PHILIPS

# Updated URGENT Field Safety Notice

Allura Xper Allura Centron, and Azurion systems
Potential loss of imaging functionality resulting from no or intermittent X-ray radiation initiation through the wired foot switch
**Philips Reference: 2023-IGT-BST-004**

27-October-2023

RE: Information to customers regarding updated Field Safety Notice

Dear Customer,

With this letter we want to inform you that Philips has updated the Field Safety Notice dated 15-August-2023 (ref. 2023-IGT-BST-004) related to the Potential loss of imaging functionality resulting from no or intermittent X-ray radiation initiation through the wired foot switch of the Philips Allura Xper, Allura Centron, and Azurion systems.

The update is to include a reminder to report to Philips any event related to a foot switch failing to activate. Refer to page 4, section 4: "Should you experience a foot switch failing to activate please report the event to Philips by contacting your local Philips representative identified in the Field Safety Notice. No other content update has been made.

In the Field Safety Notice we are asking for the return of the Response Form (page 5). If you have already sent the Reply Form in response to the first letter that we sent, then there is no need to provide the Return Form again. In case that you have not yet sent the Response Form, please use the response form included in the updated Field Safety Notice.

If you need any further information or support concerning this matter, please contact your local Philips representative identified in the Field Safety Notice.

Sincerely,

Marjan Vos

*Electronically signed by: Marjan Vos*
*Reason: I am signing as approver*
*Date: Oct 27, 2023 13:28 GMT+2*

Marjan Vos
Head of Quality – IGT Systems

PHILIPS

# URGENT Field Safety Notice

Allura Xper, Allura Centron, and Azurion systems
Potential loss of imaging functionality resulting from no or intermittent X-ray radiation initiation through the wired foot switch.

27-October-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 a potential safety issue with the wired foot switch used with the Philips Allura Xper and Azurion systems, where no or only intermittent X-ray radiation is possible.

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

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

The wired foot switch is used to control fluoroscopy, exposure, and other functions, such as single shot, light control, and toggle between X-ray planes (for bi-plane systems).

Philips has identified instances where no or only intermittent X-ray radiation initiation is possible through use of the wired foot switch, as a result of:

- A damaged foot switch cable or cable connector caused by large external force on the cable such as:
  - A stuck cable being pulled along during table pivot/swivel.
  - The cable being caught inadvertently during moving/transferring of equipment.
  - The cable being run over by other medical equipment.

- The strain relief connector[1] not being properly secured during installation/servicing or a broken strain relief connector caused by external forces applied on the foot switch cable. With loss of the strain relief connector, the foot switch cable can become disconnected from the system when force is applied to the cable.
- A damaged foot switch cable caused by the cable getting stuck between the patient table and table cover because the table plinth is not adjusted correctly to prevent a gap between the table cover and floor.
- Supplier manufacturing issues associated with the production of certain components of the foot switch.

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

When no or only intermittent X-ray radiation initiation is possible, loss of imaging functionality can occur which may result in delayed diagnosis or interruption of procedure.

The segment of the population most at risk are patients undergoing complex/high risk, and/or urgent interventions for potentially life-threatening conditions (e.g., acute ischemic stroke, ST-segment elevation myocardial ischemia). In an extremely remote situation where all clinical factors that may mitigate the risk are unavailable (e.g. using the wired foot switch in the control room, transfer of patient to another room) or insufficient (e.g. using the exposure hand switch, continued monitoring of the patient, and guided restoration and maintenance of tissue oxygen delivery, medication administration), a delay of therapy in the population requiring urgent interventions may contribute to further deterioration of their already critical condition that may potentially lead to death (i.e., critical, and catastrophic delay effects).

The probability that use of the product causes or contributes to health consequences is estimated to be remote. As of the date of this letter, one event has been reported to Philips alleging that loss of imaging functionality caused or contributed to a patient's injury. Philips estimates that 0,008% of footswitches may experience an issue leading to no or only intermittent X-ray radiation when the footswitch is activated by the user.[2]

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

**Intended use.**
See Appendix A for detailed information on the intended use of the Allura Xper, Allura Centron, and Azurion systems.

The wired foot switch is a user input device with different foot pedals to:

- initiate X-ray radiation (fluoroscopy, series exposure or single shot); and
- control other functions like examination room light, or, in case of a bi-plane system, toggle between frontal and lateral X-ray planes.

