



User Manual

English

EPIQ Series and
Affiniti 70 Diagnostic
Ultrasound Systems

PercuNav Image Fusion and Interventional Navigation

PHILIPS

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1 Read This First

This manual is intended to assist you with the safe and effective operation of your Philips product. Before attempting to operate the product, read this manual and strictly observe all warnings and cautions. Pay special attention to the information in the “Safety” section.

The user information for your Philips product describes the most extensive configuration of the product, with the maximum number of options and accessories. Some functions described may be unavailable on your product's configuration.

Transducers are available only in countries or regions where they are approved. For information specific to your region, contact your local Philips representative.



CAUTION

United States federal law restricts this device to sale by or on the order of a physician.

NOTE

"L12-5" refers to the L12-5 50 transducer.

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Intended Audience

This manual is intended for physicians, nurses, technologists, or others who operate or assist with operating the PercuNav Image Fusion and Interventional Navigation for the EPIQ series and Affiniti 70 ultrasound systems. The PercuNav system is to be used only by physicians trained in diagnostic radiology or image-guided interventions. Information in this manual may also be useful to imaging technologists, network administrators, and biomedical engineers who are involved in scanning patients and transferring images to the PercuNav system.

NOTE

The PercuNav system for the Affiniti 70 system may not be available in all countries. Check with your local representative.

For information about the ultrasound system, see the ultrasound system *Help* or *User Manual*.

NOTE

When using surgical instruments or attachments, see the “[Instruments](#)” section or the instructions for use that came with the particular instrument or attachment.

Intended Use

This product is intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in the product user information, and only for the purposes for which it was designed. However, nothing stated in the user information reduces your responsibility 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 used. Install, use, and operate the product *only* in such ways that do not conflict with applicable laws or regulations, which have the force of law.

Use of the product for purposes other than those intended and expressly stated by Philips, as well as incorrect use or operation, may relieve Philips or its agents from all or some responsibility for resultant noncompliance, damage, or injury.

**WARNING**

System users are responsible for image quality and diagnosis.

For more information about the use of this product, see [“Indications for Use” on page 58](#).

Clinical Benefits

The expected clinical benefits of the PercuNav Image Fusion and Interventional Navigation system are related to the device’s intended purpose as a stereotaxic accessory for computed tomography, cone beam computed tomography, magnetic resonance, ultrasound, and positron emission tomography, to allow multimodality image fusion. These clinical benefits can be broadly classified as providing real-time, three-dimensional visualization and navigation of the internal organs and anatomy to guide minimally invasive devices, such as needles and probes, into patients’ bodies during interventional procedures, using electromagnetic tracking technology. These image fusion and electromagnetic tracking capabilities assist the physician to provide a medical evaluation and diagnosis to direct patients’ medical care.

Warnings

Before using the PercuNav system, read these warnings and the [“Safety”](#) section.



WARNING

Do not remove the protective covers on the system; hazardous voltages are present inside. Cabinet panels must be in place while the system is in use. All internal adjustments and replacements must be made by a qualified Philips service representative.



WARNING

To avoid electrical shock, use only supplied power cords and connect only to properly grounded wall (wall/mains) outlets.

**WARNING**

Do not operate this system in the presence of flammable gases or anesthetics. Explosion can result. The system is *not* compliant in AP/APG environments as defined by IEC 60601-1.

**WARNING**

Medical equipment must be installed and put into service according to the special electromagnetic compatibility (EMC) guidelines provided in the “[Safety](#)” section.

**WARNING**

The use of portable and mobile radio-frequency (RF) communications equipment can affect the operation of medical equipment.

Images

Many images in this manual are of a standard multimodality phantom, which contains artifacts representing lesions that you can see on CT, MR, and ultrasound images.

Images, figures, diagrams, and all other graphic representations in this manual are for demonstration purposes only and may include features not included with every PercuNav system.

For questions or concerns regarding images in this manual, please contact your Philips service representative.

User Information Components

The user information provided with your product includes the following components:

- *Operating Notes*: Contains information that clarifies certain product responses that might be misunderstood or cause user difficulty.
- *PercuNav Quick Guide*: Provides the most-basic procedural steps required to operate the PercuNav system.
- *PercuNav User Manual*: Introduces you to PercuNav features and concepts, helps you set up your system, includes important safety information, and provides instructions for use specific to the PercuNav system when integrated with the ultrasound system. For information about using the ultrasound system, see the user information for your ultrasound system.

You can find user information here:

www.philips.com/IFU

Product Conventions

Your Philips product uses certain conventions throughout the interface to make it easy for you to learn and use:

- Three unlabeled buttons near the trackball are used with the trackball. The two buttons on either side of the trackball are called the "left and right trackball buttons," and they operate somewhat similarly to PC mouse buttons. The button above the trackball is called the "middle trackball button," and it is used to update the imaging display, to complete measurements, and to perform other operations as specified in procedures. The trackball arbitration icon, at the bottom of the display, indicates the current functions of the trackball buttons.
- Tabs along the top of the monitor display let you choose additional sets of setup options. Tabs along the top of the touch screen let you choose additional pages of controls.
- To type text into a text field, click in the field and use the keyboard.
- To display a list, click the down arrow . To scroll through a list, click the arrows at either end of the scroll bar or drag the scroll box up or down.

- Controls on the control panel include buttons, knobs, slide controls, and a trackball. Press a button to activate or deactivate its function. Turn a knob to change the selected setting. Press a knob-button to activate its function, or turn it to change the selected setting. Move a slide control to change its setting. Roll the trackball in the direction that you want to move an object.
- Controls on the touch screen include buttons, knob labels, and sliders. To use a touch screen button, simply touch it. To use a touch screen knob label, touch the label and adjust the corresponding knob, located directly below it on the control panel. If two knob labels are available for the knob, you must first touch the knob label that you want to adjust. To use a slider, swipe the slider button, or touch a location on the slider, to move the slider button.
- Controls on the touch screen use several methods to indicate their status. Buttons that indicate on or off status appear in the upper corner and are lit when a function is on. Buttons that select a setting generally display the active setting either within the button or on the monitor display. An arrow in the lower right corner of a button indicates that the button displays or hides a group of related buttons. Where only one button in a group can be selected at a time, the selected button is indicated by an amber outline or background.
- Many tabs on the touch screen contain two pages of controls. To display the second page, place your finger on the touch screen and swipe to the left. To return to the first page, place your finger on the touch screen and swipe to the right.
- Some areas of the display include chevrons . Clicking  displays additional information, options, or fields and clicking  hides the additional information, options, or fields.

User Information Conventions

The user information for your product uses the following typographical conventions to assist you in finding and understanding information:

- All procedures are numbered, and all subprocedures are lettered. You must complete steps in the sequence they are presented to ensure success.

- Bulleted lists indicate general information about a particular function or procedure. They do not imply a sequential procedure.
- Control names and menu items or titles are spelled as they are on the system, and they appear in bold text.
- Symbols appear as they appear on the system.
- The *pointer* is the cursor used to select elements on the display. Use the **Pointer** control to display the pointer.
- *Point* means to position the tip of the pointer or cursor on an item on the display.
- *Click* means to move the pointer or cursor to an object and press one of the unlabeled trackball buttons located on either side of the trackball.
- **Shift**+*click* means to press and hold the **Shift** key while clicking an item on the display.
- *Drag* means to place the pointer over an object and then press and hold the left or right trackball button while moving the trackball. Use this method to move an object on the display.
- *Touch* means to press a button on the touch screen, located above the control panel.
- *Turn* means to turn a control knob on the control panel, located below the touch screen.
- *Swipe* means to touch the touch screen with the tip of your finger and move your finger in a quick motion either to the left or to the right. This action displays an additional touch screen, if one is available.
- *Highlight* means to change the color of a display selection (such as an item in a list) or overlay it with a colored bar, usually by clicking.
- The left side of the system is to your left as you stand in front of the system, facing the system. The front of the system is nearest to you as you operate it.

Information that is essential for the safe and effective use of your product appears throughout your user information as follows:

**WARNING**

Warnings highlight information vital to the safety of you, the operator, and the patient.

**CAUTION**

Cautions highlight ways that you could damage the product and consequently void your warranty or service contract or ways that you could lose patient or system data.

NOTE

Notes bring your attention to important information that will help you operate the product more effectively.

Upgrades and Updates

Philips is committed to innovation and continued improvement. Upgrades may be announced that consist of hardware or software improvements. Updated user information will accompany those upgrades.

Customer Comments

If you have questions about the user information, or you discover an error in the user information, in the USA, please call Philips at 800-722-9377; outside the USA, please call your local customer service representative. You can also send e-mail to the following address:

techcomm.ultrasound@philips.com

Supplies and Accessories

Philips is continuously adding to the instrumentation that the PercuNav system supports. For more information on supported instrumentation, or to order supplies, instrumentation, or accessories, please contact your Philips representative.

To order biopsy guides and other supplies and accessories, contact CIVCO Medical Solutions:

CIVCO Medical Solutions

102 First Street South, Kalona, IA 52247-9589

Telephone: 800-445-6741 (USA and Canada), +1 319-248-6757 (International)

Fax: 877-329-2482 (USA and Canada), +1 319-248-6660 (International)

E-mail: info@civco.com

Internet: www.civco.com

For a list of supplies and accessories for the ultrasound system and transducers, see the ultrasound system's *User Manual*.

NOTE

Model numbers and part numbers in the following table are subject to change.

Approved PercuNav Instruments and Accessories

Accessory	Model Number or Part Number	Affiniti 70 System	EPIQ Series Systems
Needle Trackers			
Philips PercuNav Coaxial Needle Tracker, 13G x 11cm	40001	--	X
Philips PercuNav Coaxial Needle Tracker, 13G x 16cm	40002	--	X
Philips PercuNav Coaxial Needle Tracker, 16G x 11cm	40003	--	X
Philips PercuNav Coaxial Needle Tracker, 17G x 16cm	40004	--	X
Philips PercuNav Coaxial Needle Tracker, 18G x 8cm	40005	--	X
Philips PercuNav Coaxial Needle Tracker, 18G x 13cm	40006	--	X
Philips PercuNav Coaxial Needle Tracker, 20G x 8cm	40007	--	X
Philips PercuNav Coaxial Needle Tracker, 20G x 13cm	40008	--	X
Philips PercuNav Coaxial Needle Tracker, 20G x 17cm	40009	--	X
Philips PercuNav Adaptive Needle Tracker	41001	X	X
Other Components			
Philips PercuNav Patient Tracker	10001	X	X

Accessory	Model Number or Part Number	Affiniti 70 System	EPIQ Series Systems
Philips PercuNav Ultrasound Tracker for the C5-1, C9-2, L12-5, S5-1, and X6-1 ¹ transducers	20004	X	X
Philips PercuNav Ultrasound Tracker for the C10-4ec transducer	21001	X	X
Philips PercuNav Adaptive Needle Tracker Kit	453561715772	X	X

¹EPIQ systems only

For information on using the PercuNav instruments and accessories, see the “[Instruments](#)” section.

Customer Service

Customer service representatives are available worldwide to answer questions and to provide maintenance and service. Please contact your local Philips representative for assistance. You can also contact the following office for referral to a customer service representative, or visit the Philips "Contact Us" website:

www.healthcare.philips.com/main/about/officelocator/index.wpd

Philips Ultrasound LLC

22100 Bothell Everett Hwy, Bothell, WA 98021-8431, USA

800-722-9377

Regulatory Representatives

Australian Sponsor

Philips Electronics Australia Ltd
65 Epping Road
North Ryde NSW 2113
Australia

Brazilian Representative

Responsável Técnico:
Eligerson Angelin de Souza
CRF/SP 42230

Detentor do Registro:
Philips Medical Systems Ltda.
Avenida Julia Gaiolli, 740, Galpão T300 - Parte S5, Água Chata
Guarulhos/SP, Brasil – CEP 07.251-500
CNPJ: 58.295.213/0001-78
AFE: 102.167-1

Malaysian Authorized Representative

Wakil Diberi Kuasa:
Philips Malaysia Sdn. Berhad 196001000018 (3690-P)
Level 9, Menara Axis
2 Jalan 51A/223
46100 Petaling Jaya
Selangor Darul Ehsan,
Malaysia
Telephone: 03-7965 7488

Recycling, Reuse, and Disposal

Philips is concerned with helping protect the natural environment and helping ensure continued safe and effective use of this system through proper support, maintenance, and training. Philips designs and manufactures equipment in compliance with relevant guidelines for environmental protection. As long as the equipment is properly operated and maintained, it presents no risk to the environment. However, the equipment may contain materials that could be harmful to the environment if disposed of incorrectly. Use of such materials is essential for the implementation of certain functions and for meeting certain statutory and other requirements.

The European Union Directive on Waste Electrical and Electronic Equipment (WEEE) requires producers of electrical and electronic equipment to provide reuse and treatment information for each affected product. This information is provided in a Philips Recycling Passport. The recycling passports for the affected Philips ultrasound systems can be requested on this website:

www.healthcare.philips.com/main/about/sustainability/recycling/ultrasound.wpd

Recycling, reuse, and disposal information in this document is directed mainly at the entity with legal authority over the equipment. Operators are usually uninvolved in disposal, except in the case of certain batteries.

Passing Your System to Another User

If you pass this system to another user who will use the system for its intended purpose, then pass it on in its complete state. Particularly, ensure that all the product-support documentation, including all instructions for use, are passed on to the new user. Make the new user aware of the support services that Philips provides for installing, commissioning, and maintaining the system, and for comprehensive operator training. Existing users must remember that passing on medical electrical equipment to new users may present serious technical, medical, privacy, and legal risks. The original user may remain liable, even if the equipment is given away.

Philips strongly advises you to seek advice from your local Philips representative before agreeing to pass on any equipment.

After you pass the system to a new user, you might still receive important safety-related information, such as bulletins and medical device corrections and removals. In many jurisdictions the original owner has a clear duty to communicate such safety-related information to new users. If you are unable or unprepared to do this, inform Philips about the new user, so that Philips can provide the new user with safety-related information.

Final Disposal of Your System



Final disposal is when you dispose of the system in such a way that it can no longer be used for its intended purposes.



WARNING

Do not dispose of this system (or any parts of it) with industrial or domestic waste. The system may contain materials such as lead, tungsten, or oil, or other hazardous substances that can cause serious environmental pollution. The system also contains privacy-sensitive information, which should be properly removed (scrubbed). Philips advises you to contact your Philips service organization before disposing of this system.

Philips gives support for the following:

- Recovery of useful parts
- Recycling of useful materials by competent disposal companies
- Safe and effective disposal of equipment

For advice and information, contact your Philips service organization, or see the following website:

www.healthcare.philips.com/us/about/sustainability/recycling

Perchlorate Material

In this system, perchlorate material is present in lithium coin cells or batteries. Special handling may apply to those items. For more information, see this website:

www.dtsc.ca.gov/hazardouswaste/perchlorate

2 Safety

Please read this information before using the PercuNav system.

This section outlines the safety requirements and features of the PercuNav system, including the instrumentation and optional equipment. It also details actions that may damage the equipment.

Report any serious safety incident that occurs in relation to the ultrasound system to Philips and to the competent authority of the country in which the user and patient are established.

NOTE

The PercuNav system for the Affiniti 70 system may not be available in all countries. Check with your local representative.

NOTE

For information on the safety requirements and features of the ultrasound system, see the ultrasound system *User Manual*.

General Warnings

Additional procedural warnings are found throughout this manual and are formatted similarly to the following warnings.



WARNING

This device is intended for use by, or by the order of, and under the supervision of a licensed physician qualified to direct the use of the device.

**WARNING**

The PercuNav system is to be used by trained physicians, nurses, and operators only.

**WARNING**

The PercuNav system can be used only with the EPIQ series and Affiniti 70 systems. It must not be used with any other ultrasound system.

**WARNING**

The PercuNav system has not been specifically designed or tested for indications relating to the central circulatory system or the central nervous system.

**WARNING**

The PercuNav system has not been specifically designed or tested for transcranial navigation. Do not perform transcranial navigation with the PercuNav system.

**WARNING**

The user is responsible for ensuring that the PercuNav system is accurate. The PercuNav system can be used to assist physicians, but physicians must override the system if the PercuNav system does not appear to be accurate or otherwise working as intended.

**WARNING**

Read the instructions for use of all instrumentation used with the system. Some instrumentation components may require preparation before use.

**WARNING**

Do not alter or change the system parameters for the PercuNav system as set by Philips factory personnel.

**WARNING**

The scan parameters and scanner settings should always conform to the recommended scan settings.

**WARNING**

The PercuNav system includes non-sterile devices. Only sterile instrumentation should be used in a sterile patient environment. To prevent contamination, the PercuNav system must remain outside the patient environment. If the PercuNav system or transducers and accessories are draped, they can be introduced into a sterile patient environment.

**WARNING**

The ultrasound system monitor and control panel may affect the magnetic field that makes up the tracking volume. If the magnetic field is affected, move the ultrasound system monitor or control panel outside the patient environment.

**WARNING**

The imaging systems used for collection of pre-procedure and procedure images must be maintained and calibrated according to manufacturer's recommendations.

**WARNING**

Do not bend, kink, or run over system cables or tool cables, and do not use cables that are damaged. Regularly inspect cables for damage. Damaged cables may produce inaccurate data and result in possible personal injury.

**WARNING**

The PercuNav system is meant only to assist in positioning devices. Use direct imaging to verify the actual location of instruments before and during navigation. Physicians should use their experience to override the system or to decide to disregard the information provided, if their experience or the direct imaging differ.

**WARNING**

If you observe a malfunction, discontinue use of the PercuNav system and revert to direct imaging.

**WARNING**

Verification, by direct imaging, of tracking accuracy must be performed on all tools used for navigation, by the physician, before and during navigation.

**WARNING**

Perform continuous verification during guided navigation to verify the accuracy of the displayed images and to ensure that the display of the tracked tool moves on the display in a way that corresponds to the physical movement.

**WARNING**

Do not expose or immerse any part of the PercuNav system, including the field generator and tool connection unit, to liquids or allow fluid to enter the equipment in any way. Exposing the any part of the PercuNav system to liquids may result in equipment damage, produce a fire or shock hazard, or contribute to possible personal injury.

**WARNING**

If you use historic images, the physician is responsible for confirming the appropriateness and accuracy of those images and if they can be used for the current procedure.

General Cautions

The following actions may damage the equipment. Additional procedural cautions are found throughout this manual and are formatted similarly to the following cautions.

**CAUTION**

Changes or modifications to hardware or software that are not explicitly approved by the manufacturer or its authorized representative could void your privileges to operate the equipment.

**CAUTION**

Do not attempt to service any part of the PercuNav system. Doing so voids the system warranty.

**CAUTION**

Before disconnecting power from the ultrasound system, follow the procedure for system shutdown in the *User Manual* for the ultrasound system.

**CAUTION**

Ensure that all cables connected to the PercuNav system are placed to prevent tripping hazards and damage to tools and cables. Remove unused equipment from the vicinity of the system.

**CAUTION**

Avoid rolling over PercuNav cables or component cables with the cart or other heavy equipment. Doing so compromises the warranty.

**CAUTION**

Do not expose any part of the PercuNav system, including any tracked tools or instruments, to a high magnetic field, such as that produced by a magnetic resonance imaging (MRI) scanner. The system is neither MRI-compatible nor MRI-safe.

Electrical Safety Warnings

The PercuNav system, when integrated with the ultrasound system, complies with EN 60601-1-2: 2007 for Non Life Supporting, Group 1, Class A Equipment. This equipment has been verified by a recognized third-party testing agency as a Class I device with Type BF patient applied parts. (For the safety standards met by this system, see [“Safety Requirements” on page 353](#).) For maximum safety, observe the following warnings:

**WARNING**

Before application of a high-voltage defibrillation pulse, remove all patient-contact devices from the patient.

**WARNING**

Medical equipment must be installed and put into service according to the special electromagnetic compatibility (EMC) guidelines provided in [“Electromagnetic Compatibility” on page 61](#).

**WARNING**

Do not use the PercuNav system if any of the hardware components or connectors are damaged. Such damage may affect system functions, contribute to inaccuracies, and possibly cause personal injury.

**WARNING**

To avoid risk of electrical shock, always inspect all instruments and cables before use. Do not use if there are signs of material degradation or damage, or if the cables are abraded.

**WARNING**

Use only Philips-approved cables, instrumentation, and accessories for the PercuNav system as detailed in this manual. Electrical safety may be compromised otherwise. See [“Approved Cables for Electromagnetic Compliance” on page 73](#).

**WARNING**

Although the PercuNav system has been manufactured in compliance with existing EMI/EMC requirements, use of the PercuNav system in the vicinity of an electromagnetic field or large metal objects can affect the accuracy of the system.

**WARNING**

To avoid risk of electrical shock hazards, always turn off the system and disconnect it from the wall outlet before cleaning the system.

Environmental Warnings

**WARNING**

Do not operate this system in the presence of flammable gases or anesthetics. Explosion can result. The system is *not* compliant in AP/APG environments as defined by IEC 60601-1.

**WARNING**

The use of portable and mobile radiofrequency (RF) communications equipment can affect the operation of the PercuNav system.

Review the environment in which the system is used to identify possible sources of radiated emissions and interference. Such emissions could be from other electrical devices used in the same room or an adjacent room. Communication devices such as cellular phones and pagers can cause these emissions. The existence of radio, TV, or microwave transmission equipment located nearby can cause emissions. In cases where EMI is causing disturbances, it may be necessary to relocate the PercuNav system.

Use of the PercuNav system in the vicinity of other equipment or large metal objects may affect the PercuNav system or other equipment. If inaccuracies are detected, try the following:

- Increase the separation between the field generator and the source of the interference.
- Reorient the device cabling.
- Plug devices into separate outlet circuit branches.
- Rearrange or remove conflicting devices.

For additional information, contact Philips Technical Support.

Equipment Protection

Follow these precautions to protect your system:



WARNING

To avoid improper operation, do not place the system adjacent to nor stacked with other equipment. If it becomes necessary to stack the system with or place it adjacent to other equipment, verify normal operation before use.



CAUTION

If systems, transducers, and peripherals have been in an environment below 10°C (50°F), allow them to reach room temperature before connecting or turning them on. Allow 24 hours for complete normalization. Otherwise, condensation inside the devices could cause damage.



CAUTION

Excessive bending or twisting of cables on patient-applied parts may cause failure or intermittent operation of the system. Do not roll the system over cables, which may damage them.



CAUTION

Do not use solvents, such as thinner or acetone, or abrasive cleaners on the system, transducers, peripherals, the field generator, or the tool connection unit.



CAUTION

Do not use automated cleaning devices with the Adaptive Needle Tracker (ANT).

Symbols

The International Electrotechnical Commission (IEC) has established a set of symbols for medical electronic equipment that classify a connection or warn of potential hazards. The following symbols may be used on your product, its accessories, or its packaging.

Symbol	Standards and Reference	Reference Description	Additional Information
Safety			
	ISO 15223-1, Symbol 5.4.4 ISO 7000-0434A	Caution (ISO 7000-0434A).	--
	ISO 15223-1, Symbol 5.4.3 ISO 7000-1641	Consult instructions for use.	--

Symbol	Standards and Reference	Reference Description	Additional Information
	ISO 7010, Symbol M002	Refer to instruction manual/booklet.	--
	IEC 60417, Symbol 5019	Protective Earth; Protective ground.	--
	IEC 60417, Symbol 5017	Earth; ground.	--
	IEC 60417, Symbol 5021	Equipotentiality.	--
	IEC 60417, Symbol 5840	Type B applied part.	Non-isolated patient connection.
	IEC 60878, Symbol 5333 IEC 60417, Symbol 5333	Type BF applied part.	Isolated patient connection.
	IEC 60417, Symbol 5335	Type CF applied part.	Isolated patient connection for applied part intended for intraoperative use, including direct cardiac application and contact with major vessels.
	IEC 60417, Symbol 5334	Defibrillation-proof Type BF applied part.	--
	IEC 60417, Symbol 5336	Defibrillation-proof Type CF applied part.	--

Symbol	Standards and Reference	Reference Description	Additional Information
	ISO 15223-1, Symbol 5.4.2 ISO 7000-1051	Do not reuse.	--
	ISO 7010, Symbol P017	No pushing.	Warns of system overbalance due to external force.
	IEC 60417, Symbol 5036	Dangerous Voltages.	Appears adjacent to high-voltage terminals, indicating the presence of voltages greater than 1,000 Vac (600 Vac in the United States).
	IEC 62570	MR Unsafe.	System is MR unsafe and presents a projectile hazard. Keep outside of the MRI scanner room. When color reproduction is not practical, the icon may be printed in black and white.
Rx only	--	--	Rx Only. (USA federal law restricts this device to sale by or on the order of a physician.)
	--	--	Indicates a hazard to patients with pacemakers. Do not place field generator within 200 mm (8 in) of a patient with a pacemaker.
	--	--	Indicates a possible pinch hazard when positioning the monitor.
	ISO 7010, Symbol W024	Warning: Crushing of hands.	--

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Symbol	Standards and Reference	Reference Description	Additional Information
	--	--	Warns that the system should not be used stacked with other equipment. If the system is used stacked with or adjacent to other equipment, verify normal operation before use.
	ISO 15223-1, Symbol 5.2.8 ISO 7000-2606	Do not use if package is damaged.	--
 www.philips.com/IFU	--	--	Consult the electronic instructions for use (eIFU).
	ISO 15223-1, Symbol 5.2.7 ISO 7000-2609	Non-sterile.	--
	ISO 15223-1, Symbol 5.2.3 ISO 7000-2501	Sterilized using ethylene oxide.	--
	ISO 15223-1, Symbol 5.2.11	Single sterile barrier system.	--
	ISO 15223-1, Symbol 5.2.12	Double sterile barrier system.	--
	ISO 15223-1, Symbol 5.2.13	Single sterile barrier system with protective packaging inside.	--
	ISO 15223-1, Symbol 5.2.14	Single sterile barrier system with protective packaging outside.	--

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Symbol	Standards and Reference	Reference Description	Additional Information
	ISO 15223-1, Symbol 5.1.4 ISO 7000-2607	Use-by date.	--
	IEC 60417, Symbol 5134	Electrostatic sensitive devices.	Identifies ESD (electrostatic-discharge) sensitivity of a connector that is not tested as specified in IEC 60601-1-2. Do not touch exposed connector pins. Touching exposed pins can cause electrostatic discharge, which can damage the product.
	IEC 60417, Symbol 5140	Non-ionizing electromagnetic radiation.	Indicates that interference may occur in the vicinity of equipment marked with this symbol (IEC 60601-1-2).
Environmental			
IPX1	IEC 60529	Degrees of protection provided by enclosures (transducers).	Indicates that the device is protected against the effects of vertically falling water.
IPX4	IEC 60529	Degrees of protection provided by enclosures (foot-operated device).	Indicates that the device is protected against the effects of splashing liquids.
IPX7	IEC 60529	Degrees of protection provided by enclosures (foot-operated devices).	Indicates that the device is protected against the effects of immersion.
IPX8	IEC 60529	Degrees of protection provided by enclosures (foot-operated device or transducer).	Indicates that the device is protected against the effects of immersion for up to 60 minutes.

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Symbol	Standards and Reference	Reference Description	Additional Information
IP44	IEC 60529	Degrees of protection provided by enclosures.	Indicates that the equipment inside the enclosure is protected against ingress of solid foreign objects having a diameter of 1.0 mm and greater. Indicates that water splashed against the enclosure from any direction shall have no harmful effect.
IP67	IEC 60529	Degrees of protection provided by enclosures.	Indicates that the equipment inside the enclosure is protected against ingress of dust and effects of immersion for up to 30 minutes at 1 m of submersion.
	IEC 60417, Symbol 5957	For indoor use only.	--
	ISO 15223-1, Symbol 5.3.7 ISO 7000-0632	Temperature limit.	Indicates the temperature range (noncondensing) for transport and storage. Does not apply to media.
	ISO 15223-1, Symbol 5.3.9 ISO 7000-2621	Atmospheric pressure limitation.	Atmospheric pressure range for transport and storage.
	ISO 15223-1, Symbol 5.3.8 ISO 7000-2620	Humidity limitation.	The relative humidity range (noncondensing) for transport and storage.
	ISO 7000, Symbol 0623	This way up.	Points toward the side of the shipping crate that should be kept facing up.
	ISO 15223-1, Symbol 5.3.4 ISO 7000-0626	Keep dry.	--

Symbol	Standards and Reference	Reference Description	Additional Information
	ISO 15223-1, Symbol 5.3.1 ISO 7000-0621	Fragile, handle with care.	--
	ISO 15223-1, Symbol 5.3.2 ISO 7000-0624	Keep away from sunlight.	--
	EN 50419:2006 WEEE Directive 2002/96/EC	WEEE symbol. Indicates the need for separate collection for electrical and electronic equipment in compliance with the Waste Electrical and Electronic Equipment (WEEE) Directive. When accompanied by  or  , components of the device may contain lead or mercury, respectively, which must be recycled or disposed of in accordance with local, state, or federal laws.	--
	--	Product contains hazardous material. Dispose of properly. (Required by WEEE Directive; see EN 50419.)	--
	IEC 60878, Symbol 1135 ISO 7000-1135	General symbol for recovery/recyclable.	Do not throw away. Dispose of in accordance with local, state, or federal laws.

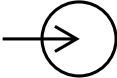
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Symbol	Standards and Reference	Reference Description	Additional Information
Connectors and Ports			
	IEC 60417, Symbol 5032	Alternating current.	--
	IEC 60417, Symbol 5031	Direct current.	--
	IEC 60417, Symbol 5010	"ON"/"OFF" (Push-Push).	
	IEC 60417, Symbol 5009	Stand-by.	On/Off control with Stand-by.
	--	--	On a two-position power switch, represents On (I) and Off (O).
	--	--	Connection for a pencil probe.
	--	--	Connection for a pencil probe.
	--	--	Connection for a transducer.
	--	--	Connection for ECG and physio leads.

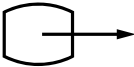
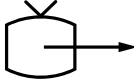
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Symbol	Standards and Reference	Reference Description	Additional Information
	--	--	Connection for ECG and physio leads.
	--	--	Print remote output.
	-	-	Input port for audio left/right, VHS/ S-VHS, microphone, CD, or DVD.
	--	--	Output port for audio left/right, VHS/ S-VHS, video patient monitor, black- and-white printer, or interlaced RGB output port.
	IEC 60417, Symbol 5034	Input.	--
	ISO 7000, Symbol 3650	USB Port.	--
	--	FireWire (IEEE 1394) input/ output port.	--
	IEC 60878 Symbol 5988	Computer Network.	Ethernet connection.
	IEC 60878, Symbol 5850	Serial Interface.	RS-232 serial port.

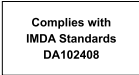
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Symbol	Standards and Reference	Reference Description	Additional Information
	--	--	System microphone.
AUX POWER ISOLATE OUTPUT	--	--	Isolated auxiliary power provided for connection of Philips-approved remote accessories.
	IEC 60417, Symbol 5114	Foot switch.	--
	IEC 60878, Symbol 5051	Television Monitor.	SVGA, DVI-I, DisplayPort, or HDMI connection.
	IEC 60878, Symbol 5529A	Video Output.	S-Video connection.
	--	--	Video output. S-Video connection.
	--	--	B/W Composite video output connection.
	--	--	Color composite video output connection.
	IEC 60878, Symbol 0093	Remote Control.	Video print trigger connection.
	--	--	VGA or parallel output port.

Symbol	Standards and Reference	Reference Description	Additional Information
	--	--	DVI video output receptacle.
	--	--	
	IEC 60417, Symbol 5016	Fuse.	Identifies fuse boxes or their locations. For continued protection from fire and shock, replace fuses only with fuses of the same type and rating.
Product Data Identifiers			
	--	--	Identifies the total mass of the system, including its safe working load, in kilograms. Indicates compliance with IEC 60601-1, Cl. 7.2.21.
	IEC 60878, Symbol 2794 ISO 7000-2794	Packaging unit.	--
	--	--	Global Medical Device Nomenclature Code.
	--	--	Global Trade Item Number.
	ISO 15223-1, Symbol 5.1.5 ISO 7000-2492	Batch code.	--

Symbol	Standards and Reference	Reference Description	Additional Information
	--	--	Indicates that the item is a medical device.
	--	--	Model name for the device.
	--	--	Model number for the device and configurations.
	ISO 15223-1, Symbol 5.1.6 ISO 7000-2493	Catalog Number.	--
	--	--	System hardware.
	ISO 15223-1, Symbol 5.1.7 ISO 7000-2498	Serial Number.	--
	--	--	Service part number / field-replaceable unit (FRU) number.
	--	--	Unique Device Identifier.
	--	--	Universal part number.
	--	--	Unique Device Identifier, 2D barcode.

Symbol	Standards and Reference	Reference Description	Additional Information
	ISO 15223-1, Symbol 5.1.3 ISO 7000-2497	Date of Manufacture.	--
	ISO 15223-1, Symbol 5.1.1 ISO 7000-3082	Manufacturer.	--
	IEC 60417	Country of Manufacture.	--
	ISO 7000-3724	Distributor.	--
	ISO 7000-3725	Importer.	--
Regulatory Compliance			
	IEC 60878, Symbol 5172	Class II Equipment.	--
	--	--	UL (Underwriters Laboratories) classification symbol.
	--	--	Indicates that the electrical and electronic equipment is in compliance with Infocomm Media Development Authority (IMDA) Standards.

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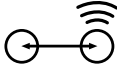
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Symbol	Standards and Reference	Reference Description	Additional Information
	--	--	With an identification code (for example, 2ATC9-PHC-11AC1), indicates that the system uses an embedded, FCC-approved wireless adapter.
	--	--	With an identification code (for example, CCAI15LP0780T9), indicates that the system uses an embedded NCC-approved (Taiwan) wireless adapter.
	--	--	CSA (CSA International) classification symbol.
	European Commission Medical Device Directive 93/42/EEC 2007/47/EC EU MDR 2017/745, Article 20, Annex 5	CE Mark of Conformity	--
	European Commission Medical Device Directive 93/42/EEC 2007/47/EC EU MDR 2017/745, Article 20, Annex 5	CE0086 - CE Mark of Conformity	--
	European Commission Medical Device Directive 93/42/EEC 2007/47/EC EU MDR 2017/745, Article 20, Annex 5	CE2797 - CE Mark of Conformity	--

Symbol	Standards and Reference	Reference Description	Additional Information
	ISO 15223-1, Symbol 5.1.2	Authorized Representative in the European community.	--
	--	--	Customs Union Mark of Conformity (EurAsian Conformity Mark).
	--	--	Chinese Environmentally Friendly Use Period symbol.
	--	--	Indicates that the system conforms with the Ukrainian Scientific Institute of Certification (UA.TR.116).
	--	--	Australian and New Zealand (RCM) Regulatory Compliance Mark indicates compliance with electrical safety, EMC, EME, and telecommunications requirements.
	--	--	KC (Korea Certification) mark for electrical and electronic equipment.
	--	--	INMETRO mark as issued by SGS. Indicates third-party approval in Brazil.
	--	--	INMETRO mark as issued by TÜV. Indicates third-party approval in Brazil.
PercuNav Option			

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Symbol	Standards and Reference	Reference Description	Additional Information
	--	--	Identifies the port for the PercuNav field generator.
	--	--	Identifies the port for the PercuNav field generator.
	--	--	Identifies the TCU port that is used to connect the TCU to the ultrasound system.
	--	--	Identifies the port for the PercuNav tool connection unit (TCU).
	--	--	China RoHS Hazardous Substances are not contained in the EIP (Electronic Information Products).

Field Generator Warnings

The following warnings are provided by the field generator manufacturer and apply to all of the PercuNav position-sensing components:



WARNING

Do not disconnect the field generator from the system while the system is powered on. Disconnecting the field generator while in use may result in generation of electrical sparks, irreparable field generator damage, and possible personal injury.

**WARNING**

Do not track instruments in an untested application environment, because an untested environment may contain elements that affect field generator functions. For example, electromagnetic field disturbances from other objects in the room and the proximity of metal and other field generators can adversely affect the system. Failure to test for such disturbances increases the possibility of inaccurate information and possible personal injury.

**WARNING**

Do not drop the field generator or subject it to impact. Physical damage to the field generator may alter its calibration and contribute to inaccurate information and possible personal injury. If the field generator is dropped or damaged, discontinue use and contact the Philips representative.

**WARNING**

Do not place the field generator within 10 m (33 ft) of another operating field generator; doing so may contribute to inaccurate information and possible personal injury.

**WARNING**

Do not operate the field generator within 200 mm (8 in) of an installed pacemaker. The magnetic field produced by the field generator may interfere with the operation of the pacemaker, which may result in personal injury.

**WARNING**

Do not expose tools to a high magnetic field, such as an MRI system, because they may become magnetized. Tracking with a magnetized sensor may result in incorrect information and result in possible personal injury. None of the equipment or tools provided by Philips for use with a PercuNav system are MRI-safe and may cause serious damage to MRI systems and personal injury.

**WARNING**

During use, do not place the field generator cable inside the magnetic field volume or wrap it around the field generator, because it may create magnetic interference that can contribute to inaccurate information and possible personal injury.

**WARNING**

Do not place tool cables within 30 mm (1.2 in) of the field generator cable during use. If placed this close, particularly if the cables are parallel to each other, the tool cable may become subject to electromagnetic interference. This interference can contribute to inaccurate information and possible personal injury.

**WARNING**

Do not coil the field generator cable during use, because it produces enough electric current that a magnetic field is created when the cable is placed in a circular formation. This magnetic field may disturb the field generator's magnetic field, contributing to inaccurate information and possible personal injury.

**WARNING**

Do not use the field generator in the presence of other magnetic fields during storage or use. To do so may lead to misleading or inaccurate information and possible personal injury.

**WARNING**

The system has not been designed or tested for use during or following cardiac defibrillation. Cardiac defibrillation may cause inaccurate information and result in possible personal injury.

Biological Safety

A list of precautions related to biological safety follows; observe these precautions when using the PercuNav system.

**WARNING**

Do not use the system if an error message on the video display indicates that a hazardous condition exists. Note the error code, turn off power to the system, and call your customer service representative.

**WARNING**

If the system becomes contaminated internally with bodily fluids carrying pathogens, you must immediately notify your Philips service representative. Components inside the system cannot be disinfected. In that case, the system must be disposed of as biohazardous material in accordance with local or federal laws.

**WARNING**

Patients with Creutzfeldt-Jakob disease (CJD), VCJD, or other known or suspected slow virus infections are contraindicated for this device.

**WARNING**

In contrast studies using a high-MI acoustic field, capillary rupture, due to microbubble expansion within a capillary in an acoustic field, can cause extravasation. References: (1) Skyba, D.M., Price, R.J., Linka, A.Z., Skalak, T.C., Kaul, S. "Direct in vivo visualization of intravascular destruction of microbubbles by ultrasound and its local effects on tissue." *Circulation*, 1998; 98:290-293. (2) van Der Wouw, P.A., Brauns, A.C., Bailey, S.E., Powers, J.E., Wilde, A.A. "Premature ventricular contractions during triggered imaging with ultrasound contrast." *Journal of the American Society of Echocardiography*, 2000; 13(4):288-94.

**WARNING**

Preventricular contractions can be caused by the oscillations of microbubbles when a high-MI acoustic field is triggered in the heart at the end of systole. In a very sick patient with certain risk factors, theoretically, this could lead to ventricular fibrillation. Reference: van Der Wouw, P.A., Brauns, A.C., Bailey, S.E., Powers, J.E., Wilde, A.A. "Premature ventricular contractions during triggered imaging with ultrasound contrast." *Journal of the American Society of Echocardiography*, 2000; 13(4):288-94.

**WARNING**

Approval of specific contrast agents and their applications differs from country to country. For approved agents and applications, check with your local or national regulatory agencies.

Indications for Use

The PercuNav system is a stereotaxic accessory for computed tomography (CT), cone beam CT (CBCT), magnetic resonance (MR), ultrasound (US), and positron emission tomography (PET). CT, Ultrasound, PET, and MR may be fused in various combinations, such as CT with MR, MR with ultrasound, and so on. It may include instrumentation to display the simulated image of a tracked insertion tool such as a biopsy needle or probe on a computer monitor screen that shows images of the target organs and the current and the projected future path of the interventional instrument. The PercuNav system is intended for treatment planning and to assist guidance for clinical, interventional, or diagnostic procedures in a clinical setting.

The PercuNav system is also intended to supplement live imaging in clinical interventions to determine the proximity of one device relative to another.

The PercuNav system is not intended to be the sole guidance for any procedure. Procedures that can be guided by the PercuNav system adjunctively include, but are not limited to, the following:

- Image fusion for diagnostic clinical examinations and procedures
- Soft tissue biopsies
- Soft tissue ablation
- Bone ablation
- Bone biopsies
- Nerve blocks and pain management
- Drainage placements

Contraindications



WARNING

Patients with Creutzfeldt-Jakob disease (CJD), VCJD, or other known or suspected slow virus infections are contraindicated for this device.

FDA Medical Alert on Latex

March 29, 1991, Allergic Reactions to Latex-Containing Medical Devices

Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), the FDA is advising health care professionals to identify their latex sensitive patients and be prepared to treat allergic reactions promptly. Patient reactions to latex have ranged from contact urticaria to systemic anaphylaxis. Latex is a component of many medical devices, including surgical and examination gloves, catheters, intubation tubes, anesthesia masks, and dental dams.

Reports to the FDA of allergic reactions to latex-containing medical devices have increased lately. One brand of latex cuffed enema tips was recently recalled after several patients died as a result of anaphylactoid reactions during barium enema procedures. More reports of latex sensitivity have also been found in the medical literature. Repeated exposure to latex both in medical devices and in other consumer products may be part of the reason that the prevalence of latex sensitivity appears to be increasing. For example, it has been reported that 6% to 7% of surgical personnel and 18% to 40% of spina bifida patients are latex sensitive.

Proteins in the latex itself appear to be the primary source of the allergic reactions. Although it is not now known how much protein is likely to cause severe reactions, the FDA is working with manufacturers of latex-containing medical devices to make protein levels in their products as low as possible.

FDA's recommendations to health professionals in regard to this problem are as follows:

- When taking general histories of patients, include questions about latex sensitivity. For surgical and radiology patients, spina bifida patients and health care workers, this recommendation is especially important. Questions about itching, rash or wheezing after wearing latex gloves or inflating a toy balloon may be useful. Patients with positive histories should have their charts flagged.
- If latex sensitivity is suspected, consider using devices made with alternative materials, such as plastic. For example, a health professional could wear a non-latex glove over the latex glove if the patient is sensitive. If both the health professional and the patient are sensitive, a latex middle glove could be used. (Latex gloves labeled "Hypoallergenic" may not always prevent adverse reactions.)

- Whenever latex-containing medical devices are used, especially when the latex comes in contact with mucous membranes, be alert to the possibility of an allergic reaction.
- If an allergic reaction does occur and latex is suspected, advise the patient of a possible latex sensitivity and consider an immunologic evaluation.
- Advise the patient to tell health professionals and emergency personnel about any known latex sensitivity before undergoing medical procedures. Consider advising patients with severe latex sensitivity to wear a medical identification bracelet.

The FDA is asking health professionals to report incidents of adverse reactions to latex or other materials used in medical devices. (See the October 1990 FDA Drug Bulletin.) To report an incident, contact the FDA Problem Reporting Program, MedWatch, at 1-800-332-1088, or on the Internet:

www.fda.gov/Safety/MedWatch/

For a single copy of a reference list on latex sensitivity, write to: LATEX, FDA, HFZ-220, Rockville, MD 20857.

Infection Control

Issues related to infection control affect the operator and the patient. Follow the infection-control procedures established in your facility for the protection of both the staff and the patient.

Removing Blood and Infectious Material

Disconnect the ultrasound system from the power supply and use a gauze pad moistened with soap and water to remove blood on the system, connectors, and cables. Then dry the equipment with a soft, dry or damp, lint-free cloth to prevent corrosion.

For more information about removing blood and other infectious material from the ultrasound system, see *Care and Cleaning of Ultrasound Systems and Transducers*, included on your system's USB media.

Disposable Drape

If you believe contamination of the ultrasound system might occur during an exam, Philips recommends that you take universal precautions and cover the system with a disposable drape. Consult your facility's rules regarding equipment use in the presence of infectious disease.



CAUTION

Position the disposable drape so that it does not block the vents on the ultrasound system, the monitors, or the peripherals.

Electromagnetic Compatibility

Electromagnetic compatibility (EMC) is defined as the ability of a product, a device, or a system to function satisfactorily in the presence of the electromagnetic phenomena that exists in the location of the product, the device, or the system being used; and, in addition, to not introduce intolerable electromagnetic disturbances to anything in that same environment.

Electromagnetic immunity is the ability of a product, a device, or a system to function satisfactorily in the presence of electromagnetic interference (EMI).

Electromagnetic emissions is the ability of a product, a device, or a system to introduce intolerable electromagnetic disturbances into the use environment.

Your system has been manufactured in compliance with existing electromagnetic compatibility requirements. Use of this system in the presence of an electromagnetic field can cause momentary degradation of the tracking ability. If this occurs often, review the environment in which the system is being used to identify possible sources of radiated emissions. These emissions could be from other electrical devices used within the same room or an adjacent room, or from portable and mobile RF communications equipment such as cellular phones and pagers, or from the existence of radio, TV, or microwave transmission equipment located nearby. In cases where electromagnetic interference (EMI) is causing disturbances, it may be necessary to relocate your system.

The system is classified as Group 1, Class A equipment in accordance with international standard CISPR 11 for radiated and conducted electromagnetic disturbances. Compliance with this standard and the emissions characteristics of this equipment makes the system suitable for use in industrial areas and hospitals. If the system is used in a residential environment (for which CISPR 11 Class B is typically required), the system might not offer adequate protection to radio-frequency communication services. You may need to take mitigation measures, such as relocating or re-orienting the equipment.

**WARNING**

Using cables, instruments, transducers, or accessories other than those specified for use with the system may result in increased emissions from, or decreased immunity of, the system.

**CAUTION**

Medical equipment has special precautions regarding EMC and must be installed and put into service according to the EMC information provided in the system's accompanying documents.

This section includes information on electromagnetic emissions and immunity as it applies to the system. Ensure that the operating environment of your system meets the conditions specified in the referenced information. Operating the system in an environment that does not meet these conditions may degrade system performance.

The information and warnings contained in this and other sections should be observed when installing and using the system to ensure its EMC.

NOTE

See the other electrical-safety warnings and cautions in this section.

Electrostatic Discharge Precautions

Electrostatic discharge (ESD), commonly referred to as a static shock, is a naturally occurring phenomenon that results in the flow of an electrical charge from a higher charged object or person to a lower charged object or person. ESD is most prevalent during conditions of low humidity, which can be caused by heating or air-conditioning. During low humidity conditions, electrical charges naturally build up on individuals and objects and can create static discharges.

The following cautions can help to reduce ESD effect:



CAUTION

Do not touch transducer connector pins or the system's transducer receptacle.



CAUTION

Handle the transducer by the metal connector housing.



CAUTION

The following precautions can help to reduce ESD: anti-static spray on carpets; anti-static spray on linoleum; anti-static mats; or a ground wire connection between the system and the patient table or bed.



CAUTION

On connectors labeled with the ESD sensitivity symbol , do not touch the connector pins, and always observe the preceding ESD precautions when handling or connecting transducers.

NOTE

Electrostatic discharges (ESDs) may cause the ECG heart rate display to increase by 10% to 15% for a few seconds after the discharge. However, the ECG heart rate display will return to normal within 4 seconds.

Electromagnetic Emissions

The system is intended for use in the electromagnetic environment specified in the table. The customer or the user of the system should ensure that it is used in such an environment.

Electromagnetic Emissions: Environment Guidance

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions, CISPR 11	Group 1	The ultrasound system with the PercuNav option uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions, CISPR 11	Class A	The ultrasound system with the PercuNav option is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. See “Avoiding Electromagnetic Interference” on page 70.
Harmonic emissions, IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions, IEC 61000-3-3	Complies	

Electromagnetic Immunity

The system is intended for use in the electromagnetic environment specified here. The customer or the user of the system should ensure that it is used in such an environment.

