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HELMED®

INFECTIOUS SEROLOGY & AUTOIMMUNITY IN ONE SYSTEM

Automated IFA Processor

INSTRUCTIONS FOR USE

HELMED Instructions For Use SW4.0 EN for US / V005a: 2025-05-07 / SAP 20140098

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1 General Safety Information

1.1 General information

User qualification

The device may only be operated by well 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.

1.2 Symbols and warnings

The following symbols will be used throughout the text:

Warning notes

WARNING Caution! Biological hazard!

Avoid contact with biologically hazardous materials.

Hazard notes

HAZARD Skin irritation!

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

Advice

ADVICE Please wear gloves!

Immediately wash hands if the skin was exposed!

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 chapter 9.4.

Disposal of potentially hazardous material

For disposal of any consumables or broken material refer to chapter 9.7 and 9.88.

0.3% Sodium hypochlorit:

H314 Causes severe skin burns and eye damage.

70% Ethanol:

H319 Causes serious eye irritation.

H225 Highly flammable liquid and vapour.

1.5 Advice

Appropriate use

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

Only qualified personnel especially trained in *in-vitro* diagnostics may operate the device. It is the responsibility of the clinical doctor or head of laboratory to work according to GLP, RilLiBäk 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 **HELMED**® 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 9.8.

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 Introduction

2.1 Instrument

The **HELMED®** Automated IFA Processor is an automated device for the performing of immunofluorescence assays (IFA) under controlled conditions regarding the humidity and temperature. It is also possible to run assays with higher incubation temperature allowing to perform most common infectious serology IFA tests (IgM). The **HELMED®** system consists of the following: the **HELMED®** workstation with external **Humidity Temperature Control (HTC) Kit (REF.HTC-1001)** and an external PC for controlling the device (and an optional printer - not included). The **HELMED®** software contains predefined **AESKU IFA** test files, but as an open system, the **HELMED®** also allows the user to define slide types and test files for the performing of IFA kits from different manufacturers. Since the **HELMED®** is evaluated on **AESKU IFA** kits, AESKU.Diagnostics GmbH & Co.KG cannot take responsibility for processing IFA kits of other manufacturers. A fluorescence microscope with specific optical filter sets (not provided) is required to review and analyse the slides processed by the **HELMED®** workstation. Please refer to the respective **Instructions For Use (IFU)** supplied with the selected IVD kit.

2.2 Intended Purpose

The **HELMED® Automated IFA Processor** is an automated system for the processing of indirect immunofluorescence assays (IIFA) under controlled conditions in terms of relative humidity and temperature; intended as an aid for in-vitro diagnosis of autoimmune and infectious diseases. The manual evaluation of processed assays should be performed 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 of indirect immunofluorescence assays (IIFA) with the **HELMED® Automated IFA Processor**.

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.US (HELIOS®)** or **REF.HEL-1000.US (HELMED®).**

The **HTC** function offering a new range of infectious serology substrates for our 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.

3 HELMED® Installation

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

3.1 Installation requirements

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

- ✓ Set up the device on a flat, horizontal surface.
- ✓ 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 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 come in contact to 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

3.2 Scope of delivery and unboxing the device

The **HELMED® Automated IFA Processor** is shipped in suitable transport packaging. Upon receipt, please check for any visible damages caused by transport.

Two persons are required to remove the device out of the box, 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. Make sure that all the following items are present:

1x **HELMED®** device (REF.HEL-1000.US)

1x **HELMED®** device software 4.0 (REF.HEL-401) (pre-installed if ordered with additional PC)

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 Needle cleaning tool (Part# 20160044)

1x Calibration Container (Part# 20160043) (= HEL Starter Package 1)

1x Spoiler Foam (5 Pcs) (Part# 20160010)

1x Instructions For Use (IFU)

If ordered with PC (REF 20160559):

1x HELMED® ALL IN ONE PC / US WIN10/LTSC

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

1x LDPE bottle 0.5l (Humidifier) (Part# 20160312)

1x Humidifier (Beurer™ LB12) (Part# 20160305)

1x Spiral hose humidifier (autoclavable) (Part# 20160307)

1x Reducing sleeve (Humidifier tube adapter) (Part# 20160308)

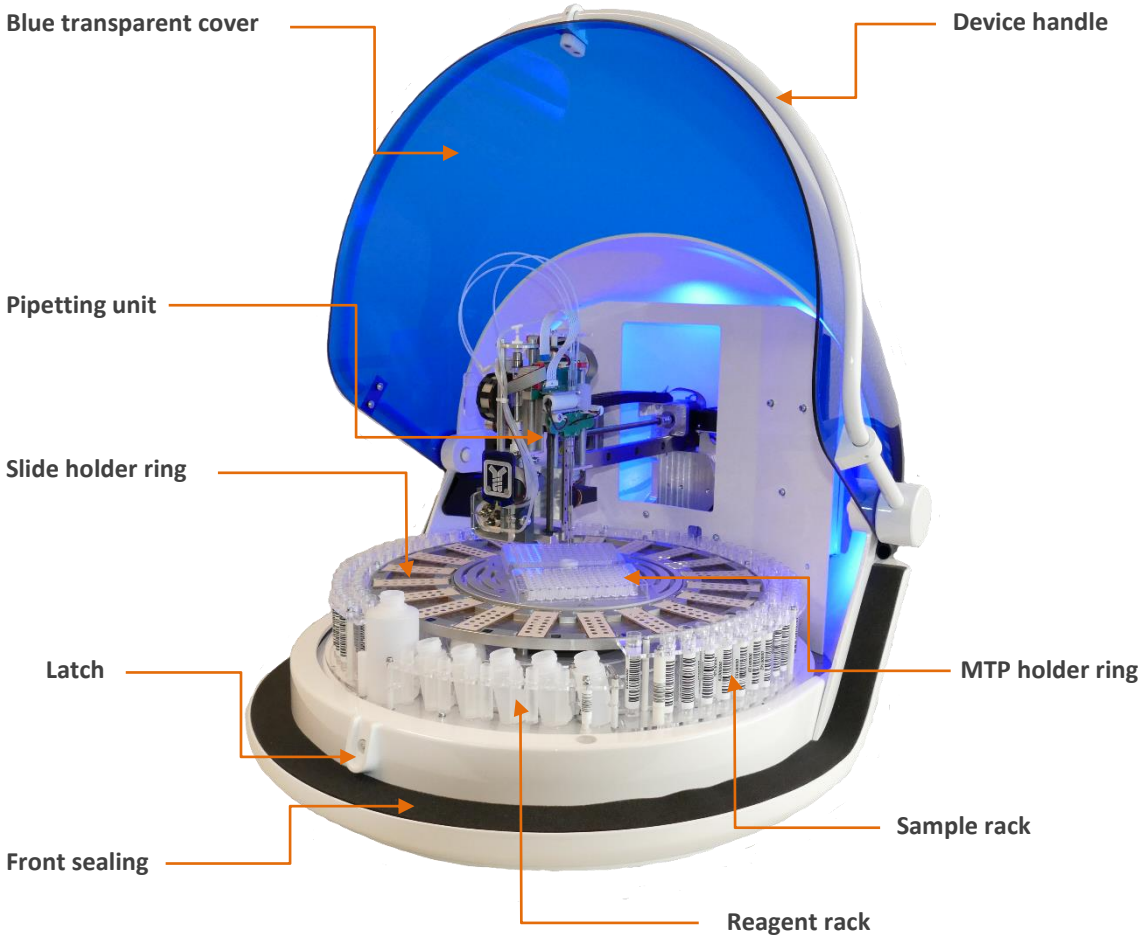
1x 24V power cable for humidifier (Part# 20160306)

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.

3.3 Description of HELMED® equipment and parts

3.3.1 Front view

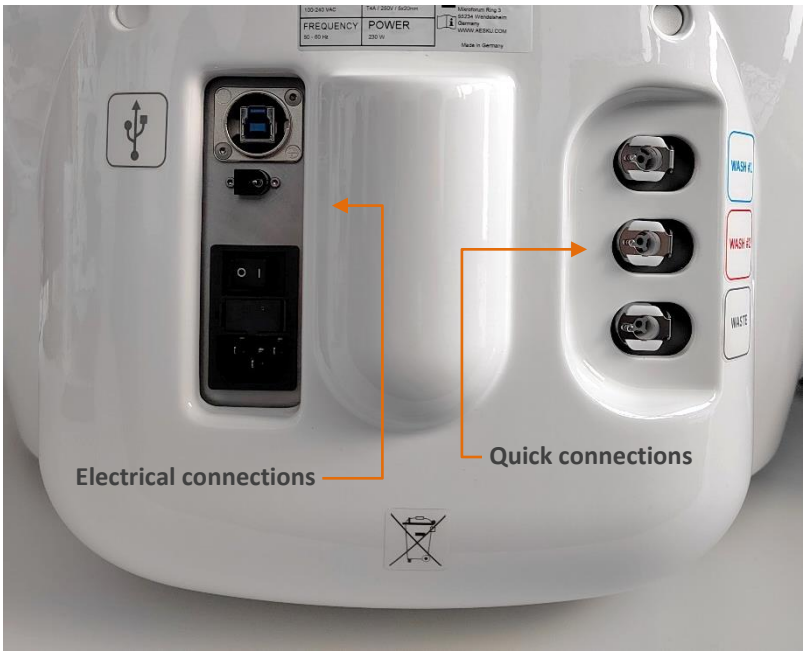


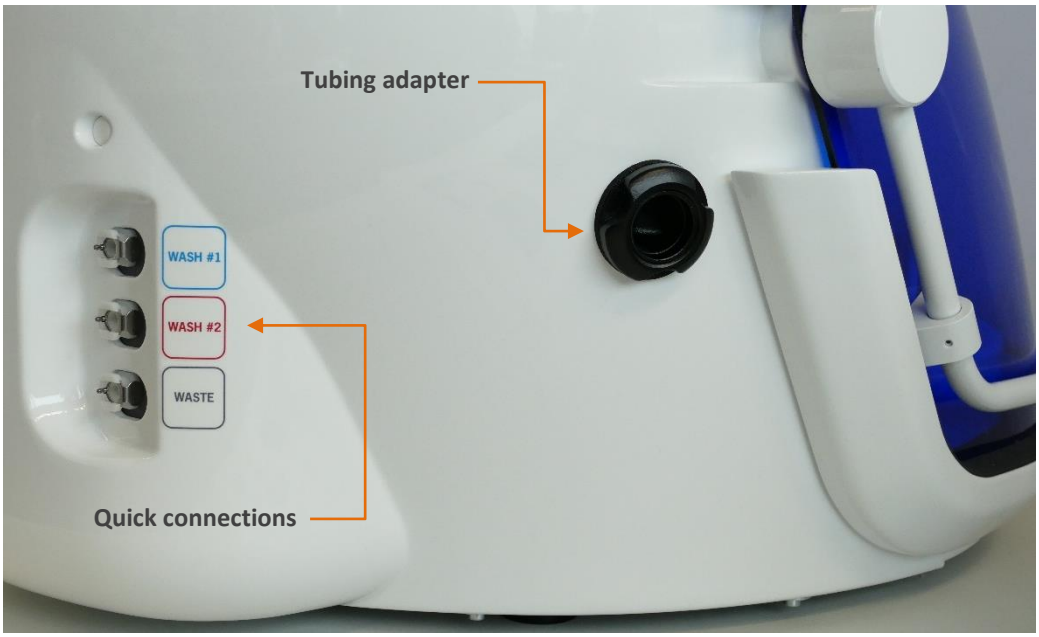
- **Blue transparent cover**: User can watch all processing steps.
- **Device handle**: To open and close the device.
- **MTP holder ring**: Prepare dilutions and transfer from micro titer plates to the slides.
- **Sample rack**: Rack for loading samples to be tested and processed.
- **Reagent rack**: Rack for loading the kit reagents.
- **Front sealing**: Seals the lid and the front panel cover to maintain stable conditions inside.
- **Latch**: Locks the cover automatically during the whole process.
- **Slide holder ring**: Positioning of slides for being processed.
- **Pipetting unit**: Automated processing and liquid handling of all samples and reagents

3.3.2 Side view

- **Top sealing**: Seals the upper lid and the back panel to maintain stable inner conditions.
- **Wash & Waste bottle set:** 2x 1L wash bottles for Wash 1 (Wash buffer) & Wash 2 (Aq. dest) and a 1 L waste bottle for liquid waste.
- **Front sealing**: Front spoiler with exchangeable foam inlay attached to the device for sealing of the lower front side of the lid.
- **Optional HTC accessory (REF.HTC-1001)**: External rack containing the humidifier, tubing adapter (reducing sleeve), CPAP tubing, power cable and 500 ml LDPE bottle. Bottles can be placed inside for safe and stable stand.

3.3.3 Back view

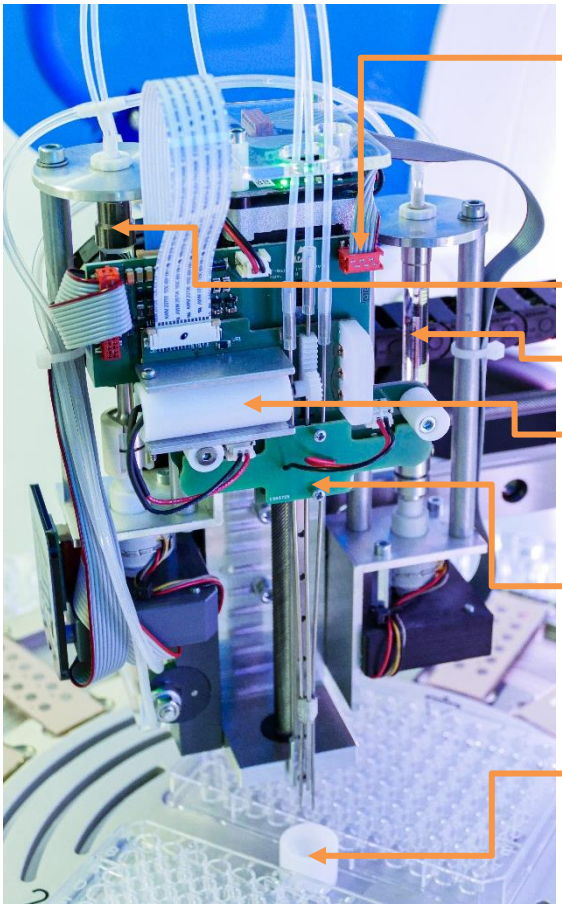




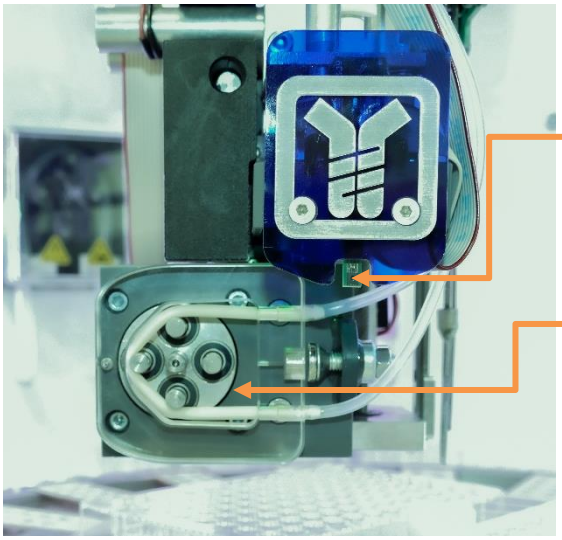
- **Electrical connections**: Power in and out connectors, USB interface, power switch and fuses (for detailed information see chapter 3.4.1)
- **Quick connections**: For connection of wash and waste bottles (for detailed information see chapter 3.4.2)
- **Tubing adapter**: To connect the CPAP tubing for humid air flow

