PHILIPS

Instructions for Use

English

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# Philips AltaTrack Equipment - US

Release 1.0

# Contents

# 1 Introduction

**About the AltaTrack Equipment**

The AltaTrack equipment is used in conjunction with a Philips Interventional X-ray system and with AltaTrack angiographic devices such as AltaTrack Catheter and AltaTrack Guidewire. The AltaTrack equipment uses FORS (Fiber-Optic RealShape) technology to provide a real-time 3D image of the shape of a connected AltaTrack angiographic device. The AltaTrack equipment overlays the FORS shape on anatomical images such as a pre-procedural CT volume and X-ray images from the X-ray system.

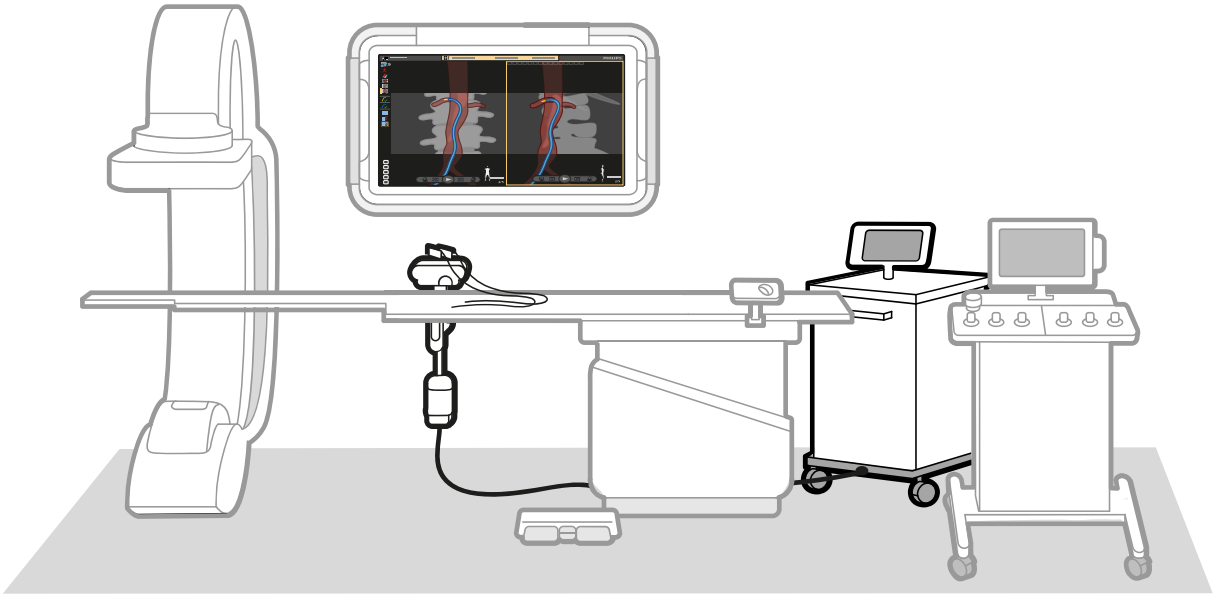

**Figure 1** AltaTrack equipment in the examination room

After setting up the AltaTrack equipment in examination room and starting the procedure, the equipment displays live guidance images on the monitors.

Tasks in the AltaTrack software guide you through the following phases to prepare and view the overlay image:

- Segmenting the pre-operative 3D data set to identify vessels.
- Planning views and tagging anatomical landmarks to assist with device navigation.
- Registering the pre-operative 3D data set with the X-ray system to provide a matched overlay image.
- Registering the AltaTrack device or devices with the X-ray system.
- Providing live guidance through a real-time 3D image of the shape of the AltaTrack devices and pre-operative 3D data-set with X-ray images during the interventional procedure.

## 1.1 About These Instructions for Use

These Instructions for Use are intended to assist you in the safe and effective operation of the AltaTrack equipment.

The AltaTrack equipment can be identified by the label on the AltaTrack trolley.

All Instructions for Use supplied with the AltaTrack equipment are identified using the name and release number (first two digits) of the software, as indicated in the footer of the document. Before using these Instructions for Use with the AltaTrack equipment, ensure that it corresponds with the software installed.

These Instructions for Use may describe some products or features that are not available in all countries. Please contact your local sales representative for the availability of products and features in your region.

Before attempting to operate the product, you must read these Instructions for Use, noting and strictly observing all **WARNING** and **CAUTION** notices.

**WARNING**
***A warning alerts you to a potential serious outcome, adverse event, or safety hazard. Failure to observe a warning may result in death or serious injury to the operator or patient.***

**CAUTION**
***A caution alerts you when special care is necessary for the safe and effective use of the system or equipment. Failure to observe a caution may result in moderate personal injury or damage to the equipment, and presents a remote risk of more serious injury or environmental pollution.***

**NOTE** ***Notes highlight unusual points as an aid to the operator.***

Pay special attention to all the information given and procedures described in the Safety section.

To identify the Instructions for Use and the software tool for which they are intended to be used, the product can be identified using the **About** box of the related software tool. The **About** box indicates the following:

- Name of the software tool
- Release number of the software tool

## 1.2 Intended Use

This Philips product is intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in these Instructions for Use for the purposes for which it was designed.

The purposes for which the product is intended are given below. However, nothing stated in these Instructions for Use reduces operators' responsibilities for sound clinical judgment and best clinical procedure.

Installation, use, and operation of this product are subject to the law in the jurisdictions in which the product is being used. Operators must only operate the product in such a way as to not conflict with applicable laws, or regulations that have the force of law.

Uses of the product for purposes other than those intended and expressly stated by the manufacturer, as well as incorrect use or operation, may relieve the manufacturer (or the manufacturer's agent) from all or some responsibility for resultant non-compliance, damage, or injury.

**CAUTION**
***In the United States, Federal law restricts this device to sale, distribution, and use by, or on the order of, a physician.***

### 1.2.1 Intended Use of the AltaTrack Equipment

The AltaTrack Equipment is an imaging device with Fiber Optic RealShape (FORS) technology intended to aid the positioning and navigation of a connected AltaTrack Catheter and/or AltaTrack Guidewire during endovascular procedures of the peripheral, aortic and aortic side branch vasculature, by creating a 3D image in real time of an AltaTrack Catheter and/or AltaTrack Guidewire.

# 1.3 Compatibility

AltaTrack can be used with a compatible Philips interventional X-ray system that is equipped with appropriate options. For details of compatible systems, contact the manufacturer.

The product described in this manual should not be used in combination with other products or components unless such other products or components are expressly recognized as compatible by Philips Medical Systems. A list of such products and components is available from the manufacturer.

The AltaTrack Catheter and AltaTrack Guidewire are not to be robotically actuated.

Changes or additions to the product should only be carried out by Philips Medical Systems or by third parties expressly authorized by Philips Medical Systems to do so. Such changes or additions must comply with all applicable laws and regulations that have the force of law within the jurisdictions concerned, and with best engineering practice.

AltaTrack is only intended to be used with the PC hardware configuration on which it is initially installed by the manufacturer. AltaTrack may only be installed or reinstalled by authorized service personnel.

Changes to the network connection or configuration may lead to non-performance or reduced performance of the product or the connected system.

## 1.3.1 Data Sets

You can open AltaTrack data indicated by the following icon:

### Overlay Data Sets

You can use a preoperative CT volume as a roadmap (overlay) during device navigation with the AltaTrack equipment.

You can import overlay volumes and data sets from CD, DVD, USB memory device, or from a PACS server. For details, refer to the Interventional Workspot Instructions for Use.

### CT Volumes

To use a CT volume as an overlay with the AltaTrack equipment, the volume must be DICOM compliant and satisfy the following requirements:

- CT angiography volume
- Single phase
- No gantry tilt
- Reconstructed with a regular grid

**NOTE** ***Volumes should contain peripheral vasculature and should not contain only cardiac or intercranial anatomy.***

**NOTE** ***Volumes larger than 400 MB are automatically down-sampled when imported.***

### CT Data Sets

CT images should be used wherever possible to assist with live guidance. The AltaTrack equipment supports CT data sets that are DICOM-compliant and that fulfill the following requirements.

- The distance between the slices is equal.
- The pixel spacing for each slice in both directions in the series is equal (square pixels).

- Two bytes per voxel shall be used (bit allocated is 16).
- The series contains at least 4 slices with a different slice location.
- All slices must have the same dimensions: 512 × 512 voxels of 2 bytes each.
- The format is classic DICOM (enhanced DICOM is not supported).
- The CT series must be contrast enhanced.

**NOTE** ***The recommended slice thickness is between 0.6 mm and 0.8 mm, with a maximum of 1 mm.***

**NOTE** ***When using a data set with more than 1600 slices, AltaTrack truncates the whole volume from cranial to caudal, using only the first 1600 slices.***

**NOTE** ***If you use derived DICOM data sets, AltaTrack may not work correctly. It is recommended that you do not use this type of data set.***

For details of importing data, refer to the Interventional Workspot Instructions for Use.

For details of compatible CT scanners, refer to the DICOM conformance statement for this product (available from the manufacturer).

**Rotational Series**

To assist with registering a CT volume with the X-ray system, you can use a 3D-RA volume or an XperCT volume. The AltaTrack equipment supports all standard non-neuro and non-intercranial 3D-RA series and XperCT series that have been created with the frontal stand of a compatible X-ray system.

### 1.3.2 Sterile Covers

Sterile covers up to a thickness of 0.5 mm are supported. The hospital should evaluate the integrity and suitability of a particular sterile cover when used with the clamping mechanism of the AltaTrack docking base and the AltaTrack Docking Top before using the sterile cover during a procedure.

## 1.4 Training

Operators of this product must have received adequate training on its safe and effective use before attempting to operate the product described in this Instructions for Use. Training requirements for this type of device will vary from country to country. Operators must make sure they receive adequate training in accordance with local laws or regulations. As a minimum level of training, operators should read and understand these Instructions for Use.

If you require further information about training in the use of this product, please contact your local Philips Medical Systems representative. Alternatively, contact the manufacturer.

## 1.5 Contacting the Manufacturer

| Manufacturer's Address |
| --- |
| Philips Medical Systems Nederland B.V.<br>Veenpluis 4-6<br>5684 PC Best<br>The Netherlands |

# 2 Safety

All Philips Medical Systems products are designed to meet stringent safety standards. To safeguard human safety all medical device software requires proper installation, use, and maintenance.

It is vital that you read, note, and where applicable strictly observe all notices and safety markings on the equipment.

To help ensure the safety of both patients and operators, it is vital that you strictly follow all directions under the heading Safety and all warnings and cautions displayed on the equipment or provided in these Instructions for Use.

Only qualified and authorized personnel may operate this product. In this context, qualified means those legally permitted to operate this type of medical electrical product in the jurisdictions in which the product is being used, and authorized means those authorized by the responsible organization.

Personnel operating the product and personnel in the examination room must observe all laws and regulations which have the force of law within the jurisdictions concerned. If you are in any doubt about the laws and regulations which apply to the operation of this product, do not use it.

The equipment has no performance that is determined to be essential performance.

## 2.1 Emergency Procedures

**Loss of Roadmap**
You should revert to using the interventional X-ray system if any of the following situations occur:
- The CT volume does not follow the geometry.
- APC is unavailable.
- The AltaTrack live image guidance software does not receive X-ray images.

## 2.2 Radiation Safety

For radiation safety please refer to the Safety section of the Instructions for Use supplied with the X-ray system.

## 2.3 Electrical Safety

Follow the electrical safety guidelines in this section. Failure to do so could cause serious or fatal injury to the patient, and could damage the equipment.

The room where the system is used must comply with all applicable laws and regulations, or regulations concerning electrical safety for this type of equipment. The combination of the system and the connected equipment must comply with the requirements for medical electrical systems as specified in the IEC 60601-1 standard.

**Voltages**
Dangerous electrical voltages are present within the system. Covers or cables should only be removed by qualified and authorized service personnel.

**WARNING**
***Do not touch electrical or network connectors on the patient table, the AltaTrack trolley, or the AltaTrack equipment cable while simultaneously touching the patient. Connector contact pins may carry low voltages that are safe to touch, but that may be harmful to the patient.***

### Electrical Grounding (Earth)

**WARNING**
***To avoid risk of electric shock, this equipment must only be connected to supply mains with protective earth.***

You can only connect medical equipment to the system if that equipment is galvanically isolated from the system. For medical equipment interfacing using Ethernet, video, or USB, galvanic isolation is ensured by using a wall connection box. For more information, contact technical support.

### Protection Against Patient Leakage Current

An equipotential ground connection point is provided at the base of the patient table. If an operating table is installed, the ground connection point is located on the surgery wall connection box. For more information, contact technical support.

### Cables

Electrical current may still be present in cables that are no longer connected to the system, but that are still connected to the wall connection box. Store these cables on the cable holder outside the patient environment. If the cable holder is located inside the patient environment, ensure that the connectors are covered with a rubber cap. If a cap is not available, take precautions to prevent cable connectors from coming into contact with liquids.

Do not use multiple socket outlets or extension cables for installing or connecting any part of the system. Such cables can compromise the electrical safety of the system, especially for equipment in the examination room near the patient.

### Cleaning

Switch the system off before cleaning or disinfecting it. Do not use cleaning agents or damp cloths on connector contact pins. For more information, see *Cleaning the AltaTrack Equipment* (page 71).

## 2.4 Mechanical Safety

### Avoiding Collisions

**WARNING**
***No modification of this equipment is allowed.***

**WARNING**
***Do not modify this equipment without authorization of the manufacturer.***

**WARNING**
***Ensure that the AltaTrack docking base is securely fixed to the table rail at an appropriate position. If the AltaTrack docking base falls off, or if there is any intentional or unintentional movement of the AltaTrack docking base, there is a risk of injury to the patient and the sterile field may be compromised. You must also perform registration for all devices again.***

**CAUTION**

***The connection box hangs below the level of the tabletop and is susceptible to collisions with the table base or the stand if the table is moved. Take care to avoid such collisions to prevent damage to the equipment or loss of registration. If necessary, re-register the device after moving the table.***

**CAUTION**

***If the patient moves during the procedure, or if the AltaTrack docking base is moved along the table rail, or if any movement causes any part of the AltaTrack equipment to collide with the stand, table, or personnel in the examination room, you must perform registration for all devices again.***

**X-ray System**

For safety information about avoiding collisions when using equipment belonging to the X-ray system (for example, the stand or the table), refer to the Instructions for Use supplied with the X-ray system.

## 2.5 Laser Safety

The AltaTrack equipment contains a class 1 laser (IEC classification).

**WARNING**

***Laser radiation. Avoid direct eye exposure. Class 1 laser product.***


## 2.6 Explosion Safety

Using the system in an environment for which it was not designed can cause fire or explosion.

Do not use the system in the presence of explosive gases or vapors, such as certain anaesthetic gases.

Do not use flammable or potentially explosive disinfectant sprays. For more information, see *Cleaning the AltaTrack Equipment* (page 71).

## 2.7 Fire Safety

Fire regulations for the type of medical environment being used should be fully observed, applied, and enforced. Using the system in an environment for which it was not designed can cause fire or explosion.

Fire extinguishers should be available for both electrical and non-electrical fires. Only use fire extinguishers on electrical or chemical fires that are specifically labeled for those purposes. Using water or other liquids on an electrical fire can cause fatal or serious personal injury.

If it is safe to do so, switch off the system before attempting to fight a fire. This reduces the risk of electric shocks.

## 2.8 Electromagnetic Compatibility

Medical electrical products require precautions regarding electromagnetic compatibility, and shall be installed and put into service according to information provided in the accompanying documents.

**WARNING**
***Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.***

**WARNING**
***Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.***

**WARNING**
***Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the AltaTrack equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.***

**NOTE** ***The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.***

The AltaTrack equipment is a medical electrical system consisting of class A, group 1 equipment.

Do not use the AltaTrack equipment in the vicinity of magnetic resonance imaging (MRI) equipment or high-frequency (HF) equipment.

The AltaTrack equipment is intended for use in a professional healthcare environment. Operation in any other environment may compromise electromagnetic compatibility. The AltaTrack equipment and its components shall not be directly connected to the public low-voltage power supply network.

The AltaTrack equipment complies with relevant international and national laws and standards (IEC60601-1-2) on electromagnetic compatibility for this type of product, when it is installed and used as intended. These laws and standards define both the permissible electromagnetic emission levels from the AltaTrack equipment and its required immunity to electromagnetic interference from external sources.

Other electronic products that exceed the limits defined in these standards could, in unusual circumstances, affect the operation of the AltaTrack equipment. Note the following:

- Radio services operating in frequency bands and disturbance characteristics that are not covered by CISPR11 edition 5 may be disturbed. If safety critical radio services are used in or near the facility where the AltaTrack equipment is used, the responsible organization should evaluate the risks associated with radio disturbance.
- Mobile devices can affect medical electrical equipment. Use caution when using such devices within the specified range of medical electrical devices.

### 2.8.1 FCC Part 15.19

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received including interference that may cause undesired operation.

## 2.9 Equipment Labels

### AltaTrack Equipment

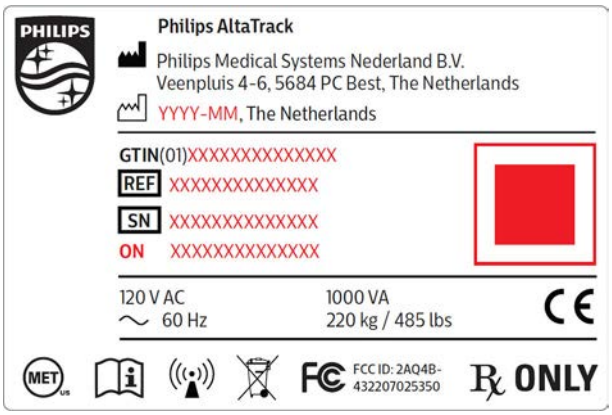


**Figure 2** AltaTrack equipment label

For information about the symbols used on this label, see *Symbols Used on the Equipment* (page 14).

### AltaTrack Docking Top

For more information about the AltaTrack Docking Top, refer to the Instructions for Use supplied with the AltaTrack Docking Top.

### AltaTrack Devices

For more information about the AltaTrack Catheter or AltaTrack Guidewire, refer to the Instructions for Use supplied with the respective device.

## 2.10 Symbols Used on the Equipment

**Power On**: This symbol identifies the mains switch on the AltaTrack trolley. When the green indicator light of the mains switch is illuminated, the AltaTrack trolley is powered on.

**Power Off**: This symbol identifies the mains switch on the AltaTrack trolley. When the green indicator light of the mains switch is not illuminated, the AltaTrack trolley is powered off.

**NOTE** ***The mains switch isolates its circuits electrically from the supply mains on all poles simultaneously.***

**Alternating Current**: This symbol indicates the presence of alternating current.

**Type B**: For more information, see *Applied Parts* (page 16).

**IPNN**: This symbol indicates the degree of protection of an enclosure and is regulated by IEC 60529. The first digit indicates the degree of protection for dust or solid objects, and the second digit indicates the protection against ingress of water.

**Manufacturer**: This symbol identifies the medical device manufacturer, as defined in EU Directive 93/42/EEC. The date of manufacture, as well as the name and address of the manufacturer, can be combined in one symbol.

**Date of Manufacture**: This symbol indicates the date when the medical device was manufactured.


**Catalog Number**: This symbol indicates the manufacturer's catalogue number so that the medical device can be identified. This symbol may be shown without the enclosure.


**Serial Number**: This symbol indicates the manufacturer's serial number so that a specific medical device can be identified. This symbol may be shown without the enclosure.

**Consult the Instructions for Use**: This symbol instructs the user to consult the Instructions for Use.

**Radio Frequency Transmitters**: This symbol indicates the presence of radio frequency transmitters.

**Product Disposal**: For more information, see *Final Disposal of the AltaTrack Equipment* (page 72).

**CE Certification**: This symbol indicates that the equipment complies with the European Communities regulation. The number of the notified body is indicated, if applicable.

**FCC**: This symbol, together with the FCC ID, indicates that the product conforms to FCC regulations.


**MET Certification**: This symbol indicates that the equipment is tested and approved by the National Test Laboratory MET.


**Prescription Only**: This symbol indicates that the device shall only be used by a practitioner qualified to use the device.

## 2.11 Hazardous Substances

Parts of the system may contain hazardous substances that must be recycled or disposed of in accordance with local, state, or federal laws.

### Perchlorate

Perchlorate material is present in lithium coin cells or batteries that are used in the system. Special handling may apply. For information, go to the following website:

www.dtsc.ca.gov/hazardouswaste/perchlorate

### REACH Declaration

REACH requires that Philips Medical Systems provides chemical content information for Substances of Very High Concern (SVHC) if they are present in amounts above 0.1% of the product weight. Components with electric or electronic equipment may contain phthalates above the threshold (for example, bis(2-ethyl(hexyl)phthalate), CAS nr.: 117-81-7). Philips Medical Systems is still in the process of investigating its supply chain to further establish which components contain phthalates. The SVHC list is updated on a regular basis. For the latest list of products that contain SVHC above the threshold, go to the following website:

www.philips.com/about/sustainability/reach

## 2.12 Applied Parts

An applied part is a part of the equipment that in normal use satisfies one of the following conditions:

- The part must come into physical contact with the patient for the equipment to perform its function.
- The part can be brought into contact with the patient.
- The part needs to be touched by the patient.

Normal use is defined as "operation, including routine inspection and adjustments by any OPERATOR, and stand-by, according to the instructions for use".

The following parts are regarded as applied parts:

- AltaTrack Catheter
- AltaTrack Guidewire

For more information about these parts, refer to the Instructions for Use supplied with the part.

## 2.13 Warning Messages

The following warning messages may be displayed in the **Live Guidance** task of the AltaTrack software.

| Message ID | Warning Message | Guidance |
|---|---|---|
| Int5 | Optical issue. See the AltaTrack touch screen for resolution | These are AltaTrack equipment (optical) issues. Follow the instructions on the AltaTrack touch screen. If the problem cannot be resolved contact technical support. |
| Int6 | Optical issue. See the AltaTrack touch screen for resolution | |
| Int19 | System issue. See the AltaTrack touch screen for resolution | |
| Int20 | Optical issue. See the AltaTrack touch screen for resolution | |
| Int39 | AltaTrack issue | These are AltaTrack angiographic device issues. Relax the bend in the device. If the problem cannot be resolved, replace the device. |
| Int40 | AltaTrack issue. Relax the distal device bend | |
| Int41 | AltaTrack issue. Relax the proximal device bend | |
| SS14 | Unsupported device combination. See the AltaTrack touch screen for resolution | The AltaTrack equipment has detected that there is an unsupported AltaTrack device combination connected. When two AltaTrack devices are connected, it should be an AltaTrack Guidewire and an AltaTrack Catheter. |
| SS17 | The device has been used before. See the AltaTrack touch screen for resolution | The AltaTrack equipment has detected that the connected device has been used before, 24 HOURS PRIOR TO THIS CONNECTION. |
| VS2 | Shapes are not registered. Perform shape registration | The AltaTrack equipment has detected that the AltaTrack devices are not registered to the X-ray system. Perform shape registration first. |
| VS3 | Shape registration may be inaccurate. Check fluoroscopy | The AltaTrack equipment has detected that the shape accuracy could have been compromised. Use fluoroscopy to check the alignment of the shape to X-ray. |
| VS4 | The table or stand has moved. Check fluoroscopy | The AltaTrack equipment has detected that the table or the gantry has been moved. These movements could compromise the shape accuracy. Use fluoroscopy to check the alignment of the shape to X-ray. |
| VS5 | The roadmap may be inaccurate. Check the position of the X-ray system | The X-ray system is in an uncalibrated position and could compromise the shape accuracy. Move X-ray system back to a calibrated position. |

| Message ID | Warning Message | Guidance |
|---|---|---|
| VS6 | No imaging performed for 5 minutes. Check fluoroscopy | The AltaTrack equipment has detected that there was no X-ray used for more than 5 minutes. The AltaTrack equipment must always be used in combination with X-ray. Use fluoroscopy to check the alignment of the shape to X-ray. |
| VS22 | The patient data does not match with the current patient on the X-ray system. Verify the patient's identity and merge the patient information | The AltaTrack equipment has detected that patient selected in the AltaTrack software differs from the current patient on the X-ray system. Verify the patient identity and merge the patient information on the AltaTrack software. |

# 3 Equipment Overview

The AltaTrack equipment integrates with the existing Philips interventional X-ray system in the examination room and in the control room.

