

URGENT – Field Safety Notice
Xper Flex Cardio Patient Monitoring System
Display of SpO₂ and NIBP Measurements May Freeze

Dear Customer,

A problem has been detected in the XPer Flex Cardio Patient Monitoring System. 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 to patients, and
- 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.

The SpO₂ and non-invasive blood pressure (NIBP) waveform and numeric values displayed on the device may freeze, resulting in the display of measurements that are not current. Although SpO₂ and NIBP monitoring and alarms are no longer functional, all other monitoring parameters are functional and visible. If this problem were to occur, the device can be reset by power cycling and the reset will allow you to continue monitoring. However, power cycling the device does not prevent the issue from recurring.

Our records indicate that you have affected devices. The following page provides instructions and actions that should be taken to address this problem, as well as how to obtain updated software for your device to resolve this issue.

If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.



Sincerely,



Rusty Kelly
Quality and Regulatory Senior Manager
Medical Sensors and Consumables



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AFFECTED PRODUCT	Product: Xper Flex Cardio Patient Monitoring System Model Numbers FC2010 and FC2020 All systems distributed prior to September 2015
PROBLEM DESCRIPTION	The SpO ₂ and non-invasive blood pressure (NIBP) waveform and numeric values displayed on the device may freeze, resulting in the display of measurements that are not current. Although SpO ₂ and NIBP monitoring and alarms are no longer functional, all other monitoring parameters are functional and visible.
HAZARD INVOLVED	Should this problem occur, SPO ₂ and NIBP no longer function, including alarms. This may result in a delay in detecting important changes in a patient's cardiovascular and respiratory condition.
HOW TO IDENTIFY AFFECTED PRODUCTS	<div style="display: flex; align-items: center;">  <div style="flex: 1;"> <p>The model number and serial number of the Xper Flex Cardio are on the bottom right corner of the back of the device.</p> </div>  </div>
ACTION TO BE TAKEN BY CUSTOMER / USER	<p>While awaiting the update to your device, you may continue to use it provided that each monitored patient is closely observed by a qualified health care professional and is not left unattended. As described in the device's Instructions for Use, "Use of the system is not intended where unattended patient monitoring is desired, or in situations where arrhythmia detection is required."</p> <p>If this problem were to occur, the device can be reset by power cycling and the reset will allow you to continue monitoring. However, power cycling the device does not prevent the issue from recurring.</p>
ACTIONS PLANNED BY PHILIPS	A Philips representative will contact you regarding your affected device. To correct the problem, a software update will be installed on affected devices. Some older devices may not be compatible with this software update and will require special handling.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.

