URGENT - Medical Device Correction
Xper Flex Cardio Patient Monitoring System

Display of Invasive Blood Pressure Measurement May Freeze

Dear Customer,

A problem has been detected in certain Philips Xper Flex Cardio Patient Monitoring System (Flex Cardio) that could possibly 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 with the equipment Instruction for Use.

The Invasive Blood Pressure (IBP) numeric values will freeze on the display when certain functions are performed. These functions are listed on the following page under the “PROBLEM DESCRIPTION” section.

Our records indicate that you have an affected Flex Cardio device. The following page provides additional instructions and actions to be taken. If you need any further information or support concerning this problem, please contact your local Philips representative: <Philips representative contact details to be completed by the KM / country>.

This notice has been reported to the appropriate Regulatory Agencies. Philips apologizes for any inconveniences caused by this problem.

Sincerely,

[redacted]

Rusty Kelly
Head of Quality & Regulatory
Medical Consumables and Sensors

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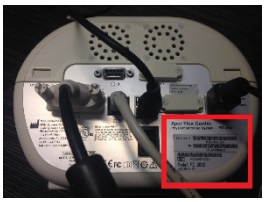
AFFECTED PRODUCTS	Flex Cardio (Model FC2010) devices, Revision D, Service #: 453564669081
PROBLEM DESCRIPTION	The Invasive Blood Pressure (IBP) numeric values will freeze on the display when any of the following functions are performed: • Change an IBP Site Label using the Site Label icon or the keyboard • Activate or deactivate the mean pressure waveform display option (On/Off) using the Invasive Pressure Options Dialog or the keyboard • Activate or deactivate the waveform hide option (On/Off) using the Invasive Pressure Options Dialog • Activate or deactivate the pressure waveform filter option (On/Off) using the keyboard • Perform a Pullback using the Pullback icon or the keyboard
HAZARD INVOLVED	The problem could interfere with the clinical staff's recognition of a change in a patient condition.
HOW TO IDENTIFY AFFECTED PRODUCTS	 The Service # and serial number of the Flex Cardio are located on the bottom right corner of the back of the device. 
ACTION TO BE TAKEN BY CUSTOMER / USER	Until Philips contacts you to arrange for a software update to address this issue, if the IBP numeric values become frozen and do not update in real-time, opening the Waveform Setup Dialog and then immediately pressing the OK button will restore the proper display of the IBP numeric values. The following is a list of alternative methods of performing the functions listed in the Problem Description section that do not cause the problem to occur: • Change an IBP Site Label using the Pressure Setup Dialog or a macro • Activate or deactivate the mean pressure waveform display option (On/Off) by using the Waveform Setup Dialog, the Pressure Setup Dialog or a macro • Activate or deactivate the waveform hide option (On/Off) using the Waveform Setup Dialog, the Pressure Setup Dialog, the keyboard or a macro • Activate or deactivate the pressure waveform filter option (On/Off) using a macro Note that performing a Pullback will cause the problem to occur. If is it necessary to perform a Pullback, ensure that the display of the IBP numeric values is restored afterwards by opening the Waveform Setup Dialog and then immediately pressing the OK button.

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ACTIONS PLANNED BY PHILIPS	A Philips representative will contact you regarding your affected Flex Cardio devices. A software update will be required on both the affected Flex Cardio device and on the host workstation's driver. These actions will be implemented free of charge by Philips.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this problem, please contact your local Philips representative: <Philips representative contact details to be completed by the KM / country>.

PHILIPS

<Name and Address of Hospital>

<Date>

TO: WHOM IT MAY CONCERN
CC: Chairman Medical Board and relevant Head of Department

Attached is a Field Safety Notice/Field Change Order pertaining to the Philips Flex Cardio (Model FC2010) devices due to FCO 72200433 _ 86400023. Please note that the serial number of the units affected are stated below:

Affected Serial Numbers: <Serial Numbers>

If you need any further information or support concerning this issue, please contact your local Philips Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number).

This is a mandatory requirement based on 21CFR Part 820 by USA FDA, thus we seek your cooperation to acknowledge that you are thus notified of the above within 5 working days from the issuance of this letter.

Acknowledged By:
Customer Name/Signature:
Company Name/Stamp:
Date:

Philips Electronics Singapore Pte Ltd
622 Lorong 1, Toa Payoh
Singapore 319763
Tel: +65 6206 8000
www.philips.com.sg

Reg. No 199705989C