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URGENT Field Safety Notice

Philips Azurion, Allura Xper, Integris and MultiDiagnost Eleva
Potential Detachment of the Cable Hose Carrier which May Result in Parts Falling and/or Part of the Cable Hose Dropping

22-AUG-2024

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 identified a potential safety issue with the Cable Hose Carriers of the Philips Azurion, Allura Xper, Integris and MultiDiagnost Eleva product families. This URGENT Field Safety Notice is intended to inform you about:

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

Philips has identified that due to the forces applied when moving or turning the monitor of the system, the bolts and plastic parts of the Cable Hose Carriers that hold the cable hose to the monitor ceiling suspension may become loose and/or break (see Figure 1). If this issue occurs, plastic parts and/or metal bolts of the Cable Hose Carrier(s) may fall and/or part of the cable hose may drop following the detachment of a Cable Hose Carrier.

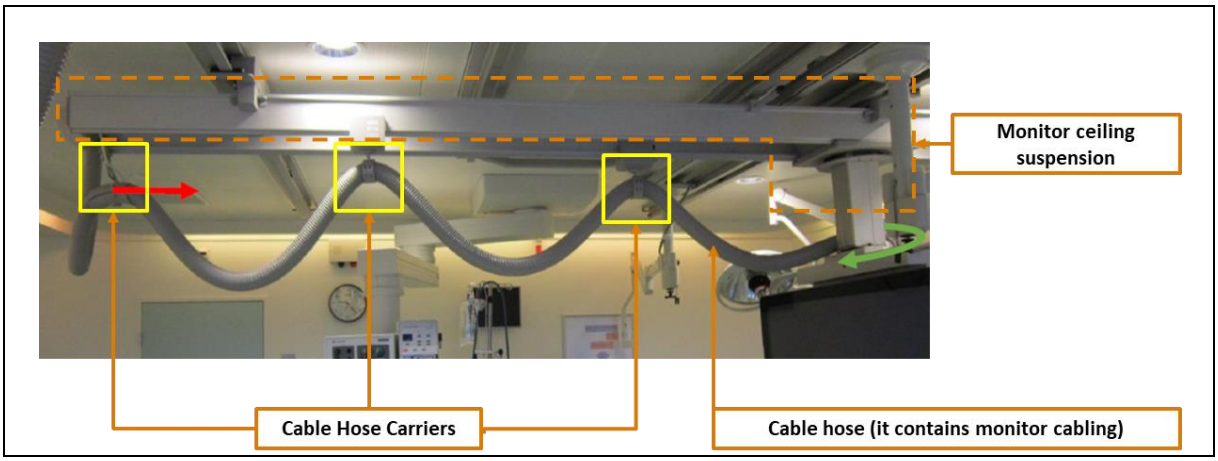
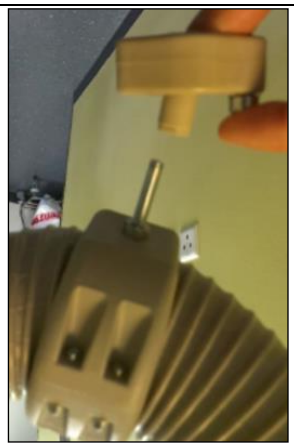
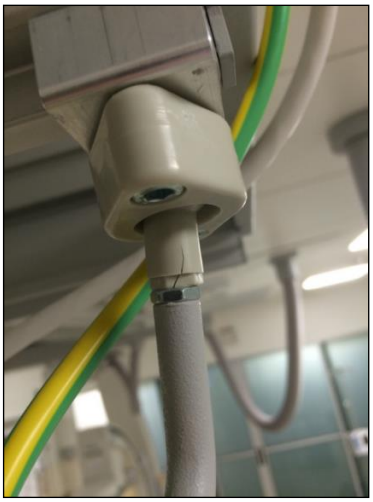


Figure 1: When the monitor is moved or turned (green arrow), the cable hose pulls the Cable Hose Carriers and applies forces to their joint and bolted connections (yellow box).



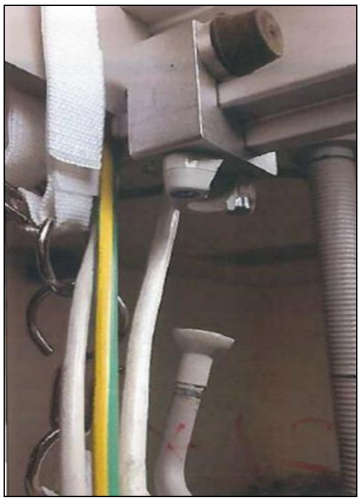
Loose bolt
This will result in the cable hose dropping

Broken bolt
This will result in the cable hose dropping



Broken plastic bearing shaft

Broken plastic bearing housing



Broken plastic bearing housing This will result in the cable hose dropping

Figure 2: Examples of loose and broken bolts and plastic parts

2. Hazard/harm associated with the issue

Falling cable carrier parts and/or a drop of the cable hose may result in harm to an operator or a bystander in the vicinity (e.g., bruises/contusions, lacerations, pain, head injury, muscle/tendon damage, and neck stiffness). No serious adverse health consequences are reasonably expected.

