ClearPoint 3.0
User's Guide

CE 0123

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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Contents

System Overview

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: When the ClearPoint System is used for MRI-guided procedures, it can be used in conjunction with MR Conditional, but not MR Unsafe deep brain stimulation (DBS) Leads or DBS Leads for which MR Testing was not performed. Placement of MR Conditional DBS electrodes using the ClearPoint 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 an MRI-guided procedure with the ClearPoint 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 System intended for MRI-guided procedure usage, 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 will demonstrate that it can position the tip of the ClearPoint Stylet within 1.5mm of the target. Upon completion of the System installation the surgeon will be required to acknowledge the System installation meets the User's requirements. During installation of the ClearPoint System intended for CT-guided procedure usage, an image acquisition test will be performed.**

The user should also consult the Navigational Accuracy section of this User's Guide to assess if the accuracy of the system is suitable for their needs.

NOTE: **The ClearPoint Workstation is intended for use with Windows 10 or Windows 11 Operating Systems.**

NOTE: **Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.**

NOTE: **The lifetime of the software, where the software is expected to remain safe and effective for use, is defined as 10 years after being placed on the market or until an end-of-support date is identified and communicated.**

Indications for Use / Intended Purpose

The ClearPoint System is intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures within an operating room environment and in conjunction with MR and/or CT imaging. During planning, the system is intended to provide functionality for the automatic identification, labeling, visualization, and quantification of segmentable brain structures from a set of loaded MR images. The ClearPoint 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) (asleep or awake) lead placement. When used in an MRI environment, 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 to assess if the accuracy of the system is suitable for your needs.

NOTE: **The ClearPoint 3.0 Software is an integral part of the ClearPoint System intended for stereotactic guidance.**

Contraindications

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

The following limitations exist when using the ClearPoint Maestro Brain Model to automatically label, visualize, and quantify anatomical structures visible in MRI images loaded onto the ClearPoint Workstation:

- Is not intended to be used with scan sequences other than T1-weighted MPRAGE equivalent sequences. The model is not trained on any other intensity values.
- Is not intended to be used for the diagnosis or treatment of any specific disease.
- Is not intended to be used with MRI data collected from patients under 2 years of age.

- Is not intended to be used with MRI data collected with the use of contrast agents.

Contraindications for the use of the ClearPoint System and Accessory Kits are those contraindications generally accepted for intracranial surgery, including, but not limited to, severe, uncorrected bleeding disorder, local or systemic infection, and/or patient inability to tolerate general anesthesia.

Intended Users

The intended users are neurosurgeons who are trained in the use of these devices by ClearPoint Neuro personnel.

Intended Patient Population

Target populations for the ClearPoint System and Accessory Kits include any patient who is a candidate for precise and accurate stereotactic, image-guided placement of an intracranial device for therapeutic or diagnostic purposes.

Security

The ClearPoint Workstation is a physical, self-contained laptop computer used to display dynamically acquired images during a neurological procedure. The workstation receives images directly from an intraoperative scanner through a dedicated network port, using the Digital Imaging and Communications in Medicine (DICOM) Standard. The images received from the 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 intraoperative scanner used during the neurological procedure.

Once the ClearPoint Workstation has been deployed at your institution, it becomes an asset that must be managed by your organization. Please ensure that the following security instructions and suggestions are followed for secure workstation performance.

Security Features

The ClearPoint 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 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 detect if any software applications being installed originated from a potentially malicious source. It is also designed to block workstation users navigating to any detected 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 procedure data folders from malicious applications and threats, like ransomware. Only ClearPoint software programs approved for clinical usage have been configured as trusted applications on the workstation, thus, preventing all other software applications from accessing the procedure data folders.

- 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. Windows Defender is designed to protect against malicious software from automatically running upon connecting the device to the workstation.

- User controlled access. The workstation has been configured with a limited set of user accounts 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.

- Secure start-up. The workstation has been configured with several security features that are designed to prevent it from being tampered with on start-up using devices loaded with untrusted software. Using its internal Trusted Platform Module (TPM), the workstation has enabled Secure Boot to ensure that hard booting of the system can only be achieved using trusted manufacturer-specific software. Furthermore, the workstation has been configured to prevent hard booting from alternative media, such as external drives. Together, these configuration changes maintain system integrity by preventing untrusted software, such as malware, start and/or take control of the device.

- 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 application log file (see Using the Application Log Window Pg. 79).

    3) Application-level logging for startup / shutdown events, image transfers, image processing tasks and other application-related events is recorded in the ClearPoint application log file (see Using the Application Log Window Pg. 79).

Security Configurations

Once the ClearPoint Workstation is deployed in your healthcare institution's environment, it becomes an asset that must be managed by your institution's security policies. To prepare the ClearPoint Workstation for use in your healthcare institution's environment, please make note of the following security configurations:

- The ClearPoint software has been installed on the workstation, which runs the Windows 10 or Windows 11 Pro 64-bit operating system. No other operating systems may be installed on the workstation.

- The workstation must be connected to an intraoperative scanner using an isolated, private network connection. A static IP address must be assigned to the workstation so that the scanner may be configured to recognize the IP address of the workstation.

- Communication between the intraoperative scanner and the ClearPoint Workstation is achieved using the DICOM Standard. The 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. 30). Similarly, the workstation should be configured to specify its AE Title and TCP/IP port number (see Configuring the DICOM Connectivity Settings Pg. 53).

- The following DICOM services are supported by the ClearPoint Workstation (see DICOM Conformance Statement for additional details):

    - STORAGE-SCP: This service allows images to be transferred from the networked 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 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 scanner for purposes of verifying network connectivity and proper DICOM interoperability (see Configuring the DICOM Connectivity Settings Pg. 53).

- All DICOM communications are transmitted on a single network port (port number: 4467) configured for the workstation (see Configuring the DICOM Connectivity Settings Pg. 53). No other network ports are required for operation of the workstation.

- All wireless communication interfaces, such as Bluetooth, have been disabled on the workstation to prevent any unintended data transfer with other devices.

- 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 detected from gaining access to the workstation.

- Prior to deployment, the latest Windows Updates have been installed on the ClearPoint Workstation.

- The workstation's Windows Security settings and Device Guard have been configured to block all other software applications other than those produced by ClearPoint Neuro, Inc. If any other detected software applications are attempted to be run on the workstation, prominent notifications will prompt you prior to executing 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\ClearPoint*).

- The workstation has been configured with Secure Boot to ensure that it starts safely and securely by preventing unauthorized software from taking control of the system at boot-up.

- The BIOS (Basic Input/Output System) for the workstation has been configured to prevent hard booting from removable media and is also password protected to prevent unauthorized access.

- The Local Group Policy for the workstation has been modified to scan for any removable drives that are connected to the computer. Windows AutoPlay for removable devices has been disabled on the workstation to prevent unauthorized software applications from automatically executing malicious source code upon connecting an external device.

- A Screen Saver Lock for the workstation has been configured after 30 minutes of user inactivity. Once this time interval lapses, the user must re-enter their credentials to gain access to the workstation again.

- The workstation has been configured to retain all audit logs, so that information regarding user account access, security configuration settings changes, and data access can be analyzed periodically for malicious activity.

- 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 Workstation backs up 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. 60). 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
    - Any warning or 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. 73).

- Screen Captures. Any patient anonymized screen captures taken throughout the course of the intraoperative procedure (see Screen Capture Tool Pg. 112).

- 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 Window (see Using the Session List Window Pg. 70) 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, Inc. 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

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

To ensure secure operation of the ClearPoint 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, Inc.

- Do not access the internet from the workstation. Only connect the workstation to an isolated, private TCP/IP connection on your institution's network to receive images from the intraoperative 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.

- If you notice any issues regarding either network throttling and/or suspicious network traffic on the workstation, consider closely monitoring network data packet transfers and/or consider implementing custom firewall rules using Windows Defender Firewall to prevent unexpected data transfers.

- Restrict user access to the workstation to prevent unauthorized 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.

- Modify the Local Administrator password upon gaining custody of the workstation. The existing administrator password can be provided to you by the ClearPoint Neuro personnel responsible for configuring the workstation for use at your institution. Any new user passwords configured must meet the security complexity rules defined by the Windows Operating System.

- Do not run the ClearPoint software with a user account that has administrative or root-level privileges. Ensure that user accounts have been configured on the workstation which do not have full administrative privileges. Only use those user accounts when attempting to run the ClearPoint software.

- Consider implementing multi-factor authentication (MFA) for all user accounts configured on the workstation. Doing this may provide an extra layer of protection against unauthorized user access, by requiring two or more verification factors to gain access to the workstation.

- Do not modify any configuration settings related to the workstation's system Basic Input/Output System (BIOS). The system has been pre-configured with several important security settings related to system start-up and boot sequencing.

- 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 to resume workflow after 30 minutes of inactivity.

- Always install the latest security updates and patches for the workstation's operating system using encrypted removable media. When deploying these updates, ensure that all electronic files required are transferred to the workstation using encrypted removable media. Do not temporarily connect the workstation to the internet to deploy these types of updates.

- Consider using Windows Encrypted File System (EFS) to keep protected health information stored on the workstation safe. The workstation's data folder (*C:\ProgramData\ClearPoint\sessions*) stores images from the scanner that contains protected health information. It is suggested that this folder be encrypted using Windows BitLocker or other file system encryption software to prevent unauthorized access.

- Only ClearPoint Neuro personnel are allowed to install the latest updates and patches for the ClearPoint software. Any software updates will be installed on-site by an employee of ClearPoint Neuro using encrypted external media.

- Only ClearPoint Neuro personnel can update the language settings on the workstation's operating system. Incorrect language settings could render the system inoperable to the end user.

- Be cautious when connecting removable media, such as USB drives, to the workstation. You are responsible for the security of any removal media, such as USB drives, connected to the workstation.

- Pay attention to any notifications provided by Windows Security Center regarding the security of the workstation. Implement all recommended actions to ensure that the security of the workstation is not compromised in any way.

- Always use the ClearPoint Software's Session Window (see Using the Session List Window Pg. 70) to move surgical procedure data off the workstation. Exporting a surgical session in this manner ensures that all data is appropriately anonymized so that no protected health information is exported.

- Consider backing up all audit logs on a consistent basis, so that user account and security-level logging actions may be analyzed frequently. Only use encrypted external devices when storing audit logs from the workstation.

Procedure Overview

Below is a summary of steps for a ClearPoint System procedure. These steps are separated into seven sections: preoperative planning, patient preparation, mount point localization, trajectory planning / finalization, positioning the cannula, device insertion, and closing. The procedure is carried out using software and disposable kits manufactured by ClearPoint Neuro, in conjunction with an MR and/or CT scanner.

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 surgery, using previously acquired images of the patient.

Using the ClearPoint 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 Workstation is used to register the images together into a single frame of reference. The surgeon then plans any number of trajectory paths using the loaded images. Optionally, the surgeon may initiate automatic model-based segmentation of the patient's brain structures from non-contrast enhanced T1-weighted MR scans to assist with planning, using the ClearPoint Maestro Brain Model. After editing and reviewing all trajectory paths, the preoperative plan is saved for future use during surgery.

During surgery, the ClearPoint 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 adjustments to their planned trajectory paths using images acquired intraoperatively.

Patient Preparation

The patient is prepared for surgery, which may include local ("awake") or general ("asleep") 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 SMARTGrid is being used for mount point localization, the surgeon positions and secures the patient on the operative table with the desired head fixation system. During MRI-guided procedures, imaging coil(s)[1] are positioned to ensure optimal coverage of the patient's head. The patient then undergoes appropriate sterile preparation and draping. One or more sterile SMARTGrid marking grids are positioned over the approximate mount point[2]. Contrast agent may be administered. The patient is then positioned in the scanner and a whole-head volume scan is acquired.

If tracking techniques are used for mount point localization, the patient is positioned on the operative table using a head fixation system before undergoing sterile preparation and draping. The surgeon then registers the patient to the surgical navigation system (SNS) tracking field and completes mount point localization. Additional imaging equipment may then be utilized, or alternatively, the patient may be transported to a separate imaging suite where the remainder of the procedure may be carried out. If an additional imaging suite is utilized, further sterile preparation and surgical draping may be required.

Mount Point Localization

The surgeon may choose to localize frame mount points on the patient using an image-guided workflow with SMARTGrid marking grids, or alternatively may use an anatomic or SNS workflow.

If the SMARTGrid is used for mount point localization, the whole-head volumetric scan is transferred to the ClearPoint Workstation via DICOM network transfer[3]. Using the workstation software, the surgeon plans 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 user may also visualize and/or use quantitative measurements of the volume and shape of segmented brain structures automatically identified using the ClearPoint Maestro Brain Model integrated within the software. The surgeon confirms that the marking grids affixed to the patient have been identified correctly by the software. The row and column coordinates of the marking grid(s) shown in the image volume are then used to determine the location of

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1 Refer to manufacturer's Instructions for Use

2 Refer to document: IFU, SMARTGrid Planning Grid

3 Refer to document: ClearPoint 3.0 DICOM Conformance Statement

the frame mount point(s) on the patient. The top layer of each marking grid is removed, leaving a grid underlay attached to the patient. Each mount point is localized by matching the grid coordinates of the mount point displayed on the ClearPoint Workstation software to the physical grid on the patient. At this point, the surgeon may opt to verify the localization of each mount point using one or more ClearPoint Fiducial Markers[4]. To do this, a marker is placed at the identified mount point location on the patient and one or more additional image scans are acquired. When the workstation displays the new image scan(s), the position of the marker can be compared to the position of the planned mount point. This additional verification may be helpful in cases where the scalp is particularly subject to movement relative to the skull. The Marking Tool is then used to mark the location of the mount point(s), and then each corresponding grid underlay can be removed and discarded. Using the mark left by the Marking Tool, the surgeon may opt to create an access hole in the skull prior to mounting the trajectory frame or may wait until later in the procedure to do so. The surgeon then centers and affixes the SMARTFrame to patient[5]. Optionally, after frame mounting, the surgeon may pre-align the frame to the intended trajectory path using frame adjustment values provided by the ClearPoint Workstation software.

If a SNS workflow is used to localize one or more mount points on the patient, the surgeon initially registers the patient to the SNS tracking field. The SNS tracking hardware is then used to determine mount point locations on the patient. The surgeon may then create an access hole in the skull at the mount point prior to mounting the trajectory frame or may wait until later in the procedure. The surgeon then centers and affixes the SMARTFrame to the patient. After frame mounting, the surgeon may choose to pre-align each trajectory frame to an intended trajectory path using the SNS tracking hardware. After all trajectory frames have been mounted, the remainder of the procedure is carried out with image guidance.

Trajectory Planning and Finalization

Once all trajectory frames have been mounted onto the patient, optional Thumbwheel Extensions may be connected to the corresponding adjustment knobs on the frame. The patient is then scanned and a whole-head volumetric scan that includes all trajectory frames is transferred to the ClearPoint Workstation via DICOM network transfer[6]. Using the workstation software, the surgeon confirms that each of the trajectory frames has been identified correctly. Any trajectories created prior to frame mounting are reviewed, adjusted (due to possible dynamic anatomical changes such

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4 Refer to document: IFU, ClearPoint Fiducial

5 Refer to document: IFU, SMARTFrame XG Trajectory Frame, Hand Controller and Accessory Kit

6 Refer to document: ClearPoint 3.0 DICOM Conformance Statement

as brain shift) and reconfirmed. If desired, the surgeon may opt to load additional scans to provide better visualization necessary to create, modify or finalize planned trajectory paths. Additionally, the surgeon may use any segmented brain structure regions automatically identified using the ClearPoint Maestro Brain Model to further identify areas that may be targeted.

Positioning the Cannula

After the surgeon has finalized each of the planned trajectory paths into the brain, the ClearPoint Workstation is used to identify the location of the Targeting Cannula attached to each mounted frame. During MRI-guided procedures, the ClearPoint Workstation provides the user with scan plane parameters necessary to acquire images that the software can use to identify the position and orientation of the Targeting Cannula. During CT-guided procedures, a whole head scan of the patient including all attached frames and associated Targeting Cannulas is acquired. On transferring these images to the ClearPoint Workstation, the software identifies the position of the Targeting Cannula and displays the adjustments required to align it to the associated trajectory path.

The surgeon then adjusts the angulation of the Targeting Cannula based on the instructions provided by the ClearPoint Workstation. The angulation of the Targeting Cannula is adjusted by turning the pitch (blue) and roll (orange) thumb wheels by the specified amount. Adjusting the X (yellow) and Y (green) offset thumb wheels causes the Targeting Cannula to shift in the corresponding direction, keeping the cannula parallel to the original angulation. Image acquisitions and adjustments are repeated iteratively until the projected path of the Targeting Cannula is in a clinically acceptable location.

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 Hand Drill[7] in combination with the corresponding Drill Guide[8] that may be inserted into the trajectory frame after alignment, or using another appropriate drill of the surgeon's choice. After drilling of the access hole has been completed, the user may opt to acquire additional scans of the Targeting Cannula to verify its final position prior to insertion.

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[7] Refer to document: IFU, SMARTTwist Hand Drill

[8] Refer to document: IFU, SMARTFrame XG Trajectory Frame, Hand Controller and Accessory Kit

Device Insertion

The ClearPoint Workstation provides the option to monitor and evaluate the insertion of one or more devices into the brain. During MRI-guided procedures, device monitoring and evaluation is only possible with MRI Conditional devices[9], that can be safely imaged in the MR scanner. If inserting a device that is not safe to be imaged, the insertion is performed without any further imaging.

For each device to be inserted, the ClearPoint Workstation provides an insertion depth value that reflects the distance from the top of the SMARTFrame to the planned target. The surgeon measures and marks the distance on the device to be inserted and then sets the depth stop to that point. A SMARTFrame Guide Tube may be used to accommodate devices with different diameters (multiple gauge devices are supported). The surgeon then passes the device manually into the brain to allow for tactile feedback.

Scans may be acquired to verify that the device is following the planned trajectory and to check for hemorrhaging. During MRI-guided procedures, only MRI Conditional device may be imaged. Using scans taken during or on completion of the insertion, the ClearPoint Workstation provides measurements between the device tip position and the planned target to assist with anatomical evaluation of the inserted device.

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[10]. The insertion depth value is then measured on the device to be inserted and the Depth Stop is set. The device is then inserted into the brain through the Peel-Away Sheath. If required by the procedure, the Peel-Away Sheath will be removed and the inserted device will be secured to the skull, leaving the device in position. The procedure is then completed according to the device manufacturer's Instructions for Use[11].

Once the device is inserted to the target site, the procedure continues with the inserted device following the device manufacturer's Instructions for Use and is completed as described in Closing Pg. 28.

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[9] Refer to manufacturer's Instructions for Use

[10] Refer to document: IFU, SMARTFrame XG Trajectory Frame, Hand Controller and Accessory Kit

[11] Refer to manufacturer's Instructions for Use

Closing

Once the procedure is complete, each SMARTFrame is then removed from the patient. 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 1 – MRI Scanner & Equipment Requirements Specifications

Navigational Accuracy

The clinical benefit and performance characteristics of the ClearPoint System including the software lie in providing accurate medical information for stereotactic guidance based on the medical information obtained through the use of other technologies (i.e., CT/MR imaging and ClearPoint System components).

For MRI-Guided procedures, results from the company's bench accuracy tests demonstrated that the mean radial error across device configurations was below 1 mm, with the highest standard deviation being 0.33 mm and the highest 99% confidence limit being 0.87 mm. Angular errors were all below 1°, with the highest standard deviation being 0.17° and the highest 99% confidence limit being 0.46°. These observed values are all below the 2 mm and 2° accuracy limits for a stereotaxic device intended for general neurological use. The full positional and angular error specifications are summarized in the table below.

Performance Validation	**Positional Error (mm)**			**Angular Error (deg.)**		
ClearPoint System (MRI-Guidance)	Mean (X,Y,Z)	Std. Dev.	99% CI	Mean	Std. Dev.	99% CI
	0.14 0.16 0.56	0.37 0.54 0.57	0.44 0.60 0.10	0.32°	0.17°	0.46°

*CI = Confidence Interval

For CT-Guided procedures, results from the company's bench accuracy tests demonstrated that the mean Positional error, in terms of Euclidean distance from the intended target point to the tip of an inserted device, was below 1 mm. Trajectory angle errors were all below 1°. These observed values are all below the 2 mm and 2° accuracy limits for a stereotaxic device intended for general neurological use. The full positional and angular error specifications are summarized in the table below.

Performance Validation	**Positional Error (mm)**			**Angular Error (deg.)**		
	Mean	Std. Dev.	99% CI	Mean	Std. Dev.	99% CI

ClearPoint System (CT Guidance)	0.81	0.49	0.93	0.31°	0.23°	0.37°

*CI = Confidence Interval

System Components

1. The ClearPoint System makes use of reusable and disposable components.
    - Reusable components: Workstation laptop with ClearPoint software
    - Disposable components:
        - SMARTGrid Planning Grid
        - SMARTFrame or SMARTFrame XG Trajectory Frames
        - SMARTFrame Accessory Kit

2. Other items required:
    - head fixation frame – to immobilize patient head with respect to scanner table.
    - imaging coil(s) – for desired imaging quality during MRI-guided procedures.

3. Optional items:
    - SMARTFrame Hand Controller
    - SMARTFrame Thumb Wheel Extension Set
    - SMARTFrame Guide Tubes
    - SMARTFrame Scalp Mount Base
    - SMARTTwist Hand Drill
    - SMARTTip Drill Kit
    - MR Neuro Procedure Drape
    - ClearPoint Fiducial
    - Wharen Centering Guide
    - ClearPoint MR Monitor (MRI-Guided procedures only)

Interoperation with MRI Scanners

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

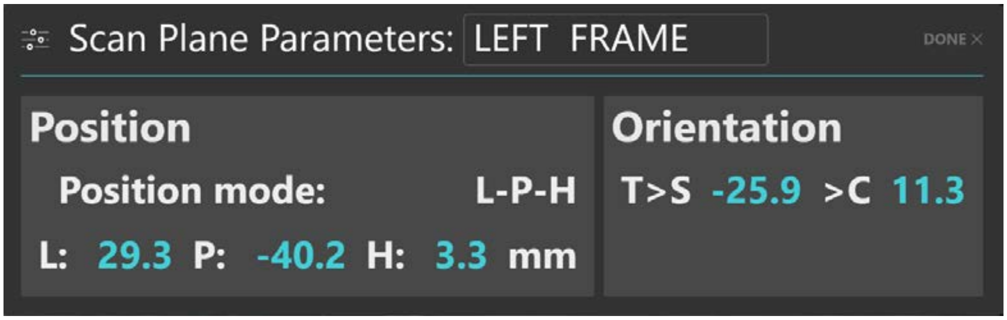
- IP Address: As configured by your site administrator
- AE Title: SVDBG
- Port: 4467

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 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 MRI Scanner Settings Pg. 55). 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 can show these parameters in a format that is appropriate for only the following three MR scanner manufacturers:

- GE Healthcare
- Philips
- Siemens Healthineers

The parameters shown by the ClearPoint 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 MRI Scanner Console is shown below.



Caution:	**For patient safety you must ensure that your MR Scanner is properly calibrated and maintained prior to using it with the ClearPoint 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 visible distortions.**

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. 288.
- Images used to detect the position of the targeting cannula. See Failed To Identify Cannula From Orthogonal Slab Pg. 302.
- Images used to identify the track of the inserted device. See Insertion Track Does Not Appear Straight Pg. 305.

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 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 Adjust (see Adjust Step Finalize the Cannula Position in an MRI Workflow Pg. 176) and Re-Adjust (see Re-Adjust Step Managing a Device Re-Insertion (MRI Workflow Only) Pg. 213) steps to ensure that the targeting cannula scans are moved as close as possible to the scanner iso-center 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 In-Plane Rotation. This provides precise control over the phase encoding direction for the scan.

The application provides an In-Plane Rotation value in the scan plane parameters prescribed in the Adjust (see Adjust Step Finalize the Cannula Position in an MRI Workflow Pg. 176), and Re-Adjust (see Re-Adjust Step Managing a Device Re-Insertion (MRI Workflow Only) Pg. 213) steps that must be entered on the Siemens MRI Scanner Console. This value is provided 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 cannula. An In-Plane Rotation value is also provided for scan plane parameters oriented along the axis of the device in the Insert step (see Insert Step Monitor and Assess Device Placement Pg. 198).

Important Notes for Using Philips Scanners

Ensuring Correct Slice Orientation

When inputting scan plane parameters into the Philips MRI Scanner Console interface, it is necessary to ensure that the slice orientation specified by the ClearPoint 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.

Entering Stack Angulation Values

In some instances, the Philips MRI Scanner Console interface may automatically adjust the stack angulation values entered in the “Offc/Ang” tab based on previously inputted values. This may result in a scan plane parameter prescription that does not match the desired scan plane required by the ClearPoint Workstation. To avoid instances where the Philips MRI Scanner Console automatically changes the stack angulation values entered based on previously inputted values, please ensure that each angulation is assigned a value of 0 degrees prior to entering the angulation values prescribed by the ClearPoint Workstation.

Important Notes for Using IMRIS Systems

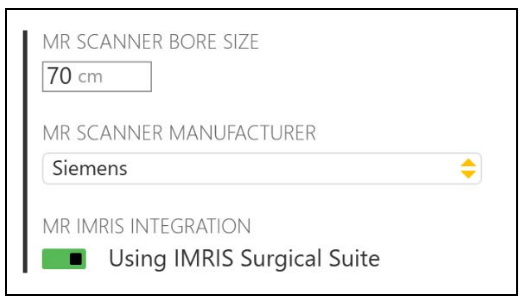
Entering a Table Position Value

When entering scan plane parameters prescribed in the Adjust (see Adjust Step Finalize the Cannula Position in an MRI Workflow Pg. 176) and/or Re-Adjust (see

Re-Adjust Step *Managing a Device* Re-Insertion Pg. 213) steps into 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.

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 Workstation should not be entered.**

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 User Settings Pg. 75).



Important Notes for Using GE Scanners

Changing the Slice Thickness / Slice Spacing Values

When the ClearPoint Workstation displays scan plane parameters to be entered on a GE MRI Scanner Console, it provides an option to modify the Slice Thickness and/or Slice Spacing of the prescribed scan. Modifying these values causes the **Scanning Range** values displayed in the prescribed scan plane parameters to change. Ensure that if any modifications are made to the Slice Thickness and/or Slice Spacing values on the ClearPoint Workstation, the resulting **Scanning Range** values are inputted correctly on the MRI Scanner Console.

Interoperation with CT Scanners

For CT-guided procedures, the ClearPoint Workstation should be positioned in the Operating Room in a location that does not compromise the sterile field, that allows connection to the intraoperative CT scanner, and that provides easy access for the surgeon and/or other team members as needed. A clear line of sight between the Workstation screen and surgeon for image/instruction visualization should be maintained as best as possible throughout the procedure.

Once positioned, the ClearPoint Workstation should be connected to the TCP/IP network upon which the intraoperative CT Scanner resides, so that the Workstation can receive images that are acquired during the neurological procedure. The CT Scanner Console must be configured to recognize the ClearPoint Workstation as a valid DICOM storage device using the following parameters:

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

Caution: **When operating the scanner during a CT-guided procedure, ensure that the scanner's Instructions for Use and operational guidelines are strictly followed. Failure to do so may result in improper device operation, compromised image quality or potential patient harm.**

Caution: **Ensure that the workstation does not obstruct pathways and that all cables are secured to prevent tripping hazards. Carefully inspect the workstation positioning prior to performing the surgical procedure to ensure that all safety-related considerations have been accounted for.**

Caution: **For patient safety ensure that your CT Scanner is properly calibrated and maintained prior to using it with the ClearPoint System. If the scanner has not been calibrated, an incorrect placement of the inserted device may result. Carefully inspect acquired images for suitable quality.**

Procedure Workflow

This section describes the procedure workflows that can be followed using the ClearPoint Workstation. The software application on the workstation offers three separate workflows that can be used to carry out aspects of an image-guided neurological procedure:

1. **Plan 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. **MRI Workflow**. An interventional MRI-guided procedure is carried out using disposable hardware kits produced by ClearPoint Neuro to guide the insertion of one or more devices into the brain.   The workflow is a series of steps that guide the user through the planning of a trajectory(s) to a brain target(s), the localization of head-affixed hardware, the alignment of the hardware to a desired trajectory(s), and the insertion of a device(s) through the hardware along the chosen trajectory using intraoperative MRI guidance.

3. **CT Workflow**. An interventional CT-guided procedure is carried out using disposable hardware kits produced by ClearPoint Neuro to guide the insertion of one or more devices into the brain. The workflow is a series of steps that guide the user through the planning of a trajectory(s) to a brain target(s), the localization of head-affixed hardware, the alignment of the hardware to a desired trajectory(s), and the insertion of a device(s) through the hardware along the chosen trajectory using intraoperative CT guidance.

Each workflow is presented as an ordered set of steps that can be performed to complete some or all of the neurological procedure.

Plan Workflow

The Plan Workflow allows you to create a presurgical plan using patient images that were acquired prior to surgery. This involves loading a set of preoperative images, selecting one of the scans to serve as the coordinate space for planning, optionally segmenting brain structures using a loaded MRI scan, and planning one or more trajectory paths into the brain. Presurgical plans created using the Plan Workflow can be used as a starting point for trajectory planning and selection during an intraoperative procedure.

There is one step within the Plan Workflow:

- **Pre-Op**. Plan one or more trajectory paths into the brain using a set of image scans that were acquired prior to the surgical procedure. The preoperative plan can be used to import trajectories into an image-guided neurological procedure. See Pre-Op Step Pg. 42 for details.

MRI Workflow

The MRI Workflow allows you to carry out an MR image-guided neuro-interventional procedure using disposable hardware kits produced by ClearPoint Neuro. This involves planning one or more trajectory paths into the brain, localizing mount point positions for one or more stereotactic frames on the patient's scalp, aligning the targeting cannula for each stereotactic frame to each of the desired planned trajectory paths and monitoring/assessing the insertion of one or more devices into the brain. If you created a preoperative plan using the Plan Workflow, any loaded scans, defined trajectory paths, and segmented brain regions from the plan will be translated into this workflow to serve as a starting point for intraoperative trajectory planning and review.

Note: Access to executing an MRI Workflow is controlled by the license installed on the workstation. The application will prevent you from carrying out an MRI Workflow unless the installed license provides feature-based access to this workflow. If you have not been granted a valid license to access the MRI Workflow and wish to carry out MR image-guided neuro-interventional procedures, please contact your clinical sales representative.

Steps within the MRI Workflow are ordered in the following manner:

- **Pre-Op**. Plan trajectory paths into the brain using a set of image scans that were acquired prior to the surgical procedure. The preoperative plan can be used to import trajectories into the MRI-guided neurological procedure. See Pre-Op Step Pg. 42 for details.

- **Entry**. Plan trajectory paths into the brain using a whole-head MRI scan with marking grids affixed, plus any additional scans that are necessary to review each trajectory path. This step may be skipped if frame mounting is carried out using a SNS. See Entry Step Pg. 43 for details.

- **Mount**. Identify the locations on the patient's scalp to mount stereotactic frames. This step may be skipped if frame mounting is carried out using a SNS. See Mount Step Pg. 44 for details.

- **Target**. Plan and/or review trajectory paths into the brain after the stereotactic frames have been mounted, using a whole-head MRI scan with frames affixed, plus any additional scans that are necessary to review each trajectory path. See Target Step Pg. 45 for details.

- **Align**. Perform coarse alignment of each frame's targeting cannula to the intended brain target using iterative alterations of the cannula's angulation until the targeting cannula(s) is in the same general plane as the desired trajectory(s), which allows for focused, time-efficient MRI scans of that plane only for all subsequent adjustments. See Align Step (MRI Workflow) Pg.46 for details.

- **Adjust**. Perform fine-tuned alignment of each frame's targeting cannula to the intended target point in the brain, by iteratively modifying the cannula's position and angulation using two independently acquired, focused MRI scans of the planes that contain the desired trajectory(s). See Adjust Step (MRI Workflow) Pg. 47 for details.

- **Insert**. Monitor, assess and evaluate placement of devices into the brain. See Insert Step Pg. 48 for details.

- **Re-Adjust**. Correct the position / orientation of a targeting cannula after a device placement has been deemed clinically unacceptable. See Re-Adjust Step Pg. 48 for details.

CT Workflow

The CT Workflow allows you to carry out a CT image-guided neuro-interventional procedure using disposable hardware kits produced by ClearPoint Neuro. This involves planning one or more trajectory paths into the brain, localizing mount point positions for one or more stereotactic frames on the patient's head, aligning the targeting cannula for each stereotactic frame to each of the desired planned trajectory paths and monitoring/assessing the insertion of one or more devices into the brain. If you created a preoperative plan using the Plan Workflow, any loaded scans, defined trajectory paths, and segmented brain regions from the plan will be translated into this workflow to serve as a starting point for intraoperative trajectory planning and review.

Note: Access to executing a CT Workflow is controlled by the license installed on the workstation. The application will prevent you from carrying out a CT Workflow unless the installed license provides feature-based access to this workflow. If you have not been granted a valid license to access the CT Workflow and wish to carry out CT image-guided neuro-interventional procedures, please contact your clinical sales representative.

Steps within the CT Workflow are ordered in the following manner:

- **Pre-Op**. Plan trajectory paths into the brain using a set of image scans that were acquired prior to the surgical procedure. The preoperative plan can be used to import trajectories into the CT-guided neurological procedure. See Pre-Op Step Pg. 42 for details.

- **Entry**. Plan trajectory paths into the brain using a whole-head CT scan with marking grids affixed. This step may be skipped if frame mounting is carried out using a SNS. See Entry Step Pg. 43 for details.

- **Mount**. Identify the locations on the patient's scalp to mount stereotactic frames. This step may be skipped if frame mounting is carried out using a SNS. See Mount Step Pg. 44 for details.

- **Target**. Plan and/or review trajectory paths into the brain after the stereotactic frames have been mounted using a whole-head CT scan with frames affixed. See Target Step Pg. 45 for details.

- **Adjust**. Perform alignment of each frame's targeting cannula to the intended target point in the brain, by iteratively modifying the cannula's position and angulation using a whole-head CT scan with frames affixed. See Adjust Step (CT Workflow) Pg. 47 for details.

- **Insert**. Monitor, assess and evaluate placement of devices into the brain. See Insert Step Pg. 48 for details.

Workflow Steps

Workflow steps provide tools necessary to perform a set of discrete, focused activities that are required to move forward in the selected workflow. Steps may provide access to optional tasks that are needed in some cases but not others. This section describes the complete set of steps that are provided by the software application.

Pre-Op Step

The Pre-Op step allows you to create a presurgical plan using patient images that were acquired prior to surgery. In this step, you may load a set of preoperative images, select one of the scans to serve as the coordinate space for planning, initiate automatic segmentation of brain structures on a loaded MRI scan, plan one or more trajectory paths into the brain, and save the preoperative plan for future usage. Preoperative images that were acquired in different frames of reference can be fused together and displayed in a single coordinate space to provide additional information for trajectory planning.

The following optional tasks are provided by the Pre-Op step:

- **Fusion**. Spatially register one or more image series acquired in different frames of reference for purposes of preoperative planning. See Fusion Task *Fusing Images* Pg. 219 for details.

- **Compare**. Perform visual comparison of any two image series loaded onto the workstation for purposes of preoperative planning. See Compare Task *Comparing Images* Pg. 232 for details.

- **AC-PC**. Review and edit anatomical landmarks needed to define and use anatomical coordinates. See ACPC Task *Reviewing Landmarks* Pg. 228 for details.

- **Preview Frame**. Visualize one or more frame(s) positioned on the patient prior to mounting using preoperative images. See Preview Frame Task Visualizing Frames Prior to Mounting Pg. 254 for details.

- **Maestro**. Perform fully automated segmentation of brain structures from non-contrast enhanced T1-weighted MR scans using the ClearPoint Maestro Brain Model. See Maestro Task Segmenting Brain Structures Pg. 264 for details.

Once you continue with the intraoperative portion of the workflow, any trajectories, anatomical landmarks, and/or segmented brain structures from this step are imported into the spatial reference of the patient during the procedure. This operation is performed by fusing the primary preoperative scan with the whole-head scan acquired intraoperatively. After the import process is complete, you can continue to modify your trajectories on images acquired during the procedure.

For additional details, see Pre-Op Step *Setting Preoperative Trajectories* Pg. 128.

Entry Step

Before entering this step, make sure that the patient is prepared for the procedure (i.e., SMARTGrid(s) are mounted over the intended entry area(s), and the patient and scanner are appropriately positioned).

The Entry step allows you to plan and/or review one or more trajectory paths into the brain using a whole-head volumetric scan with one or more SMARTGrid marking grids affixed to the patient, plus any additional scans that are necessary to review and/or verify each trajectory path. If a preoperative plan was created prior to this step, the ClearPoint Workstation will require that the image volume containing the marking grids be fused with the main image series used during preoperative planning. This defines a mechanism whereby the preoperative annotations (including trajectories, anatomical landmarks, and segmented brain structures) can be imported into the spatial reference of the patient on the day of surgery.

The following optional tasks are provided by the Entry step:

- **Fusion**. Spatially register one or more additional image series acquired in different frames of reference after one or more marking grid(s) have been affixed to the patient. See Fusion Task *Fusing Images* Pg. 219 for details.

- **Compare**. Perform visual comparison of any two image series loaded onto the workstation for purposes of trajectory planning. See Compare Task *Comparing Images* Pg. 232 for details.

- **AC-PC**. Review and edit anatomical landmarks needed to use anatomical coordinates. See ACPC Task *Reviewing Landmarks* Pg. 228 for details.

- **Preview Frame**. Visualize one or more frame(s) positioned on the patient prior to mounting using scans acquired after one or more marking grid(s) have been affixed. See Preview Frame Task Visualizing Frames Prior to Mounting Pg. 254 for details.

- **Maestro**. Perform fully automated segmentation of brain structures from any loaded MR image series using the ClearPoint Maestro Brain Model. See Maestro Task Segmenting Brain Structures Pg. 264 for details.

- **Grid**. Review and/or edit the positions/orientations of any identified marking grid(s). Create additional marking grids if they were not properly detected. See Grid Task *Editing Marking Grids* Pg. 235 for details.

For additional details, see Entry Step Setting Intraoperative Trajectories Pg. 143.

Mount Step

The Mount Step allows you to visualize the location(s) prescribed by the ClearPoint Workstation required to mount one or more SMARTFrame trajectory frames onto the patient for each of the defined trajectory paths. These locations are displayed in 3-D along with the patient head and marking grids to clearly show where each associated frame should be mounted onto the patient.

The following optional tasks are provided by the Mount step:

- **Compare**. Perform visual comparison of any two image series loaded onto the workstation for purposes of determining the mount point(s). See Compare Task *Comparing Images* Pg. 232 for details.

- **Preview Frame**. Visualize one or more frame(s) positioned on the patient prior to mounting using scans acquired after one or more marking grid(s) have been affixed. See Preview Frame Task Visualizing Frames Prior to Mounting Pg. 254 for details.

- **Grid**. Review and/or edit the positions/orientations of any identified marking grid(s). Create additional marking grids if they were not properly detected. See Grid Task *Editing Marking Grids* Pg. 235 for details.

- **Mount Point**. Review and/or refine the prescribed frame mount location for a given trajectory by visualizing and/or modifying the position/orientation of each frame base to be mounted onto the patient. Verify that each frame base correctly models how it will sit on the patient's skull when the screws are anchored into bone. See Mount Point Task Reviewing and Refining Mount Points Pg. 258 for details.

At this point, the user accesses the patient's head to peel off the image-visible (top) layer of each marking grid There are two options for affixing each trajectory frame:

<u>Mounting on the surface of the skull:</u>

If mounting the frame directly onto the surface of the skull, the Marking Tool is used to mark the skull directly beneath the mount point identified on the 3D model of the marking grid displayed by the ClearPoint Workstation.

Once the incision is completed and the scalp is retracted, a burr hole is created centered on the previously marked point. The SMARTFrame trajectory frame is then centered on the burr hole (using the Centering Tool if a 14mm burr hole is made) and secured to the skull with bone screws.

Mounting on the scalp:

If mounting the frame on the scalp, using the optional scalp-mount base, the frame should be mounted using the scalp-mount centering point provided by the workstation.

Once the frame is mounted, if indicated, the Hand Controller may be attached to the SMARTFrame before the patient is scanned in the upcoming step

For details, see Mount Step Mounting Frames Pg. 149.

Target Step

Before entering this step, prepare the patient for scanning with one or more SMARTFrame trajectory frames mounted on the head.

