

Microplate Strip Washer

 **DYNAWASH**
A U T O M A T I C



Operator's Manual

CE

Version_04
Rev_22.8.2018

Information contained in this manual is required for the operation of the instrument. Therefore please read the manual thoroughly. Pay attention to notes related to the safe operation of the instrument.

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1 General guidelines and safety

1.1 About This Manual

The Operating and maintenance manual has been written for the user (e.g. laboratory technician) and provides information on the DYNAWASH Automatic instrument. This manual contains the installation, operating and maintenance instructions for the DYNAWASH Automatic instrument.

Read this Operator's Manual fully before use. The manual must be kept near the instrument and user must have an access to it at any time.

1.2 Safety Precautions

These symbols are intended to draw your attention to essential information and alert you to the presence of hazards as indicated.

I Power ON

0 Power OFF



In vitro diagnostic medical device



Caution: Biohazard risk



Caution: Risk of personnel injury to the operator or a safety hazard to the surrounding area.



Manufacturer



Date of production

1.3 Area of application

DYNAWASH Automatic is a fully automated device filling and aspirating the wash buffer into the wells of the 96well microtiter ELISA plate, according to specifications described in this manual.

For in Vitro Diagnostic (IVD) only!

Prior to the use of the DYNAWASH Automatic for IVD, any test methods (assays) or kits must be validated by the user in combination with the system according to common clinical laboratory practice, local legislations and state of the art.

The device must only be operated by the laboratory personnel who have been trained on the use of the instrument.

The instrument must only be used in accordance with its intended use.

Warning: Using the device outside the intended use range as specified by the manufacturer may invalidate the warranty for this product.

The instrument implementation is in accordance with EU directives.

The instrument is not approved for operation in the USA and Canada

1.4 CE Marking



The marking affixed to the equipment indicates that the equipment meets the requirements of the following Directive(s):

**More information in the Declaration of Conformity*

1.4.1 Directive 2004/108/EC: Electromagnetic Compatibility

The system has been type tested by an independent, accredited testing laboratory and found to meet the requirements of EN 61326-1 Electrical equipment for measurement, control and laboratory use – EMC requirements Part 1: General requirement

Emission

Verification of compliance was conducted to the limits and methods of EN 55011 – Class B Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement.

Immunity

The system has been type tested by an independent, accredited testing laboratory and found to meet the requirements of EN 61326-1 Electrical equipment for measurement, control and laboratory use – EMC requirements Part 1: General requirements.

Verification of compliance was conducted to the limits and methods of the following:

EN 61000-3-2 Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)

EN 61000-3-3 Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current 16 A per phase and not subject to conditional connection

EN 61000-4-2 Criteria A Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test

EN 61000-4-3 Criteria A Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test

EN 61000-4-4 Criteria A Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test

EN 61000-4-5 Criteria A Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test

EN 61000-4-6 Criteria A Electromagnetic compatibility (EMC) - Part 4- 6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields

EN 61000-4-11 Criteria A, C Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests

1.4.2 Directive 2002/96/EC: (WEEE) Waste Electrical and Electronic

Disposal Notice



This instrument contains printed circuit boards and wiring with lead solder. Dispose of the instrument according to Directive 2002/96/EC on waste electrical and electronic equipment or local ordinances.

Contact your local distributor for recycling/disposal. Please note that for contaminated devices (example, biological safety equipment), it is the responsibility of the user to ensure the product is decontaminated prior to disposal and to provide Certificate of Decontamination to the distributor/disposal agency.

1.4.3 Directive 98/79/EC: In Vitro Diagnostics as amended

The risk management analysis was done for this instrument. This analysis is a part of ISO documentation and CE documentation.

1.4.4 EN 62304:2006 Medical device software – Software life-cycle processes

The software of the instrument meets the requirements of the directive EN 62304:2006.

