

DYNABLOT **AUTOMATIC**



Quick guide



WARNING

Carefully read and follow the instructions provided in this document before operating the instrument.



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Area of Application – Intended Use

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Revision Table

Revision	Date	Changes
0	7-12	First issue
1	12-12	Replenishment for the first production serie
3	02 -15	Strips drying
4	08 - 17	Corrections for DBA Variant 3 (heating)
5	10 - 17	The manual face lift

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Warning, Cautions and Notes

The following types of notices are used in this publication and highlight important information or warn the user of a potentially dangerous situation:



NOTE

Gives helpful information.



CAUTION

Indicates a possibility of instrument damage or data loss if instructions are not followed.



WARNING

Indicates the possibility of severe personal injury, loss of life or equipment damage if the instructions are not followed.



INSTRUCTION

Actions to be performed.



WARNING

This symbol indicates the possible presence of biologically hazardous material..
Proper laboratory safety precautions must be observed.



ATTENTION

Negative environmental impacts associated with the treatment of waste.
Do not treat electrical and electronic equipment as unsorted municipal waste.
Collect waste electrical and electronic equipment separately.



WARNING

Risk of fire and explosion!
Several disinfection products can be flammable and when improperly handled can lead to explosions. Proper laboratory safety precautions must be observed.



WARNING

Chemical hazardous and biohazardous waste can be associated with the waste material from the process run on DBH.
Treat these substances and disposables, such as trays, system liquid, etc. in accordance with good laboratory practice guidelines.
Inquire about appropriate collecting points and approved methods of disposal in your country, state or region.



Symbols Used



Manufacturer



Date of manufacture



In vitro diagnostics medical device



Catalogue number



Serial number



Indicates the possible presence of biologically hazardous material



Conformité Européenne



Toxic



Hot surface



Use by



Single use



USB



Consult user manual



Warning



Instruction

1 Safety

1.1 Instrument Safety

- The responsible body must ensure that appropriate decontamination is carried out if hazard material is spilt onto or into the equipment. See chapter Instrument Disinfection.
- The responsible body must ensure that the manufacturer or his agent is consulted if there is any doubt about the compatibility of buffers, decontamination or cleaning agents with parts of the equipment or with material contained in it.
- The equipment must not be used in hazardous atmospheres or with hazardous materials for which it is not designed.
- The protection provided by the equipment may be impaired if the equipment is used with accessories not provided or recommended by the manufacturer, with solutions not compatible to the instrument or used in a manner not specified by the manufacturer.



WARNING

If DYNABLOT Automatic or the firmware is modified in any way, The performance of the instrument may be negatively affected. The warranty will no longer be valid and the instrument will no longer conform to CE.



WARNING

The instrument complies with the emission and immunity requirements described in ČSN EN 61326-2-6; the electromagnetic environment should be evaluated prior to the operation of the instrument.
It is the operator's responsibility to ensure that a compatible electromagnetic environment for the instrument is maintained, so that the instrument performs as intended.
Do not operate the instrument in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional rf sources) as this may interfere with the proper function of the instrument and may also lead to incorrect results.

2 General

2.1 Introduction

DYNABLOT Automatic is a fully automated device for immunoblot and westernblot strips processing and processing of biological samples according to its specifications.

The instrument is intended for "IVD - In Vitro Diagnostics" only!

Any test methods (assays) must be validated by the user in combination with the system in accordance with proper laboratory praxis and local laws before using DYNABLOT Automatic to conduct IVD.

The instrument can only be operated by trained personnel.



IMPORTANT

If the operating directions given in this USER MANUAL are not correctly followed, the instrument may be damaged or the procedure may not be correctly performed and the safety of the operator cannot be guaranteed.

Any *in vitro* procedure for diagnostic purposes, performed on the instrument, must be validated.

2.2 Area of Application

DYNABLOT Automatic is a laboratory instrument which automatizes carrying out tests using strip methods.

All systems must be validated in accordance with European directive on IVD 98/79/ES or another relevant regulation. The waste may be hazardous or toxic.

2.3 User profile

2.3.1 Professional User – Administrator level

The administrator is a person who has suitable technical training and corresponding skills and experiences. If the product is used as intended, the person is able to recognize and avoid dangers.

The administrator has extensive skills and is able to instruct the end user or the routine user in assay protocols within the bounds of the intended use.

Computer application skills is required.

