



CLEARPOINT®  
NEURO

**ClearPoint Array™ 1.1**  
**User's Guide**



Caution: U.S. federal law restricts this device to sale by, or on the order of, a physician.

The software that is the subject matter of this document is an advisory device and is not designed or intended to substitute for the skill, knowledge or experience of the users of the software.

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## System Overview

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**WARNING:** This user's guide is intended for use only in conjunction with the specific Instructions for Use (IFU) provided with each of the referenced hardware components, as well as physician mentoring and training in the clinical aspects of the procedure. Any other components provided by a third party must only be used in accordance with their own specific IFU.

**PRECAUTION:** The ClearPoint Array™ System can be used in conjunction with MR Conditional, but not MR Unsafe DBS Leads or DBS Leads for which MR Testing was not performed. Placement of MR Conditional deep brain stimulation (DBS) electrodes using the ClearPoint Array™ System should be performed in accordance with the instructions for use for such MR Conditional DBS electrodes. The user should carefully review the instructions for use for such MR Conditional DBS electrodes prior to undertaking a procedure with the ClearPoint Array™ System. Scanning a patient using conditions other than those given in the DBS electrode instructions for use may cause severe injury or death.

**NOTE:** During installation of the ClearPoint Array™ System, system accuracy testing will be performed by a trained ClearPoint Neuro Specialist using a calibrated phantom. A minimum of two device placements (ClearPoint Stylet), 1 left side and 1 right side will be performed. The System Installation test shall demonstrate that it can position the tip of the ClearPoint Stylet within 2.0mm of the target. Upon completion of the System installation the surgeon will be required to acknowledge the System Installation meets the User's requirements.

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## Indications for Use

The ClearPoint Array™ System is intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures within the MRI environment and in conjunction with MR imaging. The ClearPoint Array™ System is intended as an integral part of procedures that have traditionally used stereotactic methodology. These procedures include biopsies, catheter and electrode insertion including deep brain stimulation (DBS) lead placement. The System is intended for use only with 1.5 and 3.0 Tesla MRI scanners and MR Conditional implants and devices. Please consult the [Navigational Accuracy](#)

section of the User's Guide to assess if the accuracy of the system is suitable for your needs.

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## Contraindications

The ClearPoint Array™ System is contraindicated for use with higher than 3.0 Tesla MRI scanners.

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## Security

The ClearPoint Array™ Workstation is a physical, self-contained laptop computer used to display dynamically acquired MR images during a neurological procedure conducted inside an MRI suite. The workstation receives images directly from an MRI scanner through a dedicated network port, using the Digital Imaging and Communications in Medicine (DICOM) Standard. The images received from the MRI scanner are cached on the workstation's local file system for purposes of procedure recovery and post-operative review but are not exported to external third-party systems. The workstation does not support any external service communications (e.g. query/retrieve) and has no requirements for external services (e.g. internet connectivity). The workstation only requires a physical networked connection with the MRI scanner used during the neurological procedure.

### Security Features

The ClearPoint Array™ Workstation has been pre-configured with the following security settings:

- Real-time antivirus and software threat protection. The workstation uses Windows Security to continually scan and monitor for malicious software, viruses and other potential security threats. In addition, Windows Security has been configured to automatically block malicious software and other potential threats upon immediate detection. In cases where potentially malicious software or viruses are detected, Windows Security will notify the end user in all instances.
- Firewall and network protection. The workstation uses Windows Defender Firewall to monitor and block potentially harmful network data packets from being accepted on the workstation. Notifications are provided to the end user in cases where potentially harmful network traffic is received.

- Real-time anti-malware protection. The workstation utilizes Microsoft Defender SmartScreen to determine if any software applications being installed originated from a potentially malicious source. It also prevents navigating to any phishing or malicious websites. End users will be notified in all instances when software is downloaded or run which may have originated from a potentially malicious source.
- Controlled folder access. The workstation uses Windows Security to help protect the ClearPoint Array™ procedure data folder from malicious applications and threats, like ransomware. Only the ClearPoint Array™ software has been configured as a trusted software application on the workstation, thus, preventing all other software applications from accessing the procedure data folder.
- Automatic scanning of removable devices. The workstation uses Windows Defender to automatically scan any removable media (e.g. USB flash drives, external hard drives) for viruses and other malicious software upon being connected to the computer. The end user will be notified if any removable media is potentially malicious in nature upon connecting the device to the computer.
- User controlled access. The workstation has been configured with a limited set of user accounts in order to prevent unauthorized access. Strict user account policies, such as strong user password complexity requirements and automatic password renewals have been configured using Microsoft Windows User Management to further control user access.
- Automatic screen lock. The workstation has been configured to automatically lock its screen after a period of inactivity using the Windows Desktop. This is done to prevent any potential unintended user access on the workstation. End users must re-enter user authentication details after the allotted time period in order to continue using the workstation.
- Audit controls. The workstation offers the following auditing capabilities:
  - 1) User account / security level logging is performed at the operating system level using Windows Event Logging.
  - 2) Data loading / access logging is recorded in the ClearPoint Array™ application log file (see [Using the Application Log Window Pg. 70](#)).
  - 3) Application-level logging for startup / shutdown events, image transfers, image processing tasks and other application-related events is recorded in the ClearPoint Array™ application log file (see [Using the Application Log Window Pg. 70](#)).

## Security Configurations

In order to prepare the ClearPoint™ Array Workstation for use in your healthcare institution's environment, please make note of the following security configurations:

- The ClearPoint™ Array software has been installed on the workstation, which runs the Windows 10 Pro 64-bit operating system. No other operating systems may be installed on the workstation.
- The workstation must be connected with an MRI scanner using a secure, private network connection. A static IP address must be assigned to the workstation so that the MRI scanner may be configured to recognize the IP address of the workstation.
- Communication between the MRI scanner and the ClearPoint™ Array Workstation is achieved using the DICOM Standard. The MRI scanner must be configured to recognize the IP address, DICOM application entity title (AE Title) and TCP/IP port number of the workstation (see [Interoperation with MRI Scanners Pg. 28](#)). Similarly, the workstation should be configured to specify its AE Title and TCP/IP port number (see [Configuring the DICOM Connectivity Settings Pg. 50](#)).
- The following DICOM services are supported by the ClearPoint™ Array Workstation (see DICOM Conformance Statement for additional details):
  - [STORAGE-SCP](#): This service allows images to be transferred from the networked MRI scanner to the workstation. The scanner is configured to push images to the workstation throughout the course of an intraoperative procedure.
  - [ECHO-SCP](#): This service allows the workstation to receive “ping” messages from the MRI scanner only for purposes of verifying network connectivity and proper DICOM interoperability.
  - [ECHO-SCU](#): This service allows the workstation to initiate “ping” messages to the MRI scanner for purposes of verifying network connectivity and proper DICOM interoperability (see [Configuring the DICOM Connectivity Settings Pg. 50](#)).
- All DICOM communications are transmitted on a single network port (port number: 4467) configured for the workstation (see [Configuring the DICOM Connectivity Settings Pg. 50](#)). No other network ports are required for operation of the workstation.
- The workstation's Windows Defender has been set up to provide firewall and network protection, by monitoring incoming data packets through the configured TCP/IP network port. If any malicious traffic is detected, Windows Defender will provide prominent notifications with critical information



regarding the incoming data, while also automatically blocking any malicious software from gaining access to the workstation.

- Prior to deployment, the latest Windows Updates have been installed on the ClearPoint Array™ Workstation.
- The workstation's Windows Defender has been configured to block all other software applications other than those produced by ClearPoint Neuro, Incorporated. Specifically, the software application executable has been added to the list of applications allowed to run on the workstation. If any other software applications are attempted to be run on the workstation, Windows Defender will prompt prior to allowing execution of the program.
- Controlled folder access has been turned on for the data folder where the procedure / session information is stored on the workstation (C:\ProgramData\ClearPointArray).
- The Local Group Policy for the workstation has been modified to scan for any removable drives that are connected to the computer.
- A Screen Saver Lock for the workstation has been configured after 30 minutes of user inactivity. Once this time period lapses, the user must re-enter their credentials in order to gain access to the workstation again.
- The Local Security Policy for the workstation has been modified to have the following values set for each user account created on the system:
  - Enforce password history: 1 password remembered
  - Maximum password age: 120 days
  - Minimum password age: 0 days
  - Minimum password length: 7 characters
  - Password must meet complexity requirements: Enabled
  - Store passwords using reversible encryption: Disabled

## Backup and Restore Features

The ClearPoint Array™ Workstation backs up all of the data relevant for an intraoperative procedure in a dedicated folder on the computer's local file system. Each intraoperative procedure folder is named based on the date and time interval for which the session corresponding to the procedure was started (see [Starting a New Session Pg. 55](#)). The following data is stored within each procedure file folder:

- Images. All DICOM images received / loaded onto the workstation during the procedure.

- Log File. A single file which stores information regarding software-related events that occur throughout the course of an intraoperative procedure. The following information is captured in the application log file:
  - User audit logging
  - Workflow step transitions
  - User-defined annotation coordinates
  - Image acquisitions received / loaded during the case
  - Segmentation results
  - Device placement errors
  - Any warning of informational messages presented during the case
  - Any critical software errors or failures encountered during the case
  
- Procedure Reports. All saved procedure reports, named by file-system creation time (see [Using the Procedure Report Window Pg. 65](#)).
  
- Screen Captures. Any patient anonymized screen captures taken throughout the course of the intraoperative procedure (see [Screen Capture Tool Pg. 97](#)).
  
- Session Files. A single file associated with the current software session, plus one back-up state file, which contains contents relevant to the software application's state at the time that the session save operation was last performed.

In the event that the workstation has been unexpectedly shut down in the middle of an intraoperative procedure, the backed-up session data can be used to restore the state of the software application at the point when the shut-down occurred. Additionally, if post-operative review and/or analysis of a given procedure is desired, the backed-up session can be retained for later use. Alternatively, the session data may be immediately deleted following the procedure using the Session List Window (see [Using the Session List Window Pg. 62](#)) if post-operative analysis is not required.

In instances where the configuration of the workstation has been maliciously tampered with, all backed-up session data can be exported from the workstation and retained on your institution's physical premises. The workstation may then be returned to ClearPoint Neuro, Incorporated where it will have its configuration restored to its original state at the initial time of deployment. Upon receiving the laptop with restored configuration, the backed-up session data may be imported back onto the workstation.

## Security Operating Instructions

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**Caution:** The ClearPoint Array™ Workstation has been pre-configured with important security settings, including real-time virus/malware detection, user access control, network protection, and system auditing. Do not disable or alter the configurations for any of these security settings.

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To ensure secure operation of the ClearPoint Array™ Workstation:

- Do not disable or alter configuration settings for the Windows Defender Security Center. It has been configured to ensure that the workstation is actively protected from malware, viruses, and other security threats.
- Do not install any other software on the workstation, unless it has been distributed by ClearPoint Neuro, Incorporated.
- Do not access the internet from the workstation. Only connect the workstation to a secure, private TCP/IP connection on the hospital network in order to receive images from the MRI Scanner.
- Do not turn off, disable, or alter any configuration settings for the Windows Defender Firewall. It has been configured to block unauthorized network traffic flowing onto the workstation.
- Restrict user access to the workstation in order to prevent unintended access. Best practices should be used when configuring user password policies, including minimum password lengths, password storage encryption, appropriate password complexities (i.e. “strong passwords”), and frequent password renewal periods. Consult HIPAA guidelines for additional information on the best practices for user management.
- Do not modify or alter any system settings related to locking the workstation via the screen saver. The system has been pre-configured to require a password in order to resume workflow after 30 minutes of inactivity.
- Always install the latest security updates and patches for the workstation’s operating system.
- Consider using Windows Encrypted File System (EFS) to keep protected health information stored on the workstation safe. The workstation’s data folder (*C:\ProgramData\ClearPointArray\sessions*) stores images from the scanner that contains protected health information. It is suggested that this folder be encrypted in order to prevent unauthorized access.
- Only allow ClearPoint Neuro personnel to install the latest updates and patches for the ClearPoint Array™ software. Any software updates will be installed on-site by an employee of ClearPoint Neuro, Incorporated.

- Be cautious when connecting removable media, such as USB drives, to the workstation. The workstation has been configured to also scan removable device for malware and viruses. Do not modify any configuration settings related to the Windows Defender Antivirus.
- Always use the ClearPoint Array™ Software's Session Export (see [Using the Session List Window Pg. 62](#)) functionality when moving surgical procedure data off of the workstation. Exporting a surgical session in this manner ensures that all data is appropriately anonymized so that no protected health information is exported.

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## Procedure Overview

Below is a summary of steps for a ClearPoint Array™ System procedure. These steps are separated into seven sections: preoperative planning, patient preparation, mount point localization, trajectory planning / finalization, positioning the targeting stem / selecting a guide, device insertion, post-insertion assessment and closing.

### Preoperative Planning

Preoperative planning is an optional step in the clinical workflow which involves planning one or more trajectory paths into the brain prior to the day of surgery, using previously acquired images of the patient.

Using the ClearPoint Array™ Workstation, presurgical images can be loaded from DICOM media or transferred from a PACS or other DICOM archive. From the list of loaded scans, the surgeon denotes a single scan which serves as the primary coordinate space used for preoperative trajectory planning. If images are loaded in a different frame of reference than the identified primary scan, the ClearPoint Array™ Workstation is used to register the images together into a single frame of reference. The surgeon then plans any number of trajectory paths into the patient using the loaded images. After sufficiently editing and reviewing all trajectory paths, the preoperative plan is saved for future intended use on the day of surgery.

On the day of surgery, the ClearPoint Array™ Workstation is used to translate the preoperative trajectories into the surgical coordinate space, by registering the preoperative primary scan with the images acquired during the intraoperative procedure. The surgeon may then review and make any adjustments to any of their planned trajectory paths using images acquired intraoperatively.

## Patient Preparation

The patient is prepared for surgery, which may include local or general anesthesia. Based on how the surgeon intends to localize one or more incision sites (i.e. mount points) on the patient, the workflow for preparing the patient for surgery will vary.

If the Operating Room (OR) is being used for mount point localization, the patient is positioned on the MR scanner gantry using a head fixation system before undergoing sterilization preparation and draping. The surgeon then registers the patient to the SNS tracking field and completes mount point localization. Once the workflow has been completed inside the OR, the patient shall be prepared for transport into the MRI Suite where the remainder of the procedure shall be carried out. The patient will be secured on the scanner table using a head fixation system and imaging coil(s)<sup>1</sup>. Additional sterilization and surgical draping may be required.

Alternatively, if the MRI Suite is being used for mount point localization, the surgeon positions and secures the patient on the scanner table with the desired patient head fixation system and imaging coil(s)<sup>1</sup>. The patient then undergoes appropriate sterilization preparation and draping<sup>2</sup>. One or more sterile SMARTGrid® marking grids are positioned over the approximate mount point<sup>3</sup>. Contrast agent may be administered to visualize vasculature. The patient is then moved to the isocenter of the scanner and a whole-head volume scan is acquired.

When working with a surgical MRI suite such as IMRIS, localization of the mount point may be done using either of the above methods. If an SNS is used, the procedure will resemble the OR workflow above, but with no need to prepare the patient for transportation.

## Mount Point Localization

The surgeon may choose to localize frame mount points on the patient using a SNS in an OR setting or alternatively may perform mount point localization inside the MRI Suite using scans of the patient with SMARTGrid® marking grids affixed.

If an OR setting is used to localize one or more mount points on the patient, the surgeon initially registers the patient to the SNS tracking field. The Entry Point Locator Tool, along with any SNS tracking hardware (i.e. Universal Tracker or Navigation System Probe) is then used to determine mount point locations on the

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<sup>1</sup> Refer to manufacturer's Instructions for Use

<sup>2</sup> Refer to document: [IFU, MR Neuro Procedure Drape](#)

<sup>3</sup> Refer to document: [IFU, SMARTGrid® MRI Planning Grid](#)

patient<sup>4</sup>. The surgeon then centers a SMARTFrame Array™ trajectory frame on each identified mount point and affixes it onto the patient<sup>4</sup>. After frame mounting, the surgeon may choose to pre-align each trajectory frame to the intended planned trajectory path using the Probe Adapter along with any SNS tracking hardware<sup>4</sup>. After all trajectory frames have been mounted, the Probe Adapters are removed and the patient is then transported to the MRI Suite where the remainder of the procedure is carried out.

If the MRI Suite is being used for mount point localization, a whole-head volumetric scan with SMARTGrid® marking grids affixed to the patient is transferred to the ClearPoint Array™ Workstation via DICOM network transfer<sup>5</sup>. Using the workstation software, the surgeon confirms that the marking grids have been identified correctly and then proceeds to plan one or more trajectory paths into the brain to determine entry points on the patient. Trajectory planning may be completed using intraoperatively acquired images and/or any existing preoperative plans that were created prior to the surgery. The row and column coordinates of the marking grid(s) shown in the image volume are then used to determine the location of the frame mount point(s) on the patient. The patient is moved out of the scanner to allow direct access to the mount point(s). The top layer of each marking grid is removed, leaving an underlay grid attached to the patient. The mount point is identified by matching the grid coordinates of the mount point displayed on the ClearPoint Array™ Workstation to the physical grid on the patient. At this point, the surgeon may opt to verify localization of each mount point using one or more SMARTFrame Array™ MRI Fiducials<sup>6</sup>. Once each mount point is confirmed, the Marking Tool can be used to mark the location of the mount point(s)<sup>7</sup>, and then each corresponding grid underlay can be removed and discarded. Using the mark left by the Mounting Tool, the surgeon may opt to create an access hole on the patient prior to mounting the trajectory frame or may wait until later in the procedure to do so. The surgeon then centers and affixes each trajectory frame onto the patient<sup>8</sup>.

See also: [Appendix 1 - B. Using the MRI to find the Mount Point](#), [Appendix 1 - C. Mounting the Scalp Mount Base](#), and [Appendix 1 - D. Attaching the SmartFrame Array Tower to the Base](#).

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<sup>4</sup> Refer to document: [IFU, SMARTFrame Array™ MRI-Guided Trajectory Frame](#)

<sup>5</sup> Refer to document: [ClearPoint® Array 1.0 DICOM Conformance Statement](#)

<sup>6</sup> Refer to document: [IFU, SMARTFrame® MRI Fiducial](#)

<sup>7</sup> Refer to document: [IFU, SMARTGrid® MRI Planning Grid](#)

<sup>8</sup> Refer to document: [IFU, SMARTFrame Array™ MRI-Guided Trajectory Frame](#)

## Trajectory Planning and Finalization

Once all trajectory frames have been mounted onto the patient, the Targeting Stem is inserted into each frame and optional Thumbwheel Extensions are connected to the corresponding adjustment knobs<sup>8</sup>. The patient is then moved into the isocenter of the MR scanner where a whole-head volumetric scan that includes all trajectory frames and their corresponding targeting stems is acquired and transferred to the ClearPoint Array™ Workstation via DICOM network transfer<sup>9</sup>. Using the workstation software, the surgeon confirms that each of the trajectory frames have been identified correctly. Each trajectory created during preoperative planning and/or mount point localization is then reviewed, adjusted (due to possible dynamic anatomical changes such as brain shift) and reconfirmed. Trajectory paths may be altered through changing the target point and/or selecting an offset device guide position to alter the entry point. If desired, the surgeon may opt to load additional scans to provide better visualization in order to modify or finalize the planned trajectory paths. Additionally, the surgeon may identify three-dimensional regions of interest in the brain that may be targeted and/or treated later in the procedure.

## Positioning the Stem and Selecting a Guide Channel

After the surgeon has finalized each of the planned trajectory paths into the brain, the ClearPoint Array™ Workstation displays the adjustments required to align the frame to the associated trajectory path. Before making the adjustments, the surgeon may opt to select an offset device guide that will be used for drilling an access hole (if required) and/or inserting the device. By default, the center device guide is selected. If the device guide selection is changed, the adjustment instructions update to align the selected offset channel to the planned target. The user then adjusts the angulation of the frame by turning the pitch (blue thumb wheel) and roll (orange thumb wheel) by the specified amount.

The workstation then provides the user with the scan plane parameters necessary to acquire images that the software can use to identify the location of the Targeting Stem in order to verify the projected path of the frame prior to drilling and/or device insertion. The surgeon verifies the position of the Targeting Stem in the resulting scans and decides to perform one of the following actions: 1) further adjust the trajectory frame with selected guide to the planned trajectory; 2) select a different guide which better aligns with the planned trajectory; or 3) proceed to insert the device into the brain using the selected guide. If the surgeon does not opt to insert the device, image acquisitions and adjustments are repeated iteratively until the projected path of the stem with the selected guide is in a clinically acceptable location.

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<sup>9</sup> Refer to document: [ClearPoint® Array 1.0 DICOM Conformance Statement](#)

If the surgeon has not yet created an access hole on the patient, they may choose to do so after the trajectory frame has been aligned to the planned trajectory. This can be accomplished using the SMARTTwist™ MRI Hand Drill<sup>10</sup> in combination with the corresponding Drill Guide<sup>11</sup> that may be inserted into the trajectory frame after alignment. In these cases, the Targeting Stem is removed and the corresponding Drill Guide is inserted into the trajectory frame which matches the guide selection shown on the workstation software<sup>11</sup>. After drilling of the access hole has been completed, the user may opt to acquire additional scans of the Targeting Stem in order to verify its final position prior to insertion.

See also: [Appendix 1 - E. MRI Workflow](#) and [Appendix 1 - F. Attachment of the Thumb Wheel Extension Set](#).

## Insertion

If inserting an MRI Conditional device<sup>12</sup>, the ClearPoint Array™ Workstation provides the option to monitor and evaluate the insertion. This can only be done with a device that can be safely imaged in the MR scanner. If inserting a device that is not safe to be imaged, the patient is moved to the back of the scanner for improved access and the insertion is performed without any further imaging.

In order to prepare the SMARTFrame Array™ MRI-Guided Trajectory Frame for device insertion, the Targeting Stem and/or Drill Guide is removed and a Device Guide corresponding to the selection made on the ClearPoint Array™ Workstation is inserted into the frame<sup>13</sup>. For each device to be inserted, the ClearPoint Array™ Workstation provides an insertion depth value that reflects the distance from the top of the trajectory frame to the planned target. The surgeon measures and marks the distance on the device to be inserted and then sets the stop to that point. A SmartFrame Array™ Guide Tube<sup>13</sup> may be used to accommodate devices with different diameters (multiple gauge devices are supported). The surgeon then passes the device manually through the Device Guide into the brain to allow for tactile feedback.

If using an MRI Conditional device, scans may be acquired to verify that the device is following the planned trajectory and also to check for hemorrhaging. Using scans

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<sup>10</sup> Refer to document: [IFU, SMARTTwist™ MRI Hand Drill](#)

<sup>11</sup> Refer to document: [IFU, SMARTFrame Array™ MRI-Guided Trajectory Frame](#)

<sup>12</sup> Refer to manufacturer's Instructions for Use

<sup>13</sup> Refer to document: [IFU, SMARTFrame Array™ MRI-Guided Trajectory Frame](#)



taken during or on completion of the insertion, the ClearPoint Array™ Workstation also provides measurements between the device tip position and the planned target.

If using a device that requires usage of a Peel-Away Sheath for access to the target site, then once the Stylet/Peel Away Sheath combination has been inserted, the Stylet is removed from the patient's head leaving the Peel-Away Sheath in place as a conduit to the target<sup>14</sup>. The insertion depth value is then measured on the device to be inserted and the Stop is set. The device is then inserted into the brain through the Peel-Away Sheath<sup>14</sup>. If required by the procedure, the inserted device may then be locked into place and the Peel-Away Sheath removed, leaving the device in position. The procedure is then completed according to the device manufacturer's Instructions for Use<sup>15</sup>.

See also: [Appendix 1 - K. Procedures utilizing the ClearPoint Neuro Stylet and Peel-Away Sheath](#), [Appendix 1 - L. Device Insertion through Peel-Away Sheath](#), and [Appendix 1 - M. Direct Insertion Procedures](#).

Once the device is inserted to the target site, the procedure continues with the inserted device following the device manufacturer's Instructions for Use<sup>15</sup> and is completed as described in [Closing Pg.26](#).

## Post-Insertion Assessment

The surgeon may optionally use the ClearPoint Array™ Workstation to assess areas within the brain that are being treated after one or more devices have been inserted. This can be achieved by acquiring follow-up scans of the areas of interest where treatment regions can be visualized. The software can then be used to identify three-dimensional areas within the brain which represent areas of treatment. These treatment areas may then be compared and assessed against previously defined volumes of interest representing patient anatomy to determine if adequate treatment coverage has been achieved. This workflow is optional and may only be performed with a device that can be safely imaged in the MR Scanner. Please refer to the manufacturer's recommendations regarding use and scanning in a MRI environment.

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<sup>14</sup> Refer to document: [IFU, SMARTFrame® Accessory Kit](#)

<sup>15</sup> Refer to manufacturer's Instructions for Use

## Closing

Once the procedure is complete, the SMARTFrame Array™ trajectory frame is then removed from the patient. The Tower section is removed first, followed by the Base. The physician finishes the procedure using standard surgical wound closing techniques, and the patient may be removed from the head fixation system.

See also: [Appendix 2 – Head Fixation Frame, Imaging Coil\(s\) & MRI Scanner Requirements Specifications](#)

## Navigational Accuracy

Results from the company's bench accuracy tests demonstrated that angular errors were all below 1°, with a mean value of 0.67°. The standard deviation was 0.14° with the highest 99% confidence limit being 0.85°. The resultant mean placement error across device configurations was below 2mm.

See also: [Appendix 1 - J. Navigational Accuracy](#).

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## System Components

1. The ClearPoint Array™ System makes use of reusable and disposable components.

Reusable components:

- Workstation laptop with ClearPoint Array™ software
- Disposable components:
  - SMARTGrid® MRI-Guided Planning Grid
  - SMARTFrame Array™ MRI-Guided Trajectory Frame
  - SMARTFrame® Accessory Kit
  - MR Neuro Procedure Drape

2. Other items required:

- head fixation frame – to immobilize patient head with respect to scanner table
- imaging coil(s) – for desired imaging quality

3. Optional items:

- SMARTFrame Array™ Thumb Wheel Extension Set

- SMARTFrame® Guide Tube Kit
- SMARTTwist™ MRII Hand Drill
- SMARTTip™ MRI Drill Kit
- SMARTFrame® MRI Fiducial
- Wharen Centering Guide
- ClearPoint® MR Monitor

See also: [Appendix 1 – SMARTFrame® Array MRI-Guided Trajectory Frame Description & Operating Instructions.](#)

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## Interoperation with MRI Scanners

The ClearPoint Array™ Workstation should be set up in the scanner control room, behind the 5 Gauss Line, in close proximity to the MRI Scanner Console. It should then be connected to the TCP/IP network upon which the MRI Scanner resides, in order to receive images that are acquired intraoperatively during the neurological procedure. The MRI Scanner Console must be configured to recognize the ClearPoint Array™ Workstation as a valid DICOM storage device using the following parameters:

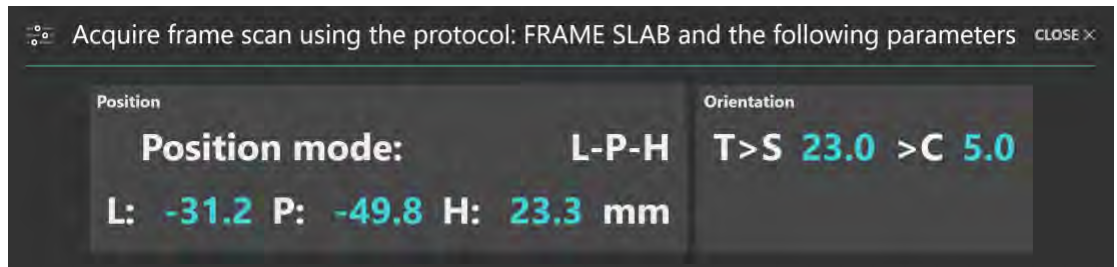
- IP Address: As configured by your site administrator
- AE Title: SVDBG
- Port: 4467

The system is intended for use only with 1.5 and 3.0 Tesla MRI scanners and MR Conditional implants and devices.

After connecting the ClearPoint Array™ Workstation to the MRI scanner for the first time, certain information about the scanner, including bore diameter and manufacturer, must be entered as system settings in the application (see [Configuring the Scanner Settings Pg. 48](#)). The bore diameter indicates to the application how much clearance there will be when inserting a device along a given trajectory path into the brain. The scanner manufacturer field determines the format that the application will use when prescribing specific scan plane parameters for images that are to be acquired. Over the course of the procedure, there are numerous times when the application will provide very specific sets of scan plane parameters that must be manually entered in the user interface of the MRI Scanner Console used to run the scanner. The application has the ability to show these parameters in a format that is appropriate for only the following three MR scanner manufacturers:

- GE Healthcare
- Philips Medical Systems
- Siemens Healthcare

The parameters shown by the ClearPoint Array™ Workstation are entered manually on the MRI Scanner Console used to perform image acquisitions throughout the neurological procedure. An example of scan plane parameters that are shown by the application in a format that can be inputted on a Siemens Healthcare MRI Scanner Console is shown below.




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**Caution:** For patient safety you must ensure that your MR Scanner is properly calibrated and maintained prior to using it with the ClearPoint Array™ System. If the scanner has not been calibrated, an incorrect placement of the inserted device may result. Even on a calibrated system images may be distorted by case-specific factors such as patient implants. Carefully inspect acquired images for any visible distortions.

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If your scanner is not correctly calibrated and geometric distortion affects the acquired images used in the following circumstances, the software will provide appropriate warnings in each instance:

- Images used to identify the fiducial markers mounted in the base of the frame. See [SMARTFrame® Markers Inconsistent with Hardware Specifications Pg. 253](#).
- Images used to detect the position of the targeting stem. See [Inconsistent Targeting Stem Positions Found Pg. 256](#).
- Images used to identify the track of the inserted device. See [Insertion Track Does Not Appear Straight Pg. 259](#).

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## Important Notes for Using Siemens Scanners

### Ensuring correct sign and direction

When entering scan plane parameters into the Siemens MRI Scanner Console interface, it is necessary to ensure that the positive direction indicated (L/R, P/A, H/F) matches the directions provided by the ClearPoint Array™ Workstation. The application specifies directions based on the positive directions being Left, Posterior, and Head. Any time a negative value is entered on the Siemens MRI Scanner Console, the negative value will be switched to a positive value and the sense of the positive direction will be reversed.

For example, if you enter: L= -32.5, the console changes this entry to R=32.5. Also, the next time you open that dialog, it prompts for a value for R rather than L. It now interprets the direction towards the patient right as being positive. In this case, entering the 'L' value provided as-is would yield an incorrect result.

There are two solutions to avoid incorrect entries:

1. Where the positive directions disagree, simply reverse the sign of the numeric value provided by the application.
2. Prior to opening the dialog, first reset the position to ISOCENTER. This causes the console to set L, P and H as the positive directions.

### Entering a Table Position Value

When entering scan plane parameters into the Siemens MRI Scanner Console interface, the dialog for entering position values also has an optional field to enter a Table Position value. This value controls automatic movement of the table, setting how it is positioned before the scan is taken.

The application provides a Table Position value for the scans prescribed in the Verify Adjustment (see [Verify Adjustment Step – Verifying the Stem Position Pg. 179](#)), Check Frame Movement (see [Check Frame Movement – Determining if the Frame Moved Pg. 210](#)) and Locate Stem Position (see [Locate Stem Position – Re-verifying the Stem Position Pg. 214](#)) steps to ensure that the targeting stem scans are moved as close as possible to the scanner isocenter to reduce the likelihood of geometric distortion.

The Table Position value **must** be entered before the H/F value is entered. Otherwise, the Siemens MRI Scanner Console interface will modify the H/F value to reflect the Table Position value being entered and you will need to re-enter the H/F value.

## Entering the In-Plane Rotation

When entering scan plane parameters into the Siemens MRI Scanner Console interface, there is a field labeled “Phase Enc Dir” for the phase encoding direction, with an associated drop down for setting a rough direction. This field also has an associated button labeled “...” that opens a dialog for numerically setting the Inplane Rotation. This provides precise control over the phase encoding direction for the scan.

The application provides an Inplane Rotation value in the scan plane parameters prescribed in the Verify Adjustment (see [Verify Adjustment Step – Verifying the Stem Position Pg. 179](#)), Check Frame Movement (see [Check Frame Movement – Determining if the Frame Moved Pg. 210](#)) and Locate Stem Position (see [Locate Stem Position – Re-verifying the Stem Position Pg. 214](#)) steps that must be entered on the Siemens MR Console. This value is calculated to minimize the effects of geometric distortion on accuracy by ensuring that the phase encoding direction lies perpendicular to the long axis of the targeting stem.

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## Important Notes for Using Philips Scanners

### Ensuring correct slice orientation

When entering scan plane parameters into the Philips MRI Scanner Console interface, it is necessary to ensure that the slice orientation specified by the ClearPoint Array™ Workstation is correctly entered prior to the acquisition of each scan. The slice orientation value provided by the application must be entered in the “Geometry” tab on the Philips MRI Scanner Console interface. The specified value will be one of: transverse, coronal or sagittal. The remaining scan plane parameters must be entered in the “Offc/Ang” tab on the Philips MRI Scanner Console interface.

### Flipping the scan plane

In rare instances, it may be possible that the ClearPoint Array™ Workstation specifies incorrect orientation values for entry within the Philips console interface, based on the orientation of the planned trajectory. In these instances, the +/- sign of one or more of the orientation values may be incorrect.

If this occurs, the ClearPoint Array™ Workstation can be made to compute the correct values by clicking on the **Flip Parameters** button. Doing so will effectively “flip” the direction of the scan plane such that the orientation values needed for entry into the Philips MRI Scanner Console interface will be correct.

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**Caution:** Please only use this workaround if it is confirmed that all scan plane parameters prescribed by the ClearPoint Array™ Workstation were entered correctly on the Philips MRI Scanner Console, and that these parameters produced images that were not oriented correctly.

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## Important Notes for Using IMRIS Scanners

### Entering a Table Position Value

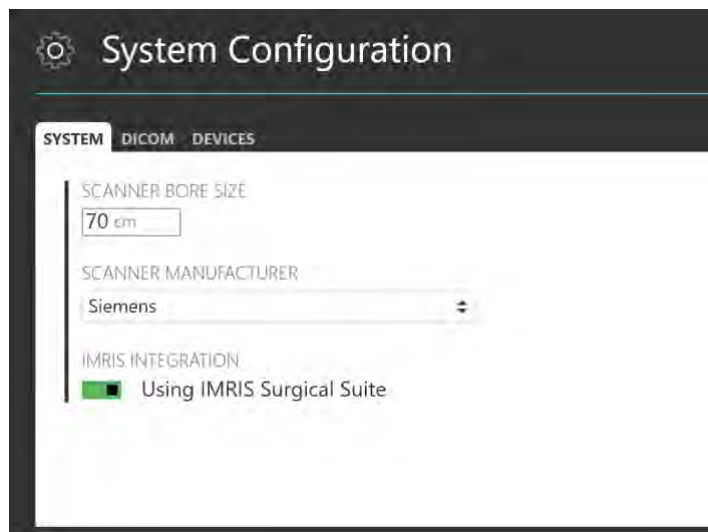
When entering scan plane parameters prescribed in the Verify Adjustment (see [Verify Adjustment Step – Verifying the Stem Position Pg. 179](#)), Check Frame Movement (see [Check Frame Movement – Determining if the Frame Moved Pg. 210](#)) and/or Locate Stem Position (see [Locate Stem Position – Re-verifying the Stem Position Pg. 214](#)) steps onto the IMRIS MRI Scanner Console interface, the dialog for entering position values also has an optional field to enter a Table Position value. This value controls automatic movement of the table, setting how it is positioned before the scan is taken.

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**Caution:** Since IMRIS systems do not have the ability to move the underlying table during a procedure, the Table Position value provided by the ClearPoint Array™ Workstation should not be entered.

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In order to prevent the Table Position value from being displayed with the scan plane parameters, indicate that an IMRIS Surgical Suite is being used via the System Configuration Window (see [Configuring System and Device Settings Pg. 66](#)).



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## Procedure Workflow

This section describes the procedure workflow that can be followed using the ClearPoint Array™ Workstation. The application divides the clinical procedure into three separate workflows:

1. **Pre-Op Workflow**. Presurgical planning occurs on the workstation using patient images that were acquired prior to the neurological procedure. One or more trajectories are planned using the loaded preoperative images, and may subsequently be used as a starting point for intraoperative trajectory determination and associated review.
2. **Grid Workflow**. Localization of mount points occurs inside the MRI Suite, using one or more SMARTGrid® marking grids. One or more SMARTFrame Array™ trajectory frames are mounted onto the patient inside the MRI Suite after frame mount locations have been determined.
3. **Frame Workflow**. One or more SMARTFrame Array™ trajectory frames have already been mounted onto the patient, either inside the MRI Suite using the Grid Workflow, or inside the OR using an independent SNS.

Each workflow is presented as an ordered set of steps that can be performed to complete a portion of the neurological procedure. These steps provide instructions and tools necessary to perform a set of discrete, focused activities that are required in order to move forward in the clinical workflow. Steps may also expose optional tasks that can be invoked to complete work that may be necessary in order to carry on in the workflow in some cases, but are not always required. Steps are grouped together according to commonalities in their underlying purpose.

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## Pre-Op Workflow



The Pre-Op Workflow allows you to create a presurgical plan using patient images that were acquired prior to the day of surgery. The workflow prompts you to load a set of preoperative images, select one of the scans to serve as the coordinate space for planning, plan one or more trajectory paths into the brain, and save the

preoperative plan for future usage. You may fuse preoperative images with different frames of reference in order to supplement the trajectory planning process.

Steps within the Pre-Op Workflow are grouped in the following manner:

- **Identify Master Scan.** Identify the primary scans that will serve as the coordinate space for preoperative planning. See [Identify Master Scan Pg. 35](#) for details.
- **Define Trajectory.** Plan one or more trajectory paths into the brain using the set of preoperative scans loaded. See [Define Trajectory Pg. 35](#) for details.

## Identify Master Scan

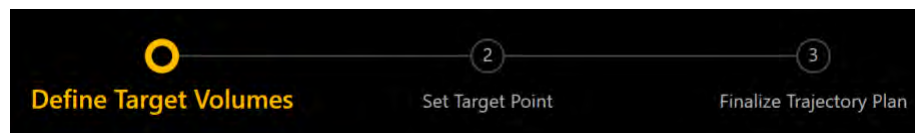


The Identify Master Scan group allows you to select a primary scan that will serve as the base coordinate system used for preoperative planning. Any additional scans that are loaded with a different frame of reference will require you to fuse those scans with the primary scan.

One step is provided in the Identify Master Scan group:

- **Identify Master Scan.** Load a set of preoperative scans and select one as the primary scan (referred to as the “master scan”) whose coordinate space will be used for preoperative planning. See [Identify Master Scan Step – Selecting a Master Scan Pg. 110](#) for details.

## Define Trajectory



The Define Trajectory group allows you to plan one or more trajectory paths into the brain using images that were acquired prior to the day of surgery. Setting a trajectory path requires defining a target point at some location within the brain, as well as an entry point on the surface of the patient’s skull. You may also optionally define volumes of interest (VOI) within the brain that you may wish to target or avoid when planning your trajectory paths.

The following steps are provided by the Define Trajectory group:

- **Define Target Volumes.** Optionally create one or more volumes of interest (VOI) within the brain using preoperative images. See [Define Target Volumes Step - Defining Volumes Pg. 114](#) for details.
- **Set Target Point.** Define one or more locations to be targeted within the brain using preoperative images. See [Set Target Point Step – Defining Target Points Pg. 120](#) for details.
- **Finalize Trajectory Plan.** Review and optionally modify each planned trajectory path and save the presurgical plan for future use. See [Finalize Trajectory Plan Step – Finalizing the Preoperative Plan Pg. 126](#) for details.

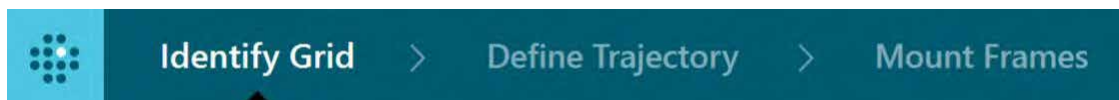
## Optional Tasks

The Pre-Op Workflow exposes the following tasks that you can use to perform additional work which may be necessary to complete the procedure:

- **Fuse Images.** Spatially register / fuse preoperative image series acquired in different frames of reference from the master scan. See [Fusion Task Fusing Images Pg. 221](#) for details.
- **Compare Images.** Perform visual comparisons of any two preoperative image series loaded into the workstation. See [Compare Task Comparing Images Pg. 229](#) for details.
- **Edit Anatomical Planes.** Review and optionally modify the plane definition used to display viewing planes that are oriented anatomically. See [Edit Anatomical Planes Task Changing Anatomical Planes Pg. 226](#) for details.

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## Grid Workflow




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*Before utilizing this workflow, ensure that the patient is prepared for the procedure (i.e., SMARTGrid® marking grids are mounted over the intended entry area(s), and the patient is placed into the MR scanner).*

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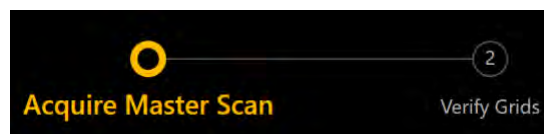
The Grid Workflow allows you to localize the position of the trajectory frame mount point(s) on the patient using one or more SMARTGrid® marking grids. You may utilize this workflow provided that marking grids have been affixed to the patient. If you created a preoperative plan using the Pre-Op Workflow, any loaded scans, defined trajectory paths and created volumes of interest from the plan will be translated into this workflow to serve as a starting point for intraoperative trajectory planning. For details on how to exercise the Pre-Op Workflow, see [Pre-Op Workflow Pg. 34](#).

The Grid Workflow prompts you to acquire a whole-head scan containing all marking grids, review and verify the identification of the markings grid(s) in the scan, plan one or more trajectory paths into the brain, and locate the position of the frame mount point(s) on the patient. You may load or acquire additional images in order to verify the location of the marking grid(s) and/or supplement the definition or modification of trajectory target and entry points.

Steps within the Grid Workflow are grouped in the following manner:

- **Identify Grid.** Confirm the position of each affixed marking grid using an acquired whole-head scan of the patient. See [Identify Grid Pg. 37](#) for details.
- **Define Trajectory.** Plan one or more trajectory paths into the brain using the whole-head scan with marking grids affixed plus any additional scans that are necessary to review and/or verify each trajectory path. See [Define Trajectory Pg. 38](#) for details.
- **Mount Frames.** Visualize trajectory frame mounting locations for each defined trajectory path with marking grids affixed. See [Mount Frames Pg. 39](#) for details.

## Identify Grid



The Identify Grid group consists of steps that allow you to identify, review and verify the position of each SMARTGrid® marking grid affixed to the patient. Each identified marking grid is used later in the workflow to prescribe the trajectory frame mount position(s) on the patient.

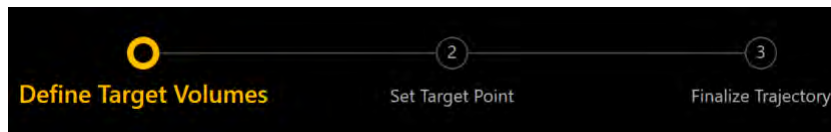
The following steps are provided by the Identify Grid group:

- **Acquire Master Scan.** Acquire a whole-head volumetric scan (referred to as the “master scan”) of the patient with one or more marking grids affixed. If necessary, fuse the master scan from the Pre-Op Workflow with the acquired master scan in order to utilize images, trajectories and VOIs defined during

preoperative planning. See [Acquire Master Scan Step - Acquiring a Grid Master Scan Pg. 131](#) for details.

- **Verify Grids.** Review and confirm the identification of one or more marking grids in the whole-head scan. See [Verify Grids Step - Confirming Marking Grids Pg. 135](#) for details.

## Define Trajectory



The Define Trajectory group allows you to plan and/or review one or more trajectory paths into the brain using the whole-head master scan with grids affixed plus any additional scans that are necessary to review and/or verify each trajectory path. Optionally, you may define and/or review any VOIs required for targeting / avoidance during the procedure. If trajectories and/or VOIs were translated from the Pre-Op Workflow, you may review and/or edit them using these steps in the frame of reference of the acquired master scan.

The following steps are provided by the Define Trajectory group:

- **Define Target Volumes.** Optionally create or edit one or more volumes of interest (VOI) within the brain. VOIs from the Pre-Op Workflow may be edited. See [Define Target Volumes Step - Defining Procedure Volumes Pg. 141](#) for details.
- **Set Target Point.** Define one or more locations to be targeted within the brain. Target points from the Pre-Op Workflow may be further edited. See [Set Target Point Step - Defining Procedure Target Points Pg. 142](#) for details.
- **Finalize Trajectory.** Review and optionally modify each planned trajectory path with marking grids affixed. Trajectories from the Pre-Op Workflow may be further edited. See [Finalize Trajectory Step - Reviewing Trajectories Pg. 145](#) for details.

## Mount Frames



The Mount Frames group allows you to visualize the locations prescribed by the software to mount trajectory frames for each of your defined trajectory paths. These locations are displayed in a three-dimensional scene along with the whole-head scan of the patient and model representations of each marking grid so that it is very clear where the associated frames should be mounted onto the patient.

One step is provided in the Mount Frames group:

- **Mount Frames.** Identify one or more mount positions for the trajectory frame(s) on the patient. See [Mount Frames Step – Mounting Frames Pg. 148](#) for details.

At this point, the patient is advanced far enough out the back of the scanner to provide access to their head, and the MRI-visible layer of the SMARTGrid® marking grid is peeled off. The SMARTFrame Array™ trajectory frame is then mounted to the patient's scalp using the Scalp Mount Base at the centering point provided by the workstation. See the [SMARTFrame Array™ MRI-Guided Trajectory Frame, Instructions for Use](#) for additional details.

Once the trajectory frame is mounted, the Targeting Stem is inserted and the Thumbwheel Extension is attached to the frame. The patient is then returned to the bore of the scanner whereby the user may continue using the Frame Workflow. See [Frame Workflow Pg. 40](#) for details.

## Optional Tasks

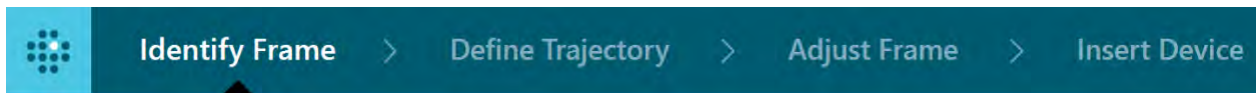
The Grid Workflow exposes the following tasks that you can use to perform additional work which may be necessary to complete the procedure:

- **Fuse Images.** Spatially register / fuse additional image series acquired in different frames of reference from the master scan. See [Fusion Task Fusing Images Pg. 221](#) for details.
- **Compare Images.** Perform visual comparisons of any two image series loaded into the workstation. See [Compare Task Comparing Images Pg. 229](#) for details.
- **Edit Anatomical Planes.** Review and optionally modify the plane definition used to display viewing planes that are oriented anatomically. See [Edit Anatomical Planes Task Changing Anatomical Planes Pg. 226](#) for details.

- **Move Grid.** Re-position any affixed marking grid on the patient if one or more planned trajectory paths do not intersect with the marking grid. See [Move Grid Task – Repositioning Marking Grids Pg. 232](#) for details.

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## Frame Workflow




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*Before utilizing this workflow, make sure that the patient is placed into the MR scanner bore with one or more SMARTFrame Array™ trajectory frames mounted on their head. If trajectory frame mounting occurred in the OR, ensure that the patient has been transported to the MRI Suite prior to exercising this workflow.*

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The Frame Workflow allows you to align one or more mounted trajectory frames to the planned trajectories before inserting one or more devices into the brain. You may utilize this workflow provided that trajectory frames have been mounted to the patient. If you performed trajectory frame mounting in the OR using a SNS, the trajectory paths will need to be re-defined on the workstation. If you performed trajectory frame mounting inside the MRI Suite using the Grid Workflow, any previously loaded scans, defined trajectory paths, and created volumes of interest will be translated into this workflow. For details on how to exercise the Grid Workflow, see [Grid Workflow Pg. 36](#). If you created a preoperative plan using the Pre-Op Workflow but skipped the Grid Workflow, then any scans, trajectory paths and volumes of interest from the preoperative plan will be translated into this workflow. For details regarding how to create a preoperative plan, see [Pre-Op Workflow Pg. 34](#).

The Frame Workflow prompts you to acquire a whole-head scan containing all trajectory frames and their targeting stems, review / verify the identification of the frames and targeting stems, plan / review one or more trajectory paths into the brain, align one or more trajectory frames to the corresponding planned trajectory paths, and insert one or more devices into the patient.

Steps within the Frame Workflow are grouped in the following manner:

- **Identify Frame.** Review and confirm the position and orientation of each trajectory frame mounted to the patient using an acquired whole-head scan of the patient with frames affixed. See [Identify Frame Pg. 41](#) for details.



- **Define Trajectory.** Plan and/or review one or more trajectory paths into the brain using the whole-head scan with trajectory frames affixed plus any additional scans that are necessary to verify each trajectory path. See [Define Trajectory Pg. 42](#) for details.
- **Adjust Frame.** Align each trajectory frame to one or more planned trajectory paths into the brain. This process may be iterative in nature until clinically acceptable alignment is achieved. See [Adjust Frame Pg. 43](#) for details.
- **Insert Device.** Monitor and assess the insertion of one or more devices into the brain, along the associated planned trajectory path. See [Insert Device Pg. 43](#) for details.
- **Re-Insert.** Optionally correct frame positioning after one or more device placements have been deemed clinically unacceptable. Steps within this group are used to troubleshoot and assist with correcting these types of device placements. See [Re-Insert Pg. 44](#) for details.

## Identify Frame



The Identify Frame group is made up of steps that allow you to identify, review and verify the position of each SMARTFrame Array™ trajectory frame mounted to the patient using a whole-head volume scan. This involves reviewing and verifying the position of each fiducial marker located in the frame's base as well as the fluid-filled targeting stem.

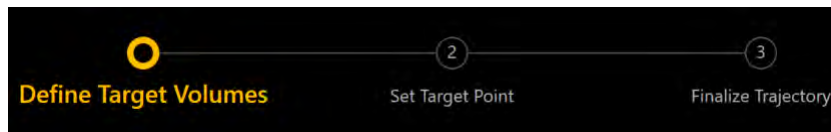
If a Pre-Op or Grid Workflow has been completed prior to this workflow, the workstation will require that the whole-head scan containing the trajectory frame(s) be fused with the master scan from the previously completed workflow. This is necessary so that images, trajectory paths and volumes of interest (VOIs) defined in the previous workflow can be translated into the frame of reference of the patient in the Frame Workflow.

The following steps are provided by the Identify Frame group:

- **Acquire Master Scan.** Acquire a whole-head volumetric scan (referred to as the "master scan") of the patient with one or more trajectory frames mounted. If necessary, fuse the master scan from the Pre-Op or Grid Workflow with the current master scan in order to utilize images, trajectories and VOIs previously defined. See [Acquire Master Scan Step – Acquiring a Frame Master Scan Pg. 153](#) for details.

- **Verify Frame Base Markers.** Review and confirm locations for each frame marker positioned in the base of each mounted frame. See [Verify Frame Base Markers Step – Confirming Frame Markers Pg. 157](#) for details.
- **Verify Targeting Stem.** Review and confirm the position and orientation of each trajectory frame’s targeting stem. See [Verify Targeting Stem Step – Confirming the Stem Pg. 165](#) for details.

## Define Trajectory

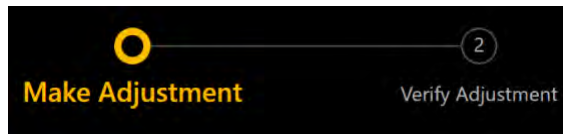


The Define Trajectory group allows you to plan and/or review one or more trajectory paths into the brain using the whole-head master scan with frames affixed plus any additional scans necessary to verify each path. Optionally, you may define and/or review any VOIs required for targeting / avoidance during the procedure. If trajectories and/or VOIs were translated from the Pre-Op or Grid Workflow, you may review and/or edit them using these steps in the frame of reference of the master scan.

The following steps are provided by the Define Trajectory group:

- **Define Target Volumes.** Optionally define or edit one or more volumes of interest (VOI) within the brain. VOIs from the Pre-Op and/or Grid Workflow may be edited. See [Define Target Volumes – Refining Procedure Volumes Pg. 168](#) for details.
- **Set Target Point.** Define one or more locations to be targeted within the brain. Target points from the Pre-Op and/or Grid Workflow may be edited. See [Set Target Point Step – Refining Procedure Target Points Pg. 169](#) for details.
- **Finalize Trajectory.** Review and optionally modify each planned trajectory path with trajectory frames mounted. Optionally select guide channels used for drilling / insertion to modify the desired entry points for each trajectory. See [Finalize Trajectory Step – Finalizing Trajectories Pg. 171](#) for details.

## Adjust Frame

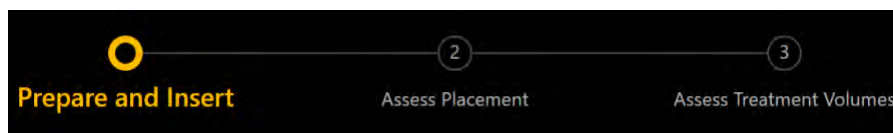


The Adjust Frame group allows you to realize adjustments on each trajectory frame in order to align the selected guide channel to the intended target location(s). This involves acquiring up-to-date scans of the targeting stem and iteratively altering its angulation until acceptable alignment with the planned trajectory is achieved. Optionally, you may select different guide channels used for drilling / insertion to select an alternate projected path that is closer to the intended target location. Doing so may reduce the number of frame adjustments required to complete alignment.

The following steps are provided by the Adjust Frame group, which can be cycled through iteratively:

- **Make Adjustment.** Carry out the pitch / roll adjustments prescribed by the workstation on the physical trajectory frame. Optionally select a different guide channel used for drilling / insertion to select a projected path that is closer to the planned target point. See [Make Adjustment Step – Setting the Frame Angulation Pg. 175](#) for details.
- **Verify Adjustment.** Acquire scans of a frame’s targeting stem to confirm its position after subsequent frame adjustment and/or prior to device insertion. Optionally select a different guide channel used for drilling / insertion to select a projected path that is closer to the planned target point. See [Verify Adjustment Step – Verifying the Stem Position Pg. 179](#) for details.

## Insert Device



The Insert Device group allows you to monitor, assess and evaluate the accuracy of a device insertion relative to its planned trajectory. You may also assess areas of interest on scans acquired during or after treatment to the patient has been delivered. **Steps in this group provide optional workflow that may only be performed when inserting MRI Conditional devices.**

The following steps are provided by the Insert Device group, and can only be used when inserting MRI Conditional devices:

- **Prepare and Insert.** Follow the instructions provided by the workstation in order to physically insert the device into the patient. Acquire a whole-head scan with one or more devices inserted and review the detected positions of

each device tip. Optionally modify the position of each device tip if necessary to ensure that its location matches with the underlying images. See [Prepare and Insert Step – Preparing and Inserting the Device Pg. 185](#) for details.

- **Assess Placement.** Evaluate the placement of one or more devices relative to the planned trajectory. Assess whether or not device placement is clinically viable. See [Assess Treatment Volumes – Evaluating Treatment Coverage Pg. 196](#) for details.
- **Assess Treatment Volumes.** If VOIs have been defined previously in the workflow for purposes of targeting, optionally acquire images during treatment of the patient and create / edit VOIs representing areas of treatment. Compare any defined treatment VOIs to the originally planned target VOIs to determine if clinically adequate treatment coverage has been achieved. See [Assess Treatment Volumes – Evaluating Treatment Coverage Pg. 196](#) for details.

## Re-Insert



The Re-Insert group guides you through the workflow for re-inserting a device into the brain after the original device placement has been rejected. In these cases, the workflow prompts you to assess the root cause of the original device placement, re-adjust the targeting stem's position and then re-insert the device.

The following steps are provided by the Re-Insert group:

- **Check Deflection.** Examine the initially inserted device path's proximity to resistant structures and assess whether deflection of the device may have occurred. See [Check Deflection Step – Assessing Proximity to Resistant Structures Pg. 207](#) for details.
- **Check Frame Movement.** Acquire scans of the targeting stem and compare to the targeting stem scans acquired prior to the insertion of the device to assess whether or not the frame may have inadvertently moved. See [Check Frame Movement – Determining if the Frame Moved Pg. 210](#) for details.
- **Locate Stem Position.** Confirm the current position of the targeting stem and determine if further frame adjustments are needed or if the device can be inserted into the patient. Optionally select a different guide channel used for re-drilling / re-insertion to select a projected path that is closer to the planned target point. See [Locate Stem Position – Re-verifying the Stem Position Pg. 214](#) for details.

- **Make Re-Adjustments.** Carry out the frame adjustments prescribed by the workstation on the physical trajectory frame in which the device will be re-inserted. Optionally select a different guide channel used for re-drilling / re-insertion to select a projected path that is closer to the planned target point. See [Make Re-Adjustments Step – Re-Adjusting the Frame Angulation Pg. 217](#) for details.
- **Prepare and Re-Insert.** Follow the instructions provided by the workstation in order to physically re-insert the device into the patient. Acquire a whole-head scan with one or more devices inserted and review the detected positions of each device tip. Optionally modify the position of each device tip if necessary to ensure that its location matches with the underlying images. See [Prepare and Re-Insert - Preparing and Re-Inserting the Device Pg. 219](#) for details.
- **Assess Revised Placement.** Evaluate the placement of the re-inserted device relative to the planned trajectory. Assess whether or not placement is clinically viable. If the device insertion is still not clinically viable, repeat the steps in the Re-Insert group. See [Assess Revised Placement - Evaluating the Re-Inserted Device Placement Pg. 220](#) for details.

## Optional Tasks

The Frame Workflow exposes the following tasks that you can use to perform additional work which may be necessary to complete the procedure:

- **Fuse Images.** Spatially register / fuse additional image series acquired in different frames of reference from the master scan. See [Fusion Task Fusing Images Pg. 221](#) for details.
- **Compare Images.** Perform visual comparisons of any two image series loaded into the workstation. See [Compare Task Comparing Images Pg. 229](#) for details.
- **Edit Anatomical Planes.** Review and optionally modify the plane definition used to display viewing planes that are oriented anatomically. See [Edit Anatomical Planes Task Changing Anatomical Planes Pg. 226](#) for details.
- **Edit Stem.** Manually override the detected position of the frame's targeting stem. This task is only available for usage in the Verify Adjustment and Locate Stem Position steps. See [Edit Stem Task – Changing the Stem Position Pg. 241](#) for details.

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## About this Guide

This user's guide assumes that you are familiar with the basic operation of personal computers, such as how to turn them on, how to use the mouse, and how to work in the Microsoft Windows Operating System environment. If you are not familiar with these operations, please refer to the documentation provided with your workstation.

### Visual Cues

- Words shown in large, boldface text, such as **Done**, indicate buttons and tools that can be clicked with the mouse.
- Words shown in Times New Roman, boldface text, such as **exit**, indicate characters that you must type into the keyboard exactly as they appear (i.e., if you are instructed to type **exit**, you should type the characters exactly as they are printed).
- Words shown in uppercase, such as ENTER, indicate keys on the keyboard that should be pressed. If several keys appear together separated by plus signs (e.g., CTRL+ALT+DELETE), it means that you should press all three keys simultaneously.
- Words shown in *italics* are used for emphasis.

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## Getting Started

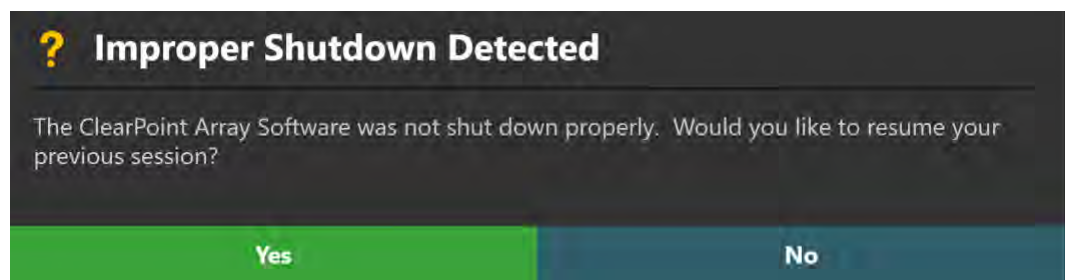
This section describes how to start the application, configure the workstation for initial use, begin a new session and shutdown the application.

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### Starting the Application

To launch the application, double-click the ClearPoint Array™ icon on the Windows desktop.

