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URGENT Field Safety Notice Update

Philips Allura and Azurion systems
Risk of patient fall from the table associated with the use of the mattress

14-May-2025

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,

This letter is an update to the URGENT Field Safety Notice letter dated 13-Jan-2025 (ref. 2023-IGT-BST-015) related to the potential safety issue(s) of the mattress used with the Philips Allura and Azurion systems.

The highlighted sections (***bold italics***) of this letter have been updated compared to the earlier notification.

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

Philips has identified some situations that may result in the patient falling from the table related to the mattress used on the patient table of the Philips Allura and Azurion systems:

- **Mattress slipping from the table:** While the patient is being transferred from the patient table to a cart/strecher/ hospital bed and vice versa, the mattress could move and slip potentially resulting in the patient falling from the table.
- **Incorrect positioning of the neuro mattress on the table:** If the neuro mattress is positioned at the top of the table, the mattress will cover the neuro table head leaving the mattress unsupported in this area. The patient could fall if while positioning/making comfortable, the patient places their hand on the side of their head, where the mattress is not supported by the tabletop (see figure 1).
- **Incorrect mattress being used on table:** If a cardiac (long) mattress is used on a neuro table, the mattress will cover the neuro table head leaving the mattress unsupported in this area. The patient could fall if while positioning/making comfortable, the patient places their hand on the side of their head, where the mattress is not supported by the tabletop (see figure 2).

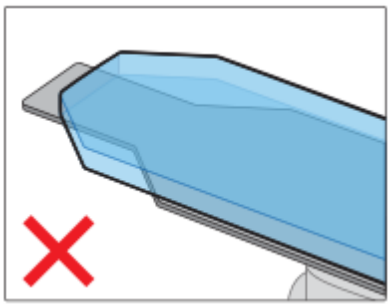

Figure 1 – Incorrect positioning of the neuro mattress

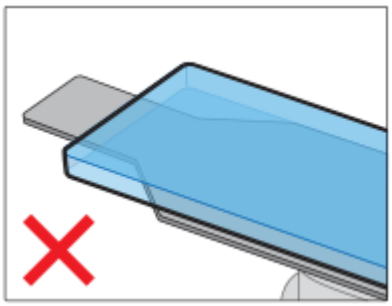

Figure 2 – Incorrect use of mattress

2. Hazard/harm associated with the issue

Mattress movement during patient transfer and/or incorrect positioning or incorrect mattress used, may lead to a patient fall which might result in harm to the patient (e.g. hematoma/bruises, scratches, skin abrasions, stiffness, contusions, intracranial hemorrhage, large/complex lacerations), and potentially may result in death. ***Hospital supporting staff could potentially also be harmed while attempting to prevent or mitigate the effect of a patient fall.***

From January 2020 to March 2025, Philips has received 24 complaints related to this issue. Eight (8) complaints reported injury, of which three (3) were serious injuries.

3. Affected products and how to identify them

All Philips Allura and Azurion systems used with a Philips mattress are affected.

Appendix A provides information on the Philips Allura and Azurion systems and their intended use.

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

- Circulate this URGENT Field Safety Notice letter to all users of the system so that they are aware of the issue.
- ***Follow the instructions provided in section 2 "Positioning the Patient on the Table" and section 4 "Mattress" of the addendum to the Instructions for Use "Patient Table" that we are providing together with this letter. This addendum includes information regarding the transfer of the patient and the correct use and positioning of the mattress. Additionally, we are providing a copy of the Quick Reference Card.***

  Note: The information in the addendum is the same as the information contained in Appendix B of the URGENT Field Safety Notice letter dated 13-January-2025. These documents can be downloaded in electronic format following the instructions of Appendix B of this letter.

- In case that the affected system has been transferred to another organization, please send a copy of this URGENT Field Safety Notice letter to that organization and inform Philips about this transfer through your local Philips representative.
- Please complete and return the Response form attached 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.

  Note: If you have already sent the Reply Form in response to the URGENT Field Safety Notice letter dated 13-January-2025, then there is no need to provide the Reply Form

again. If you have not yet sent the Response Form, please use the response form included in this updated Field Safety Notice letter.

Should you experience the issue reported in this letter, please report the event to Philips through your local Philips representative.

5. Actions planned by Philips Image Guided Therapy Systems to correct the problem

Philips is working on the development of a design solution to prevent slipping of the mattress during patient transfer. Philips will contact you to schedule a visit to install this solution on your system.

As of the date of this URGENT Field Safety Notice letter, Philips expects that this solution will be available by December 2025.

This URGENT Field Safety Notice letter 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 this issue, please contact your local Philips representative.

