

The machine described in the present document is a diffuser of ready to use liquid solutions such as:

- Medical devices
- Biocides
- Sanitizers

EU Code 2021.t - 2L hub | ~230 VAC | 50-60 Hz

US Code 2023.t - 2L hub | ~120 VAC | 50-60 Hz

# **Technical Features**

• Bottles capacity:

2 L / ½ Gallon

• Empty weight:

18.5 Kg / 40.8 LBs

· Dimensions:

(cm) W 37 x D 23 x H 40 / (inch) W 14.5 x D 9 x H 15.7

- 2 rotating emission nozzles
- Particle size: from <1 to 5 μm
- Hourly consumption: 1500 ml/h ± 10% / 50.7 ounces/h ± 10%
- Treatable volume: from 10 to 2000 m³ / from 350 to 70,000 ft³

# Features of the electronic unit

- Touchscreen man-machine interface
- Displaying/Setting in 3 languages (Italian, English and Spanish)
- Password-protected Access
- 3 cycles: sanitation, disinfection and pest control
- 300 programs for each cycle: the user can enter the name of the room, the volume and the protocol (concentration  $ml/m^3$  or ml/35  $ft^3$ ) for each program

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- 4 validated protocols (1 ml/m³ 3 ml/m³ 5 ml/m³ 5+5 ml/m³)
- A program called "WASHING CYCLE" allows emptying the pre-load tank and cleaning the pipes inside the device with distilled water. This operation is useful every time a disinfestation (pest control) cycle is followed by one of disinfection or vice-versa
- The programs can be started in 2 ways:
  - now (immediately)
  - weekly (pre-scheduled)
- Programmable start delay
- · Advanced cycle start warning
- Room temperature reading
- · Product level control
- Alarms signaling
- Unit of measurement setting: volume ( $m^3$   $ft^3$ ) and temperature ( ${}^{\circ}$ C  ${}^{\circ}$ F)
- Buzzer activation/deactivation (acoustic signal)
- Brightness adjustment and screensaver
- For each cycle, the device records: the used program, the facility name, the user identification, the product and its lot number, the volume, the protocol, the day on which it was performed, start and end time, the room temperature and possible alarms. The result of the treatments can be saved on a USB pen drive
- The Report in PDF of the cycles performed can be exported
- · Software update uploading with USB pen drive





- Room recognition with unique iRED
- Remote connection and monitoring:
  - Secure and encrypted connection via VPN (LAN, Wi-Fi and Mobile)
  - Can be installed on PC/smartphone/tablet
  - Easy and intuitive interface
  - Remote debugging of the application, total control of the device and software update
  - Notification of alarm, disconnection and/or reconnection of the device via email and/or Push notifications
  - Monitoring and display of system's variables
  - Visualization of data through graphs and creation of specific log files
  - Get the data stored in the cloud
- Optional: instrument for detecting dew point temperature, relative saturation, humidity and H<sub>2</sub>O<sub>2</sub>

#### **Medical Device Classification:**

- class I according to Regulation (EU) 2017/745 of the European Parliament and Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance)
- class I according to FDA

Appliance class: class I

## Complies with standards:

- EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use EMC requirements Part 1: General requirements. Including standard: CISPR 11; EN 61000-3-2; EN 61000-3-3; EN 61000-4-3; EN 61000-4-2; EN 61000-4-8; EN 61000-4-4; EN 61000-4-6; EN 61000-4-5: EN 61000-4-11
- EN 61010-2-040:2015 Safety requirements for electrical equipment for measurement, control and laboratory use Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials. Conjunction with: EN 61010-1:2010/A1:2019/AC:2019 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements



**EUDAMED SRN: IT-MF-000012107** 

FDA Registration No. 3011684996

# Manufacturer

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## Patents | Device for the delivery of disinfectants or similar.





**EUROPEAN PATENT** EP2852467 B1



**US PATENT** 



**MEXICAN PATENT** No. 363725





