Instructions for Use

English

UroNav

Version 4.4

PHILIPS

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1 Introduction

Product description

UroNav is a medical image processing device that provides image-guided intervention and diagnostic information, which guides interventional instrumentation to targets that have been defined by the physician.

Help and guidance information

The user information provided with your product includes the following:

- Instructions for Use (this document) — introduces you to UroNav features and concepts, helps you set up your system, includes important safety information, and provides instructions for use specific to the UroNav when integrated with the ultrasound system. For more information, see “About the Instructions for Use” on page 9.
- Shared Roles for System and Data Security — contains guidelines to help you understand how the security of your Philips product could be compromised and information on Philips efforts to help you prevent security breaches. For more information, see “Privacy and security features” on page 16.

The product is designed for use with other optional and integrated systems and equipment. These Instructions for Use provide basic information on how the system interfaces with other equipment. For information on how to use the other equipment, you should refer to the Instructions for Use supplied with the equipment.

NOTICE

When using surgical instruments or attachments, see the instructions for use for the particular instrument or attachment.

User documentation is available as PDF downloads on our website. Download all Instructions for Use (IFU) for this product and other user information from: www.philips.com/ifu. PDF file reader software—a free download from Adobe—is needed to view electronic user information. A printed version of this IFU document may be requested from Philips Customer Service, or via the Request documentation form on our website.

Contact Us

If you have questions about the user information, or you discover an error in the user information, in the USA, please call Philips Customer Service at: 1-877-468-4861.

Customer support representatives are available worldwide to answer questions and to provide support. Please contact your local Philips representative for assistance. Any serious incidents that have occurred in relation to the device should be reported to the manufacturer.

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In addition, any serious incidents that have occurred in the European Union (EU) in relation to the device should be reported to the competent authority of the EU Member State in which the user and/or patient is established.

Contact Philips Customer Service in the event of the packaging being:

- damaged;
- unintentionally opened before use; and
- if the packaging is exposed to environmental conditions outside of those specified in this IFU.

About the Instructions for Use

These Instructions for Use are intended to assist users in the safe and effective operation of the product described.

These Instructions for Use describe the most extensive configuration of the product, with the maximum number of options and accessories. Not every function described may be available on your product.

These Instructions for Use may contain descriptions regarding the features and functionalities that are not implemented on the current equipment shipped for Japan and/or the product(s) that is/are not currently sold in Japan due to limitations and restrictions under the applicable local laws and regulations in Japan. Please contact your local sales representatives and/or customer support for details.

Keep this document in a convenient location for easy reference during the use of this product.

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

Pay special attention to all the information given in “Safety” on page 20, and procedures described in “Cleaning and disinfecting UroNav” on page 45.

Conventions

Throughout this document the following conventions are used:

WARNING

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

CAUTION

A caution alerts you to where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possible in a remote risk of more serious injury, and/or cause environmental pollution.

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NOTICE

This is used to identify special advice, for example to assist the user or to improve an operating sequence.

Typographical conventions

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

- All multi-step procedures where the sequence is important are numbered. You must complete steps in the order that they are presented to ensure success.
- Single-step tasks, substeps, and procedures where the sequence is unimportant are indicated by small arrows.
- Bulleted lists indicate general information about a particular function or workflow. They do not imply a sequential procedure.
- Control names and menu items or titles are spelled as they are on the system.
- Symbols are shown in this document as they appear on the system.
- The pointer is the cursor used to select elements on the display.
- Point means to position the tip of the pointer or cursor on an item on the display.
- Click or select means to move the pointer or cursor to an object and press one of the mouse buttons.
- Double-click means to quickly click twice to select an object or text.
- 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 one of the mouse buttons while moving the pointer. Use this method to move an object on the display.
- 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.

Images

Many images in this Instructions for Use are of a standard multimodality phantom, which contains artifacts representing lesions that you can see on MR and U/S images.

Images, figures, diagrams, and all other graphic representations in this Instructions for Use are for demonstration purposes only and may include features not included with every UroNav. For questions or concerns regarding images in this Instructions for Use, please contact Philips Customer Service.

Supplies and accessories

To order additional supplies, consumable instrumentation, or accessories, please contact your Philips sales representative. Reference “Appendix B” on page 166 and “Appendix C” on page 210 for supported Ultrasound and transducer combinations.

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System servicing

The system will be serviced by the Philips engineering team if Philips deems this necessary.

Upgrades

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

Philips is continuously adding to the instrumentation that the UroNav supports. For more information on supported instrumentation, please contact your Philips representative.

Training

Training is conducted by the Philips support team with the customer on site at or after installation of the UroNav. Materials include these instructions for use, the training guide, and the system. The basis for this training is the stated Intended Use of the device and will be covered accordingly. Any training options should be discussed with the customer service organization.

If any circumstance arises that require additional information, please contact Philips Customer Service at the phone number previously provided in these instructions for use.

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2 Intended use

Indications for use

UroNav is a stereotaxic medical device intended to assist the clinician with planning and guidance for clinical, interventional and/or diagnostic procedures for biopsy and/or soft tissue ablation.

It provides 2D and 3D visualization of Ultrasound (U/S) images and the ability to fuse and register these images with those from other imaging modalities such as Magnetic Resonance (MR). It also provides the ability to display a simulated image of a tracked insertion tool such as a biopsy needle, guidewire, grid plate or probe on a computer monitor screen that shows images of the target organ and the current and projected future path of the interventional instrument taking into account patient movement.

Other software features include patient data management, multiplanar reconstruction, segmentation, image measurements and 2D/3D image registration.

UroNav is indicated for medical conditions that require interventional and/or diagnostic procedures of the prostate gland. The software is not intended for diagnosis. The software is not intended to predict ablation volumes or predict ablation success.

Intended operator profile

UroNav is to be used by trained medical professionals specialized in urology, interventional radiology, image-guided interventions or similar medical specialty.

Target population and environment

The target population for the use of UroNav includes any person who is at risk for prostate disease, and who was deemed eligible for a diagnostic MRI scan. Consequently, this target population includes adult males wherein prostate cancer risk is prevalent. Under normal use, UroNav should not come into contact with the patient.

UroNav is to be used in a clinical setting such as hospitals, outpatient clinics and intervention centers. UroNav is to be used in medical procedure rooms that are suitable for performing prostate interventions, such as soft tissue biopsies and soft tissue ablations.

Operating principle

UroNav is designed to target areas of interest visualized with pre-procedure Magnetic Resonance Imaging (MRI) during ultrasound-guided biopsy and/or ablation procedures. The fusion of the MRI dataset with the real-time ultrasound is accomplished via electromagnetic tracking, which directs the clinician to sample areas of interest detected by MRI.

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General safety and effectiveness

To facilitate safe and efficacious operation of the system by a trained healthcare professional, instructions for use are provided as part of the device labeling, and training is provided during system handover.

For more information on the Instructions for Use (IFU), see “About the Instructions for Use” on page 9. For more information about training, see “Training” on page 11.

Contraindications

The use of UroNav is contra-indicated in patients with Creutzfeldt-Jakob disease (CJD), variant Creutzfeldt-Jakob disease (vCJD), or other known or suspected slow virus infections.

Compatibility statement

UroNav is interoperable with DynaCAD for DICOM data import and export.

The product described in this Instructions for Use should not be used in combination with other products or components unless such other products or components are expressly recognized as compatible/interoperable by Philips. A list of such products and components with their versions is available from the manufacturer.

See the “Appendices” on page 163 for lists of supported 3rd party devices.

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

Changes and/or additions to the product that are carried out by persons without the appropriate training and/or using unapproved spare parts may lead to the Philips warranty being voided.

Clinical benefits and undesirable side effects

UroNav provides image-fusion guidance to facilitate navigation of interventional instruments by the user to targets that have been defined by the physician in biopsy and ablation procedures.

UroNav has no known undesirable side effects.

Essential performance

The essential performance function of the UroNav is to facilitate targeting during needle guidance. Please follow the instructions in “Safety” on page 20 to maintain the essential performance of the device. Additional recurrent testing or verification of essential performance is not necessary.

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Equipment Classification and Specifications

Classification	Specification
Type of protection against ELECTRIC SHOCK	**UroNav**: CLASS I
Degree of Protection Against INGRESS OF WATER	**UroNav**: IPX0 (Ordinary Equipment) **EM tracker, EM sensor end only**: IPX7 **EM tracker, connector end**: IPX0 (Ordinary Equipment) Reference "Cleaning and disinfecting the EM Trackers" on page 49 for information on liquid ingress restrictions and handling. **Foot pedal**: IPX7 **Field generator**: IPX0 (Ordinary Equipment)
Degree of SAFETY of application in the presence of flammable anesthetic mixture with AIR or with OXYGEN or NITROUS OXIDE	Not suitable for use in the presence of a flammable anesthetic mixture with AIR or with OXYGEN or NITROUS OXIDE
Suitability for use in an OXYGEN RICH ENVIRONMENT	Not suitable for use in an OXYGEN RICH ENVIRONMENT
Single-use, requires cleaning prior to use	Probe holder
Reusable Component, requires cleaning and disinfection prior to use	EM tracker, Stepper and Stepper arm and stand
Mode of Operation	Continuous
Means of AC Mains disconnection	Mains power cord attachment plug
Mass of UroNav	80.7 kg
Mass of EM Tracker	34 g
Mass of Probe Holder	17 g – may vary slightly with model
Mass of Stepper	1.6 kg
Mass of Stepper Arm	4.3 kg
Mass of Stepper Stand	26 kg
Range, Accuracy, and Precision of displayed values	UroNav is an image-guided system. Displayed values (mm) are for reference only and should not be used as precision navigational tools. All device positioning should be determined by a trained physician.
Image compression	Image compression is not used in the rendering of any images displayed by the UroNav.

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Regulatory compliance

The Philips product complies with relevant international and national standards and laws. Information on compliance will be supplied on request by your local Philips representative or by the manufacturer.

Customer service

Should additional assistance be required, please see the section entitled “Help and guidance information” on page 8 in this Instructions for Use for details on how to contact Philips Customer Service.

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3 Privacy and security features

The following sections relate to the privacy and protection of patient information and the security of the UroNav.

Customer role in product security partnership

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

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

As with any computer-based system, protection must be provided such that firewalls and/or other security devices are in place between the medical system and any externally accessible systems. Although the system incorporates protection mechanisms to protect it against the intrusion of malware (such as viruses), a remote possibility remains that a system can become infected, and the user might notice unfamiliar system behavior and/or performance. If this happens repeatedly, such as after the system has been switched off and on again, the user is advised to call Philips service to have the system checked and, if needed, cleaned from malware.

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Access control

The following functionality with respect to access control is implemented for UroNav:

- UroNav is configured with two user accounts by default: A clinical user account and a service user account.
- The service user account, accessible only by Philips Service personnel, is protected by two-factor authentication. This account can be used for local or remote servicing.
- By default, when UroNav starts, it displays the clinical user account. User authentication can be enabled to control access to the system and protect it from unauthorized access.
- The clinical user account is restricted to only grant access to functionality required to achieve the intended purpose of the device, including access to patient data. Installation, system configuration, and any other modification of the system software are not possible with this user account.
- It is the customer’s responsibility to manage user accounts and passwords for user authentication.
- Modification of the default administrator user account is not allowed. Please contact Philips Service.

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- The system supports only single-user sessions. It does not provide the functionality to register multiple simultaneous users or to switch between users other than via log-off/log-on.
- UroNav blocks system access through the Remote Desktop Protocol.
- The system can be configured by Philips Service personnel to synchronize with an external time source.
- Access to the BIOS is password protected.

Automatic screen lock

The following functionality with respect to automatic screen lock and blanking is implemented for UroNav:

- UroNav will automatically blank and lock the user interface after a preset time of inactivity, by default.
- Philips service personnel is able to control screen blanking through the operating system Local Group Policy.
- UroNav supports a physical button to turn off its screen.

Confidentiality of personal data

The following functionality with respect to confidentiality of personal data is implemented for UroNav:

- DICOM communication is restricted to a pre-defined node list.
- UroNav supports remote access by Philips service personnel; provision of service to UroNav may involve access to and viewing of personal health information on the system. Remote access is only allowed upon customer consent, and customers are notified by the system that a remote session has been initiated.
- Secure DICOM is supported.
- UroNav does not allow the clinical user account to sanitize personal data stored on the system for purposes like system decommissioning or resale. Please contact your local service organization for information on secure decommissioning of the device.

Security-related configuration

The default security-related configuration of UroNav can be modified up to a limited and supported extent. Please contact Philips Service for assistance.

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Contingency, data backup, and storage

UroNav may contain patient information, including protected health information; therefore, deleting patient studies may not permanently remove patient data.

Likewise, UroNav is not intended to serve as an image archive, so when it comes to backing up data, it is important to remember:

- If backups are made, be advised that certain backup media may not be supported in future releases due to technology obsolescence.
- If backups are made, be advised that these backups may contain personal data (including protected health information). Therefore, it is recommended that the target drive be encrypted.
- Please refer to the Export and Backup section of this Instructions for Use for proper backup of procedures for the UroNav. The backup procedures outlined in this section must be followed to support data migration of backed-up UroNav data (such as, to external media, network archive, etc.). Failure to follow the backup procedure may prohibit migration and recovery of any backed-up UroNav data.

Encryption and De-identification

UroNav supports the encryption of personal data (including DICOM data) for transmission or storage on removable media.

UroNav does not support the de-identification of DICOM data for export functionality.

The solid-state drive of UroNav is encrypted.

Emergency Access Procedure

UroNav does not support emergency access/backup functionality; this is outside of the scope of its intended use.

Integrity

UroNav does not have a built-in check for application or data integrity for storage, backup, or transmission.

The Active Directory domain must not push any changes to the GPO and registry of the UroNav.

Malware protection

UroNav is equipped with anti-virus software which is designed to detect viruses and to deny access to infected files before they can do any damage.

Anti-virus definitions should be updated on a regular (daily) basis. The Anti-virus definitions update mechanism automatically checks for new virus definition files at a pre-configured time (as set by a Philips service representative) and installs them, if available. It is the responsibility of the system operator to allow for the UroNav system to connect to the internet at the pre-configured times (as set by Philips service representative) so the virus definitions can be updated, if available.

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If the virus scanning software has detected infection by malware, it will attempt to block and report the infected files. Be sure to adhere to local procedures regarding malware infection of customer systems. (For example, this may include disconnecting from the network.)

CAUTION

In case of computer virus infections, always notify Philips service to assess the integrity of the system.

NOTICE

Regular (daily) anti-virus definition updates depend on a network connection allowing the internet connection to the anti-virus software.

Physical access

The following physical characteristics of UroNav will be taken into account for system operation and access control:

- UroNav does not disable physical I/O device interfaces (such as, USB) by default.
- UroNav restricts access to external bootable devices by default.
- UroNav is “service friendly” and does not require special tools to open chassis and remove solid-state drives.
- There is no detection of unauthorized physical access into the system, e.g., tamper-proof seals.
- The UroNav system should be used and stored in a secure room to prevent unauthorized access.

System and application hardening

Here are some important things to remember about system/application hardening:

- The UroNav employs a firewall; however, it is the customer’s responsibility to provide a secure operating environment for this device.
- Updates to the UroNav software, including updates to the Windows™ Operating Systems, may only be installed by a Philips service representative.

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4 Safety

Before using the UroNav, please read this safety information. This section outlines the safety requirements and warnings related to features of the UroNav, including the instrumentation and optional equipment. It also details cautions to prevent actions that may damage the equipment.

NOTICE

For information on the safety requirements and features of an Ultrasound system, see the manufacturer's user manual.

NOTICE

If you observe a malfunction, or if the system turns off unexpectedly, discontinue use of the UroNav and revert to direct imaging.

These safety warnings and pre-cautionary information are organized accordingly:

- "General warnings or cautions" on page 21
- "Electrical and Mechanical safety warnings" on page 21
- "Fire safety warnings" on page 23
- "Biological safety warnings" on page 23
- "Environmental warnings and conditions" on page 25
- "Field generator warnings and cautions" on page 28
- "Equipment protection and cable management" on page 30
- "Network/Data coupling warnings" on page 32

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General warnings or cautions

Additional safety warnings or precautionary information are found throughout these Instructions for Use and are formatted similarly to the following:

CAUTION

The UroNav is meant only to assist in positioning devices. Use direct imaging to verify the actual location of instruments positioned with it. Physicians should use their experience to override the system or to decide to disregard the information provided if their experience or the direct imaging differs.

WARNING

Always properly turn off and unplug the system before cleaning, disinfecting, connecting, or disconnecting parts or performing maintenance.

WARNING

The UroNav must remain outside the patient environment to prevent contamination.

CAUTION

The scan parameters and scanner settings of the ultrasound system should always conform to the recommended scan settings to prevent the possibility of inaccuracies.

WARNING

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

Electrical and Mechanical safety warnings

For electrical safety classifications and regulatory compliance status of UroNav, reference the table in “Equipment Classification and Specifications” on page 14. For maximum safety, observe the following warnings:

WARNING

Do not remove UroNav covers or cables from this product. Hazardous electrical voltages are present within this product's enclosure. Removing covers or cables could lead to serious or fatal personal injury. Covers or cables should only be removed by qualified and authorized service personnel. In this context, qualified means those legally permitted to work on this type of medical electrical product in the jurisdiction(s) in which the product is being used, and authorized means those authorized by the user of the product.

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WARNING

Use this product in rooms or areas that comply with all applicable law (or regulations having the force of law) concerning electrical safety for this type of product.

WARNING

To avoid the risk of electric shock, this equipment must only be connected to a Supply Mains with protective earth. Grounding reliability can only be achieved when the equipment is connected to a hospital-grade receptacle. Use only power cords meeting the specifications provided in this Instructions for Use. See “Mains power cordset requirements” on page 33 for more information.

WARNING

Electrically isolate this product from the mains electrical supply before cleaning and disinfecting.

WARNING

Medical equipment needs to be installed and put into service according to the special electromagnetic compatibility (EMC) guidelines. See “Electromagnetic Compatibility” on page 35 for more information.

WARNING

Always properly turn off and unplug the system before cleaning, disinfecting, connecting, or disconnecting parts or performing maintenance.

WARNING

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

WARNING

Use only Philips-approved cables, instrumentation, and accessories for the UroNav as detailed in this Instructions for Use. Electrical safety may be compromised otherwise. See “Approved Cables for Electromagnetic Compliance” on page 43 for more information.

WARNING

The UroNav has been tested for compliance to protect against electric shock with the monitor and UroNav medical grade power cords connected independently into AC Mains wall sockets. Additional Multiple Socket-Outlets (power strips) enabling one AC Mains plug connection or extension cords shall not be connected to the UroNav.

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WARNING

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

WARNING

External equipment intended for connection to signal inputs, signal outputs, or other connectors shall comply with the relevant product standard, such as: IEC 60950-1 or IEC 62368-1 for IT equipment and the IEC 60601-series for Medical Electrical Equipment.
In addition, all such combinations – Medical Electrical Systems – shall comply with the safety requirements stated in the general standard IEC 60601-1. Any equipment not complying with the leakage current requirements in IEC 60601-1 will be kept outside the patient environment (at least 1.5 m from the patient support, for example) or will be supplied via a separation transformer to reduce the leakage currents.
Any person who connects external equipment to signal inputs, signal outputs, or other connectors has formed a Medical Electrical System and is therefore responsible for the system to comply with the requirements. If in doubt, contact a qualified medical technician or your local representative.

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Fire safety warnings

Use of electrical product in an environment for which it was not designed can lead to fire or explosion.

WARNING

UroNav is not suitable for use in the presence of a flammable anesthetic mixture with AIR or with OXYGEN or NITROUS OXIDE. An explosion can result.

Fire regulations for the type of medical area being used should be fully applied, observed, and enforced. Fire extinguishers should be available for both electrical and non-electrical fires.

WARNING

Only use extinguishers on electrical or chemical fires, which are specifically labeled for those purposes. Using water or other liquids on an electrical fire can lead to fatal or other serious personal injury.
If it is safe to do so, attempt to isolate the product from electrical and other supplies before attempting to fight a fire. This will reduce the risk of electric shocks.

Biological safety warnings

When using UroNav, please observe the following warnings related to biological safety:

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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

UroNav utilizes both single-use disposable and reusable tools. Follow manufacturer cleaning and disinfection procedures to ensure biological safety for both patients and operators. For more information, see “Cleaning and disinfecting UroNav” on page 45.

WARNING

The EM Tracker is shipped non-sterile by the manufacturer. The EM tracker must be disinfected prior to every procedure. See “Cleaning and disinfecting the EM Trackers” on page 49 for more information.

WARNING

The EM Tracker Probe Holder is shipped non-sterile by the manufacturer. Prior to use, the UroNav EM Tracker Probe Holder must be cleaned per the procedure in this Instructions for Use: See “Cleaning the disposable EM Tracker Probe Holder before use” on page 47 for more information.

CAUTION

The EM Tracker Probe Holder has been designed, tested, and manufactured for single use. Reuse or reprocessing has not been tested and could lead to device failure and patient injury. Do not reuse, reprocess, or sterilize this device. After use, dispose of the Probe Holder per hospital medical waste and environmental policies and procedures.

WARNING

The Stepper is shipped non-sterile by the manufacturer. Prior to use, the Stepper must be disinfected per the procedure in this Instructions for Use: See “Cleaning and disinfecting the Stepper” on page 52. See also “Cleaning and disinfecting the Stepper Arm and Stepper Stand” on page 68.

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Environmental warnings and conditions

The parts of the UroNav which are suitable for use within the patient environment include the EM Sensor, Field Generator, Field Generator Articulating Arm, Stepper and Stepper Arm.

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 UroNav.

WARNING

The use of portable and mobile radio-frequency (RF) communications equipment can affect the operation of medical equipment. See “Electromagnetic Compatibility” on page 35 for more information.

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

- Increase the separation between the conflicting devices
- Reorient the device cabling
- Plug devices into separate outlet circuit branches
- Re-arrange or remove conflicting devices

NOTICE

For more information, see “Electromagnetic Compatibility” on page 35 or contact Philips Technical Support.

Normal operating environment

The normal operating environment for UroNav, EM Tracker and the Transperineal Stepper, Stepper Stand, and Stepper Arm is:
Ambient temperature range of +10°C to +30°C
Relative humidity range of 30% to 70%, non-condensing
Atmospheric pressure range of 70 kPa – 106 kPa

Transportation and storage environment

This equipment will be transported and stored under the following conditions:

UroNav and Transperineal Stepper, Stepper Stand and Stepper Arm:
Ambient temperature range of -25°C to +70°C.
Relative humidity range of 10% to 90%, non-condensing.
Atmospheric pressure range of 70 kPa to 106 kPa.

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EM Tracker and Probe Holder:
Ambient temperature range of +5°C to +55°C.
Relative humidity range of 10% to 90%, non-condensing.
Atmospheric pressure range of 70 kPa to 106 kPa.

Protective packaging markings

The following markings are displayed on the shipping carton packaging to indicate special protective handling measures required for transport. Symbol descriptions are provided in “Use of symbols in labeling” on page 159.

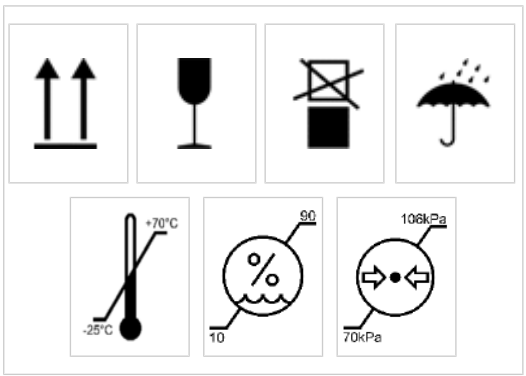

Fig. 1: Packaging labels for UroNav cart and transperineal hardware

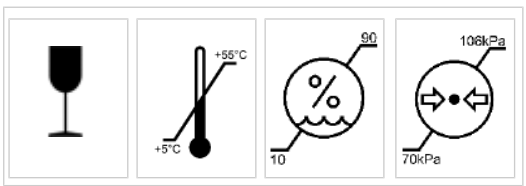

Fig. 2: Packaging labels for the EM tracker and probe holder

Expected service life and disposal of waste products

Philips is concerned to help protect the natural environment and to help ensure continued safe and effective use of this product through proper support, maintenance, and training. Therefore Philips products are designed and manufactured to comply with relevant guidelines for environmental protection. As long as the product is properly operated and maintained, it presents no environmental risks. However, the product may contain material(s) that could be harmful to the environment if disposed of incorrectly. Use of such material(s) is essential to performing the functions of the product and to meeting statutory and other requirements.

Philips supports users in:

- Recovering reusable parts
- Recycling of useful materials by competent disposal companies
- Safe and effective disposal of product

For advice and information, contact your Philips Service Organization. See “Help and guidance information” on page 8 for more details.

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The following list provides the expected service life and disposal requirements for UroNav and its components:

- **UroNav:** Expected service life of 5 years; composed of electromechanical assemblies; dispose of at dedicated electronic equipment disposal facilities (E-Waste)

NOTICE

In this product, perchlorate material is present in a coin cell battery. Special handling may apply. See the following website: https://dtsc.ca.gov/hazardouswaste/perchlorate

- **UroNav cart:** Expected service life of 5 years; composed of electro-mechanical assemblies; dispose of at dedicated electronic equipment disposal facilities (E-Waste)
- **Field Generator and Foot Pedal:** Expected service life of 5 years; composed of electromechanical assemblies; dispose of at dedicated electronic equipment disposal facilities (E-Waste)
- **Stepper, Stepper Arm, Stepper Stand, Articulated Field Generator Mounting Arm:** Expected service life of 5 years; composed of mechanical assemblies; dispose of per accepted biohazardous waste disposal methods
- **EM Tracker Probe Holder:** Single-use, disposable device; clean prior to initial use; dispose of per accepted biohazardous waste disposal methods
- **EM Tracker Cable Assembly:** Re-usable device, 100x's; disinfect prior to initial use, and clean and disinfect between each subsequent use; dispose of per accepted biohazardous waste disposal methods after 100 uses

NOTICE

The entity accountable for the use and maintenance of the UroNav will be advised that the assembly of the UroNav and modifications during the actual service life require evaluation to the requirements of IEC 60601-1.

NOTICE

UroNav software counts the number of uses based on connections to UroNav computer; however, it is the end user's sole responsibility to track the usage count.

CAUTION

The EM Tracker can be cleaned and disinfected for 100 re-uses. It is the end user's sole responsibility to track the usage count. Accurate and effective results cannot be guaranteed by Philips for the use of the UroNav EM Tracker beyond 100 re-use cycles.

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Field generator warnings and cautions

The following warnings are provided by the field generator manufacturer:

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.

WARNING

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

WARNING

Do not operate the field generator within 200mm (8in) of an installed pacemaker or other potentially electrically conductive implants such as defibrillators. The magnetic field produced by the field generator may interfere with the operation of the pacemaker, which may result in personal injury, and distortion created in the EM field by conductive implants may result in inaccurate targeting.

WARNING

Do not expose tools to a high magnetic field, such as a magnetic resonance imaging (MRI) machine, because they may become magnetized. Tracking with a magnetized EM sensor may result in incorrect information and result in possible personal injury. No equipment or tools provided by Philips for use with UroNav are MRI safe and may cause serious damage to MRI systems and possible 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.

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WARNING

Do not place tool cables within 30mm (1.2in) 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 or store the field generator in the presence of other magnetic fields. To do so may lead to misleading or inaccurate information and possible personal injury.

WARNING

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

CAUTION

Support the field generator when loosening the arm assembly, since the field generator can fall abruptly.

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Equipment protection and cable management

Follow these precautions and safety warnings to protect your system and prevent injury:

WARNING

No modification of this equipment is allowed. Do not alter or change the system parameters for UroNav as set by Philips factory personnel.

CAUTION

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

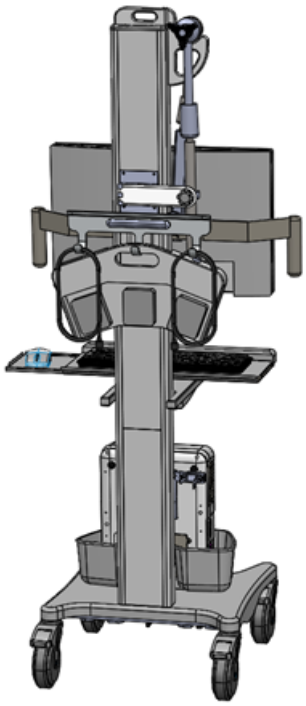
CAUTION

Do not block any of the UroNav ventilation holes. If the UroNav internal electronics overheat, it may perform unpredictably and may damage the system. This may contribute to possible personal injury.

CAUTION

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

When not in use, cables should be stored off the floor to prevent tripping. The UroNav cart has a rear handle—as shown—that may be used for this purpose.



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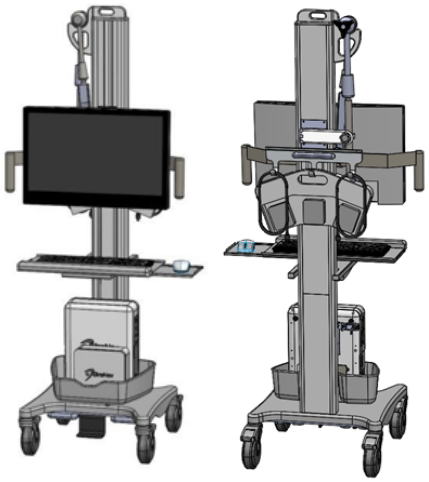
CAUTION

Remove unused components from the vicinity of the system and ensure that all cables connected to the UroNav are placed to prevent tripping hazards and damage to tools and cables. The power cable, as well as other cables, may be stored on the UroNav cart rear handle to prevent a tripping hazard.

CAUTION

Before transport of the UroNav cart, use the foot pedal at the bottom of the cart to move the height-adjustable tray to its lowest set position. Transport of the cart should only be undertaken with the tray at this position and with the Field Generator, Field Generator Arm, and Foot Pedal mounted on the UroNav cart as shown in the pictures below. Failure to transport the UroNav cart in this transport configuration may result in tipping of the UroNav cart and risk of injury.



CAUTION

When transporting the UroNav cart, always keep a firm grip on the transport handles. Failure to transport the UroNav cart in this manner may result in tipping of the UroNav cart and risk of injury.

CAUTION

Avoid sitting or setting excessive weight on the keyboard tray. Doing so may result in tipping of the UroNav cart and risk of injury.

NOTICE

To prevent unintended movement of the UroNav cart while in use (stationary), engage the four wheel locks.

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Network/Data coupling warnings

The end-user should take note of the following warnings related to network/data coupling to other equipment:

NOTICE

Connection of UroNav to a network/data coupling that includes other equipment could result in previously unidentified risks to patients, operators, or third parties. The end-user should identify, analyze, evaluate, and control these risks.

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5 Power requirements and specifications

Mains power cordset requirements

For the UroNav to remain compliant to IEC 60601-1, cordsets must meet the following technical specifications and regulatory compliance requirements:

- Appliance coupler must be type IEC 60320 C13
- Include an attachment plug with Protective Earth that is acceptable for the destination country.
- Not greater in length than 15t (4.57m)
- Needs to be certified cord type for the destination country suitable for hospital use, not less robust than ordinary polyvinyl chloride sheathed flexible cord of IEC 60227-1, with a cross-sectional area of conductors not less 1mm2.
- Switzerland power cordsets require a plug complying with IEC 60884-1, SEV 1011 and dimension sheet SEV 6534-2 Plug type 12, L+N+PE, 250V 10A.

WARNING

The UroNav has been tested for compliance to protect against electric shock with the monitor and UroNav medical grade power cords connected independently into AC Mains wall sockets. Additional Multiple Socket-Outlets (power strips) enabling one AC Mains plug connection or extension cords shall not be connected to the UroNav.

Input power requirements

Both UroNav and the monitor utilize universal AC Mains inputs; no settings are required for the 100-240 V~, 50/60 Hz AC Mains input voltage range.

UroNav: 100-240 V~ Single phase, 50-60 Hz, 1.6 - 0.5 A

Monitor: 100-240 V~ Single phase, 47-63 Hz, 0.7-1.4 A

Safety and EMC compliant to the following specific AC Mains input configurations:

- 100 V~ Single phase, 50/60 Hz
- 120 V~ Single phase, 60 Hz
- 220-240 V~ Single phase, 50/60 Hz

WARNING

To avoid the risk of electric shock, this equipment must only be connected to a Supply Mains with protective earth. Grounding reliability can only be achieved when the equipment is connected to a hospital-grade receptacle. Use only power cords meeting the specifications provided in this Instructions for Use. See “Mains power cordset requirements” on page 33 for more information.

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Replacement fuse specifications

WARNING

Fuse replacement is to be performed only by qualified Philips Service personnel. Philips Customer Service representatives are available worldwide to answer questions and to provide maintenance and service. Please contact your local Philips representative for assistance.

UroNav fuse: 2A, Time-Lag, 250V, 5mm x 20mm, Littelfuse 215 series or equivalent

IEC Marking: T2AH250V

Monitor: There is no field-accessible fuse in the monitor; it must be returned to the factory if it fails to power on.

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6 Electromagnetic and interference guidance

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 exist 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.

Medical Electrical (ME) equipment, like UroNav, needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this Instructions for Use.

Portable and mobile RF Communications Equipment can affect ME equipment.

Your system has been manufactured in compliance with existing electromagnetic compatibility requirements. The use of this system in the presence of an electromagnetic field can cause momentary degradation of the tracking ability. If this often occurs, 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.

UroNav is compliant with International Standard CISPR 11 for radiated and conducted electromagnetic disturbances. Compliance with this standard allows the system to be used in all establishments, other than domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

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

WARNING

The use of accessories, transducers and/or cables other than those specified, with the exception of those sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.

WARNING

The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

This section includes information on electromagnetic emissions and immunity as it applies to the system.

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WARNING

Ensure that the operating environment of your system meets the conditions specified in the referenced guidelines. Operating the system in an environment that does not meet these conditions may degrade system performance.

Electromagnetic Emissions

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

UroNav is intended for use in the electromagnetic environment specified in the following table, related to IEC 60601-1-2 guidance and the manufacturer's declaration about electromagnetic emissions for all ME equipment and ME systems. The customer or the user of UroNav should ensure that it is used in such an environment.

NOTICE

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

IEC 60601-1-2 – Guidance and manufacturer's declaration – Electromagnetic Emissions - All ME equipment and ME systems

Emissions test	Compliance	Electromagnetic Environment guidance
RF emissions CISPR 11	Group 1	UroNav 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	UroNav is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3 -3	Complies	

Electromagnetic Immunity

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

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UroNav was tested according to the recommendations of IEC TS 60601-4-2: Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

If affected, UroNav typically self-recovers to normal operation immediately upon termination of a transient EM disturbance. Allow up to 15 seconds after termination of disturbance for self-recovery.

UroNav is intended for use in the electromagnetic environment specified in the following table, related to IEC 60601-1-2 guidance and the manufacturer's declaration about immunity for all ME equipment and ME systems. The customer or the user of UroNav should ensure that it is used in such an environment.

IEC 60601-1-2 – Guidance and Manufacturer's Declaration – Immunity - All ME Equipment and ME Systems

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic Environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/-8 kV Contact +/-15kV Air	+/-8 kV Contact +/-15kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30 %.
Electrical fast transient (EFT) IEC 61000-4-4	+/-2 kV Mains +/-1 kV I/Os	+/-2 kV Mains N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/-1 kV Differential +/-2 kV Common	+/-1 kV Differential +/-2 kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips IEC61000-4-11	>95% Dip in U_T (1) for 0.5 Cycle >95% Dip in U_T for 1 Cycle 30% Dip in U_T for 25/30 Cycles <95% Dip in U_T for 250/300 Cycles	>95 % dip in U_T for 0.5 Cycle >95% Dip in U_T for 1 Cycle 30% Dip in U_T for 25/30 Cycles <95% Dip in U_T for 250/300 Cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of UroNav requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency 50 / 60 Hz Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

UroNav is intended for use in the electromagnetic environment specified in the following table,

(1) U_T is the AC mains voltage prior to application of the test level.

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IEC 60601-1-2, – Guidance and Manufacturer's Declaration – Immunity – ME Equipment and ME Systems that are NOT Life-supporting. The customer or the user of UroNav should ensure that it is used in such an environment.

IEC 60601-1-2, – Guidance and Manufacturer's Declaration – Immunity – ME Equipment and ME Systems that are NOT Life-supporting

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V 0.15 MHz-80 MHz 6V[(2)] in ISM between 0.15 MHz and 80 MHz[(3)] 80% AM at 1 kHz	3 V 0.15 MHz-80 MHz 6V[(2)] in ISM between 0.15 MHz and 80 MHz[(3)] 80% AM at 1 kHz	PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT

Interference may occur in the vicinity of equipment marked with the symbol shown in left margin.

NOTICE

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

NOTICE

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

NOTICE

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.

UroNav is intended for use in the electromagnetic environment specified in the following table: IEC 60601-1-2, – Guidance and Manufacturer's Declaration – Immunity to RF wireless

(2) r.m.s. before modulation is applied.

(3) The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

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communications equipment – ME Equipment and ME Systems. The customer or the user of UroNav should ensure that it is used in such an environment.

IEC 60601-1-2, – Guidance and Manufacturer's Declaration – Immunity to RF wireless communications equipment – ME Equipment and ME Systems

Test frequency	Band[4]	Service[4]	Modulation[5]	Maximum power	Distance	Immunity test level
MHz	MHz			(V/m)	MHz	MHz
385	380 - 390	TETRA 400	Pulse modulation[5] 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM[6] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 - 787	LTE Band 13, 17	Pulse modulation[5] 217 Hz	0.2	0.3	9
810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[5] 18 Hz	2	0.3	28
1720 1845 1970	1700 - 1900	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25 UMTS	Pulse modulation[5] 217 Hz	2	0.3	28
2450	2400 - 2570	Bluetooth, WLAN 820.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[5] 217 Hz	2	0.3	28
5240 5500 5785	5100 - 5800	WLAN 802.11 a/n	Pulse modulation[5] 217 Hz	0.2	0.3	9

(4) For some services, only the uplink frequencies are included.

(5) The carrier shall be modulated using a 50% duty cycle square wave signal.

(6) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

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NOTICE

If necessary to achieve the Immunity Test Level, the distance between the transmitting antenna and the ME equipment or ME system may be reduced to 1 m. The 1 m test distance is permitted by IEC 6100-4-3.

NOTICE

UroNav has also been tested for Immunity to other Common RF Emitters not expected in its intended electromagnetic use environment, such as X-ray, Metal Detectors, Electrosurgical Equipment, Diathermy Equipment, 5G Cellular, Near Field Communication (NFC), Wireless Power Transfer (WPT), and Electronic Article Surveillance (EAS) devices. It has not been tested for compatibility with every potential version of these RF Emitters on the market.

Radio-Frequency Interference

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

The UroNav 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 UroNav as recommended in the following table, according to the maximum output power of the communications equipment.

IEC 60601-1-2, – Recommended Separation Distances between portable and mobile RF communications equipment and UroNav ME equipment and ME systems that are not life-supporting

Rated Maximum Output Power of Transmitter (Watts)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz d=(1.2)(Sqrt P)	80 MHz to 800 MHz d=(1.2/E1)(Sqrt P)	800 MHz to 2.5 GHz d=(2.3)(Sqrt P)
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

NOTICE

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

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NOTICE

For transmitters rated at a maximum output power not listed in the table, the recommended separation distance 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.

NOTICE

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

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 UroNav cart more than 1m (3.3ft) 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 untested 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 EN/IEC60601-1-2.

WARNING

UroNav 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.

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 and, if not installed and used in accordance with the

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instructions, 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 field service technician for assistance.

Recommended Separation Distance

The UroNav 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 UroNav as recommended in the following table, 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 UroNav to reduce the risk of interference with the system.

NOTICE

This table indicates separation distances recommended for optimal EM Tracking performance. Another table provided in “Radio-Frequency Interference” on page 40 provides separation distance guidelines according to frequency of transmitter, but may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. These separation distances will help ensure maximum RF and EM immunity of the EM Tracking function.

Rated Maximum Output Power of Transmitter (Watts)	Separation Distance, D(m)		
	150 kHz to 80 MHz D=(3.5/V1)(Sqrt P) (for V1 = 0.30Vrms)	80 MHz to 800 MHz D=(3.5/E1)(Sqrt P) (for E1 = 0.06Vrms)	800 MHz to 2.5 GHz D=(7/E1)(Sqrt P) (for E1 = 0.06Vrms)
0.01	1.16m (45.7in)	6.0m (19.7ft)	11.5m (37.7ft)
0.1	3.67m (12.0ft)	18.97m (62.2ft)	36.37m (119.3ft)
1	11.6m (38.1ft)	60.0m (196.9ft)	115.0m (377.3ft)
10	36.68m (120.3ft)	189.0m (620.1ft)	363.66m (1193.1ft)
100	116.0m (380.6 ft)	600.0m (1968.5ft)	1150.0m (3773.0ft)

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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 symbol shown in left margin.

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.

NOTICE

For transmitters rated at a maximum output power not listed in the table, the recommended separation distance 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.

NOTICE

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

Approved Cables for Electromagnetic Compliance

Cables connected to the system may affect its emissions. Use only the cable types and lengths listed here:

Description	Part #
HDMI, 10ft, Shielded	4553-000-78711 (Quest HDI-1410)
HDMI-DVI, 3m, Shielded	4553-000-79121 (L-com HD-DVI-MM-3)
HDMI-Displayport, 10ft, Shielded	4553-000-81841 (C2G 54327)
AC Mains Power Cord	Reference the technical specifications and regulatory compliance information in “Mains power cordset requirements” on page 33

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WARNING

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

Use Restrictions Due to Interference

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

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7 Cleaning and disinfecting UroNav

Cleaning and disinfecting this product are required periodically and general guidelines for each involve:

- “Removing blood and infectious materials”
- “Cleaning the disposable EM Tracker Probe Holder before use”
- “Cleaning and disinfecting the EM Trackers”
- “Cleaning and disinfecting the Stepper”
- “Cleaning and disinfecting the Stepper Arm and Stepper Stand”
- “Cleaning the System Air Filter”

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 patients.

The UroNav, UroNav cart, foot pedal, field generator, and articulated field generator mounting arm may be cleaned using common low-level disinfection cleaning agents commonly used in hospitals and outpatient offices.

WARNING

Low-level disinfection is not sufficient for the EM Tracker and Transperineal Stepper. Reference specific enzymatic cleaning and intermediate disinfection instructions in this Instructions for Use: See “Cleaning and disinfecting the EM Trackers” on page 49 and “Cleaning and disinfecting the Stepper” on page 52 for more information.

CAUTION

Do not use the following cleaning/disinfection agents on any components of the system, as these can damage the components:

- **Solvents like thinner or benzine**
- **Abrasive cleaners**
- **Chlorine or chlorine-separating compounds**
- **Bleach-containing (sodium hypochlorite) agents**
- **Hydrogen-peroxide**

Some other general precautions for the cleaning and disinfection of your product are:

CAUTION

All components of the system are to be manually cleaned only, following the procedures provided in the following sections of the IFU. All automatic cleaning techniques, including using an autoclave, gamma radiation or gas, steam or heat sterilization, will result in severe damage.

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CAUTION

Do not immerse any part of the field generator, computer, tool connection unit, articulated arm or connector-end of cables in a liquid or allow fluid to enter the equipment in any way to prevent equipment damage.

WARNING

Do not immerse any part of the field generator, computer, tool connection unit or connector-end of cables in a liquid or allow fluid to enter the equipment in any way to prevent a fire or shock hazard or contribute to possible personal injury.

More specific warnings and cautions are included within the care and cleaning procedures of this guide and on the labels of the cleaners or disinfectants.

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Removing blood and infectious materials

If you believe contamination of the UroNav 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 UroNav computer/ display or the peripherals.

Should the UroNav become contaminated, it will be necessary to remove any blood or other infectious materials from the system:

1. Power the UroNav off. For more information, see "UroNav Power On/Off sequences" on page 89.
2. Disconnect the power cord from the AC power mains.
3. Use a gauze pad moistened with soap and water to remove blood on the system, connectors, and cables.

To prevent corrosion, dry the equipment with a soft, dry or mildly damp, lint-free cloth after cleaning.

Cleaning the disposable EM Tracker Probe Holder before use

The EM Tracker Probe Holder is shipped non-sterile by the manufacturer and must be cleaned prior to initial use. The EM Tracker Probe Holder is for single use only and must be disposed of after use per accepted biohazardous waste disposal methods.

Please use the following steps to clean the EM Tracker Probe Holder before use:

- Manually clean EM Tracker Probe Holder surfaces with a mild detergent, such as ENZOL® Enzymatic Detergent (Johnson & Johnson). Follow the manufacturer's instructions and recommendations for use.
- Wipe all EM Tracker Probe Holder surfaces with common germicidal or antiseptic wipe, such as Sani-Cloth® AF3 wipes (PDI). Follow the manufacturer's instructions and recommendations for use.
- Before use, allow the EM Tracker Probe Holder to air dry or wipe dry with a lint-free cloth.

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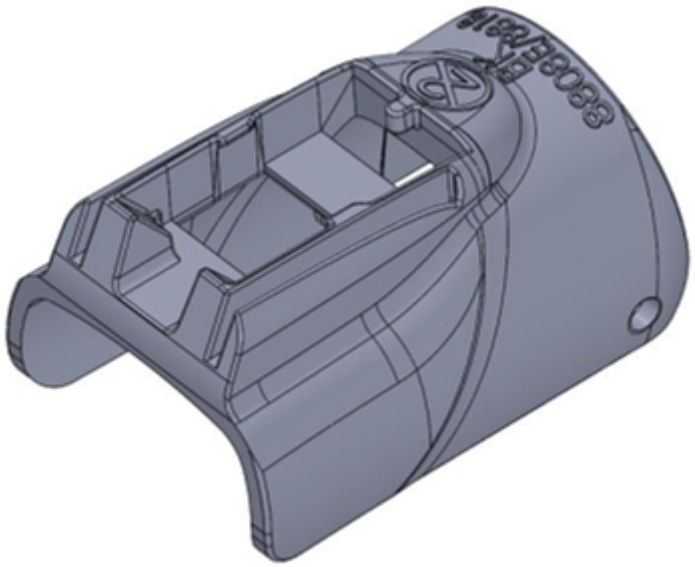

CAUTION

The EM Tracker Probe Holder has been designed, tested, and manufactured for single use. Reuse or reprocessing has not been tested and could lead to device failure and patient injury. Do not reuse, reprocess, or sterilize this device. After use, dispose of the Probe Holder per hospital medical waste and environmental policies and procedures.

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Cleaning and disinfecting the EM Trackers

The EM Tracker is shipped non-sterile by the manufacturer. The UroNav EM Tracker must be disinfected prior to initial use. Prior to re-use, the EM Trackers must be first disassembled from the Stepper, cleaned, and then disinfected.

Observe the following warnings and cautions during the cleaning and disinfection process. See also the general precautions given in “Cleaning and disinfecting UroNav” on page 45.

WARNING

The EM sensor must be cleaned and disinfected before each use. Cleaning the EM sensor is an essential step before effective disinfection. Be sure to follow the manufacturer’s instructions when using disinfectants.

CAUTION

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

CAUTION

Attempting to clean or disinfect the EM sensor by using a method other than the procedures herein can damage the device and voids the warranty.

Upon receiving the new EM Tracker, you will need to disinfect it before performing the first study. Also, be sure to clean and disinfect the EM Tracker immediately after each use to protect patients and personnel from a variety of pathogens.

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The following limitations apply to reprocessing:

- Throughout the cleaning and disinfection processes, protect the connector to keep liquid out of the connector's electrical contacts.
- Handwash only per the procedures in this section of the Instructions for Use.
- Do not allow sharp objects, such as scalpels or cauterizing knives, to come in contact with the EM sensor, cable, or connector.
- Do not use a wire brush for cleaning.

Prepare for decontamination by disassembling the EM Tracker sensor housing from the EM Tracker Probe Holder. Disassembly is described in more detail in the appendices of this IFU. For more information, see “Removal of the grid, EM sensor, and probe” on page 247 as well as subsections under “Transrectal workflow probe holder mounting instructions” on page 167 and “Transperineal workflow probe holder mounting instructions” on page 211.

To manually clean the EM Tracker:

1. Clean with a neutral or near-neutral pH detergent that contains enzymes, such as ENZOL® Enzymatic Detergent (Johnson & Johnson) or Enzyclean II LS (Micro Scientific). Follow the manufacturer’s instructions and recommendations for concentration, temperature, and contact time of the detergent.
2. With the prepared detergent solution, wet a lint-free cloth. Squeeze out excess liquid so that the cloth is damp, but not dripping.
3. Use the damp cloth to wipe the entire surface of the EM sensor housing. Wipe the EM sensor housing for the minimum contact time given by manufacturer of the detergent until all visible soil is removed.
4. Rewet the cloth with detergent water and thoroughly wipe the entire cable and connector for a minimum contact time given by manufacturer of the detergent until all visible soil is removed.
5. Wet a new clean, soft, lint-free cloth with potable water. Squeeze out excess liquid so that the cloth is damp, but not dripping.
6. Use the damp cloth to thoroughly wipe the entire surface of the EM sensor housing for to remove cleaning residue.
7. Re-wet the cloth with potable water and thoroughly wipe the entire cable and connector to remove cleaning residue.
8. After removing all cleaning residue, thoroughly dry the EM sensor housing, cable, and connector with a clean, dry, lint-free.
9. Visually inspect the EM sensor, cable, and connector in a well-lit area to confirm the absence of any soil.
10. If you see any soil, repeat the previous steps using fresh cloths until you see no soil.
11. When you see no soil and the device is completely dry, the EM sensor, cable, and connector are ready for disinfection.

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CAUTION

The EM Tracker can be cleaned and disinfected for 100 re-uses. It is the end user's sole responsibility to track the usage count. Accurate and effective results cannot be guaranteed by Philips for the use of the UroNav EM Tracker beyond 100 re-use cycles.

Intermediate level disinfection of the EM sensor uses a wipe method with an intermediate level disinfectant. Before performing the disinfection, please read all warnings and cautions provided earlier in this section of the Instructions for Use.

To disinfect the EM Tracker:

1. Ensure the EM sensor, cable and connector have been manually cleaned according to previous instructions in this section.
2. Wipe all EM sensor, cable, and connector surfaces with disinfectant wipes, such as, Sani-Cloth® AF3 wipes (PDI). Be sure to wipe all surfaces for the minimum contact time given by manufacturer of the disinfectant.
3. Allow the EM sensor, cable, and connector to air dry or dry the parts with a sterile cloth.

Maintenance and Storage

Periodically examine the EM Tracker for damage, such as cracks or splitting. If damage is evident, discontinue use of the device.

Store the EM Tracker in a clean, dry location.

These provided instructions have been validated by the manufacturer of the medical device as being capable of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the reprocessing as actually performed (by using equipment, materials, and personnel in the reprocessing facility) achieves the desired result. This normally requires validation and routine monitoring of the process.

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Cleaning and disinfecting the Stepper

The Stepper is shipped non-sterile by the manufacturer. Clean and disinfect the Stepper prior to initial use and immediately after each use to protect patients and personnel from a variety of pathogens.

Cleaning and disinfecting the Stepper involves:

- Following all warnings and cautions in “Precautions for cleaning the Stepper” on page 52 during the cleaning and disinfecting processes.
- Using the proper cleaning supplies from the provided list of “Recommended equipment and supplies” on page 52
- “Initial cleaning of the Stepper” on page 53
- “Disassemble the Stepper” on page 54
- “Detailed cleaning of the Stepper” on page 56
- “Intermediate level disinfection of the Stepper” on page 64
- “Reassemble the Stepper” on page 65
- “Final inspection” on page 67

Precautions for cleaning the Stepper

Observe the following warnings and cautions during the cleaning and disinfection process. See also the general precautions given in “Cleaning and disinfecting UroNav” on page 45.

WARNING

The Stepper must be cleaned and disinfected before each use. Cleaning the Stepper is an essential step before effective disinfection. Be sure to follow the manufacturer’s instructions when using disinfectants.

CAUTION

Do not break down the Stepper assembly more than specified in the provided procedure: “Disassemble the Stepper” on page 54.

Recommended equipment and supplies

The following is a list of equipment and/or supplies needed for the proper cleaning and disinfection of the Stepper.

- Soft bristle brush
- ¾-inch cylindrical soft-bristle brush
- 1.25-inch cylindrical soft-bristle brush
- Compatible neutral or near-neutral pH detergent such as ENZOL® Enzymatic Detergent from Johnson and Johnson or Enzyclean II LS from Micro Scientific

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- Compatible intermediate level disinfectant such as Sani-Cloth® Prime Wipes and Sani-Prime™ spray from PDI
- Dry, lint-free cloths
- Compressed air system

Initial cleaning of the Stepper

As soon as possible after a patient procedure, remove the ultrasound transmission gel, blood and other contaminates from the Stepper.

1. Place the Stepper under running potable water allowing the flowing water to remove debris.
2. Using a soft cloth moistened with potable water, wipe away any remaining debris.
3. Using a soft-bristle brush, remove debris from all crevices.

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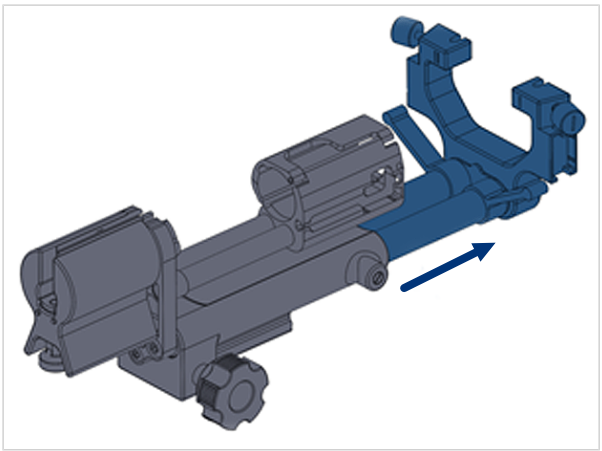
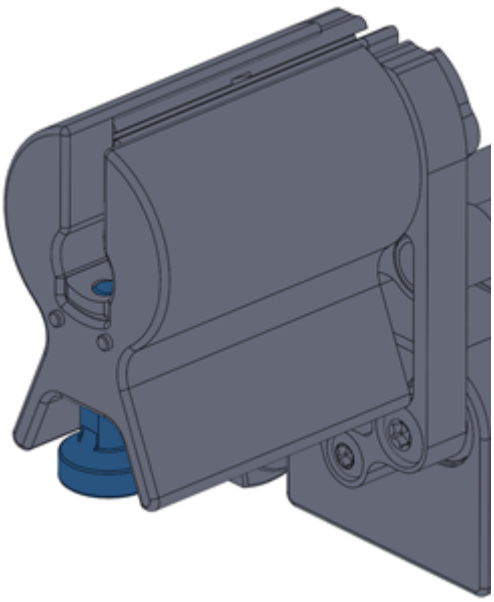
Disassemble the Stepper

After removal of all visible debris during initial cleaning, disassemble the Stepper for more detailed cleaning and disinfection.

1. Slide the front end out of the rack-and-pinon assembly. There are retaining grooves on the end of both sliding tubes, which catch on a spring and ball mechanism and help prevent accidental removal of the front end. However, with a little additional force, the front end can be removed from the rack-and-pinon assembly.



2. Locate and disengage the white release pin, as indicated by the blue highlight in the picture. To disengage, pull down on the release pin and rotate it 90 degrees. This prevents the release pin from springing back into place.



3. After the release pin is disengaged, slide the handle away from the rack-and-pinion assembly.

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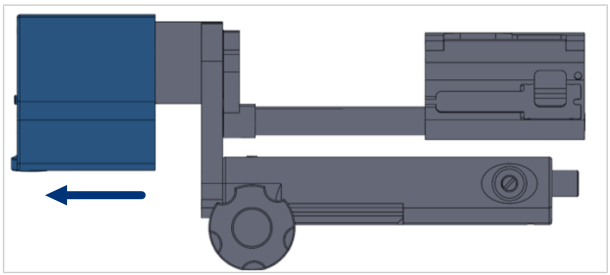
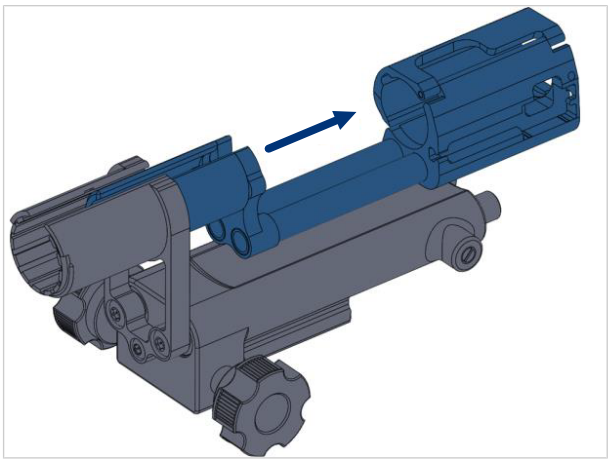


4. Remove the EM tracker probe holder from the rack-and-pinion assembly by sliding the probe holder assembly out of the rack-and-pinion assembly.



