5.4.1 Adjusting the AltaTrack Guidewire Shape Tip

This optional step is part of the **Shape Registration** task. Follow this procedure if the tip of the AltaTrack Guidewire shape does not match the position of the guidewire's tip in both of the X-ray images in the reference viewports.

1 Display the **Verify Guidewire Tip** functions by clicking **Next Step** in the task panel of the **Guidewire Registration** step of the **Shape Registration** task.

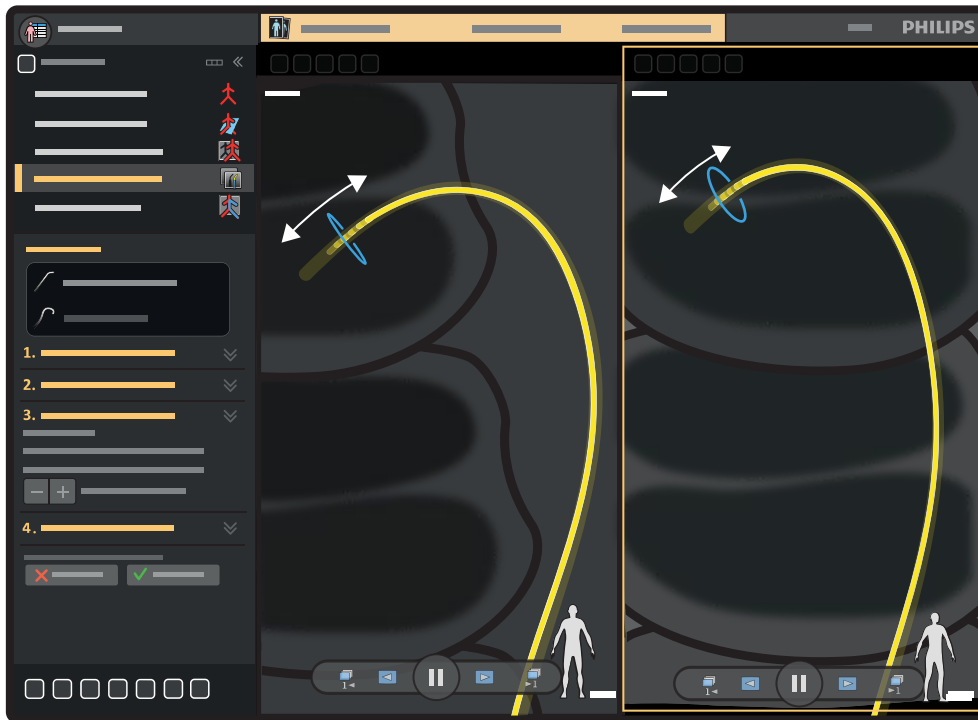**2** Use the plus and minus buttons in the task panel to increase or decrease the shape tip length.

Figure 45 Adjusting the AltaTrack Guidewire shape tip length

NOTE
It is not necessary to select a registration viewport; when you adjust the length of the tip, the adjustment is applied to both viewports simultaneously.

The goal of this step is to adjust the tip of the AltaTrack Guidewire shape for the following conditions:
- Any difference in position is minimal (approximately 2mm (0.1 in)).
- Any difference in position is of a similar magnitude in each reference image, even if one tip is shorter and the other is longer.
- There is no warning displayed about the registration result.

3 If the position of the AltaTrack Guidewire shape is satisfactory, select **Accept** in the task panel.

4 If a FORS-guided catheter is detected and should be registered, the following actions are available:
- Select **Next Step** in the task panel to display the **Catheter Registration** task panel. For more information, see Performing FORS-Guided Catheter Length Registration with the AltaTrack Guidewire in Shape Registration (page 64).
- If you prefer to perform the catheter length registration in the **Live Guidance** task, select **Accept** in the task panel.

After accepting the registration, the LumiGuide Viewing Software automatically moves to the next task: **Live Guidance**. For more information on performing shape registration in the **Live Guidance** task, see Performing or Adjusting AltaTrack Guidewire and FORS-Guided Catheter Registration in Live Guidance (page 73).

5.4.2 Performing FORS-Guided Catheter Length Registration with the AltaTrack Guidewire in Shape Registration

This procedure describes the steps to register the length of an endovascular catheter. The procedure can be performed directly after completing AltaTrack Guidewire shape registration.

This is an optional task, as catheter length registration can also be performed in the **Live Guidance** task. For more information, see Registering a New Catheter Length or Changing an Existing Catheter Length Registration (page 76).

To register an endovascular catheter, it must be connected to the AltaTrack 3D Hub otherwise the LumiGuide Equipment cannot detect the catheter. See the Instructions for Use of the AltaTrack 3D Hub on how to connect the AltaTrack 3D Hub to the catheter.

⚠️ **WARNING**
While unpacking single-use devices, pay close attention to sterility information labels on the packaging to avoid compromising the sterile field.

⚠️ **WARNING**
For optimal registration, observe the following guidelines:
- *Ensure that the AltaTrack Guidewire tip extends beyond the tip of the FORS-guided catheter.*
- *Ensure that the tips of the devices are approximately in the center of the field of view of the X-ray image.*
- *Ensure that the AltaTrack Guidewire registration is done correctly before starting FORS-guided catheter registration.*
- *Ensure that the correct catheter type, length, and size is selected.*

1 Do one of the following in the **Catheter Registration** step task panel:
   - Select the catheter in the drop-down list.
   - Alternatively, add a new catheter by entering its name.
   - Alternatively, to continue without a catheter or to register a catheter later, select **None** in the drop-down list.

Figure 46   Selecting a catheter in the task panel

2 Check whether the represented catheter length matches the X-ray image and adjust the length of the catheter when necessary using the plus and minus buttons in the task panel.

3 To show or hide the guidewire visualization, use the **Show Guidewire** button in the task panel.

4 To switch on the auto-fade function, select **Auto Fade** in the task panel.

5   To automatically zoom to the expected catheter tip, click **Recenter**.

6   When the registration is correct, select **Accept**.

6 Navigating with the LumiGuide Equipment

After registration, the **Live Guidance** task allows you to overlay the 3D volume, if used, and the AltaTrack Guidewire and FORS-guided catheter shapes on X-ray images in the main view to determine the position of interventional devices during the procedure. During live guidance, longitudinal and lateral table movements are supported, but tilt, cradle, pivot, and swivel movements are not supported.

You can perform **Live Guidance** at the tableside using the touch screen module of the X-ray system. **Live Guidance** functions are also available using the LumiGuide Viewing Software in the control room.
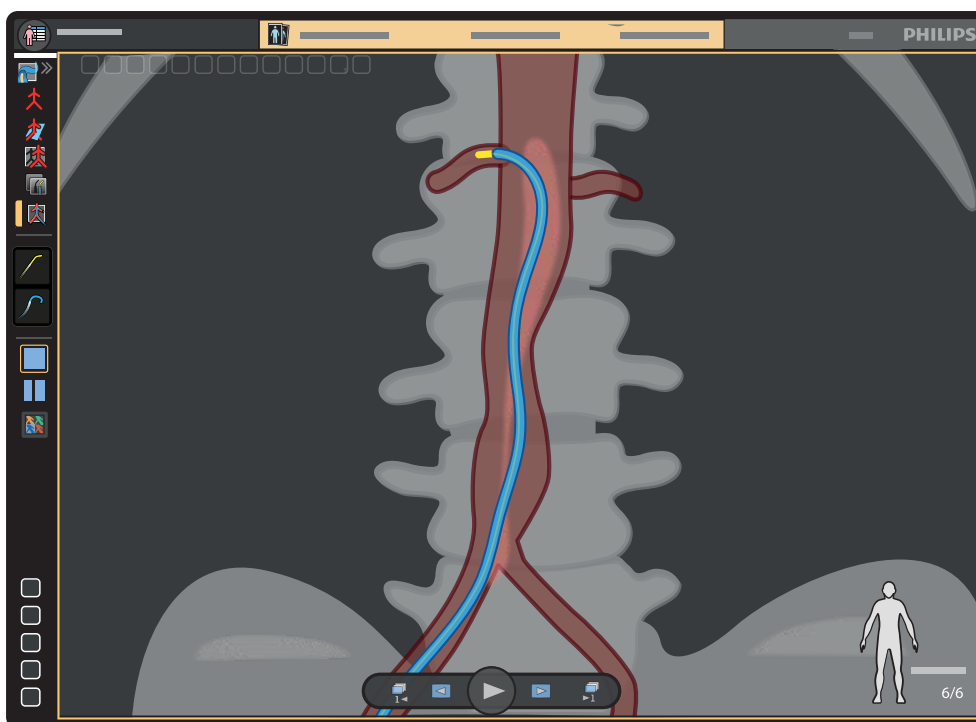

Figure 47   AltaTrack Guidewire and FORS-guided catheter navigation in the **Live Guidance** task

NOTE
Automatic replay of fluoroscopy series can be turned on or off in the Live Guidance task, according to your preferences. For details, see Setting User Preferences (page 99).

Secondary views are also available, displaying a 3D roadmap with either an X-ray image and 3D volume or just a 3D volume.
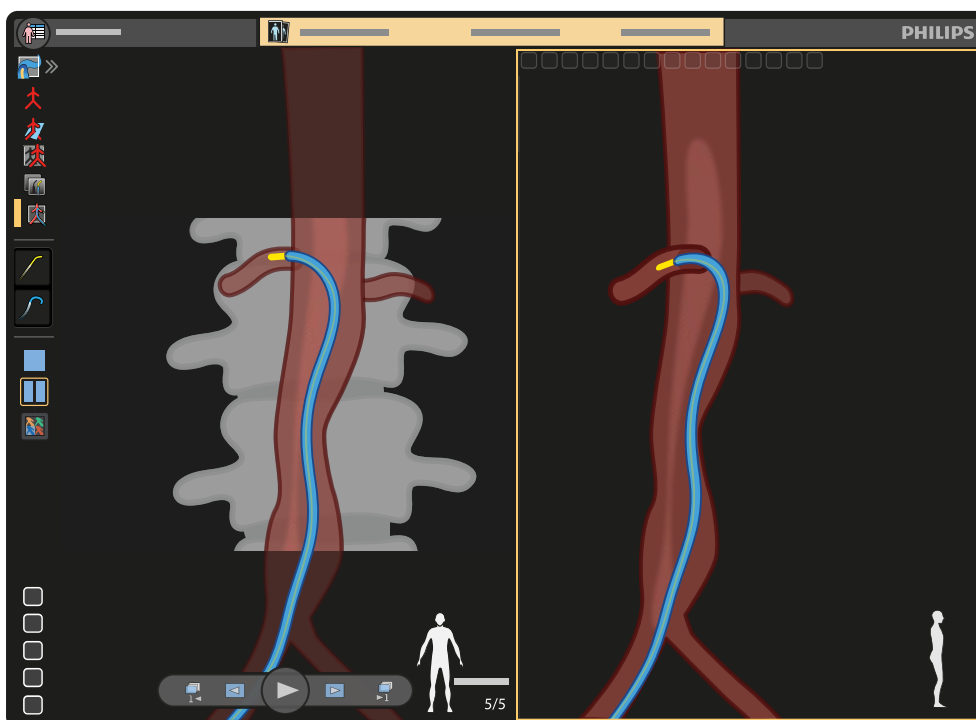
Figure 48   AltaTrack Guidewire and FORS-guided catheter navigation with 3D roadmap in the **Live Guidance** task
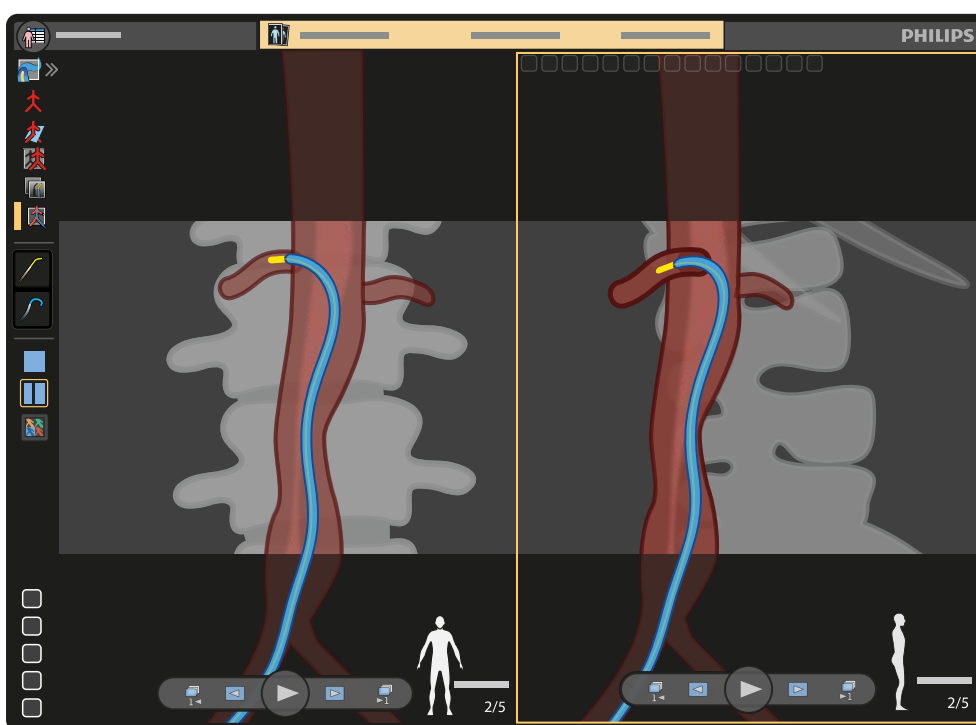

Figure 49   AltaTrack Guidewire and FORS-guided catheter navigation with 2D roadmap in the **Live Guidance** task

The size of the LumiGuide shape as displayed in the primary view is enhanced to improve visibility. The tip of the AltaTrack Guidewire and, if applicable, the FORS-guided catheter is displayed in white when facing the user to indicate the direction of the guidewire (and catheter).