2 Specifications

State indication	3 x LED
	Color display
Control	Membrane keypad

Number of cannels	8
Number of solution	2 to 4

Number of pumps	2
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Wash bottle	Optional, according to the user
Waste bottle	1000 ml

Power supply	12 V DC (e.g. Switch adapter 100-240V, 50-60 Hz)
Input	12 W max
Fuse	T3,15A/250V

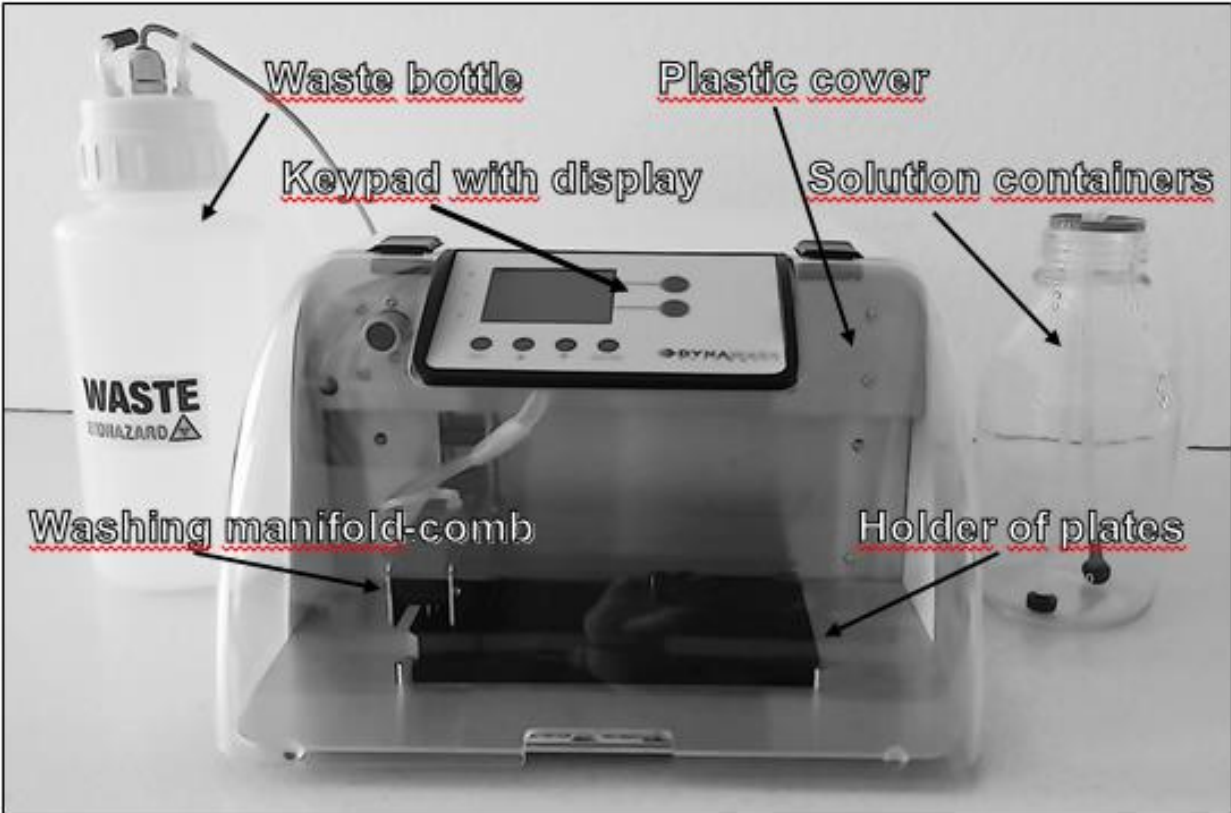
Dimensions of the main body	260 mm (W) x 360 mm(L) x 165 mm(H)
Weight	7,4 kg