NOTE

The guidelines specified here may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

NOTE

At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Electromagnetic Immunity: Environment Guidance

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD), IEC 61000-4-2	± 8 kV contact, ± 15 kV air	Same as IEC 60601-1-2 test level	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. To avoid temporary loss of tracking image due to ESD on metal shells of cable, connector, or tool connection unit, take precautions. See “Electrostatic Discharge Precautions” on page 63.
Electrical fast transient/ burst, IEC 61000-4-4	± 2 kV for power supply lines, ± 1 kV for input/ output lines > 3 m	Same as IEC 60601-1-2 test level	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Surge, IEC 61000-4-5	$\pm 0.5, \pm 1, \pm 2$ kV common mode $\pm 0.5, \pm 1$ kV differential mode on AC line	Same as IEC 60601-1-2 test level	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on AC lines, IEC 61000-4-11	Dips: 100% for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° Dips: 100% for 1.0 cycle at 0° Dips: 30% for 30 cycles at 0° Interruption: 100% for 5 seconds	Same as IEC 60601-1-2 test level	Mains power quality should be that of a typical commercial or hospital environment. If you require continued operation during power mains interruptions, Philips recommends that the system be powered from an uninterruptible power supply or a battery.
Power frequency magnetic fields, IEC 61000-4-8	30 A/m	Same as IEC 60601-1-2 test level	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF, IEC 61000-4-6	3 VRMS (0.15–80 MHz) 6 VRMS (ISM bands) AM 80% depth 1 kHz tone on AC line and I/O cables	Same as IEC 60601-1-2 test level	See “Radiofrequency Interference Guidance” on page 68 and “Recommended Separation Distance” on page 71 .

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Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Radiated RF, IEC 61000-4-3	3 V/m (80–2,700 MHz) AM 80% depth 1 kHz tone	Same as IEC 60601-1-2 test level	See “Radiofrequency Interference Guidance” on page 68 and “Recommended Separation Distance” on page 71 .
Proximity fields from RF wireless communications, IEC 61000-4-3	385 MHz 27 V/m, 450 MHz 28 V/m, 710 MHz 9 V/m, 745 MHz 9 V/m, 780 MHz 9 V/m, 810 MHz 28 V/m, 870 MHz 28 V/m, 930 MHz 28 V/m, 1,720 MHz 28 V/m, 1,845 MHz 28 V/m, 1,970 MHz 28 V/m, 2,450 MHz 28 V/m, 5,240 MHz 9 V/m, 5,500 MHz 9 V/m, 5,785 MHz 9 V/m	Same as IEC 60601-1-2 test level	See “Radiofrequency Interference Guidance” on page 68 and “Recommended Separation Distance” on page 71 .



CAUTION

If the system is connected to other customer-supplied equipment, such as a local area network (LAN) or a remote printer, Philips cannot guarantee that the remote equipment will work correctly in the presence of electromagnetic phenomena.

Although most remote devices comply with their applicable standards for immunity, those device requirements may not be as stringent as those required for medical equipment. It is the responsibility of the installer and the user of this remote customer-supplied equipment to ensure that it functions properly in the electromagnetic environment where the system is installed. Philips suggests that the installer or the user of such a system consult with experts in the field of electromagnetic compatibility and safety for guidance to ensure the safe and effective use of the created system.

Radiofrequency Interference Guidance

Use portable and mobile RF communications equipment no closer to any part of the PercuNav system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency to the transmitter.

For recommended separation distances, see [“Recommended Separation Distance” on page 71](#).

Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol .

NOTE

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level noted in [“Electromagnetic Immunity” on page 64](#), the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PercuNav system.

NOTE

Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 0.2 V/m.

Electromagnetic Interference

Additional precautions must be taken to ensure that the electromagnetic tracking system is accurate and is not affected by cable handling and other issues.

**WARNING**

Always place the tool connection unit more than 1 m (3.3 ft) from the field generator. If placed closer, the measurement volume may be affected, contributing to inaccurate measurements and possible personal injury.

**WARNING**

It is important to place the system in a location that is known to be free of electromagnetic interference. Tracking in an environment or a location known to cause electromagnetic interference can contribute to inaccurate information and possible personal injury.

**WARNING**

The use of accessories and cables other than those specified, with the exception of accessories and cables qualified and sold by Philips, may result in increased emissions or decreased immunity of the equipment and may cause the system to be non-compliant with the requirements of IEC 60601-1-2: 2007.

**WARNING**

The PercuNav system needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

**WARNING**

The PercuNav system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the equipment or shielding the location.

**WARNING**

The PercuNav system should not be used adjacent to other equipment or have other equipment stacked on it. If adjacent or stacked use is necessary, the PercuNav system should be observed to verify normal operation in the configuration in which it will be used.

Avoiding Electromagnetic Interference

The RF Emissions CISPR 11 Class A limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses, and can radiate radio frequency energy. If the equipment is not installed and used in accordance with the instructions, it may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.

- Connect the equipment into an outlet on a circuit different from that to which the other device is connected.
- Consult the manufacturer or service technician for assistance.

Recommended Separation Distance

The PercuNav system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. You can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PercuNav system as recommended, according to the maximum output power of the communications equipment. The following table provides recommended separation distances, which are guidelines on the distances that any RF transmitting equipment should be kept away from the PercuNav system to reduce the risk of interference with the system. Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range as noted in the table. Interference may occur in the vicinity of equipment marked with the following symbol: .

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level in the table, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system.

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**WARNING**

To avoid degrading system performance, keep portable RF communications equipment (including peripherals such as antenna cables and external antennas) at least 30 cm (12 in) away from any part of the ultrasound system, including cables.

NOTE

For transmitters rated at a maximum output power not listed in the following table, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE

At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE

The recommended separation distance guidelines in the following table may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

The information provided here, in conjunction with [“Electromagnetic Interference” on page 69](#), provides guidance on conducted and radiated interference from portable and fixed RF transmitting equipment.

Recommended Separation Distances by Transmitter Frequency

Rated Maximum Output Power of Transmitter (Watts)	150 kHz to 80 MHz $d = \frac{3.5\sqrt{P}}{V}$	80 to 800 MHz $d = \frac{3.5\sqrt{P}}{E}$	800 MHz to 2.5 GHz $d = \frac{7.0\sqrt{P}}{E}$
0.01	0.12 m (4.7 in)	0.12 m (4.7 in)	0.24 m (9.5 in)
0.1	0.38 m (15 in)	0.38 m (15 in)	0.76 m (30 in)
1	1.2 m (3.9 ft)	1.2 m (3.9 ft)	2.4 m (7.9 ft)
10	3.8 m (12.5 ft)	3.8 m (12.5 ft)	7.6 m (25 ft)
100	12 m (39.4 ft)	12 m (39.4 ft)	24 m (78.7 ft)

Approved Cables for Electromagnetic Compliance

Cables connected to the system may affect its emissions. Use only the TCU to PercuNav system tray cable, Philips part number 453561656561 or 453561831431.



WARNING

Using cables, instruments, transducers, or accessories other than those specified for use with the system may result in increased emissions from, or decreased immunity of, the system.

Approved Accessories for Electromagnetic Compliance

Accessories used with the system may affect its emissions. The accessories listed here, when used with the system, have been tested to comply with the Group 1, Class A emissions as required by International Standard CISPR 11. Use only the accessories listed here.

When connecting other accessories to the system, such as a remote video monitor or computer, it is the user’s responsibility to ensure the electromagnetic compatibility of the system. Use only CISPR 11 or CISPR 22, Class A-compliant devices, unless otherwise noted.



WARNING

Using cables, instruments, transducers, or accessories other than those specified for use with the system may result in increased emissions from, or decreased immunity of, the system.

NOTE

Model numbers and part numbers in the following table are subject to change.

Approved PercuNav Instruments and Accessories

Accessory	Model Number or Part Number	Affiniti 70 System	EPIQ Series Systems
Needle Trackers			
Philips PercuNav Coaxial Needle Tracker, 13G x 11cm	40001	--	X
Philips PercuNav Coaxial Needle Tracker, 13G x 16cm	40002	--	X
Philips PercuNav Coaxial Needle Tracker, 16G x 11cm	40003	--	X
Philips PercuNav Coaxial Needle Tracker, 17G x 16cm	40004	--	X

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Accessory	Model Number or Part Number	Affiniti 70 System	EPIQ Series Systems
Philips PercuNav Coaxial Needle Tracker, 18G x 8cm	40005	--	X
Philips PercuNav Coaxial Needle Tracker, 18G x 13cm	40006	--	X
Philips PercuNav Coaxial Needle Tracker, 20G x 8cm	40007	--	X
Philips PercuNav Coaxial Needle Tracker, 20G x 13cm	40008	--	X
Philips PercuNav Coaxial Needle Tracker, 20G x 17cm	40009	--	X
Philips PercuNav Adaptive Needle Tracker	41001	X	X
Other Components			
Philips PercuNav Patient Tracker	10001	X	X
Philips PercuNav Ultrasound Tracker for the C5-1, C9-2, L12-5, S5-1, and X6-1 ¹ transducers	20004	X	X
Philips PercuNav Ultrasound Tracker for the C10-4ec transducer	21001	X	X
Philips PercuNav Adaptive Needle Tracker Kit	453561715772	X	X

¹EPIQ systems only

Use Restrictions Due to Interference



WARNING

The physician needs to determine if tracking is accurate. Tracking in an environment or a location known to cause electromagnetic interference can contribute to inaccurate information and possible personal injury.

3 System Overview

PercuNav Image Fusion and Interventional Navigation provides image-guided diagnostic and intervention that enables fusion of diagnostic images and guidance of tracked instruments to physician-defined targets. The target can be indicated either pre-procedurally or intra-procedurally, either using images or relative to an indicated position on the patient.

PercuNav System Description

The PercuNav system provides real-time, three-dimensional visualization and navigation tools for all stages of diagnosis and intervention, including pre-procedure planning and procedure navigation. The system transforms two-dimensional patient images into dynamic representations that can be fused with live ultrasound or other previously acquired images. Those two-dimensional patient images, or scan sets, are derived from Ultrasound, CT, PET, PET/CT, and MRI. The resulting dynamic representation supports diagnostic review and instrument navigation.

The PercuNav system performs spatial mapping from one image space to another image space or from image space to physical space (registration), allowing the physician to correlate scan sets with each other and to the patient. The system facilitates minimally invasive diagnostic and interventional procedures.

The PercuNav system is intended for use in hospital interventional and diagnostic radiology departments, operating and procedure rooms, and outpatient clinics and intervention centers.

Features include the following:

- **Multiple Applications:** The PercuNav system supports multiple applications and can be used for ablations, biopsies, and other diagnostic and guidance procedures.
- **Multiple Modalities:** The PercuNav system works with images from multiple modalities, including but not limited to CT, MR, PET, and ultrasound.

System Components

The primary PercuNav components include:

Field Generator

The field generator emits a weak magnetic field, creating the tracking volume. The system can track the location of PercuNav instruments when they are inside the tracking volume.

Tool Connection Unit (TCU)

The TCU amplifies and converts the electrical signals, sent by the sensor coils embedded in the tracked instruments, into a digital signal. You can connect up to six instruments to the TCU.

PercuNav Software

The software takes the position data provided by the hardware in the PercuNav system tray and displays patient imaging data as well as the location and orientation of the tracked instruments connected to the system.

PercuNav System Tray

The PercuNav system tray, located on the rear top of the ultrasound system cart, provides a base for the following PercuNav components, depending on the ultrasound system:

- For EPIQ series systems, the TCU and the field generator
- For an Affiniti 70 system, the TCU

Tracked Instrumentation

A wide range of instrumentation is available for use with the PercuNav system. For details, see [“Supplies and Accessories” on page 22](#) and the [“Instruments”](#) section.

PercuNav System Tray

The PercuNav system tray, located on the rear top of the ultrasound system cart, provides a base for the following PercuNav components:

- For EPIQ systems, the TCU and the field generator
- For an Affiniti 70 system, the TCU

The PercuNav system tray also contains the hardware that collects information from the TCU. This information is used to calculate the position and orientation of sensors in the tools that are connected to the system.

To access a connection port, rotate the connection port cover away from the field generator or TCU.



PercuNav System Tray (Shown on an EPIQ Ultrasound System)

1	TCU connection port cover
2	Tool connection unit
3	Field generator
4	Field generator connection port cover

Field Generator



WARNING

Use of the PercuNav system in the vicinity of other equipment or metal objects may affect the PercuNav system or other equipment. In such cases, try increasing the separation distance between the field generator and the source of the interference, reorienting the device cabling, or plugging devices into separate outlet circuit branches.



WARNING

Never operate the system or its components in the vicinity of an MRI scanner. The system and all components are not MRI-safe. The intense magnetic field irreparably damages the system and its components.



WARNING

Do not operate the field generator within 200 mm (8 in) of an installed pacemaker. The magnetic field produced by the field generator may interfere with the operation of the pacemaker, which may result in personal injury.



WARNING

Overexposure to the field generator's electromagnetic field can injure the patient, the user, or service personnel.

The field generator emits a weak electromagnetic field (approximately 68 μT), which creates the tracking volume. The PercuNav system is then able to track the location of tracked instruments when they are placed inside of the tracking volume, by inducing a small current in the sensor coils that are embedded in the tracked instruments.



Field Generator

The side of the field generator marked with the crosshair must face the patient. The field generator connects to the ultrasound system through a port on the PercuNav system tray.

You can mount the field generator on a stand so that you can position the field generator near the area of interest during procedures. For more information, see the instructions that accompany the field generator stand or mounting arm.



WARNING

If you are using the field generator stand, make sure that all of the cables are managed appropriately to avoid contaminating the sterile field or interfering with the magnetic field.

**WARNING**

To avoid a pinching or crushing injury when repositioning the field generator stand with an articulating arm, keep your hands and fingers away from the articulation joint.

**WARNING**

You must fully support the weight of the field generator before unlocking any part of the field generator stand to re-position the field generator. Never attempt to re-position or disengage the field generator while it is suspended over the patient.

Tool Connection Unit

**WARNING**

Always place the tool connection unit more than 1 m (3.3 ft) from the field generator. If placed closer, the measurement volume may be affected, contributing to inaccurate measurements and possible personal injury.

The TCU is stored in the PercuNav system tray and connects directly to the ultrasound system with the provided cable. You can connect the instruments to any of the six labeled ports. Sufficient cable length is provided to allow you to position the TCU close to the working area for easy access during the procedure. You can also remove the TCU from the tray for CT scan acquisition and convenient placement.



Tool Connection Unit

NOTE

The tool connection unit might be warm to the touch during or after use. This is normal and is expected as part of normal operation.

Cleaning and Disinfecting the Field Generator and Cable

The products in the following table are compatible with the field generator and cable:

Cleaning Solutions	Disinfectants
Mild soap solution ¹	• 70% isopropyl alcohol (IPA) • Incidin Plus 2% • Opti-Cide3 (QUAT/IPA based) • Meliseptol

1. Mild soap solutions do not contain any harsh ingredients and are not irritating to the skin. They must not contain fragrance, oils, or alcohols. Hand sanitizers are not approved for use.



WARNING

Always use protective eyewear and gloves when cleaning, disinfecting, or sterilizing any equipment.



WARNING

Do not disconnect the field generator from the system while the system is powered on. Disconnecting the field generator while in use may result in generation of electrical sparks, irreparable field generator damage, and possible personal injury.



WARNING

Before performing any system maintenance or cleaning, always turn off the system and disconnect it from the power source.

1. Turn off power to the system.

- 2. Disconnect the field generator from the system.
- 3. Wipe the field generator and cable with a clean, soft cloth dampened with an approved product.
- 4. Allow the field generator and cable to air dry.

Cleaning and Disinfecting the TCU

The products in the following table are compatible with the TCU:

Cleaning Solutions	Disinfectants
Mild soap solution ¹	• 70% isopropyl alcohol (IPA) • Super Sani-Cloth wipes

- 1. Mild soap solutions do not contain any harsh ingredients and are not irritating to the skin. They must not contain fragrance, oils, or alcohols. Hand sanitizers are not approved for use.



WARNING

Always use protective eyewear and gloves when cleaning, disinfecting, or sterilizing any equipment.



WARNING

Do not disconnect the field generator from the system while the system is powered on. Disconnecting the field generator while in use may result in generation of electrical sparks, irreparable field generator damage, and possible personal injury.

**WARNING**

Before performing any system maintenance or cleaning, always turn off the system and disconnect it from the power source.

**CAUTION**

Do not use Sani-Cloth AF3 or Super Sani-Cloth to disinfect the ultrasound system.

1. Wipe the TCU with an approved product.
2. Allow the TCU to air dry.

4 Preparing the System

Before operating the PercuNav system, you must ensure that the system and the environment are prepared for use.

Setting Up for Intra-procedure Use

Before using the PercuNav system in procedures involving navigation, it is important that you evaluate the room setup for correct positioning of the field generator.



WARNING

Position PercuNav cables to prevent tripping hazards. Remove unused equipment from the procedure area.



WARNING

Always place the tool connection unit more than 1 m (3.3 ft) from the field generator. If placed closer, the measurement volume may be affected, contributing to inaccurate measurements and possible personal injury.



WARNING

Place the PercuNav system so that other equipment and large metal objects in the room, including patient beds, do not interfere with the magnetic tracking components. Maintain these conditions throughout the procedure.

**CAUTION**

Position PercuNav cables to prevent cable damage.

1. Move the field generator, on its stand, to the most appropriate position for the procedure being performed.
2. Position the field generator so that the side with the crosshair is facing the patient. (See the instructions for use of the mounting arm.)



Field Generator Position

3. Connect the field generator to the field generator connection port on the PercuNav system tray.
4. Connect the TCU to the TCU connection port on the PercuNav system tray. If you are using tracked instruments, you can connect them to the TCU now or wait until you have started your procedure.
5. If necessary, drape sterile barriers on the field generator and control panel.
6. Turn on the ultrasound system.

5 Scanning the Patient

This section includes detailed information on scanning the patient, image sets, and scanning parameters.

You can use two types of image sets with the PercuNav system:

- Pre-procedure and intra-procedure images
- Historic patient images

Pre-Procedure and Intra-Procedure Images

Images acquired immediately before or during the procedure for planning purposes may include the use of patient trackers or external landmarks to aid the registration or matching process. Always place patient trackers or passive body markers around the region of interest, on bony landmarks if possible, sampling as many different planes and dimensions as possible. For example, place patient trackers superior, inferior, medial, and lateral to the area of interest to provide the most-accurate registration and navigation capabilities. For information on placing patient trackers, see [“Placing and Removing a Patient Tracker” on page 217](#).

Patient Trackers

Philips manufactures patient trackers that facilitate **Patient Tracker Match** registration for external landmarks. The patient trackers may be used alone or in combination with passive body markers. Each patient tracker contains two patches (registration landmarks), with embedded electromagnetic trackers, and one connector. For improved imaging, use at least three patient trackers. Apply the patient trackers externally to the patient, around the region of interest, on bony landmarks if possible, leaving windows for needle placement and ultrasound imaging as appropriate. Place the patient trackers on the patient before acquiring pre-procedure CT or PET scans. Before using the patient trackers, see the [“Instruments”](#) section.

For all PercuNav procedures, the system needs a patient reference, which requires at least one patient tracker. If more than one patient tracker is used, the system automatically assigns the patient tracker connected to the lowest port number on the TCU as the patient reference. If a patient reference is not selected, click a connected patient tracker on the **Instruments** panel to define it as the patient reference.

All patient trackers must remain in place until registration is complete. The patient tracker that is used as the patient reference must remain in place until registration and needle navigation are complete.

**WARNING**

The patient tracker is a non-sterile instrument. Make sure that the sterility of other devices or tools is not compromised through contact with the patient tracker.

**WARNING**

Ensure that appropriate unobstructed windows (areas free of patient trackers) are available on the patient for using ultrasound transducers and inserting needles.

**WARNING**

The patient trackers must remain in place during scanning and until registration is complete.

**CAUTION**

Do not expose any part of the system or any tracked tools or instruments to a high magnetic field, such as an MRI scanner. The system and its instruments are neither MRI-compatible nor MRI-safe.

**CAUTION**

To avoid registration inaccuracies, do not place the patient trackers symmetrically in a straight line or on a single plane.

Passive Body Markers

Passive body markers are not included with the system. Place passive body markers around the region of interest, on bony landmarks if possible, leaving windows for needle placement and ultrasound imaging as appropriate. Use the passive body markers according to the instructions for use included with them.

**WARNING**

Ensure that appropriate unobstructed windows (areas free of patient trackers) are available on the patient for using ultrasound transducers and inserting needles.

**WARNING**

Place body markers and patient reference trackers on bony anatomy (for example, over ribs or the sternum) to ensure that they are not disturbed when the abdomen is compressed by the ultrasound transducer.

Patient Scanning Parameters

To ensure the image sets are compatible with the PercuNav system, scan the patient according to these specific parameters.

**WARNING**

Before scanning the patient, ensure that the scanner is properly adjusted to the PercuNav specifications in the following table. Improperly acquired images cause inaccuracies.

**WARNING**

Before scanning the patient, ensure that the scanning parameters are in-line with the optimal parameters provided in the Scanning Parameters table that follows. Scans that are acquired not in accordance with the parameters could cause registration inaccuracies.

**WARNING**

Ensure that the person performing the scan follows the scanning guidelines provided by the hospital and by the manufacturer of the scanning system.

**WARNING**

Ensure that patient trackers and passive body markers remain in place until the registration is complete. After that, only the patient reference tracker must remain undisturbed.

NOTE

If patient trackers and passive body markers are used, ensure that the scan volume includes the patient trackers and passive body markers in the scan.

NOTE

The PercuNav system does not load scout images, scans with fewer than 5 images, and scans larger than 512 MB.

Scanning Parameters

Parameter	Description
Bit data	12 bit or 16 bit
Contrast	- Contrast-enhanced image acquisition is supported. - Dual contrast phases can be loaded and viewed together through co-registration.
Duplicate slices	Duplicate slices are not allowed. Slice overlap or contiguous slices are permitted.
Gantry tilt	Maintain the gantry tilt at 0 degrees.
Gaps between slices	Acquisitions with gaps between slices are unsupported.
Modalities	- Pre-procedure CBCT, CT, MR, and PET are supported. - Intra-procedure ultrasound is supported.
Number of slices	The number of slices must be at least 5.
Overlay information	Scans with overlay information are unsupported.
Patient position	Head-first and feet-first supine, prone, and decubitus positions are supported.
Pixel size	Maintain pixel size less than 1.25 mm. Pixel size greater than 1.25 mm can reduce accuracy.
Re-center	Do not re-center during image acquisition. The field of view must be centered correctly at the start of the acquisition and remain consistent for the entire image acquisition.
Respiration	Note the patient's respiratory state during image acquisition and replicate it during the procedure to optimize consistency and accuracy.
Scan acquisition	Axial, coronal, and sagittal scan acquisitions are supported.
Scout images	Scout images cannot be loaded for navigation.
Size limit	A single scan cannot exceed 512 MB.
Slice overlap	Uniform slice overlap or contiguous slices are permitted (for example, 3 mm x 1.5 mm). Duplicate slices are not allowed.

Parameter	Description
Slice thickness and spacing	• 1-mm slice thickness is recommended for optimal accuracy. • Greater than 3-mm slice thickness can reduce accuracy. • Maintain uniform slice spacing throughout the acquisition.

Historic Images



WARNING

If you use historic images, the physician is responsible for confirming the appropriateness and accuracy of those images and if they can be used for the current procedure.

The PercuNav system permits the use of previously acquired, or "historic," images or scans. Historic images are independently acquired before the procedure, without the use of PercuNav patient trackers or passive body markers. In such cases, internal landmarks must be used that are visible in both the historic images and in live ultrasound. You can use historic images with the **Fusion** procedure. See the [“Patient and Image Selection”](#) section.

When using historic images, monitor internal patient anatomy to ensure that no drastic anatomical changes have occurred since the historic images were acquired. Changes to consider are ascites, bowel gas, weight gain or loss, and any other anatomical changes or movements.

Try to minimize external patient changes as follows:

- Replicate the patient’s respiratory state at the time of the historic images.
- Replicate the patient’s patient position as well as any immobilization devices on the table at the time of the historic images.

6 Using PercuNav Mode

When you are in PercuNav mode, the PercuNav system takes primary control of the ultrasound system. You can touch the **2D** tab to use the available 2D ultrasound controls, but it is important to remember that you are still in PercuNav mode. Also, while you are in PercuNav mode, many of the ultrasound tools that you are accustomed to using are either disabled or modified (see [“Ultrasound Controls in PercuNav Mode” on page 121](#)). To access all of the ultrasound controls, touch **Pause PercuNav** on the **Selected Workflow** tab.

PercuNav image fusion provides the capability to combine images with high tissue contrast and resolution with live ultrasound.

Image fusion displays the previously acquired images (CT, MR, and PET) and images acquired during the procedure, reformatted in real time, to continuously match live ultrasound imaging. An ultrasound tracker attached to the transducer tracks the position and orientation of the ultrasound scan plane.

NOTE

During PercuNav procedures, the acquisition frame rate of the ultrasound system may decrease during loop captures.

PercuNav Transducer Compatibility

The following transducers and imaging modes or features are compatible with PercuNav mode.

PercuNav Transducer Compatibility

Transducer	2D Echo	SonoCT Imaging	Grayscale/Color Doppler	Elevation Compounding
C5-1	X	X	X	--
C9-2	X	X	X	--
C10-4ec	X	X	X	--

Transducer	2D Echo	SonoCT Imaging	Grayscale/Color Doppler	Elevation Compounding
eL18-4 EMT ¹	X	X	X	--
L12-5	X	X	X	--
mC7-2 ¹	X	X	X	--
S5-1	X	--	X	--
X6-1 ²	X	--	X	X

¹Includes an embedded electromagnetic tracker

²EPIQ systems only

Starting and Stopping PercuNav Mode

- Before starting PercuNav mode, connect a supported transducer to the ultrasound system and ensure that the required patient trackers are connected.
- Press **2D**, if you have not done so already. Ensure that 2D imaging is live and not frozen.
- On the **2D** tab, touch **PercuNav** and select an application preset.
- Select a procedural option:
 - Ultrasound Only** starts PercuNav mode and opens the **Ultrasound Only Guide** display.
 - Select CT/MR/PET** starts PercuNav mode and opens the **Review Exam** display. After you select the images, you can start the **Fusion** or the **CT Only** procedure.

The control panel, keyboard, and monitor are now in PercuNav mode. If you are in live imaging, the **MI** and **TIB** values are displayed in the upper right corner of the imaging area.

- To exit PercuNav mode and return to the ultrasound controls, do one of the following:
 - During registration, touch **Back** on the **Selected Workflow** tab. Click **OK** when prompted to confirm that you want to end the procedure.
 - During **Guide**, touch **End PercuNav** on the **Selected Workflow** tab.

If you start a procedure without a supported transducer connected, a large, red square appears on the display. If that happens, do one of the following:

- Press **Freeze** to return to live imaging.
- On the **Field Generator Setup** tab, touch **Initialize**.

User Interface

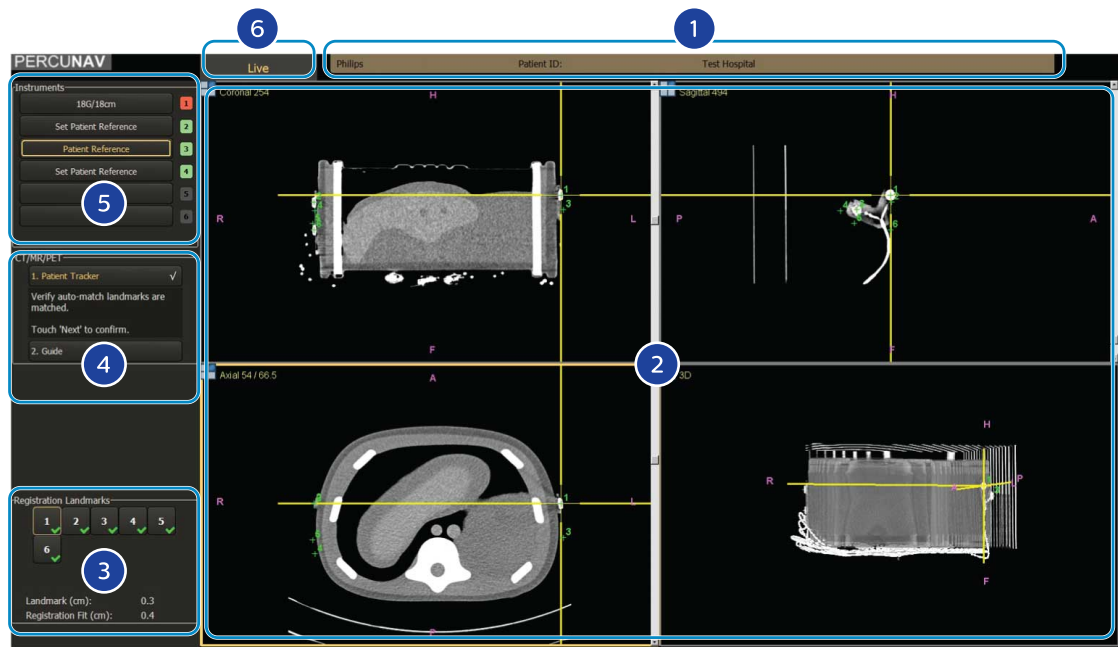
The PercuNav user interface is designed to provide consistency for ease of use. The layout of the displays throughout the workflows enables you to find the functions that you want quickly and easily, while the task-oriented menus ensure that the next step is intuitive.

User Interface Layout

The user interface displays conform to a consistent general layout, but the number and type of frames in the image display area depend on the type of procedure that you perform and the layout configuration that you select.

NOTE

If the image frame has multiple slices, the **Scroll Slice** control is activated automatically. To scroll through the slices of the image, turn the knob directly below the control. Additionally, when you use the trackball to adjust fusion in the **US Overlay** frame, the **Scroll Slice** control allows you to scroll through the cineloop.



PercuNav User Interface

1	Patient information	Displays the patient name, patient ID, date, and time.
2	Image display area	Displays the patient images in frames. The active frame has an amber border. You can use the scroll bar on the right side of each frame to scroll through slices of the image.
3	Registration Landmarks	Displays the registered landmarks and their status for the current registration method. For more information, see “Registration Landmark Icons” on page 102 .
4	Workflow	Context-sensitive area that displays the active workflow and information for completing the current task.
5	Instruments panel	Displays all of the TCU ports, by number, and the status of each connected instrument.
6	Status bar	Indicates the current status of the image (Live , Frozen , or Acquiring Sweep) and the current task (Targeting T#).

Layout Configurations

You can select how many and which image frames are shown in the image display area by touching **Layout** on the **Selected Workflow** tab. You can use **Frame** to select the active image frame. You can also change the type of view shown in the active image frame by pressing or rotating **View**.

Default Views for Each Layout Configuration

Layout	Default Views Displayed	Procedure Availability
Custom 1, Custom 2, Custom 3	Available if you touched Save Layout during a procedure.	CT Only Fusion Ultrasound Only
Fusion 1x1	US Overlay	Fusion Ultrasound Only (when US-US Fusion is active)
Fusion 1+3	US Only US Overlay Reformatted 3D	Fusion Ultrasound Only (when US-US Fusion is active)
Fusion Left/Right	US Overlay US Only	Fusion Ultrasound Only (when US-US Fusion is active)
Fusion 2x2 (When Contrast Side/Side is off)	With tracked instrument in use: US Overlay, US Only, Reformatted, and Target Without tracked instrument: US Overlay, US Only, Reformatted, and 3D	Fusion Ultrasound Only (when US-US Fusion is active)

Layout	Default Views Displayed	Procedure Availability
Fusion 2x2 (When Contrast Side/Side is on)	CEUS US Reformatted Overlay	Fusion Ultrasound Only (when US-US Fusion is active)
Oblique	Traj 0 (trajectory 0 degrees) Traj 90 (trajectory 90 degrees) Tip 3D	CT Only (requires pointing to a target with a tracked needle tip or requires an entry and target point) Fusion (requires pointing to a target with a tracked needle tip or requires an entry and target point) Ultrasound Only (when US-US Fusion is active and a tracked instrument is selected)
Triplanar	Axial Sagittal Coronal 3D (if no tracked instrument is selected) Target (if a tracked instrument is selected and a target has been defined)	CT Only Fusion Ultrasound Only (when US-US Fusion is active)

Customizing a Layout

You can customize the layout configurations for the PercuNav system.

NOTE

You can save up to three customized layouts for future procedures.

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1. To save a customized layout for future procedures, set each frame to the view that you want, touch **Layout**, and then touch one of the numbered **Save to Custom** controls.
2. To access the saved layout, touch **Layout**, and then touch one of the numbered **Custom** controls.
3. To rename the custom layout, type a new name in the box.
4. Click **OK** to save the customized layout.

NOTE

The **Layout** control is on the **Selected Workflow** tab, but it is available only in **Guide**.

NOTE

Layouts are procedure-specific. A layout saved in **CT Only** is unavailable in **Fusion** or **Ultrasound Only**.

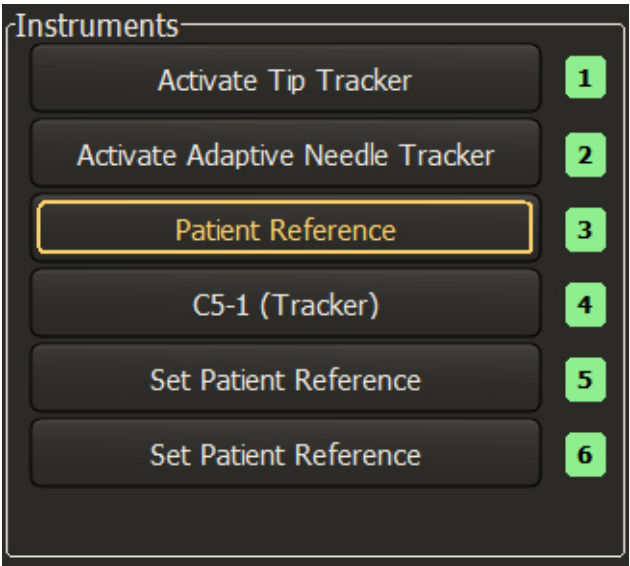
Instruments Panel

The active tracked instrument name appears under **Instruments** in the left pane of the display. Click the instrument name to display information about the instrument (for example, offset measurements).

The port number labels to the right of the instrument names are green (active) or red (inactive or out of range), depending on the status of the tracked instrument.

- **Green** indicates that the connected instrument is within the field generator volume and is tracking with acceptable error.
- **Red** indicates one of the following:
 - The tracked tool is approaching the boundary of the tracked volume generated by the field generator.

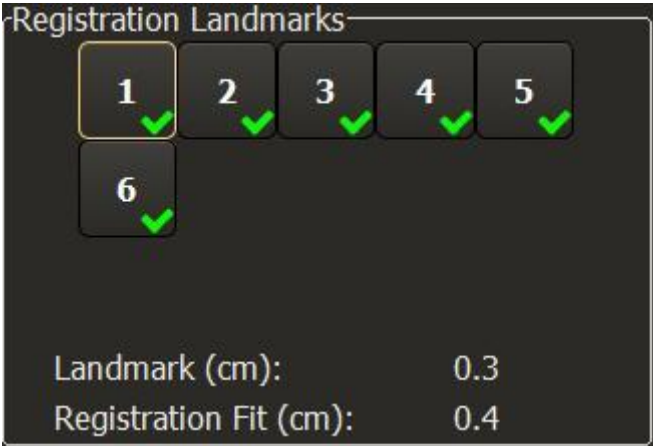
- The tracked tool is being subjected to magnetic or radiofrequency interference, which is affecting system performance.
- The tracked tool is outside of the field generator volume and is no longer being tracked.



Instruments Panel

Registration Landmark Icons

Registration landmarks are displayed at the bottom of the left pane in the imaging display.



Registration Landmarks

Each icon represents a registered landmark for the current registration method and the registration landmark's matched status. The selected landmark is outlined in amber.

Registration Landmark Icons

Icon	Definition
	Landmark is excluded.
	Landmark is matched.
	Landmark is unmatched.

Registration Landmarks also displays common RMS (root-mean-square) errors:

- **Landmark (cm):** RMS error for the selected matched landmark
- **Registration Fit (cm):** RMS error for overall registration, including all matched external and internal landmarks

**WARNING**

The Registration Fit value is only a guideline to help you obtain an accurate registration. You must confirm the accuracy and acceptability of the registration by assessing fusion and needle tracking accuracy.

Trackball

The trackball is located near the bottom of the control panel. Moving the trackball moves the active object on the display.

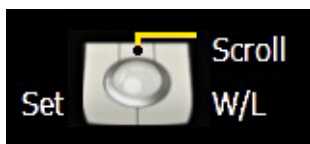
The tools and icons area of the imaging display includes a trackball arbitration icon that identifies the function assigned to each trackball button. For example, the functions of the left and right trackball buttons can include these:

- Selecting a frame
- Rotating the 3D view (middle trackball button only)
- Changing a window/level (W/L) preset in 2D (right trackball button only)

The middle trackball button's functions include turning the scroll feature on and off.

When selected, a trackball function is outlined in amber.

For more information about the trackball, see the ultrasound system *Help* or *User Manual*.



Trackball Arbitration Icon

NOTE

In PercuNav mode, the trackball icon is slightly compressed to provide more space for image viewing.

Live and Freeze States

You can use the **Freeze** control on the ultrasound system control panel to alternate between the live and frozen states of an image.

In live imaging, on frames that display the **Ultrasound Only** image or the **Fusion** overlay, the images update according to the location and orientation of the ultrasound transducer; on frames that display **CT Only** images, images update according to the tip location of the tracked tool.

When frozen, the images do not update. With **CT Only**, scroll bars on the triplanar frames allow you to scroll through the pre-procedure images to select additional targets. For **Fusion** and **Ultrasound Only**, scroll bars are available on all of the frames.

The current state (**Live** or **Frozen**) of the image is indicated in the top left corner of the selected frame.

Selected Workflow Touch Screen Controls

The PercuNav system controls are located on the **Selected Workflow** touch screen tab. They vary by the type of procedure and the current procedure step.

NOTE

The **Selected Workflow**, **Fusion Tools**, **Target Planning**, **Field Generator Setup**, and **Settings** touch screen tabs are available only after you start PercuNav mode.

To use a touch screen control or change its setting, touch it, or if it is in the bottom row, turn the knob directly below it.

Name	Description
Adjust Fusion	Allows you to adjust the registration quality in the Guide display for Fusion or for Ultrasound Only with a US-US fusion. Move the data set to match the ultrasound image within the same scan plane, using one of these options: • Transducer allows you to adjust the volume image by moving the ultrasound transducer. Available only in the Guide display for Fusion, for Internal Plane Match registration. Selected by default for the Internal Plane Match registration method and deselected by default in Guide. Unavailable if the Trackball option is on. • Trackball freezes the image, selects the US Overlay frame, and places the cursor at the center of the US Overlay frame. Rotating the trackball moves the secondary images. Available only in Fusion Guide. Deselected by default. • Point to Point fine-tunes fusion quality. Available in the Guide display for Fusion and in Ultrasound Only when US-US Fusion is enabled.
Back	On the first co-registration display, saves the registration information and moves to the previous step in the workflow. On the second co-registration display, returns to the first co-registration display.
Blend Overlay	Blends and verifies the CT/US or MR/US fusion. Blends the pre-procedure CT or MR scans (primary images) and the ultrasound reconstructed volume with the live ultrasound image that is displayed in the US Overlay frame.
Contrast Timer	Activates and displays a timer at the top center of each frame. Contrast imaging must be enabled on the ultrasound system before you can use the Contrast Timer controls in PercuNav mode.
Delete Landmark	Deletes a selected landmark from the registration method. Available when there are matched landmarks and one is selected.
Delete Target	Deletes the selected target.
End PercuNav	Ends the procedure and returns the display to the ultrasound 2D mode.
Frame	Lets you select which frame in the display is the active frame.

Name	Description
Landmark	Displays the following controls: • Exclude: Excludes the selected landmark from the registration set. • Include: Includes the selected landmark from the registration set.
Layout	Shows the Layout display where you can select how many pre-configured frames are shown in the display. Use View to select which views are shown in each frame.
Left Scan	Chooses the scan displayed on the left side of the display.
Live Ablation Zone	• Define: Opens a dialog box where the needle offset for a CNT can be specified. • Show: Displays the ablation zone according to the minimum and maximum diameter values. • Save: Saves the ablation zone according to the minimum and maximum diameter values.
Match Landmark	Automatically registers the identified landmarks. Available only when the patient reference is identified.
Move Cursor to Entry	Sends the crosshair focus to the entry of the current approach.
Needle Offset	Displays the virtual extension of the active tracked tool when you enter a virtual offset. You can use this to examine the effects of proceeding further along the current trajectory.
Next	Saves the data to the current plan, and proceeds to the next step, Guide . Available only if the registration step is complete.
Pause PercuNav	Pauses the procedure and returns the touch screen to the ultrasound 2D tab, which includes the Resume PercuNav control, used to return to the paused PercuNav procedure. When the PercuNav procedure is paused: • The selected PercuNav workflow remains the same. • The state of the PercuNav procedure remains the same.

Name	Description
Right Scan	Chooses the scan displayed on the right side of the display.
Rigid Co-Register	Starts a procedure that adjusts the two scans so that similar features are aligned.
Registration	Chooses the scan that will be registered following a co-registration procedure.
Rotate	Allows you to rotate the CT image against the ultrasound image by using the Rotate control. Available only in the Guide display for Fusion , for Internal Plane Match registration, in the US Overlay view, when Trackball is selected, and on a frozen display. Unavailable when the Adjust Fusion Transducer option is on.
Scroll Slice	Scroll Slice is activated automatically if the image frame has multiple slices and allows you to scroll through the slices of the image. Also, when Trackball is selected to adjust fusion in the US Overlay frame, Scroll Slice allows you to scroll through the cineloop.
Set Target	Adds a target at the current location while in Guide .
Show Needle Graphics	Turns on and off the display of the virtual needle images on all frames.
Show Planned Ablation Zone	Displays any planned ablation zones.
Target	Displays the next or previous target.
Target Display	Indicates which defined targets are displayed: • Show Current: Displays only the current target and entry marker. • Show All: Displays all targets and entry markers in the current orthogonal planes. • Hide All: Hides all targets.
US-US Fusion	When a patient tracker and an ultrasound tracker are connected to the TCU, displays the following controls: • 3D Sweep: Starts and stops the manual 3D sweep of the ultrasound image. • Reconstruct: Starts 3D reconstruction to generate slices of the ultrasound 3D sweep. Enabled only after a 3D sweep is acquired. Unavailable in CT Only .

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Name	Description
User-Assisted Co-Registration	Starts a procedure that aligns the two scans by deforming the earlier scan to match the later scan. This creates a third scan that is a deformed version of the earlier scan that is registered with the second.
View	Allows you to change the view shown in the selected frame. When pressed, the Scan Legend and View Selection are displayed or hidden.
W/L Preset	Allows you to select a grayscale contrast preset.

Fusion Tools Touch Screen Controls

Fusion tool controls are located on the **Fusion Tools** touch screen tab. Visibility of controls depends on the method of auto registration used.

NOTE

The **Selected Workflow**, **Fusion Tools**, **Target Planning**, **Field Generator Setup**, and **Settings** touch screen tabs are available only after you start PercuNav mode.

To use a touch screen control or change its setting, touch it, or if it is in the bottom row, turn the knob directly below it.

Control	Description
3D Image Adjustment	Displays the 3D control panel, from which you can adjust detail, opacity, brightness, and window/level of the 3D view. This control is available only when the 3D frame is selected.
Auto-Blend	Turns the auto-blend feature on or off. Automatically increases and decreases the blend of the ultrasound image and the scan data.
Blend Rate	Provides three levels to adjust the blending speed: Low , Medium , and High .

Control	Description
Left/Right Flip	Mirrors the selected image along the vertical axis. This control has no effect on frames that contain ultrasound images.
MPR	A setting that shows the segmented objects in the multiplanar reconstruction (MPR) views.
Pan	Allows you to reposition the image.
Reset	Removes all adjustments made to fusion images.
Respiration	Displays the following controls: Display Plot: Starts and stops the plotting of the respiratory motion curve based on the patient reference location. There is a learning phase at the start of each plot which can last one full respiratory cycle. Flip: When the respiration plot is displayed, inverts the gating wave along the x-axis.
Rotate 90	Rotates the selected image by 90 degrees, clockwise.
Top/Bottom Flip	Mirrors the selected image along the horizontal axis. This control has no effect on frames that contain ultrasound images.
US	A setting that shows the segmented objects in ultrasound views.
Use Default	Overwrites your current settings with the default settings for Segmented Objects .
W/L Preset	Allows you to select a grayscale contrast preset.

Segmented Objects Touch Screen Controls

The **Segmented Objects** control is located on the **Fusion Tools** touch screen tab. Visibility of controls depends on the method of auto registration used.

To use a touch screen control or change its setting, touch it, or if it is in the bottom row, turn or press the knob directly below it.

Name	Description
Close	Closes the segmented objects panel.
Find	Allows you to find the segmented objects in the MPR views.
Guide	A Visibility setting that shows the selected segmented objects in Guide procedures.
MPR	A setting that shows the segmented objects in the multiplanar reconstruction (MPR) views.
Planning	A Visibility setting that shows the selected segmented objects in Target Planning procedures.
Registration	A Visibility setting that shows the selected segmented objects in Registration procedures.
Segmented Objects	Allows you to display the auto registration vessel tree, diaphragm, or the surface of the liver from CT, MR, or ultrasound images in the Registration , Target Planning , and Guide procedures.
Set as Default	Sets the current settings as the default for future Segmented Objects views.
Show	A setting that shows segmented objects in the selected views.
Show as Lines	A setting that shows the path of the vessels as lines.
Show as Tubes	A setting that shows the path of the vessels as tubes.
Show in 3D	A CT/MR Liver setting that shows the CT or MR outline of the liver in the 3D view.
US	A setting that shows the segmented objects in ultrasound views.
Use Default	Overwrites your current settings with the default settings for Segmented Objects .

Target Planning

The **Target Planning** tab allows you to define entries, targets, and ablation zone sizes. Target planning does not require the field generator and can be performed as soon as the image set is available. For more information, see the “[Target Planning](#)” section.

NOTE

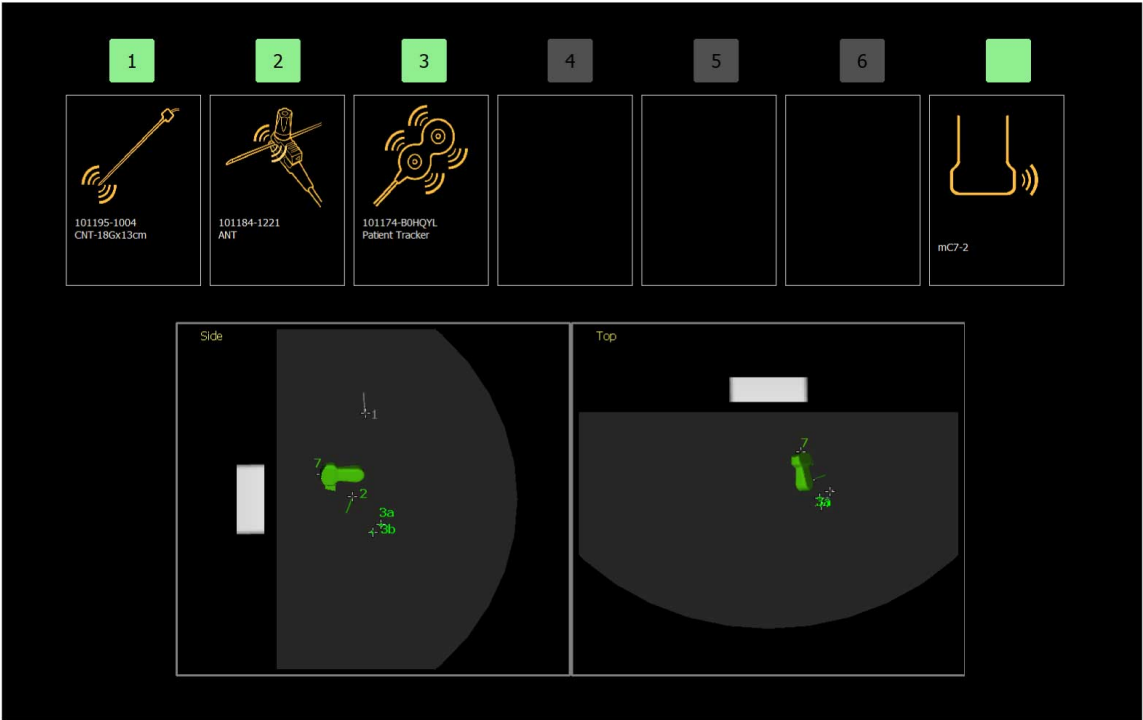
The **Selected Workflow**, **Fusion Tools**, **Target Planning**, **Field Generator Setup**, and **Settings** touch screen tabs are available only after you start PercuNav mode.