3.3.4 Detailed view on HELMED® parts

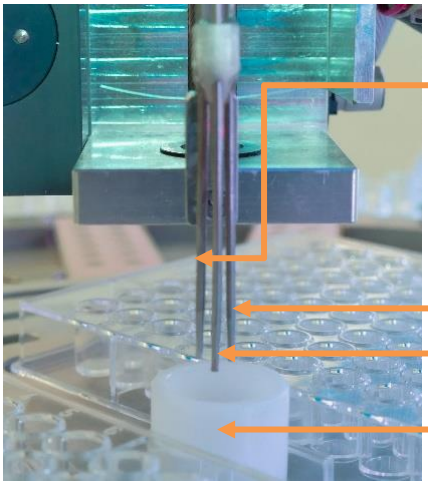
Pipetting unit side view



Pipetting unit front view



Needle assembly



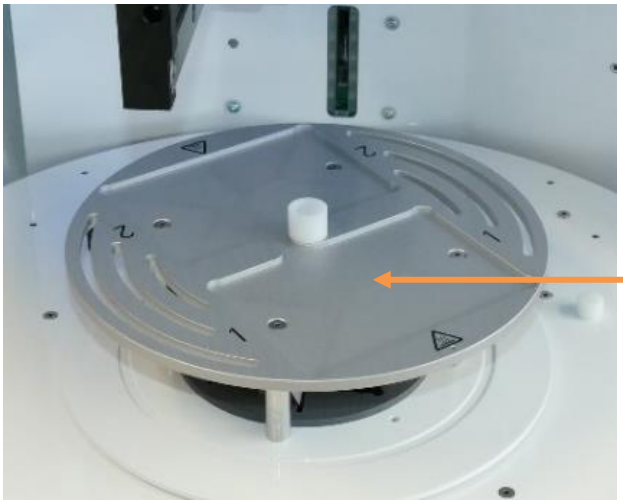
Dispensing needle (left)

Aspirating needle (right)

Third Needle (middle needle)

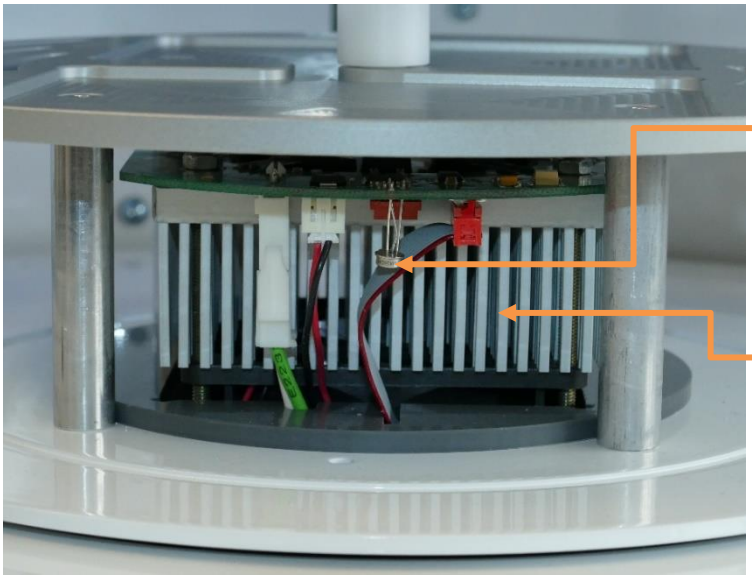
Wash cup

MTP Holder



MTP holder disc with ventilation holes

Incubator (Heating unit)



Heater temperature monitoring sensor

Heating unit with fan

Sample racks

A variety of sample racks can be used in conjunction with the **HELMED® Automated IFA Processor**. 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:

HELMED® 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

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**.

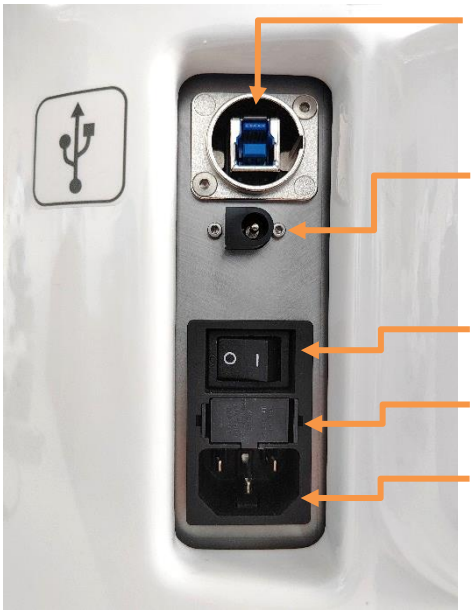
The **AESKU Mulit-Rack**, the best choice for using different sample tubes in one rack:

- 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 sample barcode reading process

3.4 Installing the HELMED®

First installation and setup should be performed by trained personnel only according to the instructions in the **Service Manual**.

3.4.1 Electrical connectors on the instrument



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 **HELMED®** instrument.

24V DC out: Use the provided cable and connect the humidifier inside the rack to the device by using the 24V DC jack located next to the USB plug.

Power switch: To turn on/off the device.

Fuse slot (see also chapter 1.5 for fuse details)

Main power inlet: The power inlet is located at the left backside of the instrument. The provided power cord must be connected here.

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

Standard	Voltage	$Current_{max}$	$Power_{max}$
USB 3.0/3.1 (Gen1)	5 V	0,9 A	4,5 W

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

3.4.2 Fluid connectors on the instrument

At the back of the device, three different quick connector clips for the wash and waste bottles can be found. The bottles and its related tubes are marked and color-coded to ensure connection of the bottles in correct order:

WASH #1 blue

WASH #2 red

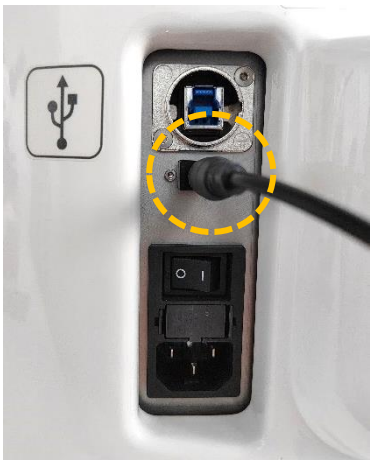
WASTE black

By default, the WASH #1 should be filled with the wash buffer solution (PBS) and WASH #2 with distilled water.

3.4.3 Connecting the external HTC accessories (REF.HTC-1001 optional available)

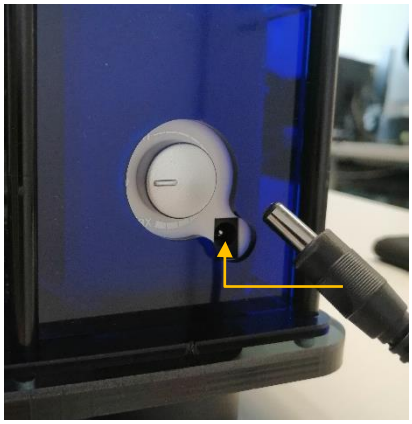
Connecting the power cable to the device and the external humidifier

- Plug in the 24V DC cable into the 24V DC 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 **HELMED** device with 24V / 500mA.

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

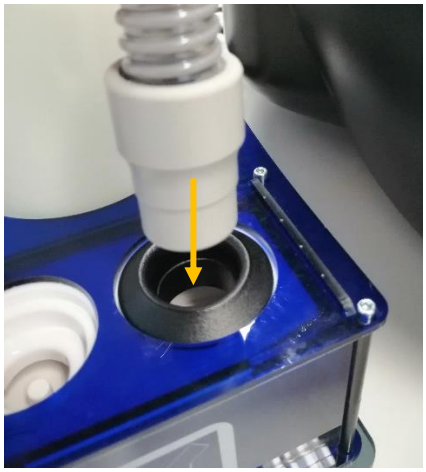



Note: The external humidifier must be powered on once manually by using the main power switch and turn it to the maximum position (recommend for all processing options).

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 and rotate left while pushing in:


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




Connecting the bottle (500 ml) 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 upside down onto the humidifier:


4 Helmed® Software

4.1 Installing the HELMED® device software package

In case the **HELMED®** device was ordered without PC, the software package can be downloaded following the instructions announced in the respective **TSB** introducing the new **software package 4.0** for **HELMED®** devices.

Note: The **HELMED®** software package will be pre-installed when the device was ordered with the PC provided by Aesku.Diagnostics GmbH & Co. KG:

- **20160559 HELMED ALL IN ONE PC / US WIN10/LTSC**

The **HELMED®** software package contains the latest versions of:

- **HELMED® 4.0 setup file**
- **HELMED® IFA setup file**
- **HELMED® test files**
- **HELMED® 4.0 Manuals (pdf)**

For proper installation and performance of the **HELMED®** software package on a PC not provided by Aesku.Diagnostics GmbH & Co. KG, the following minimum hardware specifications for PC are recommend:

- **Intel® Core™ i3-9100 processor or higher**
- **256 GB disc space or higher**
- **8 GB RAM**
- **1080p (Full HD) resolution display (1920x1080)**
- **Microsoft® Windows 10 (32/64-Bit)**

Note: Windows 10 Professional was not part of the **HELMED®** device software package 4.0 validation due to the frequent content updates provided by Microsoft. For this reason, **Windows 10 LTSC** version was chosen since only security updates are applied and installed. Thus, using Windows 10 Professional can lead to an unexpected software/hardware behavior and therefore, its usage is at your own responsibility. Aesku.Diagnostics GmbH & Co. KG recommends using **Windows 10 LTSC** as an Operating System (OS).

After the software package has been downloaded to the PC, please follow the instructions below for the installation of the **software package 4.0** for **HELMED®** devices. The **HELMED®** device should be powered on and connected with the PC via the provided USB cable after the software has been successfully installed.

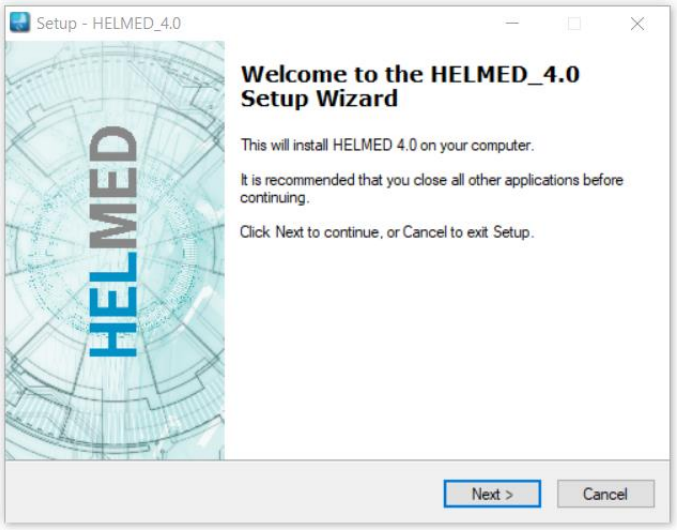
Note: Strictly keep the following order for the installation to ensure the software is working correctly.

4.1.1 Installation of HELMED® 4.0

Before installing the **HELMED® IFA** software, the **HELMED® 4.0** software must be installed first.

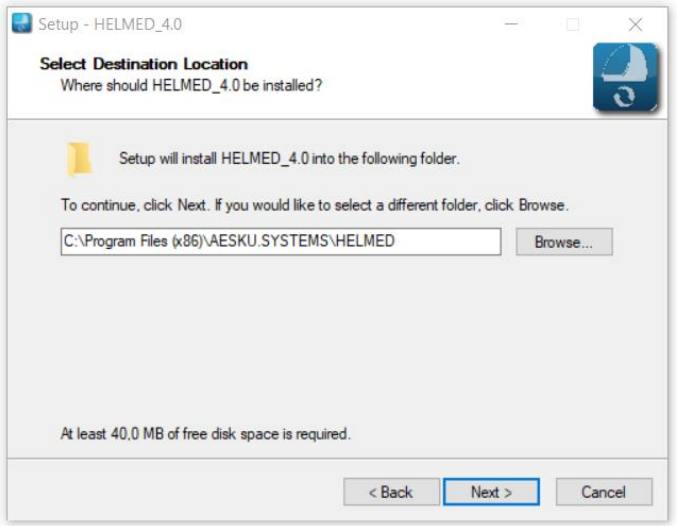
1. Start and execute the setup by double clicking the setup file **HelmedSetup_4.x.x.exe**

2. The following setup window will now open:



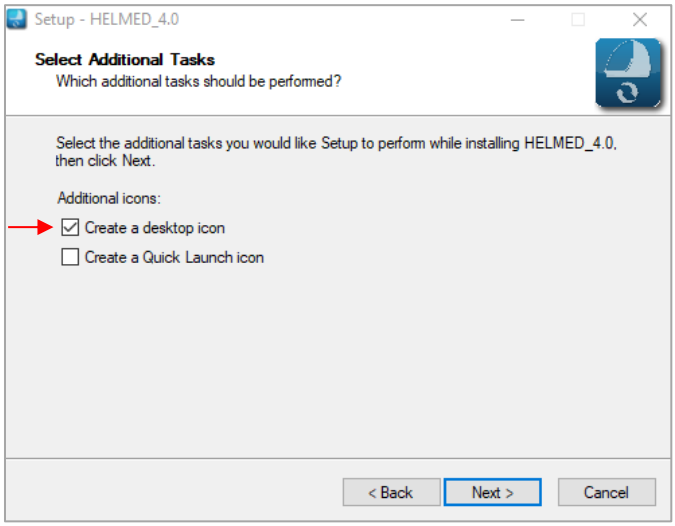
Press **Next >** to continue.

3. Default settings for installation path should not be changed:



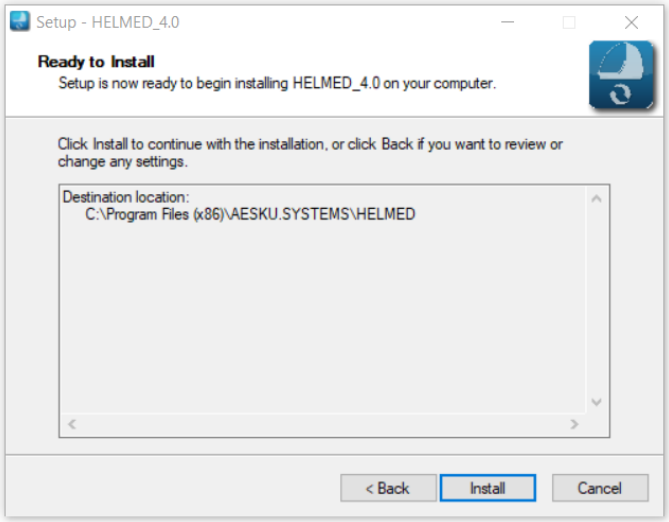
Press **Next >** to continue.

