EOlife®

US INSTRUCTIONS FOR USE

ARCHEON
MEDICAL

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MEDICAL

Table of content.

EOlife® medical device is manufactured by ARCHEON,
2 Chemin des Aiguillettes, 25000 Besançon, France.

I. Symbols used on product labelling

Symbol	Definition
LOT	Manufacturer's lot number
REF	Part number
SN	Serial number
MD	Medical device
QTY	Quantity
CE	CE marking
	Warning
	Manufacturer
	Date of manufacture
	Use by date
IP44	Ingress protection against : • Intrusion of solid objects larger than 1 mm • Water splashing from any direction
	Consult the instructions for use
	Temperature limitation
	Humidity limitation
	Do not dispose of with general waste
	Do not re-use
	Do not use if package is damaged
	MR unsafe
	Prescription use only

II. Acronyms

ACLS	Advanced Cardiovascular Life Support
AHA	American Heart Association
BLS	Basic Life Support
CPR	Cardiopulmonary resuscitation
ERC	European Resuscitation Council
LED	Light-Emitting Diode
WEEE	Waste Electrical and Electronic Equipment

III. Conditions of use

1. Indications for use

EOlife® is intended for use with emergency manual resuscitation devices to measure ventilatory flows and display visual guide on the insufflated volume, tidal volume, and ventilation frequency to ensure adequate ventilation of adult cardiopulmonary arrest patient during cardiopulmonary resuscitation (CPR) performed by healthcare professionals.

2. Patients

Adult patients between 4'7" (140 cm) and 6'7" (200 cm).

3. Environment of use

EOlife® is indicated to be used in prehospital care, during emergency patient transport in ambulance and in hospital environment.

EOlife® is intended for use in a home healthcare environment according to EN 60601-1-2.

4. Users

EOlife® is indicated to be used by healthcare professionals certified in Basic Life Support (BLS) or Advanced Cardiovascular Life Support (ACLS).
Users must inform himself about the safe use of the device before using it by reading the instructions for use.

When the device is delivered to a department by an ARCHEON staff member or approved distributor, training should be provided in the handling and use of EOlife®.

5. Contraindications

EOlife® is not approved for the following uses:

- In a hyperbaric chamber
- Near magnetic resonance imaging machines
- Air ambulance
- Pediatric and neonatal populations

IV. Safety

Precautions

▶ Before using the product, read these instructions carefully. Failure to follow the instructions can lead to improper use and expose the patient, user or persons nearby to risks.
- Use the device as intended (see "III. Conditions for use").
- Comply with the contraindications (see "III. Conditions for use").
- Carefully read theses safety instructions for use.
- Comply with all the sections in these instructions.

▶ The use of defective devices could compromise the ventilation of the patient and impact their condition and may also put the user at risk.
- Only use the EOlife® device and its accessories if they do not show any visible damage.

▶ The EOlife® device, its battery, its charger and the FlowSense® sensor must be stored and used as described in the instructions for use (see "IX. Technical data").

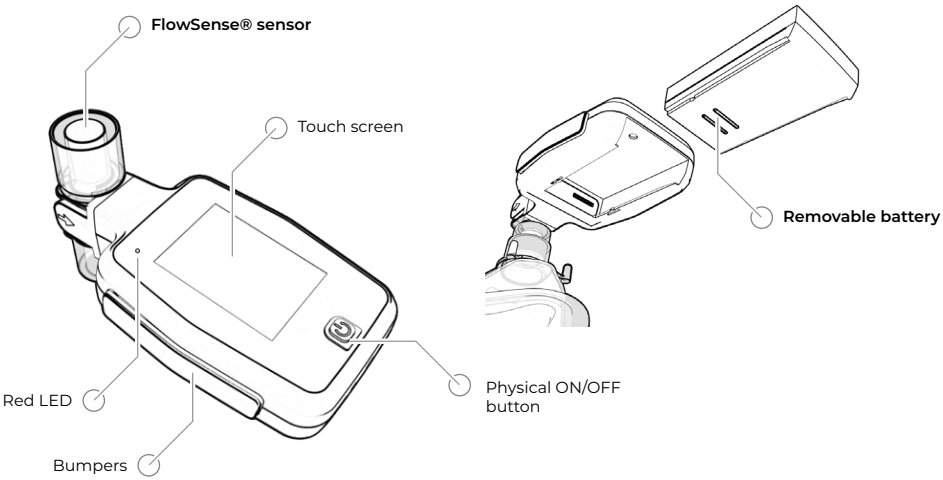
- ▶ We advise carrying the EOlife® device in its kit-bag when included in a first aid bag.
- ▶ The device can be safely used outdoors, as it is rainproof, splashproof and cannot be penetrated by solid objects larger than 1 mm (IP44 rating). However, it should be handled with care and kept away from powerful water jets and dust.
- ▶ Always check the battery level before using EOlife®. We advise recharging the battery after each use and not charging it below 10°C (50 °F). Recharge the battery if the charge is below 20%. We also advise having a spare operational battery in case this is needed.
- ▶ Using a battery with a low charge at temperatures below 0°C (32 °F) greatly reduces the run time and can cause EOlife® to stop functioning after a short time. If the device is used at low temperatures, the battery should be fully charged.
- ▶ Do not remove the battery when EOlife® is switched on.

