UV-HEROES®

UV - HEROES®
stethoscope hygiene

USER MANUAL

Welcome to UV-HEROES®, Class I medical devices compliant with Regulation (EU) 2017/745 (MDR), designed to improve stethoscope hygiene practices. Thanks to innovative multi-patented systems and the use of powerful and eco-friendly UV-C LED technology, UV-HEROES® help keep the stethoscope membrane hygienic and support the reduction of microbial contamination risk.

Please read this user and maintenance manual carefully to use the device correctly and safely, and to make the most of its features.

For further information we recommend visiting the website www.uv-heroes.com.

1. USE AND OPERATION

The device is equipped with technologies that make its use safe, easy , and rapid (Fig. 1).

Microbial inactivation starts automatically thanks to one or more LEDs that emit UV-C rays with a wavelength between 260 and 280 nm, as soon as the head of the stethoscope is inserted into UV-HEROES®. The head is inserted through a front opening that allows it to slide until it reaches the correct position, where it presses a button that activates the UV-C light emission (Fig. 2). An elastomer keeps the head stable directly above the UV-C sources, ensuring effective action and preventing radiation leakage (Figs. 1-2).

The radiation stops automatically at the end of the programmed cycle or if the stethoscope head is manually removed from the UV-HEROES®. The device ensures the safety of both the operator and the patient throughout operation.

The type of elastomer identifies the version of the device: soft elastomer (S) for the standard device and hard elastomer (H) for the pediatric device.

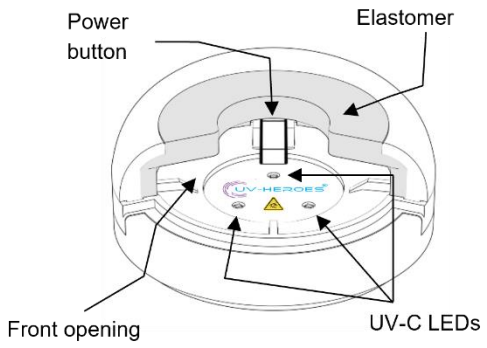

Fig. 1 – General overview

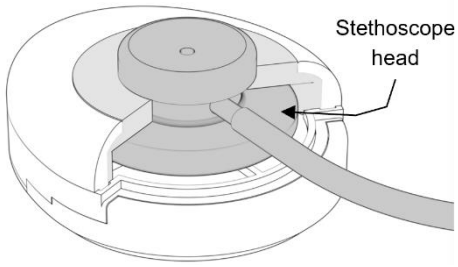

Fig. 2 – Insertion of the stethoscope into UV-HEROES®

For use with pediatric stethoscopes, it is often necessary to insert an open ring into the connecting cylinder between the primary and secondary heads of the stethoscope (**Fig. 3**). The ring is provided as standard equipment exclusively with the pediatric version of UV-HEROES®.

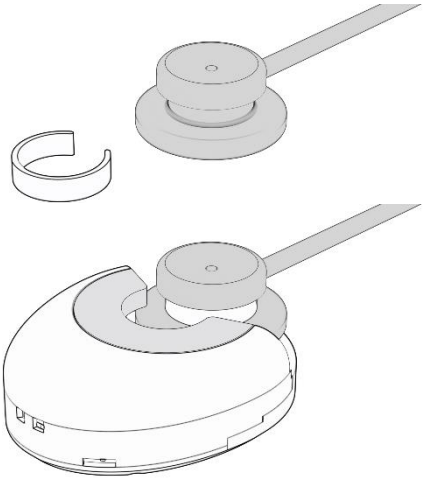

Fig. 3 – Ring for pediatric stethoscopes

2. BATTERIES

The device is powered by three CR/LIR 2032 button batteries, which must be inserted into the appropriate slots and are accessible by removing the sliding cover of the battery compartment (Fig. 4).