2.3.2 End User or Routine User

The end user or routine user is a person who has suitable technical training and corresponding skills and experiences. If the product is used as intended, the person is able to recognize and avoid dangers.

Computer application skills and good language skills for the respective national language at the installation site are required.

2.3.3 Service Technician

The service technician is a person who has suitable technical training and corresponding skills and experiences. If the product needs to be serviced or maintained, the person is able to recognize and avoid dangers.

2.4 Validation

DYNABLOT Automatic has been validated for representative applications.



INSTRUCTION

When custom made protocols and/or reagents are used, the user must validate the test set-up.



NOTE

If DYNABLOT Automatic software or firmware are modified in any way the instrument loses its guarantee and will no longer be IVD compliant for Europe.



NOTE

The operating authority must use only CE-labelled test kits for clinical diagnostic applications.

The operating authority must assure that the combination of a particular CE-labelled test kit used with the DYNABLOT Automatic has been validated according to IVD directive for Europe or by other relevant national or local regulations.

2.5 Instrument Specifications

Instrument control	PC with SW application Dynablot Automatic
Operating system	Windows 7 Professional, 64 bit and higher
Communication with PC	USB 2

Strips Processing Section

Strips trays	Plastic, disposable
Number of wells in tray	Max 44
Strip shaking	By rocking, 3 speeds
Waste bottle volume	4 l, level sensor

Reagents Section

Number of reagent pumps	8
Dispense volume	0.1 – 5 ml po 0.1 ml
Dispense accuracy	< 10 %
Bottle for reagents	Individually by the needs of user

Primary Samples Section

System solution bottle volume	1 l, optical detection of the volume
Number of positions in the rack of the primary tubes	44 – standard tubes 4 – low-volume tubes (for control samples)
Sample handling volume	15 – 200 ul with resolution of 1 ul
Accuracy	< 2 %
Minimum volume for level detection	100 ul – standard tubes 50 ul – low-volume tubes

Strip Drying and Image Capture Section

Arm fan air flow	23 CFM
Working area fans flow	2 x 60 CFM
Tray holder heating (contained in the DBA instrument variant 3 only)	35 – 55 °C, (safety limiter 75 °C)
Image Capture Principle	CCD camera, 5 Mpixel, monochromatic
Resoulution	490 DPI
Wave lenght of lense filter and dominant wave lenght of LEDs in lighting	525 nm
Connection to PC	USB 2

Power supply	100 – 230 V AC 2,1 A Max 50/60 Hz
Safety fuses	2 x T2,5 A 250 V
Maximum power supply input	140 VA
Average power supply input (during assays running)	35 VA

Dimensions	810 mm(W) x 530 mm(D) x 495 mm(H)
Weight	40 kg

2.6 EU Directives, Technical Standards



On the basis of the following guidelines and information in the manual product carries the CE mark.

* For more information, see *Declaration of Conformity*.

Directive 98/79/EC about diagnostic medical devices in vitro

Risk management analysis was conducted for this instrument. This analysis is part of documentation of the instrument.

Directive 2014/30/EU: Electromagnetic compatibility (EMC)

The instrument was tested by an independent accredited test laboratory, which found that the instrument meets the requirements of following technical standards.

Measurement of radiated interference

Testing was performed according to ČSN EN 55011 Class B industrial, scientific and medical equipment - Radio disturbance characteristics - Limits and methods of measurement.

Endurance

The instrument was tested in accordance with ČSN EN 61326-1 electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements.

Directive 2014/35/EU Electrical safety (LVD)

The instrument was tested by an independent accredited testing laboratory, and is in conformity with the provisions of the directive 2014/35/EU relating to electrical safety.

Testing was performed according to the following technical standards:

ČSN EN 61010-1 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements

ČSN EN 62304 Software of medical devices – Lifecycle of Software processes.

The software is in accordance with the requirements of standard ČSN EN 62304.

Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

The instrument meets the requirements of the directive and does not contain hazardous substances covered by the directive.

Directives that are not designed to bring the CE mark but have a significant impact on the device's life cycle include the European directive on the disposal of waste electrical and electronic equipment.

For disposal are established rules that are in accordance with the European Directive 2012/19/EU on waste electrical and electronic equipment.

Disposal Recommendation



When recycling /disposal, contact your supplier. Please note that in case of contaminated instrument it is the user's responsibility to ensure that the product has been decontaminated before disposal, and the user is required to provide a certificate of decontamination for their suppliers, which will ensure the destruction of goods.

