



AESKU.DIAGNOSTICS
THE DIAGNOSTIC TOOL THAT WORKS

HUMIDITY TEMPERATURE CONTROL



Humidity Temperature Control (HTC) Kit (REF.HTC-1001)

INSTRUCTIONS FOR USE

- valid for *HELMED*[®] / *HELIOS*[®] devices with HTC compatibility -

HELMED[®]



HELIOS[®]



HTC Instructions For Use EN_V002a: 2025-04-14 SAP: 20140114



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1 Introduction

1.1 Intended Purpose

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

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.

1.2 General Information

Note to the user (European Union)

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

2 Humidity Temperature Control (HTC) Kit Installation

It is recommended that the initial installation of the accessory is performed by trained personnel only according to the instructions in the IFU. Please note the following information prior to the installation:

2.1 Installation requirements for HELMED® / HELIOS® device with HTC accessory

- ✓ 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.
- ✓ Do not allow the device or its flexible cord come in contact to hot surfaces.
- ✓ 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

2.2 Scope of delivery and unboxing the device

The **Humidity Temperature Control (HTC) Kit (REF.HTC-1001)** is shipped in suitable transport packaging. Upon receipt, please check for any visible damages caused by transport.

The **Humidity Temperature Control (HTC) Kit (REF.HTC-1001)** contains the following components:

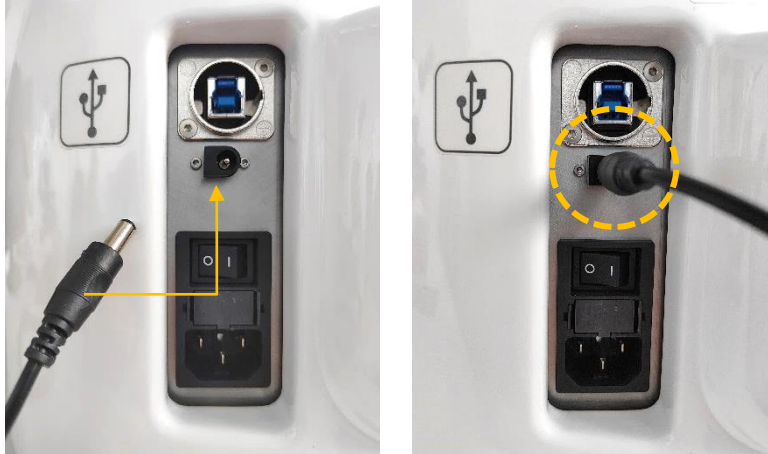
Spare Parts REF#	Component / Part description
20160305	HUMIDIFIER
20160306	CABLE DC HUMIDIFIER
20160307	SPIRAL HOSE HUMIDIFIER
20160308	REDUCING SLEEVE HUMIDIFIER
20160310	HOLDER BOTTLES / HUMIDIFIER
20160312	LDPE BOTTLE 500ML
20140114	INSTRUCTIONS FOR USE (REF.HTC-1001)

Make sure that all the items listed above are present.

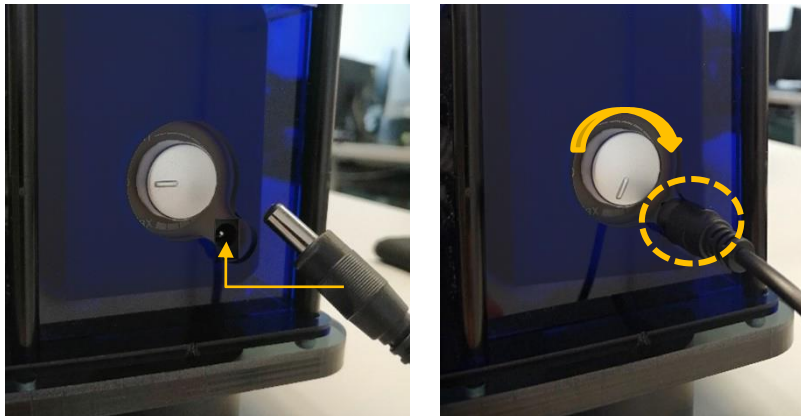
2.3 Connecting the Humidity Temperature Control (HTC) Kit (REF.HTC-1001)

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.



- 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

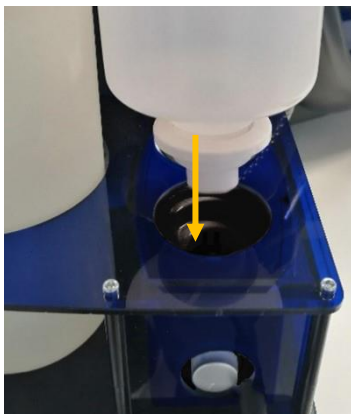
- Plug in the tubing to the adapter on the right backside of the device and rotate left while pushing in:



- 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:



3 Maintenance and cleaning of Humidity Temperature Control (HTC) Kit

3.1 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.

