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 203 **dated** 24/9/2023 **Regarding NCMDR Field Safety Corrective Action of Allura Xper, Allura Centron, Azurion and MultiDiagnost-Eleva systems 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. 203/ 2023

08 -03-1445 H

24 -09-2023

FSCA of Allura Xper, Allura Centron, Azurion and MultiDiagnost-Eleva systems from Philips Medical Systems.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19678
Product	Allura Xper, Allura Centron, Azurion and MultiDiagnost-Eleva systems.
Description	Cardiovascular imaging system.
Manufacturer	Philips Medical Systems.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Please refer to appendix B in the attachment.
Reason	Potential of the wired and wireless foot switch to become stuck in the active position resulting in unintended radiation.
Action	1. Please refer to the part "Actions that should be taken by the customer / user in order to prevent risks for patients or users" in the attachment. 2. You will be contacted by Philips distributor to schedule a visit to inspect the foot switch and provide a copy of IFU addendum. 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
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P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
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PHILIPS

URGENT Field Safety Notice

Allura Xper, Allura Centron, Azurion and MultiDiagnost-Eleva systems.
Potential of the wired and wireless foot switch to become stuck in the active position resulting in unintended radiation.

09-August-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 wired and wireless foot switch used with the Philips Allura Xper, Allura Centron, Azurion and MultiDiagnost-Eleva systems, where there is a possibility of unintended radiation.

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

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

The wired and wireless foot switch are used to control fluoroscopy, exposure and other functions, such as single shot, light control and toggle between X-ray planes (for bi-plane systems).

A foot switch pedal may get stuck in the active position when the user releases the pedal, resulting in unintended radiation, because of:

- Build-up of dense or sticky fluids on the foot switch (e.g., blood or contrast fluid), if not properly cleaned.
- Use of protective covers that are either the wrong size or incorrectly placed on the foot switch.
- Dislodgment of a screw holding the pick-up bar (see **Figure 1**) of the foot switch, subsequently becoming lodged within the foot switch housing.
- An additional screw inadvertently left inside the foot switch housing during manufacturing.

2. Hazard/harm associated with the issue

A sticking foot switch may result in unintended radiation exposure to the patient, which could contribute to the development of limited/transient (deterministic) radiation effects in the population at greatest risk (pediatric patients, pregnant women, and patients with existing radiation effects). Long term (stochastic) effects are considered unlikely.

In addition, resolving a sticking foot switch during a procedure (e.g., adjusting the switch to become unstuck) could result in a procedural delay. The probability of medically reversible or transient adverse health consequences due to procedural delay is considered remote.

Philips has not received any reports of harm resulting from sticking foot switches.

3. Affected products and how to identify them

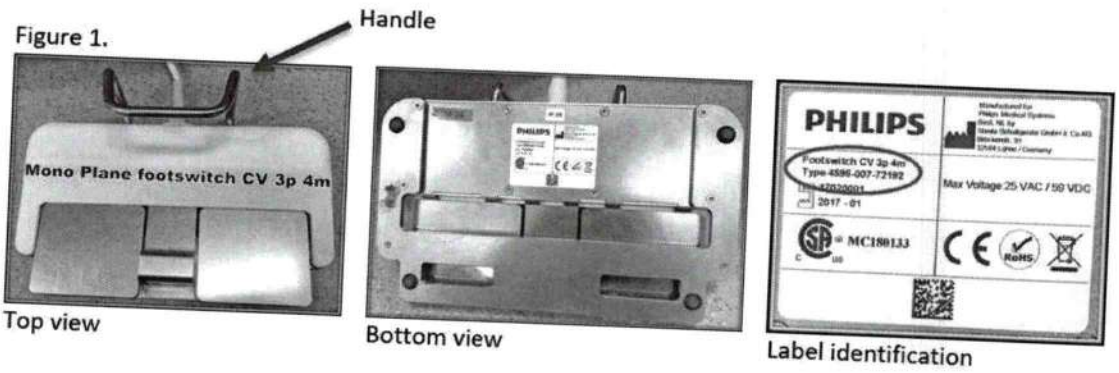
Intended Use.
See Appendix A for detailed information on the intended use of the Allura Xper, Allura Centron, Azurion and MultiDiagnost-Eleva systems.