4. Select additional icons:



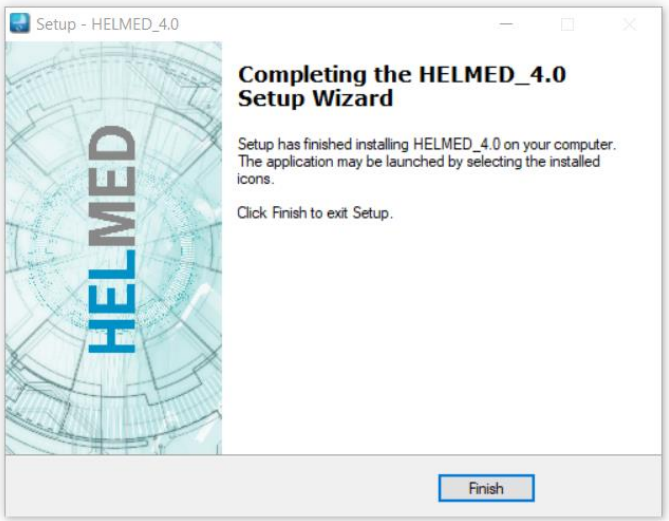
Press **Next >** to continue.

5. Double-check the settings for the installation path:



Press the **Install** button to proceed with the installation.

6. Finish installation wizard:



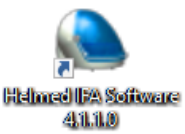
Click the **Finish** button to exit the installation setup.

4.1.2 Installation of HELMED® IFA 4.1

1. Start the installation setup by double clicking the setup file **HelmedIFASetup_4.x.x.x.exe**

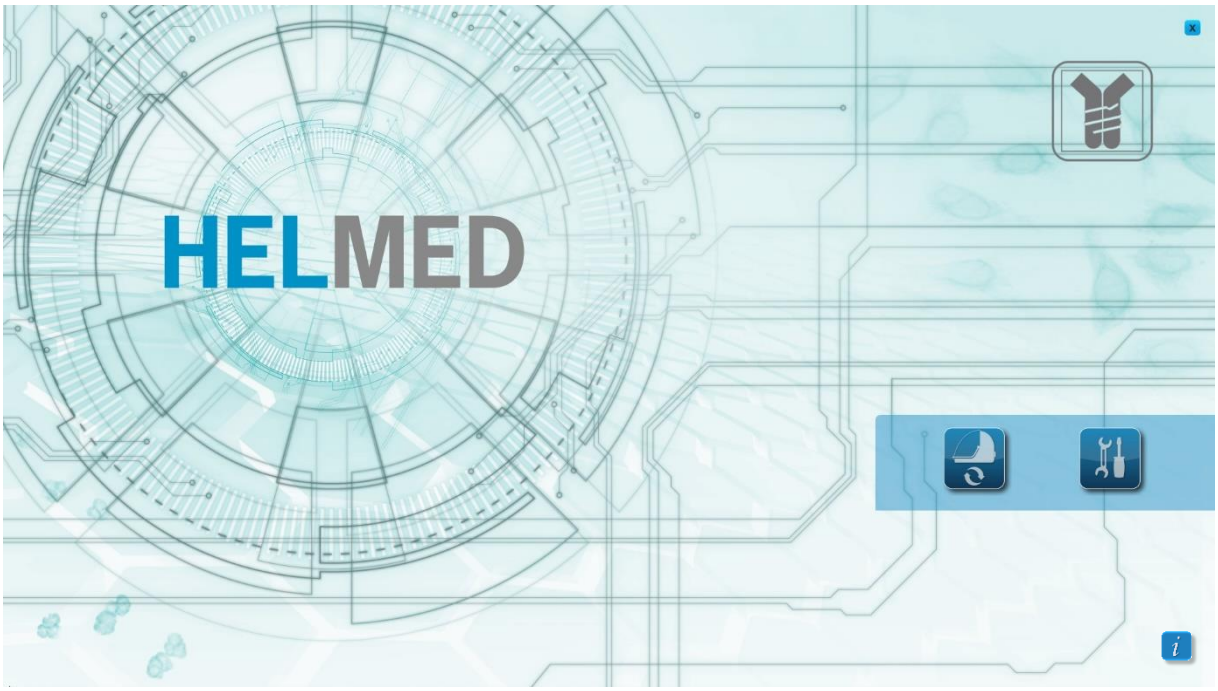
2. The Install Wizard will guide you through the installation. Keep the default path for the installation to avoid incompatibility issues between these two software modules and finish the installation of the **HELMED® IFA** software.

3. After the **HELMED® IFA** software installation has been finished successfully, the created desktop icon (shortcut) below can be deleted:



4.2 Starting the HELMED® device software

Switch on both the device and the control PC. The software can now be started by double-clicking the **HELMED®** desktop icon on the Windows™ desktop screen. When the software opens, the main menu screen will be shown providing the following options:



4.3 Software information window

The information window contains details about the software version, the manufacturer, a link to the manufacturer's homepage, regulatory symbols, etc. The window will be displayed by clicking on the info box in the lower right corner.

4.4 HELMED® IFA Module (slide processing)

By clicking this button, the user selects the **HELMED®** IFA module for slide processing. AESKUSLIDES and slides from other suppliers can be processed using this module. AESKU does not assume any liability regarding the processing of IFA kits by other suppliers.

4.5 Configuration menu

By clicking this button, the user can access the **Configuration** menu for settings adjustment. Here, the settings for the HTC functionality and settings for IFA module language can be adjusted.

4.5.1 HTC settings

The **HTC** menu contains all settings regarding the HTC functionality and can be adjusted here.

Note: These settings are predefined and should not be changed! The **HTC** menu is password protected. If settings need to be changed here, please contact **AESKU Customer Support Team!**

4.5.2 Language settings

In the **Language Settings** menu, the language for the **IFA module** can be set and adjusted by choosing and clicking the respective flag in the dropdown list for the corresponding language.

The languages available for the IFA module are:


CZECH


GREEK


POLISH


ENGLISH


HEBREW


PORTUGUESE


FRENCH


HUNGARIAN


RUSSIAN


GERMAN


ITALIAN


SPANISH

5 HELMED® IFA Module

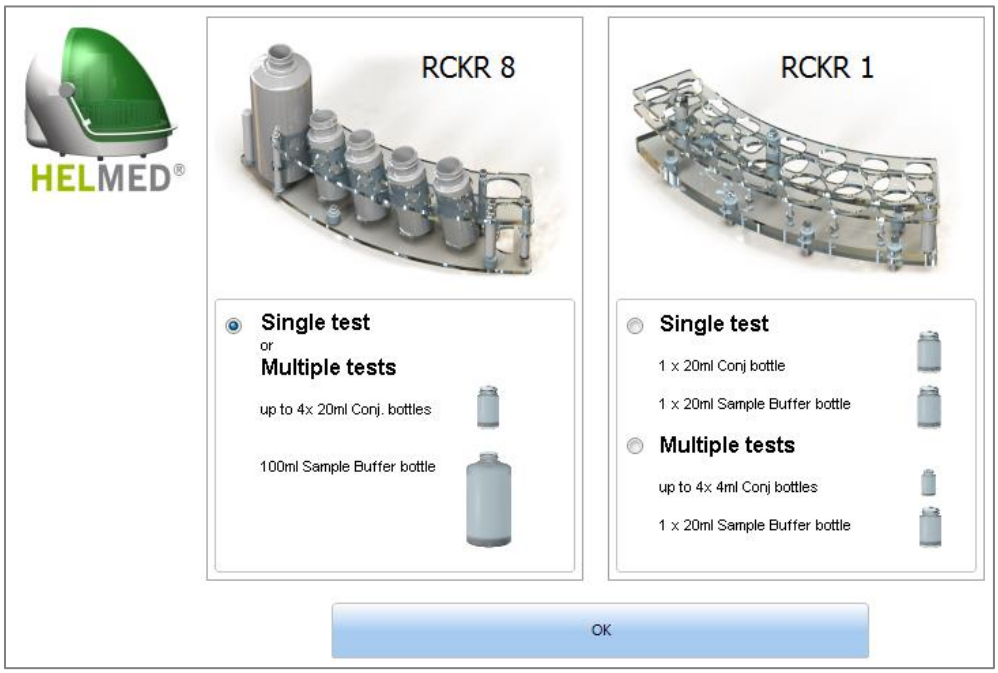
The **HELMED®** IFA software module (slide processing) provides users with the possibility to automatically perform the predefined processing of AESKUSLIDES. Slides of other manufacturers can also automatically be processed if specific tests have been created by the user.

The **HELMED®** IFA software module allows the user to create worklists for every available test including automated scanning of sample IDs. Additional information can also be entered for traceability purpose while creating a worklist.

5.1 Starting the IFA software module

The IFA processing module can be started by pressing in the main menu.

When starting the application, the following screen will appear:



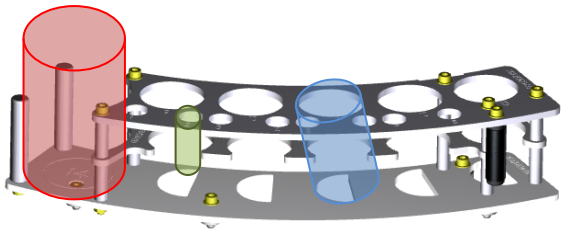
The user can now choose between two different reagent rack layouts:

- **RCKR 8** is the current and standard version used with the **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 **(RCKR1)**) is described in the following section:

RCKR 8 (standard version)

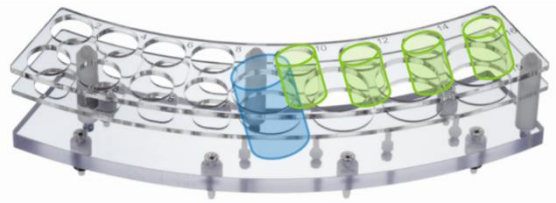
Select this reagent rack to take full advantage of the AESKUSLIDES® IFA kits.



- **100 ml bottle – 1 slot (red bottle in illustration)**
  For reagents to be used as sample or wash 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)

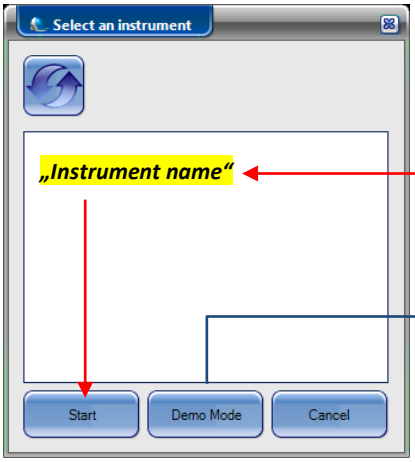
The RCKR 1 is the predecessor of the RCKR 8 providing a different layout for placing reagent bottles and vials.



- **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.)

If the device is connected to the PC, the name of the instrument appears in the white field of the **Select an instrument** window:

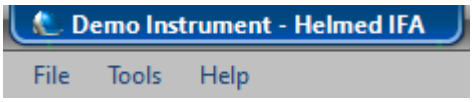


Select an instrument by clicking on its name and click **Start** to work with the instrument.

Note: By clicking the **Demo Mode** button, the software can be used without the device to familiarize with the operating methods and user interface or to even just use one of the modules, e.g. creating a new test in the **Test Designer** module.

5.2 IFA Software Main Screen

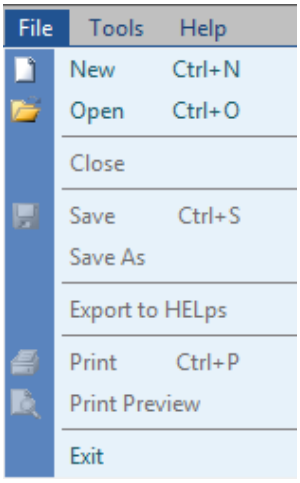
There are three tabs along the top of the screen to choose from:



Every single tab will open a dropdown menu and provide users with further options. These options will be briefly explained in the following sections.

5.3 File

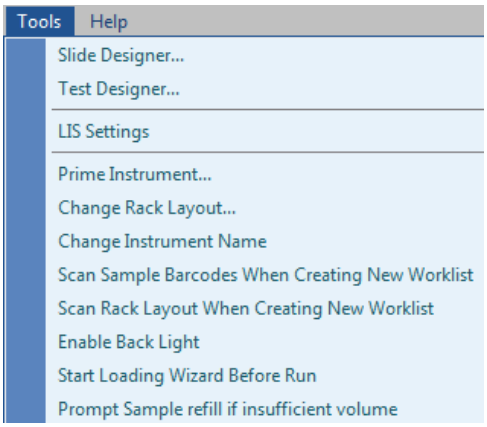
The **File** menu tab contains the following options:



- **New:** Create a new worklist
- **Open:** Open an already processed, saved worklist.
- **Close:** Close the currently open worklist.
- **Save/Save as:** Save a programmed worklist / save a programmed worklist under a specific file name.
- **Print/Print preview:** Print currently open worklist.
- **Exit:** To completely close the **HELMED IFA** software module.

5.4 Tools

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

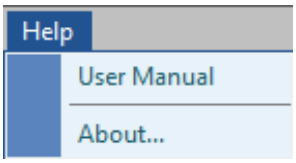


Note: The **Slide Designer** and **Test Designer** modules can be used for programming tests and related slides from other manufacturers. AESKU tests for the automated **HELMED IFA** process are predefined.

- **Slide Designer:** To access the **Slide Designer** module including the **Well Designer**.
- **Test Designer:** To access the **Test Designer** module including the **Control Designer**.
- **LIS Settings:** For further information please refer to the LIS Interface description manual.
- **Prime Instrument:** To manually flush the device with the liquid inside the connected Wash Bottle #1 or Wash Bottle #2.
- **Change Rack Layout:** Scans the configuration and layout of the racks 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:** When this option is activated, the sample barcodes will be read before creating a new worklist.
- **Scan Rack Layout When Creating New Worklist:** With this option active, the rack layout will always be scanned before creating a new worklist.
- **Enable Back Light:** With this option active, the background illumination will be turned on during whole IFA process. This option is for design purpose only and it is not recommended to have this option enabled during normal laboratory operation.
- **Start Loading Wizard Before Run:** When this option is activated, the Loading Wizard will guide the user through the individual loading steps prior to start a run.
- **Prompt Sample refill if insufficient volume:** The system signals (appearing error message on the screen and red flashing LED's combined with an acoustic signal) when the sample volume is too low and will provide the user with the option to refill or skip the respective sample. The sample will be skipped automatically after 10 minutes and the next sample will be processed if no action was taken by the operator.

5.5 Help

There are two options listed in the Help menu:



- **User Manual:**

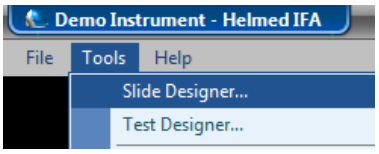
  Includes a pdf that provides a link to the AESKU homepage for downloading the newest manuals.

- **About:**

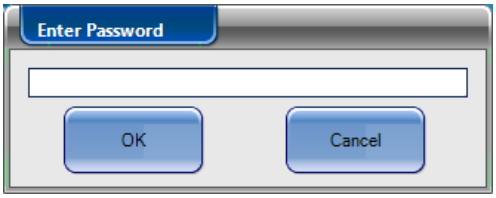
  Information pertaining software version and contact information of manufacturer.

6 Slide Designer

6.1 Slide Designer module



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:

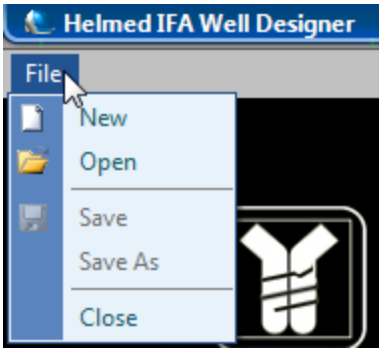
Slide: Contains options for creating a new slide or to open an existing slide.

