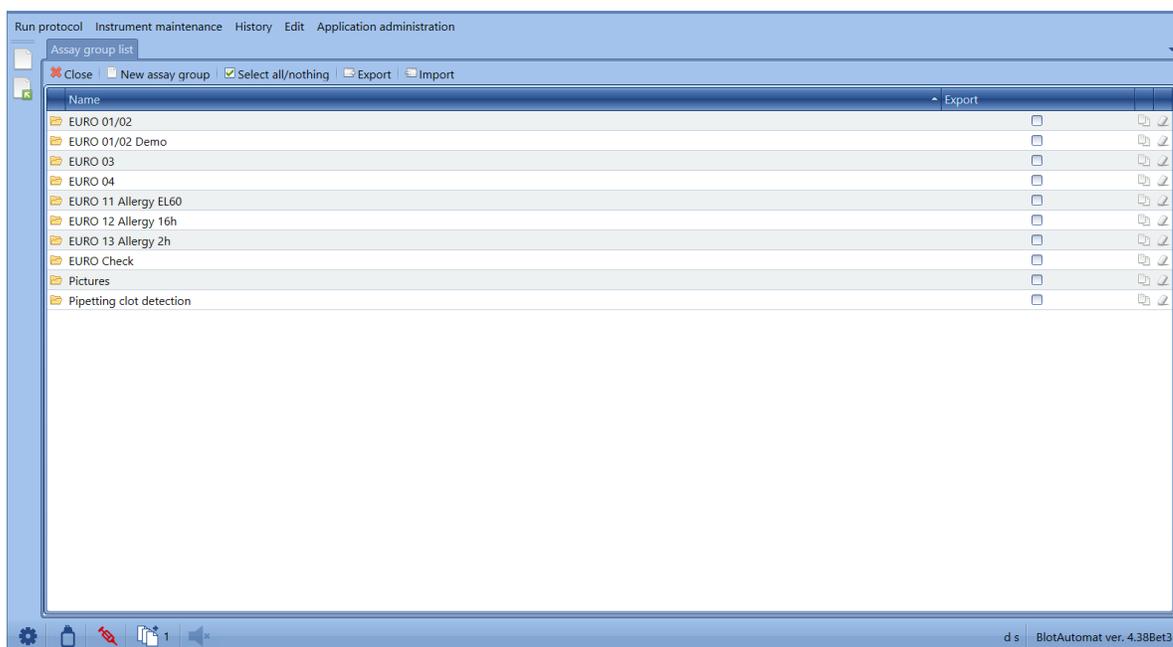
The Edit menu includes the following items :

- Assays
- Tests
- Reagents
- Tube types.

## 2.2.1 Assays

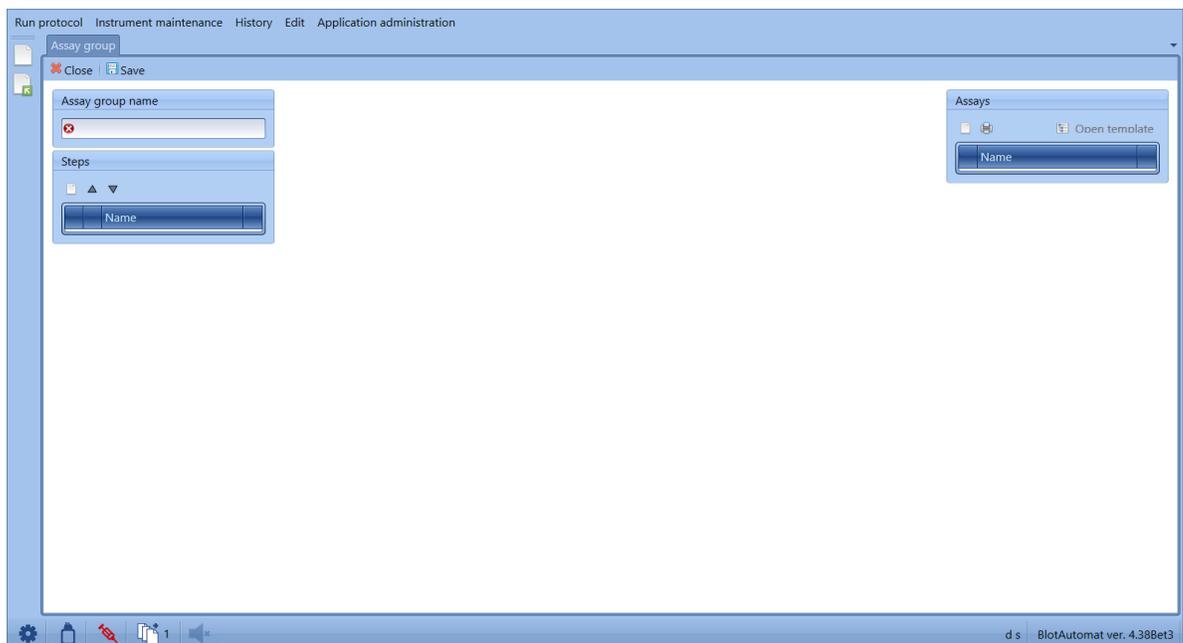
Assay groups contain individual assays, which describe the procedure of individual assays during sample processing. Creation and change of an assay group can be done only by a user with the Administrator role.

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

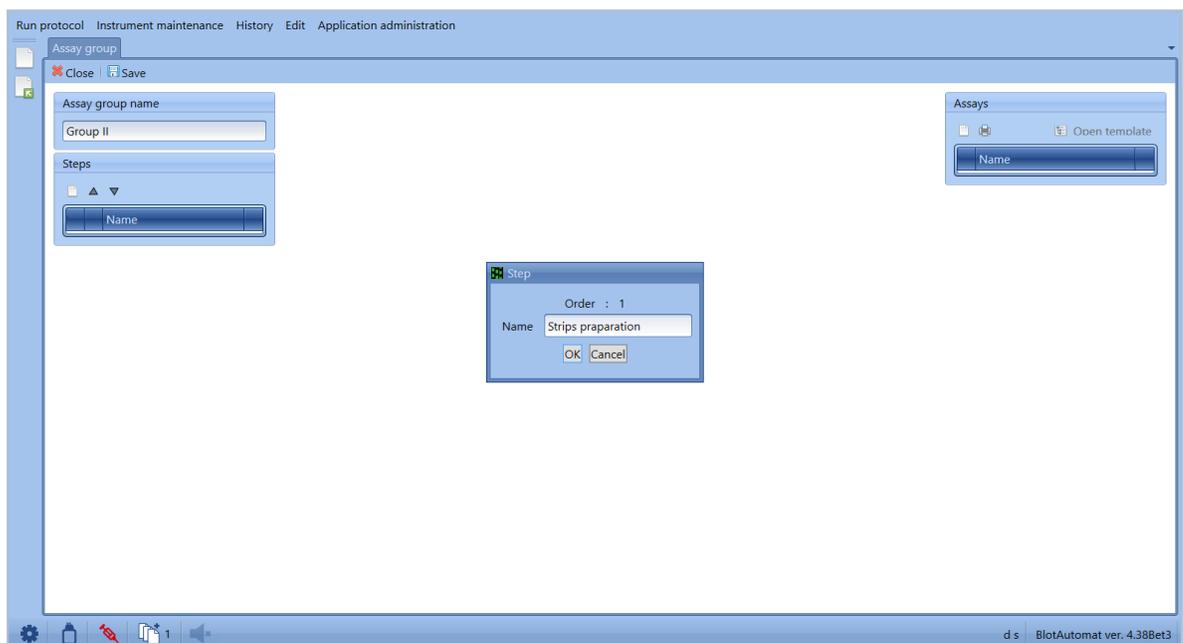


Creation of a new assay group can be done by an Administrator in the assay group list by pressing "**New assay group**". The system displays the detail of a new assay group, where the user enters the assay group name, which is unique and required, then the assay name(s) and enters individual tasks, which 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  of the relevant assay group and the system displays its detail, describing individual steps and register list of the relevant assays.



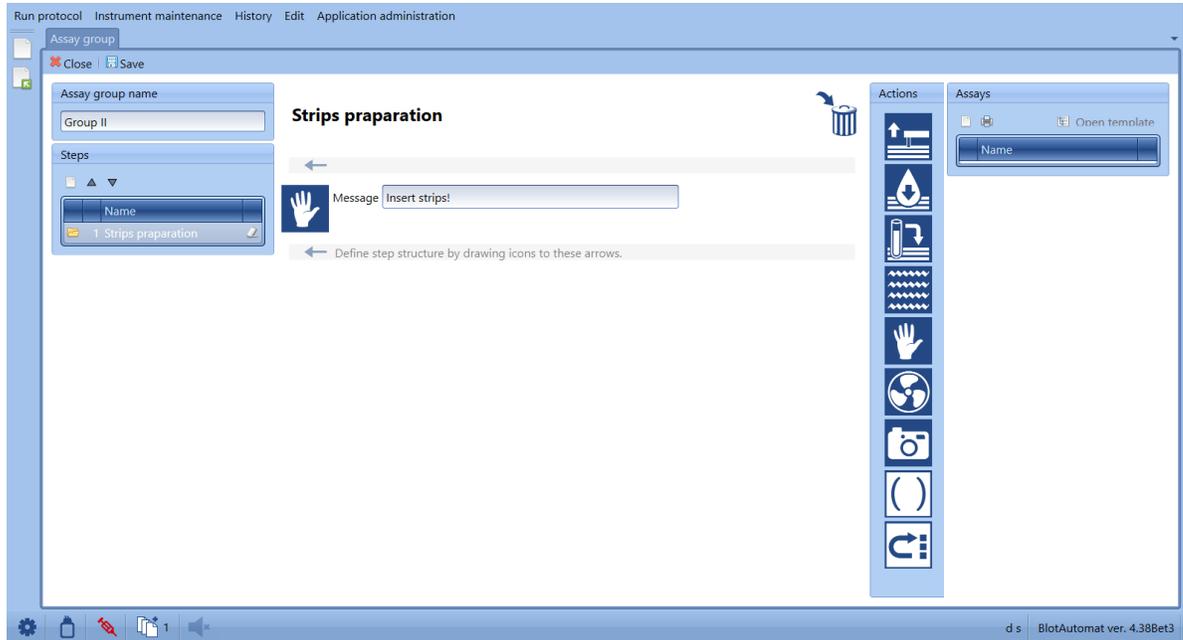
The user creates a new assays step by pressing the document icon .



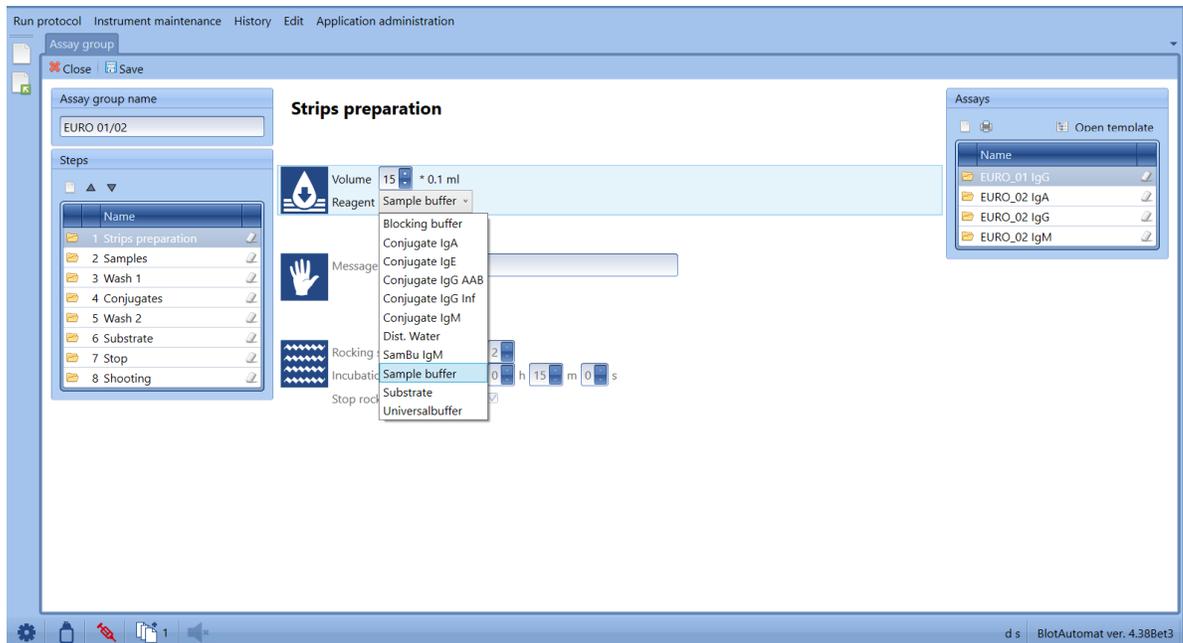
If he has selected a row with the step and presses the the **"Open template"** button in the upper right corner of the application, he can create a new step from the individual actions. By dragging the step activity icon (aspiration , dispensing , pipette samples , incubation , manual operation , drying , 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.

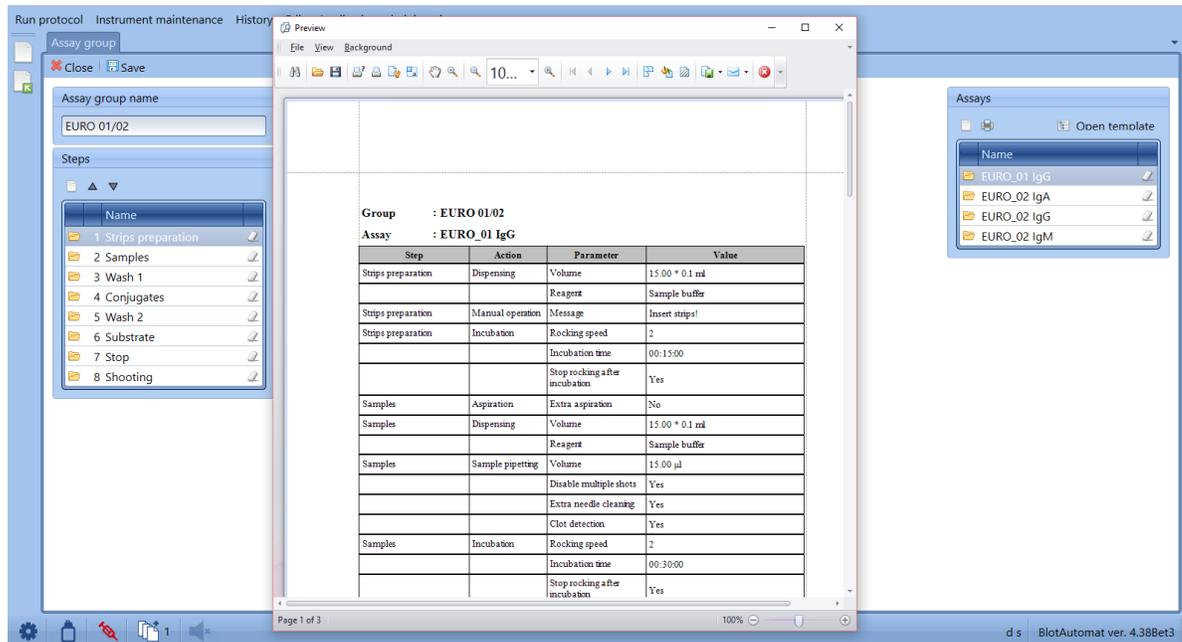
Wrongly defined actions can be removed by dragging the appropriate icon into the trash bin .



After creating an assay group the user creates individual assays by pressing icon  in windows Assays. The assays 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.



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.

