

## Correction and Removal Initiation

|   |                 |
|---|-----------------|
| <b>Correction and Removal ID Number</b> | 2023-CC-HPM-022 |
|---|-----------------|


### 1. Purpose

This **Important Product Notice** reminds you 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 the electrical interference associated with the use of a defibrillator or ESU. The purpose of this document is to record the approval to initiate the Field Safety Correction. See affected product list below.

### 2. Products Affected

| # | Product name  | Product model   |
|---|---|-----------------|
| 1 | Xper Flex Cardio device used with the Xper Flex Cardio Physiomonitring System and Philips Hemo System | FC2010 & FC2020 |

## Approval to Initiate Correction & Removal

|   |  |  |
|---|--|--|
| Angela Bandy<br>C&R Facilitator (Print Name)            | <br>Signature | <i>Electronically signed by: Angela Bandy<br/>         Reason: "I Approve"<br/>         Date: Aug 24, 2023 15:09 EDT</i><br>Date |
| Avani Pandya<br>Business Quality Leader<br>(Print Name) | <br>Signature  | <br>Date   |

Note: Date of last approval is the date upon which reporting submission timeliness are measured (e.g. submission to FDA within 10 working days).

### 3. Document Revision History

| Revision | Release Date  | Author          | Description of Changes | CR / Reason      |
|----------|---------------|-----------------|------------------------|------------------|
| 1        | See Windchill | Vedrana Sahovic | Initial Release        | C & R Initiation |

# CRI\_2023-CC-HPM-022

Final Audit Report

2023-08-24

|                 |   |
|-----------------|---|
| Created:        | 2023-08-24                                    |
| By:             | Vedrana Sahovic (Vedrana.Sahovic@philips.com) |
| Status:         | Signed  |
| Transaction ID: | CBJCHBCAABAARY5b3KvOXDA1Y9LUDsNqApnYTjy3lemo  |

## "CRI\_2023-CC-HPM-022" History



Document created by Vedrana Sahovic (Vedrana.Sahovic@philips.com)

2023-08-24 - 5:29:23 PM GMT- IP address: 155.190.21.5



Document emailed to angela.bandy@philips.com for signature

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2023-08-24 - 7:08:30 PM GMT- IP address: 104.47.0.254



Signer angela.bandy@philips.com entered name at signing as Angela Bandy

2023-08-24 - 7:09:43 PM GMT- IP address: 155.190.22.2



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|                              |           |      |
|------------------------------|-----------|------|
| Angela Bandy                 |           |      |
| C&R Facilitator (Print Name) | Signature | Date |

|   |                     |   |
|---|---------------------|---|
| Avani Pandya                            | <i>avani pandya</i> | <i>Electronically signed by: avani pandya<br/>Reason: "I Approve"<br/>Date: Aug 24, 2023 7:34 EDT</i> |
| Business Quality Leader<br>(Print Name) | Signature           | Date  |

Note: Date of last approval is the date upon which reporting submission timeliness are measured (e.g. submission to FDA within 10 working days).

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| Created:        | 2023-08-24                                    |
| By:             | Vedrana Sahovic (Vedrana.Sahovic@philips.com) |
| Status:         | Signed  |
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 Signer avani.pandya@philips.com entered name at signing as avani pandya  
2023-08-24 - 9:34:11 PM GMT- IP address: 155.190.19.5

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