Field Safety Notice

2022-JUN-22 | MX-8641 | Rev 1

MCC/22/007/NU: “Do Not Step” label on high mobile cart, Servo-air

Dear customer,

Products affected: Servo-air with High mobile cart

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
6882000	Servo-air Ventilator system	See consignee list	S/N 10001-23792
6881999	High mobile cart without drawer, flat pack	See consignee list	Delivered before 2022-02-28 or with Servo-air ventilator system with S/N 10001-23792

Description of the issue

During new environmental tests, which includes the possibility that the user steps on the wheelbase, the earlier passed test results for Servo-air regarding the standard for vertical forces (IEC 60601-1 §9.4.2.3 b) could not be reproduced when testing an equivalent product. The mitigation for Servo-air is to add the label “Do Not Step” (Figure 1) to the wheelbase on the cart. The introduction of this label is required for the installed base for Servo-air delivered with system version lower than 4.3.

No complaint has been reported related to this.

Potential hazards

We do not see any direct patient risk due to this and it does not affect the intended use of Servo-air, however there is a low risk that the Servo-air tips over and affect the patient connections which may lead to interruption of ventilation support.

Precautions

The device can be used in accordance to the instructions for use.

Corrective action

Getinge will initiate a field action of all affected device units. You will be contacted by your Getinge sales or service representative to plan for the update of your device.

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

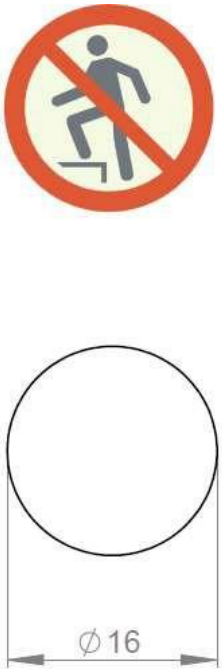

Figure 1

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 issue.

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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