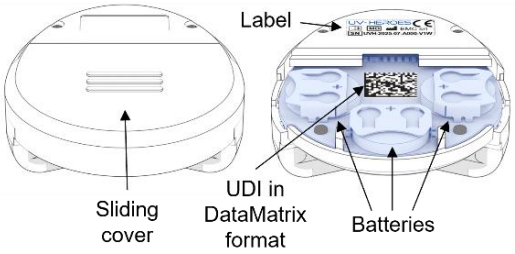

Fig. 4 – Battery compartment

3. UV-C TREATMENT

The device is designed to irradiate both surfaces of the stethoscope head: the side with the larger diaphragm as well as the side with the bell and/or smaller diaphragm, if present (Fig. 5).

Before UV-C treatment, it is necessary to remove any visible dirt or residue from the stethoscope diaphragm.

UV-HEROES®

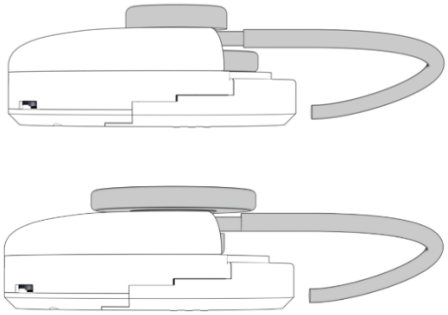

Fig. 5 – Insertion of both stethoscope heads

When the stethoscope is correctly inserted and the batteries are charged, a green indicator light turns on to signal the start of the irradiation process, which will continue for the entire programmed duration (Fig. 6). The UV-C light activates simultaneously with the green indicator.

At the end of the treatment, the indicator light will turn off at the same time as the UV-C radiation is deactivated. The process will then be complete, and the stethoscope can be removed and used.

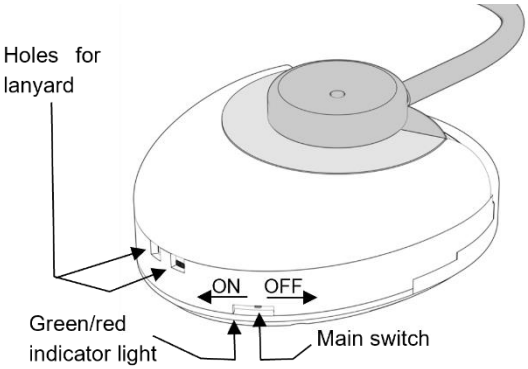

Fig. 6 – Front view of UV-HEROES®

4. MAIN SWITCH

The device is equipped with a sliding main microswitch, preset to ON and deactivatable to OFF using a sharp-end tool. In case of long periods of device inactivity, it is advisable to set the microswitch to OFF to preserve battery life.

5. BATTERY STATUS AND REPLACEMENT

The device continuously monitors the battery status in real time to ensure efficient and safe operation. When the charge level drops, a red indicator light turns on during UV radiation emission, signalling the need to plan for replacement. At this stage, the device remains operational for at least another 30 cycles. However, if the red light turns on immediately at the beginning, it means the control electronics have detected depleted batteries, which must be replaced to ensure proper functioning.

If, after inserting the stethoscope, the indicator light does not turn on, verify that the head has been fully inserted into the device. If the light still does not turn on, check that the main switch is not set to OFF. If the switch is ON and the light remains off, the batteries may be completely discharged or damaged; in this case, replace them. If the issue persists, the device may be malfunctioning.

To replace the batteries, open the battery compartment (Fig. 4), slide off the protective cover, and remove the batteries from their holders using a fingertip. If needed, carefully use a small coin, to facilitate extraction.

6. BATTERY LIFE

The table below shows the duration of each disinfection cycle for the two UV-HEROES® models and the number of cycles achievable with a set of three new batteries.

Model	LED	Action time	Numbers of cycles*
UV-HEROES® lite	1	3' 30"	100
UV-HEROES®	3	2' 30"	200

*Optimal performance with high-capacity batteries.

7. HYGIENIC PERFORMANCE

The two UV-HEROES® models were subjected to in vitro microbial inactivation tests under controlled laboratory conditions, using a protocol carefully developed by researchers at the University of Siena.

The tests were conducted using representative microorganisms, placed in the peripheral areas of the stethoscope membrane's irradiation field, where irradiance is lowest, to evaluate the device's effectiveness in the worst-case scenario.