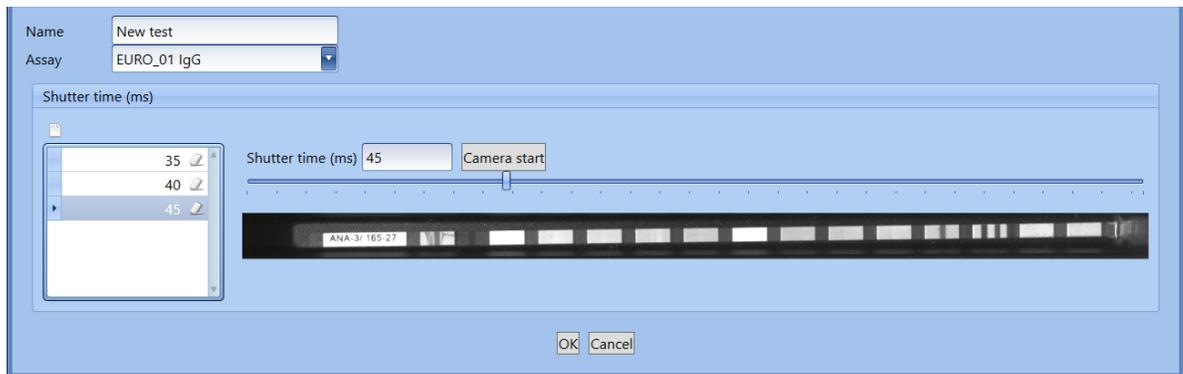
The test register must contain all test which will be used by user for worklist creation or which will be contained in protocols imported from the external system.

Name	Assay	Shutter time (ms)	Export
1111 Pipetting clot	Pipetting clot detection	50	<input type="checkbox"/>
AEA Food	EURO_11 IgE	20	<input type="checkbox"/>
AEA Inhalation	EURO_11 IgE	20	<input type="checkbox"/>
AEA Insects	EURO_11 IgE	20	<input type="checkbox"/>
AEA Pediatrics/Atopy	EURO_11 IgE	20	<input type="checkbox"/>
AEA SPAC Ins.v.1	EURO_11 IgE	20	<input type="checkbox"/>
AEA SPAC Pollen1	EURO_11 IgE	20	<input type="checkbox"/>
ALD	EURO_01 IgG Demo	20	<input type="checkbox"/>
ANA_MK	EURO_01 IgG	20	<input type="checkbox"/>
Ana15	EURO_01 IgG	20	<input type="checkbox"/>
Ana16	EURO_01 IgG	20	<input type="checkbox"/>
Ana17	EURO_01 IgG	20	<input type="checkbox"/>
Ana18	EURO_01 IgG	20	<input type="checkbox"/>
Ana1b	EURO_01 IgG	20	<input type="checkbox"/>
Ana3b	EURO_01 IgG	20	<input type="checkbox"/>
Ana5	EURO_01 IgG	20	<input type="checkbox"/>
ANCA	EURO_04 IgG	20	<input type="checkbox"/>
B. afzelii IgG	EURO_02 IgG	20	<input type="checkbox"/>
B. afzelii IgM	EURO_02 IgM	20	<input type="checkbox"/>
B. burg US IgG	EURO_02 IgG	20	<input type="checkbox"/>
B. burg US IgM	EURO_02 IgM	20	<input type="checkbox"/>
B. burg. IgG	EURO_02 IgG	20	<input type="checkbox"/>
B. burg. IgM	EURO_02 IgM	20	<input type="checkbox"/>
B. garinii IgG	EURO_02 IgG	20	<input type="checkbox"/>
B. garinii IgM	EURO_02 IgM	20	<input type="checkbox"/>

### 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.

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 entered as a numeric value or by pressing the button "**Camera start**".



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 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 or doesn't require the test to be saved, he selects "**Cancel**".

### Test deletion

A user with an Administrator 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 then 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 assay, 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".

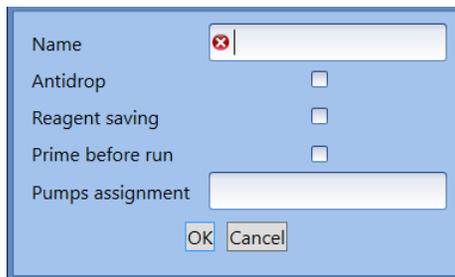
Reagent	Antidrop	Reagent saving	Prime before run	Pumps assignment
Blocking buffer	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	2
Conjugate IgA	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	3
Conjugate IgE	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	3
Conjugate IgG AAB	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	4
Conjugate IgG Inf	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	5
Conjugate IgM	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	6
Dist. Water	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	8
SamBu IgM	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	2
Sample buffer	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	2
Substrate	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	7
Universalbuffer	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	1

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 fulfilled 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.



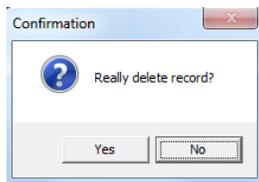
A dialog box for entering a new reagent. It has a blue background and contains the following fields and controls:

- Name:** A text input field with a red 'X' icon on the right.
- Antidrop:** A checkbox.
- Reagent saving:** A checkbox.
- Prime before run:** A checkbox.
- Pumps assignment:** A text input field.
- Buttons:** "OK" and "Cancel" buttons at the bottom.

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.

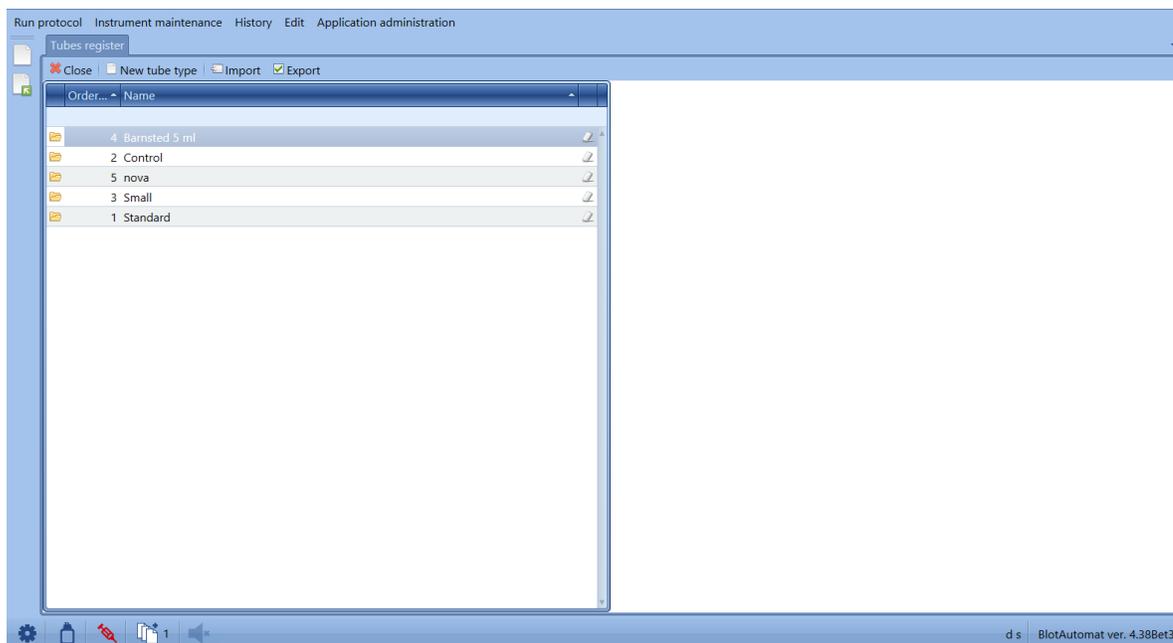
### Removing a reagent.

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.

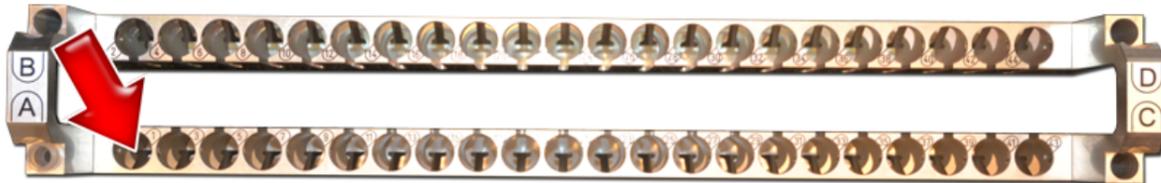


## 2.2.4 Tube types

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

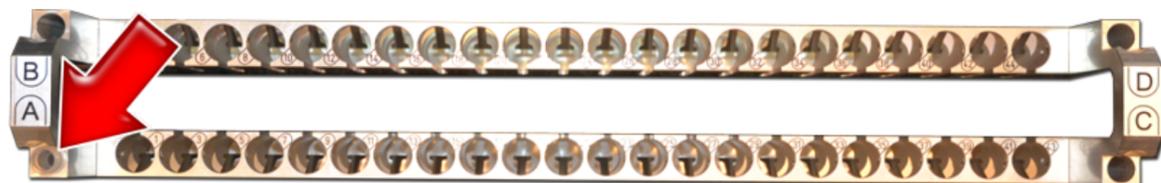


The type differ by the tube dimensions and their insertion to the sample tubes rack. From the insertion view there are 44 positions for standard tubes



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.



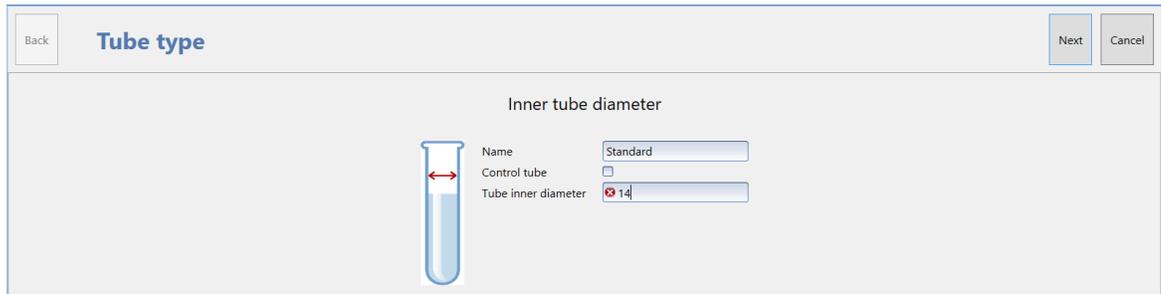
Their dimensions are limited by the holes dimensions. The bar code reading is not possible in the control tubes position.

### 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".

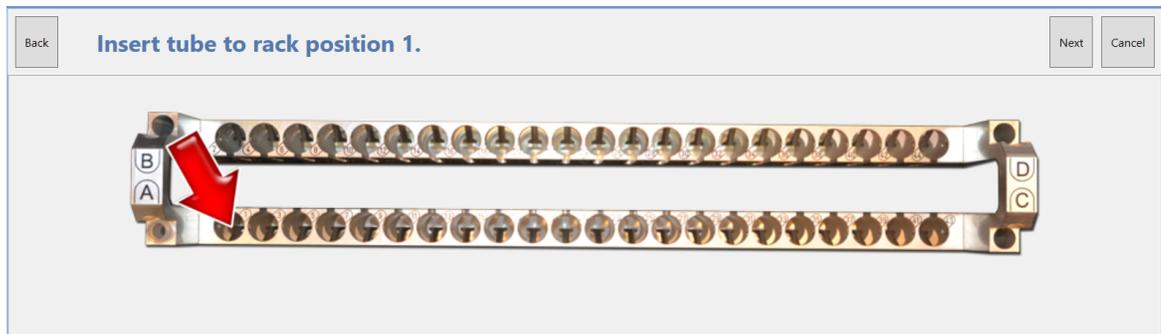
"

#### Step 1 - Determining the tube type



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.

### Step 2 - Inserting the tube into the instrument



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

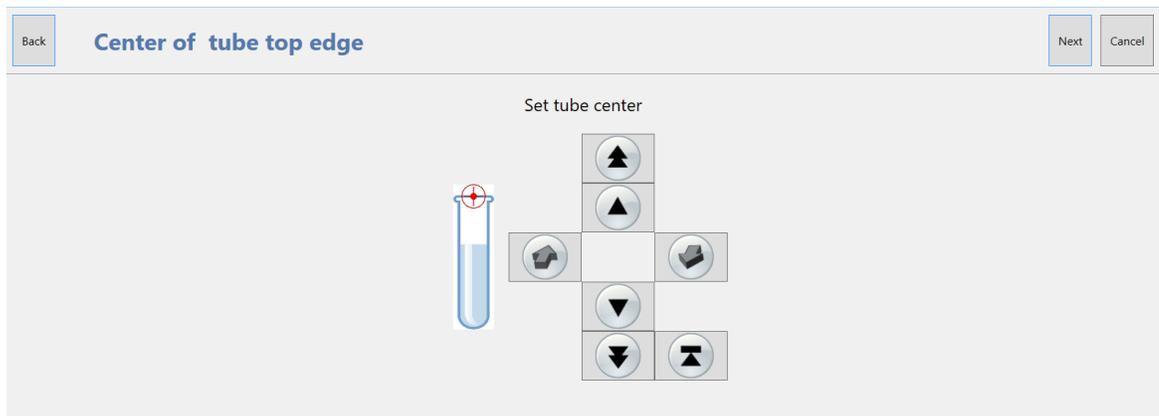
The **"Next"** button continues to next step.

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.**

### Step 3 - Setting the upper edge of the tube

System moves the arm above appropriate position of the tube rack.



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.

Buttons   move the pipetting module forward and backward. Buttons

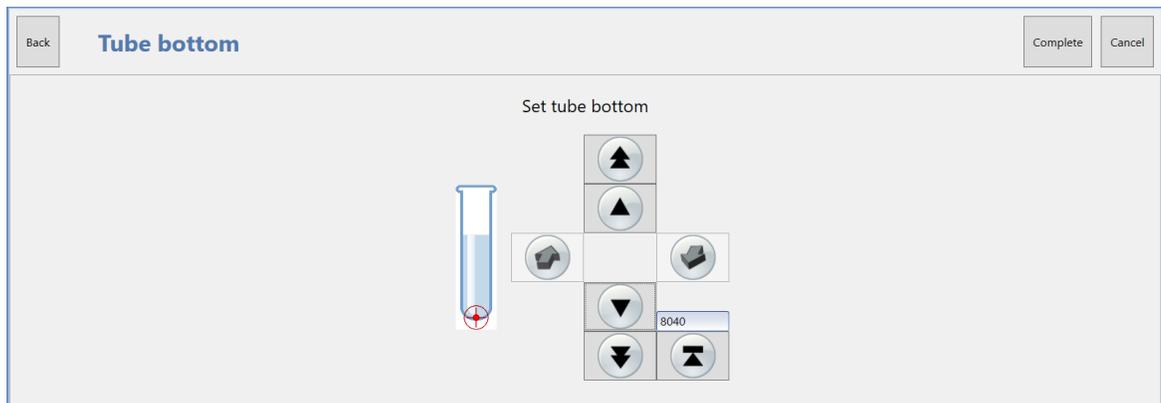


move the needle up and down. Double arrow means faster movement. If the needle hits an obstacle and the stepper motor Z loses its steps it is possible to restore its home position by the button 

The "Next" button continues to next step.

The "Cancel" button ends the entry of the new tube type

#### Step 4 - Setting the bottom of the tube



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

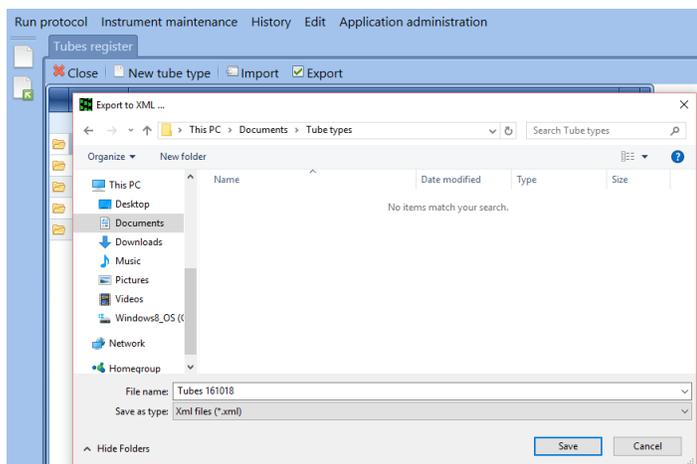
An Administrator or Service level user may choose a tube type from the list and by using the eraser



icon remove the tube from the list.