If the LumiGuide Equipment detects a degradation in the quality of the AltaTrack Guidewire shape, a warning message is displayed in the LumiGuide Viewing Software.
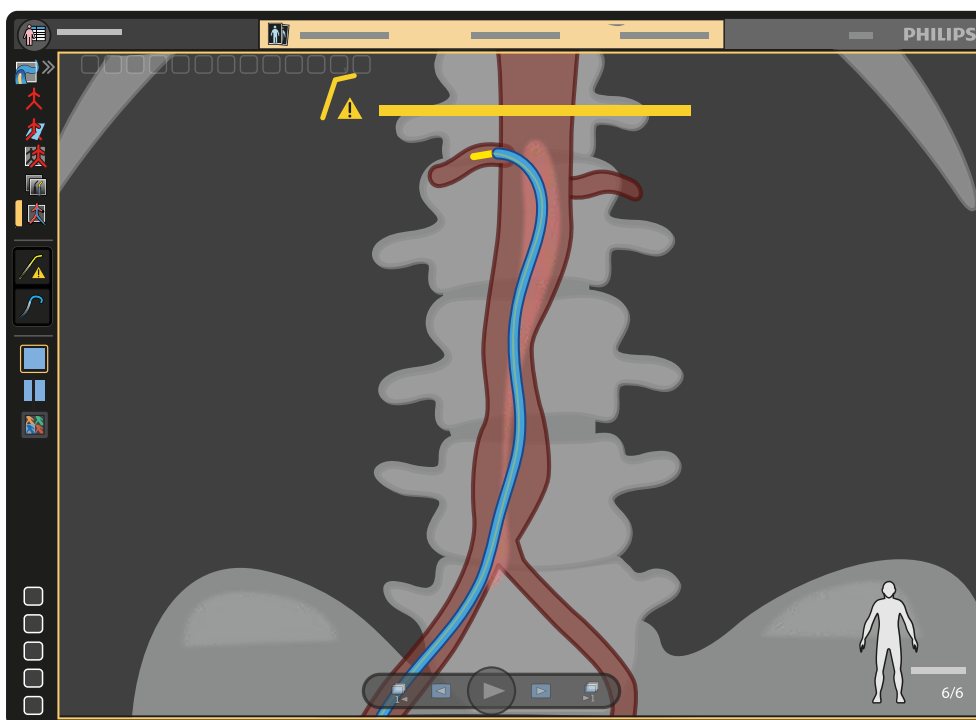
Figure 50 AltaTrack Guidewire shape warning in the **Live Guidance** task

If the quality of the AltaTrack Guidewire shape degrades and the shape cannot be reliably reconstructed, a dashed, blinking centerline is displayed over the shape and a warning symbol is displayed at the tip of the shape.
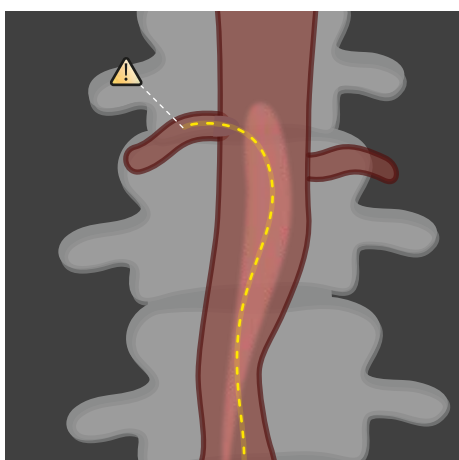

Figure 51 Degraded AltaTrack Guidewire shape

If the quality of AltaTrack Guidewire shape degrades close to the distal part of the AltaTrack Guidewire (for example, due to a sharp bend on the AltaTrack Guidewire tip), the AltaTrack Guidewire shape (and the FORS-guided catheter shape, if applicable) is displayed in full color up to the point where the degradation of the shape reconstruction is present. Beyond that point, the AltaTrack Guidewire (and the FORS-guided catheter shape, if applicable) is displayed with a dashed centerline and a warning symbol is displayed at the tip of the shape.
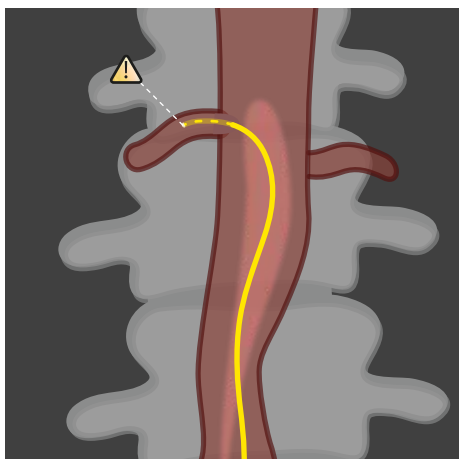
Figure 52   Degraded AltaTrack Guidewire shape at the tip

For examples of affected shape reconstructions on the FORS-guided catheter, see Navigating with FORS-Guided Catheters (page 71).

NOTE
In this case, the shape of the AltaTrack Guidewire cannot be reconstructed reliably and the LumiGuide Viewing Software displays guidance on how to attempt to resolve the issue.

NOTE
If visualization of the AltaTrack Guidewire is compromised, FORS-guided catheter visualization is also affected.

NOTE
The accuracy of the shape displayed may be compromised if there is a very tight bend at any point along the AltaTrack Guidewire.

WARNING
The accuracy of the shape displayed cannot be fully guaranteed continuously during use. Use frequent X-ray and tactile feedback from the AltaTrack Guidewire and catheter during the procedure to ensure that device registration and visualization is maintained.

WARNING
To avoid injury to the patient, do not pull strongly on the AltaTrack Guidewire while it is in use and avoid putting excessive strain on the torque-absorbing section.

CAUTION
Only the AltaTrack Guidewire is tracked with FORS technology. The endovascular catheter, when combined with the AltaTrack 3D Hub, is only correctly visualized when the tip of the AltaTrack Guidewire extends beyond the tip of the catheter. When the tip of the AltaTrack Guidewire is retracted, the part of the FORS-guided catheter visualization beyond the AltaTrack Guidewire tip is only indicative. If the AltaTrack Guidewire is retracted too far, the visualization of the catheter is removed completely.

NOTE
Check the position of the catheter with X-ray when the AltaTrack 3D Hub is removed from the catheter or when using a conventional guidewire.

CAUTION
After selecting a previously used catheter, check the registration of the catheter with X-ray. Ensure that the AltaTrack Guidewire is beyond the catheter's tip so that the catheter's shape is fully visible.

CAUTION
If any of the following events occur during the procedure, you must perform AltaTrack Guidewire registration again:
- *The LumiGuide Docking Base is moved along the table rail.*
- *An AltaTrack Guidewire is connected or disconnected.*
- *The patient moves during the procedure.*
- *Any part of the LumiGuide Equipment collides with the stand, table, or personnel in the interventional catheterization lab or operating room.*

⚠️ **CAUTION**
If an endovascular catheter is exchanged and the new one has not been registered yet, you must perform catheter length registration of the new endovascular catheter.

NOTE
In any of the following situations, you should revert to using images from the X-ray system:
- ***The CT volume (if applicable) does not follow the geometry***
- ***APC is unavailable***
- ***Live Guidance does not receive X-ray images***

6.1 Performing Live Guidance

1 Check that the LumiGuide Equipment is operational, the devices are connected, and shapes are acquired.

2 Acquire an X-ray image to start navigation.

The interventional catheterization lab or operating room monitor displays live 3D FORS shapes of the connected devices overlaid on the preoperative CT volume (if applicable) and the X-ray image.

3 Navigate the AltaTrack Guidewire toward the target anatomy, manipulating the AltaTrack Guidewire as a regular angiographic device.

Handle the AltaTrack Guidewire carefully to avoid impacting the performance of the LumiGuide Equipment.

⚠️ **WARNING**
The length of an AltaTrack Guidewire is limited. Be aware of the torque-absorbing section of the AltaTrack Guidewire. Do not pull on this section as this may pull the AltaTrack Guidewire from the patient with strong force and cause an injury to the patient.

During the **Live Guidance** task, you can perform several functions at tableside using the mouse or the touch screen module of the X-ray system:
- Correct the registration of the AltaTrack Guidewire: see Aligning the Shape of the AltaTrack Guidewire (page 73).
- Register new catheters or recall the registration of previously used catheters: see Registering a New Catheter Length or Changing an Existing Catheter Length Registration (page 76) and Selecting a Previously Registered Catheter (page 80).
- Adjust the visualization in each viewport (zoom, pan, and rotate): see Viewing Tools (page 101).
- Correct the volume registration: see Correcting Volume Registration (page 70) and Viewing Tools (page 101).
- Select a layout: see Main Display Area (page 99).
  - To change layouts using the touch screen module at the tableside, tap **Layout** repeatedly to cycle through the viewport options (**Single View**, **Dual View 1**, and **Dual View 2**) and select a layout.
- Storing series, snapshots, and movies: see Common Tools Panel (page 106), Snapshots and Movies (page 107), and Storing and Reviewing Series (page 109).
- Lock/unlock the viewing angle to/from the orientation of the C-arm: see Setting User Preferences (page 99).
- Recall planned angles.

NOTE
If the touch screen module or the tableside mouse of the X-ray system is not functioning, you can continue this task using the LumiGuide WorkSpot in the control room.

6.2 Correcting Volume Registration

During the **Live Guidance** task, small corrections to the volume registration may be required to realign the volume, for example if the patient moves.

1   Click **Correct Alignment** in the toolbar of the main viewport to turn correction mode on.

2   Use a combination of the following actions to realign the volume with the anatomy:

- Move the pointer over the volume and drag to change its position.
- Move the pointer outside the boundary of the volume and drag to rotate the volume in the viewing plane.

3   When the volume is realigned, click **Correct Alignment** again to turn correction mode off.

NOTE
You can also start correction mode using the Modify Alignment function on the touch screen module of the X-ray system. Then tap the Movement function to select Translate or Rotate In-plane. Use the arrow buttons to make corrections.
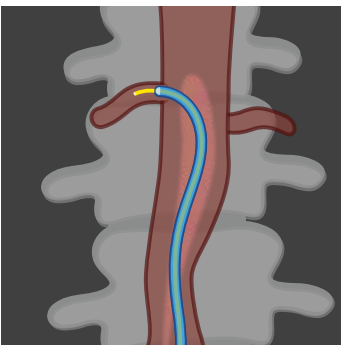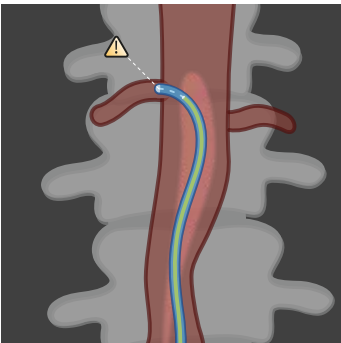
6.3 Navigating with FORS-Guided Catheters

CAUTION
Only the AltaTrack Guidewire is tracked with FORS technology. The endovascular catheter, when combined with the AltaTrack 3D Hub, is only correctly visualized when the tip of the AltaTrack Guidewire extends beyond the tip of the catheter. When the tip of the AltaTrack Guidewire is retracted, the part of the FORS-guided catheter visualization beyond the AltaTrack Guidewire tip is only indicative. If the AltaTrack Guidewire is retracted too far, the visualization of the catheter is removed completely.

NOTE
Check the position of the catheter with X-ray when the AltaTrack 3D Hub is removed from the catheter or when using a conventional guidewire.

FORS-guided catheter visualization is enabled when using a conventional catheter connected to an AltaTrack 3D Hub and combined with the AltaTrack Guidewire.

Visualization	Description
	FORS-guided catheter correctly visualized with the tip of the AltaTrack Guidewire extended beyond the tip of the catheter.
	When the AltaTrack Guidewire is retracted inside the catheter's tip, the catheter's shape is only indicative.

Visualization	Description
	The nearer the AltaTrack Guidewire comes to being retracted inside the catheter by 7.5 cm (as indicated by the circle around the catheter visualization), the more transparent the catheter shape becomes.
	When the AltaTrack Guidewire is retracted inside the catheter's tip by more than 7.5 cm, the FORS-guided catheter shape is not visible anymore.
	The AltaTrack Guidewire and FORS-guided catheter can be visualized reliably up to the point where the degradation of the shape reconstruction is applied.
	The AltaTrack Guidewire is visualized reliably up to the point where the degradation of the shape reconstruction is applied. The shape of FORS-guided catheter is extrapolated as the AltaTrack Guidewire is not extended beyond the tip of the catheter.
	The AltaTrack Guidewire and FORS-guided catheter cannot be visualized reliably due to degradation of the AltaTrack Guidewire reconstruction.

6.4   Performing or Adjusting AltaTrack Guidewire and FORS-Guided Catheter Registration in Live Guidance

During **Live Guidance**, you can perform the following actions:
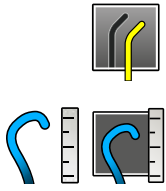
- **Align Shape**: this function allows you to adjust the registration of the AltaTrack Guidewire by acquiring an X-ray series and performing automatic registration. For more information, see Aligning the Shape of the AltaTrack Guidewire (page 73).

