PHILIPS

Instructions for Use

English

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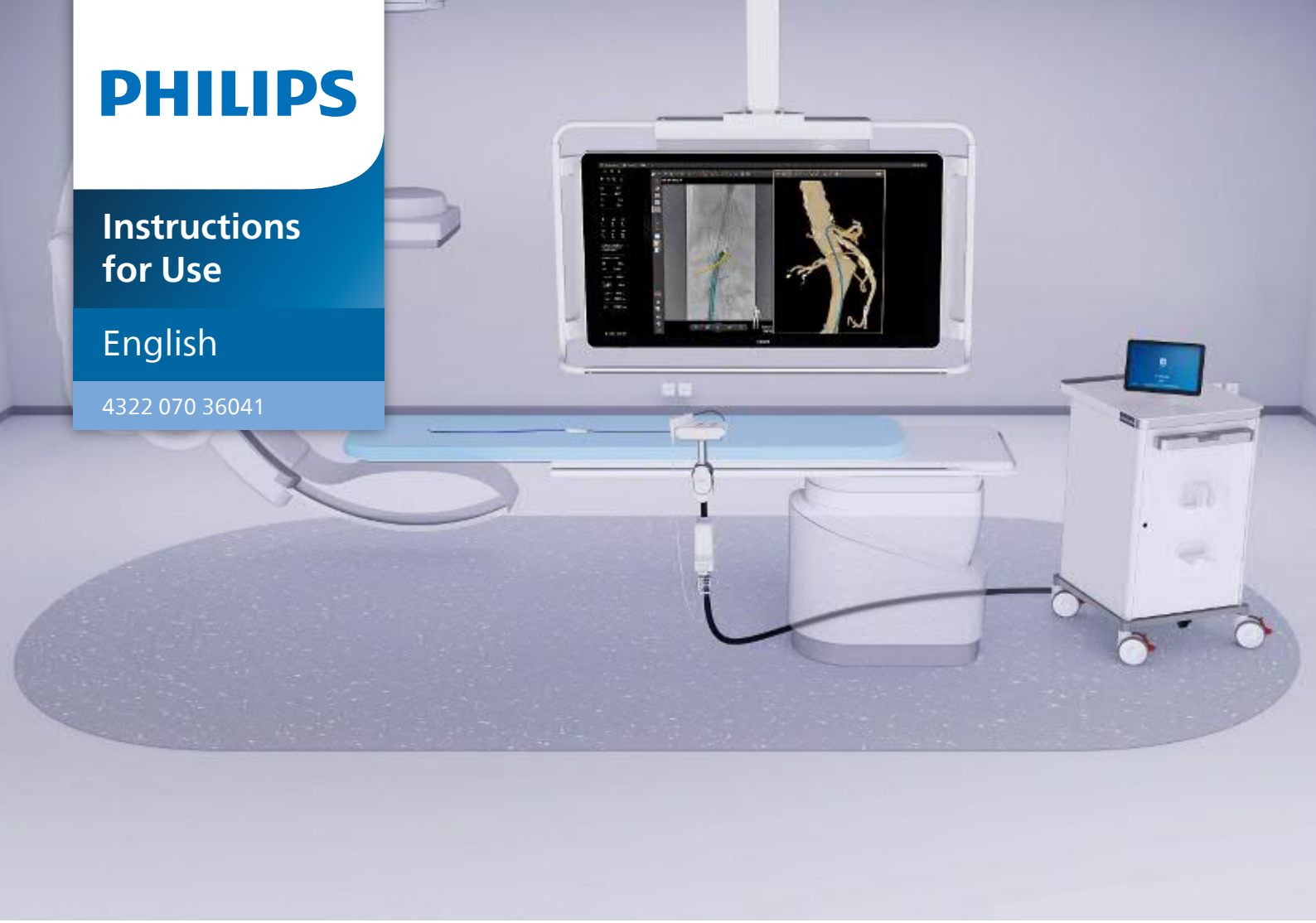


Philips LumiGuide Equipment

Release 2.0

Contents

1 About the LumiGuide Equipment

The LumiGuide Equipment is a visualization device with Fiber Optic RealShape (FORS) technology. It uses FORS technology to provide a real-time 3D image of the shape of a connected AltaTrack Guidewire and optionally an endovascular catheter when combined with the AltaTrack 3D Hub. The LumiGuide Equipment overlays the FORS visualization on anatomical images such as a pre-procedural CT volume and X-ray images from the X-ray system.

The LumiGuide Equipment is intended to be used in conjunction with a compatible Philips Interventional X-ray system, patient table and an AltaTrack angiographic device such as the AltaTrack Guidewire.

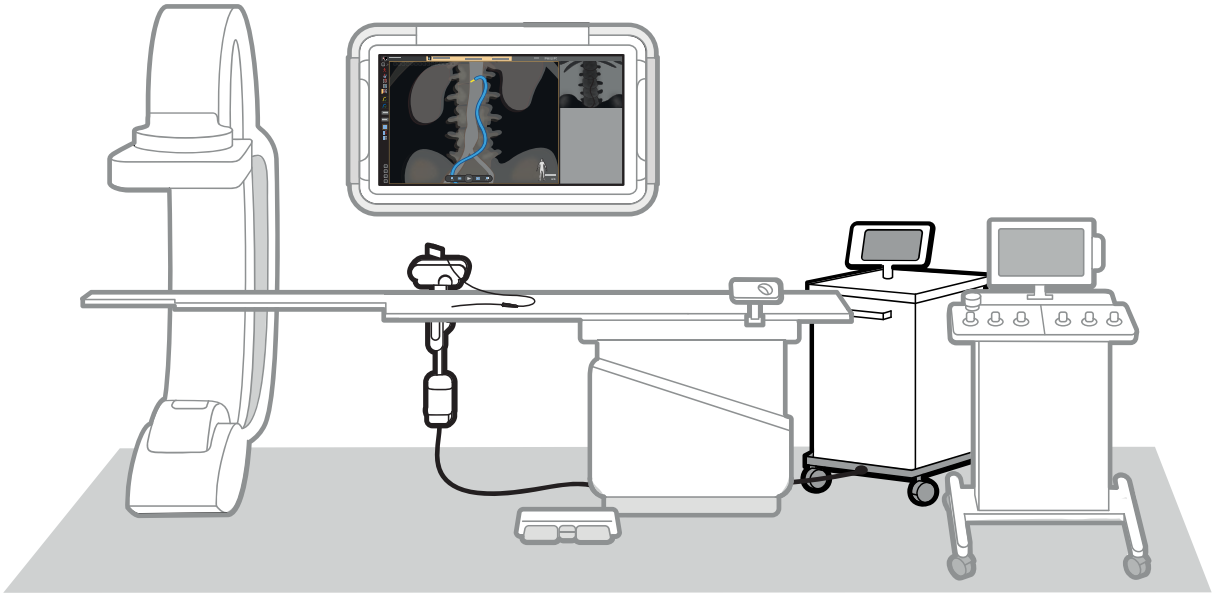


Figure 1 LumiGuide Equipment in the interventional catheterization lab or operating room

After setting up the LumiGuide Equipment in the interventional catheterization lab or operating room and starting the procedure, the equipment displays live guidance images on the monitors.

Tasks in the LumiGuide Viewing Software guide you through the following phases to prepare and view the overlay image:

- Segmenting the preoperative 3D data set to identify vessels.
- Planning views and tagging anatomical landmarks to assist with device navigation.
- Registering the preoperative 3D data set with the X-ray system to provide a matched overlay image.
- Registering the AltaTrack Guidewire and a catheter connected to the AltaTrack 3D Hub with the X-ray system.
- Providing live guidance through a real-time 3D image of the shape of the AltaTrack Guidewire and optionally an endovascular catheter when connected to the AltaTrack 3D Hub, and the preoperative 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 LumiGuide Equipment.

The LumiGuide Equipment can be identified by the label on the LumiGuide Engine.

All Instructions for Use supplied with the LumiGuide 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 LumiGuide 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.

CAUTION
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 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.

Device Description
The LumiGuide Equipment is a visualization device with Fiber Optic RealShape (FORS) technology. It uses FORS technology to provide a real-time 3D image of the shape of a connected AltaTrack Guidewire and optionally an endovascular catheter when combined with the AltaTrack 3D Hub. The LumiGuide Equipment overlays the FORS visualization on anatomical images such as a pre-procedural CT volume and X-ray images from the X-ray system.

The LumiGuide Equipment is intended to be used in conjunction with a compatible Philips Interventional X-ray system, patient table and a LumiGuide angiographic device such as the AltaTrack Guidewire.

The LumiGuide Equipment comprises of the following main parts:
- LumiGuide Engine: contains the core hardware of the LumiGuide Equipment, providing real-time 3D reconstruction of the AltaTrack Guidewire, and optionally a catheter when combined with the AltaTrack 3D Hub, on monitors in the operating room and in the control room.
- LumiGuide Touch Screen: displays pre-procedural instructions for preparing the LumiGuide Equipment and provides user assistance during use.
- LumiGuide Docking Base: provides an attachment point for the AltaTrack Docking Top and a fixed reference point that allows the AltaTrack Guidewire shape to be registered with X-ray images.

- LumiGuide Viewing Software: assists the user during the procedure by overlaying live reconstructed shapes on pre-procedural CT volume (optional) and X-ray images from the X-ray system. It is accessible in the operating room and control room.
- LumiGuide WorkSpot: provides access to the LumiGuide Viewing Software on monitors in the control room, where (optionally) data preparation tasks can be performed.

Indications for Use
The LumiGuide Equipment is a visualization device with Fiber Optic RealShape (FORS) technology intended to aid the positioning and navigation of a connected AltaTrack Guidewire and, optionally, a catheter during endovascular procedures of the peripheral, aortic and aortic side branch vasculature, by creating a 3D image in real-time of the connected AltaTrack Guidewire and, of an endovascular catheter, when combined with an AltaTrack 3D Hub.

Intended Users of the LumiGuide Equipment
The following clinical users, trained to operate and handle the LumiGuide Equipment, will use the LumiGuide Equipment:
- The physician responsible to perform the procedure.
- A user that executes certain workflow steps (either autonomously or following instructions from the physician).

Clinical environment
The LumiGuide Equipment is intended to be used in an interventional catheterization lab or operating room, in which a Philips fixed C-arm X-ray system and compatible patient table is installed, and the associated control room.

General safety and effectiveness
To facilitate safe and effective operation of the LumiGuide Equipment by a trained healthcare professional, instructions for use are provided as part of the device labeling, and training is provided for all products before use.

Patient population
The patient population is based on patients treated during endovascular procedures of the peripheral, aortic and aortic side branch vasculature. These procedures are defined as interventions intended to deliver minimally invasive treatment or diagnosis of disease and disorders affecting blood flow through vessels distal to the heart, i.e. pertaining to the peripheral circulation. This definition excludes cardiac interventions and neuro-interventions, i.e. interventions within the heart, the vessels of the brain or the spinal cavity. Philips includes the aorta within this definition of peripheral endovascular procedures.

Contraindications
There are no contraindications.

Operating Principle
The operating principle of the LumiGuide Equipment is based on FORS technology. FORS technology involves sending laser light into a specially designed optical fiber, the FORS sensor, and measures light reflected back from that sensor. This allows for real time, 3D reconstruction of the shape of that fiber optic sensor, when connected to LumiGuide Equipment containing software and electronic components. When the fiber optic sensor is integrated into a guidewire along the full length of the guidewire, it enables real time, 3D visualization of that guidewire. When used in combination with an AltaTrack 3D Hub, it also enables real time, 3D visualization of connected endovascular catheters.

1.3 Compatibility

The LumiGuide Equipment is used in interventional rooms, operating rooms, or other rooms in which a compatible Philips interventional X-ray system is installed that is equipped with appropriate options. For details of compatible systems and components, 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 Guidewire is 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.

The LumiGuide Equipment is only intended to be used with the PC hardware configuration on which it is initially installed by the manufacturer. The LumiGuide Equipment 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.

For more information about compatible devices and accessories, see Technical Information (page 93).

1.3.1 Data Sets

You can open data on the LumiGuide Equipment that is indicated by the following icon:

Overlay Data Sets
You can use a preoperative CT volume as a roadmap (overlay) during device navigation with the LumiGuide 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 preoperative CT volume as an overlay with the LumiGuide 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
The LumiGuide 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, the LumiGuide Equipment truncates the whole volume from cranial to caudal, using only the first 1600 slices.

NOTE
If you use derived DICOM data sets, the LumiGuide Equipment 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 scans, 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 LumiGuide 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 Endovascular Catheters

To enable visualization of endovascular catheters when connected to an AltaTrack 3D Hub by the LumiGuide Equipment, the endovascular catheter should meet the following requirements:
- When used in combination with an AltaTrack Guidewire, the endovascular catheter should be no longer than 95 cm.
- The endovascular catheter should have an inner diameter that is compatible with a 0.035" guidewire
- The endovascular catheter should have a Luer lock to allow connection to the AltaTrack 3D Hub.

1.3.3 Sterile Covers

CAUTION
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 LumiGuide 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 representative. Alternatively, contact the manufacturer.

1.5 Frequently Used Functions

The system provides the following frequently used functions:
- Correctly position the LumiGuide Equipment in the OR.
- Start-up the LumiGuide Equipment.
- Prepare the patient data and images for the intervention.
- Register the coordinate system of the pre-procedural CT to that of the X-ray system.
- Choose the type of AltaTrack Guidewire to be used with the LumiGuide Equipment.
- Setup of multiple AltaTrack Guidewires.
- Placing in stand-by of an AltaTrack Guidewire during procedure.
- Register the AltaTrack Guidewire with the X-ray system.
- Correct the registration of the AltaTrack Guidewire in Live Guidance.

- Register the length of conventional catheters without X-ray, by aligning tips of guidewire and catheter (tip-to-tip).
- Register the length of conventional catheters by using X-ray.
- Enhance viewing of X-ray image, pre-procedural CT, and shapes. Customize the overlay visualization.
- Live display of the 3D shapes of the connected AltaTrack Guidewire and, if applicable, a conventional catheter connected to the AltaTrack 3D Hub (FORS-guided catheter), with or without pre-procedural overlay.
- Export stored X-ray images, snapshots, and movies to a PACS system.
- Shutdown, clean, and store the LumiGuide Equipment.
- Remove the AltaTrack Guidewire from the patient, disconnect AltaTrack Guidewire and AltaTrack Docking Top.
- Dispose of the AltaTrack Guidewire, AltaTrack 3D Hub, and AltaTrack Docking Top.

1.6 Contacting the Manufacturer

Manufacturer's Contact Details	
Postal address	Philips Medical Systems Nederland B.V. Veenpluis 6 5684 PC Best The Netherlands
Website	www.philips.com/healthcare

2 Safety

WARNING
No modification of the LumiGuide Equipment is allowed. Changes or modifications that are not expressly approved by the manufacturer may void the user's authority to operate the equipment.

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, repair, or maintain 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 interventional catheterization lab or operating 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 LumiGuide Equipment has no performance that is determined to be essential performance.