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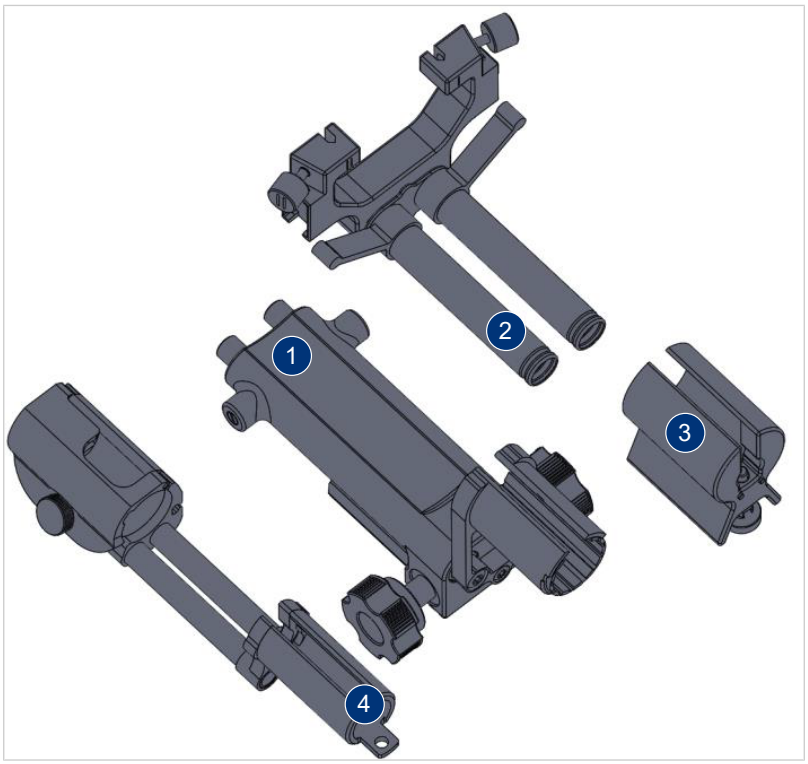
The four pieces of the fully disassembled Stepper are shown in the following image:



1	Rack-and-pinion assembly	2	Front-end assembly
3	Handle with release pin	4	EM tracker probe holder

Detailed cleaning of the Stepper

Each of the individual components must be cleaned as described in the following procedures:

- “Clean the rack-and-pinion assembly”
- “Clean the front-end assembly”
- “Clean the probe holder assembly”
- “Clean the handle”

Clean with a neutral or near neutral pH detergent that contains enzymes, such as ENZOL® Enzymatic Detergent (Johnson & Johnson) or Enzyclean II LS (Micro Scientific). Follow the manufacturer’s instructions and recommendations for concentration, temperature, and contact time of the detergent

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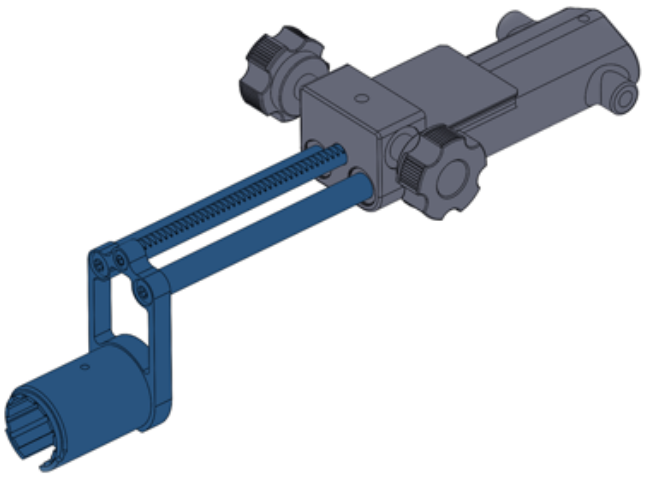
Clean the rack-and-pinion assembly

1. Using the carriage knob, move the carriage so that it is fully extended, as shown in the following image.

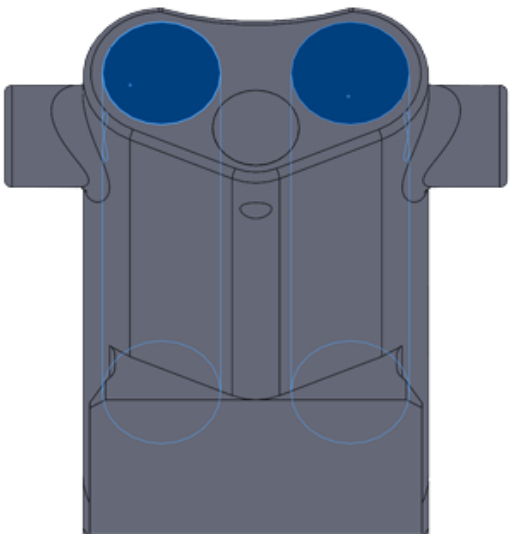


2. Immerse assembly in detergent water.
3. Thoroughly clean all surfaces with a soft-bristle brush, paying particular attention to gear teeth.

NOTICE

There are two areas that need special attention during cleaning. These areas are discussed in the following two steps.

4. The tube holes on the rack-and-pinion assembly must be clear and free of any debris or residual build up. While immersed in detergent water, use a ¾-inch cylindrical soft-bristle brush to clean these tubes.



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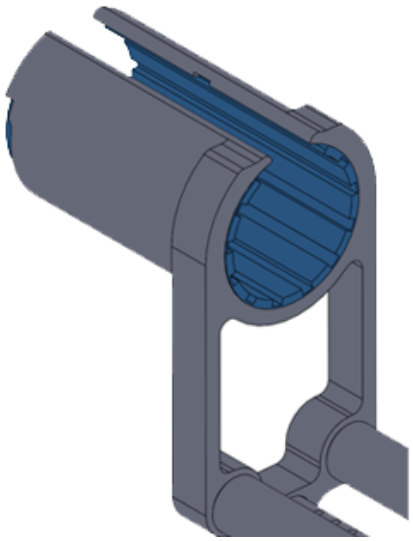
5. For proper tracking, the probe holder on the rack-and-pinion assembly must be clear and free of any debris or residual build up. While immersed in detergent water, use a 1.25-inch cylindrical soft-brittle brush to clean the probe holder area.



6. Immerse assembly in clean water (no detergent), so that all surfaces are exposed to the rinse water. Follow detergent manufacturer's recommendations for the duration of the rinse time.
7. Finish rinsing under running water, so that all surfaces are exposed to the running rinse water.
8. Exterior surfaces may be dried using a soft lint free cloth. However, the rack-and-pinion assembly must be hung so that gravity will drain the tubes and the interior of the tubes can air dry.

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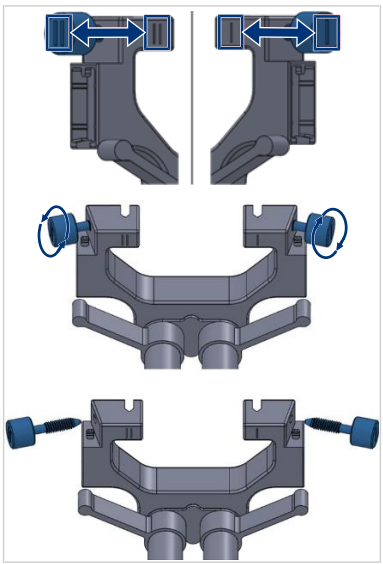
Clean the front-end assembly

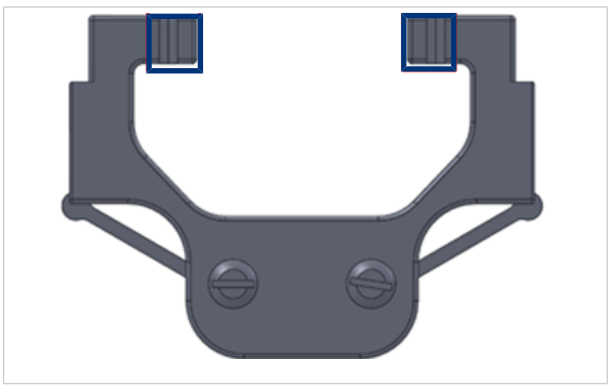
1. Remove the front-end assembly thumb screws by turning the left side counter clockwise and right side clockwise.

NOTICE

The left side thumb screw is marked with II and the right side thumb screw is marked with I, which match markings on corresponding parts of the front-end assembly.



2. Use a soft-bristle brush and detergent water to clean the thumb screws, rinse with clean water as recommended by the detergent manufacturer, and set aside.
3. Immerse the front end assembly in detergent water and thoroughly clean all surfaces with a soft cloth and soft-bristle brush.
4. While still immersed in the detergent water, use the soft-bristle brush to clean all debris and residual build up from the grid-plate slots (see boxed area in the adjacent image).



5. Use a soft-bristle brush to clean the left and right side threaded thumb screw holes.

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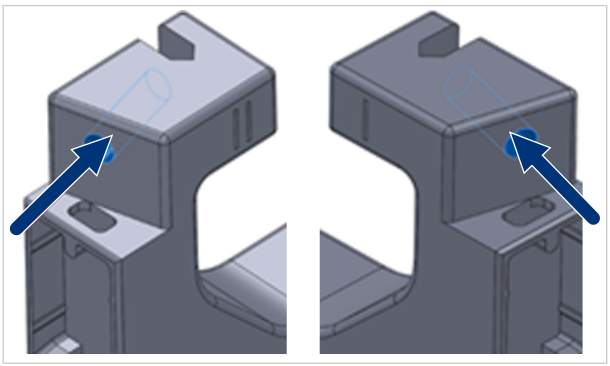
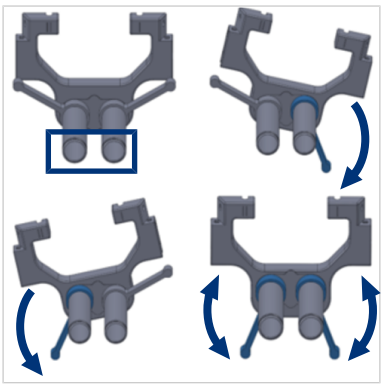
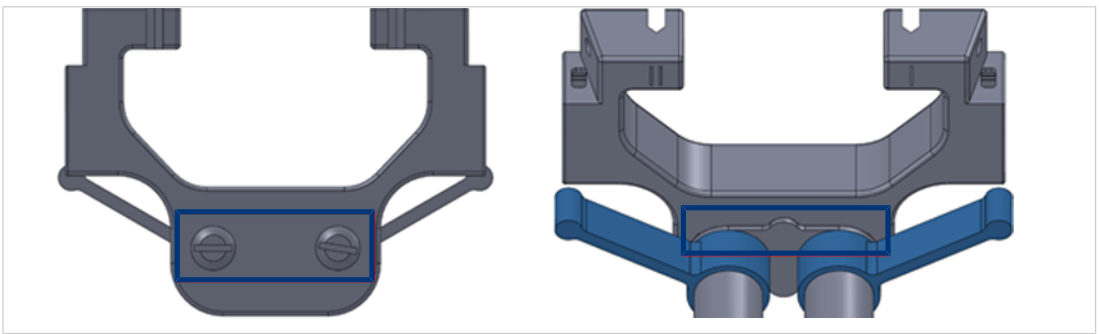


6. With the front end assembly still immersed in the detergent water, use a soft-bristle brush to clean inside both tubes. Also, rotate each of the two control levers vigorously multiple times to loosen any potentially trapped debris, as illustrated in the following image sequence:



7. While still immersed in detergent water, clean the indicated areas (blue rectangles) around the bolt heads and lever joint crevices with a soft-bristle brush. During this cleaning, rotate the control levers (blue highlight) to ensure that all crevice areas are properly cleaned.



8. While still immersed in detergent water, thoroughly clean indicated areas with a soft cloth and soft-bristle brush.

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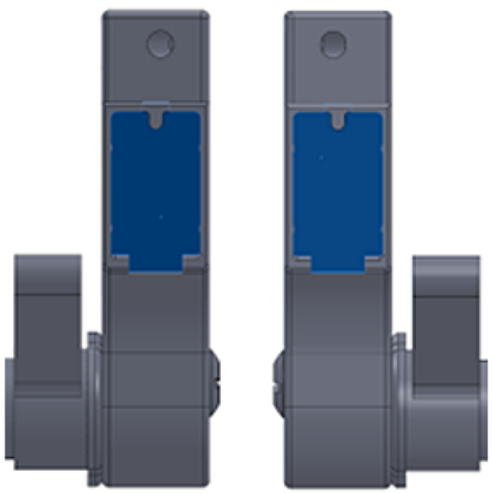

CAUTION

Areas, indicated blue in images of this procedure, must be clean and free of all debris to ensure proper tracking of the grid plate.

9. Remove the front end assembly from the detergent water and observe the color of the liquid:
   ⇨ Dripping from the tubes while holding the plastic side up
   ⇨ Dripping from the lever joint crevices while holding the assembly tube side up or to the side.

NOTICE

Compressed air may be blown through the open ends of the tubes while observing the color of the dripping liquid.

10. If the dripping liquid's color does not match the detergent water's color, immerse the front end assembly in the detergent water and repeat the process of rotating the levers with cleaning as described in the steps above. Follow detergent manufacturer's recommendations for the duration of the rinse time.
11. Immerse assembly in clean rinse water (no detergent). While submerged, rotate the front-end control levers. Ensure that all surfaces are exposed to the rinse water. Follow detergent manufacturer's recommendations for the duration of the rinse time.
12. Finish rinsing under running water. While under the running water, rotate the front-end control levers. Ensure that all surfaces are exposed to the running rinse water.
13. Exterior surfaces may be dried using a soft lint-free cloth. However, the front end assembly must be hung so that gravity will drain the tubes and the interior of the tubes can air dry.

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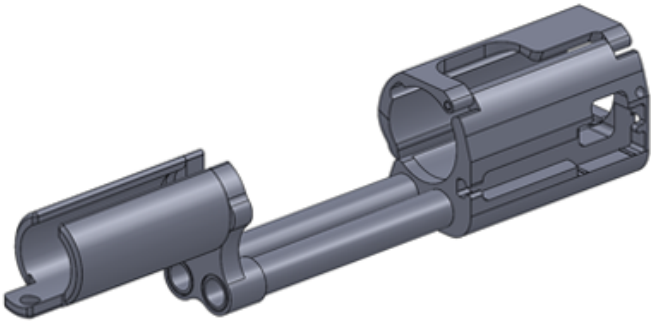
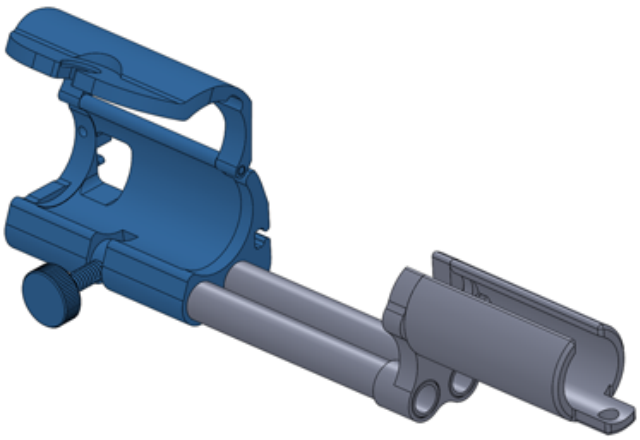
Clean the probe holder assembly

1. Immerse the probe holder assembly in detergent water.



2. Thoroughly clean all surfaces with a soft cloth and soft-bristle brush.
3. Open the probe clamp, indicated as blue area in the following image, and check for debris.



CAUTION

The interior areas of the probe clamp must be free of debris to ensure proper tracking.

4. The EM sensor holder, which is located on the probe holder (and highlighted in the following image), must be cleaned and free of debris to ensure proper tracking of the probe. Immerse assembly in detergent water and thoroughly clean indicated areas with a soft cloth and soft-bristle brush.

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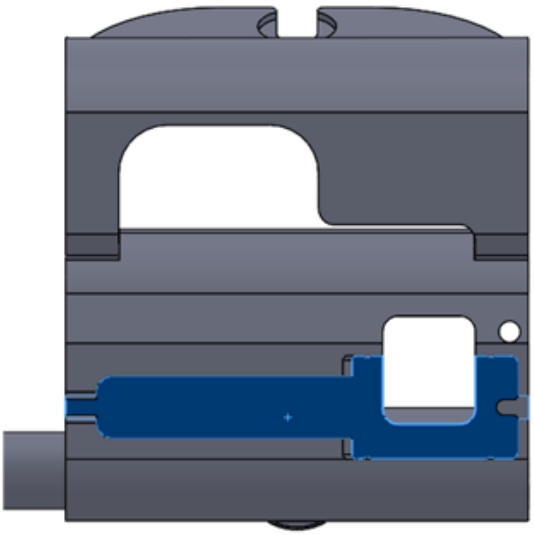
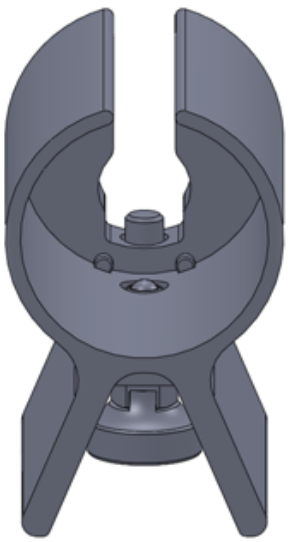


5. Immerse assembly in clean water (no detergent), so that all surfaces are exposed to the rinse water. Follow detergent manufacturer's recommendations for the duration of the rinse time.
6. Finish rinsing under running water, so that all surfaces are exposed to the running rinse water.
7. Exterior surfaces may be dried using a soft lint free cloth. However, the probe holder assembly must be hung so that gravity will drain the tubes and the interior of the tubes can air dry.

Clean the handle

1. Immerse the handle in detergent water.



2. Thoroughly clean all surfaces with a soft cloth and soft-bristle brush.
3. Use a 1.25-inch cylindrical soft-brittle brush to clean the interior of the handle.

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4. Immerse assembly in clean water (no detergent), so that all surfaces are exposed to the rinse water. Follow detergent manufacturer's recommendations for the duration of the rinse time.
5. Finish rinsing under running water, so that all surfaces are exposed to the running rinse water.
6. The handle may be dried using a soft lint free cloth or may be air dried.

Intermediate level disinfection of the Stepper

Before performing this procedure, read the warnings and cautions in "Precautions for cleaning the Stepper" on page 52. See also the general precautions given in "Cleaning and disinfecting UroNav" on page 45.

Intermediate level disinfection of the Stepper uses the spray and wiping method with an intermediate level disinfectant.

After all Stepper subassemblies are clean and dry per the detailed cleaning steps described above, follow the manufacturer's instructions and recommendations for use of the wipes and spray.

NOTICE

Ensure that the thumb screws removed during the Stepper front-end assembly cleaning are included.

1. For surfaces inaccessible with the wipes, spray with a disinfectant spray such as Sani-Prime™ spray (PDI).
2. Wipe all Stepper part surfaces with disinfectant wipes such as Sani-Cloth® Prime wipes (PDI).
3. Make adjustments to the carriage position and the grid-plate holder so that all surfaces have been wiped or sprayed.
4. Do not let the Stepper parts remain wet longer than the minimum time needed for intermediate level of disinfection.
5. After the minimum contact time of the disinfectant expires, dry using a soft lint free cloth. Allow the surfaces inaccessible to the drying cloth to air dry.

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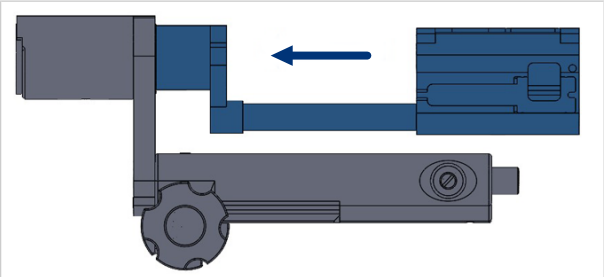
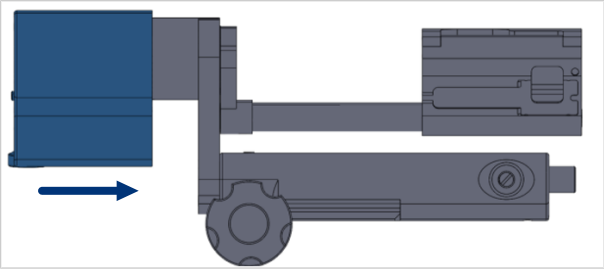
Reassemble the Stepper

After intermediate disinfection, collect all the pieces of the Stepper and reassemble in accordance with the following steps:

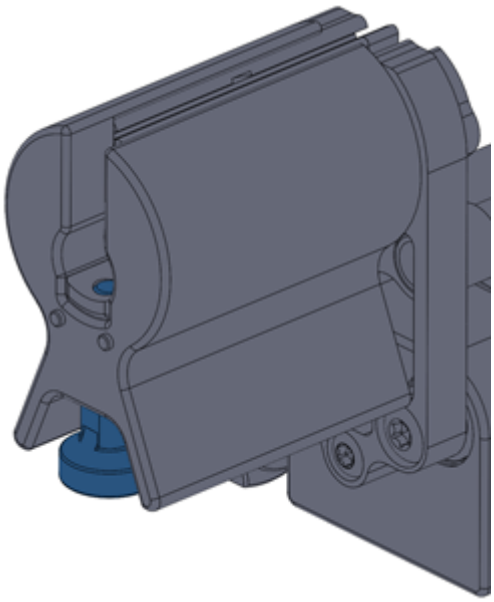
1. Reinstall the probe holder assembly by sliding it into the appropriate hole on the rack-and-pinion assembly.



2. Reattach the handle, by sliding it back on to the rack-and-pinion assembly.



3. After the handle is installed, ensure the release pin is back into its fully engaged position.



4. First, identify the left side and right side thumb screws: the left side thumb screw is marked with II and the right side thumb screw is marked with I.

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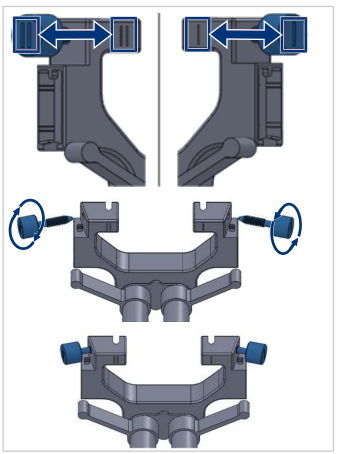
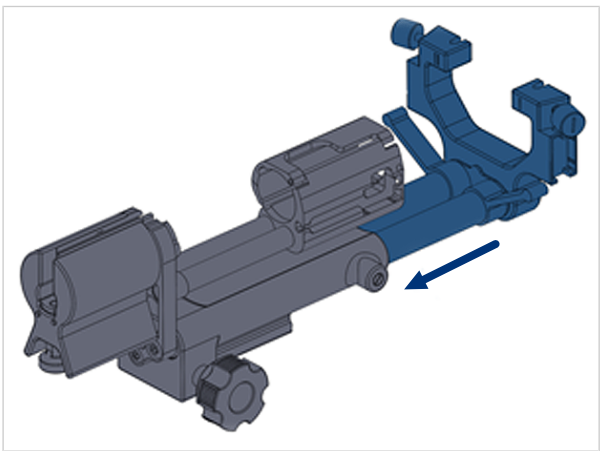
Then, properly align the screws and reinstall the front-end assembly thumb screws by turning the left side thumb screw clockwise and the right side thumb screw counter-clockwise.



CAUTION

Ensure the markings on the thumb screws match those on the front-end assembly. Failure to do so may damage the threads in this assembly.

5. Reinsert the front-end assembly into the rack-and-pinion assembly. There is a spring and ball mechanism that will catch as the front end is first installed. With a little additional force, the front-end assembly can be pushed back into the rack-and-pinon assembly.



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Final inspection

After the Stepper is fully assembled, a visual inspection should be done to ensure no damage has occurred. The inspection should include, but not be limited to, examination for cracks or other defects.

A functional test should be performed by completing the following steps:

1. Inspect the handle and probe holder. They should rotate freely. There should be no sticking or jamming during the rotation.
2. Inspect the front-end assembly. It should slide freely in and out of the rack-and-pinion assembly. There should be no sticking or jamming over the full range of movement. After the full range of motion is checked, slide the front-end assembly into its fully engaged position.
3. Using the carriage knobs, move the carriage to its full back position and then to its full forward position. Move the carriage to a mid-range position. The carriage should move with clicking detents as the carriage knobs are turned. Yet, the carriage should move without undue force or jamming.
4. Ensure that the grid-plate holder adjustments are also operating without sticking or jamming.

These provided instructions have been validated by the manufacturer of the medical device as being capable of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the reprocessing as actually performed (by using equipment, materials, and personnel in the reprocessing facility) achieves the desired result. This normally requires validation and routine monitoring of the process.

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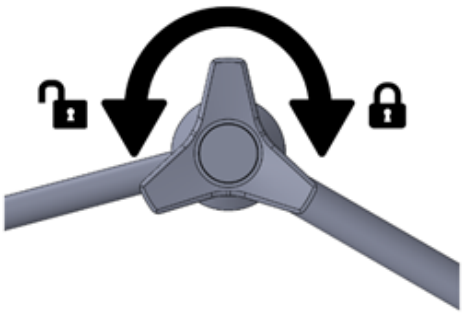
Cleaning and disinfecting the Stepper Arm and Stepper Stand

Clean and disinfect the Stepper Arm and Stepper Stand before first use and immediately after each use to protect patients and personnel from a variety of pathogens.

Follow the instructions provided below to prepare the Stepper Arm and Stepper Stand for use:

1. The central handle of the articulated arm must be tightened for cleaning and disinfection, as shown in the following image:



2. Clean all parts of the Stepper Arm and Stepper Stand with neutral or near neutral pH detergent, such as ENZOL® Enzymatic Detergent (Johnson & Johnson) or Enzyclean II LS (Micro Scientific). Follow the manufacturer's instructions and recommendations for concentration, temperature, and contact time of the detergent.
3. With the prepared detergent solution, wet a lint-free cloth. Squeeze out excess liquid.
4. Use the damp cloth to wipe off all parts. Be sure to wipe off each part for the minimum contact time given by manufacturer of the detergent until all visible soil is removed.
5. After all Stepper Arm and Stepper Stand parts are clean, wet a clean lint-free cloth with potable water and thoroughly wipe off all of the parts again to remove cleaning residue.
6. After removing all cleaning residue, thoroughly dry the Stepper Arm and Stepper Stand parts with a clean, dry, lint-free cloth.
7. Visually inspect the Stepper Arm and Stepper Stand in a well-lit area to confirm the absence of any soil or cleaning residue.
8. If you see any soil or cleaning residue, repeat the previous steps using fresh cloths until you see no soil or cleaning residue.
9. After everything is dry, wipe all of the surfaces with an intermediate level disinfection wipe; such as, Super Sani-Cloth®, Sani-Cloth Prime®, or Sani-Cloth® AF3 wipes—all from PDI. Be sure to wipe all surfaces for the minimum contact time given by manufacturer of the disinfectant.
10. Before reuse, ensure the Stepper Arm and Stepper Stand are completely dry; otherwise, wipe dry with a lint-free cloth.

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Cleaning the System Air Filter

As part of routine maintenance on your UroNav, the system air filters should be inspected weekly and cleaned as needed. If you decide to clean the air filter with soap and water, you may want to install a spare filter while the other filter is drying. To order additional air filters, contact your local Philips representative.

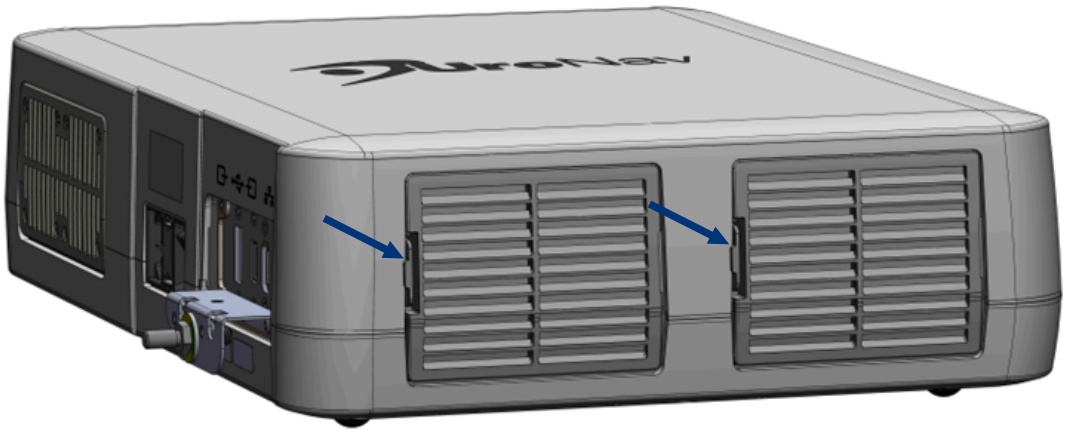
Before performing any system maintenance or cleaning, always turn off the system and disconnect it from the AC Mains power source.

CAUTION

Only install fully dry air filters to prevent damage to the system. Do not turn on the power before the filters are installed.

To inspect and clean the system air filters:

1. Remove both air filter covers on the UroNav housing.



2. Pull the air filters out.
3. Inspect the filters. Depending on the condition of the air filter, vacuum or rinse the filter with water to clean it. If the filter is worn out or cannot be cleaned, replace it with a spare.
4. Reinstall the filters and filter covers into place.

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8 Overview

Technical description

The UroNav is comprised of a mobile cart with the mounted UroNav computer (CPC) and monitor as depicted in the following image:

The UroNav cart includes a keyboard tray and horizontal work surface for mouse operation.

A USB interface HID 3-pedal foot switch — shown below — can be used to duplicate specific on-screen mouse functions for operator convenience.

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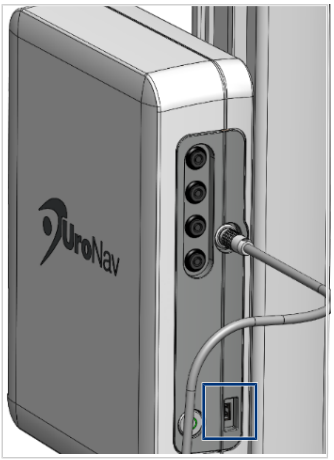
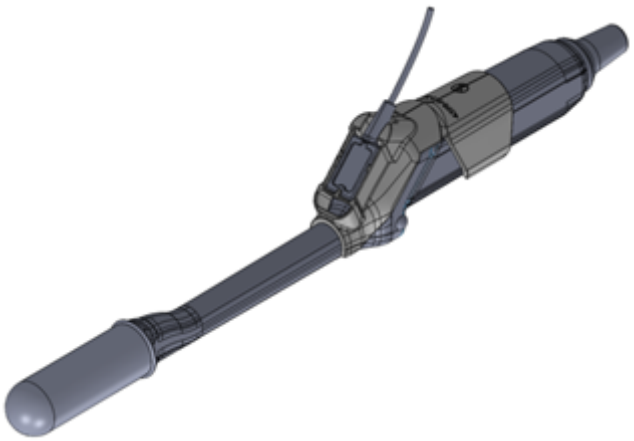
The 3-pedal foot switch is tethered to the UroNav with a 3m USB cable, plugged into either of the front or rear panel USB ports on the UroNav.

The front USB port is marked in the following image:



This allows the operator the freedom to position the foot pedal conveniently within reach, and allows hands-free operation for the SWEEP, FREEZE, and SCREEN CAPTURE functions.

In the current configuration of this system, an EM sensor, the complete sensor and cable assembly referred to as the EM Tracker, is attached to the handle of a transrectal ultrasound (TRUS) probe by insertion into a TRUS adapter clip (“probe holder”).



Alternatively, the EM sensor can be attached to the Stepper— shown below — for a transperineal procedure.

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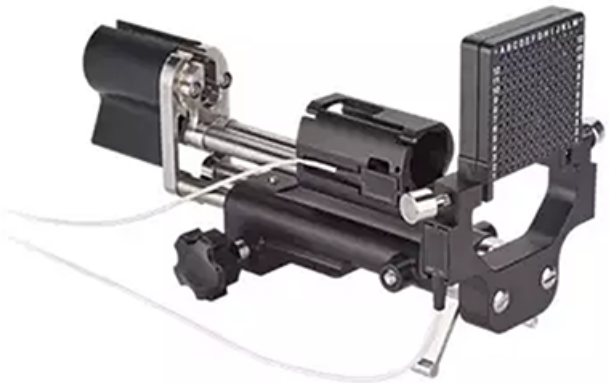

The EM sensor, probe holder, and TRUS probe are all covered by a sterile transducer cover supplied by a third party. The EM tracker is a reusable device with a requirement for intermediate-level disinfection, and the probe holder is a single-use disposable device with a requirement for cleaning prior to use.

The following image shows the stepper table rail mount:

The EM sensor is used in conjunction with the field generator for probe position sensing during the ultrasound sweep. The EM sensors detect probe position by their orientation in the EM field created by the field generator. The following image shows the field generator attached to the articulating arm:

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EM sensor and field generator signals are processed to determine and display an image of the relative position of the probe. The UroNav software application provides the operator interface and data display functions for the prostate workflows.

The prostrate workflows fuse a trans-rectal ultrasound (TRUS) with pre-procedure magnetic resonance (MR) images. This consists of motion compensation, deflection compensation as well as semi-automatic image-based registration to facilitate accurate navigation within the prostate gland.

UroNav accepts HDMI ultrasound image video formats and connections.

There are no user-serviceable parts inside the device. All service is performed by the manufacturer.

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Error codes and messages

UroNav does not display error codes for system status indication. System status is indicated via self-explanatory messages.

Requirements to operate UroNav

All users of the UroNav cart assembly or software system must be trained and must have completely read and understood these Instructions for Use.

Login — If required, a service representative can configure access control via user authentication. UroNav can be configured to authenticate users using an Active Directory group on the domain network.

NOTICE

Ensure firewall exceptions to inbound connections on domain workstations only allow authorized management systems and remote management hosts.

NOTICE

It is a violation of federal regulations to share user accounts.

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Product identification

You can access product information from within the software application.

To see the software version information:

1. Select **System Setup** > **Settings**.
2. After the **System Configuration** dialog box opens, select the **Software** tab.

To see the product labeling information:

1. Select **System Setup** > **Settings**.
2. After the **System Configuration** dialog box opens, select the **About UroNav** tab.

For more information on symbols used with this product—on its packaging, on the **About UroNav** tab, or in these Instructions for Use—see “Use of symbols in labeling” on page 159.

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9 System configuration

This chapter describes the set-up functions needed once to complete the initial configuration of UroNav. They may be repeated periodically if necessary.

This chapter has the following sections:

- “System Setup”
- “Ultrasound video calibration”

System Setup

Access System Setup from the UroNav Home screen. System Setup opens the System Configuration dialog which provides several tabs that contain settings for system configuration and general information. Those tabs are:

- “The DICOM tab”
- “The Systematics tab”
- “The Media Settings tab”
- “The Language tab”
- “The License tab”
- “The Service tab”
- The Software tab: See “Product identification” on page 75 for more information.
- The About UroNav tab: See “Product identification” on page 75 for more information.

For more information about the UroNav Home screen, see “UroNav Home screen” on page 99.

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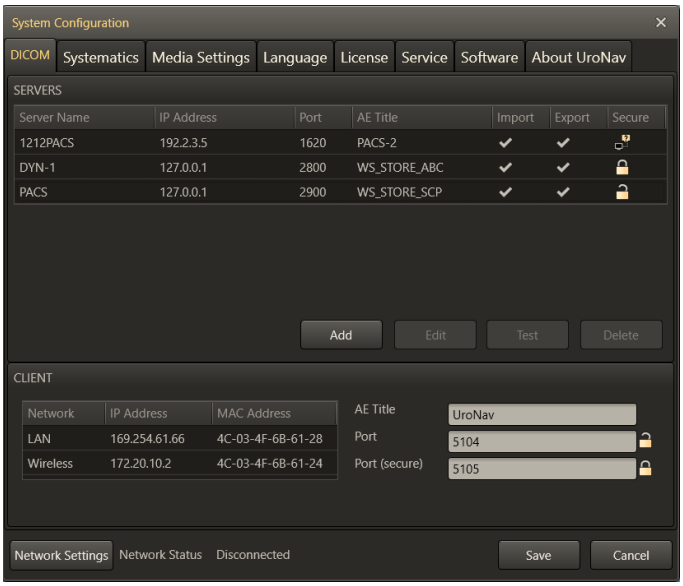
The DICOM tab

On the DICOM tab of the System Configuration dialog, remote servers (such as DynaCAD, PACS, etc.) and the default Server AE settings are determined. A secure port number can be defined for the UroNav client to facilitate a secure DICOM transfer. Any defined remote server will list a connection status.



The following image shows the Server Details dialog, used to set a server's IP address and other network settings. While configuring a new server, the connection needs to be tested before it can be saved. This will ensure that the UroNav system is aware of whether the connection can be established and whether it supports secure DICOM transfer.

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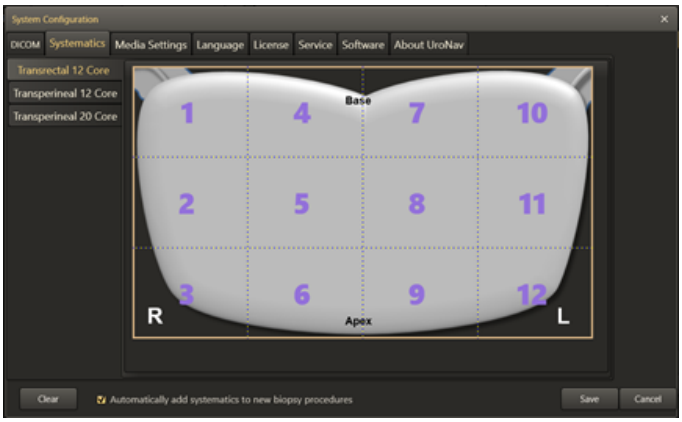
The Systematics tab

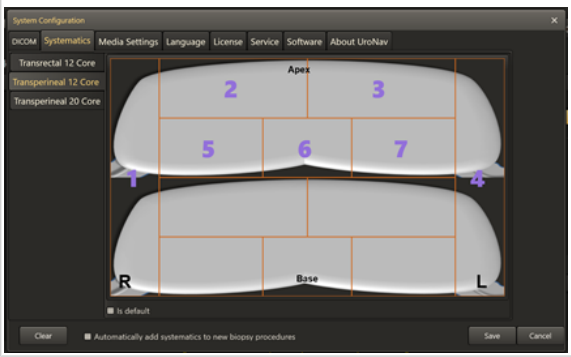
On the Systematics tab of the System Configuration dialog, the ordering of a systematic plan may be customized to accommodate both the transrectal and transperineal biopsy workflows. The following image is an example of transrectal systematic biopsy plan customization:



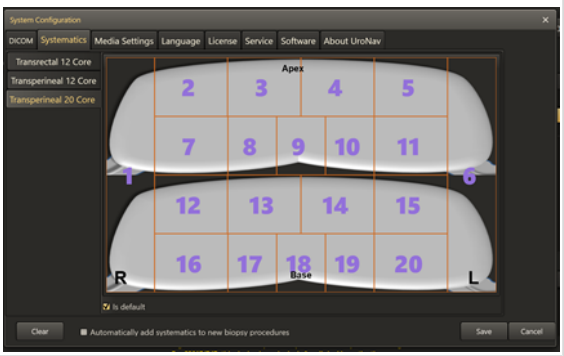
With a systematic region plan defined in the System Configuration dialog, the user can automatically add up to twelve predefined systematic target regions to a transrectal biopsy workflow by clicking the **Systematic** button in the **Navigate** screen.

For transperineal biopsy workflows, up to twelve systematic target regions can be configured with the Transperineal 12 Core configuration (left image), or up to 20 with the Transperineal 20 Core configuration (right image) as shown:

12 Core Transperineal



20 Core Transperineal



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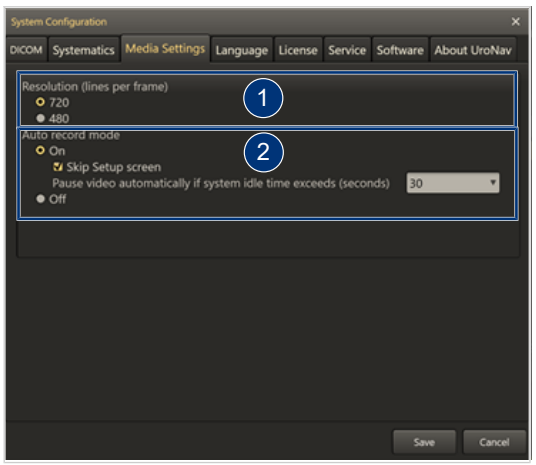
The Media Settings tab

Video recording of the workflow is captured in Full-Screen mode, which is configurable from the System Configuration dialog's Media Settings tab:



1	Resolution	2	Auto record mode

Multiple recordings can be saved per workflow.

Options for Auto record mode include:

- **On** - Select to enable automatic video recording mode.
- **Skip Setup screen** - Select the checkbox to skip the recording of "Set-up Instructions for Tracking" screen.
- **Pause video automatically if system idle time exceeds (seconds)** - Lists system idle time options to automatically pause video recording.
- **Off** - Select to enable manual video recording mode.

NOTICE

The system will prompt the user for an automatic restart to save the selected setting.

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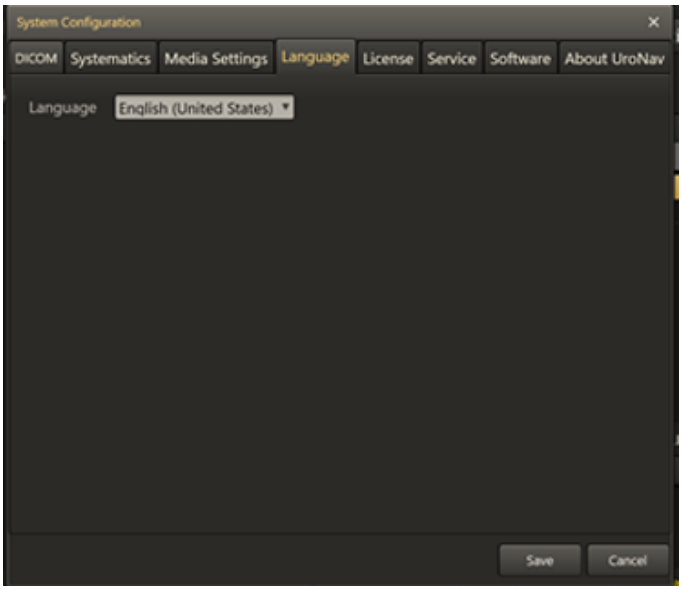
The Language tab

In the System Configuration dialog, the Language tab may be used to set the language of the user interface.



The License tab

In the System Configuration dialog, the License tab displays a list of features and expiration dates for the current system license.

The Service tab

In the System Configuration dialog, the Service tab displays the Service Equipment ID for the system. This information is used by Service users only. Additionally, the contact information for the manufacturer may also be viewed.

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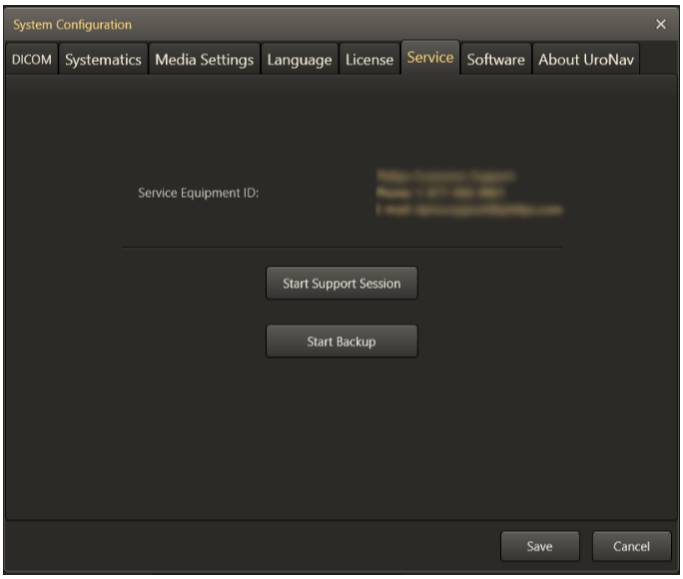

When connected to a configured local network, to start a remote support session:

1. Call Philips Customer Service.
2. When directed, click **System Setup** to open the System Configuration dialog.
3. Click the **Service** tab.
4. Select **Start Support Session**.

From the Service tab, UroNav also enables the backup of both patient and configuration data for the purpose of both migration and future restoration. The Backup operation is considered a disaster recovery plan and carried out by a Philips service representative. Backed-up patient data can only be restored by a Philips service representative.

To access the backup feature:

- Click System Setup to open the System Configuration dialog.
- Click the **Service** tab.
- Select **Start Backup** to open Backup Settings.

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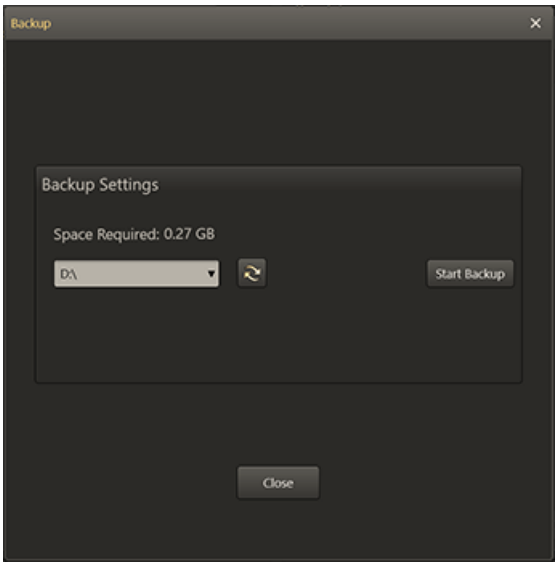

A backup location, either USB or network, must be provided before the backup can be executed —click the Refresh icon (shown in previous image) to display newly connected devices—after which, the contents are stored at the root of the selected drive. The created folder is provided with a unique name based on the date and time of the operation. After the backup operation completes successfully, the USB will be automatically disconnected from UroNav.

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Ultrasound video calibration

When using video connection to capture ultrasound images, the incoming images need to be calibrated to facilitate accurate size measurements and ensuring the availability of imaging planes and depths required for the different workflows. Ultrasound video calibration is an important service feature to ensure that all required imaging planes are calibrated and that the UroNav plane detection mechanism is functional. Properly calibrated imaging depths will ensure that UroNav handles size computations correctly whenever the computations are based on the ultrasound images. This concerns aspects like ROI volumes, line measurements, and displays of scales.

A sub-optimal video calibration can be caused by a misalignment between the actual and expected video image due to individual differences between ultrasound systems (or through user error such as non-aligned depths).

Ultrasound system settings must be properly configured by a Philips support team member before Video Calibration. It is the responsibility of the user to ensure that the proper ultrasound settings are utilized for UroNav. For more information, see “Required ultrasound system settings for transrectal workflows” on page 184 and “Required ultrasound system settings for transperineal workflows” on page 219.

Any change to the pre-calibrated ultrasound system, such as a software upgrade, will require UroNav video calibration to be repeated.

When connecting a new ultrasound system or probe combination to the UroNav system that has not been calibrated, the notice Video Calibration Required will appear on the UroNav Setup screen.

Any change to the ultrasound system and probe combination will require UroNav video calibration to be repeated.

CAUTION

Although video calibration should be carried out by a trained Philips support team, it is the responsibility of the operator to ensure that the (pre-calibrated) video calibration is correct for the specific ultrasound system in use. This can lead to a misinterpretation of the scale of the incoming image, leading to inaccurate volume calculations and overall misrepresentations of the patient’s anatomy. This may result in potential misalignment of biopsy core overlays or (user-indicated) needle path overlays. Contact Philips customer support for assistance.

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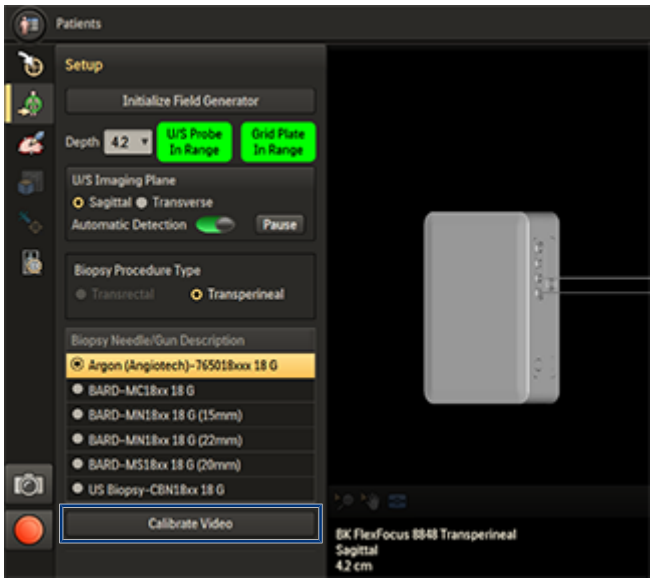

NOTICE

Multiple “different” US devices can be supported, with the software saving separate calibrations for each device. However, multiple “like” devices (such as two Philips Epiq Ultrasound units) cannot have separate calibrations saved. Therefore, customers must be sure to use the video-calibrated US system with their UroNav. Customers may want to add a label to that specific Ultrasound.

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10 Pre-workflow setup

Ultrasound Video

This section provides information related to ultrasound video, including:

- “Ultrasound video connections”
- “Ultrasound video configuration”
- “Ultrasound video calibration”

Ultrasound video connections

An HDMI connection, via a shielded video cable (see “Approved Cables for Electromagnetic Compliance” on page 43), is required for the real-time display of ultrasound image on the UroNav monitor for the duration of a workflow.

NOTICE

One of each (10 ft. HDMI, and HDMI/DVI) cable is supplied to the end-user with the UroNav.

NOTICE

To ensure that the ultrasound video connection to UroNav is successful, connect the video cable from the ultrasound system to UroNav before powering on the ultrasound system.

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Ultrasound video configuration

The Video In connections on the rear panel—dependent on hardware configuration, as shown in the following images—use the HDMI cable to display the U/S video on the UroNav screen.

Some controls on the ultrasound system are not supported with video input integration and must not be used with the system. System accuracy may be affected if unsupported modes are used. Unsupported control functions include any controls that affect the image location on the Ultrasound screen, image size, width, magnification, rotation, special report screens (Doppler trace).

Supported control functions include: focus, power settings, annotations, doppler color (but not velocity trace), depth settings, horizontal flip, and other image processing functions (such as iScan).

For more information on the supported settings for your specific ultrasound system, see “Required ultrasound system settings for transrectal workflows” on page 184 or “Required ultrasound system settings for transrectal workflows” on page 184.

UroNav cart setup overview

To prepare the UroNav cart for operation, connect peripheral equipment. Ensure that the EM system is connected, the ultrasound machine is connected, and (if required) the Stepper is mounted before attaching the ultrasound probe.

NOTICE

See “Appendix D” on page 231 for detailed instructions on the setup of the Stepper arm, Stepper , and ultrasound probes for transperineal workflows.

Connections to peripheral equipment

Universal peripheral device connectors on the UroNav—consisting of USB, HDMI, RJ-45 Network/Data coupler, and wireless keyboard and mouse—are intended for included and specified UroNav peripheral devices and connection to the end-user data network only, with the exception of end-user supplied portable USB memory drives, as specified below:

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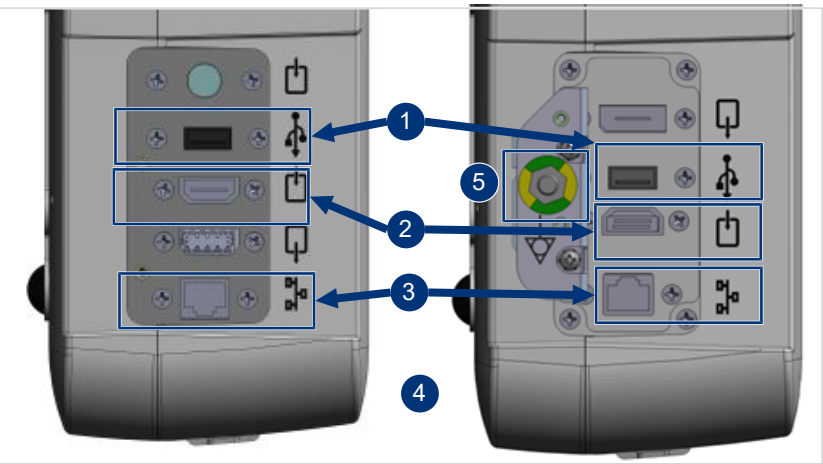

Fig. 3: Rear panel connections, dependent on hardware configuration

1	USB: 3-pedal foot switch, supplied with UroNav, and end-user-supplied portable USB memory drives	2	HDMI video input: Ultrasound video input
3	RJ-45 network coupler: End-user hospital or out-patient office network	4	Wireless: Keyboard and mouse
5	Potential equalization terminal		

The UroNav keyboard and mouse are wirelessly connected to the system.

NOTICE

Please contact Philips Customer Service if a replacement keyboard or mouse is needed. The user does not have the ability to pair these devices.

Potential equalization terminal

NOTICE

UroNav provides a DIN42801 terminal for the purposes of potential equalization. If needed, the UroNav potential equalization terminal can be connected to other medical equipment as defined in the POTENTIAL EQUALIZATION CONDUCTOR clause of IEC 60601-1.

Connect field generator and EM tracker(s)

The field generator cable is plugged into the appropriate UroNav front panel connector, unique to the field generator plug and identified by the symbol (shown in margin).

To connect:

1. Position the red alignment dot on the field generator plug to top center notch of panel connector.

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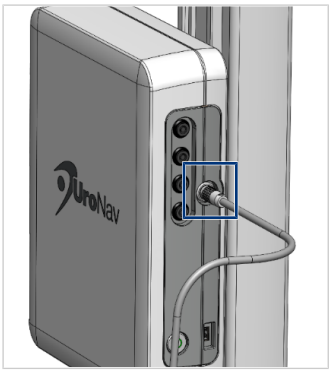


2. Insert plug; do not force insertion prior to proper alignment.

To disconnect:

- Pull gently on the plug barrel to unlock and remove; do not pull on the cable or cable strain relief.

The prostate workflow requires that a tracker be used to track the position of the ultrasound transducer. For transperineal workflows using a grid plate, an additional tracker is required for the grid plate. For free-hand transperineal workflows using a needle guide that is fixed to the ultrasound probe, only one tracker is required.

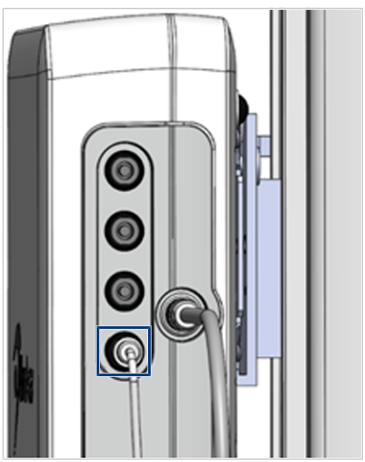
NOTICE

Do not disconnect any components from the UroNav during use. Only tracked tools and surgical instrumentation may be interchanged or disconnected from the tool connection unit during system use.

The EM Tracker connects to the UroNav via any one of four EM Tracker connectors, located on the front panel of the enclosure, unique to the EM Tracker plug.

To connect the EM Tracker:

1. Position the black arrows on the EM Tracking Sensor plug to the top center panel connector.



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2. Insert the plug. The field generator connector is keyed, and the alignment is color-coded red. Do not force insertion.

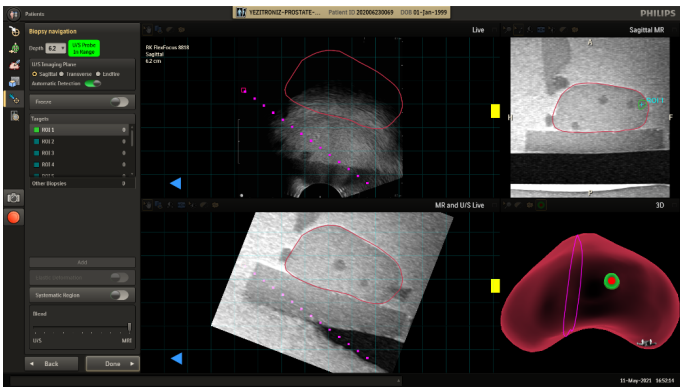
To disconnect cables from the front panel:

► Pull gently on the plug barrel to unlock and remove; do not pull on the cable or cable strain relief.