[1] The strain relief connector is a plastic tie that holds the foot switch cable to take strain off the connection between the foot switch wire and the Allura or Azurion system.

[2] Estimate based on complaint data collected from September 2020 to May 2023 and number of procedures per device.

**Identification of affected systems.**
Appendix B to this letter provides a table with the references/types and model descriptions of the affected wired foot switches.

The reference/type of the wired foot switch can be found on the label located on the bottom of the wired foot switch, as shown in Figure 1.

Figure 1.

Top view


Bottom view

Label identification

**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 to all users so that they are aware of the issue and follow the instructions below.

- While awaiting inspection of the foot switch by a Philips Service Engineer:

  - **Avoid** high pull force on the foot switch cable, especially during swivel table movement to prevent cable and/or connector damages.
  - **Avoid** the foot switch cable becoming stuck between the table cover and floor.
  - **Do not remove** the strain relief connector.

- Follow the instructions provided in the Instructions for Use (IFU) Addendum attached to this letter for handling the foot switch, including:

  - Avoid driving over the foot switch cable with other devices or equipment.
  - Perform daily verification tests before using the system to:
    - inspect the foot switch and the foot switch cable for damage, such as tears, cuts, or abrasions,
    - inspect proper connection of the foot switch to the system,
    - test all pedals on all connected foot switches for proper functioning.

    If any damage is found or if any step fails, do not use the system, and contact technical support immediately.

  - In case of failure of the foot switch to initiate X-ray, continue with image acquisition using an alternative X-Ray activation switch, such as foot switch or hand switch (for exposure) in the control room.

- If you do not use Philips to perform the preventative maintenance on your system, provide a copy of the Preventative Maintenance Manual updates attached in Appendix C to this letter to your qualified and authorized service provider.

- Keep this Field Safety Notice, the IFU Addendum and Preventative Maintenance Manual updates with the documentation of the system.

- Should you experience a foot switch failing to activate, please report the event to Philips by contacting your local Philips representative. <Philips representative contact details to be completed by the Market/Business>

- Please complete and return the attached response form 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.

**5. Actions planned by Philips IGT Systems (NL-MF-000001489) to correct the problem**

Philips has updated the Repair Instructions to ensure that the patient table and table cover is correctly adjusted to prevent a gap between the table cover and floor. Philips has also updated its Preventative Maintenance Manual to include additional activities to help ensure the proper operation of the foot switch.

Philips will be inspecting all affected systems to check the foot switch cable, to ensure that the table plinth is adjusted correctly, and to ensure that the strain relief connector is properly secured.

Philips will contact you to schedule a visit to perform this inspection (reference FCO72200534).

If you need additional information or support concerning this issue, please contact your local Philips representative. *<Philips representative contact details to be completed by the Market/Business>*

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.

Sincerely,

Marjan Vos

*Electronically signed by: Marjan Vos*
*Reason: I am signing as approver*
*Date: Oct 27, 2023 13:28 GMT+2*

Marjan Vos
Head of Quality – IGT Systems

PHILIPS

# URGENT Field Safety Notice Response Form

**Reference: 2023-IGT-BST-004:** Allura Xper, Allura Centron, and Azurion Systems.
Potential loss of imaging functionality resulting from no or intermittent X-ray radiation initiation through the wired foot switch.

**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 issue, 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 provided in the Instructions for Use with regards to daily verification tests.
- While awaiting inspection of the foot switch by a Philips Engineer:
  - **Avoid** high pull force on the foot switch cable, especially during swivel table movement to prevent cable and/or connector damages.
  - **Avoid** the foot switch cable becoming stuck between the table cover and floor.
  - **Do not remove** the strain relief connector.
- If you do not use Philips to perform the preventative maintenance on your system Provide a copy of the preventative maintenance manual to your qualified and authorized service provider.
- Keep this Field Safety Notice and the Foot Switch Instructions for Use Addendum and the Preventive Maintenance Manual updates with the documentation of the system.
- Should you experience a foot switch failing to activate, please report the event to Philips by contacting your local Philips representative. <Philips representative contact details to be completed by the Market/Business>

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 Field Safety Corrective Action.

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

PHILIPS

## *APPENDIX A*

**Intended use.**

The **Allura Xper and Allura Centron** 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, 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.