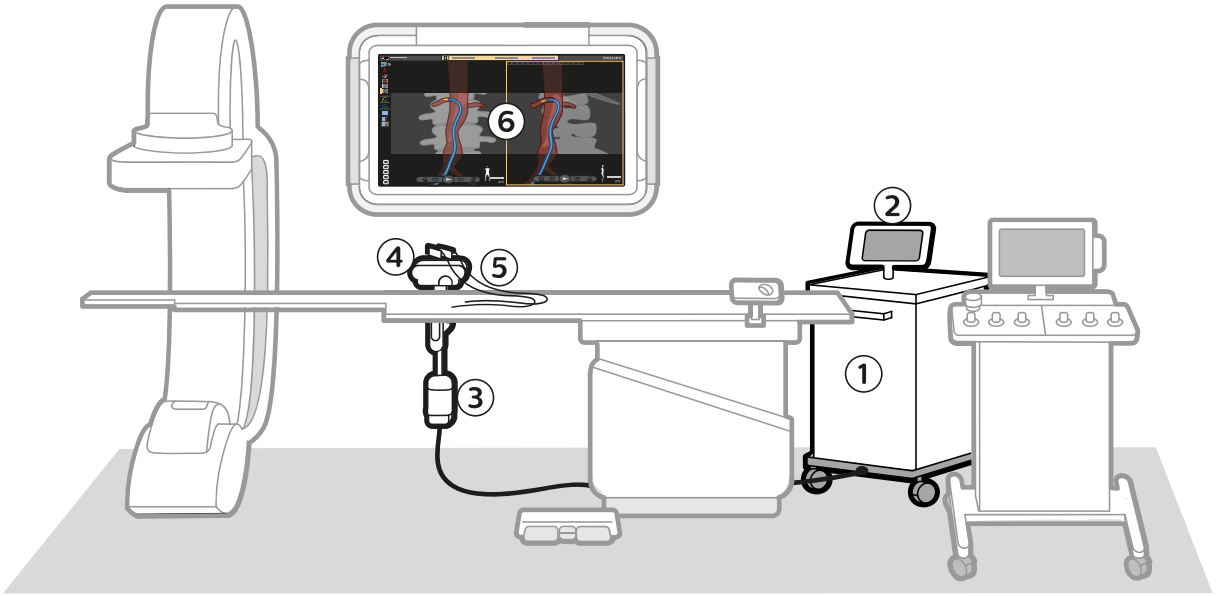


**Figure 3** AltaTrack equipment overview

| Legend | | | |
|---|---|---|---|
| 1 | AltaTrack trolley | 4 | AltaTrack Docking Top |
| 2 | AltaTrack touch screen | 5 | AltaTrack devices |
| 3 | AltaTrack docking base | 6 | AltaTrack software displayed in the examination room |

You can use the touch screen module (TSM) and the tableside mouse of the X-ray system to view images produced by the AltaTrack equipment on the monitors in the examination room. If a mouse is not available in the examination room with the X-ray system, one is provided with the AltaTrack equipment.

AltaTrack images can be viewed on monitors in the control room, where data preparation tasks can also be performed.

## 3.1 AltaTrack Trolley

The AltaTrack trolley contains the core hardware of the AltaTrack equipment. It is connected to the AltaTrack docking base by the AltaTrack equipment cable. The AltaTrack trolley has a storage hook for the docking base when it is not in use. The AltaTrack trolley is also connected to AltaTrack workstation, providing real-time 3D visualization of device shapes on monitors in the examination room and in the control room.

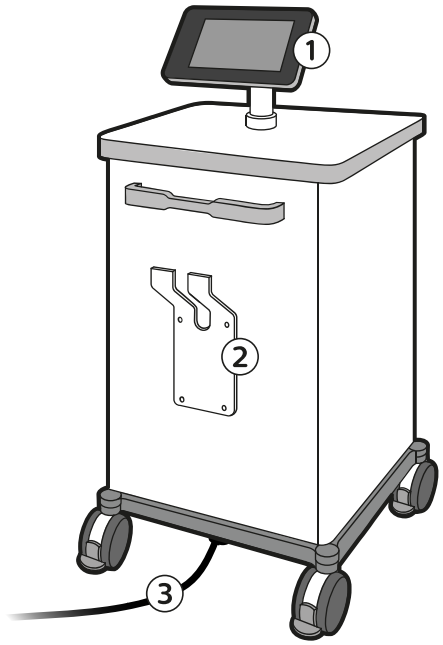


**Figure 4** AltaTrack trolley

| Legend | |
|---|---|
| 1 | AltaTrack touch screen |
| 2 | AltaTrack docking base storage hook |
| 3 | AltaTrack equipment cable |

The AltaTrack trolley can be moved to any suitable position outside the sterile zone in the examination room. A parking mechanism provides stability during use.

A rail and hook are provided on the front side of the AltaTrack trolley to store the AltaTrack docking base and the AltaTrack equipment cable while not in use. A hook is also provided on the rear side of the AltaTrack trolley to store the network cable and the power cable.

The AltaTrack trolley also has an adjustable touch screen accessible by non-sterile staff.

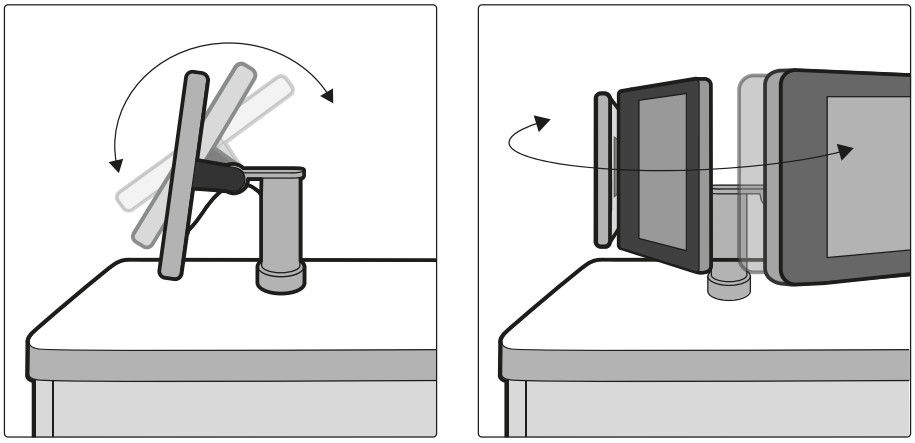

**Figure 5** AltaTrack touch screen

The AltaTrack touch screen display provides pre-procedural instructions for preparing the AltaTrack equipment. A status diagram displays the types of AltaTrack devices that are connected or parked.

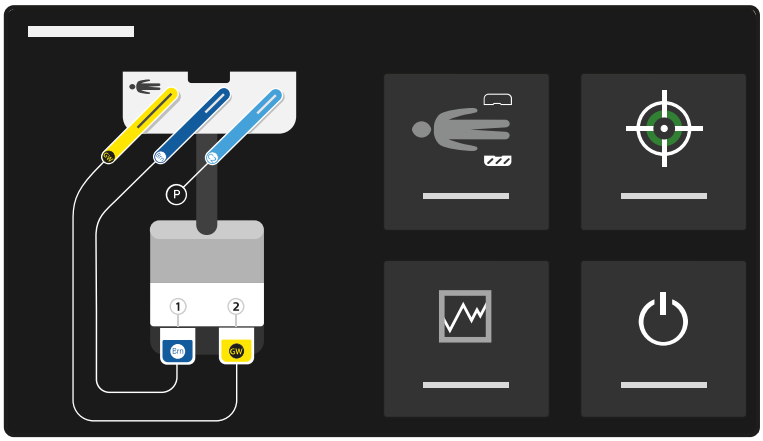

**Figure 6** AltaTrack touch screen display

The AltaTrack touch screen also provides user assistance if the AltaTrack equipment encounters issues during use. If an issue arises, an information bar is displayed at the top of the AltaTrack touch screen (the message is also displayed in the AltaTrack software window). Tap the information icon follow the instructions on the AltaTrack touch screen.

The AltaTrack touch screen is not suitable for use when wearing surgical gloves. For normal use, it is not necessary to touch the tablet's screen with gloves.

## 3.2 AltaTrack Docking Base

The AltaTrack docking base is clamped to the rail of the patient table. It provides an attachment point for the AltaTrack Docking Top and a fixed reference point that allows the AltaTrack device shapes to be registered with X-ray images.

**CAUTION**

***The connection box hangs below the level of the tabletop and is susceptible to collisions with the table base or the stand if the table is moved. Take care to avoid such collisions to prevent damage to the equipment or loss of registration. If necessary, re-register the device after moving the table.***

The AltaTrack docking base consists of the following parts.

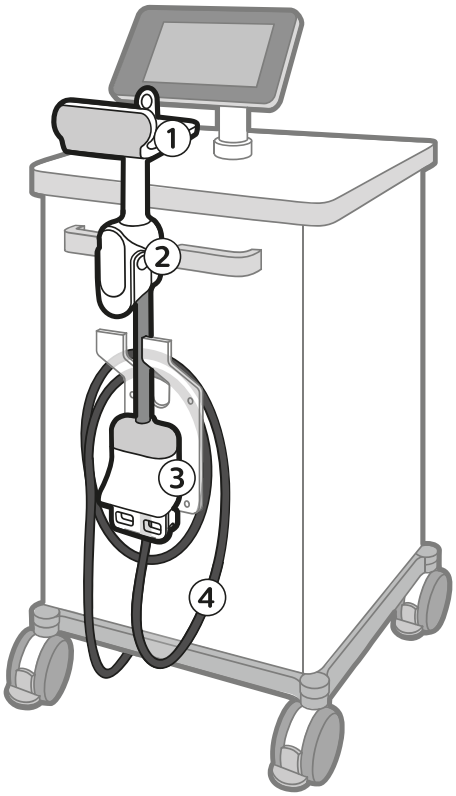


**Figure 7** AltaTrack docking base

| Legend | | | |
|---|---|---|---|
| 1 | AltaTrack docking base | 3 | AltaTrack connection box |
| 2 | AltaTrack table clamp | 4 | AltaTrack equipment cable |

The AltaTrack docking base can be attached to either side of the table. The AltaTrack Docking Top has an orientation indicator to guide you when attaching the AltaTrack Docking Top to the docking base. The AltaTrack Docking Top should be oriented so that inserted devices are always angled toward the feet end. For more information, see *Setting Up the AltaTrack Docking Base* (page 29).

The AltaTrack docking base can be detached from the table between procedures.

**WARNING**
***Detaching the AltaTrack docking base during a procedure may damage the sterile cover and cause a sterility breach.***

**NOTE** ***The AltaTrack docking base does not restrict X-ray geometry movements, or longitudinal and transverse patient table movements. However, the patient table cannot be tilted or cradled while using the AltaTrack equipment.***

### AltaTrack Connection Box

The AltaTrack connection box connects AltaTrack devices that are inserted in the AltaTrack Docking Top to the AltaTrack equipment. Additional slots are provided to assist with changing devices.

## 3.3 AltaTrack Software

The AltaTrack software is accessible in the control room and examination room to assist the physician during an endovascular interventional procedure by overlaying live reconstructed shapes on pre- and intra-procedural image data.

In preparation for the procedure, you can import the following volumes and images for use as a roadmap:

- Pre-procedural CT data from PACS or portable media
- Intra-procedural angiographic exposure images

The AltaTrack software database can only store a limited amount of image data. After the procedure, you should export acquired X-ray images and DICOM screenshots to PACS or other storage devices to ensure that free space is available for the next procedure. For information about exporting images, refer to the Instructions for Use supplied with the Interventional Workspot.

**CAUTION**

***If the free space in the AltaTrack software database falls below 10%, the AltaTrack equipment may not function as expected.***

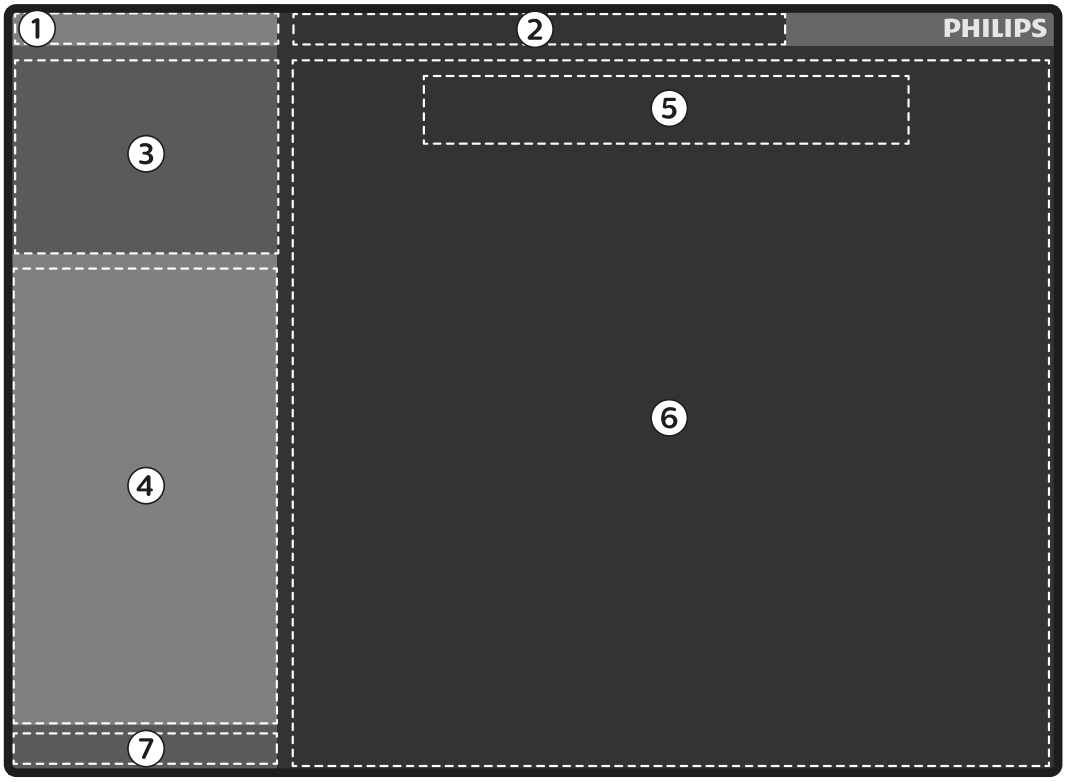


**Figure 8** AltaTrack software display layout

| Legend | | | |
|---|---|---|---|
| 1 | **Patients** button: Closes the application and displays the patient list. | 5 | User message area: Messages relating to device status and shape registration are displayed here when user action is needed to resolve an issue. |
| 2 | Patient information panel: Provides information about the patient including allergies and other health warnings. | 6 | Main display area: Displays X-ray images and device shape overlays. The CT volume is also displayed, if applicable. The configuration of the display depends on the selected task. |
| 3 | Task selection panel: Provides quick access to each task in the workflow. | 7 | Common tools panel: Provides tools for configuration, export, movies, and snapshots. |
| 4 | Task panel: Provides the functions associated with the task being performed. Moving to another task changes the controls and functions available in the task panel. | | |

### 3.3.1 Tasks

The task selection panel provides an overview of the workflow when using the AltaTrack software.

**Segmentation**

The **Segmentation** task is used with a preoperative CT volume (optional) to select anatomy to visualize and to identify vessels of interest for a clinical procedure. Segmentation activities include:

- Selecting a visualization method
- Setting a suitable viewing angle
- Segmenting the table and bones
- Segmenting vessels of interest
- Removing areas of anatomy to make segmentation easier

**Planning**

The **Planning** task is used with a preoperative CT volume (optional) to plan the procedure by preparing the AltaTrack equipment and the volume:

- Adding landmarks
- Preparing and storing viewing angles for use in the live guidance task

**Volume Registration**

The **Volume Registration** task is used with a preoperative CT volume (optional) to align the 3D volume with the images from the X-ray system. Two methods of performing registration are available:

- 2D registration, using 2D X-ray images
- 3D registration, using 3D rotational series

**Shape Registration**

The **Shape Registration** task is used to align the AltaTrack device shapes with the images from the X-ray system.

**Live Guidance**

The **Live Guidance** task provides a continuous overlay of the AltaTrack device shapes on the X-ray images and preoperative CT volume (if applicable). **Live Guidance** activities include:

- Recalling angles stored in the **Planning** task
- Navigating with the AltaTrack device shapes
- Making minor adjustments to registration to compensate for patient movement

The task selection panel can be opened or closed by clicking the expander.

## 3.4 AltaTrack Docking Top

The AltaTrack Docking Top is a single-use accessory that is supplied sterile. It attaches to the AltaTrack docking base on top of the sterile cover that covers the docking base.

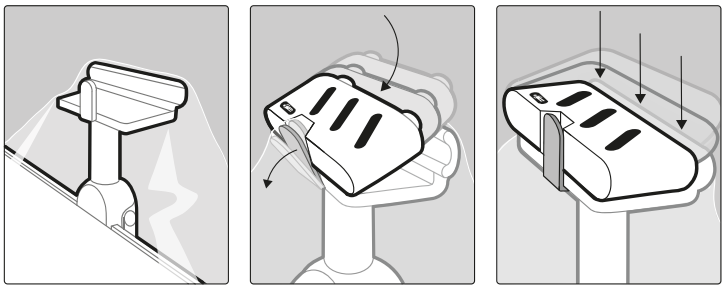

**Figure 9** AltaTrack Docking Top attached to the AltaTrack docking base

The AltaTrack Docking Top contains sterile slots for AltaTrack devices and is intended to provide a mechanical fixation of an AltaTrack Catheter or an AltaTrack Guidewire to the AltaTrack equipment within the sterile zone. The AltaTrack equipment automatically identifies devices when they are inserted in the AltaTrack Docking Top.

For more information about the AltaTrack Docking Top, refer to the Instructions for Use supplied with the AltaTrack Docking Top.

## 3.5 AltaTrack Devices

An AltaTrack device is a single-use item that used with the AltaTrack equipment and is supplied sterile. An AltaTrack device consists of a fiber-optic sensor integrated in an angiographic catheter or guidewire.

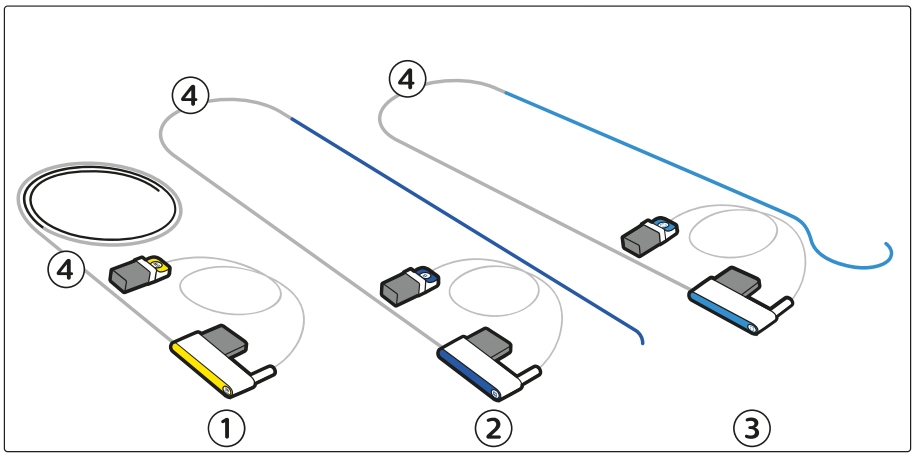


**Figure 10** AltaTrack devices

| Legend | | | |
|---|---|---|---|
| 1 | AltaTrack Guidewire | 3 | AltaTrack Catheter (Cobra 2) |
| 2 | AltaTrack Catheter (Berenstein) | 4 | Torque-absorbing section |

When using the AltaTrack equipment, you can use one or two AltaTrack devices and visualize them simultaneously. You can use the following configurations:

- An AltaTrack Guidewire with an AltaTrack Catheter
- A single AltaTrack device with any conventional angiographic device of a compatible size.

**NOTE** ***It is not possible to visualize two AltaTrack Catheter devices or two AltaTrack Guidewire devices simultaneously.***

The AltaTrack device is visualized as a real-time 3D shape by the AltaTrack equipment, providing live guidance and navigation in the vascular system when overlaid on a pre-procedural CT volume and X-ray images.

The AltaTrack devices have a torque-absorbing section that decouples rotation of the device's in-body section from the device's mechanical interface connected to the AltaTrack Docking Top.

**WARNING**

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

For more information about each AltaTrack device, refer to the Instructions for Use supplied with the device.

# 4 Preparing the AltaTrack Equipment for Use

## 4.1 Setting Up the AltaTrack Equipment

This section provides information about setting up the AltaTrack trolley, docking base, and AltaTrack Docking Top.

