



HELIA[®]

HELMED LINE IMMUNOASSAY ANALYZER

Automated Blot Analyzer INSTRUCTIONS FOR USE

- Valid from **HELIA[®]** Device Software 2.0 R1 /Patch D3



HELIA[®] Instructions for Use EN
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1 General Safety Information

1.1 General Information

GLP

Labwork and cleaning cycles should adhere to the GLP (Good Laboratory Practice) standards.

User qualification

The device may only be operated by sufficiently trained personnel.

Environment parameters

The device may only be operated in confined laboratory spaces (Pollution Degree II).

Patient contact

The device is not intended for near-patient contact.

Note to the user (European Union)

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

1.2 Symbols and their meaning

The following symbols will be used throughout the text:

Advice

ADVICE

Please wear gloves!



Immediately wash hands if skin was exposed!

Hazard notes

HAZARD

Skin irritation



0.3% Sodium hypochlorite

H314 Causes severe skin burns and eye damage!

Warning notes

WARNING

Caution! Biological materials!



Do not come in contact with biological materials.

1.3 Warning notes



Caution!

Please read the instructions for use (IFU) before working with the device. Always refer to these instructions to identify potential hazards and minimize any risks!



Notes on electromagnetic tolerance

Using this device in a dry environment especially close to synthetic materials (clothes with synthetic fibers, etc.) may result in potentially destructive electrostatic discharges that may, in turn, lead to faulty results.

Avoid direct contact with the electronic components of the device.

Before opening the hood of the device, the user must perform appropriate ESD measures.

Do not operate the device close to sources of strong electromagnetic radiation, as these may inhibit the proper operation of the device.

This device complies with the requirements of EN IEC 61326-1 on interference emission and EN IEC 61326-2-6 on electromagnetic immunity.

Note: It is recommended to perform an electromagnetic inspection before putting the device into operation.



Loss of supply voltage

Power outages may result in the disruption of process handling of the device. The process may, therefore, be canceled and/or restarted.

1.4 Hazard notes



Danger of electrical shock

The device must be connected to a grounded power supply to prevent the risk of electrical shock.



Crushing hazard on the cylinder and other moving parts

Do not open the cover of the peristaltic pump for the waste liquids during operation. The cylinders of the rotating pump may injure fingers and cause other injuries or crushing hazards. When opening the lid of the device, make sure that no other parts of the device are moving. Only touch any interior part of the device after all parts are no longer moving.



Avoid contact with biologically hazardous materials

Safe handling of biological agents. The sample tubes and the waste liquid in the two-liter waste bottle may contain infectious materials.

To prevent contact with skin or eyes, use personal protective equipment, such as lab coats, gloves, and goggles. Always comply with any applicable biohazard regulations.

Spills and cleaning

Should a sample spill onto the device, wipe off the liquid and disinfect the area immediately. For instructions, refer to chapter 8.3.

Dealing with potentially hazardous material

For disposal of any potentially hazardous material (e.g. consumables or broken material), refer to chapter 8.6 and 8.7.



0.3% Natriumhypochlorit:

H314 Causes severe skin burns and eye damage.



70% Ethanol:

H319 Causes serious eye irritation.



H225 Highly flammable liquid and vapor.

1.5 Advice

Appropriate use

The product is only to be used for in-vitro diagnostics!

Only qualified personnel especially trained in *in-vitro* diagnostics may operate the device. It is the responsibility of the clinical doctor or head of laboratory to work according to GLP, RiLiBäk or any other relevant standards. Use of this product in a different manner to that recommended by the manufacturer can make the protection provided by the equipment inoperable. The device must not be operated with flammable or combustible liquids.



Wear protective equipment!

Always wear personal protective equipment, such as lab coats, gloves and goggles, when handling biological human materials.

Use the provided cables only!

The **HELIA®** device is connected to a power source using the connector on the back of the device and using the power cable. The **installation category** is II.

Electromagnetic compatibility and electronic safety tests were performed using the cables provided by the manufacturer. If it becomes necessary to replace a cable, please contact your local distributor.



Disposal of device

Following the WEEE 2012/19/EU guideline for proper disposal of the device, local regulations must be followed when disposing the device or the device must be returned to the manufacturer. Details for disposal of the appliance see chapter 0.

Replacing fuses

When the fuses (2xT4A 250V; 5x20mm) must be replaced, ensure that the device is not connected to a power source before opening the fuse cover. Do not connect the device to a power source when the fuse cover is open. Only connect the device to a power source after the fuse was properly replaced and the cover was closed.

2 Product description

The **HELIA®** system is an automatic analyzer for line immunoassay processing with an integrated camera module.

The **HELIA®** system consists of the following components: **HELIA®** instrument, external all in one PC, keyboard, and mouse. Handheld 2D barcode scanner and the **HELIA®** device software. A printer is not included in the delivery.

This instruction manual is valid from the **HELIA®** device software, Version 2.0.

2.1 Principle of the device

The **HELIA®** system automates the processing of **AESKUBLOTS®** line immunoassays:

- Recognition of barcoded primary sample tubes,
- Generate worklist manually or via LIS request,
- Dilution and dispensing of samples,
- Dispensing and aspiration of reagents,
- Automated incubation and washing steps according to the test protocols,
- Automated reading at the end of the processing,
- Automated result calculation,
- Proofing the validation criteria,
- Result printing or result transfer to LIS,
- Documentation of results in an internal archive.

2.2 Intended Purpose

The **REF.LIA-1000-HELIA® Automated Blot System** is an immunoblot analyzer intended to aid for diagnosis that automates the pipetting, washing, incubating steps and result reading and reporting of line immunoassays (LIA) from Aesku.Diagnostics GmbH & Co. KG (**AESKUBLOTS®**) as well as from DST Diagnostische Systeme & Technologien GmbH including autoimmunity, infectious serology, allergy and food intolerance. The sample specimen are human serum/ plasma/ eluates from dried blood samples. The test result can be either quantitative or semi- quantitative. All suggested results obtained with the **HELIA® Automated Blot System** must be confirmed by trained healthcare professionals. The device is intended for professional use only.

Using a camera, the **HELIA® Automated Blot System** measures the intensity of the substrate reaction, converts it to grayscale, and uses standards to calculate a result for evaluation by the healthcare professional.

2.3 Legal and regulatory disclaimer

The **HELIA**® system is solely approved for in vitro diagnostics (IVD).

The system is typically used in a healthcare institution by professionals who have a formal education and expertise in performing IVD tests and using IVD instrumentation. These IVD tests are carried out repetitively and, in a routine, setting as part of healthcare service to the patient. Test results are interpreted by a healthcare professional as part of the clinical management of a patient.

Laboratories that use approved or cleared assays are requested to verify the performance of these assays in their laboratories before reporting patient results according to national regulations.

The information in the instructions for use (IFU) of an **AESKUBLOTS**® reagents kit is still valid and must be strictly followed, regardless of whether the is processed manually or automatically.

The highest risk class of IVDs running on the **HELIA**® system are class II IVDs (FDA, GHTF) or other IVDs (CE).

External factors (such as fluff) present during preparation may result in artifacts present in the generated image. These images should be discarded by the user and should not be used for diagnosis. Final optical examination of the strips in question should be done visually.

2.4 General and technical information

Test capacity:

- up to 9 different **AESKUBLOTS®** Tests/Lots

Sample Identification:

- by barcode. Up to 40 sample tubes

Incubations tray:

- total size 128 x 88.5 mm, with 8 troughs size 110 x 6 mm
- recommended maximum volume per trough 2.5 ml

Tray capacity:

- 5 trays

Inclination angle and frequenz of seesaw:

- $\pm 7^\circ / 26 \text{ min}^{-1}$

Incubation times:

- $\pm 15 \text{ min}$

Software Languages:

- available in English, German, Chinese and Spanish

LIS connection:

- TCIP/IP or ASTM

Pumps:

- 2 x peristaltic pump
- 1 x 50 μL syringe
- 1 x 1 ml syringe

Power consumption:

- 75 W

Fuse:

- T4A / 250V; 5x20mm

Voltage range:

- Input: 100– 240 Volt, 50– 60 Hz
- The Installation category is II

Power supply voltage fluctuations:

- Shall not exceed +/- 10% of the nominal voltage.

Transient Overvoltage:

- Device must be used in an overvoltage category II environment.

Operating conditions:

- Temperature: 20° - 35°C / 68° - 95°F
- Rel. humidity [rH]: 10% - 60%, non-condensing (electronic components specifications)
- Altitude: max. 2000m a.s.l.
- Indoor use only: **Pollution Degree II** environment

Storage conditions:

- Temperature: 0° - 40°C / 32° - 104°F
- Rel. humidity [rH]: 0% - 80%, non-condensing

Transport conditions:

- Only with the original manufacturer's packaging
- Temperature: 0° to 40°C / 32° - 104°F
- Rel. humidity [rH]: 0% to 80%, non-condensing
- Tilt angle > 50° / Shock > 50g / 0.11lbs

Dimensions and weight:

- 75 cm x 65 cm x 57 cm (depth x width x height)
- 31.5 kg (weight)

Camera:

- CMOS color image sensor
- 5-megapixel (2,592H x 1,944V)
- Autofocus

Internal Barcode scanner:

- 1D Barcode scanner for sample identification

LED module:

- Homogenous LED surface lighting

3 Installation

It is recommended that the initial installation of the device is performed only by trained personnel and in following the service manual. Before the device is entered into operation for the first time, certain configuration steps must be performed. Please note the following information:

3.1 Scope of delivery and setup

The **HELIA®** is shipped in suitable transport packaging. Upon receipt, please check for any visible damage caused by transport.

Remove the device along with all accessories from the box. Make sure that all the following items are present:

Note: The contents of delivery may differ if customer-specific accessories are ordered.

- 1x **HELIA®** device
 - 1x Monitor with integrated PC and user interface devices (mouse and keyboard)
 - 1x **HELIA®** Device Software version 2.0, already installed on the PC and on a data storage device
 - 1x Power cord
 - 1x USB cable (max. 3 meters)
 - 2x Wash bottle 1l
 - 1x Waste bottle 2l
 - 2x Reagent racks
 - 1x Sample rack
 - 1x Starter kit, including
 - 50 x 4 ml vials and caps
 - 50 x 20 ml vials and caps
 - 1x Calibration container
 - 1x Handheld 2D barcode scanner
 - 1x Needle cleaning tool
 - 1x Instruction manual
 - 1x Quick Start Guide
- Place the device on its designated spot and place the controller PC next to the device. The instrument must be placed on a level and stable surface. The air supply duct on the bottom of the device may not be blocked. This ensures the system's ventilation.
 - Open the instrument cover and carefully remove the cardboard protectors.

Note: Should the box and/or device be damaged in any way or should the device or accessories be visibly damaged, do not put the device into operation and immediately contact your distributor. Keep the original packaging for later shipment. The device may only be shipped in its original packaging.

3.2 Installation requirements

Requirements regarding the installation site for the device and the PC are as follows:

- Do not set up the device outdoors.
- Do not set up the device on flammable surfaces.
- Do not set up the device in a way that inhibits access (for care and maintenance processes).
- Do not set up the device in a way that blocks the ventilation openings.
- Do not set up the device on a site that may potentially become wet.
- Set up the device and control PC in a way that facilitates easy access to the power switch.
- Do not position the device in a way that makes it difficult to operate the main switch.
- ✓ **Caution:** The main switch does not disconnect the device from the electricity grid completely. Pull the power plug for this purpose.
- Do not set up the device, the control PC, or the connecting cables in a way that would bring them into contact with hot surfaces.
- Ensure that the power input (mains) matches the device's requirements.
- Set up the device on a flat, horizontal surface.
- Set up the device on a stable lab table and prevent any shocks to the device while operating (such as: vibrating machines, moving the table, manipulating the Bottles, etc.).
- Do not set up the device near a source of dust.
- To move the unpacked device, one person per side is required, for a total of 2. The device's center of gravity is located toward the back of the device. Carry the device with one Hand at the front base, and the other hand on the rear base of the device. This prevents the device from toppling over. Both persons should lift the device evenly and place it on the designated table.

3.3 Connections/ Connectors

3.3.1 Fluidic connectors

The quick connector clips for the washing buffers and the waste bottle are located on the device's back.

The bottles are marked as follows:

WASH # 1	blue	distilled water
WASH # 2	red	wash buffer
WASTE	black	waste bottle

The tubes are color-coded, respectively.

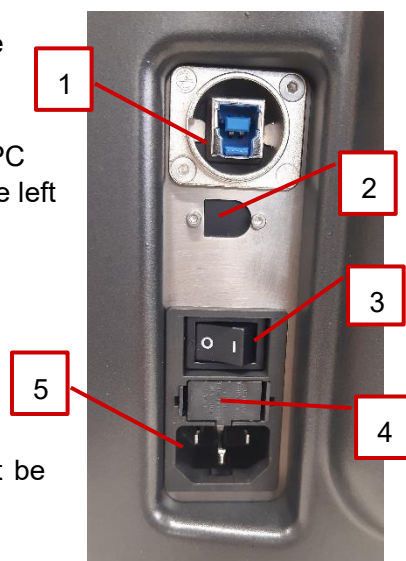


Note: Connectors for distilled water and wash buffer are inverted compared to **HELIOS®**

3.3.2 Electrical connections

The electrical connections can be found on the back of the computer and on the rear of the **HELIA®** device:

- **(1) USB 3.0 port:** Use the provided cable and connect the PC to the device by using the USB 3.0 Type B port located at the left backside of the **HELIA®** instrument.
- **(2) 24V DC out:** Not used for **HELIA®**, cover plate only
- **(3) Power switch:** To turn on/off the device.
- **(4) Fuse slot**
- **(5) Main power inlet:** The power inlet is located at the left backside of the instrument. The provided power cord must be connected here.