As of the date of this letter, eight (8) events have been reported to Philips alleging injury to operators (e.g., cuts, wounds, concussions, sores, neck stiffness, and headache).

Philips estimates that 0.0006% of the Cable Hose Carriers in the field may experience this issue during a procedure.

Falling parts and/or a drop of the cable hose do not impact system functionality.

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3. Affected products and how to identify them

Philips Azurion and Allura Xper systems with monitors mounted on a ceiling suspension, and all Integris and MultiDiagnost Eleva systems are affected by this issue.

Appendix A to this letter provides a table with the System Codes and Commercial Names, and the intended use of the affected systems.

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

a. Affected systems may continue to be used in accordance with their Instructions for Use (IFU) and the instructions below.
b. Avoid that operators or bystanders stand underneath the Cable Hose Carriers, especially when moving or turning the system monitor.
c. Avoid having the patient located underneath the Cable Hose Carriers (e.g., during transport).
d. If you notice loose or broken bolts and/or broken plastic parts of the Cable Hose Carriers (see Figure 2), please contact your local Philips representative immediately.
e. As part of the preventive maintenance cycle, Philips will check the Monitor Ceiling Suspension, including the Cable Hose Carriers, as indicated in the Preventive Maintenance Manual Update attached in Appendix B.
    - Keep a copy of this Preventative Maintenance Manual Update with your current manual.
    - If you do not use Philips to perform the preventative maintenance on your system, provide a copy of the Preventive Maintenance Manual Update to your qualified and authorized service provider.
f. Circulate this Urgent Field Safety Notice letter to all users of the system so that they are aware of the issue and follow the instructions above. Keep this Field Safety Notice letter with the documentation of the system until Philips corrects your system.
g. Complete and return the attached response form (page 4) to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent 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 is redesigning the Cable Hose Carriers. Once the redesigned cable hose carriers are available, Philips will contact you to schedule a visit to install them in the affected system(s) (reference FCO72200536, FCO72200576, and FCO72200577). As of the date of this urgent Field Safety Notice letter, Philips expects the solution to be available by Q3 2025.

This notice has been reported to the appropriate Regulatory Agencies.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need additional information or support concerning these issues, contact your local Philips representative at:

Philips regrets any inconvenience caused by this matter.

Sincerely,

Marjan Vos
Head of Quality – IGT Systems

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URGENT Field Safety Notice Response Form

Reference: 2023-IGT-BST-006: Philips Azurion, Allura Xper, Integris and MultiDiagnost Eleva; Potential Detachment of the Cable Hose Carrier which May Result in Parts Falling and/or Part of the Cable Hose Dropping

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 issues, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

a. Affected systems may continue to be used in accordance with their Instructions for Use (IFU) and the instructions below.
b. Avoid that operators or bystanders stand underneath the Cable Hose Carriers, especially when moving or turning the system monitor.
c. Avoid having the patient located underneath the Cable Hose Carriers (e.g., during transport).
d. If you notice loose or broken bolts and/or broken plastic parts of the Cable Hose Carriers (see Figure 2), please contact your local Philips representative immediately.
e. As part of the preventive maintenance cycle, Philips will check the Monitor Ceiling Suspension, including the Cable Hose Carriers, as indicated in the Preventive Maintenance Manual Update attached in Appendix B.
    - Keep a copy of this Preventative Maintenance Manual Update with your current manual.
    - If you do not use Philips to perform the preventative maintenance on your system, provide a copy of the Preventive Maintenance Manual Update to your qualified and authorized service provider.
f. Circulate this Urgent Field Safety Notice letter to all users of the system so that they are aware of the issue and follow the instructions above. Keep this Field Safety Notice letter with the documentation of the system until Philips corrects your system.

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 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 Notice.

