URGENT Field Safety Notice

RE: Potential Missed Alarms on Mobile Devices Following Software Patch

DD MMM, 2025

To: Customer Name
Customer Street Address
City, State, Zip Code

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,

Philips has become aware of a potential safety issue concerning PIC iX 4.5.0 default mobile event notification filters change. This URGENT Field Safety Notice is intended to inform you about:

What the problem is and under what circumstances it can occur

During internal investigation, Philips identified that the recent PIC iX 4.5.0 software (SW) patch modifies Mobile Event Notification filter settings without providing any indication to the user when upgrading the system. When patching a PIC iX 4.X (i.e. 4.4) system that uses the default event filters for mobile notifications, upgrading to 4.5.0 overrides existing default filters and applies the new default filters for version 4.5.0.
The overridden filters can lead to the situation where alarms, which were previously configured to distribute to mobile devices, are no longer sent and no notification is provided by the system.
While all default event filters are overridden when patching to 4.5.0, any customized configurations applied to high level filter categories/subcategories or individual filters are maintained and migrated successfully.

## Hazard/harm associated with the issue

This issue can result in loss of expected mobile device event notifications. Should the user have a system that was previously running PIC iX 4.X and was using any default event filters, patching to PIC iX 4.5.0 will override these filters with new defaults without providing notification to the user. The user may expect alarms/notifications to mobile devices that were previously configured as default under PIC iX 4.X. Therefore, this issue has the potential to lead to a delay in treatment due to missing

event notification alarms. To date, Philips has not received any reports of harm as a result of this issue.

Affected products and how to identify them

Use the following instructions to identify the software revision of PIC iX:

Access the Product Support screen by clicking the Philips icon in your PIC iX application. The PIC iX Software Serial Number and Software Version appear on the Product Support screen in the Product Information Section under Serial Number and Software Version respectively. Refer to image below:
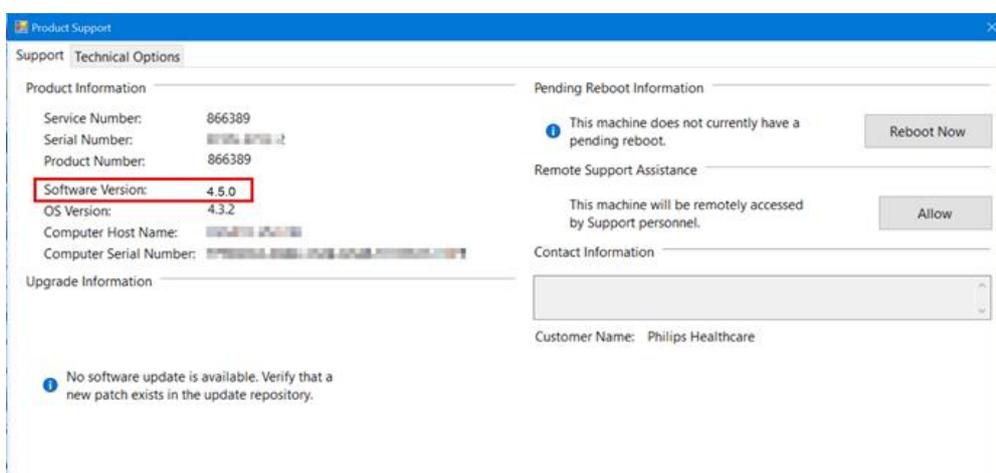
#	Product name	Product number	UDI or UPC Number
1	Patient Information Center iX	866389	(01)00884838127074(10) 4.5.0
2	Patient Information Center iX Expand	866390	

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

- Review the Mobile Notification Event Filters settings and confirm all the events intended to be sent to mobile devices automatically are enabled for Mobile Notification Event Filters.

- Pass this notice to all those who need to be aware within your organization or to any organization where affected devices have been potentially transferred.

- Complete the URGENT Field Safety Notice Response Form at the end of this notification to submit both acknowledgment of this URGENT Field Safety Notice and confirm understanding of actions to be taken.

Actions planned by Philips to correct the problem

- Philips representative will contact you to obtain PIC iX 4.5.1 SW patch for PIC iX systems running software version 4.5.0.

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/Business>

This notice has been reported to the appropriate Regulatory Agencies. Adverse reactions or quality problems experienced with the use of this product(s) may be reported to < Markets to insert to whom the customer should report>.

Philips regrets any inconvenience caused by this problem.

Sincerely,

Deborah Currlin
Head of Quality, Hospital Patient Monitoring
Philips Healthcare

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Instructions: Please complete and return this Response Form to Philips promptly and no later than 30 days from receipt. Completing this Response 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:

Review the Mobile Notification Event Filters settings and confirm all the events intended to be sent to mobile devices automatically are enabled for Mobile Notification Event Filters.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice and confirm that the information from this letter has been properly distributed to all users that handle the affected product(s).

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please email this completed form to Philips at: <Response Form return details to be completed by the KM/country>