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 7 **dated** 28/1/24 **Regarding NCMDR Field Safety Corrective Action of Allura Xper, Allura Centron, and Azurion systems from (mfr: Philips Medical Systems Nederland B.V).**

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
ISO
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
Directorate General of Pharmaceutical Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

Circular No. 7 **/ 2024**

16 -07-1445 H

28 -01-2024

Field Safety Corrective Action of Allura Xper, Allura Centron, and Azurion systems from Philips Medical Systems Nederland B.V.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19875
Product	Allura Xper, Allura Centron, and Azurion systems.
Description	Medical imaging system.
Manufacturer	Philips Medical Systems Nederland B.V.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Please refer to Appendix A in the attachment.
Reason	Three (3) components of the PCs may not perform as intended due to manufacturing issues. The PCs within your system may have one (or more) of the impacted components, that may result in a loss of system functionality.
Action	1. The three (3) components in all affected systems will be replaced by Philips. 2. Please follow "Actions that should be taken by the customer / user" in the attachment. 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

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

PHILIPS

URGENT Field Safety Notice

Allura Xper, Allura Centron, and Azurion Systems: PC Issues
Potential Loss of System Functionality which May Result in Delay or Termination of Procedure

28-December-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 issues with three (3) components in certain PCs used with the Philips Allura Xper, Allura Centron and/or Azurion systems that may result in a loss of system functionality. This Urgent Field Safety Notice is intended to inform you about:

1. What the issues are and under what circumstances they can occur

Three (3) components of the PCs may not perform as intended due to manufacturing issues. The PCs within your system may have one (or more) of the impacted components.

PC Component	Impact to System	Affected Systems	Affected PCs of System
DIMMs (Dual In-line Memory Modules)	System may stop functioning and imaging may not be possible.	• Allura Xper • Allura Centron	• Allura Xper and Allura Centron: Imaging Processing PC, Host PC, and FlexVision PC
Disk Bay	System may stop functioning and imaging may not be possible (e.g., unresponsive, frozen images).	• Allura Xper • Allura Centron • Azurion	• Allura Xper and Allura Centron: Imaging Processing PC, Host PC, and FlexVision PC • Azurion: XRay PC, Suite PC, and FlexViewing PC
Framegrabber Card	FlexVision monitor may show no viewports, or one or more viewports may show no image, a distorted image, or a frozen image. Also, switching between viewports on the FlexVision monitor may not be possible.	• Allura Xper • Azurion	• Allura Xper: FlexVision PC • Azurion: FlexViewing PC

2. Hazard/harm associated with the issues

A loss of imaging functionality could result in a delay of the procedure (including termination of the procedure, should performing a cold restart not temporarily restore system functionality). The potential delay in treatment and/or termination of the procedure may result in serious adverse health outcomes, including the possibility of death, especially when the system is used with some of the most critical patients.

To date, Philips is aware of the following adverse events associated with the component issues:

PC Component	# of Associated Adverse Events
DIMMs	3 (1 reported death and 2 reported serious injury)
Disk Bay	3 (2 reported deaths and 1 reported serious injury)
Framegrabber Card	0

Based on the complaint and repair data collected and the number of procedures per device, Philips estimates that the following components may experience an issue leading to the impacts indicated in the table of Section 1:

PC Component	%
DIMMs	0.0042
Disk Bay	0.0099
Framegrabber Card	0.0207

3. Affected products and how to identify them

Appendix A to this letter provides a table with the System Names and Model Numbers of the affected systems

4. Actions that should be taken by the customer / user

a. Circulate this Urgent Field Safety Notice to all users so that they are aware of the issue and follow the instructions below. Keep this Urgent Field Safety Notice with the documentation of the system until Philips corrects your system.

b. Establish an emergency protocol prior to all applicable diagnostics, interventional and minimally invasive procedures to manage the situation should you experience any of the component issues during a procedure.

   - If a component issue materializes during a procedure, a cold restart may temporarily resolve the issue, but it can take up to 6 minutes from initiation until system functionality is available again. After completion of the procedure, do not use the system and contact your local Philips representative immediately.

c. Perform a cold system restart every day before starting the first procedure per the instructions provided in **Appendix B**. If the system does not start up after the cold system restart or exhibits a symptom noted in **Appendix B**, your system may be impacted by a component issue. In such a case, do not use the system and contact your local Philips representative immediately.

d. For those systems connected under a remote monitoring agreement, until implementation of the correction noted below, Philips will be remotely evaluating log files of the:

   - Image Processing PC and Host PC to identify potential DIMMs component issues.
   - Image Processing PC (for Allura Xper and Allura Centron) and XRay PC (for Azurion) to identify potential Disk Bay component issues.