Note: Caution! A standard USB 3.0 has an ampacity of 900mA, which can be provided via the USB:

Standard	Voltage	Current _{max}	Power _{max}
USB 3.0/3.1 (Gen1)	5 V	0,9 A	4,5 W

Only connect a PC provided or recommend by Aesku.Diagnostics GmbH & Co. KG. Do **not** connect devices without double or reinforced insulation. Here, the external device USB port leads internally to a USB hub with separate power supply. No power is required via the external USB port as a result.

Note: Do not use USB hubs when working with the **HELIA®**!

Usage of USB hubs is not recommended by Aesku.Diagnostics GmbH & Co.KG. Power supply for each port can be interrupted when too many USB accessories are plugged in. Please use all available ports of your computer instead of a USB Hub.

Warning:



Connecting and disconnecting any device via a USB port should be avoided during the run, as this might lead to disconnection of the machine and a run stop.

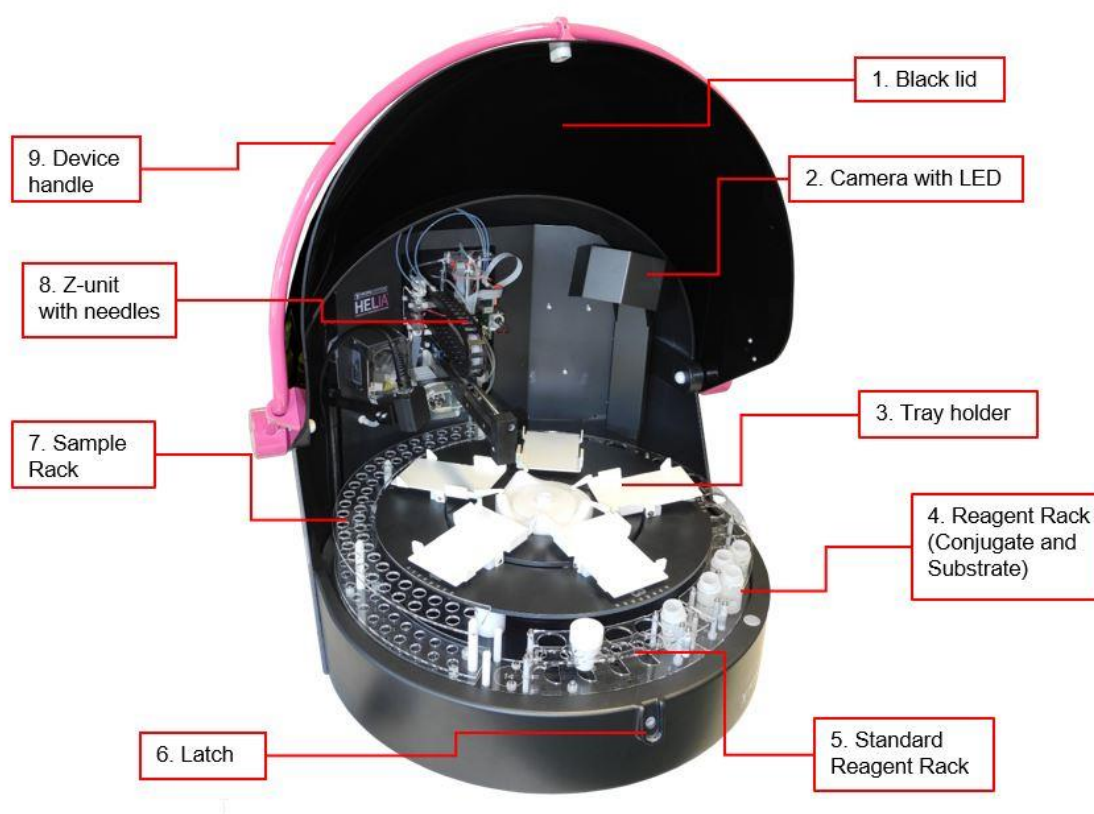
4 HELIA® device and system components

The following sections will describe the **HELIA®** device, as well as the various software modules in detail.

Note: The software is preinstalled on the delivered PC. For crash-free and safe use of the software, we recommend not installing any other software.

4.1 Device overview

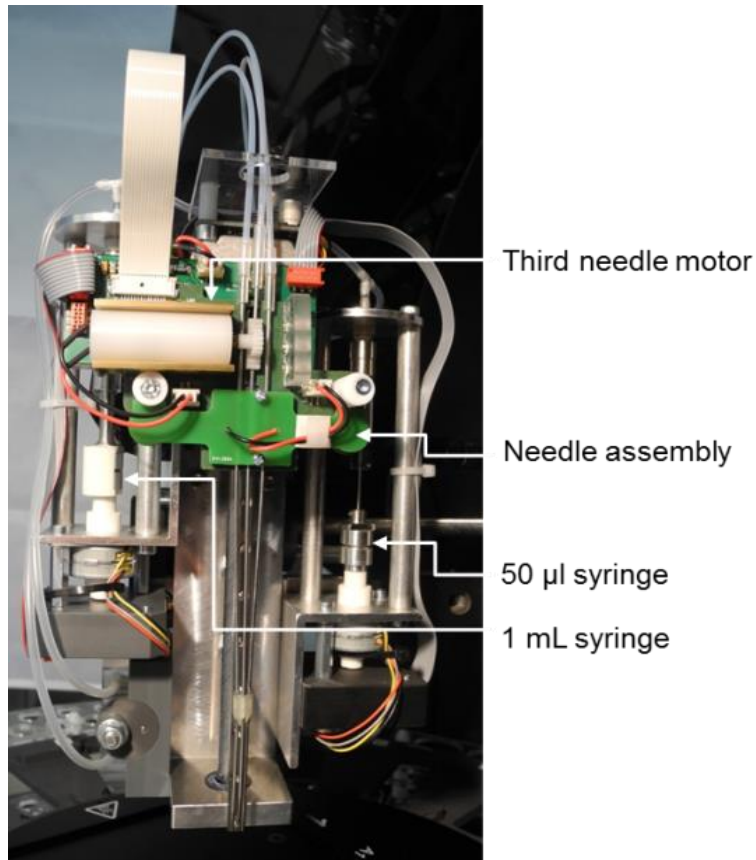
The following images will introduce you to the most important system components of **HELIA®**.



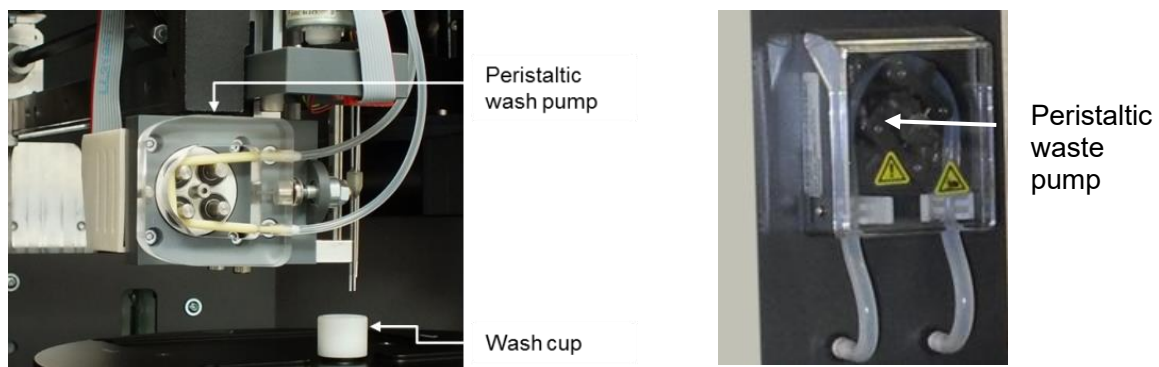
1. Black lid: Shields extraneous light and acts as a safety cover.
2. Camera with LED: Optical unit to capture images of trays.
3. Tray holder.
4. Reagent rack: Rack for conjugate and substrate bottles.
5. Standard Reagent Rack: Rack for sample buffer bottles and the calibration cup.
6. Latch: Locks the cover during operation.
7. Sample rack: Rack for samples tubes.
8. Z-unit with needles: Sample and reagents pipetting unit.
9. Device handle: For opening and closing the device.

4.2 Detailed view of the HELIA® system components

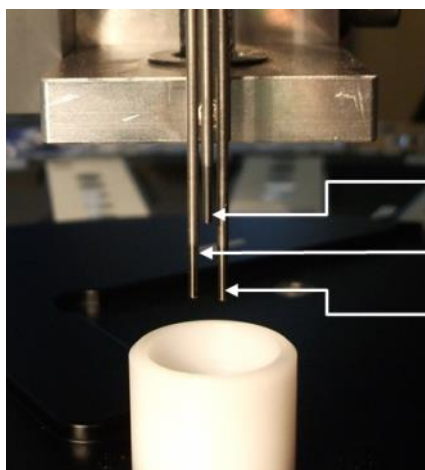
4.2.1 Z unit (pipette unit)



4.2.2 Peristaltic pumps



4.2.3 Needle unit



Middle needle (third needle)

Dispensing needle

Aspirating needle

4.2.4 Barcode reader (sample vials)

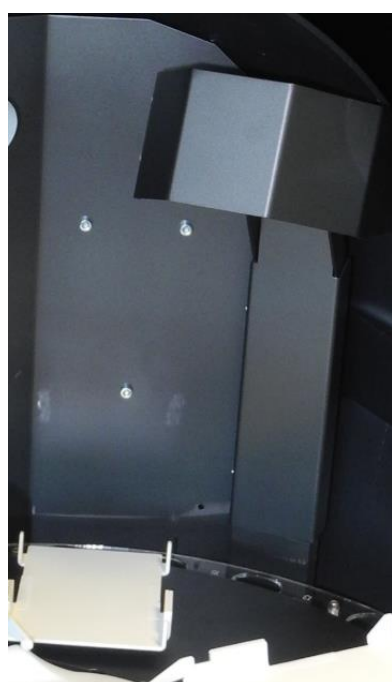


The barcode reader for Sample and Rack identification is located at the back of the device.

The user places the required sample tube rack into the **HELIA**®. Place the Sample tubes into the Rack with the Barcode facing towards the Reader. The Reader scans the sample ID and maps it to the respective tests. The Reader will also automatically identify the Racks

according to their barcodes. Several different sample tube racks - matching different vial sizes - are available.

4.2.5 Camera unit



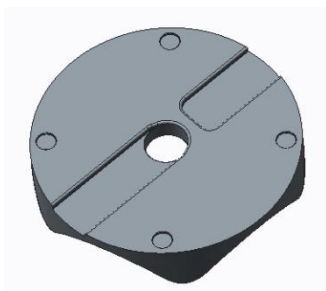
On the right side of the device is the camera unit.

The **HELIA**® image capture module starts after strip processing and commences generating images according to the respective worklist.

The lid locks shut during the entire duration of this process.

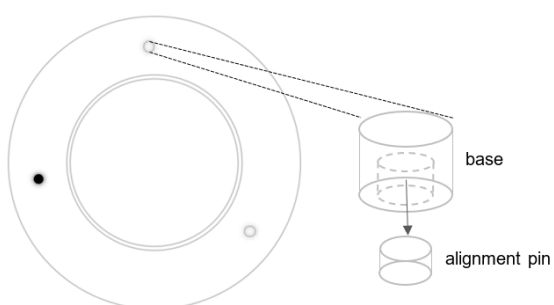
4.2.6 Inner, middle, and outer ring

Inner ring:



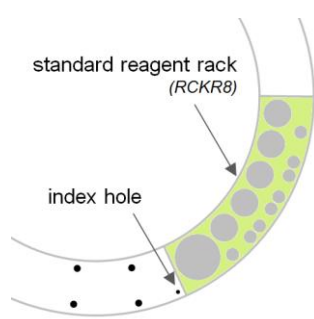
Place the cam disc on the inner ring. The notches at the bottom of the disc ensure correct fitting. The cam disc currently in use is made of a white plastic.

Middle ring:



Position the tray holder ring on the middle ring. Please take note of the color-coding of the two parts. The colors of each foot must match with the color of the alignment pin.

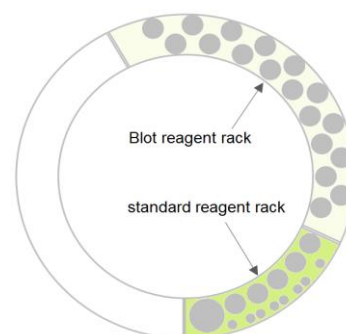
Outer ring:



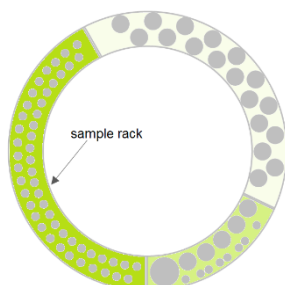
Place the standard reagent rack (RCKR8) on the outer ring to the right of the index hole.