The EM Trackers are inserted in the Stepper (as illustrated in “Appendix D” on page 231) or into a clip (as described in “Appendix B” on page 166 and “Appendix C” on page 210)

CAUTION

Failure to fully secure the EM Tracker to the Probe Holder will compromise the positional tracking of the TRUS probe resulting in grossly inaccurate registration between the US imaging and EM tracked tools, and consequently, between the U/S and MR volumes, as shown in the following image.



Network connections

A standard LAN 10/100/1000 Ethernet over a twisted pair network connection via Cat 5e cabling may be utilized for DICOM 3.0 MR data transfer to UroNav prior to the start of the workflow. Refer to UroNav DICOM Conformance Statement (Philips document number D000752081) for DICOM specifications particular to UroNav.

A persistent network connection is not required; the network cable may be disconnected after the MR data transfer has been completed. Moreover, because alternative means for transferring this data are available, a network connection is not required for UroNav to be fully operational.

UroNav Power On/Off sequences

Ensure the Field Generator and the EM Tracker(s) are connected prior to powering on the UroNav per the following instructions:

To power on UroNav:

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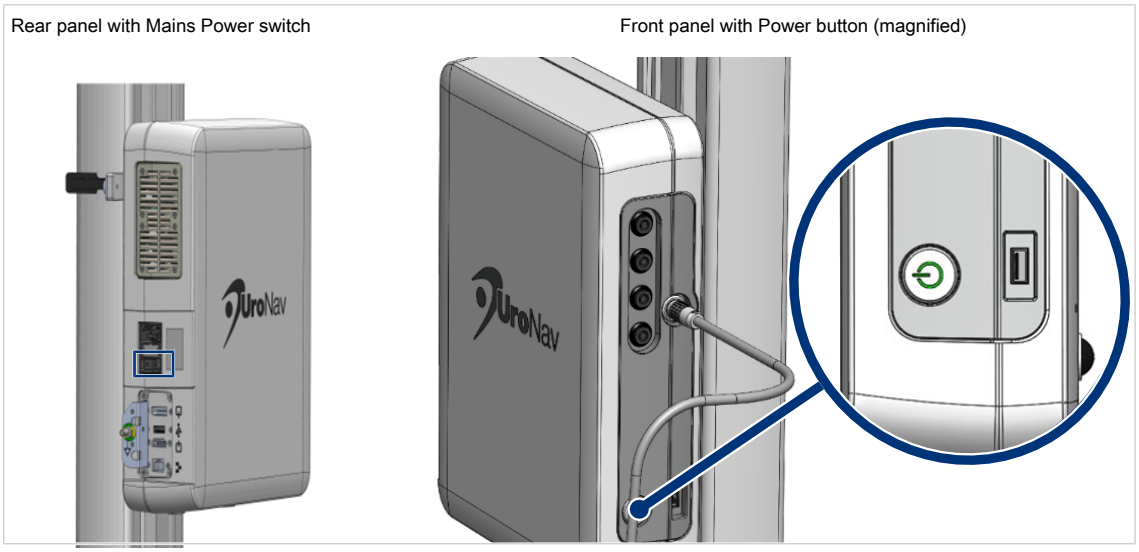
1. Ensure the UroNav rear-panel Power switch is Off prior to connecting the AC Mains power cord.
2. If not already connected, connect the IEC320 Hospital AC Supply Mains power cord plug to the UroNav cart bottom rear AC inlet.
3. Connect the cordset plug to the AC Mains source. Equipment and cables should be positioned such that the power cord plug can be readily accessed and removed from the source outlet for power disconnection from Mains supply by the operator or accompanying personnel.
4. Turn on the UroNav Mains power switch on the rear panel Mains AC appliance inlet.
5. Press the Power button on the front panel to power the system on. Green power switch LED will illuminate.
   The system is now ready for operation.



To power off UroNav:

1. Power off the system by doing either of the following:
   ⇨ Click the Shut Down button within the UroNav software application. Then, when prompted, confirm system shutdown.
   ⇨ Press the Power button on the front panel. Then press the Power button again to confirm system shutdown.
2. Turn off the UroNav Mains power switch on the rear panel Mains AC appliance inlet.

NOTICE

Alternatively, the System can be powered off by pressing and holding the computer power switch for at least 6 seconds.

NOTICE

AC Mains power disconnection is performed by disconnecting the AC Mains cordset plug from the AC Mains source outlet.

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If the Power switch is not properly communicating with the rest of the UroNav, the system will fail to shut down with a front panel Power button press, and a warning message will be displayed to the user. UroNav will continue to operate normally in all other respects, and the system can be shut down by either clicking the Shut Down button within the UroNav software application, or if UroNav is not responding to mouse commands, then by pressing and holding the Power button for at least 6 seconds.

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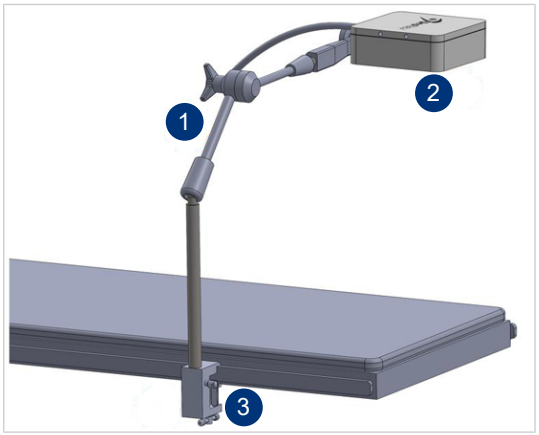
EM field generator arm setup



1	Field generator articulating arm	2	EM field generator
3	Mounting arm support clamp		

Ensure the UroNav logo is pointing upwards (as shown) and away from the treatment area.

CAUTION

Support the field generator when loosening the arm assembly, since the field generator can fall abruptly.

CAUTION

Ensure that the cable is not wedged between the field generator and the mounting arm.

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The following image shows the pole cart with the field generator mounting:

CAUTION

Accurate tracking can only be guaranteed in a 450mm x 450mm x 275mm area. Ensure that all the tracked tools are within this area by properly aligning the field generator with the patient anatomy.

NOTICE

See “Appendix D” on page 231 for detailed instructions on the setup of the Stepper arm, Stepper , and ultrasound probes for transperineal workflows.

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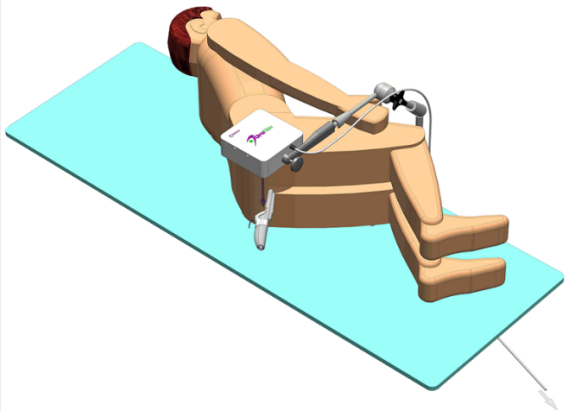
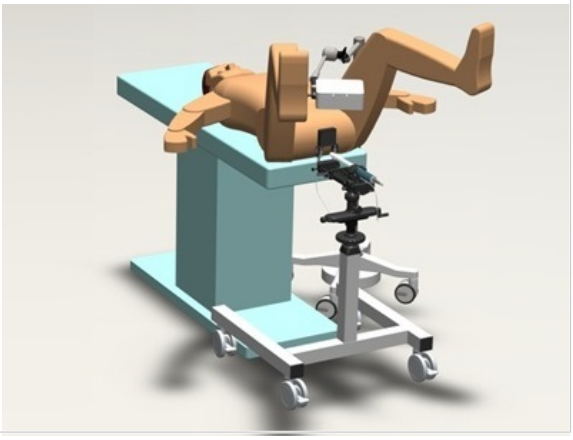
Patient and tool setup

This section involves the initialization of navigation tools, creating 3D U/S views, registration/ fusion of U/S with MRI, targeting, and recording biopsy core samples. First, ensure the patient is positioned in the Left Decubitus, Right Decubitus, or Lithotomy position and that the Field Generator is positioned several inches above the patient as shown in the following images:

Left decubitus position



Lithotomy position



The cord should exit toward the patient's head or feet and the Articulating Arm firmly affixed to a secure surface.

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11 General user interface and concepts

Message bar

The message bar located along the bottom of the screen is used to display informational messages, warning messages, and error messages. It contains a track record of all the messages that were presented during the workflow and can be expanded with the up arrow icon on the right side.

Patient identification

After a workflow has been started for a specific patient study, the patient identification information is visible at the top of the screen. The visibility of patient identification information can be toggled on / off using F12.

Visibility toggle mechanism

UroNav overlays information in the image-based viewports during the workflow. Since not all information might be desirable at all times, the user has the ability to toggle the different visual elements on or off. This can be done either via right-clicking an image viewport or using the keyboard shortcut keys.

For more information, see either “Keyboard and mouse shortcuts” on page 133 for biopsy workflows or “Keyboard and mouse shortcuts” on page 157 for advanced annotation workflows.

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Taking screenshots

UroNav supports a built-in screenshot utility to document snapshots during the workflow.

To take a screenshot:

- Click the Camera button in the Navigation menu.

- Press the foot pedal with the Camera icon.

Screenshot images taken in this manner may be reviewed during the Review portion of the workflow.

Video recording

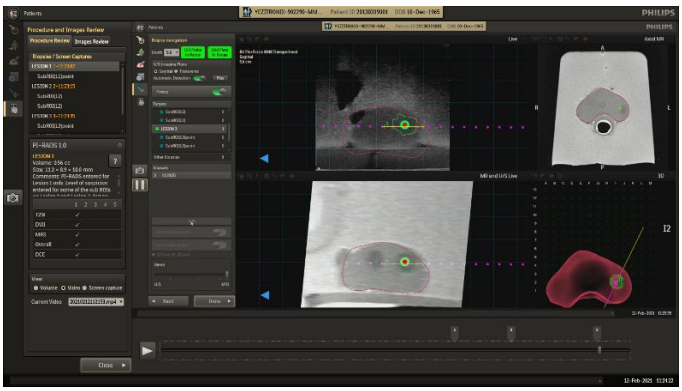
Recording begins automatically when Auto-record mode is enabled in the System Configuration by selecting the **System Setup** > **Media Settings** tab.

To manually start/stop recording video:

- Select the Record button that appears on the left side of the screen to begin recording

- Select the Pause button to stop recording.

After video is recorded, the workflow may be played back on the Review screen. Depending on the workflow, the video can include bookmarks to jump to specific recorded events.



Closing the application

After a workflow has been started, it may be canceled by selecting the Home Screen button (shown in margin).

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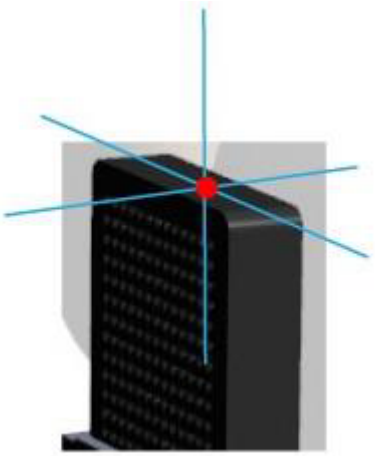
Patient coordinate system

The UroNav uses a separate coordinate system for its Graphical User Interface (GUI) than the one used when saving or exporting files:

- DICOM patient coordinate system - used when saving/exporting files
- GUI patient coordinate system - an IEC6127-compliant patient coordinate system is used in the GUI of the UroNav.

The origin of the patient coordinate systems are the same for both coordinate systems which is the center of the left-top grid template position on the patient side.



The orientation is relative with respect to the orientation of the grid template.

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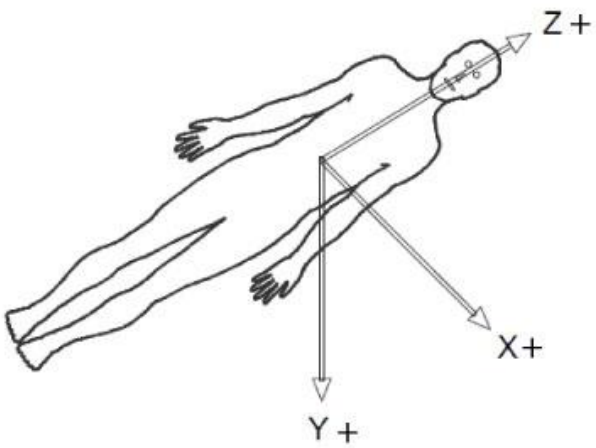
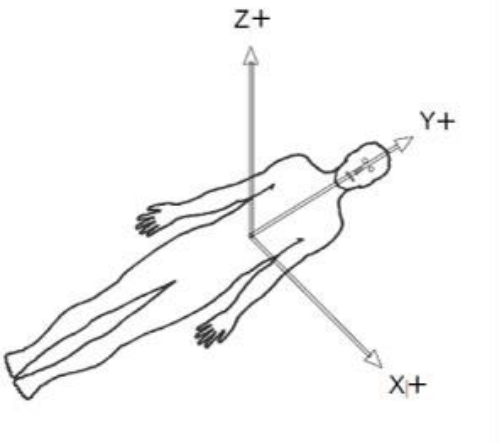
The DICOM patient coordinate system is used within saved/exported files to ensure that data sharing between the UroNav and other systems is handled properly.



In the User Interface of the UroNav, the IEC61217 compliant patient coordinate system is displayed.



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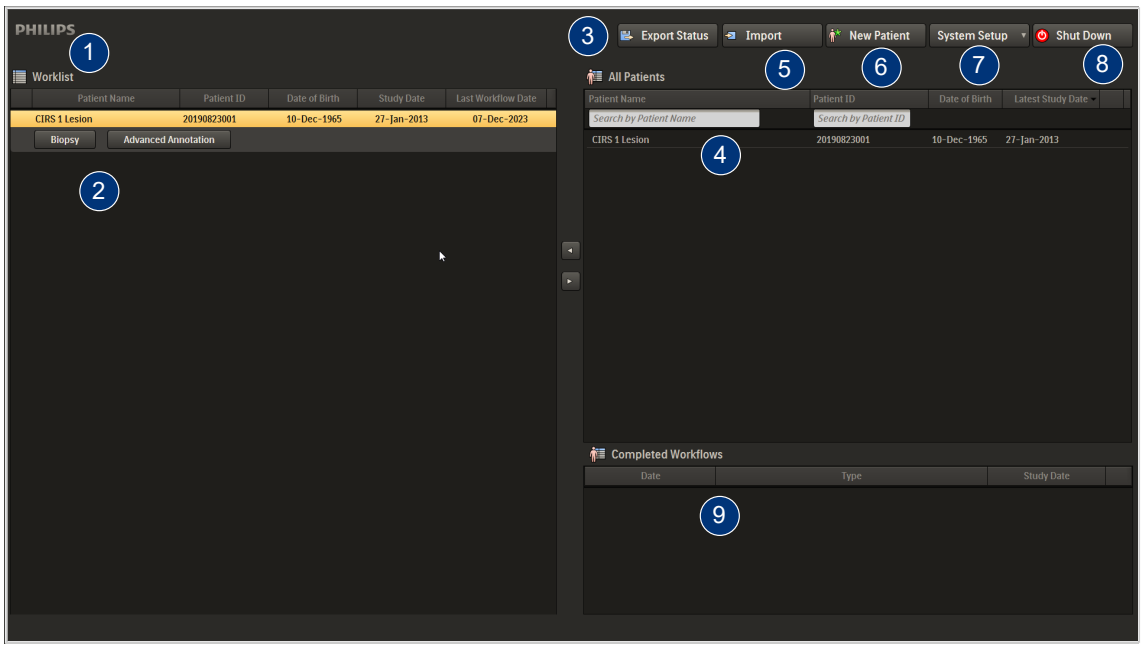
12 UroNav Home screen

The UroNav Home screen enables you to import data, configure settings, view patient history, and start a workflow. In order to start a workflow, patient studies should be available. Patient studies can either be imported from an external data source, or a new patient study can be created.



1	**Worklist:** Shows a list of scheduled patients. Using left-mouse button, drag and drop a patient from the All Patients list to the Worklist to start the workflow.
2	**Available workflows:** Shows all available workflows for the patient.
3	**Export Status:** Flashes when patient data is exported.
4	**All patients list:** Shows all imported patients.
5	“Import” on page 100: Enables the import of patient studies.
6	“New Patient” on page 102: Creates a new patient record for an ultrasound only workflow.
7	“System Setup” on page 76: Enables the editing of system configuration settings. See also “Annotation Editor” on page 104 for more information.
8	**Shut down:** Exits UroNav and powers down the system. See “Automatic screen lock” on page 17 for more information.
9	“Completed workflows” on page 102: Displays history of workflows for selected patient.

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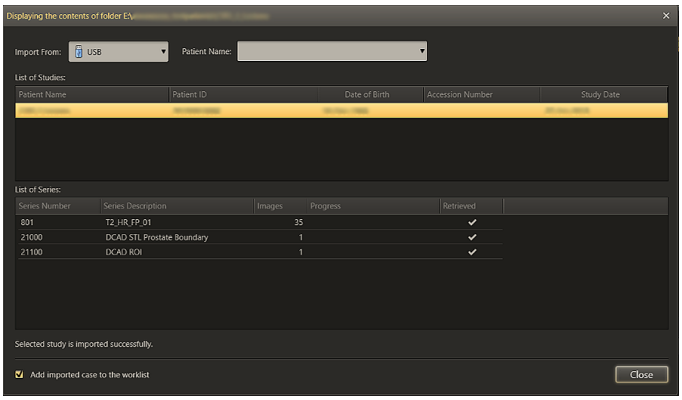
Import

UroNav supports importing of patient studies from various data sources. It can be configured to directly import studies from DynaCAD. Other data sources are USB, Disk or PACS, if so configured.

Import from DynaCAD or PACS will require a network connection. If configured, data can be imported securely from DynaCAD or PACS.

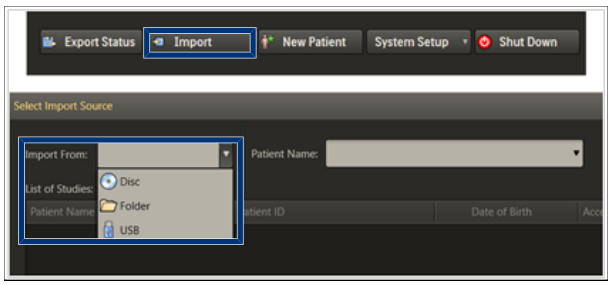
When selecting a data folder or specific patient study for import, UroNav will find and import the relevant data and store it on the hard disk. This data can subsequently be used to start a workflow on UroNav.



Do not attempt to export studies from DynaCAD to a UroNav system, as the UroNav connectivity may be limited (for example, due to being switched off or unplugged).

To import a patient study:

1. Click **Import** on the UroNav Home screen.
2. Select the data source from the **Import from** menu. UroNav will display the list of available patients in the menu on the right.



3. Select from the list the patient name that you want to import.
4. Wait for the import to complete and close the dialog.

The patient study is now available in the **All patients** list.

If the imported patient study from DynaCAD includes a UroNav plan, the associated device configuration will be saved to UroNav. The annotations defined therein can be selected as part of an Advanced Annotation workflow. If a plan is imported that contains a newer version of a

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device configuration that was already saved to UroNav, its parameters shall be updated. The saved device configurations can be reviewed in the Annotation Editor. See “Annotation Editor” on page 104 for more details.

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New Patient

An Ultrasound Only patient study may be created without associated MR data by clicking the New Patient tab, as shown in the following image:

Completed workflows

You can view the history of all workflows performed with UroNav for a specific patient. Displayed as a list in descending chronological order; the following fields are provided:

- Workflow Date
- Workflow Type
- Study Date
- Export Status

Additionally, you can delete, view and export of individual workflow data.

Data Export to DICOM Destination

UroNav workflow data can be manually exported to a preconfigured DICOM destination. If connected to the network, UroNav can also automatically export workflow data to a preconfigured DynaCAD server after the completion of a workflow, including screen captures and screen recordings. The user may cancel ongoing exports and start exports manually at a later time.

Below are the instructions to manually transfer all workflow data associated with a specific patient or a range of patients to a preconfigured DICOM destination:

1. Select the patient (or patients) from the **All Patients** list.
2. Right-click and select **Export**.
3. Choose a pre-defined DICOM destination.

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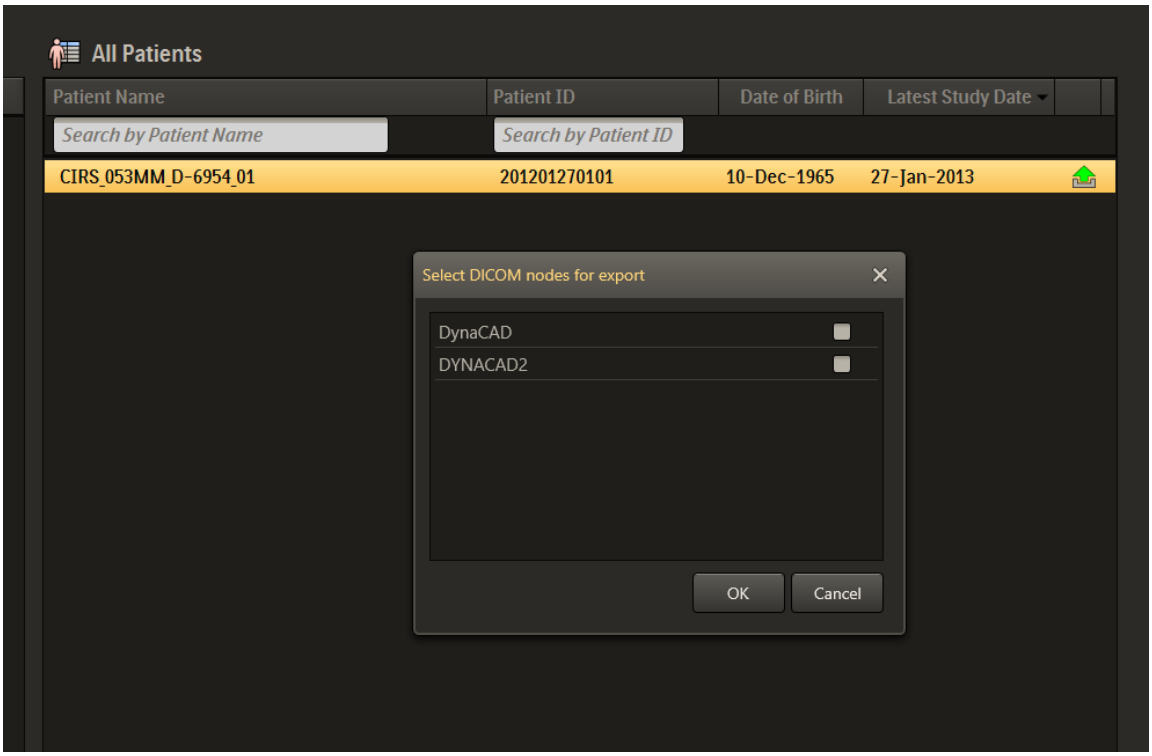

4. Select **OK** to begin exporting. UroNav will indicate data transfer progress per patient.

The patient export status indicator is successful only if all of the workflows associated with the patient are successfully exported. Failure to export any of the workflows will result in an unsuccessful export status in the All Patients panel. The export status of individual workflows can be reviewed in the Completed Workflows panel.

It is recommended that the user confirms that data has been successfully transferred to the DICOM destination before attempting to delete the corresponding data from UroNav.

Data Export to USB drive

UroNav workflow data can be exported to an external USB drive.

NOTICE

The data will be encrypted before being exported to the USB drive.

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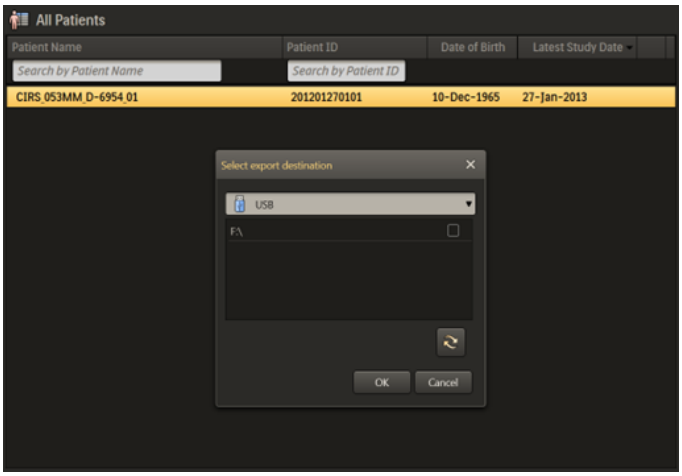

To manually transfer all workflow data associated with a specific patient or a range of patients to an external USB drive:

1. Select the patient (or patients) from the **All Patients** list.
2. Right-click and select **Export**.
3. Choose USB as the export destination.
4. Select the appropriate USB drive and click OK to begin exporting. UroNav will indicate the data transfer progress per patient.

NOTICE

The patient export state indicator is not applicable for export to USB. It is recommended that the user confirms that data has been successfully transferred to the USB drive before attempting to delete the corresponding data from UroNav.

Annotation Editor

Any annotation device configuration saved onto UroNav can be reviewed in the Annotation Editor and optionally deleted.

Annotation devices are first configured in DynaCAD Urology and then imported to UroNav via the pre-plan contained in a patient study. If a plan is imported with a different version of a device configuration, the Annotation Editor will show the most recent version. The same list of annotation devices can be selected within the Advanced Annotation workflow.

To review an annotation device:

1. Select **System Setup** > **Annotation Editor**.
2. Select the Expand button for an annotation device you want to review.
3. Inspect the configured parameters.
4. Close the Annotation Editor when finished.

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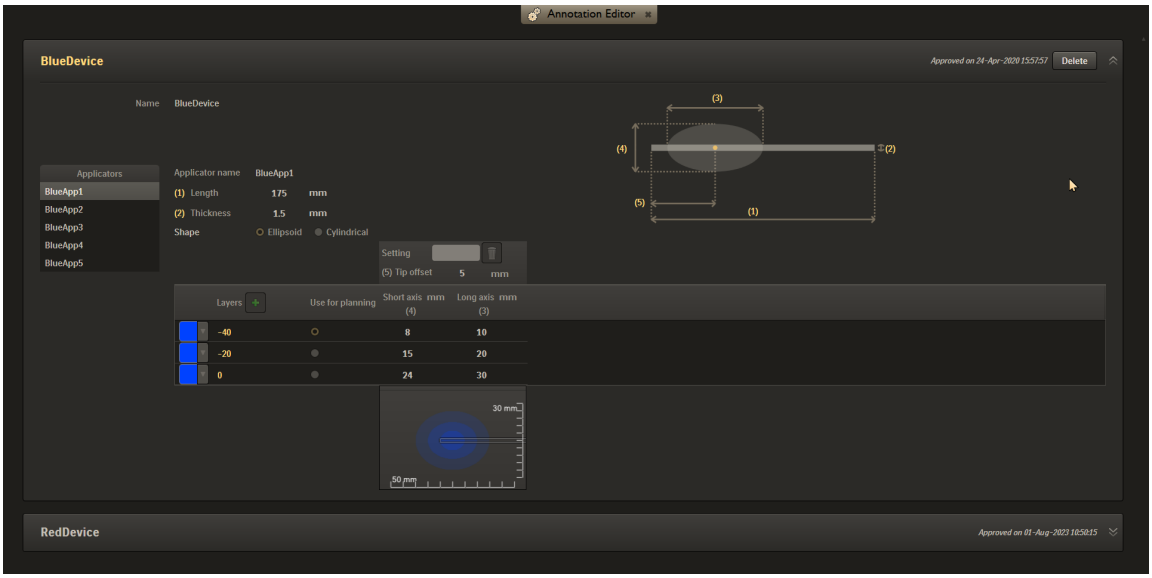
NOTICE

The annotation device parameters cannot be edited on the UroNav system and can only be imported from DynaCAD Urology via a patient study.



To delete an annotation device:

1. Select **System Setup** > **Annotation Editor**.
2. Select the Expand button for an annotation device which you want to delete.
3. Select **Delete** and confirm.

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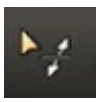
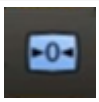
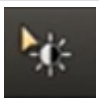
13 Biopsy

The biopsy workflow allows the user options to fuse a transrectal ultrasound (TRUS) with a previously acquired imaging study. Typically, this is a pre-procedure magnetic resonance (MR) image study but can also be a previous TRUS-based biopsy workflows. Additionally, transperineal biopsy workflows can also be completed with a similar workflow.

In-Viewport toolbar

Utilized within the Biopsy workflow, the **In-Viewport toolbar** provides quick access to several tools for making direct modifications to the image or visual overlays in the main display area. Tools are selected by clicking on the appropriate button or slider.

Slider	Action	Description
	Blend	Adjusts the amount of blend of each modality (U/S and MR).

Button	Action	Description
	Pick Point	Sets cross-correlation point in all 2D image planes.
	Zoom	Zooms image.
	Pan	Pans image or pans the registration, depending on the workflow step.
	Rotate	Rotates 3D image.
	Scroll	Scrolls through 2D data set.
	Window gray-scale adjustment	Automatically adjusts gray-scale to optimize image quality
	Reset view	Restores to default the image settings
	Gray level	Manual window width and window level adjustment

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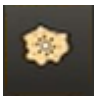
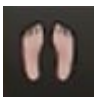
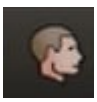
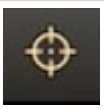
Button	Action	Description
	Show selected	Displays selected targets in all viewports
	Show all	Displays all targets in all viewports
	Adjust Mesh Boundary tool	Adjust boundary on active viewport.
	Adjust Mesh Boundary (correlation) tool	Boundary adjustment correlated and visualized in all three planes (default setting).
	Registration rotate	Rotates the registration. Rotates U/S dataset in the active viewport.
	Axial	Changes viewport to axial display.
	Coronal	Changes viewport to coronal display.
	Sagittal	Changes viewport to sagittal display.
	MRI-imported target	The bull's eye for MRI-imported targets represents the calculated center of the identified target (centroid).
	Place landmark	Placement of anatomical orientation landmarks for U/S segmentation.
	Show/Hide all graphics	Turns graphical display on/off.
	Rotational adjustment	Adjust for variances in the apex location of an end-fire ultrasound transducer’s image plane.
	Scroll through frames/adjust active biopsy core	When viewport is active (biopsy guide is magenta), allows the user to scroll through cine frames. When needle guide is active (green), allows the user to move the needle location along the needle guide.

Biopsy workflow

To start the Biopsy workflow:

1. Ensure that a patient record is available. See “UroNav Home screen” on page 99 for more information on how to import a patient record.
2. Click and drag the desired patient from the **All Patients** list to the Worklist.
3. Click **Biopsy**.

UroNav offers a Navigation toolbar (displayed on the left side of the Start screen) that you may use to navigate between different workflow steps. Each step is represented by a dedicated button, which will take you to the corresponding screen. The workflow consists of the following steps:

Button	Workflow Step	Description
	Review segmentation and targets(7)	Provides tools to review the T2 weighted MR scan including delineations.
	Setup	Select the US system, TRUS probes, grid plates, and biopsy needle option.
	Sweep & segmentation	Acquires a volumetric ultrasound image and indicate the prostate boundary.
	Align US volume with MR(7)	Fuses the MR volume and targets with the US data by adjusting the registration.
	Biopsy Navigation	Marks biopsy cores.
	Review procedure and images	Review the screen captures, video recordings of procedures, as well as segmentations and marked biopsy cores.

When transitioning between the different screens or when closing the Biopsy workflow, the workflow data up to that point (such as, the biopsies taken) will be stored, enabling the user to resume an uncompleted workflow. In the Biopsy navigation screen, any workflow data will be stored regardless of screen transitioning.

Review Segmentation and Targets screen

This section provides a preview of MRI-defined prostate boundary and biopsy targets. Users may create additional targets from here or preview cores recorded from a prior workflow. The default layout of the **Review and Segmentation and Targets** screen shows the selected target from the target list in multi-planar MRI format.

(7) Not available for ultrasound only workflows.

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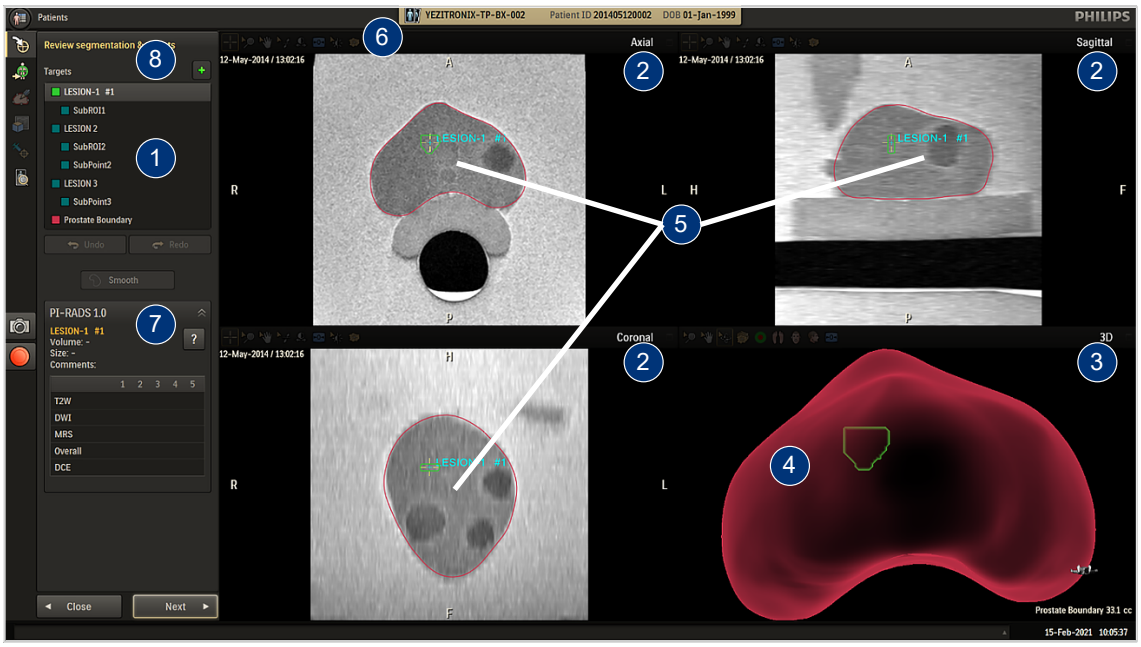
NOTICE

The Review Segmentation and Targets screen is not displayed for ultrasound-only workflows.



1	**Segmentations list:** Shows the MR segmentations that are available from DynaCAD™, including targets that are pre-defined or added by the user.
2	**MPR viewports:** Shows the MR data from the Axial, Coronal, and Sagittal views.
3	**3D viewport:** Shows the MR data as a 3D mesh.
4	**3D Segmentations:** Lesions imported from DynaCAD shown against the 3D viewport.
5	**2D Segmentations:** Lesions imported from DynaCAD shown against the MPR viewports.
6	**Patient Identification:** Displays Patient Name, Patient ID, Date of Birth, Gender.
7	**PI-RADS:** Displays Prostate Imaging Reporting and Data System information for the selected target. Click the question mark (?) for more information.
8	**Add Target:** Creates a new target at the current cursor position; note that a different color is used to distinguish the target from the imported targets.

Target Identification

A segmentation can consist of multiple targets of several distinct types. Up to 20 targets can be imported from DynaCAD. These imported targets are represented as green volumes with a green bull's eye denoting the centroid. Additional point-targets can be manually added during the workflow. If defined in DynaCAD, target hierarchies (a target within a target) and PI-RADS metadata can be imported.

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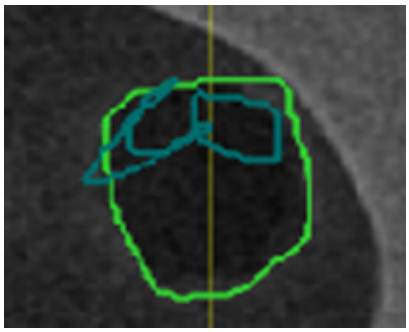
	**MRI-imported target:** The bull's eye for MRI-imported targets represents the calculated center of the identified target (centroid).
	**Manually added target:** Manually added targets are visually distinct from imported targets.
	**MRI-imported sub-region:** Sub region targets drawn in relation to the parent target (lime green).

Adjusting Prostate Boundary

The MRI-defined prostate boundary can be adjusted by the user for use during the biopsy workflow.

NOTICE

Adjustments made in the Review Segmentation and Targets screen are only displayed intra-workflow. Post-workflow results are viewed and stored on the imported, unedited MRI-defined prostate boundary.

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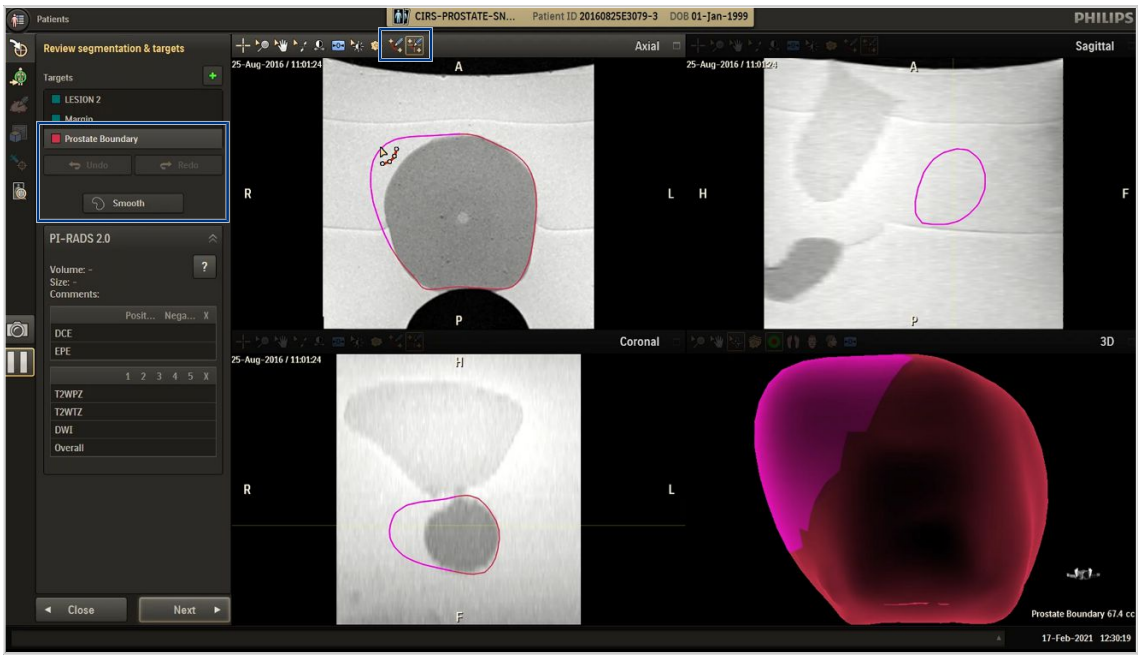
To make adjustments:

- Select the **Prostate Boundary** from the Targets list.
- Hover the mouse over the region of the boundary to be adjusted. The mouse action will change to the **Adjust Mesh Boundary** tool.
- Click and drag the boundary to make the desired change.
- Use **Smooth** to correct rough edges made during boundary editing.
- Use **Undo** and **Redo** to correct changes made during boundary editing.



Setup screen

During Setup, the user will confirm the instrument configuration and perform EM-tracking-related checks to ensure that UroNav is functioning as expected. The EM tracker and probe holder must be properly secured to the TRUS. Refer to “Appendix B” on page 166 and “Appendix C” on page 210 of this document for the TRUS type being used for correct assembly and attachment. For transperineal workflows using a grid plate, an additional EM tracker must be secured to the Stepper for use with the grid plate.

Initialization of the field generator automatically occurs at this stage or when the Initialize Field Generator button is pressed. A series of two beeps signifies the initiation of the EM field and a pop up window will appear. Click **OK**.

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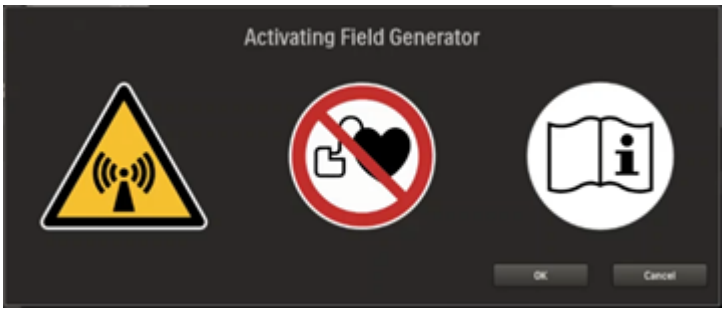

WARNING

Do not operate the field generator within 200mm (8in) of an installed pacemaker or other potentially electrically conductive implants such as defibrillators. The magnetic field produced by the field generator may interfere with the operation of the pacemaker, which may result in personal injury, and distortion created in the EM field by conductive implants may result in inaccurate targeting.

CAUTION

Use of unsupported biopsy guns and needles may cause EM interference and result in inaccurate registration and biopsy core marking.

CAUTION

Although video calibration should be carried out by a trained Philips support team, it is the responsibility of the operator to ensure that the (pre-calibrated) video calibration is correct for the specific ultrasound system in use. This can lead to a misinterpretation of the scale of the incoming image, leading to inaccurate volume calculations and overall misrepresentations of the patient's anatomy. This may result in potential misalignment of biopsy core overlays or (user-indicated) needle path overlays. Contact Philips customer support for assistance.

The Tracker viewport lets the user verify proper positioning by the generated field being within close proximity to the tracking device(s).

Correct positioning may be confirmed when the color of the connected trackers is shown as green. If the EM tracker(s) is beyond the working range of the EM field, the display will change the color of the connected port and the device to yellow or red (out of range).

For BK U/S users, UroNav can automatically detect the imaging plane of the U/S scanner using a "correlation rectangle." The location of this rectangle is provided automatically by the system but can also be set manually by the user. While Automatic Detection is enabled, and the location of the rectangle is correctly placed, the selected plane in UroNav shall match that of the connected ultrasound.

You need to initialize Navigation tools to create Electromagnetic (EM) Field for Fusion Registration, Targeting, and Recording Biopsy Core Samples.

- ► Match depth on UroNav to depth display on US.

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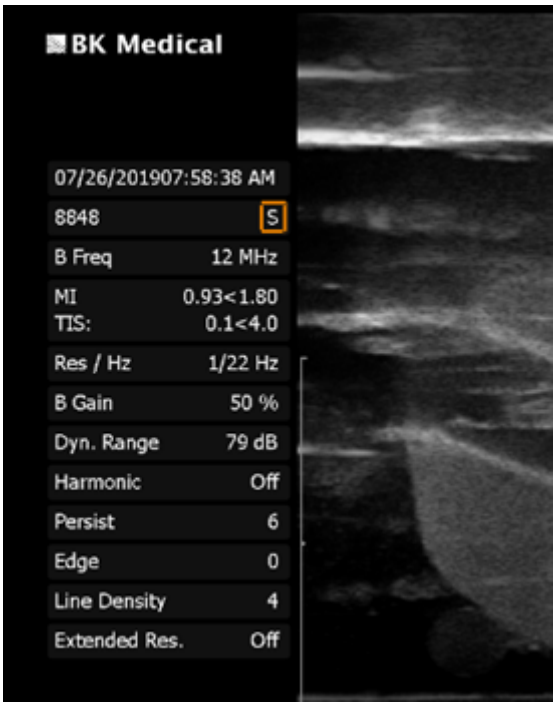
- ► Confirm biopsy needle/gun. Verify that the biopsy device to be used in the workflow matches the selection in the Biopsy Needle Gun description list. See “Supported biopsy guns and needles” on page 163 for more information.
- ► For Transperineal procedures, verify grid selection.
- ► EM tracker and grid status:
- ⇨ The color represents the range found within the generated EM field.
- ⇨ Green color shows tracking "In Range".
- ► Verify live US video feed and correlation rectangle (if applicable).



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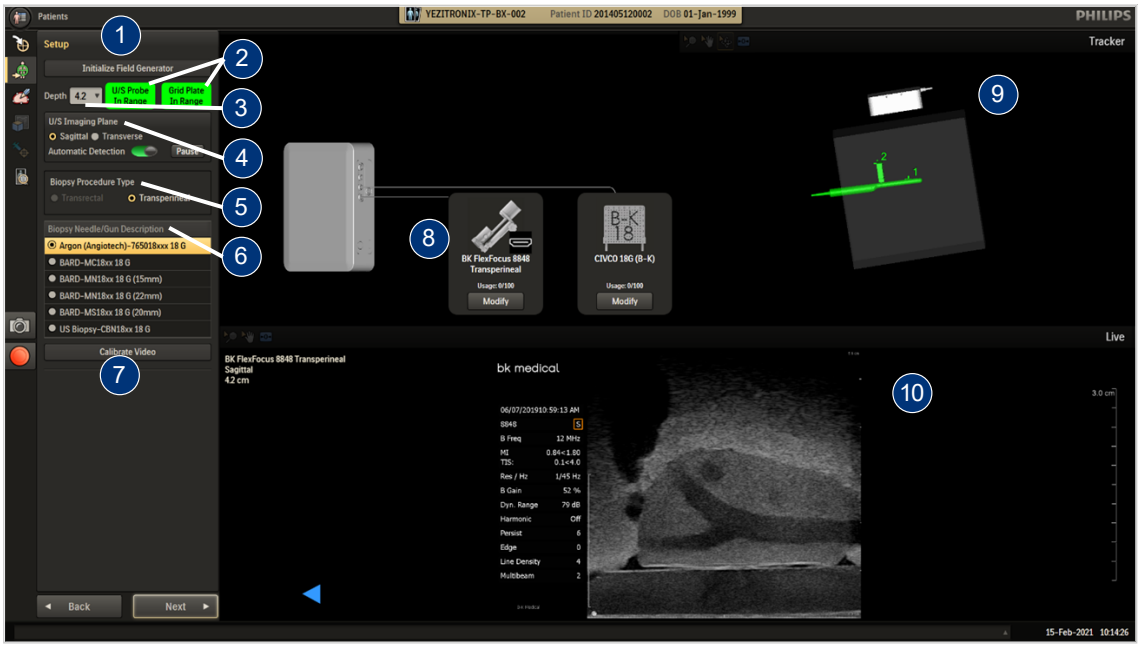
User Interface



1	**Initialize Field Generator:** Initializes the field generator creating the EM field.
2	**EM Tracker Status:** The color (green, yellow, or red) represents the range found within the EM field generated used for accurate navigation.
3	**Depth Selection:** Lists available depth options for the connected Ultrasound probe.
4	**U/S Imaging Plane:** Lists supported imaging planes for the connected EM tracker. **Sagittal:** Automatically detected. It can be manually overridden. **Transverse:** Automatically detected. It can be manually overridden. **Endfire:** Automatically detected. It can be manually overridden. **Automatic Detection:** For multi-plane ultrasound probes, an automatic plane detection control will appear.
5	**Biopsy Procedure Type:** Provides the supported biopsy procedure types based on TRUS probe selection and UroNav license purchase.
6	**Biopsy Needle Selection:** List of available biopsy needle options.
7	**Calibrate Video:** Service feature used to perform ultrasound video calibration. This step only needs to be performed once for each ultrasound/probe combination.
8	**TRUS Information:** These TRUS settings used in the previous procedure are populated automatically and graphically shows the port number in which the EM sensor is connected. Any of the four ports can be used; multiple ports are provided for convenience. The usage count of individual EM sensors is provided. White text for the usage count indicates that the EM sensor is within its normal usage limit. Red text indicates that the usage limit has been surpassed.
9	**EM Tracker Location:** This shows the placement of the TRUS in relation to the Field Generator and EM field.

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10	**Live Ultrasound:** Displays live video feed from the ultrasound system. Needle Guideline: The default needle guideline can be adjusted by clicking and dragging the magenta square to align with the U/S needle guide. **U/S Plane Indicator Rectangle:** For multi-plane BK TRUS probes, the orange ultrasound plane indicator rectangle appears. The default plane indicator rectangle can be adjusted to optimize the automatic plane detection. The factory default ultrasound plane indicator rectangle is restored after each procedure.

To adjust the U/S Plane Indicator Rectangle:

1. Hover above the rectangle until turning green.
2. Press and hold the left mouse button (pointer arrow changes to cross).
3. Move the rectangle until the ultrasound plane indicator is centered inside.
4. Release the mouse button and move the mouse pointer away until the rectangle turns orange.

Sweep and Segmentation

The Sweep and Segmentation screen consists of acquiring a volumetric ultrasound image and segmenting the prostate on the resulting ultrasound volume. This is facilitated by UroNav by recording a sagittal or transverse sweep and interpolating between the captured slices to reconstruct a volumetric ultrasound image of the patient's anatomy. EM tracked positional information of the probe's rotation is used in the reconstruction process.

Impact of inaccurate image acquisition:

CAUTION

The reconstructed U/S volume is input for the registration between MR and U/S images. Inaccurate registration could lead to an impact on targeting accuracy. Folllow the provided instructions to capture an accurate sweep.

CAUTION

Always make sure that the displayed depth and plane setting in the live imaging view is the same as on the ultrasound machine before recording the sweep.

NOTICE

Sweeps of the gland are supported with the patient in the left decubitus, right decubitus, or lithotomy position.

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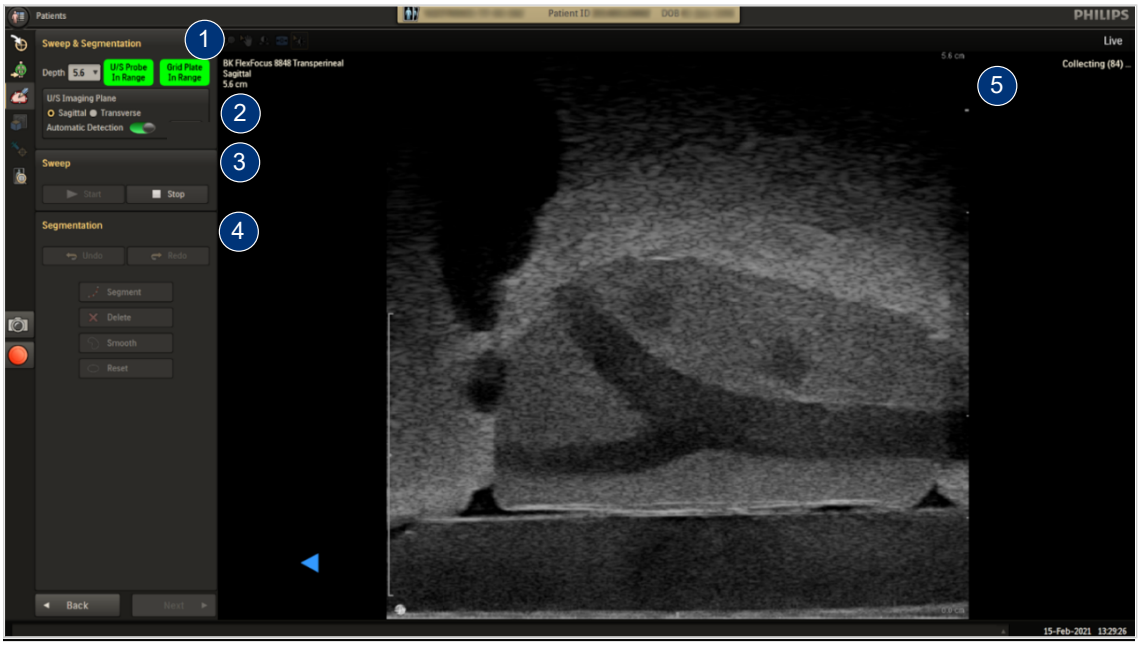

Fig. 4: User Interface (Sweep)

1	**EM Tracker Status:** The color (green, yellow, or red) represents the range found within the EM field generated and is used for accurate navigation
2	**U/S Imaging Plane:** Lists supported imaging planes for the connected EM tracker. **Sagittal:** Automatically detected. It can be manually overridden. **Endfire:** Automatically detected. It can be manually overridden. **Transverse:** Automatically detected. It can be mannual overridden. **Automatic Detection:** For multi-plane ultrasound probes, an automatic plane detection control will appear.
3	**Sweep:** Enables the user to select the sweep direction (for transverse sweeps only), and **Start/Stop** the sweep.
4	**Segmentation tools:** Enables the user to manipulate the segmentation, including through the use of **Undo/ Redo** and smoothing.
5	**Live U/S:** Provides the live ultrasound as a visual aid to the user when taking a sweep.

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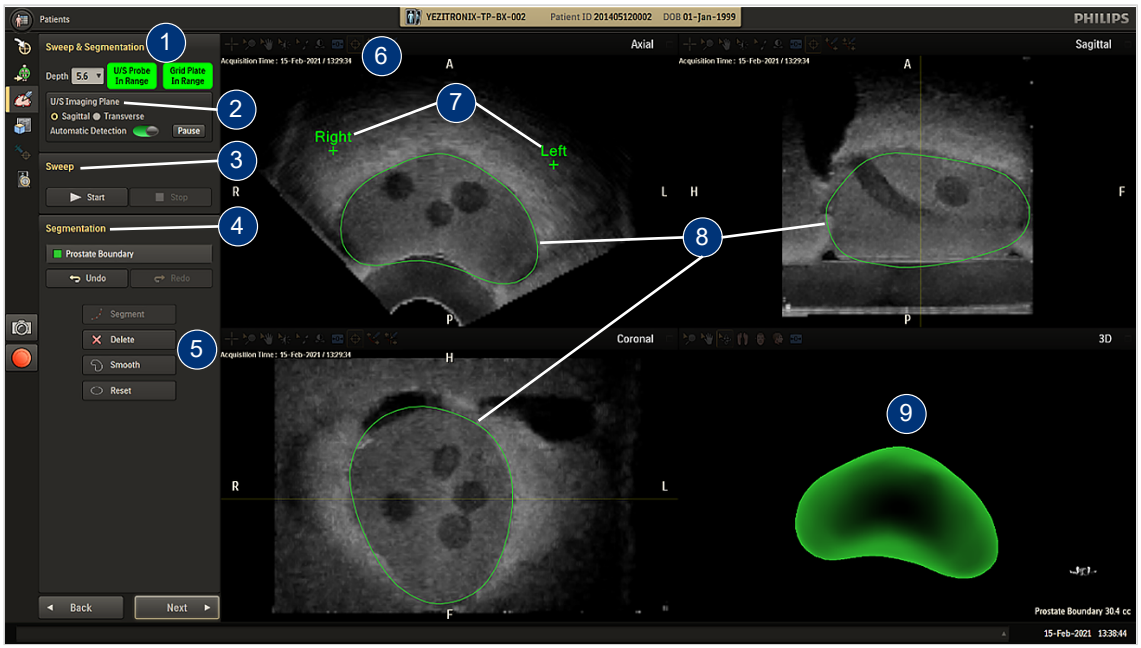

Fig. 5: User Interface (Segmentation)

1	**EM Tracker Status:** The color (green, yellow, or red) represents the range found within the EM field generated and is used for accurate navigation
2	**U/S Imaging Plane:** Lists supported imaging planes for the connected EM tracker. **Sagittal:** Automatically detected. It can be manually overridden. **Transverse:** Automatically detected. It can be mannual overridden. **Automatic Detection:** For multi-plane ultrasound probes, an automatic plane detection control will appear.
3	**Sweep:** Enables the user to select the sweep direction (for transverse sweeps only), and **Start/Stop** the sweep.
4	**Segmentation list:** Displays the segmentation captured through live U/S sweep.
5	**Segmentation tools:** Enables the user to manipulate the segmentation, including through the use of **Undo/ Redo** and smoothing.
6	**Boundary adjustment tools:** Enables the user to adjust the boundary of the U/S segmentation.
7	**Fiducial landmark:** Represents anatomical axes, guiding the segmentation creation algorithm. (The landmarks shown in the image are for reference purposes only, and are intended only for use in creation of the prostate segmentation.)
8	**MPR views:** The reconstructed U/S volume is shown in each of the orthogonal planes
9	**3D view:** Displays a 3D model of the reconstructed prostate.

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Perform sweep and segmentation

To acquire a volumetric ultrasound image:

1. Ensure the procedure area is free from electromagnetic disturbance factors and the EM tracker statuses are all green. Also, ensure the field generator does not move during the sweep.
2. Position the probe to the starting position for the sweep.

3. Click **Start**.

⇨ Alternatively, you may hold down the foot pedal with the Sweep icon (shown in left margin).

4. Rotate (sagittal sweep) or move (transverse sweep) the probe to capture the prostate. Ensure a smooth, steady motion, taking about 6 seconds while applying constant pressure.
5. Click **Stop** or release the foot pedal to stop the acquisition.