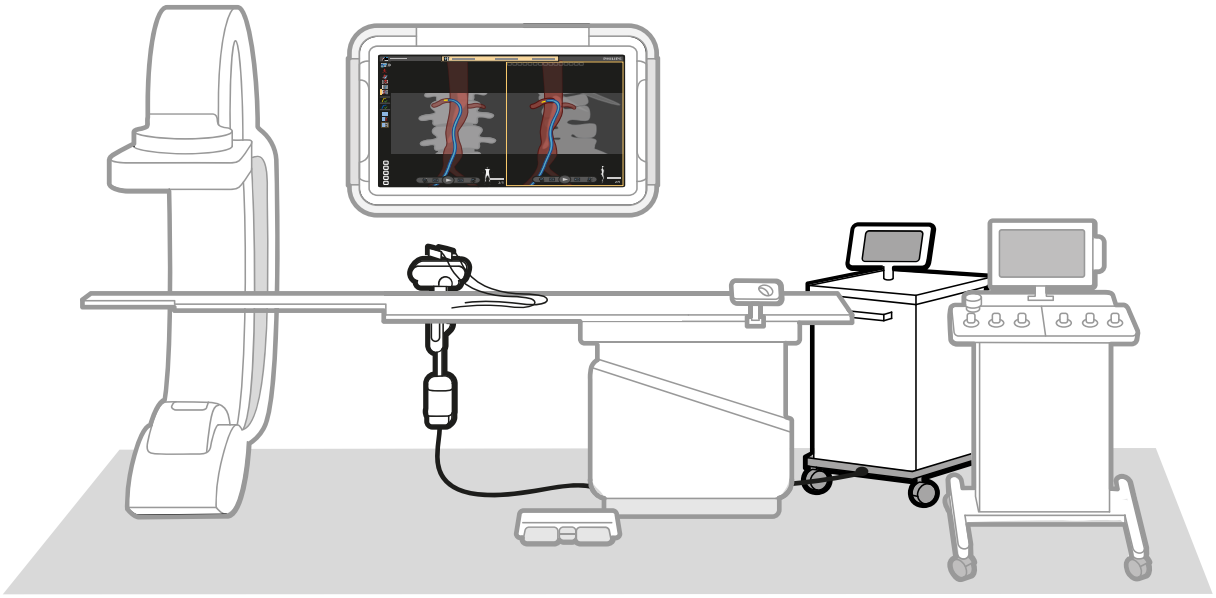

**Figure 11** AltaTrack equipment overview

### 4.1.1 Setting Up the AltaTrack Trolley

1 (**Non-sterile user**) Position the trolley in the examination room as follows:

- At least 1.5 m from the tabletop
- Outside the sterile field
- With the front of the trolley facing the patient table (the airflow outlet is located on the back of the trolley)
- Without blocking the working area of the clinical staff

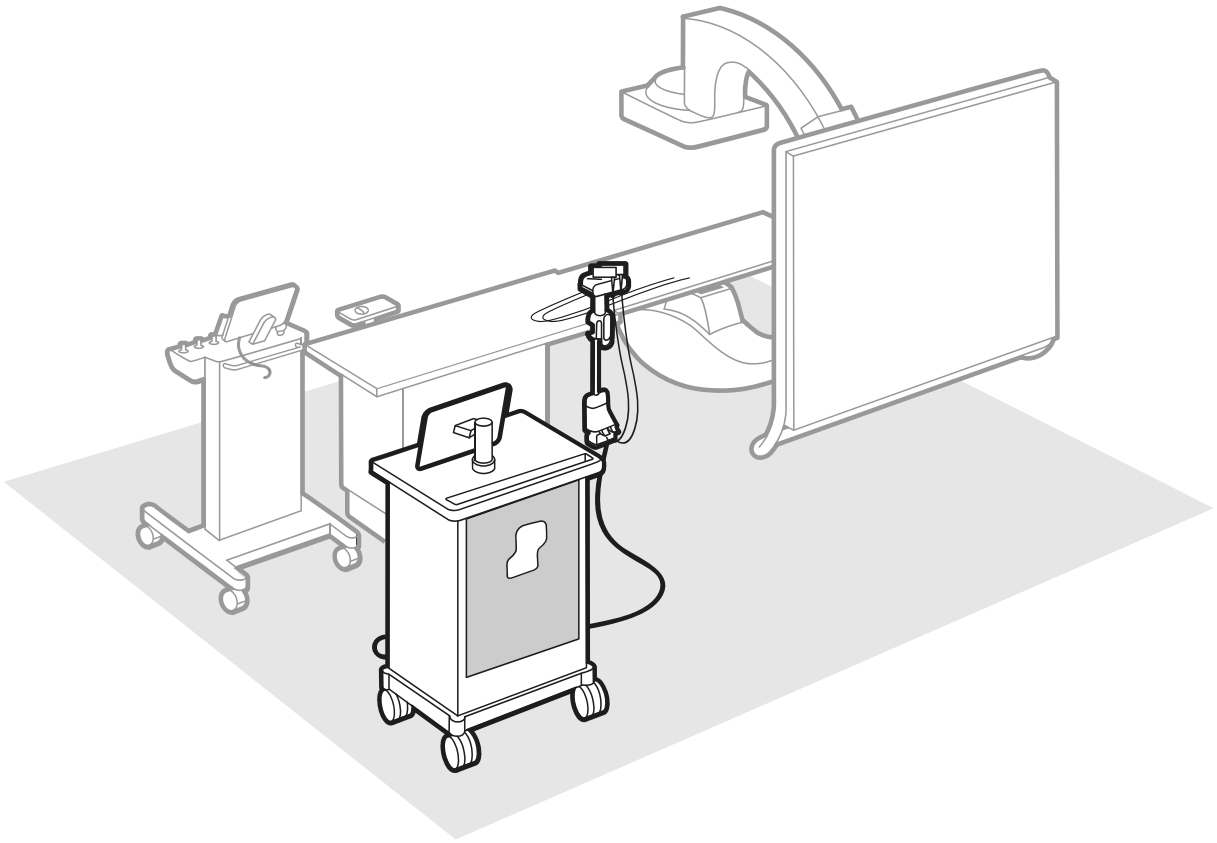

**Figure 12** AltaTrack trolley positioning

**CAUTION**
***If the AltaTrack trolley is incorrectly positioned and you have to move it during the procedure, you must perform registration for all devices again.***

**WARNING**
***Position the AltaTrack trolley in the examination room so that the airflow of the trolley does not influence the laminar airflow in the surgery room.***

Guidance on how to position the trolley is available on the AltaTrack touch screen.

2 (**Non-sterile user**) Apply the trolley brakes to park the AltaTrack trolley.

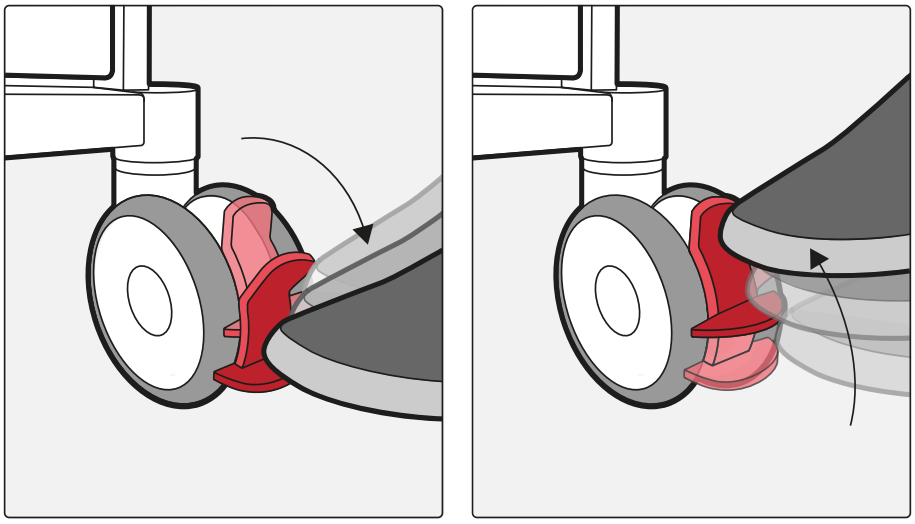

**Figure 13** AltaTrack trolley brakes: applying the brake (left) and releasing the brake (right)

3 (**Non-sterile user**) Connect the AltaTrack trolley cables:

**a** Connect the power cable to the power supply.

**b** Connect the network cable to the network.

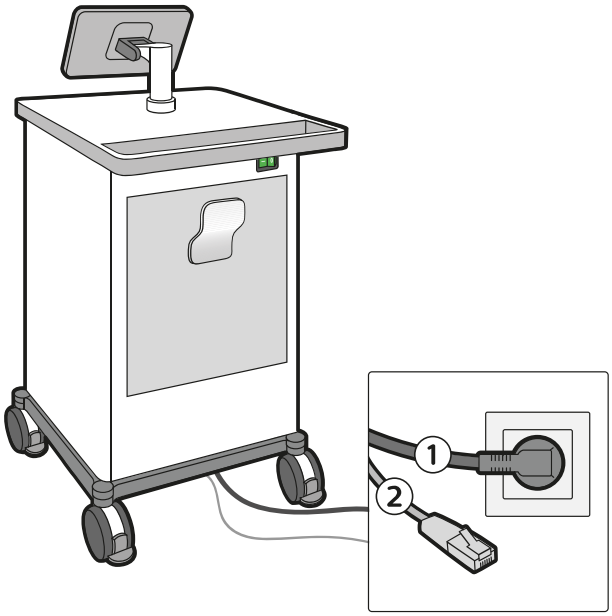


**Figure 14** AltaTrack trolley cables

| Legend | |
|---|---|
| 1 | Power cable |
| 2 | Network cable |

**WARNING**
***Do not touch electrical or network connectors on the patient table, the AltaTrack trolley, or the AltaTrack equipment cable while simultaneously touching the patient. Connector contact pins may carry low voltages that are safe to touch, but that may be harmful to the patient.***

**CAUTION**
***Position the power cable and network cable of the AltaTrack trolley so that they do not interfere with the working area of the clinical staff and cause anyone to trip.***

**CAUTION**
***Ensure that the network cable of the AltaTrack trolley is connected to the correct network port to allow proper communication of the equipment.***

**NOTE** ***The network connection of the trolley is only intended for point-to-point connection to the AltaTrack workstation. The connection characteristics are managed by the AltaTrack equipment.***

4 (**Non-sterile user**) Press the **Power On** switch on the trolley.

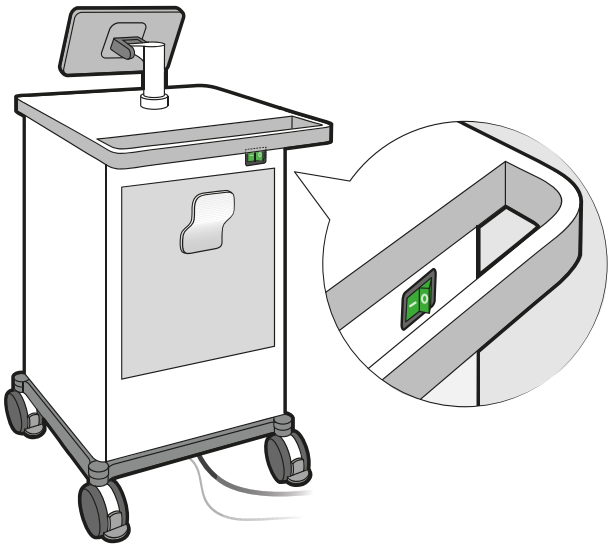

**Figure 15** AltaTrack trolley power switch

An indication of the start-up process is displayed on the AltaTrack touch screen on top of the trolley.

The AltaTrack equipment takes approximately 8 minutes to start up before it is available for use. This includes the time required for the laser to become available. However, controls for the AltaTrack equipment set-up software are available approximately 60 seconds after starting, for procedure preparation.

If a power outage occurs, the AltaTrack equipment restarts when power is restored and is available in approximately 3 minutes.

5 (**Non-sterile user**) Initialize the optical processing unit using the AltaTrack touch screen.

### 4.1.2 Setting Up the AltaTrack Docking Base

1 (**Non-sterile user**) Position the patient on the table. Do not place sterile covers yet.

**CAUTION**
***If a Maquet table is used, check that the rail is not fully extended as this will compromise the stability of the AltaTrack docking base.***

2 (**Non-sterile user**) Release the AltaTrack table clamp and remove the AltaTrack docking base from its storage position on the trolley.

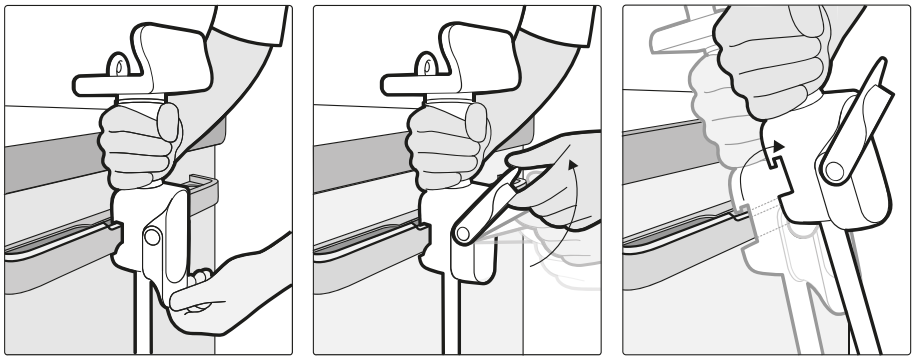

**Figure 16** Removing the AltaTrack docking base from its storage position

3 Using the AltaTrack table clamp, attach the AltaTrack docking base to the table accessory rail in a suitable position:

- At the level of the patient's knees
- So that it does not obstruct personnel or equipment in the examination room.
- So that the AltaTrack Catheter and AltaTrack Guidewire can comfortably reach the area of interest in the patient's body.

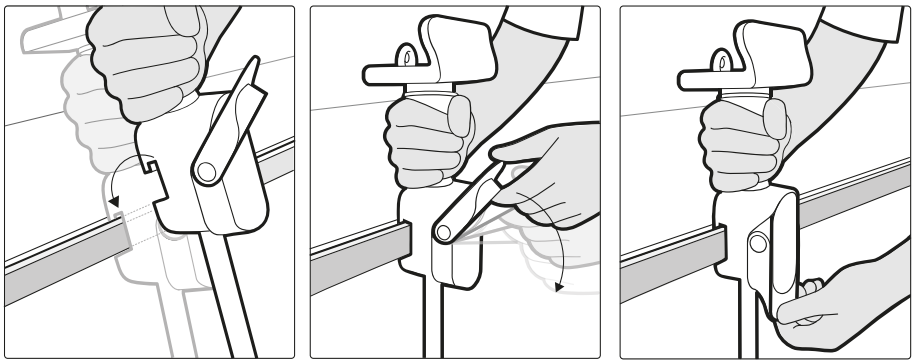

**Figure 17** Attaching the AltaTrack docking base to the table accessory rail

**NOTE** ***Do not attach the AltaTrack Docking Top to the AltaTrack docking base yet.***

Guidance on how to attach the AltaTrack docking base is also available on the AltaTrack touch screen.

**WARNING**
***Ensure that the AltaTrack docking base is securely fixed to the table rail at an appropriate position. If the AltaTrack docking base falls off, or if there is any intentional or unintentional movement of the AltaTrack docking base, there is a risk of injury to the patient and the sterile field may be compromised. You must also perform registration for all devices again.***

4 (**Non-sterile user**) On the AltaTrack touch screen, tap **Dock position** and then select the AltaTrack docking base orientation.

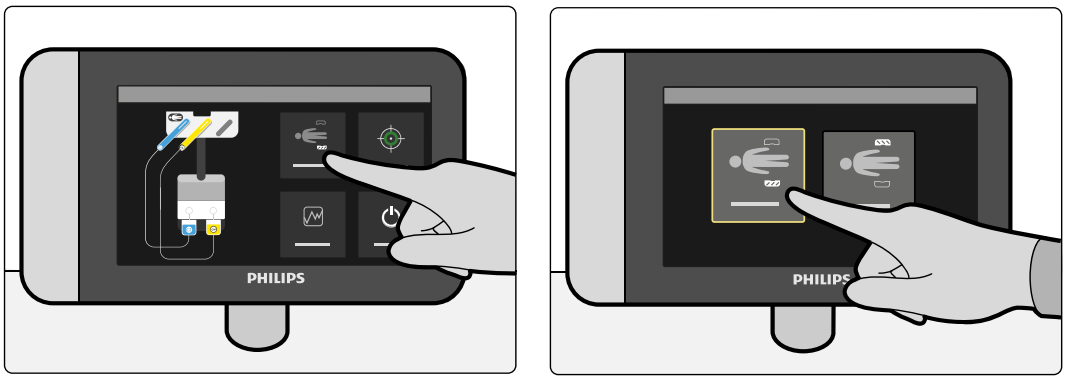


**Figure 18** Selecting the AltaTrack docking base orientation on the AltaTrack touch screen

5 (**Sterile user**) Place sterile covers over the patient and the AltaTrack docking base.

### 4.1.3 Setting Up the AltaTrack Docking Top

1 (**Non-sterile user**) Unpack the AltaTrack Docking Top and open the sterile pouch without touching the tray inside.

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

For information about unpacking the AltaTrack Docking Top, refer to the AltaTrack Docking Top Instructions for Use.

2 (**Sterile user**) Take the tray, remove the AltaTrack Docking Top, and do the following:

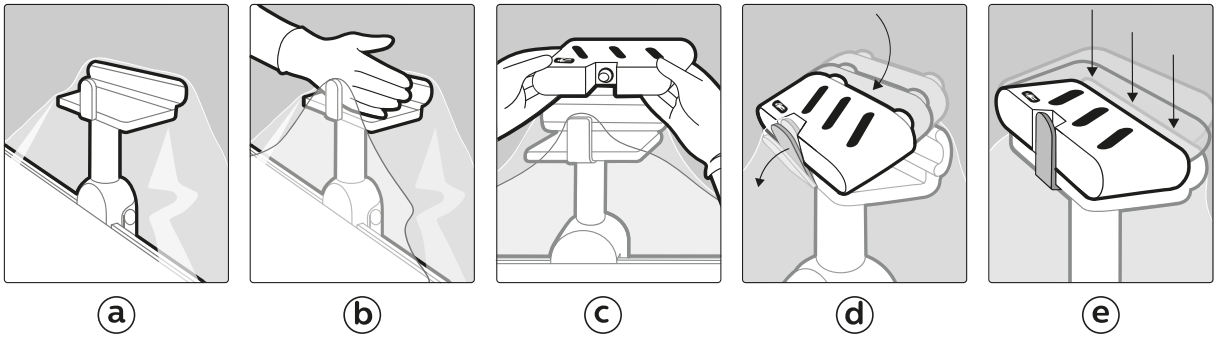


**Figure 19** Attaching the AltaTrack Docking Top

**a** Ensure that the AltaTrack docking base is covered with the sterile cover.

**b** Carefully push the sterile cover into the AltaTrack docking base recess to ensure that the AltaTrack Docking Top fits securely in the docking base.

**c** Ensure that the orientation indicator on the AltaTrack Docking Top matches the orientation of the patient on the table.

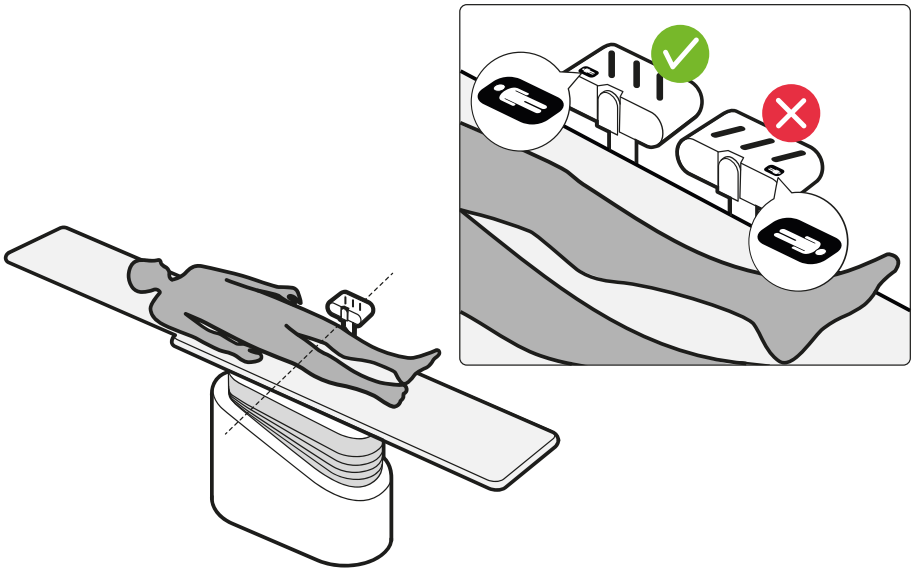

**Figure 20** AltaTrack Docking Top orientation

**d** Carefully insert the grooved edge of the AltaTrack Docking Top into the clip on the AltaTrack docking base.

**e** Carefully push the other edge of the AltaTrack Docking Top down into place on the AltaTrack docking base.

**WARNING**
***Take care when placing the AltaTrack Docking Top. Incorrect or repeated placing of the AltaTrack Docking Top may damage the sterile cover and compromise the sterile field.***

Guidance on how to attach the AltaTrack Docking Top is also available on the AltaTrack touch screen. If an issue is detected, guidance is provided on the AltaTrack touch screen: follow the steps to resolve the issue (the message is also displayed in the AltaTrack software window).

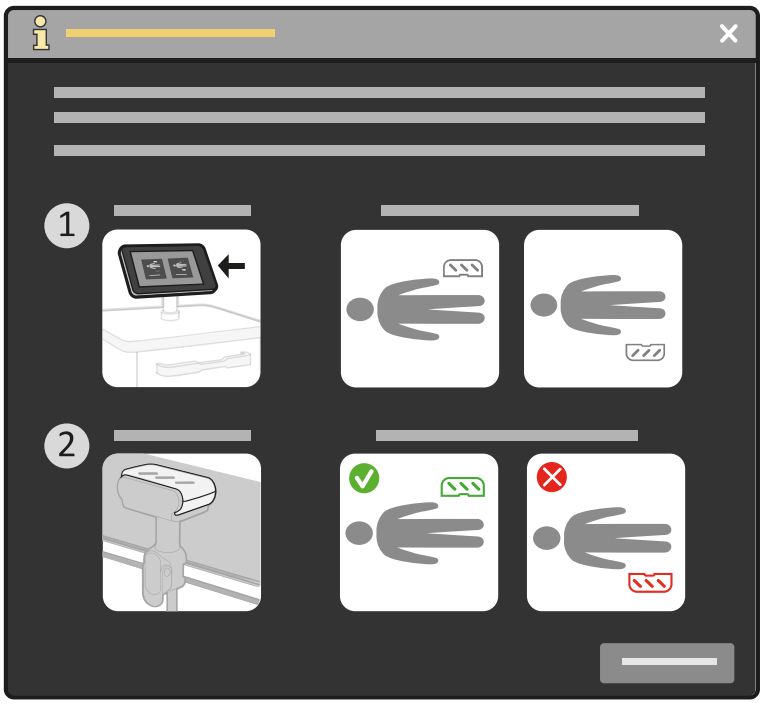


**Figure 21** Guidance is displayed on the AltaTrack touch screen when an issue is detected

Keep the AltaTrack Docking Top clean. Excessive blood may reduce the effectiveness of the docking action.

**WARNING**
***Do not apply force to the sterile cover or lean on the patient table, the AltaTrack Docking Top, or other items attached to the patient table. Doing so may cause misalignment of the shape with the anatomical roadmap.***

## 4.2 Starting the AltaTrack Software

**NOTE** ***Ensure that only one Interventional Workspot is turned on to ensure proper communication with the interventional X-ray system.***

You can use the AltaTrack software with or without a preoperative CT volume from the patient. If you use a preoperative CT volume, it provides additional navigation information during the **Live Guidance** task.

