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# URGENT Field Safety Notice

**Xper Flex Cardio Device, Model #: FC2010 & FC2020, used with the Xper Flex Cardio Physiomonitoring System and Philips Hemo System**

25-AUG-2023

**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 this letter for your records.

Dear Customer,

This **Field Safety Notice** reminds you to review the information in the Xper Flex Cardio Physiomonitoring System Instructions for Use (IFU). Specifically, about electrocardiogram (ECG) monitoring when using devices with high electronic energy bursts, such as, but not limited to: defibrillator and/or electronic surgical units (ESU). This notification alerts the users of the Xper Flex Cardio Devices, Model #: FC2010 & FC2020, that are potentially unable to recover ECG monitoring and require a restart, due to an over-energized device associated with the use of a defibrillator or ESU.

This notification is intended to inform you about:

**1. The problem and under what circumstances it can occur**

Following exposure to defibrillation voltage, the system returns to normal operating mode within 5 seconds. However, if the Xper Flex Cardio Devicehas been exposed to greater than the specified energy related to the defibrillator and/or ESU use, it might fail to return to normal operating mode within 5 seconds and it may require a restart in order to continue ECG monitoring. While this could result in a delay in treatment the risk of harm is unlilkely.

The specifications of the Xper Flex Cardio Deviceregarding the absorption of energy into the device are noted in the Instructions For Use (IFU). Additionally, the IFU contains warnings and best practices when fust in conjunction with defibrillators and ESU. This design limitation could result in an inability of the

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Xper Flex Cardio Deviceto recover and may need the user to restart the device to continue ECG monitoring.

**2. Hazard/harm associated with the issue**

If Xper Flex Cardio device experiences this issue and the clinician fails to immediately recognize a change in the patient's cardiac rhythm, this can potentially result in a delay in treatment.

**3. Affected products and how to identify them**

Affected devices include all of the Xper Flex Cardio Devices, Model #: FC2010 & FC2020, used with the Xper Flex Cardio Physiomonitoring System and Philips Hemo System. The Xper Flex Cardio Physiomonitoring System and Philips Hemo System are intended for use by professional healthcare providers for complete physiologic/hemodynamic monitoring.

**4. Actions that should be taken by the customer / user in order to prevent risks for patients or users**

Please refer to the instructions in the IFU before using Xper Flex Cardio Device, Model #: FC2010 & FC2020, specifically the following Sections:

- ***Defibrillator Protection***
- ***Use of Electrosurgical Equipment***
- ***ECG Monitoring***
- ***Specifications***

This notice should be passed on all those who need to be aware within your organization or to any organization where Xper Flex Cardio Devices, Model #: FC2010 & FC2020, have been potentially transferred.

**5. Actions planned by Philips to correct the problem**

Philips is distributing this Field Safety Notice to the affected customers / users to highlight the instructions specified in the IFU.

If you need any further information, please contact your local Philips representative at the UK Philips Customer Care Service Centre on 0870 532 9741 or Ireland Philips Customer Care Service Centre on +353 1 7640229.

Philips regrets any inconvenience caused by this problem.

Sincerely,

Angela Bandy
Senior Manager, Post Market Surveillance

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# URGENT Field Safety Notice Response Form

**Reference:** CR # 2023-CC-HPM-022, Xper Flex Cardio Device, Model #: FC2010 & FC2020, used with the Xper Flex Cardio Physiomonitoring System and Philips Hemo System

**Instructions:** Please complete and return this form to Philips Healthcare promptly upon receipt and no later than 30 days from receipt by email: recall.response@philips.com. Completing this form confirms receipt of the URGENT Field Safety Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

_____

_____

**Customer Actions:**

Please refer to the instructions in the IFU before using Xper Flex Cardio Device, Model #: FC2010 & FC2020, specifically the following Sections:

- ***Defibrillator Protection***
- ***Use of Electrosurgical Equipment***
- ***ECG Monitoring***
- ***Specifications***

This notice should be passed on all those who need to be aware within your organization or to any organization where Xper Flex Cardio Devices, Model #: FC2010 & FC2020, have been potentially transferred.

We acknowledge receipt and understanding of the accompanying Product Notice and confirm that the information from this Notification has been properly distributed to all users that handle Xper Flex Cardio devices.

**Name of person completing this form:**

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please return the completed and signed reply form to **safetynoticeuki@philips.com**