PHILIPS

URGENT Field Safety Notice

RE: Addendum to the Instructions for Use (IFU) for Microstream Advance Intubated CO2 Filter Line, VitaLine Intubated CO2 Filter Line and FilterLine Intubated CO2 Filter Line

DATE

To: Customer Name
Customer Street Address
City, State, Zip Code

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain this letter for your records.

Dear Customer,

Philips is issuing an addendum to the IFU for Microstream Advance Intubated CO2 Filter Line, VitaLine Intubated CO2 Filter Line and FilterLine Intubated CO2 Filter Line. This URGENT Field Safety Notice is intended to inform you about:

What the problem is and under what circumstances it can occur

The supplier of the Microstream Advance Intubated CO2 Filter Line, VitaLine Intubated CO2 Filter Line and FilterLine Intubated CO2 Filter Line has provided an update to the Instructions for Use (IFU) for affected product. The IFU addendum is being issued to address customer reports of difficulty or inability to disconnect an adapter from a patient's endotracheal tube in order to perform a procedure. The addendum includes information on potential adverse events that may result from a failure to follow instructions for safe use of the airway adapter, as originally stated in the IFU. Supplier did not identify any anomaly or non-conformance with the product.

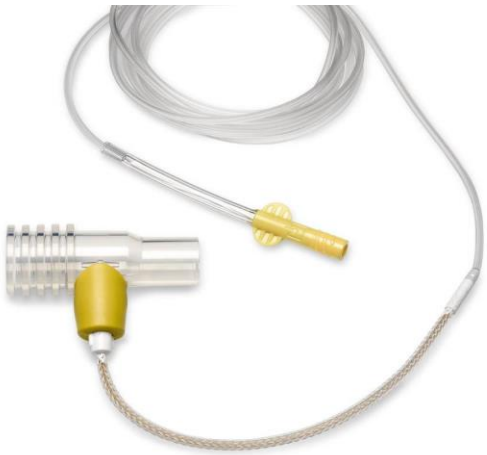
Hazard/harm associated with the issue

The inability to, or difficulty in disconnecting the adapter from the endotracheal tube to perform a procedure such as suctioning or administration of airway medication can result in an unintended extubation to perform the required procedure and/or a delay of treatment.

Affected products and how to identify them

#	Product name	Product number
1	Adt/Pedi Intub CO2 Line STerm	989803204511
2	Adt/Pedi Intub CO2 Line STerm Lng	989803204321
3	Adt/Pedi Intub CO2 Line High Humidity	989803204301
4	Adt/Pedi Intub CO2 Line LTerm Lng	989803204331
5	Adt/Pedi Intub CO2 Line LTerm	989803204521
6	Neo/Inf Intub CO2 Line LTerm	989803204531
7	Neo/Inf Intub CO2 Line High Humidity	989803204311
8	Neo/Inf Intub CO2 Line LTerm Lng	989803204341
9	VitaLine H Set Adult/Pediatric	989803159571
10	VitaLine H Set Infant/Neonatal	989803159581
11	FilterLine Set Long Adult/Pediatric	989803160241
12	FilterLine H Set Long Adult/Pediatric	989803160251
13	FilterLine H Set Long Infant/Neonatal	989803160261
14	Trade Compliant: FilterLine H, Adult/Ped	989803182921
15	Trade Compliant: FilterLine H, Infant/Neo	989803182931
16	FilterLine Set Adult/Pedi	989803105531
17	FilterLine H Set Adult/Pedi	989803105541
18	FilterLine H Set Infant/Neonatal	989803105561

Microstream Advance Neonatal-Infant Intubated CO2 Filter Line



Microstream Advance Adult-Pediatric Intubated CO2 Filter Line

Actions that should be taken by the customer / user

- Continue using the products following the instructions in IFU. During setup, ensure that the airway adapter can be easily attached and detached from the breathing circuit/tubing before proceeding. The airway adapter can be connected to the breathing circuit/tubing in a variety of configurations. These include a direct connection to the endotracheal tube.

- Pass this notice to all those who need to be aware within your organization or to any organization where affected devices have been potentially transferred.

- Complete the URGENT Field Safety Notice Response Form at the end of this notification to submit both acknowledgment of this URGENT Field Safety Notice and confirm understanding of actions to be taken.

Actions planned by Philips

- Following addendum to the IFU will be issued:
  Adverse events associated with failure to follow the Instructions for Use while attaching and detaching the airway adapter from the breathing circuit are listed in descending order of severity: unintended extubation, respiratory failure, hypoxia, low oxygen saturation, aspiration/inhalation and delay to treatment. Any serious incident related to device use that may occur should be reported immediately to the manufacturer, the local competent authority, and any other regulators as required.

If you need any further information or support concerning this issue, please contact your local Philips representative: *<Philips representative contact details to be completed by the Market/Business>*

This notice has been reported to the appropriate Regulatory Agencies. Adverse reactions or quality problems experienced with the use of this product(s) may be reported to *< Markets to insert to whom the customer should report>* Philips regrets any inconvenience caused by this problem.

Sincerely,

Deborah Currlin
Head of Quality, Hospital Patient Monitoring
Philips Healthcare

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URGENT Field Safety Notice

Reference: Addendum to Instructions for Use (IFU) for Microstream Advance Intubated CO2 Filter Line, VitaLine Intubated CO2 Filter Line and FilterLine Intubated CO2 Filter Line

Instructions: Please complete and return this Response Form to Philips promptly and no later than 30 days from receipt. Completing this Response Form confirms receipt of the URGENT Field Safety Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- Continue using the products following the instructions in IFU. During setup, ensure that the airway adapter can be easily attached and detached from the breathing circuit/tubing before proceeding. The airway adapter can be connected to the breathing circuit/tubing in a variety of configurations. These include a direct connection to the endotracheal tube.
- Pass this notice to all those who need to be aware within your organization or to any organization where affected devices have been potentially transferred.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice and confirm that the information from this letter has been properly distributed to all users that handle the affected product.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please email this completed form to Philips at: <Response Form return details to be completed by the KM/country>