Welcome to Stet Clean®: the wearable system for stethoscope chest piece sanitization. This is achieved by means of UV-C LED.
Please read this user's manual carefully in order to use the device safely and achieve its best performance.
The product was developed by egoHEALTH S.r.l. (www.egohealth.it) in collaboration with Light Progress S.r.l. (www.lightprogress.it).
For more details, please visit the website: www.stetclean.com

1. INTENDED USE

Stet Clean® is a Class I medical device specifically designed for the sanitization of stethoscopes.

2. RECEIPT

Handle with care. Fragile material! Verify that the packaging is complete and intact and be careful not to damage the contents when using sharp blades or cutters to open the box. Take out the device from the box and immediately check if it has not been damaged during transport.
Before using this device, carefully read the safety WARNINGS and all other instructions described below.

Once out of the box, we recommend connecting the Stet Clean® to the power supply to recharge the battery, using the cable included in the box. The first time you charge the battery, we recommend leaving Stet Clean® plugged in for at least 12 hours. In case of anomalies in operation, press the Reset button (6) (see section 4.4).

3. OVERVIEW

The santization process based on UV rays with wavelength 260-290 nm (UV-C) is activated 100% automatically immediately after hooking the head of stethoscope to the Stet Clean®.
Stet Clean® is disabled automatically at the end of the disinfection time set or during operation, if you voluntarily remove the stethoscope from the Stet Clean®.
The UV-C LED turns on when the stethoscope is fitted by mechanical pressure of a micro- switch (8) and the optical sensor (3) responses to darkness as shown in Figure D. This double check ensures absolute safety and deep hygiene to operator and patient, as it contains UV-C in a closed environment and enables the device only in the presence of the head of the stethoscope.

4. USE AND OPERATION

The device features mechanisms designed to ensure simple and immediate operation.

4.1. Connection to the stethoscope

Sanitization is enabled by inserting the head of the stethoscope so that the edge of the membrane is fitted under the housing (4) containing the micro-switch (8), followed by quick locking of the opposite side of the head on the spring balls (1), towards the UV-C LED (2) (Fig. D, phases I → II → III).

4.2. Membrane hygiene

Remove any dirt from the membrane before using Stet Clean®. To make the action of UV-C more effective, it is recommended to dry the membrane of the stethoscope if wet. When the stethoscope is correctly inserted, the blue light (10) indicates that the sanitization process was activated correctly, and it will flash throughout the whole period of the T1 phase of standard sanitization (see point 5).
The UV-C LED is activated a few seconds after the blue light begins to flash: this indicates that the device was inserted correctly.

4.3 Disconnecting the stethoscope

At the end of phase T2 (deep disinfection), the blue light (10) turns off at the same time as the UV-C LED. The stethoscope will be deeply sanitized and can be released by a simple reverse operation to that of fitting (Fig. D, reverse phases III → II → I).
The sanitization process, both standard and deep, may be discontinued at any time by releasing the stethoscope from Stet Clean®.
To ensure effective hygiene, we recommend that you remove the stethoscope under the conditions described in point 4.2.

4.4. Battery charging and reset button

The battery can be recharged through a micro-USB port (5). An amber light (9) flashes during the charging process, remains steadily lit when the battery is fully charged and turns off once you disconnect the cable.
A reset button (6) which can be operated via a fine tip, restores the standard conditions of the device.

4.5. Anchorage

A separate attack on tabs (7) makes it possible to anchor the Stet Clean® to operator's white coat pocket or other pockets.

5. OPERATING RANGES

Stet Clean® ensures effective sanitisation throughout the shelf life of the UV-C LED (about 50.000 uses*).

During sanitization phases, the system defines automatically a T1 step (standard), lasting 3 minutes + T2 step, adding an extra 2 minutes to sanitize the stethoscope more deeply.