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

6.1.1 Well Designer

To access the **Well Designer** module, click on the **Tools** tab in the **Slide Designer** and choose **Well Designer**.

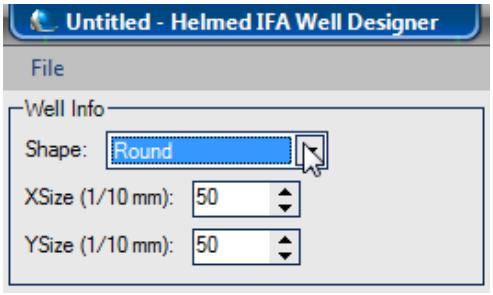
The **File** tab of the **Well Designer** menu contains five options:

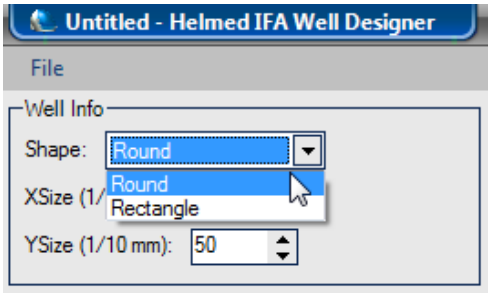


- **New:** Define a new well type.
- **Open:** Open previously defined well.
- **Save:** Quick save a defined well.
- **Save as:** Save defined well under specific name.
- **Close:** Closes the **Well Designer** and returns to the **Slide Designer** module.

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:

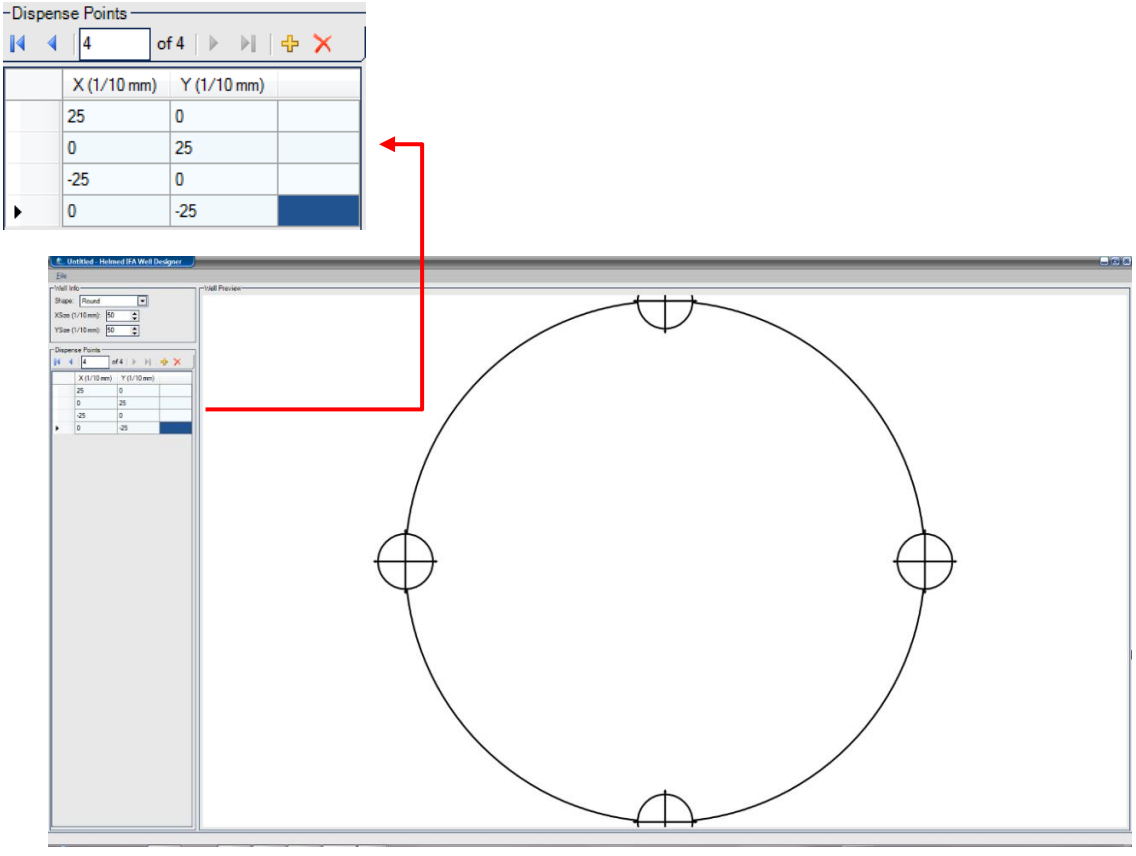




- For round wells, the diameter is measured from the center of the well.
- For rectangular wells, the width and height of the well is measured. All measurements are taken in millimeters. The result is multiplied by a factor ten (10) and in the respective X and Y coordinate fields (X and Y coordinates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



6.1.2 Creating a slide type

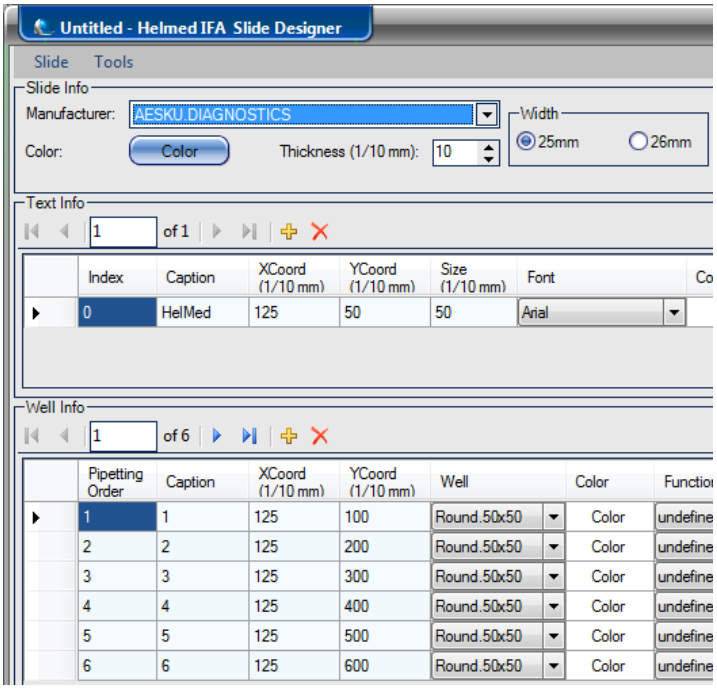
The **Slide Designer** is used to edit existing or to create new slide types that can be processed in the **HELMED® IFA** module.

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

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

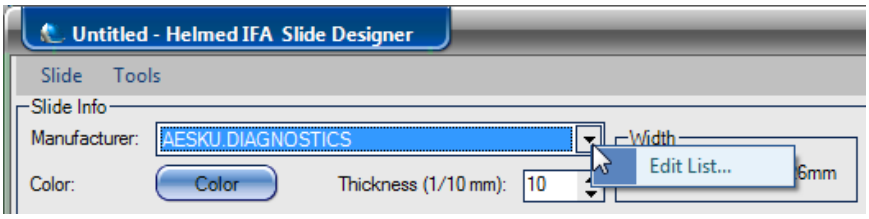
Note: When opening the **Slide Designer**, a default slide design will open. This slide can be adjusted according to the new slide specifications.

The Slide Designer menu is divided into 3 sections:

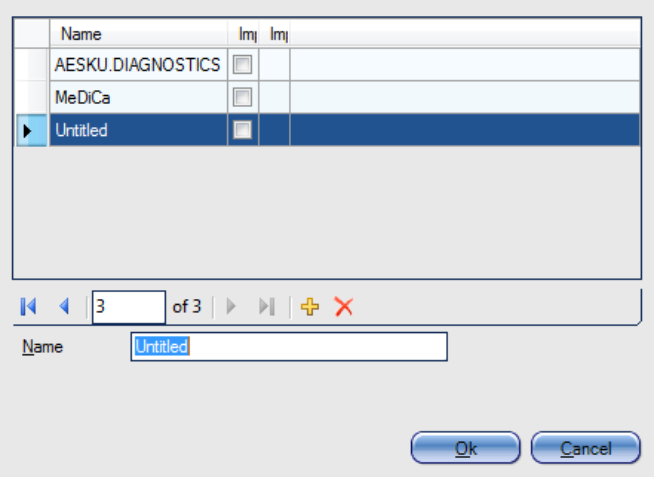


- **Slide Info:** Contains options to define or edit information related to the manufacturer, color, thickness and width of the slide.
- **Text Info:** This option allows to label the slides or edit existing labels.
- **Well Info:** Allows the user to define the number and position of wells on the slide as well as selecting the well type (created in the well designer), color (optional), function (optional) and the substrate.

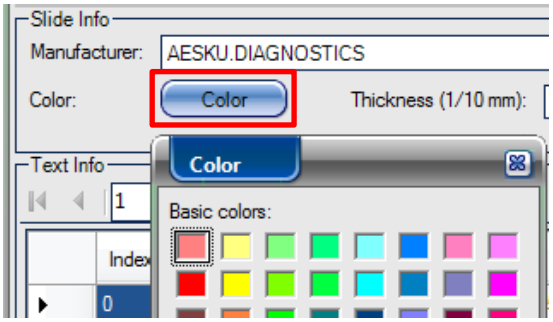
6.1.2.1 Slide Info



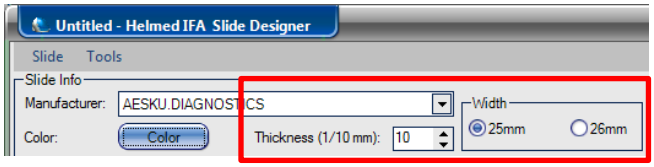
Select the slide manufacturer in the **Manufacturer** dropdown menu. To add a manufacturer, right-click the arrow of the selection menu. Click **Edit list**. A new window will open:



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.

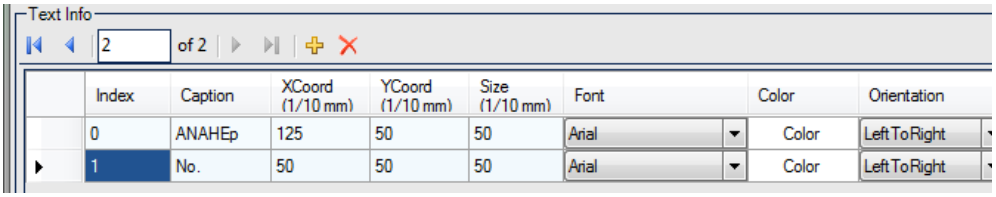


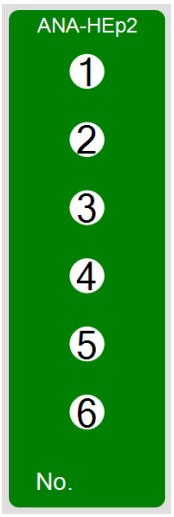
To assign a color to a slide, click the **Color** button and select a color:



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

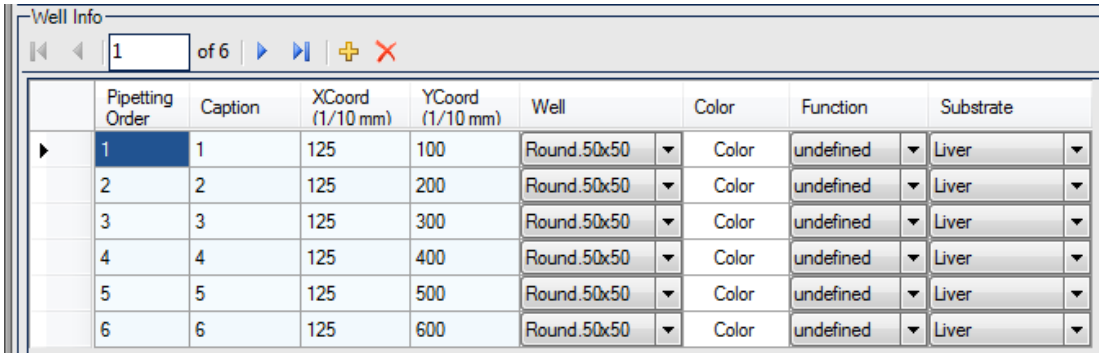
6.1.2.2 Text Info



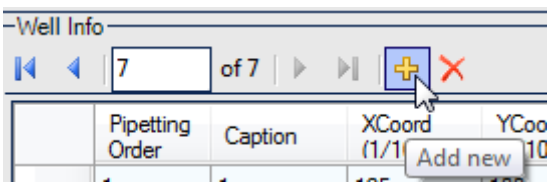


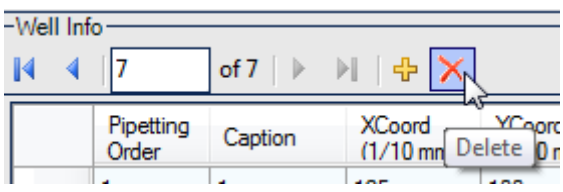
The X and Y positions are used to define the upper left position at which the text will be aligned. Enter a preferred labeling for the slide into the field **Caption**: Measure the distance from the left edge of the slide to the right edge of the text in millimeters. Multiply this value by a factor ten (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).

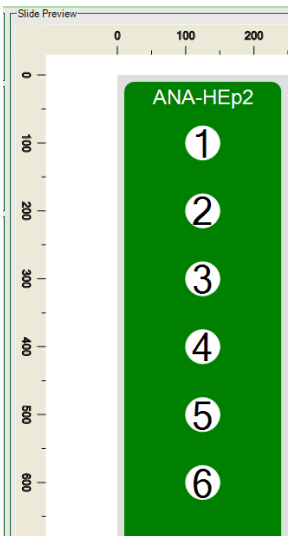
6.1.2.3 Well Info



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.





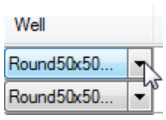


Well positions are defined by measuring from the top and left edge of the slide to the center of the well. A ruler, for X and Y positioning will be displayed on-screen. The 0/0 coordinate will be the upper left corner.

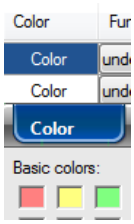
Measure the X-position of the first well using a ruler (metric). The X-position will be the distance from the left edge of the slide to the center of the well. Multiply the measured distance by a factor ten (10). Enter the result as **X-Coord** (1/10mm).

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).

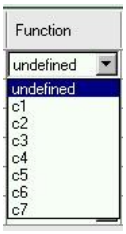
➢ Repeat this process for every single well position.



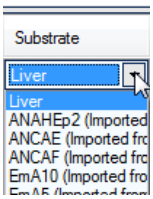
From the **Well** dropdown menu, select the corresponding well type to be used on the slide. This well was previously defined in the **Well Designer**.



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



The **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 a slide design:

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

1. Click **Slide** from the **Slide Designer** menu bar

2. Choose **Save as** from the context menu

3. Enter a name for the new created slide and click **Save**

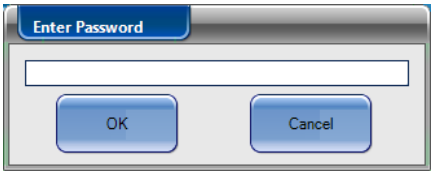
7 Test Designer

7.1 Test Designer module

The **Test Designer** module is used to create a new test or to modify an existing test if required. 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 dropdown menu to open the **Test Designer** screen.



