

EOVE SA

Bâtiment Poincaré
4 Boulevard Lucien Favre
64000 Pau - France

Pau, August 5th, 2019

To whom it may concern,

Object: EO-150 Car lighter DC cable (Ref EO-CARCBL) - Supplementary instructions for use

Dear Customer,

With this letter, we would like to inform you about a supplementary instruction for use of the EO-150 Ventilator when connected to the DC power supply system of a car.

Based on the feedback we have received from the market regarding the use of the EO-150 Ventilator connected to the DC power supply system of a car we would like to ask you to inform all patients and/or care givers using the Car lighter DC cable (Ref EO-CARCBL) to respect the following additional instruction for use:

Instability of the DC power electrical system of a car might lead to severe damage of the ventilator when the car engine is started or stopped while the device is connected. Therefore patients / care givers should strictly notice the following

- When the EO-150 ventilator is intended to be connected to the DC power supply system of a car, the engine “Auto START & STOP function” must be deactivated.
- Start the car prior plugging in the Car lighter DC cable into the socket in the car.
- Unplug the Car lighter DC cable from the socket in the car prior stopping the engine of the car.
- If the Car lighter DC cable (Ref: EO-CARCBL) is damaged or the connector does not show the correct contact arrangement don't use it. In such case, use the EO-BAT9 external battery as additional power source.
- In case of any doubt about the stability of the DC power supply system of the car or lack of information from the car manufacturer, EOVE recommends to use for ventilator dependent patients the EO-150 Ventilator with the EO-BAT9 external battery as external power source.

In support of your responsibility as our distributor to convey these important supplementary instructions to all affected patients and/or care givers the follow supporting material will be available:

1. Updated User Manual including the above-mentioned supplementary instructions

Availability: September 2019

2. Leaflet including the above-mentioned supplementary instructions, which can be used as an addendum to the existing user manual

Availability: October 2019

3. Red Labels to be attached to the Car lighter DC cables (reference EO-CARCBL) already in use with the visual reminder to disable the engine “Auto START & STOP function” of the car, to start the car prior to plugging in the Car lighter DC cable into the socket in the car and to unplug the Car lighter DC cable from the socket in the car prior stopping the engine of the car.

Availability: October 2019

4. Each packaging of the Car lighter DC cable (reference EO-CARCBL) will include the Leaflet and the Red Label attached to the Car lighter DC cable

Availability: October 2019



disable the engine “Auto START & STOP function” of the car



start the car prior to plugging in the Car lighter DC cable into the socket in the car



unplug the Car lighter DC cable from the socket in the car prior to stopping the engine of the car

In addition to the supplementary instructions and labelling to be provided to patients and/or care givers, we would kindly urge you to put more emphasis during user trainings on the different auditory alarms signal generated in the case of a breakdown of the Ventilator Module. The continuous auditory alarm signal is generated when the “involuntary ventilation stop alarm” is activated, e.g. if the instability of the DC power of the electrical system of a car has led to a severe damage of the ventilator.

Indeed, we got the feedback from the market that a user did not recognize the urgency when this auditory alarm signal was activated. It is very important that care givers immediately recognize this alarm signal and the urgency of the life-threatening situation for the ventilated patient.

The EOVE team remains at your disposal for any question or further information you might need.

With our best regards,