Warnings

- ⚠ Avoid using EOlife® next to or in combination with other devices (battery, charger or other) not recommended by ARCHEON as this could cause it to malfunction. If devices must be used next to each other or together, monitor both devices to check that they are functioning properly.
- ⚠ Using the device in a way other than as described by ARCHEON and using non-approved accessories could affect the patient's ventilation and health.
- ⚠ Never use the EOlife® device or its accessories in a hyperbaric chamber as this could cause an explosion.
- ⚠ Any technical alterations to the device could affect the patient's ventilation and health.
  - No alterations should be made to the device or its accessories.
- ⚠ The use of accessories, transducers and cables other than those specified or supplied could increase the electromagnetic emissions or decrease the electromagnetic immunity of the device and cause it to malfunction.
- ⚠ Portable high frequency communication devices (e.g. wireless devices, antennas and their cables) in close proximity to EOlife® can interfere with the device and reduce its performance. Keep EOlife® at least 12 inches (30 cm) from portable high frequency communication devices.
- ⚠ Handling the battery improperly could seriously injure the patient, user and persons nearby. The battery must not be disposed of in a fire, opened, deformed or short-circuited. The battery must be protected from humidity, high temperatures and high pressure (see "IX. Technical data").
- ⚠ The FlowSense® sensor is for single use only. It must be used as soon as it is removed from its packaging and discarded after use. Re-using or decontaminating single-use items could contaminate the patient or have unforeseeable life-threatening consequences. It is advisable to always carry a spare FlowSense® sensor.
- ⚠ If you notice any malfunction or damage to the product, do not use EOlife® or the FlowSense® sensor and return them to the manufacturer or distributor.
- ⚠ Always clean the EOlife® electronic control unit after use as instructed in "VIII. 3 b) Cleaning EOlife® and its accessories".
- ⚠ The EOlife® electronic control unit, the FlowSense® sensor, the battery and the charger must be discarded at the end of their lifetime as instructed in "VIII. 3 d) Disposal".
- ⚠ When using a mask, the actual delivered volume of air (Vt) may be less than the insufflated volume (Vi) displayed by EOlife® due to leakage.

V. Product description

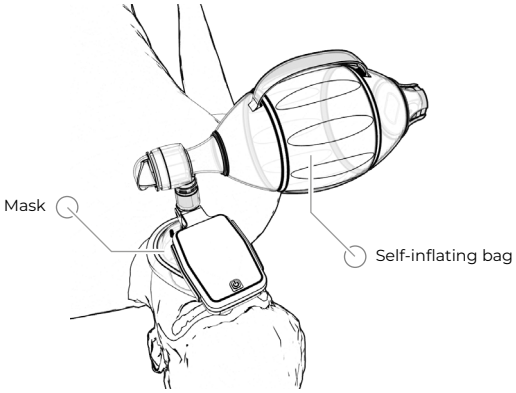
▶ The device is a portable electromedical device that includes the EOlife® electronic control unit, its removable and rechargeable battery, its charger and the single-use FlowSense® sensor (the expiry date is specified on the outer packaging).



▶ EOlife® is used with the FlowSense® sensor which is positioned between a non-invasive ventilation interface (mask), invasive ventilation interface (endotracheal tube), or any type of supraglottic airway device, and a standard self-inflating bag to manually ventilate adult patients.

Note
The ventilation interface and the self-inflating bag are accessories not supplied by ARCHEON.

Note
Inlet and outlet ports of the device are compliant with the international standard EN/ISO 5356-1. EOlife® is then compatible with all type of ventilation interface and self-inflating bag.



▶ EOlife® allows the user to choose the ventilation mode (continuous ventilation or CPR with a 30:2 compression/ventilation ratio) and the patient's height.
Based on the inspiratory and expiratory flow rates measured during ventilation, EOlife® calculates the main ventilation parameters (insufflation volumes, tidal volumes, ventilation frequency and leakage) and gives real-time feedback on the ventilation performed. EOlife® also shows the target ventilation values (in accordance with the guidelines issued by the AHA and ERC international scientific committees) to guarantee adequate ventilation.

VI. Equipment

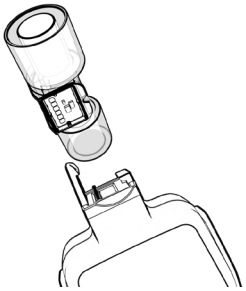
Sales references	Part number
EOlife®	*AUS00055*
EOlife® Battery	*A0000051*
EOlife® Charger	*A0000029*
FlowSense® x 10 *(Single use component)*	*A0000044*

The equipment can be ordered from approved distributors.

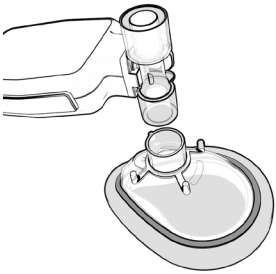
VII. Quick start guide of the device

This section gives a short step-by-step description of how to use the EOlife® device. There is a more detailed description in the next section, “VIII. Detailed product description and operating instructions”.