Outer ring:

Place the blot reagent rack to the right of the standard reagent rack.



Outer ring:



Place the sample rack to the left of the standard reagent rack.

4.2.7 Sample tube racks

The following sample tube racks are programmed for use with your device:

REF.NO	SAMPLE TUBE SIZE (mm)	TOTAL SAMPLES
20160014	75 x 12	53
20160018	75 x 13	53
20160122	100 x 12	53
20160022	100 x 13	53
20160209	(55-100) x (11-13) - multi-rack	53

Racks are provided with a barcode to allow the scanner to read the required information when Racks are inserted into the device. No technical service is necessary as users can replace the racks themselves.

5 HELIA® Login

The **HELIA®** device software version 2.0 may only be used by registered and trained personnel. To prevent abuse, the software has a user registration, described in detail below. Create at least one Administrator account during the first start of the software. You will find information regarding this process step in the next section. Create User accounts for trained personnel.

5.1 User accounts

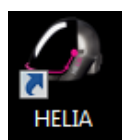
In the **HELIA®** device software, three user levels are defined and can be assigned.

User Level Accounts can carry out processes and manage results and therefore have access to **HELIA®-Process** and **HELIA®-LIS**.

Superuser Level Accounts can carry out processes, manage results, and execute organizational options and therefore have access to **HELIA®-Process**, **HELIA®-Settings**, and **HELIA®-LIS**.

Admin Level Accounts can create, manage, and delete accounts and manage results, and therefore have access to **HELIA®-Admin** and **HELIA®-LIS**.

5.2 Login



After powering the device and booting the computer, start the **HELIA®** software by double-clicking the **HELIA®** desktop icon.

The software will start and display the login screen:



Enter your username and password. If the entry was correct all icons become colored.

Press **"Enter"** to access the main menu or click one of the icons to enter the corresponding submenu.

Note: User accounts must be created in advance by an administrator. For further information, please refer to section 5.4.

5.3 Changing password

Each created user can change the stored password on the login screen.

- Enter your login and old password.

- Click the **“Change Password”** Button (red circle). A new window will open.

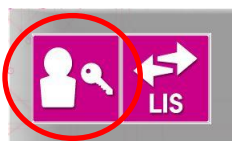
- Enter your old password.
- Enter your in the “New Password” field and again in the “Confirm Password” field.
- Confirm your entry with **“OK”**.
- Log in with your new user data.

5.4 Administrator area

An Administrator Level Account can create and edit usernames and passwords.

Log in as an administrator or use the standard admin:
Username: admin
Password: admin1234

Press “Enter” to log into the **HELIA®** software as administrator.



In the administrator screen, press the user account Button (red circle).

A new screen will open with active user definition.

Edit User

Buttons: Insert, Edit, Delete, Save, Cancel, Refresh

- Select the user you want to edit from the selection list.
- Click the “Edit” button on the right side of the screen.
- Enter the new name, password, and/or rights.
- Activate the user account by setting the checkmark.

Add user

Buttons: Insert, Edit, Delete, Save, Cancel, Refresh

- To create a user, click “Insert”.
- Enter the name, login name, password, and rights.
- Activate the user account by setting the checkmark.
- Confirm your entry by pressing Save.
- Confirm your entry by pressing Save.

Delete user

User Definition

User Name

user

superuser

- Select a user from the selection list.

Bestätigen

Delete Record?

OK Abbrechen

- To delete a user, click “delete”.



- The Log in button enables the log in as a different user.

Note: In the **HELIA®** software, a user for each user level is created by default. To ensure traceability, it is recommended to create assigned accounts.

Default User	Password
user	user1234
superuser	superuser1234
admin	admin1234

6 Software

After logging in as a user, the main menu screen will be displayed, allowing you to choose from the available routine menus.



6.1 HELIA® Process (Blot processing and imaging)



By clicking this button, the user selects the fully automated **HELIA®** process. First, the Routine work module will open. Here, the user enters all relevant information regarding sample preparation and generates a worklist (see section “7 How to perform a run” and especially “7.2 Create a worklist”).

After the **HELIA®** process starts, the individual Blot strips will be processed. The **HELIA®** Image capturing module will automatically start after the **HELIA®** blot process is complete. The fully automated functionality is exclusive to the **AESKUBLOTS®** product range.

The **Routine Work** ribbon in detail:



The button **Worklist** opens or updates the worklist screen and shows the current worklist. In this screen, a new worklist can be created. Only one worklist is active at any given time. This worklist has the status of the current worklist.



The buttons **Save** and **Open** will save the current worklist or load a saved worklist as the current worklist. Before saving the worklist, the software suggests a default file name composed of today's date and the actual time.



The **LIS Load** request button is for loading a worklist from a laboratory information system.



The **Loading Wizard** button initiates the loading wizard. The Wizard is for loading and setting up the **HELIA®** with the reagents for the **AESKUBLOTS®** assay selected in the current worklist. In up to eight steps, the wizard helps to place all test strips, samples, reagents, and buffers in the device, in sufficient quantities to process the current worklist.



The **Connect** button connects the software with the **HELIA®** device and starts the initialization of the instrument. Toggling between the gear wheels icon and the star icon will connect/disconnect the software from the **HELIA®** device.



Device connected,



Device disconnected or demo mode.



The **Prime Needles** button opens a window to select the liquid used for priming the **HELIA®** pipetting needles. This button is active only when the **HELIA®** device has been connected. For more information, refer to chapter “8.1 Daily shutdown”.

Available selections are:

1. buffer #1
2. buffer #2
3. priming with both buffers
4. decontamination (duration: 15 minutes)



The **Exit** button quits the **HELIA®** Software, saving all settings and changes. The **HELIA®** device will then disconnect.

6.2 HELIA® Image Capturing



By clicking this button, the user starts the **HELIA®** Image capturing module.

Note: Aesku.Diagnostics GmbH & Co. KG does not accept any liability regarding the processing of Blot kits of other suppliers.

6.3 HELIA® LIS



By clicking the **HELIA® LIS** button, the user selects the LIS module with the result database, validation function, and the LIS transfer button. For more detailed information regarding LIS connection, such as the interface description, refer to the LIS manual.

6.3.1 HELIA® LIS Results

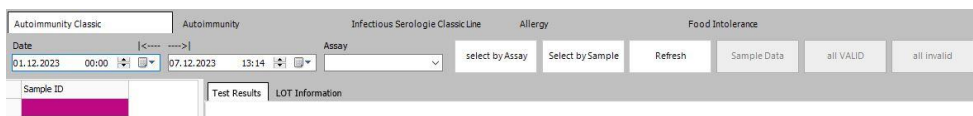
HELIA® LIS Results ribbon in detail:



The **Results to LIS** button initiate the transfer of the selected results to the laboratory information system.



The **Show Results** button opens the result screen. Here individual results can be selected, filtered by a given time frame.



By default, the actual date is pre-selected. To change this, click the **Date** fields to enter the time frame required. The dropdown checklist on the right provides all result files within the given time frame. The results can also be selected by the patient ID or assay.

Click “Refresh” after you have selected a time range, patient ID or assay.

Click “Sample Data” to retrieve and modify the data of the selected patients.



The **Show strip results** button opens the analysis overview. In this option, any blot strip that was not detected can be remastered after a process has been carried out.

Note: For further information, please refer to section “7.7.1. Remastering of non-detected stripes”.

6.3.2 HELIA® LIS Print

The **Print** ribbon in detail:



The “**Design Report**” button opens the Report designer used to design report templates. **HELIA®** comes with predefined report types. This feature is accessible with an Superuser Level Account.



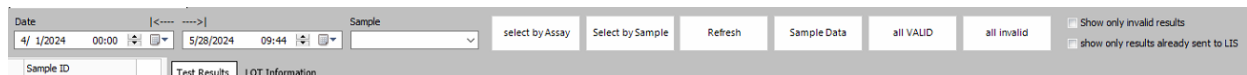
The “**Delete Report**” button opens a selection window to select which report types to delete. This feature is accessible with an Superuser Level Account.



The **Printer Settings** button starts the printer configuration.



The chevron besides the **Print** button activates a dropdown checklist to select the object to be printed. Depending on the active menu a report template can be selected.



All Buttons of the Selections Ribbon further augment the Data to be printed.

6.3.3 HELIA® LIS Information

The **Information** ribbon in detail:



The **Log File** button opens a file select box to select a log file. A log file will be created for each day the **HELIA®** software is initiated.



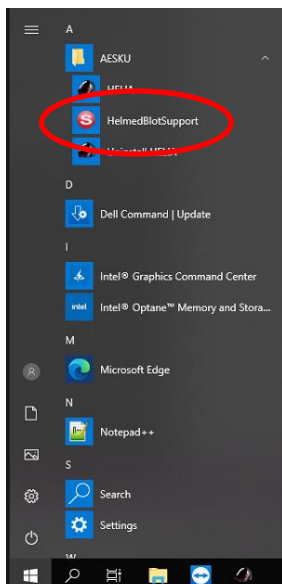
The **Help** button opens a quick guide in a separate window.



The **Information** button opens a separate window detailing the software name and version.



The **Support Request** button creates a Zip-file and stores the file on the Desktop. In case of technical issues, send this file to the technical service responsible for your instrument.



The **Support Request** is also in the start menu (red circle).

7 How to perform a run

7.1 Prepare the device

Before starting a run, check the following:

1. The correct racks are on the outer ring (section 0).
2. The device is connected to the PC.
3. The system Bottles and the terminals on the back of the device are properly connected (section 3.3.1).
4. The waste Bottle is empty.
5. Turn on the Device and the PC are powered and switched on.
6. Start the program by double-clicking the desktop shortcut (section 5.1).
7. Click the “**HELIA® Process**” Button.
8. Connect the device via the “Connect Instrument” Button of the routine work ribbon (section 6.1).
9. Rinse the instrument via the “Rinse” Button (section).

7.2 Create a worklist

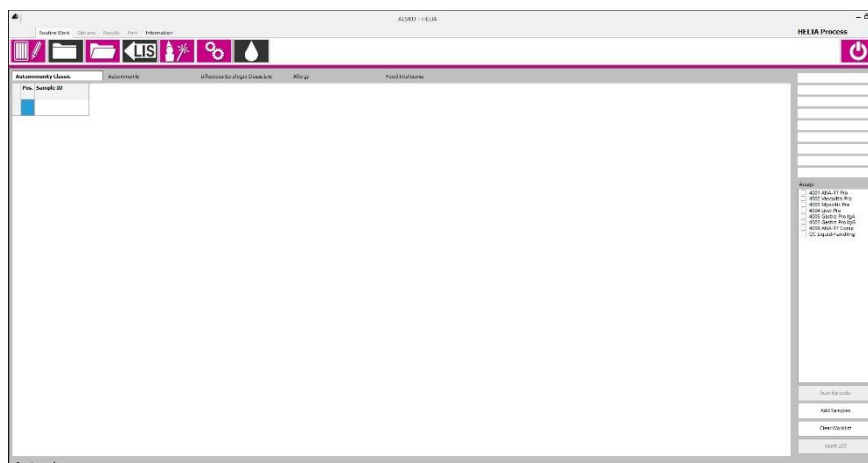
Note: Please ensure that your Sample IDs do not contain special characters like spacebars, -, +, etc.

When the device is ready, a worklist can be created as follow:

1. Click the Create Worklist button below the ribbon routine work.



2. This opens the worklist creation interface.



3. Manual entry of a worklist:



- Click the **"Add Samples"** button to add samples, lower right side, below the Test selector.

The dialog box titled "Add Samples" contains two input fields: "Number" and "Prefix". Below these fields are "OK" and "Cancel" buttons.

- Enter the number of samples in the first field, if necessary, type a prefix into the second field.
- The prefix will be placed in front of the sample ID.
- Click **"OK"** to confirm.

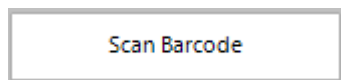
Pos.	Sample ID
1	111111
2	111112
3	111113
4	111114
5	111115
6	111116
7	111117
8	111118

- The worklist is shown with two columns per sample. The first column corresponds to the physical position of the sample on the sample rack. The second column contains the sample ID or sample name.

Note: You can place the sample tubes into the sample rack before or after creating the worklist.

4. Worklist by LIS connectivity:

Put the Tubes, barcode sticker affixed, outside facing, into the sample rack. Rotate the Tubes in the sample rack until the barcodes face outwards, so that the scanner can read the bar codes properly. Note the numbering on the sample rack. The numbers on the sample rack correspond directly to the sample display order of the worklist.



- Click the **"Scan Barcode"** button to scan the sample IDs:

The sample IDs - starting with the sample tube on position 1 - are sequentially scanned and displayed as a list. To change a sample ID click on the Sample ID column and enter the new Identifier.

A sample can be removed from the worklist by selecting the sample ID field and deleting it via the context menu (right mouse button). After confirmation, the sample is removed from the worklist, leaving a Gap in your worklist. All other samples/positions are not affected.