2.7 Instrument Description

DYNABLOT Automatic is a compact fully automatic desktop instrument for an automated processing of immunoblot and Western Blot assays from samples pipetting to camera image capture. Only insertion of samples into primary tubes, reagents preparation and insertion of strips into tray wells are required from an operator.

Its capability is up to 44 strips in one run and users can use up to 44 primary tubes which are located in a rack. The instrument is provided with a bar code reader for identification of the samples IDs. The primary samples are pipetted by a precise syringe. The detection of the sample levels in the primary tubes is controlled by a capacitance measurement principle. Reagents are dispensed by 8 peristaltic pumps. The pumps are located at the front of the machine for an easy handling. The pumps are capable of running in reverse. It enables the functions "Antidrop" (it prevents from dropping during dispensing) and "Reagents saving" (aspiration of the tubes volume back to reagent bottles after last dispensing). Wells content is aspirated to the waste bottle by vacuum. The waste bottle has volume of 4 litres and it is provided with a level sensors to prevent an overflow. A mixing of reagents in the tray during incubation is done by a rocking of the tray holder. Slow, medium or fast speed of rocking can be selected. The instrument is controlled by PC with the SW application for Dynablot Automatic. It communicates with the instrument via USB connection. The application enables easy and comfortable operation of the instrument, maintenance and assays programming. It is possible to combine varied (but compatible) assays in one protocol run.

The instrument is equipped by the fan placed on the working arm and the heating of the tray holder. Direct air flow and the tray heating improve the strips drying before their scanning by the camera. Two fans in the rear side vent the humidity from the working area.

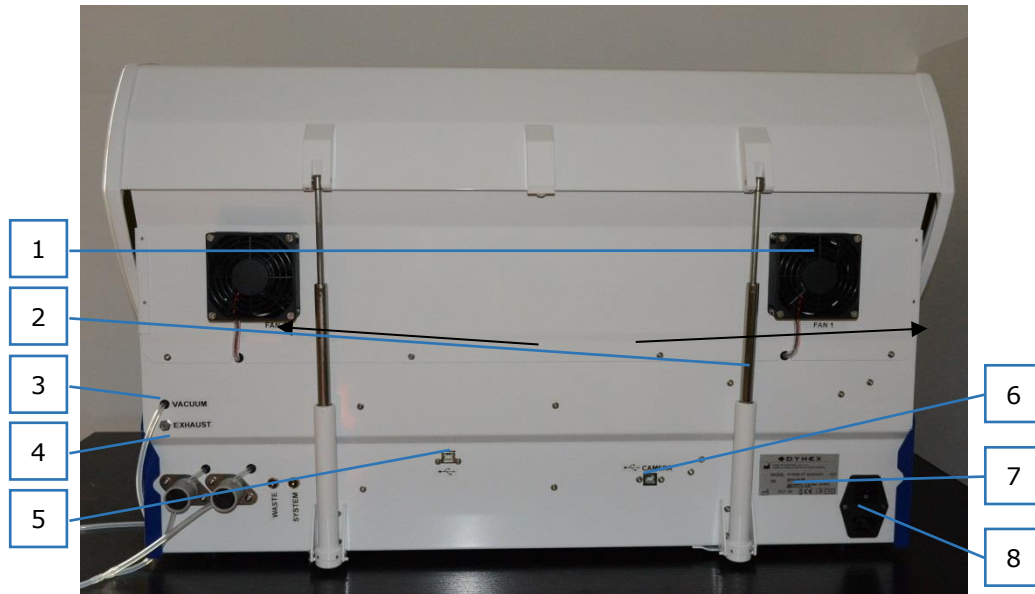
The instrument scans and saves strip pictures for automated analysis (special SW must be used for evaluation of pictures). The strip image capture is provided by a monochrome CCD camera. A green LED illumination is used during the scanning. The pictures are taken and saved strip by strip.

