



# Automation

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As a manufacturer of reagents, we fully understand the automation needs faced by end-users when handling diagnostic products on a daily basis. Whilst there are automation companies with great engineers, we believed they sometimes lacked the user's experience. Understanding these needs has encouraged us to create state-of-the-art instruments. Our systems are designed to fulfill the highest usability requirements, making our instruments practical and easy to use. Located directly by our reagents company, **AESKU.SYSTEMS** was created to develop products that adapt to the realities of the laboratory.

Based on our fundamental principles, the instrumentation company **AESKU.SYSTEMS** was founded to bring you automation tools that really simplify your work.

“

*Our products are very easy to use and reflect our understanding of your automation needs and the perfect balance between science and engineering.*

”

Starting with the right user requirement specifications at the beginning of a project is what differentiates our instruments at the end.

**AESKU.DIAGNOSTICS**, **AESKU.SYSTEMS** and **AESKU.INC** are listed at the FDA. For 510K cleared products please visit our homepage [www.aesku.com](http://www.aesku.com) and click on „**FDA cleared Product List**“ for each of the product lines.





# AESKU.SYSTEMS

THE DIAGNOSTIC AUTOMATION COMPANY



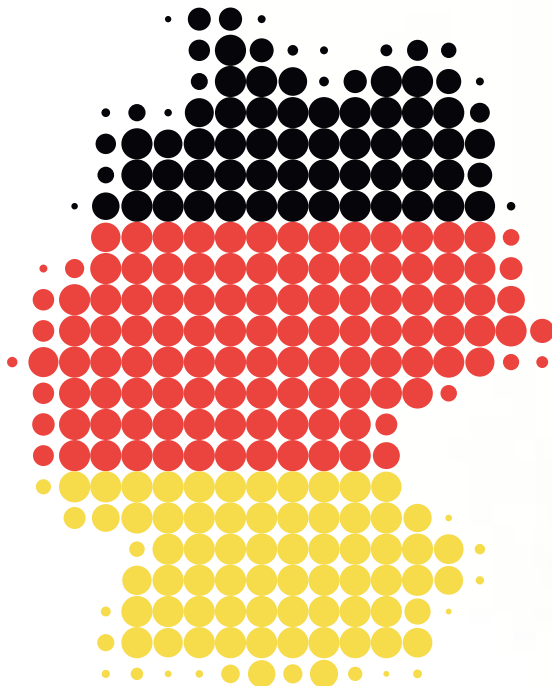
**AESKU.SYSTEMS** – part of **AESKU.GROUP** – is dedicated to meeting laboratories' need to automate their workflow. Here, our scientists and engineers unite to make devices specifically adapted to the clinical laboratory.

Fully manufactured in our facilities in Germany, the first instrument from **AESKU, HELMED®**, has a number of unique and patented features focusing on usability and flexibility – proved by its acceptance and demand from laboratories all over the world.

**AESKU** now offers complete automated solutions, expanding the **HELMED®** family with **HELIOS®** and **HELIA®**, thus meeting the needs of all types of laboratories.

The **HELIOS®** AUTOMATED IFA SYSTEM is an automated immunofluorescence processor with integrated image capturing by a built-in fluorescence microscope.

**HELIA®** is an automated analyzer for line immunoassays. The **HELIA®** system is able to perform all immunoblot processing steps, and due to an integrated camera module, is able to read and report immunoblot results.



## Quality – Made in Germany

All our devices are developed & produced in our location in Wendelsheim – Germany.



RESEARCH & DEVELOPMENT

PRODUCTION

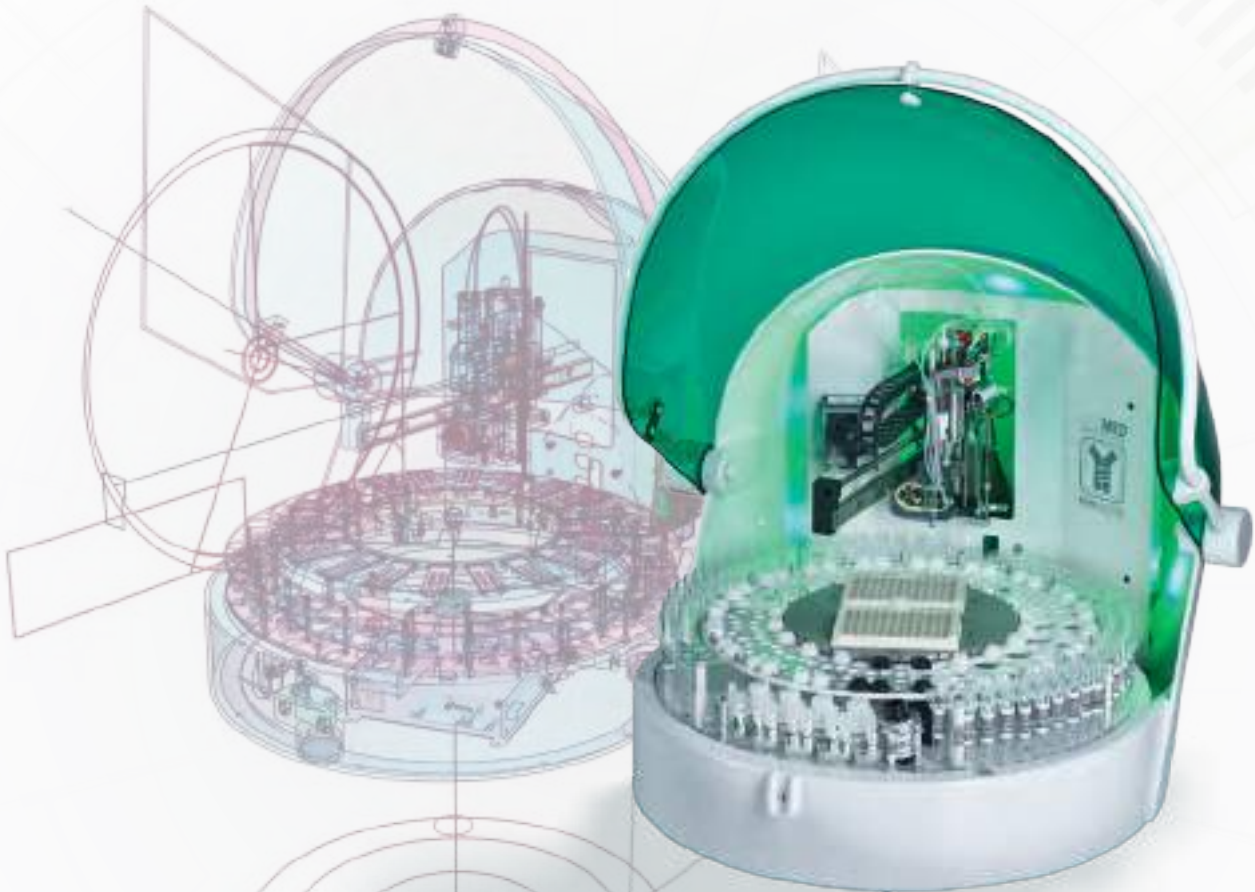
ON-SITE  
INSTALLATION

## From DNA to Kit to Complete Automation

**AESKU.SYSTEMS** is currently developing a number of projects in conjunction with the **AESKU.DIAGNOSTICS** R&D Department, to provide patient results by simply pushing a button.

# HELMED®

ADAPTS TO YOUR LAB NEEDS



The **HELMED®** offers the three major immunology lab technologies (ELISA, IFA & BLOT) on a single revolutionary platform.

With its 3 needle system, **HELMED®** washes each well individually, avoiding cross-contamination from washing by flooding.

Needle height, dispensing speed and cycles can be adjusted to achieve an automated, consistent and gentle wash. Washing & reagent addition are performed simultaneously, eliminating dry substrates.

Precise calibration ensures reagent addition is accurate with a low dead volume.