The Target step allows you to plan / review one or more trajectory paths into the brain after the frames have been mounted to the patient. At this point in the workflow, the ClearPoint Workstation will require that the image volume with frames mounted to the patient be fused with the primary image volume from the previously completed workflow step, so that previously defined annotations (including trajectories, anatomical landmarks, and segmented brain structures) can be imported into the spatial reference of the patient with the frames mounted. If you performed trajectory frame mounting using a SNS and you did not complete a presurgical plan using the Plan Workflow, the trajectory paths will need to be re-defined on the workstation.

The following optional tasks are provided by the Target step:

- **Fusion**. Spatially register one or more additional image series acquired in different frames of reference after the frame(s) have been mounted. See Fusion Task *Fusing Images* Pg. 219 for details.

- **Compare**. Perform visual comparison of any two image series loaded onto the workstation for purposes of trajectory refinement. See Compare Task *Comparing Images* Pg. 232 for details.

- **AC-PC**. Review and edit anatomical landmarks needed to use anatomical coordinates. If the patient's head has settled and/or brain shift has occurred after the frame(s) have been mounted, these values may require refinement. See ACPC Task *Reviewing Landmarks* Pg. 228 for details.

- **Maestro**. Perform fully automated segmentation of brain structures from any loaded MR image series using the ClearPoint Maestro Brain Model. See Maestro Task Segmenting Brain Structures Pg. 264 for details.

- **Frame**. Review and/or edit the positions of any identified frame. Define additional frames if they were not properly detected by the application. See Frame Task *Editing Frame Markers* Pg. 240 for details.

- **Pre-Adjust**. Perform a pre-adjustment of the targeting cannula prior to altering its angulation to align the bottom of the cannula with the planned entry point of the current trajectory. This task is only available when utilizing an MRI Workflow. See Pre-Adjust Task *Pre-adjusting the Cannula* Pg. 247 for details.

For details, see Target Step *Finalizing Trajectories* Pg. 159.

Align Step (MRI Workflow)

The Align step allows you to perform coarse alignment of each frame's targeting cannula to the intended brain target using iterative alterations of the cannula's angulation until the targeting cannula(s) is in the same general plane as the desired trajectory(s). This allows for focused, time-efficient MRI scans of that plane only for all subsequent adjustments being performed in the next step (see Adjust Step (MRI Workflow) Pg. 47). This step is only available when performing an MR-guided procedure utilizing the MRI Workflow.

The following optional tasks are provided by the Align step:

- **Fusion**. Spatially register one or more additional image series acquired in different frames of reference after the cannula alignment process has started. See Fusion Task *Fusing Images* Pg. 219 for details.

- **Pre-Adjust**. Perform a pre-adjustment of the cannula prior to altering its angulation to align the bottom of the cannula with the planned entry point of the current trajectory. If the planned entry point does not align with the bottom of the cannula, the ClearPoint Workstation will prompt you to carry out this task. See Pre-Adjust Task Pre-adjusting the Cannula in an MRI Workflow Pg. 247 for details.

- **Compare**. Perform visual comparison of any two image series loaded onto the workstation for purposes of detecting unintended patient / table movement during the cannula alignment process. See Compare Task *Comparing Images* Pg. 232 for details.

For details, see Align Step Set the Cannula Angulation in an MRI Workflow Pg. 168.

Adjust Step (MRI Workflow)

The Adjust step (MRI Workflow) allows you to further adjust and confirm the targeting cannula position / orientation using two independent MRI scans of the region containing the trajectory/targeting cannula. Using regional or "slab" scans instead of whole-head scans reduces the time of acquisition while allowing the user to fine tune the targeting cannula with angulation and/or X-Y offset adjustments, to align it precisely to the intended target(s). This step is only available when performing an MR-guided procedure utilizing the MRI Workflow.

The following optional tasks are provided by the Adjust step (MRI Workflow):

- **Fusion**. Spatially register one or more additional image series acquired in different frames of reference after the cannula alignment process has started. See Fusion Task *Fusing Images* Pg. 219 for details.

- **Compare**. Perform visual comparison of any two image series loaded onto the workstation for purposes of detecting unintended patient / table movement during the cannula adjustment process. See Compare Task *Comparing Images* Pg. 232 for details.

For details, see Adjust Step Finalize the Cannula Position in an MRI Workflow Pg. 176.

Adjust Step (CT Workflow)

The Adjust step (CT Workflow) allows visualization of the targeting cannula position/orientation and subsequent alignment to the intended trajectory(s) with changes in angulation or X-Y offsets using a single whole head CT scan. The ceramic aiming stylet in the Accessory Kit can be inserted down the targeting cannula before or after the initial CT scan to facilitate automatic detection of the cannula's position in cases where the field-of-view (FOV) may not be adequate. The FOV may be inadequate if the brain target and the upper targeting cannula cannot be captured in a single scan. For details, see the SMARTFrame XG Trajectory Frame IFU. This step is only available when performing a CT-guided procedure utilizing the CT Workflow.

The following optional tasks are provided by the Adjust step (CT Workflow):

- **Fusion**. Spatially register one or more additional image series acquired in different frames of reference after the cannula alignment process has started. See Fusion Task *Fusing Images* Pg. 219 for details.

- **Compare**. Perform visual comparison of any two image series loaded onto the workstation for purposes of detecting unintended patient / table movement during the cannula adjustment process. See Compare Task *Comparing Images* Pg. 232 for details.

For details, see Adjust Step Finalize the Cannula Position in a CT Workflow Pg. 188.

Insert Step

The Insert step allows you to monitor, assess and evaluate the accuracy of a device insertion relative to its planned trajectory. **During an MRI Workflow, this step may only be performed when inserting MRI Conditional devices**.

The following optional tasks are provided by the Insert step:

- **Fusion**. Spatially register one or more additional image series acquired in different frames of reference after the device has been inserted. This task may be required when evaluating the accuracy of a device placement using scans that are in a different frame of reference than those used to plan trajectories earlier in the workflow. See Fusion Task *Fusing Images* Pg. 219 for details.

- **Compare**. Perform visual comparison of any two image series loaded onto the workstation for purposes of detecting unintended patient / table movement during the device insertion process. See Compare Task *Comparing Images* Pg. 232 for details.

For details, see Insert Step *Monitor and Assess Device Placement* Pg. 198.

Re-Adjust Step

In instances where the device placement is not clinically acceptable, the position / orientation of the targeting cannula can be corrected in the following manner:

- If executing an MRI Workflow (see MRI Workflow Pg. 39), the Re-Adjust step can be used to assess the cause of the poor device placement and re-adjust the cannula's position / angulation to correct for the initial placement. For details, see Re-Adjust Step Managing a Device Re-Insertion (MRI Workflow Only) Pg. 213.

- If executing a CT Workflow (see CT Workflow Pg. 40), the Adjust step (CT Workflow) can be used to assess the cause of the poor placement and re-adjust the cannula's position / angulation to correct for the initial placement. For details, see Adjust Step Finalize the Cannula Position in a CT Workflow Pg. 188.

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.

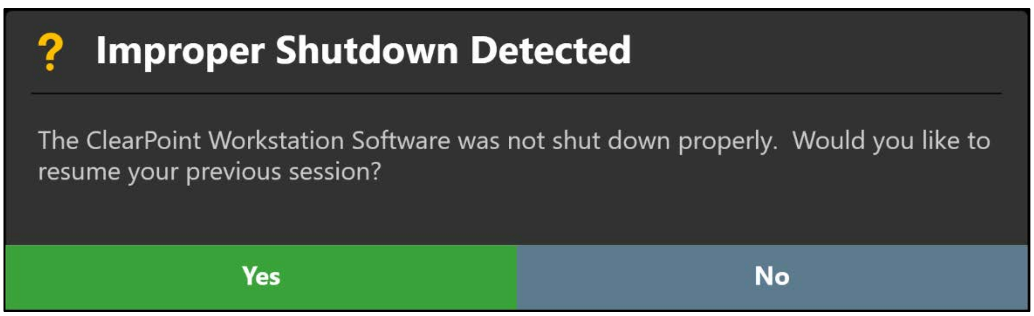
Getting Started

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

Starting the Application

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

If the ClearPoint 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.



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 several different actions:

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

- Shut down and exit the application.

Installing a System License

The ClearPoint 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.

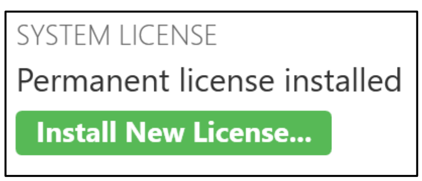
Caution:	**A valid, non-expiring clinical-use license is required to use the ClearPoint Workstation during a neurological procedure. Demonstration licenses, or unreleased software versions are not permitted for use during clinical procedures.**

Note: The ClearPoint software employs a feature-based licensing model designed to provide exclusive access to various functionality within the application. Your license has been specifically tailored to either grant or restrict access to features depending on whether you plan to utilize their underlying capabilities. The following feature sets in the software have their access controlled through licensing: the MRI Workflow (see MRI Workflow Pg. 39), the CT Workflow (CT Workflow Pg. 40) and the Maestro Task (Maestro Task Segmenting Brain Structures Pg. 264). If you have not been granted access to use these features but wish to use them in future procedures, please contact your clinical sales representative so that these functionalities can be unlocked to meet your clinical needs.

> **To install a license**

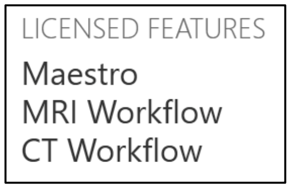
1. Launch the application.
2. From the Splash Screen, click the  button.
3. A floating window will appear, providing you with the ability to modify the configurable settings for the system.
4. Select the **SYSTEM** tab to modify the system settings.
5. Click the **Install New License…** button.

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



> **To check the list of licensed features**

1. Launch the application.
2. From the Splash Screen, click the  button.
3. A floating window will appear, providing you with the ability to modify the configurable settings for the system.
4. Select the **SYSTEM** tab to see the list of features that have been licensed for use on your workstation.

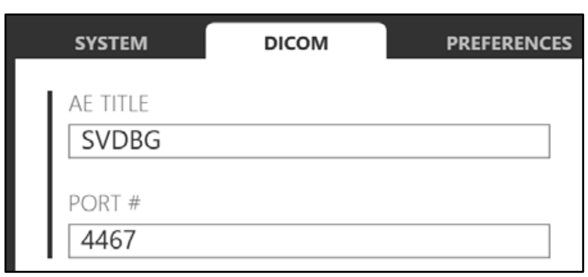


Configuring the DICOM Connectivity Settings

In order for the ClearPoint Workstation to receive DICOM images transferred from the intraoperative scanner, the workstation will need to be configured as a DICOM node on the scanner console. (See the scanner's manufacturer-specific instructions on how to set-up the workstation as a DICOM node on the 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 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 scanner console.
6. Enter the Port Number of the workstation as configured on the scanner console.

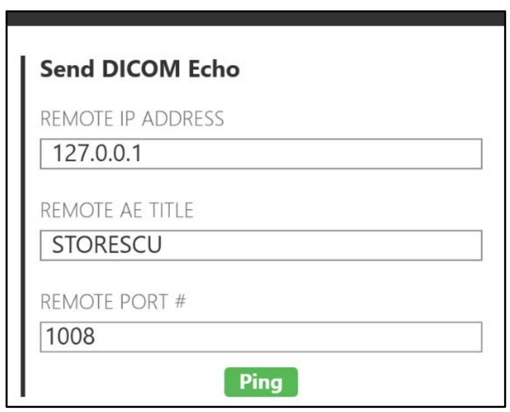


7. Select **Apply** to save the changes made.

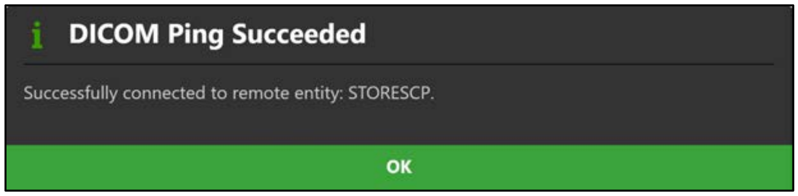
8. If you wish to change the DICOM connectivity settings at a later time, you can use the System Configuration Window to modify the appropriate fields as necessary (see Configuring System and User Settings Pg. 75).

> **To test the DICOM connectivity settings**

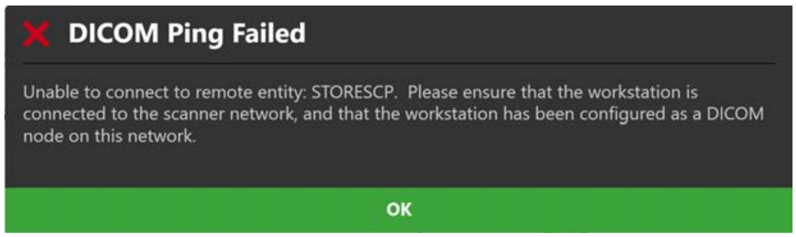
1. Launch the application.
2. From the Splash Screen, click the  button.
3. A floating window will appear, providing you with the ability to modify the configurable settings for the system.
4. Select the **DICOM** tab to modify the DICOM settings for the system.
5. Enter values for the DICOM connectivity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



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 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 scanner's network.



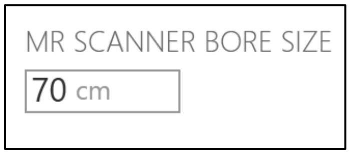
Configuring the MRI Scanner Settings

If licensed to perform MRI-guided procedures, then prior to starting a new session for the first time, you must specify information about the MRI scanner that will be transferring images to the ClearPoint Workstation during these procedures. If the workstation connects to different MRI 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 MR scanner bore size**

1. Launch the application.
2. From the Splash Screen, click the  button.
3. A floating window 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 MR scanner that the workstation is connected to.



6. Select **Apply** to save the changes made.

7. If you wish to change the MR 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 User Settings Pg. 75).

Caution: **The MR scanner bore size entered in the system configuration settings is used by the application to ensure that for a given planned trajectory path, the configured device can be physically inserted into the SMARTFrame without being obstructed by the MR scanner bore. Always ensure that the MR scanner bore size entered in the System Configuration Window is correct prior to proceeding with trajectory planning in an MRI Workflow.**

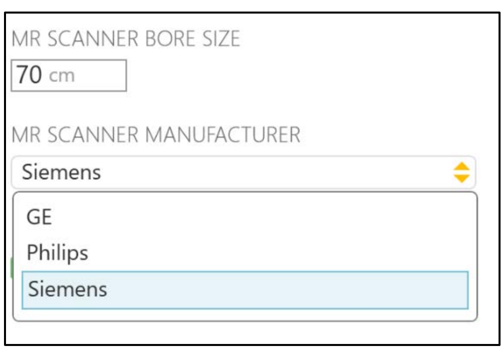
> To set the MR scanner manufacturer

1. Launch the application.

2. From the Splash Screen, click the  button.

3. A floating window 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 MR scanner to which the workstation is connected.

6. Select **Apply** to save the changes made.

7. If you wish to change the MR scanner manufacturer at a later time, use the System Configuration Window to modify the manufacturer field as necessary (see Configuring System and User Settings Pg. 75).

Caution:	**The MR 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 an MRI Workflow. Always ensure that the value entered in the System Configuration Window is correct prior to proceeding with trajectory planning.**

Configuring the List of System Preferences

Prior to using the ClearPoint Workstation for the first time, review the list of preferences that are configured for the system. These preferences include default annotation colors and landmark definitions. By default, the system is pre-configured with values for each of these settings. If you would like to make changes to the list of system preferences, specify those changes in the system configuration settings.

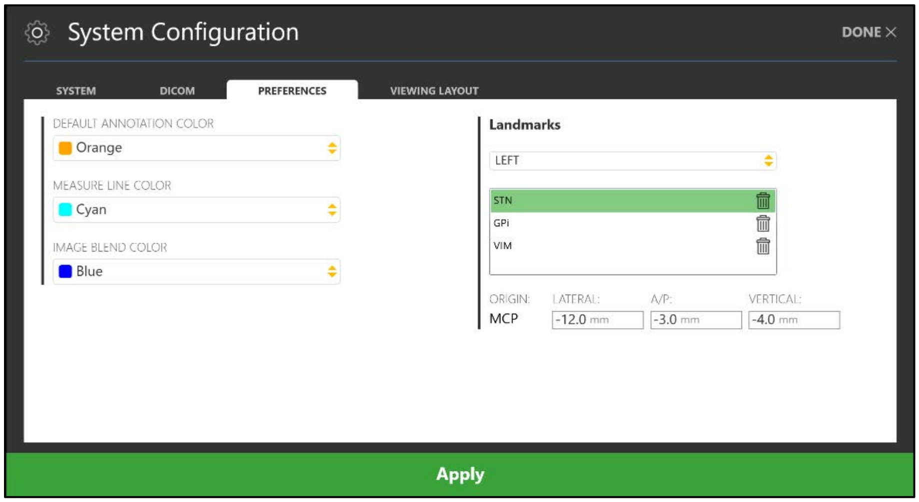
> **To configure the list of system preferences**

1. Launch the application.

2. From the Splash Screen, click the  button.

3. A floating window will appear, providing you with the ability to modify the configurable settings for the system.

4. Select the **PREFERENCES** tab to modify the user-specific preferences for the system.



5. Modify the following fields, if desired:

   - Default Annotation Color – Specify the default color shown in the user interface when creating trajectory and point annotations.

   - Measure Line Color – Specify the default color to be used when showing measure annotations (see Measure Tools Pg. 102).

   - Image Blend Color – Specify the default color shown when using the Fusion Color Tool (see Image Blend Tools Pg. 108).

6. Define any target landmarks prior to using the system (see Managing Landmarks Pg. 116).

7. Select **Apply** to save the changes made.

Configuring the Viewing Layout Preferences

Prior to using the ClearPoint Workstation for the first time, review the viewing layout preferences that are configured on the system. These preferences provide options for configuring image display within the application viewports, such as viewing orientation conventions and orientation indicator visibility. By default, the system is pre-configured with values for each of these preferences. If you would like to make changes to these preferences, specify those changes in the viewing layout configuration settings.

Caution: **Be aware that changes made to the viewing layout configuration settings affect the orientation of images rendered in the**

application viewports. Always pay attention to the orientation labels and indicators shown in the viewports to understand how images are displayed.

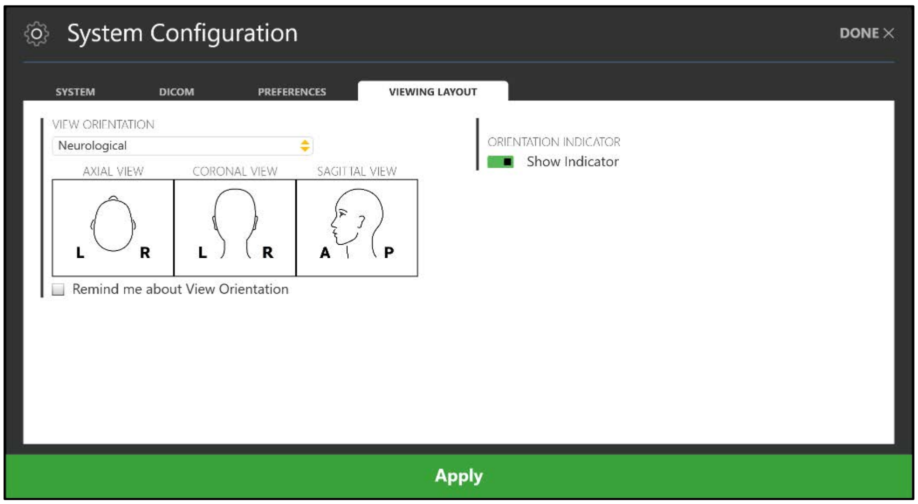
> **To configure the viewing layout preferences**

1. Launch the application.

2. From the Splash Screen, click the  button.

3. A floating window will appear, providing you with the ability to modify the configurable settings for the system.

4. Select the **VIEWING LAYOUT** tab to modify the viewing layout preferences for the system.



5. Modify the following fields if desired:

   - View Orientation – Specify the convention used for orienting images in the application viewports. Neurological orientation indicates that images are displayed such that the patient direction corresponds to the screen direction (i.e., patient left/right on screen left/right). Radiological orientation indicates that images are displayed such that the patient direction is opposite to the screen direction (i.e., patient right/left on screen left/right). The pictorials below this field depict how the view orientation affects image rendering relative to patient direction for standard axial, coronal, and sagittal views.

   - View Orientation Reminder – Specify whether to explicitly remind the user which view orientation convention is configured on the system upon starting or loading a session from the Splash Screen (see Launching the

Splash Screen Pg. 50). This is accomplished via a pop-up dialog which indicates what view orientation convention is configured for the system.

- Orientation Indicator – Configure hiding or showing the viewport orientation indicator (see Using the Orientation Indicator Pg. 95).

6. Select **Apply** to save the changes made.

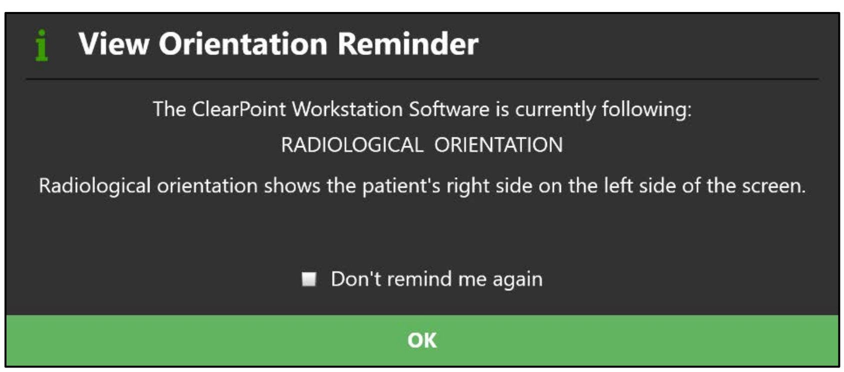
Starting a New Session

In order to start a neurological procedure using the ClearPoint Workstation, ensure that the patient is prepared for surgery, the surgical field has been set-up, and the patient has been positioned appropriately relative to the scanner. The Splash Screen can then be used to start a new clinical workflow in a new software session. When starting a new software session, the Splash Screen is used to gather basic information about the procedure, including desired workflow, laterality, target name, device lengths and type of frame base mount.

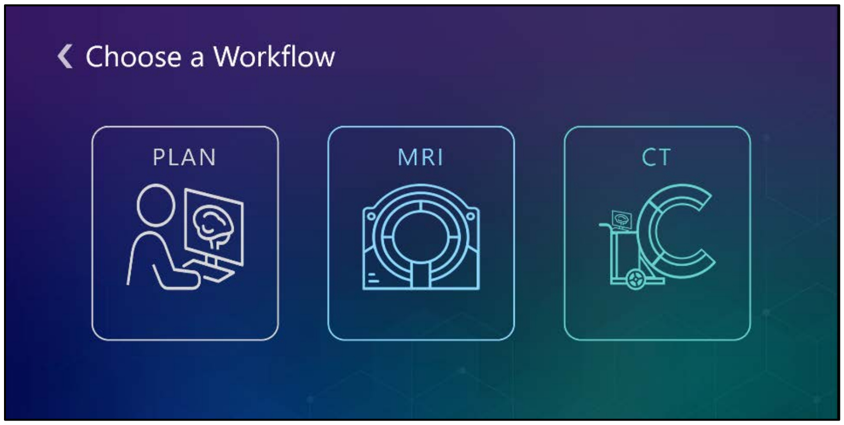
> **To start a new session**

1. From the Splash Screen select **NEW SESSION**.

2. If the system is configured to provide a reminder regarding the view orientation convention (see Configuring the Viewing Layout Preferences Pg. 58), a dialog will be presented summarizing which view orientation convention is being used. Tick the **Don't remind me again** checkbox if you no longer wish to see this dialog upon starting a new session.



3. A new page on the Splash Screen will appear, presenting you with the workflow options available to start a new session.



4. Choose a workflow that you wish to use to start a new session:

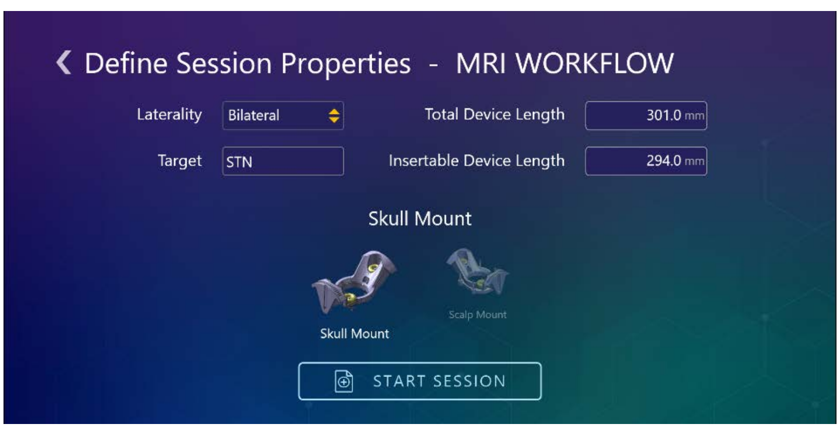
    - Select **PLAN** to start a new Plan Workflow (see Plan Workflow Pg. 38) for purposes of creating a presurgical plan prior to the neurological procedure.

    - Select **MRI** to start a new MRI Workflow (see MRI Workflow Pg. 39) for purposes of performing an MRI-guided neurological procedure.

    - Select **CT** to start a new CT Workflow (see CT Workflow Pg. 40) for purposes of performing a CT-guided neurological procedure.

5. 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.

6. Otherwise after selecting a workflow, a new page on the Splash Screen will appear, presenting you with the fields required to start a new session.



7. Fill in all the field properties required to create a new session:

- Laterality – Specify whether the planned procedure is to insert devices on left, right, or both sides of the brain.
- Target – Specify a name for the anatomical location that will be targeted during the procedure.
- Total Device Length – For the device to be inserted into the brain during the procedure, enter its total rigid length. During MRI-guided procedures, this value is used to check whether the device will physically fit within the bore of the MR scanner.
- Insertable Device Length – For the device to be inserted into the brain during the procedure, enter the length that can be inserted through the targeting cannula. 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.
- Base – From the list provided, select the base that will be used to mount the SMARTFrame(s) to the patient during the procedure.

Caution: **The correct choice of mounting base affects calculations which check whether the device will clear the MR scanner bore (MR-guided procedures only) and whether the device will reach the target. This choice is also important to ensure a viable trajectory. Always verify that the hardware image shown matches the hardware you will be using during the procedure.**

8. Select **START SESSION** to begin a new session with the selected workflow and field properties listed.
9. 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 twice to navigate back to the first page of the Splash Screen.

Loading an Existing Session

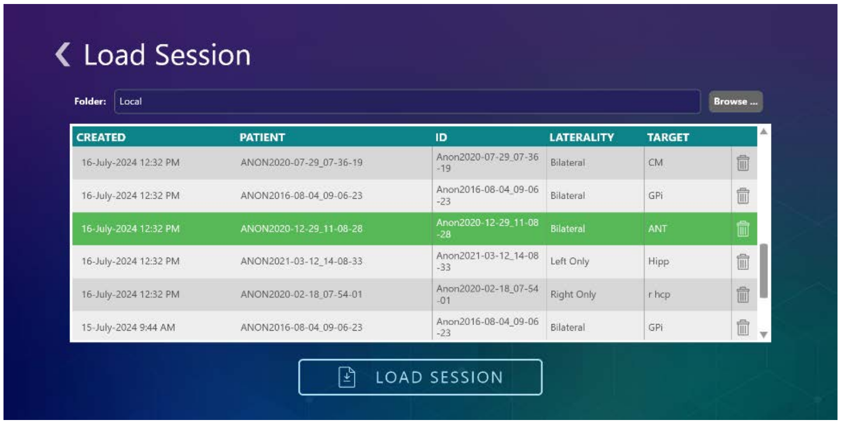
The ClearPoint Workstation also allows you to load existing sessions that may have been fully or partially completed. You may choose to load existing sessions to review procedures that have already been completed or continue a procedure that has not been completed.

> **To load a session**

1. From the Splash Screen select **LOAD SESSION**.

2. If the system is configured to provide a reminder regarding the view orientation convention (see Configuring the Viewing Layout Preferences Pg. 58), a dialog will be presented summarizing which view orientation convention is being used. Tick the **Don't remind me again** checkbox if you no longer wish to see this dialog upon loading a session.

3. A new page on the Splash Screen will appear, presenting you with a list of sessions currently saved on the workstation.



4. 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 choose a location where the session can be loaded from.

5. Select **LOAD SESSION** to load the session selected in the window.

6. 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.

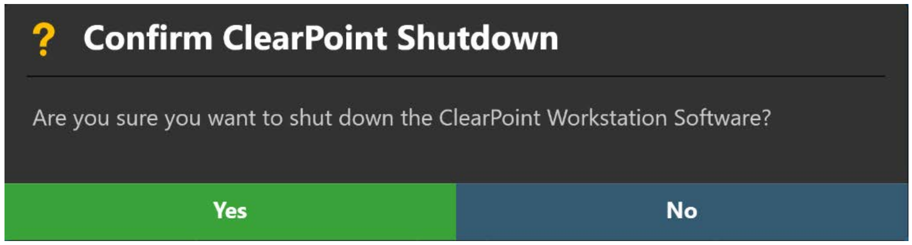
Shutdown and Exit

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

> **To exit the application**

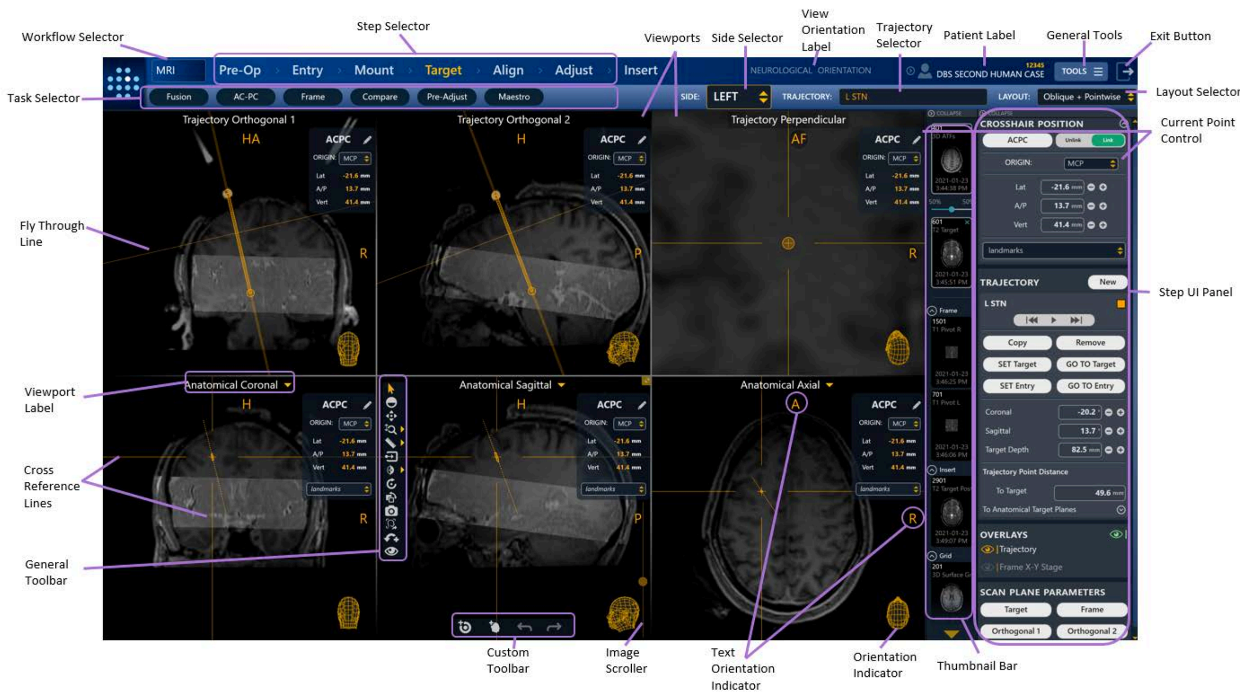
1. Select the button from the far right hand corner of the main application window or from the Splash Screen (see Launching the Splash Screen Pg. 50).

2. A floating window will prompt you prior to shutting down the application. Select **Yes** to proceed with the shutdown, or alternatively, select **No** to keep the application running.

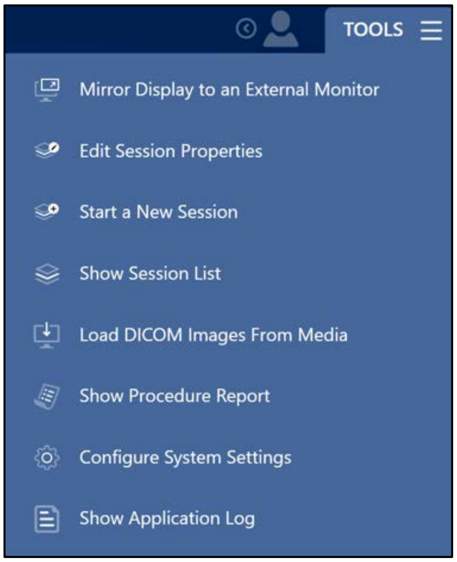


Application Overview

This section describes the general features of the application which consist of the Workflow Selector, the Step Selector, the Task Selector, set of top-level tools, the Patient Label, the Side Selector, the Trajectory Selector, the Layout Selector, the Thumbnail Bar, the Current Point Control, 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 an 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. 67).

- **Edit Session Properties** – Allows you to modify the attributes associated with the currently loaded session. (See Using the Edit Session Properties Window Pg. 68).

- **Start a New Session** – Allows you to begin a new software session by choosing a workflow and specifying the attributes associated with the session. (See Using the Start New Session Window Pg. 69).

- **Show Session List** – Allows you to manage the list of software sessions stored on the workstation. 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 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. 72).

- **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. 73).

- **Configure System Settings** – Launches an interactive window that allows you to change system and user-specific settings of the workstation (see Configuring System and User Settings Pg. 75). These settings are divided into 4 separate groupings:

  - System – system licensing information and MR scanner configuration settings (MRI Workflow only)
  - DICOM – system application entity (AE) title & port number, remote network information for testing the connection with an external entity.
  - Preferences – user preferences, such as default annotation colors and target landmark locations.
  - Viewing Layout – preferences related to image display within viewports, such as viewing orientation convention and orientation indicator visibility.

- **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. 79).

Mirroring the External Monitor

If an external monitor has been connected to the workstation, you can mirror the current workstation display onto the external monitor during the procedure. During MRI-guided procedures, the external monitor must be **MR Conditional**.

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**

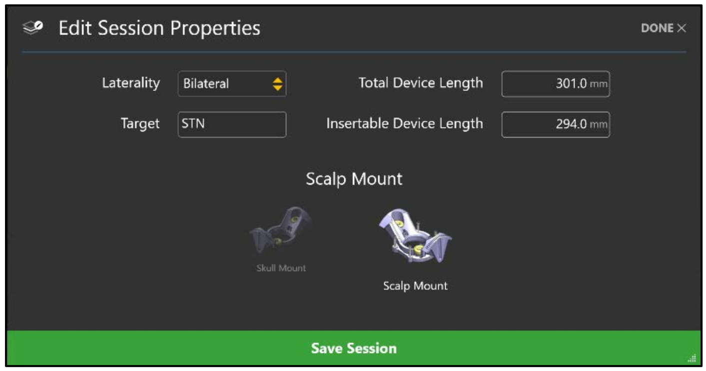
Select **Remove Display from an External Monitor** from the list of top-level tools.

Using the Edit Session Properties Window

The Edit Session Properties Window allows you to modify the attributes associated with the currently loaded software session.

> **To start a new session**

1. Select **Edit Session Properties** from the list of top-level tools.
2. A floating window will appear, prompting you to edit one or more properties associated with your current session.
3. Edit or modify one or more of the properties associated with your current session (see Starting a New Session Pg. 60).



4. Select **Save Session** to save the changes made to your currently loaded session. Otherwise select **DONE** to close the window without making any changes to the current session.

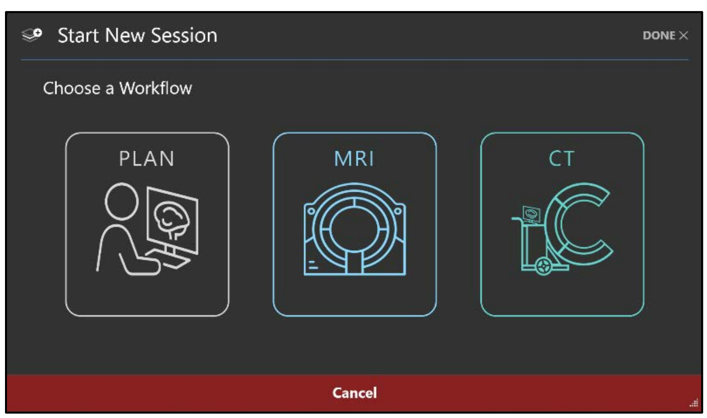
Using the Start New Session Window

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 for 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 **DONE** to dismiss the window.

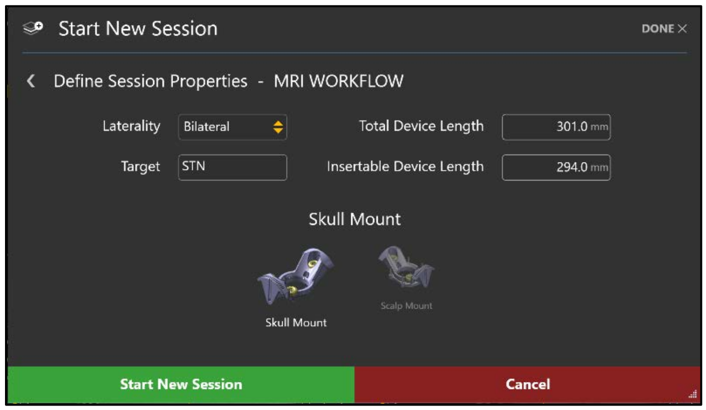
4. Otherwise, if you wish to create a new session:

    - Select **PLAN** to start a new session using the Plan Workflow (see Plan Workflow Pg. 38).

    - Select **MRI** to start a new session using the MRI Workflow (see MRI Workflow Pg. 39).

    - Select **CT** to start a new session using the CT Workflow (see CT Workflow Pg. 40).

5. Fill in all the field properties required to create a new session (see Starting a New Session Pg 60).



6. Select **Start New Session** to close the currently loaded session and start a new session with the field properties listed. Otherwise select **Cancel** or **DONE** to close the window and leave the currently loaded session active.

Using the Session List Window

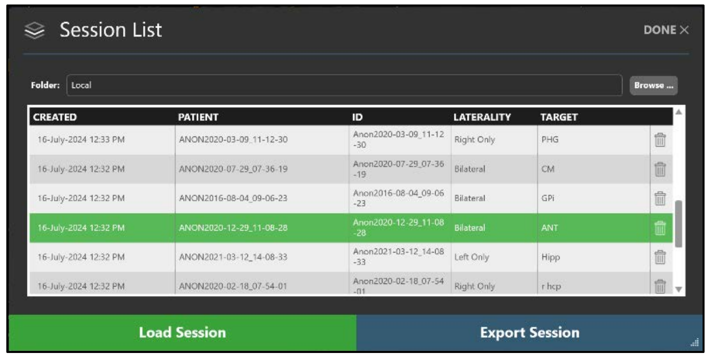
The Session List Window allows you to manage software sessions stored on the workstation.

> 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 (see Loading an Existing Session Pg. 62). 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 close the currently loaded session and load the session selected in the window. Otherwise select DONE to close the window and leave the currently loaded session active.

> 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 anonymized values. For all DICOM images associated with the session, any header fields that contain protected health information will be blanked out in the physical DICOM image files. This ensures that session data can be exported without the risk of protected health information 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 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.

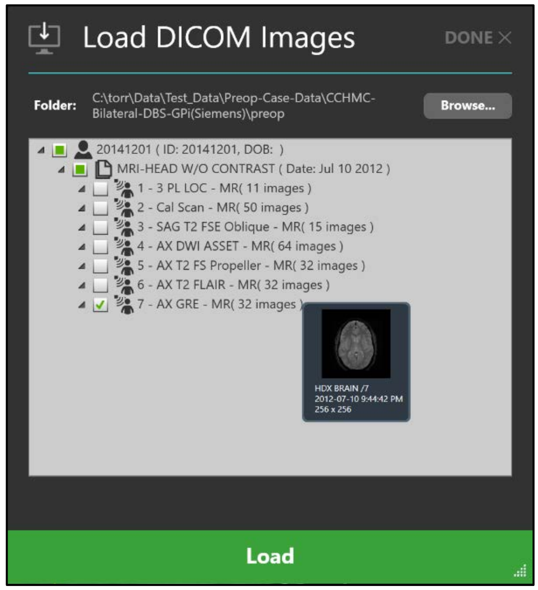
> To load images from media

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.