Note: If the barcode scanner detects an empty position, the scanning of the rack will be terminated.

Tubes without barcodes or tubes with unreadable barcodes are marked with a question mark and a continuous serial number.

5. Select the test group:



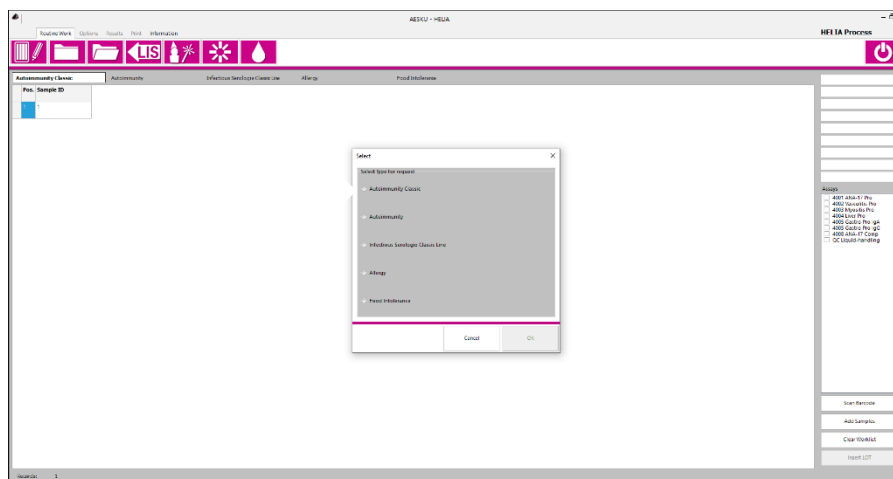
Note: Up to nine different **AESKUBLOTS®** tests of one product line can be combined in one run. Tests of Multiple product groups cannot be combined with each other.

6. Automated assignment of the tests via LIS

After the sample IDs are scanned, the preassigned tests for these sample IDs can be obtained by clicking the LIS requirement button:



Choose the group of tests from the popup menu (red arrow) and confirm by clicking “OK”.

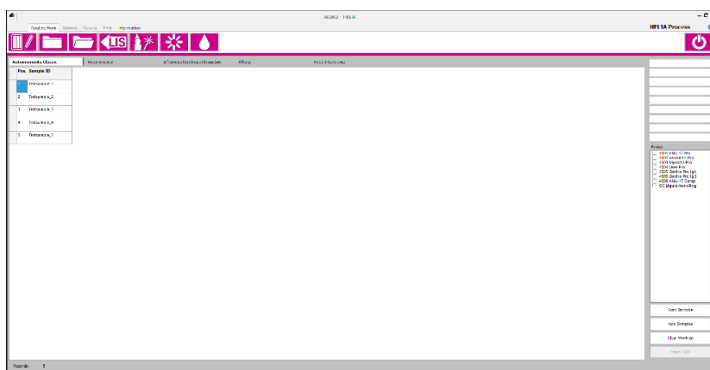


The worklist is complete once the automatic mapping is finished.



Note: If you have requested the sample test assignment from LIS, proceed with section 7.3.

7. Manual assignment of the tests



Select the tests from the right-hand side of the interface (red circle). To add a test to the worklist, checkmark the box next to the desired **AESKUBLOTS®** test.

Next, assign the samples to the desired **AESKUBLOTS®** tests.

There are several ways to achieve this:

Single sample assignment:

Autoimmunity Classic		Autoimmunity
Pos.	Sample ID	4001 ANA-17 Pro
1	Testsample_1	☒
2	Testsample_2	☒
3	Testsample_3	☒
4	Testsample_4	☒
5	Testsample_5	☒

Click the test name field of a sample to assign the test to this sample. A blue checkmark icon will visually confirm the assignment.

To unassign double-click purple checkmark icon.

Multi sample assignment:

A multi-selection can be made by left click selection of tests then using the context menu (mouse, right button). The context menu can be used to insert tests, delete tests, or invert the selection.

Autoimmunity Classic		Autoimmunity
Pos.	Sample ID	4001 ANA-17 Pro
1	Testsample_1	☒
2	Testsample_2	☒
3	Testsample_3	☒
4	Testsample_4	☒
5	Testsample_5	☒

Autoimmunity Classic		Autoimmunity
Pos.	Sample ID	4001 ANA-17 Pro
1	Testsample_1	☒
2	Testsample_2	☒
3	Testsample_3	☒
4	Testsample_4	☒
5	Testsample_5	☒

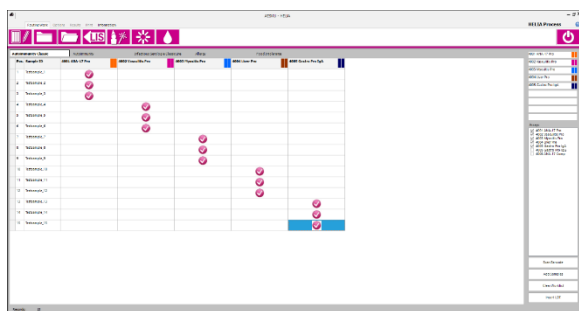
Assigning all samples to one test:

Autoimmunity Classic		Autoimmunity
Pos.	Sample ID	4001 ANA-17 Pro
1	Testsample_1	☒
2	Testsample_2	☒
3	Testsample_3	☒
4	Testsample_4	☒
5	Testsample_5	☒

A click on the colored top box (displaying the name of the selected test) assigns all samples to this test.

Note: The maximum number of blot strips is limited to 40. If the number of worklist assignments created exceeds the number of Strips that can be processed in one pass, surplus allocations will be deleted.

Activated **AESKUBLOTS® tests** are shown in the worklist in rows. Each row displays the color code and name of the respective tests:



It is possible to assign one sample to multiple Tests.

To delete the complete worklist, click on the **“Clear worklist”** button.



Saving the worklist is not necessary but is recommended. For this purpose, use the **“Save Worklist”** button. The worklist remains active until the program is terminated or until the worklist has been completely processed.

Note: We recommend saving the worklist, as this is deleted when exiting the routine work menu and must be entered again. The connection to the **HELIA®** is also interrupted and must be

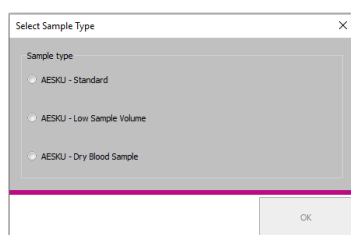
7.3 Loading Wizard



When you start the loading Wizard you are first asked to select your sample type/ processing method (7.3.1), following that, to scan the lot-specific kit barcode (7.3.2). This barcode is located on the Certificate of Analysis (COA), provided with each kit.

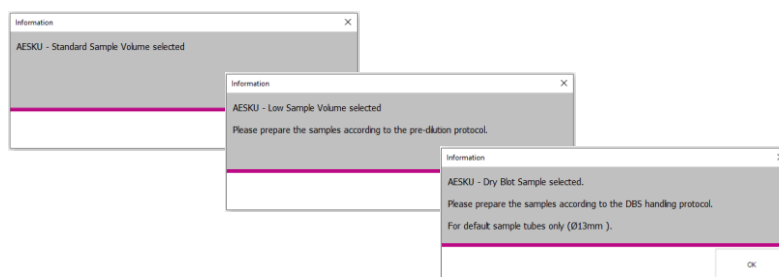
Once scanned, the lot-specific assay data are stored in the Software and can be used for all kits of this lot.

7.3.1 Select sample Type



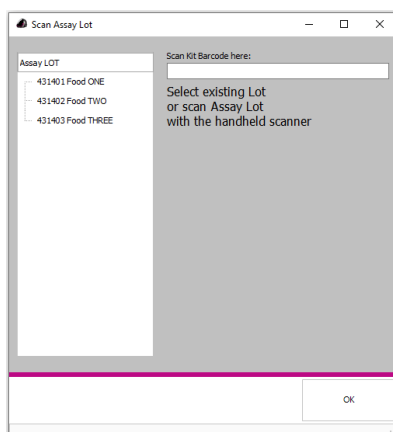
All Allergy- and Food Intolerance Panels can be performed with different processing methods, depending on the sample type. As a first step of the loading Wizard, the sample type/method needs to be selected.

After selecting the sample type/method, the user needs to confirm with **“OK”** before scanning the assay Lot.



Note: This is only relevant for Allergy and Food intolerance panels. Autoimmune and Infectious Serology panels can only be performed as **“AESKU – Standard”**.

7.3.2 Scan Assay Lot

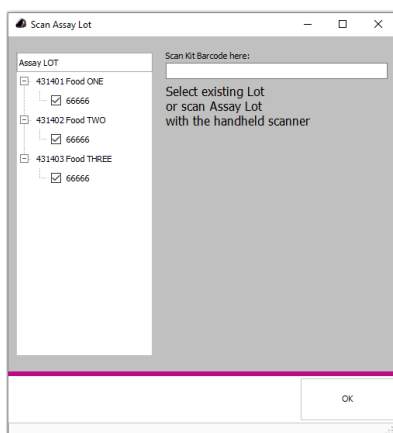


Use the **HELIA®** handheld barcode scanner to scan the 2-D barcode located on the kit-specific COA provided with each assay.

Note: Only assays in use in the current worklist can be scanned. If you try to scan a barcode of another, unused assay, the error “**Assay actually not used**” will be displayed.

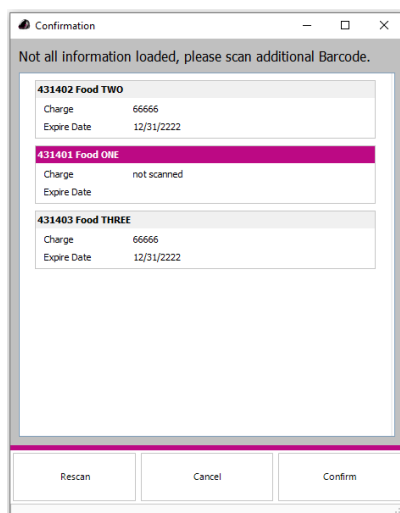
After a successful scan (or if a barcode was scanned prior), the lot of the assay will be shown in the list.

Scan any missing barcodes.



Click “**OK**” if all barcodes have been scanned, to proceed to the next step.

Note: Only lots within their expiry date are shown in the list. If there is more than one assay available, no preselection is done.



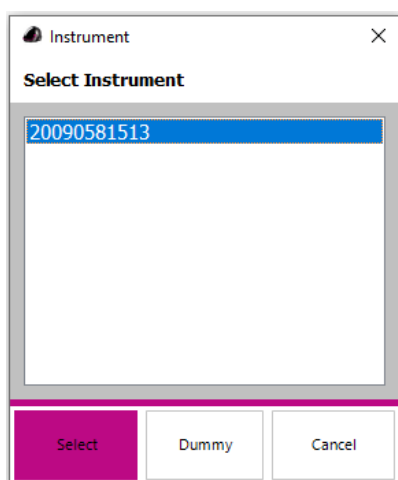
If - for any of the indicated assays - no barcode was scanned a confirmation window will open.

To scan missing barcodes, press “**Rescan**”.

To abort, press “**Cancel**”.

To continue, press “**Confirm**”.

Note: The Software will only continue if all needed lot data is available in the database.



In the next Window, select the instrument -identified by its serial number (In this Example: **20090581513**).

Confirm the selection by clicking **"Select"**. The software will establish a connection to the selected **HELIA®** device.

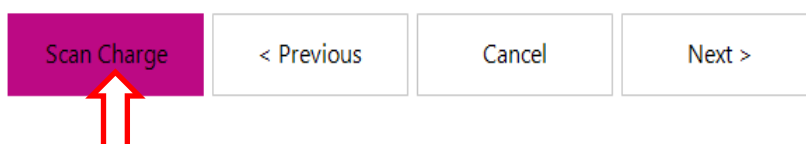
7.3.3 Loading Reagents

In up to eight steps, the loading wizard guides through the **HELIA®** set-up for **AESKUBLOTS®** processing. To navigate through the steps, press the **"Next>"** or **"<Previous"** button.

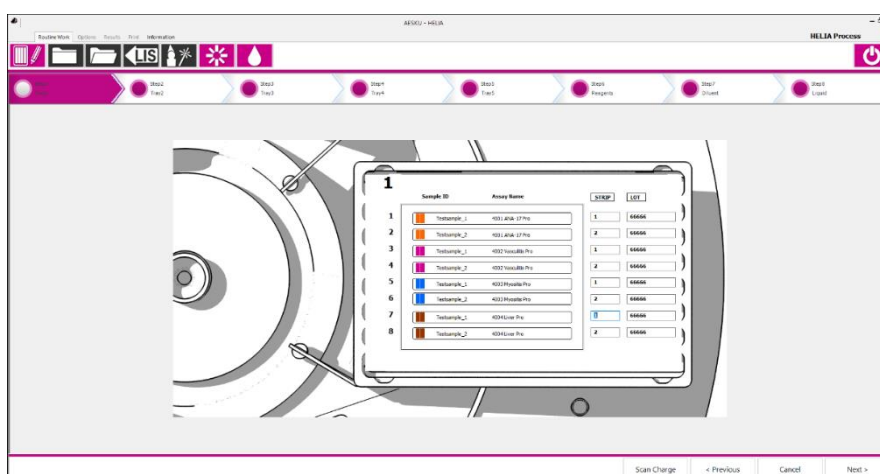
Steps 1-5: Shows test strips layout in the incubation trays 1-5. There are 8 positions per incubation tray for **AESKUBLOTS®** strips and 5 trays per device.