Finally, well-by-well time management ensures consistent incubation times to prevent plate drift.

# ADAPTS TO YOUR NEEDS

## **Innovative Traceability**

**HELMED**<sup>®</sup> was the first machine to introduce a built-in barcode reader allowing automated detection and scanning of sample tube IDs eliminating transcription errors. Communication between Lab Information System (LIS) and instrument can be done directly or via our middleware **AESKU.LAB**.

## **Outstanding reagent capacity and utility**

**AESKUBLOTS**<sup>®</sup>, **AESKULISA**<sup>®</sup> and **AESKUSLIDES**<sup>®</sup> reagent, calibrator and control vials fit directly into the corresponding positions.

## **Safe handling and secure results**

**HELMED**<sup>®</sup>'s green cover automatically locks before the assay starts running. This creates a perfect reproducible environment inside the machine and avoids interference from external factors.

## **720 tests per square meter**

## **Fewer consumables, more free space**

**HELMED**<sup>®</sup> has not only a minimal footprint, but also has a sample requirement as low as 50  $\mu$ L. The amount of reagents used and the dead volume are considerably reduced, as are consumables like plates. Due to its needle technology, no plastic tips are needed.

## **Plug & Play modular system**

**HELMED**<sup>®</sup> is capable of performing three major lab techniques: IFA, ELISA and BLOT. This is achieved by simply changing racks and rings and using dedicated software. The proprietary built-in barcode scanner allows automatic identification of the correct rack. Up to 3 machines can work in parallel with one computer.

## **Revolutionary design with the smallest footprint available**

**HELMED**<sup>®</sup>'s compact design is intended to give the technician direct and easy access to all working areas. The main instrument parts are magnetically mounted, allowing easy and fast replacement by technical service or by the operating technician. An optimal footprint (57 cm x 65 cm x 75 cm) combined with the light weight (28,5 kg) makes it suitable for any lab space.

# AESKU.READER

## ELISA MTP EXTERNAL READER

The **AESKU.READER** Software is specially designed to communicate with the **HELMED**® ELISA software and improve the **AESKULISA**® workflow on the **HELMED**®. This software manages the data of the **HELMED**® ELISA and the results of the **AESKU** Absorbance Microplate Reader (**AESKU.READER**).

In addition, the **AESKU.READER** & software can be used independently of the **HELMED**® system.

### How does it work?

1. Place the processed microtiter plate in the **AESKU.READER**.
2. Start the **AESKU.READER** Software to automatically transfer the plate layout from the **HELMED**® ELISA software.
3. Begin automatic reading and calculation of the **AESKU.READER**.
4. Review the results.
5. Select report and print or save automatically.



# ELISA MTP EXTERNAL READER

## What are the benefits?

### Full traceability

Using the plate layout from the **HELMED**<sup>®</sup> ELISA processor will carry all the information from your sample, lots, automatic processing data etc.

### User friendly

**AESKULISA**<sup>®</sup> tests are preprogrammed for the **HELMED**<sup>®</sup> ELISA software and **AESKU.READER** software.

### Digital results

Define and select your report style and view or print the results.

### Multi-channel reader

Tightest specifications during microplate reading: Precise, accurate and repeatable.

### Automated calibration

The on-board diagnostic self-test and calibration test plate makes it easy to confirm and document reader performance.

## AESKU.READER

The **AESKU Absorbance Microplate Reader** can be linked to the **HELMED**<sup>®</sup> ELISA software, or used as a stand alone unit. The external software *Gen5<sup>TM</sup> Data Analysis Software* is included.

The *Gen5<sup>TM</sup> Data Analysis Software* offers a logical interface designed to easily flow from reading parameter, to plate layout to powerful data reduction, and finally to flexible data output options. The results of this intuitive design, including the exclusive StepWise<sup>TM</sup> protocol and data reduction tools and the power of Gen5's data reduction will be evident in increased laboratory efficiency.

Ref No.	Product Name	Description
<b>HARDWARE</b>		
REF.RDR-1000	ELISA MTP External Reader Unit	external ELISA Plate Reader, <i>Gen5<sup>TM</sup> Data Analysis Software</i>
<b>SOFTWARE</b>		
REF.HEL-7004	<b>HELMED</b> <sup>®</sup> ELISA v1.0 sw Module2 EIA Reading	including Dongle for communicating with the <b>HELMED</b> <sup>®</sup> ELISA Software

# HELMED® IFA

ADAPTS TO YOUR LAB NEEDS

## Open format

The HELMED® supports slides from different manufacturers, no matter the thickness, number of wells, or format.

## High throughput

The HELMED® processes up to 190 samples or up to 20 slides and up to 4 different tests in one single run.

## Improved traceability

Automated detection and scanning of sample tube ID's. Reduces labor and errors/equivocal results by automating all IFA processing steps.

## Flexible protocol programming

The HELMED® allows the user to define conjugate / counterstain or multi-step reagent addition immediately after a specific well is washed.

## Compact footprint

Width 65 cm • Height 57 cm  
Depth 75 cm • Weight 28,5 kg



# 190 REASONS TO AUTOMATE YOUR WORKFLOW

## Small size – high throughput

Despite its small footprint, **HELMED**<sup>®</sup> is able to process up to 190 different samples in one single run.

## Open format

**HELMED**<sup>®</sup> supports slides from different manufacturers independently of thickness, well number, or format.

## 4x4 format – more slides and tests

Up to 20 slides from 4 different tests with 4 different substrates can be processed in just one run.

## Screening and titration with just one worklist

**HELMED**<sup>®</sup> allows dilution ratios from 1:1 to 1:10240 in 192 available dilution positions. One step dilution ratios range from 1:1 to 1:160; greater dilutions are performed in two steps.

## 720 tests per square meter

## Flexible protocol programming

The multi-step programmable software allows the user to define conjugate/counterstain or multi-step reagent addition immediately after a specific well is washed (not having to wait for the whole slide to be washed).

## Unparalleled reproducibility

The total sample and reagent volume is dispensed across multiple pre-set points to provide optimal sample and reagent distribution. This is especially important for tissue sections and large format wells. The wash-by-cycle system avoids cross-contamination.

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### TECHNICAL SPECIFICATIONS FOR IFA PROCESSING

<b>Sample capacity</b>	IFA: up to 190 samples, with or without barcodes
<b>Sample identification</b>	Built-in multi-type barcode reader for sample detection and identification
<b>IFA slide capacity</b>	Up to 20 slides
<b>IFA test capacity</b>	Up to 4 different tests with 4 different substrates and 4 different conjugates per run
<b>Samples &amp; reagents support</b>	Customized multi-format extractable racks
<b>Slide support</b>	26.1 x 76.1 mm (25 mm and 26 mm slide thickness within the same run)
<b>Standard sample rack tube size</b>	75 x 13 mm diameter tubes, other sizes upon request

## Semi-automated and programmable IFA steps

- Sample dilutions are prepared on a microtiter plate, no pre-dilution tubes required.
- Automatic transfers from the microtiter plate to the slides.
- Individual-well time management ensures consistent incubation times.
- Washing by cycles – avoids cross contamination from washing by flooding. Needle height, dispensing speed and cycles can be flexibly adjusted to achieve an automated, consistent and gentle wash.
- Counterstain addition is managed with precise incubation times.
- Automatic mounting medium addition is possible only with our specially formulated **AESKUSLIDES®** mounting medium.



**HELMED® IFA**  
ADAPTS TO YOUR LAB NEEDS



Ref No.	Product Name	Description
<b>DEVICE</b>		
REF.HEL-1000	<b>HELMED® IFA</b> Processor Kit	<b>HELMED® IFA</b> Processor, Standard sample and reagent racks, IFA Processing software, Starter kit, Wash bottles, Waste bottle, Power cable, USB cable, Instruction and Service manual, Cleaning wire
<b>SOFTWARE</b>		
REF.HEL-3610	IFA Software	IFA Processing software



## MOTIC LED Microscope

The **MOTIC** is a microscope for immunofluorescence applications using the latest LED light source technology. This environmentally friendly alternative brings many advantages over the old mercury/xenon lamp based microscopes:

LED'S GO<sup>®</sup>.Cam



### Quick start

Motic LED microscopes do not need to be warmed-up and since they have no lamp, there is no need to log the lamp operation times. Simply switch on, read and turn off.

