

HELIOS[®]

HELMED INTEGRATED OPTICAL SYSTEM

AUTOMATED IFA SYSTEM

INSTRUCTIONS FOR USE

— valid from HELIOS[®] device software version 4.1 —



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1 General Safety Information

1.1 General information

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 usage.

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 warnings

The following symbols will be used throughout the text:

Advice

ADVICE

Please wear gloves!



Immediately wash hands if the skin was exposed!

Hazard notes

HAZARD

Skin irritation!



Skin irritations may occur when skin is exposed to hydrochloric acid.

Warning notes

WARNING

Caution! Biological hazard!



Avoid contact with biologically hazardous 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.



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.



Hot surface / Heat

In case of a malfunction of the incubator, the labeled microtiter holding plate may be hot.

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 the chapters 15.3 & 15.4.

Disposal of potentially hazardous material

For disposal of any consumables or broken material refer to chapters 15.7 & 15.8.



Light radiation warning

The device contains a strong light source that may harm eyes if handled improperly!



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.

1.5 Advice

Appropriate use

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

Only qualified personnel experienced 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 HELIOS® 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 15.77.

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 Intended Purpose

Instrument:

The **HELIOS® Automated IFA System** is an automated laboratory device performing and analyzing the indirect immunofluorescence assays (IIFA) under controlled conditions in terms of humidity and temperature for in-vitro determination of antibodies in human serum related to autoimmune and infectious diseases. The device is an aid to diagnosis. All suggested results obtained by **HELIOS® Automated IFA System** in conjunction with other clinical and laboratory findings must be confirmed by trained healthcare professionals. The device is intended for professional use only.

Cells/tissue coated microscopy slides are used as a substrate for the qualitative and/or semi-quantitative determination of antibodies in human serum by automated processing and analyzing of indirect immunofluorescence assays (IIFA) with the **HELIOS® Automated IFA System**.

The **Humidity Temperature Control (HTC) Kit** as an optional accessory enables the system to adjust and maintain the internal parameters in terms of humidity and temperature. The **Humidity Temperature Control (HTC) Kit (REF.HTC-1001)** is intended to be used with **REF.IOS-1000 (HELIOS®)** or **REF.HEL-1000 (HELMED®)**.

The **HTC** function offering a new range of infectious serology substrates for AESKU automated IFAs, including markers for e.g., EBV, HSV, Adenovirus and Borrelia for automated determination of IgM antibodies by processing immunofluorescence assays with higher incubation temperature (35-37°C/ 95-98,6°F) in an internal adjusted environment. The device is intended for professional use only.

Assays:

AESKUSLIDES are an indirect fluorescent antibody assays utilizing cells/tissues coated slides as a substrate for the qualitative and/or semi-quantitative determination of antibodies in human serum **by manual microscopy or with the HELIOS AUTOMATED IFA SYSTEM**.

These *in-vitro* diagnostic assays are used as an aid in the diagnosis of autoimmune and infectious diseases in conjunction with other clinical and laboratory findings.

The instructions for specimen collection, transport, and preparation for analysis; storage recommendations; a summary and explanation of the test; step-by-step instructions for performing the assay; specific performance characteristics such as accuracy, precision, specificity, and sensitivity; cut-off criteria and interpretation of results; limitations of the assay; quality control recommendations; bibliography; can be found in the package insert of the **AESKUSLIDES®** assays.

Note: The procedures that describe the use of the slides in combination with the **HELIOS®** are described on the example of the **AESKUSLIDES® ANA HEp-2-Gamma** assay!

3 Product Description

The **HELIOS®** AUTOMATED IFA SYSTEM with optional **Humidity Temperature Control (HTC)** kit is an automated processor for immunofluorescence processing and image capturing with an integrated fluorescence microscope. The system is intended for routine laboratory use by professional users under controlled environmental conditions. All suggested results obtained with the **HELIOS®** must be confirmed by trained personnel.

In the first step of the workflow, the slides are processed according to a predefined preparation protocol. Subsequently, fluorescence microscopy of the wells is performed and depending on the respective substrate, each image is mapped via a pre-classification suggestion. Following this process, the user classifies each well and merges the results into one comprehensive report.

Thanks to the various **HELIOS®** software modules, the user can start the **HELIOS®** IFA module (slide processing and image capturing with user confirmation of results) or select individual process steps as needed for the daily lab requirements.

The **HELIOS®** IFA module (slide processing and image capturing) facilitates the processing of IFA slides and subsequently automatically starts the **HELIOS®** Image Capturing process. This process scans all slides and generates a predefined number of images per well and, if available for the processed substrate, provides a classification suggestion per image. The **HELIOS®** IFA module is validated with **AESKUSLIDES ANA Hep-2**, **AESKUSLIDES nDNA**, **AESKUSLIDES ANCA-E/F**, **AESKUSLIDES EMA** and **AESKUSLIDES mLKS/rLKS**. Please keep in mind that not all **AESKUSLIDES®** kits are available for each country.

Additionally, supplier-independent **HELMED®** IFA software (slide processing) is available as an open system that also includes all **AESKUSLIDES®** kit information, but also allows the creation of various slide types and tests of other IFA kit suppliers. **HELMED®** IFA was evaluated and validated for **AESKUSLIDES®** kits. **Aesku.Diagnostics GmbH & Co. KG** does not assume any liability for the processing of IFA kits of other manufacturers.

The **HELIOS®** Image Capturing module automatically scans slide barcodes, generates images and provides a pre-classification suggestion for each image which must be validated by the laboratory. The integrated microscope approaches all wells for this process step and records a user-predefined number of images per well using autofocus.

The **HELIOS®** Result Confirmation module facilitates software-based documentation of classification, to ensure results tracking. For user classification purposes, the images are available for each well along with the classification suggestion, which is not available for every single substrate. All data from the created worklist and the user classification of the wells will be merged into the report.

The **HELIOS® Automated IFA System** consists of the following components: **HELIOS®** instrument combined with an external computer, keyboard, mouse, and the **HELIOS®** device software including all the modules mentioned above. A printer is not included in the delivery. The **REF.HTC-1001** kit is optional available.

3.1 Immunofluorescence analysis with the HELIOS® system

Testing is based on the principle of indirect immunofluorescence, for that patient samples are applied to the coated slides. Should a patient sample contain antibodies against components of the cell/tissue, they will bind to the respective substrate on the slide during the first incubation step. Unbound components of the serum are removed during the washing step.

The bound patient antibodies are labelled during the second step of the process by using fluorescein-labelled anti-human secondary immunoglobulins that bind to the previous bound primary patient antibodies, making them visible by antibody attached fluorochromes. Unbound secondary antibodies are removed during the wash process.

This results in a specific fluorescence of the antigen-antibody complex that becomes visible under a fluorescence microscope. **HELIOS®** automates and simplifies the preparation as well as microscopic classification of **AESKUSLIDES®** by the user.

All information regarding the various **HELIOS®** device software sub-modules can be found in Section 6.

3.2 Legal and regulatory disclaimer

The **HELIOS®** system is solely approved for in-vitro diagnosis (IVD).

The system is typically used in a healthcare institution e.g., by professionals who have a formal education and expertise in performing IVD tests and using IVD instrumentation. These IVD tests are typically carried out repetitively 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 required to verify the performance of these assays in their laboratories before reporting patient results by country specific regulations.

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

The highest risk class of IVDs running on the **HELIOS®** system are class C IVDs (EU) or class II IVDs (US).

External factors (such as bright particles or air bubbles) during preparation may result in artefacts present in the generated image. In rare cases it is possible that the optics may focus on the artefact, resulting in incorrectly exposed images. Interpretations based on the true substrate intensity are in such cases no longer possible. The images are recognizable by the presence of bright particles, circular structures (air bubbles) or unusually deformed cells. These images should be discarded by the user and should not be used for diagnosis. Final microscopic examination of inconclusive slides or wells should be performed manually.

3.3 General and technical information

- **Sample capacity:**
With barcode: up to 190
- **Dilution Plates:**
2x 96 wells, F-bottom
- **Dilution capacity:**
IFA: 192 cavities
1/1 to 1/160: one step (one well in MTP)
1/161 to 1/25600: two steps (two wells in MTP)
- **Pumps and syringes:**
One peristaltic pump to remove liquids.
One peristaltic pump for washing and priming.
1 x 50 µl syringe
1 x 1 ml syringe
- **Power consumption:**
275 W
- **Fuse:**
2x T4A/250V; 5x20mm
- **Voltage range:**
Input: 100 - 240 VAC
Output: 24 Volt DC / 5 Volt DC
Frequency: 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° - 37°C / 68° - 98,6°F
Rel. humidity [rH]: 10% - 80%, 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% rel. humidity, 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) / 29.5" x 25.6" x 22.4"
 - 36kg (weight) / 79lbs
- **Microscope concept:**
 - Epi-fluorescence microscope with blue excitation LED (470 ~ 480nm)
 - Filter specs: EX AT480/30x / BS AT505DC / EM AT515lp
- **Lens 20x (standard):**
 - Manufacturer NIKON®
 - 20x magnification / ELWD 19mm / NA 0.40
- **Camera:**
 - USB 3.0 Vision Standard
 - CMOS imaging technology: low-power, progressive scan CMOS image sensor
 - RGB color camera, 5 Megapixel, Resolution 2.592H x 1.944V
 - 1/2.5-inch optical format
- **Microscope positioning system:**
 - 3 axes system controlled by stepper motor
- **Barcode scanner:**
 - 1D Barcode Scanner for Sample/Reagent Racks and Sample Identification
 - 2D Barcode Scanner for Slide Identification
- **Humidifier:**
 - Solis™ SK6366 (Type7212)
 - Size approx. 12.5 x 8.5 x 6.5 cm
 - Main voltage / frequency 100 – 240 V / 50/60 Hz
 - Rated power 12W
 - Ultrasonic frequency 1.7 MHz
 - Evaporation output max. 80ml/h
- **PC:**
 - 4K-UHD-Display
 - Minimum Specifications: Intel® Core™ i3-9100, 2,5"-SATA-HDD with 1 TB, 128 GB SSD, 8 GB DDR4 RAM
 - Microsoft® Windows 10 IoT Enterprise (64-Bit)

4 HELIOS Installation

It is recommended that the initial installation of the device is performed by trained personnel only according to the instructions in the **IFU** and **Service Manual**. Before the **HELIOS®** device will be installed, certain configuration steps must be performed. Please note the following information:

4.1 Scope of delivery and setup

HELIOS® is shipped in suitable transport packaging. Upon receipt, please check for any visible damages caused by transport.

Remove the device along with all accessories from the box and check that all the following items are present:

- 1x **HELIOS®** device (REF.IOS-1000)
- 1x **HELIOS®** ALL IN ONE PC / US WIN10/LTSC (REF# 20160561)
- 1x **HELIOS®** device software 4.1 (REF.IOS-411) (pre-installed)
- 1x Power cord (country specific)
- 1x USB 3.0 cable (Part# 20160325)
- 2x Wash bottle 1L ([Wash #1](#) & [Wash #2](#)) (Part# [20160040](#) / [20160041](#))
- 1x Waste bottle 2L (Part# 20160042)
- 1x Standard reagent rack (RCKR8) (Part# 20160013)
- 2x Sample racks (delivered as ordered from various options)
- 1x Starter kit #2 (Part# 20160007)
- 1x IOS Starter Package (3x Service Slides Part# 20160562 / 1x Calibration Container Part# 20160043)
- 1x Needle cleaning tool (Part# 20160044)
- 1x Instructions For Use (IFU)

If ordered with optional Humidity Temperature Control (HTC) kit (REF.HTC-1001):

- 1x LDPE bottle 0.5L for humidifier (Part# 20160312)
- 1x Humidifier (Part# 20160305)
- 1x Spiral hose humidifier (autoclavable) (Part# 20160307)
- 1x Reducing sleeve (Humidifier tube adapter) (Part# 20160308)
- 1x 24V power cable for humidifier (Part# 20160306)
- 1x Bottle Rack Humidifier (Part# 20160310)

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

4.2 Installation requirements

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

- ✓ Open the instrument cover and carefully remove the transport protection.
- ✓ Install the device on its designated spot and place the control PC next to the device. The instrument must be placed on a flat and stable surface, to ensure ventilation of the system.
- ✓ 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.
- ✓ Do not set up the device on a site that may potentially become wet.
- ✓ 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 completely from the electricity grid. Pull the power plug for this purpose.

- ✓ Do not allow the device or its flexible cord to be in contact with hot surfaces.
- ✓ Ensure that the power input matches the device's requirements.
- ✓ Set up the device on a stable lab bench and prevent any shocks to the device while operating (e.g., machines that may cause vibrations).
- ✓ Set up the device not near a source of dust.
- ✓ Pollution Degree II: Normal laboratory environment.

Two persons are required to move the unpacked device, one person on each side. One hand shall hold the front of the device at its base. The other hand shall hold the rear of the device, also at its base. This will prevent the device from toppling. Both persons should lift the device evenly and place it on the designated table. The device's center of gravity is toward the back of the device.

Note: The main supply voltage fluctuations cannot exceed $\pm 10\%$ from the nominal supply voltage (see 3.3 General and technical information).

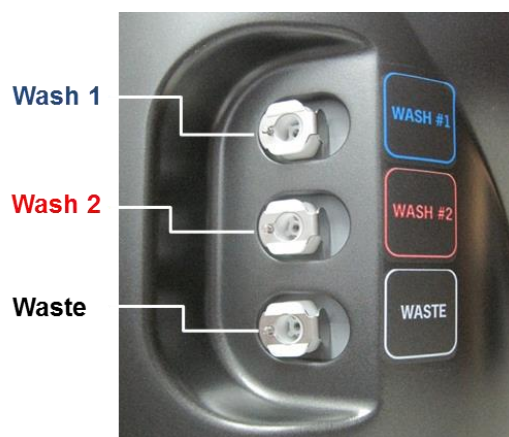
4.3 Connections/Connectors

4.3.1 Fluidic connectors

Liquid tubing and connecting the bottles to the **HELIOS®** device:

At the back of the device, you will find the quick connector clips for the wash and waste bottles.

The bottles and their respective tubing are marked and color-coded as shown in the illustration to the right.



4.3.2 Connecting the external humidifier

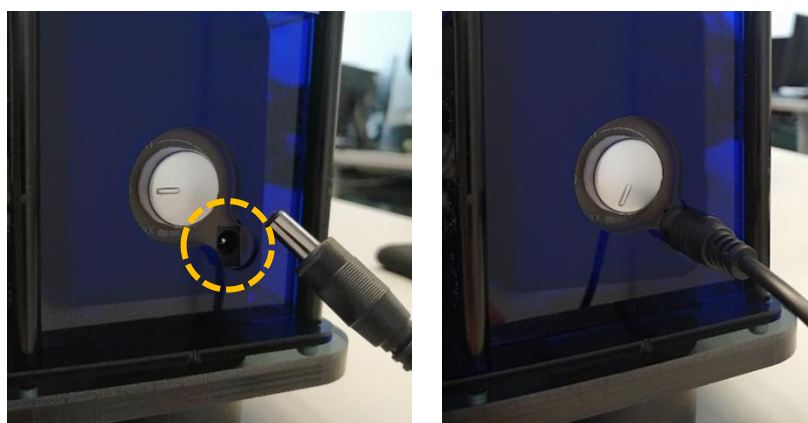
1. Connecting the power cable to the device and the external humidifier:

- Plug in the 24VDC cable into the 24VDC output jack on the backside of the device.



Note: The external humidifier has a power consumption of 12W in total and is supplied with power from the **HELIOS®** device with 24V / 500mA.

- Connect the 24VDC power cable with the external humidifier.



Note: The external humidifier has to be powered on once manually by using the main powerswitch and turn it to the maximum position.

Connect the CPAP tube with the device and the external humidifier:

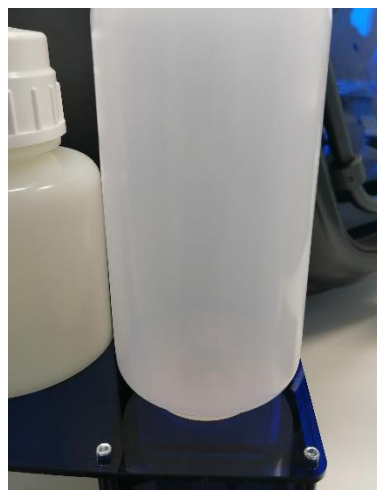
- Plug in the tubing to the adapter on the right backside of the device.



- Now connect the tubing with the adapter in the external humidifier.

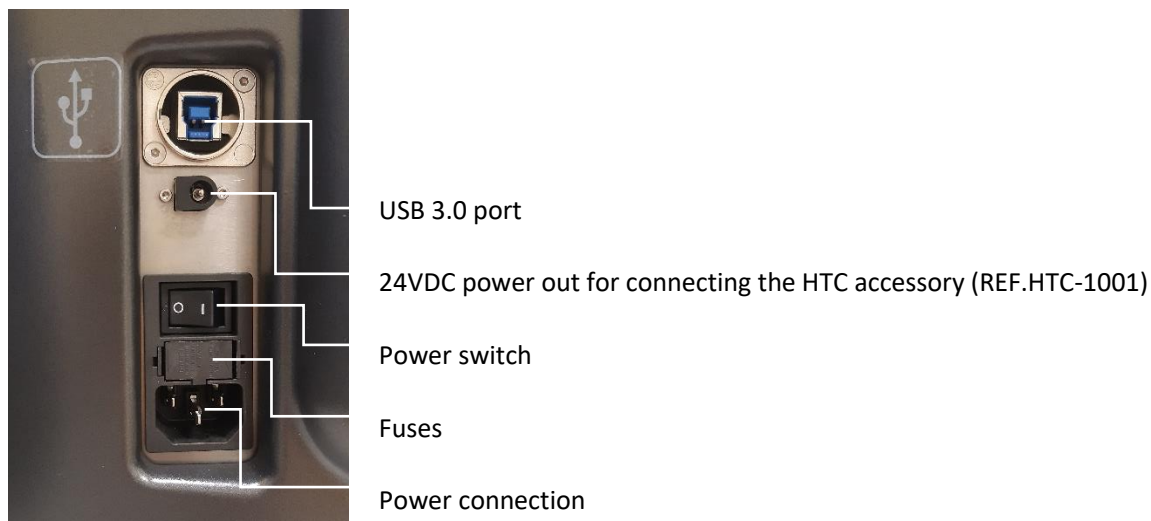
**2. Connecting the bottle (0,5 L) with the external humidifier:**

- Fill the provided bottle with distilled water to a maximum of 500 ml and screw the adapter onto the bottle. Afterwards plug the bottle onto the humidifier.



4.3.3 Electrical connections

The electrical connections can be found on the back of the computer and on the rear of the **HELIOS®** 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 **HELIOS®** instrument.

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.

2. 24V DC (power out) port:

Connect the power cable between the **HELIOS®** device and the external humidifier of the **Humidity Temperature Control (HTC) Kit** (REF.HTC-1001); if ordered separately (see chapter 4.3.2).

3. Main power supply (power in) port + power switch

Connect the power cable to the device and power on / off the device using the main power switch

5 Device functionalities

HELIOS® allows its users to automate the IFA process and slide reading, followed by confirmation done by a trained personnel or expert.



The automated process is only available for **AEKSUSLIDES®**. Slides of other manufacturers can be used as an individual process in the **HELMED® IFA module**. Aesku.Diagnostics GmbH & Co. KG does not assume any liabilities for the processing of IFA kits by other manufacturers.

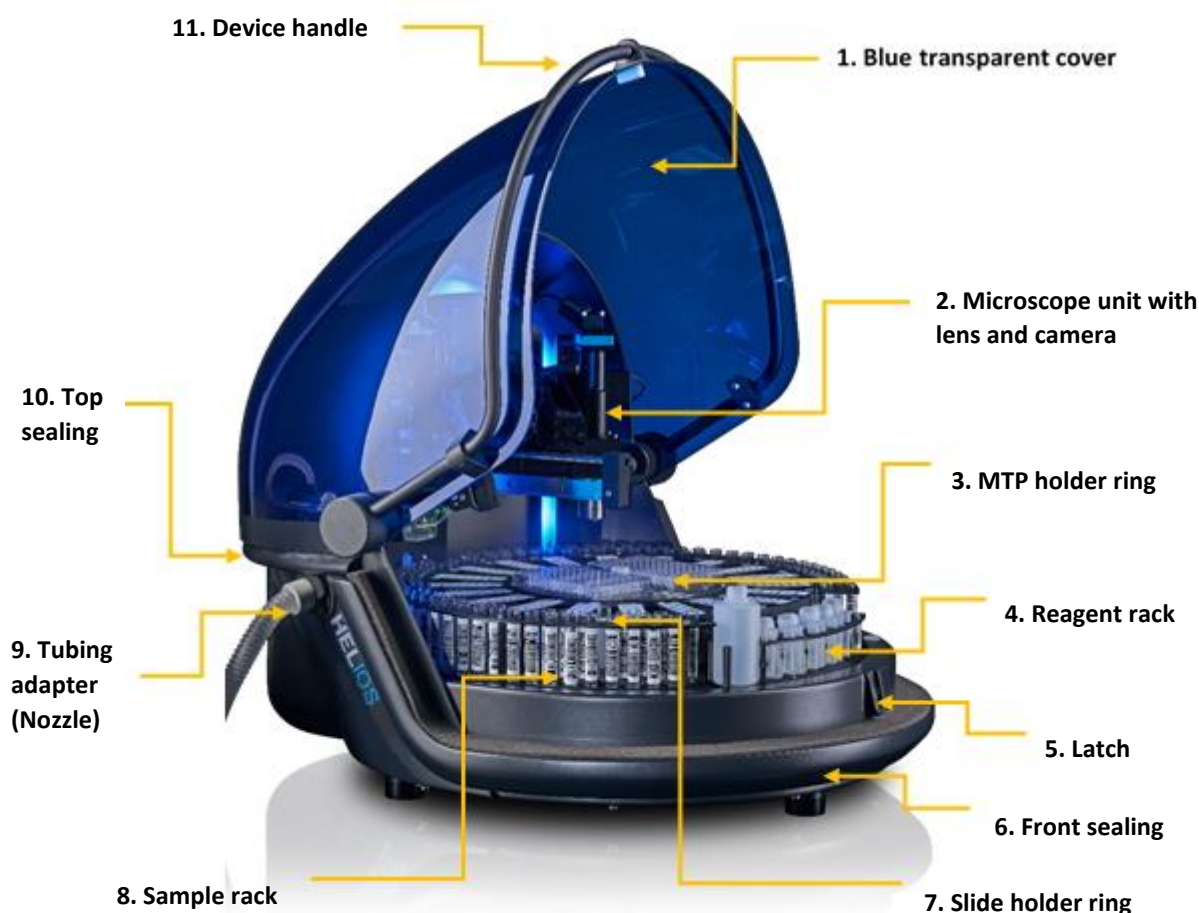
The following sections will describe the device as well as the various software modules in detail:

- ➔ **HELIOS®** Login and program overview (Section 6)
- ➔ **HELIOS®** IFA module (Section 7)
- ➔ **HELIOS®** Image capturing (Section 8)
- ➔ **HELIOS®** Result confirmation (Section 9)

Note: The software has not been validated with any other software other than what has already been provided (preinstalled on the delivered PC). Do not install any other software on this computer to avoid adverse events. If it is necessary to install virus protection software, set “D:\heliosworklists” and “My documents” directory to the exception directory for the live scan. To avoid adverse events or reduced device performance, these two directories should not be scanned by the anti-virus software.

5.1 HELIOS device and system components

5.1.1 Device overview

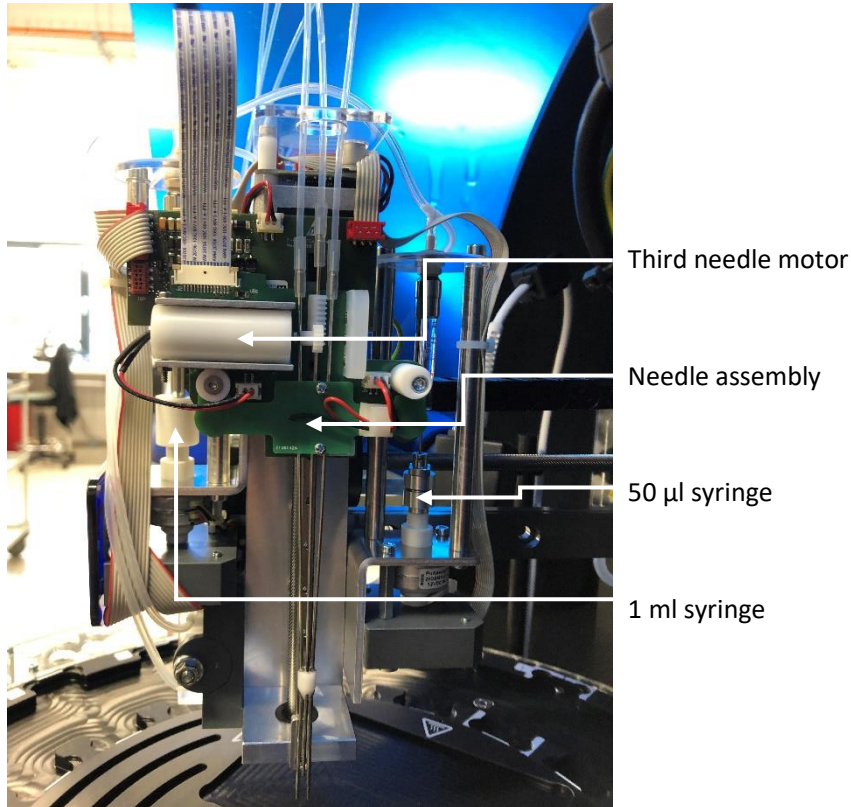


1. Blue transparent cover: User can watch progress of all processing steps.
2. Microscope with lens and camera: Optical analyzing unit, image capturing of each single well.
3. MTP holder ring: Holds the micro titer plates for sample dilutions and transfer to the slides.
4. Reagent rack: Rack for loading the kit reagents.
5. Latch: Locks the cover automatically during the whole process.
6. Front sealing: Seals the lid and the front panel cover to keep inner conditions stable.
7. Slide holder ring: Positioning of slides for being processed.
8. Sample rack: Rack for placing samples to be processed.
9. Tubing adapter: Connects the tubing from humidifier with the nozzle inside of the device.
10. Top sealing: Seals the upper lid and the back panel to keep inner conditions stable.
11. Device handle: To open and close the device.

5.1.2 Detailed view of the HELIOS system components

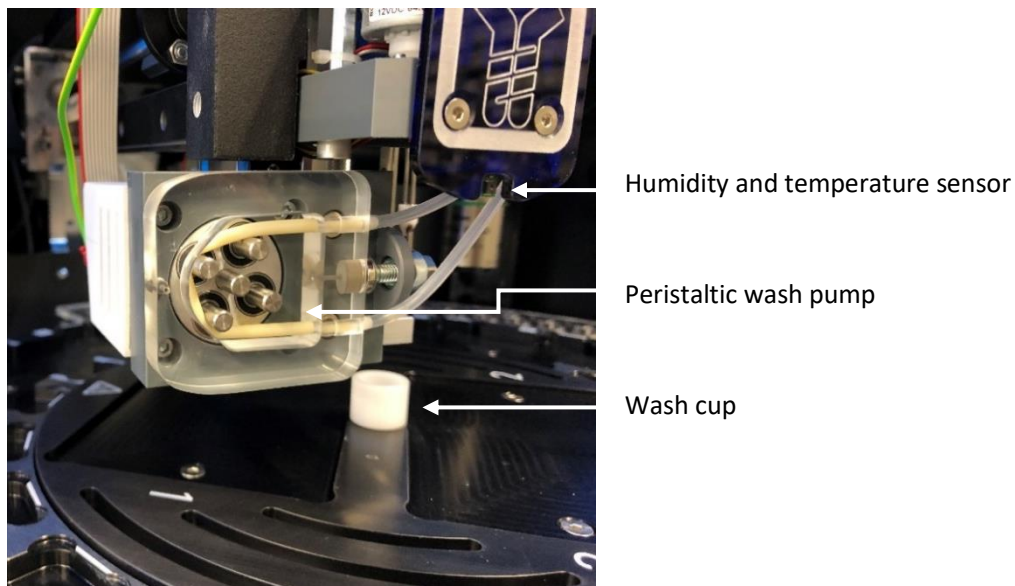
The following will provide you with an overview of the various components of the device.

Z unit (pipetting unit)



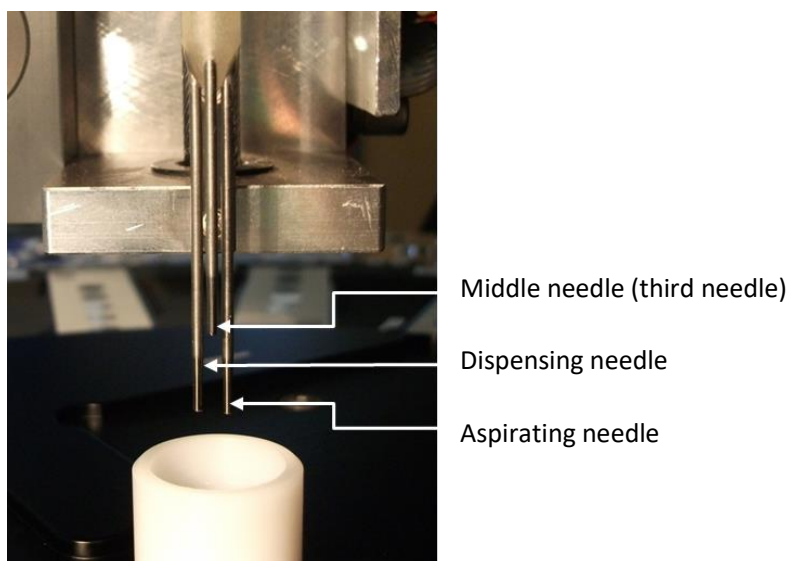
The z-assembly includes the z-motor for moving the needles up and down.

Peristaltic wash pump



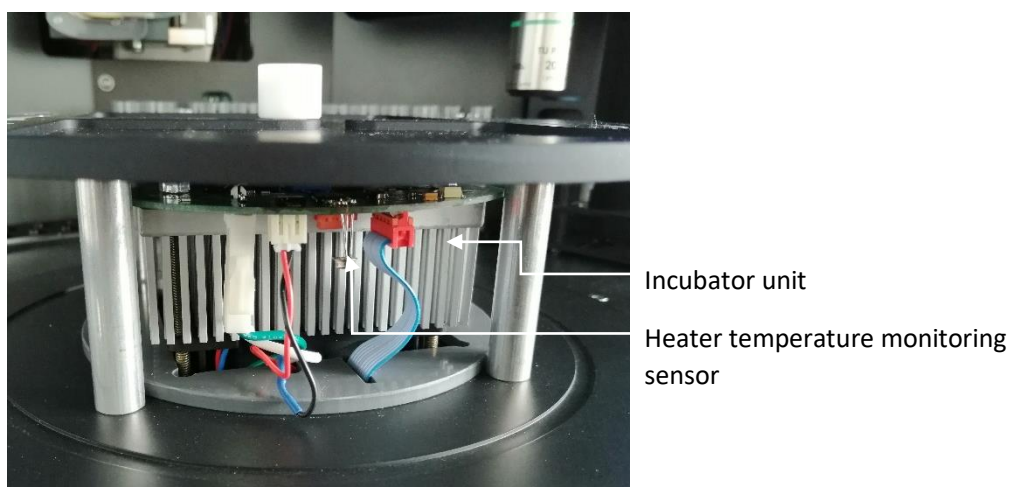
Used for all wash cycles during the IFA process and priming the instrument (needles and tubing) before and after IFA processing.

Needle unit



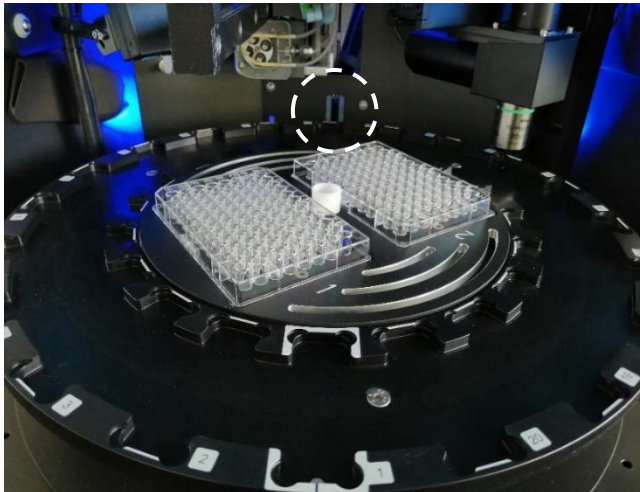
Three needle system with different needle functions: Front needle for dispensing samples and wash buffer, middle (movable) needle for dispensing reagents (conjugate, mounting media, etc.) and a rear needle for liquid aspiration.

Incubator unit



For internal temperature control and adjustment if higher temperature is required for IFA processing (sample and/or reagent incubation), for instance 35-37°C (95-98,6°F) for the determination of IgM antibodies for infectious serology test assays.

Sample barcode reader



The barcode reader for identifying the placed sample / reagent racks and the placed sample tubes is in the back of the device.

Sample tubes for processing will be placed in the sample racks. A variety of different sample racks is available. The reader will read the sample barcode ID (if present).