Load the strips into the trays exactly as shown on the screen. Note the strip orientation. The colored bar must face up and inwards. Enter the strip-number (max. 5 digits) into the **[STRIP]** field. The strip number is filled in automatically, up to number 24. The last scanned lot number becomes visible if you click into the **[Lot]** rectangle.

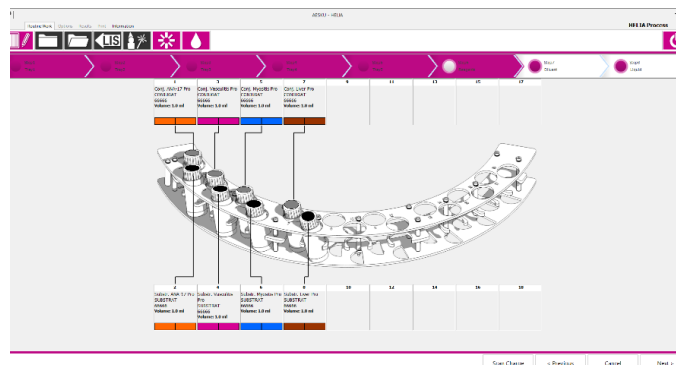
If the lot number of the kit in use is not shown, or it is not available, even after manual input, please press the **Scan Charge** button to scan the LOT, located in the lower right menu bar (red arrow).



Step 6: Shows the location of the conjugates and substrates for the different tests or lots, as well as the minimum volumes required to process the selected **AESKUBLOTS®** assays correctly.



Eighteen positions (labelled 1 to 18) are available for 20 ml vials in the outer ring of the **HELIA®**. The software automatically assigns rack positions to the reagents. Load the blot rack as displayed. Ensure that the vials are filled with the required volumes.

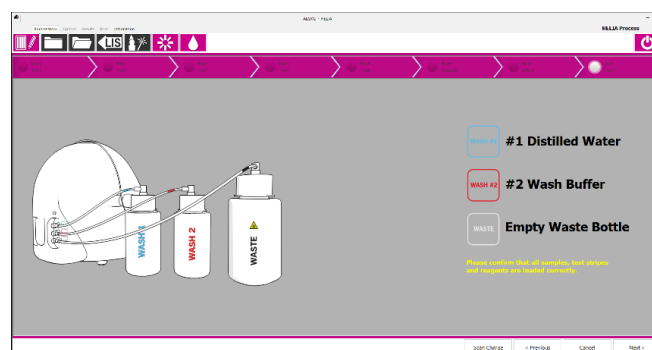


Step 7: Shows the location of sample buffer and the minimum volumes required to process the **AESKUBLOTS®** assays correctly. The software automatically allocates the reagents to their positions.

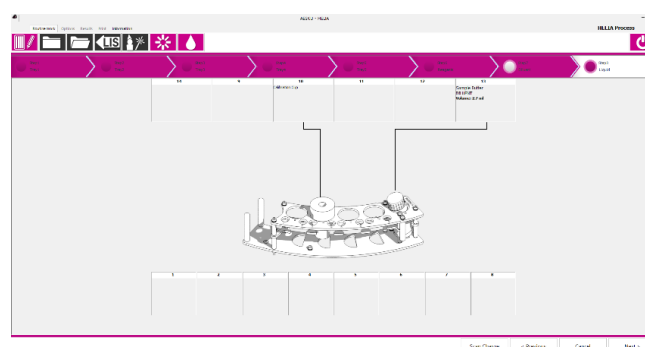
Place the sample buffer at the intended position in the standard reagents rack (RCKR8).

Check that there is no foam on the surface of the sample buffer (foam or bubbles lead to an incorrect volume detection).

Step 8: Recheck all reagents, samples, and blot strips that are required for the run. Check whether the Wash #1 and Wash #2 Bottles are filled, and the Waste Bottle is empty.



To exit the loading wizard and enter the run-screen, click the **“Next>”** Button.



Note: There is no volume check of bottles connected to “Wash#1” and “Wash#2” connectors.

Check that the bottles are sufficiently filled. Verify that the flexible tubing inside the bottle reaches the bottles bottom.

7.4 Run screen

7.4.1 Starting a run

Note: The device must be connected to initiate a run.

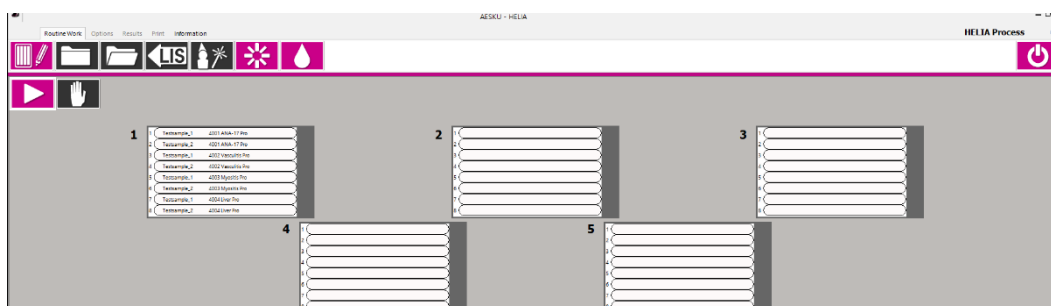
1. Please ensure that all samples, reagents, and buffers are correctly positioned, and after that, that the device lid is closed.



2. Press the **“Connect”** Button if the Device is not already connected.



3. Press the **“Start”** button to start the current workload.



Immediately after starting, the **HELIA®** checks all conjugates, substrates, and sample buffers. Errors are indicated by a warning symbol, indicating that the log file must be checked for errors. In this case, rectify the error and the process restart the processing operation.



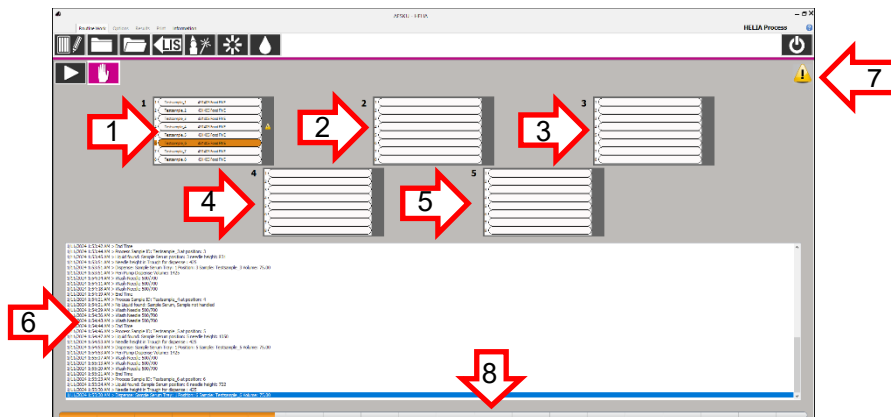
- The **“Terminate Run”** button terminates (after a confirmation prompt) processing of the current workload.



Once terminated, a run cannot be resumed!

7.4.2 Run screen

- **Incubation trays (1-5):** are indicated with samples and tests (labelled 1 to 5, accordingly).
- **Logfile (6):** the text field shows the Logfile monitoring all process steps. All errors will be logged in the log file. In case of an Error, a yellow warning signal appears. One log file is stored for each day.
- **Sampling error (7):** in case of a sampling Error, a yellow warning signal appears behind each sample.
- **Timeline (8)** is displayed at the bottom of the screen. Each processing step is shown in separate colors.



7.5 Imaging

After the processing, an acoustic signal is given, the **HELIA®** switches automatically to the home screen, and a window with a timer opens. The **HELIA®** Image Capturing (red arrow) is now available for twenty minutes.



To avoid drying effects, the Image Capturing menu will stay active for 20 minutes only. A countdown starts immediately after the image was taken. When the countdown has finished, the trays are confirmed automatically, the Image Capturing menu closes, and the images are evaluated. The results can be viewed in the LIS menu.

 After the 20 Minute timeframe, it will no longer be possible to rescan the strips of this run.

1. All trays will be shown. Each single tray image must be selected and checked.



2. Click on the Image of a tray to bring up a magnified Image of the Tray. Carefully check all strips for correct positioning. Repeat this step for all trays.



Checkmark the box in the upper right corner of the preview image (red arrow) to confirm the tray.

3. If all strips are positioned correctly, all checkboxes are activated, and the names of the tray changed to Tray confirmed, click **“Yes (Continue)”** (red arrow) and continue to step 0.



The Image capture menu will close after the confirmation and the Strips will be evaluated. The results will be available in the LIS menu.

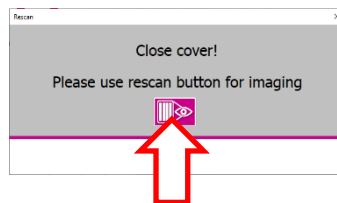
4. If one strip is turned, flipped or must be repositioned, click **“No (Rescan image)”** (red arrow).



5. The cover unlocks. Open the cover and correct the position of the strips as needed. Click **“OK”**.



6. Close the cover and click the **“Rescan”** button (red arrow).



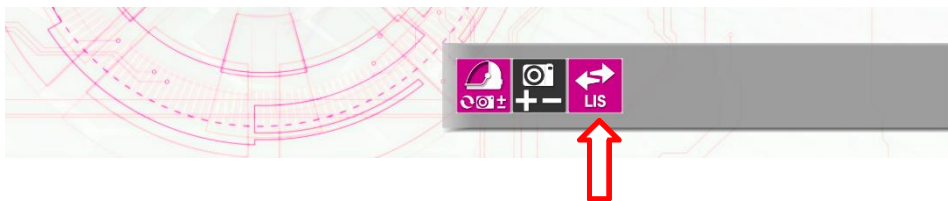
7. Proceed as described in step 3.

Note: Rescan is possible only once!

Please double-check and ensure that all strips are placed well in the trough before closing the cover and clicking the **“Rescan”** button.

7.6 Result viewing and archive

Results will be handled and stored in the **HELIA®** LIS.

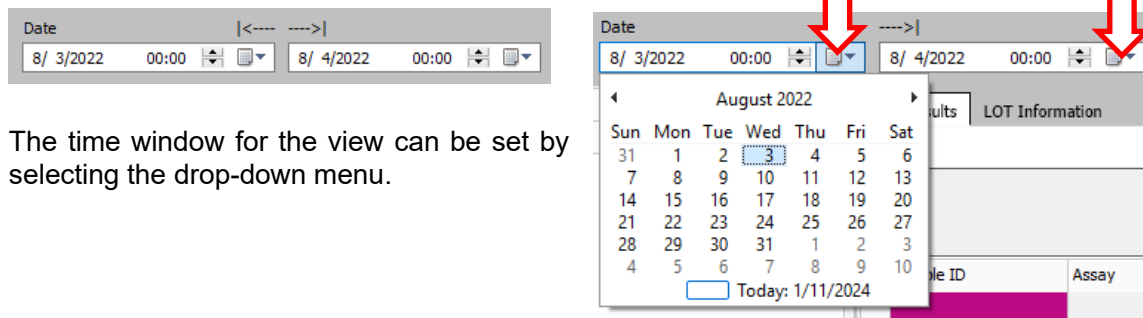


After executing this function (red arrow), the results overview opens, and the results of the last processed trays is automatically displayed.

[illegible]

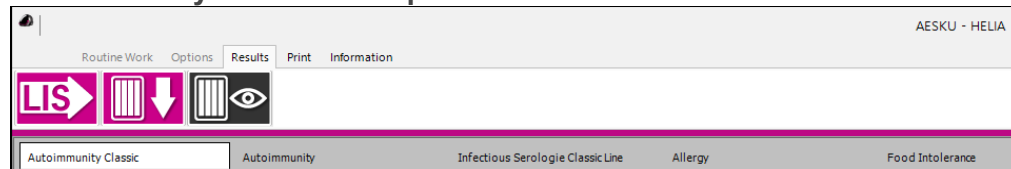
To view result data that has been previously processed, it is possible to augment the results overview using various data filters.

7.6.1 filter by Date



The time window for the view can be set by selecting the drop-down menu.

7.6.2 filter by Product Group



Assay groups are selected by clicking on the named tab. The respective assays become available in the selection.

7.6.3 filter by Sample

Sample ID	Assay	Result	Index	Value	Rating	Filter	Assay	Date/Time	Unit	Valid Day	Comment	LIS	Send	Start at
Testsample_1	421407 Allergy SEVEN	0	0	0.0				1/10/2024 10:14:00						
Testsample_2	421407 Allergy SEVEN	19	0	0.0				1/10/2024 10:14:00						
Testsample_3	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_4	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_5	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_6	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_7	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_8	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_9	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_10	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_11	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_12	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_13	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_14	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_15	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_16	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_17	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_18	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_19	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						

Select by Sample

Sample

Testsample_12
Testsample_13
Testsample_14
Testsample_15
Testsample_16
Testsample_17
Testsample_18
Testsample_19

By selecting **"Select by Sample"**, the drop-down menu becomes active and shows the available sample IDs within the selected time window and product group.