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

There are now two tabs along the top of the screen of the **Test Designer**:

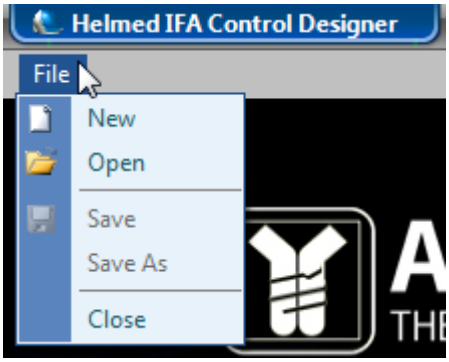
Test: Contains options for creating a new test or to open and modify an existing test.

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

The user can access the **Control Designer** by clicking on the **Tools** tab in the **Test Designer** module and then open it by left mouse-click on **Control Designer** in the context menu. The **Control Designer** and its functions will be explained in the following section 9.1.1.

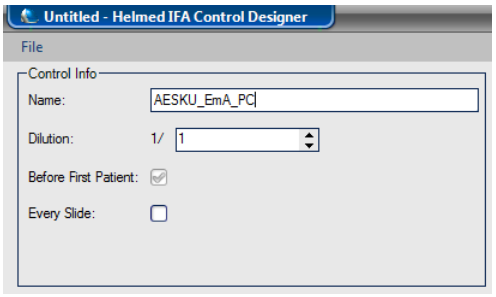
7.1.1 Control Designer

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



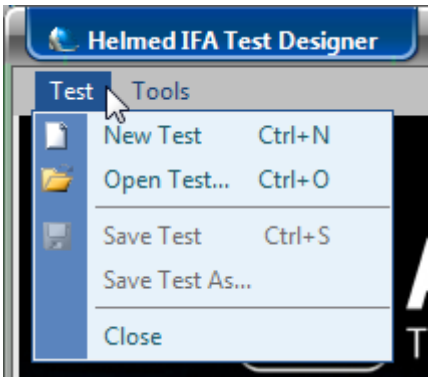
- **New:** To create a new control.
- **Open:** To open an existing control.
- **Save:** To quick save a programmed control.
- **Save as:** To save a programmed control as a named control.
- **Close:** To close the **Control Designer**.

Define a control:



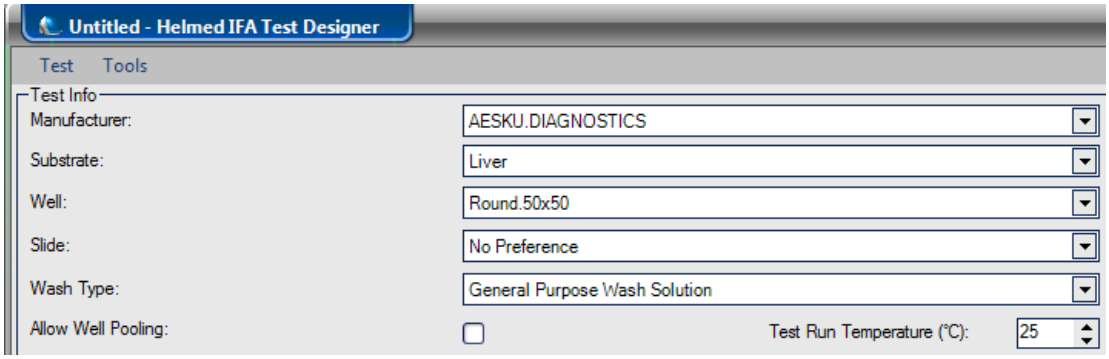
Edit the name of the control. Select a dilution if needed (default setting 1/1 for ready-to-use controls). It is possible to choose whether the control is placed on every slide or only before the first patient by marking the respective box. If a new control has been defined, click **Save** to enter a name for the control. If an existing control has been modified, the changes will be saved by clicking the **Save** button.

7.1.2 Programming a test



To start with programming new tests or create new test files, the user must first click on the **Test** tab in the **Test Designer** and choose the option **New Test**.
To modify an existing test, the user can also open a test file by clicking on **Open Test** in the context menu.

7.1.2.1 Test Info

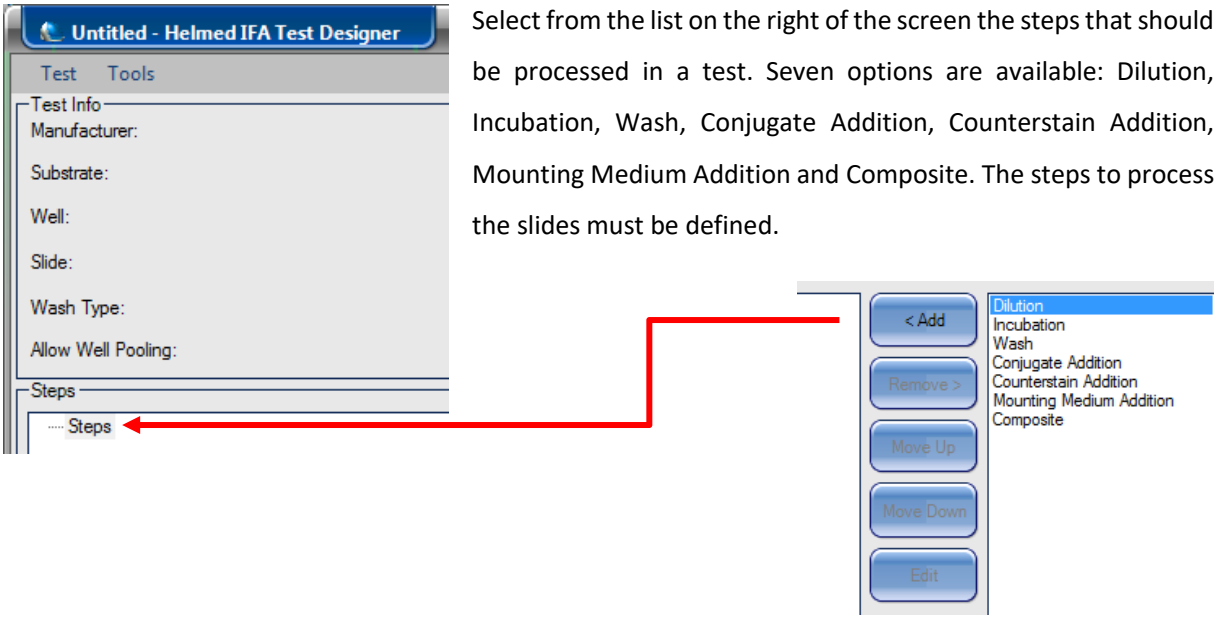


Note: The **Test Designer** main screen will open with default settings for **Test Info**. These settings must be changed before starting with the **Steps** selection.

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 the section for **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.
- **Test Run Temperature** can be adjusted and increased, if necessary, for instance running tests which require higher incubation temperature (35-37°C/95-98.6°F). The value for this parameter must be entered in Celsius degrees (°C).

7.1.2.2 Settings for Steps



Select from the list on the right of the screen the steps 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.

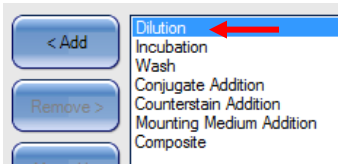
Note: All process steps will open with default settings. These settings must be changed according to the respective IFU. Process steps for **AESKUSLIDES™** are predefined and should not be edited.

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

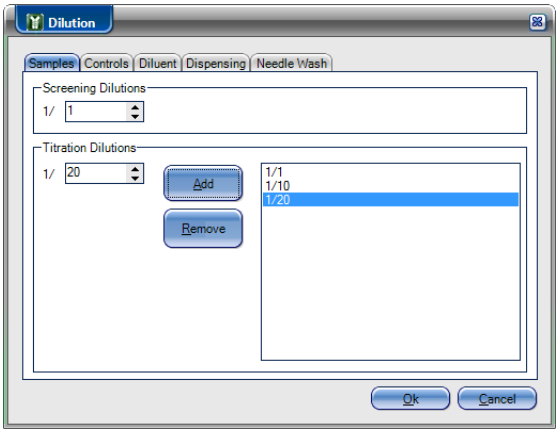
How to select and set up specific test steps will be described step by step in the following sections:

Step 1

Dilution step

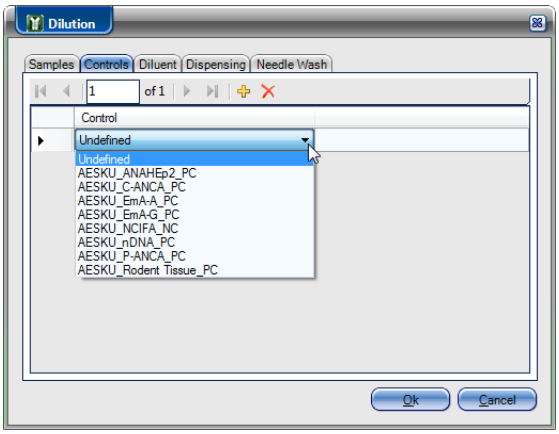


Select **Dilution** on the right of the screen (double-click or clicking the **< Add** button). A new window will open to define sample dilutions, controls, diluent, dispensing (transfer to the slide) and additional needle wash.



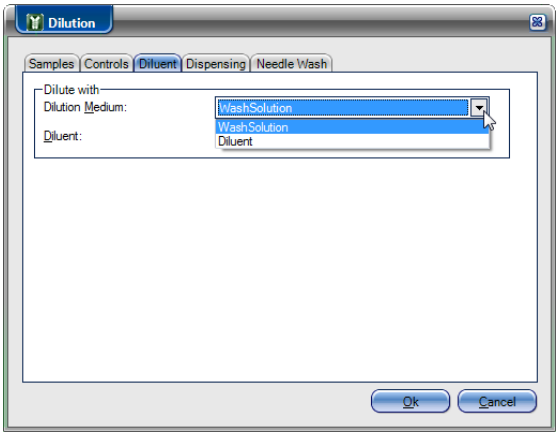
Define the sample dilutions for screening and titration.

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.



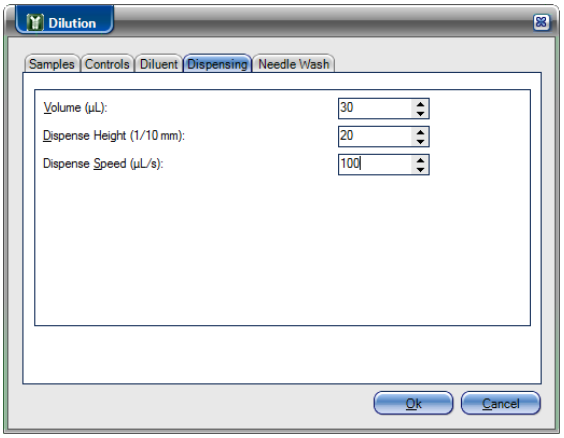
Select the controls:

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.



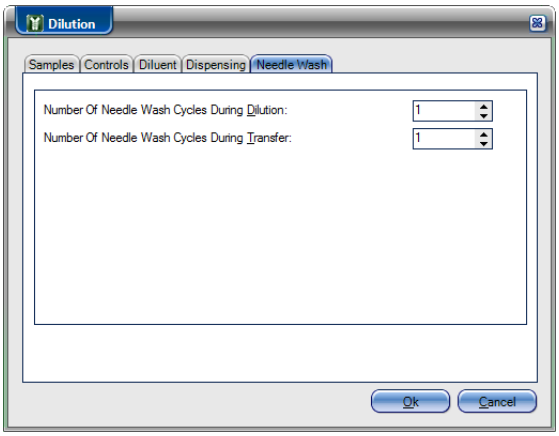
Select the diluent:

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.



Defining the dispensing settings for the transfer to the slide:

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:

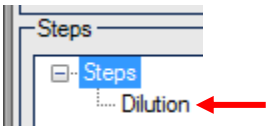
Number of needle wash cycles during <u>dilution</u>:

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 <u>transfer</u>:

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.



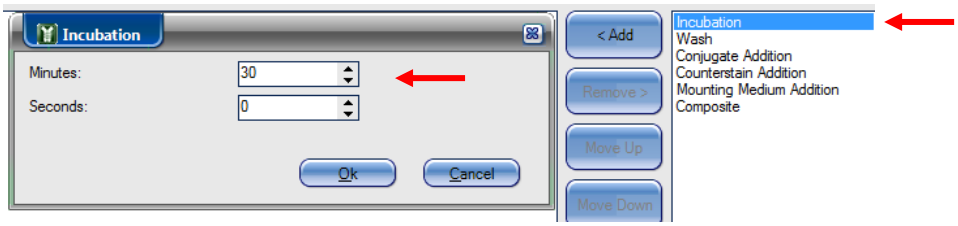
After defining all the settings, press **Ok**. The first test step **Dilution** appears in **Steps** listed on the left side of the screen.

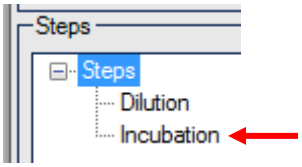
Step 2

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 **<u>NOT</u>** confirm by pressing the "**Enter**" key. Pressing the "**Enter**" key will not save the set value.



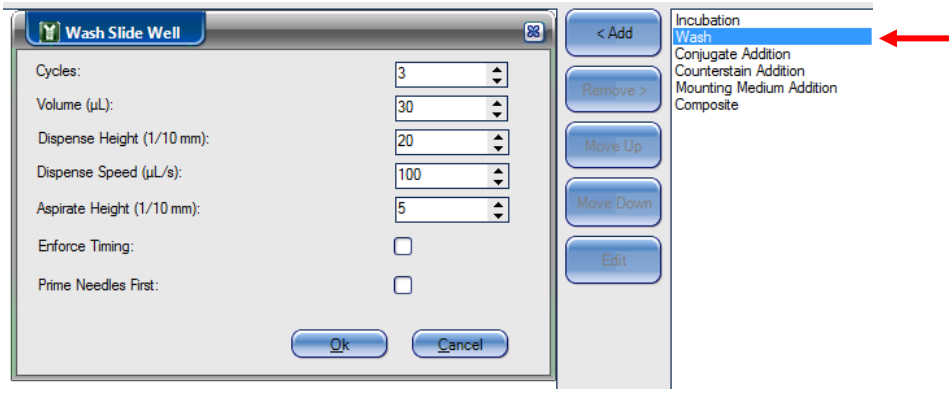


The **Incubation** step now appears on the list of **Steps** on the left side of the screen.

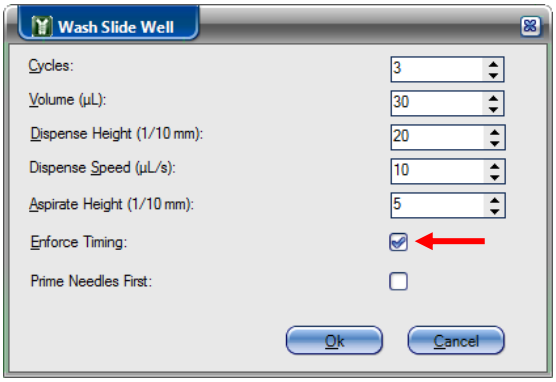
Step 3

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.