1 On the X-ray system, select or add the patient.

2 To start the AltaTrack software without using a preoperative CT volume during the procedure, do the following:

**a** On the touch screen module of the X-ray system, tap **Tools**.

**b** In the **Tools** screen, tap **Workspot**, then tap **AltaTrack**, and then tap **AltaTrack without CT**.

When using the AltaTrack software without a preoperative CT volume, the workflow consists of the following tasks:

| AltaTrack workflow without preoperative CT volume | |
|---|---|
| 1 | Setting up the AltaTrack devices |
| 2 | **Shape Registration** task (the AltaTrack software opens in this task) |

| AltaTrack workflow without preoperative CT volume | | |
|---|---|---|
| 3 |  | **Live Guidance** task |

**c** Go to *Setting Up the AltaTrack Devices* (page 49) to continue this workflow.

**3** To start the AltaTrack software with a preoperative CT volume available for reference during the procedure, do the following:

**a** On the Interventional Workspot, select the patient in the **Patients** activity.

**b** In the patient folder, right-click the preoperative CT volume, point to **View With**, and click **AltaTrack**.

**NOTE** ***If session data from a previous session is available in the patient folder, you can also start the AltaTrack software by double-clicking the session data object. AltaTrack session data displays the following icon:***

**NOTE** ***When using the AltaTrack software with a preoperative CT volume, it is not recommended to start the software from the touch screen module of the X-ray system.***

When using the AltaTrack software with a preoperative CT volume, the workflow consists of the following tasks:

| AltaTrack workflow with preoperative CT volume | | |
|---|---|---|
| 1 |  | **Segmentation** task (the AltaTrack software opens in this task) |
| 2 |  | **Planning** task |
| 3 |  | **Volume Registration** task |
| 4 | Setting up the AltaTrack devices | |
| 5 |  | **Shape Registration** task (the AltaTrack software opens in this task) |
| 6 |  | **Live Guidance** task |

**c** Go to the next section to continue this workflow.

## 4.2.1 Segmentation

You can view and segment volumes in the **Segmentation** task to identify vessels of interest and show relevant image content for the **Planning** task.

You can manipulate the volume in several ways:

- Select a visualization method
- Select a suitable orientation angle
- Segment vessels of interest
- Remove areas of anatomy to make segmentation easier

### Segmentation Viewports

Four viewports are displayed in the **Segmentation** task, each displaying a different direction of view for the same volume.

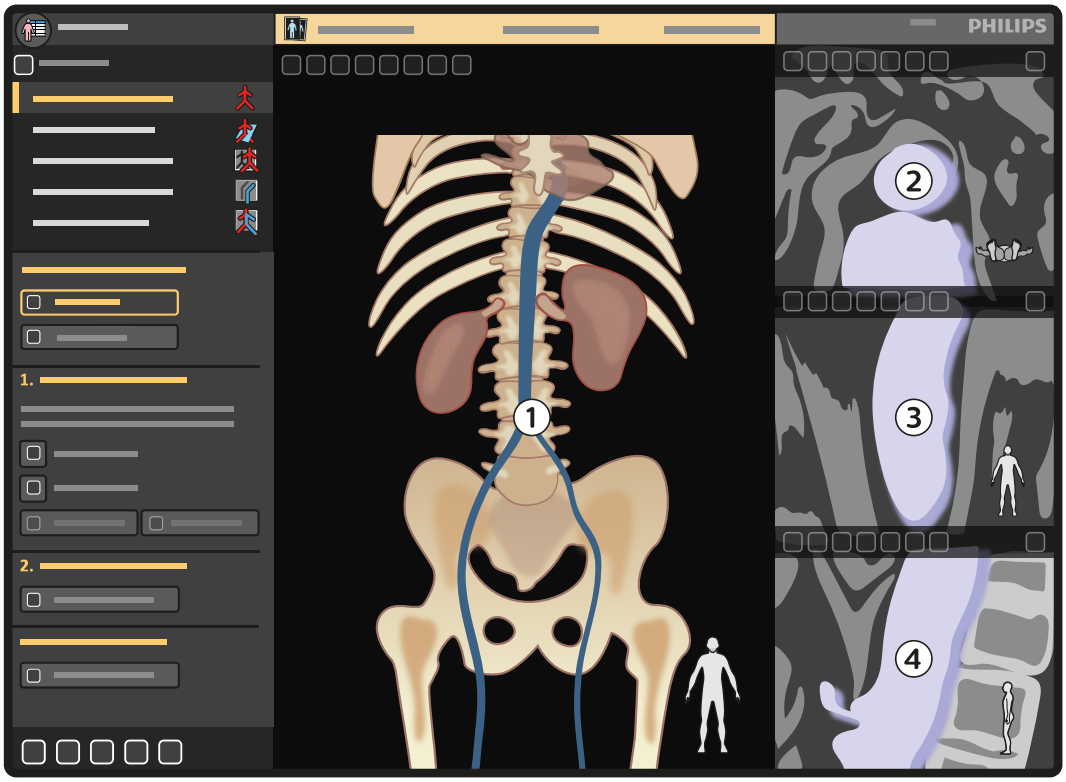


**Figure 22** Segmentation viewports

| Legend | | Default orientation |
|---|---|---|
| 1 | Volume view | Anterior posterior (coronal-anterior) |
| 2 | Slab view | Caudo cranial (axial-feet) |
| 3 | Slab view | Anterior posterior (coronal-anterior) |
| 4 | Slab view | Lateral left (saggital-left) |

### Removing the Table

If a table is detected in the volume, the system attempts to remove the table from the view before displaying the volume.

If table removal is successful, the **Hide Table** tool in the task panel is enabled. Using this tool, you can turn the visibility of the table on or off.

**NOTE** ***Table removal can only be performed on CT volumes in axial, nose-up orientation.***

### Removing Anatomy

Areas of anatomy that are not required in the view or that are obstructing a clear view of the region of interest can be removed from the volume view.

1 Adjust the windowing settings if necessary, to ensure that the vessels of interest are clearly visible.

2 To provide better visibility of the vessels of interest, you can remove the rib cage from the view by clicking **Hide Ribcage** in the task panel.

The **Hide Ribcage** tool allows you to turn the visibility of the rib cage on or off as desired.

3 Click **Cut Anatomy** in the task panel.

4 Draw a line around the anatomy to be removed by dragging the pointer in the volume viewport.

5 Release the left mouse button when the required area has been highlighted.

The area of anatomy is removed from the volume.

6 To remove all cuts that you have made in the volume, right-click in the volume viewport and click **Remove All Cuts** in the shortcut menu.

7 To undo the last change that you made, click **Undo** in the task panel.

8 To reapply the last change that was undone, click **Redo** in the task panel.

### Segmenting Vessels of Interest

1 Adjust the windowing settings if necessary, to ensure the vessels of interest are clearly visible.

2 Click **Select Vessels** in the **Segmentation** task panel.

3 In the volume view, position the cursor over the vessel you wish to segment.

The vessel is highlighted.

4 Click the left mouse button to confirm segmentation of the section of the vessel highlighted.

Segmentation of this section of the vessel is confirmed and the vessel remains highlighted.

5 Position the pointer over the next section of the vessel you wish to segment.

6 Click the left mouse button to confirm segmentation of the next portion of the vessel.

7 Alternatively, position the pointer over the vessel you wish to segment and use the mouse scroll wheel to extend the length of the highlighted section.

The vessel is highlighted further until scrolling is stopped.

8 Confirm the vessel segmentation by clicking the left mouse button.

9 Repeat these steps for all vessels to be segmented.

10 To remove a vessel, right-click the vessel and click **Remove Vessel** in the shortcut menu.

11 To remove all vessels, right-click in the volume viewport and click **Remove All Vessels** in the shortcut menu.

**12** To undo the last change that you made, click **Undo** in the task panel.

**13** To reapply the last change that was undone, click **Redo** in the task panel.

**14** Click **Show vessels** to verify the segmented vessels.

The vessels are shown over a transparent background.

## 4.2.2 Planning

You can plan the procedure in the **Planning** task, including preparations for the procedure:

- Adding landmarks
- Preparing and storing viewing angles for use in the **Live Guidance** task

### Planning Viewports

Four viewports are displayed in the **Planning** task, each displaying a different direction of view for the same volume.

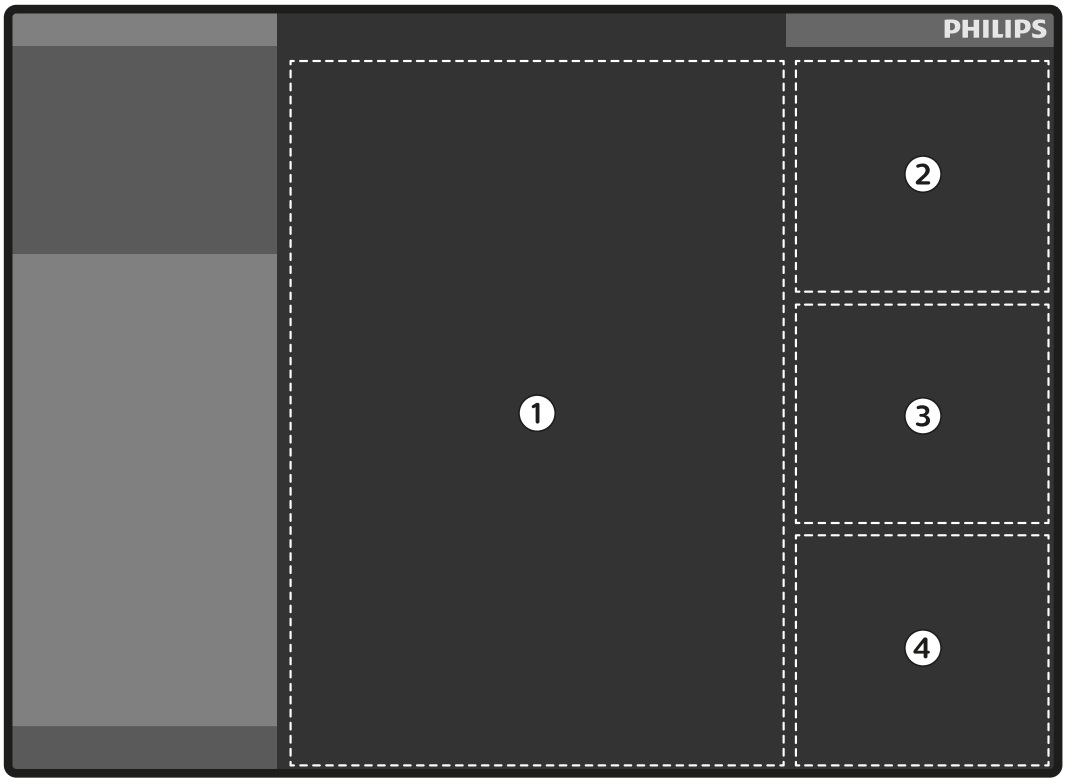


**Figure 23** Planning viewports

| View | | Default orientation |
|---|---|---|
| 1 | Volume view | Anterior posterior (coronal-anterior) |
| 2 | Slab view | Caudo cranial (axial-feet) |
| 3 | Slab view | Anterior posterior (coronal-anterior) |
| 4 | Slab view | Lateral left (saggital-left) |

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

The content of a slab view can be enlarged by displaying it in the volume viewport.

The volume view is not linked to the slab views.

Basic viewing tools are available on a toolbar in each view port to allow you to manipulate the image in the viewport.

### Placing Landmarks

You can place landmarks to the volume to assist in later tasks in the procedure.

There are two types of landmark:

- Ring landmarks are used to mark vessel ostia and landing zones to assist in catheter navigation during the procedure.
- Anatomical landmarks are used to mark a point of interest in the anatomy.

1 To provide a clear view of the segmented vessels, click **Tissue presets** and select a suitable preset.

For example, select the **Segmentation** preset to show only the segmented vessels.

2 Click **Place Ring Landmark** in the **Planning** task panel.

3 In the volume view or in the 2D view, click on the vessel at the point where you would like the ring landmark placed.

A landmark is placed in the location identified. Landmarks are numbered sequentially by default but can be renamed.

The landmark is also shown in the slab views.

4 Using the slab views, adjust the diameter and position of the landmark to ensure it is in the correct position.

5 Position the cursor over the landmark in the relevant slab view.

Adjustment handles are shown.

6 Click and drag the desired handle to change the diameter of the landmark.

7 Click and drag the landmark to reposition it.

8 To place an anatomical landmark point, click **Place Landmark** in the task panel.

9 Position the cursor where you would like the landmark to be placed and click the left mouse button.

A landmark is placed as a point on the anatomy.

10 To rename a landmark, right-click on the landmark and click **Rename Ring Landmark** or **Rename Landmark** in the shortcut menu.

The landmark name becomes editable.

11 Enter a new name for the landmark and press Enter.

12 To delete a landmark, right-click on the landmark and click **Delete Ring Landmark** or **Delete Landmark** in the shortcut menu.

13 To change the color of a landmark, right-click on the landmark and click **Change Ring Landmark Color** or **Change Landmark Color** in the shortcut menu.

A sub-menu is displayed showing available colors.

14 Click on the desired landmark color from the list.

15 To change how landmarks are displayed, click the landmark visualization button in the toolbar and choose a new setting.

| | |
|---|---|
|  | **No landmarks** |
|  | **Landmarks with text** |
|  | **Landmarks without text** |

The setting that you choose is applied to ring landmarks and anatomical landmarks.

### Storing Viewing Angles

You can manipulate the viewing angle of the 3D volume to provide suitable views of the areas of interest for use during the **Live Guidance** task. These planned angles relate to the rotation and angulation positions of the stand and can be stored and recalled when needed.

1 Click the **Store View Angles** expander.

The **Store View Angles** controls are displayed in the task panel.

2 Manipulate the volume until the desired viewing angle and optimal visibility of the area of interest is achieved.

A preview of the stand position for the current angle of the volume is shown below the list of planned angles with the rotation and angulation values displayed.

**NOTE** ***Changes made in the slab views do not affect the view and angles to be stored.***

3 Click **Store Angle** in the task panel.

The planned angle is stored and displayed in the list in the task panel showing the associated stand rotation and angulation values. A preview image of the volume at the planned angle is shown beside each planned angle in the list.

4 Repeat these steps until all of the required viewing angles have been stored as planned angles.

The **Store Angle** button is disabled when the maximum number of stored angles is reached.

5 To rename a planned angle, double-click on the angle name and enter a new name.

6 To delete a planned angle, right-click on the planned angle to be deleted and click **Remove Angle** in the shortcut menu.

7 To enlarge the preview image of the planned angle, position the pointer over the planned angle in the list.

The preview image enlarges.

### 4.2.3 Volume Registration

**NOTE** ***It is not mandatory to register a pre-procedural 3D volume when using the AltaTrack equipment. However, if you do not use a 3D volume, visualization options are limited during live guidance.***

The **Volume Registration** task allows you to register the 3D volume with the images from the X-ray system being used for the procedure. You can choose between 2D registration (with 2D X-ray images) or 3D registration (with a 3D rotational series). 2D registration can be performed using the AltaTrack software in the control room or using the touch screen module of the X-ray system at the tableside, whereas 3D registration can only be performed using the AltaTrack software. Therefore, the following registration options are available:

- 2D registration in the control room using the AltaTrack software
- 2D registration at the tableside using the touch screen module of the X-ray system
- 3D registration in the control room using the AltaTrack software

All registration options are described in this section.

**CAUTION**
***Do not move the stand or table while acquiring series for registration. Such movements may compromise the accuracy of the registration.***

#### Merging Patient Data

When there is a mismatch between the patient data in the AltaTrack equipment and the patient data on the X-ray system, you cannot continue to the **Volume Registration** task, the **Shape Registration** task, or the **Live Guidance** task. (A message is displayed if there is a mismatch.)

If both sets of data are from the same patient, you can merge the patient data and then continue with registration and guidance. If there is no mismatch between the data, merging is not required.

1 Click **Merge with current X-Ray patient** in the general toolbar.

The **Merging with current patient on X-ray system** dialog panel is displayed.

2 Verify the identity of the patient and ensure both sets of details displayed relate to the same patient.

**WARNING**
***To avoid the risk of mixing patients, it is your responsibility to ensure that you only merge personal data originating from the same patient.***

3 If you are certain the details relate to the same patient, click **OK** to merge the patient details.

#### Performing 2D Volume Registration

To perform 2D volume registration, two reference series must be obtained using the X-ray system from different projection angles and at least 30 degrees apart. The system provides suggested angles to assist to you.

After acquiring the reference series, you align the volume with the images in the reference series.

#### Other Registration Options

If you want to perform 2D volume registration at the tableside using the touch screen module of the X-ray system, see *Performing 2D Volume Registration at the Tableside* (page 44).

If you want to perform 3D volume registration using a 3D rotational series, see *Performing 3D Volume Registration* (page 45).

### Starting 2D Volume Registration

2D volume registration is the default registration method.

1 Select the **Volume Registration** task.

The **Volume Registration** task controls are displayed in the task panel with the **Registration Method** menu open.

2 In the **Registration Method** step in the task panel, click **2D Images**.

The screen layout changes to display three viewports in normal view mode.

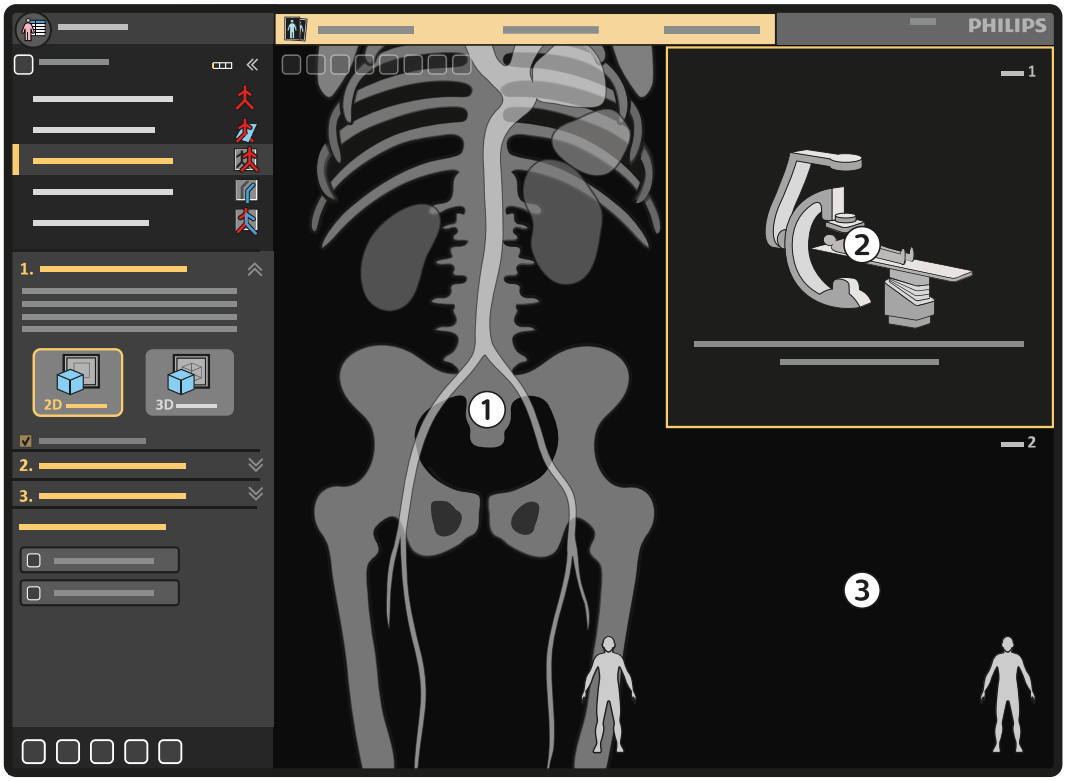


**Figure 24** Normal view mode screen layout

| Legend | |
|---|---|
| 1 | Live view |
| 2 | Reference 1 (**Ref 1**) |
| 3 | Reference 2 (**Ref 2**) |

### Acquiring Reference Series

1 Click the **Acquire images from 2 angles** expander.

The **Acquire images from 2D images** controls are displayed in the task panel.

A list of suggested angles is displayed, and the first angle is selected automatically.

2 Do one of the following:

- To use the selected angle, press the **ACC** button on the geometry module of the X-ray system.
- To use one of the other suggested angles, select the desired angle, and then press the **ACC** button on the geometry module of the X-ray system.

The X-ray system repositions the stand to the selected rotation and angulation.

**3** Acquire a fluorscopy series.

During acquisition, the images are displayed in the live viewer, overlaid on the 3D volume. After acquisition, the live view switches to review mode automatically.

The **Copy** button in the **Ref 1** viewport is blinking.

Once a reference series has been acquired, you can copy the series to a reference view. Reference series are not copied to a reference view automatically. The system suggests which reference viewer is suitable to maintain an optimum angle difference between the two reference series being used:

- For the first series acquired, **Ref 1** is always suggested.
- For the second series acquired, **Ref 2** is suggested if the difference in projection angle is sufficient.

**4** Click **Copy** in the **Ref 1** viewport.

The series is copied to the **Ref 1** viewport and a new list of suggested angles is displayed in the task panel for the next reference series. A suitable angle is automatically selected, but you can select a different one, if desired.

**5** Press the **ACC** button on the geometry module of the X-ray system to use the currently selected angle.

The X-ray system repositions the stand to the selected rotation and angulation.

**6** Acquire another fluoroscopy series.

During acquisition, the images are displayed in the live viewer, overlaid on the 3D volume. After acquisition, the live view switches to review mode automatically.

The **Copy** button in the **Ref 2** viewport is blinking.

Where more than two series have been acquired or where the second series had an unsuitable projection angle difference, the system suggests the most suitable reference view for the series:

- If the series is acquired at a projection angle which is identical to a previous reference series, the system suggests that the previous identical series is replaced with the newer series.
- If the series is acquired at a projection angle which is suitable, the system suggests that the new series replaces the existing series with the largest projection angle difference to the new series.

**NOTE** ***If a reference series is acquired at a projection angle that is unsuitable to replace any of the existing series, the system does not make a suggestion to replace to any existing reference series. A message is displayed to inform you that there is insufficient difference in the projection angle.***

**7** Click **Copy** in the **Ref 2** viewport.

The series is copied to the **Ref 2** viewport. The **Acquire images from 2 angles** task is closed, the screen layout changes to Reference view mode and the **Align volume with images** task is displayed in the task panel.

### Aligning the Volume with the Reference Series

Following the **Acquire images from 2 angles** task, the **Align volume with images** controls are displayed automatically and the screen layout is changed to Reference view mode.

The purpose of this task is to align the CT volume and the 2D image based on the anatomical landmarks (bones) that are visible in the images.