Assay:

Selecting **"Select by Assay"** will activate the drop-down menu and show the available Assay REFs within the selected time window and product group.

Sample ID	Assay	Result	Index	Value	Rating	Filter	Assay	Date/Time	Unit	Valid Day	Comment	LIS	Send	Start at
Testsample_1	421407 Allergy SEVEN	0	0	0.0				1/10/2024 10:14:00						
Testsample_2	421407 Allergy SEVEN	19	0	0.0				1/10/2024 10:14:00						
Testsample_3	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_4	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_5	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_6	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_7	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_8	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_9	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_10	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_11	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_12	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_13	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_14	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_15	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_16	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_17	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_18	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						
Testsample_19	421407 Allergy SEVEN	125	0	0.0				1/10/2024 10:14:00						

select by Assay

Assay

421407 Allergy SEVEN

Show only results already sent to LIS:

☐ Show only invalid results

☒ show only results already sent to LIS

Activating the selection **"Show only results already sent to LIS"** only shows results that have already been sent to LIS, within the selected time window and product group

Results from this overview can also be sent to LIS again or printed out.

Show only invalid results:

☒ Show only invalid results

☐ show only results already sent to LIS

Activating the selection **"Show only invalid results"** shows only invalid results, within the selected time window and product group. Set this filter to highlight results that are marked with errors.

7.7 Result validation

The “**all VALID**” button will set all results status of all samples to validated. Results with a validated status can be printed and/or sent to the LIS.

all VALID all invalid ☐ show only invalid results ☐ show only results already sent to LIS

[illegible]

The “**all invalid**” Button resets the validation status of all results to not validated. As a safety feature, the status of results that have already been sent to the LIS are locked. This prevents database discrepancies between your **HELIA®** Database and your LIS. In this Case an information pop up Window will inform you. Confirm with “**OK**”.

Information

Result data that has already been sent to the LIS can no longer be classified as invalid.

OK

The checkboxes in the “**valid**” coloumn will toggle the validation status of a single antigen/allergen separatly.

When you transmit results to the LIS and an error code was reported for a sample, a dialog window will open.

Choose one of the available options

and click **“OK”** to proceed.

Nonvalid position of samples are left blank in the PDF/CSV printed report.

Whether a blank or a value with an error Flag is submitted for a nonvalid position to your LIS is subject to your LIS settings.

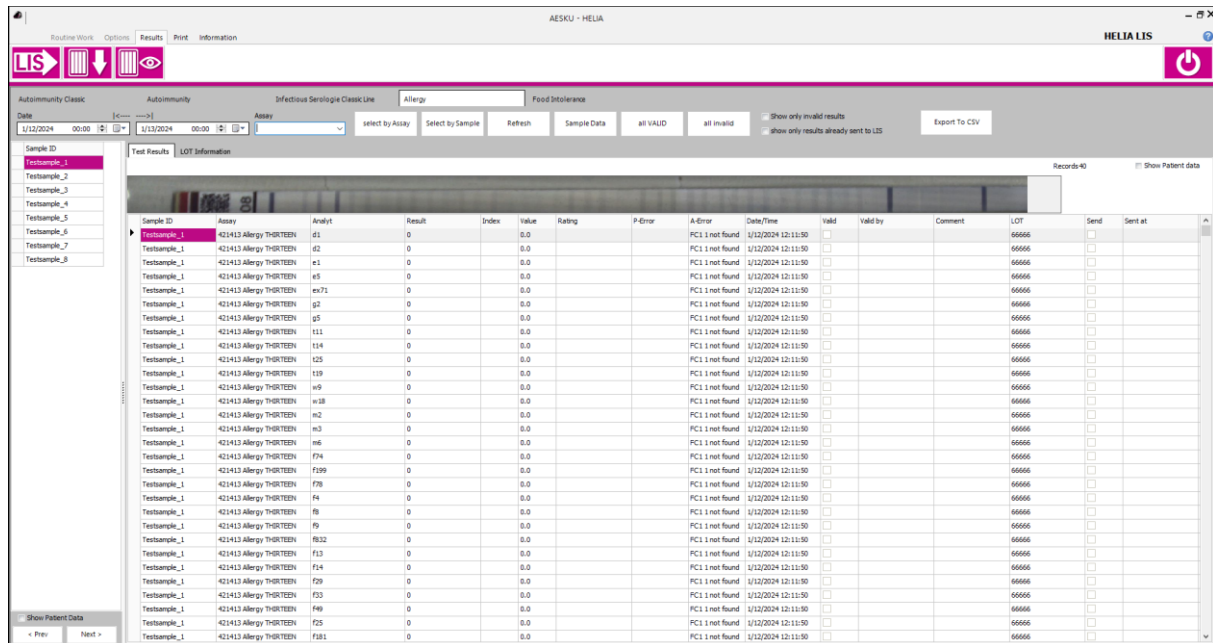
Details regarding the error codes are described in section 7.11.

The **HELIA**[®] software only checks and validates the functional criteria of the blot strips (Functional controls and Standards/Cut-offs). The **HELIA**[®] software does not validate single antigen/reagent/result bands.

The final validation of single antigen/allergen results is up to the expertise of the professional user.

7.7.1 Remastering of non-detected stripes

If a strip is marked with the A-Error message "Function control 1 or 2 not found" during the validation of a process, the user has the option to subject the strip to a new position detection. This option is only available for the last process carried out.

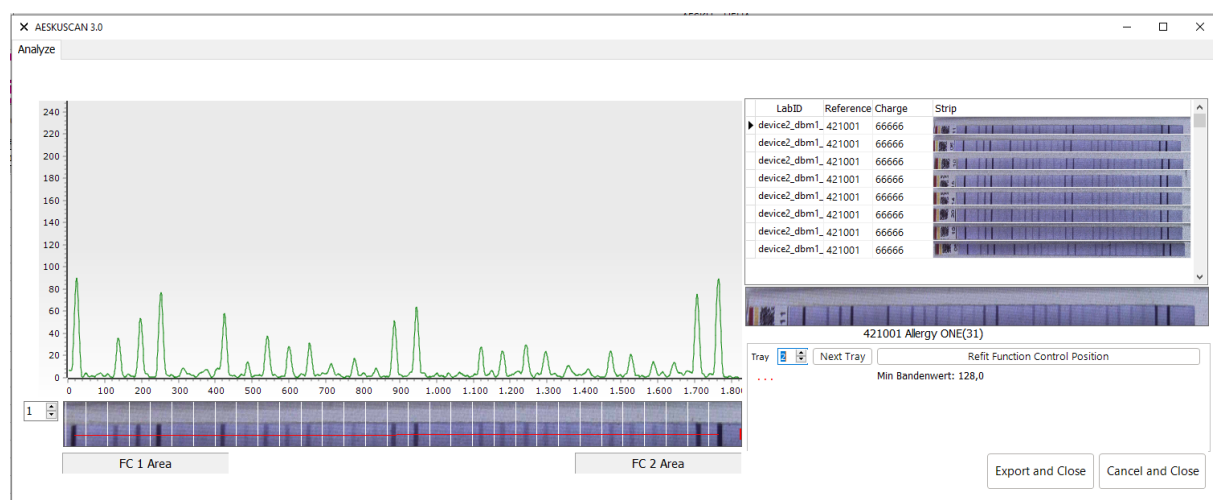


Sample ID	Assay	Analyst	Result	Index	Value	Rating	P-Error	A-Error	Date/Time	Valid	Valid by	Comment	LOT	Send	Sent at
Testsample_1	421413 Allergy THSRTEEN	d1	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	d2	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	e1	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	e5	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	ex71	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	g1	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	g5	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	h1	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	h4	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	h5	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	h9	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	h38	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	h2	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	h3	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	h6	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	F74	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	F89	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	F78	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	F4	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	F6	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	F6	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	B32	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	F13	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	F14	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	F29	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	F33	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	F49	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	F35	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	F33	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	
Testsample_1	421413 Allergy THSRTEEN	F33	0	0.0	0.0			PC1 1 not found	1/12/2024 12:11:50	☐			66666	☐	

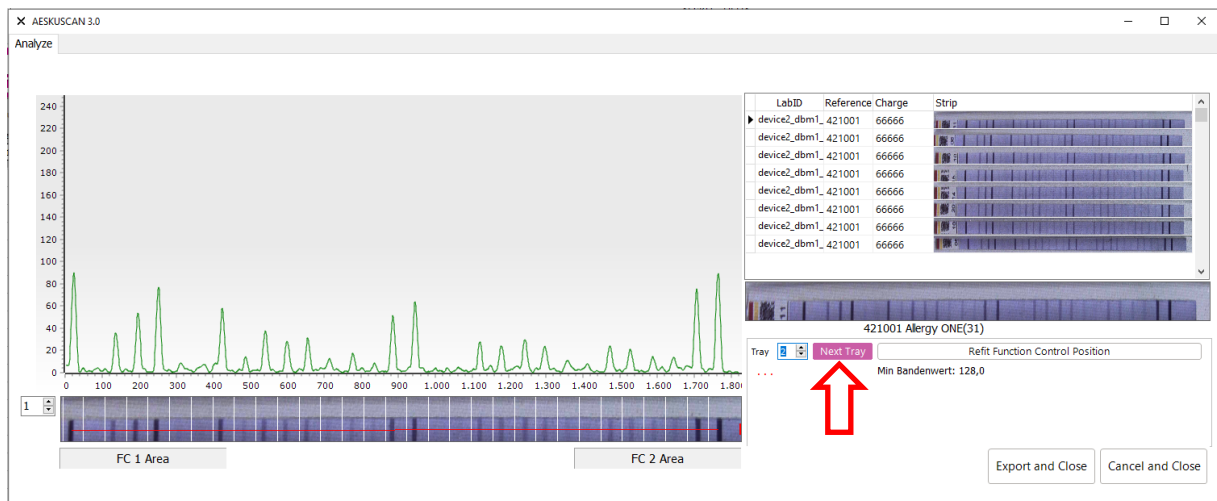


Selecting a Blot strip of the last process will activate the **"Show strip results"** Button.

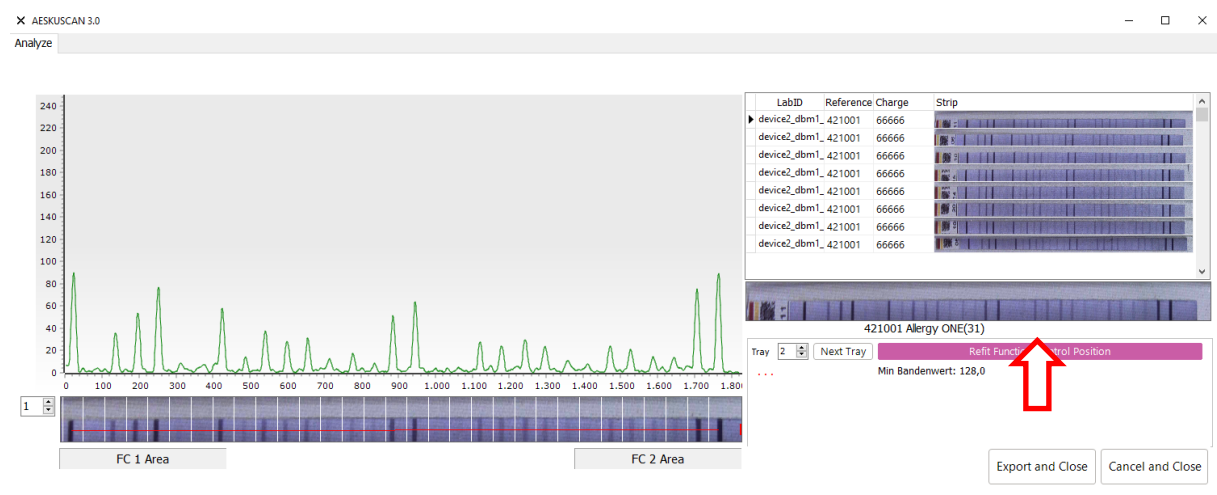
Clicking the **"Show strip results"** Button will open a specialized AESKU.SCAN 3.0 Window, showing the first strip of the first tray of the most recently completed process. Selecting positions 2 to 8 of the LabID column, the diagrams of the respective strip will be displayed on the left. Any detection error(s) will be shown in the lower right side info Area.



