

URGENT Field Safety Notice

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

DDMMYY,

Dear Distributor,

Philips is initiating an URGENT Field Safety Notice to remind customers to review the information in the Xper Flex Cardio Physiomonitring 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.

It is imperative that all customers with affected products receive the attached URGENT Field Safety Notice that informs about:

- The problem and under what circumstances it can occur
- Affected products and how to identify them
- The actions that the customer/user should take to prevent risk for patients
- The actions taken by Philips in order to prevent risks for patients or users

Philips is requesting customers to return a Response Form to acknowledge receipt and understanding of the URGENT Field Safety Notice and confirm that the information from this Letter has been properly distributed to all users that handle the affected product.

Together with this letter we are providing a list of affected products that Philips has sold to your organization. As distributor of the affected products, we kindly request that you:

- Add in the Response Form attached your contact information.
- Send the attached URGENT Field Safety Notice to each customer to whom you have distributed any affected product as soon as possible and no later than three days, together with the Reply Card.
- Perform a good faith effort to get the Reply Form by following up with the customer with a minimum of three attempts, and if possible, using multiple contact methods. Inform Philips about the responses received.

Please be assured that maintaining a high level of safety and quality is our highest priority. 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 Market>*

Sincerely,



*Electronically signed by: Angela Bandy
Reason: "I Approve"
Date: Aug 24, 2023 15:46 EDT*

Angela Bandy
Senior Manager, Post Market Surveillance

FSN_2023-CC-HPM-022_Distributor

Final Audit Report

2023-08-24

Created:	2023-08-24
By:	Vedrana Sahovic (Vedrana.Sahovic@philips.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA1LkuB-7hftUH0MQwwDYOxcTZ8YxPnK77

"FSN_2023-CC-HPM-022_Distributor" History

-  Document created by Vedrana Sahovic (Vedrana.Sahovic@philips.com)
2023-08-24 - 7:44:06 PM GMT- IP address: 155.190.21.5
-  Document emailed to angela.bandy@philips.com for signature
2023-08-24 - 7:44:37 PM GMT
-  Email viewed by angela.bandy@philips.com
2023-08-24 - 7:44:48 PM GMT- IP address: 104.47.0.254
-  Signer angela.bandy@philips.com entered name at signing as Angela Bandy
2023-08-24 - 7:46:21 PM GMT- IP address: 155.190.22.2
-  Document e-signed by Angela Bandy (angela.bandy@philips.com)
Signing reason: "I Approve"
Signature Date: 2023-08-24 - 7:46:23 PM GMT - Time Source: server- IP address: 155.190.22.2- Signature captured from device with phone number XXXXXXXX1153
-  Agreement completed.
2023-08-24 - 7:46:23 PM GMT