### Exporting tubes

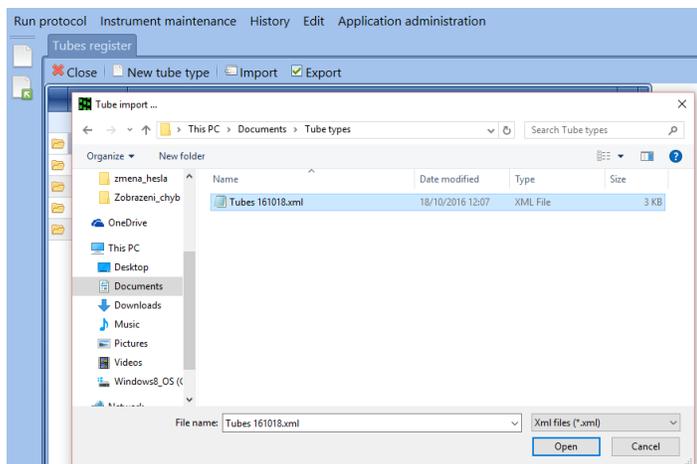
An Administrator or Service level user may **Export** tube types registered in the tube type list.



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.



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:

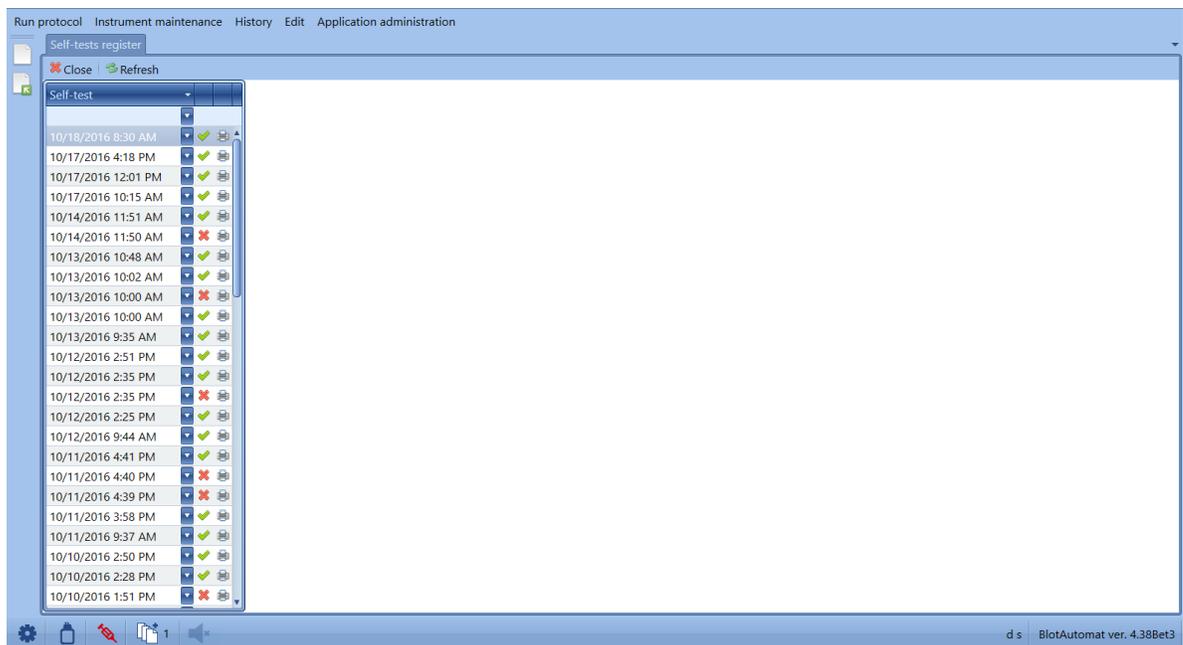
- Self-tests
- Maintenance
- Communication with the external system
- Protocols

### 2.3.1 Self-tests

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

#### Self-test list

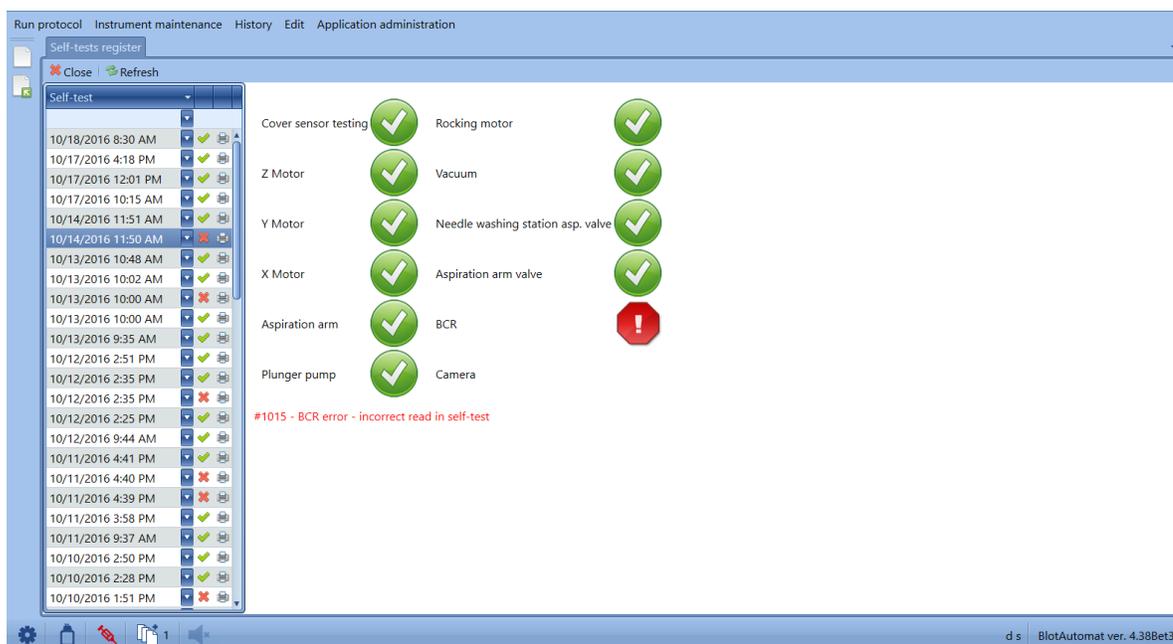
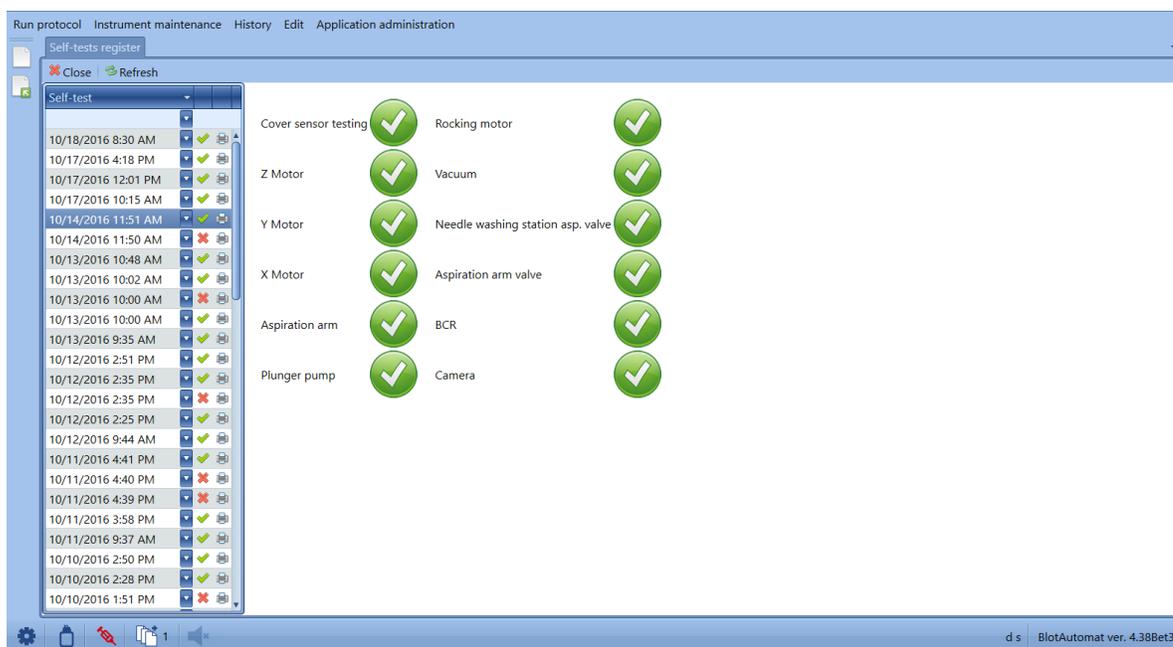
The system shows an overview of all performed self-tests together with the date and time and result of the self-test. If the user needs to find a record from a certain day, he can use the filter. After clicking into the light blue field in the header of the list he writes the requested date and the system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

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

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



Icons  and  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.

**Self-test**  
**Date** : 10/18/2016 8:30:02 AM  
**Test result** : OK

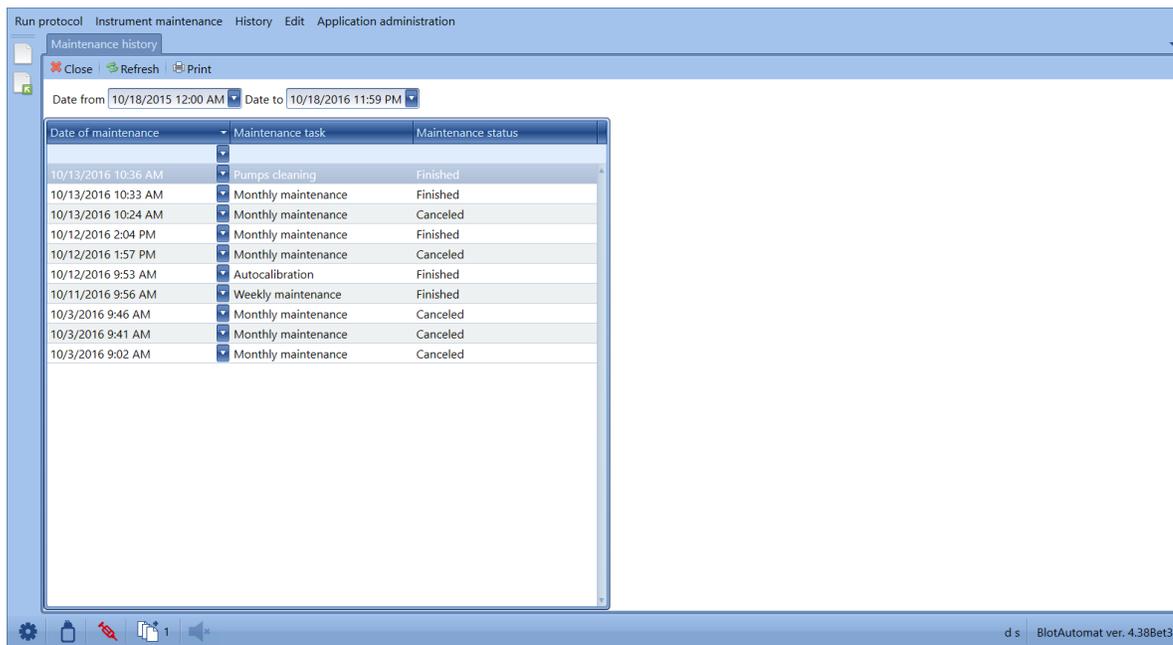
Self-test	Test result
Cover sensor testing	OK
Z Motor	OK
Y Motor	OK
X Motor	OK
Aspiration arm	OK
Plunger pump	OK
Rocking motor	OK
Vacuum	OK
Needle washing station asp. vabe	OK
Aspiration arm vabe	OK
BCR	OK
Camera	OK
Error	

**Self-test**  
**Date** : 10/14/2016 11:50:16 AM  
**Test result** : Error

Self-test	Test result
Cover sensor testing	OK
Z Motor	OK
Y Motor	OK
X Motor	OK
Aspiration arm	OK
Plunger pump	OK
Rocking motor	OK
Vacuum	OK
Needle washing station asp. vabe	OK
Aspiration arm vabe	OK
BCR	Error
Camera	Not tested
Error	#1015 - BCR error - incorrect read in self-test

## 2.3.2 Maintenance

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



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.

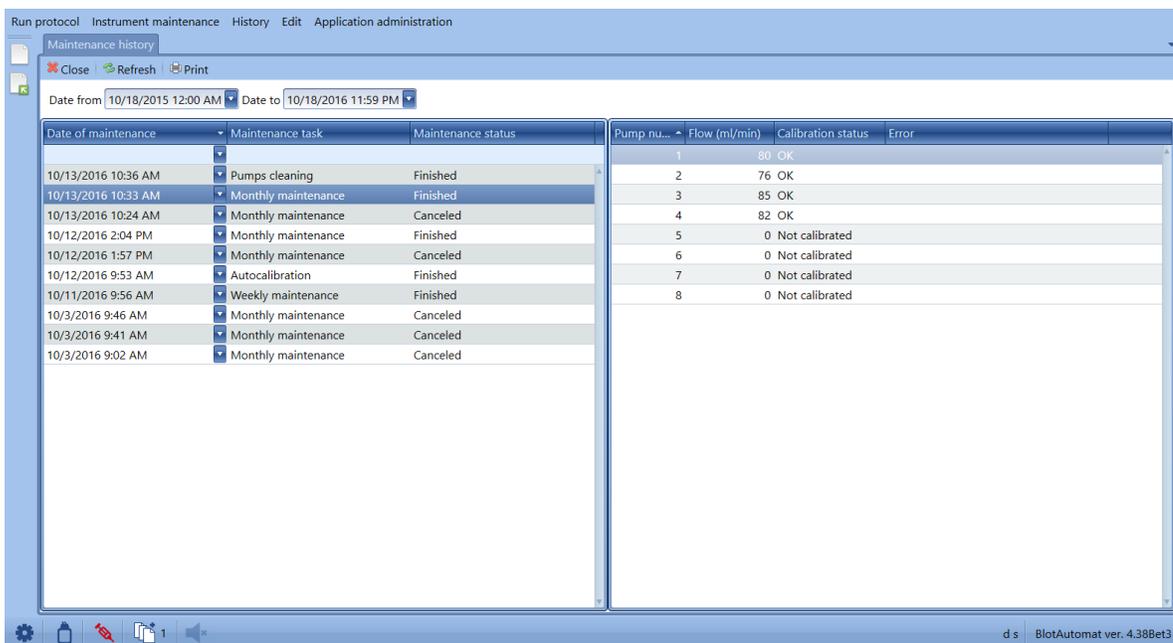
The list includes records about next types of maintenance :

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

The column *Maintenance status* contains information about the maintenance process completeness - "*Finished*" or "*Canceled*".

