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URGENT Field Safety Notice

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

01-May-2026

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 use of the mattress used with the Philips Allura and Azurion systems. 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 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).

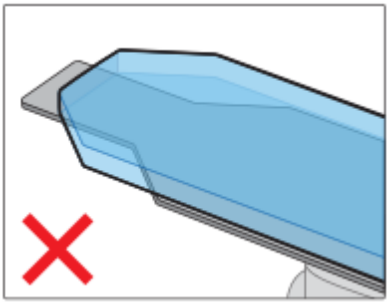

Figure 1 – Incorrect positioning of the neuro mattress

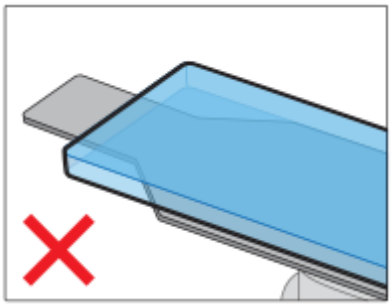

Figure 2 – Incorrect use of mattress

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 be harmed while attempting to prevent or mitigate the effect of a patient fall.

From January 2020 to April 2026, Philips has received 33 complaints related to this issue. Ten (10) complaints reported injury, of which five (5) 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 of section “2 Positioning the Patient on the Table” and section “4 Mattress” of the addendum to the Instructions for Use “Patient Table” that was provided with your system. For convenience, we are providing a copy of this addendum together with this letter. This addendum includes information for the transfer of the patient and the correct use and positioning of the mattress.
- 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

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

Philips is informing customers of this issue through this URGENT Field Safety Notice letter.

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 May 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

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URGENT Field Safety Notice Response Form

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 of section "2 Positioning the Patient on the Table" and section "4 Mattress" of the addendum to the Instructions for Use "Patient Table" that was provided with your system. For convenience, we are providing a copy of this addendum together with this letter. This addendum includes information for the transfer of the patient and the correct use and positioning of the mattress.
- 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 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.

<provide instructions here for the customer to return the form to Philips, for example, fax #, email address. For example, "Fax this completed form to Philips at (xxx)xxx-xxxx>

We kindly request that you add in the subject of the email the reference 2023-IGT-BST-015-Group 3

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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

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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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Addendum

English

4523 001 30522

Patient Table

Contents

Contents

1 Introduction

This document is an addendum to the following instructions for use:

- Allura Xper FD series and AlluraClarity family
- UNIQ series and UNIQ Clarity family
- Allura CV20
- Allura Centron
- Azurion series

For clinical user guidance, there is an applicability statement at the start of each section.

For a full system description, refer to the instructions for use supplied with your X-ray system.

2 Positioning the Patient on the Table

For Allura Xper FD series, AlluraClarity family, UNIQ series, and UNIQ Clarity family systems, this section is in addition to the following sections in the Instructions for Use:
- *Basic Operation section 3.6.4*
- *Extended Operation section 2.4.5*

For Allura Centron systems, this section is in addition to the following sections in the Instructions for Use:
- *Basic Operation section 3.5.4*
- *Extended Operation section 2.4.4*

For Allura CV20 systems, this section is in addition to section 2.5.4 in the Basic Operation Instructions for Use.

For Azurion series systems, this section is in addition to section 5.9 in the Instructions for Use.

NOTE
Take care when transferring the patient; be aware that the mattress is not fixed to the table.

Before positioning the patient on the table, read the following guidance:

Mattress Positioning
- Use a mattress that is appropriate for the table.
- When positioning the mattress, ensure that the entire mattress is supported by the tabletop.
- Pay particular attention when working with the neuro tabletop and mattress: do not position the mattress on the narrow area of the neuro tabletop.

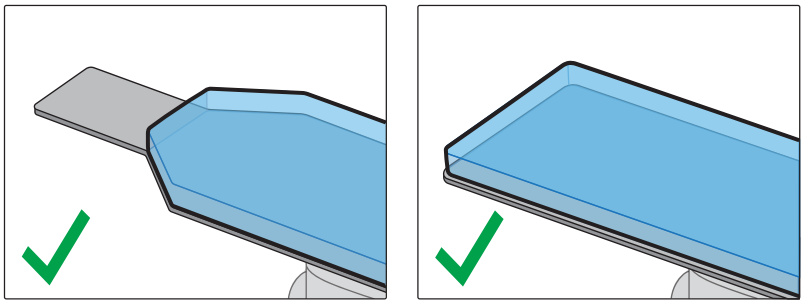

Figure 1 Correct mattress positioning: the entire mattress is supported.

