

URGENT Field Safety Notice

CareEvent & Patient Information Center iX (PIC iX)
Care Assist Application Custom Ringtone Failure

27-FEB-2024

To: Customer Name:
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 with the Care Assist IOS mobile application where the application does not play custom ringtones when the device screen is locked with a passcode.

The Care Assist mobile application can receive visual, audible and other message notification types from the Patient Information Center iX (PIC iX) and Care Event devices depending on the mobile device in use. The combination of the PIC iX system, CareEvent, and Care Assist mobile application provides users a supplemental notification system for patient alarms and events. Alarms and events generated at the point of care device are distributed to assigned users via the Care Assist application, either through the CareEvent server or the PIC iX Event Notification server.

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

1. What the problem is and under what circumstances it can occur

It was found that the Care Assist mobile application (version 4.1.1 and earlier) would not play custom ringtones when iOS device screens were locked with a passcode. The issue occurred on devices running iOS 15, 16 and 17 as well as multiple versions of iPhones. The Care Assist mobile application is not intended to replace the patient's primary alarming system. If users rely on the Care Assist application as their primary event notification alarming system, the failure of custom ringtones could result in a delay in treatment for patients experiencing a change in clinical condition.

2. Hazard/harm associated with the issue

The identified device issue has the potential to lead to missed alarms and/or the failure to respond to patient alarms and events for serious or life-threatening issues in a timely manner if a user relies solely on the Care Assist application for event notification. It is important to note that should a user miss an event notification through their Care Assist mobile application, the event is still reported as expected/configured at the bedside monitor or central station without issue.

Users of the Care Assist mobile application are unable to identify the problem prior to its occurrence. No indication is made to the user that the custom ringtone files do not have the proper file-level permissions or attributes to function properly. This issue only affects custom ringtones that are configured by the users. If a user has some events configured with custom ringtones, only those events are affected. Any alerts for events that do not have a custom ringtone configured will be unaffected and will provide audible notification using a default ringtone. At this time, no patient or user harm has been reported.

3. Affected products and how to identify them

The intended use of Philips CareEvent is to deliver supplemental medical device data associated with physiological alarms, technical alarms, clinical notifications, nurse call alarms and informational messages to a healthcare professional's end device. The user may receive visual or audible notifications, and/or other message notification types based on the communicator in use.

The intended use of the Philips Patient Information Center (PIC iX) is to receive, aggregate, process, display and distribute physiologic waves, parameters, alarms and events for multiple patients.

The Care Event and PIC iX products used with the affected Care Assist mobile application are identified below in **Table 1**.

| Product Code(s) | Model(s) | UDI(s) |
|-----------------|--------------------------------------|--|
| 866389 | Patient Information Center iX | (01)00884838104594(10) 4.0.1 (01)00884838104594(10) 4.0.2 |
| 866390 | Patient Information Center iX Expand | (01)00884838112070(10) 4.1.0 (01)00884838112070(10) 4.1.1 (01)00884838121782(10) 4.2.0 |
| 866424 | PIC iX Hardware | (01)00884838121782(10) 4.2.1 (01)00884838121782(10) 4.2.2 |
| 866435 | CareEvent | (01)00884838099128(10) C.03.XX |
| 866436 | CareEvent Upgrade | |

Table 1.

The Care Assist Mobile Application version can be found on the mobile application login page, see image 1. below:



Image 1: Care Assist Login page showing the Care Assist application version number.

The Care Assist mobile application can be found on the Apple App Store via the QR code below:



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

1. The Care Assist mobile application should be used **in conjunction** with other monitoring devices such as a bedside monitor, telemetry monitor and central monitor which continue to provide visual and audible alarm information to inform clinicians of changes in patient status.
2. Customers should update their iOS devices to version 4.1.2 of Care Assist mobile application or greater to eliminate the software defect affecting the annunciation of custom ringtones.

3. Customers should complete the URGENT Field Safety Notice Response Form at the end of the notification to submit both their acknowledgement of this recall and confirm understanding of actions to be taken.
4. This communication should be shared with all clinical staff to review and understand.
5. Place this URGENT Field Safety Notice notification with the documentation of the Care Event and Patient Information Center iX (PIC iX) Revision 4.

5. Actions planned by Philips to correct the problem

1. The action by Philips will be to send each known affected customer an URGENT Field Safety Notice.
2. The Care Assist version 4.1.2 mobile application will be made available immediately in the Apple App Store.

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 may be reported to *<Markets to insert to whom the customer should report >*.

Philips regrets any inconvenience caused by this problem.

Sincerely,

Hauke Schik

Head of Quality, Enterprise Hospital Monitoring
Philips Healthcare

URGENT Field Safety Notice Response Form

Reference: Care Assist Application Custom Ringtone Failure

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the URGENT Field Safety Notice Letter, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Check this Box if you have updated the Software on your Care Assist iOS Mobile Application to version 4.1.2 or greater as required to fix software defect.

Check this box if you do not currently use Care Assist Mobile Application on any IOS devices

Customer Actions:

1. The Care Assist mobile application should be used **in conjunction** with other monitoring devices such as a bedside monitor, telemetry monitor and central monitor which continue to provide visual and audible alarm information to inform clinicians of changes in patient status.
2. Customers should update their iOS devices to version 4.1.2 of Care Assist mobile application or greater to eliminate the software defect affecting the annunciation of custom ringtones.
3. Customers should complete the Urgent Medical Device Correction Response Form at the end of the notification to submit both their acknowledgement of this recall and confirm understanding of actions to be taken.
4. This communication should be shared with all clinical staff to review and understand.
5. Place this Urgent Medical Device Correction notification with the documentation of the Care Event and Patient Information Center iX (PIC iX) Revision 4.

We acknowledge receipt and understanding of the accompanying URGENT Field Safety Notice Letter and confirm that the information from this Letter has been properly distributed to all users that use the Care Assist mobile application.

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: *<Reply form return details to be completed by the KM / country>*