2.7.1 Front View



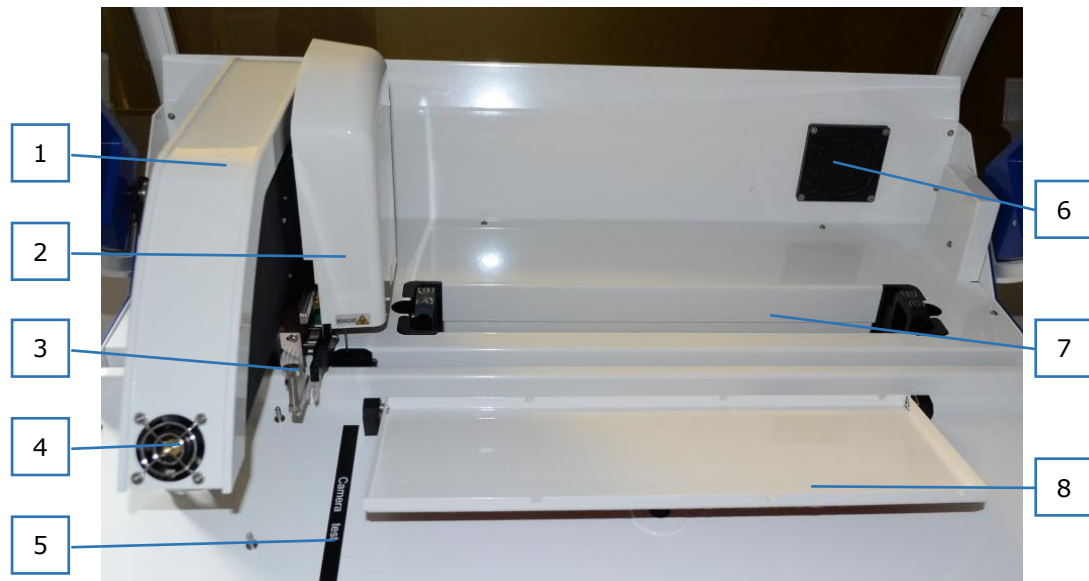
- 1 - power-on lamp
- 2 - peristaltic pumps for the reagents
- 3 - workspace cover
- 4 - peristaltic pump of the system solution
- 5 - reagent bottle pad

2.7.2 Rear View



- 1 - fans of the workspace
- 2 - spring struts of the cover
- 3 - vacuum tube outlet for the waste bottle
- 4 - vacuum pump exhaust
- 5 - USB device control connector
- 6 - USB camera connector
- 7 - manufacturing label
- 8 - power supply cable connection with integrated switch and fuse holder
- 9 - pinch valve of the aspiration cleaning needle cuvette
- 10 - pinch valve of the strip wells aspiration arm
- 11 - connector of the waste bottle liquid level sensors
- 12 - connector of the level sensors in the system solution bottle holder
- 13 - opened holder with the fuses

2.7.3 Workspace



- 1 - working arm
- 2 - pipette module
- 3 - filling and aspirating arms of the reagents
- 4 - fan of the strip drying
- 5 - label for the camera checking
- 6 - right fan of the workspace
- 7 - space for the sample tube rack
- 8 - the strips tray holder

2.7.4 Disposable tray

The disposable tray contains 44 wells. The well positions are numbered.



3 Installation Procedure

3.1 Introduction

This chapter contains the necessary information for installing the instrument.

3.2 Package Contents

1. Dynablot Automatic
2. Supply cable
3. USB cable 2 pcs
4. System solution bottle holder
5. System solution bottle 1 l
6. System solution bottle cap
7. Bottle tubing set DA21-08121
8. Priming bowl
9. Waste bottle with level sensors (4l)
10. Tube rack
11. Reagents pad
12. Pumps autocalibration cuvette
13. PC with accessories (keyboard, mouse)
14. Strips tray (10 pcs)
15. Setup clean (bottle 0,5 l)
16. Declaration of conformity
17. Final testing protocol
18. User manual

3.3 Unpacking Procedure and Inspection



NOTE

DYNABLOT Automatic is a heavy instrument. At least two people must carefully lift the instrument out of the box.

1. Visually inspect the container for damage before opening. Report any damage immediately on the installation report.
2. Place the carton in an upright position and open it.
3. Take out and set apart the packed accessories.
4. Lift the instrument out of the box and place it on a flat surface, free from dust, vibration, and away from direct sunlight.
5. Visually inspect the instrument for loose, bent or broken parts.
6. Report any damage immediately.
7. Compare the serial number on the rear panel of the instrument with the serial number on the delivery (shipping) note.
8. Check the instrument accessories with the delivery (shipping) note.
9. Take out all fixtures holding the arm and the tray holder in transport position.
10. Save all packing materials as they may be required for later transportation.

In the event of incompleteness, missing parts or damage of any part of the instrument upon delivery please contact DYNEX TECHNOLOGIES, spol. s r.o. or its representative.