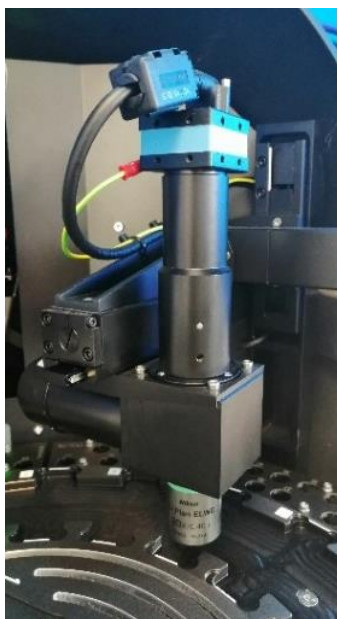
Slide barcode reader



The barcode reader for scanning **AESKUSLIDES®** is located on the left side of the device. At the beginning of the process, the barcode on the slides will be scanned. The scanned information will be stored to the worklist to ensure that the slides used will be traced.

Note: Slide barcodes of other manufacturers will not be scanned by the slide barcode reader nor accepted by the **HELIOS®** software!

Microscope unit



The microscope unit is located on the right side of the device. During preparation of the slides, the microscope will remain in parking position.

When the image capturing module of the **HELIOS®** starts, the microscope unit will be initialized and commence the image acquisition according to the respective worklist. The device cover will remain locked.

Sample racks

A variety of sample racks can be used in conjunction with the **HELIOS® Automated IFA System**. Most common racks are illustrated in the table below. For any further variants, please ask your local distributor or send your request to sales@aesku.com.

Table shows a selection of available racks:

HELIOS® RACK REFERENCE	75 x 12	75 x 12	75 x 13	75 x 13	40 x 14	100 x 12	100 x 12	100 x 13	100 x 15
Sample rack 1 REF. #	20160014	20160243	20160018	20160020	20160212	20160122	20160016	20160022	20160024
Sample rack 2 REF. #	20160015	20160244	20160019	20160021	20160213	20160123	20160017	20160023	20160025
Total samples (rack 1 + 2)	106	190	106	190	106	106	190	106	92

The **AESKU Multit-Rack**, the best choice for using different sample tubes in one rack:

- High flexibility, accepts most tubes
- Tubes ranging from 11 – 13 mm in diameter and 55 – 100 mm in length
- Sample tube capacity: 106
- The design of the rack and the clamping of the sample tubes increases overall stability
- Position numbers are clearly printed and easy to read
- The tubes are clamped in the holders to avoid rotation during the reading process of the sample barcodes



All 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 required as users can replace the racks themselves. Follow the instructions under **Scan Rack Layout** as described in sections 7.1.3 & 7.2.

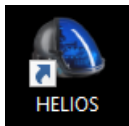
6 HELIOS Software overview

The **HELIOS**® device software may only be used by registered and trained personnel. To prevent any misuse of the device, the device features a user credential system that will be described in detail in the following section.

Administrator accounts must be created when the software is initially started. Information regarding this step can be found in the next section.

User accounts must be created for trained personnel. **Superuser** authorization will allow to change settings in the **Configuration** menu (section 6.2.5). **Admin** authorization will allow access to the **Autocalibration** function.

6.1 Login screen



After power on the device and PC, the Windows® desktop screen will be displayed. Please start the software by double-clicking the “**HELIOS**” desktop icon. The software will open with the login screen:



To login into the **HELIOS**® software, please enter the username and password and click the **OK** button.



Note: User accounts must be created in advance by an **administrator**. For further information, please refer to section 6.1.2. Default accounts for “**user**” and “**superuser**” are created by default.

6.1.1 Software information window



For general information about the software, please click on the info button on the lower right corner of the **HELIOS®** login screen. A new window will open providing all related information about the software version and release, the related REF number, the manufacturer etc.

6.1.2 Administrator area

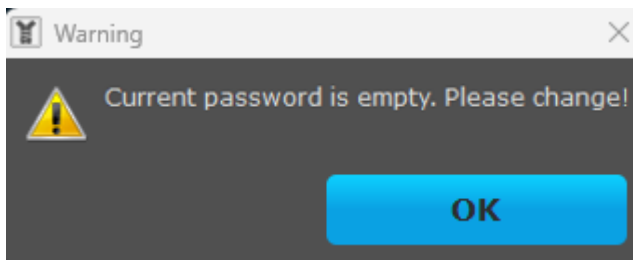
1. Log in as the administrator:

Name: **admin**; Password: - (leave blank)



Confirm entry by pressing **ENTER** or **OK** button.

2. An info window will open prompting to define a new password:

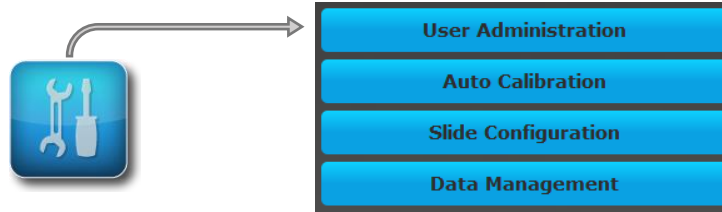


Confirm the info window by pressing the **OK** button.

3. The program overview with the selectable configurations button will be displayed:



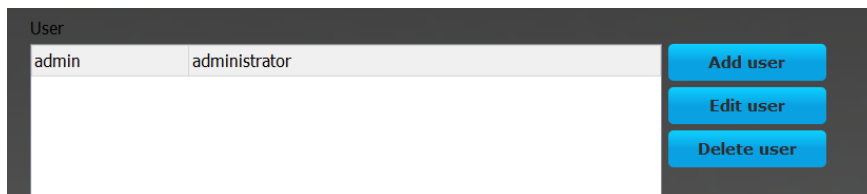
- Open the user management by clicking the **Configuration** button and afterwards the **User Administration** button:



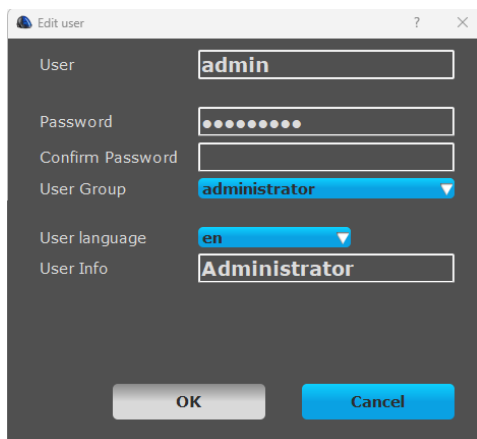
6.1.3 Edit User

Please change first the administrator password before creating new users.

- Select the **admin** user from the selection list and click the **Edit user** button:



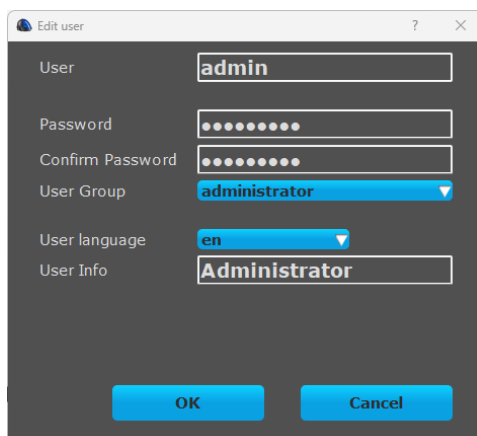
- Enter a new password:



Note: A password for user group “administrator” will never expire, while passwords for user groups “user” and “superuser” will expire after 90 days and must be changed. This will be prompted by the software.

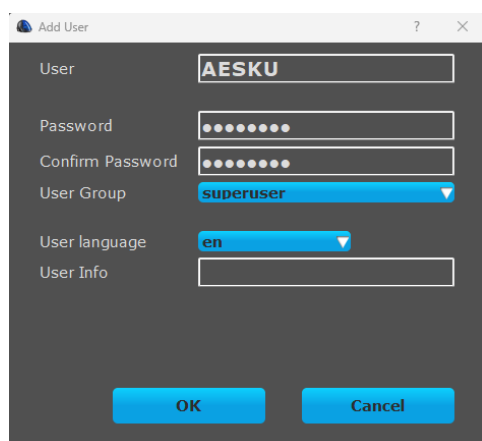
New passwords must contain at least 8 characters. Note down the new password.

- Confirm new password in the specific text box and press **OK**.



6.1.4 Add User

1. To create a user, click **Add User**.
2. Enter a specific username and password. Select a **User Group** and **User language**. Additional information about a certain user can also be optionally added in the field **User Info**.



3. Confirm all entries by clicking the **OK** button.

6.1.5 Delete User

1. Select a user from the selection list.
2. To delete the selected user, click **Delete User**.

6.2 Program overview

After login, the program overview screen will be displayed allowing to choose from the available modules or options. Available options depend on the logged in user account and related permissions (**user**, **superuser** or **administrator**). The following section will provide information on these options.



6.2.1 HELIOS IFA module (slide processing and image capturing)



By clicking this button, the user selects the automated **HELIOS**[®] processing mode (walk-away mode). First, the **HELIOS**[®] IFA module will open. The user here enters all relevant information regarding sample preparation and generates a worklist (see section 6 and especially 6.3). After the **HELIOS**[®] IFA has started, the individual slides will be processed. The subsequent **HELIOS**[®] Image capturing module will automatically start after the **HELIOS**[®] IFA process has completed (see section 8.1). The automated **HELIOS**[®] processing mode can be used only in conjunction with **AESKUSLIDES**[®].

6.2.2 HELMED IFA module (slide processing)



By clicking this button, the user selects the **HELMED**[®] IFA module which can be used for slide processing only (no image acquisition) (see section 6).

Using this module, **AESKUSLIDES**[®] and slides from other suppliers can be processed. **Aesku.Diagnostics GmbH & Co. KG** does not assume any liability in terms of processing IFA kits from other suppliers or manufacturer.

6.2.3 HELIOS Image Capturing (IC)



By clicking this button, the user selects the **HELIOS® Image Capturing** module. Cover-slipped slides or slides with a thin layer of mounting medium can be imaged using this module. The barcode of the slides will be scanned and mapped to the loaded worklist.

Note: Only previously scanned (related to the slide barcode) **AESKUSLIDES®** can be imaged. If the worklist does not contain the barcodes, no images will be captured.

6.2.4 HELIOS® Result confirmation



By clicking this button, the user can start the **Result Confirmation** module of the **HELIOS®** software. After loading a worklist, the classification of generated can be performed well by well. To support this process, the images of each well will be mapped with a classification suggestion (available for ANA, ANCA and nDNA). The user can analyze up to 10 images per well to interpret the results. All data and results of the worklist will be saved in a report to facilitate traceability.

6.2.5 Configuration



By clicking this button, a user logged in as an **administrator** can access the user management settings and edit the LIS script. If a user with “**superuser**” authorization is logged in, settings of the classification suggestion can be changed. For more detailed information, see section 12.

6.2.6 LIS



The **LIS** button is only available for users with **superuser** and **administrator** authorization. Clicking this button will access the **LIS** module. Find further information in the LIS manual.

6.2.7 HELIOS IFA mode vs. HELMED IFA mode

Function	HELIOS® IFA mode IFA processing + Image acquisition	HELMED® IFA mode IFA processing only	
Available tests	Only AESKUSLIDES® can be used for automated processing and reading	AESKUSLIDES®	Other slides
Image capturing (IC)	Automatic	manually	none
AESKUSLIDES® barcode	scanned	Scanned	Not scanned

7 HELIOS IFA Module

The **HELIOS**® IFA software module (slide processing and image capturing) provides users with the possibility to automatically perform the processing and microscopy of **AESKUSLIDES**®.

The worklist created in the **HELIOS**® IFA software module with sample IDs and traceability information is used in the image capturing software.

After entering the required information and creating the worklist, the process can be started.

7.1 Starting the program

Start the Automated **HELIOS**® IFA module (slide processing and image capturing):



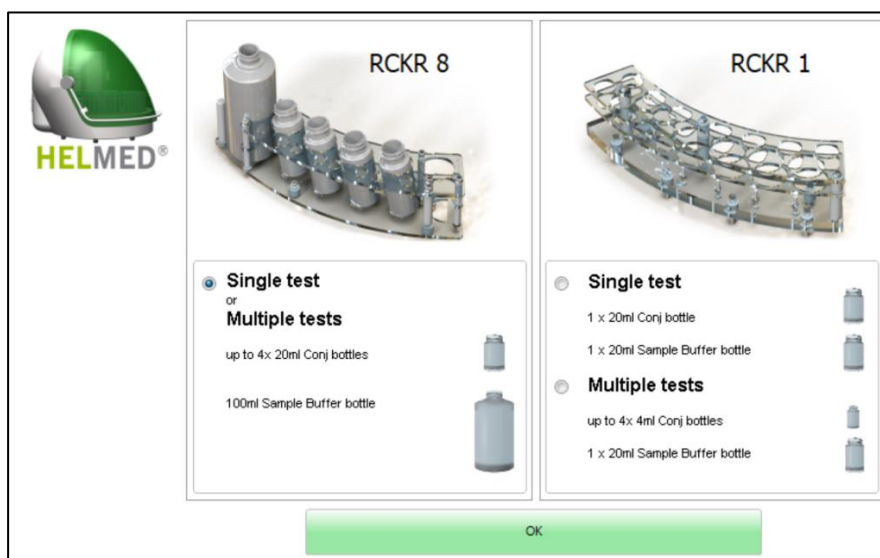
or start the **HELMED**® IFA module (slide processing):



Note: By using **AESKUSLIDES**®, the user can profit from full functionality of the **HELIOS**® IFA module. By using **slides of other manufacturers**, only processing is possible in the **HELMED**® IFA module (see also section 14.1 Slide Designer)

The **HELMED**® IFA module (slide processing) shares the same functionalities as the **HELIOS**® IFA module (slide processing and image capturing) for starting a run. The following instructions apply to both software modules if no differences are mentioned.

When starting the application, the following screen will appear:

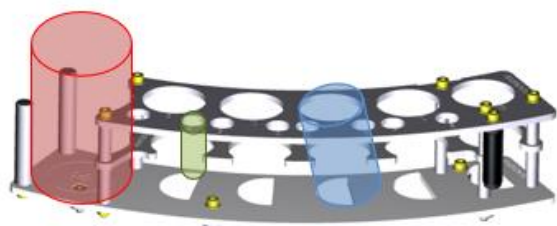


The user can now choose between two different reagent rack layouts:

- RCKR 8 is the current and standard version used with current **HELIOS®** & **HELMED®** devices.
- RCKR 1 is the predecessor and an older version of the reagent rack providing a different layout.

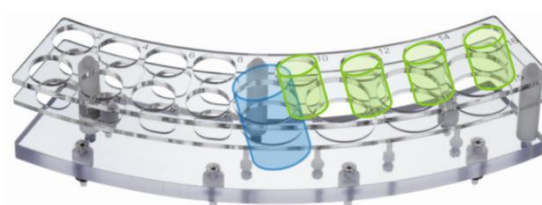
The layout of the current reagent rack **RCKR 8** and its functions (compared to the old version **RCKR 1**) is described in the following illustration:

RCKR 8 (standard version)



- **100 ml bottle – 1 slot (red bottle in illustration)**
For sample buffer
- **20ml vials – 5 slots (blue vials in illustration)**
For placing up to four different conjugates or counterstain and one slot reserved for mounting medium
- **2ml vials – 8 slots (green vial in illustration)**
For placement of up to eight combined different positive and negative controls

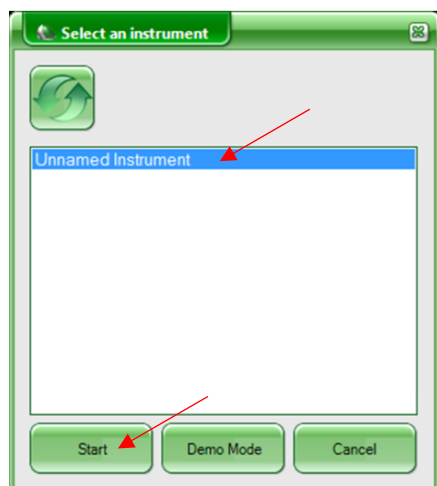
RCKR 1 (previous version)



- **20ml vials – 4 slots (blue vials in illustration)**
More than 20 slides per vial - Ideal for large screening with a single test
- **4ml vials – 12 slots (green vials in illustration)**
Up to 10 slides per vial - Ideal for combining multiple tests

Note: Only one large conjugate bottle is available. (If two tests are selected, only the first test can use the large bottle, the second test however must use the small bottle.)

Confirm the selected reagent rack layout by clicking the **Ok** button.



Click on the displayed instrument name - by default the serial number of the device is stated here - and press **Start** button to continue.

7.1.1 HELIOS IFA Main Screen



The IFA Main Screen will provide three menu tabs:

1. File contains the following options:

- **Create a new worklist**
- **Open an already processed worklist**
- **Close the currently open worklist**
- **Print the worklist**
- **Save the worklist**
- **Close the IFA software program**

2. Tools contains the modules for **Slide Designer** and **Test Designer**. It also provides the following options:

- **Prime instrument**
- **Change rack layout**
- **Change device name**
- **Scan sample ID barcode (on/off)**
- **Scan rack layout before starting worklist (on/off)**
- **Enable background illumination (on/off)**
- **Enable loading wizard (on/off)**
- **Prompt sample refill if insufficient volume (on/off)**

3. **Help** tab contains two available options:

- **About**
- **User Manual**

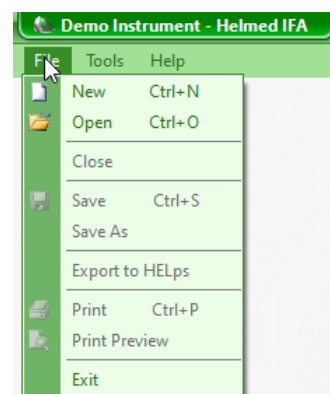
Note: When the **HELMED®** IFA (slide processing only) software is started, the IFA Main Screen will appear in blue design (instead of green) to easily distinguish between the two software modules.



7.1.2 File

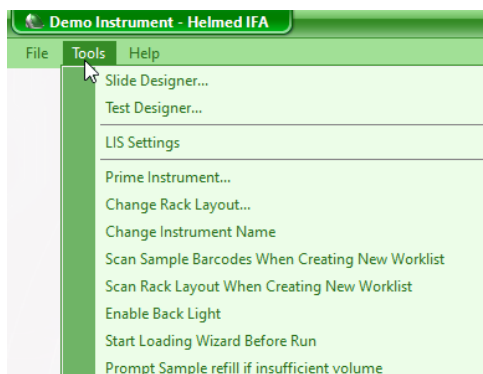
The **File** menu contains the following options:

- **New:** Creates a new worklist.
- **Open:** Opens a previously created and saved worklist.
- **Close:** Closes the currently open worklist.
- **Save/Save as:** Saves a programmed worklist with a specific file name.
- **Print/Print preview:** Prints currently open worklist.
- **Exit:** Closes the IFA software module.



7.1.3 Tools

The **Tools** menu contains several options that will be described briefly in the following section. Additional information can be found in section 14.



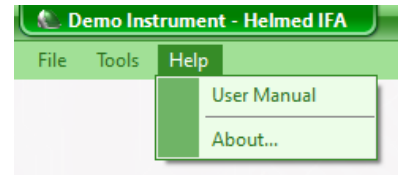
Note: The additional modules **Slide Designer** and **Test Designer** can be used for programming slides and the respective tests from other manufacturers. These can be used in the **HELMED® IFA** (slide processing) software only. **AESKU** test files for the automated **HELIOS® IFA** and **HELMED® IFA** process are predefined.

- **Slide Designer:** Contains the **Well Designer** module. Refer to section 14.1 for details of the Slide Designer screen.
- **Test Designer:** Contains the **Control Designer** module. Refer to section 14.2.3 for details of the Test Designer screen.
- **LIS Settings:** For further information, please refer to the LIS Interface description manual.
- **Prime Instrument:** Manually flush the device with the liquid inside the connected wash bottles.
- **Change Rack Layout:** Scans the racks currently placed inside the device.
- **Change Instrument Name:** The name of the device can be changed here (Please do not use any special characters).
- **Scan Sample Barcodes When Creating New Worklist:** Having the option enabled, barcode-labeled sample tubes will be read during the creation of a new worklist.
- **Scan Rack Layout When Creating New Worklist:** When activated, the racks currently placed inside the device will be scanned during the creation a new worklist.
- **Enable Back Light:** With this option active, the background illumination will be powered on during pipetting. This option is intended for design and demo purpose only and it is strongly recommended to not enable this option during normal laboratory operation.
- **Start Loading Wizard Before Run:** When activated, the Loading Wizard will guide equipping the device with the components needed for the created worklist. See also 7.2.
- **Prompt Sample refill if insufficient volume:** The software signals a too low sample volume. A warning message will be prompted on the screen in addition with an acoustic and optical signal. The following options are available:

1. **Refill sample:** The cover will become unlocked, and the respective sample can be refilled by the operator.
2. **Skip sample:** By pressing this button, the respective sample will be skipped immediately and not processed by the software. If no action is taken by the operator (no refill or skip), the respective sample will be automatically skipped after 10 minutes.

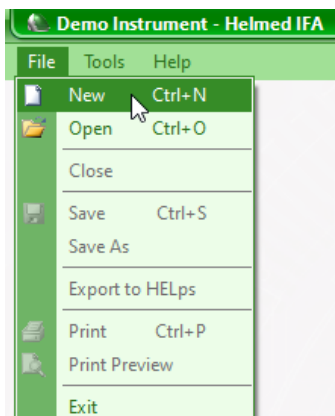
7.1.4 Help

The **Help** tab contains two options:



- **User Manual:** Contains a pdf with a link to the **HELIOS®** website providing additional information about the system, and offering a download area for downloading the latest IFUs etc. Alternatively, it is possible to ask your local distributor about the latest version of the user instruction manual.
- **About:** By clicking this option, a new window will open providing information about the installed IFA software version.

7.2 Create worklist



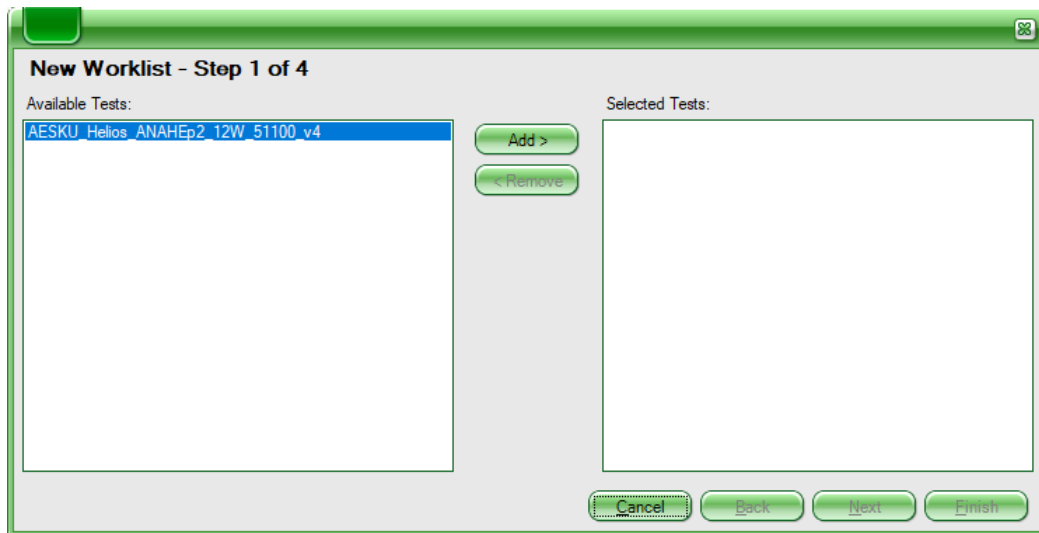
Select the **File** tab from the menu bar of the **HELIOS®** IFA main screen, and choose:

- **New:** To create a new worklist.
- **Open:** To open a previously created and/or saved worklist.

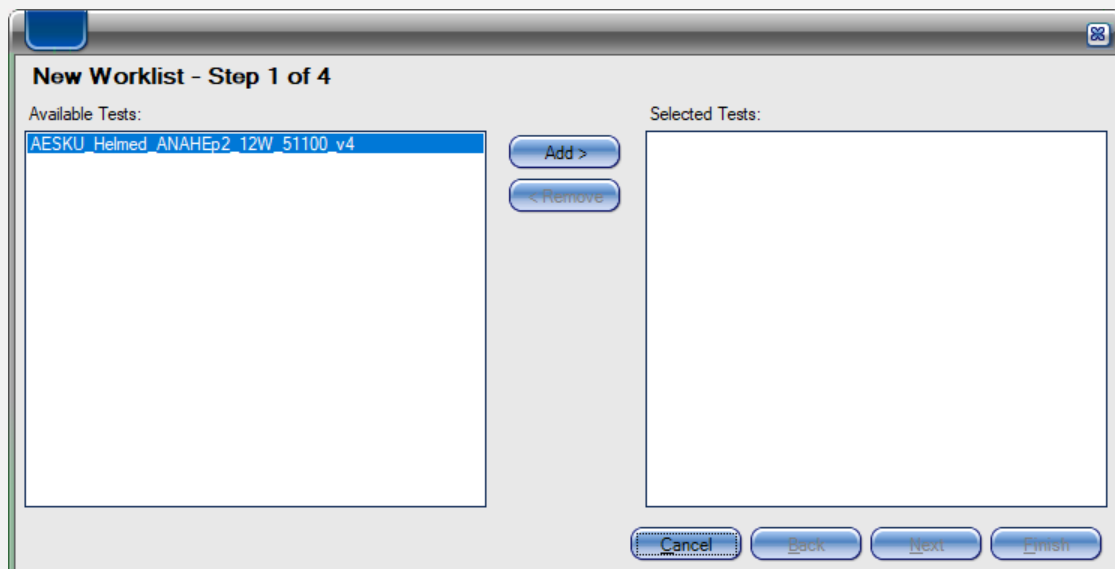
An example on **how to create** a new worklist will be shown in the following section based on **AESKUSLIDES ANA HEp2**.

How to create a new worklist:

1. In the **New worklist – Step 1 of 4** window, select and mark the **AESKU_Helios_ANAHEp2_12W_51100_v4** test from the list of available tests and add it by clicking the **Add** button.



Note: In the **HELMED®** IFA module (slide processing only), all tests predefined by **Aesku.Diagnostics GmbH & Co. KG** can be selected. User specific tests (e.g., for slides of other manufacturers) can be selected here as well. For further information, please refer to section 14.



2. The **New worklist – Step 2 of 4** window will display the selected test.

- The predefined slide for the test will be displayed in the **Slide** dropdown list
- In the **Mode** dropdown list, the user can choose between **Screening** or **Titration** mode.

3. To add an additional test, activate the **Add Another Test** checkbox.

Up to four different tests can be selected (New Worklist Step 1 of 4) to be processed in a single run / worklist. To do so, select the respective tests from **Available Tests** in the left column and add it to the **Selected Tests** in the right column.

4. If there are no more additional tests to add to this worklist, uncheck the **Add Another Test** checkbox.

5. Click **Continue**.

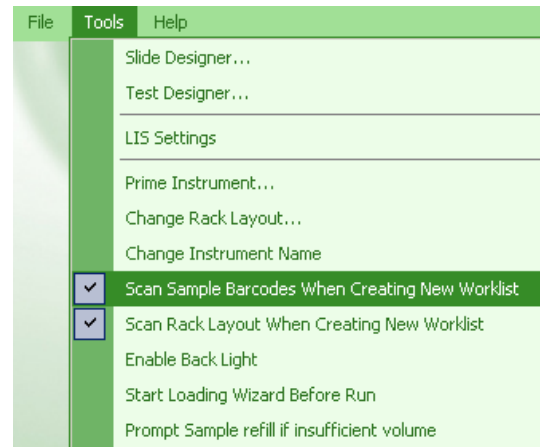
6. Clicking on the **Traceability** button will open a new window. Additional information, such as operator or LOT numbers, can be entered here. This information will be contained in the report.

Note: Regularly check that the information in the **Traceability** window is up to date! All data entered in here will be included in the report which is generated in the **HELIOS® Result Confirmation** module.

When the function **Scan Sample Barcodes When Creating New Worklist** is enabled, barcode-labeled sample tubes will be scanned during the creation of a worklist.

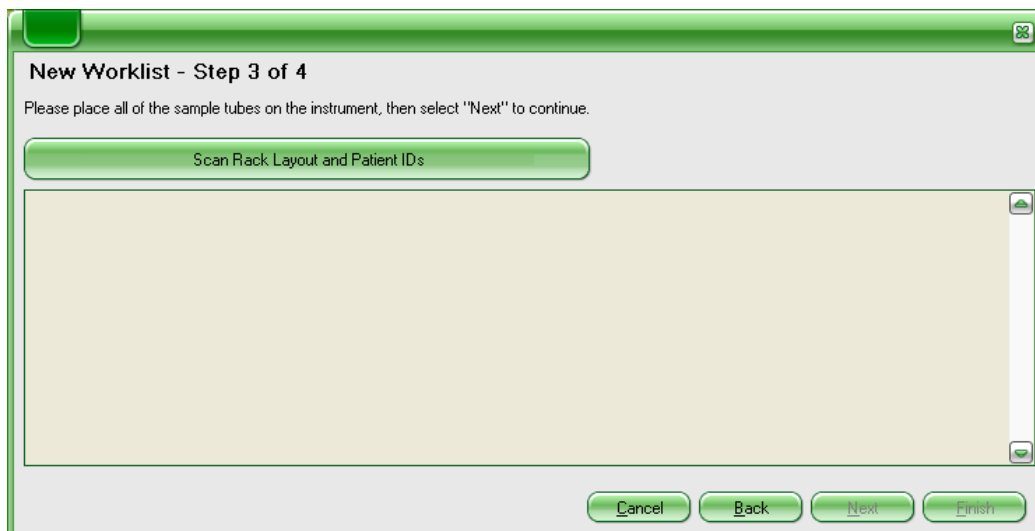
If the current placed racks should be scanned before every run, the option **Scan Rack Layout When Creating New Worklist** needs to be enabled.

1. Select the tab **Tools** in the IFA main window.
2. Activate the respective function(s) in the dropdown menu by clicking on it. A checkmark will highlight that the function has been enabled.



New Worklist - Step 3 of 4

3. To start the scanning process, click **Scan Rack Layout and Patient IDs**

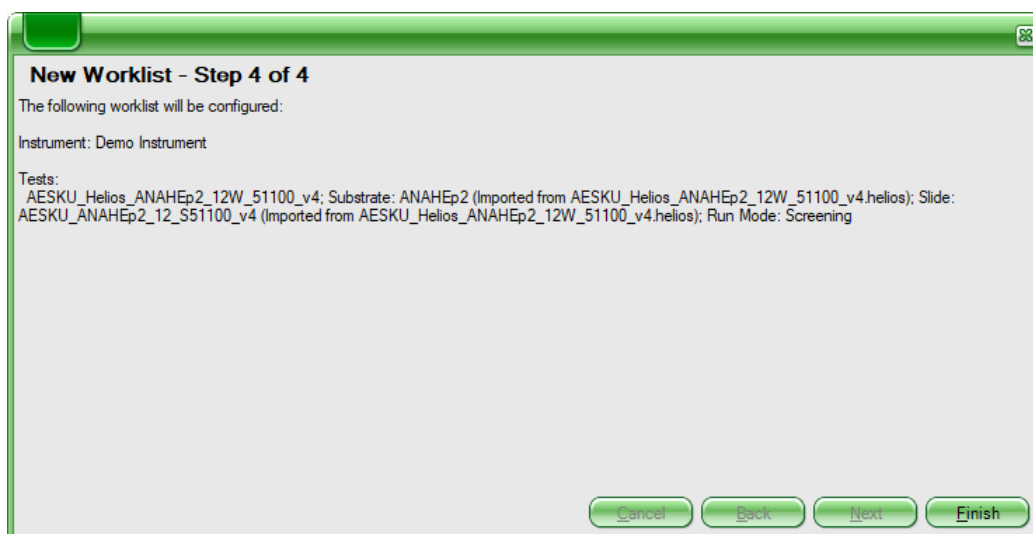


The scanning process is completed when the **Next** button becomes active. Scanned barcodes will be displayed in the window **New Worklist - Step 3 of 4**. Click **Next** to proceed with step **4 of 4**.

Note: If the barcode is not recognized, the outer ring will rotate several steps clockwise and counter-clockwise to enable enlargement of scan area. It is recommended to position the primary tubes in a way that the barcodes can be read immediately (barcode facing out) to ensure rapid processing.