- **Register or Adjust**: this function allows you to register a new catheter length or change an existing catheter length registration (using tip-to-tip or X-ray-based registration). For example, this function is useful when you need to visualize a different catheter with the AltaTrack Guidewire and you need to register its length without registering the AltaTrack Guidewire again. For more information, see Registering a New Catheter Length or Changing an Existing Catheter Length Registration (page 76).

- **Latest Catheters**: this function allows you to select a previously registered catheter. For more information, see Selecting a Previously Registered Catheter (page 80).

NOTE
You can perform catheter length registration out-of-body (on-body, tip-to-tip registration) or in-body (X-ray-based registration) close to the target anatomy. For more information, see Registering a New Catheter Length or Changing an Existing Catheter Length Registration (page 76).

6.4.1   Aligning the Shape of the AltaTrack Guidewire

If the shape of the AltaTrack Guidewire does not match the X-ray image, you can use automatic registration with the last-acquired X-ray image to correct the registration.

NOTE
When aligning the shape on a single image, the depth may not be accurate. Use two views with shape registration if the result is not satisfactory.

1   Click the AltaTrack Guidewire icon in the task panel and then click **Re-register Shape**.
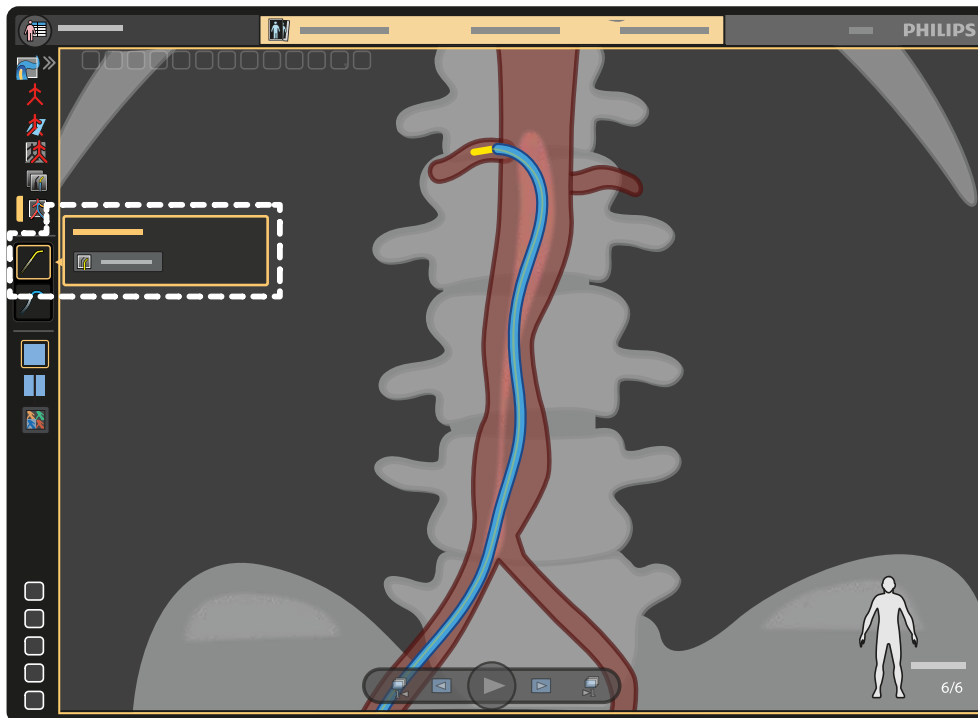

Figure 53   Modifying AltaTrack Guidewire registration

2   Follow the guidance in the pop-up panel to perform automatic registration.
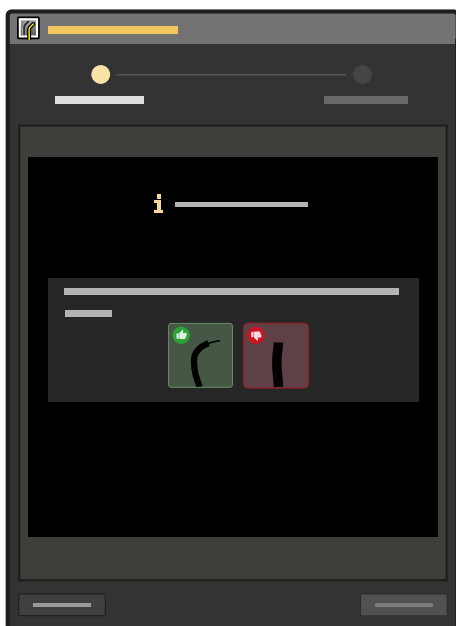

Figure 54   Guidance for performing automatic registration

Automatic registration uses the last-acquired X-ray series. If the last-acquired series is not older than one minute, do the following:

a   Ensure that the AltaTrack Guidewire is advanced beyond the catheter's tip and has enough curvature.

b   Acquire a new X-ray series.

3   Check the overlay of the AltaTrack Guidewire on the X-ray image in the pop-up panel.

4   If the registration of the AltaTrack Guidewire with the X-ray image is correct, click **Accept** to complete the automatic registration task.

Alternatively, if the shape registration is not correct, click **Adjust** in the pop-up panel and do the following:

a   Click **Place or Adjust Points** in the pop-up panel and click on the tip of the AltaTrack Guidewire in the X-ray image.

b   If needed, place additional markers along the shape of the AltaTrack Guidewire.

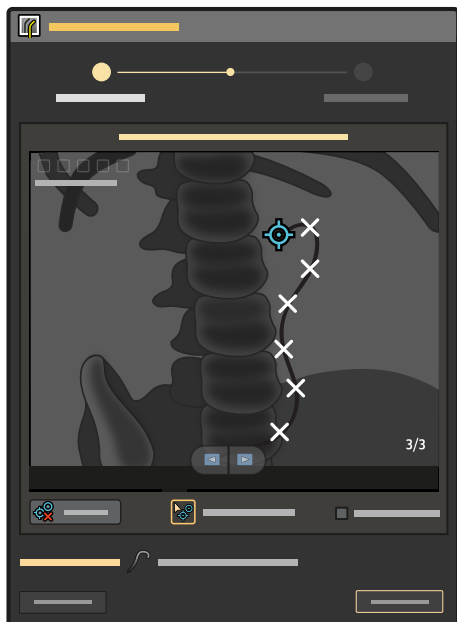For more information about placing markers, see Performing Shape Registration (page 56).

Figure 55   Place or adjust points on the shape in the X-ray image

c   Click **Compute Registration**

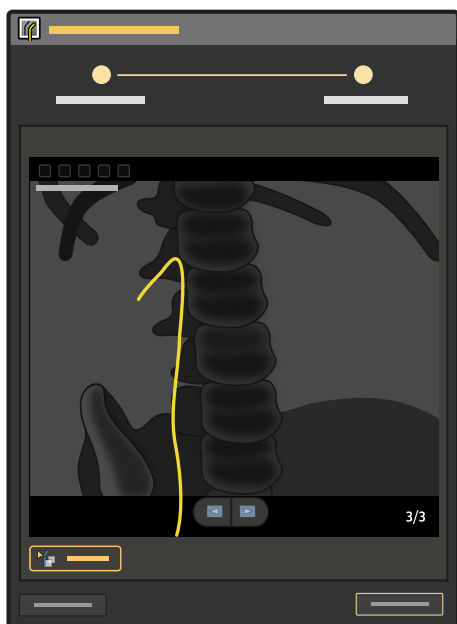The proposed registration results are displayed on the X-ray image in the pop-up panel.

Figure 56   Proposed registration results

d   Review the proposed registration results and do one of the following:

- If the proposed registration is correct, click **Accept**.
- If the proposed registration is not correct, repeat this step and try placing the points again.
- If the proposed registration is not correct after several attempts, you can try registering the AltaTrack Guidewire using two X-ray images by selecting the **Shape Registration** task in the task panel. For details, see Performing Shape Registration (page 56).

6.4.2 Registering a New Catheter Length or Changing an Existing Catheter Length Registration

This procedure describes the steps to register the length of an endovascular catheter in the **Live Guidance** task. To register a catheter, it must be connected to the AltaTrack 3D Hub and the AltaTrack Guidewire should be inserted through the catheter and the AltaTrack 3D Hub. Otherwise, the LumiGuide Equipment cannot detect the catheter. See the Instructions for Use of the AltaTrack 3D Hub on how to connect the AltaTrack 3D Hub to the catheter.

NOTE
You can perform catheter length registration out-of-body (on-body, tip-to-tip registration) or in-body (X-ray based registration) close to the target anatomy. After you have performed out-of-body registration, and after you have inserted the devices in body so that they are visible in the X-ray field of view, use fluoroscopy to ensure that the registration is valid.

WARNING
While unpacking single-use devices, pay close attention to sterility information labels on the packaging to avoid compromising the sterile field.

Tip-to-Tip Registration

This catheter length registration option provides an X-ray-free method to register a new catheter. This method can be used to register a catheter even when the AltaTrack Guidewire has not been registered yet.

NOTE
If you have already registered the AltaTrack Guidewire, ensure that the registration is performed correctly before starting tip-to-tip registration.

1 Click the catheter icon in the task panel.

2 Select the **Tip-2-Tip Registration** tab in the pop-up panel.

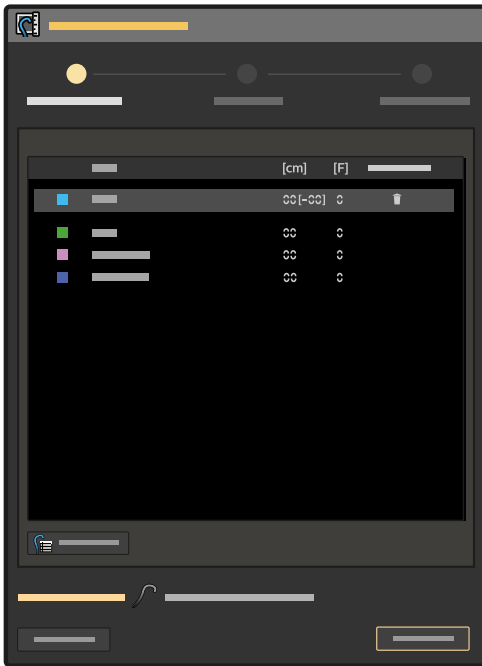**3** Select the correct catheter from the list and then click **Next**.

Figure 57 Selecting the catheter

⚠ **CAUTION**
Select the correct catheter type, length, and size during registration.

For information about configuring catheters on the LumiGuide Equipment, see Managing FORS-
Guided Catheters (page 107).

4 Align the tips of the AltaTrack Guidewire and the catheter with your fingers and when they are
aligned, select **Set Length**.

⚠ **CAUTION**
Ensure that the tip of the AltaTrack Guidewire aligns with the tip of the catheter
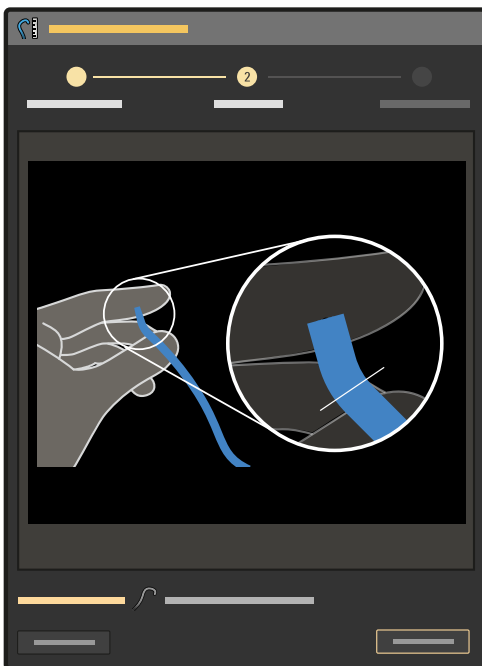

Figure 58 Guidance for performing tip-to-tip registration

5 Check that the FORS-guided catheter visualization matches and click **Accept** to confirm the catheter registration.

Figure 59 Aligning the tips of the AltaTrack Guidewire and the catheter

X-ray Registration

This catheter length registration option allows you to register a new catheter using an existing series or by acquiring a new series. This method can only be used if the AltaTrack Guidewire has already been registered in the **Shape Registration** task.

1 Click the catheter icon in the task panel.

2 Select the **X-Ray Based Registration** tab in the pop-up panel.

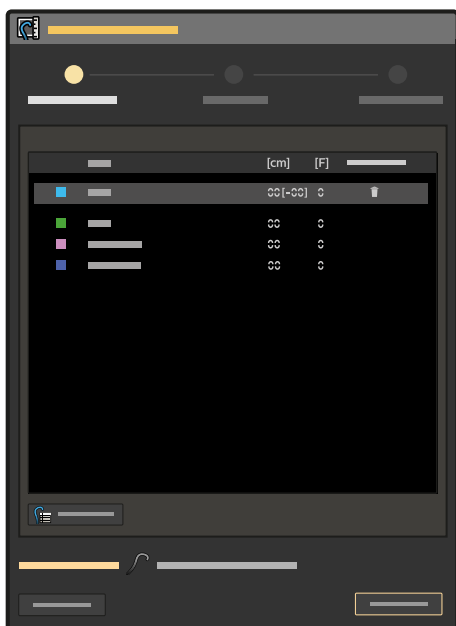**3** Select the correct catheter from the list and then click **Next**.

Figure 60 Selecting the catheter

⚠️ **CAUTION**
Select the correct catheter type, length, and size during registration.

For information about configuring catheters on the LumiGuide Equipment, see Managing FORS-
Guided Catheters (page 107).