Telephone 80 30 30 35

Email philips.service@philips.com

Philips regrets any inconvenience caused by this problem.

Sincerely,

Marjan Vos,

Head of Quality-IGT Systems

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URGENT Field safety Notice Update Response form

14-May-2025

Reference: 2023-IGT-BST-015: Risk of patient fall from the table associated with the use of the mattress.

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 issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- Circulate this URGENT Field Safety Notice letter to all users of the system so that they are aware of the issue.
- ***Follow the instructions provided in section 2 "Positioning the Patient on the Table" and section 4 "Mattress" of the addendum to the Instructions for Use "Patient Table" that we are providing together with this letter. This addendum includes information regarding the transfer of the patient and the correct use and positioning of the mattress. Additionally, we are providing a copy of the Quick Reference Card.***
- In case that the affected system has been transferred to another organization, please send a copy of this URGENT Field Safety Notice letter to that organization and inform Philips about this transfer through your local Philips representative.
- Should you experience the issue reported in this letter, please report the event to Philips through your local Philips representative.

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): _____

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.

Email this completed form to FCO.Nordic@philips.com

We kindly request that you add in the subject of the email the reference 2023-IGT-BST-015-Group 1

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Appendix A

Allura and Azurion Systems information

Commercial Name	System Code
Allura CV20	722031
Allura Xper FD10	722003
	722010
	722026
AlluraXper FD10/10	722005
	722011
	722027
Allura Xper FD10C	722001
AlluraXper FD20	722006
	722012
	722028
AlluraXper FD20 Biplane	722008
	722013
AlluraXper FD20 Biplane OR Table	722020
	722025
AlluraXper FD20 OR Table	722023 722035
AlluraXperFD20/10	722029
Allura Xper FD20/20	722038
AlluraXperFD20/15	722058
Azurion 3 M12	722063
	722221
Azurion 3 M15	722064
	722222
	722280
Azurion 5 M12	722227
	722231
Azurion 5 M20	722228
	722232
	722281
Azurion 7 B12	722067
	722225
	722235
Azurion 7 B20	722068
	722226
	722236
Azurion 7 M12	722078
	722223
	722233
Azurion 7 M20	722224
	722079
	722234
	722282
Cardiovascular-Allura Centron	722400

Intended Use

The **Allura Xper FD 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, 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 Xper FD series is compatible with a hybrid Operating Room.

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

The **Azurion series** (within the limits of the used operating room table) 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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Appendix B:

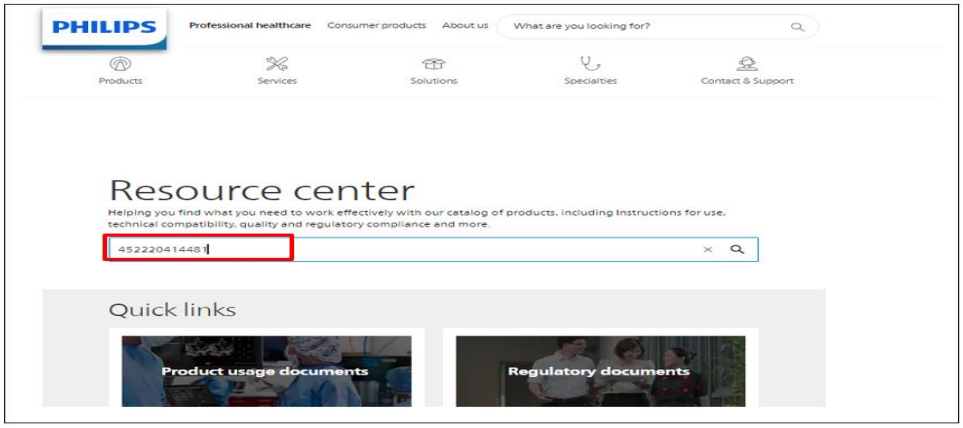
Download instructions IFU addendum and Quick Reference Card (QRC)