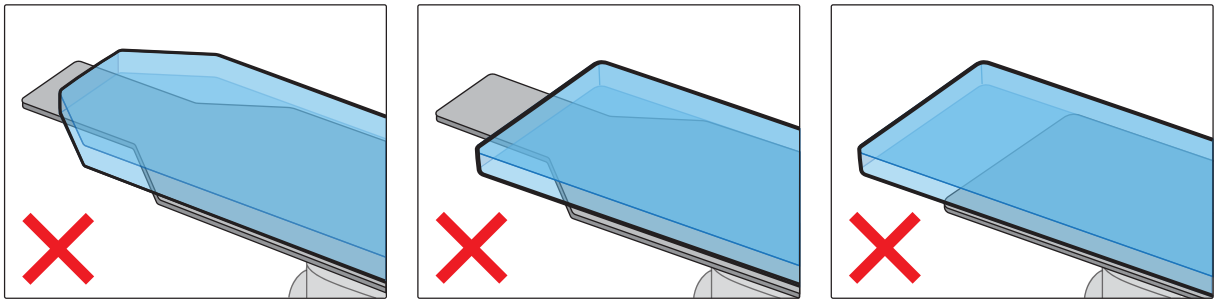

Figure 2 Incorrect mattress positioning: the entire mattress is not supported.

Possibility of Mattress Movement During Patient Transfer
- Communicate clearly with other hospital staff during the transfer process to ensure that everyone is aware of the patient's weight and position.
- Open the air plug of the mattress. Opening the air plug allows the mattress to expand and contract with the weight of the patient.
- Ensure that patient transfer devices are used correctly.
- Move the patient carefully and avoid movements that could cause the mattress to slip.
- If a patient positions themselves on the table, ensure that the patient knows that the mattress is not fixed to the table.

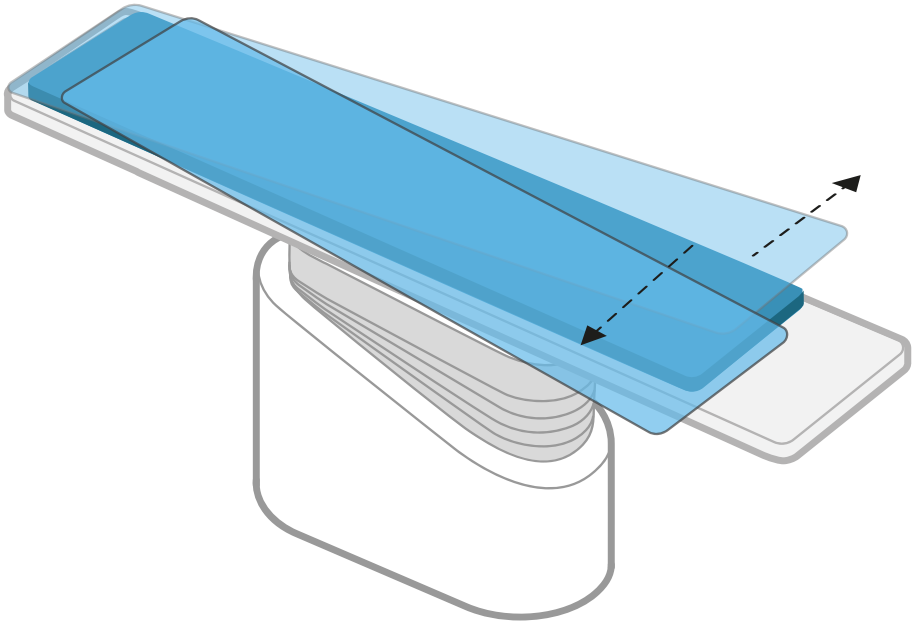

Figure 3 Example of mattress movement during patient transfer or repositioning which could lead to the patient falling

3 Positioning the Table

3.1 Floating the Tabletop

For Allura Xper FD series, AlluraClarity family, UNIQ series, and UNIQ Clarity family systems, this section is in addition to section 3.6.2 of the Basic Operation Instructions for Use.