The **Azurion series** (within the limits of the operation room table) are 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 several features to support a flexible and patient-centric procedural workflow.

PHILIPS

## *APPENDIX B*

**Product information to identify an affected foot switch.**

*Wired Foot switch*

| 12 NC | Description |
|---|---|
| 452270000141 | Footswitch CV 3p 4m |
| 452270000142 | Footswitch CV 3p 4m |
| 452270000143 | Footswitch CV 3p 4m |
| 452270000144 | Footswitch CV 3p 4m |
| 452270000381 | Footswitch CV 3p 8m |
| 452270000382 | Footswitch CV 3p 8m |
| 452270000383 | Footswitch CV 3p 8m |
| 452270000384 | Footswitch CV 3p 8m |
| 459800076001 | Biplane Footswitch (4p+2) 4m |
| 459800076002 | Biplane Footswitch (4p+2) 4m |
| 459800076003 | Biplane Footswitch (4p+2) 4m |
| 459800076004 | Biplane Footswitch (4p+2) 4m |
| 459800076021 | Biplane Footswitch (4p+2) 8m |
| 459800076022 | Biplane Footswitch (4p+2) 8m |
| 459800076023 | Biplane Footswitch (4p+2) 8m |
| 459800076024 | Biplane Footswitch (4p+2) 8m |
| 459800772191 | Footswitch CV 3p 4m |
| 459800772192 | Footswitch CV 3p 4m |
| 459800772193 | Footswitch CV 3p 4m |
| 459800772194 | Footswitch CV 3p 4m |
| 459800772201 | Footswitch CV 3p 8m |
| 459800772202 | Footswitch CV 3p 8m |
| 459800772203 | Footswitch CV 3p 8m |
| 459800772204 | Footswitch CV 3p 8m |
| 459800772211 | Biplane Footswitch (4p+2) 4m |
| 459800772212 | Biplane Footswitch (4p+2) 4m |
| 459800772213 | Biplane Footswitch (4p+2) 4m |
| 459800772214 | Biplane Footswitch (4p+2) 4m |
| 459800772221 | Biplane Footswitch (4p+2) 8m |
| 459800772222 | Biplane Footswitch (4p+2) 8m |
| 459800772223 | Biplane Footswitch (4p+2) 8m |
| 459800772224 | Biplane Footswitch (4p+2) 8m |

PHILIPS

***APPENDIX C***

## Preventive Maintenance updates for Foot Switch.

### Foot switch

Frequency: Checks to occur at 12-month intervals.

**Chapter Operator controls**

**Wired and wireless Foot switch**

Examine the Foot switch on damage, for example:

- Cable connections
- Cables
- Shielding

Examine the Foot switch on broken or loose parts, for example:

- Inside housing by shaking the foot switch
- Pick-up bar

In case of severe damage or loose parts, replace the foot switch according to the repair instructions. Do not open the foot switch for repair or inspection.

**Examine the strain relief of the wired foot switch connector**

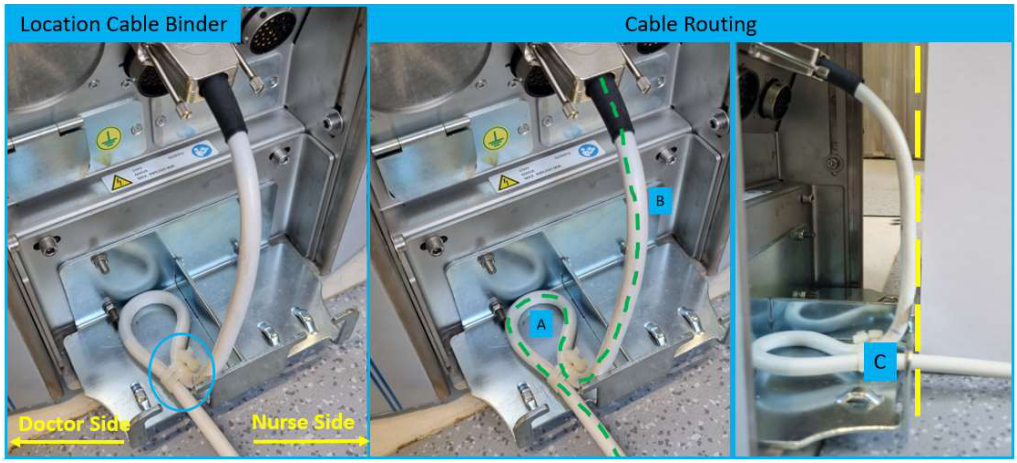
Examine if a cable binder type with the following properties is being used:

| Property | Value |
|---|---|
| Minimal width | 4.6mm |
| Minimal thickness | 1.2mm |
| Material | Polyamide (Nylon) / Non metallic |