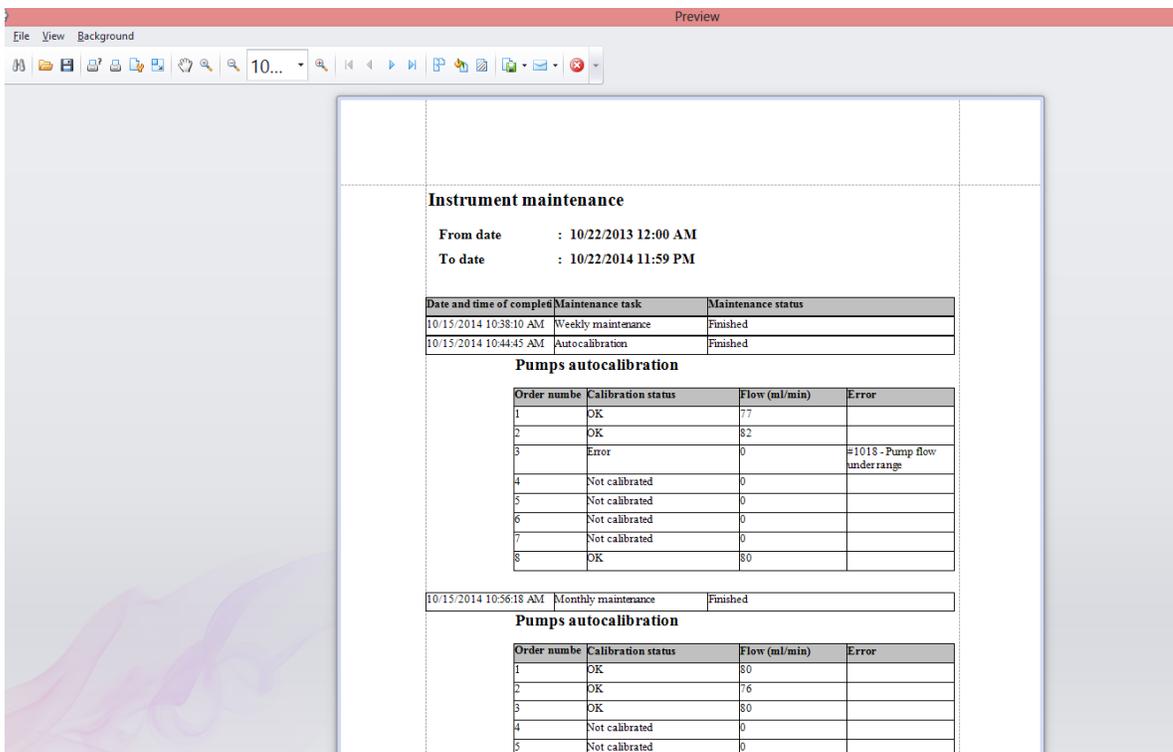
The records can be filtered by date, type and completion status of the maintenance (filter text can be inserted to the free line above the table header)

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.



### Maintenance history printing

Maintenance history database content can be printed -  .



The record from the selected period are ready for printing.

### 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

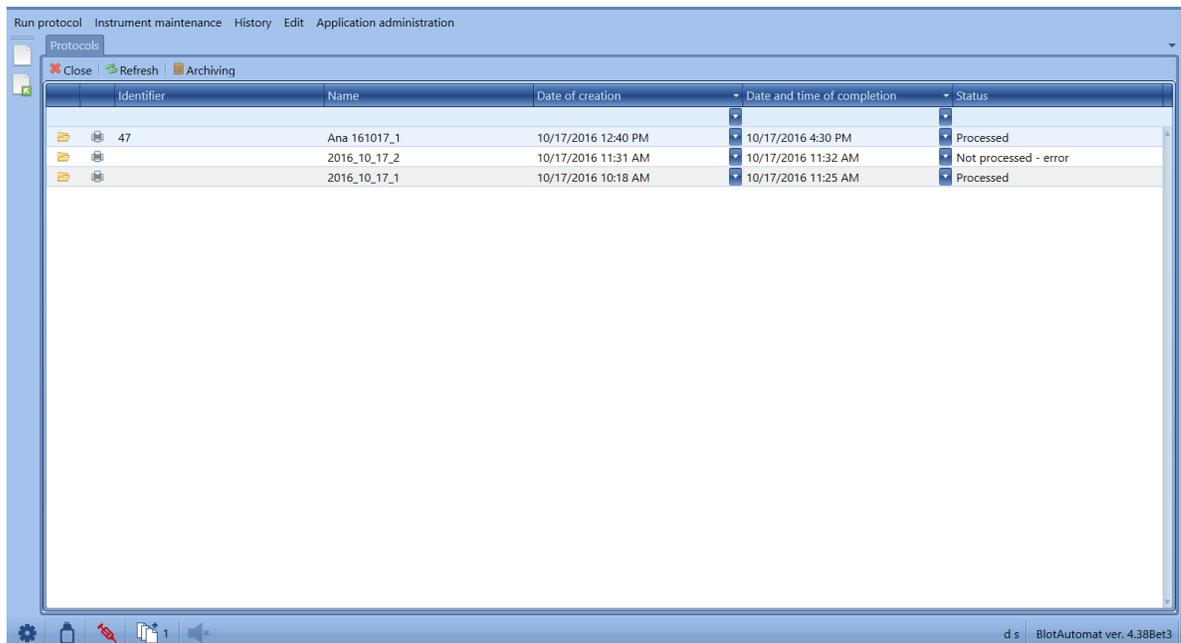
Date	Service	Protocol	Response
10/17/2016 12:41 PM	Protocol receiving	47	OK
10/17/2016 12:41 PM	Instrument status...		Waiting
10/17/2016 12:02 PM	Protocol receiving	45	OK
10/17/2016 12:02 PM	Instrument status...		Waiting
10/12/2016 10:09 AM	Protocol receiving	46	OK
10/12/2016 10:09 AM	Delete protocol	46	OK
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	OK
10/10/2016 11:48 AM	Instrument status...		Waiting
10/10/2016 11:46 AM	Protocol receiving	45	OK
10/10/2016 11:46 AM	Instrument status...		Waiting
9/27/2016 4:45 PM	Protocol receiving	44	OK
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	OK
9/27/2016 4:38 PM	Instrument status...		Waiting

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

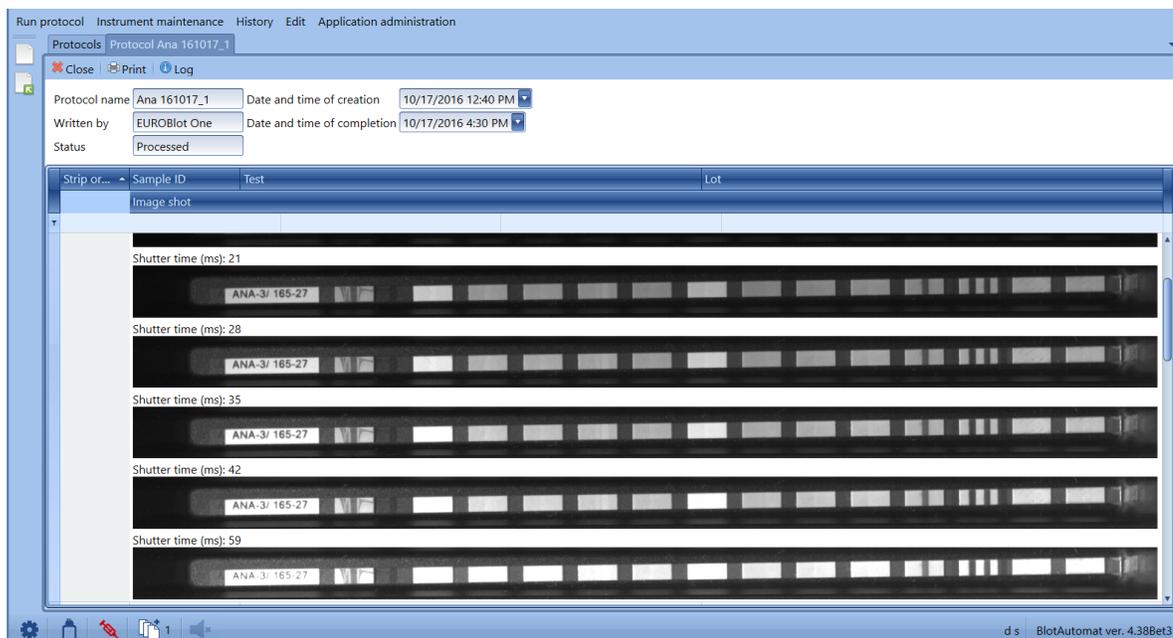
The application user may display processed protocols. These are protocols for which the instrument run has begun and they finished either successfully or with an error or the user ended them during processing. The user may filter the lists in the usual way by using the first row.



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 planned 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 planned 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

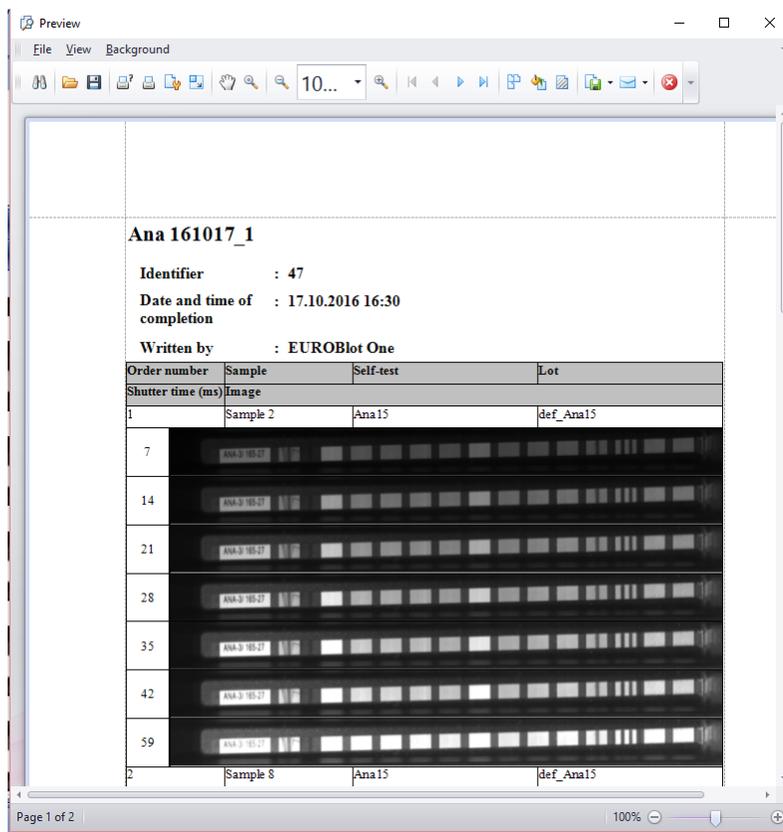
Following items are displayed for individual samples:

- **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

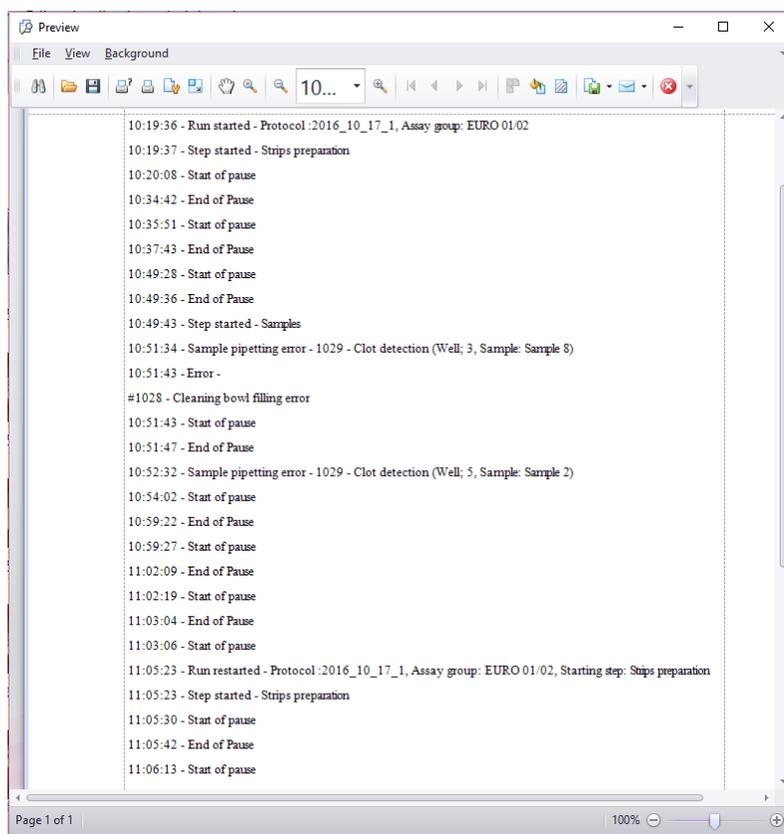
protocol document by pressing the print icon . If the assay includes the "Shooting" activity the images of strips are displayed as well



The protocol document may be printed  or saved . 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).

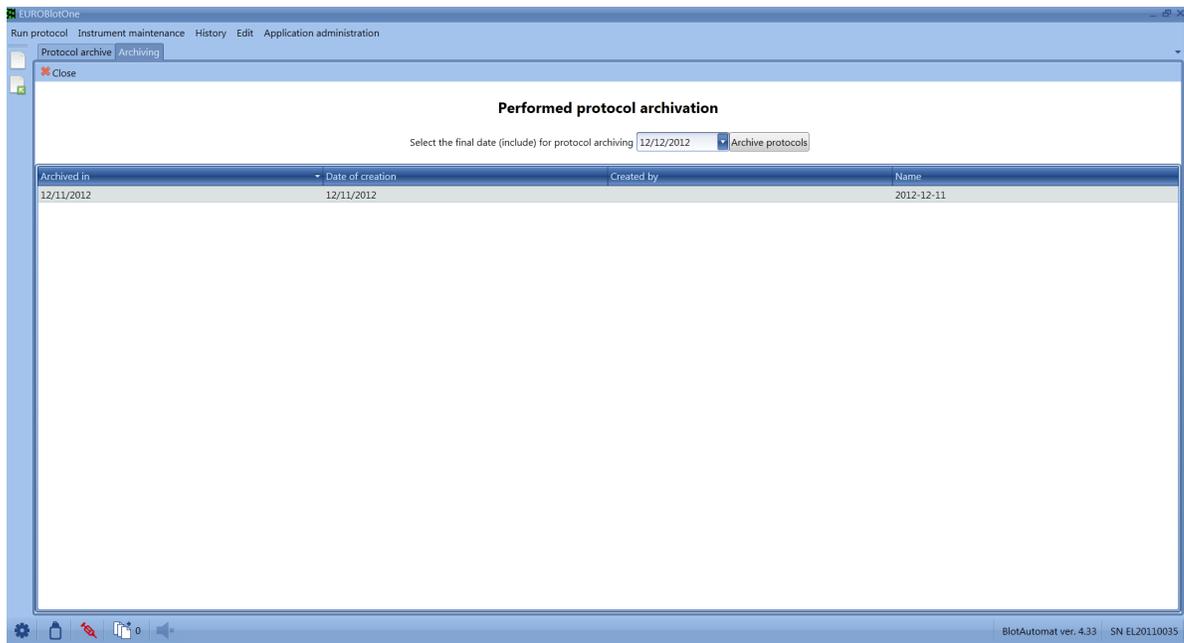
The protocol run log can be opened by the icon . The protocol run log contains next time marked information :

- 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

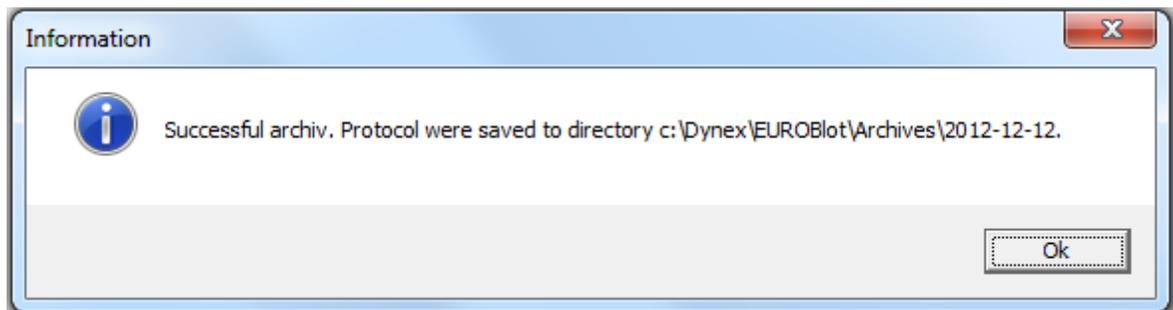


**Protocol archiving** - by pressing the archiving icon  in the protocol list the user can archive the protocols. Archiving serves to transfer the old unused data from the application so that the user could further use (display) them.

