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 Corrective Order pertaining to the Invivo Xper Flex Cardio Physiomonitoring System (Flex Cardio 2010 devices) due to FCO 86400022_72200432.

Please note that the serial number of the units affected are stated below:

Affected Serial Numbers: XXXXXX, XXXXXX, XXXXXXX, XXXXXX

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

Incorrect Firmware Installed

Dear Customer,

A problem has been detected in the 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.

Affected Flex Cardio devices were released with an incorrect firmware version installed. 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.

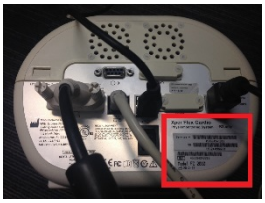
Sincerely,

[redacted]

Rusty Kelly
Head of Quality & Regulatory
Medical Consumables and Sensors

URGENT - Medical Device Correction
Xper Flex Cardio Patient Monitoring System

Incorrect Firmware Installed

AFFECTED PRODUCTS	Flex Cardio 2010 devices, Revision D, Service #: 453564669081
PROBLEM DESCRIPTION	Affected Flex Cardio devices were released with an incorrect firmware version installed.
HAZARD INVOLVED	The problem could result in intermittent loss of ECG monitoring, inaccurate ECG amplitude display and or auxiliary output, or inaccurate heart rate (HR) displayed due to QRS detection fault.
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	Users should discontinue use of affected devices immediately. A Philips representative will contact you regarding your affected device.
ACTIONS PLANNED BY PHILIPS	A Philips representative will contact you regarding your affected Flex Cardio devices. Each affected device will be replaced. 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>.