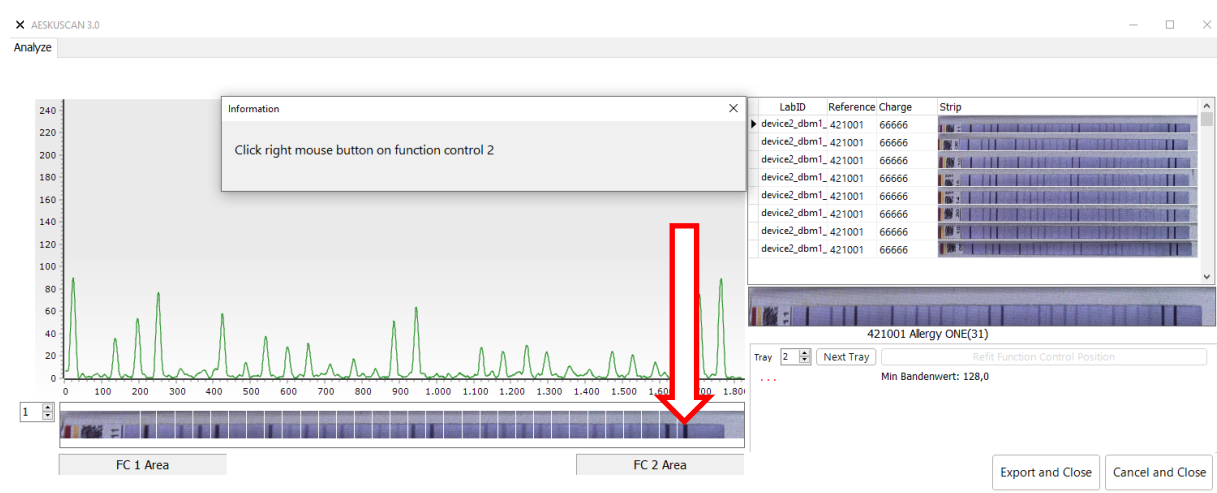
The **"Next Tray"** Button (red arrow) will toggle through tray 1 to 5 and revert to tray 1. The Tray can also be selected directly in the Tray field. Depending on the work list executed in the last process, there might be no displayable Trays beyond tray 1, in this case all Fields will remain blank.



After selecting an unrecognized strip, press the **"Refit Function Control Position"** Button (red arrow, below image).



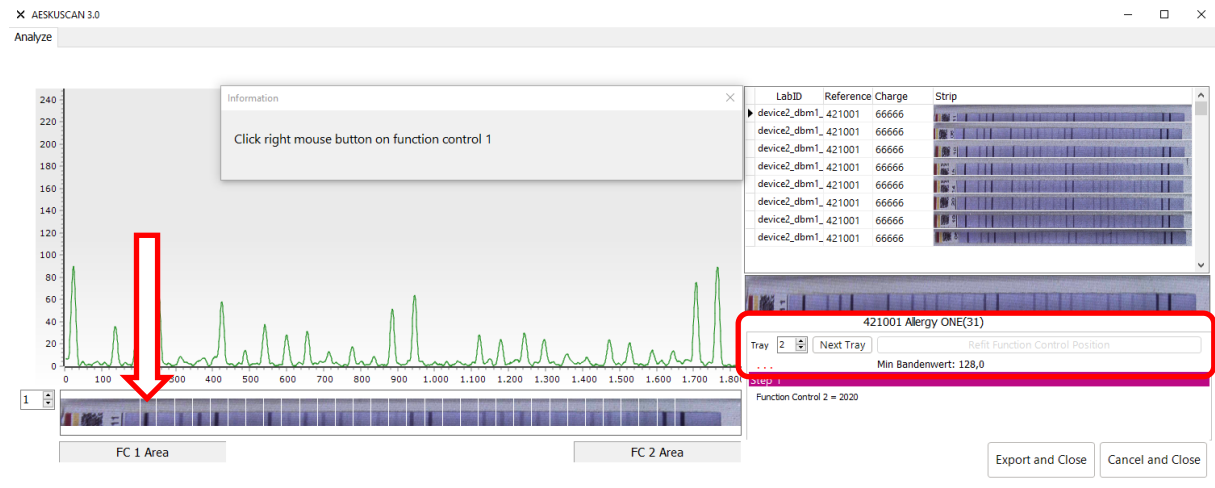
Function control 2 is always the last visible band on the right-hand side of the strip - also denoted as the "FC 2 Area" below the strip. Use the right mouse button to set the center of the FC2 Band (red arrow, below image).



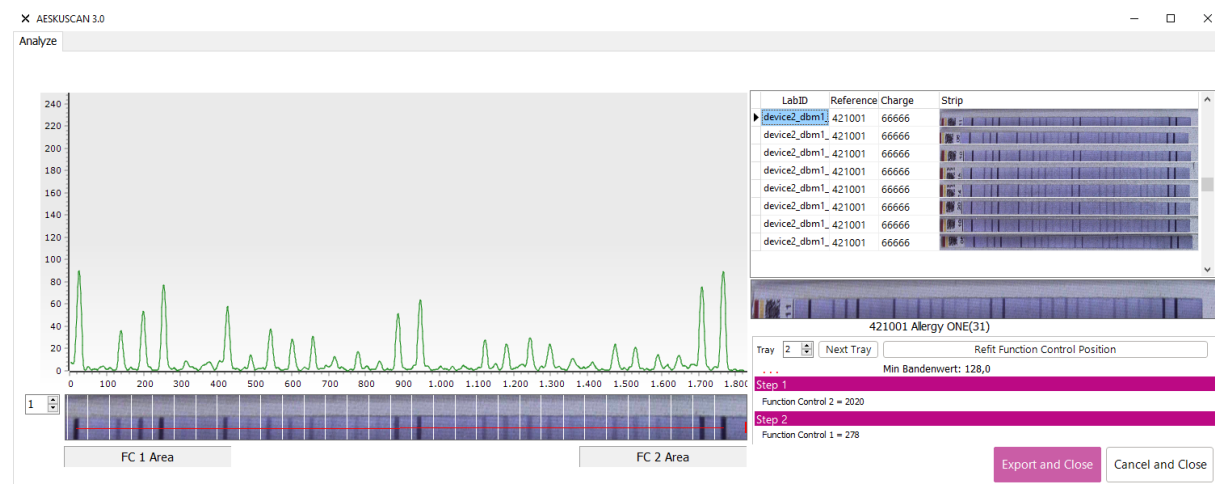
The new position of the function control 2 (FC2) and the progress of the post-processing are displayed in the overview (red circle).

Repeat for function control 1 (FC 1). It is the first visible Band, directly right of the Blot strip header, search for it in the "FC 1 Area" area and select it with the right mouse button (red arrow).

Function control 1 is the leftmost (first) result band on the left-hand side, next to the label of the strip head.



The repositioning step can be carried out individually for each selected strip of the trays 1 to 5.

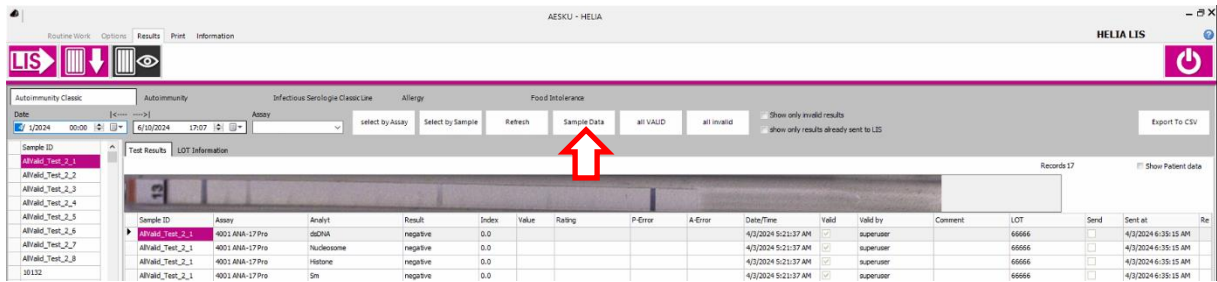


After repositioning the last position, the processing must be completed with the **"Export and close"** Button. Clicking the "Cancel and Close" Button will close the AESKUSCAN window, without saving any changes.

The **"Show strip results"** Button will stay active for the last process until you start a new process.

7.8 Enter Patient data

In the main send to LIS Screen, press the **“Sample Data”** Button (red arrow).



The 'Insert Sample Data' pop-up window contains the following fields and buttons:

- Sample ID:
- Insurance:
- First Name:
- Last Name:
- Birthdate:
- Gender:
- Buttons: Edit, Post, OK

A pop-up Window will open.

Enter patient data, confirm and store data with **“Post”** Button.

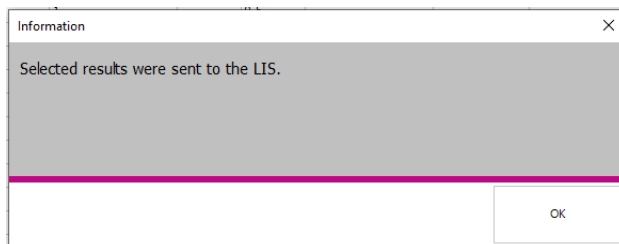
Confirm by clicking the **“OK”** button will close the window.

Note: The patient data can be moved to the background by deactivating the show patient data button to get a better overview if this is not needed.

7.9 Result export to LIS



Click the **“send to LIS”** Button to start the transmission of all validated results.



A successful transmission will be reported.

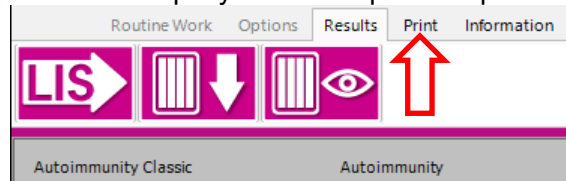
Note: In case a sample got a nonvalid position, the value for the nonvalid position is missing in the LIS report. The position gets an Error flag (E) (green marker) and/or the comment manually validated.

```
R|26|^D22412 E-12 -
LSV|kUA/L|||F||superuser||2021021
5073838|
C|1|I|0255A20451^1|L|
R|27|^D22412 E-12 -
LSV|t70^2^0.77|kUA/L|||F||superuser||20
510215073838|
```

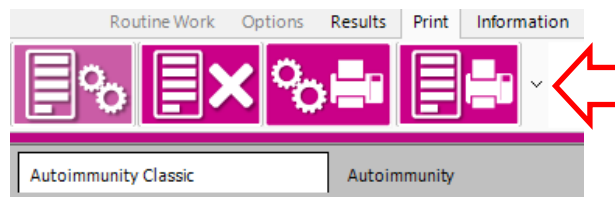
7.10 Print Results

To print a result, open the **“Print submenu”** (red arrow).

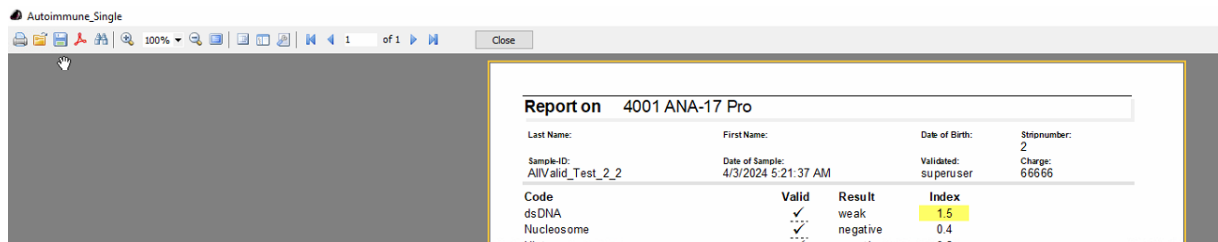
Select the product group and the sample you want to print a report of.



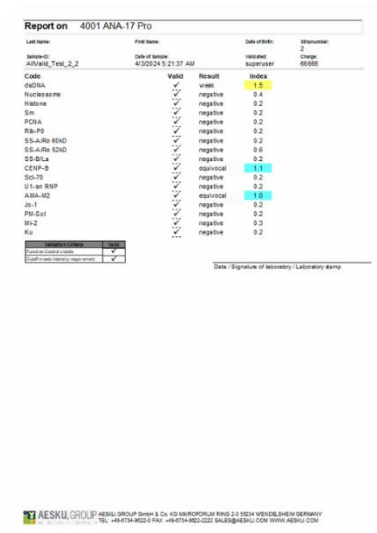
To generate a report, click the small dropdown arrow beside the printer icon (red arrow) and select the type of report:



- Select **“Report_Single”**.
- Selecting the report will start the printing process.
- After the report assembly phase finished, a preview screen will open.



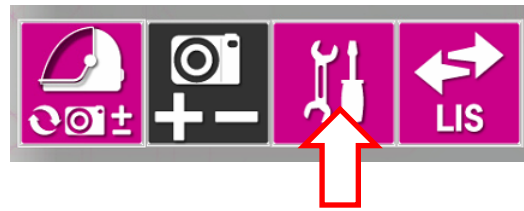
- Here you can review the file/pages, save as a PDF, send to an external PDF maker or send the report to a printer via the standard windows printer spooler.