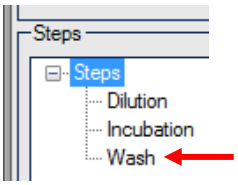


The **Volume** needed to cover the entire well depends on the size of the well. The **Aspiration** / **Dispense Height** is the distance between the needle and the slide when aspirating / dispensing fluid. The **Dispense Speed** is the amount of volume dispensed in seconds. The **Dispense Speed** should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

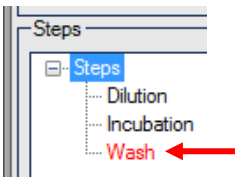


If the option **Enforce Timing** is activated, the incubation time of the step prior to washing will then be strictly adhered to.

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



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

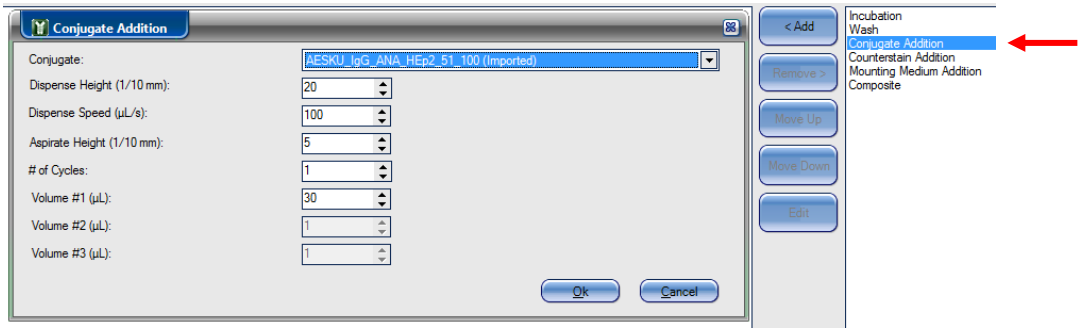


If **Enforce Timing** is activated for the incubation time, the **Wash** step is highlighted in red.

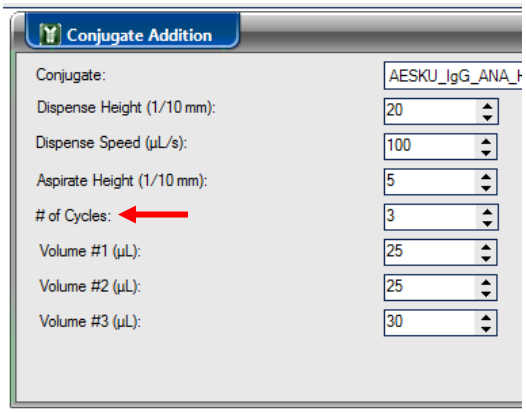
Step 4

Conjugate step

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

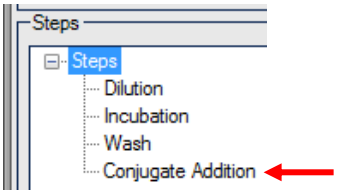


The list of conjugates can be edited by a right mouse click on the dropdown arrow. A new window will open. New conjugates can be added by clicking the **+** button to get a new line for the entry of a new or additional conjugate. Define the settings for **Conjugate Addition**, **Dispense Height**, **Dispense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

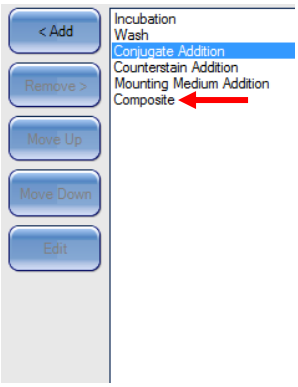


The **Conjugate Addition** step now appears on the list of **Steps** on the left side of the screen.

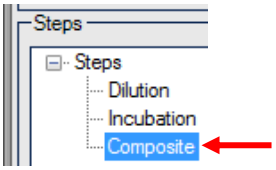
Step 3 and **Step 4** can be combined in a **Composite** step. The function of this step is to immediately add conjugate to each well after it is washed.

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

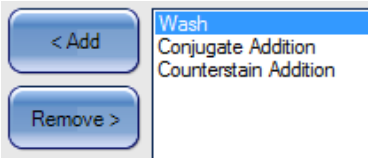
Composite step



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

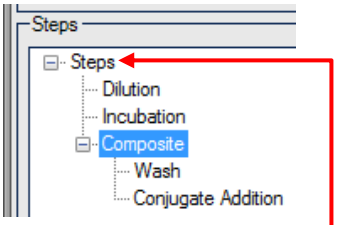


Composite step now appears on the list of **Steps** on the left of the screen. When the **Composite** step is marked on the left side, three different steps will now become available on the right of the screen:



- **Wash**
- **Conjugate Addition**
- **Counterstain Addition**

Select Wash for Composite step

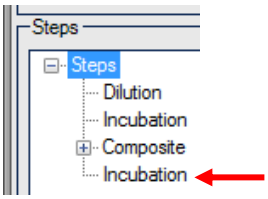


To setup a **Wash** step for composite steps, please follow and repeat the instructions in **Step 3**. The **Wash** step now appears as an own particularly sidestep of **Composite** on the left of the screen. Then select **Conjugate Addition** and follow the instructions in **Step 4**. **Conjugate Addition** 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.

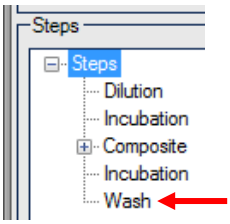


Incubation step now appears on the list of **Steps** on the left side of the screen.

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.

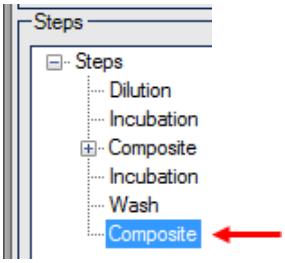
If **Enforce Timing** has been selected, the incubation time will be strictly adhered to, and the respective **Wash** step will be highlighted in red.

Step 7

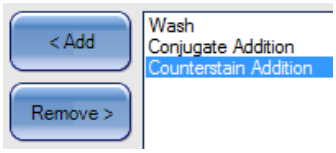
Counterstain step

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.

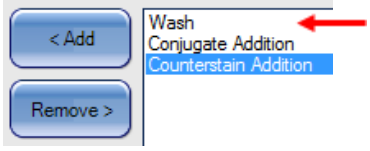


Select **Composite** on the right side of the screen and press the **< Add** button (or double-click). **Composite** now appears in the list of **Steps** on the left side of the screen.

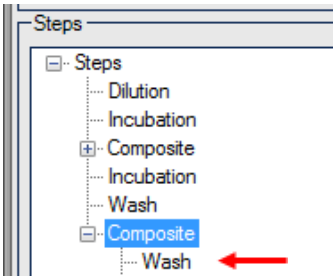


On the right side of the screen, there are now three different steps available:

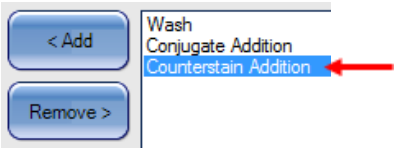
- **Wash**
- **Conjugate Addition**
- **Counterstain Addition**



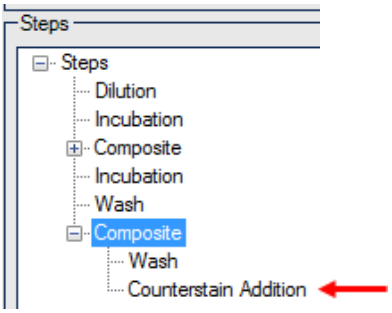
Select **Wash** as part of the **Composite** step and follow the instructions in **Step 3 / 6**.



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



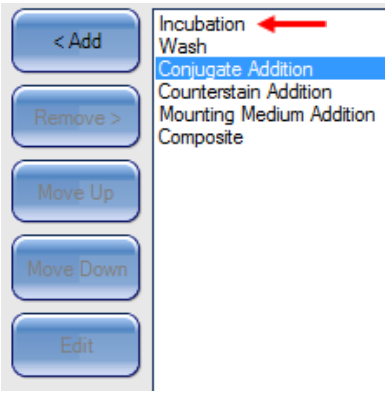
Now select **Counterstain Addition** and follow the instructions in **Step 7**.



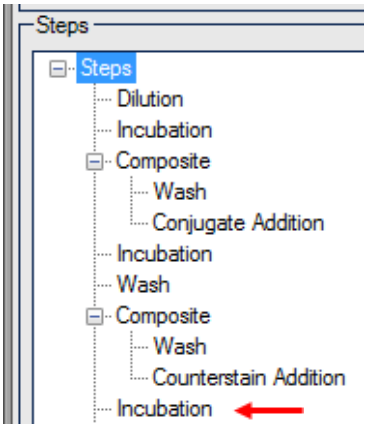
Counterstain Addition now appears as a sidestep of the **Composite** step in the main list of **Steps** on the left of the screen. To continue defining main steps, click once on **Step** on the left of the screen.

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 incubation. Then click **Ok**.

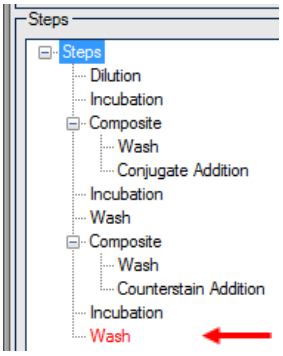


Incubation step now appears on the list of **Steps** on the left side of the screen.

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.

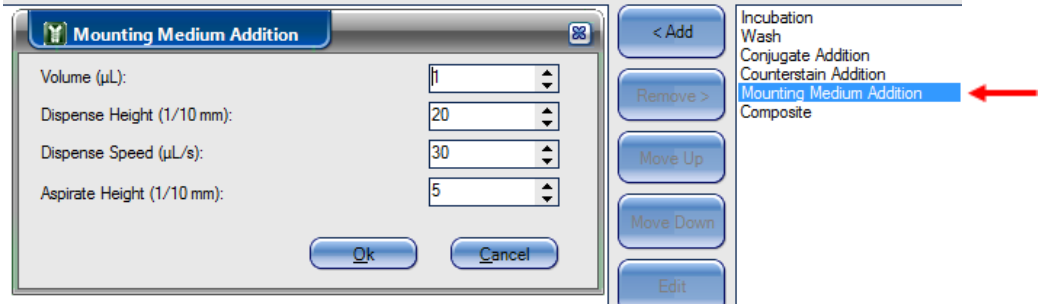
Then click **Ok**.

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

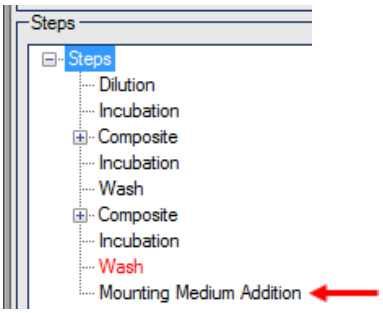
Step 10

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.

Step 11

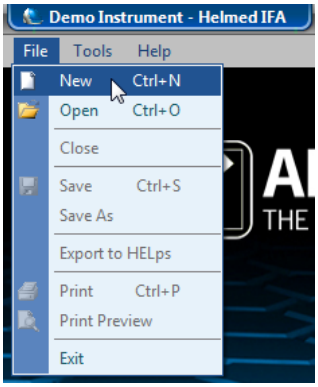
Saving a programmed test as a test file

Once all the single steps for a test are defined, the test must be saved. Follow the 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.

8 Run a worklist

Select the **HELMED® IFA** button in the **HELMED®** main screen to start the IFA module.

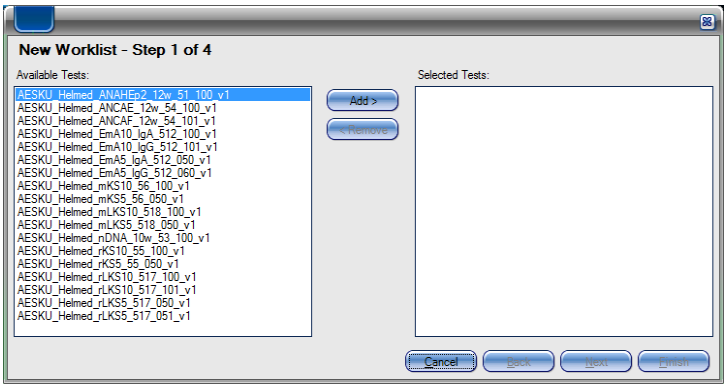


Then click on the **File** tab at the top of the **HELMED®** IFA main screen. Select **New** from the context menu to create a new worklist. Select **Open** from the context menu to open a previously saved work list file of a run.

8.1 How to create a worklist:

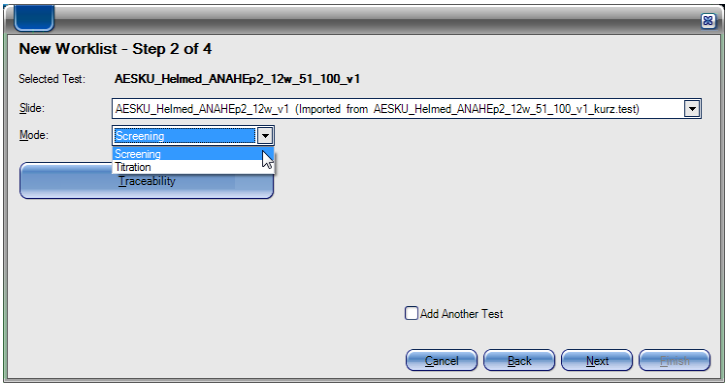
The following instructions for creating a worklist refer to the **AESKUSLIDES™** Kit for **ANA Hep2 (REF 51.100)** and are only an example:

Step 1 of 4



Select one of the available tests from the list in the window **New Worklist – Step 1 of 4** by clicking the **Add >** button. Then press the **Next** button to continue.

Step 2 of 4

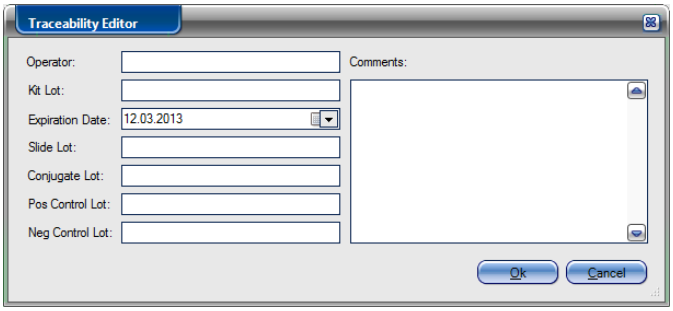


The **New worklist – Step 2 of 4** window will now display the selected test and its related slide in the **Slide** dropdown menu. The user can choose between **Screening** or **Titration** mode by using the dropdown menu in the **Mode** line.

Adding additional tests

To add additional tests, the user can now mark the **Add Another Test** checkbox. Up to four different tests can be selected to be processed in a single run. Repeat the steps 1 and 2 for adding additional test. If there are no more additional tests to add within this worklist, please uncheck the **Add Another Test** checkbox and click **Continue**.

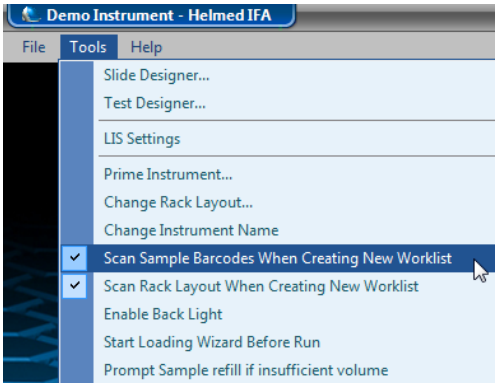
Traceability



By clicking the **Traceability** button, a new window will open. Additional information such as the username or LOT numbers can be entered here. This information will be contained within the report.