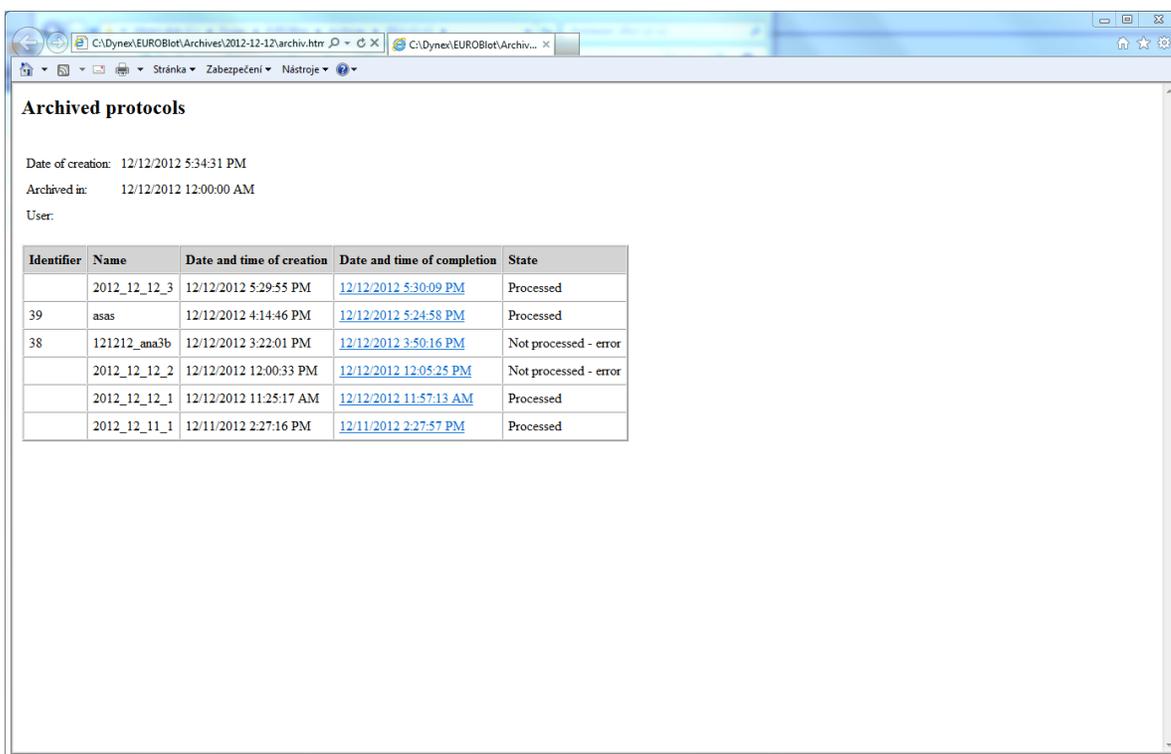
**Creating protocol archive** - the user clicks on the arrow in the row with preset date for archiving. The system displays a calendar, from which the user selects a date, by which he requires the archiving of the protocols. Then he presses the "**Archive protocols**" button and the system creates an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



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



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\EUROBlot\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.



**Archived protocols**

Date of creation: 12/12/2012 5:34:31 PM  
 Archived in: 12/12/2012 12:00:00 AM  
 User:

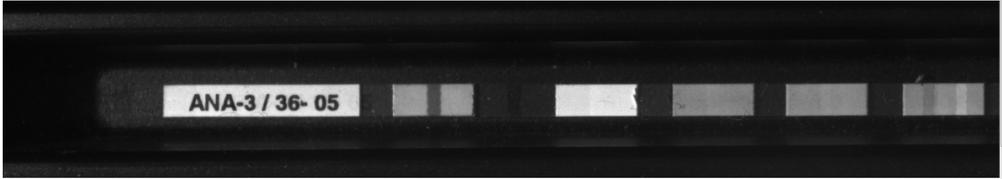
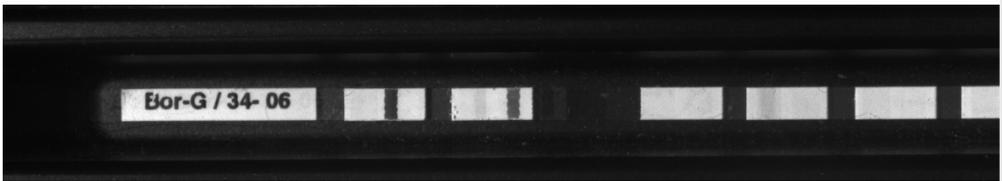
Identifier	Name	Date and time of creation	Date and time of completion	State
	2012_12_12_3	12/12/2012 5:29:55 PM	<a href="#">12/12/2012 5:30:09 PM</a>	Processed
39	asas	12/12/2012 4:14:46 PM	<a href="#">12/12/2012 5:24:58 PM</a>	Processed
38	121212_ana3b	12/12/2012 3:22:01 PM	<a href="#">12/12/2012 3:50:16 PM</a>	Not processed - error
	2012_12_12_2	12/12/2012 12:00:33 PM	<a href="#">12/12/2012 12:05:25 PM</a>	Not processed - error
	2012_12_12_1	12/12/2012 11:25:17 AM	<a href="#">12/12/2012 11:57:13 AM</a>	Processed
	2012_12_11_1	12/11/2012 2:27:16 PM	<a href="#">12/11/2012 2:27:57 PM</a>	Processed

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



**Protocol**

Protocol name: 2012\_12\_12\_3  
 Written by:  
 State: Processed  
 Date and time of creation: 12/12/2012 5:29:55 PM  
 Date and time of completion: 12/12/2012 5:30:09 PM

Sample ID	Test	Lot	Shoot
Sample 1	Shoting 40 ms		
Sample 2	Shoting 40 ms		

## 2.4 Maintenance

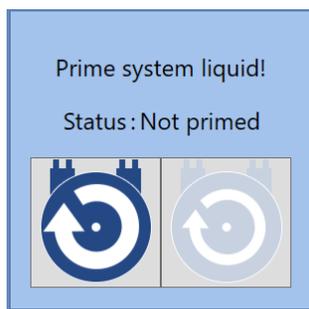
The *Instrument maintenance* menu contains items for the preparative operations before the protocol running and the maintenance operations.

The maintenance menu contains these items:

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

### 2.4.1 System liquid

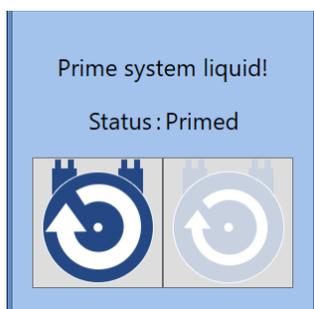
The system liquid is necessary for the pipetting action. Prior to the protocol run the user should pump the system liquid into the pipettor hydraulic system. The default status of the system solution after the application starts is “Not primed” and is signaled by an icon  in the lower bar.



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 . 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

changes to red , an error message is displayed during functions, which require the system liquid and the operation is halted. Apart from the icon color change the user is notified about the change in the

system solution volume by a sound signal, which is can be silenced by the icon  in 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.

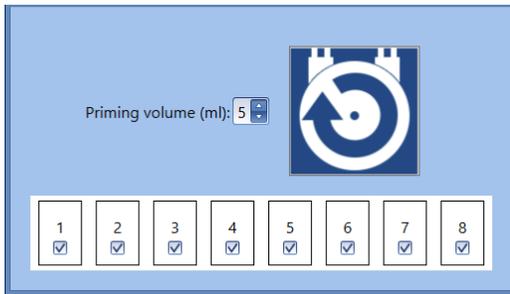
**To empty the hydraulic circuits** of the system solution remove the lid from the bottle and press the

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.

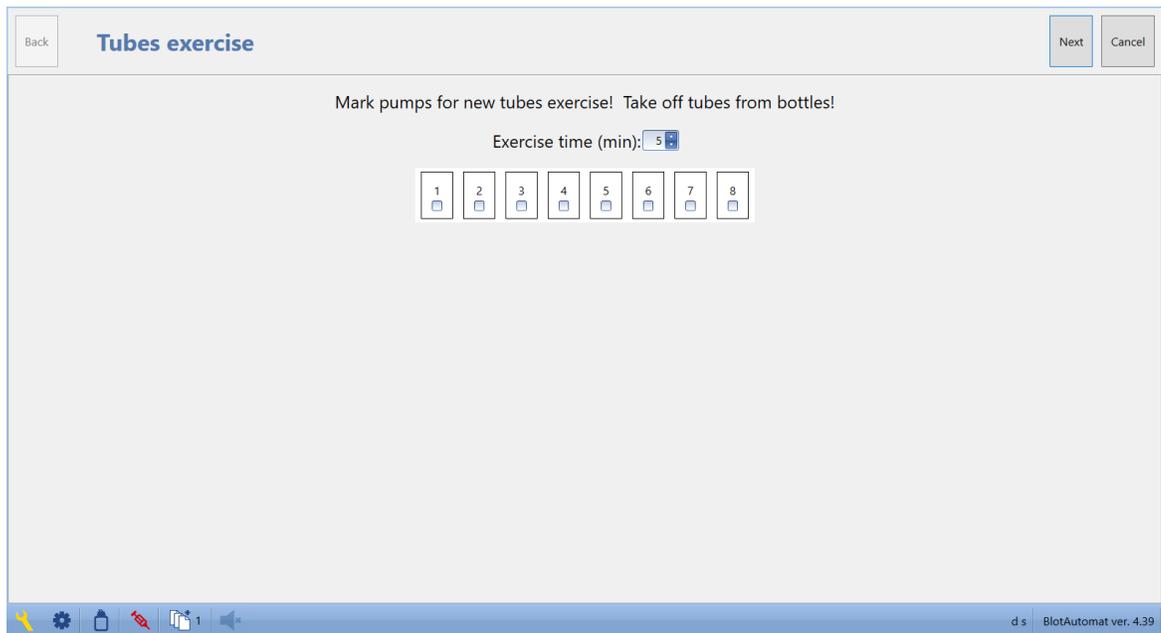


### 2.4.3 Pumps autocalibration

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:

#### Step 1 - New cassettes running-in

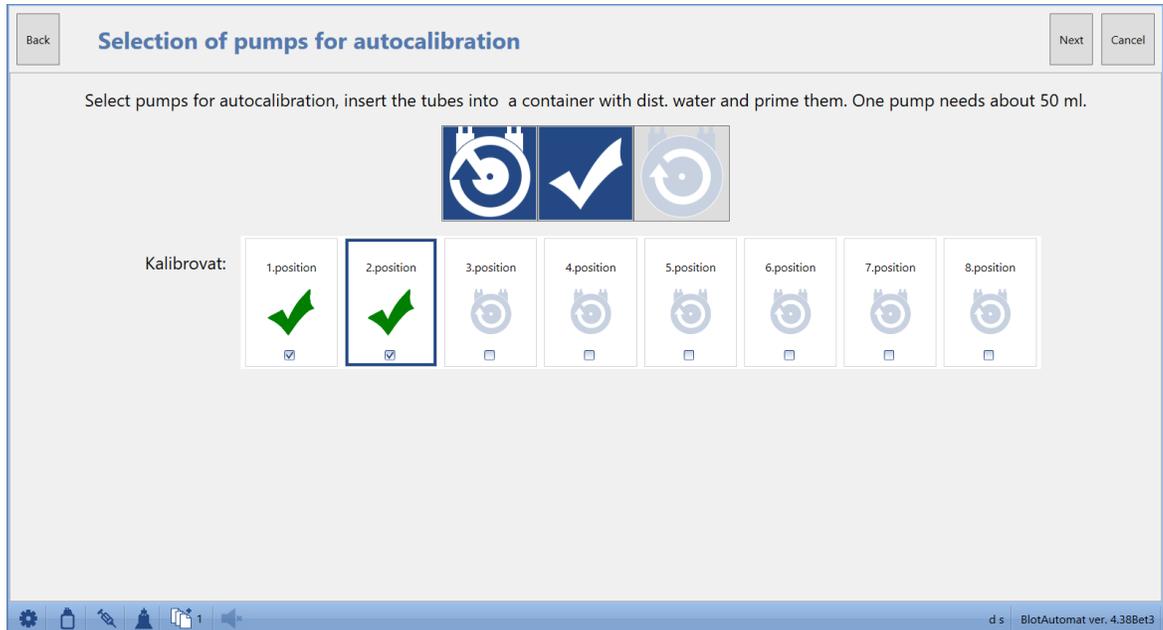


The autocalibration may include the tubes running-in. It is recommended to run-in the new pump cassettes before their first calibration. The time stability of the calibration will be higher. The user selects the pump with new cassette and sets time of the required run-in (default value is 5 min). The 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



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.

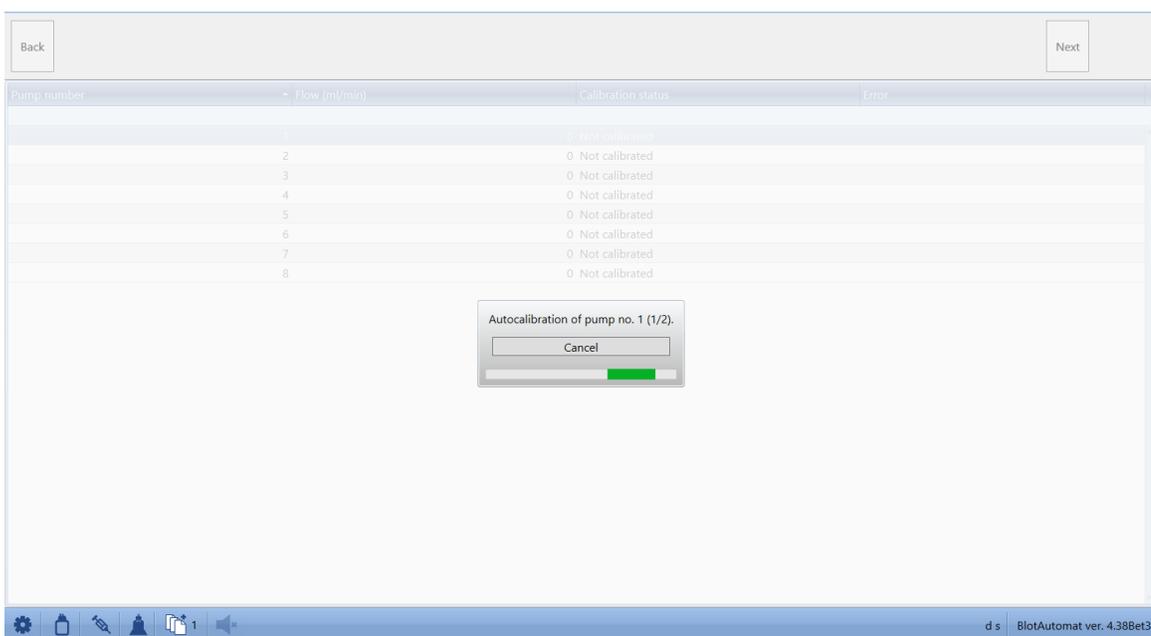
### Step 3 - Autocalibration cuvette inserting



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”.

#### Step 4 - 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.

**Step 5 - Autocalibration results**

Pump number	Flow (ml/min)	Calibration status	Error
1	82	OK	
2	76	OK	
3	0	Not calibrated	
4	0	Not calibrated	
5	0	Not calibrated	
6	0	Not calibrated	
7	0	Not calibrated	
8			

EUROBlotOne  
Pump autocalibration finished.  
OK

d s 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**”.