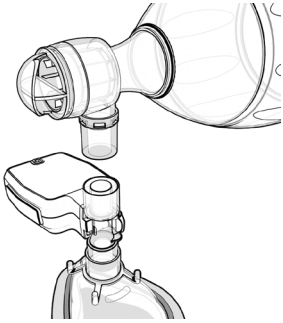
Assemble EOlife®, attaching the FlowSense® single use sensor and other devices to ventilate the patient (ventilation interface and bag)



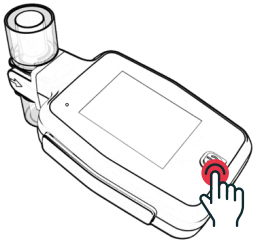
1 EOlife® assembly with the FlowSense® sensor See “VIII 1 a) Assembly”



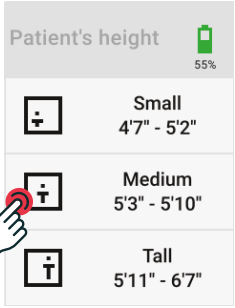
2 Assembly with the ventilation interface



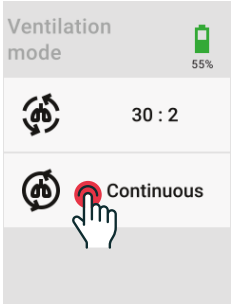
3 Assembly with the bag



4 Start up EOlife® by pressing the physical ON/OFF button

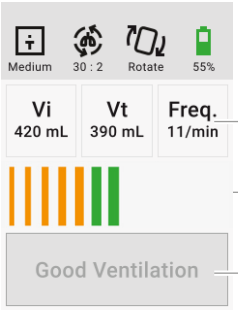


5 Press on the height of the adult patient in cardiopulmonary arrest
- **Small** : the patient’s height is between 4’7” - 5’2”
- **Medium** : the patient’s height is between 5’3” - 5’10”
- **Tall** : the patient’s height is between 5’11” - 6’7”



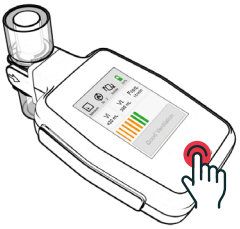
6 Choose the type of ventilation performed
- **30:2 mode**: alternating between 30 chest compressions and 2 ventilations
- **Continuous mode**: continuous ventilation at a frequency of 10 cycles per minute.

7 Ventilate the patient in cardiopulmonary arrest for as long as necessary
- See “VIII 1 b) EOlife® ventilation method” and “VIII 1 c) Visual signal”

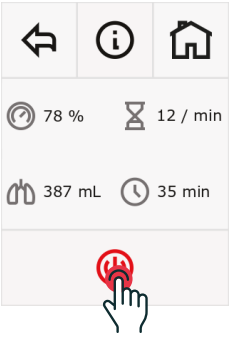


Main screen

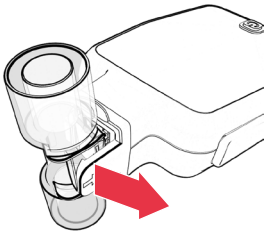
8 Switch off EOlife® by pressing the ON/OFF button for 3 seconds or by quick pressing the ON/OFF icon on the touch screen



Switching off using the stop screen



9 Disconnect the ventilation bag and interface (mask or endotracheal tube) and unclip the FlowSense® sensor by pulling the tab outwards, as shown by the arrow.



Disconnecting EOlife®

VIII. Detailed product description and operating instructions

EOlife® is controlled via the touch screen and the physical ON/OFF button.

Caution

Avoid using any object that could scratch the screen.

1. Using the device

a) Assembly/disassembly

▶ Assembly

Remove the FlowSense® single use sensor from its packaging, using the notch to tear the antistatic bag to avoid damaging the sensor.

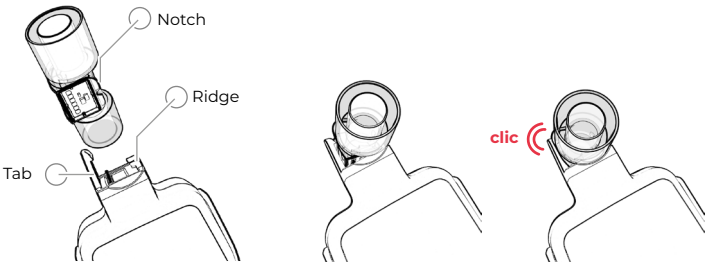
Caution

Check the sensor's expiry date before using. The use by date can be found on the label affixed to the bag (⧖).
Check that the bag is intact before using the FlowSense® sensor. If the FlowSense® sensor bag is torn, discard the sensor and use another one as water or contaminants may have entered the bag.

FlowSense® is factory calibrated. Once removed from its packaging FlowSense® is ready to be used.

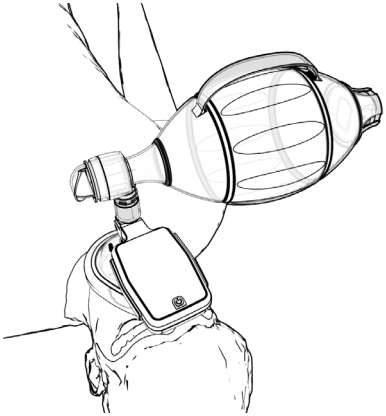
Connect the FlowSense® sensor to the EOlife® unit, taking care not to expose the printed circuit board to dust or splash it with water.
First insert the part of the FlowSense® with a notch into the connector ridge, and then press firmly on the sensor so that it comes into contact with the connector pins. You will hear a click when the connector tab holds the FlowSense® sensor in place.