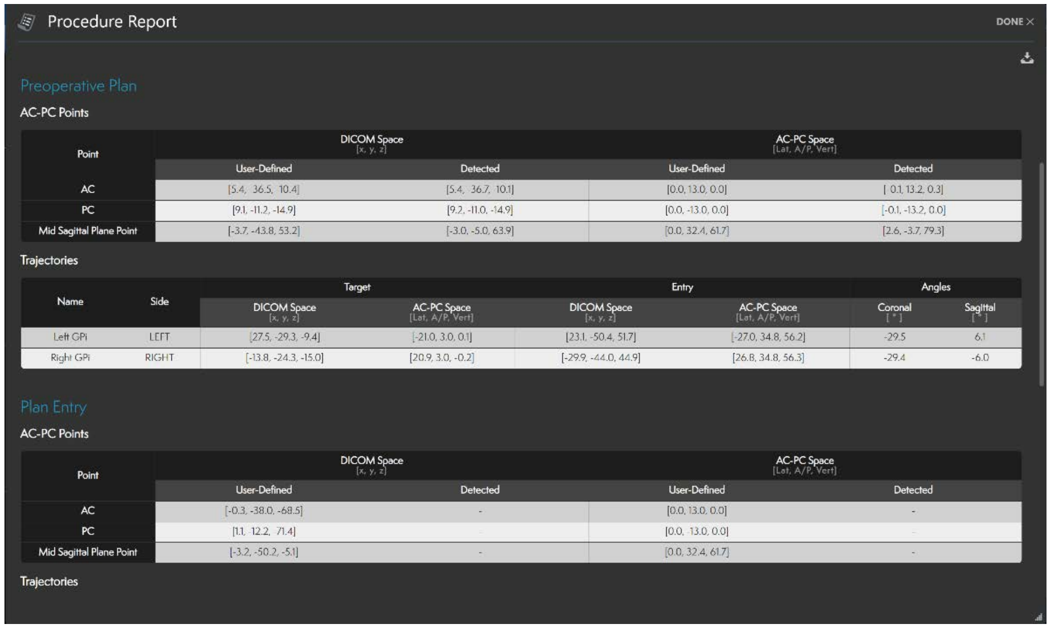
If you select a media device with a large amount of DICOM images there can be a delay while reading the data. Images saved to media from a scanner are usually saved with a DICOMDIR directory file which optimizes reading of the image files and therefore should prevent this delay. If image loading is taking too long, you can cancel the operation and simply select a specific sub-folder containing just the data of interest, or alternatively, copy the media to the workstation's local filesystem.

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, segmented brain regions, and links to any screen captures taken during the procedure.



Procedure Report

DONE ✕

Preoperative Plan

AC-PC Points

Point	DICOM Space [x, y, z]		AC-PC Space [Lat, A/P, Vert]	
	User-Defined	Detected	User-Defined	Detected
AC	[5.4, 36.5, 10.4]	[5.4, 36.7, 10.1]	[0.0, 13.0, 0.0]	[0.1, 13.2, 0.3]
PC	[9.1, -11.2, -14.9]	[9.2, -11.0, -14.9]	[0.0, -13.0, 0.0]	[-0.1, -13.2, 0.0]
Mid Sagittal Plane Point	[-3.7, -43.8, 53.2]	[-3.0, -5.0, 63.9]	[0.0, 32.4, 61.7]	[2.6, -3.7, 79.3]

Trajectories

Name	Side	Target		Entry		Angles	
		DICOM Space [x, y, z]	AC-PC Space [Lat, A/P, Vert]	DICOM Space [x, y, z]	AC-PC Space [Lat, A/P, Vert]	Coronal [°]	Sagittal [°]
Left GPi	LEFT	[27.5, -29.3, -9.4]	[-21.0, 3.0, 0.1]	[23.1, -50.4, 51.7]	[-27.0, 34.8, 56.2]	-29.5	6.1
Right GPi	RIGHT	[-13.8, -24.3, -15.0]	[20.9, 3.0, -0.2]	[-29.9, -44.0, 44.9]	[26.8, 34.8, 56.3]	-29.4	-6.0

Plan Entry

AC-PC Points

Point	DICOM Space [x, y, z]		AC-PC Space [Lat, A/P, Vert]	
	User-Defined	Detected	User-Defined	Detected
AC	[-0.3, -38.0, -68.5]	-	[0.0, 13.0, 0.0]	-
PC	[1.1, 12.2, 71.4]	-	[0.0, 13.0, 0.0]	-
Mid Sagittal Plane Point	[-3.2, -50.2, -5.1]	-	[0.0, 32.4, 61.7]	-

Trajectories

> **To review 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. The following report tools will be displayed in the top right-hand corner of the window:

3. To review any screen captures taken during the procedure, click on the  button to see the file folder location where the screen captures associated with the report are stored. Individual screen capture images, if any, 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.

3. Click on the  button to save a copy of the currently displayed report. The latest report will be saved in the report folder corresponding to the session. A copy of the report is also saved with a unique timestamp-based file name under the *Archive* subfolder. 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 exported without compromising patient confidentiality. Both versions are saved as individual files in the report folder corresponding to the session. A copy of each report is also saved with a unique timestamp-based file names for later review.

Configuring System and User Settings

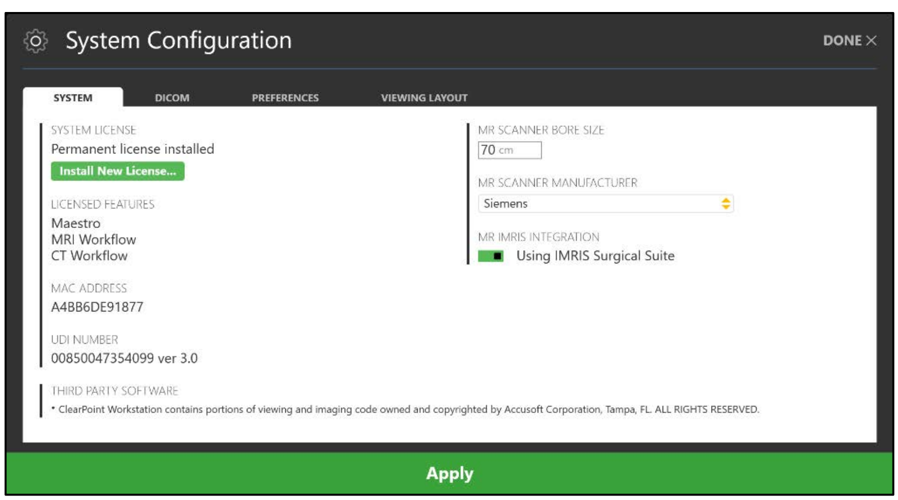
You may configure the system and user-specific settings of the ClearPoint Workstation using the System Configuration Window at any time during program execution.

> To modify system settings

1. Select **Configure System Settings** from the list of top-level tools. If running the software for the first time, you may click on the  button from the Splash Screen (see Launching the Splash Screen Pg. 50).

2. A floating window 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 licensed to use an MRI Workflow:

    - MR Scanner Bore Size – Enter or modify the diameter of the MR scanner bore in centimeters. The application uses this value along with the total device length entered during an MRI Workflow to ensure that for a given planned trajectory, the device can be physically inserted into the frame without being obstructed by the MR scanner's bore.

    - MR Scanner Manufacturer – Choose an option from the list that represents the manufacturer of the MR scanner to which the ClearPoint Workstation is connected. For Siemens MR scanners, indicate whether the scanner resides in an IMRIS Surgical Suite (see Important Notes for Using IMRIS Systems Pg. 34). For GE MR scanners, specify the number of slices to use for the orthogonal cannula 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. 51).

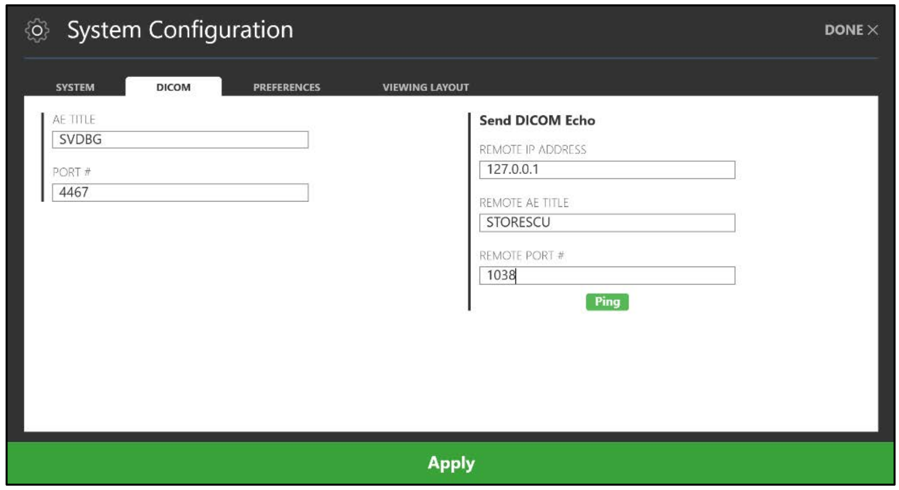
In order for the ClearPoint Workstation to receive DICOM images transferred from an image source such as a scanner or PACS, that system will need to be configured with the AE Title and Port Number configured in the application.

> **To modify DICOM settings**

1. Select **Configure System Settings** from the list of top-level tools. If running the software for the first time, you may click on the  button from the Splash Screen (see Launching the Splash Screen Pg. 50).

2. A floating window 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.



4. Modify the following fields, if necessary:

    - AE Title – Specify the Application Entity Title of the ClearPoint 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 Workstation.

5. Select **Apply** to save the changes made.

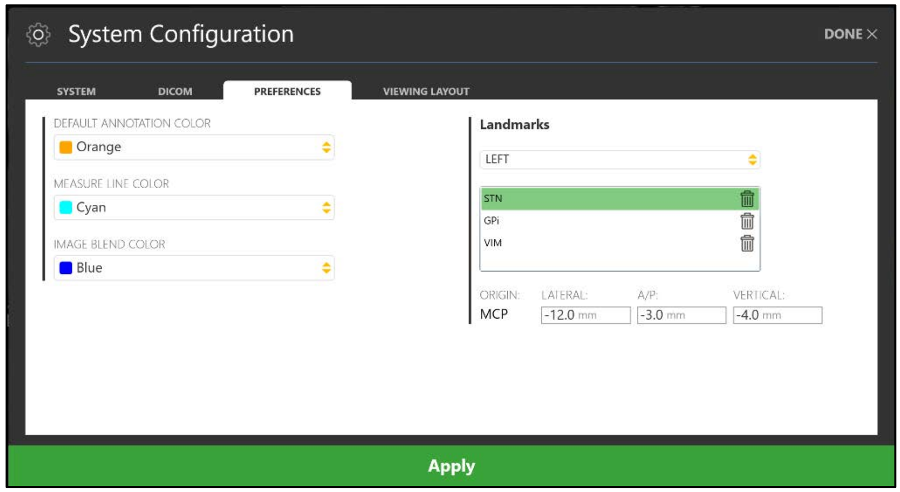
6. You may use the **Ping** button to test DICOM connectivity with the intraoperative scanner (see Configuring the DICOM Connectivity Settings Pg. 53). The entity node information (IP Address, Remote AE Title, and Remote Port Number) of the scanner will need to be specified prior to testing the workstation's remote DICOM connectivity. 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 you will need to enter all three values.

> To modify user preferences

1. Select **Configure System Settings** from the list of top-level tools. If running the software for the first time, you may click on the  button from the Splash Screen (see Launching the Splash Screen Pg. 50).

2. A floating window will appear, providing you with the ability to modify the configurable settings for the system.

3. Select the **PREFERENCES** tab to modify the user-specific preferences for the system.



4. Modify the following fields, if necessary:

   - Default Annotation Color – Indicate the default color shown in the user interface when creating trajectory and point annotations.

   - Measure Line Color – Specify the default color to be used to show measure annotations (see Measure Tools Pg. 102).

   - Image Blend Color – Specify the color shown when using the Fusion Color Tool (see Image Blend Tools Pg. 108).

5. Make any modifications to the target landmarks defined for the system (see Managing Landmarks Pg. 116).

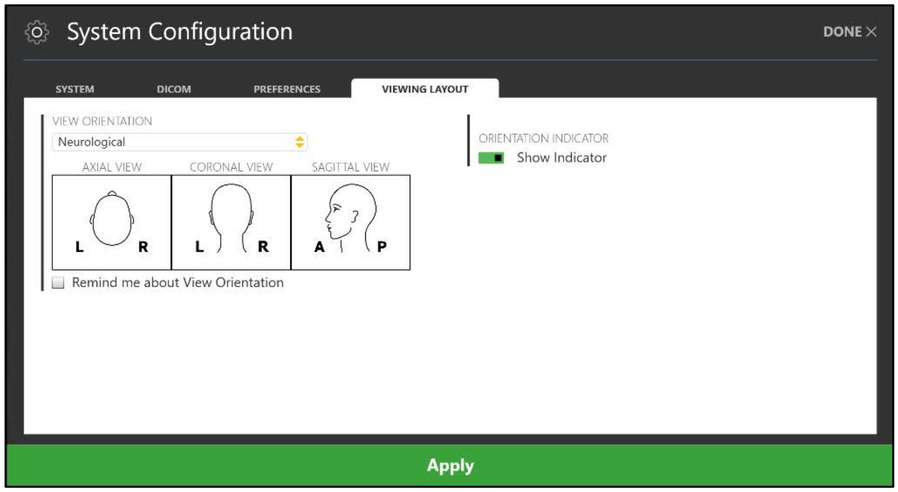
6. Select **Apply** to save the changes made.

> To modify viewing layout settings

1. Select **Configure System Settings** from the list of top-level tools. If running the software for the first time, you may click on the  button from the Splash Screen (see Launching the Splash Screen Pg. 50).

2. A floating window will appear, providing you with the ability to modify the configurable settings for the system.

3. Select the **VIEWING LAYOUT** tab to modify the viewing layout settings for the system.



4. Modify the following fields, if necessary:

   - View Orientation – Indicate the convention used for orienting images in the application viewports (see Configuring the Viewing Layout Preferences Pg. 58).

   - View Orientation Reminder – Specify whether the application should explicitly provide a reminder regarding the view orientation upon starting or loading a session from the Splash Screen (see Launching the Splash Screen Pg. 50).

   - Orientation Indicator – Toggle the **Show Indicator** switch to configure hiding or showing the viewport orientation indicator (see Using the Orientation Indicator Pg. 95).

5. Select **Apply** to save the changes made.

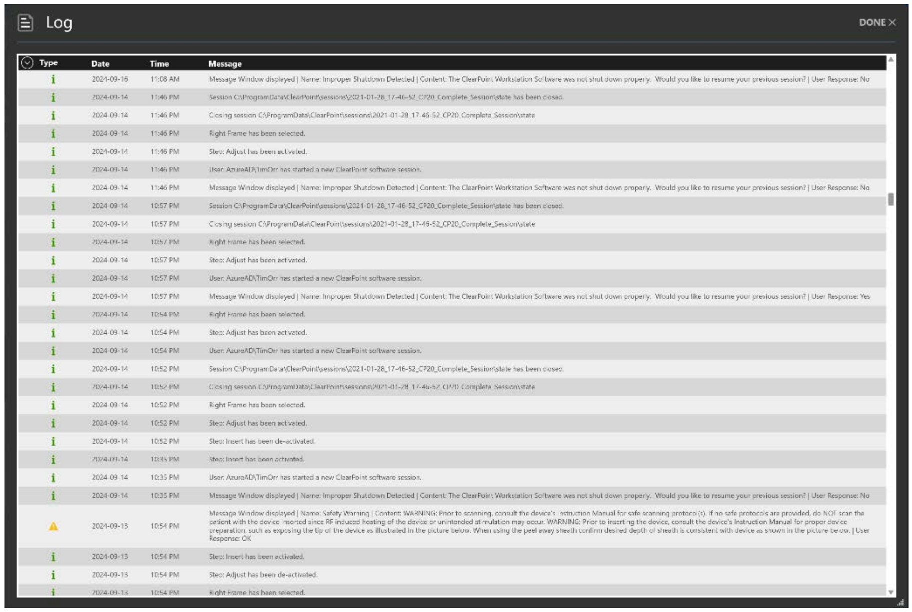
Using the Application Log Window

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 **Show Application 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**.

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

Using the Workflow Selector

The Workflow Selector displays the currently selected workflow and allows selection of a different workflow in instances where an intraoperative procedure has not started yet. If the currently selected workflow is changed, the list of steps shown in the user interface will necessarily change. For an overview of the workflows provided by the software, see Procedure Workflow Pg. 38.

Using the Step Selector

The Step Selector displays the list of steps that can be used to complete a neurological procedure. It also indicates which step is currently being worked on. At any time, you can click the desired button to change the current workflow step. For an overview of the workflow steps, see Workflow Steps Pg. 42.

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 loaded onto the workstation.

> **To review patient information**

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

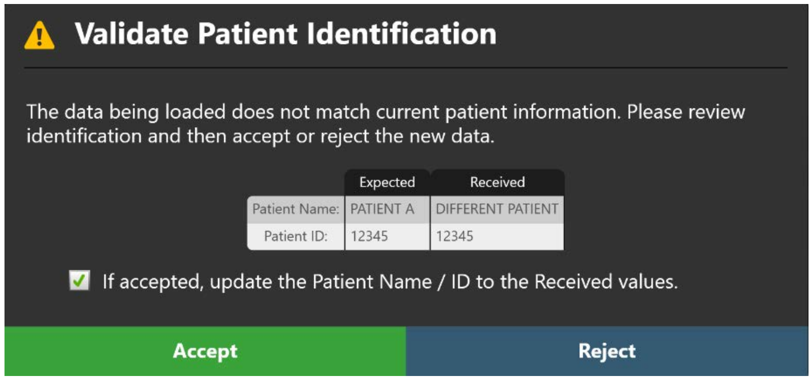
> **To show/hide patient information**

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.



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 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 (see Data Rejected by Workstation Pg. 272).

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 Side

Some steps provide a Side Selector to allow selection of the side of the brain for which you would like to define and/or visualize a trajectory. For unilateral procedures, the Side Selector will contain one item that is always selected. For bilateral procedures, you can use the Side Selector to specify whether to work on the left or right side. Steps that have the Side Selector will filter the display of trajectories for the selected side.

Selecting a Frame

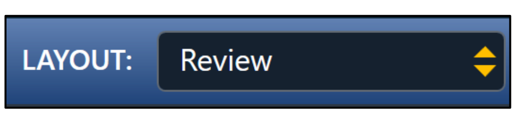
Those steps that do not provide a Side Selector display a Frame Selector to allow selection of the frame that you would currently like to work on. For procedures involving only one frame mounted on the patient, the Frame Selector will contain one item that is always selected. For those procedures involving two or more 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

Each step provides a Trajectory Selector to allow selection of the defined trajectory that you wish to work on. Entries within the Trajectory Selector are filtered based on either the currently selected side (see Selecting a Side Pg. 82), or the currently selected frame (see Selecting a Frame Pg. 83).

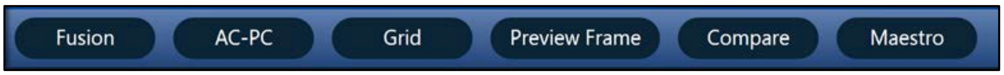
Selecting a Viewing Layout

Each step provides one or more viewing layouts which can be used to complete the step-specific workflow. The current viewing layout can be switched at any time using the Layout Selector. Each selectable viewing layout has a specific name that is used to identify the layout in the user interface.



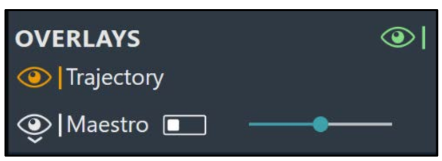
Selecting a Task

Each step contains a list of optional tasks that can be used to perform a specific, focused activity in the workflow (see Optional Tasks Pg. 219). The list of tasks varies for each step, depending on the workflow-related requirements needed to complete the step. An optional task can be invoked at any time during program execution using the Task Selector. Each task is presented as a button within the Task Selector that can be selected to invoke the task. Only one task can be activated at once and will appear as a pop-up window over top of the main application window.



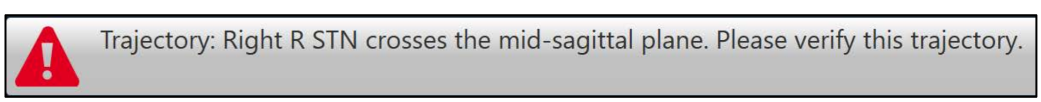
Showing / Hiding Annotations

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  toggle button allows you to hide or show all annotation overlays configured for display in each 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 steps or 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**.

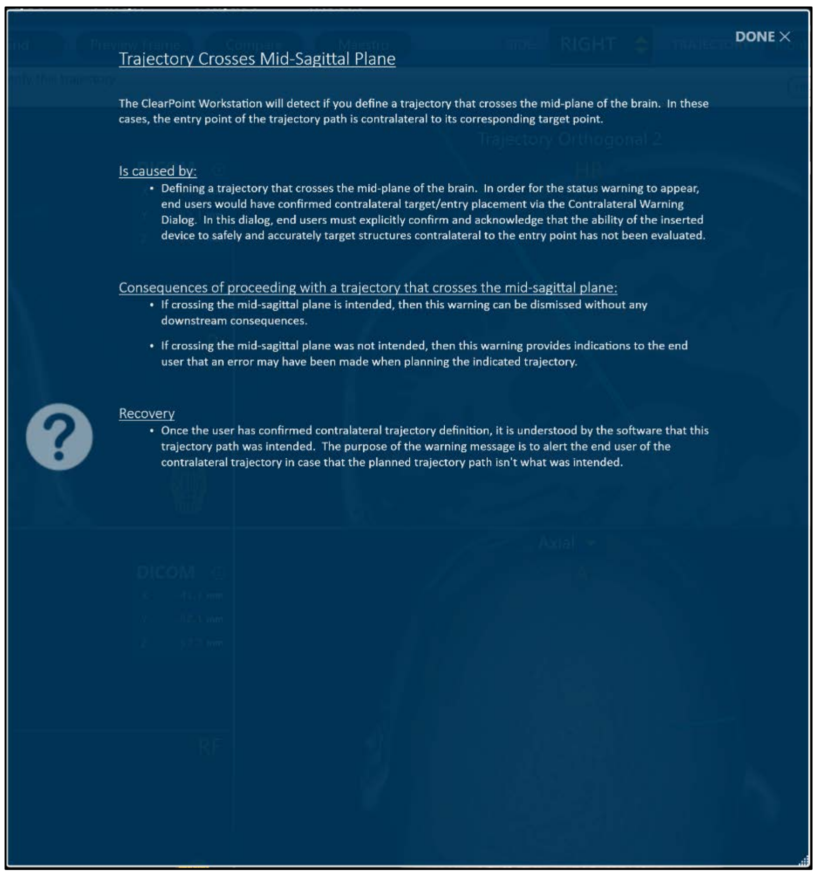


Any time a status message is presented, you have the option of bringing up troubleshooting tips which can help you to resolve the problem(s) encountered. To see a list of all troubleshooting tips provided by the application see Troubleshooting Pg. 271.

> **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 reference other help information topics that are associated with the status message just read.



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.

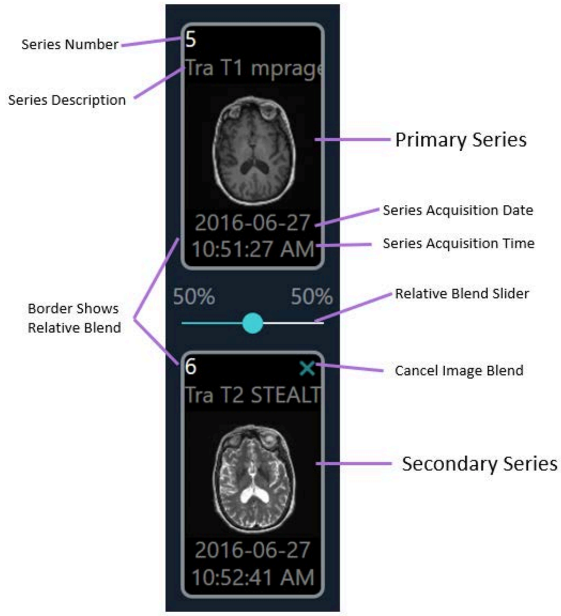
2. Alternatively, click the button and select **DISMISS ALL** to dismiss all messages currently displayed, up to a maximum of 5 messages at a time.

Using Thumbnails

Both steps and tasks provide 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 and tasks 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.



> **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 fully blend an image series**

1. From the grouping of available thumbnails, select the one that you wish to fully blend in the viewports (i.e., image blend slider at 100% for the selected series).

2. Double click on the selected thumbnail image.

3. The selected thumbnail will now be fully blended within the application viewports (i.e., image blend slider at 100% for the selected series).

> **To change the primary series with image blend**

1. From the grouping of available thumbnails, select the one that you wish to designate as the primary series.

2. Click and drag the selected thumbnail to the primary series thumbnail slot on the Thumbnail Bar.

3. The selected thumbnail will now have its corresponding image series displayed in the application viewports.

Note: The scan that is selected in the Pre-Op (see Pre-Op Step Setting Preoperative Trajectories Pg. 128), Entry (see Entry Step Setting Intraoperative Trajectories Pg. 143) and Target steps (Target Step Finalizing Trajectories Pg. 159) 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 step selected. Changing the primary series in these instances will necessarily change the master series for that step.

> **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 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. The selected thumbnail will now have its corresponding image series displayed in the application viewports.

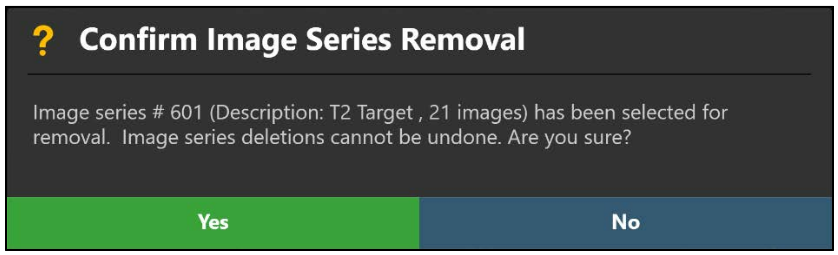
> **To remove / unload an image series**

In instances where you wish to remove or unload an image series from the application:

1. Right-click on the thumbnail corresponding to the image that you wish to remove from the application.

2. Select **Discard** from the context menu.

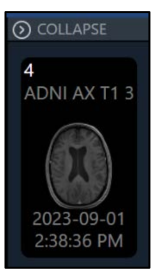
3. You will be prompted to confirm removal of the image series prior to doing so. Select **Yes** to remove the image series from the application. Otherwise, select **No** to leave the image series intact.



Note: The application may prevent you from removing an image series that was used to create annotations, define fusion transformations or for automatic detection of structures and/or hardware.

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

Select **> COLLAPSE** from the area above the top-most thumbnail in the step panel.



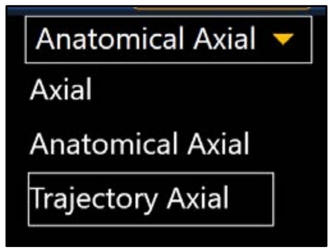
Changing a Viewing Layout Orientation

The orientation of the viewing layout can be changed by selecting the drop-down menu 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 menu at the top-center of the viewport.



3. After selecting an item from the drop-down menu, the orientation of the current viewport and any other viewports whose crosshairs are linked to the current one will change.

Using the Viewport Crosshairs

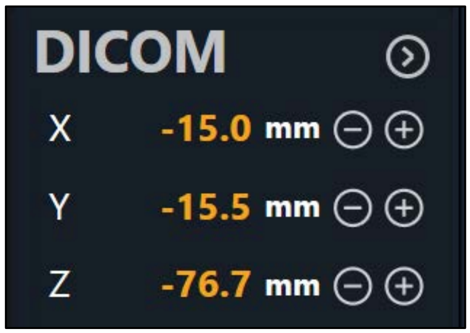
Some viewing layouts provide crosshair graphics (or cross reference lines) defining the intersection point between the coronal, sagittal and axial planes. The crosshairs are defined as follows:

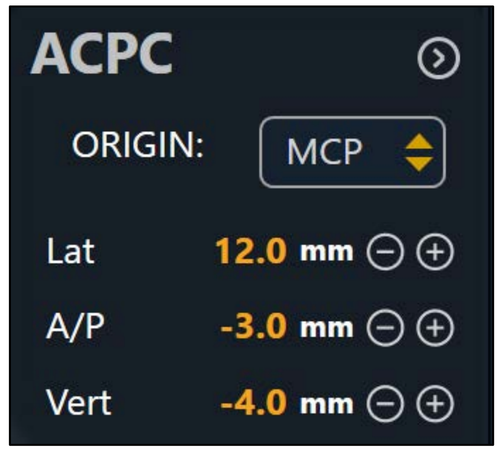
- Axial plane
  - Horizontal line represents intersection with the coronal plane.
  - Vertical line represents intersection with the sagittal plane.

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

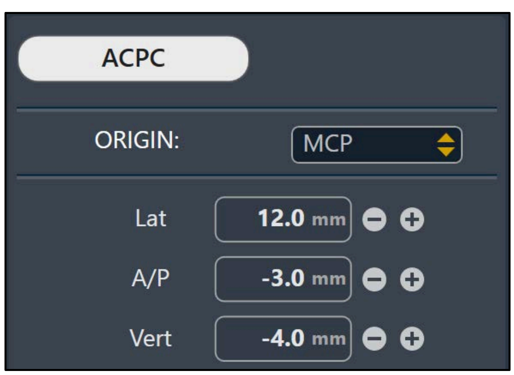
- Coronal plane
  - Horizontal line represents intersection with the axial plane.
  - Vertical line represents intersection with the sagittal plane.

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. It can be toggled between showing the value as ACPC (anatomical) or DICOM (scanner) coordinates by clicking on the label in the header. If the values are shown in ACPC coordinates, the ability to change the origin of the coordinate system to either mid-commissure (MCP) or posterior commissure (PC) is provided.

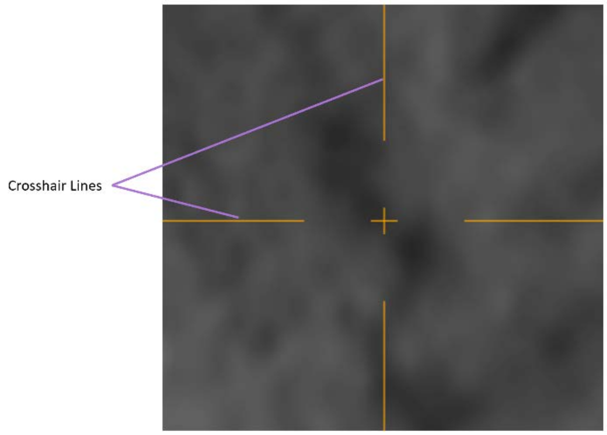




Depending on the workflow step, the Current Point Control may also be shown in the application’s side panel. In these cases, the coordinate values shown in the side panel’s Current Point Control are synchronized with those shown within each viewport.



Changing Crosshair Positions

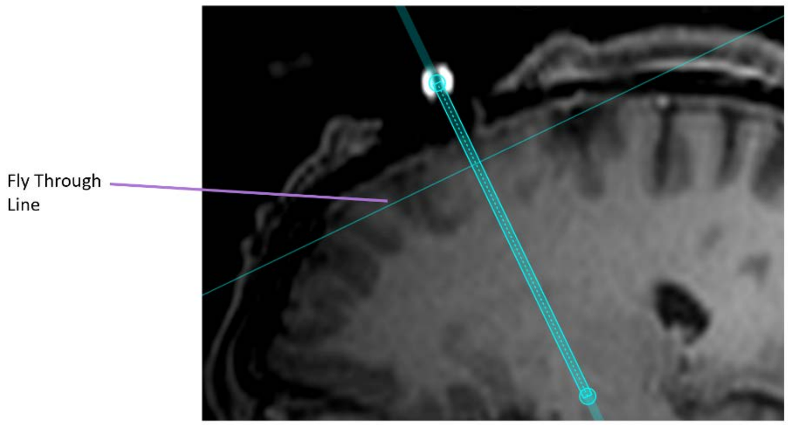


> **To change a crosshair position**

1. Select the Arrow tool (see Arrow Tool Pg. 99).
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 small 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 Current Point Control by clicking the icon and editing the points manually. This can be accomplished by typing in new values for one of more of the coordinate fields or using the **+/-** buttons to make incremental adjustments for each.
   - Click on the **landmarks** drop-down below the Current Point Control to correlate the crosshairs to the anatomical location of the selected landmark (see Managing Landmarks Pg. 116).
   - Use the Fly Through Line to adjust the crosshair position along the specific direction of a line or plane (see Fly Through Line Pg. 94).
   - Use the Image Scroller inset within each application viewport to scroll through the current viewport plane (see Image Scroller Pg. 95).
   - Press the ARROW UP or ARROW DOWN keys to scroll through the current view plane.
   - Right-click on any measurement graphic anchor point and select **Set Crosshair Position Here**. This will set the crosshair position at the location of the anchor point (see Measure Tools Pg. 102).

Fly Through Line

Some viewing layouts 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. 99).

2. Perform any of the following actions:

    - Drag the Fly Through Line in any viewport where it is displayed to adjust the position of the plane perpendicular to the line direction.
    - Use the mouse wheel to 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. 95).
    - Press the ARROW UP or ARROW DOWN keys to scroll the Fly Through Line along the line direction.
    - Right-click on the Fly Through Line in viewports orthogonal to the line direction and modify its position relative to the line's end point. This can be achieved by entering a value to adjust the distance of the Fly Through Line along the line direction and/or utilizing the **+/-** buttons to incrementally change the value.

Image Scroller

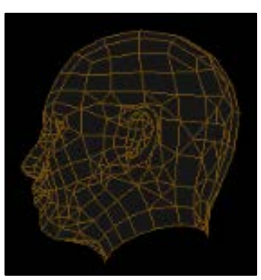
The Image Scroller allows you to scroll through images displayed in a viewport using a slider control. It appears inset vertically within the right-hand side of the viewport that is currently under the mouse cursor.

> **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. 110) or via user preferences (see Configuring System and User Settings Pg.75).

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.

Using the General Toolbar

The General Toolbar provides the main access to the application's interactive tools. It appears inset vertically within the top-left hand corner of the viewport that is currently under the mouse cursor. Some tools within the General Toolbar are grouped according to their function and can be accessed individually by expanding the tool grouping. All the tools within the Toolbar are also available from the Popup Menu (see Using the Popup Menu Pg. 97). For details on using the interactive tools, see Interactive Tools Pg.99.

> **To select a tool**

1. Left click on any tool button within the General Toolbar.

2. The tool will become selected, and the tool button will be colored to indicate that it has been selected.

> **To select a tool from a tool grouping**

1. Left click on the button beside the tool where the grouping exists.
2. Identify the tool for selection.
3. Left click on the tool button within the tool grouping.

Using Custom Toolbars

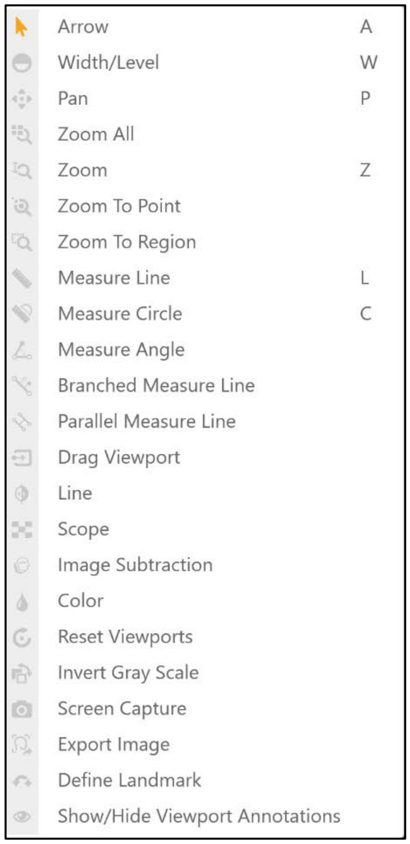
Some steps and tasks provide custom toolbars within their viewports, containing tools that are only relevant in a particular workflow context. These toolbars are oriented horizontally and positioned at the bottom of the viewport currently under the mouse cursor. Unlike the tools contained within the General Toolbar (see Using the General Toolbar Pg. 96), these tools are not accessible via the Popup Menu (see Using the Popup Menu Pg. 97), but may be contained within the Custom Toolbar or user interface panel specific to the workflow 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. It also shows the Tool Hot Key corresponding to those interactive tools which respond to keyboard input (see Tool Hot Keys Pg. 99). 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 select the appropriate option from the popup menu.



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

Tool Hot Keys

In addition to the General Toolbar (see Using the General Toolbar Pg. 96) and the Popup Menu (see Using the Popup Menu Pg. 97), 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
C	Measure Circle
L	Measure Line
P	Pan
W	Width/Level
Z	Zoom

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.
   - Hold down the CTRL key while clicking and dragging the mouse vertically and/or horizontally to cause a more significant variation in window level and/or window width.

When using the Width/Level tool with two image series that are blended, the secondary series will always be affected unless the primary series is fully blended (i.e., image blend slider at 100%). If the primary series is fully blended, then the Width/Level tool will affect that series. Alternatively, the width/level of the primary series can be changed by un-blending 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. 86 for additional details.

Zoom Tools

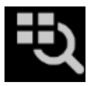
There are four separate tools for changing the zoom level.

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.

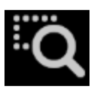


Zoom All

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 Tools

There are four separate tools which allow you to create measurement graphics on images loaded into the application.

Measure Line

1. Do one of the following to measure the linear distance, in millimeters, between two points on an image:

    - 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. Hold down the CTRL key to constrain the movement along a fixed direction (at 45° increments). 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 be shown, by default, at the mid-point between the two end points. Hold down the CTRL key while clicking and dragging either of the end points to constrain the movement along the current direction of the measure line.

5. To move the measure line, click and drag on the line joining the two end points.

6. You may align the end points of the measure line to the viewport crosshair position and/or any other measurement graphic anchor point by moving the measure line end point near these positions. Doing so will align the measure line end point with the location of interest and display a reticle graphic indicating that the points are coincident.

Measure Circle

1. Do one of the following to measure the diameter of a circle, in millimeters, on an image:

    - From the Toolbar, click the Measure Circle button.
    - Right-click any viewport and click **Measure Circle**.

2. Click at the desired center and drag to define a radius, in millimeters, 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 anchor point using either the Measure Circle tool or the default Arrow tool. The diameter value will be shown at the outside anchor point along the circumference of the circle, so that it can be positioned at any desired point around the circle.

5. To move the circle, click and drag at any other point on the circumference of the circle and/or on the radius anchor point.

6. You may align the measure circle anchor points to the viewport crosshair position and/or any other measurement graphic anchor point by moving the anchor point near these positions. Doing so will align the measure circle anchor point with the location of interest and display a reticle graphic indicating that the points are coincident.

Measure Angle

1. Do one of the following to measure the angle, in degrees, between two lines drawn on an image:
   - From the Toolbar, click the Measure Angle Line button.
   - Right-click any viewport and click **Measure Angle**.

2. Click and drag to draw a line across the span on the image for which an angle will be measured. Hold down the CTRL key to constrain the movement along a fixed direction (at 45° increments). Initially, a line graphic with three anchor points will be drawn. The tool will display the angle formed between the lines joining each of the graphic's end points and the middle anchor point.

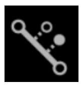
3. When you release the mouse button, the measure angle graphic and angle value (in degrees) will remain on screen.

4. Click and drag any of the measure angle graphic's anchor points to change the angle between the lines joining each of the end points to the middle anchor point. As each anchor point position changes, the angle (in degrees) between the lines from the middle anchor point to each of the graphic's end points will update.

5. Measure angles can be edited by clicking and dragging any of the measure line's anchor points using either the Measure Angle tool or the default Arrow tool. The angle value will be shown at the middle anchor point by default. Hold down the CTRL key while clicking and dragging either of the end points to constrain the movement along the direction of the line joining the middle anchor point and the end point of interest.

6. To move the measure angle graphic, click and drag on either of the lines joining the middle anchor point to the graphic's end points.