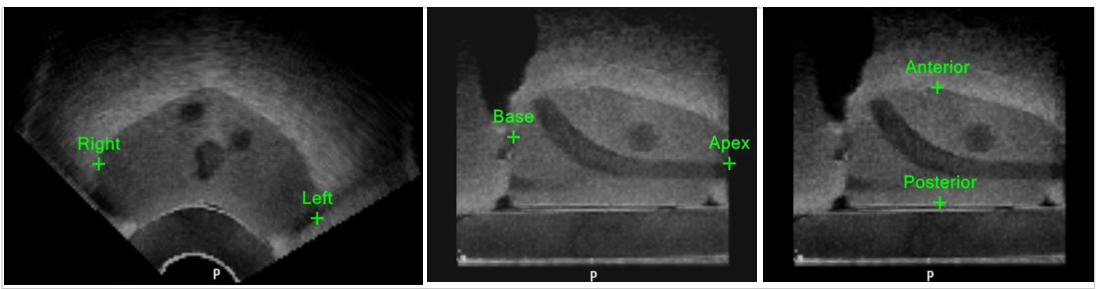
For end-fire TRUS:	Sweep transversely from base to apex (or apex to base) of the prostate without probe rotation and keeping the needle guide upward, closest to the field generator.
For side-fire TRUS:	Sweep in the sagittal view and completely from one side of the prostate to the other. Alternatively, the sweep can be performed in the transverse plane, perpendicular to the gland, from the base to apex, or apex to base.

Segmentation Action Commands to Edit 3D Boundary

Following a sweep, segment the prostate by editing the 3D boundary with the **Place Landmark** tool. As many as six axis endpoints may be placed on the images to support 3D reconstruction.

To segment the prostate:

1. Use the **Place Landmark** tool and click on the visible edges of the prostate in the ultrasound images.



⇨ Select right and left endpoints in the transverse plane to mark the largest width of the prostate.

⇨ Select base and apex endpoints in the sagittal plane to mark the largest length of the prostate.

⇨ Select anterior and posterior endpoints in the sagittal plane to mark the largest height of the prostate.

2. Click the **Segment** button to generate the segmentation.

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3. Use the **Adjust Mesh Boundary** tools to adjust the segmentation boundary by dragging the pink highlighted part of the boundary in any viewport.
4. Optionally, click the **Smooth** button to smooth out the edited segmentation boundary.

To delete a segmentation landmark:

► Right-click the endpoint's crosshair and select **Delete landmark**.

To align the segmented prostate from the ultrasound acquisition with the imported MR images and segmentations, click **Next** and continue to the **Align U/S volume with MR** screen.

Align US volume with MR screen

The **Align US volume with MR** consists of completing registration between the segmented ultrasound volume and the pre-operative MR data. A semi-automatic 3D rigid registration is applied to both volumes. Align and superimpose the green U/S prostate boundary with the red MR prostate boundary using anatomical landmarks.

Image action commands:

- Manually complete registration through Pan, Zoom, and Rotation tools.
- Confirm complete alignment using multiple anatomical landmarks in at least two planes.
- Use the Blend slider to vary the primary view of the superimposed U/S and MR boundaries for optimal visualization.

CAUTION

Verify the registration in all three orthogonal planes for use in tracking and targeting, and adjust if needed.

NOTICE

Verify depth setting selection when switching imaging planes with multi-planar US probes.

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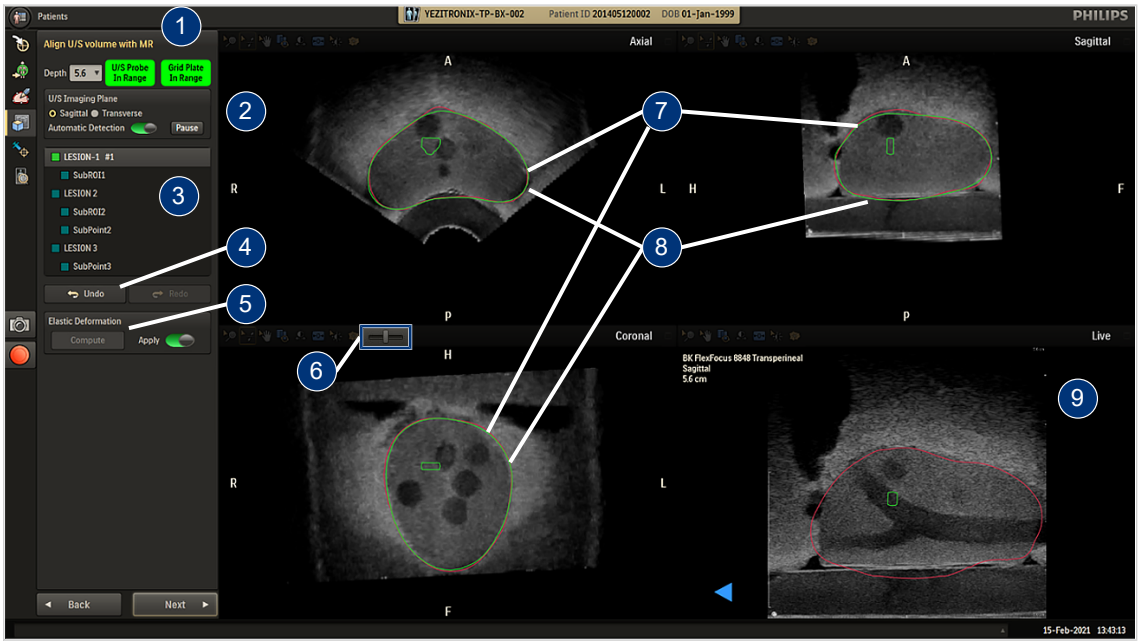

1	**EM Tracker Status:**The color (green, yellow, or red) represents the range found within the EM field generated used for accurate navigation.
2	**U/S Imaging Plane:** Lists supported imaging planes for the connected EM tracker. **Sagittal:** Automatically detected. It can be manually overridden. **Transverse:** Automatically detected. It can be manually overridden. **Endfire:** Automatically detected. It can be manually overridden. **Automatic Detection:** For multi-plane ultrasound probes, an automatic plane detection
3	**Segmentations list:** This shows the MR segmentations that are available from DynaCAD, including targets.
4	**Undo/Redo:** Enables the user to manipulate the registration between the MR and U/S data..
5	**Elastic Deformation:** **Compute:** Request an elastic registration be computed. **Apply:** Toggle between elastic (on) and rigid (off) registration modes.
6	**Blend:** Adjusts the amount of blend of each modality (U/S and MR) to optimize visualization when adjusting registration.
7	**MR MPR views:** Displays the MR volume shown in each of the orthogonal planes.
8	**U/S MPR views:** Displays the reconstructed U/S volume shown in each of the orthogonal planes.
9	**Live U/S:** Shows a live view of the U/S with superimposed MR.

The red boundary represents the 3D volume of the prostate gland borders demarcated from the pre-procedure MR images; the green boundary represents the segmentation from the U/S sweep.

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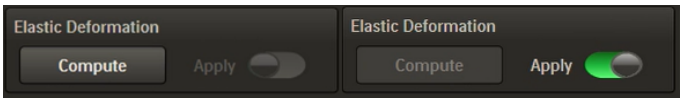
Elastic Deformation

The Registration screen provides the option to map the MR volume elastically to the ultrasound volume using the segmentation results, such as elastic deformation.

NOTICE

Elastic deformation computation is an option for use intra-procedure. Post-procedure results are viewed and stored on the imported, unedited MRI-defined prostate boundary.

Once computed, the Elastic Deformation may be toggled on or off, allowing the use of either elastic or rigid registration for the procedure.



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Navigation screen

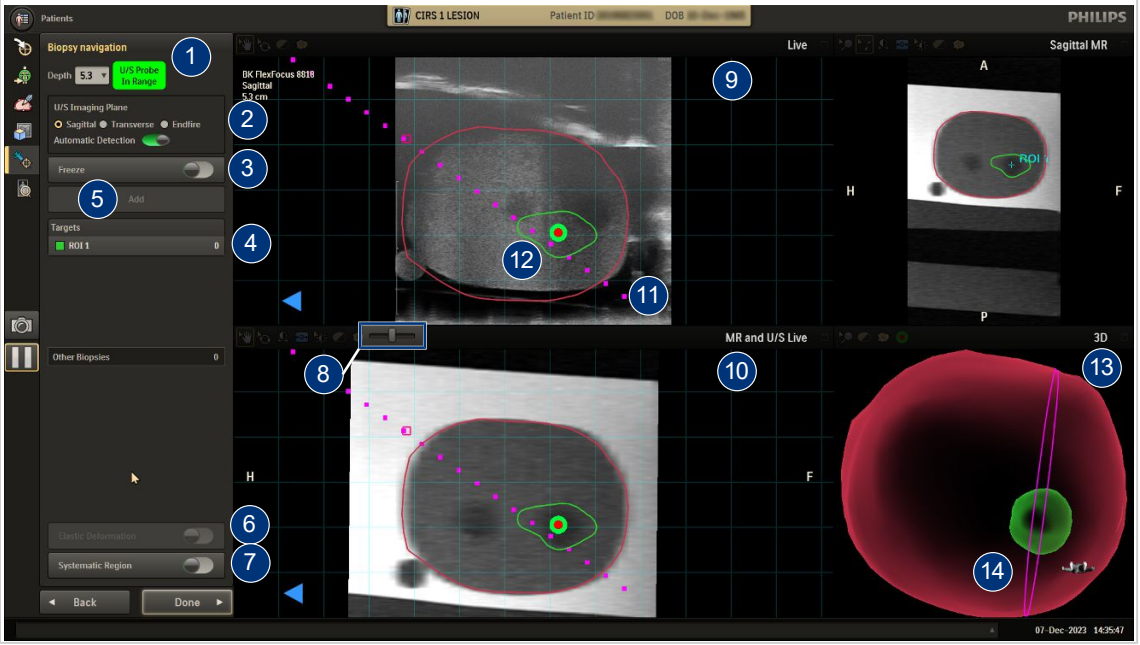
This **Biopsy Navigation** screen enables a user to capture biopsy cores from created and imported targets, as well as from configured systematic regions. The locations, times, and screenshots of captured biopsies are recorded for subsequent review.

CAUTION

Always make sure that the displayed plane and depth setting in the live imaging view is the same as on the ultrasound machine before capturing biopsy cores.

Ensure the procedure area is free from electromagnetic disturbance factors and the EM tracker statuses are all green. Always use the ultrasound image to verify the actual position of the biopsy gun and capture it as accurately as possible.

Transrectal Biopsy Navigation User Interface



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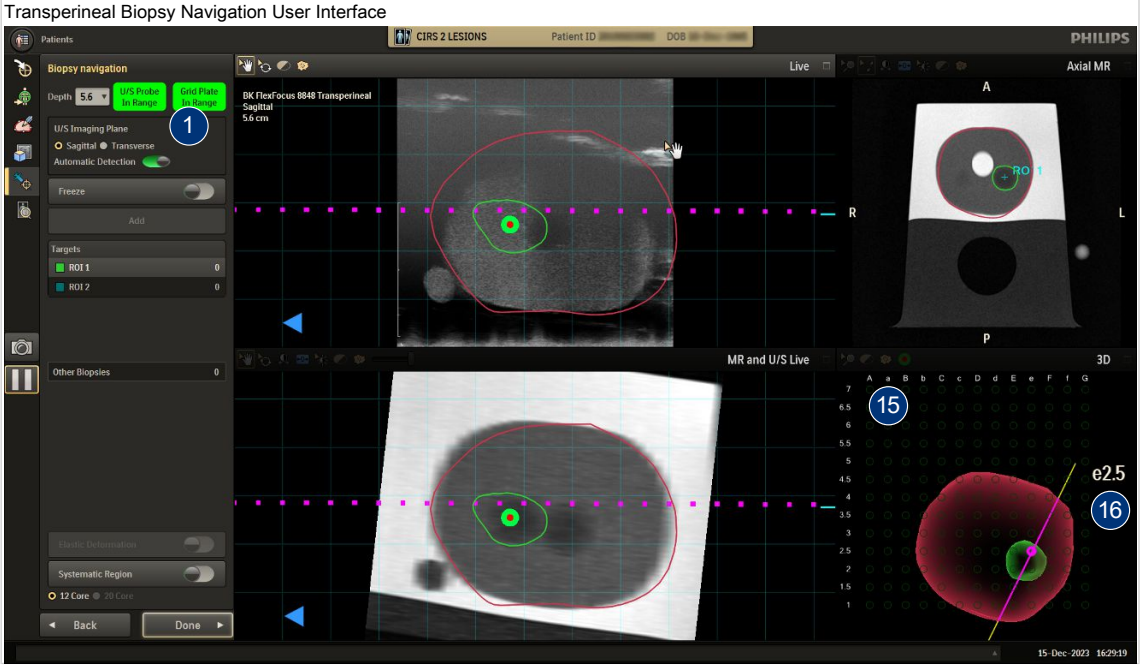
Transperineal Biopsy Navigation User Interface



1	**EM Tracker Status:** The color (green, yellow, or red) represents the range found within the EM field generated used for accurate navigation.
2	**U/S Imaging Plane:** Lists supported imaging planes for the connected EM tracker. **Sagittal:** Automatically detected. It can be manually overridden. **Transverse:** Automatically detected. It can be manually overridden. **Automatic Detection:** For multi-plane ultrasound probes, an automatic plane detection control will appear.
3	**Freeze button:** Freezes the live ultrasound view to enable capture of a biopsy.
4	**Target list:** Displays a list of targets; the selected target is shown within the MPR views and 3D view.
5	**Add biopsy button:** Toggles the ability to add biopsies in the live U/S viewport.
6	**Elastic deformation:** Toggles between elastic (on) and rigid (off) registration modes. Not available during U/S procedures.
7	**Systematic region:** Toggles configured systematic targets on/off.
8	**Blend:** A slider to adjust the blend between U/S and MR views in the US/MR viewport. During an ultrasound-only procedure, the slider adjusts the blend between the U/S segmentation and live U/S image.
9	**Live U/S:** Provides the live U/S with a superimposed MR view.
10	**Superimposed MR:** Projects over the live U/S view. Not available during U/S procedures.
11	**UroNav Biopsy Needle Guide:** Displays the needle guide for projected needle path for biopsy.
12	**Target centroid:** Highlights the center of the target.
13	**3D view:** Shows a rendering of the reconstructed prostate along with the position of the selected target.
14	**Probe rotation indicator:** This shows the probe's projected plane with reference to the prostate.

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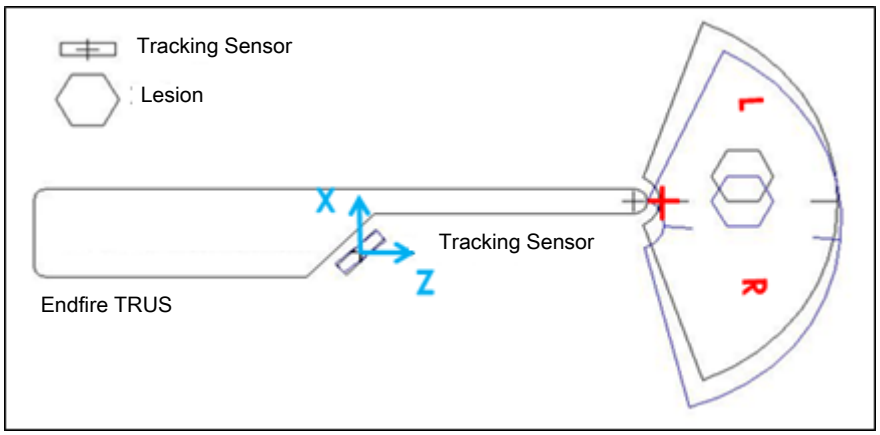
15	**Grid plate rendering:** Shows a rendering of the physical grid with reference to the prostate.
16	**Selected grid position:** Displays the label for the currently selected grid hole.

Rotational Adjustment

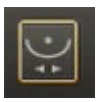
The following function allows the user to adjust for variances in the apex location of an end-fire ultrasound transducer's image plane. This variance is due to mechanical tolerances associated with the creation of the ultrasound transducer, the rendering of the image plane, and the measurement of the EM location. The following illustration shows how this variance may present to the user after rotating the probe 180° from the original sweep orientation. Depending on the tolerances listed above, an adjustment may or may not be deemed necessary by the clinician.



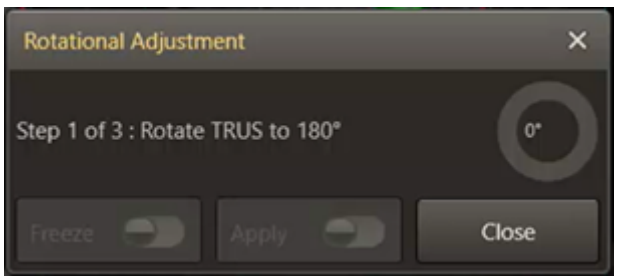
NOTICE

Initial registration should be performed prior to applying the rotational adjustment.

The following steps are used to perform this adjustment when the user wants to fine-tune the initial registration while on the Navigation Screen.



1. After selecting the Rotational Adjustment icon in the live ultrasound viewport, rotate the TRUS probe 180± 5° from the original sweep orientation used for volume acquisition and segmentation.



2. When the guide ring indicates you are in the proper orientation, the dialog changes to "Step 2".

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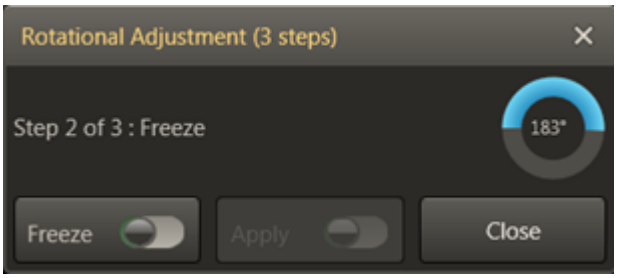
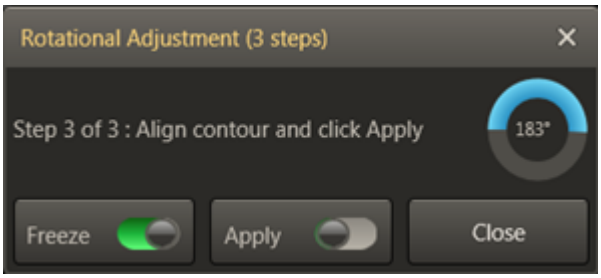


3. Select **Freeze** via the button on the rotational adjustment control. Clicking **Freeze** again will return the procedure to live action and any adjustments made during the freeze will be cleared.



4. On the bottom panel (MR view), use the Pan function to adjust the registration to align with the U/S volume in the top panel.
5. Click **Apply**. The volumes should now be in alignment when the TRUS probe is rotated in either orientation.

NOTICE

Only one rotational adjustment can be applied at any given time.

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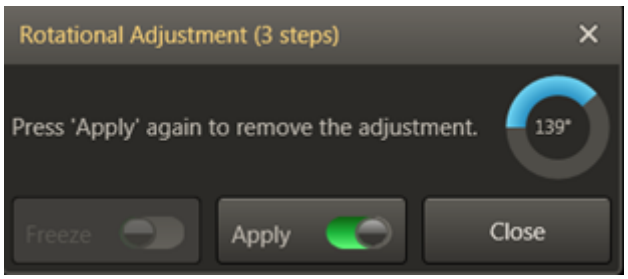
To clear the applied adjustment:

1. Select the Rotational Adjustment viewport icon.
2. Select **Apply** again.



Transrectal Biopsy Procedure

For transrectal procedures, the following steps apply to perform biopsies:

1. Ensure the EM tracker(s) display is green, indicating it is within range of EM field range.
2. Ensure the depth setting on UroNav matches the setting on the ultrasound system in both planes for a multi-plane probe.
3. Examine the Live Ultrasound viewport and bottom MR and U/S Live viewport for proper alignment throughout the procedure.

NOTICE

The 1cm on-screen grid lines are also convenient reference marks for authenticating alignment.

NOTICE

If manual adjustments do not successfully align the U/S with the MRI, it may be necessary to go back to the **Sweep and Segmentation** screen, repeat the sweep and replicate the alignment/registration steps.

4. Repeat step 3 as often as necessary throughout the procedure.
5. Select the target to be viewed or biopsied from the Target Selection list.
6. Use the color-coded guidance bars located on the right side of each viewport to locate the target. The length of the guidance bars indicates the distance away from the selected target. Navigation is easily achieved first by moving the transducer in one direction, shrinking the colored bars to get the target into view, then moving perpendicularly to align the bull's-eye target with the biopsy guide line as shown below. It is helpful to have the biopsy needle slightly inserted within the needle guide while honing in on target regions.

   The following images are examples showing the probe positions:

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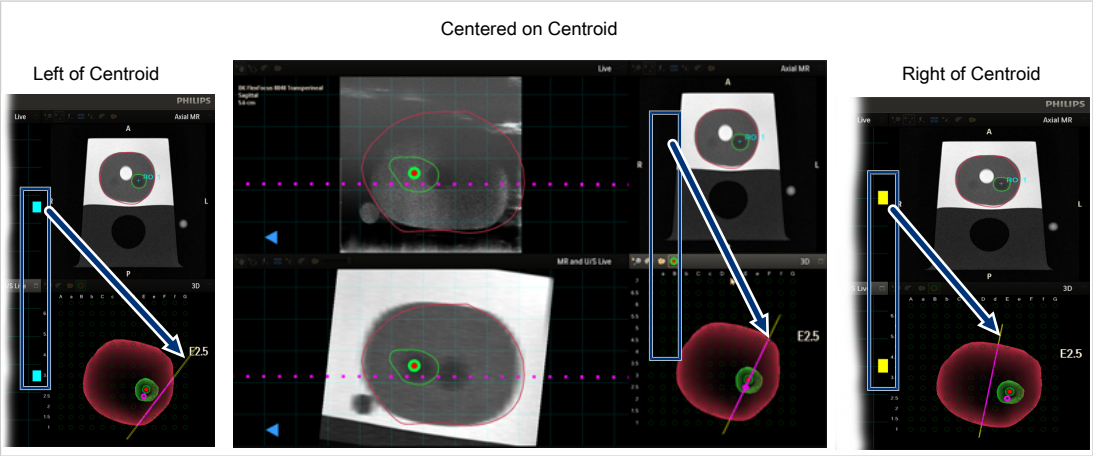

NOTICE

When using an end-fire probe, the prostate model in the 3D viewport will automatically adjust to a perspective directly orthogonal to the orientation of the imaging plane.

7. Ensure the biopsy guide line intersects the pre-selected target and advance the needle, monitoring the needle trajectory and insertion line continuously to ensure safety and proper guidance.

8. When the biopsy sample is taken:

⇨ Select **Freeze** or press the Freeze foot pedal to temporarily interrupt real-time cine viewing. Scroll through the U/S images using the mouse wheel or the cine scroll slider bar on the right side of the viewport to locate the point in time where the distal tip of the biopsy needle is visualized.

⇨ Hover the mouse cursor over the **biopsy guide line** (color changes to green) and use the mouse wheel or left mouse button to place the line marker to the distal tip of the biopsy needle. Press the **ADD** button from the Biopsies list menu to record this location and associate it with the current target. A screen capture will be acquired and a time stamp will be recorded and displayed, as shown in the following image:

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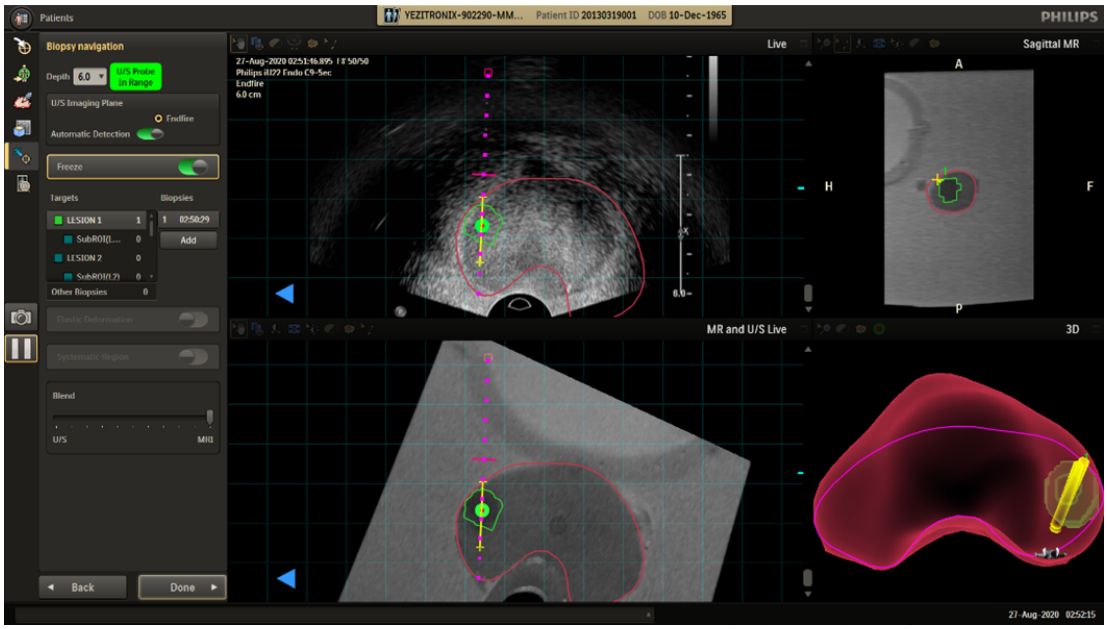

NOTICE

When the U/S Cine image is active, the middle mouse wheel has two functions. When the mouse cursor hovers over the biopsy needle guideline, it changes to green (active), which allows the user to use the mouse wheel to mark the distal tip of the biopsy needle. When the mouse cursor is away from the guide line (color turns magenta), the mouse wheel scrolls through the cine images.

When the U/S Cine image is active, the left mouse button has an additional function. Double-clicking allows the user to adjust the trajectory of the needle guideline. The needle guideline will be redrawn to accommodate the marked needle tip location.

If systematic targets have been configured, toggle the Systematic Regions icon to activate biopsy regions.

Transperineal Biopsy Procedure

For transperineal procedures, the following steps apply to perform biopsies:

1. Select the target to be viewed or biopsied from the Target Selection commands.
2. Rotate the TRUS transducer. Use the projected ultrasound plane intersection in the 3D viewport to view the target in the ultrasound image.

   The following image is an example of transperineal navigation with grid plate overlay (intersecting U/S imaging plane).

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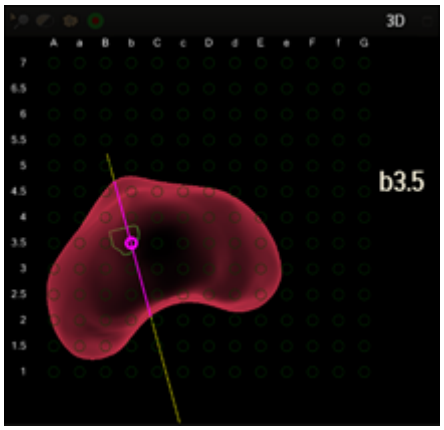
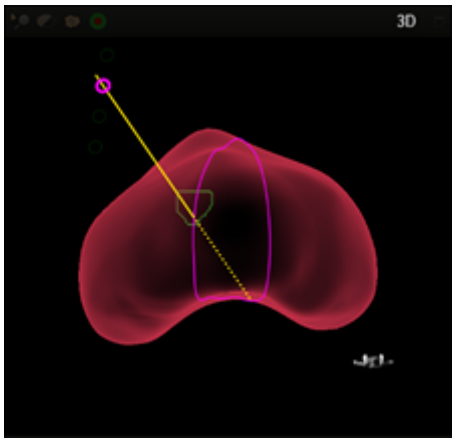


The following image is an example of free-hand transperineal navigation with a needle guide that is attached to the ultrasound probe (intersecting U/S imaging plane and target).



Navigation is easily achieved by rotating the transducer in the transperineal Stepper assembly.

3. In free-hand transperineal workflows where the needle guide is attached to the ultrasound probe, the displayed needle guideline can be adjusted vertically in live mode. This adjustment may be necessary, for example, if tape is added to the probe to improve grip of the attached needle.

   To vertically adjust the needle guideline, click the hollow magenta square and drag it, up or down, to align with the physical needle.

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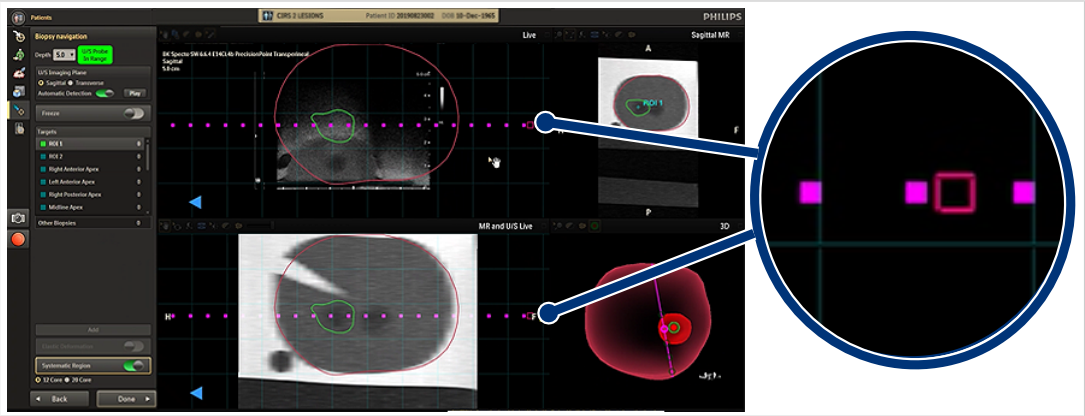
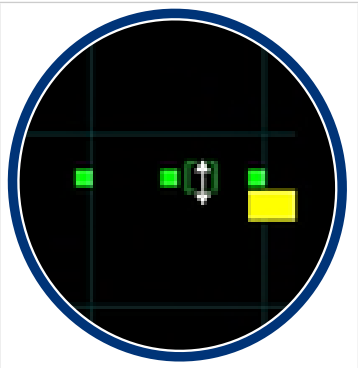


The square and the needle guidelines will change to green during adjustment (while being dragged).



The rectangular grid overlay provides navigation guidance on where the needle is to be inserted.

4. Ensure the biopsy guide line intersects the pre-selected target and advance the needle in through the highlighted grid hole, monitoring the needle trajectory and insertion line continuously to ensure safety and accuracy. The clinician has the flexibility to use the highlighted grid hole or manually override the selection to insert the needle.

5. When the biopsy sample is taken, select **Freeze** or press the foot pedal to temporarily interrupt real-time, cine viewing. Scroll through the U/S images using the mouse wheel or the cine scroll slider bar on the right side of the viewport to locate the point in time where the distal tip of the biopsy needle is fully deployed.

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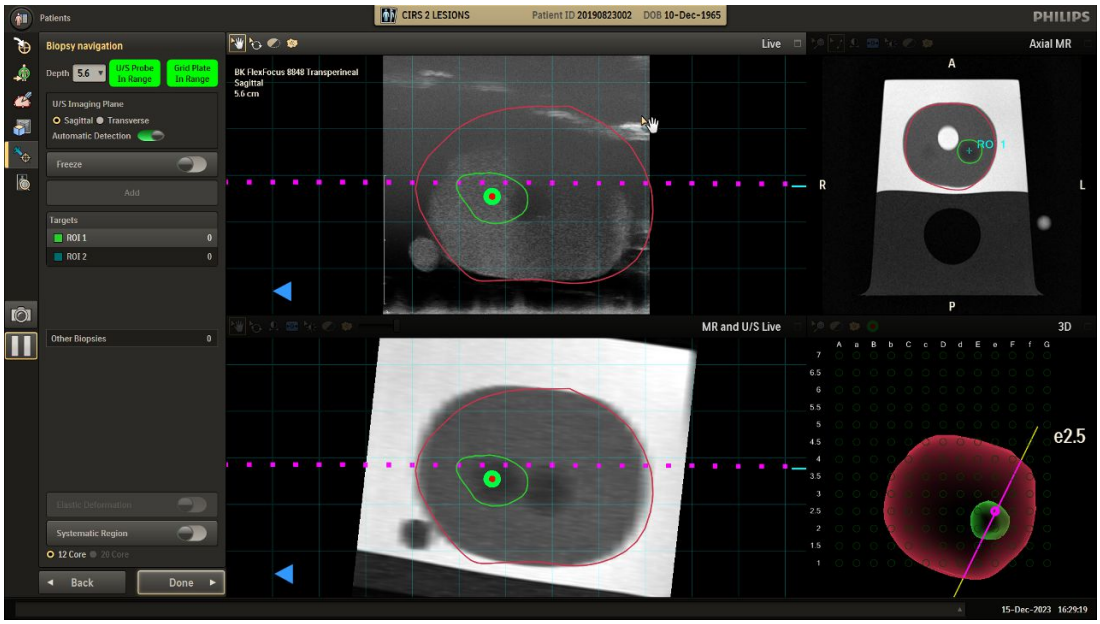

6. Hover the mouse cursor over the biopsy guideline (color changes to green) and use the mouse wheel or left mouse button to place the line marker to the distal tip of the biopsy needle.
7. Press the **Add** button from the Biopsies list menu to record this location and associate it with the current target. A screen capture will be acquired and a time stamp will be recorded and displayed.

Procedure and Images Review screen

The **Procedure and Images Review** screen lets you review the screen captures and video recordings of the procedure, as well as the segmentations and marked biopsy cores.

NOTICE

The Procedure and Images Review screen will display reconstructed ultrasound images for U/S Only patients.

The screen has two tabs — one for the Procedure Review and the other for Images Review — that enable you to toggle between the reviews.

The **Procedure Review tab** enables the 3D review of biopsies and targets projected in the unedited MRI-defined prostate boundary, in addition to captured screenshots and videos.

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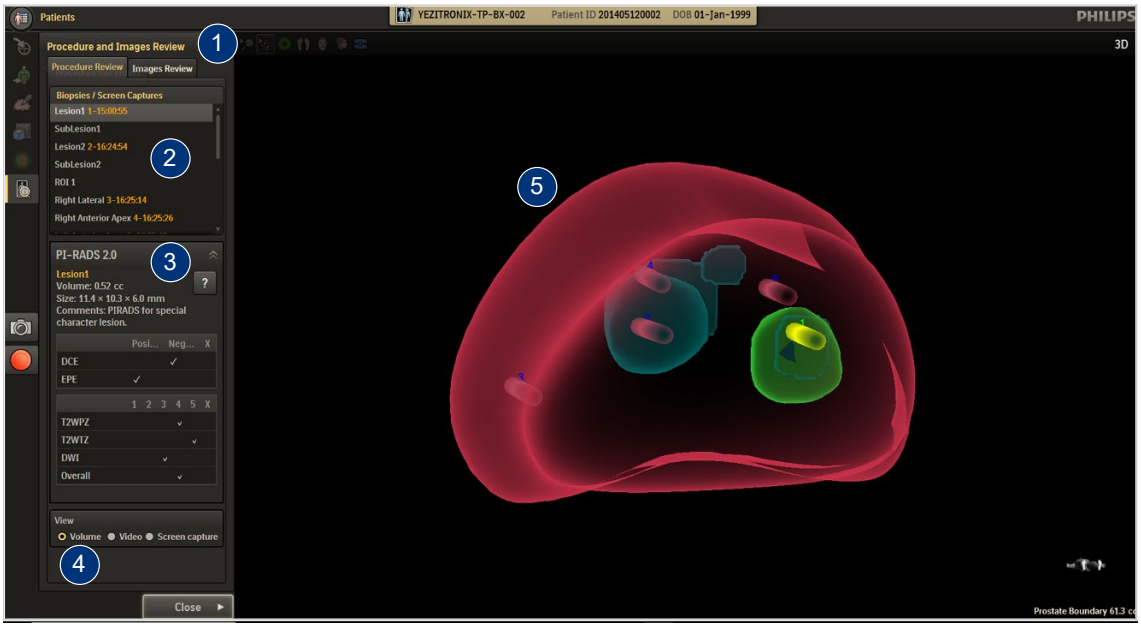

1	**Review tabs:** Use to toggle between Procedure and Images Reviews.
2	**Biopsy/Screen Captures list:** Displays a list of targets (white text) and associated captured biopsy cores (yellow text). Biopsy cores are defined by their number and time of capture. Manual screenshots taken during the procedure can also be reviewed from this list.
3	**PI-RADS:** Displays a list of all screen captures taken during the procedure.
4	**View:** Provides different views for targets (volume) and biopsies (volume/ automatic screen capture). It also enables the review of videos and manual screenshots taken during the procedure.
5	**3D mesh:** While Volume is selected in View, it shows a 3D summary of the prostate boundary, targets, and biopsy cores. Selected targets (both systematic and non-systematic) and cores are highlighted.

The **Images Review tab** enables the review of the biopsies obtained overlayed on the imported multi-planar MRI.

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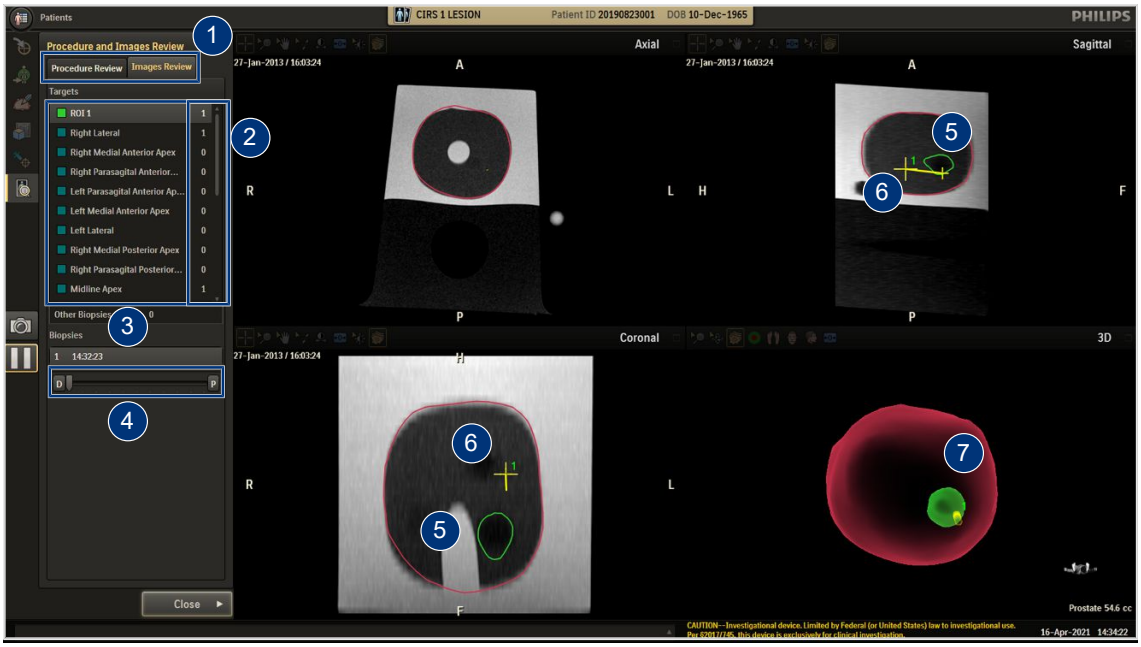

1	**Review tabs:** Use to toggle between Procedure and Images Reviews.
2	**Biopsy list:** Displays a list of systematic and non-systematic target.
3	**Target list:** Displays a list of all screen captures taken during the procedure.
4	**D-P slider:** Enables the review of a selected biopsy core in the MPR views from the distal to proximal ends.
5	**Selected Target:** Displays the selected target in MPR views.
6	**Selected Biopsy:** Displays the selected biopsy in MPR views.
7	**3D Mesh** Shows a 3D summary of the prostate boundary, targets, and biopsy cores. Selected targets (both systematic and non-systematic) and cores are highlighted.

Keyboard and mouse shortcuts

Not all shortcuts are available on all screens. Use the following legend to determine on which screens the biopsy-related shortcut functionality may be applied.

Shortcut	Function	Workflow Context
F2	Toggle visibility of segmentations	All 2D/3D viewports: • In 3D views, the prostate mesh cannot be toggled off. • In the Biopsy Navigation screen, F2 toggles the visibility of grid template and uniform grid overlay.
F6	Toggle visibility of grid template visual overlay	Navigation (3D viewport)

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Shortcut	Function	Workflow Context
F7	Toggle visibility of uniform grid overlay	Navigation (U/S, U/S and MR viewports)
F12	Toggle visibility of patient information	Available on all screens
Hold middle mouse button + drag	Adjust window width/level values	Review Segmentation and Targets (MPR viewports) Sweep and Segmentation (Reconstructed images)
G	Toggle needle guideline	Navigation (U/S, U/S and MR viewports)
Mouse Wheel	Reposition needle guideline depth cursor (while Freeze Mode is enabled, and the guideline is active or green)	Navigation (U/S, U/S and MR viewports)
Mouse Wheel	Scroll through image frames/slices/cine by hovvering the mouse in the viewport, and while the guideline is active or magenta	All MPR viewports Navigation (U/S viewport in Freeze Mode)
Left Mouse Click	Reposition needle guideline depth cursor (while Freeze Mode is enabled, and the guideline is active or green)	Navigation (U/S, U/S and MR viewports)
	Add anatomical fiducial landmarks (while Landmark Placement Interactor is selected)	Sweep and Segmentation
Left Mouse Drag	Reposition needle guideline depth cursor (while Freeze Mode is enabled, and the guideline is active or green	Navigation (U/S, U/S and MR viewports)
Right Mouse Drag	Registration pan	All Fusion viewports
Left Mouse + Right Mouse Drag	Registration rotate	All Fusion viewports
Left Mouse Double-Click	Place needle tip marker off of needle guideline and reposition depth cursor (while Freeze Mode is enabled)	Navigation (U/S, U/S and MR viewports)
ALT+F	Applies a horizontal flipping transformation to the ultrasound coordinate system	All live viewports
Up / Down Arrow Keys	Scroll through images in 1mm increments	All MPR viewports

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Shortcut	Function	Workflow Context
Ctrl + Z	Undo last action	Multiple screens: • Review Segmentation and Targets • Sweep and Segmentation • Align U/S volume with MR • Navigation
Ctrl + Y	Redo last action	Multiple screens: • Review Segmentation and Targets • Sweep and Segmentation • Align U/S volume with MR • Navigation

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14 Advanced Annotation Workflow

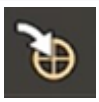
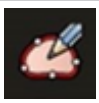
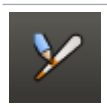
Overview

The Advanced Annotation workflow enables you to display imported regions of interest (ROIs) as overlays on MR and (live) TRUS images. You can add (volumetric) annotations as overlays to represent locations of applicators.

To start a workflow:

1. Ensure that a patient case is available. See “UroNav Home screen” on page 99 for more information on how to import a patient case.
2. Click and drag the patient case from the **All Patients** list to the Worklist.
3. Click **Advanced Annotation**.

You may use buttons on the Navigation toolbar (displayed on the top) to navigate between different workflow steps. Each step is represented by a dedicated button, which will take you to the corresponding screen. The workflow consists of the following steps:

Button	Workflow Step	Description of main actions
	Review ROIs & targets	Provides tools to review the imported MR images and associated ROIs.
	Setup	Select the appropriate configuration for the workflow and start up the EM tracking system.
	Sweep & segmentation	Acquire a volumetric ultrasound image and indicate the prostate boundary.
	Align U/S volume with MR	Define the registration between the imported MRI data and live U/S images
	Navigate	Add annotations on the live ultrasound imaging.
	Review workflow	Review the screen captures, video recordings and workflow summary.

When transitioning between the different screens or when stopping the workflow, the recorded data up to that point will be stored, enabling the possibility to resume an uncompleted workflow. In the Navigate screen, any procedure data will be stored regardless of screen transitioning.

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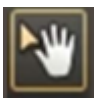
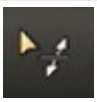
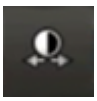
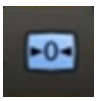
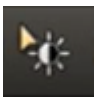
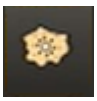
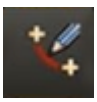
In-Viewport toolbar

The **In-Viewport toolbar** provides quick access to several tools for making direct modifications to the image or visual overlays in the main display area. Tools are selected by clicking on the appropriate button or slider.

Slider	Action	Description
	Blend	Adjusts the amount of blend of each modality (U/S and MR).

Button	Action	Description
	Pick Point	Sets cross-correlation point in all 2D image planes.
	Zoom	Zooms image.
	Pan	Pans image or pans the registration, depending on the workflow step.
	Rotate	Rotates 3D image.
	Scroll	Scrolls through 2D data set.
	Window gray-scale adjustment	Automatically adjusts gray-scale to optimize image quality
	Reset view	Restores to default the image settings
	Gray level	Manual window width and window level adjustment
	Show selected	Displays selected targets in all viewports
	Show all	Displays all targets in all viewports
	Adjust Mesh Boundary tool	Adjust boundary on active viewport.

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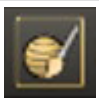
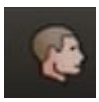
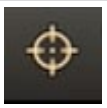
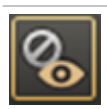
Button	Action	Description
	Adjust Mesh Boundary (correlation) tool	Boundary adjustment correlated and visualized in all three planes (default setting).
	3D Brush tool	Edit a boundary. Applying from inside a selected boundary expands the boundary. Applying from outside a selected boundary reduces the boundary.
	Reduce brush size	Reduce size of 3D Brush tool.
	Enlarge brush size	Enlarge size of 3D Brush tool.
	Registration rotate	Rotates the registration.
	Registration pan of selected ROI	Pans the registration of individually selected ROI.
	Registration rotate of selected ROI	Rotates the registration of individually selected ROI.
	Place annotation	Toggles the ability to place an annotation in the ultrasound image.
	Axial	Changes viewport to axial display.
	Coronal	Changes viewport to coronal display.
	Sagittal	Changes viewport to sagittal display.
	Show ROI centroid	Displays or hides the calculated center (centroid). of ROIs
	Place landmark	Placement of anatomical orientation landmarks for U/S segmentation.
	Hide all user-defined ROIs	Toggles the visibility of all user-defined ROIs.

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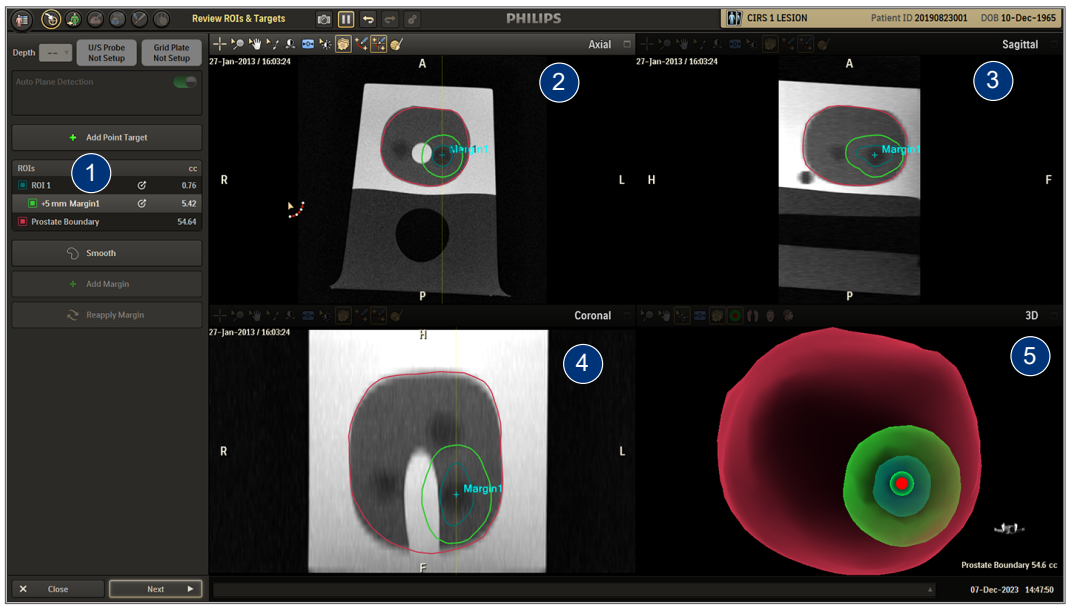
Review ROIs and Targets screen

The **Review ROIs and Targets** screen provides tools to enable you to review the imported MR images and associated ROIs. See “Import” on page 100 for more information on data import. You may designate any ROI as a target or no-go zone, and optionally, add margins or point targets.



1	**ROIs:** Displays a list of ROIs, including target or no-go zone designations and volumes in cc.
2	**Axial:** Displays the axial view of the imported MR images and its visual overlays.
3	**Sagittal:** Displays the sagittal view of the imported MR images and its visual overlays.
4	**Coronal:** Displays the coronal view of the imported MR images and its visual overlays.
5	**3D:** Displays MR ROIs in 3D.

Adjusting ROI boundaries

The imported prostate ROI boundary and margin boundaries may be manually edited. This functionality is not available for imported target ROI.

NOTICE

Boundary adjustments made in the Review ROI and Targets screen are only retained for the remainder of the workflow and will not be stored or exported. Workflow results are viewed and stored on the imported, unedited MRI-defined prostate ROI.

The **Adjust ROI Boundary** tool will let you drag the boundary of an ROI to a specified location and update the boundary shape in 3D accordingly. The **Adjust ROI Boundary and cursor** tool functions the same, but will also update all 2D viewports to display the current image slice of where the mouse cursor is currently being dragged.

To adjust ROI boundaries:

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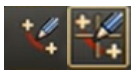
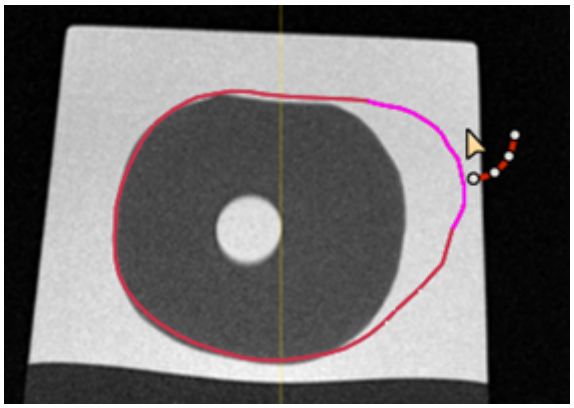
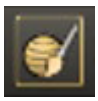


1. Click the prostate ROI or a margin in the ROIs list.
2. Select an **Adjust ROI Boundary** tool from the toolbar in the image viewport.
3. Use the mouse cursor to hover over an area of the ROI boundary that you want to move; it will light up in a pink color.
4. Click the left mouse button and drag the boundary to a different location.

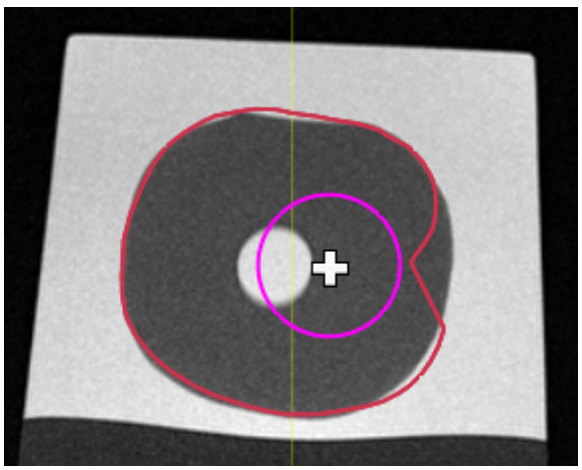


5. Release the mouse button to end the action.
6. (Optional) Click the **Smooth** button to smooth out the edited boundary.

To adjust ROI boundaries using the **3D Brush** tool:



1. Click the prostate ROI or a margin in the ROIs list.
2. Select the **3D Brush** tool from the toolbar in the image viewport.
3. Move the mouse cursor over the images. If you hover on the inside of the selected ROI boundary, you will see a plus (+) sign. Click the left mouse button and drag the plus (+) sphere around to add areas to the existing ROI boundary.



4. If you hover on the outside of the selected ROI bounday, you will see a minus (-) sign. Click the left mouse button and drag the minus (-) sphere around to remove areas from the existing ROI boundary.
5. Release the mouse button to end the action.

6. (Optional) Click the **Smooth** button to smooth out the edited boundary.

The 3D Brush tool may also be resized.

- Select one of the following icons in the toolbar to adjust the size of the 3D brush:

  Enlarge brush size (icon shown in left margin - above).

  Shrink brush size (icon shown in left margin - below).

- Alternately, press the Plus key (+) to increase or Minus key (-) to decrease the brush size.

If necessary, you can clear a manually created ROI boundary and redo it using the 3D Brush tool.

To clear an ROI boundary:

- Right-click the ROI in the ROIs list and select **Clear**.

Adding margins

A margin represents a copy of a selected ROI with a specified offset.

To add a margin:

1. Select the ROI for which a margin should be added.
2. Click **Add margin**.
3. Specify the name, size (positive or negative offset in millimeters) and color.
4. (Optional) Change the **Is Target** or **Is no-go** designation.
5. Click **OK** to add the margin. The margin is displayed as an additional ROI in the ROIs list and viewports.

You may edit margin settings or delete the margin after it was created.

To edit margin settings:

- Right-click the margin in the ROIs list and click **Edit**.

You may also adjust the boundary of the margin like any other ROI.

To reset a margin to its original offset:

- Click **Re-apply margin**.

Adjusting ROI designations

A Region of Interest (ROI) can have one of two designations for use during the workflow: Target or No-go zone. These ROI designations are input to constraint-driven planning; see “Navigate screen” on page 150 for more information. For a Target ROI, the system will propose a set of annotations that maximize its volumetric coverage. For a No-go zone, the system will avoid applicator paths that intersect the ROI and minimize its volumetric coverage.

To adjust the ROI designation:

1. Right-click the ROI in the list and select one of two designations:

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2. Either select the **Is Target** checkbox,

3. Or select the **Is no-go** checkbox.

The ROI list will display the corresponding icon to represent the selected designation.

Deleting ROIs

Any ROI, except for the imported prostate ROI, can be deleted.

To delete an ROI:

1. Right-click the ROI in the ROIs list.
2. Select **Delete**.
3. When a confirmation dialog appears, click **OK** to confirm the deletion.

Adding point targets

A point target can be added manually. The point target is represented as a point within the image volume and is displayed as an overlay in the subsequent workflow screens.

To add a point target:

- Select the **Pick Point** tool and click a point within the MR images.
- Select **Add Point Target** to add a point target at the indicated location.

The ROI list and viewports will display the added point.

To continue to the Setup screen, click **Next**.

NOTICE

If a UroNav plan has been imported from DynaCAD, annotations from the plan are displayed and can be hidden by pressing F3; see “Keyboard and mouse shortcuts” on page 157 for more information.

Setup screen

In the **Setup** screen, you select the ultrasound system and probe, transperineal grid template and the annotation device to be used during the workflow. The Field Generator will be initialized, and its positioning can be verified. To capture ultrasound images, the video connection will also be initialized.

Before the field generator is initialized, a confirmation dialog is displayed.

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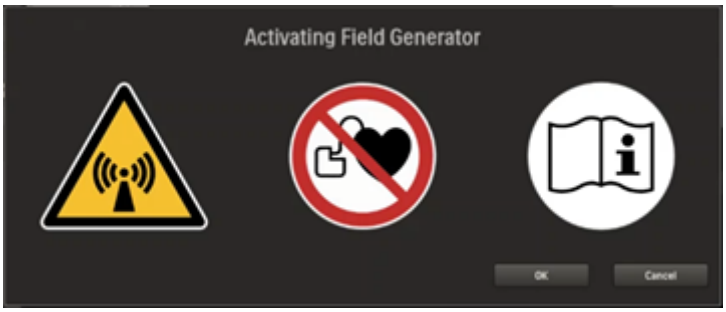
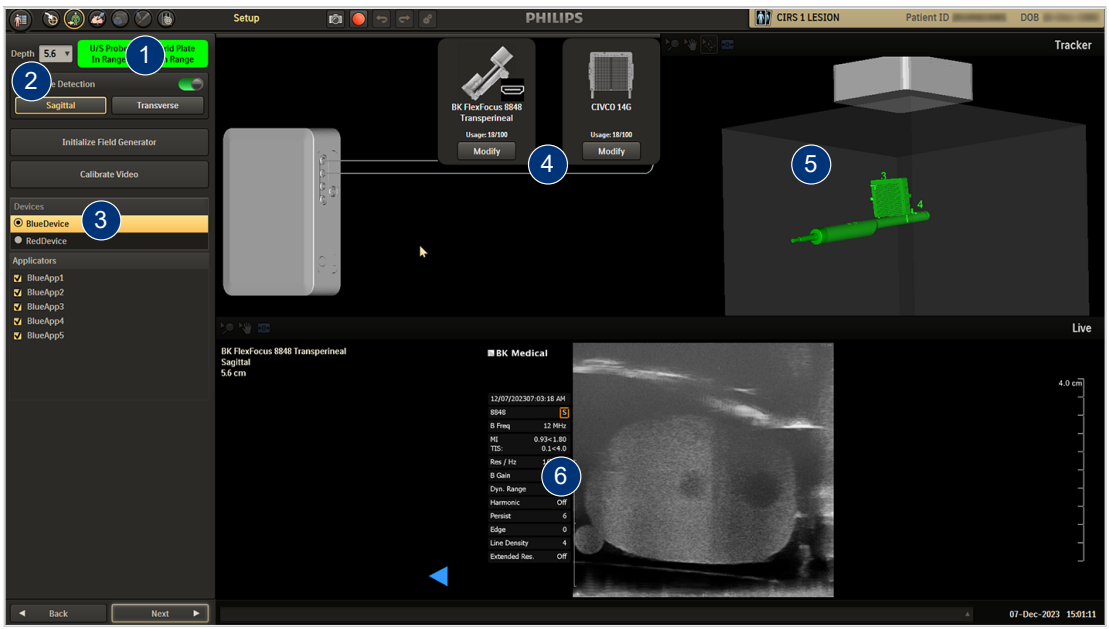


WARNING

Do not operate the field generator within 200mm (8in) of an installed pacemaker or other potentially electrically conductive implants such as defibrillators. The magnetic field produced by the field generator may interfere with the operation of the pacemaker, which may result in personal injury, and distortion created in the EM field by conductive implants may result in inaccurate targeting.