For Allura Centron systems, this section is in addition to section 3.5.2 of the Basic Operation Instructions for Use.

For Allura CV20 systems, this section is in addition to section 2.5.1 in the Basic Operation Instructions for Use.

For Azurion series systems, this section is in addition to the following sections in the Instructions for Use:
- *Azurion release 1.x: section 5.10.6*
- *Azurion release 2.0: section 5.10.7*
- *Azurion release 2.1: section 5.10.8*
- *Azurion release 2.2: section 6.8.2*
- *Azurion release 3.x: section 6.8.2*

WARNING

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

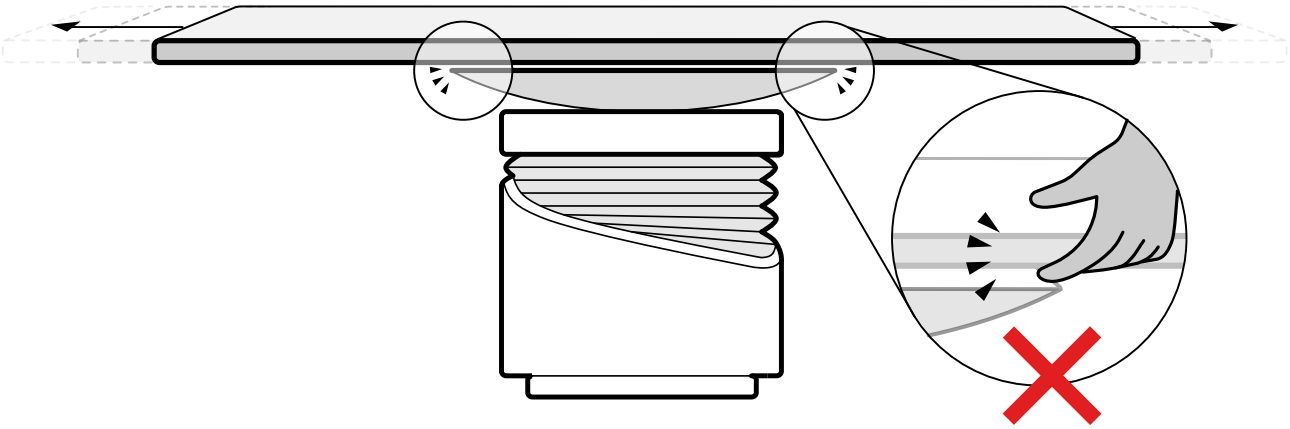

Figure 4 Table float (longitudinal) movement finger entrapment risk areas

3.2 Tilting the Table

For Allura Xper FD series, AlluraClarity family, UNIQ series, and UNIQ Clarity family systems, this section is in addition to section 2.5.1 of the Extended Operation Instructions for Use.

For Azurion series systems, this section is in addition to the following sections in the Instructions for Use:
- *Azurion release 1.x: section 5.10.6*
- *Azurion release 2.0: section 5.10.7*
- *Azurion release 2.1: section 5.10.8*
- *Azurion release 2.2: section 6.8.3*
- *Azurion release 3.x: section 6.8.3*