4 Follow the guidance in the pop-up panel to perform automatic registration.
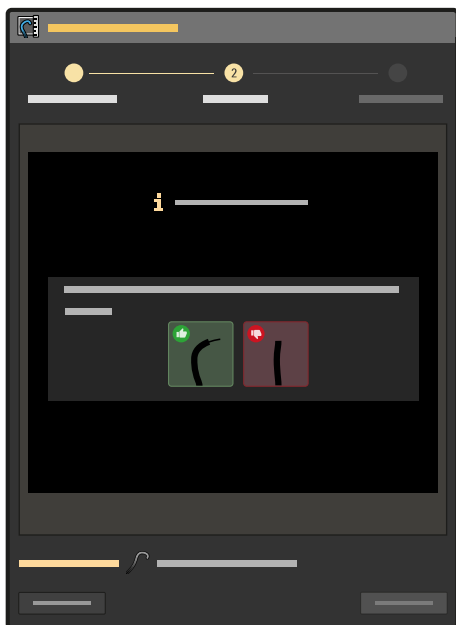

Figure 61 Guidance for performing X-ray-based registration

Automatic registration uses the last-acquired X-ray series. If the last-acquired series is not older than one minute, do the following:

a Ensure that the AltaTrack Guidewire is advanced beyond the catheter's tip and has enough curvature.

b Acquire a new X-ray series.

5 Review the registration of the AltaTrack Guidewire.

- If the registration is accurate, click **Accept**. X-ray registration of the AltaTrack Guidewire is now complete.
- If the registration is not accurate, do the following to adjust the registration of the AltaTrack Guidewire:

a   Click **Adjust**.

b   Click **Place or Adjust Points** and mark the tip of the AltaTrack Guidewire shape on the X-ray image.

c   If needed, mark additional points (displayed as white crosses) along the shape.

For more information about placing points, see Performing Shape Registration (page 56).

d   To remove the points and start over, click **Clear Points**.

e   When you have marked points on the shape, click **Compute Registration** to perform registration.

f   Review the registration and do one of the following:

- If the proposed registration is correct, click **Next**.
- If the proposed registration is not correct, you can try registering the AltaTrack Guidewire using two X-ray images by selecting the **Shape Registration** task in the task panel. For details, see Performing Shape Registration (page 56).

6   Select **Center on Tip** in the pop-up panel view to set the focus on the tip of the catheter.

7   Adjust the length of the FORS-guided catheter to match the X-ray image using the plus and minus buttons in the pop-up panel.
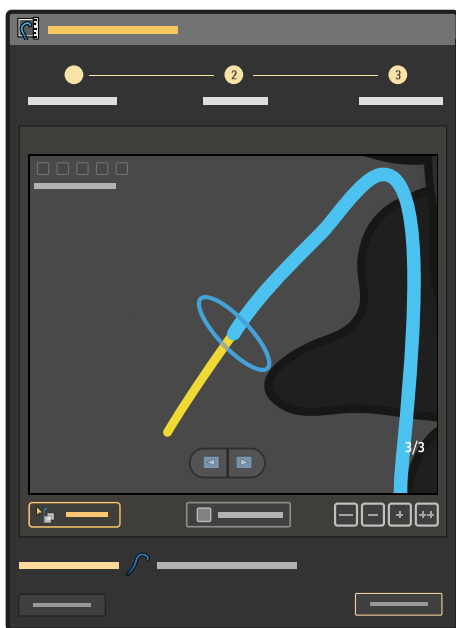

Figure 62   Adjusting the length of the FORS-guided catheter

The **+** and **-** buttons provide a small adjustment, while the **+ +** and **- -** buttons provide a larger adjustment.

8   Verify that the visualized catheter tip matches the tip in the X-ray image or continue making adjustments until they match.

9   To confirm the registration, click **Accept** in the pop-up panel.

6.4.3   Selecting a Previously Registered Catheter

You can use a previously registered catheter during a procedure.

⚠ **CAUTION**
Check the catheter length registration with X-ray after reselecting a previously used catheter.

1   Ensure that the catheter is prepared correctly:
    • The catheter is connected to the AltaTrack 3D Hub.
    • The AltaTrack Guidewire is inserted through the catheter.
    • The catheter is recognized by the LumiGuide Equipment.

2   Click the catheter icon in the task panel.

3   Select the current catheter in the **Recent Catheters** list in the task panel.

4   Ensure that the AltaTrack Guidewire is at or ahead of the catheter, so that the FORS-guided catheter shape visualization is fully visible.

5   Verify that catheter length registration is correct by checking with X-ray.

6.5   Exchanging a Guidewire

During a procedure, you can exchange an AltaTrack Guidewire with a conventional guidewire. For details, see the following tasks.

⚠️ **WARNING**
Do not cut the AltaTrack Guidewire during or after removal.

6.5.1   Exchanging an AltaTrack Guidewire with a Conventional Guidewire During a Procedure

1   Ensure that the AltaTrack Guidewire is not entangled with any other device on the table.

2   Remove the AltaTrack Guidewire from the patient.

3   Remove the AltaTrack 3D Hub from the catheter (if applicable).

4   Insert the conventional guidewire to the patient following standard angiographic techniques.

NOTE
You will need to use fluoroscopy more often during the procedure as the conventional guidewire is only visible with X-ray imaging.

6.5.2   Exchanging a Conventional Guidewire with an AltaTrack Guidewire During a Procedure

1   Remove the conventional guidewire following standard angiographc techniques.

2   If FORS-guided catheter visualization is needed, connect an AltaTrack 3D Hub to the endovascular catheter.

3   Ensure that the AltaTrack Guidewire that you want to use for navigation is connected and visible to the LumiGuide Equipment.

4   Insert the AltaTrack Guidewire to the patient and continue with navigation.

For more information, see Performing Live Guidance (page 70).

6.6   Exchanging a Catheter

This procedure provides guidance on exchanging a catheter with a different catheter.

1   Remove the AltaTrack Guidewire from the catheter with the connected AltaTrack 3D Hub.

2   (**Optional step**) Disconnect the AltaTrack 3D Hub from the catheter.

3   Connect an AltaTrack 3D Hub to the new catheter.

4   Insert the AltaTrack Guidewire.

5   Perform catheter length registration (see Registering a New Catheter Length or Changing an Existing Catheter Length Registration (page 76)).

6.7 Navigating Without an AltaTrack Guidewire

At any point during a procedure, you can revert to navigation using two conventional devices.

1   Ensure that the AltaTrack Guidewire is secured away from the X-ray field of view.

2   Continue navigation using conventional devices with fluoroscopy according to your standard practice.

6.8 Disposing of AltaTrack Products

6.8.1 Disposing of the AltaTrack 3D Hub

1   (**Sterile user**) Remove the AltaTrack Guidewire and the FORS-guided catheter connected to AltaTrack 3D Hub from the patient.

2   (**Sterile user**) Remove the AltaTrack 3D Hub from the catheter.

3   (**Sterile user**) Hand the AltaTrack 3D Hub over to the non-sterile user.

4   (**Non-sterile user**) Dispose of the AltaTrack 3D Hub in the appropriate bin.

6.8.2 Disposing of an AltaTrack Guidewire

You can detach and dispose of an AltaTrack Guidewire without compromising the sterile field by performing the following standard steps.

1   (**Sterile user**) Remove the AltaTrack Guidewire from the patient.

2   (**Sterile user**) Remove the docking fin of the AltaTrack Guidewire from the AltaTrack Docking Top.

3   (**Non-sterile user**) Remove the AltaTrack Guidewire connector from the connection box.

4   (**Sterile user**) Hand the AltaTrack Guidewire over to the non-sterile user.

5   (**Non-sterile user**) Dispose of the AltaTrack Guidewire in the appropriate bin.

6.8.3 Disposing of an AltaTrack Docking Top

You can detach and dispose of an AltaTrack Docking Top without compromising the sterile field, using standard hospital techniques.

1   (**Sterile user**) Remove the AltaTrack Guidewire from the patient.

2   (**Sterile user**) Remove the docking fin of the AltaTrack Guidewire from the AltaTrack Docking Top.

3   (**Sterile user**) Remove the AltaTrack Docking Top from the LumiGuide Docking Base.

4   (**Sterile user**) Hand the AltaTrack Docking Top over to the non-sterile user.

5   (**Non-sterile user**) Disposes of the AltaTrack Docking Top in the appropriate bin.

7 Postoperative Steps

1   Remove the AltaTrack Guidewire and, if applicable, the FORS-guided catheter from the patient.

2   Close the LumiGuide Viewing Software.

3   Do any of the following to store patient data:
  • Archive DICOM snapshots to a PACS system using the **Export** activity on the Interventional Workspot. For information about using the **Export** activity, refer to the Instructions for Use supplied with the Interventional Workspot.
  • Transfer snapshots and movies to a USB storage device using the movie export tool. For more information, see Movie Export tool (page 109).

  For information about cleaning the destination drive of the LumiGuide WorkSpot, refer to the Instructions for Use supplied with the Interventional Workspot.

4   Remove the AltaTrack Guidewire from the AltaTrack Docking Top.

5   Disconnect the AltaTrack Guidewire connector from the connection box.

6   Dispose of the AltaTrack products in the appropriate bin.

7   Tap **Shut Down** in the lower-right corner of the LumiGuide Touch Screen and then confirm your action to shut down the LumiGuide Equipment.
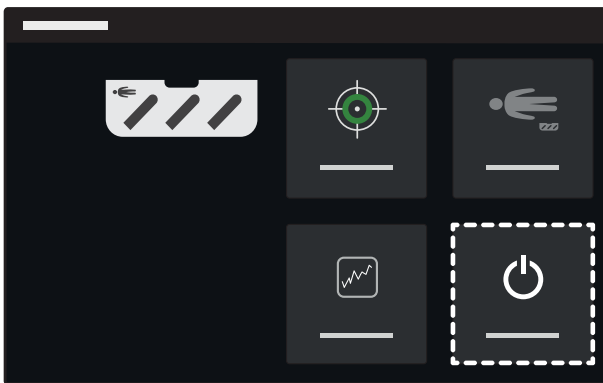
Figure 63   Shut Down button on the LumiGuide Touch Screen

8   After tapping **Shut Down**, the LumiGuide Touch Screen displays guidance for powering off the LumiGuide Equipment correctly.
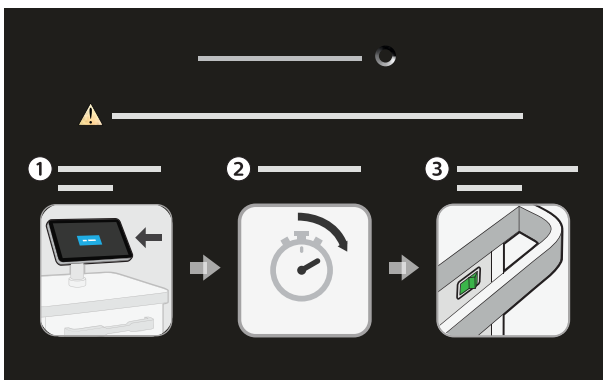
Figure 64   Guidance on the LumiGuide Touch Screen

a   Wait for the touch screen to turn black (after a few seconds) and display a blue "No signal" message.

b   After seeing this message, wait ten seconds.

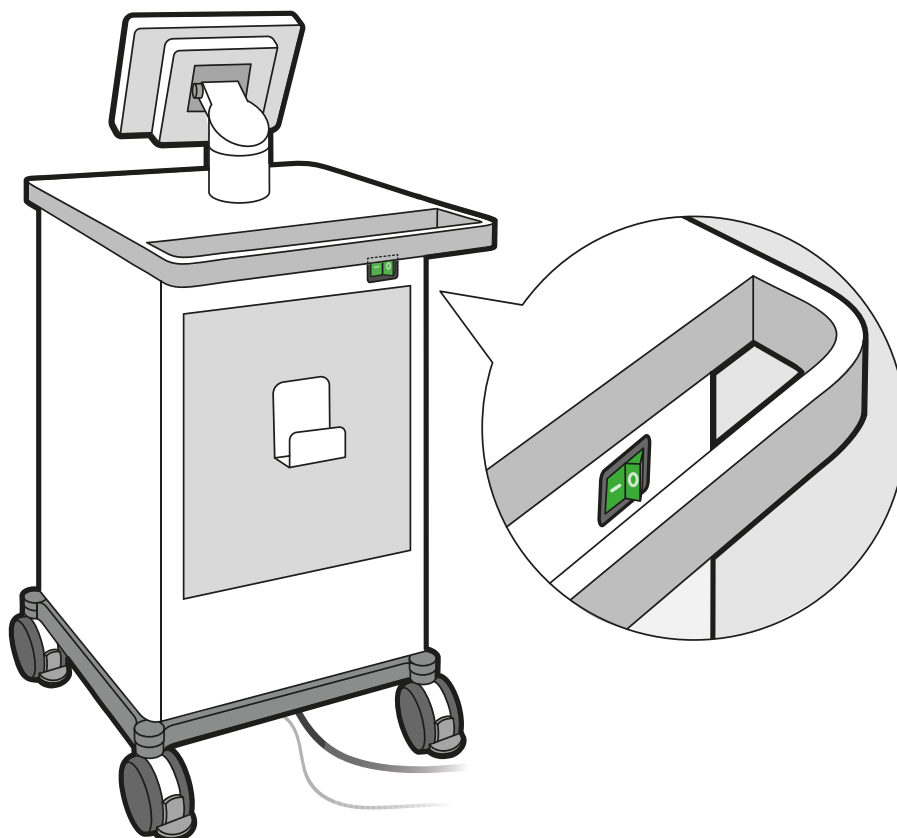c   You can now power off the LumiGuide Equipment using the switch on the rear side of the LumiGuide Engine.