NOTE

The **Target Planning** tab is unavailable in the **Ultrasound Only** procedure.

Field Generator Setup

The **Field Generator Setup** tab allows you to align the tools within the working volume of the field generator's electromagnetic field. To re-initialize the field generator, touch **Initialize**.



Field Generator Setup

If no PercuNav instruments are connected to the TCU during initialization, you can touch **End PercuNav** on the **Field Generator Setup** tab to exit the PercuNav software.

Settings

The **Settings** tab provides access to general user preferences, needle offset presets, and display settings.

System Settings

The **System Settings** display provides access to a variety of settings that affect respiratory tracking, planning, overlays, and presets.

Control	Description
Acquisition/ Capture Modality	Sets the modality to associate with a screen capture. This setting is persistent. Available modalities include: • OT: Other • SC: Secondary capture • CT: Computed tomography • MR: Magnetic resonance • PET: Positron emission tomography • US: Ultrasound Includes the DICOM-compliant screen captures in modality searches, when they are uploaded to a PACS server. For example, if the screen capture modality is set to MR, all subsequent screen captures uploaded to the PACS server show the modality of the study containing the screen captures as MR. You can then find the screen capture in a PACS by searching for studies with the MR modality.
CT/MR/PET Images	Zoom All MPR Planes Together adjusts all of the MPR frames when using the control. Otherwise, the current view is adjusted with Zoom. Deselected by default. Do Not Blend Active Scan in Co-Registration allows rotation of Blend to change the blending ratio of only the inactive scan. When deselected, allows rotation of Blend to change the blending ratio of both displayed scans. Deselected by default. Allow Vessel Segmentation During Co-Registration allows the use of the auto-co-registration tools. Order Datasets According to Selection Sequence manually designates which data sets are assigned as Scan 1, Scan 2, and Scan 3 for co-registration. Use Same Scale to Show the Scans During Co-Registration sets all scans to the same scale. Scan Legend Default Show Protocol Name Instead of Series Description shows the name of the protocol instead of the series description.

Control	Description
Default Registration	Selects the default registration for the Fusion procedure: Internal Plane , Internal Landmark , External Landmark , Patient Tracker Match , or Auto Registration . Internal Landmark is the default setting for Fusion studies and Patient Tracker Match is the default setting for CT studies if more than one patient tracker is connected.
Planning	Show Distance Between Planned Trajectories displays the distance value between planned trajectories in the frames. Deselected by default. Enable Targeting Using 3D Viewer Orientation makes the displayed targeting orientation dependent on the orientation of the 3D viewer. Otherwise, the displayed targeting orientation is determined by the location of the field generator relative to the patient. Do Not Move Cursor to Target Automatically prevents the cursor from moving to the current target in target planning. Do Not Move Cursor When Going to Target Planning prevents the cursor from moving when you touch the Target Planning tab. Always Start a New Plan creates a new plan when a scan is loaded from Patient Directory display. Otherwise, the user is prompted to select a plan saved from a previous procedure, if applicable. Selected by default. Always Use Default Layout uses the factory-default layout for guide steps. Selected by default. If deselected, uses the layout that was used in the previous procedure of the same type. Target Visibility Automatically Switch to Current Volume shows the targets in the current volume when you change volumes.
Respiratory Tracking	Beep sets the system to emit a confirmation tone when the patient reference is within the patient reference zone. Deselected by default. Patient Reference Zone defines the size of the patient reference zone in centimeters. Default is 0 cm.

Control	Description
Ultrasound	Show Out-of-plane Target with Circle displays a circle with its center at the target and its radius representing the distance from the target to the ultrasound scan plane. Deselected by default. Add Auto-Registration Sweep for US-US Fusion Automatically saves the auto-registration sweep for use during a subsequent Fusion procedure.
US Overlay Maps	US Image sets the color for the ultrasound image. Chroma 1 is selected by default. Scan 1 sets the color for Scan 1. Gray is selected by default. (Fusion is selected if the scan is PET.) Scan 2 sets the color for Scan 2. Blue is selected by default. (Rainbow is selected if the scan is PET.) Scan 3 sets the color for Scan 3. Chroma 2 is selected by default. (Hot Metal is selected if the scan is PET.) Scan 4 sets the color for Scan 4. Green is selected by default. (SUVI is selected if the scan is PET.) Scan 5 sets the color for Scan 4. Red is selected by default. (Pet is selected if the scan is PET.)
Window/Level Presets	Displays window/level presets for the selected scan and modality (CT, MR, or PET). Also allows customization of window/level presets.

Needle Offset Presets

The **Needle Offset Presets** display provides access to a variety of settings that affect needle tracking. You cannot add two presets with the same name for a single CNT model. You cannot delete a preset that has been assigned to the currently tracked CNT.

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**WARNING**

Ensure the offset is correct for the device being used. An incorrect offset or device deflection may result in inaccurate placement.

**WARNING**

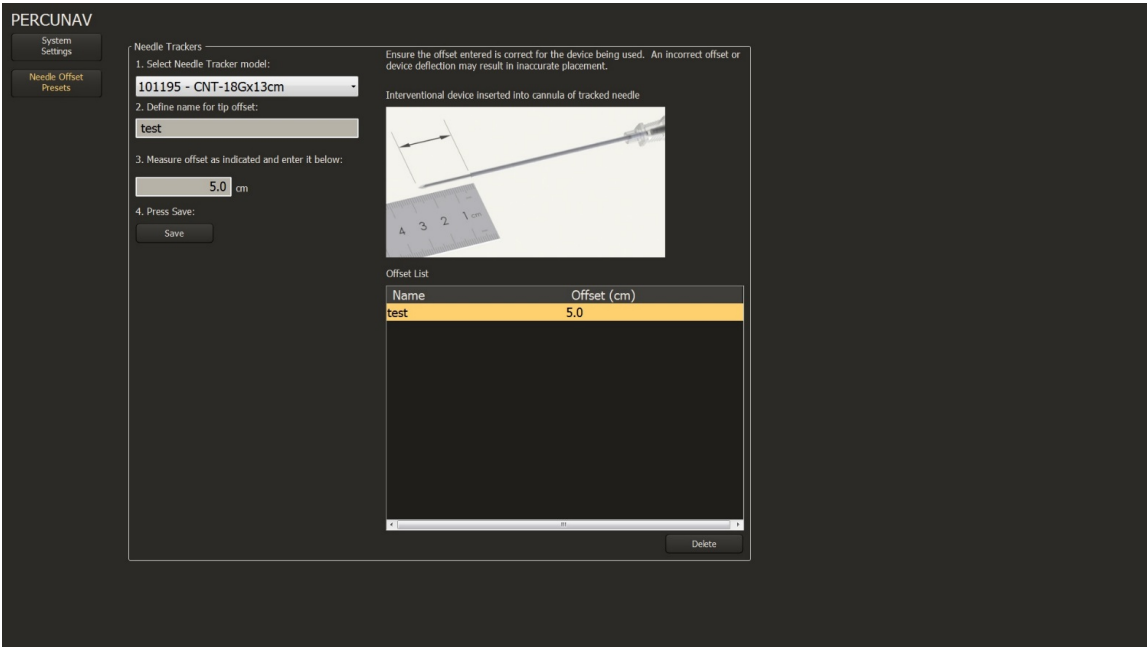
If you are using a coaxial needle tracker (CNT) for your procedure, verify that the registration is accurate with a needle tracker before entering any offset value. For details on verifying the CNT, see [“Preparing and Using the Coaxial Needle Tracker” on page 208](#).

**WARNING**

To avoid introducing inaccuracies during a procedure, do not use a Philips tracked stylet with another manufacturer's cannula.

NOTE

The tip offsets listed in the **Needle Offset Presets** display are also available in the **Edit Offset** dialog box for all PercuNav procedures.



Device Settings

Field	Description
Select Needle Tracker Model	Lists all supported needle trackers. The active tracker is selected by default.
Define Name for Tip Offset	Displays user-provided device name in the Offset List .
Measure Offset as Indicated and Enter it Below	Indicates the distance from the tip of the untracked needle to the distal end of the cannula.
Press Save	Saves the named tip offset to the Offset List .
Offset List	Lists all preset tip offsets on your ultrasound system.

Keyboard Commands

If the ultrasound system supports a physical keyboard, you can use keyboard commands to accomplish common tasks.

NOTE

To use these commands, the pointer must be inside the selected frame.

Key Label or Combination	Function
H	Display the pixel intensity at the cursor location of the CT, MR, or PET image.
Left Arrow, Right Arrow, Up Arrow, and Down Arrow	Move the current approach on the Target Planning display.
Page Up and Page Down	Rotate the current approach around the target on the Target Planning display.

View Types

Throughout the PercuNav workflows, various views are available. The available view types depend on the procedure that you are performing.

The standard labels on a view represent directionality relative to the patient and are provided to help orient you to each view.

NOTE

The view labels are available only during procedures involving CT, MR, and PET images.

For image orientations less than 25° from true axial/coronal/sagittal, the following view labels apply:

View Label	Definition
A	Anterior
P	Posterior
L	Left
R	Right
H	Head
F	Feet

For image orientations greater than 25° and less than 45° from true axial/coronal/sagittal, the following view labels apply:

View Label	Definition
(A)	Anterior
(P)	Posterior
(L)	Left
(R)	Right
(H)	Head
(F)	Feet

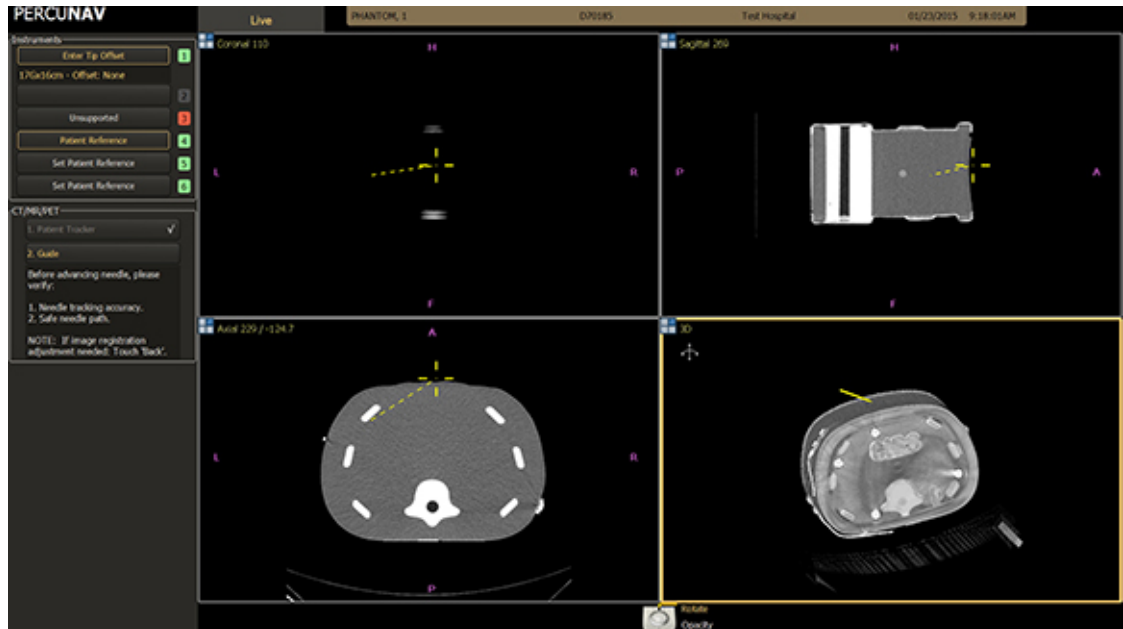
For information on the graphics on the views in **Guide**, see the “[Guide](#)” section.

Orthogonal Views: Axial, Coronal, and Sagittal (Triplanar)

The standard orthogonal views (axial, coronal, and sagittal) are available throughout the workflows during planning, registration and navigation.

The intersection of the crosshair represents one of the following:

- The stylet tip, when no offset is applied.
- The virtual tip, when offset is applied.



Orthogonal Views: Axial, Coronal, and Sagittal

Ultrasound Controls in PercuNav Mode

When in PercuNav mode, the keyboard, monitor, control panel, and touch screen controls are managed by the PercuNav software. Some ultrasound controls are still available to you on the touch screen and control panel.

- 2D ultrasound controls are available on the **2D** touch screen tab. See [“2D Ultrasound Touch Screen Controls in PercuNav Mode” on page 122.](#)
- On the control panel, available controls are lit, but some may have different behavior in PercuNav mode than in regular 2D imaging. See [“Ultrasound Control Panel Controls in PercuNav Mode” on page 124](#) and [“Ultrasound Controls with Different Behavior in Fusion” on page 124.](#)

2D Ultrasound Touch Screen Controls in PercuNav Mode

The 2D controls are located on the **2D** touch screen tab while in PercuNav mode. The available controls depend on the active transducer.

To use a touch screen control or change its setting, touch it, or if it is in the bottom row, turn the knob directly below it.

Control	Description
2D Opt	Provides up to three settings that can be used to optimize 2D imaging for resolution (Res), penetration (Pen), or general (Gen), which is a balance between resolution and penetration. (When Harmonic imaging is on, the optimization settings are HGen , HRes , or HPen .)
Biopsy	Displays the biopsy guideline for the selected transducer.
Chroma Map	A control used to assign a color map that replaces the grayscale map to improve contrast resolution. The Chroma map setting appears in the image information as Chroma X , where X is either Off or a map number.
Compress	A control used to select a compression curve for the image display. A higher compression curve softens the image; a lower compression curve produces a high-contrast image.
Contrast	Turns on the Contrast imaging mode.
Contrast Side/Side	Displays simultaneous 2D contrast and tissue images side by side during PercuNav procedures. Available only if Contrast is enabled on the ultrasound system.
Contrast Timer	Activates and displays a timer at the top center of each frame. Available only if Contrast is enabled on the ultrasound system.
Gray Map	Assigns a grayscale map to the displayed image.

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Control	Description
Harmonics	A control used to start and stop Tissue Harmonic Imaging (THI). When Harmonics is on, depending on the active transducer, two or more 2D Opt setting options are provided: HGen , HRes , HPen , HPGen , or HGRes . The setting appears on the left side of the display.
Left/Right	Mirrors the selected image along the vertical axis.
Output Power	Selects the ultrasound acoustic power density produced by the transducer measured in watts per square centimeter (W/cm ²).
PercuNav	Starts PercuNav mode. When PercuNav mode is running, this control is outlined in amber and cannot be selected.
Persistence	Selects the level of persistence for the image display. Persistence is also called smoothing or frame averaging. Use Persistence to average consecutive frames to provide a smoother appearance with less noise. Use lower persistence values for fast-moving organs or tissues and higher persistence values for slower moving organs or tissues.
Res/Spd	Resolution/Speed. Selects from a range of frame-rate settings that vary the balance between image quality (resolution) and frame rate. As resolution increases, the frame rate decreases. As the frame rate increases, the resolution decreases. The default setting depends on the transducer and preset selected.
Sector Width	Adjusts the width of the left, right, or both images. A narrower sector width increases frame rate.
SonoCT	Turns on and off SonoCT Real-time Compound Imaging.
TIB	Thermal Index, Bone. Provides information about the conditions that exist that might lead to an increase in temperature at the point of focus of the ultrasound beam on bone.
Top/Bottom	Mirrors the selected image along the horizontal axis.
XRES	Applies XRES image processing.

Ultrasound Control Panel Controls in PercuNav Mode

These ultrasound control-panel controls are available in PercuNav mode.

NOTE

Some controls are available but behave differently in PercuNav mode than in regular 2D imaging. Those controls are listed in [“Ultrasound Controls with Different Behavior in Fusion” on page 124.](#)

Ultrasound Control	Description
2D Gain	Use this control to adjust the 2D gain settings.
Depth	Use this control to change the depth of the ultrasound scan plane.
Focus	Turn this control to adjust the focal position or focal range. Press this control to select whether focal range or focal position is adjusted when you turn Focus .
TGC controls	Use the slide controls to control TGC.

Ultrasound Controls with Different Behavior in Fusion

While using **Fusion** in PercuNav mode, the following ultrasound controls on the control panel have slightly different behavior than in regular 2D imaging.

Ultrasound Control	Description
Annotate	Use to turn Annotation mode on and off.
Erase	Use to erase the annotation text, and distance and angle measurements.
Measure	Use to turn line measurements on and off.

Ultrasound Control	Description
Zoom	Use to specify the magnification of the selected frame or image: fit to depth, fit to original, or fit to width. The selection shown on the display follows: • D: fit to depth • O: fit to original • W: fit to width

Switching Between PercuNav and Ultrasound Modes

During a PercuNav procedure, you can switch control to the ultrasound system, perform a procedure, and then return to the PercuNav display. The PercuNav system returns you to the same display and workflow location that you were in before switching control to the ultrasound system.

1. Press **2D** if you have not done so already.
2. On the **2D** touch screen tab, touch **PercuNav**.
3. Select a procedural option:
 - **US Only** starts PercuNav mode and opens the **US Only Guide** display.
 - **Select CT/MR/PET** starts PercuNav mode and opens the **Review Exam** display. After you select the images, you can start the **CT Only** or the **Fusion** procedure.
4. Begin a procedure.
5. To return to the ultrasound controls, touch the **2D** tab. To return to the PercuNav controls, touch the **PercuNav** tab.
6. If you want to access ultrasound modes that are inaccessible for the current PercuNav procedure, touch the **2D** tab.
7. Perform ultrasound work in any of the available modes.
8. To return to the **PercuNav** procedure, touch the **PercuNav** tab. If you have paused the PercuNav procedure, touch **Resume PercuNav**.

NOTE

The **Pause PercuNav** and **Resume PercuNav** controls are unavailable on the touch screen until **Guide** is displayed.

Switching Among Active Transducers

**CAUTION**

Although registration is maintained when switching transducers during a procedure, Philips recommends that you confirm that the registration (fusion and needle tracking) is accurate.

You can switch among active, supported transducers while the PercuNav software is running. Simply touch the transducer name and select the application.

NOTE

Only one type of ultrasound tracker can be connected to the tool connection unit at a time.

7 Procedure Selection

The PercuNav system supports various types of procedures based on the imaging modalities that are used.

After you have started PercuNav mode, you can select a procedure to perform. You may use pre-procedure images, intra-procedure images, or a combination of both to complete it.

Additionally, you can export patient data, access the setups, or perform a system command.

The following procedures are available:

- **Fusion**
- **CT Only**
- **Ultrasound Only**

System Operation and Workflows

The typical workflow sequences for performing procedures with the PercuNav system are detailed in the following tables. The examples highlight the differences in the workflows for the **Ultrasound Only**, **CT Only**, and **Fusion** procedures.

In some cases, your workflow may vary from these examples.

Typical Workflow Sequence for CT Only or Fusion Procedure

Step	Task	Reference
Pre-Procedure Workflow		
1	Prepare and scan the patient (required for same-day procedures but not when using historic image sets)	“Scanning the Patient”
2	Select an image	“Patient and Image Selection”
3	Select a CT Only or Fusion procedure	“Selecting a Procedure” on page 128
4	Select a target plan (optional)	“Target Planning”

Step	Task	Reference
5	Co-Registration (optional)	“Preparing for Co-Registration” on page 163
Procedure Workflow		
6	Set up tools	“Setting Up Instruments for Fusion” on page 278 “Setting Up Instruments for a CT Only Procedure” on page 320
7	Registration	“Registration: Fusion” on page 280 “Registration: CT Only” on page 321
8	Guide	“Guide: Fusion” on page 311 “Guide: CT Only” on page 332

Typical Workflow Sequence for an Ultrasound Only Procedure

Step	Task	Reference
Pre-Procedure Workflow		
1	Select the Ultrasound Only procedure	“Selecting a Procedure” on page 128
2	Select a target plan (optional)	“Target Planning”
Procedure Workflow		
2	Set up tools	“Setting Up Instruments for Ultrasound Only” on page 260
3	Guide	“Guide: Ultrasound Only” on page 270

Selecting a Procedure

1. Press **2D**.
2. On the **2D** tab, touch **PercuNav**.
3. Select a procedural option:

- **DICOM Direct Load** allows you to load DICOM images from removable media. For more information, see [“Loading a Procedure from Removable Media” on page 129](#).
 - **Ultrasound Only** starts PercuNav mode and opens the **Ultrasound Only Guide** display (see the [“Procedure: Ultrasound Only”](#) section).
 - **Select CT/MR/PET** starts PercuNav mode and opens the **Patient Directory** display.
 - Click the patient name to select **Fusion** or **CT Only**.
 - Click the patient name to go to Review mode, from which you can select the image series and then select **Fusion** or **CT Only**.
4. After you select the images, you can start the **Fusion** (see the [“Procedure: Fusion”](#) section) or the **CT Only** (see the [“Procedure: CT Only”](#) section) procedure.
 5. Continue with the procedure in the **Selected Workflow** tab.

Loading a Procedure from Removable Media

1. Connect the USB device containing the data to a USB port on the system.
2. Click **DICOM Direct Load**.
3. Select a drive to search for DICOM files. To reduce search time, you can double-click a drive to expand its folder structure and select a lower-level folder to search.
4. Click **Search**.
5. Select the check box next to the series to load.
6. Select **CT Only** or **Fusion**.

NOTE

Some DICOM formats may not load properly, including data that has been so heavily anonymized that critical information is missing or data that stores images in compressed format (such as JPEG). If the data does not load properly, delete the patient from the patient list and retry the import using another method. For example, if the data was sent or copied to removable media using the PACS system, try to send or save the data directly from the scanner.

8 Patient and Image Selection

If the selected procedure involves pre-procedure images such as CT, MR, or PET, you must select the patient and images from the **Review Exam** display. When using scan sets from a CD, a DVD, or a USB storage device, you must manually import the images first. To import DICOM data from removable media, see [“Loading a Procedure from Removable Media” on page 129](#).

All targets and entries are associated with the active scan when the target is created. You can select two to five series and use co-registration to fuse the images. The series can be from the same study or separate studies. You can also select two to five phases from a multiphase scan within a single series. For more information, see [“Preparing for Co-Registration” on page 163](#).



WARNING

When selecting a study or images, you are responsible for ensuring that your selection matches the patient.

Image Transfer

The PercuNav Image Fusion and Interventional Navigation feature can access scans that are available on the ultrasound system. Through the ultrasound system, you can transfer pre-procedure scans over the network or by local media. You can also request the scans from the network directly. For information on transferring images from local media or over a network, see the ultrasound system *Help*.

Imaging equipment that provides scan sets or imaging data to the PercuNav system must support the American College of Radiology/National Electronics Manufacturers Association (ACR/NEMA) Digital Imaging and Communications in Medicine (DICOM) 3.0 compatible interface standards for sending data.

Exact transfer methodology is site-dependent due to scanner and PACS variations. In most cases, when data is sent through a network connection, the scans are automatically transferred to the PercuNav system.

NOTE

If the selected scan set was acquired incorrectly and is therefore incompatible with the system, the system will display a warning message.

NOTE

Some DICOM formats may not load properly, including data that has been so heavily anonymized that critical information is missing or data that stores images in compressed format (such as JPEG). If the data does not load properly, delete the patient from the patient list and retry the import using another method. For example, if the data was sent or copied to removable media using the PACS system, try to send or save the data directly from the scanner.

Patient Data and Image Review

The patient data and image review information is shown in the **Review Exam** display.



Review Exam Display

1	Source	Allows you to browse to the ultrasound system's hard drive and external media devices (CD, DVD, or USB storage device) to import images. See the ultrasound system <i>Help</i> .
2	Patient list	Displays the list of available patient images. You can search this list by Patient Name , Patient ID , or Description .
3	Image preview	Displays thumbnail images of the image sets or studies available for the selected patient.
4	Display controls	Allows the available actions for the patient images to be visible on the display. Use the trackball to select a control.

Review Exam Touch Screen Controls

Control	Description
Close	Closes the Review Exam display.
End Exam	Ends exam. Returns to the Select PercuNav Procedure touch screen.

Selecting Patients and Images



WARNING

When selecting a study or images, you are responsible for ensuring that your selection matches the patient.

When selecting images for a **CT Only** or **Fusion** procedure, you must first select the patient and images from the **Review Exam** display. The procedure for the image selection then depends on the size of the study that you are using and the slice consistency of the images within that study.

If your study is large (more than 512 images) or the study images have inconsistent slice spacing, see [“Selecting Images or Phases” on page 137](#).

If your study is small (less than 512 images) and the study images have consistent spacing, see [“Selecting Images from a Small Study” on page 135](#).

If you are retrieving patient images from removable media, such as a CD, a DVD, or a USB storage device, complete the import process before proceeding. If the removable media contains DICOM data, see [“Loading a Procedure from Removable Media” on page 129](#). For information loading other studies, see the ultrasound system *Help*.

Selecting Images from a Small Study

1. After you have started PercuNav mode, touch **Select CT/MR/PET**.
2. On the **Review Exam** display, select the patient in the top pane to display the available studies for that patient in the bottom pane.
3. Select a study that has fewer than 512 images and has consistent slice spacing.
4. Select an image.
5. Select one of the following procedures:
 - **Fusion**
 - **CT Only**
6. If the **Select Plan** dialog box appears, do one of the following:
 - Select a plan from the existing list.
 - Create a new plan.
7. Continue with the procedure in the **Selected Workflow** tab.

Plans

Plans are groups of data associated with patient scan sets that can include approaches and registration points.

If the images have previously been loaded and **Always Start a New Plan** is deselected in the **System Settings**, the **Select Plan** dialog box appears and prompts you either to create a new plan or to update or review the previously created plan. Plan data is associated automatically with the registration scan.

The leading eight numbers in the plan name correspond to the date the plan was created, in year, month, and day (yyyymmdd) format and are arranged with the most-recent plan at the bottom of the list. The six numbers following the date correspond to the time the plan was created, in hours, minutes, seconds (hhmmss).

You can highlight and select a plan using **Select**, create a new plan using **Create New**, or exit the dialog box by clicking **Cancel**.

Multiphase Scan Selection and Slice Sorting

You can select and load one to three phases from a single multiphase series for navigation. you can also select one to three subsets of slices (also known as images) from a series with more than 512 slices.

NOTE

If the series exceeds the maximum allowable number of slices, or if the PercuNav system detects changes in slice spacing, the **Select Slices** dialog box opens automatically.

Multiphase Scan Selection

If you load a multiphase series, the PercuNav system opens the **Select Slices** dialog box with a list of phases that are detected within the multiphase series. The **Select Slices** dialog box groups images into separate phases based on content time, instance number, and image position, and assigns a number to each group. You can select and load up to three phases from the available phases.

You can arrange the individual images (scan slices) by time, accession number, or image description by selecting a column title. You can select individual scan slices by selecting the corresponding thumbnail image below the image list.

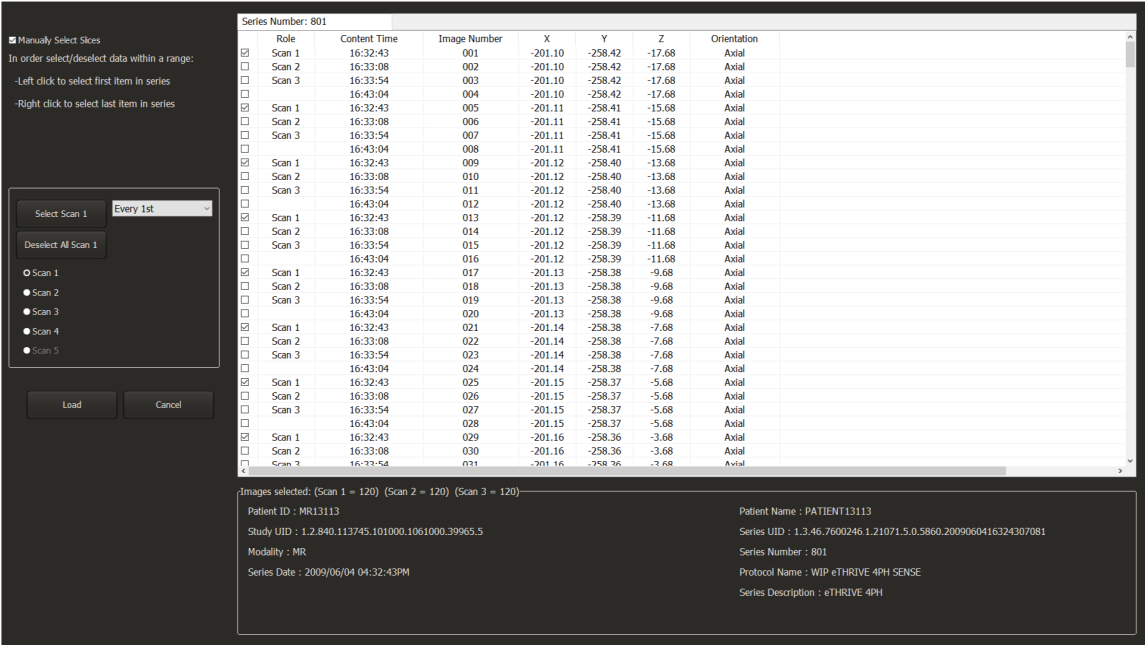
1. After you have started PercuNav mode, touch **Select CT/MR/PET**.
2. On the **Patient Directory** display, select the patient in the top pane to display the available studies for that patient in the bottom pane.
3. Select a study that has more than 512 images or has inconsistent slice spacing.
The **Select Slices** dialog box appears automatically.
4. Select phases from the study or select individual images manually. For details about selecting individual images manually, see [“Slice Sorting and Selection” on page 138](#).
5. To load the selected phases or images, touch **Load**.
6. If the **Select Plan** dialog box appears, do one of the following:
 - Select a plan from the existing list.
 - Create a new plan.
 - Select **Do not show this dialog again. Always start a new plan**.
7. Continue with the procedure in the **Selected Workflow** tab.

Slice Sorting and Selection

NOTE

If you select a series of images that does not meet the loading criteria (for example, matching image orientation or matching slice spacing), the **Select Slices** dialog box opens automatically.

If a multiphase series or a series with more than 512 slices is loaded, you can manually select a subset of images from the series for loading.



Slice Sorting and Selection

If you load a series of images for sorting, the **Select Slices** dialog box groups the images based on their content time, instance number, and image position, and assigns a number to each group. You can select up to three groups and then click **Load** to load the group.

To select or remove specific images in the load list, select **Manually Select Slices** and then select the check box to the left of an image or use the **Select Every nth** function.

To select a range of images, press the left trackball button on a row (not the check box) to indicate the beginning of the range. Press the right trackball button on a different row (not the check box) to indicate the end of the range.

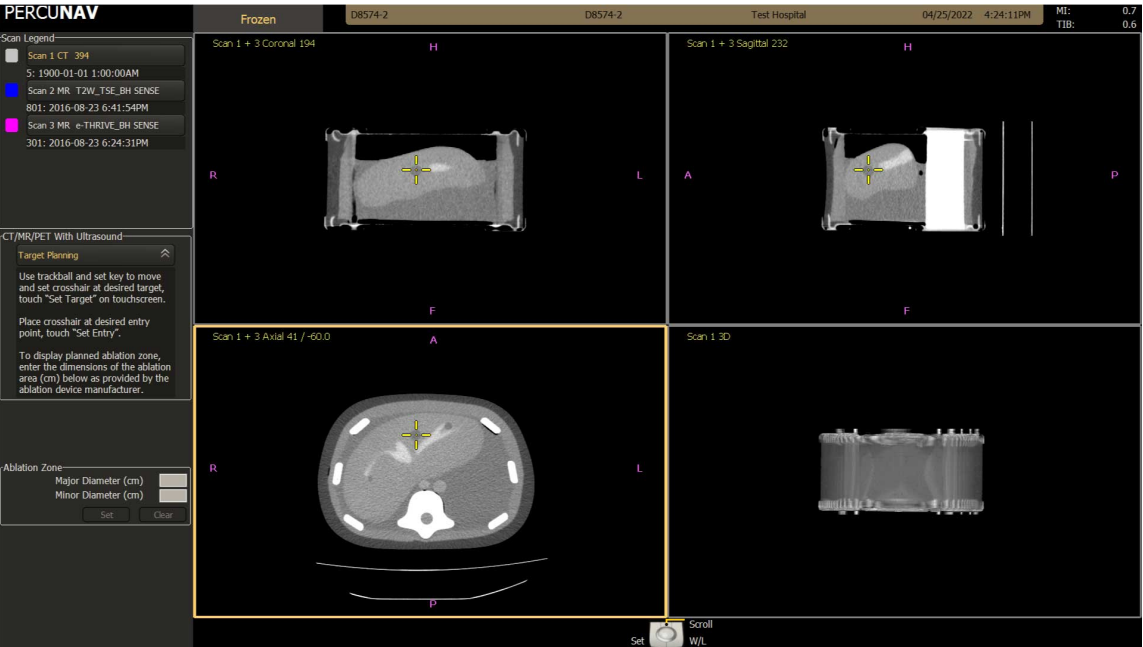
NOTE

If you select slices by defining a range, all other slice selections from the current series are deleted.

After you select the series and click **Load**, the selected series is validated. If it is validated, then the series is ready for co-registration. If the series is not validated, then the **Select Slices** dialog box reopens to allow you to select other series.

9 Target Planning

Target planning is an optional step that allows you to define entry/target pairs and set ablation zone sizes. Target planning does not require the field generator and can be performed as soon as the image set is selected.



Target Planning

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Tumor Contouring

Tumor contouring is a semi-automated tool that allows you to outline the 3D contour of a region of interest in CT, MR, and ultrasound images. This feature enables the contouring of lesions, structures, and other regions of interest. This contour can be visualized in the original image and can be reformatted and overlaid on other image modalities. In target planning, a standard target is a point. A target with a 3D contour is a volume target.

Volume targets can be used for ablation planning by providing 3D visualization of a lesion. Tumor ablation often targets a small margin of healthy tissue around a lesion to ensure complete ablation and reduce the probability of recurrence. You can add a 3D safety margin around the boundaries of the volume target to visualize and plan the ablation area.

Volume targets can also help in biopsy and ablation planning. You can display the volume target on the live ultrasound image to help guide the interventional device.



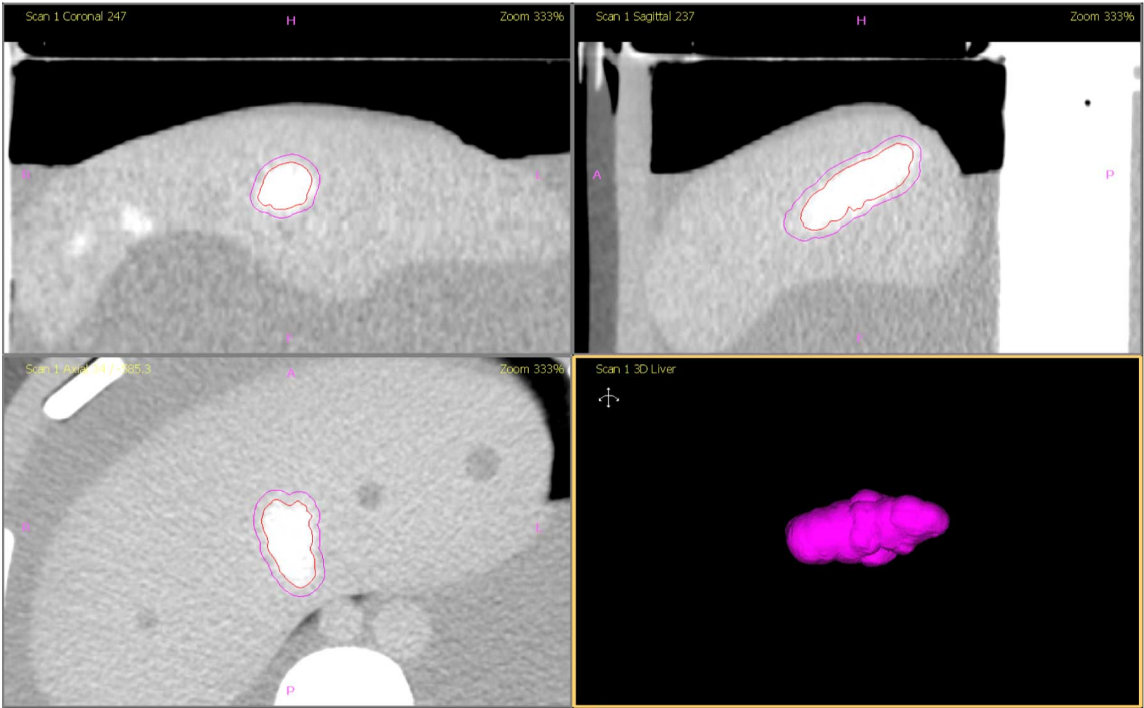
WARNING

The displayed volume values for a volume target are for comparative purposes only, and should not be the sole basis for a treatment decision or the selection of settings on a treatment device.



WARNING

3D tumor contouring requires that the target is either brighter or darker than the background tissue. Isoechoic targets distinguished by texture differences with the background are not good candidates for this feature.



Target Planning Volume Targets

Target Planning Touch Screen Controls

To use a touch screen control or change its setting, touch it, or if it is in the bottom row, turn the knob directly below it.

NOTE

If the patient reference is not defined, all of the controls on the **Target Planning** tab are disabled, and registration cannot be performed.

Name	Description
Adaptiveness	Adjusts how adaptive the brush is to a rough or spiculated contour. Turning the control to the left makes the brush smoother. To the right makes it more closely follow a rough contour. Pressing the control sets the current setting as the default.
Always Show This Volume	Makes the current volume always shown regardless of the setting of the Volume Display control.
Add Volume	Enables the drawing tools to add a volume target.
Blend	Adjusts the amount of blending of the displayed scans after registration. If Link US/Volume Image Blending is selected (default selection), turning Blend adjusts the blending of the scans at an equal ratio (one decreasing and the other increasing) between the range of 0% and 100%. If Link US/Volume Image Blending is deselected, turning Blend adjusts the blend ratio of only the selected modality. Pressing Blend switches between the listed modalities.
Contour Display	Indicates which contours of the volume targets are displayed: • ROI displays only the volume target. • Margin displays only the safety margin around the volume target. • ROI & Margin displays the ROI and the safety margin. • Residual displays the volume target with the proposed ablated volume subtracted. • Residual & Margin displays the volume target with the proposed ablated volume subtracted and the safety margin.
Copy Entry	If the current target has an entry, saves a copy of the position information of the entry.
Custom Volume Color	Allows you to set the color of the volume target.
Delete Target	Deletes the current target.
Delete Volume	Deletes the selected volume target.
Frame	Selects a frame on the display.

Name	Description
Move Cursor to Entry	Sends the crosshair focus to the current entry point.
Oblique	Changes the display layout to oblique.
Pan Target/Entry	Allows you to make translational adjustments to the target and entry point.
Paste Entry	If there is a copy of a target entry, pastes the copied entry as the entry of the current target.
Rename Target	Allows you to change the name of the current target.
Safety Margin	Allows you to set the safety margin around a volume target.
Scroll Slice	Scrolls through the available slices. Use the middle trackball button to turn Scroll Slice on and off.
Set Entry	Sets the entry to the current location of the crosshair.
Set Target	Sets the target to the current location of the crosshair.
Show Path	Touch Show Path to display the graphical connection for each approach that has a defined target and an entry point, including those outside the orthogonal planes shown in the frame. To display the distance between the cursor point and the current path to other paths, select Show Distance Between Planned Trajectories in the System Settings display and Show All and Show Path in the Target Planning touch screen.

Name	Description
Target Display	Indicates which defined targets are displayed: • Show Current: Displays only the current target and entry marker, including those outside the orthogonal planes shown in the frame. • Show All: Displays all targets, volume targets, and entry markers in the current orthogonal planes. • Hide All: Hides all targets. • Volume (#): Displays the current point target associated with the current volume (# is a placeholder for the volume number). • Volume (All): Displays all the point targets associated with the current volume.
Trajectory Path	Scrolls through the slices between the entry and the target when both an entry and a target are defined.
Triplanar	Changes the display layout to triplanar.
Update Target	Makes the current location of the crosshair the new location for the selected target.
View	Allows you to change the view shown in the selected frame.
Volume	Scrolls through the available volume targets.
Volume Display	Indicates which defined volume targets are displayed: • Show Current: Displays only the current volume target. • Show All: Displays all volume targets. • Hide All: Hides all volume targets.
W/L Preset	Allows you to select a grayscale contrast preset.

Add Volume Touch Screen Controls

To use a touch screen control or change its setting, touch it, or if it is in the bottom row, turn or press the knob directly below it.

Name	Description
Accept	Accepts the current contour. Available when Continuous Brush is off.
Accept and Continue	Accepts the current contour. The brush remains active. Available when Continuous Brush is on.
Adaptiveness	Adjusts how adaptive the brush is to a rough or spiculated contour. Turning the control to the left makes the brush smoother. To the right makes it more closely follow a rough contour.
Add Volume	Enables the drawing tools to add a volume target.
Brush Size	Adjusts the size of the drawing tool. Available when Draw Mode is set to Brush .
Continuous Brush	Controls whether the brush remains on after you accept a draw.
Cursor Display	Controls the display of the cursor.
Discard	Removes the volume target that is currently being drawn. Available after you touch End Draw .
Draw	Starts the currently selected drawing tool.
Draw Mode	Brush creates a 3D brush of variable size that you can use to add new area to the volume or subtract from it. Balloon allows you to anchor the volume near the center of the target and expand the area like a balloon until it is the size you want.
End Draw	Turns off the drawing tools.
Safety Margin	Allows you to set the safety margin around a volume target.
W/L Preset	Allows you to select a contrast preset.
View	Allows you to change the selected view.

Creating a Target

NOTE

Target planning is optional.

A target plan can include a target entry pair or just a target. To identify targets before starting the **Guide** process, touch the **Target Planning** tab. If you are in **Guide**, touch the **Selected Workflow** tab.

1. To select the target for your target plan, press the middle trackball button, use the trackball to scroll through the image set until you see the target, and press the middle trackball button again.
2. Touch **Target Planning**.
3. To place the crosshair, click the intended target image. Ensure that the crosshair is centered on the region of interest in all three orthogonal planes.

NOTE

To optimize the image, adjust the **W/L** settings.

4. Touch **Set Target**.

NOTE

If you use the **Zoom** function to set the target, the zoom is focused on the crosshair position, not the center of the display. In the **Settings**, deselect **Zoom all MPR Planes Together** to zoom to a specific location.

5. To enter a meaningful name to the plan (for example, "Lesion 1"), touch **Rename Target**. The target name can have a maximum of 9 characters.
6. If you want to set a planned entry point, scroll through the image set and do one of the following:
 - Use the trackball and crosshair on the display to locate the planned entry point, and touch **Set Entry**.
 - Place the tip of a trackable instrument on the patient at the planned entry point, and touch **Set Entry**.

NOTE

To preview the line from entry to target, touch **Show Path**. To "fly" through the path, turn **Trajectory Path**.

7. To create another target or target entry pair, repeat steps 1 through 6.
 8. When you are finished, touch the **Selected Workflow** tab to continue the procedure.
- If you want, you can now define the ablation zone. See [“Defining a Planned Ablation Zone Around a Tracked Location” on page 154](#).

Adding a Volume Target

You can draw the volume target in any and all of the scan planes. During drawing, you can toggle between add and subtract modes. Add mode adds area to the volume; subtract mode subtracts it. The brush outline is green in add mode and orange in subtract mode.

1. To select the target for your target plan, press the middle trackball button, use the trackball to scroll through the image set until you see the target, and press the middle trackball button again.
2. To place the crosshair, click in the intended target area.

3. Touch **Target Planning**.
4. If necessary, get a better view of the target area by adjusting the **W/L** settings, **Zoom**, or other image settings.
5. Touch **Add Volume**.
6. Select drawing tools with the **Draw Mode**, **Continuous Brush**, and **Cursor Display** controls.
7. To begin drawing the volume target, touch **Draw**.
8. To draw while **Balloon** is selected, do any of the following:
 - To switch between add and subtract mode, press the middle trackball button.
 - To add or subtract the area, place the cursor near the center of the area and press the left trackball button. Then, drag to resize the balloon and press the left trackball button again.
 - To change the way the balloon follows the outer contour of the shape, turn the **Adaptiveness** knob.
 - To undo the previous action, touch **Undo**.
 - To accept the changes to the target volume, press **Accept**.
9. To draw while **Brush** is selected, do any of the following:
 - To switch between add and subtract mode, press the middle trackball button.
 - To add or subtract the area, press the left trackball button.
 - To change the size of the drawing tool, turn the **Brush Size** knob.
 - To change the way the brush follows the outer contour of the shape, turn the **Adaptiveness** knob.
 - To undo the previous action, touch **Undo**.
 - To accept the changes to the target volume, press **Accept** or **Accept and Continue**.
 - To end drawing while **Continuous Brush** is selected, touch **End Draw**.
10. Turn the **Scroll Slice** knob to scroll through the target. If you notice another area to add or subtract from the volume, press the middle trackball button to re-enter draw mode.
11. Touch **Done**.

Deleting a Target

When you delete a target, all remaining targets retain their T# designation. For example, if you have targets **T1**, **T2**, and **T3**, and you delete **T2**, the remaining two targets are still labeled **T1** and **T3**.

1. To select the target on the image that you want to delete, turn **Target**.
2. Touch **Delete Target**.

Deleting a Volume Target

1. If necessary, press the **Volume/Target** control to select **Volume**.
2. To select a volume target, turn **Volume**.
3. Touch **Delete Volume**.
4. If the volume has point targets associated with it, a system message asks if you want to also delete the point targets. Click **Yes** or **No**.
5. Do one of the following:
 - To delete the volume, click **Yes**.
 - To cancel the deletion, click **No**.

Hiding or Showing Targets

You can control the display of targets and entry markers on the images. If there are multiple volumes defined, and targets associated with each volume, the current volume controls display the targets associated with the current volume.

1. In the **PercuNav** tab, touch **Target Planning**.
2. Touch **Target Display** to select which defined targets you want to show:
 - **All Hidden**: Hides all targets.
 - **All Shown**: Displays all targets and entry markers in the current orthogonal planes.

- **All Shown (Current Volume):** Displays all targets associated with the current volume.
- **Current:** Displays only the current target and entry marker.
- **Current (Current Volume):** Displays the current target associated with the current volume.

NOTE

The label for **Target Display** indicates the next available state, not the current state.

Hiding or Showing Volume Targets

Turn the **Volume** knob to select your current preference, or do the following:

1. In the **PercuNav** tab, touch **Target Planning**.
2. Touch **Volume Display** and select your choice.

Hiding or Showing Contours

1. In the **PercuNav** tab, touch **Target Planning**.
2. Touch **Contour Display** and select your choice.

Ablation Zone and Tip Settings

The planned ablation zone function displays the estimated ablation area based on user-defined values. Ablation zones are theoretical treatment areas, displayed around the predefined target point, that take into account the planning target, entry point, and the user-defined ablation zone dimensions.

The live ablation zone function displays the estimated ablation area based on user-defined values and the position, orientation, and location of the probe. The live ablation zone options appear when either CNT with an applied offset or ANT is the active tool.

**WARNING**

The ablation zone is displayed based on the major and minor diameter values you enter as provided by the instructions for use for each ablation instrument. Make sure that the entered values are correct for the instrument and procedure used.

**WARNING**

The ablation zone function is for planning purposes only and is to be used at the sole discretion of the physician. The actual ablation zone is influenced by many factors that must be considered. Improper use of the ablation zone feature could result in inaccuracies and possible personal injury.

**WARNING**

The actual ablation area should be confirmed with a direct imaging technique to ensure that the displayed ablation zone matches the actual ablation zone.

NOTE

The live ablation zone options do not appear when CNT is the active tool but the offset is either not applied or is turned off, or when the eTRAX needle tip tracking system is the active tool.