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Appendix A - Affected Systems

System Code	Commercial Name
722282	Azurion 7 M20
722281	Azurion 5 M20
722236	Azurion 7 B20
722235	Azurion 7 B12
722234	Azurion 7 M20
722233	Azurion 7 M12
722228	Azurion 5 M20
722227	Azurion 5 M12
722226	Azurion 7 B20
722225	Azurion 7 B12
722224	Azurion 7 M20
722223	Azurion 7 M12
722222	Azurion 3 M15
722221	Azurion 3 M12
722079	Azurion 7 M20
722078	Azurion 7 M12
722068	Azurion 7 B20
722067	Azurion 7 B12
722064	Azurion 3 M15
722063	Azurion 3 M12
722059	Allura Xper FD20/15 OR Table
722058	Allura Xper FD20/15
722044	INTEGRIS Allura 15-12 (biplane)
722043	Integris Allura 15 & 12 (monoplane)
722039	Allura Xper FD20/20 OR Table
722038	Allura Xper FD20/20
722035	Allura Xper FD20 OR Table
722030	Integris CV Cesar-Powerpack-Visub-Nicol

System Code	Commercial Name
722029	Allura Xper FD20/10
722028	Allura Xper FD20
722027	Allura Xper FD10/10
722026	Allura Xper FD10
722025	Allura Xper FD20 Biplane OR Table
722023	Allura Xper FD20 OR Table
722021	INTEGRIS Allura 9 (biplane)
722020	Allura Xper FD20 Biplane OR Table
722018	Integris Allura 9
722017	Integris H5000 F / Allura 9F
722016	Integris H5000 C / Allura 9C
722015	Allura Xper FD20 OR Table
722013	Allura Xper FD20 Biplane
722012	Allura Xper FD20
722011	Allura Xper FD10/10
722010	Allura Xper FD10
722008	Allura Xper FD20 Biplane
722006	Allura Xper FD20
722005	Allura Xper FD10/10
722003	Allura Xper FD10
722002	Allura Xper FD10F
722001	Allura Xper FD10C
708038	MultiDiagnost Eleva with Flat Detector
708037	MultiDiagnost Eleva with Flat Detector
708036	MultiDiagnost Eleva
708034	MultiDiagnost Eleva with Flat Detector
708032	MultiDiagnost Eleva

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.
- Additionally:
    - The Azurion series can be used in a hybrid operating room.
    - The Azurion series contains a number of features to support a flexible and patient-centric procedural workflow.

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

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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 peripheral, cerebral, thoracic and abdominal angiography, as well as PTAs, stent placements, embolizations 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 Xper series (excluding Centron) is compatible with a hybrid Operating Room.
    - The Allura Xper FD 10 Systems (excluding Centron) are compatible with specified magnetic navigation systems.

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

The **Integris series** is intended for diagnostic cardiovascular, vascular and therapeutic procedures.

The **MultiDiagnost Eleva** is intended to be used as a multifunctional/universal system. General R/F, Fluoroscopy, Radiography and Angiography can be performed along with more specialized interventional applications.

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Appendix B - Preventative Maintenance Manual Update

1.1. Monitor ceiling suspension (Ceiling rails)

1.1.1. Examine the monitor frame (Philips Azurion, and Allura Xper)

1. Make sure that the hand grips attach tightly.
2. Make sure that monitors attach tightly.
3. Examine the physical stiffness of the monitor frame.
4. If applicable, make sure that the Wall Connection Box (WCB) bracket and WCB attachments attach tightly.

1.1.2. Examine the cable hose carriers (Philips Azurion, Allura Xper, Integris, and MultiDiagnost Eleva)

1. Identify the cable hose carriers.
2. Make sure the movable cable hose carriers run smoothly.
3. Make sure the bolts and nuts of the cable hose carriers are fixed properly.

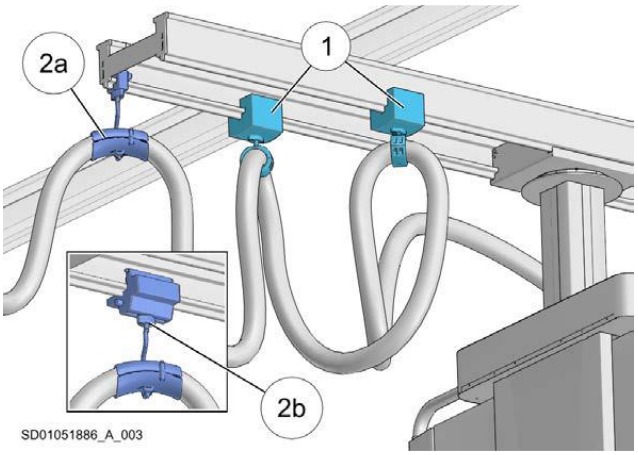

Fig. 01: Movable hose carriers (1+2b) and fixed hose carriers (2a)

4. Examine the attachment and condition of the mounting base (B)

   - If there is any damage to the mounting base (for example cracks or broken parts), replace the mounting base.

