

URGENT - Medical Device Recall

Philips Microstream® Infant/Neonatal M1923A Filterline H Set and 989803159581 Vitaline H Set

Dear Customer,

The manufacturer of the Philips Microstream® M1923A Filterline and 989803159581 Vitaline products for infants/neonates has informed Philips of a problem in certain manufacturing lots of these devices, which could pose a risk for patients. These products are used with Philips Monitors for the measurement of endtidal CO₂ in infants and neonates

This Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients or users
- the actions planned by Philips to correct the problem.

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.


Affected lots may contain small plastic strands that could be inhaled. They were produced from October 2010 through February 2011. Please see the attached Field Safety Notice, which describes how to identify affected devices and provides instructions for actions to be taken. Please follow the “ACTION TO BE TAKEN BY CUSTOMER/USER” section of the notice.

Should you have any questions or concerns about this recall, please contact your local Philips representative <Philips representative contact details to be completed by the KM/country>.

This recall has been reported to the appropriate Regulatory Agencies.

Ensuring that you have the highest quality medical devices, accessories and supporting documentation is our top priority. Your satisfaction with Philips products is very important to us.

Sincerely,



Director of Quality & Regulatory Affairs

Attachment



URGENT - Medical Device Recall

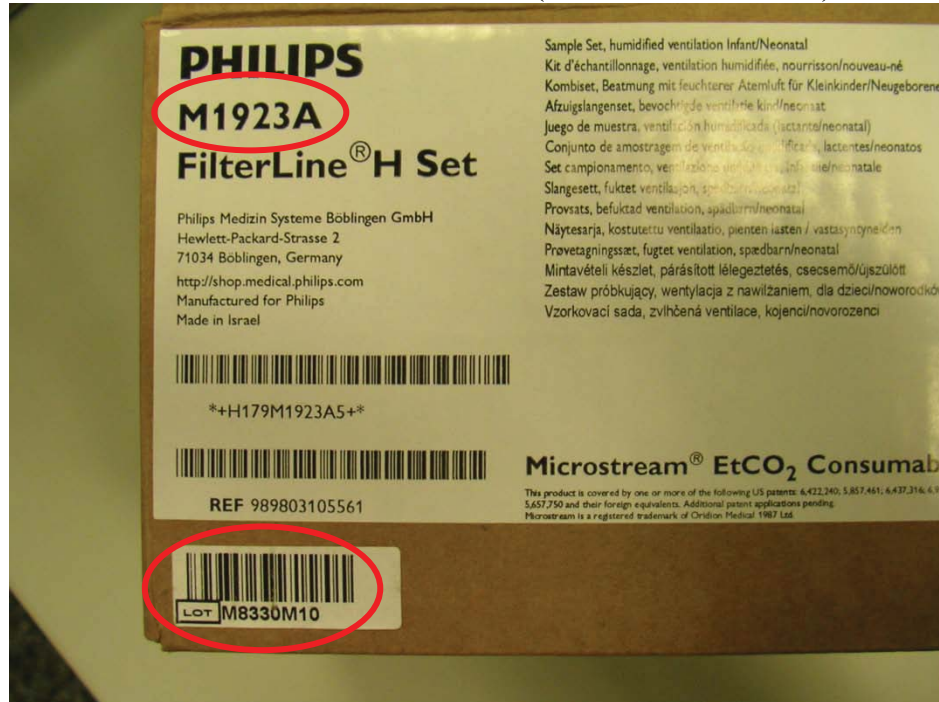
Philips Microstream® Infant/Neonatal M1923A Filterline H Set and 989803159581 Vitaline H Set

<p>AFFECTED PRODUCTS</p>	<p>Philips Microstream® Infant/Neonatal Filter Line products manufactured between Oct. 2010 and Feb. 2011 with the following lot codes:</p> <table border="1"> <thead> <tr> <th><u>Product</u></th> <th><u>Product Lot Codes</u></th> </tr> </thead> <tbody> <tr> <td>M1923A Filterline H Set Infant/Neo</td> <td>M8330M10 M8386N10 M8411P10 M8451P10 M8477A11 M8514A11 M8572B11</td> </tr> <tr> <td>989803159581 Vitaline H Set Infant/Neo</td> <td>M8409P10</td> </tr> </tbody> </table> <p>These products are used with Philips monitors for the measurement of endtidal CO₂ in infants and neonates. Currently shipping products are not affected.</p> <p><u>Note:</u> The M1923A Filterline H Set is also shipped as part of the M3015A Measurement Server Extension, Product Option #K33.</p>	<u>Product</u>	<u>Product Lot Codes</u>	M1923A Filterline H Set Infant/Neo	M8330M10 M8386N10 M8411P10 M8451P10 M8477A11 M8514A11 M8572B11	989803159581 Vitaline H Set Infant/Neo	M8409P10
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989803159581 Vitaline H Set Infant/Neo	M8409P10						
<p>PROBLEM DESCRIPTION</p>	<p>Fine plastic strands inside the endotracheal tube side of the airway adapter may become dislodged and subsequently inhaled by the patient. The strands are typically 5 mm long and 100 microns in diameter, about the thickness of a human hair.</p>						
<p>HAZARD INVOLVED</p>	<p>If not expelled by the patient, the inhaled strands could cause a local inflammatory response and ultimately a granuloma. The probability of patient harm is considered to be low even though the probability of a strand breaking free is assumed to be high.</p>						

HOW TO IDENTIFY AFFECTED PRODUCTS

Check the product number and the product lot code which can be located on the outer box and on the individual unit packaging.

Outer Box of M1923A FilterLine H Set (contains 25 filterlines)



Individual Filterline packaging(paper label in plastic bag with product)



Outer Box of and 989803159581 VitaLine H Set (contains 25 filterlines)



Individual Filterline packaging (paper label in plastic bag with product)



<p>ACTION TO BE TAKEN BY CUSTOMER / USER</p>	<p>Immediately identify all products from affected lots, remove from inventory and dispose in accordance with local regulations. New products will be sent proactively to each affected customer.</p> <p>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 KM/country></p>
<p>ACTIONS PLANNED BY PHILIPS</p>	<p>Philips is voluntarily initiating a recall action consisting of:</p> <ul style="list-style-type: none"> • Distribution of this Field Safety Notice (FSN). • Replacement of affected units.
<p>FURTHER INFORMATION AND SUPPORT</p>	<p>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 KM/country></p>