Defining a Planned Ablation Zone Around a Tracked Location



WARNING

To ensure optimal accuracy, you must hold the cannula in place when removing the stylet and inserting the ablation device. Movement of the cannula after the tracked stylet is removed can result in inaccurate placement of the ablation device, leading to possible injury.

1. Create an entry and a target for the ablation zone. See [“Creating a Target” on page 148](#).
2. If required, touch the **Target Planning** tab.
3. In the left pane, under **Ablation Zone**, enter the **Major Diameter (cm)** and **Minor Diameter (cm)** values in centimeters as provided by the probe manufacturer's instructions.
4. Click **Set** to link the ablation zone to the current entry and target. The ablation zone shading appears.
5. To adjust the position of the ablation zone, select a new target and touch **Update Target**. To adjust the entry point, select a new entry point and touch **Set Entry**.

Displaying a Planned Ablation Zone

If a planned ablation zone is defined, click **Show Planned Ablation Zone** to display the planned ablation zone on the image.

Defining a Live Ablation Zone Around a Tracked Location



WARNING

To ensure optimal accuracy, you must hold the cannula in place when removing the stylet and inserting the ablation device. Movement of the cannula after the tracked stylet is removed can result in inaccurate placement of the ablation device, leading to possible injury.

NOTE

If an ablation zone was set on the **Target Planning** tab, the major and minor diameters populate the Define Live Ablation Zone dialog box.

1. Select the active tool:
 - CNT with an active offset
 - ANT
2. Click the **Selected Workflow** tab.
3. Under **Live Ablation Zone**, click **Define**.
4. Select the ablation zone offset, as defined by the manufacturer of the device:
 - **Needle Placement Proximal to Target**
 - **Needle Placement Distal to Target**
5. Enter the offset value in centimeters (cm), as defined by the manufacturer of the device.
6. Click **Apply**.

Displaying a Live Ablation Zone

If a live ablation zone is defined, click **Show** in the **Define Live Ablation Zone** dialog box to display or hide the live ablation zone on the image.

Adding a Safety Margin

After the modeling of the volume target is complete, you can add a safety margin. The main display indicates the distance that the safety margin is offset from the volume target and the volume of the volume target plus the safety margin. Volume is shown in mL.

Do one of the following:

- To set the safety margin to 5 mm, press **Safety Margin**.
- To adjust the safety margin in 1-mm increments, turn **Safety Margin**.

User-Assisted Ablation Planning

The Ablation Planning licensed option can help you plan coverage of a volume with a single entry and from one to six targets. You change the variables and start a new plan, or refine your current plan for better coverage.

Planning an Ablation



WARNING

The safety and acceptability of the planned trajectory provided by the user-assisted ablation planning feature must be verified and confirmed by the physician before and during the procedure.

The planning algorithm continually refines the target planning to cover a larger area. The amount of increase it is able to find diminishes over time. The planning is set to time-out after 90 s. You can stop the planning in progress at any time and use the current best calculated trajectory or trajectories. You will have the option to save the planned results to the current volume or a new cloned volume. Saving the results to a new cloned volume allows you to compare two results to each other.

1. Create a volume target for the ablation zone. See [“Adding a Volume Target” on page 149](#).
2. Touch the **Target Planning** tab.
3. Click the image to set the cursor position as the entry point.
4. In the left pane, under **Ablation Zone**, enter the **Major Diameter (cm)** and **Minor Diameter (cm)** values in centimeters as provided by the probe manufacturer's instructions.
5. Under **User-Assisted Ablation Planning**, select **New Plan** and enter the number of targets you plan to use.
6. Click **Plan**.
7. To stop the planning and use the current result, press **Stop**.
8. Do one of the following:
 - To save the planned results to the current volume, click **Current Volume**.
 - To save the planned results to a new cloned volume, click **New Cloned Volume**.
 - To discard the results, click **Cancel**.

NOTE

The results of the planning algorithm is not necessarily the optimal solution. The feature is designed to assist the physician in finding trajectories that offer coverage of the target given the planning parameters.

Refining an Ablation



WARNING

The safety and acceptability of the planned trajectory provided by the user-assisted ablation planning feature must be verified and confirmed by the physician before and during the procedure.

The planning algorithm continually refines the target planning to cover a larger area. The amount of increase it is able to find diminishes over time. The planning is set to timeout after 90 s. To run the algorithm for longer to see if it can find better coverage, refine an existing plan. The refined plan is always the same or better than the current plan.

1. Select a volume with an existing plan.
2. Confirm the **Major Diameter (cm)** and **Minor Diameter (cm)** values and number of targets.
3. Under **User-Assisted Ablation Planning**, select **Refine Current Plan**.
4. Click **Plan**.
5. To stop the planning and use the current result, press **Stop**.
6. Do one of the following:
 - To save the planned results to the current volume, click **Current Volume**.
 - To save the planned results to a new cloned volume, click **New Cloned Volume**.
 - To discard the results, click **Cancel**.

Custom Volume Color Touch Screen Controls

To use a touch screen control or change its setting, touch it, or if it is in the bottom row, turn or press the knob directly below it.

Name	Description
Close	Closes the custom volume color panel.
Residual 2D Fill	Sets the fill value for the 2D outlines in the frames.
Residual 3D Opacity	Sets the opacity of the color in the 3D render frame.
Residual Color	Selects the color for the residual image.
Restore System Default	Returns all color values to the system default colors.
ROI 2D Fill	Sets the fill value for the 2D outlines in the frames.
ROI 3D Opacity	Sets the opacity of the color in the 3D render frame.
ROI Color	Selects the color of the region of interest (volume target).
Safety Margin 2D Fill	Sets the fill value for the 2D outlines in the frames.
Safety Margin 3D Opacity	Sets the opacity of the color in the 3D render frame.
Safety Margin Color	Selects the color of the safety margin.
Set as Default	Sets the current color choices as the default for future volume targets.
Use Default	Changes the color scheme to your set default, or if you have not set one, to the system default.

Customizing the Volume Target Color

After you have completed a volume target, you can customize the color of the volume target. You can individually control the color of the 2D outline in the three quadrants and the 3D model for the region of interest (ROI), the safety margin, and the residual volume. Fill and opacity can be changed in 0.1 increments from 0.0 to 1.0. At 0.0 the fill color is for the outline only. When fill color is 1.0 the 2D outline is fully filled with the chosen color. At 0.0 the opacity the 3D volume is fully transparent (not visible). At 1.0 the 3D volume is fully opaque.

1. Touch **Custom Volume Color**.
2. To change a color, touch a color for **ROI Color**, **Safety Margin Color**, and **Residual Color**.

- 3. To change a fill value, turn the fill value control for **ROI 2D Fill**, **Safety Margin 2D Fill**, and **Residual 2D Fill**.
- 4. To set your current color choices as the default for future volume targets, touch **Set as Default**.
- 5. To replace the current color choices with defaults, touch **Use Default** or **Restore System Default**.
- 6. When finished setting colors, touch **Close**.

Panning Touch Screen Controls

To use a touch screen control or change its setting, touch it, or if it is in the bottom row, turn or press the knob directly below it.

Name	Description
In/Out	Allows you to move in or out through the view.
Move Cursor to Entry	Sends the crosshair focus to the entry of the current approach.
Move Cursor to Target	Sends the crosshair focus to the target of the current approach.
Move Cursor to Volume	Sends the crosshair focus to the current volume target.
Pan Entry	Allows you to pan the entry point with the trackball.
Pan Target	Allows you to pan the volume target with the trackball.
Show Path	Displays the graphical connection for each approach that has a defined target and an entry point, including those outside the orthogonal planes shown in the frame.

Panning a Target and Entry

You can pan the target and entry points to adjust the planned approach. You can move the entire path by panning the target and entry at the same time.

1. Touch **Pan Target/Entry**.
2. Do any of the following:
 - To move the cursor to the target, touch **Move Cursor to Target**.
 - To move the cursor to the entry point, touch **Move Cursor to Entry**.
 - To move the cursor to the volume target, touch **Move Cursor to Volume**.
 - To show the path between the target and entry, touch **Show Path**.
 - To pan the target, touch **Pan Target**. Use the trackball to move the target.
 - To pan the entry, touch **Pan Entry**. Use the trackball to move the entry.
 - To extend the target along the current path, turn **Extend Target**.
 - To extend the entry along the current path, turn **Extend Entry**.
3. When you are finished, do one of the following:
 - To discard the changes, touch **Cancel**.
 - To accept the changes and return to the **Target Planning** touch screen, touch **OK**.

10 Data Set Co-Registration

Preparing for Co-Registration

You can load two to five scans of the same patient, or two to five phases of a multiphase scan, and use co-registration tools to fuse the scans or phases. With co-registration, the scans are identified as **Scan 1**, **Scan 2**, **Scan 3**, **Scan 4**, and **Scan 5**. Scans are sorted according to the selection sequence.

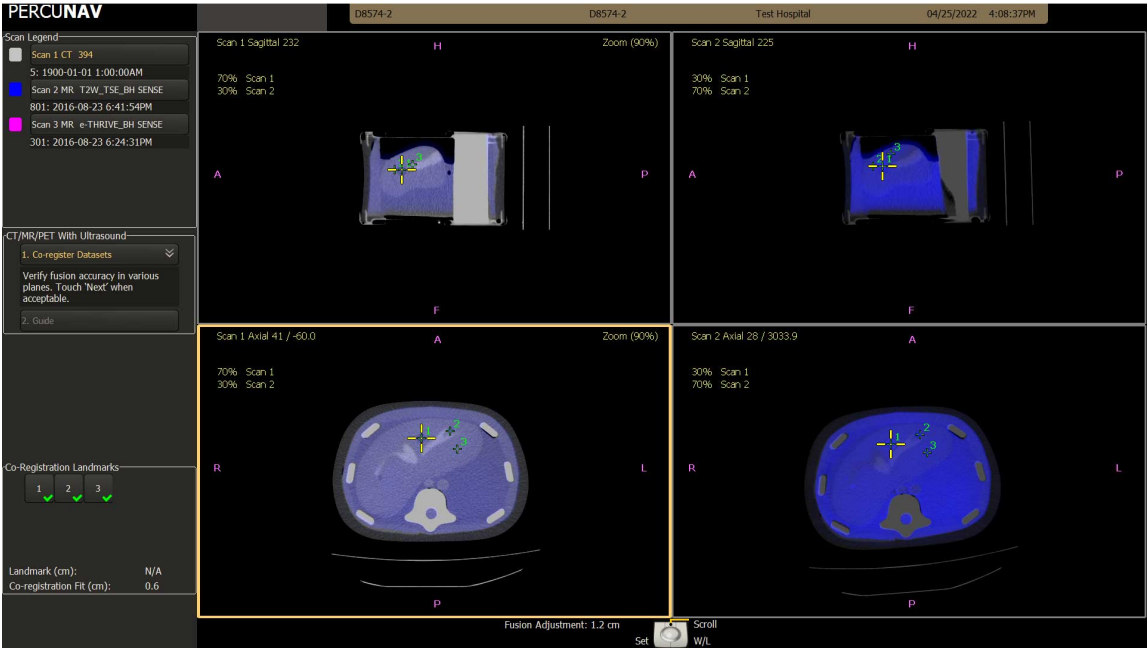
You can use **View** to change which scan is considered by the system to be **Scan 1**, **Scan 2**, **Scan 3**, **Scan 4**, or **Scan 5**. By default **Scan 1** is considered the registration scan and is the scan that all registrations are performed against. You can change which scan is the registration scan using the **Registration** control. In this manual, **Scan 1** is assumed to be the registration scan. When selecting the registration scan, consider:

- The time lapse between time of acquisition and the time of the procedure.
- Which scan has the most visible anatomical landmarks.

The primary objective in the **Data Set Co-Registration** display is to fuse the registration scan with the other scans so that they become one fused image. For more information on the co-registration process, see [“Co-Registering Data Sets” on page 167](#).

In the **Data Set Co-Registration** display, **Left Scan** in the left frame, and **Right Scan** in the right frame, are on the first pair to be co-registered. To choose which scans appear in **Left Scan** and **Right Scan**, touch the controls and choose a scan. To choose the registration scan, touch **Registration**. After the left scan and right scan are co-registered, the chosen registration scan appears in the right frame and is co-registered with **Left Scan**.

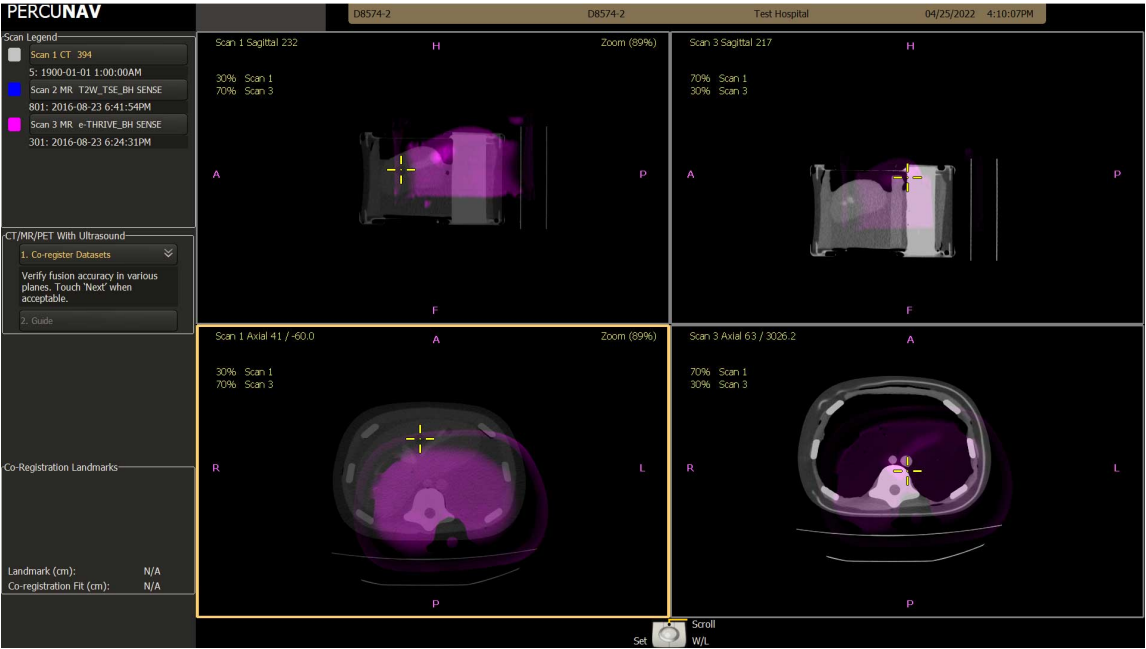
After scans are co-registered, you can increase the blending level of the opposing scans in each frame. For example, in the right frame, increasing the blending level would increase the visibility of the registration scan in that frame.



Data Set Co-Registration - Scan 1 and Scan 2

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Data Set Co-Registration - Scan 1 and Scan 3

Data Set Co-Registration Touch Screen Controls

To use a touch screen control or change its setting, touch it, or if it is in the bottom row, turn the knob directly below it.

Control	Description
Adjust Fusion	Displays the following controls: • Trackball: Activates the trackball rotate and scroll features for use when fine-tuning of co-registration. • Reset: When the image is frozen, clears all adjustments and returns the data set to its original state.

Control	Description
Auto Vessel	Displayed when Allow Vessel Segmentation During Co-Registration is selected in System Settings . Performs auto vessel segmentation of the active scan.
Vessel Auto Co-register	Displayed when Allow Vessel Segmentation During Co-Registration is selected in System Settings . Performs auto co-registration of the two scans using the segmentation results.
Back	On the first co-registration display, saves the registration information and moves to the previous step in the workflow. On the second co-registration display, returns to the first co-registration display.
Blend	Changes the blending of the co-registered scans. Available for Fusion and CT Only procedures. For more information, see “Blend” on page 345 .
Delete Landmark	Deletes a matched landmark from the co-registration set.
Frame	Selects a frame on the display.
Landmark	Displays the following controls: • Exclude: Excludes the selected landmark from the registration set. • Include: Includes the selected landmark from the registration set.
Left Scan	Chooses the scan displayed on the left side of the display.
Match Landmark	Matches two corresponding landmarks that you have positioned on the left and right images.
Next	Proceeds to the next step in the workflow.
One Click Vessel	Displayed when Allow Vessel Segmentation During Co-Registration is selected in System Settings . Performs auto one-click vessel segmentation of the active scan using the selected point.

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Control	Description
One Click Boundary	Defines the search region when you use the Find Vessel control during auto registration in a Fusion procedure.
Registration	Selects the next scan as the registration scan. Changing the registration scan will clear existing registrations.
Reset	Clears the current fusion adjustment.
Right Scan	Chooses the scan displayed on the right side of the display.
Rigid Co-Register	Starts a procedure that adjusts the two scans so that similar features are aligned.
Rotate	Rotates the selected image to fine-tune co-registration.
Select Landmark	Selects a frame on the display.
Show Vessel	Displayed when Allow Vessel Segmentation During Co-Registration is selected in System Settings . Displays and hides the segmentation results.
User-Assisted Co-Registration	Starts a procedure that aligns the two scans by deforming the earlier scan to match the later scan. This creates a third scan that is a deformed version of the earlier scan that is registered with the second.
View	Allows you to change the view shown in the active frame. Turn View to select a different view. Press View to display the Scan control, which lets you replace the current scan with a different scan.

Co-Registering Data Sets



WARNING

If you use historic images, the physician is responsible for confirming the appropriateness and accuracy of those images and if they can be used for the current procedure.

**WARNING**

Any and all anatomical changes between the loaded scans must be considered when co-registering, including patient position, weight changes, respiratory state, change to tumor size, internal organ shifts, and so on. Physicians must use their discretion when selecting appropriate images to co-register.

**WARNING**

You are responsible for ensuring that the co-registration of series on the PercuNav system is accurate.

**WARNING**

You must accept the current quality of co-registration between the loaded scans before you continue with your procedure.

There are several methods of scan fusion:

- Default: This method requires no action.
- Manual drag: Use this method to manually drag one scan until it visually aligns with the other (see [“Manual Drag Method” on page 169](#)).
- Match landmark: Use this method to specify a matching landmark on each scan (see [“Match Landmark Method” on page 169](#)).
- **Rigid Co-Registration**: This method uses an algorithm to align the scans with one another.
- **User-Assisted Co-Registration**: This method uses an algorithm to deform the older scan so that the two scans match up more closely.

You can also combine these methods to create a fused image. For example, combine the match landmark and manual drag methods to manually adjust the scan fusion after matching the landmark, or use **Rigid Co-Registration** and then manually adjust the results.

Manual Drag Method

For information on how the scans are designated, see [“Preparing for Co-Registration” on page 163](#).

1. If you need to change the scan to register against, use **Registration** to select the scan to be the registration scan.
2. To adjust the fusion, touch **Trackball** under **Adjust Fusion**, and then drag the misaligned scan into alignment.
 - Turn the **Rotate** control to move the scans into alignment around a selected point.
 - Select **Scroll** to adjust the scan vertically with the trackball.

Match Landmark Method

For information on how the scans are designated, see [“Preparing for Co-Registration” on page 163](#).

1. If you need to change the scan to register against, use **Registration** to select the scan to be the registration scan.
2. Using the trackball, select corresponding landmarks from the two image data sets.
3. Touch **Match Landmark**.
4. Repeat steps 2 and 3 if required. Additional landmarks improve the quality of the co-registration.
5. Use the **Blend** control to verify that the anatomy is aligned on all of the imaging planes.

Rigid Co-Registration Method



WARNING

You are responsible for verifying and confirming the accuracy and acceptability of the co-registration of series on the PercuNav system before using the series for guidance or diagnosis.

The rigid co-registration method uses an algorithm to align two scans in much the same way you would do a manual co-registration. When the rigid co-registration is complete, review and adjust the results as necessary before going on to the next step.

For information on how the scans are designated, see [“Preparing for Co-Registration” on page 163](#).

1. Touch **Rigid Co-Register**.
2. Allow the co-registration algorithm to complete.
3. Use the **Blend** control to verify that the anatomy is aligned on all of the imaging planes.
4. Adjust the co-registration, if necessary.

User-Assisted Co-Registration Method



WARNING

You are responsible for verifying and confirming the accuracy and acceptability of the co-registration of series on the PercuNav system before using the series for guidance or diagnosis.



WARNING

A PET/CT data set is imported as two separate series (one PET series and one CT series), along with a separate same-day CT. In such cases, user-assisted co-registration (deformable registration) is not recommended, because only the two CT series can undergo deformable registration. The PET series cannot undergo deformable registration and may be misaligned with the co-registered CT series.

The user-assisted co-registration method is available to co-register CT scans. The user-assisted co-registration method deforms the previous scan so that the features align better. The user-assisted co-registration may be used with landmarks or without. Deformable auto co-

registration is available only from an older data set to a newer data set or between two data sets with the same time stamp. You can compare the results of a rigid co-registration with a deformable co-registration to see what was changed in the deformable auto co-registration. There must be at least one open scan slot for the deformed scan to complete the co-registration.

For information on how the scans are designated, see [“Preparing for Co-Registration” on page 163](#).

1. Touch **User-Assisted Co-Registration**.
2. Choose the **Left** and **Right** scans.
3. Touch **Deformable Co-Register**.

When the algorithm completes, the upper-left and lower-left views show the two input data sets registered to each other using a rigid registration. The upper-right and lower-right views shows the same two data sets registered using deformable registration.

4. Use the **Blend** control to verify that the anatomy is aligned on all of the imaging planes.
5. Do one of the following:
 - To accept the co-registration, touch either **Add as Scan #** or, if there is a scan generated from a previous deformable co-registration, **Overwrite Scan #**. (The # is the scan number.)
 - To reject the co-registration, touch **Cancel**.

A deformed data set is marked by an asterisk (*). If the scan description for the deformed **Scan 3** is **1 --> 2**, it means that data set 1 was deformed to match data set 2, and the resulting scan was stored as **Scan 3**.

6. Verify and confirm the accuracy of the co-registration in all planes. To go to the next step, touch **Next**.

11 Instruments

**WARNING**

Inspect all components, including cables and instruments, for damage before using them with the PercuNav system.

**WARNING**

All instrumentation is designed for use only with the PercuNav system. Before using the instrumentation with the system, see the instructions included with each component. Some instrumentation components require preparation before use.

**CAUTION**

You are responsible for verifying with the manufacturer of the ablation device that external devices are permitted to be attached to the ablation device.

NOTE

Some instruments and accessories may not be included with your PercuNav system. For more information, contact Philips.

NOTE

Components of the PercuNav instruments that come in contact with patients or users contain metal, synthetic adhesives, synthetic thermoplastics, and synthetic elastomers.

NOTE

The PercuNav software can track only one interventional instrument (for example, a biopsy needle) at a time.

Instrumentation Options

A variety of instrumentation is designed for use with the PercuNav system. For more information on these items, contact Philips. These are the instruments available for each licensed option:

Fusion Option

- Patient tracker: Acts as a patient reference. Monitors motion caused by respiration or patient movement, allowing the PercuNav system to compensate for motion. When you use more than one patient tracker, the trackers act as active registration body markers that support **Patient Tracker Match**.
- Ultrasound tracker: Allows the system to display the position and orientation of the transducer.
- Adaptive needle tracker (ANT): Used with a stylus for pre-procedural planning and to identify external landmarks during registration. When used without a stylus and attached to an interventional device, the ANT allows the system to track the position of the interventional device and the orientation of the needle tip during needle-based procedures.

(EPIQ Systems Only) Fusion and Navigation Option

- Patient tracker: Acts as a patient reference. Monitors motion caused by respiration or patient movement, allowing the PercuNav system to compensate for motion. When you use more than one patient tracker, the trackers act as active registration body markers that support **Patient Tracker Match**.
- Ultrasound tracker: Allows the system to display the position and orientation of the transducer.

- Adaptive needle tracker (ANT): Used with a stylus for pre-procedural planning and to identify external landmarks during registration. When used without a stylus and attached to an interventional device, the ANT allows the system to track the position of the interventional device and the orientation of the needle tip during needle-based procedures.
- Needle tracker: Allows the system to display the position and orientation of the needle tip when navigating to a target location. Needle trackers include: the Philips coaxial needle tracker (CNT) and the CIVCO eTRAX needle tip tracking system.

Ultrasound Only Option

- Patient tracker: Acts as a patient reference. Monitors motion caused by respiration or patient movement, allowing the PercuNav system to compensate for motion. When you use more than one patient tracker, the trackers act as active registration body markers that support **Patient Tracker Match**.
- Ultrasound tracker: Allows the system to display the position and orientation of the transducer.
- Adaptive needle tracker (ANT): Used with a stylus for pre-procedural planning and to identify external landmarks during registration. When used without a stylus and attached to an interventional device, the ANT allows the system to track the position of the interventional device and the orientation of the needle tip during needle-based procedures.
- (EPIQ systems only) Needle tracker: Allows the system to display the position and orientation of the needle tip when navigating to a target location. Needle trackers include: the Philips coaxial needle tracker (CNT) and the CIVCO eTRAX needle tip tracking system.

Licensed Options for Each System

Instrument and Procedure Availability for Licensed Options for EPIQ Systems

Option	Supported Procedures	Ultrasound Tracker	Patient Tracker	ANT	Needle Tracker
Fusion	CT Only	X	X	X	–
	Fusion	X	X	X	–
	Ultrasound Only	X	X	X	–

Option	Supported Procedures	Ultrasound Tracker	Patient Tracker	ANT	Needle Tracker
Fusion and Navigation	CT Only	X	X	X	X
	Fusion	X	X	X	X
	Ultrasound Only	X	X	X	X
Ultrasound Only	Ultrasound Only	X	X	X	X

Instrument and Procedure Availability for Licensed Options for Affiniti 70 Systems

Option	Supported Procedure	Ultrasound Tracker	Patient Tracker	ANT
Fusion	CT Only	X	X	X
	Fusion	X	X	X
	Ultrasound Only	X	X	X
Ultrasound Only	Ultrasound Only	X	X	X

Patient Tracker

The patient tracker acts as a patient reference and monitors motion caused by respiration or patient movement, allowing the PercuNav system to compensate for motion. Attach the patient tracker close to the area of interest, on the skin over bony areas such as the sternum or ribs. The patient tracker is also used for **Patient Tracker Match** when you use more than one patient tracker for a procedure that involves a same-day, pre-procedural CT scan.

NOTE

If you are using respiratory tracking, place the patient tracker on an area that is stable and provides the best sample respiratory motion. When used in this way, tracking monitors surface motion, rather than internal organ shift, during respiration.

Ultrasound Tracker

For ultrasound procedures, you must attach a tracker to the ultrasound transducer to allow the system to display the position and orientation of the transducer. See [“Attaching and Removing the Model 20004 Ultrasound Tracker” on page 230](#) or [“Attaching and Removing the Model 21001 Ultrasound Tracker” on page 243](#).

Adaptive Needle Tracker

You can attach the ANT to an instrument to guide the procedure needle to a location, while tracking the needle tip during an interventional procedure. You can also use the ANT with a stylus for registering external landmarks and for pre-procedural planning.

Needle Trackers

The CNT and the eTRAX needle tip tracking system both use a stylet-cannula pair for tip tracking to navigate to a target location. When the predefined target is reached, replace the stylet with the instrument to be used for the interventional procedure.

Instrument Warnings

Obey the following safety precautions when using the PercuNav system instruments.



WARNING

You must visually inspect the packaging for each instrument before use. If the packaging has been compromised, contact your local Philips representative.



WARNING

You must visually inspect each instrument before use. If an instrument shows any sign of material degradation or damage, or if the label has become illegible, do not attempt to use the instrument.

**WARNING**

Users of the instruments must be specialists trained to perform the procedures for which these instruments are intended.

**WARNING**

Before the first use, disinfect the patient tracker. See [“Disinfecting the Patient Tracker” on page 225](#) for instructions.

**WARNING**

Before the first use, disinfect or sterilize the ANT, depending on the procedure. See [“Disinfecting the Adaptive Needle Tracker” on page 195](#) or [“Sterilizing the Adaptive Needle Tracker” on page 199](#) for instructions.

**WARNING**

Non-sterile instruments (patient tracker and adaptive needle tracker) are reusable but must be cleaned and disinfected under the guidelines in this manual, before initial use and after any use. Failure to follow the cleaning and disinfection guidelines creates a risk of contamination and patient infection, including but not limited to, the transmission of infectious diseases from one patient to another, with the potential for illness and death.

**WARNING**

If you are using an instrument that is non-sterile, make sure that the sterility of other devices or tools is not compromised through contact with that instrument.

**WARNING**

Do not expose any instrument to a strong magnetic field (for example, an MRI scanner). These instruments are neither MRI-compatible nor MRI-safe.

Recommended Instrument Disinfectants

This topic lists the disinfectants specified for use with the instruments. For more information, see the following:

- [“Disinfecting the Adaptive Needle Tracker” on page 195](#)
- [“Disinfecting the Patient Tracker” on page 225](#)
- [“Disinfecting the Model 20004 Ultrasound Tracker” on page 239](#)
- [“Disinfecting the Model 21001 Ultrasound Tracker” on page 253](#)

Adaptive Needle Trackers: Ready-to-use Cidex OPA (ortho-phthalaldehyde) solution

Patient Tracker

- Pre-saturated cleaning wipes with a 1:10 bleach solution as the active ingredient (for example, Sani-Cloth Bleach Wipes or Dispatch Wipes)
- Clean, lint-free, sterile wipes saturated with a spray containing a quaternary ammonium disinfection solution
- Clean, lint-free, sterile wipes saturated with a 1:10 bleach solution of 100 ml (3.4 oz) household bleach (4% to 6% sodium hypochlorite) in 900 ml (1 qt) lukewarm distilled water (22°C to 43°C [72°F to 110°F])

Ultrasound Trackers

- Pre-saturated cleaning wipes with a 1:10 bleach solution as the active ingredient (for example, Sani-Cloth Bleach Wipes or Dispatch Wipes)
- Clean, lint-free, sterile wipes saturated with a spray containing a quaternary ammonium disinfection solution

- Clean, lint-free, sterile wipes saturated with a 1:10 bleach solution of 100 ml (3.4 oz) household bleach (4% to 6% sodium hypochlorite) in 900 ml (1 qt) lukewarm distilled water (22°C to 43°C [72°F to 110°F])

NOTE

When using wipes (pre-saturated, sprayed, or saturated in a solution), be sure to use a new wipe when disinfecting each portion of the instrument or for each new step of the procedure, unless specifically instructed otherwise.

Adaptive Needle Tracker (ANT)

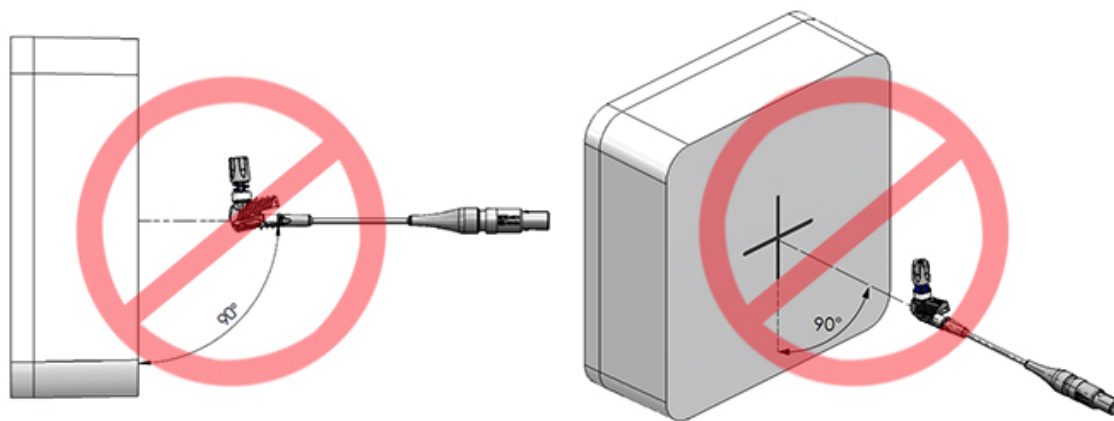
NOTE

The adaptive needle tracker is available only in selected regions. For information specific to your region, contact your local Philips representative.

Use the following information to ensure that the PercuNav system and the adaptive needle tracker (ANT) perform optimally, that the ANT is used correctly, and that the ANT is cleaned and disinfected or sterilized thoroughly. Before using the ANT, consider the following:

- To ensure optimal performance of the ANT, position the reference patient tracker as close as possible to the point where the needle will penetrate the skin.
- If you are using the ANT in a sterile environment, have a second set of the sterile ANT accessory parts available during the procedure, in case component parts are lost or sterility is compromised inadvertently.

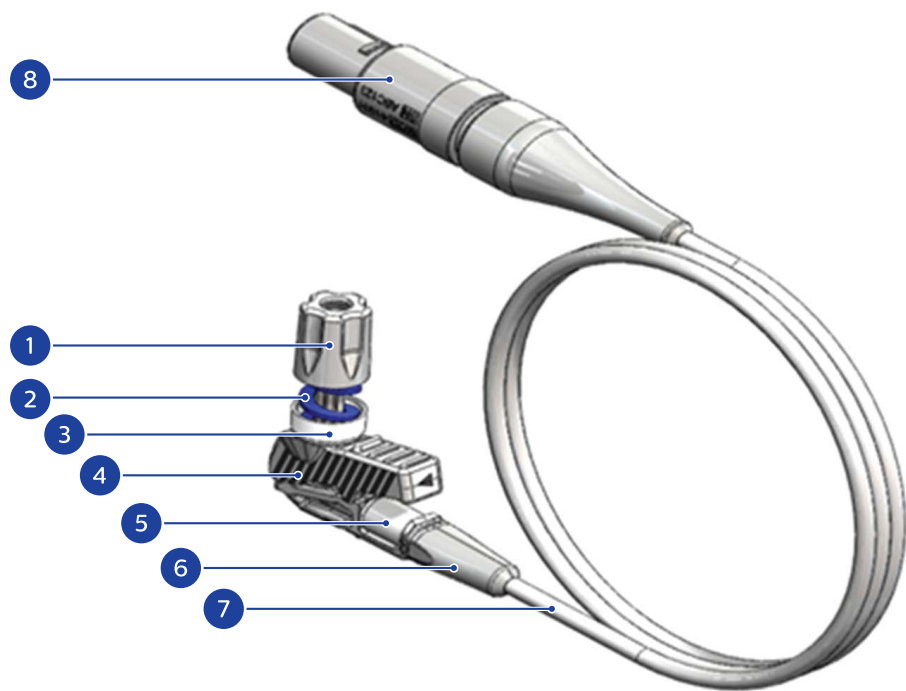
- If you are using the ANT with a spring-loaded biopsy device, reconfirm the secure attachment and correct location of the ANT after using the biopsy device and before resuming navigation. Confirm the location by measuring from the flat face (striped side) of the ANT to the distal tip of the tracked instrument, and then compare that measurement to the offset shown on the PercuNav display.
- Using thin or long needles can affect system accuracy. For more information, contact your local product-application specialist.
- If you use a sterile cover or sheath with the ANT, always inspect the cover or sheath for damage before and after use. Also, to avoid damaging the sterile cover or sheath, ensure that it has sufficient slack when you cover the ANT.
- To avoid compromising tracking accuracy, do *not* position the ANT perpendicular to the field generator.



Incorrect Orientation of the ANT Relative to the Field Generator

The ANT is an electromagnetic tracker that is designed to be used only with the PercuNav system. The ANT can turn any compatible needle device into a tracked PercuNav instrument. It can also be used with a stylus to identify external landmarks during registration.

The ANT consists of a spring, a spring seat, an upper and lower jaw, a clamp nut, a cable, a connector, and a stylus. A ruler is also provided for offset measurements.



ANT Components

1	Clamp nut
2	Spring
3	Spring seat
4	Upper jaw
5	Lower jaw
6	Strain relief
7	Cable
8	Connector

An accessory kit is included with the ANT. The kit contains a spring, a spring seat, an upper jaw, a clamp nut and a stylus. If you lose a component, replace it with one from the kit. If you require additional accessory kits, contact your Philips representative.



ANT Accessory Kit



WARNING

Before the first use, clean and disinfect, or sterilize the components in the accessory kit. If you are unable to sterilize the kit components, they should be handled and used as if they were non-sterile.

Attaching and Using an Adaptive Needle Tracker

Before using this instrument, read these warnings, the instrument-specific [“Instrument Warnings” on page 177](#), and the [“Safety”](#) section.

**WARNING**

When you use the adaptive needle tracker for virtual tracking, in certain anatomies and disease states, the tracked instruments may behave differently due to needle bending when inserted in tissue. Be aware that factors such as gauge size, instrument length, anatomy, tumor size and type, and operator skill contribute to the overall accuracy of the system. If necessary, contact your Philips representative for clarification.

**WARNING**

If you encounter any unusual resistance while advancing the adaptive needle tracker (ANT), or if the instrument's tip behavior or location seem incorrect, stop manipulating the instrument and attempt to determine the cause (for example, by direct imaging). Failure to use proper caution may result in damage to the ANT, the tracked instrument, or patient tissue.

**WARNING**

Do not use the adaptive needle tracker as a handle to guide the tracked instrument.

**WARNING**

When performing ablation procedures, you must use the insulated cannulae provided with the device.

**WARNING**

Employ safe sharp handling techniques when using the adaptive needle tracker.

**WARNING**

Ensure the offset is correct for the device being used. An incorrect offset or device deflection may result in inaccurate placement.

**WARNING**

If the adaptive needle tracker is removed or moved after the offset value has been entered in the PercuNav system, re-tighten and re-measure, and then re-enter the correct offset value prior to use.

**WARNING**

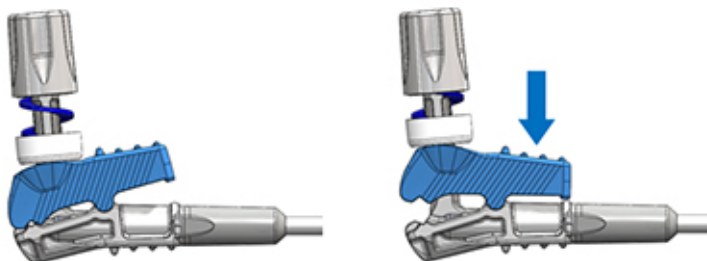
Position the ultrasound system and the tool connection unit so that the cable length of the adaptive needle tracker is sufficient to accommodate patient movement and for the physician to perform the procedure without straining the cable.

NOTE

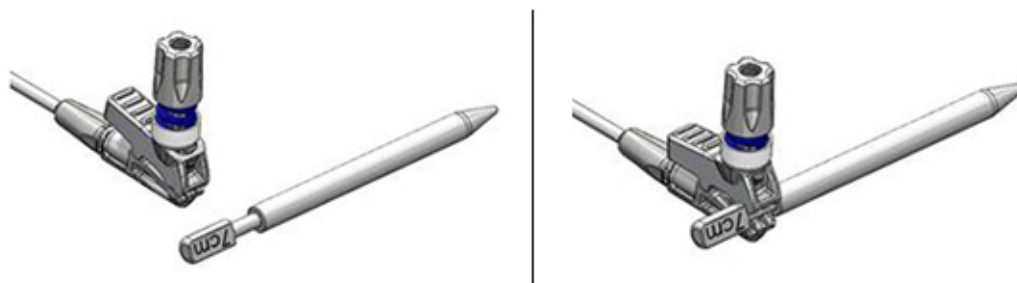
The PercuNav software can track only one instrument at a time. You can connect more than one needle tracker (CNT or eTRAX system) of different models to the tool connection unit (TCU), or a CNT and an ANT, but you can select only one for tracking. If you connect two needle trackers of the same model to the TCU, neither of those needle trackers can be selected for tracking.

1. Using standard aseptic techniques, remove the ANT from any packaging.
2. Note the two directional markers, one at either end, and the striped side of the ANT. Make sure the markers point to the tip of the tracked instrument.
3. Unscrew the clamp nut, as required, to allow the jaws to open. Do not remove the clamp nut.

4. Open the jaws of the clip mechanism to attach the ANT to the shaft of the instrument or stylus to be tracked.



5. Attach the ANT to the shaft of the interventional instrument or to the attachment notch of the stylus.

**WARNING**

Do not slide the ANT over the tip of the instrument. This could lead to operator injury and improper attachment.

6. Secure the ANT in position along the shaft of the device. Ensure the ANT does not move axially along the shaft.

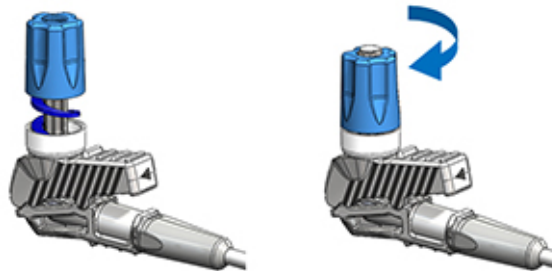
**CAUTION**

To avoid damaging the instrument, do not overtighten the screw mechanism when locking the ANT in position.

**CAUTION**

To prevent impairing the performance of automated biopsy guns, do not overtighten the screw mechanism and test the biopsy mechanism with the ANT attached before proceeding with the biopsy procedure.

7. Lock the ANT in position by turning the screw mechanism until the clamp nut meets the spring seat and the jaws clamp onto the shaft. The spring should disappear into the spring seat.

**WARNING**

After attaching the ANT to the interventional instrument, ensure that the shaft of the instrument is undamaged. Damage to the insulation of an ablation device may result in serious burns to the patient or user.

8. Verify that the ANT cannot move along the shaft of the tracked instrument.

9. Connect the ANT to the TCU. Verify that the device functions within the field generator volume.
10. Enter the offset measurement (in centimeters, to one decimal place) from the flat face (striped side) of the ANT to the distal tip of the tracked instrument. If you are tracking the stylus, refer to the offset value stamped on the end of the stylus.

**WARNING**

Ensure the offset entered is correct for the device being used. An incorrect offset or device deflection may result in inaccurate placement.

11. Complete the selected registration method.
12. After the selected anatomical location is reached, check to make sure that the ANT's cable is supported properly.
13. Verify the location of the device tip by using direct imaging.

**WARNING**

If the ANT moves along the shaft of the interventional device at any time during the procedure, remeasure and reenter the offset value to avoid inaccurate tracking and potential injury to the patient.

**WARNING**

During ablation, the ablation device can interfere with the tracking volume. To avoid tracking errors or inaccuracies, do not attempt to track the interventional device during ablation.

14. When the PercuNav procedure is complete:
 - a. Remove the interventional instrument from the patient per standard operating procedures.
 - b. Unscrew the clamp nut and open the jaws to remove the ANT from the interventional instrument.
 - c. Unplug the ANT connector from the TCU.

**CAUTION**

To disconnect the instrument from the tool connection unit, grasp the connector plug and pull gently. Do not pull on the cable.

15. Immediately after each use, clean the ANT (see [“Cleaning the Adaptive Needle Tracker” on page 190](#)) and then do one of the following:
 - If the ANT *will not* be used in a sterile field, disinfect it (see [“Disinfecting the Adaptive Needle Tracker” on page 195](#)).
 - If the ANT will be used in a sterile field, sterilize it (see [“Sterilizing the Adaptive Needle Tracker” on page 199](#)).

Cleaning Overview: Adaptive Needle Tracker

**WARNING**

The high-level disinfection process excludes the electrical connector of the adaptive needle tracker (ANT). Handle the electrical connector as non-sterile, and be careful to prevent contamination of the disinfected or sterilized ANT. Use of a contaminated ANT could result in infection.

**CAUTION**

This information is provided as a summary for the cleaning procedure. Be sure to follow the full cleaning procedure in this manual.

Cleaning Overview: ANT

1. Disassemble the ANT.
2. Prepare the cleaning solution and soak the ANT for 2 minutes.
3. Rinse the ANT under running water.

Cleaning the Adaptive Needle Tracker

Establish and clearly post the following cleaning and disinfection procedures. Cleaning the tracker is an essential step before effective disinfection.

Immediately after each patient use, decontaminate the tracker according to these cleaning and disinfection procedures, to protect patients and personnel from transmission of potential pathogens.

**WARNING**

Always use protective eyewear and gloves when cleaning, disinfecting, or sterilizing any equipment.

**WARNING**

Throughout the cleaning procedure, discard and replace soiled wipes or cotton swabs as needed. Continue cleaning until you have removed all visible soil from the tracker.

**CAUTION**

Do not use alcohol or any alcohol-based chemicals to clean the tracker.

**CAUTION**

Do not allow sharp objects, such as scalpels or cauterizing knives, to come in contact with the tracker, including the cable.

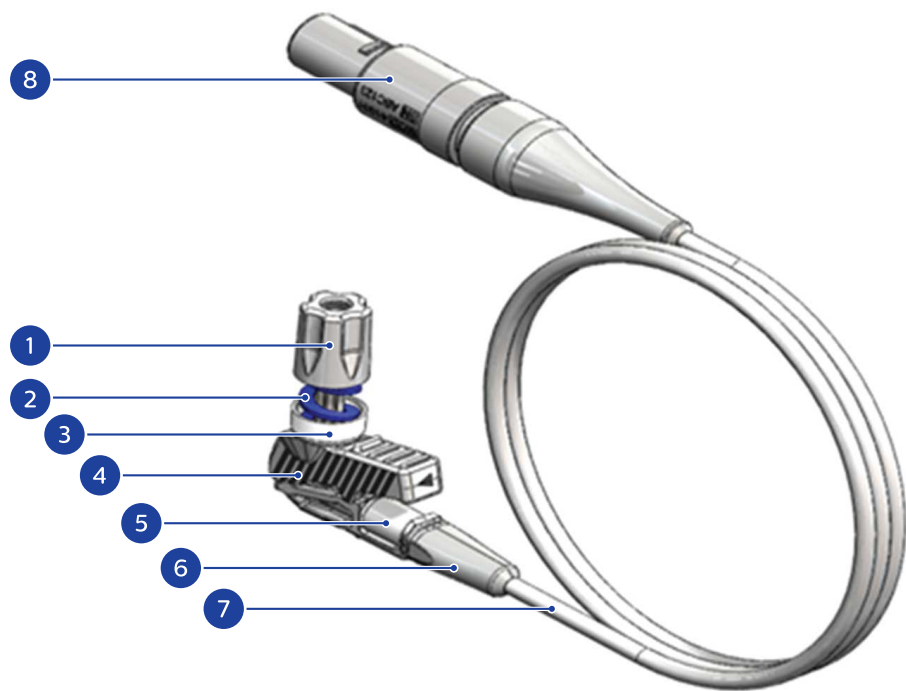
**CAUTION**

Do not use a wire brush to clean the tracker.

**CAUTION**

Do not use automated cleaning devices with the Adaptive Needle Tracker (ANT).

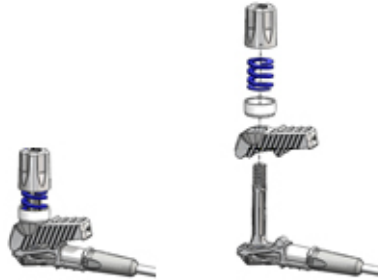
For assistance during cleaning, see the following figure.



ANT Components

1	Clamp nut
2	Spring
3	Spring seat
4	Upper jaw
5	Lower jaw
6	Strain relief
7	Cable
8	Connector

1. Disassemble the adaptive needle tracker:



- a. Rotate the clamp nut counterclockwise until it spins freely.
 - b. Slide the spring, spring seat, and upper jaw off the lower jaw and cable assembly.
 - c. Loosely coil the cable. Secure the excess cable near the connector.
2. Prepare one of the following solutions for use in this cleaning process:
 - A mild detergent solution or surfactant: 5 ml (1 tsp) of concentrated liquid detergent into 3.8 l (1 gal) of lukewarm tap water (22°C to 43°C [72°F to 110°F])
 - An enzymatic cleaning solution prepared according to the manufacturer's instructions, such as Enzol Enzymatic Detergent or Steris Prolystica 2x Concentrate Enzymatic Presoak and Cleaner.
3. Immerse all components in the prepared cleaning solution for a minimum of 2 minutes.
4. Use a soft-bristled brush to clean all immersed component surfaces for a minimum of 1 minute.
5. Remove the components from the cleaning solution.
6. Recoil the cable and secure the excess.
7. Immerse all components in a bath of lukewarm tap water (22°C to 43°C [72°F to 110°F]) for a minimum of 1 minute.
8. Remove all components from the bath and thoroughly dry the components with a clean, dry, lint-free wipe or cloth.