3.4 Power Requirements

The device is powered by supply voltage, which must meet the values in accordance with the technical parameters of the device.

There is no need to set the instrument to the correct voltage.

Connect the power only to an electricity supply system with protective earth.

In case of an electric black out, a power failure occurs.

3.5 Environmental Requirements

The instrument should be placed on a level surface that is free from dust, solvents and acidic vapours.

Vibration, strong magnetic field, direct sunlight, draught, high humidity levels and large temperature fluctuations must be avoided to ensure correct results.

Operating temperature:	+5°C - + 40°C - this range is considered for the operation of the instrument itself. The used reagent kits temperature range must be taken in account for real operating. IMPORTANT: If the device was exposed to temperatures outside of this range, it has to be left to stand for some time before being turned on to be able to properly function in the given temperature range. Neglecting this procedure may lead to damaging of the device.
Storage Temperature:	1°C - 50°C
Operating altitude:	Up to 2000 MASL
Max. relative humidity:	80%, non-condensing

3.6 Instrument Installation Procedure



CAUTION

Before the instrument is installed and switched on, it should be left to stand for at least 3 hours so there is no possibility of condensation causing a short circuit.

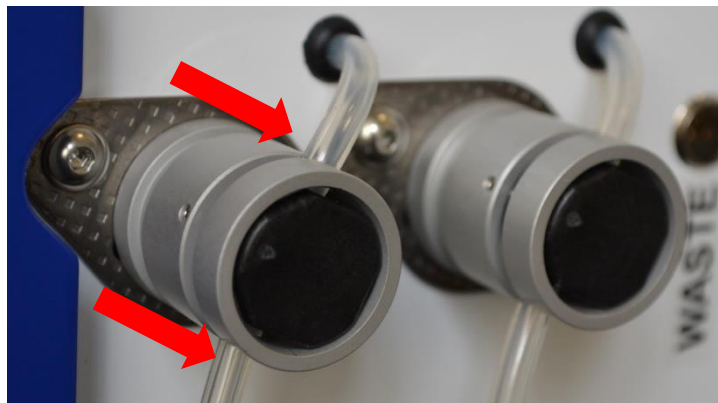
The following procedure describes the necessary steps to be followed when installing the instrument.

1. Place the instrument on a level surface.
2. Ensure that the distance between the back panel of the instrument and the wall is at least 10 cm.
3. Place the waste bottle near the right side of the instrument. Connect the tubes from the rear of the instrument to the connectors placed on the bottle cap – the "VACUUM" tube to the V connector and the tube from the Y fitting to the W connector. Connect the waste bottle overflow sensors connector to the connector "WASTE" on the rear side of the instrument. Tighten the bottle cap.



INSTRUCTION

Check the correct position of the tubes in the pinch valves. They must be placed in the back corner of the valves notch.



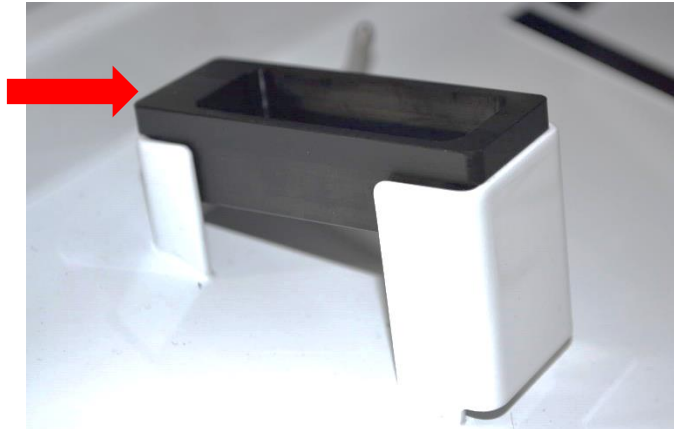
4. Put the reagent pad in front of the instrument below the peristaltic pumps.
5. Put the holder with the system solution bottle in front of the waste bottle. Connect the the tube of the system solution bottle cap to the "SYSTEM" pump on the front of the instrument. The connector of the level sensor has to be connected to the connector "SYSTEM" on the back side of the instrument.



6. Remove black caps from peristaltic pump tubes and connect tubes (Bottle tubing set) according to numbers 1 – 8.



7. Place the priming bowl to the frame at the left side of the working area (the wider edge backward).



8. Assemble the PC and connect it with the instrument by 2 USB cables to the connectors on the back side of the machine (sequence is not important).