7. You may align any of the measure angle graphic anchor points to the viewport crosshair position and/or any other measurement graphic anchor point by moving the angle graphic end point near these positions. Doing so will align the measure angle end point with the location of interest and display a reticle graphic indicating that the points are coincident.



Branched Measure Line

1. Do one of the following to draw a measure line graphic which displays the linear distance between two points, in millimeters, as well as the perpendicular distance between the drawn line and a given point, segregated at one-third increments along the line's length:

    - From the Toolbar, click the Branched Measure Line button.
    - Right-click any viewport and click **Branched Measure Line**.

2. Click and drag to draw a line across the span on the image to be measured. Hold down the CTRL key to constrain the movement along a fixed direction (at 45° increments). The tool will display a line graphic representing the length of the drawn line, as well as two dotted lines drawn perpendicular to the line graphic, segregated at one-third increments along its length. Each dotted line graphic will be drawn at a default distance of 3 mm from the axis of the line graphic. The current length of the measure line will be shown at one of the line's end points.

3. When you release the mouse button, the measure line, distance value and segregated perpendicular lines drawn at one-third increments along the line's length will remain on screen.

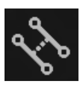
4. Click and drag each of the measure line's end points to change the linear distance between the two points. As each end point position changes, the distance value, in millimeters, will be updated. Hold down the CTRL key while clicking and dragging either of the end points to constrain the movement along the direction of the measure line.

5. Click and drag on either of the segregated line anchor points to change the perpendicular distance of each line relative to the axis of the line graphic. As each anchor point position changes, the perpendicular distance value, in millimeters, will be updated. Hovering the mouse over each of the segregated lines will display the perpendicular distance to the line's axis, in millimeters. The anchor points can be dragged on either side of the graphic line's axis.

6. Branched measure lines can be edited by clicking and dragging on either the line graphic's end points or the end points of the segregated perpendicular lines, using the Branched Measure tool or the default Arrow tool. The distance value between the two end points will be shown, by default, at one of the end points. The distance between each of the segregated perpendicular line anchor points and the line graphic's axis will be shown when the mouse is hovered over either of the segregated lines.

7. To move the branched measure line, click and drag on any of the lines which make up the graphic.

8. You may align the anchor points of the branched measure line to the viewport crosshair position and/or any other measurement graphic anchor point by moving the point of interest near these positions. Doing so will align the branched measure line anchor point with the location of interest and display a reticle graphic indicating that the points are coincident.



Parallel Measure Line

1. Do one of the following to draw a measure line graphic which displays the linear distance between two parallel lines, in millimeters, as well as the length of each parallel line:

    - From the Toolbar, click the Parallel Measure Line button.
    - Right-click any viewport and click **Parallel Measure Line**.

2. Click and drag to draw a line across the span on the image to be measured. Hold down the CTRL key to constrain the movement along a fixed direction (at 45° increments). The tool will display two measure line graphics drawn parallel to one another, with a dotted line drawn perpendicular to the parallel lines joined at their mid-point. The two parallel measure line graphics will initially be drawn with a default perpendicular distance of 6 mm between them. The current length of each parallel measure line will be shown at each of the line's end points. The length of the perpendicular dotted line displaying the distance between the two lines will be shown at its midpoint.

3. When you release the mouse button, the parallel measure lines, their distance values, the perpendicular distance line, and its distance value will remain on screen.

4. Click and drag each of the parallel measure line's end points to change the linear distance of the parallel measure line of interest. As each end point position changes, the distance value, in millimeters, of the edited parallel line will be updated. Additionally, the orientation of the corresponding parallel measure line shall update to ensure that it is always parallel to the edited measure line. Hold down the CTRL key while clicking and dragging either of the end points to

constrain the movement along the direction of the measure line. Doing so will not cause any updates to the corresponding parallel measure line, since no orientation changes to parallel measure line have been made.

5. To move the two parallel measure lines in tandem, click and drag on either of the lines joining the end points of each parallel measure line.

6. Click and drag on either of the perpendicular line anchor points to change the perpendicular distance between the two parallel measure lines. To move the perpendicular line's position along the two parallel measure lines, click and drag on the dotted line joining the two end points.

7. Parallel measure lines can be edited by clicking and dragging on either the parallel line graphic's end points or the end points of the perpendicular line joining the two parallel lines, using the Parallel Measure Line tool or the default Arrow tool. The distance value for each parallel line will be shown, by default, at one of the end points of each measure line. The distance between the two parallel lines will be shown by default at the midpoint of the perpendicular dotted line drawn between the two parallel lines.

8. You may align the anchor points of the parallel measure line to the viewport crosshair position and/or any other measurement graphic anchor point by moving the point of interest near these positions. Doing so will align the parallel measure line anchor point with the location of interest and display a reticle graphic indicating that the points are coincident.

To delete a measurement graphic created using any of the Measure Tools, do one of the following:

- Right-click on the measurement graphic and select **Delete**
- Drag the measurement graphic over the icon positioned in the bottom left corner of the currently selected viewport. This icon appears when you begin moving the measurement graphic.

To move any measurement value from its default location along the measurement graphic, click on the value and drag it away from its current position. If you move the measurement graphic, the measurement value will remain at its position on screen and will not move along with the graphic. If you would like to return the value to its original position, drag it over top of the reticle icon positioned at the default location of the value when the measurement graphic was drawn. In this position, the measurement value will move along with the measurement graphic as it is moved.

Image Blend Tools

There are four tools that can be used when blending image series together (see Using Thumbnails Pg. 86).

 **Scope**

1. Do one of the following to display the secondary image series inset in a square window overtop of the primary series:

    - 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 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. Alternatively, right click anywhere on the border of the scope and select **Close Scope Window** to close the window.

 **Line**

1. Do one of the following to present a split blended view between primary and secondary series:

    - From the Toolbar, click the Line button.
    - Right-click the desired viewport and click **Line**.

2. Click and drag 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. Dragging the mouse horizontally across the viewport will create a vertically-oriented split blended view, whereby the primary series content is displayed to the left of the line, and the secondary image series content is displayed to the right of the line. Dragging the mouse vertically across the viewport will create a horizontally-oriented split blended view, whereby the primary series content is displayed overtop of the line, and the secondary image series content is displayed below the line.

4. If you are using a mouse with a mouse wheel, you can rotate the mouse wheel to cause the secondary and primary 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. Alternatively, right click anywhere on the line and select **Close Line Tool** to dismiss the blend line.

Color

1. Do one of the following to apply color to the image blend between two image series:

    - From the Toolbar, click the Color button.
    - Right-click the desired viewport and click **Color**.

2. This will apply color to the secondary image series content. The Image Blend Color configured in the System Configuration Window will be used as the image blend color. To apply a different color to the secondary image series content, use the System Configuration Window to change the Image Blend Color (see Configuring System and User Settings Pg. 75).

3. To remove color from the image blend, select the Color tool again. This will toggle the image blend back to greyscale.

Image Subtraction

1. Do one of the following to subtract pixel intensities between two blended image series:

    - From the Toolbar, click the Image Subtraction button.
    - Right-click the desired viewport and click **Image Subtraction**.

2. This will apply a blend such that each rendered pixel represents an intensity subtraction between the primary and secondary series being blended. Each pixel rendered in the blend will reflect the grayscale intensity difference between the two corresponding images at that pixel value. This means that pixels with identical intensity values between the two blended images will appear with no signal rendered (i.e., black). When blending CT and MRI scans together, one end result will be that bony structures from the CT scan will be overlaid on soft tissue structures from the MRI scan.

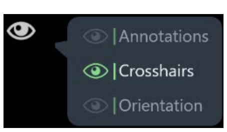
3. If you are using a mouse with a mouse wheel, you can rotate the mouse wheel to change the direction of the intensity subtraction. By default, the tool subtracts secondary series pixels from those in the primary series. Using the mouse wheel, you may change the direction of the subtraction so that primary series pixels are subtracted from those in the secondary series.

4. To remove the image subtractive blend from the viewport, use the relative blend slider in the Thumbnail Bar (see Using Thumbnails Pg. 86) to re-apply a blend between the two selected image series. This will toggle the image blend back to an additive blend.

Note: Pixel intensity values used by the Image Subtraction Tool are affected by the Width/Level display settings (see Window Width and Level Tool Pg. 100) applied to each image series being blended. This allows you to set comparable intensities on scans that would otherwise be too different to compare through intensity subtraction techniques.

Show/Hide Crosshairs, Annotations and Orientation Indicators

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



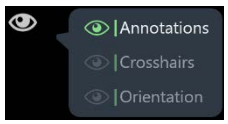
To show or hide crosshairs

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**.



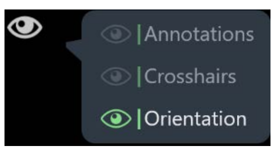
To show or hide annotations

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
    - image blends

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. 73).

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 dialog window will prompt you for a filesystem location on the workstation where you would like to save the screen capture. By default, this location will reflect the current session folder. Note that only screen captures saved to this default session folder will be included in the procedure report (see Using the Procedure Report Window Pg. 73) and exported with the session (see Using the Session List Window Pg. 70).

3. 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. 79).

Export Image Tool

Use the Export Image Tool to save an individual viewport image in DICOM format to the local filesystem on the workstation. This can be accomplished using the original image resolution of the series rendered in the viewports or using a system configured image resolution.

Export viewport image

1. Do one of the following:

   - From the Toolbar, click the Export Image button.
   - Right-click any viewport and click **Export Image**.

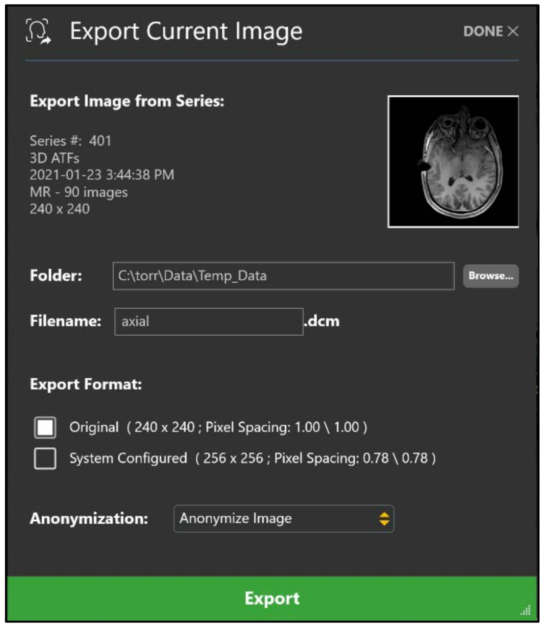
2. A floating window will appear prompting you to specify the parameters for saving the selected viewport image as an individual DICOM file.

   - Folder – Select **Browse …** to specify a folder on the local workstation filesystem where the viewport image will be exported to. A dialog window will prompt you for a filesystem location on the workstation where you would like to save the image file.

   - Filename – Specify a name for the image file to be saved.

   - Export Format – Choose one of two export formats: 1) **Original**: The image resolution of the series loaded in the application viewports; or 2) **System Configured**: A custom image resolution defined locally by the application.

   - Anonymization – Specify whether the image file will be saved in anonymized format to the selected filesystem location.



When a viewport image is saved with the Anonymization option specified, any fields in the DICOM header that contain protected health information will be blanked out in the exported DICOM image file. This ensures that the image file can be exported without the risk of protected health information exposure. If the Anonymization option is not specified, ensure that the exported DICOM image file is saved to an encrypted folder on the workstation filesystem to prevent exposure of protected health information.

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3. A message pop-up will appear in the bottom right corner of the application window, indicating the file location of where the image file was saved on the workstation. This message can also be reviewed using the Application Log Window (see Using the Application Log Window Pg. 79).

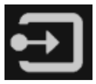
Single / Multi Viewport Tool

 **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.

Define Landmarks Tool

Define landmark

Ensure that the anatomical coordinate system has been explicitly reviewed using the ACPC Task (see ACPC Task Reviewing Landmarks Pg. 228) prior to using the Define Landmarks Tool.

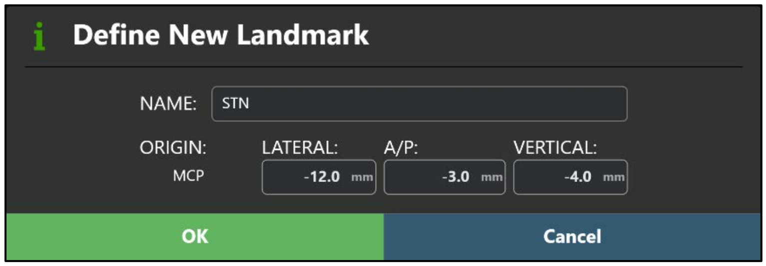
---

1. Move the crosshairs (see Changing Crosshair Positions Pg. 93) to the anatomical location where you would like to define a landmark.

2. Do one of the following:

   - From the Toolbar, click the Define Landmark button.
   - Right-click any viewport and click **Define Landmark**.

3. A window will display prompting you to enter a name and confirm the anatomical coordinates for the landmark to be created.



4. Select **Ok** to save the landmark.

5. See Managing Landmarks Pg. 116 for details on how to manage landmarks created using the Define Landmarks tool.

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.

Managing Landmarks

You can save and manage any number of pre-defined locations in anatomical coordinates, called "landmarks", in any workflow step or task. Once saved, these pre-defined locations will be available to you or other users for all subsequent procedures.

> **To save a landmark**

1. Ensure that your AC/PC locations have been verified (see ACPC Task *Reviewing Landmarks* Pg. 228).

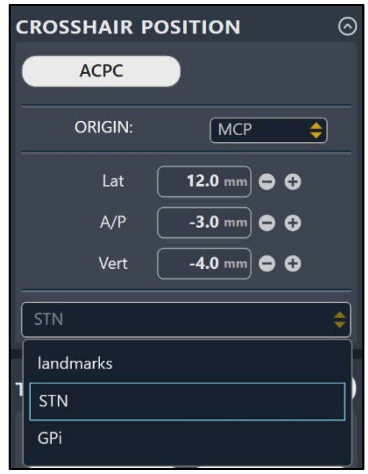
2. Use the **Define Landmarks Tool** (see Define Landmarks Tool Pg. 115).

> **To correlate to a landmark**

1. Ensure that the viewport supports displaying crosshairs and that your AC/PC locations have been verified (see ACPC Task *Reviewing Landmarks* Pg. 228).

2. Locate the Current Point Control and click the icon (see Using the Viewport Crosshairs Pg. 91)

3. Click the **landmarks** drop-down menu and select the landmark to which you wish to reposition the crosshairs.



4. The viewport's crosshairs will correlate to the location of the landmark in anatomical coordinates.

> To change the coordinate origin for a landmark

1. Locate the Current Point Control (see Using the Viewport Crosshairs Pg. 91).

2. Change the origin for anatomical coordinates using the **ORIGIN** drop-down. The selected origin will be used to save the coordinates associated with the landmark when the **Define Landmarks Tool** is used (see Define Landmarks Tool Pg. 115).

> To modify a landmark

1. Open the **PREFERENCES** tab in the System Configuration Window (see Configuring the List of System Preferences Pg. 57).

2. Select the landmark of interest by filtering based on side and then choosing one from the list.

3. Change any of the field values: **LATERAL**, **A/P**, **VERTICAL**.

4. Select **Apply** to save the changes made.

> **To remove a landmark**

1. Open the **PREFERENCES** tab in the System Configuration Window (see Configuring the List of System Preferences Pg. 57).

2. Select the landmark of interest by filtering based on side and then choosing one from the list.

3. Click the  icon.

4. Select **Apply** to save the changes made.

Working with Trajectory Annotations

The application provides several general tools that can be used with trajectory annotations defined in the application. This also includes annotations representing the inserted device track.

> **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. 83).

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

1. Select the Arrow tool (see Arrow Tool Pg. 99).

2. Do one of the following:

   - Reposition the crosshairs in the viewports (see Changing Crosshair Positions Pg. 93) to a location where you would like to set the target point. Use the **SET Target** 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** or **Trajectory Orthogonal** orientation (see Changing a Viewing Layout Orientation Pg. 90), the following mechanisms can be used to edit the target point in the **Trajectory Orthogonal 1**, **Trajectory Orthogonal 2, Trajectory Coronal**, **Trajectory Sagittal** or **Trajectory Axial** 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.

  - 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** or **Trajectory Orthogonal** orientation (see Changing a Viewing Layout Orientation Pg. 90), the target point can be edited in the **Trajectory Axial** or **Trajectory Perpendicular** viewports by positioning the Fly Through Line at or below the target point (see Fly Through Line Pg. 94) 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**

1. Select the Arrow tool (see Arrow Tool Pg. 99).

2. Do one of the following:

   - Reposition the crosshairs in the viewports (see Changing Crosshair Positions Pg. 93) to a location where you would like to set the entry point. Use the **SET Entry** button in the step's control panel to set the entry point at the current crosshair location.

   - If the viewport is set to the **Trajectory** or **Trajectory Orthogonal** orientation (see Changing a Viewing Layout Orientation Pg. 90), the following mechanisms can be used to edit the entry point in the **Trajectory Orthogonal 1**, **Trajectory Orthogonal 2**, **Trajectory Coronal**, **Trajectory Sagittal**, or **Trajectory Axial** 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 above 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.

- If the viewport is set to the **Trajectory** or **Trajectory Orthogonal** orientation (see Changing a Viewing Layout Orientation Pg. 90), the entry point can be edited in the **Trajectory Axial** or **Trajectory Perpendicular** viewports using the following mechanism:

  - Position the Fly Through Line above the target point (see Fly Through Line Pg. 94) and then click and drag the trajectory cross section. Doing so will cause the entry point to pivot about its target point.

> To twist the crosshairs about a trajectory annotation's axis

1. If the viewport is set to the **Trajectory Perpendicular** orientation, hover the mouse over that viewport and select the **Twist Trajectory** tool from the custom toolbar (see Using Custom Toolbars Pg. 97).

2. Do one of the following:

   - Click and drag the crosshair line in the **Trajectory Perpendicular** viewport to cause the crosshairs to twist about the axis of the trajectory annotation. Performing this action will change the orientation of the **Trajectory Orthogonal 1** and **Trajectory Orthogonal 2** viewports to match the twisted crosshair lines, while keeping the trajectory's entry and target points fixed.

   - Hold down the CTRL key while clicking and dragging one of the crosshair lines in the **Trajectory Perpendicular** viewport to cause the selected crosshair line to twist about the trajectory axis, while keeping the other crosshair line fixed. Performing this action will change the orientation of either the **Trajectory Orthogonal 1** or **Trajectory Orthogonal 2** viewport, depending on which crosshair line was twisted. In this case, the orientation of the viewport will match the twisted crosshair, while keeping the trajectory's entry and target points fixed.

Note: Any crosshair twist applied for a given trajectory is saved by the application so that any viewing layouts containing Trajectory Orthogonal 1, Trajectory Orthogonal 2, and Trajectory Perpendicular viewports will consider this twist when displaying any images in its viewports.

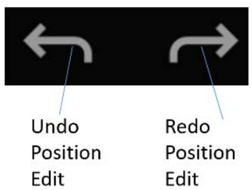
> **To reset the crosshair twist applied to a trajectory annotation**

1. If the viewport is set to the **Trajectory Perpendicular** orientation, hover the mouse over that viewport and select the **Reset Trajectory Twist** tool from the custom toolbar (see Using Custom Toolbars Pg. 97).

2. Observe any twist previously applied to the crosshairs is reset back to its default value.

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

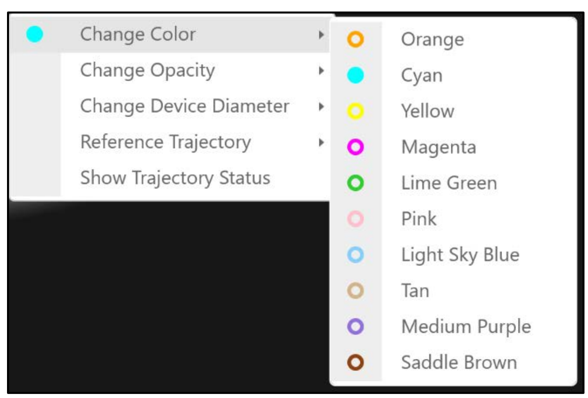
Use the custom toolbar inset within the viewport to undo or redo any number of position changes associated with the editable annotation.



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

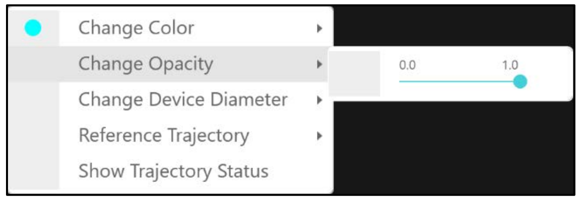
1. Right-click on the trajectory annotation cross section in any viewport and select **Change Color** from the menu:

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 cross section in any viewport and select **Change Opacity** from the menu:



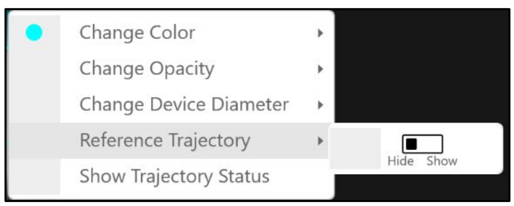
2. Use the slider bar to change the opacity of the trajectory annotation.

> **To compare a trajectory that was created using one from a different step**

1. Ensure that the trajectory selected was created from a previous workflow step. This means that it was imported / created in a different workflow step and transformed into the frame of reference of the current workflow step.

2. Visualize the trajectory in any viewport named **Trajectory Axial** or **Trajectory Perpendicular.** Comparison between trajectories in this manner can only be performed in viewports with these identifiers.

3. Select **Reference Trajectory** from the context menu.

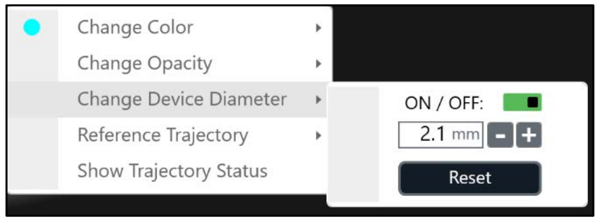


4. Toggle between **Hide** and **Show** to display the trajectory that was used to create the currently selected trajectory.

5. The trajectory from a previous workflow step that was used to create the currently selected trajectory will be displayed as follows:

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

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



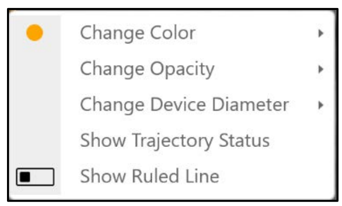
2. Type in a new value for the device diameter or use the **+/-** buttons to change the value incrementally.

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.

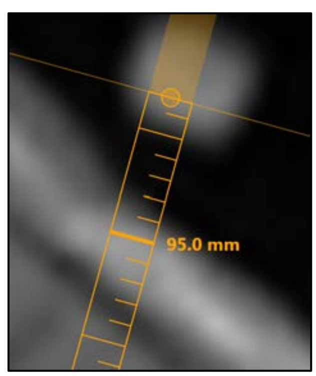
> **To display distance graduations along a trajectory annotation**

1. If the viewport is set to the **Trajectory** or **Trajectory Orthogonal** orientation (see Changing a Viewing Layout Orientation Pg. 90), right-click on the trajectory annotation cross section in the viewport and identify the **Show Ruled Line** entry from the menu:



2. Use the toggle button to switch between displaying graduated markings at one-millimeter increments along the trajectory annotation or not.

3. If distance graduations are displayed along the trajectory annotation, you may hover the mouse over the markings to see the distance from the trajectory's target point.



4. You may also double-click on any of the distance graduations to display the distance from the trajectory's target point. Double-clicking on the distance graduation again will hide the distance from the trajectory's target point.

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

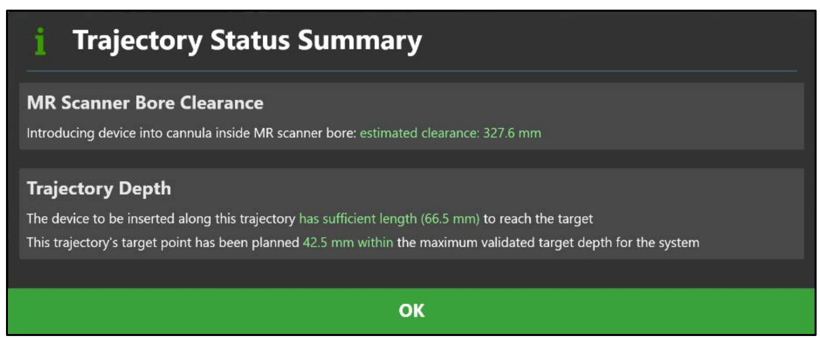
1. Right-click on the trajectory annotation cross section in any viewport and select **Show Trajectory Status** from the menu.

2. A dialog will display:

   - During an MRI Workflow (see MRI Workflow Pg. 39), the MR scanner bore clearance for the device to be inserted along the selected trajectory. (Note that this information is not shown while in the Pre-Op Step, because the patient position during preoperative image acquisition will not reflect the patient position on the day of surgery).

   - The amount of device clearance required to reach the selected trajectory's target point.

   - The amount of clearance from the maximum validated target depth for the system.

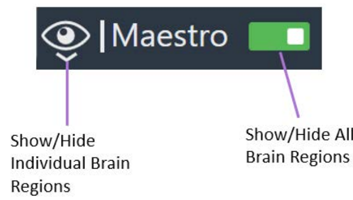


Working with Maestro Brain Regions

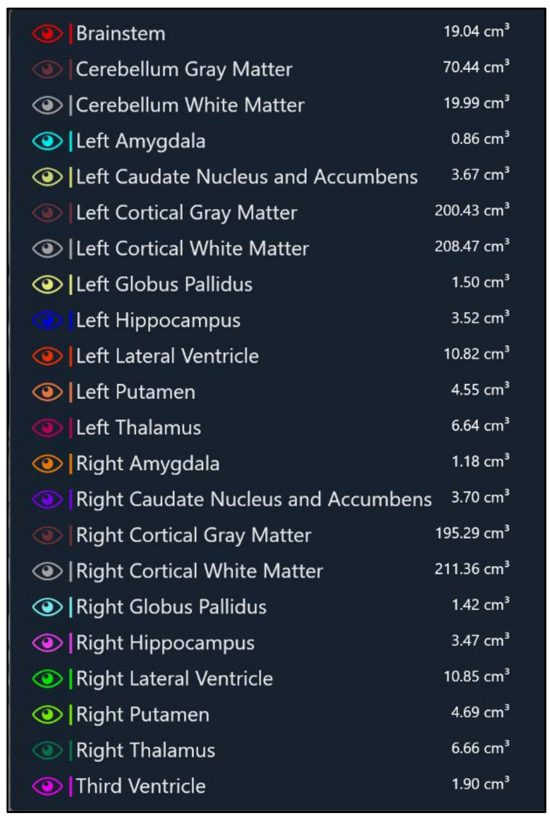
The application has several tools for working with brain region overlays produced from ClearPoint Maestro Brain Model segmentations. For details on how to execute a fully automated segmentation of brain structures from a given scan, see Maestro Task Segmenting Brain Structures Pg. 264.

> **To change the visibility of one or more brain regions**

1. Click on the toggle switch beside the **Maestro** toggle button in the step's control panel to control the visibility of all segmented brain regions displayed in the viewports.



2. Click on the **Maestro** visibility toggle button to control the visibility of each segmented brain region using a menu control. For the brain region of interest, use the visibility toggle button to switch between showing or hiding the overlay.



> **To change the opacity of brain regions**

1. Use the slider bar beside the **Maestro** toggle button to control the opacity of all segmented brain regions displayed in the viewports. Drag to the left to decrease

the opacity of the brain regions. Drag to the right to increase the opacity of the brain regions.

Note: Changing the opacity of brain regions only affects the cross-sectional graphics shown in the multi-planar reformat (2D) viewports. Opacity changes are not applied to three-dimensional representations of the brain regions in volumetric (3D) viewports.

> **To review the volume measurements for one or more brain regions**

1. Click on the **Maestro** visibility toggle button. For each segmented brain region shown in the menu, review its associated volume measurement.

Shutdown and Exit

Exiting the application indicates that you have finished working with the ClearPoint Workstation.

> **To exit the application**

Select from  the far-right hand corner of the main application window or from the Splash Screen (see Launching the Splash Screen Pg. 50).

Preoperative Planning

This section describes how to use the ClearPoint Workstation for preoperative planning. To achieve 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 master series, and complete trajectory planning using the preoperatively acquired images.

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, external hard drive) or from an existing DICOM archive (e.g., PACS).

Loading Preoperative Images

To create a preoperative plan, you will need to load a set of patient scans acquired prior to surgery. Patient scans can be loaded onto the workstation from removable DICOM media, such as CD or external hard drive, or alternatively, may be pushed to the workstation via DICOM network transfer from an existing DICOM archive system.

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. 21 for additional guidance regarding connecting removable media to the workstation.**

> **To load preoperative images**

1. Start a new session, choosing an appropriate workflow for which to create a preoperative plan. (see Starting a New Session Pg. 60).

2. Select the Pre-Op step using the Step Selector (see Using the Step Selector Pg. 81).

3. Use the DICOM Media Browser to browse to the directory containing the preoperative images of the patient (see Using the DICOM Media Browser Pg. 72). Alternatively, identify the DICOM archive that can be used to transfer the preoperative images to the workstation.

4. Select and load one or more image series (see Using the DICOM Media Browser Pg. 72). 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.

5. By default, the software will select one of the loaded image series as the master series.

6. The software will automatically pop-up the Fusion task (see Fusion Task Fusing Images Pg. 219) to allow you to fuse these images with the master series. Use the task to fuse each loaded image series with the master series.

7. The application will then automatically detect the anatomical reference points from the master series selected.

8. For any subsequent image series loaded in the Pre-Op step, the software will automatically pop-up the Fusion task (see Fusion Task Fusing Images Pg. 219) to allow you to fuse these additional images with the master series.

9. At any given time, you may use the Fusion task (see Fusion Task Fusing Images Pg. 219) within the step to assess and/or edit the fusion transformation between any given image series and the master series.

> **To select a different master scan**

To change the scan that will serve as the base coordinate space for all other scans loaded in this step (i.e., the "master scan"), use the Thumbnail Bar to change the primary series image (see Using Thumbnails Pg. 86). Any additional series loaded can be blended with the master series after using the Fusion Task (see Fusion Task *Fusing Images* Pg. 219) to fuse the series together.

Pre-Op Step Setting Preoperative Trajectories

The Pre-Op Step allows you to create one or more trajectory paths into the brain, using images that were acquired prior to surgery. Each trajectory path is made up of a pair of entry and target points planned using the application. The Pre-Op Step provides a comprehensive set of tools that can be used to define, plan, and review any number of trajectories defined on preoperative images.

When images are initially loaded into the ClearPoint Workstation with the Pre-Op Step selected, the application automatically detects and identifies candidate positions for the anatomical reference points on the master series. Together, these points define the AC-PC (anatomical) coordinate system used by the application to align its viewports to anatomical orientations, while also providing you with the ability to plan trajectories relative to this coordinate system.

The following high-level features are offered by the Pre-Op Step:

- Defining one or more trajectory paths (see Creating Trajectories Pg. 131).
- Editing the target and/or entry point for one or more trajectory paths into the brain (see Editing Trajectory Points Pg. 133).
- Changing the annotation properties associated with one or more trajectory paths (see Editing Trajectory Properties Pg. 136).
- Removing unwanted trajectory paths previously defined (see Removing Trajectories Pg. 138).
- Reviewing initially planned trajectory paths (see Reviewing Trajectories Pg. 138).

Within the Pre-Op step, you have the option to perform the following workflow-specific tasks:

- The Fusion Task (see Fusion Task *Fusing Images* Pg. 219) may be used to review and / or modify the fusion transformation between any loaded image series and the master series.
- The ACPC Task (see ACPC Task *Reviewing Landmarks* Pg. 228) may be used to review and / or modify the anatomical reference points automatically detected by the software. Doing so enables the ability to set trajectories relative to the anatomical coordinate system.
- The Compare Task (see Compare Task *Comparing Images* Pg. 232) may be used to compare preoperative image series in their individual acquisition planes or standard scanner planes.
- The Preview Frame Task (see Preview Frame Task Visualizing Frames Prior to Mounting Pg. 254) may be used to visualize one or more frames positioned on the patient prior to frame mounting, for each trajectory path defined.
- The Maestro Task (see Maestro Task Segmenting Brain Structures Pg. 264) may be used to automatically segment brain structures from any preoperatively-loaded MR image series using the ClearPoint Maestro Brain Model.

Trajectory Planning Viewing Layouts

The Pre-Op Step provides 3 viewing layouts that can be used to create, edit, and review trajectory paths into the brain. These viewing layouts are selectable via the Layout Selector (see Selecting a Viewing Layout Pg. 83).

1) Pointwise Layout – This layout provides you with the ability to create, edit and review trajectories by analyzing the trajectory's entry and target points individually. The Pointwise Layout provides 3 associated viewport orientations that can be switched throughout the trajectory planning process:

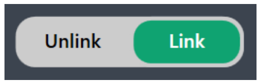
    - Scanner View – Aligns viewports to scanner axes.
    - Anatomical View – Aligns viewports to ACPC (anatomical) planes.
    - Trajectory View – Aligns viewports such that the Trajectory Coronal and Trajectory Sagittal planes are orthogonally aligned along the trajectory path, and the Trajectory Axial plane is aligned perpendicular to the trajectory path. This view is only available after at least one trajectory has been defined.

2) Review Layout – This layout provides you with the ability to create, edit and review trajectories by visualizing both entry and target points at the same time. It also provides a volume rendered view to review the planned trajectories in three dimensions. The Review layout provides a single viewing orientation, aligned along the currently selected trajectory.

3) Oblique & Pointwise Layout – This layout combines the functionality in the Pointwise and Review layouts, providing 6 viewports that can be used to create, edit, and review trajectories. The row of 3 viewports at the top of the viewing layout are analogous to those trajectory-oriented viewports shown in the Review layout. The row of 3 viewports at the bottom of the viewing layout are analogous to the viewports shown in the Pointwise layout. In this viewing layout, there are two distinct locations for the crosshairs. One crosshair location links the upper row of viewports, and the other crosshair location links the bottom row of viewports. You may decide to link the crosshairs in all 6 viewports, if desired.

> **To link viewing layout crosshairs**

1. Switch to the **Oblique + Pointwise** layout (see Selecting a Viewing Layout Pg. 83).
2. To link crosshairs between all 6 viewports in this layout, click the **Unlink/Link** toggle button in the Current Point Control inset in the step's control panel.



3. To un-link crosshairs between all 6 viewports, leaving the top row of viewports with a different crosshair location than the bottom row of viewports, click the **Unlink/Link** toggle button in the Current Point Control inset in the step's control panel.

Creating Trajectories

Using the Pre-Op Step, you may create one or more trajectory paths into the brain using preoperative images. Creation of a trajectory path involves explicitly selecting a side for which you would like to associate the trajectory.

> To create a trajectory annotation

1. Select a side for which you would like to associate a trajectory (see Selecting a Side Pg. 82).

2. If additional image series are required to plan your trajectory, load or acquire/transfer the scan(s) to the workstation, and use the Fusion Task (see Fusion Task *Fusing Images* Pg. 219) to fuse the scans with the master series.

3. If necessary, select an additional image series for blending with the master series using the Thumbnail Bar (see Using Thumbnails Pg. 86).

4. Change the crosshair position to a location within the master series or selected blended series that you wish to define either a target point or entry point on the trajectory path (see Changing Crosshair Positions Pg. 93). If you wish to view one or more segmented brain regions while defining a target or entry point location, you may display them using the **Maestro** visibility toggle button (see Working with Maestro Brain Regions Pg. 124).

5. Click on **New** from the step control panel under the **TRAJECTORY** group-box heading.

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.

- Target – Specify a location for the trajectory's target point. You may select **Custom** to manually enter coordinate values, in DICOM or ACPC (anatomical) space.

- Entry – Specify a location for the trajectory's entry point. You may select **Custom** to manually enter coordinate values, in DICOM or ACPC (anatomical) space.

- Device Diameter – Specify the diameter of the device to be inserted along the trajectory, in millimeters. The trajectory annotation will be rendered at the specified diameter.

7. Select **Add** to define a trajectory path in the user interface. Select **Cancel** to cancel the trajectory creation.

> **To copy an existing trajectory**

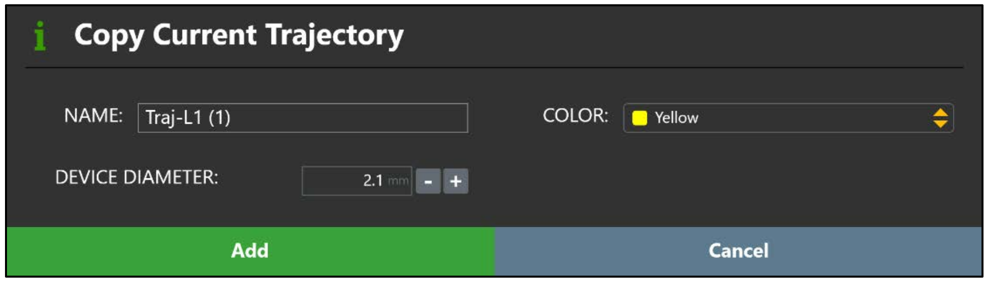
1. Use the Trajectory Selector available in the step control panel to select a trajectory annotation that you wish to copy (see Selecting a Trajectory Pg. 83).

2. Select **Copy** from the step control panel.

3. 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. By default, the name of the trajectory to be copied is combined with an index number to create a unique name. (Note: The application will prevent identical naming of trajectories).

- Color – Specify a color defining how the trajectory will be displayed in the user interface.
- Device Diameter – Specify the diameter of the device to be inserted along the trajectory, in millimeters. The trajectory annotation will be rendered at the specified diameter.



4. Select **Add** to create a copy of the currently selected trajectory in the user interface. Select **Cancel** to cancel the trajectory copy.

Editing Trajectory Points

The Pre-Op Step may also be used to edit any existing trajectory annotations previously defined.

> **To edit a target point**

1. Use the Trajectory Selector available in the step control panel to select a trajectory annotation whose target point you wish to edit (see Selecting a Trajectory Pg. 83).
2. If necessary, select an additional image series for blending with the master series using the Thumbnail Bar (see Using Thumbnails Pg. 86).
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. 93).
4. Select **SET Target** from the step control panel.
5. You may also edit the target point using mouse click and drag operations (see Working with Trajectory Annotations Pg. 118).
6. You may also use the **Target Depth** field to change the selected trajectory's target point along the direction of the trajectory path such that the distance from entry to target will match what is shown in the step control panel. You

can manually enter a new depth value or click the **+/-** buttons to change the value.

> **To edit an entry point**

1. Use the Trajectory Selector available in the step control panel to select a trajectory annotation whose entry point you wish to edit (see Selecting a Trajectory Pg. 83).

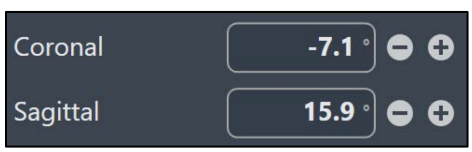
2. If necessary, select an additional image series for blending with the master series using the Thumbnail Bar (see Using Thumbnails Pg. 86).

3. Correlate the crosshairs to a new location within the master series or selected blended series where you wish to set the entry point (see Changing Crosshair Positions Pg. 93).

4. Select **SET Entry** from the step control panel.

5. You may also edit the entry point using mouse click and drag operations (see Working with Trajectory Annotations Pg. 118).

6. You may also use the **Coronal** and **Sagittal** fields to change the approach angles that the trajectory forms with each of the corresponding anatomical axes. Changing these values causes the trajectory's entry point to pivot about its target point to realize the specified angle formed with the corresponding anatomical plane. You can manually enter a new angle value or click the **+/-** buttons to change each value.



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

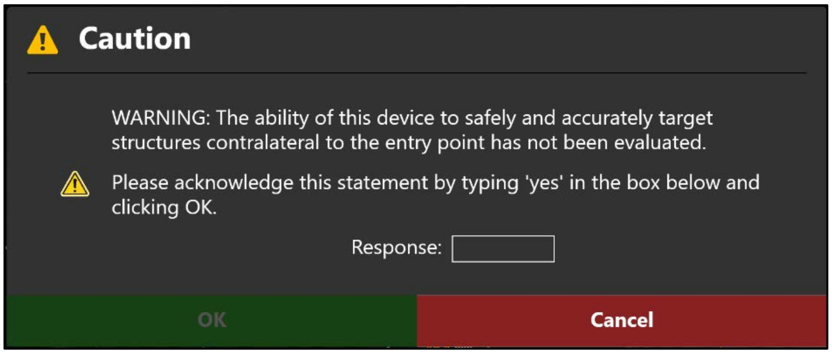
Use the **Trajectory Undo** and **Trajectory Redo** tools to undo or redo any trajectory point changes made to the selected trajectory annotation shown on screen.