Check that the FlowSense® sensor is held properly in place before starting up the EOlife® unit.



Connect the ventilation interface (mask or endotracheal tube) to the compatible end of the FlowSense® sensor. The sensor ends are shaped differently to ensure that the interface cannot be connected to the wrong end.

Connect the bag to the other end of the FlowSense® sensor. The device must be assembled as shown below:



▶ Disassembly

To remove the accessories from the product, take the FlowSense® sensor out of the ventilation interface (mask or endotracheal tube) by gently pulling vertically on the FlowSense® sensor. Then remove the ventilation bag at the other end in the same way.

⚠ Caution

If the patient is intubated and secretions appear in the FlowSense® sensor during ventilation: remove the sensor very carefully from the endotracheal tube (or other supraglottic airway device) by holding the tube firmly with one hand and gently pulling the FlowSense® sensor upwards with the other hand to disconnect it from the tube. To avoid the penetration of substances or liquid into FlowSense® (patient regurgitation, patient secretion, condensation...) that could disturb the flow measurements and lead to injury to the patient, we recommend to use a HMEF filter (Heat and Moisture Exchange Filters) placed between the ventilation interface (mask or endotracheal tube) and FlowSense®. We recommend using the FDA 510(k) cleared HMEF INTERSURGICAL - INTER-THERMTM breathing filter (K092451) that has been tested with EOlife®.

b) EOlife® ventilation method

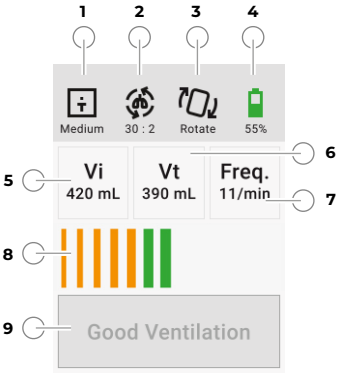
EOlife® gives the user real-time feedback on the quality of the ventilation performed on the patient based on a cyclic analysis of inspiratory and expiratory flow rates. It must therefore be positioned proximally to be able to measure both the inspiratory and expiratory flow rates, calculate the volumes insufflated and expired, the ventilation frequency and leakage, estimate the tidal volumes, and generate user visual signals if the ventilation parameters are unacceptable.

EOlife® also uses algorithms to filter out small airflows generated by chest compressions so as not to display anomalous volume and ventilation frequency values and to avoid measurement artefacts. During ventilation, be sure to generate enough flow (minimum 20L/min) to be detected by the device.

⚠ Caution

When ventilating a patient with a mask, ensure it is correctly held on the patient's face during insufflation and for the entire duration of expiration so that EOlife® can measure the exhaled volume.

The main screen guides the user by displaying the ventilation parameters and visual guide showing the ideal air/oxygen volume to administer and when to administer it. The main screen also uses visual signals to warn the user if the patient is not ventilated correctly.



Main screen

1. Displays the patient's height selected and quick access key to change the patient's height.

2. Displays the chosen ventilation mode and quick access key to change the ventilation mode.

3. Rotation icon and key to rotate the screen 180° to adjust the direction of the screen to the user's position during ventilation.
   The user can perform ventilation and change the patient's height or the ventilation mode in this position. The screen returns to its normal position if the user:
   - Presses again on the rotation icon
   - Presses the physical ON/OFF button to show the stop screen
   - Presses the physical ON/OFF button for 3 seconds to switch the device off.

4. Displays the battery level
   - See "VIII. 3 a) Charging the battery".

5. Displays the actual volume insufflated (Vi) for each ventilation cycle (value in mL).

6. Displays the actual tidal volume (Vt) (value in mL)

Note
The tidal volume is the estimated volume of air/oxygen actually reaching the patient's lungs based on both the measurement of the volume of air expired and the leak calculated during the insufflation/expiration phases.
The ERC and AHA recommend that an adult patient in cardiopulmonary arrest should be ventilated with a tidal volume of 6 to 8 mL/kg of Ideal body weight.

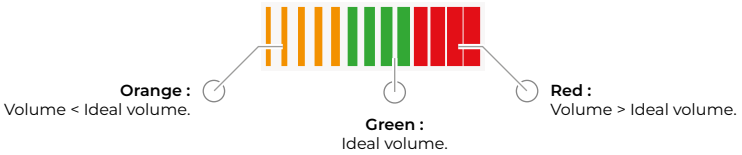
7. Displays the trend value of the ventilation frequency (Freq.) (cycles/minute) taking into account the frequency of the last ventilation cycles performed:

   - For the 30:2 mode → value available from the third ventilation cycle.
   - For the continuous mode → value available from the fourth ventilation cycle.

Note
The ERC and AHA recommend that an adult patient in cardiopulmonary arrest should be ventilated at a frequency of 10 ventilations per minute during continuous cardiac massage.

8. Real-time indication of how to ventilate:

- A bar graph shows whether the volume insufflated/exhaled is adequate:

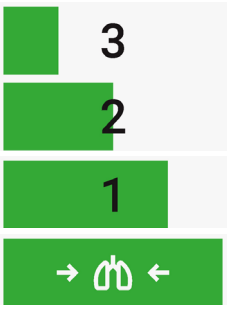


When the user ventilates the patient, the bar graph shows in real time the quantity of air/oxygen that must be insufflated to the patient based on ERC and AHA guidelines.