3 Introducing the instrument

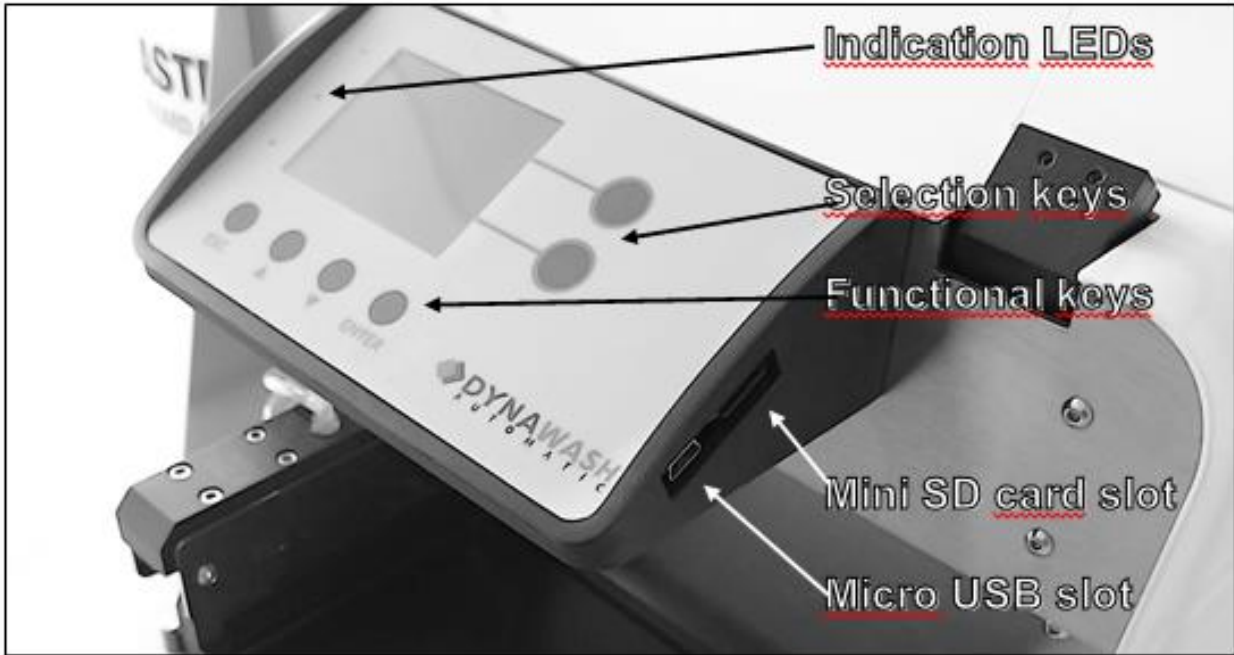
DYNAWASH Automatic is an 8-channel automatic washing device, structure of which allows the use of the standard 96-well microtiter plate. The wash cycle is fully automated, using arm movements with the wash manifold over all positions of the ELISA plate with a dispensing and aspirating pump.

The user interface provides a membrane keypad with a colour display. Washer software and washing user programs are stored in a micro SD card inserted into the right slot under the keypad. For the communication with the external PC a micro USB connector located next to the SD micro card can be used. By connecting the washer with a PC using software “Washer Assay Editor” any number of washing programs can be created limited only by the capacity of the SD card.