Figure 65   LumiGuide Engine power switch

9   Remove the AltaTrack Docking Top from the LumiGuide Docking Base and dispose of it in the appropriate bin.
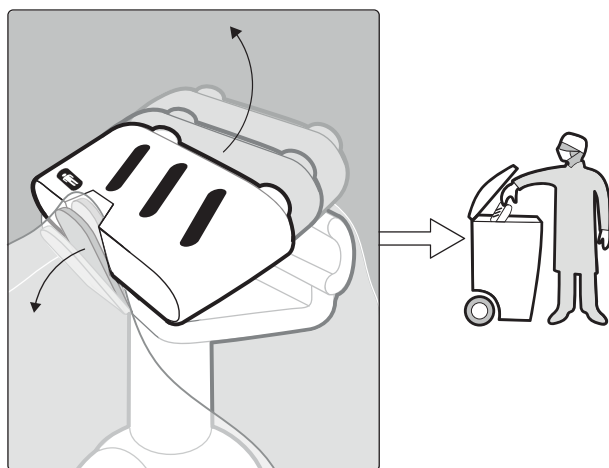

Figure 66   Removing and disposing of the AltaTrack Docking Top

⚠️   **WARNING**
The AltaTrack Docking Top is a single-use component and it should be properly disposed of after the procedure. Do not reuse the AltaTrack Docking Top for another procedure.

10 Remove the sterile cover.

11 Release the table clamp and remove the LumiGuide Docking Base from the table.
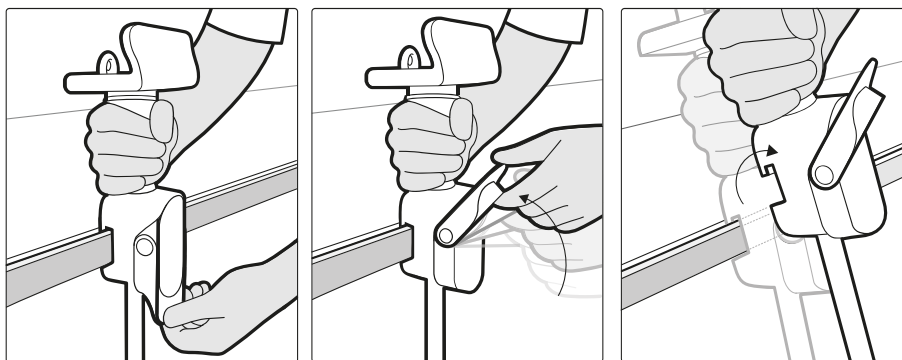

Figure 67   Removing the LumiGuide Docking Base

NOTE
If the LumiGuide Docking Base is contaminated, it should be cleaned before it is stored. For information about cleaning, see Cleaning the LumiGuide Equipment (page 87).

12 Follow your local procedures for managing the patient.

13 Store the LumiGuide Docking Base and the LumiGuide Equipment cable in the storage location on the LumiGuide Engine.
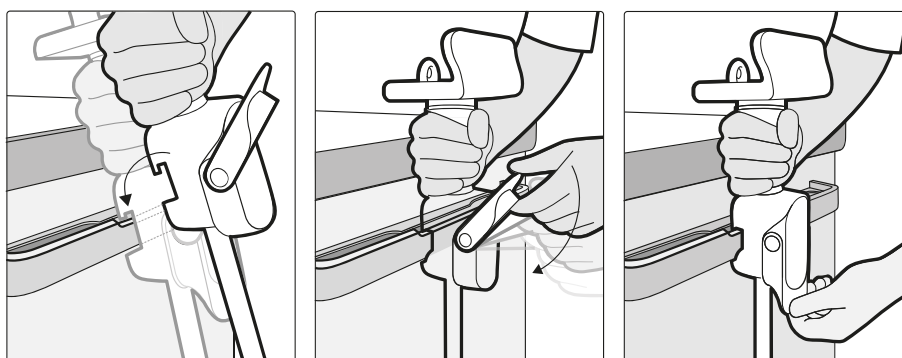
Figure 68   Storing the LumiGuide Docking Base

14 Disconnect the power cable and the network cable of the LumiGuide Engine from the wall sockets and store the cables on the hooks on the LumiGuide Engine.

15 Clean the LumiGuide Engine and wipe the power cable and the network cable, if needed.

For information about cleaning, see Cleaning the LumiGuide Equipment (page 87).

16 Release the brakes of the LumiGuide Engine, move it to its park position, and reapply the brakes.

8 Maintenance

Planned Maintenance Program
To ensure that maintenance is performed at the required intervals, the responsible organization (the owner of the LumiGuide Equipment) should issue a request to the maintenance organization for maintenance to be carried out in accordance with the Planned Maintenance Program described in this section.

Planned maintenance may only be carried out by qualified and authorized personnel, and is comprehensively described in the service documentation.

Philips Medical Systems provides a full planned maintenance and repair service on both a call basis and a contract basis. Full details are available from your Philips representative.

A summary of the planned maintenance program appears in the table below. You should always take all practical steps to make sure that the Planned Maintenance Program is fully up to date before using the product with a patient.

Philips Medical Systems will make available, on request, circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist technical support personnel to repair those parts of the equipment that are designated by Philips Medical Systems as repairable by technical support personnel.

For a complete list of consumables, contact Philips technical support.

Operators may perform cleaning tasks on the LumiGuide Equipment. For more information, see Cleaning the LumiGuide Equipment (page 87).

NOTE
Do not perform service tasks or maintenance checks while using the LumiGuide Equipment with a patient.

Planned Maintenance Checks

Task	Frequency	Required personnel
Check labels	Every 6 months	Philips Service
Check thermal aspects	Every 6 months	Philips Service
Check electrical aspects	Every 6 months	Philips Service
Check mechanical aspects and functions	Every 6 months	Philips Service
Update device database	Depending on use	Philips Service
Perform 3D verification	Every year	Philips Service
Check electrical safety	Every 2 years	Philips Service

User Checks
To maintain optimal operating performance, restart the LumiGuide Equipment daily.

Field Service
The field service function provides the capability for Philips to perform service actions on the equipment. The field service function is provided by the Philips SupportConnect application installed on your equipment. Field service is designed to reduce equipment down time and improve equipment performance through proactive maintenance.

Geometry Calibration
If a system message indicates that geometry calibration of the X-ray system has not been performed, contact Philips technical support.

8.1   Cleaning the LumiGuide Equipment

All parts of the LumiGuide Equipment may be cleaned by the hospital staff. Follow these guidelines to ensure that the system is properly cleaned.

When cleaning the equipment, follow these general guidelines:
- Do not allow liquids to enter the equipment. This may cause corrosion or electrical damage.
- Do not apply cleaning liquid or spray directly onto the system. Always use a cloth dampened with the cleaning product.
- Do not use corrosive or abrasive agents or pads.
- Clean the equipment by wiping it gently and without undue force.
- When cleaning scratched or worn painted surfaces, it is to be expected that some additional paint is removed.
- The AltaTrack Docking Top and AltaTrack 3D Hub should not be cleaned, but should be disposed of immediately after use. For more information, see Postoperative Steps (page 83).

8.1.1   Cleaning Workflow

The cleaning workflow consists of the following tasks:
- Preparation
- Manual cleaning
  - Cleaning
  - Rinsing
  - Drying

Initial treatment of the equipment is not required for effective cleaning.

Cleaning Frequency
Clean the LumiGuide Equipment after each procedure.

8.1.2   Preparation Task

You should prepare the equipment for cleaning before starting these tasks.

Note the following guidance:
- Disassembly of the medical device is not required.
- Testing the equipment to determine whether cleaning is necessary is not required.
- Pre-cleaning the equipment to remove debris is not required.

The following tools are required:
- Goggles, gloves, and protective equipment are required for cleaning staff, according to hospital regulations.
- Ready-to-use wipes.
- If ready-to-use wipes are not available, then dry, lint-free wipes that do not leave residues should be used.
- Cleaning agent, if ready-to-use wipes are not available.

It is not necessary to switch the system off when cleaning the system between patients.

1   Remove the AltaTrack Docking Top and disconnect the AltaTrack Guidewire from the LumiGuide Docking Base.

2   Remove any sterile covers.

8.1.3   Manual Cleaning

This section provides details of a validated manual procedure for cleaning, rinsing, and drying the equipment. Automatic cleaning of the equipment is not possible.

The following cleaning agents are permitted for cleaning any part of the LumiGuide Equipment:

Cleaning Agent	Application
Ethanol 70%	Cleaning and disinfecting small and large surfaces
Isopropanol 100%	Cleaning and degreasing small surfaces

The following cleaning agents are permitted for cleaning the cable and the LumiGuide Docking Base:

Cleaning Agent	Application
Ethanol 70%	Cleaning and disinfecting small and large surfaces
Isopropanol 100%	Cleaning and degreasing small surfaces
0.5% Chlorehexidine in 70% Ethanol	Cleaning, disinfecting, and degreasing small and large surfaces and instrumentation
Haemo-sol, 1% in water	Removing blood, disinfecting small surfaces and instrumentation
500 ppm Chlorine solution	Cleaning, disinfecting, and degreasing large surfaces

1 If ready-to-use wipes are not available, apply the cleaning agent to dry, lint-free wipes.

Never apply the cleaning agent directly to the equipment. Doing so may lead to ingress of liquid.

Spraying can cause a fire risk or rust, as aerosol cleaning agent may get inside the equipment.

2 Clean the parts of the system with a linear motion.

The contact time of the cleaning agent with the equipment is not relevant.

3 While cleaning, change wipes as necessary and at least between cleaning each part of the equipment.

4 Continue cleaning until all visible residues are removed.

5 After cleaning all parts of the equipment, rinse the equipment with damp, lint-free wipes using a linear motion.

Wipes can be dampened with tap water or demineralized water. The temperature of the water should be between 15°C and 35°C.

6 After rinsing all parts of the equipment, dry the equipment with a dry, lint-free wipe using a linear motion.

Always dry the equipment after rinsing it. Continue drying the equipment until it is visibly dry. Drying agent is not required.

8.1.4 Incompatible Cleaning Agents

Part	Incompatible with the Following Agents	Effects
Connection box	Long term exposure to Ethanol 70 % or 0.5% Chlorhexidine in Ethanol 70%	Gloss change
Launch base: aluminum anodized parts	Long term exposure to Haemo-sol 1%	Gloss change or stain
LumiGuide Equipment: label	Long term exposure to Isopropanol 100%	Glue softens
LumiGuide Engine: painted metal parts	Long term exposure to Isopropanol 100%	Gloss change
LumiGuide Engine: top surface	Long term exposure to Isopropanol 100% or Ethanol 70%	Gloss change
LumiGuide Engine: aluminum anodized parts	Long term exposure to Haemo-sol 1%	Stain

8.1.5 Supplementary Information about Cleaning

Degradation or Limitations of the Process
Cleaning the equipment in accordance with these instructions is not known to lead to degradation that might limit the service life of the equipment.

The service life of the equipment is not known to be limited by the number of cleaning cycles performed.

Inspection and Maintenance
Calibration after cleaning is not needed.

Lubrication after cleaning is not needed because only the outer surfaces of the equipment covers are cleaned.

8.2 Environmental Impact of the LumiGuide Equipment

To reduce the environmental impact of the LumiGuide Equipment, switch it off when it is not in use. However, bear in mind any clinical limitations that might make switching the LumiGuide Equipment off impractical.

For information, visit the following website and select one of the available guides:

www.cocir.org/initiatives/ecodesign-initiative/saving-energy

8.3 Final Disposal of the LumiGuide Equipment

Philips Medical Systems is concerned to help protect the natural environment, and to help ensure continued safe and effective use of this product, through proper support, maintenance, and training.

Therefore, Philips Medical Systems products are designed and manufactured to comply with relevant guidelines for environmental protection. As long as the product is properly operated and maintained, it presents no environmental risks. However, the product may contain materials that could be harmful to the environment if disposed of incorrectly. Use of such materials is essential to implement certain functions of the product, and to meeting statutory and other requirements. This section of these Instructions for Use is directed at the owner of the product.

The LumiGuide Equipment, or any part of it, should not be disposed of with industrial or domestic waste. Philips Medical Systems supports users in the following actions:
- Recovering reusable parts
- Recycling of useful materials by competent disposal companies
- Disposing of the product safely and effectively

For advice and information, contact the manufacturer (see Contacting the Manufacturer (page 12)).

For more information about recycling Philips Medical Systems products or about obtaining the WEEE recycling passport, refer to the following website:

www.medical.philips.com/main/about/sustainability/recycling/index.wpd

8.3.1 Disposing of Batteries

This section provides information about the responsible disposal of batteries from the LumiGuide Equipment.

Your product contains lithium batteries covered by the European Directive 2006/66/EC, which cannot be disposed of with normal household waste. Inform yourself about the local regulations on separate collection of batteries. Correct disposal of batteries helps prevent negative consequences for the environmental and human health. If you cannot dispose of the battery in your area, return it to the manufacturer for disposal.

PC Battery
The PC contains a lithium coin cell battery, and must be disposed of according to local, state, and federal laws regarding the disposal of lithium batteries.

8.4 Passing the LumiGuide Equipment to Another User

If this product passes to another user, it must be in its complete state, including all product support documentation. Make the new user aware of the support services that Philips Medical Systems provides for installing, commissioning, and maintaining the product.

Before passing on the product or taking it out of service, all patient data must be deleted and unrecoverable on the product (backed up elsewhere, if necessary).