**Step 6 - 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.

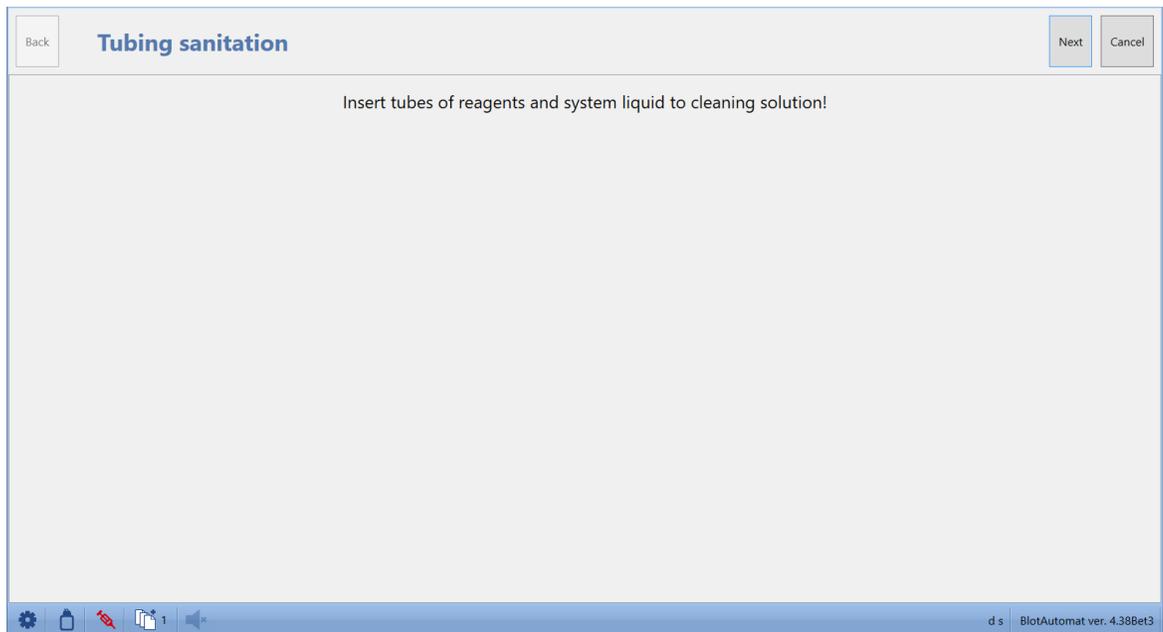
## 2.4.4 Weekly maintenance

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.

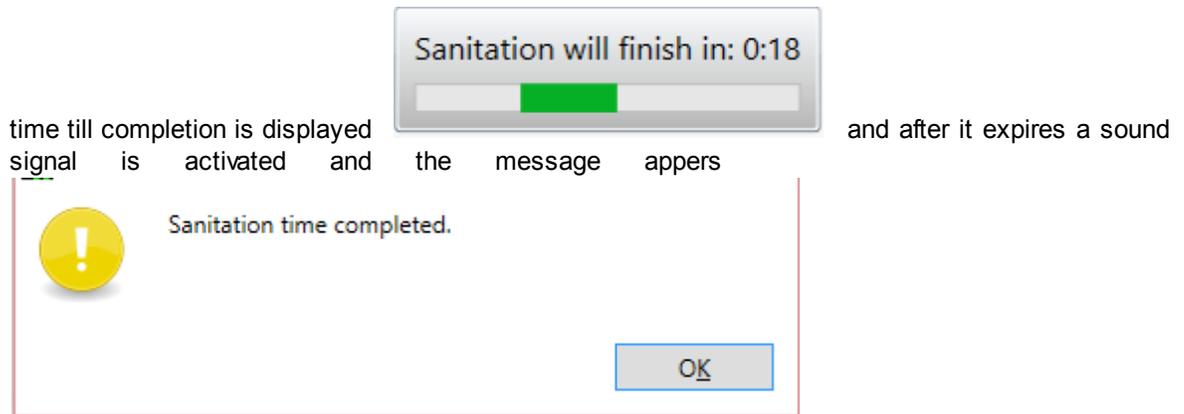
Weekly maintenance consists of several steps:

### Step 1 - Tubing sanitation



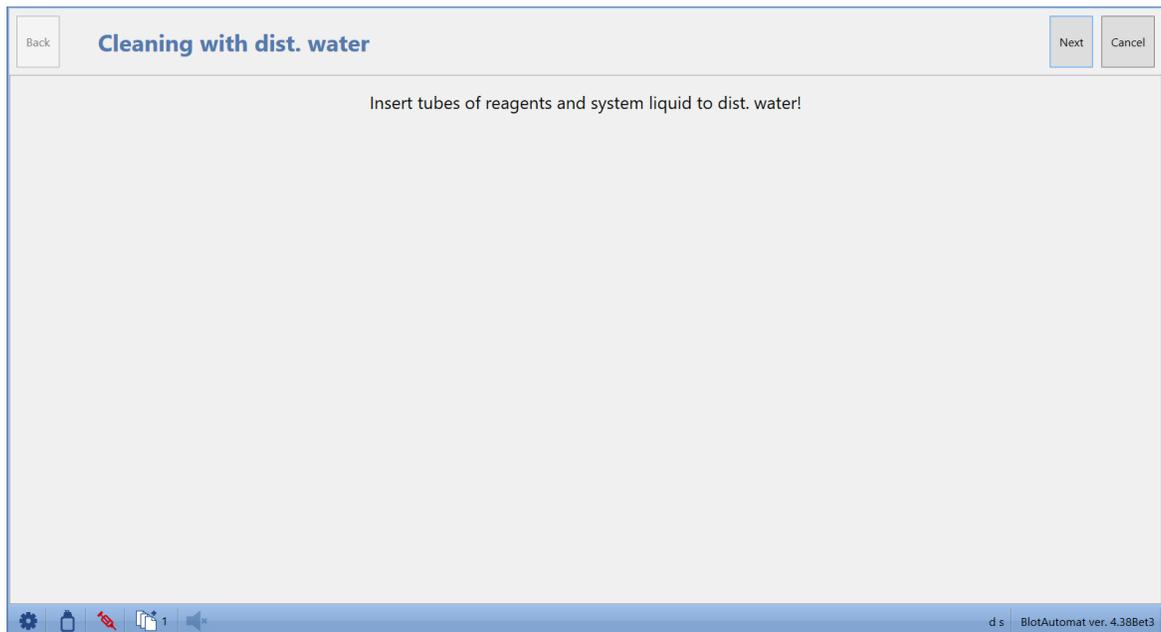
The user inserts the system solution and reagent pump tubing into a bottle with the cleaning solution. By pressing the **"Next"** button the system flushes tubes with a cleaning solution. The volume for the flush is set by *Pumps cleaning volume* in the menu *Application administration / Settings* .

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



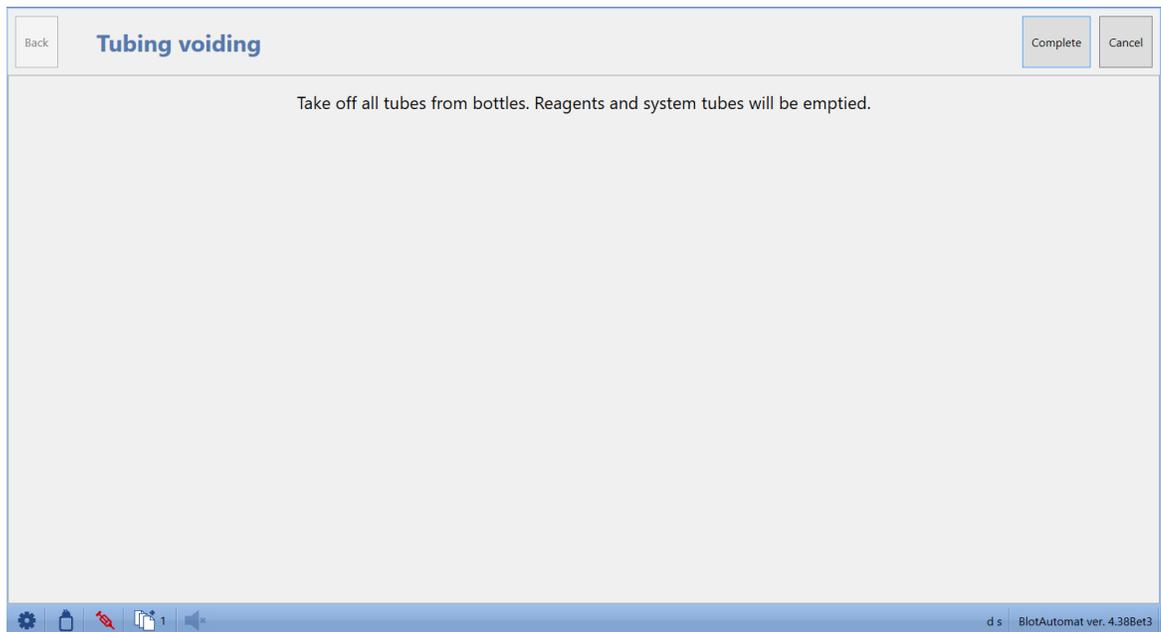
The time is set in by *Pumps sanitation time* in the menu *Application administration / Settings* .

### **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** - 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").

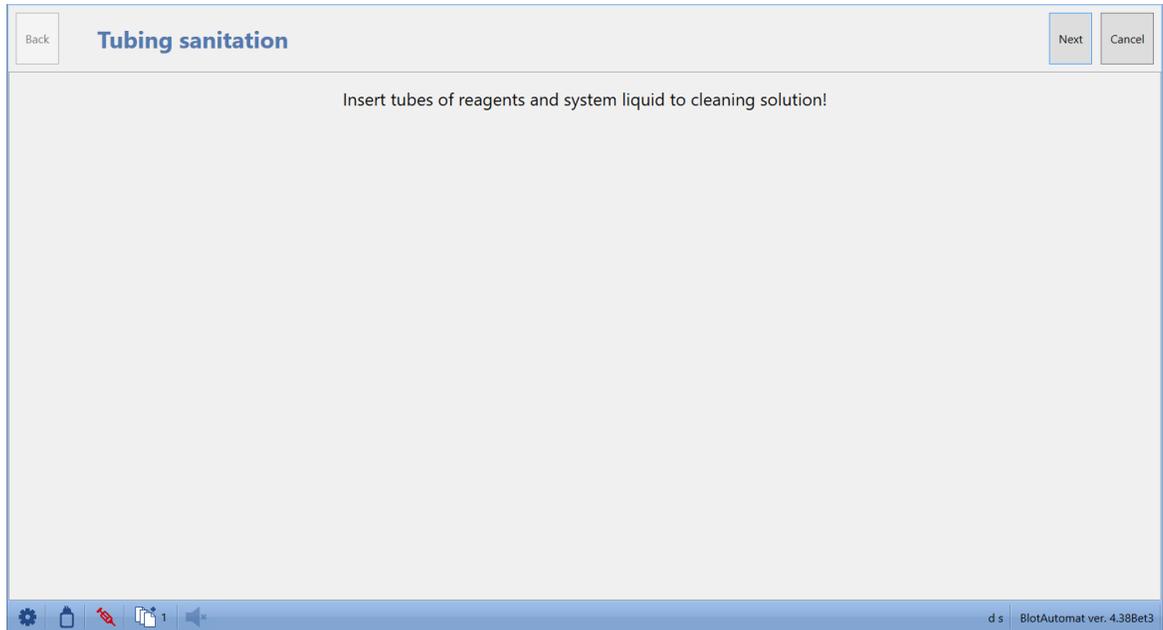
## 2.4.5 Monthly maintenance

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  in the status bar.

Monthly maintenance consists of several steps:

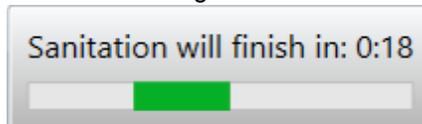
### Step 1 - Tubing sanitation



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*.

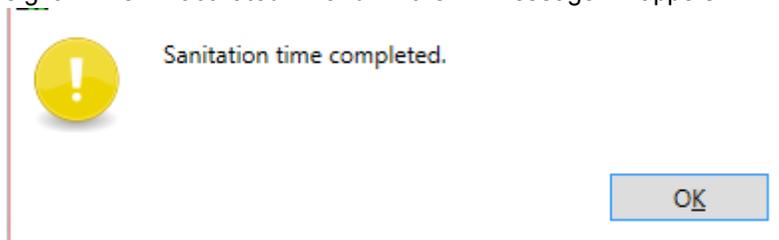
A period of sanitizing of the tubes with the cleaning solution follows. During this period the remaining

time till completion is displayed



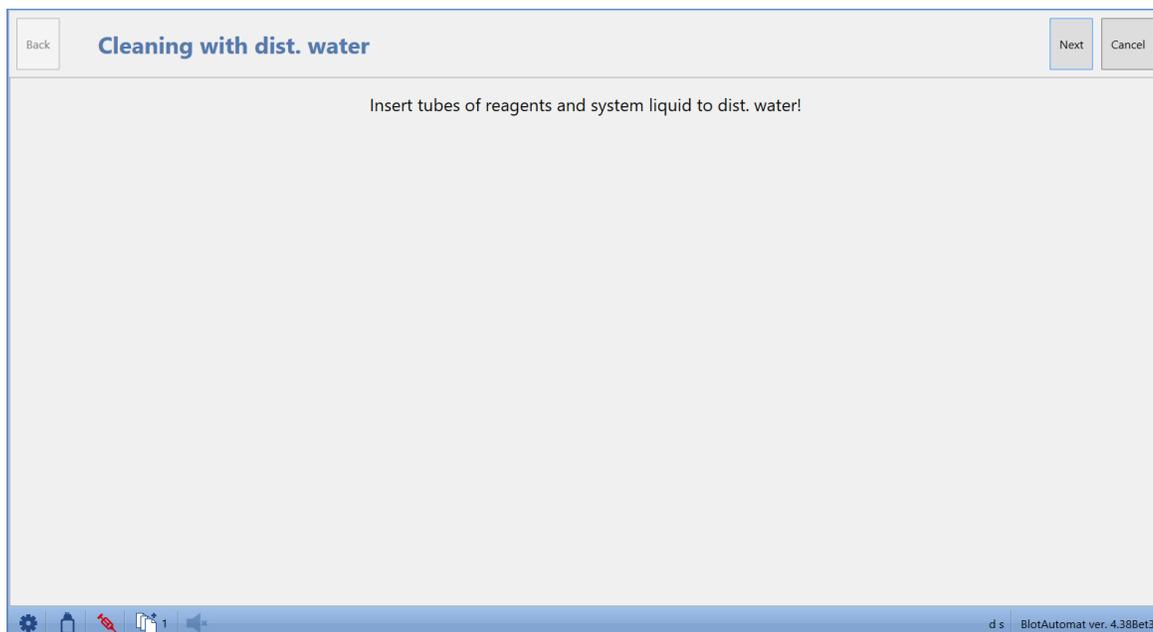
signal is activated and the message appears