New Worklist - Step 4 of 4

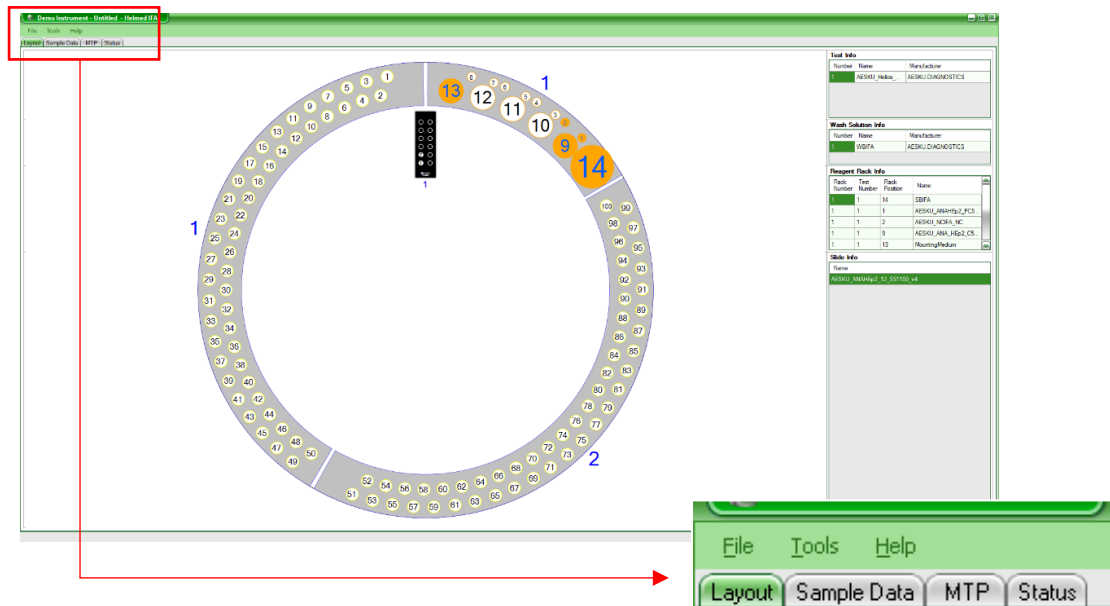
Provides information about the device name as well as the selected tests for the worklist to be processed.



To proceed to the worklist layout overview, click the **Finish** button.

7.2.1 Created worklist - Overview

The worklist overview will open by default showing the **Layout** tab with additional info fields on the right side providing information about the tests, wash solution and required reagents.

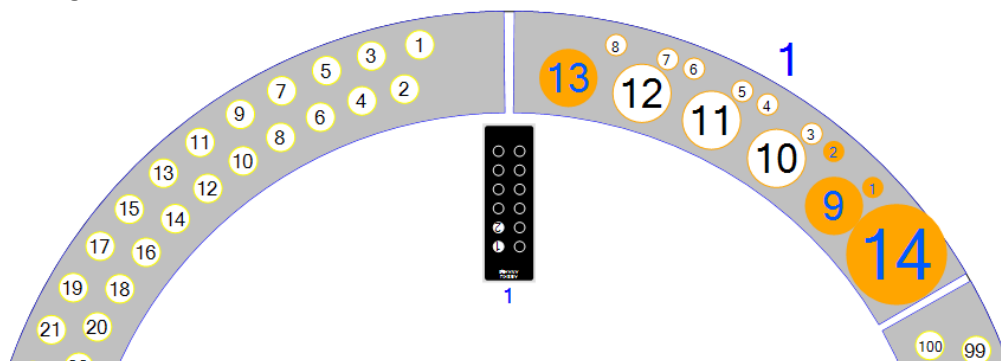


The following tabs are available in the worklist overview window:

- Layout
- Sample Data
- MTP
- Status

7.2.1.1 Layout tab

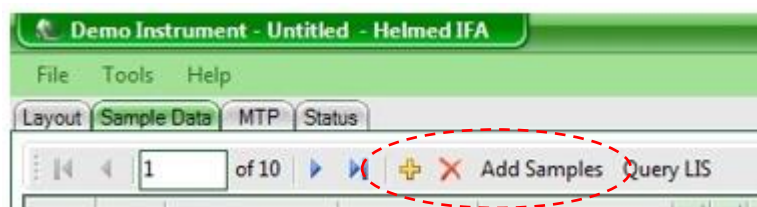
The **Layout** tab provides information where all the reagents, controls, samples and slides are located or need to be placed. After the necessary dilutions for the samples are selected by placing a checkmark (see **Sample Data tab** section), the layout view will provide the updated information on the required slides and reagents:



7.2.1.2 Sample Data tab

Sample information needs to be provided here. For sample and reagent preparation, please refer to the IFUs from **Aesku.Diagnostics GmbH & Co. KG** for using **AESKUSLIDES®** or any other kit manufacturer.

If non-barcode labeled sample tubes are used, and therefore no IDs could be scanned, please use the  icon to manually add samples.



The **Add Samples** option allows the user to enter the required number of samples with automatically generated sample IDs. All samples and the respective dilution used for analysis must be selected. It is also possible to add patient names, comments, and remarks in addition to every single sample ID:

	#	Rack Position	Sample Id	Remarks	Firstname	Lastname	1/1	1/80	1/160	1/320	1/640	1/1280	1/2560	1/5120	1/10240	1/20480
▶	1	1.1	Sample ID #1				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	2	1.2	Sample ID #2				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	3	1.3	Sample ID #3				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	4	1.4	Sample ID #4				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	5	1.5	Sample ID #5				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	6	1.6	Sample ID #6				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Note: Please do not use any special characters in the fields. Usage of dots and brackets (<>) can cause issues loading the worklist in the **Result Confirmation** modul.

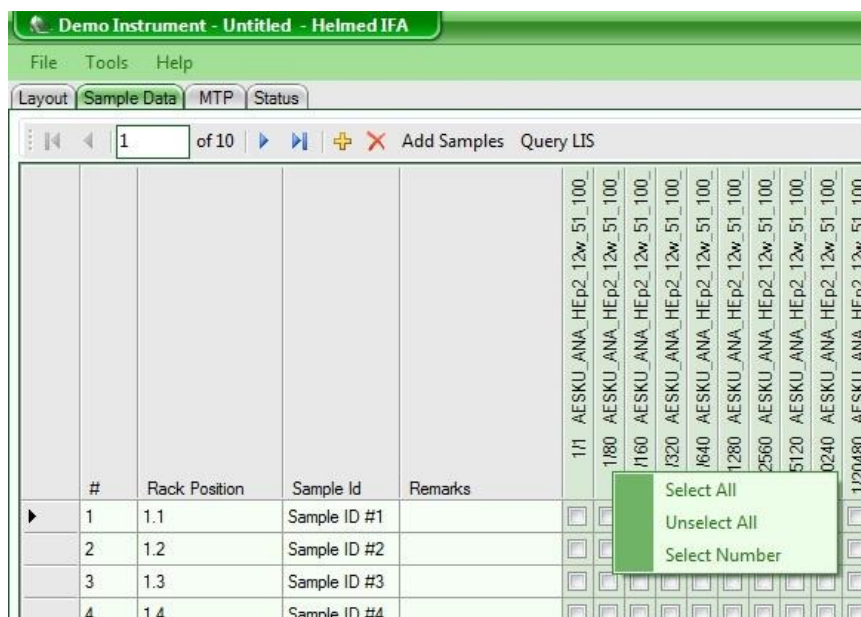
	#	Rack Position	Sample Id	Remarks	Firstname	Lastname	1/1 AES	1/40 AES	1/80 AES	1/160 AES	1/320 AES	1/640 AES	1/1280 AES	1/2560 AES	1/5120 AES	1/10240 AES
▶	1	1.1	12345678	Remark	John	Doe	☐	☒	☒	☒	☐	☐	☐	☐	☐	☐

The data entered in here will also be included in the worklist worksheet, which can be printed from the **File** menu:

Well	ID or Name	Dilution [1:x]	Testname	Result	Remark / Comment
1	AESKU_ANAHEp2_PC	1	AESKU_Helios_ANAHEp2_12w_51_T00_v1		
2	AESKU_NCIFA_NC	1	AESKU_Helios_ANAHEp2_12w_51_T00_v1		
3	12345678 Doe, John	40	AESKU_Helios_ANAHEp2_12w_51_T00_v1		Remark
4	12345678 Doe, John	80	AESKU_Helios_ANAHEp2_12w_51_T00_v1		Remark
	12345678				Remark

Dilution management

For processing a sample, a dilution needs to be selected. If a sample is loaded but no dilution is checked, it will not be processed. By right clicking on a specific dilution, three options will become available:

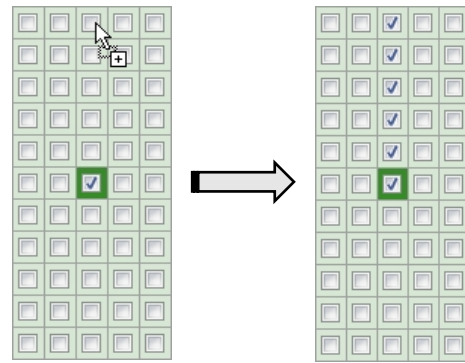


Select all: Checks all samples for this dilution column

Unselect all: Unchecks all samples for this dilution column

Select number: Enter required number of samples for this column. The **Select Number** function always starts with the first sample in a column – from top to bottom.

To select multiple samples in a column, select the last sample ID needed for the assay by clicking on the left mouse button. After checking the box, click and hold on the right mouse button and move the cursor upwards to the first sample ID needed for the assay. All the samples selected this way should now have a checkmark in the box.



Note: The selection of multiple samples can only be performed from bottom to top. Moving the cursor down will not yield any results!

7.2.1.3 MTP tab

The MTP tab provides information and a preview on how many wells are needed for the dilution process. The type of dilution is indicated by color code:

- Orange: indicates a diluted control
- Yellow: indicates one-step dilution for samples
- Light-Yellow: indicates two-step dilution > 1/160 for samples

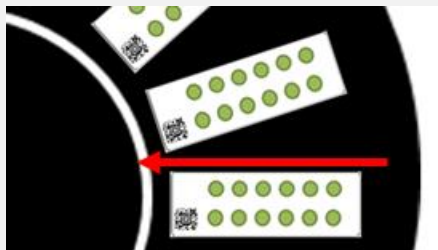
Layout Sample Data MTP Status												
	1	2	3	4	5	6	7	8	9	10	11	12
▶ A	Orange	Light-Yellow										
B	Yellow	Yellow										
C	Yellow	Light-Yellow										
D	Yellow	Yellow										
E	Yellow	Light-Yellow										
F	Yellow	Yellow										
G	Yellow											
H	Yellow											

The software can handle 192 dilutions in total using 2 MTPs with 96 well layout.

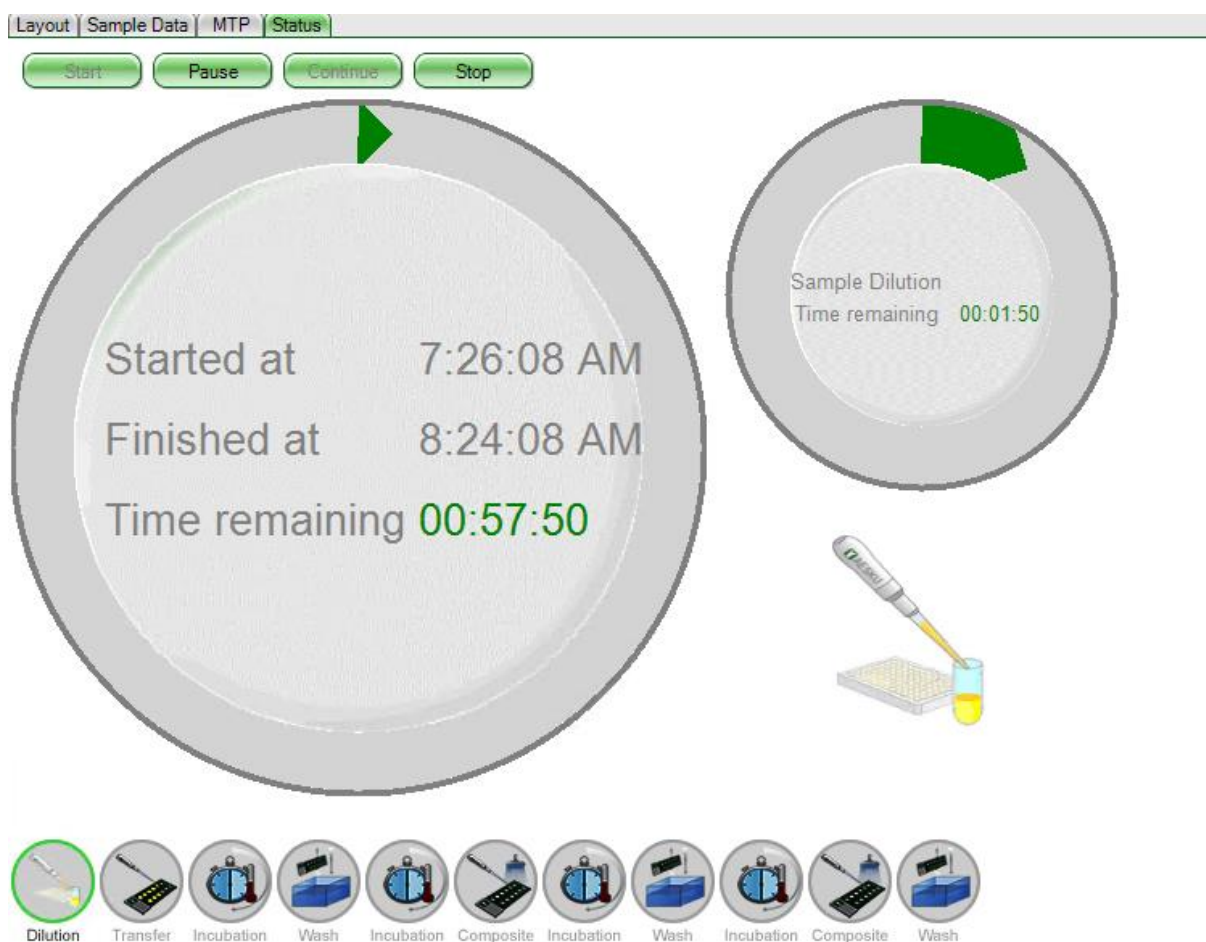
7.2.1.4 Status tab

After all slides, reagents, controls, and samples are loaded, the process can be started in the **Status** tab by clicking the **Start** button. Please ensure that all the required reagents and slides are positioned properly inside the device.

Note: Slides must be placed with the barcode directed towards the center of the ring:



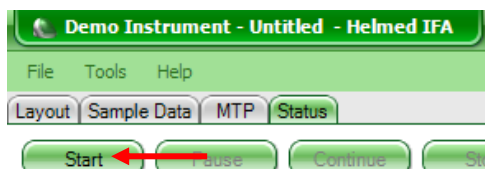
The **Status** tab will also provide all the necessary information pertaining to the current process step after the process has been started by the user:



7.3 Starting the automated HELIOS IFA process

The following instructions are shown by the example of an **AESKUSLIDES® ANA HEp-2** assay:

1. To commence with the automated **HELIOS®** IFA process of the created worklist, click **Start**.



2. Confirm the suggested worklist name or enter an individual worklist file name. The current date and time stamp will be automatically placed in front of the file name after clicking the **Ok** button.



Note: If entering a specific worklist name, please do not use space and special characters like e.g. "dots".

Note: Worklists created in the **HELMED®** IFA module (blue design / background color) will not be saved automatically. If they need to be saved, please save them manually.

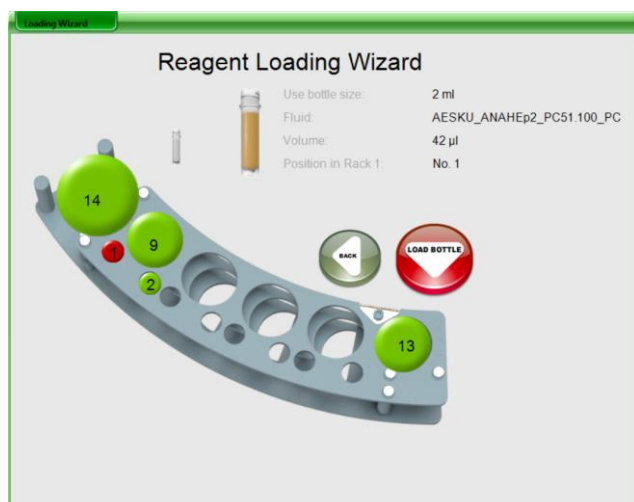
Should the worklist contain **AESKUSLIDES®**, it can be loaded in the image capturing module. **Please ensure that the slides are covered with Mounting Medium (or cover-slipped) to prevent them from drying out! Please ensure that the slides are positioned in the same order for reading, as they were processed!**

In the **HELIOS®** IFA module (green design / background color), worklists are saved automatically to ensure automated processing.

3. The IFA software will now initialize the device and start processing (if the **Start Loading Wizard Before Run** option has not been activated). If the Loading Wizard has been activated prior to the run, proceed with the steps # 4 – 7.

Note: If the option **Start Loading Wizard Before Run** has been activated, the mentioned Loading Wizard will open after clicking on the **Start** button. It is recommended to enable this option to assist the operator placing required reagents and consumables.

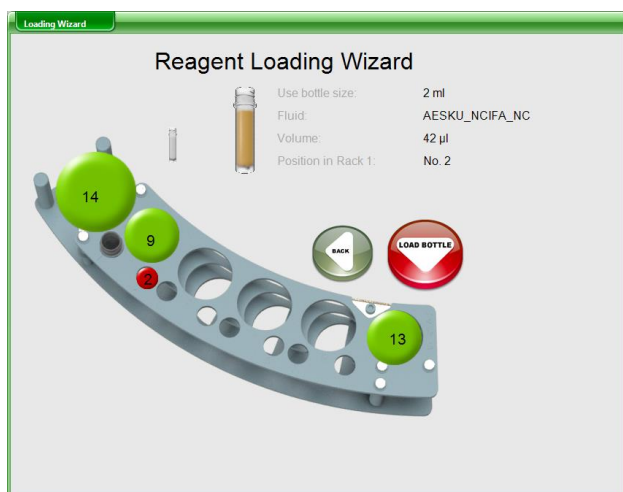
4. Loading the reagents in the reagent rack:



For example: Place the bottle **AESKU_ANAHEp2_PC51.100_PC** on position 1 (marked red).

Note: Information about the required reagents is displayed in the upper section of the window.

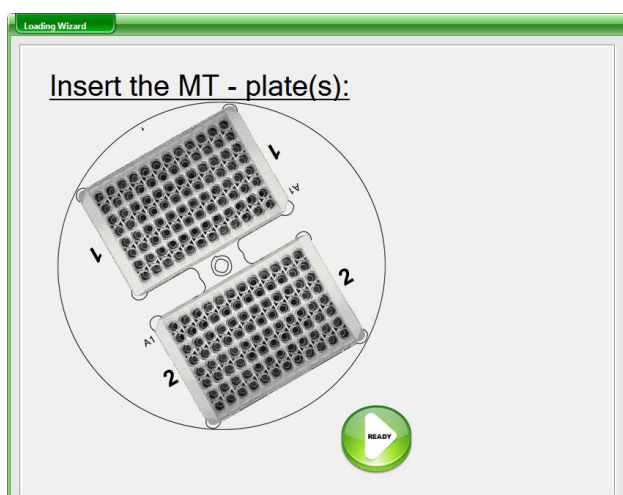
Click **LOAD BOTTLE** (a bottle is displayed on position 1; position 2 will be marked red).



Proceed with the next reagent and place it on the position marked red.

Continue until all reagents are loaded.

5. Insert the required microtiter plate(s) on the designated notch:



Click the button **READY** when the microtiter plate(s) is/are inserted.

6. Fill in enough wash buffer solution and distilled water:



Click the button **READY** once the required amount of wash solution and distilled water are added.

Note: The **HELIOS®** system primes automatically with 9 cycles of distilled water after every run to flush out any salt residues and particles that may remain within the tubes. To ensure this process, please fill the bottle labeled **Wash2** with distilled water and connect it to the device on the **Wash2** connector.

7. Empty the waste bottle before starting IFA process:

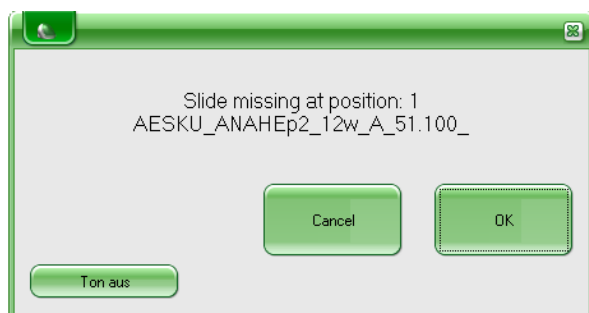


Click the button **READY** after emptying the waste bottle.

The **Loading Wizard** will automatically close, and the device will commence initialization. If the device has passed its initialization process without displaying an error message, it is ready for operation.

Note: If an error message comes up during initialization, please consult distributor's customer service.

Following the initialization process, the **AESKUSLIDES®** will be scanned and the barcode information is stored in the worklist. If a slide barcode cannot be scanned, the software will display a message and the device will provide an acoustic warning signal combined with a red indicator light. The carousel will turn the slide with the not scanned barcode towards the red flashing LED in the front cover. The front cover is unlocked and can be opened.



A message will be displayed on the screen prompting the user to replace the missing slide. After replacing the slide, close the lid.

Click **Ok** to continue.

After the slide barcodes have been scanned successfully, the software will check that slides are correctly placed and not inserted tilted. In the next step, the device will be primed, and the processing of the worklist will commence.



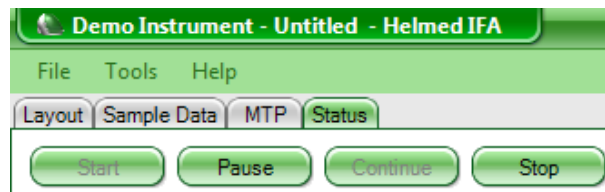
After the assay process is started by the user, the Status tab will display information about the overall process time remaining (big timer) and the current on-going process step (small timer).

On the right side, 2 indicator bars will show humidity [% relative humidity] and temperature [°C].

The temperature bar will only be available for tests running > 30°C (> 86°F).

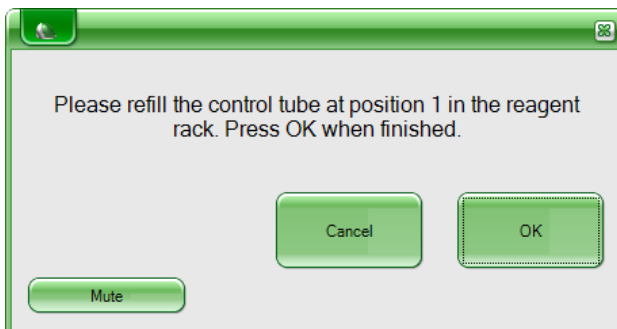
Note: The displayed **Time remaining** is an estimation for the IFA process and can slightly differ from the real time the process ends.

If necessary, the IFA process can be paused by clicking the **Pause** button. The lid will be unlocked, allowing to remove samples for example. To continue the process, click **Continue**.



Note: It is strongly recommended to pause the process only during an incubation step, or else it can impact with the time management performed by the software for each further processing step. Moreover, during the incubation step, fewer device components are actively controlled and therefore the USB communication is less susceptible for any eventual crashes.

If any reagent is missing (sample buffer, controls, conjugate, or mounting medium), the device will provide an acoustic warning signal and a red flashing light will turn on. The device will be unlocked, and the IFA process will be paused. The empty reagent bottle will be moved in front of the red flashing indicator light.



A message will be displayed on the screen prompting the user to replace the missing reagent. After replacing the reagent, the lid needs to be closed again.

Click **OK** to continue the IFA process.

Any error that occurs will be displayed under **Status**. All errors will also be posted in the IFA report for traceability purposes.

8 HELIOS Image Capturing

Images of wells and classification suggestions per image are generated during the image acquisition in the **HELIOS® Image Capturing** module. There are two ways the **HELIOS® Image Capturing** module can be used:

1.) Automatically after an automated **HELIOS®** IFA process:

When a **HELIOS®** IFA process has been finished successfully, the worklist is automatically transferred to the Image capturing module and images will be taken.

2.) Manually:

There is, as well, the option to manually start the image capturing process of already processed and coverslipped **AESKUSLIDES®**.

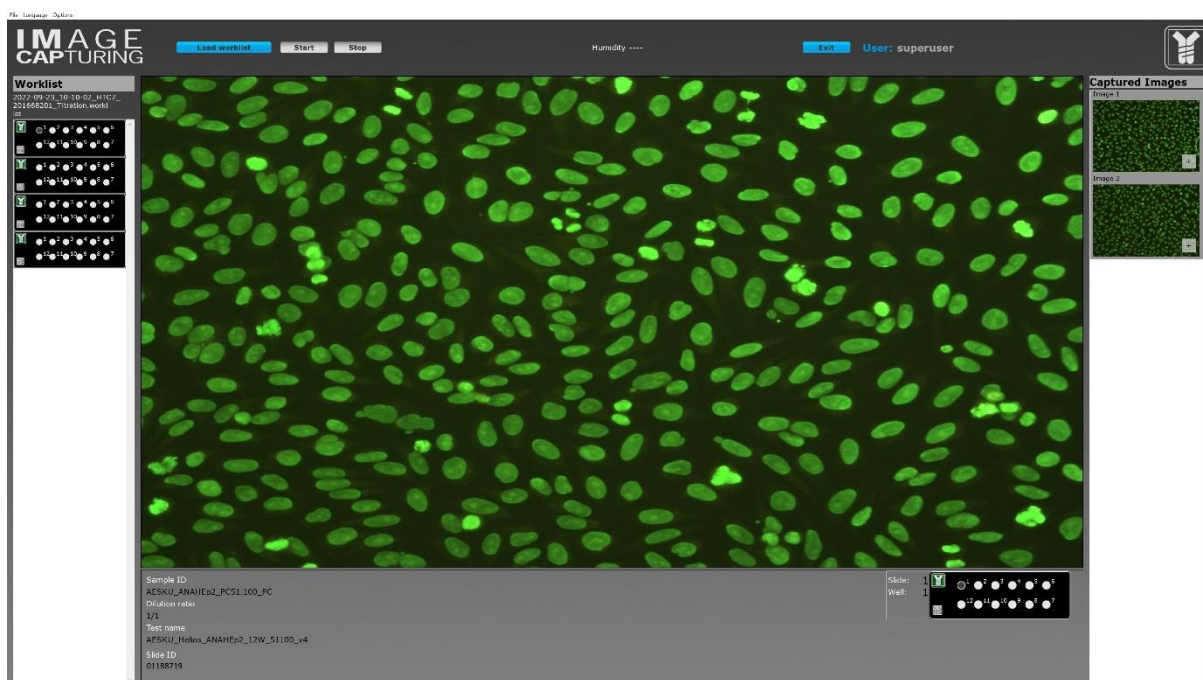
Note: Do not lean on the device during the image acquisition and avoid any kind of vibration and shocks during the entire process!

8.1 Automatic start of HELIOS Image Capturing module

Transition from **IFA** processing to **Image Capturing (HELIOS® IFA mode)** is done automatically. The **AESKUSLIDES®** on the slide holder ring will be scanned by the barcode reader. This barcode information will be compared to the one stored in the worklist to ensure compatibility.

Note: Image Capturing can only be performed with **AESKUSLIDES®**.

If a worklist has been loaded and the image acquisition has started, the following interface will be shown on the screen (on the example of an ANA HEp2 worklist in progress):



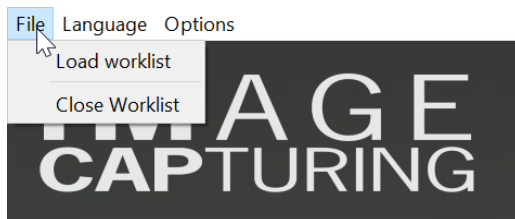
8.2 The menu bar

The user interface of the **Image Capturing** module provides a menu bar with the following functions:

File Language Options



8.2.1 File



Load Worklist

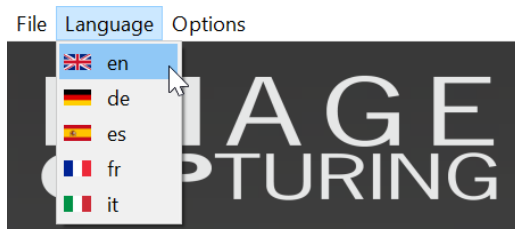
A worklist can be loaded either here or by using the **Load worklist** button:



Close Worklist

With this option, the current open worklist will be closed.

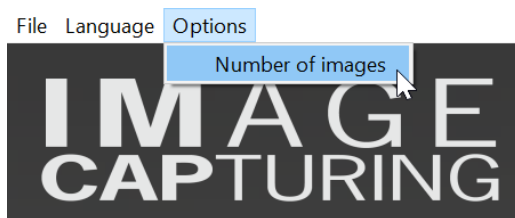
8.2.2 Language



By clicking on the tab **Language**, the user can choose between five different language settings for the image capturing module: English, German, Spanish, French or Italian language.

8.2.3 Options

Number of images



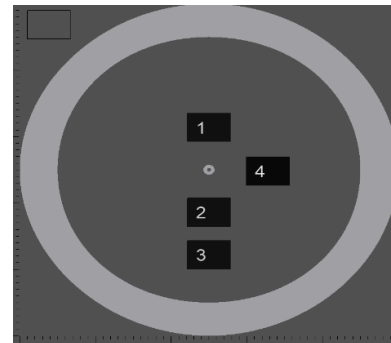
Allows the user to adjust the number of images (from 1 up to 10) per well, the position of the images and the installed objective type.

Note: The default settings for the number and position of images are recommendations. These settings can be adjusted and evaluated by the lab.

8.2.3.1 Set the number of images and the position per well



To add additional image capture points for a slide type, left click on the empty frame stack in the upper left side of the options window (highlighted in red) and move it via drag & drop to its designated position inside the well. Then double-click on the empty frame box to activate it.

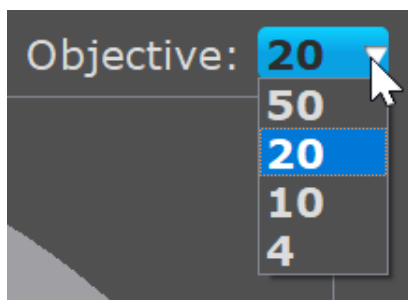


Once activated, the new additional image position will be displayed with a filled black frame and the new increment number. Activated image capture points can be positioned anywhere within the well borders (light gray circle) via drag & drop. It is possible to add up to 10 images in total. To reduce the number of images, left double-click again on an already activated box.

To confirm the changes, click the **OK** button.

To restore default positions for a slide type, click the **Reset** button.

8.2.3.2 Change objective type



There are four different objective types available to choose from. Depending on which kind of objective has been installed in the device, the user must choose the correct objective type from the dropdown menu to apply the specific objective-related functionalities in terms of image size, stitching (combining single image ("tiles") to form an overview image in tissue mode), etc.

Note: To avoid any damage to the microscope unit, it is recommend that only trained personnel should change the current installed objective type (Hardware). Aesku.Diagnostics GmbH & Co. KG cannot be held responsible for any damage caused by improper handling. Autocalibration must be performed after changing the objective type.

8.2.3.3 Positioning test for image acquisition

The **Positioning test** feature can be used to optically verify the set-up image positions by the user, for single images and stitched images (tissue mode, e.g. 7x7 images (49 in total) for overview picture).

Therefore, setup the preferred image positions for a slide type, and insert that slide type in slot # 1 of the slide holder ring. Then proceed with the following steps:



1. Press the “Init Microscope” button:

The microscope unit will be initialized and the **Pos. Slide** button will become active (green) afterwards.

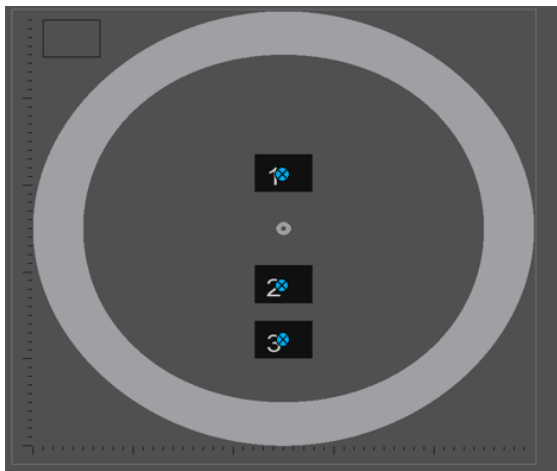
2. Press the “Pos. Slide” button:

The slideholder ring will move the slide in slot # 1 to the reading position below the microscope. The **Show Positions** button will now become active (green).

3. Press the “Show Positions” button:

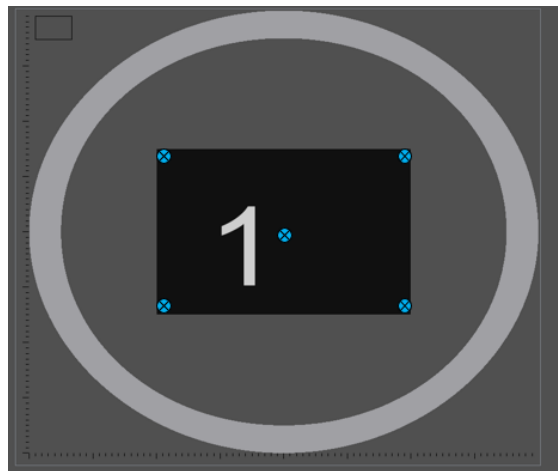
Depending on the image capture settings like for instance single images or stitched overview image (tissue mode), the **Positioning test** will be performed different:

Single image positions



The microscope will move to the centre of each single image position and verify the position by a blinking LED spot.

Stitched image positions (tissue mode)



The microscope first moves to the center position, followed by all four corner edge positions of the stitched image verified by blinking LED spot.