### Cost efficiency

This affordable lamp-free LED microscope has over 30.000 hours of lifetime, compared to the average 250 hours mercury lamp. To achieve the same lifetime in a mercury based microscope, the lamp would need to be replaced 120 times.

### Consistency

Although mercury lamps have an average life time of 250 hours, light intensity decreases towards the end of the lamps life which could result in misleading interpretation of results. LED light intensity is much more stable and for years you will observe no differences. Resulting in stable and comparable results over a number of years.

### Increased performance

A great signal-to-noise ratio is enhanced by the LED light source as it emits a highly efficient spectrum at the desired bandwidth. Photo bleaching is minimized by variable light control adjustment of illumination intensity.

Ref No.

Product Name

Description

### DEVICE

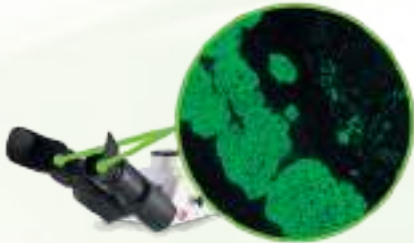
REF.LED-1002

**MOTIC** LED Fluorescence microscope

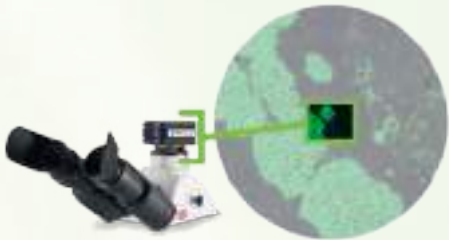
MOTIC Trinocular LED microscope (10x, 20x, 40x and 60x)

# MOTIC LED MICROSCOPE AND LED'S GO.CAM

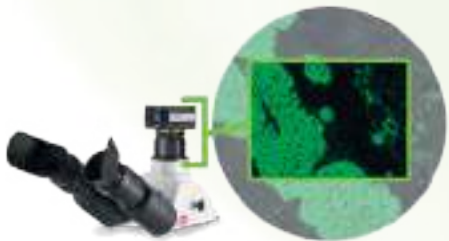
## Improve your field of view with the Optical Correction Adaptor



Field of view through the eyepieces.



Field of view through trinocular head without optical correction.



Field of view through trinocular head with its adaptor. Other microscopes are only able to show about 50% of the field of view.

## LED's GO.CAM Camera

Connect this 5MP camera to the MOTIC microscope and save images or record videos. The LED's **GO.CAM** software is included and allows you to view or acquire the following:

- single images (BMP, JPEG)
- sequences of single images (BMP, JPEG)
- image data streams (AVI)



## More than just a microscope

- cost-effective, environmentally friendly and energy efficient
- ensures a constant light intensity
- brightfield and Immunofluorescence microscopy can be performed with one microscope
- no more warm-up time
- lower sample loading thanks to variable regulation of light intensity
- easy handling

Ref No.	Product Name	Description
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### DEVICE

REF.LED-3002	LED'S <b>GO.CAM</b>	USB CMOS Camera, 1/2.5" Sensor, 2592x1944 resolution; LED's <b>GO.CAM</b> software included
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# HELMED<sup>®</sup> BLOT

ADAPTS TO YOUR LAB NEEDS

## Improved traceability

Automated detection and scanning of sample tube ID's, reducing errors and setup time.

## No sample pre-dilution

The HELMED<sup>®</sup> BLOT prepares dilutions directly in the trays – reducing time, costs and waste.

## Throughput & versatility

The HELMED<sup>®</sup> BLOT processes up to 40 samples / 40 strips from up to 9 different tests in one single run.

## Compact footprint

Width 65 cm • Height 57 cm  
Depth 75 cm • Weight 28,5 kg

## Optimal incubation procedure

Consistent incubation and washing time for every single strip is ensured by the system.



# REPRODUCIBILITY AT A NEW LEVEL

## Complete workflow

Confirm your IFA screening in the same instrument using the BLOT module.

## No sample pre-dilution required

Dilutions are prepared directly in the trays.

## Reproducibility across all strips

Time management of the **HELMED**<sup>®</sup> BLOT ensures a consistent incubation and washing time for all strips tested.

## Great versatility

40 strips from up to 9 different tests can be run at the same time.

## Reagent optimization

**AESKUBLOTS**<sup>®</sup> reagents are optimized for **HELMED**<sup>®</sup> BLOT. A perfect fit in the reagent racks and offering the lowest „dead volume“ on the market ensure the best experience and minimum hands on time.

## 120 tests per square meter

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### TECHNICAL SPECIFICATIONS FOR BLOT PROCESSING

<b>Sample capacity</b>	40 samples
<b>Sample identification</b>	Built-in multi-type barcode reader for sample identification
<b>BLOT strip capacity</b>	Up to 40 strips
<b>BLOT test capacity</b>	Up to 9 different assays per run
<b>Samples &amp; reagents support</b>	Customized multi-format extractable racks
<b>Tray support</b>	5 x 8 strip trays
<b>Standard sample rack tube size</b>	75 mm x 13 mm diameter tubes, other sizes upon request

## Semi-automated Aeskublots® processing steps

Sample dilutions are prepared in the trays, no pre-dilution tubes required.

- 40 strips and 9 different tests can be run at once.
- Reagents are transferred directly from racks to trays.
- Instrument time management ensures consistent incubation and washing times, for every single strip.
- The **HELMED®** BLOT communicates with **AESKU.SCAN** software for automated evaluation.
- „Plug & Play“ design makes it easy to switch from IFA or EIA mode to BLOT mode in less than 1 minute.



**HELMED® BLOT**  
ADAPTS TO YOUR LAB NEEDS

Ref No.	Product Name	Description
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### DEVICE

REF.HEL-8000	<b>HELMED® BLOT</b>	<b>HELMED® BLOT</b> Processor kit, Standard Sample and BLOT Reagent racks, BLOT Processing software, Starter kit, Wash bottles, Waste bottle, Power cable, USB cable, Instruction and Service manual, Cleaning wire
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### UPGRADE

REF.HEL-8002	<b>HELMED® BLOT</b> Upgrade	BLOT processing software, BLOT ring, Blot middle ring, BLOT reagent rack, Sample D13 / H75 / 1-50 for existing HEL-1000 ( <b>HELMED®</b> IFA Processor) or HEL-7000 ( <b>HELMED®</b> ELISA Processor)
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# AESKU.SCAN

SCANNING AND INTERPRETATION SOFTWARE FOR **AESKUBLOTS**®

**AESKU.SCAN** is a software designed specifically for analysis of **AESKUBLOTS**® (Immunoblot) reagents. This software uses the latest technology and provides a very accurate interpretation of the image with a highly sensitive detection of band intensity.



## How does it work?

1. Create an electronic worklist in just a few seconds.
2. Print the worklist template (barcoded with ID for automatic recognition after scanning).
3. Attach the **AESKUBLOTS**® immunoblot strips to the above template and then scan it.
4. Review the automatically generated results.
5. Select report and print or save electronically.

## What are the benefits?

### Standardization

**AESKU.SCAN** brings consistency to the laboratory thanks to the automated interpretation process.

### Accuracy

High sensitivity in band detection combined with outstanding correlation with the cut-off ensures accuracy of results.

### Easy to Use

The worklist is prepared in seconds and works securely thanks to the barcoded worklist template function.

### Improve Lab Accreditation

Improve your lab efficiency, standardization and accreditation with this software developed in accordance with IVDD 98/79/EC.