1. Use the following link below or QR Code to access the site with the IFU addendum and Quick Reference Card:

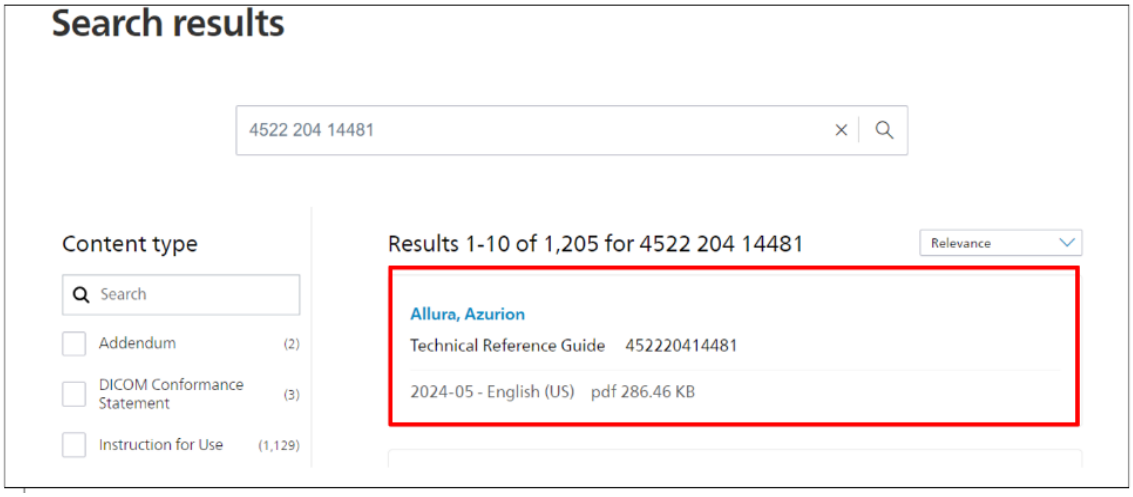
   Link: https://www.usa.philips.com/healthcare/about/support/resource-center

   QR code:

2. Type the Code number of the IFU Addendum or QRC in the search field (see below the code numbers per language). Then click on the magnifying glass or press “enter”



3. Open the document by double clicking on “Allura, Azurion”



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Language codes for the IFU addendum and QRC

Language	Language code for QRC	Language code for IFU addendum for CE Mark countries	Language code for IFU addendum for Non CE Mark countries	Language code for IFU adddendum for systems manufactured in China
American English	4522 204 14482	4523 001 30522	4523 001 30852	-
Bahasa Indonesian	4522 204 14602	4523 001 30592	4523 001 32482	-
Brazilian Portuguese	4522 204 14712	4523 001 30702	4523 001 32592	-
Bulgarian	4522 204 14492	4523 001 30472	4523 001 32382	-
Croatian	4522 204 14582	4523 001 30572	4523 001 32462	-
Czech	4522 204 14502	4523 001 30482	4523 001 32392	-
Danish	4522 204 14512	4523 001 30492	4523 001 32402	-
Dutch	4522 204 14692	4523 001 30682	4523 001 32572	-
Estonian	4522 204 14552	4523 001 30542	4523 001 32432	-
Finnish	4522 204 14562	4523 001 30552	4523 001 32442	-
French	4522 204 14572	4523 001 30562	4523 001 32452	-
German	4522 204 14522	4523 001 30502	4523 001 32412	-
Greek	4522 204 14532	4523 001 30512	4523 001 32422	-
Hungarian	4522 204 14592	4523 001 30582	4523 001 32472	-
Italian	4522 204 14612	4523 001 30602	4523 001 32492	-
Japanese	4522 204 14622	4523 001 30612	4523 001 32502	-
Kazakh	4522 204 14632	4523 001 30622	4523 001 32512	-
Korean	4522 204 14642	4523 001 30632	4523 001 32522	-
Latvian	4522 204 14662	4523 001 30652	4523 001 32542	-
Lithuanian	4522 204 14652	4523 001 30642	4523 001 32532	-
Macedonian	4522 204 14672	4523 001 30662	4523 001 32552	-
Norwegian	4522 204 14682	4523 001 30672	4523 001 32562	-
Polish	4522 204 14702	4523 001 30692	4523 001 32582	-
Romanian	4522 204 14722	4523 001 30712	4523 001 32602	-
Russian	4522 204 14732	4523 001 30722	4523 001 32612	-
Serbian	4522 204 14762	4523 001 30752	4523 001 32642	-
Simplified Chinese	4522 204 14813	4523 001 30802	4523 001 30872	4523 001 30832
Slovak	4522 204 14742	4523 001 30732	4523 001 32622	-
Slovene	4522 204 14752	4523 001 30742	4523 001 32632	-
Spanish	4522 204 14542	4523 001 30532	4523 001 30862	-
Swedish	4522 204 14772	4523 001 30762	4523 001 32652	-
Traditional Chinese	4522 204 14822	4523 001 30812	4523 001 32692	-
Turkish	4522 204 14782	4523 001 30772	4523 001 32662	-
Ukrainian	4522 204 14792	4523 001 30782	4523 001 32672	-
Vietnamese	4522 204 14802	4523 001 30792	4523 001 32682	-