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 Flex Cardio due to FCO 72200408 _ 86400018. Please note that the serial number of the units affected are stated below:

Affected Serial Numbers: <Affected 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:

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www.philips.com.sg

Reg. No 199705989C

URGENT - Medical Device Correction
Xper Flex Cardio Patient Monitoring System

Intermittent Communication between Host and Flex Cardio

Dear Customer,

A problem has been detected in the Philips Xper Flex Cardio Patient Monitoring System ("Flex Cardio") that, if it were to recur, could pose a risk for patients or users. 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 Instruction for Use.

Because of intermittent communication between the host system and the Flex Cardio, it is possible for any of the following conditions to occur, which could result in delays in diagnosis or treatment:

- Boom Monitor (display) may not display all active waveform and/or vital sign data.
- Delayed audible and visual alarms at the Flex Cardio and Boom Monitor respectively, due to a mismatch between the alarm limits on the host system and the Flex Cardio/Boom Monitor.
- After patient admission and case initiation at the host system, the case may not be fully transmitted to the Flex Cardio. In this case, the Boom Monitor in the exam/procedure room will display vital sign data, but the Flex Cardio will not provide audible alarms.
- After patient discharge and case termination at the host system, case termination may not be transmitted to the Flex Cardio. In this case, the Boom Monitor in the exam/procedure room will continue to display vital sign data, and the Flex Cardio will continue to provide audible alarms.

Our records indicate that you have an affected product. This notice only applies to Revs. A and B of the Flex Cardio; a separate notice with different instructions is being sent to users with Flex Cardio Rev. C. The following page provides additional instructions and actions to be taken, including how to determine which revision of Flex Cardio you have; refer to the "Action to Be Taken by Customer / User" section for more information. 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 Agency. Philips apologizes for any inconveniences caused by this problem.

Sincerely,

[redacted]

Rusty Kelly
Senior Manager, Quality & Reg ulatory

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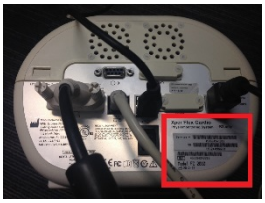
AFFECTED PRODUCTS	Flex Cardio devices, Revisions A and B To assist in identifying affected devices, each affected device has at least one of the following numbers on the label on its back: Service #: 453564241901 and 453564483321 NOTE: A separate notice (FSN86400014A) was sent to customers with Flex Cardio, Rev. C.
PROBLEM DESCRIPTION	Because of intermittent communication between the host system and the Flex Cardio, it is possible for any of the following conditions to occur: • Boom Monitor (display) may not display all active waveform and/or vital sign data. • Delayed audible and visual alarms at the Flex Cardio and Boom Monitor respectively, due to a mismatch between the alarm limits on the host system and the Flex Cardio/Boom Monitor. • After patient admission and case initiation at the host system, the case may not be fully transmitted to the Flex Cardio. In this case, the Boom Monitor in the exam/procedure room will display vital sign data, but the Flex Cardio will not provide audible alarms. • After patient discharge and case termination at the host system, case termination may not be transmitted to the Flex Cardio. In this case, the Boom Monitor in the exam/procedure room will continue to display vital sign data, and the Flex Cardio will continue to provide audible alarms.
HAZARD INVOLVED	Depending upon the condition that occurs because of an intermittent communication problem, the following hazards may be present: • Delayed diagnosis/treatment due to unavailability of study data. • Delay in treatment resulting from delay or failure to recognize deterioration in a patient's condition. • User confusion resulting from unexpected behavior of the device.
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. 

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ACTION TO BE TAKEN BY CUSTOMER / USER	A Philips representative will contact you regarding your affected device. You may continue to use the device provided that each monitored patient is closely observed by a qualified health care professional and is not left unattended, as specified in the device's instructions for use. To reduce the probability of intermittent communication issues described in this notice: • The Flex Cardio must communicate with its host system via an isolated, dedicated Ethernet port. • Do not turn the Flex Cardio device on and/or off while a patient case is open. Close the patient case prior to powering down the Flex Cardio device. Open a patient case after the Flex Cardio device is fully powered on. • Verify that the patient name is visible on the Boom Monitor, which is an indication that the patient case has fully transferred and audible alarms are active. Also, if all expected vital signs are not displayed on the Boom Monitor, close and then re-open the case to resynchronize the Flex Cardio and the host system.
ACTIONS PLANNED BY PHILIPS	An addendum to the device's Instructions for Use will be provided to all affected customers by a Philips representative. A Philips representative will also review the contents of the Instructions for Use addendum with each customer and confirm understanding of the addendum's contents. A PDF viewer will be needed in order to view the Instructions for Use addendum. Also, all affected customers will be provided with an updated Software and Documentation Media Kit, which contains the IFU addendum. Customers will be asked to destroy all existing Software and Documentation Media Kits. These corrective 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>.