9. Make sure the instrument switch is in the 0 position (Off). Using a power cable connect the instrument to a power socket with a protective earth.



INFORMATION

A two-year warranty will only be guaranteed if a completed copy of the enclosed Installation report is sent to the address of DYNEX TECHNOLOGIES, spol. s r.o.

4 Operating Instructions

4.1 Switching ON the Instrument

Switch on the instrument by the power switch (left back part of the instrument). The power on is indicated by a lightening of a blue pilot light at the front of the instrument.



CAUTION

Check for any possible obstruction to avoid collision of the moving unit.

Switch on the PC and start running of SW Dynablot Automatic. The instrument initialization and self-test automatically start.

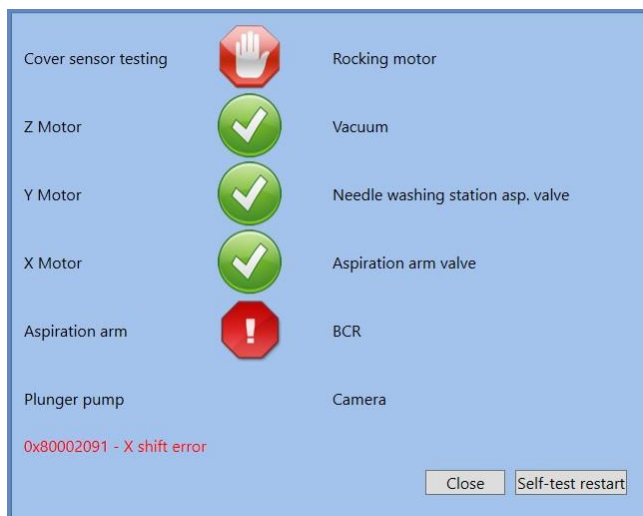
The aim of the self-test is to set the default positions of movements and ensure functionality of individual functional parts of the instrument.



NOTE

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

The self-test process is shown in the following window.



Meaning of the icons :



- test successful

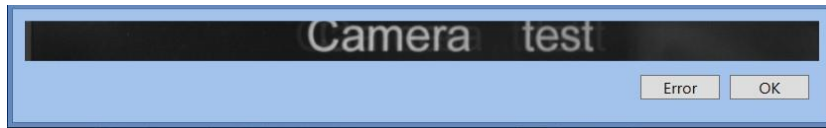


- error during the test. The error number and description are in red text in the window bottom.



- 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 the label 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 following steps and instructions with detailed description of the application software are stated in the User manual, Dynablot Automatic. It can be found as the on-line Help in the *About application menu* or in the electronic or printed forms.



4.2 System solution

The System solution must be prepared for the pipetting system. The solution can be diluted directly in the system solution glass bottle. The 3 ml of Setup clean are added to 1000 ml of distilled water.

Before the protocol run the bottle with system solution is inserted to the holder and the lid with suction tube is inserted inside it.



NOTE

Because the liquid level is checked by the optical system keep the bottle clean and do not place any irritating label on the bottle part which is placed in the holder.

The bottle with rest of solution can be closed by the blue lid and stored in the refrigerator. It can be used for next runs. The shelf life of the solution is 14 days from the date of preparation.



NOTE

A poor purity of the distilled water and the system solution bottle and also its incorrect storing can cause a contamination of the solution. It can cause a contamination during pipetting of the samples.

4.3 The instrument shut down

Close the SW Dynablot Automatic, switch off the computer.
Turn the instrument OFF by its power switch.


5 Maintenance

5.1 Cleaning

5.1.1 After each run

Clean tubes with distilled water after each protocol run. To do so use *Pump priming* menu offered after completing a run or it can be found in the *Instrument maintenancen* menu. Put the pump tubes into a vessel with distilled water and start the priming. The tubes will then be flushed with the set volume of water. The initial amount is 5 ml (per one channel). The volume can be increased in case of need of a more thorough flushing. The tubes can be emptied after cleaning by placing the tubes out of the vessel and starting the priming with a volume of at least 15 ml. Then wipe the rinsing cuvette surroundings. Empty the waste bottle and wash it out at the end of the workday.

5.1.2 Weekly and monthly cleaning

The application software watches the intervals of the weekly and monthly maintenance. The needed maintenance procedure is started by clicking the maintenance icon . The icon appears in the bottom bar when the time from the last cleaning expires. The cleaning procedures can be started from the *Instrument maintenancen* menu anytime.