The results show microbial inactivation greater than 99% and 99.9% for the UV-HEROES® lite (1 LED) and UV-HEROES® (3 LEDs) models, respectively.

Further details and information are available on the website www.uv-heroes.com.

8. RELIABILITY

UV-HEROES® devices use high-reliability UV-C LEDs, designed to operate for tens of thousands of sanitizing cycles while maintaining consistent performance. The technology is specifically engineered to ensure a perfect balance between efficiency and reliability, thus guaranteeing constant results over time. Tests have further demonstrated that the device's action maintains the mechanical performance of the membrane unaltered and is ineffectual on its chromatic characteristics; this ensures the integrity of the instrument even after prolonged use.

During production and assembly, each electronic and mechanical component of the device is inspected to ensure compliance and operational efficiency. Additionally, its unique characteristics are laser-marked on the electronic board to guarantee precise identification. Each unit also undergoes rigorous final testing to verify full functionality.

To safely check the correct operation of the UV-C LEDs, the user can insert the transparent plastic disc provided with the device into the LED chamber in place of the stethoscope head. Gently press the disc with a fingertip until the activation button is triggered. The plastic material completely blocks the UV-C component of the light, preventing any radiation from escaping, while allowing the visible light fringe to be seen, thus confirming LED activation (Fig. 7).

UV-HEROES®

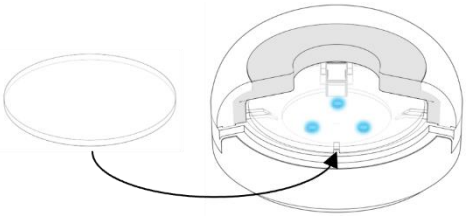

Fig. 7 – UV-C LED functionality test disk

9. WEIGHT AND DIMENSIONS

Weight: 58 g, including batteries

Dimensions: 77 × 64 × 25 mm

10. COMPATIBILITY

UV-HEROES® is compatible with most of stethoscopes with a circular head.

The pediatric version (hard elastomer, H) is designed for pediatric stethoscopes and generally requires the use of the specific ring provided (Fig. 3).

For stethoscope compatibility verification, or to see the necessary dimensions, visit our website www.uv-heroes.com.

11. DEVICE CLEANING

Preferably use a soft, dry cloth. If necessary, to remove organic residues or stubborn dirt, slightly moisten the cloth with denatured alcohol and clean gently. Ensure that the cloth is not overly soaked to avoid liquid infiltration into the device's openings, which could damage the electronic components.

12. DISPOSAL

Dispose of the batteries and the device in accordance with local regulations, as the product contains an electronic circuit board.

13. ENVIRONMENTAL CONDITIONS

Operating temperature: 0°C to +40°C

Operating relative humidity: < 90% RH

Storage temperature: -20°C to +50°C

Storage relative humidity: < 90% RH

14. WARNINGS

Compliance with the following warnings is strongly recommended.

⚠	Keep out of reach of children
⚠	Keep away from heat sources, sunlight, moisture, and water
⚠	Remove any visible residues from the stethoscope diaphragm to ensure optimal sanitization
⚠	Keep UV-HEROES® away from sources of electromagnetic waves and ionizing radiation (X-rays, microwaves, etc.)
⚠	Do not tamper with or force the UV-C activation mechanism
⚠	Before use, check that the device is completely intact in its mechanical parts: any damage or cracks may compromise safety due to possible UV-C radiation leakage
⚠	Clean the UV-C LEDs only when strictly necessary, using a soft cloth slightly moistened with denatured alcohol to remove any residue. Pay special attention during this operation: any damage to the protective quartz layer will render the LEDs unusable
⚠	UV-C light can be harmful to skin and eyes even after a few seconds of exposure. Although the device is designed to prevent any leakage, in the event of a malfunction that activates the radiation without the stethoscope inserted, avoid close exposure (within a few cm)
⚠	In the event of a serious incident related to the use of the device, the user and/or patient must report it to the manufacturer and to the competent authority of the Member State in which the user or patient is established, as required by applicable regulations

15. APPLICABLE REGULATIONS

The devices described in this manual have been designed and manufactured in compliance with European regulations for medical devices. Specifically:

- Regulation (EU) 2017/745 (MDR) on medical devices.
- ISO 14971:2019 – Application of risk management to medical devices.
- CEI EN 60601-1-2:2018 – Requirements for emission and immunity tests related to electromagnetic compatibility (EMC).
- IEC 62471:2006 and subsequent updates – Photobiological safety of lamps and lamp systems.