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

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

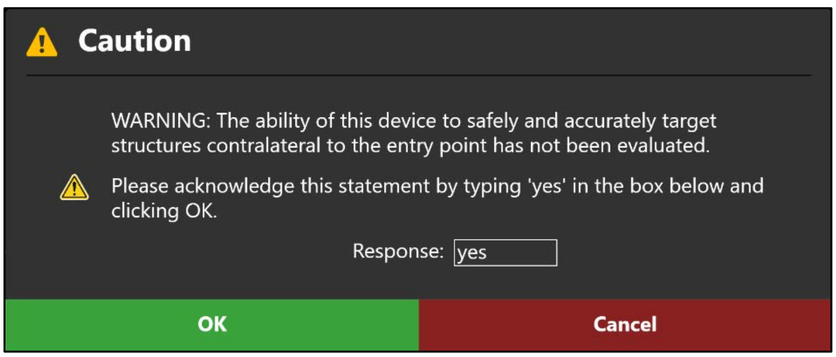
Defining Contralateral Targets

If you attempt to create or edit a trajectory such that the target point is contralateral to the associated entry point, you will be presented with the following warning.



If the edit was inadvertent, select **Cancel** and the change will be discarded.

To use your modified trajectory, you must type the word **yes** in the Response box.



Doing so will enable the **OK** button. Click **OK** to save your updated trajectory.

After you have accepted the new trajectory, the status area will continue to display the following reminder unless explicitly dismissed.

Caution: **When planning contralateral trajectories, be aware that structures greater than 125 mm from the entry point should not be targeted, as placement accuracy beyond 125 mm has not been validated. If structures greater than 125 mm are targeted, the application will display a warning. See Trajectory Depth is Beyond Maximum Validated System Depth Pg. 283.**

Editing Trajectory Properties

You may also use the Pre-Op Step to make changes to the properties associated with a trajectory annotation, including name, color, opacity, and device diameter.

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

1. Use the Trajectory Selector available in the step control panel to select a trajectory annotation for which you wish to change the name (see Selecting a Trajectory Pg. 83).

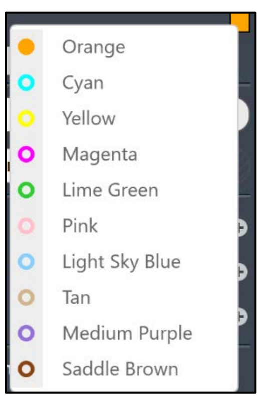
2. In the step control panel, click on the name of the currently selected trajectory. The field becomes editable and will allow keyboard input to change the name of the currently selected trajectory.

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

1. Use the Trajectory Selector available in the step control panel to select a trajectory annotation for which you wish to change the color (see Selecting a Trajectory Pg. 83).

2. In the step control panel, click on the colored square which reflects the color of the currently selected trajectory.

3. Select the desired color from the list of preset colors.



4. You may also change the color of any trajectory using the context menu associated with the annotation (see Working with Trajectory Annotations Pg. 118).

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

1. Use the Trajectory Selector available in the step control panel to select a trajectory annotation for which you wish to change the opacity (see Selecting a Trajectory Pg. 83).

2. Use the annotation context menu to change the selected trajectory's opacity (see Working with Trajectory Annotations Pg. 118).

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

1. Use the Trajectory Selector available in the step control panel to select a trajectory annotation for which you wish to change the device diameter (see Selecting a Trajectory Pg. 83).

2. Use the annotation context menu to change the selected trajectory's device diameter (see Working with Trajectory Annotations Pg. 118).

> **To change the crosshair twist about a trajectory annotation's axis**

1. Use the Trajectory Selector available in the step control panel to select a trajectory annotation for which you wish to change the crosshair twist (see Selecting a Trajectory Pg. 83).

2. Switch to the **Review** or the **Oblique + Pointwise** layout (see Selecting a Viewing Layout Pg. 83).

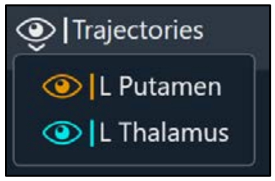
3. Select the **Trajectory Twist** tool in the **Trajectory Perpendicular** viewport (see Using Custom Toolbars Pg. 97).

4. Use mouse click and drag operations on the crosshairs in the **Trajectory Perpendicular** viewport to twist one or more crosshairs about the axis of the trajectory annotation (see Working with Trajectory Annotations Pg. 118).

5. If required, you may select the **Reset Trajectory Twist** tool in the **Trajectory Perpendicular** viewport to reset the crosshair twist about the trajectory axis back to its default value (see Using Custom Toolbars Pg. 97).

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

1. Use the **OVERLAYS** group-box in the step control panel to toggle the visibility of the currently selected trajectory and/or any other trajectory annotations that are defined on the currently selected side. If there is more than one trajectory defined on the currently selected side, click the **Trajectories** button to see a list of trajectories whose visibility can be toggled on or off.



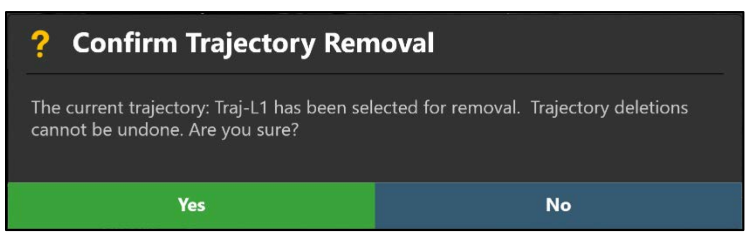
2. Use the **Show/Hide Viewport Annotations** tool to change the visibility of all trajectories (see Show/Hide Crosshairs, Annotations and Orientation Indicators Pg. 110).

Removing Trajectories

You may also use the Pre-Op Step to remove any unwanted trajectories defined in the application.

> **To delete a trajectory annotation**

1. Use the Trajectory Selector available in the step control panel to select a trajectory annotation that you wish to remove (see Selecting a Trajectory Pg. 83).
2. Select **Remove** from the step 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, automatically scroll through each path, 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 control panel to select a trajectory annotation that you wish to review (see Selecting a Trajectory Pg. 83).

2. Select **GO TO Target** from the step control panel to navigate to the selected trajectory's target point. Alternatively, if the **Review** or **Oblique + Pointwise** layouts are selected, you may also click the ⏭ button in the step control panel.

3. Select **GO TO Entry** from the step control panel to navigate to the selected trajectory's entry point. Alternatively, if the **Review** or **Oblique + Pointwise** layouts are selected, click the ⏮ button in the step control panel.

4. If the **Review** or **Oblique + Pointwise** layouts are selected, then you may automatically scroll from the selected trajectory's entry point to target point, using the ▶ button from the step control panel. To stop automatic scrolling along the selected trajectory path, click the ■ button. (Note: Automatic scrolling along the selected trajectory path will stop once the target point location is reached).

> **To review trajectory point distances**

1. Use the Trajectory Selector available in the step control panel to select a trajectory annotation that you wish to review (see Selecting a Trajectory Pg. 83).

2. Switch to the **Review** or the **Oblique + Pointwise** layout (see Selecting a Viewing Layout Pg. 83).

3. Click and drag the Fly Through Line along the currently selected trajectory (see Fly Through Line Pg. 94).

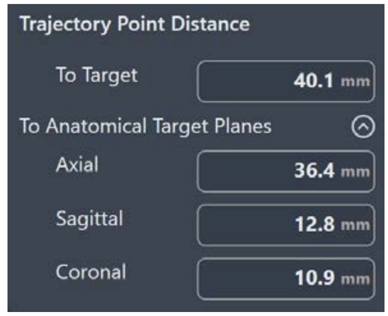
4. As the position of the Fly Through Line changes, the following trajectory point distances are shown in the step control panel:

    - To Target – Distance, in millimeters, from the current crosshair location to the target point, measured along the direction of the currently selected trajectory.

    - To Anatomical Axial Plane – Distance, in millimeters, from the current crosshair location to the anatomical axial plane passing through the target point. This distance is measured along the head-foot axis.

    - To Anatomical Sagittal Plane – Distance, in millimeters, from the current crosshair location to the anatomical sagittal plane passing through the target point. This distance is measured along the anterior-posterior axis.

- To Anatomical Coronal Plane – Distance, in millimeters, from the current crosshair location to the anatomical coronal plane passing through the target point. This distance is measured along the left-right axis.



> **To review trajectory depth measurements**

1. Use the Trajectory Selector available in the step control panel to select a trajectory annotation that you wish to review (see Selecting a Trajectory Pg. 83).

2. Use the annotation context menu to show the Trajectory Status Dialog (see Working with Trajectory Annotations Pg. 118).

Localize Mount Points

If a SNS workflow is being used to localize mount point locations on the patient, then the steps in this section may be skipped.

This section describes how to use image-based navigation with the ClearPoint Workstation to mount one or more SMARTFrame trajectory frame(s) onto the patient. To achieve this, acquire a whole head scan of the patient with SMARTGrid Planning Grid(s) affixed, complete trajectory planning, confirm and verify the positions of the grids in the application, and identify the intended locations where the frame(s) should be mounted on the patient.

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

- One or more SMARTGrid Planning Grids have been affixed to the patient.
- The patient has been appropriately positioned such that a scan can be obtained of the whole head.

Loading Intraoperative Grid Images

To begin localizing mount point positions on the patient's head, you will need to acquire a whole-head scan of the patient with one or more marking grids affixed. This can be accomplished using the scanner connected to the ClearPoint Workstation (see Interoperation with MRI Scanners Pg. 30 or Interoperation with CT Scanners Pg. 36 depending on the modality of the scanner being utilized). The acquired scan can then be transferred to the workstation and reviewed to ensure that correct anatomical coverage is acquired within the scan's field-of-view.

The whole-head scan with marking grids affixed 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 step selected. If additional scans are loaded that have a different frame of reference than the master series, you will be required to fuse these scans with the master series to use the images. See Fusion Task Fusing Images Pg. 219 for details.

> **To load intraoperative images used for localizing mount point(s)**

1. If a preoperative plan was created using the Plan Workflow, load the session and choose an appropriate workflow to execute the intraoperative procedure (see Using the Workflow Selector Pg. 80). Otherwise, start a new session choosing

an appropriate workflow for which to execute the intraoperative procedure (see Starting a New Session Pg. 60).

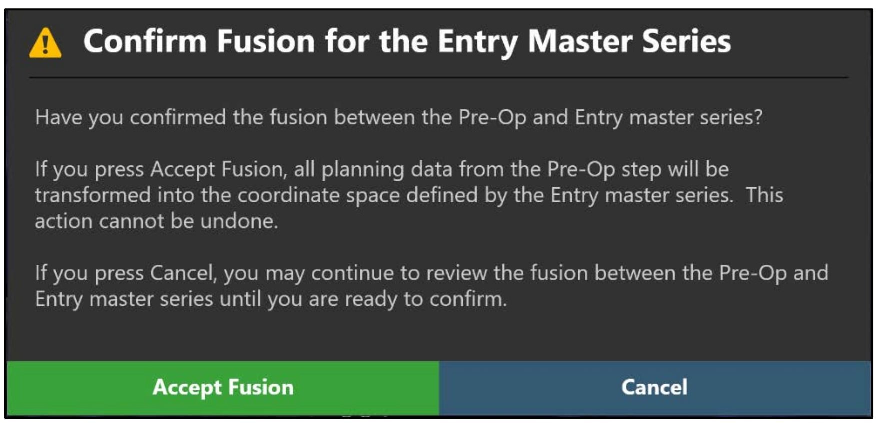
2. Select the Entry Step using the Step Selector (see Using the Step Selector Pg. 81).

3. Use the Scanner Console to acquire a whole-head scan of the patient with one or more marking grids affixed. Ensure that the scan's field-of-view completely encapsulates the entire head (including brain stem) and all affixed marking grids.

4. Transfer the whole-head scan to the workstation.

5. If you created a preoperative plan using the ClearPoint Workstation prior to activating this step (see Preoperative Planning Pg. 127), use the pop-up Fusion Task (see Fusion Task *Fusing Images* Pg. 219) to fuse the master series from the Pre-Op Step with the image series just loaded into the application.

6. If you created a preoperative plan, then when the Fusion Task is dismissed, you will be prompted to confirm the fusion between the Pre-Op and Entry Steps' master series. Select **Accept Fusion** to confirm that you have accepted the fusion between the two scans. Otherwise, choose **Cancel** to continue to review and/or modify the fusion between the two scans in the Fusion Task.



If you accept the fusion between the two master series, the application will transform all trajectories, segmented brain regions, and anatomical reference points created in the Pre-Op Step into the coordinate space defined by the intraoperative images containing the affixed marking grid(s). If you have not created a preoperative plan, the application will automatically detect the anatomical reference points from the loaded master series.

Upon receiving the whole-head scan, the application will automatically search for any SMARTGrid 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 (see SMARTGrid Not Found / Detected Incorrectly Pg. 279). In these instances, you may use the Grid Task (see Grid Task Editing Marking Grids Pg. 235) to manually detect additional marking grids and/or acquire additional scans containing the marking grids affixed to the patient.

> **To select a different master scan**

To change the scan that will serve as the base coordinate space for all other scans loaded in this step (i.e., the “master scan”), use the Thumbnail Bar to change the primary series image (see Using Thumbnails Pg. 86). Any additional series loaded can be blended without further action if they are in the same frame of reference as the master series. If they are not within the same frame of reference as the master series, use the Fusion Task (see Fusion Task *Fusing Images* Pg. 219) to fuse the series together to allow for image blending functionality in this step.

Entry Step Setting Intraoperative Trajectories

The Entry Step gives you the ability to revise any preoperative trajectories and/or create any number of new trajectory paths into the brain using a whole-head scan of the patient with SMARTGrid marking grids affixed. Trajectory planning at this stage in the workflow is performed for the purpose of determining mount point locations for the SMARTFrame trajectory frame(s) on the patient’s head during the procedure.

When images are first loaded into the ClearPoint Workstation with the Entry Step selected, the application automatically detects the position(s) of one or more marking grids that are affixed to the patient’s scalp. Reviewing and verifying the location of these marking grids within the application ensures correct localization of the mount points required to affix the frame(s) on the patient.

If you completed a preoperative plan prior to using the Entry Step, then any trajectories, segmented brain regions, and anatomical reference points created will be transformed into the coordinate space of the scan denoted as the master series defined in this step. These annotations may be reviewed or edited based on the currently loaded image series for purposes of trajectory planning.

Like the Pre-Op Step (see Pre-Op Step *Setting Preoperative Trajectories* Pg. 128), 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 to Localize Mount Points Pg. 144).
- Editing the target and/or entry point for one or more trajectory paths into the brain with marking grids affixed to the patient (see Editing Trajectories to Localize Mount Points Pg. 145).
- Changing the annotation properties associated with one or more trajectory paths (see Editing Trajectory Properties Pg. 136).
- Removing unwanted trajectory paths previously defined (see Removing Trajectories Pg. 138).

- Reviewing planned trajectory paths into the brain with marking grids affixed to the patient (see Reviewing Trajectories to Localize Mount Points Pg. 147).

Within the Entry Step, you have the option to perform the following workflow-specific tasks:

- The Fusion Task (see Fusion Task Fusing Images Pg. 219) may be used to fuse additional image series used for trajectory planning or entry point verification purposes that are not in the same frame of reference as the step's master series. The application will automatically prompt you to fuse any additionally loaded images if they are not in the same frame of reference as the step's master series. If you load additional image series that are in the same frame of reference as the master series, no action is required.

- The ACPC Task (see ACPC Task Reviewing Landmarks Pg. 228) may be used to review and / or modify the anatomical reference points automatically detected by the software. If a preoperative plan was created, the anatomical reference points are imported from the Pre-Op Step.

- The Compare Task (see Compare Task Comparing Images Pg. 232) may be used to compare intraoperative image series in their individual acquisition planes or standard scanner planes.

- The Preview Frame Task (see Preview Frame Task Visualizing Frames Prior to Mounting Pg. 254) may be used to visualize one or more frames positioned on the patient prior to frame mounting, for each trajectory path defined.

- The Grid Task (see Grid Task Editing Marking Grids Pg. 235) may be used to review and / or edit the positions of any defined marking grids on the patient. It can also be used to define additional marking grids that were not originally detected by the application.

- The Maestro Task (see Maestro Task Segmenting Brain Structures Pg. 264) may be used to automatically segment brain structures from any loaded MR image series using the ClearPoint Maestro Brain Model. If a preoperative plan was created, any segmented brain regions are imported from the Pre-Op Step.

Creating Trajectories to Localize Mount Points

The Entry Step may be used to create trajectory paths that can be used to localize one or more frame mount points on the patient's head.

> **To create a trajectory annotation**

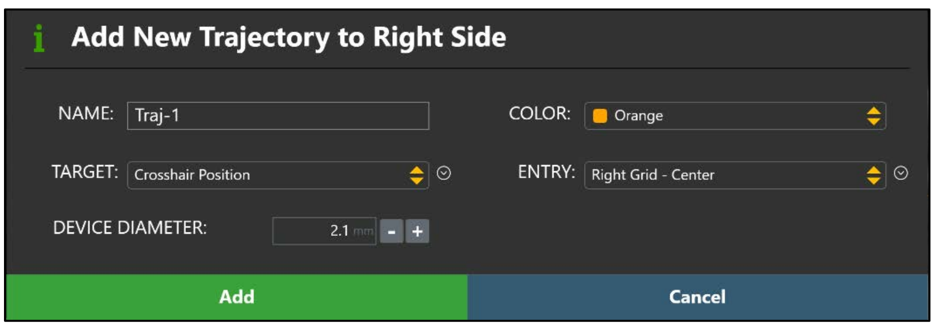
1. Select a side for which you would like to associate a trajectory (see Selecting a Side Pg. 82).

2. If additional images are required to plan the target point for your trajectory, acquire and transfer or load the images onto the workstation. If you are performing an MRI Workflow (see MRI Workflow Pg. 39) you may use the scan plane parameters provided by the step to acquire high-resolution MR scans at the target location. Click **Target** under the **SCAN PLANE PARAMETERS** group-box heading to bring up the scan plane parameters to acquire a high-resolution scan at the target location.

3. If necessary, select an additional image series for blending with the master series using the Thumbnail Bar (see Using Thumbnails Pg. 86).

4. Use the tools provided in the step control panel (see Creating Trajectories Pg. 131) to create one or more trajectories into the brain using intraoperative images with the marking grids affixed.

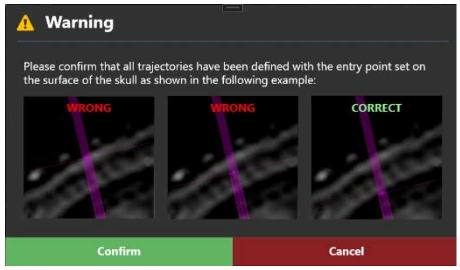
5. When the floating window appears prompting you to create a trajectory, note that the default location for the trajectory's entry point defaults to the center of the first marking grid on the selected side.

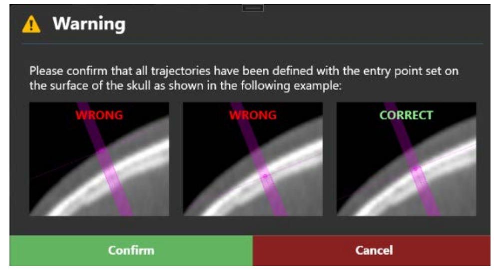


Editing Trajectories to Localize Mount Points

The Entry Step may also be used to edit existing trajectory annotations defined with marking grids affixed to the patient.

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).**





MRI Workflow **CT Workflow**

> **To edit or revise a target point**

1. Use the Trajectory Selector available in the step control panel to select a trajectory annotation whose target point you wish to edit (see Selecting a Trajectory Pg. 83).

2. If additional images are required to edit the target point for your trajectory, acquire and transfer or load the images on the workstation. If you are performing an MRI Workflow (see MRI Workflow Pg. 39) you may use the scan plane parameters provided by the step to acquire high-resolution MR scans at the target location for the currently selected trajectory. Click **Target** under the **SCAN PLANE PARAMETERS** group-box heading to bring up the scan plane parameters to acquire a high-resolution image scan located at the selected trajectory's target point.

3. If necessary, select an additional image series for blending with the master series using the Thumbnail Bar (see Using Thumbnails Pg. 86).

4. Use the tools provided in the step control panel (see Editing Trajectory Points Pg. 133) to edit the currently selected trajectory's target point.

> **To edit or revise an entry point**

1. Use the Trajectory Selector available in the step control panel to select a trajectory annotation whose entry point you wish to edit (see Selecting a Trajectory Pg. 83).

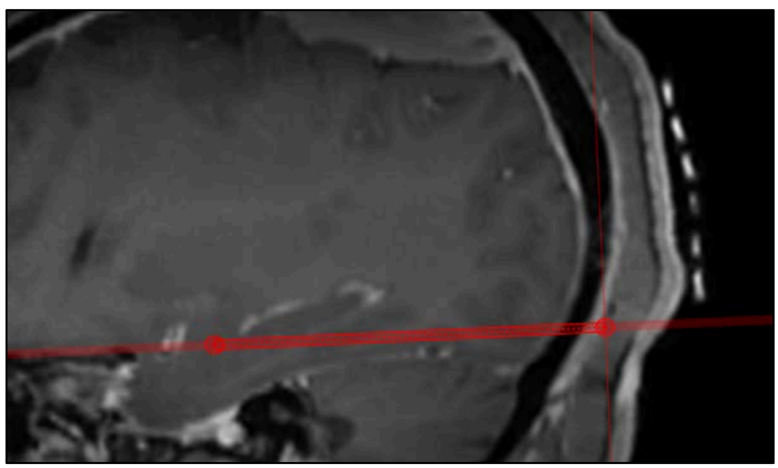
2. If additional images are required to edit the entry point for your trajectory, acquire and transfer or load the images onto the workstation. If you are performing an MRI Workflow (see MRI Workflow Pg. 39), you may use the

scan plane parameters provided by the step to acquire high-resolution MR scans at the entry location for the currently selected trajectory. Click **Entry** under the **SCAN PLANE PARAMETERS** group-box heading to bring up the scan plane parameters to acquire a high-resolution image scan located at the selected trajectory's entry point.

3. If necessary, select an additional image series for blending with the master series using the Thumbnail Bar (see Using Thumbnails Pg. 86).

4. Use the tools provided in the step control panel (see Editing Trajectory Points Pg. 133) to edit the currently selected trajectory's entry point.

If you attempt to make entry point edits such that the selected trajectory will not intersect a marking grid, the application will change the color of the selected trajectory to red and present a warning message (see Trajectory Does Not Intersect SMARTGrid Pg. 280). All defined trajectory paths must intersect a marking grid so that the application can prescribe valid frame mount point location(s). If the desired trajectory path does not intersect the selected marking grid, edit the trajectory of interest and/or reposition the selected marking grid on the patient.



Reviewing Trajectories to Localize Mount Points

During an MRI Workflow (see MRI Workflow Pg. 39), in addition to the features offered to review a trajectory path (see Reviewing Trajectories Pg. 138), you may also review the MR scanner bore clearance for each trajectory defined in the coordinate space of the whole-head master scan.

> **To review the MR scanner bore clearance**

1. Use the Trajectory Selector available in the step control panel to select a trajectory annotation that you wish to review (see Selecting a Trajectory Pg. 83).

2. Use the annotation context menu to show the Trajectory Status Dialog (see Working with Trajectory Annotations Pg. 118).

Mount Step Mounting Frames

The Mount Step can be used to physically locate the mount points for each SMARTFrame trajectory frame to be mounted onto the patient. This is achieved by reviewing and confirming the position and orientation of each detected SMARTGrid marking grid on one or more scans, and then physically identifying the mount point location for each frame on the patient using the affixed marking grid(s). The viewports presented in the step display three-dimensional models of each marking grid, and based on the trajectory selected for each, will display the location of the frame mount point on the grid underlay. This provides enough information so that physical localization of all frame mount positions can be achieved.

Caution:	**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 Entry Step prior to activating this step. See Entry Step *Setting Intraoperative Trajectories* Pg. 143 for details.**

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

- Confirming the position and orientation of each identified marking grid on one or more scans (see Confirming Marking Grids Pg. 150).
- Localizing one or more trajectory frame mount points on the patient (see Locating Mount Points Pg. 152).
- Realizing one or more mount points on the patient (see Realizing Mount Points Pg. 154).
- Verifying the location of one or more mount points on the patient (see Verifying Mount Points Pg. 154).
- Mounting one or more trajectory frames on the patient (see Mounting the Frame Pg. 156).

Within the Mount Step, you have the option to perform the following workflow-specific tasks:

- The Fusion Task (see Fusion Task Fusing Images Pg. 219) may be used to fuse additional image series used for mount point localization or verification purposes that are not in the same frame of reference as the master series. The application will automatically prompt you to fuse any additionally loaded images if they are not in the same frame of reference as the master series. If you load additional image series that are in the same frame of reference as the master series, no action is required.

- The Compare Task (see Compare Task Comparing Images Pg. 232) may be used to compare intraoperative image series in their individual acquisition planes or standard scanner planes.

- The Grid Task (see Grid Task Editing Marking Grids Pg. 235) may be used to review and / or edit the positions of any defined marking grids on the patient. It can also be used to define additional marking grids that were not originally detected by the application.

- The Preview Frame Task (see Preview Frame Task Visualizing Frames Prior to Mounting Pg. 254) may be used to visualize one or more frames positioned on the patient prior to frame mounting, for each trajectory path defined. It can also be used to prescribe frame adjustments to pre-align each frame's targeting cannula to the selected trajectory prior to mounting the frame.

- The Mount Point Task (see Mount Point Task Reviewing and Refining Mount Points Pg. 258) may be used to make corrections to the prescribed frame mount location(s) by modelling the position and orientation of the selected frame base on the patient's skull. This task is only available for mount point locations prescribed using the scalp mount base.

Confirming Marking Grids

Upon first launching the Mount Step, you are prompted to review and confirm the position and orientation of each detected marking grid using the master series from the Entry Step. You may load additional image series to review and confirm each marking grid detected by the application.

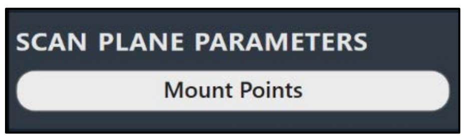
> To review marking grid detections

1. Verify that the application has not presented you with any warnings regarding inability to detect one or more marking grids (see SMARTGrid Not Found / Detected Incorrectly Pg. 279). If this warning was presented, use the Grid Task (see Grid Task Editing Marking Grids Pg. 235) to make corrections to the detected marking grid(s) and/or identify marking grids that have not been detected.

If the software was unable to detect the position of one or more marking grids, you will see a warning message and the grid model(s) will not be displayed in the viewing layout. You have the option to proceed manually if you are confident in identifying *the mount locations on the grid visually. See Trajectory Does Not Intersect SMARTGrid Pg. 280 for details.*

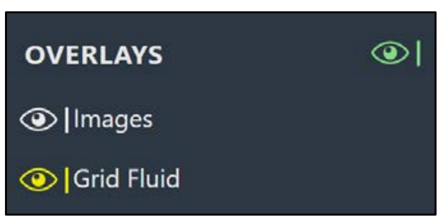
If you cannot identify the corresponding marking grid in the master series, you can acquire and blend in additional image scans which can be used to better visualize the marking grid(s). You may then use the Grid Task (see Grid Task Editing Marking Grids Pg. 235) to identify one or more marking grids from the newly acquired images.

2. If additional images are required to visualize the affixed marking grids, acquire and transfer or load the images onto the workstation. If you are performing an MRI Workflow (see MRI Workflow Pg. 39), you may use the scan plane parameters provided by the step to acquire high-resolution MR scans at the entry point for each of the defined trajectories. Click **Mount Points** under the **SCAN PLANE PARAMETERS** group-box heading to bring up the scan plane parameters to acquire high-resolution image scans at each of the trajectory's entry points. (The scan plane window allows you to select each trajectory for which scan plane parameters can be displayed).



3. Select an image series from which to review the selected grid using the Thumbnail Bar (see Using Thumbnails Pg. 86).

4. Use the **Grid Fluid** button in the step control panel to toggle the visibility of each identified marking grid's fluid cells. This can be used to determine if the marking grid's three-dimensional model matches up with the underlying images showing the physical marking grid(s) acquired from the scan.



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.**

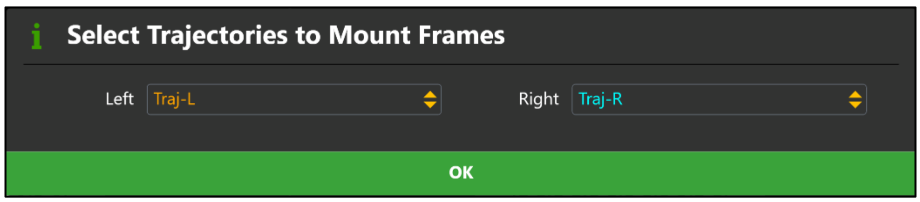
5. Use the **Images** button in the step control panel to toggle the visibility of the underlying images acquired from the scan. This can be used to help determine if the marking grid's three-dimension model matches up with the

underlying images showing the physical marking grid(s) acquired from the scan.

> **To verify marking grid detections**

1. If you have reviewed the position and orientation of all identified marking grids in the application, select **All Grids Verified** from the step control panel.

2. If more than one trajectory intersects a given marking grid, you will be presented with a dialog to select the corresponding trajectory path that you wish to show the mount point for. From the dialog, select a trajectory for each marking grid that has multiple trajectory paths which intersect it.



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 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 label indicating the trajectory whose frame mount point is displayed. This is done so that there is no confusion over which trajectory mount point is being prescribed for which grid.

There are two options when mounting each SMARTFrame trajectory frame. You can mount the frame directly on the skull surface after retracting the scalp using the SMARTFrame Skull Mount Base, or alternatively, you can mount the frame on the scalp using the SMARTFrame Scalp Mount Base. The Scalp Mount Base offsets the frame vertically from the surface of the scalp. This can introduce an offset to the mount point to be able to align the cannula to the entry and target points. For this reason, the Mount Step provides the ability to show two different mount points: the burr hole mount point and the scalp mount point.

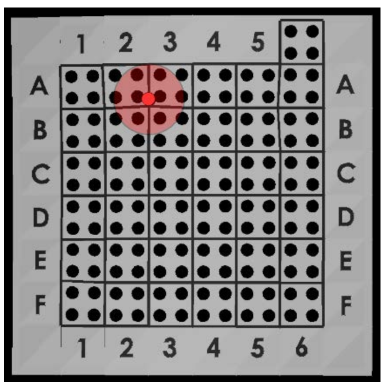
If one or more marking grids were not detected by the application or it was found in an incorrect location, displaying the scalp mount centering point will not be possible. If this occurs and you are using the Scalp Mount Base, you will need to correct the position of the marking grid or detect a new one using the Grid Task. See SMARTGrid Not Found / Detected Incorrectly Pg. 279 for details.

> **To find the frame mounting point(s)**

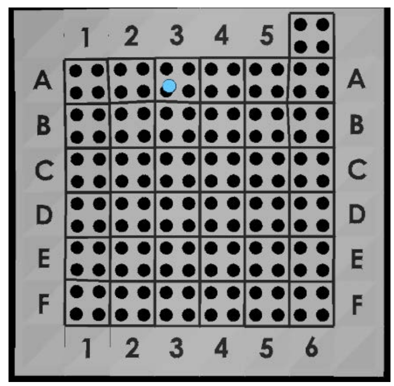
1. After confirming the position and orientation of all marking grids (see Confirming Marking Grids Pg. 150), a model of the grid underlay will be displayed in each viewport, along with the proposed mounting point. If the SMARTFrame Skull Mount Base was specified when you created (see Starting a New Session Pg. 60) or edited (see Using the Edit Session Properties Window Pg. 68) your session, then the **Burr Hole** mount point will be displayed. If the SMARTFrame Scalp Mount Base was specified when you created or edited your session, then the **Scalp Mount Point** will be displayed.

Caution:	**If you are mounting the frame on the skull using the Skull Mount Base, mount the frame at the Burr Hole Mount Point. If you are mounting the frame on the scalp using the Scalp Mount Base, mount the frame at the Scalp Mount Point.**

2. Visualize the mount point annotation on the three-dimensional grid underlay model.



Burr Hole Mount Point



Scalp Mount Point

3. You may toggle the display of the burr hole mount point by selecting the **Burr Hole** button from the step's control panel.

4. You may toggle the display of the scalp mount point by selecting the **Scalp Mount Point** button from the step's control panel.

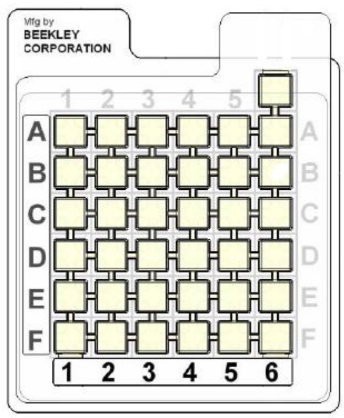
5. If more than one trajectory intersects a given marking grid and you would like to change the trajectory selection for which you would like to see the frame mount point, click on the **Select Trajectories** button from the step control panel. Doing so will bring up the dialog where you may select the trajectory for which you would like to see the frame mount point for a given marking grid.

Realizing Mount Points

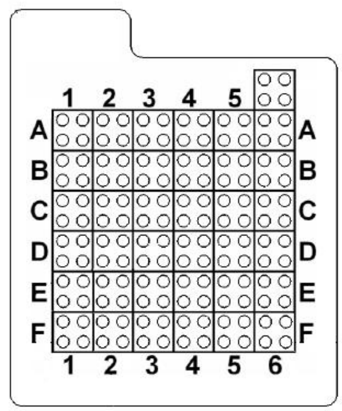
After you have identified the mount point(s) using the application, locate the physical position of the mount point(s) on the patient.

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

1. 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 the frame hardware has been mounted (both sides in the bilateral case) and the patient is positioned for scanning.**

Verifying Mount Points

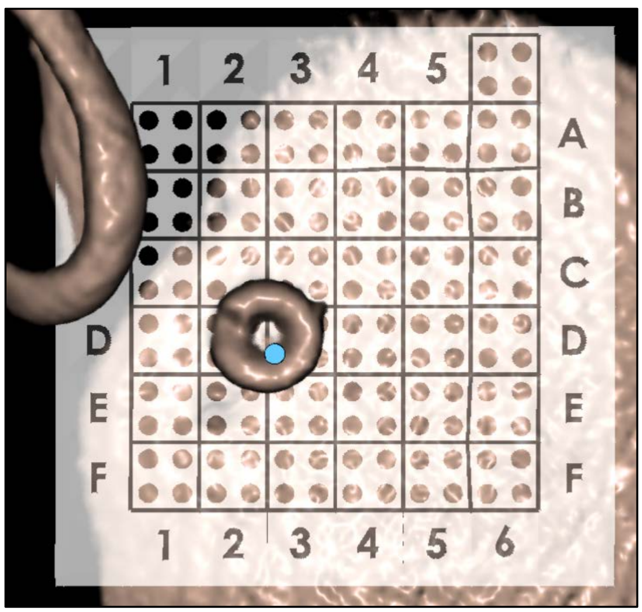
The Mount Step also provides you with the ability to verify the mount point(s) after the marking grid(s) have been removed from the patient. This is optional workflow that allows you to rule out factors that may cause inaccuracies when localizing the mount point on the patient, such as patient scalp shift, and can provide you with assurances that the mount point(s) have been realized correctly on the patient.

> **To verify the mount point(s) on the patient**

1. After marking the mount point of interest, place the ClearPoint Fiducial Marker directly on the marked mount point.

2. Use the Scanner Console to acquire a scan of the patient with one or more Fiducial Markers affixed. If you are performing an MRI Workflow (see MRI Workflow Pg. 39), you may use the scan plane parameters provided by the step to acquire high-resolution MR scans at the entry point for each of the defined trajectories. These scans should contain the affixed fiducial markers on the patient. Click **Mount Points** under the **SCAN PLANE PARAMETERS** group-box heading to bring up the scan plane parameters to acquire high-resolution image scans at each of the trajectory's entry points.

3. Load/transfer the scan and compare the marker shown in the image with the annotation shown in the application.



4. If the marker is not within a clinically acceptable distance of the burr hole mount point (for the Skull Mount Base) or the scalp mount point (for Scalp Mount Base), reposition the marker and re-scan. Repeat as necessary. Use the Measure Line tool (see Measure Tools Pg. 102) to determine how far the image marker is from the mount point annotation shown in the software.

5. Once the marker appears at the correct location, use the revised point to mount the frame.

Mounting the Frame

After reviewing and verifying the mount points using the application, take the appropriate steps necessary to mount the frame hardware.

Skull mounting:

- Marking the Entry Point — Before you create the incision, use the Marking Tool to create a recognizable mark on the skull at the desired position for the entry point.

- Incision and Burring — Perform incision and burring as appropriate.

- Mounting the SMARTFrame trajectory frame — Mount the frame according to the Instructions for Use provided. When it is complete, proceed to the Target step (see Target Step Finalizing Trajectories Pg. 159).

Scalp mounting:

- Attaching the Scalp Mount base - Consult the Instructions for Use provided with the Scalp Mount Base.

After mounting each frame, you may optionally pre-align the frame to a given trajectory before proceeding to the next step. The Preview Frame task can provide the necessary frame adjustments. See Prescribing Pre-Alignment Frame Adjustments Pg. 257 for further details.

Finalize Trajectories

This section describes how to use image-based navigation with the ClearPoint Workstation to finalize trajectory planning with one or more SMARTFrame trajectory frames mounted onto the patient. To achieve this, it is necessary to acquire a whole head scan of the patient with one or more frames affixed, review and verify the position(s) of all frames defined in the application, and complete planning of all trajectory paths into the brain.

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

- One or more SMARTFrame trajectory frames have been mounted onto the patient.
- During CT guided procedures, insertion of a ceramic aiming stylet from the Accessory Kit down the center of each affected frame to expand the field-of-view, if required. See SMARTFrame XG Trajectory Frame IFU for details.
- The patient has been positioned appropriately for scan acquisition.

Loading Intraoperative Frame Images

To begin finalizing the position of your planned trajectories with frames mounted onto the patient, you will need to acquire a whole-head scan of the patient's head with all frames mounted. The field-of-view of the scan should encapsulate the patient's entire head, the fiducial makers in the base of each mounted frame, and as much of each frame's targeting cannula as possible. This whole-head scan can be acquired using the scanner connected to the ClearPoint Workstation (see Interoperation with MRI Scanners Pg. 30 or Interoperation with CT Scanners Pg. 36 depending on the modality of the scanner being utilized). 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.

Caution:	**In a CT-guided procedure, the scanner field-of-view should include the targeting cannula for all mounted frames as well as all planned targets. If the field-of-view cannot extend far enough to include the upper cannula of any frame, a ceramic aiming stylet from the Accessory Kit should be used to improve cannula visibility.**

The whole-head scan with frames mounted 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. If additional scans are loaded that have a different frame of reference than the master series, you will be required to fuse these scans with the master series to use the images. See Fusion Task Fusing Images Pg. 219 for details.

> **To load intraoperative images used to plan trajectories with frame(s) mounted**

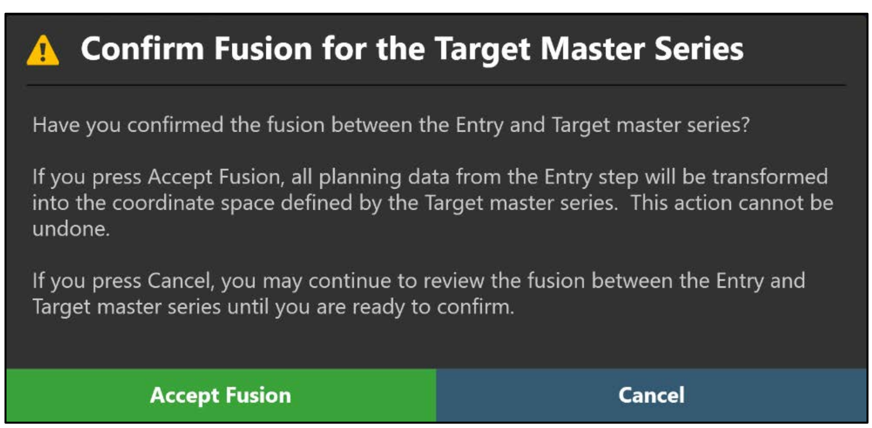
1. Select the Target Step using the Step Selector (see Using the Step Selector Pg. 81).