Ref No.	Product Name	Description
<b>SOFTWARE</b>		
REF.HEL-8001	<b>AESKU.SCAN</b>	Blot Interpretation Software <i>Hardware not included</i>
<b>DEVICE</b>		
REF.HEL-8004	SCANNER	USB / Flat-bed scanner, Canon Scan LiDe 220 (REF.HEL-8004) validated for AESKU.SCAN

# WORKFLOW



Process Samples



Create Worklist



Print Worklist Template



Affix Strips and  
Scan Worklist Template



Generated Automatically  
Interpreted Results



Print Report /  
Save as PDF /  
Save to Database

## HELMED<sup>®</sup> HTC

(Humidity temperature controlled)  
INFECTIOUS SEROLOGY & AUTOIMMUNITY IN ONE SYSTEM

### Humidity controlled environment

The HTC provides optimal humidity over long time periods.

### Improved traceability

Automated detection and scanning of sample tube ID's. Reduces labor, errors and equivocal results by automating all HELMED<sup>®</sup> HTC processing steps.



### Throughput & versatility

The HELMED<sup>®</sup> HTC processes up to 190 samples or up to 20 slides and up to 4 different tests in one single run.

The HELMED<sup>®</sup> HTC Edition (Humidity & Temperature Controlled) is a special HELMED<sup>®</sup> version designed with chassis modifications that include tight seals and a deep ring to hold distilled water.

IFA incubations at temperatures of up to 37°C in a moist chamber optimizes reactions and eliminates the risk of sample evaporation.

By maintaining the optimum humidity and temperature levels Infectious Serology slides can also be automated as the substrates are not dried during this process.

# HUMIDITY & TEMPERATURE CONTROLLED

## Open format

The HTC supports slides from different manufacturers, no matter of the thickness, number of wells, or format.

## No sample pre-dilution

The **HELMED®** HTC prepares dilutions directly in the trays – reducing time, costs and waste.

A

## Deep ring

To be filled with a sponge and distilled water in order to keep humidity during incubation at optimum levels.

B

## Tight seals

Special chassis modification brings improved humidity and temperature distribution in the chamber.

## 37°C Incubation

For IFA incubations up to 37°C and up to 2h. The ring moves every 10 seconds to guarantee temperature homogeneity.

**720 tests per square meter**

## Compact footprint

Width 65 cm • Height 57 cm  
Depth 75 cm • Weight 28 kg

Ref No.

Product Name

Description

**DEVICE**

REF.HEL-1600

**HELMED®** HTC

Humidity & Temperature Controlled IFA Processor

# HELMED®

ADAPTS TO YOUR LAB NEEDS



**HELMED® IFA: UPGRADE KIT BLOT**  
REF.HEL-8002



**HELMED® BLOT: UPGRADE KIT ELISA**  
REF.HEL-7002



**HELMED® BLOT: UPGRADE KIT IFA**  
REF.HEL-1003



**HELMED® IFA: UPGRADE KIT ELISA**  
REF.HEL-7001

All Upgrade kits will be delivered in a box, ready to use.

The Upgrade kit contains all racks, holder rings and associated software needed to convert the appropriate **HELMED®** module.

Our “Plug & Play” design makes it easy to switch from the IFA mode to the ELISA or Blot mode in less than 1 minute. Doing so, one system can be used for all 3 configurations of the **HELMED®** family (IFA, ELISA, BLOT).

To switch from one module to another some minor configuration changes.

# UPGRADE KITS READY TO USE

Depending on your installed **HELMED®**, the following Upgrade Kits are available:

Ref No.	Product Name	Description
<b>UPGRADE</b>		
REF.HEL-1003	<b>HELMED® BLOT</b> UPGRADE KIT IFA	Standard Sample Racks 75x13mm (1-53 & 54-106), Slide holder ring IFA, MTP holder ring IFA (silver edition), IFA processing software  <i>Must be ordered separately:</i> <b>MOTIC</b> LED Fluorescence microscope (REF.LED-1002) LED's <b>GO.CAM</b> incl. capturing software (REF.LED-3002) Software <b>HELPS+</b> V3.1 (REF.HPS-2002)
REF.HEL-7002	<b>HELMED® BLOT</b> UPGRADE KIT ELISA	Sample Rack 75x13mm (51-100), reagent rack 20ML / 4ML, Slide holder ring complete, MTP holder ring, ELISA processing software  <i>Must be ordered separately:</i> <b>HELMED®</b> ELISA v1.0 software Module2 EIA Reading (REF.HEL-7004) ELISA MTP External Reader Unit (REF.RDR-1000)
REF.HEL-7001	<b>HELMED® IFA</b> UPGRADE KIT ELISA	Sample racks 75x13mm (1-50 & 51-100), reagent rack 20ML / 4ML, Slide holder ring complete, ELISA processing software  <i>Must be ordered separately:</i> <b>HELMED®</b> ELISA v1.0 software Module2 EIA Reading (REF.HEL-7004) ELISA MTP External Reader Unit (REF.RDR-1000)
REF.HEL-8002	<b>HELMED® IFA</b> UPGRADE KIT BLOT	Sample rack 75x13mm (1-50), BLOT reagent rack, BLOT tray holder ring, BLOT cam ring (inner), BLOT processing software  <i>Must be ordered separately:</i> <b>AESKU.SCAN</b> Software + Romlock (REF.HEL-8001) Flat-bed scanner, Canon Scan LiDe 220 (REF.HEL-8004)

# HELIOS<sup>®</sup>

HELMED INTEGRATED OPTICAL SYSTEM

[WWW.WHATISHELIOS.COM](http://WWW.WHATISHELIOS.COM)



**HELIOS<sup>®</sup>** is a revolutionary IFA automation system that completely automates processing and image capture, freeing up the experts' time to actually evaluate the images.

It offers unparalleled process control, traceability, standardization, ease of use, and maximum efficiency by requiring technical intervention only for expert review.

Load your samples and reagents, review your images. It's as simple as that.

# HELMED INTEGRATED OPTICAL SYSTEM

## Compact footprint

Width 65 cm • Height 57 cm  
Depth 75 cm • Weight 33 Kg

## Sample barcode reader

The sample barcode reader ensures sample traceability and eliminates time and error associated with manual entry of long patient ID numbers.

## IFA processing

Based on the **HELMED**<sup>®</sup> system, the **HELIOS**<sup>®</sup> system is capable of performing all IFA process steps automatically. It includes a feature for imaging through the mounting medium, enabling complete processing prior to evaluation of result.

**720 tests per square meter**

## Slide barcode reader

Slide barcode reader ensures slide traceability. **AESKUSLIDES**<sup>®</sup> are barcoded with all necessary information (reference, lot, etc.) including a unique serial number. This feature ensures traceability for the whole process, aiding compliance with laboratory accreditation requirements.

## Built-in LED microscope

The integrated microscope (incorporating Nikon-based optics) is complemented by the **AESKU** engineered motor-arm ensuring both accuracy and speed.

## Image capturing

The built-in camera uses high-tech autofocus algorithms so that clear pictures from the wells are gathered and stored according to user specifications.

# HELIOS®

HELMED INTEGRATED OPTICAL SYSTEM

## Maximize Time Management

The unique hardware capabilities of the **HELIOS®** are complemented by a well developed and lab proven software. It empowers you to not run the **HELIOS®** as a black box machine, but to fully integrate the **HELIOS®** into your established IFA workflow.

- Up to 190 samples, up to 20 slides, up to 4 different assays per run.
- Sample dilutions are prepared on a microtiter plate, no pre-dilution tubes required.
- Individual well time management ensures consistent incubation times.
- Thanks to the **AESKU** patented 3 needle assembly, washing by cycles avoids cross contamination compared to washing by flooding.
- Automatic mounting medium addition is possible with our specially formulated **AESKUSLIDES®** mounting medium.
- No need for coverslips or transfer of slides, reading will start automatically.
- Pre-classification suggestion – user confirms results and selects follow up tests.
- Confirmation is a breeze with a side-by-side image library for easy comparison.
- "Show all results" function displays all images and results collected for the same sample ID in one screen.