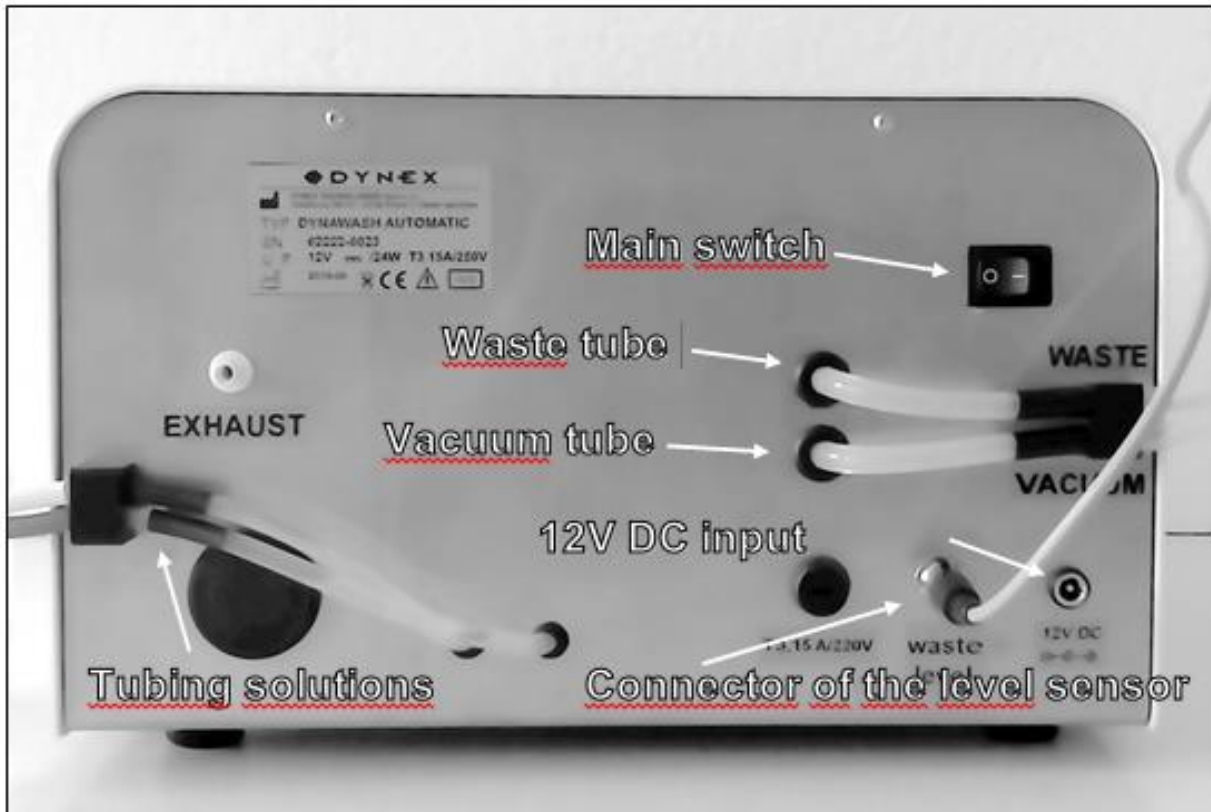
Front side:



Keypad, LED, USB connector USB and SD card slot:



Rear side:



4 Shipping, assembling and setting up the instrument

4.1 Shipping and unpacking the instrument

The device and its components are transported in special shipping containers protecting them from damage.

Unpack the instrument and components from the shipping container and check for completeness and condition of each item according to the following list:

1. DYNAWASH Automatic (main body)
2. Washing manifold - comb
3. Power supply
4. Waste bottle (1l)
5. Set of the clearing wires
6. Operator's Manual

If the washer is damaged or incomplete, please contact the DYNEX TECHNOLOGIES or your local distributor.

4.2 Environmental requirements

The device is designed to be placed in an indoor environment. Place the unit in a room so that it is protected from excessive dust, vibrations, strong magnetic fields, direct sunlight, drafts, high humidity or large temperature fluctuations.

Operating conditions:	+15°C - +40°C IMPORTANT: After transport or storage in humid conditions, dry out the unit (2-3 h) before connecting it to the supply voltage. Disregarding this process can cause damage of the instrument.
Storage conditions:	1°C – 50°C
Operating altitude:	max 2000 m
Maximal relative humidity:	80%, non-condensing

4.3 Setting up the instrument

Place the instrument on a desktop so that there is enough space around the unit for installation and handling of waste and washing solution containers. Remove the securing tape from the dispensing head and the filler which secures head movements. Insert the tubes into the solenoid valves. For 62222 type into the solenoid valve on the front panel, for 62224 type into solenoid valve on the front panel and into the solenoid valves on the rear panel.

Place the waste bottle on the left side of the device. Fit the waste tubing (shown in black) onto the outlet of the bottle labelled with the W symbol, the outlet is inside extended by tube (to avoid spraying the aspirated solution in the vicinity of the float). Fit the vacuum hose (unmarked) on the outlet of the bottle labelled with V symbol. Plug the connector of the waste bottle overfilling sensor into the socket on the rear of the main unit.

Put the individual tubes for working solutions into the appropriate containers (not included with the device). Tubes are marked for better orientation in colour, where **white is always intended for distilled water**, blue for buffer A, red for buffer B and yellow for buffer C.

Make sure the switch is in position 0, connect the power supply (adapter) into the wall socket and connect its output cable to the power connector on the rear of the main unit.

