ARCHEON
2 Chemin des Aiguillettes
25000 Besançon (France)
+33 (0)3 81 66 23 80
v.oqda@archeon-medical.com

Besançon, March 10th, 2022

Subject: Field safety notice – EOlife® medical device

Dear customer,

You are receiving this letter because our traceability data indicates that you are using the EOlife® medical device.

The purpose of this safety notice is to inform you that ARCHEON has initiated a voluntary safety corrective action regarding the EOlife® medical device.

This safety corrective action concerns a conversion deviation achieved by the device under certain conditions of use. The detailed description of the problem, the possible consequences as well as the precautions to be taken are described in the following safety notice.

ARCHEON has not identified any incidents and has not received any complaints or adverse event reports related to this issue.

ARCHEON's ambition is to improve the care of patients in life-threatening emergency situations, while guaranteeing their safety. This policy orchestrates all our activities and our organisation. Therefore, we ask you to take into account this safety notice and to follow the precautions for use that we recommend.

Field safety notice: EOlife® medical device

To the attention of ARCHEON distributors and all current users of the EOlife® device.

FSN reference: FSN-2022-N°01

FSCA reference: FSCA-2022-N°01

Product reference	Designation	Batch number
A0000055	EOlife®	F201000140
A0000060	EOlife® Premium Pack	F201000141

Important note

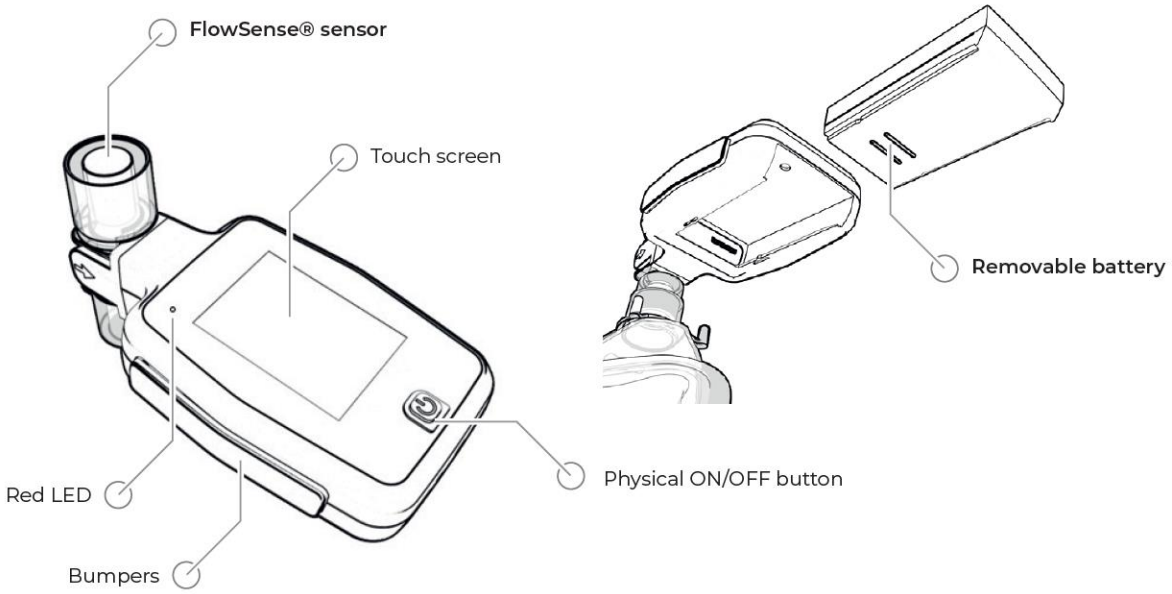
It is important that the distributors and users to whom this notice is addressed follow the measures outlined in this document and confirm receipt of the notice.

The response of distributors and users is necessary for us to be able to monitor the progress of the corrective and preventive actions we are implementing.

Information on the medical device

EOlife® is medical device intended to help professional rescuers in their practice of pulmonary ventilation during cardiopulmonary resuscitation and to adapt their actions to comply with the international guidelines of the AHA (American Heart Association) and the ERC (European Resuscitation Council).

The device is a portable device that combines the EOlife® electronic control unit, its removable rechargeable battery, and the single use sensor FlowSense®.



EOlife® is connected with the FlowSense® sensor which is placed between a ventilation interface (mask or probe) and a standard self-inflating bag for manual ventilation of the adult patient.

