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 148 **dated** 18/7/23 **Regarding NCMDR Field Safety Corrective Action of Allura Xper and Azurion systems from (mfr: Philips Healthcare).**

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
ISO 9001:2015 CERTIFIED

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

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سلطنة عُمان
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Circular No. 148 **/ 2023**

30 -12-1444 H

18 -07-2023

Field Safety Corrective Action of Allura Xper and Azurion systems from Philips Healthcare.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19615
Product	Allura Xper and Azurion systems.
Description	Cardiovascular X-ray system.
Manufacturer	Philips Healthcare.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Model numbers of wireless foot switches: 459800772231, 459800772233, 459800772261, 459800772263, 459800415531, 459800415532, 459800415533, 459800415534, 459800415535, 459800415571, 459800415572, 459800415573, 459800415574, 459800415575
Reason	Potential for wireless foot switch loss of availability.
Action	1. Please follow "Actions that should be taken by the customer / user in order to prevent risks for patients or users" in the attachment. You will be contacted to schedule a Field Service Engineer visit, to confirm that the wired foot switch is connected to the system, perform a check of the charger, cable and/or connector of the wireless foot switch and provide you with a hardcopy of the addendum to the Instructions for Use and the Quick Reference Card. 2. 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

PHILIPS

URGENT Field Safety Notice

Allura Xper and Azurion systems
Potential for wireless foot switch loss of availability

23-June-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 wireless foot switch used with the Philips Allura Xper and Azurion systems, where the wireless foot switch may not be available for use. This URGENT Field Safety Notice is intended to inform you about:

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

The wireless foot switch is used to control fluoroscopy and exposure with the Philips Allura Xper and Azurion systems.

Philips has become aware of several situations that can result in a loss of availability of the wireless foot switch during a procedure. Identified issues that may result in the wireless foot switch not being available are:

- Loss of Bluetooth connection due to interferences from other radio equipment
- Battery not fully charged
- Battery not holding its charge
- Damage in the charger, cable and/or connector of the wireless foot switch

2. Hazard/harm associated with the issue

If the wireless foot switch is not available during a procedure, there will be a delay in the procedure and potentially an abortion of the procedure.

To date, Philips has not received any reports of harm associated with any of the specific issues identified.

3. Affected products and how to identify them

The Allura Xper series are intended for use on human patients to perform:

- Vascular, cardiovascular and neurovascular imaging applications, including diagnostic, interventional and minimally invasive procedures. This includes, e.g., peripheral, cerebral, thoracic and abdominal angiography, as well as PTAs, stent placements, embolisations and thrombolysis.
- Cardiac imaging applications including diagnostics, interventional and minimally invasive procedures (such as PTCA, stent placing, atherectomies), pacemaker implantations, and electrophysiology (EP).
- Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures.

The Azurion series (within the limits of the operation room table) are intended for use to perform:

- Image guidance in diagnostic, interventional, and minimally invasive surgery procedures for the following clinical application areas: vascular, non-vascular, cardiovascular, and neuro procedures.
- Cardiac imaging applications including diagnostics, interventional and minimally invasive surgery procedures.
  - Additionally:
    - The Azurion series can be used in a hybrid operating room.
    - The Azurion series contain several features to support a flexible and patient-centric procedural workflow.

The following wireless foot switches are affected by this issue:

Model Number
459800772231
459800772233
459800772261
459800772263
459800415531
459800415532
459800415533
459800415534
459800415535
459800415571
459800415572
459800415573
459800415574
459800415575

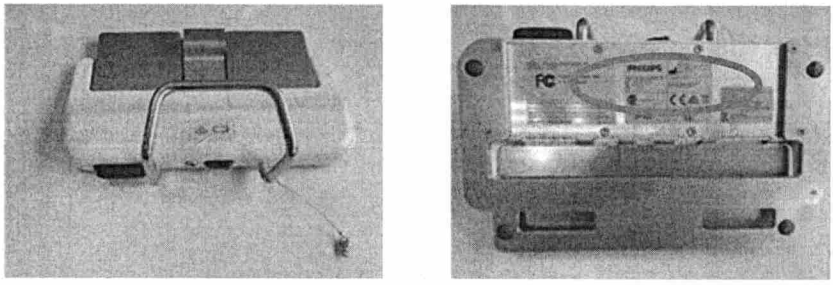

Figure 1: Label location on the bottom of the foot switch

The model number can be found on the label located on the bottom of the foot switch, as shown in Figure 1.