1	EM Tracking tools, including colored status indicators per sensor and an initialization tool.
2	Video connection tools, including depth and plane selection tools.
3	List of available devices and virtual applicators.
4	Sensor configuration tools, including menus to select the ultrasound system and probe, and the transperineal grid template to be used during the workflow.
5	**Tracker:** This shows the placement of the TRUS and grid in relation to the field generator and EM field.
6	**Live:** Displays live video feed from the ultrasound system including U/S plan indicator rectangle.

To select the appropriate setup for the workflow:

1. Make sure that the safety requirements—as shown in the **Activating Field Generator** warning dialog—are fulfilled.
2. Click **OK** to initiate the field generator.
3. Confirm correct operation of EM tracking. Ensure that the EM trackers are properly secured to the stepper, in accordance with instructions provided in “Appendix D” on page 231, and verify that:

⇨ The status for both sensors is green.

⇨ The relative positioning of the U/S probe, the transperineal grid template, and the field generator in **Tracker** is correct.

⇨ Both sensors have not been used more than the indicated usage limit (counter text is not red).

4. Select the device and virtual applicators that will be used in the workflow. Unchecking a virtual applicator from the list will make it unavailable to select in the subsequent workflow screens.

   If the imported plan contains an older version of the device configuration, either the imported or the latest version can be selected.
5. Select the transperineal grid template. If needed, click **Modify** and select another transperineal grid template.
6. Select U/S system and probe. If needed, click **Modify** and select another U/S system and probe.
7. When using BK U/S system and probes, verify correct positioning of the correlation rectangle. To adjust, hover above the correlation rectangle until it turns green, and drag it until the U/S plane indicator is centered inside.
8. Confirm correct operation of the U/S video capture, by verifying the following conditions:

⇨ The live images update continuously.

⇨ The depth used in UroNav matches the depth displayed by the U/S system (adjust if necessary).

⇨ The plane used in UroNav matches the plane displayed by the U/S system (adjust if necessary).

NOTICE

The adjusted correlation rectangle will not be persisted. Set the location of the correlation rectangle during video calibration to persist it between workflows.

Please verify proper video calibration before proceeding to Sweep acquisition by clicking **Next**. See “Ultrasound video calibration” on page 83 for further instructions.

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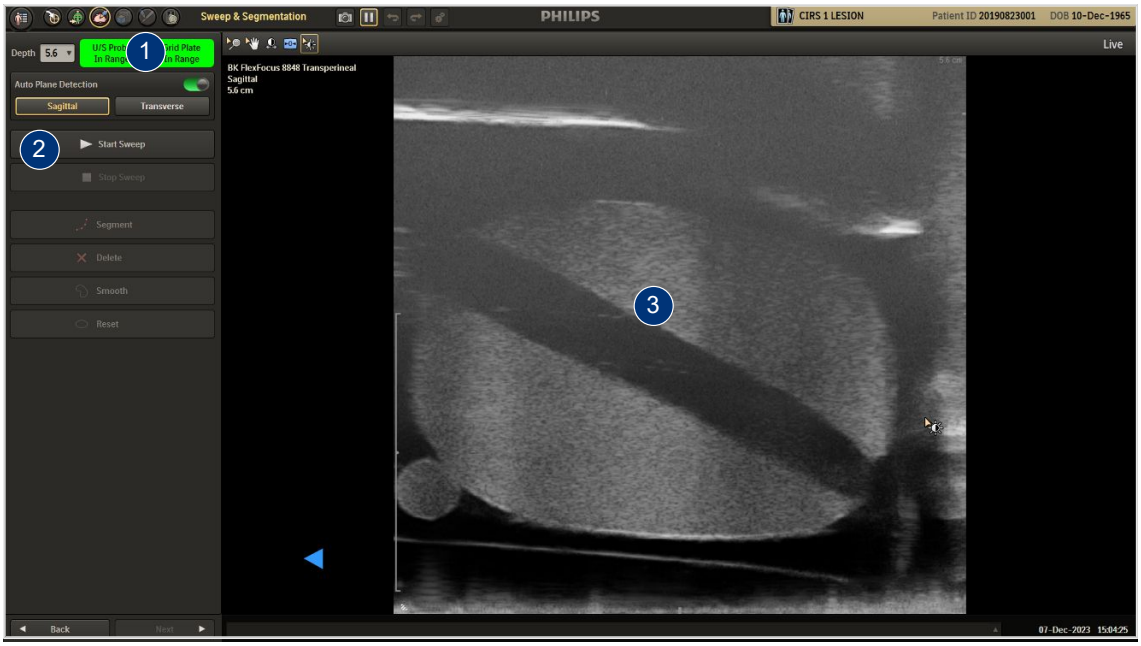
Sweep and Segmentation

The **Sweep & Segmentation** screens enables you to acquire a volumetric ultrasound image and indicate the boundary of the prostate ROI, which is needed for subsequent registration between the U/S and imported MR images. In a sagittal or transverse sweep, EM tracked positional information of the probe's rotation is used to interpolate between the acquired slices to create a volumetric image.

You can indicate the visible prostate boundary on the images with landmark fiducials, after which a prostate ROI is generated. You can manually adjust the generated prostate boundary.



1	Ultrasound settings and tracking status
2	**Sweep:** controls to start and stop the sweep recording
3	**Live:** viewport displaying the live ultrasound image

CAUTION

Always make sure that the displayed depth and plane setting in the live imaging view is the same as on the ultrasound machine before recording the sweep.

CAUTION

The reconstructed U/S volume is input for the registration between MR and U/S images. Inaccurate registration could lead to an impact on targeting accuracy. Folllow the provided instructions to capture an accurate sweep.

The reconstructed U/S volume is input for the registration between MR and U/S images. To avoid subsequent impact on overlay visualization, follow the instructions below:

To acquire a volumetric ultrasound image:

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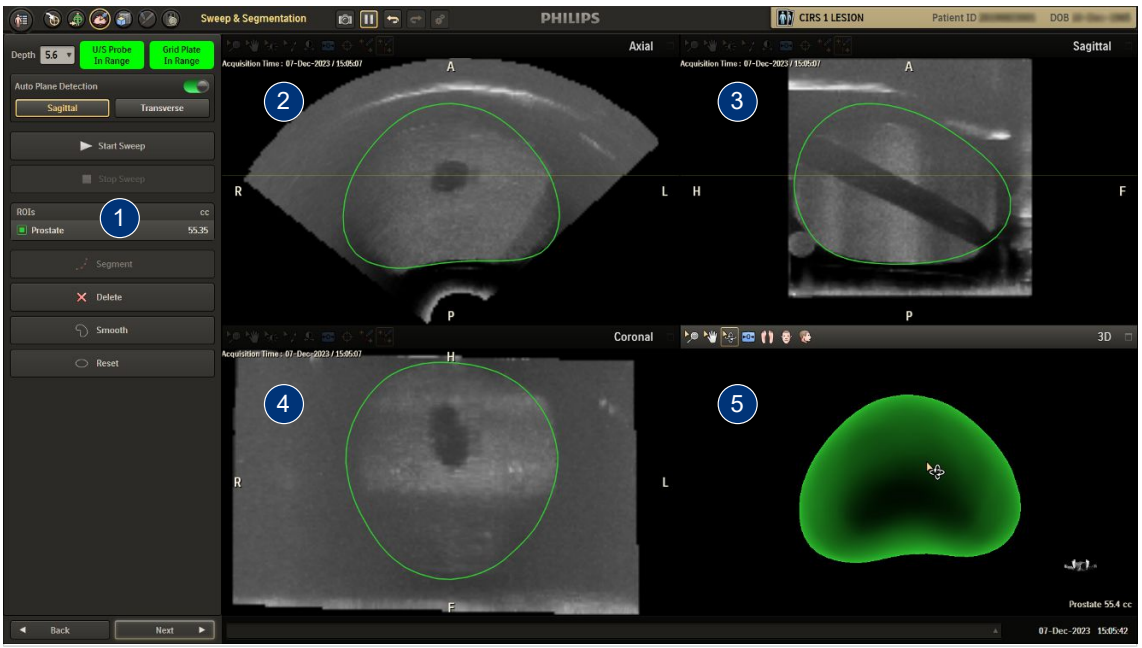
1. Ensure the procedure area is free from electromagnetic disturbance factors and the EM tracker statuses are all green. Also, ensure the field generator does not move during the sweep.
2. Position the probe to the starting position for the sweep.

3. Click **Start**.

⇨ Alternatively, you may hold down the foot pedal with the Sweep icon (shown in left margin).

4. Rotate (sagittal sweep) or move (transverse sweep) the probe to capture the prostate. Ensure a smooth, steady motion, taking about 6 seconds while applying constant pressure.
5. Click **Stop** or release the foot pedal to stop the acquisition.

The volumetric image will be reconstructed and displayed to start segmentation.



1	**ROIs:** Display of the prostate ROI and tools to edit, delete, smooth and reset the ROI boundary.
2	**Axial:** Displays an axial view of the reconstructed U/S volume and the prostate ROI.
3	**Sagittal:** Displays a sagittal view of the reconstructed U/S volume and the prostate ROI.
4	**Coronal:** Displays a coronal view of the reconstructed U/S volume and the prostate ROI.
5	**3D:** Displays the prostate ROI as a 3D model.

To create the prostate ROI:

1. Use the **Place Landmark** tool and click on the visible edges of the prostate in the ultrasound images.

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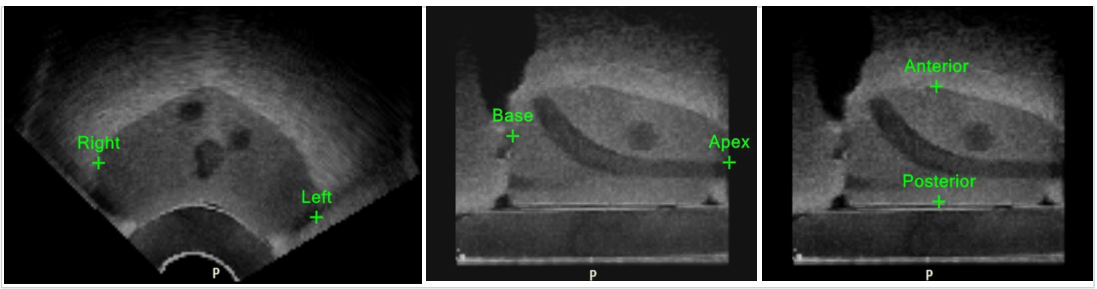

⇨ Select right and left endpoints in the transverse plane to mark the largest width of the prostate.

⇨ Select base and apex endpoints in the sagittal plane to mark the largest length of the prostate.

⇨ Select anterior and posterior endpoints in the sagittal plane to mark the largest height of the prostate.

2. Click the **Segment** button to generate the ROI boundary.
3. Use the **Adjust Mesh Boundary** tools to adjust the ROI boundary by dragging the pink highlighted part of the boundary in any viewport.
4. Optionally, click the **Smooth** button to smooth out the edited ROI boundary.

To delete a landmark:

► Right-click the endpoint's crosshair and select **Delete landmark**.

To align the prostate ROI from the ultrasound acquisition with the imported MR images and ROIs, click **Next** and continue to the **Align U/S volume with MR** screen.

Align US volume with MR screen

In the **Align US volume with MR** screen, you define the registration between the imported MRI data and live U/S images. This is achieved by first aligning the reconstructed U/S volume with the MRI volume, and subsequently adjusting the resulting registration between the MRI volume and the live U/S images. If necessary, you may adjust the registration for individual user-defined ROIs or adjust the boundary of ROIs.

CAUTION

Verify the registration in all three orthogonal planes for use in tracking and targeting, and adjust if needed.

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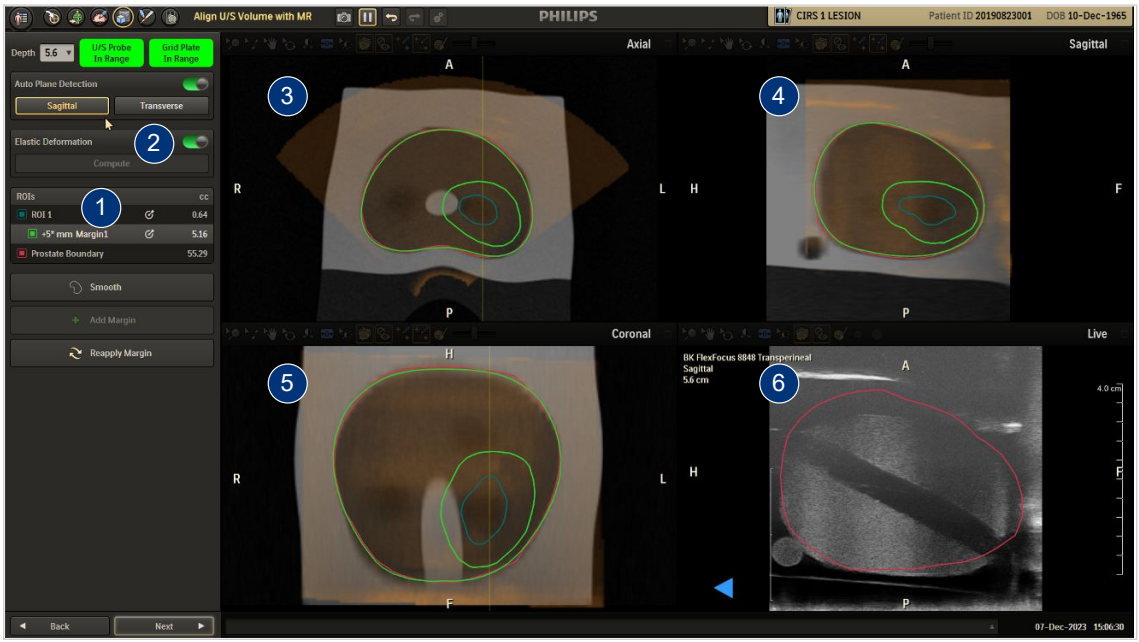
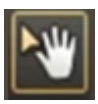


1	**ROIs:** Displays a list of ROIs.
2	**Elastic deformation:** Compute and toggle elastic deformation.
3	**Axial:** Displays an axial view of the reconstructed U/S volume with MR and U/S ROI overlays. If blending is enabled, the same axial view from the registered MR volume is visible as well.
4	**Sagittal:** Displays a sagittal view of the reconstructed U/S volume with MR and U/S ROI overlays. If blending is enabled, the same sagittal view from the registered MR volume is visible as well.
5	**Coronal:** Displays a coronal view of the reconstructed U/S volume with MR and U/S ROI overlays. If blending is enabled, the same coronal view from the registered MR volume is visible as well.
6	**Live:** Displays live U/S images with MR and U/S ROIs on top. If blending is enabled, the same view from the registered MR volume is visible as well.

To align the U/S and MR images:



1. Adjust the overall translation by selecting the prostate ROI in the ROIs list. Then select **Registration pan** and drag across the Axial, Sagittal, or Coronal view.

2. Adjust the overall rotation by selecting the prostate ROI in the ROIs list. Then select **Registration rotate** and drag across the Axial, Sagittal, or Coronal view.
3. Click **Compute** to use elastic deformation. You may now toggle the elastic deformation by clicking **Apply**.

4. Adjust the translation for individual user-defined ROIs by selecting the appropriate ROI in the ROIs list. Then select **Registration pan of selected ROI** and drag across the Axial, Sagittal, or Coronal view.

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5. Adjust the rotation for individual user-defined ROIs by selecting the appropriate ROI in the ROIs list. Then select **Registration rotate of selected ROI** and drag across the Axial, Sagittal, or Coronal view.

6. Adjust the resulting translation between MR and live US by selecting the Prostate segmentation in the Segmentations list. Then select **Registration pan** and drag across the Live view.

7. Adjust the resulting rotation between MR and live US by selecting the Prostate segmentation in the Segmentations list. Then select **Registration rotate** and drag across the Live view.

NOTICE

Use the Blend slider in the viewport toolbar to blend the visualization between the ultrasound and MR images.

NOTICE

The red boundary represents the imported prostate ROI; the green boundary represents the prostate ROI as defined on the reconstructed U/S volume in the previous workstep.

NOTICE

If manual adjustments do not successfully align the U/S with the MRI, it may be necessary to go back to the **Sweep and Segmentation** screen, repeat the sweep and replicate the alignment/registration steps.

Elastic Deformation

The Registration screen provides the option to map the MR volume elastically to the ultrasound volume using the two prostate ROIs as references.

NOTICE

Elastic deformation computation is optionally applied in the workflow. Post-workflow results are viewed and stored on the imported, unedited MRI-defined prostate ROI.

Once computed, the Elastic Deformation may be toggled on or off, allowing the use of either elastic or rigid registration methods for the workflow.

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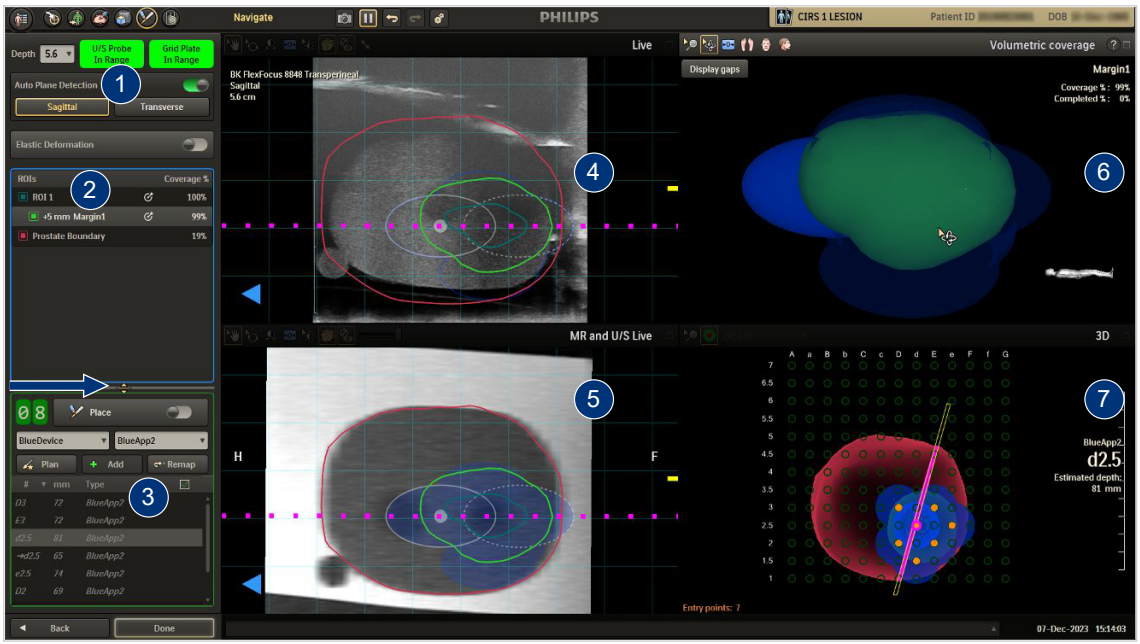
Navigate screen

The **Navigate** screen offers fusion guidance to navigate applicators to their intended location. Once positioned as intended, you can mark the applicator tip location. Annotations will be displayed relative to these applicator tip locations. The location of these annotations is overlaid on MR and (live) TRUS imaging and stored in relation to the imported MR images. Screenshots are captured automatically when annotating the images.

In addition, the Navigate screen offers manual and/or constraint-driven planning of applicator tip locations on the medical images. During planning, the system displays coverage as a percentage of ROI volume, covered by annotations that are positioned relative to the applicator tip locations. The user can review the coverage and make plan adjustments where necessary.

When a UroNav plan is imported from DynaCAD Urology, annotations from the plan are displayed when first entering the screen.

The size of panel sections can be adjusted, as needed, by click-and-dragging the divider bar, indicated by the blue arrow in image below.



1	Ultrasound settings and tracking status.
2	**ROIs:** Displays a list of ROIs.
3	**Annotations:** Displays list with grid hole, estimated depth and type of each annotation. You can change the height of the annotations list by dragging the separator between the ROIs list and Annotations list.
4	**Live:** Displays live U/S images with overlays.
5	**MR and U/S Live:** Displays live U/S images with overlays and registered MR image.
6	**Volumetric coverage:** Displays 3D view of selected ROI and annotations.
7	**3D:** Tracked grid template overlay with U/S plan indication, ROIs and annotations.

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Imported annotations

When the imported patient case contains a UroNav plan, the imported annotations are displayed when first entering the Navigate screen. Based on the alignment between the MR and live U/S imaging, the location of the annotations can be updated.

1. If necessary, click Remap to move the planned annotations to the location closest to their initial location (relative to the ROIs).
2. Review the imported annotations by performing a volumetric assessment.
3. If necessary, adjust the plan using manual tools or generate a new plan.

Generating a plan

Plans can be generated at any time during the workflow. The proposed annotations will optimize volumetric coverage of the target ROIs, respecting placed and completed annotations, if present.

To generate a plan:

1. Click **Settings** to verify your preferences and adjust if necessary, and then select OK. If the imported patient case contains a UroNav plan, the settings from the plan are used by default. See the table below for an explanation of the different settings.
2. Click **Plan**.
3. Review the proposed annotations by assessing volumetric coverage.
4. If necessary, adjust the plan using manual tools.

Setting	Description (when setting is turned on)
Minimum needle spacing	Minimum distance between grid holes of proposed annotations.
Restrict annotation centers to the prostate	Proposed annotations shall have centroids that are contained within the prostate ROI.
Allow multiple annotations per grid path	If necessary to achieve volumetric coverage of an ROI, multiple annotations can be planned in the same grid hole trajectory.
Show centroid for ROI	ROI centroids are visible.

NOTICE

When using the CIVCO 14G grid, no annotations will be proposed in its “F” column because there are no grid holes in that column.

Volumetric assessment

You may perform volumetric assessment by doing the following:

1. Assess the overlays of the annotations and the ROIs on the image viewports. If the selected annotation is defined with multiple layers, use the right-click menu, selecting Visibility > Layers to toggle them on or off.

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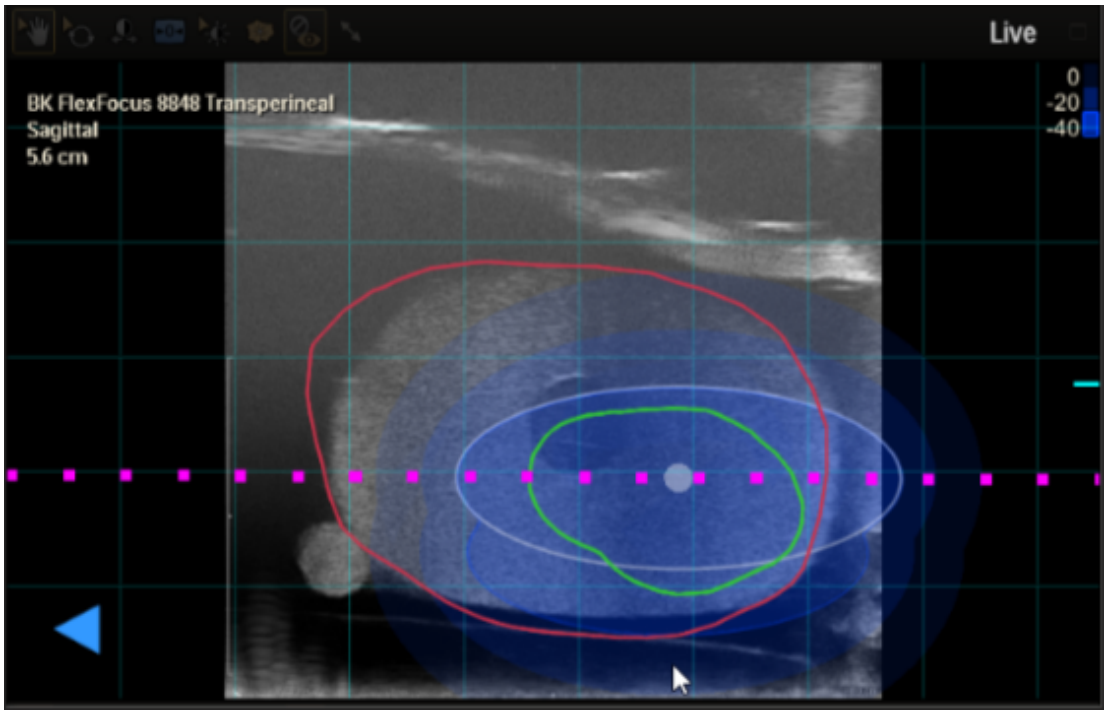

Fig. 6: Viewport showing layers

NOTICE

Layers can be configured in DynaCAD Urology.

2. Assess the 3D model of the ROIs and the annotations in the **Volumetric coverage** and **3D** viewports.
3. Assess the percent coverage as displayed in the **ROIs** list and **Volumetric coverage** viewport.

   Two percentage values are displayed:

   Coverage %: The estimated coverage between the ROI and all annotations

   Completed %: The estimated coverage between the ROI and completed annotations.
4. Click **Display gaps** to see a subtraction of the combined annotation volume from the ROI volume.

NOTICE

Each annotation is visualized according to its final geometric properties; there is no interaction among annotations.

NOTICE

Percent coverage is strictly a geometric-based estimate of the intersection of the discretized 3D structures and is not based on any live imaging source.

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CAUTION

The features in the Advanced Annotation workflow are not intended to represent any ablation energy modality, control any such device, nor predict ablation outcomes. The Advanced Annotation feature is intended only for 3D visualization and volumetric assessment. The physician remains in full control at all times; any annotations proposed by the system can be modified or deleted based on the judgement of the physician.

NOTICE

UroNav estimates the volume and percent coverage of annotations to within 2% of the analytic value.[8]

Working with annotations

To manually plan an annotation:

1. Select a grid hole, by clicking it in the 3D view.
2. Rotate the ultrasound probe to the corresponding grid hole, using the display in the 3D viewport.
3. Select an annotation type from the pull-down menu.
4. Click **Add**. The system starts showing a preview of the annotation when hovering over the guideline in the U/S view.
5. Click the appropriate location along the guideline in the U/S view. The annotation is added to the list.

To adjust the location of a planned annotation:

1. Select a planned annotation from the **Annotations** list.
2. Click and drag the annotation center to the appropriate location along the guideline in the U/S view.

To change the type of an annotation (such as change size):

1. Select an annotation from the **Annotations** list.
2. Click the text label in the **Type** column of the **Annotations** list.
3. Select the appropriate annotation from the pull-down menu. The system will immediately apply the selected annotation type.

To delete an annotation:

1. Right-click the annotation in the **Annotations** list.
2. Click **Delete**.

(8) Given an annotation of size 0.5 CC or greater, the expected (99% confidence interval) discretization error is within 2% of its analytic value.

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To resize an annotation:

1. Select the annotation in the **Annotations** list.

2. Click the **Resize annotation** tool. If applicable, all annotation layers are displayed.
3. Click and drag the annotation boundary.
4. Release the left mouse button to apply the resize.

Registration changes and remap

If the registration is manually adjusted, the ROI overlays and completed annotations will move concurrently with the MR images. Planned and placed annotations will keep their position relative to the transperineal grid template.

Similarly, if the tracked transperineal grid template is moved, the planned and placed annotation locations will be updated to reflect the new position of the grid template. Completed annotations are not affected by tracked grid movement.

If through registration changes or grid movements, the location of planned annotations and the ROIs no longer overlap, you may use **Remap** to move the planned annotations to the location closest to their initial location (relative to the ROIs).

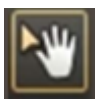
NOTICE

The **Remap** function is only available before placing annotations.

Marking applicator locations

To mark an applicator tip location:

1. Ensure the EM tracker statuses are all green.
2. Ensure the registration between the prostate outline and the live image is correct.



3. If adjusting the alignment is necessary, use the **Registration pan** tool.

4. If rotation is necessary, use the **Registration rotate** tool.
5. Select a planned annotation from the Annotations list. This will highlight the associated grid hole.
6. Rotate the TRUS probe to have the imaging plane intersect with the selected grid hole and the pink dots are displayed in the Live U/S view, representing the projection of the grid hole.
7. Click **Place** to display a virtual applicator on the planned location.
8. Insert the applicator through the selected grid hole and monitor its trajectory on the live TRUS image.
9. When the applicator has reached its intended location, mark the tip location with a left-click. Ensure that the tip is marked accurately as this will determine where the associated annotation will be placed in relation to the MRI-derived ROIs. A screenshot is automatically collected at this time.

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CAUTION

Always ensure that the displayed plane and depth setting in the live imaging view is the same as on the ultrasound machine before marking applicator locations.

To adjust the location of the virtual applicator tip:

1. Select a placed annotation from the **Annotations** list.
2. Click and drag the tip of the virtual applicator to edit its position. The automatically collected screenshot is updated at this time.

To update the status of the an annotation:

► Click the check box in the **Annotations** list. The check box will display a green checkmark indicating a completed annotation.

NOTICE

You can only edit applicators that do not have the green checkbox selected in the list.

NOTICE

Only annotations that have been checked as completed will be visible in DynaCAD Urology for review.

After you have completed the workflow, select **Done** to proceed to the **Review Workflow** screen.

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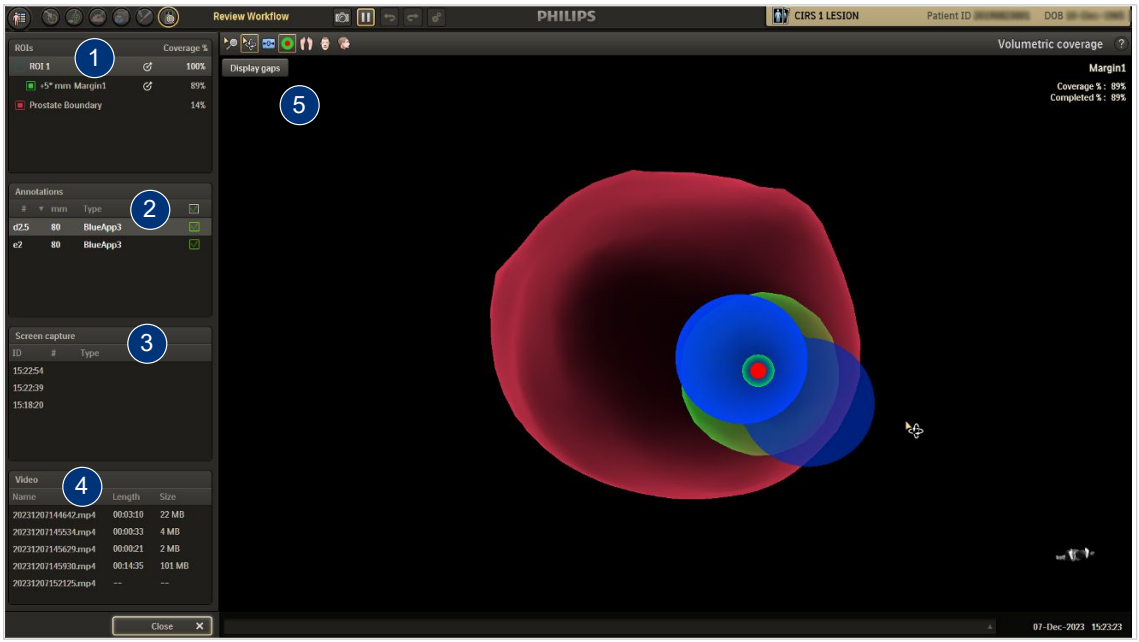
Review Workflow screen

The **Review Workflow** screen allows the user to view the screen captures, ROIs, annotations, and video recordings of the workflow.

NOTICE

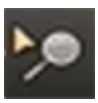
Review Workflow presents information relative to the MRI and the imported ROIs. Coverage percentages and renderings may differ between Review Workflow and Navigate screens whenever ROIs were modified or elastic registration was used. Screen captures and videos will reflect the situation as observed during the workflow.



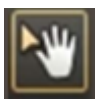
1	**ROIs** list of regions of interest.
2	**Annotations** list of annotations.
3	**Screen captures:** Displays list of all screen captures taken during the procedure.
4	**Videos:** Displays a list of video recordings taken during the procedure.
5	**Volumetric coverage:** Displays 3D rendering of ROIs and annotations.

To view screen captures:

1. Click one of the screen captures in the list to display the capture.



2. (Optional) Use the **Zoom** to inspect the capture.



3. (Optional) Use the **Pan** to adjust the capture during inspection.
4. Click any ROI in the **ROIs** list to return to the previous view.

To view video recordings:

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1. Click one of the video recordings in the list to display the video.

2. Use the **Play** button to start playback of the video.
3. When done, click **Close** to end the playback.

Keyboard and mouse shortcuts

Not all shortcuts are available on all screens. Use the following legend to determine on which screens the shortcut functionality may be applied.

Shortcut	Function	Workflow Context
F2	Toggle visibility of ROIs	All 2D/3D viewports: • In 3D views, the prostate ROI cannot be toggled off.
F3	Toggle visibility of annotations	Navigate (2D/3D viewports) Review Workflow (2D/3D viewports)
F4	Toggle visibility for annotation layers if available	Navigate (2D viewports)
F5	Toggle visibility of virtual applicators	Navigate (2D viewports)
F6	Toggle visibility of grid template visual overlay	Navigate (3D viewports)
F7	Toggle visibility of uniform grid overlay	Navigate (2D viewports)
F12	Toggle visibility of patient information	Available on all screens
Hold middle mouse button + drag	Adjust window width/level values	Review ROIs and Targets (2D viewports) Setup (Live viewport) Sweep and Segmentation (2D viewports) Align U/S Volume with MR (Live viewport)
Mouse Wheel	Scroll through image frames/slices/cine by hovering the mouse in the viewport, and while the guideline is inactive or magenta.	All 2D viewports
Right Mouse Drag	Registration pan	All Fusion viewports
Left Mouse + Right Mouse Drag	Registration rotate	All Fusion viewports
ALT+F	Applies a horizontal flipping transformation to the ultrasound coordinate system	All Live viewports
+ (Plus Key)	Increase brush size (while 3D brush tool is selected)	Review ROIs and Targets (2D viewports) Align U/S Volume with MR (2D viewports)

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Shortcut	Function	Workflow Context
- (Minus Key)	Decrease brush size (while 3D brush tool is selected)	Review ROIs and Targets (2D viewports) Align U/S Volume with MR (2D viewports)
CTRL	Overrule brush functionality (draw/erase, depending on mouse position, while 3D brush tool is selected)	Review ROIs and Targets (2D viewports) Align U/S Volume with MR (2D viewports)
Up / Down Arrow Keys	Scroll through images in 1mm increments	All 2D viewports

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15 Use of symbols in labeling

The following internationally recognized symbols are used on your Philips product and its accessories and packaging:

Symbols	Description
	To identify a type BF applied part complying with IEC 60601-1.
	To identify equipment meeting the safety requirements specified for Class II equipment according to IEC 61140.
	Indication that item is a medical device.
	Consult the Instructions for Use (IFU) or consult electronic Instructions for Use (when appearing with an eIFU indicator, such as the manufacturer's website URL).
	Serial Number
	Catalogue number
	This prescription symbol indicates that the sale of the product in the USA is restricted by FDA regulations to sale by or on the order of a licensed healthcare practitioner.
	Indicates the manufacturer’s batch code so that the batch or lot can be identified.
	Alternating Current (AC)
	To indicate the entity importing the medical device into the locale.
	Fuse
	The WEEE mark, indicating separate collection for waste of electrical and electronic equipment.
	Intertek certification Mark

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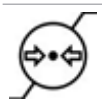
Symbols	Description
	Unique Device Identifier of the device
	To indicate generally elevated, potentially hazardous, levels of non- ionizing radiation, or to indicate equipment or systems, such as in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.
	A warning alerts you to a potential serious outcome, adverse event or safety hazard. Failure to observe a warning may result in death or serious injury to the user or patient.
	A CAUTION alerts you to where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possibly in a remote risk of more serious injury, and/or cause environmental pollution.
 YYYY-MM-DD	Date of manufacture and country of origin
	Manufacturer
	To indicate that the device that is normally provided sterile in the same or similar packaging has not been sterilized.
	Authorized representative in the European community.
	To indicate the maximum and minimum temperature limits at which the item will be stored, transported or used.
	To indicate the acceptable upper and lower limits of relative humidity for transport and storage.
	To indicate the acceptable upper and lower limits of atmospheric pressure for transport and storage.
	Use by date.
	Single use disposable; Do not reuse.

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Symbols	Description
	To indicate that transport package shall not be exposed to sunlight.
	Do not use if package is damaged.
	No sitting
	No pushing
	Universal serial bus (USB) port/plug
	Computer network
	Video input
	Video output
	Equipotentiality
	Field generator connection
	General mandatory action
	Refer to instruction manual booklet
	This way up
	Do not stack

Symbols	Description
	To indicate that the contents of the transport package are fragile and the package will be handled with care.
	To indicate that the transport package will be kept away from rain and in dry conditions.
	To indicate the number of pieces in the package.
	Warning; Non-ionizing radiation
	No access for people with active implanted cardiac devices.
	Sweep
	Screen capture
	Freeze
	By affixing the CE marking to a product, the manufacturer declares that the product meets all the legal requirements for CE marking and can be sold throughout the EEA. This also applies to products made in other countries that are sold in the EEA.

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16 Appendices

Appendix A

Supported biopsy guns and needles

The following table provides a list of supported biopsy guns and needles:

Manufacturer	Gun	Needles
Argon Medical Systems (Angiotech)	Pro-Mag™ Ultra Reusable Automatic Biopsy Instrument, 7675	Pro-Mag Biopsy Needle, 18Gx20cm, 765018200
		Pro-Mag Biopsy Needle, 18Gx25cm, 765018250
		Pro-Mag Biopsy Needle, 18Gx30cm, 765018300
Argon Medical Devices (US Biopsy®)	Fully Automated Core Biopsy System, MBD-23	Core Biopsy Needle, 18Gx20cm, CBN1820
		Core Biopsy Needle, 18Gx25cm, CBN1825
		Core Biopsy Needle, 18Gx30cm, CBN1830
BARD®	MAX-CORE® Disposable Core Biopsy Instrument, 18Gx20cm, MC1820	
	MAX-CORE Disposable Core Biopsy Instrument, 18Gx25cm, MC1825	
	MAGNUM® Reusable Core Biopsy Instrument, MG1522	MAGNUM Disposable Core Tissue Biopsy Needle, 18Gx20cm, MN1820
		MAGNUM Disposable Core Tissue Biopsy Needle, 18Gx25cm, MN1825
		MAGNUM Disposable Core Tissue Biopsy Needle, 18Gx30cm, MN1830
URO-1™	SUREcore™ Plus Disposable Core Biopsy Instrument, 18Gx22cm, SP-LA18-22	
	SUREcore Plus Disposable Core Biopsy Instrument, 18Gx25cm, SP-LA18-25	

CAUTION

Use of unsupported biopsy guns and needles may cause EM interference and result in inaccurate registration and biopsy core marking.

Applicator compatibility

The following table provides a list of needles/applicators/tools that have been found compatible for use in the operating environment of the UroNav system.

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Manufacturer	Needles
Varian	V-Probe®, CVA2400RA
	TempProbe® Short, CRYO-55-F
CLS	TRANBERG® MR Introducer, 4013-14
	TRANBERG® Laser applicator non-cooled, Radial, 1 mm, 4012-01
	TRANBERG Laser applicator non-cooled, Diffuser, 15 mm, 4017-01
	TRANBERG Laser applicator non-cooled, Diffuser, 25 mm, 4017-03
	TRANBERG® Tissue Temp Probe, 100 mm, Blue, 1 sensor, 3001-01
	TRANBERG Tissue Temp Probe, 100 mm, White, 1 sensor, 3002-01
	TRANBERG Tissue Temp Probe, 100 mm, Green, 4 sensors, 3003-01
	TRANBERG Tissue Temp Probe, 100 mm, Black, 4 sensors, 3004-01
	TRANBERG Tissue Temp Probe, 200 mm, Blue, 1 sensor, 3001-02
	TRANBERG Tissue Temp Probe, 200 mm, White, 1 sensor, 3002-02
	TRANBERG Tissue Temp Probe, 200 mm, Green, 4 sensors, 3003-02
	TRANBERG Tissue Temp Probe, 200 mm, Black, 4 sensors, 3004-02
Boston Scientific	IcePearl™ 2.1 CX, FPRPR3603
	IceForce™ 2.1 CX, FPRPR3604
	IceRod™ 1.5 i-Thaw™, FPRPR4009
	Multi-Point Thermal Sensor, FPRPR4010

CAUTION

Use of unsupported tools, needles, and applicators may cause EM interference and result in inaccurate registration and marking of tool, needle, and applicator locations.

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Supported Stepper accessories

The following table provides a list of supported Stepper accessories:

Manufacturer	Description	Manufacturer's part number
CIVCO	Sterile 17G Grid	610-905
	Sterile 18G Grid	610-906
	Sterile 14G Grid	610-977
	Sterile Flat Polyethylene Drape	610-870
	Latex-Free Endocavity Balloon	610-898
DK	Sterile 14G Grid	GM13004030

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Appendix B

Supported ultrasound and transducer probe combinations for transrectal workflows

The following table provides a list of supported transrectal procedure ultrasound systems and associated transducer probes:

Ultrasound	Transducer probes
BK FlexFocus 400/500/700/800	8808e, 8818, and 8819
BK 3000/5000	E10C4 and E14C4t
BK Specto	[9]E10C4 and E14C4t
GE Logiq F8 R.2.x.x	E8C and E8CS
GE Logiq S7 R3 .x.x	IC-5-9
GE Versana Premier	E8CS-RS
Hitachi Noblus	C4IV
Hitachi/Fujifilm Arietta Precision	C4IV and CC41R2
Hitachi/Fujifilm Arietta 65	C4IV and CC41R2
Philips Affiniti	C10-4ec
Philips Epiq 5/7/Elite	C10-4ec
Siemens S2000/S3000	MC9-4

The following list provides part numbers for reordering probe holders for transrectal procedures:

Ultrasound transducer probe	Philips part number	Reorder part number
BK 8808e, 8818, and E14C4t	4598-012-32081	FCS0135 (Set of 25)
BK 8819 and E10C4	4598-007-92361	FCS0136 (Set of 25)
GE E8C, E8CS, E8CS-RS, and IC5-9-D	4535-303-71181	FCS0054 (Set of 25)
Hitachi C41V	4598-013-25761	FCS0146 (Set of 25)
Fujifilm CC41R2	300013688811	FCS0415 (Set of 25)
Siemens MC9-4	4598-007-92382	FCS0165 (Set of 25)

The following list provides part numbers for reordering EM trackers:

(9) Compatibility for the E10C4 transducer is only with BK Specto software version 6.6.4. For any potential limitations on supported ultrasound system software versions, please see the *452299184541 UroNav 4 specifications and compatibility list*.

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Description	Philips part number	Reorder part number
EM tracker	4598-007-83602	FCS0140 (Set of 3)

To order additional supplies, consumable instrumentation, or accessories, please contact Philips Customer Service. See “Help and guidance information” on page 8.

Transrectal workflow probe holder mounting instructions

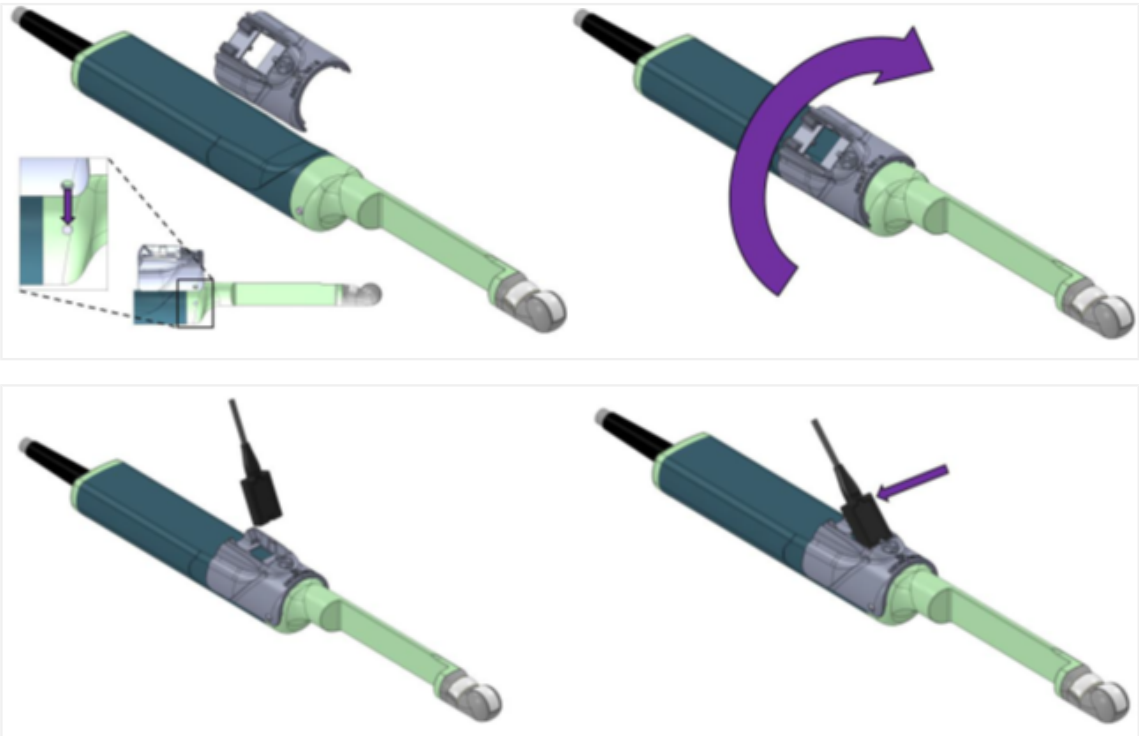
CAUTION

Failure to fully secure the EM Tracker to the Probe Holder will compromise the positional tracking of the TRUS probe resulting in grossly inaccurate registration between the US imaging and EM tracked tools.

CAUTION

Failure to fully secure the Probe holder to the Probe will compromise the positional tracking of the TRUS probe resulting in grossly inaccurate registration between the US imaging and EM tracked tools.

BK 8808e, 8818, and E14C4t Probe Holder mounting instructions



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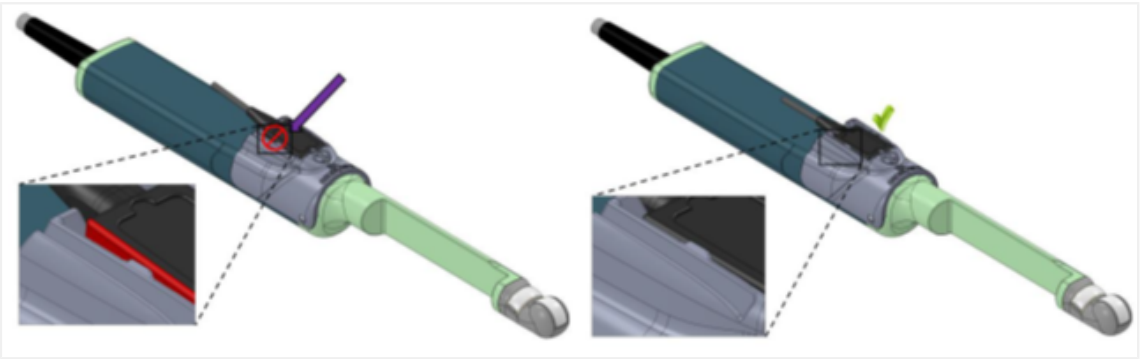
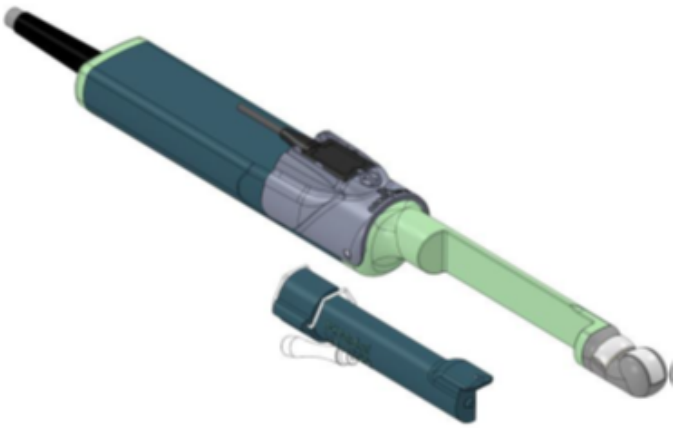


Install cover per the manufacturer's instructions over transducer and UroNav probe holder.



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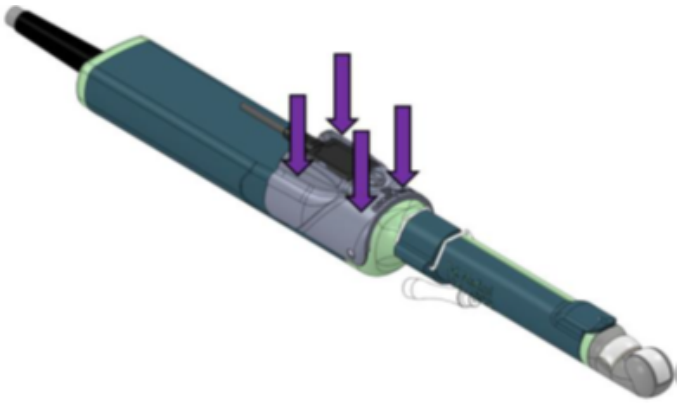
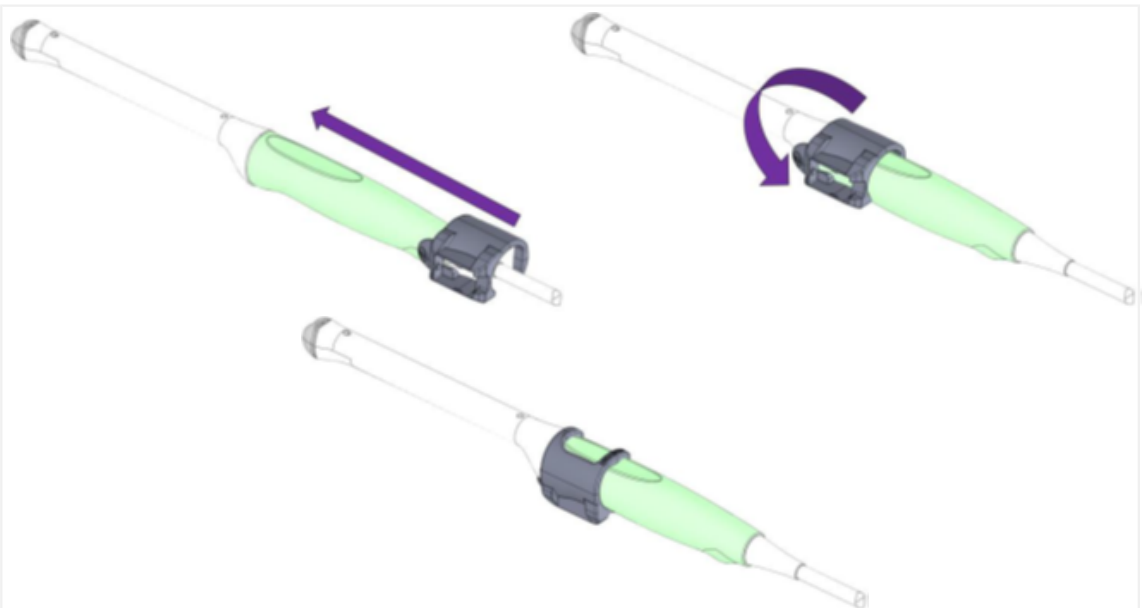
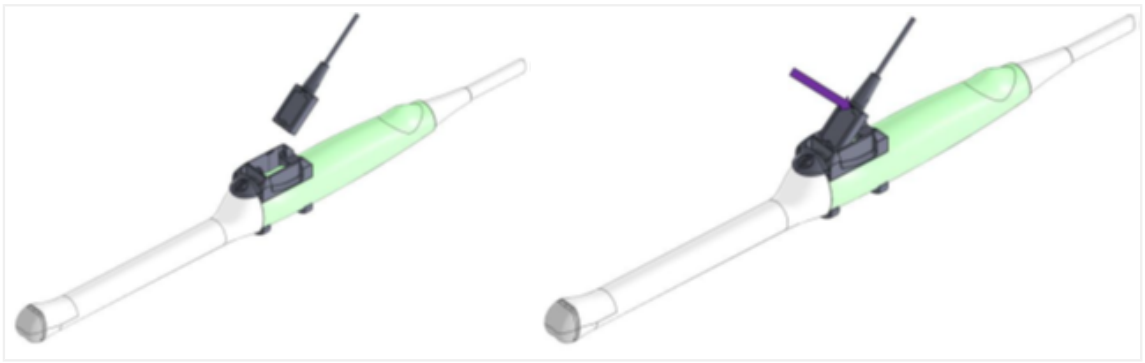


Tracker removal from BK 8808e, 8818, and E14C4t probe holders

BK 8819 and E10C4 Probe Holder mounting instructions





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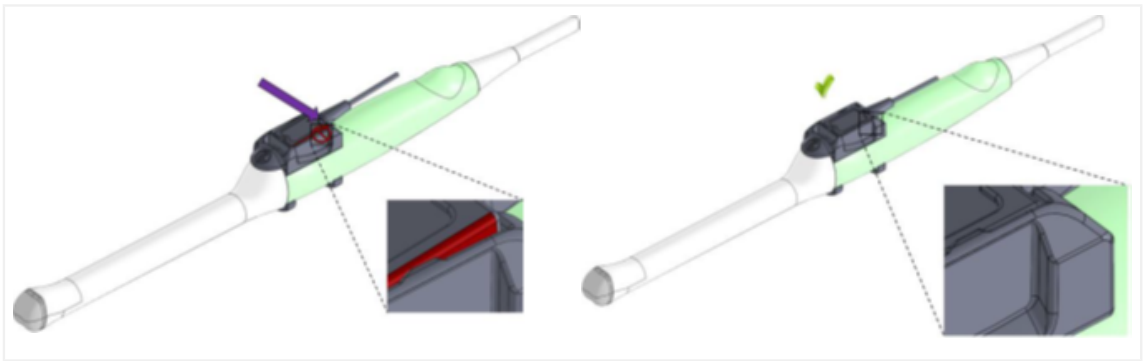
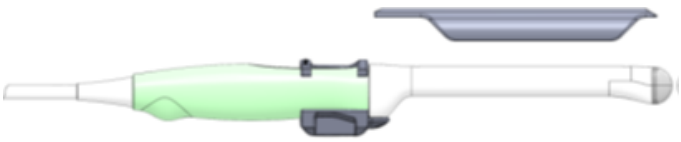


Install cover per the manufacturer's instructions over transducer and UroNav probe holder.



Apply force to reseat.