From the ventilatory flows provided by the user and measured by the FlowSense® sensor, EOlife® calculates the main ventilation parameters (insufflated volumes, tidal volumes, ventilation frequency, leaks) and provides a real time feedback to the user. The device also indicates the target range of ventilation parameters to ensure adequate ventilation

Reason for deployment of the safety corrective measure

Description of the problem

The EOlife® device does not require manual calibration as the FlowSense® sensor is self-calibrated over its entire operating range and self-compensated for temperature. The FlowSense® sensor measures air/oxygen mass flow rates which are therefore reliable over all claimed temperature and pressure ranges, i.e. over temperature ranges from -20°C to 50°C and up to 4000 m altitude. From the mass flow rates measured by the sensor, the data is converted into volume flow rates to display the insufflated volumes of air/oxygen. This conversion is done by the EOlife® software in the SLM unit (standard liter per minute), international unit of volume flow which takes into account the density of the gas under standard conditions of temperature and pressure

The conversion to SLM does not consider the expansion of the gas at room temperature and the atmospheric pressure to adjust the density of the gas.

The conversion difference in question results in an underestimation of the volume of air/oxygen insufflated to the patient.

This deviation is negligible at low altitude but could become significant at altitudes above 1000 m, potentially exceeding the 20% error tolerated by international standards for mechanical ventilators (ISO 80601-2-84*).

**Note:*

Although not applicable to EOlife® (standard applicable to mechanical ventilators), this standard is used by ARCHEON in order to obtain an acceptable measurement accuracy reference consistent with the product indication.

Consequence of the problem

In case of conversion deviation induced by the use of the EOlife device in conditions far from the standard conditions, the compliance of the ventilation provided by the rescuer with the European Resuscitation Council (ERC) recommendations of 6ml/kg is not guaranteed.

Currently, more than 80% of patients are subject to hyperventilation during cardiopulmonary resuscitation, as it is impossible to measure the volume of air/oxygen delivered to the patient during manual resuscitation, without the use of a mechanical ventilator. Thanks to the real-time measurement of air/oxygen volumes delivered to the patient, the EOlife® product is the only medical device available on the market today capable of reducing these risks of hyperventilation near to zero.

Regarding the benefit/risk ratio, ARCHEON considers that the use of the EOlife® device at altitudes below 1000m is acceptable, considering that it cannot lead to a deterioration of the patient's health status.

Although no incident has occurred, the problem occurs in specific conditions of use and very few devices are likely to be concerned, ARCHEON wishes to deploy corrective and preventive actions to ensure the safety of all patients in all potential use scenarios.

Safety measure to be taken

Measures to be taken by EOlife® distributors and users

1. Stop of the shipments/deliveries of products to customers (end users) until a patch is deployed.

2. To transmit this safety notice to all its customers in order to ensure that everyone is aware of the measures to be taken. And ask them of not using EOlife® at an altitude exceeding 1000 meters while waiting for the deployment of the patch.
   Under these conditions, the EOlife® device can be used in complete safety.

3. Return to ARCHEON the ‘User Return Form’ (APPENDIX A) completed by its entity.

Please note that the patch will be available in May 2022. ARCHEON will come back to you at that time to update the products.

Measures taken by ARCHEON

ARCHEON undertakes to carry out the following actions without delay:

1. To carry out a correction aiming at integrating a conversion formula guaranteeing an adequate level of accuracy over the entire range of use of the product, i.e., over temperature ranges from -20°C à 50°C and up to 4000 m altitude.

2. To carry out an update of the products on the market (to be available in May 2022).

The French national agency for the safety of medicines and health products (ANSM) has been informed of this communication.

ARCHEON is committed to provide quality products to its customers to ensure patient safety. We apologize for any inconvenience this may cause.

Furthermore, we would be grateful if you could fill in the User Return Form attached in APPENDIX A, and return it to us as soon as possible by e-mail to the following address: v.oqda@archeon-medical.com

ARCHEON is at your disposal for any further information at:

+33(0)3 81 66 23 80

Thank you for trusting us. We wish to assure you, dear customer, of our highest consideration.

ARCHEON

2 Chemin des Aiguillettes

25000 Besançon

APPENDIX A

User Return Form

PLEASE SEND THIS FORM BY E-MAIL TO: v.ogda@archeon-medical.com

Name of the device:	
IDU number of the devices concerned:	

Name of the institution/company:	
Form completed by:	
Position:	
E-mail address:	
Phone number:	
Comments (voluntary)	

☐ I acknowledge receipt of the safety notice referenced FSN-2022-N°01 and confirm that:

I have taken note of this safety notice

I am passing it onto the users concerned by the product in my establishment/company

I am taking all necessary measures to implement the recommended corrective actions.

……..

Date:

Signature Stamp of the institution/company