Note

- The bar graph is displayed on each validation cycle and is incremented in proportion to the volume insufflated.
- During expiration, the bar graph is decremented in proportion to the measured volume of air/oxygen exhaled.
- Take care to generate enough flow for the system to detect the insufflation and ensure that it is not mistaken for an artefact or an involuntary movement of air caused by chest compressions or handling the bag.

▸ **Display in continious mode :**



In continuous ventilation mode, EOlife® generates a visual countdown to show the user when to ventilate to deliver 10 ventilations per minute. When the green lung is displayed, the user must ventilate the patient.

▸ **Display in 30:2 mode :**

In 30:2 mode, the countdown function is disabled as the person ventilating must wait for 30 chest compressions before delivering 2 ventilations. In this mode the ventilation frequency depends on the person (or machine) performing the chest compressions.
The green lung is shown permanently to indicate that the device is waiting to detect a ventilation to display the bar graph.

9. Visual signal display area :

- Good Ventilation — all the ventilation parameters calculated are within the appropriate range of values as defined in the international guidelines.
- Insufficient Volume — the volume of air insufflated to the patient is significantly lower than the values given in the international guidelines.
- Excessive Volume — the volume of air insufflated to the patient is significantly higher than the values given in the international guidelines.
- Low Frequency — the ventilation frequency is much significantly than the values given in the international guidelines.
- High Frequency — the ventilation frequency is significantly higher than the values given in the international guidelines.
- Important Leakage — the difference calculated between the volume of air/oxygen insufflated and the volume exhaled is too great. This may be because the mask is not positioned correctly, due to improper intubation (oesophageal intubation) or because the ventilation circuit is not properly sealed.

Note
See details of visual signals in "VIII. 1 c) Visual signals".

c) Visual signals

Visual signals related to ventilation parameters

Visual signals may appear during ventilation when the ventilation parameters exceed the threshold values and are persistently outside the ranges given below.
The screen shows the visual signals in the visual signal display area (lower part of the screen) as a message.

The visual signals concern :

▶ The tidal volume (Vt) :

Visual signal conditions	Cause		Solution
	Patient height	Tidal volume value	
Insufficient volume	Small	< 225 mL	Insufflate a volume of air within the appropriate range as defined in the international guidelines.
	Medium	< 285 mL	
	Tall	< 350 mL	
Excessive volume	Small	> 430 mL	
	Medium	> 565 mL	
	Tall	> 710 mL	

Note
- In continuous ventilation mode the visual signal condition is calculated based on the trend value of the volumes. If the trend value and the current value of the tidal volume are as described in the table above, the tidal volume visual signal is triggered.
- In 30:2 CPR mode the visual signal condition is calculated based on the mean value of the tidal volumes during two consecutive ventilation cycles.

▶ The ventilation frequency (Freq.) :

Visual signal conditions	Ventilation frequency value	Solution
Low frequency (continuous mode)	No insufflation during 9 seconds	Ventilate the patient at an appropriate frequency, as recommended in the international guidelines
Low frequency (30:2 mode)	No insufflation during 24 seconds	
High frequency	> 15 bpm	

Note
- In continuous ventilation mode the frequency is calculated based on the trend value of the ventilation frequency. If the trend value and the current value of the frequency are as described in the table above, the ventilation frequency visual signal is triggered.
- In 30:2 CPR mode the visual signal condition is calculated based on the actual value of the pause time.

▶ Leakage :

Visual signal conditions	Valeur de la fuite	Solution
Important leakage	> 40 %	Depending on the cause of the leakage, several solutions are possible (non-exhaustive list): ▶ Reposition the tracheal tube if the patient is improperly intubated (selective intubation, tube not deep enough inside the trachea) or inflate the bag more if the ventilation circuit is not properly sealed ▶ Reposition the mask properly on the patient's face to ensure that the ventilation circuit is properly sealed ▶ Completely free the patient's airways

Note
- In continuous ventilation mode leakage is calculated based on the trend value of the leakages. If the trend value and the current leakage value are as described in the table above, the leakage visual signal is triggered.
- In 30:2 CPR mode the visual signal condition is calculated based on the mean value of the leakages during two consecutive ventilation cycles.

▶ Visual signal prioritization :

All visual signal messages appear in the same display area, therefore a system is necessary to prioritize the visual signals. Visual signals prioritization also enables the user to focus first on correcting the most critical problem in terms of patient safety, and avoids the additional stress of multiple simultaneous visual signals.

The visual signals were prioritized with clinical experts based on the risk level:

High and low frequency > Excessive volume > Important leakage > Insufficient volume

Visual signal message linked to the FlowSense® sensor

During ventilation, if the FlowSense® single use sensor is defective or not properly connected or if a foreign object on the connector interferes with the signal transmission, a visual signal is displayed:

« FlowSense failure »
screen

You must reconnect a functional FlowSense® single use sensor as described above to clear the “FlowSense failure” screen.

Note
The “FlowSense failure” screen can only be displayed from the main screen.

EOlife® device failure

If there is an EOlife® device failure or a loss of essential performances, the red LED in the top left of the screen comes on. This red LED indicates a failure whatever the state of the device (on or off).

Warnings

Do not use the EOlife® device if the red LED remains on.
See “X. What to do in the event of an incident ”.

