

URGENT Field Safety Notice

Patient Information Center (PIC iX) Release 4.x Surveillance Crash Caused by Intel Graphics Driver Error

DDMMYY,

Dear Distributor,

Philips is initiating an URGENT Field Safety Notice because we became aware of a potential safety issue with the Patient Information Center (PIC iX) Release 4.x where Surveillances or Overviews intermittently crash/freeze with a blank screen and subsequently require a manual reboot of the hardware to restart and continue central patient monitoring.

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: Correction
Communication
Date: Aug 17, 2023 08:40 EDT

Angela Bandy
Senior Manager, Post Market Surveillance

FSN_2023-CC-HPM-027_Distributor

Final Audit Report

2023-08-17

Created:	2023-08-16
By:	Vedrana Sahovic (Vedrana.Sahovic@philips.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAe1BN6hTbgt91yycnrX-Yoe--QT2qUU3X

"FSN_2023-CC-HPM-027_Distributor" History

-  Document created by Vedrana Sahovic (Vedrana.Sahovic@philips.com)
2023-08-16 - 11:13:36 PM GMT- IP address: 155.190.33.31
-  Document emailed to angela.bandy@philips.com for signature
2023-08-16 - 11:14:10 PM GMT
-  Email viewed by angela.bandy@philips.com
2023-08-17 - 12:38:57 PM GMT- IP address: 104.47.0.254
-  Signer angela.bandy@philips.com entered name at signing as Angela Bandy
2023-08-17 - 12:40:33 PM GMT- IP address: 155.190.22.2
-  Document e-signed by Angela Bandy (angela.bandy@philips.com)
Signing reason: Correction Communication
Signature Date: 2023-08-17 - 12:40:35 PM GMT - Time Source: server- IP address: 155.190.22.2- Signature captured from device with phone number XXXXXXXX1153
-  Agreement completed.
2023-08-17 - 12:40:35 PM GMT