URGENT MEDICAL DEVICE CORRECTION

GE Healthcare
9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Deployment>

GEHC Ref# 36111

To: Healthcare Administrator / Risk Manager
Chief of Nursing
Director of Biomedical Engineering

RE: **Potential loss of gas monitoring due to occlusion of D-Fend/D-Fend+ water traps used with Compact Airway Modules E/M-C(Ai)O(V)(X) and Cardiocap/5 monitors**

GE Healthcare has recently become aware of a potential safety issue due to loss of gas monitoring associated with occlusion of specific D-Fend/D-Fend+ water traps used with Compact Airway Modules E/M-C(Ai)O(V)(X) and Cardiocap/5 monitors. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

Occlusion of specific lots of D-Fend/D-Fend+ water traps could occur immediately after replacement. This water trap occlusion could cause a loss of respiratory airway gas monitoring. When this issue is detected the connected monitoring device will issue an audio alarm and display "low gas sample flow", "replace water trap" or "sampling line blocked" warning messages. Unattended or prolonged warnings could lead to an adverse clinical situation if the CO2 value would rapidly change in certain clinical conditions.

Safety Instructions

1) Collect and dispose of the affected water traps. See Affected Product Details below for how to identify affected water traps.

2) Complete and return the attached Medical Device Correction Confirmation form.

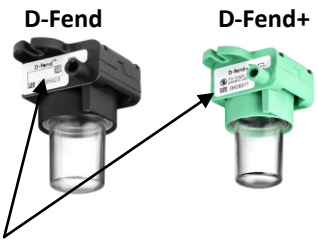
Affected Product Details

The following table includes the manufacturing LOT numbers that may include affected products:

D-Fend p/n 876446-HEL	D-Fend+ p/n 881319-HEL
J9964985, J10201698, J10258248, J10284871, J10284872, J10344108	J9906966, J9965152, J10258251, J10300071

The LOT number can be found on the water trap shelf boxes and on an individual water trap. Water traps are used in Anesthesia and Critical Care areas. Replacement water traps may also be found in stock or service departments.

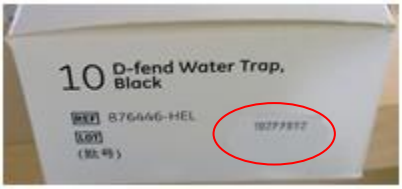
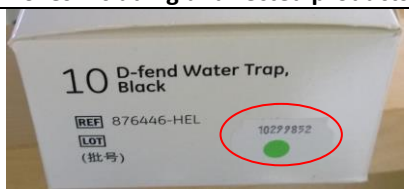
LOT number is marked on the white label on the box



LOT number is marked on the white label on the front of the individual water trap

Identification of affected and unaffected products:

Part of the water traps with above specified LOT numbers have been inspected by GE Healthcare prior shipment and are not affected.

Boxes including affected products	Boxes including unaffected products
	
Water trap boxes **with above specified LOT number without the Green Dot Sticker** are affected and should be **removed from your stock and service departments.**	Water trap boxes marked **with above specified LOT number and a Green Dot Sticker** next to the LOT number are not affected. They **can remain in use/stock**. *Green dot sticker next to the LOT number is marked on the white label on the box.*

Product Correction GE Healthcare will replace all affected products at no cost to you. Complete and return the Medical Device Correction Confirmation form attached to this notification. Once the confirmation form is received, GE Healthcare will arrange replacement product delivery.

Contact Information If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately per the contact information above.

Sincerely,

[redacted]

James W. Dennison
Vice President Devices
GE Healthcare

[redacted]

Jeff Hersh, M.D.
Chief Medical Officer – Medical Solutions
GE Healthcare

MEDICAL DEVICE CORRECTION CONFIRMATION

CUSTOMER RESPONSE REQUIRED

PLEASE COMPLETE and return to GE Healthcare

Account Name: _____

Account Number: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

Phone Number: _____

It is important that we confirm our customers have received this correction notice. As such, we require that you complete this confirmation form and email or fax it to fmi.mshelsinki@ge.com or +358 9 140 597. This step needs to be completed before the replacement and shipping process can commence.

By sending back this notice, you acknowledge receipt of the Medical Device Correction Notice and have alerted the appropriate personnel at your facility regarding the safety issue and instructions. Please select one:

☐ We have received your Medical Device Correction Notice and no longer have any of the listed lot numbers for these product codes.

☐ We have collected any and all of the affected lot numbers for these product codes, disposed of them, and listed in the table below.

Please fill in the information below for quantities you have and leave blank otherwise:

Product Code	**Lot Code**	**Quantity of affected unopened boxes (box of 10 pcs)**	**Quantity of affected individual water traps from an E/M-C(Ai)O(V)(X) Compact Airway module or Cardiocap/5 monitor, or from opened boxes**
D-Fend p/n 876446-HEL	J9964985		
D-Fend p/n 876446-HEL	J10201698		
D-Fend p/n 876446-HEL	J10258248		
D-Fend p/n 876446-HEL	J10284871		
D-Fend p/n 876446-HEL	J10284872		
D-Fend p/n 876446-HEL	J10344108		

D-Fend+ p/n 881319-HEL	J9906966		
D-Fend+ p/n 881319-HEL	J9965152		
D-Fend+ p/n 881319-HEL	J10258251		
D-Fend+ p/n 881319-HEL	J10300071		

Please provide the name of the individual with responsibility for risk and compliance.

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

Customer Support will arrange replacement product delivery based on this confirmation form.

Please fax or email to:
Fax Number: +358 9 140 597
Email Address: **fmi.mshelsinki@ge.com**