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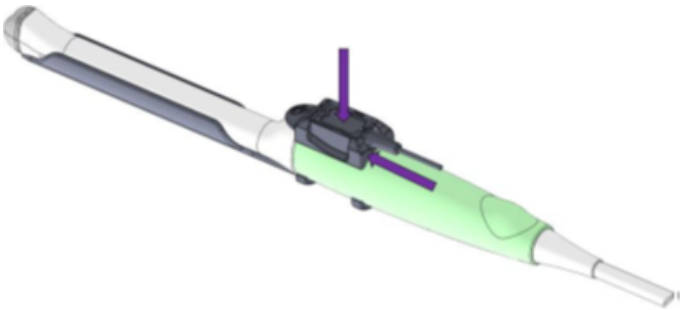
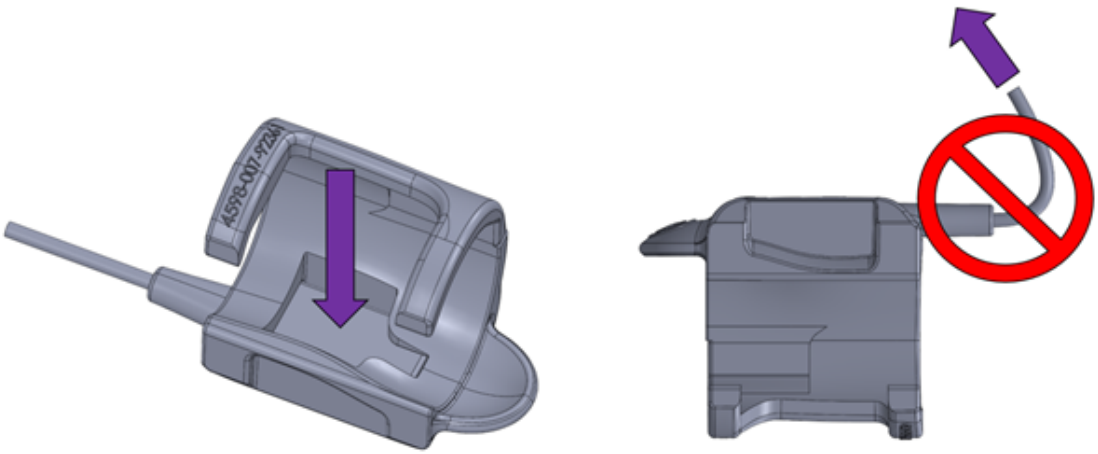
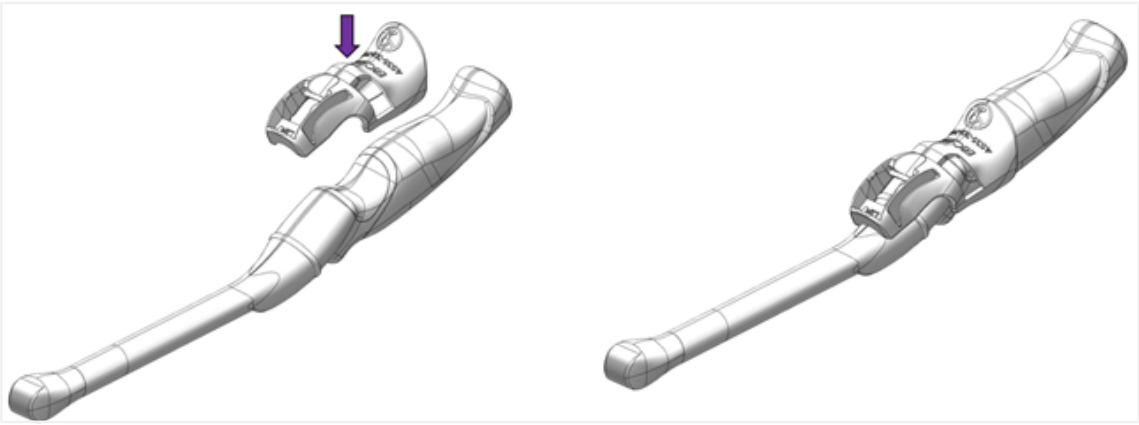
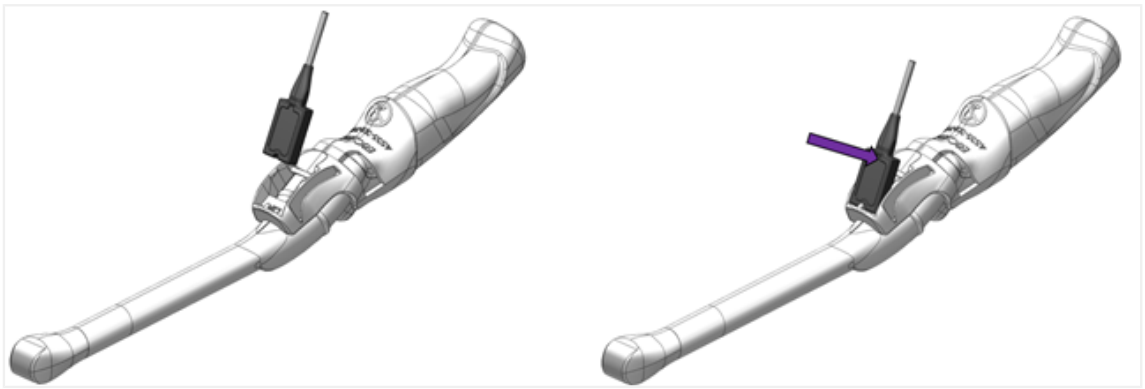


Tracker removal from BK 8819 and E10C4 probe holders



GE E8C, E8CS, E8CS-RS, and IC5-9-D Probe Holder mounting instructions





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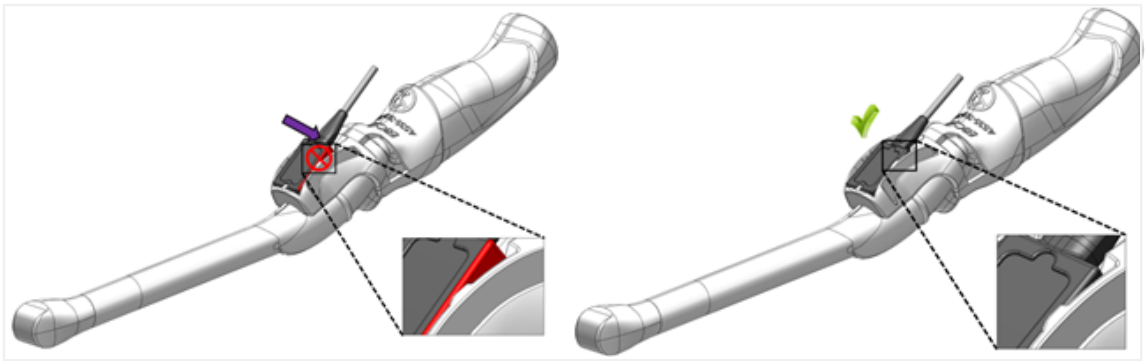
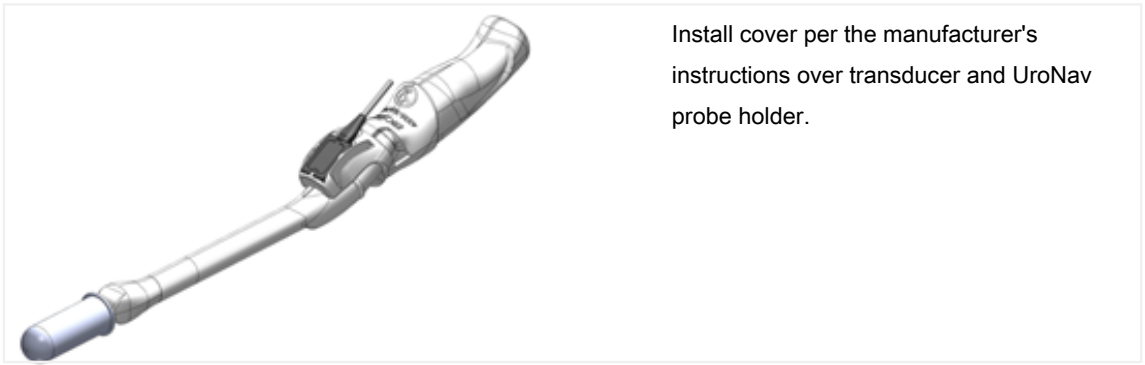
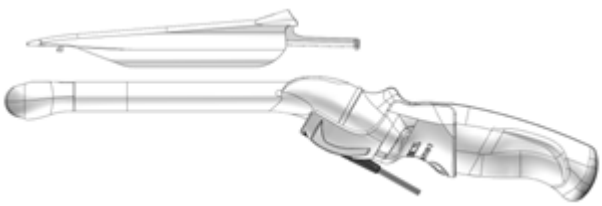




Install cover per the manufacturer's instructions over transducer and UroNav probe holder.



Apply force to reseat.

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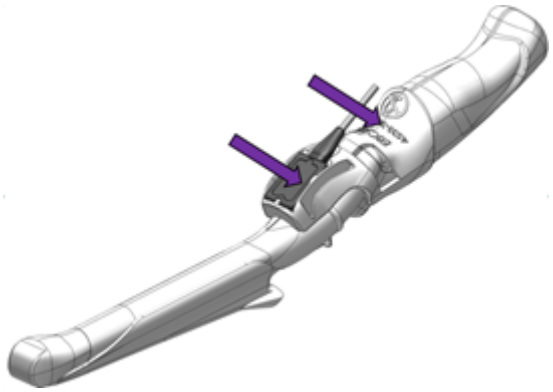
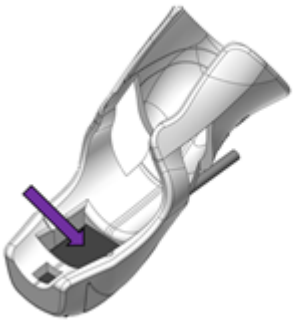
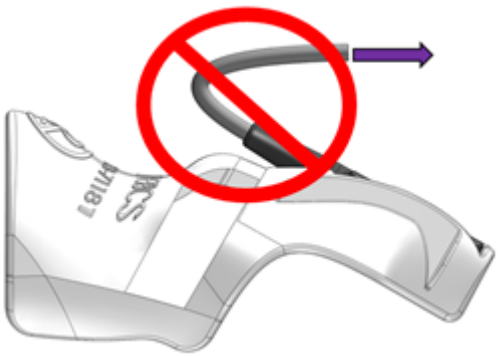
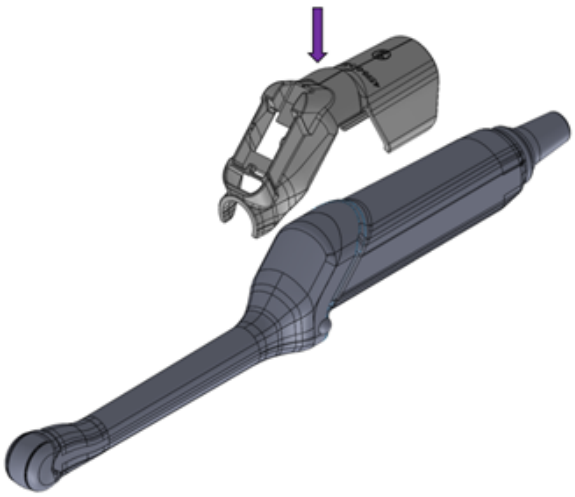


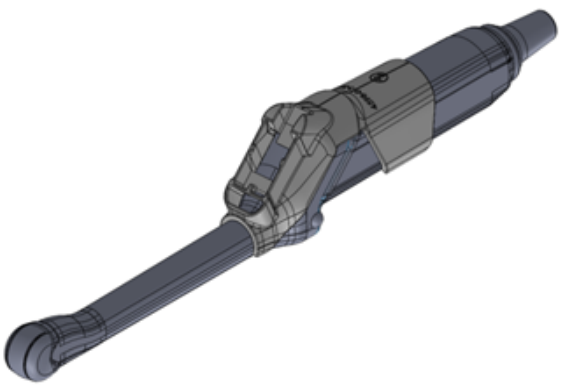
Tracker removal from E8C, E8CS, E8CS-RS, and IC5-9-D





Hitachi C41V Probe Holder mounting instructions





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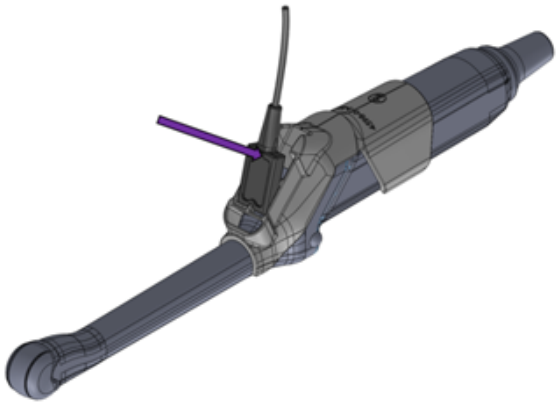

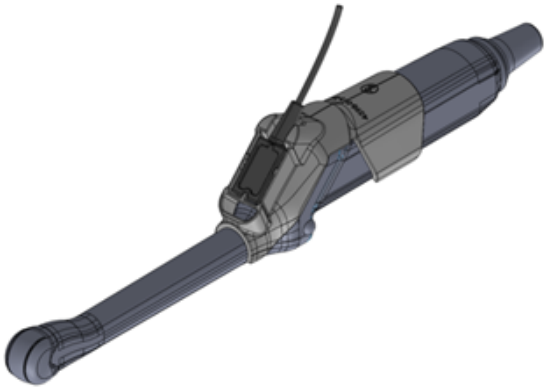

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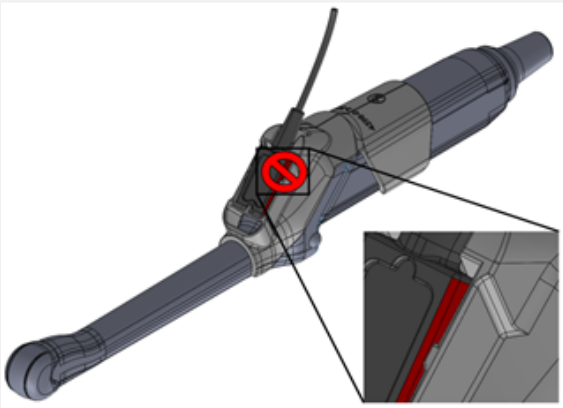
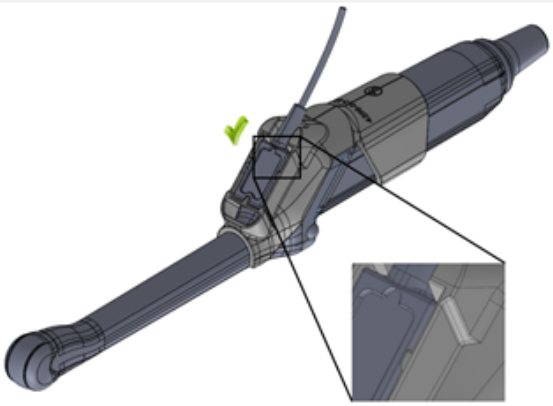
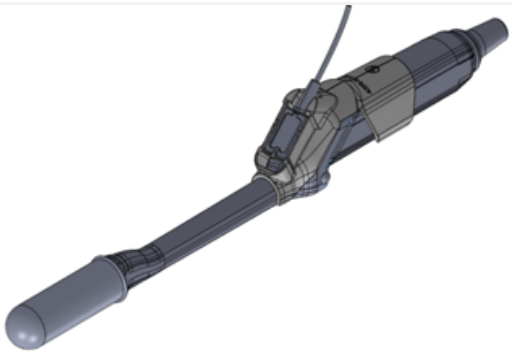
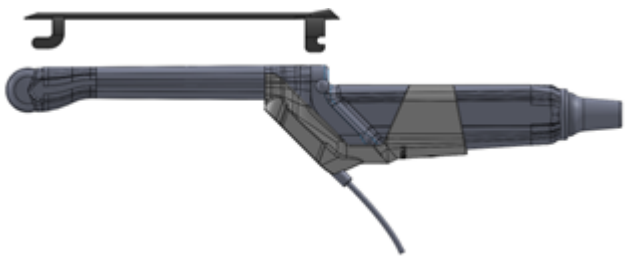






Install cover per the manufacturer's instructions over transducer and UroNav probe holder.



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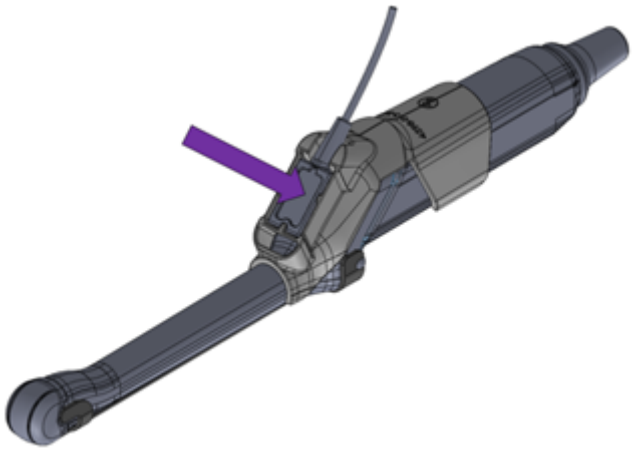
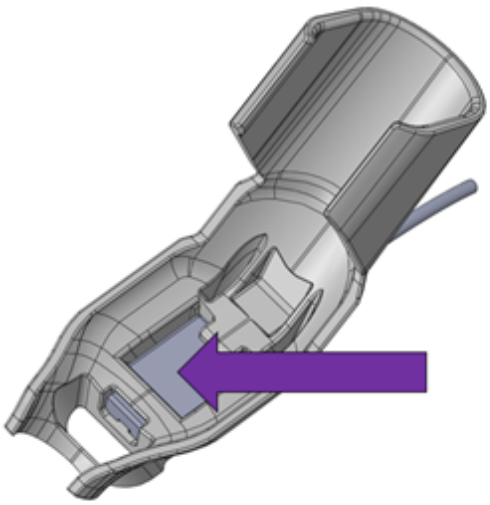
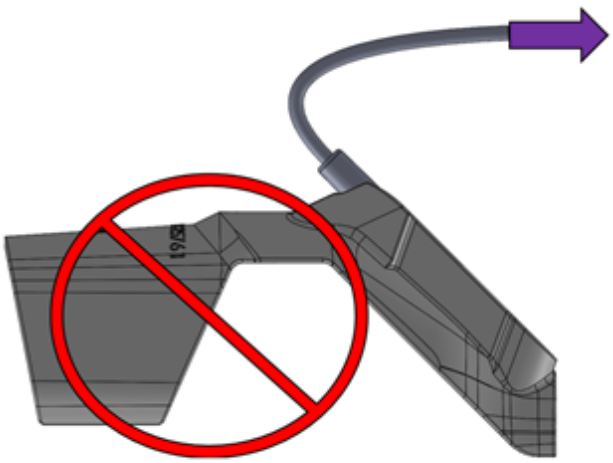
Apply force to reseat.



Tracker removal from Hitachi C41V





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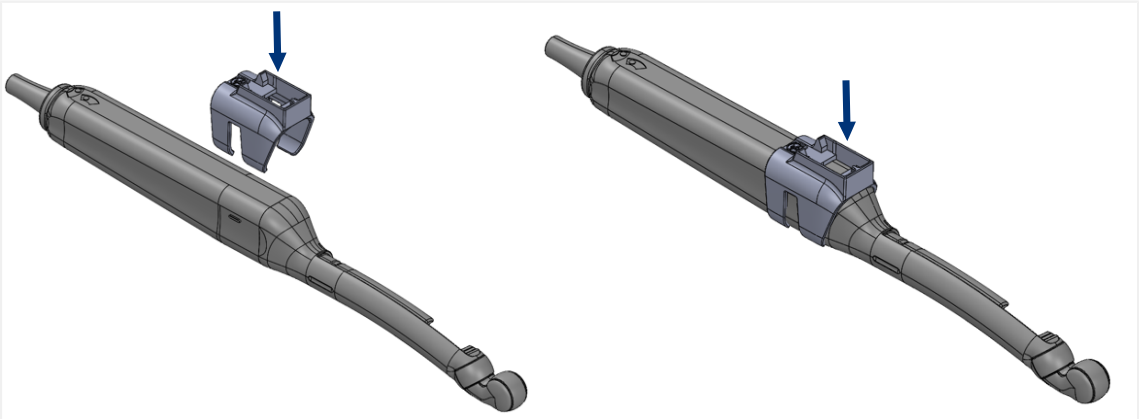
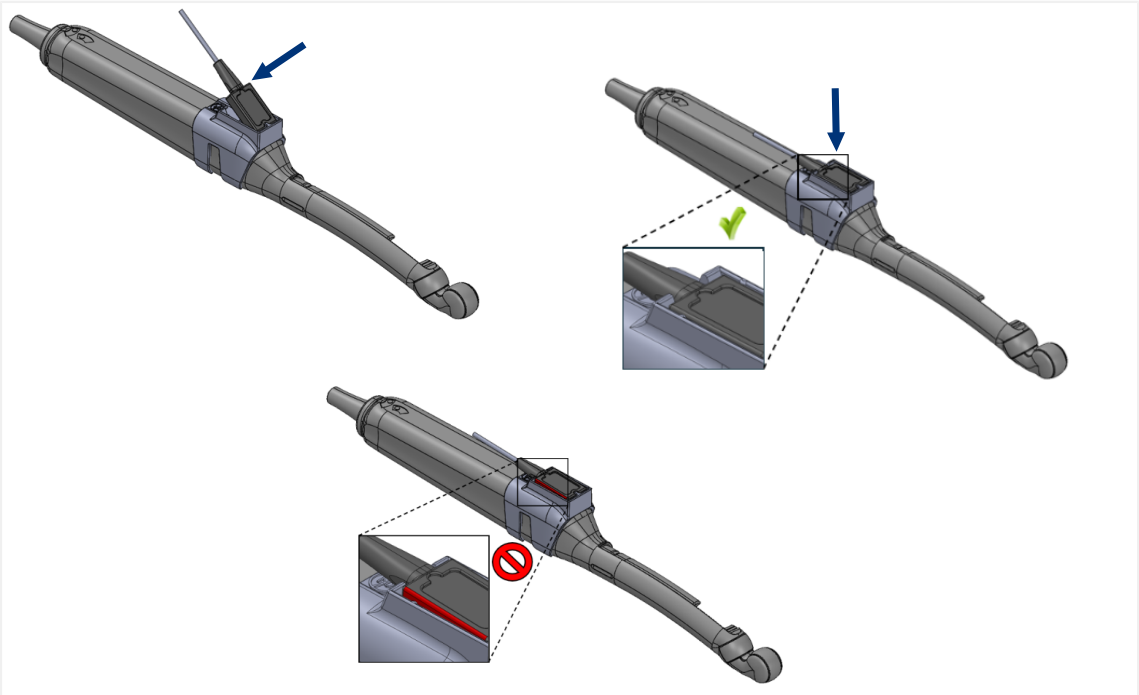
FujiFilm CC41R2 Probe Holder mounting instructions





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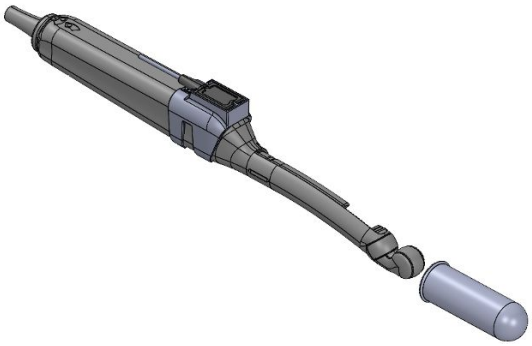
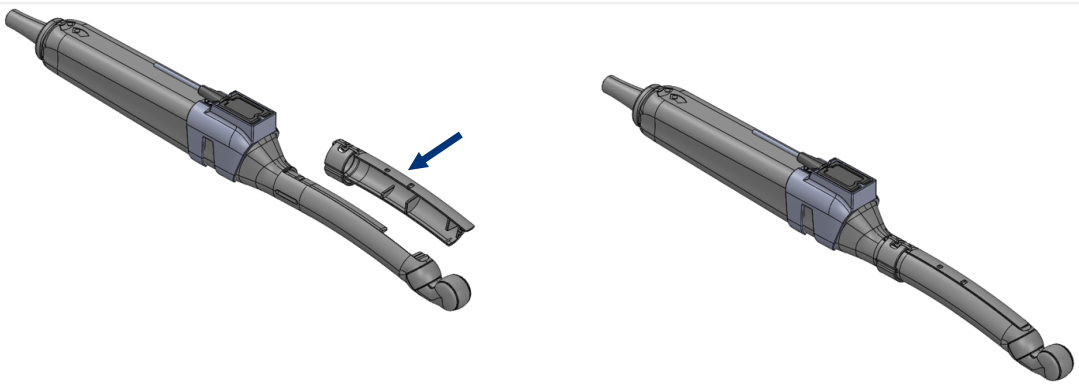
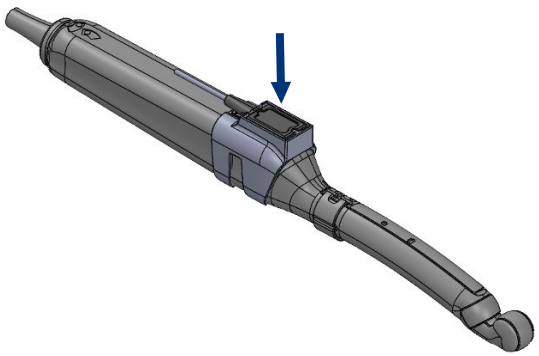


Install cover per the manufacturer's instructions over transducer and UroNav probe holder.



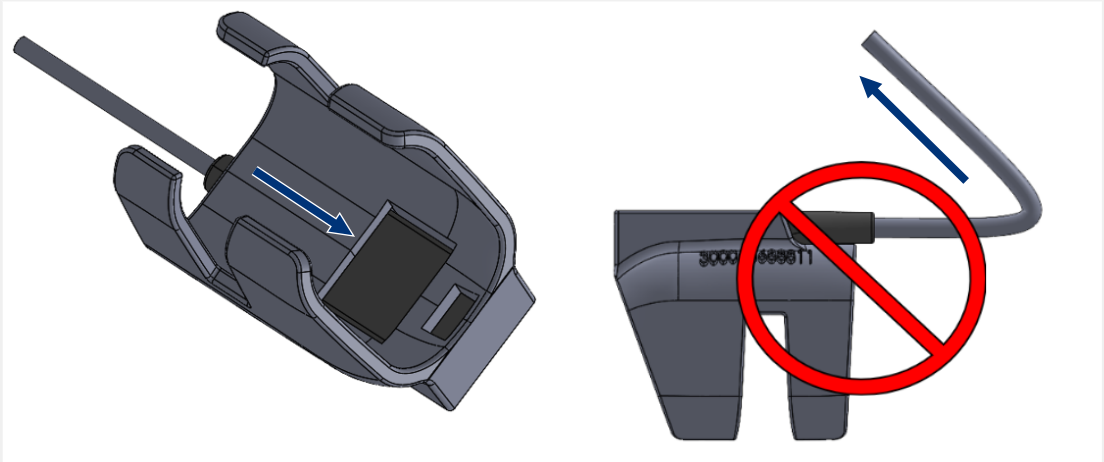
Apply force to reseat.



NOTICE

The on-screen needle guideline as displayed on UroNav corresponds with the number 3 slot on the CC41R2 needle guide.

Tracker removal from FujiFilm CC41R2



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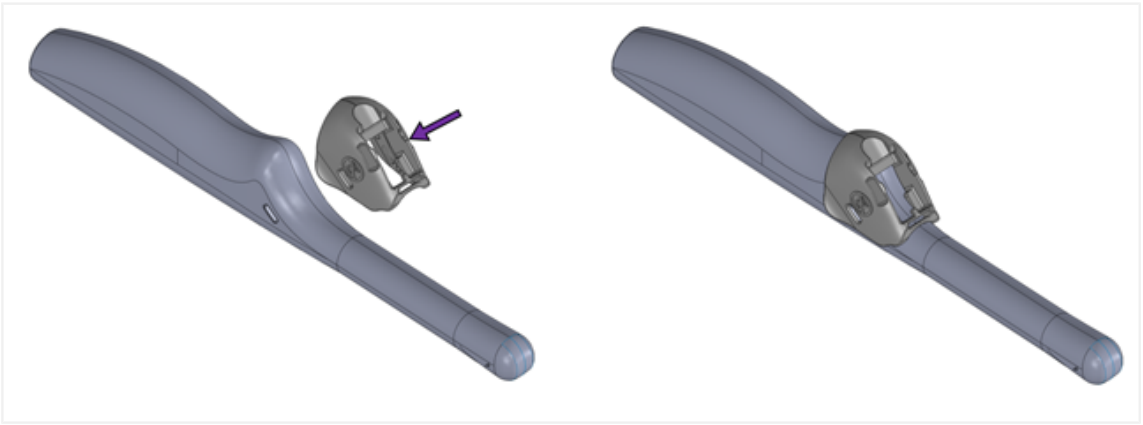
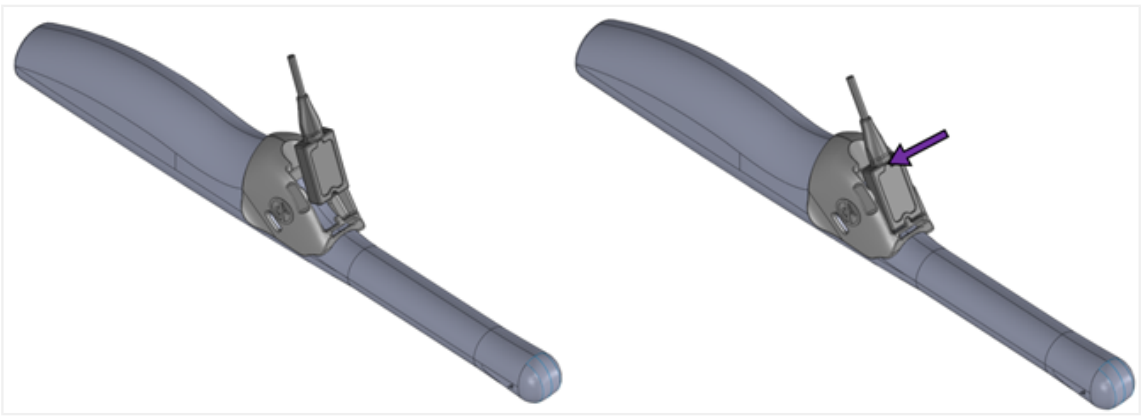
Philips C10-4ec Probe Holder mounting instructions





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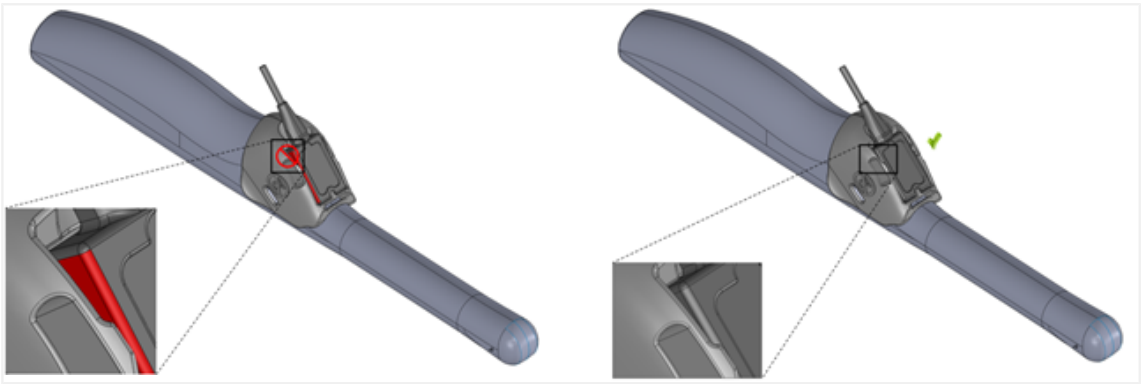
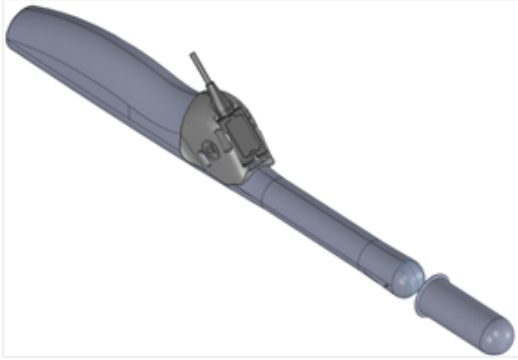
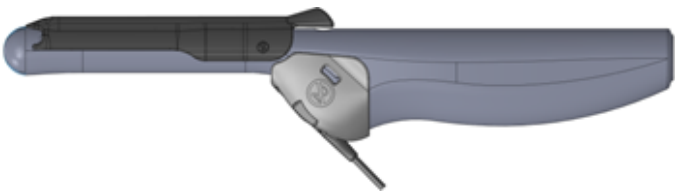


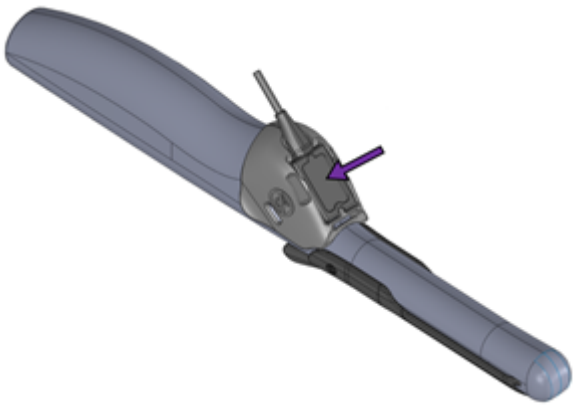
300014220451/ * 2025-06-02



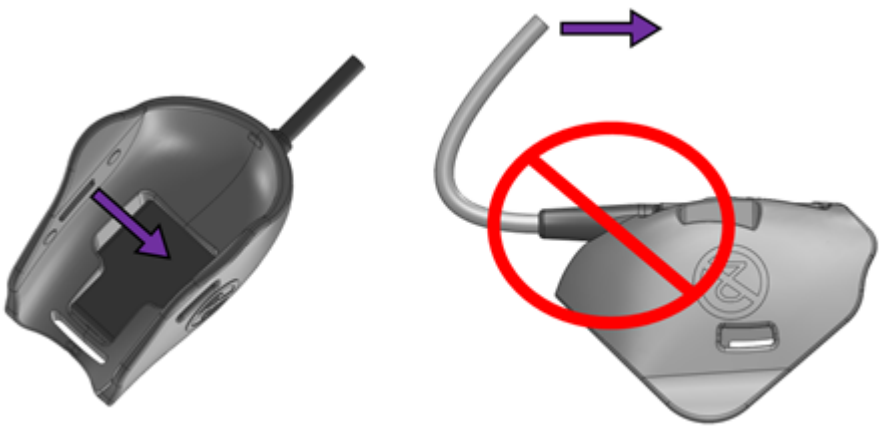
Install cover per the manufacturer's instructions over transducer and UroNav probe holder.



Apply force to reseat.



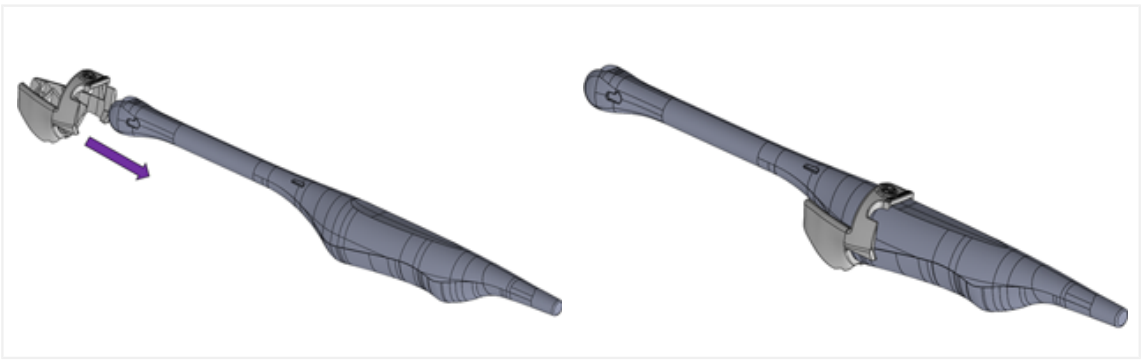
Tracker removal from Philips C10-4ec

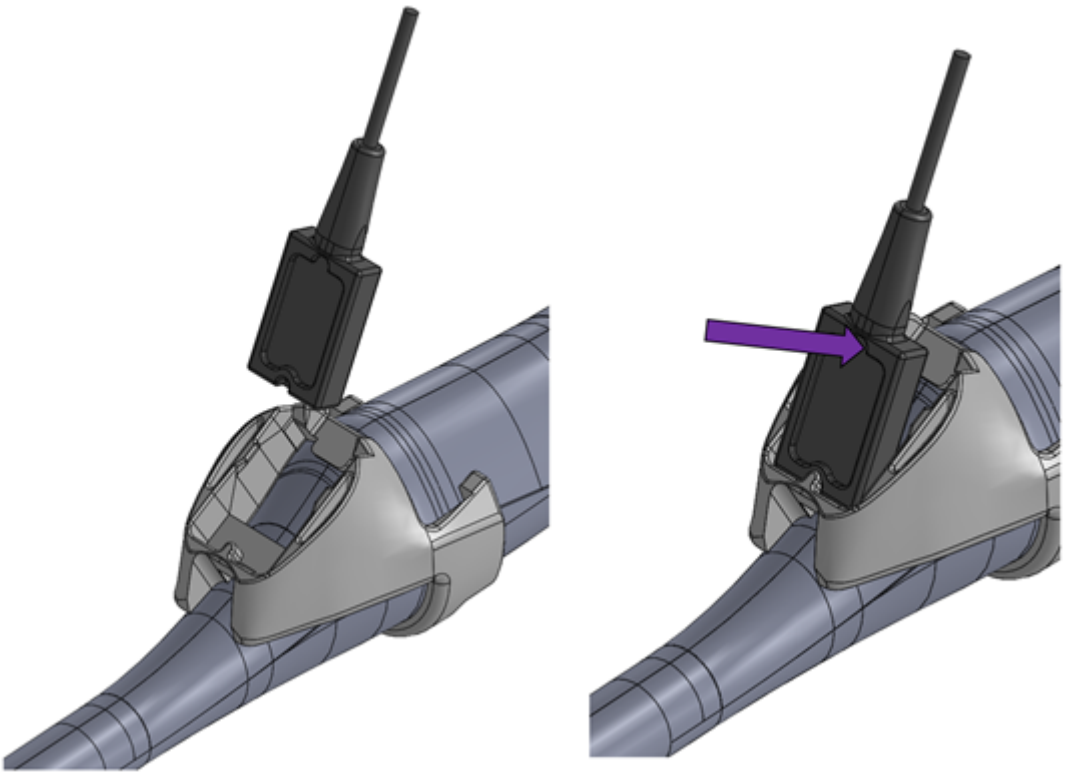


300014220451/ * 2025-06-02

Philips

Siemens MC9-4 Probe Holder mounting instructions





Apply force until flush.

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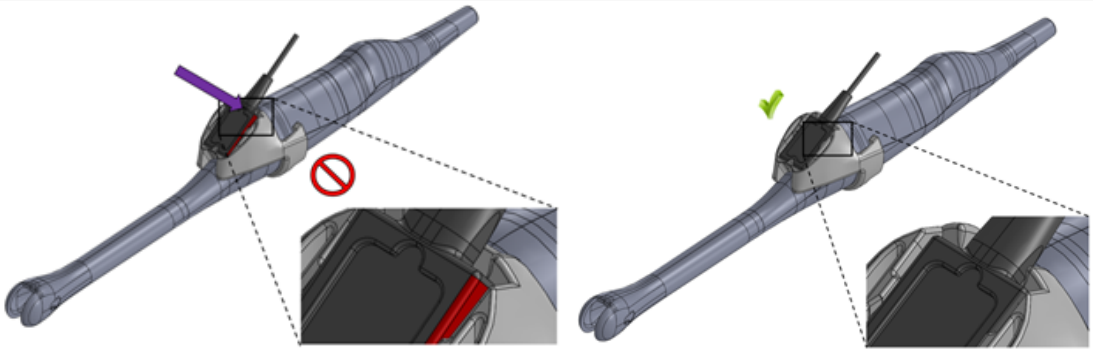
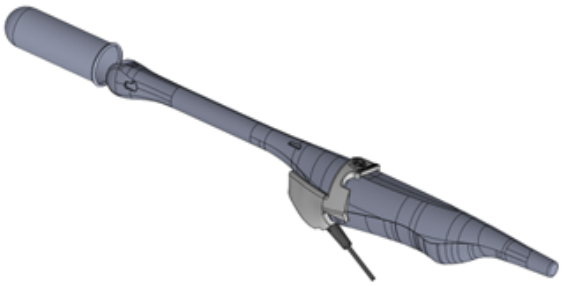
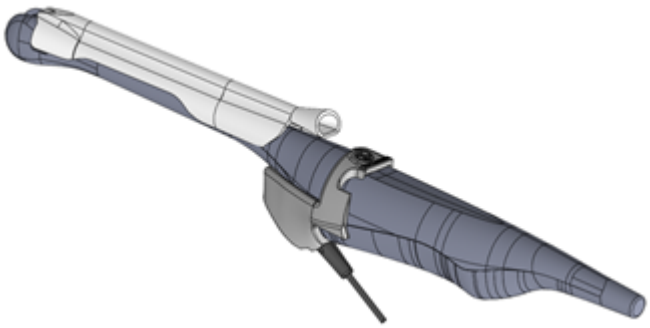
Philips





Install cover per the manufacturer's instructions over transducer and UroNav probe holder.



Apply force to reseat.

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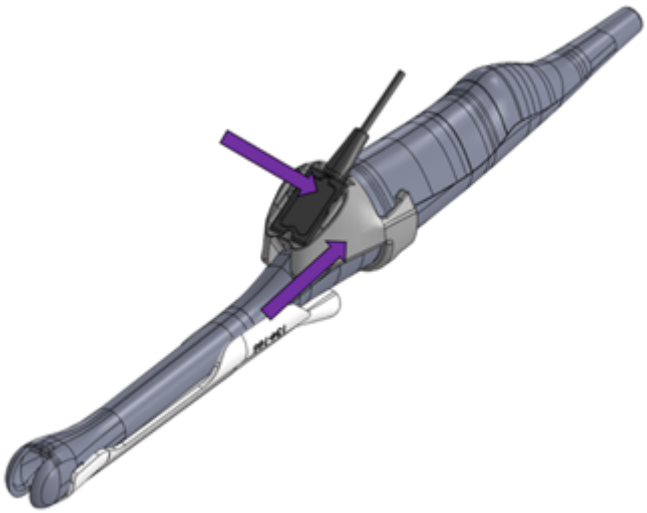
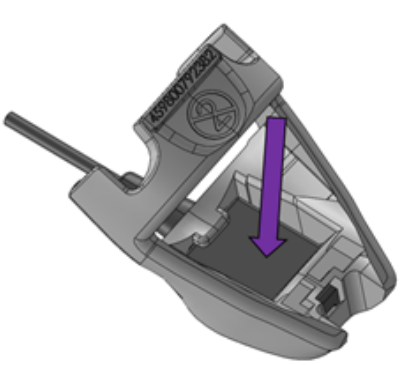
Philips



Tracker removal from Siemens MC9-4



300014220451/ * 2025-06-02

Philips

Required ultrasound system settings for transrectal workflows

This section provides the required ultrasound system settings for transrectal workflows that facilitates proper video calibration with UroNav used with specific transducer probes and needle guides.

BK Flex Focus and 8808e

Flex Focus Ultrasound Function Compatibility:

Function	Setting
Preset	“Uro Prostate: Prostate S” or “Uro Prostate: Prostate 6”
Biopsy	Must be ON
Color	Not Supported
Depths	4.0cm, 4.1cm, 5.1cm, 5.4cm, 6.0cm, 6.3cm, 7.1cm, 7.4cm, 8.3cm, 8.5cm
Doppler/M-mode	Not Supported
Dual View	Not Supported
Harmonic	Not Supported
Imaging	2D, Sagittal and Transverse Planes
Orientation	Bottom View (L/R Off, U/D On, Small BK Logo Bottom Left or Right). Note that the user may need to adjust the orientation on UroNav via the ALT-F key binding.
Size	100% Only
Video I/O	Digital (DVI-HDMI): Must be Passive Display, Large Font, Black and White
Width	100% Only
Zoom	Not Supported
Font Size	Large

Supported Needle Guide:

Manufacturer	Description	Manufacturer’s Part Number
BK Medical	Single-Use Biplane Biopsy Guide	UA1322-S

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BK Flex Focus and 8818

Flex Focus Ultrasound Function Compatibility:

Function	Setting
Preset	Digital (DVI-HDMI): “Uro Prostate: Prostate L” or “Uro Prostate: Prostate 12”
Biopsy	Must be ON
Color	Not Supported
Depths	Digital (DVI-HDMI): 4.0cm, 4.5cm, 5.0cm, 5.3cm, 5.9cm, 6.2cm, 6.9cm, 7.2cm, 8.1cm, 8.4cm, 9.0cm, 9.8cm
Doppler/M-mode	Not Supported
Dual View	Not Supported
Harmonic	Not Supported
Imaging	2D, Sagittal, Transverse and Endfire Planes
Orientation	Bottom View (L/R Off, U/D On, Small BK Logo Bottom Left or Right). Note that the user may need to adjust the orientation on UroNav via the ALT-F key binding.
Size	100% Only
Video I/O	Digital (DVI-HDMI): Must be Passive Display, Large Font, Black and White
Width	100% Only
Zoom	Not Supported
Font Size	Large

Supported Needle Guide:

Manufacturer	Description	Manufacturer’s Part Number	Imaging Plane
BK Medical	Single-Use Dual Biopsy Guide	UA1329-S	All
BK Medical	Single-Use Biplane Biopsy Guide	UA1322-S	Sagittal only

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Philips

BK Flex Focus and 8819

Flex Focus Ultrasound Function Compatibility:

Function	Setting
Preset	“Uro Prostate: Prostate S” or “Uro Prostate: Prostate 6”
Biopsy	Must be ON
Color	Not Supported
Depths	4.6cm, 5.4cm, 6.3cm, 6.4cm, 7.4cm, 7.5cm, 8.3cm, 8.6cm, 9.3cm, 10.0cm
Doppler/M-mode	Not Supported
Dual View	Not Supported
Harmonic	Not Supported
Imaging	2D, Endfire Plane
Orientation	Bottom View (L/R Off, U/D On, Small BK Logo Bottom Left)
Size	100% Only
Video I/O	Digital (DVI-HDMI): Must be Passive Display, Large Font, Black and White
Width	100% Only
Zoom	Not Supported

Supported Needle Guide:

Manufacturer	Description	Manufacturer’s Part Number
CIVCO	Needle Guide	610-958

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Philips

BK 3000/5000 (software version 5.8.0 - 5.14.8) and E10C4

BK 3000/5000 Ultrasound Function Compatibility:

Function	Setting
Biopsy	Must be ON
Color	Not Supported
Depths	4.0cm, 5.0cm, 6.0cm, 7.0cm, 8.0cm, 9.0cm
Doppler/M-mode	Not Supported
Dual View	Not Supported
Harmonic	Not Supported
Imaging	2D, Endfire Plane
Orientation	Bottom View (L/R Off, U/D On, Small BK Logo Bottom Left)
Size	100% Only
Video I/O	Digital (DVI): Must be Passive Display, Large Font, Black and White
Width	100% Only
Zoom	Not Supported

Supported Needle Guide:

Manufacturer	Description	Manufacturer's Part Number
CIVCO	Needle Guide	610-958

300014220451/ * 2025-06-02

Philips

BK 3000/5000 (software version 5.8.0 - 5.14.8) and E14C4t

BK 3000/5000 Ultrasound Function Compatibility:

Function	Setting
Biopsy	Must be ON
Color	Not Supported
Depths	4.0cm, 5.0cm, 6.0cm, 7.0cm, 8.0cm, 9.0cm
Doppler/M-mode	Not Supported
Dual View	Not Supported
Harmonic	Not Supported
Imaging	2D, Sagittal, Transverse, and Endfire Planes
Orientation	Bottom View (L/R Off, U/D On, Small BK Logo Bottom Left)
Size	100% Only
Video I/O	Digital (DVI): Must be Passive Display, Large Font, Black and White
Width	100% Only
Zoom	Not Supported

Supported Needle Guide:

Manufacturer	Description	Manufacturer's Part Number	Imaging Plane
BK Medical	Single-Use Dual Biopsy Guide	UA1329-S	All
BK Medical	Single-Use Biplane Biopsy Guide	UA1322-S	Sagittal only

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BK 3000/5000 (software version 5.16.x) and E10C4

BK 3000/5000 (SW Version 5.16.x) Ultrasound Function Compatibility:

Function	Setting
Exam Type	Prostate (Any Preset)
R/L Invert	OFF
Sector Width	100
U/D Invert	ON
Image Size	100%
Dual Layout	OFF
Dual	OFF
Biopsy, E10C4	ON (Endfire)
Video Output Mode	Passive
Video Output Port	DVI

Supported Needle Guide:

Manufacturer	Description	Manufacturer's Part Number
CIVCO	Needle Guide	610-958

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Philips

BK 3000/5000 (software version 5.16.x) and E14C4t

BK 3000/5000 (SW Version 5.16.x) Ultrasound Function Compatibility

Function	Setting
Exam Type	Prostate (Any Preset)
R/L Invert	OFF
Sector Width	100
U/D Invert	ON
Image Size	100%
Dual Layout	OFF
Dual	OFF
Biopsy, E14C4t	ON (Sagittal and Endfire)
Video Output Mode	Passive
Video Output Port	DVI

Supported Needle Guide:

Manufacturer	Description	Manufacturer's Part Number	Imaging Plane
BK Medical	Single-Use Dual Biopsy Guide	UA1329-S	All
BK Medical	Single-Use Biplane Biopsy Guide	UA1322-S	Sagittal only

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Philips

BK Specto (software version 6.6.4) and E10C4

BK Specto (SW v6.6.4) Ultrasound Function Compatibility:

Function	Setting
Biopsy	Must be ON
Color	Not Supported
Depths	4.0cm, 5.0cm, 6.0cm, 7.0cm, 8.0cm, 9.0cm, 10.0cm, 11.0cm, 12.0cm
Doppler/M-mode	Not Supported
Dual	OFF
Dual Layout	OFF
Exam Type	Prostate (Any Preset)
Harmonic	Not Supported
Image Size	100% Only
Imaging	2D, Endfire Plane
Monitor	Portrait Orientation
Orientation	Bottom View (Small BK Logo Bottom Left)
R/L Invert	OFF
Sector Width	100
U/D Invert	ON
Video Output Mode	Passive
Width	100% Only
Zoom	Not Supported
Video Output Port	HDMI

Supported Needle Guide:

Manufacturer	Description	Manufacturer's Part Number
CIVCO	Needle Guide	610-958

When using Civco 610-958 needle guide for E10C4 TRUS probe, the needle guide UA1350 will be displayed in Ultrasound system.

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Philips

BK Specto and E14C4t

BK Specto Ultrasound Function Compatibility:

Function	Setting
Biopsy	Must be ON (Sagittal and Endfire)
Color	Not Supported
Depths	4.0cm, 5.0cm, 6.0cm, 7.0cm, 8.0cm, 9.0cm, 10.0cm, 11.0cm, 12.0cm
Doppler/M-mode	Not Supported
Dual	OFF
Dual Layout	OFF
Exam Type	Prostate (Any Preset)
Harmonic	Not Supported
Image Size	100% Only
Imaging	2D, Sagittal, Transverse, and Endfire Planes
Monitor	Portrait Orientation
Orientation	Bottom View (Small BK Logo Bottom Left)
R/L Invert	OFF
Sector Width	100
U/D Invert	ON
Video Output Mode	Passive
Width	100% Only
Zoom	Not Supported
Video Output Port	HDMI
Font size	Small (for BK Specto software version 6.6.8 and greater)

Supported Needle Guide:

Manufacturer	Description	Manufacturer's Part Number	Imaging Plane
BK Medical	Single-Use Dual Biopsy Guide	UA1329-S	All
BK Medical	Single-Use Biplane Biopsy Guide	UA1322-S	Sagittal only

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GE Logiq F8 (software version R2.x.x) and E8C

Logiq F8 Ultrasound Function Compatibility:

Function	Setting
Biopsy	Must be ON
Preset	Prostate
Width	128
Colorize	Tint Map D
Depths	4.0cm, 5.0cm, 6.0cm, 7.0cm, 8.0cm, 9.0cm
CrossXBeam	Not Supported
ECG-mode	Not Supported
Harmonics	Not Supported
Imaging Mode	B-Mode, 2D
M-mode	Not Supported
Orientation	Down (Small “LOGIQ F” Logo Bottom Left or Right). Note that the user may need to adjust the orientation on UroNav via the ALT-F key binding.
PDI-mode	Not Supported
PWD-mode	Not Supported
Video I/O	HDMI Video Output, Resolution: 1280x1024
Zoom	Not Supported (Default E8C Urology Prostate setting)

Supported Needle Guide:

Manufacturer	Description	Manufacturer’s Part Number
CIVCO	Needle Guide	742-306

30001422045l/ * 2025-06-02

Philips

GE Logiq F8 (software versions R2.x.x) and E8CS

Logiq F8 Ultrasound Function Compatibility:

Function	Setting
Biopsy	Must be ON
Preset	Prostate
Width	135
Colorize	Tint Map D
Depths	4.0cm, 5.0cm, 6.0cm, 7.0cm, 8.0cm, 9.0cm
CrossXBeam	Not Supported
ECG-mode	Not Supported
Harmonics	Not Supported
Imaging Mode	B-Mode, 2D
M-mode	Not Supported
Orientation	Down (Small “LOGIQ F” Logo Bottom Left or Right). Note that the user may need to adjust the orientation on UroNav via the ALT-F key binding.
PDI-mode	Not Supported
PWD-mode	Not Supported
Video I/O	HDMI Video Output, Resolution: 1280x1024
Zoom	Not Supported (Default E8CS Urology Prostate setting)

Supported Needle Guide:

Manufacturer	Description	Manufacturer’s Part Number
CIVCO	Needle Guide	742-306

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Philips

GE Logiq S7 (software versions R3.x.x) and IC5-9-D

NOTICE

GE Logiq S7 R3.x.x is only compatible with UroNav 4.x when the S7 has been factory-installed with R3.x.x software versions. If the S7 system has been upgraded from R2.x.x to R3.x.x software versions, it is not compatible with UroNav 4.x.

Logiq S7 R3 Ultrasound Function Compatibility:

Function	Setting
Biopsy	Must be ON
Preset	Prostate
Width	146
Color Flow Mode	Not Supported
Depths	4.0cm, 5.0cm, 6.0cm, 7.0cm, 8.0cm, 9.0cm
CrossXBeam	Not Supported
Dual View	Not Supported
ECG-mode	Not Supported
Harmonics	Not Supported
Imaging Mode	B-Mode, 2D
M-mode	Not Supported
Orientation	Down (Small “LS7” Logo Bottom Left or Right). Note that the user may need to adjust the orientation on UroNav via the ALT-F key binding.
Image Display Area	Extra Large
PDI-mode	Not Supported
PWD-mode	Not Supported
Video I/O	Digital (HDMI): Resolution 1920x1080
Zoom	Not Supported

Supported Needle Guide:

Manufacturer	Description	Manufacturer’s Part Number
CIVCO	Needle Guide	742-306

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Philips

GE Versana Premier and E8Cs-RS

GE Versana Premier Ultrasound Function Compatibility:

Function	Setting
Exam Preset	Urology > Prostate
Display Image Size	Large
Auto Zoom	OFF (Not Supported)
Automatic Wide Screen	OFF (Not Supported)
Depths	4.0, 5.0, 6.0, 7.0, 8.0, 9.0, 10.0, 11.0, 12.0
Imaging Mode	B-Mode
Zoom	OFF (Not Supported)
Rotation	Down (Small “GE” Logo Bottom Left or Right)
Biopsy Kit	E8CS_TR5
Width	135
Video I/O	HDMI Video Output, Resolution 1920x1080

Supported Needle Guide:

Manufacturer	Description	Manufacturer’s Part Number
CIVCO	Needle Guide	742-306

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Hitachi Noblus and C41V

Hitachi Noblus Ultrasound Function Compatibility:

Function	Setting
Biopsy	Must be ON
Angle	5
B Gray Map	5
B Color	4
Up-Down Shift	OFF
Vertical Shift	0
Texture	Smooth
Depths	4.0cm, 5.0cm, 6.0cm, 7.0cm, 8.0cm, 9.0cm
Hi REZ+	5
dTHI	OFF
HI Support	OFF
PW	OFF
Imaging Mode	B-Mode, 2D
Orientation	Down (Small “H” Logo Bottom Left or Right). Note that the user may need to adjust the orientation on UroNav via the ALT-F key binding.
Video I/O	Digital (DVI-HDMI): Resolution 1024x768
Zoom	Not Supported

Supported Needle Guide:

Manufacturer	Description	Manufacturer’s Part Number
CIVCO	Needle Guide	644-069

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Philips

Hitachi/Fujifilm Arietta Precision and C41V

Hitachi/Fujifilm Arietta Precision Ultrasound Function Compatibility:

Function	Setting
Condition, C41V	Prostate Monoplane
Initial Mode	Single
Single Format Size (W)	Wide
B Mode Format Size (H)	Wide
Scan Area (B)	100%
Invert L/R	OFF
Image Rotation	180 deg
Vertical Shift	0.0 cm
Biplane Invert L/R (L)	ON
Biplane Invert L/R (T)	OFF
Biplane Image Rotation (L)	180 deg
Biplane Image Rotation (T)	180 deg
Full Image	OFF
Puncture Guide Line, C41V	ON
Puncture Guide Line, C41L47RP	OFF
Mirror Inversion Display	OFF
External Output	HDMI
Depths	4.0cm, 5.0cm, 6.0cm, 7.0cm, 8.0cm, 9.0cm

Supported Needle Guide:

Manufacturer	Description	Manufacturer's Part Number
CIVCO	Needle Guide	644-069

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Philips

Hitachi/Fujifilm Arietta Precision and CC41R2

Hitachi/Fujifilm Arietta Precision Ultrasound Function Compatibility:

Function	Setting
Preset	Prostate Biplane
Plane +	Sole Supported Function for Switching Planes
Plane	Not Supported
Select	Not Supported
Initial Mode	Single
Single Format Size (W)	Wide
B Mode Format Size (H)	Wide
Scan Area (B)	100%
Invert L/R	OFF
Image Rotation	180 deg
Cine Memory Division	2
Vertical Shift	0.0 cm
Biplane Invert L/R (L)	ON
Biplane Invert L/R (T)	OFF
Biplane Initial Plane	T
Biplane Image Rotation (L)	180 deg
Biplane Image Rotation (T)	180 deg
Biplane Label	ON
Real-time Biplane	OFF
Puncture Guide Line	ON
Puncture Angle Select	3
Puncture Display Pattern	Single
Full Image	OFF
Mirror Inversion Display	OFF

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Philips

Function	Setting
External Output	HDMI
Depths	4.0cm, 5.0cm, 6.0cm, 7.0cm, 8.0cm, 9.0cm, 10.0cm, 11.0cm, 12.0cm

Supported Needle Guide:

Manufacturer	Description	Manufacturer's Part Number
CIVCO	Needle Guide	644-102 (REF 134-217)

NOTICE

The on-screen needle guideline as displayed on UroNav corresponds with the number 3 slot on the CC41R2 needle guide.