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

- Ensure that the wired footswitch is always connected to the system (a wired footswitch is always provided with the Allura Xper and the Azurion systems).
- Immediately start using the wired foot switch in case the wireless foot switch becomes unavailable.
- Download a copy of the addendum to the Instructions for Use for the wireless foot switch and the Quick Reference Card (QRC) at http://www.philips.com/doc_library (Please see Appendix A for download instructions). The addendum to the Instructions for Use and Quick Reference Card includes additional information for the safe use of the system.
- Distribute a copy of the aforementioned materials to all users of the system and retain a copy with the Instructions for Use of the system.
- Place this Field Safety Notice in a place likely to be seen/viewed with your system documentation.
- Circulate this Field Safety Notice (FSN), the IFU addendum, and the QRC to all users of this device so that they are aware of the issue.
- Complete and return the attached response form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Field Safety Notice, understanding of the issue, and required actions to be taken.

5. Actions planned by Philips IGT Systems [SRN: NL-MF-000001489] to correct the problem

Philips will contact you to schedule a Field Service Engineer visit, to confirm that the wired foot switch is connected to the system, perform a check of the charger, cable and/or connector of the wireless foot switch and provide you with a hardcopy of the addendum to the Instructions for Use and the Quick Reference Card.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need additional information or support concerning this issue, please contact your local Philips representative: *met.quality@philips.com*

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconvenience caused by this problem.

Sincerely,

PHILIPS

URGENT Field Safety Notice Response Form

Reference: 2022-IGT-BST-011: Allura Xper and Azurion systems
Potential for wireless footswitch loss of availability

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, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- Ensure that the wired footswitch is always connected to the system (a wired footswitch is always provided with the Allura Xper and the Azurion systems).
- Immediately start using the wired foot switch in case the wireless foot switch becomes unavailable.
- Download a copy of the addendum to the Instructions for Use for the wireless foot switch and the Quick Reference Card (QRC) at http://www.philips.com/doc_library (Please see Appendix A for download instructions). The addendum to the Instructions for Use and Quick Reference Card includes additional information for the safe use of the system.
- Distribute a copy of the aforementioned materials to all users of the system and retain a copy with the Instructions for Use of the system.
- Place this Field Safety Notice in a place likely to be seen/viewed with your system documentation.
- Circulate this Field Safety Notice (FSN), the IFU addendum, and the QRC to all users of this device so that they are aware of the issue.

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 impacted system(s).

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

"Please send this completed form to met.quality@philips.com"

