

## **URGENT Field Safety Notice**

Risk of finger entrapment during manual movements of the patient tabletop

AD7 and AD7X patient tables which are part of Philips Allura and Azurion systems

13-Jan-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,

Philips has become aware of a potential safety issue with the AD7 and AD7X patient tables (both tilt and non-tilt versions) which are part of the Philips Allura and Azurion systems which could pose a risk for operators and service personnel.

This URGENT Field Safety Notice Letter is intended to inform you about:

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

Philips has identified that during manual repositioning of the patient tabletop, a finger can get entrapped between the longitudinal guiding rails and the tabletop, possibly resulting in an injury of the finger (see Figure 1). This risk is applicable for the operators and service personnel.

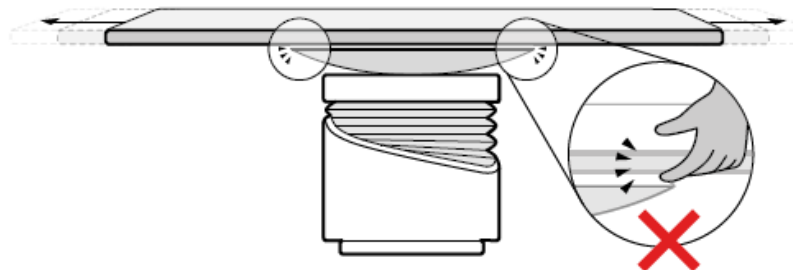


Figure 1. Finger entrapment risk areas.

### **2. Hazard/harm associated with the issue**

If a finger is entrapped between the longitudinal guiding rails and the tabletop, it may result in harm to an operator or service personnel (e.g., bruises, small cuts, lacerations, and bone-fractures).

At the date of this letter, Philips has received 21 complaints related to this issue. These complaints reported injury to operator/service personnel, of which 1 (one) was a serious injury.

### 3. Affected products and how to identify them

The AD7 or an AD7X table types (tilt and non-tilt versions) are used with the Philips Allura and Azurion systems.

The model of the table can be identified by the label attached at the bottom of the table. To see the label: raise the table to its highest position and check the label “patient table” as shown in Figure 2.

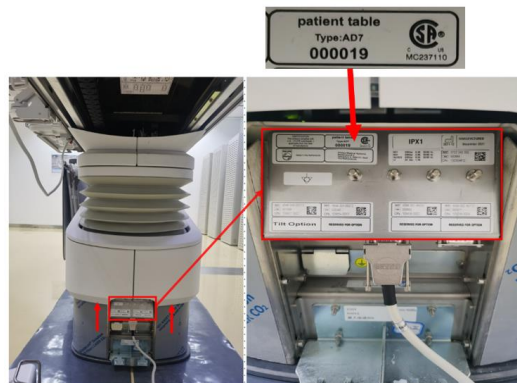


Figure 2. Location of table labels with table in highest position (left side) and label with table type (right side)

**Appendix A** to this letter provides information on the Allura and Azurion systems that contain the affected AD7 and AD7X and their intended use.

### 4. Actions that should be taken by the customer / user in order to prevent risks for operators and service personnel

- Circulate this URGENT Field Safety Notice letter to all users of the system so that they are aware of the issue.
- Follow the additional instructions when positioning the patient table included in Appendix B. These instructions include information of potential finger entrapment areas when moving the table.

The information of this Appendix is being included in an Addendum to the Instructions for Use. Additionally, Philips is creating a Quick Reference Card. The Addendum and the Quick Reference Card will be available as from end of March 2025. Please refer to Appendix C on how to download the Addendum to the Instructions for Use and 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.
- 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.
- 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 IGT-S to correct the problem

Philips is releasing an addendum to the instructions for use and a Quick Reference Card that will be available for customers at the end of March 2025.

Philips is working on the design of additional brackets for the AD7 tables, and a new redesigned table cover for AD7X tables (ref. FCOs: FCO72200516, FCO72200552, FCO72200553, FCO72200554, FCO72200555, FCO72200556). Philips will contact you to schedule a visit once the new redesigns are available. As of the date of this URGENT Field Safety Notice letter, Philips expects the solution to be available by Q1 2026.

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.

Philips regrets any inconvenience caused by this problem.

Sincerely,



Marjan Vos,  
Head of Quality – IGT Systems

**URGENT Field Safety Notice Response Form**

**Reference: 2022-IGT-BST-007:** Risk of finger entrapment during manual movements of the patient tabletop.

**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 additional instructions when positioning the patient table included in Appendix B. These instructions include information of potential finger entrapment areas when moving the table.

The information of this Appendix is being included in an Addendum to the Instructions for Use. Additionally, Philips is creating a Quick Reference Card. The Addendum and the Quick Reference Card will be available as from end of March 2025. Please refer to Appendix C on how to download the Addendum to the Instructions for Use and 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.

Please complete and return this form to Philips.

**Appendix A**

**Allura and Azurion Systems with affected Patient Tables**

<b>Commercial Name</b>	<b>System Code</b>
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

## 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 **Allura CV20** is intended for physicians (e.g. cardiologists and radiologists), assisted by trained hospital staff (e.g. nurses and lab technicians), who are qualified to perform medical procedures on humans (having a maximum weight of 250 kg.) with probable internal diseases or injuries for:

- Dedicated vascular and carotid imaging applications, including diagnostic and interventional procedures.
- Cardiac imaging applications including diagnostics, interventional procedures, pacemaker implantations and electrophysiology (EP).
- Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures.