Check the strain relief and routing of the wired foot switch cable:

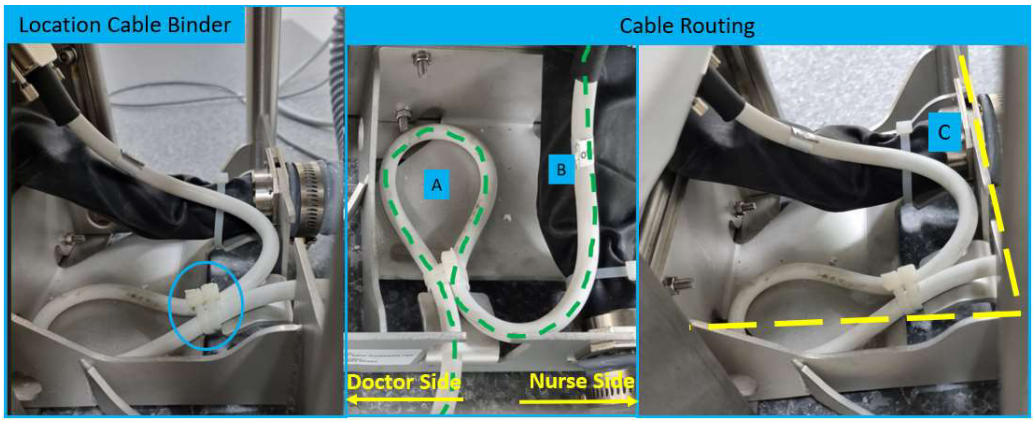
- Cable binder used for strain relief:
  - Type of cable binder(s)
  - Number of cable binder(s)
  - Position of cable binder(s)
- Cable routing (depending on picture indicated with “A” “B” “C”)
- For AD7NT, there are 2 possibilities for strain relief:
  - Strain relief by means of bushing (Figure 4a)
  - Strain relief by cable binder (Figure 4b)
- For correct routing and strain relief, see Figures 1-6 below.

**Figure 1: AD7XT and AD7XNT Patient Table**



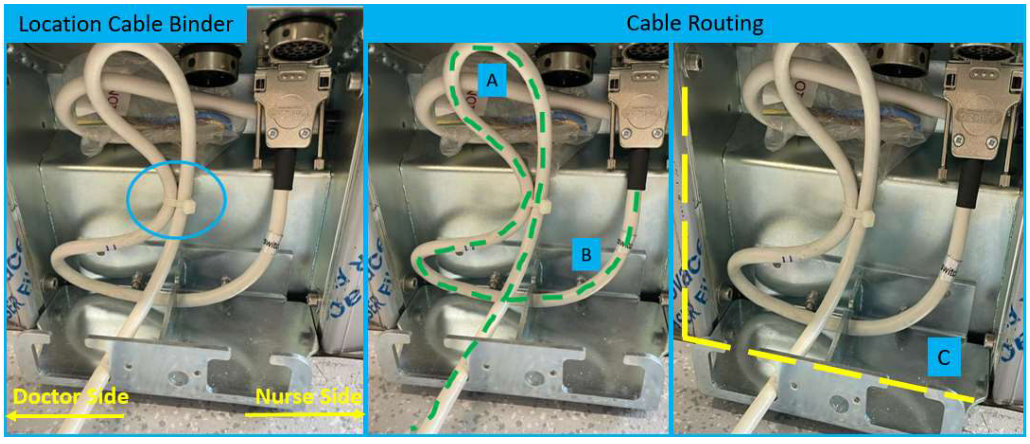

Number of cable binder(s): 2 (two)

**Figure 2: AD7XT and AD7XNT Auxiliary OP Rail Patient Table Strain Relief**




Number of cable binder(s): 2 (two)

**Figure 3: AD7 Patient Table**




Number of cable binder(s): 1 (one)