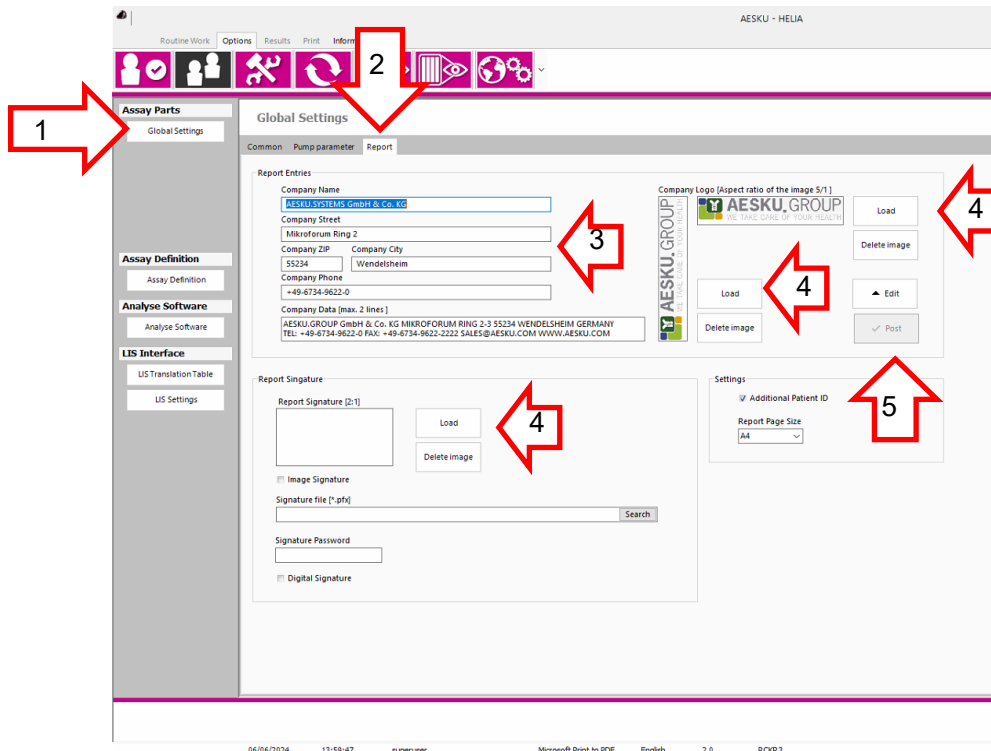
Example print out of an Autoimmune Single report.

Print outs of single reports are only possible for validated blots.

The company logo and company data can be customized via the Global Settings menu:



After logging in with superuser credentials, click the settings Button and choose your Device from the pop-up menu. This will open the settings screen.



On the settings screen, click the **“Global Settings”** Button (red arrow one), and switch to the report tab (red arrow two). On the left-hand side of the Tab, the company Data (red arrow three) can be changed. Clicking the **“Load”** Buttons (red arrows four) will open a File selection pop-up to choose the new Logos. .png, .jpg and .bmp are accepted File formats, Files will automatically be scaled to fit within the 5:1 Aspect ratio for horizontal logos, respectively, 1:5 for vertical logos, or 2:1 for signature images.

Note that only one active signature can be set per one machine.

Pressing a **“Delete Image”** Button will clear the Image but leave the file on the device.

Confirm changes by hitting the **“Post”** Button. Unposted Changes will reset to the unchanged values once the settings screen is closed.

7.11 Error codes

Two types of errors are listed in the result view, on the reports, and transmitted to the LIS.

1. P-Error: Processing errors. No results will be calculated for a sample with a processing error flag.
2. A-Error: Analysis error, detected by the imaging software according to the validation criteria of the tests and according to the optical specifications defined in the software. Manual validation of results is possible in some cases. Please refer to table A-Errors.

P- Errors:

Errorcode	Description
0/1	OK
90	No Buffer
900	No Sample
9000	No Conjugate
90000	No Substrate
900000	General error

Yellow warning symbol



A-Errors:

Error message	Meaning	Recommendation
FC 1 not found	Function control 1 not detected.	Do not validate the test. Retest the sample. It might be possible to Remaster the result (see chapter 7.7.1)
FC 2 not found	Function control 2 not detected.	Do not validate the test. Retest the sample. It might be possible to Remaster the result (see chapter 7.7.1)
Cut-off too small	cut-off band signal too low.	Do not validate the test. Retest the sample.
Standard curve	The verification of the linear slope of the standards, as a validation criterion, could not be carried out successfully.	Do not validate the test. Retest the sample.
Conjugate error	Only Borrelia, control IgG > IgM for IgM.	Do not validate the test. Retest the sample.
FC too small	Signal of Function control too low	Do not validate the test. Retest the sample.
Double peak	Two signals in the position of the line.	Manual validation is possible. The result will be flagged.
Particle found	A Particle is found in the position of the line.	Manual validation is possible. The result Will be flagged.
Background high	The background is significantly higher in this position.	Manual validation is possible. The result will be flagged.
Homogeneous	One antigen; Signal not homogeneous for this line.	Manual validation is possible. The result will be flagged.

If there are several errors for one position, only the most important one is displayed.

8 Maintenance

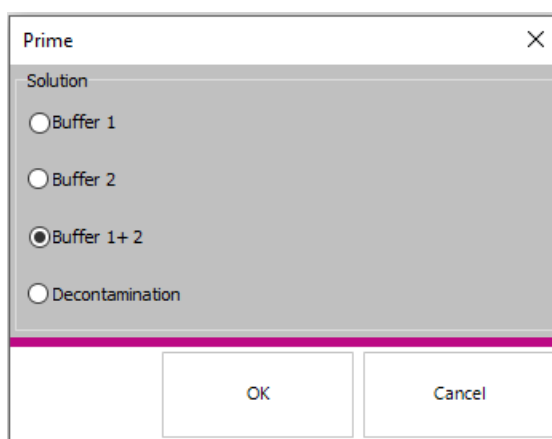
Regular preventive maintenance should be carried out by the service provider as a minimum once per year. For HELIA® devices with an increased workload (i.e. greater than 1 run per day) a six-month maintenance schedule is recommended.

Daily and weekly maintenance tasks are crucial for ensuring proper operation of the device and should be completed even on units with very low throughput.

8.1 Daily shutdown

After processing a worklist, the instrument should be primed with distilled water. For this purpose, replace the wash solution ("Wash#2" connector) with distilled water.

1. Rinse the calibration cup with distilled water.
2. Remove the Calibration cup from position 10 of the Standard Reagent Rack, rinse thoroughly with distilled water and dry it. Finally, place it in position 10 of the reagent rack.
3. Wipe the outside of the needles, first with a tissue containing 70% ethanol, then with distilled water.
4. Empty the wash bottle (#2) and rinse the bottle with distilled water. Fill bottles #1 and #2 with 100ml distilled water.
5. Connect the device.
6. Click **"Prime Needles"**
7. choose the washing option **"Buffer 1+2"**.



8. Confirm with **"OK"**.
9. Empty the liquid waste bottle after flushing and clean with water.

8.2 Weekly maintenance / Decontamination

Prime the instrument once a week with 0.3 % sodium hypochlorite (NaOCl) solution, or alternatively, 70 % ethanol.

Caution:



0.3% sodium hypochlorite:
H314 Causes severe skin burns and eye damage!



70% ethanol:
H319 Causes serious eye irritation.



H225 Highly flammable liquid and vapor.

Note: After cleaning the instrument with sodium hypochlorite (NaOCl) solution, it is essential to prime the device with distilled water. The decontamination solution must not contain any surfactants, as these are very persistent and can affect the needle level detection behavior. Commercially available chlorine cleaners contain surfactants!

1. Empty all bottles (#1, #2 and waste), check the Bottles for discoloration or wear and rinse the bottles with distilled water. If a Bottle shows signs of discoloration or brittleness, it needs to be replaced. Clean the Bottle caps and check growth, ensure that the pressure equalization holes on top of the Bottle caps are free.

Click **“Next”** to continue

2. Connect the device.

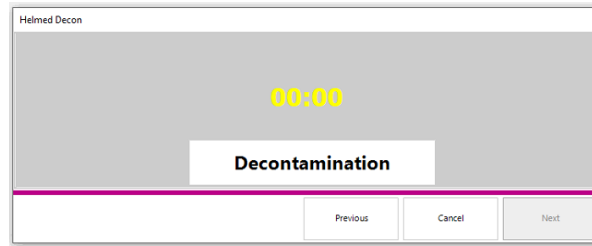
3. Click **“Prime Needles”**



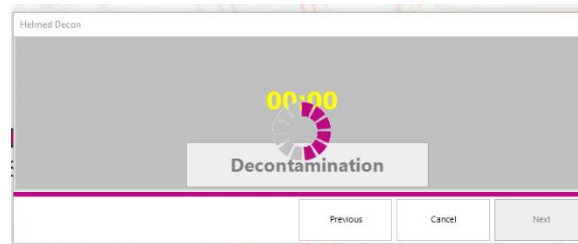
4. choose the washing option **“Decontamination”**.

5. Confirm with **“OK”**.

6. Follow the Steps on screen, advance with the **“Next”** Button



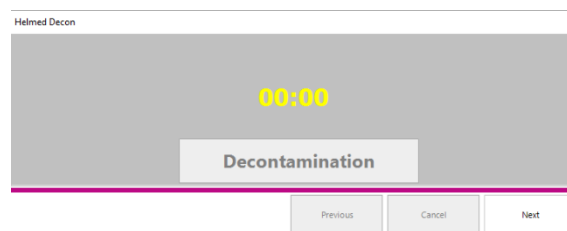
7. Start the Decontamination with the **“Decontamination”** Button.



8. The Device will start decontaminating by ingesting the decontamination fluid.



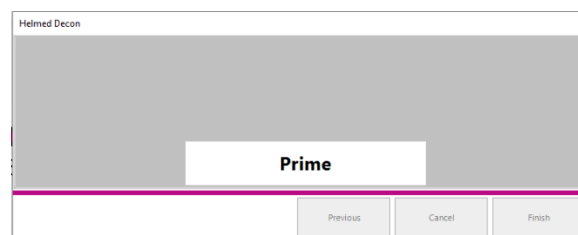
9. Once all tubing has been filled with the decon liquid, a 15 minute timer will start.



10. **Do not unnecessarily prolong the Decon Time as this will deteriorate the device.**

Click **“Next”** to continue.

11. Follow the Steps on screen, advance with the **“Next”** Button.



12. Start Priming with distilled Water with the **“Prime”** Button.

13. The Device will flush the decon liquid with distilled water.



14. Finish the Decontamination with the **“Finish”** Button.

8.3 Cleaning of the device

The surfaces and the accessible parts of the unit should be cleaned with water and a mild pH-neutral detergent. To prevent contact with skin or eyes, use personal protective equipment, such as lab coats, gloves, and goggles. The racks and the central ring may be removed for cleaning and for disinfecting, if necessary. It is recommended to clean the surfaces every week. Only use cleaning agents (e.g. 70% EtOH) recommend by Aesku.Diagnostics GmbH & Co. KG to avoid any damage to the device and/or equipment. For further cleaning advise, please contact **AESKU** Customer Support Team.

8.4 Disinfection of the device

The surfaces and all accessible parts of the equipment should be disinfected with 70% ethanol, if necessary. Do not use pump sprays to avoid flammable vapors. To prevent contact with skin or eyes, use personal protective equipment, such as lab coats, gloves, and goggles. The racks and the central ring may be removed for cleaning and for disinfecting, if necessary. It is recommended to disinfect the surfaces and especially the racks regularly. Only use cleaning agents (e.g. 70% EtOH) recommend by Aesku.Diagnostics GmbH & Co. KG to avoid any damage to the device and/or equipment. For any further disinfection advise, please contact your local distributor or **AESKU** Customer Support Team.

8.5 Calibration

It is recommended to calibrate the carousels as part of the maintenance. The interval depends on the frequency of use. From rare to daily use, we recommend quarterly to annual maintenance.

After any mechanical adjustments or intervention to the camera unit, a recalibration of the camera is mandatory.

All calibrations may only be performed by trained personnel!

8.6 Taking the device out of service

The device must be decontaminated (Section 02) before decommissioning.

Drain the wash bottles and rinse them with distilled water.

Drain the waste container, rinse and disinfect.

The device must be cleaned (Section 8.3) and disinfected (Section 8.4).

The unit must be stored in a dry place under storage conditions (Section 2.4).

8.7 Dealing with potentially hazardous material

If equipment conforming to IEC 61010-1 is used with equipment conforming to this standard, and if there is a hazard due to moisture or liquids in case of equipment spills, container breakage and similar malfunctions of any consumables, please clean and disinfect the affected area, refer and follow up country and lab specific legal requirements for disposal of potentially contaminated broken material. For cleaning, do not use any cleaning agents that could possibly damage the device or parts of the device. Only use cleaning agents (e.g. 70% EtOH) recommend by Aesku.Diagnostics GmbH & Co. KG to avoid any damage to the device and/or equipment. For cleaning and disinfection advice or replacement of broken material, please contact your local distributor or the **AESKU** Customer Support Team.

8.8 Disposal

Before the proper disposal or shipment of the device, it is essential to ensure that the device is cleaned and disinfected, following sections 8.2, 8.3, and 8.4.



Disposal of device

In accordance with the WEEE 2012/19/EU guideline for proper disposal of the device, local regulations must be followed when disposing of the device, or the device must be returned to the manufacturer. For further information on return and disposal, please contact your distributor or the manufacturer.

Contact details are provided on the last page of the manual.

9 Regulatory symbols



In-vitro Diagnostic (IVD)



European Conformity



Observe the instructions for use



CAUTION!



Manufacturer



Date of Manufacture



Reference Number



Serial Number



Unique Device Identification



Laboratory Equipment
Electrical Safety UL 61010-1



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