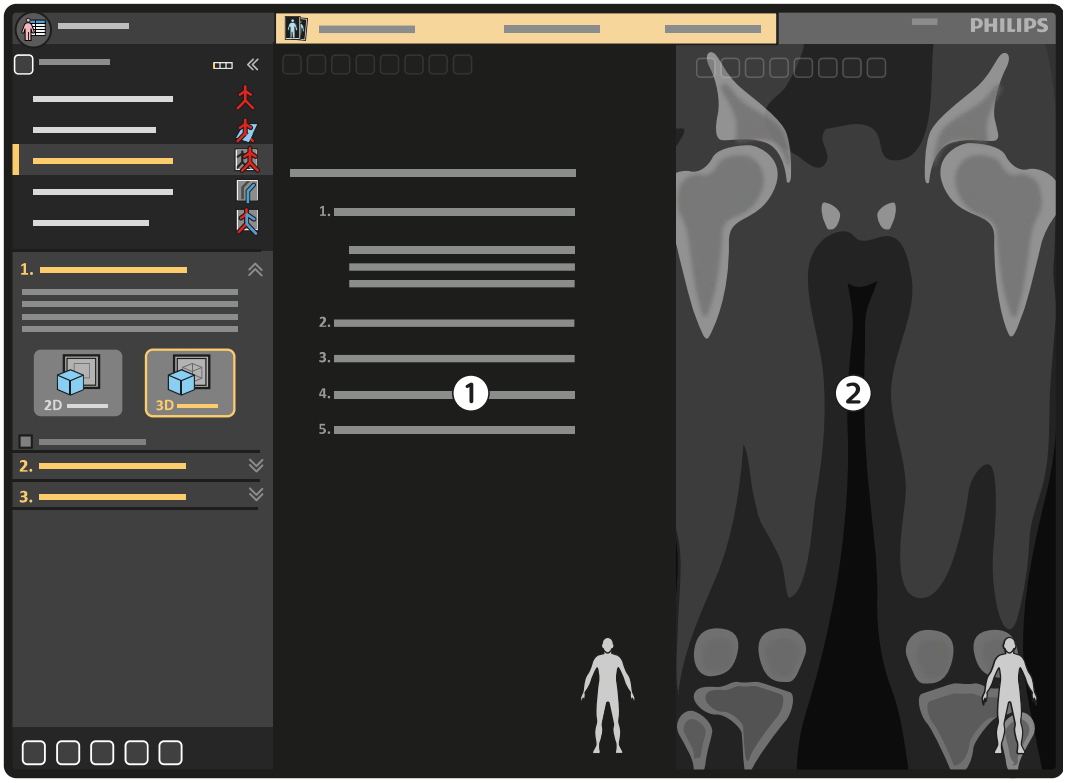


**Figure 25** Registration view mode

| Legend | |
|---|---|
| 1 | Reference 1 (**Ref 1**) |
| 2 | Reference 2 (**Ref 2**) |

**1** To change the tissue visualization, click **Tissue presets** and select a different preset for the volume.

**NOTE** ***The default tissue preset that is already selected is optimized for performing registration and does not usually need to be changed.***

**2** To enhance visualization of bone structure in the X-ray image, click **Boost Bone**.

The outlines of bones are enhanced in the X-ray image.

**3** If desired, adjust the contrast and brightness of the X-ray image.

See *Adjusting the Contrast and Brightness of the X-ray Image* (page 81) for information about how to adjust the contrast and brightness of the X-ray image.

**4** Click **Translate Volume** and click and drag the volume in each viewport to align the bone structures.

**5** To roll the volume freely in any direction, click **Roll Volume** and do the following in each viewport as desired:

- Move the pointer inside the boundary of the volume.
- Drag the volume to roll it to the desired orientation.

**6** To rotate the volume in the viewing plane, click **Rotate Volume** and do the following in each viewport as desired:

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

7 To change the center of rotation, drag the rotation point interactor to a new position before rolling or rotating the volume.

NOTE ***The rotation point interactor is visible in the viewports when you select the Roll Volume tool or Rotate Volume tool.***

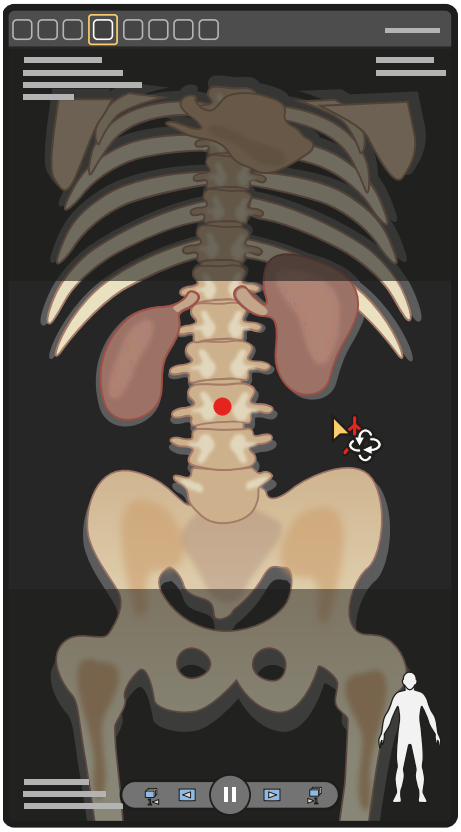

**Figure 26** Rotation point

8 Verify alignment of the volume and the X-ray image by clicking **Auto Fade**.

The volume fades in and out repeatedly to allow you to see whether the volume and the X-ray image are sufficiently aligned.

You can leave the auto fade cycle turned on while you make adjustments. To turn it off, click **Auto Fade** again.

9 Check alignment of the volume with the X-ray image.

10 If necessary, repeat the steps above until the volume and X-ray image are sufficiently aligned.

11 To reset the volume to the original position and orientation, click **Reset Alignment**.

All alignments of the volume are undone.

12 To reset only the translation alignment performed, right-click in the viewport and select **Reset alignment translation**.

Only translation alignments are undone.

13 To reset only the rotation alignment performed, right-click in the viewport and select **Reset alignment rotation**.

Only rotation alignments are undone.

## Performing 2D Volume Registration at the Tableside

To perform 2D volume registration, two reference series must be obtained using the X-ray system from different projection angles and at least 30 degrees apart. The system provides suggested angles to assist to you.

After acquiring the reference series, you align the volume with the images in the reference series.

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

### Other Registration Options

If you want to perform 2D volume registration using the AltaTrack software in the control room, see *Performing 2D Volume Registration* (page 39).

If you want to perform 3D volume registration using a 3D rotational series, see *Performing 3D Volume Registration* (page 45).

### Starting 2D Volume Registration at the Tableside

Volume registration of 2D X-ray images can also be performed at the tableside using the touch screen module of the X-ray system.

For information about acquiring X-ray images, refer to the Instructions for Use for the X-ray system in use.

1 Tap **AltaTrack** on the touch screen module of the X-ray system.

2 Tap **Goto 2D Images Registration** (this is the default method).

### Acquiring Reference Series at the Tableside

1 Tap **Select Registration Angle**.

A set of suggested angles is displayed, and the first angle is selected automatically.

2 Do one of the following:

- To use the selected angle, press the **ACC** button on the geometry module of the X-ray system.
- To use one of the other suggested angles, select the desired angle, and then press the **ACC** button on the geometry module of the X-ray system.

The X-ray system repositions the stand to the selected rotation and angulation.

3 Acquire a fluoroscopy series.

Any acquisition setting and projection angle can be used.

4 Tap **Copy to Ref 1** to copy the acquired series to the **Ref 1** view.

5 Tap **Select Registration Angle**.

A new set of suggested angles is displayed in the task panel for the next reference series. A suitable angle is automatically selected, but you can select a different one, if desired.

6 Press the **ACC** button on the geometry module of the X-ray system to use the currently selected angle.

The X-ray system repositions the stand to the selected rotation and angulation.

7 Acquire a second fluoroscopy series.

This reference series should be obtained using a projection angle difference of at least 30 degrees.

8 Tap **Copy to Ref 2** to copy the acquired series to the **Ref 2** view.

**Aligning the Volume with the Reference Series at the Tableside**

1 Tap **Adjust Registration** to begin aligning the volume and the X-ray images.

2 Select the reference view to be manipulated by tapping **Active View** to select **Ref 1**.

Tapping **Active View** allows you to select which reference view you are manipulating by toggling between **Ref 1** and **Ref 2**.

3 Select an adjustment method by tapping **Movement** until the desired method is displayed on the button.

Tapping **Movement** cycles the function through the following adjustment methods.
- **Translate**
- **Roll**
- **Rotate In-plane**
- **Rotation Center**

4 Use **Translate** to translate the volume using the arrow buttons.

5 Use **Roll** to roll the volume freely around the center of rotation using the arrow buttons.

If desired, use **Rotation Center** to adjust the center of rotation for the roll action.

6 Use **Rotate In-plane** to rotate the volume in the viewing plane around the center of rotation using the arrow buttons.

If desired, use **Rotation Center** to adjust the center of rotation for the rotate action.

7 Tap **Active View** to toggle to **Ref 2**.

8 Repeat the steps above for the **Ref 2** image.

9 Check alignment of the volume with the X-ray image by tapping **Auto Fade**.

10 When you have confirmed that the volume and X-ray images are properly registered, tap **Go to Live Guidance**.

## Performing 3D Volume Registration

To register the volume (pre-op) using a 3D rotational series, a suitable XperCT series or 3DRA series (intra-op) must be acquired, or if such a series is available, it must be loaded.

### Other Registration Options

If you want to perform 2D volume registration using the AltaTrack software in the control room, see *Performing 2D Volume Registration* (page 39).

If you want to perform 2D volume registration at the tableside using the touch screen module of the X-ray system, see *Performing 2D Volume Registration at the Tableside* (page 44).

### Starting 3D Volume Registration

1 Select the **Volume Registration** task.

2 In the **Registration Method** step in the task panel, select **3D Scan**.

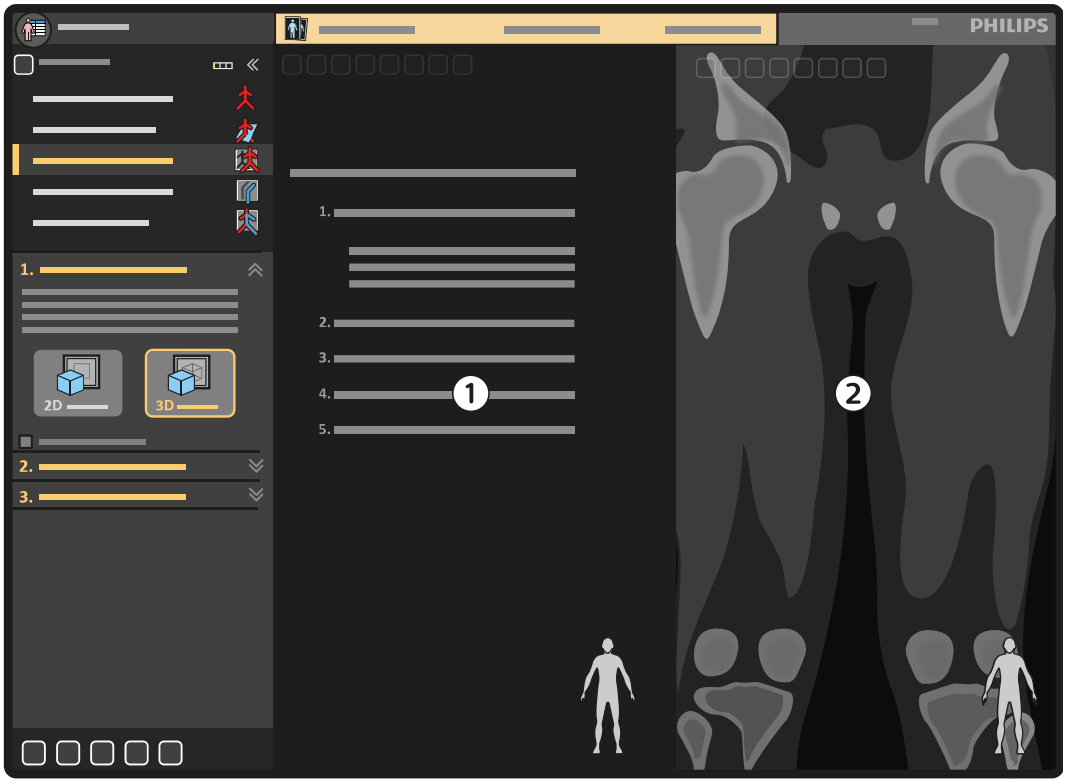


**Figure 27** Registration view mode

| Legend | |
|---|---|
| 1 | Intra-op |
| 2 | Pre-op |

3 You can either acquire a 3D rotational series at this point, or load a previously acquired 3D rotational series.

Until a suitable volume is acquired or loaded, the intra-op viewport displays the recommended process to be followed to acquire a suitable intra-op volume. For information about how to acquire a rotational series, refer to the Instructions for Use for the X-ray system in use.

If you acquire a 3D rotational series, it is loaded automatically. After the series is acquired and loaded, see *Aligning the Volume with the 3D Rotational Series* (page 47).

If you want to load a previously acquired 3D rotational series, see *Loading a 3D Rotational Series* (page 46).

### Loading a 3D Rotational Series

1 Click **Load** in the intra-op viewport or on the intra-op viewport toolbar.

The **Open Xper CT/3DRA volume** dialog panel is displayed.

2 From the list of available series, select the desired XperCT or 3DRA series and click **OK**.

**NOTE** ***When loading an older XperCT, 3DRA, or X-ray run for volume registration, the patient may have moved or the anatomy may have deformed in the meantime, limiting the quality of the registration.***

A progress bar is displayed while the series loads. The series is displayed in the intra-op viewport.

### Aligning the Volume with the 3D Rotational Series

To register the volume with the 3D rotational series, a minimum of three registration points must be placed in the series and in the corresponding positions in the volume.

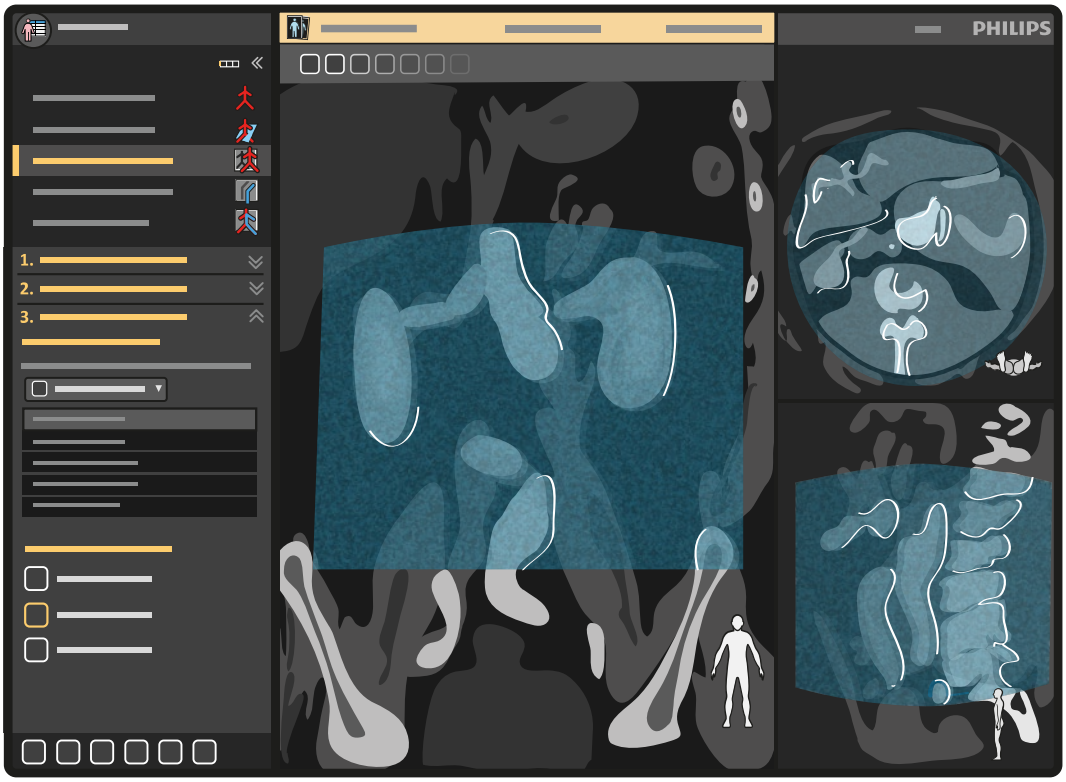


**Figure 28** Placing registration points

1 Manipulate the intra-op series and the pre-op volume to identify a suitable matching anatomical point, ensuring the same anatomical point is clearly visible in both viewports.

For example, a vessel calcification.

2 Click **Place Point Couple** in the task panel or in the toolbar.

3 Click on the identified anatomical point in the intra-op viewport.

The point is marked in the series and is identified as point 1.

4 Click on the same anatomical point in the pre-op viewport.

Each point couple displays the same annotation number to indicate that the points are paired.

5 Repeat the steps above until you have placed at least three point couples.

**NOTE** ***For accurate registration of the volume with the 3D rotational series, a minimum of three points is recommended.***

The system matches the point couples to align the series and volume in three dimensions. If any of the point couples cannot be matched, an error message is displayed telling you that one or more registration points may have been placed incorrectly. If this happens, check the point couples.

6 To move a point, click and drag the point to the new desired position.

7 To delete a point, right-click on the point to be deleted and click **Remove Point** in the shortcut menu.

8 To delete a point couple, right-click on one of the points in the couple or on the point couple in the task panel list, and click **Remove Point Couple** in the shortcut menu.

9 To delete all points, right-click anywhere in the viewport and click **Remove All Points** in the shortcut menu.

10 To increase the size of the viewport being manipulated, click the maximize view toggle button.

11 To return to the split screen reference view mode, click the maximize view toggle button again.

12 Once all point couples have been correctly placed, click **Compute Alignment** in the task panel.

The screen layout changes and three orthogonal views of the overlaid series and volume are shown.

13 To adjust the alignment, click **Translate Volume** and click and drag the volume to align the anatomy.

14 To rotate the volume in the viewing plane, click **Rotate Volume** and do the following in each viewport as desired:

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

15 To change the center of rotation, drag the rotation point interactor to a new position before rolling or rotating the volume.

**NOTE** ***The rotation point interactor is visible in the viewports when you select the Roll Volume tool or Rotate Volume tool.***

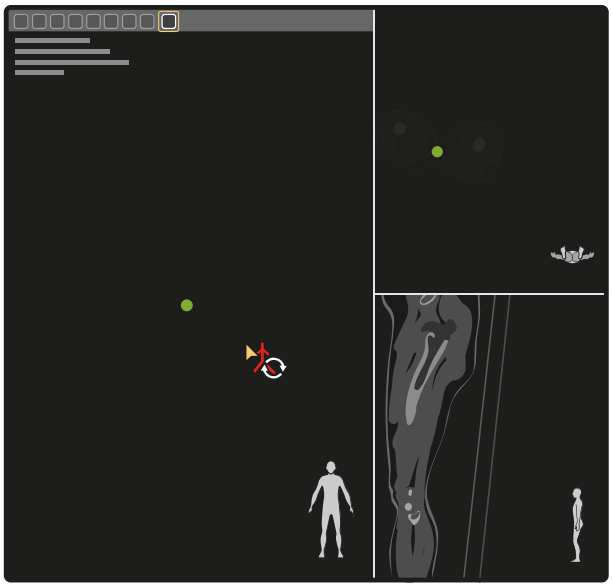

**Figure 29** Rotation point

16 Verify alignment of the volume and the series by clicking **Auto Fade**.

The volume fades in and out repeatedly to allow you to see whether the volume and the rotational series are sufficiently aligned.

You can leave the auto fade cycle turned on while you make adjustments. To turn it off, click **Auto Fade** again.

17 Check alignment of the volume with the series.

18 If necessary, repeat the steps above until the volume and rotational series are sufficiently aligned.

### Adjusting Opacity

You can adjust the opacity of a 3D volume to blend it more easily with 2D X-ray images or a 3D rotational series.

The volume opacity can be adjusted from 0%, where only the 2D X-ray image or 3D series is visible, to 100%, where only the 3D volume is visible. The default volume opacity is 40%.

1 Select the volume opacity mode by clicking **Volume Opacity** on the toolbar.

2 Adjust the opacity by doing one of the following:

- Drag the pointer upward to increase transparency.
- Drag the pointer downward to decrease transparency.

When dragging, the pointer changes to indicate the opacity level is being adjusted.

**NOTE** ***Volume opacity settings are linked in all viewports where the volume is displayed.***

3 To reset the volume opacity, double-click in the viewport.

### Reviewing 2D Series in Volume Registration

To assist in checking the registration match of images with the 3D volume or to assist in reporting, you can review a 2D series overlaid on the 3D volume.

Review mode is automatically started after acquiring exposure series. Automatic review of fluoroscopy series can be turned on or off in the task panel.

1 In the live view, click **Play** in the review toolbar.

The series is played at the speed at which the images were acquired.

2 To pause the review of the series, click **Pause** on the reviewing toolbar.

The series is paused at the image displayed when the pause button was clicked.

3 Navigate to the next or previous images using **Next Image** or **Previous Image** on the reviewing toolbar.

4 Navigate to the start or end of the series using **First Image** and **Last Image** on the review toolbar.

## 4.3 Setting Up the AltaTrack Devices

**WARNING**
***Ensure that you use correctly sized devices for the procedure.***

1 (**Non-sterile user**) Open the outer packing of the device without touching the tray inside.

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

For information about unpacking the AltaTrack device, refer to the AltaTrack device Instructions for Use.

2 (**Sterile user**) Take the tray, remove the device, and pass the empty tray back to the non-sterile user.

Handle the AltaTrack devices carefully to avoid impacting the performance of the AltaTrack equipment.

3 (**Non-sterile user**) Move the empty tray away from the working area.

4 (**Sterile user**) Place the docking fin in the AltaTrack Docking Top.

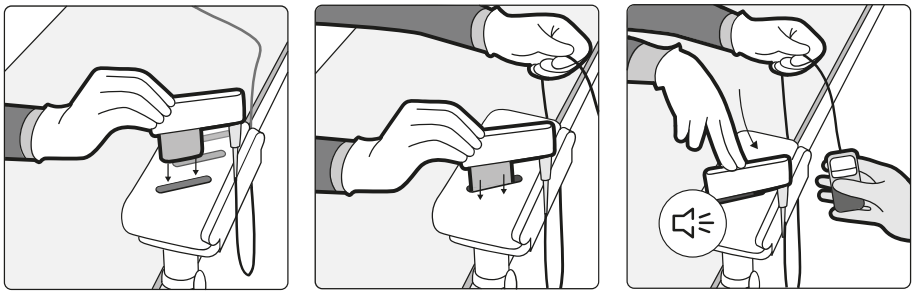

**Figure 30** Connecting the device to the AltaTrack Docking Top

The display on the AltaTrack touch screen indicates that the device is docked.

5 (**Sterile user**) Pass the device connector to a non-sterile user.

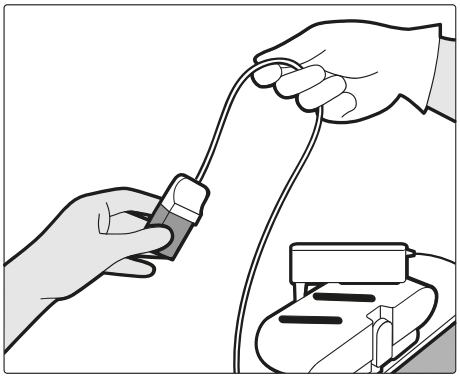

**Figure 31** Handing over the device connector

6 (**Non-sterile user**) Connect the device connector to the connection box using one of the active connection slots.