### Notification

The new notification system informs the user by SMS or Email about important **HELIOS®** status updates, like errors or the finalization of the complete **HELIOS®** process.



# INTUITIVE SOFTWARE



## IFA processing & image capturing

The **HELIOS**<sup>®</sup> processor is capable of performing all IFA processing and image capturing automatically.



## IFA processing

The **HELIOS**<sup>®</sup> uses the robust and widely adopted **HELMED**<sup>®</sup> IFA software, which is compatible with most IFA test kits, regardless of their manufacturer. However, non-**AESKU** slides will be processed without reading.



## Image capturing

This module starts automatically after slide processing is complete or can be used independently from other modules. Well imaging positions and image number is user configurable for all **AESKUSLIDES**<sup>®</sup> tests, prior to reading. A pre-classification suggestion (+ or -) is performed for each **AESKUSLIDES**<sup>®</sup> ANA HEp-2, ANCA and nDNA (via activated DNA Pattern Plus) image.



## Result confirmation

All IFA images are organized for patient by patient analysis, which is complemented by the **AESKU** pattern library. The "sample overview" option shows all results associated with each sample, simplifying multi-substrate testing. The "show all negatives" option displays all pre-classified negative results, helping save reporting time by automatically releasing all negative results with a simple click. Activating the pattern recognition tool lets the **HELIOS**<sup>®</sup> autonomously suggest the most probable IFA patterns for HEp-2 and ANCA. This module can be provided independently of the main software.



## Configuration

The configuration module enables authorized users to define the pre-classification criteria.



## LIS

This module sends all classified results to the LIS. Now, the user is able to send results to the LIS during the image capturing process, too.

ASTM standard connection configuration is done via a user-friendly interface.

Ref No.	Product Name	Description
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### DEVICE

REF.IOS-1000	<b>HELIOS</b> <sup>®</sup> Automated IFA System	Automated IFA Processor and Reader, inclusive All-in-One-PC, latest <b>HELIOS</b> <sup>®</sup> software version, Starter kit, Starter package, 20x Nikon objective (10x system available upon request), Rack reagent 100 ml / angular 20 ml, Power cords, USB cord, Wash bottles, Waste bottle, Cleaning wire, Standard sample rack*, Instruction manual * <i>'Universal'</i> multi-rack and non-standard racks available upon request.
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## Estimated Endpoint Titer (EEPT)

Change the way you titer – make it easier to find the endpoint while reducing dilution steps. The endpoint titer is defined as the highest dilution in which staining intensity is detectable, and is an important indicator for classification of immunofluorescence images. The **HELIOS®** EEPT Plus offers the possibility to estimate an endpoint titer for wells that were pre-classified as positive. Using this estimation, the next dilution steps can easily be selected during the user classification process.



Available under the screening mode.

Ref No.	Product Name	Description
---------	--------------	-------------

### FEATURE

REF.IOS-2002	<b>HELIOS®</b> EEPT	Estimated Endpoint Titer add-on
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*The **HELIOS®** EEPT tool is a pre-installed option. Activation only on customer request – activation key is sold separately.*

## Integrated Pattern Knowledge Database

The **HELIOS®** integrated library allows the user to compare their own images with reference images of the most clinical relevant patterns. This feature is extremely helpful in a daily laboratory routine and also an excellent education tool. The library covers all the **AESKUSLIDES®** IFA line.

Recently the **HELIOS®** library was updated, with the inclusion of more patterns and according to the ICAP\* classification.

\*ICAP (International Consensus on ANA Patterns) (<https://www.anapatterns.org>)

# FEATURES – MORE THAN EVER

## Pattern Recognition (PR)

**Add-ons to recognize most common patterns.** The pattern recognition add-ons let the **HELIOS®** autonomously suggest the most probable IFA pattern in the captured IFA images. The pattern recognition add-ons are available for ANA HEp-2, ANCA and nDNA.



Ref No.	Product Name	Description
<b>ADD-ON</b>		
REF.IOS-2101	<b>HELIOS®</b> PR ANA	This add-on is able to recognize the following ANA HEp-2 IFA patterns: Centromere, Cytoplasmic, Homogenous, Nuclear membrane, Nuclear dots, Nucleolar, Speckled (granular).
REF.IOS-2102	<b>HELIOS®</b> PR ANCA	This add-on is able to recognize the following ANCA IFA patterns: P-ANCA, C-ANCA, unknown positive.
REF.IOS-2103	<b>HELIOS®</b> PR Pos /Neg nDNA	This add-on is able to discriminate positive/negative nDNA samples. <i>The <b>HELIOS®</b> Pattern Recognition tool is a pre-installed option. Activation only on customer request – activation key is sold separately.</i>

# HELIOS®

HELMED INTEGRATED OPTICAL SYSTEM

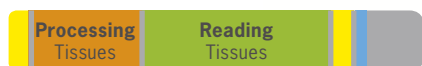
## Improved tissue processing

For high-throughput customers who wish to improve their workflow and can dedicate a **HELIOS®** just for tissue slides, the 10x objective is the optimal solution. Using the 10x objective will make image capture up to 5x faster and will increase the quality of stitched images.

The **HELIOS®** with the 10x objective is optimized for tissue slides (EMA & LKS) and will be strictly dedicated for these substrates.



10x **HELIOS®** dedicated to tissue-based assay (run with 20 slides / 5 wells)



Time for 100 tissue-based assays: 8h 50 min

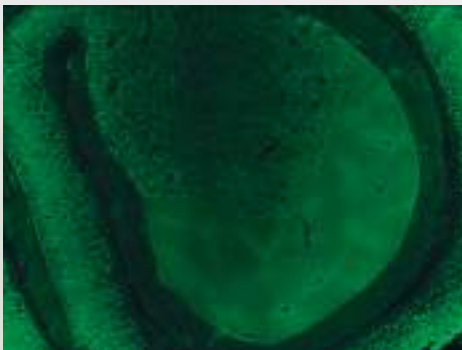
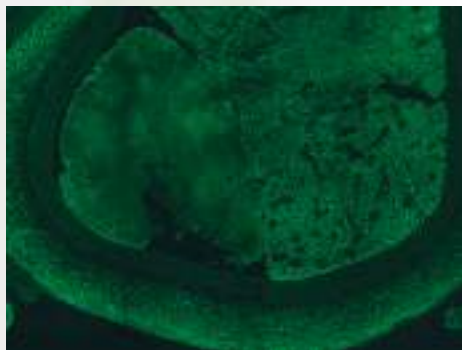
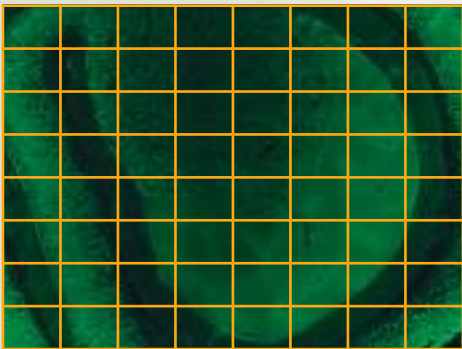

20x **HELIOS®** dedicated to tissue-based assay (run with 20 slides / 5 wells)



Time for 100 tissue-based assays: 28h 50 min

■ Hands-on Time  
 ■ Processing  
 ■ Reading  
 ■ Daily Maintenance

# COMPARISON 10x AND 20x OBJECTIVE

	HELIOS® 20x Objective	HELIOS® 10x Objective
<p><b>Stitched Overview</b> Same LKS slide, well and field of view</p>		
<p><b>Assembly Grid</b> Same LKS slide, well and field of view</p>	 <p><b>8x8 Images</b></p>	 <p><b>4x4 Images</b></p>
<p><b>Acquisition</b> (for stitched overview)</p>	15–18 minutes per well	3–5 minutes per well
<p><b>Substrate</b></p>	<p>LKS yes</p> <p>EMA yes</p> <p>ANA yes</p> <p>ANCA yes</p> <p>nDNA yes</p>	<p>LKS yes</p> <p>EMA yes</p> <p>ANA no</p> <p>ANCA no</p> <p>nDNA no</p>
<p><b>Single Images</b></p>	Up to 64 (max. 8x8 images)	Up to 16 (max. 4x4 images)
<p><b>Speed</b></p>	<p>Minutes per well 15–18</p> <p>Minutes per slide (5 well slide) 75–90</p>	<p>Minutes per well 3–5</p> <p>Minutes per slide (5 well slide) 15–25</p>



HUMIDITY TEMPERATURE CONTROLLED  
**HELIOS HTC**  
HELMED INTEGRATED OPTICAL SYSTEM



## What are the benefits?

### Modified housing

Allows to control process parameters like temperature and humidity.