*If the ClearPoint Array™ Workstation has been unexpectedly shut down, then on restarting the workstation the application displays a prompt. You have the choice of resuming the previous session or starting a new one.*



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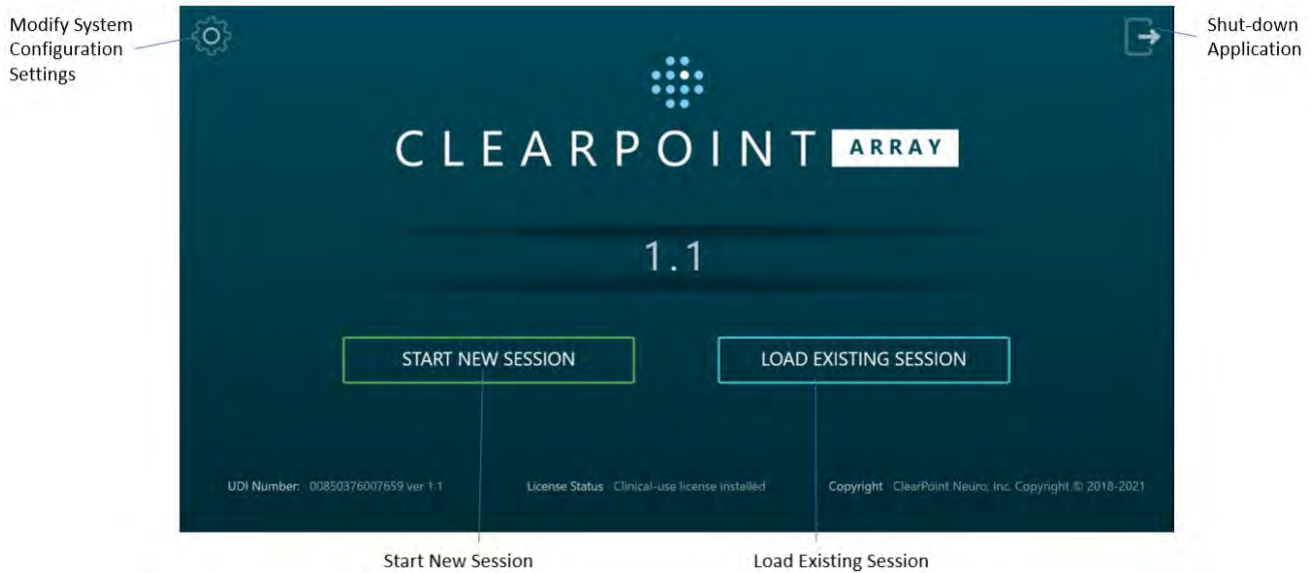
### Launching the Splash Screen

When the application first launches, a Splash Screen is displayed which identifies the name and version of software installed on the workstation. It also indicates the current system licensing status as well as the Unique Device Identification Number associated with the software application.

The Splash Screen allows you to perform a number of different actions:

- Modify system configuration settings
- Start a new software session
- Load an existing software session

- Shut down and exit the application





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## Configuring the Scanner Settings

Prior to starting a new session for the first time, you must specify information about the scanner that will be transferring images to the ClearPoint Array™ Workstation during the interventional procedure. If the workstation connects to different intraoperative scanners within the same institution, this information must be changed each time the connection between the scanner and workstation is changed.

### > To set-up the scanner bore size

1. Launch the application.
2. From the Splash Screen, click the  button.
3. A floating window with 3 distinct tabs will appear, providing you with the ability to modify the configurable settings for the system.
4. Select the **SYSTEM** tab to modify the system settings.
5. Enter the diameter of the bore, in centimeters, for the scanner that the workstation is connected to.





6. Select **Apply** to save the changes made.
7. If you wish to change the scanner bore size at a later time, use the System Configuration Window to modify the scanner bore size value as necessary (see [Configuring System and Device Settings Pg. 66](#)).

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**WARNING:** The scanner bore size entered in the system configuration settings is used by the application to ensure that for a given planned trajectory path, any of the configured devices can be physically inserted into the SMARTFrame Array™ without being obstructed by the scanner bore.

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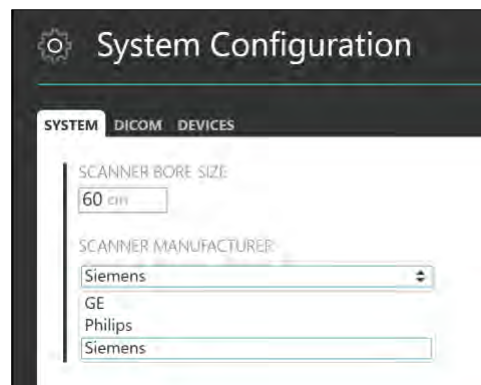
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**WARNING:** Always ensure that the scanner bore size entered in the System Configuration Window is correct prior to proceeding with trajectory planning.

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> **To set the scanner manufacturer**

1. Launch the application.
2. From the Splash Screen, click the  button.
3. A floating window with 3 distinct tabs will appear, providing you with the ability to modify the configurable settings for the system.
4. Select the **SYSTEM** tab to modify the system settings.



5. Choose an item from the list which indicates the manufacturer of the scanner to which the workstation is connected.
6. Select **Apply** to save the changes made.
7. If you wish to change the scanner manufacturer at a later time, use the System Configuration Window to modify the manufacturer field as necessary (see [Configuring System and Device Settings Pg. 66](#)).

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**WARNING:** The scanner manufacturer specified in the system configuration settings is used to determine the format for the scan plane parameters displayed by the application throughout various steps in the clinical workflow.

Always ensure that the value entered in the System Configuration Window is correct prior to proceeding with trajectory planning.


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## Configuring the DICOM Connectivity Settings

In order for the ClearPoint Array™ Workstation to receive DICOM images transferred from the MRI Scanner, the workstation will need to be configured as a DICOM node on the MRI Scanner Console. (See the scanner's manufacturer-specific instructions on how to set-up the workstation as a DICOM node on the MRI Scanner's network). The DICOM connectivity parameters that are required for this set-up are specified as configuration settings in the system.


### > To set-up the DICOM connectivity fields

1. Launch the application.
2. From the Splash Screen, click the  button.
3. A floating window with 3 distinct tabs will appear, providing you with the ability to modify the configurable settings for the system.
4. Select the **DICOM** tab to modify the DICOM settings for the system.
5. Enter the Application Entity Title of the workstation as configured on the MRI Scanner Console.
6. Enter the Port Number of the workstation as configured on the MRI Scanner Console.

The screenshot shows a configuration window with three tabs: SYSTEM, DICOM, and DEVICES. The DICOM tab is selected. It contains two input fields: 'AE TITLE' with the value 'SVDBG' and 'PORT #' with the value '4467'.

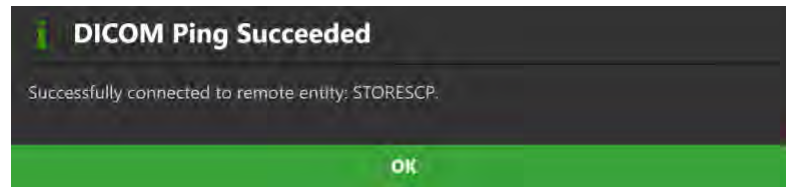
7. Select **Apply** to save the changes made.
8. If you wish to change the DICOM connectivity settings at a later time, you can use the System Configuration Window to modify the appropriate fields as necessary (see [Configuring System and Device Settings Pg. 66](#)).

> **To test the DICOM connectivity settings**

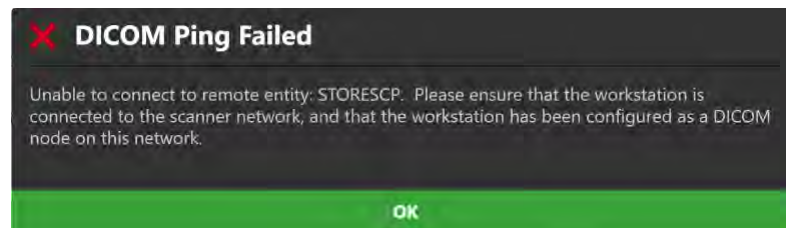
1. Launch the application.
2. From the Splash Screen, click the  button.
3. A floating window with 3 distinct tabs will appear, providing you with the ability to modify the configurable settings for the system.
4. Select the **DICOM** tab to modify the DICOM settings for the system.
5. Enter values for the DICOM connectivity parameters corresponding to the MRI Scanner (these can be looked up using the MRI Scanner Console interface):
  - IP Address
  - Remote Application Entity Title
  - Remote Port Number

The screenshot shows a 'Send DICOM Echo' window. It has three input fields: 'REMOTE IP ADDRESS' with the value '127.0.0.1', 'REMOTE AE TITLE' with the value 'STORESCU', and 'REMOTE PORT #' with the value '1008'. A green 'Ping' button is located at the bottom center.

6. Click the **Ping** button.
7. If the DICOM connection with the scanner has been set-up correctly, the DICOM Echo / Ping test will succeed.



8. If the DICOM connection with the scanner has not been configured properly, the DICOM Echo / Ping test will fail and you will need to re-visit the steps taken above to set-up the workstation as a DICOM node on the MRI Scanner's network. You may also refer to the scanner manufacturer's instructions on how to set up the workstation as a DICOM note on the MRI Scanner's network.




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## Installing a System License


The ClearPoint Array™ Workstation must be licensed appropriately with a valid, permanent license intended for clinical usage and distributed by ClearPoint Neuro Incorporated. If you do not have a valid system license or are unsure how to obtain one, please contact your clinical sales representative.

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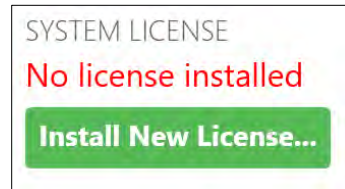
**WARNING:** A valid, non-expiring clinical-use license is required in order to use the ClearPoint Array™ Workstation during a neurological procedure. Demonstration licenses, or unreleased software versions are not permitted for use for clinical procedures.

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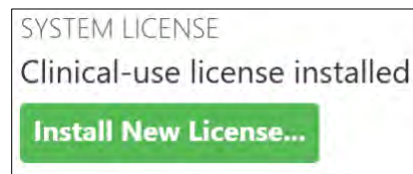
### > To install a license

1. Launch the application.
2. From the Splash Screen, click the  button.

3. A floating window with 3 distinct tabs will appear, providing you with the ability to modify the configurable settings for the system.
4. Select the **SYSTEM** tab to modify the system settings.
5. Click the **Install New License...** button.



6. Navigate to a directory which contains a permanent license file intended for clinical usage provided to you by ClearPoint Neuro Incorporated.
7. Select the appropriate license file. The application will indicate that a clinical-use license has been installed.





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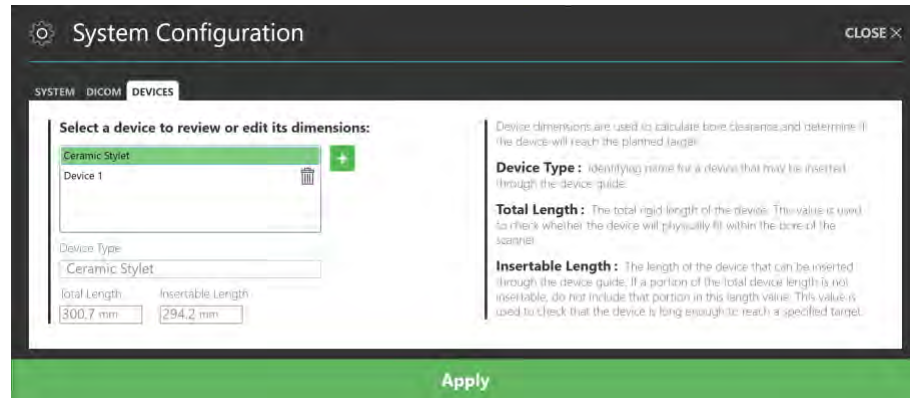
## Configuring the List of Insertable Devices



Prior to using the ClearPoint Array™ Workstation for the first time, please review the list of devices that may be inserted into the patient's brain based on the neurological procedures that are being performed using the system. By default, the system is pre-configured with the ClearPoint® Neuro Stylet device. If there are any additional devices that may be used for any current or future procedures, specify them in the system configuration settings.

### > To configure the list of insertable devices

1. Launch the application
2. From the Splash Screen, click the  button.
3. A floating window with 3 distinct tabs will appear, providing you with the ability to modify the configurable settings for the system.

- Select the **DEVICES** tab to modify the list of devices that will be used with the system.



- To add a new device that may be inserted using the system, click on the  button.
- Specify a name for the device in the **Device Type** field.
- Specify the total rigid length of the device in the **Total Length** field. This value is used by the application to check whether, for a given trajectory path, the device will physically fit within the bore of the scanner.
- Specify the insertable length of the device in the **Insertable Length** field. This length represents the portion of the device that is actually insertable into the patient. If a portion of the total device length cannot be inserted into the patient, do not include that portion in the value specified.
- You may remove a device by clicking on the  button.
- Select **Apply** to save the changes made.

---

**WARNING:** Ensure that the list of configurable devices is always up to date. Re-visit the list of configurable devices on a regular basis to ensure that it reflects the up-to-date list of devices that are being used in combination with the ClearPoint Array™ System for neurological procedures performed at your site.

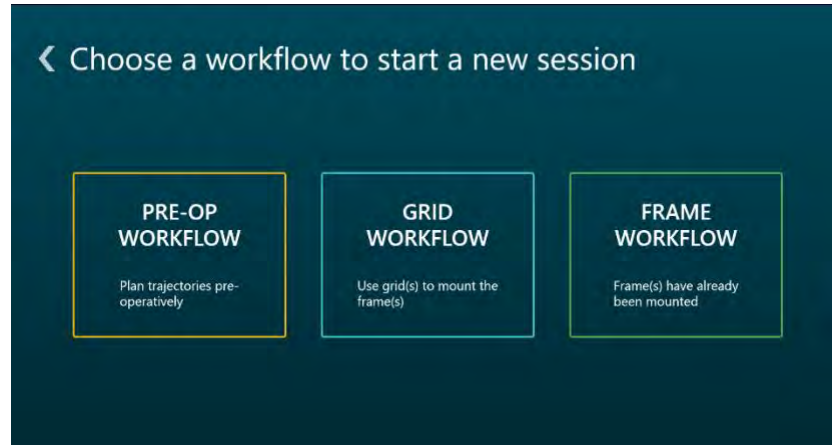
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## Starting a New Session

In order to start a neurological procedure using the ClearPoint Array™ Workstation, ensure that the patient is prepared for surgery, the surgical field inside the MRI Suite has been set-up, and that the patient has been positioned appropriately on the MRI scanner table. The Splash Screen can then be used to start a new procedure, using the Pre-Op Workflow (see [Pre-Op Workflow Pg. 34](#)), Grid Workflow (see [Grid Workflow Pg. 36](#)) or Frame Workflow (see [Frame Workflow Pg. 40](#)).

### > To start a new session

1. From the Splash Screen select **START NEW SESSION**.
2. A new page on the Splash Screen will appear, presenting you with the workflow options available to start a new session.



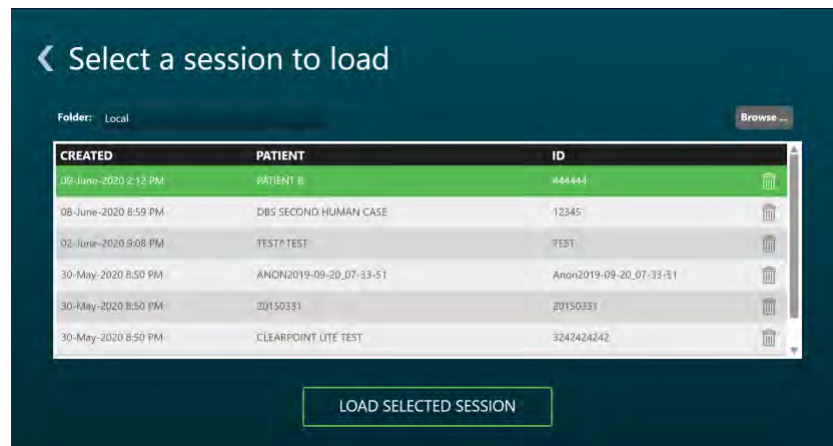
3. Select **PRE-OP WORKFLOW** to start a Pre-Op Workflow (see [Pre-Op Workflow Pg. 34](#)) for purposes of creating a presurgical plan prior to the neurological procedure.
4. Select **GRID WORKFLOW** to start a Grid Workflow (see [Grid Workflow Pg. 36](#)) with the intention of mounting one or more trajectory frames onto the patient inside the MRI Suite.
5. Select **FRAME WORKFLOW** to start a Frame Workflow (see [Frame Workflow Pg. 40](#)) with one or more trajectory frames already mounted to the patient.
6. If you do not wish to start a new session, but instead would like to load an existing session, modify system configuration settings, or shut down the application, click the  button to navigate back to the first page of the Splash Screen.


## Loading an Existing Session

The ClearPoint Array™ Workstation also allows you to load existing sessions that may have been fully or partially completed. You may choose to load existing sessions to review procedures that have already been completed or continue a procedure that has not been completed.

### > To load a session

1. From the Splash Screen select **LOAD EXISTING SESSION**.
2. A new page on the Splash Screen will appear, presenting you with a list of sessions currently saved on the workstation.



3. Choose the session that you wish to load from the list of sessions shown. If the session that you wish to load is not shown in the list of session, select **Browse...** to select a location where the session can be loaded from.
4. Select **LOAD SELECTED SESSION** to load the session selected in the window.
5. If you do not wish to load an existing session, but instead would like to start a new session, modify system configuration settings or shut down the application, click the  button to navigate back to the first page of the Splash Screen.



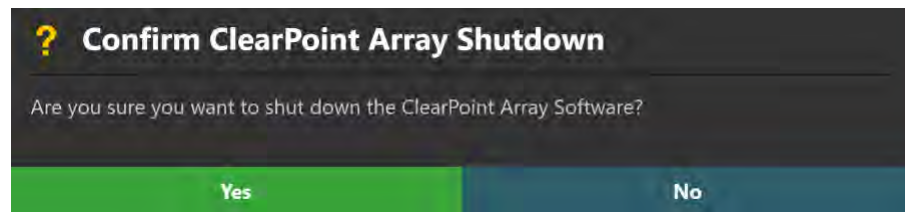
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## Shutdown and Exit

Exiting the application indicates that you have completed the neurological procedure and are finished working with the ClearPoint Array™ Workstation.

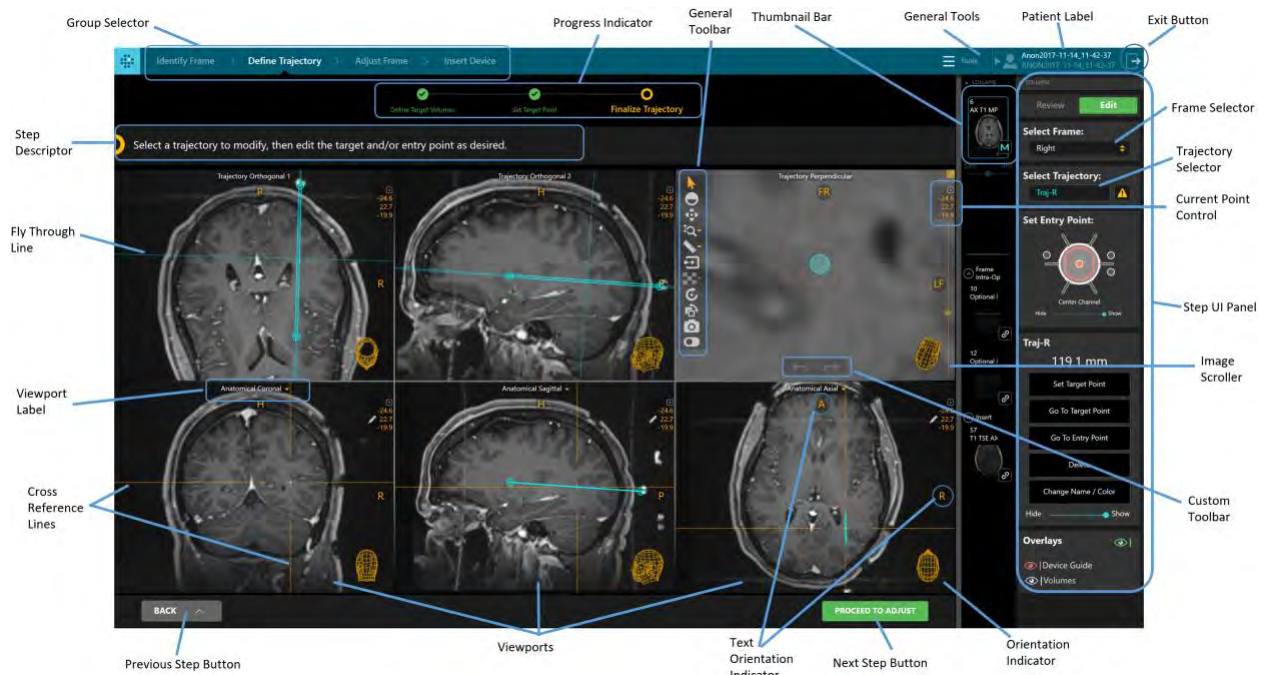
> **To exit the application**

1. Select the button from the far right hand corner of the main application window or from the Splash Screen (see [Launching the Splash Screen Pg. 47](#)).
2. A floating window will prompt you prior to shutting down the application. Select **Yes** to proceed with the shut down, or alternatively, select **No** to keep the application running.

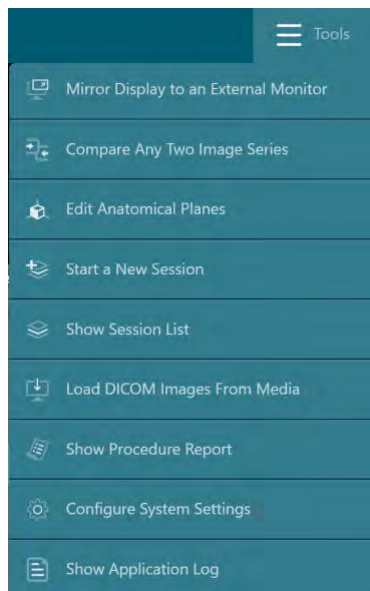


# Application Overview

This section describes the general features of the application which consist of the Group Selector, the Progress Indicator, the Step Descriptor, the Step Selector, set of top-level tools, the Patient Label, the Thumbnail Bar, viewport-specific tools, annotation-specific tools, and step-specific controls.



## Top-Level Tools



The application has the following top-level tools:

- **Mirror Display to an External Monitor** – Clones the current application window onto the MRI-compatible in-room computer monitor, without compromising the display resolution of the workstation. If a dialog window is being shown it will be cloned instead of the application window, and scaled to fill the in-room monitor to ensure readability. This functionality can be toggled on or off as needed (see [Mirroring the External Monitor Pg. 60](#)).
- **Compare Any Two Image Series** – Launches the Compare Images task window, which allows you to compare any two loaded image series, side-by-side in different viewing orientations (see [Compare Task Comparing Images Pg. 229](#)).
- **Edit Anatomical Planes** – Launches the Edit Anatomical Planes task window, which allows you to review and modify the **Anatomical** viewing orientation used throughout the application in different viewing layouts (see [Edit Anatomical Planes Task Changing Anatomical Planes Pg. 226](#)).
- **Start a New Session** – Allows you to begin a new software session by choosing a workflow: a Pre-Op Workflow, a Grid Workflow or a Frame Workflow (see [Using the Start New Session Window Pg. 61](#)).
- **Show Session List** – Allows you to manage the list of software sessions stored on the workstation (see [Using the Session List Window Pg. 62](#)). Specifically, you can:

- Load an existing session from the workstation
  - Remove an existing session from the workstation
  - Export an existing session from the workstation to an alternate file location
- **Load DICOM Images From Media** – Launches an interactive media browser window which allows you to load images into the current session. Loaded files must be encoded in the DICOM format in order to be recognized. Only images with a modality type of MR and CT are supported; all other modality types are restricted from being loaded onto the workstation (see [Using the DICOM Media Browser Pg. 64](#)).
  - **Show Procedure Report** – Generates and displays the current procedure report in a separate window. You can use the procedure report to review detailed information about the procedure, including all relevant coordinate values, software session properties, system information, and any screen captures taken during the procedure (see [Using the Procedure Report Window Pg. 65](#)).
  - **Configure System Settings** – Launches an interactive window that allows you to change system and user-specific settings on the workstation (see [Configuring System and Device Settings Pg. 66](#)). These settings are divided into 3 separate groupings:
    - System – scanner bore size & manufacturer, system licensing information
    - DICOM – system application entity (AE) title & port number, remote network information for pinging an external entity
    - Device – list of devices configured for use on the workstation, where each of the following device-specific parameters are specified: device type, total rigid length of device and device length portion that can be inserted into the frame.
  - **Show Application Log** – Displays the contents of the application log file in a separate window. The log file contains information such as: all error/warning messages, informational reminders and verbose debugging trace statements. You can use this tool to assist with analyzing problems or issues that may arise during the course of a procedure (see [Using the Application Log Window Pg. 70](#)).

## Mirroring the External Monitor

If a **MR Conditional** external monitor has been connected to the workstation, you can mirror the current workstation display onto the external monitor during the procedure.

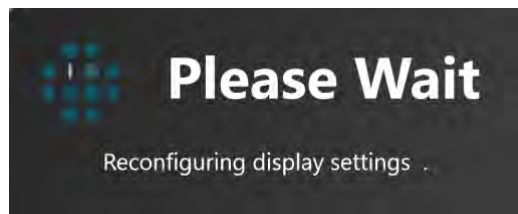
---

*Mirroring the workstation display onto an in-room external monitor will retain the display resolution of the workstation. No additional actions are required to modify the display resolution of either the workstation monitor or the external monitor prior to using this feature.*

---

> **To mirror the workstation display on an external monitor**

1. Connect the external monitor to the workstation
2. If the workstation software is currently running, a floating window will display a **Please Wait** message and the user interface will be blurred until the external monitor is detected.



3. Select **Mirror Display to an External Monitor** from the list of top-level tools.

> **To turn off mirroring of an external monitor**

Select **Remove Display from an External Monitor** from the list of top-level tools.

## Using the Start New Session Window

The Start New Session Window allows you to start a new software session with one already loaded.

> **To start a new session**

1. Select **Start a New Session** from the list of top-level tools.
2. A floating window will appear, prompting you to choose a workflow which you would like to use to start a new session.



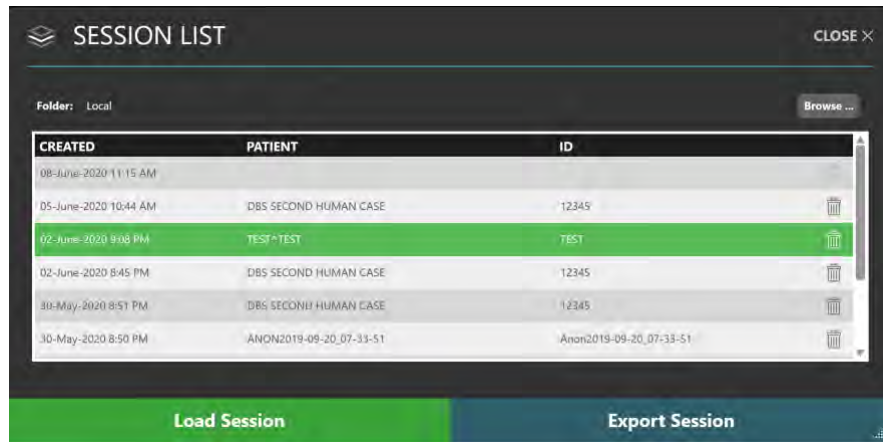
3. If you wish to cancel the session creation and leave the current session loaded, select **Cancel** or **CLOSE** to dismiss the floating window.
4. Otherwise, if you wish to create a new session:
  - Select **PRE-OP WORKFLOW** to start a new session using the Pre-Op Workflow (see [Pre-Op Workflow Pg. 109](#))
  - Select **GRID WORKFLOW** to start a new session using the Grid Workflow (see [Grid Workflow Pg. 129](#)).
  - Select **FRAME WORKFLOW** to start a new session using the Frame Workflow (see [Frame Workflow Pg. 151](#)).

## Using the Session List Window

The Session List Window allows you to manage software sessions stored on the workstation.

### > To load an existing session

1. Select **Show Session List** from the list of top-level tools.
2. A floating window will appear showing the list of sessions stored on the workstation.
3. Choose the session that you wish to load from the list of sessions shown. If the session that you wish to load is not shown in the list of sessions, select **Browse...** to select a location where the session can be loaded from.



4. Select **Load Session** to load the session selected in the window.

> **To export a session**

1. Select **Show Session List** from the list of top-level tools.
2. A floating window will appear showing the list of sessions stored on the workstation.
3. Choose the session that you wish to export from the list of sessions shown.
4. Select **Export Session**.
5. Browse to a location where you would like the selected session to be exported.
6. Select **OK**. The session will be exported in anonymized format to the selected location.


---

*Whenever a session is exported, the patient name and ID within the session will be replaced with the date/time stamp of the start of the procedure. For all DICOM images associated with the session, any header fields that contain protected health information (PHI) will be blanked out in the physical DICOM image files. This ensures that session data can be shared without the risk of PHI exposure.*

---

> **To delete a session**

1. Select **Show Session List** from the list of top-level tools.
2. A floating window will appear showing the list of sessions stored on the workstation.
3. Choose the session that you wish to delete from the list of sessions presented.

4. Click the  button.
5. Select **Yes** to confirm removal of the session.

---

*The application prevents you from deleting the session that is currently loaded. If you wish to delete the session that is currently loaded, load another session and then open the Session List Window again to remove the session of interest.*

---

## Using the DICOM Media Browser

To load images onto the workstation, you can either push images through a DICOM network connection or load images from DICOM media.

### > To load images from media

1. Select **Load DICOM Images From Media** from the list of top-level tools.
2. A floating window will appear prompting you to browse to a directory containing one or more image series.
3. Select **Browse** within the window.
4. Navigate to a directory containing one or more image series.




---

*If you select a media device with a large amount of DICOM images there can be a delay while reading the data. Images saved to media from a scanner is usually saved with a DICOMDIR directory file which optimizes reading of the image files and*



therefore should prevent this delay. If image loading is taking too long, you can cancel the operation and simply select a specific sub-folder containing just the data of interest.

5. Select one or more image series to load by ticking the checkbox beside each description corresponding to the image series that you wish to load. You may preview the image series by hovering the mouse over the series description.
6. Select **Load** at the bottom of the window to load the images into the application.

## Using the Procedure Report Window

When you open the Procedure Report Window, the application automatically generates a procedure report and displays it for review purposes. The report includes detailed information about the procedure, including all relevant coordinates, session information, patient information, trajectory and corresponding device placement coordinates, volume of interest measurements, and links to any screen captures taken during the procedure.

The screenshot shows the 'Procedure Report' window with the following data:

Patient Information				System Information		
ID:	ANON2017-11-14_11-42-37			Software Version:	1.0.0.0	
Name:	ANON2017-11-14_11-42-37			Station Name:	SFC-IMDMRSKYRA3	
Gender:	D			Scanner Manufacturer:	SIEMENS	
Birth Date:	No Data Available			Scanner Model:	Siyra	
Age:	No Data Available			Scanner Bore Size:	70 cm	
Physician:	No Data Available			License:	Clinical-use license installed	
Organization:	VAMCSP					

Trajectories					
Name	Frame	Target	Entry	Angles	
				Coronal	Sagittal
Traj-L	Left	[21.5, -43.1, -34.2]	[47.2, 68.9, -0.1]	85.4 °	71.8 °
Traj-R	Right	[24.4, -27.7, -29.8]	[24.8, 79.2, -13.4]	82.8 °	-159.0 °

Volumes			
Target Volume	Treatment Volume	Size	Overlap with Target Volume

### > To review the report

1. Select **Show Procedure Report** from the list of top-level tools.
2. A floating window will display the procedure report using a single continuous page by default. The following report tools will be displayed at the bottom of the window:



3. Use the following controls to change the layout of the report:
  - Two-Page Mode – Select this mode to display the report with two pages at a time. Use the pagination controls to navigate through the report.
  - Scroll Mode – Select this mode to display the report in a single continuous page. Use the scrollbar to navigate through the report.
4. To review any screen captures taken during the procedure, navigate to the **Screenshots** section of the report. Select **Click here to view screenshots** to see the file folder location where all of the screen captures associated with the report are stored. Individual screen capture images can be reviewed within the file explorer window shown.

#### > To save the report

1. Select **Show Procedure Report** from the list of top-level tools
2. A floating window will display the report using a single continuous page by default.
3. Select **Save** to save a copy of the currently displayed report. The latest report will always be saved using the filename **Report.xps** and any previous copy is renamed with a unique timestamp based file name. This allows for multiple copies of the report to be saved at different time intervals throughout the procedure.

---


*The application generates two versions of the report when saved: a full version that includes patient information and an anonymous version that can be distributed without compromising patient confidentiality. Both versions are saved as individual files in the report folder corresponding to the session.*

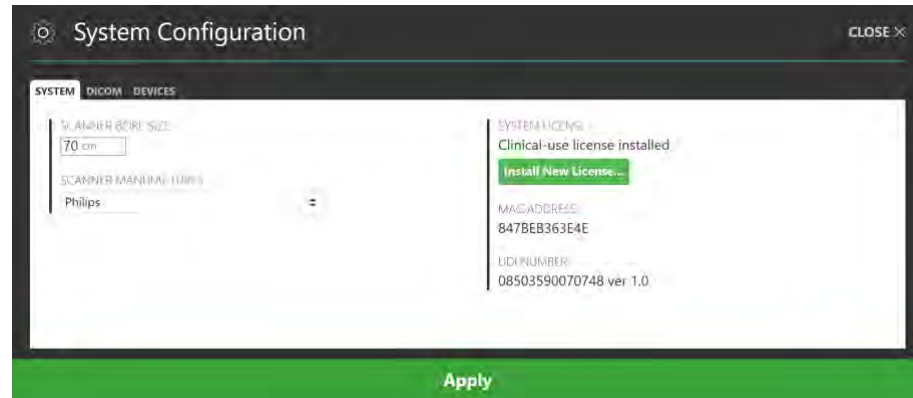
---

## Configuring System and Device Settings

You may configure the system settings and list of devices to be used with the workstation using the System Configuration Window at any time during program execution.

> **To modify system settings**

1. Select **Configure System Settings** from the list of top-level tools. If you are running the software for the first time, you may click on the  button from the Splash Screen (see [Launching the Splash Screen Pg. 47](#)).
2. A floating window with 3 distinct tabs will appear, providing you with the ability to modify the configurable settings for the system.
3. Select the **SYSTEM** tab to modify the system settings.




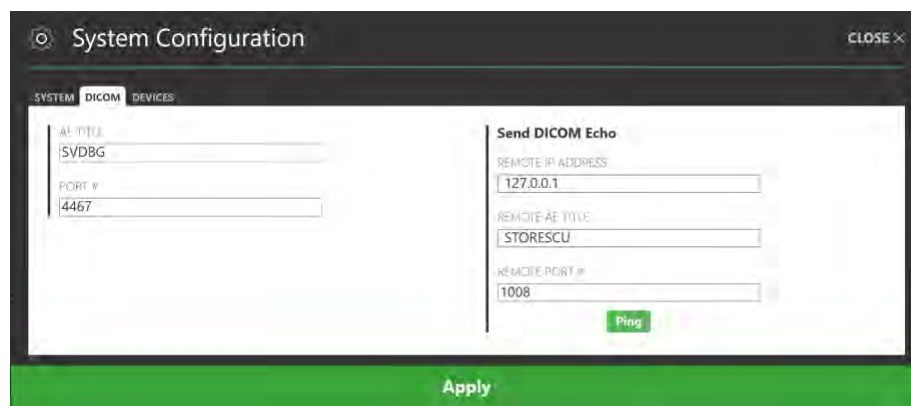
4. Modify the following fields, if necessary:
  - **Scanner Bore Size** – Modify the diameter of the scanner bore in centimeters. The application uses this value along with the total length of each of the configured devices to ensure that for a given planned trajectory path, any of the configured devices can be physically inserted into the SMARTFrame Array™ without being obstructed by the scanner's bore.
  - **Scanner Manufacturer** – Choose an option from the list which represents the manufacturer of the scanner to which the workstation is connected. For Siemens scanners, indicate whether or not the scanner resides in an IMRIS Surgical Suite (see [Important Notes for Using Siemens Scanners Pg. 30](#)). For GE scanners, specify the number of slices to use for the orthogonal targeting stem scans.
5. Select **Apply** to save the changes made.
6. To install a new system license, select **Install New License...** and browse to a location that contains a valid license file (see [Installing a System License Pg. 52](#)).

In order for the ClearPoint Array™ Workstation to receive DICOM images transferred from an image source such as a scanner or PACS, that system will

need to be configured with the AE Title and Port Number configured in the application. See [Configuring the DICOM Connectivity Settings Pg. 50](#) for additional details.

> **To modify DICOM connectivity settings**


1. Select **Configure System Settings** from the list of top-level tools. If you are running the software for the first time, you may click on the  button from the Splash Screen (see [Launching the Splash Screen Pg. 47](#)).
2. A floating window with 3 distinct tabs will appear, providing you with the ability to modify the configurable settings for the system.
3. Select the **DICOM** tab to modify the DICOM settings for the system.

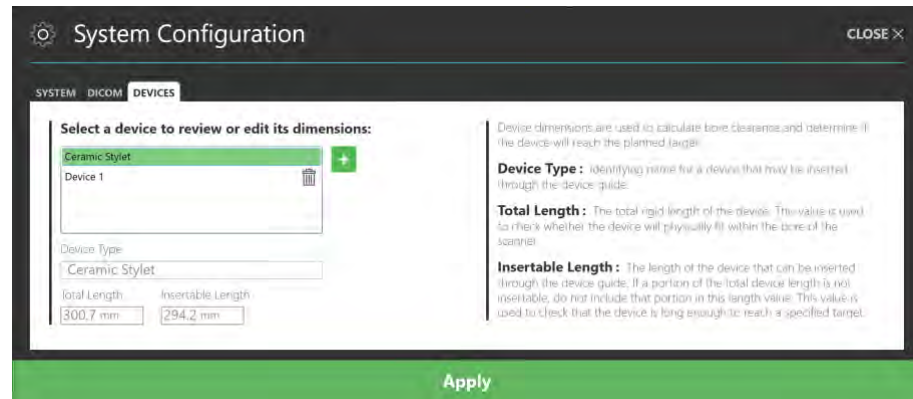




The screenshot shows the 'System Configuration' window with the 'DICOM' tab selected. The 'AE TITLE' field contains 'SVDBG' and the 'PORT #' field contains '4467'. On the right, the 'Send DICOM Echo' section has 'REMOTE IP ADDRESS' set to '127.0.0.1', 'REMOTE AE TITLE' set to 'STORESCU', and 'REMOTE PORT #' set to '1008'. A green 'Ping' button is located below these fields. A green 'Apply' button is at the bottom of the window.

4. Modify the following fields, if necessary:
  - AE Title – Specify the Application Entity Title of the ClearPoint Array™ Workstation. The intraoperative scanner uses this information to establish an end point of DICOM information exchange with the workstation.
  - Port Number – Indicate the port number over which DICOM information will be exchanged between the intraoperative scanner and the ClearPoint Array™ Workstation.
5. Select **Apply** to save the changes made.
6. You may use the **Ping** button to test DICOM connectivity with the intraoperative scanner. The entity node information (IP Address, Remote AE Title and Remote Port Number) of the scanner will need to be specified prior to testing the workstation's remote DICOM connectivity to it. If images have previously been sent to the workstation successfully, only the port number will be blank and will need to be entered. Otherwise if data has not yet been sent from the scanner, you will need to enter all three values. See [Configuring the DICOM Connectivity Settings Pg. 50](#) for additional details.

> **To modify the list of devices**

1. Select **Configure System Settings** from the list of top-level tools. If you are running the software for the first time, you may click on the  button from the Splash Screen (see [Launching the Splash Screen Pg. 47](#)).
2. A floating window with 3 distinct tabs will appear, providing you with the ability to modify the configurable settings for the system.
3. Select the **DEVICES** tab to modify the list of devices that will be used with the system.



4. For each listed device, you may modify the following fields, if necessary:
  - **Total Length** – The total rigid length of the device to be inserted into the brain. This value is used by the application to check whether the device will physically fit within the scanner bore during insertion.
  - **Insertable Length** – The length of the device that can be inserted through the device guide into the brain. If a portion of the total device length is not insertable, do not include that portion in this length value. This value is used to check that the device is long enough to reach a specified target.
5. You may add a new device by clicking on the  button. Adding a new device requires that the **Total Length** and **Insertable Length** values are specified in the corresponding fields in order to be saved.
6. You may remove a device by clicking on the  button.
7. Select **Apply** to save the changes made.

---

*Note that the ClearPoint® Neuro Stylet (**Ceramic Stylet**) device has been pre-configured with the workstation. Therefore, it cannot be removed and its corresponding **Total Length** and **Insertable Length** values cannot be modified.*

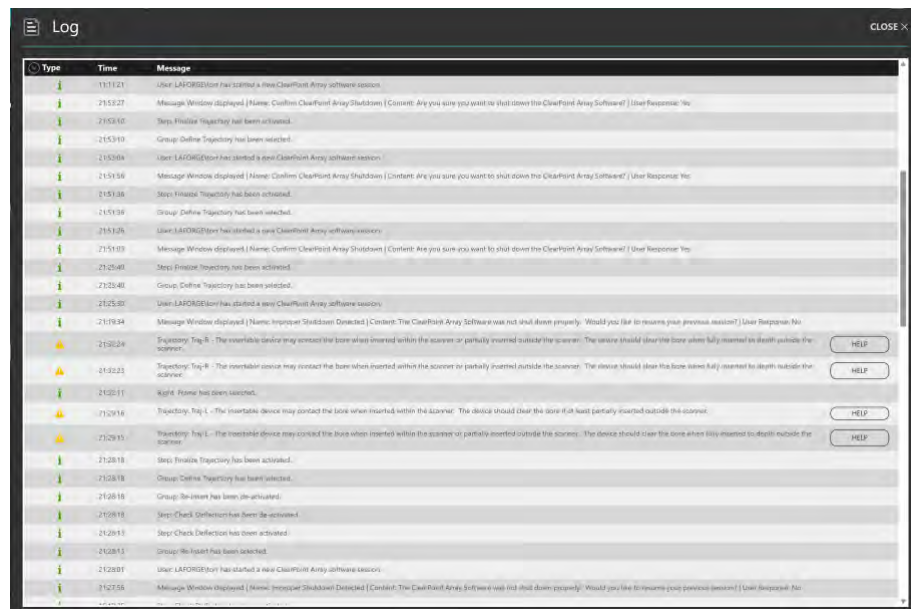
---

## Using the Application Log Window

The Application Log Window allows you to review the contents of the application log file at any time during program execution.

### > To review the log

1. Select **Log** from the list of top-level tools
2. A floating window will appear displaying the log content for the application.



3. Click on the collapsible button beside the **Type** column to filter messages by type: **Information**, **Warning**, **Error**, **Debug**.

---

*By default, the log message filter does not show **Debug** messages due to the fact that there are many messages of this type that are logged throughout program execution. To see **Debug** messages, you must explicitly modify the filter to show them.*

---

4. For messages of type **Warning**, select **HELP** to view more information on the specific message displayed.

## Using the Workflow-Specific Controls

There are several user interface controls that allow you to navigate through the procedure workflow.

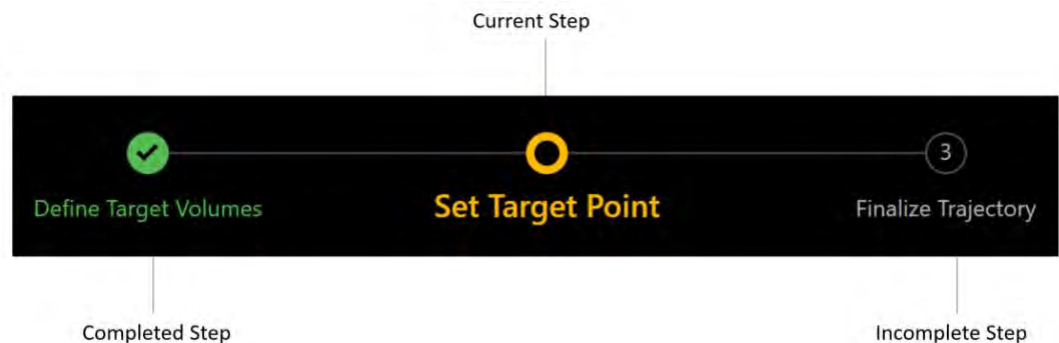
### Selecting a Group

The Group Selector displays a grouping of steps that can be used to complete a neurological procedure. It also indicates which step grouping is currently being worked on. At any time, you can click the desired button to change the currently selected group. Doing so will activate the currently selected step within that group. For an overview of the workflow groups, see [Procedure Workflow Pg. 34](#).



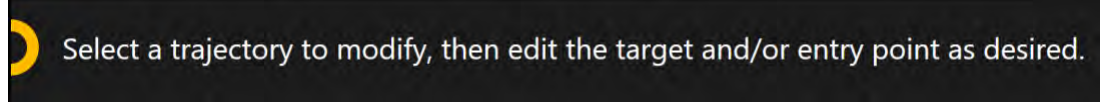
### Workflow Progress Indicator

The Workflow Progress Indicator provides you with an indication of where you are currently positioned in the procedure workflow. It displays the complete list of steps contained within the currently selected group, and also which step is currently selected. Those steps that have been completed as well as those that still require completion are also appropriately indicated. For details on how steps within the workflow are divided into groups, see [Procedure Workflow Pg. 34](#).



## Step Guidance

Each step provides you with instructions on how to complete the work associated within the step. These instructions are displayed in the guidance area portion of the user interface. The content in the guidance area will be updated each time the currently active step changes.

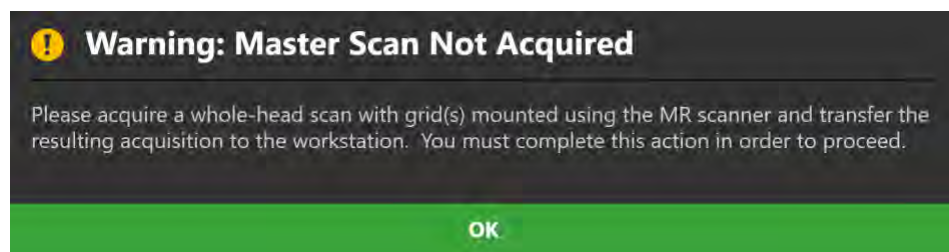


## Selecting a Step

The Step Selector allows you to navigate between steps in the workflow, one at a time. Depending on the step, one or more options for proceeding forward in the workflow will be presented. You may move forward in the workflow by clicking on any one of the *Green* buttons shown in the Step Selector. You may also navigate backwards in the workflow using the *Gray* button, in order to revisit steps that have already been completed. When navigating backwards in the workflow, you may choose to either activate the last completed step or alternatively, use the menu to activate any of the previously completed steps in the currently selected group.



*If you attempt to move on in the workflow to the next step and the criteria for completing the currently selected step has not been realized, you will be prevented from moving on in the workflow. In these cases, the application will present a warning message indicating the actions that must be completed in order to satisfy the completion criteria for the step. For example, the following warning is presented to the user if they attempt to move past the Acquire Master step without transferring a master scan to the application:*






---

## Using the Patient Label



The Patient Label displays information about the patient that is currently being treated. The application reads this information from the DICOM images received by the workstation.



### > To review patient information

1. Hover your mouse over the  icon.
2. A tool-tip will appear providing additional information about the patient, including, date of birth, sex, and age.

### > To show/hide patient information

1. Click on the  icon to hide patient information.
2. Click on the  icon to show patient information.

---

*Sometimes, there may be discrepancies in the patient's name and/or identification number in images received by the scanner. If this scenario arises, the application will prompt you to confirm the patient information associated with the newly received images from the scanner. This is an important fail-safe to ensure that images loaded into the application match the patient currently being treated.*

---

### > To handle patient information discrepancies

1. Observe the **Expected** and **Received** values for both patient name and identification number in the **Validate Patient Identification** window.

**⚠ Validate Patient Identification**

The data being loaded does not match current patient information. Please review identification and then accept or reject the new data.

	Expected	Received
Patient Name:	DBS SECOND HUMAN CASE	20140205
Patient ID:	12345	20140205

If accepted, update the Patient Name / ID to the Received values.

Accept
Reject

2. Determine if the images just received by the workstation match the patient currently being treated.
3. If the images received match the current patient, select **Accept**. If you wish to have the patient name and identification label of the incoming images shown in the Patient Label, tick the **If accepted, update the Patient Name / ID to the Received values** checkbox. Otherwise, untick this checkbox. The images will be loaded into the application, and depending on whether or not the checkbox was ticked, the Patient Label may be updated.
4. If the images received do not correspond to the current patient being treated, select **Reject**. The images just received will be rejected by the workstation and will not be loaded.

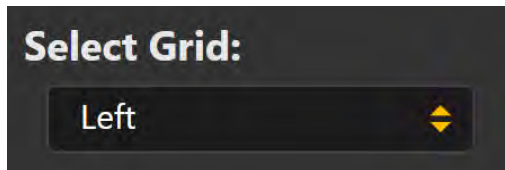
---

## Using the Step-Specific Controls

Each step contains specific user interface controls that may be presented depending on their position in the workflow.

### Selecting a Grid

Some steps in the Grid Workflow (see [Grid Workflow Pg. 129](#)) provide a Grid Selector to allow you to select the marking grid that you would like to work on. For procedures where only one marking grid is affixed to the patient, the Grid Selector will contain one entry that is always selected. For those procedures involving two or more marking grids affixed to the patient, you may use the Grid Selector to select a marking grid that you wish to work on.



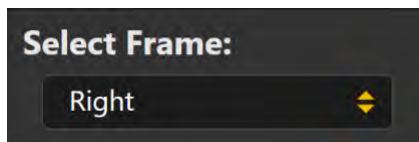

---

*The application only supports defining 3 marking grids on each side of the patient's head. Affixing any more than 3 marking grids per side of the patient's head is not advised and is therefore not supported by the application.*

---

## Selecting a Frame

There are some steps in the Frame Workflow (see [Frame Workflow Pg. 151](#)) that provide a Frame Selector which allow you to select a trajectory frame that you would like to work on. For procedures involving only one trajectory frame mounted on the patient, the Frame Selector will contain one entry that is always selected. For those procedures involving two or more trajectory frames that are mounted on the patient, you can use the Frame Selector to select the frame that you wish to work on.



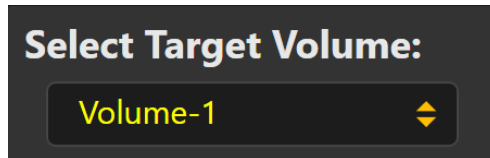
## Selecting a Trajectory

Some steps in the procedure workflow provide a Trajectory Selector which allow you to select a trajectory path that you wish to work on. In the Grid Workflow, entries within the Trajectory Selector are filtered based on the currently selected marking grid (see [Selecting a Grid Pg. 74](#)). In the Frame Workflow, entries are filtered on the currently selected frame (see [Selecting a Frame Pg. 75](#)). You may also display the device clearance and reach information associated with the currently selected trajectory (see [Working with Trajectory Annotations Pg. 99](#) for details).



## Selecting a Volume of Interest

There are some steps that provide a Volume Selector to change the volume of interest (VOI) that you would like to work on. The Volume Selector allows you to change the currently selected VOI in steps that allow for volume editing and associated review.




## Selecting a Guide Channel

Some steps provide you with the ability to select a guide channel during trajectory planning and/or trajectory frame adjustment. The Guide Channel Selector presents you with 7 different guide channels options that you can use to insert a device into the brain. During trajectory planning, selecting a different guide channel allows you to offset the entry point of the currently selected trajectory such that it aligns with the channel corresponding to the selection. During the frame adjustment process, selecting a different guide channel can be used to select a new trajectory path which more suitably aligns with the planned trajectory and/or reduces the number of frame adjustments required. In either case, selecting a guide channel will result in angular adjustments being prescribed such that the selected channel is aligned with the desired target point.

Selecting a guide channel can be achieved using the Guide Channel Selector, which allows selection of any available guide channel as well as review and display of the selection made prior to device insertion.



## Showing / Hiding Annotations

A general mechanism of showing or hiding all annotation overlays displayed within a step can be achieved using the Annotation Overlays control. Clicking on the  icon.

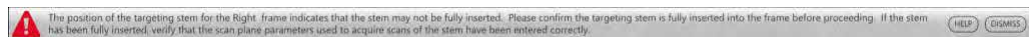
toggle button allows you to hide or show all annotations overlays configured for display in a given step. Some steps provide the ability to show or hide individual annotations or associated annotation groupings using toggle buttons instantiated within the Annotation Overlays control.




---

## Status Messages

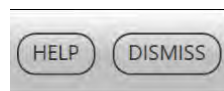
Status messages appear just below the top banner in the main application window, as well as within windows displaying workflow tasks. These messages indicate important warning or error conditions that may arise throughout the course of the neurological procedure. You should always take the time to read and pay attention to any status messages displayed by the application.



Any time a status message is presented, you have the option of bringing up troubleshooting tips which can help you to resolve the problem(s) encountered. To see a list of all troubleshooting tips provided by the application see [Troubleshooting Pg. 244](#).

### > To bring up troubleshooting tips for a warning message

1. Select the **HELP** button from the status message area.



2. A window will appear containing additional information about the status message presented, including troubleshooting tips and/or details concerning any downstream workflow implications. The window may also contain links to other help information topics that are associated with the status message just read.

### Targeting Stem May Not Be Fully Inserted CLOSE X

The ClearPoint Array Workstation has detected that the selected frame's targeting stem may not be fully inserted into the frame. The targeting stem must be fully inserted to the frame after the frame has been mounted onto the patient and should remain that way until device insertion. **Failure to do so can result in an insertion that is deeper than planned.**

**Can be caused by:**

- The targeting stem not entirely being inserted into the frame.
- Image Distortion and/or artifacts in the images used to detect the position of the frame markers and/or the targeting stem. This may result in the software detecting a position for the bottom portion of the frame's targeting stem which makes it appear as though the stem is not fully inserted, even though it is. (For other causes see also [Targeting Stem Appears Out of Position](#)).

**Consequences of selected frame's stem not fully inserted:**

- The software uses the stem position to compute insertion depth values. If the targeting stem is not fully inserted into the frame at the time when scans of the targeting stem are acquired during the frame adjustment process, then the depth value computed will be incorrect.
- If the stem is confirmed as being fully inserted despite the message, this may indicate that there is error in the detected position of the targeting stem relative to the frame base markers. The consequence could be increased placement error if not corrected.

**Recovery:**

- If the cause for this warning was due to the stem being not fully inserted, ensure that it is correctly inserted and then acquire at least one more pair of orthogonal scans of the stem before proceeding with the device insertion. This will ensure that the computed depth value is based on the stem being fully inserted.
- If the targeting stem is properly inserted and you are still receiving this warning, ensure that you check both the pulse sequence and associated scan plane parameters to ensure that all values are being inputted correctly at the scanner console. Ensure that 3D distortion correction for this pulse sequence is turned on. Review your frame marker positions in the Verify Frame Base Markers step. If you continue to see this warning after ensuring that all scan plane parameters have been entered correctly, then image distortion is most likely the cause so please proceed with caution.


See also: [Targeting Stem Appears Out of Position](#)

Once you have read the status message and thoroughly understand the reason for its display, you may opt to dismiss it so that it no longer appears in the user interface. If multiple status messages are presented at any given time, you may opt to dismiss each message individually or the entire set at one time, in groups of 5 messages at a time.

> **To dismiss a status message**

1. Select the **DISMISS** button from the status message area.



- Alternatively, click the  button and select **DISMISS ALL** to dismiss all messages currently displayed, up to a maximum of 5 messages at a time.

---

## Using Thumbnails

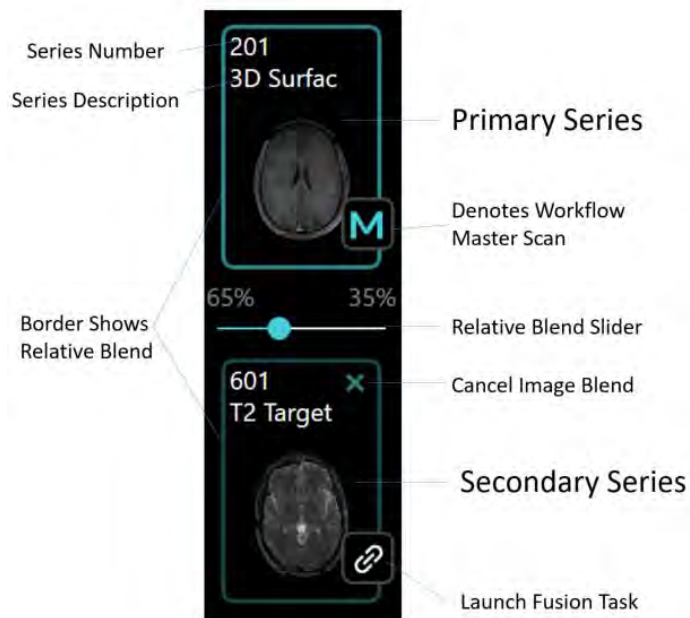
The step user interface provides you with the ability to change the images that are being displayed in the viewing layouts. Each image series is represented as a thumbnail image in the Thumbnail Bar. Thumbnail images are further organized into groups based on where in the workflow they were acquired or loaded. Thumbnail groups can be expanded and collapsed, and within each group the thumbnail images are ordered by oldest to newest acquisition time.

Some steps allow you to select two series to display in the viewing layout, as a blend between the two image sets. The primary image series is displayed as the top-most thumbnail within the Thumbnail Bar and is always displayed in the viewing layout. The secondary image series is displayed as a child thumbnail under the top-most thumbnail, and will be blended with the primary series in the viewing layout. The application uses the border around the two thumbnails to illustrate which two series are currently being displayed and their relative contribution to the blended output image shown in the viewports. A slider bar indicating the relative weighting of the two blended series can also be used to change the blend of the displayed image.


---

*Hovering the mouse over a thumbnail will display a tooltip containing additional information about the image series being represented.*

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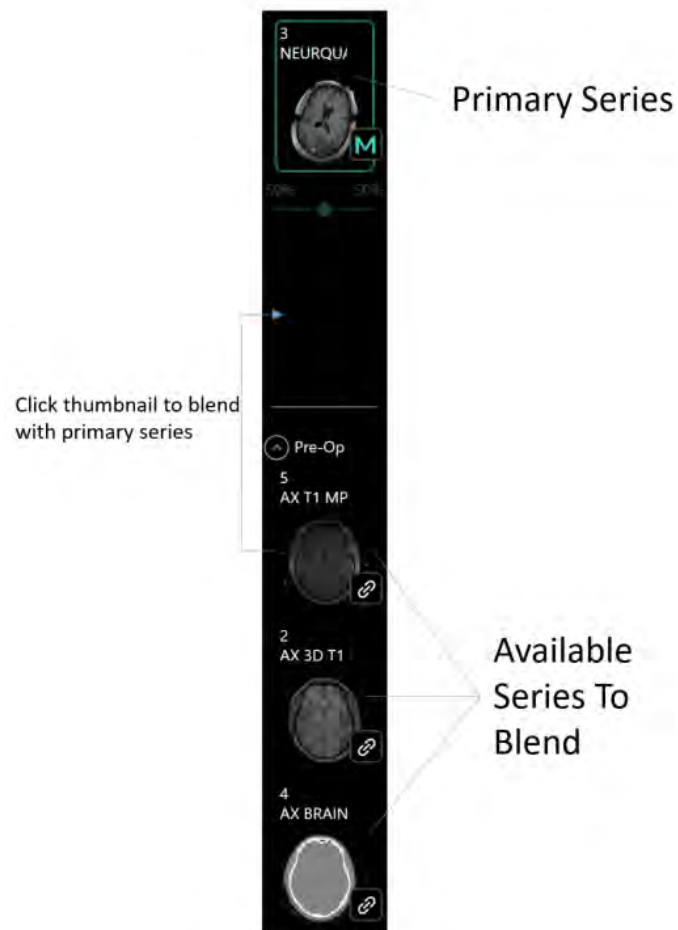
---

You may launch the Fusion Task through the Thumbnail Bar by clicking on the  button in any image thumbnail. This will allow you to make any changes to the fusion between the image series from the Thumbnail Bar and the workflow master series. See [Fusion Task Fusing Images Pg. 221](#) for details.

---

> **To blend two images**

1. From the grouping of available thumbnails, select one that you wish to blend with the primary image series.
2. Click on the selected thumbnail image.




3. The selected thumbnail will move to the secondary thumbnail slot on the Thumbnail Bar. The relative blend slider will be enabled.



4. The selected thumbnail will now have its corresponding image series blended with the primary series in the application viewports.

> **To cancel an image blend**

1. With an image series selected in the secondary thumbnail slot, click on the  icon.
2. The image series will no longer be blended with the primary series in the application viewports.

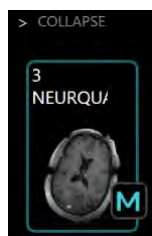
Some steps and tasks only provide image series selection capabilities, not blend-related ones. In these instances, only the primary image series is displayed as the top-most thumbnail, with all of the available thumbnails grouped below it. There is no secondary thumbnail slot, relative blend slider, or borders surrounding the thumbnails representing the relative image blend.