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Philips

Hitachi/Fujifilm Arietta 65 and C41V

Hitachi/Fujifilm Arietta 65 Ultrasound Function Compatibility:

Function	Setting
Info Display Position	Lower
Vertical Shift [mm]	0
HI Zoom	OFF
PAN Zoom	OFF
Scan Area (B)	100
Biplane Scan Area (B) (T)	100
Biplane Scan Area (B) (L)	100
Initial Mode	B
B Mode Format Size (H)	Normal
B Invert L/R	OFF
B Invert U/R	OFF
B Image Rotation	180 deg
Biplane Invert L/R (L)	ON
Biplane Invert L/R (T)	OFF
Biplane Invert U/L (L)	OFF
Biplane Invert U/L (T)	OFF
Biplane Image Rotation (L)	180 deg
Biplane Image Rotation (T)	180 deg
Trapezoidal Scanning	OFF
Puncture Guide Line, C41V	ON
External Output	EXTOUT HDMI port of the EU-9210 option box with the switches set to the following: Margin = Off, XGA = Off, and CLIP = On
Depths	4.0cm, 5.0cm, 6.0cm, 7.0cm, 8.0cm, 9.0cm, 10.0cm, 11.0cm, 12.0cm

Supported Needle Guide:

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Manufacturer	Description	Manufacturer's Part Number
CIVCO	Needle Guide	644-068

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Philips

Hitachi/Fujifilm Arietta 65 and CC41R2

Hitachi/Fujifilm Arietta 65 Ultrasound Function Compatibility:

Function	Setting
HI Zoom	OFF
PAN Zoom	OFF
Plane +	Sole Supported Function for Switching Planes
Plane	Not Supported
[Dual] key, [Single] key	Not Supported
Vertical Shift [mm]	0
Scan Area (B)	100
Wide Scanning	OFF
Biplane Scan Area (B) [T]	100
Biplane Scan Area (B) [L]	100
Initial Mode	B
B Mode Format Size (H)	Normal
B Invert L/R	OFF
B Invert U/L	OFF
B Image Rotation [deg]	180 degrees
Biplane Invert L/R [L]	ON
Biplane Invert L/R [T]	OFF
Biplane Invert U/L [L]	OFF
Biplane Invert U/L [T]	OFF
Biplane Image Rotation [L] [deg]	180 degrees
Biplane Image Rotation [T] [deg]	180 degrees
Trapezoidal Scanning	OFF
Puncture Guide Line, CC41R2	ON

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Philips

Function	Setting
Puncture Angle Select, CC41R2	#3(47°)
Cine Memory Division	2
Biplane Initial Plane	T
Info Display Position	Lower
External Output (Must have the EU-9210 option box installed)	1920x1080 EXTOUT HDMI port of the EU-9210 option box with the switches set to the following: Margin = Off, XGA = Off, and CLIP = On
Depths	4.0cm, 5.0cm, 6.0cm, 7.0cm, 8.0cm, 9.0cm, 10.0cm, 11.0cm, 12.0cm

Supported Needle Guide:

Manufacturer	Description	Manufacturer's Part Number
CIVCO	Needle Guide	644-102 (REF 134-217)

NOTICE

The on-screen needle guideline as displayed on UroNav corresponds with the number 3 slot on the CC41R2 needle guide.

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Philips

Philips Affiniti 50/70 and C10-4ec

CIVCO Part Number:

Description	Manufacturer's Part Number
Tracking Bracket for Endocavity Transducer	667-145

Affiniti Ultrasound Function Compatibility :

Function	Setting
XRES	ON
WideScan	OFF
Depths	4.0cm, 5.0cm, 6.1cm, 7.0cm, 8.0cm, 9.1cm
SonoCT	ON
Harmonics	OFF
2D OPT	Gen
Dyn Range	60
Loop Length	3 sec
AutoScan	OFF
Contrast	OFF
Res/Spd	Shaded area in the middle of fan
Grey Map	3
Chroma Map	OFF
Persistence	OFF
Output Power	-1.0dB
ECG	OFF
M-Mode	OFF
CPA	OFF
PW	OFF
Color	OFF
3D	OFF
External Video DisplayPort Format	Digital (DisplayPort-HDMI): Select "Full-screen 1080p (S-video disabled)"

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Philips

Supported Needle Guide:

Manufacturer	Description	Manufacturer's Part Number
CIVCO	Needle Guide	667-133

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Philips

Philips Epiq 5/7/Elite and C10-4ec

CIVCO Part Number:

Description	Manufacturer's Part Number
Tracking Bracket for Endocavity Transducer	667-145

Epiq 5/7 Ultrasound Function Compatibility:

Function	Setting
XRES	ON
WideScan	OFF
Depths	4.0cm, 5.0cm, 6.1cm, 7.0cm, 8.0cm, 9.1cm
SonoCT	ON
Harmonics	OFF
2D OPT	Gen
Dyn Range	60
Loop Length	3 sec
AutoScan	OFF
Contrast	OFF
PercuNav	OFF
Res/Spd	Shaded area in the middle of fan
Grey Map	3
Chroma Map	OFF
Persistence	OFF
Output Power	-1.0dB
ECG	OFF
M-Mode	OFF
CPA	OFF
PW	OFF
Color	OFF
3D	OFF
External Video DisplayPort Format	Digital (DisplayPort-HDMI): Select "Full-screen 1080p (S-video disabled)"

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Philips

Supported Needle Guide:

Manufacturer	Description	Manufacturer's Part Number
CIVCO	Needle Guide	667-133

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Philips

Siemens S2000/S3000 and MC9-4

Siemens S2000/S3000 Ultrasound Function Compatibility:

Function	Setting
Biopsy	ON
Size	3 (to match fan beam)
Preset	Prostate (Factory Default)
Depths	4.0cm, 5.0cm, 6.0cm, 7.0cm, 8.0cm, 9.0cm
Live Dual	OFF
Full Screen	Enable
Imaging Mode	2D
PW Mode	OFF
Orientation	(Full Screen On, L/R Off, U/D On, Small A Bottom Left)
Color Doppler (C)	OFF (Not Supported)
Dynamic TCE	Low

Supported Needle Guide:

Manufacturer	Description	Manufacturer's Part Number
CIVCO	Needle Guide	676-157

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Appendix C

Supported ultrasound and transducer probe combinations for transperineal workflows

The following table provides a list of supported transperineal workflow ultrasound systems and associated transducer probes:

Ultrasound	Transducer probes
BK 3000/5000	E14CL4b (with UroNav Stepper) E14CL4b (with PrecisionPoint™, CIVCO TP Pivot Pro™)
BK FlexFocus 400/500/700/800	8848 (with UroNav Stepper) 8848 (with PrecisionPoint, CIVCO TP Pivot Pro)
BK Specto(10)	E14CL4b (with UroNav Stepper) E14CL4b (with PrecisionPoint, CIVCO TP Pivot Pro)
Hitachi Noblus	C41L47RP (with UroNav Stepper)
Hitachi/Fujifilm Arietta Precision	C41L47RP (with UroNav Stepper) C41L47RP (with PrecisionPoint) CL4416R1 (with PrecisionPoint, CIVCO TP Pivot Pro)
Hitachi/Fujifilm Arietta 65	C41L47RP (with UroNav Stepper) C41L47RP (with PrecisionPoint) CL4416R1 (with PrecisionPoint, CIVCO TP Pivot Pro)

NOTICE

Free-hand, transperineal workflows are only supported in the biopsy workflow and requires the use of the probe holder listed below:

The following list provides part numbers for reordering probe holders for transperineal workflows:

Ultrasound transducer probe	Philips part number	Reorder part number
BK 8848 and E14CL4b	4598-014-79211	FCS0137 (Set of 25)
Hitachi/Fujifilm C41L47RP	3000-088-65321	FCS0147 (Set of 25)
Hitachi/Fujifilm CL4416R1	3000-137-74381	FC50416 (Set of 25)

The following list provides part numbers for reordering EM trackers:

(10) For any potential limitations on supported ultrasound system software versions, please see the *452299184541 UroNav 4.3 specifications and compatibility list*.

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Philips

Description	Philips part number	Reorder part number
EM tracker	4598-007-83602	FCS0140 (Set of 3)

To order additional supplies, consumable instrumentation, or accessories, please contact Philips Customer Service. See “Help and guidance information” on page 8.

Transperineal workflow probe holder mounting instructions

CAUTION

Failure to fully secure the EM Tracker to the Probe Holder will compromise the positional tracking of the TRUS probe resulting in grossly inaccurate registration between the US imaging and EM tracked tools.

CAUTION

Failure to fully secure the Probe holder to the Probe will compromise the positional tracking of the TRUS probe resulting in grossly inaccurate registration between the US imaging and EM tracked tools.

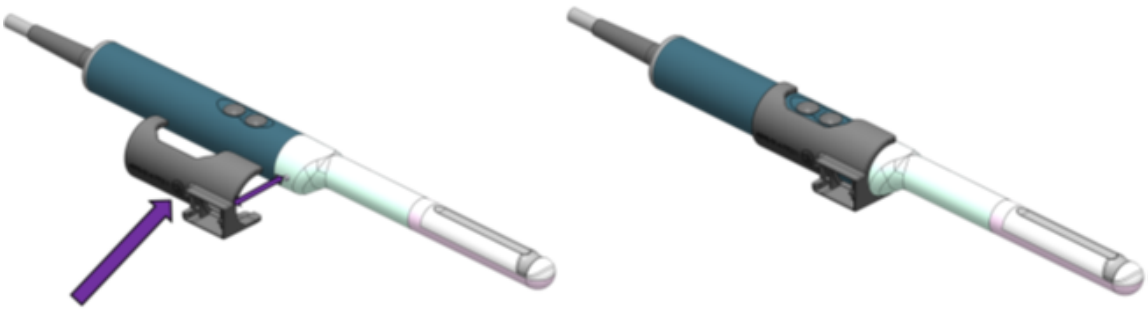
CAUTION

Improper or insecure mounting of free-hand transperineal needle guide can lead to the needle guideline moving out of imaging plane resulting in inaccurate targeting.

NOTICE

See “Appendix D” on page 231 for instructions on mounting the ultrasound transducer probes to the Stepper.

BK 8848 and E14CL4b free-hand transperineal probe holder mounting instructions



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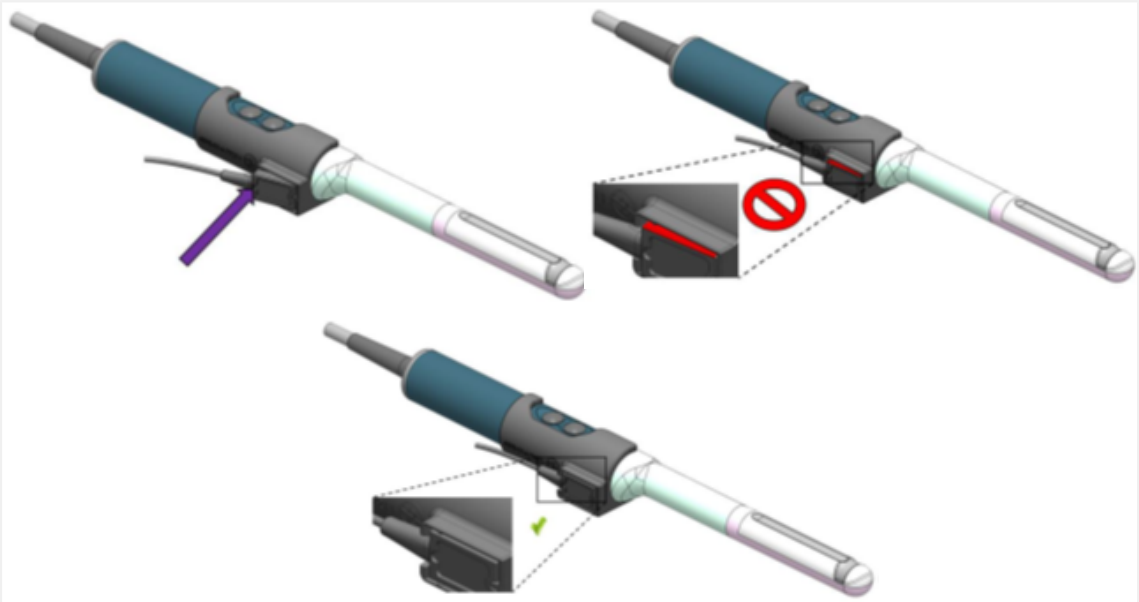
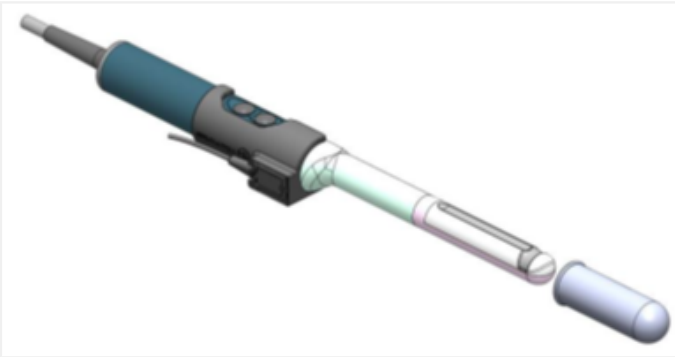
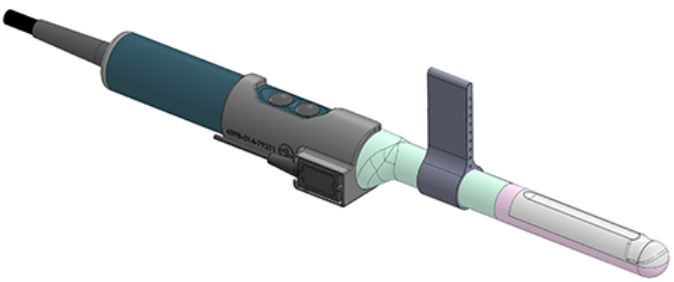


Apply force until flush.



Install cover per the manufacturer's instructions over transducer and UroNav probe holder.



Apply force to reseat.

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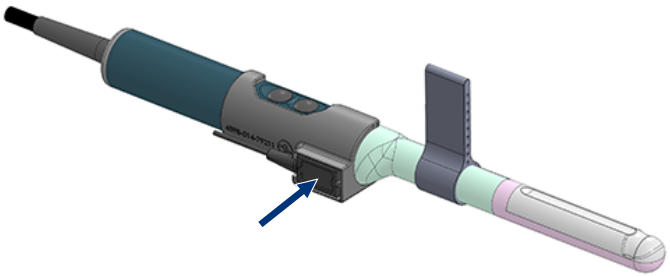
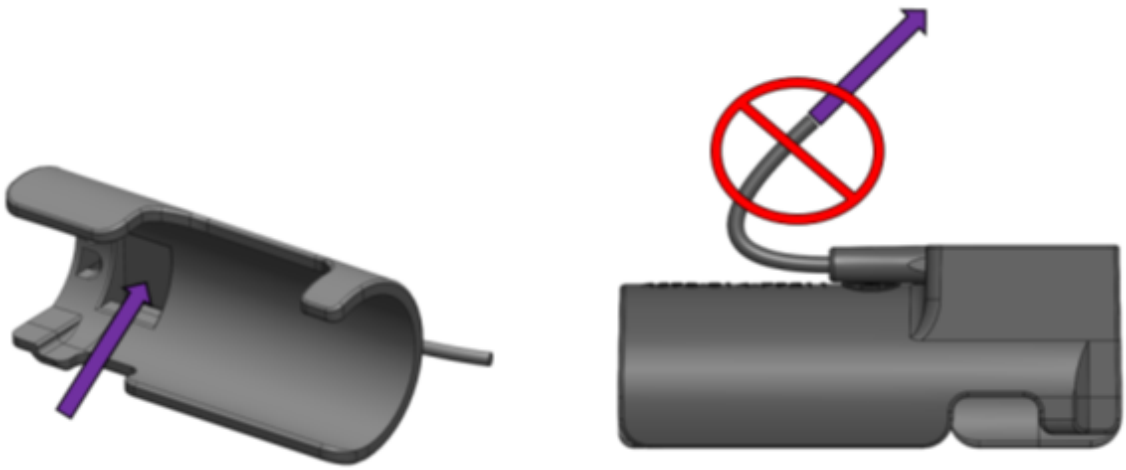
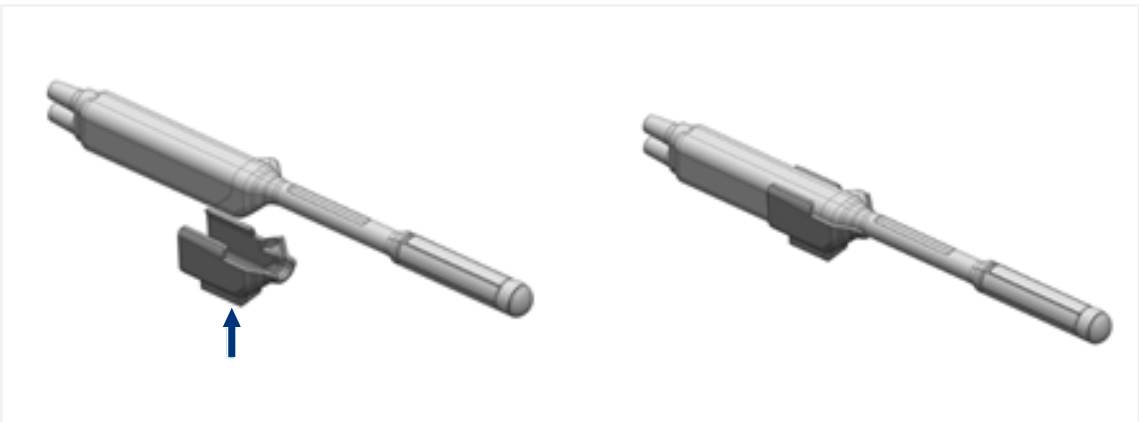
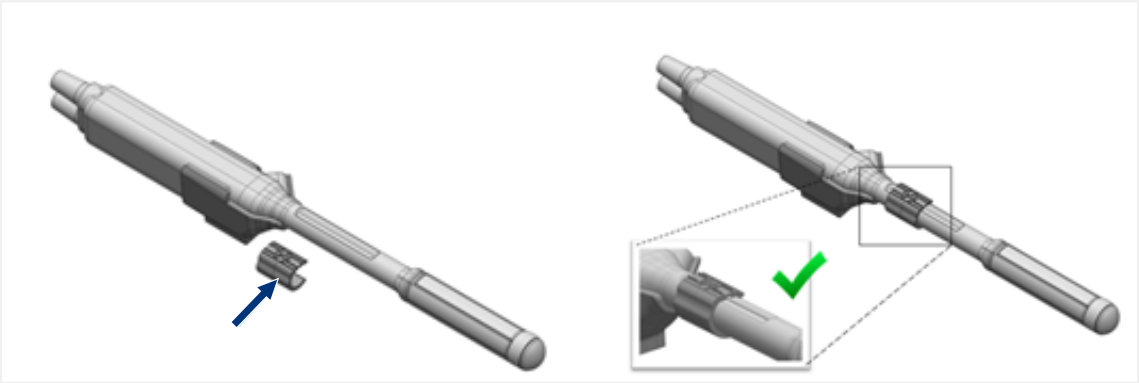


Tracker removal from BK 8848 and E14CL4b probe holders

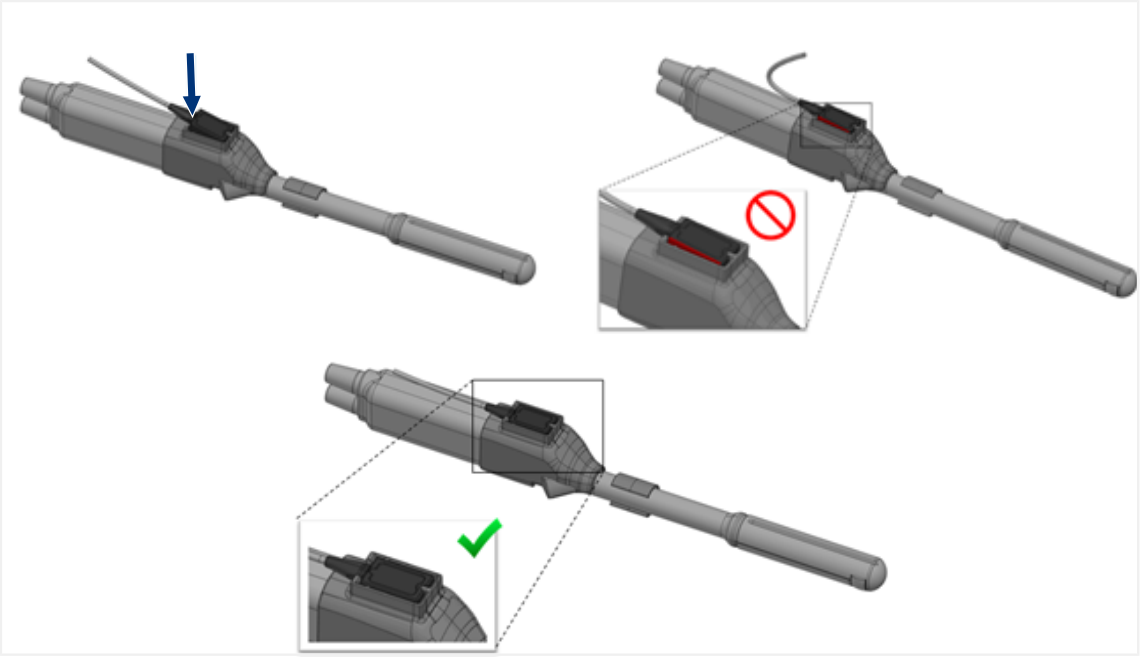


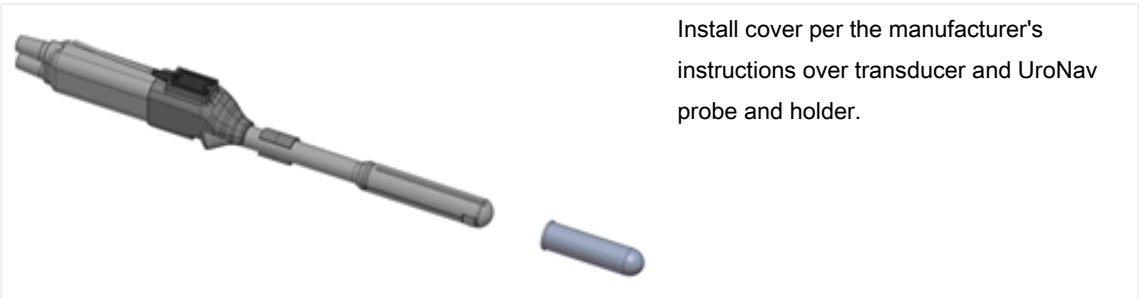
Hitachi C41L47RP free-hand transperineal probe holder mounting instructions





Apply force until flush.





Install cover per the manufacturer's instructions over transducer and UroNav probe and holder.

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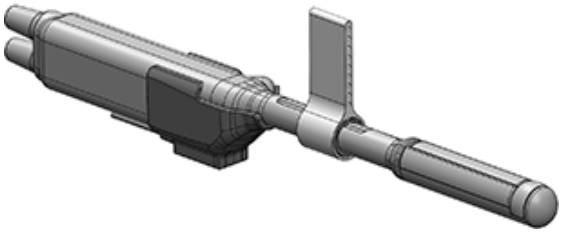
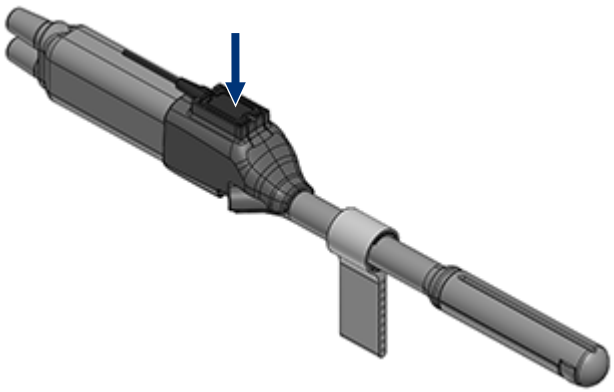
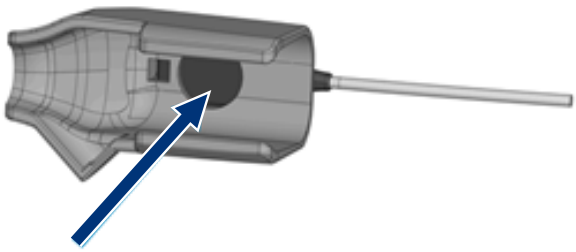


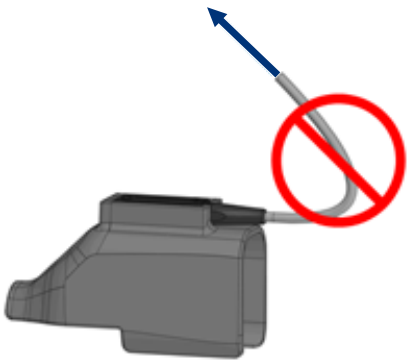
Install free-hand transperineal needle guide per the manufacturer's instructions.

Apply force to reseat.

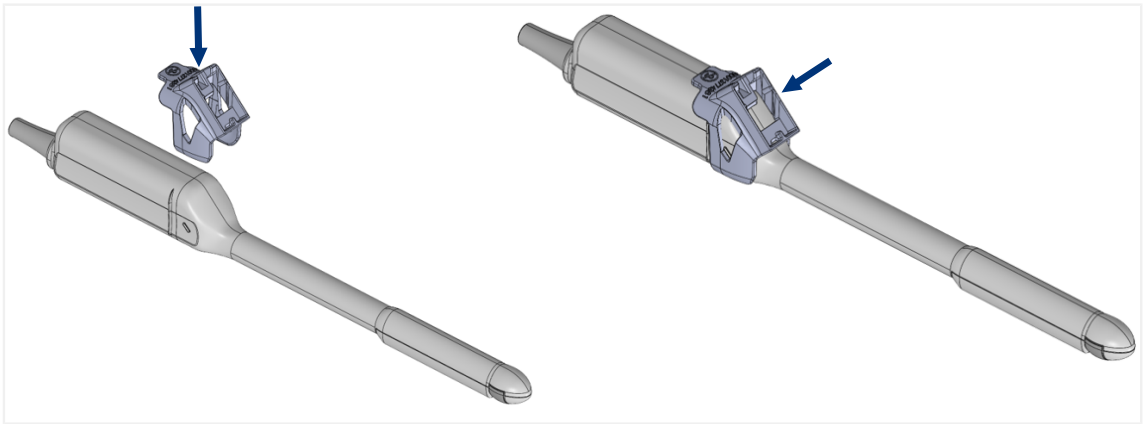


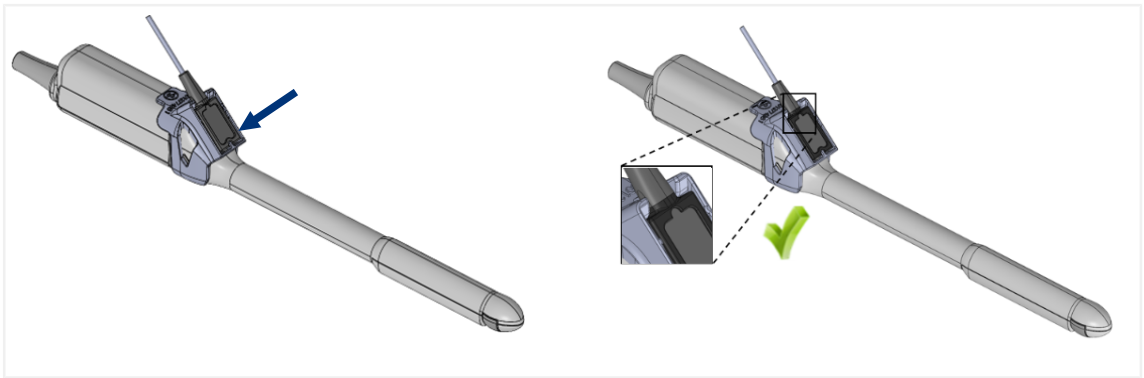
Tracker removal from Hitachi C41L47RP



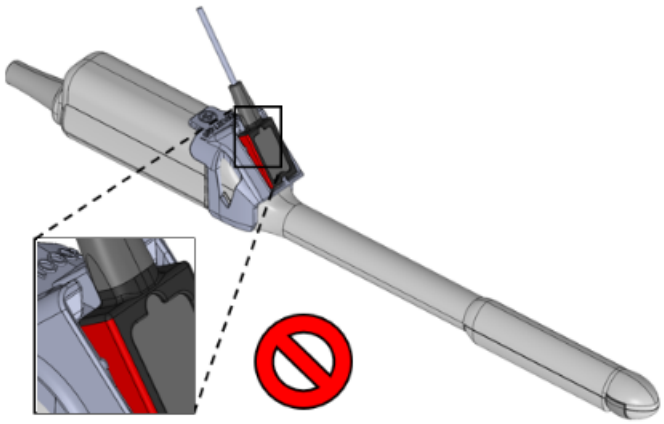


Hitachi/Fujifilm CL4416R1 free-hand transperineal probe holder mounting instructions





Apply force until flush.



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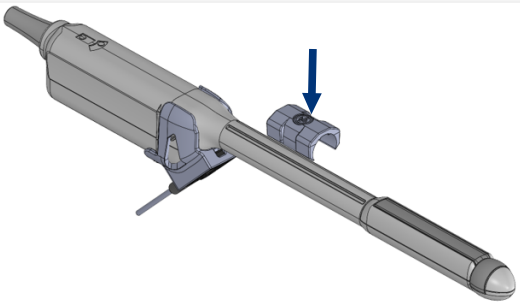
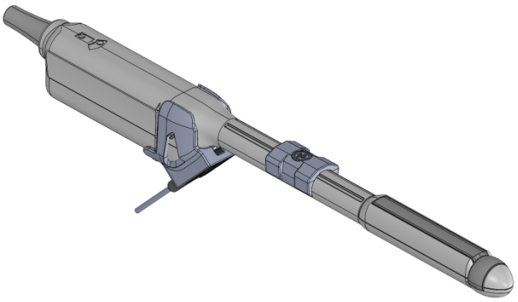
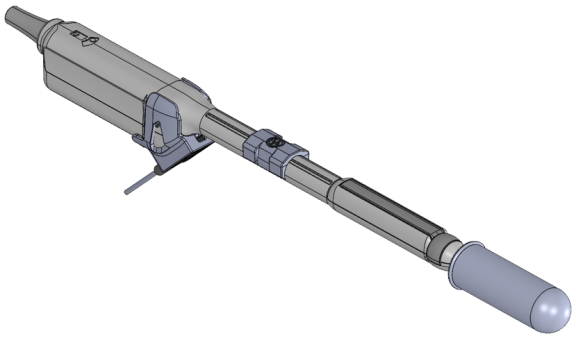
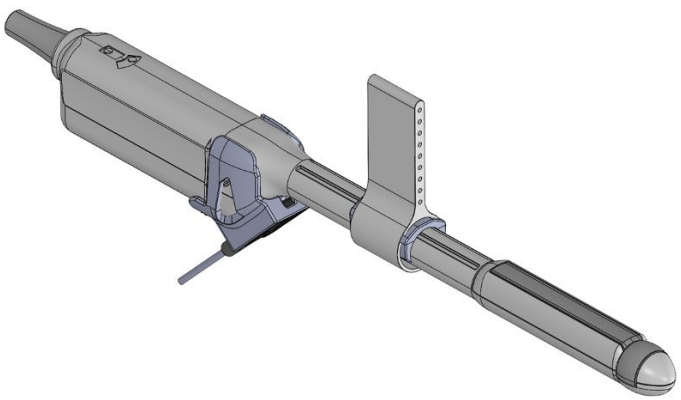






Install cover per the manufacturer's instructions over transducer and UroNav probe holder.



Apply force to reseat.

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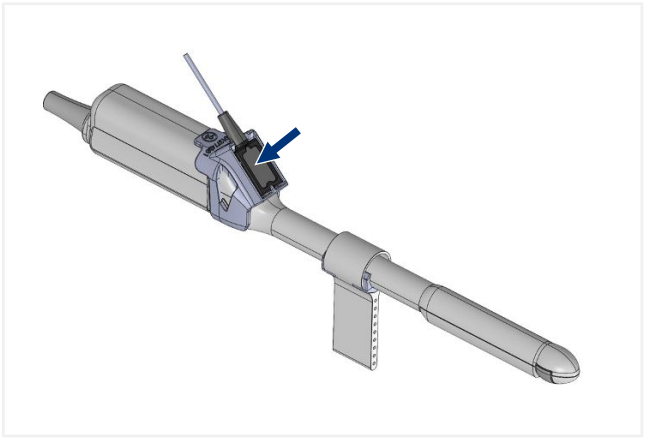
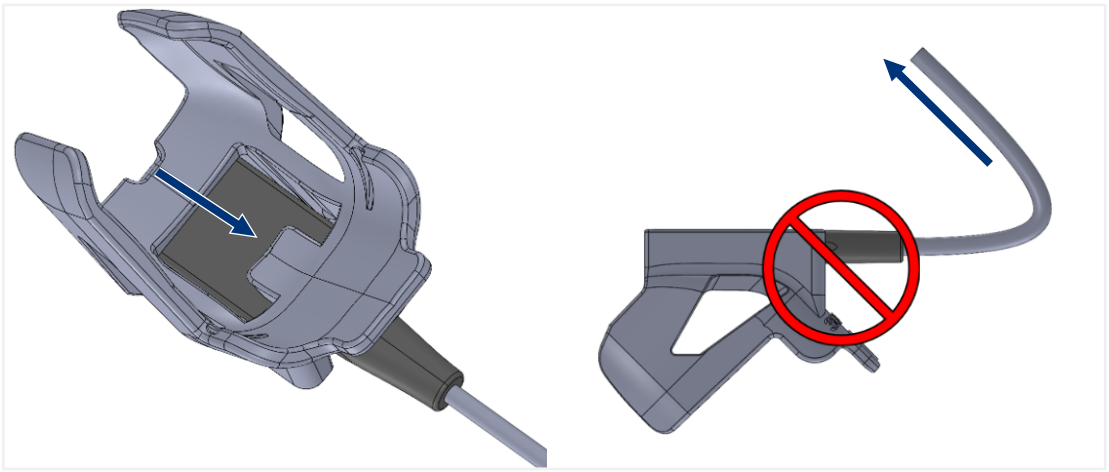


Tracker removal from Hitachi/Fujifilm CL4416R1



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Philips

Required ultrasound system settings for transperineal workflows

This section provides the required ultrasound system settings for transperineal workflows that facilitates proper video calibration with UroNav used with specific transducer probes and needle guides.

BK Flex Focus and 8848

Flex Focus Ultrasound Function Compatibility:

Function	Setting
Preset	“Uro Prostate: Prostate L” or “Uro Prostate: Prostate 12”
Color	Not Supported
Depths	Sagittal Imaging Plane: 4.2cm, 5.6cm 6.4cm, 6.5cm, 7.4cm, 7.5cm, 8.5cm Transverse Imaging Plane: 4.6cm, 5.4cm, 6.3cm, 7.3cm, 7.4cm, 8.5cm
Doppler/M-mode	Not Supported
Dual View	Not Supported
Harmonic	Not Supported
Imaging	2D, Sagittal and Transverse Planes
Orientation	Bottom View (L/R Off, U/D On, Small BK Logo Bottom Left)
Size	100% Only
Video I/O	Digital (DVI-HDMI): Must be Passive Display, Large Font, Black and White
Width	100% Only
Zoom	Not Supported

Supported Needle Guide:

Manufacturer	Description
PERINEOLOGIC	PrecisionPoint Transperineal Access System
CIVCO	TP Pivot Pro

NOTICE

The list of supported grid plates and accessories for the UroNav Stepper can be viewed in “Supported Stepper accessories” on page 165.

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Philips

BK 3000/5000 (software versions 5.8.0 – 5.14.8) and E14CL4b

BK 3000/5000 (SW versions 5.8.0 - 5.14.8) Ultrasound Function Compatibility:

Function	Setting
Color	Not Supported
Depths	4.0cm, 5.0cm 6.0cm, 7.0cm, and 8.0cm
Doppler/M-mode	Not Supported
Dual View	Not Supported
Harmonic	Not Supported
Imaging	2D, Sagittal and Transverse Planes
Orientation	Bottom View (L/R Off, U/D On, Small BK Logo Bottom Left)
Size	100% Only
Video I/O	Digital (DVI): Must be Passive Display, Large Font, Black and White
Width	100% Only
Zoom	Not Supported

Supported Needle Guide:

Manufacturer	Description
PERINEOLOGIC	PrecisionPoint Transperineal Access System
CIVCO	TP Pivot Pro

NOTICE

The list of supported grid plates and accessories for the UroNav Stepper can be viewed in “Supported Stepper accessories” on page 165.

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Philips

BK 3000/5000 (software version 5.16.x) and E14CL4b

BK 3000/5000 (SW v5.16.x) Ultrasound Function Compatibility:

Function	Setting
Exam Type	Prostate (Any Preset)
R/L Invert	OFF
Sector Width	100
U/D Invert	ON
Image Size	100%
Dual Layout	OFF
Dual	OFF
Biopsy, E14CL4b	OFF
Video Output Mode	Passive
Video Output Port	DVI

Supported Needle Guide:

Manufacturer	Description
PERINEOLOGIC	PrecisionPoint Transperineal Access System
CIVCO	TP Pivot Pro

NOTICE

The list of supported grid plates and accessories for the UroNav Stepper can be viewed in “Supported Stepper accessories” on page 165.

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BK Specto and E14CL4b

BK Specto Ultrasound Function Compatibility:

Function	Setting
Biopsy	OFF
Color	Not Supported
Depths	4.0cm, 5.0cm 6.0cm, 7.0cm, and 8.0cm
Doppler/M-mode	Not Supported
Dual	OFF
Dual Layout	OFF
Exam Type	Prostate (Any Preset)
Harmonic	Not Supported
Image Size	100% Only
Imaging	2D, Sagittal and Transverse Planes
Monitor	Portrait Orientation
Orientation	Bottom View (Small BK Logo Bottom Left)
R/L Invert	OFF
Sector Width	100
U/D Invert	ON
Video Output Mode	Passive
Width	100% Only
Zoom	Not Supported
Video Output Port	HDMI
Font size	Small (for BK Specto software version 6.6.8 and greater)

Supported Needle Guide:

Manufacturer	Description
PERINEOLOGIC	PrecisionPoint Transperineal Access System
CIVCO	TP Pivot Pro

NOTICE

The list of supported grid plates and accessories for the UroNav Stepper can be viewed in “Supported Stepper accessories” on page 165.

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Hitachi Noblus and C41L47RP

Hitachi Noblus Ultrasound Function Compatibility:

Function	Setting
Curved Transverse (T): Angle	5
Linear Sagittal (L): Angle	6
B Gray Map	5
Up-Down Shift	OFF
Vertical Shift	0
Texture	Smooth
Density	3
B Dyn.	65
Depths	4.0cm, 5.0cm, 6.0cm, 7.0cm, 8.0cm, 9.0cm
Hi REZ+	5
dTHI	OFF
HI Support	OFF
PW	OFF
Imaging Mode	B-Mode, 2D
Orientation	Down (Small “H” Logo Bottom Left or Right). The user may need to adjust the orientation on UroNav via the ALT-F key binding. Sagittal Plane: the “H” logo is oriented opposite of the orientation indicator on UroNav.
Video I/O	Digital (DVI-HDMI): Resolution 1024x768
Zoom	Not Supported

NOTICE

The list of supported grid plates and accessories for the UroNav Stepper can be viewed in “Supported Stepper accessories” on page 165.

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Philips

Hitachi/Fujifilm Arietta Precision and C41L47RP

Hitachi/Fujifilm Arietta Precision Ultrasound Function Compatibility:

Function	Setting
Condition, C41L47RP	Prostate Biplane
Initial Mode	Single
Single Format Size (W)	Wide
B Mode Format Size (H)	Wide
Scan Area (B)	100%
Invert L/R	OFF
Image Rotation	180 deg
Vertical Shift	0.0 cm
Biplane Invert L/R (L)	ON
Biplane Invert L/R (T)	OFF
Biplane Image Rotation (L)	180 deg
Biplane Image Rotation (T)	180 deg
Full Image	OFF
Puncture Guide Line, C41V	ON
Puncture Guide Line, C41L47RP	OFF
Mirror Inversion Display	OFF
External Output	HDMI
Depths	4.0 cm, 5.0 cm, 6.0 cm, 7.0 cm, 8.0 cm, 9.0 cm,10.0 cm,11.0 cm, 12.0 cm

Manufacturer	Description
PERINEOLOGIC	PrecisionPoint Transperineal Access System

NOTICE

The list of supported grid plates and accessories for the UroNav Stepper can be viewed in “Supported Stepper accessories” on page 165.

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Philips

Hitachi/Fujifilm Arietta 65 and C41L47RP

Hitachi/Fujifilm Arietta 65 Ultrasound Function Compatibility:

Function	Setting
Info Display Position	Lower
Vertical Shift	0 mm
HI Zoom	OFF
PAN Zoom	OFF
Scan Area (B)	100
Biplane Scan Area (B) (T)	100
Biplane Scan Area (B) (L)	100
Initial Mode	B
B Mode Format Size (H)	Normal
B Invert L/R	OFF
B Invert U/L	OFF
B Image Rotation	180 deg
Biplane Invert L/R (L)	ON
Biplane Invert L/R (T)	OFF
Biplane Invert U/L (L)	OFF
Biplane Invert U/L (T)	OFF
Biplane Image Rotation (L)	180 deg
Biplane Image Rotation (T)	180 deg
Trapezoidal Scanning	OFF
Puncture Guide Line, C41L47RP	OFF
External Output (Must have the EU-9210 option box installed)	EXTOUT HDMI port of the EU-9210 option box with the switches set to the following: Margin = Off, XGA = Off, and CLIP = On
Available Depths	4.0 cm, 5.0 cm, 6.0 cm, 7.0 cm, 8.0 cm, 9.0 cm,10.0 cm,11.0 cm, 12.0 cm

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Supported Needle Guide:

Manufacturer	Description
PERINEOLOGIC	PrecisionPoint Transperineal Access System

NOTICE

The list of supported grid plates and accessories for the UroNav Stepper can be viewed in “Supported Stepper accessories” on page 165.

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Philips

Hitachi/Fujifilm Arietta Precision and CL4416R1

Hitachi/Fujifilm Arietta Precision Ultrasound Function Compatibility:

Function	Setting
Preset	Prostate Biplane
Plane +	Sole Supported Function for Switching Planes
Plane	Not Supported
Select	Not Supported
Initial Mode	Single
Single Format Size (W)	Wide
B Mode Format Size (H)	Wide
Scan Area (B)	100%
Invert L/R	OFF
Image Rotation	180 deg
Cine Memory Division	2
Vertical Shift	0.0 cm
Biplane Invert L/R (L)	ON
Biplane Invert L/R (T)	OFF
Biplane Initial Plane	T
Biplane Image Rotation (L)	180 deg
Biplane Image Rotation (T)	180 deg
Biplane Label	ON
Real-time Biplane	OFF
Full Image	OFF
Puncture Guide Line	ON
Puncture Angle Select	3
Puncture Display Pattern	Single
Mirror Inversion Display	OFF

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Philips

Function	Setting
External Output	HDMI
Depths	4.0 cm, 5.0 cm, 6.0 cm, 7.0 cm, 8.0 cm, 9.0 cm, 10.0 cm, 11.0 cm, 12.0 cm

Manufacturer	Description
PERINEOLOGIC	PrecisionPoint Transperineal Access System
CIVCO	TP Pivot Pro

NOTICE

The list of supported grid plates and accessories for the UroNav Stepper can be viewed in “Supported Stepper accessories” on page 165.

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Philips

Hitachi/Fujifilm Arietta 65 and CL4416R1

Hitachi/Fujifilm 65 Ultrasound Function Compatibility:

Function	Setting
HI Zoom	OFF
PAN Zoom	OFF
Plane +	Sole Supported Function for Switching Planes
Plane	Not Supported
[Dual] key, [Single] key	Not Supported
Vertical Shift [mm]	0
Scan Area (B)	100
Wide Scanning	OFF
Biplane Scan Area (B) [T]	100
Biplane Scan Area (B) [L]	100
Initial Mode	B
B Mode Format Size (H)	Normal
B Invert L/R	OFF
B Invert U/L	OFF
B Image Rotation [deg]	180 degrees
Biplane Invert L/R [L]	ON
Biplane Invert L/R [T]	OFF
Biplane Invert U/L [L]	OFF
Biplane Invert U/L [T]	OFF
Biplane Image Rotation (L) [deg]	180 degrees
Biplane Image Rotation (T) [deg]	180 degrees
Trapezoidal Scanning	OFF
Puncture Guide Line, CL4416R1	OFF

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Philips

Function	Setting
Cine Memory Division	2
Biplane Initial Plane	T
Info Display Position	Lower
External Output	1920x1080
(Must have the EU-9210 option box installed.)	EXTOUT HDMI port of the EU-9210 option box with the switches set to the following: Margin = Off, XGA = Off, and CLIP = On
Depths	4.0 cm, 5.0 cm, 6.0 cm, 7.0 cm, 8.0 cm, 9.0 cm, 10.0 cm, 11.0 cm, 12.0 cm

Manufacturer	Description
PERINEOLOGIC	PrecisionPoint Transperineal Access System
CIVCO	TP Pivot Pro

NOTICE

The list of supported grid plates and accessories for the UroNav Stepper can be viewed in “Supported Stepper accessories” on page 165.

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Philips

Appendix D

Stepper arm setup

This appendix provides detailed instructions on the setup of the Stepper arm (shown below), the Stepper, and ultrasound probes, used for transperineal procedures.

This appendix describes:

- a “Stepper arm overview” on page 232
- “Attaching Stepper arm to examination table” on page 233
- the “Stepper setup” on page 238, which includes further details about attaching/removing EM sensors, probes, and grid plates.
- and more information about the “Stepper stand” on page 251

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Stepper arm overview

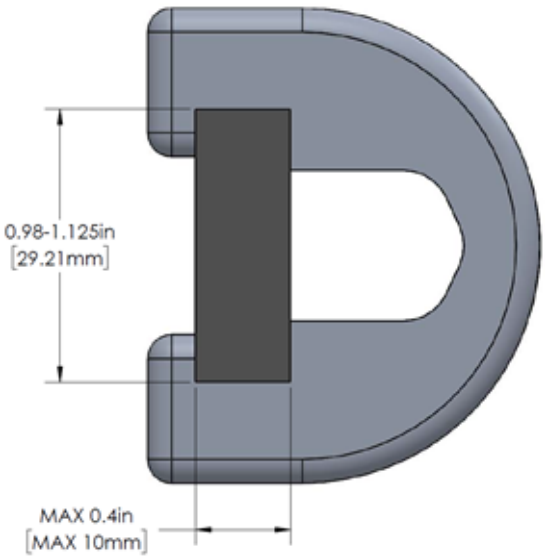
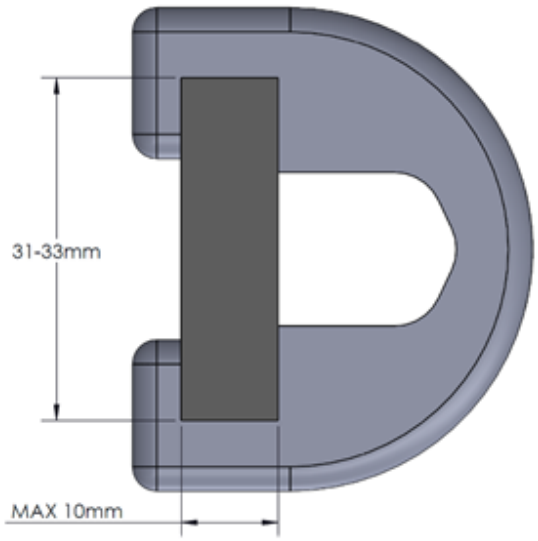
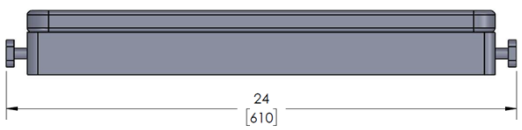
Diagram	Description
	The Stepper arm clamps to EU tables with support bar dimensions of 10mm by 25mm and U.S. tables with support bar dimensions of 0.375 inches by 1.125 inches, as illustrated in the following image:
	The Stepper arm clamps to Japanese tables with support bar dimensions of 9mm by 32mm.
	The Stepper arm accommodates a maximum table width of 24 inches (610 mm).

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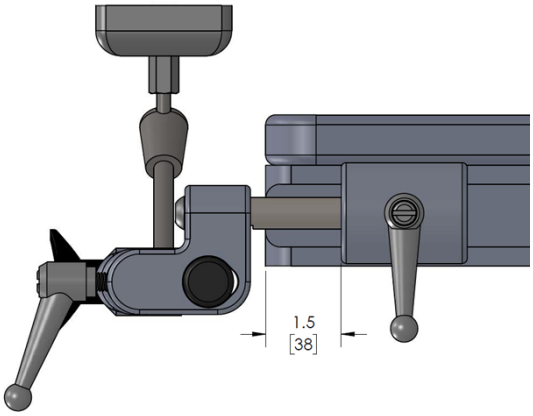
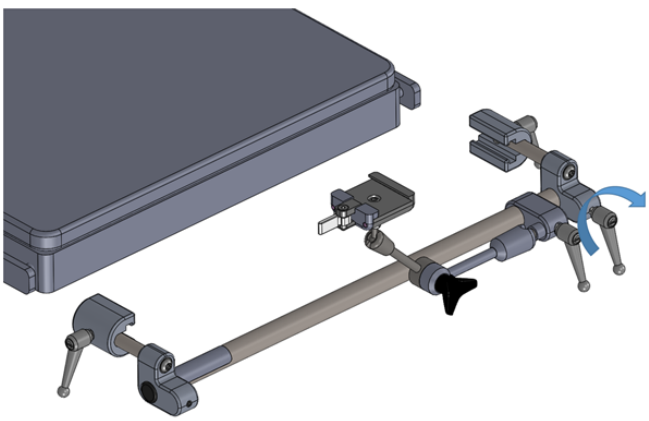
Diagram	Description
	The table support bar must be within 1.5 inches (38mm) from the end of the table.

Attaching Stepper arm to examination table

To attach the Stepper arm to the examination table:

1. Open the width adjustment handle.



2. Place left-side clamp onto the table support bar.
3. Adjust width of the right-side clamp to the width of the table and place right-side clamp onto the table support bar.

NOTICE

When the width adjust handle is open, the clamp can slide off the end of the tube. Do not allow this to happen, as components of the clamp can fall out.

4. Clamp to the proper distance and tighten clamps down carefully.

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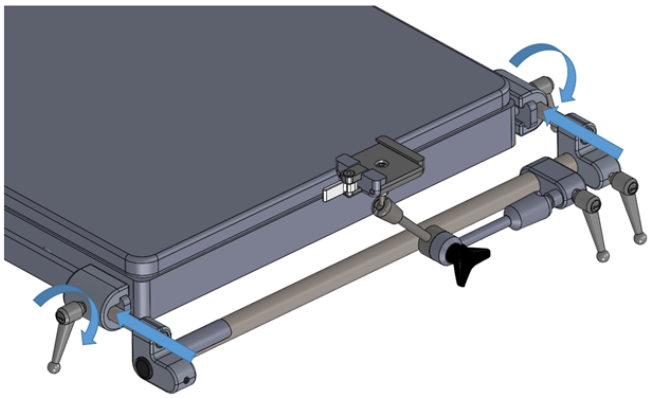
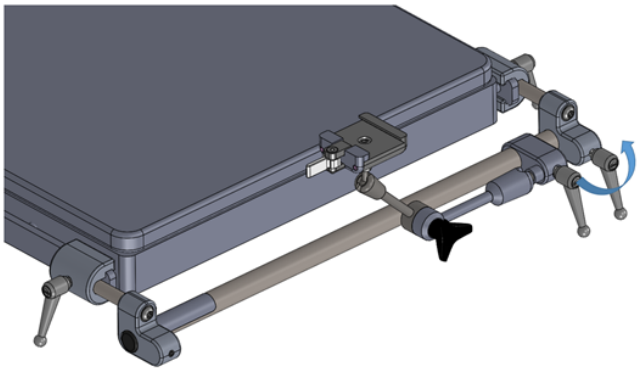
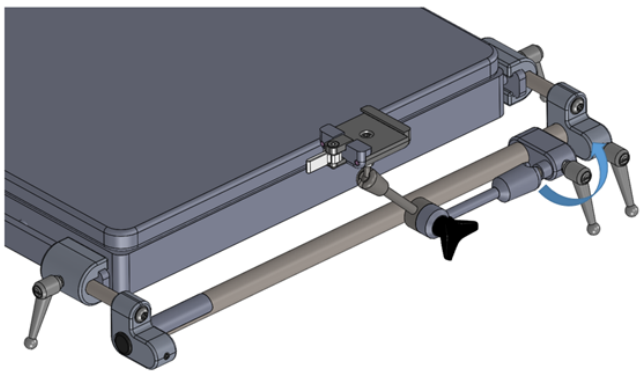


5. Tighten the width adjustment handle once the proper width is found.



The articulated arm can be set for right-hand use or left-hand use. To change handedness:

6. Open the arm adjustment handle.



7. Remove the arm adjustment handle and pull the articulated arm out from the holder.

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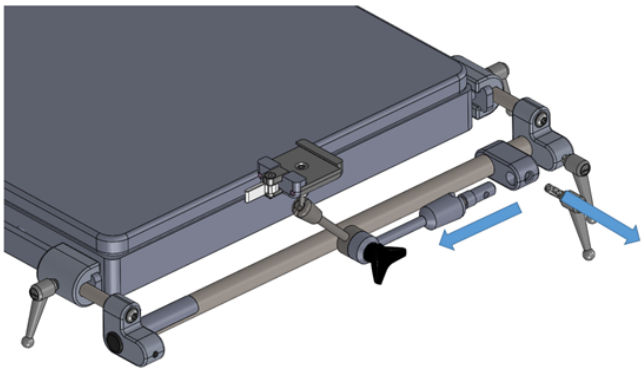
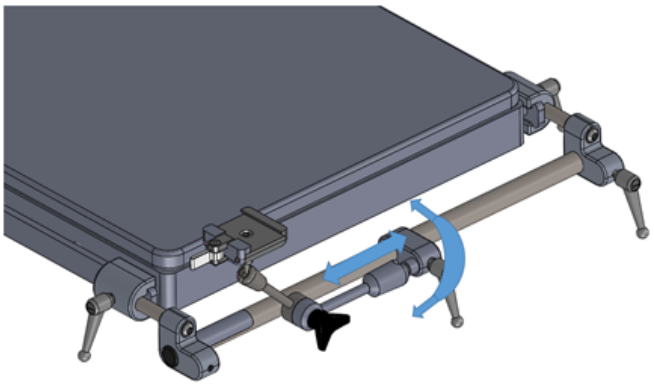


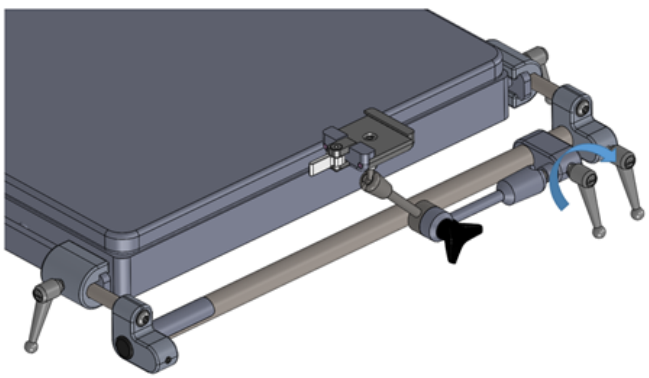
8. Install the articulated arm on the opposite side.
9. Reinstall the arm adjustment handle and tight.
10. Find the optimal vertical and horizontal position for the articulated arm. The horizontal position is adjusted by sliding the articulated arm along the supporting rod. The vertical position is adjusted by rotating the articulated arm around the supporting rod.