2. Use the Scanner Console to acquire a whole-head scan of the patient with one or more frames mounted. Ensure that the scan's field-of-view completely encapsulates the entire skull and all frames as specified above.

3. Transfer the whole-head scan to the workstation.

4. If you localized one or more mount points for the frame(s) using the ClearPoint Workstation prior to activating this step (see Localize Mount Points Pg. 141), use the pop-up Fusion Task (see Fusion Task *Fusing Images* Pg. 219) to fuse the master series from the Entry step with the image series just loaded into the application. If you created a preoperative plan without localizing mount points using the ClearPoint Workstation (see Preoperative Planning Pg. 127), then use the Fusion Task to fuse the master series from the Pre-Op step with the image series just loaded into the application

5. If the pop-up Fusion Task was used to fuse the whole-head scan with frame(s) mounted to a master series from a previously completed step, then when the Fusion Task is dismissed, you will be prompted to confirm the fusion between the two scans. Select **Accept Fusion** to confirm that you have accepted the fusion between the two scans. Otherwise, choose **Cancel** to continue to review and/or modify the fusion between the two scans in the Fusion Task.



If you accept the fusion between the two master series, the application will transform all trajectories, segmented brain regions, and anatomical reference points created in the previously completed step into the coordinate space defined by the intraoperative images containing the mounted frame(s). If you have not localized mount points or created a preoperative plan using the ClearPoint Workstation prior to activating this step, the application will automatically detect the anatomical reference points from the loaded master series.

Upon receiving the whole-head scan, the application will automatically search for any SMARTFrame trajectory frames in the scan. If the application fails to detect any frames, you will be notified via a status message that no frames could be identified (see SMARTFrame Not Found / Detected Incorrectly Pg. 286*). In these instances, you may use the Frame Task (see* Frame Task Editing Frame Markers Pg. 240*) to manually detect additional frames and/or acquire additional scans containing the frames affixed to the patient.*

> **To select a different master scan**

To change the scan that will serve as the base coordinate space for all other scans loaded downstream in the workflow (i.e., the “master scan”), use the Thumbnail Bar to change the primary series image (see Using Thumbnails Pg. 86). Any additional series can be loaded without further action if they are in the same frame of reference as the master series. If they are not within the same frame of reference as the master series, use the Fusion Task (see Fusion Task *Fusing Images* Pg. 219) to fuse the series together to allow for loading into the application.

Target Step Finalizing Trajectories

The Target Step provides the ability to revise any planned trajectories created in the Pre-Op or Entry Steps and/or create any number of new trajectory paths into the brain after one or more SMARTFrame trajectory frames have been mounted on the patient. At this stage in the workflow, trajectory planning is required to finalize the set of trajectories that will be used to align the frames to the desired target point(s) in the brain. Reviewing each trajectory path is advised to account for any anatomical changes in the patient’s head, such as brain shift, which may have occurred due to mounting one or more frames onto the patient’s skull.

When images are loaded into the ClearPoint Workstation with the Target Step selected, the application automatically detects the position of each fiducial marker located in the base of each frame mounted to the patient. Reviewing and verifying the detected location of each of the frame markers ensures that appropriate frame adjustment and device insertion depth values are prescribed by the application.

If you localized mount points or completed a preoperative plan without localizing mount points using the ClearPoint Workstation, then any trajectories, segmented brain regions, and anatomical reference points created will be transformed into the coordinate space of the scan denoted as the master series defined in this step. These annotations may be reviewed or edited based on the currently loaded image series for purposes of trajectory planning and review.

Like the Pre-Op Step (see Pre-Op Step *Setting Preoperative Trajectories* Pg. 128), this step provides you with the following high-level features:

- Defining one or more trajectory paths for each frame mounted on the patient (see Creating Trajectories with Frames Mounted Pg. 161).
- Reviewing planned trajectory paths into the brain with frames mounted to the patient (see Reviewing Trajectories with Frames Mounted Pg. 162).
- Editing the target and/or entry point for one or more trajectory paths into the brain with frames mounted to the patient (see Editing Trajectories with Frames Mounted Pg. 165).
- Changing the annotation properties associated with one or more trajectory paths (see Editing Trajectory Properties Pg. 136).
- Removing unwanted trajectory paths previously defined (see Removing Trajectories Pg. 138).

Within the Target step, you have the option to perform the following workflow-specific tasks:

- The Fusion Task (see Fusion Task Fusing Images Pg. 219) may be used to fuse additional image series for trajectory planning or review purposes that are not in the same frame of reference as the step's master series. The application will automatically prompt you to fuse any additionally loaded images if they are not in the same frame of reference as the step's master series. If you load additional image series that are in the same frame of reference as the master series, no action is required.
- The ACPC Task (see ACPC Task Reviewing Landmarks Pg. 228) may be used to review and / or modify the anatomical reference points automatically detected by the software. If mount points were localized using the application, the anatomical reference points are imported from the Entry Step. If a preoperative plan was created without localizing mount points using the application, then anatomical reference points are imported from the Pre-Op Step.
- The Compare Task (see Compare Task Comparing Images Pg. 232) may be used to compare intraoperative image series in their individual acquisition planes or standard scanner planes.
- The Frame Task (see Frame Task Editing Frame Markers Pg. 240) may be used to review and / or edit the positions of the fiducial markers associated

with each frame mounted on the patient. It may also be used to define additional frames that were not originally detected by the application.

- During an MRI Workflow (see MRI Workflow Pg. 39), the Pre-Adjust Task (see Pre-Adjust Task Pre-adjusting the Cannula Pg. 247) may be used to perform a series of X/Y frame adjustments in order to align the selected frame's ball marker to the planned trajectory's entry point, prior to modification of the targeting cannula's angulation. The Pre-Adjust Task is only available for use during an MRI Workflow.

- The Maestro Task (see Maestro Task Segmenting Brain Structures Pg. 264) may be used to automatically segment brain structures on any loaded MRI image series using the ClearPoint Maestro Brain Model. If brain regions were segmented earlier in the workflow, then they are imported from the previous step from which they were segmented from.

Creating Trajectories with Frames Mounted

The Target Step may be used to create one or more trajectory paths into the brain for each frame defined in the application.

> **To create a trajectory annotation with frames mounted**

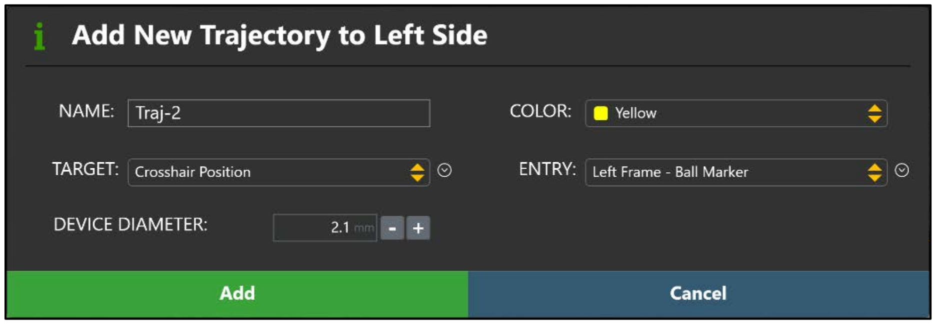
1. Select a side for which you would like to associate a trajectory (see Selecting a Side Pg. 82).

2. If additional image series are required to plan the target point for your trajectory, acquire and transfer or load the images onto the workstation. If you are performing an MRI Workflow (see MRI Workflow Pg. 39), you may use the scan plane parameters provided by the step to acquire high-resolution MR scans at the target location. Click **Target** under the **SCAN PLANE PARAMETERS** group-box heading to bring up the scan plane parameters to acquire a high-resolution scan at the target location.

3. If necessary, select an additional image series for blending with the master series using the Thumbnail Bar (see Using Thumbnails Pg. 86).

4. Use the tools provided in the step control panel (see Creating Trajectories Pg. 131) to create one or more trajectories into the brain using intraoperative images with one or more frames mounted.

5. When the floating window appears prompting you to create a trajectory, note that the default location for the trajectory's entry point defaults to the ball marker fiducial of the first frame on the selected side.



Reviewing Trajectories with Frames Mounted

After detecting one or more frames from the master series, the Target Step automatically sets the entry point for each trajectory transformed into the intraoperative coordinate space to the position of the ball marker fiducial of the closest frame. This is done to ensure that each entry point is set to be within the physical X-Y extents of its associated frame. This action is also performed if additional images encapsulating a frame are loaded into the application. In these instances, the application will notify you that the entry point for each trajectory has been updated to match the ball marker position of the closest frame (see Entry Point(s) Updated to Match Ball Marker Pg. 296). In these cases, it is recommended that you carefully review each trajectory path to ensure that it is anatomically viable. If edits to a trajectory path are required as a result of the review, use the edit tools offered in the Target Step to make the required changes (see Editing Trajectories with Frames Mounted Pg. 165).

In addition to the features offered to review a planned trajectory path (see Reviewing Trajectories Pg. 138), you may also: review the MR scanner bore clearance for each trajectory defined in the coordinate space of the whole-head master scan (MRI Workflow only), review the position of the trajectory relative to the physical X-Y extents of its associated frame, acquire additional scans orthogonal to the planned trajectory path (MRI Workflow only), and compare the position of the realized trajectory after frame mounting with the planned trajectory prior to frame mounting.

> **To review the MR scanner bore clearance**

1. During an MRI Workflow (see MRI Workflow Pg. 39), use the Trajectory Selector available in the step control panel to select a trajectory annotation that you wish to review (see Selecting a Trajectory Pg. 83).

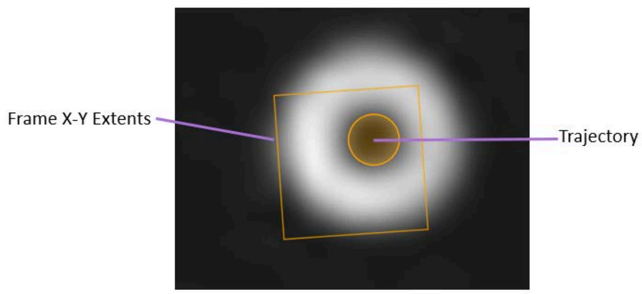
2. Use the annotation context menu to show the Trajectory Status Dialog (see Working with Trajectory Annotations Pg. 118).

> **To review the position of the trajectory relative to the X-Y frame extents**

1. Use the Trajectory Selector available in the step control panel to select a trajectory annotation that you wish to review (see Selecting a Trajectory Pg. 83).

2. Select either the **Review** or **Oblique + Pointwise** layout using the Layout Selector (see Selecting a Viewing Layout Pg. 83).

3. Use the **Frame X-Y Stage** button in the step control panel to show a graphic in the **Trajectory Perpendicular** viewport that represents the physical X-Y extents of the frame associated with the selected trajectory. The graphic provides a visual indication of whether the planned entry point for a given trajectory can be reached using a X or Y frame adjustment.



4. Review the position of the trajectory relative to the frame X-Y extents graphic in the **Trajectory Perpendicular** viewport.

Caution: **You must ensure that your planned trajectory's entry point is within the X-Y extents of its associated frame. If not, this may mean that your planned entry point may not be realizable through frame adjustments.**

> **To change the visibility of the frame's X-Y extents graphic**

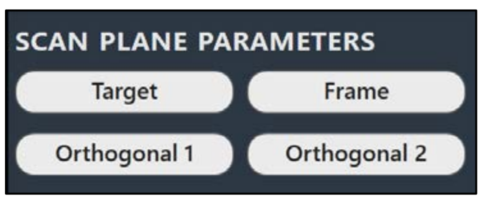
1. Use the **OVERLAYS** group-box in the step control panel to toggle the visibility of the graphic representing the physical X-Y extents of the frame associated with the currently selected trajectory. This graphic is only rendered in viewing layouts offering **Trajectory Perpendicular** viewports. Use the **Frame X-Y Stage** toggle button to change the visibility of the X-Y frame extents graphic in the viewport.

2. Use the **Show/Hide Viewport Annotations** tool to change the visibility of all trajectories (see Show/Hide Crosshairs, Annotations and Orientation Indicators Pg. 110).

> **To acquire additional images orthogonal to the planned trajectory**

1. During an MRI Workflow (see MRI Workflow Pg. 39), use the Trajectory Selector (see Selecting a Trajectory Pg. 83) available in the step control panel to select a trajectory annotation that you wish to acquire independent orthogonal scans for. Acquiring images orthogonal to the axis of the selected trajectory may further assist with assessing its anatomical viability.

2. Use the **Orthogonal 1** and **Orthogonal 2** buttons under the **SCAN PLANE PARAMETERS** group-box heading to bring up scan plane parameters that you must enter on the MRI Scanner Console to acquire scans orthogonal to the planned trajectory.



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 will, by default, blend the received image series with the master series in the step.

> **To compare the realized trajectory with the planned trajectory**

1. Use the Trajectory Selector available in the step control panel to select a trajectory annotation that you wish to review (see Selecting a Trajectory Pg. 83).

2. Select either the **Review** or **Oblique + Pointwise** layout using the Layout Selector (see Selecting a Viewing Layout Pg. 83).

3. Select **Reference Trajectory** from the context menu associated with the trajectory graphic annotation in the **Trajectory Perpendicular** viewport (see Working with Trajectory Annotations Pg. 118).

4. Visually compare the planned trajectory from the previous workflow step with the currently realized trajectory with frame(s) mounted.

Editing Trajectories with Frames Mounted

The Target Step may be used to edit existing trajectory annotations defined with frames mounted on the patient. Edits to the target point may be accomplished manually using the trajectory edit tools (see Editing Trajectory Points Pg. 133). Entry point edits may be realized manually by positioning the entry point at the desired location or automatically by loading up-to-date scans of the frame. Realization of the entry point can be achieved by making X or Y adjustments on the frame to align the ball marker to the planned entry point. During an MRI Workflow (see MRI Workflow Pg. 39), entry point realization can be achieved using the Pre-Adjust Task (see Pre-Adjust Task Pre-adjusting the Cannula Pg. 247). During a CT Workflow (see CT Workflow Pg. 40), entry point realization can be achieved using the Adjust (CT Workflow) step (see Adjust Step Finalize the Cannula Position in a CT Workflow Pg. 188).

> **To edit or revise a target point manually**

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. 83).

2. If additional image series are required to edit the target point for your trajectory, acquire and transfer or load the images on the workstation. If you are performing an MRI Workflow (see MRI Workflow Pg. 39), you may use the scan plane parameters provided by the step to acquire high-resolution MR scans at the target location for the currently selected trajectory. Click **Target** under the **SCAN PLANE PARAMETERS** group-box heading to bring up the scan plane parameters to acquire a high-resolution image scan located at the selected trajectory's target point.

3. If necessary, select an additional image series for blending with the master series using the Thumbnail Bar (see Using Thumbnails Pg. 86).

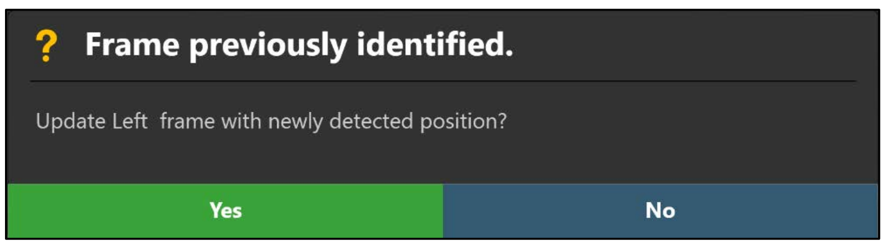
4. Use the tools provided in the step control panel (see Editing Trajectory Points Pg. 133) to edit the currently selected trajectory's target point.

> **To edit or revise an entry point automatically by loading a frame scan**

1. Use the Trajectory Selector available in the step control panel to select a trajectory annotation whose entry point you wish to set at the ball marker of the closest frame (see Selecting a Trajectory Pg. 83).

2. Acquire and then transfer or load new images containing the frame on the workstation. If you are performing an MRI Workflow (see MRI Workflow Pg. 39), you may use the scan plane parameters provided by the step to acquire a localized image scan at the base of the frame closest to the entry point of the selected trajectory. Click **Frame** under the **SCAN PLANE PARAMETERS** group-box heading to bring up the scan plane parameters for this scan.

3. On receiving the new scan with frame encapsulated, the application will automatically detect the new positions of the frame's fiducial markers and will prompt you on whether you wish the update the frame with the newly detected marker positions. Select **Yes** to update the frame with the positions just detected by the application. Select **No** to leave the frame's previous fiducial marker positions intact.



4. If you opted to update the frame marker positions, a floating window will display a **Please Wait** message and the user interface will be blurred while the application searches for the frame fiducial markers in the scan.

5. After the application detects the positions of the frame fiducial markers in the scan, the entry point for the selected trajectory will be updated to reflect the detected position of the ball marker. You may review the detected position of the ball marker in each of the application viewports. If necessary, you may review the automatic detection of the entire set of frame fiducial markers using the Frame Task (see Frame Task Editing Frame Markers Pg. 240).

Caution: **Each time you update the position of the frame's ball marker, all planned trajectories associated with that frame will have their entry points automatically updated to reflect this ball marker position. Please review all planned trajectories after updating the frame's ball marker position.**

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6. Use the tools provided in the step control panel to review the resulting trajectory path (see Reviewing Trajectories with Frames Mounted Pg. 162).

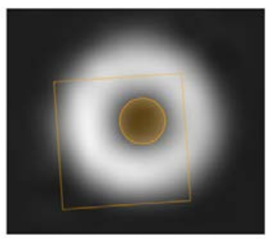
> **To edit or revise an entry point manually**

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. 83).

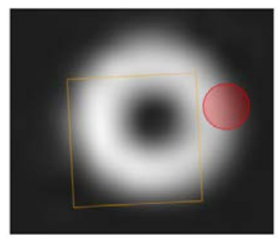
2. If necessary, select an additional image series for blending with the master series using the Thumbnail Bar (see Using Thumbnails Pg. 86).

3. Use the tools provided in the step control panel (see Editing Trajectory Points Pg. 133) to edit the currently selected trajectory's entry point.

If you attempt to make entry point edits such that the selected trajectory lies outside of the X-Y extents of its associated frame, the application will change the color of the selected trajectory to red and present a warning message (see Trajectory Not Within X-Y Limits of the Frame Pg.291). All defined trajectory paths should fall within the X-Y extents of their associated frame, otherwise, the planned entry point may not be realizable through frame adjustments. If the desired trajectory path does not lie within the X-Y limits of the frame, either edit the trajectory of interest, acquire additional images of the frame, and/or remount the frame on the patient.



Valid Entry Point
Within X-Y Limits



Invalid Entry Point
Not Within X-Y Limits

Align and Adjust Cannula in an MRI Workflow

This section describes how to use the ClearPoint Workstation to position a frame such that its targeting cannula is aligned to the desired trajectory during an MRI Workflow (see MRI Workflow Pg. 39).

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

- An MRI Workflow must be selected within the session.
- All planned trajectories have been defined, reviewed, and verified.
- Each frame physically mounted onto the patient has been identified.
- Each frame's fiducial markers have been defined, reviewed, and verified.
- Each frame's targeting cannula has been physically locked in the "down" position.

Align Step Set the Cannula Angulation in an MRI Workflow

The Align Step provides the ability to modify the angulation of the targeting cannula until it is sufficiently aligned with the planned target point of the selected trajectory during a MRI Workflow. This is required so that the targeting cannula of the frame can be imaged in the subsequent step (see Adjust Step Finalize the Cannula Position in an MRI Workflow Pg. 176). If the frame's targeting cannula has already been sufficiently aligned to the selected trajectory, then any minute frame adjustments may be skipped, and you may proceed in the MRI Workflow.

To sufficiently align the cannula position to the planned target point in this step, the application is used to prescribe a single, two-dimensional MR image acquisition through the top end of the targeting cannula. Upon loading this two-dimensional slice onto the workstation, the application automatically detects the top end of the cannula from the image and provides a set of frame adjustments that can be used to align the cannula to the planned target point. This process may be used iteratively to continually adjust the frame until the cannula is aligned with the planned trajectory.

The following high-level features are offered by the Align Step:

- Prescribing the necessary adjustments to align the targeting cannula to the selected trajectory's target point (see Prescribing Pitch/Roll Frame Adjustments Pg. 169).

- Specifying the scan plane parameters needed to acquire scans through the top end of the targeting cannula (see Acquiring Scans of the Cannula's Top End Pg. 170).

- Reviewing and modifying the current position of the targeting cannula based on scans through the top of the frame (see Reviewing the Cannula Position in an MRI Workflow Pg. 171).

- Reviewing the planned trajectory and associated projected cannula path (see Reviewing Trajectory and Cannula Paths Pg. 173).

Within the Align step, you have the option to perform the following workflow-specific tasks:

- The Fusion Task (see Fusion Task Fusing Images Pg. 219) may be used to fuse additional image series for cannula review purposes that are not in the same frame of reference as the current master series. The application will automatically prompt you to fuse any additionally loaded images if they are not in the same frame of reference as the Target step's master series (see Target Step Finalizing Trajectories Pg. 159).

- The Pre-Adjust task (see Pre-Adjust Task *Pre-adjusting the Cannula* Pg. 247) may be used to perform a series of X-Y frame adjustments in order to align the selected frame's ball marker to the planned trajectory's entry point, prior to modification of the cannula's angulation. If the position of the ball marker is such that it does not agree with the planned trajectory's entry point, you will be warned that a cannula pre-adjustment may be required (see Selected Trajectory Needs Pre-Adjustment Pg. 300).

- The Compare task (see Compare Task *Comparing Images* Pg. 232) may be used to compare intraoperative image series in their individual acquisition planes or standard scanner planes.

Prescribing Pitch/Roll Frame Adjustments

You may use the frame adjustments prescribed in the Align Step to make physical adjustments on the corresponding frame mounted on the patient. This is required to adequately align the frame's targeting cannula to the target point of the selected trajectory, such that further imaging of the cannula can be achieved with a time-efficient MRI slab focused on the trajectory plane instead of the whole head.

Upon first activating the Align Step, the application attempts to detect the top end of the frame's targeting cannula from the whole-head master scan. This can be used to prescribe the first set of frame adjustment instructions without requiring a dedicated scan of the targeting cannula's top end. (Note that the application will also automatically detect the top end of the frame's targeting cannula from the whole-head master scan in instances where the master scan's acquisition time is more recent than the most recently acquired scan of the targeting cannula). After performing the first set of frame adjustment instructions, it is recommended that additional acquisitions of the targeting cannula's top end are carried out so that the angulation of the frame's targeting cannula can be confirmed prior to proceeding to the next workflow step.

> **To realize a pitch/roll frame adjustment**

1. Use the Frame Selector available in the step control panel to select a frame that you would like to adjust (see Selecting a Frame Pg. 83).

2. Use the Trajectory Selector available in the step control panel to select a trajectory for which you would like to align the selected frame (see Selecting a Trajectory Pg. 83).

3. Using the **FRAME ADJUSTMENTS** display in the step 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. 67).

Acquiring Scans of the Cannula's Top End

The Align Step provides the ability to display scan plane parameters that can be used to acquire a MR scan through the top end of the targeting cannula. Once loaded onto the workstation, the application uses this scan to detect the upper cannula marker position of the frame and subsequently compute the projected path of the cannula.

> **To acquire MR scans of the targeting cannula's top end**

1. Use the Frame Selector available in the step control panel to select a frame that you would like to adjust (see Selecting a Frame Pg. 83).

2. Use the Trajectory Selector available in the step control panel to select a trajectory for which you would like to align the selected frame (see Selecting a Trajectory Pg. 83).

3. Click **Scan Plane** under the **SCAN PLANE PARAMETERS** group-box heading to bring up the scan plane parameters to acquire a scan at the top end of the targeting cannula. Acquire the scan using the parameter values entered on the MRI Scanner Console and transfer or load the images onto the workstation (see Interoperation with MRI Scanners Pg. 30).

4. On receiving the scan through the top end of the targeting cannula, the application verifies:

   - That the incoming scan intersects the upper portion of the targeting cannula.

   - 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 cannula.

5. If the application accepts the scan, it will search for the upper cannula marker from the image(s) received.

With each new acquisition, the application updates the position for the top of the cannula. Doing so allows the application to recalculate the projected path that would be followed if a device were to be inserted at the current cannula angulation. This path is projected down to the selected plane containing the planned target point of the selected trajectory.

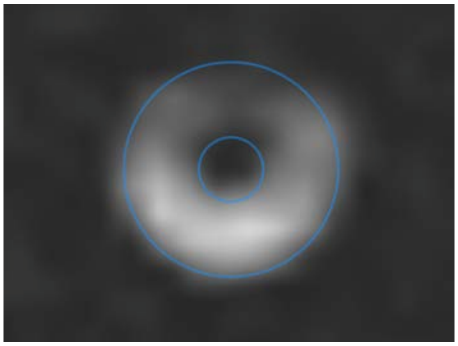
6. If the application succeeds in finding the upper cannula marker from the scan, it will overlay a two-dimensional cross-section of the cannula at the location where it detected its top end, in the left-most viewport. If the application failed to detect the upper cannula marker from the scan, a warning will be issued (see Failed to Detect SMARTFrame Upper Cannula Marker Pg. 299).

Reviewing the Cannula Position in an MRI Workflow

You may use the Align Step to review the detection result for the upper cannula marker in the acquired scan through the top of the cannula. In cases where the application's detection of the upper cannula marker is incorrect, you may manually modify the position of the cannula cross section so that it matches up with the signal of the top end of the cannula in the loaded scan.

> **To review the upper cannula marker position**

1. Observe the outline overlay of the upper cannula marker position overlaid on the acquired scan in the left-most **Trajectory Axial** viewport.

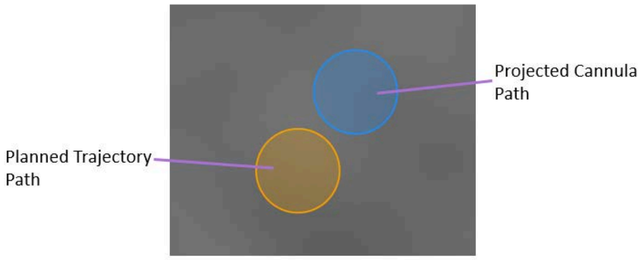


2. Verify that the outline of the targeting cannula overlay matches up with the signal from the top end of the cannula in the underlying images. If the outline of the targeting cannula does not match up with the underlying images, proceed to manually modify the position of the upper cannula marker.

3. Observe the graphic annotations overlaid on the scan rendered in the right-most viewport. The following graphics are shown:

   - A cross section of the planned trajectory, rendered at the device diameter specified for that trajectory (see Working with Trajectory Annotations Pg. 118).

   - A cross section of the projected path of the targeting cannula, also rendered at the device diameter specified for the selected trajectory.



> **To manually modify the targeting cannula position**

1. If the upper cannula marker position detected by the application appears incorrect in the left-most **Trajectory Axial** viewport, you may edit its position using the following techniques:

    - Drag the cannula cross section in the left-most viewport so that it aligns with the signal from the top end of the cannula.

    - Change the crosshair location to the intended position (see Changing Crosshair Positions Pg.93) and use the **Set Cannula Marker Point** tool ( ) in the step's custom toolbar (see Using Custom Toolbars Pg. 97).

2. To undo or redo any position edits made to the currently selected frame's upper cannula marker position:

    - Select the button from the custom toolbar to undo a position edit made to the upper cannula marker cross section shown on screen.

    - Select the button from the custom toolbar to redo a position edit made to the upper cannula marker cross section shown on screen.

Reviewing Trajectory and Cannula Paths

You may review the paths for both the planned trajectory and projected targeting cannula paths using tools in the step control panel.

> **To review the selected trajectory path**

1. Use the Trajectory Selector available in the step control panel to select a trajectory path that you would like to review (see Selecting a Trajectory Pg. 83).

2. If necessary, change the orientation of the viewing layout to the desired orientation (see Changing a Viewing Layout Orientation Pg. 90).

3. Observe the graphic annotations overlaid on the scan rendered in the right-most viewport to visually assess the cross section of the planned trajectory.

4. Use the Image Scroller (see Image Scroller Pg. 95) or Arrow tool (see Arrow Tool Pg. 99) to scroll along the trajectory path in the right-most viewport.

5. Select **GO TO Target** from the step control panel to navigate to the selected trajectory's target point. Alternatively, click the button.

6. Select **GO TO Entry** from the step control panel to navigate to the selected trajectory's entry point. Alternatively, click the ⏮ button.

7. To automatically scroll from the selected trajectory's entry point to target point, click the ▶ button from the step control panel. To stop automatically scrolling along the selected trajectory path, click the ■ button from the step control panel. (Note: Automatic scrolling along the selected trajectory path will stop once the target point location is reached).

8. You may use the **OVERLAYS** group-box in the step control panel to toggle the visibility of the planned trajectory. This can be useful to visually assess the planned trajectory relative to underlying anatomy. You may also use the **Show/Hide Viewport Annotations** tool to change the visibility of all annotations shown in this step (see Showing / Hiding Annotations Pg. 84).

> **To review the projected cannula path**

1. Use the Frame Selector available in the step control panel to select a frame whose cannula's projected path you would like to review (see Selecting a Frame Pg. 83).

2. If necessary, change the orientation of the viewing layout to the desired orientation (see Changing a Viewing Layout Orientation Pg. 90).

3. Observe the graphic annotations overlaid on the scan rendered in the right-most viewport to visually assess the cross section of the targeting cannula's projected path relative to the planned target point.

4. You may use the **OVERLAYS** group-box in the step control panel to toggle the visibility of the projected cannula path. This can be useful to visually assess the path of the targeting cannula relative to underlying anatomy.

5. Use the **ERROR MEASUREMENTS** group-box in the step control panel to assess how the projected cannula path compares to the planned target on the selected error plane. As the angulation of the cannula changes, so do the error measurements.

For each selected measurement plane, the error between the projected cannula path and the selected trajectory's target point is expressed as follows:

- If the selected plane is **Trajectory Axial**, the two axes used to decompose the error are the corresponding frame's X and Y directions.

- If the selected plane is **Anatomical Axial**, the two axes used to decompose the error are sagittal and coronal, and the corresponding labels for the error are lateral/medial and anterior/posterior respectively.

- If the selected plane is **Anatomical Coronal**, the two axes used to decompose the error are sagittal and axial, and the corresponding labels for the error are lateral/medial and superior/inferior respectively.

- If the selected plane is **Anatomical Sagittal**, the two axes used to decompose the error are coronal and axial, and the corresponding labels for the error are anterior/posterior and superior/inferior respectively.

The application always defaults to show projected cannula error measurements relative to the Trajectory Axial plane to prevent potential confusion with respect to the values displayed. If you decide to change the selection, be aware which plane has been used to compute these error measurements.

Proceeding to Further Align the Cannula in an MRI Workflow

You may choose to make further adjustments to the cannula's angulation to adequately align it with the planned trajectory's target point during an MRI Workflow. It is suggested that the cannula be further adjusted until the total predicted residual error is less than 1.0 mm. To make further adjustments on the currently selected frame

1. Use the Frame Selector available in the step control panel to select a frame that you would like to adjust (see Selecting a Frame Pg. 83).

2. Use the Trajectory Selector available in the step control panel to select a trajectory for which you would like to align the selected frame (see Selecting a Trajectory Pg. 83).

3. Acquire a MR scan through the top of the cannula using the scan plane parameters provided in the **SCAN PLANE PARAMETERS** group-box in the step control panel (see Acquiring Scans of the Cannula's Top End Pg. 170).

4. Acquire the MR scan using the parameter values entered on the MRI Scanner Console and transfer or load the images onto the workstation (see Interoperation with MRI Scanners Pg. 30).

5. Allow the application to detect the upper cannula marker position from the loaded scan. Review the detection of the upper cannula marker using the tools offered in this step (see Reviewing the Cannula Position in an MRI Workflow Pg. 171).

6. Review the projected path of the targeting cannula and assess its anatomical viability (see Reviewing Trajectory and Cannula Paths Pg. 173).

7. Realize the frame adjustments as prescribed by the software on the frame mounted to the patient (see Prescribing Pitch/Roll Frame Adjustments Pg. 169).

8. You may iteratively continue to align the cannula until the predicted residual error is deemed clinically acceptable.

Adjust Step Finalize the Cannula Position in an MRI Workflow

The Adjust Step (MRI Workflow) allows you to fine-tune the angulation and position of the targeting cannula using MR images to align it with the target point of the selected trajectory during an MRI Workflow. To achieve this, the MRI Scanner is used to acquire orthogonal image slabs along the length of the selected frame's targeting cannula. By identifying the position of the targeting cannula within the image slabs, the application computes a new projected path for the cannula so that you may visualize differences in its angulation relative to the planned trajectory. You may then assess whether inserting a device into the cannula at its current position is deemed acceptable based on the anatomical location of the planned trajectory. If the projected error between the current position of the targeting cannula and the planned target point is deemed unacceptable, you may continue to adjust the frame and verify its position by acquiring additional orthogonal image slabs until an acceptable residual error is achieved. Otherwise, you may proceed to insert the device.

Prior to utilizing this step, the targeting cannula must be sufficiently aligned with the selected trajectory, otherwise the orthogonal image slabs may not completely contain the cannula in their field-of-view. Ensure that the Align Step (see Align Step Set the Cannula Angulation in an MRI Workflow Pg. 168) has been completed prior to this step.

The following high-level features are offered by the Adjust Step (MRI Workflow):

- Specifying the scan plane parameters needed to acquire orthogonal scans of the targeting cannula (see Acquiring the Orthogonal Cannula Scans Pg. 178).

- Reviewing and modifying the current position of the targeting cannula based on the acquired orthogonal scans (see Reviewing the Cannula Position in the Orthogonal Scans Pg. 180).

- Prescribing the frame adjustments required to align the cannula to the selected trajectory's target point (see Prescribing Frame Adjustments from Orthogonal Scans Pg. 184).

- Reviewing the planned trajectory and associated projected cannula path (see Reviewing Trajectory and Cannula Paths Prior to Insertion in an MRI Workflow Pg. 185).

Within the Adjust Step (MRI Workflow), you have the option to perform the following workflow-specific tasks:

- The Fusion Task (see Fusion Task Fusing Images Pg. 219) may be used to fuse additional image series for cannula review purposes that are not in the same frame of reference as the current master series. The application will automatically prompt you to fuse any additionally loaded images if they are not in the same frame of reference as the Target step's master series (see Target Step Finalizing Trajectories Pg. 159).

- The Compare task (see Compare Task *Comparing Images* Pg. 232) may be used to compare intraoperative image series in their individual acquisition planes or standard scanner planes.

Acquiring the Orthogonal Cannula Scans

When the Adjust Step (MRI Workflow) is first activated, the current cannula projection and planned trajectory annotations are shown in the right-most viewport to provide an indication of how well the cannula is aligned to the planned target point. If the targeting cannula is not well aligned to the planned trajectory, return to the Align Step (see Align Step Set the Cannula Angulation in an MRI Workflow Pg. 168), and complete the required workflow.

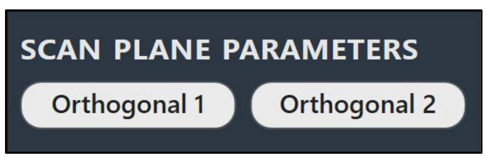
The Adjust Step (MRI Workflow) provides the ability to acquire two independent scans of the selected frame's targeting cannula. These scans are prescribed to be aligned orthogonally to the planned trajectory path.

> **To acquire orthogonal scans of the targeting cannula**

1. Use the Frame Selector available in the step control panel to select a frame that you would like to adjust (see Selecting a Frame Pg. 83).

2. Use the Trajectory Selector available in the step control panel to select a trajectory for which you would like to adjust the selected frame (see Selecting a Trajectory Pg. 83).

3. Use the **Orthogonal 1** and **Orthogonal 2** buttons under the **SCAN PLANE PARAMETERS** group-box heading to bring up scan plane parameters that you must enter on the MRI Scanner Console to acquire orthogonal MR scans of the targeting cannula.



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. 32.

For IMRIS systems, a Table Position should not be entered in this step. See Important Notes for Using IMRIS Systems Pg. 34.

4. Enter the values on the MRI Scanner Console, scan and transfer or load the images onto the workstation.

5. 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.

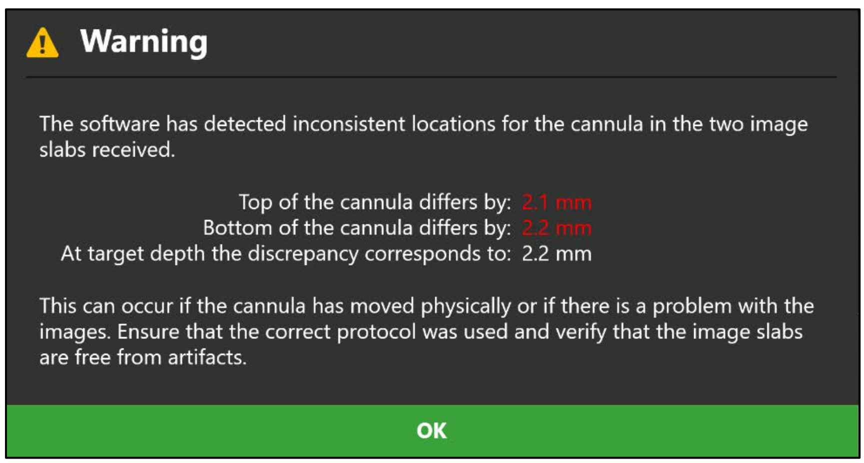
- That the scan received contains up-to-date images of the targeting cannula.

6. 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 cannula in the scan.

7. Once the application has detected the targeting cannula from each of the orthogonal scans, a check is then performed to verify that the detected positions of the cannula in both scans agree. If they don't agree, then this may indicate that the targeting cannula moved in-between scanning or that the acquired images are affected by geometric distortion artifacts.

   To assess the amount of discrepancy between the two image slabs, a warning message is shown with discrepancy measurements at the top and bottom of the cannula. Numerical values shown in red indicate that they are beyond the configured tolerance. A green value indicates that the value is within tolerance.

   A third value is also provided which shows the magnitude of the difference when it's extended down to the target depth. This can give a sense of the potential impact of the positional discrepancies on the radial error when the device is inserted.



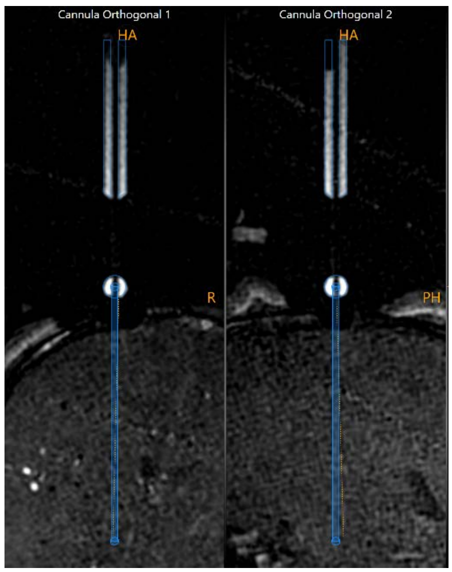
8. If the application fails to detect the targeting cannula in one or both of the orthogonal scans, a warning will be shown (see Failed To Identify Cannula From Orthogonal Slab Pg. 302). This may indicate that the cannula itself is cut-off in the scans, incorrect scan plane parameters were used, or there is a lack of fluid within the targeting cannula and/or frame ball marker.

Reviewing the Cannula Position in the Orthogonal Scans

You may use the Adjust Step (MRI Workflow) to review the detection results for the targeting cannula in each of the acquired orthogonal scans.

> **To review the targeting cannula position**

1. Observe the graphic cross sections of the targeting cannula and associated ball marker overlaid on the individual scans in the **Cannula Orthogonal 1** and **Cannula Orthogonal 2** viewports.



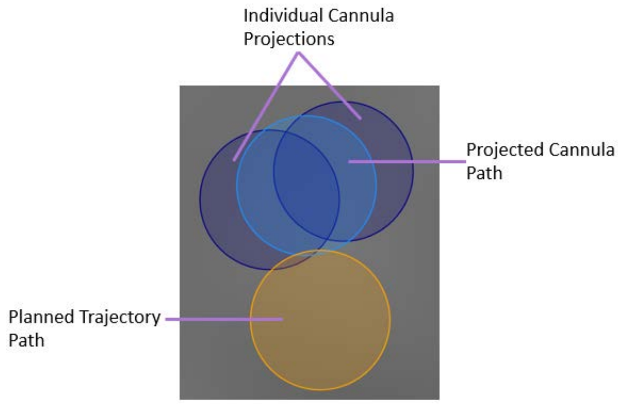
2. Verify that the outline of the targeting cannula and ball marker overlays matches up with the signal from the cannula and associated ball marker. If the graphic outlines for the cannula and ball marker do not match up with the underlying images, proceed to manually modify the position of the cannula.