and after it expires a sound



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

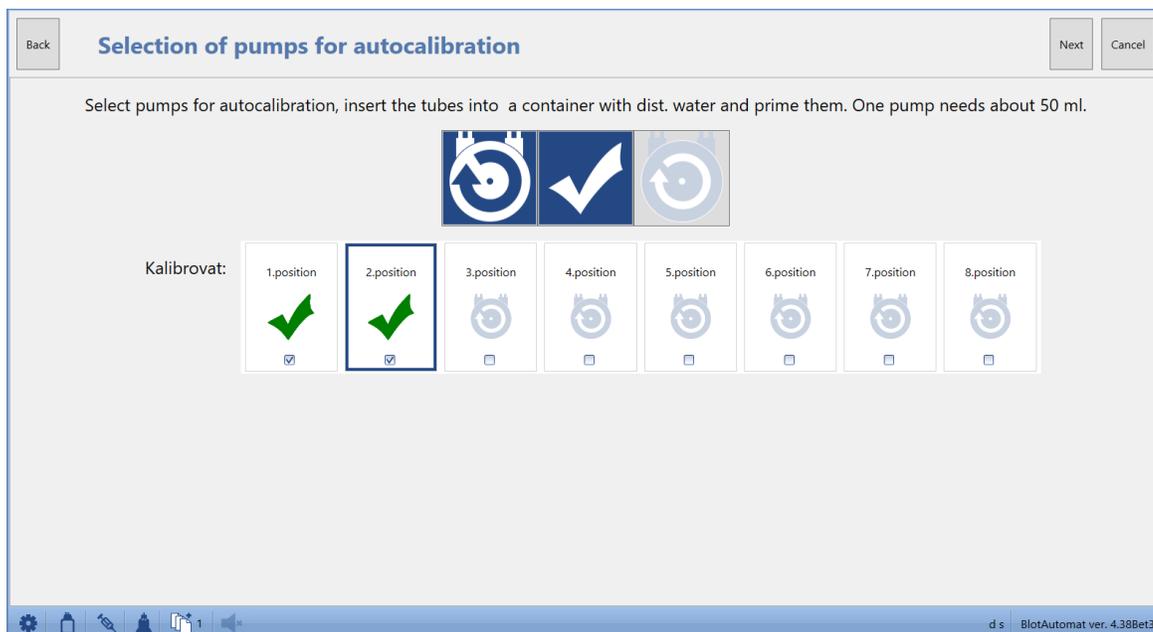
### Step 2 - Cleaning with DI water



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

By pressing "**Cancel**" 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

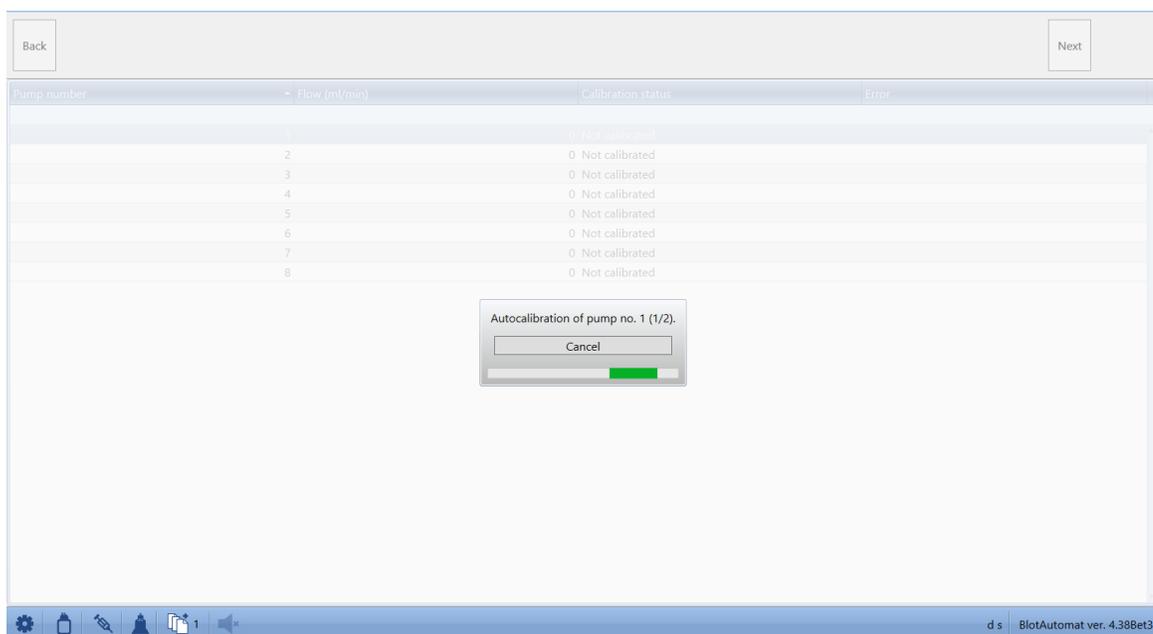


The user places the calibration cuvette on the upper case of the instrument according to the picture and connects the cuvette tube to the waste bottle with a self-closing clutch.

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

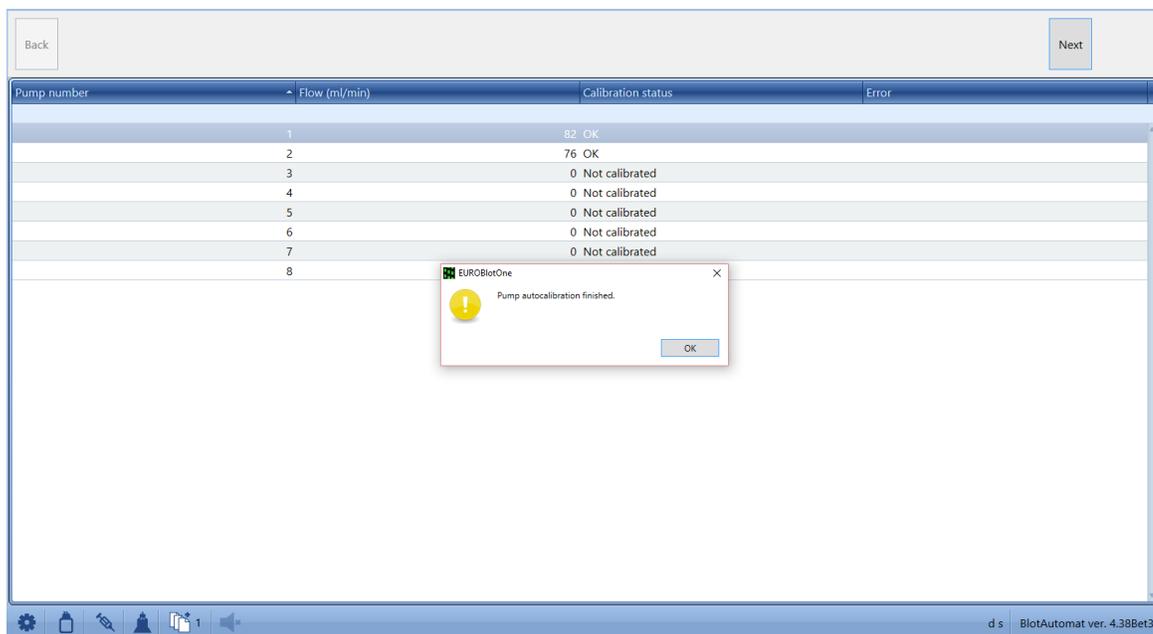
#### Step 5 - The process of autocalibration

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



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.

### Calibration results

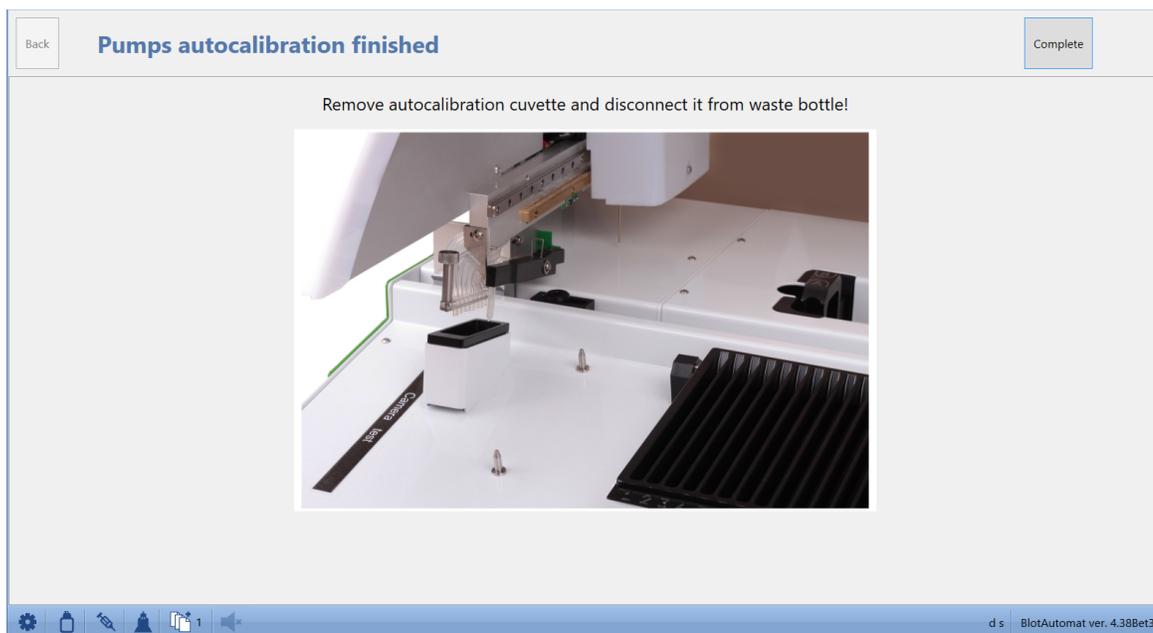


If the autocalibration is error-free and the value of the given pump is found in the requested range the pump status is set to "OK".

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.

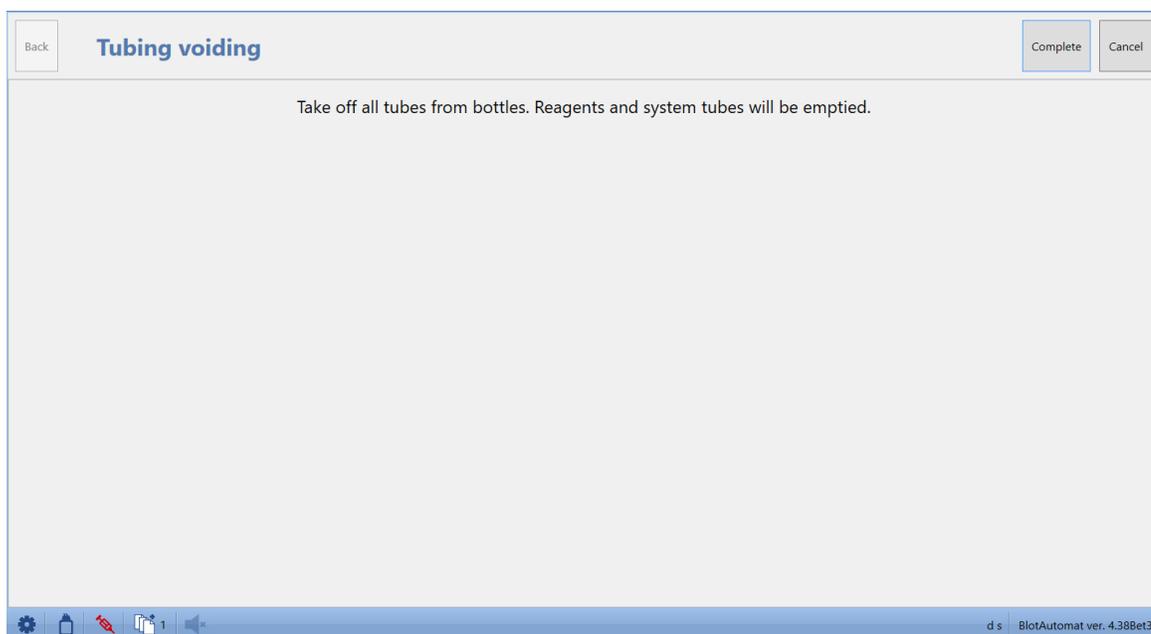
### **Step 6** - Pumps autocalibration finishing



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.

### **Step 7** - 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.

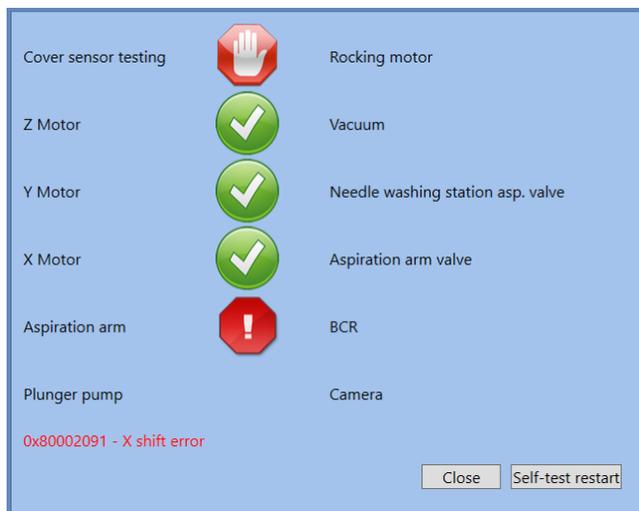
The self-test tests the following:

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

- |                                   |  |
|-----------------------------------|--|
| • 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 pipettor module) | - 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!

The self-test process is shown in the window



Meaning of the icons :



- test successful

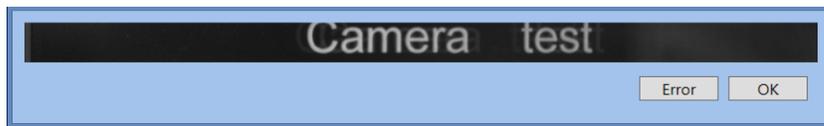


- error during the test. The error number and description are in red text in the window bottom.



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

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.



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



not

ready and



ready .

## 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

- 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.

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.

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.

Original password

New password

Confirm password

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

New password

Confirm password

Passwords are not identical

OK Cancel

Original password

New password

Confirm password

Invalid original password.

OK Cancel

### 2.5.3 List of users

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

Surname	Name	User name		
Polak	Karel	Polak		
Urban	Josef	Urban		
s	d	ds		
Schmidt	Johan	schmidt		
Salavova	Jana	Salavova		

The user information can be changed after pressing the icon at his line.

The button in an user line opens the window for his password change.

User

New password

Confirm password

OK Cancel

Pressing the eraser icon in an user line deletes his record.

The button *New user* opens window for a new user data entering.

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

functions. The role is selected by using of buttons  and .

Roles description :

#### **Administrator (admin)**

Full access.

#### **Service**

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

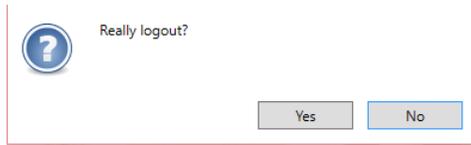
#### **User**

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

## 2.5.4 Logout

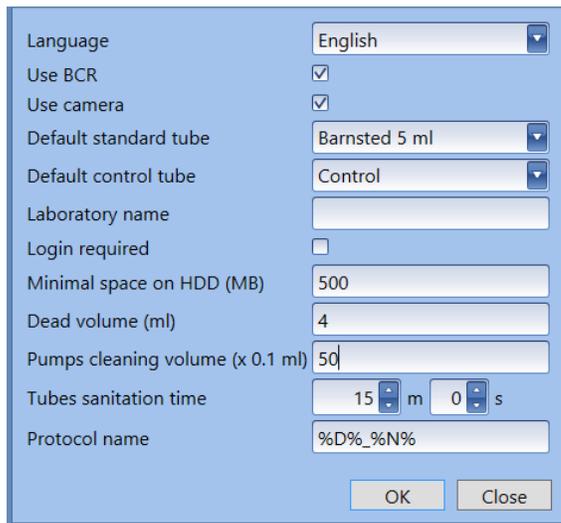
The logged in user may log out of the application. After choosing "**Log out**" the system displays a query, whether the user is sure he wants to log out. If the user presses "**Yes**", the system logs out the user from the application and updates the lower bar. If the user selects "**No**", the system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

User query



## 2.5.5 Settings

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



The screenshot shows a settings dialog box with the following fields and controls:

- Language: English (dropdown)
- Use BCR:
- Use camera:
- Default standard tube: Barnsted 5 ml (dropdown)
- Default control tube: Control (dropdown)
- Laboratory name: (text input)
- Login required:
- Minimal space on HDD (MB): 500 (text input)
- Dead volume (ml): 4 (text input)
- Pumps cleaning volume (x 0.1 ml): 50 (text input)
- Tubes sanitation time: 15 m 0 s (spinners)
- Protocol name: %D%\_%N% (text input)

Buttons: 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

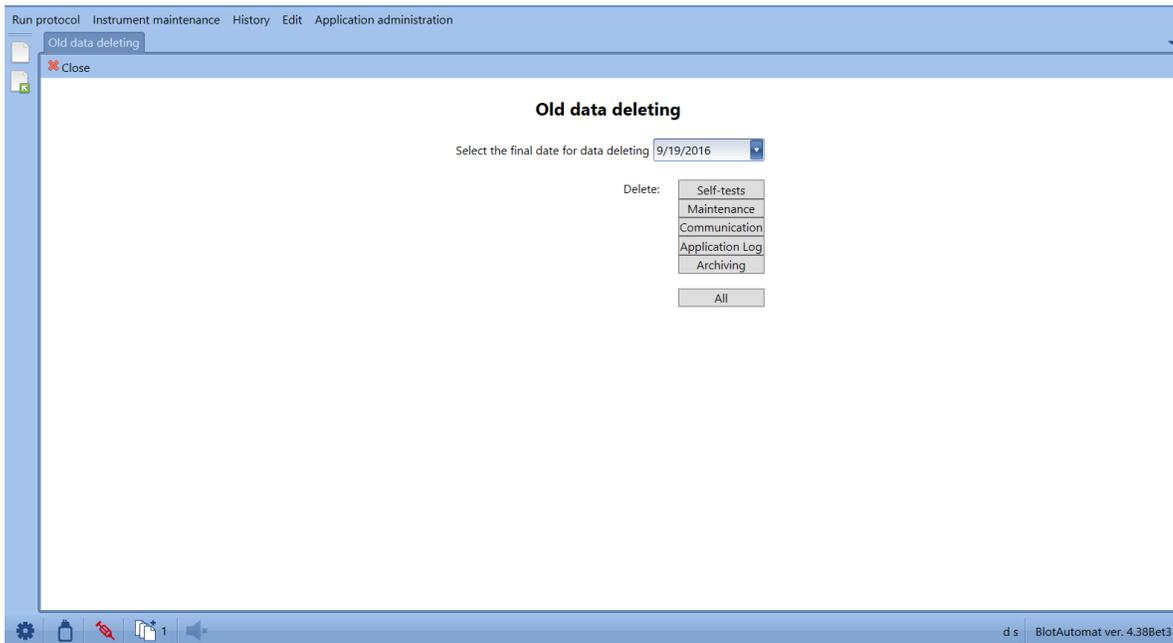
An Administrator or Service level user may remove unnecessary data from the application, which would otherwise use the computer's memory. Removal of the data is an irreversible process.