This procedure can be repeated for different slide types after the first slide has been positioned. Therefore, replace the slide type in the slide holder ring, choose the corresponding slide type from the dropdown menu and press the **“Show Positions”** button again to verify the set-up image positions.

8.3 The user interface and its functionalities

The user interface contains all necessary information for monitoring the image capturing process. The interface is divided into several areas, described in the following sections:

8.3.1 Worklist



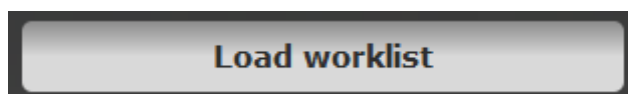
Once loaded, the generated worklist is displayed on the left side of the **Image Capturing** screen. In this example, the worklist contains 4 slides of ANA HEp2. Every slide type / substrate has its own color code when displayed in the worklist bar, e.g. ANA HEp2 slides are black, ANCA-F are green etc. If the number of slides exceeds the display area, it is possible to scroll through the menu. The image acquisition progress status is shown by a dark grey filled well which indicates that this well is currently being in progress (here it is well #1 on slide #1).

8.3.2 Load, start & stop a worklist

In the upper left side of the Image Capturing screen, there are three buttons available:



1. The **Load worklist** button is active when no worklist is loaded or when the current loaded worklist is not being captured. During an on-going image capturing process, no new worklists can be loaded, and the button is inactivated (grey):



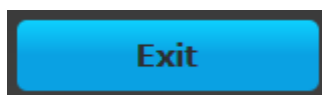
2. Once a worklist has been loaded, the **HELIOS® Image Capturing** process (image acquisition) can be started by pressing the **Start** button. The captured images will be saved automatically:



3. The **Start** button will remain inactive during an ongoing image capturing process. The **Stop** button can be clicked at any time to stop the process:



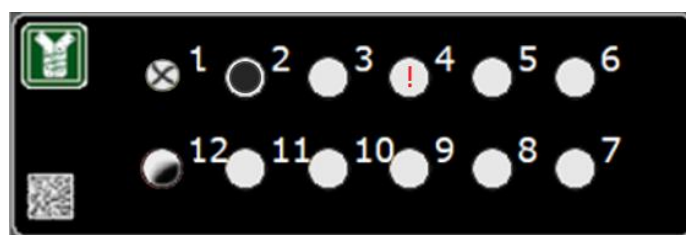
4. The Exit button can be used to leave **HELIOS® Image Capturing** module. The image acquisition process will be continued in the background. It is now possible to enter the **Result Confirmation** or release results via the **LIS** module:



Note: To prevent the slides being dried out, please remove them all from the device and coverslip after the image acquisition has finished. The user can also manually inspect the wells or load the worklist again into the **Image capturing** module to reimagine.

8.3.3 Worklist progress, status, and symbols

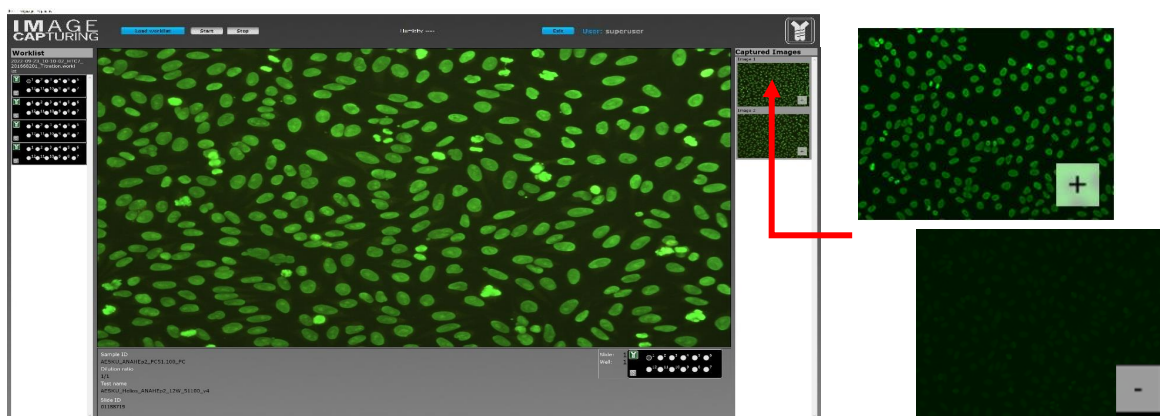
Several symbols may be displayed for a well during the image acquisition process. The meaning of each symbol is explained in the table below on the example of an ANA HEp2 slide:



Well #	Symbol	Meaning
1		A dark grey "x" symbol indicates that image acquisition for this well has been finished.
2		A dark grey filled circle is indicating the well currently in progress.
3		An empty white well indicates that this well contains a sample and still needs to be captured.
4		A red exclamation mark inside the well indicates that no sample volume has been dispensed due to an error. E.g. empty sample tube or no diluted sample was transferred from the MTP to this well. A well indicated with an error will not be captured.
12		The half black / half white symbol indicates that this well was not used by a sample during the creation of a worklist. Therefore, it will not be captured.

8.3.4 Image capturing and classification suggestion

In the center of the **Image Capturing** screen, the live imaging process of the current captured well is displayed:



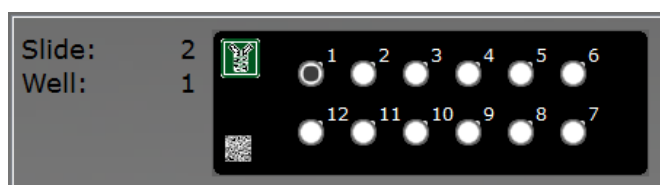
The already captured images of the respective well are shown on the right side of the interface.

If available and / or additionally activated*, a corresponding classification suggestion per image will be shown as “+” for a positive sample or “-” for a negative sample; or no symbol, if the sample couldn’t be defined neither and was so classified as “unknown” due to air bubbles, particles, or any other interferences during image acquisition.

*Positive / Negative Pre-Classification feature can only be applied for ANA HEp2 and ANCA substrates. It can also be available for nDNA (*Crithidia luciliae*) but must be activated and unlocked by license.

Note: Classification suggestions applied for **ANA HEp2** and **ANCA-E/F** for each image are based on the defined Cut-Off settings in the **Operational Adjustment** menu and must be double-checked and confirmed by trained and qualified personnel to ensure correct classification of the wells.

8.3.5 Current slide



Below the live imaging screen, an information is displayed about on which slide and well number the image acquisition is currently in progress.

8.4 Manual start of Image Capturing

The **Image Capturing** process can also be started manually from the main menu to capture images of cover slipped **AESKUSLIDES®**.

Note: Only worklists including **AESKUSLIDES®** can be loaded. If the **HELMED** IFA module is used, please ensure to save the worklist after the IFA process has finished. The default folder for saving IFA worklists is: **"My Documents\AESKU.SYSTEMS IFA Software\4.0.0.0\Worklists"**.

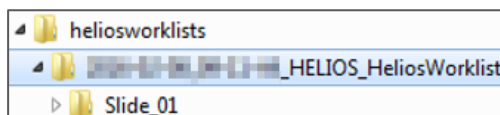
1. Place the **AESKUSLIDES®** correctly on the slide holder ring (barcodes pointing inwards). Ensure that the **AESKUSLIDES®** are placed in the same order as loaded during IFA process.
2. Close the cover.
3. Load the worklist created and saved in IFA module (My Documents\AESKU.SYSTEMS IFA Software\4.0.0.0\Worklists).
4. Click **Start**.

After image capturing, the program will close automatically and return to the main screen.

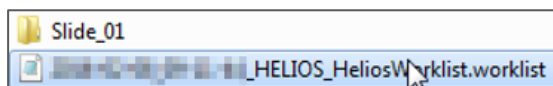
8.4.1 File structure of captured images

When capturing worklists, the software will create a folder and file structure in the configured path which is by default **D:\heliosworklists**.

Worklists can be loaded from their respective worklist file located in the folders:



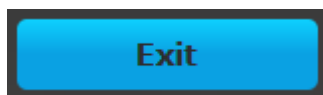
The worklist folder contains all relevant files pertaining to the worklist. Here, all captured images including classification suggestions and the results of the user result confirmation will be stored:



Note: To prevent any data loss, it is recommended to frequently backup old worklists to an external storage or network server to ensure sufficient memory on the hard disk drive for new worklists. Aesku.Diagnostics GmbH & Co. KG cannot be hold responsible in case of any data loss.

8.5 Exit program or leave image capturing screen

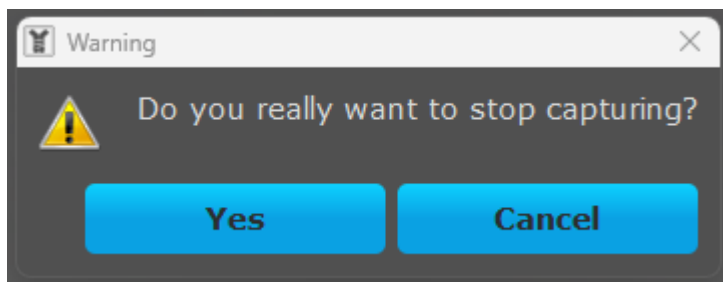
By using the **Exit** button without clicking on the **Stop** button before, the user will be able to leave the screen without interrupting the current image capturing process. This allows the user to access the **Result Confirmation** module or the **LIS** module of the **HELIOS®** software during an ongoing image acquisition.



All accessible modules are highlighted in blue. To enter the image capturing screen again, click on the related icon (marked red).



During an ongoing image capturing process, the **Stop** button can be used to end the process. There will be a warning confirming the user to stop the image-capturing process:



After image acquisition has finished, the worklist can be classified in the **HELIOS® Result confirmation** module.

9 HELIOS Result confirmation

The **HELIOS® Result Confirmation** module allows the user to perform the classification of previously generated worklists and to create reports of these worklists with all the results contained in it. Therefore, a processed worklist containing the captured images and their related classification suggestions must be loaded into the **Result Confirmation** module.

Each well can be classified individually or sorted by its classification suggestion. Several options are provided to further specify the classification.

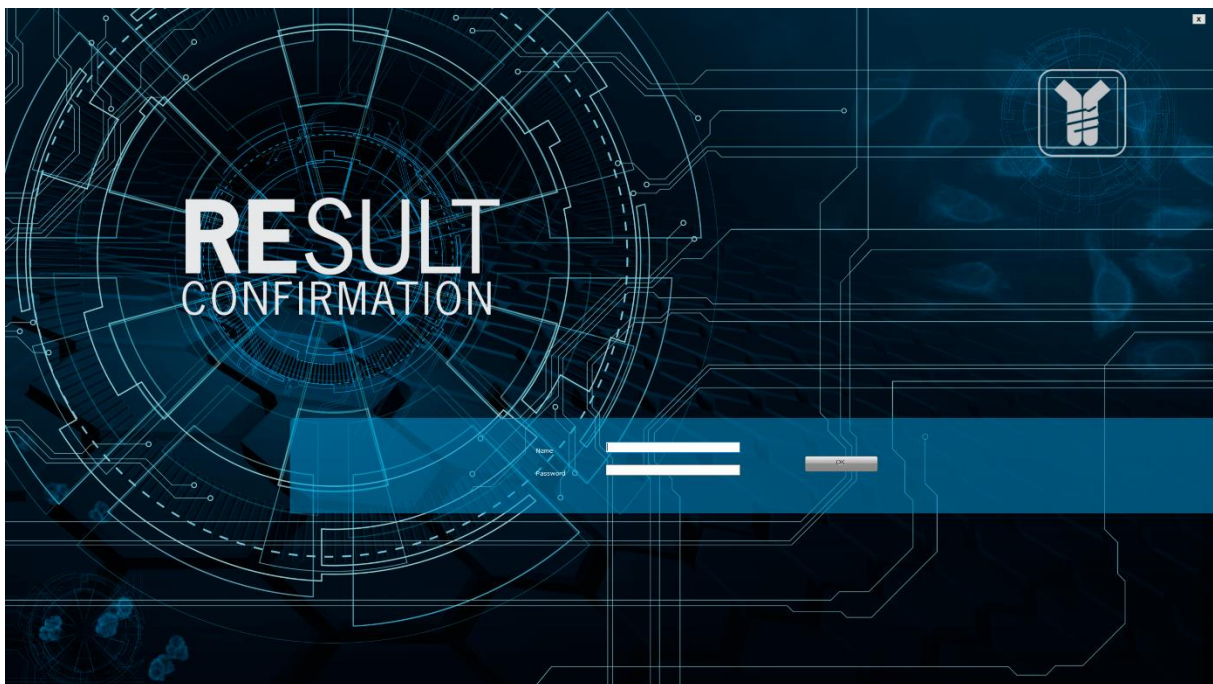
The **Result Confirmation** module may be used by registered and trained personnel only!

To start the application, click the **Result confirmation** button:



The login screen will be displayed.

9.1 Login



Enter **username** and **password**.

Click **OK**.

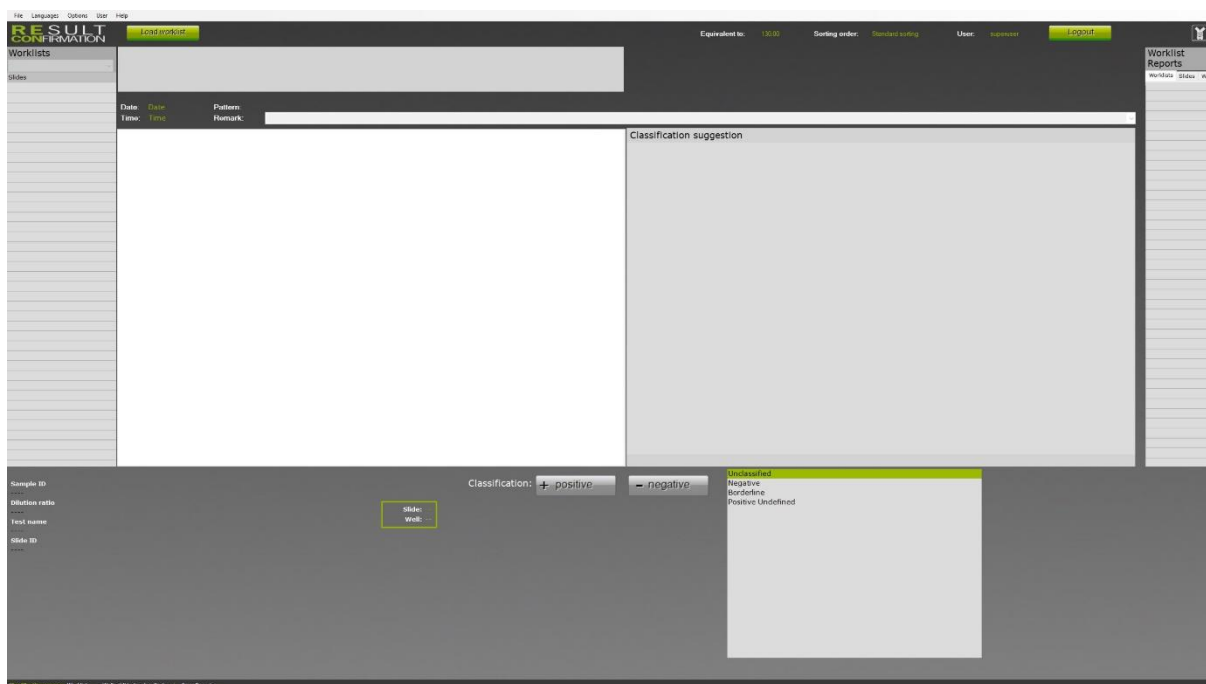
Note: Specific user accounts must be created in advance by a user with administrator rights.

9.1.1 User and Superuser accounts and privileges

The **HELIOS® Result Confirmation** module is only accessible with an existing user account. Accounts with **user** privileges can classify worklists and make changes to classification within the current session. When the session is closed, and the same worklist is loaded again, already classified wells cannot be changed by accounts with **user** rights. Only accounts with **superuser** privileges can re-classify results - if necessary.

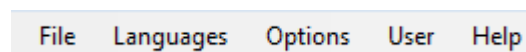
9.1.2 The Result Confirmation interface - overview

After login as a **user** or **superuser**, the following user interface will be displayed:



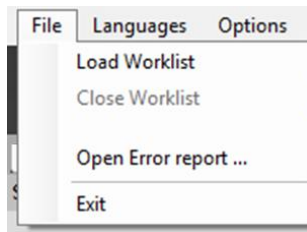
9.2 The menu bar

In the upper left main menu bar of the graphical user interface, there are 5 different options or tabs available to choose from:



Each of these options will be further described in the sections below.

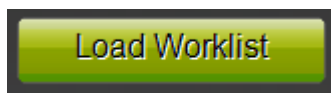
9.2.1 File



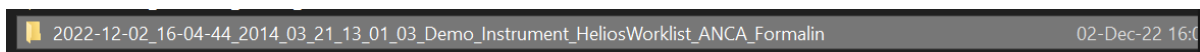
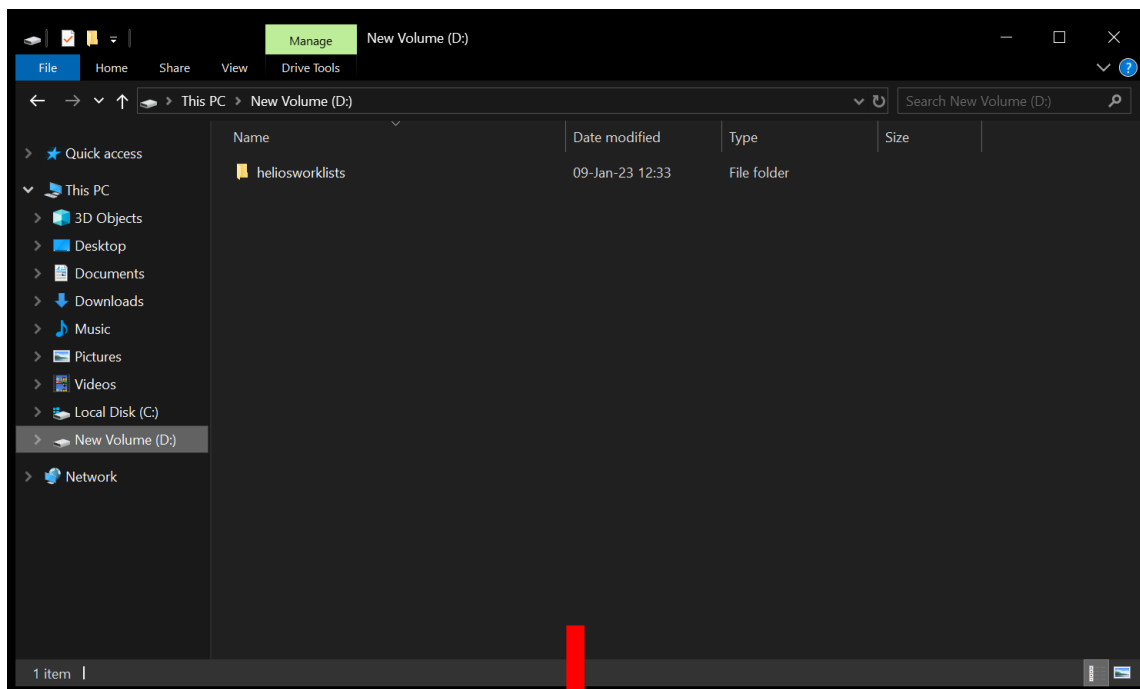
- Load Worklist
- Close Worklist
- Open Error Report...
- Exit

▪ Load worklist

1. On top of the **HELIOS® Result Confirmation** main screen, click on the tab **File**. Select **Load Worklist** from the dropdown menu or click on the **Load Worklist** button, located on the main screen:

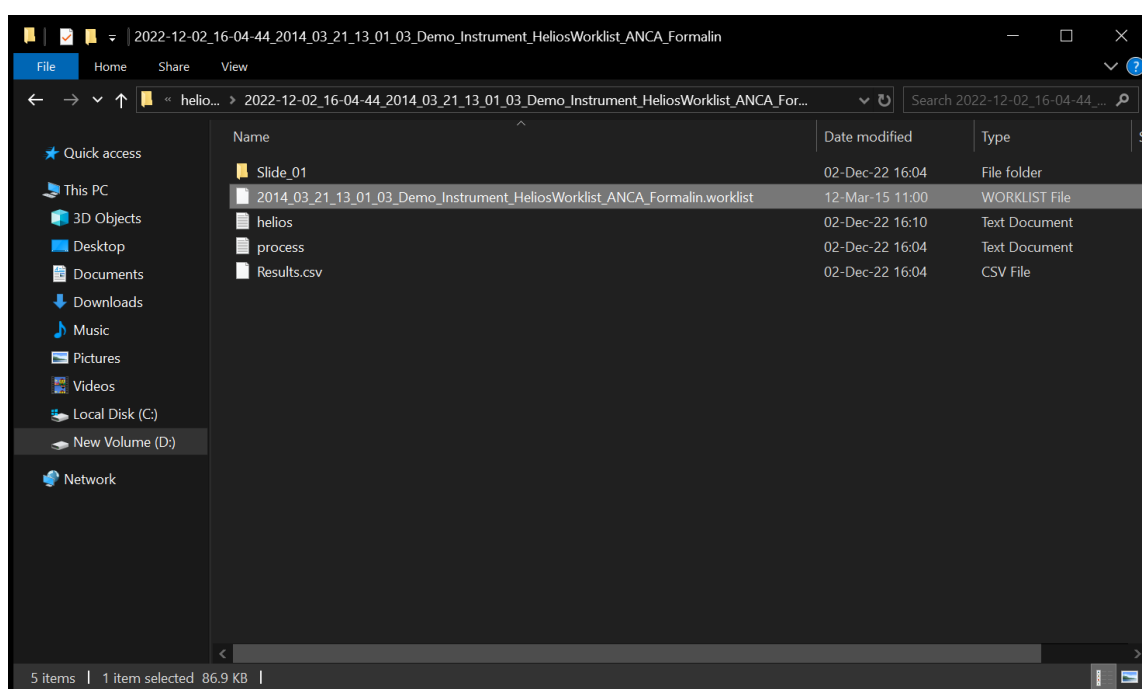


Select the respective worklist folder located in the main folder "**D:\heliosworklists**" (set by default) and press the **Open** button:

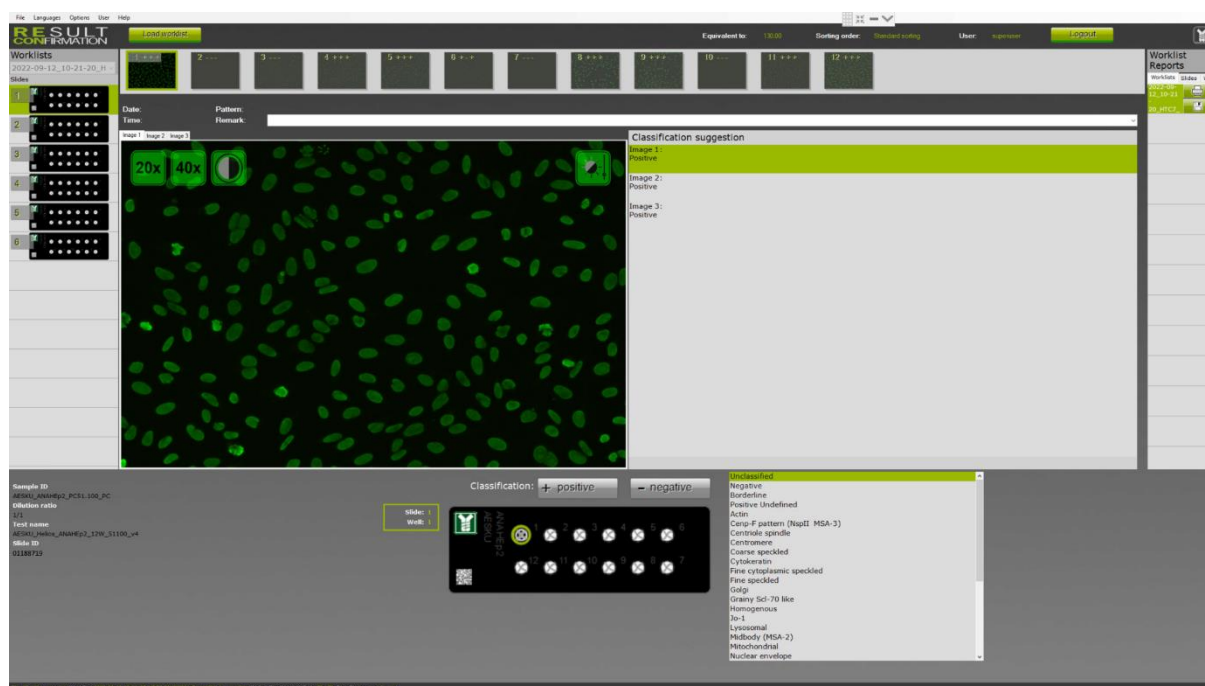


Note: Depending on the PC model that is supplied with the device, the default path for saving the worklists can vary. For PC models with a combination of SSD (solid state drive) and HDD (hard disk drive), the default folder for saving the worklists is "**D:\heliosworklists**".

2. Select the **“*.worklist”** file and click the **Open** button to open it in the **HELIOS® Result Confirmation**:



3. When a worklist has been opened, the following (exemplary) screen will be displayed:



Close Worklist

To close the current open worklist, click **Close Worklist**.

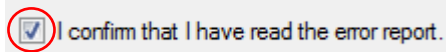
▪ Open Error report

When opening a worklist for the first time, an info box will open prompting to confirm that the report has been read. If the error report is not confirmed, a respective note will be stated in the results report.

AESKU_ANA_HEp2_12w_51.100

Info: Error report was not read and confirmed!

To confirm that the error report has been read, mark the check box.



It is possible to open and confirm the report at any time by clicking **Open Error report**.

The confirmation status of the error report is shown in the status bar: **confirmed** or **not confirmed**.

Error Report: **not confirmed**

▪ Exit

To close the **Result Confirmation** module and return to the login screen, click **Exit**.

9.2.2 Languages

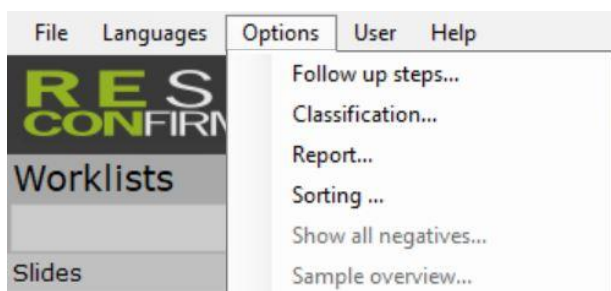
By selecting the **Languages** tab, it is possible to change the language of the user interface.

All supported languages are displayed here:



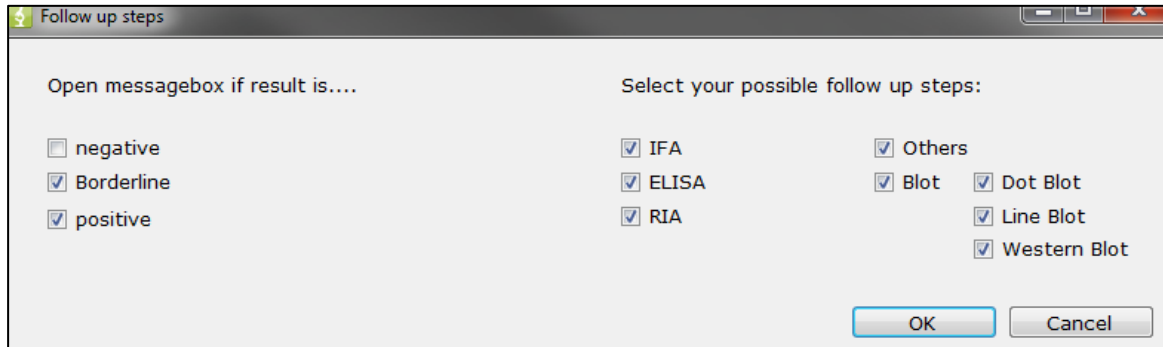
9.2.3 Options

The **Options** tab allows to modify the settings for classifications and reports:



▪ Follow up steps

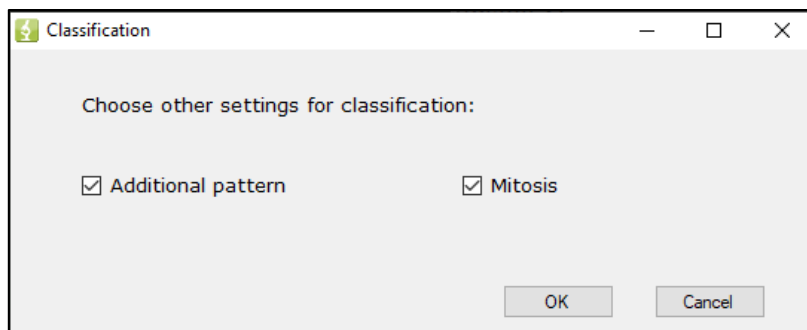
It is possible to define **Follow up steps** for each result. The user can make changes in the selection window to meet the needs of the laboratory. By checking the respective boxes, various follow up steps can be selected.



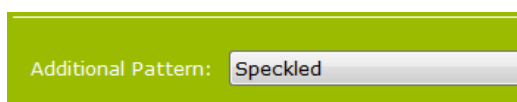
If these **Follow up steps** are checked during classification, the respective information will be transferred to the LIS.

▪ Classification

In the classification window, further settings for **AESKUSLIDES® ANA HEp2** test classification can be selected.



- **Additional pattern:** With this checkbox active, a selection menu will appear during the classification process. The user will be able to select an additional pattern for classification.

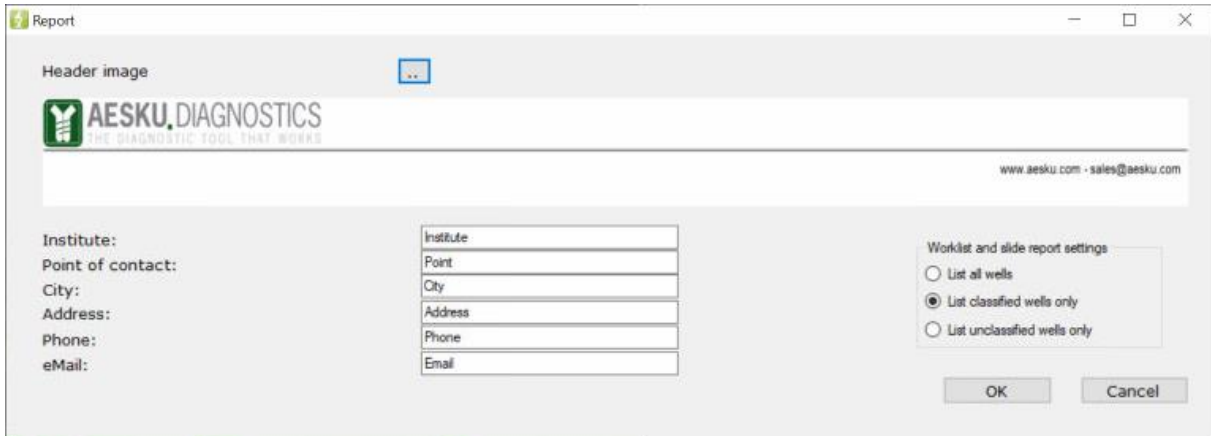


- **Mitosis:** With this checkbox active, two additional checkboxes will appear during the classification process. Here, the user can indicate whether the mitosis is positive or negative.

Mitosis: ☐ negative ☐ positive

▪ Report

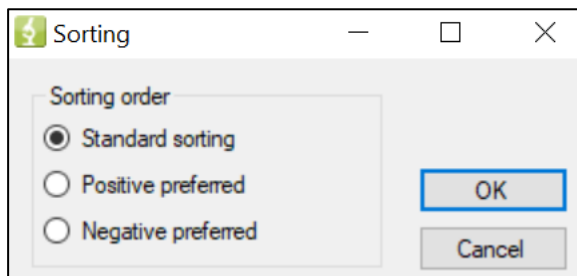
The header of the results report printout will (by default) contain the company logo of Aesku.Diagnostics GmbH & Co. KG:



This can be modified by clicking the  button. In the next window, a png, jpg, bmp or tif file can be selected to replace the default header image. Contact information such as the institute and its related address can be added in the respective lines and saved by clicking the **OK** button. On the right side, worklist and slide report content settings can be changed. Choose **List all wells** if the report should contain classified and unclassified wells. If a report should contain only classified or unclassified wells, either the option **List classified wells only** or **List unclassified wells only** should be selected.