3. Observe the graphic annotations overlaid on the scan rendered in the right-most viewport. The following graphics are shown:

   - A cross section of the planned trajectory, rendered at the device diameter specified for that trajectory (see Working with Trajectory Annotations Pg.118).

   - A cross section of the projected path of the targeting cannula, also rendered at the device diameter specified for the selected trajectory.

   - Two individual cross sections representing the projected placements for the device if the **Orthogonal 1** and **Orthogonal 2** scans are each considered in isolation. These graphics can be useful to understand the potential difference in projected placement values when there is a meaningful discrepancy between the detected results of the targeting cannula in the scans. Hover the mouse over each graphic cross section to indicate which projection corresponds to the orthogonal scan where the cannula was detected from. A pop-up tooltip will indicate whether the graphic represents the projected path from the **Orthogonal 1** or **Orthogonal 2** scan.



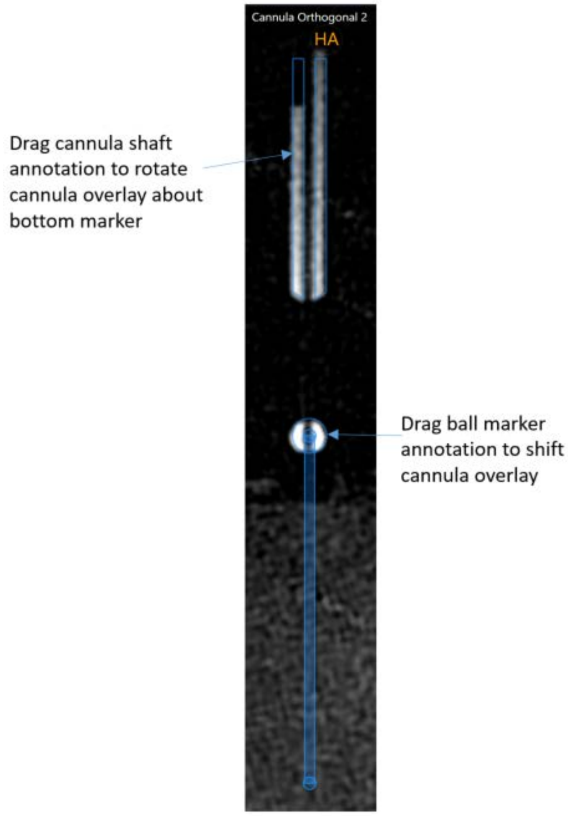
> **To manually modify the targeting cannula position**

1. If the graphic overlays representing the targeting cannula and/or ball marker overlays do not match up with the signal from the cannula in the orthogonal scans shown in the **Cannula Orthogonal 1** and **Cannula Orthogonal 2** viewports, you may manually modify the cannula's position as follows:

   - Drag the graphic cross section representing the ball marker to fit the image of the spherical ball marker at the bottom of the cannula in the underlying images.

   - Once the circle has been fitted to the bottom marker, drag the cannula cross section to align with the upper shaft of the cannula in the underlying images. Fit the graphic cross section by comparing the overlay lines to the edges of the lumen and the outside edge of the cannula in the underlying images.

   - Use the Zoom Tools (see Zoom Tools Pg.100) and the Single/Multi Viewport Tool (see Single / Multi Viewport Tool Pg. 114) to ensure the best possible match in both views.



2. To undo or redo any position edits made to the targeting cannula or ball marker:

    - Select the button from the custom toolbar to undo a position edit made to the upper cannula marker cross section shown on screen.

    - Select the button from the custom toolbar to redo a position edit made to the upper cannula marker cross section shown on screen.

> **To restore the initial detection of the targeting cannula position**

1. If manual edits were made to the targeting cannula and/or ball marker overlays and you wish to restore their initial positions as originally detected from the orthogonal scans, select **Re-Detect Cannula** from the step control panel.

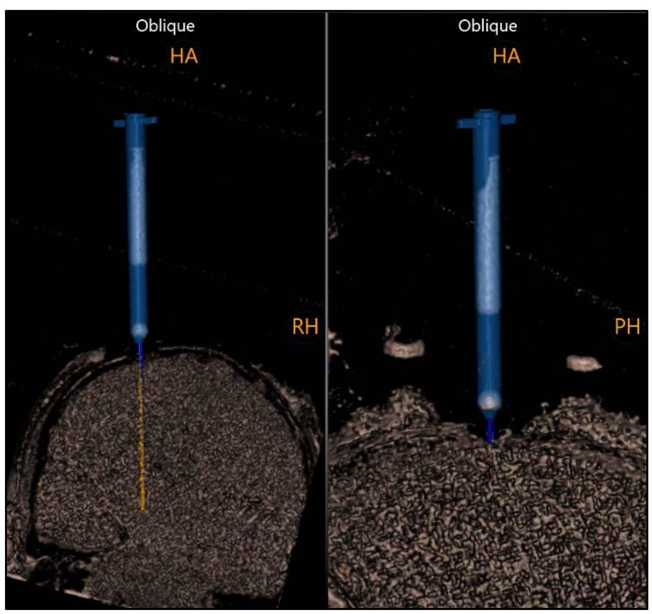
2. The application will display a floating window with a **Please Wait** message and the user interface will be blurred while the application searches for the targeting cannula in the two loaded orthogonal scans.

3. Once the application has re-detected the targeting cannula from the orthogonal scans, a check is performed to verify that the detected position of the cannula in the scans agree (see Acquiring the Orthogonal Cannula Scans Pg. 178). If the application fails to re-detect the targeting cannula, a warning will be shown (see Failed To Identify Cannula From Orthogonal Slab Pg. 302).

> **To assess geometric distortion artifacts in the orthogonal cannula scans**

1. Use the Layout Selector to choose the **3D Adjust** viewing layout (see Selecting a Viewing Layout Pg. 83). This layout displays two additional three-dimensional views of the orthogonal cannula slabs to help assess for geometric distortion artifacts present in the underlying images. These additional views display three-dimensional representations of the image slabs as well as the cannula models to allow for visual comparison between the two.

Caution: **If the signal from the cannula in one or both image slabs does not appear straight, this may indicate that geometric distortion artifacts are present in the acquired images. If this occurs, the image scans should not be used to further align the targeting cannula. You will need to acquire image scans of the cannula that are not subject to these distortion artifacts to accurately align the cannula to the planned trajectory's target point.**



2. Use the Window Width/Level Tool (see Window Width and Level Tool Pg. 100) to filter out any noise in the scan so that signal from the cannula and associated ball marker can be seen in the underlying images.

3. Compare the three-dimensional cannula model with the underlying images and assess for any visible geometric distortion artifacts.

4. If you determine that geometric distortion artifacts may be present, take any steps to reduce noise or other artifacts in the scans and repeat the acquisitions (see Acquiring the Orthogonal Cannula Scans Pg. 178).

Prescribing Frame Adjustments from Orthogonal Scans

Like the Align Step, you may use the frame adjustments prescribed in the Adjust Step (MRI Workflow) to make physical adjustments on the corresponding frame mounted on the patient (see Prescribing Pitch/Roll Frame Adjustments Pg. 169). In addition to prescribing pitch and roll adjustments, the Adjust Step (MRI Workflow) is also able to prescribe X and Y adjustments to allow for further alignment of the targeting cannula to the target point of the selected trajectory. Note that turning X or Y knob(s) will result in a change to the location of the entry point, so if you wish to retain the position of the ball marker / current entry point, only use Pitch/Roll frame adjustments in this step.

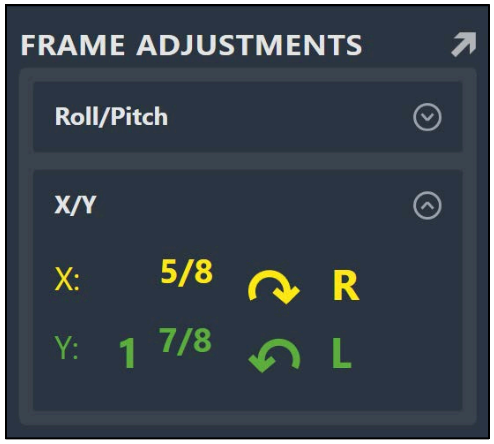
The position of the targeting cannula as defined in this step (see Reviewing the Cannula Position in the Orthogonal Scans Pg. 180) is used to represent the expected result if the device were to be fully inserted through the cannula to target depth. The user interface will show the necessary frame adjustments required to reach the planned target point.

> To make a frame adjustment

1. Use the Frame Selector available in the step control panel to select a frame that you would like to adjust (see Selecting a Frame Pg. 83).

2. Use the Trajectory Selector available in the step control panel to select a trajectory for which you would like to align the selected frame (see Selecting a Trajectory Pg. 83).

3. Using the **FRAME ADJUSTMENTS** display in the step control panel, make the prescribed adjustments on the physical frame mounted on the patient. By default, pitch/roll adjustments will be shown in the step control panel. You may toggle between showing pitch/roll or X/Y frame adjustments. You may also 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. 67).



Note: X and Y offset adjustments will result in a change to the entry point.

Reviewing Trajectory and Cannula Paths Prior to Insertion in an MRI Workflow

In addition to the features provided in the Align Step for reviewing both the planned trajectory and projected targeting cannula paths (see Reviewing Trajectory and Cannula Paths Pg. 173), the Adjust Step (MRI Workflow) also offers the ability to review the individual projection paths for the cannula detected from each of the orthogonal scans.

> **To review the selected trajectory path**

1. Use the Trajectory Selector available in the step control panel to select a trajectory path that you would like to review (see Selecting a Trajectory Pg. 83).
2. If necessary, change the orientation of the viewing layout to the desired orientation (see Changing a Viewing Layout Orientation Pg. 90).
3. Observe the graphic annotations overlaid on the scan rendered in the right-most viewport to visually assess the cross section of the planned trajectory.
4. Use the Image Scroller (see Image Scroller Pg. 95) or mouse wheel to scroll along the trajectory path in the right-most viewport.
5. Select **GO TO Target** from the step control panel to navigate to the selected trajectory's target point. Alternatively, click the ⏭ button.
6. Select **GO TO Entry** from the step control panel to navigate to the selected trajectory's entry point. Alternatively, click the ⏮ button.

7. To automatically scroll from the selected trajectory's entry point to target point, click the ▶ button from the step control panel. To stop automatically scrolling along the selected trajectory path, click the ■ button from the step control panel. (Note: Automatic scrolling along the selected trajectory path will stop once the target point location is reached).

8. You may use the **OVERLAYS** group-box in the step control panel to toggle the visibility of the planned trajectory. This can be useful to visually assess the planned trajectory relative to underlying anatomy. You may also use the **Show/Hide Viewport Annotations** tool to change the visibility of all annotations shown in this step (see Showing / Hiding Annotations Pg. 84).

> **To review the projected cannula path**

1. Use the Frame Selector available in the step control panel to select a frame whose cannula's projected path you would like to review (see Selecting a Frame Pg. 83).

2. If necessary, change the orientation of the viewing layout to the desired orientation (see Changing a Viewing Layout Orientation Pg. 90).

3. Observe the graphic annotations overlaid on the scan rendered in the right-most viewport to visually assess the cross section of the targeting cannula's projected path relative to the planned target point. Also note the individual cross sections representing the projected cannula path from each of the orthogonal scans. Note that the targeting cannula's projected path is an average of the two individual cannula projections from the orthogonal scans.

4. You may use the **OVERLAYS** group-box in the step control panel to toggle the visibility of the projected cannula path and the individual cannula projections from each of the orthogonal scans. This can be useful to visually assess the path of the targeting cannula relative to underlying anatomy, as well as any differences between the detected cannula positions between the two orthogonal scans.

5. Use the **ERROR MEASUREMENTS** group-box in the step's control panel to assess how the projected cannula path compares to the planned target on the selected error plane (see Reviewing Trajectory and Cannula Paths Pg. 173).

Proceeding to Further Adjust the Cannula in an MRI Workflow

You may choose to make further adjustments to the cannula's angulation to sufficiently align it with the planned trajectory's target point during an MRI Workflow. It is suggested that the cannula be further adjusted until the projected device placement is clinically acceptable.

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

1. Use the Frame Selector available in the step control panel to select a frame that you would like to adjust (see Selecting a Frame Pg. 83).

2. Use the Trajectory Selector available in the step control panel to select a trajectory for which you would like to align the selected frame (see Selecting a Trajectory Pg. 83).

3. Acquire two orthogonal scans of the currently selected frame's targeting cannula using the **SCAN PLANE PARAMETERS** group-box in the step control panel (see Acquiring the Orthogonal Cannula Scans Pg. 178).

4. Acquire the MR scan using the parameter values entered on the MRI Scanner Console and transfer or load the images onto the workstation (see Interoperation with MRI Scanners Pg. 30).

5. Allow the application to detect the cannula and frame ball marker from each of the loaded scans. Review the detection of the cannula using the tools offered in this step (see Reviewing the Cannula Position in the Orthogonal Scans Pg. 180).

6. Review the projected path of the targeting cannula from each of the orthogonal scans, and assess their projected placement viability (see Reviewing Trajectory and Cannula Paths Prior to Insertion in an MRI Workflow Pg. 185).

7. Realize the frame adjustments as prescribed by the software on the frame mounted to the patient (see Prescribing Frame Adjustments from Orthogonal Scans Pg. 184).

8. You may iteratively continue to adjust the cannula until the predicted path is clinically acceptable.

Adjust Cannula in a CT Workflow

This section describes how to use the ClearPoint Workstation to position a frame such that its targeting cannula is aligned to the desired trajectory during a CT Workflow (see CT Workflow Pg. 40).

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

- A CT Workflow must be selected within the session.
- All planned trajectories have been defined, reviewed, and verified.
- Each frame physically mounted onto the patient has been identified.
- Each frame's fiducial markers have been defined, reviewed, and verified.

Caution:	**In a CT-guided procedure, the scanner field-of-view should include the targeting cannula for all mounted frames as well as all planned targets. If the field-of-view cannot extend far enough to include the upper cannula of any frame, a ceramic aiming stylet from the Accessory Kit should be used to improve cannula visibility.**

Adjust Step Finalize the Cannula Position in a CT Workflow

The Adjust Step (CT Workflow) provides the ability to modify the angulation and position of the targeting cannula to align with a planned trajectory using CT images. The step provides frame adjustment instructions to align the targeting cannula for two different scenarios, which the user will choose based on the clinical need:

1) Target Only: The prescribed instructions align the cannula to the target point of the planned trajectory without regard for the entry point. These instructions are best used when the physical entry point has already been created (e.g., drilled) and confirmed using methods like tactile or visual inspection or other surgical navigation software to ensure adequate clearance through the skull and safe entry into the brain.

2) Target and Entry: The prescribed instructions align the cannula to both target and entry points of the selected trajectory. These instructions are best used when the physical entry point has not yet been created and/or when the

entry point needs to align exactly with the pre-planned entry due to patient-specific anatomy and safety concerns like brain arteries on the surface.

Prior to utilizing this step, you should evaluate the scanner field-of-view to assess if scans of the targeting cannula can capture the entire skull and the upper targeting cannula. If the field-of-view cannot capture both landmarks, then a ceramic aiming stylet from the Accessory Kit should be used to assist the software with automatic localization of the cannula axis. See SMARTFrame XG Trajectory Frame IFU for details.

To achieve targeting cannula alignment, the CT Scanner is used to acquire whole-head scans of the patient with frame(s) affixed. The software identifies the targeting cannula in the scan and computes the projected cannula path so differences in angulation and position relative to the planned trajectory are visualized. You may then insert a device into the cannula at its current position if the error between the projected and desired position to target is clinically acceptable. If the projected error between the current position of the targeting cannula and the planned target/trajectory is deemed unacceptable, continue to adjust the frame, and verify its position by acquiring additional whole-head scans until an acceptable error is achieved.

The following high-level features are offered by the Adjust Step (CT Workflow):

- Reviewing and modifying the current position of the targeting cannula based on acquired whole-head scans (see Reviewing the Cannula Position in Whole-Head Scans Pg. 190).
- Prescribing the frame adjustments required to align the cannula to the selected trajectory's target point or entry/target point combination using a single scan (see Prescribing Frame Adjustments from a Single Scan Pg. 194).
- Reviewing the planned trajectory and associated projected cannula path (see Reviewing Trajectory and Cannula Paths Prior to Insertion in a CT Workflow Pg. 195).

Within the Adjust Step (CT Workflow), you have the option to perform the following workflow-specific tasks:

- The Fusion Task (see Fusion Task Fusing Images Pg. 219) may be used to fuse additional whole-head scans with frame(s) affixed that are not in the same frame of reference as the current master series. The application will automatically prompt you to fuse any additionally loaded images if they are not in the same frame of reference as the Target step's master series (see Target Step Finalizing Trajectories Pg. 159).
- The Compare task (see Compare Task *Comparing Images* Pg. 232) may be used to compare intraoperative image series in their individual acquisition planes or standard scanner planes.

Reviewing the Cannula Position in Whole-Head Scans

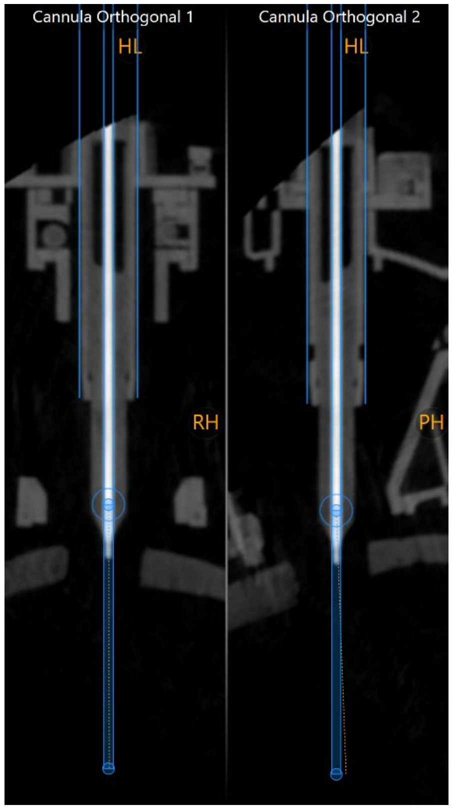
When the Adjust Step (CT Workflow) is first activated, the application will detect the targeting cannula from the most recently acquired scan loaded in the application. On initial step activation, this scan should reflect the most recently acquired scan loaded in the Target step (see Loading Intraoperative Frame Images Pg. 157). The step will also detect the targeting cannula from the most recently acquired scan when switching frame selections. Additional scans may be acquired to further adjust the targeting cannula and/or verify its position prior to device insertion.

Caution: **When acquiring whole-head scans including frames in a CT-guided procedure, ensure that the imaging field-of-view encapsulates the entire length of each trajectory and as much of the targeting cannula as possible. This will allow for full visualization of all planned trajectories and the associated projected cannula paths within the scan. The software will warn you if the loaded scan's field-of-view does not fully encapsulate all of the defined trajectories.**

You may use the Adjust Step (CT Workflow) to review the detection results for each targeting cannula on the most recently loaded scan.

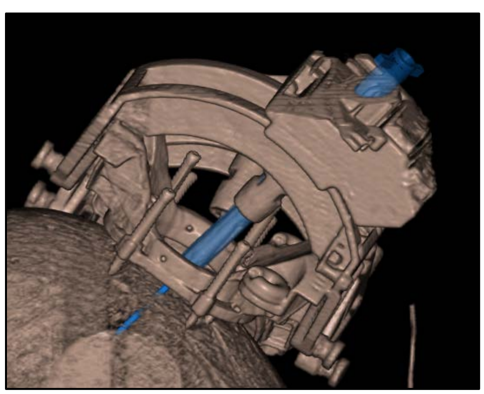
> **To review the detected targeting cannula position**

1. Observe the graphic cross sections of the targeting cannula overlaid on the individual scans in the **Cannula Orthogonal 1** and **Cannula Orthogonal 2** viewports.



2. Verify that the graphic outline of the targeting cannula matches up with the signal from the cannula. If the graphic outline for the cannula does not match up with the underlying images, proceed to manually modify the position of the cannula.

3. Assess the position of the three-dimensional targeting cannula model rendered in the 3D viewport. Verify that the model of the targeting cannula is positioned consistently with the associated frame in the acquired image series.



4. Observe the graphic annotations overlaid on the scan rendered in the right-most viewport. The following graphics are shown:

- A cross section of the planned trajectory, rendered at the device diameter specified for that trajectory (see Working with Trajectory Annotations Pg.118).

- A cross section of the projected path of the targeting cannula, also rendered at the device diameter specified for the selected trajectory.

5. If necessary, select an additional image series for blending with the master series using the Thumbnail Bar (see Using Thumbnails Pg. 86). If this action is performed, ensure to evaluate the detected targeting cannula position on the primary series in the viewing layout, since this represents the most recently acquired image series loaded into the application.

6. Use the Frame Selector available in the step control panel to select another frame whose detected cannula that you would like to review (see Selecting a Frame Pg. 83).

Note: If you change the frame selection to one in which its associated targeting cannula has not yet been detected by the application on the most recently acquired scan, the application will initiate automatic detection of that targeting cannula.

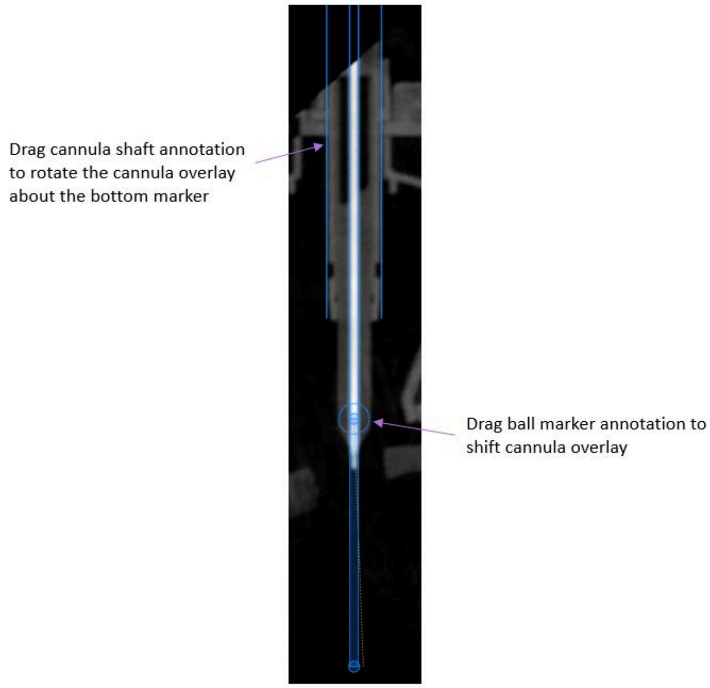
> **To manually modify the targeting cannula position**

1. If the graphic overlay representing the targeting cannula does not match up with the signal from the cannula in the scan shown in the **Cannula Orthogonal 1** and **Cannula Orthogonal 2** viewports, you may manually modify the cannula's position as follows:

   - Drag the cannula cross section to align the upper shaft of the cannula in the underlying images. Fit the graphic cross section by comparing the outer borders of the cross section to the outer shell of the physical targeting cannula. If a ceramic aiming stylet is used, additionally compare the signal from the ceramic aiming stylet to the inner borders of the cross section.

   - Drag the ball marker graphic to shift the entire cannula cross section. This may be necessary if it is not possible to completely match the cannula cross section to the physical cannula in the underlying images.

   - Use the Zoom Tools (see Zoom Tools Pg.100) and the Single/Multi Viewport Tool (see Single / Multi Viewport Tool Pg. 114) to ensure the best possible match in both views.



2. To undo or redo any position edits made to the targeting cannula:

    - Select the button from the custom toolbar to undo a position edit made to the targeting cannula cross section shown on screen.

    - Select the button from the custom toolbar to redo a position edit made to the targeting cannula cross section shown on screen.

> **To restore the initial detection of the targeting cannula position**

1. If manual edits were made to the targeting cannula and you wish to restore its initial position as originally detected from the most recent whole-head scan, select **Re-Detect Cannula** from the step control panel.

2. The application will display a floating window with a **Please Wait** message and the user interface will be blurred while the application searches for the targeting cannula in the loaded scan. If the application fails to re-detect the targeting cannula, a warning will be shown (see Failed To Identify Cannula Pg. 303).

Prescribing Frame Adjustments from a Single Scan

You may use the frame adjustments prescribed in the Adjust Step (CT Workflow) to make physical adjustments on the corresponding frame mounted on the patient. The step supplies two modes that can be used to prescribe frame adjustments as described above:

1) Target Only – In this mode, the step will display either Pitch/Roll or X/Y adjustments necessary to align the targeting cannula to the planned target point without regard to the planned entry point. These instructions are best used when the physical entry point has already been created (i.e., drilled) and confirmed using methods like tactile or visual inspection or other surgical navigation software to ensure adequate clearance through the skull and safe entry into the brain. Making a X/Y frame adjustment to align the targeting cannula to the planned target point will necessarily result in a change to the location of the entry point, which may not be desired per above, so caution is advised if using X/Y for Target Only instructions.

2) Target and Entry – In this mode, the step will display adjustment instructions for Pitch, Roll, X and Y simultaneously so that the targeting cannula may be aligned to both the target and entry points of the planned trajectory. The Pitch/Roll angulation adjustments provided would necessarily align the cannula parallel to the planned trajectory, and the X/Y adjustments would shift the cannula to be coincident with the planned trajectory. These instructions are best used when the physical entry point has not yet been created (e.g., drilled) and/or when the entry point needs to align exactly with the pre-planned entry due to patient-specific anatomy and safety concerns like arteries on the brain's surface.

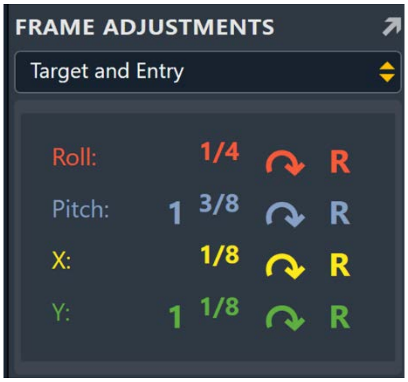
The position of the targeting cannula as defined in this step (see Reviewing the Cannula Position in Whole-Head Scans *Pg. 190**) is used to represent the expected result if the device were to be fully inserted through the cannula to target depth. The user interface will show the necessary frame adjustments required to achieve either the planned target point or entire planned trajectory (entry & target points).*

> **To make a frame adjustment**

1. Use the Frame Selector available in the step control panel to select a frame that you would like to adjust (see Selecting a Frame Pg. 83).

2. Use the Trajectory Selector available in the step control panel to select a trajectory for which you would like to align the selected frame (see Selecting a Trajectory Pg. 83).

3. Using the **FRAME ADJUSTMENTS** display in the step control panel, select the appropriate instructions: **Target Only** or **Target and Entry**. By default, **Target Only** adjustments will be displayed in the step control panel.



4. Make 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 in-room monitor (see Mirroring the External Monitor Pg. 67).

Note: Using X and Y offset adjustments in Target Only mode will result in a change to the entry point.

Reviewing Trajectory and Cannula Paths Prior to Insertion in a CT Workflow

The Adjust Step (CT Workflow) offers several tools in the step control panel that can be used to review the planned trajectory and projected targeting cannula on the most recent scan.

> **To review the selected trajectory path**

1. Use the Trajectory Selector available in the step control panel to select a trajectory path that you would like to review (see Selecting a Trajectory Pg. 83).
2. If necessary, change the orientation of the viewing layout to the desired orientation (see Changing a Viewing Layout Orientation Pg. 90).
3. Observe the graphic annotations overlaid on the scan rendered in the right-most viewport to visually assess the cross section of the planned trajectory.
4. Use the Image Scroller (see Image Scroller Pg. 95) or mouse wheel to scroll along the trajectory path in the right-most viewport.
5. Select **GO TO Target** from the step control panel to navigate to the selected trajectory's target point. Alternatively, click the ⏭ button.

6. Select **GO TO Entry** from the step control panel to navigate to the selected trajectory's entry point. Alternatively, click the ⏮ button.

7. To automatically scroll from the selected trajectory's entry point to target point, click the ▶ button from the step control panel. To stop automatically scrolling along the selected trajectory path, click the ■ button from the step control panel. (Note: Automatic scrolling along the selected trajectory path will stop once the target point location is reached).

8. You may use the **OVERLAYS** group-box in the step control panel to toggle the visibility of the planned trajectory. This can be useful to visually assess the planned trajectory relative to underlying anatomy. You may also use the **Show/Hide Viewport Annotations** tool to change the visibility of all annotations shown in this step (see Showing / Hiding Annotations Pg. 84).

> **To review the projected cannula path**

1. Use the Frame Selector available in the step control panel to select a frame whose cannula's projected path you would like to review (see Selecting a Frame Pg. 83).

2. If necessary, change the orientation of the viewing layout to the desired orientation (see Changing a Viewing Layout Orientation Pg. 90).

3. Observe the graphic annotations overlaid on the scan rendered in the right-most viewport to visually assess the cross section of the targeting cannula's projected path relative to the planned target point.

4. You may use the **OVERLAYS** group-box in the step control panel to toggle the visibility of the projected cannula path. This can be useful to visually assess the path of the targeting cannula relative to underlying anatomy.

5. Use the **TARGET ERROR MEASUREMENTS** group-box in the step's control panel to assess how the projected cannula path compares to the planned target on the selected error plane (see Reviewing Trajectory and Cannula Paths Pg. 173).

6. Use the **ENTRY ERROR MEASUREMENTS** group-box in the step's control panel to assess the radial error from the targeting cannula's ball marker to the planned entry point. This provides an indication of how far the physical ball marker is from the planned entry point.

Proceeding to Further Adjust the Cannula in a CT Workflow

You may choose to make further adjustments to each cannula's position to sufficiently align it with the planned target point or entire trajectory (target & entry) during a CT Workflow. It is suggested that each cannula be further adjusted until the projected device placement and/or entry point error is clinically acceptable.

> **To make further frame adjustments**

1. Acquire a whole-head CT scan using Scanner Console and transfer or load the images onto the workstation (see Interoperation with CT Scanners Pg. 36).
2. Allow the application to detect the cannula from the loaded scans. Review the detection of the cannula using the tools offered in this step (see Reviewing the Cannula Position in Whole-Head Scans Pg. 190).
3. Use the Frame Selector available in the step control panel to select a frame that you would like to adjust (see Selecting a Frame Pg. 83).
4. Use the Trajectory Selector available in the step control panel to select a trajectory for which you would like to align the selected frame (see Selecting a Trajectory Pg. 83).
5. Review the projected path of the targeting cannula on the loaded scan and assess its projected placement and entry point viability (see Reviewing Trajectory and Cannula Paths Prior to Insertion in a CT Workflow Pg. 195).
6. Make the frame adjustments as prescribed by the software based on the mode selected in the step control panel (see Prescribing Frame Adjustments from a Single Scan Pg. 194).
7. You may iteratively continue to adjust the cannula until the predicted path and/or entry point error is clinically acceptable.

Insert Device

This section describes how to use the ClearPoint Workstation to assist you in preparing your device(s) for insertion, monitor the progress of the device insertion(s) to target depth, and assess the placement of one or more devices relative to a planned trajectory path into the brain.

Caution:	**This section describes an optional workflow that is not required to complete a neurological procedure. For MR-guided procedures, it is only to be performed if the manufacturer's instructions for the inserted device provide a safe scanning protocol. If no safe protocols are provided, the procedure must be completed without further scanning. In this case the patient should be removed from the scanner.**

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

- The current angulation and position of the targeting cannula corresponding to the frame that you will use to insert the device has been verified. This includes ensuring that the projected path of the cannula is in a clinically acceptable location within the brain.
- The frame's cannula must be locked in the "down" position.
- For MR-guided procedures, safe scanner protocols must be configured on the scanner and verified to be safe for clinical use.

Insert Step Monitor and Assess Device Placement

The Insert Step can be used to assist you in preparing your device(s) for insertion, monitoring the progress of one or more device insertions into the brain, and assessing the anatomical placement of devices relative to planned trajectory paths. Prior to using this step, ensure that the position of the targeting cannula corresponding to the frame that you will use to insert the device has been reviewed and verified.

Caution:	**This is an optional workflow step. For MR-guided procedures, 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 Insert Step allows you to perform the following workflow-related actions:

- Preparing the device(s) for insertion (see Preparing the Device for Insertion Pg.199).
- Monitoring the progress of a device insertion (see Monitoring Insertion Progress Pg. 201).
- Reviewing the inserted device track (see Reviewing the Inserted Device Path Pg. 202).
- Editing the position of the inserted device track (see Editing the Inserted Device Path Pg. 205).
- Assessing the device placement (see Assess Device Placement Pg. 207).
- Accepting or rejecting the anatomical placement of a device (see Accept or Re-Adjust Placement Pg. 209).

Within the Insert step, you have the option to perform the following workflow-specific tasks:

- The Fusion Task (see Fusion Task *Fusing Images* Pg. 219) may be used to fuse additional image series that contain the inserted device(s). If inserting the device has necessitated changing the frame of reference used to scan the patient, the Fusion Task can be used to fuse the newer scans containing the device with the original volume scan containing the frame. This allows you to assess the device on images where the frame of reference may have changed.
- The Compare Task (see Compare Task *Comparing Images* Pg. 232) may be used to compare post-insertion / post-operative images in their individual acquisition planes or standard scanner planes.

Preparing the Device for Insertion

Prior to inserting the device, refer to the device's Instruction Manual for proper preparation. During MR-guided procedures, this may include instructions for safe scanning. The application will issue a reminder of this prior to proceeding with the workflow.

Caution:	**Prior to device insertion inside or outside of the scanner, visually and tactilely assess clearance with the physical scanner to ensure that the device can be safely inserted without contacting any scanner surfaces. Performing this manual check can help prevent unintended deviations from the planned trajectory path.**

> **To prepare a device for insertion**

1. Navigate to the Insert Step.

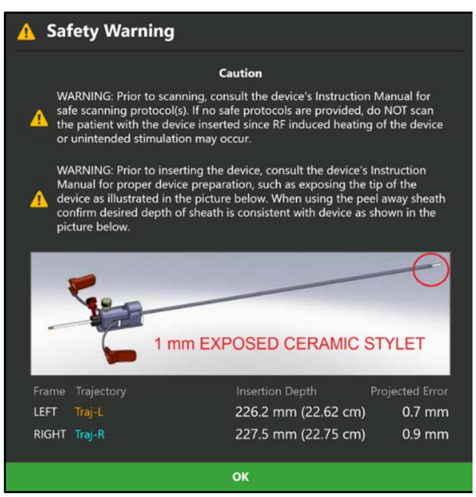
2. Note the **Safety Warning** dialog and perform the following actions:

   - For MR-guided procedures using an MRI Workflow, ensure that the RF pulse sequences that will be used to acquire images of the patient with the device(s) in place are safe for use with the device(s) to be inserted.

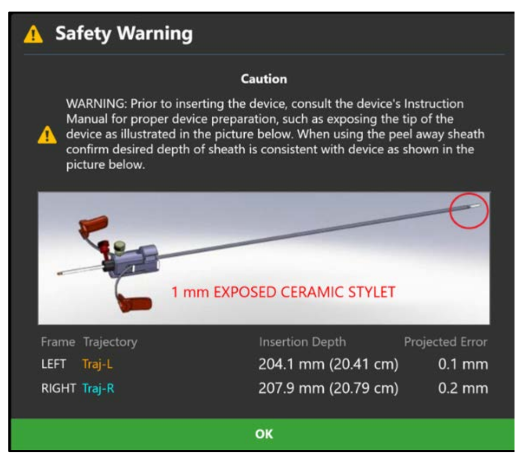
   - Prepare the device according to its instruction manual.

   - Verify that the residual error left in the frame alignment steps (see Align and Adjust Cannula in an MRI Workflow Pg. 168 or Adjust Cannula in a CT Workflow Pg. 188) is adequate for device insertion. This value can be found under the **Projected Error** field for each trajectory listed in the dialog. Note that if a residual error of more than 1.5 mm is present in the frame alignment steps, the application will warn you of this condition (see Frame Cannula Not Sufficiently Aligned to Trajectory Pre-Insertion Pg. 304). The user then decides if a targeting error larger than 1.5 mm is clinically acceptable for the inserted device.

   - Measure and mark the depth for the device to be inserted. The depth value required to reach the target point of each trajectory listed in the dialog is provided under the **Insertion 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 depth stop appropriately.



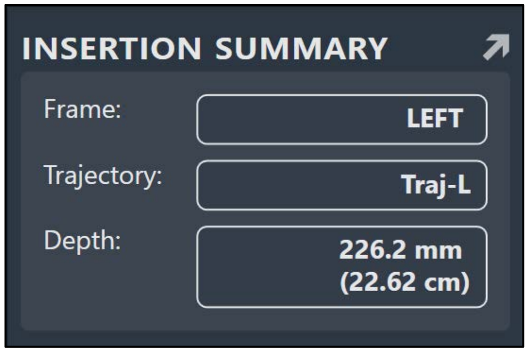
MRI Workflow



CT Workflow

3. Select **Ok** to close the dialog.

4. Once dismissed, you may use the **INSERTION SUMMARY** group-box in the step control panel to re-visit the insertion depth value for the currently selected trajectory.



5. Insert the device into the targeting cannula of the appropriate frame, going partially or fully to target per the user's discretion prior to scanning again.

Monitoring Insertion Progress

You may use the Insert Step to monitor the progress of a device insertion if clinically indicated or desired by the user. Scans may be acquired with the device partially inserted to assess the projected device path into the brain.

Caution:	**Consider acquiring scans multiple times during the device insertion to confirm a safe insertion path into the brain. Imaging can provide assurances that the inserted device is following the planned trajectory path. Frequent scans may also help with the early detection of hemorrhage.**

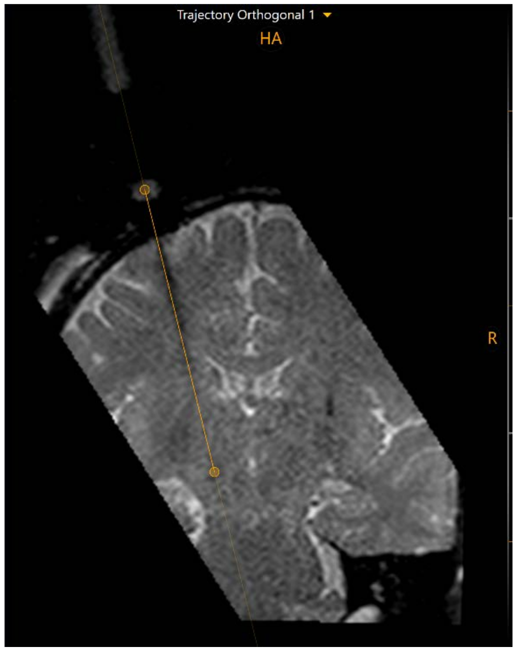
> **To monitor a device insertion**

1. Use the Frame Selector available in the step control panel to select a frame into which the device has been inserted (see Selecting a Frame Pg. 83).

2. Use the Trajectory Selector available in the step control panel to select a trajectory for which you would like to monitor the inserted device against (see Selecting a Trajectory Pg. 83).

3. Acquire an image series of the patient with the device inserted and transfer or load the images onto the workstation. If you are performing an MRI Workflow (see MRI Workflow Pg. 39), you may use the **Orthogonal 1** and **Orthogonal 2** buttons under the **SCAN PLANE PARAMETERS** group-box heading to acquire orthogonal scans along the planned trajectory.

4. On loading the image scans, the application displays the images with a graphic overlay representing the planned trajectory path. You may visually compare the graphic representing the planned trajectory path with the images containing the inserted device track.



The most recently acquired scans will be automatically connected to the viewing layout upon loading new images. If desired, you may change the currently selected image series using the Thumbnail Bar in the step control panel (see Using Thumbnails Pg. 86).

5. If necessary, acquire additional scans along the planned trajectory path with the device inserted at different depths to monitor the insertion to target depth.

6. If desired, review and/or edit the inserted device path on the acquired images (see Reviewing the Inserted Device Path Pg. 202).

Reviewing the Inserted Device Path

You may use the Insert Step to define and review the position of the inserted device track into the brain.

> **To define the inserted device path**

1. Use the Frame Selector available in the step control panel to select a frame into which the device has been inserted (see Selecting a Frame Pg. 83).

2. Use the Trajectory Selector available in the step control panel to select a trajectory for which you would like to compare the inserted device path against (see Selecting a Trajectory Pg. 83).