9. Visually inspect the components in a well-lit area to confirm the absence of any soil or adhesive.
10. If you see any soil or adhesive, repeat step 2 through step 9 (using fresh wipes) until you see no soil or adhesive.
11. If you see no soil or adhesive, and the components are completely dry, do one of the following:
 - If the ANT *will not* be used in a sterile field, disinfect it (see [“Disinfecting the Adaptive Needle Tracker” on page 195](#)).
 - If the ANT will be used in a sterile field, sterilize it (see [“Sterilizing the Adaptive Needle Tracker” on page 199](#)).

Disinfection Overview: Adaptive Needle Tracker



CAUTION

This information is provided as a summary for the disinfecting procedure. Be sure to follow the full disinfecting procedure in this manual.

High-level Disinfection Overview: ANT

1. Prepare a ready-to-use disinfectant, and pour it into a sterile container.
2. Soak the ANT for 12 minutes.



CAUTION

Do not immerse the connector.

**CAUTION**

Throughout the cleaning process, protect the connector to keep liquid out of the connector's electrical contacts.

3. Remove the tracker from the disinfection solution, and then immerse it in a sterile water bath for a minimum of 1 minute.

**CAUTION**

Do not immerse the connector.

**CAUTION**

Throughout the cleaning process, protect the connector to keep liquid out of the connector's electrical contacts.

4. Repeat immersion three times using fresh, sterile water each time.

After cleaning and high-level disinfection, the adaptive needle tracker (ANT) may be used in a sterile environment only when placed under a sterile cover (the CIVCO CIV-Flex cover). For disinfection instructions, see [“Disinfecting the Adaptive Needle Tracker” on page 195](#).

Disinfecting the Adaptive Needle Tracker

**WARNING**

Always use protective eyewear and gloves when cleaning, disinfecting, or sterilizing any equipment.

**CAUTION**

Do not use alcohol or any alcohol-based chemicals to clean the tracker.

**CAUTION**

Throughout the cleaning process, protect the connector to keep liquid out of the connector's electrical contacts.

**CAUTION**

Do not use automated cleaning devices with the Adaptive Needle Tracker (ANT).

NOTE

If the ANT *will not* be used in a sterile field, disinfect it after you clean it. The ANT also can be used with a sterile cover (such as the CIVCO CIV-Flex cover) after intermediate disinfection. If the ANT *will* be used in a sterile field, sterilize it (see [“Sterilizing the Adaptive Needle Tracker” on page 199](#)).

For assistance during disinfecting, see the ANT figure in [“Cleaning the Adaptive Needle Tracker” on page 190](#).

1. Prepare a ready-to-use Cidex OPA (ortho-phthalaldehyde) solution for a high-level disinfection.
2. Verify that the Cidex OPA solution contains the minimum effective concentration by using a Cidex OPA solution test strip per the manufacturer's instructions.
3. Heat the solution to a temperature of 20°C (68°F), and pour it into a secondary container.
4. Loosely coil the cable. Secure the excess cable near the connector.

5. Immerse all components in the prepared disinfecting solution for a minimum of 12 minutes.

**CAUTION**

Do not immerse the connector.

**CAUTION**

Throughout the cleaning process, protect the connector to keep liquid out of the connector's electrical contacts.

6. Immerse all components in a bath of sterile water for a minimum of 1 minute.

**CAUTION**

Do not immerse the connector.

**CAUTION**

Throughout the cleaning process, protect the connector to keep liquid out of the connector's electrical contacts.

7. Remove the components and immerse them twice more, in fresh sterile water, for a total of three rinses.
8. Dry the components with a sterile, dry, lint-free wipe or cloth.
9. Reassemble the ANT:

- a. Loosely coil the cable. Secure the excess cable near the connector.
 - b. Slide the spring, spring seat, and upper jaw on to the lower jaw and cable assembly.
 - c. Rotate the clamp nut clockwise for one-quarter turn. Do not tighten the nut.
10. Place the disinfected device in an appropriate dry storage area.

**CAUTION**

Keep the clamp nut loose for storage.

Before using the ANT again, see [“Inspecting the Adaptive Needle Tracker” on page 202.](#)

Sterilization Overview: Adaptive Needle Tracker

**CAUTION**

This information is provided as a summary for the sterilization procedure. Be sure to follow the full sterilization procedure in this manual.

**CAUTION**

The steam sterilizer should be validated to the requirements of any local standards (e.g. EN 285) and be in compliance with the equipment manufacturer’s instructions regarding installation and maintenance.

The adaptive needle tracker (ANT) can be sterilized using steam sterilization, which is a specific type of autoclaving process.

Steam Sterilization Overview

1. Review steam sterilization records. Discard the ANT if it has already been steam-sterilized for more than 20 cycles.
2. Place the disassembled ANT, the stylus, and the ruler together in a double-pouched configuration and place the pouch in sterilization chamber.
3. The ANT has been validated for two different steam sterilization cycles based on international standards to achieve a sterility assurance level (SAL) of 10⁻⁶. Please use the cycle appropriate for your geography:

	For USA customers (or geographies that are harmonized with USA regulation)	For EU customers (or geographies that are harmonized with EU-MDR regulation)
Sterilization type	Pre-vacuum	
Configuration	Double pouch	
Temperature	132°C (269.6°F)	134 °C (273.2°F)
Exposure time	4 minutes	3 minutes
Dry time	30 minutes	

4. Record the number of steam sterilization cycles.
5. Store the sterile ANT.

For the complete steam sterilization procedure, see [“Steam Sterilizing the Adaptive Needle Tracker” on page 200](#).

Sterilizing the Adaptive Needle Tracker



WARNING
Always use protective eyewear and gloves when cleaning, disinfecting, or sterilizing any equipment.

**CAUTION**

Do not use alcohol or any alcohol-based chemicals to clean the tracker.

**CAUTION**

Do not use automated cleaning devices with the Adaptive Needle Tracker (ANT).

If the ANT *will* be used in a sterile field, sterilize it after you clean it.

If the ANT *will not* be used in a sterile field, disinfect it (see [“Disinfecting the Adaptive Needle Tracker” on page 195](#)).

After the ANT has been cleaned, it is ready for sterilization.

Before starting sterilization, disassemble the ANT. For details, see [“Cleaning the Adaptive Needle Tracker” on page 190](#).

Steam Sterilizing the Adaptive Needle Tracker

**WARNING**

If the adaptive needle tracker is used in a sterile field or regularly contacts sterile tissue, you must sterilize it before use or storage.

**WARNING**

Always follow the indicated steam sterilization settings. Using other settings could result in unsuccessful sterilization or damage to the device.

**WARNING**

Do not steam sterilize the adaptive needle tracker for more than 20 cycles. Each steam sterilization cycle decreases product life. Sterilization beyond 20 cycles may compromise the structural integrity of the device and may lead to device failure or a risk of contamination, which may result in patient injury or illness. For tracking purposes, use the serial number found on the connector.

**WARNING**

After steam sterilization and before clinical use, inspect the adaptive needle tracker (ANT) for any signs of damage or degradation (such as cracked or broken plastic parts) before assembling the ANT and attaching it to the instrument. If you have questions about the warranty period and coverage in your purchase contract, contact your Philips representative.

**CAUTION**

The steam sterilizer should be validated to the requirements of any local standards (e.g. EN 285) and be in compliance with the equipment manufacturer's instructions regarding installation and maintenance.

1. Review steam sterilization records to ensure that the device has been steam-sterilized for less than 20 cycles.
2. Disassemble the ANT (see [“Cleaning the Adaptive Needle Tracker” on page 190](#)).
3. Place the disassembled ANT, the stylus, and the ruler together in a double-pouched configuration.
4. Place the pouch in the sterilization chamber.

- 5. The ANT has been validated for two different steam sterilization cycles based on international standards to achieve a sterility assurance level (SAL) of 10⁻⁶. Please use the cycle appropriate for your geography:

For USA customers (or geographies that are harmonized with USA regulation)		For EU customers (or geographies that are harmonized with EU-MDR regulation)
Sterilization type	Pre-vacuum	
Configuration	Double pouch	
Temperature	132°C (269.6°F)	134 °C (273.2°F)
Exposure time	4 minutes	3 minutes
Dry time	30 minutes	

- 6. Record the number of steam sterilization cycles. Use the ANT serial number (located on the connector) for tracking purposes.



- 7. Store the sterile ANT.
- 8. Before use, see [“Inspecting the Adaptive Needle Tracker” on page 202.](#)

Inspecting the Adaptive Needle Tracker

- 1. Visually inspect the adaptive needle tracker (ANT) for any degradation or damage to the device, such as cracks in the plastic housing. If you find damage, discard the ANT.
- 2. Turn on the ultrasound system and start PercuNav mode.
- 3. Connect the ANT to the tool connection unit (TCU). Ensure that the indicator on the TCU is green and that the ANT is tracking accurately within the tracking volume.

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Philips

Coaxial Needle Tracker (CNT)

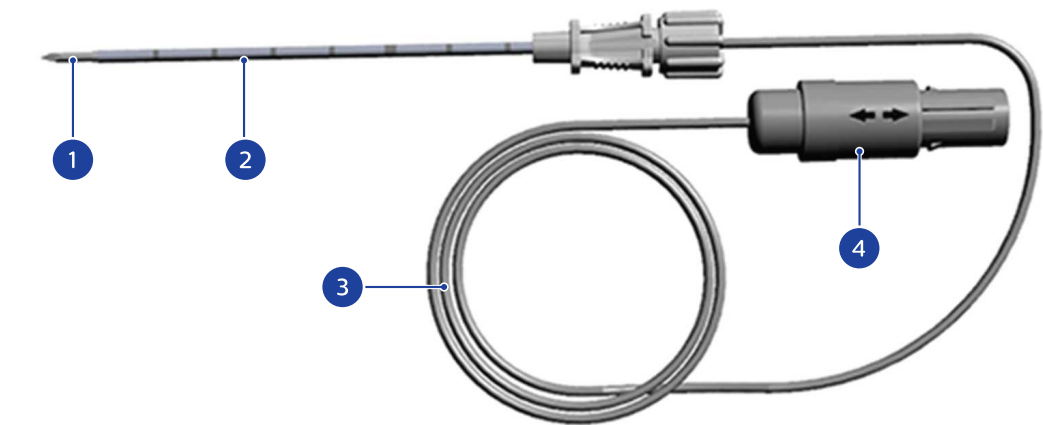
NOTE

The coaxial needle tracker is incompatible with the Affiniti 70 system.

Use the following information to ensure that the PercuNav system and the coaxial needle tracker (CNT) perform optimally, and that the CNT is used correctly.

CNTs are designed to be used only with the PercuNav system to target anatomical locations during percutaneous procedures (ablations and biopsies).

A CNT consists of a tracked stylet, an insulated cannulae, a cable, and a connector. A ruler is also provided for offset measurements.



CNT Components

1	Tracked stylet
2	Cannulae
3	Cable

Intended Patient Population

PercuNav Coaxial Needle Tracker (CNT) is intended for use with adult patients.

Coaxial Needle Tracker Warnings

Before using this instrument, read these warnings, the instrument-specific [“Instrument Warnings” on page 177](#), and the [“Safety”](#) section.



WARNING

The coaxial needle tracker is for single-patient use only. Do not reuse, reprocess or re-sterilize the tracker. Reuse, reprocessing, or re-sterilization may compromise the structural integrity of the device or may lead to device failure, which may result in patient injury, illness, or death. Also, reprocessing or re-sterilization of single-use devices may create a risk of contamination or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.



WARNING

When you use the coaxial needle tracker for virtual tracking, in certain anatomies and disease states, the tracked instruments may behave differently due to the needle bending when inserted in tissue. Be aware that factors such as gauge size, instrument length, anatomy, tumor size and type, and operator skill contribute to the overall accuracy of the system. If necessary, contact your Philips representative for clarification.

**WARNING**

If you encounter any unusual resistance while advancing the coaxial needle tracker (CNT), or if the instrument's tip behavior or location seem incorrect, stop manipulating the instrument and attempt to determine the cause (for example, by direct imaging). Failure to use proper caution may result in damage to the CNT, the tracked instrument, or patient tissue.

**WARNING**

The Coaxial Needle Tracker is EO-sterilized. Store in original packaging, indoors, cool, dry, and away from sunlight.

**WARNING**

The outer packaging is not sterile; the inner pouch is the Sterile Barrier System. Do not use the coaxial needle tracker if it is expired or its packaging has been previously opened, or the packaging or pouch damaged.

**WARNING**

When ready to use, open outer packaging using designated tabs. Open the pouch aseptically, avoid non-sterile contact, and present contents onto sterile field.

**WARNING**

Do not use the coaxial needle tracker if it is expired or its packaging has been previously opened or damaged.

**WARNING**

Do not attempt to use the coaxial needle tracker (CNT) if it is bent, damaged, or reshaped. Damage to the insulation of the CNT cannulae may result in serious burns to the patient or user.

**WARNING**

Do not attempt to use the coaxial needle tracker (CNT) if the PercuNav system generates a “tool not recognized” message when the CNT is connected to the PercuNav system.

**WARNING**

Only the stylet portion of the coaxial needle tracker is a tracked instrument. After the stylet is removed from the cannula, the cannula should remain in the pre-positioned location and orientation. If the cannula is displaced at any time, it should be repositioned using the PercuNav system with the tracked stylet and direct imaging.

**WARNING**

The coaxial needle tracker is designed for navigation through soft tissue and therefore is not to be used as a lever or chisel.

**WARNING**

Each coaxial needle tracker (CNT) is designed to function with various devices of a particular size from other manufacturers. Ensure the CNT selected is the appropriate gauge and length for the instrument being used. If necessary, contact your Philips representative for clarification.

**WARNING**

Do not perform PercuNav navigation while the ablation device is active, because system accuracy may be affected by noise generated by the ablation system.

**WARNING**

Ensure the offset is correct for the device being used. An incorrect offset or device deflection may result in inaccurate placement.

**WARNING**

Position the PercuNav system and tool connection unit so that the cable length of the coaxial needle tracker is sufficient to accommodate patient movement and for the physician to perform the procedure without straining the cable.

**WARNING**

Visually inspect the interventional device being used to ensure that there is no damage to the active tip or insulation. Follow the instructions for use provided by the manufacturer of the interventional device.

**WARNING**

Each coaxial needle tracker (CNT) consists of an electrically insulated metal introducer. Ensure that the CNT is safe to use with the selected interventional device.

**WARNING**

Follow the specifications provided by the manufacturer of the interventional device to determine how much of the device shall be exposed.

**WARNING**

Employ safe sharp handling techniques when using the coaxial needle tracker.

**WARNING**

After use, dispose of the coaxial needle tracker and its packaging in accordance with hospital, administrative, and local-government policy.

**WARNING**

To avoid introducing inaccuracies during a procedure, do not use a Philips tracked stylet with another manufacturer's cannula.

Preparing and Using the Coaxial Needle Tracker

NOTE

The PercuNav software can track only one instrument at a time. You can connect more than one needle tracker (CNT or eTRAX system) of different models to the tool connection unit (TCU), or a CNT and an ANT, but you can select only one for tracking. If you connect two needle trackers of the same model to the TCU, neither of those needle trackers can be selected for tracking.

**CAUTION**

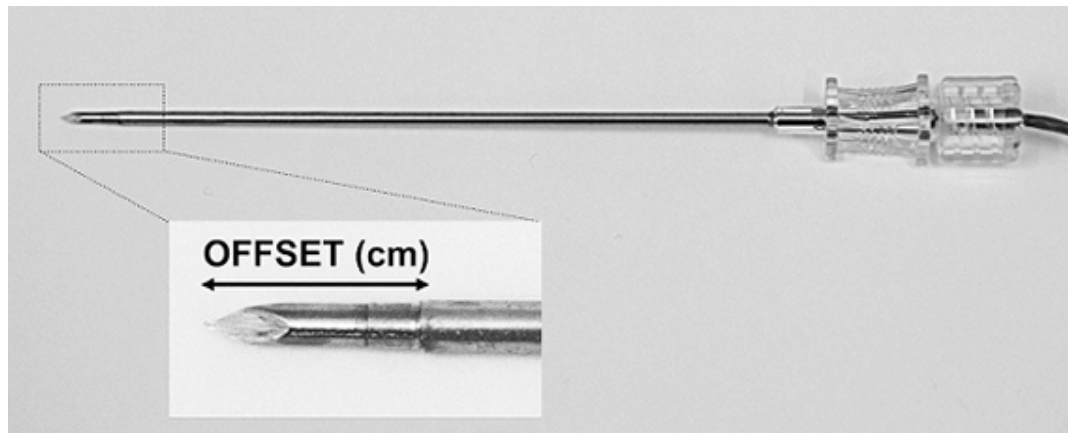
Throughout the following procedure, continuously verify the location of the stylet by using direct imaging.

1. Select the appropriate CNT for the instrument by referring to the cannula gauge and total cannula length indicated on the label. Ensure that the device will fit inside the cannula and that the exposed tip of the device (for example, sample notch, radiating tip) will extend fully beyond the distal end of the cannula.
2. Using standard aseptic technique, remove the CNT from the sterile pouch.

**WARNING**

Carefully perform the fit check, to avoid damage to the instrument (for example, exposed tip, insulation) and yourself.

3. Perform a fit check to confirm that the correct CNT is selected for the device being used. During the fit check, insert the device fully into the CNT cannula. The exposed tip (for example, sample notch, radiating tip) should extend beyond the distal end of the cannula.
4. For virtual tip tracking procedures, determine the tip offset value by measuring the distance from the distal end of the cannula to the distal tip of the instrument during the fit check.

**NOTE**

The hubs of each device should be touching.

5. Connect the CNT to the TCU. Verify that the device functions within the field generator volume.
6. If you are selecting the offset from a list of preset values, ensure the following:
 - The CNT has been identified properly. Check the catalog number and description reported by the PercuNav system.
 - The offset value applied to the CNT is correct and based on current specifications of the interventional device being used.
 - Settings in the selected instrument preset profile match the settings required for your procedure.

NOTE

During registration, only default offsets are available. During **Fusion/Nav**, both default and user-defined offsets are available.

7. Assemble the CNT with the tracked stylet. Make sure the tracked stylet is inserted into the cannula and is locked in place.
8. Complete the selected registration method and visually verify that the needle is tracking accurately.
9. If required, enter the offset measurement from the fit check or select the offset from your list of offset presets.

**WARNING**

Ensure the offset entered is correct for the device being used. An incorrect offset or device deflection may result in inaccurate placement.

10. Guide the CNT to the selected anatomical location. The cannula is marked with centimeter depth markings, and may be used as visual indicators during guidance.
11. After the targeted anatomical location is reached, hold the cannula in place, unlock the tracked stylet, and remove it from the cannula.
12. Verify the location of the stylet tip by using direct imaging.

NOTE

Touch **Needle Offset** to show or hide the offset display.

NOTE

The cannula should remain fixed in this position and orientation for the remainder of the procedure. If the cannula is displaced at any time, it should be repositioned with the tracked stylet or by using direct imaging.

NOTE

Additional cannulae may be positioned by inserting the tracked stylet into another cannula and repeating steps 1 through 12.

13. Fully insert the interventional device in the positioned cannula.
14. Verify the location of the interventional device by using direct imaging.
15. When the PercuNav procedure is complete:
 - a. Remove the interventional device from the cannula, and the cannula from patient per standard operating procedures.
 - b. Unplug the connector from the TCU.

**CAUTION**

To disconnect the instrument from the tool connection unit, grasp the connector plug and pull gently. Do not pull on the cable.

CIVCO eTRAX Needle Tip Tracking System

EPIQ systems support the CIVCO eTRAX needle tip tracking system (eTRAX system).

NOTE

The eTRAX system is incompatible with the Affiniti 70 system.

NOTE

Needle offset functions are not supported for the eTRAX system.

NOTE

The live ablation zone function is not supported for the eTRAX system.

The instructions for use (IFU) supplied with the CIVCO eTRAX system provide the following information:

- Description of components
- Illustration of components
- Indications for use
- Cautions and warnings
- Needle system assembly instructions
- Stylet removal instructions
- Cleaning and disinfecting instructions

The eTRAX system is designed to be used only with the PercuNav system to target anatomical locations during percutaneous procedures.

To ensure that the PercuNav system and the eTRAX system perform optimally and that the eTRAX sensor is used correctly, see [“Preparing and Using the eTRAX Needle Tip Tracking System” on page 214](#).

Preparing and Using the eTRAX Needle Tip Tracking System



CAUTION

Throughout the following procedure, continuously verify the location of the stylet by using direct imaging.

NOTE

The PercuNav software can track only one instrument at a time. You can connect more than one needle tracker (CNT or eTRAX system) of different models to the tool connection unit (TCU), or a CNT and an ANT, but you can select only one for tracking. If you connect two needle trackers of the same model to the TCU, neither of those needle trackers can be selected for tracking.

1. To assemble the eTRAX system, follow the instructions in the CIVCO eTRAX user documentation.



WARNING

Carefully perform the fit check, to avoid damage to the instrument (for example, exposed tip, a coating on the shaft of ablation devices) and yourself.



WARNING

Confirm that the treatment zones for ablation devices will be completely outside of the non-insulated sheath.

2. Perform a fit check to confirm that the correct eTRAX disposable needle system is selected for the device being used. During the fit check, insert the interventional device fully into the eTRAX sterile sheath. The exposed tip (for example, sample notch, radiating tip) should extend beyond the sterile (outer) sheath. The interventional device should also fit into the sheath without any resistance.
3. Connect the eTRAX sensor to the TCU. Verify that the device functions within the field generator volume.
4. Assemble the reusable sensor and the disposable needle system. Make sure the tracked stylet is properly inserted into the sheath. For assembly details, see the CIVCO eTRAX user documentation.
5. Guide the eTRAX needle system to the selected anatomical location. The sheath is marked with centimeter depth markings, which may be used as visual indicators during guidance.
6. After the targeted anatomical location is reached, hold the sheath in place and remove the tracked stylet from the sheath.

NOTE

The sheath should remain fixed in this position and orientation for the remainder of the procedure. If the sheath is displaced at any time, it should be repositioned with the tracked stylet or by using direct imaging.

7. Insert the interventional device in the positioned sheath.
8. Verify the location of the interventional device by using direct imaging.
9. When the PercuNav procedure is complete, remove the interventional device from the sheath, and then remove the sheath from the patient per standard operating procedures.



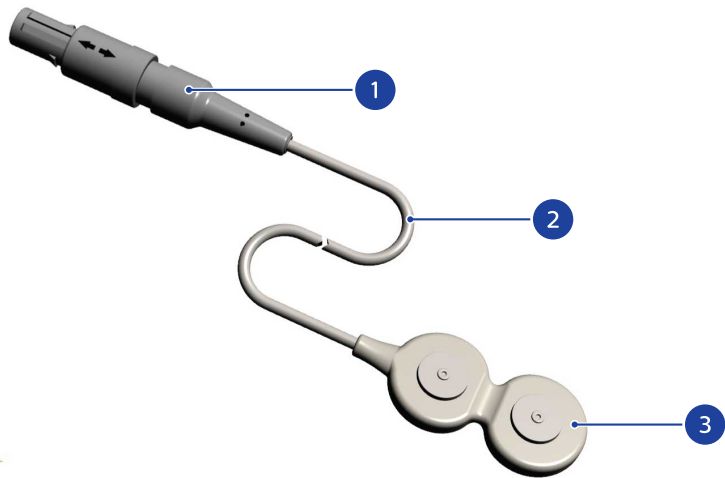
CAUTION

To disconnect the instrument from the tool connection unit, grasp the connector plug and pull gently. Do not pull on the cable.

Patient Tracker

Use the following information to ensure that the PercuNav system and the patient trackers perform optimally, and that the trackers are placed correctly and cleaned and disinfected thoroughly. The patient tracker is designed for use with the PercuNav system as a patient reference and, when three patient trackers are used, as a registration patch for the **Patient Tracker Match** registration method.

The patient tracker consists of a patch that contains two markers that are visible in CT, a cable, and a connector.



Patient Tracker Components

1	Connector
2	Cable

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3 Patch (circular features point away from the patient's skin)

To ensure optimal performance of the patient tracker:

- If you will be using the PercuNav respiratory tracking function, secure the patient reference tracker on a bony structure that moves with respiratory motions (for example, the sternum).
- Ensure that windows for ultrasound imaging and needle placement are available and uninhibited by placement of the patient tracker and that they are within the field generator volume. When used for registration, ensure placement near area of interest in various planes.

NOTE

The respiratory motion curve reflects the motion of the patient tracker and does not correlate directly to internal organ motion during respiration.

Placing and Removing a Patient Tracker

Before using this instrument, read these warnings, the instrument-specific [“Instrument Warnings” on page 177](#), and the [“Safety”](#) section.



WARNING

Before the first use, disinfect the patient tracker. See [“Disinfecting the Patient Tracker” on page 225](#).



WARNING

Ask the patient if they are allergic to adhesives, to determine what type of adhesive to use.

**WARNING**

Apply the patient tracker only to intact skin. This instrument is for external use only.

**WARNING**

Avoid placing the patient tracker near any sources of metal interference, such as the CT gantry and patient table.

**WARNING**

To reinforce patch placement, it may be necessary to shave or clean the patient's skin with alcohol. Allow the alcohol to dry before applying the patient tracker.

**WARNING**

The patient trackers must remain in place during scanning and until registration is complete.

**WARNING**

This instrument may perform suboptimally on obese patients, due to a lack of palpable bony structures to guide the placement of the patient tracker. As a result, the accuracy of the image registration may also be suboptimal.

**CAUTION**

If the patient tracker is damaged, or after the final use, dispose of the instrument in accordance with hospital, administrative, or local-government policy.

**CAUTION**

Do not bend the patient tracker patch more than necessary.

NOTE

When you use a CNT, ANT, or eTRAX system in **Fusion/Nav**, position the reference patient tracker as close as possible to the intended navigation target, to ensure optimal instrument performance.

For information on using the patient tracker for registration, see [“Registration: Fusion” on page 280](#) or [“Registration: CT Only” on page 321](#).

For assistance during placement, see the figure in [“Patient Tracker” on page 216](#).

1. Place the patient tracker, with the circular features pointing away from the skin, on bony structures surrounding the area of interest for optimal registration accuracy, and with the cable directed away from the work area.
2. Secure the patient trackers to the patient’s skin around the region of interest on bony structures using an adhesive (for example, Tegaderm dressing). It is imperative that the trackers remain fixed in position on the patient's skin.
3. Connect the patient tracker to the TCU. Verify that the device functions within the field generator volume.
4. Start a PercuNav procedure.
5. When the procedure is complete, disconnect the patient trackers from the TCU, and remove the patch from the patient by first removing the adhesives.

**CAUTION**

To disconnect the instrument from the tool connection unit, grasp the connector plug and pull gently. Do not pull on the cable.

- 6. Immediately after each use, follow the cleaning and disinfection guidelines to decontaminate the instrument. See [“Cleaning the Patient Tracker” on page 221](#) and [“Disinfecting the Patient Tracker” on page 225](#).

Cleaning Overview: Patient Tracker



CAUTION

This information is provided as a summary for the cleaning procedure. Be sure to follow the full cleaning procedure in this manual.

Cleaning Overview: Patient Tracker

- 1. Prepare the cleaning solution.
- 2. Soak a lint-free cloth and a cotton swab in the cleaning solution.
- 3. Using the soaked cloth and the cotton swab, wipe and swab each section of the tracker for the time indicated in the following table and until visible soil is removed.



WARNING

Use a new wipe and swab for each tracker section.

- 4. Repeat the wipe and swab with lukewarm tap water (22°C to 43°C [72°F to 110°F]) to remove cleaning residue.

Cleaning Wipe and Swab Durations

Sensor Housing	Sensor Housing Pinholes	Cable	Connector Pinholes	Connector
1 minute	As required	30 seconds	As required	30 seconds

Cleaning the Patient Tracker

Establish and clearly post the following cleaning and disinfection procedures. Cleaning the tracker is an essential step before effective disinfection.

Immediately after each patient use, decontaminate the tracker according to these cleaning and disinfection procedures, to protect patients and personnel from transmission of potential pathogens.



WARNING

Always use protective eyewear and gloves when cleaning, disinfecting, or sterilizing any equipment.



WARNING

Throughout the cleaning procedure, discard and replace soiled wipes or cotton swabs as needed. Continue cleaning until you have removed all visible soil from the tracker.



CAUTION

Do not use alcohol or any alcohol-based chemicals to clean the tracker.



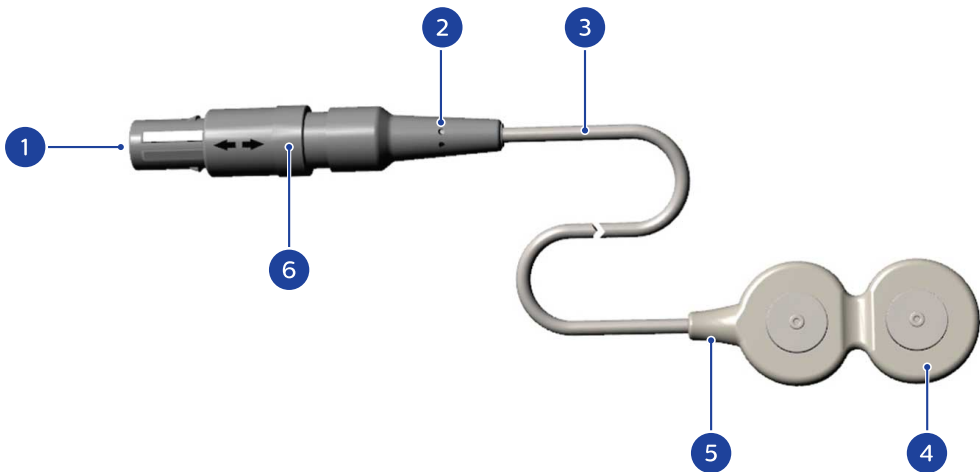
CAUTION

Do not allow sharp objects, such as scalpels or cauterizing knives, to come in contact with the tracker, including the cable.



CAUTION
Do not use a wire brush to clean the tracker.

For assistance during cleaning, see the following figure.



Patient Tracker Components

1	Opening to electrical connections
2	Pinholes on the connector strain relief
3	Cable
4	Patch
5	Pinholes on the patch strain relief
6	Connector

1. Prepare one of the following solutions for use in this cleaning process:
 - A mild detergent solution or surfactant: 5 ml (1 tsp) of concentrated liquid detergent into 3.8 l (1 gal) of lukewarm tap water (22°C to 43°C [72°F to 110°F])

- An enzymatic cleaning solution prepared according to the manufacturer's instructions, such as Enzol Enzymatic Detergent or Steris Polystica 2x Concentrate Enzymatic Presoak and Cleaner.
2. With the prepared solution, wet a lintless, sharp-tip, cotton swab and a clean, soft, lint-free wipe (or cloth), and squeeze out the excess liquid.

NOTE

The swab and the wipe or cloth should be damp but not dripping.

3. Use the damp swab to thoroughly clean the pinholes on the patch strain relief, until you remove all visible soil.
4. Use the damp wipe to thoroughly wipe the entire surface of the patient tracker patch. Pay careful attention to the area where the adhesive was applied, to remove any adhesive residue. Wipe the patch for a minimum of 1 minute and until you remove all visible soil.
5. Use a new solution-dampened wipe to thoroughly wipe the entire cable for a minimum of 30 seconds and until you remove all visible soil.
6. Use a new solution-dampened swab to thoroughly clean the pinholes on the connector strain relief, until you remove all visible soil.
7. Use a new solution-dampened wipe to thoroughly wipe the connector portion of the patient tracker. Wipe the connector for a minimum of 30 seconds and until you remove all visible soil.

**CAUTION**

Throughout the cleaning process, protect the connector to keep liquid out of the connector's electrical contacts.

8. Wet a new clean, soft, lint-free wipe (or cloth) with lukewarm tap water (22°C to 43°C [72°F to 110°F]). Squeeze out excess liquid.

NOTE

The wipe or cloth should be damp but not dripping.

9. Use the damp wipe to thoroughly wipe the patient tracker patch for a minimum of 30 seconds to remove cleaning residue.
10. Rewet the wipe with lukewarm tap water and thoroughly wipe the entire cable for a minimum of 30 seconds.
11. Rewet the wipe with lukewarm tap water and carefully wipe the connector portion for a minimum of 30 seconds.
12. After wiping, thoroughly dry the patient tracker patch, cable, and connector with a clean, dry, lint-free wipe or cloth.
13. Visually inspect the patient tracker in a well-lit area to confirm the absence of any soil or adhesive.
14. If you see any soil or adhesive, repeat step 2 through step 13 (using fresh wipes and cotton swabs) until you see no soil or adhesive.
15. If you see no soil or adhesive, and the device is completely dry, the patient tracker is ready for disinfection (see [“Disinfecting the Patient Tracker” on page 225](#)).

Disinfection Overview: Patient Tracker**CAUTION**

This information is provided as a summary for the disinfecting procedure. Be sure to follow the full disinfecting procedure in this manual.

Intermediate-level Disinfection Overview: Patient Tracker

- 1. Using a disinfectant wipe, wipe each section of the tracker for the time indicated in the following table and until the surface is damp.



WARNING
Use a new wipe for each tracker section.

- 2. Allow the tracker to stand for the minimum time required by the disinfectant manufacturer.
- 3. With sterile water, repeat the wipe for at least 1 minute.

Disinfection Wipe and Swab Durations

Sensor Housing	Sensor Housing Pinholes	Cable	Connector Pinholes	Connector	Entire Tracker
30 seconds	3 seconds	30 seconds	3 seconds	30 seconds	30 seconds

Disinfecting the Patient Tracker

After the tracker has been cleaned, it is ready for disinfection.



WARNING
Always use protective eyewear and gloves when cleaning, disinfecting, or sterilizing any equipment.

**CAUTION**

Do not use alcohol or any alcohol-based chemicals to clean the tracker.

**CAUTION**

Throughout the cleaning process, protect the connector to keep liquid out of the connector's electrical contacts.

**CAUTION**

Do not autoclave the tracker.

For assistance during disinfection, see the image in [“Cleaning the Patient Tracker” on page 221](#).

1. Put the cleaned tracker alone in a clean, dry, disinfected or sterilized basin, placing the connector in an upward position, away from the cable and patch portions of the device, to prevent liquid or moisture from entering the connector.
2. Using one of the disinfectant wipes described in [“Recommended Instrument Disinfectants” on page 179](#), thoroughly wipe the entire surface of the patient tracker patch for a minimum of 30 seconds.
3. Use a new disinfectant wipe to thoroughly wipe the cable portion of the patient tracker in both directions for a minimum of 30 seconds.
4. Use a new disinfectant wipe to thoroughly wipe the connector portion of the patient tracker for a minimum of 30 seconds.

**CAUTION**

Throughout the cleaning process, protect the connector to keep liquid out of the connector's electrical contacts.

5. Use a disinfectant-saturated swab to wipe each pinhole on the patch and connector strain reliefs for 3 seconds.

NOTE

The swab should be damp but not dripping.

6. Use a new disinfectant wipe to thoroughly wipe all sections of the patient tracker for a minimum of 30 seconds to ensure that all surfaces are damp.
7. Allow the patient tracker to stand after wiping for the minimum time required by the wipe manufacturer. If you are using the 1:10 bleach solution, allow the tracker to stand for a minimum of 4 minutes.
8. After the minimum standing time, saturate a clean, lint-free, sterile wipe with sterile water and squeeze out excess liquid.

NOTE

The wipe or cloth should be damp but not dripping.

9. Use the wipe saturated with sterile water to thoroughly wipe the patch, cable, and connector portion of the patient tracker for a minimum of 1 minute. Pay careful attention to the pinholes on the strain reliefs.



CAUTION

Throughout the cleaning process, protect the connector to keep liquid out of the connector’s electrical contacts.

- 10. Allow the patient tracker to air dry and place the disinfected device in an appropriate dry storage area.

Ultrasound Trackers

The PercuNav system supports two ultrasound trackers, model numbers 20004 and 21001. The trackers are approved for use with the following transducers:

Ultrasound Trackers and Supported Transducers

Ultrasound Tracker Model Number	Supported Transducers
20004	C5-1, C9-2, L12-5, S5-1, X6-1 ¹
21001	C10-4ec

¹ EPIQ systems only

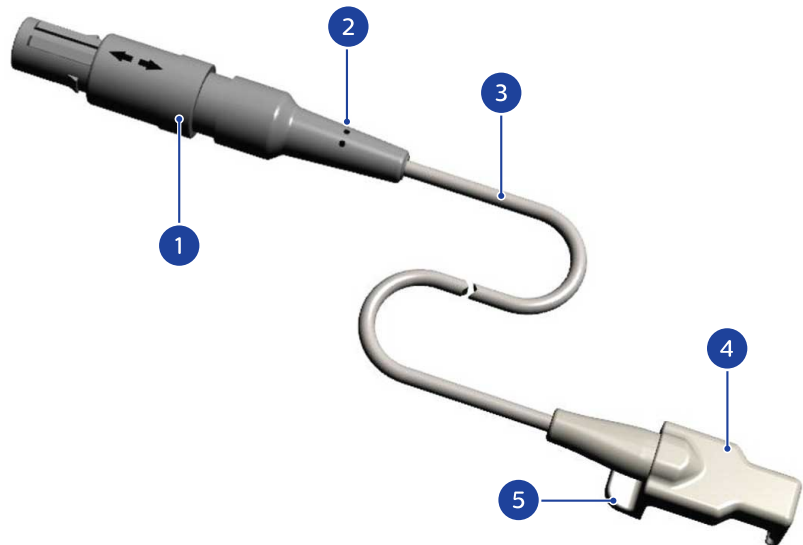
Use the following information to ensure that the PercuNav system and the ultrasound tracker perform optimally, and that the trackers are used correctly and cleaned and disinfected thoroughly. The ultrasound trackers are designed to be used with the PercuNav system for a variety of diagnostic or interventional procedures using ultrasound. For more information, see the “[Procedure: Ultrasound Only](#)” section or the “[Procedure: Fusion](#)” section.

Model 20004 Ultrasound Tracker

The Model 20004 ultrasound tracker is for use with the C5-1, C9-2, L12-5, S5-1, and X6-1 (EPIQ systems only) transducers. The ultrasound tracker consists of a connector, a cable, and a tracked-sensor housing with a release tab that attaches to the CIVCO needle-guidance system.

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Model 20004 Ultrasound Tracker Components

1	Connector (opening to electrical connections)
2	Pinholes on the connector strain relief
3	Cable
4	Sensor housing
5	Release tab



WARNING

Before use, each tracker must be cleaned and disinfected according to the instructions provided in this manual. Failure to follow the cleaning and disinfection instructions creates a risk of contamination and patient infection. See [“Cleaning the Model 20004 Ultrasound Tracker” on page 234](#) and [“Disinfecting the Model 20004 Ultrasound Tracker” on page 239](#).

**WARNING**

Before use, inspect the tracker for any signs of damage or degradation. Do not use if it shows any sign of damage or degradation.

**CAUTION**

Do not attempt to service the tracker. Doing so voids the warranty.

Attaching and Removing the Model 20004 Ultrasound Tracker

Before using the Model 20004 ultrasound tracker, read these cautions, the instrument-specific [“Instrument Warnings” on page 177](#), and the [“Safety”](#) section.

**CAUTION**

Position the PercuNav system and tool connection unit so that the tracker cable is not strained during the procedure.

NOTE

Make sure that the CIVCO needle guidance system is compatible with the transducer model that you are using.

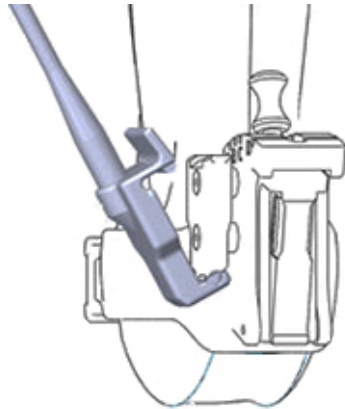
For assistance during placement, see the image in [“Model 20004 Ultrasound Tracker” on page 228](#).

1. Select the appropriate ultrasound tracker for the transducer that you will use for the procedure.

NOTE

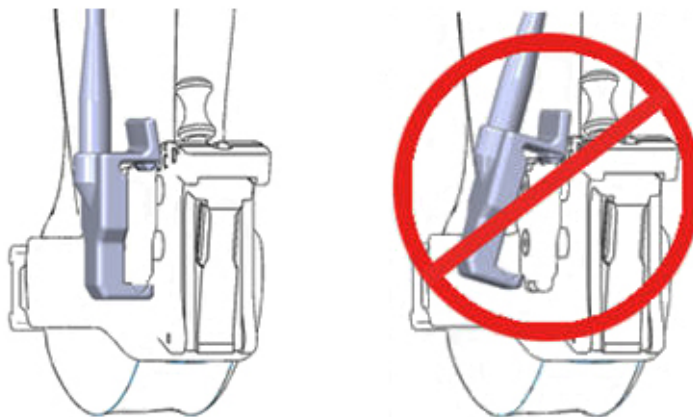
Check the label on the sensor housing to make sure that it is compatible with the transducer that you are using.

2. Select the appropriate CIVCO tracking bracket for the transducer that you will use for the procedure.
3. Attach the CIVCO tracking bracket to the transducer. For details, see the instructions provided with the tracking bracket.
4. Securely attach the tracker to the mounting feature of the tracking bracket.
 - a. Align the bottom of the tracker with the bracket-mounting feature.
 - b. Push the tracker onto the bracket-mounting feature, until it snaps into place.



**CAUTION**

Do not attach the top of the tracker first. This can damage the tracker.

**NOTE**

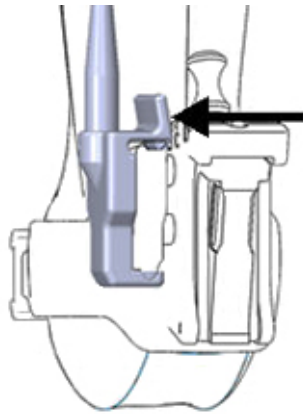
Step 5 is optional. Your procedure may not require a cover for the transducer and needle-guidance bracket.

5. Insert the transducer and the tracking bracket into the cover provided with the tracking bracket. For details, see the instructions provided by the manufacturer.
6. Connect the tracker to the TCU. Verify that the device functions within the field generator volume.

**CAUTION**

Do not strain the tracker cable near the attachment site of the needle-guidance system.

7. Start a PercuNav procedure. For details, see the [“Procedure: Ultrasound Only”](#) section or the [“Procedure: Fusion”](#) section.
8. When the PercuNav procedure is complete, remove the cover from the transducer and tracking bracket (if applicable).
9. Unclip the tracker from the tracking bracket by gently pulling the top release tab away from the transducer.



10. Disconnect the tracker from the TCU.

**CAUTION**

To disconnect the instrument from the tool connection unit, grasp the connector plug and pull gently. Do not pull on the cable.

11. Immediately after each use, clean and disinfect the tracker. For more information, see [“Cleaning the Model 20004 Ultrasound Tracker” on page 234](#) and [“Disinfecting the Model 20004 Ultrasound Tracker” on page 239](#).

Cleaning Overview: Model 20004 Ultrasound Tracker



CAUTION

This information is provided as a summary for the cleaning procedure. Be sure to follow the full cleaning procedure in this manual.

- 1. Prepare the cleaning solution.
- 2. Soak a lint-free cloth and a cotton swab in the cleaning solution.
- 3. Using the soaked cloth and the cotton swab, wipe and swab each section of the tracker for the time indicated in the following table and until visible soil is removed.



WARNING

Use a new wipe and swab for each tracker section.

- 4. Repeat the wipe with lukewarm tap water (22°C to 43°C [72°F to 110°F]) to remove cleaning residue.

Cleaning Wipe and Swab Durations: Model 20004 Ultrasound Tracker

Sensor Housing	Cable	Connector Pinholes	Connector
1 minute	30 seconds	As required	30 seconds

Cleaning the Model 20004 Ultrasound Tracker

Establish and clearly post the following cleaning and disinfecting procedures.

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Cleaning the tracker is an essential step before effective disinfection. Immediately after each use, remove the tracker from the transducer and disconnect it from the TCU. Then clean and disinfect the tracker using these procedures, to protect patients and personnel from transmission of potential pathogens.

**WARNING**

Always use protective eyewear and gloves when cleaning, disinfecting, or sterilizing any equipment.

**WARNING**

Throughout the cleaning procedure, discard and replace soiled wipes or cotton swabs as needed. Continue cleaning until you have removed all visible soil from the tracker.

**CAUTION**

Do not use alcohol or any alcohol-based chemicals to clean the tracker.

**CAUTION**

Do not allow sharp objects, such as scalpels or cauterizing knives, to come in contact with the tracker, including the cable.

**CAUTION**

Throughout the cleaning process, protect the connector to keep liquid out of the connector's electrical contacts.

**CAUTION**

Do not use a wire brush to clean the tracker.

**CAUTION**

Do not autoclave the tracker.

For assistance during disinfection, see the figure in [“Model 20004 Ultrasound Tracker” on page 228](#).

1. Prepare one of the following solutions for use in this cleaning process:
 - A mild detergent solution or surfactant: 5 ml (1 tsp) of concentrated liquid detergent into 3.8 l (1 gal) of lukewarm tap water (22°C to 43°C [72°F to 110°F])
 - An enzymatic cleaning solution prepared according to the manufacturer’s instructions, such as Enzol Enzymatic Detergent or Steris Prolystica 2x Concentrate Enzymatic Presoak and Cleaner.
2. With the prepared solution, wet a clean, soft, lint-free wipe (or cloth), and squeeze out the excess liquid.

NOTE

The wipe or cloth should be damp but not dripping.

3. Use the damp wipe to thoroughly wipe the entire surface of the sensor housing and release tab. Pay careful attention to the finger grips on the release tab. Wipe the sensor housing and release tab for a minimum of 1 minute and until you remove all visible soil.
4. Use a new solution-dampened wipe to thoroughly wipe the entire cable for a minimum of 30 seconds and until you remove all visible soil.

5. With the prepared solution, wet a lintless, sharp-tip, cotton swab and squeeze out the excess liquid.

NOTE

The swab should be damp but not dripping.

6. Use the swab to thoroughly clean the pinholes on the connector strain relief, until you remove all visible soil.
7. Use a new solution-dampened wipe to thoroughly wipe the connector portion of the ultrasound tracker for a minimum of 30 seconds and until you remove all visible soil.



CAUTION

Throughout the cleaning process, protect the connector to keep liquid out of the connector's electrical contacts.

8. Wet a new clean, soft, lint-free wipe (or cloth) with lukewarm tap water (22°C to 43°C [72°F to 110°F]). Squeeze out excess liquid.

NOTE

The wipe or cloth should be damp but not dripping.

9. Use the damp wipe to thoroughly wipe the release tab and sensor housing for a minimum of 30 seconds to remove cleaning residue.
10. Rewet the wipe with lukewarm tap water and thoroughly wipe the entire cable for a minimum of 30 seconds.

11. Rewet the wipe with lukewarm tap water and carefully wipe the connector portion for a minimum of 30 seconds.
 12. After wiping, thoroughly dry the release tab, sensor housing, and cable with a clean, dry, lint-free wipe or cloth.
 13. Visually inspect the tracker in a well-lit area to confirm the absence of any soil or adhesive.
 14. If you see any soil or adhesive, repeat step 2 through step 13 (using fresh wipes and cotton swabs) until you see no soil or adhesive.
 15. If you see no soil or adhesive, and the tracker is completely dry, it is ready for disinfection.
- For more information, see [“Disinfecting the Model 20004 Ultrasound Tracker”](#) on page 239.

Disinfection Overview: Model 20004 Ultrasound Tracker



CAUTION

This information is provided as a summary for the disinfecting procedures. Be sure to follow the full disinfecting procedure in this manual.

Intermediate-level Disinfection Overview

1. Using a disinfectant wipe, wipe each section of the tracker for the time indicated in the following table and until the surfaces are damp.



WARNING

Use a new wipe for each tracker section.

2. Allow the tracker to stand for the minimum time required by disinfectant manufacturer.
3. With sterile water, repeat the wipe for at least 1 minute.