▪ Sorting

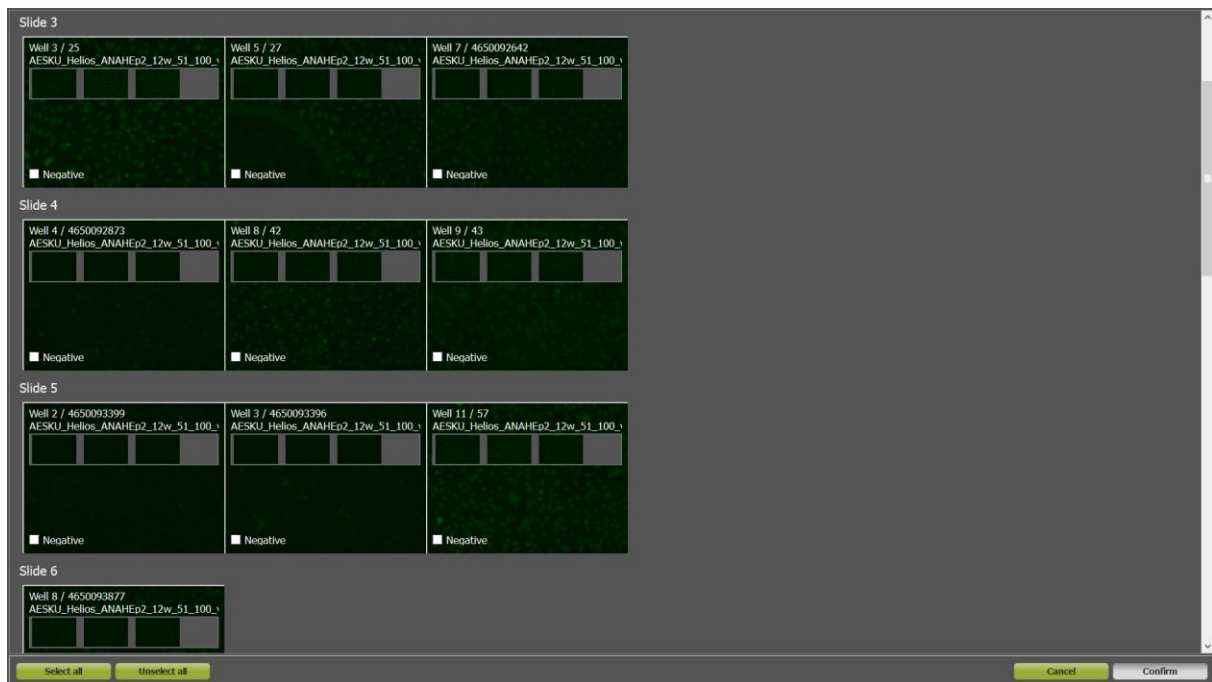
Before loading a worklist, a specific sorting priority can be selected:



Depending on the prioritization, the wells will be loaded in a certain order. The wells will be displayed in descending order according to the positive or negative classification suggestions. The selected sorting preference will then be displayed on the user interface.

▪ Show all negatives

After a worklist has been loaded, all negative pre-classified images can be listed and shown in a separate window by using the function **Show all negatives**:



The **Show all negatives** function is designed to facilitate the classification process after screening runs by allowing to select all negative pre-classified wells at once using the **Select all** button on the lower left corner on the screen. All as negative selected wells can be recognized by the marked white checkbox (see below).



It is the responsibility of the user to recheck all wells selected in this manner and to deselect (clicking on the white checkboxes) all wells identified as false negatives.

If all wells are checked, the selection can be confirmed via the **Confirm** button, on the right lower corner on the screen.

All wells classified in that way will get the remark **Manual classification for negative group of wells** which will be stated in the final report as well.

▪ Sample overview

After a worklist has been loaded, all wells related to the same specific sample can be shown in the window **Sample overview**. Since this is just an overview function, classification of samples on that screen cannot be performed.

▪ Start Pattern Suggestion

After a worklist has been loaded, the pattern suggestion calculation can be started. For additional information, refer to the chapter for **“Pattern Recognition”**.

9.2.4 User



To exit the **Result Confirmation** module, either select **Logout** from the **User** tab or click the **Logout** button on the **Result Confirmation** screen.

9.2.5 Help



Help

Contains information regarding keyboard shortcuts and editing functionalities:

F5: Switch well images to fullscreen

F6: Switch database image to fullscreen

F7: Next slide

F8: Previous slide

Enter: Confirm (selected classification/remark)

Space bar: Confirm (selected classification)

Left arrow: Previous well

Up arrow: Previous classification

Right arrow: Next well

Down arrow: Next classification

Page up: Previous image

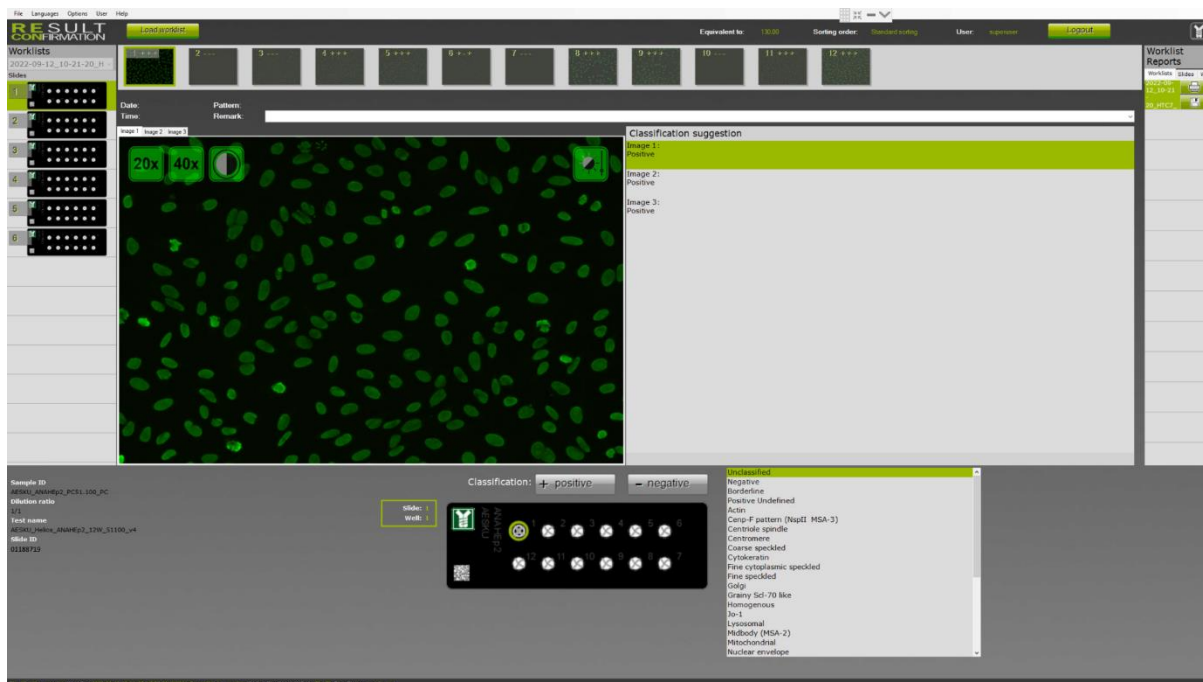
Page down: Next image

About

Contains information regarding the manufacturer and the software version.

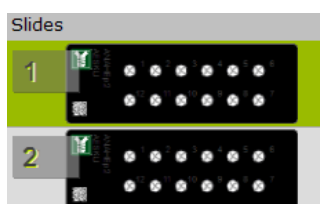
9.3 The user interface and main functions

The user interface contains all necessary information to perform the classification of results. The interface is split into several areas that will be described in the following section. When performing classifications, the user can use the keyboard for navigation. An overview of the keyboard layout can be found in the **Help** context menu.



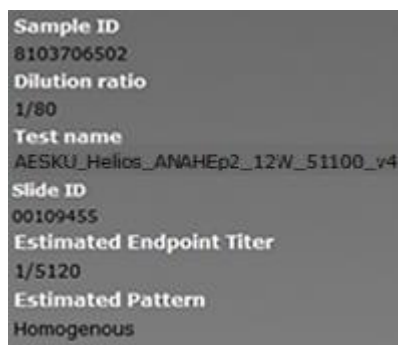
Note: Active buttons and main fields of the user interface will be displayed in green.

9.3.1 Worklists



All slides of a loaded worklist will be displayed in the “**Slides**” bar on the left side of the user interface. The currently selected slide will be highlighted in green.

9.3.2 Information on selected well



Below the “**Slides**” bar, information regarding the currently selected well can be found. In addition, the estimated endpoint titer and pattern suggestion (if activated by valid license) will be displayed.

9.3.3 Status bar

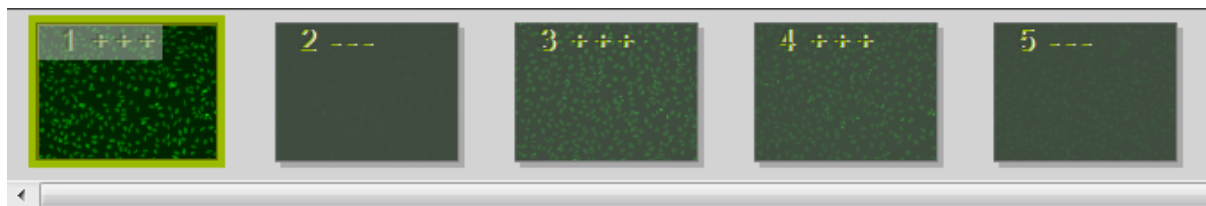
The status bar can be found on the lower edge of the screen:

Classification process Worklist:     Testunit_ANA_ANCAE_NDNA Wells still to be classified: 27 / 34 Error Report: confirmed

The name of the currently active worklist is displayed here. Additional information on how many wells need to be classified and if the error report was confirmed or not is stated here as well.

9.3.4 Image bar

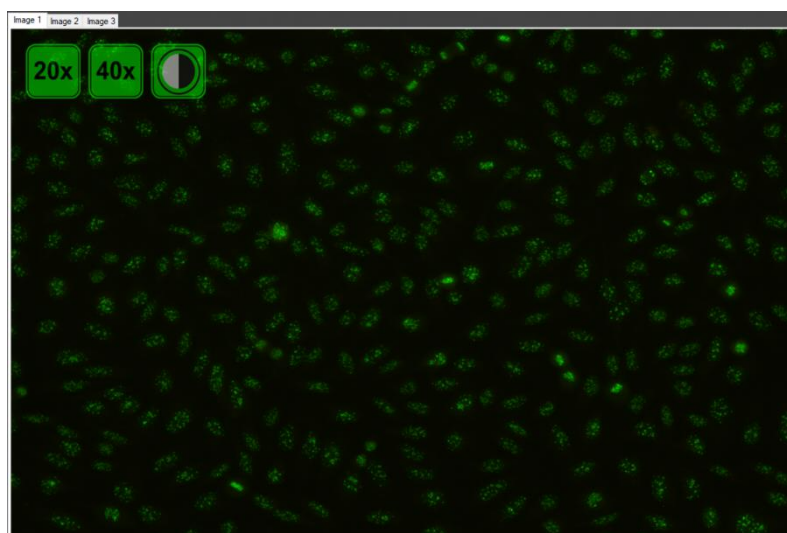
The image bar on top of the screen displays all the wells from the current selected slide of a worklist.



The current selected well is marked with a green frame. Use the mouse or the arrow keys (←/→) to navigate between the wells.

9.3.5 Captured images of the well

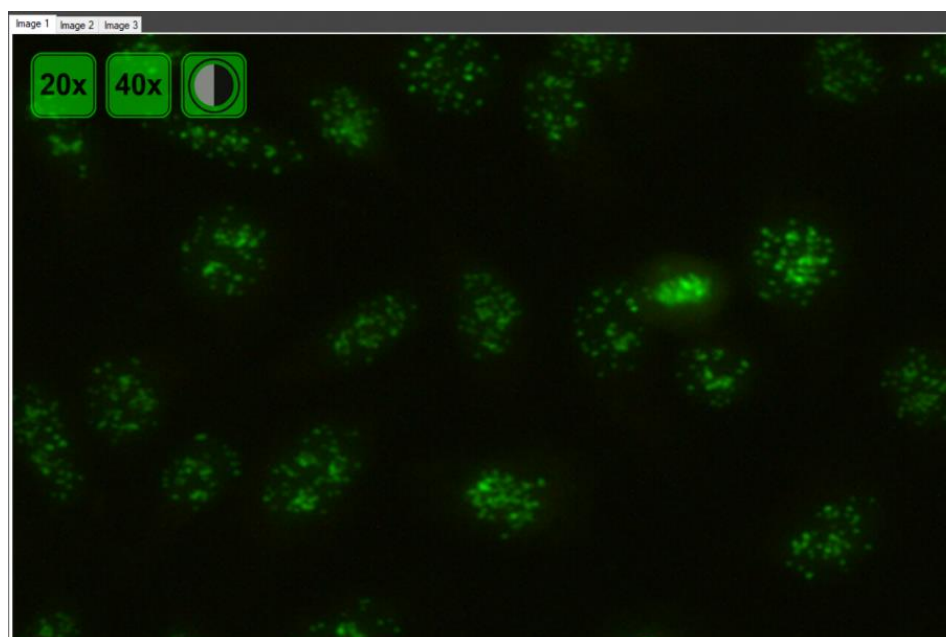
The images taken in the **Image Capturing** module will be displayed right to the worklist and slide bar.



The 3 images can be selected by clicking on the respective tab by using the **Page up** and **Page down** keys.

Note: Verify that the set number of images for every well was captured before classifying the well.

By clicking the **40X** button, the currently viewed part of the image will be enlarged (like 40x objective magnification). The mouse wheel can be used to zoom in and zoom out. To return to the full-size image, click the button **20X**.



9.3.6 Classification suggestion

Classification suggestion
Image 1: Positive
Image 2: Positive
Image 3: Positive

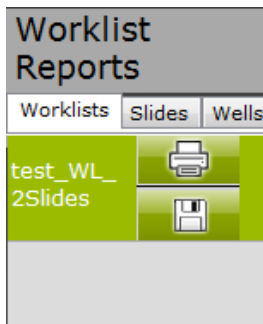
Classification suggestions for the captured images are displayed on the right next to it. The classification suggestion for the currently selected image will be highlighted in green.

9.3.7 Zoom factor, sorting, user

Between the menu tabs and the image bar (close to the **Logout** button), information on zoom factor, the sorting order and the user can be found here:

Equivalent to:	130,00	Sorting Order:	Standard sorting	User:	user
----------------	--------	----------------	------------------	-------	------

9.3.8 Worklist reports



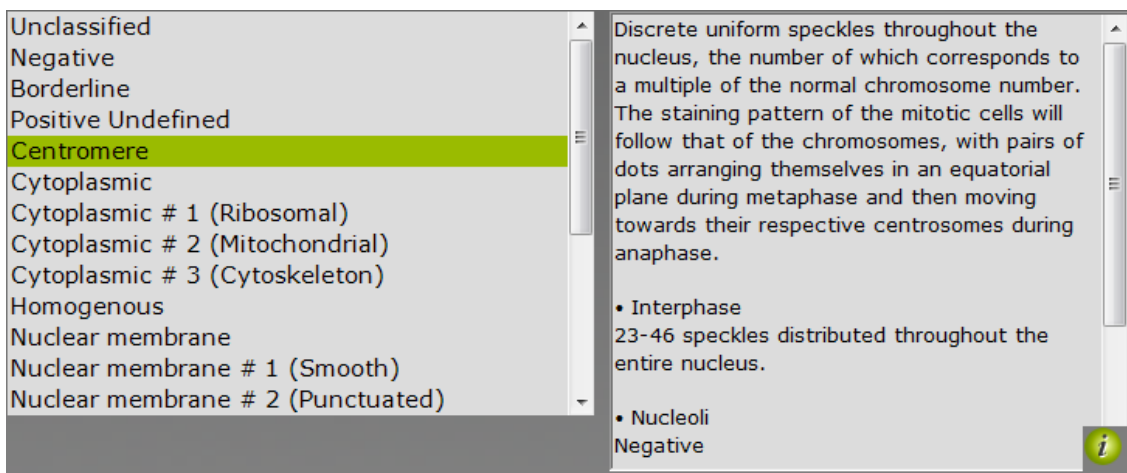
The options for creating reports can be found on the right panel of the user interface.

For further information, refer to the **Result reports** section (9.4.6).

Note: If a specific image of the well should be printed, please select the image and print the report of the current well (Well Report) subsequently.

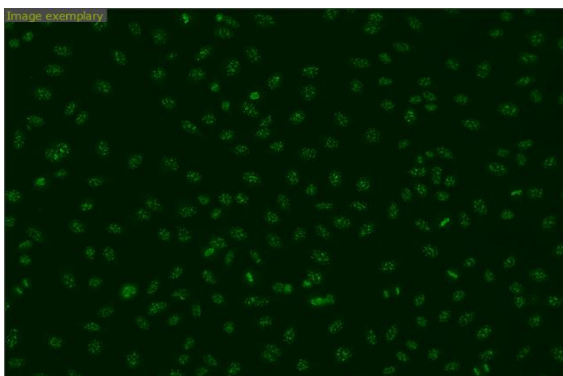
9.3.9 Library function

For classification, the **Result Confirmation** module contains a library of typical patterns (here shown on the example of an ANA HEp2 assay). Select a pattern with the mouse or the arrow keys (↑/↓).



Note: There are three different **Result Confirmation** libraries available (Not all are available in every country). If a library needs to be changed or installed in addition, the distributor must perform the installation. The following libraries are available:

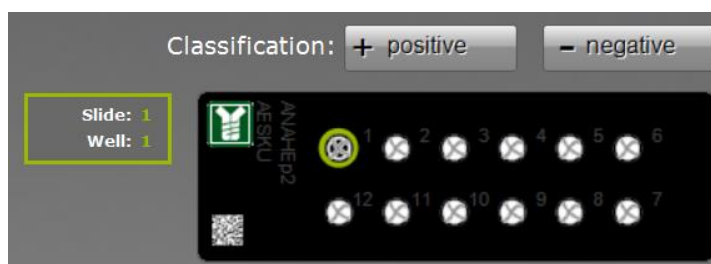
- AESKU Default library
- ICAP+ library
- AESKU.BION Infectious Serology library



The selected pattern (here “Centromere”) will be displayed instead of the classification suggestion. Additionally, a descriptive text will be displayed next to the list of patterns. Further information on certain ANA HEp2 patterns (PDF files) are available. These can be opened by clicking the  button in the lower right corner.

9.3.10 Classification field

The classification field provides information on the current selected slide and well (highlighted by a green circle) as well as the classification buttons “**positive**” and “**negative**”. Information about the current slide and well number will be displayed in the green box.



9.4 Working with the HELIOS Result Confirmation

9.4.1 Navigation

For any assistance regarding the keyboard controls and navigation, press the F1 key to open the help menu. Functionalities such as **Enlarge image** and **Enlarge library image** are triggered by pressing the respective F-key on the keyboard. Other functions, such as **Confirm** (classification, remark) can be issued either using the mouse or the keyboard.

9.4.2 Performing classifications in a worklist

1. Select sorting:

Before loading a worklist, select the preferred sorting option. For further information, please refer to the **Options** section (9.2.3).

2. Load worklist:

Select the worklist to be classified and load it into the **Result Confirmation** module.

3. Pattern suggestion calculation (optional):

Start the pattern suggestion calculation for the loaded worklist.

4. Analyze:

Review and analyze the images and classification suggestions for current selected well.

5. Select classification (Classification performed by user):

Select the corresponding pattern or classification such as **Negative**, **Borderline** or **Positive undefined** from the list. **Borderline** classification can be used to describe when the sample is on the border of positive/negative, but still considered as weak positive. Consult the library images and descriptions for reference.

6. Confirm classification:

Confirm classification by pressing the **ENTER** key or by clicking the **+ positive** or **- negative** button.



7. Enter remark / comment:

After classification has been confirmed, a message box will open where the user can optionally enter a remark and/or recommend follow up steps if this setting was selected in **Options**:



AC13_Pleomorphic PCNA

Additional pattern:

Mitosis: ☐ negative ☐ positive

Choose follow up steps-Enter your comment

☐ IFA ☐ 1/40 ☐ 1/80 ☐ 1/160 ☐ 1/320 ☐ 1/640 ☐ 1/1280 ☐ 1/2560 ☐ 1/5120 ☐ 1/10240 ☐ 1/20480

☐ ELISA

AESKULISA

☐ RIA

☐ Blot ☐ Dot Blot ☐ Line Blot ☐ Western Blot

☐ Others

Confirm with "enter" or "OK"

8. Confirm comment:

Any comments can be confirmed by pressing the **ENTER** key or by clicking the **OK** button.

9. Perform classification process for next well:

The software will move to the next well to be classified within the sorting list.

Note: All controls are selected first when a worklist is processed. This function is independent of the selected sorting.

After all wells in a worklist have been classified, the following message will be displayed:

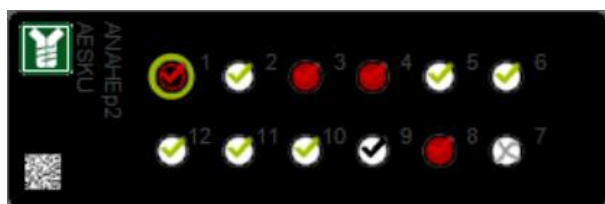


Confirm by pressing **OK**.

Reports can be opened at any time during the process. Please be aware that the reports will only be updated after they have been closed.

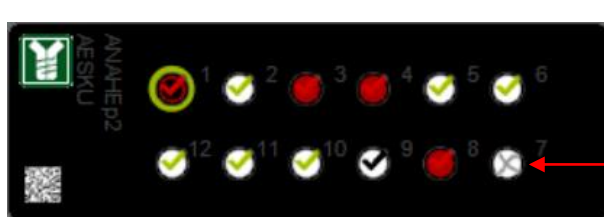
9.4.3 Color and symbols for classified wells

The exemplary image below shows a slide with different classification results on its corresponding wells. The wells are marked in different ways and color depending on their specific classification:

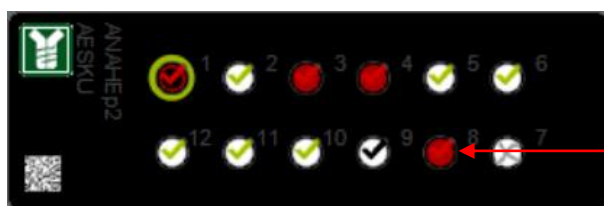


Explanation of well color and symbols:

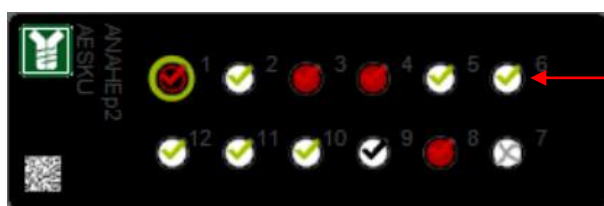
Unclassified wells will be displayed with a white background and a grey cross.



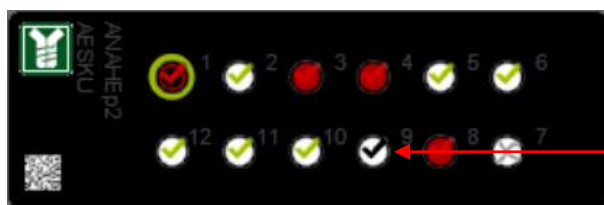
Positive wells will be displayed with a red background and a red checkmark.



Negative wells will be displayed with a white background and a green checkmark.



Borderline wells will be displayed with a white background and a black checkmark.



Note: If a control is not classified according to its specification (for e.g. positive control classified as negative), a warning message will be displayed, and a note will be added to the report.

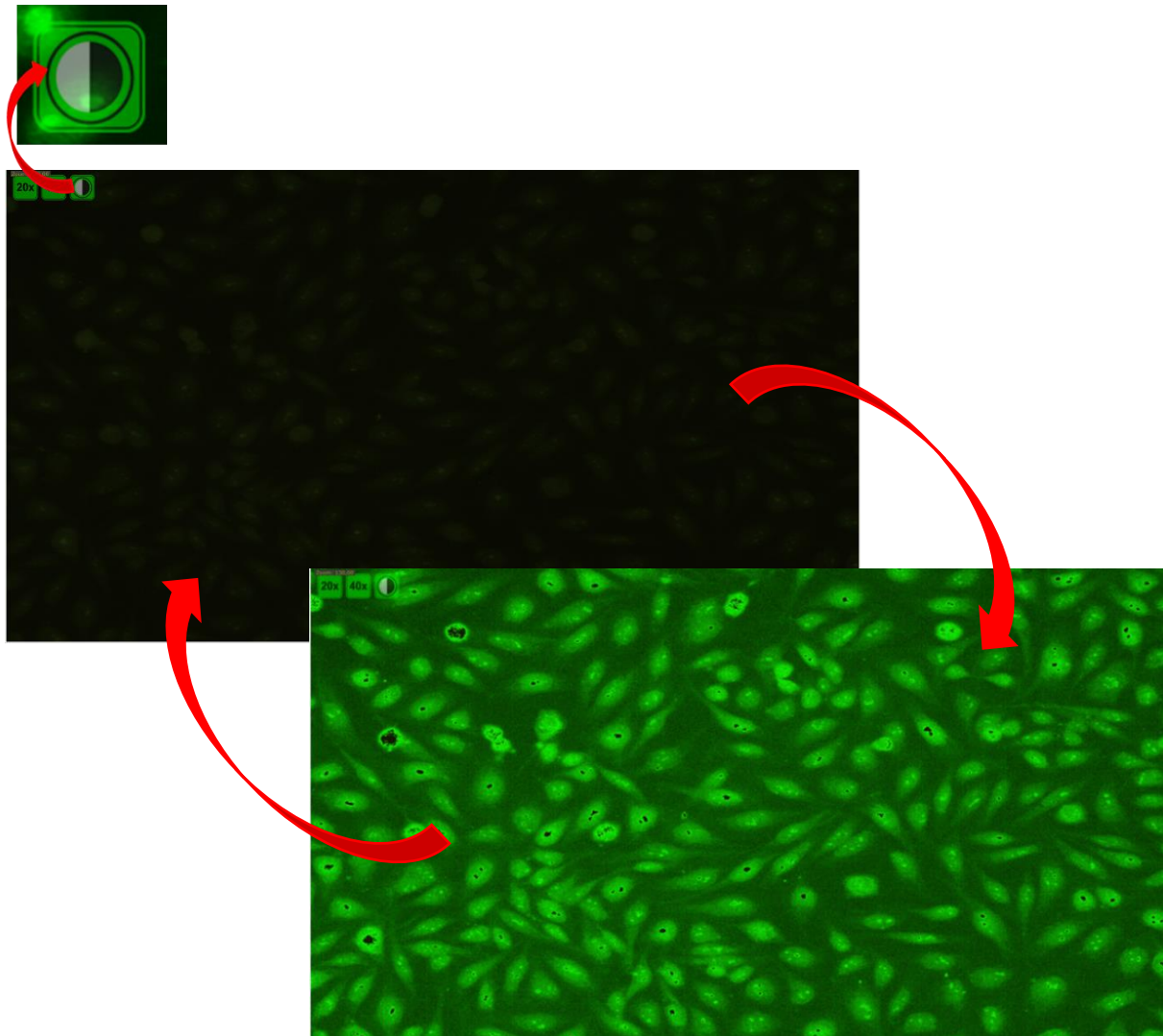
9.4.4 Contrast view

The **Contrast View** feature is a function in the **Result Confirmation** module that allows the user to digitally modify the contrast on a captured image.

Cells - respectively the cellular structures - are becoming more visible by using this function. This can be used to have a better validation of the captured image.

Example: Using **Contrast view** feature on a captured image of an **ANA HEp2** slide.

- Activate the feature by clicking the **Contrast View** button (see image below) in the upper left corner of the image.



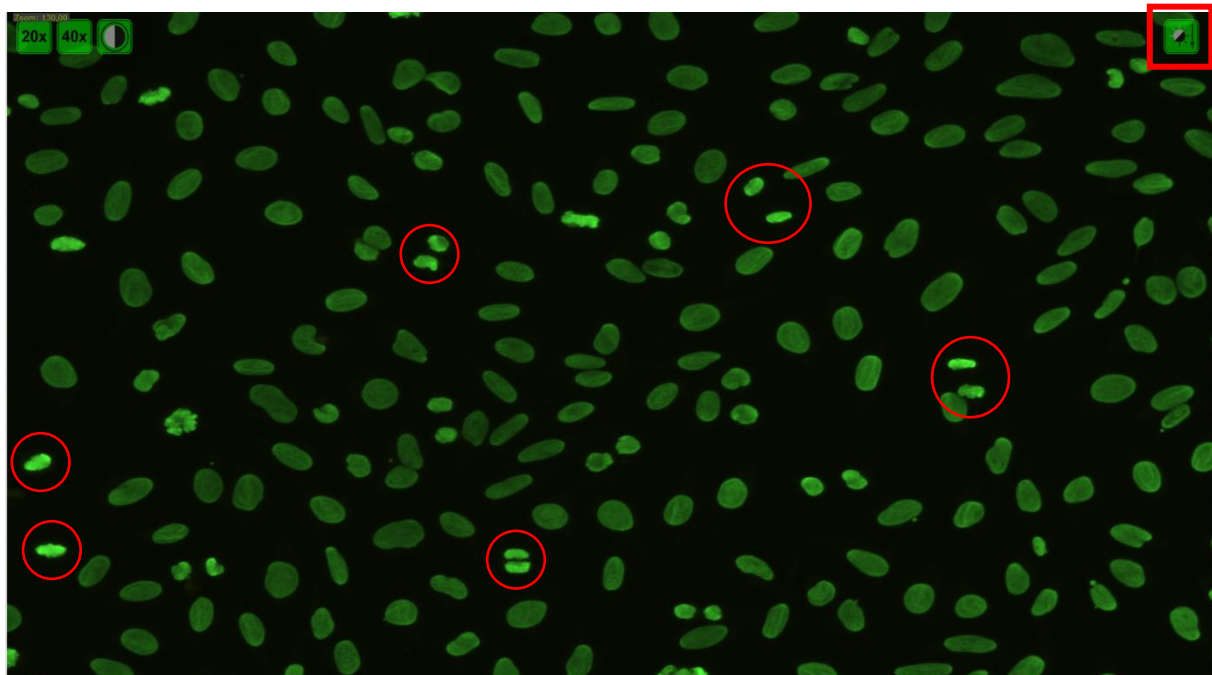
- To reverse the **Contrast View**, just click the **Contrast View** button again.
- Changes on the image while using the **Contrast View** feature are only temporarily and will not be saved.
- **Contrast View** function is available for all substrates.

9.4.5 Brightness Index



The “**Brightness Index**” symbol will be displayed in the **Result Confirmation** module for images which have been adjusted in brightness by the software to make all cells and cellular structures clearly visible and reviewable by the user without being overexposed. Therefore, the digital image is down regulated in brightness.

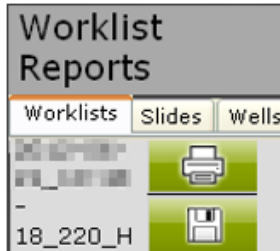
In the exemplary image below, the brightness of this homogenous ANA HEp2 pattern image was lowered by the software due to very bright mitoses until the mitoses and mitotic phases are clearly visible, indicated by the specific “**Brightness Index**” icon in the upper right corner.



Note: When the “Brightness Index” logo will be displayed, a sample can appear brighter when manually reviewed on a microscope rather than shown on the digital image.

9.4.6 Result reports

The panel for displaying reports can be found on the right side of the user interface. The following three report options are available:



- **Worklist Reports** – to print a full report of the worklist



- **Slide Reports** – to print a report of the selected slide



- **Well Reports** – to print a report of the selected well (including the current selected image)

A result report contains the following parts:

- **Header:** The header of the report can be customized as described in the **Options** section (9.2.3).

Institute:	Institute	Point of contact:	Point
City:	City	Address:	Address
Phone:	Phone	eMail:	Email

- **Test / Slide info:** Each page of the report also includes information regarding the test, the slide number, and the slide ID.



▪ **Worklist info / Traceability:**

Worklist name
Operator Helios
Printed at / Printed by
Kit lot
Expiry date
Slide lot
Conjugate lot
Positive control lot
Negative control lot
Comments
Run mode

For traceability reasons, the report also contains all information from the worklist as well as the Lot or expiry date of the reagents, etc. This information is only available if entered during the creation of the worklist in the IFA module – refer to chapter 7.2.

- **Classification / Evaluation:** This part contains a list of the wells with the respective classifications, comments and the name of the user that performed the classification.