5 Language selection

Turn the device on using the switch at the rear. The green LED indicator - on. Wait until the initialization process fails. Pres the keys ▼ and ESC on the membrane keypad, then it will open the language selection menu:



Using the selection keys ▲ and ▼, choose the language and press ENTER to confirm. Selected language will be used even after switching off.

6 Operating of DYNAWASH Automatic

6.1 Switching-on the instrument

Turn the device on using the switch at the rear. The green LED indicates that the device is on. Wait until the initialization process is over. The screen initially displays information about activating device with the firmware version number (version number may vary):



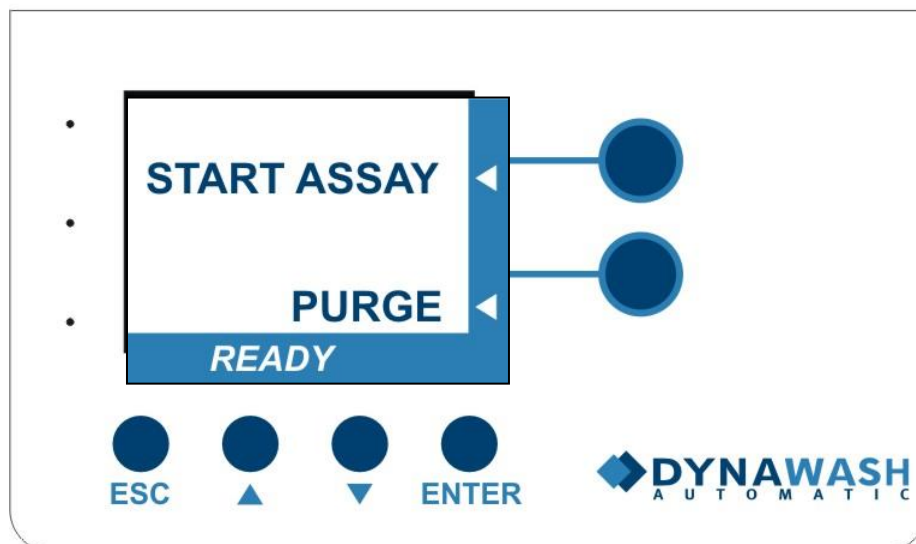
Readiness of the machine is displayed using the screen:



6.2 Description of the controls

Membrane keypad and display

All information is displayed on the colour display of the instrument and device functions are controlled via the membrane keypad.



6.3 Keypad signal lights

3 individual LEDs are located at the left side of the membrane keypad.

LED functions are from above:

Green – lights when instrument is on

Orange – indication of the firmware updating or service functions of the instrument

Red – lights when waste bottle is full

6.4 Membrane keys

Membrane keys are touch sensitive. Each pressing is accompanied by the sound signal.

6.4.1 Selection keys

Selection buttons refer to the current information on the display. Text information of the display shows the connection with the appropriate button. Function of the buttons is programmed by the software.

6.4.2 Functional buttons and arrows

The functional buttons are located under the display. The ESC button is used to exit the menu option one level back or to interrupt the ongoing program.

The ENTER button is used to select the function selected in the menu displayed on the display.

The up arrow “▲” and down arrow “▼” are auxiliary buttons for selecting functions referring to the position of the display. For example is the selection of the washing program by scrolling up or down. Further example is selection of numerical values by selecting a higher or lower number - rank first and last strip or the number of washes. The buttons are also used for final confirmation before running washing run - symbol YES, NO.

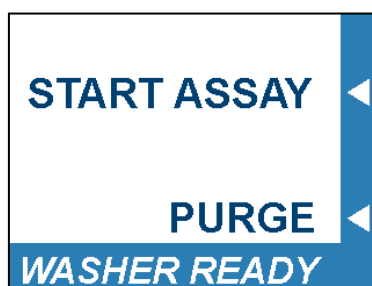
7 General usage guidelines

7.1 System Startup

Before starting the work, make sure that the waste bottle is empty, properly closed and connected to the device. On the right side of the main part of the device place the container with washing solution and insert the aspirating tubes with weights at their ends. Turn on the instrument.

7.2 PURGE

Choose the function PURGE from the main screen by using the function buttons.