2.1 Serious Incidents

If a serious incident has occurred in relation to the device, it should be reported to the manufacturer and the competent authority of the country in which the user and/or patient is established. A serious incident means any incident that directly or indirectly led, might have led or, in case of recurrence, could lead to any of the following: the death of a patient, user or other person, the temporary or permanent serious deterioration of a patient's, user's, fetus or other person's state of health, or a serious public health threat.

For manufacturer contact details, see Contacting the Manufacturer (page 12).

2.2 Emergency Procedures

Loss of Roadmap

NOTE
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 LumiGuide Viewing Software does not receive X-ray images.***

2.3 Radiation Safety

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

2.4 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 LumiGuide Equipment is used must comply with all applicable laws and regulations, or regulations concerning electrical safety for the LumiGuide Equipment. The combination of the LumiGuide Equipment 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 LumiGuide Equipment. Doors, covers, or cables should only be removed or opened by qualified and authorized service personnel.

WARNING
Do not touch electrical or network connectors on the patient table, the LumiGuide Engine, or the LumiGuide 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, the LumiGuide Equipment must only be connected to supply mains with protective earth.

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

Cables
Electrical current may still be present in cables that are no longer connected to the LumiGuide Equipment, 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 LumiGuide Equipment. Such cables can compromise the electrical safety of the LumiGuide Equipment, especially in the interventional catheterization lab or operating room near the patient.

Cleaning
Switch the LumiGuide Equipment off before cleaning or disinfecting it. Do not use cleaning agents or damp cloths on connector contact pins. For more information, see Cleaning the LumiGuide Equipment (page 87).

2.5 Mechanical Safety

WARNING
Ensure that the LumiGuide Docking Base is securely fixed to the table rail at an appropriate position. If the LumiGuide Docking Base falls off, or if there is any intentional or unintentional movement of the LumiGuide 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.

NOTE
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 the registration accuracy of the AltaTrack Guidewire is insufficient after moving the table, register the AltaTrack Guidewire again.

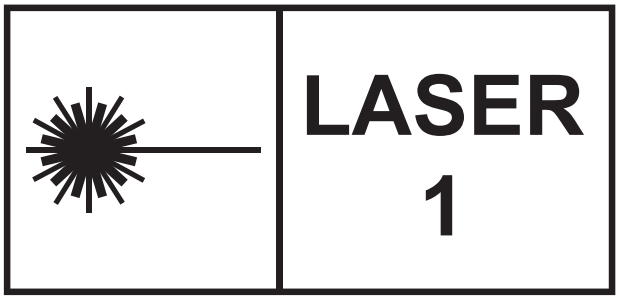
CAUTION
If any of the following events occur during the procedure, you must perform AltaTrack Guidewire registration again:
- ***The LumiGuide Docking Base is moved along the table rail.***
- ***An AltaTrack Guidewire is connected or disconnected.***
- ***The patient moves during the procedure.***
-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

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

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.

2.6 Laser Safety

The LumiGuide Equipment contains a class 1 laser product (IEC classification). This laser is safe under all conditions of normal use.



NOTE
Complies with FDA performance standards for laser products except for conformance with IEC 60825-1 Ed. 3., as described in Laser Notice No. 56, dated May 8, 2019.

2.7 Explosion Safety

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

Do not use the LumiGuide Equipment 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 LumiGuide Equipment (page 87).

2.8 Fire Safety

Fire regulations for the type of medical environment being used should be fully observed, applied, and enforced. Using the LumiGuide Equipment in an environment for which it was not designed can cause fire or explosion. The device is not intended to be used in an oxygen rich environment.

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 LumiGuide Equipment before attempting to fight a fire. This reduces the risk of electric shocks.

2.9 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 LumiGuide 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 LumiGuide Equipment is a medical electrical system consisting of class A, group 1 equipment.

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

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

The LumiGuide 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 LumiGuide 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 LumiGuide 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 LumiGuide 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.

2.10 Equipment Labels

NOTE
The following images are indicative of the actual labels used on the equipment.

For information about the symbols used on these labels, see Symbols Used on the LumiGuide Equipment (page 18).

LumiGuide Equipment

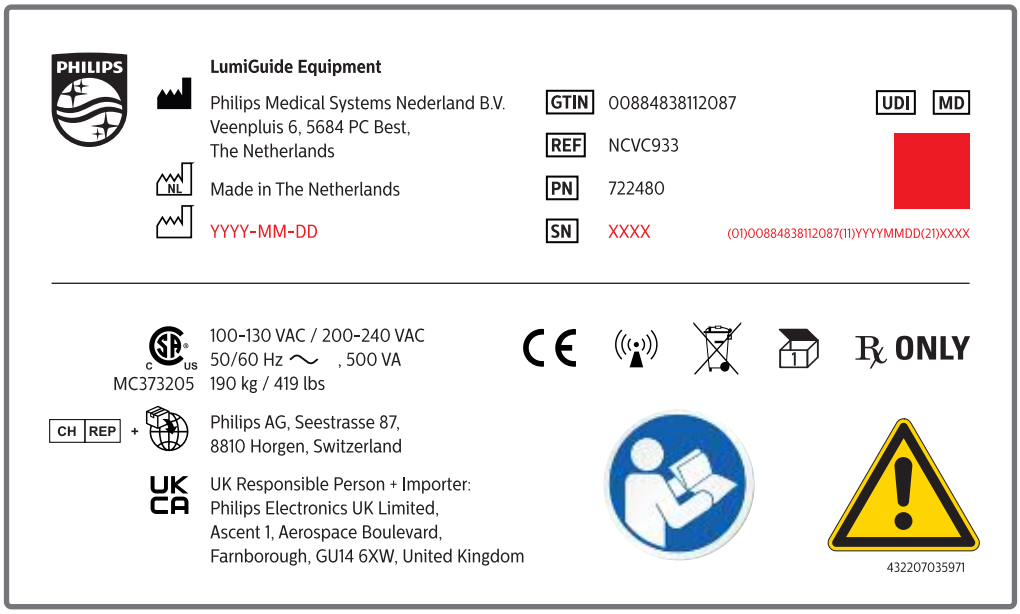


Figure 2 LumiGuide Equipment label

Figure 3 Laser certification label

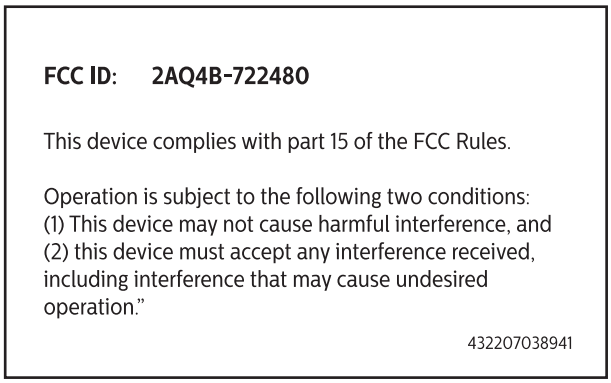


Figure 4 FCC label

AltaTrack Docking Top

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

AltaTrack 3D Hub

For information about the AltaTrack 3D Hub, refer to the Instructions for Use supplied with the AltaTrack 3D Hub.

AltaTrack Guidewire
For information about the AltaTrack Guidewire, refer to the Instructions for Use supplied with the AltaTrack Guidewire.

2.11 Symbols Used on the LumiGuide Equipment

For information about the symbols that are used with this product, refer to the following website:

www.symbols.philips.com

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

Power Off: This symbol identifies the mains switch on the LumiGuide Engine. When the green indicator light of the mains switch is not illuminated, the LumiGuide Engine 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.

Protective Earth: This symbol indicates the location of protective earth (ground).

Type B: For more information, see Applied Parts (page 20).

IP Code: IP stands for International Protection. The IP code 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. The date of manufacture, as well as the name and address of the manufacturer, can be combined in one symbol.

Country of Manufacture: This symbol indicates the country of manufacture of the medical device.

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

Medical Device: This symbol indicates the equipment is a medical device.

Global Trade Identification Number: This symbol indicates a product's unique trade item identifier.

Unique Device Identifier: This symbol indicates a carrier that contains Unique Device Identifier information.

Catalog Number: This symbol indicates the manufacturer's catalog number so that the medical device can be identified.

Serial Number: This symbol indicates the manufacturer's serial number so that a specific medical device can be identified.

Part Number: This symbol indicates the Philips internal part number.

Caution: This symbol indicates that the user should consult the Instructions for Use for details of specific warnings or precautions that are associated with the medical device.

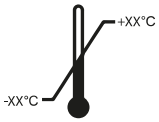
Consult the Instructions for Use: This symbol indicates that you should read the Instructions for Use as operator awareness or operator action is required to avoid undesirable consequences.

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

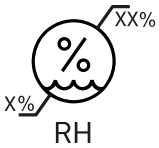
Product Disposal: This symbol indicates that the equipment contains materials that are harmful to the environment if disposed of incorrectly. For more information, see Final Disposal of the LumiGuide Equipment (page 89).

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

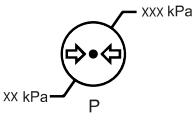
Packaging Unit: This symbol indicates the number of products in the package.



Temperature Limits: This symbol indicates the upper and lower temperature limits within which the system should be used.



Humidity Limits:This symbol indicates the upper and lower humidity limits within which the system should be used.



Atmospheric Pressure Limits: This symbol indicates the upper and lower atmospheric pressure limits within which the system should be used.

Authorized Representative: This symbol indicates the authorized representative in Switzerland.

Importer: This symbol indicates the entity importing the medical device into the locale.

CE Certification: This symbol indicates that the equipment complies with applicable European directives and regulations. The number of the notified body is indicated, if applicable.

Canadian Standards Association: This symbol indicates that the equipment has been tested and certified by the Canadian Standards Association to comply with the applicable U.S. and Canadian Standards.

UK Conformity Assessed: This symbol indicates that the equipment complies with applicable regulations and directives in the United Kingdom. The number of the UK approved body is indicated, if applicable.

2.12 Hazardous Substances

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

WARNING
California's Proposition 65 requires Philips to provide reasonable safety warning information when a released substance is above safe harbor levels. The internal components of this product may contain substances that, when exposed, are known to the State of California to cause cancer or reproductive harm. Based on the risk assessment performed by Philips, there is no risk or low risk to patient or hospital staff. Service personnel may be exposed to internal components while servicing the equipment. For information about risks to service personnel, refer to the service documentation.

For more information about California's Proposition 65, see the following websites:

www.philips.com/about/sustainability

www.p65warnings.ca.gov

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

www.dtsc.ca.gov/hazardouswaste/perchlorate

REACH Declaration
For information about REACH substances that may be contained in some Philips products, refer to the following website:

www.philips.com/reach

2.13 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 Guidewire

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

2.14 Warning Messages

The following warning messages may be displayed on the LumiGuide Viewing Software screen.

NOTE
The warning messages on the LumiGuide Viewing Software refer to the AltaTrack Guidewire as the LumiGuide Wire: a FORS-enabled guidewire connected to the LumiGuide Equipment. For information about product names, see Compatibility (page 9).

Warning Message	Guidance
Cannot visualize the catheter tip. Extend the LumiGuide Wire beyond the catheter tip or use fluoroscopy.	The LumiGuide Equipment has detected that the AltaTrack Guidewire is retracted inside the lumen of the catheter, behind the catheter's tip, and therefore the extrapolated tip shape of the catheter is not fully reliable. Extend the AltaTrack Guidewire beyond the catheter's tip to fully visualize it or use fluoroscopy.
Catheter registration may be inaccurate. Check length with fluoroscopy.	The LumiGuide Equipment detected that a previously registered catheter is selected, while the AltaTrack Guidewire is beyond catheter's tip and therefore fully visualized. Check the catheter length registration using fluoroscopy.
Confirm shape registration result.	The LumiGuide Equipment has detected that the user has not confirmed registration results during Shape Registration. Please accept registration to proceed to live Guidance or Reject and redo registration.
Extend the guidewire beyond the catheter tip or use fluoroscopy.	The LumiGuide Equipment detected that that a previously registered catheter is selected, while the AltaTrack Guidewire is still inside the catheter. As in this situation the catheter's shape is reconstructed and not reliable, check the catheter's position with fluoroscopy or make sure to extend the AltaTrack Guidewire beyond the catheter to its full shape.
Guidewire not registered. Perform Shape Registration.	The LumiGuide Equipment has detected that the AltaTrack Guidewire is not registered to the X-ray system. Perform shape registration first.
Guidewire registration may be inaccurate. Check with fluoroscopy.	The LumiGuide Equipment has detected that the shape accuracy could have been compromised. Use fluoroscopy to check the alignment of the shape to X-ray.
LumiGuide Engine issue. See LumiGuide Touch Screen for resolution.	For additional information on messages that appear on the LumiGuide Touch Screen and resolution thereof, see Guidance for Resolving Issues (page 109).
LumiGuide Engine issue. See LumiGuide Touch Screen for resolution.	Follow the instructions on the LumiGuide Touch Screen. If the problem cannot be resolved contact Philips technical support.
LumiGuide Wire issue.	There is a problem with reconstruction of the shape. If the problem cannot be resolved, replace the device.
LumiGuide Wire issue. Relax distal LumiGuide Wire bend.	Relax the bend in the device. If the problem cannot be resolved, replace the device.
LumiGuide Wire issue. Relax proximal LumiGuide Wire bend.	Relax the bend in the device. If the problem cannot be resolved, replace the device.
LumiGuide Wire issue. See LumiGuide Touch Screen for resolution.	Follow the instructions on the LumiGuide Touch Screen. If the problem cannot be resolved contact Philips technical support.
No FORS signal is being received.	The LumiGuide Equipment detected that no FORS signal was detected. Check the connections and try again.
No X-ray imaging performed for 5 minutes. Check with fluoroscopy.	The LumiGuide Equipment has detected that there was no X-ray used for more than 5 minutes. The LumiGuide Equipment must always be used in combination with X-ray. Use fluoroscopy to check the alignment of the shape to X-ray.
Possible overlay mismatch: X-ray run was acquired in uncalibrated X-ray system position.	The X-ray system was in an uncalibrated position when the X-ray run was acquired. Shape accuracy could have been compromised. Move X-ray system back to a calibrated position and acquire a new X-ray run.

Warning Message	Guidance
Possible overlay mismatch: X-ray run was acquired while table was cradled, tilted or pivoted.	The table was in a cradled, tilted or pivoted position when the X-ray run was acquired. The accuracy of the overlay matching FORS visualization may be impacted. Put the table in zero-position and acquire a new X-ray run.
Registration inaccuracy detected. Adjust registration if needed.	The LumiGuide Equipment has detected that the automatic shape registration may be inaccurate. If needed, adjust registration by placing points on the X-ray shape of the AltaTrack Guidewire.
Table or gantry has moved. Check with fluoroscopy.	The LumiGuide 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.
The LumiGuide Wire has been used before. See LumiGuide Touch Screen for resolution.	The LumiGuide Equipment has detected that the connected AltaTrack Guidewire has been used before, 24 hours prior to this connection.
The patient data does not match with the current patient on the X-ray system. Verify the identity of the patient and merge the patient information.	The LumiGuide Equipment has detected that patient selected in the LumiGuide Viewing Software differs from the current patient on the X-ray system. Verify the patient identity and merge the patient information in the LumiGuide Viewing Software.
The X-ray system is in a non-calibrated position. Move the X-ray system to a calibrated position.	The X-ray system is in an uncalibrated position and could compromise the shape accuracy. Move X-ray system back to a calibrated position.