3.2 Humidifier (REF # 20160305)

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

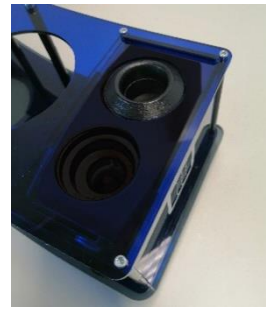
CAUTION:

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.

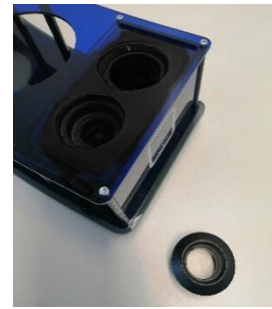
How to remove the humidifier from the rack:



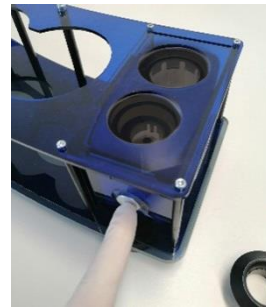
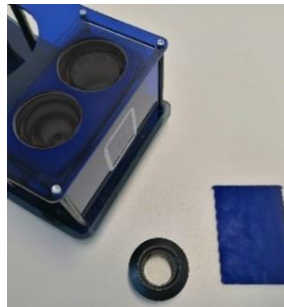
1) Unplug the 24V cable



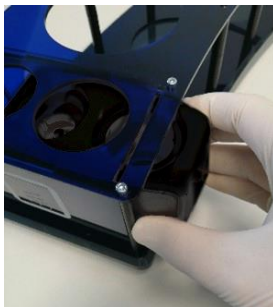
2) Remove the tubing adapter



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

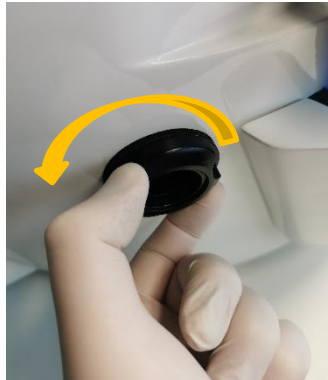


INSTRUCTIONS:

- 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.

3.3 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.

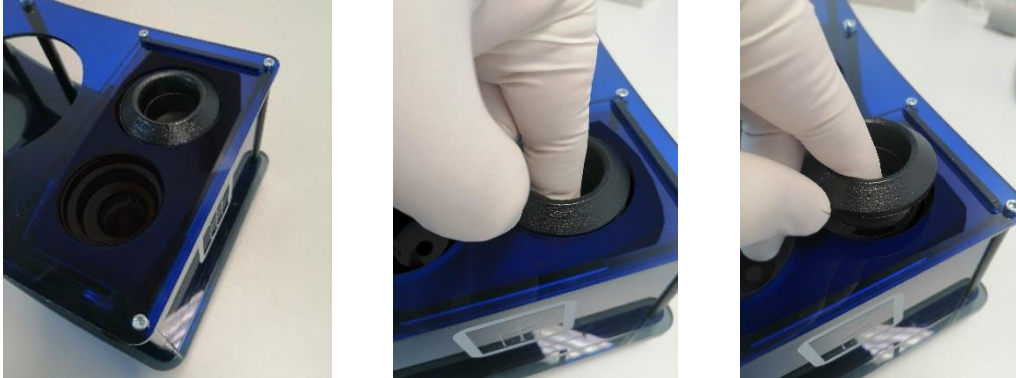


- 3) Rinse or flush the nozzle with 70% ethanol and clean the surface to prevent any contaminations. Let it dry for several minutes before inserting the nozzle again. It is recommended to clean the nozzle weekly together with the other accessories according to their maintenance schedule.



3.4 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.

4 General and technical specifications

- **Power consumption:**
12 W
- **Dimensions and weight:**
40 cm x 15 cm x 11,5 cm (depth x width x height) / 15.7" x 5.9" x 4.5"
2.0 kg / 4.4 lbs
- **Humidifier**
Solis™ SK6366 (Type7212)
Size approx. 12.5 x 8.5 x 6.5 cm
Main voltage / frequency 100 – 240 V / 50/60 Hz
Rated power 12W
Ultrasonic frequency 1.7 MHz
Evaporation output max. 80ml/h
- **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

5 Regulatory symbols



In-vitro Diagnostic (IVD) use



European Conformity



Observe the instructions for use



Manufacturer



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