WARNING

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

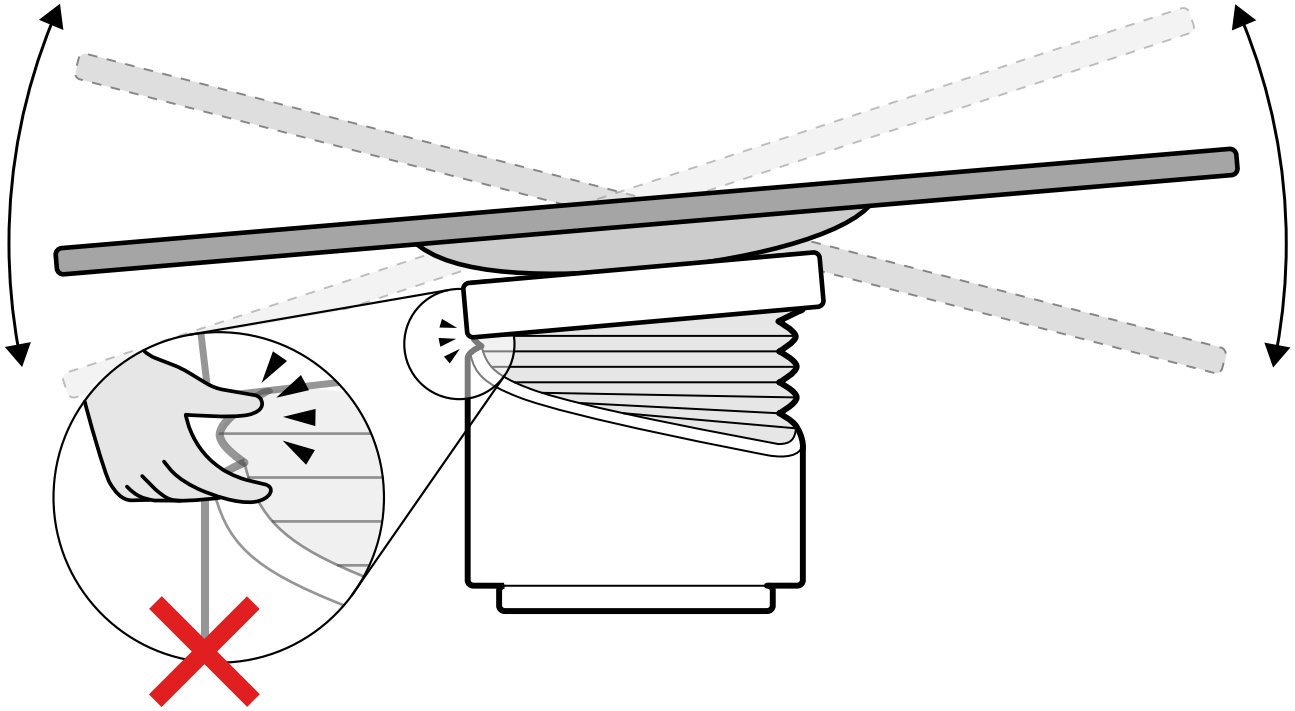

Figure 5 Table tilt movement finger entrapment risk areas

3.3 Cradling the Table

For Allura Xper FD series, AlluraClarity family, UNIQ series, and UNIQ Clarity family systems, this section is in addition to section 2.5.4 of the Extended Operation Instructions for Use.

For Azurion series systems, this section is in addition to the following sections in the Instructions for Use:

- *Azurion release 1.x: section 5.10.6*
- *Azurion release 2.0: section 5.10.7*
- *Azurion release 2.1: section 5.10.8*
- *Azurion release 2.2: section 6.8.4*
- *Azurion release 3.x: section 6.8.4*

WARNING

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.