3 LumiGuide Equipment Overview

The LumiGuide Equipment integrates with the existing Philips interventional X-ray system in the interventional catheterization lab or operating room and in the control room.

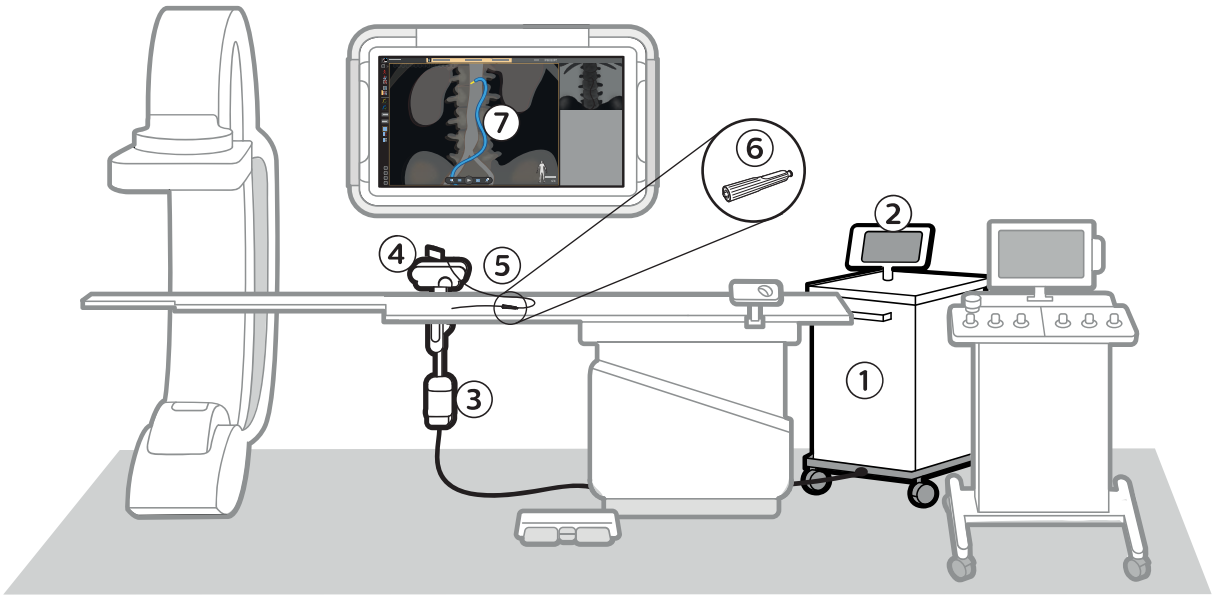


Figure 5 LumiGuide Equipment overview in the interventional room

Legend			
1	LumiGuide Engine	5	AltaTrack Guidewire
2	LumiGuide Touch Screen	6	AltaTrack 3D Hub
3	LumiGuide Docking Base	7	LumiGuide Viewing Software displayed in the interventional catheterization lab or operating room
4	AltaTrack Docking Top		

You can use the touch screen module (TSM) and the tableside mouse of the X-ray system to view images produced by the LumiGuide Equipment on the monitors in the interventional catheterization lab or operating room. If a mouse is not available in the interventional catheterization lab or operating room with the X-ray system, one is provided with the LumiGuide Equipment.

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

NOTE
In this document, the term FORS-guided catheter refers to the combination of a conventional endovascular catheter with the AltaTrack 3D Hub. A FORS-guided catheter is therefore a conventional endovascular catheter visualized with FORS technology.

3.1 LumiGuide Engine

The LumiGuide Engine contains the core hardware of the LumiGuide Equipment. It is connected to the LumiGuide Docking Base by a cable. The LumiGuide Engine has a storage hook for the LumiGuide Docking Base when it is not in use.

The LumiGuide Engine is also connected to the LumiGuide WorkSpot, providing real-time 3D visualization of the AltaTrack Guidewire and an endovascular catheter when connected to the AltaTrack 3D Hub on monitors in the interventional catheterization lab or operating room and in the control room.

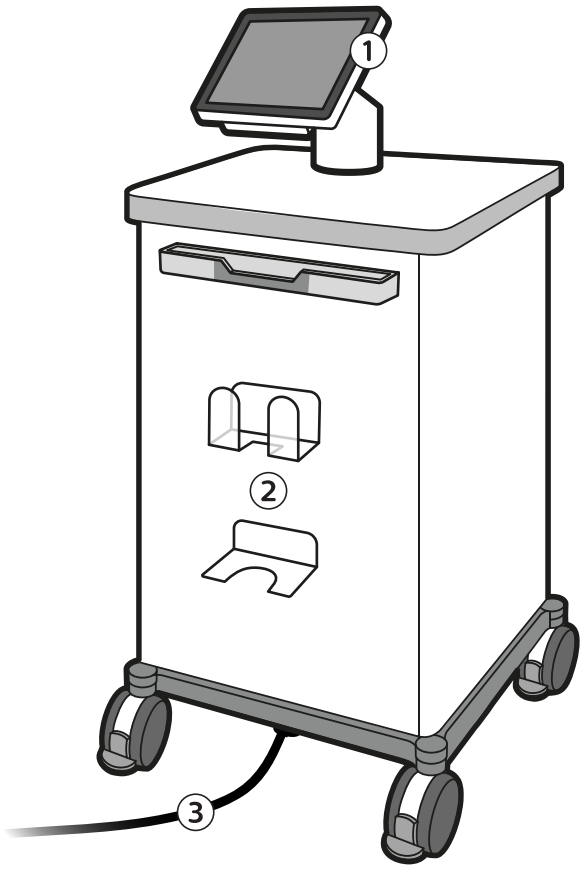


Figure 6 LumiGuide Engine

Legend	
1	LumiGuide Touch Screen
2	Storage hook of the LumiGuide Docking Base
3	Cable

The LumiGuide Engine can be moved to any suitable position outside the sterile zone in the interventional catheterization lab or operating room. A parking mechanism provides stability during use.

A rail and hook are provided on the front side of the LumiGuide Engine to store the LumiGuide Docking Base and the cable while not in use. A hook is also provided on the rear side of the LumiGuide Engine to store the network cable and the power cable.

The LumiGuide Engine also has an adjustable touch screen accessible by non-sterile staff.

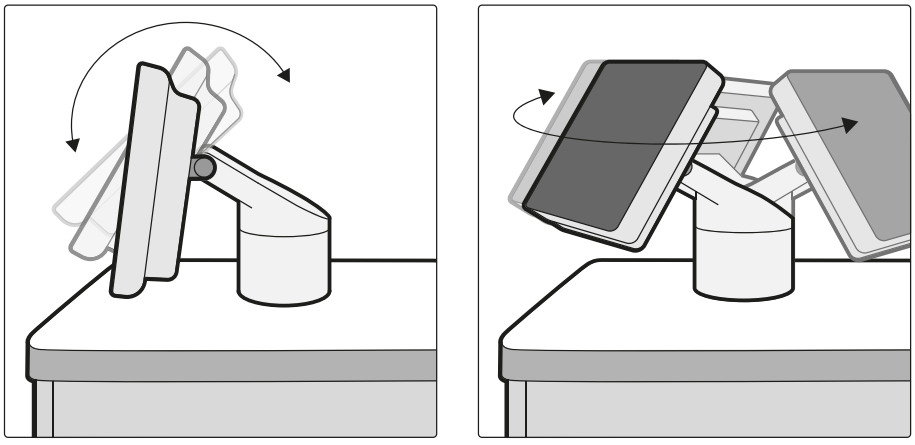


Figure 7 LumiGuide Touch Screen

The LumiGuide Touch Screen display provides pre-procedural instructions for preparing the LumiGuide Equipment. A status diagram indicates if an AltaTrack Guidewire is connected or parked.

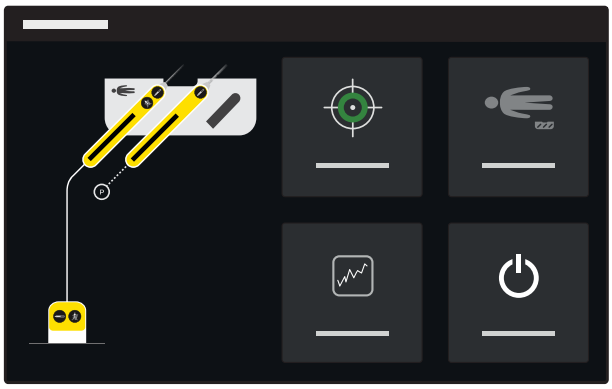


Figure 8 LumiGuide Touch Screen display

The LumiGuide Touch Screen also provides user assistance if the LumiGuide Equipment encounters issues during use. If an issue arises, an information bar is displayed at the top of the LumiGuide Touch Screen (a message is also displayed in the LumiGuide Viewing Software window). Tap the information icon follow the instructions on the LumiGuide Touch Screen.

For more information, see Guidance for Resolving Issues (page 109).

The LumiGuide 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 LumiGuide Docking Base

The LumiGuide 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 Guidewire shape to be registered with X-ray images.

NOTE
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 the table has moved, check the accuracy of the AltaTrack Guidewire registration with fluoroscopy. If needed, perform a new registration of the AltaTrack Guidewire.

The figure below shows the parts of the LumiGuide Docking Base.

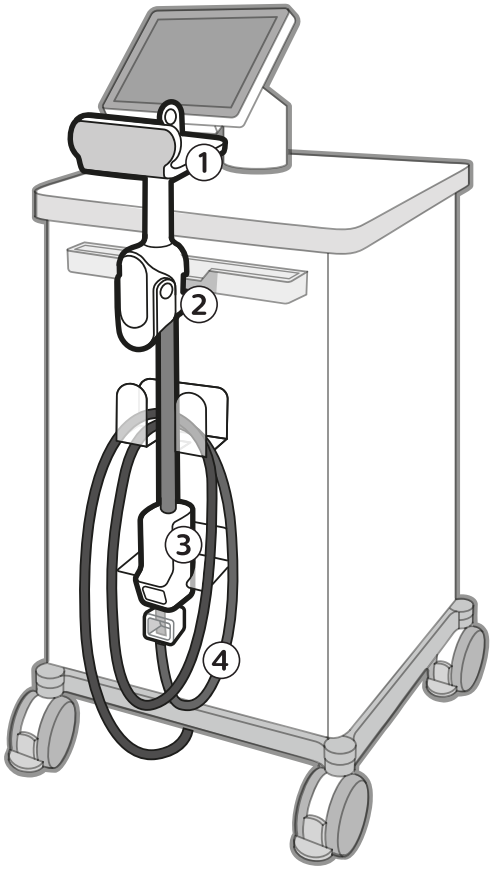


Figure 9 LumiGuide Docking Base

Legend			
1	LumiGuide Docking Base	3	Connection box
2	Table clamp	4	Cable

The LumiGuide 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 LumiGuide 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 LumiGuide Docking Base (page 35).

The LumiGuide Docking Base can be detached from the table between procedures.

CAUTION
Detaching the LumiGuide Docking Base during a procedure may damage the sterile cover and cause a sterility breach.

NOTE
The LumiGuide 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 LumiGuide Equipment.

Connection Box
The connection box connects the AltaTrack Guidewire that is inserted in the AltaTrack Docking Top to the LumiGuide Equipment. One additional slot is provided to assist with changing devices.

3.3 LumiGuide Viewing Software

The LumiGuide Viewing Software is accessible in the control room and interventional catheterization lab or operating 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 LumiGuide Viewing 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.

NOTE
If the free space in the LumiGuide Viewing Software database falls below 10%, the LumiGuide Equipment may not function as expected.

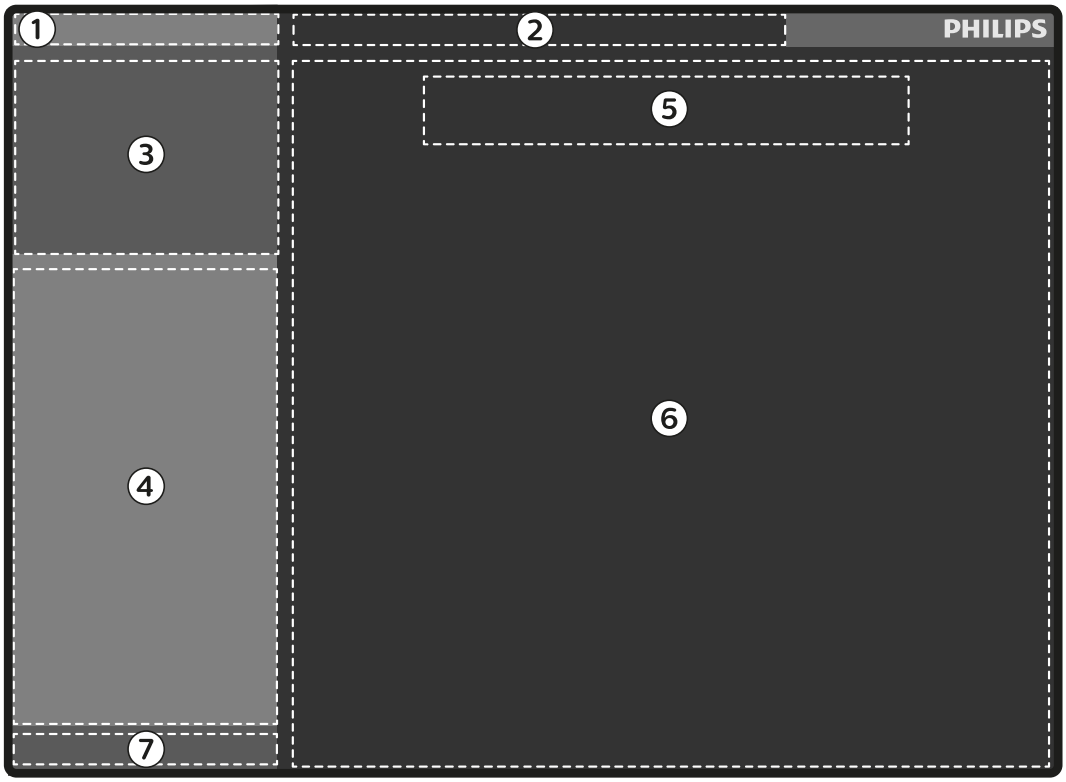


Figure 10 LumiGuide Viewing Software display layout

Legend			
1	Patients button: Closes the application and displays the patient list.	5	User message area: Messages relating to the LumiGuide Equipment 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 LumiGuide 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 configuring user preferences, 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

Tasks provide a workflow for using the LumiGuide Viewing Software. You can find tasks in the task selection panel (see Figure 10: LumiGuide Viewing Software display layout (page 27)).

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 LumiGuide 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 Guidewire shape and optionally an endovascular catheter's shape with the images from the X-ray system.

