PHILIPS

URGENT Field Safety Notice

RE: Philips Patient Information Center iX (PIC iX) 4.x Failure of Watchdog to Restart Process

31 July 2026

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 with the Philips Patient Information Center iX (PIC iX) 4.x systems where the system freezes, becoming nonresponsive. The Patient Information Center iX is intended for use by trained healthcare professionals in professional healthcare facilities and is not intended for home use. The web and mobile applications may be used remotely, and any action on the mobile application affecting active patient monitoring is intended for use in professional healthcare facilities.

PIC iXis used to receive, aggregate, process, display and distribute physiologic waves, parameters, alarms and events for multiple patients through:

- Determining alarm conditions and generating alarm signals for Philips-approved medical devices that send physiological data and do not have the ability to determine the alarm condition.
- The PIC iX system provides the ability to manage alarms and initiate measurements remotely
- Performing diagnostic 12-Lead analysis and interpretation based on raw ECG data samples provided from Philips-approved medical devices.
- Providing review and trend application data, designed to contribute to the screening of patient condition.

This URGENT Field Safety Notice is intended to inform you about:

What the problem is and under what circumstances it can occur

Philips received reports that some PIC iX systems were frozen and could not be used. It was determined that failure of the watchdog may cause the system to be in an unknown state and therefore potentially prevent alarms from being generated or logged.

Following the initial system error which triggers the watchdog, staff may observe unexpected system behavior while the watchdog attempts recovery. The observed behavior depends on the underlying software issue and may include:

- Inability to interact with the PIC iX user interface. If real-time waveforms, numeric data, and alarms remain operational, there is no impact to bedside or central monitoring and alarming.
- The user will not recognize the device issue before the hazardous situation occurs if the observed behavior is: Loss of central alarming Loss of, or frozen, waveforms/data display
- Bedside monitors and Telemetry devices could generate a 'No Central Mon' INOP.

Hazard/harm associated with the issue

The failure of the watchdog may cause the system to remain in an unknown state during which central monitoring and alarming may not occur. This may also be associated with a failure of connected telemetry devices to disconnect and provide local alarming. While this harm has not been demonstrated to date, there is evidence of events involving frozen data and absent alarming occurring which required manual intervention to resolve.

The most probable immediate and long-term health consequence that may result from use of impacted PIC iX systems is no harm. However, the highest potential severity of immediate and long-term health consequences is delay of treatment leading to serious injury or death.

Affected products and how to identify them

The Philips Patient Information Center (PIC) iX are identified below:

#	Product Name	Product/Model Number
1	Patient Information Center iX	866389
2	PIC iX Essentials	867093

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

- In cases where central monitoring has halted, please ensure that triaging of patients at bedside and a change in workflow occurs to more closely monitor patient status. Ensure audible alarm volume is on high in patient rooms in case bedside devices disconnect and do not provide visual indicators that communication with the central.
- Pass this notice to all those who need to be aware within your organization or to any organization where affected product(s) have been potentially transferred.
- Place this Urgent notification with the documentation of the Philips Patient Information Center (PIC) iX and associated devices in a place where it is most likely to be seen and viewed
- Implement the Technical Solution established by Philips as soon as available within the defined timeframe
- 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

A Philips representative will contact customers to arrange a software update to correct the issues listed.

If you need any further information or support concerning this issue, please contact your local Philips representative at the Philips Customer Care Service Centre by:

Telephone: UKI: +448000260086
NI: +448000260430
ROI: +3531800832340

Email: UKFCO@philips.com

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 your Regulatory Agency.

Philips regrets any inconvenience caused by this problem.

Sincerely,

Deborah Currlin
Head of Quality, Hospital Patient Monitoring
Philips Healthcare

PHILIPS

URGENT Field Safety Notice

Reference: Philips IntelliVue Patient Monitors Continuous Reboot with Active Display.

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/Postcode: _____

Customer Actions:

- In cases where central monitoring has halted, please ensure that triaging of patients at bedside and a change in workflow occurs to more closely monitor patient status. Ensure audible alarm volume is on high in patient rooms in case bedside devices disconnect and do not provide visual indicators that communication with the central.
- Pass this notice to all those who need to be aware within your organization or to any organization where affected product(s) have been potentially transferred.
- Place this Urgent notification with the documentation of the Philips Patient Information Center (PIC) iX and associated devices in a place where it is most likely to be seen and viewed
- Implement the Technical Solution established by Philips as soon as available within the defined timeframe.

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