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:

- Inability of the Flex Cardio to connect to the host system.
- 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. The following page provides additional instructions and actions to be taken; 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 & Regulatory

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AFFECTED PRODUCTS	All Flex Cardio devices, Revision C Model/Product Numbers: 453564634201, 453564534211, 453564621791, 453564621801, 860335 and 860338
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: • Inability of the Flex Cardio to connect to the host system. • 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 the device or 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 model number 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: • If using an XDS host system, ensure the Flex Cardio device is connected to the XDS computer's Ethernet port labeled "LAN 1." If using other host systems, connect the Flex Cardio only 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	Each device will require configuration and Instructions for Use updates by Philips. Additionally, all Software and Documentation Media Kits will be replaced. 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>.