### Transparent cover

Process monitoring is possible at any time.

### Improved temperature control

Temperature can be controlled as a process parameter.

### External humidifier

Humidity generated and introduced into the interior of the housing by an integrated air duct. It can be also controlled and adjusted as process parameter.

### Processing of infectious serological kits

Adjustable process parameters allow the processing of infectious serological kits as well as general IgM test kits requiring a process temperature of 35–37°C.

### 720 tests per square meter

### New Design

Based on the modern design of the HELIOS®, the HELIOS® HTC has a new color code – black and blue.

# HELIA®

HELMED LINE IMMUNOASSAY ANALYZER



**HELIA®** is an automated analyzer for line immunoassays. The **HELIA®** system is able to perform all immunoblot processing steps, and due to an integrated camera module, it is able to read and report immunoblot results. The **HELMED®** processor architecture and the **HELIA®** system unites proven lab automation with innovative immunoblot processing and reading technology. **HELIA®** was developed to simplify and automate immunoblot testing with a focus on standardization, minimal footprint and easy implementation.

**HELIA®** includes a pre-installed and configured space-saving All-in-one PC.

**AESKU** develops, designs and produces the **HELIA®** system and all associated reagents, offering complete control of the entire product life cycle.

# HELMED LINE IMMUNOASSAY ANALYZER

## Walk away

Total immunoblot automation from primary sample tube to result interpretation. The **HELIA**® system offers a complete walk-away solution.

## Proven reliability

The **HELIA**® uses **HELMED**® hardware-architecture, which has more than 800 installed systems.

## High resolution

Camera with a 5 megapixel resolution CMOS color sensor.

## LIS connection

Bidirectional connection with **AESKU.LAB** middleware and / or LIS.

## Sample barcode

Barcode scanner for automatic sample detection and identification.

## User friendly software

**HELIA**® device software offers a sleek interface with a comprehensive workflow management suite and intuitive customization.

## Level detection

All conjugates, substrates, samples and sample buffers are checked before pipetting and all errors are logged.

## Faster

The multiplex technology yields up to 1600 results in 3.5 hours.

## High capacity

- Up to 9 different **AESKUBLOTS**® tests / lots per run
- 18 reagent positions plus 2 system liquids
- 5 trays each with 8 **AESKUBLOTS**® strips, up to 40 strips in total
- 120 tests per square meter

## Traceability

Complete tracking of entire immunoblot procedure.

## Compact footprint

Width 65 cm • Height 57 cm  
Depth 75 cm • Weight 31,5 kg

## Additional features

Minimal footprint • No consumables  
• Low sample dead volume (< 50 µl)

# HELIA<sup>®</sup>

HELMED LINE IMMUNOASSAY ANALYZER

Based on the acclaimed and widely adopted **HELMED<sup>®</sup>** platform **HELIA<sup>®</sup>** combines the **HELMED<sup>®</sup>** BLOT processor and **AESKU.SCAN** interpretation software in one automated system for **AESKUBLOTS<sup>®</sup>**.

- Up to 9 different **AESKUBLOTS<sup>®</sup>** tests / lots and 40 samples per run.
- Sample dilutions are prepared directly in each tray, no pre-dilution tubes required.
- Automatic aspiration of stop solution after run.
- No drying step before reading.
- Automatic image capture of each tray.
- Every strip is independently interpreted and displayed in the result overview.
- Scanner and available LIS interface offer seamless workflow and full traceability of results.
- Flexible software lets users easily find information and display results as they want them.



# SOFTWARE *SIMPLE & INTUITIVE*

The **HELIA**® device software is very user friendly. It offers a menu control panel with different toolbars (ribbons) for each menu option and easy user-management.



### Processing, image capturing & interpretation

combines all necessary steps to generate **AESKUBLOTS**® results. LIS connectivity and electronic worklists allow users to get started in a few clicks. All **AESKUBLOTS**® kit protocols are validated and provided.



### Image review

displays blot images. The user confirms quality, then releases them for automatic software evaluation.



### LIS connectivity

displays results for user validation. After review, results are sent to the LIS or to **AESKU.LAB** middleware.

Ref No.	Product Name	Description
<b>DEVICE</b>		
REF.LIA-1000	<b>HELIA</b> ® Automated BLOT System	Blot Immunoassay Analyzer with pre-installed and configured compact system ( <i>monitor with integrated PC</i> ), USB cable, Power cord(s), Wash bottles, Waste bottle, Calibration cup/blot, Cleaning wire, Software, <b>HELIA</b> ® Consumable starter kit, <b>HELIA</b> ® Instruction Manual EN, <b>HELIA</b> ® Quick Start Guide EN

# SQII



**SQII** is a fully automated two plate ELISA Analyzer based on the Dynex DS2 instrument\*, but customized for **AESKULISA**<sup>®</sup> reagents.

**SQII** is a fully walk-away system that quickly and easily processes two 96-well micro titer plates (MTP) and up to 4 different assays simultaneously (with **AESKULISA**<sup>®</sup> rack), featuring a user friendly interface, sample ID and reagent bar-code reading, and assay protocol and instrument self-diagnostics.

Versatile and truly innovative in its process simulation and ease of use, the **SQII** software (DS-Matrix) allows the integration of automation in your lab with confidence. The simple, graphical interface enables every lab technician to use the **SQII** with minimal training. The assay creator, with its drag-and-drop icons, leads you through the entire programming process, prompting you step by step, making assay set-up a breeze.

Did you miss a critical process step? **SQII** will let you know before you can move on.

\*Manufacturer: DYNEX Technologies, Inc., Sullyfield Circle Chantilly, VA 20151, USA; with the EC Representative: DYNEX Technologies, Inc., Yeoman Gate, Yeoman Way, Worthing, West Sussex, BN13 3QZ, UK

# AUTOMATED ELISA PROCESSOR

Optimize your lab routine with the **SQII** ELISA processing system and benefit from the wide range of standardized **AESKULISA**® tests available for all major autoimmune diseases and hemostasis.

**AESKULISA**® kits are designed to use the same test procedure and common reagents as much as possible to make the complex autoimmune testing routine – manually or automated – an easier task.

As an open system, **SQII** is capable of processing virtually any ELISA application – from clinical diagnostics, such as autoimmune, allergy and infectious disease, to food safety and drugs-of-abuse testing.

## Traceability

Give extra confidence to your workflow with a barcode scanner for sample identification.