   If Philips determines through remote monitoring that a system is impacted, you will be instructed to stop use of the system. Note that the DIMMs and Disk Bay component issues may not always be detected through monitoring of the log files noted above.

   - Should you not already be a remote monitoring customer of Philips, sign up for free remote monitoring by contacting your local Philips representative.[1]

e. If you receive (or have received) one of the Warning Messages below while the PC system image storage space is (or was) not full[2], then your system may be impacted by the Disk Bay issue. Do not use the system and contact your local Philips representative immediately.

	Warning Message Displayed by System
Allura Xper and Allura Centron	• *Image storage not available Call Service* • *Exposure not possible. Image disk full* • *Fluo store unavailable. Image disk full* • *WARNING: Fluo storage not poss. Image disk problem* • *WARNING: Write problem. Images possibly lost*
Azurion	• *Image disk problem: Deselect Roadmap* • *Image storage is not possible because of an image disk problem*

f. In addition to the monitoring described in items c-e, as part of the preventative maintenance cycle Philips will evaluate PC log files to assess whether the system is experiencing issues with any of the three (3) components. Should Philips identify any impacted component during the cycle, do not use the system and follow the instructions provided by Philips.

   - Keep a copy of the Preventative Maintenance Manual Update attached in **Appendix C.**
   - If you do not use Philips to perform the preventative maintenance on your system, provide a copy of **Appendix C** to your qualified and authorized service provider. The Update includes steps to perform the evaluation described above. If component(s) are determined to experience the issues noted in this field action, do not use the system and contact your local Philips representative immediately.

g. Please complete and return the attached response form (on page 5) to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice and understanding of the issue and required actions to be taken.

[1] Subject to technical feasibility, applicable laws, and customer agreement with the applicable terms and conditions.
[2] See applicable sections of the IFUs for Allura Xper, Allura Centron, and Azurion on how to manage your PC system image storage space.

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

Philips will be replacing the three (3) components in all affected systems. Component replacements will be prioritized to those customers that have experienced or may be experiencing a component issue, followed by age of the PC. Philips will contact you to schedule a visit to replace the affected components (reference 2023-IGT-BST-027).

***

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 matter.

Sincerely,

Marjan Vos
Head of Quality – IGT Systems

PHILIPS

URGENT Field Safety Notice Response Form

Reference: 2023-IGT-BST-027: Allura Xper, Allura Centron, and Azurion Systems: PC Issues
Potential Loss of System Functionality which May Result in Delay or Termination of Procedure

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 issues, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- Circulate the Urgent Field Safety Notice to all users so that they are aware of the issue and follow the instructions below.
- Establish an emergency protocol prior to all applicable diagnostics, interventional and minimally invasive procedures to manage the situation should you experience any of the component issues during a procedure.
- Perform a cold system restart every day before starting the first procedure per the instructions provided in **Appendix B**. If the system does not start up after the cold system restart or exhibits a symptom noted in **Appendix B**, your system may be impacted by a component issue. In such a case, do not use the system and contact your local Philips representative immediately.
- Should you not already be a remote monitoring customer of Philips, sign up for free remote monitoring by contacting your local Philips representative.
- If you receive (or have received) one of the Warning Messages indicated in Section 4-item e of this Field Safety Notice while the PC system image storage space is (or was) not full, then your system may be impacted by the Disk Bay issue. Do not use the system and contact your local Philips representative immediately.
- Keep the Preventative Maintenance Manual Update attached in **Appendix C** and provide a copy to your qualified and authorized service provider. If component(s) are determined to experience the issues noted in this field action, do not use the system and contact your local Philips representative immediately.

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.

Appendix A – Affected Systems

System Name	Model Number
Allura Xper FD10	722003
	722010
	722026
Allura Xper FD10 OR Table	722022
	722033
Allura Xper FD10/10	722005
	722011
	722027
Allura Xper FD10C	722001
Allura Xper FD20	722012
	722006
	722028
Allura Xper FD20 Biplane	722013
	722008
Allura Xper FD20 Biplane OR Table	722025
Allura Xper FD20 OR Table	722015
	722023
	722035
Allura Xper FD20/10	722029
Allura Xper FD20/15	722058
Allura Xper FD20/15 OR Table	722059
Allura Xper FD20/20	722038
Allura Xper FD20/20 OR Table	722039
Allura Centron	722400
Azurion 3 M12	722063
	722221
Azurion 3 M15	722280
	722222
	722064
Azurion 5 M12	722227
Azurion 5 M20	722228
Azurion 7 B12	722067
	722225
Azurion 7 B20	722226
	722068
Azurion 7 M12	722223
	722078
Azurion 7 M20	722224
	722079

Intended Use.