**WARNING**
***Do not to use X-ray while a non-sterile user connects or disconnects a device at the connection box, as the connection box is close to the X-ray tube.***

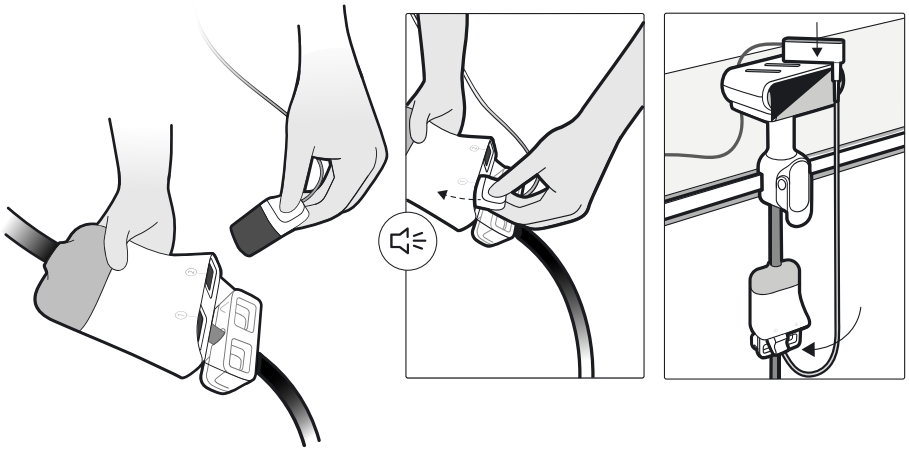

**Figure 32** Inserting the device connector

When the device connector is connected successfully, the equipment responds with an audible and tactile confirmation. The display on the AltaTrack touch screen indicates that initialization is in progress. Refer to the AltaTrack software window for confirmation that the device is correctly connected. Connection status can be viewed in the task panel of the **Shape Registration** task.

**Figure 33** AltaTrack device connection status in the task panel

The device is ready for use after approximately 10 seconds.

7 If you are using two devices, such as a catheter and guidewire, repeat these steps for the second device.

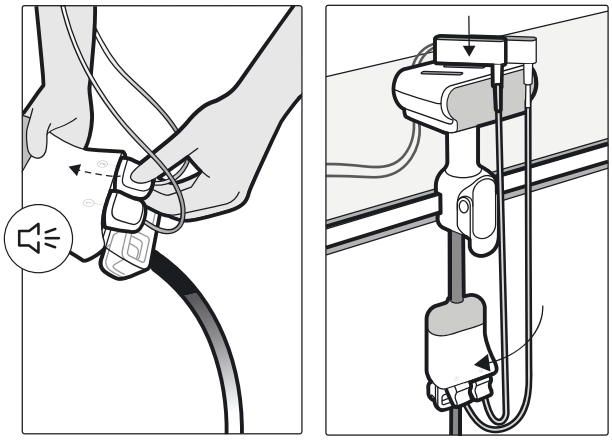

**Figure 34** Inserting a second device connector

You can set up one, two, or three AltaTrack devices, depending on the procedure and your workflow. Although only two devices can have a simultaneous optical connection to provide visualization on the AltaTrack equipment, an additional connection slot is provided so that you can set up a third device in advance. This makes switching devices during the procedure faster and easier. You can set up all devices without the risk of compromising the sterile field.

**NOTE** ***It is not possible to visualize two AltaTrack Catheter devices or two AltaTrack Guidewire devices simultaneously.***

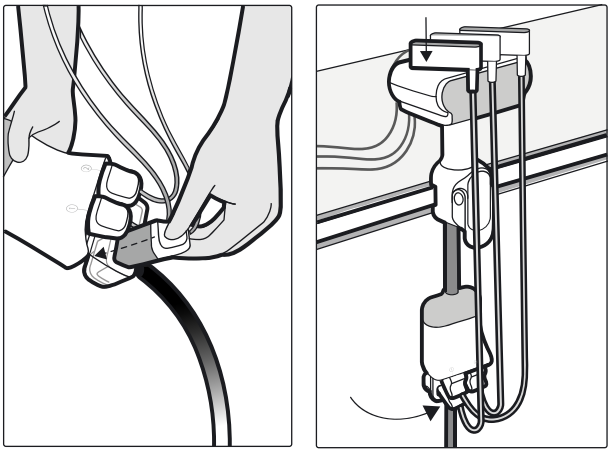

**Figure 35** Setting up an additional device connector

8 (**Sterile user**) Follow the procedure provided in the AltaTrack device Instructions for Use to flush or wipe each device in use.

9 If you are using two AltaTrack devices, front-load the catheter on to the guidewire.

Connecting the device provides initial registration in relation to the AltaTrack docking base.

## 4.4 Performing Shape Registration

This procedure describes the steps to register the AltaTrack devices (AltaTrack Guidewire and AltaTrack Catheter). You can also use this procedure if you are registering a single AltaTrack device (AltaTrack Guidewire or AltaTrack Catheter).

If you are only registering a single AltaTrack device, the procedure is the same, but note that when actions for two AltaTrack devices are described, you need only perform the action once. The AltaTrack software recognizes how many AltaTrack devices are connected and the user guidance in the task panel and main display area will be appropriate for your configuration.

**NOTE** ***You can perform Shape Registration out-of-body (on-body) or in-body 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**
***If you register the devices at a location that is not near the target anatomy, you should check with fluoroscopy to ensure that the registration is still valid.***

1 If not already selected, click **Shape Registration** in the task selection panel and verify that the AltaTrack devices are connected correctly.

**Figure 36** AltaTrack device connection status in the task panel

2 Advance the AltaTrack Guidewire so that the guidewire tip extends at least 2 cm (0.8 in) from the catheter.

**WARNING**
***When using an AltaTrack Guidewire with an AltaTrack Catheter, avoid tangling the tips of the two devices.***

**NOTE** ***If you are using an AltaTrack Catheter as a single device, the predicate device should be inserted in the AltaTrack device and should extend at least 2cm (0.8 in) from its tip.***

3 Bring the AltaTrack devices into the X-ray field of view near the location of the target anatomy and confirm their position with fluoroscopy.

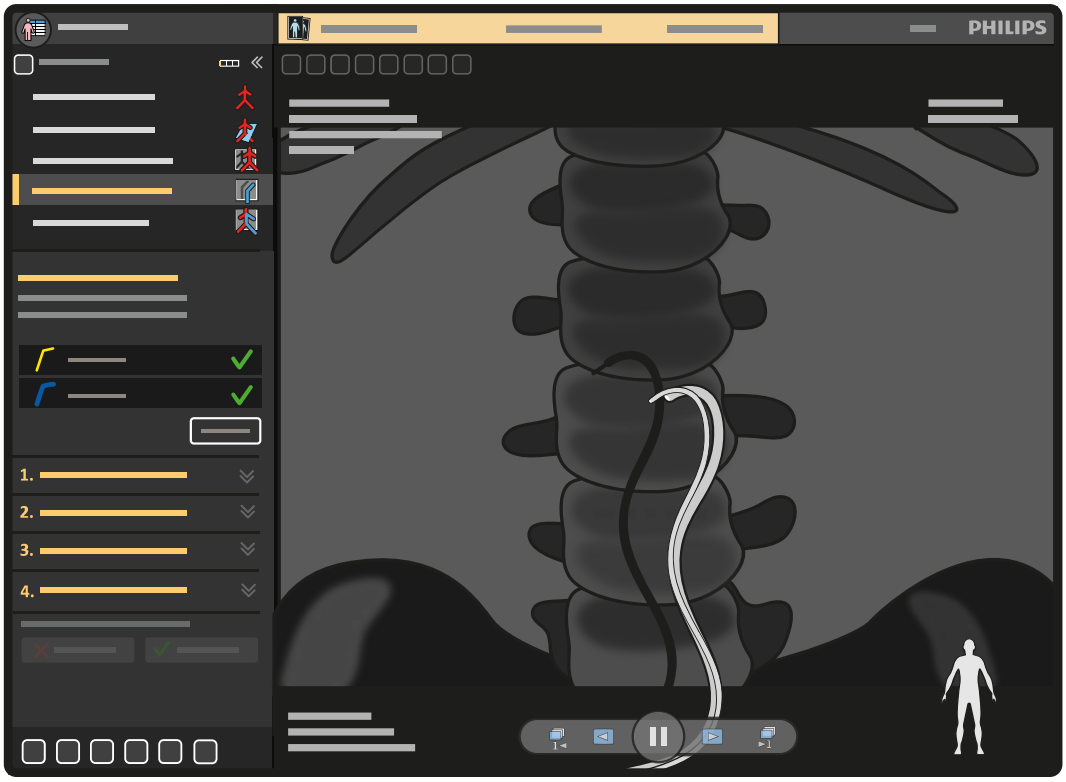


**Figure 37** Bringing the AltaTrack devices into the X-ray field of view

4 Click **Next Step** in the task panel to continue the shape registration procedure: **Acquire X-ray runs from 2 angles**.

Guidance is provided in the main window for positioning and orienting the AltaTrack devices for registration:

**Figure 38** AltaTrack device positioning and orientation guidance

**WARNING**

***For optimal registration, observe the following guidelines:***

- ***Ensure that a significant part of the AltaTrack device is visible in the field view, with the tip of the device near the center of the view. If necessary, select a larger field of view.***
- ***Ensure that there is some curvature in the tip of the device that is visible in the image.***
- ***Ensure that there is some curvature where the devices overlap.***

5 Acquire the first registration series using fluoroscopy.

**CAUTION**

***Do not move the stand or table while acquiring series for registration. Such movements may compromise the accuracy of the registration.***

6 Click **Copy** in the **Ref1** viewport to copy a reference image from the registration series to the viewport.

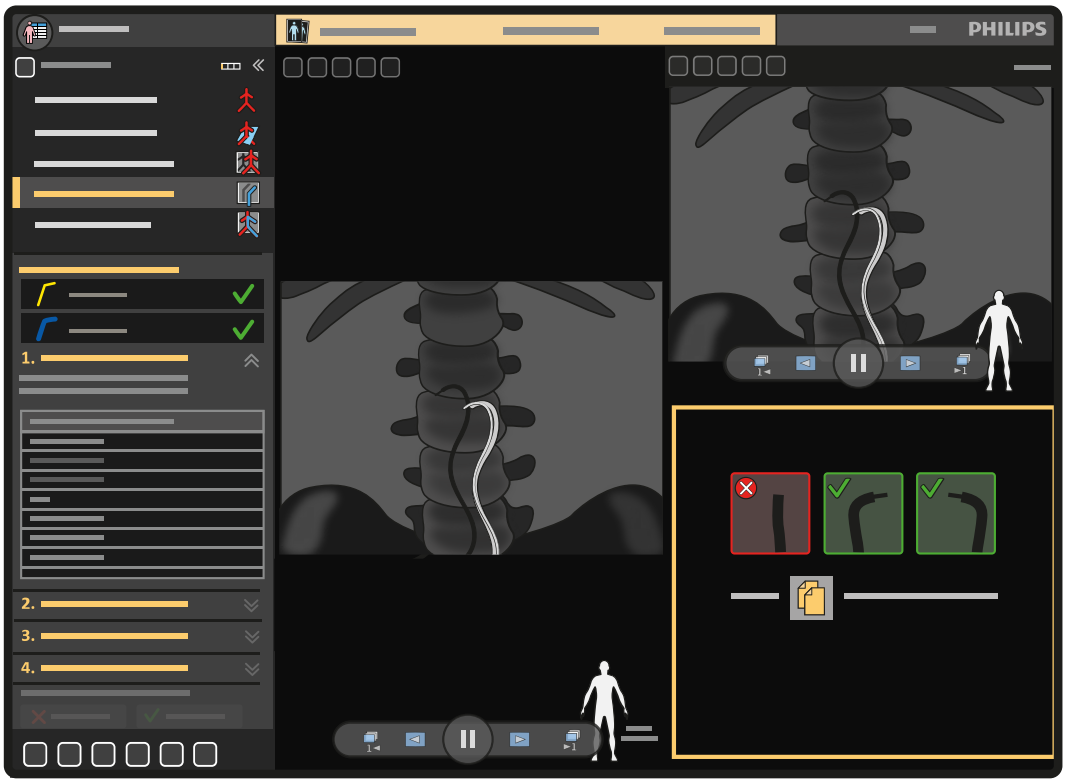


**Figure 39** Acquiring reference images

7 Do one of the following to position the stand for the second registration series:
- Select an angle from the list in the task panel.
- Position the stand manually.

The difference in angle with the first registration series should be at least 30 degrees and no more than 150 degrees. Unsuitable or unobtainable angles are grayed in the list.

8 Acquire the second registration series using fluoroscopy.

9 Click **Copy** in the **Ref2** viewport to copy a reference image from the registration series to the viewport.

After both reference viewports are filled, the registration task automatically moves to the next step: **Place Points**.

The reference viewports are displayed side by side so that you can identify the AltaTrack devices.

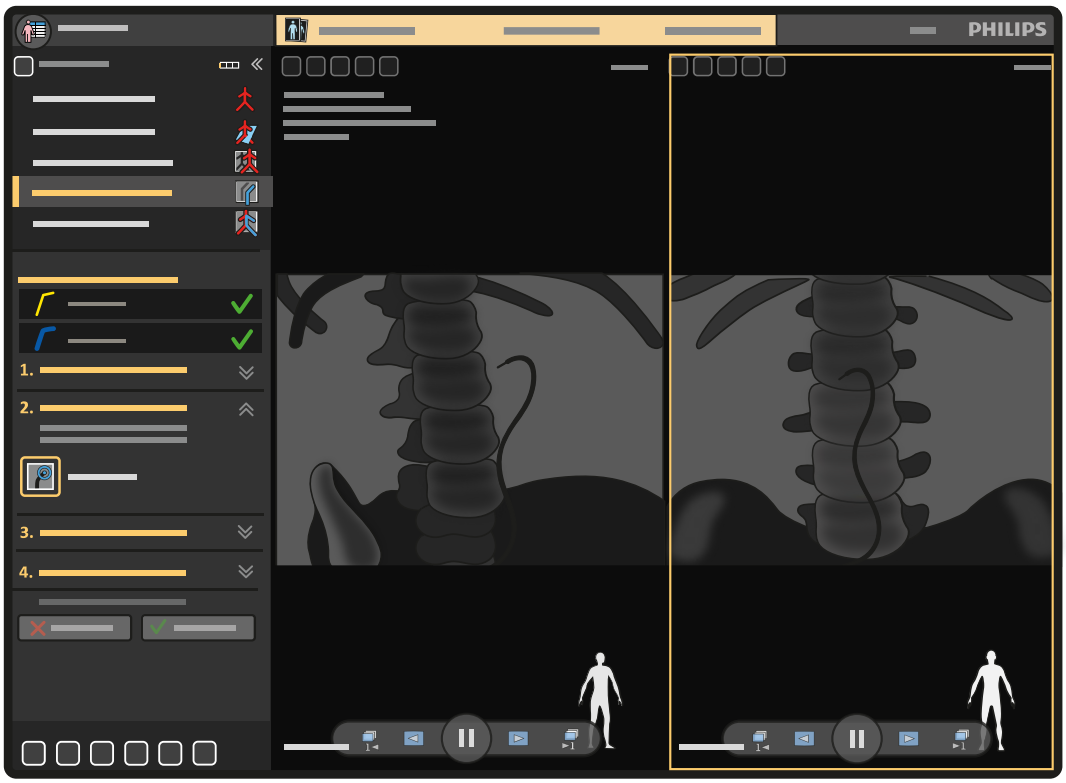


**Figure 40** Reference images displayed side by side for AltaTrack device identification

The **Place Point** tool is automatically enabled in the task panel to allow you to place points on the devices.

**10** Click on the tip of the AltaTrack Guidewire in the first reference image to identify it.

**NOTE** ***If desired, rotate the wheel button on the mouse to zoom in while performing this step.***

**NOTE** ***If you are using an AltaTrack Catheter as a single device, click on the tip of the AltaTrack Catheter.***

The software identifies the AltaTrack device and automatically adds markers (white crosses) along the device.

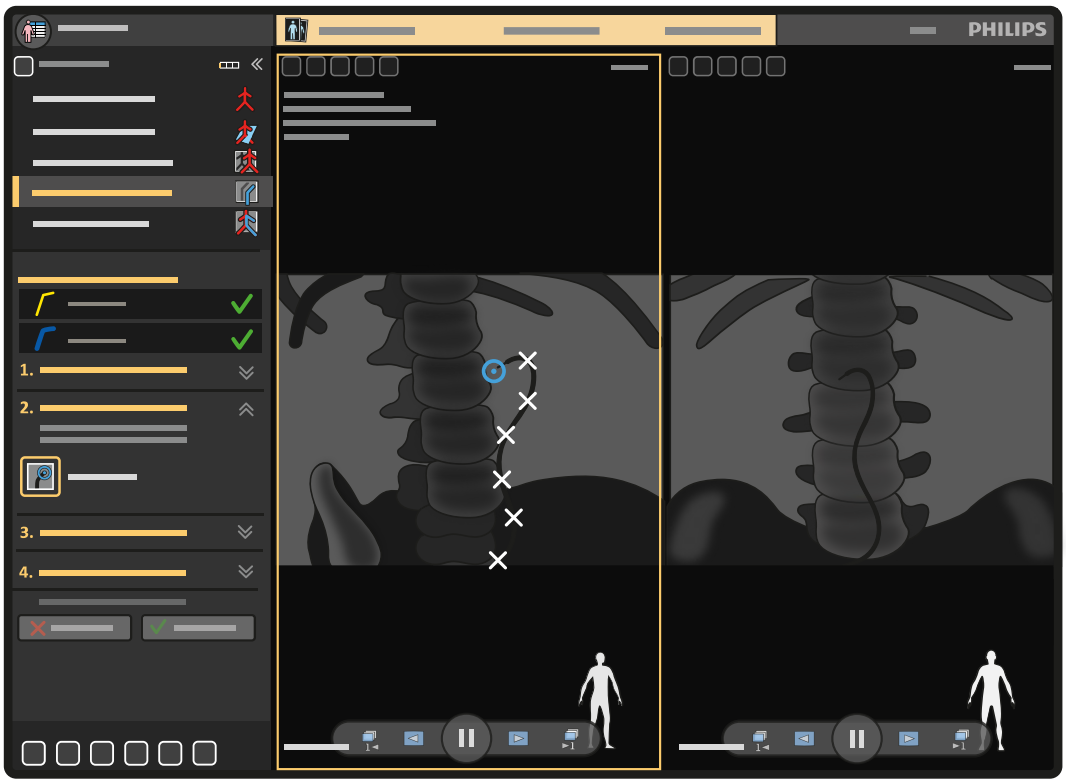


**Figure 41** Identifying the AltaTrack device in the first registration image

**11** Verify that the markers are correctly positioned on the AltaTrack device.

If the markers are not correctly positioned, click on the device at a more proximal position. The software updates the device identification markers according to the newly placed marker.

**12** Click on the tip of the AltaTrack Guidewire in the second reference image to identify it.

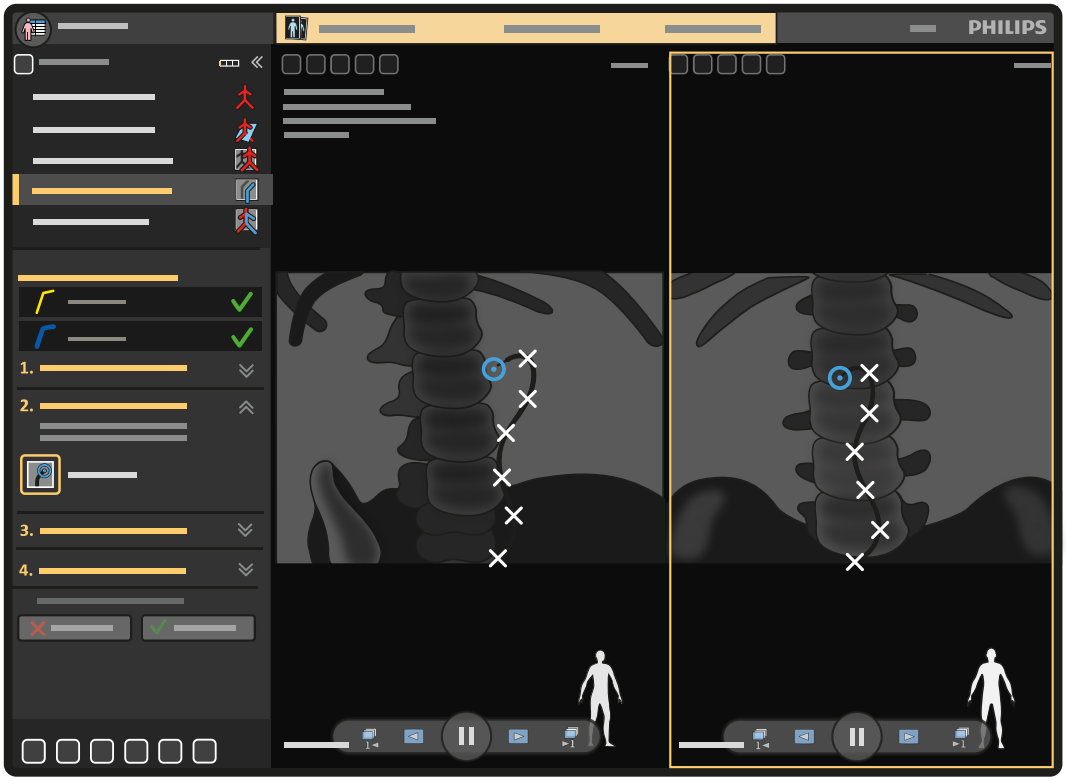


**Figure 42** Identifying the AltaTrack device in the second registration image

13 Verify that the device points in the second reference viewport are correctly positioned on the AltaTrack Guidewire device.

14 When all device points are correctly positioned, click **Next Step** in the task panel: **Compute Registration**.

The AltaTrack equipment computes the registration of the shapes and displays them as overlays on the reference images.

The shape overlays are faded in and out for a short duration to assist with viewing the results of shape registration. You can also activate this function manually by clicking **Auto Fade** in the task panel. Alternatively, click the **Shape Opacity** tool in the toolbar and adjust the opacity of the shapes manually by dragging upward or downward.