**Figure 4a: AD7NT Patient Table with bushing strain relief**

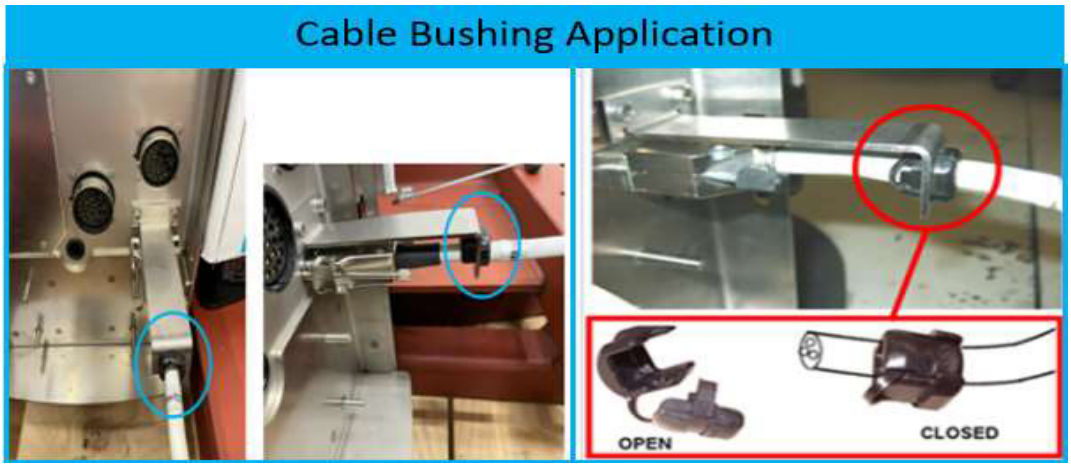
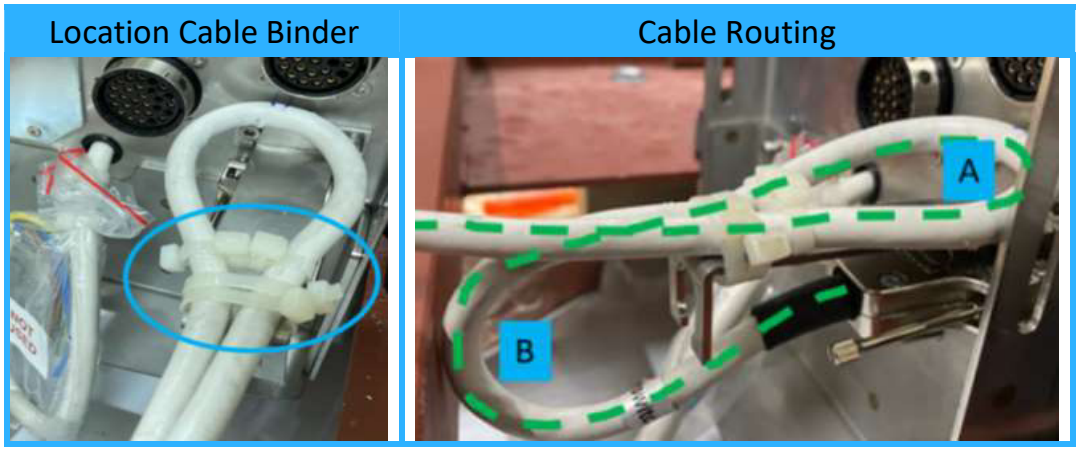
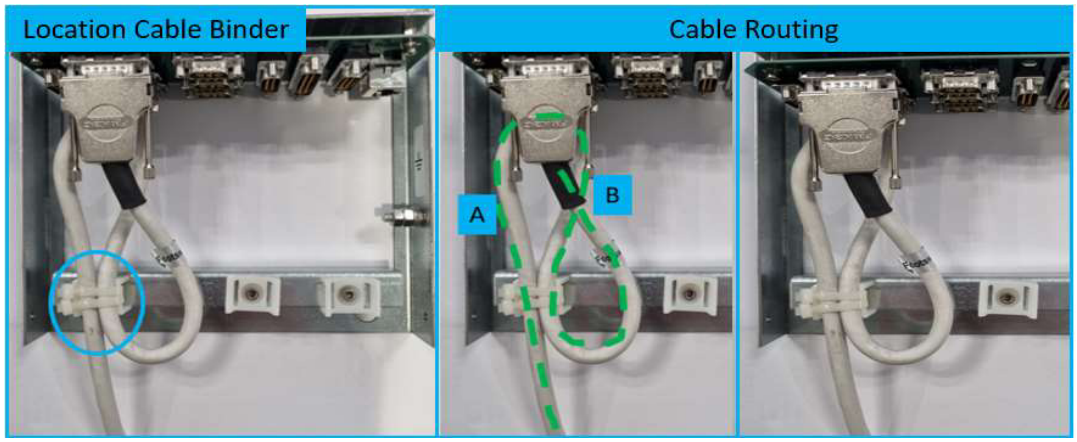