Well	ID	Diln.	Result	Pattern	Remark	Username
1	AESKU_ANAHEp2_PC	1/1	+	Homogenous		user
2	AESKU_NCIFA_NC	1/1	-	Negative		user
3	Sample ID #1	1/80	+	Positive Undefined	to be checked Estm. endpt. titer:1/5120	user
4	Sample ID #2	1/80	+	Speckled	Estm. endpt. titer:1/5120	user
5	Sample ID #3	1/80	+	Nucleolar	Estm. endpt. titer:1/1280 Mitosis: negative	user
6	Sample ID #4	1/80	-	Negative		user
7	Sample ID #5	1/80	+	Cytoplasmic	Estm. endpt. titer:1/1280	user
8	Sample ID #6	1/80	+	Nuclear membrane	Estm. endpt. titer:1/160	user

Note: If results were reviewed and changed (overwritten) by a user with **superuser** permission, the report will incorporate this information:

Well	ID	Diln.	Result	Pattern	Remark	Username
1	AESKU_ANAHEp2_PC	1/1	+	Homogenous		user
2	AESKU_NCIFA_NC	1/1	-	Negative		user
3	Sample ID #1	1/80	+	Positive Undefined	to be checked	user
3	Sample ID #1	1/80	+	Centromere	to be checked Estm. endpt. titer:1/5120 Mitosis: positive	superuser
4	Sample ID #2	1/80	+	Speckled	Estm. endpt. titer:1/5120	user
5	Sample ID #3	1/80	+	Nucleolar	Estm. endpt. titer:1/1280 Mitosis: negative	user
6	Sample ID #4	1/80	-	Negative		user
6	Sample ID #4	1/80	+	Positive Undefined	Estm. endpt. titer:negative Follow up: IFA: ELISA:	superuser
7	Sample ID #5	1/80	+	Cytoplasmic	Estm. endpt. titer:1/1280	user
8	Sample ID #6	1/80	+	Nuclear membrane	Estm. endpt. titer:1/160	user

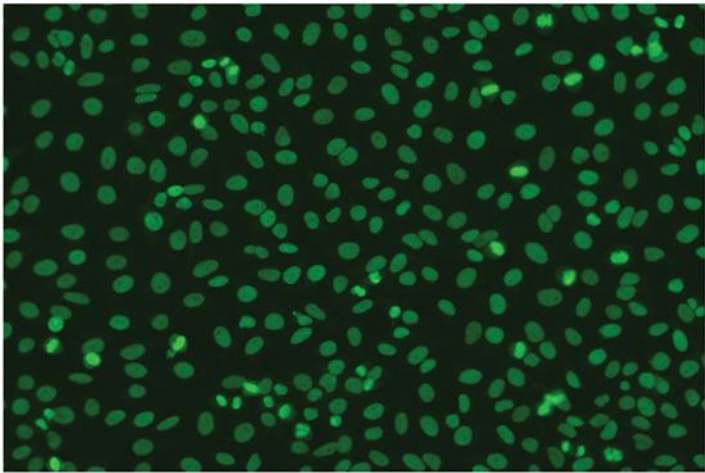
Only the “Well Report” contains an image:

Institute:	Institute	Point of Contact:	Point
City:	City	Address:	Address
Phone:	Phone	eMail:	Email

AESKU_ANAHEp2_12w_51_100_v007	Slide No: 1
-------------------------------	-------------

Worklist Name	2012-10-08_10-49-14_Helios_IFAWorklist
Operator Helios	AESKU.Systems
Printed at / Printed by	2012/10/8 / superuser
Kit Lot	-
Expiry Date	2013-09-01
Slide Lot	12040
Conjugate Lot	12030
Positive Contol Lot	11500
Negative Control Lot	11500
Comments	HELIOS
Run Mode	Screening

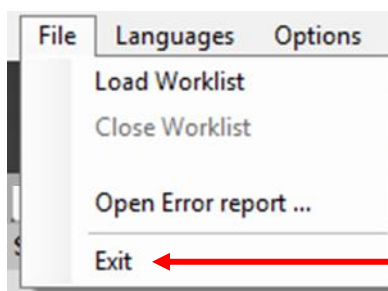
Image Nr.: 1	Run Nr.: 1
--------------	------------



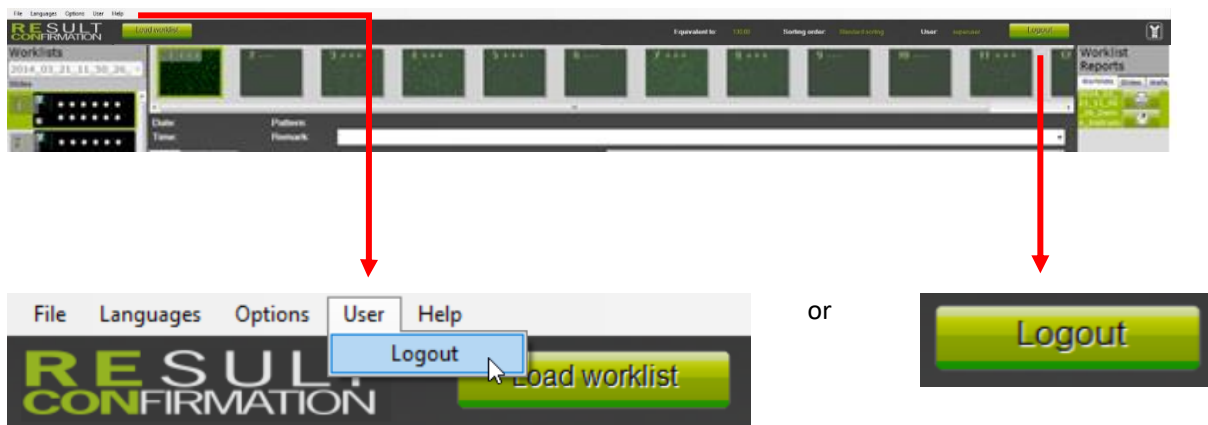
Well	ID	Titer	Result	Pattern	Remark	Username
8	Sample ID #6	1/80	+	Homogenous		user

9.5 Closing the program

Close the program by clicking **Exit** in the **File** menu. The program will close, and the software will return to the **HELIOS®** main screen.



To return to the login screen of the **Result Confirmation** module, please use the **Logout** button or log out by clicking **Logout** in the **User** tab:



10 Estimated endpoint titer (EEPT)

For classification of immunofluorescence images, the endpoint titer is an important indicator. After the first screening, a titration of positive samples is recommended. The highest dilution in which staining intensity just appears positive, is expressed as endpoint titer.

The **HELIOS®** software offers the possibility to perform screening and titration runs. Depending on the lab needs, the function **estimated endpoint titer** (in short **EEPT**) can be activated by license for screening runs. After activation of the function, the software calculates an estimation of the possible endpoint titer for each positive patient sample. The calculation will be executed during image capturing process by the **HELIOS®** device software.

The calculated EEPT for a screening run can be checked when the respective worklist is opened in the **Result Confirmation** module (here explained on the example of an ANA HEp-2 assay):



Figure: Process steps for using EEPT function

Note: The estimation of the endpoint titer is a support feature and should only be used by trained personnel. Keep in mind that this is an estimation which can differ from the real endpoint titer of the sample.

10.1 Activation

A unique license number will be created to activate the **estimated endpoint titer (EEPT)** function. Please contact your local distributor for further information. Please be aware that this function might be available only for specific countries and for **ANA HEp2** and **ANCA E /F** substrates only.

Note: When the EEPT feature is enabled, no value is calculated for positive samples in previously processed worklists.

10.2 How to use the EPT estimation?

10.2.1 Creating an ANA HEp-2 screening run

For using the **EEPT** function during the sample classification process, an ANA HEp-2 screening run has to be performed.

1. Start the IFA slide processing and image capturing module:



2. Create a worklist and select the **Screening** mode in the window “**New Worklist - Step 2 of 4**”.

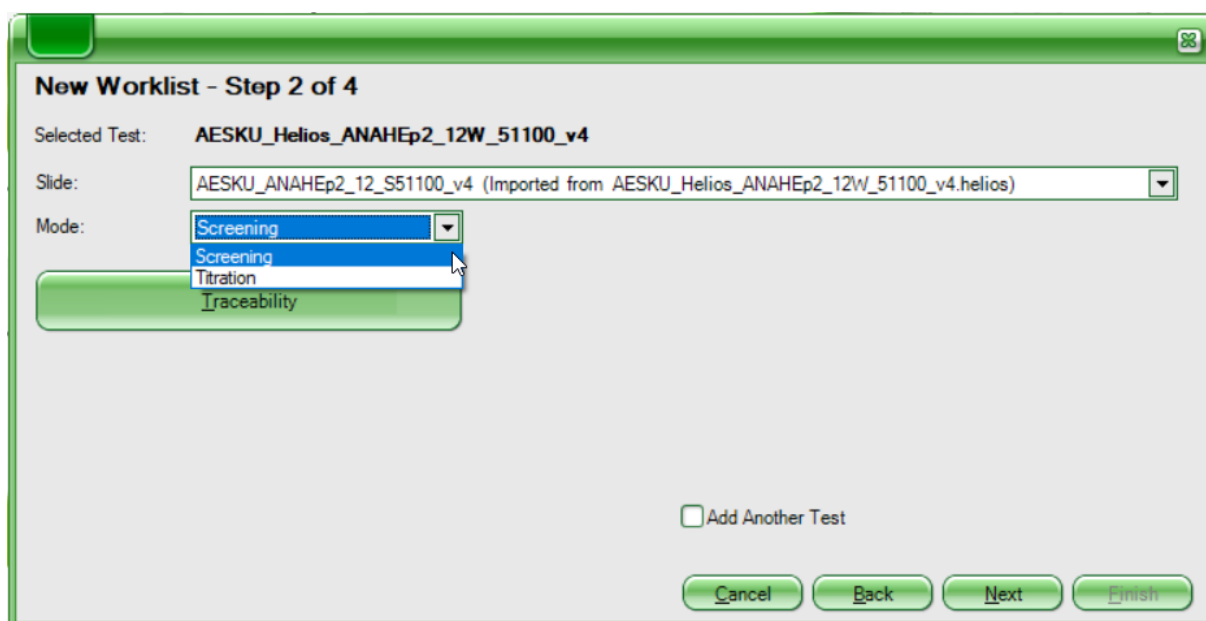


Figure: Selection of "Screening" mode

Note: A combination of tests running in **Screening** and **Titration** mode in one worklist is possible, but the **EEPT** will only be displayed for the **Screening** tests.

3. Start the worklist and wait until the **Image Capturing** process is finished.

The estimated endpoint titer calculation is performed by the **HELIOS®** software during the image acquisition.

10.2.2 User classification

The processed worklist must be opened in the **Result Confirmation** module.

1. Start the **Result confirmation** module and login with a user account:



2. Open the processed worklist.

Note: The **estimated endpoint titer (EEPT)** is generated per well, based on all captured images rated with a positive pre-classification. If negative and / or unknown pre-classifications for all number of images of a single well are predominant, no EEPT will be displayed.

Once activated, the **estimated endpoint titer** for each well (in **Screening** mode) will be displayed as part of the sample information in the lower left corner of the **Result Confirmation** module as shown in the figure below:

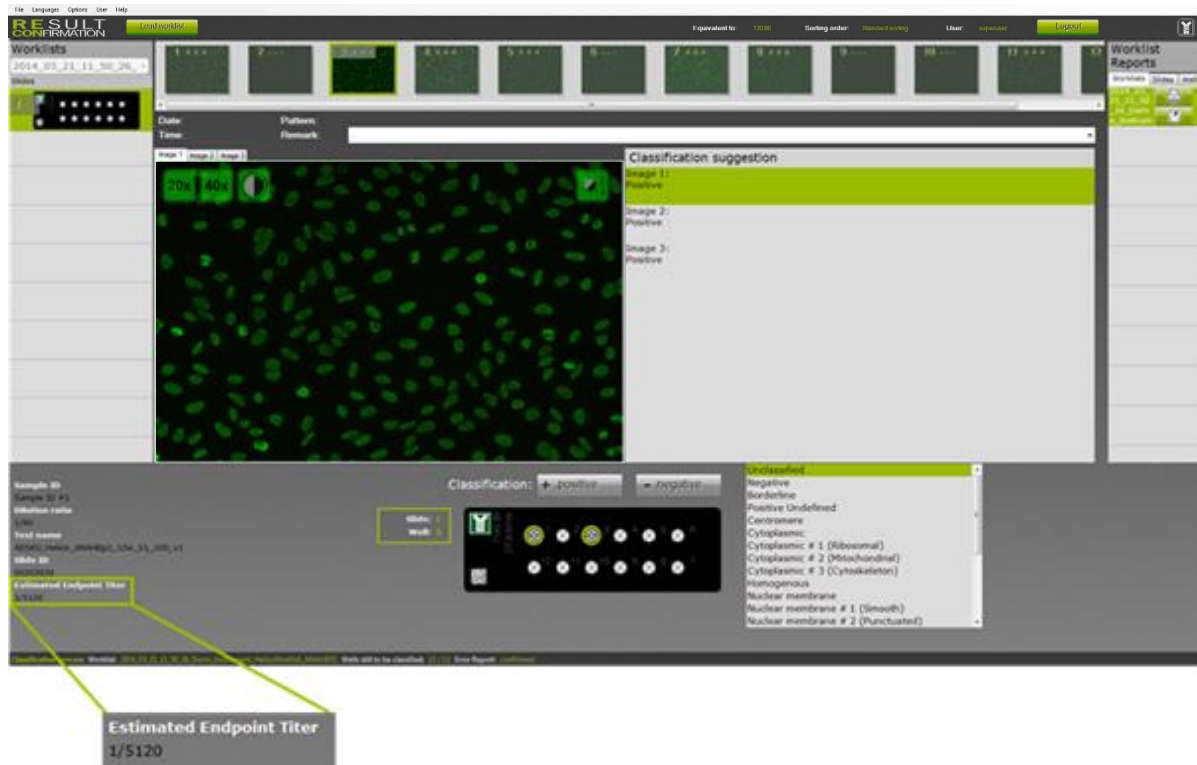


Figure: Example of calculated estimated endpoint titer

11 Pattern Recognition

11.1 Pattern Recognition Module

The **Pattern Recognition (PR)** is an additional module which can be ordered separately for the **HELIOS** device software. An activation code is required after the installation. A pattern suggestion calculation can be applied for a loaded worklist in the **Result Confirmation** module for **ANA HEp2** and **ANCA E / F** substrates.

Note: The pattern suggestion is a support feature and should only be used by trained personnel. Keep in mind that this is a suggestion and may differ from the real pattern of the sample.

11.2 Activation

The **Pattern Recognition** module can be activated via paid license and activation code. Please contact your local distributor for any further information.

Note: The **Pattern Recognition** module can be activated for **ANA HEp2** and **ANCA Ethanol / Formalin** substrates and might be available in specific countries only.

11.3 How to use the pattern recognition?

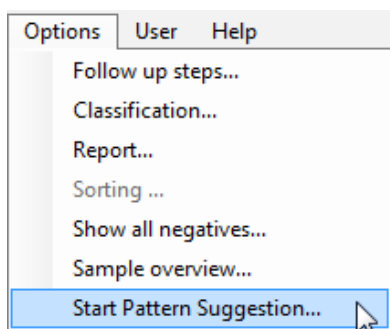
11.3.1 Load a worklist

A processed worklist must be opened in the **Result Confirmation** module.

1. Start the **Result Confirmation** module and login with a user account:



2. Load a processed worklist.
3. Choose **Start Pattern Suggestion...** from the **"Options"** tab.



When the calculation is finished, the estimated **Pattern Suggestion** will be displayed as part of the sample information in the lower left corner of the **Result Confirmation** module as shown in the figure below:

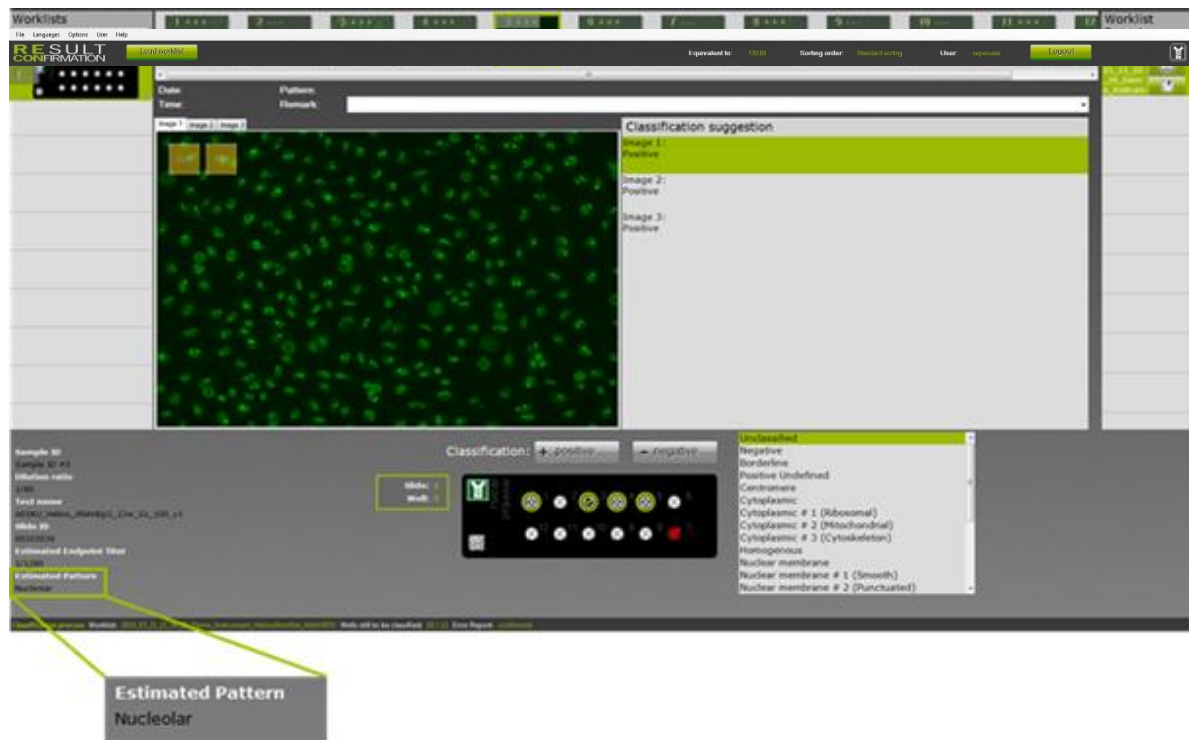
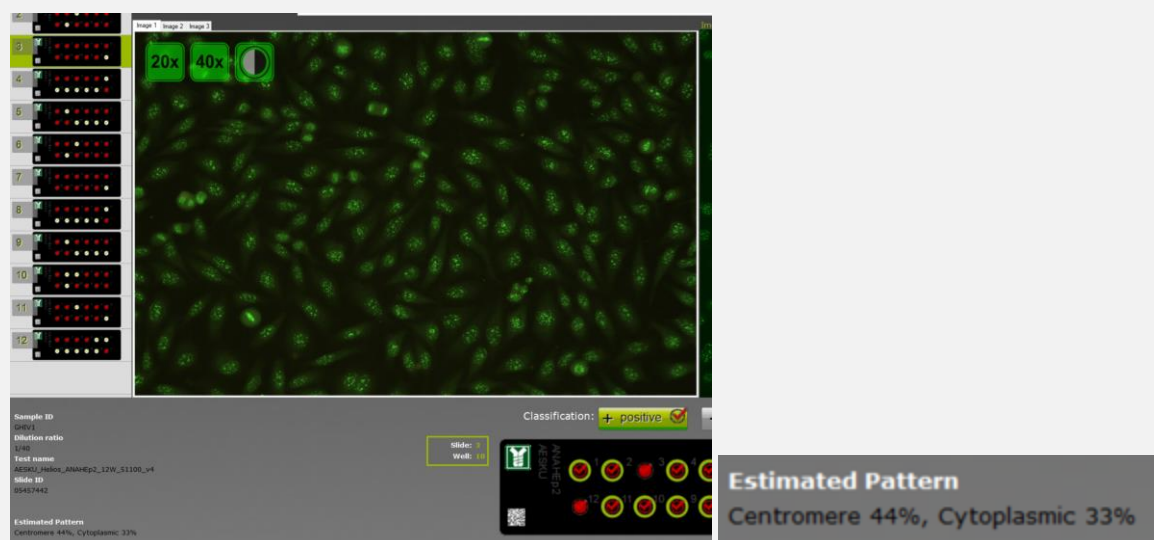


Figure: Example of displayed estimated pattern

Note: The **Pattern Suggestion** is generated per well, based on all captured images rated with a positive pre-classification.

The pattern suggestion for **ANA HEp2** can include more than one possible pattern for a certain sample in case no clear (100%) assignment is applied (e.g. different criteria for different pattern were recognized or mixed pattern). Therefore, the two highest probabilities (in %) for a pattern are given instead:



12 Operational Adjustment (Configuration)

Only a user logged in with **superuser permission** can access the **Operational Adjustment** menu allowing to change the settings (Cut-off) for the positive or negative pre-classification suggestion (only applies to **ANA (HEp2)**, **ANCA E** and **ANCA F**). In addition, there is the possibility to adjust the endpoint titer estimation, if this function has been activated via paid license (see chapter 10).

Log in as a user with **superuser** rights and click on the **Configuration** button:



Select **Operational Adjustment** from the menu list on the upper left side of the user interface:

Operational Adjustment

Note: Before working with the HELIOS® system, the settings for the classification suggestion must be evaluated by the lab!

12.1 Cut-off adjustment

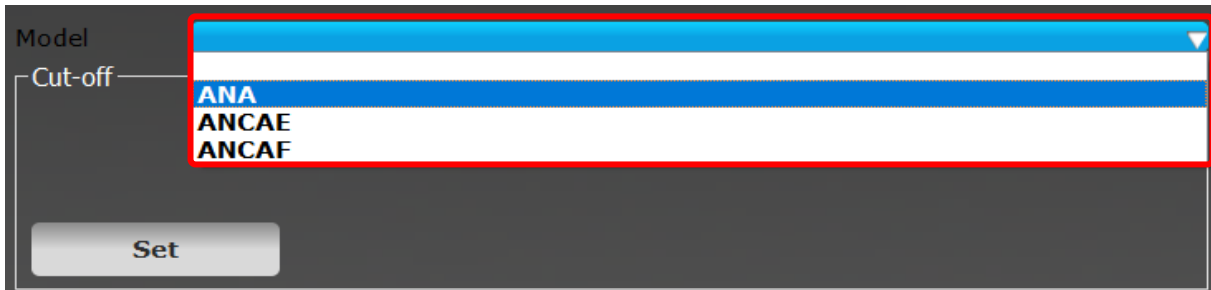
The cut-off settings can be found at the top of the “**Operational Adjustment**” user interface, when the respective **Model** has been selected from the dropdown menu (here: **ANA (HEp2)**):

The value named “**Absolute Brightness (ABRT)**” controls the cut-off for positive/negative identification by the **HELIOS®** software. A value for “**Cut-off adjustment (Absolute Brightness)**” is already set by default. With the setting of **ABRT = 70** for instance, all images rated with **ABRT < 70** are identified as negative, all images with **ABRT ≥ 70** will be identified as positive. Once an **ABRT** value is defined as a cut-off, it will be applied for the selected model (**ANA**, **ANCAE** or **ANCAF**).

Note: Changes to the pre-classification suggestion have no influence on already captured images. Only trained personnel should change settings in here. Contact your local distributor for any further information.

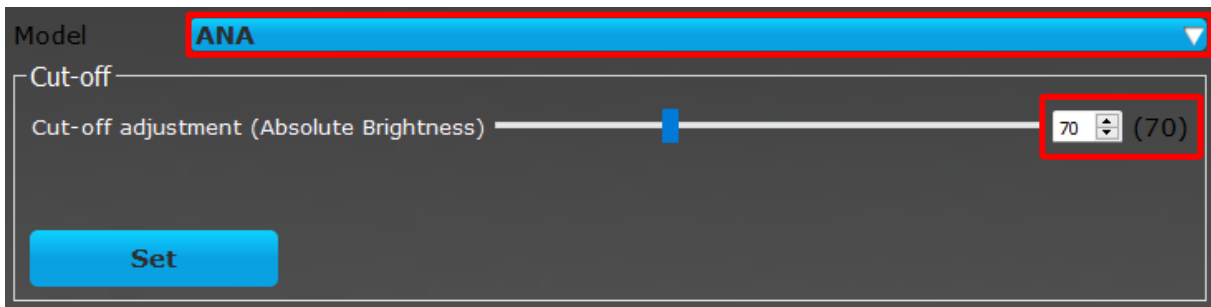
The following procedure for any **Cut-off adjustment** must be led by the distributor **Applications Support** and is **NOT** for routine/regular adjustment by the end users. Though, any **Cut-off adjustment** must be evaluated by the end-user.

1. Please select the model that needs to be adjusted from the dropdown menu:



The screenshot shows a software interface with a 'Model' dropdown menu. The dropdown is open, displaying three options: 'ANA', 'ANCAE', and 'ANCAF'. The 'ANA' option is highlighted in blue. A red rectangular box is drawn around the dropdown menu. Below the dropdown is a 'Set' button.

2. As an example, "ANA" is selected, and the default **Cut-off (Absolute Brightness)** is 70:



The screenshot shows the software interface with 'ANA' selected in the 'Model' dropdown. Below it, the 'Cut-off' section features a slider labeled 'Cut-off adjustment (Absolute Brightness)'. The slider has a blue handle in the middle. To the right of the slider is a numeric input field showing '70' with up and down arrows, and '(70)' next to it. A red rectangular box is drawn around the numeric input field. A 'Set' button is located at the bottom left.

3. Now open a processed worklist with known samples by selecting "**Select Worklist**":



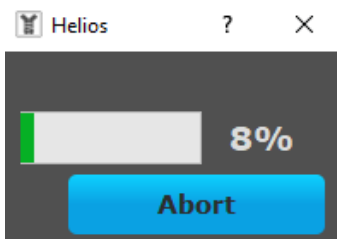
The screenshot shows the 'Test parameters' section of the software. It contains four buttons: 'Select Image Directory', 'Select Worklist', 'Check all', and 'Chg. Pre-Class.'. The 'Select Worklist' button is highlighted with a red rectangular box.

- Select a **ANA HEp2 worklist (.worklist)** file to be opened.

4. The loaded worklist can now be checked by clicking on "**Check all**":



The screenshot shows the 'Test parameters' section of the software. It contains four buttons: 'Select Image Directory', 'Select Worklist', 'Check all', and 'Chg. Pre-Class.'. The 'Check all' button is highlighted with a red rectangular box.



The screenshot shows a progress bar window titled 'Helios'. It has a question mark icon and a close button. The progress bar is partially filled with green, and the text '8%' is displayed next to it. Below the progress bar is a blue 'Abort' button.

Please wait until the "**Check all**" procedure has been successfully completed.

5. After all wells have been checked by the software, a respective overview is presented:

Test parameters

Select Image Directory Select Worklist Check all Chg. Pre-Class.

	+ EPT:1/1280 (DS610), dil:80, ABRT:624 (MV:28 MFV:89 OE:0 E:0.1875 BR:132 BL:15 ...	Slide_02/classified/Well_10_Img_01.png
	+ EPT:1/1280 (DS610), dil:80, ABRT:693 (MV:23 MFV:93 OE:1 E:0.1875 BR:144 BL:14 ...	Slide_02/classified/Well_10_Img_02.png
	+ EPT:1/1280 (DS610), dil:80, ABRT:698 (MV:19 MFV:92 OE:2 E:0.1875 BR:143 BL:12 ...	Slide_02/classified/Well_10_Img_03.png
	+ EPT:1/80 (GHIV), dil:80, ABRT:75 (MV:16 MFV:31 OE:0 E:0.4 BR:44 BL:14 BG...	Slide_02/classified/Well_11_Img_01.png
	+ EPT:1/80 (GHIV), dil:80, ABRT:72 (MV:15 MFV:31 OE:0 E:0.4 BR:43 BL:14 BG...	Slide_02/classified/Well_11_Img_02.png
	- EPT:1/80 (GHIV), dil:80, ABRT:62 (MV:16 MFV:29 OE:0 E:0.4 BR:39 BL:14 BG...	Slide_02/classified/Well_11_Img_03.png

↓

	+ EPT:1/80 (GHIV), dil:80, ABRT:75 (MV:16 MFV:31 OE:0 E:0.4 BR:44 BL:14 BG...	Slide_02/classified/Well_11_Img_01.png
	+ EPT:1/80 (GHIV), dil:80, ABRT:72 (MV:15 MFV:31 OE:0 E:0.4 BR:43 BL:14 BG...	Slide_02/classified/Well_11_Img_02.png
	- EPT:1/80 (GHIV), dil:80, ABRT:62 (MV:16 MFV:29 OE:0 E:0.4 BR:39 BL:14 BG...	Slide_02/classified/Well_11_Img_03.png

In this example the value is **70 (default)**, so **ABRT** values **below or equal 70** will be given **negative** whereas values **higher 70** will be given **positive**.

6. To change the **Cut-Off**, for example to **60**, enter the respective value in the textbox (or using the regulator) and confirm this new value by clicking the **“Set”** button.

Model **ANA**

Cut-off

Cut-off adjustment (Absolute Brightness)

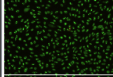
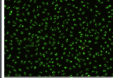
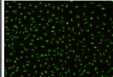
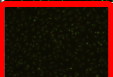
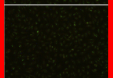
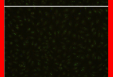
60 (70)

Set

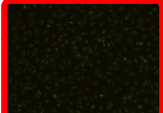
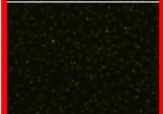
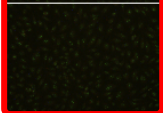
7. Clicking again now on “**Check all**” after changing the value from 70 to 60, will lead to the following result:

Test parameters

[Select Image Directory](#)
[Select Worklist](#)
[Check all](#)
[Chg. Pre-Class.](#)

	+ EPT:1/1280 (DS610), dil:80, ABRT:624 (MV:28 MFV:89 OE:0 E:0.1875 BR:132 BL:15 ...	Slide_02/classified/Well_10_Img_01.png
	+ EPT:1/1280 (DS610), dil:80, ABRT:693 (MV:23 MFV:93 OE:1 E:0.1875 BR:144 BL:14 ...	Slide_02/classified/Well_10_Img_02.png
	+ EPT:1/1280 (DS610), dil:80, ABRT:698 (MV:19 MFV:92 OE:2 E:0.1875 BR:143 BL:12 ...	Slide_02/classified/Well_10_Img_03.png
	+ EPT:1/80 (GHIV), dil:80, ABRT:75 (MV:16 MFV:31 OE:0 E:0.4 BR:44 BL:14 BG...	Slide_02/classified/Well_11_Img_01.png
	+ EPT:1/80 (GHIV), dil:80, ABRT:72 (MV:15 MFV:31 OE:0 E:0.4 BR:43 BL:14 BG...	Slide_02/classified/Well_11_Img_02.png
	+ EPT:1/80 (GHIV), dil:80, ABRT:62 (MV:16 MFV:29 OE:0 E:0.4 BR:39 BL:14 BG...	Slide_02/classified/Well_11_Img_03.png

↓

	+ EPT:1/80 (GHIV), dil:80, ABRT:75 (MV:16 MFV:31 OE:0 E:0.4 BR:44 BL:14 BG...	Slide_02/classified/Well_11_Img_01.png
	+ EPT:1/80 (GHIV), dil:80, ABRT:72 (MV:15 MFV:31 OE:0 E:0.4 BR:43 BL:14 BG...	Slide_02/classified/Well_11_Img_02.png
	+ EPT:1/80 (GHIV), dil:80, ABRT:62 (MV:16 MFV:29 OE:0 E:0.4 BR:39 BL:14 BG...	Slide_02/classified/Well_11_Img_03.png

Now, all three images will be given **positive**.

Note: It is recommended that this procedure is performed on an “unclassified” worklist to adopt the new changes. It is also recommended that clinically confirmed samples are used just above and below the new cutoff setting.

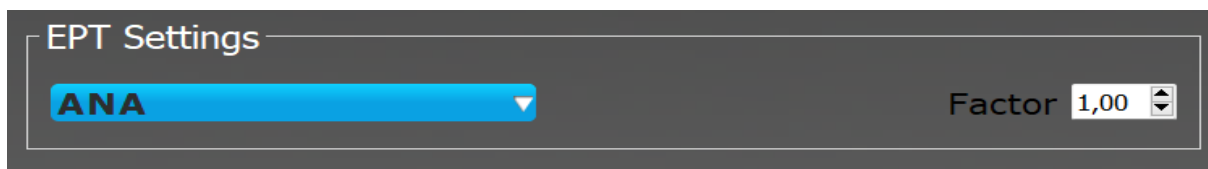
12.2 Save settings for cut-off

The settings for the cut-off adjustment can be saved by:

1. Choose model from the dropdown list:
 - ANA (HEp2)
 - ANCAE
 - ANCAF
2. Enter a new preferred value for cut-off adjustment and press the **Set** button to confirm entry.
3. Value will automatically be saved after pressing the **Set** button

12.3 EPT settings

If the function for **endpoint titer estimation (EEPT)** has been activated via license, an additional menu will be available in the **Operational Adjustment** menu, the **EPT Settings** menu:



By default, the value is set to the “Factor 1.00” which complies to 100%. If the value for the correction factor will be increased for example to 1.20, then the calculated EPT will be multiplied by 1.20 and therefore provide a higher estimation for the EPT. The adjustment will be applied for the current selected substrate in the dropdown menu. The settings for EEPT function (endpoint titer estimation) can separately be adjusted for:

- ANA (HEp2)
- ANCAE
- ANCAF

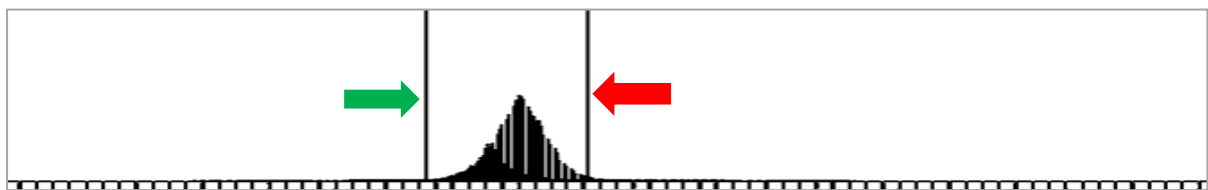
Note: Before working with the EEPT function, the settings for the endpoint titer estimation must be evaluated by the lab!