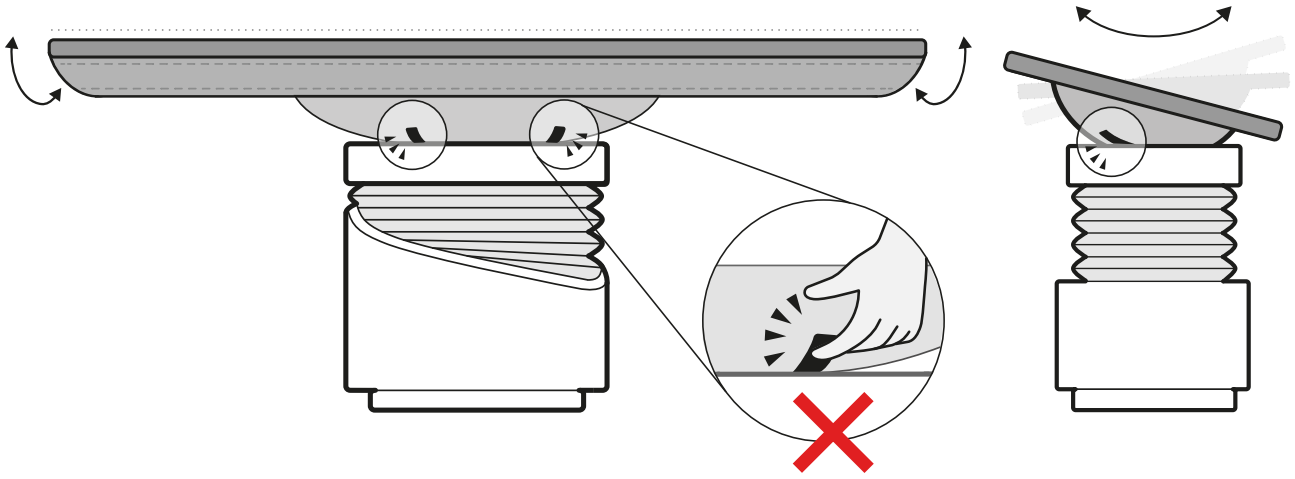

Figure 6 Table cradle movement finger entrapment risk areas

4 Mattress

For Allura Xper FD series and AlluraClarity family release 7.x systems, this section is in addition to section 3.7.6 in the Accessories Instructions for Use.

For Allura Xper FD series and AlluraClarity family release 8.x systems, this section is in addition to section 2.7.5 in the Accessories Instructions for Use.

For UNIQ series and UNIQ Clarity family release 8.x systems, this section is in addition to section 2.7.5 in the Accessories Instructions for Use.

For Allura CV20systems, this section is in addition to section 3.5.4 in the Accessories Instructions for Use.

For Azurion release 1.0 systems, this section replaces section 11.11 in the Instructions for Use.

For Azurion release 1.1 systems, this section replaces section 11.13 in the Instructions for Use.

For Azurion release 1.2 systems, this section replaces section 11.1.11 in the Instructions for Use.

For Azurion release 2.0 systems, this section replaces section 11.1.7 in the Instructions for Use.

For Azurion release 2.1 systems, this section replaces section 11.1.8 in the Instructions for Use.

For Azurion release 2.2 systems, this section replaces section 12.1.8 in the Instructions for Use.

For Azurion release 3.0 systems, this section replaces section 12.1.7 in the Instructions for Use.

For Azurion release 3.1 systems, this section replaces section 12.1.8 in the Instructions for Use.

The mattress provides comfort for the patient and spreads the weight of the patient evenly. There are three types of mattress available:

- Standard
- Cardio
- Neuro

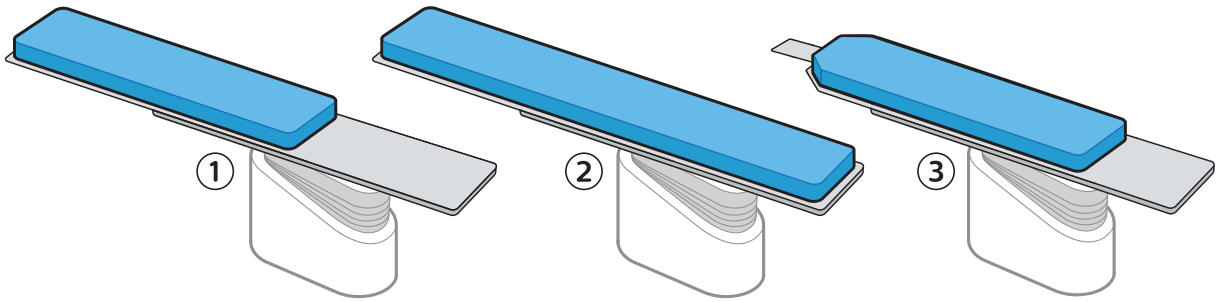

Figure 7 Mattress types

Legend	
1	Standard mattress
2	Cardio (long) mattress
3	Neuro mattress

NOTE
The mattress does not contain latex (natural rubber).

Before positioning the patient on the mattress, open the air plug to allow the mattress to expand and contract properly with the weight of the patient.

Close the air plug while cleaning the mattress. When the mattress is not in use, the air plug can be pushed all the way in to the mattress.

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www.philips.com/healthcare

4523 001 30522 * 2024-12

CE 0344

This medical device conforms with the applicable requirements set out by the European Union, as demonstrated in the Declaration of Conformity.

