

Philips Healthcare

Anesthesia Care

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FSN86600018

2014 December

URGENT –Field Safety Notice Philip’s Anesthesia Machines Control dial may get stuck

Dear Customer,

A potential risk has been identified in some anesthesia machines manufactured by Philips Anesthesia Care A/S that, if it were to occur, could pose a risk for patients. This communication 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
- 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.

Please retain a copy of this Field Safety Notice with the equipment User Manual.

The control dial serves an important role in setting and controlling the anesthesia machine functions. The control dial may get stuck when pushed, thus preventing the normal and expected function of the control dial. It can be brought to working condition again by simply pulling it out.

Philips has not received any reports of harm related to this issue.

Please refer to the following page, which provide instructions for actions to be taken. Follow the “Action to be taken by Customer/User” section of the instructions.

If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,



Peter Jørgensen
Senior Quality System Specialist

Philips Healthcare

Anesthesia Care

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AFFECTED PRODUCTS	<p>The following products and S/N ranges may be affected:</p> <p><u>Siesta i Breasy (P/N # 866204/10652-00):</u> S/N: 200XXXXXX, AMXXXXXX, DK30100002-DK301000032</p> <p><u>Siesta i Whispa (P/N # 866202/10651-00):</u> S/N: 200XXXXXX, AMXXXXXX, DK30100001-DK301000151</p> <p><u>Dameca MRI 508 (P/N # 866203/10651MRI-00):</u> S/N: 200XXXXXX, AMXXXXXX, DK30100001-DK301000082, MRI5087001-MRI5087218</p> <p><u>Siesta i TS (P/N # 866163/10653-00):</u> S/N: 200XXXXXX, AMXXXXXX, DK25100001-DK25100031</p> <p><u>IntelliSave AX700(P/N # 866205/10623-00):</u> S/N: AMXXXXXX, DK30100001-DK40601022</p>
PROBLEM DESCRIPTION	<p>The spring-function of the control dial may not work, which may cause the control dial to get stuck when pushed, thus preventing its normal and expected function.</p> <p>The control dial is part of the user interface and serves an important role in setting and controlling the anesthesia machine functions as it is used to adjust and confirm settings made by the user.</p>
HAZARD INVOLVED	<p>The control dial may become stuck preventing the normal and expected function of the control dial, and the user may be unaware that the control dial can be brought to working condition by simply pulling it out.</p> <p>For Siesta i Breasy, Siesta i Whispa and MRI 508 freshgas regulation and ventilator mode change (Manual or Ventilator) can still be done as this is mechanical and/or soft key controlled and doesn't need confirmation by the control dial.</p> <p>For Siesta i TS and IntelliSave AX700 it is not possible to regulate freshgas delivery or change ventilator mode as this needs confirmation by the control dial.</p> <p>For all machine types ventilation will continue at the previously set parameters</p> <p>In the worst case scenario where the user is unable to change oxygen concentration the issue may lead to temporary hypoxia, because it is expected to take time for the user to analyze the problem and switch to an alternative method of delivery of freshgas flow.</p>
HOW TO IDENTIFY AFFECTED PRODUCTS	<p>All the anesthesia machines listed in the "Affected Products" section may be affected by this issue. The product type and S/N can be found on a label on the back of the anesthesia machine.</p>

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ACTION TO BE TAKEN BY CUSTOMER / USER	<p>The customer should read the Field Safety Notice and ensure that they understand it and that all personnel using the device are informed about the content in this Field Safety Notice.</p> <p>An anesthesia machine that has a control dial that gets stuck can continue to be used as the control dial can be pulled out, making the control dial work.</p> <p>If a machine is exhibiting the issue with the control dial getting stuck, Philips should be contacted in order to have the control dial replaced.</p>
ACTIONS PLANNED BY PHILIPS	<p>Philips is voluntarily initiating a correction to affected devices. Customers with devices that exhibit control dial issue will receive a replacement control dial free of charge.</p>
FURTHER INFORMATION AND SUPPORT	<p>If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.</p>