Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No. 265 **dated** 21/12/23 **Regarding NCMDR Field safety corrective action of PIC iX Version 4.X and CareEvent Version C.03.X from (mfr: Philips Medical Systems).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

Sultanate of Oman
Ministry of Health
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سلطنة عُمان
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Circular No. 265 / 2023

08 -06-1445 H
21 -12-2023

Field Safety Corrective action of PIC iX Version 4.X and CareEvent Version C.03.X from Philips Medical

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19814
Product	PIC iX Version 4.X and CareEvent Version C.03.X.
Description	Software for Clinical Information Systems.
Manufacturer	Philips Medical Systems.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Product Name (Model Number): Patient Information Center iX (866389); Patient Information Center iX Expand (866390); PIC iX Hardware (866424); CareEvent (866435); CareEvent Upgrade (866436) Check details of UDI in the attachment
Reason	Background notifications for the Care Assist application fail to send from PIC iX Event Notification and CareEvent under certain conditions. This failure is applicable to Apple iOS devices only.
Action	1. If you use iOS devices (e.g iPhone, iPad) to receive event notifications: a) Please conduct patient monitoring at the central station or patient bedside. b) Please do not use iOS event notifications for patient monitoring. 2. A Philips representative will contact you to schedule a visit to install a software patch to your device which will correct the current issue. Patch PIC iX 4.2.2 will be provided for PIC iX 4.X and patch CareEvent C.03.07 will be provided for CareEvent C.03.X. 3. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control
ISO

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PHILIPS

URGENT Field Safety Notice

Care Assist Application Background Alerts Failure for iOS Devices (e.g iPhone, iPad)

30 November 2023

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 application background alerts for iOS devices (e.g iPhone, iPad). This notification is intended to inform you about:

1. The problem and under what circumstances it can occur

It has been discovered that background notifications for the Care Assist application fail to send from PIC iX Event Notification and CareEvent under certain conditions. This failure is applicable to Apple iOS devices only.

Specifically, when a user places the Care Assist application into the background on an iOS device by opening a different application or locking the device, etc., the user is registered as being logged off from the device. Under this condition, push notifications are no longer sent to the user. If the Care Assist application is in the foreground (i.e., actively open on the user device), the events are correctly sent to the connected iOS device.

2. Hazard/harm associated with the issue

If the Care Assist application background alerts failure happens, due to the loss of event notification on iOS devices, there is a potential for a delay in the detection of a change in a patient condition. Although unlikely, this could potentially result in a patient harm.

3. Affected products and how to identify them

CareEvent and PIC iX Event Notification are tools for healthcare providers intended to provide supplemental patient, technical, and nurse call alarms, as well as provide system information messages (events).

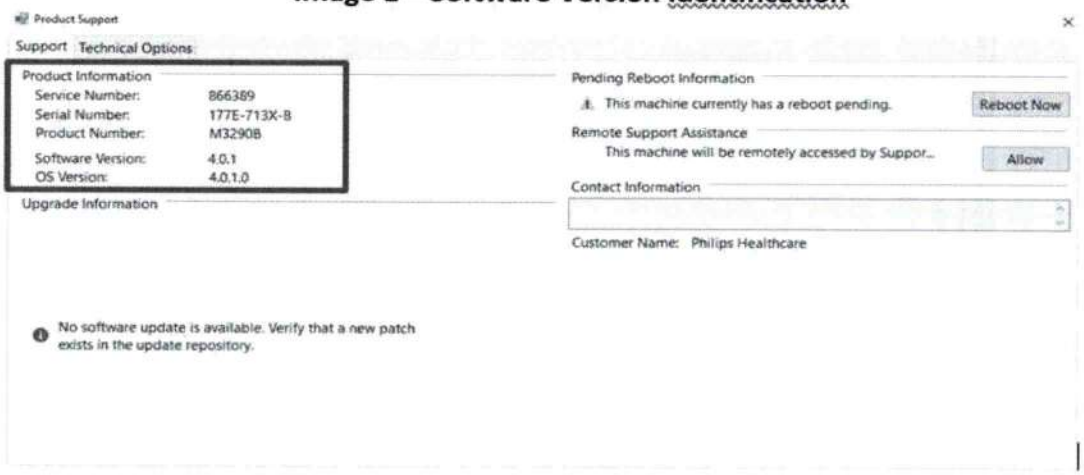
Affected Devices:
PIC iX Version 4.X and CareEvent Version C.03.X are affected by this issue:

#	Product Name(s)	Model Number(s)	UDI
1	Patient Information Center iX	866389	(01)00884838104594(10)4.0.1 (01)00884838104594(10)4.0.2 (01)00884838112070(10)4.1.0 (01)00884838112070(10)4.1.1 (01)00884838121782(10)4.2.0 (01)00884838121782(10)4.2.1
2	Patient Information Center iX Expand	866390	
3	PIC iX Hardware	866424	
4	CareEvent	866435	(01)00884838099128(10)C.03.00
5	CareEvent Upgrade	866436	

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 1 below:

Image 1 – Software Version Identification



Use the following instructions to identify the software revision of CareEvent:

You can locate CareEvent version identifier on the product support page that is displayed when you select Help>About from a CareEvent application, or you will find it printed on the Philips-supplied software media kits.

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

If you use iOS devices (e.g iPhone, iPad) to receive event notifications:

1) Please conduct patient monitoring at the central station or patient bedside.
2) Please do not use iOS event notifications for patient monitoring.

This notice should be passed on to all those who need to be aware within your organization or to any organization where affected devices have been transferred.

5. Actions planned by Philips to correct the problem

A Philips representative will contact you to schedule a visit to install a software patch to your device which will correct the current issue. Patch PIC iX 4.2.2 will be provided for PIC iX 4.X and patch CareEvent C.03.07 will be provided for CareEvent C.03.X.

If you need any further information, please contact your local Philips representative:
met.quality@philips.com

Philips regrets any inconvenience caused by this problem.

Sincerely,

Deborah Currlin,
Head of Quality

PHILIPS

URGENT Field Safety Notice Response Form

Reference: CR # 2023-CC-HPM-046, Care Assist Application Background Alerts Failure for iOS Devices (e.g iPhone, iPad)

Instructions: Please complete and return this form to Philips Healthcare promptly upon receipt and no later than 30 days from receipt by email: **met.quality@philips.com**. Completing this 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:

If you use iOS devices (e.g iPhone, iPad) to receive event notifications:

1) Please conduct patient monitoring at the central station or patient bedside.
2) Please do not use iOS event notifications for patient monitoring.

- Review the contents of this letter with your staff.
- 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.

We acknowledge receipt and understanding of the accompanying Product Notice and confirm that the information from this Notification has been properly distributed to all users that handle affected devices.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____