The purpose of purging is to fill the working part of the pump, tubing and wash rack with washing solutions. For the correct functioning of the pump the air must be removed from all tubing and the pump must be filled with liquid.

Therefore, prior to washing put all tubes into the relevant solutions. If the wash buffer is not selected, insert the tubes into a container of distilled water. By pressing the button referring to the PURGE function (flushing) the pump is turned on and all solutions are gradually dispensed and aspirated through the wash manifold and waste tray. If visibly one of the solutions is not aspirated into the wash head (air bubbles remain in the tubing), this operation can be repeated several times.

Use the PURGE function also after the termination of the washing before shutting down of the washer. In this case, insert all the dispensing tubes in distilled water (you can use one common bottle). Rinsing with distilled water removes residual of salty washing buffers and avoids crystallization of salts in the area of the membrane pump. If the pump is not thoroughly washed with distilled water, it may be damaged by the residue and crystals from the washing solutions.

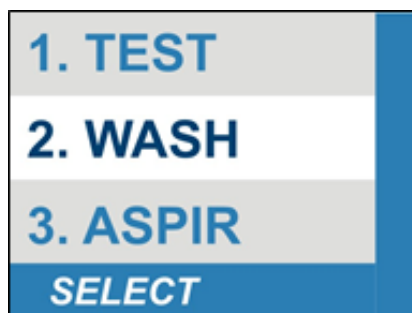
7.3 Run Wash Program

Open the plastic cover of the workspace.

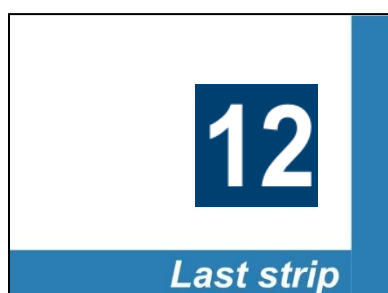
Place the microplate into the holder and close the cover. From the main screen, choose using the function buttons selected function – START ASSAY.

Afterward a list of washing programs stored in the SD memory of the washer is displayed. List of programmes and actual washing programs are created by the “Washer Assay Editor” program. Features of this program are described in a separate manual.

Press the ENTER button to confirm the selected washing program.



In the next step the request for the first, respectively last position of the strip, alternatively the number of repetitions of washing cycles is displayed:



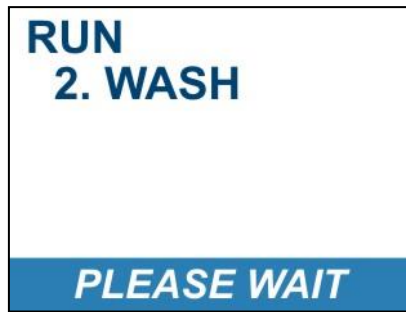
Select the number with the selection button and press ENTER. Once the selection is completed a well-arranged information window for the selected wash program appears:



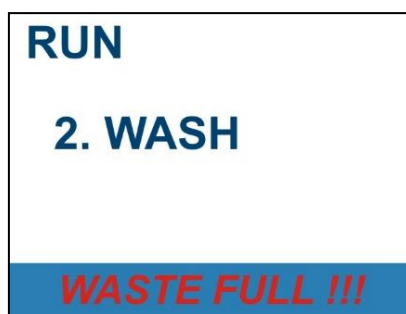
The outline of display and request for the selection of the first and last positions of the strip, as well as the number of cycles and final overview, may differ for various washing programs. It depends on the programming of the washing features in the “Washer Assay Editor” software. The function of the strip selection may be completely abolished and the final overview may not be displayed at all.

The actual start of the washing program is started by confirmation - highlighting the symbol YES with the arrow function keys and pressing ENTER afterwards.