NOTICE

The optimal position depends on the individual patient and therefore, the arm position may need adjustment before each procedure.

11. After finding the optimal position, tighten handle.



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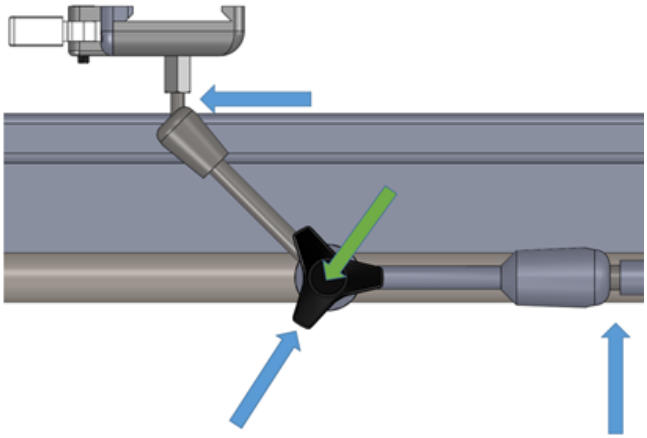
NOTICE

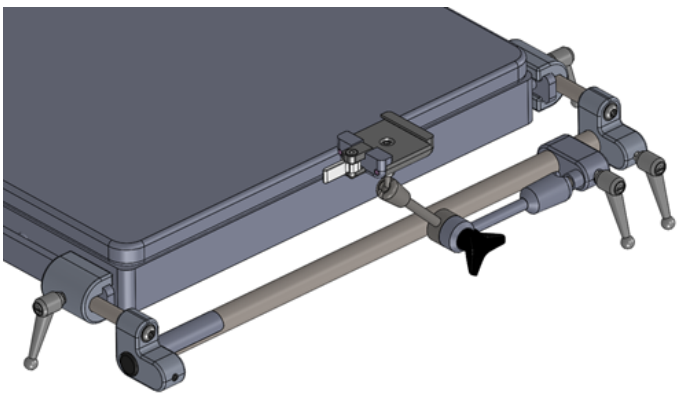
The Stepper Arm is designed to only hold the Stepper. Do not attach any additional devices to the holder assembly.

12. The hand knob releases all three joints of the articulated arm.



NOTICE

Before release, be ready to hold up the Stepper. After the articulated arm is adjusted, tighten hand knob properly. A loose hand knob can cause the joints to drift.



Do not use the Stepper arm if it feels loose or unsteady after installation and adjustment.

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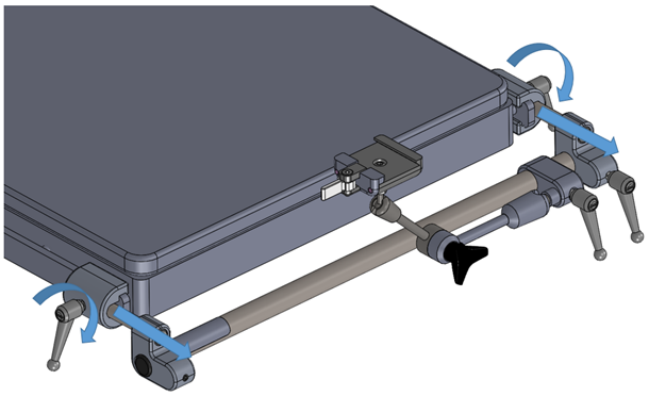
Stepper arm removal

To remove the Stepper arm:

1. Open the clamp handles.
2. Remove the clamps from the table support bar.



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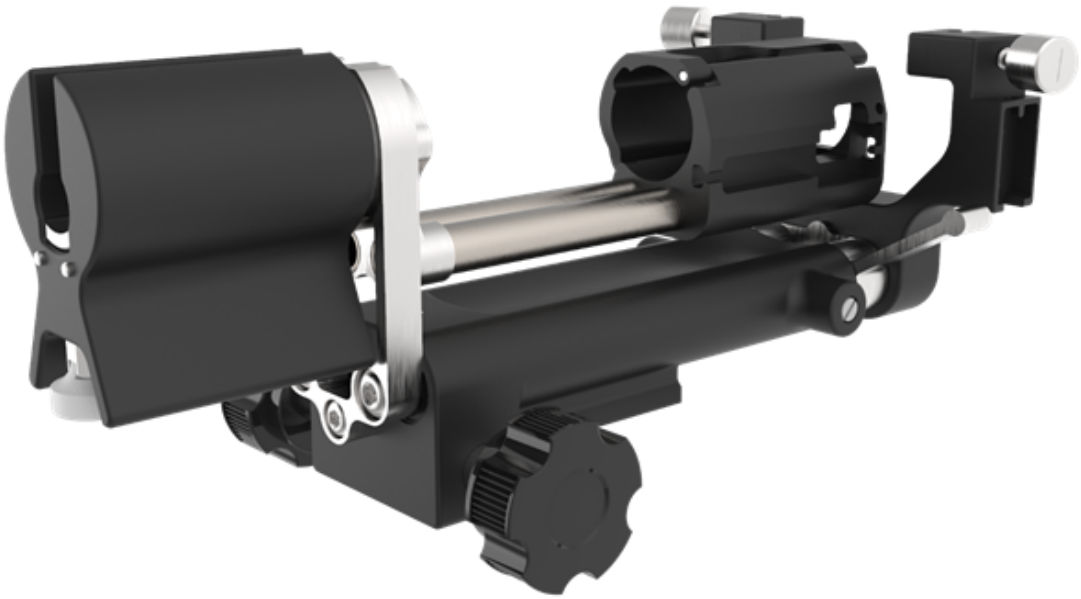
Stepper setup



This section provides further details, including visual examples, related to the Stepper, its installation to the arm, plus installation of EM sensors, probes, and the grid plate. For more information regarding probe or grid plate movements, see “Probe movements” on page 244 and “Grid plate linear and micro movements” on page 245. For information on how to remove EM sensors, probes, and the grid plate, see “Removal of the grid, EM sensor, and probe” on page 247.

Attaching Stepper to the Stepper arm

To install the Stepper to the arm:

- Slide the Stepper in the arm mount and close the lever.

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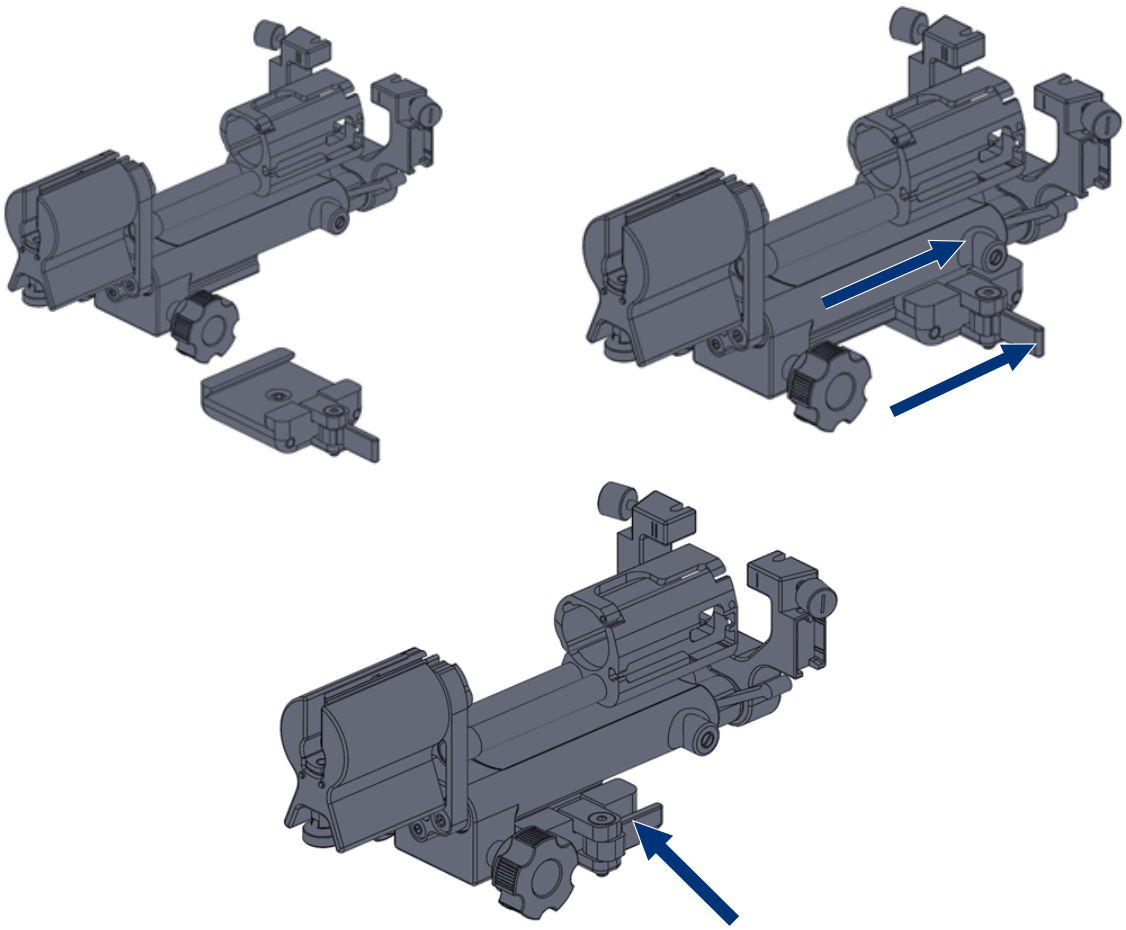

Close the lever forward so it does not interfere with the Stepper.

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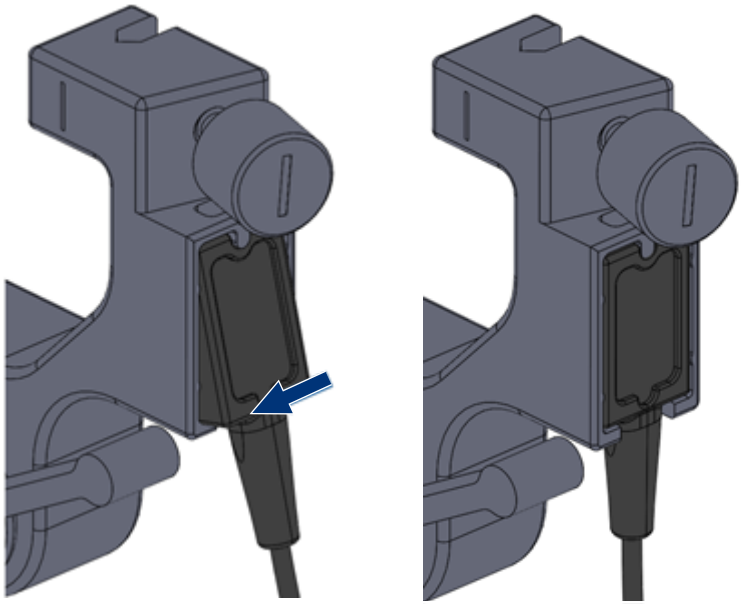
EM sensor installation

To install the EM sensor:



► Push EM sensor into place.

Ensure that the EM sensor is pushed down properly.

CAUTION

Improper mounting of EM sensor to the Stepper can result in inaccurate tracking of the grid compromising the accuracy of the procedure.

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The following images depict examples of various EM sensor installations:

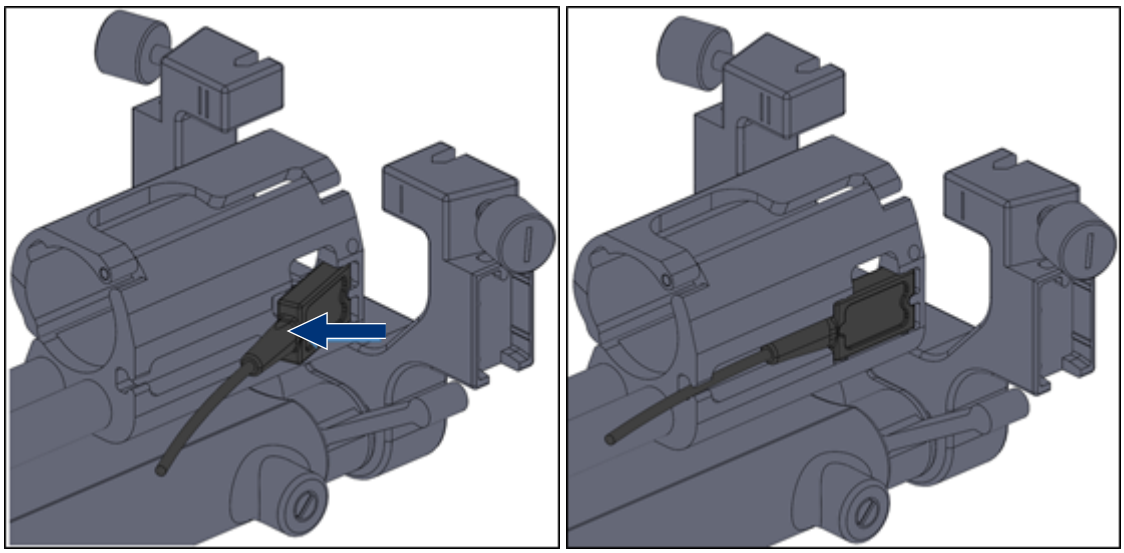

Fig. 7: BK 8848 and E14CL4B EM sensor installation

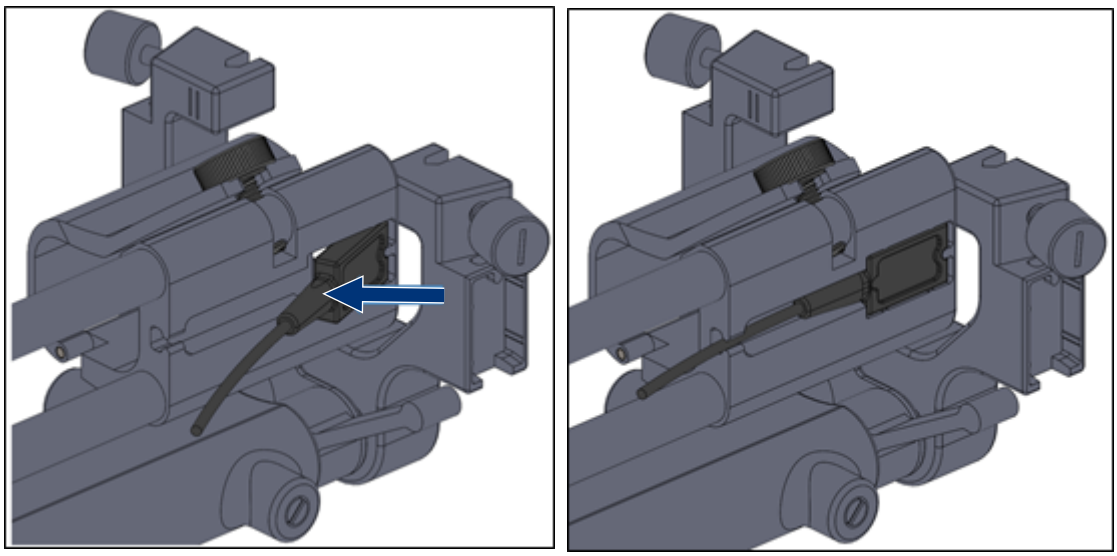

Fig. 8: Hitachi C41L47RP EM sensor installation

CAUTION

Failure to fully secure the EM Tracker to the Probe Holder will compromise the positional tracking of the TRUS probe resulting in grossly inaccurate registration between the US imaging and EM tracked tools.

Probe installation

To install the probe:

1. Slide the probe into place, aligning the reference pin with the holder hole.
2. Close the clamp and tighten the thumbscrew.

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Ensure the probe is firmly and properly mounted.

CAUTION

Improper mounting of the probe to the Stepper could result in inaccurate tracking of the probe, thereby compromising the accuracy of the procedure.

The following images depict examples of various probe installations:

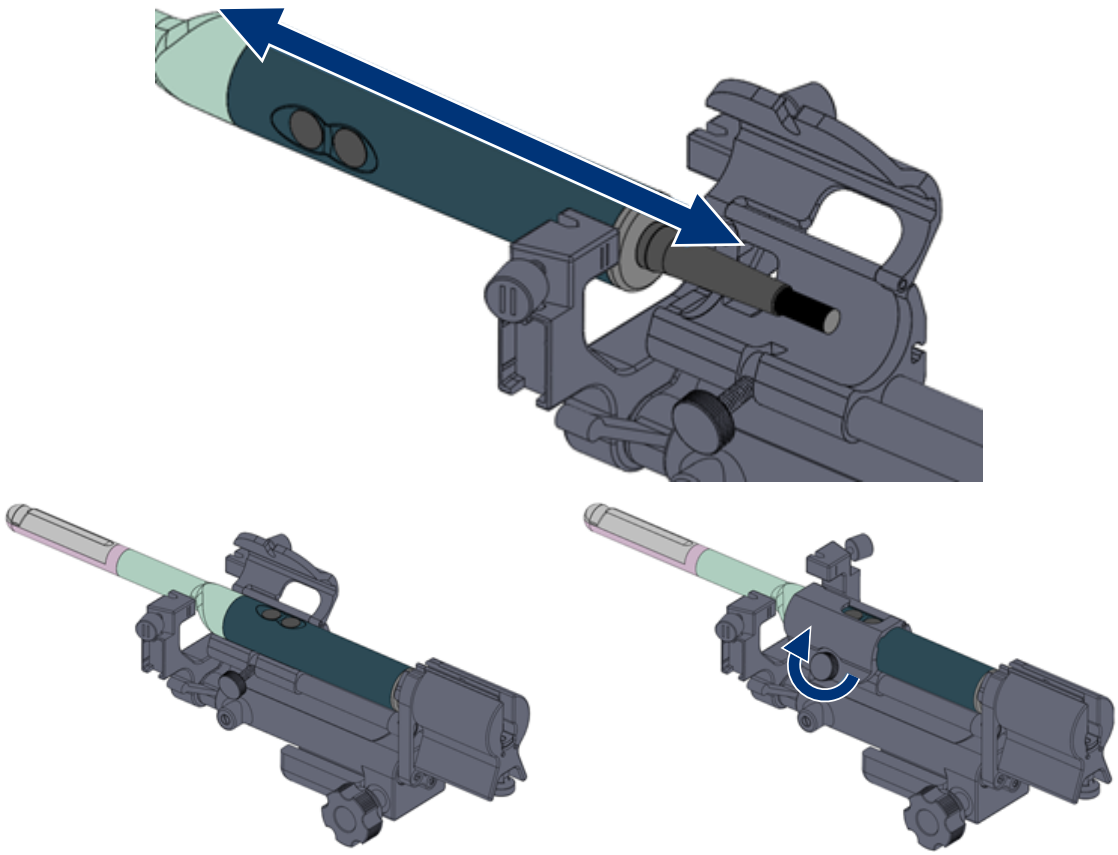

Fig. 9: BK 8848 and E14CL4B Probe Installation

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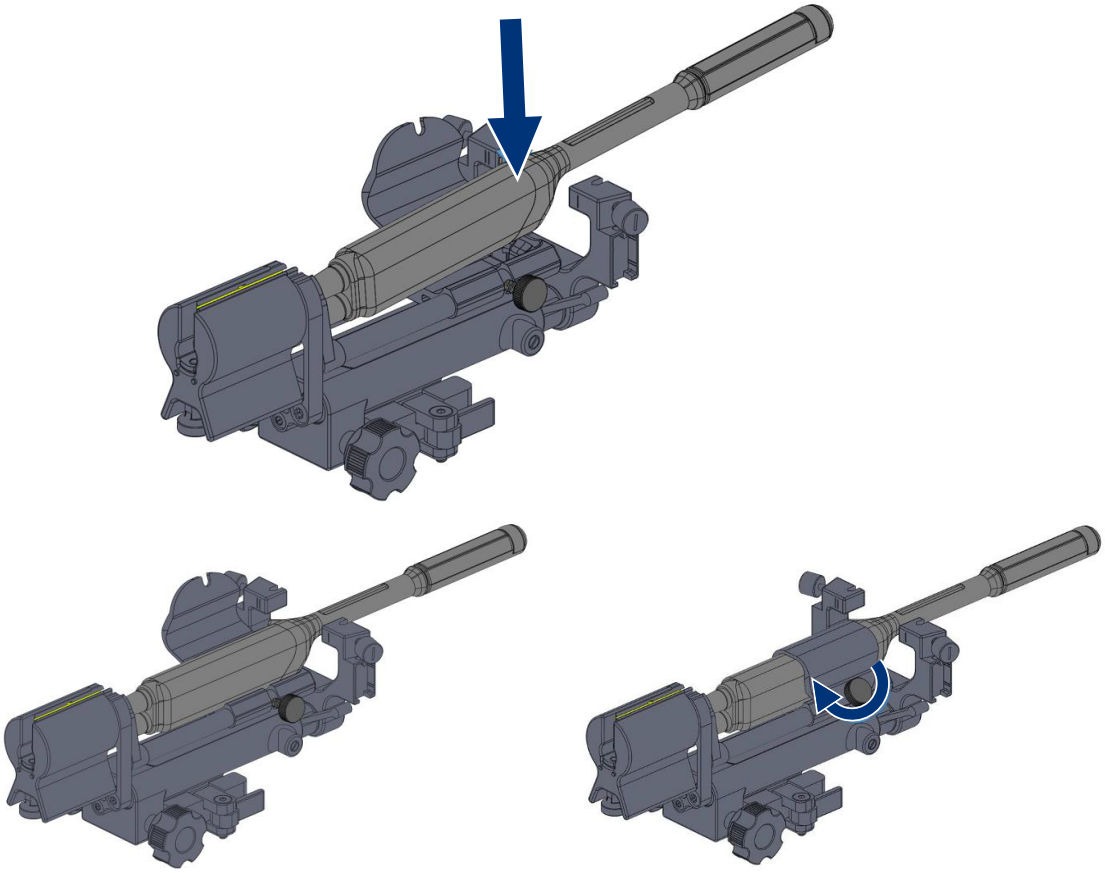
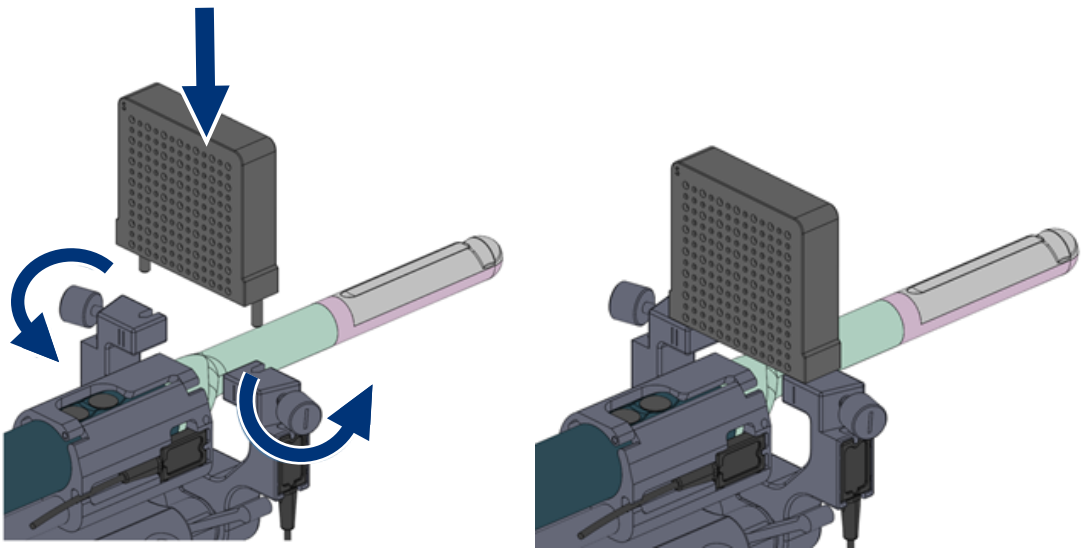


Fig. 10: Hitachi C41L47RP Probe Installation

Grid plate installation

To install the grid plate:



1. Loosen thumbscrews, if necessary, and push grid plate down into place.

2. Tighten thumbscrews. The right side screw is left-hand threaded, so it works in a direction opposite than usual.

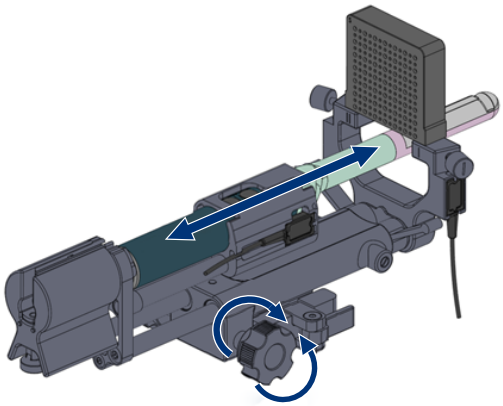
Ensure that the grid plate is pushed properly down.

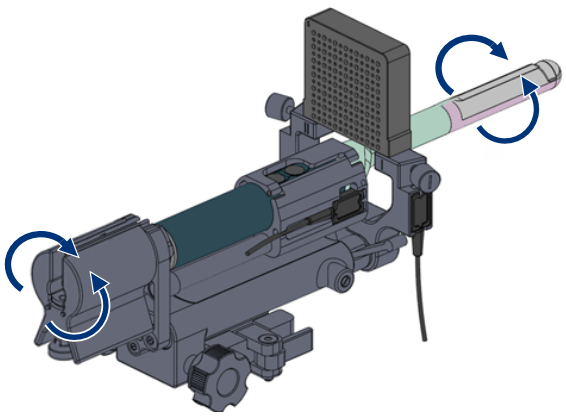
CAUTION

Improper mounting of the grid to the Stepper results in inaccurate tracking of the grid, compromising the accuracy of the procedure.

Probe movements

The following images illustrate possible probe movements:





Use the rotation handle with caution. The opening on the rotation handle may create a pinching point hazard.

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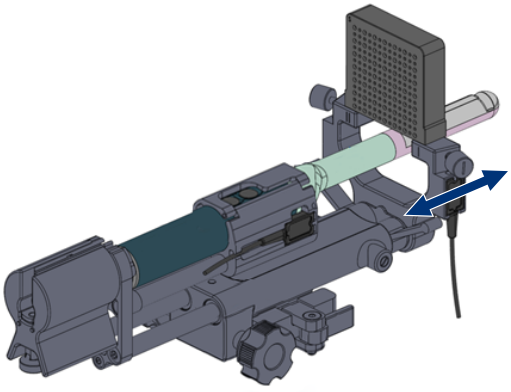
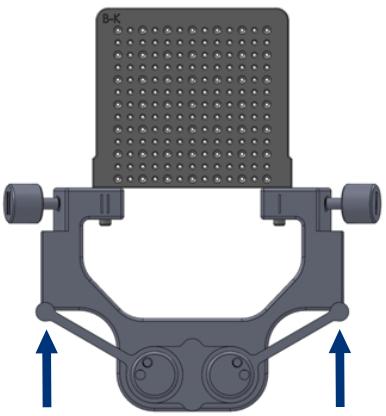
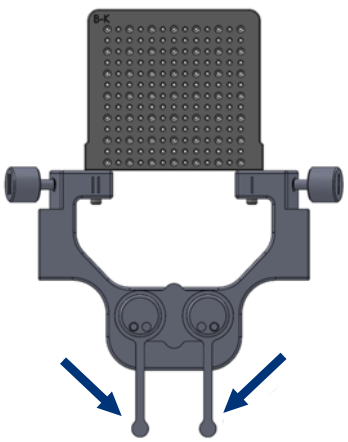
Grid plate linear and micro movements



Before the procedure, lift both levers to the highest position. This is the highest position where the grid plate can be, and it is centralized.



When the levers are pushed down, the grid plate moves vertically downward.



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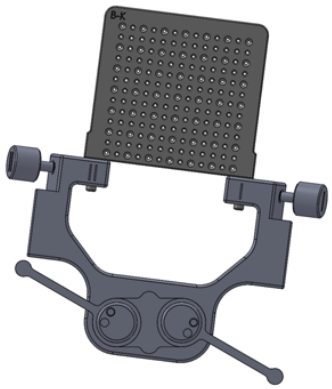
NOTICE

The grid plate can go lower than the probe and interference is possible.

Do not force the grid plate down if it touches the probe.

Moving one lever while the other one remains stationary achieves horizontal movement of the grid plate.



It is always possible to centralize the grid plate. Lift both levers up to centralize the grid plate.

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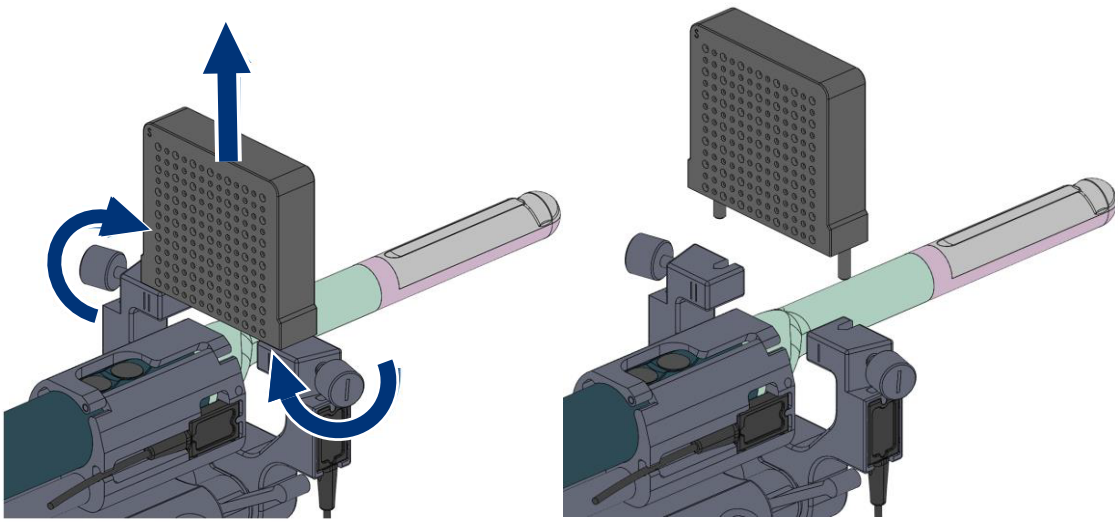
Removal of the grid, EM sensor, and probe

This section provides further details, including visual examples, related to the removal of EM sensors, probes, and the grid plate.

Grid plate removal

To remove the grid plate:

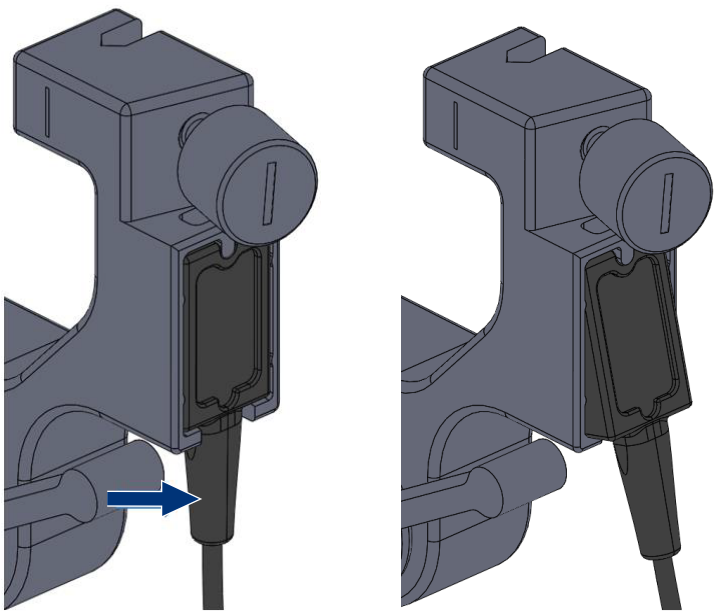
- Loosen thumbscrews, if necessary, and pull grid plate out.



EM sensor removal

To remove the EM sensor from the grid plate mount:

- Push EM sensor out of its place.



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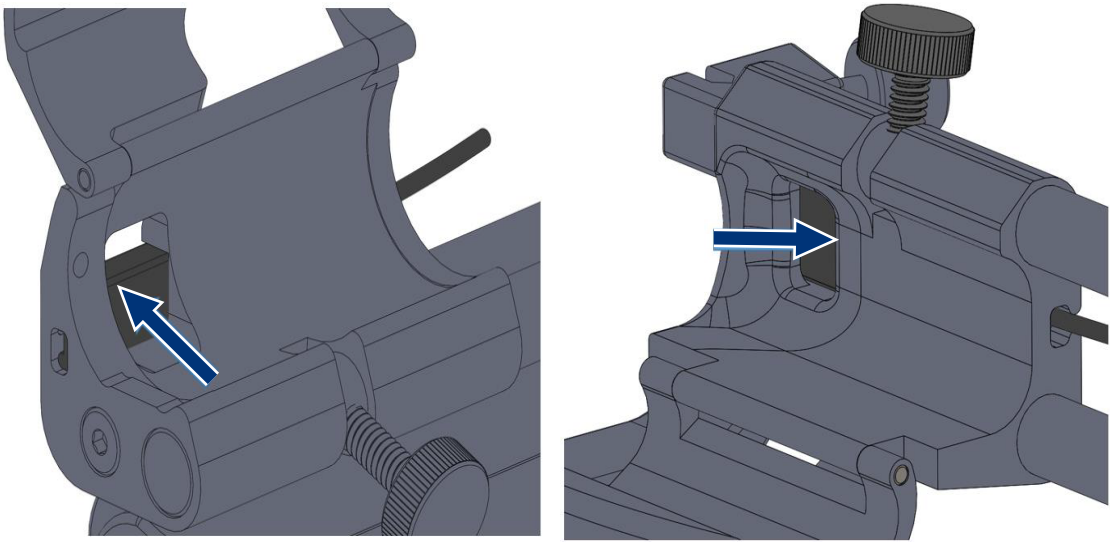
Do not use the cable to pull the EM sensor out.

The following images depict EM sensor removal from the clamp:



To remove the EM sensor from the clamp:

- Push EM sensor out from the opening.

Probe removal

To remove the probe:

1. Loosen the thumbscrew and open the clamp.
2. Lift and slide the probe out of its place.

The following images depict examples of various probe removals:

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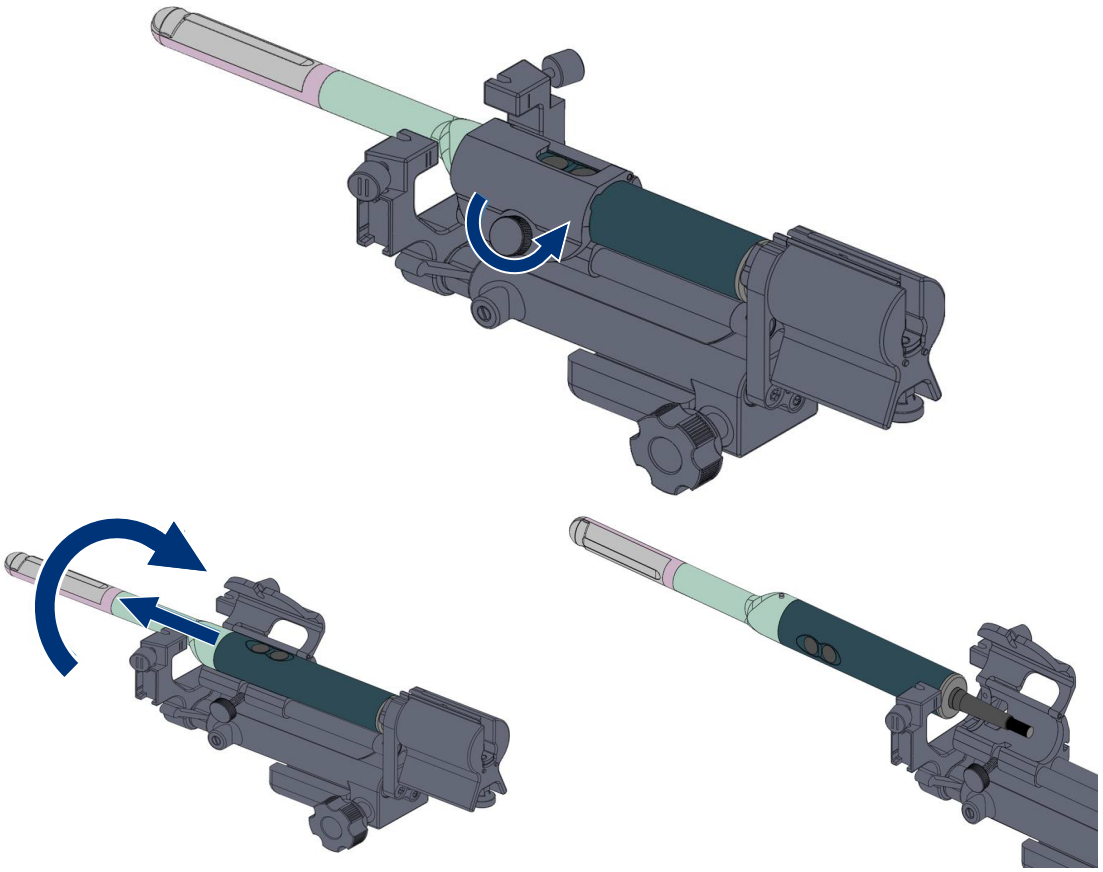

Fig. 11: Probe removal for BK 8848 and E14CL4B

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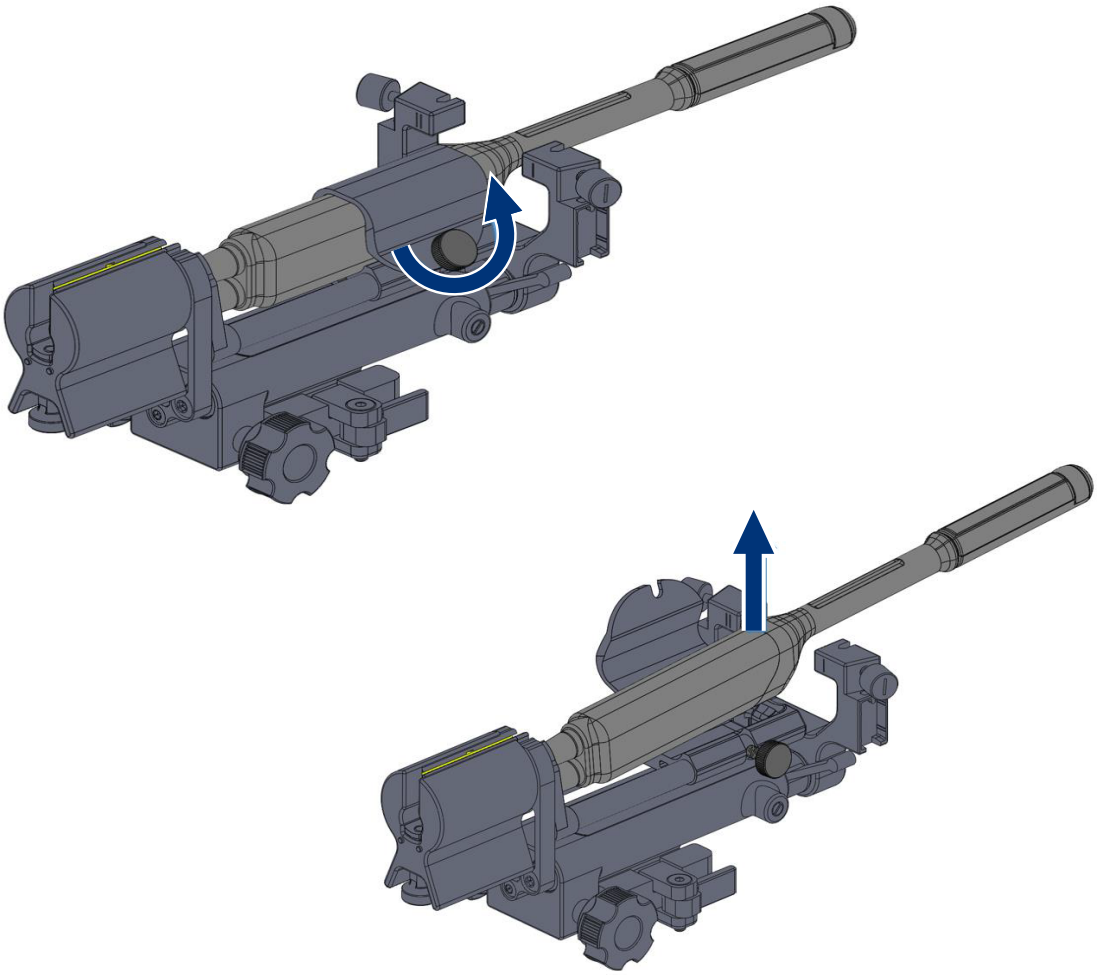

Fig. 12: Probe removal for Hitachi C41L47RP

Stepper removal

To remove the stepper:

- ► Open the lever and pull the stepper out.

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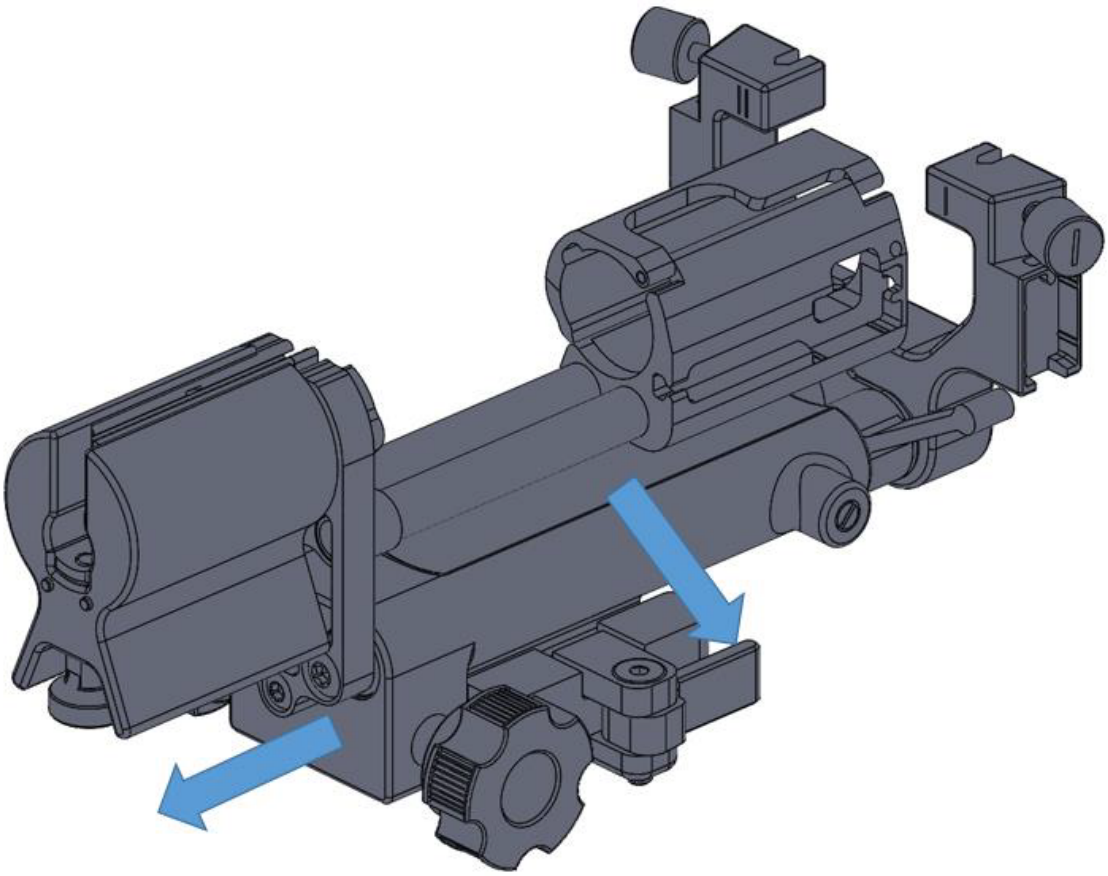

Stepper stand

The following image shows the Stepper attached to the Stepper stand instead of the Stepper arm.

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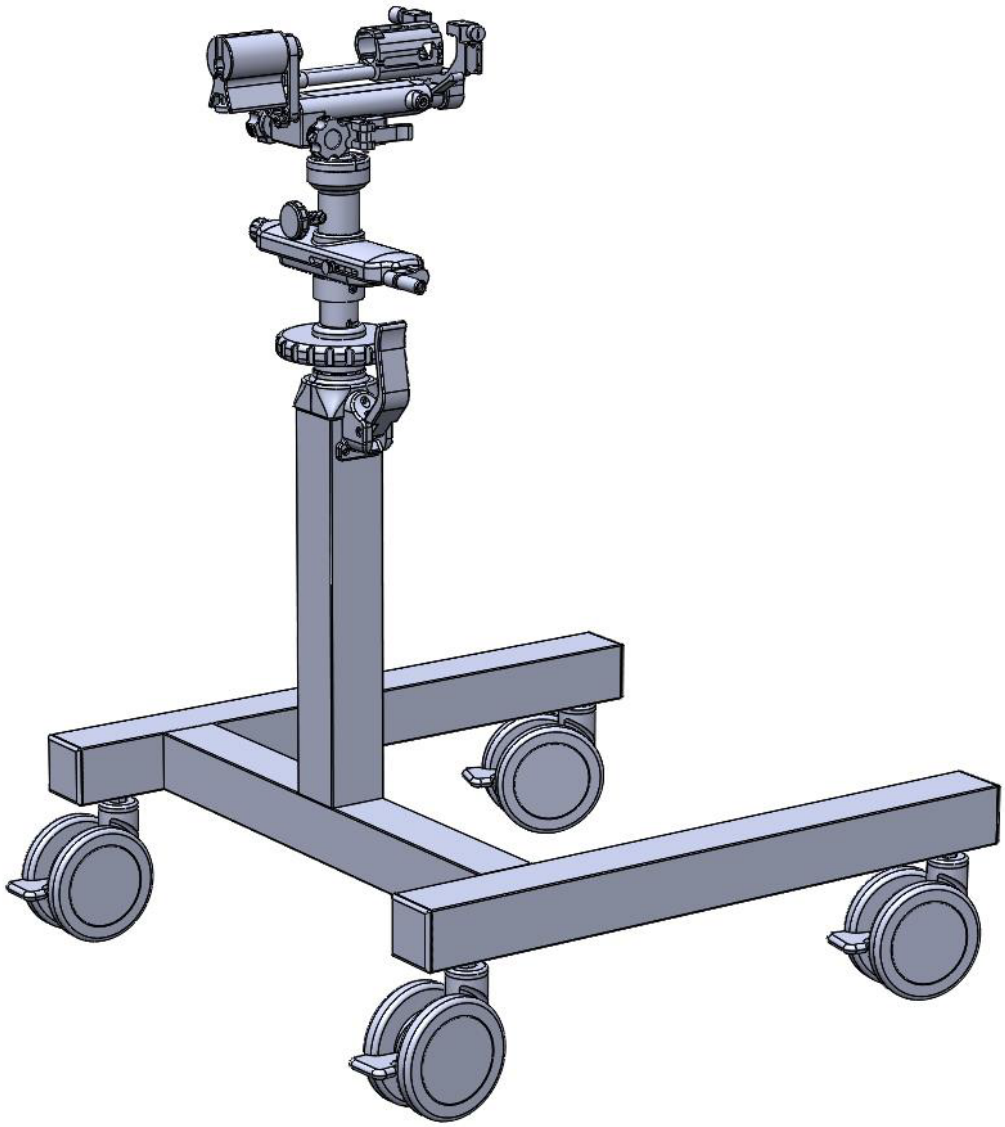

To install the Stepper on the Stepper stand:

- Slide the stepper in the arm mount.
- Close the lever.

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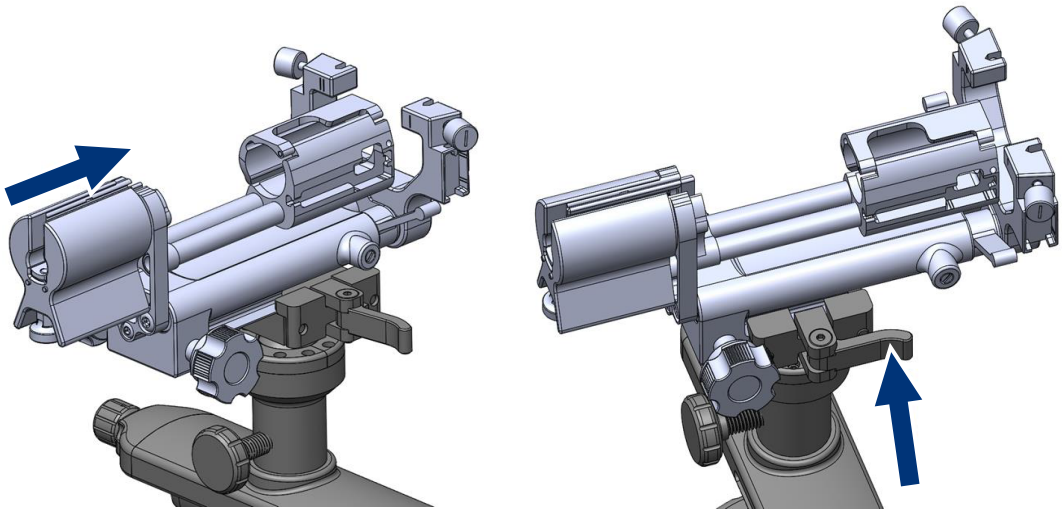
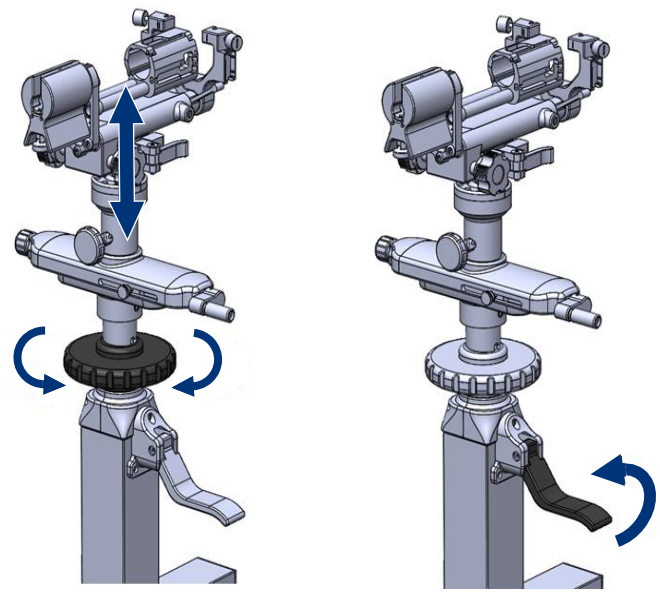


Close the lever forward so it does not interfere with the stepper itself.

Stand adjustments

The stand allows 10 inches of gross vertical adjustment.

Set the adjustment to middle position before the procedure.



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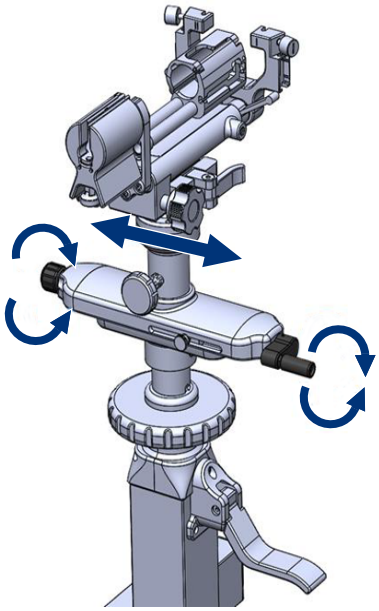
Gross left/right



Gross stepper/stand positioning

Relock all castors after any positioning adjustment.

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CAUTION

After positioning the optional Stepper stand, ensure all castors are in the locked (down) position.

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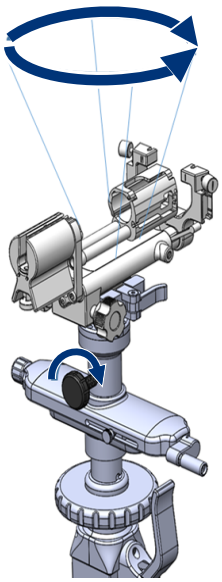
Universal adjustments



Retighten knob after adjustment to prevent stepper movement.

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17 Importer Information

This section provides addresses for importers of UroNav to European countries.

Philips Austria GmbH Kranichberggasse 4 1120 WIEN AUSTRIA	**Philips GmbH** Röntgenstraße 24 22335 HAMBURG GERMANY	**Philips AB** Herrjärva Torg 4 17067 Solna SWEDEN
Philips Česká republika s.r.o. Philips Healthcare Rohanské nábřeží 678/23, Karlin 186 00 PRAHA 8 CZECH REPUBLIC	**Philips Electronics Ireland Limited** Prosperity Chambers, 19-22 Baggot Street Lower DUBLIN 2, D02X658 IRELAND	**Philips AG** Seestrasse 87 8810 HORGEN SWITZERLAND
Philips Danmark A/S Gammel Kongevej 60 1850 FREDERIKSBERG C DENMARK	**Philips S.p.A** Viale Sarca 235 20126 MILAN ITALY	**Philips Medical Systems Nederland B.V** Veenpluis 6 5684 PC BEST THE NETHERLANDS
Philips Oy Miestentie 7 02150 ESPOO FINLAND	**Philips Norge AS** Innspurten 15 0663 OSLO NORWAY	**Philips Nederland B.V** High Tech Campus 52 5656 AG EINDHOVEN THE NETHERLANDS
Philips France Commercial Rue de Verdun 33 92150 SURESNES FRANCE	**Philips Portuguesa S.A.** Rua Encosta das Lagoas, 16/28/34/40 Lagoas Park-Edificio 14 2740-244 PORTO SALVO PORTUGAL	**Philips Electronics UK Limited** Ascent 1, Aerospace Boulevard Farnborough, GU14 6XW UNITED KINGDOM
	Philips Ibérica SA (Sociedad Unipersonal) Ciudad de la Salud María de Portugal 1 28050 MADRID SPAIN	

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CH-REP + Importer: Philips AG, Seestrasse 87, CH-8810 Horgen, Switzerland

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Glossary

A/m	Ampere per meter - international unit of magnetic field strength
AC	Alternating current
BF	Body floating - a part having conductive, medium or long-term contact with a patient
BIOS	Basic Input/Output System
CISPR	Comité International Spécial des Perturbations Radioélectriques - as part of IEC, CISPR is the international standards organization regulating technical requirements related to RF interference of electronic devices.
DICOM	Digital Imaging and Communications in Medicine; sometimes referred to as DICOM standard. Specifies a non-proprietary digital imaging format and protocol for exchanging bio-medical images and associated information.
EEA	European economic area — consists of the European Union (EU) member states and three countries in the European Free Trade Association (EFTA)
EFT	Electrical Fast Transient
EM	Electromagnetic
EMC	Electromagnetic compatibility
EMI	Electromagnetic interference
ESD	Electrostatic Discharge
FDA	Food and Drug Administration - a federal agency within the U.S. Department of Health and Human Services.
GPO	Microsoft's Group Policy Object (GPO) is a collection of Group Policy settings that defines what a system looks like and how it behaves for a defined group of users.
HDMI	High definition multimedia interface
I/O	Input/output

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IEC	International Electrotechnical Commission - headquartered in Switzerland, the organization publishes international standards for all electronic-related technologies.
IFU	Instructions for Use
ISM	Industrial, Scientific, and Medical
kV	kilovolt - a unit of electromotive force, equal to 1000 volts
ME	Medical Electrical - electrical equipment or system with a medical purpose
MR	Magnetic resonance
MRI	Magnetic resonance imaging
RF	Radio frequency
ROI	Region of Interest
TRUS	Transrectal ultrasound
U/S	Ultrasound
USB	Universal serial bus
V/m	Volt per meter
WEEE	Waste of Electrical and Electronic Equipment

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