Live Guidance

The **Live Guidance** task provides a continuous overlay of the AltaTrack Guidewire and a catheter when connected to the AltaTrack 3D Hub on the X-ray images and preoperative CT volume (if applicable). **Live Guidance** activities include:

- Navigating with the AltaTrack Guidewire and an endovascular catheter when connected to the AltaTrack 3D Hub
- Registering new endovascular catheters connected to the AltaTrack 3D Hub and retrieving the registration of pre-registered endovascular catheters.
- Re-registering the AltaTrack Guidewire
- Making minor adjustments to volume registration to compensate for patient movement
- Recalling angles stored in the **Planning** task
- Adjusting visualization settings

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

4 LumiGuide Products Overview

4.1 AltaTrack Docking Top

The AltaTrack Docking Top is a sterile, single-use accessory to the LumiGuide Equipment that provides a mechanical fixation of the AltaTrack Guidewire to the LumiGuide Equipment within the sterile zone. It attaches to the LumiGuide Docking Base on top of a sterile cover that covers the LumiGuide Docking Base. The LumiGuide Docking Base is a component of the LumiGuide Equipment and provides an attachment point for the AltaTrack Docking Top as well as a fixed reference point that allows the AltaTrack Guidewire shape to be registered with X-ray images.

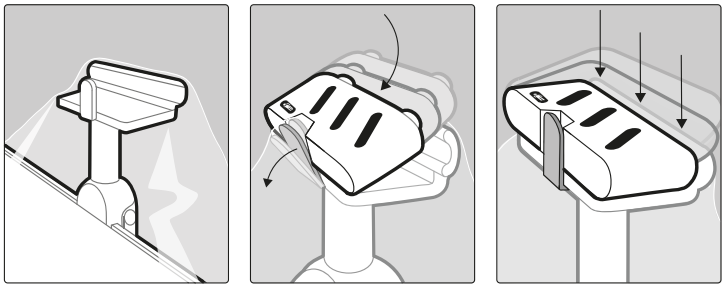


Figure 11 AltaTrack Docking Top attached to the LumiGuide Docking Base

The AltaTrack Docking Top contains sterile slots that fit the docking fin of the AltaTrack Guidewire. The LumiGuide Equipment automatically identifies the AltaTrack Guidewire when it is inserted in one of the sterile slots of the AltaTrack Docking Top. The AltaTrack Docking Top is sterilized with ethylene oxide gas.

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

4.2 AltaTrack Guidewire

The AltaTrack Guidewire is a sterile single use angiographic guidewire with Fiber Optic RealShape (FORS) technology.

The AltaTrack Guidewire is sterilized with ethylene oxide gas. When connected to the LumiGuide Equipment and combined with a conventional endovascular catheter that is connected to the AltaTrack 3D Hub, it enables 3D image visualization in real time of the conventional endovascular catheter.

When connected to the LumiGuide Equipment, the AltaTrack Guidewire can be displayed as an overlay to X-ray images and optionally on a pre-procedural CT volume.

The AltaTrack Guidewire comprises the following parts:

- In-body section: this is the only section of the AltaTrack Guidewire to enter the patient and contains a hydrophilic coating.
- Torque-absorbing section: to decouple rotation of the in-body section from the docking fin, while allowing manipulation of the in-body section by the user.
- Torquer: to aid the handling of the AltaTrack Guidewire. The torquer can also be removed from the AltaTrack Guidewire.
- Docking fin: to provide a mechanical connection and stable fixation to the AltaTrack Docking Top.
- Wire connector: provides an optical connection to the LumiGuide Docking Base.

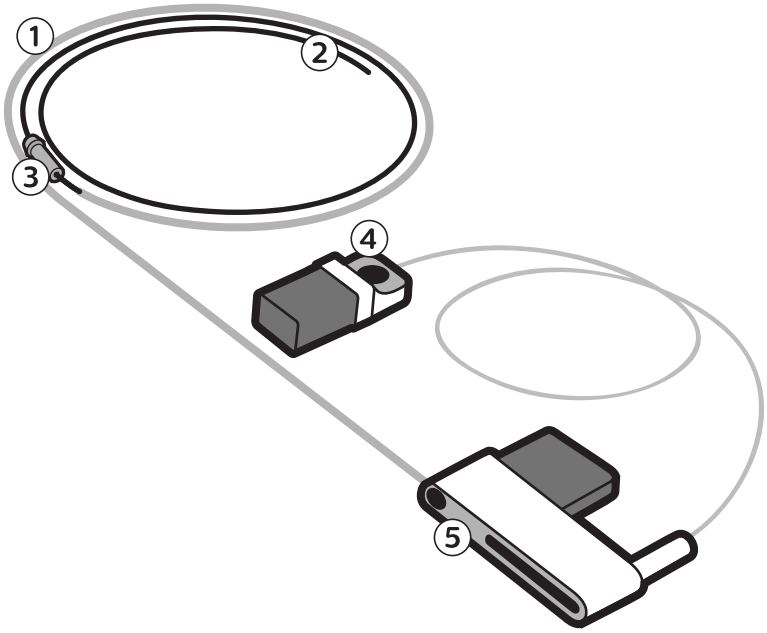


Figure 12 AltaTrack Guidewire

Legend			
1	Torque-absorbing section	4	Wire connector
2	In-body section	5	Docking fin
3	Torquer		

When using the LumiGuide Equipment, you can only visualize one AltaTrack Guidewire.

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

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

4.3 AltaTrack 3D Hub

The AltaTrack 3D Hub is a sterile, single-use hub that is an accessory to the LumiGuide Equipment that connects to the Luer connection of endovascular catheters. It has a male and female Luer lock to attach to the proximal end of an endovascular catheter, and optionally allows use of accessories, such as flow check valves or syringes, on its proximal end. The AltaTrack 3D Hub is sterilized with ethylene oxide gas.

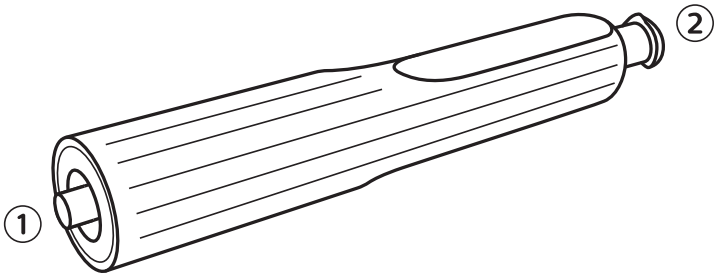


Figure 13 AltaTrack 3D Hub

Legend	
1	Male Luer connector
2	Female Luer connector

For more information about the AltaTrack 3D Hub, refer to the Instruction for Use supplied with the AltaTrack 3D Hub.

5 Preparing the LumiGuide Equipment for Use

5.1 Setting Up the LumiGuide Equipment

This section provides information about setting up the LumiGuide Engine, LumiGuide Docking Base, and AltaTrack Docking Top in the interventional catheterization lab or operating room.

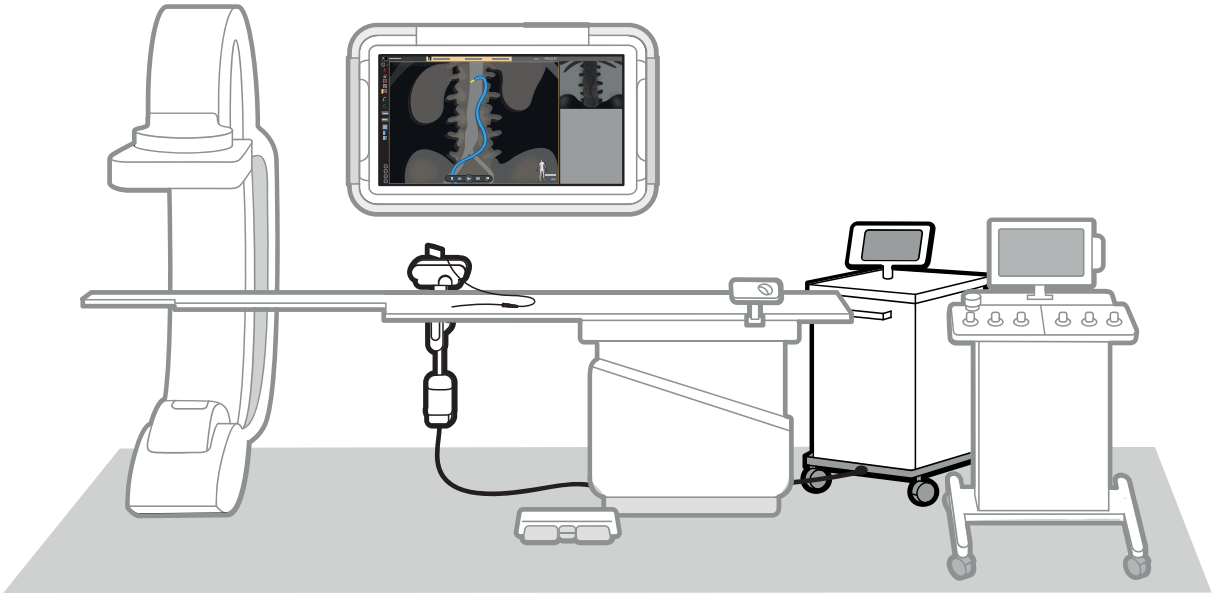


Figure 14 LumiGuide Equipment overview

5.1.1 Setting Up the LumiGuide Engine

1 (**Non-sterile user**) Position the LumiGuide Engine in the interventional catheterization lab or operating room as follows:

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

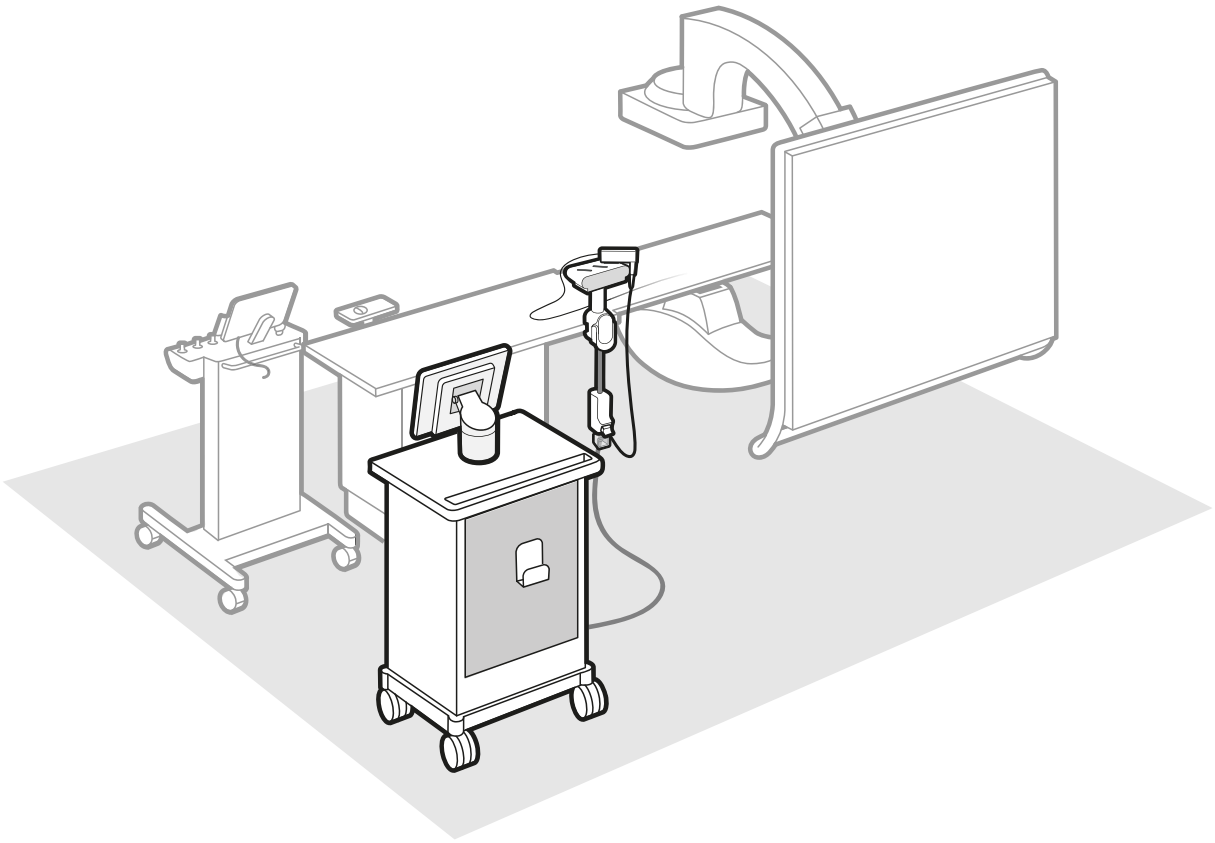


Figure 15 LumiGuide Engine positioning

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

WARNING
Position the LumiGuide Engine in the interventional catheterization lab or operating room so that the airflow of the LumiGuide Engine does not influence the laminar airflow in the surgery room.

NOTE
Do not put or store items on top of the LumiGuide Engine; it is not intended to support additional load.

Guidance on how to position the LumiGuide Engine is available on the LumiGuide Touch Screen.

2 (**Non-sterile user**) Apply the brakes to park the LumiGuide Engine.

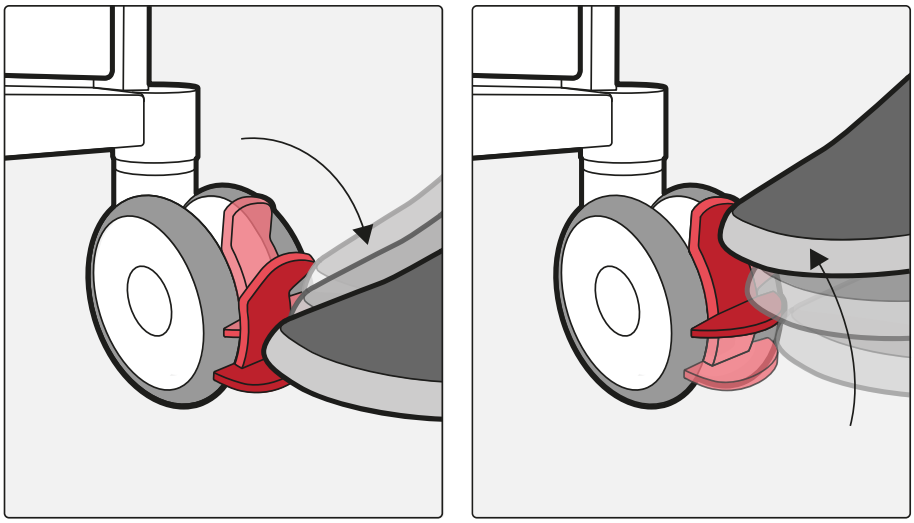


Figure 16 Applying the brake (left) and releasing the brake (right) on the LumiGuide Engine

3 (**Non-sterile user**) Connect the cables of the LumiGuide Engine:

a Connect the power cable to the power supply.

b Connect the network cable to the dedicated LumiGuide network connection on the LumiGuide WorkSpot.