* use = T1 “standard sanitization”

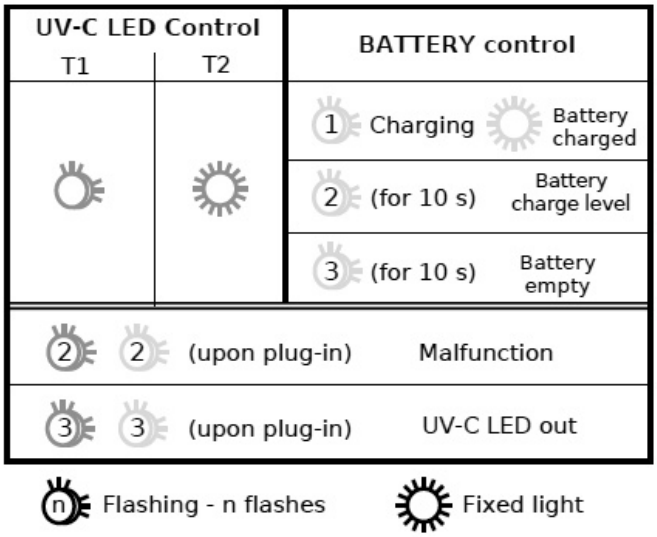
6. LIGHTSIGNALS

The operating lights indicate:

-Blue light = UV-C LED operation

-YELLOW light = battery operation

6.1 Summary table of light signals



7. LIMITATIONS

Stet Clean® can be used with most of stethoscopes, on the condition they all have head diameter between 46.5 and 47.4 mm.

Poor overhead lighting can prevent the activation of the device. Heads of stethoscopes that feature special pads must not be forced under the housing, but fitted through a rotation by90°.

8. IMPORTANT WARNINGS

We recommend you follow the instructions below.

⚠ Keep away from heat, sunlight, moisture and water.

⚠ It is recommended to dry the membrane of the stethoscope before inserting it into Stet Clean®, to avoid the formation of condensate and ensure optimal sanitization.

⚠ Keep the Stet Clean® away from sources of electromagnetic waves and ionising radiation (MRI, x-ray, microwave, etc.).

⚠ Do not tamper with or force the fitting mechanism, to avoid activating the UV-C LED with the stethoscope placed incorrectly.

⚠ Should the UV-C LED be activated when the stethoscope is not attached, never direct the UV-C LED towards skin and eyes.

9. DEVICE CLEANING

Preferably use a soft dry cloth. If necessary, clean organic residues or stubborn dirt with denatured alcohol.

10. DISPOSAL

Dispose of the device properly, keeping in mind that it contains a lithium battery.

10.1. Main reference standards

- EC Directive 93/42/EEC as amended (2007/47/EC)
- Law Decree 46 of 1997
- CEI 14971:2012
- CEI 60601-1:2010
- CEI 60601-1-2:2007

11. TECHNICAL SPECIFICATIONS

11.1. General features

Power supply:
rechargeable lithium-polymer battery;
3,7V - 1000mAh voltage 5V ± 5%,
non replaceable.
Consumption UV LED: 120 mA
Battery autonomy: 150 consecutive uses,
5 days in standby mode.
Input connector: micro-USB port (micro-B).

11.2. Environmental conditions

Operating temperature: from 0°C to +40°C.
Relative operating humidity: < 90% RH.
Storage temperature: from -20°C to +50°C.
Relative storage humidity:: < 90% RH.

12. SYMBOLS

CE Mark

Manufacturer

Device Disposal

See Instruction Manual

Serial Number

Humidity Limitation

UV rays source

do not wet

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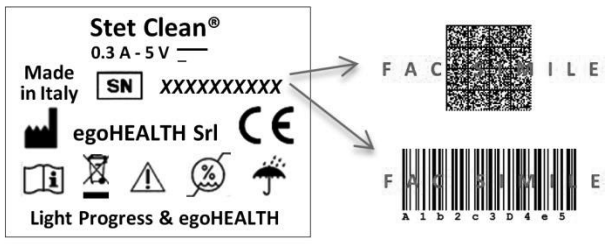

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