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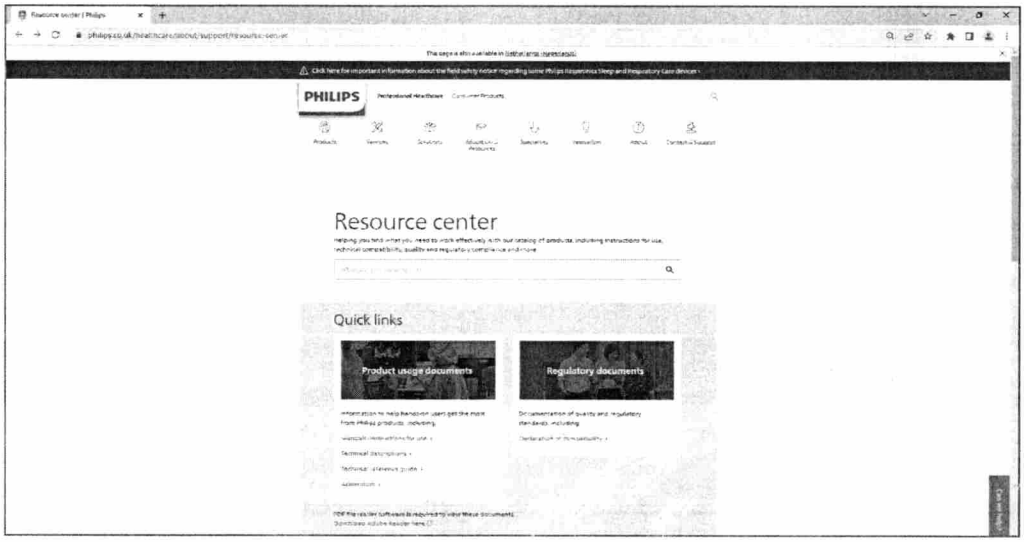
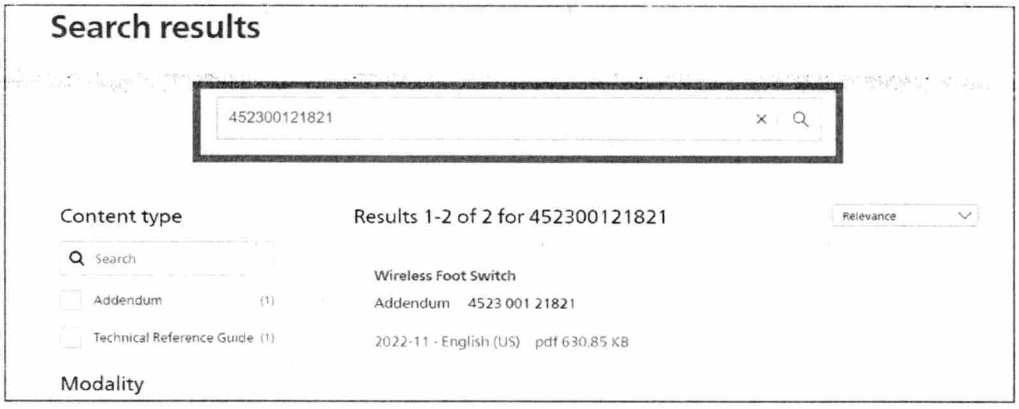
Appendix A: download instructions IFU addendum and Quick Reference Card

To download the applicable documents from http://www.philips.com/doc_library, please follow the below instruction:

• Go to http://www.philips.com/doc_library



• Type the Code number of the Addendum or QRC in the search field (Please refer to the table provided below for your preferred language). Then click on the magnifying glass or press "enter"



• Open the document by double clicking on "Wireless Foot Switch"

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Language codes for the IFU Philips wireless foot switch addendum

Code number	Language
452300121771	Bulgarian
452300121781	Czech
452300121791	Danish
452300121801	German
452300121811	Greek
452300121821	American English
452300121831	Spanish
452300121841	Estonian
452300121851	Finnish
452300121861	French
452300121871	Croatian
452300121881	Hungarian
452300121891	Bahasa Indonesian
452300121901	Italian
452300121911	Japanese
452300121921	Kazakh
452300121931	Korean
452300121941	Lithuanian
452300121951	Latvian
452300121961	Macedonian
452300121971	Norwegian
452300121981	Dutch
452300121991	Polish
452300122001	Brazilian Portuguese
452300122011	Romanian
452300122021	Russian
452300122031	Slovak
452300122041	Slovene
452300122051	Serbian
452300122061	Swedish
452300122071	Turkish
452300122081	Ukrainian
452300122091	Vietnamese
452300122101	Simplified Chinese
452300122111	Traditional Chinese

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Language codes for the Quick reference card - Wireless foot switch

Code number	Language
452220412481	American English
452220412491	Bulgarian
452220412501	Czech
452220412511	Danish
452220412521	German
452220412531	Greek
452220412541	Spanish
452220412551	Estonian
452220412561	Finnish
452220412571	French
452220412581	Croatian
452220412591	Hungarian
452220412601	Bahasa Indonesian
452220412611	Italian
452220412621	Japanese
452220412631	Kazakh
452220412641	Korean
452220412651	Lithuanian
452220412661	Latvian
452220412671	Macedonian
452220412681	Norwegian
452220412691	Dutch
452220412701	Polish
452220412711	Brazilian Portuguese
452220412721	Romanian
452220412731	Russian
452220412741	Slovak
452220412751	Slovene
452220412761	Serbian
452220412771	Swedish
452220412781	Turkish
452220412791	Ukrainian
452220412801	Vietnamese
452220412811	Simplified Chinese
452220412821	Traditional Chinese