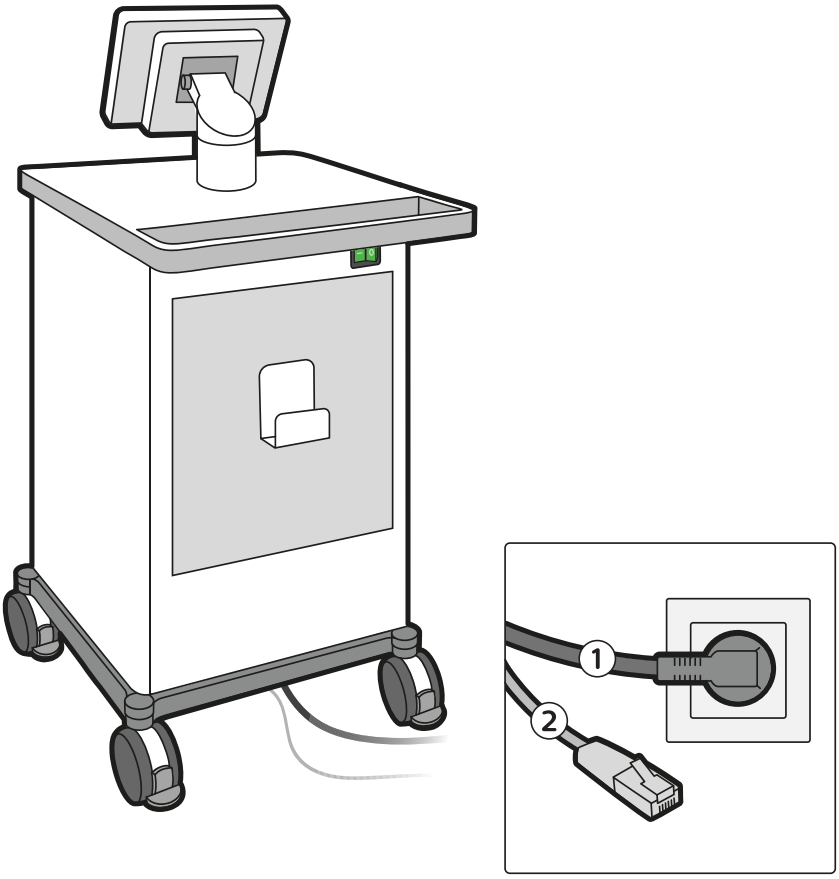


Figure 17 Cables of the LumiGuide Engine

Legend	
1	Power cable
2	Network cable

WARNING
Do not touch electrical or network connectors on the patient table, the LumiGuide Engine, or the LumiGuide 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 LumiGuide Engine so that they do not interfere with the working area of the clinical staff and cause anyone to trip, and so that they are easy to disconnect when necessary.

CAUTION
Ensure that the network cable of the LumiGuide Engine is connected only to the network of the LumiGuide WorkSpot to allow proper communication.

NOTE
The network connection of the LumiGuide Engine is only intended for point-to-point connection to the LumiGuide WorkSpot. The connection characteristics are managed by the LumiGuide Equipment.

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

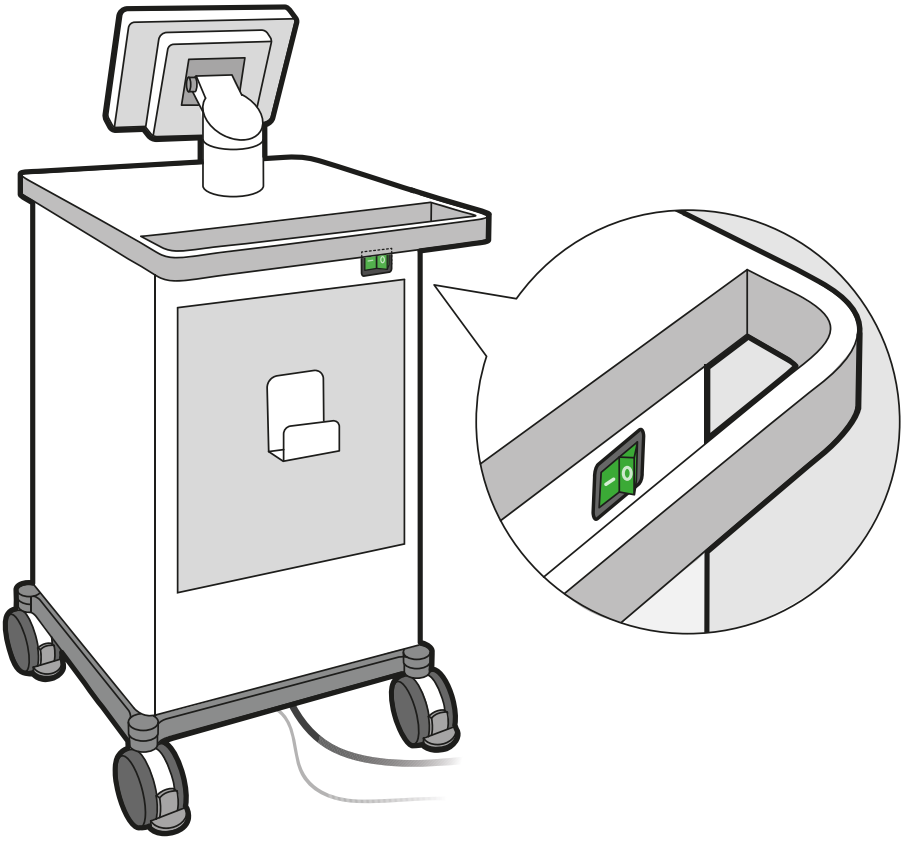


Figure 18 LumiGuide Engine power switch

An indication of the start-up process is displayed on the LumiGuide Touch Screen on top of the LumiGuide Engine.

The LumiGuide 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 LumiGuide Equipment set-up software are available within approximately 3 minutes after starting, for procedure preparation.

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

5 (**Non-sterile user**) Initialize the optical processing unit using the LumiGuide Touch Screen.

5.1.2 Setting Up the LumiGuide Docking Base

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

2 (**Non-sterile user**) Release the table clamp and remove the LumiGuide Docking Base from its storage position on the LumiGuide Engine.

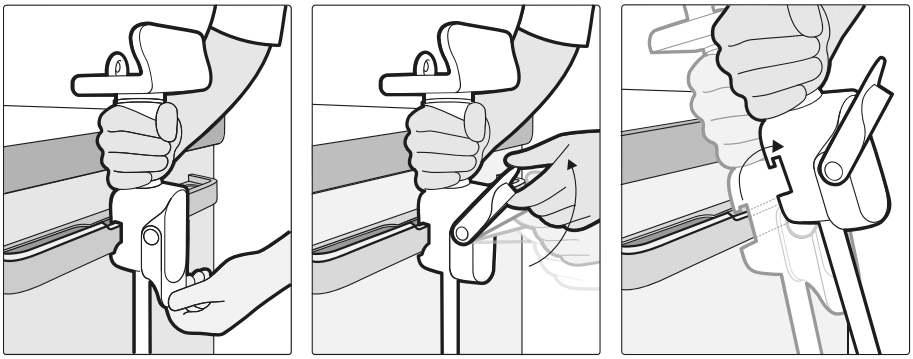


Figure 19 Removing the LumiGuide Docking Base from its storage position

3 Using the table clamp, attach the LumiGuide 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 interventional catheterization lab or operating room.
- So that the AltaTrack Guidewire can comfortably reach the area of interest in the patient's body.

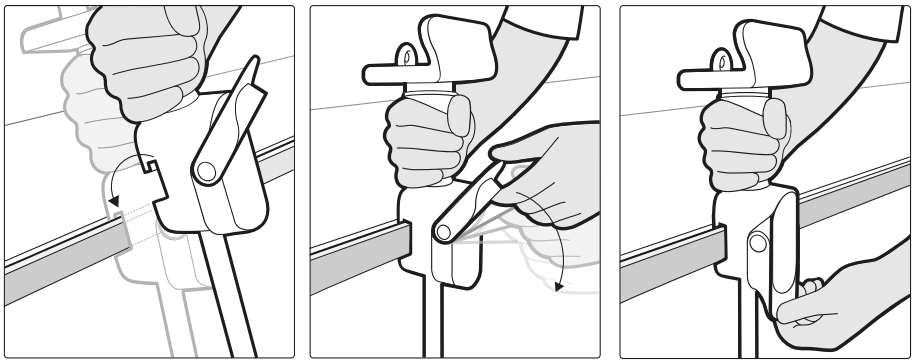


Figure 20 Attaching the LumiGuide Docking Base to the table accessory rail

NOTE
Do not attach the AltaTrack Docking Top to the LumiGuide Docking Base yet.

Guidance on how to attach the AltaTrack Docking Top is also available on the LumiGuide Touch Screen.

WARNING
Ensure that the LumiGuide Docking Base is securely fixed to the table rail at an appropriate position. If the LumiGuide Docking Base falls off, or if there is any intentional or unintentional movement of the LumiGuide 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 LumiGuide Touch Screen, tap **Dock position** and then select the LumiGuide Docking Base orientation.

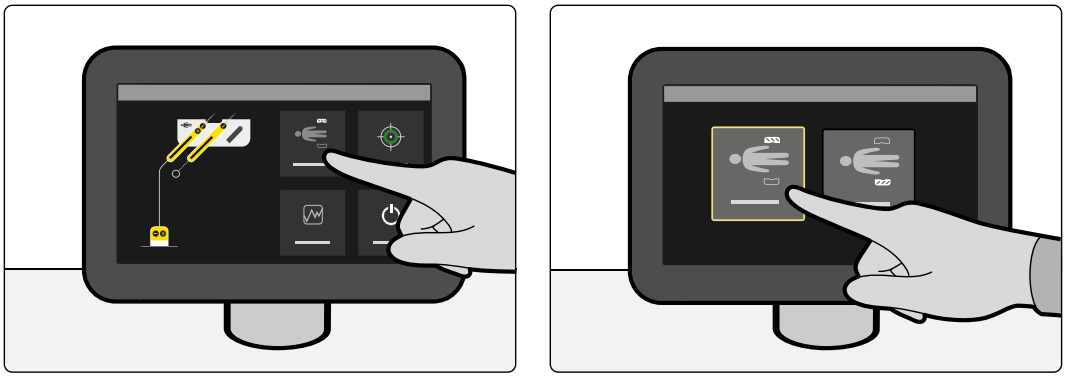


Figure 21 Selecting the LumiGuide Docking Base orientation on the LumiGuide Touch Screen

5 (**Sterile user**) Place sterile covers over the patient and the LumiGuide Docking Base.

5.1.3 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:

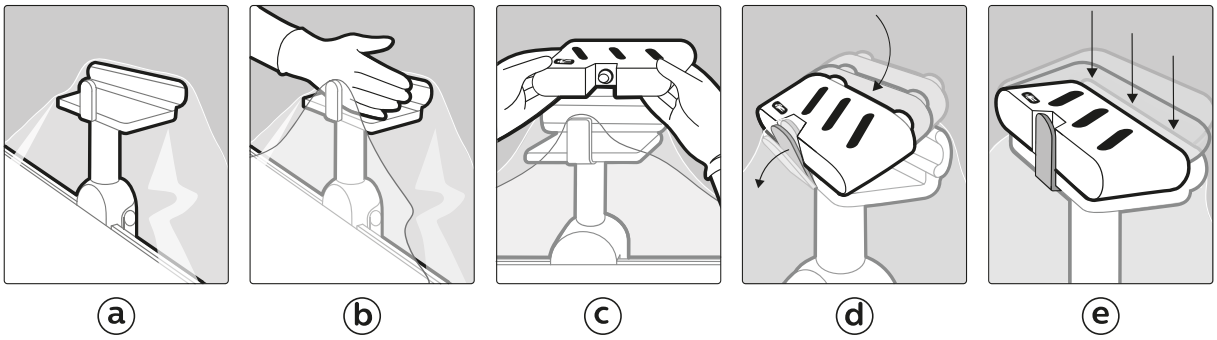


Figure 22 Attaching the AltaTrack Docking Top

a Ensure that the LumiGuide Docking Base is covered with the sterile cover.

b Carefully push the sterile cover into the LumiGuide 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.

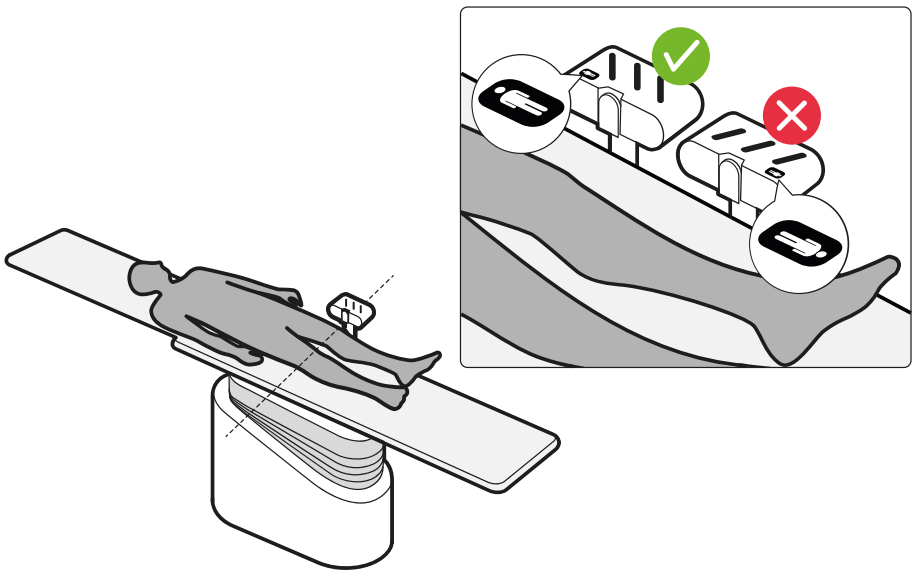


Figure 23 AltaTrack Docking Top orientation

d Carefully insert the grooved edge of the AltaTrack Docking Top into the clip on the LumiGuide Docking Base.

e Carefully push the other edge of the AltaTrack Docking Top down into place on the LumiGuide 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 LumiGuide Touch Screen.

Figure 24 Guidance on how to attach the AltaTrack Docking Top

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.

5.2 Starting the LumiGuide Viewing Software

You can use the LumiGuide Viewing 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.

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

When an overlay modality is selected for the procedure (with or without preoperative CT), you can use the AltaTrack Guidewire with the selected overlay modality in the LumiGuide Viewing Software.

5.2.1 Starting the LumiGuide Viewing Software without CT Overlay

1. On the X-ray system, select or add the patient.
2. On the touch screen module of the X-ray system, tap **Tools**.

3 In the **Tools** screen, tap **Workspot**, then tap **LumiGuide**, and then tap **FORS + Xray**.

When using the LumiGuide Viewing Software without a preoperative CT volume, the workflow consists of the following tasks:

LumiGuide Workflow without a Preoperative CT Volume		
1	Setting up the AltaTrack Guidewire	
2		**Shape Registration** task (the LumiGuide Viewing Software opens in this task)
3		**Live Guidance** task

4 Go to Setting Up the AltaTrack Guidewire (page 54) to continue this workflow.

5.2.2 Starting the LumiGuide Viewing Software with CT Overlay

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

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

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

NOTE
When using the LumiGuide Viewing 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 LumiGuide Viewing Software with a preoperative CT volume, the workflow consists of the following tasks:

LumiGuide workflow with preoperative CT volume		
1		**Segmentation** task (the LumiGuide Viewing Software opens in this task)
2		**Planning** task
3		**Volume Registration** task
4	Setting up the AltaTrack Guidewire and optionally FORS-guided endovascular catheters	
5		**Shape Registration** task (the LumiGuide Viewing Software opens in this task)
6		**Live Guidance** task

3 Go to the next section to continue this workflow.

5.2.3 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.

