

URGENT - Medical Device Correction Avalon Fetal Monitors FM20, FM30

Interruption of power-up/boot sequence may cause the paper scale and recorder speed settings of the monitor to revert to factory defaults.

Dear Customer,

A problem has been detected with the Philips Avalon Fetal Monitors FM20 and FM30 that could pose a risk for patients. Our records indicate that you have received a product potentially bearing such risk.

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.

Please retain a copy with the equipment Instructions for Use.

In rare circumstances, the settings for paper scale type and recorder speed may revert back to the factory default settings, which are: US paper style and 3 cm / min paper speed. This behavior would have the most impact in Europe and Asia/Pacific where other settings are preferred. If this change remains undetected by the user, it may lead to misinterpretation of the fetal trace and potential incorrect clinical decisions regarding patient care.


Please refer to the attached information that provides instructions for actions to be taken. Currently shipping products are not affected by this action.

This action has been reported to the appropriate Regulatory Agency.

If you need further information or support concerning this issue, please contact your local Philips representative or the Philips response center at *(Philips contact details to be completed by the KM / country)*.

Philips apologizes for any inconveniences caused by this problem.


Sincerely,



Sr. Director, Quality & Regulatory Affairs

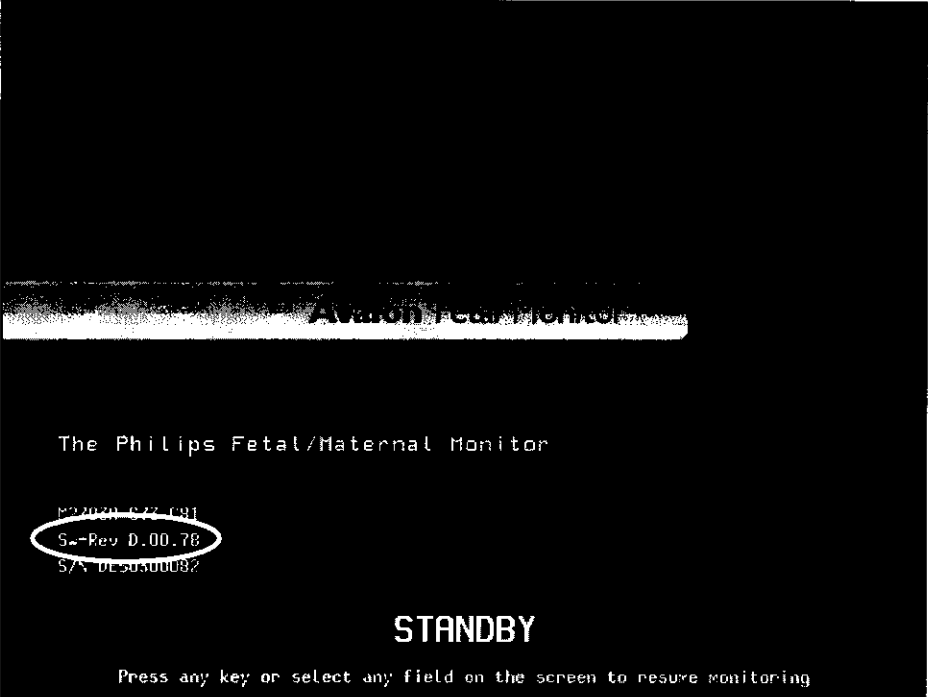
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<p>AFFECTED PRODUCTS</p>	<p>The following products in the serial number range from DE53001002 to DE53107383 may contain software revisions C or D and experience the described behavior:</p> <p>M2702A Avalon Fetal Monitor FM20 M2703A Avalon Fetal Monitor FM30</p>
<p>PROBLEM DESCRIPTION</p>	<p>The settings for paper scale type and recorder speed may in rare cases revert back to the factory default settings, which are: US paper style and 3 cm/min paper speed. This behavior would have the most impact in Europe and Asia/Pacific where other settings are preferred.</p> <p>The problem occurs when the power-up/boot sequence of the fetal monitor is interrupted, e.g. switching the monitor off or unplugging the power cord before it has completed the boot sequence and switching it on again immediately (within 60 sec) after the interruption</p> <p>If the system resets to factory defaults, the default paper speed of 3 cm/min will be printed in the header of the recorder paper. If non-US paper scale is present in the monitor, the INOP message “wrong paper scale” is displayed on the fetal monitor screen and printed on the paper, starting on the third printed page at the latest. In addition the recorder icon displays a “?”</p> <div style="text-align: right;">  </div>
<p>HAZARD INVOLVED</p>	<p>An unnoticed recorder speed change may lead to misinterpretation of the fetal trace by the user and to potential incorrect clinical decisions regarding patient care. The paper scale type change is of secondary impact on the interpretation of the fetal trace.</p>

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<p>HOW TO IDENTIFY AFFECTED PRODUCTS</p>	<p>Only software revisions C and D are affected. The software revision is displayed during monitor standby mode on the display in the lower left corner. Monitor Standby mode is reached by choosing "Main Setup" and then "Monitor Standby" on your Monitor menu.</p>  <p>The screenshot shows the monitor's standby screen. At the top, it says "Avalon Fetal Monitor". Below that, it says "The Philips Fetal/Maternal Monitor". In the lower left corner, there is a small box containing the text "FM20/30 C/D", "Sw-Rev D.00.76", and "S/N DE5050008?". The text "Sw-Rev D.00.76" is circled in red. At the bottom of the screen, it says "STANDBY" and "Press any key or select any field on the screen to resume monitoring".</p>
<p>ACTIONS PLANNED BY PHILIPS</p>	<p>Philips is voluntarily initiating a correction of the affected devices and will upgrade all Fetal Monitors with a new software revision free of charge.</p> <p>A Philips Healthcare representative will contact customers with affected devices to arrange for the software revision upgrade. This action will start at the end of May 2009.</p>

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ACTION TO BE TAKEN BY CUSTOMER / USER	<p>During the interim period the device can continue to be used. The issue can be avoided by either configuring the "Auto Defaults" to OFF or by not interrupting the boot sequence of the fetal monitor.</p> <p>As a general matter, Philips recommends that users routinely check all visual and acoustic indicators as well as technical alarms (INOPs) to ensure the device is operating as desired. In particular, users should pay attention to:</p> <ul style="list-style-type: none">• The INOP message "WRONG PAPER SCALE" displayed on the fetal monitor screen and printed on the paper; <p>In addition, the Instructions for Use provide important information regarding:</p> <ul style="list-style-type: none">• Checking the actual paper speed as printed in the header on the recorder paper,• The recorder icon displaying a "?"
FURTHER INFORMATION AND SUPPORT	<p>If you need any further information or support concerning this issue, please contact your local Philips representative or the Philips response center at: <i>(Philips contact details to be completed by the KM / country)</i></p>