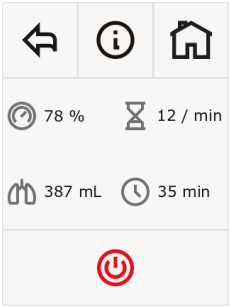
d) Automatic shutdown

If there is no user action (a press of the physical ON/OFF button, a touch of the screen when the device is running or the detection of the inspiration phase when a ventilation sequence is running.) for 1 hour, the device turns itself off completely.

To turn the device on again, simply press the physical ON/OFF button.

2. EOlife® device information screen

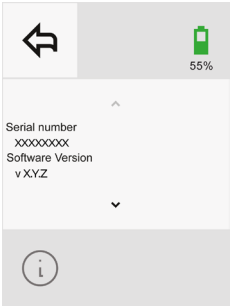
Select by a quick press the information button to display the EOlife® stop screen.



Stop screen

The information contained in the EOlife® device includes:

- ▶ The EOlife® serial number
- ▶ The software version
- ▶ The operating conditions
- ▶ Temporary operating conditions
- ▶ Storage conditions
- ▶ The manufacturer
- ▶ The manufacturer's address



Information screen

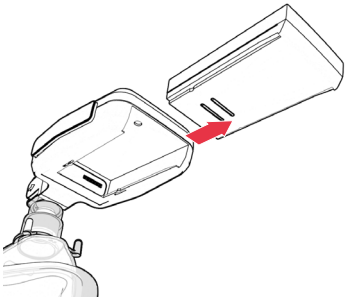
3. Cleaning and maintenance

a) Charging the battery

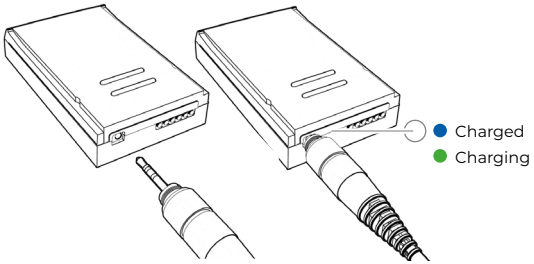
Recharging the EOlife® battery :

Note
The battery must be removed from the EOlife® unit before recharging.
Turn off the device before battery removal.

1. Remove the battery.



2. Plug the jack on the charger cable provided into the battery.



3. Plug the charger cable to the mains socket

Warnings

- Only recharge the EOlife® battery using the charger provided.
- Only use the EOlife® battery referred to on the list of accessories and equipment.
- If the charge is too low, do not interrupt ventilation to replace the battery. Continue ventilation without real-time feedback from EOlife®.

Always check the battery level before placing the device in the emergency bag. The battery level is shown in the top right corner of the start-up screen.

The battery icon fills as the charge increases and also changes color:

	Green Run time ≥ 50%	**Orange** 50% > Run time ≥ 20%	**Red** 20% > Run time
Charge			

Note
Under normal conditions of use and when the operating conditions specified in “IX. Technical data” are met, the run time is around 5 hours from fully charged.

Caution

When the symbol ‘Battery defect’ appears on the screen, the battery is probably defective, and you should use another battery to avoid a power failure during ventilation.

b) Cleaning EOlife® and its accessories

- **FlowSense®**
  The FlowSense® sensor is a single-use component of EOlife® (see “VIII. d) Disposal”).

- **Electronic control unit and removable battery**
  The electronic control unit and the removable battery are reusable EOlife® parts that must be cleaned after each use to avoid cross-contamination.

Caution

The EOlife® device must be switched off before being cleaned.

Cleaning

The electronic control unit and the removable battery of EOlife are reusable components. It is recommended to clean them after each use.

The battery should be removed from the EOlife® electronic control unit. Before applying the cleaning solution, remove any adherent material left on the unit and wipe throughly with a water-soaked cloth.

Then, use a cloth soaked in the cleaning solution and wipe out all accessible surface of the device and its battery.
To the naked eye and under normal light, no adherent material should be visible on the entire surface of the product after the cleaning.
If anything is visible, the process should be repeated.

Caution

The device must never be submerged. Do not drip or spill fluid on the device.

EOlife® and its battery are compatible with solutions such as “SURFANIOS Premium” and “Septalkan” including Didecyldimethylammonium chloride and Isopropyl alcohol.

Note
EOlife® has been tested to resist to Isopropyl alcohol according to ISO 60601-1 requirements.

c) Storing EOlife®

After cleaning the electronic control unit and the removable battery, check the battery level (see “VIII. 3 a) Charging the battery”).

Once charged, reconnect the battery to electronic control unit and store EOlife® and its accessories in a place that meets the storage conditions (see “IX. Technical data”).

d) Disposal

At the end of the EOlife® device’s lifetime (lifetime of the various parts specified in “IX. Technical data”), it should be disposed of as follows:

1. The EOlife® electronic control unit, battery and charger contain electronic components and must be disposed of in an appropriate recycling facility, in accordance with European Directive 2012/19/EU on waste electrical and electronic equipment (WEEE).
   They must not be disposed of with household waste. Take them to an electrical and electronic equipment recycling collection point. They must be disposed of in accordance with local environmental regulations on waste disposal. For more detailed information on the handling, collection and recycling of this product, contact your environmental officer or local council.