**Figure 4b: AD7NT Patient Table with cable tie strain relief**



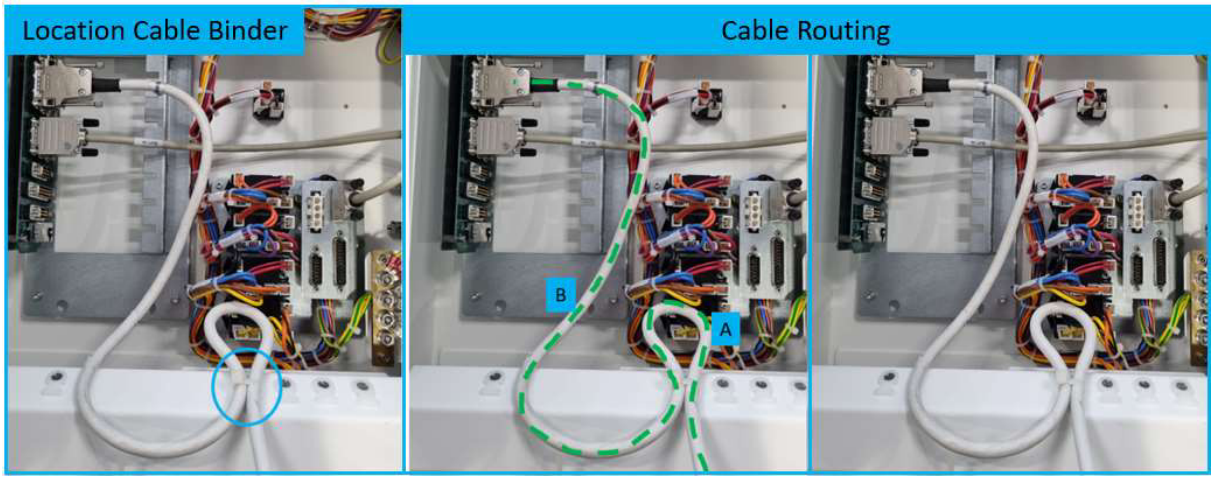

Number of cable binder(s): 5 (five)

**Figure 5: Pedestal Wall Connection Box**




Number of cable binder(s): 2 (two)

**Figure 6: Surgery Wall Connection Box**




Number of cable binder(s): 1 (one)

If strain relief or routing is not correct, repair according to the repair instructions.

## AD7X Plinth Cover

**AD7NT, AD7X(N)T patient support**

**Plinth cover**

Check the clearance of the plinth cover:

- For a non-swivel table
  - Make sure that the clearance to the fluid protection plate is 3-4 mm
  - Refer to Figure 7
- For a swivel table
  - Make sure that the clearance to the swivel cover is 3-4 mm
  - Refer to Figure 8

**Figure 7: Non-swivel table (AD7NT, AD7XT and AD7XNT)**

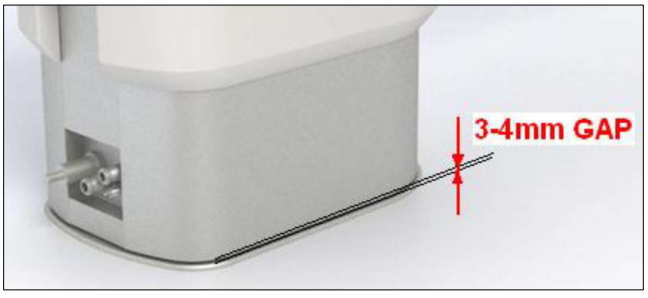



**Figure 8: Swivel table (AD7NT, AD7XT and AD7XNT)**


If the gap between the plinth covers and the floor does not satisfy the above requirement, adjust the plinth cover according to the repair instructions.