16. DEVICE INFORMATION

Label

The label is affixed directly to the back of the device and includes:

- the device name, UV-HEROES;
- CE mark;
- a symbol indicating to consult the instructions for use;
- an indication of the product as a medical device (MD);
- the name of the manufacturer;
- the serial number (SN), which also includes the manufacturing date and the UV-HEROES model.

Specifically, the serial number follows this format:

HDDMMYYMSWBANN, where:

- H → UV-HEROES® brand ID
- DD → Day of production (e.g., 18)
- MM → Month of production (e.g., 03 for March)
- YY → Last two digits of the year of production (e.g., 25)
- L → Model: L = UV-HEROES® lite, H = UV-HEROES®
- S → Type of elastomer: S=soft; standard, H=hard, pediatric
- W → Device color (e.g., W = white)
- B → UV-C LED brand
- A → Production batch (A-Z)
- NN → Product number (e.g., 01)

UV-HEROES®

The label measures 24 x 9 mm and appears as shown in Fig. 8.

Fig. 8 – Label on the device

UDI code

The UDI (Unique Device Identifier) code is located inside the battery compartment of UV-HEROES®. It is permanently printed on the electronic board in DataMatrix format and is clearly visible (Fig. 4).

Packaging Information

In addition to including the same information found on the device label, the UV-HEROES® packaging also provides further details in accordance with Regulation (EU) 2017/745 (MDR) on medical devices. Specifically, the packaging includes the following additional information:

- Full name, registered trademark of the device, and description of its intended function.
- Contents of the device package.
- Name, trade name, registered trademark of the manufacturer, and address of the manufacturing site.
- Device model.
- UDI in both DataMatrix format and human-readable text.
- Information regarding proper handling and storage of the device (e.g., temperature conditions, warnings, etc.).
- Essential safety instructions.
- Infographic illustrating the features and proper use of the device.
- QR code linking to the manual on the website.

Complete instructions for use, warnings, and precautions are provided in this manual.

17. SYMBOLS USED

The symbols shown on the device label and packaging comply with applicable international standards and are intended to provide important information regarding the safe and correct use of the device. Below is a list of symbols and their meanings.

CE	CE mark
MD	Medical Device
UDI	Unique Device Identifier
	Manufacturer
	Device disposal
	Refer to the user manual
SN	Serial Number
	Humidity limitation
	Do not wet
+50 °C -20 °C	Storage temperatura
	UV radiation

18. CREDITS AND INTELLECTUAL PROPERTY

Technology and Design

egoHEALTH S.r.l.; c/o Toscana Life Sciences, Via Fiorentina, 1, 53100 Siena
https://www.egohealth.it

Manufacturer

EMC S.r.l.; Via della Repubblica, 48, 50050 Gambassi Terme – Firenze
https://www.emcr.it

Patents and Trademarks

egoHEALTH S.r.l. holds a broad portfolio of granted international patents, as well as others pending registration, protecting this medical device.

The trademark UV-HEROES® is a registered trademark and may not be used, reproduced, or distributed without prior written authorization.

19. WARRANTY

The UV-HEROES® device is covered by a 1-year warranty against manufacturing defects, in compliance with Regulation (EU) 2017/745 (MDR) for Class I medical devices. The warranty does not cover damage resulting from misuse, wear and tear, or tampering.

20. TECHNICAL SUPPORT

For any technical support needs, malfunctions, or information requests about the device, you can contact our support service.

Email: support@uv-heroes.com

Website: www.uv-heroes.com