It must be remembered by all existing users that passing on medical electrical products to new users may create serious technical, medical, and legal risks (concerning privacy, for example). Such risks can arise even if the product is given away. Existing users are strongly advised to seek advice from their local Philips Medical Systems representative before committing themselves to passing on any product. Alternatively, contact the manufacturer (see Contacting the Manufacturer (page 12)).

Once the product has been passed on to a new user, a previous user may still receive important safety-related information, such as bulletins and field change orders. In many jurisdictions, there is a clear duty on the previous user to communicate such safety-related information to new users. Previous users who are not able or prepared to do this should inform Philips Medical Systems about the new user, so that the new user can be provided with safety-related information.

9 Security

9.1 Customer Role in the Product Security Partnership

Philips recognizes that the security of its products is an important part of your facility's in-depth security strategy. However, these benefits can only be realized if you implement a comprehensive, multi-layered strategy (including policies, processes, and technologies) to protect information and systems from external and internal threats.

Following industry-standard practice, your strategy should address physical security, operational security, procedural security, risk management, security policies, and contingency planning. The practical implementation of technical security elements varies by site and may employ a number of technologies, including firewalls, virus-scanning software, and authentication technologies.

As with any computer-based system, protection must be provided such that firewalls or other security devices are in place between the medical system and any externally accessible systems. The USA Veterans Administration has developed a widely used Medical Device Isolation Architecture for this purpose. Such perimeter and network defenses are essential elements in a comprehensive medical device security strategy.

The latest information on security and privacy, including recommended customer actions, can be found on the following website:

www.philips.com/productsecurity

NOTE
Check the system's published cyber security status regularly on this website.

9.2 Risks Related to Security

To ensure the confidentiality, integrity, and availability of the device and related data, you should assess the risks to security based on the following recommendations.

- Implement network and physical access controls to limit the likelihood of compromise. For more information, see Customer Role in the Product Security Partnership (page 91).
- Monitor the manufacturer's product security recommendations on a regular basis. For more information, see Malware (page 92).

The assessment should be repeated whenever changes are made to the network. Such changes include the following:
- Changes in the network configuration
- Connection of additional items to the network
- Disconnection of items from the network
- Updates or upgrades to items that are connected to the network

9.3 Detecting Security Failures

The LumiGuide WorkSpot is designed to handle errors, including security failures, and restricts user access to the application level only. The LumiGuide Equipment provides logging capabilities for local and remote services that support diagnostics and forensics.

Security failures arising from user actions display error messages for the user and create audit events according to the IHE ATNA integration profile.

Network communication failures are audited. An error message is displayed for the user when user interaction is required.

System failures are handled depending on the nature and severity of the failure and may result in changes to the workflow, error messages, logging, or audit events. For example, software that is not on the whitelist is not executed and the failure is logged.

A number of security features have been implemented in this product. It is recommended to contact technical support to activate these features, in cooperation with the IT specialist of the hospital. A number of security features are implemented on the Interventional Workspot on which the LumiGuide WorkSpot is based. Refer to the Instruction for Use supplied with the Interventional Workspot for details of these features.

9.4 Emergency Access

For information about accessing the LumiGuide WorkSpot in an emergency situation, refer to the Instructions for Use supplied with the Interventional Workspot.

9.5 Malware

Despite preventive measures already implemented, a remote possibility remains that the equipment may become infected with malware. When malware is detected, or if you notice that unfamiliar behavior or degraded performance occurs repeatedly, including after the equipment is switched off and on again, you should contact technical support. If an inspection confirms an infection by malware, be sure to take measures to contain and remove the source of infection. Technical support will reinstall the equipment's software to bring the equipment back into specification. Technical support can also assist in accessing the equipment's event log, which may provide information useful for the investigation.

9.6 Whitelist Protection

Whitelist protection software is installed on this equipment. The whitelist identifies all trusted software that is allowed to execute on the equipment.

The protection software prohibits the execution of untrusted software, thus effectively blocking malware before damage is done. Instead of relying on frequent updates, as for antivirus software, it offers proactive protection against a wide spectrum of malware and malware alterations.

Since only known trusted software is allowed to run, no regular updates are required.

9.7 Audit Trail

Any user action on the LumiGuide WorkSpot involving personal data is logged to allow analysis as to whether any hostile action has been performed on the personal data. The LumiGuide Engine has no access to personal data and only service actions are logged in a local log file.

9.8 Network Time Synchronization

This function ensures that every device on the network uses the same time so that all relevant user actions and data transmissions, including audit trail actions, can be checked in chronological order. This function can be configured by the service engineer during installation.

9.9 Security Patches

The systematic analysis on cyber security vulnerabilities includes an assessment on the applicability and need for applying security patches taking into account mitigating circumstances in the intended use and design of this equipment.

Security patches alter the equipment's design and thus require proper validation and approval by Philips Medical Systems.

The latest information, including recommended customer actions, can be found at:

www.philips.com/productsecurity

10 Technical Information

Environmental Conditions for Operation, Storage, and Transportation

Item	Specification
Temperature range	• For operation: +18°C to +28°C • For storage and transportation: -20°C to +60°C
Relative humidity	• For operation: 20% to 80% • For storage and transportation (non-condensing): 10% to 90%
Air pressure	• For operation: 87.5 kPa to 110 kPa • For storage and transportation: 70 kPa to 110 kPa
Operating altitude	0 to 2000 m

Classifications

Item	Classification
LumiGuide Equipment	According to the IEC60601-1 definition, the equipment is classified as class I equipment for continuous operation.
Mains type	Single phase AC
AltaTrack Guidewire	Applied part type B

Laser Safety

Standard	
EN/IEC 60825-1:2014 + C11:2017 + A11:2021 + C11:2022	Safety of laser products - Part 1: Equipment classification and requirements

Working Conditions

The LumiGuide Equipment has the following working states:
• Starting up
• Ready for reconstruction
• Reconstructing a shape
• Shutting down

Accessories

The following items are compatible accessories to the LumiGuide Equipment:
• AltaTrack Docking Top
• AltaTrack 3D Hub

Other Equipment

The following items are compatible with the LumiGuide Equipment:
• AltaTrack Guidewire
• Philips Interventional X-ray system (contact the manufacturer for details on compatible versions, see Contacting the Manufacturer (page 12))
• Angiographic devices that are compatibile with a 0.035" wire

LumiGuide Engine

Item	Specification
Weight	190 kg (419 lb)
IP protection	IP20
Voltage	• 100-130 VAC • 200-240 VAC • 50/60 Hz (single phase)

Item	Specification
Peak power consumption	600 VA
Average power consumption	400 VA
Heat emission	350 W
Fuses	• Cartridge 20x5mm, 250V, BC 1500 A • 100-130 VAC : 2 x T 12 A • 200-240 VAC : 2 x T 6 A
Mains cable length	7 m
Network cable length	7 m

NOTE
Fuses should only be replaced by an authorized Philips service engineer.

LumiGuide Docking Base

Item	Specification
Weight	3 kg
IP protection	• LumiGuide Docking Base: IP23 • LumiGuide Equipment cable: IPX4

LumiGuide WorkSpot

Item	Specification
Weight	15 kg (33 lb)
Voltage	100-240 V, 50-60 Hz
Peak power consumption	850 W
Average power consumption	750 W
Safety	Complies with IEC 62368-1:2018 or IEC 60950-1:2005/AMD2:2013

Optical Processing Unit

Item	Specification
Laser type	External cavity tunable laser
Wavelength range	1520-1600 nm
Output power	≤5 mW (on the accessible point on the LumiGuide Docking Base
Laser safety class	Class I according to IEC 60825:2007/IEC 60825:2014+A11:2021

Batteries

Item	Specification	
Coin cell in the reconstruction PC	Type	CR2450 Lithium Coin Cell battery
	Weight	6.2 g (approximately)
Coin cell in the LumiGuide WorkSpot	Type	CR2450 Lithium Coin Cell battery
	Weight	6.2 g (approximately)

Ethernet Interfaces (LumiGuide WorkSpot)

Item	Exchange of Data with the X-ray System	Hospital Connection	LumiGuide Engine Connection
Type of interface	Standard network communication	Standard network communication	Standard network communication
Interface specification/ standard	IEEE Std. 802.3u/x (1000 Mbps)	IEEE Std. 802.3u/x (1000 Mbps)	IEEE Std. 802.3u/x (1000 Mbps)
Summary of testing	Refer to the standard	Refer to the standard	Refer to the standard
Time synchronization	Not applicable	Refer to the standard	Refer to the standard
Fault tolerance behavior, boundary condition testing, or fail safe	Refer to the standard	Refer to the standard	Refer to the standard
Limitations, contraindications	None	None	None
Recommended connections	None	None	Connection to the LumiGuide Engine
Recommended settings or configurations	Not applicable	See the Instructions for Use supplied with the Interventional Workspot	Not applicable
Connection to IT network	Not applicable	• PACS • RIS • HIS • Philips Service	Not applicable
Instructions for connecting	Ethernet can be connected and disconnected from the X-ray system at the wall connection box	Ethernet can be connected and disconnected from the hospital network by inserting/removing the cable from the appropriate ethernet socket	Ethernet can be connected and disconnected at the wall connection box

Open-Source Software
This product uses other software, including open source software, for which licenses and copyright notices can be found in the following location on the installation medium:

3rd_party_sw\ReadMeLeaflet.txt

10.1 Regulatory Information

UK Responsible Person + Importer
UK CA   Philips Electronics UK Limited
Ascent 1, Aerospace Boulevard
Farnborough, GU14 6XW
United Kingdom

10.2 Electromagnetic Compatibility

You should only use the LumiGuide Equipment in an electromagnetic environment similar to the environment described in this section.

The LumiGuide Equipment, has been tested and complies with IEC 60601-1-2:2014 (edition 4) and IEC 60601-1-2:2014/AMD1:2020 (edition 4.1) (collateral standard - electromagnetic disturbances) for medical electrical equipment.

Intended Use Environment
The LumiGuide Equipment has been designed for the professional healthcare environment and do not require additional shielding against electromagnetic disturbances.

If the responsible organization requires continued operation during power mains interruptions, it is recommended that the LumiGuide Equipment is powered from a compatible uninterruptable power supply. Contact a Philips representative for details.

10.2.1 Emissions

IEC60601-1-2 Edition 4.1
The LumiGuide Equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Emissions Test	Test Standard	Compliance
RF emissions	CISPR 11	Group 1
		Class A
Harmonic emissions	IEC 61000-3-2	Not applicable, the LumiGuide Equipment is not intended to be connected to the public mains network
Voltage fluctuations/flicker emissions	IEC 61000-3-3	Not applicable, the LumiGuide Equipment is not intended to be connected to the public mains network

10.2.2 Immunity

Description of Immunity Test	Test Standard	Compliance
Electrostatic discharge (ESD)	IEC 61000-4-2	±8 kV contact
		±2, 4, 8, 15 kV air
		See note 3
Radiated RF electromagnetic fields	IEC 61000-4-3	80-2700 MHz
		80% AM 1 kHz
		3 V/m
Proximity fields	IEC 61000-4-3	Frequencies and levels determined by EMC risk management. Refer to the table below.
		See notes 2 and 3
Electrical fast transients and bursts	IEC 61000-4-4	±1 kV, 100 kHz (signal ports), see note 3
		±2 kV, 100 kHz (AC power ports), see note 3
Surges	IEC 61000-4-5	±0.5, 1 kV (line-line)
		±0.5, 1, 2 kV (line/PE)
Conducted disturbances, induced by RF fields	IEC 61000-4-6	0.15 – 80 MHz 80% AM 1 kHz
		3 V_{rms}, see note 4
		6 V_{rms} ISM freq. (refer to the table below)
Voltage dips, short interruptions and voltage variations on power supply input lines	IEC 61000-4-11	Voltage dips:
		0% UT 0º, 45º,.. ,315º - 10 ms, see note 5
		0% UT 0º - 20 ms
		70% UT 0º - 500 ms
		0% UT 0º - 5000 ms
Power frequency magnetic fields	IEC 61000-4-8	50 Hz and 60 Hz
		30 A/m

Description of Immunity Test	Test Standard	Compliance
Proximity magnetic fields	IEC 61000-4-39	134.2 kHz, pulse modulation
		2.1 kHz, 65 A/m
		13.56 MHz, pulse modulation
		50 kHz, 7.5 A/m
		The carrier was modulated using a 50% duty cycle square wave signal.
		The test level is the r.m.s., before modulation is applied.

Note 1: U_T is the AC mains voltage prior to application of the voltage dip or short interruption test.

Note 2: A system error may be detected for proximity fields from RF wireless communication equipment that may automatically recover or needs a reboot when the interference stopped. Basic safety is not affected by the interference.

Note 3: A system error may be detected for transients or bursts on the mains cable, ethernet cable, or system cable that may automatically recover or needs a reboot when the interference stopped. Basic safety is not affected by the interference.

Note 4: A system error may be detected for conducted disturbances between 12 MHz and 72 MHz that may automatically recover when the interference stopped. Basic safety is not affected by the interference.

Note 5: During a voltage dip at 230 V, the 6 A fuse may be damaged. System operation can be restored by qualified Philips service personnel by exchanging the fuse. During a voltage interruption, the equipment may shut down and will automatically recover when the interference is stopped. Basic safety is not affected by the interference.

10.2.3 ISM Frequency

The following table of reasonable foreseeable ISM frequencies for conducted disturbance testing has been determined via EMC risk management.

