Field Safety Notice

15-01-2024 MX-9049 | Rev 3

MCC-23-003-IU: HFOV limited performance

Products affected:

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
66 88 600	Servo-n base unit*	See attached list	N/A
68 88 011	Servo-n HFOV SW option *	See attached list	N/A
*Only for Servo-n System version 4.4 or 4.5 with HFOV SW option and when used with Fisher & Paykel FP950 humidifier and circuit.			

Description of the issue

Getinge is initiating a Field Safety Correction Action to inform users about a limitation of the intended performance of Servo-n during high frequency oscillatory ventilation (HFOV) when using the Fisher & Paykel neonatal circuit (950N81*) and the humidifier FP950. Getinge received one complaint that HFOV was not performing as expected for patients with certain body weights, with regard to pressure amplitude (Pampl) and high frequency tidal volume (VThf).

The investigation of the complaint indicated that the use of a relatively small endotracheal (ET) tube in relation to body weight and in combination with the Fisher & Paykel neonatal circuit* that is used with the FP950 humidifier limits the delivered Pampl and therefore reduces the delivered VThf.

*950N81 or equivalent products, i.e. 950N80, 950N81J, 950N80J

Potential hazards

The hazardous situation may include the risk of hypoxia/hypoxemia and hypercapnea/ hypoventilation due to:

- **Delivery of insufficient tidal volumes during HFOV and/or**
- **the potential need to replace the breathing circuit and humidifier and/or ventilator, or to switch to other modes of ventilation or to extracorporeal membrane oxygenation (ECMO).**

Precautions

As stated in chapter 1.2 Safety Guidelines in the IFU:

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

In addition, it is recommended to pay extra attention to ET tube size in relation to body weight when using Fisher & Paykel 12 mm circuit 950N81 with Servo-n HFOV for patients 1-3 kg* and, if possible, to optimize ET tube size in relation to the patient's weight and anatomy. If available, it is recommended to use the Getinge 15 mm HFOV circuit and Fisher & Paykel's MR850 humidifier for infants (1-3 kg) in case a relatively small ET tube size is used in relation to body weight as well as for infants >3 kg.

**see clarification of maximum weight in chapter 'Corrective action' below*

Corrective action

New information, including a warning, will be added into Servo-n IFU for System Version 4.4 and later software versions regarding the following topics:

1. ET Tube

A WARNING was added in Chapter 5.8. High Frequency Oscillatory Ventilation (HFOV), 5.8.1. General:

Ensure appropriate ET tube size.[1] A reduction in tube size may compromise the performance of HFOV. [1]See Patient circuit on page … for information about ET tube size.

and a Note was added in the same section (5.8.1):

When using small endotracheal tube sizes in relation to patient weight, volume and amplitude delivery may be restricted.

Chapter 9.5. 'Patient circuit': Some details regarding test scenarios used were added:

Endotracheal tube	
Endotracheal tube sizes	**In HFOV** **In order to achieve VThf of at least 2ml/kg:** **• 2.5 – 3.0 mm, patient weight 0.3 – 2.0 kg[1]** **• 3.0 – 3.5 mm, patient weight 0.8 - 3.0 kg[1]** **• 3.5 - 4.0 mm, patient weight 1.4 - 8 kg[2]**
[1] With patient circuit configuration for MR850 or FP950 [2] With patient circuit configuration for MR850	

2. Weight ranges

In Servo-n System version 4.4. it was established that the F&P950 humidifier and its Fisher & Paykel neonatal circuit (950N81) can be used during HFOV as demonstrated by tests that were in accordance with HFO standard, ISO 80601-2-87.
The maximum weight range for HFOV (as stated in the IFU chapter 9.1. System) is 300 g to 8 kg, which applies to the 15 mm diameter Getinge HFO circuit in combination with the Fisher & Paykel MR850 humidifier. Since the Fisher & Paykel 12 mm neonatal circuit (950N81) for FP950 has a higher resistance, the maximum weight limit for this circuit is lower than the 8 kg. This is clarified in the updated IFU with addition of the following information

High Frequency Oscillatory Ventilation
• Neonatal weight: 0.3 - 8kg[1] with the patient circuit configuration for MR850
• Neonatal weight: 0.3 - 3kg[1] with the patient circuit configuration for FP950
Footnote: [1]See Patient circuit on page … for information about ET tube size.

3. Clarification why 'Set P_{ampl} cannot be reached' alarm may occur:

The following text is inserted at the end of Chapter 6.5 Pressure Amplitude;

The system will prioritize Pmean delivery in situations where both Pmean and Pampl cannot simultaneously be achieved. In such situation Pampl delivery will be restricted.

The revised IFU will be distributed to all affected customers.

Distribution

This Getinge Field Safety Notice needs to be distributed to those individuals who need to be made aware within your organization or to any organization where the potentially affected devices have been transferred.

Please maintain awareness of this notice to ensure the effectiveness of the corrective action.

In the event you as customer choose not to proceed with completion of the corrective action requirements, Getinge cannot accept any responsibility for safety related issues or legal liabilities caused by the failure to respond to this Field Safety Notice. A Field Safety Corrective Action report has been submitted to the Competent Authorities of Sweden and other impacted EEA Competent Authorities. Getinge's Notified Body TÜV SÜD has been informed of this issue.

Getinge apologizes for any inconvenience this may cause and will do its utmost to complete this Field Action as quickly as possible. Getinge remains committed to further develop its products, in collaborations with our partners, to ensure the best care possible.

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

Sincerely,

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