> **To change the primary series image**

1. From the grouping of available thumbnails, select one that you wish to display in the viewports.
2. Click on the selected thumbnail image.
3. Selected thumbnail will now have its corresponding image series displayed in the application viewports.

> **To collapse the entire thumbnail bar in the step panel**

Select > **COLLAPSE** from the area about the master thumbnail in the step panel.



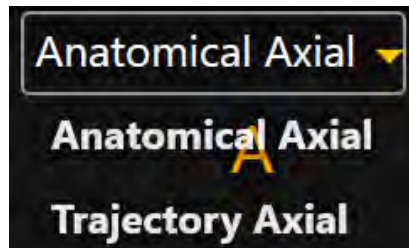
---

## Changing a Viewing Layout Orientation

The orientation of the viewing layout can be changed by selecting the drop-down located at the top-center of each viewport. The number of available options will be dependent on the step or task in which you are currently working. Changing this selection will change the orientation of the current viewport and any other viewports whose crosshairs are linked to the current one.

> **To change the viewing layout orientation**

1. Identify the viewport for which you would like to change the orientation.
2. Click on the orientation drop-down control at the top-center of the viewport.



3. After making a selection from the drop-down, the orientation of the current viewport and any other viewports whose crosshairs are linked to the current one will change.

---

## Using the Viewport Crosshairs

Some viewing layouts provide crosshair graphics (or cross reference lines) defining the intersection point between the coronal, sagittal and axial planes. The crosshairs are defined as follows:

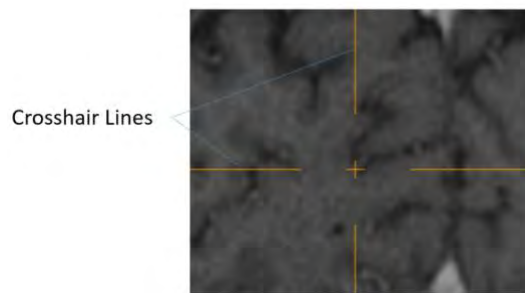
- Axial plane
  - Horizontal line represents intersection with the coronal plane.
  - Vertical line represents intersection with the sagittal plane.
- Sagittal plane
  - Horizontal line represents intersection with the axial plane.
  - Vertical line represents intersection with the coronal plane.

- Coronal plane
  - Horizontal line represents intersection with the axial plane.
  - Vertical line represents intersection with the sagittal plane.



The Current Point Control in the top right corner of each viewport shows the numeric location for the intersection point of the coronal, sagittal and axial planes in MR (DICOM) coordinates.



## Changing Crosshair Positions



### > To change a crosshair position

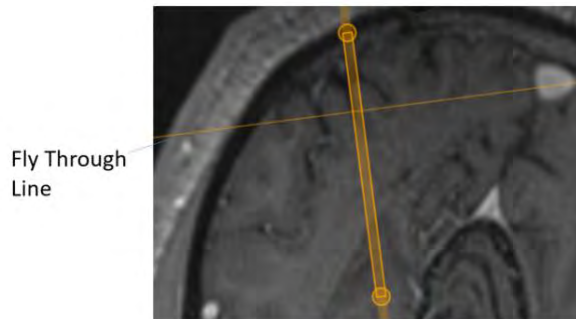
1. Select the Arrow tool (see [Arrow Tool Pg. 89](#)).
2. Do any of the following:
  - Double-click to reposition the crosshairs to a specific point on any viewport where the crosshairs are shown.
  - Drag any of the lines to adjust the position of the corresponding plane.
  - Drag the cross  at the center of the crosshairs in one viewport to change the two referenced perpendicular planes.
  - Use the mouse wheel to shift the plane of the current viewport perpendicular to its own view plane.
  - Modify the numeric values in the viewport's Current Point Control by clicking the  icon and editing the points manually. This can be

accomplished by typing in new values for one or more of the coordinate fields or using the +/- buttons to make incremental adjustments for each.

- Use the Fly Through Line to adjust the crosshair position along the specific direction of a line or plane (see [Fly Through Line Pg. 84](#)).
- Use the Image Scroller inset within each application viewport to scroll through the current viewport plane (see [Image Scroller Pg. 84](#)).

## Fly Through Line

Some viewing layout restrict modifying the crosshair position based on the direction of a line, such as a trajectory path. In these cases, the intersection point between the viewport planes is represented as a single Fly Through Line.



### > To change the fly through line position

1. Select the Arrow tool (see [Arrow Tool Pg. 89](#)).
2. Perform any of the following actions:
  - Drag the Fly Through Line in any viewports where it is displayed to adjust the position of the plane perpendicular to the line direction.
  - Use the mouse wheel scroll the Fly Through Line along the line direction.
  - Use the Image Scroller inset within each application viewport to scroll along the line direction (see [Image Scroller Pg. 84](#)).

## Image Scroller

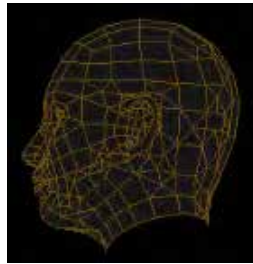
The Image Scroller allows you to scroll through images displayed in a given viewport using a slider control. It appears inset vertically within the right-hand side of the viewport that is currently under the mouse cursor.

- > **To scroll through images within a viewport**
  1. Hover the mouse over the viewport of interest.
  2. Click and drag the slider displayed on the right-hand side of the viewport.

---

## Using the Orientation Indicator

Each viewport provides the ability to display a three-dimensional model that visually portrays the orientation of the selected viewport. This three-dimensional model is a wire-frame representation of human head, whose orientation matches that of the selected viewport.



- > **To turn the orientation indicator on/off**

Change the orientation indicator visibility via the Show / Hide Orientation tool (see [Show/Hide Crosshairs, Annotations and Orientation Indicators Pg. 95](#)).

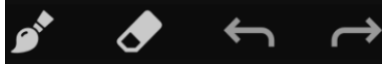
---

## Using the Toolbars

Within the application viewports, there are different toolbars that you can interact with: the General Toolbar and the Custom Toolbar. The General Toolbar exposes the main interactive viewport tools that can be used throughout the application. Custom Toolbars provide tools that are specific to the step or task currently activated.



orientated horizontally and positioned at the bottom of the viewport currently under the mouse cursor. Unlike the tools contained within the General Toolbar (see [Using the General Toolbar Pg. 86](#)), these tools are not accessible via the Popup Menu (see [Using the Popup Menu Pg. 87](#)), but may be contained within the Custom Toolbar or user interface panel specific to the step or task of interest. For details on the specific custom toolbars offered by each workflow step or task, refer to the corresponding section for each.



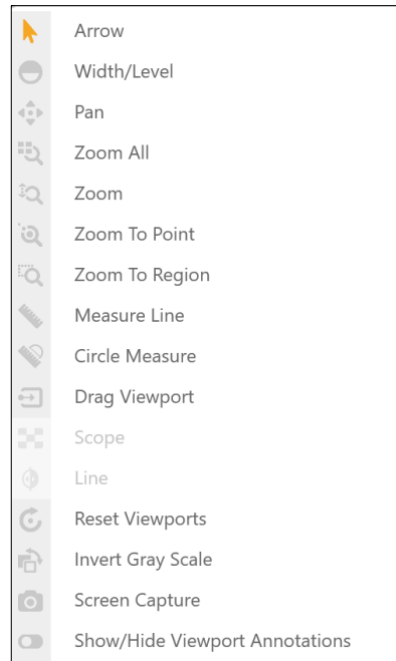
---

## Using the Popup Menu

The Popup Menu allows you to see the complete list of interactive tools that are available for a given application viewport, and subsequently, select one for use. To access the Popup Menu, right-click on an application viewport. You may then select a tool which you would like to use from the menu.

> **To use the popup menu**

1. Right-click any viewport and review the list of tools available for use.



2. Select the menu item that corresponds to the tool that you would like to use.



---

## Using Tool Hot Keys

In addition to the General Toolbar (see [Using the General Toolbar Pg. 86](#)) and the Popup Menu (see [Using the Popup Menu Pg. 87](#)), there is also a way to momentarily switch interactive tools using the keyboard.

With any tool selected for use, you can toggle to one of the most-commonly used tools by holding down a key on the keyboard. When you release the key, the tool automatically reverts to your previous selection.

The keyboard keys and their associated interactive tools are as follows:

Key	Interactive Tool
a	Default Arrow Tool
c	Measure Circle
l	Measure Line
p	Pan Tool
w	Width/Level Tool
z	Zoom All Tool

---

## Interactive Tools

The following tools are provided to manipulate the images shown in the application viewports.

---

*If you are using a mouse with a mouse wheel, you can rotate the mouse wheel to scroll through the images within a viewport.*

---

### Arrow Tool



Use the Arrow tool to move crosshairs and annotations within the viewports. It can also be used to rotate images displayed in volumetric (3D) viewports.

To select the **Arrow** tool, do one of the following:

- From the Toolbar, click the Arrow button.
- Right-click a viewport and click **Arrow**.

## Window Width and Level Tool



The window settings (i.e., window width and window level) on digital images are similar to the contrast and brightness, respectively, on your computer screen. The window width can be wide (many grays, less contrast) or narrow (fewer grays, more contrast). The window level can be high (dark) or low (bright).

To change the window settings

1. Do one of the following:
  - From the Toolbar, click the Width/Level button.
  - Right-click the desired viewport and click **Width/Level**.
2. Adjust the window width and/or level as follows:
  - Click and drag the mouse vertically over the selected image to adjust the window level.
  - Click and drag the mouse horizontally over the image to adjust the window width.

---

*When using the Width/Level tool with two image series that have been blended together, only the secondary series will be affected. To change the width/level for the primary series, you must un-blend the secondary series using the Thumbnail Bar so that no secondary series is selected. In that case, Width/Level changes will only be applied to the primary series. See [Using Thumbnails Pg. 79](#) for additional details.*

---

## Zoom Tools

There are four separate tools for changing the zoom level.



**Zoom**

1. Do one of the following:
  - From the Toolbar, click the Zoom button.
  - Right-click the desired viewport and click **Zoom**.
2. Click and drag the mouse vertically over the image and the zoom level will change just for that image.



### Zoom All

1. Do one of the following:
  - From the Toolbar, click the Zoom All button.
  - Right-click a viewport and click **Zoom All**.
2. Click and drag the mouse vertically over the image in any viewport. The images in the other viewports zoom in parallel with the selected image.



### Zoom To Region

1. Do one of the following:
  - From the Toolbar, click the Zoom To Region button.
  - Right-click the desired viewport and click **Zoom To Region**.
2. Click and drag the mouse over the image to select a rectangular region.
3. When you release the mouse button, the application zooms the viewport to show the selected region.



### Zoom to Point

1. Do one of the following:
  - From the Toolbar, click the Zoom To Point button.
  - Right-click the desired viewport and click **Zoom To Point**.

2. Click at a point of interest on the image and drag the mouse vertically. The application zooms about the selected point, automatically panning to ensure the initial point clicked remains on-screen.

## Pan Tool



**Pan an image within a viewport**

1. Do one of the following:
  - From the Toolbar, click the Pan button.
  - Right-click any viewport and click **Pan**.
2. Click and drag the image to change its position in the viewport.

## Invert Grayscale Tool



**Invert the image grayscale for a negative image display.**


1. Do one of the following:
  - From the Toolbar, click the Invert Gray Scale button.
  - Right-click any viewport and click **Invert Gray Scale**.
2. The application inverts the image grayscale for all current viewports.
3. You can click the button again to return to the original setting.

## Measure Line Tool



**Measure linear distances on an image**

1. Do one of the following:


- From the Toolbar, click the Measure Line button.
  - Right-click any viewport and click **Measure Line**.
2. Click and drag to draw a line across the span on the image to be measured. The tool will display the current length of the measure line as it is drawn.
  3. When you release the mouse button, the measure line and distance value will remain on-screen.
  4. Measure lines can be edited by clicking and dragging the end points using either the Measure tool or the default Arrow tool. The distance value will always be shown at the mid-point between the two end points.
  5. To delete measure lines, do one of the following:
    - Right-click on the measure line and select **Delete**
    - With the measure line selected, press the DELETE key on the workstation keyboard.
    - Drag the measure line over the  icon positioned in the bottom left corner of the currently selected viewport. This icon appears when you begin dragging the measure line.
  6. To move the measurement value from its default location along the measure line, click on the value and drag it away from its current position. If you move the measure line, the measurement value will remain at its position on screen and will not move along with the measure line. If you would like to return the value to its original position, drag it over top of the reticle icon positioned at the mid-point between the two measure line end points. In this position, the measurement value will move along with the measure line as it is moved.

## Circle Measure Tool



### Measure the diameter of a circle on an image

1. Do one of the following:
  - From the Toolbar, click the Circle Measure Line button.
  - Right-click any viewport and click **Circle Measure Line**.
2. Click at the desired center and drag to define a radius across the region on the image to be measured. The tool will display the current diameter of the circle as it is drawn.

3. When you release the mouse button, the measure circle and diameter value will remain on-screen.
4. Measure circles can be edited by clicking and dragging the radius handle using either the Circle Measure tool or the default Arrow tool. The diameter value will be shown at the end-point of the radius so it can be positioned at any desired point around the circle. To move the circle, click and drag at any other point on the circumference of the circle.
5. To delete measure circles, do one of the following:
  - Right-click on the circle and select **Delete**
  - With the circle selected, press the DELETE key on the workstation keyboard.
  - Drag the measure circle over the  icon positioned in the bottom left corner of the currently selected viewport. This icon appears when you begin dragging the circle.
6. To move the diameter value from its default location, click on the value and drag it away from its current position. If you move the circle, the diameter value will remain at its position on screen and will not move along with the circle. If you would like to return the value to its original position, drag it over top of the reticle icon positioned at the radius handle. In this position, the diameter value will move along with the circle as it is moved.


## Image Blend Tools

There are two complimentary tools that can be used in addition to the thumbnail slider bar (see [Using Thumbnails Pg. 79](#)) for image blending.




**Scope**

1. Do one of the following:
  - From the Toolbar, click the Scope button.
  - Right-click the desired viewport and click **Scope**.
2. Click on the viewport where you would like to position the image blend scope.
3. An inset scope window appears centered on the mouse position, showing the secondary image series. The primary series is shown outside of the scope window boundaries.

4. If you are using a mouse with a mouse wheel, you can rotate the mouse wheel to change the size of the scope window. Rotate forward to increase the window size and backwards to decrease it.
5. In combination with rotating the mouse wheel, you can use the CTRL key to add alternating squares showing the secondary image series content followed by the primary image series content respectively. The number of alternating squares changes as the mouse wheel is rotated. Rotate forward to decrease the number of squares and backwards to increase the number of squares.
6. Click on the  icon to close the scope window

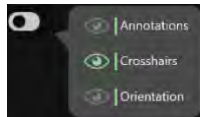


### Line


1. Do one of the following:
  - From the Toolbar, click the Line button.
  - Right-click the desired viewport and click **Line**.
2. Click on the viewport where you would like to position a line representing a split blended view between the primary and secondary series.
3. A two-dimensional line is drawn on screen. To the left of the line, the primary series image content is shown. To the right of the line, the secondary series image content is shown.
4. If you are using a mouse with a mouse wheel, you can rotate the mouse wheel to cause the secondary and primary image series to change places. If you have not yet clicked on the viewport or have already dismissed the blend line, rotating the mouse wheel will cause the entire viewport to alternate between the primary and secondary series.
5. Click on the  icon to dismiss the blend line, thus showing only the primary series image content in the viewport.

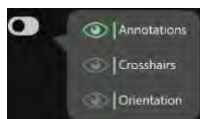
## Show/Hide Crosshairs, Annotations and Orientation Indicators

You can toggle between displaying and hiding crosshairs, annotations and orientation indicators for each viewport.




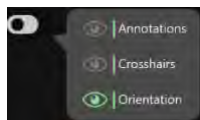
### To show or hide crosshairs

1. Do one of the following:
  - From the Toolbar, click the Show/Hide Viewport Annotations button.
  - Right-click any viewport and click **Show/Hide Viewport Annotations**.
2. A pop-out menu appears beside the Show/Hide Viewport Annotations button.
3. Click on the  icon in the pop-out menu corresponding to **Crosshairs**.




### To show or hide annotations

1. Do one of the following:
  - From the Toolbar, click the Show/Hide Viewport Annotations button.
  - Right-click any viewport and click **Show/Hide Viewport Annotations**.
2. A pop-out menu appears beside the Show/Hide Viewport Annotations button.
3. Click on the  icon in the pop-out menu corresponding to **Annotations**.



### To show or hide orientation indicators

1. Do one of the following:
  - From the Toolbar, click the Show/Hide Viewport Annotations button.
  - Right-click any viewport and click **Show/Hide Viewport Annotations**.
2. A pop-out menu appears beside the Show/Hide Viewport Annotations button.
3. Click on the  icon in the pop-out menu corresponding to **Orientation**.



## Reset Viewports Tool



### Reset viewport display parameters

1. Do one of the following:
  - From the Toolbar, click the Reset Viewports button.
  - Right-click any viewport and click **Reset Viewports**.
2. This will reset the following viewport attributes for all viewports in the current workflow step or task.
  - window width and level
  - zoom
  - pan

## Screen Capture Tool

You can capture images of the application screen at any time during the procedure. The tool captures the complete workstation window including the images shown in the viewports as well as the rest of the application interface. **Protected Health Information is not shown in the captured screen images.** All captured images are included in the final report automatically generated at the end of the procedure (see [Using the Procedure Report Window Pg. 65](#)).



### Capture screen images for report


1. Do one of the following:
  - From the Toolbar, click the Screen Capture button.
  - Right-click any viewport and click **Screen Capture**.
2. A message pop-up will appear in the bottom right corner of the application window, indicating the file location of where the screen capture was saved on the workstation. This message can also be reviewed using the Application Log Window (see [Using the Application Log Window Pg. 70](#)).

✓ Screenshot successfully saved  
 C:\ProgramData\ClearPointArray\sessions\2020-06-09\_14-12-44\screencaptures\Set Target Point1.png

## Single / Multi Viewport Tool



**Toggle between single or multiple viewports**

1. Click on the  icon in the top right-hand corner of the desired viewport.
2. The selected viewport will be shown in a one-up display. Repeat the previous step to toggle back to multi-viewport display.

## Drag Viewport Tool



**Drag an image view from one viewport to another**

1. Do one of the following:
  - From the Toolbar, click the Drag Viewport button.
  - Right-click any viewport and click **Drag Viewport**.
2. Click and drag an image from one viewport to another. This will cause the images in the source and destination viewports to switch places.

## Viewport Resizing Tool

The application provides you with the ability to resize viewports by dragging the border between any two viewports. When the mouse is positioned over the border between two viewports the cursor will change to a horizontal or vertical arrow icon. Click and drag with the left mouse button to move the window border and resize the adjacent viewports.

This can be done with any of the interactive tools selected.

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## Working with Trajectory Annotations

The application provides a number of general tools that can be used with trajectory annotations defined in the application.

### > To select a trajectory annotation

To select a trajectory annotation that you would like to work on, use the Trajectory Selector available in the currently active step (see [Selecting a Trajectory Pg. 75](#)).

### > To modify a trajectory annotation's target point

---

*Editing a trajectory annotation's target point is only offered in some steps during the procedure workflow. Other steps may prevent you from changing the target point if the purpose of the step is to perform other actions not related to trajectory target point modification.*

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1. Select the Arrow tool (see [Arrow Tool Pg. 89](#)).
2. Do one of the following:
  - Reposition the crosshairs in the viewports (see [Changing Crosshair Positions Pg. 83](#)) to a location where you would like to set the target point. Use the **Set Target Point** button in the step's control panel to set the target point at the current crosshair location.
  - If the viewport is set to the **Trajectory** orientation (see [Changing a Viewing Layout Orientation Pg. 82](#)), the following mechanisms can be used to edit the target point in the **Trajectory Coronal** and **Trajectory Sagittal** viewports:
    - Click and drag on the target point of the trajectory to a new location within the viewport. Doing so will cause the target point to pivot about its entry point.
    - Hold down the CTRL key while moving the target point to constrain the movement to shift along the current direction of the trajectory path.
    - Click and drag in between the trajectory end points (i.e. on the trajectory path cross section) to cause the target point to pivot about its entry point.
  - If the viewport is set to the **Trajectory** orientation (see [Changing a Viewing Layout Orientation Pg. 82](#)), the target point can be edited in the **Trajectory Axial** viewport by clicking and dragging on the trajectory path

cross section. Doing so will cause the target point to pivot about its entry point.

- If the viewport is set to the **Trajectory Orthogonal** orientation (see [Changing a Viewing Layout Orientation Pg. 82](#)), the following mechanisms can be used to edit the target point in the **Trajectory Orthogonal 1** and **Trajectory Orthogonal 2** viewports:
  - Click and drag the target point of the trajectory to a new location within the viewport. Doing so will cause the target point to pivot about its entry point.
  - Hold down the CTRL key while moving the target point to constrain the movement to shift along the current direction of the trajectory path.
  - Click and drag on the trajectory path extension below the target point to cause the target point to pivot about its entry point.
  - In steps or tasks where the trajectory entry point is not editable, click and drag in between the trajectory end points (i.e. on the trajectory path cross section) to cause the target point to pivot about its entry point.
  - In steps or tasks where the trajectory entry point is editable, hold down the ALT key while clicking and dragging on the trajectory path annotation to shift the entire trajectory path. This causes both entry and target points to shift by the same amount.
- If the viewport is set to the **Trajectory Orthogonal** orientation (see [Changing a Viewing Layout Orientation Pg. 82](#)), the target point can be edited in the **Trajectory Perpendicular** viewports by positioning the Fly Through Line at or below the target point (see [Fly Through Line Pg. 84](#)) and then clicking and dragging the trajectory cross section. Doing so will cause the target point to pivot about its entry point.

#### > To modify a trajectory annotation's entry point

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*Editing a trajectory annotation's entry point is only offered in some steps during the procedure workflow. Other steps may prevent you from changing the entry point if the purpose of the step is to perform other actions not related to trajectory entry point modification.*

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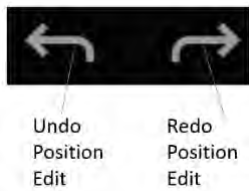
1. Select the Arrow tool (see [Arrow Tool Pg. 89](#)).
2. Do one of the following:
  - If the viewport is set to the **Trajectory Orthogonal** orientation (see [Changing a Viewing Layout Orientation Pg. 82](#)) and the step allows the entry point to be freely edited, the following mechanisms can be used to

edit the entry point in the **Trajectory Orthogonal 1** and **Trajectory Orthogonal 2** viewports:

- Click and drag the entry point of the trajectory to a new location within the viewport. Doing so will cause the entry point to pivot about its target point.
  - Hold down the CTRL key while moving the entry point to constrain the movement to shift along the current direction of the trajectory path.
  - Click and drag on the trajectory path extension about the entry point to cause the entry point to pivot about its target point.
  - Click and drag in between the trajectory end points (i.e. on the trajectory path cross section) to cause the entry point to pivot about its target point.
  - Hold down the ALT key while clicking and dragging on the trajectory path annotation to shift the entire trajectory path. This causes both entry and target points to shift by the same amount.
  - In steps where the entry point is not freely editable, you may select a guide channel to change the entry point such that it aligns with the channel selected (see [Working with Guide Channel Annotations Pg. 107](#)).
- If the viewport is set to the **Trajectory Orthogonal** orientation (see [Changing a Viewing Layout Orientation Pg. 82](#)), the entry point can be edited in the **Trajectory Perpendicular** viewports using the following mechanisms:
    - In steps or tasks where the entry point can be freely edited, position the Fly Through Line above the target point (see [Fly Through Line Pg. 84](#)) and then click and drag the trajectory cross section. Doing so will cause the entry point to pivot about its target point.
    - In steps where the entry point is not freely editable, you may select a guide channel to change the entry point such that it aligns with the channel selected (see [Working with Guide Channel Annotations Pg. 107](#)).

> **To undo or redo position edits made to a trajectory annotation**

Use the custom toolbar inset within the viewport to undo or redo any number of position changes associated with the editable annotation.



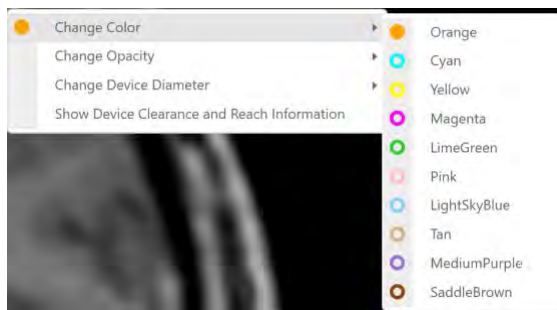

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*It is not possible to undo / redo a trajectory position edit made as the result of selecting a guide channel. You must re-perform the guide channel selection explicitly if you wish to undo or redo changes made to the selected guide channel intended for use during drilling / insertion.*

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> **To modify the color of a trajectory annotation**

1. Right-click on the trajectory annotation in any viewport and select **Change Color** from the menu:
2. Select the desired color from the list of preset colors.



> **To modify the opacity of a trajectory annotation**

1. Right-click on the trajectory annotation in any viewport and select **Change Opacity** from the menu:



2. Use the slider bar to change the opacity of the trajectory annotation.

> **To change the device diameter represented by a trajectory annotation**

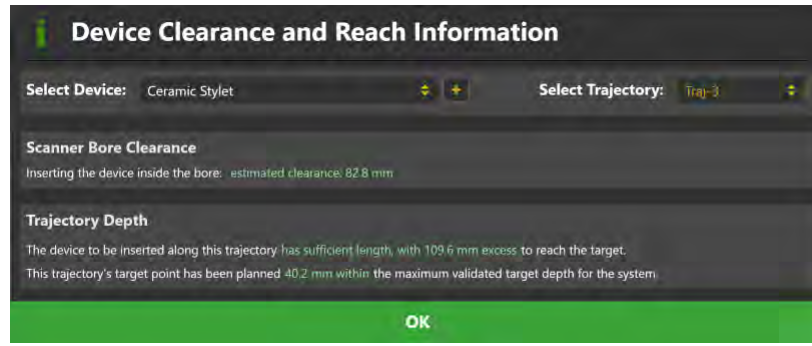
1. Right-click on the trajectory annotation in any viewport and select **Change Device Diameter** from the menu:



2. Type in a new value for the device diameter or use the +/- buttons to change the value incrementally.
3. Select **Reset** to restore the device diameter value to its default value.
4. Use the **ON / OFF** switch to toggle between displaying the trajectory with a thickness equivalent to the device diameter or not. If set to **OFF**, the trajectory will display as a singular line with no thickness value set.

> **To review scanner bore clearance and trajectory depth measurements**

1. Right-click on the trajectory annotation in any viewport and select **Show Device Clearance and Reach Information** from the menu. Alternatively, click on the button beside the Trajectory Selector (see [Selecting a Trajectory Pg. 75](#)).
2. Select a device. A dialog will display:
  - The scanner bore clearance for the selected device along the selected trajectory. (Note that this information is not shown while in the Pre-Op Workflow, because the patient position during preoperative image acquisition will not reflect the patient position on the day of surgery).
  - The amount of clearance required by the selected device to reach the selected trajectory's target point.
  - The amount of clearance for the selected device from the maximum validated target depth for the system.




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## Working with Volume of Interest Annotations

There are a number of tools available to you for volume of interest (VOI) annotations defined in the application.

### > To select a VOI annotation

To select a VOI annotation that you would like to work on, use the Volume Selector available in the currently active step (see [Selecting a Volume of Interest Pg. 76](#)).

### > To edit a VOI annotation

1. Select the VOI annotation that you wish to edit.
2. To add voxels to the VOI annotation, use the **Volume Brush** tool:
  - Select the  button from the custom toolbar.
  - Hold down the CTRL key and rotate the mouse wheel to change the size of the spherical brush used to add voxels to the VOI annotation that you are working on.
  - Click and drag the mouse over the areas of the image that you would like to add to the VOI annotation using the specified brush size. Doing so will fill in voxels at the specified areas within the image and associate them with the VOI.
3. To remove voxels from the VOI annotation, use the **Volume Eraser** tool:
  - Select the  button from the custom toolbar.



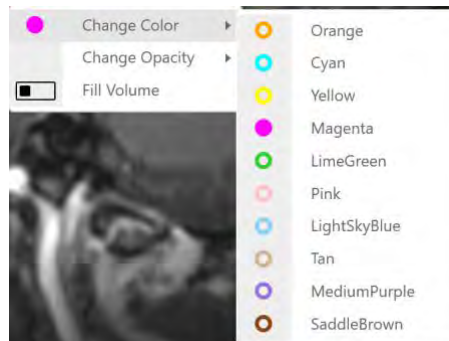
- Hold down the CTRL key and rotate the mouse wheel to change the size of the spherical eraser used to remove voxels from the VOI annotation that you are working on.
- Click and drag the mouse over areas of the image that contain voxel groupings in the VOI that you would like to remove using the specified eraser size. Doing so will remove those voxels from the VOI.

> **To undo or redo edits made to a VOI annotation**

Use the custom toolbar inset within the viewport to undo or redo any number of voxel additions or removals performed on the VOI annotation.

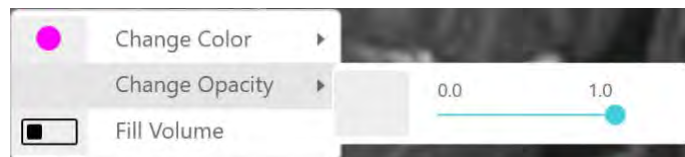
> **To modify the color of a VOI annotation**

1. Right-click on the VOI annotation in any viewport and select **Change Color** from the menu:
2. Select the desired color from the list of preset colors.



> **To modify the opacity of a VOI annotation**

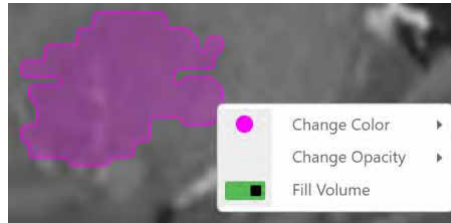
1. Right-click on the VOI annotation in any viewport and select **Change Opacity** from the menu:



2. Use the slider bar to change the opacity of the VOI annotation.

> **To modify the fill settings for a VOI annotation**

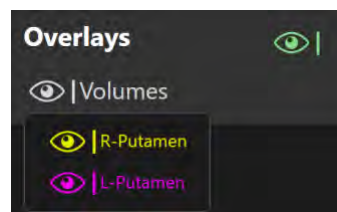
Right-click on the VOI annotation in any viewport and use the **Fill Volume** switch to toggle between displaying fill shading or no shading (outline only) for the annotation.



Some steps and tasks allow you to change the visibility of VOI annotations defined throughout the procedure.

> **To change the visibility of a VOI annotation**

1. Click on the **Volumes** visibility toggle button in the step's control panel.

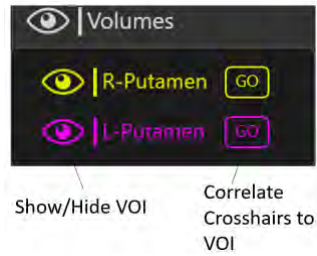


2. For the VOI annotation of interest, use the visibility toggle button to switch between showing or hiding the annotation.

Some steps and tasks allow you to correlate to the center of a defined VOI annotation.

> **To correlate to the center of a VOI annotation**

1. Click on the **Volumes** visibility toggle button in the step's control panel.



- For the VOI annotation of interest, select the **GO** button beside the visibility toggle button. The crosshairs will then correlate to the center of the corresponding VOI.

---

## Working with Guide Channel Annotations

The Guide Channel annotations allow you to specify a channel for the intended trajectory path into the brain while planning the trajectory and/or adjusting the trajectory frame. During trajectory planning, selecting a channel guide allows you to make entry point adjustments after the trajectory frame has been mounted to the patient. In these cases, the application prescribes frame adjustments that align the selected channel guide to the planned target point. During frame adjustment, selecting a channel guide allows you to specify an alternate trajectory path for device insertion which may be closer to the intended target point, allowing you to reduce or completely eliminate having to make additional adjustments prior to device insertion.

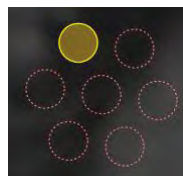
---

**Caution:**      **Changing the selected channel guide will modify the planned trajectory path used to insert a device into the brain. Please review and verify the resulting trajectory path each time you change the guide channel selection.**

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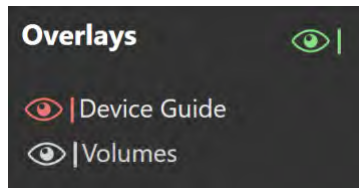
### > To select a guide channel

- Use the Guide Channel Selector to specify a guide channel for intended drilling and/or device insertion (see [Selecting a Guide Channel Pg. 76](#)).
- Alternatively, select the guide channel intended for drilling and/or device insertion using the channel projection annotations show in the viewport.



> **To change the visibility of a guide channel annotation**

Click on the **Device Guide** visibility toggle button in the step's control panel to switch between showing or hiding the Guide Channel annotation.



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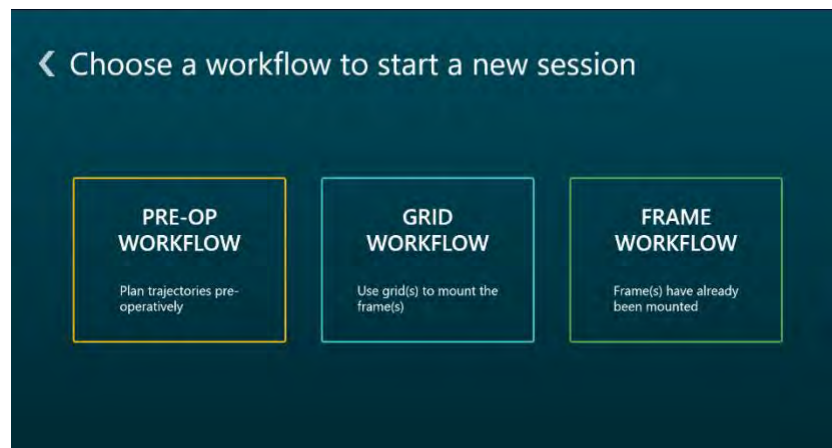
## Pre-Op Workflow

This section describes how to use the ClearPoint Array™ Workstation to create a preoperative plan prior to the day of surgery. To do this, it is necessary to: load one or more scans of the patient that were acquired prior to the procedure, identify one scan as the primary / master series, complete trajectory planning, and save the preoperative plan for future use.

Prior to starting this workflow, one or more preoperative scans of the patient must be available for loading. Images can be made available on DICOM media (e.g. CD, DVD, external hard drive) or from an existing DICOM archive (e.g. PACS).

### > To start a Pre-Op Workflow

1. Launch the application.
2. Using the Splash Screen, select **START NEW SESSION** (see [Launching the Splash Screen Pg. 47](#))
3. A new page on the Splash Screen will appear, presenting you with the workflow options available to start a new session.



4. Select **PRE-OP WORKFLOW** to start a Pre-Op Workflow.

---

## Identify Master Scan Step – *Selecting a Master Scan*

The Identify Master Scan step prompts you to load a set of patient scans acquired prior to the day of surgery, and then select one to serve as the frame of reference for preoperative planning. Patient scans can be loaded onto the workstation from removable DICOM media, such as a CD or external hard drive, or alternatively may be pushed to the workstation via DICOM network transfer from an existing DICOM archive system. From the list of patient scans loaded, the step prompts you to select one which will serve as the primary frame of reference for the Pre-Op Workflow. The selected scan should encapsulate the whole-head so that effective registration with patient scans acquired during the intraoperative procedure can be achieved.

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**Caution:** Prior to loading patient images from external media, ensure that the workstation has completed scanning the device for malicious software. See [Security Operating Instructions Pg. 19](#) for additional guidance regarding connecting removable media to the workstation.

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*The scan that is selected in the Identify Master Scan step is referred to as the “master series”, and its frame of reference will serve as the base coordinate space for all other scans loaded into the application with the current workflow selected. If additional scans are loaded that have a different frame of reference coordinate space than the master series, you will be prompted to fuse these scans with the master series prior to proceeding in the workflow. See [Fusion Task Fusing Images Pg. 221](#) for details.*

---

## Loading Preoperative Images

To create a preoperative plan using the ClearPoint Array™ Workstation, you will need access to images of the patient acquired prior to the procedure, so that they can be loaded into the application. The Pre-Op Workflow supports blending of images that are acquired in same or different frames of reference.

### > To load preoperative images

1. Use the DICOM Media Browser to browse to the directory containing the preoperative images of the patient (see [Using the DICOM Media Browser Pg. 64](#)). Alternatively, identify the DICOM archive that can be used to transfer the preoperative images to the workstation.
2. Select and load one or more image series (see [Using the DICOM Media Browser Pg. 64](#)). Alternatively, initiate a transfer of images from the DICOM

archive. Ensure that at least one image series is loaded which encapsulates the patient's entire head.

3. The images will be loaded and displayed in the Identify Master Series step. By default, the software will denote one of the loaded image series as the master series in the step's Thumbnail Bar (see [Using Thumbnails Pg. 79](#)).

## Selecting the Master Scan

The Identify Master Scan step may be completed when a whole-head scan is identified in the software. Selection of the master scan can be achieved using the step's Thumbnail Bar.

### > To select a master scan

1. Use the Thumbnail Bar to choose a whole-head image series of the patient that was acquired preoperatively (see [Using Thumbnails Pg. 79](#)). The selected image series will appear in the application viewports and will be denoted as the master series in the Thumbnail Bar.
2. If you wish to change the denoted master scan, the Thumbnail Bar may be used to select a different image series (see [Using Thumbnails Pg. 79](#)).

## Reviewing the Master Scan

You may review the denoted master scan on the workstation at any point in time after selection.

### > To review the master scan

1. Use the Arrow Tool (see [Arrow Tool Pg. 89](#)) to rotate the 3D view displaying the master series and verify that adequate coverage of the patient's head is achieved.
2. Review the master series image properties to verify that patient position, acquisition time and image series description matches the intended scan selected.



## Clearing Preoperative Images

You may want to clear the entire set of preoperative images on the workstation in cases where an incorrect set of images was loaded. In these instances, you may use the Identify Master Scan Step to clear all of the loaded preoperative image scans.

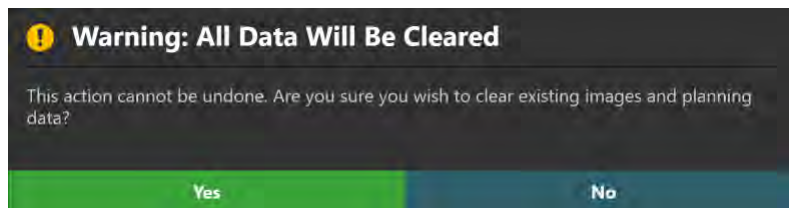
---

**Caution:** Clearing the loaded preoperative images after downstream steps have been completed will also clear any trajectories and VOIs that may have been defined in the workflow. Please ensure that clearing images after additional steps have been completed is the correct action before proceeding.

---

### > To clear preoperative images

1. Select the **Clear All Data** button from the step's control panel.
2. You will be prompted prior to clearing the images. Select **Yes** to clear the currently loaded preoperative images. Select **No** to leave the preoperative images loaded in the application.



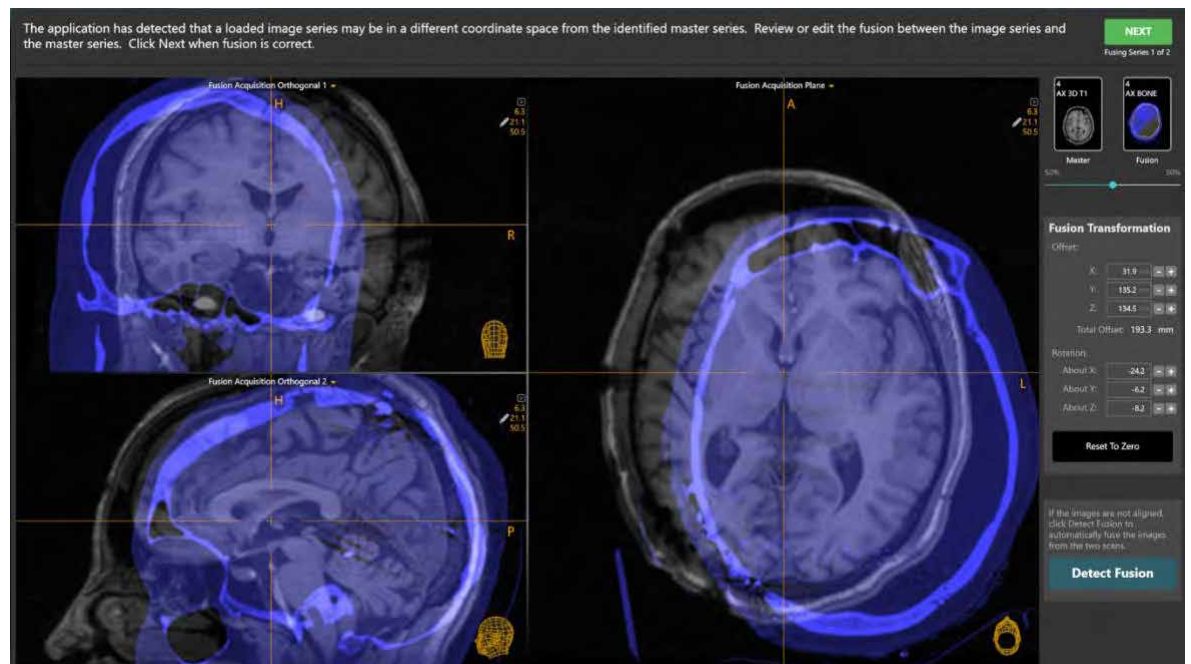


## Fusing Preoperative Images

In cases where you have loaded one or more series that were acquired in a different frame of reference from the denoted master scan, the Identify Master Series step will automatically prompt you to fuse these scans with the master scan upon leaving the step. This ensures that all loaded preoperative image series will be presented in the same frame of reference when performing preoperative planning in later workflow steps.

### > To fuse preoperative images

1. For preoperative images that are acquired in a different frame of reference than the master series, the software will automatically pop-up the Fusion task to allow you to fuse these image series with the master series upon leaving the Identify Master Series step.



2. Use the pop-up Fusion task (see [Fusion Task Fusing Images Pg. 221](#)) to fuse each preoperative series with the master series.
3. For preoperative images that are acquired in the same frame of reference as the master series, you may use the Thumbnail Bars in downstream steps to assess and/or edit the fusion transformation between any given image series and the master series (see [Using Thumbnails Pg. 79](#)).

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## Define Target Volumes Step - *Defining Volumes*

The Define Target Volumes step may be used to create or edit one or more volumes of interest (VOIs) using any image series loaded for the given session. VOIs created in this step can be used to define areas in the brain which you would like to target or avoid during trajectory planning and/or subsequent frame alignment. For this reason, these VOIs are referred to as “target” volumes. (VOIs that are created after treatment has begun on the patient are referred to as “treatment” volumes). The step allows for the following operations:

- Defining new target VOI annotations (see [Creating Target Volumes Pg. 114](#)).
- Editing target VOI annotations that have already been defined (see [Editing Target Volumes Pg. 115](#)).
- Reviewing one or more target VOI annotations (see [Reviewing Target Volumes Pg. 118](#)).
- Removing one or more unwanted target VOI annotations previously defined (see [Removing a Target Volume Pg. 119](#)).

Definition, editing and review of VOI annotations can only be performed using the **Scanner** viewing orientation.

Completing the Define Target Volumes step is optional. You may choose to move forward in the workflow without creating any target VOIs. However, if you decide to create one or more VOIs, each one must be non-empty (i.e. contain at least 1 voxel) in order to move forward in the workflow.

---

*If no target VOIs are created, then you will not be able to use the Assess Treatment Volumes step (see [Assess Treatment Volumes – Evaluating Treatment Coverage Pg. 196](#)) in order to assess volumes representing treatment areas within the brain after a device insertion has been made.*

---

### Creating Target Volumes

The Define Target Volumes step allows you to create new target VOI annotations on any loaded image series, by defining a grouping of voxels that define a region of interest in the patient’s brain. These regions can represent certain anatomical regions that you wish to target during the procedure (i.e. “target” areas), or may be used to represent areas that you wish to avoid during the procedure (i.e. “no go” areas).

> **To create a target VOI annotation**

1. Select an image series that you would like to use to create a target VOI annotation using the Thumbnail Bar (see [Using Thumbnails Pg. 79](#)).
2. Change the crosshair position to a location within the selected image series that you wish to define a target VOI (see [Changing Crosshair Positions Pg. 83](#)).
3. Select **New Target Volume** from the step's control panel.
4. A floating window will appear prompting you define the following attributes for the volume to be created.
  - Name – Specify a unique name that will identify the volume in the user interface. (Note: The application will prevent identical naming of volumes).
  - Color – Specify a color defining how the volume will be displayed in the user interface.





5. Select **OK** to define a volume in the user interface. Select **Cancel** to cancel the target volume creation.
6. Note that the **Volume Brush** tool has been automatically selected. Use the **Volume Brush** tool to add a grouping of voxels to the target VOI annotation (see [Working with Volume of Interest Annotations Pg. 104](#)).

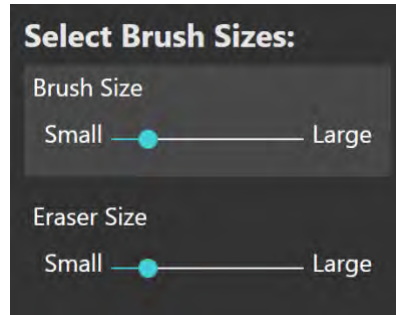
## Editing Target Volumes

The Define Target Volumes step may also be used to edit any existing target VOI annotation previously defined. Editing a target volume involves changing the grouping of voxels and/or properties associated with the VOI annotation.

> **To edit a target VOI annotation**



1. Use the Volume Selector available in the step's control panel to select a target VOI annotation that you wish to edit (see [Selecting a Volume of Interest Pg. 76](#)).

2. Select an image series that you would like to use to edit the target VOI using the Thumbnail Bar (see [Using Thumbnails Pg. 79](#)).
3. Use the **Volume Brush**  and **Volume Eraser**  tools to add or remove voxel groupings from the target VOI annotation (see [Working with Volume of Interest Annotations Pg. 104](#)). You may change the brush and eraser sizes for the VOI editing tools using the sliders in the step's control panel. Note that changing the brush size will automatically select the **Volume Brush** tool, and that changing the eraser size will automatically select the **Volume Eraser** tool.



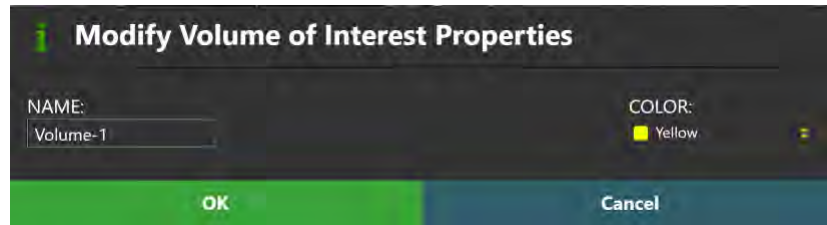
> **To undo or redo edits made to a target VOI annotation**

Use the **VOI Undo** and **VOI Redo** tools to undo or redo any changes made to the selected VOI annotation shown on screen.

- Select the  button from the custom toolbar to undo a change made to the selected target VOI shown on screen.
- Select the  button from the custom toolbar to redo a change made to the selected target VOI shown on screen.

> **To edit the name or color of a target VOI annotation**

1. Use the Volume Selector available in the step's control panel to select a target VOI annotation for which you wish to change the name and/or color (see [Selecting a Volume of Interest Pg. 76](#)).
2. Select **Change Name / Color** from the step's control panel.
3. A floating window will appear prompting you to change the name and / or color of the target VOI annotation.



4. Make the desired changes to the name and/or color of the target VOI annotation.
5. Select **OK** to apply the changes to the selected VOI annotation. Select **Cancel** to cancel to discard the changes made to the selected VOI annotation.
6. You may also change the color of any target VOI using the context menu associated with the annotation (see [Working with Volume of Interest Annotations Pg. 104](#)).

> **To edit the opacity of a VOI annotation**

1. Use the Volume Selector available in the step's control panel to select a target VOI annotation for which you wish to change the opacity (see [Selecting a Volume of Interest Pg. 76](#)).
2. Select the slider associated with the currently selected target VOI annotation from the step's control panel. Use the slider in the step control panel to change the opacity of the selected VOI annotation. Drag to the left to decrease the opacity of the annotation. Drag to the right to increase the opacity of the annotation.



3. You may also change the opacity of a target VOI using the context menu associated with the annotation (see [Working with Volume of Interest Annotations Pg. 104](#)).

> **To turn on volume filling for a target VOI annotation**

1. Use the Volume Selector available in the step's control panel to select a target VOI annotation for which you wish to turn on filling (see [Selecting a Volume of Interest Pg. 76](#)).
2. Turn on volume filling using the context menu associated with the target VOI annotation (see [Working with Volume of Interest Annotations Pg. 104](#)).

## Reviewing Target Volumes

Measurements associated with a target volume may be reviewed using the Define Target Volume step or the procedure report.

### > To correlate to the center of a target VOI annotation

1. Use the Volume Selector available in the step's control panel to select a VOI annotation (see [Selecting a Volume of Interest Pg. 76](#)).
2. The crosshairs will automatically correlate to the center the selected target VOI.
3. If the crosshairs are moved away from the center of the selected target VOI, select **Go To Center** in the step's control panel.
4. The crosshairs will automatically correlate to the center of the selected target VOI.

### > To review a volume measurement


1. Use the Volume Selector available in the step's control panel to select a target VOI annotation for which you wish to see a volume measurement (see [Selecting a Volume of Interest Pg. 76](#)).
2. Observe the volume measurement value in the step control panel.



Volume-1  
1.408 cm<sup>3</sup>

### > To review a volume measurement using the procedure report

1. Open the Procedure Report Window (see [Using the Procedure Report Window Pg. 65](#)).
2. Navigate to the **Volumes of Interest** section.



Target Volume	Treatment Volume	Size	Overlap with Target Volume
R-Pituitary		2.420 cm <sup>3</sup>	
L-Pituitary		3.503 cm <sup>3</sup>	

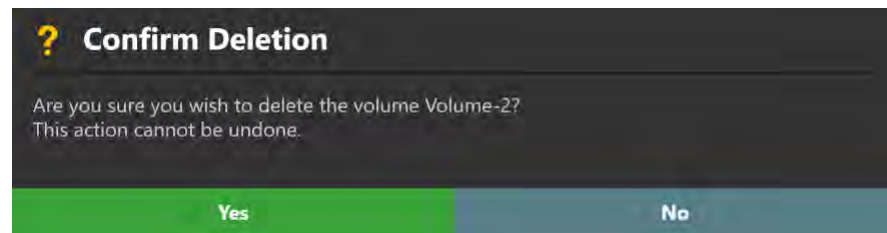
3. Observe the volume measurements for each target volume.

## Removing a Target Volume

You may also use the Define Target Volumes step to remove any unwanted target VOIs defined in the application.

### > To delete a target VOI annotation

1. Use the Volume Selector available in the step's control panel to select a target VOI annotation that you wish to remove (see [Selecting a Volume of Interest Pg. 76](#)).
2. Select **Delete** from the step's control panel.
3. You will be prompted to confirm the removal of the target VOI annotation before proceeding. Select **Yes** to proceed with the deletion of the selected target VOI. Otherwise, choose **No** to leave the target VOI intact.



---

## Set Target Point Step – *Defining Target Points*

The Set Target Point step lets you create one or more trajectory paths into the brain, by first defining a target point. You may use the step to make further edits to the target point for each trajectory, using additional image acquisitions to better visualize areas in the brain to be targeted. Entry point modification is accomplished in downstream workflow steps. You may complete the step and move on in the workflow when at least one trajectory path has been created.

The following high-level features are offered by the Set Target Point step:

- Defining one or more trajectory paths (see [Creating Trajectories Pg. 120](#)).
- Editing the target point for one or more trajectory paths into the brain (see [Editing Target Points Pg. 121](#)).
- Changing the annotation properties associated with one or more trajectory paths (see [Editing Trajectory Properties Pg. 122](#)).
- Removing unwanted trajectory paths previously defined (see [Remove Trajectories Pg. 123](#)).
- Reviewing initially planned trajectory paths (see [Reviewing Trajectories Pg. 124](#)).

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*When a new trajectory is defined in the Pre-Op Workflow by specifying the target point, the entry point will default to a location 100 mm up from the target point, along the anatomical z-axis. This default entry point location can be edited in later workflow steps.*

---

### Creating Trajectories

Using the Step Target Point step, you may create one or more trajectory paths into the brain by first specifying a target point.

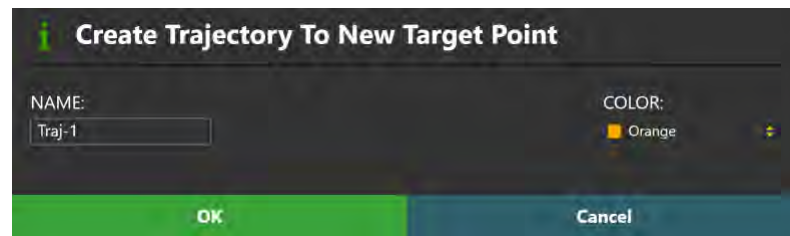
**> To create a trajectory annotation**

1. If additional image series are required to plan your target point, load or acquire/transfer the scan(s) to the workstation.
2. If necessary, select an additional image series for blending with the master series using the Thumbnail Bar (see [Using Thumbnails Pg. 79](#)).
3. Change the crosshair position to a location within the master series or selected blended series that you wish to define a trajectory path (see



[Changing Crosshair Positions Pg. 83](#)). If you wish to use a target VOI to help define the target point location, you may correlate to the center of any defined target VOI using the **Volumes** visibility toggle button (see [Working with Volume of Interest Annotations Pg. 104](#)).

4. Select **New Target Point** from the step's control panel.
5. A floating window will appear prompting you define the following attributes for the trajectory annotation to be created.
  - Name – Specify a unique name that will identify the trajectory in the user interface. (Note: The application will prevent identical naming of trajectories).
  - Color – Specify a color defining how the trajectory will be displayed in the user interface.



6. Select **OK** to define a trajectory path in the user interface. Select **Cancel** to cancel the trajectory creation.
7. If a new trajectory has been created, note that a new graphic annotation corresponding to a path connecting the target point just defined to a default entry point location 100 mm up from the target along the anatomical z-axis is shown in the application viewports.

## Editing Target Points

The Set Target Point step may also be used to edit any existing trajectory annotation previously defined. In this step, only the target point may be edited.



### > To edit a target point

1. Use the Trajectory Selector available in the step's control panel to select a trajectory annotation whose target point you wish to edit (see [Selecting a Trajectory Pg. 75](#)).
2. If necessary, select an additional image series for blending with the master series using the Thumbnail Bar (see [Using Thumbnails Pg. 79](#)).

3. Correlate the crosshairs to a new location within the master series or selected blended series where you wish to set the target point (see [Changing Crosshair Positions Pg. 83](#)).
4. Select **Set Target Point** from the step's control panel.
5. You may also edit the target point using mouse click and drag operations (see [Working with Trajectory Annotations Pg. 99](#)).

> **To undo or redo target point edits made to a trajectory annotation**

Use the **Trajectory Undo** and **Trajectory Redo** tools to undo or redo any target point changes made to the selected trajectory annotation shown on screen.

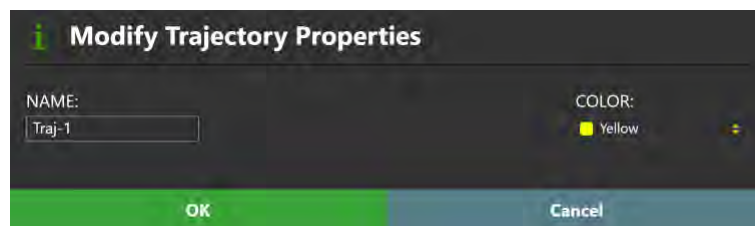
- Select the  button from the custom toolbar to undo a target point edit made to the selected trajectory annotation shown on screen.
- Select the  button from the custom toolbar to redo a target point edit made to the selected trajectory annotation shown on screen.

## Editing Trajectory Properties

You may also use the Set Target Point step to make changes to the properties associated with a trajectory annotation, including: name, color, opacity and device diameter.

> **To edit the name or color of a trajectory annotation**

1. Use the Trajectory Selector available in the step's control panel to select a trajectory annotation for which you wish to change the name and/or color (see [Selecting a Trajectory Pg. 75](#)).
2. Select **Change Name / Color** from the step's control panel.
3. A floating window will appear prompting you to change the name and / or color of the trajectory annotation.



4. Make the desired changes to the name and/or color of the trajectory annotation.
5. Select **OK** to apply the changes to the selected trajectory annotation. Select **Cancel** to discard the changes made to the selected trajectory annotation.
6. You may also change the color of any trajectory using the context menu associated with the annotation (see [Working with Trajectory Annotations Pg. 99](#)).

> **To edit the opacity of a trajectory annotation**

1. Use the Trajectory Selector available in the step's control panel to select a trajectory annotation for which you wish to change the opacity (see [Selecting a Trajectory Pg. 75](#)).
2. Select the slider associated with the currently selected trajectory annotation from the step's control panel. Use the slider in the step control panel to change the opacity of the selected trajectory annotation. Drag to the left to decrease the opacity of the annotation. Drag to the right to increase the opacity of the annotation.



3. You may also change the opacity of a trajectory using the context menu associated with the annotation (see [Working with Trajectory Annotations Pg. 99](#)).

> **To change the device diameter represented by a trajectory annotation**

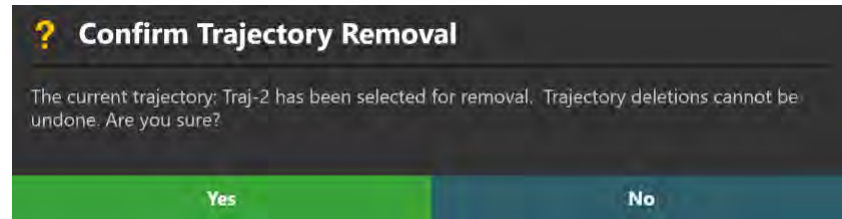
1. Use the Trajectory Selector available in the step's control panel to select a trajectory annotation for which you wish to change the device diameter (see [Selecting a Trajectory Pg. 75](#)).
2. Use the annotation context menu to change the device diameter associated with the trajectory path (see [Working with Trajectory Annotations Pg. 99](#)).

## Remove Trajectories

You may also use the Set Target Point step to remove any unwanted trajectories defined in the application.

> **To delete a trajectory annotation**

1. Use the Trajectory Selector available in the step's control panel to select a trajectory annotation that you wish to remove (see [Selecting a Trajectory Pg. 75](#)).
2. Select **Delete** from the step's control panel.
3. You will be prompted to confirm the removal of the trajectory annotation before proceeding. Select **Yes** to proceed with the deletion of the selected trajectory. Otherwise, choose **No** to leave the trajectory intact.

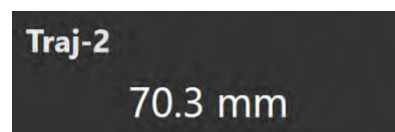


## Reviewing Trajectories

You may review the position of each end point as well as review depth measurements for a particular trajectory.

> **To navigate to a trajectory's end points**

1. Use the Trajectory Selector available in the step's control panel to select a trajectory annotation that you wish to review (see [Selecting a Trajectory Pg. 75](#)).
2. Select **Go To Target Point** from the step control panel to navigate to the selected trajectory's target point.
3. Select **Go To Entry Point** from the step control panel to navigate to the selected trajectory's entry point.
4. Review the linear distance between the two trajectory end points using the value specified in the step control panel.



> **To review trajectory depth measurements**

1. Use the Trajectory Selector available in the step's control panel to select a trajectory annotation that you wish to review (see [Selecting a Trajectory Pg. 75](#)).
2. Click on the device clearance and reach information button beside the selected trajectory item (see [Selecting a Trajectory Pg. 75](#)).
3. Alternatively, use the annotation context menu to show the Device Clearance and Reach Information Dialog (see [Working with Trajectory Annotations Pg. 99](#)).

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## Finalize Trajectory Plan Step – *Finalizing the Preoperative Plan*

The Finalize Trajectory Plan step allows you to: set entry points for each of the preoperative trajectories defined in the Set Target Point step, review each resulting trajectory path, and save the preoperative plan for future use. You may complete the step and save your preoperative plan when all defined trajectory paths have been reviewed.

The Finalize Trajectory Plan step offers the following high-level features:

- Modifying the entry point for one or more trajectory paths into the brain (see [Editing Entry Points Pg. 126](#)).
- Revising the target point for one or more trajectory paths into the brain (see [Revising Target Points Pg. 127](#)).
- Saving the preoperative plan for use in a future intraoperative procedure (see [Saving a Preoperative Plan Pg. 128](#)).