The Allura CV20 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) 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 few 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.

## Appendix B

### Instructions for Positioning the Patient Table

#### Floating the Tabletop:

Beware of finger entrapment. Do not place your fingers beneath the tabletop when floating the tabletop.

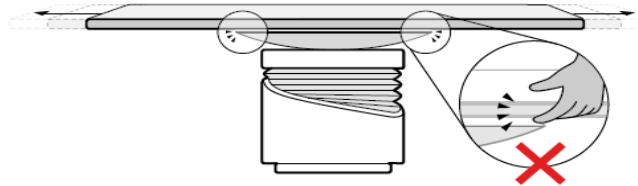


Figure 1. Table float (longitudinal) movement finger entrapment risk areas

#### Tilting the Table:

Beware of finger entrapment. Do not place your fingers on the table bellows during tilting.

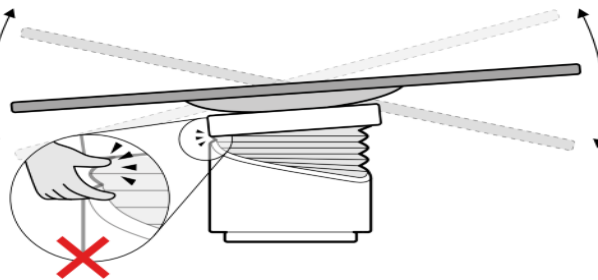


Figure 2. Table tilt movement (option) finger entrapment risk areas

#### Cradling the Table

Beware of finger entrapment. Do not place your fingers where the tabletop meets the table base when cradling the tabletop. Depending on your patient table configuration, there may be more than one opening below the tabletop.

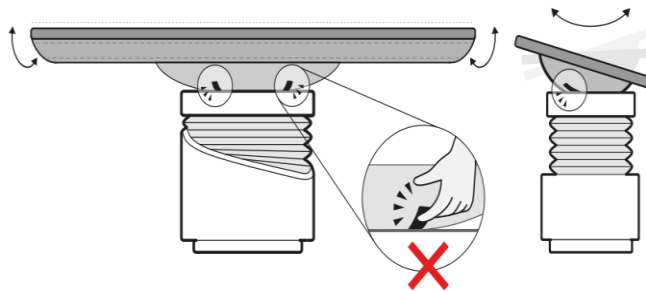


Figure 3: Table cradle movement (option) finger entrapment risk areas

## Appendix C

### Download instructions IFU addendum and Quick Reference Card (QRC)

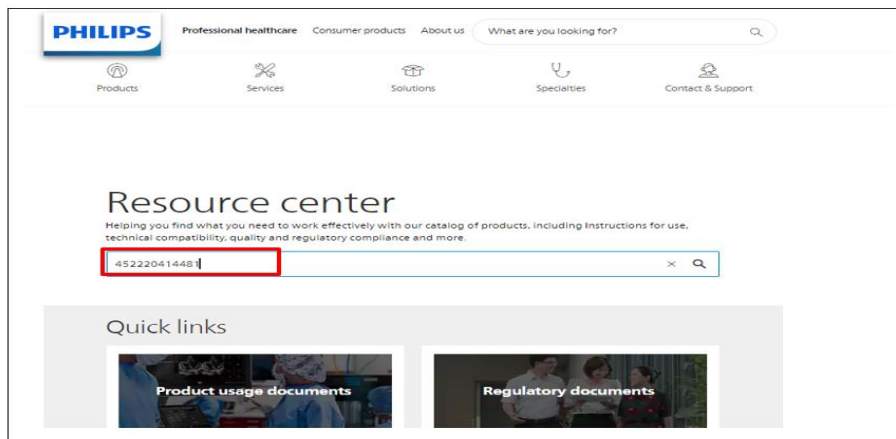
1. Use the following link below or QR Code to access the site with the IFU addendum and Quick Reference Card.

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

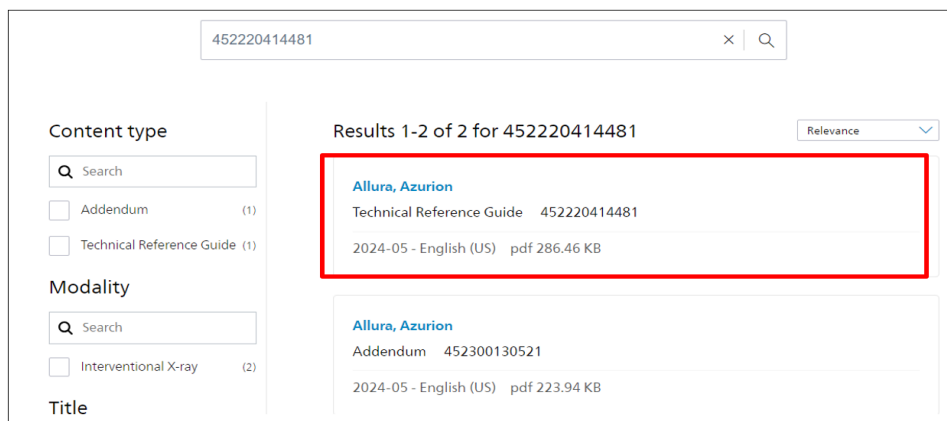
QR code:



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”





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 addendum 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	-