## Maximum Accessory Space

- 100 barcoded sample positions
- 216 sample tips
- 20 reagent tips
- 96 dilution vessels in convenient 8 well strips
- 32 calibrator and control positions
- 1 large sample diluent bottle & 6 medium reagent bottles (**AESKULISA**® rack)
- 32 standard control vials (**AESKULISA**® rack)

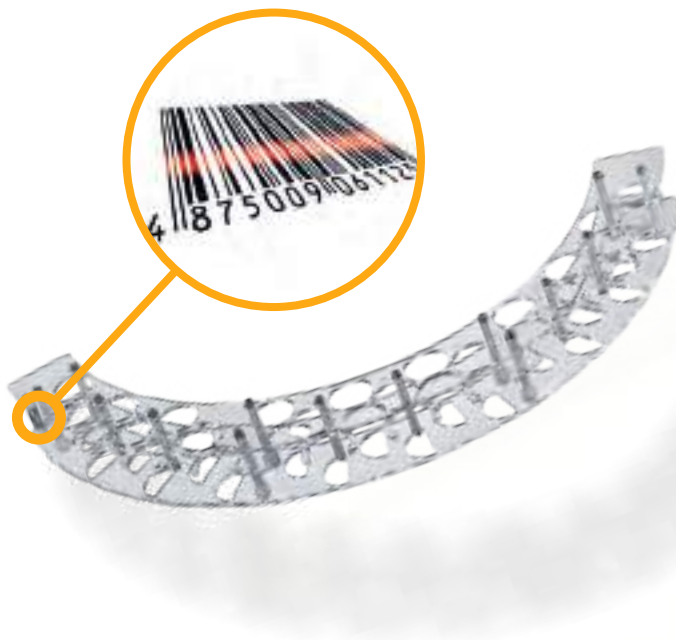
**AESKULISA** custom-made rack perfectly fits **AESKULISA**® reagent bottles so pour-off, relabeling, and storage of secondary containers is unnecessary.

## Compact footprint

Width 54 cm • Height 66 cm  
Depth 68 cm • Weight 48 kg

Ref No.	Product Name	Description
<b>DEVICE</b>		
REF.SQII-1000	<b>SQII</b> Automated ELISA Processor + Accessories	<b>SQII</b> automated ELISA processing system
20160142	<b>SQII</b> Dilution Strips	250 x 8-well
20160143	<b>SQII</b> Sample Tips, racked	4 x 108
20160144	<b>SQII</b> Reagent Tips, racked	4 x 108
20160145	<b>SQII</b> Reagent Bottles	20 ml (24 pack) for use with <b>SQII</b> / <b>AESKULISA</b> ® rack
20160005	Polyvial 1.5 ml	1.5 ml (48 pack) for use with <b>SQII</b> / <b>AESKULISA</b> ® rack
20160006	Polyvial 100 ml	100 ml (24 pack) for use with <b>SQII</b> / <b>AESKULISA</b> ® rack

## AESKU Reagent and Sample Racks



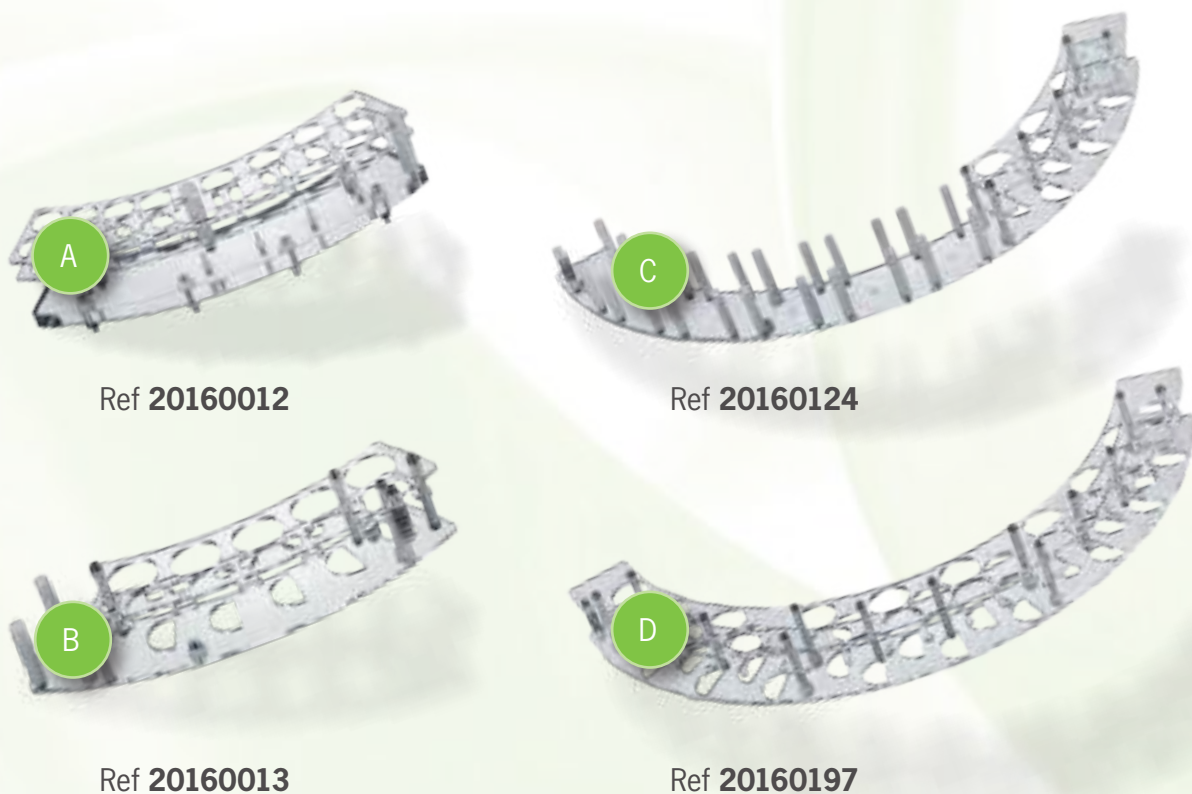
Sample and reagent racks are simply held in place by magnets and can be easily interchanged. All necessary information is contained on the rack's barcode which is read by the systems internal barcode reader.

Since our systems contain all the necessary programming, no technical service intervention is required.

Autoimmune Sample Amount	Small		Medium		Large		Very Large	
Samples per day	5	40	50	100	150	600	800	2000
Samples per year	1300	10400	13000	26000	39000	156000	208000	520000
AESKU Automation solutions			SQII					
			HELIOS®		x3		x4 x5	
	HELIA®		x2		x3			
	HELMED® IFA / EIA / BLOT				x2			
	Reader							

# AESKU REAGENT RACKS

**AESKU.SYSTEMS** offers 4 different reagent rack types to guarantee the highest throughput for your chosen system (method), whether you use the **HELMED®** for IFA, ELISA, or BLOT, **HELIOS®**, or **HELIA®**.



Ref No.      Product Name      Description

## ACCESSORIES

			VOLUME	HELMED® IFA	HELMED® ELISA	HELMED® BLOT	HELIA®	HELIOS®
<b>A</b>	20160012	Reagent Rack	20 ml / 4 ml	no	yes	no	no	no
<b>B</b>	20160013	Reagent Rack	100 ml / ANGULAR 20 ml	yes	no	yes	yes	yes
<b>C</b>	20160124	Reagent Rack	BLOT 100 ml	no	no	no	yes	no
<b>D</b>	20160197	Reagent Rack	BLOT	no	no	yes	yes	no



# AESKU SAMPLE RACKS

Ref No. 1+2    Product Name    Description

## ACCESSORIES

			Sample tube size (mm)	Positions Sample Rack 1	Positions Sample Rack 2	Total Sample Rack 1+2	HELMED® IFA Software: 3.1.0.29	HELMED® HTC Software: 2.0	HELMED® BLOT (only sample rack 1) Software: 1.0.0.17	HELIA® (only sample rack 1) Software: 2.0 R1	HELIOS® Software: 3.1R2
1	20160014	Sample Rack	75 x 12	1-53		106	yes	yes	no	yes	yes
	20160015				54-106				no		
2	20160016	Sample Rack	100 x 12	1-95		190	yes	no	no	no	yes
	20160017				95-190						
3	20160018	Sample Rack (Standard Rack)	75 x 13	1-53		106	yes	yes	yes	yes	yes
	20160019				54-106				no	no	
4	20160020	Sample Rack	75 x 13	1-95		190	yes	no	no	no	yes
	20160021				95-190						
5	20160022	Sample Rack	100 x 13	1-53		106	yes	(yes)**	no	yes	yes
	20160023				54-106					no	
6	20160122	Sample Rack	100 x 12	1-53		106	yes	(yes)**	no	yes	yes
	20160123				54-106					no	
7	20160209	Multi Rack	(55-100)	1-53		106	yes	yes	yes	yes	yes
	20160210		x (11-13)		54-106				no	no	

\*\*on request

**AESKU.LAB** not only provides the possibility to connect different instruments in one laboratory to an existing LIS installation, but to completely interconnect a multi-centric laboratory organization.

