Field Safety Notice

March-10-2022 | MCC/22/001/IU | MX-8482 | Rev 01

AC/DC Power supply board (PC 1955) in Servo-u and Servo-n ventilator systems

Products affected:

Dear Customer

Our records indicate that the below listed products were delivered to your location. Please verify if you have any of the listed products and complete the information below.

Model number	Getinge trade name	Serial numbers	Manufacturing dates
6888800	Servo-u ventilator system	See consignee list	2015 - 2017
6688600	Servo-n ventilator system	See consignee list	2015 - 2017

Description of the issue

For ventilators operating at mains power voltage 220V-240V, we have identified that a current-limiting resistor on the AC/DC Power supply board (PC 1955) may degrade over time, and prevent the AC/DC from performing as specified.

The root cause investigation has concluded that the resistor component had been exposed to mechanical stress during assembly which eventually caused the pre-mature degradation. The assembly process for the resistor has been corrected to eliminate the potential occurrence of the degradation.

When the AC/DC Power supply board stops working as specified, the ventilator loses mains power, and automatically switches to battery back-up mode and activates the Battery operation alarm to alert the users.

With two fully charged standard batteries, the battery back-up time is at least 1 hour. When battery time is consumed there will be three additional alarms activated before the ventilator completely may shut down due to low battery voltage. After that a final power-out alarm will sound for at least 2 minutes.

Maquet Critical Care has received 32 complaints describing the above described issue. The failure rate in relation to the installed base is approximately 0,08%.

No patient or operator adverse events have been reported in relation to any of these complaints. In one of the complaints it was reported that the patient had de-saturated at the time manual ventilation was initiated.

Potential hazards

A Health Hazard Evaluation concluded that the issue may not directly cause patient harm, however there may be an indirect risk of hypoxia that comes with a replacement of the affected ventilator, where manual ventilation of the patient may be required to sustain oxygenation.

With patients at higher risk of hypoxia and de-recruitment appropriate medical risk mitigating systems (e.g. manual resuscitators) must be in place to be able to manage a temporary disconnection while transitioning the patient to a replacement ventilator, as stated in the User´s manual.

Precautions

The affected ventilators can be used in accordance to the User´s manual, with extra attention to the following precautions, as listed in chapter *1.2 Safety Guidelines* of the User´s manual:

- To guarantee reliable battery back-up, two fully charged battery modules must be connected at all times.
- Battery status should be checked in the user interface window *SYSTEM STATUS/Batteries* after periods of battery operation, e.g. intrahospital transport.
- When not in use the ventilator system should always be connected to the mains power to ensure fully charged batteries.
- The patient must never be left unattended when connected to the ventilator system.
- Always make sure that a manual resuscitator is readily available.

Corrective action

Getinge will initiate an immediate field action of all affected ventilator systems, where the affected AC/DC power supply boards (PC 1955) will be replaced. The issue is limited to countries operating at high mains voltage of 220V - 240V.

You will be contacted by your Getinge sales or service representative to plan for the update of your devices.

In addition, AC/DC Power supply boards manufactured during the years 2018-2021 will as an extra precautionary measure be replaced after 5 years of operation as part of the preventive maintenance for the ventilator system.

Please complete & return the attached acknowledgement form and maintain awareness on this notice and related actions until your ventilator systems have been updated to ensure effectiveness of the corrective action.

Distribution

This Getinge Field Notice needs to be distributed to those individuals who need to be aware within your organization - or to any organization where the potentially affected devices have been transferred. Please maintain awareness of this notice and resulting action for the use period of the device to ensure effectiveness of the corrective action. In cases where you as customer choose not to proceed with completion of the corrective action requirements described above, Getinge cannot accept any responsibility for safety related issues or legal liabilities caused by the failure to respond to this Field Safety Notice. The competent authority (the Swedish Medical Products Agency) has been informed about this communication and issue.

We apologize for any inconvenience that this may have caused and will do our utmost effort to provide a reasonable solution as swiftly as possible.

Should you have questions or require additional information, please contact your local Getinge representative.

Yours sincerely,

Jxxx
Maquet Critical Care AB

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