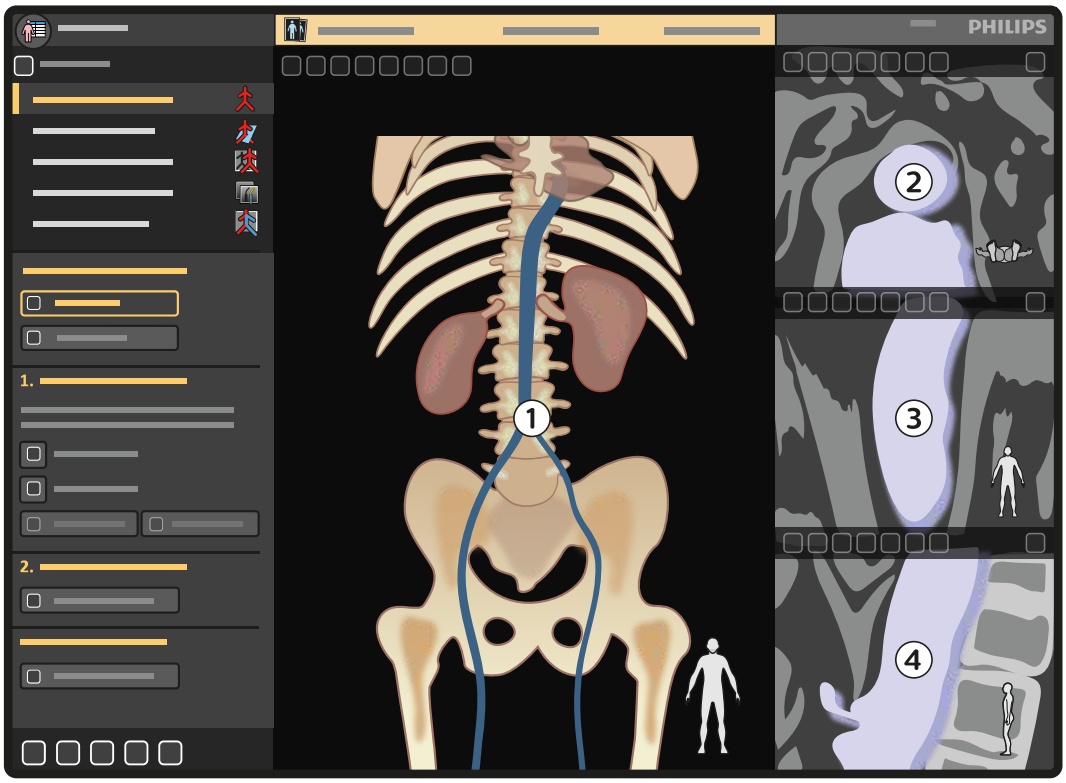


Figure 25 Segmentation viewports

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.

5.2.4 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.

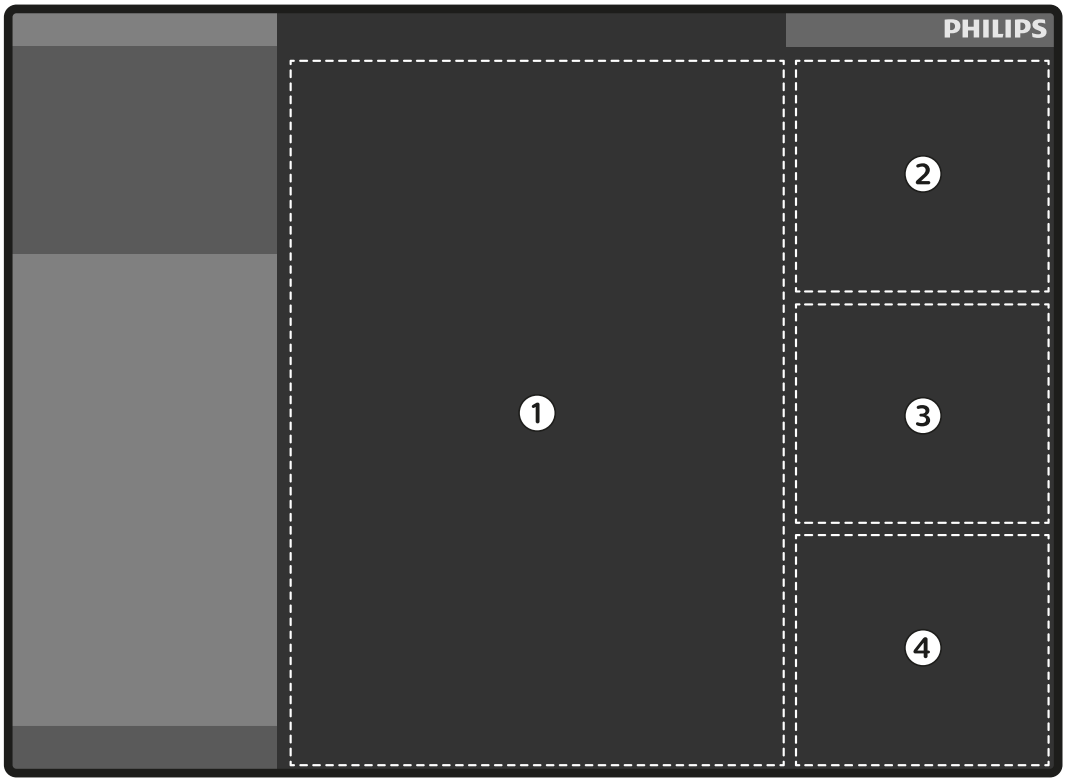


Figure 26 Planning viewports

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 on 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 navigation of guidewires and catheters 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.

5.2.5 Volume Registration

NOTE
It is not mandatory to register a pre-procedural 3D volume when using the LumiGuide 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 LumiGuide Viewing 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 LumiGuide Viewing Software. Therefore, the following registration options are available:

- 2D registration in the control room using the LumiGuide Viewing Software
- 2D registration at the tableside using the touch screen module of the X-ray system
- 3D registration in the control room using the LumiGuide Viewing Software

All registration options are described in this section.

NOTE
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 LumiGuide 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, at least 30 degrees apart. The system provides suggested angles to assist you.

After acquiring the two reference series, you should align the volume with the images in the reference series. You can perform 2D volume registration in the control room or in the interventional room, using the mouse at the tableside.

2D volume registration is the default registration method.

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 49).

If you want to perform 3D volume registration using a 3D rotational series, see Performing 3D Volume Registration (page 50).

Starting 2D Volume Registration

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.

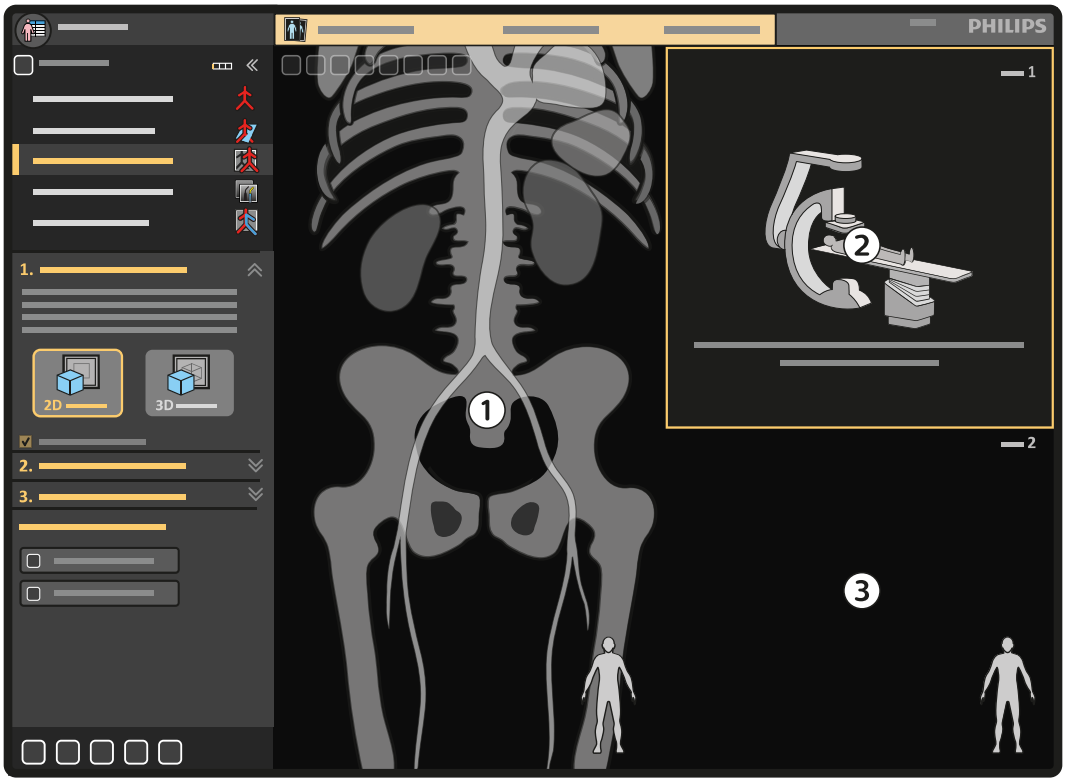


Figure 27 Normal view mode screen layout

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 X-ray 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 X-ray 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 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.

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.

2 To enhance visualization of the 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 104) 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.

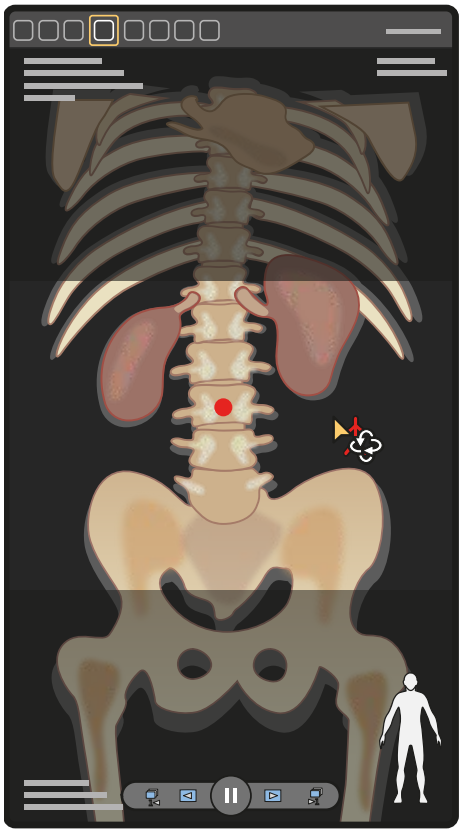


Figure 28 Rotation point

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 should be obtained using the X-ray system from different projection angles, at least 30 degrees apart. The system provides suggested angles to assist 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 LumiGuide WorkSpot in the control room.

Other Registration Options

If you want to perform 2D volume registration using the LumiGuide Viewing Software in the control room, see Performing 2D Volume Registration (page 45).

If you want to perform 3D volume registration using a 3D rotational series, see Performing 3D Volume Registration (page 50).

Acquiring Reference Series at the Tableside using the Touch Screen Module (TSM)

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 **FORS + CT Overlay** on the touch screen module of the X-ray system.

Follow the guidance in the **2D Image Registration** step on the touch screen module to acquire two reference series (this is the default method). There should be a difference in angle of at least 30 degrees between the two images.

2 Do one of the following:
- Select one of the suggested angles and press the **ACC** button on the geometry module of the X-ray system.
- Move the stand to your preferred acquisition angle (any acquisition setting and projection angle can be used).

3 Acquire the first fluoroscopy series.

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

5 Do one of the following:
- Select one of the suggested angles and press the **ACC** button on the geometry module of the X-ray system.
- Move the stand to your preferred acquisition angle. There should be a difference of at least 30 degrees in the angle between the first reference image and the second reference.

6 Acquire the second fluoroscopy series.

7 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 **Next Align Volume** to begin aligning the volume and the X-ray images.

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

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, do one of the following:
- To register the AltaTrack Guidewire, tap **Go to Shape Registration**. See Performing Shape Registration (page 56).
- To start navigation, tap **Go to Live Guidance**. See Navigating with the LumiGuide Equipment (page 66).

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 LumiGuide Viewing Software in the control room, see Performing 2D Volume Registration (page 45).

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 49).

Starting 3D Volume Registration

1 Select the **Volume Registration** task.

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

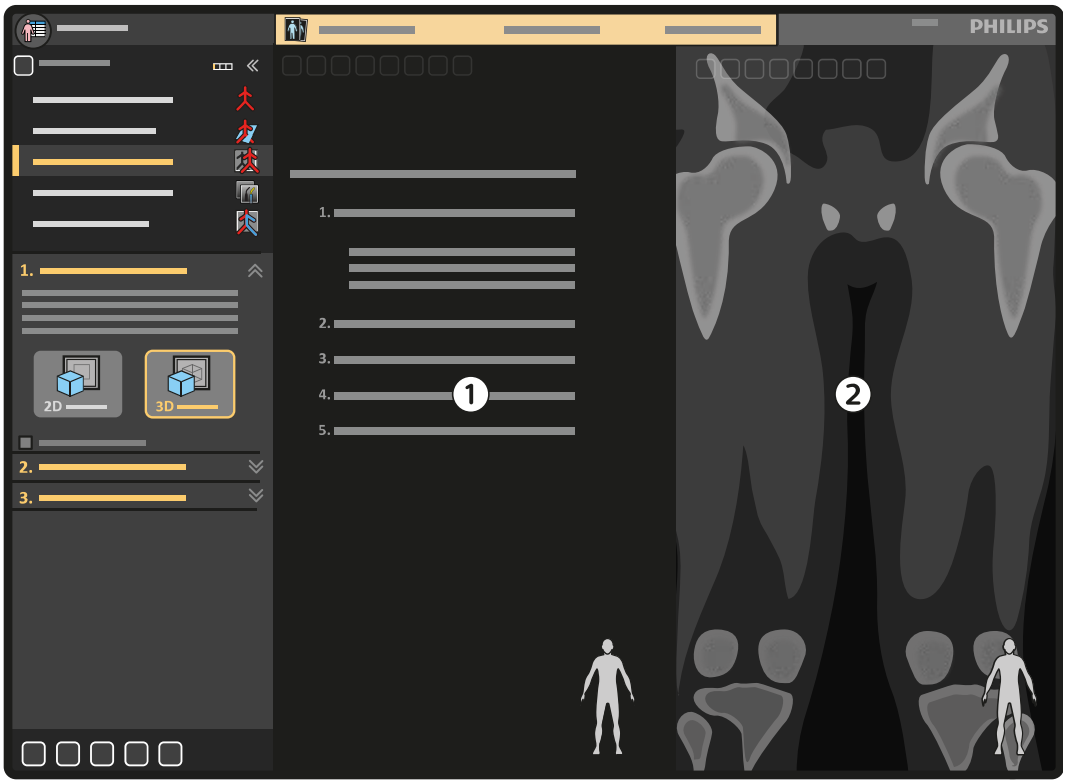


Figure 29 Registration view mode

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 52).