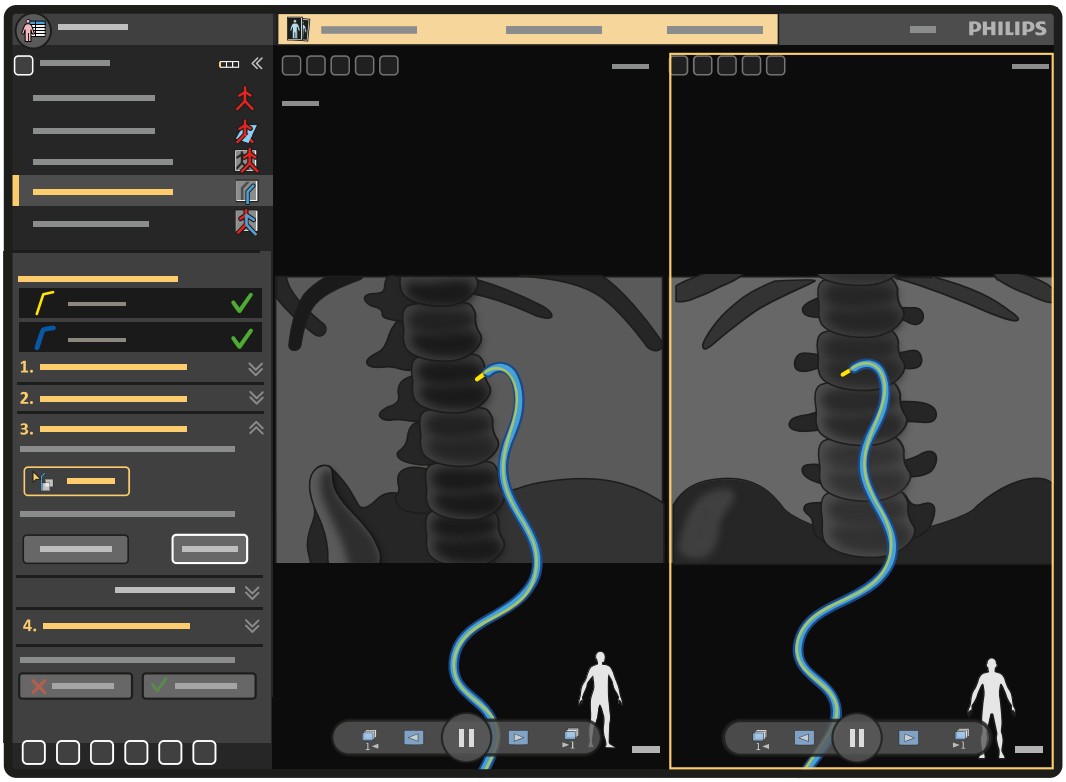


**Figure 43** Shape overlays on the reference images

15 Do the following to verify the accuracy of the shape registration:

**a** Examine the position of the shape overlay in each reference viewport and ensure that it follows the AltaTrack device in the X-ray image.

**b** Examine the position of the tips of the AltaTrack shapes compared to the tips of the devices in the X-ray images and ensure the following:

- 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.

16 If the position of the AltaTrack device shapes is satisfactory, click **Accept** in the task panel.

After accepting the registration, the AltaTrack software automatically moves to the next task: **Live Guidance**. For more information, see *Navigating with the AltaTrack Equipment* (page 60).

Alternatively, the following actions are available:

**a** If the position of the tips of the AltaTrack shapes do not match the tips of the AltaTrack devices in the X-ray images, click **Next Step** in the task panel to display the **Verify Device Tip** functions. For more information, see *Adjusting the AltaTrack Device Shape Tips* (page 58).

**b** If the results of the registration are not satisfactory, click **Reject** to discard the registration results and restart the **Shape Registration** task.

**NOTE** ***While it is possible to adjust the registration of the AltaTrack device shapes manually using the Pan Shape and Rotate Shape tools in the toolbar, these complex actions are recommended for advanced users only.***

### 4.4.1 Adjusting the AltaTrack Device Shape Tips

This optional step is part of the **Shape Registration** task. Follow this procedure if the tips of the AltaTrack device shapes are not close to the position of the device tips in the X-ray images in the reference viewports.

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

2 In the task panel, select the AltaTrack device shape that you want to adjust using the color-coded options.

3 Use the left and right arrow buttons in the task panel to increase or decrease the shape tip length.

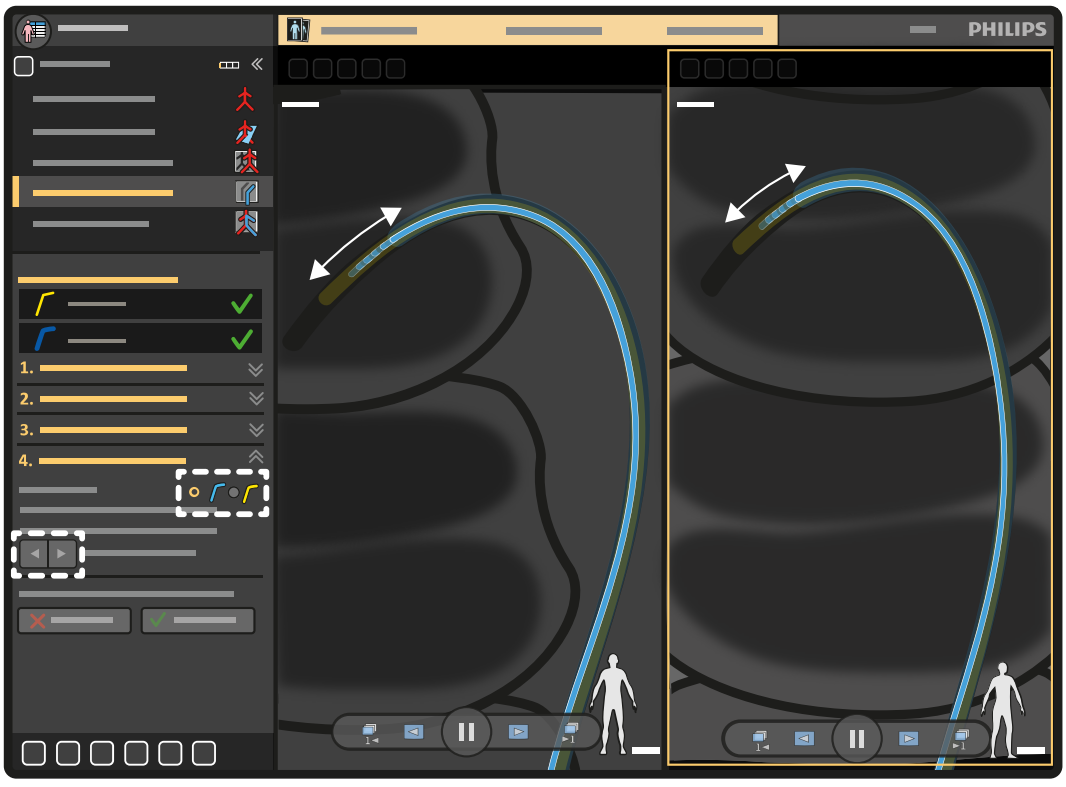


**Figure 44** Adjusting the AltaTrack device shape tips lengths

**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 tips of the AltaTrack device shapes 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.

4 If needed, select the other AltaTrack device shape option in the task panel and use the arrow buttons to adjust the tip shape.

5 If the position of the AltaTrack device shapes is satisfactory, click **Accept** in the task panel.

After accepting the registration, the AltaTrack software automatically moves to the next task: **Live Guidance**. For more information, see *Navigating with the AltaTrack Equipment* (page 60).

# 5 Navigating with the AltaTrack Equipment

After registration, the **Live Guidance** task allows you to overlay the 3D volume, if used, and the device 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 AltaTrack software in the control room.

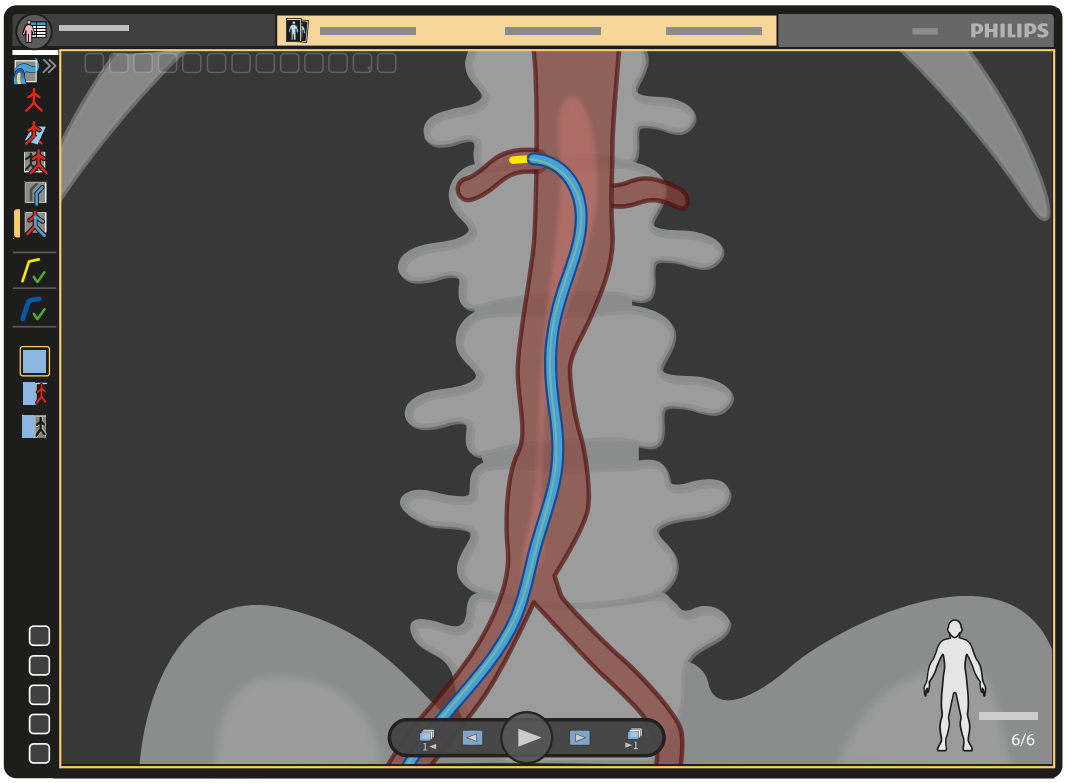


**Figure 45** Device navigation in the **Live Guidance** task

**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 78)******.***

Secondary views are also available, displaying a 3D roadmap with either an X-ray image and 3D volume or just a 3D volume.

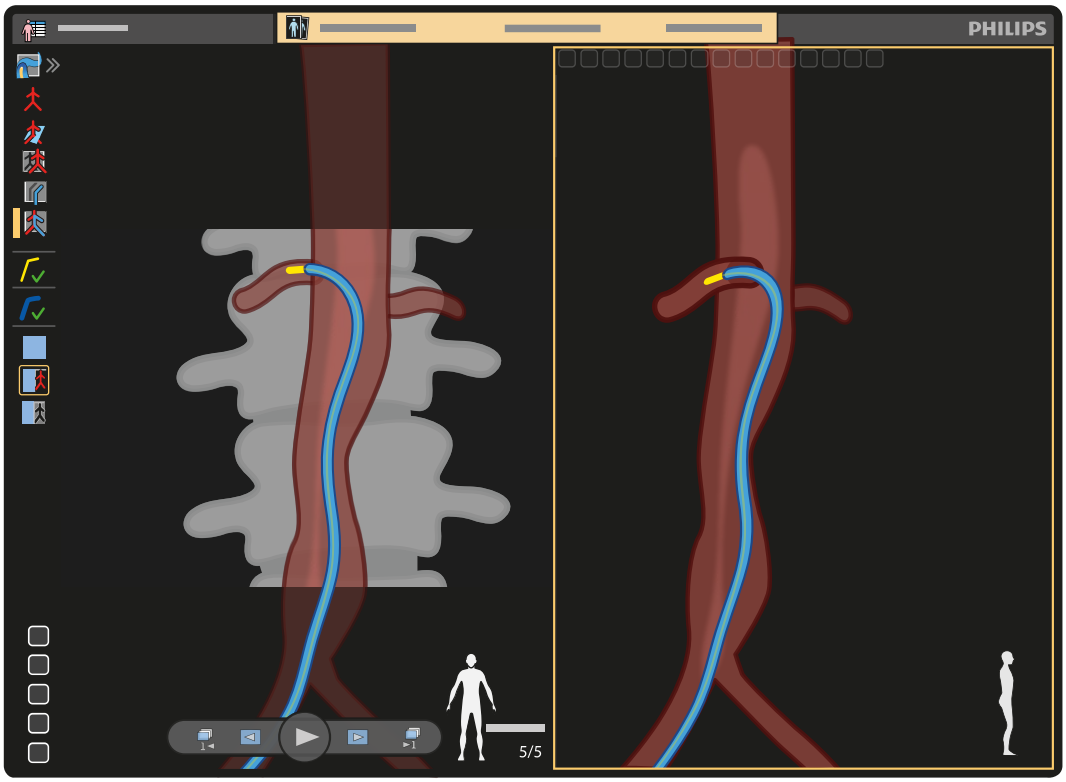


**Figure 46** Device navigation with 3D roadmap in the **Live Guidance** task

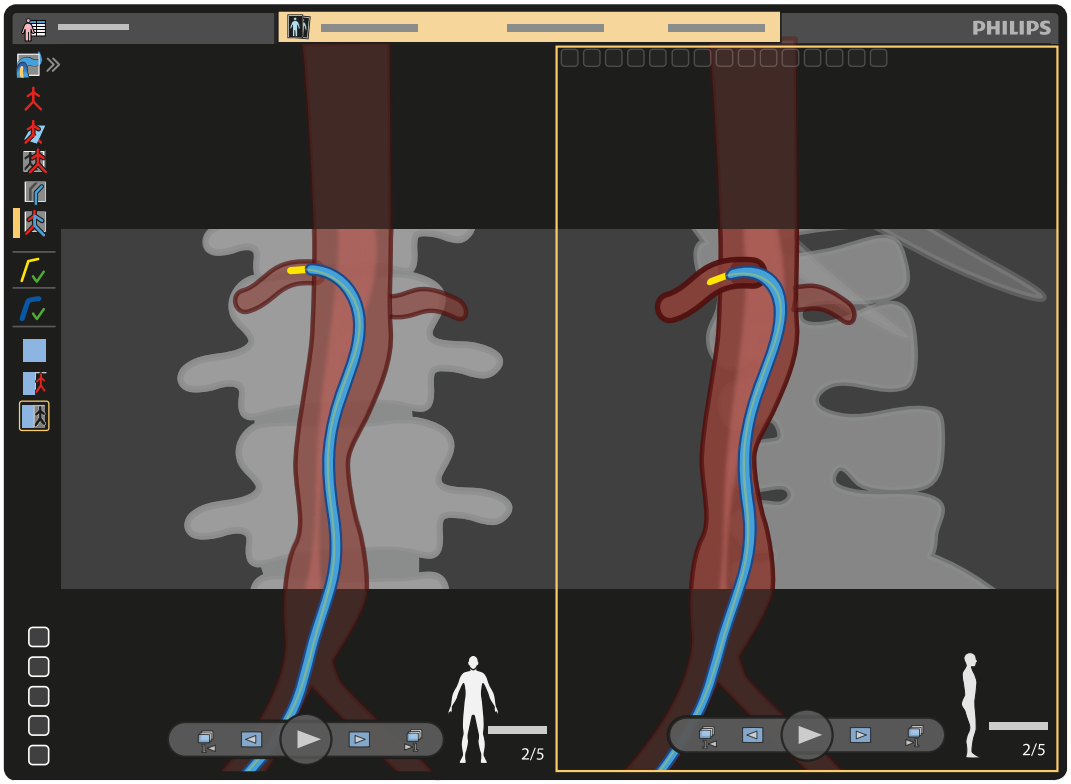


**Figure 47** Device navigation with 2D roadmap in the **Live Guidance** task

The size of the AltaTrack device shape as displayed in the primary view is enhanced to improve visibility. The tip of the AltaTrack device shape is displayed in white to indicate the direction of the device.

If the AltaTrack equipment detects a degradation in the quality of theAltaTrack device shape, a warning message is displayed in the AltaTrack software window.

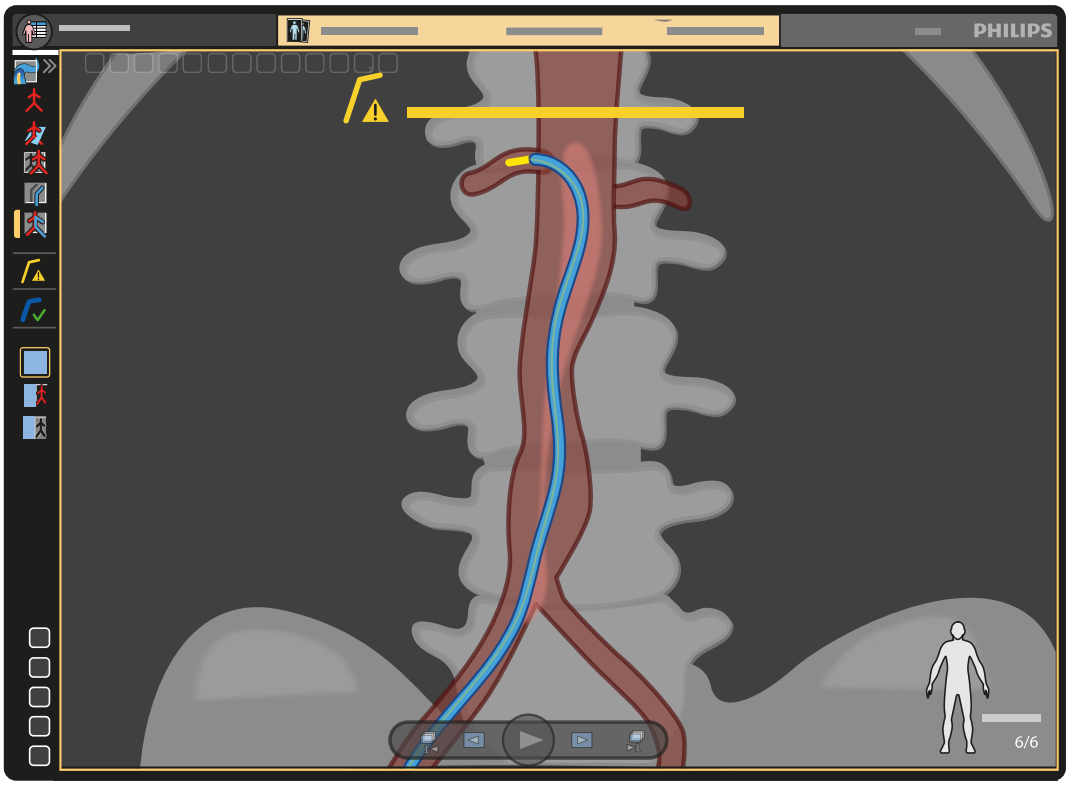


**Figure 48** Device shape warning in the **Live Guidance** task

If the quality of AltaTrack device shape degrades for a short time, a dashed, blinking centerline is displayed over the AltaTrack device shape and a warning symbol is displayed at the tip of the shape.

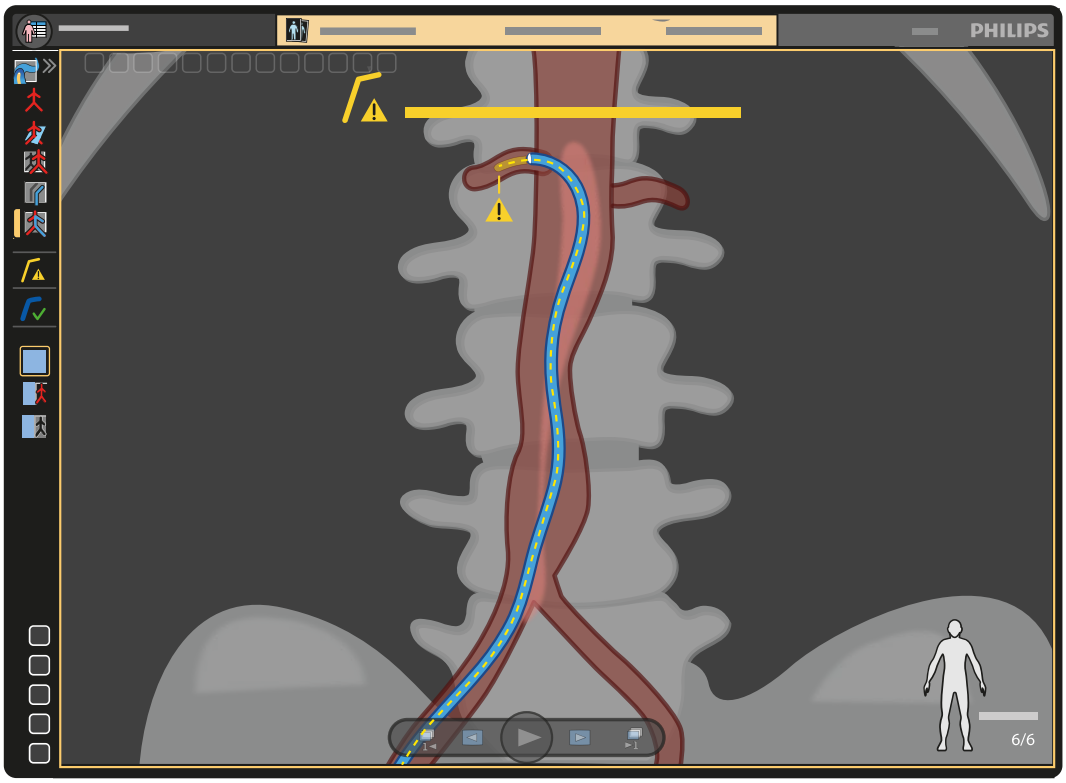


**Figure 49** Degraded device shape in the **Live Guidance** task

**NOTE** ***In this situation the AltaTrack software displays guidance on how to attempt to resolve the issue.***

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

**WARNING**
***The accuracy of the shape displayed cannot be fully guaranteed in all circumstances. Use frequent X-ray and tactile feedback from the device itself 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 device while it is in use and avoid putting excessive strain on the torque-absorbing section.***

**CAUTION**
***If the patient moves during the procedure, or if the AltaTrack docking base is moved along the table rail, or if any movement causes any part of the AltaTrack equipment to collide with the stand, table, or personnel in the examination room, you must perform registration for all devices again.***

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

## 5.1 Performing Live Guidance

The touch screen module of the X-ray system provides the following functions at the tableside during the **Live Guidance** task:

- Recalling planned angles
- Correcting volume registration
- Correcting shape registration
- Adjusting the visualization
- Storing series, snapshots, and movies

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

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

2 Tap **Layout** repeatedly to cycle through the viewport options (**Single View**, **Dual View 1**, and **Dual View 2**) and select a layout.

The examination room monitor displays live 3D FORS shapes of the connected devices overlaid on the preoperative CT volume (if applicable).

3 Tap either **Main View Control** or **Ref View Control** to apply visualization controls in the selected viewport.

4 To align the volume with the X-ray image (if applicable), tap **Main View Control**, then tap **Align Volume**, and then tap the corresponding arrow buttons to make adjustments.

5 To align the shape with the X-ray image (if applicable), tap **Main View Control**, then tap **Align Shape**, and then tap the corresponding arrow buttons to make adjustments.

6 Acquire an X-ray image to start navigation.

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

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

Handle the AltaTrack devices carefully to avoid impacting the performance of the AltaTrack equipment.

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

## 5.2 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.***

## 5.3 Changing an AltaTrack Device During a Procedure

The AltaTrack connection box provides two active connection slots and two standby slots. During a procedure, you can switch devices from an active connection slot to the standby slot, and from the standby slot to an active connection slot. You can switch between devices in the optical connections at any time without compromising the sterile field. Keep the AltaTrack connection box clean. Excessive blood may reduce the effectiveness of the docking action.

Handle the AltaTrack devices carefully to avoid impacting the performance of the AltaTrack equipment.

**NOTE** ***To assist you when swapping devices, AltaTrack devices are color-coded.***

If you store a device in the standby slot and then reconnect the device later, the registration information is retained, but you should verify the accuracy of the registration with X-ray.

If you store a device in the standby slot, and then reconnect the device later to a different slot than the one from which it was removed you must verify the accuracy of the registration.

The following procedure assumes that you are exchanging an active AltaTrack device with an AltaTrack device that is already parked in the standby slot and is already registered.