Multiple laboratories, multiple sites on different continents, single or multi LIS integration, are all a valid possibility with **AESKU.LAB**.

**AESKU.LAB** allows central management of all pre-analytical, analytical, post-analytical instruments, supporting global control of processes and guaranteeing a complete response for the connectivity demands of analytical laboratories. Although the complete range of **AESKU** instruments is already pre-configured, **AESKU.LAB** is not limited to **AESKU**'s machine environment.

**AESKU.LAB** enables efficient communication between the LIS and instruments, whether on site or distributed worldwide.



# CONNECTS YOUR LAB-ROUTINES

## **One installation of AESKU.LAB offers a multitude of possibilities for organizational connectivity**

- Client / Server based
- If LIS is offline, operability is maintained
- Multi Lab connectivity
- Multi Site connectivity
- Multi LIS connectivity
- Multi System connectivity

## **AESKU.LAB provides a flexible rule engine (workflow) to automate routine tasks**

- Rule based automatic decisions
- Rule based autoverification

## **Manage and review all relevant information, recent or stored, at a glance and in one place**

- Patient history
- Image management
- View all the sample's tests together in one screen

## **AESKU.LAB's sample sorting features help to organize and balance workload in advance**

- Sample storage / retrieval
- Sample tracking / routing

## **AESKU.LAB's QC uses the power of West Gard rules, Levey Jenning Charts & the users own QC**

- Real time alarm system
- Real time interactive QC

## **Real time dashboard**

- TAT (turnaround time) control
- User alarm system
- Worklist management
- Rerun/Reflex

## What are the benefits?

### Save costs

All **AESKU** instruments are already connected to **AESKU.LAB**. Establishing a single connection between **AESKU.LAB** and the LIS will network all instruments with your LIS via our middleware. If you add a new **AESKU** instrument to your lab, there will be no costs to connect it to the LIS as it will already be available via **AESKU.LAB**. **AESKU.LAB** is compatible with other compliant instruments and softwares.\*

### Save work

No need to connect each instrument individually to the LIS; all instruments will be automatically networked to the LIS by establishing a single connection between the **AESKU.LAB** and your LIS.

### Save time

Automate your routine tasks such as worklist creation, sample re-run, reflex, QC results verification, data transfer etc.  
Improve lab accreditation: Safer data handling, eliminate transcription of patient IDs or results.

### Improve transparency

The sample sorting features clearly shows status and location of all your samples, whether stored, in process or finished.

### Flexibility

Flexible rule engine allows you to configure your own workflow.

### Enhanced efficiency

Manage and review all relevant information, recent or stored, at a glance and in one place with the new patient history and image management.

*\*Development costs may apply*

## **AESKU.LAB rule engine**

**AESKU.LAB**'s flexible rule engine offers users a comprehensive, freely accessible tool to automate routine tasks such as worklist creation, re-runs, reflex testing etc. Due to its ease of use and programmability the rule engine enables users to customize **AESKU.LAB**'s inner workings to be in sync with their in-house specifications and norms.

**AESKU.LAB** is the software solution for you, if you need complete access to the entire feature set of this well-established and field-proven software, right now.

During the initial launch phase some advanced options of **HERA**s feature set (Quality control management, TAT evaluation, LIMS-like operations such as order entry and barcode printing) will not be available.

# CONNECTS YOUR LAB-ROUTINES



Ref No.

Product Name

Description

**SOFTWARE**

REF.LAB-1000

**AESKU.LAB**

Middleware; 1 x License;  
available in English, French, German, Italian, Polish  
and Spanish language

## HERA – THE AESKU LABORATORY AUTOMATION MANAGER

HERA is a **smart gateway** between analyzers and LIS.

It offers a **high degree of flexibility**, full **connectivity** and **result management** through its powerful **expert rules** system.

HERA is a scalable solution for controlling various degrees of complexity in the clinical laboratory, from a small laboratory to a **multi-site** and **multi-LIS** organization.



# CONVERTS DATA INTO INFORMATION

NEW

## Flexibility

- Multi-site, multi-Lab, multi-LIS
- Shared patient history
- User-right management

## Real time ergonomic dashboard featuring

- Instrument overview
- Sample state overview
- Test state overview
- Alarm panel
- Simple and intuitive user interface

## Result management

- Customizable real-time expert rule system
- Rerun, reflex, flag
- Patient history
- Image management

## Full connectivity

- Powerful communication engine
  - Connect to LIS (ASTM, HL7)
  - Connect to any analyzer

## Traceability

- Sample logging

## TECHNICAL HIGHLIGHTS

Web application

Touch screen GUI

Runs on real or virtual environments

Operating System independent (Linux/Windows)

Uses standard or custom communication protocols to connect to any LIS/device software

## HERA VALUE

VALUE	PROOF
<b>Easy to learn</b> <b>Easy to use</b>	<b>Usability tests</b> on customers
<b>Enhanced performance</b>	Compared to <b>AESKU.LAB</b> by testing various different workloads
<b>Made by AESKU</b>	AESKU dedicated team Continuous further development based on long-term roadmap and annually defined milestones
<b>Adaptable to various lab scenarios</b>	<b>Flexible</b> architecture <b>Rules</b> to build any lab workflow flowchart
<b>Improvement of laboratory accreditation</b>	Latest technology for more security in data management Compliance with GDPR requirements <b>CE</b> marking
<b>AESKU future platform</b>	<i>... for harmonization of instrument interface and operational control</i> Guided by market requirements AESKU solution concept
<b>Modular</b>	New 'self-contained' features can be developed as independent, activatable modules on the HERA platform (as QC module, TAT control, statistics, business intelligence)
<b>Portable</b>	Ready for standalone implementation ( <i>app</i> ) running on small and portable instruments as POC

**AESKU.LAB** is the software solution for you, if you need complete access to the entire feature set of this well-established and field-proven software, right now.

During the initial launch phase some advanced options of **HERAs** feature set (Quality control management, TAT evaluation, LIMS-like operations such as order entry and barcode printing) will not be available.

# CONVERTS DATA INTO INFORMATION



Ref No.

Product Name

Description

**SOFTWARE**

HER-1000

**HERA**

Available in English, German, Italian  
CE marked





# IMPRINT

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## **Personally Liable Partner**

Aesku Verwaltungs GmbH  
District Court – Register Court Mainz: HRB 44372  
Managing Director: Dr. Torsten Matthias  
Registered Office: Wendelsheim  
Value Added Tax Identification Number: DE296332404

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Should any special advice or instruction be needed, [sales@aesku.com](mailto:sales@aesku.com) may be contacted.

## **Availability of Products and Services**

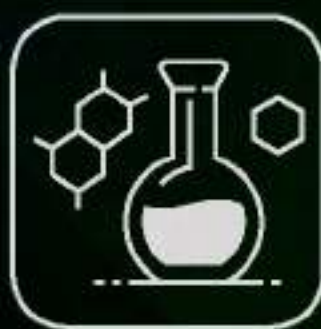
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## **Sale of AESKU.GROUP Products and Services**

The products and services of AESKU.GROUP are sold in accordance with the current version of our General Terms and Conditions.

## **Last Update**

June 17, 2019



**EXPERTS IN DIAGNOSTICS**