

Pau, 10<sup>th</sup> August 2018

**EOVE SA**

Batiment NEWTON

4 rue Jules Ferry

64000 Pau France

## **Field Safety Notice (FSN)**

### **Important Information for the safety of the EO-150 Ventilator (Ref AC18-008)**

Dear Customer,

by this letter you receive a Field Safety Notice important for the safety of the EO-150 ventilator.

To ensure the high level of safety for all patients being ventilated with the EO-150 ventilator we ask you to transfer this information to all members of your teams involved in the application of the EO-150 ventilator.

As you might know from various press reports cyber-attacks are increasingly threatening IT technologies, also medical devices utilizing network technologies like Bluetooth or WiFi.

Initiated by a general cyber-attack scenario investigation of the Federal Office for Information Security in Germany we deeply reviewed and analyzed the application of the wireless Bluetooth and WiFi technology used with the EO-150 ventilator. During this Cyber threat investigation we identified a potential vulnerability of the wireless technology safety concept implemented in the EO-150 ventilator system.

No incident based on this potential vulnerability has been reported up to now. Nevertheless EOVE has decided to initiate a Field Service Corrective Action (FSCA) on all EO-150 ventilators in use to ensure our high level of intrinsic product safety for all patients ventilated with the EO-150 ventilator. This FSCA will be implemented in 2 steps:

#### **1. Immediate mandatory preventive action**

- Stop using all smartphone application in connection with the EO-150 ventilator.
- Use the EO-150 VENTILATION MODULE applied to ventilator dependent patients all times in combination with the EO-150 DOCKING STATION or the EO-REMOTE VISION TABLE only until the following FSCA is implemented in your product. This means, ventilator dependant patients shall not be ventilated with the EO-150 VENTILATION MODULE only

## 2. Field Service Corrective Action

In order to improve the safety of EO-150 ventilator in reference to the preventive action described above EOVE would like to inform you about the following mandatory FSCA.

This corrective action is a software update which includes:

1. Change of the of the WiFi configuration data used in the software of the EO-150 DOCKING STATION and the EO-REMOTE VISION TABLET
2. Elimination of the smartphone application in connection with the EO-150 ventilator
3. Implementation of a new Bluetooth pairing principle randomly generated during the first connections to the EO 150 DOCKING STATION or the EO REMOTE VISION TABLET
4. Implementation of a new highly dedicated Bluetooth connectivity of EO-150 VENTILATION MODULE to connect the EO 150 DOCKING STATION and the EO REMOTE VISION TABLET

EOVE will provide this software update to its local authorized service partners in time that the implementation of the FSCA can start on the 1<sup>st</sup> of November 2018.

Considering the different clinical conditions of patients ventilated with EO-150 ventilators EOVE requests to perform the above corrective action within the following time frame:

- within 6 months on all EO-150 ventilators in use with ventilator dependent patients
- within 12 month on all other EO-150 ventilators in use

Your EOVE contact partner or your local partner will contact you in time to organize the software upgrade of the EO-150 ventilator concerned. Should you have any questions or need further information regarding this information, please do not hesitate to contact us at:

- From France: 05 59 21 86 84
- From Abroad: +33 559 21 86 84

**Until the above corrective action has been completed we advise you to maintain the immediate mandatory preventive action mentioned above, especially with EO-150 ventilators being used with ventilator dependent patients.**

This Field Safety Notice and the following Field Service Corrective Action have been reported to the appropriate regulatory agencies.

We apologize for any inconvenience caused by the immediate mandatory preventive action and implementing the corrective action. Our team will offer a particular service handling your individual requests. Please contact [Jean.leroux@eove.fr](mailto:Jean.leroux@eove.fr); [gaetan.lhermitte@eove.fr](mailto:gaetan.lhermitte@eove.fr); [melissa.sauzer@eove.fr](mailto:melissa.sauzer@eove.fr)

Yours Sincerely,