If you want to load a previously acquired 3D rotational series, see Loading a 3D Rotational Series (page 51).

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 should be placed in the series and in the corresponding positions in the volume.

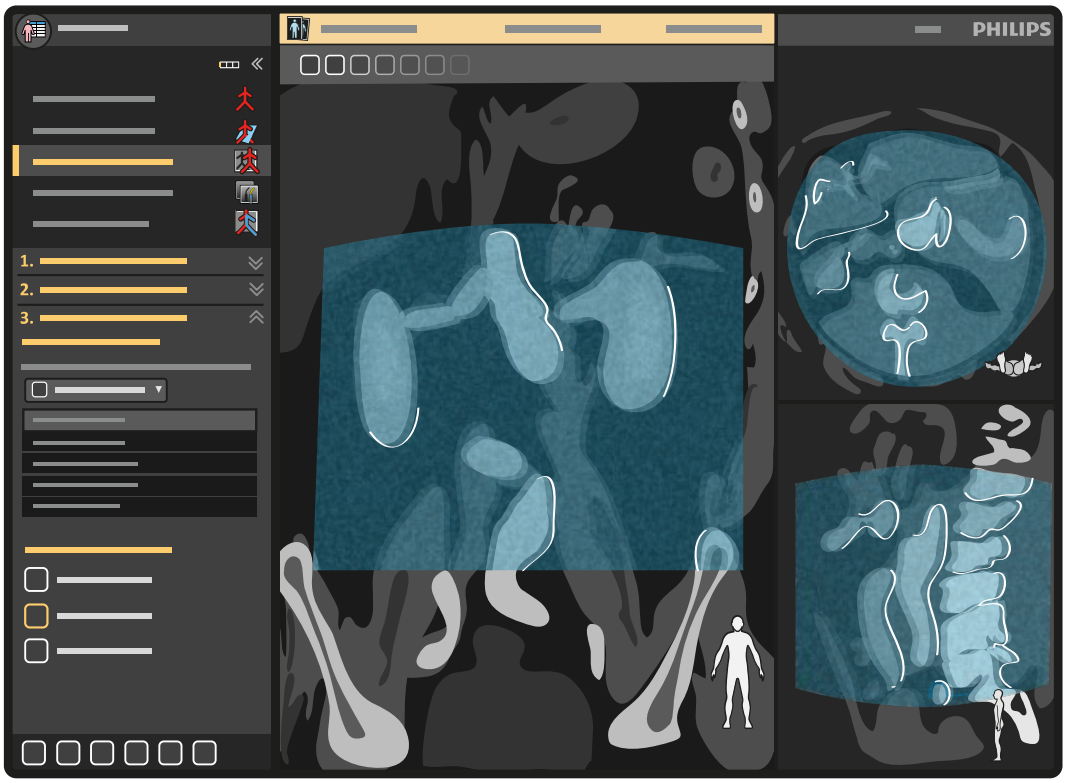


Figure 30 Placing registration points

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.

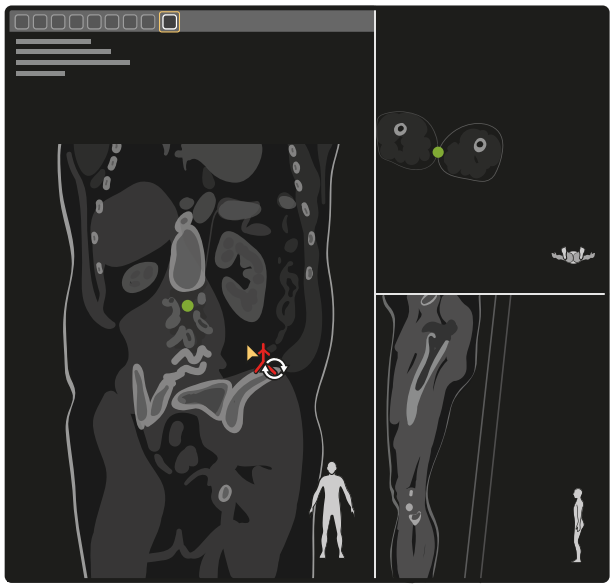


Figure 31 Rotation point

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.

5.3 Setting Up the AltaTrack Guidewire

1 (**Non-sterile user**) Open the outer packing of the AltaTrack Guidewire 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 Guidewire, refer to the AltaTrack Guidewire 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 Guidewire carefully to avoid impacting the performance of the LumiGuide Equipment.

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

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

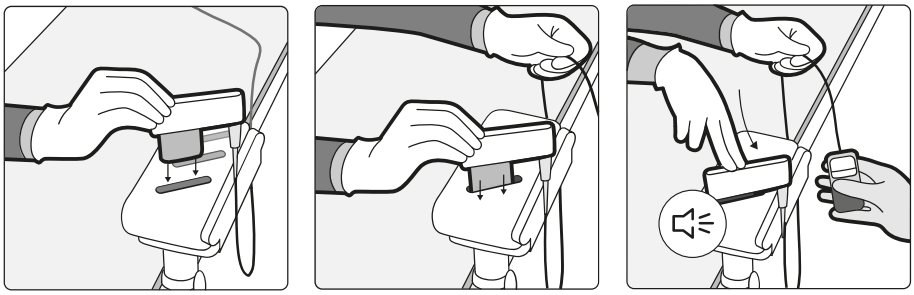


Figure 32 Connecting the AltaTrack Guidewire to the AltaTrack Docking Top

The display on the LumiGuide Touch Screen indicates that the device is docked.

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

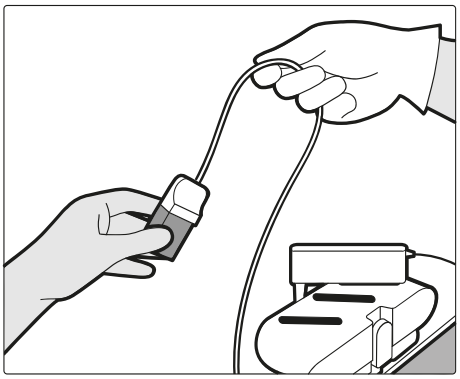


Figure 33 Handing over the AltaTrack Guidewire connector

6 (**Non-sterile user**) Connect the AltaTrack Guidewire connector to the connection slot of the LumiGuide connection box.

CAUTION
Do not touch the sterile field when connecting or disconnecting the connector.

CAUTION
Do not use X-ray while a non-sterile user connects or disconnects an AltaTrack Guidewire at the LumiGuide connection box, as the LumiGuide connection box is close to the X-ray tube.

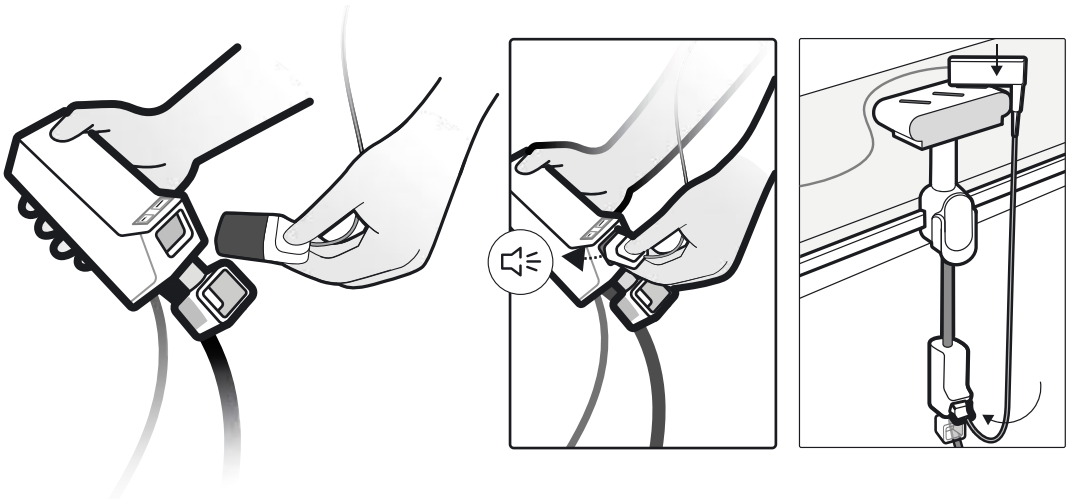


Figure 34 Inserting the AltaTrack Guidewire connector

When the AltaTrack Guidewire connector is connected successfully, the LumiGuide Equipment responds with an audible and tactile confirmation. The display on the LumiGuide Touch Screen indicates that initialization is in progress. Refer to the LumiGuide Viewing Software window for

confirmation that the AltaTrack Guidewire is correctly connected. Connection status can be viewed in the task panel of the **Shape Registration** task.

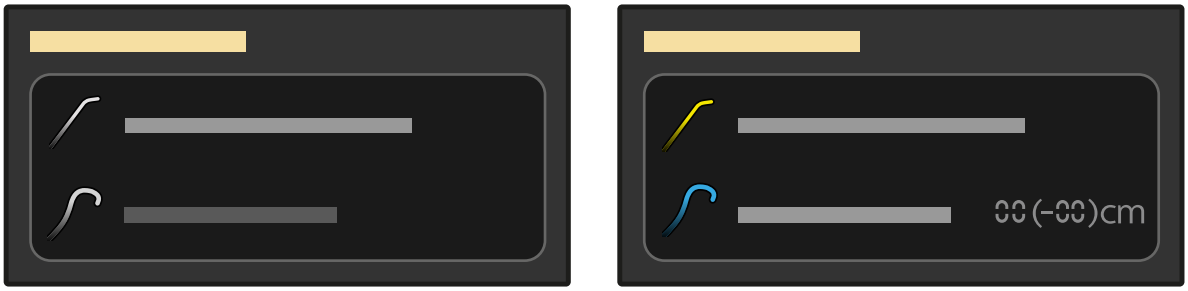


Figure 35 AltaTrack Guidewire and FORS-guided catheter connection status in the task panel: unregistered (left) and registered (right)

A successfully connected AltaTrack Guidewire is initially shown in gray at the top of the status panel, and then in yellow when it is registered. The name of the AltaTrack Guidewire is also displayed. The status of a FORS-guided catheter is shown at the bottom of the status panel. The catheter is initially shown in gray when detected and not registered, and then in color (at selection of the catheter, except yellow) after catheter length registration.

The AltaTrack Guidewire is ready for use after approximately 10 seconds.

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

8 If you use an AltaTrack Guidewire and an endovascular catheter connected to the AltaTrack 3D Hub, front-load the catheter with the AltaTrack 3D Hub on to the AltaTrack Guidewire.

When the LumiGuide Equipment detects that a FORS-guided catheter is present, its presence is marked in the status in the task panel, as shown in the figure above (left side).

5.4 Performing Shape Registration

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

This procedure describes the steps to register the AltaTrack Guidewire and, if connected, the FORS-guided catheter (catheter length registration), in the **Shape Registration** task.
- To perform AltaTrack Guidewire registration only, refer to the instructions in this task and in Adjusting the AltaTrack Guidewire Shape Tip (page 63).
- To perform shape registration for the AltaTrack Guidewire together with a FORS-guided catheter, refer to the instructions in this task and in Performing FORS-Guided Catheter Length Registration with the AltaTrack Guidewire in Shape Registration (page 64).

The LumiGuide Viewing Software recognizes the type of the connected AltaTrack Guidewire and the user guidance in the task panel and main display area reflects the setting enabled by the AltaTrack Guidewire configuration.

If the AltaTrack Guidewire is registered together with an endovascular catheter, ensure that the following actions are performed:
- The AltaTrack 3D Hub is connected to the catheter and flushed with sterile saline.
- The AltaTrack Guidewire is inserted through the catheter and extends beyond the catheter's tip for at least 2 cm before starting the **Shape Registration** task.

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 AltaTrack Guidewire in body so that it is visible in the X-ray field of view, use fluoroscopy to ensure that the registration is valid.

WARNING
If you register the AltaTrack Guidewire 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 Guidewire is connected correctly and is visible in the X-ray image.

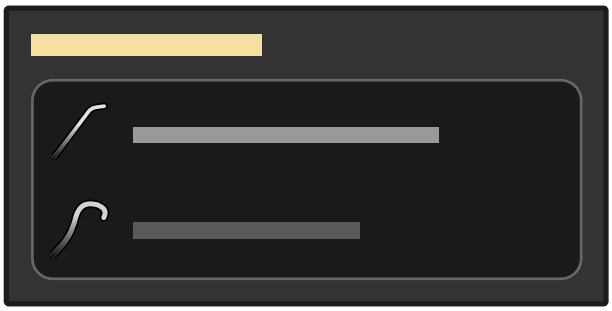


Figure 36 AltaTrack Guidewire and FORS-guided catheter connection status in the task panel

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

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

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

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

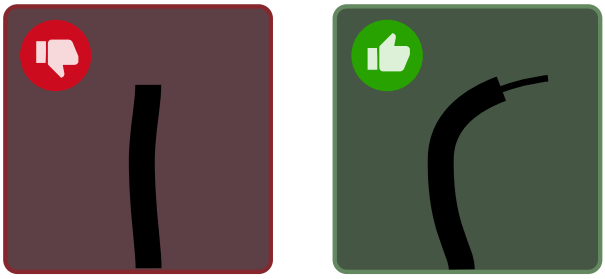


Figure 38 AltaTrack Guidewire positioning and orientation guidance

WARNING
For optimal registration, observe the following guidelines:
- ***Ensure that a good portion of the AltaTrack Guidewire is visible in the field of view, with the tip of the AltaTrack Guidewire near the center of the view. If necessary, select a larger field of view.***
- ***Ensure that there is curvature in the tip of the AltaTrack Guidewire that is visible in the image. A message is displayed if the curvature is too low to ensure proper registration.***

4 Follow the guidance provided in the **Acquire X-ray runs from 2 angles** step in the task panel:

a Acquire the first registration series using fluoroscopy.