Manufacturer's address
Philips Medical Systems Nederland B.V.
Veenpluis 6
5684 PC Best
The Netherlands

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Image Guided Therapy

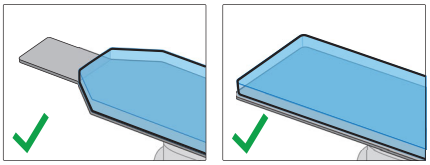
Quick reference card

Patient table risks

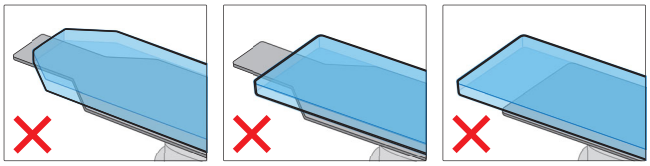
The mattress is not fixed to the tabletop.
This could lead to the patient falling during patient transfer or repositioning.

Mattress position

- Use a mattress that is appropriate for the table.
- When positioning the mattress, ensure that the entire mattress is supported by the tabletop.
- Pay particular attention when working with the neuro tabletop and mattress: Do not position the mattress on the narrow area of the neuro tabletop.



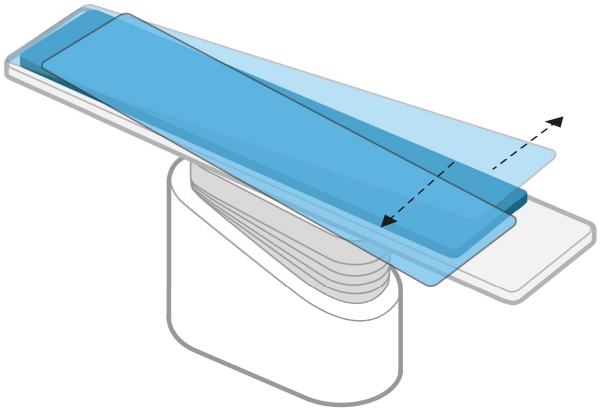
Correct mattress positioning. The entire mattress is supported.



Incorrect mattress positioning. The entire mattress is not supported.

Mattress movement risk during patient transfer

- Communicate clearly with other hospital staff during the transfer process to ensure that everyone is aware of the patient's weight and position.
- Open the air plug of the mattress. Opening the air plug allows the mattress to expand and contract with the weight of the patient.
- Ensure that patient transfer devices are used correctly.
- Move the patient carefully and avoid movements that could cause the mattress to slip.
- If a patient positions themselves on the table, ensure that the patient knows that the mattress is not fixed to the table.



Example of mattress movement during patient transfer or repositioning which could lead to the patient falling

Finger entrapment risk areas

Beware of finger entrapment.
Do not place your fingers on the table bellows during tilting or beneath the tabletop when floating or cradling the tabletop.

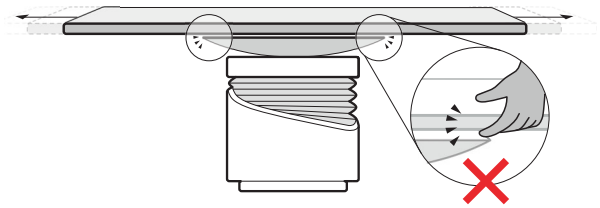


Table float (longitudinal) movement finger entrapment risk areas

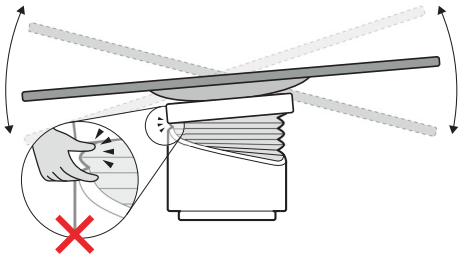


Table tilt movement (option) finger entrapment risk areas

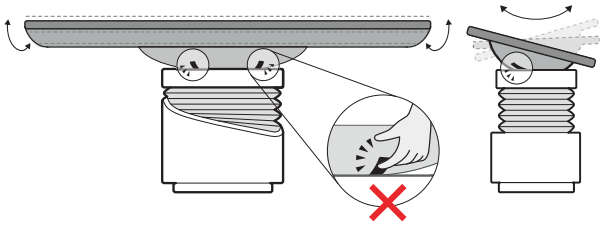


Table cradle movement (option) finger entrapment risk areas

For more information, refer to the Instructions for Use supplied with your product.

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