The Azurion series is 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.

The Azurion series is intended for all human patients of all ages. Patient weight is limited to the specification of the patient table.

The Allura Xper series is 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, embolization 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 Allura Centron uses X-Ray Fluoroscopy and Acquisition imaging for Cardiac and Peripheral procedures:

- Vascular diagnostic and interventional procedures (Angiogram, Balloon Angioplasty, Stenting)
- Cardiac diagnostics and interventions (PCI)
- Pacemaker implantations and implantable defibs
- Electrophysiology (EP) and RF ablation
- Non-vascular interventions such as drainages, biopsies and vertebroplasty procedures

The system is not intended for Surgical use. It is only meant for interventional use.

Appendix B – Cold Restart Instructions & Symptoms

Perform a cold system restart every day before starting the first procedure, as follows:

a) On the Review Module, press and hold "Power Off".
b) Release the button when the indicator light begins to flash.
c) When the indicator light stops flashing, wait for 10 seconds.
d) On the Review Module, press and hold "Power On".

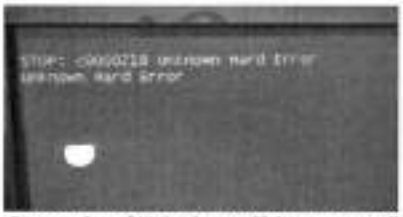
NOTE: Do not operate any of the controls while the system is powering on, as this may inhibit the start-up process.

If your system exhibits one or more of the following symptoms after the cold restart:

1. Switch to a different viewport on the FlexVision monitor. Upon switching viewports on the FlexVision monitor, FlexVision shows no image, a distorted image, a frozen image, or you are unable to switch between viewports (i.e., warning/error message displays *"Switching not possible. Call Service"*); or

2. System displays a Windows "blue screen" (see example below), regardless of what specific message is provided on the screen.

Do not use the system and contact your local Philips representative immediately.



Example of Windows "blue screen"

Appendix C - Preventive Maintenance Manual Update

4 Workflow

4.1 Onsite preparations

4.1.1 Interviewing the customer

Interview the customer to find out if there are problems which need attention during maintenance.

4.1.1.1 Ask the customer about the experienced PC issues

- Ask the customer if they have experienced:
  - A blue screen and, or
  - Any of the user messages shown on the table below while there was enough free storage space in the system.

TIP

Please notice that these user messages could be shown in the language of the system interface.

User messages for PC failures (Allura R8.x, Centron)

User message
Image storage not available. Call Service.
Exposure not possible: Image disk full
Fluo store unavailable: Image disk full
WARNING: Fluo storage not poss. Image disk problem
WARNING: Write problem: Images possibly lost
Switching not possible. Call Service.

User messages for PC failures (Azurion)

User message
Image disk problem: Deselect Roadmap
Exposure Image storage is not possible because of an image disk problem

4.1.2 Use the applicable procedure to check the error messages

4.1.2.1 Check the logging for PC issues (Allura R8.x, Centron)

1. Do the service procedure **Survey > Logging > View Technical Event Log**.
2. Examine the log file for any of the error messages in the tables below.
3. Take the action indicated in the Cause and Solution column.

Action 1 - Check error messages

Error messages

Event ID	Error message	Additional information	Cause and solution
070000003	POST - Frontal IP PC Failed	POSTItem: Frontal IP- PC Memory # Done/ Failed	DIMM problem: replace the IP PC of the frontal channel.
	POST - Lateral IP PC Failed	POSTItem: Lateral IP- PC Memory # Done/ Failed	DIMM problem: replace the IP PC of the lateral channel.
	POST - Host PC Failed	POSTItem: Host IP-PC Memory # Done/Failed	DIMM problem: replace the Host PC.
070000140	PC hardware Error	Frontal IP-PC Memory #	DIMM problem: replace the IP PC of the frontal channel.
		Lateral IP-PC Memory #	DIMM problem: replace the IP PC of the lateral channel.
		Host IP-PC Memory #	DIMM problem: replace the Host PC.
850000001	Failed to initialize all grabber cards	-	Grabber card problem: replace the FlexVision PC.