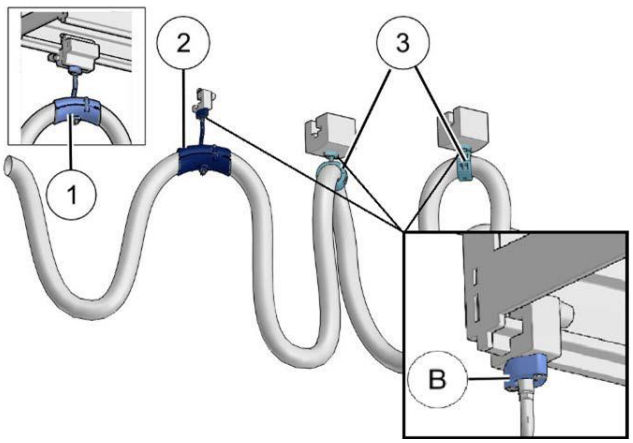

Fig. 02: The mounting base of the hose carriers

5. Make sure that all the nuts are tightened.
6. See if there is a visible gap.

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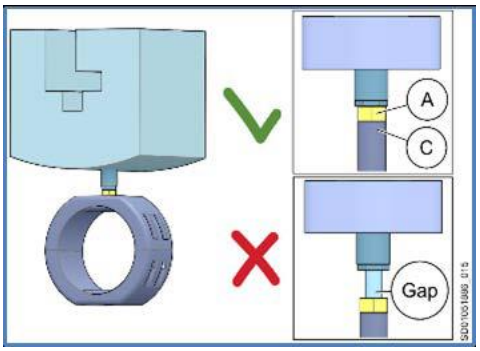
- 

Fig. 03: Correct 'V' and incorrect 'X' ring carrier suspension

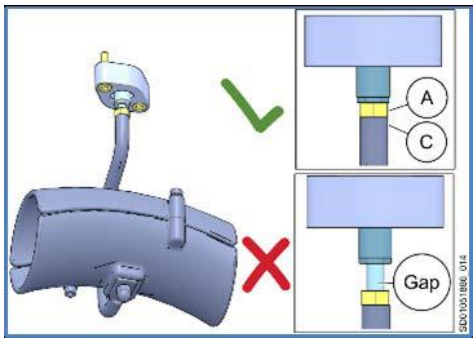


Fig. 04: Correct 'V' and incorrect 'X' banana carrier suspension

7. If there is a visible gap for a carrier with ring:

- Loosen base (1) (2x M6).
- Loosen the plastic arm carrier (A) with nut (D).
- Loosen nut (C).
- Apply Loctite 243 to the thread of the bolt (B).
- Assemble the hose ring with bolt (B) and nut (C).

- Hold the nut (C) in position, then rotate and tighten the plastic arm carrier (A) with nut (D) until there is no gap.

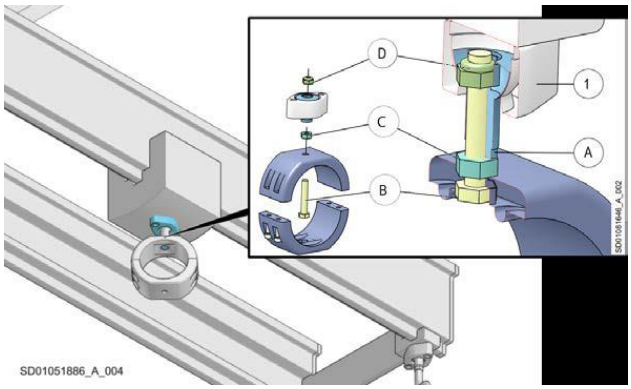


Fig. 05: Cable hose carrier with ring

8. If there is a visible gap for a carrier with hook:

- Loosen base (E) (2x M6).
- Hold the hook (F) in position and loosen the nut (C).
- Loosen the bolt (B) with the plastic arm carrier (A).
- Apply Loctite 243 to the thread of the bolt (B) and the thread inside the hook (F).
- Assemble the plastic arm carrier (A) with the bolt (B) and nut (C).
- Tighten the nut (C) to the plastic arm of carrier (A).
- Rotate and tighten the arm carrier (A) with bolt (B) into the hook until there is no gap.

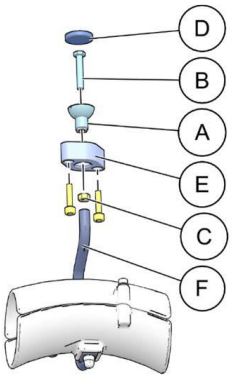


Fig. 06: Cable hose carrier with hook

9. Install the assembly with the base (2x M6).