Some functionality offered by the Set Target Point (see [Set Target Point Step – Defining Target Points Pg. 120](#)) step is also offered in the Finalize Trajectory Plan step, including:

- Removing unwanted trajectory paths previously defined (see [Remove Trajectories Pg. 123](#)).
- Modifying properties associated with one or more trajectory annotations (see [Editing Trajectory Properties Pg. 122](#)).
- Reviewing planned trajectory paths (see [Reviewing Trajectories Pg. 124](#)).

### Editing Entry Points

You may use the Finalize Trajectory Plan step to edit the entry point for any trajectory annotation defined in the Pre-Op Workflow. Entry point edits are performed in views aligned obliquely along the defined trajectory path.



#### > To edit an entry point

1. Use the Trajectory Selector available in the step's control panel to select a trajectory annotation whose entry point you wish to edit (see [Selecting a Trajectory Pg. 75](#)).

2. If necessary, select an additional image series for blending with the master series using the Thumbnail Bar (see [Using Thumbnails Pg. 79](#)).
3. Edit the selected trajectory's entry point using mouse and click drag operations (see [Working with Trajectory Annotations Pg. 99](#)).

> **To undo or redo entry point edits made to a trajectory annotation**

Use the **Trajectory Undo** and **Trajectory Redo** tools to undo or redo any entry point changes made to the selected trajectory annotation shown on screen.

- Select the  button from the custom toolbar to undo an entry point edit made to the selected trajectory annotation shown on screen.
- Select the  button from the custom toolbar to redo an entry point edit made to the selected trajectory annotation shown on screen.

## Revising Target Points

The Finalize Trajectory Plan step may be used to revise the target point for a given trajectory in the Pre-Op Workflow, in views aligned obliquely to the currently selected trajectory.

> **To revise a target point**

1. Use the Trajectory Selector available in the step's control panel to select a trajectory annotation whose target point you wish to edit (see [Selecting a Trajectory Pg. 75](#)).
2. If necessary, select an additional image series for blending with the master series using the Thumbnail Bar (see [Using Thumbnails Pg. 79](#)).
3. Revise the selected trajectory's target point using mouse and click drag operations (see [Working with Trajectory Annotations Pg. 99](#)).

> **To undo or redo target point revisions made to a trajectory annotation**

Use the tools provided in the custom toolbar to undo or redo any changes to the target point for the selected trajectory annotation (see [Editing Target Points Pg. 121](#)).

## Saving a Preoperative Plan

You may use the Finalize Trajectory Plan step to explicitly save your preoperative plan, including all defined trajectory and volume of interest annotations. You may then use the preoperative session as a starting point for a future intraoperative procedure.

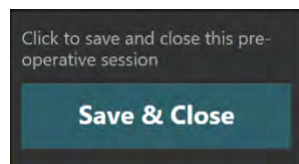
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*The ClearPoint Array™ Workstation automatically saves your software session throughout the course of working on your preoperative plan. In case of unexpected workstation shut-downs, you will be able to recover any work performed in your preoperative planning session. See [Backup and Restore Features Pg. 17](#) for details.*

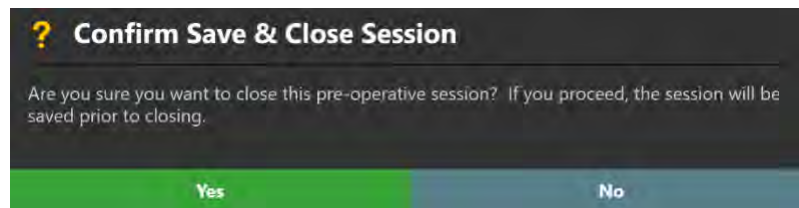
---

### > To save a preoperative plan

1. Select **Save & Close** in the step's control panel.



2. You will be prompted prior to saving the preoperative plan. Select **Yes** to save and close the currently loaded preoperative planning session. Select **No** to leave the session open for edit / review.





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## Grid Workflow

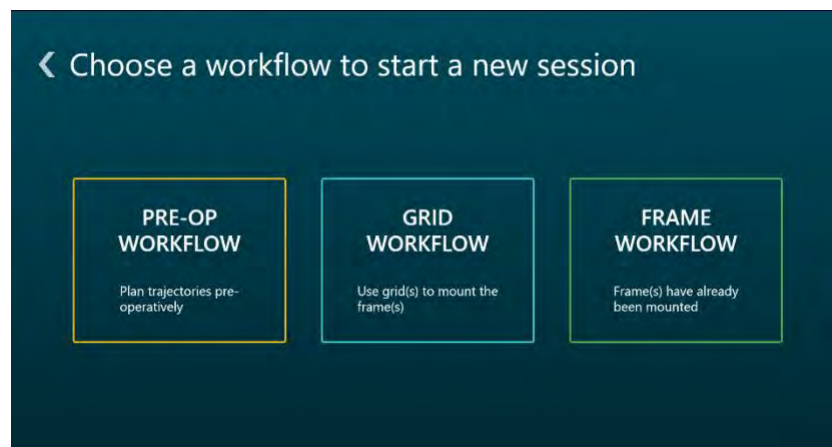
This section describes how to use the ClearPoint Array™ Workstation for determining how the SMARTFrame Array™ trajectory frame(s) can be mounted onto the patient in a MRI environment. To achieve this, it is necessary to: acquire a whole head scan of the patient with SMARTGrid® MRI Planning Grids affixed, confirm and verify the positions of the MRI Planning Grids in the application, complete trajectory planning, and identify the intended locations on where the trajectory frame(s) should be mounted on the patient.

Prior to starting this workflow, the following conditions must be met:

- One or more SMARTGrid® MRI Planning Grids have been affixed onto the patient.
- The patient has been moved to MRI Scanner isocenter.

### > To start a Grid Workflow

1. Launch the application.
2. Using the Splash Screen, select **START NEW SESSION** (see [Launching the Splash Screen Pg. 47](#))
3. A new page on the Splash Screen will appear, presenting you with the workflow options available to start a new session.



4. Select **GRID WORKFLOW** to start a Grid Workflow.

> **To start a Grid Workflow after completing a Pre-Op Workflow**

1. Complete a Pre-Op Workflow using the application (see [Pre-Op Workflow Pg. 109](#)).
2. After loading the preoperative session prior to the procedure, select **START GRID WORKFLOW** using the Step Selector in the Finalize Trajectory Plan step (see [Finalize Trajectory Plan Step – Finalizing the Preoperative Plan Pg. 126](#)).

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## Acquire Master Scan Step - *Acquiring a Grid Master Scan*

The Acquire Master Scan step prompts you to acquire a whole-head scan of the patient with one or more SMARTGrid® marking grids affixed. The acquired scan can then be transferred to the workstation and reviewed to ensure that correct anatomical coverage is achieved within the scan's field-of-view (FOV). In cases where the whole-head scan of the patient does not achieve adequate coverage of the head and/or marking grids, the scan can be cleared from the application, and a new one may be acquired and transferred to the workstation.

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*The scan that is loaded into the application in the Acquire Master Scan step is referred to as the “master series”, and its frame of reference will serve as the base coordinate space for all other scans loaded into the application with the current workflow selected. If additional scans are loaded that have a different frame of reference coordinate space than the master series, you will be prompted to fuse these scans with the master series prior to proceeding in the workflow. See [Fusion Task Fusing Images Pg. 221](#) for details.*

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### Acquiring a Grid Master Series

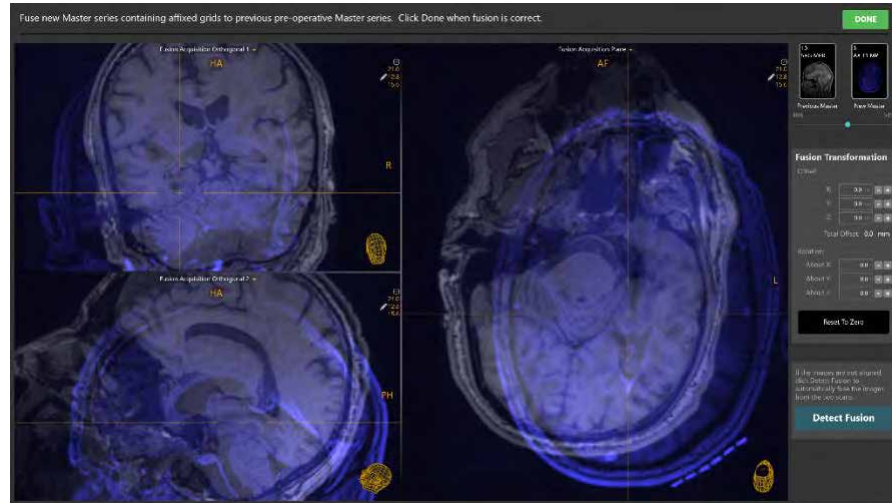
You may complete the Acquire Master Scan step when a whole-head scan containing all affixed marking grids has been acquired and loaded onto the workstation. When images are loaded onto the workstation with the Acquire Master Scan step selected, the application automatically detects the position of any marking grids that are affixed to the patient.

#### > To acquire a master series

1. With the patient inside the bore of the scanner, use the MRI Scanner Console to acquire a T1-weighted whole-head scan of the patient with one or more marking grids affixed. Ensure that the scan's field-of-view (FOV) completely encapsulates all marking grids. Also ensure that the scan is aligned to patient anatomy.



2. Transfer the scan to the workstation.
3. If you completed a Pre-Op Workflow prior to this step, use the pop-up Fusion task (see [Fusion Task Fusing Images Pg. 221](#)) to fuse the newly acquired master series with the master series from the Pre-Op Workflow.



4. If you completed a Pre-Op Workflow prior to this step, the application will transform all trajectories and volumes of interest created in that workflow into the coordinate space defined by the intraoperative images containing the affixed marking grids.

---

*Upon receiving the master series in the Acquire Master Scan step, the application will automatically search for any SMARTGrid® MRI Planning Grids in the scan. If the application fails to detect any marking grids, you will be notified via a status message that no marking grids could be identified. In these instances, you may still move forward in the workflow to manually detect additional marking grids and/or acquire additional scans containing the marking grids affixed to the patient.*

---

## Reviewing the Master Series

You may review the master series on the workstation once it has been transferred from the MRI Scanner.

### > To review the master series

1. Use the Arrow Tool (see [Arrow Tool Pg. 89](#)) to rotate the 3D view displaying the master series and verify that adequate coverage of the patient's head and any affixed hardware is achieved.

2. Review the master series image properties to verify that patient position, acquisition time and image series description matches the intended scan acquired.



## Clearing the Master Series

You may want to clear the master series after reviewing it for adequate patient coverage. In these instances, you may use the Acquire Master Scan step to clear the existing master series and acquire / load a new master series.

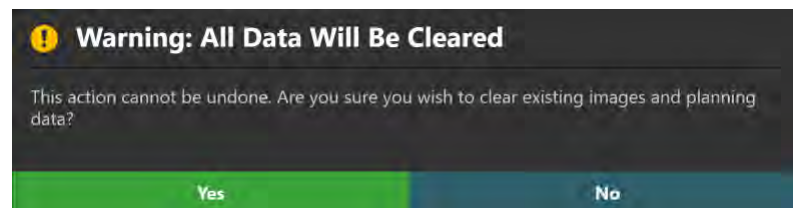
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**Caution:** Clearing the master series after downstream steps have been completed will also clear any loaded images, trajectories and VOIs that may have been defined in the workflow. Please ensure that clearing the master series after additional steps have been completed is the correct action before proceeding.

---

### > To clear the master series

1. Select the **Clear All Data** button from the step's control panel.
2. You will be prompted prior to clearing the master series. Select **Yes** to clear the currently loaded master series. Select **No** to leave the currently loaded master series intact.



## Re-activating the Pre-Op Workflow

If you completed a Pre-Op Workflow (see [Pre-Op Workflow Pg. 109](#)) prior to this step, the Acquire Master Scan step allows you to navigate back to the steps completed as part of that workflow.

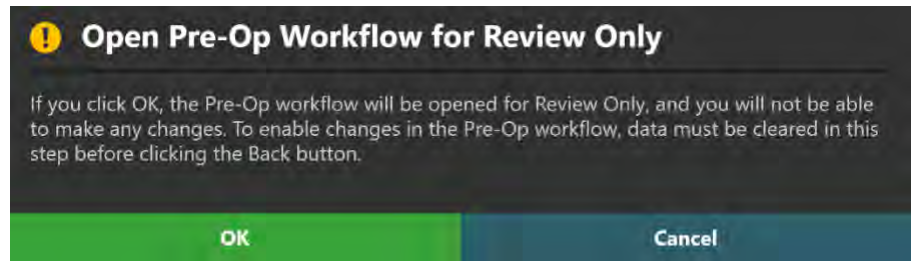
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*Navigating back to a previously completed Pre-Op Workflow after a Grid Workflow has been started will prevent you from making any changes to the Pre-Op Workflow. In these cases, the Pre-Op Workflow will be placed in **REVIEW ONLY** mode, whereby any attempted edits made to previously defined trajectories and/or VOIs as well as image loading operations will be disallowed. You will only be able to make changes in the Pre-Op Workflow if the master series and all associated data is cleared from the Grid Workflow.*

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### > To re-activate a completed Pre-Op Workflow

1. Using the Step Selector, use the **BACK** button to navigate to the previously completed workflow step (see [Selecting a Step Pg. 72](#)).
2. You will be prompted to confirm navigation to the Pre-Op Workflow. Select **OK** to confirm navigation back to the Pre-Op Workflow, where any attempted annotation edits and image loading operations will be disallowed. Otherwise, click **Cancel** to leave the Acquire Master Scan step activated.



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## Verify Grids Step - *Confirming Marking Grids*

The Verify Grids step allows you to review and confirm the position and orientation of each detected SMARTGrid® MRI Planning Grid on one or more scans. Additionally, the step allows for the following operations:

- Manually edit the position and/or orientation for each marking grid, in instances where the identified grid does not match up with the physical grid in the underlying images (see [Modifying Marking Grids Pg. 136](#))
- Identify one or more marking grids that were not detected automatically in the Acquire Master step and/or not yet defined (see [Managing Marking Grids Pg. 138](#)).
- Remove marking grids that may not correspond to grids affixed physically to the patient (see [Managing Marking Grids Pg. 138](#)).

When images are loaded into the workstation with the Verify Grids step selected, the application automatically attempts to detect any marking grids from the loaded image series. You may complete the step and move on in the workflow when at least one marking grid has been defined in the application.

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*The application only supports defining 3 marking grids on each side of the patient's head. Affixing any more than 3 marking grids per side of the patient's head is not advised. The application will prevent you from moving on in the workflow if more than 3 marking grids have been defined on either side of the patient's head.*

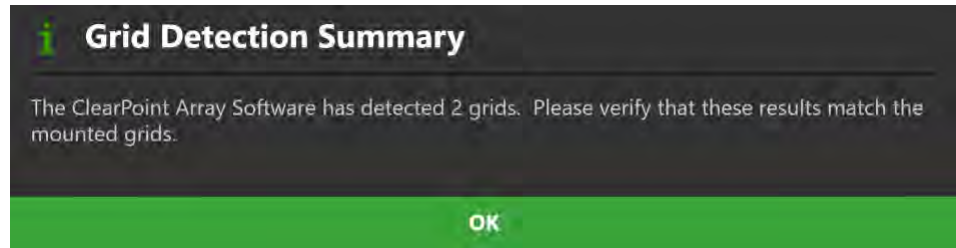
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### Reviewing Marking Grids

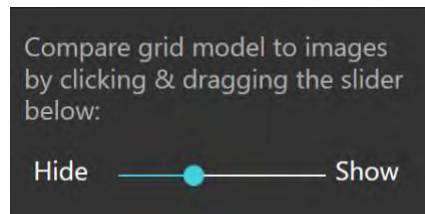
You may review the position and orientation of each defined marking grid relative to any image series loaded into the Grid Workflow.

> **To review marking grid detections**

1. Review the informational dialog that appears when the Verify Grids step is first activated. Verify that the number of grids detected matches up with the number of marking grids affixed to the patient.



2. Using the Grid Selector, select a detected grid to review (see [Selecting a Grid Pg. 74](#)).
3. Select an image series for which to review the selected grid using the Thumbnail Bar (see [Using Thumbnails Pg. 79](#)).
4. Use the slider in the step control panel to change the opacity of each detected 3D marking grid model. Drag to the left to decrease the opacity of the 3D model. Drag to the right to increase the opacity of the 3D model. Verify that the model aligns with the signal of the physical marking grid affixed to the patient and encapsulated in the scan.




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**Caution:** It is important to be certain that the extra grid square above the A-6 position on the grid is correct because it is used by the application to determine the orientation of the marking grid to provide correct row and column labels.

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5. Repeat the above steps for each marking grid detected by the application.








## Modifying Marking Grids

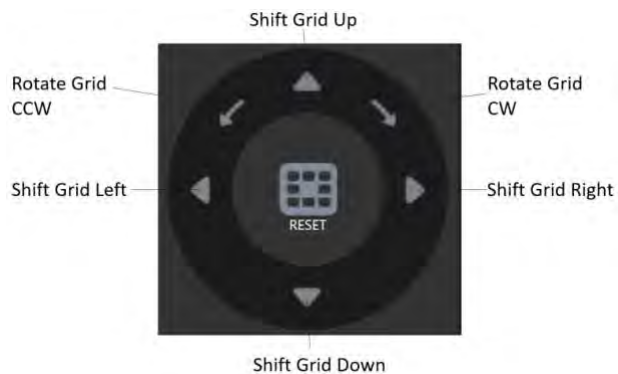
The Verify Grids step also allows you to explicitly modify the position and/or orientation of each defined marking grid. This may be necessary if the application incorrectly identifies one or more marking grids in the Acquire Master step, due to signal attenuation, image artifacts, or other issues in the acquired master series.

### > To manually modify a marking grid

1. Click on the **Edit** tab in the step's control panel.





2. Using the Grid Selector, select a marking grid to modify (see [Selecting a Grid Pg. 74](#)).
3. Use the Grid Editor control to make any of the following modifications to the selected marking grid:
  - Click the  button to shift the selected marking grid one column at a time to the left.
  - Click the  button to shift the selected marking grid one column at a time to the right.
  - Click the  button to shift the selected marking grid one row at a time upwards.
  - Click the  button to shift the selected marking grid one row at a time downwards.
  - Click the  button to rotate the selected marking grid's orientation cell (A-6) clockwise by 90 degrees from its current position.
  - Click the  button to rotate the selected marking grid's orientation cell (A-6) counter-clockwise by 90 degrees from its current position.
  - Click the  button to reset the position / orientation of the selected marking grid back to its originally detected position / orientation.



### > To undo or redo edits made to a marking grid

Use the **Grid Edit Undo** and **Grid Edit Redo** tools to undo or redo any changes made to the selected grid shown on screen.

- Select the  button from the custom toolbar to undo a change made to the selected grid shown on screen.

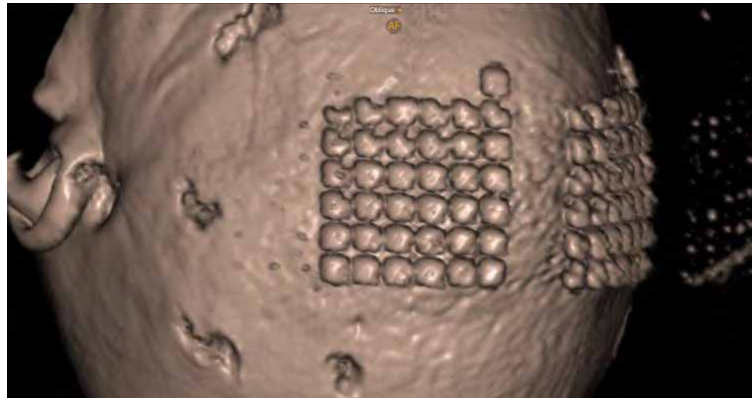
- Select the  button from the custom toolbar to redo a change made to the selected grid shown on screen.

## Managing Marking Grids

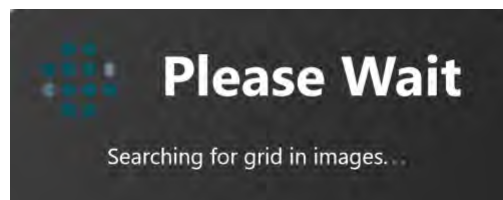
You may also use the Verify Grids step to manage the marking grids defined in the application. Specifically, you can detect one or more marking grids from any selected image series and/or delete any existing marking grids presently defined.

### > To automatically detect a new marking grid from an existing series

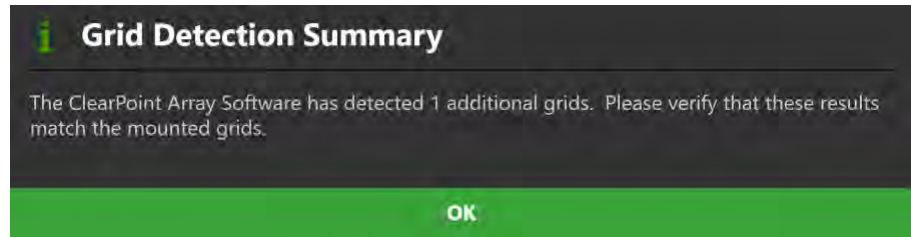
1. Select **Edit** tab in the step's control panel.
2. Select an image series from the Thumbnail Bar (see [Using Thumbnails Pg. 79](#)) to use to detect a new marking grid.
3. Using the Arrow Tool (see [Arrow Tool Pg. 89](#)), rotate the 3D view such that is perpendicular to the center of the non-identified marking grid that you wish to detect.



4. Click on the **Detect Additional Grid** button on the step's control panel.
5. A floating window will display a **Please Wait** message and the main application window will be blurred.



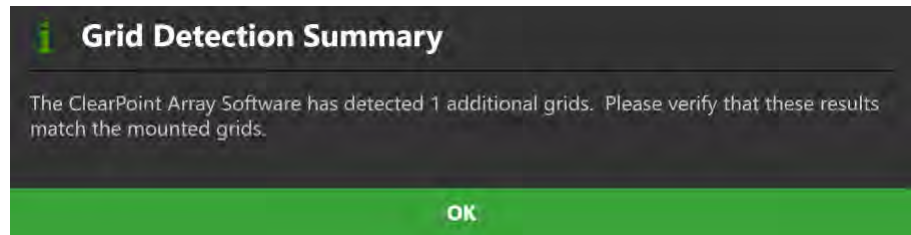
- The results of the automatic grid detection will be summarized in a pop-up window.



- The newly detected marking grids will be shown in the viewport.

> **To automatically detect a new marking grid from a new series**

- Transfer a newly acquired image series to the workstation.
- A floating window will display a **Please Wait** message and the main application window will be blurred while the application searches for new grids in the acquired image series.
- The results of the automatic grid detection will be summarized in a pop-up window.



> **To delete a marking grid**

- Using the Grid Selector, select a marking grid that you wish to delete (see [Selecting a Grid Pg. 74](#)).
- Click on the **Delete Selected Grid** button from the step's control panel.
- You will be prompted to confirm the removal of the marking grid before proceeding. Select **Yes** to proceed with the deletion of the selected marking grid. Otherwise, choose **No** to leave the selected marking grid intact.

### **Confirm Grid Removal**

The Left grid has been selected for removal. Are you sure that you would like to delete it?

**Yes**

**No**

---

## Define Target Volumes Step - *Defining Procedure Volumes*

The Define Target Volumes step in the Grid Workflow gives you the ability to revise any volumes of interest (VOIs) created during the Pre-Op Workflow and/or create new volumes of interest using any image series loaded in the given session. Like the Define Target Volumes step in the Pre-Op Workflow (see [Define Target Volumes Step - Defining Volumes Pg. 114](#)), this step offers the following functionality:

- Defining new target VOI annotations (see [Creating Target Volumes Pg. 114](#)).
- Editing target VOI annotations that have already been defined (see [Editing Target Volumes Pg. 115](#)).
- Reviewing one or more target VOI annotations (see [Reviewing Target Volumes Pg. 118](#)).
- Removing one or more unwanted target VOI annotations previously defined (see [Removing a Target Volume Pg. 119](#)).

If you completed the Define Target Volumes step in the Pre-Op Workflow, then any VOI annotations created will be transformed into the coordinate space of the master series. Those VOI annotations will be available for edit, review and/or removal in the Grid Workflow.

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*If no target VOIs are created, then you will not be able to use the Assess Treatment Volumes step (see [Assess Treatment Volumes – Evaluating Treatment Coverage Pg. 196](#)) in order to assess volumes representing treatment areas within the brain after a device insertion has been made.*

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## Set Target Point Step – *Defining Procedure Target Points*

The Set Target Point step in the Grid Workflow gives you the ability to revise target points for any defined trajectory paths created in the Pre-Op Workflow and/or create any number of new trajectory paths into the brain by first defining a target point. Like the Set Target Point step in the Pre-Op Workflow (see [Set Target Point Step – Defining Target Points Pg. 120](#)), this step provides you with the following high-level features:

- Defining one or more trajectory paths for each marking grid affixed to the patient (see [Creating Trajectories Pg. 142](#)).
- Editing the target point for one or more trajectory paths into the brain (see [Editing Target Points Pg. 121](#)).
- Changing the annotation properties associated with one or more trajectory paths (see [Editing Trajectory Properties Pg. 122](#)).
- Removing unwanted trajectory paths previously defined (see [Remove Trajectories Pg. 123](#)).
- Reviewing planned trajectory paths (see [Reviewing Trajectories Pg. 144](#)).

If you completed a Pre-Op Workflow, then any trajectory annotations created will be transformed into the coordinate space of the grid master series. If one or more of the transformed trajectories do not intersect a marking grid, the Set Target Point step will automatically launch the Move Grid task, so that you may either modify the trajectory such that it intersects a grid, or alternatively, move the marking grid to realize the desired trajectory (see [Move Grid Task – Repositioning Marking Grids Pg. 232](#)).

Trajectories in this workflow are filtered based on the marking grid that they are closest to, and are available for edit, review and or removal. New trajectories that are created will have their entry points set at the center of the selected marking grid. Entry point modification can be accomplished in downstream workflow steps. You may complete the step and move on in the workflow when at least one trajectory path has been created for each marking grid defined in the application.

---

*When a new trajectory is defined by specifying the target point, the entry point will default to the center of the marking grid for which the trajectory was defined. This default entry point location can be changed in later workflow steps.*

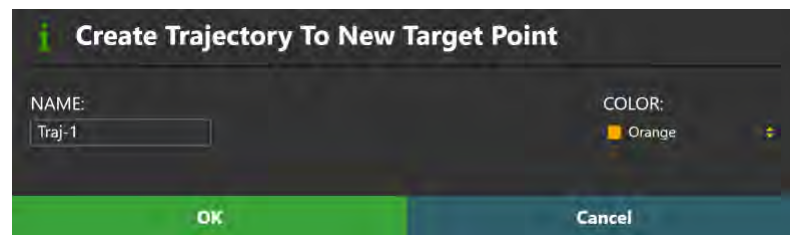
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### Creating Trajectories

You may create one or more trajectory paths into the brain for each marking grid defined in the application. Creation of a trajectory path involves explicitly selecting a marking grid for which you would like to associate a trajectory.

> **To create a trajectory annotation**

1. Select a marking grid for which you would like to associate a trajectory (see [Selecting a Grid Pg. 74](#)).
2. If additional image series are required to plan your target point, acquire and transfer the scan(s) to the workstation.
3. If necessary, select an additional image series for blending with the master series using the Thumbnail Bar (see [Using Thumbnails Pg. 79](#)).
4. Change the crosshair position to a location within the master series or selected blended series that you wish to define a trajectory path (see [Changing Crosshair Positions Pg. 83](#)). If you wish to use a target VOI to help define the target point location, you may correlate to the center of any defined target VOI using the **Volumes** visibility toggle button (see [Working with Volume of Interest Annotations Pg. 104](#)).
5. Select **New Target Point** from the step's control panel.
6. A floating window will appear prompting you define the following attributes for the trajectory annotation to be created.
  - Name – Specify a unique name that will identify the trajectory in the user interface. (Note: The application will prevent identical naming of trajectories).
  - Color – Specify a color defining how the trajectory will be displayed in the user interface.



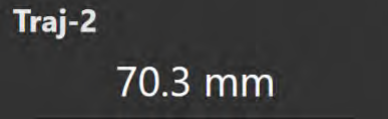
7. Select **OK** to define a trajectory path in the user interface. Select **Cancel** to cancel the trajectory creation.
8. If a new trajectory has been created, note that a new graphic annotation corresponding to a path connecting the target point just defined to a default entry point location at the center of the currently selected marking grid is shown in the application viewports.

## Reviewing Trajectories

You may review the position of each end point as well as review scanner bore clearance and depth measurements for a particular trajectory.

### > To navigate to a trajectory's end points

1. Use the Trajectory Selector available in the step's control panel to select a trajectory annotation that you wish to review (see [Selecting a Trajectory Pg. 75](#)).
2. Select **Go To Target Point** from the step control panel to navigate to the selected trajectory's target point.
3. Select **Go To Entry Point** from the step control panel to navigate to the selected trajectory's entry point.
4. Review the linear distance between the two trajectory end points using the value specified in the step control panel.



Traj-2

70.3 mm

### > To review scanner bore clearance and trajectory depth measurements

1. Use the Trajectory Selector available in the step's control panel to select a trajectory annotation that you wish to review (see [Selecting a Trajectory Pg. 75](#)).
2. Click on the device clearance and reach information button beside the selected trajectory item (see [Selecting a Trajectory Pg. 75](#)).
3. Alternatively, use the annotation context menu to show the Device Clearance and Reach Information Dialog (see [Working with Trajectory Annotations Pg. 99](#)).



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## Finalize Trajectory Step - *Reviewing Trajectories*

The Finalize Trajectory step allows you to set entry points for each of the trajectories defined prior to localizing mount point(s) for one or more trajectory frames onto the patient. You may complete the step and move on in the workflow when all defined trajectory paths have been reviewed. This includes ensuring that the trajectory paths reach the intended target point without crossing through any unintended anatomical structures, as well as confirming that each trajectory path's entry points has been set on the surface of the patient's skull.

The Finalize Trajectory step offers the following high-level features:

- Modifying the entry point for one or more trajectory paths into the brain (see [Editing Entry Points Pg. 145](#)).
- Revising the target point for one or more trajectory paths into the brain (see [Revising Target Points Pg. 147](#)).
- Providing guidance to move one or more marking grids in order to realize an anatomically viable trajectory path (see [Move Grid Task – Repositioning Marking Grids Pg. 232](#)).

Some functionality offered by the Set Target Point (see [Set Target Point Step – Defining Procedure Target Points Pg. 142](#)) step is also offered in the Finalize Trajectory step, including:

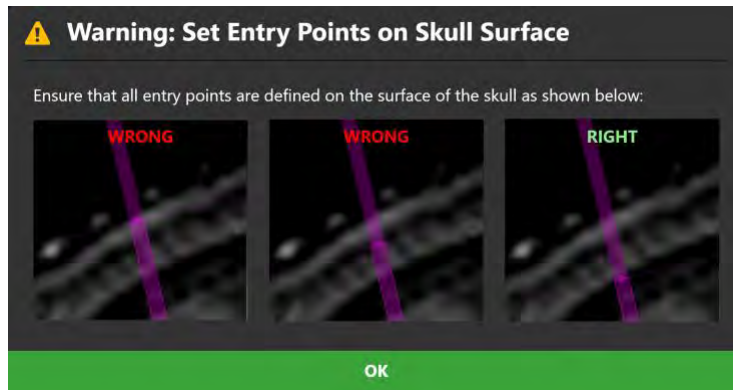
- Removing unwanted trajectory paths previously defined (see [Remove Trajectories Pg. 123](#)).
- Modifying properties associated with one or more trajectory annotations (see [Editing Trajectory Properties Pg. 122](#)).
- Reviewing planned trajectory paths (see [Reviewing Trajectories Pg. 124](#)).

### Editing Entry Points

You may use the Finalize Trajectory step to edit the entry points for any trajectory annotation defined in the Grid Workflow. Entry point edits are performed in views aligned obliquely along the defined trajectory path.

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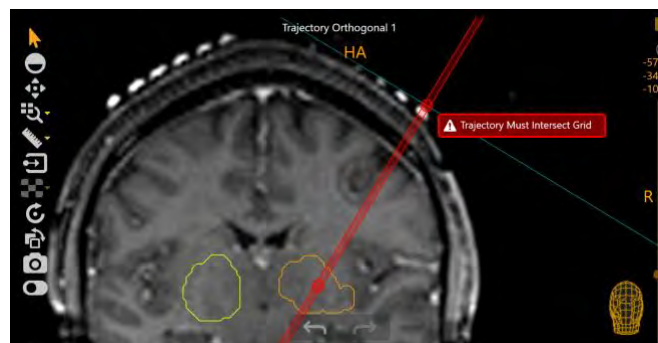
**Caution:** Confirm that entry points for all trajectories intersecting the selected marking grid have been defined correctly as shown in the dialog below. Failure to set the entry point on the surface of the skull may result in parallax error when identifying the mounting location for the trajectory frame(s).



> **To edit an entry point**



1. Use the Trajectory Selector available in the step's control panel to select a trajectory annotation whose entry point you wish to edit (see [Selecting a Trajectory Pg. 75](#)).
2. If necessary, select an additional image series for blending with the master series using the Thumbnail Bar (see [Using Thumbnails Pg. 79](#)).
3. Edit the selected trajectory's entry point using mouse and click drag operations (see [Working with Trajectory Annotations Pg. 99](#)).

*If you attempt to make entry point edits such that the selected trajectory will not intersect the selected marking grid, the application will prevent such edits and present a warning message. It is necessary that all defined trajectory paths must intersect the selected marking grid in order for the application to prescribe valid frame mount point location(s). If the desired trajectory path does not intersect the selected marking grid, use the Move Grid task to reposition the selected marking grid on the patient. See [Move Grid Task – Repositioning Marking Grids Pg. 232](#) for further details.*



> **To undo or redo entry point edits made to a trajectory annotation**

Use the **Trajectory Undo** and **Trajectory Redo** tools to undo or redo any entry point changes made to the selected trajectory annotation shown on screen.

- Select the  button from the custom toolbar to undo an entry point edit made to the selected trajectory annotation shown on screen.
- Select the  button from the custom toolbar to redo an entry point edit made to the selected trajectory annotation shown on screen.

## Revising Target Points

The Finalize Trajectory step may be used to revise the target point for a given trajectory, in views aligned obliquely to the currently selected trajectory.

> **To revise a target point**

1. Select **Edit** tab in the step's control panel.
2. Use the Trajectory Selector available in the step's control panel to select a trajectory annotation whose target point you wish to edit (see [Selecting a Trajectory Pg. 75](#)).
3. If necessary, select an additional image series for blending with the master series using the Thumbnail Bar (see [Using Thumbnails Pg. 79](#)).
4. Revise the selected trajectory's target point using mouse and click drag operations (see [Working with Trajectory Annotations Pg. 99](#)).

> **To undo or redo target point revisions made to a trajectory annotation**

Use the tools provided in the custom toolbar to undo or redo any changes to the target point for the selected trajectory annotation (see [Editing Target Points Pg. 121](#)).

---

## Mount Frames Step – *Mounting Frames*

Use the Mount Frames step to locate the mount points for each SMARTFrame Array™ trajectory frame to be mounted to the patient. The viewports presented in the step display 3D models of each marking grid underlay, and based on the trajectory selected for each, will display the location of the frame mount point on the grid underlay. This provides you with enough information so that you can localize the position of where the frame should be mounted for a particular planned trajectory on the patient. You may complete the step when the trajectory frame base has been mounted onto the patient, and the targeting stems for each frame have been inserted into the base.

---

**Caution:** It is important to ensure that all marking grids have been identified correctly by the software before visualizing the frame mount points. Ensure that you have performed this action properly using the Verify Grids step prior to activating this step. See [Verify Grids Step - Confirming Marking Grids Pg. 135](#) for details.

Please ensure that all trajectory entry points have been set on the surface of the skull prior to visualizing the frame mount points. Ensure that you have performed this action properly using the Finalize Trajectory step prior to activating this step. See [Finalize Trajectory Step - Reviewing Trajectories Pg.145](#) for details.

---

The Mount Frames step allows you to perform the following workflow-related actions:

- Localizing one or more trajectory frame mount points on the patient (see [Locating Mount Points Pg. 148](#))
- Realizing one or more mount points on the patient (see [Realizing Mount Points Pg. 150](#)).
- Mounting one or more trajectory frames on the patient (see [Mounting the Frames Pg. 150](#)).

### Locating Mount Points

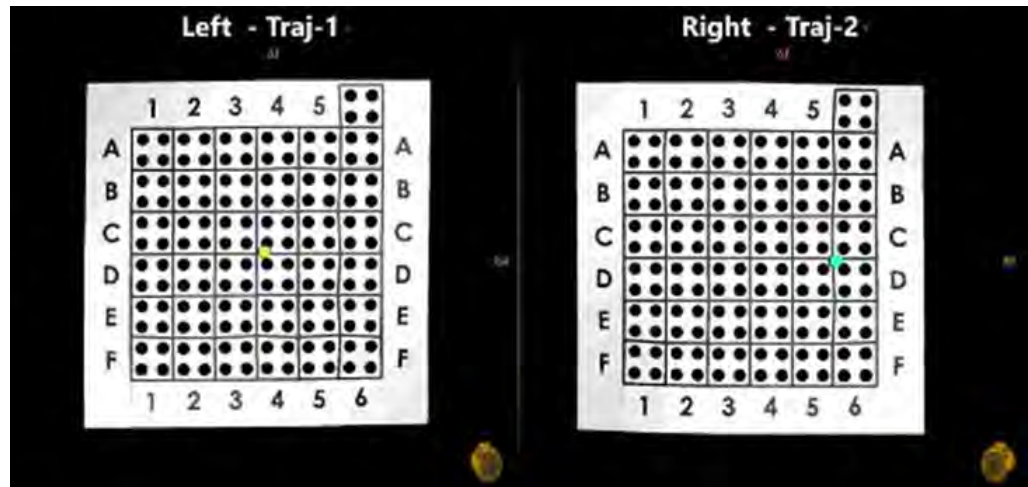
You may visualize the mount points prescribed by the software for each defined planned trajectory path using the viewing layout in the Mount Frames step. The viewing layout is dynamically constructed based on the number of marking grids defined in the application. Each viewport will display a different marking grid affixed to the patient, with a menu to select a trajectory associated with the given marking

grid for which the frame mount point shall be displayed. This is done so that there is no confusion over which mount point is being prescribed for which grid.

---

*If one or more trajectories have been planned such that a frame mount point cannot be localized (i.e. mount point would be outside of the bounds of the grid), you will be prevented from activating the Mount Frames step until a frame mount point can be prescribed by the application for all defined trajectories.*

---

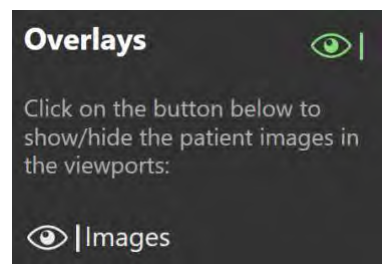


> **To find the frame mounting point**

1. Use the viewport orientation selector to select a trajectory for which you would like to see the frame mount point.
2. Visualize the mount point annotation on the 3D grid underlay model. Note that the mount point annotation matches the color of the corresponding trajectory annotation.

> **To show patient images**

To show the grid underlay model and mount point annotation overlaid on patient images, select the **Images** visibility toggle to show / hide images of the patient.

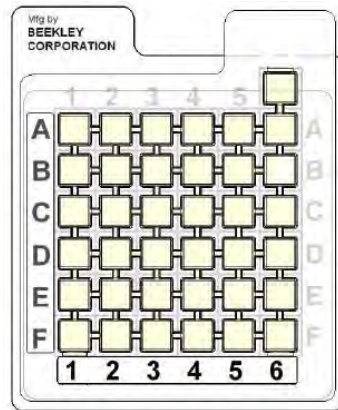


## Realizing Mount Points

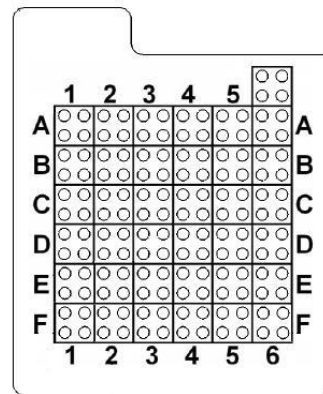
After you have identified the mount point(s) using the application, locate the physical position of the mount point(s) on the patient. See [Appendix 1 - B. Using the MRI to find the Mount Point](#).

### > To physically correlate the mount point(s) on the patient

1. Move the patient to the back of the scanner bore to provide access to their head.
2. Remove the top layer of the marking grid containing the fluid-filled squares to access the layer underneath. This layer has four holes for each grid square. Identify the hole in the physical marking grid which matches the hole in the model representation displayed in the software.



Grid top layer and labels



Grid with fluid-filled portion removed

---

**Caution:** Do not proceed to the next workflow step until all of the frame hardware has been mounted onto the patient, a targeting stem is inserted into each frame, and the patient is returned to the scanner bore.

---

## Mounting the Frames

After reviewing and verifying the mount points using the application, take the appropriate steps to mount the frame hardware and insert the targeting stems for each frame.

See [Appendix 1 - C. Mounting the Scalp Mount Base](#) and [Appendix 1 - D. Attaching the SmartFrame Array Tower to the Base](#).

---

## Frame Workflow

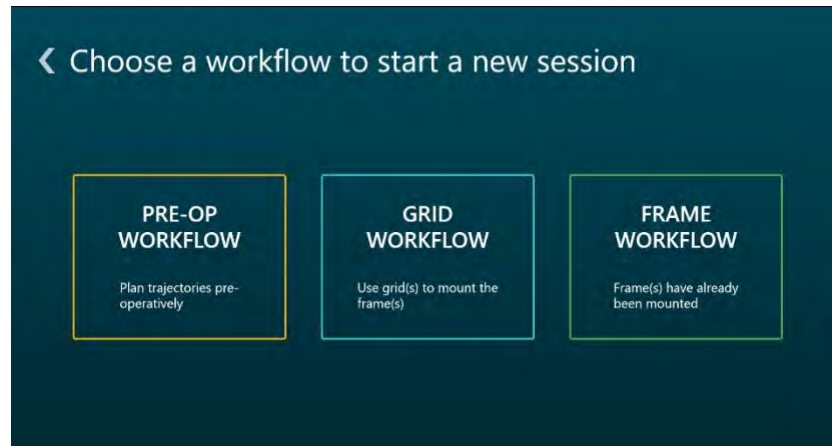
This section describes how to use the ClearPoint Array™ Workstation to finalize planned trajectories into the brain with one or more SMARTFrame Array™ trajectory frames mounted, align those trajectory frames to the planned trajectories, and then insert one or more devices into the brain. To carry out this workflow, it is necessary to: acquire a whole head scan of the patient with one or more trajectory frames affixed, confirm and verify the positions of the trajectory frames in the application, complete trajectory planning, align one or more trajectory frames to the planned trajectories, select guide channels to insert one or more devices into the brain, monitor the insertion of those devices into the patient, and assess the anatomical viability of the device placements.

Prior to starting this workflow, the following conditions must be met for each trajectory requiring a separate frame:

- One or more SMARTFrame Array™ trajectory frames have been mounted onto the patient. This may have been accomplished using the following means:
  - By previously completing a Grid Workflow (see [Grid Workflow Pg. 129](#)) to identify mount point locations for each of the trajectory frames and performing frame mounting in the MRI Suite.
  - By mounting frames in the operating room (OR) using a surgical navigation system (SNS).
- The targeting stem for each trajectory frame has been inserted into the frame.
- The patient has been moved to the MRI Scanner isocenter.

### > To start a new Frame Workflow

1. Launch the application.
2. Using the Splash Screen, select **START NEW SESSION** (see [Launching the Splash Screen Pg. 47](#))
3. A new page on the Splash Screen will appear, presenting you with the workflow options available to start a new session.



4. Select **FRAME WORKFLOW** to start a Frame Workflow.

> **To start a Frame Workflow by completing a Grid Workflow**

1. Complete a Grid Workflow using the application (see [Grid Workflow Pg. 129](#)).
2. After mounting one or more trajectory frames onto the patient, select **ALL FRAMES MOUNTED** using the Step Selector in the Mount Frames step (see [Mount Frames Step – Mounting Frames Pg. 148](#)).
3. A new Frame Workflow will be started by the application.

> **To start a Frame Workflow after completing a Pre-Op Workflow**

1. Complete a Pre-Op Workflow using the application (see [Pre-Op Workflow Pg. 109](#)).
2. After loading the preoperative session prior to the procedure, select **START FRAME WORKFLOW** using the Step Selector in the Finalize Trajectory Plan step (see [Finalize Trajectory Plan Step – Finalizing the Preoperative Plan Pg. 126](#)).



---

## Acquire Master Scan Step – *Acquiring a Frame Master Scan*

The Acquire Master Scan step prompts you to acquire a whole-head scan of the patient with one or more SMARTFrame Array™ trajectory frames affixed. The acquired scan can then be transferred to the workstation and reviewed to ensure that adequate coverage of the patient anatomy and mounted hardware is achieved within the scan's field-of-view (FOV). In cases where the whole-head scan of the patient does not achieve adequate coverage of the head and/or trajectory frames (including targeting stems), the scan can be cleared from the application, and a new scan can be acquired and transferred to the workstation.

---

*The scan that is loaded into the application in the Acquire Master Scan step is referred to as the “master series” and its frame of reference will serve as the base coordinate space for all other scans loaded into the application with this workflow selected. If additional scans are loaded that have a different frame of reference coordinate space than the master series, you will be prompted to fuse these scans with the master series prior to proceeding in the workflow. See [Fusion Task Fusing Images Pg. 221](#) for details.*

---

In terms of high-level functionality, the Acquire Master Scan step in the Frame Workflow is analogous to the Acquire Master Scan step in the Grid Workflow (see [Acquire Master Scan Step - Acquiring a Grid Master Scan Pg. 131](#)). The following operations are also offered by the Acquire Master step in the Frame Workflow:

- Reviewing the master series to ensure that it is correct prior to proceeding in the workflow (see [Reviewing the Master Series Pg. 132](#)).
- Clearing an unwanted master series in cases where it was acquired incorrectly or an incorrect scan was sent to the workstation (see [Clearing the Master Series Pg. 133](#)).

---

*If you completed a Pre-Op or Grid Workflow prior to activating this step, you will be prompted to fuse the master series from the prior workflow with the whole-head scan of the patient acquired in this step. This allows for your trajectories and VOIs from the prior workflow to be automatically translated into the frame of reference of the master series with frames mounted.*

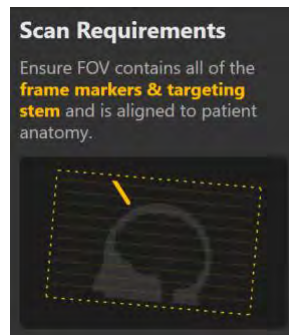
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## Acquiring a Frame Master Series

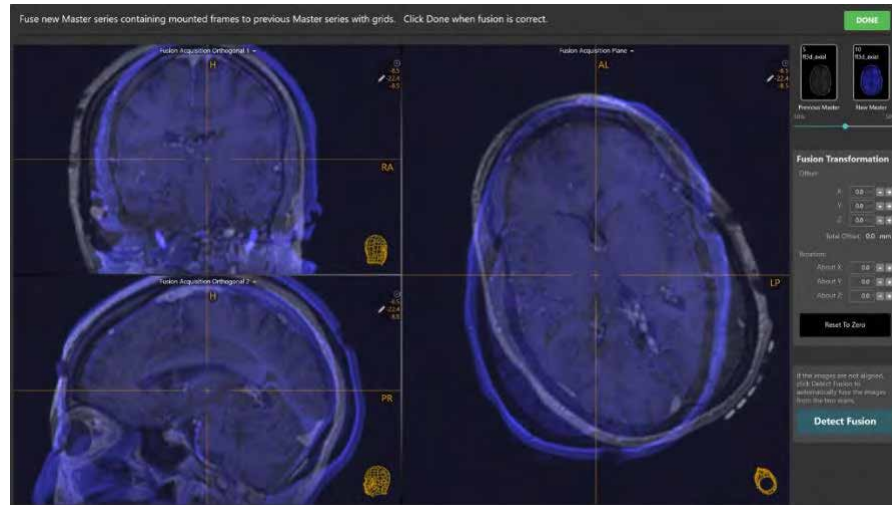
You may complete the Acquire Master Scan step when a whole-head scan containing all mounted trajectory frames has been acquired and loaded onto the workstation. When images are loaded onto the workstation with the Acquire Master Scan step selected, the application automatically detects the position of any SMARTFrame Array™ trajectory frames that are mounted to the patient.

### > To acquire a master series

1. With the patient inside the bore of the scanner, use the MRI Scanner Console to acquire a T1-weighted whole-head scan of the patient with one or more trajectory frames mounted to the patient. Ensure that the scan's field-of-view (FOV) completely encapsulates all trajectory frames, including their corresponding targeting stems. Also ensure that the scan is aligned to patient anatomy.



2. Transfer the scan to the workstation.
3. If you completed a Pre-Op or Grid Workflow prior to this step, use the pop-up Fusion task (see [Fusion Task Fusing Images Pg. 221](#)) to fuse the newly acquired master series with the master series from the prior workflow.



- If you completed a Pre-Op or Grid Workflow prior to this step, the application will transform all trajectories and volumes of interest created in that workflow into the coordinate space defined by the intraoperative images containing the trajectory frames.

---

*Upon receiving the master series in the Acquire Master Scan step, the application will automatically search for any SMARTFrame Array™ trajectory frames in the scan. If the application fails to detect any trajectory frames, you will be notified via a status message that no frames could be identified. In these instances, you may still move forward in the workflow to manually detect additional trajectory frames and/or acquire additional scans containing the trajectory frames affixed to the patient.*

---

## Re-activating Prior Workflows

If you completed a Pre-Op (see [Pre-Op Workflow Pg. 109](#)) or Grid Workflow (see [Grid Workflow Pg. 129](#)) prior to this step, the Acquire Master Scan step allows you to navigate back to the steps completed as part of that prior workflow.

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*Navigating back to a previously completed workflow after a Frame Workflow has been started will prevent you from making any changes to that prior workflow. In these cases, the prior workflow will be placed in **REVIEW ONLY** mode, whereby any attempted edits made to previously defined trajectories and/or VOIs as well as image loading operations will be disallowed. You will only be able to make changes in the prior workflow if the master series and all associated data is cleared from the Frame Workflow.*

---

> **To re-activate a completed workflow**

1. Using the Step Selector, use the **BACK** button to navigate to the previously completed workflow step (see [Selecting a Step Pg. 72](#)).
2. You will be prompted to confirm navigation to the prior workflow. Select **OK** to confirm navigation back to the prior workflow, where any attempted annotation edits and image loading operations will be disallowed. Otherwise, click **Cancel** to leave the Acquire Master Scan step activated.



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## Verify Frame Base Markers Step – *Confirming Frame Markers*

The Verify Frame Base Markers step allows you to review and confirm the location of the fiducial markers in the base of each detected SMARTFrame Array™ trajectory frame using one or more scans. Additionally, the step allows for the following operations:

- Manually or automatically updating the position of each fiducial marker in instances where it does not match up with the physical frame base shown in the underlying images (see [Modifying Frame Markers Pg. 158](#)).
- Identifying one or more trajectory frames that were not detected automatically in the Acquire Master step and/or not yet defined (see [Managing Frame Base Markers Pg. 162](#)).
- Remove trajectory frames that may not correspond to trajectory frames physically mounted on the patient (see [Managing Frame Base Markers Pg. 162](#)).

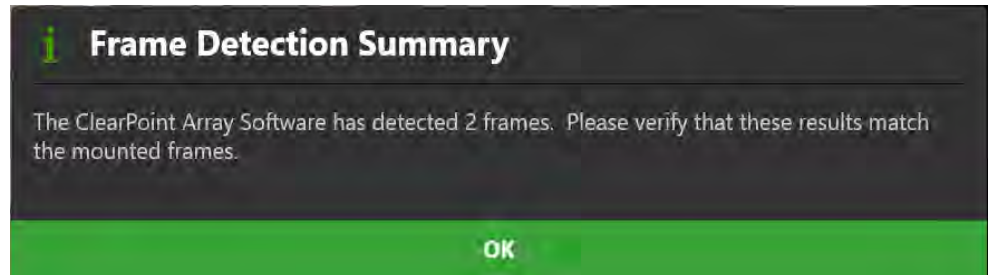
When images are loaded into the workstation with the Verify Frame Base Markers step selected, the application automatically attempts to detect any SMARTFrame Array™ trajectory frames from the loaded image series. You may complete the step and move on in the workflow when at least one trajectory frame has been defined in the application.

### Reviewing Frame Markers

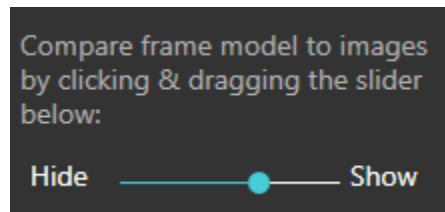
You may review the positions of the fiducial markers associated with each of the defined frames relative to any image series loaded in the Frame Workflow.

#### > To review frame markers

1. Review the informational dialog that appears when the Verify Frame Base Markers step is first activated. Verify that the number of trajectory frames detected matches up with the number of trajectory frames mounted on the patient.



2. Using the Frame Selector, select a frame whose fiducial markers you would like to review (see [Selecting a Frame Pg. 75](#)).
3. The viewport's orientation will align to the plane created by the three frame markers located in the base of the selected frame.
4. Use the slider in the step's control panel to change the opacity of each 3D trajectory frame model shown in the viewports. Drag to the left to decrease the opacity of the 3D model. Drag to the right to increase the opacity of the 3D model. Verify that the base markers in the model align with the signal from the physical base markers encapsulated in the scan.



5. Repeat the above steps for each trajectory frame detected by the application.

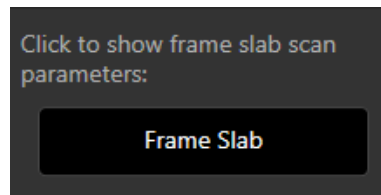
## Modifying Frame Markers

The Verify Frame Base Markers step also allows you to modify the position of each of the selected frame's fiducial markers. This may be necessary if the application incorrectly identifies one or more frame markers in the Acquire Master step, due to signal attenuation, image artifacts, or other issues in the acquired master series.

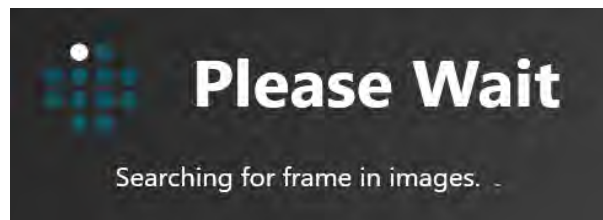
### > To automatically edit the frame markers

1. Select **Edit** in the step's control panel.
2. Using the Frame Selector, select a trajectory frame to modify (see [Selecting a Frame Pg. 75](#)).

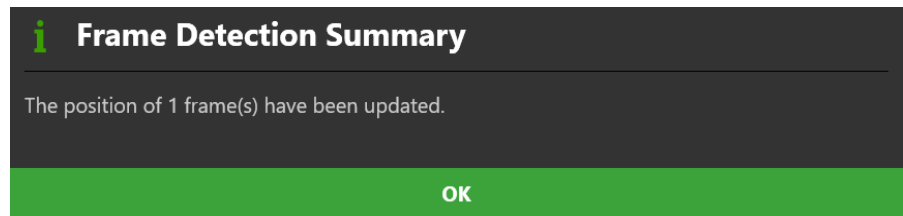
3. Select **Frame Slab** in the step's control panel to display scan plane parameters to be entered on the MRI Scanner Console to perform an image acquisition of the selected frame.



4. Acquire the scan using the parameter values entered on the MRI Scanner Console. Transfer or load the images onto the workstation.
5. Upon receiving the frame scan, a floating window will display a **Please Wait** message and the user interface will be blurred while the application searches for the trajectory frame(s) in the scan.



6. The results of the automatic frame detection will be summarized in a pop-up window.



7. To review the results of the automatic frame detection, use the slider in the step control panel to change the opacity of the 3D trajectory frame model shown in the viewports. Drag to the left to decrease the opacity of the 3D model. Drag to the right to increase the opacity of the 3D model. Verify that the base markers in the model align with the signal of the physical base markers encapsulated in the scan.



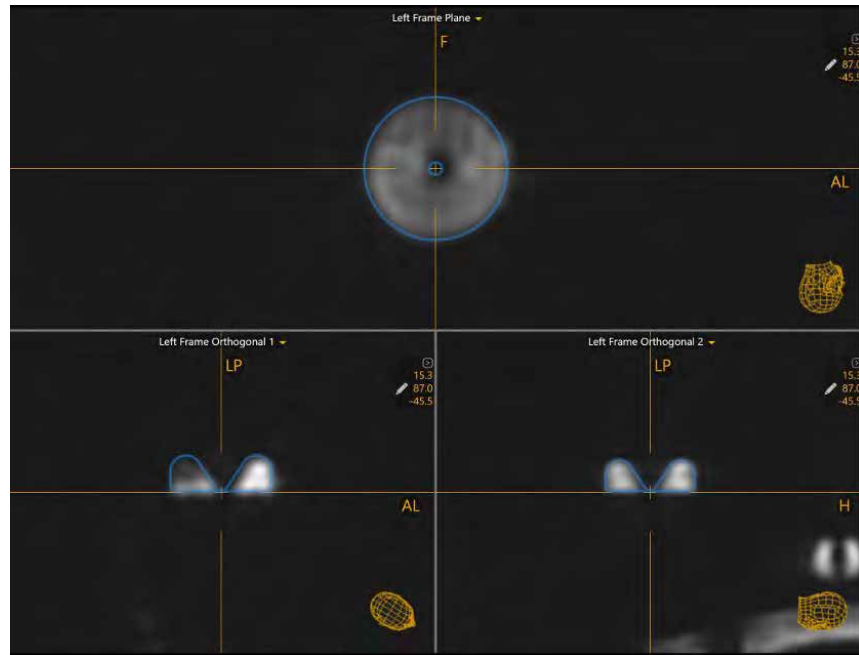
> **To manually modify edit the frame markers**

1. Select **Edit** in the step's control panel.
2. Using the Frame Selector, select a trajectory frame to modify (see [Selecting a Frame Pg. 75](#)).
3. In the step's control panel, click on the frame marker (either 1, 2 or 3) that you wish to modify. This will select the marker for modification. Alternatively, you may click on the frame marker directly in the 3D viewport to select the frame marker to modify.



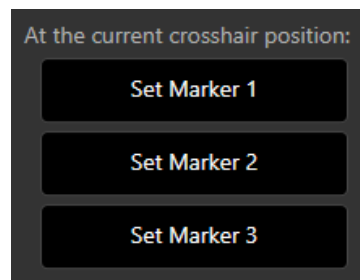
4. The viewport crosshairs will automatically move to the currently defined position of the selected base marker. A graphic representation of the marker outline will be shown in each viewport.






5. To modify the position of the selected base marker:


- With the Arrow tool selected (see [Arrow Tool Pg. 89](#)), click and drag the blue outline to match the cross section of the physical base marker displayed in the images.
- Alternatively, move the crosshairs (see [Changing Crosshair Positions Pg. 83](#)) to the physical center of the base marker displayed in the images and press the appropriate **Set Marker** button.



> **To undo or redo edits made to frame base markers**

Use the **Frame Edit Undo** and **Frame Edit Redo** tools to undo or redo any changes made to the base markers for the selected trajectory frame.

- Select the  button from the custom toolbar to undo a change made to a base marker of the selected trajectory frame.

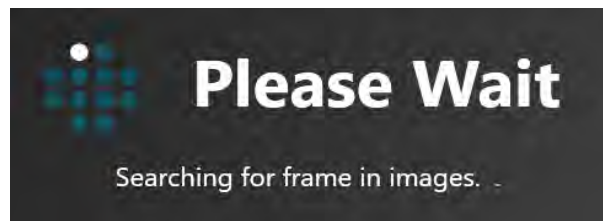
- Select the  button from the custom toolbar to redo a change made to a base marker of the selected trajectory frame.

## Managing Frame Base Markers

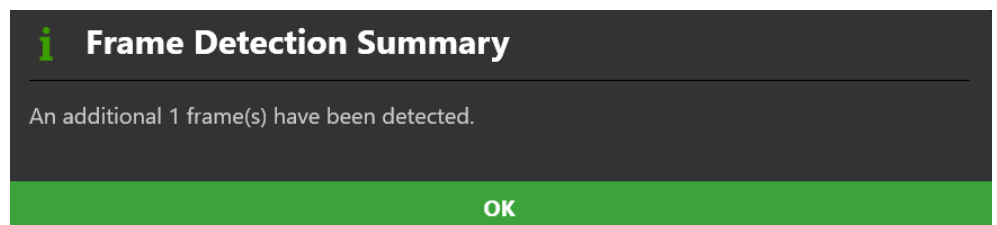
You may also use the Verify Frame Base Markers step to manage the trajectory frames defined in the application. Specifically, you can detect one or more additional trajectory frames from any selected image series and/or delete any existing trajectory frames presently defined.

### > To automatically detect a new frame using an existing series

1. Select **Edit** in the step's control panel.
2. Select an image series from the Thumbnail Bar (see [Using Thumbnails Pg. 79](#)) to use to detect the new frame.
3. Move the crosshairs to the base of the frame that you wish to detect (see [Changing Crosshair Positions Pg. 83](#)).
4. Select **Search for Frame** in the step's control panel.
5. A floating window will display a **Please Wait** message and the user interface will be blurred while the application searches for the trajectory frame in the scan.



6. The results of the automatic frame detection will be summarized in a pop-up window.



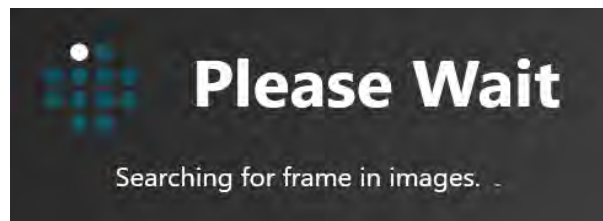
7. The newly detected frame will be added to the Frame Selector (see [Selecting a Frame Pg. 75](#)).

8. To review the results of the automatic frame detection, use the slider in the step control panel to change the opacity of the 3D trajectory frame model shown in the viewports. Drag to the left to decrease the opacity of the 3D model. Drag to the right to increase the opacity of the 3D model. Verify that the base markers in the model align with the signal of the physical base markers encapsulated in the scan.

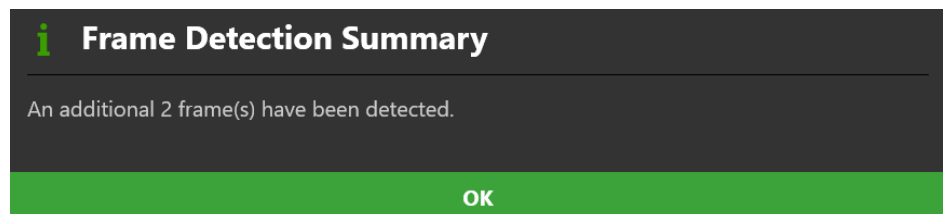


> **To automatically detect a new frame from a newly acquired series**

1. Transfer a newly acquired image series to the workstation. A whole-head scan containing all mounted trajectory frames and their targeting stems is recommended.
2. A floating window will display a **Please Wait** message and the user interface will be blurred while the application searches for the trajectory frame(s) in the scan.



3. The results of the automatic frame detection will be summarized in a pop-up window.

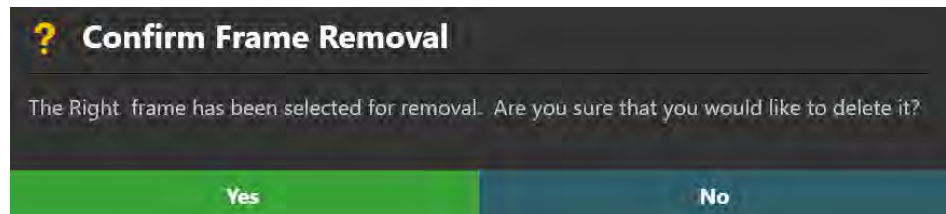


4. To review the results of the automatic frame detection, use the slider in the step control panel to change the opacity of the detected 3D trajectory frame model. Drag to the left to decrease the opacity of the 3D model. Drag to the right to increase the opacity of the 3D model. Verify that the base markers in the model align with the signal of the physical base markers encapsulated in the scan.



> **To delete a trajectory frame**

1. Select **Edit** in the step's control panel.
2. Using the Frame Selector, select the trajectory frame you wish to delete (see [Selecting a Frame Pg. 75](#)).
3. Select **Delete** in the step's control panel.
4. You will be prompted to confirm the removal of the trajectory frame before proceeding. Select **Yes** to proceed with the deletion of the selected trajectory frame. Otherwise, choose **No** to leave the selected trajectory frame intact.



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## Verify Targeting Stem Step – *Confirming the Stem*

The purpose of the Verify Targeting Stem step is to allow you to review and edit the initially detected position and angulation of the targeting stem for each trajectory frame mounted on the patient. This position is used by the application to prescribe you with the first set of adjustments needed to align the trajectory frame to a planned trajectory path. You may complete this step when the targeting stems for each trajectory frame has been reviewed and verified.

The Verify Targeting Stem step allows for the following operations:

- Review the detected position of the targeting stem for each mounted trajectory frame (see [Reviewing Targeting Stems Pg. 165](#)).
- Manually edit the position and/or orientation of the targeting stem for each mounted frame, in instances where the identified targeting stem does not match up with the physical stem shown in the underlying images (see [Modifying Targeting Stems Pg. 166](#)).

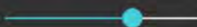
### Reviewing Targeting Stems

You may review the position and orientation of each targeting stem relative to any image series loaded into the Frame Workflow.

#### > To review targeting stem detections

1. Using the Frame Selector, select a trajectory frame whose targeting stem you would like to review (see [Selecting a Frame Pg. 75](#)).
2. Select an image series for which to review the selected frame's targeting stem using the Thumbnail Bar (see [Using Thumbnails Pg. 79](#)).
3. Use the slider in the step control panel to change the opacity of each 3D targeting stem model shown in the viewports. Drag to the left to decrease the opacity of the 3D model. Drag to the right to increase the opacity of the 3D model. Verify that the model aligns with the signal of the physical targeting stem inserted into the trajectory frame affixed to the patient and encapsulated in the scan.

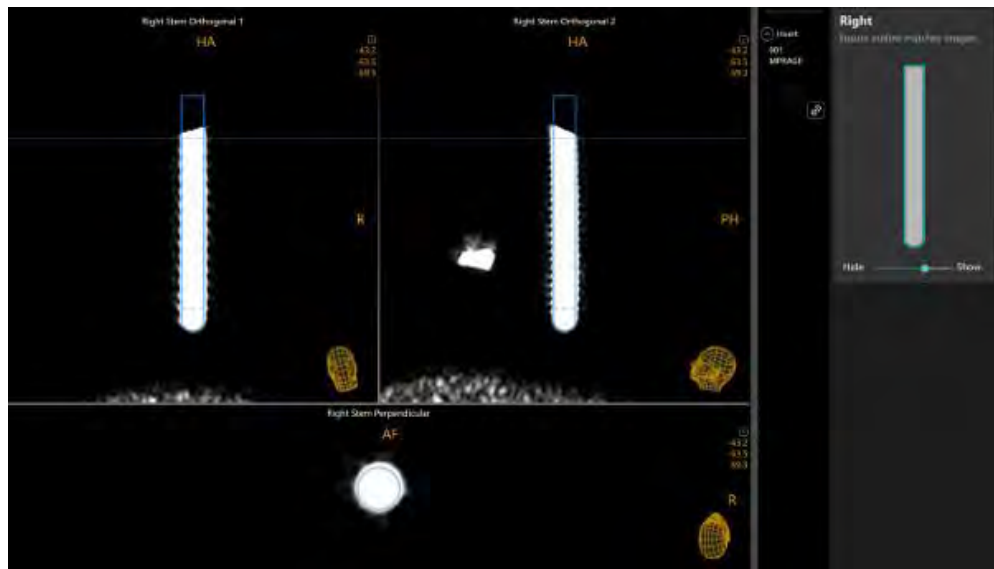
Compare targeting stem model to images by clicking & dragging the slider below:

Hide  Show

- Repeat the above steps for each trajectory frame defined in the application.

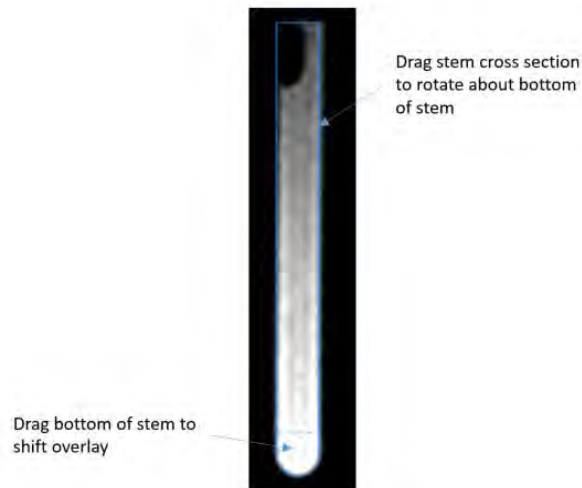
## Modifying Targeting Stems

The Verify Targeting Stem step also allows you to explicitly modify the position and/or orientation of each defined targeting stem. This may be necessary if the application incorrectly identifies one or more targeting stems in the Acquire Master step, due to signal attenuation, image artifacts, a reduced field-of-view and/or other issues in the acquired master series.



### > To modify the targeting stem position

- Select **Edit** the step's control panel.
- To edit the position of the targeting stem in the **Orthogonal 1** and/or **Orthogonal 2** viewports:
  - To shift the entire targeting stem cross section to correct for positional discrepancies when compared to the underlying images, hover the mouse over the bottom portion of the stem graphic (below the dotted line). Click and drag with the mouse over the bottom portion of the stem graphic to shift the cross section.
  - To rotate the targeting stem cross section to correct for orientation discrepancies when compared to the underlying images, hover the mouse over the stem graphic (above the dotted line). Click and drag with the mouse over the stem graphic to rotate it about the bottom position of the stem.





3. To edit the position of the targeting stem in the **Perpendicular** viewports:

- To shift the entire targeting stem cross section to correct for positional discrepancies when compared to the underlying images, drag the Fly Through Line in the **Orthogonal 1** or **Orthogonal 2** viewports to be positioned below the bottom portion of the stem graphic (below the dotted line). Click and drag with the circle cross section in the **Perpendicular** viewport to shift the entire targeting stem cross section.
- To rotate the targeting stem cross section to correct for orientation discrepancies when compared to the underlying images, drag the Fly Through Line in the **Orthogonal 1** or **Orthogonal 2** viewports to be positioned above the bottom portion of the stem graphic (above the dotted line). Click and drag the circle cross section in the **Perpendicular** viewport to rotate the targeting stem graphic about the bottom position of the stem.

> **To undo or redo edits made to the targeting stem**

Use the **Targeting Stem Undo** and **Targeting Stem Redo** tools to undo or redo any changes made to the selected targeting stem graphic shown on screen.

- Select the  button from the custom toolbar to undo a position or orientation edit made to the targeting stem graphic shown on screen.
- Select the  button from the custom toolbar to redo a position or orientation edit made to the targeting stem graphic shown on screen.

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## Define Target Volumes – *Refining Procedure Volumes*

The Define Target Volumes step in the Frame Workflow gives you the ability to revise any volumes of interest (VOIs) created during the Pre-Op/Grid Workflows and/or create new volumes of interest using any image series loaded in the given session. Like the Define Target Volumes step in the Pre-Op/Grid Workflow (see [Define Target Volumes Step - Defining Volumes Pg. 114](#)) this step offers the following functionality:

- Defining new target VOI annotations (see [Creating Target Volumes Pg. 114](#)).
- Editing target VOI annotations that have already been defined (see [Editing Target Volumes Pg. 115](#)).
- Reviewing one or more target VOI annotations (see [Reviewing Target Volumes Pg. 118](#)).
- Removing one or more unwanted target VOI annotations previously defined (see [Removing a Target Volume Pg. 119](#)).

If you completed the Define Target Volumes step in the Pre-Op and/or Grid Workflows, then any VOI annotations created will be transformed into the coordinate space of the frame master series. Those VOI annotations will be available for edit, review and/or removal in the Frame Workflow.

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*If no target VOIs are created, then you will not be able to use the Assess Treatment Volumes step (see [Assess Treatment Volumes – Evaluating Treatment Coverage Pg. 196](#)) in order to assess volumes representing treatment areas within the brain after a device insertion has been made.*

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## Set Target Point Step – *Refining Procedure Target Points*

The Set Target Point step in the Frame Workflow gives you the ability to revise target points for any defined trajectory paths created in the Pre-Op/Grid Workflows and/or create any number of new trajectory paths into the brain by first defining a target point. Like the Set Target Point step in the Pre-Op/Grid Workflows (see [Set Target Point Step – Defining Target Points Pg. 120](#)) this step provides you with the following high-level features:

- Defining one or more trajectory paths for each trajectory frame mounted on the patient (see [Creating Trajectories Pg. 169](#)).
- Editing the target point for one or more trajectory paths into the brain (see [Editing Target Points Pg. 121](#)).
- Changing the annotation properties associated with one or more trajectory paths (see [Editing Trajectory Properties Pg. 122](#)).
- Removing unwanted trajectory paths previously defined (see [Remove Trajectories Pg. 123](#)).
- Reviewing planned trajectory paths (see [Reviewing Trajectories Pg. 144](#)).

If you completed a Pre-Op and/or Grid Workflow, then any trajectory annotations created will be transformed into the coordinate space of the frame master series, with entry points set at the pivot point of the closest trajectory frame. Trajectories in this workflow are filtered based on the trajectory frame that they are closest to, and are available for edit, review and or removal. New trajectories that are created will have their entry points set at the pivot point of the selected trajectory frame. Entry point modification after the trajectory frames are mounted can be accomplished in further workflow steps. You may complete the step and move on in the workflow when at least one trajectory path has been created for each trajectory frame defined in the application.

---

*When a new trajectory is defined by specifying the target point, the entry point will be defaulted at the pivot point of the trajectory frame for which the trajectory was defined. This default entry point location may be changed in further workflow steps by selecting a guide channel. See [Selecting a Guide Channel Pg. 76](#) for further details.*

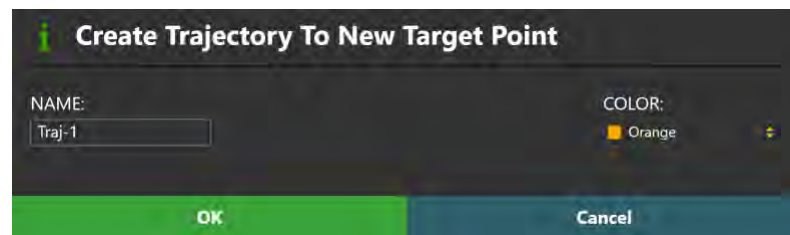
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### Creating Trajectories

You may create one or more trajectory paths into the brain for each trajectory frame defined in the application. Creation of a trajectory path involves explicitly selecting a trajectory frame with which you would like to associate a trajectory.

> **To create a trajectory annotation**

1. Select a trajectory frame with which you would like to associate a trajectory (see [Selecting a Frame Pg. 75](#)).
2. If additional image series are required to plan your target point, acquire and transfer the scan(s) to the workstation.
3. If necessary, select an additional image series for blending with the master series using the Thumbnail Bar (see [Using Thumbnails Pg. 79](#)).
4. Change the crosshair position to a location within the master series or selected blended series where you wish to define a trajectory path (see [Changing Crosshair Positions Pg. 83](#)). If you wish to use a target VOI to help define the target point location, you may correlate to the center of any defined target VOI using the **Volumes** visibility toggle button (see [Working with Volume of Interest Annotations Pg. 104](#)).
5. Select **New Target Point** from the step's control panel.
6. A floating window will appear prompting you define the following attributes for the trajectory annotation to be created.
  - Name – Specify a unique name that will identify the trajectory in the user interface. (Note: The application will prevent identical naming of trajectories).
  - Color – Specify a color defining how the trajectory will be displayed in the user interface.



7. Select **OK** to define a trajectory path in the user interface. Select **Cancel** to cancel the trajectory creation.
8. If a new trajectory has been created, note that a new annotation corresponding to a path connecting the target point just defined to a default entry point location at the pivot point of the currently selected trajectory frame is shown in the application viewports.

---

## Finalize Trajectory Step – *Finalizing Trajectories*

The Finalize Trajectory step allows you to review and finalize all planned trajectories prior to adjusting one or more trajectory frames. If it is necessary to make one or more entry point changes to the planned trajectories at this stage in the workflow, this can be accomplished by selecting a channel guide for device insertion. Later in the workflow, frame adjustment instructions will be provided to align the selected channel guide to the planned target point. If it is necessary to revise the target point for a given trajectory, this can be accomplished as well using the step. You may complete the step and move on in the workflow when all of the trajectory paths have been reviewed for anatomical viability.

The Finalize Trajectory step offers the following high-level features:

- Modifying the entry point for one or more trajectory paths into the brain by selecting a guide channel to be used for drilling / device insertion (see [Editing Entry Points by Changing the Guide Channel Pg. 171](#)).
- Revising the target point for one or more trajectories (see [Revising Target Points Pg. 172](#)).

Some functionality offered by the Set Target Point (see [Set Target Point Step – Refining Procedure Target Points Pg. 169](#)) step is also offered in the Finalize Trajectory step, including:

- Removing unwanted trajectory paths previously defined (see [Remove Trajectories Pg. 123](#)).
- Modifying properties associated with one or more trajectory annotations (see [Editing Trajectory Properties Pg. 122](#)).
- Reviewing planned trajectory paths (see [Reviewing Trajectories Pg. 124](#)).

### Editing Entry Points by Changing the Guide Channel

You may use the Finalize Trajectory step to edit the entry points for any trajectory annotation defined in the Frame Workflow. Entry point edits are performed by selecting a channel guide to be used for drilling / device insertion for the trajectory path of interest.

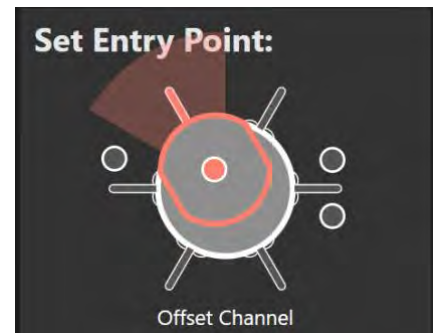
#### > To edit an entry point

1. Use the Trajectory Selector available in the step's control panel to select a trajectory annotation whose entry point you wish to edit (see [Selecting a Trajectory Pg. 75](#)).

2. Select **Edit** from the step's control panel.
3. If necessary, select an additional image series for blending with the master series using the Thumbnail Bar (see [Using Thumbnails Pg. 79](#)).
4. Edit the selected trajectory's entry point by selecting a guide channel, either by clicking on the desired projected guide channels shown in the **Trajectory Perpendicular** viewport or using the Guide Channel Selector in the step's control panel (see [Selecting a Guide Channel Pg. 76](#)).



**Click on the projected channel graphic to select a guide channel**



**Use the Guide Channel Selector to select a guide channel**

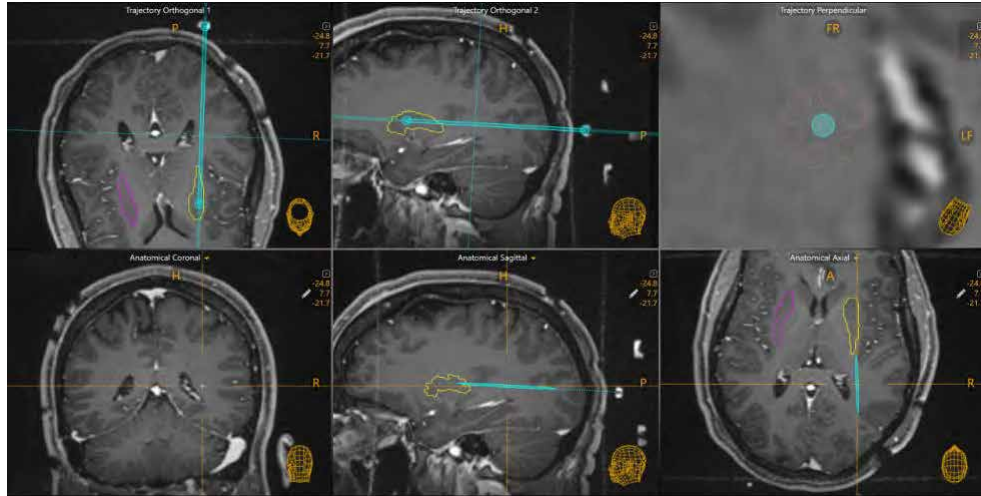
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*Since the trajectory frames have been mounted to the patient at this stage in the workflow, the application will disallow freeform edits of the trajectory entry point(s) using mouse click and drag operations. The only mechanism that can be used to edit the entry point(s) at this stage in the workflow is to select a different guide channel.*

---

## Revising Target Points

The Finalize Trajectory step may also be used to revise the target point for a given trajectory.





> **To revise a target point**

1. Use the Trajectory Selector available in the step's control panel to select a trajectory annotation whose target point you wish to edit (see [Selecting a Trajectory Pg. 75](#)).
2. If necessary, select an additional image series for blending with the master series using the Thumbnail Bar (see [Using Thumbnails Pg. 79](#)).
3. In the **Trajectory Orthogonal 1** and/or **Trajectory Orthogonal 2**, viewports, use mouse click and drag operations to edit the target point in views aligned obliquely to the currently selected trajectory path (see [Working with Trajectory Annotations Pg. 99](#)).
4. In the **Trajectory Perpendicular** viewport, use mouse click and drag operations to edit the target point in a view aligned perpendicular to the currently selected trajectory path (see [Working with Trajectory Annotations Pg. 99](#)).
5. In bottom row of viewports, you may edit the target point by moving the crosshairs (see [Changing Crosshair Positions Pg. 83](#)) to a desired location in the images and select **Set Target Point** in step's control panel.
6. In the bottom row of viewports, you may also edit the target point by changing the viewport orientation to **Trajectory** (see [Changing a Viewing Layout Orientation Pg. 82](#)) and using mouse click and drag operations (see [Working with Trajectory Annotations Pg. 99](#)).

> **To undo or redo entry point edits made to a trajectory annotation**

Use the **Trajectory Undo** and **Trajectory Redo** tools to undo or redo any target point changes made to the selected trajectory annotation shown on screen.

- Select the  button from the custom toolbar to undo a target point edit made to the selected trajectory annotation shown on screen.
- Select the  button from the custom toolbar to redo a target point edit made to the selected trajectory annotation shown on screen.

---

## Make Adjustment Step – *Setting the Frame Angulation*

The Make Adjustment step prescribes the physical adjustments that should be made on the selected trajectory frame such that the chosen guide channel can be aligned to the planned target point of the selected trajectory. You can use the step to either realize the adjustments on the corresponding frame and/or select an alternate guide channel that is projected to be closer to the planned trajectory's target point. If the trajectory frame's Targeting Stem has already been sufficiently aligned to the selected planned trajectory, then any minute frame adjustments can be skipped and you may proceed in the workflow. You may complete the step by either realizing the prescribed frame adjustments or opting not to prescribe the frame adjustments if they are considered to be minute and/or unnecessary. This step may be used iteratively with the Verify Frame Adjustments step to continually make adjustments until the frame is aligned with the planned trajectory.

The following features are offered by the Make Adjustment step:


- Prescribing the necessary frame adjustments to align the chosen guide channel to the planned trajectory (see [Prescribing Frame Adjustments Pg. 175](#)).
- Changing the guide channel selection to bring the projected frame path closer in alignment with the planned trajectory (see [Changing the Guide Channel Pg. 176](#)).
- Reviewing the planned trajectory and associated projected frame path (see [Reviewing Trajectory and Frame Paths Pg. 177](#)).

### Prescribing Frame Adjustments

You may use the frame adjustments prescribed in the Make Adjustment step to make physical adjustments on the corresponding trajectory frame mounted on the patient. Please see [Appendix 1 - G. Set Trajectory](#) for details on how to realize the prescribed adjustments on the trajectory frame.

#### > To realize a frame adjustment

1. Use the Frame Selector available in the step's control panel to select a trajectory frame that you would like to adjust (see [Selecting a Frame Pg. 75](#)).
2. Use the Trajectory Selector available in the step's control panel to select a trajectory annotation to which you would like to align the selected frame (see [Selecting a Trajectory Pg. 75](#)).

3. Using the **Frame Adjustments** display in the step's control panel, realize the prescribed adjustments on the physical frame mounted on the patient. You may expand the **Frame Adjustments** display using the  button so that it can be displayed larger if you are using an external in-room monitor (see [Mirroring the External Monitor Pg. 60](#)).



In the above example, the **Frame Adjustments** display shows that the orange Roll knob should be rotated to the right by  $3/8$  turns. The blue Pitch knob should be rotated to the right by  $1/2$  turns.

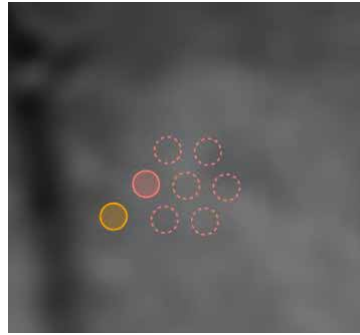
## Changing the Guide Channel

You may also change the chosen guide channel for the given trajectory in order to bring the projected path of the Targeting Stem closer to the planned trajectory. This can be useful if a projected device channel realizes a path that is closer to the intended planned trajectory. Performing this action may also reduce the number of frame adjustments required during the procedure.

### > To change the guide channel selection

1. Use the Frame Selector available in the step's control panel to select a trajectory frame that you would like to adjust (see [Selecting a Frame Pg. 75](#)).
2. Use the Trajectory Selector available in the step's control panel to select a trajectory annotation to which you would like to align the selected frame (see [Selecting a Trajectory Pg. 75](#)).
3. Edit the selected guide channel by clicking on the desired projected guide channels shown in the **Trajectory Perpendicular** viewport or using the Guide Channel Selector in the step's control panel (see [Selecting a Guide Channel Pg. 76](#)).





Click on the projected channel graphic to select a guide channel



Use the Guide Channel Selector to select a guide channel

## Reviewing Trajectory and Frame Paths

You may review the paths for both selected trajectory as well as the selected frame using the Make Adjustment step.

### > To review the selected trajectory path

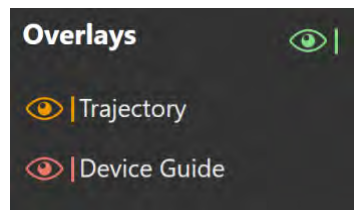
1. Use the Trajectory Selector available in the step's control panel to select a trajectory annotation that you would like to review (see [Selecting a Trajectory Pg. 75](#)).
2. Use the Fly Through Line (see [Fly Through Line Pg. 84](#)) or Image Scroller (see [Image Scroller Pg. 84](#)) to scroll along the trajectory path.
3. Select **Go To Target Point** in the step control panel to navigate to the selected trajectory's target point.
4. Select **Go To Entry Point** in the step control panel to navigate to the selected trajectory's entry point.



5. Review the device clearance and reach information for the selected trajectory by clicking on the button beside the Trajectory Selector in the step control panel (see [Selecting a Trajectory Pg. 75](#)) or through the trajectory's annotation context menu (see [Working with Trajectory Annotations Pg. 99](#)).

> **To review the projected path of the frame**

1. Use the Frame Selector available in the step's control panel to select a trajectory frame whose projected path that you would like to review (see [Selecting a Frame Pg. 75](#)).
2. In the viewport displaying the guide channel annotations, visualize the position of the center channel relative to the selected planned trajectory path.
3. Use the Annotation Overlays control to show / hide the guide channel annotation projections.



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## Verify Adjustment Step – *Verifying the Stem Position*

The Verify Adjustment step allows you to confirm the position of the trajectory frame's Targeting Stem after physical adjustments to the frame have been made. To do this, use the MRI Scanner to acquire orthogonal image slabs along the length of the trajectory frame's Targeting Stem. By identifying the position of the Targeting Stem within the image slabs, the application computes a new projected path for the frame so that you may visualize the frame's position relative to the planned trajectory. You may then assess whether inserting a device along the chosen channel at the current position of the frame's Targeting Stem is deemed acceptable prior to inserting the device. If the projected error between the current position of the frame's Targeting Stem and the planned target point is deemed unacceptable, you may proceed back to the Make Adjustment step to make further adjustments or you may select an alternate guide channel. Otherwise, you may proceed to insert the device.

The position of the trajectory frame's Targeting Stem must be verified prior to inserting a device into the patient. This means that you must complete the Verify Adjustment step before moving on to insert the device. You can complete the Verify Adjustment step by acquiring and sending two orthogonal scans of the currently selected frame's Targeting Stem to the workstation.

The following features are offered by the Make Adjustment step:

- Specifying the scan plane parameters needed to acquire orthogonal scans of the currently selected frame's Targeting Stem (see [Acquiring the Orthogonal Targeting Stem Scans Pg. 180](#)).
- Reviewing the current position of the Targeting Stem based on the orthogonal stem scans (see [Reviewing the Targeting Stem Position Pg. 181](#)).
- Proceed to make further adjustments to either the currently selected trajectory frame or another trajectory frame mounted on the patient (see [Proceeding to Further Adjust the Targeting Stem Pg. 184](#)).
- Proceed to insert the device based on the current position of the frame's targeting stem (see [Proceed to Insert the Device Pg. 184](#)).

The Verify Adjustment step also offers following features that are also provided in the Make Adjustment step (see [Make Adjustment Step – Setting the Frame Angulation Pg. 175](#)):

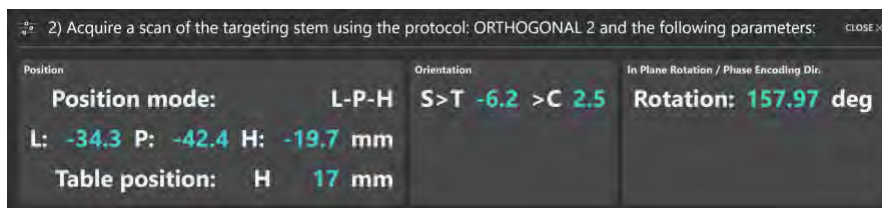
- Changing the guide channel selection to bring the projected frame path closer in alignment with the planned trajectory (see [Changing the Guide Channel Pg. 176](#)).
- Reviewing the planned trajectory and associated projected frame path (see [Reviewing Trajectory and Frame Paths Pg. 177](#)).

## Acquiring the Orthogonal Targeting Stem Scans

On initial activation, the Verify Adjustment step prompts you to acquire two independent scans of the currently selected frame's Targeting Stem. These scans are prescribed to be aligned orthogonally to the planned trajectory path.

### > To acquire scans of the Targeting Stem

1. Upon activating the step, you will be presented with two dialogs indicating the scan plane parameters that you must enter on the MRI Scanner Console in order to perform the image acquisitions for the orthogonal scans of the currently selected frame's Targeting Stem.



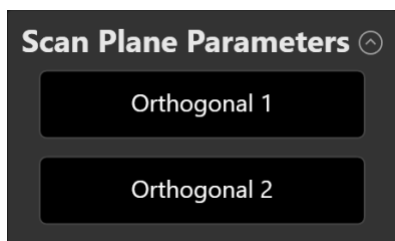

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*For Siemens scanners, a Table Position value is shown as part of the scan plane parameters for this step. In the MRI Scanner Console interface, be sure to enter the Table Position value before entering the H/F value. Otherwise the H/F value will be modified by the scanner interface and will not be correct. See [Entering a Table Position Value Pg. 30](#).*

*For IMRIS scanners, a Table Position should not be entered in this step. See [Important Notes for Using IMRIS Scanners Pg. 33](#).*

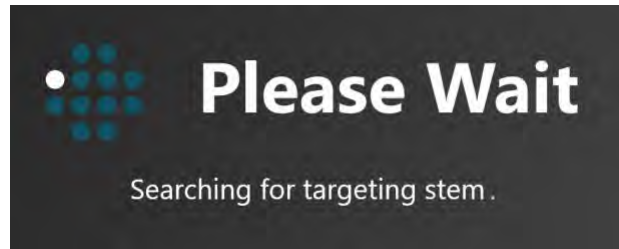
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2. You may bring up the scan plane parameters for each orthogonal scan manually using the **Scan Plane Parameters** group box in the step's control panel.



3. Enter the values on the MRI Scanner Console, scan and transfer or load the images onto the workstation.
4. On receiving each orthogonal image scan, the application verifies:
  - That the planned trajectory path is contained completely within the scan to ensure that the correct images were transferred.

- That the scan was acquired using the scan plane parameters prescribed by the step.
  - That the scan received contains up-to-date images of the Targeting Stem.
5. On receiving each orthogonal image scan, a floating window will display a **Please Wait** message and the user interface will be blurred while the application searches for the Targeting Stem in the scan.



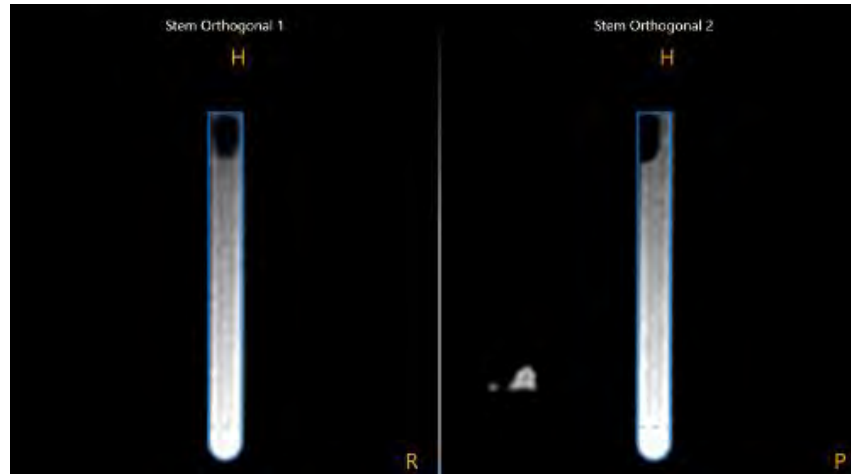
6. Once the application has detected the Targeting Stem from each of the orthogonal scans, a check is then performed to verify that the detected positions of the Targeting Stem in both scans agree. If they don't agree, then this may indicate that the Targeting Stem moved in-between scanning, or that the acquired images are affected by geometric distortion artifacts. If there is a significant discrepancy between the Targeting Stem positions as detected in the two independent scans, a warning will be shown by the application (see [Inconsistent Targeting Stem Positions Found Pg. 256](#)).

## Reviewing the Targeting Stem Position

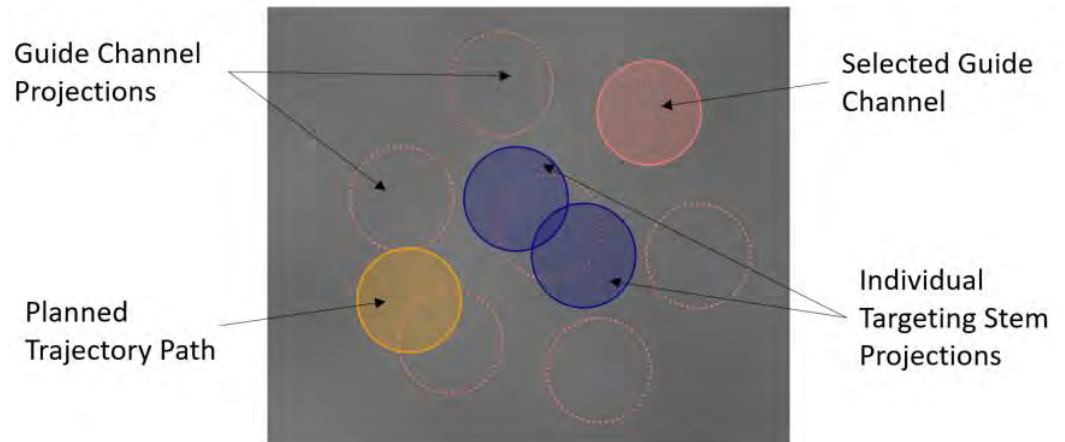
You may use the Verify Adjustment step to review the detection results for the Targeting Stem in each of the acquired orthogonal scans.

### > To review the Targeting Stem position

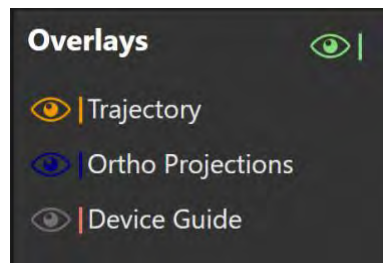
1. Observe the outline overlay of the currently selected frame's Targeting Stem overlaid on the individual scans in the **Stem Orthogonal 1** and **Stem Orthogonal 2** viewports.



2. Verify that the outline of the Targeting Stem overlay matches up with the signal from the stem in the underlying images. If the outline of the Targeting Stem does not match up with the underlying images, select **Edit Stem** from the step's control panel. Doing so will launch the Edit Stem task, where you may manually edit the position of the Targeting Stem such that it matches up with its position as seen in the acquired scans (see [Edit Stem Task – Changing the Stem Position Pg. 241](#)).
3. Observe the graphic annotations rendered on the right-hand side viewport. The following graphics are shown:
  - A cross section of the planned trajectory is shown, rendered at the device diameter specified for that trajectory (see [Working with Trajectory Annotations Pg. 99](#)).
  - Cross sections of the projected guide channels are rendered for the given trajectory (see [Working with Guide Channel Annotations Pg. 107](#)).
  - If desired, cross sections of the individual projections of the Targeting Stem from each of the independent scans in isolation.



- You may use the Annotation Overlays control to show the individual projections of the Targeting Stem from each of the independent scans in isolation. This can be useful to understand the differences along the planned trajectory path when there is a significant discrepancy between the Targeting Stem detection results. Hover the mouse over each blue circle to show which image scan projects that particular point.



- You may also review the resulting projected frame path annotations along the direction of the trajectory (see [Reviewing Trajectory and Frame Paths Pg. 177](#)).
- Observe the resultant projected error between the selected guide channel and the planned trajectory path to determine the how far off the Targeting Stem projection is from the planned trajectory path.



## Proceeding to Further Adjust the Targeting Stem

You may choose to make further adjustments to the currently selected trajectory frame in order to adequately align it with the planned trajectory path.

### > To make further adjustments on the currently selected frame

Using the Step Selector (see [Selecting a Step Pg. 72](#)), select **ADJUST CURRENT FRAME** (in the case where multiple trajectory frames are mounted on the patient) or **ADJUST FRAME** (in the case where only one trajectory frame is mounted on the patient). This will navigate you back to the Make Adjustments (see [Make Adjustment Step – Setting the Frame Angulation Pg. 175](#)) step where further adjustments are prescribed for the currently selected frame.

### > To make adjustments for another frame

If there are multiple trajectory frames mounted on the patient, select **ADJUST ANOTHER FRAME** using the Step Selector (see [Selecting a Step Pg. 72](#)). This will navigate you back to the Make Adjustments (see [Make Adjustment Step – Setting the Frame Angulation Pg. 175](#)) step where further adjustments are prescribed for another frame defined in the application.

## Proceed to Insert the Device

If you are satisfied with the current position of the frame's Targeting Stem and are ready to insert the device based on reviewing its projected path, you may proceed to insert the device.

### > To proceed to insert the device

Using the Step Selector (see [Selecting a Step Pg. 72](#)), select **PROCEED TO INSERT**. This will navigate you to the Prepare and Insert step (see [Prepare and Insert Step – Preparing and Inserting the Device Pg. 185](#)) where you will be given instructions on how to insert the device.



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## Prepare and Insert Step – *Preparing and Inserting the Device*

The Prepare and Insert step can be used to assist you in preparing your device for insertion as well as monitoring the progress of a device insertion to target depth. Prior to using this step, ensure that the position of the Targeting Stem corresponding to the frame that you will use to insert the device has been verified and that a guide channel for the trajectory path that you wish to insert the device along has been selected. You may complete this step and move forward in the workflow when a device track has been identified for the planned trajectory path of interest.

---

**Caution:** This step provides optional workflow that is not required to complete a neurological procedure. It is only to be performed if the manufacturer's instructions for the device to be inserted provide a safe scanning protocol. If no safe protocols are provided, the procedure must be completed without further scanning. In these cases, the patient should be removed from the scanner.

---

The Prepare and Insert step allows you to perform the following workflow-related actions:

- Preparing the device(s) for insertion (see [Preparing the Device Pg. 185](#)).
- Monitoring the progress of the insertion (see [Monitoring Insertion Progress Pg. 187](#)).
- Reviewing the detected position of the inserted device track (see [Reviewing the Inserted Device Path Pg. 189](#)).
- Editing the position of position of the inserted device track (see [Editing the Inserted Device Path Pg. 190](#)).

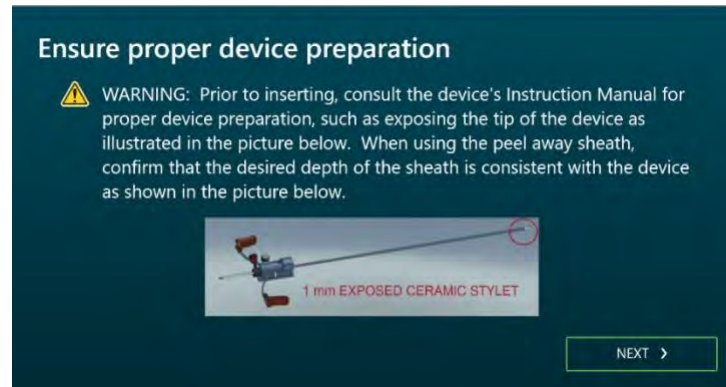
### Preparing the Device

Prior to inserting the device, refer to the device's Instruction Manual for proper device preparation and instructions for safe scanning in a clinical MRI environment. The application will remind you of this prior to proceeding with the workflow that involves monitoring and assessing the device insertion.

> **To bring up prompts to prepare the device**

1. Navigate into the Prepare and Insert step.

2. Note the **Ensure proper device preparation** dialog. Prepare the device accordingly.



3. Select **NEXT**.
4. Note the **Ensure safe scanning protocols** dialog. Ensure that the RF pulse sequences used to acquire images of the patient with the device(s) in place are safe for use with the device(s) to be inserted.



5. Select **NEXT**. (You may select **PREVIOUS** to view the previous dialog regarding proper device preparation).
6. Note the **Device Insertion Instructions** dialog. Use the dialog to select a frame and trajectory path for which you would like to insert the device. Then perform the following actions:
  - Remove the Targeting Stem from the trajectory frame. See [Appendix 1 - G. Set Trajectory](#).
  - Verify that the residual error left in the frame alignment steps is adequate for device insertion. This value can be found under the **Projected Error** field. Note that if a residual error of more than 1.5 mm is left in the frame alignment steps, the application will warn you of this condition (see [Targeting Stem Not Sufficiently Aligned to Trajectory Pg. 258](#)).

- Measure and mark the depth for the device to be inserted. The depth value required to reach the target point of the selected trajectory is provided in the dialog under the **Measure Depth** field. If you wish to stop your insertion prior to reaching the target point itself, subtract the desired offset from the values provided and then set the stop appropriately. See [Appendix 1 - K. Procedures utilizing the ClearPoint Neuro Stylet and Peel-Away Sheath](#).
- If drilling an access hole at this point is required, insert the drill guide corresponding to the selected guide channel into the frame. After drilling, insert the guide channel corresponding to the device to be inserted with any reducer tubes required. If an access hole has already been made, insert the guide channel corresponding to the device into the frame. The selected guide channel is shown under the **Set Device Guide** field. See [Appendix 1 - H. Using the Drill Guides in the MRI](#) (not required if the Access Hole was already created) and [Appendix 1 - I. Using the Insertion Guides](#).
- Select **DONE** to close the dialog. (You may also select **PREVIOUS** to return to the **Ensure safe scanning protocols** dialog).



7. Once dismissed, you may bring up the insertion instructions again by selecting **Show Insertion Instructions** from the step's control panel.

## Monitoring Insertion Progress

You may use the Prepare and Insert step to monitor the progress of a device insertion. Scans may be acquired with the device partially inserted to visually assess the projected device path into the brain. See [Appendix 1 - L. Device Insertion through Peel-Away Sheath](#) and [Appendix 1 - M. Direct Insertion Procedures](#) for further details.

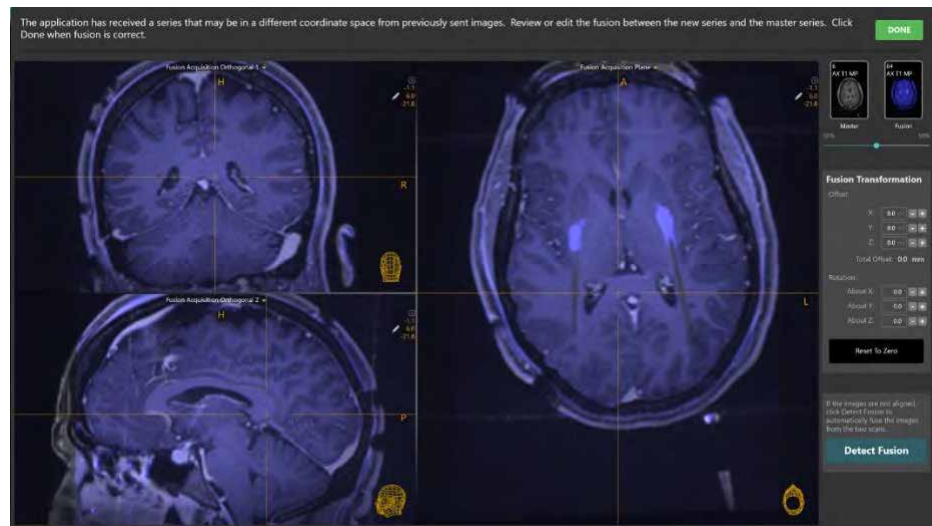
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**Caution:** You should acquire scans multiple times during the device insertion, if possible. These images provide assurance that the

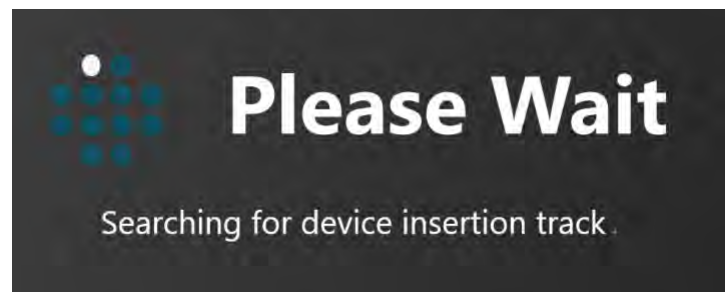
inserted device is actually following the planned trajectory path. Frequent scans may also help with the early detection of hemorrhage.

> **To monitor a device insertion**

1. Acquire a whole head scan of the patient with the device partially or fully inserted.
2. Send or load the acquired images onto the workstation.
3. Use the pop-up Fusion task to fuse the newly acquired image series with device(s) inserted with the master series (see [Fusion Task Fusing Images Pg. 221](#)).



4. Once the Fusion task window is closed, a floating window will display a **Please Wait** message and the user interface will be blurred while the application automatically searches for the inserted device track along the planned trajectory path.

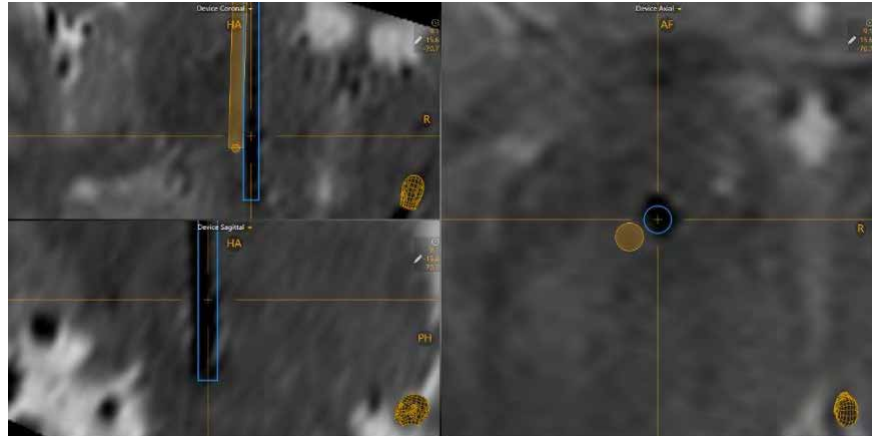


*While detecting the device track in the images, the application assesses whether or not it appears straight in the acquired images. If the device track*

does not appear straight, this may indicate that geometric distortion artifacts are present in the acquired images or that physical device deflection occurred. See [Insertion Track Does Not Appear Straight Pg. 259](#) for additional details.

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- The application will display a graphic annotation that corresponds to the device track detected in the images.



- Visually compare the detected device track with the planned trajectory path. If the inserted device track does not appear to be following the planned trajectory path, proceed to remove the device and assess the cause.
- Acquire additional whole-head scans of the patient with the device inserted at different depths to monitor the device insertion to target depth.

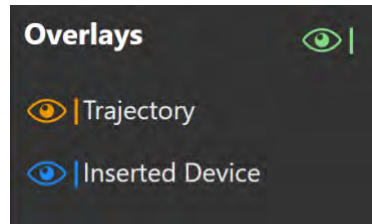
## Reviewing the Inserted Device Path

You may use the Prepare and Insert step to review the detected position of the inserted device track.

### > To review the inserted device path

- Change the viewport orientation to the desired viewing orientation that you would like to use to review the inserted device path (see [Changing a Viewing Layout Orientation Pg. 82](#)).
- Select an image series for which to review the defined device track using the Thumbnail Bar (see [Using Thumbnails Pg. 79](#)).
- To reposition the crosshairs on the currently selected device tip, select **Go To Device Tip** from the step control panel.

- You may toggle the visibility of the trajectory and device path annotations using the toggle buttons in the **Overlays** group box in the step control panel.



## Editing the Inserted Device Path

You may also manually override the detected position of the inserted device track and/or initiate a device detection on a newly acquired image series using the Prepare and Insert step.

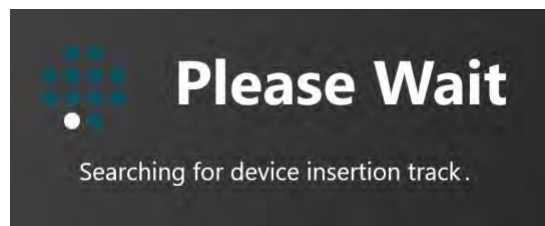
### > To manually modify the device tip position

- Change the viewport orientation to the desired viewing orientation that you would like to use to set the device tip (see [Changing a Viewing Layout Orientation Pg. 82](#)).
- Select an image series for which to edit the defined device track using the Thumbnail Bar (see [Using Thumbnails Pg. 79](#)).
- Edit the device tip using the following mechanisms:
  - Reposition the crosshairs in the viewports (see [Changing Crosshair Positions Pg. 83](#)) to a location where you would like to set the device tip. Select **Set Device Tip** in the step control panel to set the tip of the device at the current position of the crosshairs.
  - If the viewport orientation is set to **Device**, the following mechanisms can be used to edit the device tip in **Device Coronal** and **Device Sagittal** viewports:
    - Drag the end point of the device path to a new location within the viewport
    - Hold down the CTRL key while dragging the device path end point to constrain the movement to shift along the current direction of the device.
    - Drag the device path in between its end points (i.e. on the device path cross section) to cause the device's end point to pivot about the entry point.

- If the viewport orientation is set to **Device**, then in the **Device Axial** viewport: drag the cross section anywhere along the device path to cause the device's end point to pivot about the entry point.

> **To automatically detect the position of the device tip from an image series**



1. Select an image series for which to edit the defined device track using the Thumbnail Bar (see [Using Thumbnails Pg. 79](#)).
2. Select **Detect Device Tip** from the step's control panel.
3. A floating window will display a **Please Wait** message and the user interface will be blurred.



4. The application will display a graphic annotation that corresponds to the device track detected in the images.

> **To undo or redo edits made to the device tip**

Use the **Device Edit Undo** and **Device Edit Redo** tools to undo or redo any changes made to the device tip shown on screen.

- Select the  button from the custom toolbar to undo a change made to the device tip shown on screen.
- Select the  button from the custom toolbar to redo a change made to the device tip shown on screen.

---

## Assess Placement Step – *Evaluating the Device Placement*

You may use the Assess Placement step to perform qualitative and quantitative assessment of the placement of a device relative to a planned trajectory path. Based on this assessment, you can then decide whether or not the final device placement is clinically acceptable. You may complete this step by performing the assessment of the device placement and then deciding how to proceed in the workflow. The application allows you to make the following choices with respect to moving forward in the workflow after assessing a device placement:

- Accept the device placement and proceed to complete the procedure (see [Closing Pg. 26](#)).
- Accept the device placement proceed to insert another device along a different trajectory planned during the procedure (see [Prepare and Insert Step – Preparing and Inserting the Device Pg. 185](#)).
- Accept the device placement and assess regions of treatment on scans acquired after the treatment to the patient is being delivered (see [Assess Treatment Volumes – Evaluating Treatment Coverage Pg. 196](#)).
- Reject the placement of the device and assess the root cause of the original placement (see [Rejecting a Device Placement Pg. 195](#)).

---

**Caution:** This step provides optional workflow that is not required to complete a neurological procedure. It is only to be performed if the manufacturer’s instructions for the device to be inserted provide a safe scanning protocol. If no safe protocols are provided, the procedure must be completed without further scanning. In these cases, the patient should be removed from the scanner.

---

### Assessing the Device Placement

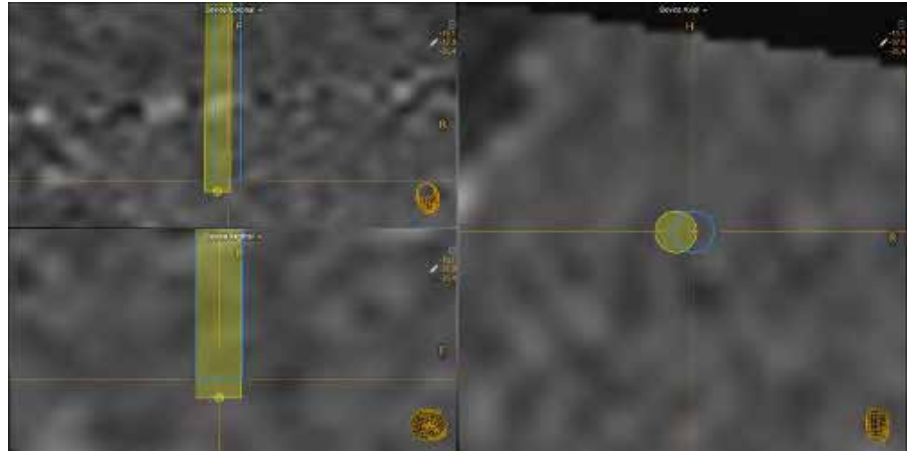
You may use the Assess Placement step to qualitatively and/or quantitatively evaluate if the insertion of the device along a planned trajectory path is clinically acceptable.

> **To evaluate the placement of the device**

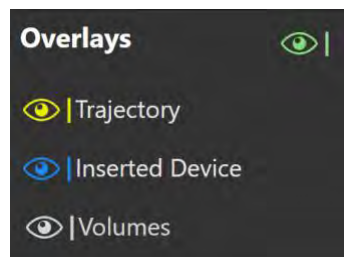
1. Select the trajectory frame used for the device insertion (see [Selecting a Frame Pg. 75](#)).



2. Select a planned trajectory used for the device insertion (see [Selecting a Trajectory Pg. 75](#)).
3. Select an image series for which to evaluate the device placement using the Thumbnail Bar (see [Using Thumbnails Pg. 79](#)).
4. Select a viewing orientation for which you would like to assess the device placement (see [Changing a Viewing Layout Orientation Pg. 82](#)).
5. In the viewports visually compare the inserted device track and planned trajectory graphic annotations.



6. You may toggle the visibility of the trajectory and device path annotations using the toggle buttons in the **Overlays** group box in the step control panel to compare either path to the underlying images and associated patient anatomy.



7. Use the **Error Measurements** group box in the step's control panel to quantitatively assess the error measurements comparing the inserted device tip to the planned trajectory's target point. The following error measurements are shown in the panel:
  - Radial – The distance between the planned trajectory's target point and the intersection of the device path with the target plane.
  - Depth - The distance along the device path between device tip and the intersection of the device path with the target plane. Negative

values indicate that the device is shallow relative to the target plane. Positive values indicate that the device has been inserted past the target plane.

#### Error Measurements

Radial 0.9 mm  
Depth -0.8 mm

8. You may acquire additional scans with the device in place to assess the viability of the placement relative to anatomical structures that may be better visualized on other scans. You may transfer these acquired scans to the workstation with the step active in order to perform this assessment.

## Accepting a Device Placement

If you have deemed that a device placement is clinically acceptable, you may choose to proceed in the workflow in a number of different ways.

### > To insert another device

In the case of multiple planned trajectories, you may opt to insert another device along another planned trajectory path. In these cases, use the Step Selector to select **INSERT ANOTHER DEVICE** (see [Selecting a Step Pg. 72](#)). This will navigate you back to the Prepare and Insert step where you may proceed to prepare and insert another device along another planned trajectory path (see [Prepare and Insert Step – Preparing and Inserting the Device Pg. 185](#)).

---

**Caution:** If you are inserting another device after confirming placement, you must follow the device manufacturer's guidelines for acquiring MR scans with the device inserted. Failure to do so may result in injury or death to the patient.

---

### > To assess images acquired during treatment delivery

You may opt to assess regions of interest on scans acquired while treatment is being delivered to the patient. To do this, use the Step Selector (see [Selecting a Step Pg. 72](#)) to select **ASSESS TREATMENT VOLUMES**. This will navigate you to the Assess Treatment Volumes step (see [Assess Treatment Volumes – Evaluating Treatment Coverage Pg. 196](#)).

---

**Caution:** If you are scanning during treatment delivery to the patient, you must ensure that safe scanning protocols are used with the device(s) used to delivery the treatment. If no safe

protocols are provided, the procedure must be completed without further scanning.

---

## Rejecting a Device Placement

If you have determined that the device placement is not clinically acceptable, you may opt to re-adjust the trajectory frame and re-insert the device (see [Device Re-Insertion and Bias Compensation Pg.204](#)).

### > To reject a device placement

If you have decided to reject the placement, use the Step Selector to select **REJECT PLACEMENT** (see [Selecting a Step Pg. 72](#)). This will navigate you to the Re-Insert group where you may carry out workflow to re-adjust the frame and re-insert the device.

---

## Assess Treatment Volumes – *Evaluating Treatment Coverage*

The Assess Treatment Volumes step allows you to define volumes of interest (VOIs) on scans acquired during the delivery of treatment to the patient. VOIs created in this step can be used to define areas in the brain that are being treated, where the corresponding treatment region is shown in the underlying images. For this reason, these VOIs are referred to as “treatment volumes”. The Assess Treatment Volumes step also allows you to compare created treatment volumes to target volumes created in the Define Target Volumes step (see [Define Target Volumes – Refining Procedure Volumes Pg. 168](#)). This comparison may assist you with assessing treatment coverage relative to a planned target volume of interest.

The Assess Treatment Volumes step allows you to perform the following operations:

- Defining new treatment VOI annotations (see [Creating Treatment Volumes Pg. 196](#)).
- Editing treatment VOI annotations that have already been defined (see [Editing Treatment Volumes Pg. 198](#)).
- Reviewing one or more treatment VOI annotations (see [Reviewing Treatment Volumes Pg. 201](#)).
- Removing one or more unwanted treatment VOI annotations previously defined (see [Removing a Treatment Volume Pg. 203](#)).

---

**Caution:** This step provides optional workflow that is not required to complete a neurological procedure. It is only to be performed if the manufacturer’s instructions for the device(s) delivering treatment to the patient provide a safe scanning protocol. If no safe protocols are provided, the procedure must be completed without further scanning. In these cases, the patient should not be scanned while treatment is being delivered.

---

## Creating Treatment Volumes

The Assess Treatment Volumes step allows you to create new treatment VOI annotations on images acquired after the device insertion, during treatment of the patient. These regions should represent areas of treatment that you wish to compare to an original target VOI.

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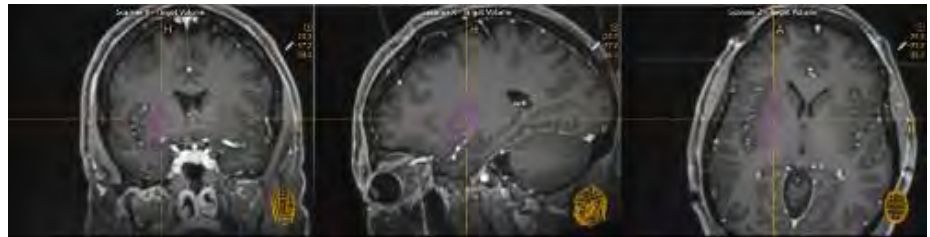
*Each treatment VOI created is associated with a corresponding target VOI. Therefore, if you have not defined any target VOIs using the Define Target Volumes*

step, you will not be able to use this step. See [Define Target Volumes – Refining Procedure Volumes Pg. 168](#) for additional details.

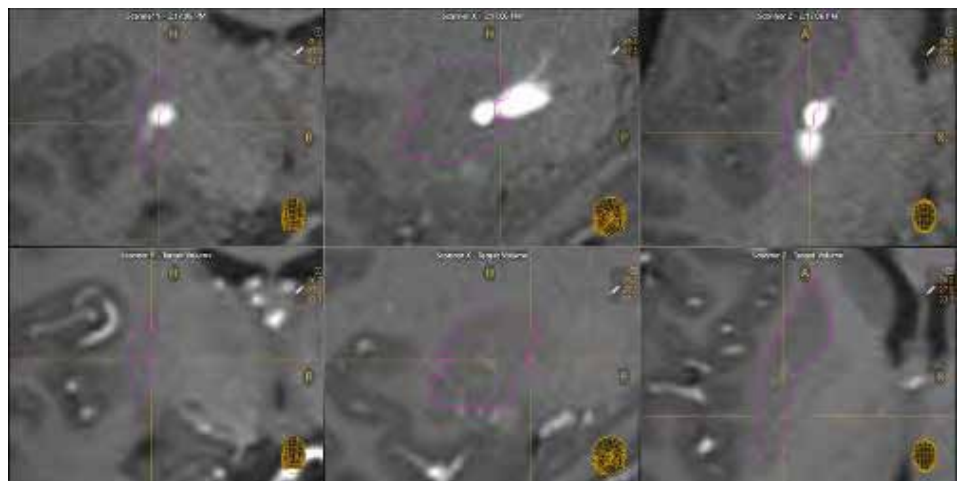
---

> **To create a treatment VOI annotation**

1. Use the Volume Selector for target volumes in the step control panel to select a target volume for which treatment volumes will be compared against (see [Selecting a Volume of Interest Pg. 76](#)).
2. The bottom row of viewports within the step's viewing layout will render the images series for which the selected target volume was defined on.



3. Acquire an image series which encapsulates a location within the brain to which treatment is being delivered.
4. Transfer the acquired image series to the workstation.
5. The top row of viewports within the step's viewing layout is populated with the image series just acquired. The acquisition time of the acquired image series is displayed in the labels for the viewports on the top row. The bottom row of viewports within the step's viewing layout remain to show the image series for which the selected target volume was defined on.



6. Change the crosshair position to a location within or near a treatment region within the acquired image series (see [Changing Crosshair Positions Pg. 83](#)).

7. Select **New Treatment Volume** from the step's control panel.
8. A floating window will appear prompting you define the following attributes for the treatment volume to be created.
  - Name – Specify a unique name that will identify the volume in the user interface. (Note: The application will prevent identical naming of volumes).
  - Color – Specify a color defining how the volume will be displayed in the user interface.
  - Copy Volume – Specify whether or not you would like to create a new treatment volume based on voxels from an existing treatment volume associated with the same target volume. (Note: This field will not be displayed if you are creating the first treatment volume for a given target volume).



9. Select **OK** to define a treatment volume. Select **Cancel** to cancel the treatment volume creation.
10. Note that the **Volume Brush** tool has been automatically selected. Use the **Volume Brush** tool to add a grouping of voxels to the treatment VOI annotation (see [Working with Volume of Interest Annotations Pg. 104](#)).
11. You may continue to acquire up-to-date image series where treatment regions continue to change over time. You may create additional treatment volumes for each of the scans sent.

## Editing Treatment Volumes



The Assess Treatment Volumes step may also be used to edit any existing treatment VOI annotation previously defined. Editing a treatment volume involves changing the grouping of voxels and/or properties associated with the VOI annotation.

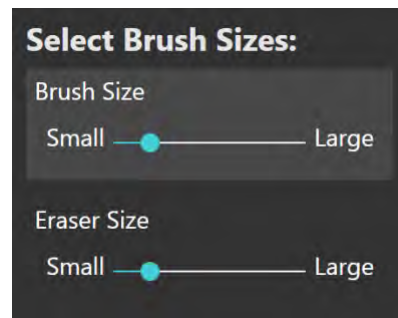
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*Only treatment volumes may be modified using the Assess Treatment Volumes step. Target volumes cannot be edited using the Assess Treatment Volumes step.*

---



> **To edit a treatment VOI annotation**

1. Use the Volume Selector for treatment volumes available in the step's control panel to select a treatment VOI annotation that you wish to edit (see [Selecting a Volume of Interest Pg. 76](#)). This will automatically select the image series for which the treatment VOI was created for in the Thumbnail Bar.
2. Alternatively, you may select an image series in the Thumbnail Bar to select a treatment VOI. Doing so will automatically select a treatment volume that has been defined on that image series (see [Using Thumbnails Pg. 79](#)).
3. Use the **Volume Brush**  and **Volume Eraser**  tools to add or remove voxel groupings from the treatment VOI annotation (see [Working with Volume of Interest Annotations Pg. 104](#)). You may change the brush and eraser sizes for the VOI editing tools using the sliders in the step's control panel. Note that changing the brush size will automatically select the **Volume Brush** tool, and that changing the eraser size will automatically select the **Volume Eraser** tool.



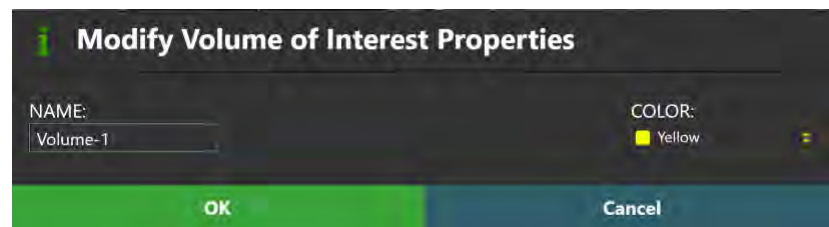
> **To undo or redo edits made to a treatment VOI annotation**

Use the **VOI Undo** and **VOI Redo** tools to undo or redo any changes made to the selected treatment VOI annotation shown on screen.

- Select the  button from the custom toolbar to undo a change made to the selected treatment VOI shown on screen.
- Select the  button from the custom toolbar to redo a change made to the selected treatment VOI shown on screen.

> **To edit the name or color of a treatment VOI annotation**

1. Use the Volume Selector for treatment volumes available in the step's control panel to select a treatment VOI annotation for which you wish to change the name and/or color (see [Selecting a Volume of Interest Pg. 76](#)).
2. Alternatively, you may select an image series in the Thumbnail Bar to select a treatment VOI. Doing so will automatically select a treatment volume that has been defined on that image series (see [Using Thumbnails Pg. 79](#)).
3. Select **Change Name / Color** from the step's control panel.
4. A floating window will appear prompting you to change the name and / or color of the treatment VOI annotation.



5. Make the desired changes to the name and/or color of the treatment VOI annotation.
6. Select **OK** to apply the changes to the selected VOI annotation. Select **Cancel** to cancel to discard the changes made to the selected VOI annotation.
7. You may also change the color of any target or treatment VOI using the context menu associated with each annotation (see [Working with Volume of Interest Annotations Pg. 104](#)).

> **To edit the opacity of a treatment VOI annotation**

1. Use the Volume Selector for treatment volumes available in the step's control panel to select a treatment VOI annotation for which you wish to change the opacity (see [Selecting a Volume of Interest Pg. 76](#)).
2. Alternatively, you may select an image series in the Thumbnail Bar to select a treatment VOI. Doing so will automatically select a treatment volume that has been defined on that image series (see [Using Thumbnails Pg. 79](#)).
3. Select the slider associated with the currently selected treatment VOI annotation from the step's control panel. Use the slider in the step control panel to change the opacity of the selected VOI annotation. Drag to the left to decrease the opacity of the annotation. Drag to the right to increase the opacity of the annotation.





4. You may also change the opacity of a target or treatment VOI using the context menu associated with the annotation (see [Working with Volume of Interest Annotations Pg. 104](#)).

> **To turn on volume filling for a treatment VOI annotation**

1. Use the Volume Selector available for treatment volumes in the step's control panel to select a treatment VOI annotation for which you wish to turn on filling (see [Selecting a Volume of Interest Pg. 76](#)).
2. Alternatively, you may select an image series in the Thumbnail Bar to select a treatment VOI. Doing so will automatically select a treatment volume that has been defined on that image series (see [Using Thumbnails Pg. 79](#)).
3. Turn on volume filling using the context menu associated with either the treatment or target VOI annotation shown in the viewports (see [Working with Volume of Interest Annotations Pg. 104](#)).

## Reviewing Treatment Volumes

Measurements associated with a treatment volume as well as overlap measurements with its corresponding target volume may be reviewed using the Assess Treatment Volumes step or the procedure report.

> **To correlate to the center of a target VOI annotation**

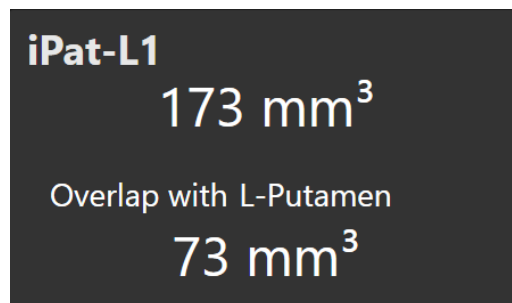
1. Use the Volume Selector for treatment volumes available in the step's control panel to select a treatment VOI annotation (see [Selecting a Volume of Interest Pg. 76](#)).
2. Alternatively, you may select an image series in the Thumbnail Bar to select a treatment VOI. Doing so will automatically select a treatment volume that has been defined on that image series (see [Using Thumbnails Pg. 79](#)).
3. The crosshairs will automatically correlate to the center the selected treatment VOI.
4. If the crosshairs are moved away from the center of the selected treatment VOI, select **Go To Center** in the step's control panel.

> **To review volume measurements**

1. Use the Volume Selector for target volumes available in the step's control panel to select a target VOI annotation for which you wish to see a volume measurement (see [Selecting a Volume of Interest Pg. 76](#)).



2. Observe the volume measurement value for the target VOI in the step's control panel
3. Use the Volume Selector for treatment volumes available in the step's control panel to select a treatment VOI annotation for which you wish to see a volume measurement (see [Selecting a Volume of Interest Pg. 76](#)).



4. Observe both the volume measurement for the treatment VOI, as well as a measurement corresponding to its physical overlap with the target VOI.

> **To review volume measurements using the procedure report**

1. Open the Procedure Report Window (see [Using the Procedure Report Window Pg. 65](#)).
2. Navigate to the **Volumes of Interest** section.

Target Volume	Treatment Volume	Size	Overlap with Target Volume
R-Putamen	iPat-R1	0.227 cm <sup>3</sup>	0.176 cm <sup>3</sup>
L-Putamen	iPat-L1	0.317 cm <sup>3</sup>	0.073 cm <sup>3</sup>

3. Observe the volume measurements for each target volume, as well as any measurement overlap between any treatment volumes defined throughout the procedure.

## Removing a Treatment Volume

You may also use the Assess Treatment Volumes step to remove any unwanted treatment VOIs defined in the application.

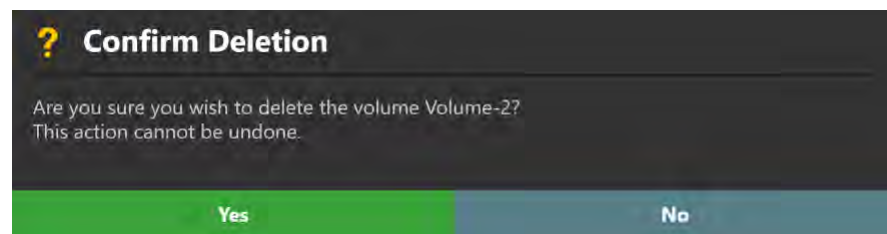
---

*Only treatment volumes may be deleted using the Assess Treatment Volumes step. Target volumes cannot be deleted using the Assess Treatment Volumes step.*

---

### > To delete a treatment VOI annotation

1. Use the Volume Selector for treatment volumes available in the step's control panel to select a treatment VOI annotation that you wish to remove (see [Selecting a Volume of Interest Pg. 76](#)).
2. Alternatively, you may select an image series in the Thumbnail Bar to select a treatment VOI. Doing so will automatically select a treatment volume that has been defined on that image series (see [Using Thumbnails Pg. 79](#)).
3. Select **Delete** from the step's control panel.
4. You will be prompted to confirm the removal of the treatment VOI annotation before proceeding. Select **Yes** to proceed with the deletion of the selected treatment VOI. Otherwise, choose **No** to leave the treatment VOI intact.



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## Device Re-Insertion and Bias Compensation

This section describes how to use the ClearPoint Array™ Workstation to re-insert a device into the brain after its original placement was rejected. The steps responsible for guiding you through re-inserting a device into the brain are contained within the Re-Insert workflow group. This grouping of steps becomes visible once you decide to reject a device placement.

The workflow employed in the Re-Insert group assists you in first determining the root cause of the originally rejected device placement, and then guiding you to through correcting the original device placement with a subsequent device re-insertion. The following points need to be considered when determining whether or not a device re-insertion will improve the original device placement.

- If the error is less than half the thickness of the inserted device, subsequent insertions are very likely to follow the original insertion track. Re-insertion is not recommended in this case.

---

**Caution:** Re-inserting the device introduces the possibility of following the previous insertion track. If necessary, chose an alternate guide channel for insertion to ensure that the device will insert along a new track. See [Selecting a Guide Channel Pg. 76](#) for additional details.

---

- The following possible sources of error may exist which have caused the original placement:
  - Accidental movement of the frame on patient
  - Unintended movement of the patient in fixation
  - Movement of MRI Scanner table
  - Device deflection during insertion
  - Geometric distortion of images used to perform frame adjustments.

---

**Caution:** Bias compensation will not correct random, one-time or non-linear errors. It must only be used when systematic, consistent geometric distortion in the acquired images has been identified.

---

To carry out the workflow outlined in the group, it is necessary to: assess the root cause of the original device placement (e.g. device deflection, unintended movement of the trajectory frame / patient, geometric distortion artifacts, etc.), re-adjust the trajectory frame based on understanding the root cause of the original placement, and re-insert the device into the patient.

Prior to starting this workflow, you must perform the following actions in the following order:

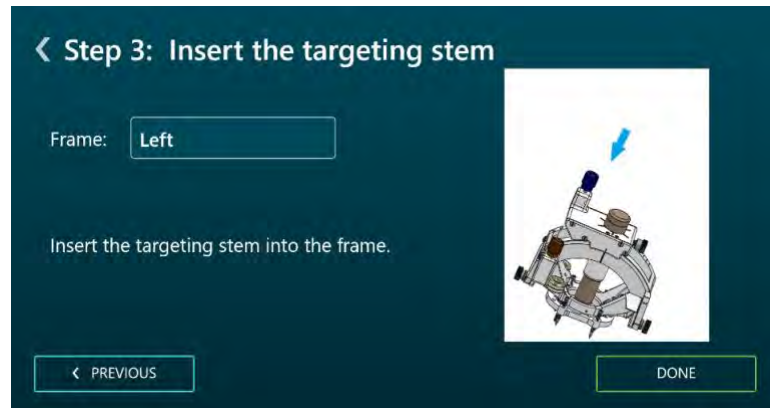
- 1) Move the patient out of the MRI Scanner bore
- 2) Withdraw the original device from the device guide.



- 3) Remove the device guide from the trajectory frame.



- 4) Re-insert the targeting stem into the trajectory frame.



- 5) Return the patient to the MRI Scanner bore.

Refer to [Appendix 1 - G. Set Trajectory](#) for further details on how to perform the above-mentioned actions.

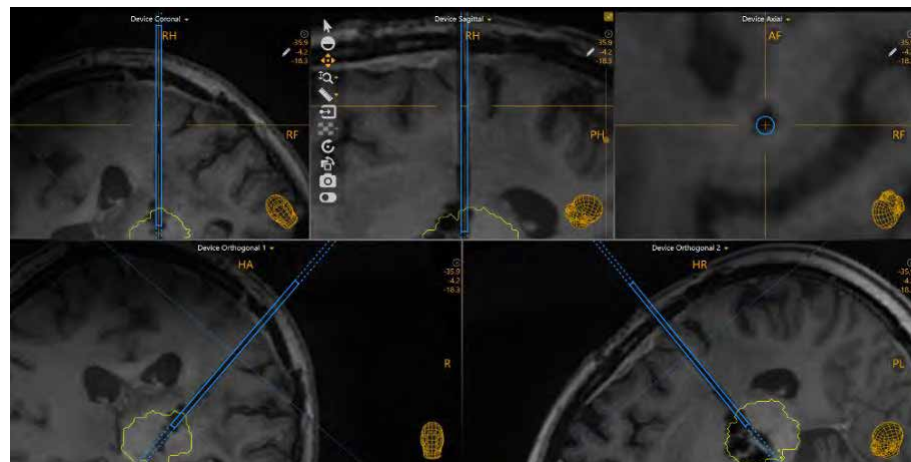
## Check Deflection Step – *Assessing Proximity to Resistant Structures*

The Check Deflection step is the first workflow step presented to you after rejecting the original placement of the device. Its purpose is to assist you with determining whether or not the initial placement was caused by deflection of the device during the insertion process. To achieve this, the step provides you with several viewing orientations to determine if deflection of the device may have occurred when inserting the device into the patient. You should use this step in combination with the tactile feedback that you felt when originally inserting the device. You may complete this step when you have indicated whether or not you believe that device deflection may have occurred based on the tactile feedback felt as well as analysis of the images acquired during device insertion.

The Check Deflection step allows you to visualize the inserted device track, planned trajectory and projected path of the frame's Targeting Stem in different viewing orientations, using any image series loaded into the application with the Frame Workflow selected. You may also acquire additional images to help make this determination.

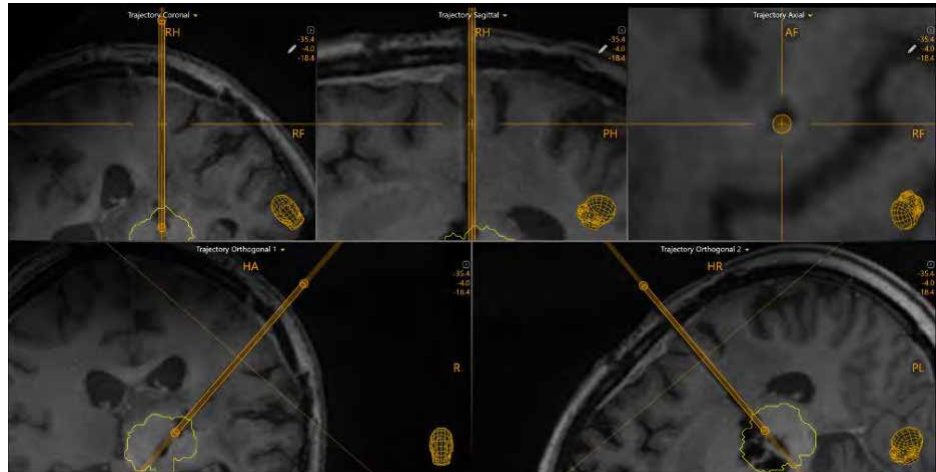
### > To visually assess for device deflection

1. With the orientation of the viewing layout set to **Device**, analyze the position of the inserted device graphic annotation relative to the underlying images. Use the **Overlays** group box to toggle the visibility of the other annotations using this viewing orientation.

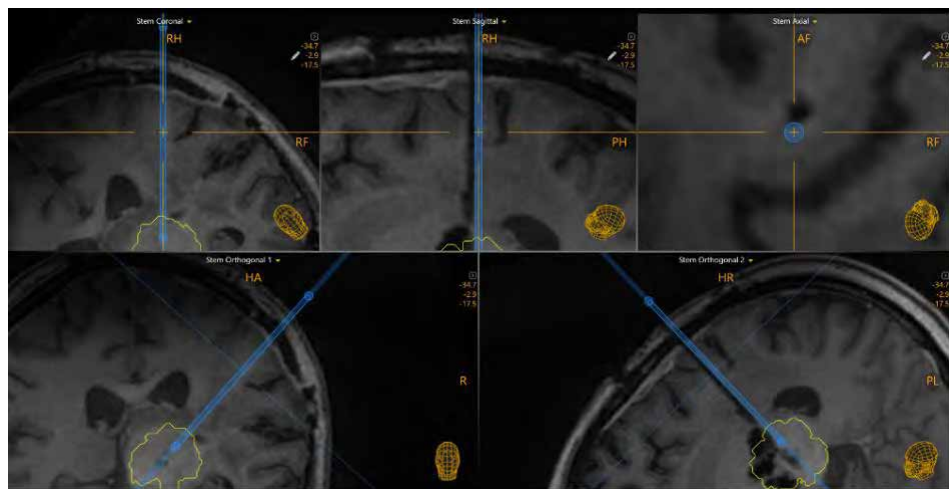


2. With the orientation of the viewing layout set to **Trajectory**, analyze the position of the planned trajectory graphic annotation relative to the underlying

images. Use the **Overlays** group box to toggle the visibility of the other annotations using this viewing orientation.



3. With the orientation of the viewing layout set to **Stem**, analyze the position of the projected Targeting Stem graphic annotation relative to the underlying images. Use the **Overlays** group box to toggle the visibility of the other annotations using this viewing orientation.



4. Based on your analysis of all of the above views as well as the tactile feedback received during the device insertion, assess whether or not physical deflection may have occurred via an anatomical structure (e.g. skull, dura, etc.)

> **To indicate that device deflection occurred**

If you have decided that device deflection most likely occurred, use the Step Selector (see [Selecting a Step Pg. 72](#)) to select **DEVICE DEFLECTED**. This will navigate you to the Locate Stem Position step (see [Locate Stem Position – Re-](#)

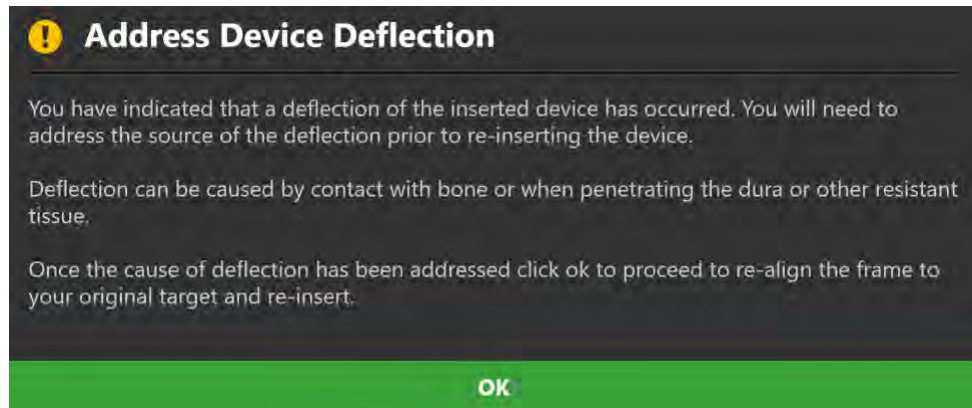


[verifying the Stem Position Pg. 214](#)) where you can re-adjust the frame to account for the deflection based on the determined cause.

---

**Caution:** If you have determined that deflection of the device occurred during your original insertion, you must physically address the source of the deflection prior to re-inserting the device to allow for a safe insertion.

---



> **To indicate that device deflection did not occur**

If you have decided that device deflection did not occur, use the Step Selector (see [Selecting a Step Pg. 72](#)) to select **DEVICE DID NOT DEFLECT**. This will navigate you to the Check Frame Movement step (see [Check Frame Movement – Determining if the Frame Moved Pg. 210](#)) where you can then access if the frame and/or Targeting Stem may have inadvertently moved.

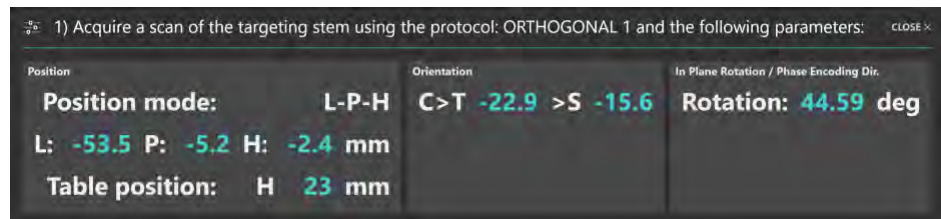
## Check Frame Movement – *Determining if the Frame Moved*

If you have determined that device deflection did not contribute to the original device placement, the next step is to determine if unintended movement of the frame or patient in fixation may have been the cause. The Check Frame Movement step allows you to visually compare newly acquired scans of the frame with Targeting Stem in place with the last set of orthogonal Targeting Stem scans that were acquired prior to device insertion. Visually assessing the differences between these two sets of scans can help you determine if the patient, frame and/or Targeting Stem may have moved during access hole drilling and/or device insertion. You may complete this step when you have indicated whether or not you believe that unintended movement of the frame may have occurred, causing the original device placement.

The Check Frame Movement step prompts you to acquire two orthogonal scans of the frame's Targeting Stem, similar to the Verify Adjustment step (see [Verify Adjustment Step – Verifying the Stem Position Pg. 179](#)). These scans can then be visually compared with the last set of orthogonal scans of the frame's Targeting Stem acquired prior to device insertion to assess whether or not frame movement may have occurred.

### > To visually assess for frame movement

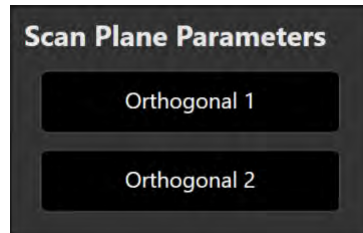
1. Upon activating the step, you will be presented with two dialogs indicating the scan plane parameters that you must enter on the MRI Scanner Console in order to perform the image acquisitions for the orthogonal scans of the currently selected frame's Targeting Stem.



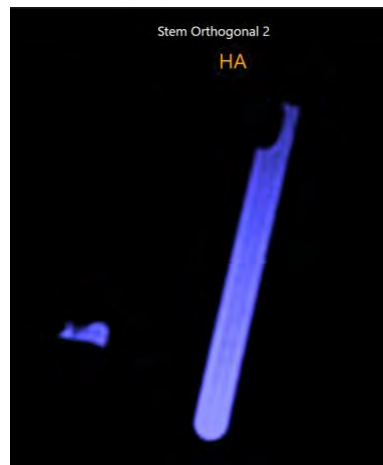
*For Siemens scanners, a Table Position value is shown as part of the scan plane parameters for this step. In the MRI Scanner Console interface, be sure to enter the Table Position value before entering the H/F value. Otherwise the H/F value will be modified by the scanner interface and will not be correct. See [Entering a Table Position Value Pg. 30](#).*

*For IMRIS scanners, a Table Position should not be entered in this step. See [Important Notes for Using IMRIS Scanners Pg. 33](#).*

2. You may bring up the scan plane parameters for each orthogonal scan manually using the **Scan Plane Parameters** group box in the step's control panel.

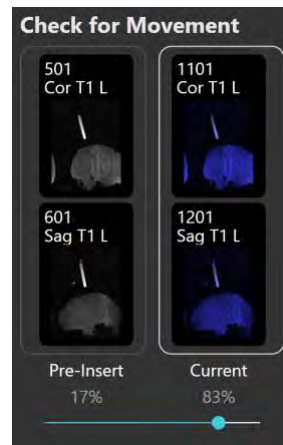


3. Enter the values on the MRI Scanner Console, scan and transfer or load the images onto the workstation.
4. On receiving each orthogonal image scan, the application verifies:
  - That the planned trajectory path is contained completely within the scan to ensure that the correct images were transferred.
  - That the scan was acquired using the scan plane parameters prescribed by the step.
  - That the scan received contains up-to-date images of the Targeting Stem.
5. Once the application has received both orthogonal Targeting Stem scans, you may visually compare them in the application viewports. The current scans of the Targeting Stem are rendered with a blue tint and the pre-insertion Targeting Stem scans are rendered as grayscale images. This allows you to visually distinguish between the two sets of scans in each viewport.



6. Use the **Check for Movement** group box in the step's control panel to visually distinguish between the scans. The thumbnails can be used to clearly identify which set of images series corresponds to pre or post insertion scans. The slider can be used to modify the additive blend between the two scans rendered in the viewports. Drag to the left to decrease the blend corresponding to the current pair of Targeting Stem scans. Drag to the right to decrease the blend corresponding to the pre-insertion pair of

Targeting Stem scans. Dragging the slider back and forth can assist you in determining whether or not movement of the frame may have occurred in-between final frame alignment and device insertion.



> **To indicate that the frame moved**

If you have determined that the frame moved during insertion, use the Step Selector (see [Selecting a Step Pg. 72](#)) to select **FRAME MOVED**. This will navigate you to the Locate Stem Position step (see [Locate Stem Position – Re-verifying the Stem Position Pg. 214](#)) and prompt you to re-adjust the frame to align with the originally planned trajectory path.

> **To indicate that the frame did not move**

If you have determined that the frame did not move during insertion, use the Step Selector (see [Selecting a Step Pg. 72](#)) to select **FRAME DID NOT MOVE**. This will navigate you to the Locate Stem Position step (see [Locate Stem Position – Re-verifying the Stem Position Pg. 214](#)) and prompt you to re-adjust the frame to align with a new target location prescribed by the application that attempts to correct for systematic scan distortion. This new target location is called the *bias compensation target*.

---

**WARNING:** Bias compensation will only work properly when the error to be corrected is a consistent bias rather than random error or a one-time occurrence. When using bias compensation, additional scans are recommended during the subsequent insertion to verify that the inserted device is in fact following the desired trajectory.

---

**! Warning: Bias Compensation Will Be Used**

You have indicated that the source of error for the device re-insertion is not due to accidental movement of the patient/frame or deflection of the device during initial insertion. Therefore, the system will now guide you through correcting the initial device placement using bias compensation.

Bias compensation is used to correct for a consistent bias on the scanner. An alternate target location will automatically be defined by the software to prescribe frame instructions to compensate for the bias on the scanner. This approach will not work for random, one-time or non-linear errors. If the source of error for the device re-insertion is due to patient/frame movement or device deflection, proceed back to the "Check Frame Movement" and/or "Check Deflection" steps and follow the instructions to continue through the workflow.

**OK**

---

## Locate Stem Position – *Re-verifying the Stem Position*

The Locate Stem Position step allows you to identify the current position of the Targeting Stem, for purposes of re-adjusting the frame to correct the original device placement. At this point in the re-insert device workflow, you have assessed the root cause of the original device placement. Depending on the root cause determined, the Locate Stem Position step will prompt you to perform a different set of actions:

- If the root cause of the original placement was determined to be device deflection, the Locate Stem Position step will specify the scan plane parameters needed to acquire orthogonal scans of the currently selected frame's targeting stem (see [Acquiring the Orthogonal Targeting Stem Scans Pg. 180](#)).
- If the root cause of the original placement was determined to be unintended movement of the frame and/or the patient, the Locate Stem Position step will prompt you to review the current position of the Targeting Stem based on the orthogonal stem scans acquired in the Check Frame Movement step (see [Reviewing the Targeting Stem Position Pg. 181](#)).
- If the root cause of the original placement was determined to be caused by systematic scan distortion, the Locate Stem Position step will prompt you to review the current position of the Targeting Stem and review the trajectory resulting from utilizing the bias compensation target (see [Reviewing the Bias Compensating Trajectory Path Pg. 215](#)).

The Locate Stem Position step offers the same functionality as the Verify Adjustment step (see [Verify Adjustment Step – Verifying the Stem Position Pg. 179](#)). This means that you may:

- Display the scan plane parameters needed to acquire orthogonal scans of the currently selected frame's Targeting Stem (see [Acquiring the Orthogonal Targeting Stem Scans Pg. 180](#)).
- Review the current position of the Targeting Stem based on the orthogonal stem scans (see [Reviewing the Targeting Stem Position Pg. 181](#)).
- Proceed to make further adjustments to either the currently selected trajectory frame or another trajectory frame mounted on the patient (see [Proceeding to Further Adjust the Targeting Stem Pg. 184](#)).
- Proceed to insert the device based on the current position of the frame's targeting stem (see [Proceed to Insert the Device Pg. 184](#)).
- Change the guide channel selection to bring the projected frame path closer in alignment with the planned or bias compensating trajectory (see [Changing the Guide Channel Pg. 176](#)).

- Review the planned trajectory and associated projected frame path (see [Reviewing Trajectory and Frame Paths Pg. 177](#)).

## Reviewing the Bias Compensating Trajectory Path

If you have determined that systematic scan distortion was the reason for the original device placement, the application has computed a bias compensation target to account for the scanner bias. The application will prescribe frame adjustments to align the frame's Targeting Stem to the bias compensation target location in an attempt to account for the systematic scan distortion observed. You may use the Locate Stem Position to review the resulting bias compensating trajectory path.

---

*The bias compensating target will be defined on the opposite side from the device tip, at the same distance from the target. It will be used by the application to calculate the frame instructions required to align the Targeting Stem to an alternate location that will account for a systematic scanner bias.*

---



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**WARNING:** Bias compensation will only work properly when the error to be corrected is a consistent bias rather than random error or a one-time occurrence. When using bias compensation, additional scans are recommended during the subsequent insertion to verify that the inserted device is in fact following the desired trajectory.

---

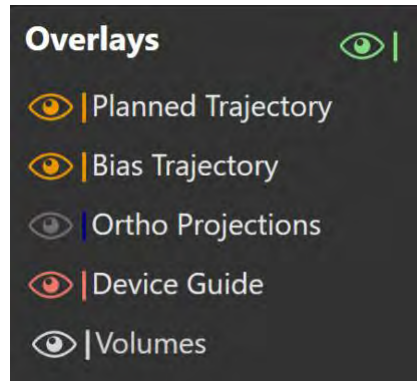
### > To review the bias compensating trajectory path

1. In the step's control panel, verify that bias compensation has been turned **On** or **Off**, depending on the root cause assessment performed for the original device insertion.

**Bias Compensation: On**

Aligning frame to bias compensating target.

2. Use the **Overlays** group box in the step's control panel to toggle the visibility of a graphic representing the bias compensating trajectory path.



> **To make physical adjustments to the frame**

You may proceed with the workflow for adjusting the frame by selecting **ADJUST FRAME** using the Step Selector (see [Selecting a Step Pg. 72](#)). This will navigate you to the Make Re-Adjustments step (see [Make Re-Adjustments Step – Re-Adjusting the Frame Angulation Pg. 217](#)) so that you may carry out the adjustments on the physical frame.

> **To re-insert the device without making further adjustments**

You may opt to re-insert the device if the position of the frame is adequate for device re-insertion. Use the Step Selector (see [Selecting a Step Pg. 72](#)) to select **RE-INSERT DEVICE** to re-insert the device into the patient. This will navigate you to the Prepare and Re-Insert step (see [Prepare and Re-Insert - Preparing and Re-Inserting the Device Pg. 219](#)) where you may proceed to re-insert the device.



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## Make Re-Adjustments Step – *Re-Adjusting the Frame Angulation*

The Make Re-Adjustments step prescribes the physical adjustments that should be made on the selected trajectory frame such that the chosen guide channel can be aligned to either the planned target point or the bias compensation point. The physical adjustment prescription will depend on the root cause assessment of the original device placement:

- If the original device placement was caused by device deflection and/or unintended movement of the frame, the Make Re-Adjustments step will prescribe the necessary frame adjustments to align the chosen guide channel to the planned trajectory (see [Prescribing Frame Adjustments Pg. 175](#)).
- If the original device placement was caused by systematic scan distortion, the Make Re-Adjustments step will prescribe the necessary frame adjustments to align the chosen guide channel to the bias compensating trajectory path (see [Reviewing the Bias Compensating Trajectory Path Pg. 215](#)).

Similar to the Make Adjustments step, the Make Re-Adjustments step allows you to be perform the following actions:

- Prescribing the necessary frame adjustments to align the chosen guide channel to either the planned or bias compensation trajectory (see [Prescribing Frame Adjustments Pg. 175](#)).
- Changing the guide channel selection to bring the projected frame path closer in alignment with either the planned or bias compensation trajectory (see [Changing the Guide Channel Pg. 176](#)).
- Reviewing the planned or bias compensation trajectory and associated projected frame path (see [Reviewing Trajectory and Frame Paths Pg. 177](#)).

### Prescribing Frame Adjustments to Account for Scanner Bias

If you have determined that systematic scan distortion was the reason for the original device placement, the application has computed a bias compensation target to account for the scanner bias. The application prescribes frame adjustments to align the frame's Targeting Stem to the bias compensation target location in an attempt to account for the systematic scan distortion observed. You may use the Make Re-Adjustments step realize the adjustments on the physical frame.

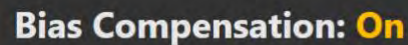
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**WARNING:** Bias compensation will only work properly when the error to be corrected is a consistent bias rather than random error or a one-time occurrence. When using bias compensation, additional scans are recommended during the subsequent insertion to verify that the inserted device is in fact following the desired trajectory.

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> **To realize a frame adjustment to account for scanner bias**

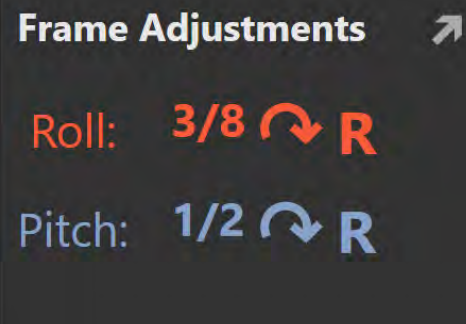
1. In the step's control panel, verify that bias compensation has been turned **On** or **Off**, depending on the root cause assessment performed for the original device insertion.



**Bias Compensation: On**

Aligning frame to bias compensating target.

2. Using the **Frame Adjustments** display in the step's control panel, realize the prescribed adjustments on the physical frame mounted on the patient. You may expand the **Frame Adjustments** display using the  button so that it can be displayed larger if you are using an external in-room monitor.



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## Prepare and Re-Insert - *Preparing and Re-Inserting the Device*

The Prepare and Re-Insert step may be used to assist you in preparing your device for re-insertion into the brain, as well as monitoring the progress of the re-insertion. This step allows you to perform the same workflow-related actions as the Prepare and Insert step (see [Prepare and Insert Step – Preparing and Inserting the Device Pg. 185](#)):

- Preparing the device(s) for insertion (see [Preparing the Device Pg. 185](#)).
- Monitoring the progress of the insertion (see [Monitoring Insertion Progress Pg. 187](#)).
- Reviewing the detected position of the inserted device track (see [Reviewing the Inserted Device Path Pg. 189](#)).
- Editing the position of position of the inserted device track (see [Editing the Inserted Device Path Pg. 190](#)).

---

**Caution:** This step provides optional workflow that is not required to complete a neurological procedure. It is only to be performed if the manufacturer's instructions for the device to be inserted provide a safe scanning protocol. If no safe protocols are provided, the procedure must be completed without further scanning. In these cases, the patient should be removed from the scanner.

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## Assess Revised Placement - *Evaluating the Re-Inserted Device Placement*

The Assess Revised Placement step allows you to perform assessment of the re-inserted device placement relative to the original planned trajectory path. Based on this assessment, you can decide whether or not the re-inserted placement is clinically acceptable. If the re-inserted placement is still not clinically acceptable, you have the option to re-performing the re-insert device workflow. The application allows you to make the following choices with respect to moving forward in the workflow after assessing a device placement:

- Accept the device placement and proceed to complete the procedure (see [Closing Pg. 26](#)).
- Accept the device placement proceed to insert another device along a different trajectory planned during the procedure (see [Prepare and Insert Step – Preparing and Inserting the Device Pg. 185](#)).
- Accept the device placement and assess regions of treatment on scans acquired after the treatment to the patient is being delivered (see [Assess Treatment Volumes – Evaluating Treatment Coverage Pg. 196](#)).
- Reject the placement of the device and assess the root cause of the original placement (see [Rejecting a Device Placement Pg. 195](#)).

---

**Caution:** This step provides optional workflow that is not required to complete a neurological procedure. It is only to be performed if the manufacturer’s instructions for the device to be inserted provide a safe scanning protocol. If no safe protocols are provided, the procedure must be completed without further scanning. In these cases, the patient should be removed from the scanner.

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## Optional Tasks

This section describes how to use the optional workflow tasks provided by the ClearPoint Array® Workstation.

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### Fusion Task *Fusing Images*

You can use the Fusion task to align a selected image series into the same coordinate space as the master series. The Fusion task may also be used to review and/or edit the fusion between any image series loaded into the application and the master series.

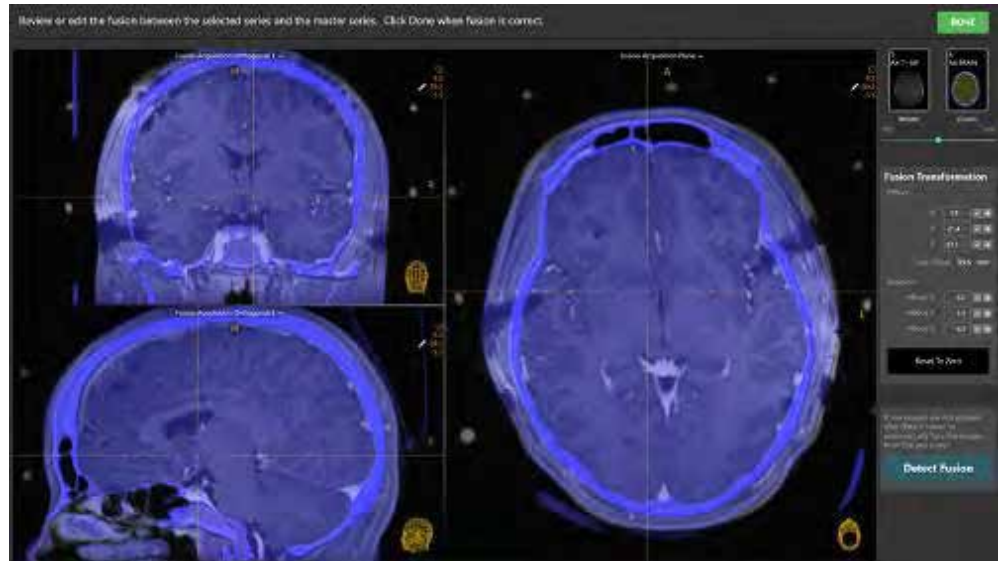
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*If one or more image series are loaded into the workstation that have a different frame of reference as the master series, the application will automatically launch the Fusion task and prompt you to fuse each newly loaded image series with the master series.*

---

The application offers you with the following capabilities with respect to the Fusion task:

- Review the fusion between a loaded image series and the master series (see [Reviewing Image Fusions Pg. 222](#)).
- Automatically fuse a loaded image series with the master series (see [Automatically Fusing Images Pg. 223](#)).
- Manually override and/or edit the fusion transformation between a loaded image series and the master series (see [Manually Editing Image Fusions Pg. 224](#)).

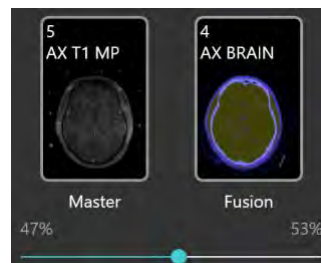


## Reviewing Image Fusions

The Fusion task allows you to review the fusion transformation between any loaded image series and the master series.

### > To review an image fusion

1. Launch the Fusion task using the Thumbnail Bar (see [Using Thumbnails Pg. 79](#)). (The Fusion task may also be automatically launched if you attempt to load an image series with a different frame of reference than the master series).
2. Use the slider in the task's control panel to change the relative weighting of the blend between the selected image series (denoted "fusion series") and the master series. Drag to the left to change the image blend weighting closer to the master series. Drag to the right to change the image blend weighting closer to the selected image series.



3. Use image blend tools (see [Image Blend Tools Pg. 94](#)) within the task's viewports to review the automatic fusion result.

- Review the fusion translational and rotational offset values in the task control panel, to understand the linear distance (in millimeters) and rotational (in degrees) differences found between the two images series.



**Fusion Transformation**

Offset:

X: 1.8 mm - +

Y: -21.4 mm - +

Z: 97.3 mm - +

Total Offset: 99.6 mm

Rotation:

About X: -4.0 ° - +

About Y: 1.5 ° - +

About Z: -6.3 ° - +

## Automatically Fusing Images

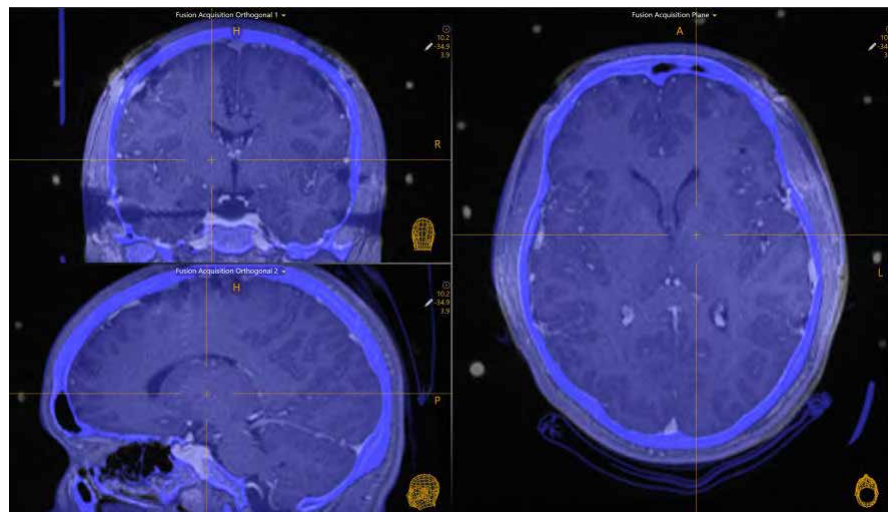
You may use the Fusion task to automatically fuse an image series to the master series.

### > To exercise automatic fusion

- Launch the Fusion task using the Thumbnail Bar (see [Using Thumbnails Pg. 79](#)). (The Fusion task may also be automatically launched if you attempt to load an image series with a different frame of reference than the master series).
- Select **Detect Fusion** from the task's control panel.
- A floating window will display a **Please Wait** message and the task user interface will be blurred.



4. After the automatic fusion completes, the results will be displayed within the viewports. A status message will pop-up indicating that the automatic fusion process has completed successfully.







## Manually Editing Image Fusions

The Fusion task may also be used manually edit the defined fusion transformation between a selected image series and the master series.

### > To manually edit an image fusion

1. Launch the Fusion task using the Thumbnail Bar (see [Using Thumbnails Pg. 79](#)). (The Fusion task may also be automatically launched if you attempt to load an image series with a different frame of reference than the master series).



2. Use the **Fusion Pan** tool in the task's custom toolbar to pan the fusion series (i.e. introduce a translational component to the fusion transformation) relative to the master series. To use the **Fusion Pan** tool:
  - Select the  button from the custom toolbar
  - Click and drag the fusion image to change its position relative to the master.
  
3. Use the **Fusion Rotate** tool in the task's custom toolbar to rotate the fusion series (i.e. introduce a rotational component to the fusion transformation) relative to the master series. To use the **Fusion Rotate** tool:
  - Select the  button from the custom toolbar
  - Click and drag the fusion image to change its orientation relative to the master.
  
4. Use the **Fusion Undo** and **Fusion Redo** tools to undo or redo any changes made to the fusion shown on screen.
  - Select the  button from the custom toolbar to undo a change to the fusion shown on screen.
  - Select the  button from the custom toolbar to redo a change to the fusion shown on screen.

> **To reset an image fusion**

1. Launch the Fusion task using the Thumbnail Bar (see [Using Thumbnails Pg. 79](#)). (The Fusion task may also be automatically launched if you attempt to load an image series with a different frame of reference than the master series).
2. Select **Reset To Zero** from the task's control panel.
3. The fusion transformation between the selected image series and the master series will be reset to have no offset or rotation.

## Edit Anatomical Planes Task *Changing Anatomical Planes*

You may use the Edit Anatomical Planes task to review and/or modify the planar definition corresponding to the anatomical viewing orientation. This feature may be useful to you if the anatomical viewing orientation shown on the workstation does not correspond to the anatomical orientation of the patient in the rendered images.

*The Acquire Frame Master step prompts you to acquire the master series aligned to patient anatomy so that the acquisition planes of the scan correspond to the anatomical orientation of the patient. If the master series is acquired in this manner, then changing the anatomical plane definition is not necessary. [See Acquire Master Scan Step - Acquiring a Grid Master Scan Pg. 131](#) and/or [Acquire Master Scan Step - Acquiring a Frame Master Scan Pg. 153](#) for further details.*

The following operations are provided by the Edit Anatomical Planes Task:

- Reviewing the planar definition used to formulate the anatomical viewing orientation (see [Reviewing the Anatomical Planes Pg. 226](#)).
- Modifying the planar definition used to formulate the anatomical viewing orientation (see [Editing the Anatomical Planes Pg. 227](#)).

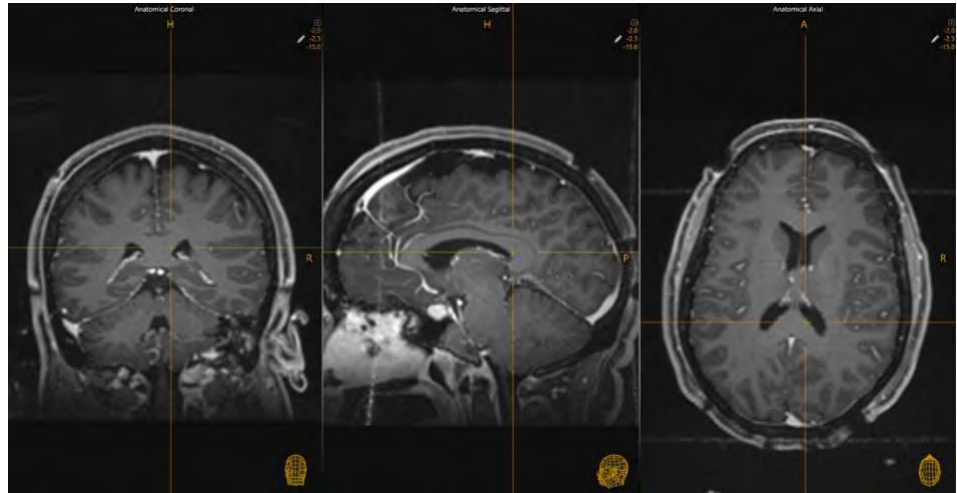


### Reviewing the Anatomical Planes

You may review the definition of the anatomical viewing planes by launching the Edit Anatomical Planes task and observing the resulting viewport orientation.

> **To review the anatomical viewing orientation**

1. Launch the Edit Anatomical Planes task using the top-level tools menu (see [Top-Level Tools Pg. 59](#)).
2. The master scan associated with the current workflow will be displayed in the viewports, aligned to the anatomical viewing orientation currently defined in the application.



3. Review the images to ensure that they are oriented along the anatomical directions of the patient.




## Editing the Anatomical Planes

If you did not acquire the master series aligned to patient anatomy, you may notice that the anatomical viewing orientation does not align with patient anatomy. In these cases, you may edit the application's definition of the anatomical viewing orientation using the Edit Anatomical Planes task.

> **To edit the anatomical viewing planes**

1. Launch the Edit Anatomical Planes task using the top-level tools menu (see [Top-Level Tools Pg. 59](#)).
2. The master scan associated with the current workflow will be displayed in the viewports, aligned to the anatomical viewing orientation currently defined in the application.
3. Use the **Rotate Anatomical Planes** tool in the task's custom toolbar to rotate the master series in each viewing plane such that the patient anatomy aligns with the

viewing orientation shown in the viewports. To use the **Rotate Anatomical Planes** tool:

- Select the  button from the custom toolbar. (Note that the **Rotate Anatomical Planes** tool is selected by default when the task is launched).
  - Click and drag in any viewport to change the orientation of the images such that they agree with the orientation shown by the orientation indicators.
4. Use the **Rotate Anatomical Planes Undo** and **Rotate Anatomical Planes Rotate Redo** tools to undo or redo any changes made to the planar definition of the anatomical viewing orientation shown on screen.
- Select the  button from the custom toolbar to undo a change to the anatomical viewing orientation shown on screen.
  - Select the  button from the custom toolbar to redo a change to the anatomical viewing orientation shown on screen.

---

*Since the viewing orientation is always set to **Anatomical** in this task, whenever you change the anatomical planar definition using the **Rotate Anatomical Planes** tool, the Orientation Indicator will remain unchanged. This is because the Orientation Indicator represents the anatomical orientation of the patient, which is being modified using the **Rotate Anatomical Planes** tool. See [Using the Orientation Indicator Pg. 85](#) for additional details.*

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## Compare Task *Comparing Images*

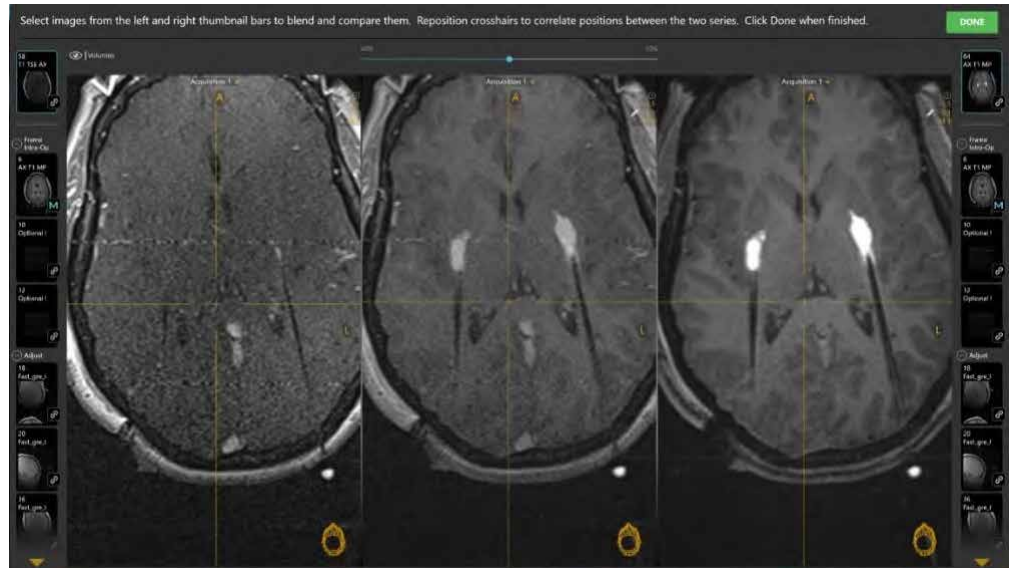
The Compare task offers the ability to visually compare two image series, side-by-side in different viewing orientations. This functionality may be useful for a number of workflow-related needs, such as:

- Visualizing locations between two image series acquired using different pulse sequences (see [Comparing Images Pg. 230](#)).
- Visualizing and comparing volumes of interest (see [Overlaying Volumes Pg. 231](#)).
- Viewing one or more scans in the exact orientation in which they were acquired.
- Determining whether or not the patient has moved within fixation between two scans.
- Determining whether or not the scanner table has inadvertently moved between two scans.

The Compare task offers the following viewing orientations in its layout:

- Acquisition 1 View – Aligns viewports to the plane where the first image series selected for comparison was acquired in.
- Acquisition 2 View – Aligns viewports to the plane where the second image series selected for comparison was acquired in.
- Anatomical Axial View – Aligns viewports to the anatomical axial plane.
- Anatomical Coronal View – Aligns viewports to the anatomical coronal plane.
- Anatomical Sagittal View – Aligns viewports to the anatomical sagittal plane.
- Trajectory Axial View – Aligns viewports perpendicular to any of the trajectory paths defined in the application. If you select a different trajectory the viewport will realign to match.
- Trajectory Coronal View – Aligns viewports orthogonal to any of the trajectory paths defined in the application, as close as possible to the scanner coronal plane. If you select a different trajectory the viewport will realign to match.
- Trajectory Sagittal View – Aligns viewports orthogonal to any of the trajectory paths defined in the application, as close as possible to the scanner sagittal

plane. If you select a different trajectory the viewport will realign to match.



## Comparing Images

The Compare task allows you to compare two different image series in a variety of different viewing orientations.

### > To compare two image series

1. Launch the Compare task using the top-level tools menu (see [Top-Level Tools Pg. 59](#)).
2. The two most recently acquired image series are automatically selected in each Thumbnail Bar. The most recent image series is selected on the right-hand side Thumbnail Bar, and the next most recent image series is selected on the left-hand side Thumbnail Bar.
3. Use the slider bar in the task control panel to change the relative weighting of each image series in the center viewport. Drag to the left to change the image blend weighting closer to the series selected on the left-hand side Thumbnail Bar. Drag to the right to change the image blend weighting closer to the series selected on the right-hand side Thumbnail Bar.
4. You may change the image series selections in each Thumbnail Bar as desired (see [Using Thumbnails Pg. 79](#)).

> **To change the comparison viewing orientation**

Change the viewport orientation in one of the viewports (see [Changing a Viewing Layout Orientation Pg. 82](#)). The orientation of all viewports will match the one just selected.

## Overlaying Volumes

You may also overlay and/or correlate the crosshairs to any VOI annotation created throughout the course of procedure on images shown in the Compare Task.

> **To overlay VOI annotations**

1. Launch the Compare task using the top-level tools menu (see [Top-Level Tools Pg. 59](#)).
2. Change the visibility of any VOI annotation using the **Volumes** toggle button in the task control panel (see [Working with Volume of Interest Annotations Pg.104](#)).

> **To correlate to a VOI annotation**

1. Launch the Compare task using the top-level tools menu (see [Top-Level Tools Pg. 59](#)).
2. Click on the **Volumes** toggle button and then select the **GO** button beside the VOI annotation to which you wish to correlate the crosshairs. The crosshairs will then correlate to the center of the corresponding VOI annotation (see [Working with Volume of Interest Annotations Pg. 104](#)).

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## Move Grid Task – Repositioning Marking Grids

The Move Grid task provides you with the ability to re-position a marking grid on the patient in order to accommodate for a trajectory path that doesn't intersect its associated marking grid. In order for the application to prescribe the frame mount point for a given trajectory, it must intersect a marking grid.

The task is available for use in two possible workflow scenarios:

- 1) If one or more trajectories defined in the Pre-Op Workflow do not intersect any marking grids detected by the application. In these cases, the Move Grid task is automatically launched by the software upon entering the Set Target Points step (see [Set Target Point Step – Defining Procedure Target Points Pg. 142](#)). You may proceed in the workflow by moving the associated marking grid in order to realize the preoperative trajectory path, or alternatively, edit the trajectory in order to intersect one of the marking grids.
- 2) If trajectories in the Grid Workflow require edits such that they no longer intersect a marking grid. In this case, the Finalize Trajectory step (see [Finalize Trajectory Step - Reviewing Trajectories Pg. 145](#)) prevents edits to the currently selected trajectory if it is moved such that it would no longer intersect its associated marking grid. You may proceed in the workflow by re-affixing the marking grid(s) to the patient, re-acquiring a whole head scan of the patient with marking grid(s) re-affixed, fusing the newly acquired whole head scan with the original workflow master series, and verifying the identification of the re-affixed marking grid(s).

The Move Grid task allows you to perform the following actions in order to carry out workflow in each of the above-mentioned scenarios:

- Modify the trajectory of interest to a desired position. The trajectory may be freely modified, regardless of any constraints in the underlying workflow step. This may be necessary to position a trajectory to an off-grid location such that it can be realized by physically moving the associated marking grid, or alternatively, to re-position an already off-grid trajectory such that it intersects an associated marking grid (see [Editing the Trajectory Pg. 233](#)).
- Re-position the marking grid physically on the patient using visual guidance from the task (see [Re-Positioning the Grid Pg. 236](#)).
- Re-acquire a new whole-head scan of the patient with the marking grid re-affixed to the patient (see [Re-Scanning the Patient Pg. 237](#)).
- Fuse the new whole-head scan of the patient with the original master series containing originally affixed marking grids (see [Fusing the New Grid Scan Pg. 237](#)).



- Verify the marking grid identification and resulting trajectory path (see [Reviewing the New Grid Detection and Trajectory Pg. 238](#)).
- Accept the position of the newly affixed marking grid (see [Accepting the New Grid Pg. 239](#)).

## Editing the Trajectory

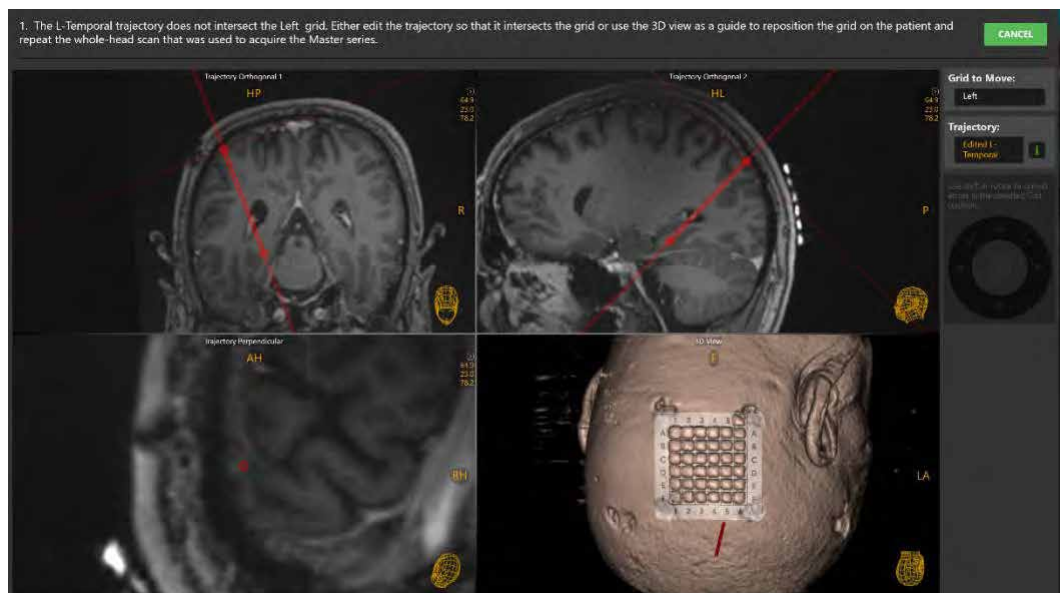
There are two scenarios under which you may use the Move Grid task to edit a trajectory:

- 1) In cases of re-positioning a preoperatively planned trajectory that was transformed into intraoperative space and does not intersect a marking grid.
- 2) In cases where a defined intraoperative trajectory cannot be realized due to the current position of a marking grid on the patient.

In either case, the Move Grid task allows you to edit the trajectory on the master series containing the originally affixed marking grid(s), in a manner such that you may move forward in the workflow.

### > To edit a trajectory that does not intersect a marking grid

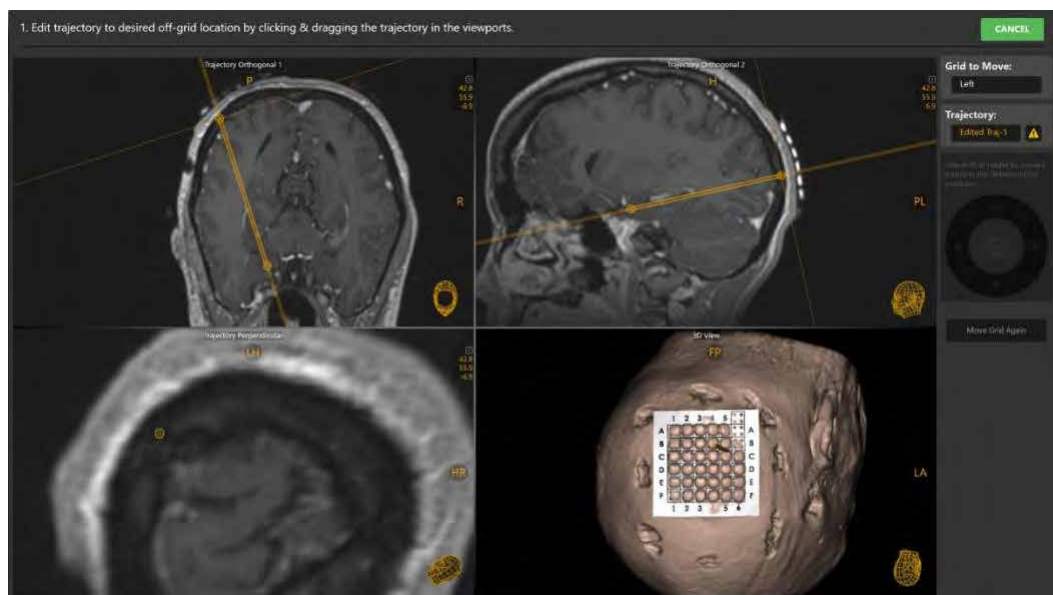
1. Upon navigating to the Set Target step in the Grid Workflow (see [Set Target Point Step – Defining Procedure Target Points Pg. 142](#)), the Move Grid task will be launched automatically for each trajectory that does not intersect a marking grid.



2. Edit the selected trajectory's entry and/or target points using mouse and click drag operations (see [Working with Trajectory Annotations Pg. 99](#)) until it is in the desired position.
3. If edits were made to the trajectory such that it now intersects the associated marking grid, select **DONE** to close the task window and have the edits realized in the underlying step. Alternatively, you may opt to re-position the marking grid in order to realize a trajectory that does not intersect the associated grid (see [Re-Positioning the Grid Pg. 236](#)).

> **To edit a trajectory to an off-grid location**



1. In the Finalize Trajectory step in the Grid Workflow (see [Finalize Trajectory Step - Reviewing Trajectories Pg. 145](#)), select **Move Grid** in the step's control panel.



2. Edit the selected trajectory's entry and/or target points using mouse and click drag operations (see [Working with Trajectory Annotations Pg. 99](#)) until it is in the desired position.
3. The resulting trajectory can then be used to provide you with guidance on how to physical re-affix the marking grid to the patient (see [Re-Positioning the Grid Pg. 236](#)).

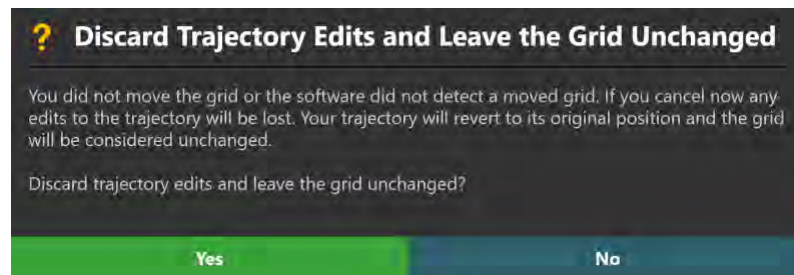
> **To undo or redo edits made to the trajectory annotation**

Use the **Trajectory Undo** and **Trajectory Redo** tools to undo or redo any point changes made to the selected trajectory annotation shown on screen.

- Select the  button from the custom toolbar to undo a point edit made to the selected trajectory annotation shown on screen.
- Select the  button from the custom toolbar to redo a point edit made to the selected trajectory annotation shown on screen.

> **To discard all changes made to the trajectory**

1. Select **CANCEL** from the upper-right hand corner of the task window.
2. If, prior to opening the task, the selected trajectory intersected a marking grid, you will be prompted to confirm that any edits made to the trajectory using the task will be discarded if you proceed. Select **Yes** to proceed to discard the trajectory edits and close the task window. Otherwise, select **No** to leave the trajectory edits intact and leave the task window open.

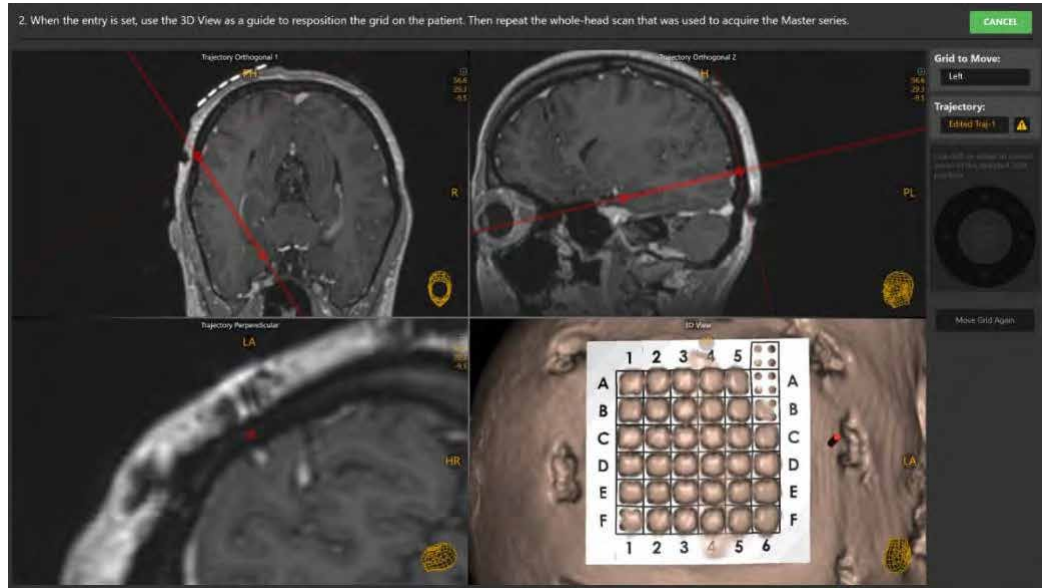


3. If, prior to opening the task, the selected trajectory did not intersect a marking grid, you will be prompted to delete the selected trajectory prior to closing the task. The reason is because a frame mount point for the selected trajectory cannot be prescribed unless it intersects a marking grid. Select **Delete Trajectory** in order to remove the selected trajectory and close the task window to return to the underlying step. Select **Make Further Changes** to stay in the task and make edits to the selected trajectory such that it intersects an associated marking grid.



## Re-Positioning the Grid

After editing the trajectory to the desired location in the master series, the 3D viewport shown in the task can be used to provide guidance on how to re-position the marking grid of interest onto the patient, if desired.



### > To re-position the grid on the patient

1. Draw your attention to the viewport named **3D View**. Observe how the trajectory line is positioned anatomically to its associated marking grid.
2. Measure the distance between the center of the grid and the trajectory line in the **3D View** viewport (see [Measure Line Tool Pg. 92](#)). Note the directionality of the distance using the orientation indicators within the viewport.
3. Move the patient to the back of the scanner bore in order to provide access to their head.
4. Refer to the task panel within the application to identify which grid requires re-positioning.

**Grid to Move:**

Left

5. Remove both layers of the physical grid from the patient and re-affix it to the patient's head using the distance and anatomical directions shown in the **3D View** viewport.

6. Return the patient to the scanner bore for further scanning.

## Re-Scanning the Patient

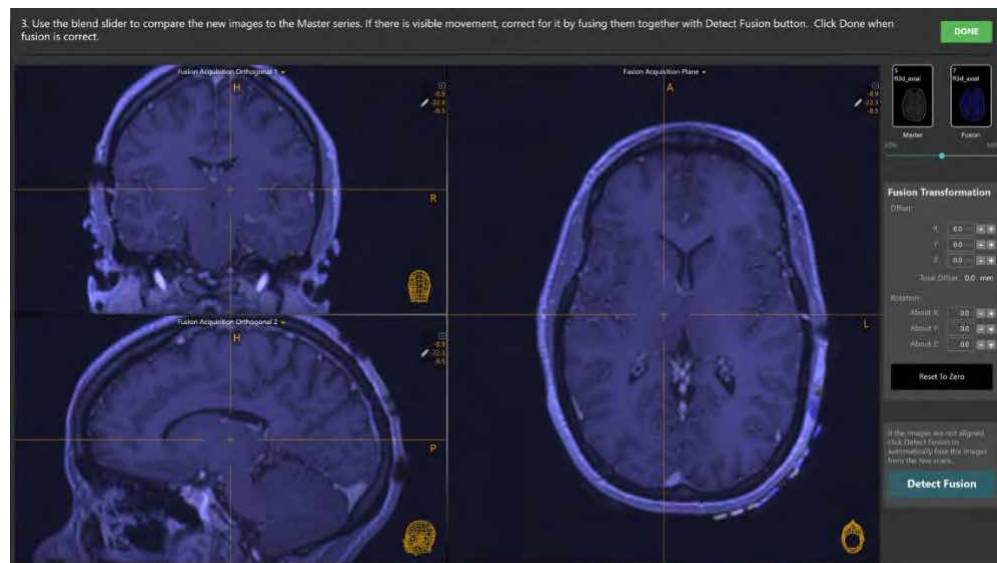
After the indicated marking grid has been physically re-affixed to the patient, re-acquire a T1-weighted whole head scan of the patient, ensuring that all marking grids are visible.

### > To acquire a scan with the grid re-positioned

1. Re-acquire a new whole-head scan using the same specifications indicated in the Acquire Frame Master step (see [Acquiring a Grid Master Series Pg. 131](#)).
2. Transfer the scan to the workstation.

## Fusing the New Grid Scan

Upon receiving the newly acquired scan with the marking grid re-affixed to the patient, the application will automatically prompt you to fuse the new scan with the original master series.



> **To fuse new grid series with the original master series**

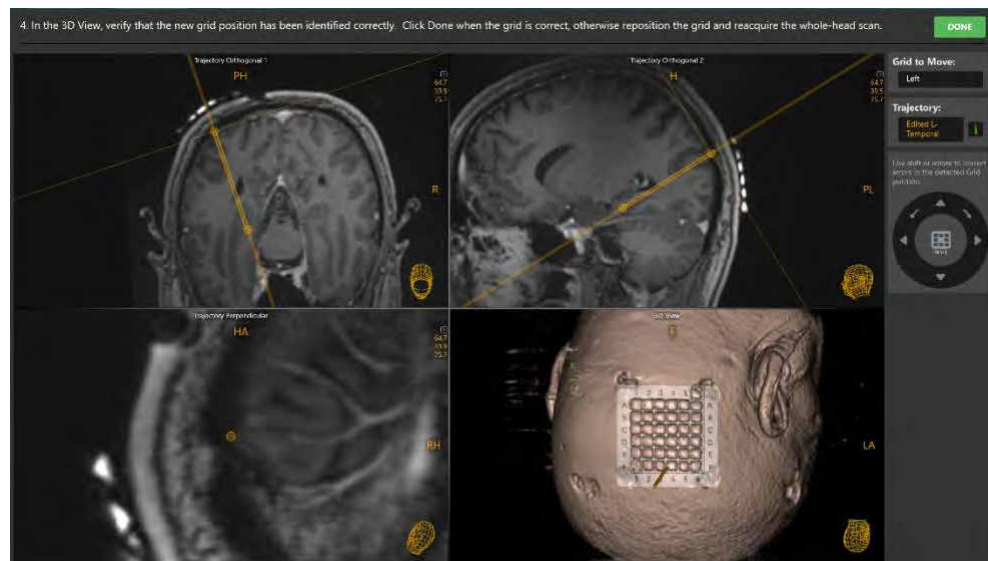
1. Use the Fusion Task to fuse the new grid series to the original master series (see [Fusion Task Fusing Images Pg. 221](#)).
2. Close the Fusion Task.
3. A floating window will display a **Please Wait** message and the main application window will be blurred.



4. The results of the automatic grid detection will be shown in the viewports associated with the task window.

## Reviewing the New Grid Detection and Trajectory

After the Move Grid task automatically detects the newly affixed marking grid in the scan, you must review and verify the detected position of the grid in order to proceed.



> **To review the marking grid detection**

Draw your attention to the viewport named **3D View**. Observe how the 3D model of the grid aligns with its position in the underlying images.

---

**Caution:** It is important to be certain that the extra grid square above the A-6 position on the detected grid is correct because it is used by the application to determine the orientation of the grid to provide correct row and column labels.

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> **To manually modify the detected marking grid**

Use the Grid Editor control (see [Modifying Marking Grids Pg. 136](#)) to make edits to the selected grid, if required.

> **To move the detected marking grid again**

If you wish to physically move the selected marking grid again, you must complete the following actions:

- Re-position the marking grid physically on the patient using visual guidance from the task (see [Re-Positioning the Grid Pg. 236](#)).
- Re-acquire a new whole-head scan of the patient with the moved marking grid affixed to the patient (see [Re-Scanning the Patient Pg. 237](#)).
- Fuse the new whole-head scan of the patient with the original master series containing originally affixed marking grids (see [Fusing the New Grid Scan Pg. 237](#)).
- Verify the marking grid identification and resulting trajectory path (see [Reviewing the New Grid Detection and Trajectory Pg. 238](#)).

## Accepting the New Grid

If you have performed all of the actions required by the Move Grid task and have successfully re-positioned a grid on the patient, you must close the task in order to realize the changes.

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*Once you have sent a new scan containing the re-positioned grid to the application, this scan will now become the master series for the Grid Workflow upon closing the Move Grid task.*

---

> **To accept the re-positioned grid**

Select **DONE** from the upper-right hand corner of the task window.



## Edit Stem Task – *Changing the Stem Position*

The Edit Stem task provides you with the ability to modify the position of the Targeting Stem on a set of two orthogonal image series acquired along its length. This task is only available for use in the Verify Adjustment (see [Verify Adjustment Step – Verifying the Stem Position Pg. 179](#)) and Locate Stem Position (see [Locate Stem Position – Re-verifying the Stem Position Pg. 214](#)) steps in the Frame Workflow. In those steps, orthogonal scans encapsulating the Targeting Stem for a given frame are used to detect the current position of the stem. If you find that the detected position of the stem does not match up with the underlying images, you can use this task to modify its position accordingly.

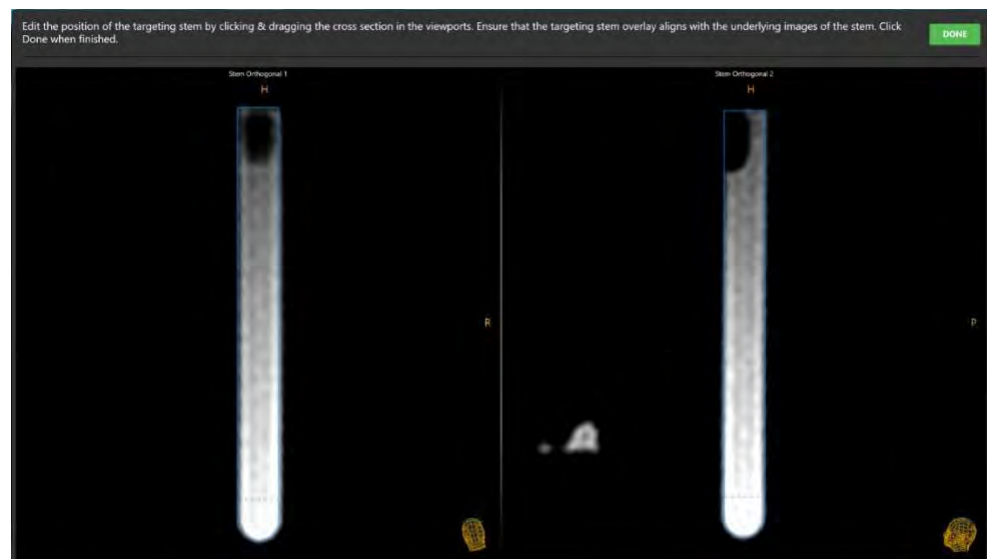
---

*Additional scans of the Targeting Stem cannot be loaded onto the workstation when the Edit Stem task is activated. The sole purpose of this task is to edit the position of the Targeting Stem in scans already loaded. If you wish to acquire additional scans of the Targeting Stem, you must return to the Verify Adjustment step. See [Verify Adjustment Step – Verifying the Stem Position Pg. 179](#) for further details.*

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The following operations are provided by the Edit Anatomical Planes Task:

- Reviewing the position of the Targeting Stem in two orthogonal viewing planes (see [Reviewing the Targeting Stem Position Pg. 242](#)).
- Modifying the position of the Targeting Stem (see [Modifying the Targeting Stem Position Pg. 242](#)).

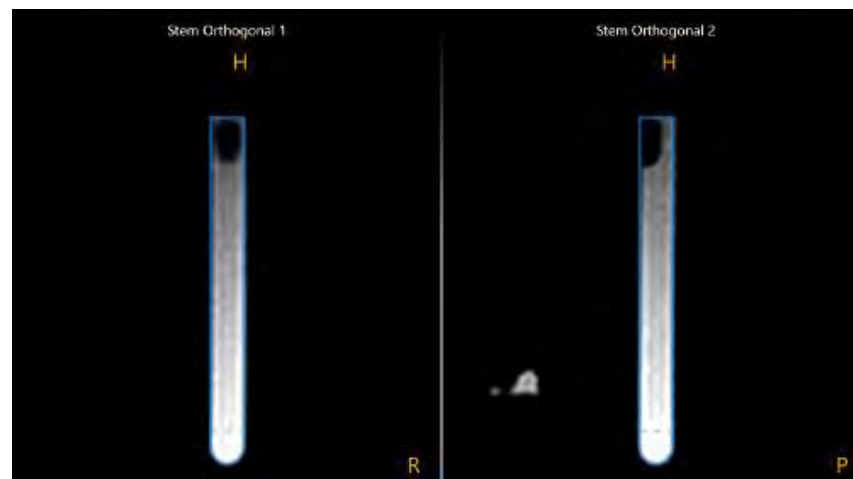


## Reviewing the Targeting Stem Position

You may use the Edit Stem task to review the current position of the Targeting Stem in each of the orthogonal stem scans acquired.

### > To review the Targeting Stem position

4. Observe the outline overlay of the currently selected frame's Targeting Stem overlaid on the individual scans in the **Stem Orthogonal 1** and **Stem Orthogonal 2** viewports.



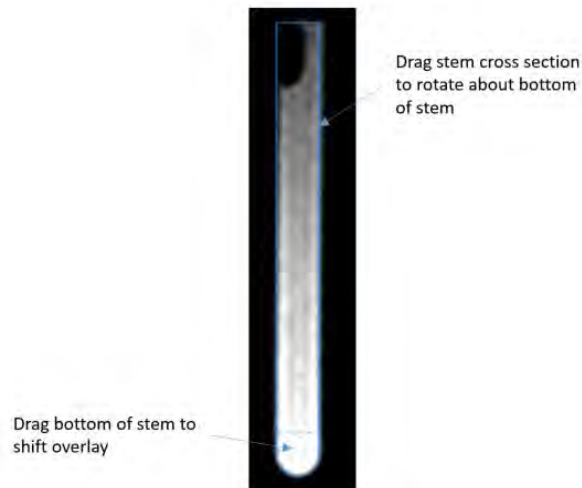
5. Verify that the outline of the Targeting Stem overlay matches up with the signal from the stem in the underlying images. If the outline of the Targeting Stem does not match up with the underlying images, you may proceed to modify the overlay to change the position of the Targeting Stem.

## Modifying the Targeting Stem Position

The Edit Stem task can be used to modify the current position of a frame's Targeting Stem using two independent orthogonal scans.

### > To modify the Targeting Stem position



1. To shift the entire Targeting Stem cross section to correct for positional discrepancies when compared to the underlying images, hover the mouse over the bottom portion of the stem graphic (below the dotted line). Click and drag with the mouse over the bottom portion of the stem graphic to shift the cross section.



2. To rotate the Targeting Stem cross section to correct for orientation discrepancies when compared to the underlying images, hover the mouse over the stem graphic (above the dotted line). Click and drag with the mouse over the stem graphic to rotate it about the bottom position of the stem.

> **To undo or redo edits made to the Targeting Stem**

Use the **Targeting Stem Undo** and **Targeting Stem Redo** tools to undo or redo any changes made to the selected Targeting Stem graphic shown on screen.

- Select the  button from the custom toolbar to undo a position or orientation edit made to the Targeting Stem graphic shown on screen.
- Select the  button from the custom toolbar to redo a position or orientation edit made to the Targeting Stem graphic shown on screen.

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# Troubleshooting

This chapter describes how to troubleshoot problems that you may encounter while using the ClearPoint Array™ Workstation. This content is also contained as integrated help topics within the application whenever a warning message is displayed. See [Status Messages Pg. 77](#) for details on how to view integrated help content within the application.

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## DICOM Association Lost

The DICOM connection between the ClearPoint Array™ Workstation and the scanner has been abruptly lost, preventing further transfer of images. This could be due to an inherent network connection problem or intermittent network connectivity.

### Can be caused by:

- Intermittent or one time network connection failure, causing data packet loss
- Persistent network connectivity issues
- Unexpected DICOM communication error which prevents the workstation and scanner from further communicating with one another

### Consequences of losing a DICOM association between scanner and workstation:

- Transfer of images from scanner to workstation will be increasingly difficult depending on the cause.
- If the lost association is a one-time event, then additional images can be sent without further issue.
- If the lost association is persistent, then network connectivity resolution is required.

### Recovery:

- If the lost association is a one-time event, then the series can be re-sent and any missing images from that series will be added to the application.
- If the lost association is persistent throughout the duration of the case, it is strongly suggested to make the hospital IT team aware of the issue. Any network connectivity issues can be resolved by the hospital IT team in such instances.
- If the hospital IT team is unavailable or cannot resolve the network connectivity issues causing the lost DICOM association, then manually loading images from removable media is the only recourse. Use the Load DICOM Images Window if images from the scanner can be written to removable media.

---

## Failed to Load Data into Workstation

The series just received could not be loaded into the ClearPoint Array™ Workstation. This indicates a serious problem with the images just received or a critical error in the software.

**Can be caused by:**

- Images received are corrupted and/or incomplete
- Byte encoding of images are invalid

**Consequences of failure to load images into workstation:**

- If the workstation is unable to load the images just received, then they cannot be viewed within the software application. Either changes need to be made to the acquisition received or the software needs to be restarted.

**Recovery:**

- This may indicate a serious problem with the data sent to the workstation. Review the acquisition with the imaging technician and ensure that it can be viewed on the scanner console. Attempt to resend the series if there aren't any problems with the acquisition itself.
- This may also indicate a serious problem with the software. Attempt to restart the software and resend the series.

---

## Data Received Older Than One Hour

The image series just received has an acquisition time stamp that is older than one hour from the current time on the workstation. During intra-operative procedures, it is unlikely that breaks between data acquisitions will be extremely lengthy, unless problems were encountered during the procedure. These images must be reviewed carefully so that appropriate clinical decisions can be made based on when this data was acquired.

**Is caused by:**

- Images just received are older than one hour. The software analyzes the DICOM header tags: (0008, 0021) – Series Date and (0008, 0031) – Series Time to make this determination.

**Consequences of data received being older than one hour:**

- There are no real consequences from a software standpoint. Users should be aware in case an incorrect series was sent to the workstation erroneously.

**Recovery:**

- If there is a solid understanding of why the images just sent are older than one hour, the warning message can be safely dismissed.
- If you don't understand why you are receiving this message, it would be wise to check that the acquisition just sent to the workstation is current.

---

## Data Received Older Than Previously Loaded Data

The image series just received has an acquisition time stamp that is older than data previously loaded into the software. This effectively means you are viewing images that are 'out of date'. The images must be reviewed carefully so that appropriate clinical decisions can be made based on when this data was acquired.

**Is caused by:**

- Images just received are older than previously loaded data. The software analyzes the DICOM header tags: (0008, 0021) – Series Date and (0008, 0031) – Series Time to make this determination.

**Consequences of data received being older than previously loaded data:**

- Some workflow steps will allow the series to still be loaded if it is older than previously loaded data. However, you should take caution in using this data because it is effectively 'out of date' when compared to data loaded into the session.
- Other workflow steps will prevent data from being loaded if it is older than previously loaded data. The reason for this is to prevent providing instructions or performing calculations based on data that is not current.

**Recovery:**

- For those steps that still allow older data to be loaded, the warning message can be safely dismissed, providing the user is aware of the fact that they are loading older data. Please carefully review the images and understand that other images have been loaded that are newer than this series.
- For those steps that prevent older data from being loaded, the only remedy is to acquire a new series and send it to the workstation.

---

## Busy Indication Window Dismissed by User

During a time intensive operation, the ClearPoint Array™ Workstation's busy indication window has been dismissed by pressing the ESC key. The busy indication window is used by the software to indicate that a time intensive, background computation/operation is being performed and that it is in the user's best interest to allow it to complete fully before proceeding. Some examples are: searching for frames mounted on the patient, performing an image fusion, loading a software session, etc. If the busy indication window is dismissed, the software will still attempt to complete the background operation, but will return control of the UI back to the user so that they can continue through the workflow.

### Is caused by:

- Pressing the ESC key while the software is performing a time intensive operation.

### Consequences if busy indication window is dismissed:

- The software may lag in performance after the window is dismissed while it tries to complete the operation/computation of interest.
- Suggestion is to give the software a minute or two to complete processing prior to proceeding with the workflow.

### Recovery:

- The ability to dismiss the busy indication window is provided to allow the user to proceed with the workflow if the software gets stuck during a time intensive operation. This is extremely unlikely and should never occur, but the software provides this ability so that the user can proceed through the workflow if necessary.
- If the ESC key is accidentally pressed with the busy indication window showing, allow the software a minute or two to complete its background processing prior to proceeding with the workflow.

---

## Scanner Bore Size Not Configured

If the scanner bore size has not been set in the System Configuration Window, then every time an image series is received by the workstation, a warning message concerning the scanner bore size will be shown. The software uses the bore size in combination with the list of configured devices in the System Configuration Window to ensure that for a given trajectory path, any of the devices can be physically inserted into the SMARTFrame Array™ without being blocked by the scanner bore. Without this information, the software will not be equipped with the inputs it needs in order to provide this warning for a given trajectory path. The scanner bore size only

needs to be specified once and does not need to change unless the workstation is connected with a different scanner.

**Is caused by:**

- Scanner bore size not specified in the System Configuration Window ('SYSTEM' tab)

**Consequences if the scanner bore size is not configured:**

- If the software is not aware of what the scanner bore size is, it is unable to warn about potential bore collisions prior to the device being inserted.

**Recovery:**

- Use the System Configuration Window to specify the scanner bore size (see 'SYSTEM' tab).

## SMARTGrid™ Not Found

The ClearPoint Array™ Workstation has failed to detect at least one SMARTGrid® from the loaded scan.

**Can be caused by:**

- Loss of fluid in the grid
- Loaded scan cuts off part of the grid
- Insufficient signal from the grid in the scan due to poor coil placement
- Patient orientation was entered incorrectly on scanner
- Imaging artifacts in the loaded scan which may obscure the grid
- Grids overlapping or too close to one another in the loaded scan
- Re-affixed grid being too far away from the planned trajectory

**Consequences if the SMARTGrid® is not detected by the software:**

- If no grids are defined in the software, you will not be able to move forward in the workflow. You must define at least one grid in the software in order to proceed through the Grid Workflow.
- If the grid for which you plan to localize one or more entry points on the patient is not identified in the software, you will not be able to realize a trajectory path which intersects that grid. In order to localize one or more entry points associated with a given grid, it must be identified within the software.

**Recovery:**

- If the software failed to detect one or more grids from a scan in the software, you are encouraged to acquire or use a new scan where the grid(s) are clearly



visible. The new scan should have no significant image cut-offs, distortion or significant noise artifacts present.

- If the initial detection of one or more grids failed in the whole-head master scan acquired in the Acquire Master Scan step, you may use the Verify Grids step to manually search for a grid in a more localized area of interest. This can be accomplished by rotating the view to 'look along' the axis of the grid and then clicking the 'Detect Additional Grid' button. For procedures where more than one grid has been affixed to the patient, be sure to position the view angle so that you are looking directly at the grid of interest. Otherwise, the grid that you wish to identify may not be detected correctly by the software. If manually searching for a grid is unsuccessful, acquire a localized scan which contains the grid(s) of interest. Send the acquisition to the workstation with the Verify Grids step active and allow the software to automatically detect one or more grids from the acquisition.
- If the detection of a re-affixed grid failed in the whole-head scan acquired in the Move Grid task, you are encouraged to review the scan to ensure that: a) the grid of interest is not cut-off in any way; b) significant distortion or noise artifacts are not present in the images; and c) the physical grid is not significantly far away from the planned trajectory. Any needed corrections to either the physical grid placement or to the planned trajectory should be made prior to acquiring a new whole-head scan with the marking grid re-affixed.

---

## Trajectory May Cause Device to be Obstructed by Scanner Bore

The trajectory path mentioned in the warning message has an angulation such that insertion of one or more of the configured devices during the procedure may be obstructed or blocked by the scanner bore. The software uses the 'SCANNER BORE SIZE' variable in the System Configuration Window as well as the 'Total Length' specified for each of the configured devices to determine whether or not the planned trajectory may cause one or more of the configured devices to be blocked by the scanner bore during insertion.

There are three possible warning messages that the software may display if it determines that one or more of the configured devices may be obstructed by the scanner bore if inserted along the given trajectory:

1. Device insertion inside the scanner bore may result in an obstruction.
2. Device insertion into the targeting stem down to the entry point prior to returning the patient into the bore may result in an obstruction.
3. Device insertion all the way to target depth prior to returning the patient into the bore may result in an obstruction.

**Is caused by:**

- Defining a trajectory that may cause at least one of the configured devices to be obstructed by the scanner bore during insertion.

**Consequences of proceeding with a trajectory that may cause a device to be obstructed by the scanner bore:**

- During device insertion, the surgeon may not be able to insert the device into the patient. This depends on the rigidity/flexion of the device to be inserted as well as the possible options for inserting the device into the patient.
- The surgeon may have to explore other options for device insertion, including inserting a portion or all of the device with the patient outside of the scanner bore.

**Recovery:**

- Warning up front about potential device obstruction is key to ensuring that problems do not manifest during the device insertion stage. Ensure that this warning is taken seriously during trajectory planning in order to prevent further problems later in the workflow.
- Use the Device Clearance and Reach Information Window (exercised by clicking on the link in the status message) to view the device clearance measurements. This will indicate the various options for device insertion that will be available to you at the time of insertion.
- Do not use a planned trajectory that has the potential to cause device obstruction. Plan an alternate trajectory for which bore obstruction is less likely to occur (i.e. significant bore clearance).

---

## Device is Not Long Enough to Reach Target

This warning message indicates that one or more of the devices configured during this procedure may not be long enough to reach the target point of the trajectory path mentioned in this warning message. The software uses the 'Insertable Length' specified for each of the configured devices in the System Configuration Window as well as the length of the planned trajectory to determine whether or not each of the configured devices can reach the target point. If this message is shown, it is recommended that the planned trajectory be carefully reviewed prior to proceeding in the workflow, in order to ensure that the device that will be inserted during the procedure is able to reach the planned target point.

**Is caused by:**

- Defining a trajectory that will not allow the device to reach the target point during insertion.

**Consequences of proceeding with a trajectory that may cause a device not to reach its target:**

- During insertion, the device may not be able to reach the target. This may cause the procedure to be incomplete. Trajectory re-planning and re-insertion may be required in these instances.

**Recovery:**

- Paying attention to this warning is critical to ensuring that problems do not manifest during the device insertion stage. Ensure that this warning is taken seriously during trajectory planning in order to prevent further problems later in the workflow.
- Use the Device Clearance and Reach Information Window (exercised by clicking on the link in the status message) to view the trajectory depth measurements. In cases where the device to be inserted can reach the planned target, the measurement will indicate how much sufficient length the device has to reach the target. In other cases where the device is unable to reach the target, the measurement will indicate how much distance is required to reach the target. Use this information to make decisions about how to effectively plan your trajectory.
- Do not use a planned trajectory that has the potential to not reach the target. Make modifications to the trajectory so that the device has sufficient length to reach the target point.

---

## Trajectory Depth is Beyond Maximum Validated System Depth

If a trajectory path is planned such that the maximum validated device placement accuracy depth is exceeded, this warning message will appear. The ClearPoint Array™ system has the ability to guide a device to an intended target in the brain with in-plane errors less than 2.0 mm, however this has only been validated at maximum insertion depths of 125 mm. Insertion depths greater than 125 mm are not endorsed and if attempted, may result in higher device placement errors. If you receive this warning, make changes to the planned trajectory such that the maximum validated system depth will not be exceeded.

**Is caused by:**

- Defining a trajectory whose length causes the maximum validated system depth (125 mm) to be exceeded.

**Consequences of proceeding with a trajectory that exceeds the maximum validated system depth:**

- Since the ClearPoint Array™ system has not been validated at depths greater than 125 mm, you may experience higher device placement errors at the target. Factors such as image distortion may come into play more readily at these increased insertion depths.

**Recovery:**

- It is strongly encouraged that planned trajectories do not exceed the maximum validated system depth of 125 mm. Do not use planned trajectories that exceed this depth.

## SMARTFrame® Not Found

The ClearPoint Array™ Workstation has failed to detect the indicated SMARTFrame® present in the loaded scan of the patient.

**Can be caused by:**

- Frame markers not completely contained within the loaded scan
- Patient orientation was entered incorrectly on scanner
- Fluid loss in one or more frame markers
- Image artifacts, such as wrapping/ghosting, cause multiple frame markers to appear on top of one another in the loaded scan

**Consequences if the SMARTFrame® is not detected by the software:**

- If no frames are identified in the software, you will not be able to move forward in the workflow past the Verify Frame Base Markers step. You must define at least one frame in the software in order to proceed through the Frame Workflow.
- If a trajectory that you have planned in the Grid Workflow corresponds to a mounted frame that was not detected in the software, that trajectory will not be available for use until the frame is identified in the software. If the software is not aware of the frame's location in space, it cannot prescribe any adjustment instructions to align the frame of interest to the desired planned trajectory path.

**Recovery:**

- Use the scan plane parameters in the Verify Frame Base Markers step to acquire a frame slab by clicking the 'Frame Slab' button. Send the acquisition to the workstation in order to trigger automated detection of the frame.
- Use the Verify Frame Base Markers step to search for the frame of interest in a more localized area. This can be accomplished by using the cross-hairs to identify a search area and clicking the 'Search for Frame' button.
- Manually set the marker positions using the Verify Frame Base Markers step.

---

## SMARTFrame® Markers Inconsistent with Hardware Specifications

The ClearPoint Array™ Workstation has determined that the three donut-shaped markers in the base of the frame are not in their correct relative positions as detected / defined in the images. The software has knowledge of the hardware specifications of the markers and their relative distances to one another. If the positions set for the markers in the images don't agree with these values then either the positions weren't set correctly or the images don't agree with physical reality.

### Can be caused by:

- Markers set incorrectly by user
- Image distortion / artifacts which cause frame markers to appear in different physical locations than they actually are

### Consequences of leaving incorrectly set frame markers inconsistent with their hardware specifications:

- Depending on how far off the markers are from one another, this can significantly impact a number of computations made by the software. In particular, the accuracy of the frame adjustment instructions may be affected, making additional adjustment iterations necessary.

### Recovery:

- If you see this message, confirm the location of all frame markers in the Verify Frame Base Markers step. Modify frame marker positions if they appear incorrect relative to the underlying images.
- If the frame marker positions appear correct relative to the underlying images, acquire a frame slab in the Verify Frame Base Markers step where distortion artifacts will most likely be minimized. Send the acquisition to the workstation in order to trigger automated detection of the frame.
- If you still see this warning after attempting to detect the frame from a frame slab, then ensure that 3D distortion correction is enabled for the scan protocol of interest.

---

## SMARTFrame® Targeting Stem Not Found

The ClearPoint Array™ Workstation was unable to identify an initial position for the SMARTFrame®'s targeting stem in the loaded scan of the patient.

### Can be caused by:

- Loss of fluid in the targeting stem.
- Loaded scan cuts off a portion of the targeting stem.
- Incorrect scan plane parameters.
- Excessive noise in acquired image(s).
- Insufficient signal at the position where the targeting stem is being imaged.
- Loaded scans are subject to image distortion and/or artifacts, causing the software to fail on the detection of the targeting stem.

**Consequences of proceeding with a failed targeting stem detection:**

- If the software fails to detect the position of the targeting stem when one has not been defined yet for a given frame, it will set a default position that you must review in the Verify Targeting Stem step prior to proceeding in the workflow. If, in the Verify Targeting Stem step, the graphic overlay representing the targeting stem does not correspond to the physical position of the cannula in the images, **the initial frame instructions provided in the Make Adjustments step will be incorrect.**
- If the software fails to detect the position of the targeting stem after it has been already identified for a given frame, then the software will use the last known position of the targeting stem to prescribe frame instructions. In these instances, verification of the position and orientation of the targeting stem is encouraged using the Verify Targeting Stem step.

**Recovery:**

- If the targeting stem cannot be seen in the scan, use the scan plane parameters in the Verify Frame Base Markers step to acquire a frame slab by clicking the 'Frame Slab' button. The frame slab should include the entire targeting stem, if possible. Send the acquisition to the workstation in order to trigger automated detection of the frame and associated targeting stem.
- If the targeting stem can be seen in the scan, then manually edit the default orientation and position using the Verify Targeting Stem step, such that it lines up with the underlying images corresponding to the targeting stem.
- If excessive noise is causing the targeting stem detection to otherwise fail, then ensure that you have configured the correct coil for scanning (i.e. flex coil instead of body coil). You may be able to further reduce noise by 'loading' the coil with a saline or gel bag positioned superior to the patient, within the imaging area.
- If significant image artifacts are causing the targeting stem detection to fail, then ensure that 3D distortion correction is enabled for the scan protocol of interest.

---

## Failed To Identify Targeting Stem From Orthogonal Slab

The ClearPoint Array™ Workstation was unable to automatically identify the targeting stem from the most recently sent image series in the Verify Adjustment step.

### Can be caused by:

- Loss of fluid in the physical targeting stem.
- Incorrect scan plane parameters.
- Orthogonal slab has been clipped by the edge of the slab. This can occur if the targeting stem slab is made too thin or if the targeting stem has not been reasonably aligned to the planned trajectory prior to acquiring the orthogonal slab.

### Consequences of orthogonal slab stem detection failure:

- If the software fails to detect the targeting stem in one or both of the two orthogonal image series, then it will use the last known position of the targeting stem for computations moving forward in the workflow.
- If the graphic cross-section representing the targeting stem does not correspond to the physical position of the cannula in the underlying images, **the frame instructions and projected error values shown going forward will be incorrect.**

### Recovery:

- Ultimately, it is your responsibility to ensure that the automatic detection of the targeting stem has been performed correctly. To do this, zoom in on the stem in the Orthogonal 1 and Orthogonal 2 views and verify that the 2D graphic overlay produced by the software matches up with the targeting stem in the underlying images. If they do not match up, use the Edit Stem task to manually modify the position of the 2D graphic overlay in one or both views to better align with the stem in the underlying images.
- If targeting stem detection failures continue to persist, consider increasing the size of the orthogonal slabs to rule out unnecessary clipping of the targeting stem.
- Ensure that fluid within the targeting stem shaft is sufficient. The software has specific knowledge about the physical dimensions of the stem, so if it does not appear clearly in the acquired images, the software will have no way to automatically detect it reliably. If there are fluid problems within the stem, consider replacing it with a new one.
- Check that the scan plane parameters for the orthogonal targeting stem scans are correct.

---

## Inconsistent Targeting Stem Positions Found

The ClearPoint Array™ Workstation has found inconsistent positions for the targeting stem in the two most recently acquired orthogonal scans.

### Can be caused by:

- Geometric distortion artifacts in one or both of the scans causing positional inconsistencies.
- Low signal-to-noise on one or both of the scans causing incorrect targeting stem detection.
- Artifacts in the images causing incorrect targeting stem detection.
- Physical movement between the two scans causing positional inconsistencies.

### Consequences of inconsistent targeting stem scans:

- In all cases, the inconsistency between targeting stem scans may cause increased angular error on the final device insertion.
- If the inconsistency warning was caused by physical movement of the frame or targeting stem between scans, this means that the software will be using an out-of-date position for the stem when prescribing frame instructions and displaying projected error values.

### Recovery:

- Review the positioning of the patient within the scanner bore as a possible source of geometric distortion artifacts in the acquired scans. Also ensure that 3D distortion correction is enabled for the scan protocol of interest.
- Ensure that there is no movement of the frame or targeting stem between the orthogonal scan acquisitions. Use the Compare Images task to blend between the two most recently acquired orthogonal scans to make this determination.
- Optimize coil positioning to improve signal to noise in the acquired orthogonal scans.
- Eliminate the source of any image artifacts in the scans.
- Acquire a new pair of orthogonal scans after identifying the source of the problem to ensure that there are no targeting stem position inconsistency warnings presented.

---

## Targeting Stem May Not Be Fully Inserted

The ClearPoint Array™ Workstation has detected that the selected frame's targeting stem may not be fully inserted into the frame. The targeting stem must be fully



inserted to the frame after the frame has been mounted onto the patient and should remain that way until device insertion. **Failure to do so can result in an insertion that is deeper than planned.**

**Can be caused by:**

- The targeting stem not entirely being inserted into the frame.
- Image Distortion and/or artifacts in the images used to detect the position of the frame markers and/or the targeting stem. This may result in the software detecting a position for the bottom portion of the frame's targeting stem which makes it appear as though the stem is not fully inserted, even though it is. (For other causes see also [Targeting Stem Appears Out of Position](#)).

**Consequences of selected frame's stem not fully inserted:**

- The software uses the stem position to compute insertion depth values. If the targeting stem is not fully inserted into the frame at the time when scans of the targeting stem are acquired during the frame adjustment process, then the depth value computed will be incorrect.
- If the stem is confirmed as being fully inserted despite the message, this may indicate that there is error in the detected position of the targeting stem relative to the frame base markers. The consequence could be increased placement error if not corrected.

**Recovery:**

- If the cause for this warning was due to the stem being not fully inserted, ensure that it is correctly inserted and then acquire at least one more pair of orthogonal scans of the stem before proceeding with the device insertion. This will ensure that the computed depth value is based on the stem being fully inserted.
- If the targeting stem is properly inserted and you are still receiving this warning, ensure that you check both the pulse sequence and associated scan plane parameters to ensure that all values are being inputted correctly at the scanner console. Ensure that 3D distortion correction for this pulse sequence is turned on. Review your frame marker positions in the Verify Frame Base Markers step. If you continue to see this warning after ensuring that all scan plane parameters have been entered correctly, then image distortion is most likely the cause so please proceed with caution.

---

## Targeting Stem Appears Out of Position

The ClearPoint Array™ Workstation has detected that the selected frame's targeting stem appears lower than it should be relative to the frame markers.

**Can be caused by:**

- Inadvertent patient movement between trajectory planning and frame alignment steps.
- The frame's markers were detected incorrectly in the most recently received images of the frame.
- The frame's markers were detected on images in the last set of frame scans that were subjected to image distortion/artifacts that caused their positions in space to not reflect where they are physically located.
- The selected frame's targeting stem was detected incorrectly in the most recently received images of the frame.
- The most recently received images of the selected frame's targeting stem were subjected to image distortion/artifacts that caused its position in space to not reflect where it is located physically.

**Consequences of selected frame's targeting stem being out of position:**

- This indicates that detection of the selected frame's frame markers and/or targeting stem is not consistent based on previous acquisitions. This will involve some investigation to determine which images are the source of the discrepancy.
- If not corrected, increased placement error may result.

**Recovery:**

- If the patient has inadvertently moved between frame acquisitions, then return to the Verify Frame Base Markers step, re-acquire an entire frame volume and register this to the master series. Proceed through the workflow and with frame alignment after this has been accomplished.
- Otherwise, if the cause is due to inconsistent frame/targeting stem positions on subsequent scans, then analyze all scans of the frame and associated stem to rule out any artifacts in the acquired images. Ensure that the correct scan protocols and associated parameters were used.
- If, after checking all scans and associated parameters for correctness, you still encounter this warning, then proceed with caution during the device insertion process since image distortion may be involved.

---

## Targeting Stem Not Sufficiently Aligned to Trajectory

If the currently selected SMARTFrame® is not aligned within 1.5 mm of the selected trajectory prior to insertion, then the Prepare & Insert step will display this warning message. The purpose of the warning message is to notify the user that they have left a significant residual error when adjusting the frame's targeting stem to the planned trajectory, and that it should be addressed prior to insertion.

**Can be caused by:**

- Leaving a fairly large residual error in the frame alignment steps.
- Positional inconsistencies of the targeting stem from the orthogonal slabs in the Verify Adjustment step.
- Changing the trajectory selection without adjusting the corresponding frame.

**Consequences if the selected frame is not well aligned to the trajectory:**

- This could result in a poor device placement

**Recovery:**

- Ensure that the selected frame is well aligned to the planned trajectory by exercising all frame adjustment instructions provided in the frame alignment steps. Leave small residual in-plane errors prior to insertion.
- If the warning is caused by inconsistent targeting stem positions in the orthogonal slabs, ensure that the correct pulse sequences and associated scan plane parameters are used. In particular:
  - If 3D error correction is available on the scanner, ensure that it was turned on and that the 3D-corrected series was sent.
  - If the scanner supports table-movement, verify that the Table Position value was entered correctly.
  - For Siemens scanners, ensure that the direction of phase encoding has been set correctly using the 'InPlane Rotation' angle provided by the Scan Plane Parameters Dialog. This will ensure that spatial accuracy is preserved for the orthogonal scans, and that any wrap-around artifacts are minimized.
  - Take all possible steps to reduce noise in the scan.

---

## Insertion Track Does Not Appear Straight

The ClearPoint Array™ Workstation has determined that the detected signal void left by the device appears to be curved. This could indicate that geometric distortion artifacts are present in the acquired images or that physical device deflection may have occurred.

**Can be caused by:**

- Geometric image distortion artifacts which make the device signal void appear non-straight in the acquired images
- Deflection of the device during insertion
- Device broke during insertion, causing it to bend

**Consequences of detected device track not appearing straight:**

- This warning message can be dismissed without any direct consequences. Users can choose to define the location of the device tip on the set of acquired images that caused the warning to appear. However, it is recommended that the images are carefully reviewed because they may be subject to geometric distortion artifacts that may impact the final position of the device tip. This may potentially invalidate final placement errors reported by the software.

**Recovery:**

- Review the images and analyze whether or not the device track is actually curved (use views that are oriented along the device track). Attempt to distinguish between potential geometric distortion and physical device deflection.
- Ensure that 3D distortion correction is enabled on the scan protocol used to acquire the insertion scan.

---

## Failed to Detect Inserted Device Track

The ClearPoint Array™ Workstation has failed to detect the signal void left by the inserted device track in the acquired images.

**Can be caused by:**

- Device track does not appear in acquired images.
- Image stack may be too thin and/or cut off the device tip.
- Geometric image distortion artifacts which make the device signal void appear non-straight in the acquired images.

**Consequences of failure to detect device track:**

- Users are still able to set the device tip manually so there are no real software consequences.

**Recovery:**

- If the software fails to detect the device track but you are still able to see the signal void in the acquired images, you may set the device tip manually using the 'Set Device Tip' button in the Prepare and Insert step. You should only use this approach if you can confirm that the device track appears straight in the acquired images.
- Always review the detected device tip position, even if the segmentation succeeds.
- If the device track does not appear in the acquired images and/or the insertion scan is too thin, re-acquire a new scan and assess the tip position on that scan.

---

## Selected Volume Cannot Be Edited

This warning message is displayed when a target volume has been selected for editing in cases where it has associated treatment volumes defined downstream in the workflow. In these instances, editing of the target volume is not permitted because there are one or more treatment volumes which depend on their associated target volume.

### Is caused by:

- Returning to the Define Target Volumes step and selecting a target volume for which associated treatment volumes have been created in the Assess Treatment Volumes step.

### Consequences in selecting a target volume for which treatment volumes have been defined downstream:

- Editing the original target volume is not permitted.

### Recovery:

- Create a new target volume in the Define Target Volumes step which reflects the VOI of interest.
- If editing of the original target volume is desired, return to the Assess Treatment Volumes step and delete all of its associated treatment volumes.



---

## Appendix 1 – SMARTFrame® Array MRI-Guided Trajectory Frame Description & Operating Instructions

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### A. Device Description (All devices are not made with natural rubber Latex and are provided sterile for single use only)

The SmartFrame® Array Scalp Mount Base, used to attach to patient's head is completely made of plastic, except for the bone screws and stand-off pins (which are made of Titanium). The SMARTFrame® Array Tower, also completely made of plastic, (See Figure 1) attaches to the Base and together is designed to provide multi-directional orientation adjustments in the Operating Room using the Probe Adapter, with Surgical Navigation System (SNS) probes or universal trackers. The Probe Adapter includes a Titanium Tracker Rod that can be used to attach a SNS universal tracker. The Tower also provides orientation adjustments in the MRI Scanner using the Targeting Stem. The Targeting Stem has a fluid-filled column that is MRI visible. The Tower, when attached to the Scalp Mount Base, provides adjustments in the roll and pitch directions by turning the appropriate thumb wheels. It also offers six discrete offset positions in the X-Y direction. Once aligned, the Targeting Stem is replaced with the Center or Offset Guides, and Guide Tubes for insertion of different sized instruments. See Figure 2.

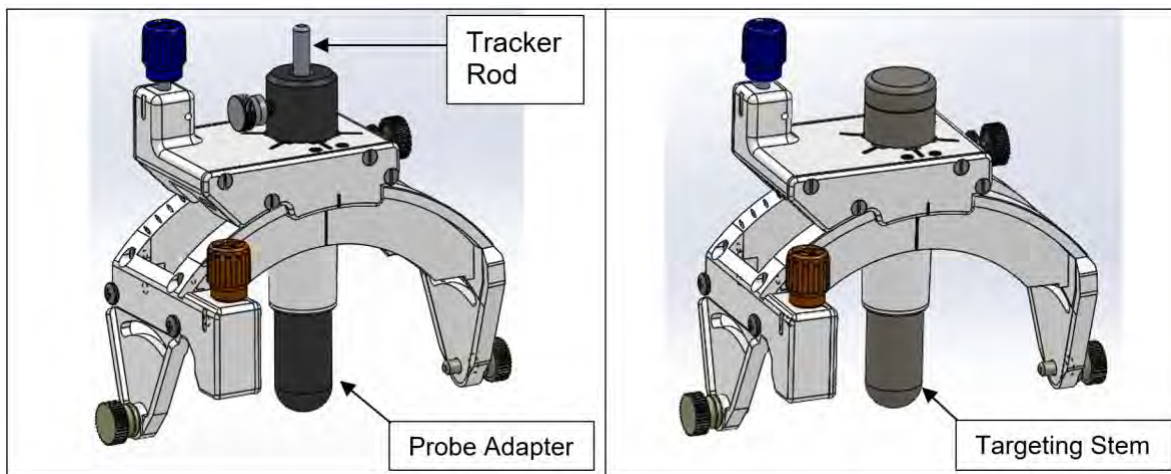
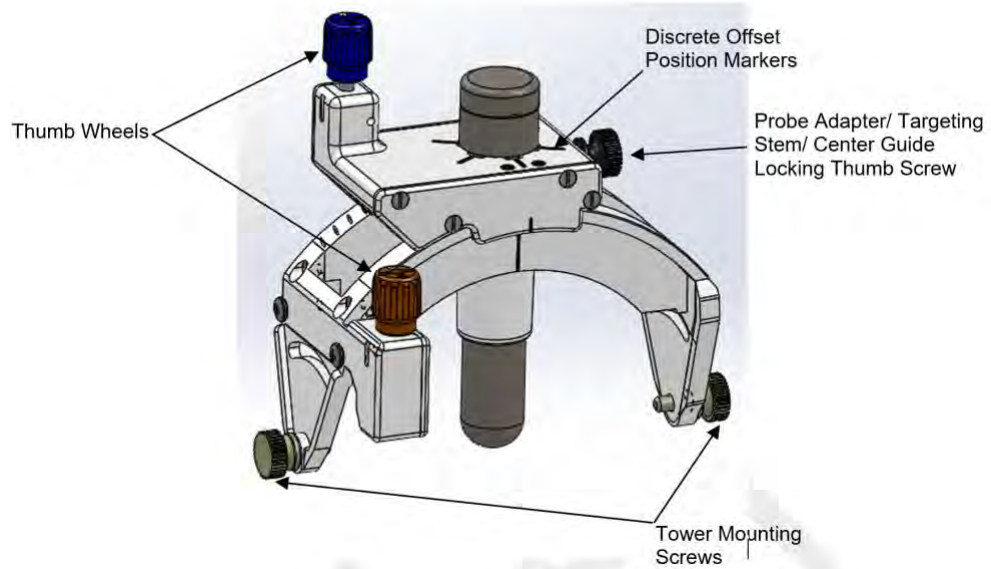


Figure 1: SMARTFrame® XG Tower with Probe Adapter (L) and Targeting Stem (R)



**Figure 2: SMARTFrame® XG Tower Components**

The adjustments can be made by directly turning the thumb wheels or by using the ClearPoint Neuro Thumb Wheel Extension Set. The Thumb Wheel Extension Set is an approximately 60 cm long mechanism that can be attached to the SMARTFrame® Array and utilized to rotate the thumb wheels while the patient is inside of the MR scanner bore.

---

## B. Using the MRI to find the Mount Point

1. The Patient's head shall be prepared just prior to surgery by either shaving the entire head and applying incise tape or by shaving the area that will be covered with the Marking Grids and the area around them.
2. The patient's head is positioned outside the scanner at the head end of the scanner.
3. Position and secure the patient in an appropriate head fixation frame to immobilize the patient's head and select an appropriate imaging coil(s) to achieve desired image quality and provide access to the procedure site.

---

**Caution: The patient's head must remain immobile throughout the procedure**

---

4. Install ClearPoint Neuro MR Neuro Procedure Drape following the Instructions for Use (IFU).



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**Caution:** Examine the SmartGrid packaging for any damage or leaks. verify there is no leakage (fluid) visible on the Tower, or packaging. Do not use any device if leakage is identified.

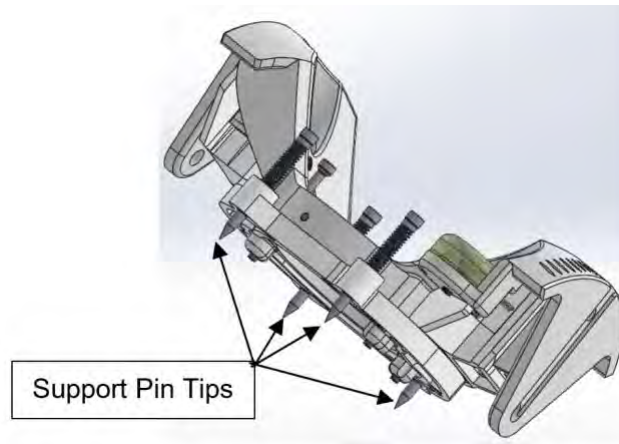
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5. Determine and mark the location for burr-hole following the SmartGrid® IFU and using the Mount Frames step in the software (see [Mount Frames Step – Mounting Frames Pg. 148](#)).
6. If identifying points on the scalp with an MRI Fiducial is desired, follow the SMARTFrame® MRI Fiducial IFU.
7. The Wharen Guide may also be used to mark the entry point. Follow the Wharen Guide IFU if that method is desired.
8. Once the entry point is identified and the SmartGrid is removed, attach the SmartFrame Array Scalp Mount Base to the skull
9. **See Section [C. Mounting the Scalp Mount Base](#) for detailed instructions on securing the Base to the patient’s skull.**
10. Once the Base(s) are securely attached to the skull, the SMARTFrame® Array Tower is ready to be mounted.
11. **See Section [D. Attaching the SmartFrame Array Tower to the Base](#) for detailed instructions on attaching the SmartFrame Array Tower to the Base. Once the Tower is attached, proceed to Section [E. MRI Workflow](#).**

---

## C. Mounting the Scalp Mount Base

1. This section provides instructions for securing the Scalp Mount Base to the patient’s skull. This procedure may be performed in either the Operating Room or in the MRI Scanner. The method of securing the Scalp Mount Base to the skull is identical in either workflow.
2. The Scalp Mount Base has three inner screws and four support pins. The support pins have sharp tips. **See Figure 3.** They have small protective tubes covering them. Remove the tubes before proceeding.

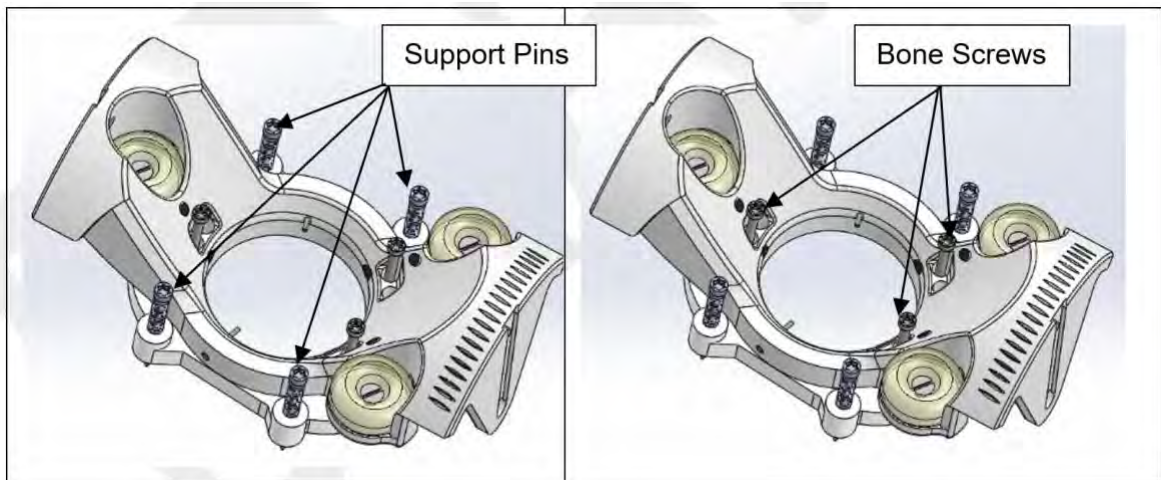


**Figure 3: SmartFrame Array Scalp Mount Base**

**NOTE:** The Scalp Mount Base is intended for use with a maximum scalp thickness of 9 mm using the pre-loaded screws, and 11 mm using the Long Rescue Screws. Usage with thicker scalps may prevent the Scalp Mount Base from being stabilized properly.

**NOTE:** In order to use the Scalp Mount Base for scalp thicknesses from 9 to 11 mm, ensure that only Long Rescue Screws are used.

3. The Scalp Mount Base has four adjustable height support pins and three self-tapping bone screws. **See Figure 4.**



**Figure 4: SmartFrame Array Scalp Mount Base**

**NOTE:** In the event a replacement screw is required for securing the Scalp-Mount Base, additional Scalp Mount Screws (3) can be provided.

**NOTE:** A second set of screw mounting holes are located in the Scalp-Mount Base adjacent to the preloaded screw holes.