The start of the washing program turns on the white LED illuminating strip above the plate and the display shows:

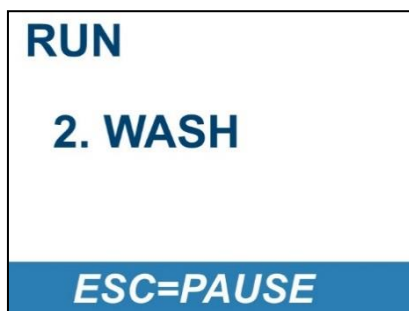


Do not open the plastic cover of the workspace during the washing process. The cover is designed to protect personnel against the aerosols from the washing solutions. In the event that during the washing is overfilled waste bottle, the red LED turns on the panel keypad. Information on the waste bottle full text is displayed in the bottom of the display:

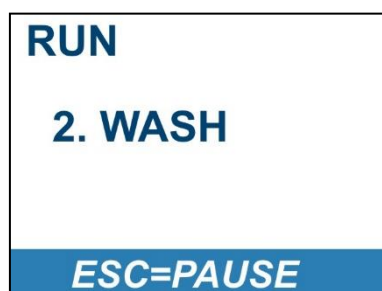


The wash cycle will be completed. But if you do not empty the waste bottle, you cannot re- run the next wash program.

The wash cycle can be interrupted by pressing the ESC key . Continuation of the wash cycle done by pressing ENTER.

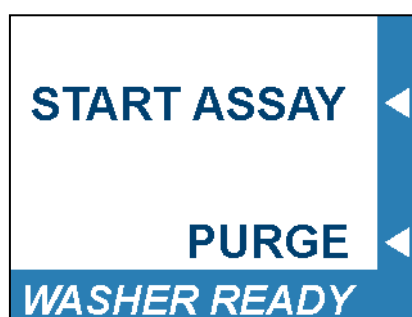


Ending the wash cycle is displayed:





“AGAIN” button starts the wash program with preset settings. Using the selection key to select EXIT, the machine returns to the menu selection washing programs. Press ESC to return the system to the start menu:



Before turning off the device, use the PURGE function, when you put all dosing tube in a container with distilled water.

8 Maintenance

The device is relatively maintenance free. The tubing should, however, be kept clean to ensure good operation of pumps and to prevent contamination of strips.

8.1 Cleaning of the main body

Clean the surface of the device with a damp paper or cloth. If particularly dirty use a detergent. In the event of the contamination, microplate holder can be removed and put back after cleaning.

8.2 Cleaning of the washer manifold

If your device is regularly properly rinsed with distilled water and the washing solutions do not contain debris (bacterial contamination, fibres and crystals) manifold does not need to be cleaned.

In the event of the blockage or malfunction of the dispensing and aspirating tube, remove the manifold from the bracket and clean the individual channels using the supplied cleaning wires. Simultaneously clean the outer surface of the tubes with a cloth soaked with alcohol; avoid fraying of the cloth at the edges of the tubes. Replace the manifold into the bracket and re-use the PURGE function. If you are unable to remedy the defect, contact a service technician.

8.3 Tubing exchange

We recommend carrying the tubing exchange once in every 2-3 years depending on their actual condition.

Tube exchange is carried out by service technician on request. For proper functioning of the tubes, we recommend to release the hose from the valve on the rear of the instrument once a month. Push the black part of the valve head to loosen the grip, slide the tube about 3 mm to one side, at the next check move the tube back in the opposite direction. Always make sure that the tube was properly seated after the release of the valve.

8.4 Long-Term Storage Maintenance

If the washer is not in use for more than 10 days, wash the tubing thoroughly with distilled water using the PURGE function. Consequently, it is recommended to remove all tubes from the container with distilled water and start the PURGE program with ingestion of air into the tubing. After switching off, release all silicone tubing from the valve on the rear panel. This will prevent the deformation of the tubing caused by long disuse. The re-launch of the washer must be preceded with the installation of tubing to the correct position of valves and re-filling of tubes and pump with distilled water using PURGE function.

9 Troubleshooting

Problem	Possible Solution
After switching on the green LED is not on, the pump does not work.	Defective power supply - replace the power supply. Defects in the electronics – hand over to professional service for repair.
Red LED is lit, the pump does not work.	The waste bottle is full - empty the bottle. The connector of the overfilling sensor is not connected - connect the connector.
Some of the wells are not filled with a solution or wells are filled unevenly.	Blocked dispensing needles – clear the needles using the thin wires from the cleaning kit.
The content of some of the wells is not aspirated.	Blocked aspirating needles – clear the needles using the thick wires from the cleaning kit.