Urgent Field Safety Notice

Aeonmed VG70
FSCA2020_002 Dated 2021-02-16, Rev.02

Details on affected devices:
Aeonmed, VG70, Critical Care Ventilator with software version
1.1.9.80/ 1.1.9.82/ 1.1.9.83/ 1.1.9.87/ 1.1.9.90
1.2.9.81/ 1.2.9.86/ 1.2.9.88/ 1.2.9.91

Dear valued customer,

Beijing Aeonmed Co., Ltd. is an expert of anesthesia and ventilation devices. Therefore, we have implemented a strong standard of quality for our medical devices. With this Field Safety Notice, we would like to inform you that we identified the below mentioned issue.

Description of the problem:
All VG 70 Critical Care Ventilators uses a differential pressure principle sensor to measure the ventilation flow of the patient. The differential pressure sensor is greatly affected by ambient atmospheric pressure, which is the input value of the tidal volume compensation algorithm. In order to ensure the accuracy of ventilation flow of the patient, a compensation according to the altitude of the ventilator installation site must be made.
The common solution for this issue is that the altitude of the installation site is entered manually during the installation by the authorized personnel of the device or the ventilator has a built-in atmospheric pressure sensor whereby the altitude compensation will be performed automatically by the device.
It was identified that VG 70 Critical Care Ventilators with the above mentioned software version, **which did not have a build-in atmospheric pressure sensor,** were placed on the market with an incorrect instructions for use. The provided instructions for use outlines that these devices have an atmospheric pressure sensor included and no manual altitude change is necessary.

Due to the fact that all affected VG 70 Critical Care Ventilator with the above mentioned software version were provided with factory default setting (50 meters above sea level (≈1006 hPa)) there is a risk that the provided flow is not within the outlined specifications of the device due to missing tidal volume compensation.

All devices without atmospheric pressure sensors need manually input of the altitude.

Advise on action to be taken by the user:
- Please check the device regarding the above mentioned software version
- Inform all users of the device regarding this Urgent Field Safety Notice
- Contact your authorized dealer, so that he can enter manually the correct altitude before use
- Replace the instructions for use

- Please send the ACKNOWLEDGEMENT FORM back to your authorized dealer
- Please be informed the “Warning Label” will be pasted at the right side of the screen of affected device by authorized personnel. Please pay attention to the content of the Warning Label. Please review below sample of the Warning label:

- Below information has been updated in the IFU and on the Warning label, please follow the information as provided:
  1. Contact the manufacturer before putting into service at a different installation location
  2. The device is only suitable for patients ⩾ 3Kg.
- The affected VG70 in German market will be installed the atmospheric sensor. For other regions, please contact Aeonmed or authorized distributor if the devices will be used in plateau or mountainous area.

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

If the device has been transferred to another organization, please kindly provide the details of the ‘other organization’ to Aeonmed, and a copy of this Field Safety Notice needs to be passed on to the organization to which the device has been transferred.

The national competent authority has been informed of this Field Safety Corrective Action (FSCA).

Contact reference person:

.....

HEYER Medical AG, Carl-Heyer-Str. 1/3

56130 Bad Ems, Germany,

Tel.:+492603 791 340,

Email: .....

ACKNOWLEDGEMENT FORM

Attention: Aeonmed

We,_____[Company name with address]_____, have acknowledged and are aware of the contents and requests of the Field Safety Notice (FSN), reference:FSCA2020_002. The Urgent Field Safety Notice will be passed on to those who need to be aware of it within/outside of the organization.

Hereby the reply to this acknowledgement form is to confirm the receipt of acknowledgement.

Company:
Address:
Contact:
Name:
Signature: