UroNav
4.1
Instructions for Use

Instructions for Use

PHILIPS

Invivo Corporation
3545 SW 47th Ave
Gainesville, FL 32608 USA

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1. Read This First

This section contains important information about the user information for your product and about customer service.

Help information

User information is available on our website. You can download all instructions for use for this product and other user information from: *www.philips.com/IFU.* A printed version of this Instructions for Use document may be requested from Customer Service.

See 3.6 Customer Service on how to reach Philips Customer Service if additional assistance is required.

1.1. About the Instructions for Use

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

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 and procedures described in the **SAFETY** section.

⚠ **WARNINGS**:
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 possibly in a remote risk of more serious injury, and/or cause environmental pollution.

NOTE:
Notes highlight unusual points as an aid to a user.

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.

This 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.

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

2. Intended Use

2.1. 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.

2.2. Indications for Use

UroNav is a stereotaxic medical device intended to assist the clinician with treatment 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 (US) 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.

2.3. Intended Operator profile

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

2.4. 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.

2.5. Operating Principle

UroNav is designed to target areas of interest visualized with pre-procedure 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.

2.6. 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.

3. 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.

3.1. 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 Philips. A list of such products and components with their versions is available from the manufacturer. See the appendices 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. As with all complex technical products, maintenance by persons not appropriately qualified and/or using unapproved spare parts carries serious risks of damage to the product and of personal injury.

3.2. 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.

3.3. 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 ultrasound 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 support

3.4. User Information Components

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

- Instructions for Use (i.e., 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.
- 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. See the Privacy and Security Features section.

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.

3.5. 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.

3.6. Customer Service

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

The user and the patient should report any serious incident that has occurred in relation to this medical device to the manufacturer and the authority having jurisdiction in their locale.

Contact Customer Service in the event of the packaging being:

1) damaged;
2) unintentionally opened before use; and
3) if the packaging is exposed to environmental conditions outside of those specified.

3.7. Supplies and Accessories

To order additional supplies, consumable instrumentation, or accessories, please contact your Philips sales representative: reference Appendix B and Appendix C for supported Ultrasound and transducer combinations.

3.8. System Servicing

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

3.9. 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.

3.10. Training

Training will be conducted by Philips support team with the customer site at or after installation of the UroNav. Materials include this IFU, 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 support team per the phone number previously provided.

4. Privacy and Security Features

The following section relates to the privacy and protection of patient information and the security of the UroNav.

4.1. Customer Role in the 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 (e.g., 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, e.g., also 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.

4.2. Access Control

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

- Access control to the UroNav is disabled by default. When access control is disabled, the system automatically starts UroNav at power on and grants unlimited access to any patient data. User authentication can be enabled to control access to the system and protect the data from unauthorized access.
- Only username/password authentication is supported if user authentication is enabled; no additional mechanisms are supported, e.g., two-factor authentication using smart-cards.
- It is the customer’s responsibility to manage user accounts and passwords for user authentication.
- Modification of the default administrator user account is not recommended. Please contact Philips Service.
- UroNav does not support single sign-on.

- 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.
- Remote login into the system is restricted to Philips Service personnel only and is password protected.
- UroNav does not use Remote Desktop Protocol.
- The system can be configured by Philips Service personnel to synchronize with an external time source.
- All user access control passwords are unique. BIOS access password is shared across devices and across releases.

4.3. Auto log-off

- UroNav implements automatic log-off by default. Philips service personnel is able to control auto log off through the operating system Local Group Policy.
- UroNav does not support a factory default shortcut key to log off the user.

4.4. Confidentiality of Personal Data

- 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. Customers are notified by the system that a remote session has been initiated, and remote access is only allowed upon customer consent.
- UroNav will automatically blank and lock the user interface after a preset time of inactivity. Philips service personnel is able to control screen blanking through the operating system Local Group Policy.
- UroNav does not support Instructions for Use blanking of the display.
- UroNav does not include protected health information in its system log files.
- Secure DICOM is not supported.
- UroNav does not sanitize and does not provide the capability to sanitize personal data stored on the system.
- UroNav does not provide functionality facilitating the removal of personal data for purposes of system decommissioning or resale.

4.5. Configuration

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

4.6. Contingency, Data Backup, and Storage

- UroNav is not intended to serve as an image archive. 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.
- UroNav may contain patient information, including protected health information. Deleting patient studies may not permanently remove patient data.
- 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 (e.g., to external media, network archive, etc.). Failure to follow the backup procedure may prohibit migration and recovery of any backed-up UroNav data.

4.7. Encryption and De-identification

- UroNav does not support the encryption of personal data (including DICOM data) for transmission or storage on removable media.
- Philips Clinical Solutions products do not support the de-identification of DICOM data for export functionality.

4.8. Emergency Access Procedure

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

4.9. Integrity

- UroNav does not have a built-in check for application or data integrity for storage or transmission.
- The Active Directory domain must not push any changes to the GPO and registry of the UroNav.

4.10. 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 are 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.

- 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 (e.g., this may include disconnecting from the network).

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

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

4.11. 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 (e.g., 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 hard drives.
- There is no detection of unauthorized physical access into the system, e.g., tamper-proof seals

4.12. System and Application Hardening

- UroNav may not remove or disable all unnecessary services and applications.
- UroNav may not block or disable all unused ports.
- The UroNav employs the McAfee® 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.
- UroNav password protects the BIOS.
- UroNav operates in a single-user or "Kiosk mode," which allows access to the Uronav application only --- standard users cannot access other applications or operating system functions including the Control Panel, Task Manager, and File Explorer.

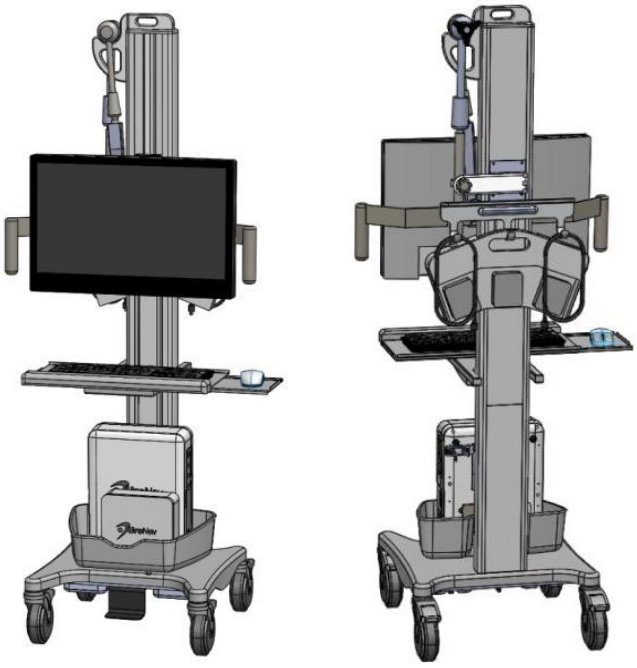
5. Safety

Please read this information before using the UroNav. This section outlines the safety requirements and features of the UroNav, including the instrumentation and optional equipment. It also details actions that may damage the equipment.

NOTE: For information on the safety requirements and features of an Ultrasound system, see the Manufacturer's User Manual.

- This device is intended for use by, or by order of, and under the supervision of a licensed physician qualified to direct the use of the device.
- Before using the UroNav, read these warnings.
- No modification of this equipment is allowed. Do not alter or change the system parameters for UroNav as set by Philips factory personnel.
- Do not remove UroNav cart covers; hazardous voltages are present inside the enclosure.
- Do not use UroNav if physical damage to any enclosure is evident.
- Before use, ensure cooling fans and vents are free from any damage or blockage.
- 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.
- Transport of the UroNav cart should only be undertaken with the height-adjustable tray in its lowest set 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.



⚠ Use the foot pedal at the bottom of the UroNav cart to lower the height-adjustable tray in its lowest position

⚠ 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.

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

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

⚠ Medical equipment needs to be installed and put into service according to the special electromagnetic compatibility (EMC) guidelines provided.

⚠ The use of portable and mobile radio-frequency (RF) communications equipment can affect the operation of medical equipment. Reference Electromagnetic Compatibility (EMC) guidelines provided.

⚠ 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 in the Mains Power Cord Requirements section of this Instructions for Use.

⚠ The EM Tracker is shipped non-sterile by the manufacturer. Prior to initial use, the UroNav EM Tracker must be disinfected per the procedure in this document,

- Cleaning and Disinfection of the UroNav EM Tracker.

⚠ 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.

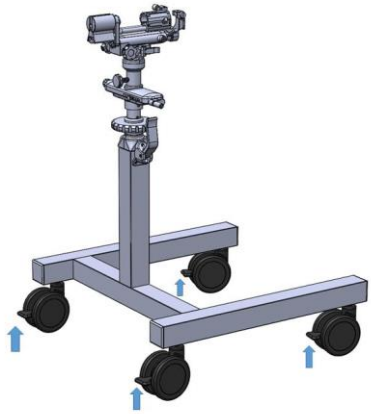
⚠ Prior to re-use, the EM Trackers must be first disassembled from the Stepper, cleaned, and then disinfected per the procedures in this document, Cleaning and Disinfection of the UroNav EM Tracker.

⚠ The Stepper is shipped non-sterile by the manufacturer. Prior to initial use, the Stepper must be disinfected per the procedure in this document, Cleaning and Disinfection of the Transperineal Stepper.

⚠ The EM Tracker Probe Holder is shipped non-sterile by the manufacturer. Prior to initial use, the UroNav EM Tracker Probe Holder must be cleaned per the procedure in this document, "Cleaning of the EM Tracker Probe Holder."

⚠ 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 re-sterilize this device. After use, dispose of the Probe Holder per hospital medical waste and environmental policies and procedures.

⚠ After positioning the optional Stepper stand, ensure all castors are in the locked position.



5.1. Essential Performance

The essential performance function of the UroNav is to facilitate targeting during needle guidance. Please follow the instructions in Section 5: Safety to maintain the essential performance of the device. Additional recurrent testing or verification of essential performance is not necessary.

Table 1: Classification and 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 EM Tracker Cleaning and Disinfection Instructions for 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	EM Tracker
Reusable, requires cleaning prior to use	Stepper and bedmount
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	26kg
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.

Table 1: Classification and Specification

Regulatory Compliance	CB Scheme - IEC 60601-1:2012 Ed:3.1 Medical electrical equipment – Part 1: General requirements for safety and essential performance IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

5.2. General Warnings and Cautions

Additional procedural warnings are found throughout this Instructions for Use and are formatted similarly to the following warnings.

5.2.1. WARNINGS

The UroNav is to be used by trained and authorized physicians only.

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

⚠ The UroNav can be used to assist physicians, but physicians must override the system if the UroNav does not appear to be accurate or otherwise working as intended.

⚠ Read *Instructions for Use* for all instrumentation used with the system. Some instrumentation components may require preparation before use.

⚠ Do not alter or change the system parameters for the UroNav as set by Philips factory personnel, or otherwise modify the equipment.

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

⚠ Using images from scanners not qualified via the image calibration procedure upon initial installation may result in inaccurate information and possible personal injury.

⚠ The UroNav includes non-sterile devices, reusable components that must be cleaned by the health care facility prior to use.

⚠ The UroNav must remain outside the patient environment to prevent contamination and to prevent the magnetic field from being affected by the metal components of the system.

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

⚠ 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.

⚠ 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.

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

⚠ Multiple pre-operative datasets loaded into the UroNav must either be co-registered before loading or be co-registered in the UroNav before you use them for planning or navigation.

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

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

5.2.2. CAUTIONS

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

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

⚠ Before disconnecting power from the system, follow the procedure for system shutdown as detailed in UroNav Operational Setup.

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

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

⚠ Do not expose any part of the UroNav, including any tracked tools or instruments, to a high magnetic field, such as that produced by a magnetic resonance imaging (MRI) scanner. The system is neither MR Conditional nor MR Safe.

5.3. Network/Data Coupling to other equipment

The end-user should take note of the following warnings related to Network/Data Coupling:

⚠ 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.

⚠ Subsequent changes to the Network/Data Coupling could introduce new Risks and require additional analysis; and

⚠ Changes to the Network/Data Coupling include:

- Changes in Network/Data Coupling configuration
- Connection of additional items to the Network/Data Coupling
- Disconnecting items from the Network/Data Coupling
- Update of equipment connected to the Network/Data Coupling
- Upgrade of equipment connected to the Network/Data Coupling

5.4. Electrical Safety Warnings

For electrical safety classifications and regulatory compliance status of UroNav, reference the "Classification and Specification" Table 1. For maximum safety, observe the following warnings:

⚠ Do not remove covers or cables from this product. Dangerous electrical voltages are present within this product. 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.

⚠ 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.

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

⚠ 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.

⚠ Medical equipment needs to be installed and put into service according to the special electromagnetic compatibility (EMC) guidelines provided in the Safety section of this Instructions for Use. See "Electromagnetic Compatibility" section.

⚠ Always properly turn off the system and unplug it before cleaning, connecting, or disconnecting parts.

⚠ 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.

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

⚠ 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 inaccuracies and possible personal injury.

⚠ 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".

⚠ 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

⚠ 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.

⚠ 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 Ed 3.1

⚠ External equipment intended for connection to signal inputs, signal outputs, or other connectors shall comply with the relevant product standard, e.g., 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, edition 3.1, clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 will be kept outside the patient environment, i.e., at least 1.5 m from the patient support, 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.

5.5. Mechanical Safety Warnings

⚠ Do not remove covers or cables from this product. Dangerous electrical voltages are present within this product. 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.

5.6. Environmental Warnings

⚠ 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.

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

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.

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.

NOTE: For additional information, reference the Electromagnetic Compatibility section of this Instructions for Use or contact Philips Technical Support.

5.7. Fire Safety Warnings

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

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.

⚠ 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.

5.8. Equipment Protection

Follow these precautions to protect your system:

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

⚠ Do not submerge the connector end of cables of patient-applied parts in a solution. The cables are not liquid-tight beyond the cable/connector interface.

⚠ Do not use solvents, such as thinner or benzene, or abrasive cleaners on any component of the system.

5.9. Field Generator Warnings

The following warnings are provided by the Field Generator manufacturer:

- 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.
- 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.
- 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.
- 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.
- 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.
- Do not track a tool unless it has been verified as described in this Instructions for Use. Using an unverified tool may produce inaccurate information and could cause personal injury.
- 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.
- 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.
- 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.

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

⚠ 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.

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

5.10. Biological Safety

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

⚠ Do not use the system if an error message on the video display indicates that a hazardous condition exists. Call your customer service representative.

⚠ 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.

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

⚠ UroNav utilizes both single-use disposable and reusable tools. Follow manufacturer cleaning and disinfection procedures to ensure biological safety for both patients and operators.

5.11. Ultrasound Video Connections

⚠ An S-video or HDMI connection, via a shielded video cable (see Electromagnetic Compatibility – Approved Cables for Electromagnetic Compliance section), is required for

the real-time display of ultrasound image on the UroNav monitor for the duration of a procedure.

⚠ The lack of availability of a shielded video cable or failure of the video cable to maintain its functional characteristics during a procedure may introduce the following potentially hazardous situations:

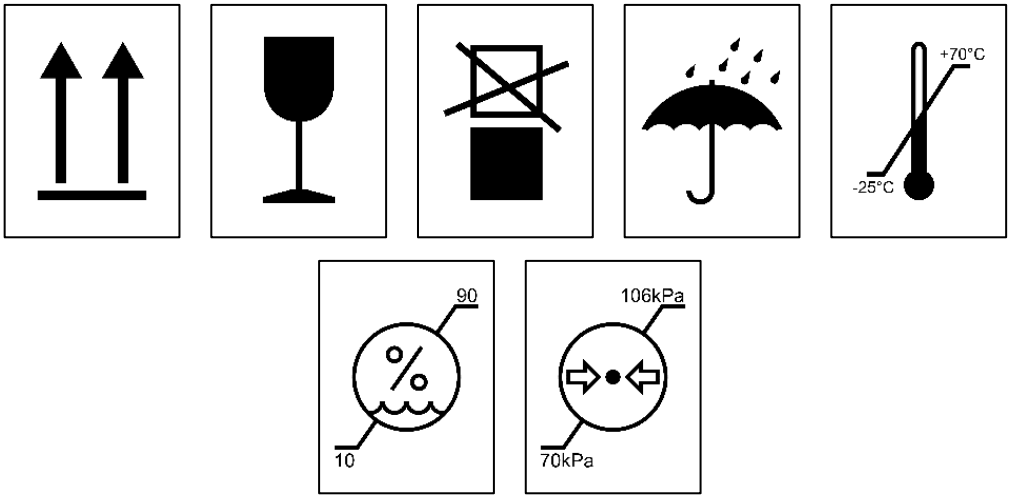
- U/S Video not available to UroNav will prevent the use of UroNav for the prostate procedure. The biopsy procedure would necessarily be conducted per conventional U/S prostate biopsy procedural methods without the enhancement that UroNav provides.

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

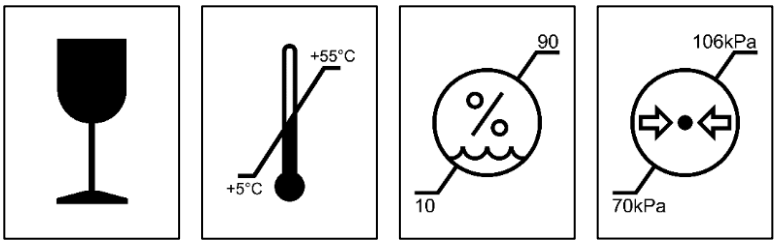
5.12. Protective Packaging Markings

The following markings are displayed on the packaging to indicate special handling measures required for transport and handling. Symbol descriptions are referenced in the Symbols table.

UroNav cart and Transperineal hardware Shipping Carton Protective Packaging Labels:



EM Tracker and Probe Holder Shipping Carton Protective Packaging Labels:



5.13. 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.

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.

5.14. Normal Operating Environment

UroNav, EM Tracker and Transperineal Stepper, Stepper Stand, Stepper Arm

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

5.15. 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

⚠ 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.

5.16. Mains Power Cordset Requirements

Cordsets must meet the following requirements for the UroNav to remain compliant to IEC 60601-1:2012 Edition 3.1.

1. Appliance coupler must be type IEC 60320 C13
2. Include an attachment plug with Protective Earth that is acceptable for the destination country.
3. Not greater in length than 15t (4.57m)
4. 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 60227-1:1993, Annex A, Designation 53, with a cross-sectional area of conductors not less 1mm^2.
5. Switzerland power cordsets require a plug complying with IEC 60884-1 (3rd Ed) + am 1, SEV 1011 and dimension sheet SEV 6534-2:2009 Plug type 12, L+N+PE, 250V 10A.

5.17. Replacement Fuse Specifications

⚠ 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.

5.18. Means of AC Mains Disconnection

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

⚠ Equipment and cables should be positioned such that the power cord attached plug can be readily accessed and removed from the source outlet for power disconnection from Mains supply by operator or accompanying personnel.

5.19. 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 3.6 Customer Service.

Following is 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).
- 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.

NOTE: 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.

5.20. UroNav Operational Setup

Connect the Field Generator and the EM Tracker(s) prior to powering on the UroNav per the following Power On and Power Off Sequence:

⚠ 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.

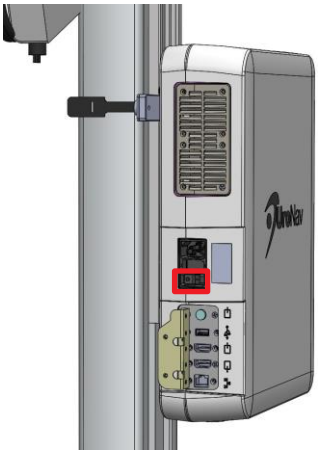
5.20.1. UroNav Power On and Power Off Sequences

Power ON Sequence

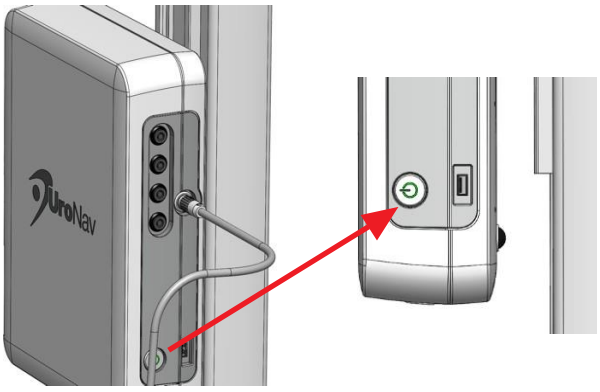
1. Ensure the UroNav rear-panel Power switch is Off prior to connecting the AC Mains power cord.
2. If not already connected from the UroNav installation, connect the IEC320 Hospital AC Supply Mains power cord plug to the UroNav cart bottom rear AC inlet.
3. Connect the cordset plug to the AC Mains source.

⚠ Equipment and cables should be positioned such that the power cord attached plug can be readily accessed and removed from the source outlet for power disconnection from Mains supply by the operator or accompanying personnel.

Rear View Mains Power



Magnified Front View Power



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.
6. The system is now ready for operation.

Power OFF Sequence

1. Power off the System from the "Shut Down" button within the UroNav software or press the front panel power button.
2. Confirm the shutdown dialog prompt within the UroNav software or press the front panel power button again.
3. Turn Off the UroNav Mains power switch on the rear panel Mains AC appliance inlet.

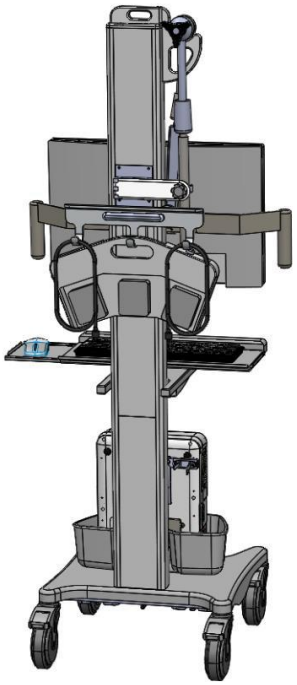
NOTE: Alternatively, the System can be powered off by pressing and holding the computer power switch for at least 6 seconds.

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

⚠ 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 switch 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 application if operable or by pressing the Power switch for at least 6 seconds if UroNav is not responding to mouse commands.

5.21. Cable Management

When not in use, cables can be stored as indicated below to keep them off the floor and prevent a tripping hazard.

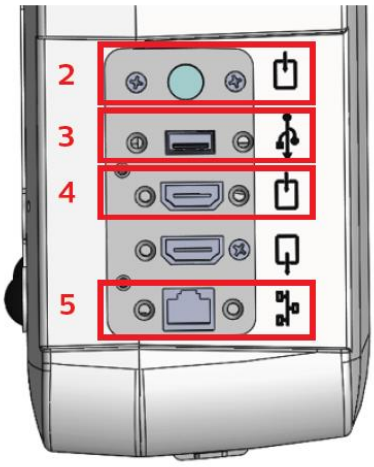


Cable Storage:

⚠ To prevent a tripping hazard, the power cable, as well as other cables, may be stored on the UroNav cart rear handle.

5.22. Connections to Peripheral Equipment

Universal peripheral device connectors on the UroNav, consisting of wireless keyboard and mouse, USB, S-Video, HDMI, and RJ-45 Network/Data coupler, 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:



Rear Panel Connections

1. Wireless: Keyboard, mouse
2. S-Video input: Ultrasound video input
3. USB: 3-pedal foot switch, supplied with UroNav, and end-user supplied portable USB memory drives.

4. HDMI Video input: Ultrasound video input
5. RJ-45 Network Coupler: End-user hospital or out-patient office network.

5.23. Product Identification

To see the software versioning information, click the **System Setup** > **Software** tab of the system menu in the top right.

To see the product label, click the **System Setup** > **About UroNav** tab of the system menu in the top right.

For an explanation of the symbols used in the product labelling, see section 15 Symbols.

5.24. Error Codes and Messages

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

5.25. Electromagnetic Compatibility

- Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Accompanying Documents.
- Portable and mobile RF Communications Equipment can affect Medical Electrical Equipment.

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.

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

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

Your system has been manufactured in compliance with existing electromagnetic compatibility requirements. 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.

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

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

⚠ 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.

⚠ 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.

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

5.26. Electromagnetic Emissions

The system is intended for use in the electromagnetic environment specified in the following table, IEC 60601-1-2, Table 3 – Guidance and Manufacturer's Declaration – Electromagnetic Emissions-All ME Equipment and ME Systems. The customer or the user of the system should ensure that it is used in such an environment.

Table 2: IEC 60601-1-2, – Guidance and Manufacturer's Declaration – Electromagnetic Emissions, All ME Equipment and ME Systems

Guidance and manufacturer's declaration – Electromagnetic Emissions		
UroNav is intended for use in the electromagnetic environment specified below. The customer or the user of UroNav should ensure that it is used in such an environment.		
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	

5.26.1. Electromagnetic Immunity

The system is intended for use in the electromagnetic environment specified in the following table, IEC 60601-1-2, Table 4 – Guidance and Manufacturer's Declaration – Immunity - All ME Equipment and ME Systems. The customer or the user of the system should ensure that it is used in such an environment.

Table 3: IEC 60601-1-2, – Guidance and Manufacturer's Declaration – Immunity, All ME Equipment and ME Systems

Guidance and Manufacturer's Declaration – Electromagnetic immunity			
UroNav is intended for use in the electromagnetic environment specified below. The customer or the user of UroNav should ensure that it is used in such an environment.			
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 / burst IEC 61000-4-4	+/-2 kV Mains +/-1 kV I/Os	+/-2 kV Mains +/-1 kV I/Os	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, short interruptions, and voltage variations on power supply input lines IEC61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle) 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0.5 cycle) 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	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	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Table 4: IEC 60601-1-2, – Guidance and Manufacturer's Declaration – Immunity, ME Equipment and ME Systems that are NOT Life-supporting

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
UroNav is intended for use in the electromagnetic environment specified below. The customer or the user of UroNav should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	$[V_1]$ = 3 V [E1] = 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of UroNav, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: *d* = (3.5/V1)(Sqrt P) = 1.2(Sqrt P) 150kHZ to 80MHz *d* = (3.5/E1)(Sqrt P) = 1.2(Sqrt P) 80 MHZ to 800 MHz *d* = (7/E1)(Sqrt P) = 2.3(Sqrt P) 800 MHZ to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] 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 measure field strength in the location in which UroNav is used exceeds the applicable RF compliance level above, UroNav should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating UroNav.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ = 3 V/m.

⚠ 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.

5.27. Radio-Frequency Interference Guidance

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. For minimum recommended separation distances, reference the following "Recommended Separation Distance" table:

Table 5: 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

Recommended Separation Distances for UroNav.			
UroNav is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the UroNav can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the UroNav as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d=(1.2)(\text{Sqrt } P)$	**80 MHz to 800 MHz** $d=(1.2/E_1)(\text{Sqrt } P)$	**800 MHz to 2.5 GHz** $d=(2.3)(\text{Sqrt } P)$
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
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **NOTE 1:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **NOTE 2**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

5.28. 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.

⚠ 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.

⚠ 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.

⚠ 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/IEC60601-1-2:2014.

⚠ 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.

⚠ 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.

5.29. 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 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.

5.30. Recommended Separation Distance

⚠ 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.

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, 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. Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range as noted in the table. Interference may occur in the vicinity of equipment marked with the following symbol:  .

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

NOTES:

- For transmitters rated at a maximum output power not listed in the following 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.
- At 80 MHz and 800 MHz, the higher frequency range applies.
- The recommended separation distance guidelines shown in Table 5 may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. Table 6 indicates separation distances recommended for optimal EM Tracking performance. These separation distances will help ensure maximum RF and EM immunity of the EM Tracking function.

Table 6: Recommended Optimal Separation Distances by Transmitter Frequency

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)

5.31. 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 #
S-Video, Molded, 10ft, Shielded	4535-303-59281 (L-com CCD234MM-10)
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	4598-000-81841 (C2G 54327)
AC Mains Power Cord	Reference Mains Power Cordset Requirements Technical Specifications and Regulatory Compliance section.

⚠ 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.

5.32. 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 and possible personal injury.

5.33. Cleaning and Disinfection

Cleaning and disinfection of this product is required periodically. General guidelines for each are given below.

⚠ Do not use flammable or potentially explosive disinfecting sprays. Such sprays create vapors, which can ignite, causing fatal or other serious personal injury.

⚠ Disinfecting a medical procedure room by means of sprays is not recommended since the vapor could penetrate the product, causing electrical short-circuits, metal corrosion, or other damage to the product.

⚠ Never expose the EM Sensor, Stepper, Stepper Arm, or Stepper stand to automatic cleaning/disinfection, autoclave, gamma-radiation, gas, steam, or heat sterilization techniques. Severe damage will result. Avoidable damage is not covered by the warranty or service contract.

5.33.1. Cleaning the UroNav and UroNav cart

Issues related to infection control affect the operator and the patient. Follow the infection-control procedures established in your facility for the protection of both the staff and the patient. The UroNav, UroNav cart, Foot Pedal, Field Generator, and Articulated Field Generator mounting Arm can be cleaned using common Low-Level disinfection cleaning agents commonly used in hospitals and outpatient offices.

⚠ 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 for EM Tracker cleaning and disinfection.

⚠ These components are to be manually cleaned only, do not immerse in liquids.

⚠ The use of chlorine or chlorine separating compounds is not recommended for the articulated Field Generator mounting Arm.

5.33.2. Removing Blood and Infectious Material from the System

Power the UroNav off per the UroNav Power On and Power Off Sequences section, and disconnect the power cord from the AC power Mains. Use a gauze pad moistened with soap and water to remove blood on the system, connectors, and cables. **NOTE:** Do not pour cleaning solution directly onto the system components. Then dry the equipment with a soft, dry or damp, lint-free cloth to prevent corrosion.

5.33.3. Disposable Drape

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.

⚠ Position the disposable drape so that it does not block the vents on the UroNav computer/display or the peripherals.

5.33.4. Cleaning of the disposable EM Tracker Probe Holder before use

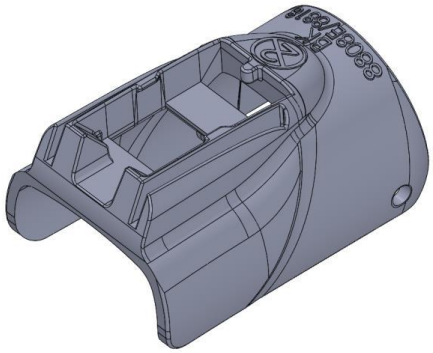
⚠ Users are responsible for providing the highest degree of infection control to patients, co-workers, and themselves. Follow all infection control policies established by your facility to avoid cross-contamination.

⚠ Do not place in a mechanical washer.

⚠ Do not use ethylene oxide or autoclave to sterilize.

NOTE: The parts are non-sterile. Please use the following steps to clean the parts before use. The parts are for single use only and shall be disposed of after use.

1. 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.
2. 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.
3. Before use, allow the EM Tracker Probe Holder to air dry or wipe dry with a lint-free cloth.



5.33.5. Cleaning and Disinfection of the EM Trackers

Observe the following warnings and cautions during cleaning and disinfection procedures and when using disinfectants. More specific warnings and cautions are included within the care and cleaning procedures and on the labels of the cleaners or disinfectants.

⚠ The EM sensor can be cleaned and disinfected for 100 reuses.

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

⚠ Always use proper protection, like protective eyewear and gloves, when cleaning and disinfecting any equipment.

⚠ If a pre-mixed solution is used, be sure to observe the solution expiration date.

⚠ Follow the recommendations of the disinfectant manufacturer.

⚠ Using non-recommended disinfectants, incorrect solution strengths, or immersing the EM sensor longer than recommended can damage or discolor the EM sensor and voids the warranty.

⚠ 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.

⚠ Do not expose the EM sensor to cleaning and disinfectant agents for extended periods of time. Limit the time that the EM sensor is exposed to cleaning and disinfectant agents to the minimum time recommended by the manufacturer

⚠ Before storing the EM sensor, ensure that it is thoroughly dry. If it is necessary to dry the EM sensor after cleaning, use a soft lint-free cloth.

⚠ Do not use alcohol or any alcohol-based chemicals to clean the EM Sensor. Do not expose the EM sensor to cleaning and disinfectant agents containing bleach (sodium hypochlorite) or hydrogen peroxide.

⚠ Before using the EM sensor for the first time, follow the instructions provided below to prepare the EM sensor for use.

Limitations on reprocessing	• Do not allow sharp objects, such as scalpels or cauterizing knives, to come in contact with the EM sensor, cable, or connector. • Throughout the cleaning process, protect the connector to keep liquid out of the connector's electrical contacts. • Do not use a wire brush for cleaning. Hand-wash only per the following procedure. • Throughout the disinfection process, protect the connector to keep liquid out of the connector's electrical contacts.

Instructions	
Point of use:	Upon receiving the new EM Tracker, disinfect it before performing the first study. Clean and disinfect the EM Tracker immediately after each use to protect patients and personnel from a variety of pathogens.
Preparation for decontamination:	Disassemble the EM Tracker sensor housing from the EM tracker probe holder. This is described in detail in sections 12, 13, and 14.

Instructions	
Cleaning: Manual	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. **NOTE:** The cloth should be 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. CAUTION: keep liquid out of the connector's electrical contacts. 5. Wet a new clean, soft, lint-free cloth with potable water. Squeeze out excess liquid. **NOTE:** The cloth should be 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. Rewet the cloth with potable water and thoroughly wipe the entire cable and connector to remove cleaning residue. CAUTION: keep liquid out of the connector's electrical contacts. 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 above 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. 12. The EM sensor, cable, and connector can be cleaned and disinfected for 100 reuses
Disinfection:	Intermediate level disinfection of the EM sensor uses a wipe method with an intermediate level disinfectant. Before performing this procedure, read the warnings and cautions in the "Warnings and Cautions" section. Procedure 1. Clean the EM sensor, cable, and connector per cleaning instructions as described in 5.33.5. 2. Wipe all EM sensor, cable, and connector surfaces with disinfectant wipes. Such as, Sani-Cloth® AF3 wipes (PDI). Wipe all surfaces for the minimum contact time given by manufacturer of the disinfectant. CAUTION: keep liquid out of the connector's electrical contacts
Drying	EM sensor, cable, and connector: Air dry or dry with a sterile cloth.
Maintenance, inspection and Testing:	Examine the EM Tracker for damage, such as cracks or splitting. If damage is evident, discontinue use of the device
Storage:	Clean dry location

The instructions provided above 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 using equipment, materials and personnel in the reprocessing facility achieve the desired result. This normally requires validation and routine monitoring of the process

5.33.6. Cleaning and Disinfection of the Stepper

- Observe the following warnings and cautions during cleaning and disinfection procedures and when using disinfectants. More specific warnings and cautions are included within the care and cleaning procedures and on the labels of the cleaners or disinfectants.

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

⚠ Always use proper protection like protective eyewear and gloves when cleaning and disinfecting any equipment.

⚠ If a pre-mixed solution is used, be sure to observe the solution expiration date.

⚠ Follow the recommendations of the disinfectant manufacturer.

⚠ Using non-recommended disinfectants, using incorrect solution strengths, or immersing the Stepper longer than recommended can damage or discolor the Stepper and voids the Stepper warranty.

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

⚠ Do not expose the Stepper to cleaning and disinfectant agents containing bleach (sodium hypochlorite) or hydrogen peroxide.

⚠ Do not expose the Stepper to cleaning and disinfectant agents for extended periods of time. Limit the time that the Stepper is exposed to cleaning and disinfectant agents to the minimum time recommended by the manufacturer.

⚠ Before storing the Stepper, ensure that it is thoroughly dry. If it is necessary to dry the Stepper after cleaning, use a soft lint free cloth.

⚠ Do not break down the Stepper assembly more than specified in the following procedure.

Cleaning the Stepper

The Stepper must be cleaned after each use including the first use. Cleaning the Stepper is an essential step before effective disinfection. Clean and disinfect the Stepper immediately after each use to protect patients and personnel from a variety of pathogens. Before cleaning the Stepper, read the "Warnings and Cautions" section.

Recommended equipment/supplies:

- Soft bristle brush
- 1.25-inch cylindrical soft-bristle brush
- ¾-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.
- Compatible intermediate level disinfectant such as Sani-Cloth® Prime Wipes and Sani Prime™ spray from PDI.
- Dry, lint-free cloths
- Compressed air system

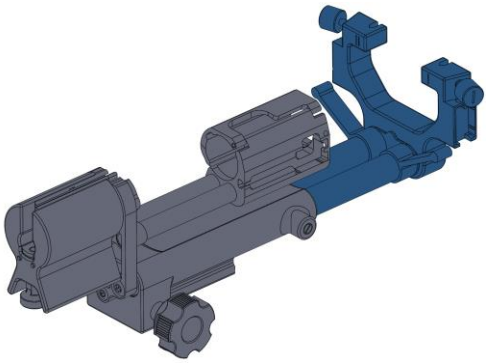
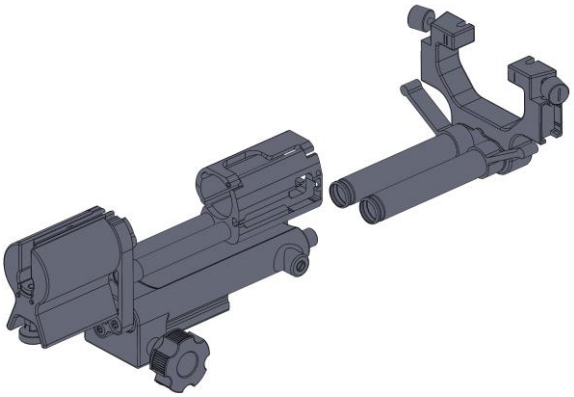
Initial Cleaning

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.

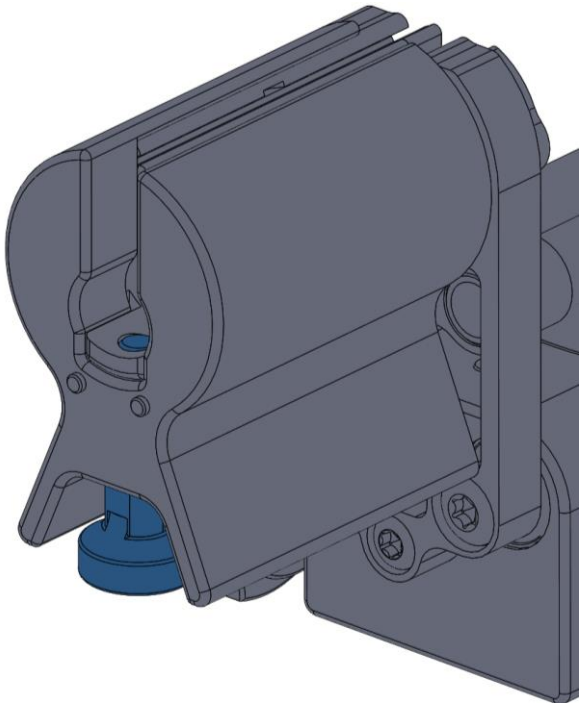
Disassembly of Stepper

After removal of all visible debris, disassemble the Stepper.

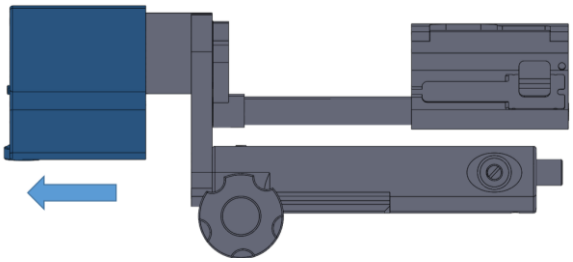
Stepper Disassembly	
1. Slide the front end out of the rack-and-pinon assembly. Note that there are retaining grooves on the end of both sliding tubes. These grooves catch on a spring and ball mechanism, which help prevent accidental removal of the front end. However, with little additional force the front end can be removed from the rack-and-pinon assembly.	
2. The adjacent picture shows the two pieces separated.	

Stepper Disassembly

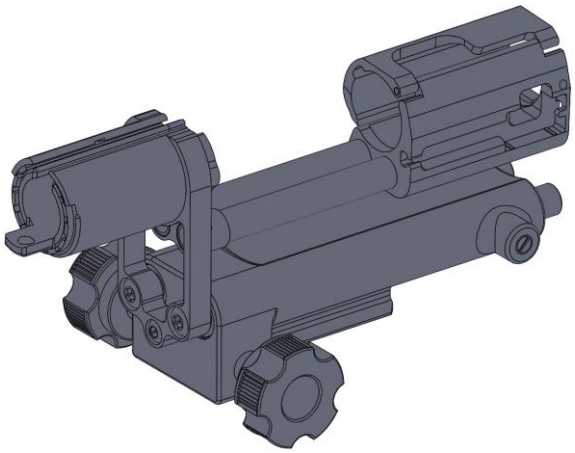
4. Locate the white release pin, as indicated in the adjacent picture.
5. Pull down on the release pin and rotate it 90 degrees. This prevents the release pin from springing back into place.

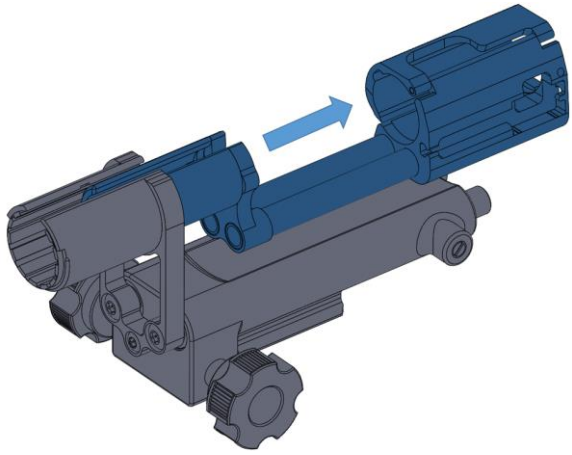
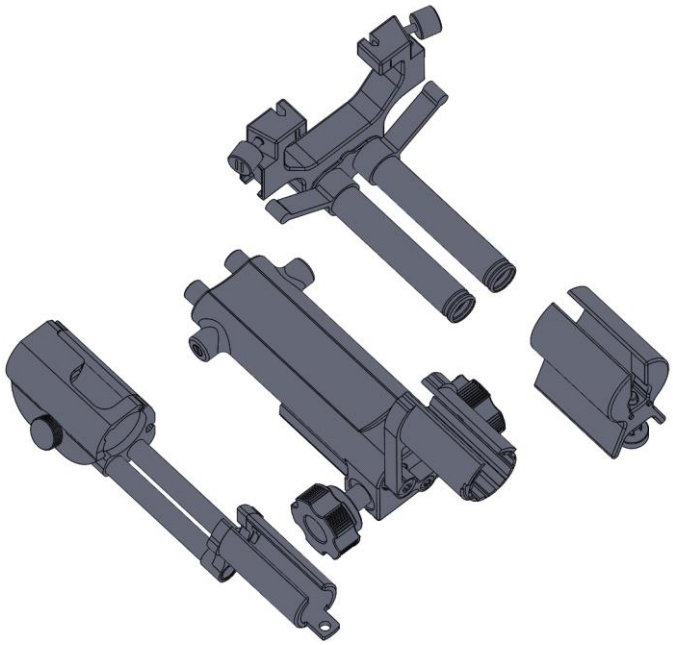


6. After the release pin is disengaged, slide the handle away from the rack-and- pinion assembly. The adjacent picture shows the handle partially removed.



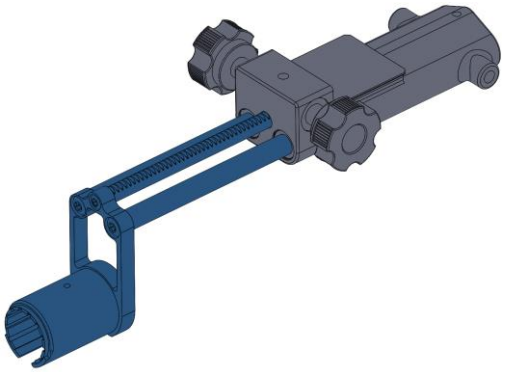
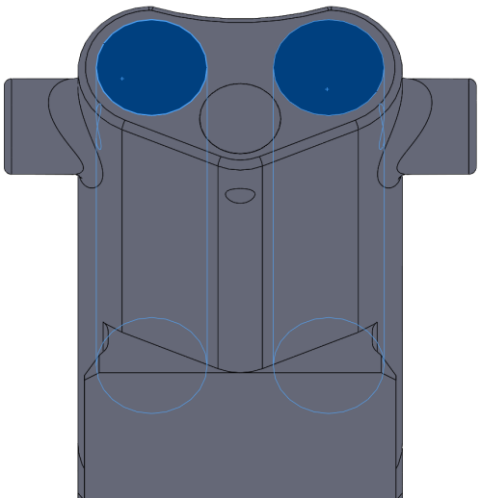
7. The adjacent picture shows the handle fully removed from the rack-and-pinion assembly.



Stepper Disassembly	
8. 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, as illustrated in the adjacent picture.	
9. The four pieces of the fully disassembled Stepper are shown is the adjacent picture.	

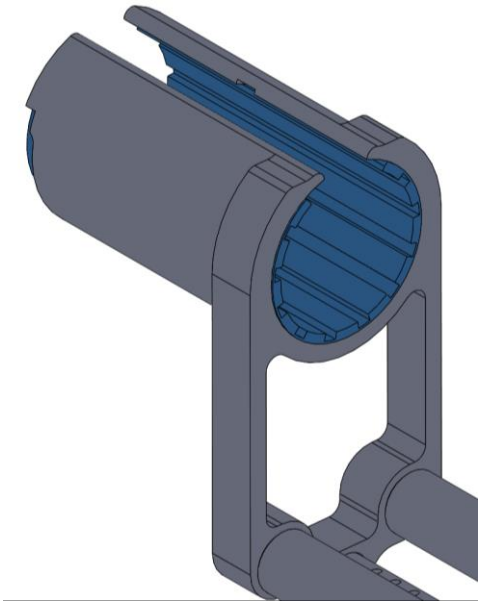
Detailed Cleaning

Each of the individual component must be cleaned as described below. 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.

Cleaning: Rack-and-Pinion Assembly
1. Using the carriage knob, move the carriage so that it is fully extended, as shown in the adjacent picture. 2. Immerse assembly in detergent water. 3. Thoroughly clean all surfaces with a soft-bristle brush. 4. Pay particular attention to gear teeth. **NOTE**: There are two areas that need special attention during cleaning. These areas are discussed in the following two steps.   
5. 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.   

Cleaning: Rack-and-Pinion Assembly

6. 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.

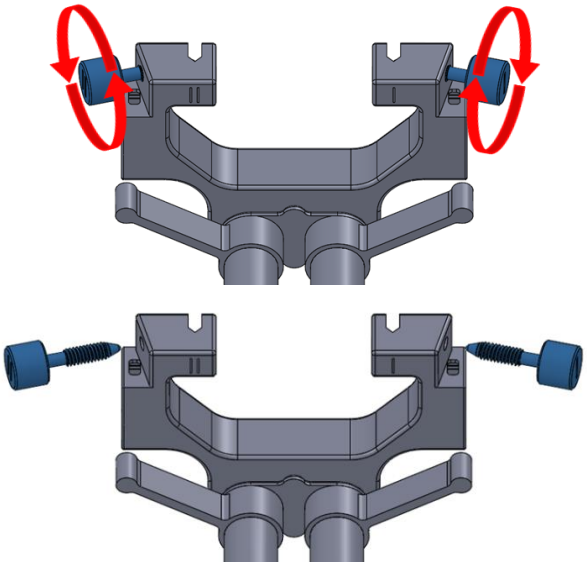


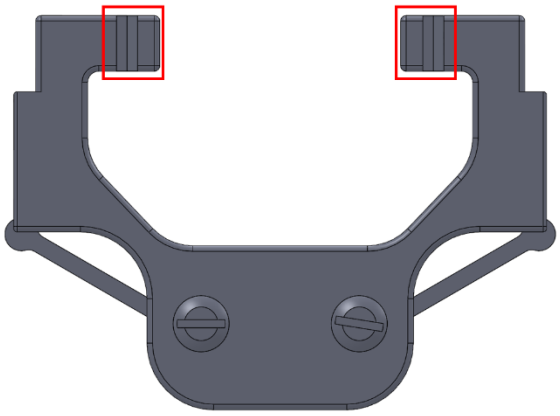
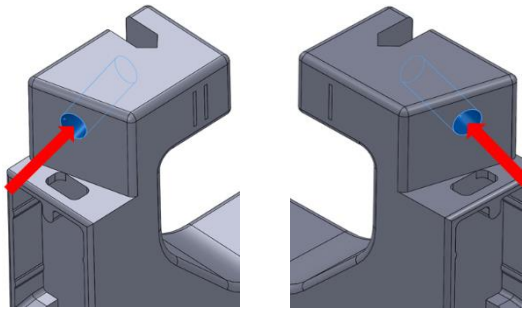
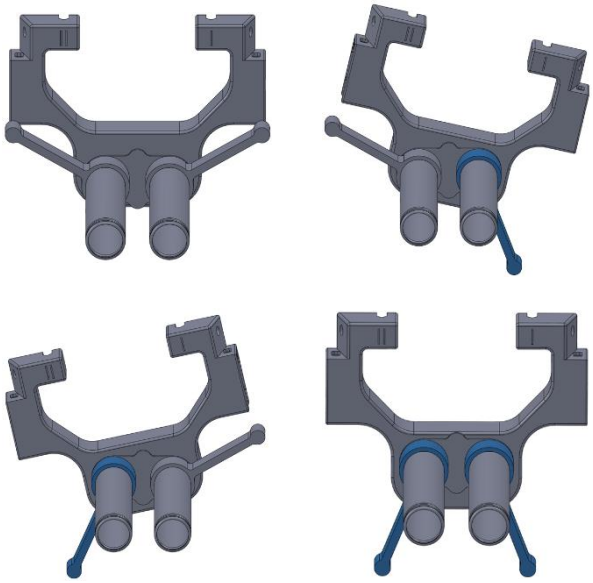
7. Follow detergent manufacturer's recommendations for the duration of the rinse time.
8. Immerse assembly in clean water (no detergent). Ensure that all surfaces are exposed to the rinse water.
9. Finish rinsing under running water. Ensure that all surfaces are exposed to the running rinse water.
10. 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.

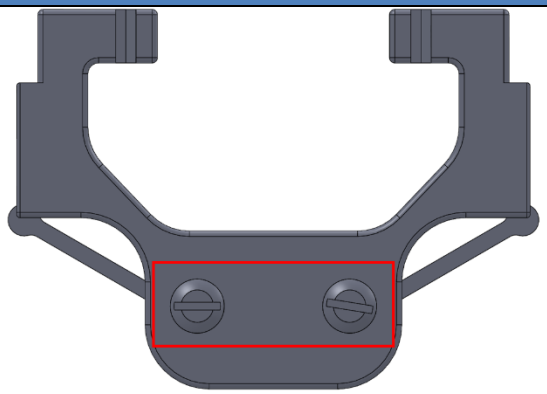
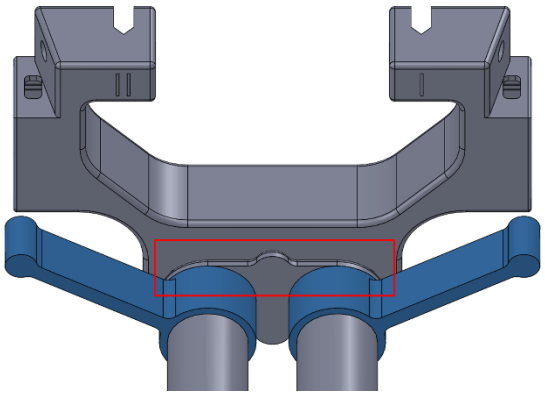
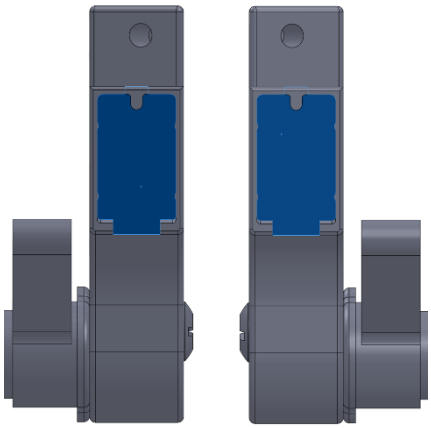
Cleaning: Front End Assembly

1. As illustrated in the adjacent images, remove the front end assembly thumb screws by turning the left side counter clockwise and right side clockwise.
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.

NOTE: The left side thumb screw is marked with **II** and the right side thumb screw is marked with **I**.



Cleaning: Front End Assembly
3. Immerse the front end assembly in detergent water. 4. While immersed in the detergent water, thoroughly clean all surfaces with a soft cloth and soft-bristle brush.
5. While immersed in the detergent water, use a soft-bristle brush to clean all debris and residual build up from the grid-plate slots (see red boxed area in the adjacent image). ⚠ Grid-plate slots on the front end assembly must be free and clear of any of any debris or residual build up to ensure good alignment of the grid plate.   
6. Use a soft-bristle brush to clean the left and right side threaded thumb screw holes (see red arrows in the adjacent images).   
7. With the front end assembly immersed in the detergent water, rotate each of the two control levers vigorously multiple times to loosen any potentially trapped debris (illustrated in the adjacent images). 8. Use a soft-bristle brush to clean inside both tubes.   

Cleaning: Front End Assembly	
9. While immersed in detergent water, clean the indicated areas around the bolt heads and lever joint crevices with a soft-bristle brush (see red boxed areas in the adjacent images). During this cleaning, rotate the control levers to ensure that all crevice areas are properly cleaned.	 
10. While immersed in detergent water, thoroughly clean indicated areas with a soft cloth and soft-bristle brush. ⚠ Areas indicated must be clean and free of all debris to ensure proper tracking of the grid plate.	

Cleaning: Front End Assembly

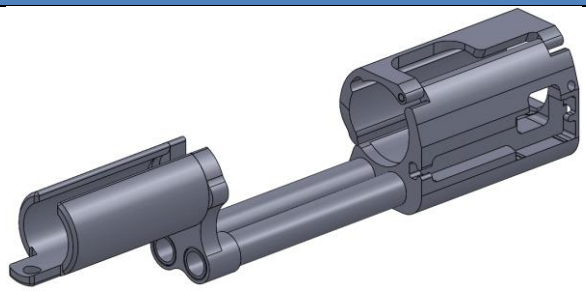
11. Remove the front end assembly from the detergent water and observe the color of the liquid:
    - Dripping from the tubes while holding the plastic side up
    - Dripping from the lever joint crevices while holding the assembly tube side up or to the side

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

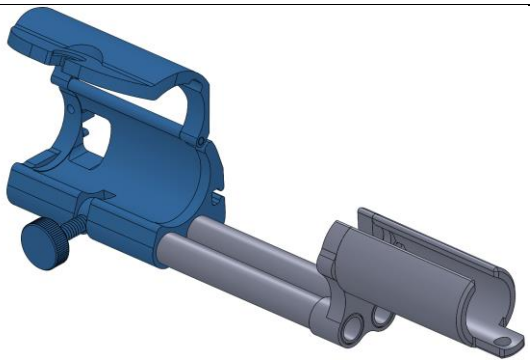
12. If the dripping liquid's color does not match the detergent water's color, immerse the front end assembly in the detergent water and repeat the process of rotating the levers with cleaning as described in the steps above.
13. Follow detergent manufacturer's recommendations for the duration of the rinse time.
14. Immerse assembly in clean water (no detergent). While submerged, rotate the front end control levers. Ensure that all surfaces are exposed to the rinse water.
15. 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.
16. 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.

Cleaning: Probe Holder Assembly

1. Immerse the probe holder assembly in detergent water. The probe holder assembly is shown in the adjacent picture.
2. Thoroughly clean all surfaces with a soft cloth and soft-bristle brush.



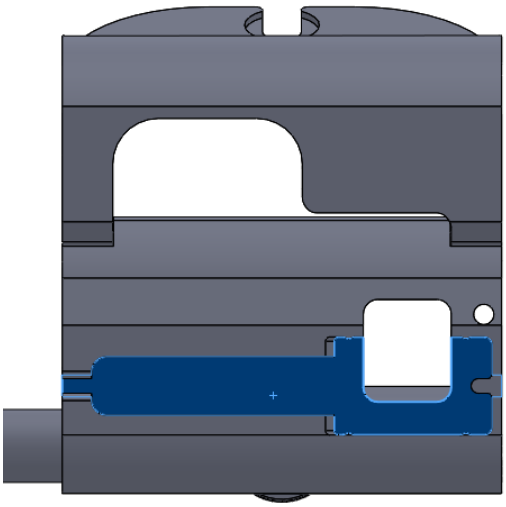
3. Open the probe clamp, as indicated in the adjacent picture. Ensure that the interior area of the probe clamp is cleaned and free of all debris.



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

Cleaning: Probe Holder Assembly

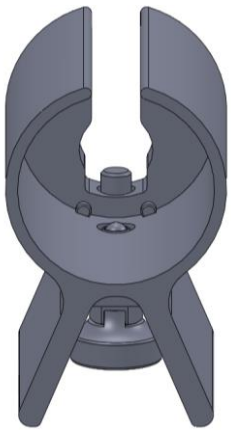
4. The EM sensor holder, which is located on the probe holder and depicted in the adjacent pictures, must be cleaned and free of debris to ensure proper tracking of the probe.
5. Immerse assembly in detergent water.
6. Thoroughly clean indicated areas with a soft cloth and soft-bristle brush.



7. Follow detergent manufacturer's recommendations for the duration of the rinse time.
8. Immerse assembly in clean water (no detergent), so that all surfaces are exposed to the rinse water.
9. Finish rinsing under running water, so that all surfaces are exposed to the running rinse water.
10. 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.

Cleaning: Handle

1. Immerse the handle in detergent water. The handle is shown in the adjacent picture.
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.



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

Intermediate Level Disinfection of the Stepper

Intermediate level disinfection of the Stepper uses the spray and wiping method with an intermediate level disinfectant. Before performing this procedure, read the warnings and cautions in the "Warnings and Cautions" section.

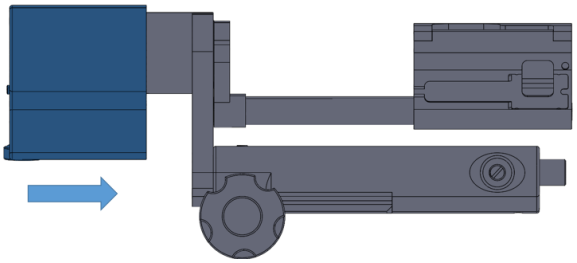
After all Stepper subassemblies are clean and dry per the detailed cleaning steps described above, follow the manufacturer's instructions and recommendations for use of the wipes and spray.

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

Stepper Disinfection
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.

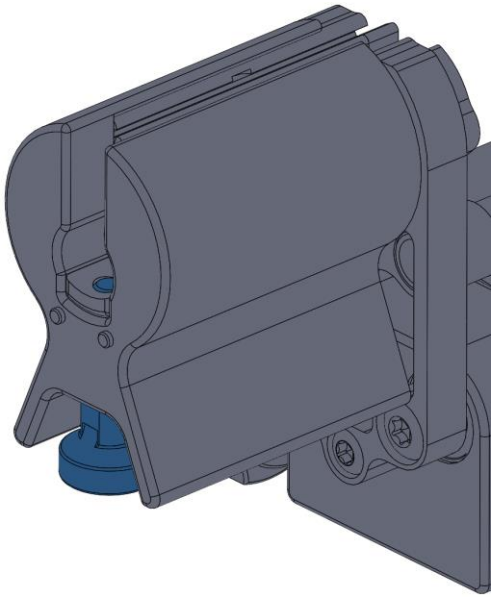
Reassemble Stepper

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

Stepper Reassembly
1. Reinstall the probe holder assembly by sliding it into the appropriate hole on the rack-and-pinion assembly, as indicated in the adjacent picture.
2. Reattach the handle, by sliding it back on to the rack-and-pinion assembly, as shown in the adjacent picture. 

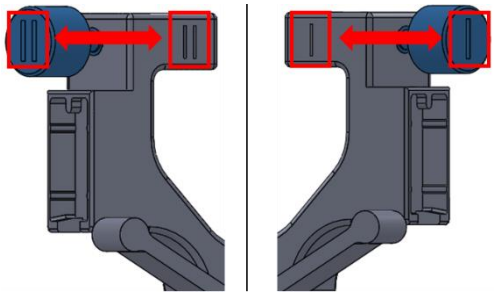
Stepper Reassembly

3. Once the handle is installed, ensure the release pin is back into its fully engaged position, as indicated in the adjacent picture.

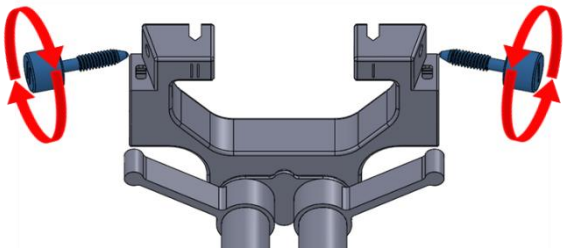


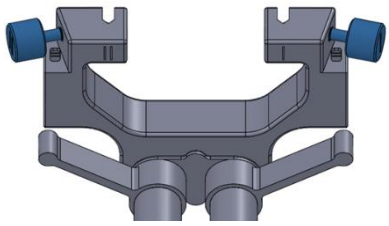
4. As illustrated in the adjacent images, reinstall the front end assembly thumb screws by turning the left side clockwise and right side counter clockwise.

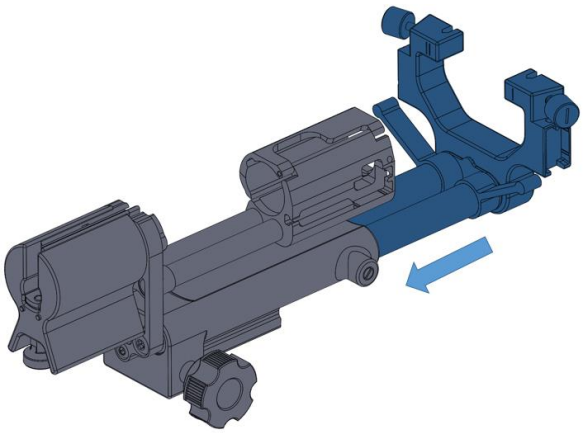
   NOTE: The left side thumb screw is marked with **II** and the right side thumb screw is marked with **I**.



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





Stepper Reassembly
5. Reinsert the front end into the rack-and-pinion assembly, as shown in the adjacent picture. Note that 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 can be pushed back into the rack-and-pinon assembly. 

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 limited to, examination for cracks or other defects.

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

1. The handle and probe holder should rotate freely. There should be no sticking or jamming during the rotation.
2. The front-end assembly 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. Once 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.

The instructions provided above 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 using equipment, materials and personnel in the reprocessing facility achieve the desired result. This normally requires validation and routine monitoring of the process.

5.33.7. Cleaning of the Stepper Arm

⚠ Users are responsible for providing the highest degree of infection control to patients, co-workers and themselves. Follow all infection control policies established by your facility to avoid cross-contamination.

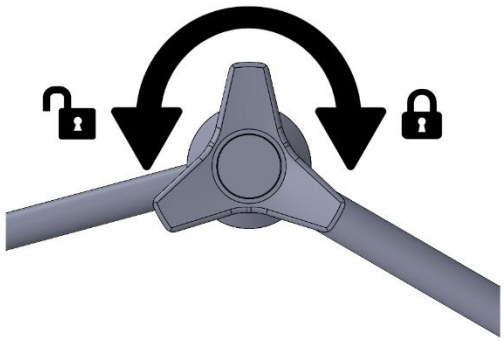
⚠ Do not place in a mechanical washer.

⚠ Do not use ethylene oxide, disinfectant agents containing bleach (sodium hypochlorite) or autoclave to sterilize.

⚠ Before using the Stepper Arm for the first time, follow the instructions provided below to prepare the Stepper Arm for use. Clean and disinfect the Stepper Arm immediately after each use to protect patients and personnel from a variety of pathogens.

⚠ The articulated arm must not be sprayed or immersed in liquids.

1. The central handle of the articulated arm must be tightened for cleaning and disinfection, as displayed in the graphic below.



2. Clean the Stepper arm parts 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 the Stepper arm parts. Wipe the Stepper arm parts for the minimum contact time given by manufacturer of the detergent until all visible soil is removed.
5. Once all Stepper arm parts are clean, wet a clean lint-free cloth with potable water and thoroughly wipe the Stepper arm parts to remove cleaning residue.
6. After removing all cleaning residue, thoroughly dry the Stepper arm parts with a clean, dry, lint-free cloth.
7. Visually inspect the Stepper arm parts 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 above steps using fresh cloths until you see no soil or cleaning residue.

9. Once dry, wipe all the Stepper arm surfaces with an intermediate level disinfection wipe; such as, Super Sani-Cloth®, Sani-Cloth Prime®, or Sani-Cloth® AF3 wipes all from PDI.
10. Wipe all surfaces for the minimum contact time given by manufacturer of the disinfectant.
11. Before reuse, allow the Stepper arm to air dry or wipe dry with lint-free cloth.

5.33.8. Cleaning of the Stepper Stand

⚠ Users are responsible for providing the highest degree of infection control to patients, co-workers and themselves. Follow all infection control policies established by your facility to avoid cross-contamination.

⚠ Do not place in a mechanical washer.

⚠ Do not use ethylene oxide, disinfectant agents containing bleach (sodium hypochlorite) or autoclave to sterilize.

⚠ Before using the Stepper Stand for the first time follow the instructions provided below to prepare the Stepper Stand for use. Clean and disinfect the Stepper Stand immediately after each use to protect patients and personnel from a variety of pathogens.

1. Clean the Stepper Stand parts 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.
2. With the prepared detergent solution, wet a lint-free cloth. Squeeze out excess liquid.
3. Use the damp cloth to wipe the Stepper Stand parts. Wipe the Stepper Stand parts for the minimum contact time given by manufacturer of the detergent until all visible soil is removed.
4. Once all Stepper Stand parts are clean, wet a clean lint-free cloth with potable water and thoroughly wipe the Stepper Stand parts to remove cleaning residue.
5. After removing all cleaning residue, thoroughly dry the Stepper Stand parts with a clean, dry, lint-free cloth.
6. Visually inspect the Stepper Stand parts in a well-lit area to confirm the absence of any soil or cleaning residue.
7. If you see any soil or cleaning residue, repeat the above steps using fresh cloths until you see no soil or cleaning residue.
8. Once dry, wipe all the Stepper Stand surfaces with an intermediate level disinfection wipe; such as, Super Sani-Cloth®, Sani-Cloth Prime®, or Sani-Cloth® AF3 wipes all from PDI.
9. Wipe all surfaces for the minimum contact time given by manufacturer of the disinfectant.
10. Before reuse, allow the Stepper Stand to air dry or wipe dry with lint-free cloth.

5.34. Routine Maintenance

Cleaning the System Air Filter

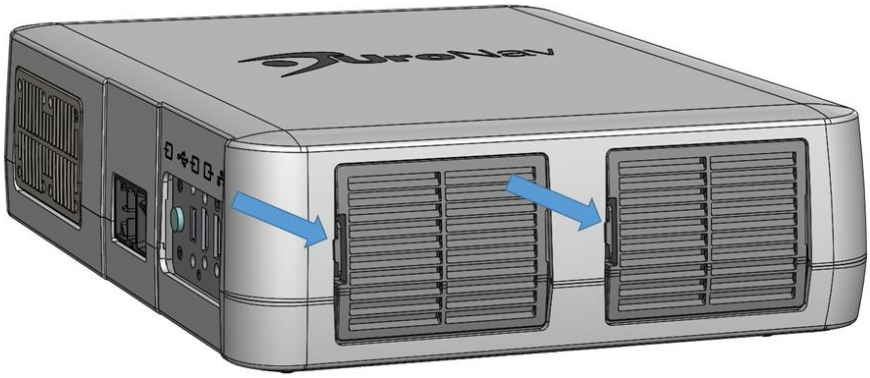
The system air filters should be inspected weekly and cleaned as needed. If you decide to clean the air filter with soap and water, you may want to install a spare filter while the other filter is drying. To order additional air filters, contact your local Philips representative.

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

⚠ Do not turn on the power without the air filter installed.

⚠ Ensure that the air filter is dry before installing it. Installing a wet or damp air filter can damage the system.

- Remove both air filter covers on the UroNav housing
- Pull the air filters out
- 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.
- Reinstall the filters and filter covers into place



6. Overview, Procedure Requirements, General Workflow

6.1. Technical Description

The UroNav is comprised of a mobile cart with the mounted UroNav computer (CPC) and monitor as depicted in Figure 1. The UroNav cart includes a keyboard tray and horizontal work surface for mouse operation. A USB interface HID foot pedal can be used to duplicate specific on-screen mouse functions for operator convenience.

Figure 1: UroNav

Figure 2: Foot Pedal

Figure 3: Field Generator and Articulating Arm

Figure 4: Stepper

Figure 5: EM Tracker with Probe Holder

Figure 6: Stepper Table Rail Mount

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 for a transperineal procedure. 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 high-level disinfection, and the probe holder is a single-use disposable device with a requirement for cleaning prior to use.

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. 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 prostate 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 S-Video or HDMI Ultrasound image video formats and connections.

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

6.2. Product Conventions

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

- To type text into a text field, click in the field and use the keyboard.
- To display a list, click the down arrow. To scroll through a list, click the arrows at either end of the scroll bar or drag the scroll box up or down.
- Controls on the screen use several methods to indicate their status. Buttons that are either on or off have an indicator in the upper corner that lights when it is on. Buttons that select a setting display the active setting either within the button or on the monitor display. An arrow in the lower right corner of a button indicates that the button displays or hides a group of related buttons. Where only one button in a group can be selected at a time, the selected button is indicated by a gold outline or background.

6.3. User Information Conventions

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

- All procedures are numbered, and all sub procedures are lettered. You must complete steps in the sequence they are presented to ensure success.
- Bulleted lists indicate general information about a particular function or procedure. They do not imply a sequential procedure.
- Control names and menu items or titles are spelled as they are on the system, and they appear in bold text.
- Symbols appear as they appear on the system.
- The pointer is the cursor used to select elements on the display.
- 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 Select 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.

6.4. 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
Access Control via user authentication can be configured by a service representative if required. UroNav can be configured to authenticate users using an Active Directory group on the domain network.

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

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

7. 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 procedures.
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 segmentation 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 (see Appendix B and C).

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 UroNav that has not been calibrated, the notice *Video Calibration Required* will appear on the UroNav Setup screen seen in Figure 8 *Video Calibration Required*. Any change to the ultrasound system and probe combination will require UroNav video calibration to be repeated.

⚠ 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.

NOTE: Contact Philips support for assistance

NOTE: Multiple "different" US devices can be supported, with the software saving separate calibrations for each device. However, multiple "like" devices (I.E. 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.

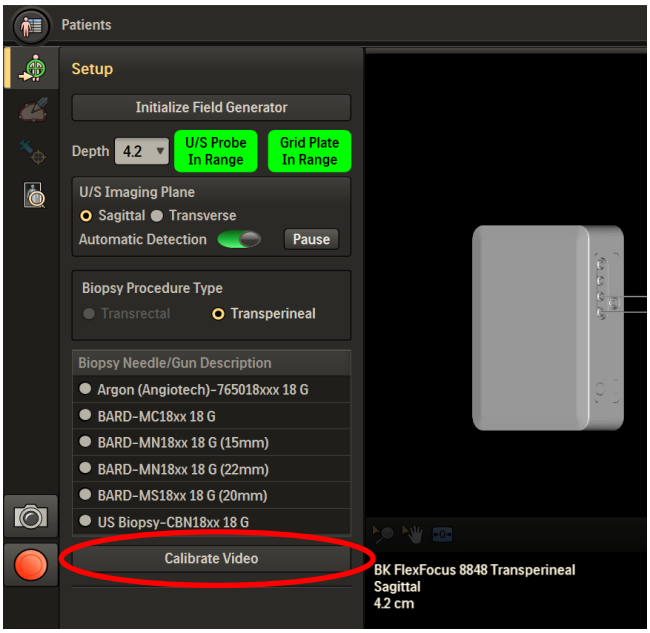


Figure 7: Service Feature - Calibrate Video

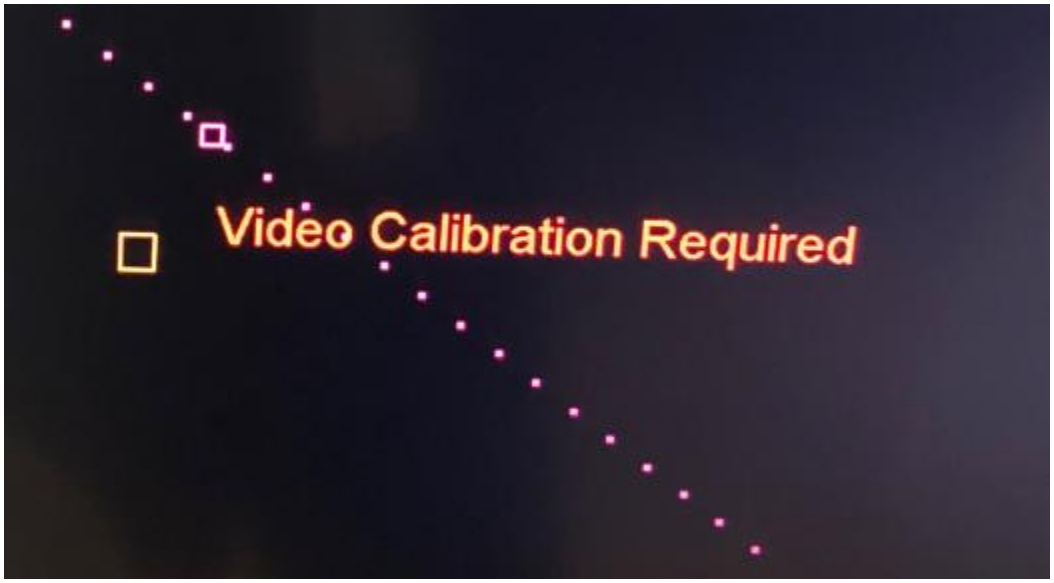


Figure 8: Video Calibration Required Prompt

8. Pre-Procedure Setup

In this section, all the necessary steps are detailed to prepare the system for use in fusion guided procedures. It covers the setup of the UroNav cart with the EM tracking system, the Stepper assembly, ultrasound video connection, and the import/creation of patient data.

8.1. UroNav Cart Setup Overview

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

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

NOTE: Please contact Philips customer support if a replacement keyboard or mouse is needed. The user does not have the ability to pair these devices.

8.1.1. 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 per the Symbols Table in the ***Safety*** section of this Instructions for Use. Position the red alignment dot on Field Generator plug to top center notch of panel connector, also marked in red, and then insert plug; do not force insertion prior to proper alignment. Pull gently on the plug barrel to unlock and remove; do not pull on the cable or cable strain relief.

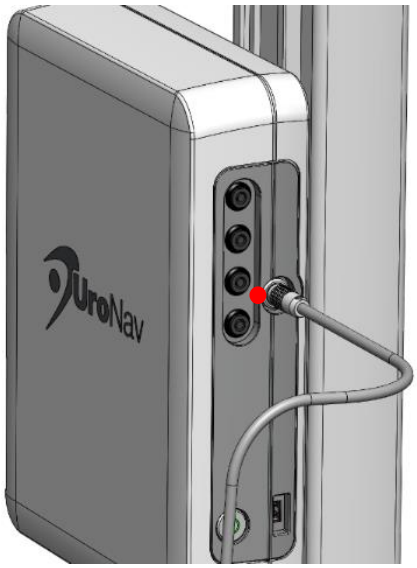


Figure 9: Field Generator front panel connection

The prostate workflow requires that a tracker be used to track the position of the ultrasound transducer. For the transperineal workflows using a grid plate, an additional tracker is required for the grid plate. For the transperineal workflow using the PrecisionPoint™ Transperineal Access System, only one tracker is required.

The EM Tracker connects to the UroNav via any one of 4 EM Tracker connectors, located on the front panel of the enclosure, unique to the EM Tracker plug. Position the black arrows on the EM Tracking Sensor plug to the top center panel connector, and then insert the plug. Field Generator connector is keyed and the alignment is color-coded red. Do not force insertion. Pull gently on the plug barrel to unlock and remove; do not pull on the cable or cable strain relief.

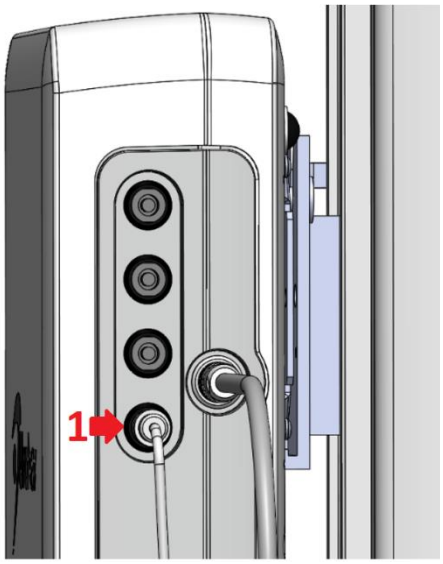


Figure 10: EM Tracker Port 1-of-4 (Bottom-Top) connection locations

The EM Trackers are inserted in the Stepper as illustrated in Section 14.2 ,or into a clip on as described in Sections 12.2 and 13.2.

⚠ 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 (see Figure 11).

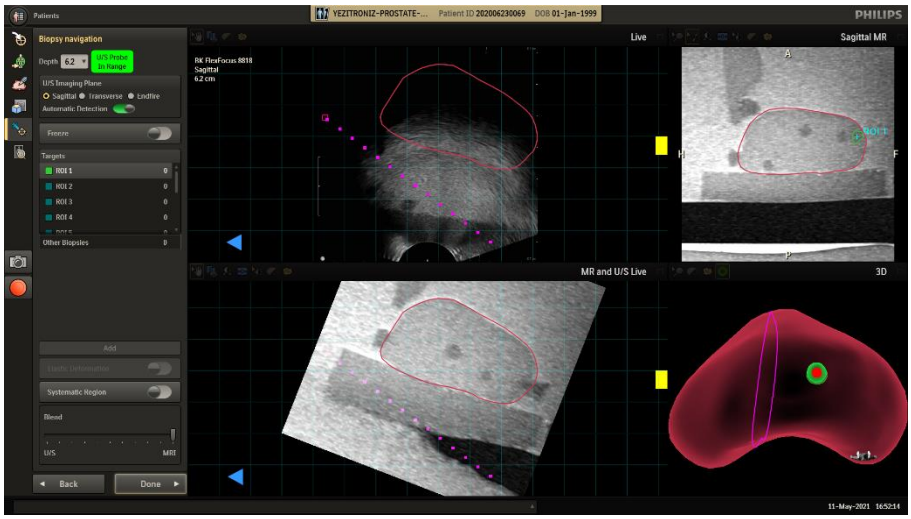


Figure 11: Inaccurate registration due to improperly secured EM Tracker

8.1.2. Ultrasound Video Configuration

The Video In connections use the supplied S-video or HDMI cable to display the U/S video on the UroNav screen.

When connecting Mini DIN-4 S-video cable from U/S system video, position alignment tab of S-video plug to align with the slot in the panel connector, and then insert the plug. S-video connector is keyed; do not force insertion prior to proper alignment.

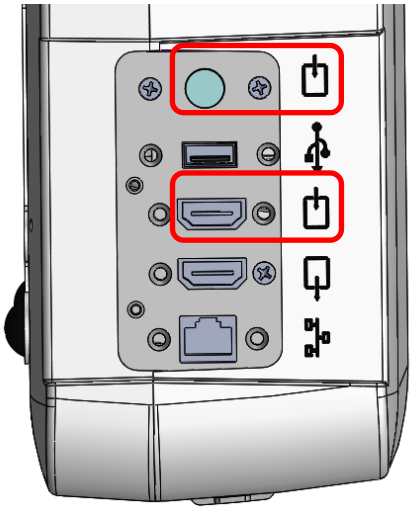


Figure 12: Video input, rear panel connections

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. Refer to Section 12 and Section 13 for more information on supported modes.

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 (e.g., iScan)

8.1.3. Foot Pedal

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

Figure 13: Foot Pedal

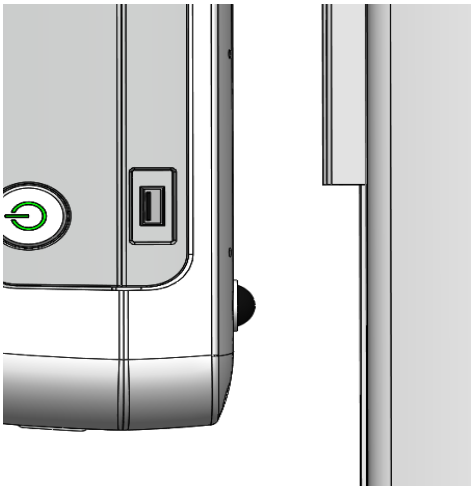


Figure 14: Foot Pedal front panel USB port connection. Rear panel USB port may also be used

8.2. Network Connections:

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

8.3. EM Field Generator Arm Setup

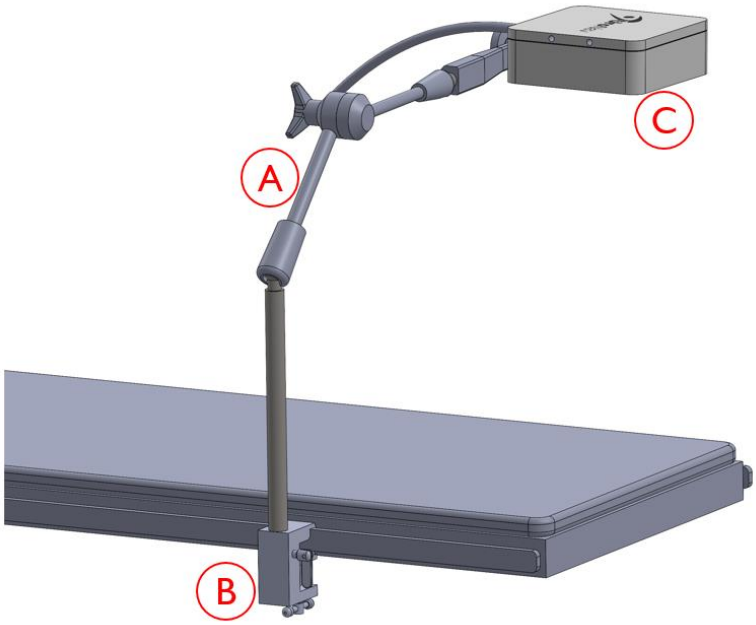


Figure 15: Articulating arm with Field Generator attached

A	Field Generator Mounting Arm
B	Mounting Arm Support Clamp
C	EM Field Generator

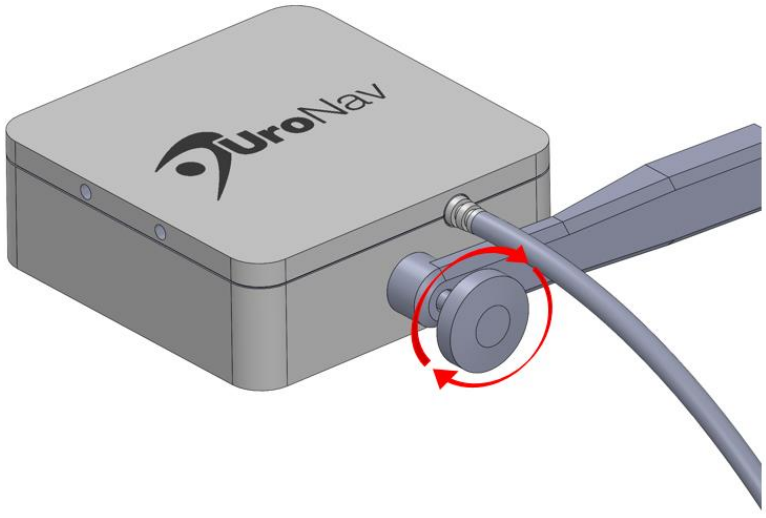


Figure 16: Attaching the Field Generator to the articulating arm

⚠ Ensure the UroNav logo is pointing upwards and away from the treatment area and that the cable is not wedged between the Field Generator and the mounting arm.

Figure 17: Pole Cart Field Generator Mounting

For information on how to use the EM Field Generator Arm Setup, you should refer to the Instructions for Use supplied with the equipment.

8.4. Stepper Setup for Use with Transperineal US Probe

See Section 14 Appendix D for detailed instructions on the usage of the Stepper and Stepper arm for trans-perineal procedures.

This describes:

- Attaching the Stepper arm to the hospital bed
- Attaching the Stepper to the Stepper arm
- Attaching/removing of the Ultrasound probe into the Stepper
- Attaching/removing the EM Trackers
- Attaching /removing the grid template onto the Stepper

8.5. 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 (see Figure 18 and Figure 19). The cord should exit toward the patient's head or feet and the Articulating Arm firmly affixed to a secure surface.

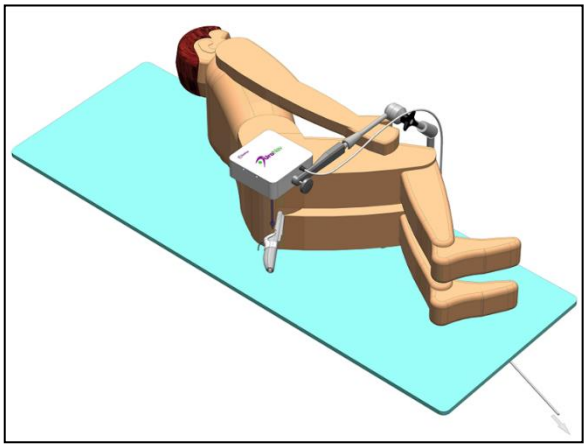


Figure 18: Left Decubitus Position

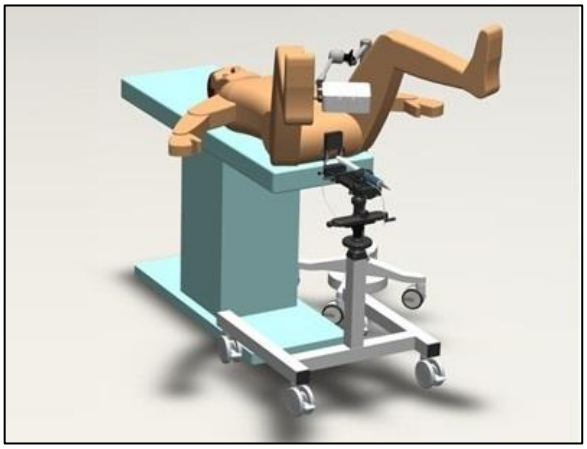


Figure 19: Lithotomy position

8.6. 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 data should be available. Patient records can either be imported from an external data source, or a patient record can be created.

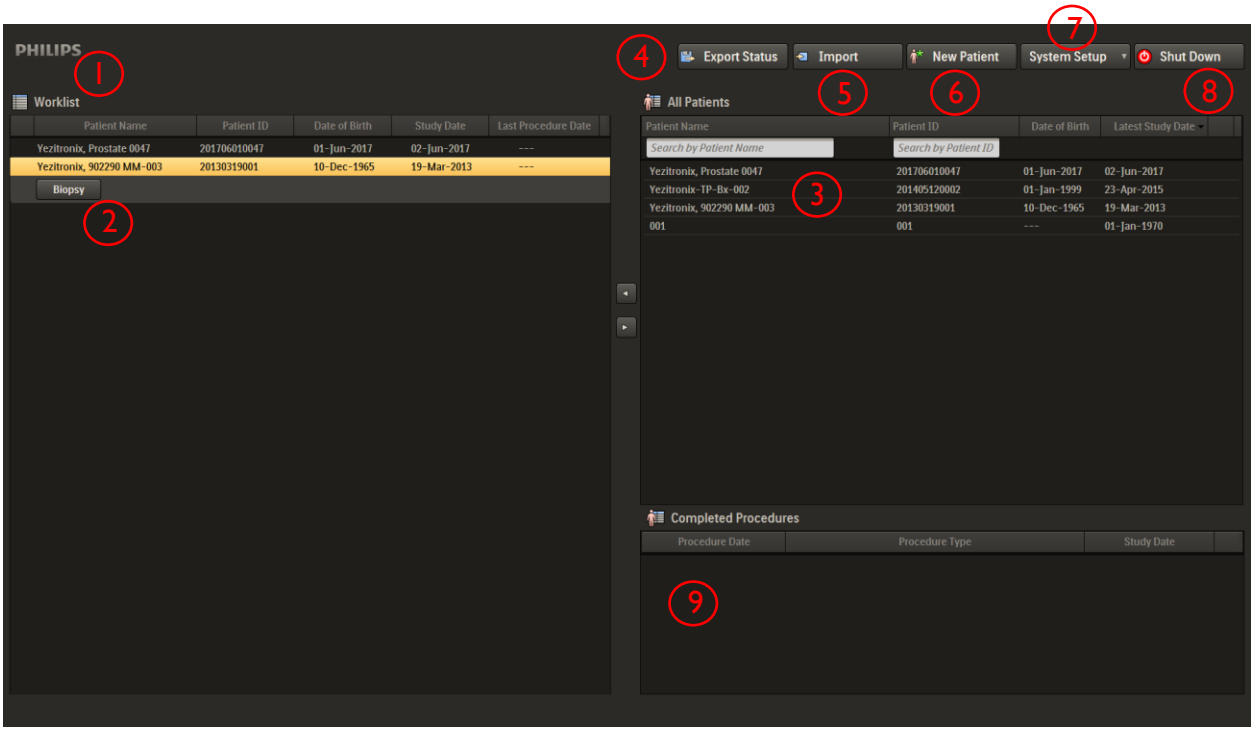


Figure 20: Home Screen / Data Handler

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	**All patients list:** Shows all imported patients.
4	**Export Status:** Flashes when patient data is exported.
5	**Import:** Enables the import of patient data.
6	**New patient:** Create a new patient record for an Ultrasound Only workflow.
7	**System setup:** Enables the editing of system settings.
8	**Shut down:** Exit UroNav and power down the system.
9	**Completed Procedures:** Displays history of procedures for selected patient.

8.6.1. Completed Procedures

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

- Procedure Date

- Procedure Type
- Study Date
- Export Status

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

8.6.2. Import

When patient data is imported from DynaCAD™, the most recently created segmentation and targets will be imported automatically. It is then possible to start the Biopsy workflow using the resulting study.

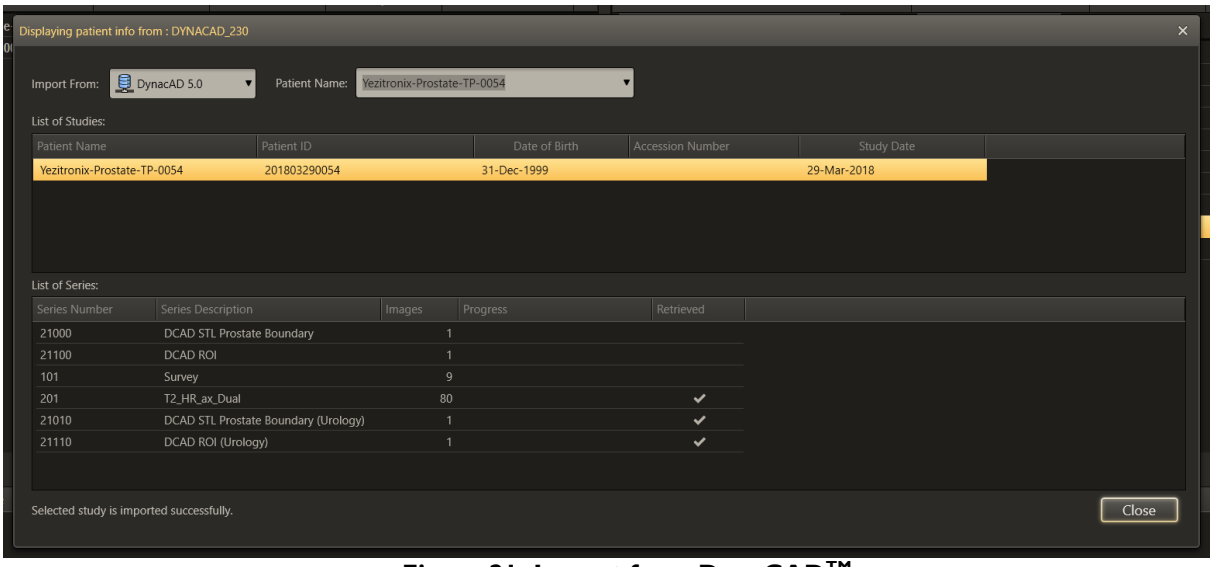


Figure 21: Import from DynaCAD™

Use UroNav to directly import images created from DynaCAD™. If a network connection is unavailable, import images from a disk or USB created from DynaCAD™. Do not attempt to export images from DynaCAD™, as the UroNav connectivity may be limited (e.g., due to being switched off or unplugged).

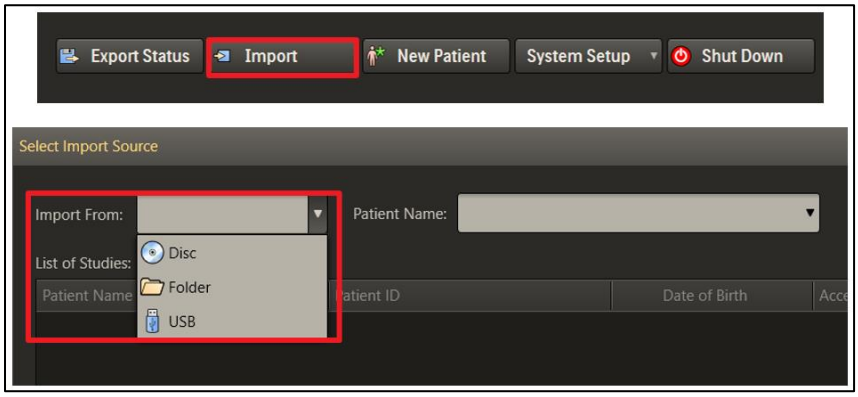


Figure 22: Import

8.6.3. New Patient

An Ultrasound Only patient study can be created without associated MR data by clicking the New Patient tab (Figure 23).

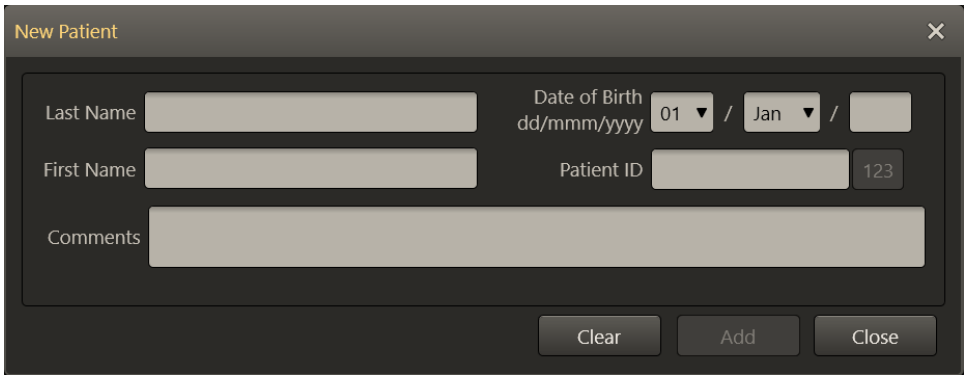


Figure 23: New Patient window

8.7. System Setup

The **System Setup** tab contains settings for system configuration and general information.

8.7.1. DICOM

In the DICOM tab of the Configuration menu, remote servers (e.g., DynaCAD™, PACS, etc.) and the default Server AE settings are determined. (See Figure 24).

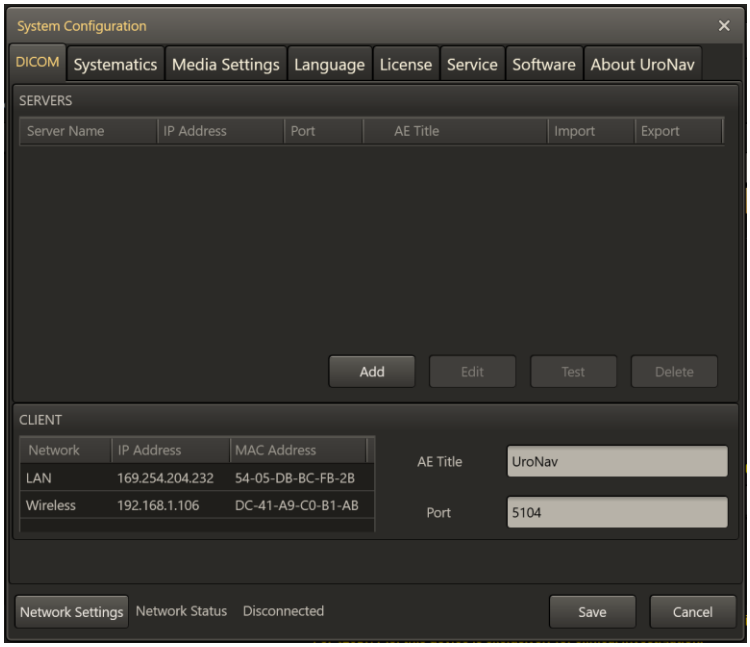


Figure 24: System Configuration DICOM servers

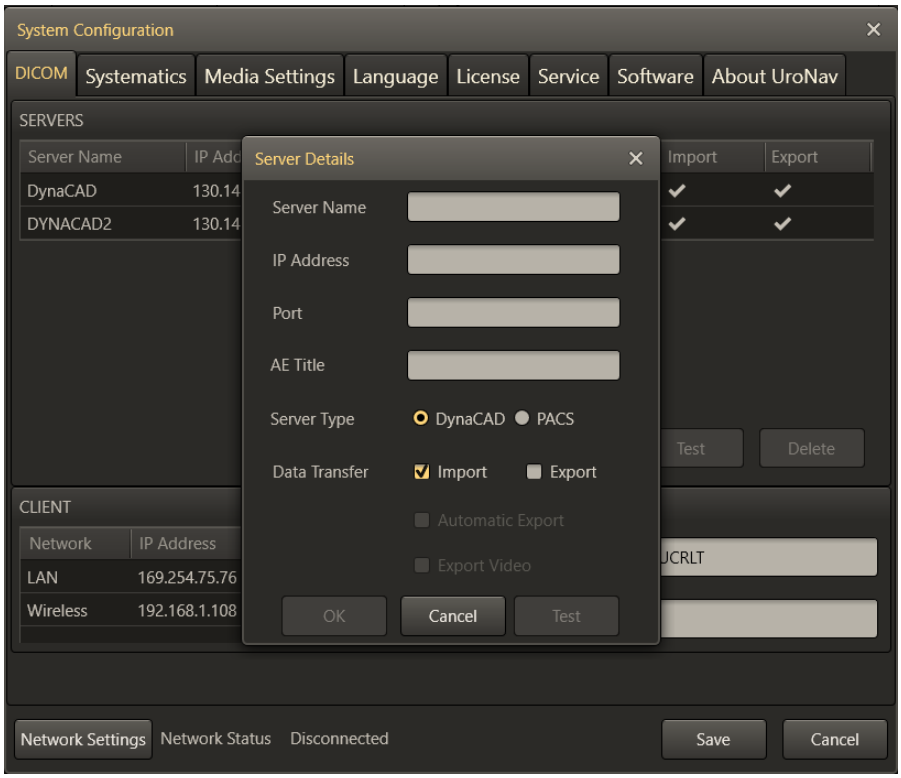


Figure 25: Network Settings, Set IP Address

8.7.2. Systematic Regions

In the Systematics tab of the Configuration menu, the ordering of a systematic plan can be customized to accommodate both the Transrectal and Transperineal biopsy workflows.

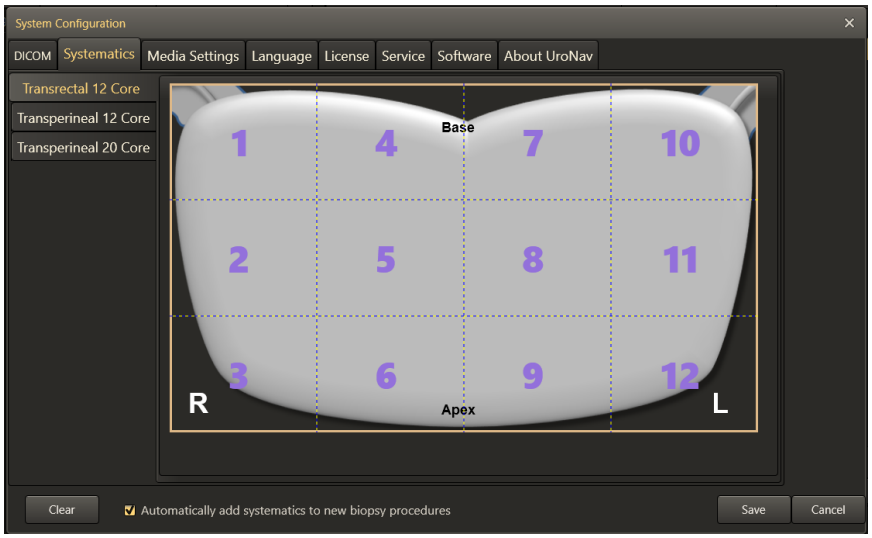


Figure 26: Transrectal Systematic Biopsy Plan Customization

With a systematic region plan defined in the System Configuration window, the user can automatically add up to twelve predefined systematic target regions to a Transrectal biopsy procedure by clicking the **Systematic** button in the Biopsy screen. For transperineal biopsy procedures, up to twelve systematic target regions can be configured with the Transperineal 12 core configuration (Figure 27), or up to 20 with the Transperineal 20 core configuration (Figure 28).

See Section 9 for information on how to add systematic regions to a biopsy procedure.

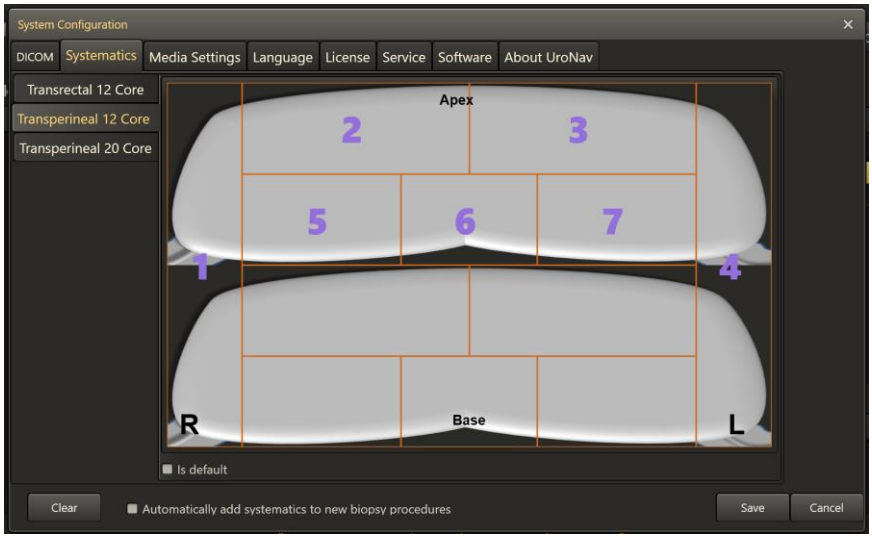


Figure 27: Core Transperineal Systematic Biopsy Plan Customization

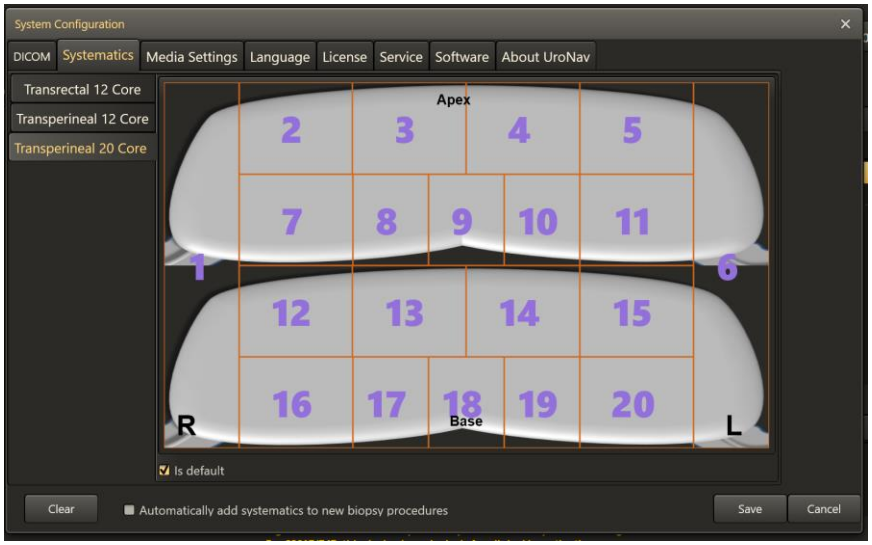


Figure 28: Core Transperineal Systematic Biopsy Plan Customization

8.7.3. Media Settings / Video Recording

Video recording of the procedure is captured in Full-Screen mode, which is configurable from the System Configuration menu, **Media Settings** tab (Figure 29). Multiple recordings can be saved per procedure.

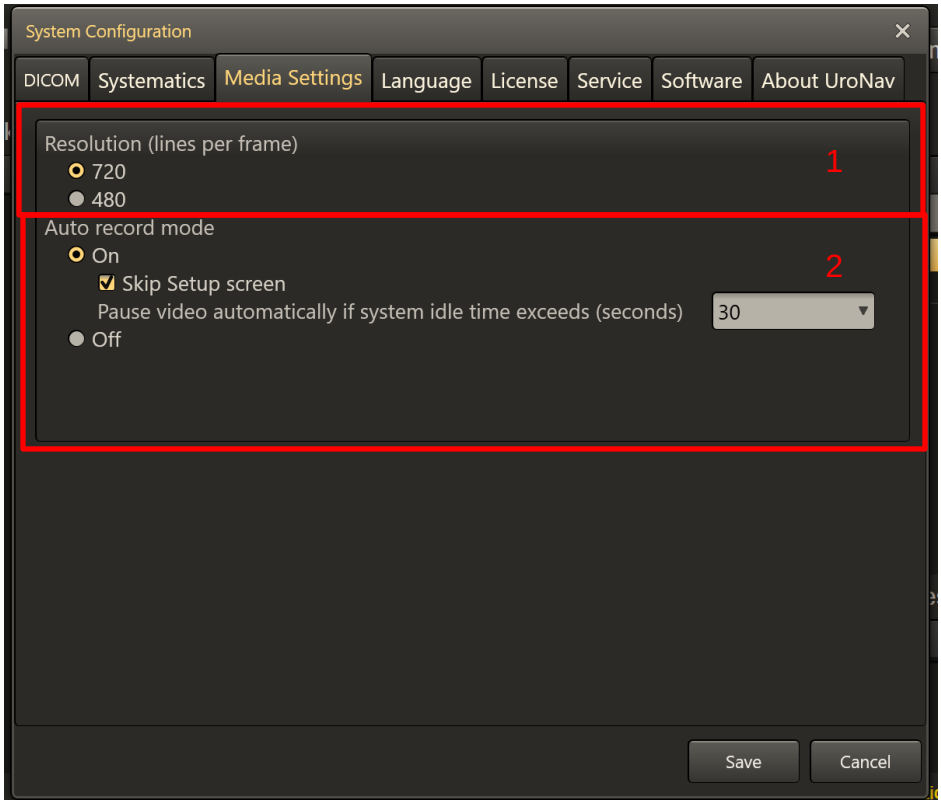


Figure 29: System Configuration Operational Mode

1	**Resolution**: List options to save video recording in one of the selected resolution.
2	**Auto record mode** **On** - Select to enable automatic video recording mode. **Skip Setup screen** – Check to skip the recording of "Set-up Instruments 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.

NOTE: The system will prompt the user for an automatic restart in order to save the selected setting.

8.7.4. Language

The Language tab can be used to set the language of the user interface (Figure 30).

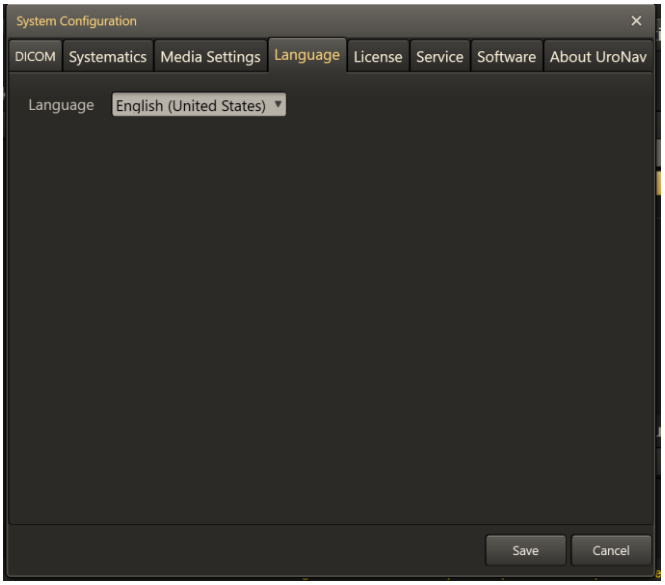


Figure 30: Set Language

8.7.5. Service / Start Support Session

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

- Call Philips customer support
- When directed, click **System>Service>Start Support Session**.

In the Service tab of the Configuration menu, the Service Equipment ID for the system can be viewed. This information is used by Service users only. In addition, the Contact Information for the manufacturer can also be viewed.

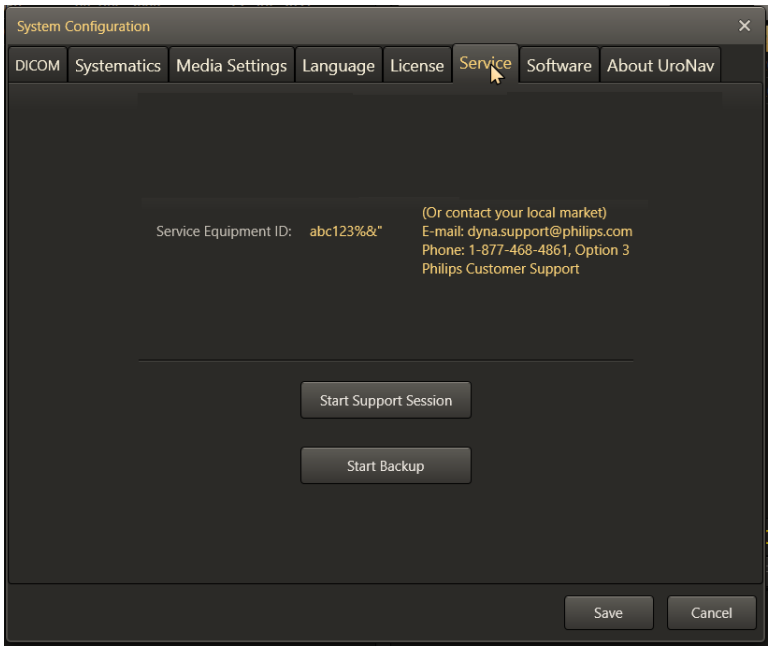


Figure 31: Service Tab

8.7.6. Service / Backup

UroNav enables the backup of both patient and configuration data for the purpose of both migration and future restoration. The backup feature can be accessed from the *Home Screen* by clicking **System Setup**, then the **Service** tab (see Figure 31).

A backup location (either USB or network) must be provided before the backup can be executed (Click the **Refresh** icon 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. Once the backup operation completes successfully, the USB will be automatically disconnected from UroNav.

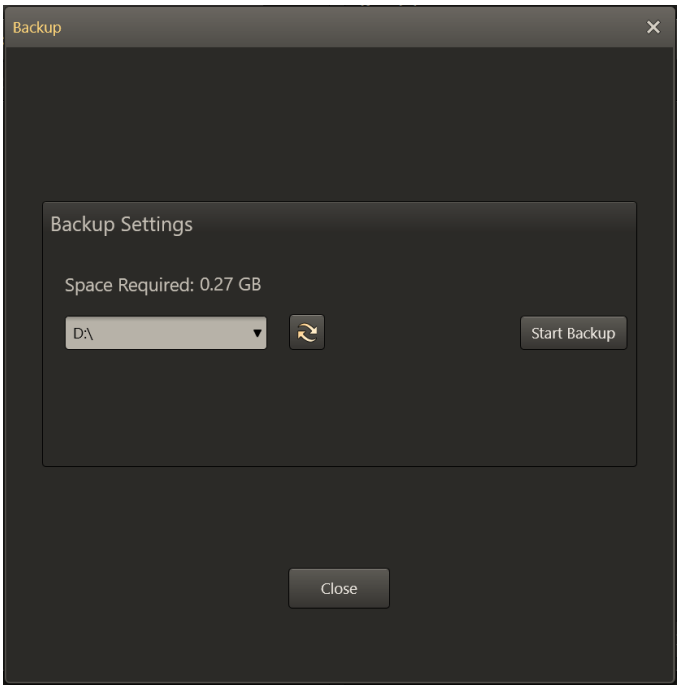


Figure 32: Backup Configuration

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.

8.8. General concepts

8.8.1. Patient Identification

Once a procedure has been started for a specific patient, the patient identification information is visible at the top of the screen. The visibility of patient identification information can be toggled on / off using a keyboard shortcut key (see Section see Section 9.7 Keyboard & Mouse Shortcuts).

8.8.2. Closing the Application

Once a procedure has been started, it can be canceled by selecting the  button.

8.8.3. Message bar

The message bar in 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 procedure and can be expanded with the **up arrow** icon on the right side.

8.8.4. 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 (see Section9.7 Keyboard & Mouse Shortcuts). Note that the content of this menu will differ per screen as different screens contain different visual layers.

8.8.5. Taking Screenshots

UroNav supports a built-in screenshot utility to document snapshots during the procedure. The screenshot utility is can be triggered in multiple ways:

- Click the  button in the navigation side bar.
- Use the foot pedal (left button with the camera icon)

Images taken in this manner can be reviewed in the Review procedure step.

8.8.6. Video Recording

Recording begins automatically when Auto-record mode is selected in the System Configuration by clicking the **System Setup>Media Settings** tabs. In manual video recording mode, press the **Record** button () that appears on the left side of the screen to begin recording and then pressed the **Pause** button () to stop recording.

Once recorded, the procedure can be played back on the **Procedure and Images Review** screen which includes bookmarks on the playback timeline that correspond to the recorded biopsies (Figure 33). The file can also be played back using Windows® media player or other player capable of playing MP4 video; however, the bookmarks will not be available.

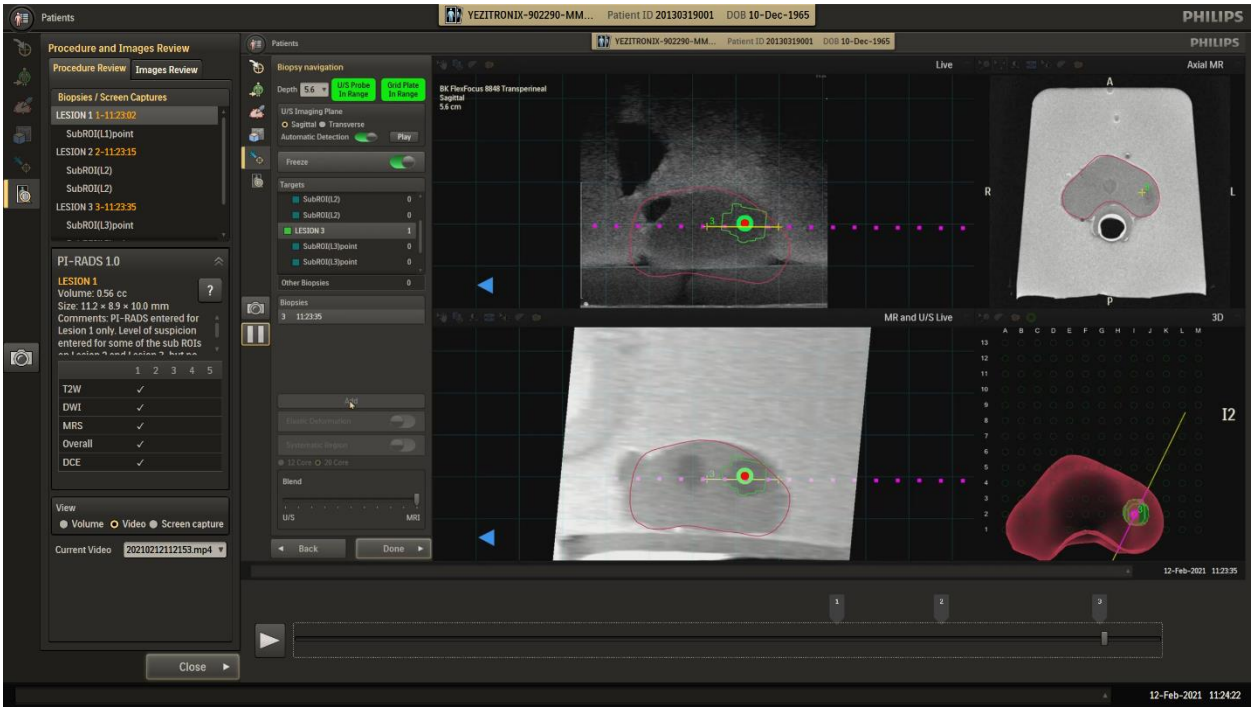


Figure 33: Transperineal Biopsy Procedure Review Video Recording

8.8.7. Patient Coordinate System

The UroNav uses a separate coordinate system for its Graphical User Interface than is used when saving or exporting files.

8.8.7.1. Origin

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* (see Figure 34). The orientation is relative with respect to the orientation of the grid template.

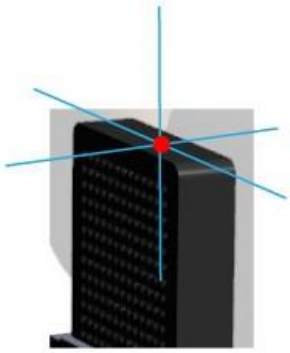


Figure 34: Patient coordinate system origin and orientation

8.8.7.2. DICOM patient coordinate system

The DICOM patient coordinate system (see Figure 35) is used within saved/exported files to ensure that data sharing between the UroNav and other systems is handled properly.

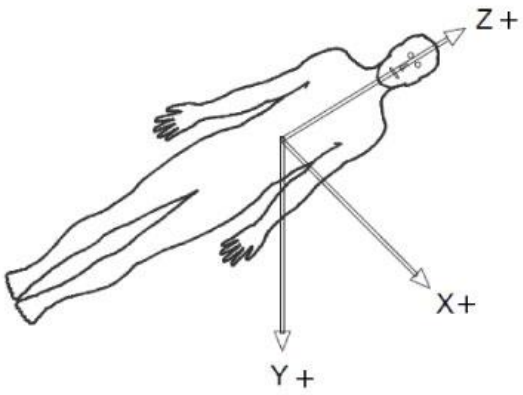


Figure 35: DICOM patient coordinate system used when saving/exporting files

8.8.7.3. Patient coordinate system used in the User Interface

In the User Interface of the UroNav, the IEC61217 compliant patient coordinate system is displayed, see Figure 36.

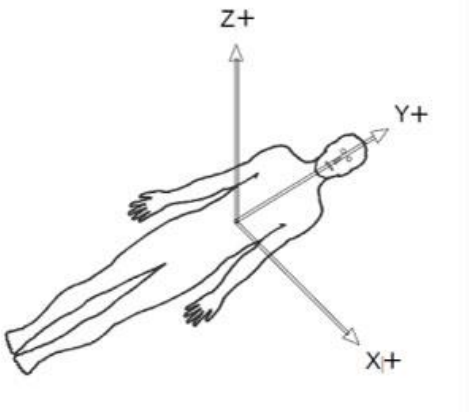


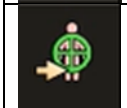
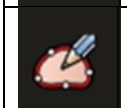
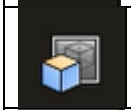
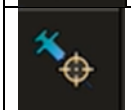
Figure 36: GUI patient coordinate system

9. Biopsy Workflow

To start the Biopsy workflow:

1. Ensure that a patient record is available, see section 8 **UroNav Home Screen** 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 menu* to navigate between different procedure steps. On the start screen, the navigation menu is displayed on the left; the different steps are presented as separate buttons that take the user to its dedicated screen. The UroNav flow consists of the following steps:

Icon	Step	Description
	Review segmentation & targets[1]	Reviewing the T2 weighted MR scan including delineations.
	Setup	Selecting the US system, TRUS probes, grid plates, and biopsy needle option.
	Sweep & segmentation	Acquiring ultrasound slices during a sagittal sweep and reconstructing an US volume.
	Align US volume with MR[1]	Fusing the MR volume and targets with the US data by adjusting the registration.
	Biopsy Navigation	Marking biopsy cores.
	Procedure and Images Review	View the screen captures and video recording of the procedure, as well as the segmentations and marked biopsy cores.

[1] Not available for ultrasound only procedures

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

9.1. Review Segmentation & Targets Screen

NOTE: The *Review Segmentation & Targets* screen is not displayed for ultrasound-only procedures.

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 procedure.

The default layout of the *Review Segmentation & Targets* screen shows the selected target from the target list in multi-planar MRI format (Figure 37).

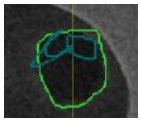
9.1.1. User Interface

Figure 37: Review Segmentation & Targets User Interface

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
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 procedure. If defined in DynaCAD™, target hierarchies (a target within a target) and PI-RADS metadata can be imported.

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

9.1.2. PI-RADS Target Metadata

Prostate Imaging Reporting and Data System (PI-RADS) can be provided in DynaCAD™ and displayed in UroNav.

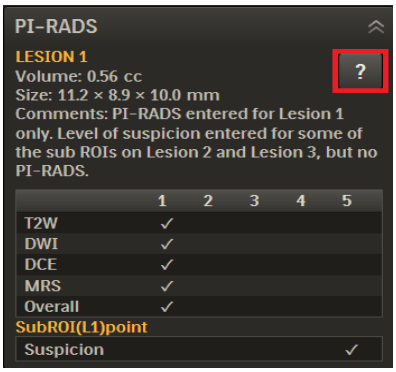


Figure 38: PI-RADS Information

By clicking the question mark (?) on any of the PI-RADS controls (see Figure 38), the PI-RADS details are displayed, providing detailed descriptions of each of the parameters' significance (see Figure 39).

NOTE: UroNav supports PI-RADS version standard 1.0, 2.0 and 2.1 (depends on DynaCAD™ version).

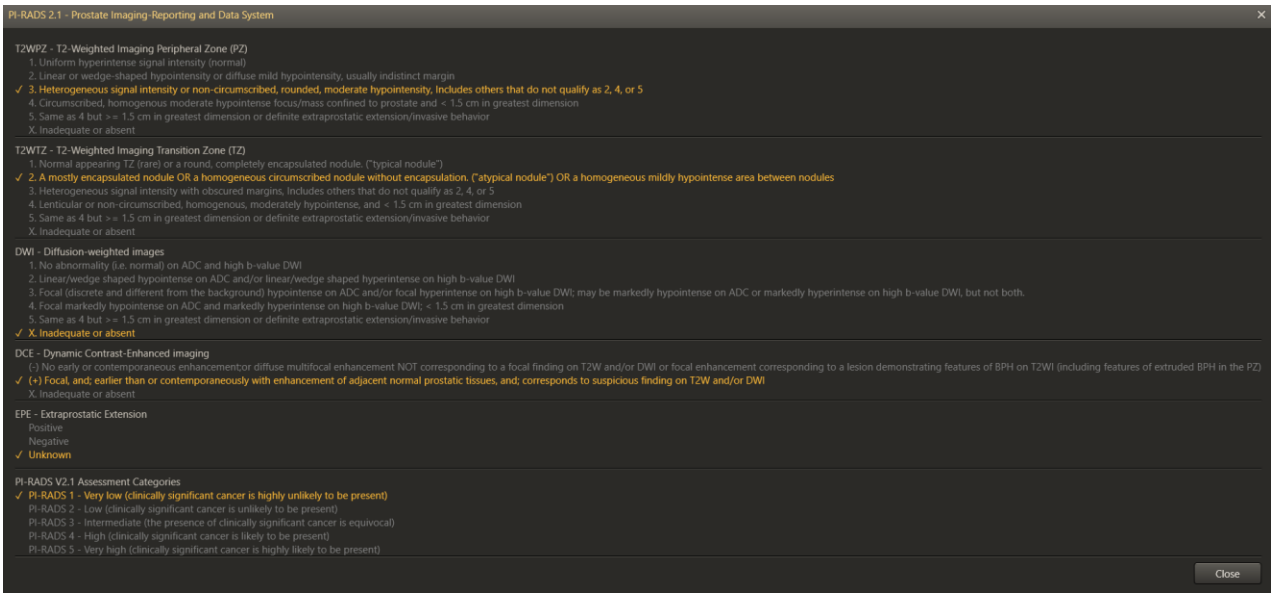
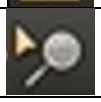
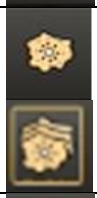
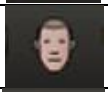


Figure 39: PI-RADS 2.1 Details

9.1.3. In-viewport Icons

Icon	Step	Description
	Pick Point	Sets cross-correlation point in all 2D image planes.
	Zoom	Zooms image.
	Pan	Pans image.
	Rotate	Rotate 3D image.
	Scroll	Scrolls through 2D data set.
	Automatically adjust window width and window level	Automatically adjusts gray-scale to optimize image quality.
	Reset viewing settings	Restores to default image settings.
	Gray level	Manual window width and window level adjustment.
	Show all/selected	Displays all or selected Targets in all viewports.
	Adjust mesh boundary tool	Adjust boundary on active viewport. Boundary adjustment correlated and visiualized in all three planes (default setting).
	MRI-imported target	The bull's eye for MRI-imported targets represents the calculated center of the identified target (centroid).
	Axial	Changes viewport to axial display.
	Coronal	Changes viewport to coronal display.
	Sagittal	Changes viewport to sagittal display.

9.1.4. Adjusting Prostate Boundary

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

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

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.
- **Smooth** can be used to correct rough edges made during boundary editing.
- **Undo** and **Redo** can be used to correct changes made during boundary editing.

Figure 40: Adjusting Prostate Boundary

9.2. 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 Section 12 and Section 13 of this document for the TRUS type being used for correct assembly and attachment.
For non-PrecisionPoint transperineal procedures, an additional EM tracker must be secured to the Stepper for use with the grid plate.

Initialization of the Field Generator (FG) 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**.

Figure 41: Activating Field Generator

⚠ 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.

⚠ It is advised that the user verify that the biopsy device to be used matches the selection in the Biopsy Needle Gun description list. Use of unsupported biopsy guns and needles may cause EM interference and result in inaccurate registration and biopsy core marking.

- The Tracker viewport allows the user to verify proper positioning by the generated field being within close proximity to the tracking device(s).
- Correct positioning can 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 (see Figure 42), the selected plane in UroNav shall match that of the connected ultrasound.

Initialize Navigation Tools to create Electromagnetic EM) Field for Fusion Registration, Targeting, and Recording Biopsy Core Samples.

1. Match Depth on UroNav to Depth Display on US.
2. Confirm Biopsy Needle/Gun.
3. Verify FG Tracker Connection, US Model, and Probe Selection.
4. For Transperineal procedures, verify grid selection.
5. EM Tracker and Grid Status:
    a. The color represents the range found within the generated EM field.
    b. Green color shows tracking "In Range."
6. Verify live US Video feed and "correlation rectangle" (if applicable).

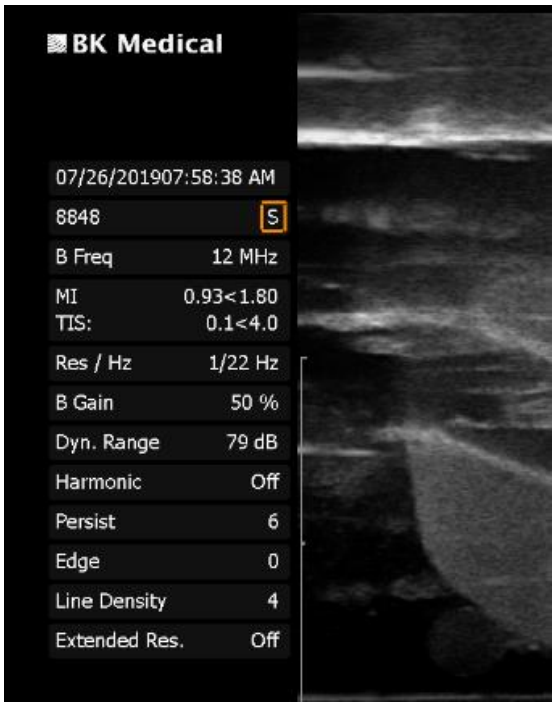


Figure 42: BK U/S Correlation Rectangle

9.2.1. User Interface

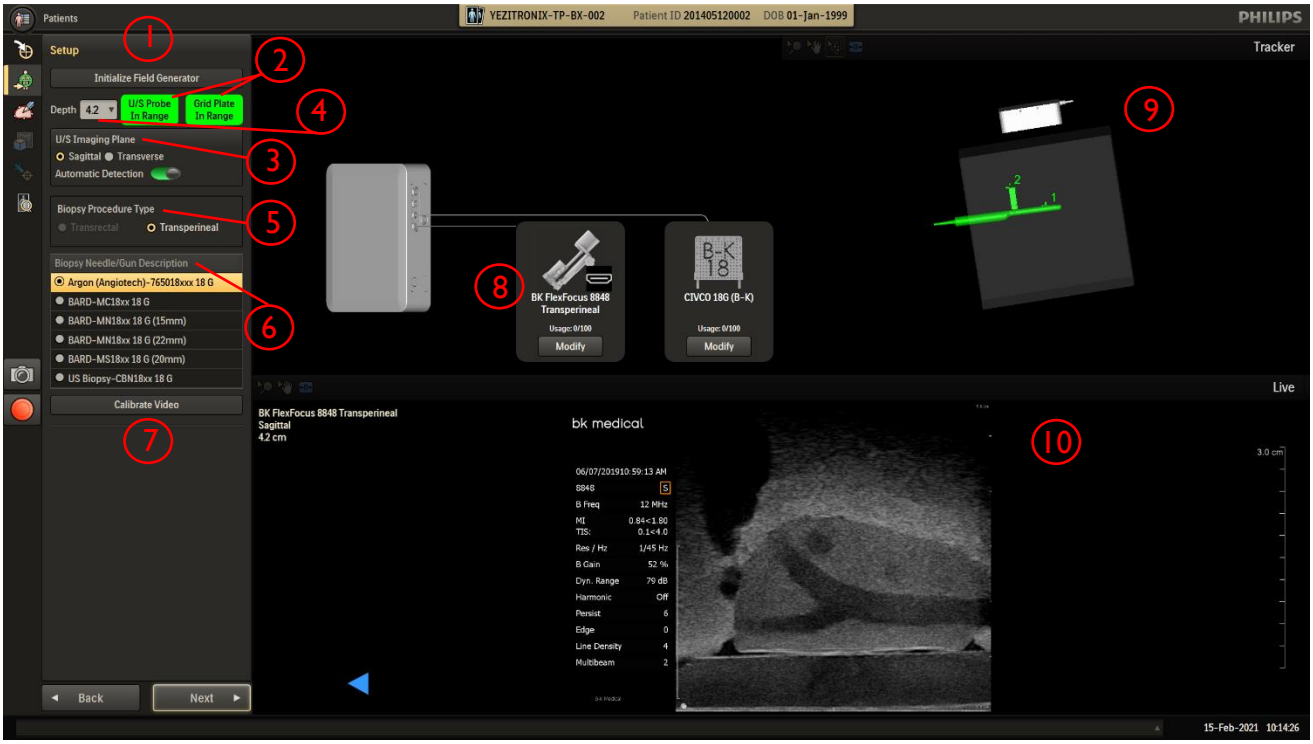
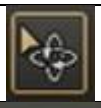


Figure 43: User Interface Setup Screen (Transperineal)

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	**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.
4	**Depth Selection:** Lists available depth options for the connected Ultrasound probe.
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. Note that 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.
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: Hover above the rectangle until turning green Press and hold the left mouse button (pointer arrow changes to cross) Move the rectangle until the ultrasound plane indicator is centered inside Release the mouse button Move the mouse pointer away until the rectangle turns orange

9.2.2. In-viewport Icons

Icon	Step	Description
	Zoom	Zooms image.
	Pan	Pans image.
	Rotate	Rotate 3D image.
	Reset viewing settings	Restores to default image settings.

9.3. Sweep & Segmentation Screen

Sweep & Segmentation 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:

⚠ The reconstructed U/S volume is input for the registration between MR and U/S images. The sweep is best performed as a smooth, steady motion, taking about 6 seconds, applying constant pressure.

⚠ 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.

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

9.3.1. User Interface (Sweep)

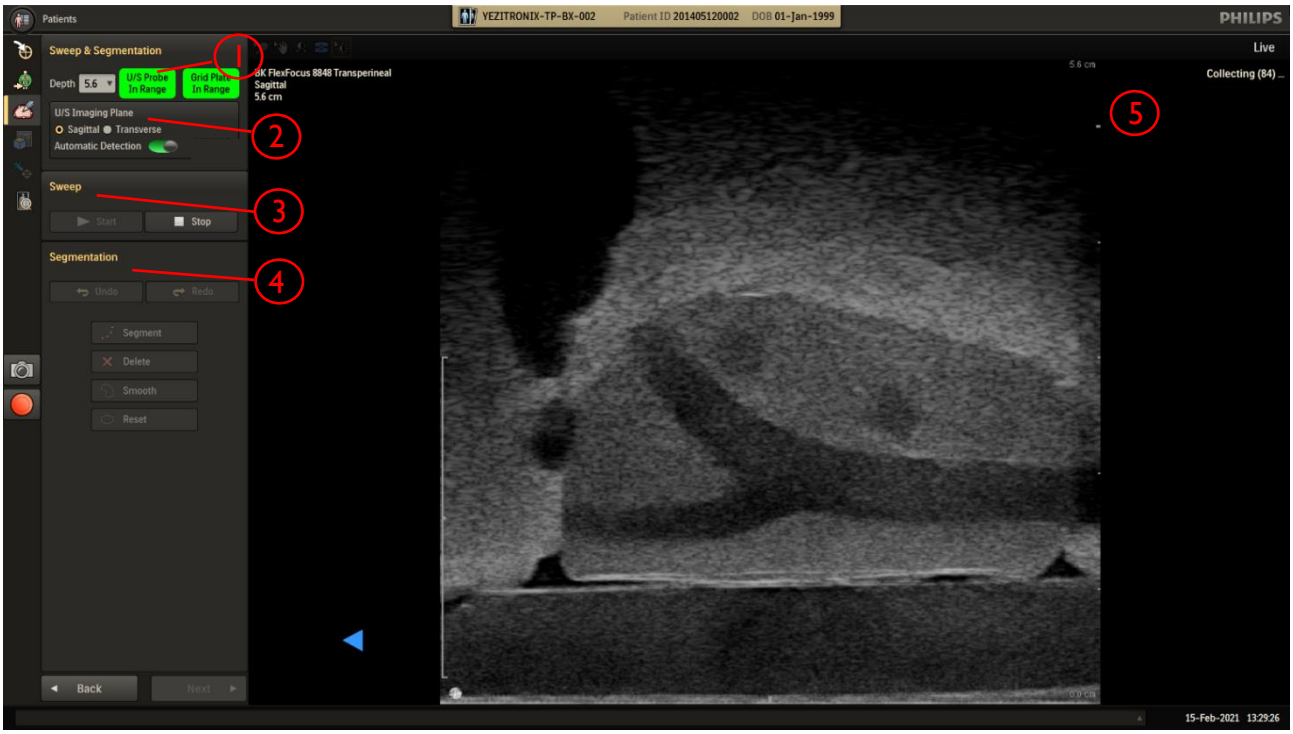


Figure 44: User Interface (Sweep)

1.	**EM Tracker Status:** The color (green, yellow, or red) represents the range found within the EM field generated 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 control will appear.
3.	**Sweep:** Enables the user to select the sweep direction (for transverse and endfire sweeps) and **Start**/**Stop** the sweep.
4.	**Segmentation tools:** Enables the user to manipulate the segmentation, including the use of **Undo**/**Redo**.
5.	**Live U/S:** Provides the live ultrasound as a visual aid to the user when taking a sweep.

9.3.2. User Interface (Segmentation)

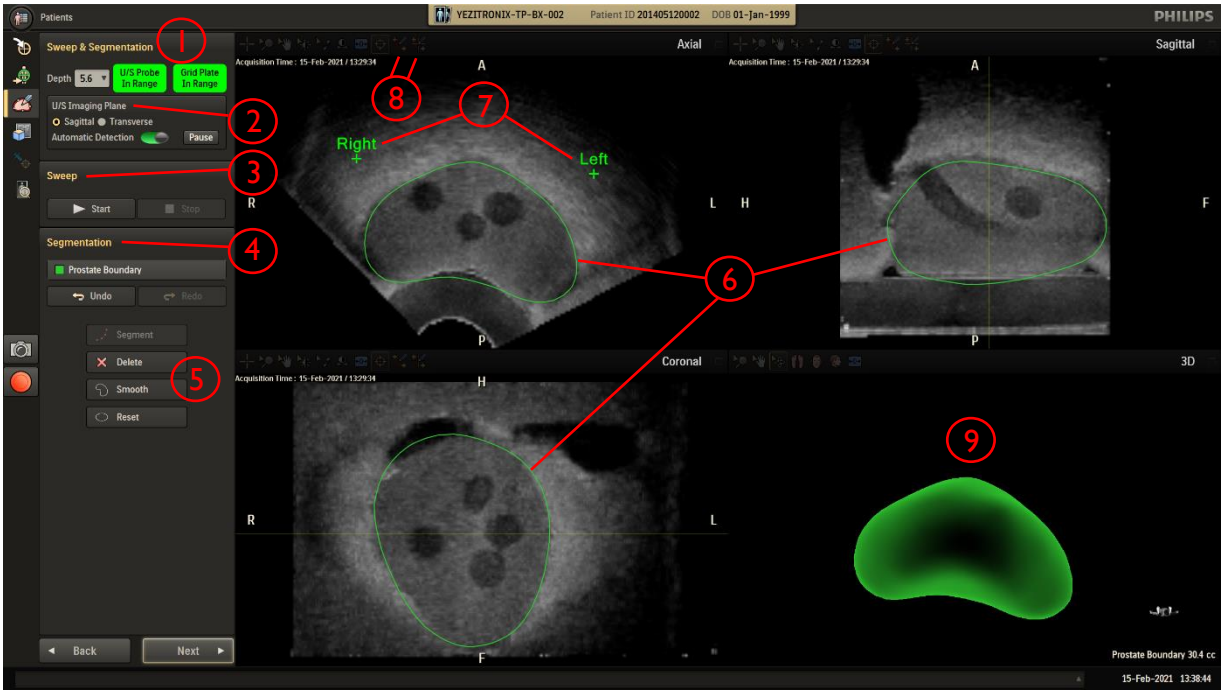
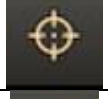


Figure 45: User Interface (Segmentation)

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.	**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.	**MPR views:** The reconstructed U/S volume is shown in each of the orthogonal planes.
7.	**Fiducial landmark:** Represents anatomical axes, guiding the segmentation creation algorithm. **NOTE:** The landmarks shown in the image above are for reference purposes only, and are intended only for use in creation of the prostate segmentation.
8.	**Boundary adjustment tools:** Enables the user to adjust the boundary of the U/S segmentation
9.	**3D view:** Displays a 3D model of the reconstructed prostate.

9.3.3. In-viewport Icons

Icon	Step	Description
	Pick Point	Sets cross-correlation point in all 2D image planes.
	Zoom	Zooms image.
	Pan	Pans image.
	Gray level	Manual window width and window level adjustment.
	Scroll	Scrolls through 2D data set.
	Automatically adjust window width and window level	Automatically adjusts gray-scale to optimize image quality.
	Reset viewing settings	Restores to default image settings.
	Place landmark	Placement of anatomical orientation landmarks for U/S segmentation.
	Adjust mesh boundary tool	Adjust boundary on active viewport. Boundary adjustment correlated and visiualized in all three planes (default setting).

9.3.4. Perform Sweep and Segmentation

9.3.4.1. Acquire US Sweep to Reconstruct a 3D Model of the Prostate:

1. Press the **Start** button or depress and hold the Sweep Pedal on the supplied foot pedal to begin collecting ultrasound images of the prostate gland.
2. Press the **Stop** button or release the Sweep foot pedal to halt image collection and allow for 3D reconstruction.

The sweep is best performed as a smooth, steady motion, applying constant pressure lasting approximately 6 seconds.

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

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 FG.

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.

9.3.4.2. Segmentation Action Commands to Edit 3D Boundary:

Following a sweep, the default Anatomical Fiducial Landmark Tool allows as many as six axis endpoints can be placed to support 3D reconstruction.

1. Press the **Segment** button to complete segmentation and view 3D rendering.
2. Modify boundary by clicking Action Commands or by dragging the left mouse button using the default **Adjust Mesh Boundary** Tool in any viewport.

9.4. Align U/S volume with MR Screen

Align U/S 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.

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

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** slide bar to vary the primary view of the superimposed U/S and MR boundaries for optimal visualization

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

9.4.1. User Interface

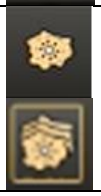
Figure 46: Align US volume with MR User Interface

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. **Endfire:** Automatically detected. It can be manually overridden. **Automatic Detection:** For multi-plane ultrasound probes, an automatic plane detection control will appear.
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 (MR and U/S) to optimize visualization when adjusting registration.

7.	**U/S MPR views:** Displays the reconstructed U/S volume shown in each of the orthogonal planes.
8.	**MR MPR views:** Displays the MR 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.

9.4.2. In-viewport Icons

Icon	Step	Description
	Zoom	Zooms image.
	Scroll	Scrolls through 2D data set.
	Registration Pan	Pan U/S dataset in the active viewport.
	Registration rotate	Rotate U/S dataset in the active viewport.
	Automatically adjust window width and window level	Automatically adjusts gray-scale to optimize image quality.
	Reset viewing settings	Restores to default image settings.
	Gray level	Manual window width and window level adjustment.
	Show all/selected	Displays all or selected Targets in all viewports.

9.4.3. Elastic Deformation

The registration screen provides the option to map the MR volume elastically to the ultrasound volume using the segmentation results, i.e., elastic deformation.

NOTE: 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** can be toggled on or off, allowing the use of either elastic or rigid registration for the procedure.

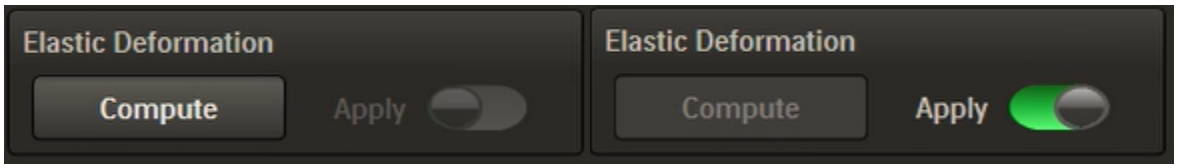


Figure 47: Elastic Deformation

9.5. Navigation Screen

The *Biopsy Navigation* step 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.

⚠ 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.

9.5.1. User Interface

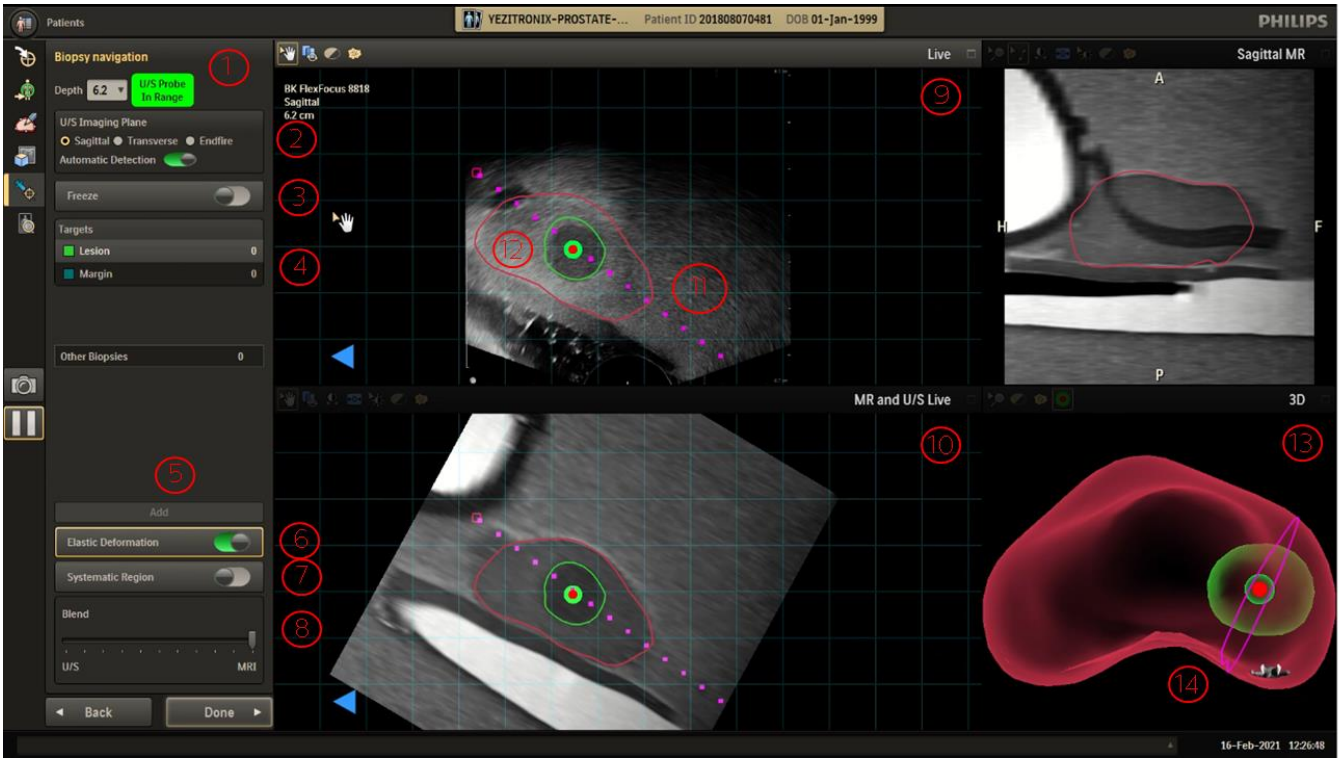


Figure 48: Transrectal Biopsy Navigation User Interface

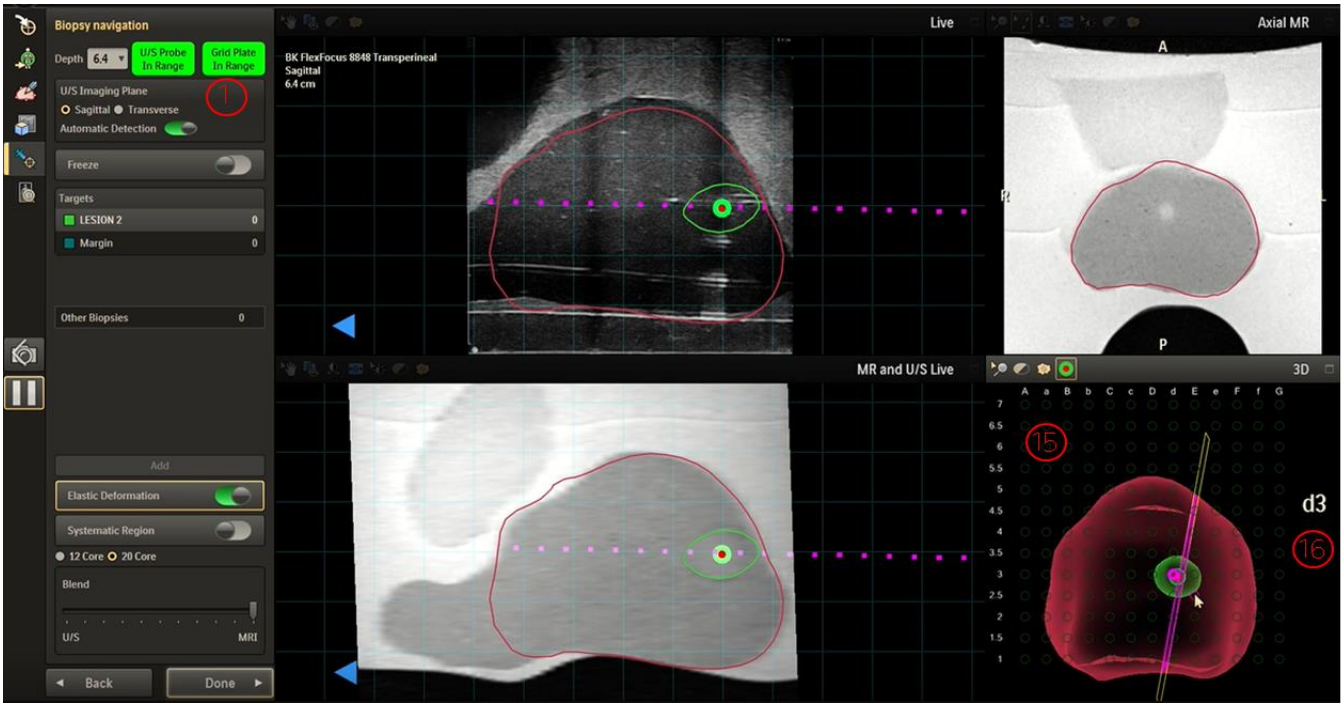
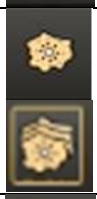
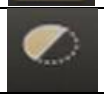


Figure 49: Transperineal Biopsy Navigation User Interface

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:** Toggle 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:** Provide 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.
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

9.5.2. In-viewport Icons

Icon	Step	Description
	Zoom	Zooms image.
	Scroll	Scrolls through 2D data set.
	Registration Pan	Pan registration in the active viewport.
	Registration rotate	Rotate registration in the active viewport.
	Automatically adjust window width and window level	Automatically adjusts gray-scale to optimize image quality.
	Reset viewing settings	Restores to default image settings.
	Gray level	Manual window width and window level adjustment.
	Show all/selected	Displays all or selected Targets in all viewports.
	Show/Hide all graphics	Turns graphical display off/on.
	Rotational adjustment	Adjust for variances in the apex location of an end-fire ultrasound transducer's image plane.
	MRI-imported target	The bull's eye for MRI-imported targets represents the calculated center of the identified target (centroid).

9.5.2.1. 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, Figure 50, 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.

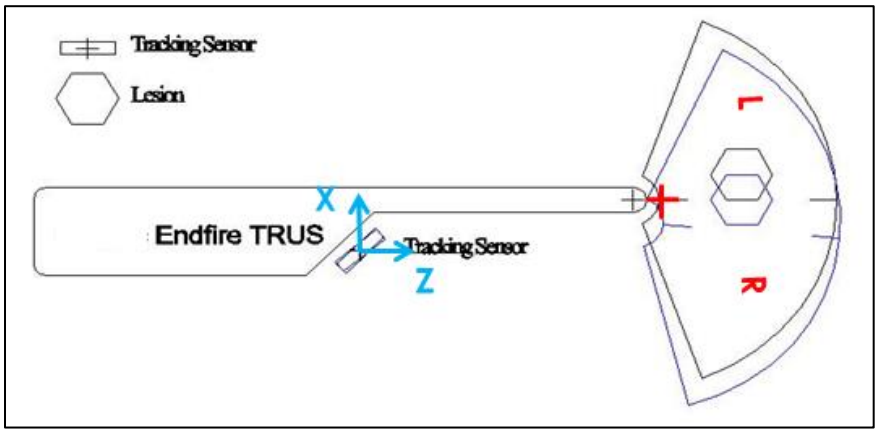


Figure 50: Apex Rotation Variance

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

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

1. After selecting the "Rotational Adjustment" viewport icon in the live ultrasound viewport, rotate the TRUS probe 180± 5° (Figure 51) from the original sweep orientation used for volume acquisition and segmentation.

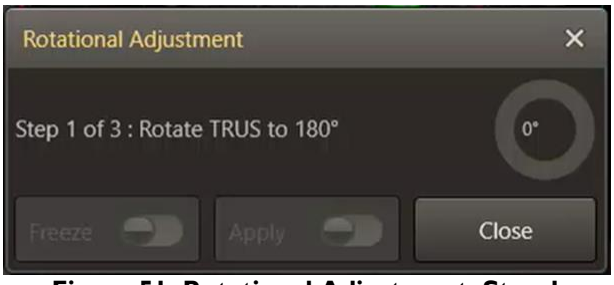


Figure 51: Rotational Adjustment, Step 1

2. When the guide ring indicates you are in the proper orientation, the dialog changes to "Step 2" as shown in Figure 52.
3. Select "Freeze" via the button on the rotational adjustment control.

NOTE: Clicking "Freeze" again will return the procedure to live action and any adjustments made during the freeze will be cleared.

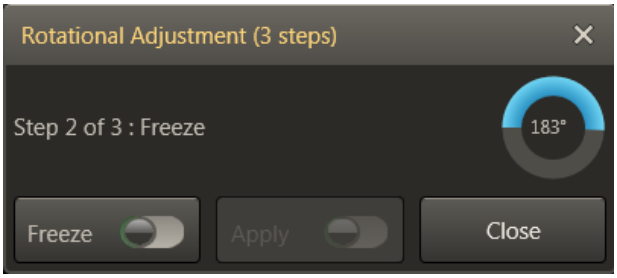


Figure 52: Rotational Adjustment, Step 2

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, highlighted in Figure 53.

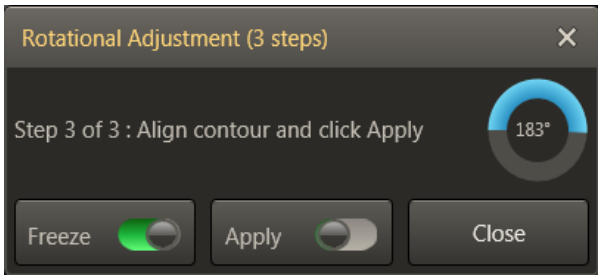


Figure 53: Rotational Adjustment, Step 3

The volumes should now be in alignment when the TRUS probe is rotated in either orientation.

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

To clear the applied adjustment, select the "Rotational Adjustment" viewport icon, and select "Apply" again, highlighted in Figure 54.

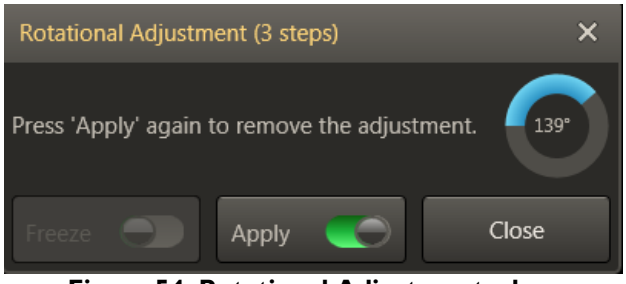


Figure 54: Rotational Adjustment, clear

⚠ With end-fire TRUS transducers, confirmation in two planes is ESSENTIAL prior to navigating to the first selected target region.

9.5.3. Transrectal Biopsy Procedure

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. Exaine the *Live* ultrasound viewport and bottom *MR and U/S Live* viewport for proper alignment throughout the procedure.

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

⚠ 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 desired 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.

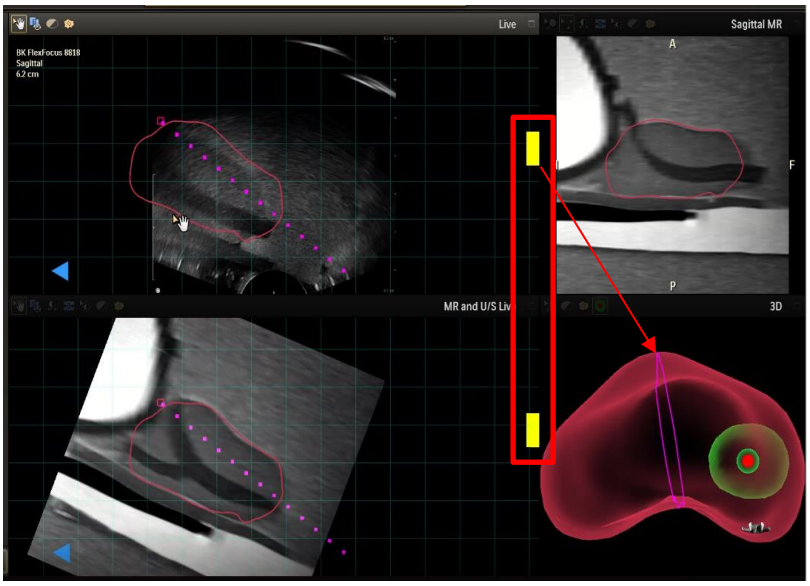


Figure 55: Probe position to the right of centroid

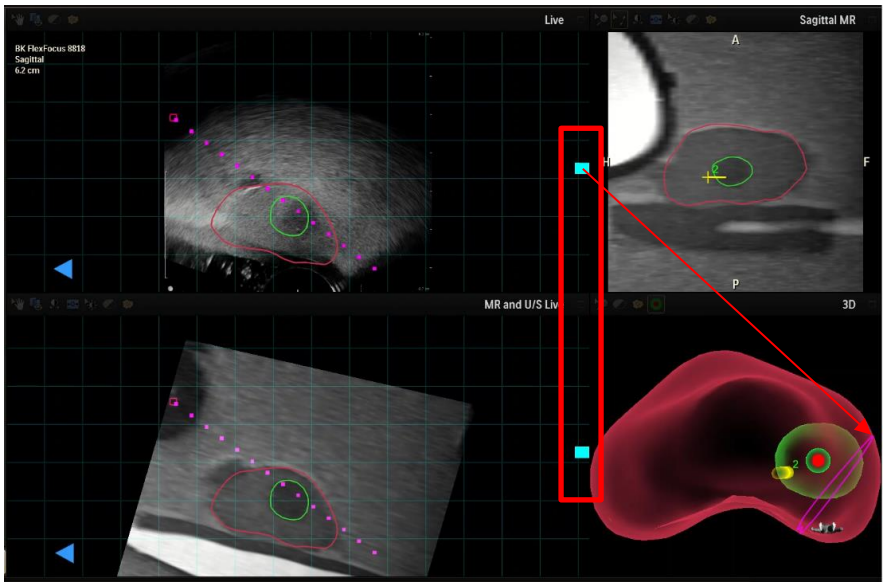


Figure 56: Probe position to the left of centroid

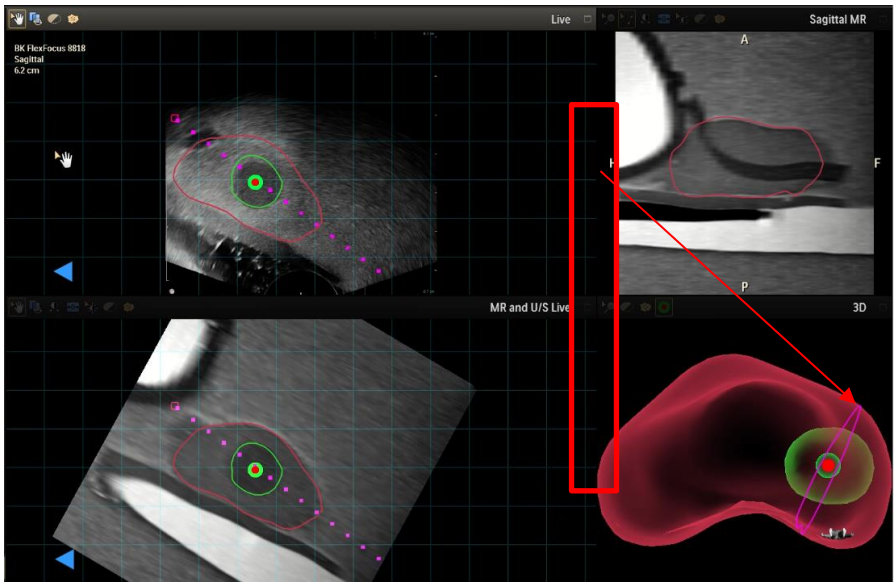


Figure 57: Probe position centered on centroid

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:
   a. 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.
   b. 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 (Figure 58).

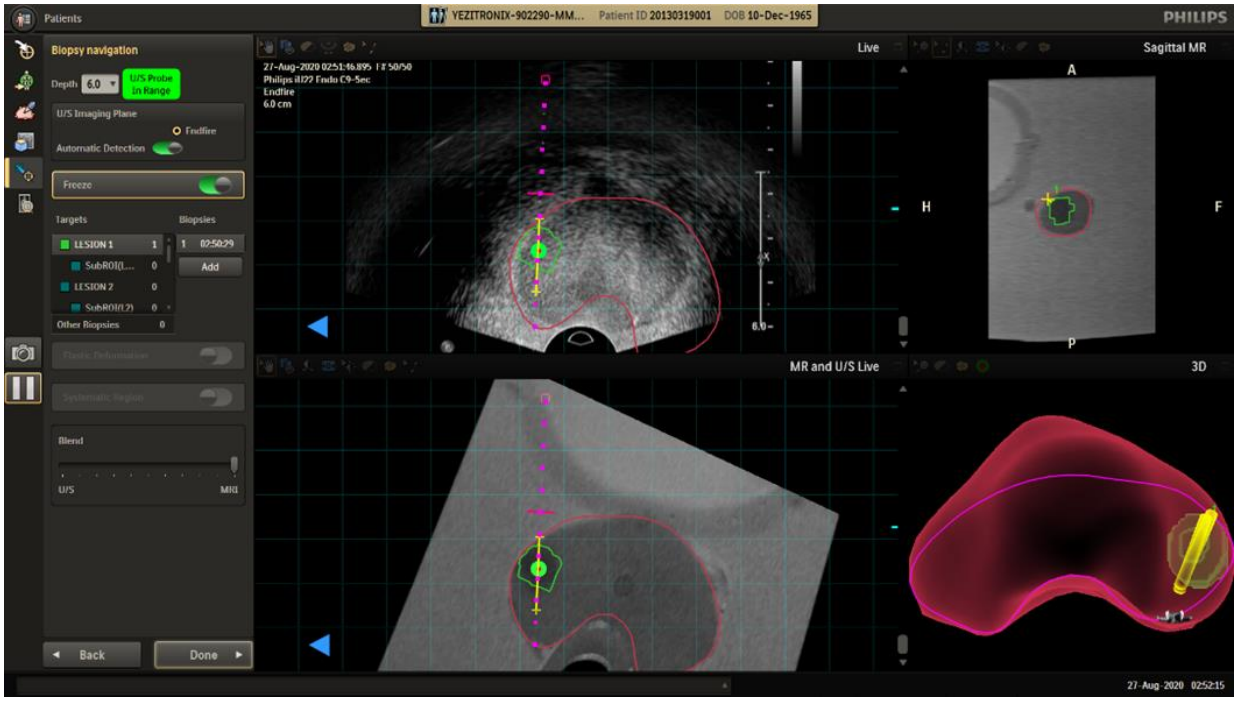


Figure 58: Recording a Biopsy Location

NOTE: 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.

NOTE: 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.

9.5.4. Transperineal Biopsy Procedure

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

1. Select the desired 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 (Figure 59 and Figure 60) to view the target in the ultrasound image. Navigation is easily achieved by rotating the transducer in the transperineal Stepper assembly. Use the color-coded guidance bars in the Live viewport to locate the target location (see decription in 9.5.3).

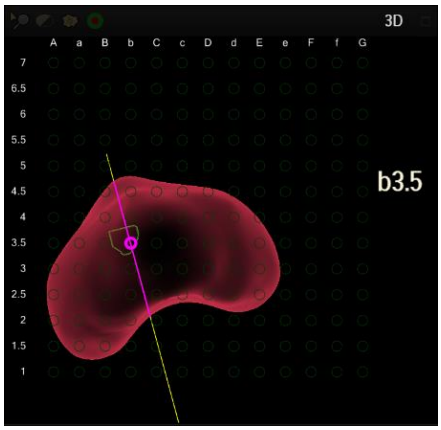


Figure 59: Transperineal Navigation with Grid Plate Overlay (Intersecting U/S Imaging Plane)

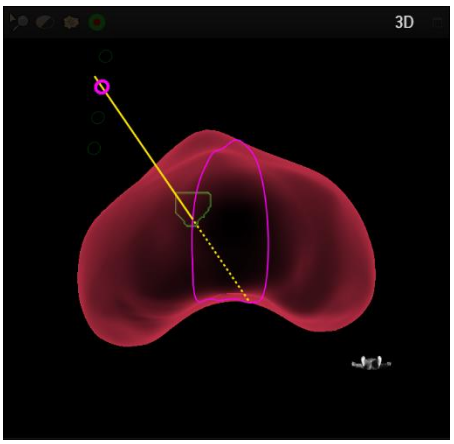


Figure 60: Transperineal Navigation with PrecisionPoint™ Transperineal Access System option (Intersecting U/S imaging plane and target)

3. 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 (Figure 61).

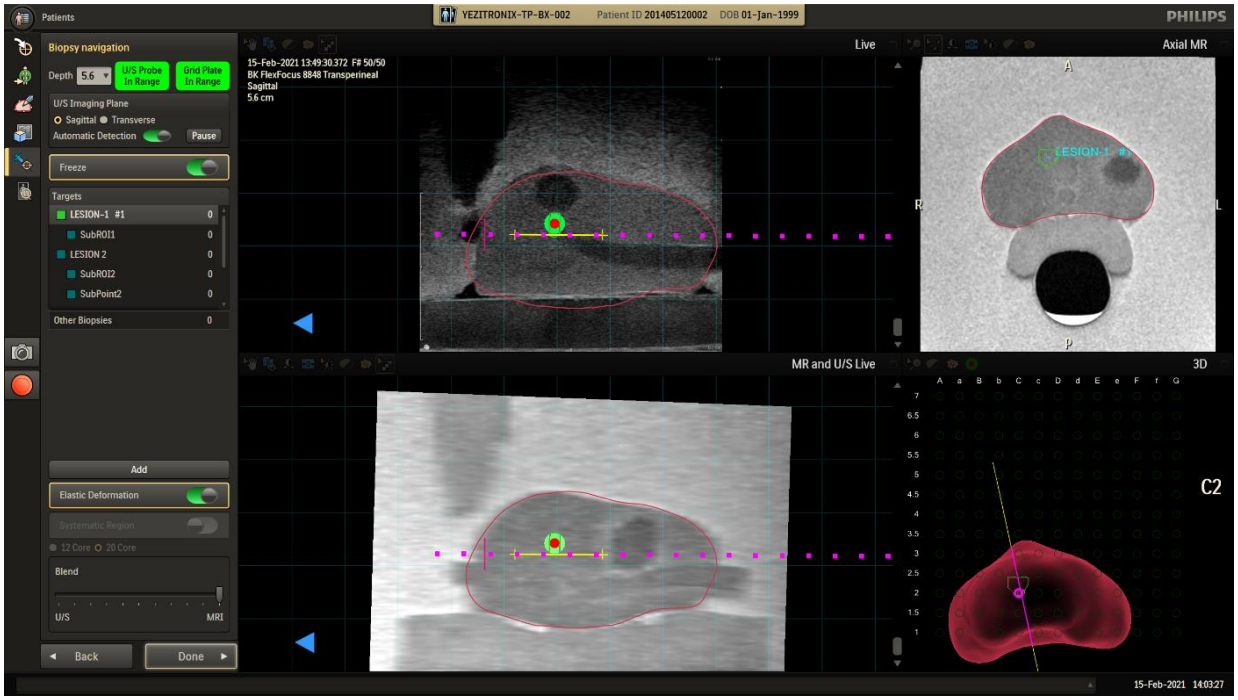


Figure 61: Transperineal Biopsy with Grid Plate

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. 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.

9.6. Procedure and Images Review Screen

The *Procedure and Images Review* screen enables the user to view the screen captures and video recording of the procedure, as well as the segmentations and marked biopsy cores.

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.

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

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

9.6.1. User Interface (Procedure Review)

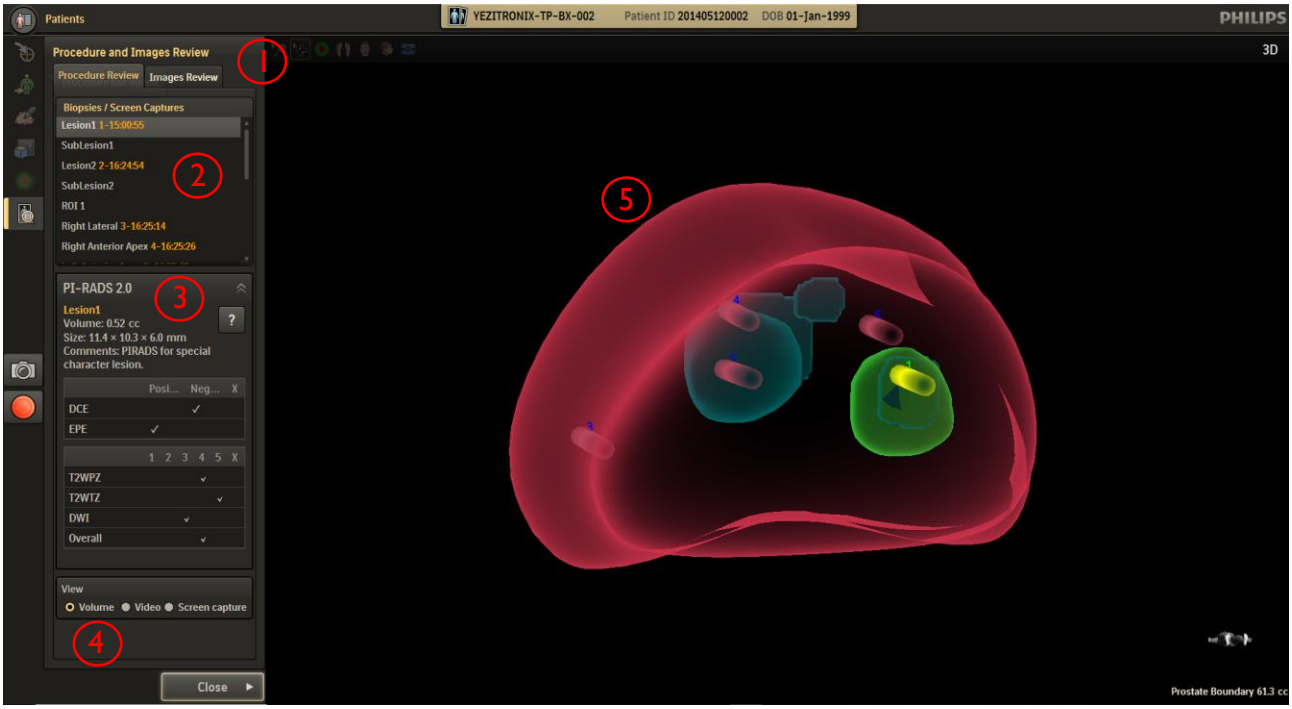


Figure 62: Procedure Review User Interface

1.	**Review tabs:** Enables the toggling between Procedure and Images review
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.

9.6.2. User Interface (Images Review)

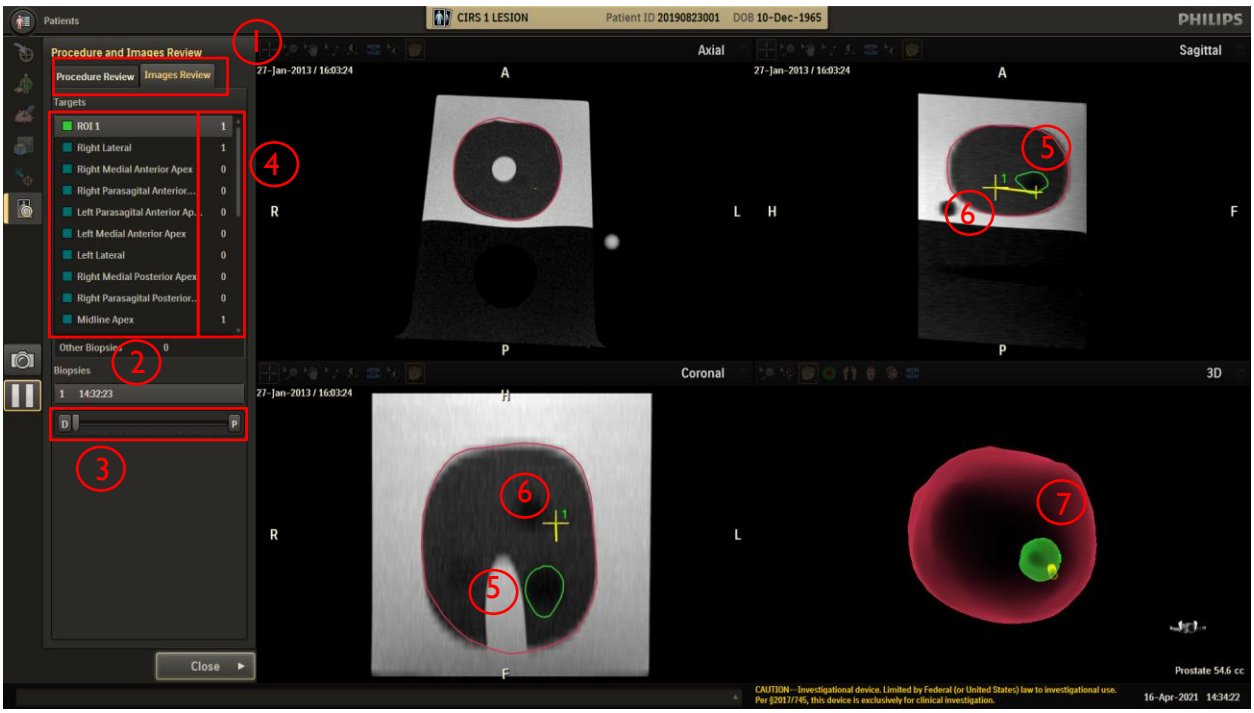
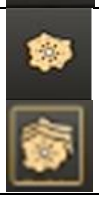
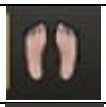
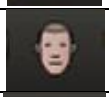


Figure 63: Images Review User Interface

1.	**Review tabs:** Enables the toggling between Procedure and Images review
2.	**Target list:** Displays a list of systematic and non-systematic target
3.	**D-P slider:** Enables the review of a selected biopsy core in the MPR views from the distal to proximal ends.
4.	**Biopsy list:** Displays a list of all biopsies associated with the selected target.
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.

9.6.3. In-viewport Icons

Icon	Step	Description
	Pick Point	Sets cross-correlation point in all 2D image planes.
	Zoom	Zooms image.
	Pan	Pans image.
	Rotate	Rotate 3D image.
	Scroll	Scrolls through 2D data set.
	Automatically adjust window width and window level	Automatically adjusts gray-scale to optimize image quality.
	Reset viewing settings	Restores to default image settings.
	Gray level	Manual window width and window level adjustment.
	Show all/selected	Displays all or selected Targets in all viewports.
	MRI-imported target	The bull's eye for MRI-imported targets represents the calculated center of the identified target (centroid).
	Axial	Changes viewport to axial display.
	Coronal	Changes viewport to coronal display.
	Sagittal	Changes viewport to sagittal display.

9.7. Keyboard & Mouse Shortcuts

Key Stroke	Function	Workflow Context
F2	Toggle visibility of segmentations	• All 2D/3D viewports) **NOTE**: In 3D views, the prostate mesh cannot be toggled off **NOTE**: 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)
F7	Toggle visibility of uniform grid overlay	• Navigation (US, US/MR viewports)
F12	Toggle visibility of patient information	Available on all screens
Hold middle mouse button + drag	Adjust window width/level values	• Review Segmentation & Targets (MPR viewports) • Sweep & Segmentation (Reconstructed images)
G	Toggle needle guideline	• Navigation (US, US/MR viewports)
Mouse Wheel	Reposition needle guideline depth cursor (while Freeze Mode is enabled and guideline is active or green in color).	• Navigation (US, US/MR viewports)
Mouse Wheel	Scroll through image frames/slices/cine by hovering the mouse in the viewport, and the guideline is inactive or magenta.	• All MPR Viewports • Navigation (US 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 (US, US/MR viewports)
	Add anatomical fiducial landmarks (while landmark placement interactor is selected)	• Sweep & Segmentation

Key Stroke	Function	Workflow Context
Left-Mouse Drag	Reposition needle guideline depth cursor (while **Freeze** Mode is enabled, and the guideline is active or green)	• Navigation (US, US/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 (US, US/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 1 mm increments	• All MPR viewports

10. Data Export

Existing UroNav procedure data can be exported to a preconfigured DICOM destination for permanent storage and are subsequently removed from the UroNav computer. If connected to the network, procedure data (i.e. marked biopsy locations for Biopsy workflows) including screen captures and screen recordings will be exported automatically to the configured DynaCAD™ server after the completion of each procedure.
The user can cancel the export and start the export manually at a later time if desired.

Below are the instructions to transfer all procedure data associated with a specific patient or a range of patients:

1. Select the patient (or patients) from the All Patients list
2. Right click and select **Export**
3. Choose a pre-defined DICOM destination
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 procedures associated with the patient are successfully exported. Failure to export any of the procedures will result in

unsuccessful export status. The export status of individual procedures can be seen through entries within the *Completed Procedures* list in the home screen.

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.

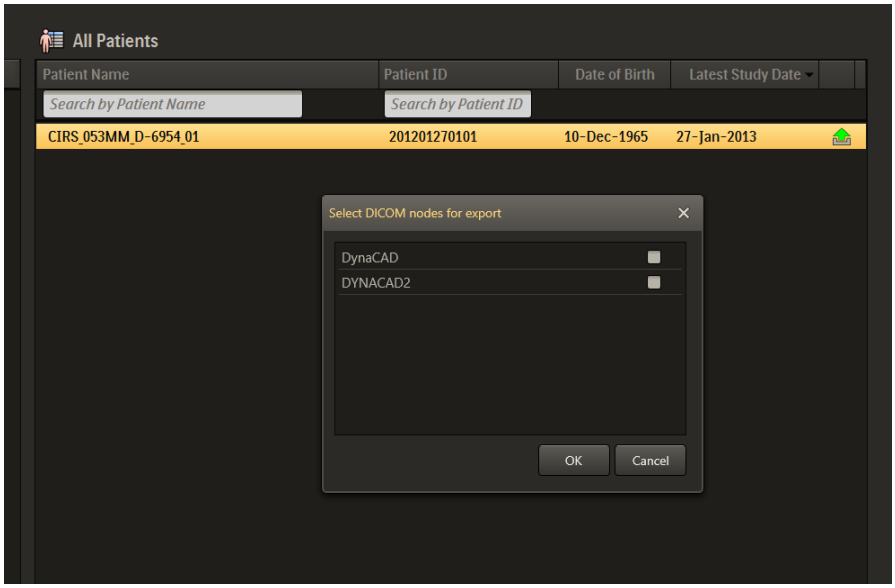


Figure 64: Export Function and Status

11. Appendix A

11.1. Supported Biopsy Guns & Needles

Table 7: Supported Biposy Guns & Needles

Manufacturer	Gun	Needles
Argon Medical Systems (Angiotech)	Pro-Mag™ Ultra Reusable Autoamtic 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

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

11.2. Supported Stepper Accessories

Table 8: 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

12. Appendix B

12.1. Supported Ultrasound and Transducer Probe Combinations for Transrectal Procedures

Table 9: 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 3000/5000 SW Version 5.16	E10C4 and E14C4t
BK Specto SW Version 6.6.4	E10C4 and E14C4t
BK Specto SW Version 6.6.8	E14C4t
GE Logiq F8 R.2.x.x	E8C and E8CS
GE Logiq P5/A5/A5Pro/P6/P6Pro	E8C and E8CS
GE Logiq S7 R3 .x.x	IC-5-9
GE Versana Premier	E8CS-RS
Hitachi Noblus	C41V
Hitachi Arietta Precision	C41V
Hitatchi Arietta 65	C41V
Philips Affiniti	C10-4ec
Philips Epiq 5/7/Elite	C10-4ec
Philips HD11XE	C9-5ec
Philips iU22	C9-5ec
Siemens S2000/S3000	MC9-4
Siemens X150/X300	EC9-4

Table 10: Probe Holder Reorder Part Numbers for Transrectal Procedures

Ulrasound 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)
Philips C9-5ec	4598-010-06681	FCS0105 (Set of 25)
Siemens EC9-4	4598-007-92371	FCS0164 (Set of 25)
Siemens MC9-4	4598-007-92382	FCS0165 (Set of 25)

Table 11: EM Tracker Reorder Part Number

Description	Philips Part Number	Reorder Part Number
EM Tracker	4598-007-83602	FCS0140 (Set of 3)

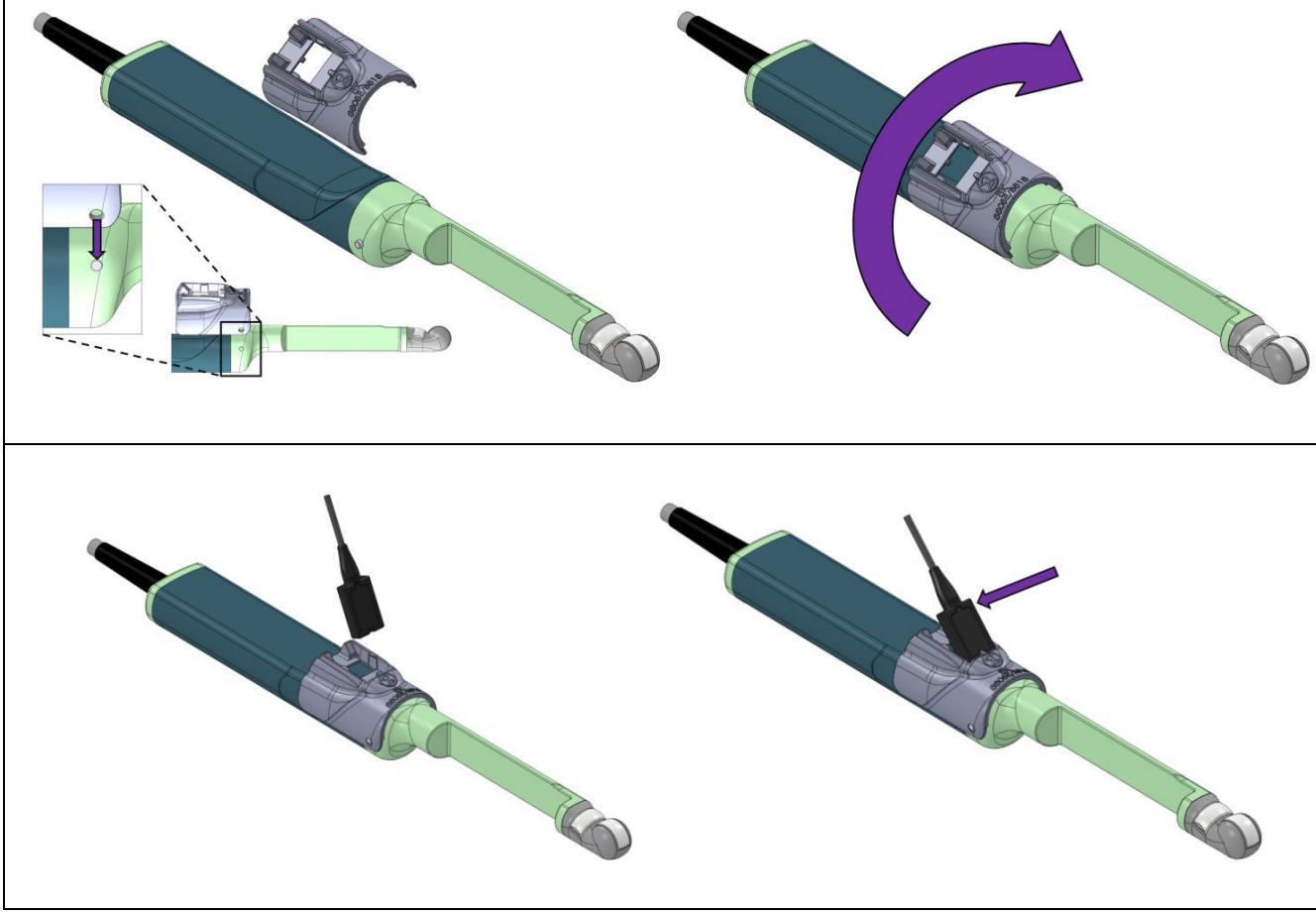
To order additional supplies, consumable instrumentation, or accessories, please contact Philips Customer Service, see section 3.6 Customer Service.

12.2. Transrectal Procedure Probe Holder Mounting Instructions

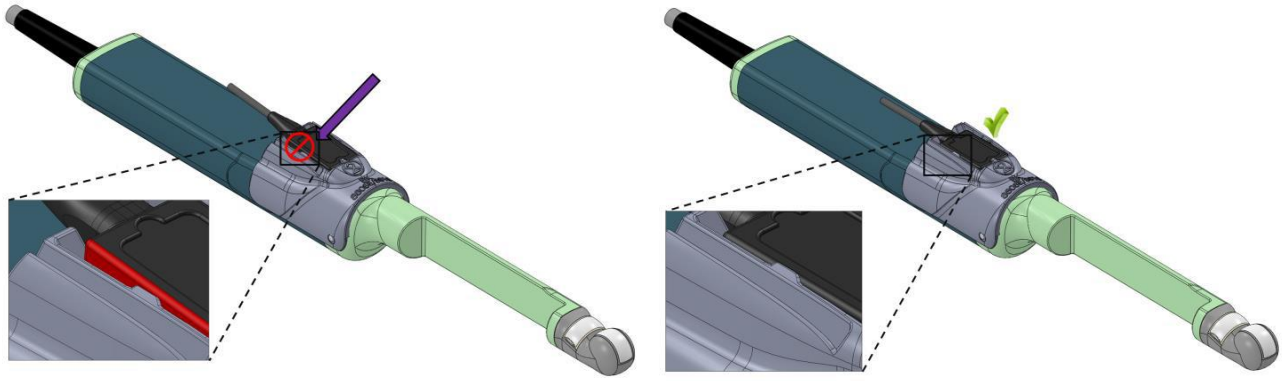
⚠ Failure to fully secure the EM Tracker to the Probe Holder or the Probe Holder to the Probe will compromise the positional tracking of the TRUS probe resulting in grossly inaccurate registration between the US imaging, and EM tracked tools.

12.2.1. BK 8808e, 8818, and E14C4t Probe Holder Mounting Instructions

BK 8808e, 8818, and E14C4t Probe Holder Installation



BK 8808e, 8818, and E14C4t Probe Holder Installation



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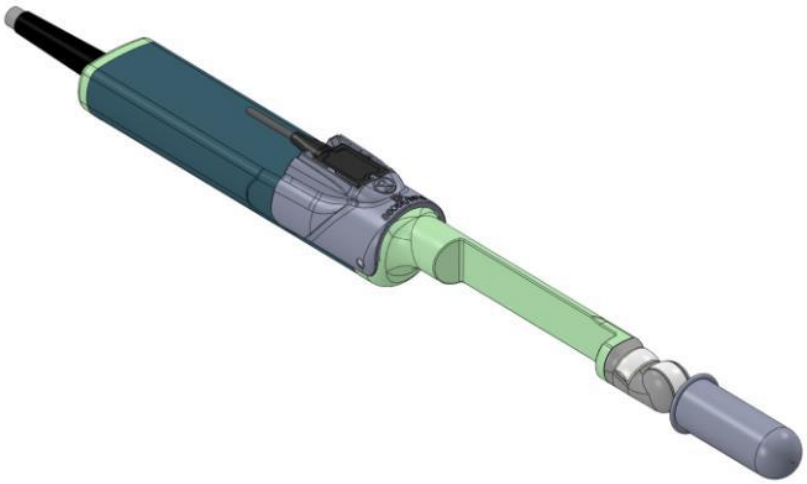
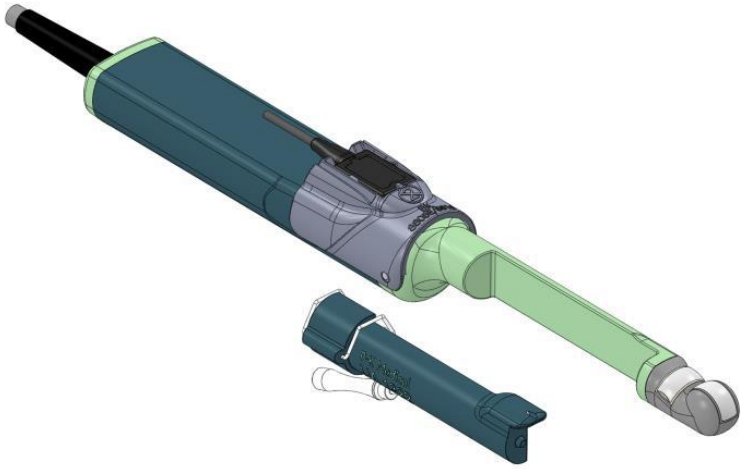
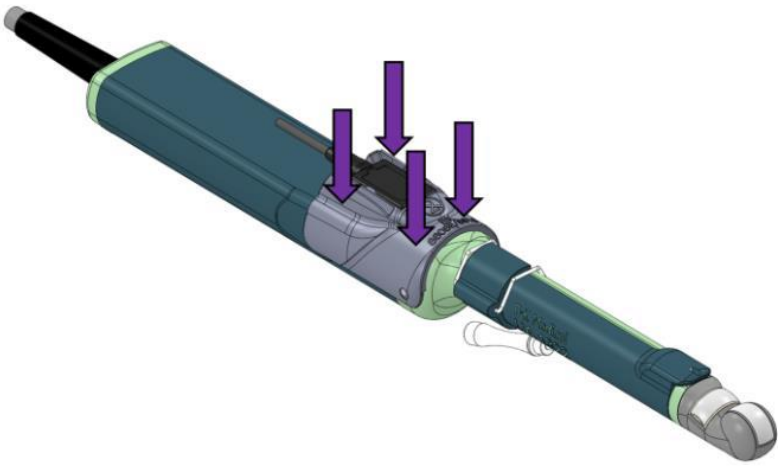


Install cover per the manufacturer's instructions over transducer and UroNav® probe and holder.

BK 8808e, 8818, and E14C4t Probe Holder Installation



The transducer cover is not shown.

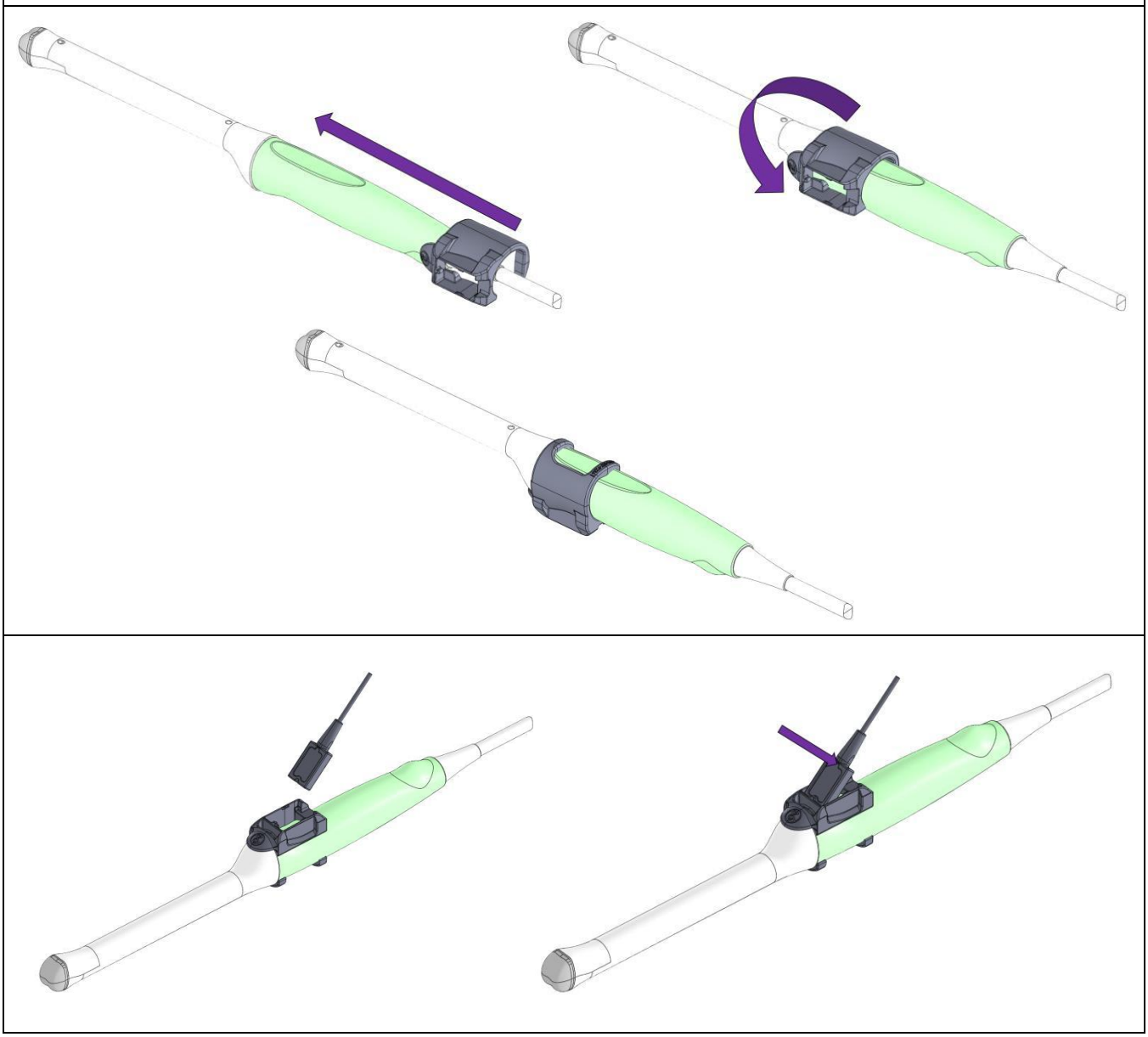


Apply force to reseat. The transducer cover is not shown.

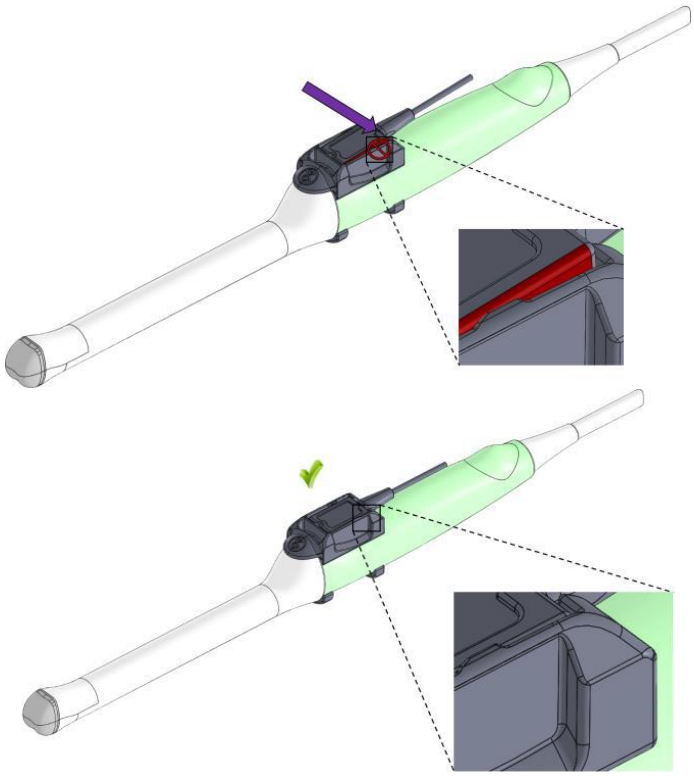
Tracker Removal from BK 8808e, 8818, and E14C4t Probe Holder

12.2.2. BK 8819 and E10C4 Probe Holder Mounting Instructions

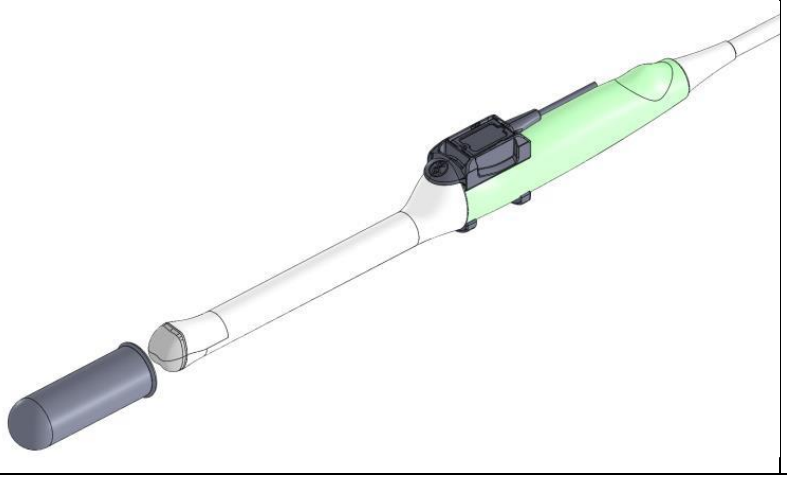
BK 8819 and E10C4 Probe Holder Installation



BK 8819 and E10C4 Probe Holder Installation

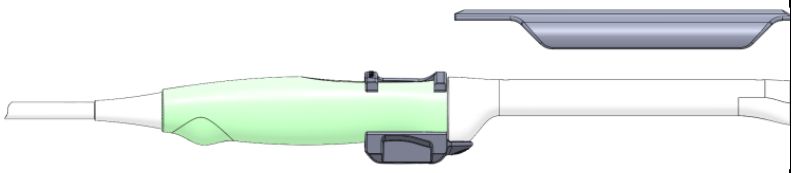


Apply force until flush

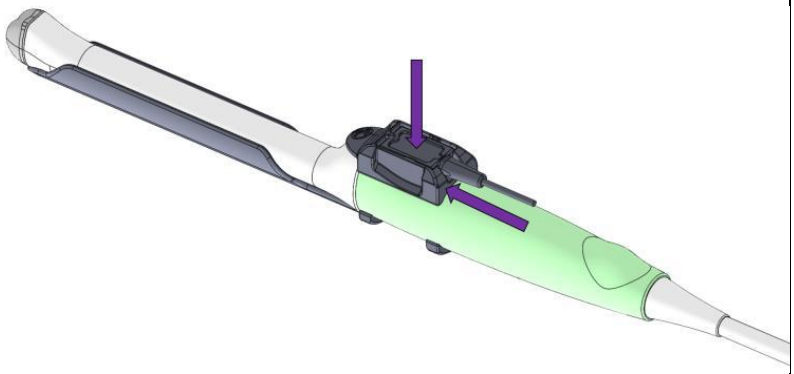


Install cover per the manufacturer's instructions over transducer and UroNav® probe and holder.

BK 8819 and E10C4 Probe Holder Installation

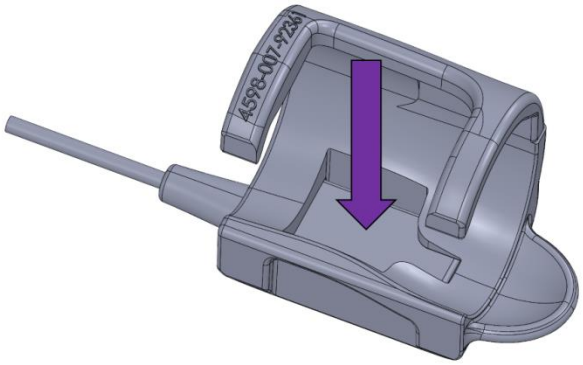


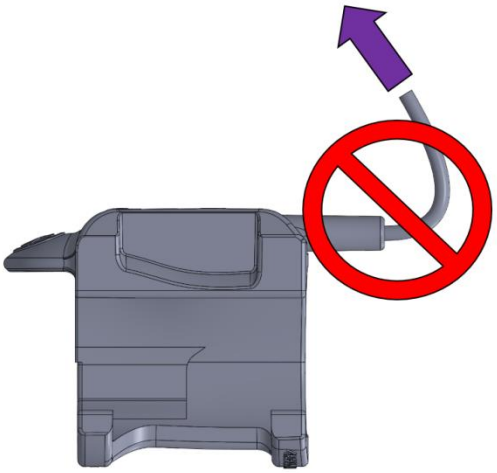
The transducer cover is not shown.



Apply force to reseat. The transducer cover is not shown.

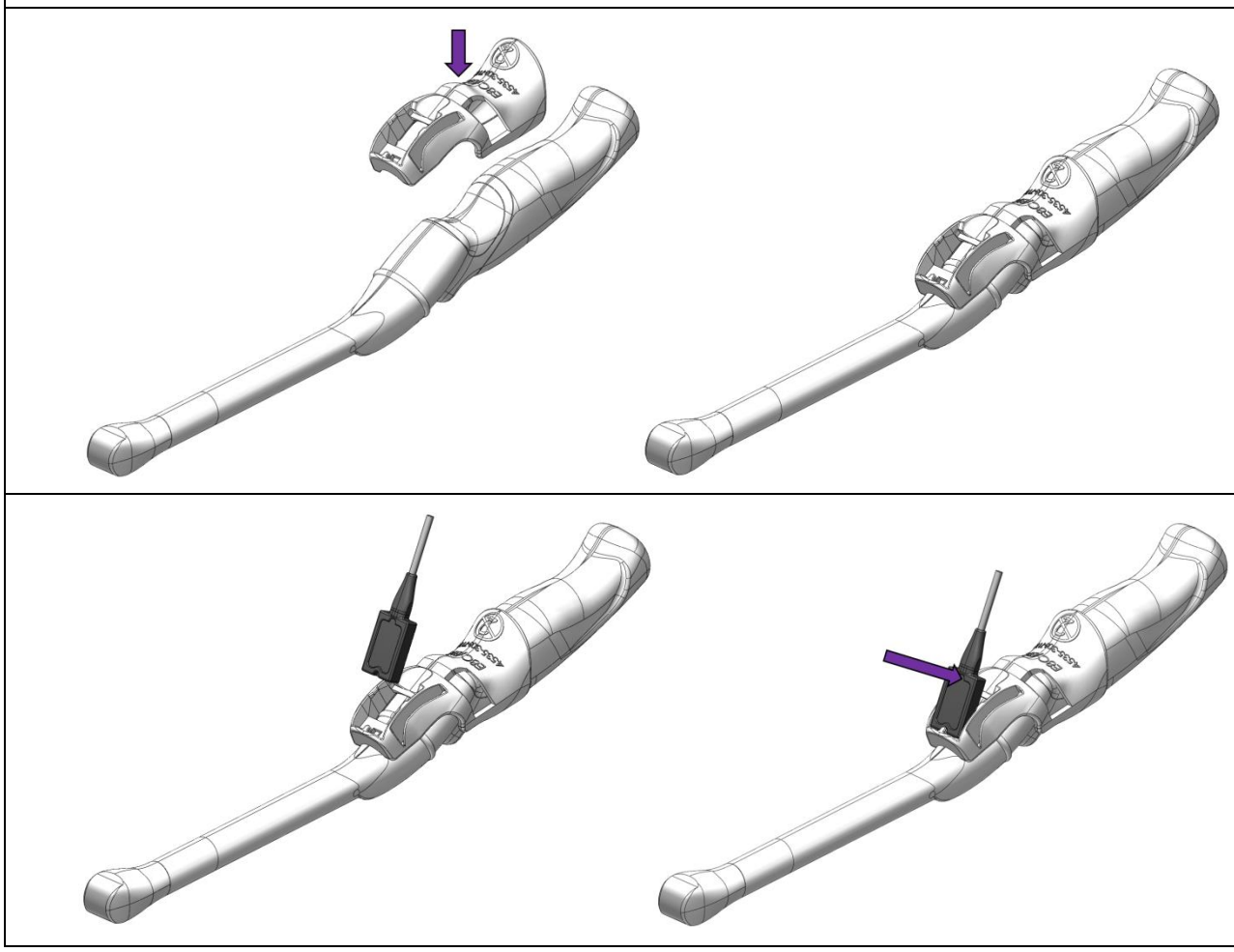
Tracker Removal from BK 8819 and E10C4 Probe Holder



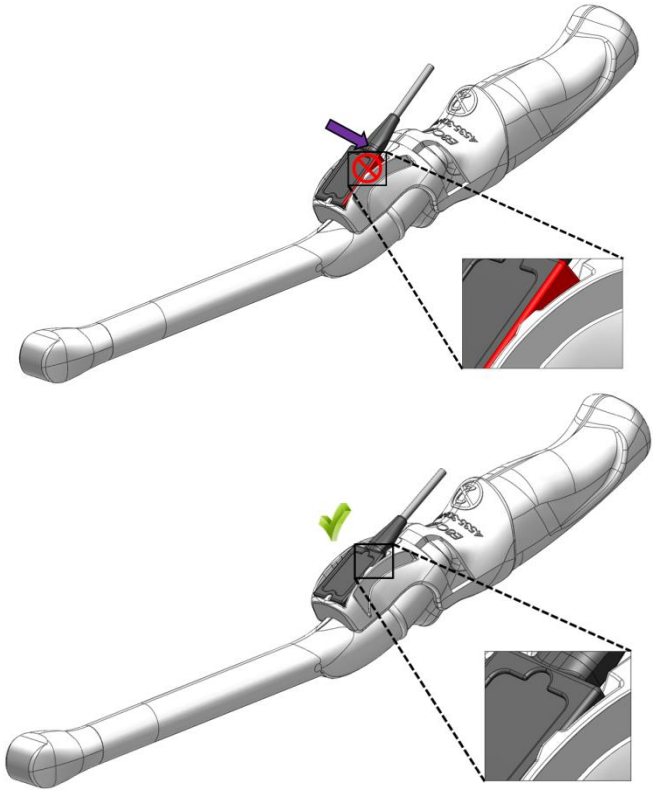


12.2.3. GE E8C, E8CS, E8CS-RS, and IC5-9-D Probe Holder Mounting Instructions

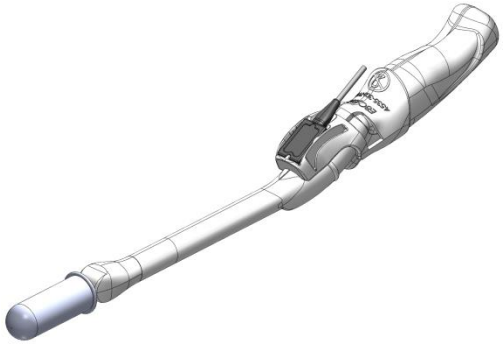
E8C, E8CS, E8CS-RS, and IC5-9-D Probe Holder Installation



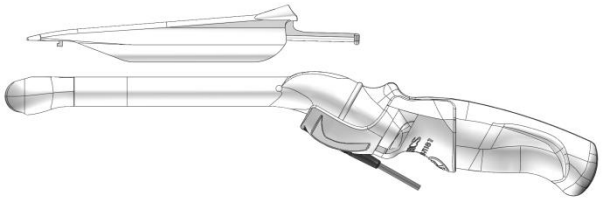
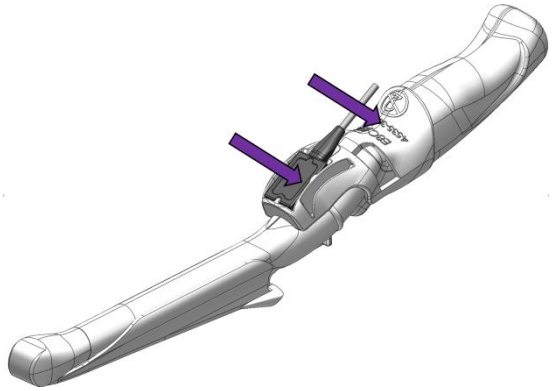
E8C, E8CS, E8CS-RS, and IC5-9-D Probe Holder Installation

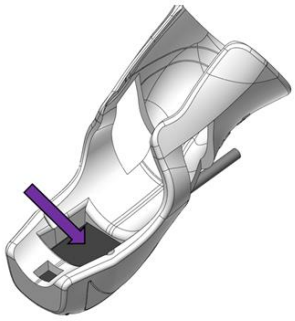
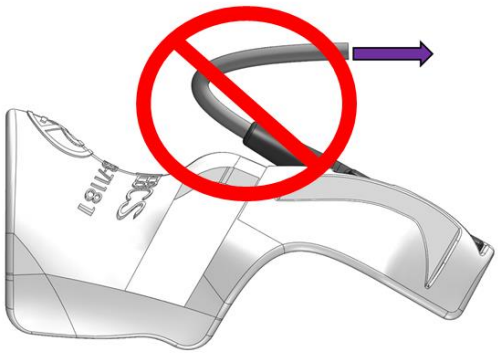


Apply force until flush



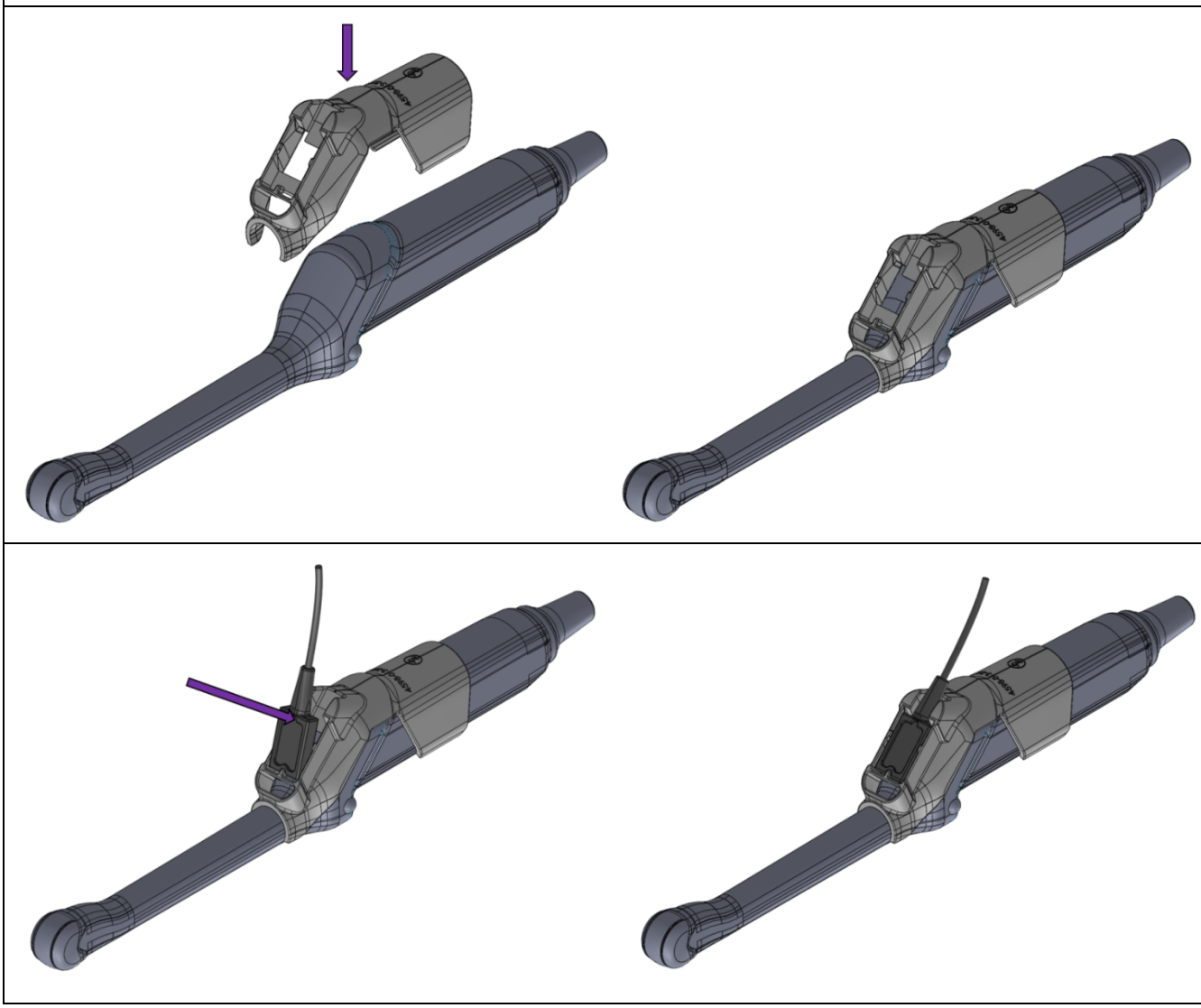
Install cover per the manufacturer's instructions over transducer and UroNav® probe and holder.

E8C, E8CS, E8CS-RS, and IC5-9-D Probe Holder Installation	
	The transducer cover is not shown.
	Apply force to reseat. The transducer cover is not shown.

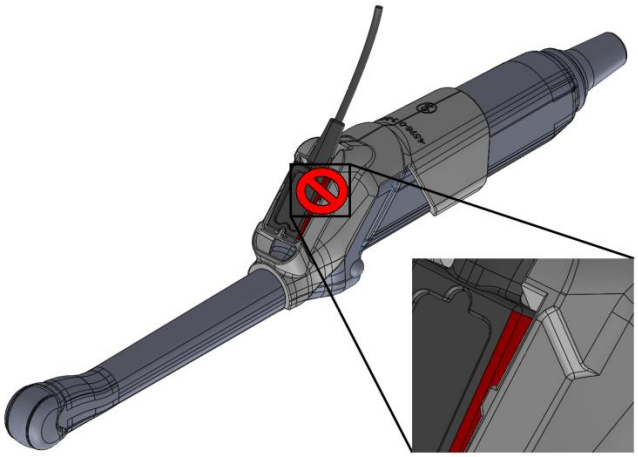
Tracker Removal from E8C, E8CS, E8CS-RS, and IC5-9-D Probe Holder
 

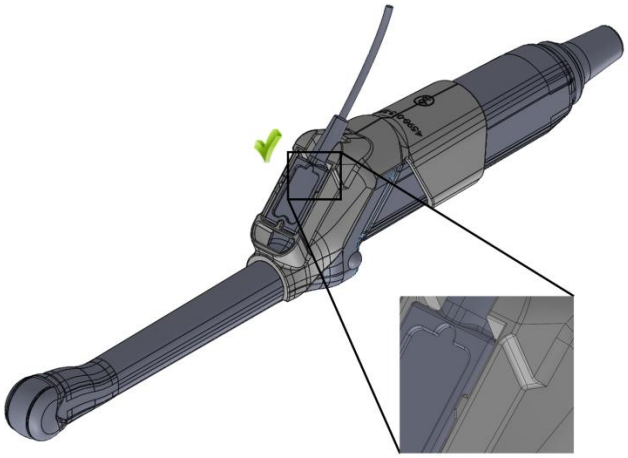
12.2.4. Hitachi C41V Probe Holder Mounting Instructions

Hitachi C41V Probe Holder Installation

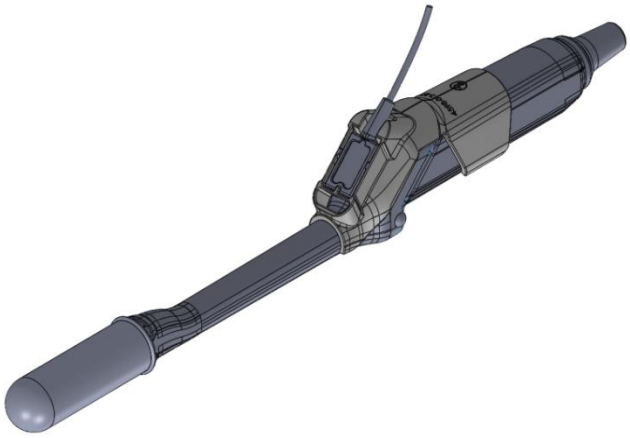


Hitachi C41V Probe Holder Installation

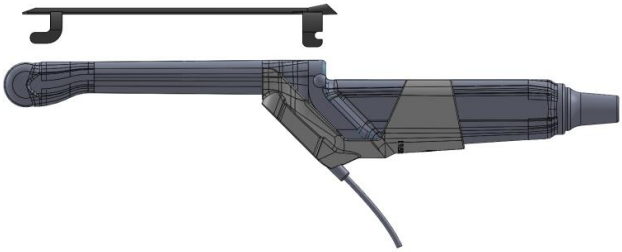




Apply force until flush

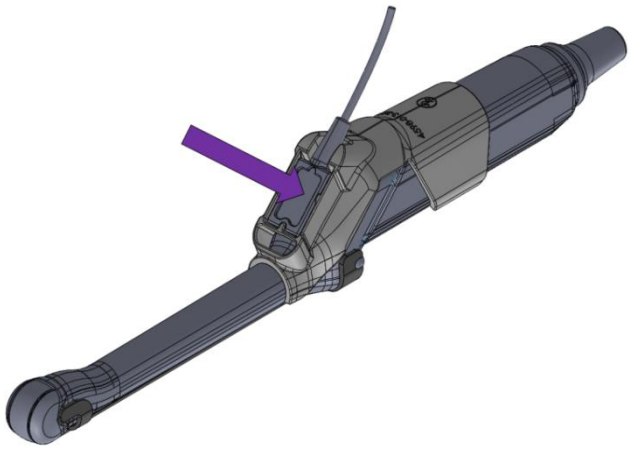


Install cover per the manufacturer's instructions over transducer and UroNav® probe and holder.



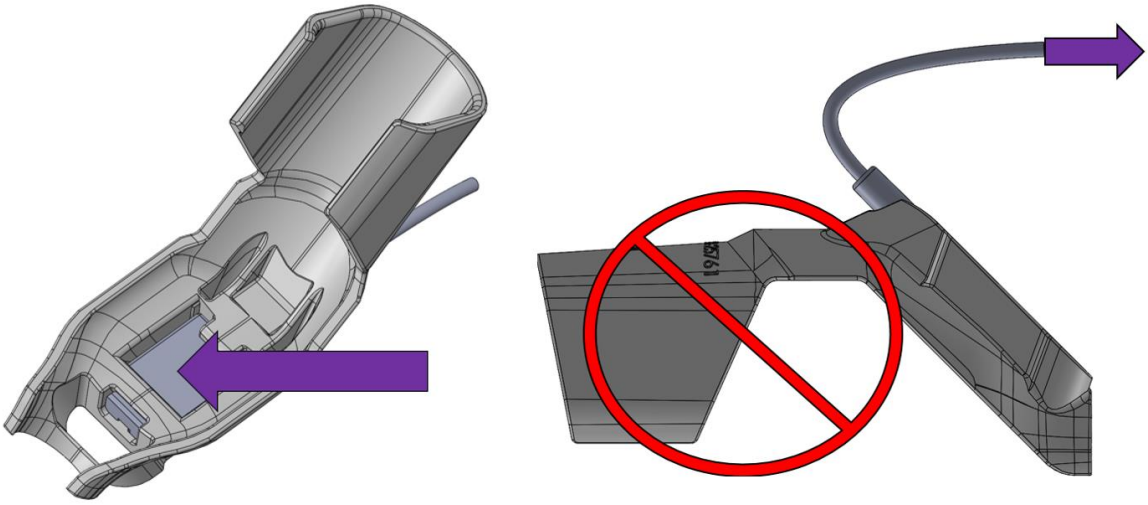
The transducer cover is not shown.

Hitachi C41V Probe Holder Installation



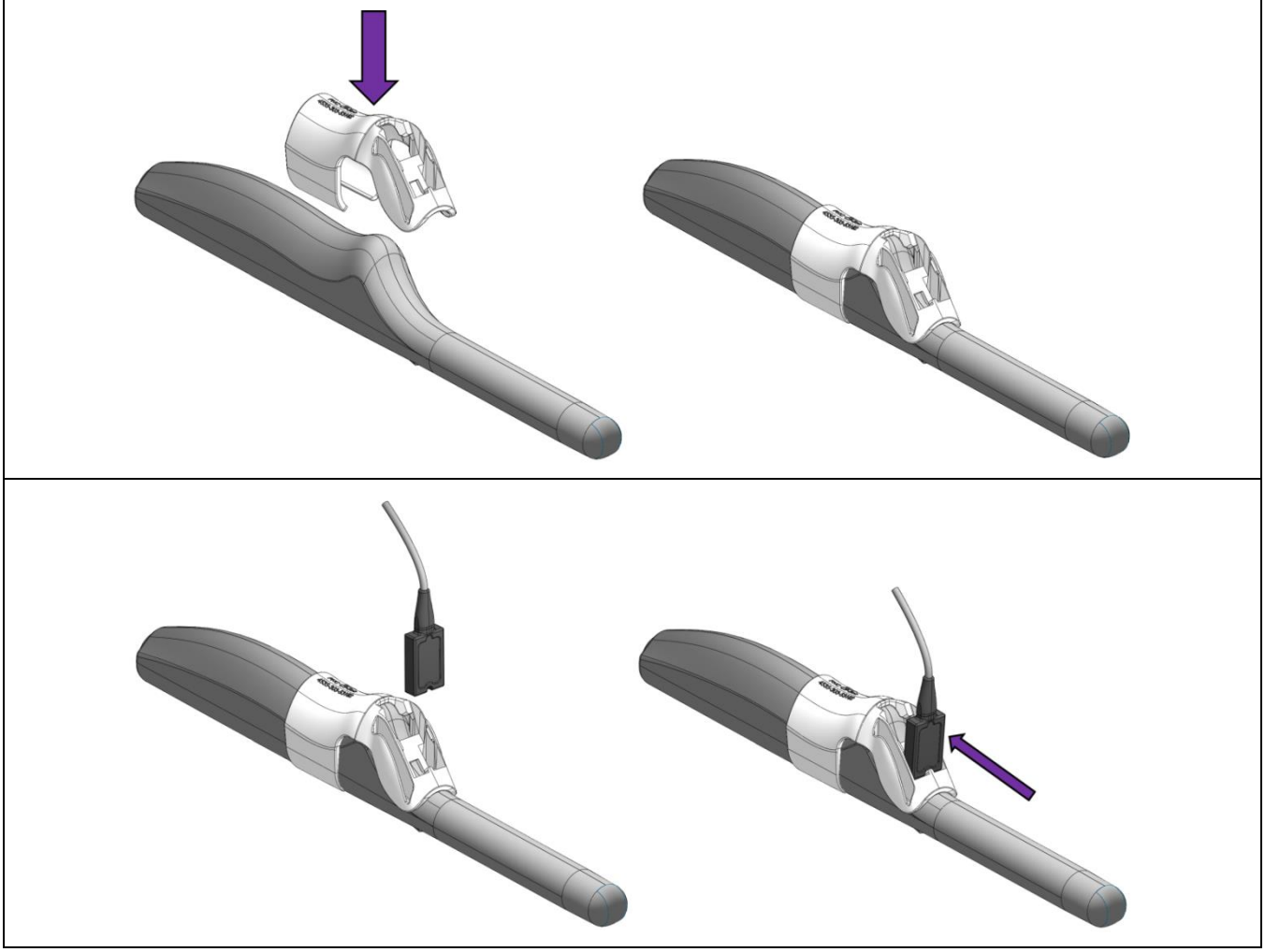
Apply force to reseat. The transducer cover is not shown.

Tracker Removal from Hitachi C41V Probe Holder

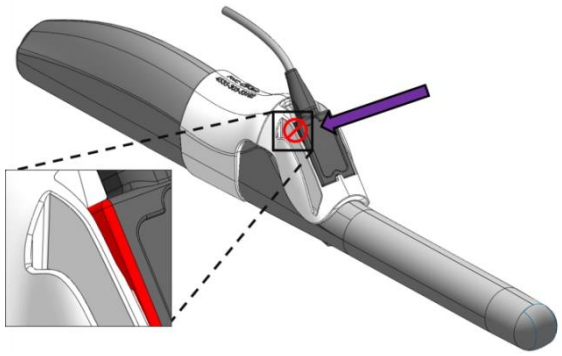


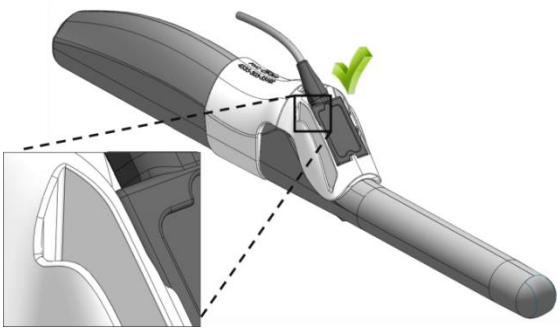
12.2.5. Philips C9-5ec Probe Holder Mounting Instructions

Philips C9-5ec Probe Holder Installation

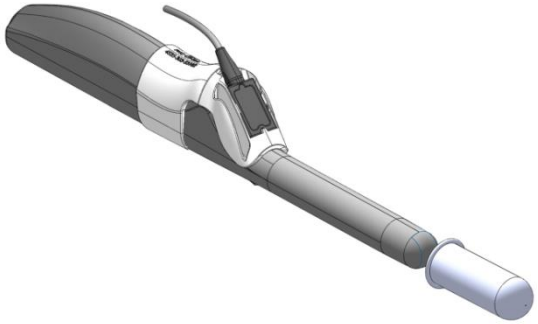


Philips C9-5ec Probe Holder Installation

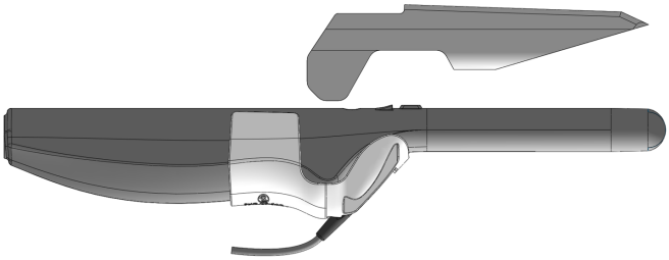




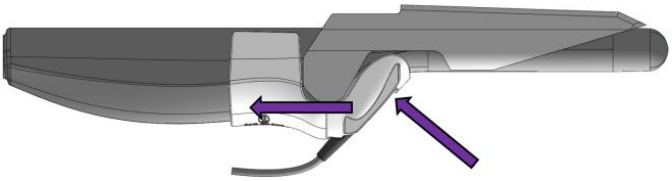
Apply force until flush



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

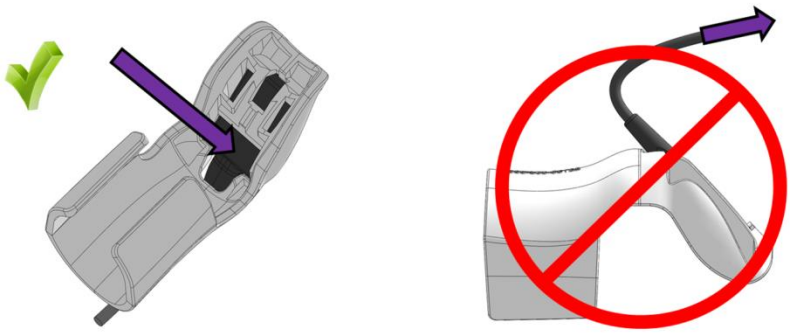


The transducer cover is not shown.



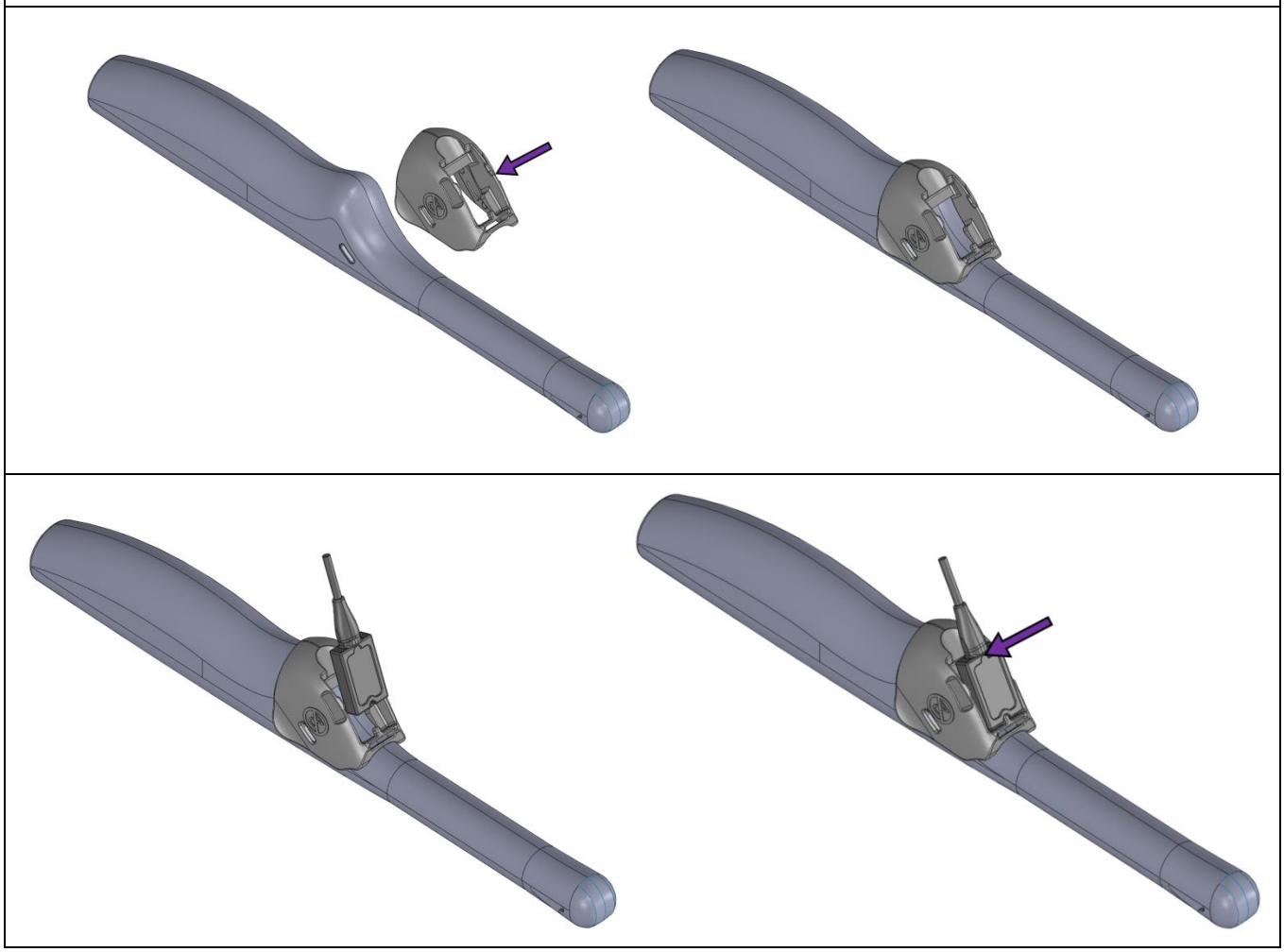
Apply force to reseat. The transducer cover is not shown.

Tracker Removal from Philips C9-5ec Probe Holder

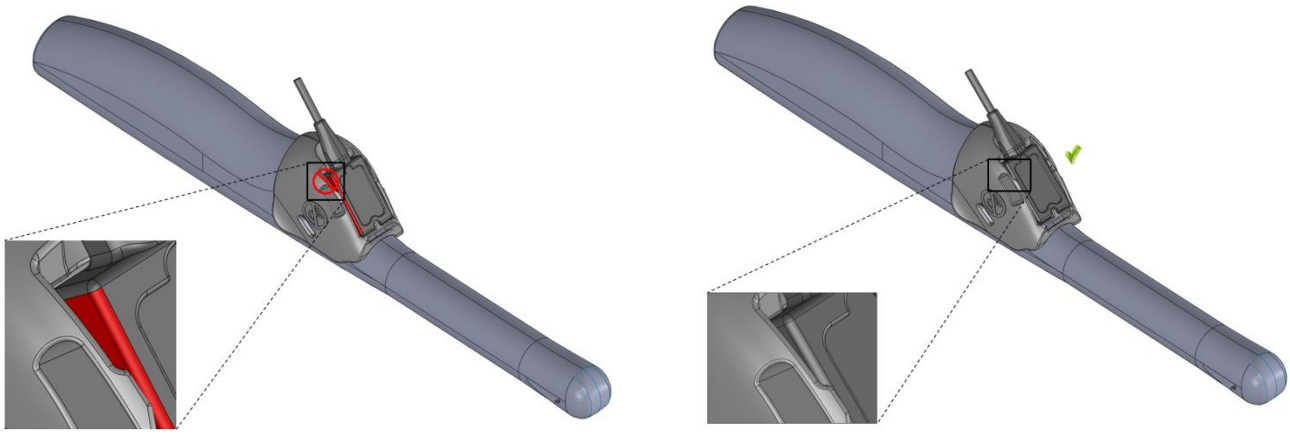


12.2.6. Philips C10-4ec Probe Holder Mounting Instructions

Philips C10-4ec Probe Holder Installation

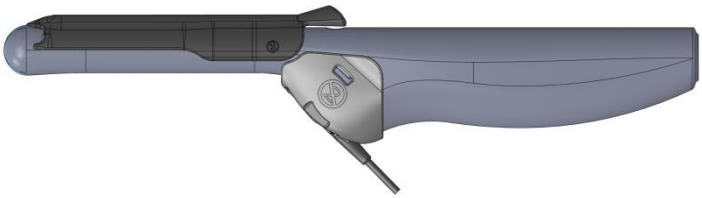


Philips C10-4ec Probe Holder Installation



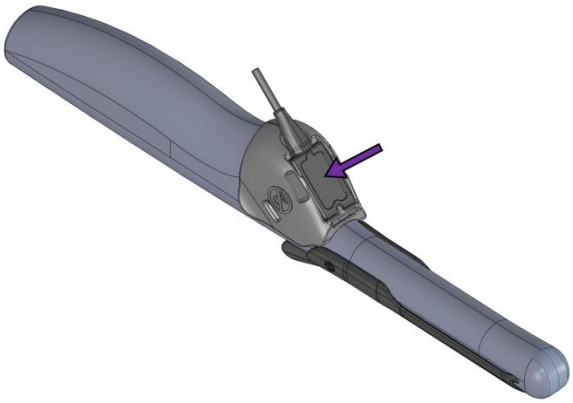
Apply force until flush

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



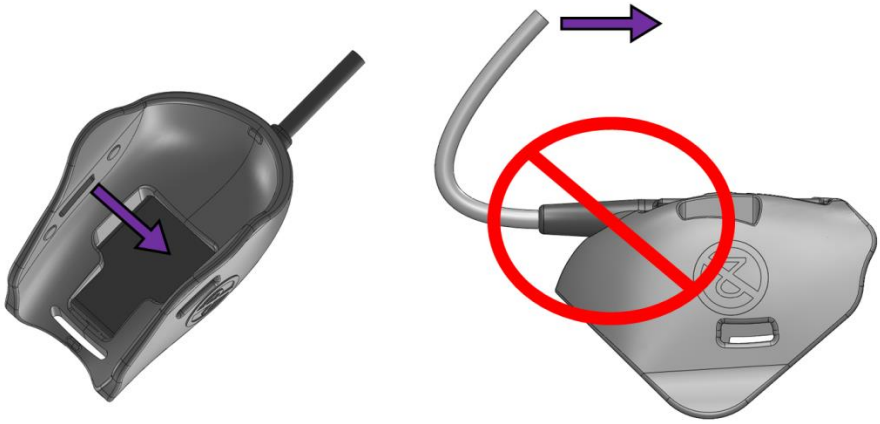
The transducer cover is not shown.

Philips C10-4ec Probe Holder Installation



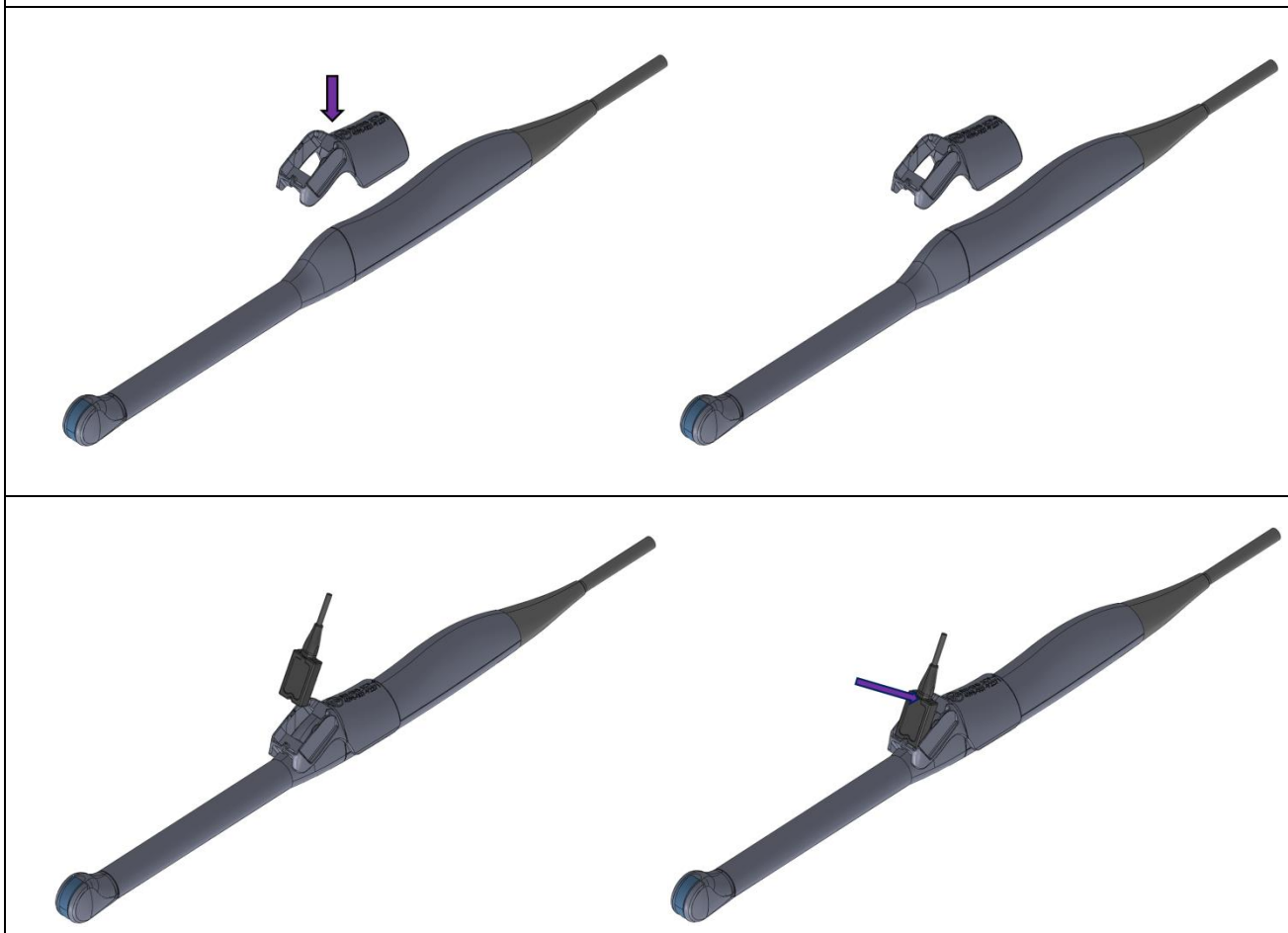
Apply force to reseat. The transducer cover is not shown.

Tracker Removal from Philips C10-4ec Probe Holder

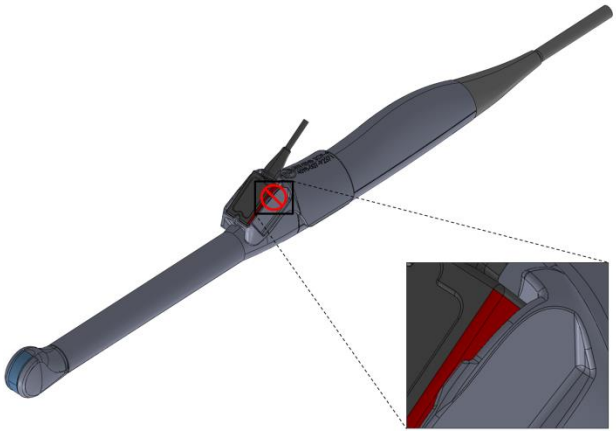


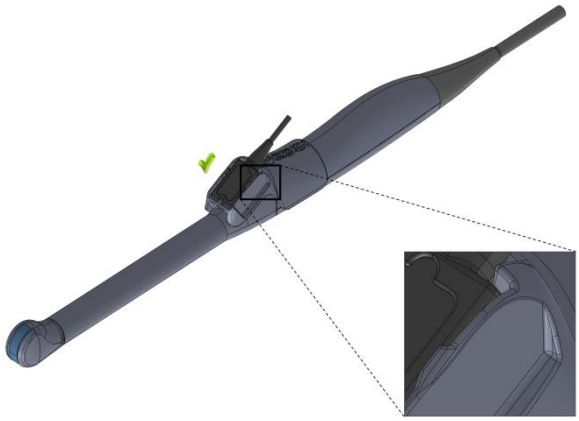
12.2.7. Siemens EC9-4 Probe Holder Mounting Instructions

Siemens EC9-4 Probe Holder Installation



Siemens EC9-4 Probe Holder Installation



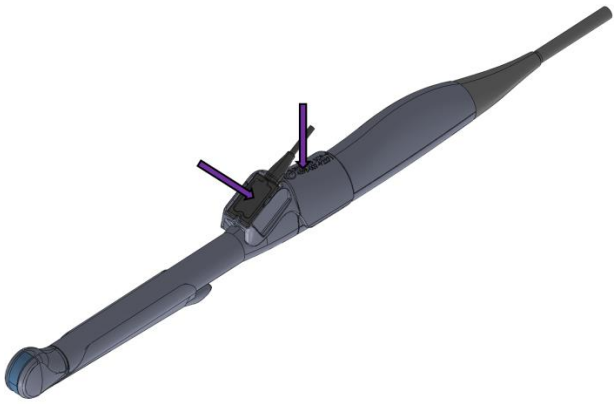


Apply force until flush

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

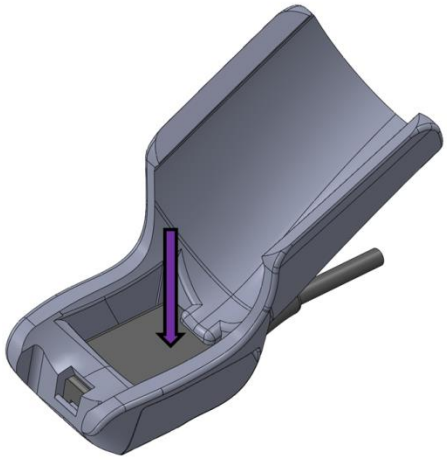
The transducer cover is not shown.

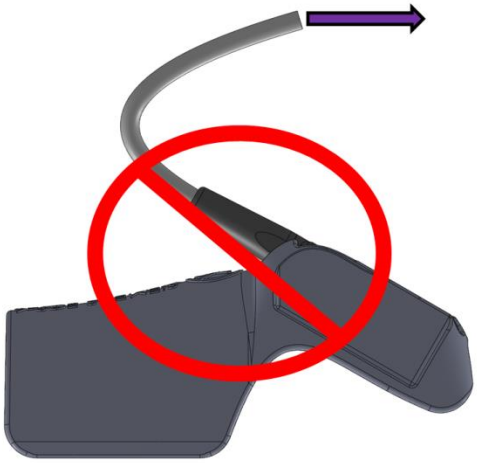
Siemens EC9-4 Probe Holder Installation



Apply force to reseat. The transducer cover is not shown.

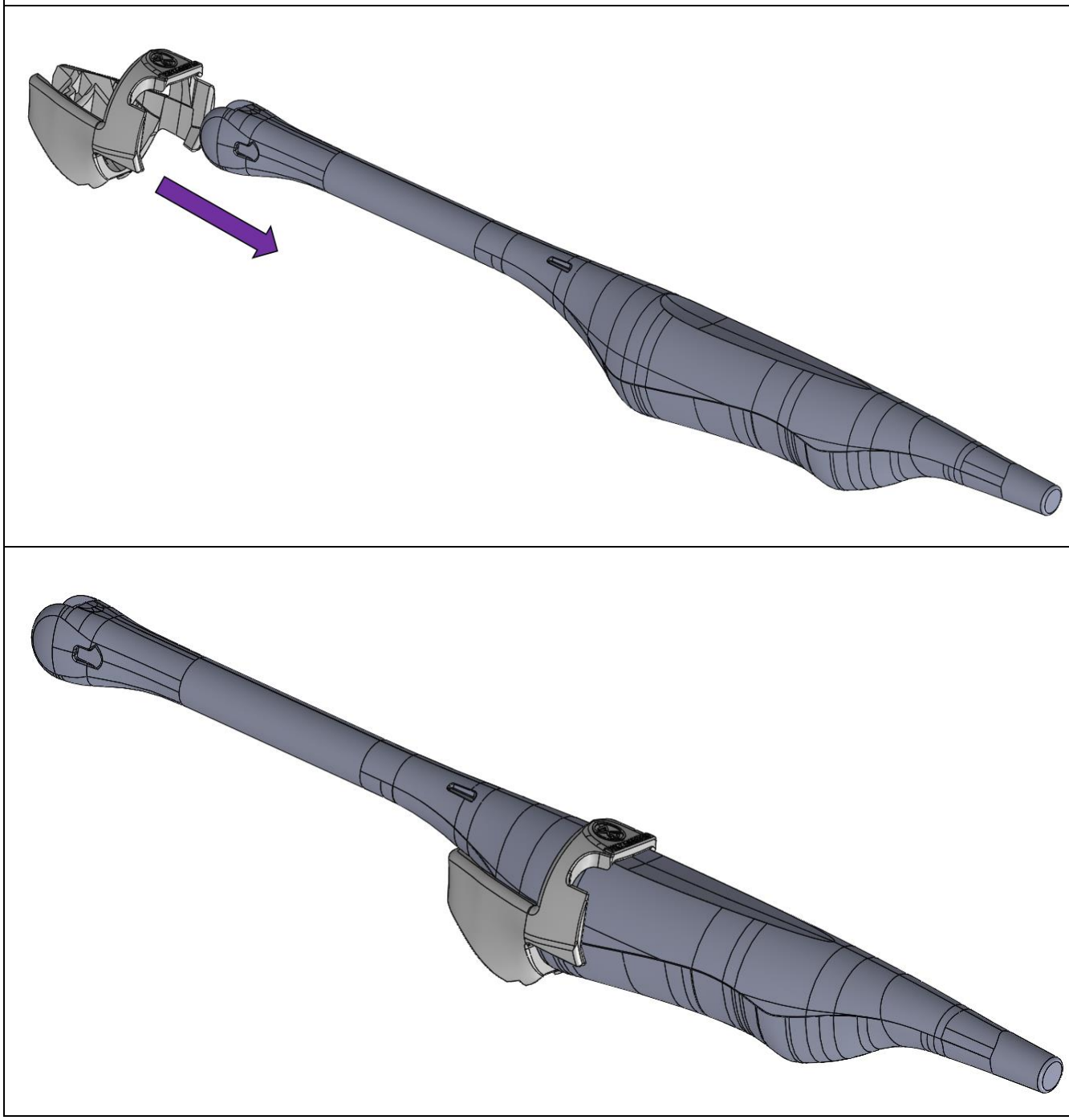
Tracker Removal from Siemens EC9-4 Probe Holder



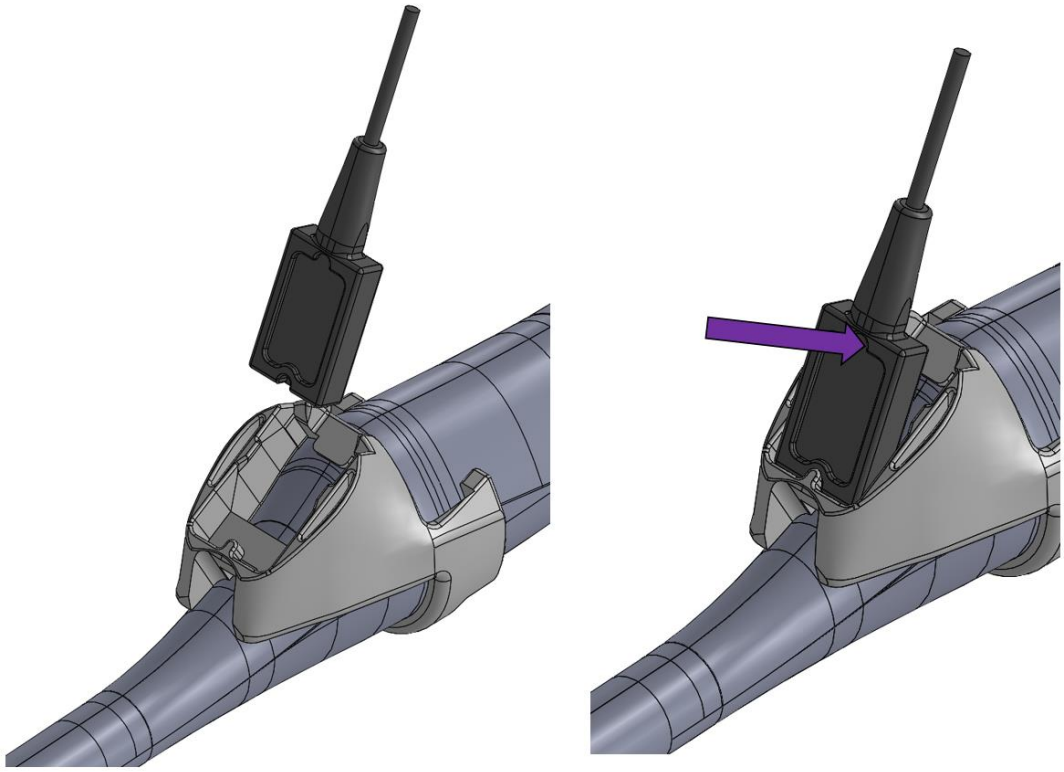


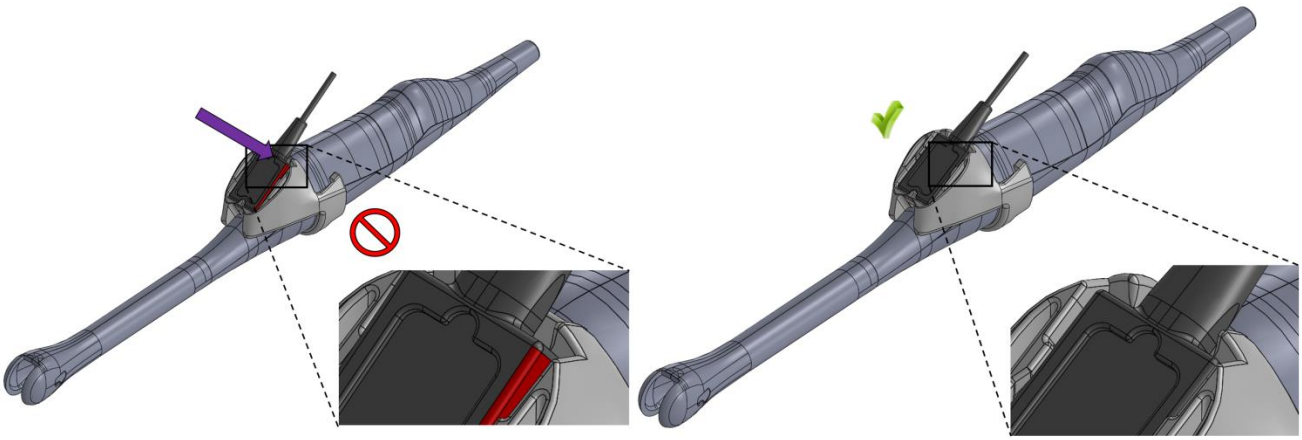
12.2.8. Siemens MC9-4 Probe Holder Mounting Instructions

Siemens MC9-4 Probe Holder Installation



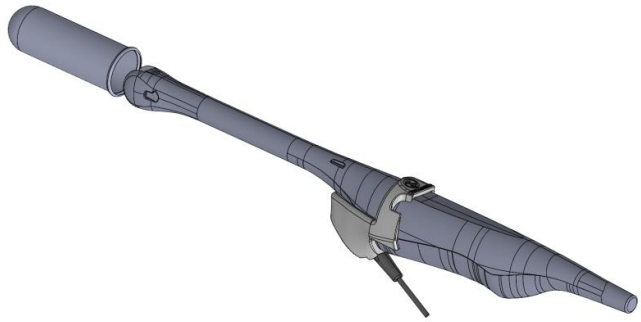
Siemens MC9-4 Probe Holder Installation



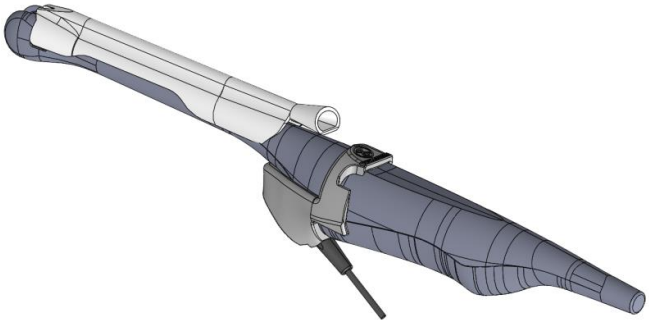


Apply force until flush

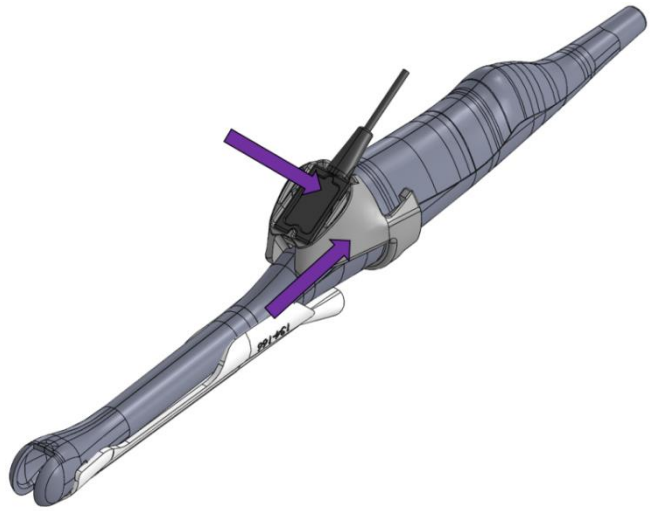
Siemens MC9-4 Probe Holder Installation



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

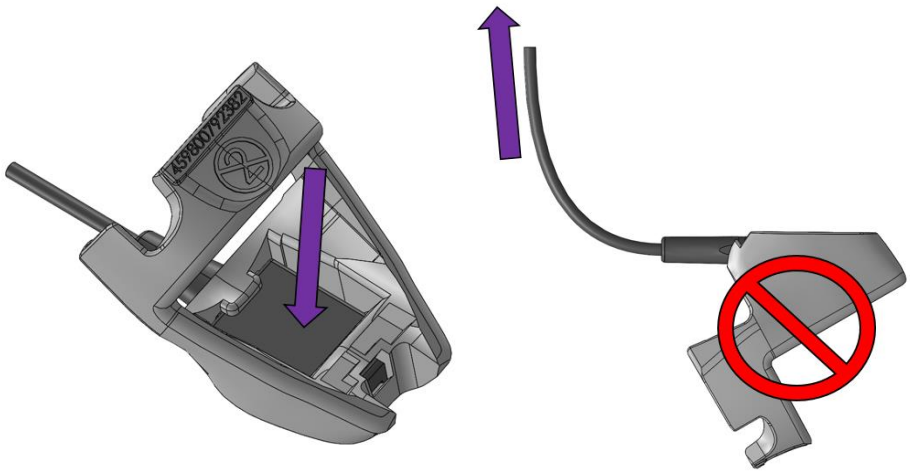


The transducer cover is not shown.



Apply force to reseat. The transducer cover is not shown.

Tracker Removal from Siemens MC9-4 Probe Holder



12.3. Required Ultrasound System Settings for Transrectal Procedures

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

12.3.1. BK Flex Focus and 8808e

Flex Focus Ultrasound Function Compatibility

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

12.3.2. BK Flex Focus and 8818

Flex Focus Ultrasound Function Compatibility

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

12.3.3. BK Flex Focus and 8819

Flex Focus Ultrasound Function Compatibility

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

12.3.4. BK 3000/5000 (software version 5.8.0 – 5.14.8) and E10C4

BK 3000/5000 Ultrasound Function Compatibility

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

12.3.5. BK 3000/5000 (software version 5.8.0 – 5.14.8) and E14C4t

BK 3000/5000 Ultrasound Function Compatibility

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

12.3.6. BK 3000/5000 (software version 5.16.2) and E10C4

BK 3000/5000 (SW Version 5.16.2) Ultrasound Function Compatibility

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	HDMI

Supported Needle Guide:

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

12.3.7. BK 3000/5000 (software version 5.16.2) and E14C4t

BK 3000/5000 (SW Version 5.16.2) Ultrasound Function Compatibility

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 & Endfire)
Video Output Mode	Passive
Video Output Port	HDMI

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

12.3.8. BK Specto (software version 6.6.4) and E10C4

BK Specto (SW Version 6.6.4) Ultrasound Function Compatibility

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

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.

12.3.9. BK Specto (software version 6.6.4) and E14C4t

BK Specto Ultrasound Function Compatibility

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

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

12.3.10. BK Specto (software version 6.6.8) and E14C4t

BK Specto (SW Version 6.6.8) Ultrasound Function Compatibility

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
Font size	Small
Video Output Port	HDMI

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

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

Logiq F8 Ultrasound Function Compatibility

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

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

Logiq F8 Ultrasound Function Compatibility

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

12.3.13. GE Logiq P5/A5/A5Pro/P6/P6Pro and E8C

Logiq P5/A5/A5Pro/P6/P6Pro Ultrasound Function Compatibility

Biopsy	Must be ON
Preset	Prostate
Width	133
Color Flow Mode	Not Supported
Depths	4.0cm, 5.0cm, 6.0cm, 7.0cm, 8.0cm, 9.0cm
Dual View	Not Supported
ECG-mode	Not Supported
Harmonics	Not Supported
Imaging	2D
LV-mode	Not Supported
M-mode	Not Supported
Orientation	Down (Small "GE P5" Logo Bottom Left or Right). Note that the user may need to adjust the orientation on UroNav via the ALT-F key binding.
Scan Area/Width	Not Supported (Default E8C Urology Prostate setting)
PDI-mode	Not Supported
PWD-mode	Not Supported
Video I/O	Video Output Format: NTSC
Zoom	Not Supported (Default E8C Urology Prostate setting)

Supported Needle Guide

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

12.3.14. GE Logiq P5/A5/A5Pro/P6/P6Pro and E8CS

Logiq P5/A5/A5Pro/P6/P6Pro Ultrasound Function Compatibility

Biopsy	Must be ON
Preset	Prostate
Width	133
Color Flow Mode	Not Supported
Depths	4.0cm, 5.0cm, 6.0cm, 7.0cm, 8.0cm, 9.0cm
Dual View	Not Supported
ECG-mode	Not Supported
Harmonics	Not Supported
Imaging	2D
LV-mode	Not Supported
M-mode	Not Supported
Orientation	Down (Small "GE P5" Logo Bottom Left or Right). Note that the user may need to adjust the orientation on UroNav via the ALT-F key binding.
Scan Area/Width	Not Supported (Default E8CS Urology Prostate setting)
PDI-mode	Not Supported
PWD-mode	Not Supported
Video I/O	Video Output Format: NTSC
Zoom	Not Supported (Default E8CS Urology Prostate setting)

Supported Needle Guide

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

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

Logiq S7 R3 Ultrasound Function Compatibility

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

12.3.16. GE Versana Premier and E8Cs-RS

GE Versana Premier Ultrasound Function Compatibility

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

12.3.17. Hitachi Noblus and C41V

Hitachi Noblus Ultrasound Function Compatibility

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	644-068

12.3.18. Hitachi Arietta Precision and C41V

Hitachi Arietta Precision Ultrasound Function Compatibility

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

12.3.19. Hitachi Arietta 65 and C41V

Hitachi Arietta 65 Ultrasound Function Compatibility

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/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, C41V	On
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
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

Supported Needle Guide

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

12.3.21. 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

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)"

Supported Needle Guide

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

12.3.22. 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

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)"

Supported Needle Guide

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

12.3.23. Philips HD11XE and C9-5ec

HD11XE Ultrasound Function Compatibility

Biopsy	Must be ON (Gun)
Chroma Map	Not Supported
Depths	4.0cm, 5.0cm, 6.0cm, 7.0cm, 8.0cm
Dual View	Not Supported
Imaging	2D
M-mode	Not Supported
Orientation	Bottom View (Blue Circled "P" must be bottom left or right). Note that the user may need to adjust the orientation on UroNav via the ALT-F key binding.
Sector Width	Not Supported
SonoCT	Must be ON
Zoom	Not Supported

Supported Needle Guide

Manufacturer	Description	Manufacturer's Part Number
CIVCO	Needle Guide	613-246
CIVCO	Needle Guide with Cover	613-245

12.3.24. Philips iU22 and C9-5ec

iU22 Ultrasound Function Compatibility

Biopsy	Must be ON
Chroma Map	Not Supported
Depths	4.0cm, 5.0cm, 6.0cm, 7.1cm, 8.1cm, 9.0cm
Dual View	Not Supported
Imaging	2D
M-mode	Not Supported
Orientation	Bottom View (Blue Circled "P" must be bottom left or right) Note that the user may need to adjust the orientation on UroNav via the ALT-F key binding.
Sector Width	Not Supported
SonoCT	Must be ON
Widescan	Not Supported
xPlane	Not Supported
Zoom	Not Supported, must be left at 1.0

Supported Needle Guide

Manufacturer	Description	Manufacturer's Part Number
CIVCO	Needle Guide	613-246
CIVCO	Needle Guide with Cover	613-245

12.3.25. Siemens S2000/S3000 and MC9-4

Siemens S2000/S3000 Ultrasound Function Compatibility

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

12.3.26. Siemens X150/X300 and EC9-4

Siemens X150/X300 Ultrasound Function Compatibility

Multi-Hertz	6.7MHz
Edge	1
DR	60dB
Depths	4.0cm, 5.0cm, 6.0cm, 7.0cm, 8.0cm, 9.0cm
Split	OFF
2D Size	All Up
Map	C
Tint	0
Persist	2
U/D Flip	D
L/R Flip	L or R
P	100%
R/S	3
4B	OFF
Modify Map	OFF
Clarify VE	OFF
SieClear	OFF

Supported Needle Guide

Manufacturer	Description	Manufacturer's Part Number
CIVCO	Needle Guide	676-132

13. Appendix C

13.1. Supported Ultrasound and Transducer Probe Combinations for Transperineal Procedures

Table 12: Supported Tranperineal Procedure Ultrasound Systems and Associated Transducer Probes

Ultrasound	Probe
BK 3000/5000	E14CL4b (with UroNav Stepper) E14CL4b (with PrecisionPoint™)
BK3000/5000 SW Version 5.16	E14CL4b (with UroNav Stepper) E14CL4b (with PrecisionPoint™)
BK FlexFocus 400/500/700/800	8848 (with UroNav Stepper) 8848 (with PrecisionPoint™)
BK Specto SW Version 6.6.4	E14CL4b (with UroNav Stepper) E14CL4b (with PrecisionPoint™)
BK Specto SW Version 6.6.8	E14CL4b (with UroNav Stepper) E14CL4b (with PrecisionPoint™)
Hitachi Noblus	C41L47RP (with UroNav Stepper)
Hitachi Arietta Precision	C41L47RP (with UroNav Stepper)
Hitachi Arietta 65	C41L47RP (with UroNav Stepper)

NOTE: Use of PrecisionPoint™ is only supported in the Biopsy workflow and requires the use of the proble holder listed in **Table 13** below.

Table 13: Probe Holder Reorder Part Numbers for Transperineal Procedures

Ulrasound Transducer Probe	Philips Part Number	Reorder Part Number
BK 8848 and E14CL4b	4598-014-79211	FCS0137 (Set of 25)

NOTE: See Table 11 in section 12.1 for the EM Tracker Reorder Part Number.

To order additional supplies, consumable instrumentation, or accessories, please contact Philips Customer Service, see section 3.6 Customer Service.

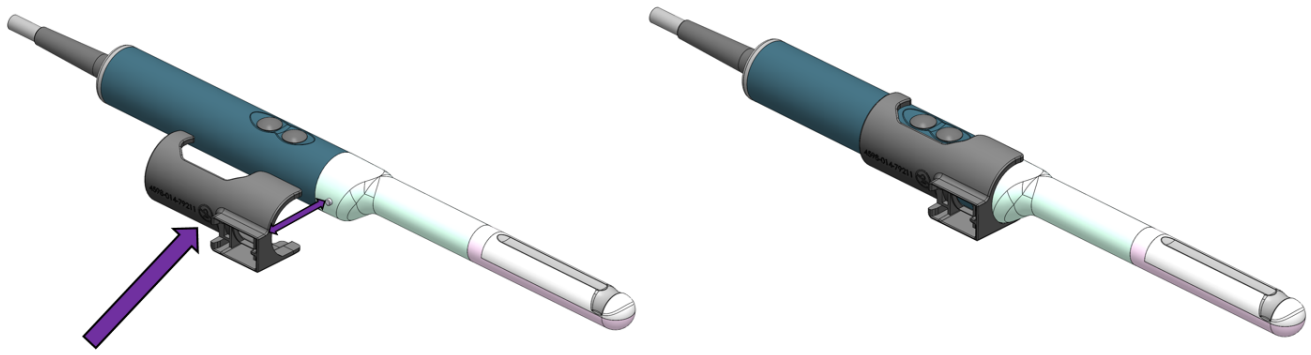
13.2. Transperineal Procedure Probe Holder Mounting Instructions

⚠ 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.

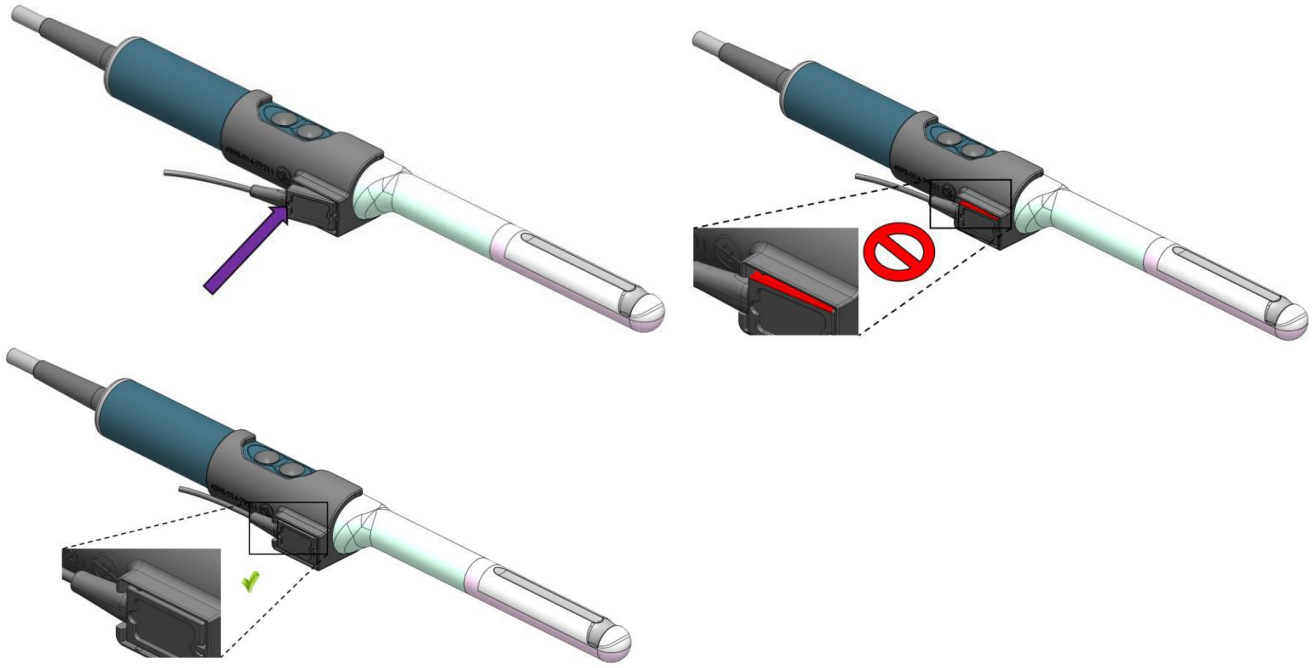
⚠ Improper or insecure mounting of PrecisionPoint™ needle guideline leads to needle guideline moving out of imaging plane resulting in inaccurate targeting.

NOTE: See Section 14 for instructions on mounting the ultrasound transducer probes to the Stepper.

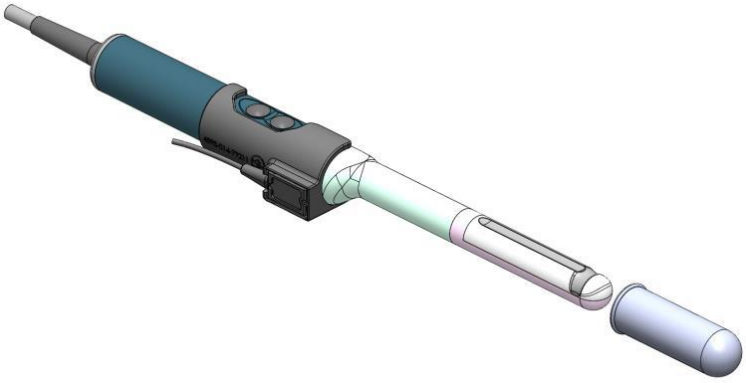
BK 8848 and E14CL4b Probe Holder Installation



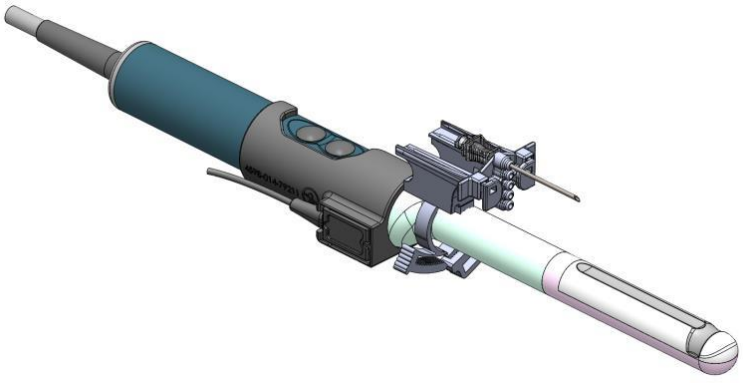
BK 8848 and E14CL4b Probe Holder Installation



Apply force until flush

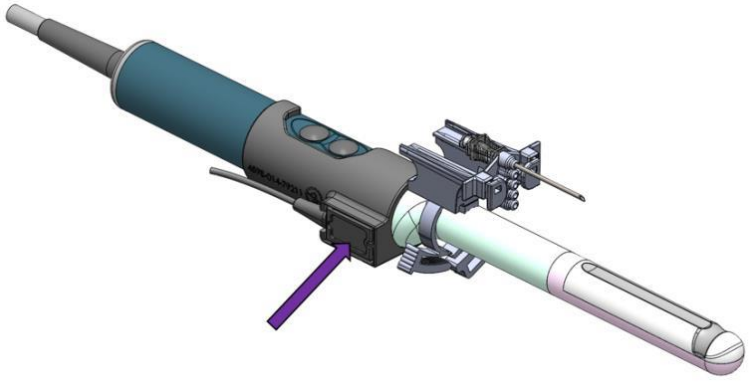


Install cover per the manufacturer's instructions over transducer and UroNav® probe and holder.



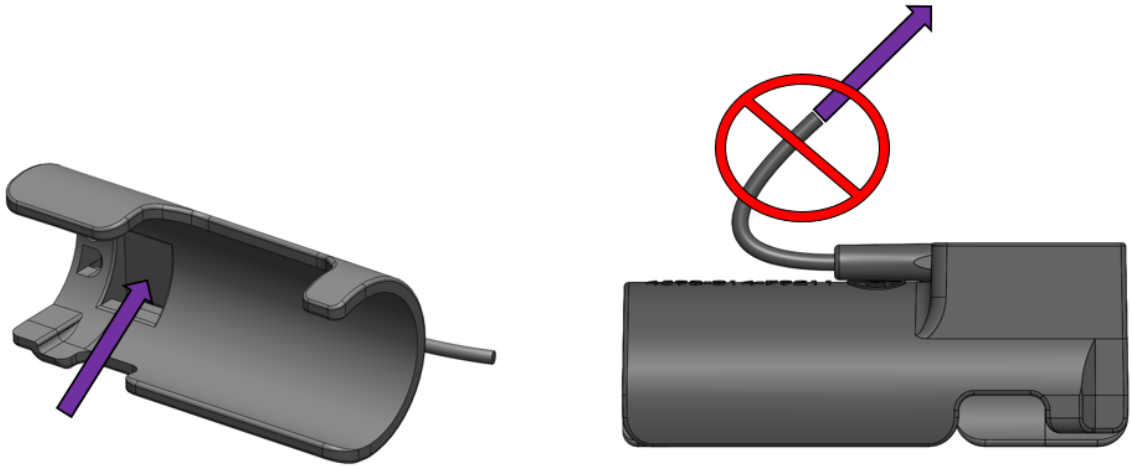
The transducer cover is not shown.

BK 8848 and E14CL4b Probe Holder Installation



Apply force to reseat. The transducer cover is not shown.

Tracker Removal from 8848 and E14CL4b Probe Holder



13.3. Required Ultrasound System Settings for Transperineal Procedures

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

13.3.1. BK Flex Focus and 8848

Flex Focus Ultrasound Function Compatibility

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
Font Size	Large

Supported Needle Guide

Manufacturer	Description
PERINEOLOGIC	PrecisionPoint™ Transperineal Access System

NOTE: The list of supported grid plates and accessories for the UroNav Stepper can be viewed in section 11.2.

13.3.2. BK 3000/5000 (software version 5.8.0 – 5.14.8) and E14CL4b

BK 3000/5000 (SW versions 5.8.0 – 5.14.8) Ultrasound Function Compatibility

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

NOTE: The list of supported grid plates and accessories for the UroNav Stepper can be viewed in section 11.2.

13.3.3. BK 3000/5000 (software version 5.16.2) and E14CL4b

BK 3000/5000 (SW Version 5.16.2) Ultrasound Function Compatibility

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	HDMI

Supported Needle Guide

Manufacturer	Description
PERINEOLOGIC	PrecisionPoint™ Transperineal Access System

NOTE: The list of supported grid plates and accessories for the UroNav Stepper can be viewed in section 11.2.

13.3.4. BK Specto (software version 6.6.4) and E14CL4b

BK Specto SW Version 6.6.4) Ultrasound Function Compatibility

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

Supported Needle Guide

Manufacturer	Description
PERINEOLOGIC	PrecisionPoint™ Transperineal Access System

NOTE: The list of supported grid plates and accessories for the UroNav Stepper can be viewed in section 11.2.

13.3.5. BK Specto (software version 6.6.8) and E14CL4b

BK Specto (SW Version 6.6.8) Ultrasound Function Compatibility

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
Font size	Small
Video Output Port	HDMI

Supported Needle Guide

Manufacturer	Description
PERINEOLOGIC	PrecisionPoint™ Transperineal Access System

NOTE: The list of supported grid plates and accessories for the UroNav Stepper can be viewed in section 11.2.

13.3.6. Hitachi Noblus and C41L47RP

Hitachi Noblus Ultrasound Function Compatibility

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). Note that 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

NOTE: The list of supported grid plates and accessories for the UroNav Stepper can be viewed in section 11.2.

13.3.7. Hitachi Arietta Precision and C41L47RP

Hitachi Arietta Precision Ultrasound Function Compatibility

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

NOTE: The list of supported grid plates and accessories for the UroNav Stepper can be viewed in section 11.2.

13.3.8. Hitachi Arietta 65 and C41L47RP

Hitachi Arietta 65 Ultrasound Function Compatibility

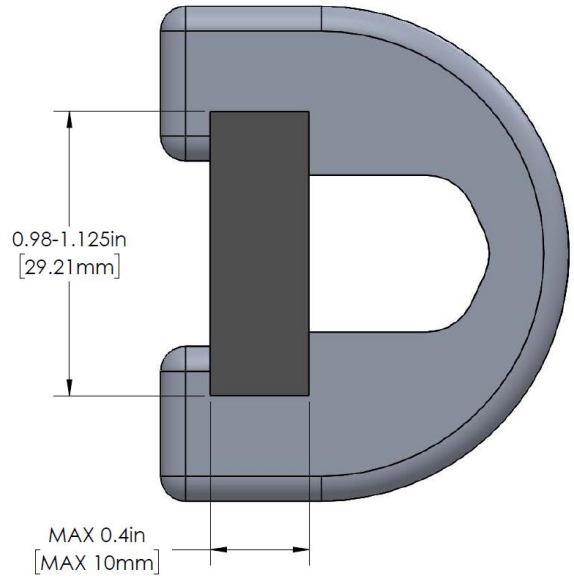
Vertical Shift	0 mm
HI Zoom	Off
PAN Zoom	Off
Scan Area (B)	100
Biplane Scan Area (B) (T)	100
Biplane Scan Area (B) (L)	100
Initial Mode	B
B Mode Format Size (H)	Normal
B Invert L/R	Off
B Invert U/L	Off
B Image Rotation	180 deg
Biplane Invert L/R (L)	On
Biplane Invert L/R (T)	Off
Biplane Invert U/L (L)	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
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

NOTE: The list of supported grid plates and accessories for the UroNav Stepper can be viewed in section 11.2.

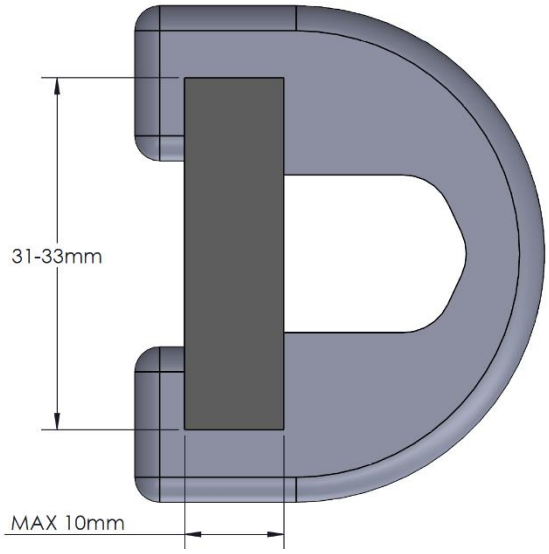
14. Appendix D

14.1 Stepper Arm

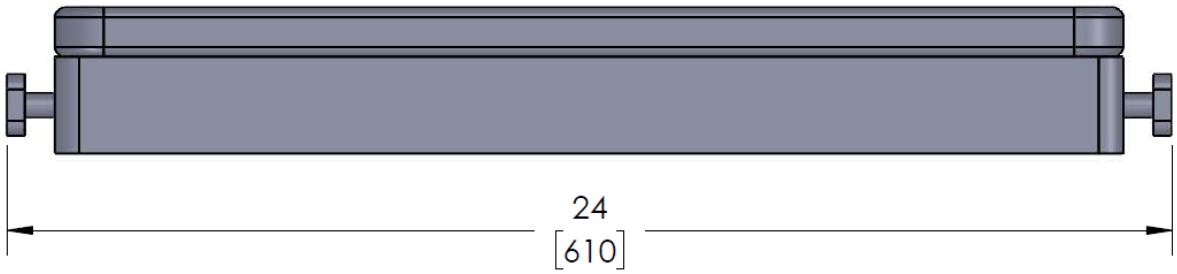
SUPPORT TABLE DIMENSIONS



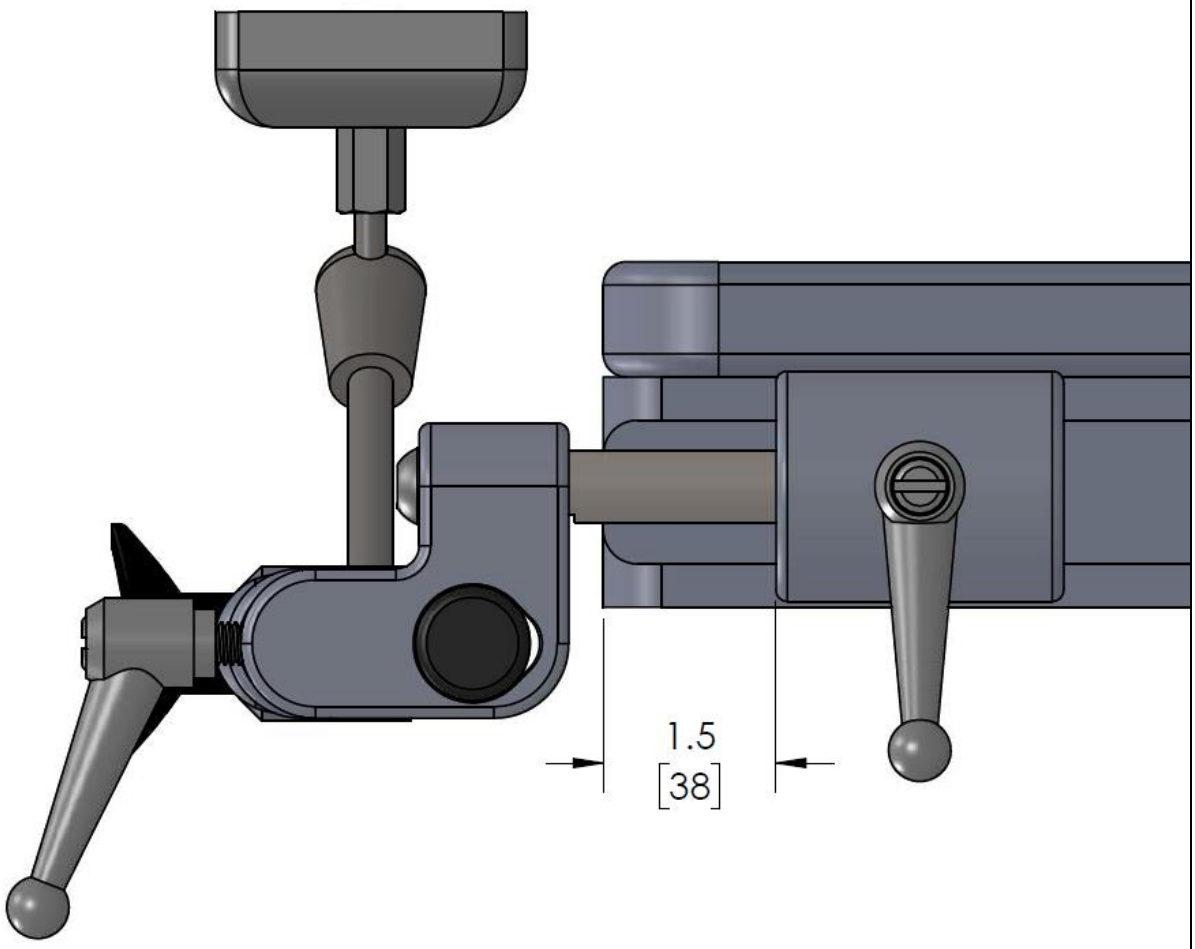
The Stepper Arm Clamps to EU tables with support bar dimensions of 10 mm by 25 mm and U.S. tables with support bar dimensions of 0.375 inches by 1.125 inches, as illustrated in the above picture.



The Stepper Arm Clamps to Japanese tables with support bar dimensions of 9 mm by 32 mm.

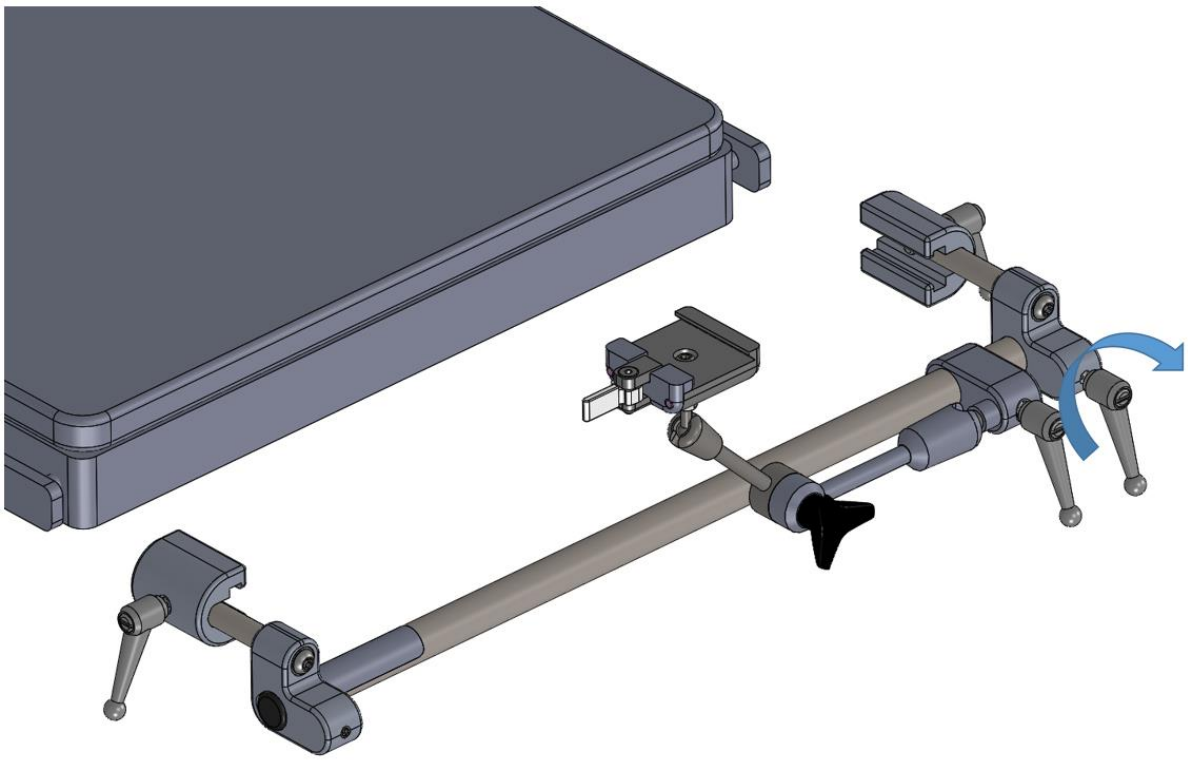


The Stepper Arm accommodates a maximum table width of 24 inches (610 mm).



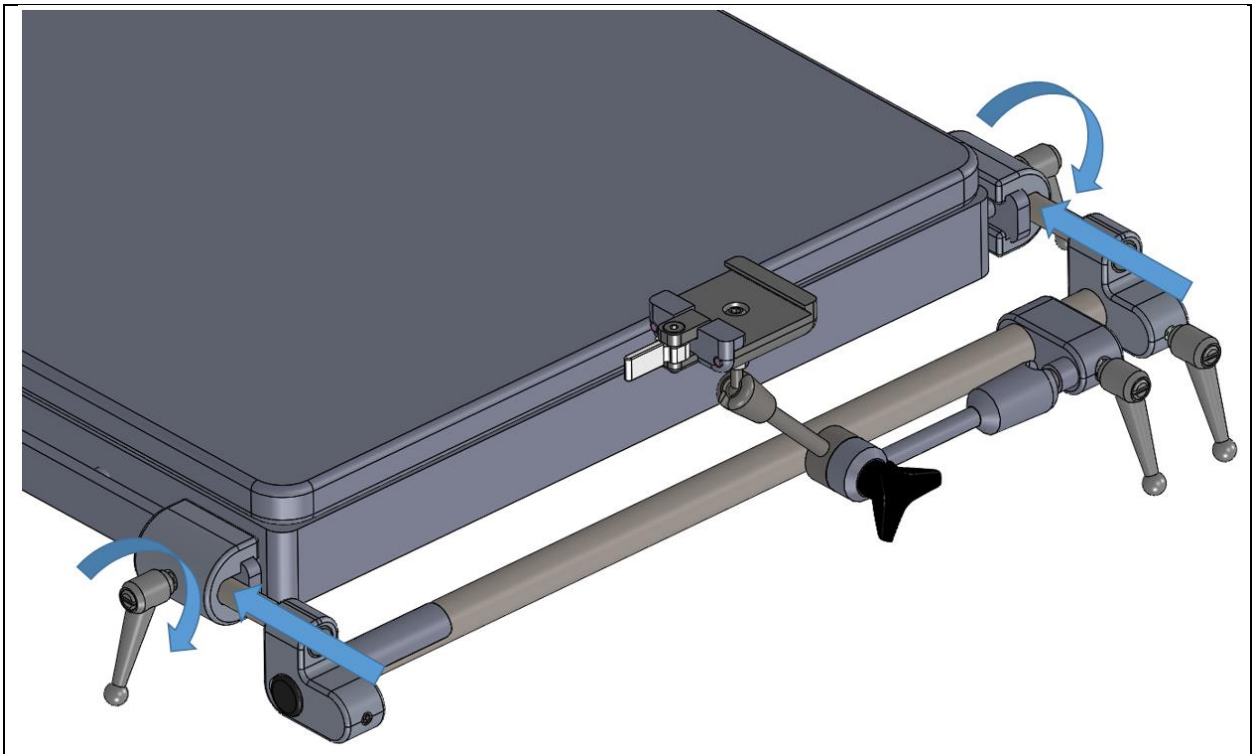
The table support bar must be within 1.5 inches (38 mm) from the end of the table.

STEPPER ARM INSTALLATION

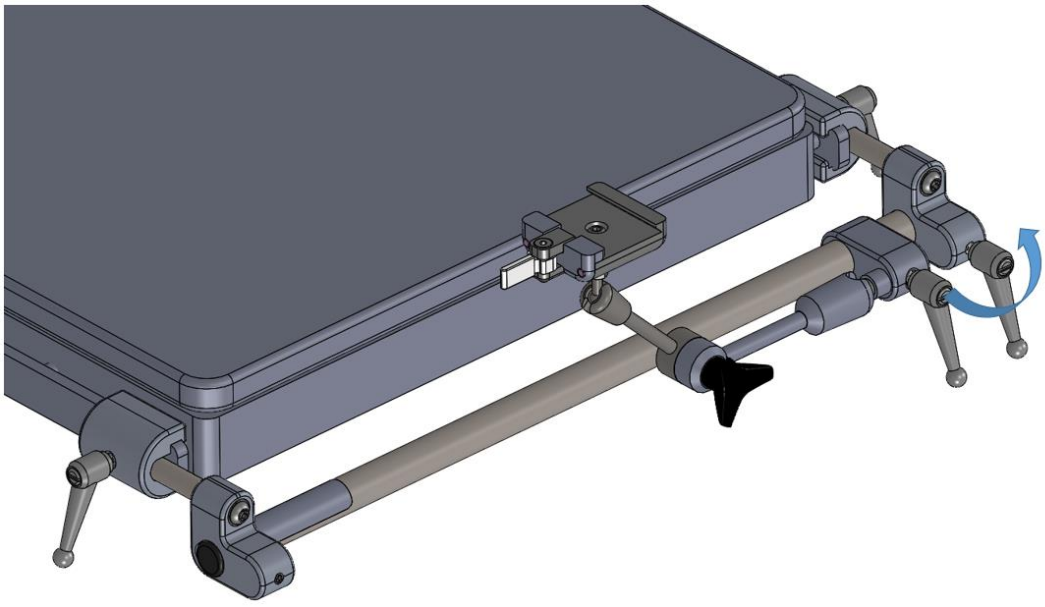


Open the width adjustment handle. Place left-side clamp on to table support bar. Adjust width of the right-side clamp to the width of the table and place right-side clamp on to table support bar.

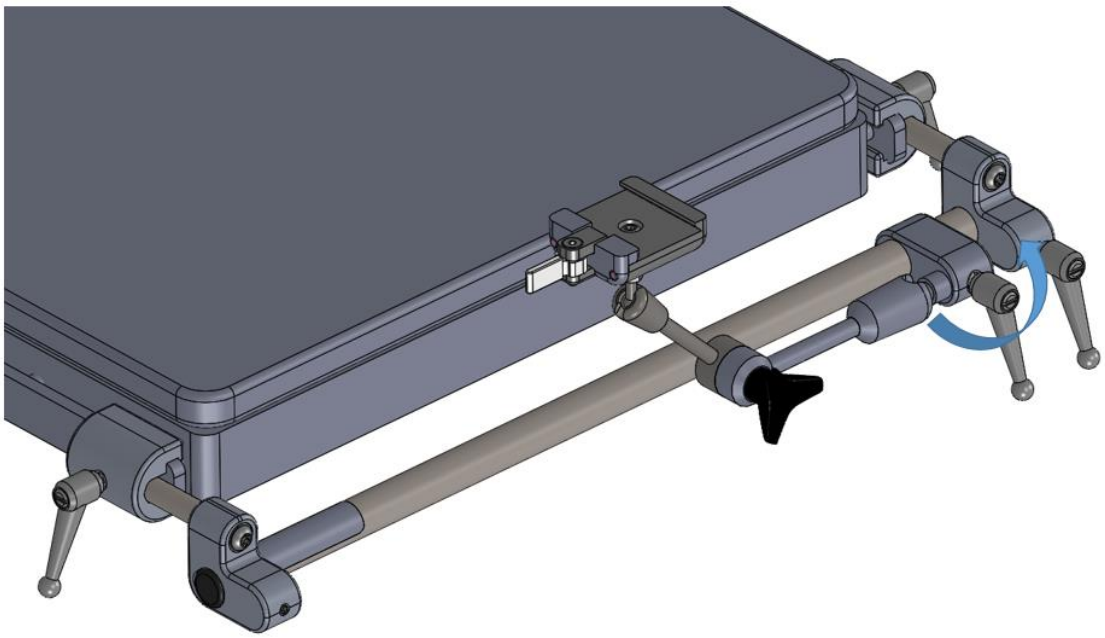
When the width adjust handle is open, the clamp can slide off the end of the tube. Do not allow this to happen, as components of the clamp can fall out.



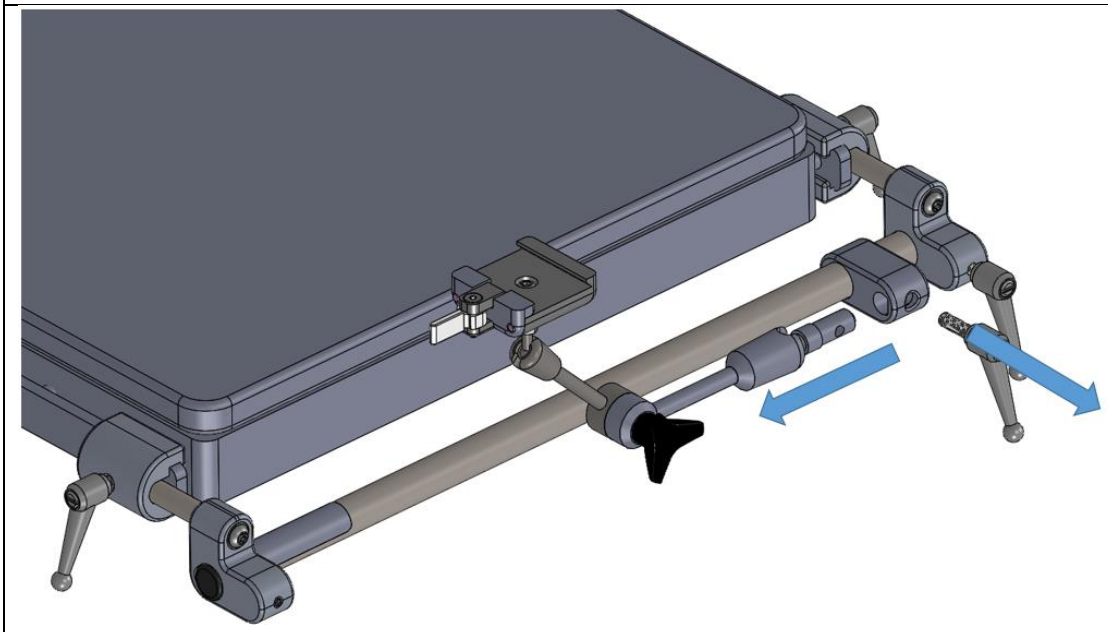
Clamp to the proper distance and tighten clamps down carefully.



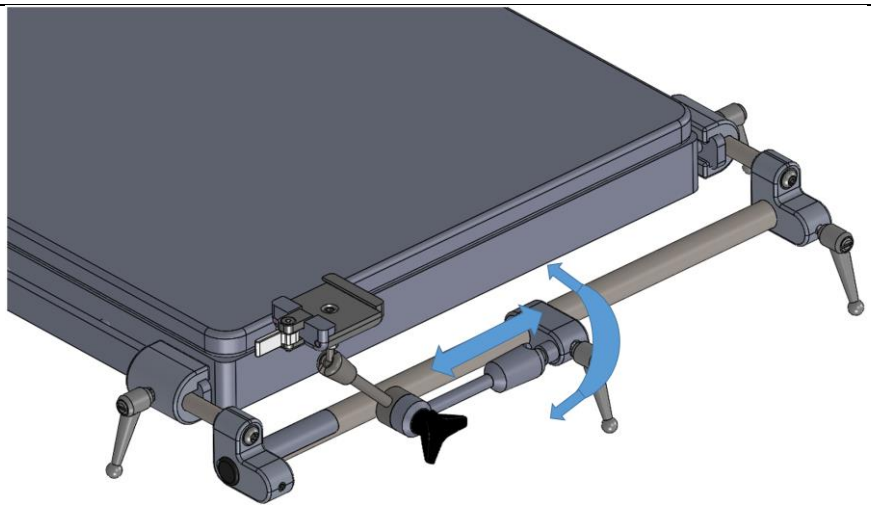
Tighten the width adjustment handle once the proper width is found.



The articulated arm can be set for right-hand use or left-hand use. To change the handedness, open the arm adjustment handle and follow the steps below.

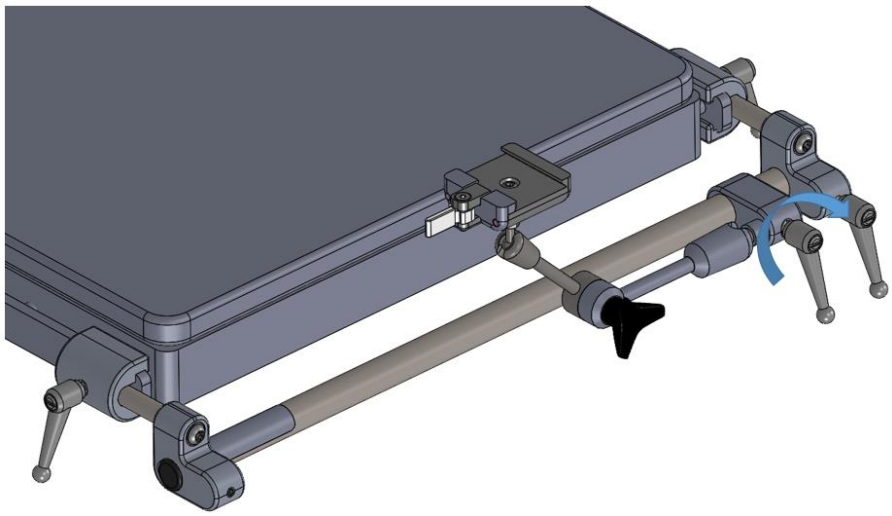


To change handedness, remove the arm adjustment handle and pull the articulated arm out from the holder. Install the articulated arm on the opposite side. Reinstall the arm adjustment handle and tight.



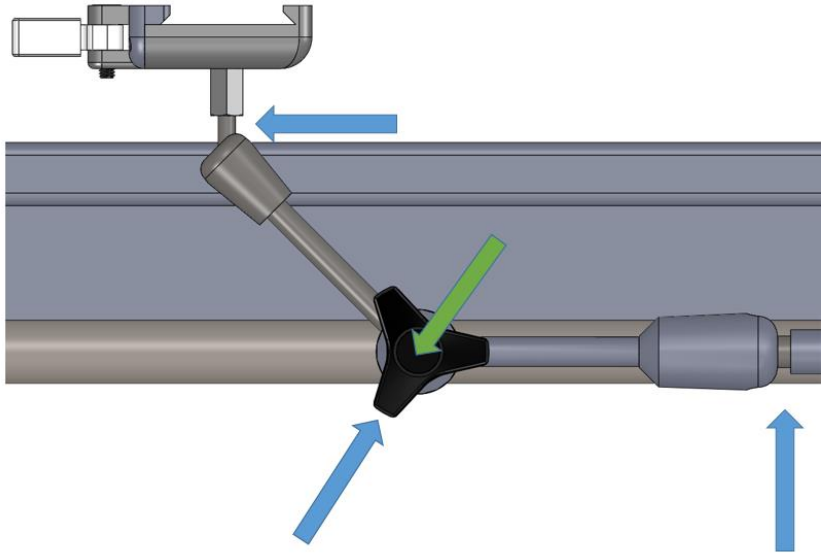
Find the optimal vertical and horizontal position for the articulated arm. The horizontal position is adjusted by sliding the articulated arm along the supporting rod. The vertical position is adjusted by rotating the articulated arm around the supporting rod.

The optimal position depends on the individual patient and therefore the arm position may need adjustment before each procedure.



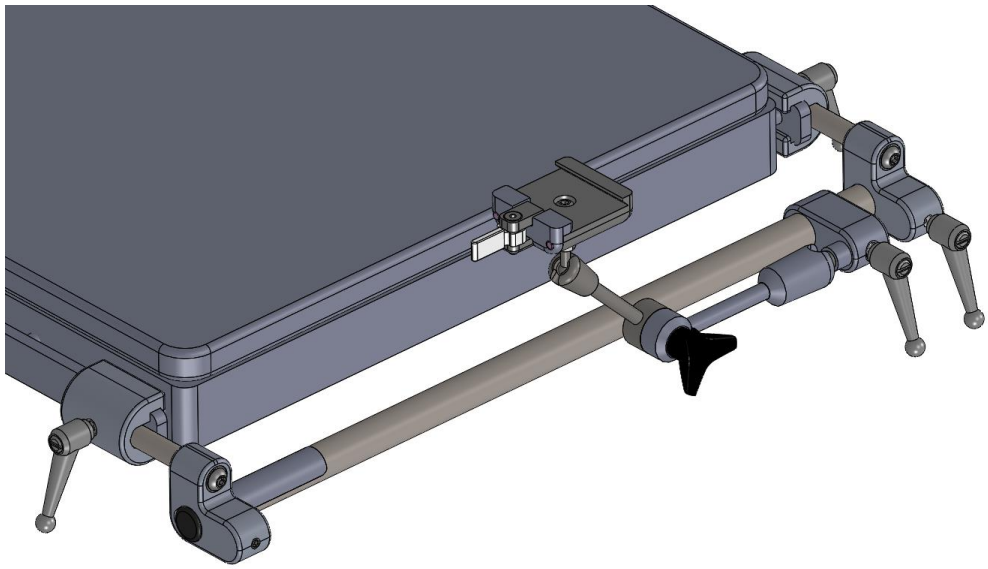
After finding the optimal position, tighten handle.

The Stepper Arm is designed to only hold the Stepper. Do not attach any additional devices to the holder assembly.



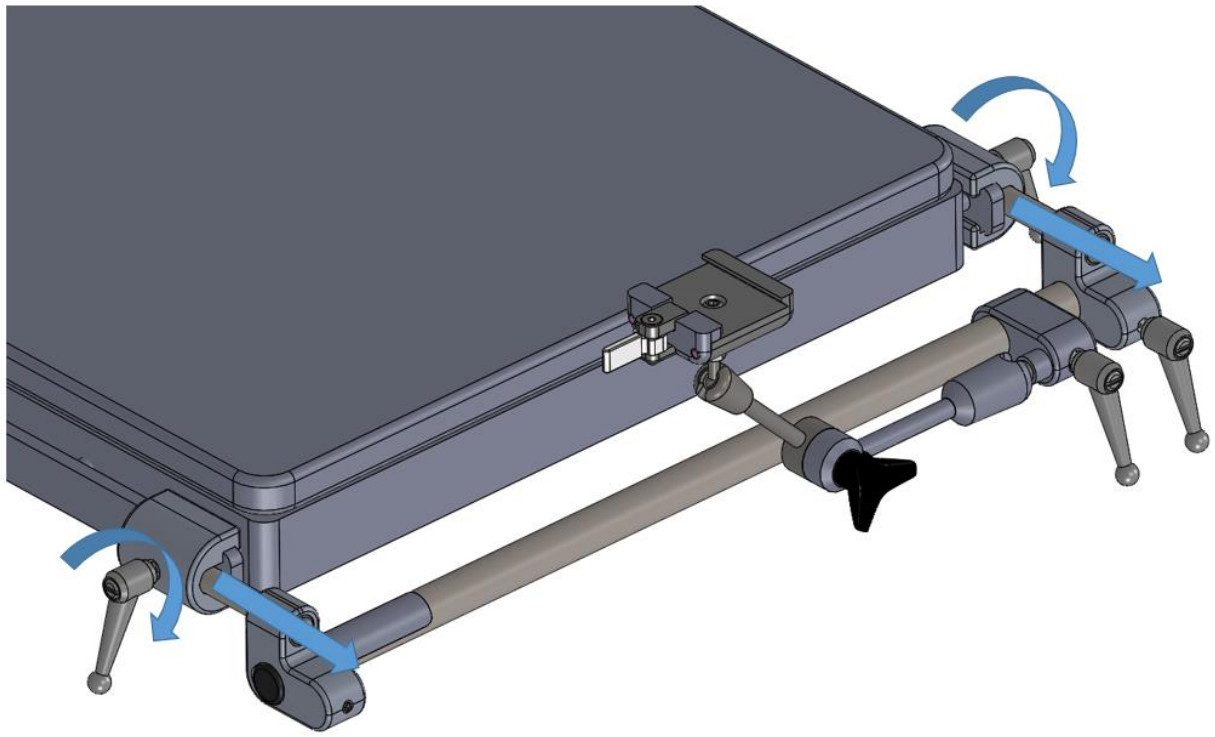
The hand knob releases all 3 joints of the articulated arm.

Before release, be ready to hold up the Stepper. After the articulated arm adjusted, tighten hand knob properly. A loose hand knob can cause the joints to drift.



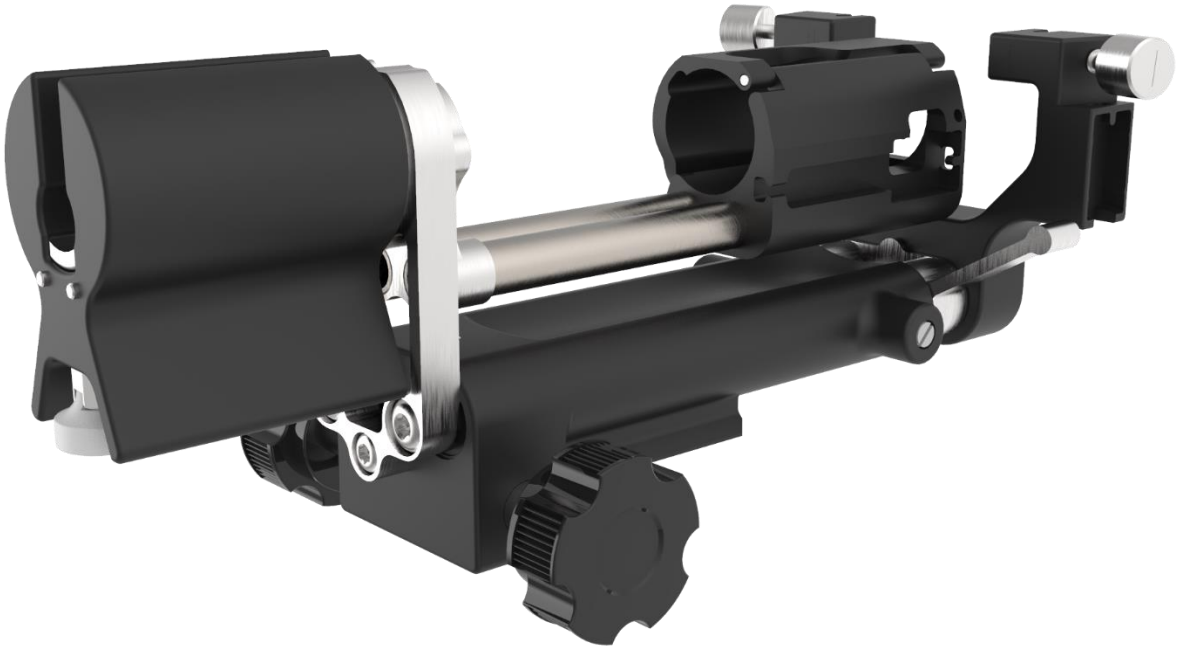
Do not use the Stepper arm if it feels loose or unsteady after installation and adjustment.

STEPPER ARM REMOVAL

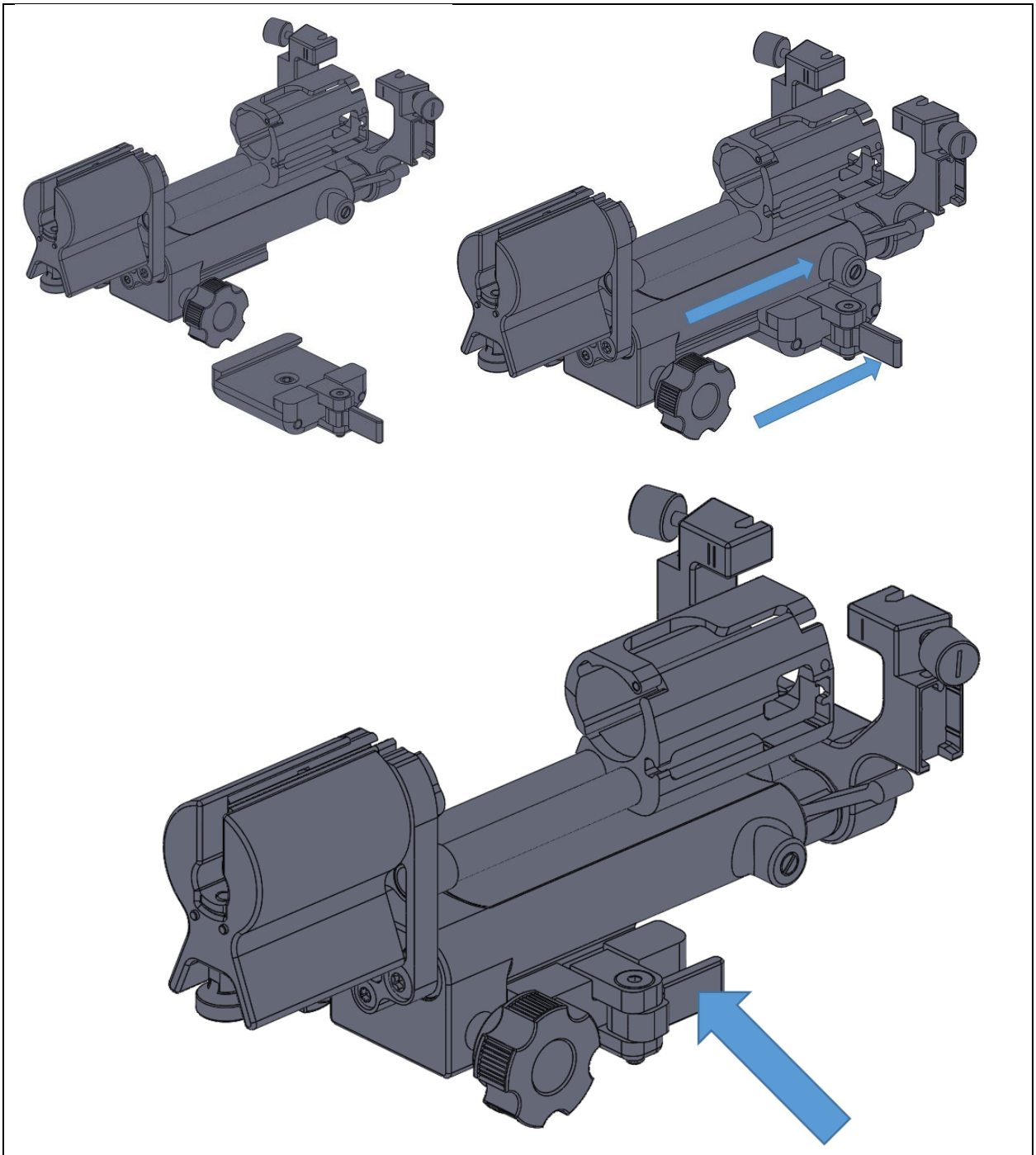


Open the clamp handles and remove the clamps from the table support bars.

14.2 Stepper



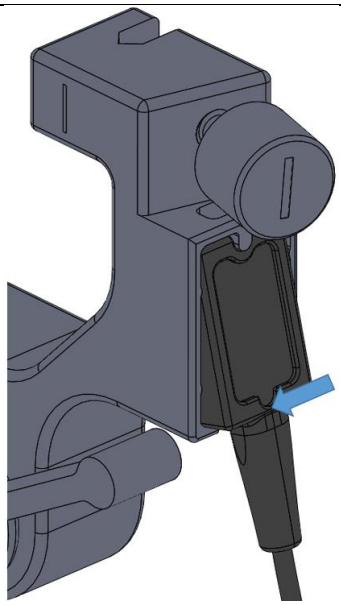
14.2.1 Stepper Installation to the Arm

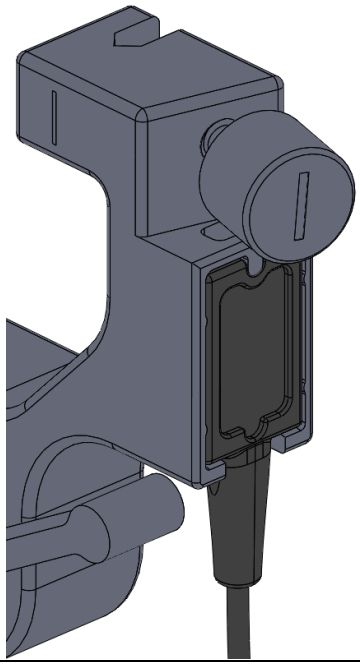


Slide the Stepper in the arm mount and close the lever.

Close the lever forward so it doesn't interfere with the Stepper

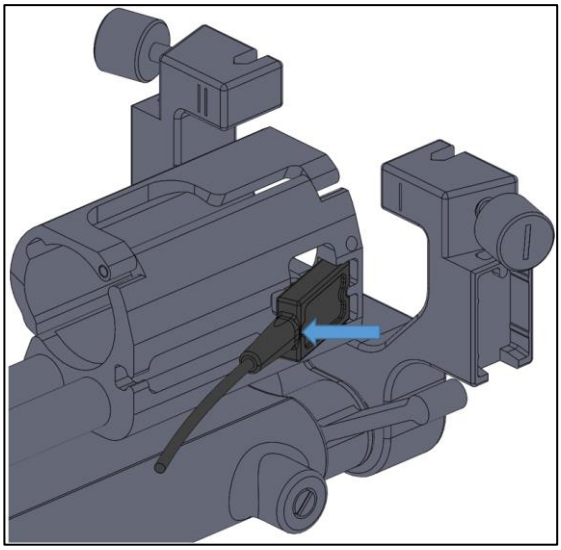
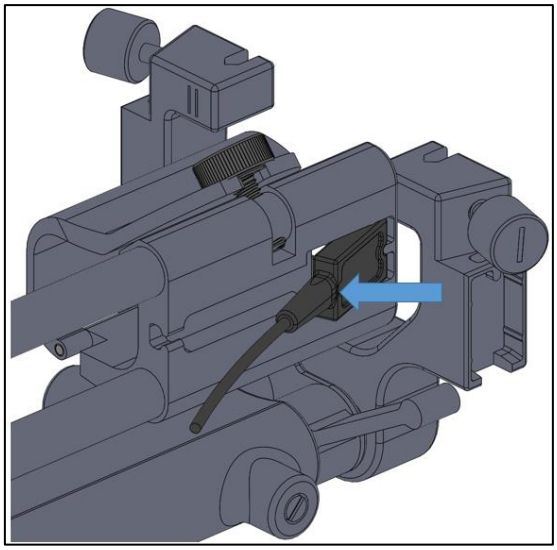
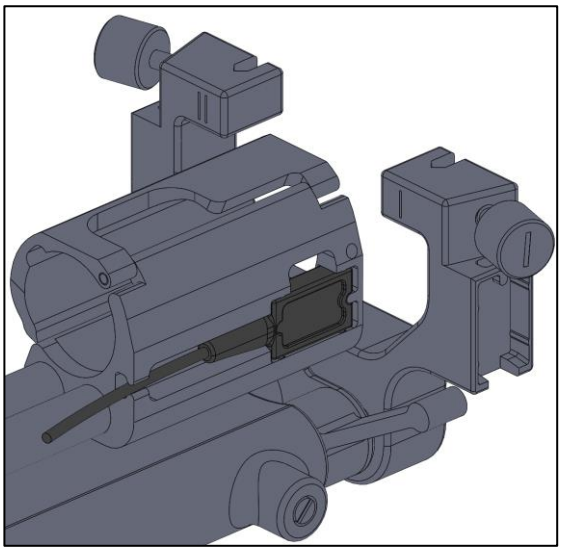
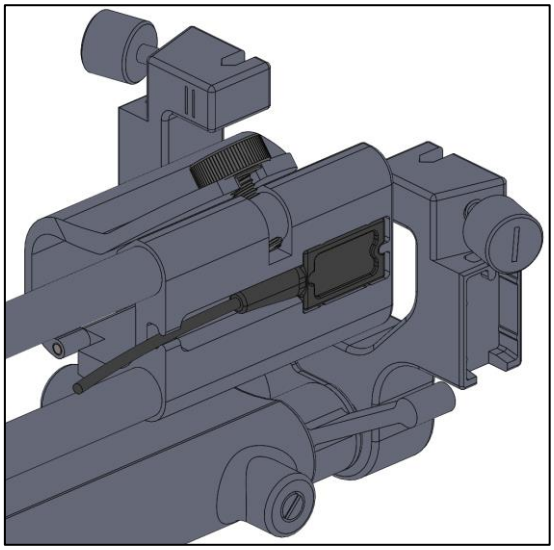
14.2.1.1 Probe, Grid and EM Sensor Installation





Push EM sensor on place and ensure that it is pushed down properly.

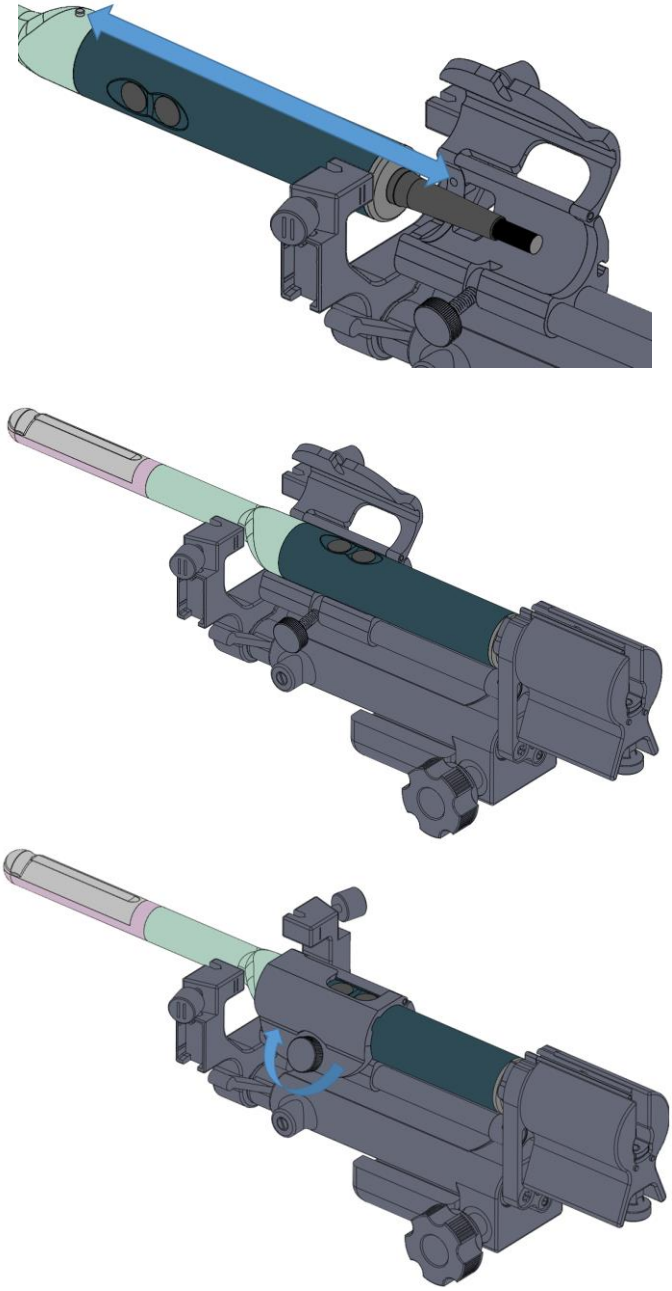
Improper mounting of EM sensor to the Stepper result in inaccurate tracking of the grid compromising the accuracy of the procedure.

BK 8848 & E14CL4B	HITACHI C41L47RP
	
	

Push EM sensor on place and ensure that it is pushed down properly.

Improper mounting of EM sensor to the Stepper result in inaccurate tracking of the probe compromising the accuracy of the procedure.

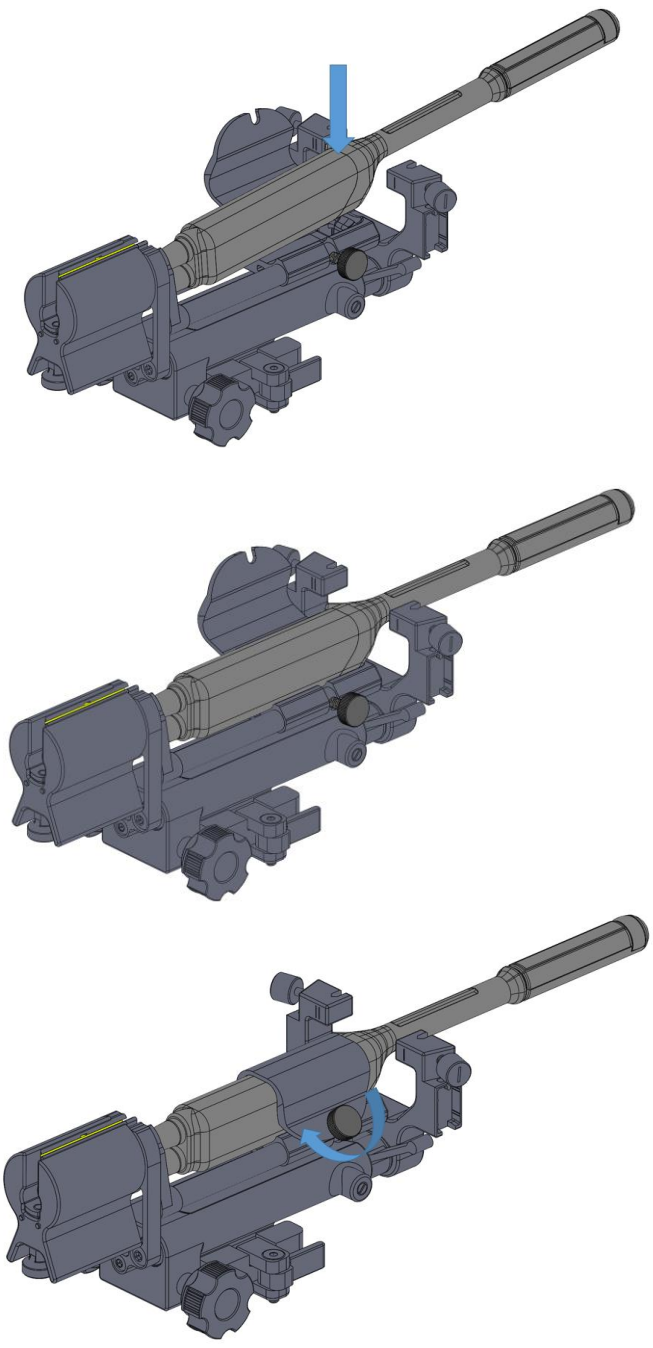
14.2.1.1.1 BK 8848 & E14CL4B



Slide the probe in place and match the reference pin into the holder hole.
Close the clamp and tighten thumbscrew.

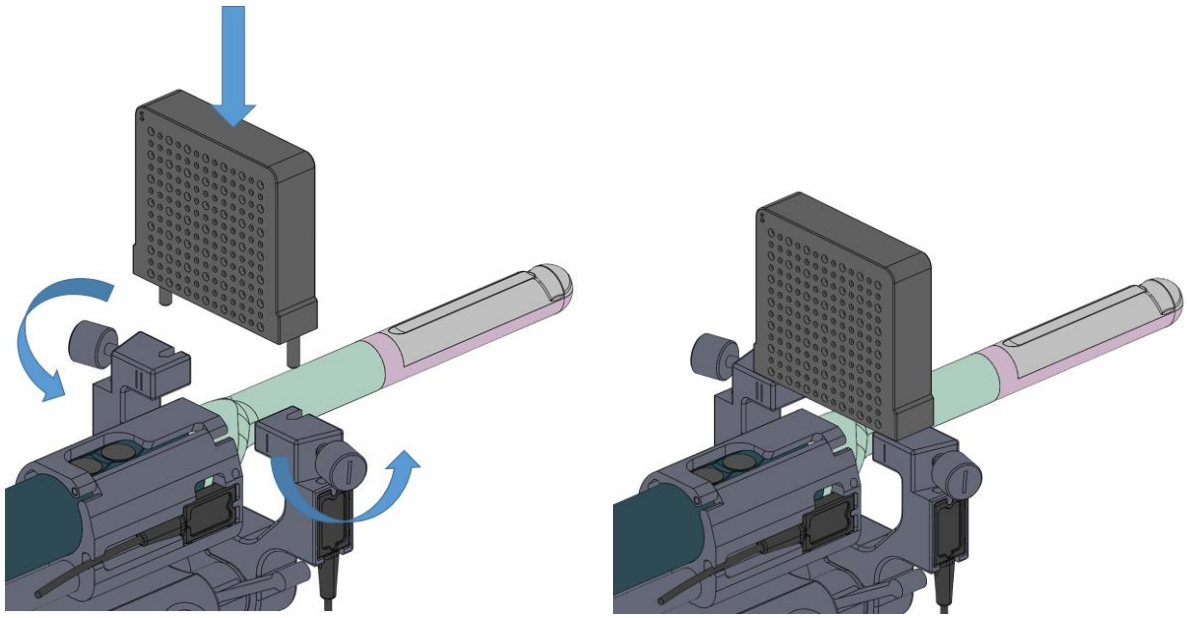
Improper mounting of the probe to the Stepper could result in inaccurate tracking of the probe, compromising the accuracy of the procedure.

14.2.1.1.2 HITACHI C41L47RP



Slide the probe in place and close the clamp and tighten thumbscrew.

Improper mounting of the probe to the Stepper could result in inaccurate tracking of the probe, compromising the accuracy of the procedure.

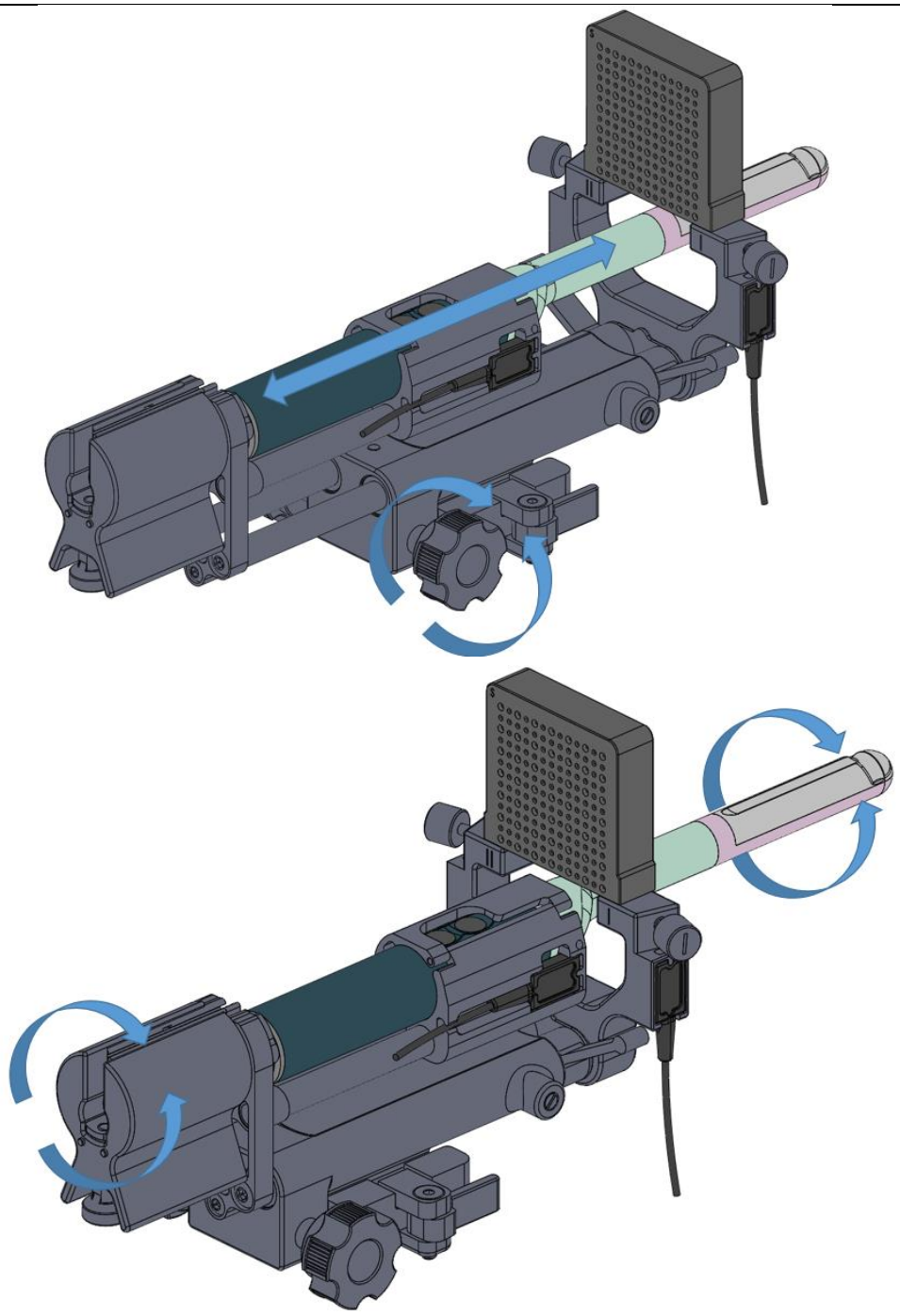


Push grid plate down and tighten thumbscrews.

Ensure that grid plate is pushed properly down. Note that right side screw is left-hand threaded and works opposite direction than usually.

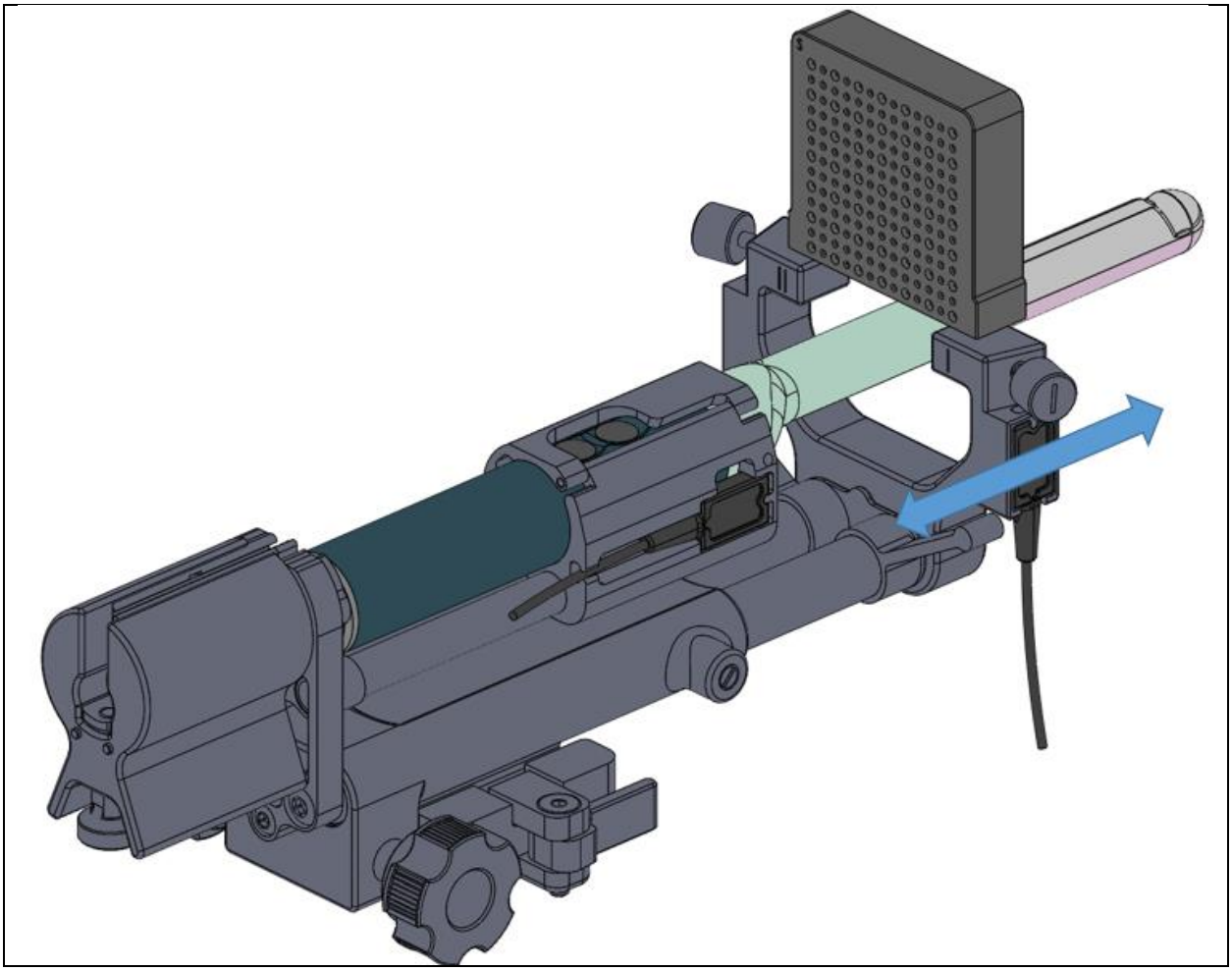
Improper mounting of the grid to the Stepper results in inaccurate tracking of the grid, compromising the accuracy of the procedure.

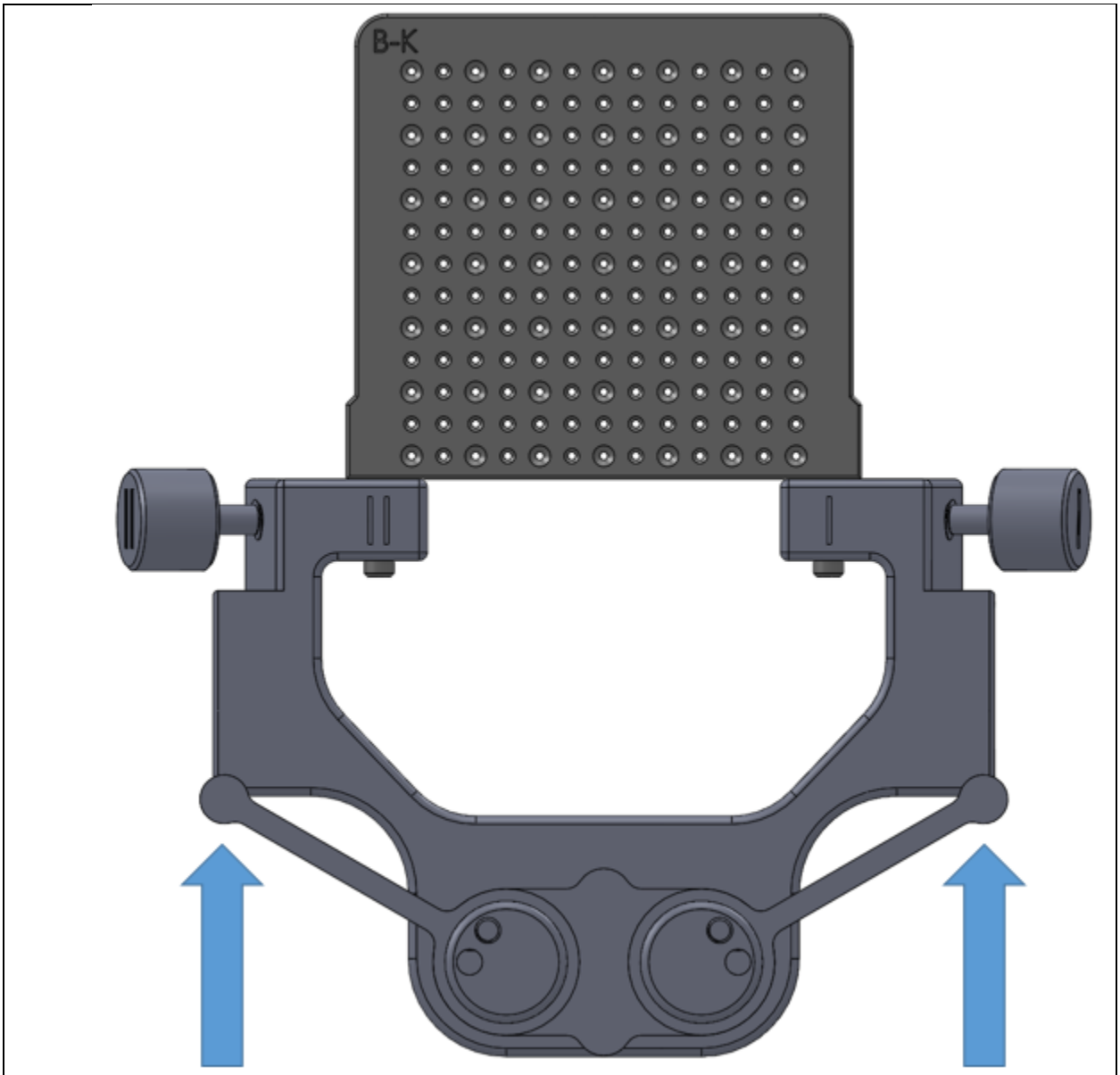
14.2.1.2 Probe Movements



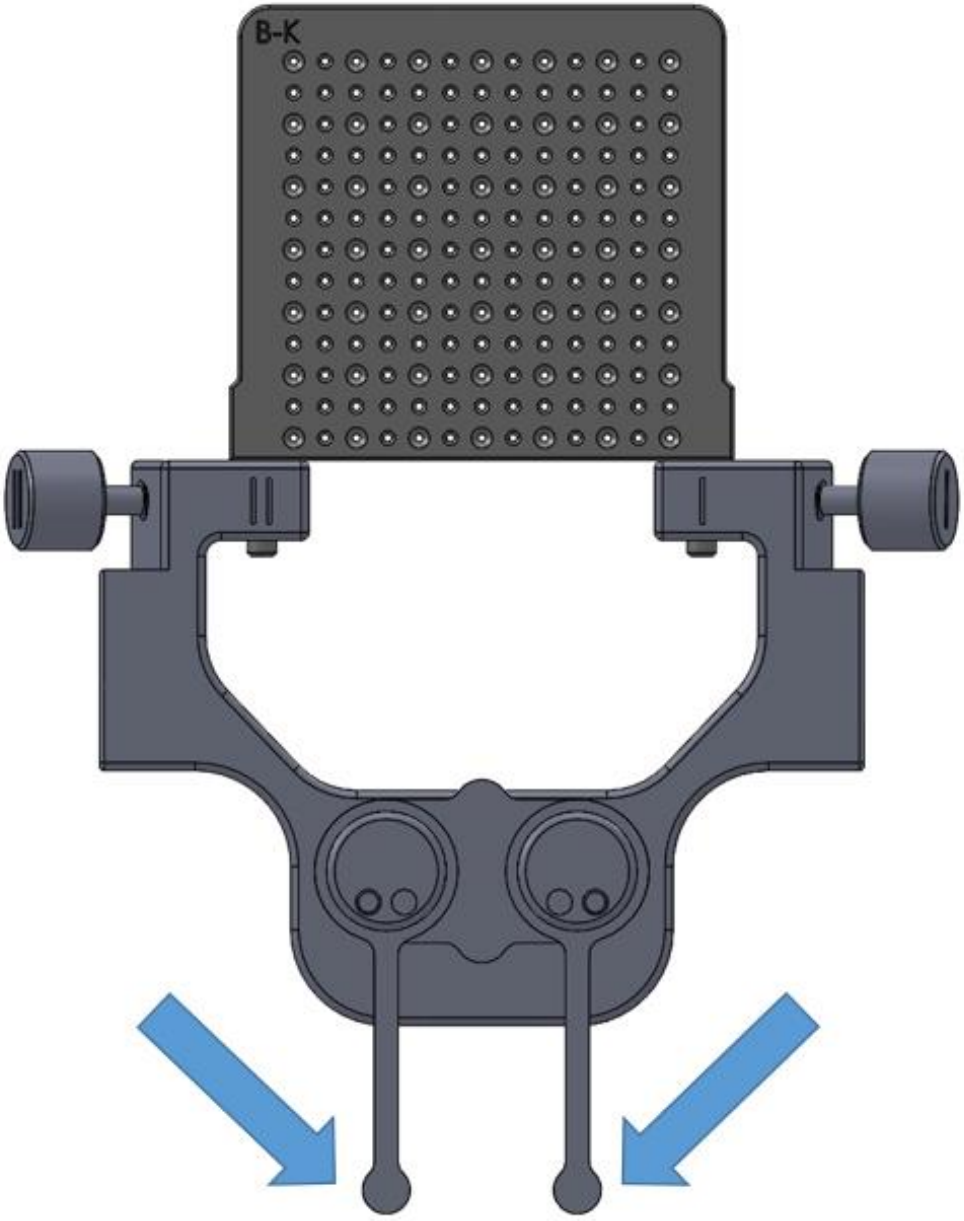
The opening on the rotation handle may create a pinching point hazard. Use the handle with caution.

14.2.1.3 Grid Plate Linear and Micro Movement



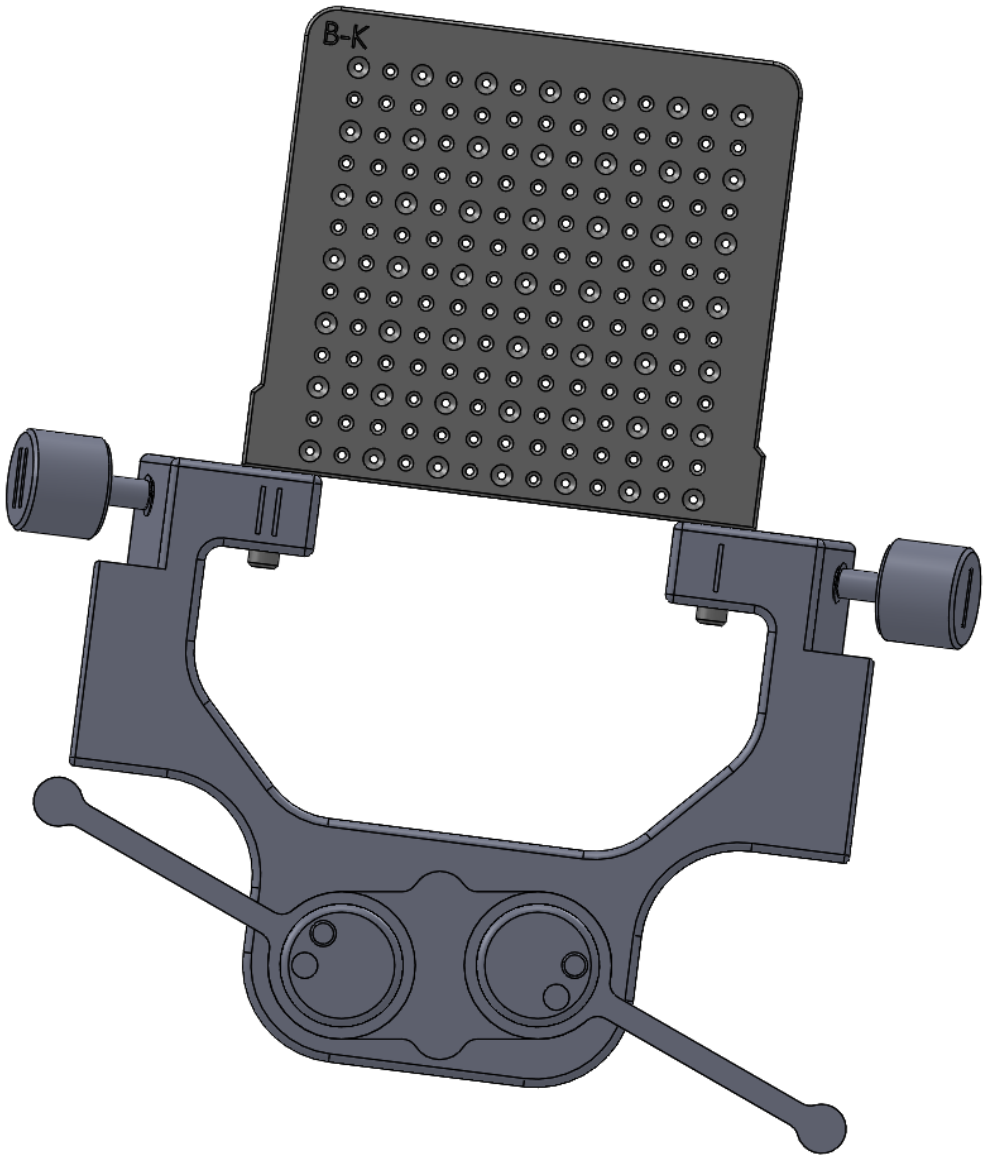


Before the procedure, lift both levers to the highest position. This is the highest position where the grid plate can be and it is centralized.



When the levers are pushed down, grid plate travels vertically down.

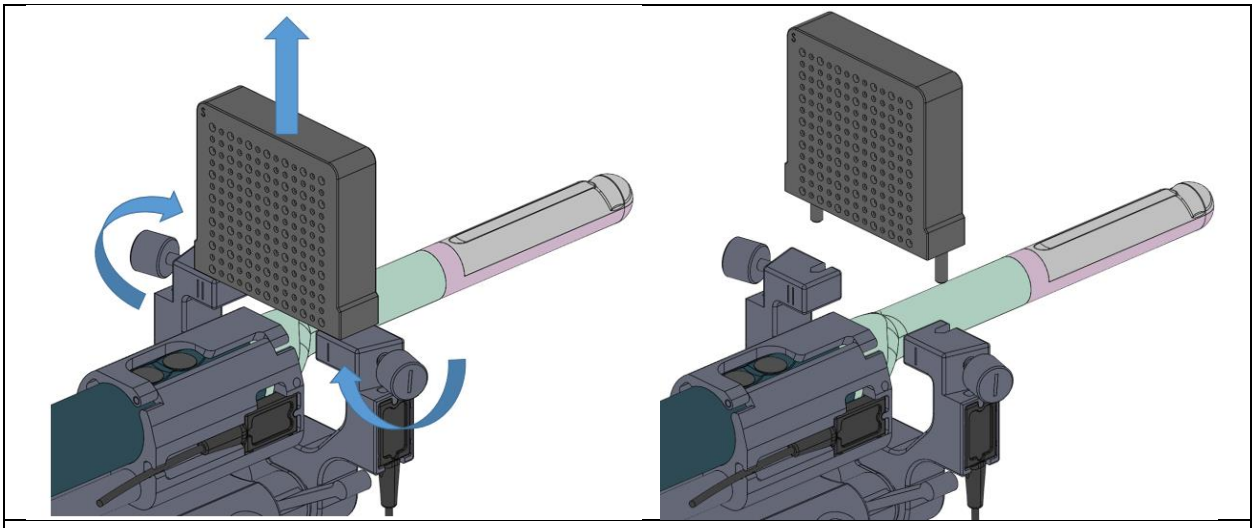
The grid plate can go lower than the ultrasound probe and interference is possible. Don't force the grid plate down, if it touches the probe. This can cause tracking inaccuracy.



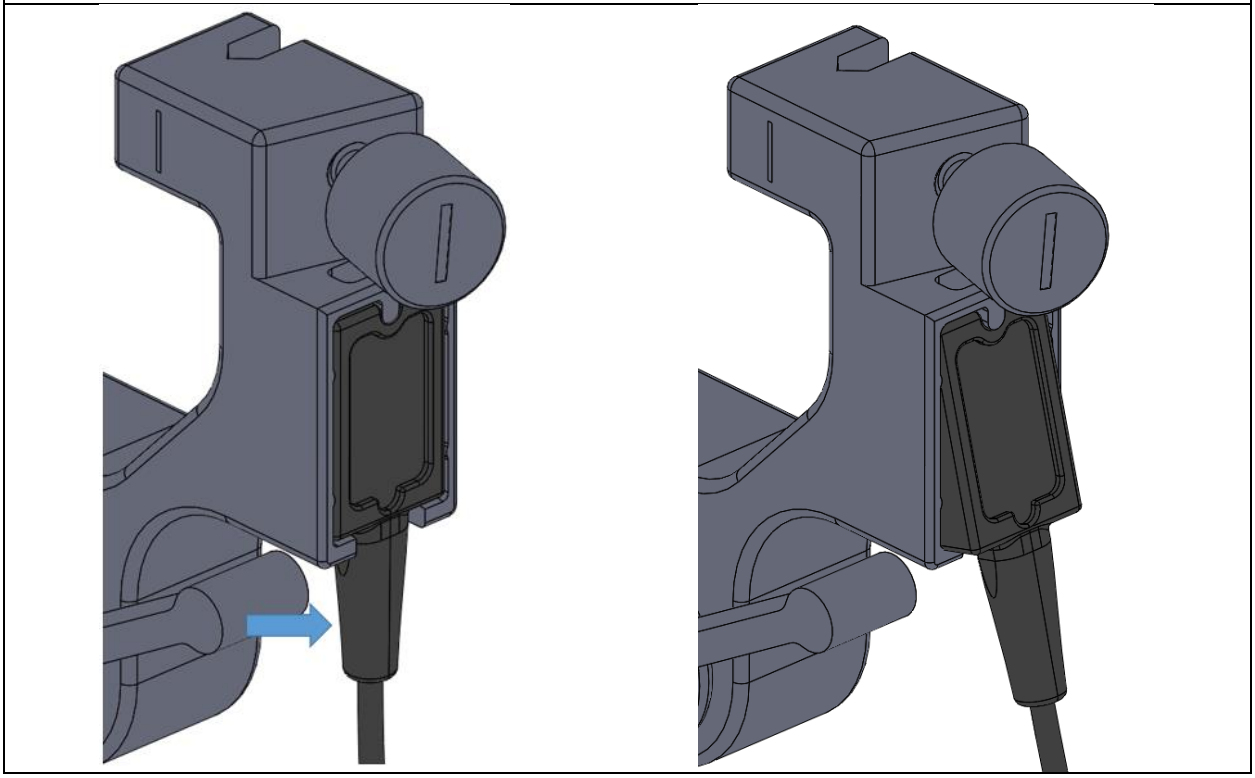
Grid plate horizontal movement is achieved by moving just one lever when other one remains stationary.

The Grid plate can always be centralized by lifting both levers up.

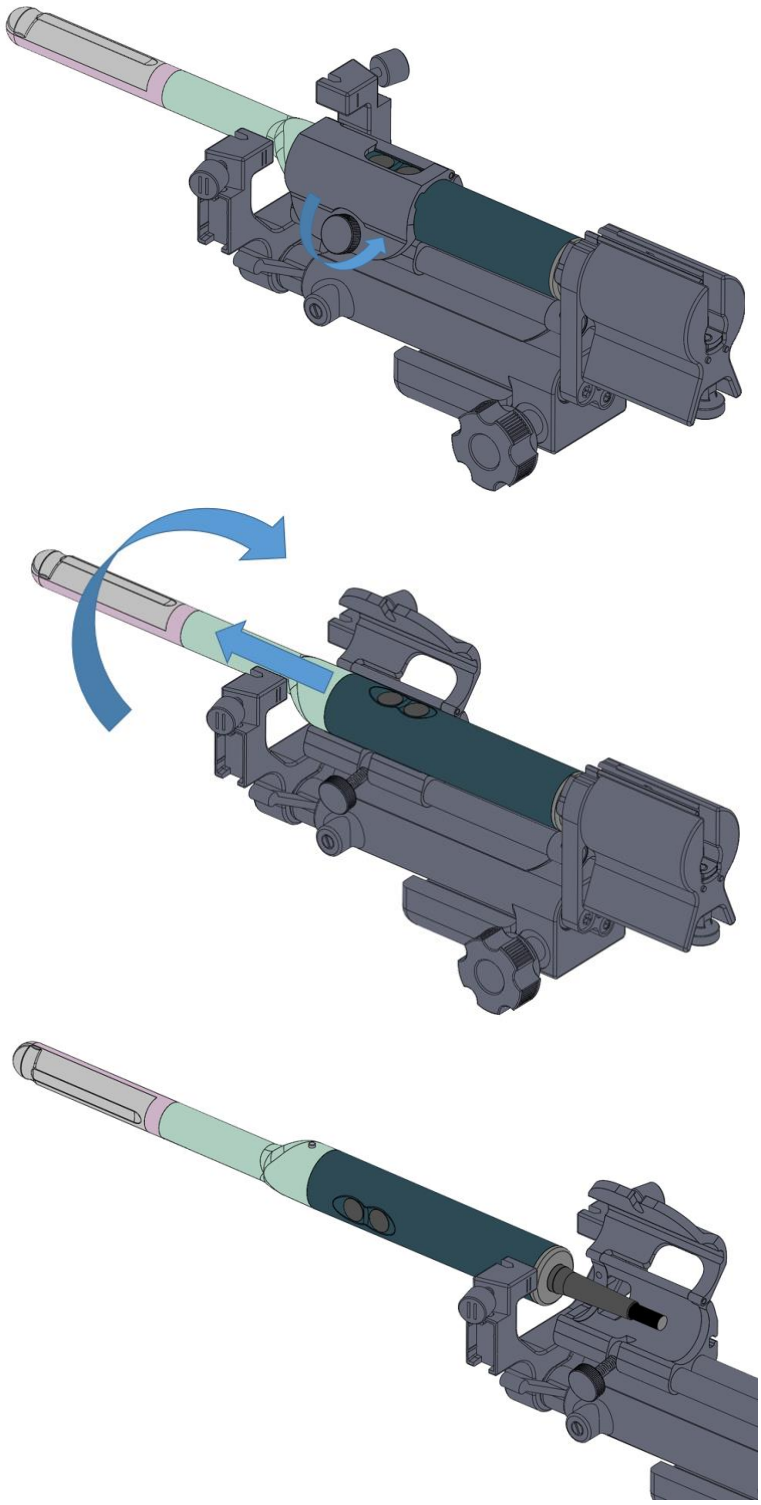
14.2.1.4 Probe, Grid and EM Sensor Removal



Open the knobs and pull the grid plate out.

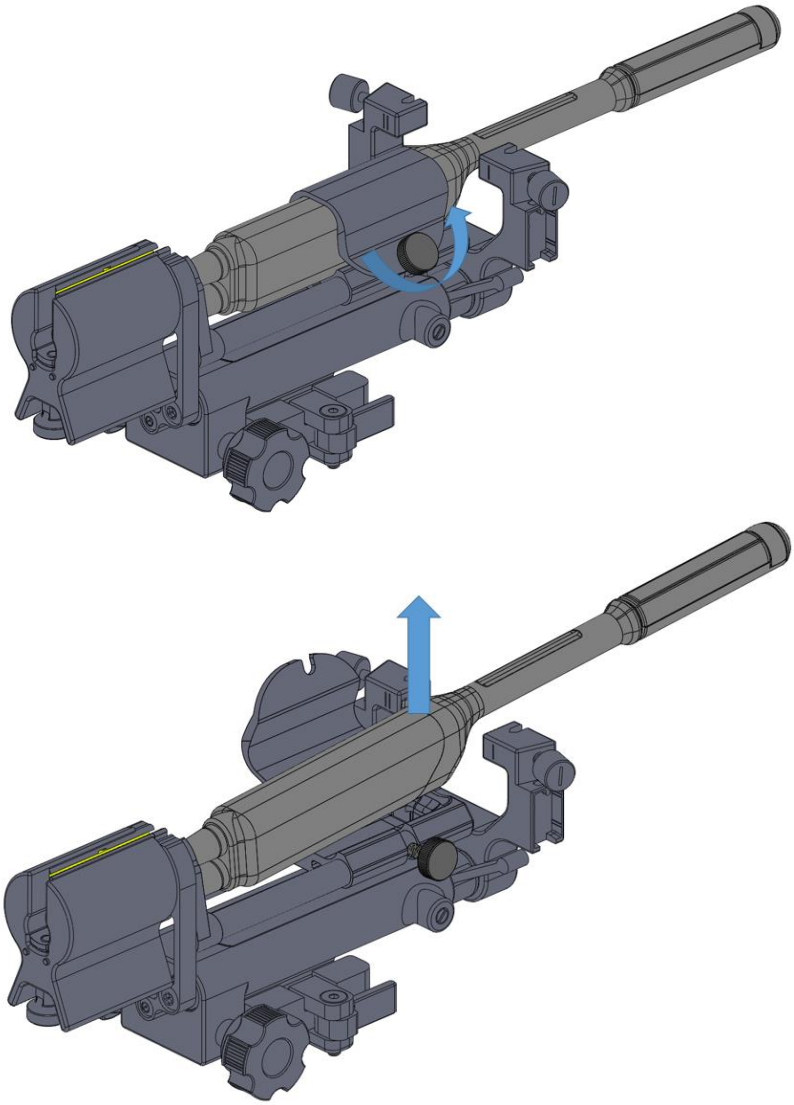


14.2.1.4.1 BK 8848 & E14CL4b

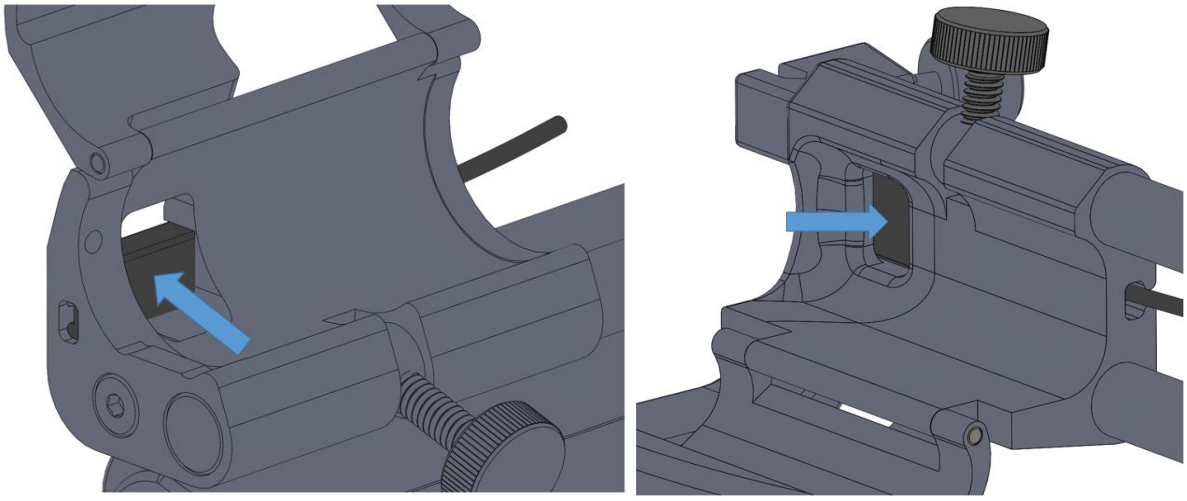


Open the clamp screw and lift the clamp. Lift the probe and pull it out.

14.2.1.4.2 HITACHI C41L47RP



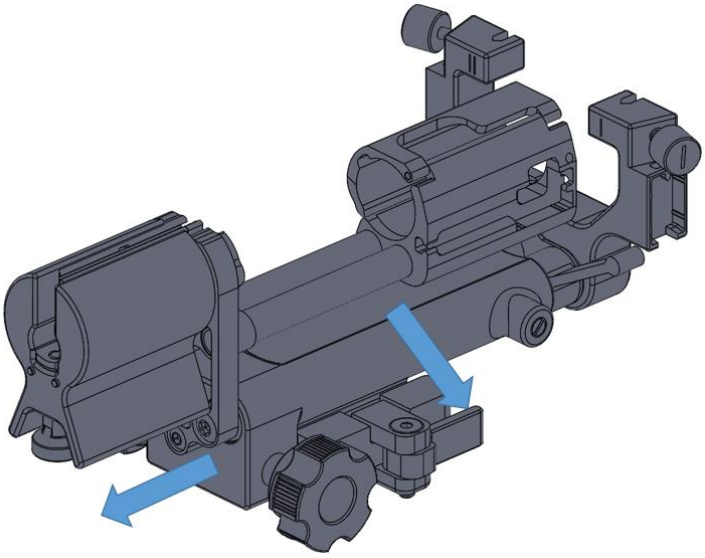
Open the clamp screw and lift the clamp. Lift the probe and pull it out.



Push the EM sensor out from the opening.

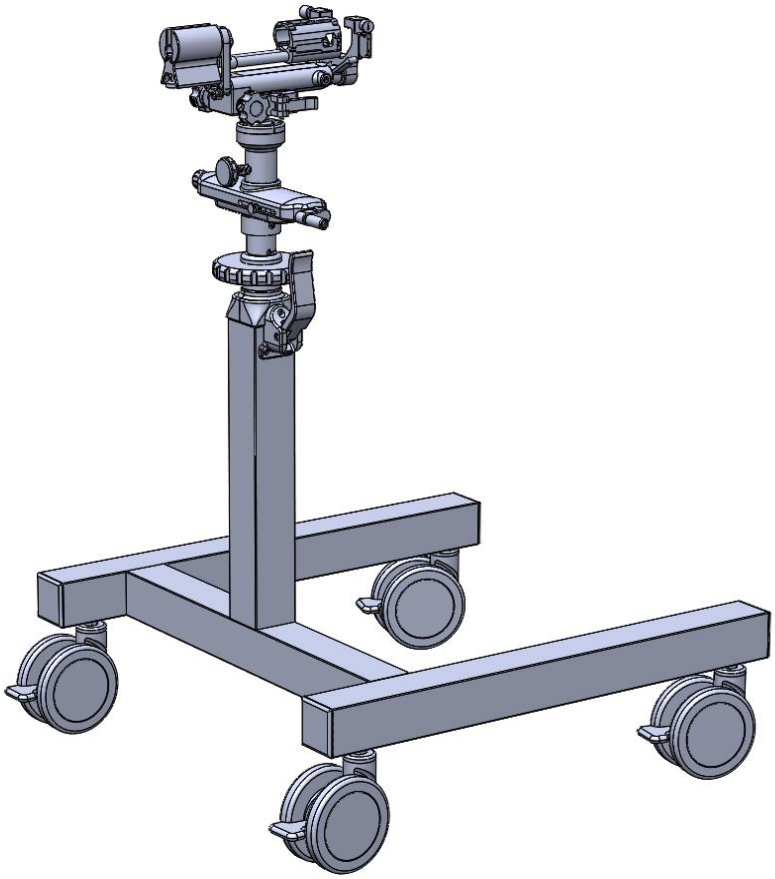
Don’t pull the EM sensor out from the cable.

14.2.1.5 Stepper Removal

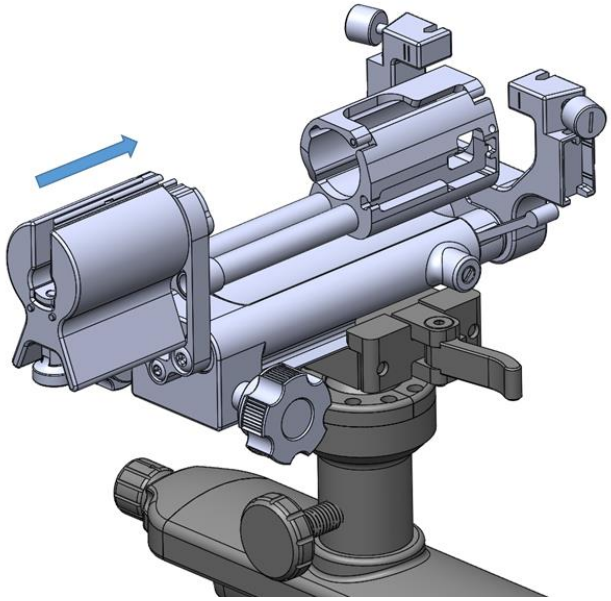


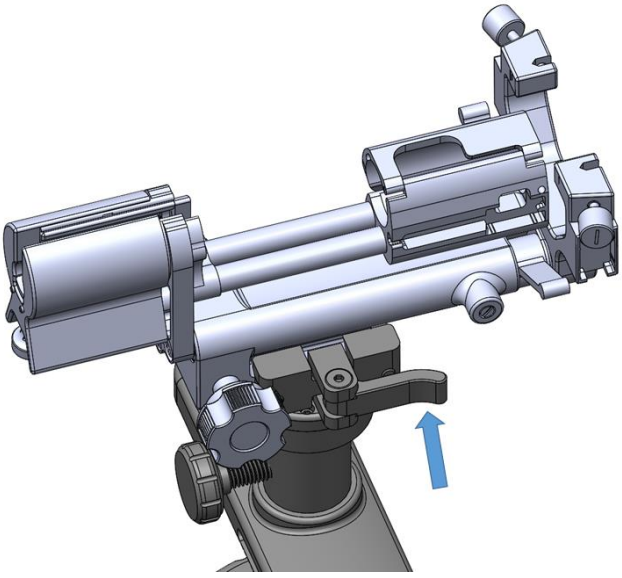
Open the lever and pull Stepper out.

14.3 Stepper Stand



14.3.1 Stand Movements



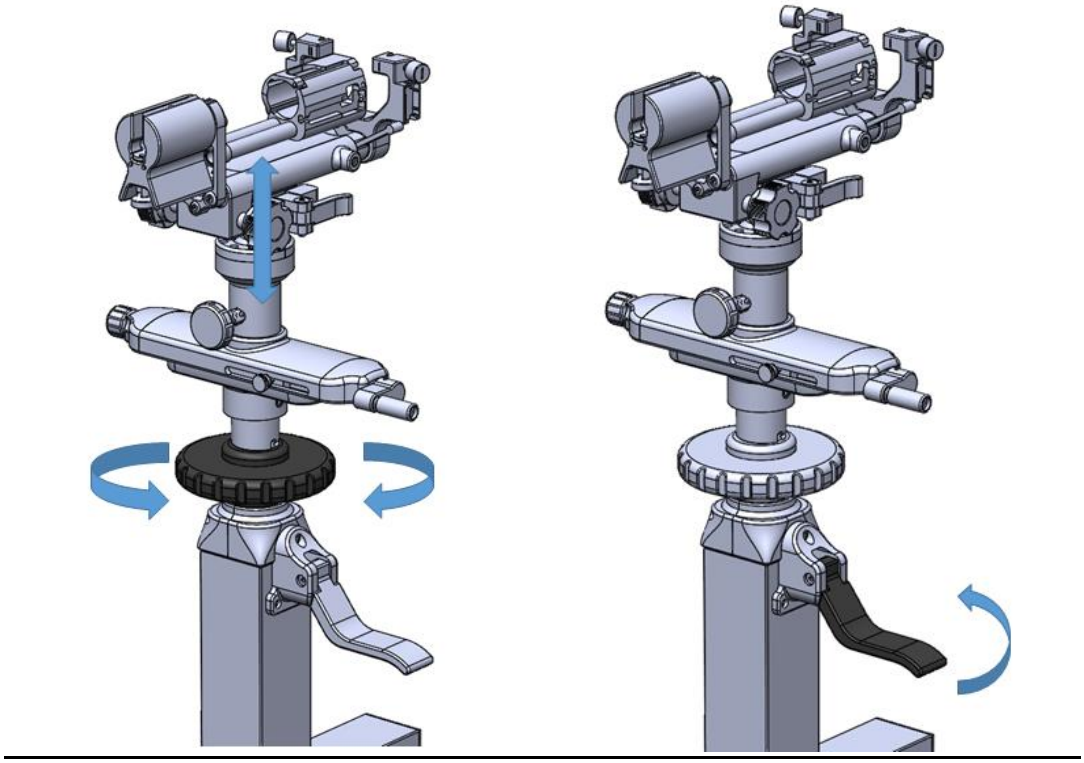


Slide the Stepper in the arm mount and close the lever.

Close the lever forward so it doesn't interfere with the Stepper

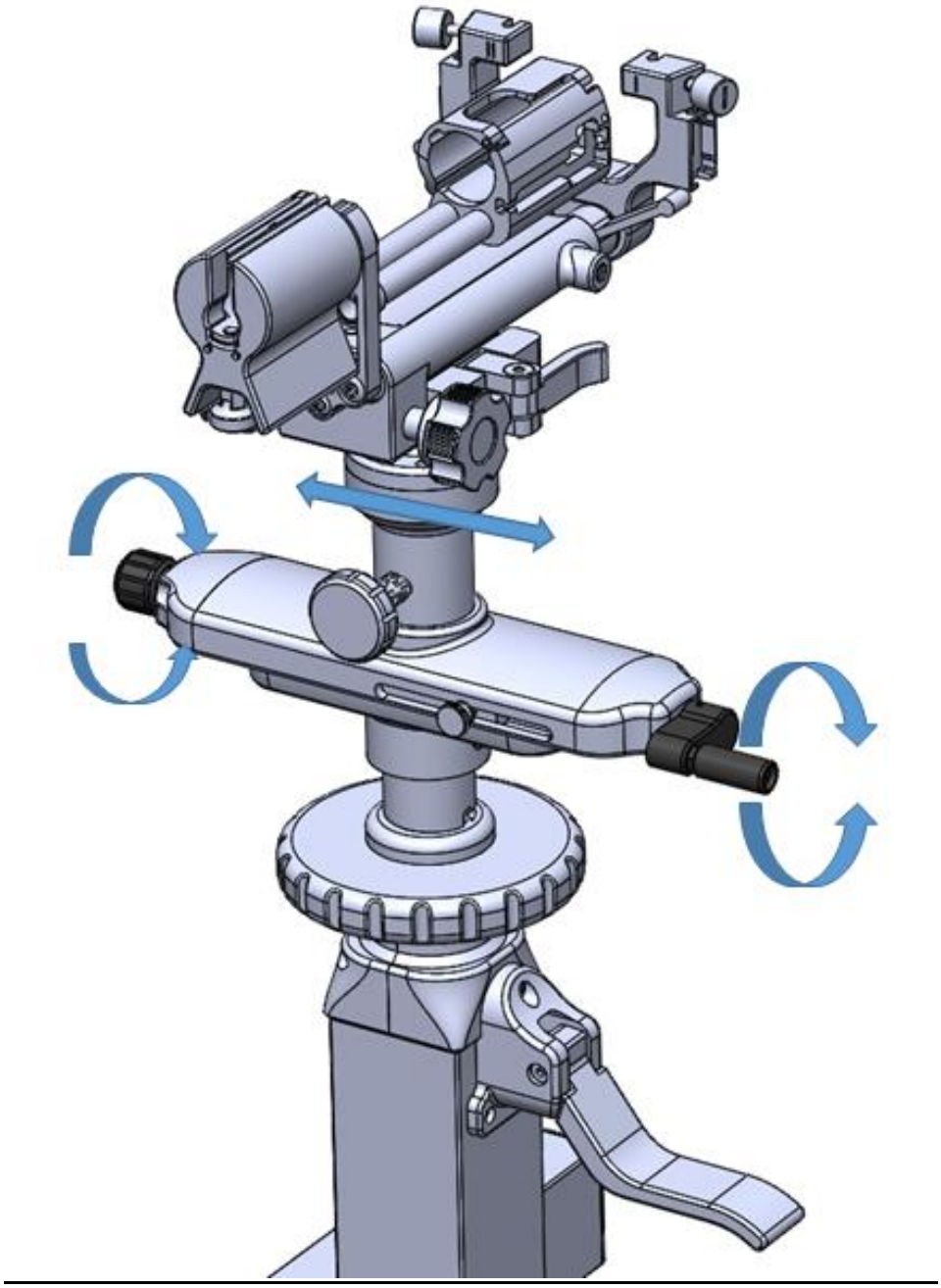
14.3.2 Stand Adjustments

Gross Vertical



The Stand allows 10” gross vertical adjustment. Set the adjustment to middle position before the procedure

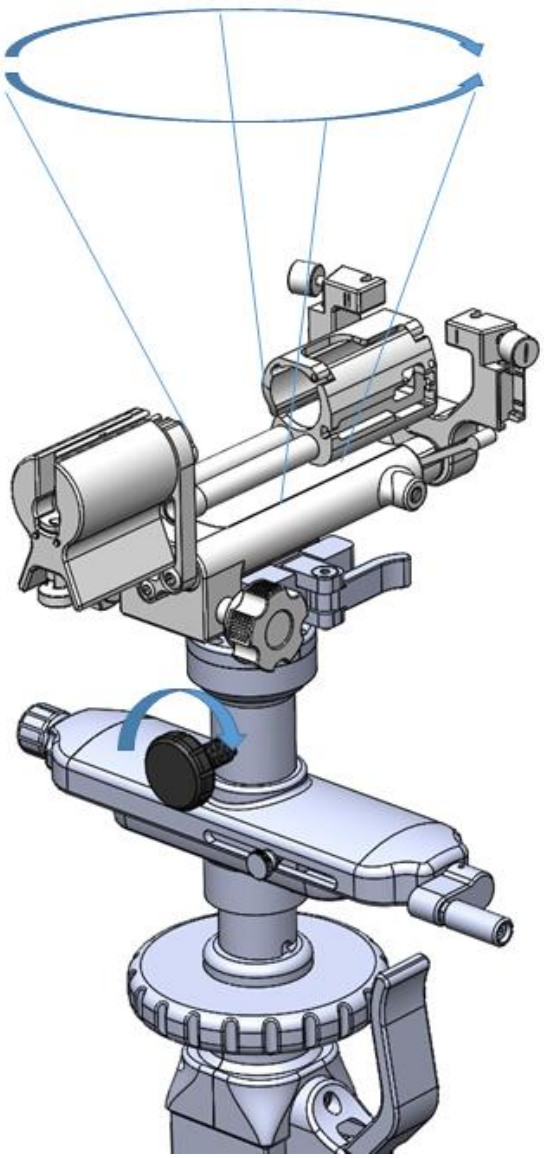
Gross Left/Right



Gross Stepper/Stand Positioning

Relock ALL castors after any positioning adjustment.

Universal



Retighten knob after adjustment to prevent Stepper movement.

15. Symbols

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

Table 14: Symbols

	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
	Electronic instructions for use
	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)
	Fuse
	The WEEE mark, indicating separate collection for WEEE- Waste of electrical and electronic equipment.
	Intertek certification Mark
	Unique Device Identifier of the device
	To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g., in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment

Table 14: Symbols

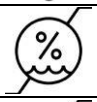
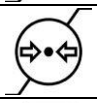
	General Caution (see About the Instructions for Use 1.1) Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Consult Instructions for Use
 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
	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 -
	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

Table 14: Symbols

	Field Generator Connection
	General mandatory action
	Refer to instruction manual booklet
	General Warning (see About the Instructions for Use 1.1)
	This Way Up
	Do Not Stack
	To indicate that the contents of the transport package are fragile and the package shall be handled with care.
	To indicate that the transport package shall 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

16. Identification and Publication Details

Published by Philips Corporation

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Invivo Corporation
3545 SW 47th Ave
Gainesville, FL 32608
U.S.A.

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