The foot switch is a user input device with different foot pedals to:
- initiate X-ray radiation (fluoroscopy, series exposure or single shot); and
- control other functions like examination room light, or, in case of a bi-plane system, toggle between frontal and lateral x-ray planes.

Identification of affected systems.
Appendix B to this letter provides a table with the references/types and model descriptions of the affected foot switches.

The reference/type of the foot switch can be found on the label located on the bottom of the foot switch, as shown in Figure 1.

Figure 1.



Top view | Bottom view | Label identification

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

- Circulate this Field Safety Notice letter to all users so that they are aware of the issue and follow the instructions below.

Foot switch Cleaning and Use of Protective Covers

- In accordance with the Instructions for Use ("IFU") Addendum attached to this letter:
  - Clean the foot switch to remove any dense or sticky fluids.
  - Use a cover bag to protect the foot switch against debris during surgical procedures.
- Continue using a cover bag and cleaning the foot switch in accordance with the frequency requirements provided in the IFU Addendum.

If there are any questions with the cleaning methods or approach, *please contact* your local Philips representative.

Screw Dislodgment

- Inspect the handle of the foot switch to ensure that it is securely attached and has not become loose. If the foot switch handle has become dislodged, stop using the foot switch and contact Philips for a foot switch replacement.
- Follow the instructions in the attached IFU Addendum for handling the foot switch. Specifically:
  - ***Only*** use the handle of the foot switch to lift and reposition it.
  - Do ***not*** step or stand on the handle.

- Keep this Field Safety Notice letter and the IFU Addendum with the documentation of the system.
- Please complete and return the attached response form to Philips promptly and no later than 30 days from receipt. Completing this form confirms the receipt of the Field Safety Notice letter and understanding of the issue and required actions to be taken.

5. Actions planned by Philips IGT Systems to correct the problem

Philips will contact you to schedule a visit to inspect the foot switch and provide a copy of IFU addendum (reference FCO72200545).

Based on available information, systems may safely continue to be used in accordance with the device instructions for use and the provided instructions in this Urgent Field Safety Notice letter.

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.

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconvenience caused by this problem.

Sincerely,

Marjan Vos
Head of Quality – IGT Systems

PHILIPS

URGENT Field Safety Notice Response Form

Reference: 2023-IGT-BST-013: Allura Xper, Allura Centron, Azurion and MultiDiagnost-Eleva systems.
Potential of the wired and wireless foot switch to become stuck in the active position resulting in unintended radiation.

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:

- Circulate the Urgent Field Safety Notice letter to all users so that they are aware of the issue and follow the Instructions for Use Addendum provided with regards to:
  - *Foot switch Cleaning and Use of Protective Covers*
  - inspection of the handle of the foot switch
  - Handling of the foot switch
- Keep the Urgent Field Safety Notice letter and the IFU Addendum with the documentation of the system.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notification 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): _____

It is important that your organization acknowledges receipt of this letter. Your organization's reply is the evidence required to monitor the progress of this Urgent Field Safety Corrective Action.

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

APPENDIX A

Intended use.

The **Allura Xper, Allura Centron 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.

- Additionally:
    - The Allura Centron is not intended for surgical use. It is only meant for interventional use.

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 **MultiDiagnost-Eleva** is a multifunctional / universal imaging application system, General R/F, Fluoroscopy, Radiography and Angiography can be performed along with more specialized interventional applications on human patients. This includes the following general areas:

- Digestive system: Swallowing studies, Oesophagus, Stomach, Small intestine, Colon, Defeacography, ERCP, T-tube cholangiogram, Liver biopsies, Transjugular Intrahepatic Portosystemic Shunts (TIPS).
- Skeletal system: Bone studies.
- Urinary system: IVP, Cystograms, Percutaneous, Nephrolithotomy, Nephrostomy tube replacement.
- Reproductive system: Hysterosalpingogram, Vena spermatica, Cavernography.
- Respiratory system: Thorax, Bronchoscopy, Pulmonary biopsies.
- Circulatory system: Venography, Arteriography, Thrombolytic Therapy, Embolizations, Embolectomy, IVC filter placement, Dilatations, Stent placement.
- Various: Arthrograms, Myelograms, Facet joint injections, Discography, Sialography.