Note: Regularly check whether the information in the **Traceability** window is up to date! All data entered in here will be included in the report.

Scanning the rack layout and patient IDs



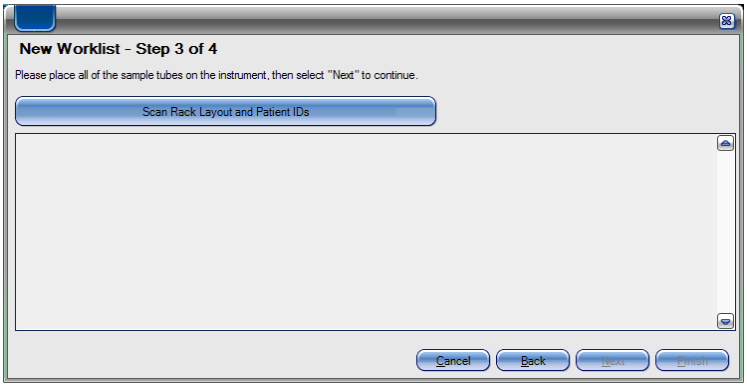
When using sample tubes with barcode identification (standard sample tubes are 5 ml tube with dimension Ø13 x 75mm), the optional function **Scan Sample Barcodes When Creating New Worklist** needs to be activated before creating a worklist:

- Select **Tools** in the **HELMED**® IFA main screen and activate the function in the context menu.

Repeat the same step for activating the function **Scan Rack Layout When Creating New Worklist** for always scanning the rack layout prior to start a worklist.

The barcodes of the samples and of the racks will be scanned in the next window **New Worklist – Step 3 of 4**.

Step 3 of 4

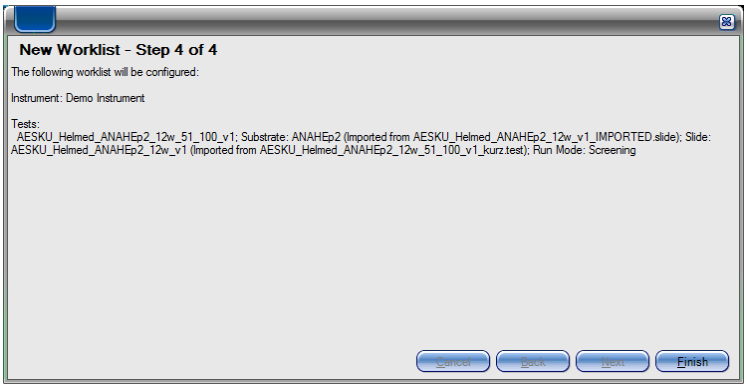


To start the scanning process, click **Scan Rack Layout and Patient IDs**. The scanning process is completed when the **Next** button becomes active. Scanned barcodes will be shown in the **New Worklist – Step 3 of 4** window after scan process has finished an.

Click **Next** to proceed to step 4 of 4.

Note: If a sample barcode is not recognized, the outer ring will rotate several steps to enlarge the 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.

Step 4 of 4

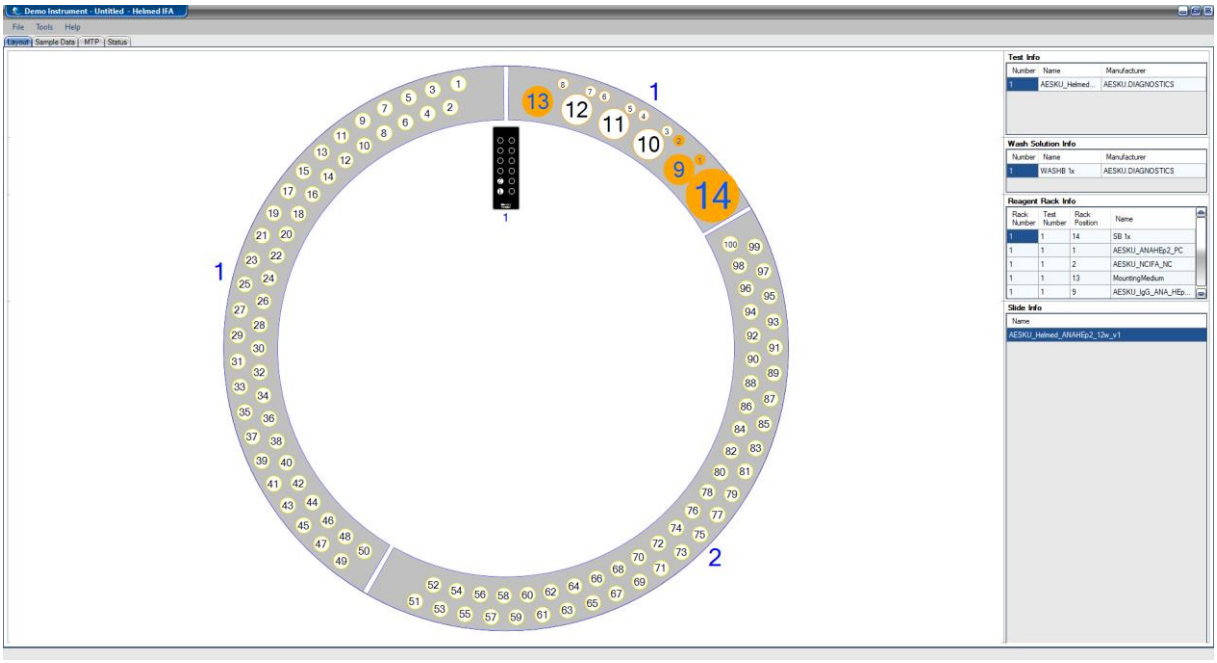


The **New Worklist – Step 4 of 4** window provides information about the device name and the tests selected for creating the worklist.

After completing all four steps of the worklist creator, press the **Finish** button to proceed to the worklist layout overview of the **HELMED**® IFA software.

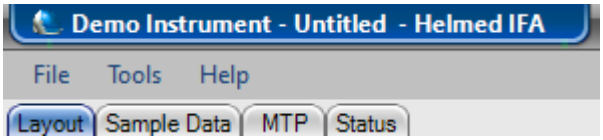
8.2 Layout Screen

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.

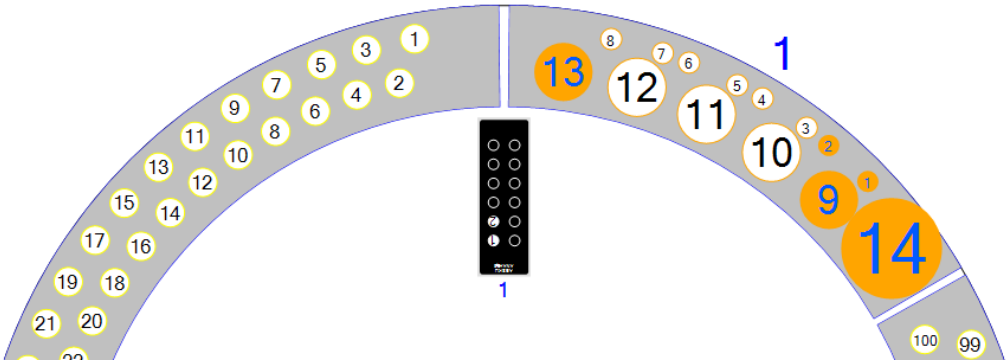


At the top of the screen, the user can switch between the following tabs:

- Layout
- Sample Data
- MTP
- Status



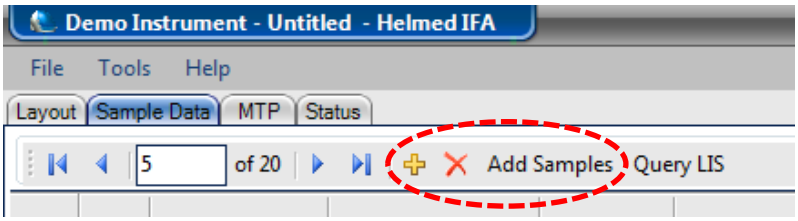
The **Layout** tab provides information where all the reagents, controls, samples, and slides are located or need to be placed. After the necessary dilutions for the samples are selected by placing a checkmark (see **Sample Data tab** section), the layout view will provide the updated information on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



8.3 Sample data handling

Sample information needs to be provided here. For sample and reagent preparation, please refer to the **IFUs** from **AESKU.DIAGNOSTICS** 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:

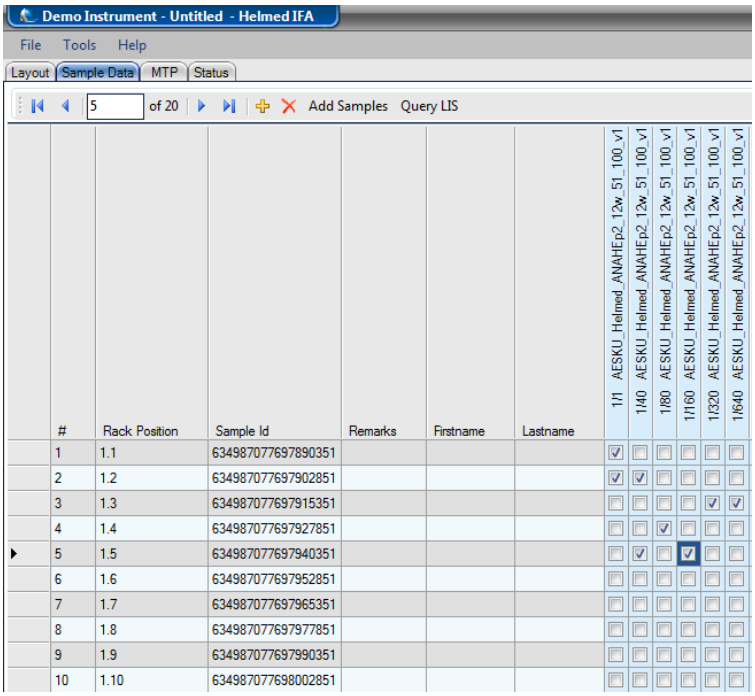
	#	Rack Position	Sample Id	Remarks	Firstname	Lastname	1/1	1/40	1/80	1/160	1/320	1/640	1/1280	1/2560	1/5120	1/10240
	1	1.1	634987077697890351				☑	☐	☐	☐	☐	☐	☐	☐	☐	☐
	2	1.2	634987077697902851				☑	☑	☐	☐	☐	☐	☐	☐	☐	☐
	3	1.3	634987077697915351				☐	☐	☐	☐	☑	☑	☐	☐	☐	☐
	4	1.4	634987077697927851				☐	☐	☑	☐	☐	☐	☐	☐	☐	☐
▶	5	1.5	634987077697940351				☐	☑	☐	☑	☐	☐	☐	☐	☐	☐
	6	1.6	634987077697952851				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	7	1.7	634987077697965351				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	8	1.8	634987077697977851				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	9	1.9	634987077697990351				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	10	1.10	634987077698002851				☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

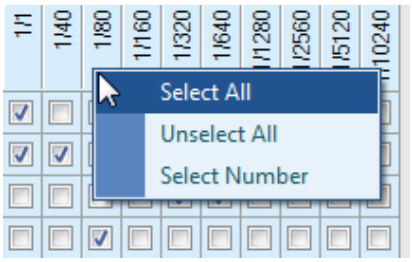
Note: Please do not use any special characters in the fields, like for instance dots and brackets (<>).

The entered data will be included in the IFA report, which can be printed from the **File** tab.

Well	ID or Name	Dilution [1:x]	Testname	Result	Remark / Comment
1	AESKU_ANAHEp2_PC	1	AESKU_Helios_ANAHEp2_12w_51_100_v1		
2	AESKU_NCIFA_NC	1	AESKU_Helios_ANAHEp2_12w_51_100_v1		
3	12345678 Doe, John	40	AESKU_Helios_ANAHEp2_12w_51_100_v1		Remark
4	12345678 Doe, John	80	AESKU_Helios_ANAHEp2_12w_51_100_v1		Remark

8.4 Dilution management





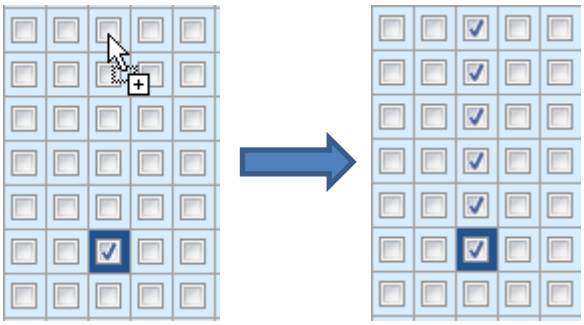
For processing a sample, a dilution needs to be selected. If a sample is loaded but no dilution is checked, it will not be processed. By right clicking on a specific dilution, three options will become available:

Select all: All available samples in this column will be checked

Unselect all: All available samples in this column will be unchecked

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

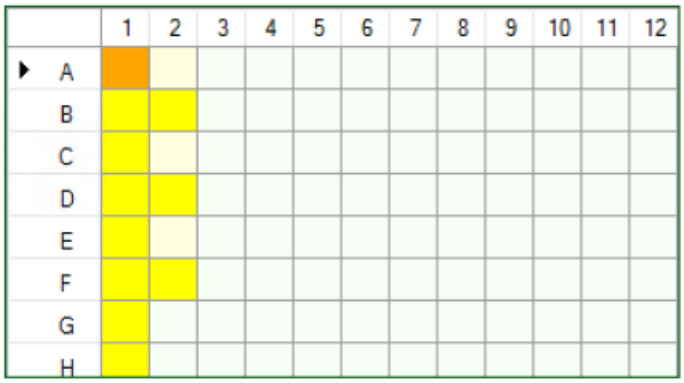
To select multiple samples in a column, select the last sample ID needed for the assay by clicking on the left mouse button. After checking the box, click and hold on the right mouse button and move the cursor upwards to the first sample ID needed for the assay. All the samples selected this way should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

8.5 MTP tab for dilution preview

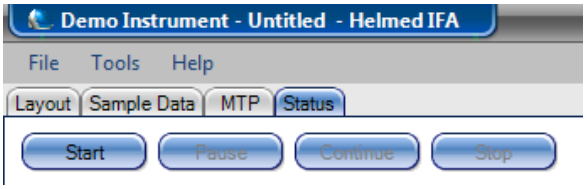
The MTP tab provides information and a preview on how many wells are needed for the dilution process. The type of dilution is indicated by color code:



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

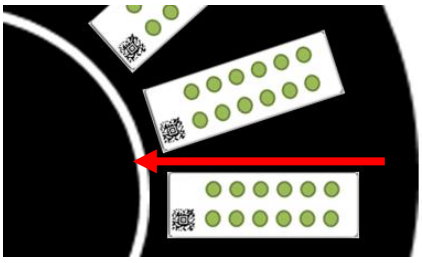
The software can handle 192 dilutions in total using 2 MTPs with 96 well layout.