Intermediate Disinfection Wipe and Swab Durations

Sensor Housing	Cable	Connector Pinholes	Connector	Entire Tracker
30 seconds	30 seconds	3 seconds	30 seconds	30 seconds

Disinfecting the Model 20004 Ultrasound Tracker

After the tracker has been cleaned, it is ready for disinfection.



WARNING

Always use protective eyewear and gloves when cleaning, disinfecting, or sterilizing any equipment.



CAUTION

Do not use alcohol or any alcohol-based chemicals to clean the tracker.



CAUTION

Throughout the cleaning process, protect the connector to keep liquid out of the connector’s electrical contacts.



CAUTION

Do not autoclave the tracker.

For assistance during disinfection, see the figure in [“Model 20004 Ultrasound Tracker” on page 228](#).

1. Put the cleaned tracker alone in a clean, dry, disinfected or sterilized basin, placing the connector in an upward position, away from the cable, to prevent liquid or moisture from entering the connector.
2. Using one of the disinfectant wipes described in [“Recommended Instrument Disinfectants” on page 179](#), thoroughly wipe the entire surface of the sensor housing and release tab for a minimum of 30 seconds.
3. Use a new disinfectant wipe to thoroughly wipe the cable portion of the ultrasound tracker in both directions for a minimum of 30 seconds.
4. Use a new disinfectant wipe to thoroughly wipe the connector portion of the ultrasound tracker for a minimum of 30 seconds.

**CAUTION**

Throughout the cleaning process, protect the connector to keep liquid out of the connector's electrical contacts.

5. Use a disinfectant-saturated swab to wipe each pinhole on the connector strain relief for 3 seconds.

NOTE

The swab should be damp but not dripping.

6. Use a new disinfectant wipe to thoroughly wipe all sections of the tracker for a minimum of 30 seconds to ensure that all surfaces are damp.

7. Allow the tracker to stand after wiping for the minimum time required by the wipe manufacturer. If you are using the 1:10 bleach solution, allow the tracker to stand for a minimum of 4 minutes.
8. After the minimum standing time, saturate a clean, lint-free, sterile wipe with sterile water and squeeze out excess liquid.

NOTE

The wipe or cloth should be damp but not dripping.

9. Use the wipe saturated with sterile water to thoroughly wipe the sensor housing, release tab, cable, and connector portion of the tracker for a minimum of 1 minute. Pay careful attention to the pinholes on the connector strain relief.

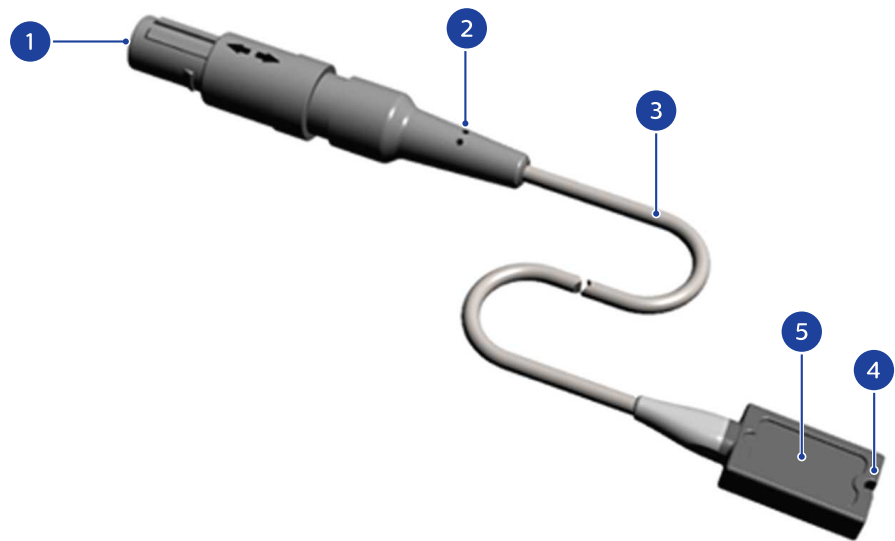
**CAUTION**

Throughout the cleaning process, protect the connector to keep liquid out of the connector's electrical contacts.

10. Allow the tracker to air dry.
11. Place the disinfected device in an appropriate dry storage area.

Model 21001 Ultrasound Tracker

The Model 21001 ultrasound tracker is for use with the C10-4ec transducer and consists of a connector, a cable, and a tracked-sensor housing that attaches to the CIVCO tracking bracket.



Cleaning: Model 21001 Ultrasound Tracker Components

1	Connector (opening to electrical connections)
2	Pinholes on the connector strain relief
3	Cable
4	Tracker sensor housing
5	Tracker indent (for aligning to the tracking bracket)



WARNING

Before use, each tracker must be cleaned and disinfected according to the instructions provided in this manual. Failure to follow the cleaning and disinfection instructions creates a risk of contamination and patient infection. See [“Cleaning the Model 21001 Ultrasound Tracker” on page 247](#) and [“Disinfecting the Model 21001 Ultrasound Tracker” on page 253](#).

**WARNING**

Before use, inspect the tracker for any signs of damage or degradation. Do not use if it shows any sign of damage or degradation.

**CAUTION**

Do not attempt to service the ultrasound tracker. Doing so voids the warranty.

Attaching and Removing the Model 21001 Ultrasound Tracker

Before using the Model 21001 ultrasound tracker, read the following cautions, the [“Instrument Warnings” on page 177](#), and the [“Safety”](#) section.

**CAUTION**

Position the PercuNav system and tool connection unit so that the tracker cable is not strained during the procedure.

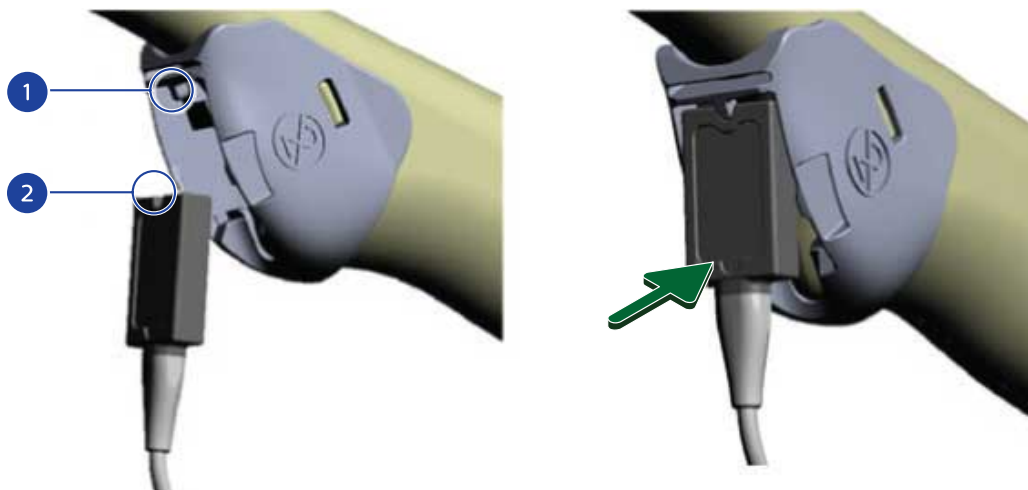
**CAUTION**

Ensure that the CIVCO tracking bracket is compatible with the transducer that you are using.

For assistance during placement, see the figure in [“Model 21001 Ultrasound Tracker” on page 241](#).

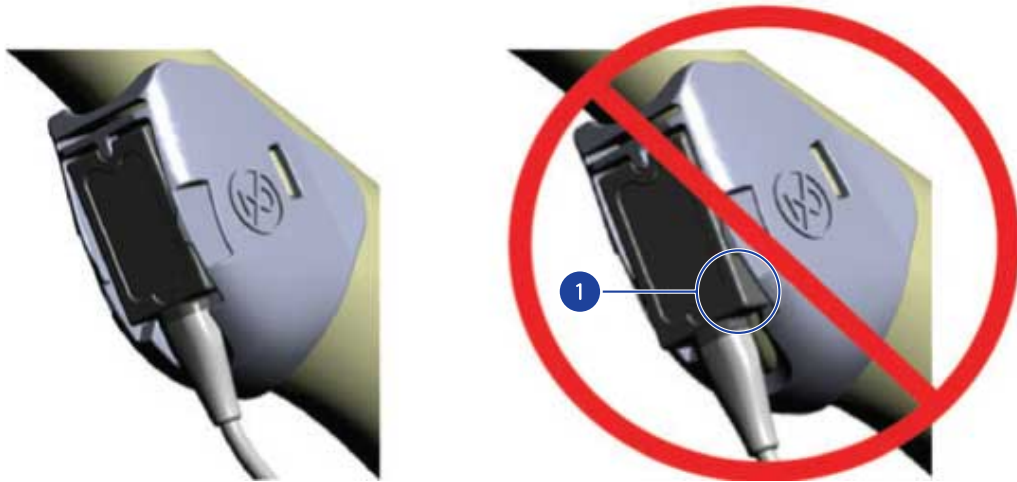
1. Select the CIVCO tracking bracket that is compatible with the transducer model that you are using.

2. Attach the CIVCO tracking bracket to the transducer. For details, see the instructions provided with the CIVCO tracking bracket. Ensure that the bracket is securely attached to the transducer.
3. Attach the tracker sensor housing to the CIVCO tracking bracket.
 - a. Align the indent (see callout 2 in the following figure) of the tracker sensor housing with the raised feature (see callout 1 in the following figure) on the bracket.
 - b. Press the tracker sensor housing into the tracking bracket, until it is seated fully and snaps into place.



**CAUTION**

Ensure that the tracker sensor housing is seated fully in the bracket, with no gap (see callout 1 in the following figure) between the tracker sensor housing and the bracket.



4. Insert the transducer, the tracker, and the tracking bracket into the sterile CIVCO cover. For details, see the instructions provided with the tracking bracket.

**WARNING**

Follow your site-specific protocols to ensure that there is no risk of patient cross-contamination.

5. Connect the tracker to the tool connection unit (TCU). Verify that the tracker is being tracked within the field generator volume.

**CAUTION**

Do not strain the tracker cable near the attachment site of the tracking bracket.

6. Start a PercuNav procedure. For details, see the [“Procedure: Ultrasound Only”](#) section or the [“Procedure: Fusion”](#) section.

**WARNING**

Pressure on the tissue may cause tissue deformation and degradation in image fusion quality. To best match the patient anatomy as imaged with MRI, cautiously apply only minimal pressure with the transducer.

7. When the PercuNav procedure is complete, remove the CIVCO needle-guidance system (if necessary) and the cover from the transducer and tracking bracket.
8. Detach the tracker sensor housing from the tracking bracket by gently pulling the tracker strain relief away from the transducer and tracking bracket.
9. Disconnect the tracker from the TCU.

**CAUTION**

To disconnect the tracker from the TCU, grasp the connector plug and pull gently. Do not pull on the cable.

10. Immediately after each use, clean and disinfect the tracker. For more information, see [“Cleaning the Model 21001 Ultrasound Tracker”](#) on page 247 and [“Disinfecting the Model 21001 Ultrasound Tracker”](#) on page 253.

Cleaning Overview: Model 21001 Ultrasound Tracker



CAUTION

This information is provided as a summary for the cleaning procedure. Be sure to follow the full cleaning procedure in this manual.

- 1. Prepare the cleaning solution.
- 2. Soak a lint-free cloth and a cotton swab in the cleaning solution.
- 3. Using the soaked cloth and the cotton swab, wipe and swab each section of the tracker for the time indicated in the following table and until visible soil is removed.



WARNING

Use a new wipe and swab for each tracker section.

- 4. Repeat the wipe and swab with lukewarm tap water (22°C to 43°C [72°F to 110°F]) to remove cleaning residue.

Cleaning Wipe and Swab Durations: Model 21001 Ultrasound Tracker

Sensor Housing	Cable	Connector Pinholes	Connector
1 minute	30 seconds	As required	30 seconds

Cleaning the Model 21001 Ultrasound Tracker

Establish and clearly post the following cleaning and disinfection procedures.

Cleaning the tracker is an essential step before effective disinfection. Immediately after each use, remove the tracker from the transducer and disconnect it from the TCU. Then clean and disinfect the tracker using these procedures, to protect patients and personnel from transmission of potential pathogens.

**WARNING**

Always use protective eyewear and gloves when cleaning, disinfecting, or sterilizing any equipment.

**WARNING**

Throughout the cleaning procedure, discard and replace soiled wipes or cotton swabs as needed. Continue cleaning until you have removed all visible soil from the tracker.

**CAUTION**

Do not use alcohol or any alcohol-based chemicals to clean the tracker.

**CAUTION**

Do not allow sharp objects, such as scalpels or cauterizing knives, to come in contact with the tracker, including the cable.

**CAUTION**

Throughout the cleaning process, protect the connector to keep liquid out of the connector's electrical contacts.

**CAUTION**

Do not use a wire brush to clean the tracker.

**CAUTION**

Do not autoclave the tracker.

For assistance during cleaning, see the figure in [“Model 21001 Ultrasound Tracker” on page 241](#).

1. Prepare one of the following cleaning solutions:
 - A mild detergent solution or surfactant: 5 ml (1 tsp) of concentrated liquid detergent in 3.8 l (1 gal) of lukewarm tap water (22°C to 43°C [72°F to 110°F])
 - An enzymatic cleaning solution prepared according to the manufacturer’s instructions, such as Enzol Enzymatic Detergent or Steris Prolystica 2x Concentrate Enzymatic Presoak and Cleaner.
2. With the prepared solution, wet a clean, soft, lint-free wipe (or cloth), and squeeze out the excess liquid.

NOTE

The wipe or cloth should be damp but not dripping.

3. Use the damp wipe to thoroughly wipe the entire surface of the tracker sensor housing. Pay careful attention to the indent at the top of the tracker sensor housing. Wipe the tracker sensor housing and indent for a minimum of 1 minute and until you remove all visible soil.

4. Use a new solution-dampened wipe to thoroughly wipe the entire cable for a minimum of 30 seconds and until you remove all visible soil.
5. With the prepared solution, wet a lintless, sharp-tip, cotton swab and squeeze out the excess liquid.

NOTE

The swab should be damp but not dripping.

6. Use the swab to thoroughly clean the pinholes on the connector strain relief, until you remove all visible soil.
7. Use a new solution-dampened wipe to thoroughly wipe the connector portion of the tracker for a minimum of 30 seconds and until you remove all visible soil.

**CAUTION**

Throughout the cleaning process, protect the connector to keep liquid out of the connector's electrical contacts.

8. Wet a new clean, soft, lint-free wipe (or cloth) with lukewarm tap water (22°C to 43°C [72°F to 110°F]). Squeeze out excess liquid.

NOTE

The wipe or cloth should be damp but not dripping.

9. Use the damp wipe to thoroughly wipe the tracker sensor housing for a minimum of 30 seconds to remove cleaning residue.

10. Rewet the wipe with lukewarm tap water and thoroughly wipe the entire cable for a minimum of 30 seconds.
11. Rewet the wipe with lukewarm tap water and carefully wipe the connector for a minimum of 30 seconds.
12. After wiping, thoroughly dry the tracker sensor housing and cable with a clean, dry, lint-free wipe or cloth.
13. Visually inspect the tracker in a well-lit area to confirm the absence of any soil or adhesive.
14. If you see any soil or adhesive, repeat step 2 through step 13 (using fresh wipes and cotton swabs) until you see no soil or adhesive.
15. If you see no soil or adhesive, and the tracker is completely dry, it is ready for disinfection.

Disinfection Overview: Model 21001 Ultrasound Tracker



CAUTION

This information is provided as a summary for the disinfecting procedures. Be sure to follow the full disinfecting procedure in this manual.

The Model 21001 ultrasound tracker can be disinfected using either intermediate-level or high-level disinfection.

Intermediate-level Disinfection Overview

1. Using a disinfectant wipe, wipe each section of the tracker for the time indicated in the following table and until the surfaces are damp.



WARNING

Use a new wipe for each tracker section.

- 2. Allow the tracker to stand for the minimum time required by disinfectant manufacturer.
- 3. With sterile water, repeat the wipe for at least 1 minute.

Intermediate Disinfection Wipe Durations

Sensor Housing	Cable	Connector Pinholes	Connector	Entire Tracker
30 seconds	30 seconds	3 seconds	30 seconds	30 seconds

High-level Disinfection Overview

- 1. Prepare a ready-to-use disinfection solution.
- 2. Immerse the tracker in the disinfection solution.
 - Cidex OPA: Minimum of 12 minutes at 20°C (68°F)
 - Glutaraldehyde 3.4% (MetriCide Plus): Minimum of 20 minutes at 25°C (77°F)



CAUTION
Do not immerse the connector.



CAUTION
Throughout the cleaning process, protect the connector to keep liquid out of the connector’s electrical contacts.

- 3. Remove the tracker from the disinfection solution, and then immerse it in a sterile water bath for a minimum of 1 minute.
- 4. Repeat the immersion three times with fresh, sterile water each time.

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Philips

**CAUTION**

Do not immerse the connector.

**CAUTION**

Throughout the cleaning process, protect the connector to keep liquid out of the connector's electrical contacts.

Disinfecting the Model 21001 Ultrasound Tracker

After the tracker has been cleaned, it is ready for disinfection. It can be disinfected using either intermediate-level or high-level disinfection.

**WARNING**

Always use protective eyewear and gloves when cleaning, disinfecting, or sterilizing any equipment.

**CAUTION**

Do not use alcohol or any alcohol-based chemicals to clean the tracker.

**CAUTION**

Throughout the cleaning process, protect the connector to keep liquid out of the connector's electrical contacts.

**CAUTION**

Do not autoclave the tracker.

For assistance during disinfection of the ultrasound tracker, see [“Model 21001 Ultrasound Tracker” on page 241](#).

Intermediate-level Disinfection

1. Put the cleaned tracker in a clean, dry, disinfected or sterilized basin, placing the connector in an upward position, away from the cable and housing portions of the tracker, to prevent liquid or moisture from entering the connector.
2. Using one of the disinfectant wipes described in [“Recommended Instrument Disinfectants” on page 179](#), thoroughly wipe the entire surface of the sensor housing and indent (at the top of the tracker) for a minimum of 30 seconds.
3. Use a new disinfectant wipe to thoroughly wipe the cable portion of the tracker in both directions for a minimum of 30 seconds.
4. Use a new disinfectant wipe to thoroughly wipe the connector portion of the tracker for a minimum of 30 seconds.

**CAUTION**

Throughout the cleaning process, protect the connector to keep liquid out of the connector’s electrical contacts.

5. Use a disinfectant-saturated swab to wipe each pinhole on the connector strain relief for 3 seconds.

NOTE

The swab should be damp but not dripping.

6. Use a new disinfectant wipe to thoroughly wipe all sections of the tracker for a minimum of 30 seconds to ensure that all surfaces are damp.
7. After wiping, allow the tracker to stand for the minimum time required by the wipe manufacturer. If you used a 1:10 bleach solution, allow the tracker to stand for a minimum of 4 minutes.
8. After the minimum standing time, saturate a clean, lint-free, sterile wipe with sterile water and squeeze out the excess liquid.

NOTE

The wipe or cloth should be damp but not dripping.

9. Use the wipe saturated with sterile water to thoroughly wipe the sensor housing, indent, cable, and connector for a minimum of 1 minute. Pay careful attention to the pinholes on the connector strain relief.

**CAUTION**

Throughout the cleaning process, protect the connector to keep liquid out of the connector's electrical contacts.

10. Allow the tracker to air dry.
11. Place the disinfected tracker in an appropriate dry storage area.

High-level Disinfection

1. Prepare a ready-to-use Cidex OPA (ortho-phthalaldehyde) or Glutaraldehyde 3.4% (MetriCide Plus) solution.
2. Verify the disinfectant solution as follows:
 - Cidex OPA: Verify that it contains the minimum effective concentration per the manufacturer's instructions.
 - Glutaraldehyde 3.4% (such as MetriCide Plus): Activate it according to the label and verify that the solution contains the minimum effective concentration using the manufacturer's instructions.
3. Heat the solution to the following temperature, and pour it into a labeled, secondary container:
 - Cidex OPA: 20°C (68°F)
 - Glutaraldehyde 3.4% (such as MetriCide Plus): 25°C (77°F)
4. Loosely coil the cable. Secure the excess cable near the connector.
5. Immerse all components, except the connector, in the prepared disinfectant solution as follows:
 - Cidex OPA: Minimum of 12 minutes at 20°C (68°F)
 - Glutaraldehyde (such as MetriCide Plus): Minimum of 20 minutes at 25°C (77°F)

**CAUTION**

Do not immerse the connector.

**CAUTION**

Throughout the cleaning process, protect the connector to keep liquid out of the connector's electrical contacts.

6. Immerse all components, except the connector, in a bath of sterile water for a minimum of 1 minute.
7. Remove the components and immerse them twice more, in fresh sterile water, for a total of three rinses.
8. Dry the components with a sterile, dry, lint-free wipe or cloth.
9. Place the disinfected tracker in an appropriate dry storage area.

12 Procedure: Ultrasound Only

The **Ultrasound Only** procedure does not require a registration or reference points (patient trackers or external landmarks). If a patient tracker is used as a reference, then a target may be specified (see the “[Target Planning](#)” section).

Instruments: Ultrasound Only

Required

- Ultrasound tracker: Allows the system to display the position and orientation of the transducer.
- Patient tracker: To mark areas of interest, define targets, track respiration, or use **US-US Fusion**, a patient reference must be defined. The patient tracker can be used as the patient reference.

Optional

Ultrasound procedures may benefit from the use of the following optional instruments:

- Coaxial needle tracker (CNT): Facilitates needle-based interventional procedures by allowing you to target areas of interest on pre-procedure images and to use the **External Landmark** registration method.
- CIVCO eTRAX needle tip tracking system: Facilitates needle-based interventional procedures by allowing you to target areas of interest on pre-procedure images and to use the **External Landmark** registration method.

NOTE

The coaxial needle tracker and the CIVCO eTRAX needle tip tracking system are incompatible with the Affiniti 70 system.

- Adaptive needle tracker (ANT): Provides needle tracking for interventional procedures or, when used with a stylus, identifies external landmarks during registration.

**WARNING**

Do not expose any instrument to a strong magnetic field (for example, an MRI scanner). These instruments are neither MRI-compatible nor MRI-safe.

NOTE

For information on the patient tracker or other instruments, see the [“Instruments”](#) section.

Setting Up Instruments for Ultrasound Only

For procedures using only ultrasound imaging, the only required instrument is an ultrasound tracker. However, if you want to mark areas of interest, define targets, track respiration, or use **US-US Fusion**, you must use a patient tracker.

For procedures that benefit from the ability to label targets and areas of interest, you must connect a patient tracker to serve as the patient reference. When the patient tracker is in place, you can do the following:

- Define target points.
- Monitor respiration.
- Define and access targets with tracked instruments.
- Complete **US-US Fusion**

Needle-based interventional procedures that use tracked needles are also identified on the **Field Generator Setup** tab and require a patient tracker.

1. Ensure that the patient tracker, which serves as the patient reference, is placed close to the ROI to optimize accuracy. For more information about placing the patient tracker, see [“Placing and Removing a Patient Tracker”](#) on page 217.

2. Ensure that all tracked instruments to be used in the procedure, including the patient tracker, are connected to the tool connection unit.

NOTE

Sterile instruments may be connected to the tool connection unit during the procedure.

3. Ensure appropriate positioning of the patient and the field generator by examining the **Field Generator Setup** tab.
4. Continue with the procedure in the **Selected Workflow** tab.

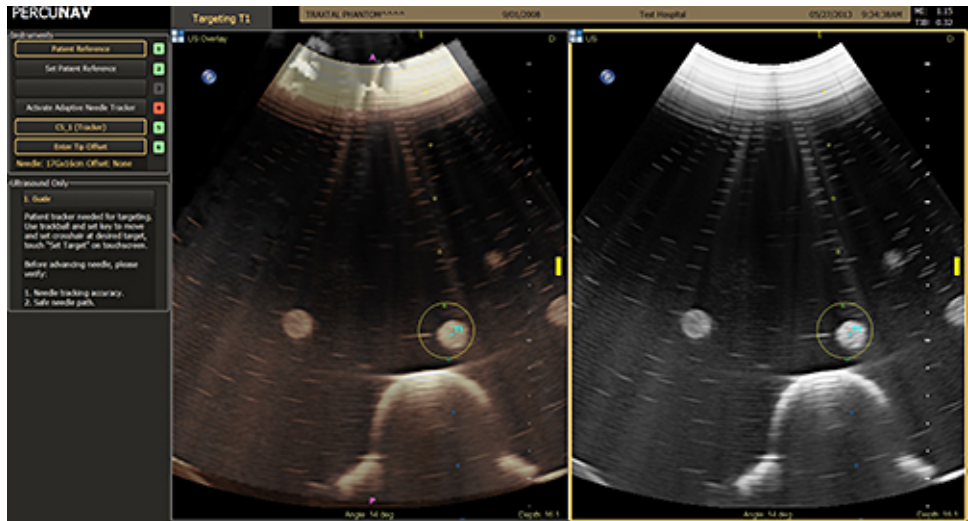


WARNING

Do not displace the patient reference tracker at any time during the procedure. Displacement may cause tracking inaccuracy.

Ultrasound Only US to US Fusion

In the **Ultrasound Only** procedure, you can use a manual 3D ultrasound sweep of an anatomical location to acquire and reconstruct a 3D volume. The 3D volume then can be fused to CT/MR and real-time ultrasound, or real-time ultrasound alone, to assist with image fusion or interventional procedures.



Ultrasound Only US-to-US Fusion
US to US Fusion is also available in the **Fusion** procedure.

US to US Fusion Touch Screen Controls

To use a touch screen control or change its setting, touch it, or if it is in the bottom row, turn the knob directly below it.

The controls for US to US Fusion appear on the **Selected Workflow** touch screen tab.

Control	Description
Blend	Controls the blending of the 3D sweep ultrasound image with the live ultrasound image. Disabled if Reconstruct is off.
Frame	Touch to select a frame to view in the imaging display. Disabled if Reconstruct is off.
Trim Left/Right	Excludes unwanted frames from the cineloop sequence before you reconstruct the cineloop sequence as a 3D ultrasound volume.

Control	Description
US-US Fusion	Displays the following controls: • 3D Sweep: Starts and stops the 3D sweep of the ultrasound image. • Reconstruct: Performs a 3D reconstruction of the ultrasound sweep and automatically fuses the reconstruction with the live ultrasound image. Enabled only after a 3D sweep is acquired. Disabled if a patient reference is not defined.

Creating US to US Fusion

1. Using a patient tracker, examine the side view and top view images on the **Field Generator Setup** tab to ensure that the field generator and patient are appropriately positioned for optimal tracking. Place the tools in the area where they will be used, and ensure that they are displayed in the side view and top view images. You may need to move the field generator or reposition the patient so that the area of interest and tools are centered in the electromagnetic field of view. For information on the **Field Generator Setup** controls, see [“Field Generator Setup” on page 112](#).
2. Connect an ultrasound tracker to the transducer and the TCU.
3. Touch **3D Sweep Start** or press the middle trackball button to start the 3D ultrasound sweep.

NOTE

To ensure that data is collected, keep the ultrasound tracker and patient reference within the magnetic field during the sweep. The instrument status is indicated in the **Instruments** panel.

4. When the sweep is complete, touch **3D Sweep Stop** or press the middle trackball button. The image freezes automatically.
5. Trim the sweep to between 5 and 300 frames (inclusive).

6. Touch **Reconstruct** to complete the fusion and view the new image.

NOTE

Do not change the ultrasound depth setting during sweep acquisition or before the exam is complete. Doing so will clear the frames acquired during the sweep.

NOTE

You can adjust the color maps for the images in the **US Overlay Maps** section of **System Settings**. For more information, see [“System Settings” on page 113](#).

NOTE

You can adjust the brightness of the Ultrasound images with the **Blend** control. For more information, see [“Blend” on page 345](#).

NOTE

During an **Ultrasound Only** procedure, you can turn on the ultrasound system Color mode and adjust the size and position of the color box. However, the **Hide Color** and **Color Compare** controls are unavailable in PercuNav mode. For more information about Color mode, see the ultrasound system *Help*.

Verification: Ultrasound Only



WARNING

Violating any of the guidelines provided in the “**Safety**” section may greatly reduce the accuracy of the system.

Verification is the process of ensuring that the information displayed by the PercuNav system is accurate. Verification is mandatory and must be performed on all tools used for navigation, by the physician, before and during the Guide process.

Visual verification, including direct imaging, ensures that the tracked tools are functioning correctly and accurately, and that the ultrasound images and fusion are accurate.

Ultrasound verification ensures the accuracy of the ultrasound tracking features. The goal is to visualize the echo of the needle with ultrasound and verify that the needle-highlighted images by the PercuNav system are overlaid correctly. Perform verification in both in-plane (ipsilateral and contralateral) approaches and out-of-plane approaches.

Performing Ultrasound Verification

To visually verify the accuracy of the system using the Ultrasound workflow, you must perform Ultrasound Only verification in the **Guide** display.

NOTE

When you are using needle navigation, you can perform Ultrasound Only verification in a water bath or with an ultrasound phantom before starting the procedure, with a non-sterile tool. If the needle is being placed by direct imaging guidance, ultrasound verification may be performed on that needle after placement.

**WARNING**

If you are using a coaxial needle tracker (CNT) in your procedure, verify the system with the CNT before you apply the offset value. Use the default offset for verification. (See [“Preparing and Using the Coaxial Needle Tracker” on page 208](#)).

**WARNING**

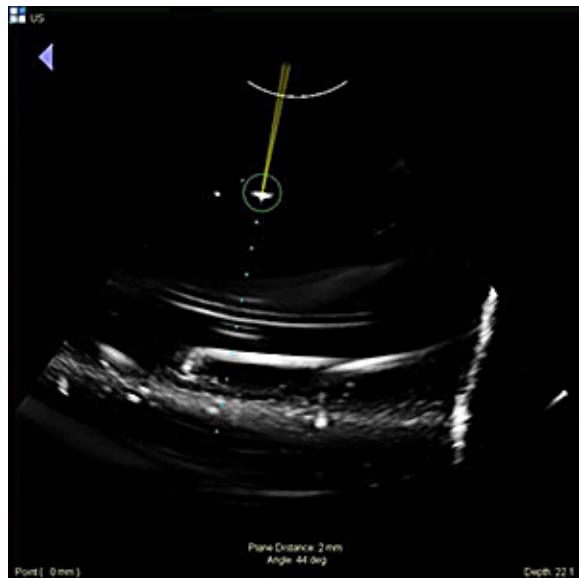
If you are using an adaptive needle tracker (ANT) in your procedure, ensure that the offset is properly measured. Apply the offset before you verify the system with the ANT. (See [“Attaching and Using an Adaptive Needle Tracker” on page 183](#).)

1. Using the tracked ultrasound transducer, image the tracked needle along the length of the needle in plane.
2. Verify that the PercuNav needle-highlighted images and the echo of the needle as displayed by ultrasound are overlaid accurately, as shown here:



Ultrasound Verification: In-Plane

3. Using the tracked ultrasound transducer, image the tip of the tracked needle out of plane (at an angle greater than 15 degrees).
4. Verify that the PercuNav needle-highlighted images and the echo of the needle tip as displayed by ultrasound are overlaid accurately, as shown here:



Ultrasound Verification: Out-of-Plane

5. If you are satisfied with the verification, continue to [“Guide: Ultrasound Only” on page 270](#).
If you want to set a target and an entry, see the [“Target Planning”](#) section.

Contrast Timers

During contrast studies, you can activate timers that show elapsed time from injection of the contrast agent. The timers display in minutes and seconds, and they appear at the top of all **Ultrasound** frames, including **US Overlay** and **Reformatted** frames. General imaging applications have two timers available. All other applications have one.

NOTE

Contrast imaging must be enabled on the ultrasound system before the **Contrast Timers** controls can be used in PercuNav mode.

NOTE

When contrast imaging is enabled on the ultrasound system, touch **Contrast Side/Side** on the **2D** tab to display simultaneous 2D contrast and tissue images side by side during PercuNav procedures. Ultrasound image controls affect both the contrast image and the tissue images in both the ultrasound views and the PercuNav views.

You control the timer with **C1** and **C2** on the **Ultrasound Only** and the **Fusion** procedures during contrast imaging. These controls have two functions:

- The first click of **C1** or **C2** displays and starts the timer.
- The second click of **C1** or **C2** resets and hides the timer.

In general imaging applications, you can change transducers and presets without affecting the timers. In other applications, selecting a new transducer or preset turns off the timer. The timer stops when it reaches its maximum duration of 99:59 (99 minutes and 59 seconds).

When you press **Freeze**, the system displays both the live timer and the elapsed time at the time of capture.

Using Contrast Timers

During contrast exams, you can activate timers that show elapsed time from injection of the contrast agent. The timers display in minutes and seconds, and appear at the top of the image area.

1. To display the contrast timer, touch **Timer 1** or **Timer 2**.
2. To acquire an image, press **Freeze**. A second timer displays the elapsed time from acquisition.
3. To resume scanning, press **Freeze** again. The elapsed time is hidden.
4. To reset and hide the timer, click **Timer 1** or **Timer 2** again.

Guide: Ultrasound Only



WARNING

The accuracy of the plane intersection circle decreases as the angle between the tracked tool and ultrasound transducer decreases. For greatest accuracy and stability, ensure that the angle between the tracked tool and transducer is greater than 15 degrees.

After you start an **Ultrasound Only** procedure, the PercuNav system takes you directly to **Guide**.

The **Guide** display in the **Ultrasound Only** procedure uses live ultrasound imaging to allow you to mark areas of interest and confirm safe paths for needle-based procedures using needle graphics for in-plane and out-of-plane approaches and target planning.



Ultrasound Only Guide Display

- | | |
|---|-------------------------------|
| 1 | Scan plane orientation marker |
| 2 | Plane intersection circle |
| 3 | Guidance bars |
| 4 | Depth display |
| 5 | Angle |

The scan plane orientation marker indicates the orientation of the ultrasound image.

The color of the needle indicates the relative position of the needle to the ultrasound scan plane:

- Yellow indicates that the needle is approaching the ultrasound scan plane.
- Green indicates that the needle is entering the ultrasound scan plane.
- Blue indicates that the needle has passed the ultrasound scan plane.

The circle calculation becomes unstable and extremely noise-sensitive when the needle is approximately co-planar with the ultrasound scan plane and is hidden when the angle between the needle and plane is less than 5 degrees. Because it is usually possible to see the echo of the needle when in-plane to the ultrasound transducer, that is usually not a problem.

The depth display indicates the depth setting.

The angle between the tracked tool and the ultrasound scan plan is displayed in degrees.

Ultrasound Only Guide Touch Screen Controls

To use a touch screen control or change its setting, touch it, or if it is in the bottom row, turn the knob directly below it.

Name	Description
Contrast Timer	Activates and displays a timer at the top center of each frame. Available only if contrast imaging is enabled on the ultrasound system.
Copy Entry	If the current target has an entry, saves a copy of the position information of the entry.
Delete Target	Deletes the selected target.
End PercuNav	Ends the procedure and returns the touch screen to the ultrasound 2D tab.
Needle Offset	Allows you to apply or remove the active CNT offset. Enabled when CNT is the active instrument and offset was selected for it.

Name	Description
Pause PercuNav	Pauses the procedure and returns the touch screen to the ultrasound 2D tab, which includes the Resume PercuNav control, used to return to the paused PercuNav procedure. When the PercuNav procedure is paused: • The selected PercuNav workflow remains the same. • The state of the PercuNav procedure remains the same.
Paste Entry	If there is a copy of a target entry, pastes the copied entry as the entry of the current target.
Set Target	Adds a target in Guide.
Show Needle Graphics	Turns on and off the display of the virtual needle images on all frames.
Show Planned Ablation Zone	Turns on and off the display of a planned ablation zone.
Target	Displays the next or previous target.
Target Display	Indicates which defined targets are displayed: • Show Current: Displays only the current target and entry marker. • Show All: Displays all targets and entry markers in the current orthogonal planes. • Hide All: Hides all targets.
US-US Fusion	Displays the following controls: • 3D Sweep: Starts and stops the 3D sweep of the ultrasound image. • Reconstruct: Performs a 3D reconstruction of the ultrasound sweep and automatically fuses the reconstruction with the live ultrasound image. Enabled only after a 3D sweep is acquired. US-US Fusion is disabled if a patient reference is not defined.
View	Allows you to change the view shown in the selected frame.

Navigating with the Ultrasound Only Guide

For information on setting a target or an entry, see the procedures in the [“Target Planning”](#) section.



WARNING

The needle may appear on the ultrasound image before it crosses the middle of the scan plane. Be aware that the ultrasound scan plane has a finite thickness and that the thickness may increase with depth.

1. Ensure that the correct tool is connected to the TCU and is displayed in the **Instruments** panel. If necessary, click the instrument name in the **Instruments** panel to change the active tracked tool to another connected instrument.
2. If you are using an ANT or a CNT, ensure that you have completed verification and that the correct offset is selected.
3. Scan the patient with the ultrasound transducer and use the ultrasound guidance bars to locate the target. For details on the ultrasound guidance bars, see [“Ultrasound Guidance Bars” on page 341](#).
4. Adjust the needle trajectory so that it intersects the predefined target. When navigating off-plane, adjust the angle of the needle to the scan plane, so that the intersection circle is positioned over the predefined target.

NOTE

For off-plane approaches, the angle between the tracked tool and the ultrasound scan plane should be greater than 15 degrees.

NOTE

The color of the displayed needle graphic changes based on its position relative to the imaging plane. For details, see [“Ultrasound Views” on page 340](#).

NOTE

Continuously verify the location of the needle by using direct imaging.

NOTE

On the displayed image, the circle that appears represents the distance from the tracked tool to the target. The distance to the target is displayed in centimeters in the bottom left corner of the frame.

NOTE

You can also use the biopsy guidelines. For more information on the biopsy guidelines, see the ultrasound system *Help*.

13 Procedure: Fusion

The **Fusion** procedure uses pre-procedure images combined with live ultrasound imaging scanned during the procedure. You can use this procedure to mark areas of interest and facilitate diagnostic procedures and needle-based interventional procedures.

For information on pre-procedure imaging and permitted ultrasound settings, see the [“Scanning the Patient”](#) section.

NOTE

During a **Fusion** procedure, you can turn on the ultrasound system Color mode and adjust the size and position of the color box. However, the **Hide Color** and **Color Compare** controls are unavailable in PercuNav mode. For more information about Color mode, see the ultrasound system *Help*.

Instruments: Fusion

Required

Each **Fusion** procedure requires the following instruments:

- Ultrasound tracker: Allows the system to display the position and orientation of the transducer.
- Patient tracker: Acts as a patient reference. Monitors motion caused by respiration or patient movement, allowing the PercuNav system to compensate for motion. When you use more than one patient tracker, supports **Patient Tracker Match**. Patient trackers can be imaged with CT or PET.

Optional

The **Fusion** procedure may benefit from the use of the following optional instruments:

- Coaxial needle tracker (CNT): Used for tip tracking to navigate to a target location.

- CIVCO eTRAX needle tip tracking system: Facilitates needle-based interventional procedures by allowing you to target areas of interest on pre-procedure images and to use the **External Landmark** registration method.

NOTE

The coaxial needle tracker and the CIVCO eTRAX needle tip tracking system are incompatible with the Affiniti 70 system.

- Adaptive needle tracker (ANT): Can be used with a stylus to identify external landmarks during registration and for procedural planning.



WARNING

Do not expose any instrument to a strong magnetic field (for example, an MRI scanner). These instruments are neither MRI-compatible nor MRI-safe.

NOTE

For information on the patient tracker or other instruments, see the [“Instruments”](#) section.

Setting Up Instruments for Fusion

The ultrasound tracker and the tracked needle are selected automatically if no more than one of each type is connected. For **Patient Reference**, if more than one patient tracker is connected to the tool connection unit (TCU), then the PercuNav system assigns the patient tracker connected to the port with the lowest number as the patient reference. If only one patient tracker is connected to the TCU, then that patient tracker becomes the patient reference automatically.

1. Ensure that the patient tracker that will serve as the patient reference is placed close to the ROI to optimize accuracy. For more information about placing the patient tracker, see [“Placing and Removing a Patient Tracker” on page 217](#).
2. Ensure that all tracked instruments to be used in the procedure, including the patient reference tracker, are connected to the TCU.
3. If the **Patient Reference** is not assigned automatically, click the patient tracker in the **Instruments** panel.
4. Examine the side view and top view images on the **Field Generator Setup** tab to ensure that the field generator and patient are appropriately positioned for optimal tracking. Place the instruments in the area where they will be used, and ensure that they are displayed in the side view and top view images. You may need to move the field generator or reposition the patient so that the area of interest and instruments are centered in the electromagnetic field of view. For information on the **Field Generator Setup** controls, see [“Field Generator Setup” on page 112](#).
5. When you are satisfied with the instrument selection, touch the **Selected Workflow** tab to continue the procedure.

**WARNING**

Do not displace the patient reference tracker at any time during the procedure. Displacement may cause tracking inaccuracy.

Fusion 3D Sweep

In the **Fusion** procedure, you can use a 3D ultrasound sweep, also known as **US-US Fusion**, to create a 3D reconstruction of an image. You can then use this image as preoperative scans or overlay them on the live ultrasound image to assist live navigation. For details about 3D ultrasound sweep, see [“Ultrasound Only US to US Fusion” on page 261](#).

Registration: Fusion



WARNING

For all registration methods, make sure that the patient remains immobile. Also, replicate the patient's respiratory state, the patient's physical position, and the position of any immobilization devices on the table at the time of the historic scan.

You use the registration process to map ultrasound images to previously acquired images such as CT, MR, or PET scans. These methods of registration are available:

- **Patient Tracker Match:** Used with ultrasound to register same-day scans that were acquired with patient trackers placed on the patient before scan acquisition.
- **External Landmark Match:** Used with ultrasound to register same-day scans that were acquired with landmarks placed on the patient before scan acquisition.
- **Internal Plane Match:** Used with ultrasound to correlate ultrasound image to previously acquired scans by matching a single image plane.
- **Internal Landmark Match:** Used with ultrasound to correlate ultrasound image to previously acquired scans by matching three or more landmarks visible in both imaging modalities.
- **Auto Registration:** A licensed option used for automatically using segmented vessels or the surface of the liver as a reference for matching.

Any combination of registration methods can be used; however, auto registration cannot be used in combination with any other registration methods. The maximum number of matched landmarks is 15 for any registration method.

NOTE

When performing registrations, the previously acquired image (MR or CT) is not magnified. This presentation allows you to see the complete image, regardless of the transducer depth setting and image aspect ratio.

Patient Tracker Match Touch Screen Controls

To use a touch screen control or change its setting, touch it, or if it is in the bottom row, turn the knob directly below it.

Control	Description
Add Landmark	Marks and identifies the location of a patient tracker on the images. Landmarks are numbered sequentially as you add them and are displayed in the Registered Landmarks section of the left pane on the imaging display.
Back	Saves the data to the current plan and then prompts you to end the procedure.
Blend	Changes the blending of the co-registered scans. For more information, see “Blend” on page 345 .
Clear Match	Clears the registration from selected landmarks. Disabled if the landmarks are not registered.
Delete Landmark	Deletes a selected landmark from the registration method. Available when there are matched landmarks and one is selected.
Find Landmarks	Performs a system search of the images in the registration scan for patient trackers and automatically adds them as landmarks, using the search criteria set in Landmark Find Settings .
Frame	Selects a frame on the display.
Landmark	Displays the following controls: • Exclude: Excludes the selected landmark from the registration set. • Include: Includes the selected landmark from the registration set.

Control	Description
Landmark Find Settings	Displays the Find Landmark search criteria applied when a search is performed for patient trackers in the patient scan. Values that you enter in the Landmark Find Settings dialog box during a PercuNav session are saved and persist to your next PercuNav session.
Match Landmark	Automatically registers the identified landmarks. Available only when the patient reference is identified.
Next	Proceeds to the next step in the workflow.
Pause PercuNav	Pauses the procedure and returns the touch screen to the ultrasound 2D tab, which includes the Resume PercuNav control, used to return to the paused PercuNav procedure. When the PercuNav procedure is paused: • The selected PercuNav workflow remains the same. • The state of the PercuNav procedure remains the same.
Registration	Lists all of the registration methods. Touch to select a registration method. The touch screen controls update automatically after you select a registration method. The default registration method is determined by the loaded data set and connected instruments. The active method is displayed on the control label. For CT Only , the Internal Plane Match and Internal Landmark Match methods are unavailable.
Scroll Slice	Scrolls through the available image slices in the selected frame. Use the middle trackball button to turn Scroll Slice on and off.
Select Landmark	Selects the previous or next landmark.
View	Allows you to change the view shown in the selected frame.

Using Patient Tracker Match



WARNING

The Registration Fit value is only a guideline to help you obtain an accurate registration. You must confirm the accuracy and acceptability of the registration by assessing fusion and needle tracking accuracy.



WARNING

For all registration methods, make sure that the patient and the landmarks remain immobile between scan and registration. Also, replicate the patient's respiratory state, the patient's physical position, and the position of any immobilization devices on the table at the time of the historic scan.



WARNING

To avoid inaccuracies, do not disturb the field generator during the registration.

NOTE

For registration, a minimum of three landmarks are needed. The landmarks can be any combination of patient trackers, external landmarks, or internal landmarks and planes (if using ultrasound).

If the patient was imaged with CT using patient trackers, follow this procedure to complete the registration automatically. For information on the **Patient Tracker Match** controls, see [“Patient Tracker Match Touch Screen Controls” on page 281](#).

1. Click the image series to select the series from the **Review Exam** display, select a procedure, and co-register any images, if necessary.
2. Set up the tools (see [“Setting Up Instruments for Fusion” on page 278](#)).
3. Touch **Patient Tracker Match** under **Registration** on the **Selected Workflow** tab. **Patient Tracker Match** is the default registration method if more than one patient tracker is connected to the TCU.
4. Registration is completed automatically. Proceed to step 7. If registration does not complete automatically, proceed to step 5, step 6, or step 7.

NOTE

If three landmarks were detected and matched and you want to add additional landmarks, click each tracker point. The system will update the registration result.

5. If fewer than three landmarks were detected and matched, click each landmark, and then touch **Add Landmark**
6. If more than six landmarks are identified, select each landmark and ensure that it was appropriately selected by clicking the **Registration Landmark** icons. You can also turn the **Select Landmark** control. If it is an extraneous tracker point, click **Delete Landmark**. Repeat this step until only six patient trackers are selected.
7. In the rare instance that the PercuNav system does not find all patient tracker landmarks, you can either add a landmark manually (for each image, place the crosshair on the patient tracker landmark and press the left trackball button to set the landmark) or alter the patient tracker landmark settings, using the following steps:
 - a. Place the crosshair on a patient tracker landmark that was omitted. Ensure accuracy in all three orthogonal planes.
 - b. Click **Landmark Find Settings**.
 - c. Compare the displayed values to the **Min** and **Max** columns and adjust the values accordingly to include the omitted landmark.

- d. Click **OK** to close the settings dialog box.
- e. Click **Find Landmark**. The following message may appear: "Some match landmark(s) already exist."
- f. Repeat steps a through e until all patient tracker landmarks have been located.
- g. When all patient tracker landmarks have been identified, ensure the field generator is positioned close to the area of interest and select **Match Landmark**.

NOTE

A minimum of three points must be identified to yield a registration fit value and progress to the next step in the workflow.

NOTE

The **Patient Tracker Find** settings persist for future procedures.

8. Review the **Registration Fit (cm)** value. You may need to select each patient tracker individually to examine the **Landmark (cm)** value. If required, you may use **Landmark Exclude** to exclude patient trackers from the registration set.
9. To refine the registration, use the controls under **Adjust Fusion** on the **Selected Workflow** tab.
10. When you are satisfied with the match, touch **Next** to proceed to **Guide**, or touch **Back** to end the current registration method and restart using another registration method.
11. If you want to use a different registration method, touch **Back** to end the procedure and save the registration.

Internal Plane Match Touch Screen Controls

To use a touch screen control or change its setting, touch it, or if it is in the bottom row, turn the knob directly below it.