---

**Caution:** Only ClearPoint Neuro-provided screws should be used for securing the Scalp-Mount Base.

---

4. Secure the three bone screws into the skull. While screwing in the bone screws, check the security of the Base repeatedly, and check that the Base can lift off the scalp as it becomes secure in the skull.
5. Once the bone screws are secure in the skull, deploy the four support pins by screwing them down. The support pins will penetrate the scalp and will stop against the skull. The further they are deployed down, the more the Base will rise away from the scalp.
6. Repeatedly check the security of the Base during this operation. Once the Base is secure, proceed to the next step. Check that the Scalp-Mount Base is secure and does not move. Confirm by feeling and observing for any movement while attempting to impart a rocking motion to the Scalp Mount Base after mounting to the skull.
7. Once the Base(s) are securely attached to the skull, the SMARTFrame® Array Tower is ready to be mounted. Secure the three bone screws into the skull. While screwing in the bone screws, check the security of the Base repeatedly, and check that the Base can lift off the scalp as it becomes secure in the skull.

---

## D. Attaching the SmartFrame Array Tower to the Base

This section provides instructions for attaching the SmartFrame Array Tower to the Base. This part of the procedure may be performed in the Operating Room or in the MRI Scanner. The method of attaching the Tower to the Base is identical for either workflow.

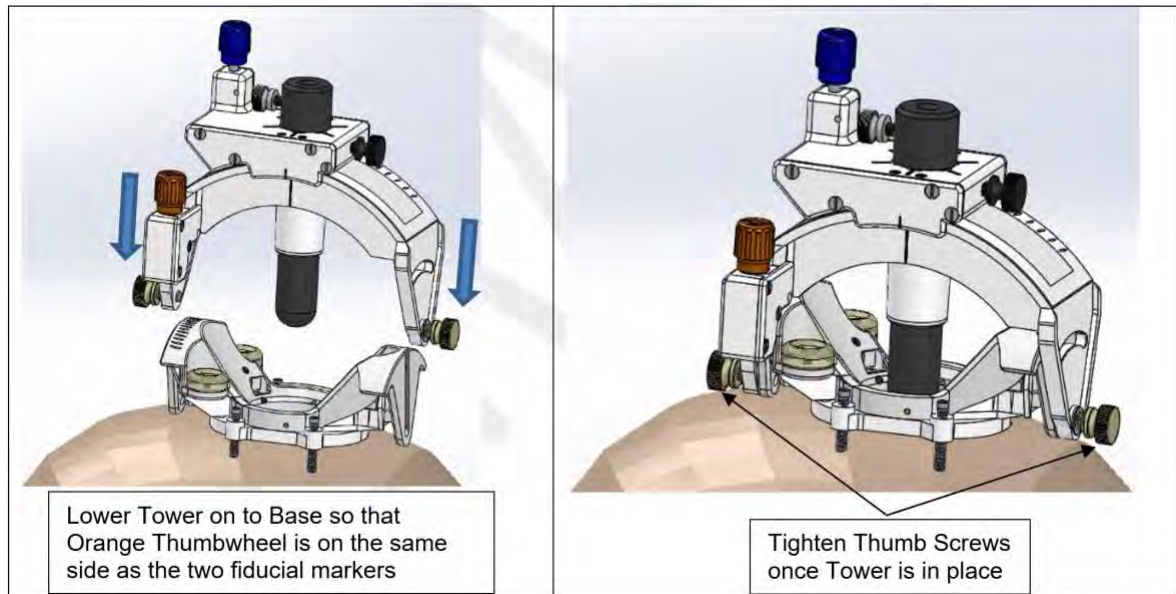
1. Orient the Tower, relative to the Base, by placing the thumb wheels of the Tower toward the two fiducial marker side of the Base. Mount the Tower onto the Base by first loosening then grasping the Tower Mounting Screws.
2. Grasp the Tower by the top rectangular gear housing. Align each screw with the mating grooves on the Base. **See Figure 5.** Slide the Tower into place and ensure screws seat into the mounting holes on the Base. Tighten the Tower side thumb screw to secure the Probe Adapter inside the tower.

---

**Caution:**     **Avoid applying pressure to the Tower Thumb Wheels while grasping the Tower.**

---

3. Tighten the two Tower Mounting Screws and confirm that the screws are completely seated with the Base.



**Figure 5: Assembling the Tower to the Base**

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**Warning:** *The stability of the SMARTFrame® Array should be checked prior to continuing. An unstable attachment of the SMARTFrame® Array may result in an incorrect alignment to target or movement of the inserted device.*

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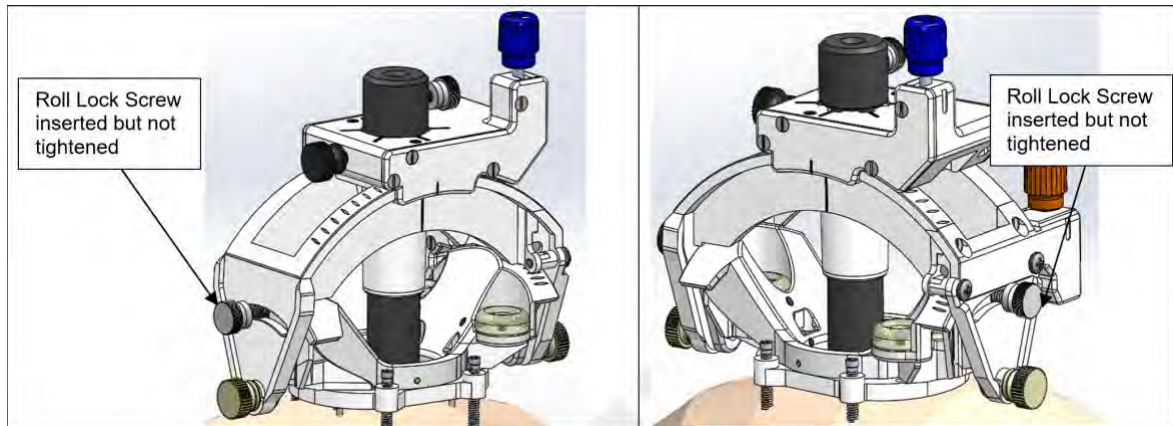


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**Caution:**     **The Tower will mount securely to the Base. If the Tower moves relative to the Base, it is not mounted correctly.**

---

4. Remove the two Roll Lock Screws w/washer from the SMARTFrame® Array package to pre-mount in SMARTFrame® Array. Screw in partially to the appropriate location on the SMARTFrame® Array. **See Figure 6.** Ensure the Roll Lock Screws w/washer are not tight. These screws will be tightened later in the procedure.



**Figure 6: Roll lock screws inserted into SmartFrame, but not tightened**

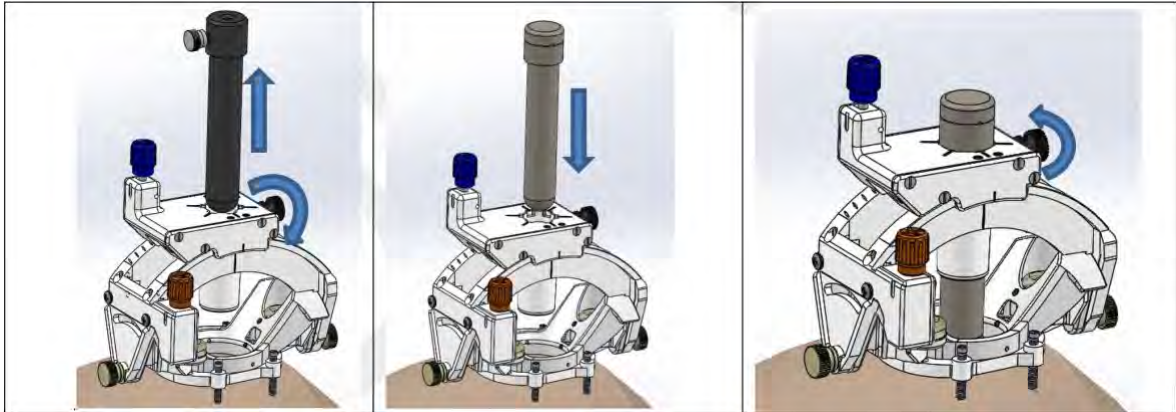
---

**Caution:** The Roll Lock Screw w/washer should not be tightened until final positioning is selected. If the Roll Lock Screw w/washer is tight during roll adjustments, adjustments will be affected and may result in inappropriate alignment.

---

## E. MRI Workflow

1. The Tower is provided with an SNS Probe Adapter assembled to it. Remove the Probe Adapter and replace it with the Targeting Stem, provided in the packaging tray.
2. Remove the Probe Adapter from the Tower by loosening the Tower side thumb screw and pulling the Probe Adapter out of the Tower. **See Figure 7 (L).**
3. Remove the Targeting Stem from the packaging tray and insert it into the SmartFrame Array Tower until it bottoms out. Then, tighten the Tower side thumb screw to secure the Targeting Stem in the Tower. **See Figure 7 (M) and (R).**



**Figure 7: Removing the Probe Adapter (L), Inserting the Targeting Stem (M), and Locking the Targeting Stem in the Tower (R)**

---

**Warning:** *The stability of the SMARTFrame® Array should be checked prior to continuing. An unstable attachment of the SMARTFrame® Array may result in an incorrect alignment to target or movement of the inserted device.*

---

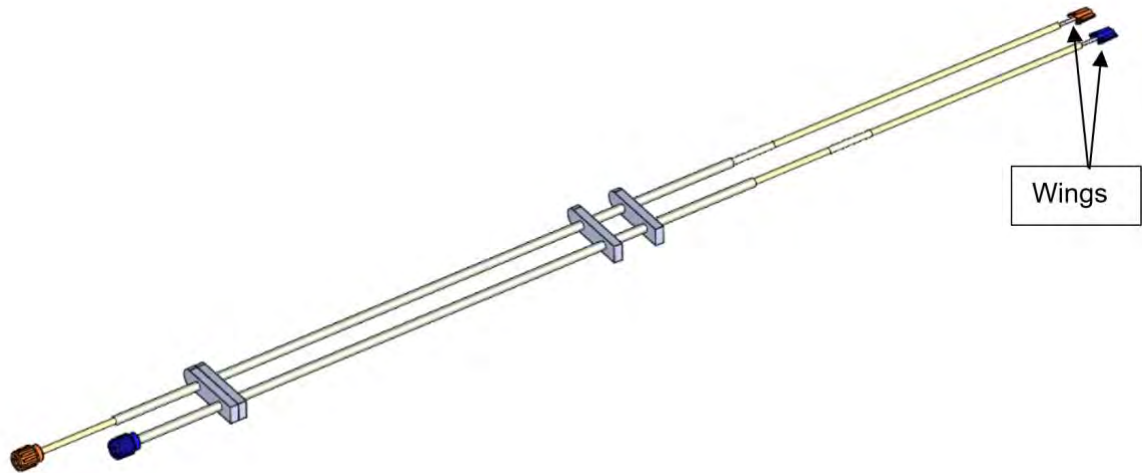
**Caution:** The Tower will mount securely to the Base. If the Tower moves relative to the Base, it is not mounted correctly.

**Caution:** The Roll Lock Screws should not be tightened until final positioning is selected. If the Roll Lock Screws are tight during roll adjustments, adjustments will be affected and may result in inappropriate alignment.

---

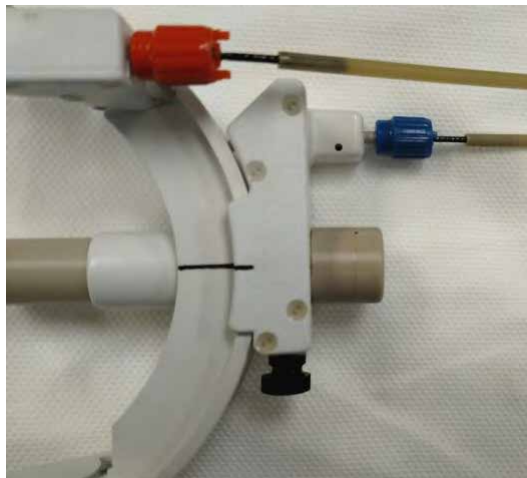
## F. Attachment of the Thumb Wheel Extension Set

1. Remove the Thumb Wheel Extension Set from its sterile barrier package. See Figure 8.



**Figure 8: Thumbwheel Extension**

2. Attach the distal ends (wings) of the Thumb Wheel Extension Set to the matching colored thumb wheels on the SMARTFrame® Array. **See Figure 9.**
3. The Thumb Wheel Extension Set thumb wheels may require rotation to properly orient the wings into the SMARTFrame® Array thumb wheels. The wings should slide to the bottom of the thumb wheels and seat into place. **See Figure 9.**

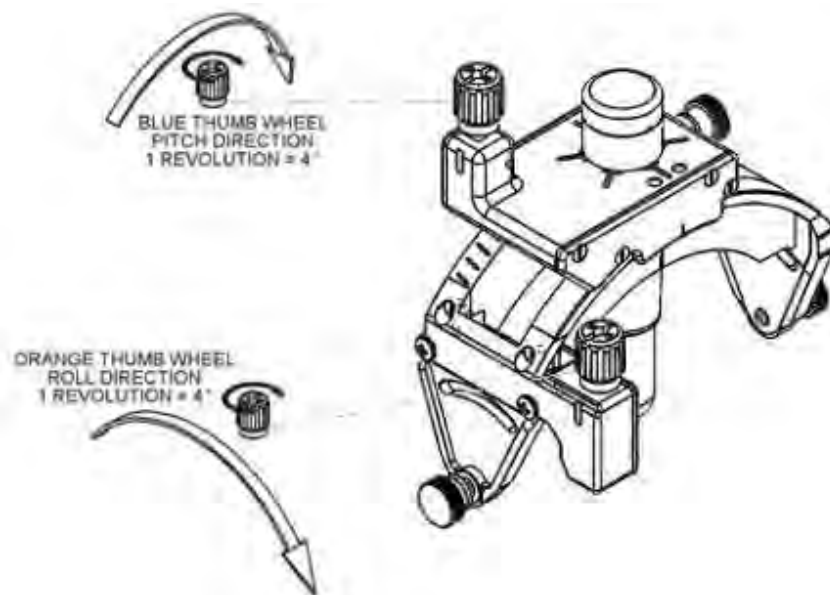


**Figure 9: Thumbwheel Extension wings seated into SmartFrame Thumbwheels**

## G. Set Trajectory

**NOTE:** A clear understanding of and training of the ClearPoint Array Workstation is required to complete the following steps.

1. Move the patient's head to the isocenter of the MR scanner and complete the Frame Workflow (see [Frame Workflow Pg. 151](#)) up until the Make Adjustment step (see [Make Adjustment Step – Setting the Frame Angulation Pg. 175](#)) in the software.
2. The thumb wheels are color coded: Pitch is Blue, Roll is Orange. **See Figure 10.**



**Figure 10: SmartFrame Array Thumbwheel Directions**

3. Using the **Frame Adjustments** display on the ClearPoint Array Workstation, adjust the SMARTFrame® Array to the desired trajectory (see [Prescribing Frame Adjustments Pg. 175](#)). The SMARTFrame® Array trajectory is adjusted by turning the two thumb wheels directly on the Tower or by turning the associated thumb wheels on the Thumb Wheel Extension Set.
4. If a change in the entry point is desired, an offset channel may be selected in the Make Adjustment step prior to making angular adjustments (see [Changing the Guide Channel Pg. 176](#)). Selecting an offset channel will result in the angular adjustments being made such that the selected channel is aligned with the desired target point.



5. **If the desired Entry Point is too far to reach with any of the offset channels, the Scalp Mount Base may be removed and remounted such that the Entry Point can be reached. To remove the Base from the skull, unscrew the standoff pins first, and then unscrew the titanium bone screws. Lift the Base away from the scalp, reposition it, and repeat the Base mounting procedure.**
6. The angular adjustments are made with the Pitch and Roll thumb wheels which will orient the SMARTFrame® Array to align the selected channel with the desired target point.

**NOTE:** The Tower movements are limited to +/- 26 degrees in roll and +/- 33 degrees in pitch directions.

**NOTE:** The center-to-center distance of the offset guide positions is 3.0 mm.

---

**Caution:** **Once the trajectory is established, ensure the Thumb Wheels do not move.**

**Caution:** **Care should be taken not to induce side loading of the Tower Assembly during device insertion.**

---

7. The Targeting Stem of the SMARTFrame® Array is now aligned with the Target based on the selected channel.
8. Verify that the selected channel aligns to the target, or select any of the other channel positions to set the desired trajectory (see [Selecting a Guide Channel Pg. 76](#) for detailed instructions on selecting a channel).

---

**Caution:** **Any subsequent angular adjustments that use the Pitch and Roll thumb wheels will require using the Make Adjustment Step (see [Make Adjustment Step – Setting the Frame Angulation Pg. 175](#)) in the software.**

---

9. Once the trajectory is set and the desired channel is selected, use the roll locking screws to secure the position of the Frame in the pitch-roll direction.

---

**Caution:** **Avoid bumping or applying excessive loads to the Tower or Cannula after the trajectory is set.**

---

10. Once the roll lock screws are secured, remove the Targeting Stem by unlocking the tower side thumb screw and pulling the stem out. **See Figure 11.**

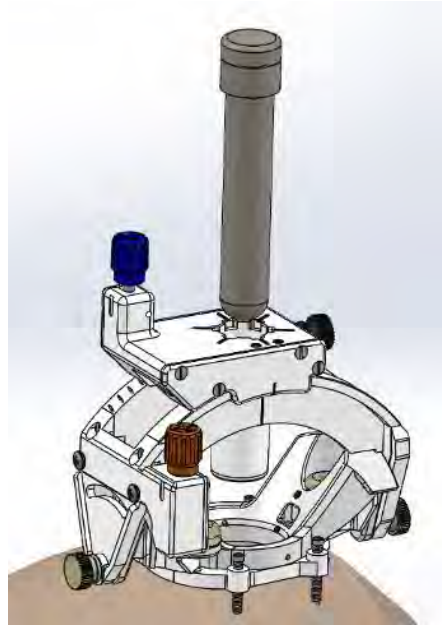


Figure 11: Removing the Targeting Strem from the SmartFrame tower

11. If the access hole was already created, proceed directly to Section [I. Using the Insertion Guides](#). Otherwise, continue to Section [H. Using the Drill Guides in the MRI](#) (not required if the Access Hole was already created).

---

## H. Using the Drill Guides in the MRI (not required if the Access Hole was already created)

**NOTE:** Drill Guides are not required if the access hole has already been created. **If the access hole has already been created, proceed directly to Section [I. Using the Insertion Guides](#).**

---

**Caution:** The Drill Guides and Drill Guide Tubes are compatible with ClearPoint Neuro's MRI Drill Bit Kits (NGS-DB-01 and NGS-SDB-01). If using non-ClearPoint-Neuro drill bits, verify MR safety and fit with the Drill Guides prior to use.

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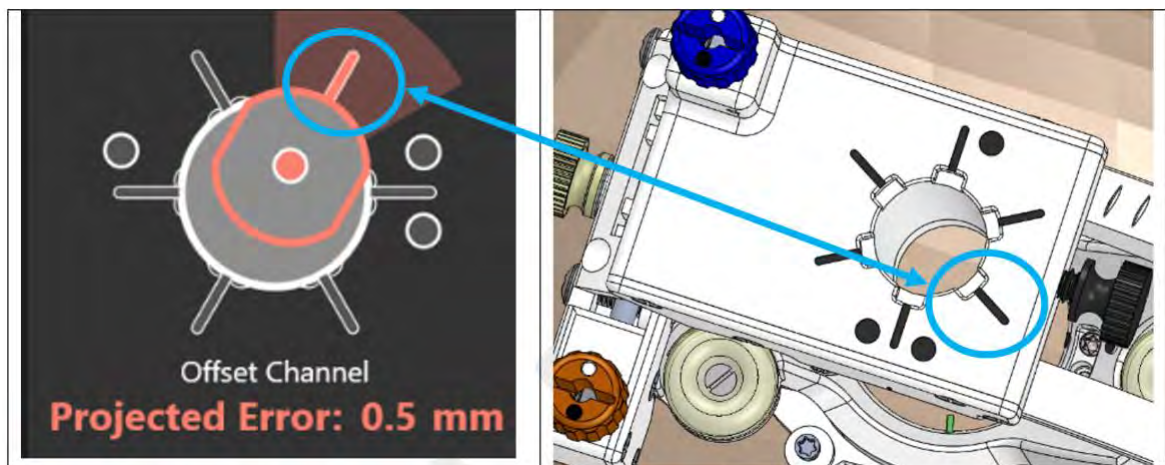
1. **Fully tighten both roll locking screws.** If the center channel position was selected during final alignment, use the Center Drill Guide. **See Figure 12 (L).** If one of the outer channels was selected during final alignment, use the

offset drill guide. **See Figure 12 (R)**. The offset guide has a tab with a white line on the side near the offset hole.



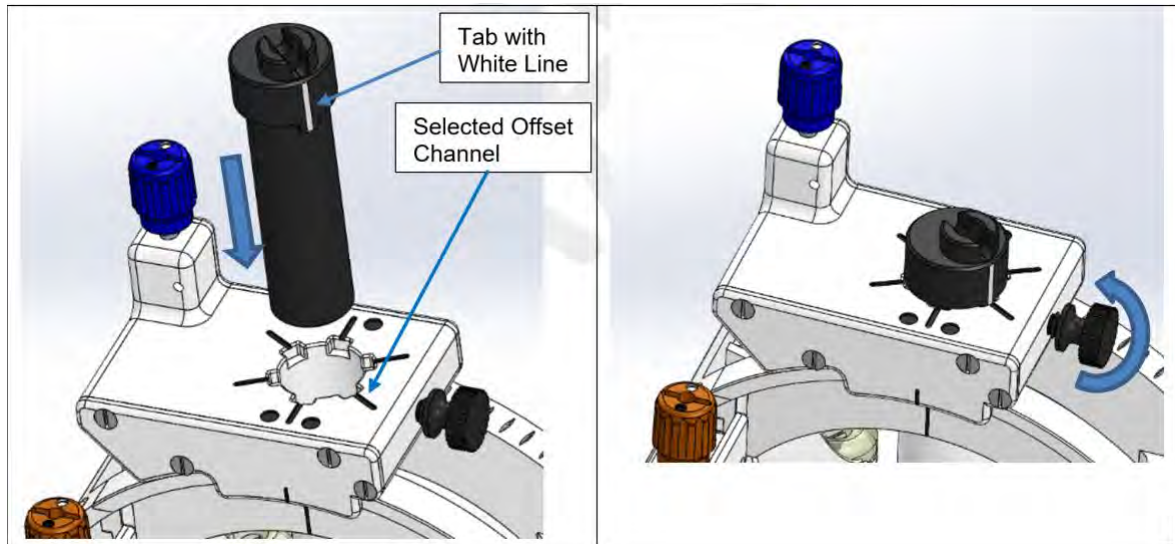
**Figure 12: Center Drill Guide (L) and Offset Drill Guide (R)**

2. If the CENTER GUIDE was selected, insert it into the SmartFrame tower until it fully stops. Then, tighten the tower side Thumbscrew. Skip to Step 6.
3. If the OFFSET GUIDE was selected, line up the side tab with the channel position line on the tower. The orientation dots on the tower match those shown in the Software. **See Figure 13 and Figure 14.**



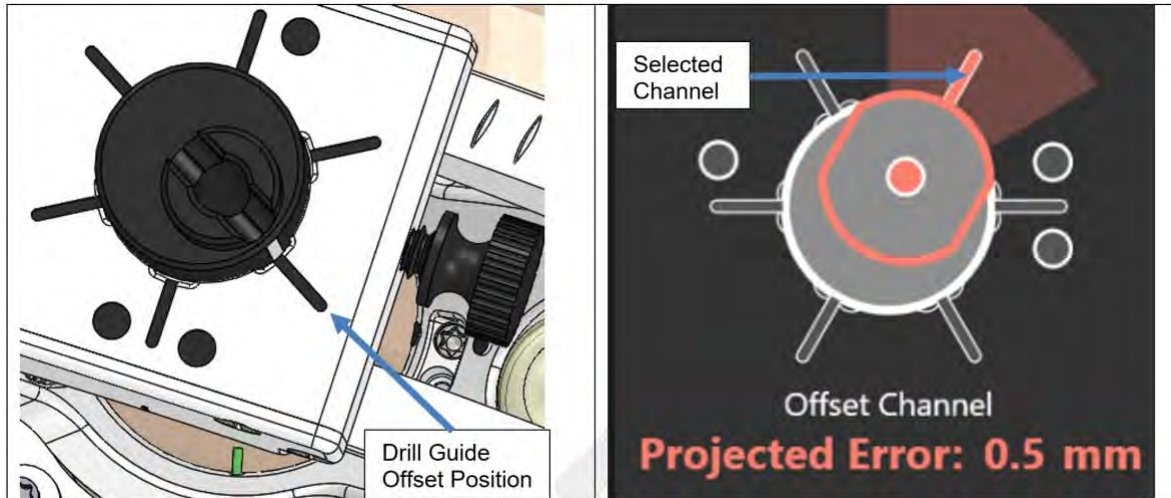
**Figure 13: Offset channel selected in the software (L), and the corresponding position on the SmartFrame tower (R)**

4. Insert the Guide so that the tab clicks into the slot that corresponds to the selected channel. **See Figure 14.**



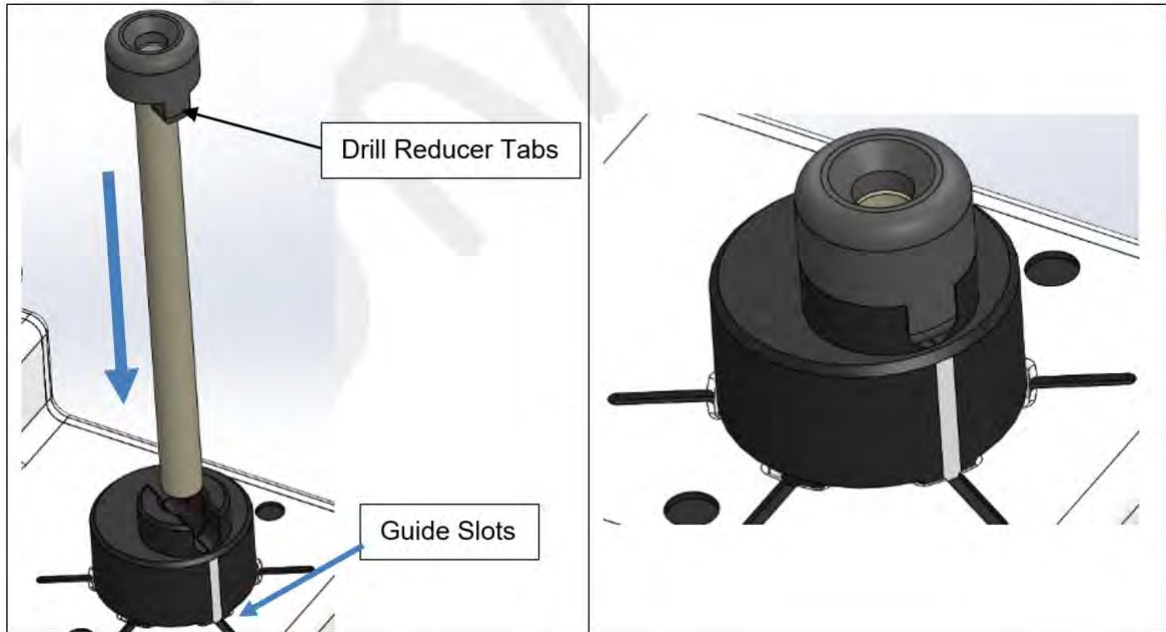
**Figure 14: Offset Drill Guide Inserted into the desired offset position on the SmartFrame tower**

5. Verify that the Drill Guide is positioned in the channel selected in the ClearPoint Array software. The orientation dots on the tower match up with those shown on the software. **See Figure 15.** If it is not, loosen the tower side thumbscrew, raise the Drill Guide and rotate it until the tab (white line) aligns with the correct position. Then, repeat Step 4.



**Figure 15: Offset Drill Guide inserted into the position that was selected in the ClearPoint Array Software**

6. Once the Drill Guide is locked in place, a drill bit may be used to create the access hole.
7. The Drill Guide will accept a ClearPoint Neuro 4.5-mm Drill Bit. If using the ClearPoint Neuro 3.4-mm Drill Bit is desired, then the Drill Reducer Tube must be inserted into the Drill Guide prior to drilling. If using a 4.5-mm Drill Bit, proceed with drilling and skip to Step 10. If using the 3.4-mm Drill Bit see Step 8.
8. Remove the Drill Reducer Tube from the tray and insert it into the Drill Guide such that the tabs on the Reducer Tube line up with the slots on the Drill Guide.
9. Insert the Reducer Tube until it stops and the Reducer Tubes are fully engaged in the Drill Guide slots. This operation is the same whether using the Center Drill Guide or Offset Drill Guide. **See Figure 16.**



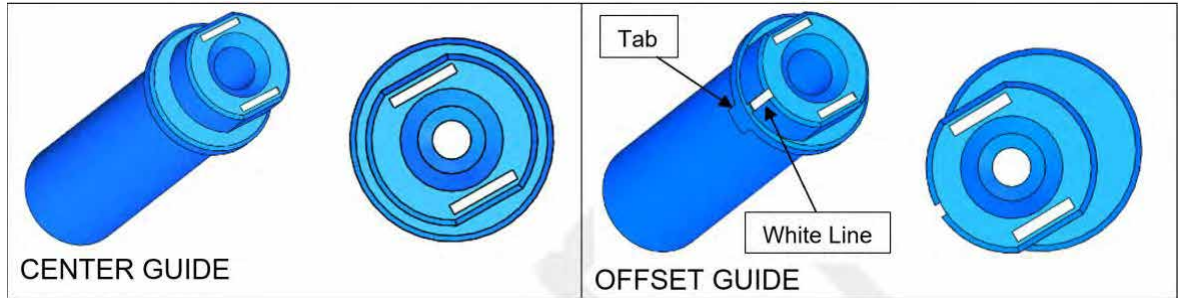
**Figure 16: Drill Reducer inserted into Drill Guide**

10. Once the access hole is drilled, remove the Drill Guide by loosening the Tower Side Thumbscrew and pulling the Drill Guide out.

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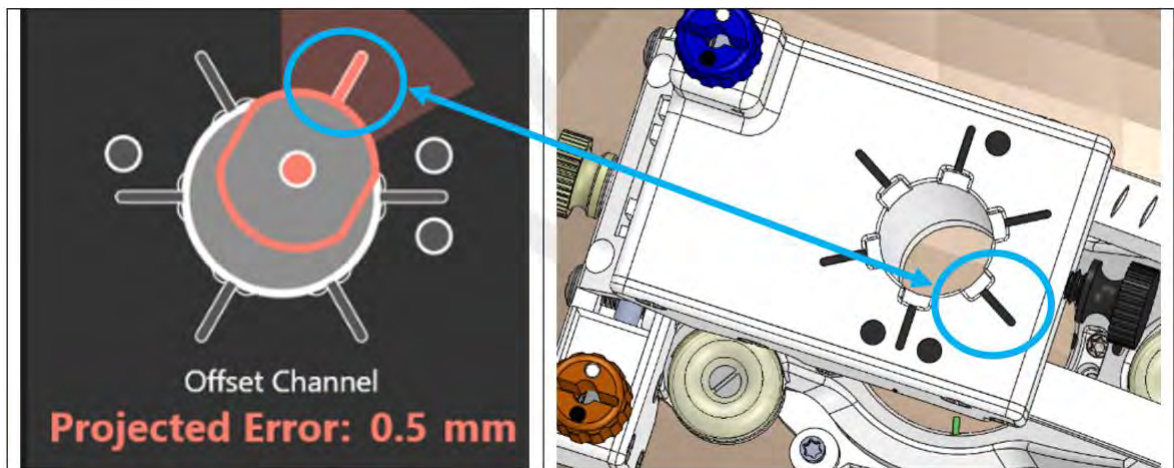
## I. Using the Insertion Guides

1. Once the trajectory and desired channel position is confirmed, use either CENTER Insertion Guide or the OFFSET Insertion Guide to prepare for device insertion. The insertion guides are blue with “racetrack” features on the top. **See Figure 17.**
2. Use the CENTER Insertion Guide if the center channel was selected. Use the OFFSET Insertion Guide if one of the outer channels was selected. The Offset Guide has a White Line and a Tab on its side, and the hole is offset from the center. **See Figure 17.**



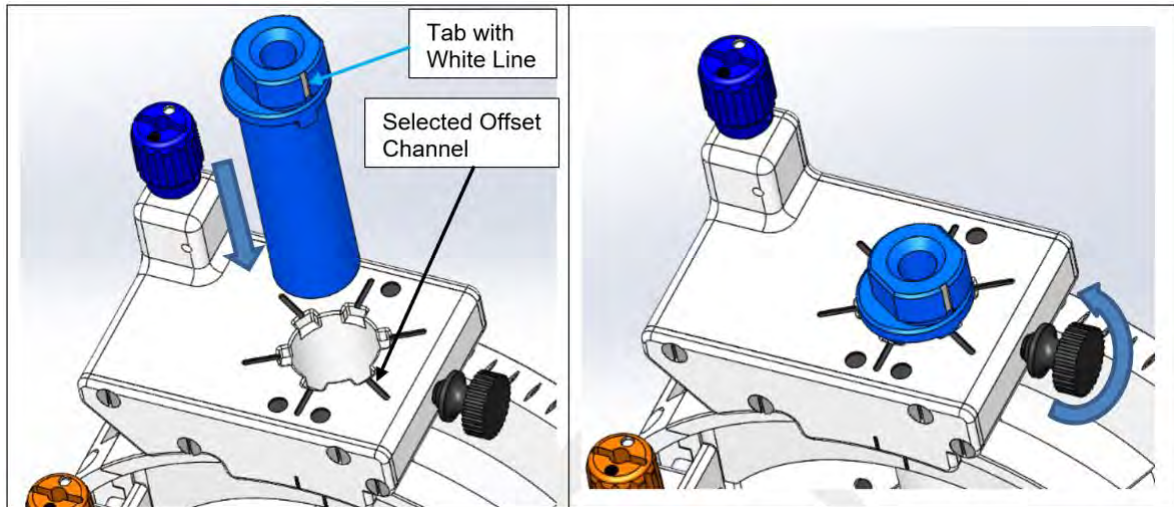
**Figure 17: Center Guide (L) and Offset Guide (R)**

3. If using the CENTER Insertion Guide, insert the Guide into the Tower until it stops. Then, tighten the Tower Side Thumbscrew to lock it into place.
4. If using the OFFSET Guide, line up the side tab with the channel position line on the tower. The orientation dots on the tower match those shown in the Software. **See Figure 18.**



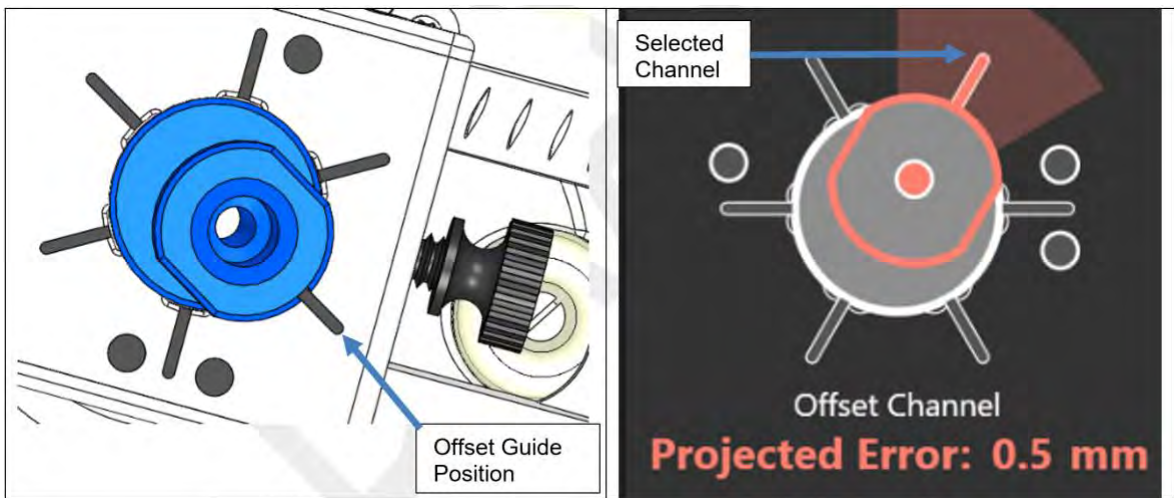
**Figure 18: Offset channel selected in the software (L), and the corresponding position on the SmartFrame tower (R)**

5. Insert the Guide so that the tab clicks into the slot that corresponds to the selected channel. **See Figure 19.**



**Figure 19: Offset Drill Guide Inserted into the desired offset position on the SmartFrame tower**

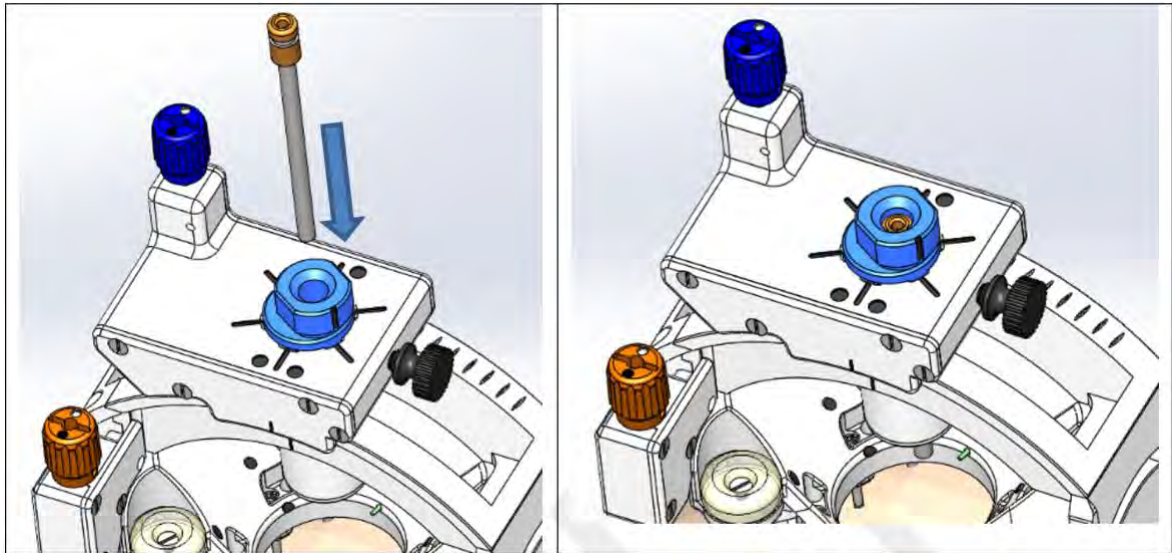
6. Verify that the Offset Guide is positioned in the channel selected in the ClearPoint Array software. The orientation dots on the tower match up with those shown on the software. **See Figure 20.** If it is not, loosen the tower side thumbscrew, raise the Offset Guide and rotate it until the tab (white line) aligns with the correct position. Then, repeat Step 6.



**Figure 20: Offset Guide inserted into the position that was selected in the ClearPoint Array Software**



7. Once the position of the Insertion Guide is verified to be in the selected channel, verify the size of the device to be inserted.
8. If using the Guide Tube is desired, then insert the Guide Tube into the Insertion Guide's inner diameter such that the top of the Guide is below the top surface of the Insertion Guide. **See Figure 21.**



**Figure 21: Guide Tube inserted into Insertion Guide**

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## Device Insertion Options

The remaining instructions are divided into procedural paths. Follow the instructions applicable to the device being used with the SMARTFrame®.

### Procedures utilizing the ClearPoint Neuro Stylet and Peel-Away Sheath

Procedures that require a Peel-Away Sheath with Stylet to confirm position by scanning and/or to create a path to the target. See [Section K. Procedures utilizing the ClearPoint Neuro Stylet and Peel-Away Sheath.](#)

## Direct Insertion Procedures

Procedures that do not need placement of the Peel-Away Sheath with Stylet. See Section [M. Direct Insertion Procedures](#).

---

**Caution:** The compatibility of neurological instruments and devices should be evaluated before use with the ClearPoint SMARTFrame® Array System and SMARTFrame® Accessory Kits.

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## J. Navigational Accuracy

The device can provide a trajectory for placement of tools to targets within the brain. The radial (X-Y) plane trajectory error is < 2.0 mm at a 99% confidence interval. The angular error is < 0.9° at a 99% confidence interval.

---

**Caution:** The Z-plane or depth accuracy can only be verified by the user during real-time MR intraoperative imaging during placement of the instrument.

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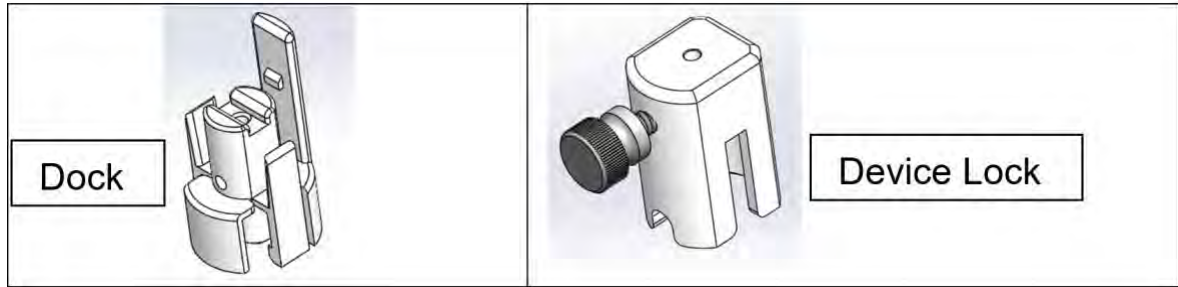
## K. Procedures utilizing the ClearPoint Neuro Stylet and Peel-Away Sheath

The following section covers procedures where the Peel-Away Sheath with Stylet is used to create a path to the target and/or scanning to confirm target acquisition.

**NOTE:** Identify the Stylet and the Lancet in the tray before removing them. The Stylet has a bull-nose tip, whereas the Lancet has a pointed tip. Make sure the Stylet is removed first. **NOTE:** The Lancet is not available in Europe

### Peel-Away Sheath/Stylet Preparation and Insertion

1. Remove the Dock (**see Figure 22L**) and Device Lock (**see Figure 22R**) from the SMARTFrame® Array package.



**Figure 22: Dock (L) and Device Lock (R)**

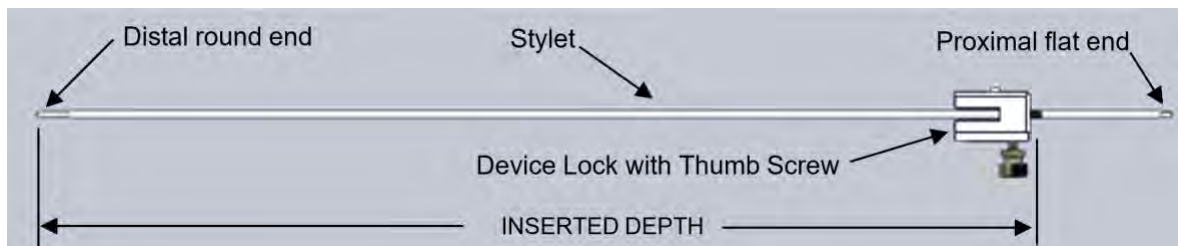
**NOTE:** Use the Dock and Lock provided in the SmartFrame Array Kit with corresponding Stylet.

2. Remove the Peel-Away Sheath, the Stylet, and the Depth Stop from the Accessories package. Confirm that the Stylet has a bull nose tip.

**NOTE:** The distal end of the Stylet has a bull nose tip and the proximal end of the Stylet is denoted with a blue marking.

**NOTE:** When Sheath/Stylet insertion is used only for trajectory and position conformation, it may be desired to stop short of the target, leaving undisturbed tissue for the final device. Subtract this distance “offset” from the depth value provided in the Prepare and Insert Step (see [Prepare and Insert Step – Preparing and Inserting the Device Pg. 185](#)) in the software.

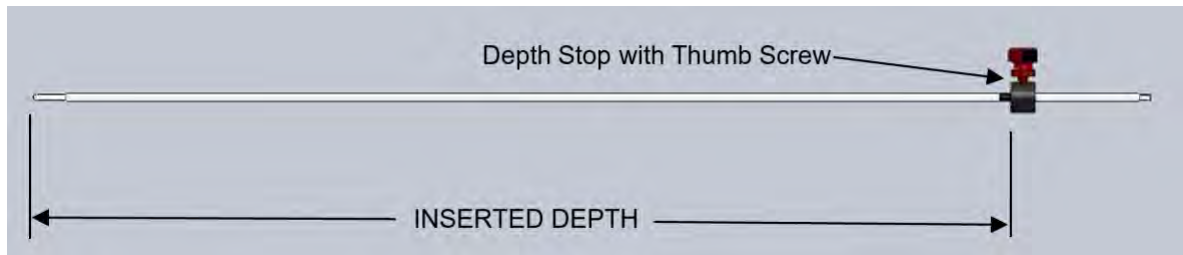
3. Mark the target’s depth on the Stylet using the Ruler and Marking Pen with the depth value shown in the Prepare and Insert Step (see [Prepare and Insert Step – Preparing and Inserting the Device Pg. 185](#)) in the software.
4. Position the Device Lock on the depth mark on the Stylet and tighten the thumb screw. The inserted depth of the Stylet is defined by the proximal side face of the Device Lock to the distal tip of the Stylet. Confirm the length using the Ruler. **See Figure 23.**



**Figure 23: Device Lock attached to the Stylet**

5. When utilizing the Depth Stop, the inserted depth of the Stylet is defined by the distal side face of the Depth Stop to the distal tip of the Stylet. See

**Figure 24.** Slide the stylet into Device Lock until the Depth Stop rests on top of Device Lock. Then tighten Device Lock. Confirm the length using the Ruler.



**Figure 24: Stylet with Depth Stop attached to the Insertion Depth**

6. A Lancet has been provided as an alternate method to create an insertion point in the dura and/or pia. If using the Lancet proceed to step 7. If not using the Lancet, proceed to step 14.
7. Remove the Lancet from the Accessory package.

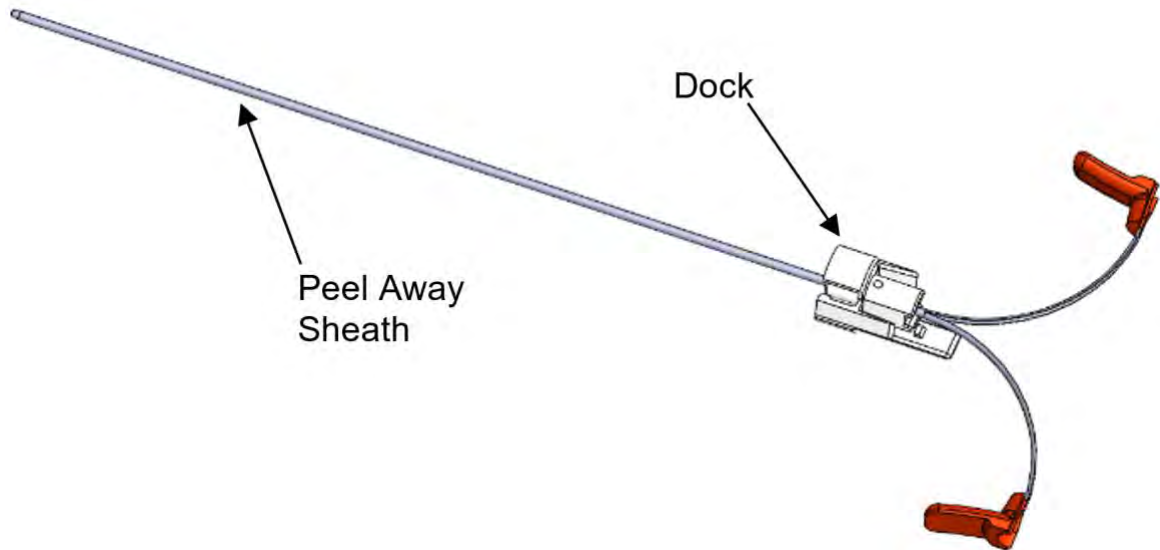
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**Caution:** The distal end of the Lancet has a pointed tip and the flat proximal end is denoted with a green marking. Handle the Lancet near the proximal end. Avoid contacting the distal end.

---

8. Place a depth stop on the Lancet such that the distance from the distal point of the Lancet to the depth stop is approximately 1 inch greater than the distance from the inside of the dura or pia to the top of the ATF tower.
9. Remove one of the Peel Away Sheaths from the Accessory Kit.
10. Separate the hub and peel away approximately 4 inches of the Sheath.
11. Insert the Lancet into the Peel Away Sheath until the pointed end protrudes approximately three (3) to five (5) millimeters. A slight resistance should be felt. If the Depth Stop interferes with the Sheath before the Lancet can be full inserted, peel the sheath away further until the Lancet can be fully inserted.
12. By holding the exposed proximal end of the Lancet, insert the Lancet through the Targeting Cannula and through the burr hole until it contacts the dura or pia. Gently push on the Lancet until the dura and/or pia is pierced.
13. After piercing the dura and/or pia, withdraw the Lancet-Sheath Assembly from the Targeting Cannula.

14. Remove a new Peel Away Sheath from the Accessory Kit and separate the hub and peel away approximately one (1) inch of the Sheath. Place the Peel Away Sheath through the Dock.
15. Insert the peeled Sheath sides into the grooves of the Dock. **See Figure 25.**



**Figure 25: Peel Away Sheath Inserted into Dock**

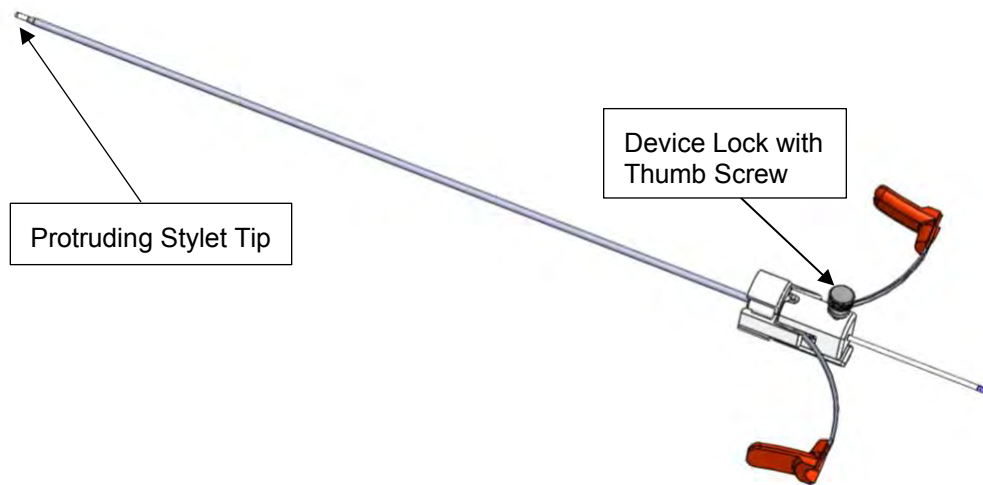
16. Insert the Stylet into the Sheath. The distal end of the Stylet should protrude between one (1) and five (5) mm from the end of the Sheath. If it is not protruding, pull on both ends of the hub, peel the Sheath until the distal end of the Stylet protrudes between one (1) and five (5) mm. A slight resistance should be felt.
17. Insert the Stylet into Dock until Device Lock mates and snap locks to Dock. **See Figure 26.**

**NOTE:** While peeling the Sheath to expose the Stylet tip, the force should be steady and the peel smooth.

---

**Caution:** Do not over tighten the thumb screw on Device Lock or Depth Stop to avoid damaging the Stylet.

---



**Figure 26: Dock and Lock Assembled to Stylet and Sheath**

---

**Caution:** DO NOT insert Peel Away Sheath and Stylet through the SmartFrame without the Guide Tube in place. Without the Guide Tube in place, the Sheath-Stylet may not follow the desired trajectory when inserted into the brain.

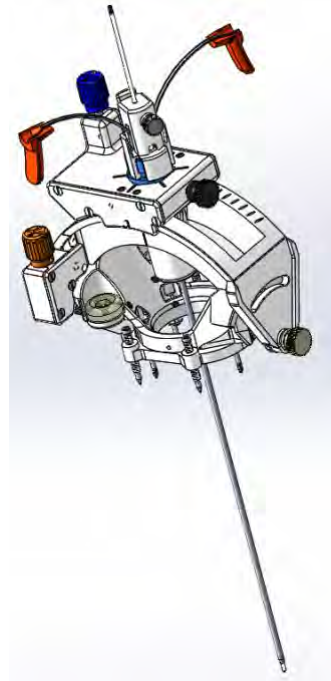
---

18. Insert the tip of the Stylet Assembly into the proximal end of the Insertion Guide.
19. During insertion, view the advancement of the Stylet Assembly using the ClearPoint® Array software as appropriate (see [Monitoring Insertion Progress Pg. 187](#)). This insertion and visualization may be performed in 1/3 increments. **See Figure 27 for Stylet Assembly inserted into SMARTFrame® Array.**

---

**Caution:** Use the Prepare and Insert step (see [Prepare and Insert Step – Preparing and Inserting the Device Pg. 185](#)) on the ClearPoint® Array Workstation to confirm the acceptability of the trajectory.

---



**Figure 27: Stylet-Sheath-Dock-and-Lock Assembly Inserted into the SmartFrame Array**

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**Warning:** Do not adjust SMARTFrame® Array while Stylet Assembly is inserted. If the trajectory needs to be modified, completely remove the Stylet Assembly prior to adjusting the SMARTFrame® Array.

---



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**Caution:** Do not over tighten thumb screw on Device Lock or Depth Stop to avoid damaging the Stylet.

---

**NOTE:** Devices that do not require the Peel-Away Sheath for insertion shall skip the steps below and go to [Section M. Direct Insertion Procedures](#).

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## L. Device Insertion through Peel-Away Sheath

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**Caution:** If device to be inserted is not to be imaged, position patient's head outside the scanner at the head end of the scanner.

---

1. Loosen the Device Lock thumb screw, and remove the Stylet from the Peel-Away Sheath.
2. Use the Depth Stop or marking pen to mark the inserted depth on the device.

---

**Caution:** Do not over tighten the Depth Stop which could damage the device.

---

3. Insert the device into the top of the Peel-Away Sheath through the Device Lock.

---

**Caution:** Do not advance a device through the Targeting Cannula or Peel-Away Sheath that is not resistant to compression and that may change in length with insertion. This may prevent accurate placement relative to the desired target.

---

4. Advance the device until the Depth Stop or the mark rests on top of the Device Lock.
5. Tighten the thumb screw of the Device Lock onto the device.

---

**Caution:** Do not over tighten Device Lock which could damage the device.

---

6. If appropriate, remove the Peel-Away Sheath by simultaneously pulling both ends of the split red hub until the Sheath is entirely removed in two pieces.

---

## M. Direct Insertion Procedures

**NOTE:** This section covers preparation and direct insertion of devices that are 1.7 mm to 3.1 mm in diameter.

### Preparation and Insertion

NOTE: Verify the device that is to be inserted corresponds to the size of the Guide Tube provided in the SmartFrame Array Kit or the SmartFrame Array Guide Tube Kit in the table below. The Guide Tubes in the SmartFrame Array Guide Tube Kit are labeled with the device size that fits into the Guide Tube.



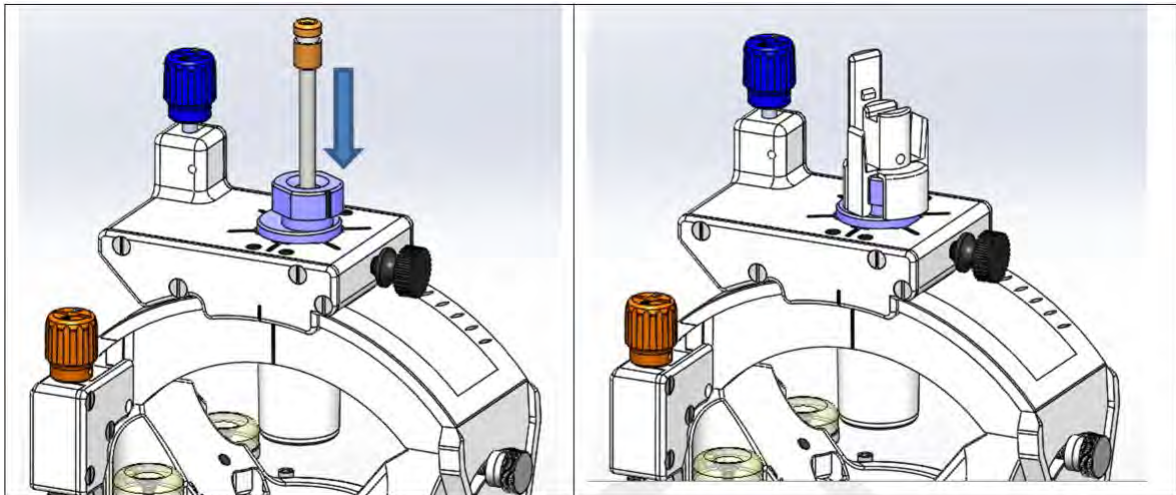
Device Diameters		SmartFrame Array Kit
0.067 in	1.7 mm	NGS-SFA-GT-01
0.083 in	2.1 mm	NGS-SFA-01-2
0.098 in	2.5 mm	NGS-SFA-GT-01
0.122 in	3.1 mm	NGS-SFA-GT-01

---

**Caution:** If using a device size that is not listed, always verify the fit with the SmartFrame Array Kit's Dock, Lock, and Guide Tube prior to using the device with the SmartFrame Array

---

1. If device to be inserted is not to be imaged, position the patient's head outside the scanner at the head end of the scanner.
2. If the Stylet Assy was used previously, remove the Stylet Assembly including the Peel-Away Sheath, Device Lock, Stylet, and Depth Stop (if used) from SMARTFrame® Array and separate these components from one another.
3. If necessary, insert the Guide Tube into the Insertion Guide. **See Figure 28.**
4. Insert and snap lock the Dock in place. **See Figure 28.**



**Figure 28: Inserting Guide Tube (L) and Attaching Dock (R) to the SmartFrame Tower**

5. Insert the device into the top of the Device Lock.
6. Set the inserted depth on the device from the distal end of the device to the top of the Device Lock using the Ruler. Lock the device to the Device Lock with the thumb screw. Verify the measured inserted depth. Alternately, the bottom of the Depth Stop can be located at the appropriate position and locked into place on the device with the thumb screw prior to inserting the device into the Device Lock. **See Figure 23 and Figure 24** for similar placement of the Depth Stop or Device Lock onto Stylet.

---

**Caution:**      **Do not over tighten the thumb screw which could damage the device.**

---

7. Insert the device into the Dock through the Guide Tube until the Device Lock snaps and locks onto the Dock.

---

**Caution:**      **Do not advance a device through the Guide Tube that is not resistant to compression and that may change in length with insertion. This may prevent accurate placement relative to the desired target.**

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8. Perform the procedure as intended.

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## Appendix 2 – Head Fixation Frame, Imaging Coil(s) & MRI Scanner Requirements Specifications

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### Head Fixation Requirements Specification

A suitable head fixation frame for use with the ClearPoint Array™ System must:

1. Be intended for rigid cranial stabilization / immobilization during neurosurgical procedures
2. Be MRI Conditional.
3. Have at least 3 fixation points (skull pins).
4. When fixated, withstand any movement of the patients head when an approximate 5 lb. load is applied in any direction.

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### Imaging Coil(s) Requirements Specification

Suitable Imaging Coil(s) for use with the ClearPoint Array™ System must meet the requirements stated in this section.

#### Dimensional / Mechanical

The imaging coil(s) should not obstruct access to the area of interest (typically the top of patient's skull) or impede the adjustment of the SMARTFrame Array™ once it has been placed on the patient's skull. Refer to [SMARTFrame Array™ MRI-Guided Trajectory Frame. Instructions for Use](#) for specifications.

#### Image Quality

- Signal to Noise Ratio (SNR):  
The SNR at the center of an imaging coil(s) used for a ClearPoint Array™ Procedure should be at a minimum of 80% of the system

installed “Birdcage” Head Coil as measured by using the appropriate NEMA standards: MS - 1-2008, MS 6-2008 and MS 9-2008.










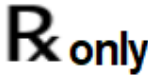
- Uniformity / Homogeneity:  
Image uniformity / homogeneity should not vary more than 30% throughout the FOV as measured by using the appropriate NEMA standards: MS 3-2008, MS 6-2008 and MS 9-2008.

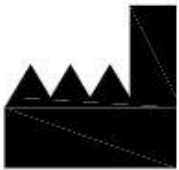
## MRI Scanner Requirements Specification

A suitable MRI scanner for use with the ClearPoint Array™ System must meet the following requirements:

Field Strength	1.5T or 3T
Bore Diameter	60 cm or greater

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SYMBOL	DEFINITION	SYMBOL	DEFINITION
	Consult instructions for use		Keep away from sunlight
	Catalogue number		Keep dry
	Batch code		Manufacturer
	MR Unsafe		Date of Manufacture
	Do not use if the product sterilization barrier or its packaging is compromised		Prescription Device



**Manufactured by:**

ClearPoint Neuro, Inc.  
6349 Paseo Del Lago  
Carlsbad, CA 92011  
USA  
949-900-6833