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APPENDIX B

Product information to identify an affected foot switch.

Wired Foot switch

Ref / Type	Model
452270000141	Footswitch CV 3p 4m
452270000142	Footswitch CV 3p 4m
452270000143	Footswitch CV 3p 4m
452270000144	Footswitch CV 3p 4m
452270000151	Footswitch MD 3p 6m
452270000152	Footswitch MD 3p 6m
452270000153	Footswitch MD 3p 6m
452270000154	Footswitch MD 3p 6m
452270000381	Footswitch CV 3p 8m
452270000382	Footswitch CV 3p 8m
452270000383	Footswitch CV 3p 8m
452270000384	Footswitch CV 3p 8m
459800076001	Biplane Footswitch (4p+2) 4m
459800076002	Biplane Footswitch (4p+2) 4m
459800076003	Biplane Footswitch (4p+2) 4m
459800076004	Biplane Footswitch (4p+2) 4m
459800076021	Biplane Footswitch (4p+2) 8m
459800076022	Biplane Footswitch (4p+2) 8m

Ref / Type	Model
459800076023	Biplane Footswitch (4p+2) 8m
459800076024	Biplane Footswitch (4p+2) 8m
459800772191	Footswitch CV 3p 4m
459800772192	Footswitch CV 3p 4m
459800772193	Footswitch CV 3p 4m
459800772194	Footswitch CV 3p 4m
459800772201	Footswitch CV 3p 8m
459800772202	Footswitch CV 3p 8m
459800772203	Footswitch CV 3p 8m
459800772204	Footswitch CV 3p 8m
459800772211	Biplane Footswitch (4p+2) 4m
459800772212	Biplane Footswitch (4p+2) 4m
459800772213	Biplane Footswitch (4p+2) 4m
459800772214	Biplane Footswitch (4p+2) 4m
459800772221	Biplane Footswitch (4p+2) 8m
459800772222	Biplane Footswitch (4p+2) 8m
459800772223	Biplane Footswitch (4p+2) 8m
459800772224	Biplane Footswitch (4p+2) 8m

Wireless Foot switch:

Ref / Type	Model
459800415531	Wireless FootSwitch 3P (WFS 3P)
459800415532	Wireless FootSwitch 3P (WFS 3P)
459800415533	Wireless FootSwitch 3P (WFS 3P)
459800415534	Wireless FootSwitch 3P (WFS 3P)
459800415535	Wireless FootSwitch 3P (WFS 3P)
459800415571	Wireless Footswitch 4p+2 (WFS 4p+2)
459800415572	Wireless Footswitch 4p+2 (WFS 4p+2)
459800415573	Wireless Footswitch 4p+2 (WFS 4p+2)
459800415574	Wireless Footswitch 4p+2 (WFS 4p+2)
459800415575	Wireless Footswitch 4p+2 (WFS 4p+2)

Ref / Type	Model
459800772231	Wireless Footswitch 3P (WFS 3P)
459800772232	Wireless Footswitch 3P (WFS 3P)
459800772233	Wireless Footswitch 3P (WFS 3P)
459800772261	Wireless Footswitch 4P+2 (WFS 4P+2)
459800772262	Wireless Footswitch 4P+2 (WFS 4P+2)
459800772263	Wireless Footswitch 4P+2 (WFS 4P+2)
459801238191	Wireless Footswitch 3P
459801238211	Wireless Footswitch 4P+2
459801238231	Wireless Footswitch 3P
459801238251	Wireless Footswitch 4P+2