Control	Description
Back	Saves the data to the current plan and then prompts you to end the procedure.
Blend	Changes the blending of the co-registered scans. For more information, see “Blend” on page 345 .
Clear Match	Clears all internal planes and their match points.
Delete Landmark	Deletes a selected landmark from a set of registration landmarks.
Frame	Selects a frame on the display.
Landmark	Displays the following controls: • Exclude: Excludes the selected landmark from the registration set. • Include: Includes the selected landmark from the registration set.
Match Plane	Matches the selected internal planes on the image. Disabled when a patient reference is not selected, when an ultrasound tracker is not connected, when an ultrasound point is not selected, and when reference landmarks are not selected on each image.
Next	Saves the data to the current plan, and proceeds to the next step, Guide . Available only if the registration step is complete.
Orientation	Provides plane viewing options for the right frame on the imaging display, enabling selection of the axial, coronal, or sagittal plane for matching.
Registration	Lists all of the registration methods. Touch to select a registration method. The touch screen controls update automatically after you select a registration method. The default registration method is determined by the loaded data set and connected instruments. The active method is displayed on the control label. For CT Only , the Internal Plane Match and Internal Landmark Match methods are unavailable.
Rotate	Rotates the image incrementally, clockwise or counterclockwise.

Control	Description
Transducer	Enables rotating the transducer to fine-tune the registration on the frozen image.
View	Allows you to change the view shown in the selected frame.

Using Internal Plane Match

Use this procedure to conduct registration by matching an internal imaging plane between corresponding pre-procedure and ultrasound images.



WARNING

For all registration methods, make sure that the patient and the landmarks remain immobile between scan and registration. Also, replicate the patient’s respiratory state, the patient’s physical position, and the position of any immobilization devices on the table at the time of the historic scan.



WARNING

If you use historic images, the physician is responsible for confirming the appropriateness and accuracy of those images and if they can be used for the current procedure.

NOTE

When using historic scans, be sure to assess the historic scan for its suitability for use with the PercuNav system.

When performing an **Internal Plane Match** registration, monitor internal patient anatomy to ensure that no drastic anatomical changes have occurred since the historic images were acquired. Changes to consider are ascites, bowel gas, weight gain or loss, and any other anatomical changes or movements. **Internal Plane Match** is available only in the **Fusion** procedure. Only one plane is required for **Internal Plane Match**.

For more information on the **Internal Plane Match** controls, see [“Internal Plane Match Touch Screen Controls” on page 286](#).

NOTE

If you use only **Internal Plane Match**, the **Registration Fit (cm)** value is 0.0 for one point-plane pair.

1. Make sure you have selected your images, selected a procedure, and co-registered any images, if necessary.
2. Set up the tools (see [“Setting Up Instruments for Fusion” on page 278](#)).
3. Touch **Internal Plane Match** under **Registration** on the **Selected Workflow** tab.
4. Select **Axial**, **Sagittal**, or **Coronal** to select the image orientation to be used for ultrasound plane registration.
5. Use the middle trackball button to scroll through the CT, MR, or PET images in the **Axial**, **Sagittal**, or **Coronal** frame. Select an image that can be replicated with ultrasound, with the transducer positioned in the respective plane (not oblique), and place the crosshair on an internal landmark that will also be visualized with ultrasound.

If necessary, rotate and flip the image of the pre-procedure orientation used for matching (axial, sagittal, or coronal) to approximate the gross orientation of the ultrasound image.

6. Using ultrasound, with the transducer positioned in the respective plane (not oblique), locate the corresponding axial, sagittal, or coronal image. When you locate the corresponding ultrasound image, place the crosshair on the same internal landmark in the ultrasound image that correlates to the landmark indicated in step 5. The ultrasound image and the previously acquired image are now overlaid on each other in the left frame.

- 7. Make sure that the ultrasound image and the previously acquired image are on the same plane.
- 8. Use the motion of the transducer to tilt, rock, and rotate the transducer to refine the fusion before completing registration. Rotate and adjust the ultrasound plane registration in the z-axis, as required.
- 9. Use the **Blend** controls to adjust the blend ratio to check the overlay match of the images.
- 10. When you are satisfied with the ultrasound plane registration, touch **Match Plane** to continue to **Guide**.
- 11. To refine the registration, use the controls under **Adjust Fusion** on the **Selected Workflow** tab.

Internal Landmark Match Touch Screen Controls

To use a touch screen control or change its setting, touch it, or if it is in the bottom row, turn the knob directly below it.

Control	Description
Back	Saves the data to the current plan and then prompts you to end the procedure.
Blend	Changes the blending of the co-registered scans. For more information, see “Blend” on page 345 .
Clear Match	Clears all internal landmark matches.
Delete Landmark	Deletes a selected landmark from the registration method.
Frame	Selects a frame on the display.
Landmark	Displays the following controls: • Exclude: Excludes the selected landmark from the registration set. • Include: Includes the selected landmark from the registration set.

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Control	Description
Match Landmark	Matches the selected internal landmark on the volume image with the corresponding landmark on the frozen ultrasound image. A minimum of three landmark matches is required to create a registration. Disabled when a patient reference is not selected, when an ultrasound tracker is not plugged in, when an ultrasound point is not selected, and when reference landmarks are not selected on each image.
Next	Saves the data to the current plan, and proceeds to the next step, Guide . Available only if the registration step is complete.
Registration	Lists all of the registration methods. Touch to select a registration method. The touch screen controls update automatically after you select a registration method. The default registration method is determined by the loaded data set and connected instruments. The active method is displayed on the control label. For CT Only , the Internal Plane Match and Internal Landmark Match methods are unavailable.
Select Landmark	Selects the previous or next landmark.
View	Allows you to change the view shown in the selected frame.

Using Internal Landmark Match



WARNING

The Registration Fit value is only a guideline to help you obtain an accurate registration. You must confirm the accuracy and acceptability of the registration by assessing fusion and needle tracking accuracy.

**WARNING**

For all registration methods, make sure that the patient and the landmarks remain immobile between scan and registration. Also, replicate the patient's respiratory state, the patient's physical position, and the position of any immobilization devices on the table at the time of the historic scan.

**WARNING**

If you use historic images, the physician is responsible for confirming the appropriateness and accuracy of those images and if they can be used for the current procedure.

Use this procedure to conduct registration by selecting internal landmarks on the previously acquired CT, MR, or PET images and the ultrasound images.

When performing an **Internal Landmark Match** registration, monitor internal patient anatomy to ensure that no drastic anatomical changes have occurred since the historic images were acquired. Changes to consider are ascites, bowel gas, weight gain or loss, and any other anatomical changes or movements. **Internal Landmark Match** is available only in the **Fusion** procedure.

For more information on the **Internal Landmark Match** controls, see [“Internal Landmark Match Touch Screen Controls” on page 289](#).

For improved results, consider these recommendations for selecting landmarks:

- Select landmarks in and around the area of interest.
 - Sample various planes.
 - Use vessel bifurcations instead of the lumen of a structure.
1. Make sure you have selected your images, selected a procedure, and co-registered any images, if necessary.
 2. Set up the tools (see [“Setting Up Instruments for Fusion” on page 278](#)).

- 3. Touch **Internal Landmark Match** under **Registration** on the **Selected Workflow** tab. You can make this your default registration method by selecting **Internal Landmark** under **Default Registration** in **System Settings**.
- 4. Identify the location of the internal landmark on the previously acquired CT, MR, or PET image. Use the middle trackball button to scroll through the frames to select the landmark or point, position the crosshair, and then press the left trackball button.
- 5. Press **Freeze**, and then press the middle trackball button to scroll through the frames to locate the corresponding internal landmark. When the corresponding landmark is identified, position the crosshair and then press the left trackball button.
- 6. Touch **Match Landmark**.
- 7. Repeat steps 3 through 6 for each internal landmark to be registered.
- 8. When three or more registration points are matched, the system displays the **Landmark (cm)** and **Registration Fit (cm)** values.
- 9. Review the **Registration Fit (cm)** value. You may need to select each reference point individually to examine the **Landmark (cm)** value for each point. If required, you can use **Landmark Exclude** to exclude points from the registration.
- 10. To refine the registration, use the controls under **Adjust Fusion** on the **Selected Workflow** tab.
- 11. When you are satisfied with the match, touch **Next** to proceed to **Guide**, or touch **Back** to end the current registration method and restart using another registration method.

External Landmark Match Touch Screen Controls

To use a touch screen control or change its setting, touch it, or if it is in the bottom row, turn the knob directly below it.

Control	Description
Back	Saves the data to the current plan and then prompts you to end the procedure.
Blend	Changes the blending of the co-registered scans. For more information, see “Blend” on page 345 .

Control	Description
Clear Match	Clears all external landmark (excluding patient tracker) matches.
Delete Landmark	Deletes a selected landmark from the registration method.
Frame	Selects a frame on the display.
Landmark	Displays the following controls: • Exclude: Excludes the selected landmark from the registration set. • Include: Includes the selected landmark from the registration set.
Match Landmark	Matches the selected external landmark on the image to the point on the patient that the transducer touches. Disabled when a patient reference is not selected, when a transducer is not selected, and when the transducer is not detected within the field generator volume.
Next	Saves the data to the current plan, and proceeds to the next step, Guide . Available only if the registration step is complete.
Registration	Lists all of the registration methods. Touch to select a registration method. The touch screen controls update automatically after you select a registration method. The default registration method is determined by the loaded data set and connected instruments. The active method is displayed on the control label. For CT Only , the Internal Plane Match and Internal Landmark Match methods are unavailable.
Scroll Slice	Scrolls through the available image slices in the selected frame. Use the middle trackball button to turn Scroll Slice on and off.
Select Landmark	Selects the previous or next landmark. Disabled if no landmarks are defined.
View	Allows you to change the view shown in the selected frame.

Using External Landmark Match



WARNING

The Registration Fit value is only a guideline to help you obtain an accurate registration. You must confirm the accuracy and acceptability of the registration by assessing fusion and needle tracking accuracy.



WARNING

For all registration methods, make sure that the patient and the landmarks remain immobile between scan and registration. Also, replicate the patient's respiratory state, the patient's physical position, and the position of any immobilization devices on the table at the time of the historic scan.

If the patient was imaged with external landmarks, use this procedure to perform manual registration. For information on the **External Landmark Match** controls, see [“External Landmark Match Touch Screen Controls” on page 292](#). You can also use the ANT attached to a stylus to match landmarks. For details on preparing an ANT, see [“Attaching and Using an Adaptive Needle Tracker” on page 183](#).

NOTE

For registration, a minimum of three landmarks are needed. The landmarks can be any combination of patient trackers, external landmarks, or internal landmarks and planes (if using ultrasound).

1. Ensure that the external landmarks were placed close to the ROI, that you have sampled various planes, and that you placed the landmarks on the patient before acquiring the images.
2. Make sure you have selected your images, selected a procedure, and co-registered any images, if necessary.
3. Set up the tools (see [“Setting Up Instruments for Fusion” on page 278](#)).
4. Touch **External Landmark Match** under **Registration** on the **Selected Workflow** tab.
5. Using the trackball, place the crosshair on the external landmark and press the left trackball button to set the landmark.
6. The selected landmark is displayed as a new icon in the **Registration Landmark** section, and as a plus sign (+) on the images with the crosshair. Find the corresponding landmark on the patient and touch the tip of the tracked stylus to that point.
7. Touch **Match Landmark**. A green check mark appears on the landmark's icon under **Registration Landmarks** in the left pane to indicate that the landmark has been matched.
8. Repeat steps 4 through 7 for each remaining landmark.
9. Review the **Registration Fit (cm)** value. You may need to select each landmark individually to examine the **Landmark (cm)** value for each landmark. If required, you can use **Landmark Exclude** to exclude points from the registration. Alternatively, you may resample points by repeating steps 4 through 6.
10. To refine the registration, use the controls under **Adjust Fusion** on the **Selected Workflow** tab.
11. When you are satisfied with the match, touch **Next** to proceed to **Guide**, or touch **Back** to end the current registration method and restart using another registration method.

Auto Registration Touch Screen Controls

To use a touch screen control or change its setting, touch it, or if it is in the bottom row, turn the knob directly below it.

Name	Description
Back	Saves the PercuNav procedure data into the current plan, and then ends the procedure and returns to 2D ultrasound mode.
Blend Overlay	Blends and verifies the CT/US or MR/US fusion. Blends the pre-procedure CT or MR scans (primary images) and the ultrasound reconstructed volume with the live ultrasound image that is displayed in the US Overlay frame.
Find Vessel	Starts segmentation using the location of the cursor placed on the volume image when One Click is selected.
Liver Sweep Start	Starts acquisition of a manual liver sweep. Allows the user to start acquiring the sweep manually. (You can also press the middle trackball button to acquire the manual liver sweep.) Available only when: • Using a C5-1, a C9-2, or an S5-1 transducer with an ultrasound tracker. • A method, patient reference, and matching tracker are selected. • If Surface Based is selected, the sternum and navel are marked.
Liver Sweep Stop	Stops acquisition of a manual liver sweep.
Load Registration	Restores the saved auto registration result, including fusion adjustment, to the current method. This clears all previous auto registration results.
Mark Navel	Records or updates the position of the transducer and ultrasound tracker as the navel location. Available when Surface Based is selected.
Mark Sternum	Records or updates the position of the transducer and ultrasound tracker as the sternum location. Available when Surface Based is selected.
Method	Selects the method used for registration. The available methods are Vessel Based (the default), Surface Based , and One Click .
Next	If a valid registration exists, saves the PercuNav procedure data into the current plan, and continues to the next step in the workflow (Guide).
One Click	Performs auto one-click registration of the active scan using the selected point.
One Click Boundary	Defines the search region for registration.

Name	Description
Pause PercuNav	Pauses PercuNav mode and returns the touch screen to the ultrasound 2D tab. To return to the PercuNav procedure, touch Resume PercuNav. When PercuNav mode is paused: • The selected PercuNav workflow remains the same. • The state of the PercuNav procedure remains the same.
Point to Point	Enabled when there is an auto registration result. Displays the reformatted ultrasound view. Point to Point fusion adjustment performs 3D space translation based on two landmarks; rotational adjustment is not available.
Register	If you are using a C5-1, a C9-2, or an S5-1 transducer, starts the registration process.
Registration	Selects the type of registration. Auto registration is allowed if the CT auto registration license is installed and a primary CT scan is loaded or if the MR auto registration license is installed and a primary MR scan is loaded.
Rotate	Rotates the CT or MR image over the ultrasound image in the US Overlay frame. Available if Trackball is selected.
Save Registration	Saves the current auto registration result, including fusion adjustment.
Scroll Slice	When a multi-slice image is selected, scrolls through the slices. When you use the trackball to adjust fusion in the US Overlay frame, scrolls through the cineloop. Available when the image frame has multiple slices.
Sweep	Starts or stops acquisition of a 3D volume of the current scanned liver. Available only when Find Vessel is touched, when sternum and navel are marked, or when using an X6-1 transducer with an ultrasound tracker. (You can also press the middle trackball button to acquire the 3D volume.)
Trackball	Selects the US Overlay frame, places the cursor at the center of the US Overlay frame, freezes the image, and allows you to use the trackball to adjust the registration. Unavailable if Transducer or Point to Point is selected.

Name	Description
Transducer	Freezes the ultrasound image and allows you to move the transducer to adjust the volume image. Unavailable if Trackball or Point to Point is selected.
View	Allows you to change the view shown in the selected frame.

Using Auto Registration

Auto registration automatically fuses a historic CT or MR data set to a live ultrasound liver sweep, using the vessel tree or the surface of the liver as a landmark. This method of registration automatically uses the segmented vessels or surface of the liver as a reference for matching, so that you do not have to select them. CT auto registration is allowed if the CT auto registration license is installed and a CT scan is loaded. MR auto registration is allowed if the MR auto registration license is installed and an MR scan is loaded. A PET scan can be used as a secondary scan.

Auto registration cannot be combined with other registration methods. If another registration exists (internal plane match, internal landmark match, patient tracker match, or external landmark match) and you perform auto registration, the system prompts you to confirm the exclusion of other registrations before you proceed with auto registration. When any other registration method is successful, the auto registration match is excluded. Also, only one auto registration result can exist at a time.

When you use an EPIQ system with the X6-1 transducer, which supports 3D imaging, auto registration provides a swept ultrasound volume for registering with a CT or MR scan. When you use the C5-1, the C9-2, or the S5-1 transducers, which support only 2D imaging, a 3D ultrasound volume acquired with a freehand sweep over a region of interest is required.

Preparing for Auto Registration

Before starting auto registration, do the following:

1. Touch **Select CT/MR/PET**.
2. Load a previously acquired CT or MR data set composed of a single image series.

NOTE

To ensure that the correct image series for the procedure has been selected, scroll through the image series in Review mode. To select an image, click the number on the image.

NOTE

When you load both primary and secondary data sets, the co-registration begins. After co-registration is complete, you can touch **Next** to save the data. You can then select the registration method. Auto registration uses only the primary data set.

3. Connect a supported transducer to the ultrasound system:
 - EPIQ systems: C5-1, C9-2, S5-1, or X6-1
 - Affiniti 70 system: C5-1, C9-2, or S5-1
4. Attach an ultrasound tracker to the transducer, and connect the tracker to the tool connection unit (TCU).
5. Place a patient tracker on the patient, connect the tracker to the TCU, and assign the patient tracker as the patient reference.
6. Position the field generator so that all the instruments are within the field generator volume. Use the tools in the **Field Generator Setup** tab as needed.

Showing Segmented Objects

In an auto registration procedure, objects of interest are segmented from the 3D images. Auto registration uses the segmented objects to align the images. The **Segmented Objects** touch screen control makes the segmented objects visible in selected views. **Segmented Objects** is available in Ultrasound Only procedures and during auto registration in Fusion procedures. For more information, see [“Segmented Objects Touch Screen Controls” on page 110](#).

In the procedure that follows, # is a placeholder for an ultrasound scan sequence number.

1. Touch **Segmented Objects**.

2. If you are in the **US Only** view, to locate segmented objects, touch **Find**.
3. To show the liver outline in the 3D view, under **CT/MR Liver**, touch **Show in 3D**.
4. To show the diaphragm outline, under **US Diaphragm** or **Scan # Diaphragm**, touch **Show**.
5. To show the vessels, do one of the following:
 - To show vessels as tubes, under **CT/MR Vessels**, **Scan # Vessels**, or **US Vessels**, touch **Show as Tubes**.
 - To show vessels as lines, under **CT/MR Vessels**, **Scan # Vessels**, or **US Vessels**, touch **Show as Lines**.
6. If one of the vessels or diaphragm choices is selected, do one or more of the following:
 - To show vessels or diaphragm in MPR views, touch **MPR**.
 - To show vessels or diaphragm in ultrasound views, touch **US**.
7. Under **Visibility**, select the procedures in which you want to see the segmented objects.
8. To store your current selections as the default for future views, touch **Set as Default**.
9. To overwrite your current selections with the stored defaults, touch **Use Default**.
10. When you are finished, touch **Close**.

Performing Vessel Based or Surface Based Auto Registration

NOTE

You can set the default registration method in **Settings**. For more information, see [“Settings” on page 113](#).

NOTE

You can change the color maps in **Settings**. For more information, see [“Settings” on page 113](#).

NOTE

You can pause the PercuNav system and enter 2D ultrasound mode from the auto registration display. To pause and go to 2D ultrasound mode, touch **Pause PercuNav** (you may want to optimize the 2D image before acquiring the sweep). To return to the PercuNav procedure, touch **Resume PercuNav** on the ultrasound **2D** tab.

1. Perform the steps in [“Preparing for Auto Registration” on page 298](#).
2. Under **Registration**, touch **Auto Registration**.

NOTE

Auto registration cannot be combined with other registrations. If another registration exists, the system prompts you to confirm the exclusion of other registrations before you proceed with auto registration.

3. Select a method:
 - If you are using a contrast CT or MR data set, set **Method** to **Vessel Based** (the default type). If the **Vessel Based** method does not produce satisfactory results, set **Method** to **Surface Based**
 - If you are using a non-contrast CT or MR data set, set **Method** to **Surface Based**. With a non-contrast data set, typically you do not see the vessels of the liver
4. Before you start the acquisition sweep, perform a test scan the patient to identify the optimal scanning window for the selected method.
5. If you are using the **Surface Based** method for CT or MR data sets, record the position of the sternum and the navel:
 - Place the transducer and ultrasound tracker above the sternum, and touch **Mark Sternum**.
 - Place the transducer and ultrasound tracker above the navel, and touch **Mark Navel**.

The sternum and navel positions are stored.

6. Perform an oblique intercostal scan with the transducer and acquire a live ultrasound sweep of the liver. Ensure that the patient tracker and the ultrasound tracker are being tracked within the field generator volume while acquiring the sweep.

If you are using an X6-1 transducer, touch **Sweep** to acquire a 3D volume of the area of interest. Proceed to step 7.

If you are using a C5-1, a C9-2, or an S5-1 transducer, which support only 2D imaging, the sweep can collect and store a maximum of 300 ultrasound images.

- a. Touch **Liver Sweep Start** or press the middle trackball button to begin the liver sweep.
- b. Keeping your scanning hand steady, move the transducer over the area of interest at a consistent rate. For the **Surface Based** method, the sweep should include as much of the diaphragm or surface of the liver as possible. For the **Vessel Based** method, the sweep should include as much of the vessels from the portal venous study as possible.
- c. Touch **Liver Sweep Stop** or press the middle trackball button to end the liver sweep.

NOTE

The display shows breathing instructions that must be communicated to the patient. Instruct patients to breathe normally and then hold their breath during the sweep acquisition. They can resume breathing normally after sweep acquisition. Holding a deep breath is not recommended.

7. If you are using the X6-1 transducer, registration occurs automatically. The contents of the touch screen display will also change automatically. Proceed to step 8.

If you are using a C5-1, a C9-2, or an S5-1 transducer, touch **Register**.

The following occurs:

- The **US Overlay, Reformatted, US Only**, and **3D** frames appear.
- If **Method** is set to **Vessel Based**, the segmented vessels appear in all the frames, so that you can review the segmentation quality.

NOTE

If the **US Overlay**, **Reformatted**, **US Only**, or **3D** frame is active, the fusion may become misaligned when you use the trackball. To realign the fusion, touch **Reset** to undo and reapply fusion adjustments, as needed.

8. To unfreeze the image, press **Freeze**.
9. Verify the accuracy of the auto registration result by comparing the live ultrasound image to the reformatted scan. For more information on verification, see [“Verification: Fusion” on page 306](#).
10. Do one of the following:
 - If the registration is acceptable, touch **Next**.
 - If the registration is unacceptable, repeat step 6 to step 9.

NOTE

Auto registration results are used in the current study only; they are not saved to the plan.

Performing One Click Auto Registration

Use the **One Click** method for atypical cases that require more flexibility than the **Vessel Based** or **Surface Based** methods provide, such as cases where part of the liver has been resected.

NOTE

You can use the **One Click** method only with contrast data sets.

NOTE

You can set the default registration method in **Settings**. For more information, see [“System Settings” on page 113](#).

NOTE

You can change the color maps in **Settings**. For more information, see [“System Settings” on page 113](#).

NOTE

You can pause the PercuNav system and enter 2D ultrasound mode from the auto registration display. To pause and go to 2D ultrasound mode, touch **Pause PercuNav** (you may want to optimize the 2D image before acquiring the sweep). To return to the PercuNav procedure, touch **Resume PercuNav** on the ultrasound **2D** tab.

1. Perform the steps in [“Preparing for Auto Registration” on page 298](#).
2. Under **Registration**, touch **Auto Registration**.

NOTE

Auto registration cannot be combined with other registrations. If another registration exists, the system prompts you to exclude that registration before you proceed with auto registration.

3. Set **Method** to **One Click**.
4. Scroll through the image to an area that shows the vessels intended for use with registration.

NOTE

To scroll through the image, you can use the middle trackball button or the **Scroll Slice** control.

5. Click a vessel of the liver (for example, right portal vein).
6. If you want to specify a search area, do the following:
 - a. Press the **One Click Boundary** soft key. A circular target area appears around the selected vessel.
 - b. To increase or decrease the size of the search area, turn **One Click Boundary**.
 - c. To remove the search target, press **One Click Boundary** again.
7. Touch **Find Vessel**.
8. Perform an oblique intercostal scan with the transducer and acquire a sweep of the same vessel or in the same area as the vessel that was marked in the slice. Ensure that the patient tracker and the ultrasound tracker are being tracked within the field generator volume while acquiring the sweep.

If you are using the X6-1 transducer, registration occurs automatically. The contents of the touch screen display will also change automatically. Proceed to step 9.

If you are using a C5-1, a C9-2, or an S5-1 transducer, touch **Register**.

The following occurs:

- The **US Overlay, Reformatted, US Only**, and **3D** frames appear.
 - The segmented vessels appear in all the frames, so that you can review the segmentation quality.
9. Verify the accuracy of the auto registration result by comparing the live ultrasound image to the reformatted CT or MR scan. For more information on verification, see [“Verification: Fusion” on page 306](#).
 10. Do one of the following:
 - If the registration is acceptable, touch **Next**.
 - If the registration is unacceptable, repeat step 4 to step 9.

NOTE

Auto registration results are used in the current study only; they are not saved to the plan.

Verification: Fusion

**WARNING**

Violating any of the guidelines provided in the **“Safety”** section may greatly reduce the accuracy of the system.

Verification is the process of ensuring that the information displayed by the PercuNav system is accurate. Verification is mandatory and must be performed on all tools used for navigation, by the physician, before and during the Guide process.

Visual verification, including direct imaging, ensures that the tracked tools are functioning correctly and accurately, and that the ultrasound images and fusion are accurate.

The accuracy of the tracked tools and ultrasound fusion are a function of the registration as described in **“Registration: Fusion”** on page 280.

Performing Fusion Verification

To ensure that the system and registration for the **Fusion** procedure remain accurate, you must verify the tracked tool and ultrasound fusion. Verification is accomplished by scanning with ultrasound in the ROI and assessing fusion accuracy in various planes.

**WARNING**

If you are using a coaxial needle tracker (CNT) in your procedure, verify the system with the CNT before you apply the offset value. Use the default offset for verification. (See [“Preparing and Using the Coaxial Needle Tracker” on page 208.](#))

**WARNING**

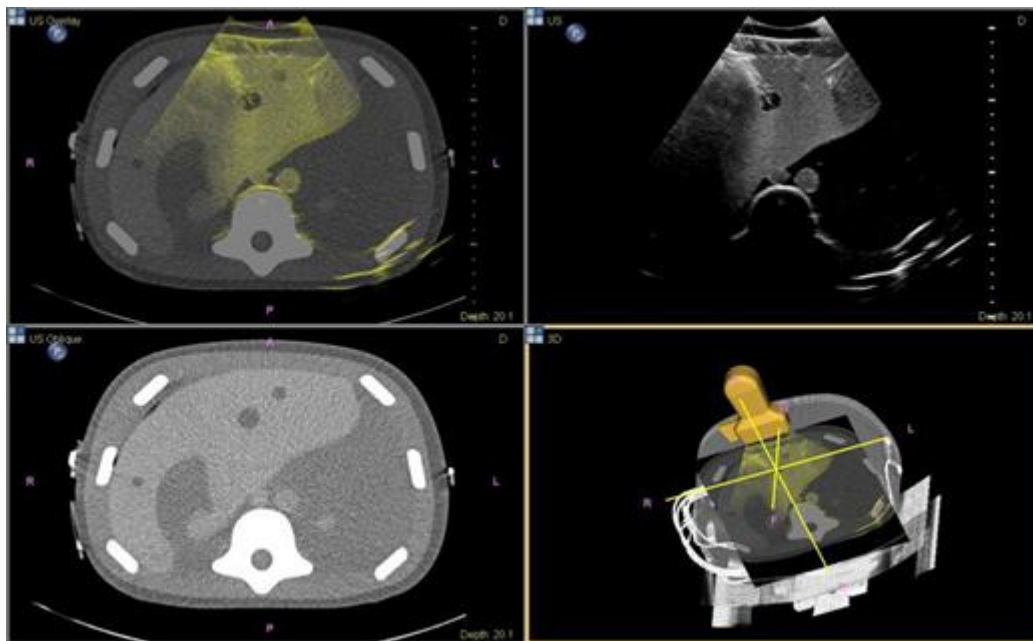
If you are using an adaptive needle tracker (ANT) in your procedure, ensure that the offset is properly measured. Apply the offset before you verify the system with the ANT. (See [“Attaching and Using an Adaptive Needle Tracker” on page 183.](#))

**WARNING**

Metal interference may cause the fusion or tip tracking to appear inaccurate, when the registration is acceptable.

1. Using the active tracked tool, gently move the tracked tool over the patient's skin.
2. Confirm that the crosshair on the patient image moves across the images in the same anatomical location as the tool on the patient's skin. Check the x-, y-, and z-axis.
3. Using the tracked ultrasound transducer, examine a range of scan planes.
4. Confirm accurate anatomical overlay of both the ultrasound and previously acquired CT, MR, or PET images.
5. If the ultrasound images do not align with the CT, MR, PET images, do any of the following:
 - Perform registration again.
 - During live imaging, touch **Transducer** under **Adjust Fusion**, and move the transducer to rotate and adjust the quality of the fusion.

- During live imaging, touch **Trackball** under **Adjust Fusion**, drag the scan on the **Guide** display if the misalignment is in the same plane, and turn **Rotate** and **Scroll Slice** to adjust the fusion as required.
 - During live ultrasound imaging, fine-tune the fusion quality. Touch **Point to Point**, under **Adjust Fusion**, and move the transducer to find a landmark in the ultrasound image.
6. Press **Freeze** to save the changes.



Fusion Verification

7. If you are satisfied with the verification, continue to [“Guide: Fusion” on page 311](#). If you want to set a target and an entry, see the [“Target Planning”](#) section.

Point to Point Fusion Adjustment

Point to Point allows you to adjust the image fusion by using landmarks common to both the ultrasound and CT/MR images that are close to the region of interest.

1. Ensure that the ultrasound system is in live imaging.
2. Using the transducer, find a landmark in the ultrasound image and click it to tag the spatial location.
3. Find the corresponding landmark on the CT/MR image, and then click to mark it. The ultrasound system freezes the image and displays both tagged images.
4. To store the fusion adjustment and return to live imaging, do one of the following:
 - Press **Point to Point**.
 - Press **Freeze**.

NOTE

Point to Point is available only in the **Guide** display during a **Fusion** procedure. This fusion adjustment only performs 3D space translation using the two tagged landmarks; rotational adjustment is not available.

Contrast Timers

During contrast studies, you can activate timers that show elapsed time from injection of the contrast agent. The timers display in minutes and seconds, and they appear at the top of all **Ultrasound** frames, including **US Overlay** and **Reformatted** frames. General imaging applications have two timers available. All other applications have one.

NOTE

Contrast imaging must be enabled on the ultrasound system before the **Contrast Timers** controls can be used in PercuNav mode.

NOTE

When contrast imaging is enabled on the ultrasound system, touch **Contrast Side/Side** on the **2D** tab to display simultaneous 2D contrast and tissue images side by side during PercuNav procedures. Ultrasound image controls affect both the contrast image and the tissue images in both the ultrasound views and the PercuNav views.

You control the timer with **C1** and **C2** on the **Ultrasound Only** and the **Fusion** procedures during contrast imaging. These controls have two functions:

- The first click of **C1** or **C2** displays and starts the timer.
- The second click of **C1** or **C2** resets and hides the timer.

In general imaging applications, you can change transducers and presets without affecting the timers. In other applications, selecting a new transducer or preset turns off the timer. The timer stops when it reaches its maximum duration of 99:59 (99 minutes and 59 seconds).

When you press **Freeze**, the system displays both the live timer and the elapsed time at the time of capture.

Using Contrast Timers

During contrast exams, you can activate timers that show elapsed time from injection of the contrast agent. The timers display in minutes and seconds, and appear at the top of the image area.

1. To display the contrast timer, touch **Timer 1** or **Timer 2**.
2. To acquire an image, press **Freeze**. A second timer displays the elapsed time from acquisition.
3. To resume scanning, press **Freeze** again. The elapsed time is hidden.
4. To reset and hide the timer, click **Timer 1** or **Timer 2** again.

Guide: Fusion

The **Fusion Guide** workflow uses previously acquired CT, MR, or PET images and live ultrasound images to allow you to mark areas of interest. It also facilitates needle-based intervention procedures using needle highlighting, out-of-plane approaches, and targeting functions.



WARNING

If you are using a coaxial needle tracker (CNT) in your procedure, verify the system with the CNT before you apply the offset value. Use the default offset for verification. (See [“Preparing and Using the Coaxial Needle Tracker” on page 208.](#))



WARNING

If you are using an adaptive needle tracker (ANT) in your procedure, ensure that the offset is properly measured. Apply the offset before you verify the system with the ANT. (See [“Attaching and Using an Adaptive Needle Tracker” on page 183.](#))

Fusion Guide Touch Screen Controls

To use a touch screen control or change its setting, touch it, or if it is in the bottom row, turn the knob directly below it.

Name	Description
Back	Returns to a previous step in the workflow.
Contrast Timer	Activates and displays a timer at the top center of each frame. Available only if Contrast is enabled on the ultrasound system.
Delete Target	Deletes the selected target.
End PercuNav	Ends the procedure and returns the touch screen to the ultrasound 2D tab.

Name	Description
Frame	Selects a frame on the display.
Layout	Allows you to select an image display layout.
Needle Offset On/Off	Applies the offset to or removes the offset from the active CNT if an offset has been selected for the CNT. Available when the CNT is the active tool and an offset was selected for it. The coaxial needle tracker is incompatible with the Affiniti 70 system.
Pause PercuNav	Pauses the procedure and returns the touch screen to the ultrasound 2D tab, which includes the Resume PercuNav control, used to return to the paused PercuNav procedure. When the PercuNav procedure is paused: • The selected PercuNav workflow remains the same. • The state of the PercuNav procedure remains the same.
Set Target	Adds a target during navigation. See “Creating a Target” on page 148 .
Show Needle Graphics	Turns on and off the display of the virtual needle images on all frames.
Show Planned Ablation Zone	Turns on and off the display of a planned ablation zone.
Target	Displays next or previous target.
Target Display	Indicates which defined targets are displayed: • Show Current: Displays only the current target and entry marker. • Show All: Displays all targets and entry markers in the current orthogonal planes. • Hide All: Hides all targets.
Trim Left/Right	Controls used to display and position trim cursors on the cineloop bar. Excludes unwanted frames from the cineloop sequence before you reconstruct that cineloop sequence as a 3D ultrasound volume.

Name	Description
US-US Fusion	Displays the following controls: • 3D Sweep: Starts and stops the 3D sweep of the ultrasound image. • Reconstruct: Performs a 3D reconstruction of the ultrasound sweep and automatically fuses the reconstruction with the live ultrasound image. Enabled only after a 3D sweep is acquired. Available if only one data set has been selected or loaded.
View	Allows you to change the view shown in the selected frame.

Navigating Using the Fusion Guide

For information on setting a target or an entry, see the procedures in the “[Target Planning](#)” section.



WARNING

To optimize registration and tracking accuracy, keep patient respiration consistent between scan acquisition, registration, and needle advancement.



WARNING

The needle may appear on the ultrasound image before it crosses the middle of the scan plane. Be aware that the ultrasound scan plane has a finite thickness and that the thickness may increase with depth.

**WARNING**

CT, MR, and PET pre-procedure images used for navigation are meant for planning and guidance and must be verified by a form of direct, live imaging to ensure continued accuracy.

**WARNING**

You are responsible for ensuring that the PercuNav system is accurate. The PercuNav system can be used to assist physicians, but physicians must override the system if it does not appear to be accurate or otherwise working as intended.

**WARNING**

When positioning the tracked tool, ensure that the angle between the tracked tool and transducer is greater than 15 degrees.

**WARNING**

Continuously throughout the procedure, verify the location of the needle and the needle path by using direct imaging.

NOTE

To ensure that the PercuNav system remains accurate, use direct imaging to verify the actual location of instruments before and during navigation.

NOTE

You can also use the biopsy guidelines. For more information on biopsy guidelines, see the ultrasound system *Help*.

1. Ensure that the correct tool is connected to the TCU and is displayed in the **Instruments** panel. If necessary, click the instrument name in the **Instruments** panel to change the active tracked tool to another connected instrument.
2. Examine the images in the frames.
 - If necessary, change the displayed image and the image layout using the **View** control.
 - To view one large image, rather than four quadrants, select **Fusion 1x1** under **Layout** on the **Selected Workflow** tab. (3D is unavailable if **Fusion 1x1** is selected.)
 - To specify which view to be displayed on the 1x1 layout, use the **View** control.
 - To return to four quadrants, select **Triplanar**, **Oblique**, or **Fusion Targeting 2x2** under **Layout** on the **Selected Workflow** tab.
3. Scan the patient with the ultrasound transducer and use the ultrasound guidance bars to locate the target. For details on the ultrasound guidance bars, see [“Ultrasound Guidance Bars” on page 341](#).
4. Position the tracked tool by doing one of the following:
 - For ultrasound images, position the tracked tool so that the needle trajectory intersects the target. The needle graphic will be yellow or blue, depending in its position relative to the ultrasound scan plane.
 - For an out-of-plane approach in an ultrasound view, position the tracked tool so that the intersection circle indicates that the instrument will intersect the target, ensuring that the angle between the tracked tool and transducer is greater than 15 degrees.

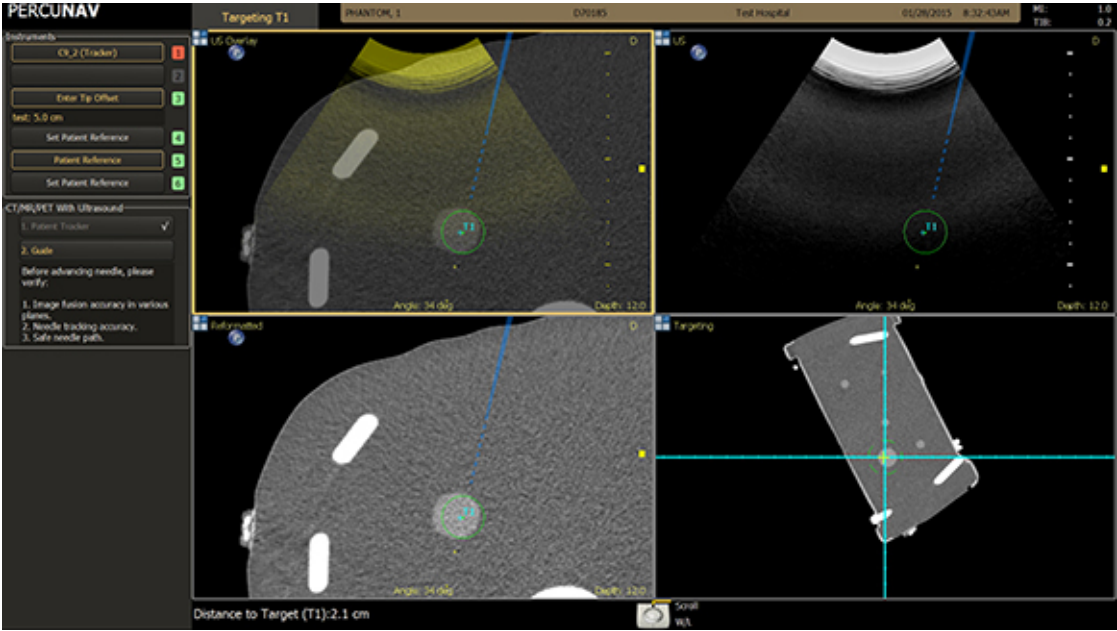
To turn the display of the needle graphics and intersection circle on and off, touch **Show Needle Graphics**. This control is available on the **Ultrasound** and **Ultrasound Overlay** frames.

- Position the tracked tool at the selected entry point. In **Targeting** view, pivot the handle (like a joystick) to align the yellow crosshair over the blue crosshair.
If an entry point was defined in the **Target Planning** tab, move the needle tip along the surface of the patient, until the yellow crosshair is aligned with the pink crosshair.
5. When the crosshair is properly aligned, view the planned trajectory and the ultrasound scan of the needle path to ensure that it is safe and free of obstructions.
 6. Verify the location of the needle and the needle path by using direct imaging.

**WARNING**

Monitor the needle trajectory and intersection circle continuously in Targeting view to ensure safety and accuracy.

7. Advance the needle toward the target. In ultrasound only, ultrasound overlay, and reformatted views, the circle that appears in the **Targeting** frame represents the distance from the tracked tool to the target. The portion of the displayed graphic that represents the tracked tool changes color when it is in front, behind, or in the ultrasound scan plane (yellow, blue, green, respectively). For details, see [“Ultrasound Views” on page 340](#). The distance to the target is also displayed in centimeters in the bottom left corner of the frame.



Targeting View

For information on the needle graphics and the ultrasound overlay view, see the [“Guide”](#) section.

14 Procedure: CT Only

The **CT Only** procedure uses pre-procedure images to target areas of interest for needle-based interventional procedures.

For information on pre-procedure imaging parameters, see the [“Scanning the Patient”](#) section.

Instruments: CT Only

Required and Optional Instruments

- Patient tracker: Required as the patient reference to monitor patient and field generator movement and track patient respiration. The patient reference tracker can be imaged with CT or PET.
- Coaxial needle tracker (CNT): Optional for facilitating needle-based interventional procedures by allowing you to target areas of interest on pre-procedure images and to use the **External Landmark** registration method.
- CIVCO eTRAX needle tip tracking system: Facilitates needle-based interventional procedures by allowing you to target areas of interest on pre-procedure images and to use the **External Landmark** registration method.

NOTE

The coaxial needle tracker and the CIVCO eTRAX needle tip tracking system are incompatible with the Affiniti 70 system.

- Adaptive needle tracker (ANT): Optional for providing needle tracking for interventional procedures or, when used with a stylus, identifies external landmarks during registration.

Optional Tools

The **CT Only** procedure may benefit from the use of additional patient trackers which can be used for **Patient Tracker Match** and to expand patient tracking functions.

**WARNING**

Do not expose any instrument to a strong magnetic field (for example, an MRI scanner). These instruments are neither MRI-compatible nor MRI-safe.

NOTE

For information on the patient tracker or other instruments, see the [“Instruments”](#) section.

NOTE

The PercuNav software can track only one instrument at a time. You can connect more than one needle tracker (CNT or eTRAX system) of different models to the tool connection unit (TCU), or a CNT and an ANT, but you can select only one for tracking. If you connect two needle trackers of the same model to the TCU, neither of those needle trackers can be selected for tracking.

Setting Up Instruments for a CT Only Procedure

The PercuNav system automatically assigns the patient tracker connected to the port with the lowest number as the patient reference. If a patient reference is not selected, click a connected patient tracker on the **Instruments** panel to define it as the patient reference.

NOTE

Sterile instruments may be connected to the tool connection unit during the procedure.

1. Ensure that the patient tracker that will serve as the patient reference is placed close to the ROI to optimize accuracy. For more information about placing the patient tracker, see [“Placing and Removing a Patient Tracker” on page 217](#).

2. Ensure that all tracked instruments to be used in the procedure, including the patient reference tracker, are connected to the TCU.
3. Examine the side view and top view images on the **Field Generator Setup** tab to ensure that the field generator and patient are appropriately positioned for optimal tracking. Place the instruments in the area where they will be used, and ensure that they are displayed in the side view and top view images. You may need to move the field generator or reposition the patient so that the area of interest and instruments are centered in the electromagnetic field of view. For information on the **Field Generator Setup** controls, see [“Field Generator Setup” on page 112](#).
4. When you are satisfied with the instrument selection, touch the **Selected Workflow** tab to continue the procedure.

**WARNING**

Do not displace the patient reference tracker at any time during the procedure. Displacement may cause tracking inaccuracy.

Registration: CT Only

**WARNING**

For all registration methods, make sure that the patient remains immobile. Also, replicate the patient's respiratory state, the patient's physical position, and the position of any immobilization devices on the table at the time of the historic scan.

**WARNING**

Make sure the field generator remains undisturbed during the registration.

You use the registration process to map the previously acquired images (such as CT, MR, or PET scans) to the patient. The following methods of registration are available:

- **Patient Tracker Match:** Used to automatically register same-day scans that were acquired with the landmarks placed on the patient prior to scan acquisition.
- **External Landmark Match:** Used to manually register same-day scans that were acquired with the landmarks placed on the patient prior to scan acquisition.

Patient Tracker Match Touch Screen Controls

To use a touch screen control or change its setting, touch it, or if it is in the bottom row, turn the knob directly below it.

Control	Description
Add Landmark	Marks and identifies the location of a patient tracker on the images. Landmarks are numbered sequentially as you add them and are displayed in the Registered Landmarks section of the left pane on the imaging display.
Back	Saves the data to the current plan and then prompts you to end the procedure.
Blend	Changes the blending of the co-registered scans. For more information, see “Blend” on page 345 .
Clear Match	Clears the registration from selected landmarks. Disabled if the landmarks are not registered.
Delete Landmark	Deletes a selected landmark from the registration method. Available when there are matched landmarks and one is selected.
Find Landmarks	Performs a system search of the images in the registration scan for patient trackers and automatically adds them as landmarks, using the search criteria set in Landmark Find Settings .
Frame	Selects a frame on the display.

Control	Description
Landmark	Displays the following controls: • Exclude: Excludes the selected landmark from the registration set. • Include: Includes the selected landmark from the registration set.
Landmark Find Settings	Displays the Find Landmark search criteria applied when a search is performed for patient trackers in the patient scan. Values that you enter in the Landmark Find Settings dialog box during a PercuNav session are saved and persist to your next PercuNav session.
Match Landmark	Automatically registers the identified landmarks. Available only when the patient reference is identified.
Next	Proceeds to the next step in the workflow.
Pause PercuNav	Pauses the procedure and returns the touch screen to the ultrasound 2D tab, which includes the Resume PercuNav control, used to return to the paused PercuNav procedure. When the PercuNav procedure is paused: • The selected PercuNav workflow remains the same. • The state of the PercuNav procedure remains the same.
Registration	Lists all of the registration methods. Touch to select a registration method. The touch screen controls update automatically after you select a registration method. The default registration method is determined by the loaded data set and connected instruments. The active method is displayed on the control label. For CT Only, the Internal Plane Match and Internal Landmark Match methods are unavailable.
Scroll Slice	Scrolls through the available image slices in the selected frame. Use the middle trackball button to turn Scroll Slice on and off.
Select Landmark	Selects the previous or next landmark.
View	Allows you to change the view shown in the selected frame.

Using Patient Tracker Match



WARNING

The Registration Fit value is only a guideline to help you obtain an accurate registration. You must confirm the accuracy and acceptability of the registration by assessing fusion and needle tracking accuracy.



WARNING

For all registration methods, make sure that the patient and the landmarks remain immobile between scan and registration. Also, replicate the patient's respiratory state, the patient's physical position, and the position of any immobilization devices on the table at the time of the historic scan.



WARNING

To avoid inaccuracies, do not disturb the field generator during the registration.

NOTE

For registration, a minimum of three landmarks are needed. The landmarks can be any combination of patient trackers, external landmarks, or internal landmarks and planes (if using ultrasound).

If the patient was imaged with CT using patient trackers, follow this procedure to complete the registration automatically. For information on the **Patient Tracker Match** controls, see [“Patient Tracker Match Touch Screen Controls” on page 322](#).

1. Click the image series to select the series from the **Review Exam** display, select a procedure, and co-register any images, if necessary.
2. Set up the tools (see [“Setting Up Instruments for a CT Only Procedure” on page 320](#)).
3. Touch **Patient Tracker Match** under **Registration** on the **Selected Workflow** tab. **Patient Tracker Match** is the default registration method if more than one patient tracker is connected to the TCU.
4. Registration is completed automatically. Proceed to step 7. If registration does not complete automatically, proceed to step 5, step 6, or step 7.

NOTE

If three landmarks were detected and matched and you want to add additional landmarks, click each tracker point. The system will update the registration result.

5. If fewer than three landmarks were detected and matched, click each landmark, and then touch **Add Landmark**
6. If more than six landmarks are identified, select each landmark and ensure that it was appropriately selected by clicking the **Registration Landmark** icons. You can also turn the **Select Landmark** control. If it is an extraneous tracker point, click **Delete Landmark**. Repeat this step until only six patient trackers are selected.
7. In the rare instance that the PercuNav system does not find all patient trackers, you can either add a landmark manually (place the crosshair on the patient tracker and press the left trackball button to set the landmark) or alter the **Patient Tracker Find** settings, using the following steps:
 - a. Place the crosshair on a patient tracker that was omitted. Ensure accuracy in all three orthogonal planes.
 - b. Click **Landmark Find Settings**.
 - c. Compare the displayed values to the **Min** and **Max** columns and adjust the values accordingly to include the omitted landmark.