ISM frequency table 0.15 MHz-80 MHz conducted disturbances induced by RF fields testing:

Frequency band [MHz]	Test frequencies [MHz]	Modulation	Compliance (see note)
6.765-6.795	6.765, 6.795	80% AM, 1 kHz	6 V
13.553-13.567	13.56	80% AM, 1 kHz	6 V
26.957-27.283	26.957, 26.03, 27.283	80% AM, 1 kHz	6 V
40.66-40.70	40.66, 40.70	80% AM, 1 kHz	6 V

Note: A system error may be detected for conducted disturbances between 26-28 MHz and 40-41 MHz that may automatically recover when the interference stopped. Basic safety is not affected by the interference.

The following table of reasonable foreseeable ISM frequencies for proximity field testing has been determined.

Test Frequency (MHz)	Band (MHz)	Modulation	Maximum Power (W)	Immunity Test Level (V/m)
385	380-390	Pulse modulation 18 Hz	1.8	27
450	430-470	Pulse modulation 18 Hz	2	28
710	704-787	Pulse modulation 217 Hz	0.2	9
745				
790				
810	800-960	Pulse modulation 18 Hz	2	28
870				
930				
1,720	1,700-1,990	Pulse modulation 217 Hz	2	28
1,845				
1,970				
2,450	2,400-2,570	Pulse modulation 217 Hz	2	28

Test Frequency (MHz)	Band (MHz)	Modulation	Maximum Power (W)	Immunity Test Level (V/m)
5,240	5,100-5,800	Pulse modulation 217 Hz	0.2	9
5,500				
5,785				

Note: The pulse modulation carrier was modulated using a 50% duty cycle square wave signal.

10.2.4 RFID

Every AltaTrack Guidewire has a unique identifier that is transmitted to the LumiGuide Equipment using wireless RFID technology. The LumiGuide Equipment uses this unique identifier to identify the AltaTrack Guidewire and its specific data stored on the LumiGuide Equipment.

Standard: ISO/IEC15693	Specification
Frequency of reception	13.56 MHz
Frequency of transmission	13.56 MHz ± 500 kHz
Bandwidth of the receiving section	3.1 MHz
Type and frequency characteristics of the modulation	Modulation acc. To ISO15693 (10% to 30% ASK or 100% ASK Manchester coding 26 kbit/sec)
Effective radiated power	≤100 mW

NOTE
The LumiGuide Equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. The LumiGuide Equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If the LumiGuide Equipment does cause harmful interference to other equipment, which can be determined by turning the LumiGuide Equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
*   *Reorient or relocate the receiving antenna.*
*   *Increase the separation between the LumiGuide Equipment and receiver.*
*   *Connect the LumiGuide Equipment into an outlet on a circuit different from that to which the receiver is connected.*
*   *Consult the Philips service technician for help.*

NOTE
"Harmful interference" is defined in 47 CFR §2.1 by the FCC as follows: Interference which endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the ITU Radio Regulations.

11 Appendix

This section provides background information and reference information for the LumiGuide Equipment.

Tooltips
More information about the function of a specific button or element in the user interface of the LumiGuide Viewing Software can be found by reading the related tooltip. To display the tooltip, position the pointer over the button or element (without clicking).

11.1 Main Display Area

The main display area is divided into smaller viewing areas called viewports. The layout of viewports changes according to the task being performed to provide the optimum layout for each task. You can change the layout manually using tools in the task panel.

Layout Options
☐ Single viewport
☐☐ Side-by-side viewports

Each viewport contains a toolbar for manipulating the image and an orientation indicator to indicate the orientation of the image in the viewport.
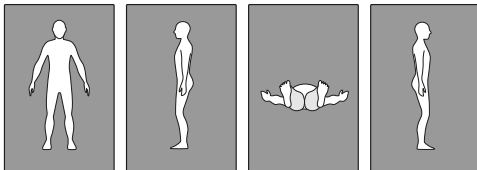
Figure 69   Orientation indicator

11.2 Setting User Preferences

You can configure your preferences for the viewing environment, navigation, and visualization of the AltaTrack Guidewire.

1   Select **User Preferences** in the common tools panel to display the **User Preferences** dialog box.

Figure 70   User Preferences dialog box

Legend	
1	**General** preferences
2	**Live Guidance** preferences
3	**LumiGuide Visualization** preferences

2   Configure the **General** as needed.

Settings	Options	Explanation
Default shape registration mode	**Automatic**	When performing AltaTrack Guidewire registration, automatic registration can be applied as the default option instead of performing manual registration.
	Manual	
View orientation indicator	**On**	Displays the human figure to indicate the orientation of the image in the viewport.
	Off	
Patient info level	**None**	Displays different levels of patient information.
	Essential	
	All	
Angle flavor	**Radiology**	Applies angle presets appropriate to the selected flavor.
	Cardiology	

3 Configure the **Live Guidance** as needed.

Settings	Options
Reset pan and zoom to X-ray image	**On**: Reset the pan and zoom settings to the field of view of newly acquired X-ray series.
	Off: Maintain the current pan and zoom settings when a new X-ray series is acquired.
Fluoro playback in main view	**Last image hold**
	Auto replay
Lock main view angle to X-ray system	**Always**
	Allow lock/unlock: Allows you to lock or unlock this setting during **Live Guidance** using the following function displayed in the main view.
	The viewing angle is locked to the orientation of the C-arm. Select this icon to unlock the viewing angle.
	The viewing angle is unlocked. Select this icon to lock the viewing angle to the orientation of the C-arm.
	When the viewing angle is unlocked and you rotate the volume using the roll interactor, the current X-ray image is flushed. To recall the previous X-ray image, double-click the main display area to reset the field of view. Alternatively, acquire a new X-ray image.

4 Configure the **LumiGuide Visualization** as needed.

Settings	Options
Shape diameter	**Not enlarged**
	50% enlarged: The thickness of the AltaTrack Guidewire (and FORS-guided catheter, if applicable) is enlarged for improved visualization.
Show guidewire during catheter registration	**Yes**
	No: Hides visualization of the AltaTrack Guidewire to improve the visibility of the catheter's tip. You can use the **Show Guidewire** function to display the visualization again.

5 Select **Close** to close the **User Preferences** dialog box and save your settings.

11.3 Viewing Tools

Viewing tools are available on a toolbar in each viewport to allow you to manipulate the image in the viewport.

NOTE
Slab views are linked. Actions performed in one view are also performed in the other slab views.

NOTE
The volume view is not linked to the slab views.

11.3.1 Zooming

You can enlarge or reduce the image displayed in the viewport by zooming in or out of the image.

1 Click **Zoom** on the toolbar and do the following:

- To zoom in, drag upward.
- To zoom out, drag downward.

NOTE
The orientation indicator, patient information, and annotations are not zoomed.

2 To reset the image to the default zoom level, double-click in the viewport.

3 To access the **Zoom** tool while another tool is selected, use the following mouse shortcut:

- Rotate the mouse wheel forward to zoom in.
- Rotate the mouse wheel backward to zoom out.

This mouse shortcut is only available when a volume view is displayed.

11.3.2 Panning

Panning the image allows the area of interest to be positioned in the center of the viewport.

1 Click **Pan** on the toolbar.

2 Pan the image by dragging it.

The image pans in the direction of movement.

3 To reset the image to the default position, double-click in the viewport.

4 To access the **Pan** tool while another tool is selected, drag with the right mouse button.

11.3.3 Rotating

The volume can be rotated to provide better visibility of the vessels of interest and to achieve the desired viewing or rotation angle.

1 Click **Rotate** on the toolbar.

2 To roll the volume freely in any direction around the center of rotation, move the pointer over the volume and drag in direction that you want to roll it.

3 To rotate the volume in the viewing plane, move the pointer outside the boundary of the volume and drag in the direction that you want to rotate it.

The volume rotates in the viewing plane around the center of rotation.

When you roll or rotate the volume, the rotation indicator is displayed as a red dot at the center of rotation. It indicates the volume axes and direction of rotation.

4 To move the center of rotation, drag it to the desired position.

5 To reset the image to the default orientation, double-click in the viewport.

11.3.4 Spatial Navigation

You can navigate through the slices of a volume in a direction perpendicular to the view.

In the volume view, the **Cutplane** function is used.

In the slab views, the **Scroll** function is used.

Cutplane (Volume)

1 Select **Cutplane** on the toolbar.

A box is displayed showing your viewing position in the volume. The slice that you are currently viewing is highlighted.
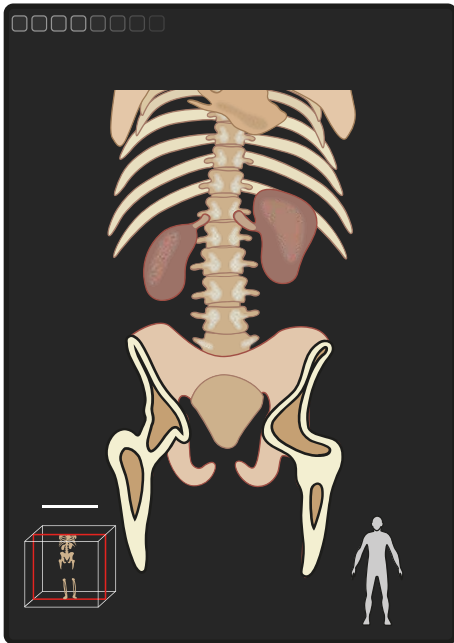
Figure 71 Cutplane indication box

2 Click and drag the pointer upward to move through the slices towards the rear of the volume.

The indicator moves towards the rear of the box, indicating your new viewing position.

Slices that you have navigated past are no longer visible.

3 Click and drag the pointer downward to move through the slices towards the front of the volume.

The indicator moves towards the front of the box, indicating your new viewing position.

Slices that you previously navigated past are now visible again.

4 To reset the view to the default position, click **Click here to reset**.

The viewing position is set to the front of the volume, showing all slices.

Scroll (slab)

1 Select **Scroll** on the toolbar.

2 Click and drag the pointer upward to move through the slices towards the rear of the slab.

Slices that you have navigated past are no longer visible.

3 Drag the pointer downward to move through the slices towards the front of the slab.

Slices that you previously navigated past are now visible again.

4 To reset the view to the default position, double-click in the slab view.

The viewing position is set to the front of the volume, showing all slices.

5 To access the **Scroll** tool while another tool is selected, use the following mouse shortcut:

- Rotate the mouse wheel forward to move through the slices towards the rear of the slab.
- Rotate the mouse wheel backward to move through the slices towards the front of the slab.

This mouse shortcut is only available when a slab view is displayed.

11.3.5 Adjusting the Contrast and Brightness of the X-ray Image

During the procedure, you can adjust the contrast and brightness of the X-ray image in the **Live Guidance** task if necessary.

1 Click **Contrast and Brightness** on the toolbar and do the following:

- Drag the pointer upward to decrease the brightness level.
- Drag the pointer downward to increase the brightness level.
- Drag the pointer to the right to decrease the contrast level.
- Drag the pointer to the left to increase the contrast level.

2 To access the **Contrast and Brightness** tool while another tool is selected, use the following mouse shortcut:

- Drag the middle mouse button upward to increase the window level.
- Drag the middle mouse button downward to decrease the window level.
- Drag the middle mouse button left to decrease the window width.
- Drag the middle mouse button right to increase the window width.

This mouse shortcut is only available in the 2D views of the **Segmentation** and **Planning** tasks.

11.3.6 Adjusting Window Width and Window Level Settings

To provide optimum visualization of anatomy and vessels of interest, you can adjust the window width and window level (WW/WL) settings using the windowing function. The windowing function adjusts what anatomy is visible in the volume based on the differing densities of anatomical objects.

1 Click **Windowing** on the toolbar and do the following:

- Drag the pointer upward to increase the window level.
- Drag the pointer downward to decrease the window level.
- Drag the pointer to the left to decrease the window width.
- Drag the pointer to the right to increase the window width.

Windowing settings are displayed in the histogram, which provides a graphical representation of grey value distribution.
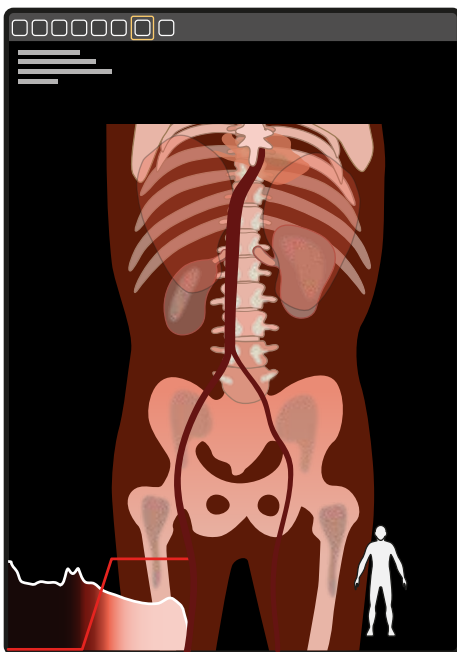
Figure 72 Histogram

2 To access the **Windowing** tool while another tool is selected, use the following mouse shortcut:

- Drag the middle mouse button upward to increase the window level.
- Drag the middle mouse button downward to decrease the window level.

- Drag the middle mouse button left to decrease the window width.
- Drag the middle mouse button right to increase the window width.

11.3.7 Adjusting the Opacity of the Volume

Adjusting the opacity of the CT volume (if applicable) allows you to view the AltaTrack Guidewire, the FORS-guided catheter, if applicable, or anatomical objects in the vicinity of the volume more easily.

- Click **Volume Opacity** on the toolbar and do the following:
  - Drag the pointer upward to decrease the opacity of the volume.
  - Drag the pointer downward to increase the opacity of the volume.

11.3.8 Rotating the Volume

You can rotate the volume to adjust the alignment with the X-ray images. It is recommended to make adjustments in side-by-side viewing mode.