2. Users must dispose of the FlowSense® sensor as biohazardous waste.

IX. Technical data

1. Technical data related to the device

Specifications	EOlife®
Dimensions (W x H x D)	130 mm x 75 mm x 30 mm (5.11 inches x 2.95 inches x 1.18 inches)
Weight	170g ± 5 g (5.3 oz ± 0.011 oz)
Operating conditions	• Temperature between 0°C and 40°C (32°F and 104°F) • Relative humidity between 15% and 95% (non-condensing) • Atmospheric pressure range of 620 hPa (altitude of 4000 m) to 1,060 hPa (altitude of -500 m)
Transient operating conditions (maximum 20 min)	• Temperature between -20°C and 50°C (-4°F and 122°F) • Relative humidity between 15% and 90% (non-condensing)
Storage/transport conditions	• Temperature between -10°C and 35°C (-14°F and 95°F) • Relative humidity between 10% and 90% (non-condensing)
Lifetime	5 years
Run time	5 hours
Classification according to EN 60601-1: • Type of protection against electric shock • IP rating for protection against electric shock	The entire device except for the charger (electronic control unit, battery and FlowSense sensor) has been designed to meet the requirements for type BF applied parts.
IP rating for protection against solids, dust and ingress of water	IP44 (in use configuration, i.e., EOlife®, its battery and FlowSense® connected)
Electromagnetic compatibility (EMC) according to EN 60601-1-2	The control parameters and threshold values can be obtained from the manufacturer.
Shock and vibration resistance	EN 60601-1-12 (category: resistance in an emergency vehicle)
Screen	2.4 inches Resolution 320 x 240 pixels

Applicable standards	EN 60601-1:2006/A1:2013/A12:2014 EN 60601-1-2:2015/A1:2021 EN 60601-1-12:2015 EN 62366-1:2015 EN 62304:2006/A1:2015 ISO 18562-1:2017 ISO 18562-2:2017 ISO 18562-3:2017 ISO 10993-1: 2018
Essential performance requirements	Under normal conditions of use, EOlife® must provide a reactive user interface (ex: bar graph in real time, no freeze of the screen). EOlife® must displays measured values (insufflated volume and ventilation frequency) without deviation.
Measurement accuracy	Volume measurements are based on FlowSense® sensor measurements and are expressed in mL for the BTPS (body temperature and pressure, saturated). The measurement accuracies of the values displayed on the screen are as follows: • Vi (volume insufflated): ± 4.9% of the actual value measured under normal conditions of use • Vt (tidal volume) without leakage: ± 5.5% of the actual value measured under normal conditions of use • Freq (ventilation frequency): ± 1 cycle per minute FlowSense® data: • Flow range: ± 250 slm (standard litre per minute) • Dead space: < 10 ml Note : Certain types of ventilation bag can affect the measurement accuracy due to their design (non-laminar outgoing air flow). A slight measurement deviation may be seen but which has no impact on compliance with regulatory requirements.

2. Technical data related to the power supply

Specifications	EOlife® Battery
Dimensions WL x H x D)	73 mm x 40 mm x 14 mm (2.87 inches x 1.57 inches x 0.55 inches)
Weight	50 g ± 5 g (1.8 oz ± 0.011 oz)
Shelf-life	12 months (with a storage temperature between -10°C and 35°C (-14°F and 95°F) Charging the device every 6 months allows to increase battery shelf-life . ***Caution:*** *The shelf-life of the battery may be reduced if the storage temperature is not respected. To improve the shelf life of the battery, user have to keep the battery capacity between 30% and 60%. To do so, user have to charge the battery every 12 months during at least 45 minutes.*
Battery type	Li-ion
Nominal capacity	1,900 mAh (7.03 Wh)
Nominal voltage	3.7 V
Charging voltage	12V DC
Charging time (0 % to 95 %)	Approx. 2 hours
Recommended charging temperature	10°C to 45°C (50°F to 113°F)
Certifications	IEC 62133 UN38.3 UL1642

Specifications	EOlife® Charger
AC input voltage	100 V – 240 V (± 10 %)
AC input current	Max. 250 mA
AC input frequency	60 Hz / 50 Hz
DC output	12 V 1000 mA
Output protection	Short-circuit
Certification	EN IEC 61204-3:2018 EN 62368-1: 2014 + A11: 2017
Protection class	II
Unit casing material	ABS plastic, in accordance with standard UL 94V-0

3. Technical data related to consumable FlowSense®

Specifications	FlowSense®
Dimensions (W x H x D)	Length: 69.3 mm (2.72 inches). Flow tube diameter: 11.25 mm (0.43 inches). FlowSense® inlet and outlet connections comply with the EN 5356 standard.
Weight	< 20 g (< 0.7 oz)
Shelf-life	3 years at room temperature ***Caution:*** *The shelf-life of the FlowSense® may be reduced if the storage/ transport conditions are not respected for more than 48 hours.*

4. Technical data related to electromagnetic compatibility (EMC)

Manufacturer statement and guidance - Electromagnetic interference		
EOlife® is designed to operate in an electromagnetic environment as defined below. The user should ensure that the device is used in such an environment.		
Interference measurements	**Conpliance**	**Electromagnetic environment – Guidance**
Conducted emissions – Mains terminal disturbance voltage according to CISPR11	Classe B : 150 kHz to 30 MHz	Equipment suitable for use in households and buildings used for domestic purposes directly connected to a low voltage power supply.
Radiated emissions – Radiation disturbance according to CISPR11	Classe B : 30 MHz - 1 GHz	
Harmonic current emissions according to IEC 61000-3-2	Class A: 0 kHz to 2 kHz	/
Voltage fluctuations/flicker according to IEC 61000-3-3	0 kHz to 2 kHz	/