8.6 Status tab



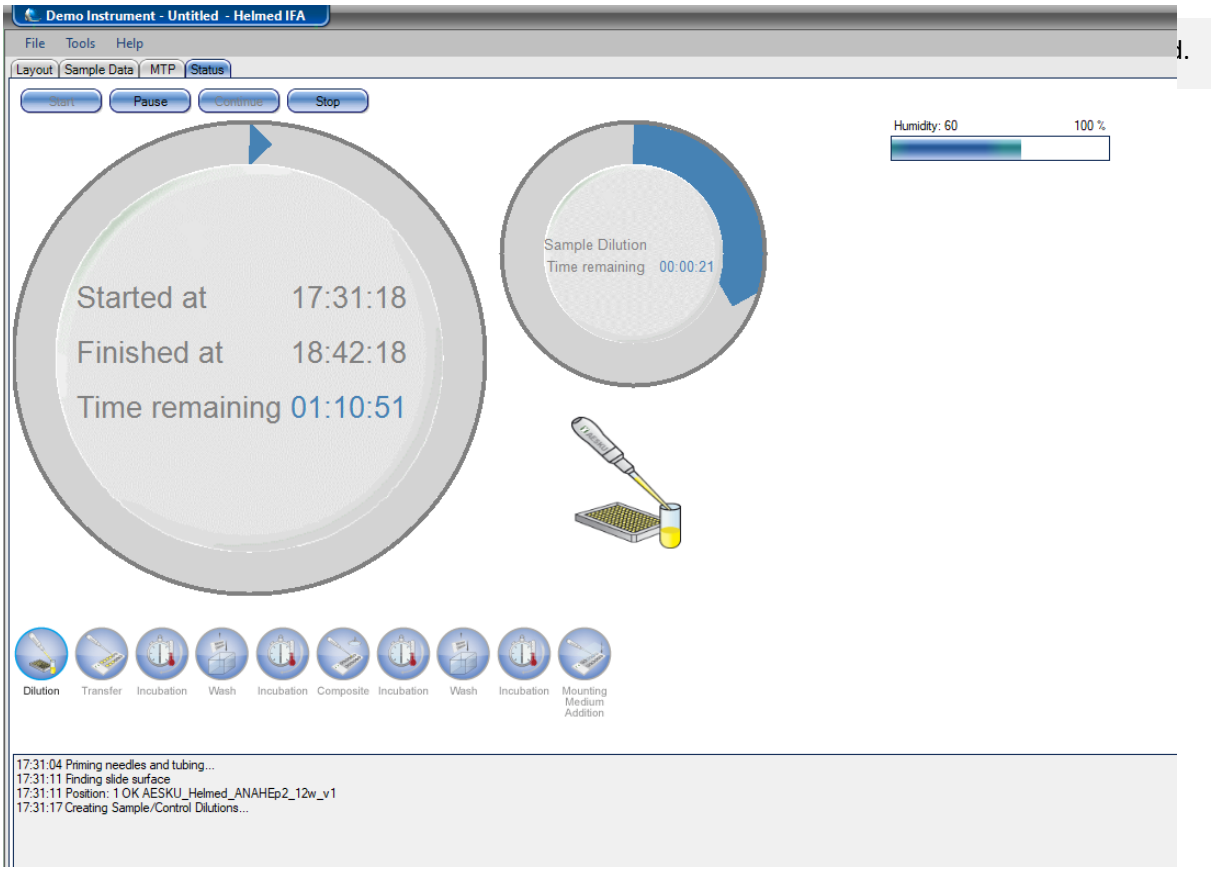
After all slides, reagents, controls, and samples are loaded, the process can be started in the **Status** tab by clicking the **Start** button. Please ensure that all the required reagents and slides are positioned properly inside the device.

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



If the function **Start Loading Wizard Before Run** was selected, the device will remain unlocked after pressing **Start** and the loading assistant starts.

After pressing **Start**, the instrument will lock the lid and start with the process.



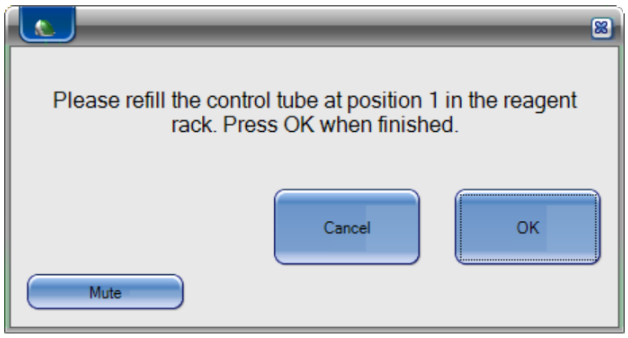
After the slide barcodes have been scanned successfully, the software will check that slides are correctly placed and not inserted tilted. In the next step, the device will be primed, and the processing of the worklist will commence. After the assay process is started by the user, the Status tab will 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 assay process and can slightly differ from the time the process will end.

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.

9 Maintenance

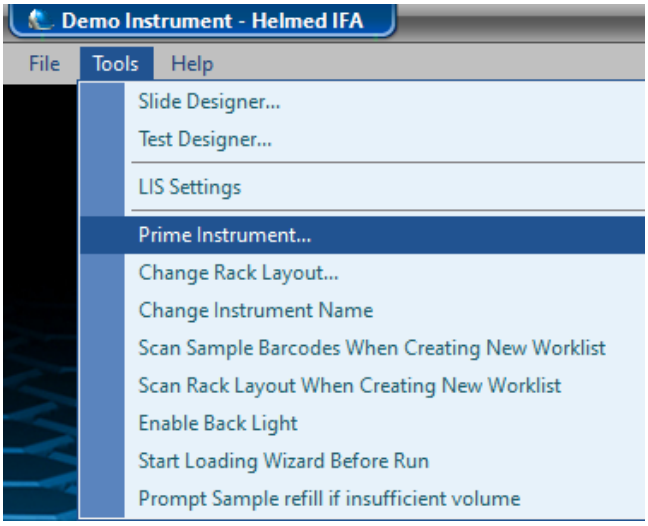
Regular maintenance is important for the proper operation and functionality of the device. The following procedures are recommended by AESKU.Diagnostics GmbH & Co. KG:

9.1 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:

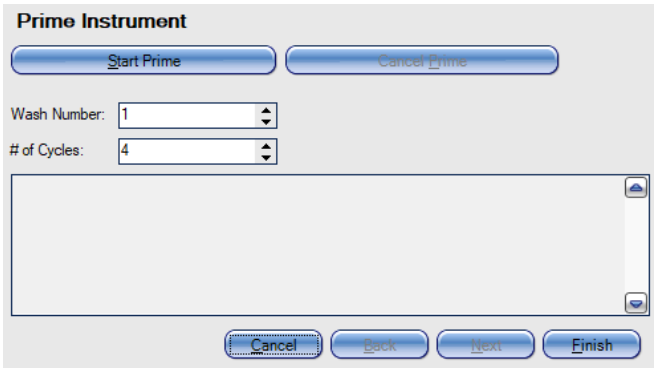
Empty wash bottle #1, rinse the bottle with distilled water and fill the bottle with approximately 100ml of distilled water. Alternatively, remove the quick connector from wash bottle #1 and attach to wash bottle #2 containing distilled water by using the quick connector.



Priming the instrument:

Select **Tools** from the IFA main screen.

Afterwards select **Prime instrument**.



Wash Number and **# of Cycles**:

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, please replace it immediately for your safety.

9.2 Weekly maintenance

Flush the device once per week with 0.3% sodium hypochlorite solution (NaOCl), alternatively 70% ethanol. Follow the instructions from section 9.1 to flush the instrument. Allow at least 15 minutes of incubation time. After that, flush the device with distilled water at least 3 times with 9 cycles each.

Caution:

Risk of irritation when handling sodium hypochlorite (NaOCl)!

Note: The device must be flushed with distilled water after it was cleaned 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.

9.3 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 for disinfection, if necessary. It is recommended to clean the surfaces regularly. Only use cleaning agents (e.g. 70% EtOH) recommend by AESKU.Diagnostics GmbH & Co. KG to avoid any damage to the device and/or equipment. For further cleaning advise, please contact AESKU Customer Support Team.

9.4 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 for disinfection, if necessary. It is recommended to disinfect the surfaces and especially the racks regularly. Only use disinfection agents (e.g. 70% EtOH) recommend by AESKU.Diagnostics GmbH & Co. KG to avoid any damage to the device and/or equipment. For any further disinfection advise, please contact your local distributor or AESKU Customer Support Team.

9.5 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.

9.6 Maintenance and cleaning of HTC accessories for HELMED® devices

9.6.1 Spiral Hose Humidifier (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:

Hypochloride, 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 at min. 132°C/269.6°F to max. 135°C/275°F for 15 minutes. Allow 30 minutes for 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.

9.6.2 Humidifier (Ref # 20160305)

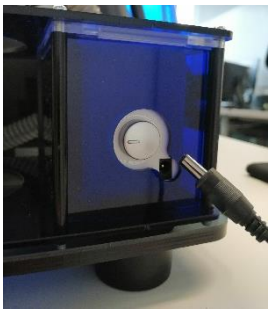
Weekly cleaning and disinfection are required for fault-free and hygienic operation.

CAUTION:

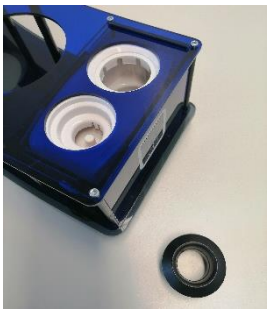
Switch off the air humidifier each time before cleaning. Pull the plug out of the mains socket.

For cleaning of the external humidifier, 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.

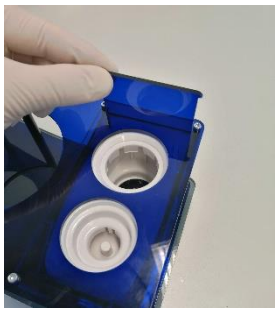
How to remove the humidifier from the rack:

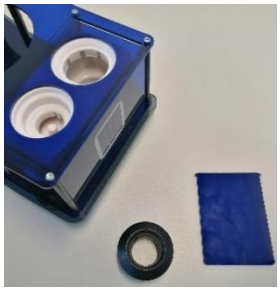


1) Unplug the 24V cable

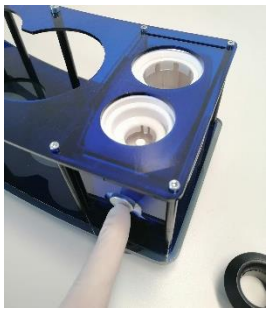


2) Remove the tubing adapter

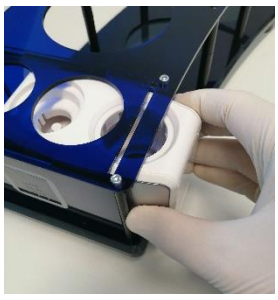




3) Remove the side panel by pulling up and taking out



4) Push the humidifier out of the housing



5) Pull the humidifier out of the rack

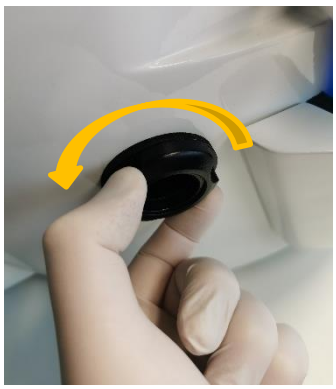
6) Open the lid of the humidifier for cleaning inside

INSTRUCTIONS:

- Never submerge the base in water.
- Empty the water from the base unit via the side rim. Ensure that 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 with 70% EtOH if the device has not been used for over three days.
- Clean the device using only the methods specified.
- Do not use any solvent-based cleaning products.
- Clean all parts that are in contact with 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.

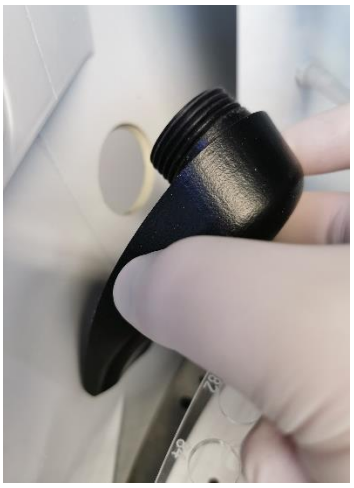
9.6.3 Nozzle

1) Unscrew and remove the outer union nut from the nozzle.


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

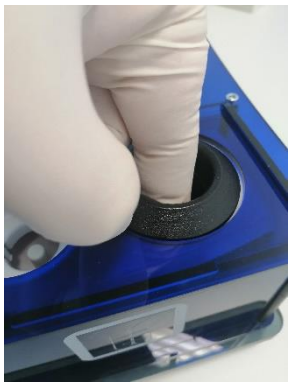
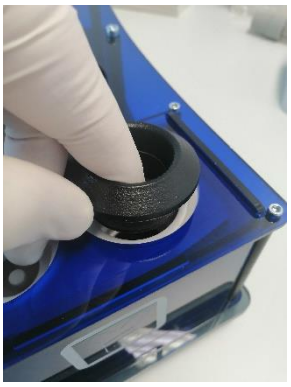




3) Rinse or flush the nozzle with 70% ethanol and clean the surface to prevent any contaminations. Let it dry for several minutes before inserting the nozzle again. It is recommended to clean the nozzle weekly together with the other accessories according to their maintenance schedule.

9.6.4 Reducing sleeve Humidifier (REF # 20160308)

1) To remove the **Reducing Sleeve Humidifier (REF # 20160308)** from the top of the humidifier, just pull it upwards to take it out.

2) For cleaning the reducing sleeve, just wipe off the surface using 70% ethanol and let it dry for several minutes before inserting again.

3) It is recommended to clean the reducing sleeve weekly together with all the other accessories according to their maintenance schedule.

9.7 Take the device out of service

The device must be flushed in accordance with section 9.1 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 9.3) and disinfected (Section 9.4). The unit must be stored in a dry place under storage conditions.

9.8 Disposal

Before the proper disposal or shipment of the device, make sure that the device is cleaned and disinfected in accordance with sections 9.3 and 9.4. 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.

9.9 Dealing with potentially hazardous material

If equipment conforming to IEC 61010-1 is used with equipment conforming to this standard, and if there is a hazard due to moisture or liquids in case of equipment spills, container breakage and similar malfunctions of any consumables, please clean and disinfect the affected area 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 agents (e.g. 70% EtOH) recommend by AESKU.Diagnostics GmbH & Co. KG to avoid any damage to the device and/or equipment. For cleaning and disinfection advise or replacement of broken material please contact your local distributor or AESKU Customer Support Team.

10 General and technical specifications

- **Sample capacity:**

  With barcode: up to 190

- **Dilution Plates:**

  2x 96 well micro titer plates, F-bottom

- **Dilution capacity:**

  IFA: 192 positions

  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:**

  230 W

- **Fuse:**

  2xT4A/250V; 5x20mm

- **Voltage range:**

  Input: 100 - 240 VAC

  Output: 24 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 64 cm x 58 cm (depth x width x height) / 29.5” x 25.2” x 22.8”

  29kg / 64lbs (weight)

- **Barcode scanner:**

  1D Barcode Scanner for Sample/Reagent Racks and Sample Identification

- **Humidifier (if ordered with REF.HTC-1001)**

  Beurer™ LB12

  Size approx. 12 x 7.5 x 9 cm

  Main voltage / frequency 24 V DC / 50/60 Hz

  Rated power 12W

  Ultrasonic frequency 1.7 MHz

  Evaporation output max. 80ml/h

11 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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