Note: Changes to the **endpoint titer estimation (EEPT)** have no affect on already EEPT rated images. Only trained personnel should change settings in here. Contact your local distributor for further information.

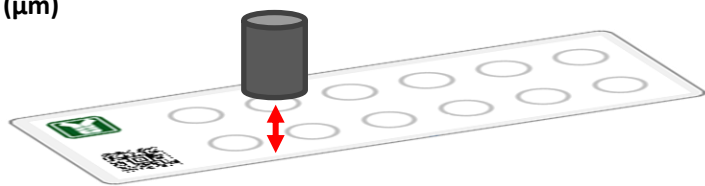
12.4 Scan Range Adjustment

Scan Range Adjustment	
#1	Range start for scanning on the mask (um): 22949 (22949)
#2	Range end for scanning on the mask (um): 22439 (22439)
#3	Range for scanning within the well (um): 70 (70)
#4	Range for scanning within the well, tissue mode (um): 80 (80)

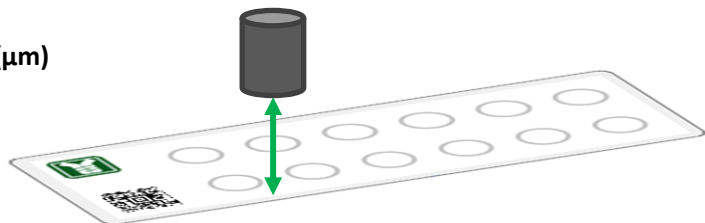
In the **Scan Range Adjustment** menu, there are four different values that can be adjusted if necessary. The values #1 and #2 in the list above will be automatically set after autocalibration has been performed and describe the range for focusing on the mask in [μm]. Range start value is indicated by the **red arrow**, and the range end value is indicated by the **green arrow** in the illustrations below.



- Range start for scanning on the mask (μm)



- Range end for scanning on the mask (μm)



The total range will be automatically calculated and set by the software after the autocalibration procedure. These values are predefined by the software and should **not** be changed.

The values #3 and #4 are already optimized factory settings by default and define the scan range within the well, for cell based substrates (#3) and for tissues (#4). These values are predefined and should **not** be changed as well.

Note: Changing any of these settings in **Scan Range Adjustments** is allowed to **trained personnel only**!

It is highly recommended to not touch or modify any of these settings since it is not necessary under normal circumstances! Contact your local distributor for further information.

13 Data Management (Configuration)

Only a user logged in with **superuser** or **admin permission** can access the **Data Management** menu. The **Data Management** menu provides different options which will be further described in detail in the following sections.

To access the Data Management menu, log in with **superuser** or **admin** rights and click on the **Configuration** button:



Select **Data Management** from the menu list on the upper left side of the user interface:



13.1 Data cleansing

In the upper part of the menu, the settings for the automated data cleansing can be defined according to the requirements of the user. These settings can be adjusted for the following data type:

- **HELIOS log files**
- **LIS data**
- **HELIOS config backup files**

Note: The automated data cleansing option allows to keep the system clean and to save storage capacity by deleting no longer used or obsolete data.

For each of these data types, a specific period of time can be defined, after which the according data will be automatically deleted. The specific time period can be selected via dropdown menu:

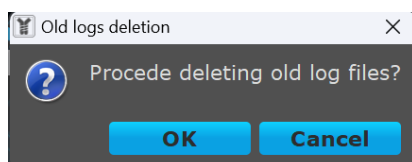
The screenshot shows a configuration window with the following settings:

- Delete logs from the directory ~/Documents/AESKU.SYSTEMS/HELIOS/LOG, which are older then: **1 month** (dropdown menu)
- Commit old logs deletion: ☒ (checkbox)
- Delete LIS data, which are older then: **1 month** (dropdown menu)
- Commit old LIS data deletion: ☒ (checkbox)
- Delete config backup data from the directory ~/Documents/AESKU.SYSTEMS/HELIOS/data, which are older then: **1 month** (dropdown menu)
- Commit old config back-up deletion: ☒ (checkbox)

Red arrows point to the dropdown menus and the checkboxes. To the right of the screenshot, three dropdown menu lists are shown, each with a red arrow pointing to it from the configuration window:

- Dropdown 1: 1 month, never delete, 1 month, 3 months, 6 months, 1 year
- Dropdown 2: 1 month, never delete, 1 week, 2 weeks, 1 month, 3 month
- Dropdown 3: 1 month, never delete, 1 month, 3 months, 6 months, 1 year

With these boxes checked, an additional window will open prompting the user to confirm deletion when the software starts (see exemplary illustration below):



If not marked, the respective data will be automatically deleted in the background (silent delete). If the option **“never delete”** was chosen from the dropdown list, the respective data will not be deleted automatically and must be deleted manually by the user or technician if necessary.

13.2 Worklist storage folder

Below the **Data Cleansing** section, a text box can be found showing the current storage location or output folder for saving the HELIOS worklists, named “**Results directory**”. This **Results directory** path can be changed by (a) either typing a path right into the box (e.g. “**d:/heliosworklists**”) or (b) use the green “...” button to browse for a folder destination using “**Select directory**” explorer window.

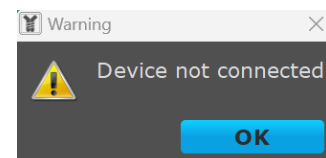


13.3 Check device connection



With this box checked, a warning window will pop up once the button for **HELIOS® walk-away mode** (Processing and image acquisition) or **HELMED® mode** (Processing only) has been clicked and the device has not yet been connected or powered on at this time:

By removing the check mark, the IFA modules can also be executed in “**DEMO**” mode with access to all submodules like for instance the Slide and Test Designer, etc.



13.4 Backup Manager

The **Backup Manager** can be manually started from the **Data Management** menu by clicking the respective button:



Refer to the **Service Manual** for a detailed description on how to use the **Backup Manager** tool.

13.5 License window

In the lower part of the **Data Management** menu, a **License window** is displayed showing all current activated licenses including the expiration day in case any licenses have been activated (see exemplary illustration below for activated EPT license). If no licenses have been activated, the **License window** remains empty.



Note: All optional functions like e.g. EPT Estimation, Pattern Suggestion or Pos / Neg Pre-Classification for nDNA (*Crithida luciliae*) are separately available and can be activated via paid license. Please ask your local distributor for any further information.

14 Additional Functionalities HELMED IFA Module

The **HELMED® IFA** module (blue IFA module) allows processing of IFA kits (slides) from other manufacturers. Please note that this functionality is limited to processing slides only and does not include image acquisition.

The **Well Designer** is used to define wells on a slide (size [diameter], type (shape [round; rectangular])).

The **Control Designer** is used to determine the controls used when performing a test.

The **Slide Designer** is used to define the positions of the wells, labeling and substrates used on the slide.

The **Test Designer** is used to define how a slide will be processed. Dilution factors for screening and titration, number of controls on the slide and process steps can be defined.

14.1 Slide Designer



Select **Tools** at the top of the **HELMED® IFA** start screen. From the dropdown menu, select **Slide Designer**.



Note: This function is password protected. If it will become necessary to change settings here or create slides from different manufacturers, please contact your local distributor for more information.

The slide must be designed before creating or design a new test file. The **HELMED® IFA** software already contains all **AESKUSLIDES™** types, but as an open system it is possible to create slides from other manufacturers as well.

Two options are available:



Slide: Contains options for creating a new slide or to open an existing slide.

Tools: Contains the **Well Designer** for creating new wells or to open an existing well.

14.1.1 Slide

The **Slide Designer** is used to edit existing or to create new slide types that can be processed in the **HELMED® IFA** module.

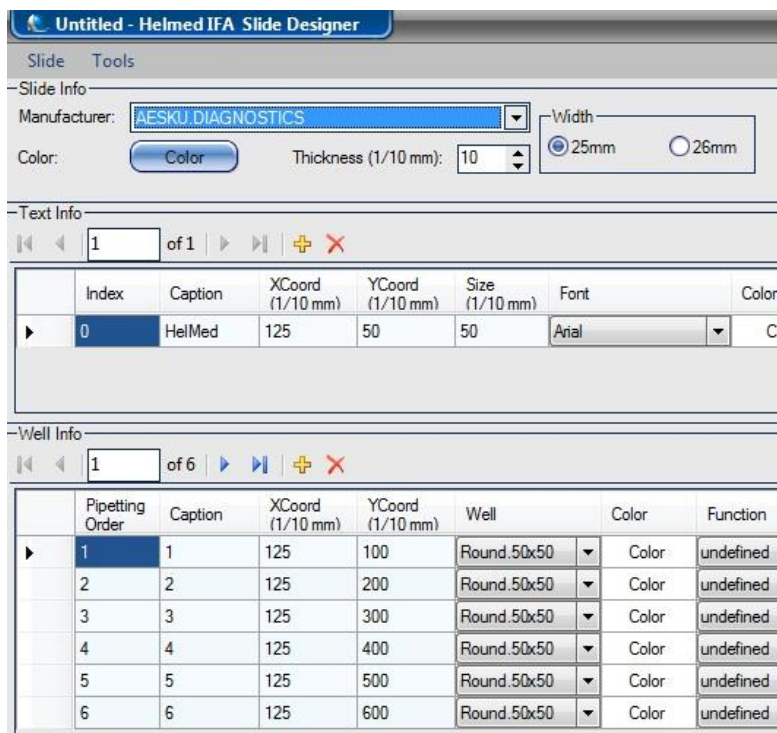
Note: All **AESKUSLIDES™** types are predefined and should not be edited.

The **Slide Designer** is an open and flexible system; allowing to create most IFA slides. If a new slide is configured, the user will be responsible for the verification and validation of the slide design and corresponding test functionality.

This section will provide information on how to create new slides.

Note: When opening the **Slide Designer**, a default slide design will open. This slide can be adjusted according to the new slide specifications.

The **Slide Designer** menu is divided into 3 sections:



The screenshot shows the 'Untitled - Helmed IFA Slide Designer' window. It has three main sections: Slide Info, Text Info, and Well Info.

Slide Info: Includes a 'Manufacturer' dropdown set to 'AESKU DIAGNOSTICS', a 'Color' button, a 'Thickness (1/10 mm)' spinner set to 10, and a 'Width' section with radio buttons for 25mm (selected) and 26mm.

Text Info: Includes a '1 of 1' indicator and a table with one row:

Index	Caption	XCoord (1/10 mm)	YCoord (1/10 mm)	Size (1/10 mm)	Font	Color
0	HelMed	125	50	50	Arial	C

Well Info: Includes a '1 of 6' indicator and a table with 6 rows:

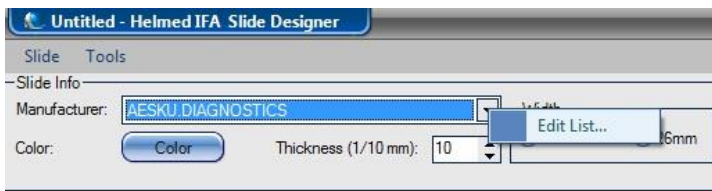
Pipetting Order	Caption	XCoord (1/10 mm)	YCoord (1/10 mm)	Well	Color	Function
1	1	125	100	Round.50x50	Color	undefined
2	2	125	200	Round.50x50	Color	undefined
3	3	125	300	Round.50x50	Color	undefined
4	4	125	400	Round.50x50	Color	undefined
5	5	125	500	Round.50x50	Color	undefined
6	6	125	600	Round.50x50	Color	undefined

Slide Info: Contains options to define/edit information related to manufacturer, color, thickness, and width of the slide.

Text Info: This option allows to edit the labeling of the slide.

Well Info: Contains options for defining the number and position of the wells on the slide. Select the well (created in the **Well Designer**), color of the well (optional), map a function (optional) and select/edit the substrate.

Slide Info

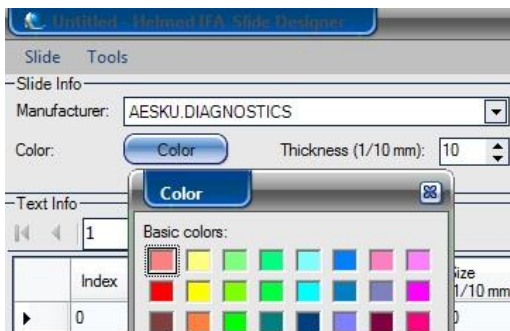


Select the slide manufacturer in the **Manufacturer** dropdown menu. To add a manufacturer, right-click the arrow of the selection menu. Click **Edit list**. A new window will open:

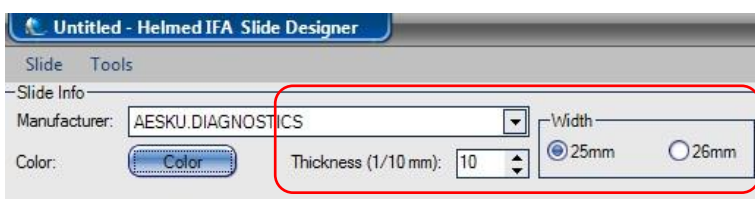


Click the **+** button. A text field will be added. Type the manufacturers name and confirm entry by clicking **Ok**. A manufacturer entry can be deleted from the list by selecting the line and clicking the **x** button.

To assign a color to a slide, click the **Color** button and select a color:



The thickness of a slide can be set in the **Thickness** text box and there are two dimensions for the **Width** of a slide to choose from, **25 mm** or **26 mm**:



Text Info

The X and Y positions are used to define the upper left position at which the text will be aligned. Enter a preferred labeling for the slide into the field **Caption**:

Text Info

2 of 2

	Index	Caption	XCoord (1/10 mm)	YCoord (1/10 mm)	Size (1/10 mm)	Font	Color	Orientation
	0	ANA-HEp2	125	50	30	Arial	Color	LeftToRight
▶	1	No.	80	700	30	Arial	Color	LeftToRight



Measure the distance from the left edge of the slide to the right edge of the text in millimeters. Multiply this value by a factor ten (10) and enter the result as **X-Coord (1/10mm)**. Measure the distance from the upper edge of the slide to the upper edge of the text in millimeters. Multiply this value by a factor ten (10) and enter the result as **Y-Coord (1/10mm)**. Texts can be oriented from left to right, top to bottom, bottom to top (Orientation field).

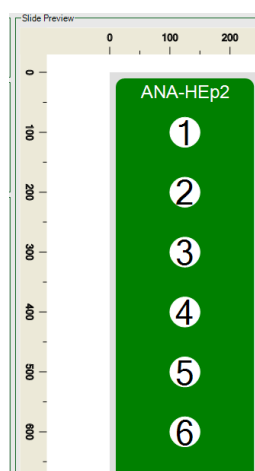
Well Info

Well Info

1 of 6

	Pipetting Order	Caption	XCoord (1/10 mm)	YCoord (1/10 mm)	Well	Color	Function	Substrate
▶	1	1	125	100	Round.50x50	Color	undefined	Liver
	2	2	125	200	Round.50x50	Color	undefined	Liver
	3	3	125	300	Round.50x50	Color	undefined	Liver
	4	4	125	400	Round.50x50	Color	undefined	Liver
	5	5	125	500	Round.50x50	Color	undefined	Liver
	6	6	125	600	Round.50x50	Color	undefined	Liver

The number of wells is defined by clicking the **+** button in the **Well Info** field. Complete the **Caption** field by numbering the wells continuously. Wells can also be deleted by clicking the **X** button.

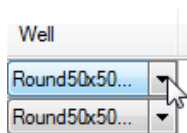


Well positions are defined by measuring from the top and left edge of the slide to the center of the well. A ruler, for X and Y positioning will be displayed on-screen. The 0/0 coordinate will be the upper left corner.

Measure the X-position of the first well using a ruler (metric). The X-position will be the distance from the left edge of the slide to the center of the well. Multiply the measured distance by a factor ten (10). Enter the result as **X-Coord (1/10mm)**.

Measure the Y-position of the first well using a ruler (metric). The Y Position will be the distance from the top edge of the slide to the center of the well. Multiply the measured distance by a factor ten (10). Enter the result as **Y-Coord (1/10mm)**.

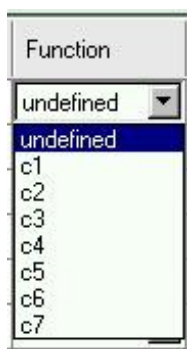
➤ Repeat this process for every single well position.



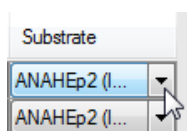
- From the **Well** dropdown menu, select the corresponding well type to be used on the slide. This well was previously defined in the **Well Designer**. For more information on the **Well Designer**, please refer to section 14.1.2.



- To assign a color to the wells, use the **Color** tab.



- The menu **Function** must be set to undefined for the settings and should never be changed!



- Select a substrate in the **Substrate** tab. Additional substrates can be added by right clicking the arrow of the selection menu. Click the **Edit list** button. A new window will open. Add a **Name** and a **Manufacturer** line by clicking the **+** button. Enter the new substrate here. Entering the name of the manufacturer is not mandatory.

Saving the slide

After a new slide has been created and defined, it needs to be saved.

- Click **Slide** from the **Slide Designer** menu bar
- Choose **Save as** from the context menu
- Enter a name for the new created slide and click **Save**
- The slide will be saved.

14.1.2 Well Designer



The **File** tab of the **Well Designer** menu contains five options:



- **New:** Define new well.
- **Open:** Open previously defined well.
- **Save:** Quick save defined well.
- **Save as:** Save defined well under specific name.
- **Close:** Closes the **Well Designer** and returns to the **Slide Designer** module.

Creating a new well type:

To create a new well, enter the respective information on type and size (height and width) of the well. The size of a round or rectangular well is measured as follows:

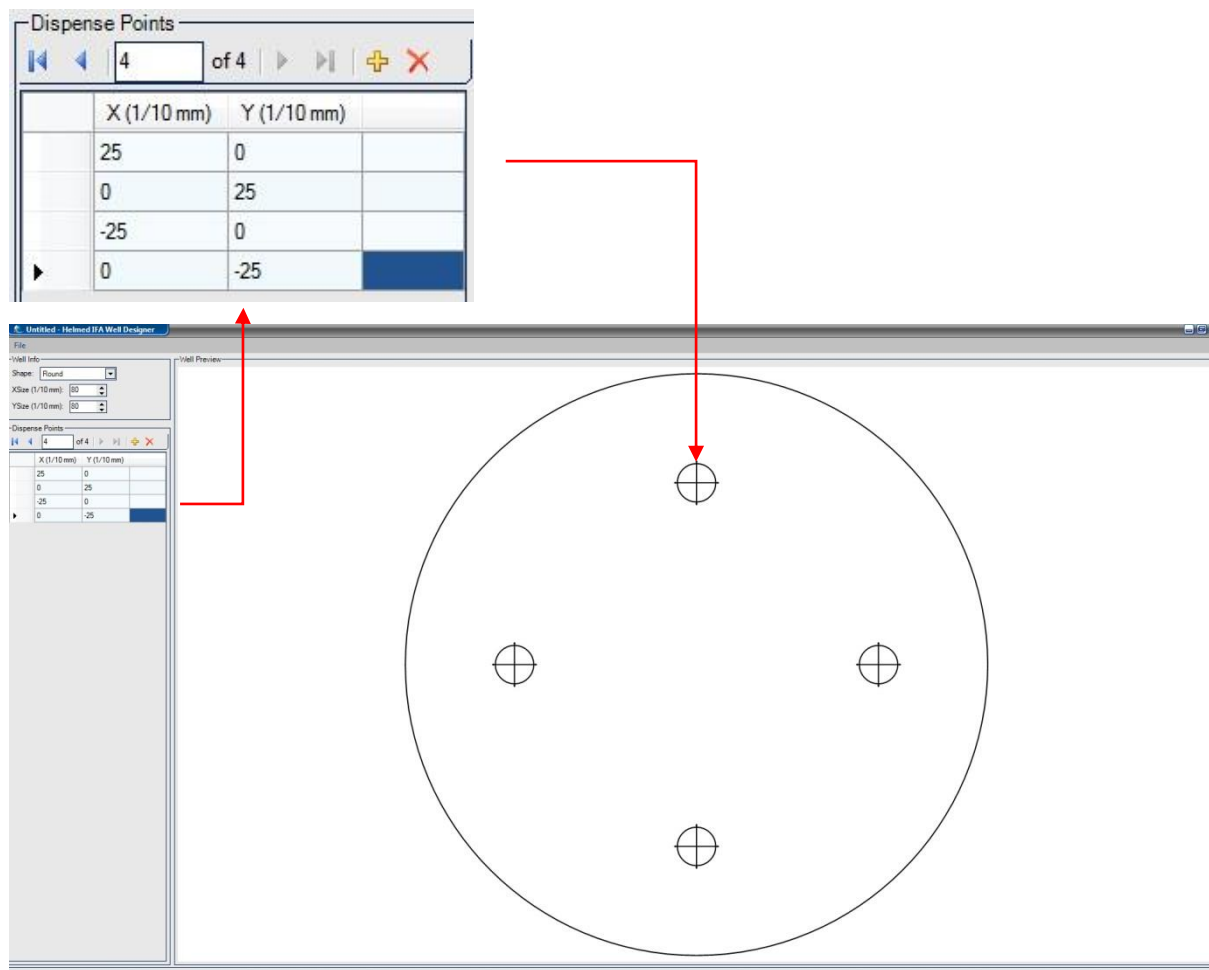


- For round wells, the diameter is measured from the center of the well.
- For rectangular wells, the width and height of the well is measured. All measurements are taken in millimeters. The result is multiplied by a factor ten (10) and in the respective X and Y coordinate fields (X and Y coordinates must be the same for round wells).

Create and manage dispensing points

Up to a maximum of 5 dispensing points can be defined in this module (recommended for larger wells).

To add a dispensing point, click the **+** button. The dispensing point within the well can be moved by entering X and Y coordinates. Dispensing points can also be deleted again by pressing the **x** button.



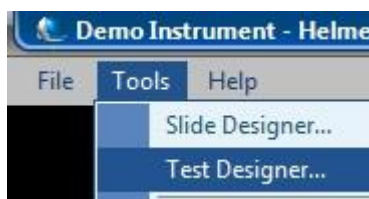
14.2 Test Designer

The **Test Designer** is used to create a new test or to change settings of an existing test, if required. Refer to section 14.1 for details on creating a new slide.

Note: All **AESKUSLIDES™** types are predefined and should not be edited.

The **Test Designer** has the flexibility to program most IFA assays. The parameters of these assays should be based on the instructions for use (IFU) contained within the kit.

Note: Each test should have at least one control defined to be placed in the reagent rack. It is the responsibility of the user to make proper adjustments and validate the test before use.



Select the **Tools** tab at the top of the **HELMED® IFA** main screen and choose **Test Designer** from the drop down menu to open the **Test Designer** screen.



Note: This function is password protected. Please contact your local distributor for any further information.

There are two options along the top of the screen:



- **Test:** Contains options for creating a new test or to open an existing test.



- **Tools:** Contains the module of the **Control Designer** for creating a new control or to open an existing control.

14.2.1 Settings for Test Info

The screenshot shows the 'Untitled - Helmed IFA Test Designer' application window. The 'Test Info' tab is selected. The settings are as follows:

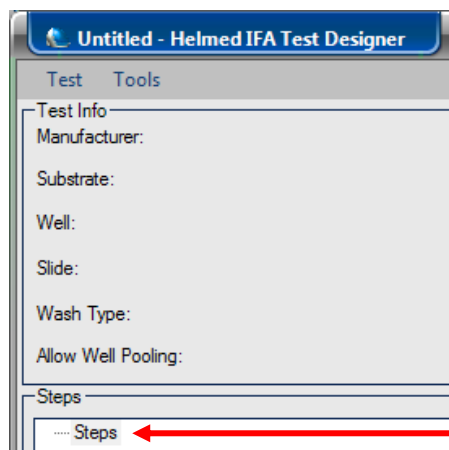
Field	Value
Manufacturer:	AESKU.DIAGNOSTICS
Substrate:	ANAHEp2 (Imported from AESKU Helios ANAHEp2_12w_51_100_v1.helios)
Well:	Round.50x50
Slide:	No Preference
Wash Type:	General Purpose Wash Solution
Allow Well Pooling:	☐
Test Run Temperature (°C):	25

Note: The **Test Designer** main screen will open with default settings for **Test Info**. These settings must be changed before starting with the **Steps** selection.

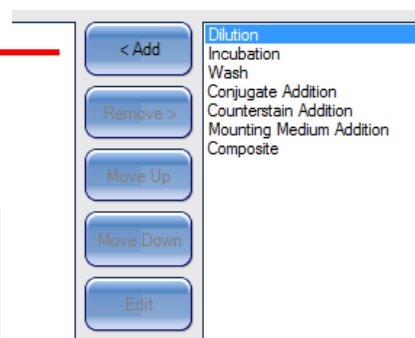
Select a manufacturer, substrate, well, slide and wash type suitable for the selected test from the dropdown menus:

- **Manufacturer:** Select a manufacturer from the dropdown menu. A manufacturer's name can be added by a right mouse click on the arrow. A new window will open. Press the **+** button to get a new line for entering the name of an additional manufacture. To remove or delete a manufacturer again, select the manufacturer with a mouse click and press the **X** button.
- **Substrate:** Select a substrate from the dropdown menu. Substrates are defined in the **Slide Designer**. For further information, refer to the section **Well Info**.
- **Well:** Select a well type from the dropdown menu. Wells are defined in the **Well Designer**. For further information, refer to section 14.1.2 **Well Designer**.
- **Slide:** Select a slide type from the dropdown menu. Slides are defined in the **Slide Designer**.
- **Wash Type:** Select a wash type from the dropdown menu. Wash types can be added by a right mouse click on the dropdown button. A new window will open. Press the **+** button to get a new line for entering an additional wash buffer. To delete a wash buffer from the list, select the one to delete with a mouse click and press the **X** button.
- **Allow Well Pooling:** Activating this function enables the use of different conjugates on the same well. The box must be checked to activate this function.

14.2.2 Settings for steps



Select the steps from the list on the right of the screen that should be processed in a test. Seven options are available: Dilution, Incubation, Wash, Conjugate Addition, Counterstain Addition, Mounting Medium Addition and Composite. The steps to process the slides must be defined.



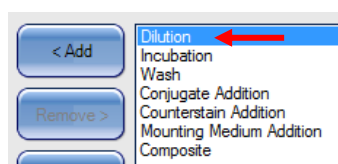
Note: All process steps will open with default settings. These settings must be changed according to the respective IFU. Process steps for **AESKUSLIDES™** are predefined and should not be edited.

The following instructions for creating test steps are only an example and refer to the instruction manual of the **AESKUSLIDES™** IFA kit.

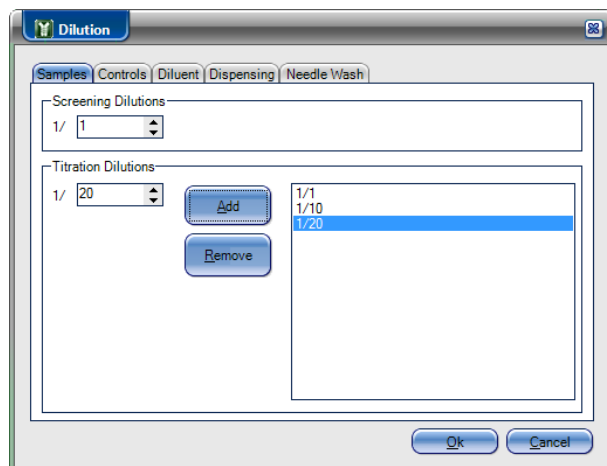
How to select and set up specific test steps will be described step by step in the following sections:

Step 1

Dilution step



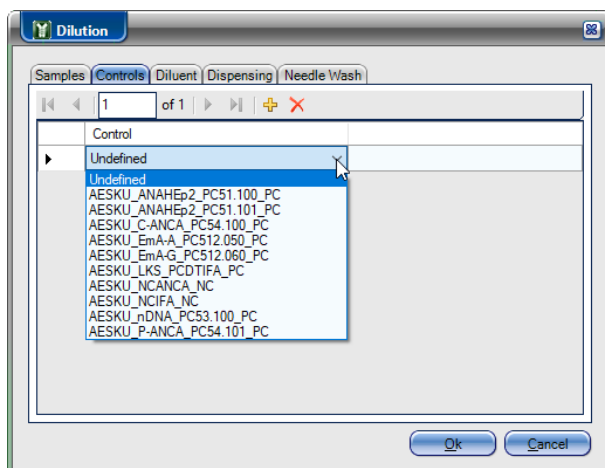
Select **Dilution** on the right side of the screen (double-click or clicking the **< Add** button). A new window will open to define sample dilutions, controls, diluent, dispensing (transfer to the slide) and additional needle wash.



Define the sample dilutions for screening and titration.

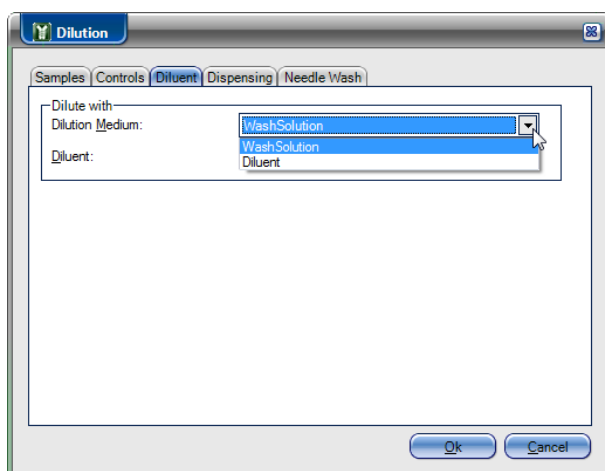
The dilution set up for **Screening Dilutions** will be used for all patient samples run in **Screening Mode**.

Titration Dilutions of interest for patient samples can be defined and added by clicking the **Add** button.



Select the controls:

Controls can be added to the test by clicking the **+** button. Controls can be selected from the dropdown list which contains all predefined or user defined controls.



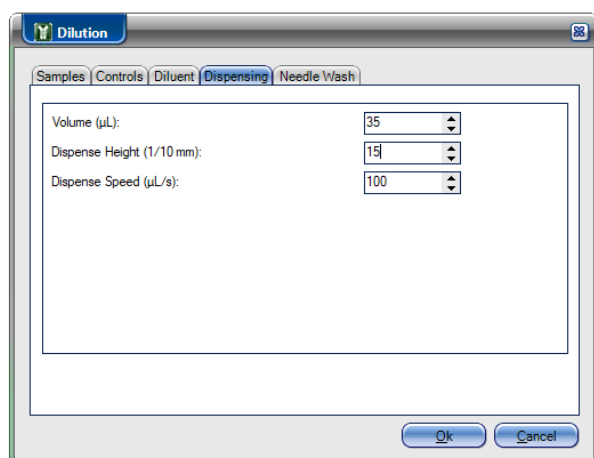
Select the diluent:

Here it can be selected if the patient samples should be diluted using **Wash Solution** or **Diluent** solution.

If **Wash Solution** is selected, the bottle connected to **Wash Line 1** will be used to dilute patient samples.

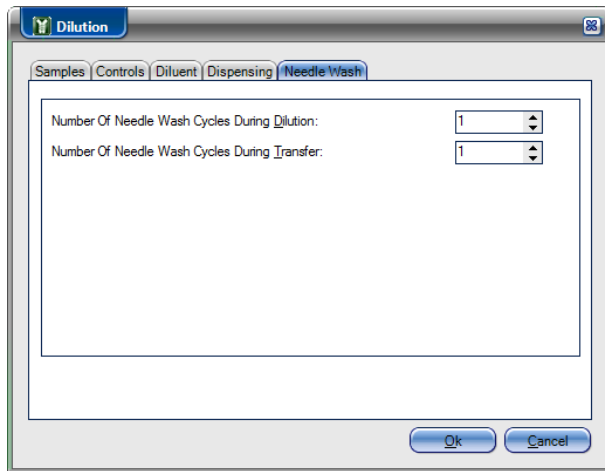
Selecting **Diluent** will use the 100 ml bottle placed into the reagent rack on position 14.

The respective diluent can be selected from the drop-down menu. New diluents can be added by right-clicking on the drop-down button.



Define the dispensing for slide transfer:

Volume, **Dispense Height** and **Dispense Speed** for patient samples and controls is defined here. The volume needed to cover the entire well depends on the well size (e.g. Round 50x50 = 35µl; Round 80x80 = 70µl). The **Dispense Height** is the height distance between the needle and the slide when dispensing fluid. The **Dispense Speed** is the amount of volume dispensed in seconds. The Dispense Speed should not be below 100µl/s.

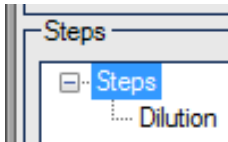
**Needle Wash:****Number of needle wash cycles during dilution:**

The needle wash cycles in between each patient sample can be increased up to 10 cycles when creating dilutions in the MTP.

Number of needle wash cycles during transfer:

The needle wash cycles in between each patient sample can be increased up to 10 cycles during the transfer to the slide.

The default value for both is 1 cycle.