Manufacturer statement and guidance - Electromagnetic immunity		
EOlife® is designed to operate in an electromagnetic environment as defined below. The user should ensure that the device is used in such an environment.		
Immunity tests	**IEC 60601 test level**	**Level of compliance**
Electrostatic discharge (ESD) according to IEC 61000-4-2	Contact : ±8 kV Air : ±2 kV ±4 kV, ±8 kV, ±15 kV	Contact: ±8 kV Air: ±15 kV
Electrical fast transients/bursts according to IEC 61000-4-4	Access by power AC/DC: ± 2kV, f = 100 kHz	5/50 ns, 100 kHz; ±2 kV
Shock waves/surges according to IEC 61000-4-5	Access by AC/DC power ports: ± 0.5 kV, ±1 kV (Line/Line)	1.2/50 (8/20) µs LtL: ±1.0 kV
Voltage dips, short interruptions and voltage variations according to IEC 61000-4-11	Min. & max. voltage: 0% UT for 0.5 cycle 0% UT for 1 cycle 70% UT for 25/30 cycles 0 % UT for 250/300 cycles	0% UT for 0.5 cycle (1 phase) 0% UT for 1 cycle 70% UT for 25/30 cycles 0% UT for 250/300 cycles (50/60 Hz)
Conducted disturbances according to IEC 61000-4-6	Access by AC/DC power ports: 3 V (0.15 MHz to 80 MHz) 6 V (+ ISM bands) 80% mA, 1 kHz	150 kHz – 80 MHz 3 V ISM/amateur bands 6 V 80% / 1 kHz other as defined in RMF
Power frequency magnetic field according to IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 45 50 Hz or 60 Hz
Radiated disturbances according to IEC 61000-4-3	80 MHz to 2.7 GHz AM modulation 80%, f = 1 kHz 10 V/m: Home	80 MHz to 2.7 GHz Home Healthcare 10 V/m Prof. Healthcare 3 V/m 80% / 1 kHz other as defined in RMF
EOlife® has been tested for immunity to the radio services listed below. If the field strength measured on the site where EOlife® is used exceeds the level of compliance below, it is advisable to monitor EOlife® to ensure that it is functioning properly. If this is not the case, it may be necessary to take additional measures, such as changing the direction or location of EOlife®. Specific examples of RF emitters that are known sources of electromagnetic disturbance are diathermy, electrocautery, RFID and security systems (e.g., electromagnetic anti-theft systems, and metal detectors). Some of these RF emitters (e.g., RFID) in the intended environment of use might be concealed and the device can potentially be exposed to fields from these RF emitters.		
Proximity fields from RF wireless communications equipment according to IEC 61000-4-3	380 to 390 MHz 27 V/m; PM 50%; 18 Hz 430 to 470 MHz 28 V/m; (FM ± 5 kHz, 1 kHz sin) PM; 18 Hz 704 to 787 MHz 9 V/m; PM 50%; 217 Hz 800 to 960 MHz 28 V/m; PM 50%; 18 Hz 1700 to 1990 MHz 28 V/m; PM 50%; 217 Hz 2400 to 2570 MHz 28 V/m; PM 50%; 217 Hz 5100 to 5800 MHz 9 V/m; PM 50%; 217 Hz	380 to 390 MHz 27 V/m; PM 50%; 18 Hz 430 to 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz 704 to 787 MHz 9 V/m; PM 50%; 217 Hz 800 to 960 MHz 28 V/m; PM 50%; 18 Hz

X. What to do in the event of an incident

If there is a persistent problem or a major adverse event occurs when using EOlife® (e.g. battery problem or sudden device failure), ask your approved distributor what procedure to follow and/or contact the manufacturer ARCHEON at this address: product-request@archeon-medical.com.

Any incident occurring with the EOlife® product must be reported to the manufacturer, which must inform the Competent Authority.

XI. Warrantly and limits of liability

1. The manufacturer guarantees that the EOlife® device was manufactured in accordance with the technical specifications, good manufacturing practices and other industrial standards and applicable regulations.
2. The manufacturer undertakes to replace or refund any EOlife® product with hidden defects before the warranty expires, providing that it receives the lot/serial number of the defective product.
3. This warranty supersedes any other written or oral, express or implied, statutory or other guarantee, and no commercial or other warranty that differs from this one will be applicable. The only legal remedy in the event of manufacturing defects is the warranty provided above. This warranty does apply in the event of loss, damage, injury or expenses incurred directly or indirectly linked to the use of EOlife®.
4. The manufacturer is released from any responsibility in the event of misuse or improper handling, non-compliance with warnings and instructions, damage occurring after EOlife® is offered for sale, or for any other guarantee given by approved distributors.
5. The manufacturer's warranty is valid for the following periods:

Product	Warantly period
EOlife® electronic control unit	2 years
Battery	2 years
Charger	2 years

6. The manufacturer is ARCHEON, 2 Chemin des Aiguillettes, 25000 Besançon, France. contact@archeon-medical.com