Field Safety Notice

2022-Jun-22 | MX-8645 | Rev 1

MCC-22-008-IU: Issues addressed in Servo Ventilator System Version 4.4

Products affected: Servo-u / Servo-u MR / Servo-n

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.

Item number	Getinge Order Reference	Serial number	Manufacturing date
6694800	Servo-u ventilator system	See consignee list	All devices delivered
6888800	Servo-u MR ventilator system	See consignee list	All devices delivered
6688600	Servo-n ventilator system	See consignee list	All devices delivered

Description of the issues

We have identified 3 issues that need to be corrected through a Field Update:

The following issue may occur with Servo-u, Servo-u MR and Servo-n ventilators:

Technical errors: combination of **TE 10, TE 16, TE 55 with Servo-u, Servo-u MR, or Servo-n**

It has been reported in complaints that ventilators have generated a combination of alarms; Technical Error 10 (Ventilation stopped), Technical Error 16 (Ventilation error) and Technical Error 55 (Communication errors) and stopped ventilating. If any plug-in module is inserted TE7 (Software error) is also generated. The analysis has concluded that a malfunction in breathing system SW can eventually lead to loss of communication and trigs technical alarms and stop of ventilation. The likelihood for a single device to experience this error is estimated to be less than 0.0005%.

The following issues may occur with the Servo-n ventilator:

TE 10 in HFO with Servo-n

There have been 3 cases with TE10 (Ventilation stopped), when patients have been treated with HFO on Servo-n. Analysis indicated that this is most likely due to the expiratory flow meter getting stuck at a high flow reading resulting in TE 10 being triggered. The likelihood for a single device to experience this error is estimated to be less than 0.002%.

Vigorous spontaneous breathing in HFO on Servo-n

At one hospital a complaint was reported that a term neonatal patient with a strong breathing drive could not be treated with the set pressure amplitude in Servo-n HFO. This is due to a default ventilator priority setting – the system prioritized to maintain mean airway pressure at settings where both amplitude and mean airway pressures could not be achieved simultaneously with the current algorithm. The patient must be of large size and active for this rare situation to occur.

Potential hazards

A health hazard evaluation was performed for each of the topics listed above.

Although these issues may not directly cause patient harm 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:

- The patient must never be left unattended when connected to the ventilator system.
- Always make sure that a manual resuscitator is readily available.
- Ensure adequate external monitoring and blood gas analysis during HFOV.

Corrective action

Getinge will initiate an immediate field action of all affected devices. The issues listed above have been addressed in Software version 4.4. Your Getinge sales or service representative will contact you to plan for the update of your devices. The timing of the availability of SW 4.4. will be dependent upon local regulatory processes within your market. For more information on this please contact your local Getinge representative.

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

Distribution

This Getinge Field Safety 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 (Läkemedelsverket), has been informed about this communication and issues.

We apologize for any inconvenience this may cause and we will do our outmost to carry through this action as swiftly as possible.

Should you have questions or require additional information, please let us know.

Sincerely,

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