5.1.3 Waste Bottle

Empty the waste bottle after finishing work. Keep the bottle clean. If needed, rinse the overflow sensor floats with water and detergent. Make sure the floats are able to move slightly on the guiding rod. The bottle cap has to be tightened during the work.

5.1.4 Workspace

Clean the instrument surface by a damp paper or cloth. If the pollution is heavy use some detergent. Clean the aspirating tube, priming bowl and their surroundings by isopropanol. The same procedure should be used for cleaning of the bottom end of the pipetting needle and neck of its cleaning cuvette.

If the bar code reader mirror is polluted, remove the tube rack of, switch off the power supply, move the working arm to the right so the mirror can be reached and clean it by a soft cloth (the cloth can be damp). You can use an alcohol for final cleaning.

5.1.5 Outer Surface and Cover

Outer surface and cover of the instrument may be cleaned using a soft tissue moistened with water and a mild detergent.



CAUTION

Never use organic solvents (e. g. acetone) – they irreversibly damage the cover.

5.1.6 Instrument disinfection

The user must ensure that the appropriate decontamination is carried out if hazard material is spilt onto or into the equipment.



WARNING

It is advisable to wear protective gloves, glasses and clothing when disinfecting the instrument.

It is very important that the instrument is thoroughly disinfected before it is removed from the laboratory or any servicing is performed on it.

Before the instrument is returned to the distributor for servicing, it must be disinfected and a disinfection certificate completed.

5.1.7 Disinfection procedure

The user must ensure that the manufacturer or his agent is consulted if there is any doubt about the compatibility or decontamination or cleaning agents with parts of the equipment or with material contained in it.



WARNING

Risk of fire and explosion!
Several disinfection products can be flammable and when improperly handled can lead to explosions. Proper laboratory safety precautions must be observed.



CAUTION

Please note that the disinfectant can influence the performance of the instrument if it is applied inside the instrument.

Filling and aspiration system disinfection

1. Prepare ca. 50 ml of disinfectant
2. Start the weekly maintenance and follow its steps
3. Wait the exposition time prescribed for the solution (it it differs from the Pumps sanitation time which is set in the *Settings* menu)
4. After the procedure finish turn the instrument off and disconnect it from the mains
5. Disconnect the waste bottle from the instrument. Empty it and clean it (including floaters)

Surface disinfection

6. Carefully spray the surface of the instrument and the workspace with a disinfectant (or use a disposable soft paper towel moistened with a disinfectant solution)
7. Repeat the previous step after at least 10 minutes of exposure
8. Wipe the surface of the instrument and workspace with a soft paper towel moistened with a solution of water and detergent or just distilled water after at least 5 hours of exposure and remove the remains of the disinfectant
9. Dry the surfaces with paper towels
10. Wrap the instrument and its accessories
11. Disinfect your hands, then wash them using a soap
12. Fill the disinfection protocol (App 1) and place it on the outer side of the box with the instrument for it to be clearly visible.

5.2 Reagent peristaltic pumps care

To keep the reagents dispensing accuracy it is necessary to periodically calibrate the peristaltic pumps. That eliminates gradual wear of plastic components and pump cassette tubing.

The pump calibration is a part of monthly maintenance. If necessary, it is possible to do the calibration in a shorter interval. Use the *Instrument maintenance / Pumps autocalibration* menu.

The peristaltic pumps are equipped with a changeable plastic cassette with the gearing and the tube. In normal use of the instrument it is recommended to replace the cassettes together with reagent tubes annually (See Service manual).

After changing of cassettes it is necessary to do training and calibration of these pumps.

Appendix 1 : Decontamination protocol

I declare that the instrument in this package has been decontaminated or disinfected to remove or inactivate any biological material, which could be dangerous to the service personnel, or that it has never been exposed to any hazardous biological material.

Contact person:.....

Company:

Function:

.....

Phone/Fax:

E-mail:

.....

Date of decontamination:

Method of decontamination applied:

.....

Date:

Signature:

.....

I declare that the instrument in this package has been decontaminated or disinfected to remove or inactivate any biological material, which could be dangerous to the service personnel, or that it has never been exposed to any hazardous biological material.

Contact person:.....

Company:

Function:

.....

Phone/Fax:

E-mail:

.....

Date of decontamination:

Method of decontamination applied:

.....

Date:

Signature:

.....