- d. Click **OK** to close the settings dialog box.
- e. Click **Find Landmark**. The following message may appear: "Some match landmark(s) already exist."
- f. Repeat steps a through e until all patient trackers have been located.
- g. When all patient trackers have been identified, ensure the field generator is positioned close to the area of interest and select **Match Landmark**.

NOTE

A minimum of three patient trackers must be matched to yield a registration fit value and progress to the next step in the workflow.

NOTE

The **Patient Tracker Find** settings persist for future procedures.

8. Review the **Registration Fit (cm)** value. You may need to select each patient tracker individually to examine the **Landmark (cm)** value. If required, you may use **Landmark Exclude** to exclude patient trackers from the registration set.
9. To refine the registration, use the controls under **Adjust Fusion** on the **Selected Workflow** tab.
10. When you are satisfied with the match, touch **Next** to proceed to **Guide**.
11. If you want to use a different registration method, touch **Back** to end the procedure and save the registration.

External Landmark Match Touch Screen Controls

To use a touch screen control or change its setting, touch it, or if it is in the bottom row, turn the knob directly below it.

Control	Description
Back	Saves the data to the current plan and then prompts you to end the procedure.
Blend	Changes the blending of the co-registered scans. For more information, see “Blend” on page 345 .
Clear Match	Clears all external landmark (excluding patient tracker) matches.
Delete Landmark	Deletes a selected landmark from the registration method.
Frame	Selects a frame on the display.
Landmark	Displays the following controls: • Exclude: Excludes the selected landmark from the registration set. • Include: Includes the selected landmark from the registration set.
Match Landmark	Matches the selected external landmark on the image to the point on the patient that the transducer touches. Disabled when a patient reference is not selected, when a transducer is not selected, and when the transducer is not detected within the field generator volume.
Next	Saves the data to the current plan, and proceeds to the next step, Guide . Available only if the registration step is complete.
Registration	Lists all of the registration methods. Touch to select a registration method. The touch screen controls update automatically after you select a registration method. The default registration method is determined by the loaded data set and connected instruments. The active method is displayed on the control label. For CT Only , the Internal Plane Match and Internal Landmark Match methods are unavailable.
Scroll Slice	Scrolls through the available image slices in the selected frame. Use the middle trackball button to turn Scroll Slice on and off.
Select Landmark	Selects the previous or next landmark. Disabled if no landmarks are defined.
View	Allows you to change the view shown in the selected frame.

Using External Landmark Match



WARNING

The Registration Fit value is only a guideline to help you obtain an accurate registration. You must confirm the accuracy and acceptability of the registration by assessing fusion and needle tracking accuracy.



WARNING

For all registration methods, make sure that the patient and the landmarks remain immobile between scan and registration. Also, replicate the patient's respiratory state, the patient's physical position, and the position of any immobilization devices on the table at the time of the historic scan.



WARNING

To avoid inaccuracies, do not disturb the field generator during the registration.

If the patient was imaged with CT using patient trackers, use this procedure to perform manual registration. For information on the **External Landmark Match** controls, see [“External Landmark Match Touch Screen Controls” on page 326](#). You can also use the ANT attached to a stylus to match landmarks. For details on preparing an ANT, see [“Attaching and Using an Adaptive Needle Tracker” on page 183](#).

1. Click the image series to select the series from the **Review Exam** display, select a procedure, and co-register any images, if necessary.
2. Set up the tools (see [“Setting Up Instruments for a CT Only Procedure” on page 320](#)).
3. Touch **Patient Tracker Match** under **Registration** on the **Selected Workflow** tab. **Patient Tracker Match** is the default if more than one patient tracker is connected to the TCU.

4. Using the trackball, place the crosshair on the external landmark and press the left trackball button to set the landmark.
5. Confirm that all of the matched landmarks are the patient trackers by turning **Select Landmark** and visually assessing the landmark on the display.
6. The selected landmark is displayed as a new icon in the **Registration Landmark** section, and as a plus sign (+) on the images with the crosshair. Find the corresponding landmark on the patient and touch the tip of the tracked stylus to that point.
7. Touch **Match Landmark**. A green check mark appears on the landmark's icon under **Registration Landmarks** in the left pane to indicate that the landmark has been matched.
8. Repeat steps 4 through 7 to register a minimum of three landmarks.
9. Review the **Registration Fit (cm)** value. You may need to select each landmark individually to examine the **Landmark (cm)** value for each landmark. If required, you can use **Landmark Exclude** to exclude points from the registration. Alternatively, you may resample points by repeating steps 4 through 6.

**CAUTION**

The Registration Fit value is only a guideline to help you obtain an accurate registration. You must confirm the accuracy and acceptability of the registration by assessing fusion and needle tracking accuracy.

10. When you are satisfied with the match, touch **Next** to proceed to **Guide**, or touch **Back** to end the current registration method and restart using another registration method.

Verification: CT Only



WARNING

Violating any of the guidelines provided in the [“Safety”](#) section may greatly reduce the accuracy of the system.

Verification is the process of ensuring that the information displayed by the PercuNav system is accurate. Verification is mandatory and must be performed on all tools used for navigation, by the physician, before and during the Guide process.

Visual verification, including direct imaging, ensures that the tracked tools are functioning correctly and accurately, and that the ultrasound images and fusion are accurate.

The accuracy of the tracked tools is a function of the registration process (see [“Registration: CT Only”](#) on page 321).

Performing CT Only Verification



WARNING

If you are using a coaxial needle tracker (CNT) in your procedure, verify the system with the CNT before you apply the offset value. Use the default offset for verification. (See [“Preparing and Using the Coaxial Needle Tracker”](#) on page 208.)



WARNING

If you are using an adaptive needle tracker (ANT) in your procedure, ensure that the offset is properly measured. Apply the offset before you verify the system with the ANT. (See [“Attaching and Using an Adaptive Needle Tracker”](#) on page 183.)

**WARNING**

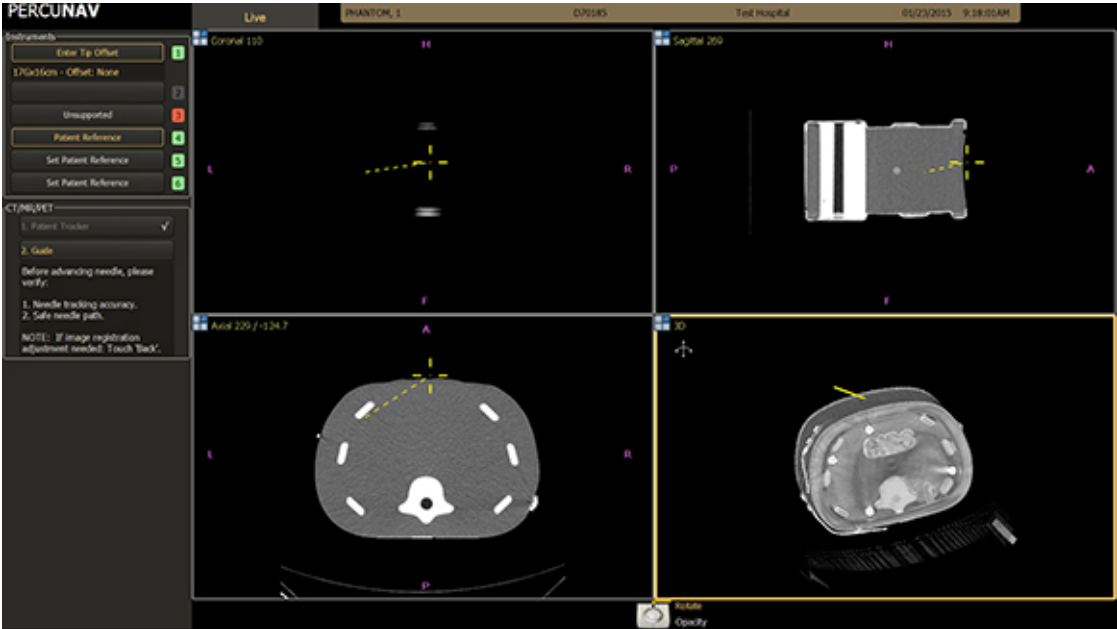
Continuously throughout the procedure, verify the location of the needle and the needle path by using direct imaging.

**WARNING**

Metal interference may cause the fusion or tip tracking to appear inaccurate, when the registration is acceptable.

To visually verify the accuracy of the system and registration for the **CT Only** procedure, you must perform tracked tool verification in the **Guide** display.

1. Using the active tracked tool, gently move the tracked tool over the patient's skin.
2. Confirm that the crosshair on the patient image moves across the images in the same anatomical location as the tool on the patient's skin. Check the x-, y-, and z-axis.
3. If you are satisfied with the verification, continue to [“Guide: CT Only” on page 332](#). If you want to set a target and an entry, see the [“Target Planning”](#) section.



CT Only Verification Display

Guide: CT Only

The **CT Only Guide** procedure uses previously acquired images to allow you to mark areas of interest and track instruments to facilitate needle-based interventional procedures.

CT Only Guide Touch Screen Controls

To use a touch screen control or change its setting, touch it, or if it is in the bottom row, turn the knob directly below it.

Name	Description
Delete Target	Deletes the selected target. The selected target's ID is displayed in the top left corner of the frame.

Name	Description
End PercuNav	Ends the procedure and returns the touch screen to the ultrasound 2D tab.
Frame	Selects a frame on the display.
Layout	Allows you to select an image display layout. See “Layout Configurations” on page 99 .
Needle Offset	Displays the virtual extension of the active tracked tool when you enter a virtual offset. You can use this to examine the effects of proceeding further along the current trajectory.
Pause PercuNav	Pauses the procedure and returns the touch screen to the ultrasound 2D tab, which includes the Resume PercuNav control, used to return to the paused PercuNav procedure. When the PercuNav procedure is paused: • The selected PercuNav workflow remains the same. • The state of the PercuNav procedure remains the same.
Set Target	Adds a target during navigation.
Target	Displays the next or previous target.
Target Display	Indicates which defined targets are displayed: • Show Current: Displays only the current target and entry marker. • Show All: Displays all targets and entry markers in the current orthogonal planes. • Hide All: Hides all targets.
View	Allows you to change the view shown in the selected frame.

Navigating Using the CT Only Guide

For information on setting a target or an entry, see the procedures in the [“Target Planning”](#) section.

**WARNING**

To optimize registration and tracking accuracy, keep patient respiration consistent between scan acquisition, registration, and needle advancement.

**WARNING**

You are responsible for ensuring that the PercuNav system is accurate. The PercuNav system can be used to assist physicians. Physicians must override the system if the PercuNav system does not appear to be accurate or otherwise working as intended.

**WARNING**

Continuously throughout the procedure, verify the location of the needle and the needle path by using direct imaging.

NOTE

To ensure that the PercuNav system remains accurate, use direct imaging to verify the actual location of instruments before and during navigation.

1. Ensure that the correct tool is connected to the TCU and is displayed in the **Instruments** panel. If necessary, click the instrument name in the **Instruments** panel to change the active tracked tool to another connected instrument.
2. Examine the images in the frames. If necessary, change the displayed image by using the **View** control.

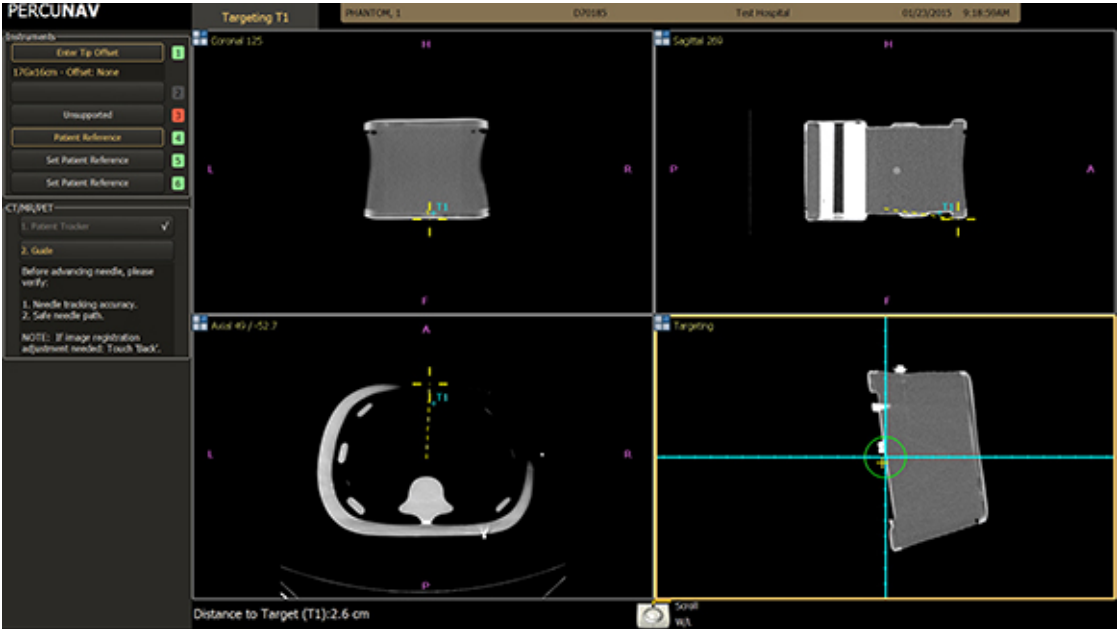
NOTE

You can save your preferences as a custom layout for use in any subsequent procedure. See [“Customizing a Layout” on page 100](#).

3. At the entry point, use the **Targeting** view to align the needle trajectory to the predefined target: adjust the angle of the needle to align the yellow crosshair with the blue crosshair.
4. When the tracked tool is aligned properly, use the **Trajectory 0** or **Trajectory 90** view of the needle path to ensure it is safe and free of critical structures.
5. Verify the location of the needle along the needle path by using direct imaging.
6. Advance the needle toward the target. Monitor the needle trajectory and crosshair continuously to ensure safety and accuracy. The circle that appears represents the distance from the tracked tool to the target. As the tracked tool approaches the predefined target, the circle is green and decreases in size (shown in the **Targeting** view). The distance to the target is also displayed in centimeters in the bottom left corner of the frame.

NOTE

When navigating with an offset, the offset is the virtual extension to the needle tracker in use.

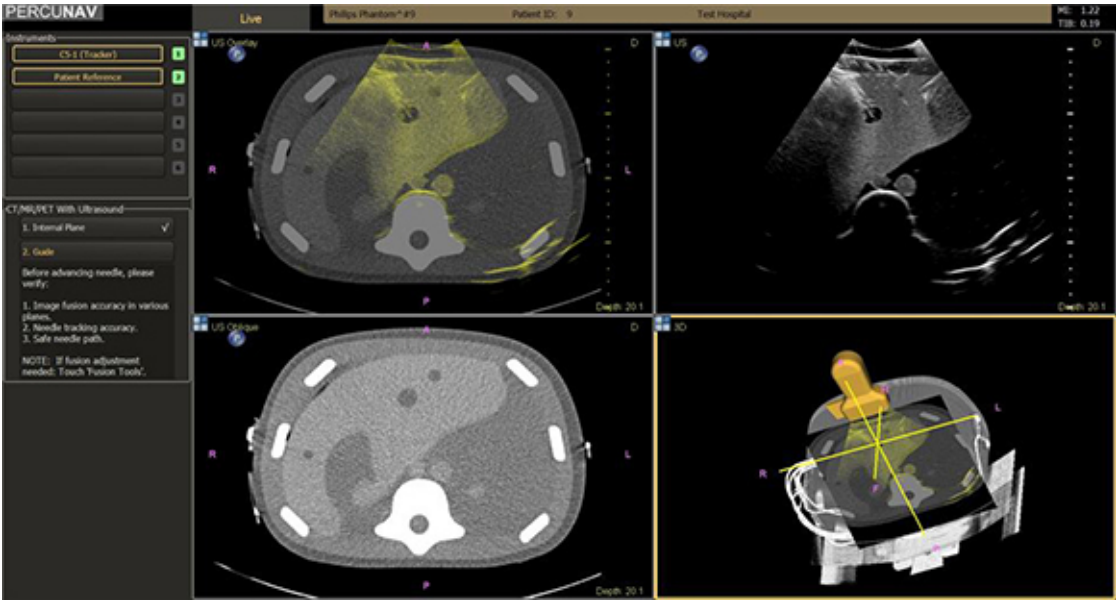


CT Only Guide Display

For information on the needle graphics and the ultrasound overlay view, see the [“Guide”](#) section.

15 Guide

The configuration of the **Guide** display depends on the workflow or procedure selected. This section details the common elements and features of all **Guide** displays. The **Guide** display for each modality is detailed in the section dedicated to that modality.



Guide Display

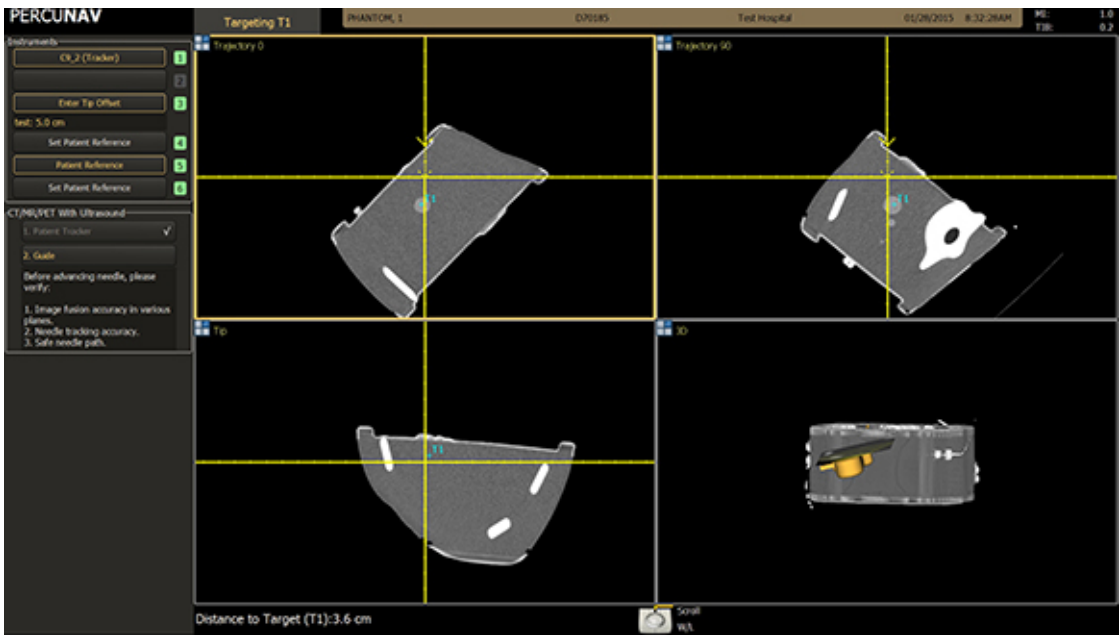
Trajectory Views: 0°, 90°, and Tip

The trajectory views display the pre-procedure images reformatted along the axis of the tracked needle. The yellow crosshair represents the current location of the tip of the tracked tool.

For the trajectory 0 and 90 degrees, the yellow line down from the crosshair shows the projected trajectory of the needle if advanced along the current path. The **Trajectory 0** and **Trajectory 90** views are 2D representations of the pre-procedure images which display the projected needle path and must be used together to accurately position the needle to safely reach the region of interest.

When offset is applied, the solid arrow is the tip of the stylet, and the dotted arrow and the intersection of the crosshair are the virtual tip.

For the **Tip** image, the pre-procedure images are reformatted perpendicular to the tip of the tracked needle.



Trajectory Views: 0°, 90°, and Tip

If you are using a coaxial needle tracker with an offset applied:

- The line has two arrowheads. The solid arrowhead represents the tracked stylet tip. The dashed arrowhead represents the virtual needle tip (with offset applied).

- The solid line represents the tracked tip of the needle; the dotted line and the center of the crossed lines are the virtual tip.

If you are using an adaptive needle tracker with an offset applied, the solid line represents the tracked tip of the needle. There is no dotted line.

Targeting Views

The targeting circle guides the tracked tool to the trajectory to intersect the region of interest. The color of the circle indicates the relative position of the tracked tool to the region of interest:

- The green circle indicates that the tracked tool is approaching the region of interest.
- The red circle indicates that the tracked tool has passed the region of interest.

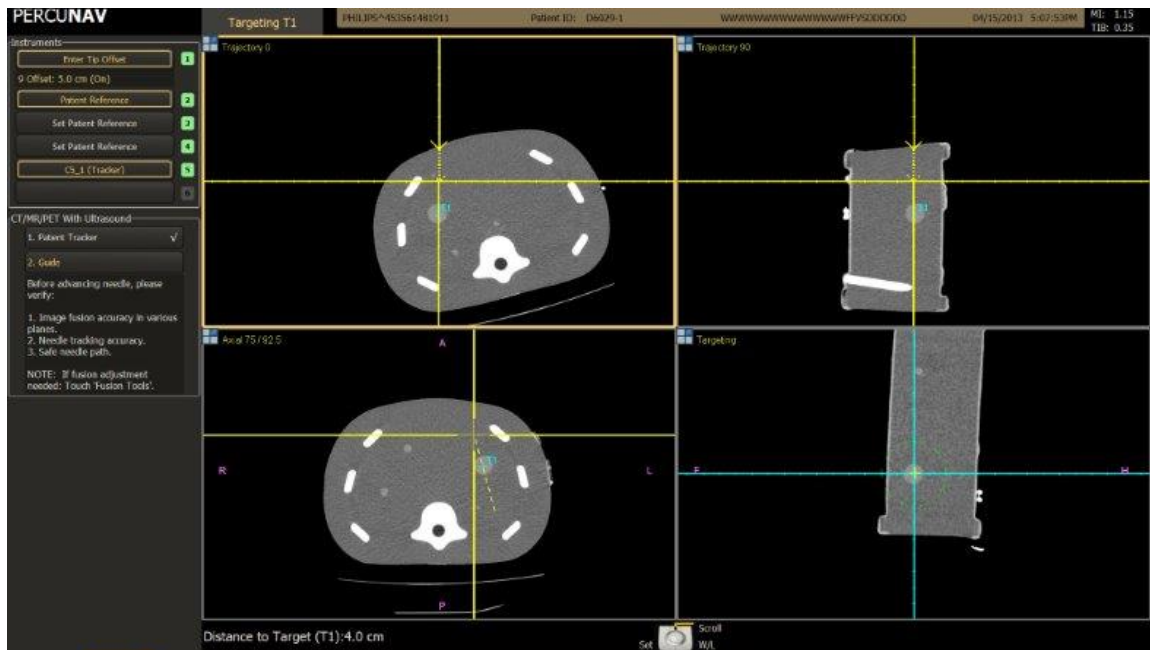
You can adjust the orientation of this view to simulate the physical direction by rotating the 3D view to the same orientation of the patient relative to yourself.

There may be several crosshairs displayed on the screen. The color of each crosshair indicates a specific targeting element:

- The yellow crosshair represents the tracked tool.
- The blue crosshair represents the currently selected target.
- The pink crosshair represents any previously defined entry point.

Position the tracked tool such that the yellow crosshair on the targeting view is aligned on top of the blue target crosshair by pivoting the handle of the instrument.

Once aligned properly, view the planned trajectory of the needle path, using the **Trajectory 0** and **Trajectory 90** frames, and ensure that the path is safe and free of obstructions.



Targeting View

If you are using a coaxial needle tracker with an offset applied:

- The targeting circle appears dashed.
- You can switch between the tracked tip of the needle and the virtual tip by touching **Needle Offset (On/Off)**.
- The solid line represents the tracked tip of the needle; the dotted line and the intersection of the crosshair are the virtual tip.

Ultrasound Views

The ultrasound image can be displayed without the pre-procedure images.

The ultrasound views include **US Only**, **US Overlay**, and **Reformatted**.

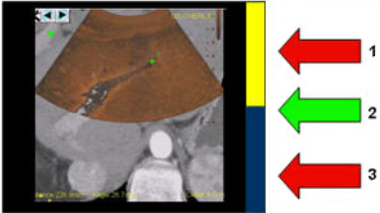
Ultrasound Overlay View

The **US Overlay** view shows the live ultrasound images superimposed on the previously acquired CT, MR, or PET images. The previously acquired images are reformatted along the axis of the ultrasound transducer to match the same imaging plane as the ultrasound image. As the ultrasound transducer is moved, the previously acquired images are automatically reformatted and updated.

Ultrasound Guidance Bars

The PercuNav system provides guidance bars to guide you to the location of the target quickly and easily. The following image is a representation of the guidance bar function. As you move the ultrasound transducer closer to the target scan plane, the colored bars decrease in size. While imaging the scan plane of the target, the colored bars disappear completely.

Ultrasound Guidance Bars

1	Distal to scan plane	
2	Target scan plane	
3	Distal to scan plane	

NOTE

Ultrasound guidance bars appear only on ultrasound frames when a target has been defined.

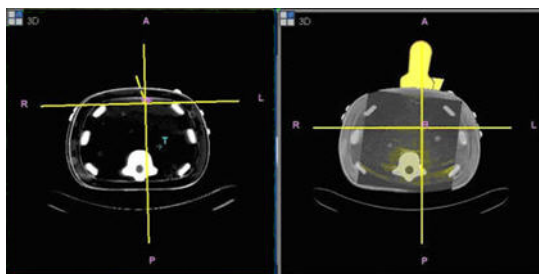
3D Views

The 3D view displays the position and orientation of the ultrasound transducer when using the ultrasound fusion workflow. You can rotate the view with the trackball and adjust the detail and opacity using the controls on the **Fusion Tools** touch screen (see [“Fusion Tools Touch Screen Controls”](#) on page 109).

The yellow crosshair represents the location of the tracked needle tip in three dimensions.

NOTE

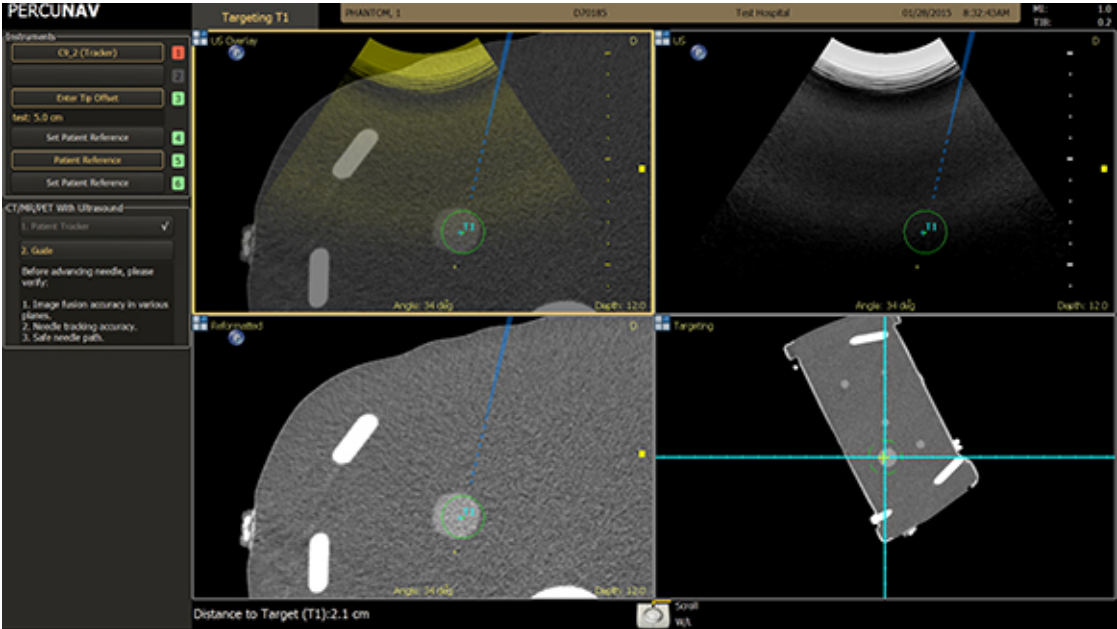
You can use the 3D view to verify that the orientation of the ultrasound transducer or the tracked tool, or both items simultaneously, is correct with respect to the patient volume.



3D Views

Needle Graphics

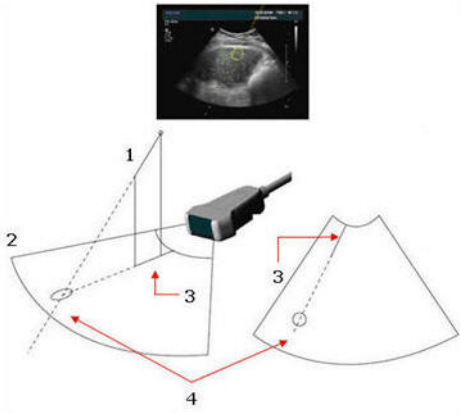
When **Show Needle Graphics** is selected, the **Guide** display includes graphics on the image to help guide you to the target.



Needle Graphics

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Plane Intersection Circle

1	Needle
2	Scan plane
3	Projection of the needle on the scan plane
4	Calculated intersection point between the needle trajectory and the scan plane

The solid line on the display represents the tracked needle, the dotted line on the display represents the trajectory of the needle, and the circle represents the point where the projected needle path will cross the ultrasound scan plane. The color of the lines and the circle represents the location of the needle tip in relation to the scan plane:

- Yellow when the needle tip is in front of the ultrasound scan plane.
- Blue when the needle tip is behind the ultrasound scan plane.
- Green as the needle tip is in the ultrasound scan plane.

When you are guiding the tracked needle to a target, consider the following:

- If you are using a coaxial needle tracker with an offset applied, the solid line represents the tracked tip of the needle; the dotted line is the virtual tip.
- The portion of the tracked needle that is in front, behind, or in the ultrasound scan plane also changes color (yellow, blue, green, respectively).

- The intersection circle does not appear when the angle between the tracked needle and the ultrasound scan plane is less than 5 degrees.

Needle Graphics

Graphic	Description
Needle	Needle • Yellow indicates that the needle is approaching the scan plane • Green indicates the needle is entering the scan plane. • Blue indicates the needle has passed the scan plane. When using a coaxial needle tracker with an offset applied, the solid line represents the tracked tip; the dotted line represents the virtual tip.
Dotted line	Needle trajectory
Yellow crosshair	(Targeting view) Needle tip
Blue crosshair	(Targeting view) Target
Pink crosshair	(Targeting view) Defined entry point.
Green targeting circle	(Targeting view) Shows the relationship between the needle and the target. As the target is approached, the circle decreases in size.
Green intersection circle	(Ultrasound views) Shows the point where the projected needle path will cross the ultrasound scan plane when the angle of intersection is greater than 5 degrees.

Blend

Link US/Volume Images Blending

Turning **Blend** opens the **Blend** display. The functions of the **Blend** control are described in this section.

For both conventional and oversaturation blending:

- To adjust the brightness levels of each modality independently, deselect **Link US/Volume Images Blending**.
- To adjust both the ultrasound and MR brightness at the same time, for example, increasing the ultrasound brightness decreases the MR brightness, select **Link US/Volume Images Blending**.

Conventional Blending

Conventional blending is the default blending function. If **Overlay** is displayed and if the active frame is **Overlay** or **Ultrasound**, controls on the **Blend** display adjust the blending of the volume image (combined if applicable) and ultrasound image simultaneously, increasing one and decreasing the other (with the sum being 100%).

If the active frame displays only volume images and more than one volume scan exists in it (including US to US fusion volume), controls on the **Blend** display adjust the blending of the volume scans simultaneously, increasing one and decreasing the other (with the sum being 100%).

Oversaturation Blending

If **Overlay** is displayed, the list of modalities includes volume modalities plus ultrasound if the active frame is **Overlay** or **Ultrasound**. Pressing **Blend** selects a modality from the list of modalities shown in the active frame. The list of modalities includes volume modalities if the active frame contains only volume images and more than one volume exists. The controls on the **Blend** display adjust the blending of the selected modality between 0% and 100% without affecting the blending of other modalities.

Blend is disabled if **Overlay** is not displayed and **US** is the active frame or if the active frame displays a volume image only and only one volume scan exists.

You can use the **Auto-Blend** control to automatically blend the ultrasound image to the CT, MR, or PET image and provide a dynamic fusion display in a continuous loop.

Pointer

By default, the pointer is hidden from all guide displays. To display the pointer, press **Pointer**.

Layout

You can use the **Layout** control to switch the touch screen to the layout screen that lists the following layout options, depending upon the procedure:

- **Triplanar**
- **Oblique**
- **Fusion 1x1**
- **Fusion Left/Right**
- **Fusion 2x2**
- **Contrast Side/Side 2x2**
- **Custom 1**
- **Custom 2**
- **Custom 3**

You can use the custom options to save custom layouts.

Respiratory Tracking

The **Respiratory Tracking** function monitors and displays patient tracker or patient tracker movement, which can be used to indicate patient respiratory motion. When the **Respiratory Tracking** function is active, the control is green, and a wave is displayed to represent the patient's respiratory cycle.

To turn **Respiratory Tracking** on and off, touch **Respiration** on the **Fusion Tools** touch screen.



WARNING

The **Respiratory Tracking** function and the definition of the **Patient Reference zone** are to be used at the sole discretion of the physician. The movement of the patient reference tracker may be influenced by many factors and may not reflect actual respiration.

Respiratory Tracking starts or stops drawing the respiratory motion curve based on Patient Reference Zone location. There is a learning phase when the **Respiratory Tracking** function is engaged. This learning phase lasts at least one full respiratory cycle. During the learning phase, the system collects the patient reference location data and finds the magnitude of location variation of the patient reference. This magnitude is then used to normalize the respiratory motion curve plot so that a consistent image is drawn.

NOTE

The respiratory motion curve does not correlate directly to internal organ motion during respiration.

The vertical axis on the curve plot indicates the value of the safe zone (in cm) of the reference location, which is the location when you start the respiratory tracking. Two horizontal green lines are displayed to represent the safe zone. One horizontal green line is displayed if the safe zone is 0 cm. If the patient reference is out of view or in error, no respiratory curve is plotted. You can use the **Flip** control to invert the wave along the x-axis.

NOTE

If the placement of the patient, the field generator, or the Patient Reference changes, you must reinitialize the **Respiratory Tracking** function.

The **Patient Reference Zone** feature under **Respiratory Tracking** in the **System Settings** display allows you to define a range of movement for the patient tracker during respiration. See [“Patient Reference Zone” on page 349](#). You can activate the **Beep** function to receive an audio cue when the patient tracker is within the patient reference zone.

Patient Reference Zone



CAUTION

The **Respiratory Tracking** function and the definition of the **Patient Reference Zone** are to be used at the sole discretion of the physician. The movement of the patient tracker may be influenced by many factors and may not reflect actual respiration.

The **Patient Reference Zone** allows you to define a range of the curve (in centimeters), which aids in visualizing the movement of the patient tracker within this range. This feature is available in the **Respiratory Tracking** section of the **System Settings** display. When you set a range, a second horizontal line appears on the respiratory motion curve to indicate the **Patient Reference Zone**. The **Patient Reference Zone** must be defined before **Respiratory Tracking** is turned on or during the learning phase.

NOTE

If you are using the **Respiratory Tracking** function, place the patient tracker on an area that is stable and provides the best sample respiratory motion. When used in this way, respiratory tracking monitors surface motion, rather than internal organ shift, during respiration.

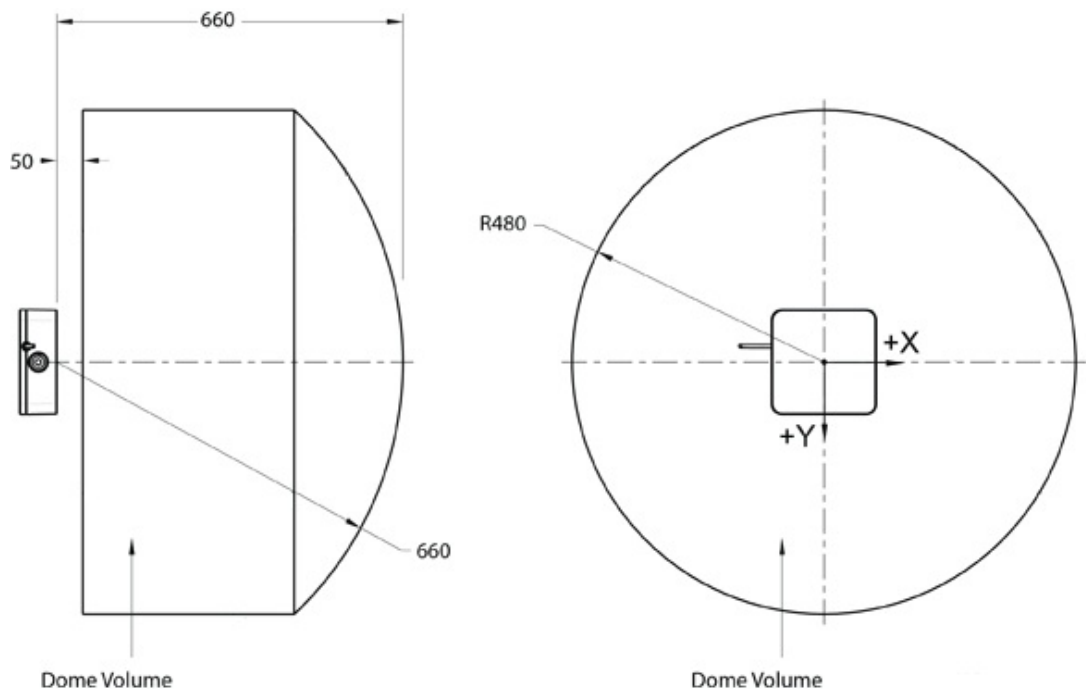
16 Specifications

System Specifications

Specification	Value
Maximum number of tools	6
Measurement rate	40 Hz (< 3 sensors)
Tools	5 or 6 degrees of freedom
Measurement volume	The field generator is characterized with a dome measurement volume. For the dimensions of the characterized volume (in millimeters), see the figure. (This figure provides context only and should not be used for inspection.)
Offset	50 mm
Connector	Lanyard

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Dome Measurement Volume in Millimeters (mm)

Storage and Transportation Specifications

For storage and transportation specifications, see the ultrasound system's *User Manual*.

Operating Environment Specifications

For operating environment specifications, see the ultrasound system's *User Manual*.

Electrical Specifications

For electrical specifications, see the ultrasound system's *User Manual*.

Modality Interface

DICOM standard. DICOM conformance statements for Philips products are available at this website:

www.healthcare.philips.com/main/about/connectivity/dicom_conformance_main.wpd

Safety Requirements

Electrical Safety

The PercuNav system, when integrated with EPIQ series or Affiniti 70 ultrasound systems, complies with the requirements of IEC 60601-1 Medical Electrical Equipment, General Requirements for Safety, including all applicable collateral and particular standards, as well as all applicable national deviations.

Electromagnetic Compatibility

The PercuNav system, when integrated with EPIQ series or Affiniti 70 ultrasound systems, complies with EN 60601-1-2: 2007 for Non Life Supporting, Group 1, Class A Equipment.

Electromagnetic Compatibility and Compliance

For information on electromagnetic compatibility and compliance, see the [“Safety”](#) section.

Service Life

Service life is defined by IEC 60601-1 as expected operational duration of medical device components under normal use conditions, ensuring continued safety and essential performance throughout that period.

NOTE

Regular service and maintenance are necessary for a medical device or component to perform for its expected service life. Expected service life is also contingent on proper care, cleaning and handling. Reasonable care includes inspection, cleaning, and disinfection, as necessary.

The service life for the PercuNav components is as follows:

- System software: 10 years

- Field generator: 80,000 hours
- Tool connection unit (TCU): 80,000 hours (including TCU cabling)
- System tray: 80,000 hours

The service life of the tracked instrumentation is as follows:

- Adaptive needle tracker (ANT): 3 years, 1,000 uses, or 20 steam sterilization cycles, whichever comes first
- Coaxial needle tracker (CNT): restricted to single-patient use only. Shelf life of the CNT sterile packaging is 3 years.
- Patient tracker: 3 years or 1,000 uses, whichever comes first.
- Ultrasound tracker: 3 years or 1,000 uses, whichever comes first.

Incident Reporting

If a serious incident (death, injury, impairment, or intervention) occurs while the device is in use, report immediately to the manufacturer and/or the competent authority of the member state where the user or patient is located.

17 Troubleshooting Guide

The troubleshooting information provided here is a summary of common errors and error messages along with suggested solutions for these errors.

NOTE

For errors not listed here, contact your Philips representative.

Errors and Troubleshooting Steps

Error	Reason	Solution
Instruments do not consistently track.	Instrument is near the out-of-volume region of the field generator.	Move the field generator or instrument so it is positioned entirely within the volume of the field generator.
	Interference	Ensure the environment is free of metal objects, such as stretchers, monitors, and metal procedure tables. If metal is found, increase the distance between the working area and the metal object.
	Tracked instrument is not functional.	Replace instrument and contact Philips.
	Tracked instrument is damaged.	Replace instrument.

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Error	Reason	Solution
Instrument does not track or is not recognized by system.	Tracked instrument is not functional.	For non-eTRAX systems, replace instrument and contact Philips. For eTRAX systems (EPIQ systems only), contact CIVCO.
	Tool is not connected properly.	Connect tool to a different tool port.
	TCU is not connected properly.	Reconnect the TCU to the PercuNav system tray. If the problem persists, contact Philips.
	TCU failed.	Reconnect the TCU to the PercuNav system tray. If the problem persists, contact Philips.
	Tracked instrument is not supported by this version of the PercuNav software.	Replace with supported instrument. See “Supplies and Accessories” on page 22.
	Tracked instrument is not supported by the PercuNav licensed option installed on this ultrasound system.	Replace with supported instrument or update the PercuNav licensed option.
	Field generator is incompatible.	Ensure the connected field generator is designed to work with this version of the PercuNav software.
	The required offset for tool is not applied.	Apply tool offset.
	The connected ultrasound tracker is incompatible with the currently selected ultrasound transducer.	Replace either the ultrasound tracker or ultrasound transducer to ensure a match.
	PercuNav system tray is not functional.	Contact Philips.

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Error	Reason	Solution
Cannot select the patient scan for viewing.	Scan set contains unsupported parameters.	Re-scan patient using the guidelines provided in the “Scanning the Patient” section.
	Scan contains invalid parameters and cannot be imported.	Re-scan patient using the guidelines provided in the “Scanning the Patient” section.

Error	Reason	Solution
Registration Fit (cm) values are too high.	One or more landmarks are not matched accurately.	Do one of the following: - Find the landmark with the highest Landmark Error values and exclude it. - Match additional landmarks to improve the registration fit value.
	High interference	Adjust your workspace to reduce interference. Ensure the environment is free of metal objects, such as stretchers, monitors, and metal procedure tables. If metal is found, increase the distance between the working area and the metal object.
	Incorrect patient scan loaded.	End the current PercuNav procedure, select the correct patient scan, and restart the PercuNav procedure.
	Patient moved during registration.	Make sure that the patient is immobilized during registration.
	Patient trackers or external landmarks were disturbed between scan acquisition and registration.	Ensure the following: - Patient is immobilized between scan acquisition and completion of registration. - Patient reference tracker is applied securely (see “Placing and Removing a Patient Tracker” on page 217).

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Error	Reason	Solution
Ultrasound verification is not accurate, or overlay is not accurate.	Ultrasound tracker is not positioned properly or has been moved.	Check the ultrasound tracker to ensure the following: • Tracker is attached to the transducer properly. • Mounting plate on the bracket of the tracker is stable. Adjust the ultrasound tracker as necessary and re-verify. See “Ultrasound Trackers” on page 228. If you are using the C5-1 single-use ultrasound transducer tracker (model no. MEG005), ensure the transducer clamp is set at position "A."
	High interference	Adjust your workspace to reduce interference. Ensure the environment is free of metal objects, such as stretchers, monitors, and metal procedure tables. If metal is found, increase the distance between the working area and the metal object.
	Incorrect patient scan loaded.	End the current PercuNav procedure, select the correct patient scan, and restart the PercuNav procedure.
	Patient moved during registration.	Make sure that the patient is immobilized during registration.

Error	Reason	Solution
Ultrasound verification is not accurate, or overlay is not accurate. (continued)	Patient trackers or external landmarks were disturbed between scan acquisition and registration.	Ensure the following: • Patient is immobilized between scan acquisition and completion of registration. • Patient reference tracker is applied securely (see “Placing and Removing a Patient Tracker” on page 217).
	Images from a historic data set may not be appropriate for fusion due to patient weight loss, hydrodissection, or positional variance between scan and procedure.	End the current PercuNav procedure, select a more current patient scan, and restart the PercuNav procedure.
	Various	Verify that ultrasound settings are supported and consistent with the PercuNav system. If the system is inaccurate, stop the procedure immediately and determine cause of inaccuracy.
System does not appear to be accurate.	Various	• Verify that ultrasound settings are supported and consistent with the PercuNav system. If the system is not accurate, stop the procedure immediately and determine cause of inaccuracy. • Ensure the environment is free of metal objects, such as stretchers, monitors, and metal procedure tables. If metal is found, increase the distance between the working area and the metal object.

Error	Reason	Solution
Patient Tracker Match does not work or is inaccurate.	Patient trackers or external landmarks were disturbed between scan acquisition and registration.	Ensure the following: • Patient is immobilized between scan acquisition and completion of registration. • Patient reference tracker is applied securely (see “Placing and Removing a Patient Tracker” on page 217).
	Tracked instrument is not functional.	Replace instrument.
	High interference	Adjust your workspace to reduce interference. Ensure the environment is free of metal objects, such as stretchers, monitors, and metal procedure tables. If metal is found, increase the distance between the working area and the metal object.
Cannot enter or reenter PercuNav mode.	PercuNav option is not installed.	Contact Philips service.
	Ultrasound system is in a mode that is incompatible with the PercuNav software.	Do the following: 1. On the 2D tab, touch Pause PercuNav. 2. Turn off incompatible modes. 3. On the 2D tab, touch Resume PercuNav.
	A supported ultrasound transducer is not connected.	Connect a supported ultrasound transducer.

Error	Reason	Solution
System appears accurate but progressively becomes less accurate during procedure.	Patient trackers or external landmarks were disturbed between scan acquisition and registration.	PercuNav accuracy is directly related to the position of the patient reference tracker during registration. If the patient reference tracker is moved after registration, the system does not function accurately. Re-register with the current patient reference tracker location. If initial registration used patient trackers exclusively, re-scan the patient and re-register using the new scan.
	Respiratory cycle changed during procedure.	Perform registration again ensuring standardized respiration. (For example, if CT was acquired at full inspiration, perform registration, verification, and guide at full inspiration.)
	Movement of internal structures due to procedure.	Some intra-procedural tasks change position and orientation of internal structures compared with the relative position when images were acquired before the procedure. Acquire and import a fresh scan for registration, verification, and guide.

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Error	Reason	Solution
PercuNav system becomes unresponsive during a procedure.	Various	Do the following: 1. Press the power button on the ultrasound system to restart the system and enter PercuNav mode. 2. Check all of the connections between the PercuNav system tray and the ultrasound system. 3. Re-select the procedure type. 4. Re-select the scan data (if applicable). 5. Re-select the plan data (if applicable) to restore targets and registration. If problems persist, if other malfunctions occur, or if the system turns off, discontinue use of the PercuNav system and revert to direct imaging.
Lost communication or connection with the field generator.	Temporary data disruption	Do one of the following: • On the Field Generator Setup display, touch Initialize to re-initialize the field generator. • Re-select the plan data (if applicable) to restore targets and registration. • If the problem persists, end and restart the procedure. • If the problem persists, end the procedure and restart the ultrasound system.

Error	Reason	Solution
Auto registration failed at the reconstruction step.	Liver sweep reconstruction failed.	Ensure that the cineloop contains the intended liver sweep before touching Register . Ensure that the ultrasound trackers are within the volume for the entire sweep acquisition.
Auto registration failed at the segmentation step.	Vessel segmentation failed. No vessel tree is drawn.	Retry the registration, using a non-contrast data set. If vessels are visible, retry using One Click registration and specify a vessel location.
Auto registration failed at the registration step.	Vessel or surface segmentation failed. The vessel tree is drawn.	Retry the liver sweep with different depth values or views.
Auto registration failed.	Various	Retry the auto registration, or select another registration method.

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