URGENT - Medical Device Correction

Philips IntelliVue Patient Monitors:

MP5 (M8105A), MP5SC (M8105AS), MP5T (M8105AT), MP5 Upgrades (M8105AU, 866327)

Philips Avalon Fetal Monitors:

FM20 (M2702A), FM30 (M2703A), FM50 (M2705A)

Dear Customer,

A problem has been detected with the Philips IntelliVue Patient Monitors & Philips Avalon Fetal Monitors that, if it were to occur, could pose a risk for patients. 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
- 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 Notice.

Philips has recently discovered that in time-synchronized automatic/sequence mode, the NBP automatic measurement series is stopped inadvertently, which could lead to a delay in treatment.

This issue affects certain Philips MP5 IntelliVue Patient Monitors and Philips Avalon Fetal Monitors.

Please refer to the following pages, which provide information on how to identify affected devices and instructions for actions to be taken. Follow the “Action to be taken by Customer/User” section of the notice.

Should you have any questions or concerns about this issue, please contact your local Philips representative or the UK Philips Customer Care Centre on 0870 532 9741.

This issue 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,

Hauke Schik
Director of Quality & Regulatory Affairs

Attachment

URGENT - Medical Device Correction

Philips IntelliVue Patient Monitors:
MP5 (M8105A), MP5SC (M8105AS), MP5T (M8105AT), MP5 Upgrades (M8105AU, 866327)

Philips Avalon Fetal Monitors:
FM20 (M2702A), FM30 (M2703A), FM50 (M2705A)

AFFECTED PRODUCTS	The following Philips IntelliVue and Avalon Monitors are affected: Philips IntelliVue Monitors with software revisions J.21.03, J.21.19. **Model** **Product** MP5 M8105A MP5SC M8105AS MP5T M8105AT MP5 Upgrade M8105AU MP5SC Upgrade 866327 Philips Avalon Monitors with software revision J.30.58: **Model** **Product** FM20 M2702A FM30 M2703A FM50 M2705A
PROBLEM DESCRIPTION	In time-synchronized automatic/sequence mode the NBP automatic measurement series is stopped inadvertently, if the repetition interval is increased manually by the user (e.g. from 5 to 15 minutes) in between two consecutive measurements. • A prompt message “Any ongoing NBP measurement and automatic cycle stopped” is displayed and a single tone sounds when the measurement series is stopped. • After the automated measurement series has been stopped, NBP numeric, repetition time, and time to next measurement are no longer displayed, i.e. the NBP numeric field is blank.
HAZARD INVOLVED	If the NBP measurement is stopped, and a patient’s blood pressure is not being monitored, a delay in treatment could occur.
HOW TO IDENTIFY AFFECTED PRODUCTS	Philips IntelliVue Patient Monitors and Philips Avalon Fetal Monitors Running software revisions J.21.03, J.21.19 (IntelliVue MP5) and J.30.58 (Avalon FM) are affected. The Product Number is contained on the devices product label, located on the back of the device. The SW revision can be accessed via the Revision Screen at the bedside monitor.

ACTIONS PLANNED BY PHILIPS	Philips is voluntarily initiating a correction consisting of: • Distribution of this Field Safety Notice (FSN). • Software upgrade of the affected units. A Philips Healthcare representative will contact customers with affected devices to arrange a software upgrade to correct the issues.
ACTION TO BE TAKEN BY CUSTOMER / USER	During the interim period until the SW is upgraded please make sure, if the NBP repetition interval needs to be increased (e.g. from 5 to 15 minutes), to restart the automatic NBP measurement. Please review this 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.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Centre on 0870 532 9741.