1 Click **Rotate Volume** in the toolbar of a viewport and do the following:

- Move the pointer outside the boundary of the volume.
- Drag the volume to rotate it to the desired orientation.

2 Repeat this action in the other viewport.

11.3.9 Translating the Volume

You can translate the volume to adjust the alignment with the X-ray images. It is recommended to make adjustments in side-by-side viewing mode.

1 Click **Translate Volume** in the toolbar of a viewport and drag the volume to align the anatomy.

2 Repeat this action in the other viewport.

11.3.10 Adjusting the Opacity of the AltaTrack Guidewire Shape

Adjusting the opacity of the AltaTrack Guidewire shape allows you to view anatomical objects in the vicinity of the shape more easily.

- Click **Shape Opacity** on the toolbar and do the following:
  - Drag the pointer upward to decrease the opacity of the AltaTrack Guidewire shape.
  - Drag the pointer downward to increase the opacity of the AltaTrack Guidewire shape.

11.3.11 Selecting a Preset Orientation

You can select a preset orientation for viewing the volume.

1 To select a preset orientation, click the orientation button in the toolbar of the viewport to be changed.

2 Select the desired orientation in the drop-down list.

Preset Orientations	
	Coronal (anterior-posterior, this is the default orientation)
	Saggital (lateral left)
	Saggital (lateral right)
	Axial (caudo cranial)

11.3.12 Enlarging a View

You can enlarge a slab view and display it in the volume viewport.

1 Click **Enlarge view** in the slab view toolbar.

The image from the slab view is shown in the main volume viewport.

2 Click **Enlarge view** again to return to the previous viewing configuration.

11.4 Common Tools Panel

The common tools panel is available in all tasks, but not all tools in the panel are available in each task.

Common Tools	
	Merge with X-ray Modality Patient This tool is only available in the **Volume Registration** task and the **Live Guidance** task.
	User Preferences
	Manage Catheter List
	Export to USB
	Snapshot
	DICOM Snapshot
	Movie

11.5 Managing FORS-Guided Catheters

You can change the properties of configured FORS-guided catheter types, add new catheter types, or delete existing ones.

You manage catheters using the **Catheter list manager** dialog box.

Figure 73 Catheter list manager dialog box

1 To display the **Catheter list manager** dialog box, do one of the following:
   • In the common tools panel, select **Manage Catheter List**.
   • During catheter registration, select **Manage List**.

2 To change the properties of an existing catheter type, select new values in the drop-down lists for corresponding type of catheter.

   You can change the following properties:
   • Color
   • Type
   • Length (cm)
   • Size (F)

3 To add a new type of catheter, select **Add Catheter** and set its properties using the drop-down lists.

   You can add up to 20 catheter types.

4 To delete a catheter type, select **Delete** next to the catheter type.

5 After making changes in the **Catheter list manager** dialog box, select **Save**.

11.6 Snapshots and Movies

The following sections provide information about making snapshots and movies while using the LumiGuide Viewing Software, and how to export them to a USB storage device.

11.6.1 Making a Snapshot

You can make the following kinds of snapshot in all tasks:

- A standard snapshot in JPEG format that can be exported and viewed on a standard computer.
- A DICOM snapshot in Secondary Capture (SC) format that can be sent to a PACS.

1 To make a standard snapshot, do one of the following:

a In the LumiGuide Viewing Software window, click **Snapshot** in the common tools panel.

b On the touch screen module of the X-ray system, tap **Movie/Snapshot** and then tap **Fullscreen Snapshot**.

A snapshot of the whole display is created. You can export the snapshot to a USB device using the Movie Export tool.

NOTE
When you make a snapshot, the patient information overlay is automatically hidden.

NOTE
If you make a snapshot using the Snagit® capture tool, the snapshot may contain personal information about the patient, which is not de-identified. The snapshot may be accessible by other operators after export. It is your responsibility to ensure that patient privacy is not compromised at the export destination.

2 To create a DICOM snapshot, do one of the following:

a In the LumiGuide Viewing Software window, click **DICOM Snapshot** in the common tools panel.

b On the touch screen module of the X-ray system, tap **Movie/Snapshot** and then tap **DICOM Snapshot**.

A snapshot of the current viewports is created. You can export the DICOM snapshot using the **Export** activity.

NOTE
Personal data that appears in the DICOM snapshot cannot be de-identified. Set the patient information overlay to none before creating the snapshot. You must ensure that snapshots do not contain information that may identify a patient before exporting them. The DICOM snapshot may be accessible by other operators after export. It is your responsibility to ensure that patient privacy is not compromised at the export destination.

11.6.2 Making a Movie

The **Movie** function is available in all tasks.

NOTE
When you record a movie using the movie function, the patient information overlay is automatically hidden.

NOTE
When you record a movie, the software automatically attempts to hide the patient information. However, the tool does not guarantee that no patient information is visible in the movie, and you are advised to check manually.

1 To record a movie, do one of the following:

a In the LumiGuide Viewing Software window, click **Movie** in the common tools panel.

b On the touch screen module of the X-ray system, tap **Movie/Snapshot** and then tap **Movie**.

The recording function starts and captures the whole display.

The recording time is indicated in the common tools panel. Recording stops after 30 minutes or when you manually stop recording. Closing the application also stops any recording that is in progress.

2 To stop recording, click or tap **Movie** again.

The **Movie** function is unavailable for a short time while the movie is stored.

You can export the movie to a USB device using the Movie Export tool. The movie is exported in MP4 format. For details, see Movie Export tool (page 109).

11.6.3 Movie Export tool

You can use the Movie Export tool to export snapshots and movies to a USB device.

1 Click **Export to USB** in the general toolbar.

2 Click the **USB Memory Stick** arrow and select the drive letter of a connected USB device.

Snapshots and movies are exported to the root directory of the USB device. Subfolders cannot be used.

3 Select the capture on the left side that you want to export.

4 Click **Export** to export them to the USB device.

5 To delete captures, select the capture you want to delete, and then click **Delete**.

You can delete captures from the system (left side) or from the USB device (right side).

6 To refresh the view, click **Refresh**.

7 To close the Movie Export tool, click **Close**.

11.7 Storing and Reviewing Series

You can store series that you acquired during an intervention and review them later to assist with reporting tasks.

1 To store a series using the touch screen module of the X-ray system, do the following:

a Tap **Advanced**.

b Tap **Store 2D Runs** and then tap **Store Run**.

c Tap **Back** to close the **Advanced** screen.

2 To store a series using the LumiGuide Viewing Software window, click **Store Fluoroscopy Image** on the toolbar of the main viewport.

The current series is saved to the database and the button is unavailable until a new series is acquired.

3 To review a previously stored series, do the following:

a Click **Load Run** on the toolbar of the main viewport.

A dialog box displays available series.

b Select the series to be loaded and click **OK**.

c Review the series using the reviewing toolbar at the bottom of the viewport.

11.8 Guidance for Resolving Issues

When the LumiGuide Engine detects an issue with the LumiGuide Equipment or the AltaTrack Guidewire, a warning message is displayed on the LumiGuide Viewing Software (see 2.14).

Guidance for resolving issues is also displayed on the LumiGuide Engine touch screen. Issues may be related to the AltaTrack Guidewire, the LumiGuide Equipment, or optical calibration. Issues may also relate to whether the hard disk where LumiGuide data is saved is full.

The nature of the issue is displayed at the top of the LumiGuide Engine touch screen (1). A message in (2) displays the first high level resolution guidance. The main screen (3) provides illustrated guidance to resolve the issue.
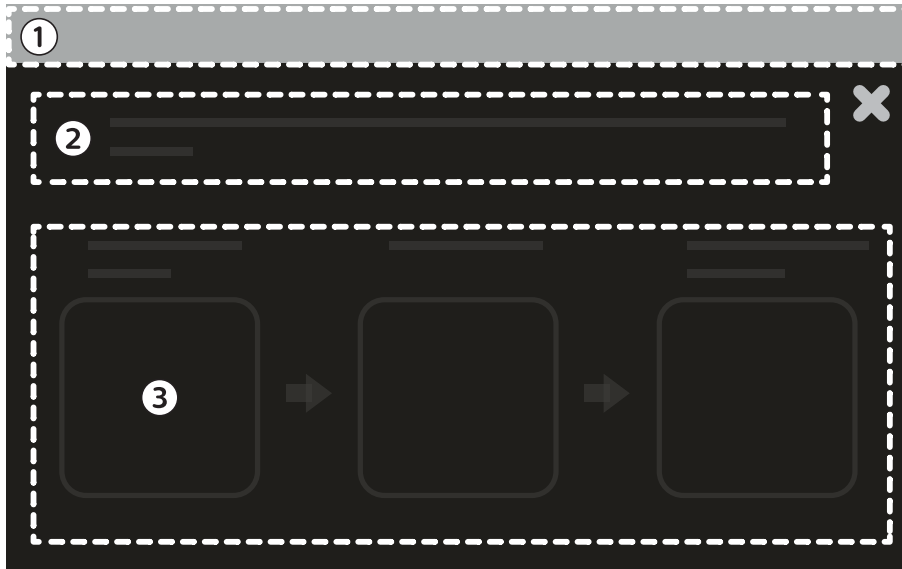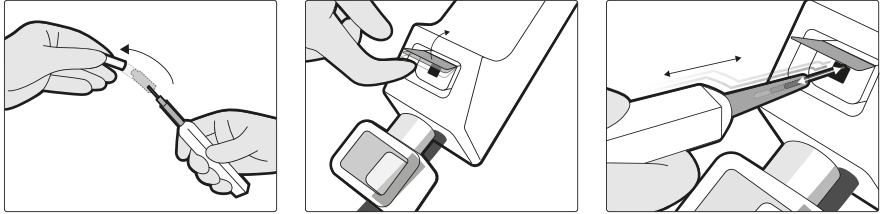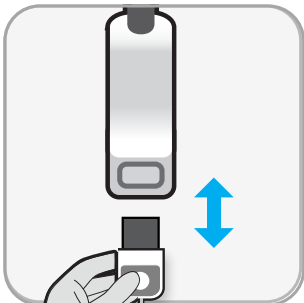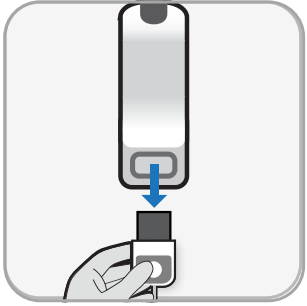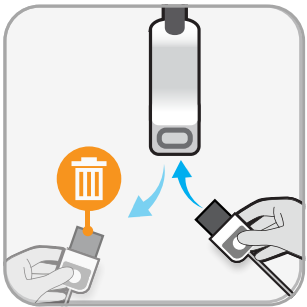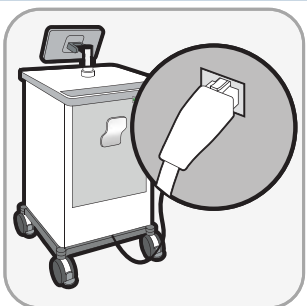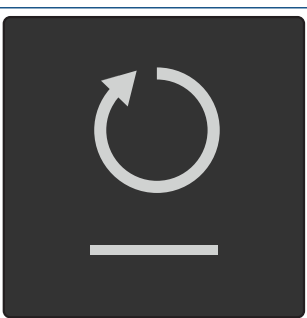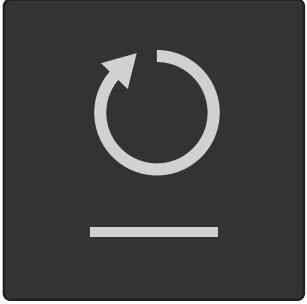
Figure 74 Guidance on the touch screen of the LumiGuide Engine

Legend	
1	Nature of the issue
2	High-level guidance
3	Illustrated guidance

You should attempt to resolve the issue using the illustrated guidance, starting from the first illustration on the left. If this does not solve the issue and the error message persists, continue with the next resolution, moving from left to right until the issue is resolved. If the issue cannot be resolved using this guidance, you are advised to contact technical support.

The table below summarizes the illustrations and explains the guidance you are expected to follow when attempting to resolve the issues.

Guidance Illustration	Guidance Information
	Clean the optical connector by using the fiber cleaning pen Use the fiber cleaning pen to clean the optical connector within the connection slot of the connection box. Perform the following steps: 1 Take the cleaning pen and remove its cap. 2 Lift up the lid of the connection slot. 3 Insert the pen into the optical connection, and push the cleaning pen in and out for at least 3 times.
	Reconnect the Guidewire Disconnect and then re-insert the AltaTrack Guidewire in the connection slot.

Guidance Illustration	Guidance Information
	Remove the Guidewire Remove the AltaTrack Guidewire from the connection slot.
	Replace the Guidewire Disconnect the current AltaTrack Guidewire and discard it. Replace the AltaTrack Guidewire with a new one and connect it to the connection slot.
	Check network cable Check that the network cable is connected between LumiGuide Engine and LumiGuide WorkSpot.
	Check status of LumiGuide WorkSpot Check that the LumiGuide Viewing Software on the LumiGuide WorkSpot is on.
	Re-initialize Tap this button to re-initialize the LumiGuide Equipment. **NOTE** ***Re-initializing the LumiGuide Engine can take up to 30 seconds.***

Guidance Illustration	Guidance Information
	Re-start Tap this button to re-start the LumiGuide Engine. **NOTE** ***Restarting the LumiGuide Engine will take 2-3 minutes.***
	Calibrate Tap this button to recalibrate the LumiGuide Equipment.
	Contact Philips technical support Contact Philips technical support and provide the error number indicated below the image on the LumiGuide Engine touch screen.

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

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