Action 2 Disk and Disk Bay

Execute checks and actions in sequential order:

PART 1 - Check errors and preconditions

Event ID	Error message	Precondition	Cause and solution
0510999920	Image storage not available. Call Service	-	If any of these message are present and the precondition is met, continue with PART2.
	WARNING: Fluo storage not poss. Image disk problem		
	Exposure not possible. Image disk full	Without prior "disk space low"	
	Fluo store unavailable. Image disk full		
	WARNING: Write problem. Images possibly lost	>= 5 times a day)	

PART 2 - Check for additional errors

Event ID	Error message	Additional information	Cause and solution
070000119	Image Disk Error	Frontal IP-PC Image Disk #	If any of the error messages are present continue with PART3
		Lateral IP-PC Image Disk #	
070000122	Image Disk Error (Read Error)	-	
070000123	Image Disk Error (Write Error)		
070000145	One or more POSTs failed	IpPcFrontalPCImageDi sk	
		IpPcLateralPCImageDis k	
070000146	Image Processing malfunction	Timeout during stop of ImageStoreSinkNode	
		ImageStoreSourceNod e: ReleasePlaylist failed	If any of these error messages are present, continue with Part 3.
		ImageStoreSourceNod e: Start failed	
0510020523	Write errors: no storage possible	-	

PART 3 - Check Smart Data of Frontal and Lateral IP PC (if applicable)

Event ID	Error message	Additional info	Limit value	Cause and solution
N.A.	SMART Data	Read Error Rate: 200 <#>	# = max 30	Disk issue: if any value in Additional Info exceeds the Limit Value, replace the image disk of the applicable IP PC. Disk Bay issue: If no disk problem, replace the applicable IP PC.
		Reallocated Sectors Count: 200 <#>	# = max 10	
		UnCorrectableSectorC ount: 200 <#>	# = max 0	
		Current Pending Sector Count: 200 <#>	# = max 1	

4.1.2.2 Check the logging for PC issues (Azurion)

1. Do the service procedure **System > Copy Event Logging**.
2. Select the Start Date and End Date.
3. Click **Export**.
4. Save the file to the USB flash drive.
5. Examine the log file for any of the error messages in the tables below.
6. Take the action indicated in the Cause and Solution column.

Action 1 - Check error messages

Error messages

Event ID	Error message	Cause and solution
2055FLV0000002	Cannot display grabbed video inputs. Software driver returned an	Grabber card problem: replace the FlexViewing PC

	error for all video frame grabber cards

Action 2 Disk and Disk Bay

Execute checks and actions in sequential order:

PART 1 – Check errors

Event ID	Error message	Cause and solution
N/A	User guidance: Image storage is not possible because of an image disk problem	Release 1.x to 2.0, if any of the error messages are present, replace the X-ray PC with all disks (HDD / SSD). Release 2.1 and higher, continue with PART 2.
	User guidance: WARNING: Image storage is not possible because of an image disk problem	
	User guidance: Image disk problem: Deselect Roadmap	
20SSIEC0014029	ImageStore: Usable disk space smaller than licensed space	
20SSIEC0014045	XrayService: Insufficient memory for next acquisition	

PART2 - A: Check Smart Data of the X-ray PC with HDD

Event ID	Error message	Additional info	Limit value	Cause and solution
N/A	SMART Disk Data	Read Error Rate: 200 <#>	# = max 30	Disk issue: if any value in Additional Info exceeds the Limit Value, replace the image disk of the XRay PC. Disk Bay issue: If there are no errors, replace the XRay PC.
		Reallocated Sectors Count: 200 <#>	# = max 10	
		UnCorrectableSectorCount: 200 <#>	# = max 0	
		Current Pending Sector Count: 200 <#>	# = max 1	

PART2 - B: Check Smart Data of the Xray PC with SSD

Event ID	Error message	Additional info	Limit value	Cause and solution
N/A	SMART Disk Data	SSDProgramFailCount: 100 <#> SSDEraseFailCount: 100 <#> ReportedUncorrectableErrors: 100 <#> EndtoEnderror: 100 <#>	# = max 0	Disk issue: if any value in Additional Info exceeds the Limit Value, replace the image disk of the XRay PC. Disk Bay issue: If there are no errors, replace the XRay PC.