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

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

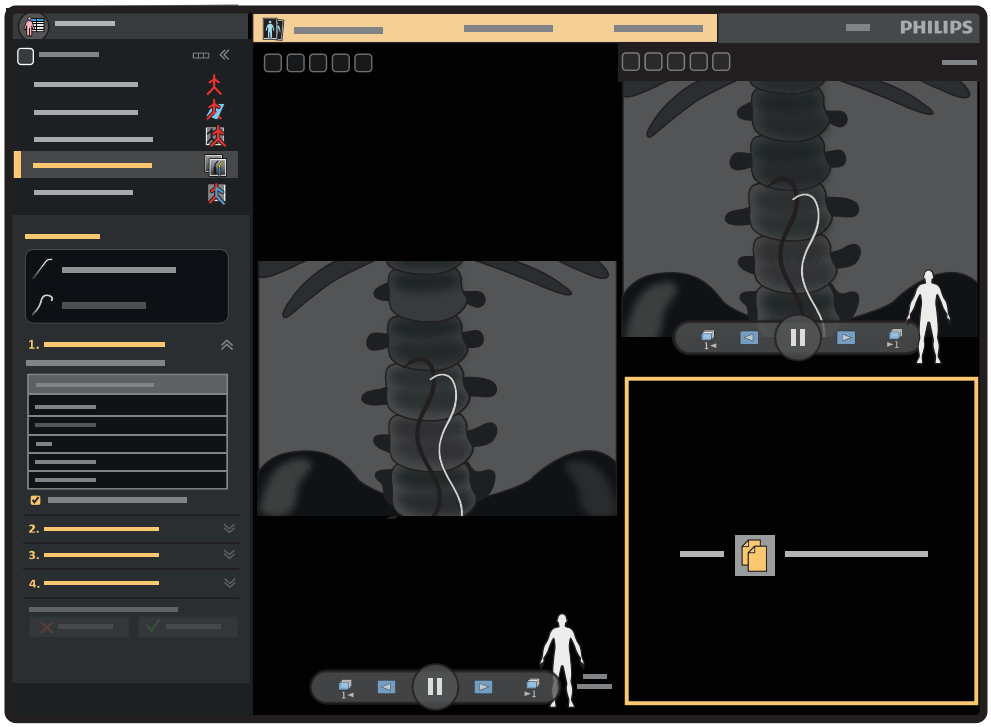


Figure 39 Acquiring reference images

c 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 dimmed in the list.

d Acquire the second registration series using fluoroscopy.

e 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: **Guidewire Registration** in the task panel.

If **Automatic Registration** was enabled, the LumiGuide Viewing Software performs automatic detection of the AltaTrack Guidewire shapes in both images.

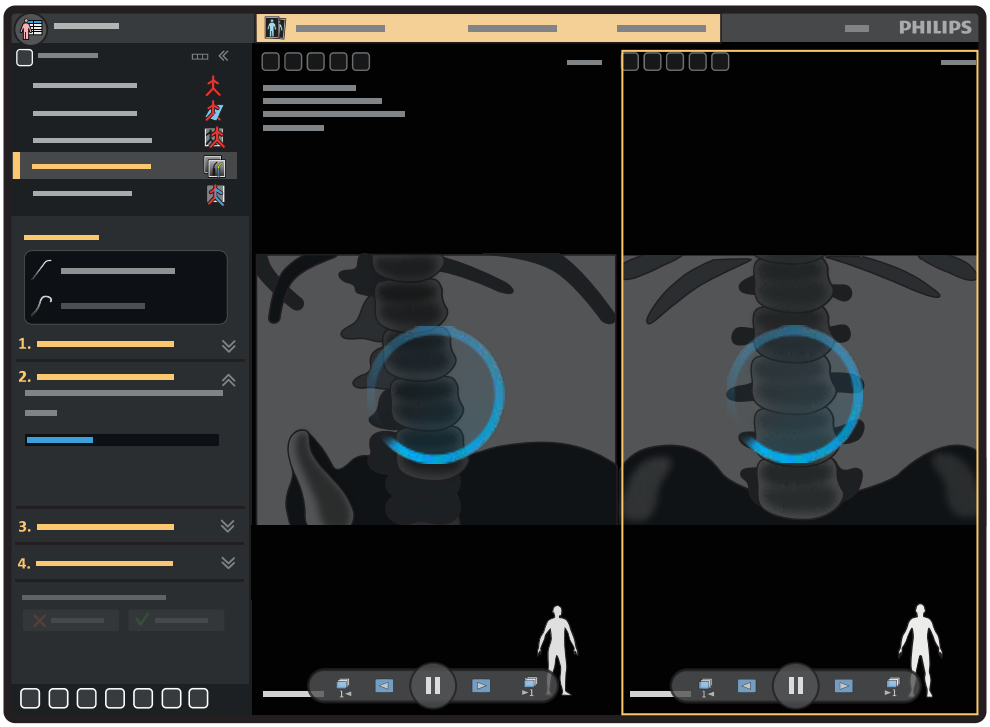


Figure 40 Automatic registration in progress

When automatic registration is complete, the identified shapes of the AltaTrack Guidewire are displayed in both reference viewports. The reference viewports are displayed side by side so that you can identify the AltaTrack Guidewire in each of them.

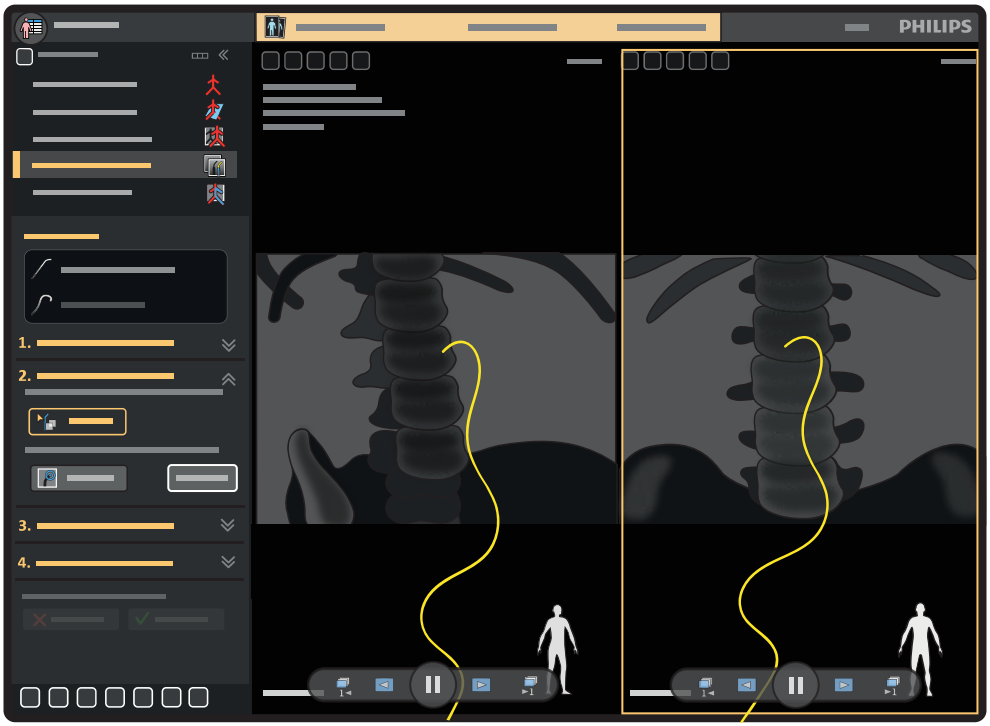


Figure 41 Results of automatic registration

5 If the AltaTrack Guidewire shape registration is correct, click **Next Step** in the task panel and continue to step 7 in this task (below).

Alternatively, if the shape registration is not correct, click **Adjust** in the task panel and do the following.

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

and the AltaTrack Guidewire is identified with additional markers.

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

The tip point marker is displayed and the software automatically adds markers (white crosses) along the AltaTrack Guidewire to identify it.

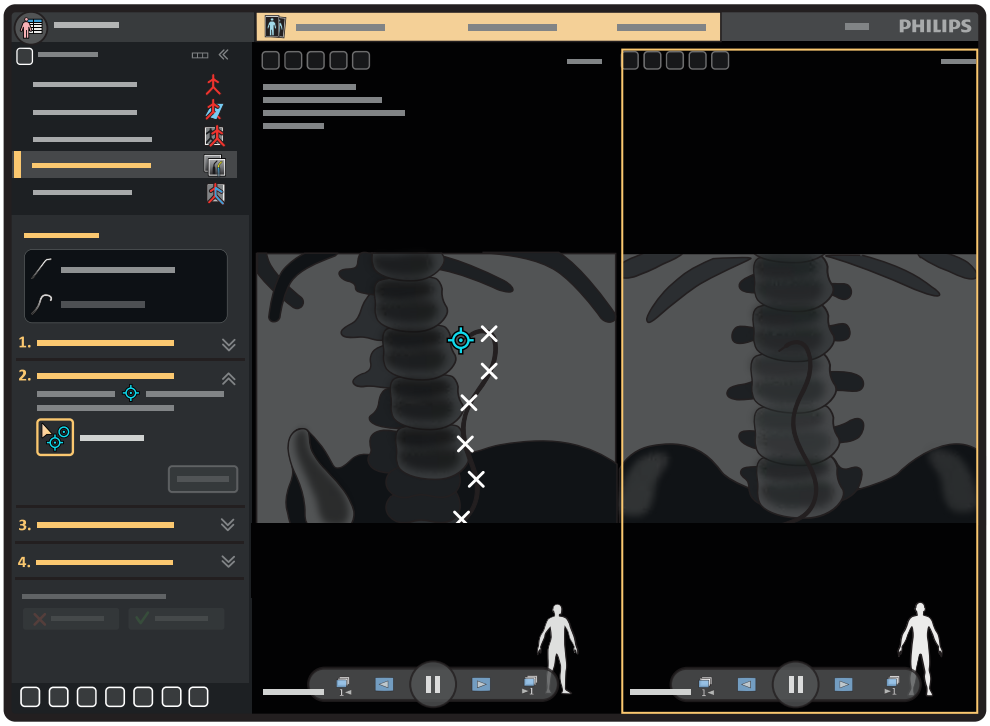


Figure 42 Identifying the AltaTrack Guidewire in the first registration image

b Verify that the markers are correctly positioned on the AltaTrack Guidewire.

c If the markers are not correctly positioned, do the following:

- Click on the AltaTrack Guidewire close to the visible proximal end in the image to add a new point. The software updates the AltaTrack Guidewire identification markers according to the newly placed marker.
- If needed, add more points to the AltaTrack Guidewire.
- If points are not correctly placed, drag points to correct their position or right-click to delete points and place new points.

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

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

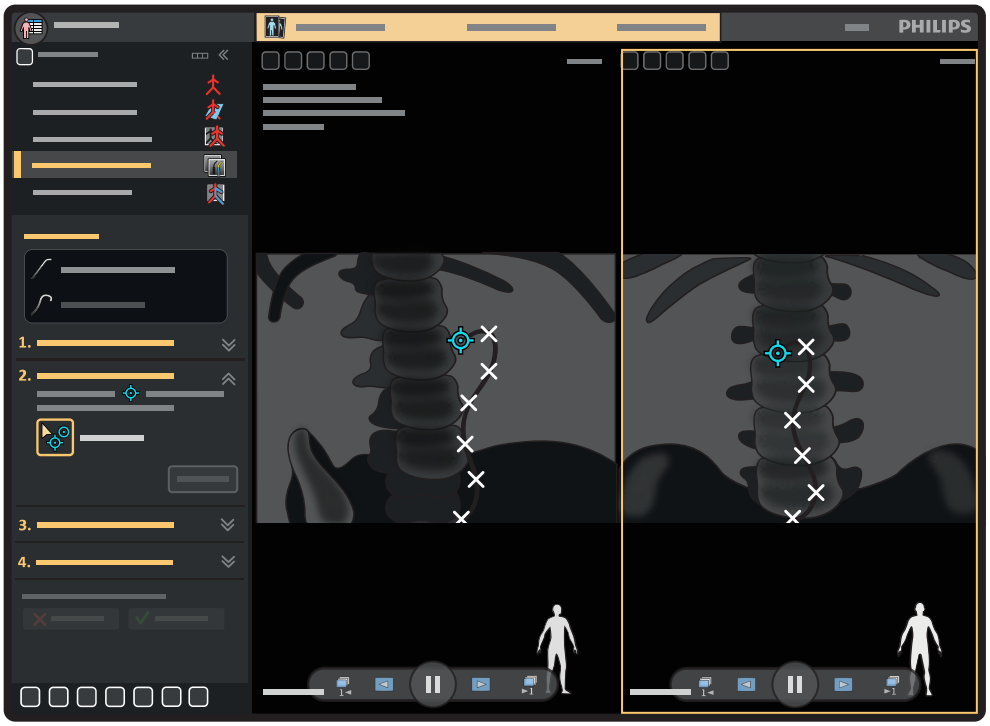


Figure 43 Identifying the AltaTrack Guidewire in the second registration image

f If the markers are not correctly positioned, do the following:

- Click on the AltaTrack Guidewire close to the visible proximal end in the image to add a new point. The software updates the AltaTrack Guidewire identification markers according to the newly placed marker.
- If needed, add more points to the AltaTrack Guidewire.
- If points are not correctly placed, drag points to correct their position or right-click to delete points and place new points.

g When the markers are correctly positioned in both references images, click **Compute Registration**.

The LumiGuide 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.

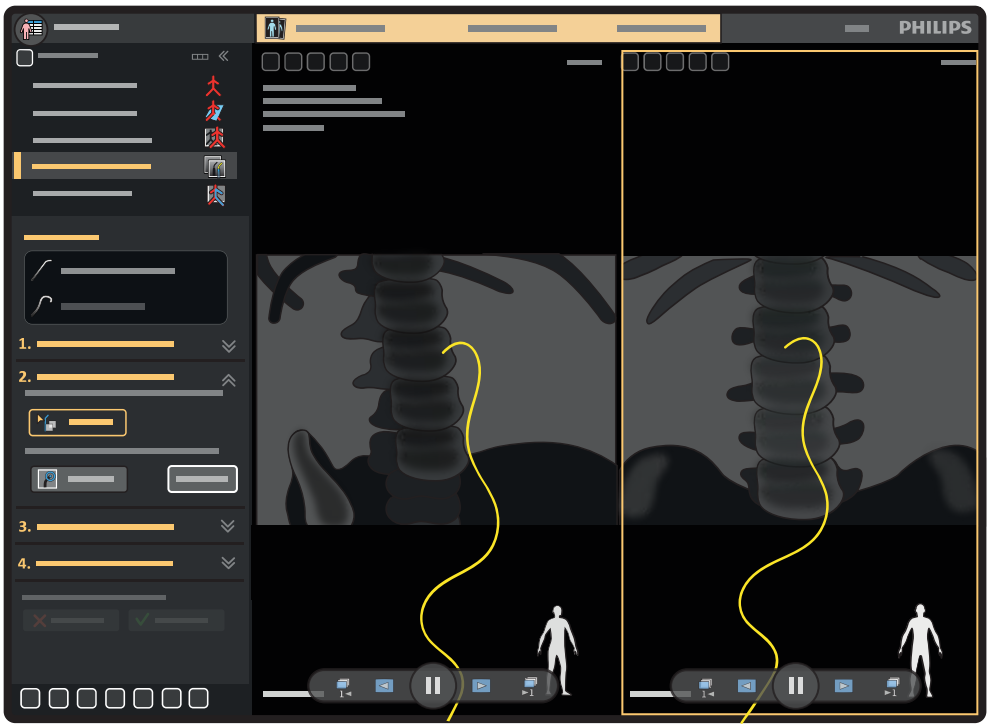


Figure 44 Shape overlays on the reference images

6 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 Guidewire in the X-ray image.

b Examine the position of the tip of the LumiGuide shapes compared to the tip of the AltaTrack Guidewire 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.

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

After accepting the registration, the LumiGuide Viewing Software automatically moves to the next task: **Live Guidance**. For more information, see Navigating with the LumiGuide Equipment (page 66).

Alternatively, the following actions are available:

a If the position of the tips of the LumiGuide shapes do not match the tips of the LumiGuide devices in the X-ray images, click **Next Step** in the task panel to display the **Verify Guidewire Tip** functions. For more information, see Adjusting the AltaTrack Guidewire Shape Tip (page 63).

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