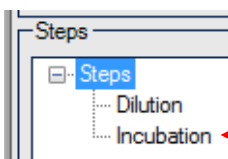
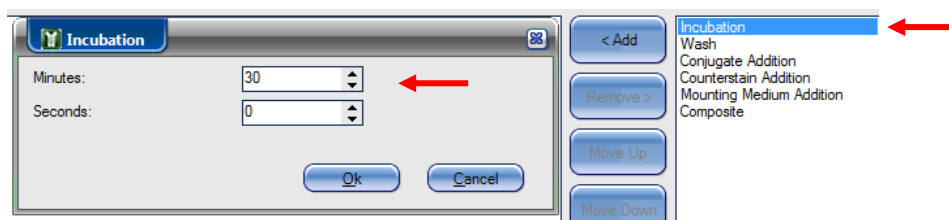


After defining all the settings, press **Ok**. The first test step **Dilution** appears in **Steps** listed on the left side of the screen.

Step 2**Incubation step**

Select **Incubation** on the right side of the screen and click the **< Add** button (or double-click on **Incubation**). A new window will open to define the incubation time for the first incubation step. Enter an incubation time and click **Ok**.

Note: Do NOT confirm by pressing the “Enter” key. Pressing the “Enter” key will not save the set up value.

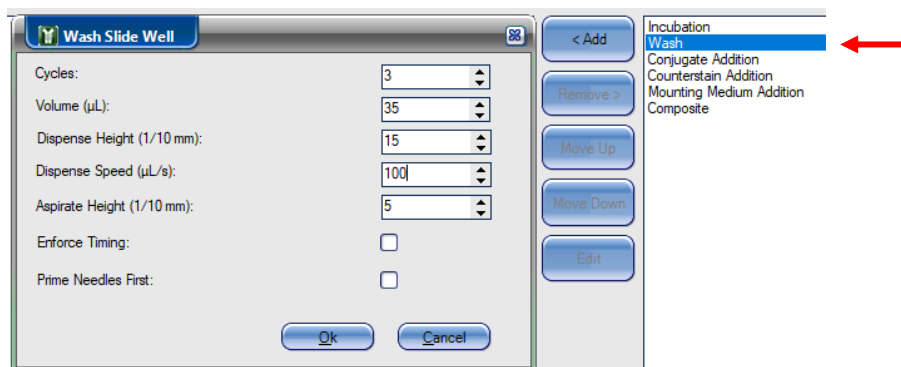


The **Incubation** step now appears on the list of **Steps** on the left side of the screen.

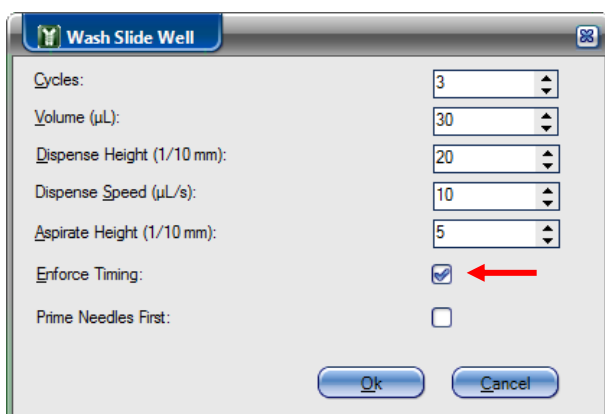
Step 3

Wash step

Select **Wash** on the right side of the screen and click the **< Add** button (or double-click **Wash**). Enter the number of required wash cycles. The settings for **Volume**, **Dispense Height**, **Dispense Speed** and **Aspirate Height** must be verified and validated by the user.

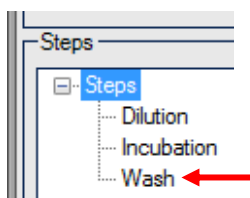


The **Volume** needed to cover the entire well depends on the size of the well. The **Aspiration / Dispense Height** is the distance between the needle and the slide when aspirating / dispensing fluid. The **Dispense Speed** is the amount of volume dispensed in seconds. The **Dispense Speed** should not be below 100µl/s.

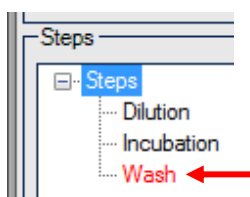


If the option **Enforce Timing** is activated, the incubation time of the step prior to washing will then be strictly adhered to.

After entering the settings, press **Ok**.



The **Wash** step now appears on the list of **Steps** on the left side of the screen.

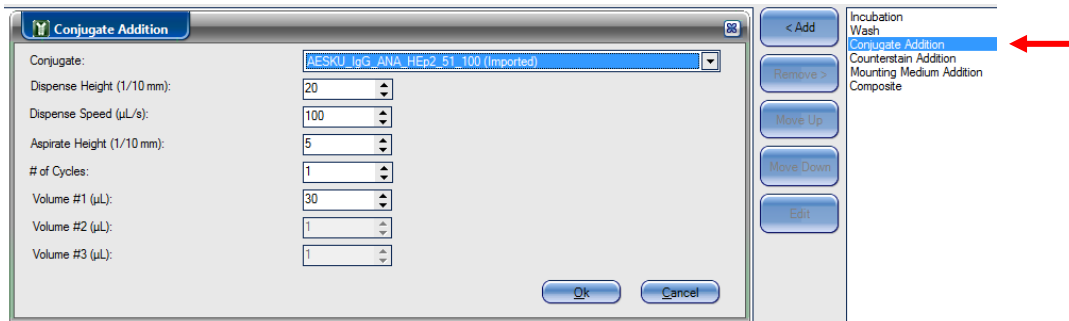


If **Enforce Timing** is activated for the incubation time, the **Wash** step is highlighted in red.

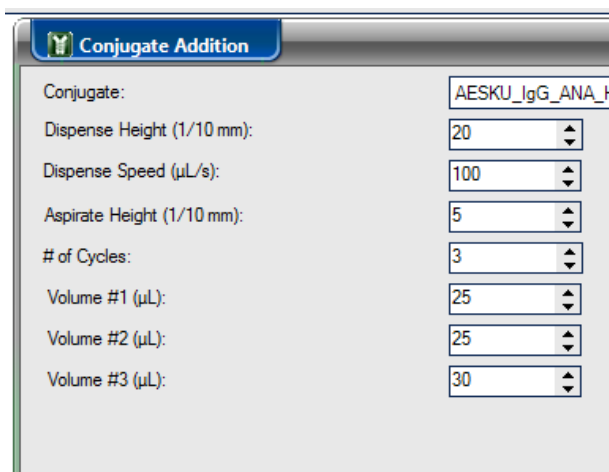
Step 4

Conjugate step

Select **Conjugate Addition** from the right side of the screen (double-click or **< Add** button). Select a conjugate from the dropdown list in the **Conjugate** line.

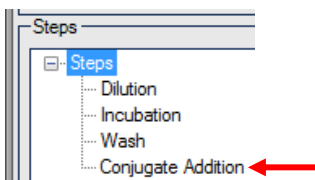


The list of conjugates can be edited by a right mouse click on the dropdown arrow. A new window will open. New conjugates can be added by clicking the **+** button to get a new line for the entry of a new or additional conjugate. Define the settings for **Conjugate Addition**, **Dispense Height**, **Dispense Speed** and **Aspirate Height**. These settings must be verified and validated.



If it is necessary to first wash the wells with conjugate, the number of cycles must be defined then. Up to three cycles are possible. Set the volume needed to cover the entire well for every cycle. If there is no need for more than one cycle of **Conjugate Addition**, then only enter the volume in [µl] needed for **Volume #1**.

After these settings are done, press **Ok**.

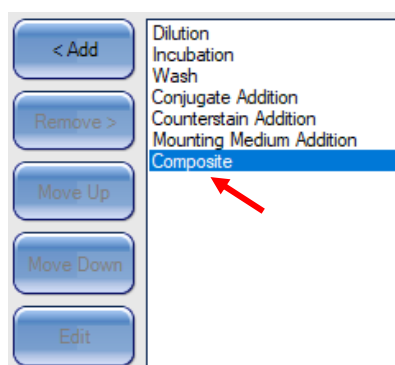


The **Conjugate Addition** step now appears on the list of **Steps** on the left side of the screen.

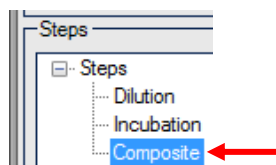
Step 3 and **Step 4** can be combined in a **Composite** step. The function of this step is to immediately add conjugate to each well after it is washed.

How to use and setup a composite step for a test will be explained in the following section.

Composite step

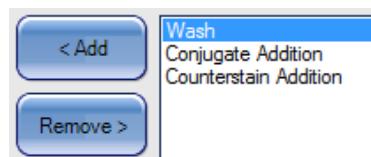


Select **Composite** on the right side of the screen and click the **< Add** button (or double-click).

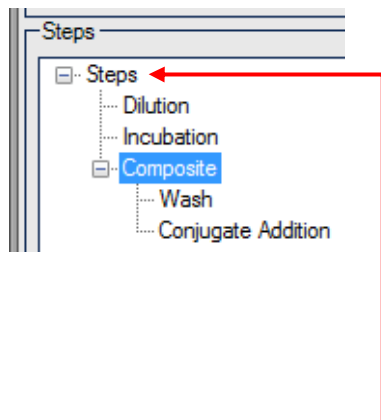


Composite step now appears on the list of **Steps**. When the **Composite** step is marked on the left side, three different steps will now become available on the right of the screen:

- Wash
- Conjugate Addition
- Counterstain Addition



Select Wash for Composite step

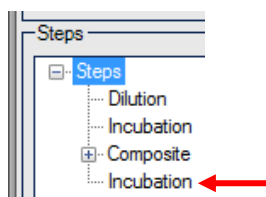


To setup a **Wash** step for composite steps, please follow and repeat the instructions in **Step 3**. The **Wash** step now appears as an own particularly sidestep of **Composite** on the left of the screen. Then select **Conjugate Addition** and follow the instructions in **Step 4**. **Conjugate Addition** now appears as well as an own particularly sidestep of **Composite** on the left side of the screen. To continue defining main steps, click once on **Steps** on top of the left **Steps** screen box.

Step 5

Conjugate Incubation

Select **Incubation** on the right side of the screen (double-click or **< Add** button) and define the incubation time needed for conjugate. Then press the **Ok** button.

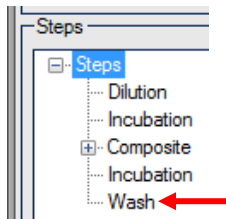


Incubation step now appears on the list of **Steps** on the left side of the screen.

Step 6

Wash step after Conjugate Incubation

Select **Wash** from the right side of the screen (double-click or < **Add** button). Define the number of wash cycles per well. Settings such as **Volume**, **Dispense Height**, **Dispense Speed**, **Aspirate Height** must be verified and validated. The volume needed to cover the entire well depends on the size of the well. The **Aspiration / Dispense Height** is the distance between the needle and the slide when aspiration / dispensing fluid. The **Dispense Speed** is the amount of volume dispensed in seconds. The **Dispense Speed** should not be below 100µl/s. If the option **Enforce Timing** is selected, then the incubation time of the step before the washing step will be strictly adhered to.



After entering these settings, press **Ok**.

The **Wash** step now appears on the list of **Steps** on the left side of the screen.

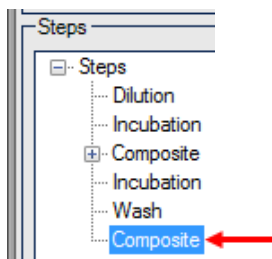
If **Enforce Timing** has been selected, the incubation time will be strictly adhered to and the respective **Wash** step will be highlighted in red.

Step 7

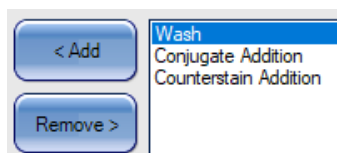
Counterstain step

As an optional step for IFA processing, you may select **Counterstain Addition** on the right of the screen (double-click or < **Add** button). Define the volume needed to cover the entire well. The **Aspiration / Dispense Height** is the distance between the needle and the slide when aspiration / dispensing fluid. The **Dispense Speed** is the amount of volume dispensed in seconds. The **Dispense Speed** should not be below 100µl/s. Settings, such as **Volume**, **Dispense Height**, **Dispense Speed** and **Aspirate Height** must be verified and validated.

Step 6 and **Step 7** can be combined in a **Composite** step. The function of this step is to immediately add counterstain to each well after it is washed.

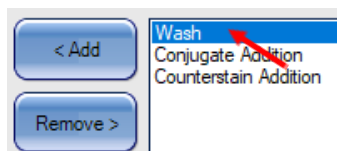


Select **Composite** on the right side of the screen and press the < **Add** button (or double-click). **Composite** now appears in the list of **Steps** on the left side of the screen.

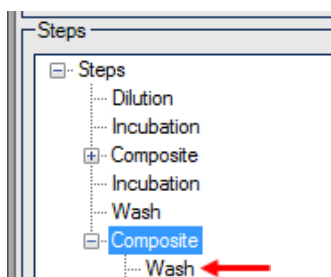


On the right side of the screen, there are now three different steps available:

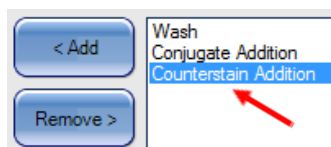
- Wash
- Conjugate Addition
- Counterstain Addition



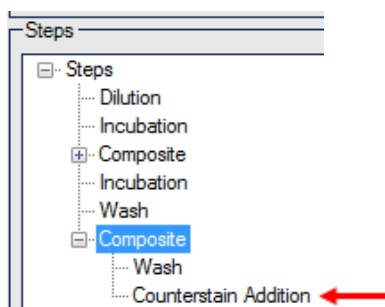
Select **Wash** as part of the **Composite** step and follow the instructions in **Step 3 / 6**.



Wash step now appears as a sidestep of the **Composite** step in the main list of **Steps** on the left side of the screen.



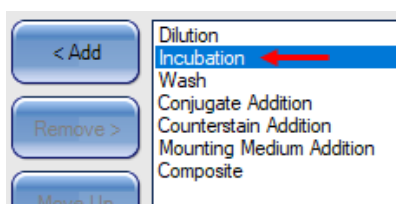
Now select **Counterstain Addition** and follow the instructions in **Step 7**.



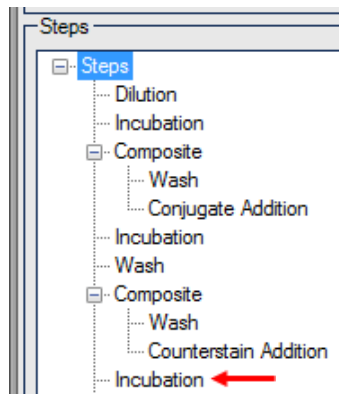
Counterstain Addition now appears as a sidestep of the **Composite** step in the main list of **Steps** on the left of the screen. To continue defining main steps, click once on **Step** on the left of the screen.

Step 8

Counterstain Incubation step



Select **Incubation** on the right of the screen (double-click or **< Add** button) and define the incubation time needed for counterstain. Then click **Ok**.

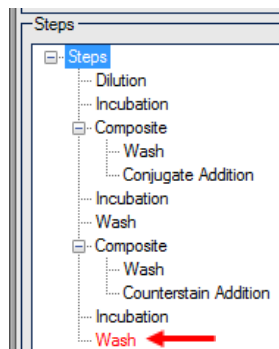


Incubation step now appears on the list of **Steps** on the left side of the screen.

Step 9

Wash step after Counterstain Incubation

Select **Wash** on the right side of the screen (double-click or < **Add** button). Define the number of wash cycles. Settings as **Volume**, **Dispense Height**, **Dispense Speed** and **Aspirate Height** must be verified and validated. The volume needed to cover the entire well depends on the size of the well. The **Aspiration** / **Dispense Height** is the distance between the needle and the slide when aspiration / dispensing fluid. The **Dispense Speed** is the amount of volume dispensed in seconds. The **Dispense Speed** should not be below 100µl/s.



It is recommended to select **Enforce Timing** for the **Counterstain Incubation**. If activated, the incubation time will be strictly adhered to and the respective **Wash** step will be highlighted in red.

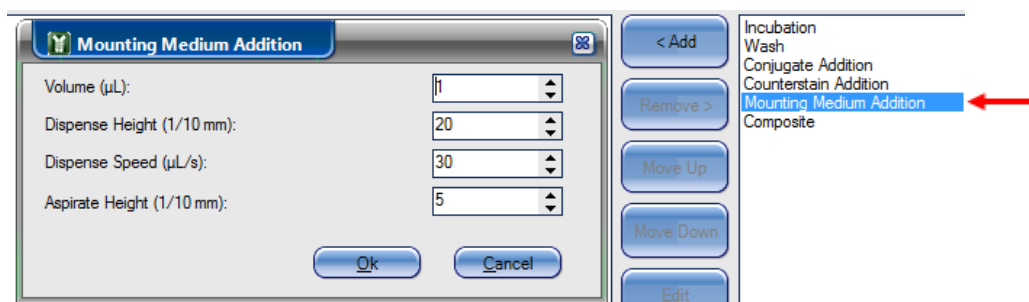
Then click **Ok**.

Wash step now appears on the main **Steps** list on the left side of the screen.

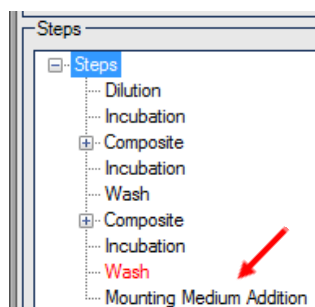
Step 10

Mounting Medium Addition step

Select **Mounting Medium Addition** on the right side of the screen (double-click or < **Add** button).



Define the settings of the **Mounting Medium Addition: Volume, Dispense Height, Dispense Speed** and **Aspirate Height**. These settings must be verified and validated. The volume needed to cover the entire well depends on the size of the well. The **Aspiration / Dispense Height** is the distance between the needle and the slide when aspiration / dispensing fluid. Please be aware that the **Dispense Speed** for **Mounting Medium** should be set to 300µl/s (max value) due to its higher viscosity. After defining those settings, press the **Ok** button.



The **Mounting Medium Addition** step now appears in the main list of **Steps** on the left of the screen.

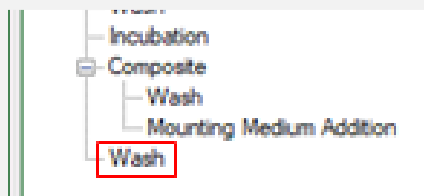
Step 9 and Step 10 can be combined in a **Composite** step. Its function is to immediately add mounting medium to each well after it is washed.

Note: Please be aware that the combination of the steps **Mounting Medium Addition** and **Composite** is only working for the **HELIOS® IFA** module (green IFA).

➤ Select “Mounting Medium Addition” as “Composite” step (only green HELIOS® IFA module):

Add **Composite** step from the right side of the screen (double-click or < **Add** button). **Composite** appears under **Steps** on the left side of the screen. On the right side of the screen, there are now four different steps available: **Wash**, **Conjugate Addition**, **Counterstain Addition** and **Mounting Medium Addition**. Select **Wash** step first and follow the instructions in step 6. Afterwards, add the **Mounting Medium Addition** and follow the instructions as described in step 10.

The following **Wash** step is used for mounting medium aspiration, therefore the aspiration height is critical here. Volume, Speed and dispense height are default settings.



Please be aware that the aspiration of mounting medium is only applied to **AESKUSLIDES™**. Its purpose is to create a flat and even surface for the Image Capturing process, so aspiration height is critical value here.

Step 11

Saving a programmed test as a test file

Once all the single steps for a test are defined, the test must be saved. Follow these steps to save a programmed test as a specific test file:

1. Select the **Test** tab from the **Test Designer** screen.
2. Select **Save / Save as** from the context menu.
3. Enter a name for the test file and click on the Save button. The test will be saved in the appropriate folder in the **HELMED® IFA** software.

14.2.3 Control Designer

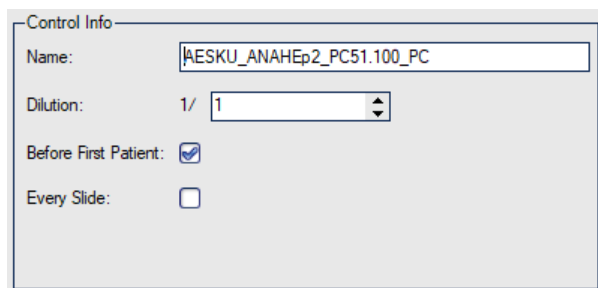


There are five options listed in the **Control Designer** menu.



- **New:** To create a new control.
- **Open:** To open an existing control.
- **Save:** To quickly save a programmed control.
- **Save as:** To save a programmed control as a named control.
- **Close:** To close the **Control Designer**.

Define the Controls:



Edit the name of the control. Select a dilution if needed (default setting 1/1 for ready-to-use controls). It is possible to choose whether the control is placed on every slide or only before the first patient by marking the respective box.

If a new control has been defined, click **Save** to enter a name for the control. If an existing control has been modified, the changes will be saved by clicking the **Save** button.

15 Maintenance

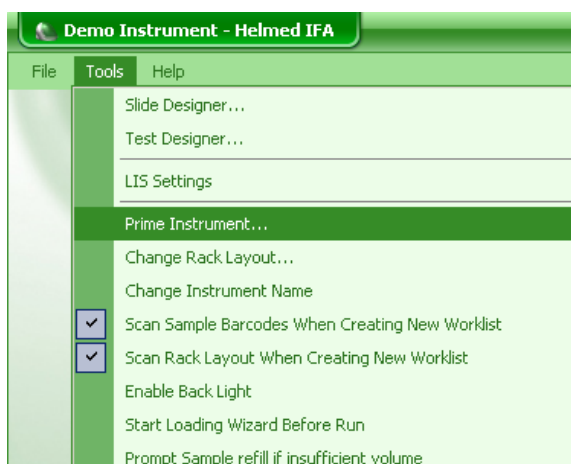
Regular maintenance is important for the proper operation and functionality of the device. The following procedures are recommended by Aesku.Diagnostics GmbH & Co. KG:

15.1 Daily maintenance

The device needs to be flushed with distilled water to keep the tubing in prime condition and to prevent any remaining residue in the needles or tubing. Therefore, replace the wash buffer with distilled water.

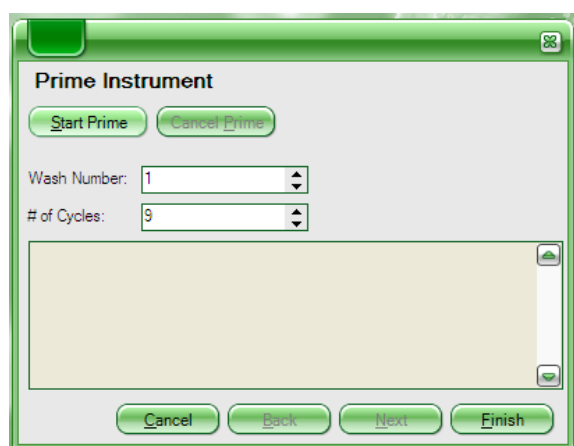
Replacing wash buffer with distilled water:

Empty wash bottle #1, rinse the bottle with distilled water and fill the bottle with approximately 100ml of distilled water. Alternatively, remove the quick connector from wash bottle #1 and attach to wash bottle #2 containing distilled water by using the quick connector.



Priming the instrument:

Select **Tools** from the IFA main screen. Afterwards select **Prime instrument**.



Select bottle number and number of cycles. It is recommended to flush the device with distilled water 1-3 times with 9 cycles each.

Spoiler foam:

Please check visually the foam status that seals the blue cover (REF#20160010 – SPOILER FOAM FOR HTC 5 PCS). If the foam was in contact with hazardous material, replace it immediately for your safety.

15.2 Weekly maintenance

Flush the device once per week with 0.3% sodium hypochlorite solution (NaOCl), alternatively 70% ethanol. Follow the instructions from section 15.1 to flush the instrument. Allow at least 15 minutes of incubation time. After that, flush the device with distilled water at least 3 times using 9 cycles each.

Caution:

Risk of irritation when handling sodium hypochlorite (NaOCl)!

Note: The device must be flushed with distilled water after it was primed with sodium hypochlorite solution (NaOCl). The decontamination solution may not contain any cleaning detergents as they are very persistent and may potentially negatively influence the filling level detection of the needles.

Surface disinfection: It is recommended to disinfect the surfaces and racks to be free of blood stains and dust.

15.3 Cleaning of the device

The surfaces and the accessible parts of the unit should be cleaned with 70% ethanol. To prevent contact with skin or eyes, use personal protective equipment, such as lab coats, gloves, and goggles. The racks and the middle ring (slide holder ring) may be removed for cleaning and disinfection, if necessary. It is recommended to clean the surfaces regularly. Only use cleaning reagents (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.

15.4 Disinfection of the device

The surfaces and the accessible parts of the equipment should be disinfected with 70% ethanol, if necessary. Do not use any pump sprayer or evaporators due to flammable vapors. To prevent contact with skin or eyes, use personal protective equipment, such as lab coats, gloves, and goggles. The racks and the middle ring (slide holder ring) may be removed for cleaning and disinfection, if necessary. It is recommended to disinfect the surfaces and especially the racks regularly. Only use cleaning reagents (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.

15.5 Periodic Preventive Maintenance Service

Periodic preventive maintenance should be carried out by your service provider at a minimum frequency of once per year.

Laboratories should open their annual workload requirements in terms of slide/well consumption (including any non-AESKU slides being processed) to their service provider to allow the appropriate maintenance frequency to be determined.

15.6 Taking the device out of service

The device must be flushed in accordance with section 15.1 before decommissioning. Drain the wash bottles and rinse them with distilled water. Then drain the waste container, rinse, and disinfect it. The device must be cleaned (Section 15.3) and disinfected (Section 15.4). The unit must be stored in a dry place under storage conditions (Section 3.3 General and technical information).

15.7 Disposal

Before the proper disposal or shipment of the device, make sure that the device is cleaned and disinfected in accordance with section 15.6.

The device must be disposed properly after end of use and according to national legal requirements. There is also the possibility that the customer returns the device to the manufacturer for disposal.



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.

For manufacturer contact details, refer to last page of the manual.

15.8 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, lock-ups, container breakage and similar malfunctions of any consumables, please clean and disinfect the affected area and 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 reagents (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 advise or replacement of broken material please contact your local distributor or Aesku Customer Support Team.

15.9 Maintenance and cleaning of HTC accessories for HELIOS devices

15.9.1 Spiral Hose Humidifier



Spiral hose (tubing) for connecting the humidifier with the HELIOS (Ref # 20160307)

CAUTION:

Make sure that the cuffs are properly fixed to the device's connectors. The tube should be attached and detached by handling only the cuffs. Do not pull or twist the tubing.



The following liquids are **not allowed** to be used in combination with the tube:

- Hypochlorite, Phenol (> 5%), Formaldehyde
- Ketone, chlorinated Hydrocarbone
- Aromatic Hydrocarbone, inorganic Acids

Limitation of reprocessing:

According to DGSV Classification of Medical Devices 2013 the tube is evaluated as Semi Critical B.

INSTRUCTIONS:

- **Cleaning and disinfection (manually):** For cleaning and disinfection of the tube use 70% ethanol to rinse and flush. Then, thoroughly rinse with distilled water and hang it up for drying. This procedure must be performed weekly.
- **Sterilization:** Autoclavable. Min. 132 °C/269.6 °F – max. 135 °C/275 °F for 15 minutes – 30 minutes drying
- **Inspection and functional check:** In case of fissures, holes or other damages, the tube must be replaced.
- **Compliance Standards** DIN EN ISO 5356; ISO 17664:2017; ISO 14937:2009; ISO 17665-1:2006
- **Waste disposal:** The local instructions must be followed.
- This product is CE marked according to the EC Directive 93/42 EEC for medical products and classified as class II a.

15.9.2 Humidifier

Weekly cleaning and disinfection is a requirement for fault-free and hygienic operation.

CAUTION:

Switch off the air humidifier each time before cleaning. Pull the plug out of the mains socket.

For cleaning of the external humidifier (Ref # 20160305), it needs to be removed out of the rack. To do so, just follow the six steps shown below and the instructions for cleaning the device.

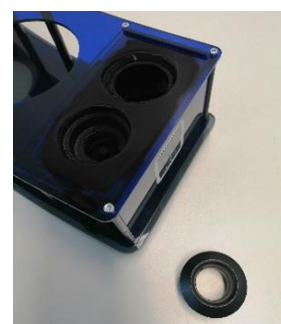
How to remove the humidifier out of the rack:



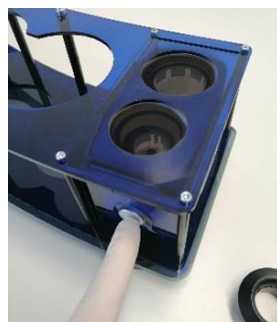
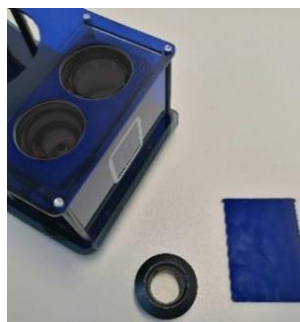
1. Unplug the 24V cable



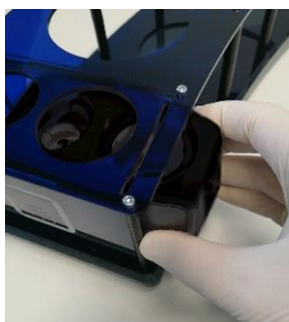
2. Remove the tubing adapter



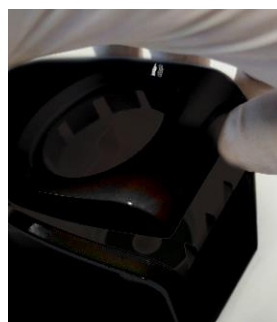
3. Remove the rack lid by pulling up



4. Push the humidifier out of the rack



5. Pull the humidifier out of the rack



6. Remove the lid from the humidifier for cleaning



CLEANING INSTRUCTIONS:

- Never submerge the base in water.
- Empty the water from the base unit via the side rim. Ensure no water gets inside the device, e.g. via the air outlet or the control dial.
- Completely clean the LDPE bottle 500ML (Ref # 20160312) and the air humidifier (use 70% ethanol) if the device has not been used for over three days.
- Clean the device using only the methods specified below.
- Do not use any solvent-based cleaning products.
- Clean all parts having contact to water on a weekly basis with 70% ethanol.
- Completely remove the reducing sleeve Humidifier (REF # 20160308), then remove the top in an upward direction.
- To avoid damaging the ultrasonic membrane, never scrape with sharp, hard objects. Rinse out the base if necessary.
- Wipe the interior of the base with a damp cloth with 70% ethanol. Rinse out the base, if necessary.
- Wipe the exterior housing of the base with a damp cloth with 70% ethanol.
- Clean all removable parts, such as the LDPE bottle 500ML (Ref # 20160312), bottle adapter, reducing sleeve Humidifier (REF # 20160308).
- Dry the parts with a soft cloth and only reassemble them when they are completely dry.

15.9.3 Nozzle

- Unscrew and remove the outer union nut from the nozzle.



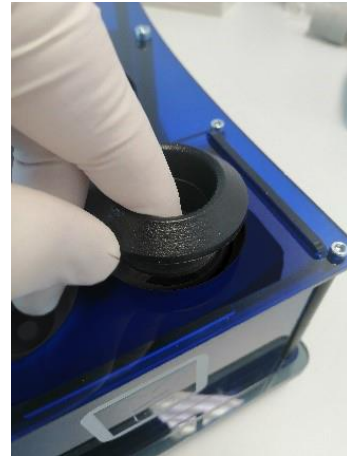
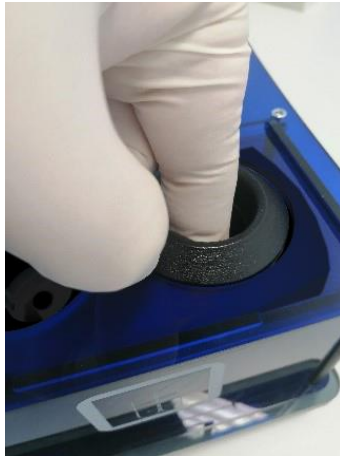
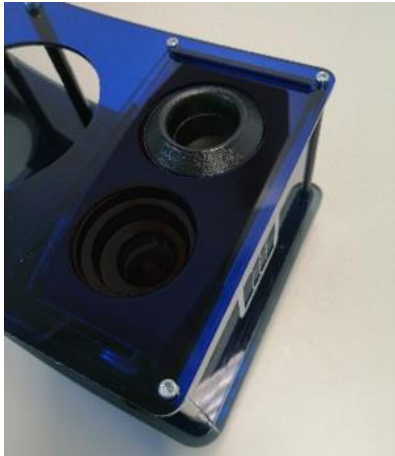
- Remove the nozzle by turning it 90 degrees downwards, pull back out of the housing and lift it up.



- Rinse or flush the nozzle with 70% ethanol and clean the surface to prevent any contaminations. Let it dry for several minutes before inserting the nozzle again. It is recommended to clean the nozzle weekly together with the other accessories according to their maintenance schedule.

15.9.4 Reducing sleeve Humidifier

- To remove the reducing sleeve Humidifier (REF # 20160308) from the top of the humidifier, just pull it upwards to take it out.



- For cleaning the reducing sleeve Humidifier (REF # 20160308) just wipe off the surface using 70% ethanol and let it dry for several minutes before inserting again.
- It is recommended to clean the reducing sleeve Humidifier weekly together with all the other accessories according to their maintenance schedule.

16 Regulatory symbols



In-vitro Diagnostic (IVD) use



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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