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 according 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

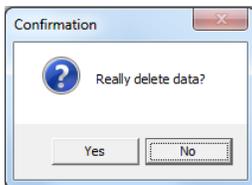
- All - all types of records



The calendar window can be opened for date selection :



The selected data will be removed after confirmation :



## 2.5.8 About application

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

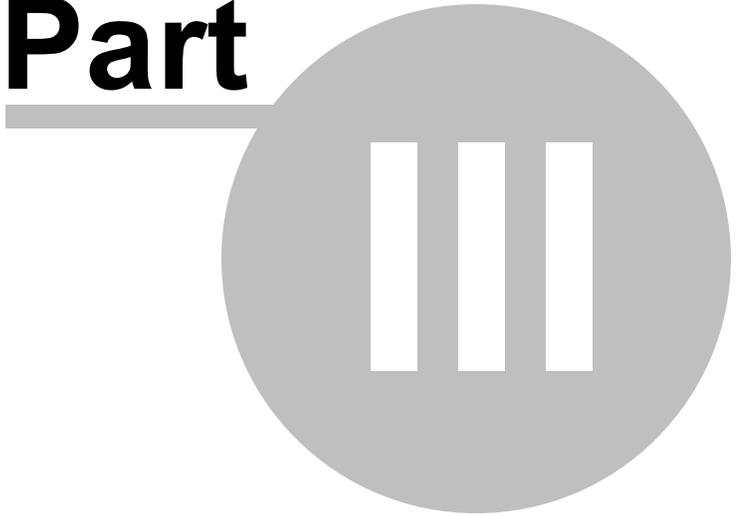
**Application author** - ASD Software, s.r.o. with a link to the website

**Name of laboratory** - name of the lab, which uses this application

**Help** - link to the application help



**Part**



## 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:**

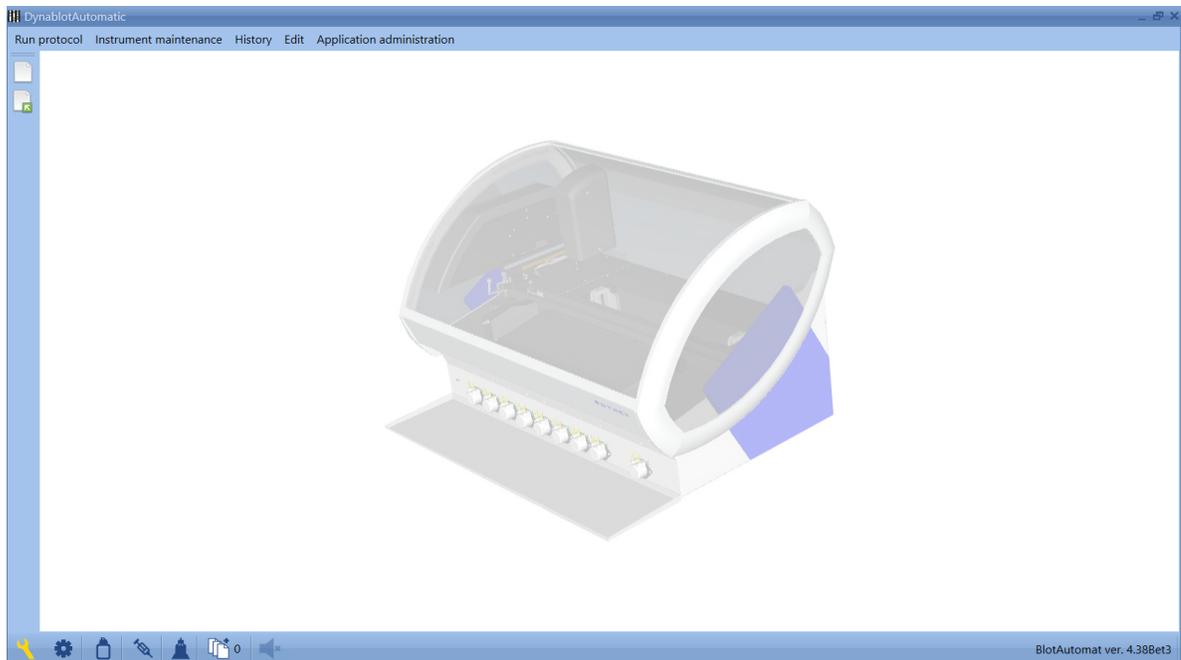
- Starting the application
- Changing the default settings
  - Principle of the protocol run
- Creation of assays and test
- Preparation of the instrument for testing
- Sample testing
  - Shooting of the imported protocol
  - Monitoring the instrument's status
- Maintenance
- Ending the instrument's 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 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. H<sub>2</sub>O, 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 assigned 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* , primarily 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  and you can repeat it by menu *Maintenance\Run 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.

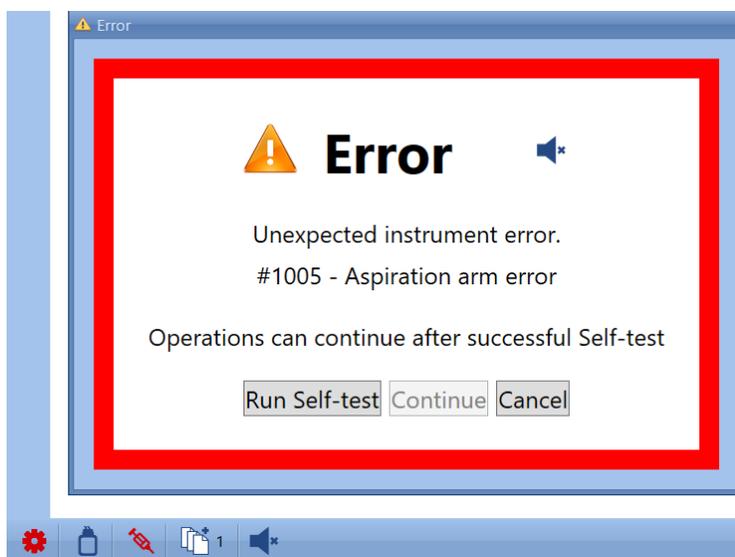
The maintenance history can be checked in menu *History / Maintenance history*.

### 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



### 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 requires 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 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 not active



signal is active. By clicking on the icon it 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 liquid 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 cassette 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  or extra according to a need, for example if the user suspects that the tubing is contaminated.

- 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. - Protocol receiving

Query - external system sends a protocol into the application, the application system performs a check of the protocol for uniqueness of ID samples, known tests and number of tests (maximum of 44)

Reply - 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

processing  which is one more than before.

#### Service 2. - Device status report

Query - external system sends query into the application about the instrument status

Reply - 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 3. - **Protocol status report**

Query - external system queries the status of the specific protocol

Reply - 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**

Query - external system requires the strip image (protocol ID and the order number of the strip), which is processed in the application (status "Processed"/"Unprocessed - error")

Reply - the system of the application transfers the protocol strip image into the external system

#### Service 5. - **Protocol deletion**

Query - 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

Reply - 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)

#### Service 6. - **Sample ID taken by BCR transmitting**

Query - the external system requests the sending of samples IDs which were taken by the BCR

Reply - if the application is in the Worklist window and the reading of the sample IDs was done the application system sends samples IDs

#### Service 7. - **Processed protocols list transmitting**

Query - the external system requests the sending of the list of processed protocols with parametres "Date from" and "Date to"

Reply - the application system sends the list

#### Service 8.- **Processed protocol transmitting**

Query - the external system requests the sending of the processed protocol with parameter ID ( acquired by Service 7]

Reply - the application system sends the protocol

## 3.12 Samples ID reading for the export to the external system

The sending of the samples ID acquired by the instrument BCR is one of the functions of the communication with the external system. The external system uses the samples ID for the protocol creation. Then the protocol is sent to the instrument application to be processed as an imported protocol. If this protocol contains the samples ID acquired by the instrument only the BCR will not be used during the protocol run preparation again. The important condition is that the tubes positions in the rack must not be changed between the sample ID reading and the protocol run.

The procedure of the samples ID reading for the export to the external system is similar like the New protocol preparation - see Run protocol / New protocol . The rack with the tubes is inserted to the instrument and the samples ID are scanned - see Step 1. After the reading finish the samples ID sending can be done by appropriate function of the external system. The Worklist window is automatically closed after the transmission.



**Part**



## 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.

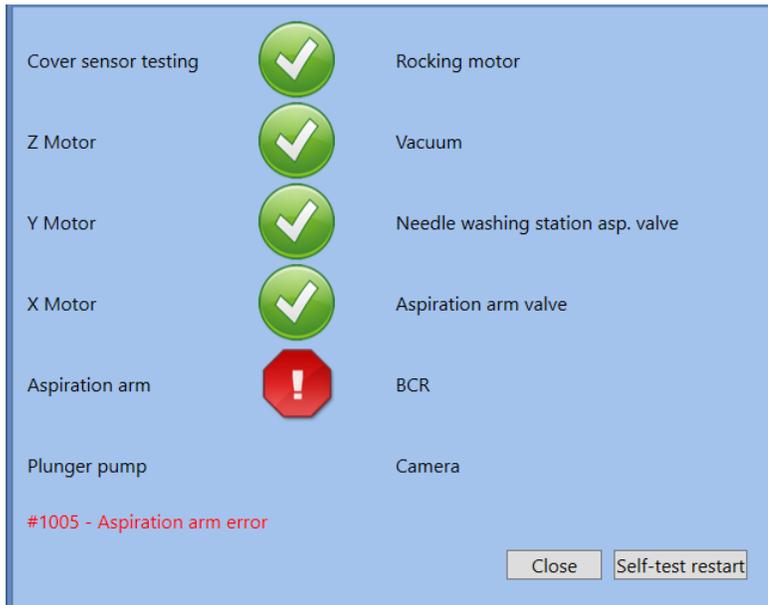
Error display

Error list

### 4.1 Error display

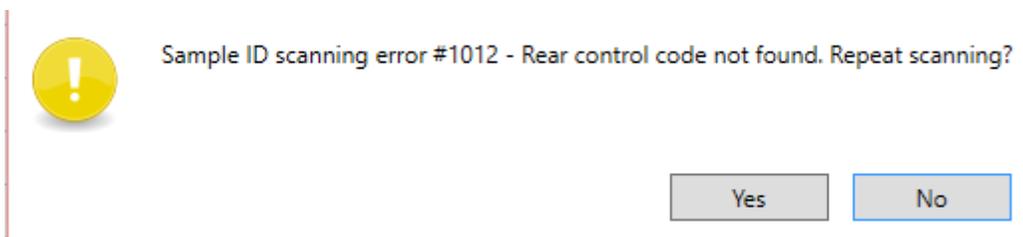
Errors are displayed in several ways according to the current activity of the instrument. The error type is identified by a number and description of the current activity.

#### Error display during a self-test



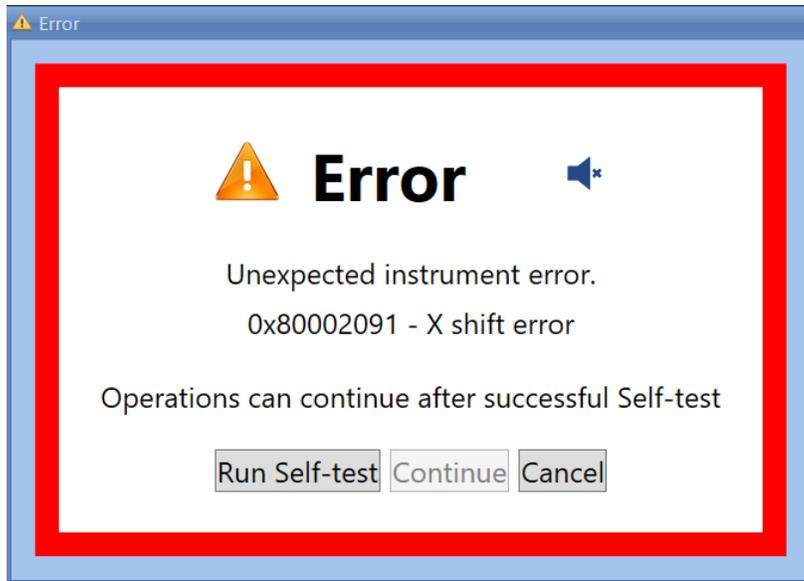
The number and error description are displayed by red text in the lower left corner. After the error is removed it is possible to repeat the self-test by pressing *Self-test restart*

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



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



The windows contains the error number and description.

The icon  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

Number	Name	Description	Corrective action
1001	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
1002	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.
1003	Y doesn't leave home	The referential sensor of y movement is unexpectedly constantly switch on	Probable movement hindrance, remove obstacle - run self-test. Referential position sensor or motor error - service required.
1004	X doesn't leave home	The referential sensor of x movement is unexpectedly constantly switch on	Probable movement hindrance, remove obstacle - run self-test. Referential position sensor or motor error - service required.
1005	Aspiration arm error	The aspiration arm sensor is unexpectedly constantly switch on	Probable hindrance of aspiration arm movement or the Y-movement, remove obstacle - run self-test
1006	Syringe doesn't leave home	The referential position sensor of the syringe is unexpectedly constantly switch on	Probable syringe or the system solution hydraulic circuits, run self-test. If the self-test is unsuccessful - service required
1007	Rocking doesn't leave home	The referential position rocking sensor is unexpectedly constantly switch on	Probable movement hindrance, remove obstacle - run self-test. Referential position sensor or motor error - service required.
1008	Vacuum switch error	Vacuum switch in the waste bottle unexpectedly switch on during self-test	Impassible aspiration tubing, remove obstacles - run self-test. vacuum sensor - service required
1009	Vacuum low	Insufficient vacuum in the waste bottle	Check the waste bottle seal after 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 self-test Vacuum pump, regulator or vacuum sensor error - service required
1010	Cleaning bows aspiration valve error	The pressure in the waste bottle didn't decrease when opening the pinch-valve of the aspiration of the cleaning needle cuvette	Impassible aspiration tubing, remove obstacles - run self-test. Pinch valve error - service necessary
1011	Strip aspiration valve error	The pressure in the waste bottle didn't decrease when opening the pinch-valve of the aspiration of wells	Impassible aspiration tubing, remove obstacles - run self-test.. Pinch valve error - service necessary

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 was 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

		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
102 3	Syringe 3-way valve error	.During the preparation of the system solution the 3-way valve wasn't switched and the system solution flows into the cleaning bowl through the syringe.	3-way valve error - 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 aspiration 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 required.
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	Communication and system commands errors	Call the service
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		
131 075	Constants motor/valve error		
131 076	SMS code not recognised		
131 077	Command code parse error		
131 078	Bad command code parameter		
131 079	Constants serialize error		
131 080	Dictionary argument error		
131 081	USB get data page timeout		
131 082	Property datatype not accept		
131 083	Errors buffer overflow		
131 098	USB get data failed		