1 Remove all devices from the patient and wipe or flush them.

**WARNING**
***Do not cut the device during or after removal.***

If you are using an AltaTrack Guidewire with an AltaTrack Catheter, and you intend to move the catheter to the standby slot on the AltaTrack connection box, you must remove both devices from the patient. Withdraw the guidewire from the catheter and secure the catheter away from the X-ray field of view.

2 Secure the device to the covers using a hook-and-loop fastener.

3 (**Non-sterile user**) Disconnect the device connector from the AltaTrack connection box and ensure that the optical connector is properly stored in a standby slot.

**WARNING**
***Do not to use X-ray while a non-sterile user connects or disconnects a device at the connection box, as the connection box is close to the X-ray tube.***

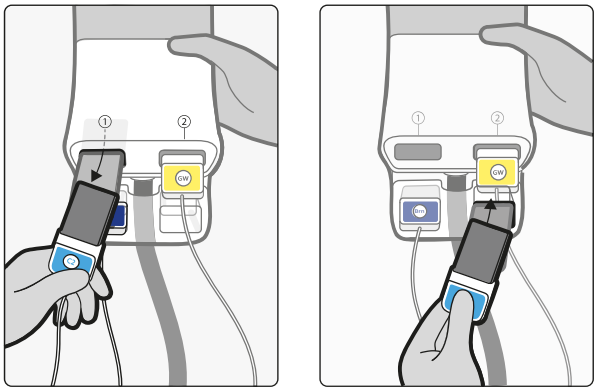

**Figure 50** Disconnecting a device connector from the AltaTrack connection box

4 (**Non-sterile user**) Connect the device connector of the new AltaTrack device to the AltaTrack connection box.

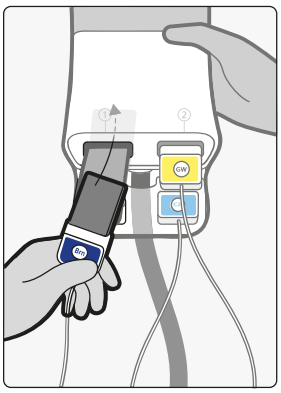

**Figure 51** Connecting a new device to the AltaTrack connection box

5 Combine the two AltaTrack devices and introduce the devices into the patient.

6 Use X-ray to confirm that the registration is still accurate.

## 5.4 Changing an AltaTrack Device for a Conventional Device During a Procedure

1 Ensure that the AltaTrack device that you want to use for navigation is connected.

2 Disconnect all other devices and secure them away from the X-ray field of view.

3 Combine the AltaTrack device and the conventional device that you want to use.

4 Introduce the devices in-body.

5 Check the registration of the AltaTrack device shape to X-ray and re-register if necessary.

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

## 5.5 Navigating Without AltaTrack Devices

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

1 Ensure that the AltaTrack devices are secured away from the X-ray field of view.

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

## 5.6 Disposing of an AltaTrack Device

You can detach and dispose of an AltaTrack device without compromising the sterile field, using the following standard hospital technique.

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

2 (**Sterile user**) Remove the AltaTrack device's docking fin from the AltaTrack Docking Top.

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

4 (**Sterile user**) Pass the device to the non-sterile user.

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

# 6 Performing Post-Operative Steps

1 Remove the AltaTrack devices from the patient.

2 Close the AltaTrack 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 85).

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

4 Remove the AltaTrack devices from the AltaTrack Docking Top.

5 Disconnect the device connectors from the AltaTrack connection box.

6 Dispose of the AltaTrack devices in the appropriate bin.

7 Tap **Shut Down** in the lower-right corner of the AltaTrack touch screen and then confirm your action to shut down the AltaTrack equipment.

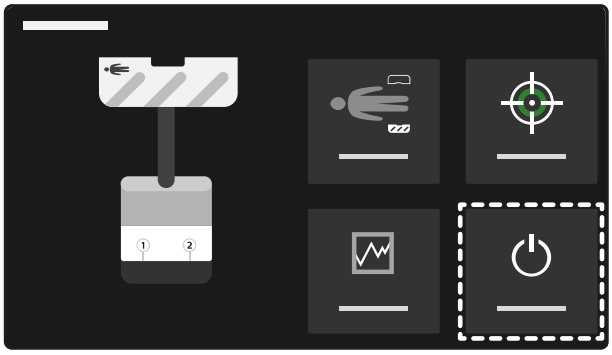

**Figure 52** **Shut Down** button on the AltaTrack touch screen

8 Follow the guidance on the AltaTrack touch screen until you are instructed to press the **Power Off** switch on the rear side of the AltaTrack trolley.

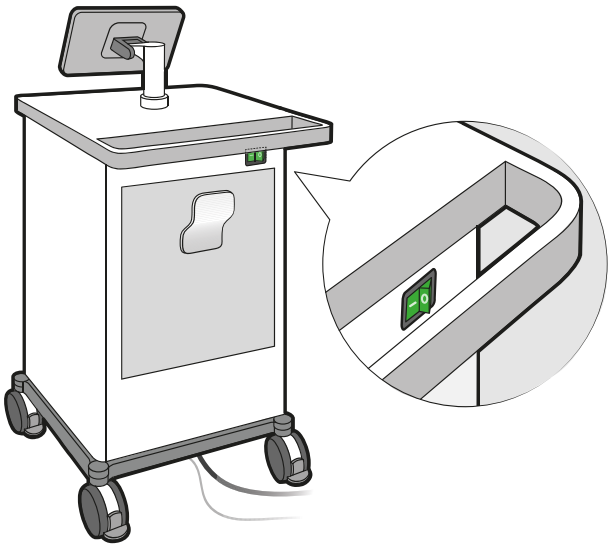

**Figure 53** AltaTrack trolley power switch

9 Remove the AltaTrack Docking Top from the AltaTrack docking base and dispose of it in the appropriate bin.

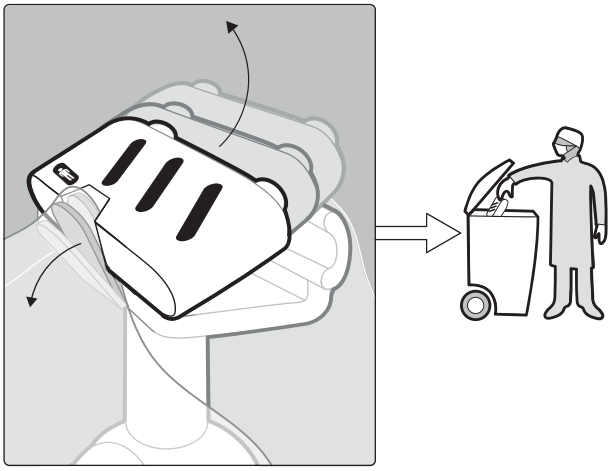

**Figure 54** Removing and disposing of the AltaTrack Docking Top

**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 AltaTrack table clamp and remove the AltaTrack docking base from the table.

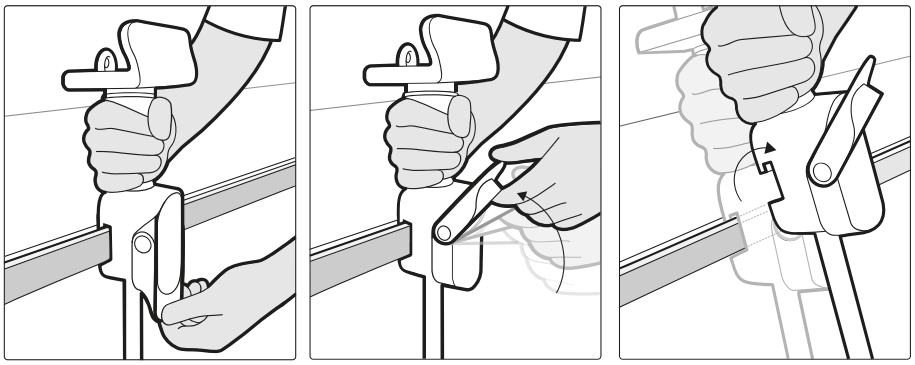

**Figure 55** Removing the AltaTrack docking base

**NOTE** ***If the AltaTrack docking base is contaminated, it should be cleaned before it is stored. For information about cleaning, see Cleaning the AltaTrack Equipment (page 71).***

12 Follow your local procedures for managing the patient.

13 Store the AltaTrack docking base and the AltaTrack equipment cable in the storage location on the AltaTrack trolley.

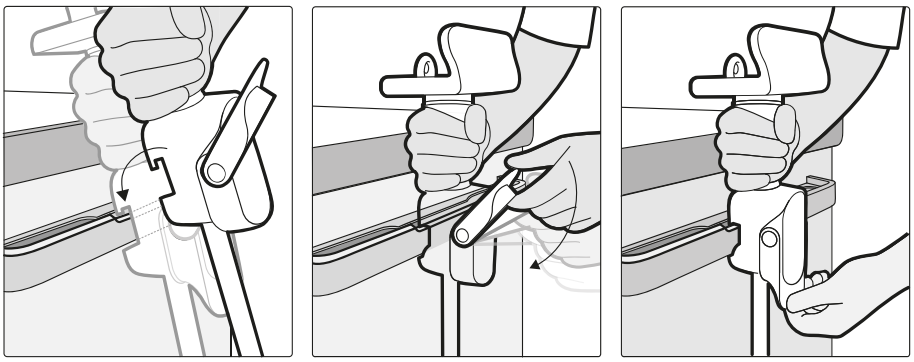

**Figure 56** Storing the AltaTrack docking base

**14** Disconnect the power cable and the network cable of the AltaTrack trolley from the wall sockets and store the cables on the hooks on the trolley.

**15** Clean the AltaTrack trolley and wipe the power cable and the network cable, if needed.

For information about cleaning, see *Cleaning the AltaTrack Equipment* (page 71).

**16** Release the brakes of the AltaTrack trolley, move it to its park position, and reapply the brakes.

# 7 Maintenance

### Planned Maintenance Program

To ensure that maintenance is performed at the required intervals, the responsible organization 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 technical support.

Operators may perform cleaning tasks on the AltaTrack equipment. For more information, see *Cleaning the AltaTrack Equipment* (page 71).

### Planned Maintenance Checks

| Task | Frequency | Required personnel |
|---|---|---|
| Check labels | Every 6 months | User |
| Check thermal aspects | Every 2 months | Technician |
| Check electrical aspects | Every 2 months | Technician |
| Check cleanliness | Every 2 months | Technician |
| Check mechanical aspects and functions | Every 2 months | Technician |
| Update device database | Every 2 months | Technician |
| Perform 3D calibration | Every year | Technician |
| Check electrical safety | Every 2 years | Technician |

### User Checks

To maintain optimal operating performance, restart the AltaTrack 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 technical support.

### 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.

### 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.

### 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

## 7.1 Cleaning the AltaTrack Equipment

All parts of the AltaTrack equipment including accessories may be cleaned by the hospital staff.

### Cleaning Guidance

- Clean the AltaTrack equipment after every intervention.
- Prevent cleaning fluid from dripping inside any enclosures.
- Clean the equipment by wiping it gently and without undue force with a mild soap solution.
- The AltaTrack Docking Top should not be cleaned, but should be disposed of immediately after use. For more information, see *Performing Post-Operative Steps* (page 67).

### Cleaning Agents

The following cleaning agents are permitted for cleaning any part of the AltaTrack 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 AltaTrack equipment cable and the AltaTrack components attached to the table:

| Cleaning Agent | Application |
|---|---|
| Ethanol 70% | Cleaning and disinfecting small and large surfaces |

| Cleaning Agent | Application |
|---|---|
| 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 |

## 7.2 Final Disposal of the AltaTrack 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 performing the functions of the product, and to meeting statutory and other requirements. This section of these Instructions for Use is directed mainly at the owner of the product.

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.

**Passing the System 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.

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.

# 8 Technical Information

## Environmental Conditions for Storage and Performance

| Item | Specification |
|---|---|
| Temperature range | • For performance: +18°C to +26°C<br>• For storage and transportation: -20°C to +60°C |
| Relative humidity | • For performance: 20% to 80%<br>• For storage and transportation (non-condensing): 10% to 90% |
| Air pressure | • For performance: 88 kPa to 110 kPa<br>• For storage and transportation: 70 kPa to 110 kPa |

## Classifications

| Item | Classification |
|---|---|
| AltaTrack equipment | According to the IEC60601-1 definition, the equipment is classified as class I equipment for continuous operation. |
| Mains type | Single phase AC |
| AltaTrack Catheter (Berenstein) | Applied part type B |
| AltaTrack Catheter (Cobra 2) | Applied part type B |
| AltaTrack Guidewire | Applied part type B |

## Standards and Regulations

| Item | Standard | |
|---|---|---|
| Laser safety<br>Complies with IEC60825-1:2007 | IEC 60825-1:2014 | Safety of laser products - Part 1: Equipment classification and requirements |
| | IEC 60825-1:2007 | Safety of laser products - Part 1: Equipment classification and requirements |

### Working Conditions

The AltaTrack equipment has the following working states:

- Starting up
- Ready for reconstruction
- Reconstructing one or two shapes
- Shutting down

### Accessories

The following items are compatible accessories to the AltaTrack equipment:

- AltaTrack Docking Top

### Other Equipment

The following items are compatible with the AltaTrack equipment:

- AltaTrack Catheter (Berenstein)
- AltaTrack Catheter (Cobra 2)
- AltaTrack Guidewire

### AltaTrack Trolley

| Item | Specification |
|---|---|
| Weight | 220 kg |
| IP protection | IP20 |
| Voltage | 120 V, 60 Hz (single phase) |
| Peak power consumption | 1000 VA |
| Average power consumption | 700 VA |
| Fuses | T 12 A, 120 V, size 6.3 x 32 mm |

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

### AltaTrack Docking Base

| Item | Specification |
|---|---|
| Weight | 3 kg |
| IP protection | • AltaTrack docking base: IP23<br>• AltaTrack equipment cable: IP54 |

### AltaTrack Workstation

| Item | Specification |
|---|---|
| Weight | 40 kg |
| Voltage | 100-240 V, 50-60 Hz |
| Peak power consumption | 1000 W |
| Average power consumption | 1000 W |

### Optical Processing Unit

| Item | Specification |
|---|---|
| Number of interrogators | 2 |
| Number of lasers for each interrogator | 1 |
| Laser type | External cavity tunable laser |
| Wavelength range | 1520-1600 nm |
| Output power | ≤5 mW (on the accessible point on the AltaTrack docking base |
| Laser safety class | Class I according to IEC 60825:2007/IEC 60825:2014 |

### Open-Source Software

Open-source software is used in this product. Refer to the installation media for license information and source code.

## 8.1 Electromagnetic Compatibility

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

The system, has been tested and complies with IEC60601-1-2:2014 (edition 4: collateral standard - electromagnetic disturbances) for medical electrical equipment.

### Intended Use Environment

The system 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 system is powered from a compatible uninterruptable power supply. Contact a Philips representative for details.

## 8.1.1 Emissions

### IEC60601-1-2 Edition 4

The system 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.

Guidance and manufacturer's declaration – electromagnetic emissions: The system is intended for use in the electromagnetic environment specified below. The operator of the system or the responsible organization should ensure that it is used in such an environment.

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

## 8.1.2 Immunity

| Description of Immunity Test | Test Standard | Compliance |
|---|---|---|
| Electrostatic discharge (ESD) | IEC 61000-4-2 | ±8 kV contact<br>±2, 4, 8, 15 kV air<br>See note 3 |
| Radiated RF electromagnetic fields | IEC 61000-4-3 | 80-2700 MHz<br>80% AM 1 kHz<br>3 V/m |
| Proximity fields | IEC 61000-4-3 | Frequencies and levels determined by EMC risk management. Refer to the table below.<br>See notes 2 and 3 |
| Electrical fast transients and bursts | IEC 61000-4-4 | ±1 kV (signal ports), see note 2<br>±2 kV (AC power ports) |
| Surges | IEC 61000-4-5 | ±0.5, 1 kV (line-line)<br>±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<br>3 $V_{rms}$, see note 2<br>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:<br>0% UT 0º, 45º,.. ,315º - 10 ms<br>0% UT 0º - 20 ms<br>70% UT 0º - 500 ms<br>0% UT 0º - 5000 ms |
| Power frequency magnetic fields | IEC 61000-4-8 | 50 Hz<br>30 A/m |
| *Note 1: $U_T$ is the AC mains voltage prior to application of the voltage dip or short interruption test.* | | |

| Description of Immunity Test | Test Standard | Compliance |
|---|---|---|
| *Note 2: A loss of LAN communication may be detected for the following cases: conducted disturbance between 750 kHz and 50 MHz on the LAN port, Electrical Fast Transients of 1 kV on the LAN port, or conducted disturbance between 1.2 and 1.5 MHz on the mains port. Basic safety and essential performance are not affected by this loss of communication.* | | |
| *Note 3: A system error may be detected for contact discharges on the tablet screen or cover around the tablet in excess of +2 kV or -8 kV or air discharges in excess of +4 kV or -15 kV. Follow the instructions on the tablet screen to resolve the issue. In case the error cannot be resolved, please call service. Basic safety and essential performance are not affected by these system errors.* | | |

### 8.1.3 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 loss of LAN communication may be detected for the following cases: conducted disturbance between 750 kHz and 50 MHz on the LAN port, Electrical Fast Transients of 1 kV on the LAN port, or conducted disturbance between 1.2 and 1.5 MHz on the mains port. Basic safety and essential performance are not affected by this loss of communication.* | | | |

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<br>18 Hz | 1.8 | 27 |
| 450 | 430-470 | FM<br>± 5 kHz deviation<br>1 kHz sine | 2 | 28 |
| 710 | 704-787 | Pulse modulation<br>217 Hz | 0.2 | 9 |
| 745 | | | | |
| 790 | | | | |
| 810 | 800-960 | Pulse modulation<br>18 Hz | 2 | 28 |
| 870 | | | | |
| 930 | | | | |
| 1,720 | 1,700-1,990 | Pulse modulation<br>217 Hz | 2 | 28 |
| 1,845 | | | | |
| 1,970 | | | | |
| 2,450 | 2,400-2,570 | Pulse modulation<br>217 Hz | 2 | 28 |
| 5,240 | 5,100-5,800 | Pulse modulation<br>217 Hz | 0.2 | 9 |
| 5,500 | | | | |
| 5,785 | | | | |

### 8.1.4 RFID

RFID communication frequency between the equipment and AltaTrack devices.

| Item | 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 |

# 9 Appendix

This section provides background information and reference information for the AltaTrack equipment.

## 9.1 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.

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

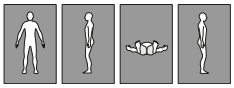

**Figure 57** Orientation indicator

## 9.2 Setting User Preferences

You can configure your preferences for the viewing environment using the **User Preferences** dialog box.

1 Click **User Preferences** in the common tools panel.

2 Configure the settings in the **User Preferences** dialog box.

| Settings | Options |
|---|---|
| **Orientation indicator** | **On** |
| | **Off** |
| **Patient info level** | **None** |
| | **Essential** |
| | **All** |
| **Angle flavor** | **Radiology** |
| | **Cardiology** |
| **Automatically replay Fluoro in Live Guidance** | **On** |
| | **Off** |

3 Click **Close** to close the **User Preferences** dialog box and save your settings.

## 9.3 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.***

### 9.3.1 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.

### 9.3.2 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.

### 9.3.3 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 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.

## 9.3.4 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.

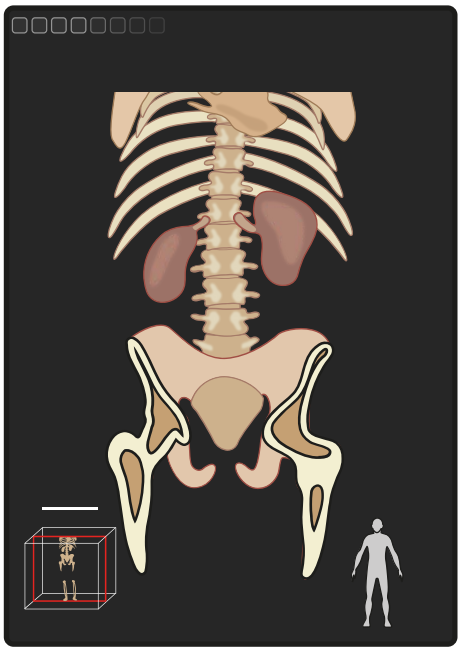

**Figure 58 Cutplane** indication box

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.

### 9.3.5 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.

### 9.3.6 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.

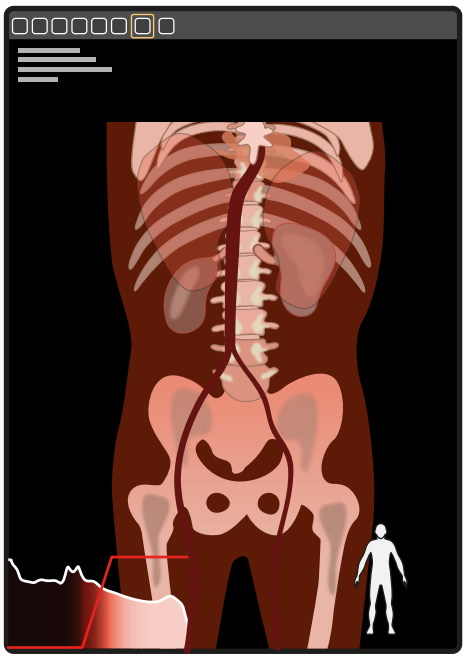

**Figure 59** Histogram

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.

### 9.3.7 Adjusting the Opacity of the Volume

Adjusting the opacity of the CT volume (if applicable) allows you to view the AltaTrack device shapes or anatomical objects in the vicinity of the volume more easily.

1 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.

### 9.3.8 Panning the AltaTrack Device Shapes

Panning the AltaTrack device shapes allows you to adjust the registration of the shapes manually.

**NOTE** ***While it is possible to adjust the registration of the AltaTrack device shapes manually using the Pan Shape and Rotate Shape tools in the toolbar, these complex actions are recommended for advanced users only.***

1 Click **Pan Shape** on the toolbar.

2 Pan the AltaTrack device shape by dragging it.

The AltaTrack device shape pans in the direction of movement.

### 9.3.9 Adjusting the Opacity of the AltaTrack Device Shapes

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

1 Click **Shape Opacity** on the toolbar and do the following:
- Drag the pointer upward to decrease the opacity of the device shapes.
- Drag the pointer downward to increase the opacity of the device shapes.

### 9.3.10 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) |

### 9.3.11 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.

## 9.4 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** |

| Common Tools | |
|---|---|
|  | **Export to USB** |
|  | **Snapshot** |
|  | **DICOM Snapshot** |
|  | **Movie** |

# 9.5 Snapshots and Movies

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

## 9.5.1 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 AltaTrack 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:, click **DICOM Snapshot** in the common tools panel.

**a** In the AltaTrack 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.***

### 9.5.2 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.***

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

**a** In the AltaTrack 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 85).

### 9.5.3 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**.

## 9.6 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 AltaTrack 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.

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The device meets the requirements of the 93/42/EEC Medical Device Directive, 2014/53/EU Radio Equipment Directive, and Directive 2011/65/EU Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment.

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