URGENT - Field Safety Notice
Medical Device Correction
Xper Flex Cardio Physio Monitoring System

Dear Customer,

Several problems have been detected in the Philips Xper Flex Cardio Physio Monitoring System (Flex Cardio), that, if they were to re-occur, could pose a risk for patients. This Field Safety Notice is intended to inform you about:

- The potential issues and under what circumstances they may occur
- The action(s) that you as a customer can take to minimize the effect of the problem
- 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.

Our records indicate that you have an affected Flex Cardio Device. The following pages provide a summary of the issue(s), associated hazards, additional instructions, and actions to be taken.

If you need any further information or support concerning this issue, 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.

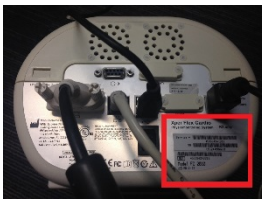
Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Christine Trefethen
Head of Quality and Regulatory Affairs
General & Specialty Care

DEVICE DESCRIPTION	Xper Flex Cardio Physio Monitoring System, models: FC2010 and FC2020 The Xper Flex Cardio Physio Monitoring System is used to facilitate invasive investigation of heart and vascular disease when non-invasive indicators warrant such. The Xper Flex Cardio Physio Monitoring system may be used to display and analyze surface ECG (electrocardiogram), respiration, invasive pressure, SpO2 (pulse oximetry), end tidal CO2 (ETCO 2) and non-invasive pressure waveforms; surface body temperature and thermal cardiac output curves.
AFFECTED PRODUCTS	Philips Xper Flex Cardio (FC2010, Procedure Room and FC2020, Bedside Monitor) devices Service Numbers: 453564241901 / 453564675021 453564241911 / 453564669081 453564483321 / 453564675001 453564483331 / 453564674581 453564621791 / 453564845841 453564621801 / 453564845861 453564845881 For purposes of communicating with the regulatory bodies, most of the affected devices may also include one of the Unique Device Identifier (UDI) numbers listed below: (01)00884838082113 (01)00884838083516 (01)00884838084902 (01)00884838084919 (01)00884838103245 (01)00884838083820 (01)00884838086005 (01)00884838083820 (01)00884838093645 (01)00884838093652 (01)00884838095052

PROBLEM DESCRIPTION	Philips is initiating a correction to correct several performance issues with the Xper Flex Cardio Physio Monitoring System. The Xper Flex Cardio is a real time monitoring system. The issues include: 1. A potential delay of up to 10 seconds in displaying ECG, invasive blood pressure and other parameters on the boom monitor after the data is acquired. Philips, received one complaint that was associated with a death. Philips' investigation concluded that the death was not a direct result of a product issue. 2. Displayed patient weight is rounded to the nearest whole kilogram. 3. Xper IM software used with the Xper Flex Cardio Physio Monitoring System may periodically crash, resulting in a loss of a visual display of waveforms and numerics on the displays driven by the Xper IM software, but the alarms and monitoring displays driven by the Xper Flex Cardio continue to function normally. 4. No SpO2 numeric or plethysmography is displayed when SpO2 is connected to the Flex Cardio device. 5. The display of certain data from the FC2010 becomes frozen, i.e., waveforms cease sweeping and updating and the ECG, IBP, and respiration numeric values cease to update. 6. The ECG, IBP, and respiration waveforms become flat lines and no audible alarms are produced for HR and IBP. 7. Upon start up, an unexpected non physiological ECG waveform, erratic heart rate numeric value, and non-physiological display of any other active waveforms may appear on the Boom Monitor.

HAZARD INVOLVED	Hazards associated with performance issues: 1. A 10 second delay between displaying ECG, invasive blood pressure and other parameters on the boom monitor, and the occurrence of the patient's actual ECG activity could lead to a delay in treatment 2. When the patient's weight rounds to the nearest whole kilogram, this issue is most serious with pediatric patients where weight may be used to calculate medication dosage. This could result in a miscalculation of medication or radiopaque contrast dosage. 3. If the Xper IM software associated with the Xper Flex Cardio Physio Monitoring System crashes, this could result in a loss of monitoring outside the procedure room, e.g. in the patient holding area. Monitoring displays in the procedure room and audio alarms are not affected and continue to function normally. 4. If no SpO2 numeric or plethysmography is displayed when SpO2 is connected to the Flex Cardio device, this will result in an inability to monitor oxygen saturation. 5. A frozen display of outdated ECG, IBP and respiration waveforms and numerics from the FC2010 may lead to a delay in or incorrect treatment. 6. When the ECG, IBP, and respiration waveforms become flat lines and no audible alarms are produced for HR and IBP, this could result in a delay in or incorrect treatment. 7. Upon start up, an unexpected non physiological ECG waveform, an erratic heart rate numeric value, and a non-physiological display of any other active waveforms, may appear on the Boom Monitor which could result in a delay in treatment.
HOW TO IDENTIFY AFFECTED PRODUCTS	The service number and serial number of the Flex Cardio are located on the bottom right corner of the back of the device. **Front of Device**  **Back of Device** 

ACTION TO BE TAKEN BY CUSTOMER / USER	The information in this notice should be provided to all the users of the Xper Flex Cardio System. Because the issues listed above can be promptly identified by a qualified health care professional who has reviewed this notice and is closely observing the monitored patient, the Xper Flex Cardio may continue to be used if this step is taken. Resetting the device as described in the IFU (Section 4, page 87), is likely to return the device to normal operation, which takes approximately 3-5 minutes. To reset your Flex Cardio device, close any patient cases and then turn the power switch off (see back of device for the power switch). Wait 5-10 seconds then turn the power switch back on. Allow the device to fully restart and restore the monitoring display. Please complete and return the Customer Reply Form included on the last page of this communication indicating your receipt and understanding of this information.
ACTIONS PLANNED BY PHILIPS	Philips will provide a software update for the Xper Flex Cardio to correct all but, issue #7 above at no charge. A Philips representative will contact you when the software is available for installation. Philips has also added directions to the IFU for the Xper Flex Cardio on how to reset the device in the event that the user observes issue #7 above. An IFU addendum with the directions will be provided to all affected users when it becomes available.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: 800-669-1328 option 2, then option 3.

Customer Reply Form

Contact Telephone Number	
Contact Email Address	
Facility Name	
Street Address City, State/Country Zip or Postal Code	
Customer ID	

CUSTOMER ACKNOWLEDGEMENT:

☐ I acknowledge that I have read and understood the Field Safety Notice FSN-CC-MA-002-001.

_____ _____

CONTACT NAME (please print) **TITLE**

_____ _____

SIGNATURE **DATE**

Please return the completed and signed reply form to Philips via fax at 1-877-499-7223 or email at recall.response@philips.com.