3. Change the viewport orientation to the desired viewing orientation that you would like to use to define the inserted device path (see Changing a Viewing Layout Orientation Pg. 90).

4. Identify the tip of the inserted device using the **INSERTION REVIEW** group-box in the step control panel using an image series selected from the Thumbnail Bar (see Using Thumbnails Pg. 86). Defining the tip of the inserted device can be performed manually or automatically.

5. To automatically identify the tip of the inserted device in the selected image series click on the **Detect Device** button or use the **Segment Device Tip** button from the custom toolbar inset within the viewport. A floating window will display a **Please Wait** message and the user interface will be blurred while the application searches for the device track in the selected scan.

While detecting the device track in MR images during an MRI Workflow, the application assesses whether the track 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. 305* *for additional details.*

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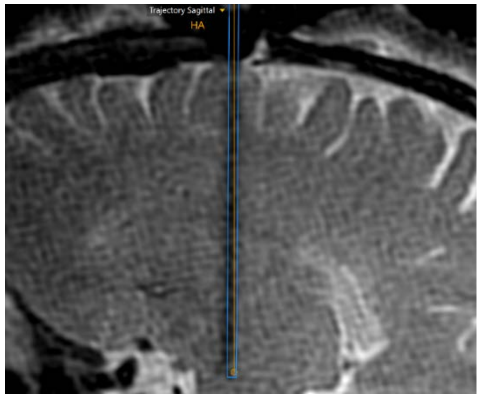
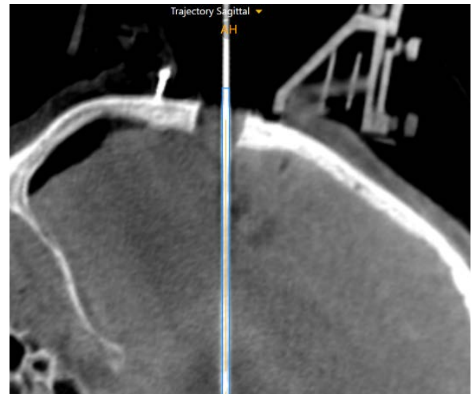
6. To manually set the tip of the inserted device, click on the **SET Tip** button or use the **Set Device Tip** button from the custom toolbar inset within the viewport.

7. After identifying the inserted device tip, the application will automatically change the viewing orientation of the layout to be oriented along the device path. A graphic representation of the device track will be rendered in the viewports.



MRI Workflow



CT Workflow

8. If necessary, acquire additional scans of the patient with the device inserted to better define the inserted device track.

> **To review the inserted device path**

1. Change the viewport orientation to the desired viewing orientation that you would like to review the inserted device path (see Changing a Viewing Layout Orientation Pg. 90).
2. Select an image series for which to review the defined device track using the Thumbnail Bar (see Using Thumbnails Pg. 86).
3. To reposition the crosshairs on the currently selected device tip, click the **GO TO Tip** button in the **INSERTION REVIEW** group-box in the step control panel.
4. To reposition the crosshairs on the currently selected trajectory's target point, click the **GO TO Target** button in the **INSERTION REVIEW** group-box in the step control panel.
5. 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.
6. You may acquire additional images with the device track inserted. If you are performing an MRI Workflow (see MRI Workflow Pg. 39), you may use the **Orthogonal 1** and **Orthogonal 2** buttons under the **SCAN PLANE PARAMETERS** group-box heading to acquire orthogonal scans along the inserted device track.
7. Visually compare the defined device track with the planned trajectory path. If the inserted device track does not appear to follow the planned trajectory path:

- If executing an MRI Workflow, proceed to reject the placement and assess the cause (see Device Re-Insertion & Bias Compensation Pg. 211).
- If executing a CT Workflow, remove the device and assess the cause (see Adjust Step Finalize the Cannula Position in a CT Workflow Pg. 188).

Editing the Inserted Device Path

After defining the inserted device track, you may make edits manually and/or initiate a device detection on a newly acquired image series using the Insert Step.

> **To manually modify the device tip position**

1. Use the Trajectory Selector available in the step control panel to select a trajectory whose device tip position that you wish to edit (see Selecting a Trajectory Pg. 83).
2. 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. 90).
3. Select an image series for which to edit the defined device track using the Thumbnail Bar (see Using Thumbnails Pg. 86).
4. Reposition the crosshairs in the viewports (see Changing Crosshair Positions Pg. 93) to a location where you would like to set the device tip. Click the **SET Tip** button in the step control panel or use the **Set Device Tip** button from the custom toolbar to set the tip of the device at the current position of the crosshairs.
5. You may also edit the device tip using mouse click and drag operations (see Working with Trajectory Annotations Pg. 118). Note that the click and drag operations for editing the device track are operational when the viewport orientation is set to **Device** or **Device Orthogonal** orientation (see Changing a Viewing Layout Orientation Pg. 90), and when the following viewports are used: **Device 1**, **Device 2**, **Device Perpendicular**, **Device Coronal**, **Device Sagittal**, or **Device Axial**.

> **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. 86).

2. Click the **Detect Device** button in the step control panel or use the **Segment Device Tip** button from the custom toolbar to automatically search for the device tip in the selected image series.

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 manually modify the device entry point

1. Use the Trajectory Selector available in the step control panel to select a trajectory whose device entry point position that you wish to edit (see Selecting a Trajectory Pg. 83).

2. Change the viewport orientation to the desired viewing orientation that you would like to use to set the device entry point (see Changing a Viewing Layout Orientation Pg. 90).

3. Select an image series for which to edit the defined device track using the Thumbnail Bar (see Using Thumbnails Pg. 86).

4. Use mouse click and drag operations to modify the device entry point position (see Working with Trajectory Annotations Pg. 118). Note that the click and drag operations for editing the device track are operational when the viewport orientation is set to **Device** or **Device Orthogonal** orientation (see Changing a Viewing Layout Orientation Pg. 90), and when the following viewports are used: **Device 1**, **Device 2**, **Device Perpendicular**, **Device Coronal**, **Device Sagittal**, or **Device Axial**.

Note: The software will prevent free-form edits to the device entry point if the resulting edit will move the entry point too far away from the currently selected frame. Editing the device entry point is confined to the general vicinity of the currently selected frame.

> To undo or redo edits made to the device tip

Use the **Undo Device Tip Change** and **Redo Device Tip Change** tools in the viewport's custom toolbar 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.

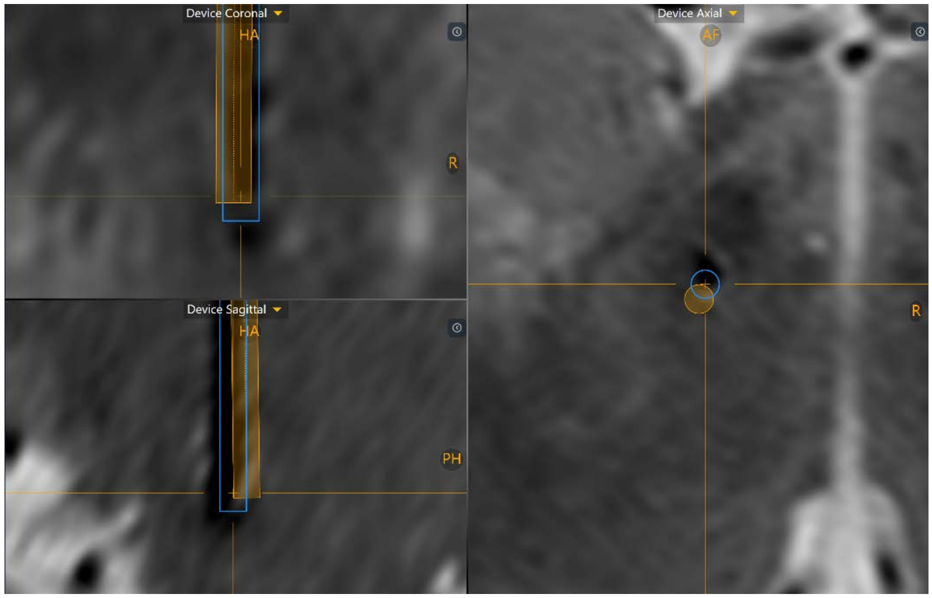
- Select the button from the custom toolbar to redo a change made to the device tip shown on screen.

Assess Device Placement

The Insert Step may be used to assess the placement of a partially or fully inserted device. Based on this assessment, you can then decide whether the final device placement is clinically acceptable.

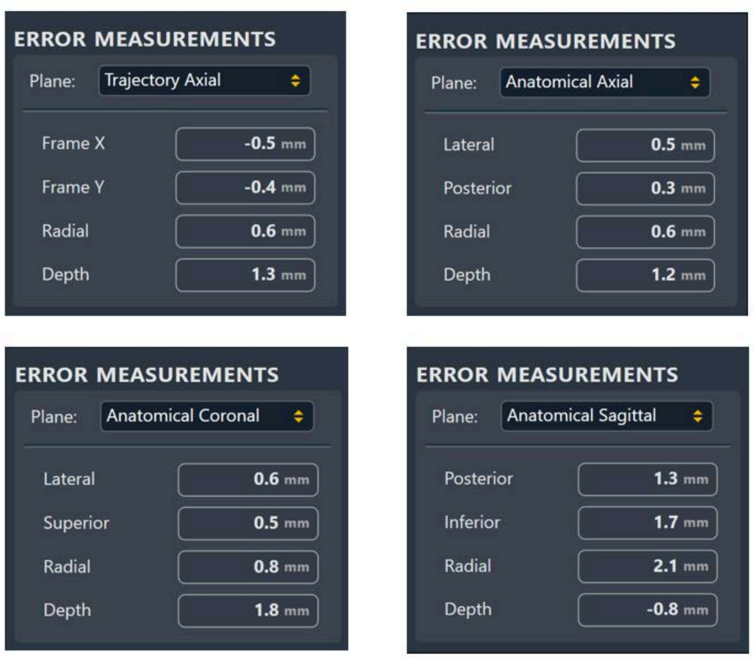
> **To evaluate the placement of the device**

1. Select the frame used for the device insertion (see Selecting a Frame Pg. 83).
2. Select a planned trajectory used for the device insertion (see Selecting a Trajectory Pg. 83).
3. Select a viewing orientation for which you would like to assess the device placement (see Changing a Viewing Layout Orientation Pg. 90).
4. If additional images are required to assess the device placement, acquire and transfer or load the images onto the workstation. If you are performing an MRI Workflow (see MRI Workflow Pg. 39), you may use the scan plane parameters provided by the step to a acquire high-resolution MR scan at the target location. Click **Target** under the **SCAN PLANE PARAMETERS** group-box heading to bring up scan plane parameters to acquire a high-resolution scan at the target location.
5. Select an image series for which to assess the inserted defined device track using the Thumbnail Bar (see Using Thumbnails Pg. 86).
6. Review and edit the inserted device path on the selected scan (see Reviewing the Inserted Device Path Pg. 202).
7. In the viewports, visually compare the inserted device track and planned trajectory graphic annotations.



8. 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 qualitatively compare either path to the underlying images and associated patient anatomy.

9. Use the **ERROR MEASUREMENTS** group box in the step control panel to quantitatively assess the error measurements comparing the inserted device tip to the planned trajectory's target point. Using the drop-down menu, select a plane for which to express the error measurements:



For each selected measurement plane, the error between the inserted device tip and the selected trajectory's target point is expressed as follows:

- If the selected plane is **Trajectory Axial**, the two axes used to decompose the error are the corresponding frame's X and Y directions.
- If the selected plane is **Anatomical Axial**, the two axes used to decompose the error are sagittal and coronal, and the corresponding labels for the error are lateral/medial, and anterior/posterior respectively.
- If the selected plane is **Anatomical Coronal**, the two axes used to decompose the error are sagittal and axial, and the corresponding labels for the error are lateral/medial, and superior/inferior respectively.
- If the selected plane is **Anatomical Sagittal**, the two axes used to decompose the error are coronal and axial, and the corresponding labels for the error are anterior/posterior, and superior/inferior respectively.
- Radial – The distance between the target and the intersection of the device axis with the target plane. This is also referred to as the 'in-plane' error.
- Depth – The distance along the device axis between device tip and the intersection of the device axis with the selected measurement plane through the target (target plane). Negative values indicate that the device is shallow relative to the target plane, whereas positive values indicate that it has been inserted past the target plane.

10. 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 load these acquired scans onto the workstation with the step active to perform this assessment.

Accept or Re-Adjust Placement

If, after evaluating the placement of the device relative to the planned target, you have determined that placement is clinically acceptable, you may proceed to insert additional devices for additional trajectories, if applicable.

Caution:	**For MR-guided procedures, if you are inserting another device after confirming the placement, you must follow the device manufacturer's guidelines for performing MR scans with the device inserted. Failure to do so may result in injury or death to the patient.**

If you have determined that the device placement is not clinically acceptable:

- If executing an MRI Workflow (see MRI Workflow Pg. 39), proceed to reject the placement and assess the cause (see Device Re-Insertion & Bias Compensation Pg. 211).
- If executing a CT Workflow (see CT Workflow Pg. 40), remove the device and assess the cause (see Adjust Step Finalize the Cannula Position in a CT Workflow Pg. 188).

> 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 Trajectory Selector (see Selecting a Trajectory Pg. 83) to select another trajectory for which you would like to assess a device insertion against. The **INSERTION SUMMARY** group box in the step control panel will be populated with the insertion depth value for the selected trajectory (see Preparing the Device for Insertion Pg. 199).

> To reject a device placement in an MRI Workflow

When executing an MRI Workflow, if you have decided to reject the placement of the device, select **Re-Adjust** from the step control panel. This will navigate you to the Re-Adjust step (see Re-Adjust Step Managing a Device Re-Insertion (MRI Workflow Only) Pg. 213), where you may assess the root cause of the original placement, re-adjust the selected frame and re-insert the device.

Device Re-Insertion & Bias Compensation (MRI Workflow Only)

This section describes how to use the ClearPoint Workstation to re-insert a device into the brain after its original placement was rejected during an MRI Workflow (see MRI Workflow Pg. 39). The workflow employed in the application assists you in first determining the root cause of the originally rejected device placement, and then guiding you through correcting the original device placement with a subsequent device re-insertion. This step is specific to the MRI Workflow because it can address potential geometric distortion of the images used to position the device at target. This is an issue that is specific to Magnetic Resonance Imaging (MRI) and does not occur with Computed Tomography Imaging (CT).

The following points need to be considered when determining whether a device re-insertion will improve the original device placement during the MRI-guided procedure:

1. If the error is less than half the thickness of the inserted device, subsequent insertions are very likely to follow the first insertion track. Re-insertion is not recommended in this case.

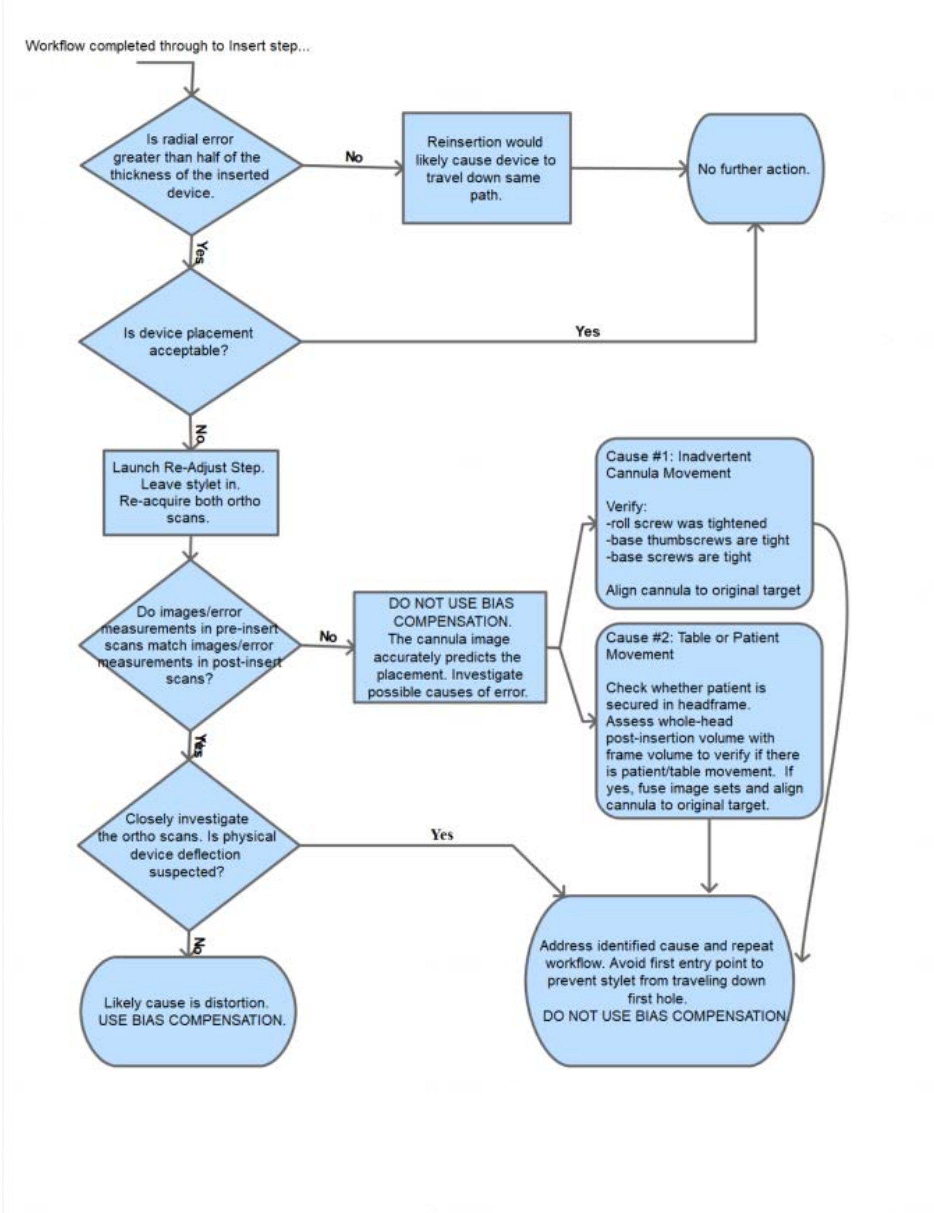
Caution:	**Re-inserting the device introduces the possibility of following a previous insertion track. If necessary, perform a manual X/Y adjustment to ensure that the device will insert along a new track. Be aware that making X/Y adjustments will change the entry point.**

2. The following possible sources of error may exist which caused the original placement:

   - Accidental movement of the targeting cannula.
   - Accidental movement of the frame on the patient.
   - Unintended movement of the patient in fixation.
   - Movement of the MRI Scanner table.
   - Device deflection during insertion.
   - Geometric distortion of images used to perform frame adjustments. This is the only case where bias compensation can be expected to improve the result.

Caution:	**Bias compensation will not correct random, one-time, or non-linear errors. It must only be used when geometric distortion in the acquired images has been identified.**

The following flowchart describes how to assess the root cause of the original device placement and decide whether re-inserting the device will improve the final placement during an MRI Workflow.



Re-Adjust Step Managing a Device Re-Insertion (MRI Workflow Only)

The Re-Adjust Step allows you to correct cannula positioning after a device placement has been deemed clinically unacceptable. This step is only available during an MRI Workflow (see MRI Workflow Pg. 39) because it can address potential geometric distortion of the images used to position the device at target. This is an issue specific to Magnetic Resonance Imaging (MRI) and does not occur with Computed Tomography Imaging (CT).

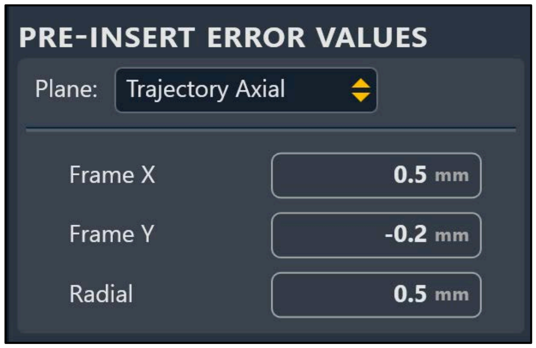
Caution:	**You must remove the inserted device prior to performing any further adjustments of the cannula.**

The following high-level features are offered in the Re-Adjust Step to assist you with determining the root cause of the original device placement, as well as providing guidance to re-adjust the targeting cannula in cases where a device re-insertion is necessary:

- Providing views to assess and check for device deflection.
- Providing image blend features to assess / check for unintended frame movement.
- Prescribing frame adjustments required to align the cannula based on determination of the original device placement.
- Reviewing the planned trajectory and associated projected cannula path.

> **To re-adjust the cannula**

1. Launch the Re-Adjust step by selecting **Re-Adjust** in the Insert step (see Accept or Re-Adjust Placement Pg. 209).
2. The viewing layout will display the most recent set of orthogonal cannula scans that were last acquired for the selected trajectory's frame. These acquisitions were loaded when the Adjust step (MRI Workflow) (see Adjust Step Finalize the Cannula Position in an MRI Workflow Pg. 176) was completed for the selected trajectory. The residual error measurements achieved using these orthogonal cannula scans are displayed in the **PRE-INSERT ERROR VALUES** group box in the step control panel.



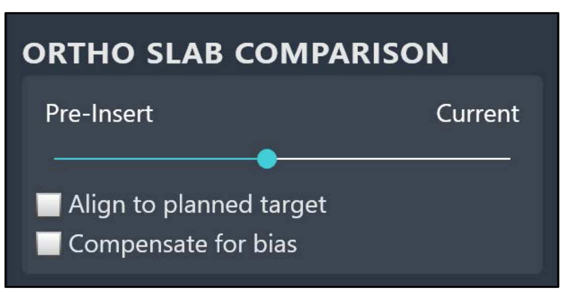
3. Acquire two independent scans of the cannula, aligned orthogonally to the planned trajectory using the scan plane parameters provided in the step panel (see Interoperation with MRI Scanners Pg. 30).

4. Enter the values on the scanner console, scan, and transfer or load the images onto the workstation.

5. On receiving the orthogonal scans, the application performs the same set of operations as the Adjust Step (MRI Workflow) (see Adjust Step Finalize the Cannula Position in an MRI Workflow Pg. 176) in order to detect the current position of the targeting cannula.

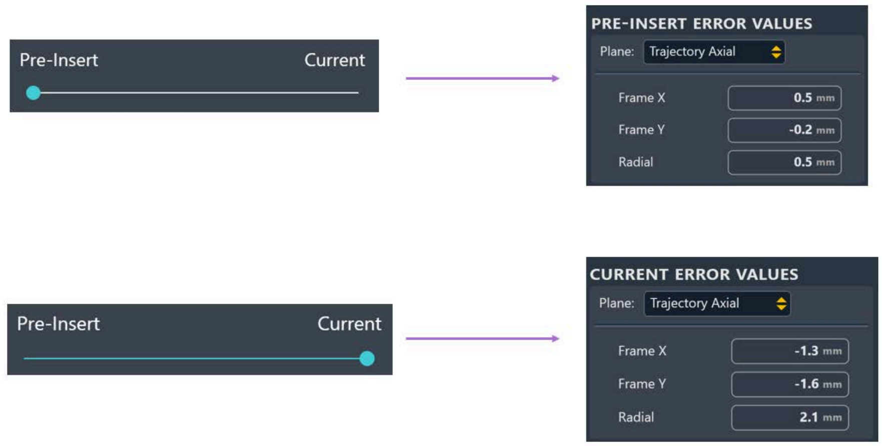
6. Use any of the tools discussed in the Adjust Step (MRI Workflow) to review the current position of the cannula and manually position it if necessary.

7. Use the slider bar in the **ORTHO SLAB COMPARISON** group box to blend between the cannula scans acquired prior to insertion (**Pre-Insert**) and those just recently acquired (**Current**).



8. Moving the slider bar to the far left under **Pre-Insert** will display the cannula scans acquired prior to insertion in the viewports (with no image blending) along with the **Pre-Insert Error Measurements**. Moving the slider bar to the far right under **Current** will display the cannula scans most recently acquired in the viewports (with no image blending) along with the **Current Error**

Measurements. If the slider bar is in between **Pre-Insert** and **Current**, an image blend of the cannula scans acquired prior to insertion and those acquired recently will be shown. No errors values will be shown in these instances.



9. Use the blended cannula images and presented error measurements to determine how to proceed with re-positioning the cannula. Note that if the error measurements in the two image conditions do not match, then there has been inadvertent movement of the targeting cannula, scanner table, or patient. If the error measurements in the two image conditions are identical, then there has been device deflection or image distortion artifacts are present in the images.

    - If the device placement was caused by inadvertent cannula movement, verify that the frame's roll locking screw, base thumbscrews and base screws have been tightened appropriately. Select the **Align to planned target** checkbox to show the frame instructions required to align the cannula to the originally planned target point (see Prescribing Frame Adjustments from Orthogonal Scans Pg. 184).

    - If the device placement was caused by scanner table or patient movement within fixation, check whether the patient is secured in the head frame, acquire a whole-head image volume post-insertion and fuse it with the master series from the Target Step using the Fusion Task in the Insert step (see Fusion Task Fusing Images Pg. 219).

Select the **Align to planned target** checkbox to show the frame instructions required to align the cannula to the originally planned target point (see Prescribing Frame Adjustments from Orthogonal Scans Pg. 184).

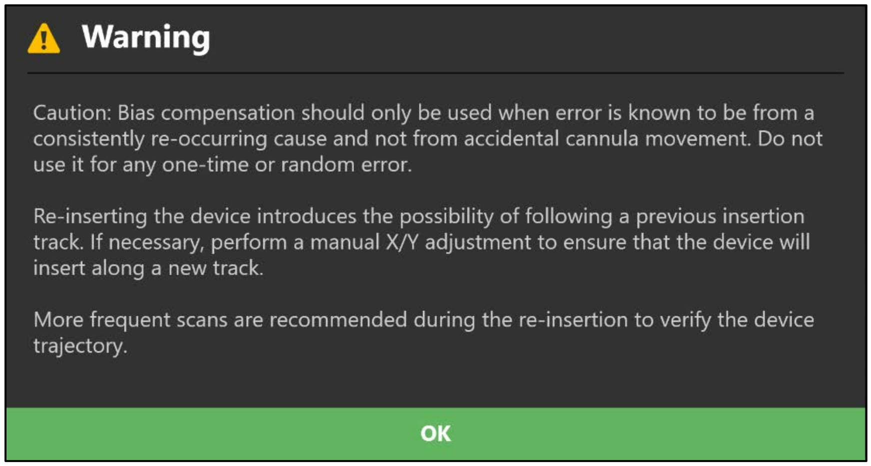
- If the device placement was caused by device deflection on an anatomical feature (e.g., bone-edge), repeat the clinical workflow to re-plan a trajectory that is far enough away from the existing device path as to prevent any subsequent device insertions from travelling down the same path while avoiding the cause of the deflection.

- If the device placement was not caused by any of the above conditions, then using bias compensation is appropriate for correcting the placement. **Before proceeding, double check that the error measurements between the two image conditions are identical.** Select the **Compensate for bias** checkbox to show the frame instructions required to align the cannula to the bias compensate target (see Prescribing Frame Adjustments from Orthogonal Scans Pg. 184).

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 cannula to an alternate location that will account for a systematic scanner bias but will not be shown in the viewports or anywhere else in the user interface.

Caution: **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.**

10. If bias compensation was used to re-position the cannula, read the message dialog presented and selected **OK.**



11. From this point you may proceed with the workflow from adjusting the cannula positioned as outlined in Adjust Step Finalize the Cannula Position in an MRI Workflow Pg. 176.

Note: An optional alternative approach is to make the prescribed adjustments needed to align to the bias compensation target and then proceed with device insertion without acquiring any further image slabs to confirm that adjustments were made correctly. While this has the advantage of eliminating the effects of potential variability in distortion between different image scans, it has the disadvantage that any error made in adjusting the frame will not be detected prior to inserting the device. This approach necessitates extreme care when turning the frame adjustment knobs to ensure that the prescribed turns are made correctly.

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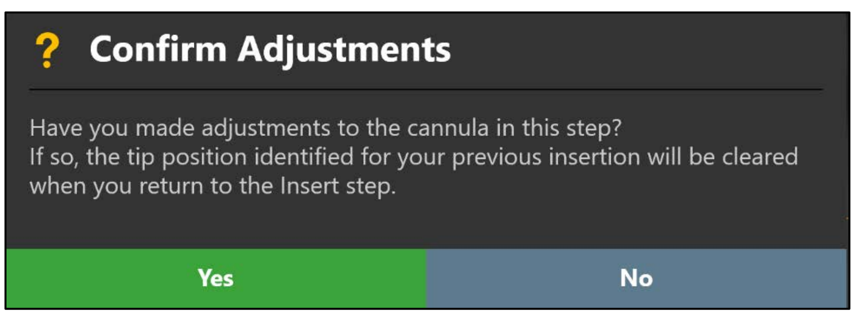
12. After all cannula adjustments have been made to re-position the frame to the selected trajectory, close the step. The application will prompt you to confirm that you have made cannula adjustments in this step. If so, select **Yes** and any defined insertion tracks for the planned trajectory will be cleared in the application. If not, select **No** and no insertion tracks will be cleared.



13. Proceed with the insertion of the device (see Preparing the Device for Insertion Pg. 199).

14. Monitor and assess the device placement (see Monitoring Insertion Progress Pg. 201 and Assess Device Placement Pg. 207).

Optional Tasks

This section describes how to use the optional workflow tasks provided by the ClearPoint Workstation.

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. Usage of the Fusion Task may be necessary so that images that were acquired in different frames of reference may be blended.

If one of 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. 219).
- Automatically fuse a loaded image series with the master series (see Automatically Fusing Images Pg. 221).
- Manually override and/or edit the fusion transformation between a loaded image series and the master series (see Manually Editing Image Fusions Pg. 226).

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. Select the Fusion Task using the Task Selector (see Selecting a Task Pg. 84). The master series will be set automatically based on the master series defined in the workflow. You may not change the master series selection in the Fusion Task.

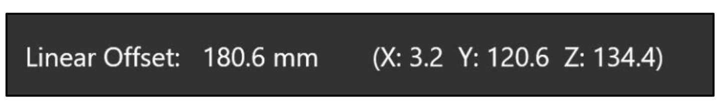
2. Select an image series from the task's Thumbnail Bar to review the fusion with the master series (see Using Thumbnails Pg. 86). If the fusion between the selected image series and the master series has been previously accepted, a check mark will be shown on the thumbnail. If the fusion between the selected image series and the master series has not been accepted, a question mark will be shown on the thumbnail.

Fusion Not Accepted

Fusion Accepted

3. Use the image blend tools (see Image Blend Tools Pg. 108) within the task's viewports to review the fusion between the selected scan and the master series.

4. Review the fusion translational offset values in the task control panel to understand the linear distance (in millimeters) found between the selected image series and the master series. This value represents the distance that a point in the master series will be shifted to align with its corresponding point in the selected image series. It is not a measure of the quality of the fusion but rather an indication of the overall difference between the original image positions before the fusion was applied.



5. If the fusion between the selected image series and the master series appears correct but has not yet been explicitly accepted, select **Accept Fusion** from the task control panel. If the fusion appears incorrect, either automatically (see Automatically Fusing Images Pg. 221) or manually (see Manually Editing Image Fusions Pg. 226) fuse the image series together.

If the application detects that a loaded image series is in a different frame of reference as the master series, the Fusion task will automatically launch to prompt fusion of the loaded series with the master series. In this case, only the loaded image series and the master series will be shown in the Fusion task's Thumbnail Bar.

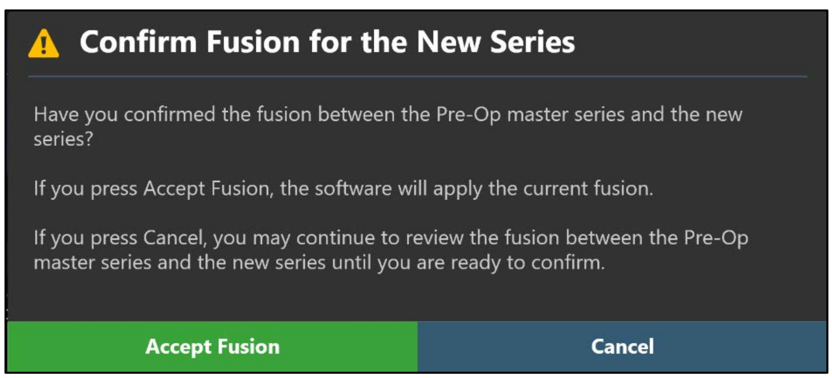
> **To review an image fusion when there is a frame of reference change**

1. Use the image blend tools (see Image Blend Tools Pg. 108) within the task's viewports to review the fusion between the loaded scan and the master series. If the images do not appear to be in the same frame of reference, fuse the image series together, using automatic (see Automatically Fusing Images Pg. 221) or manual (see Manually Editing Image Fusions Pg. 226) means.

2. Review the fusion translational offset values in the task control panel to understand the linear distance (in millimeters) differences between the loaded image series and the master series.

3. If the fusion between the loaded image series and the master series appears correct, select **DONE** in the top-right hand corner of the task window. (Note: If multiple image series are loaded that are in different frames of reference, the Fusion task will prompt you to fuse each scan with the master series. Select **NEXT>** in the top-right hand corner of the task window to select the next image series whose frame of reference differs from the master series).

4. When prompted, select **Accept Fusion** to accept the fusion between the loaded series and the master series. Otherwise, select **Cancel** to remain in the task and continue to review the fusion between the loaded series and the master series.



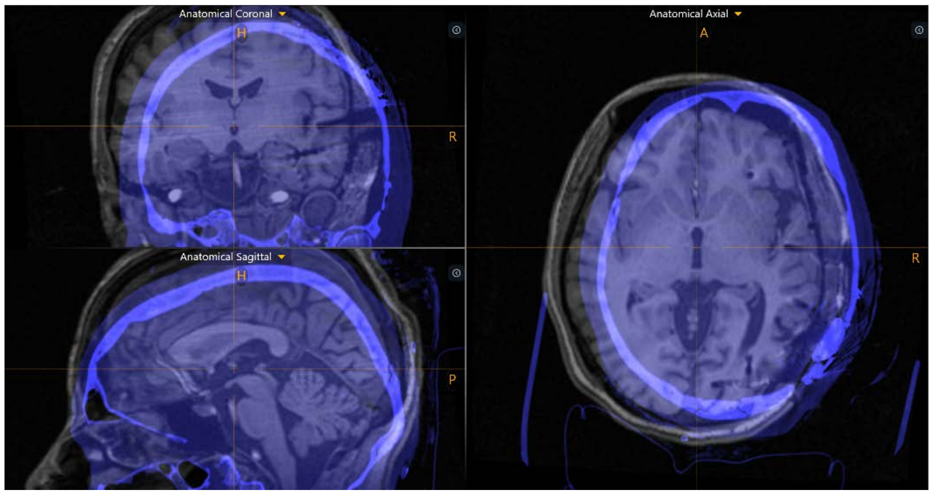
Automatically Fusing Images

You may use the Fusion Task to automatically fuse an image series to the master series. Automatic fusion can be achieved using several different mechanisms, including unseeded image fusion, seeded image fusion and image fusion using region of interest tools.

> **To exercise an unseeded automatic fusion**

1. Select the Fusion Task using the Task Selector (see Selecting a Task Pg. 84). (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).

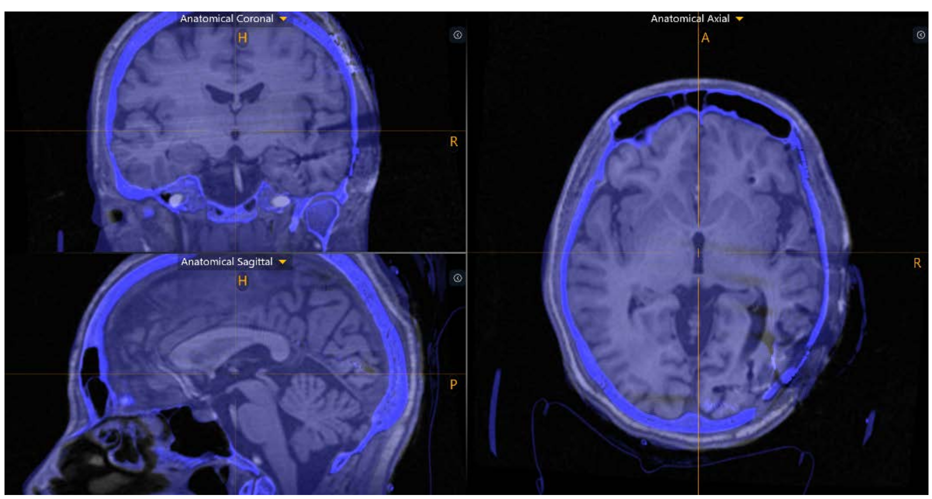
2. If necessary, select an image series to fuse using the Thumbnail Bar (see Using Thumbnails Pg. 86).



3. Select **Detect Fusion** from the task's control panel.

4. A floating window will display a **Please Wait** message and the task user interface will be blurred.

5. After the automatic fusion is completed, the results will be displayed within the viewports. A status message will pop-up indicating that the automatic fusion has completed successfully.



6. Review the resulting fusion between the images (see Reviewing Image Fusions Pg. 219).

7. If the resulting fusion appears correct, accept the fusion transformation using the task (see Reviewing Image Fusions Pg. 219). If the resulting fusion appears incorrect, you may use a seeded automatic fusion, fusion region of interest tools, and/or manual fusion tools (see Manually Editing Image Fusions Pg. 226) to modify the result until it appears correct.

> **To exercise a seeded automatic fusion**

1. Select the Fusion Task using the Task Selector (see Selecting a Task Pg. 84). (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. If necessary, select an image series to fuse using the Thumbnail Bar (see Using Thumbnails Pg. 86).

3. Use one or more manual fusion tools (see Manually Editing Image Fusions Pg. 226) to pan and/or rotate the selected image series so that it is more closely aligned with the master series. The application will use the transformation defined between the selected image series and the master series as a starting point (or "seed") for automatic fusion.

4. Select **Detect Fusion** from the task's control panel.

5. A floating window will display a **Please Wait** message and the task user interface will be blurred.

6. After the automatic fusion is completed, the results will be displayed within the viewports. A status message will pop-up indicating that the automatic fusion has completed successfully.

7. Review the resulting fusion between the images (see Reviewing Image Fusions Pg. 219).

8. If the resulting fusion appears correct, accept the fusion transformation using the task (see Reviewing Image Fusions Pg. 219). If the resulting fusion appears incorrect, you may use fusion region of interest tools, manual fusion tools (see Manually Editing Image Fusions Pg. 226), or reset the image fusion and use an unseeded automatic fusion to modify the result until it appears correct.

Executing automatic fusion using a pre-determined region of interest (ROI) may be useful in cases where the jaw or cervical spine structures are included in the image acquisition and are in substantially different positions between the two image series. A user may wish to focus the fusion on the intracranial contents and/or the skull itself.

This can be accomplished using the fusion ROI tools offered by the software application.

> To exercise an automatic fusion using fusion ROI tools

1. Select the Fusion Task using the Task Selector (see Selecting a Task Pg. 84). (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. If necessary, select an image series to fuse using the Thumbnail Bar (see Using Thumbnails Pg. 86).

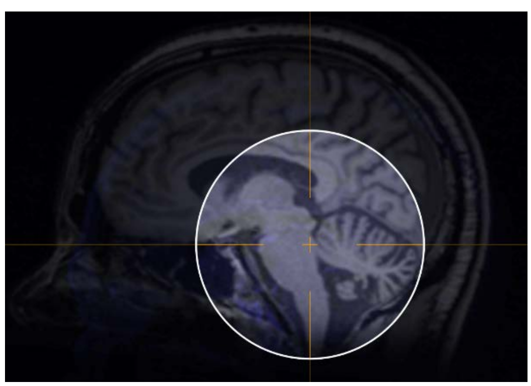
3. Use the **Primary Series ROI** tool in the task's custom toolbar to define a spherical region of interest that will be used in the master series when performing an automatic fusion with the selected image series. Note that only the image voxels contained within the spherical region of interest on the master series will be considered when executing an automatic fusion. To use the **Primary Series ROI** tool:

    - Select the  button from the custom toolbar. A spherical region of default size will be drawn on screen. Cross-sections of the region may be visualized in each of the viewports.

    - Click anywhere on the white region of interest cross-sections to re-size the spherical region with respect to the master series.

    - Click and drag the viewport crosshairs (see Using the Viewport Crosshairs Pg. 91) to move the region in the viewports.

    - Select the  button to accept the region of interest. Select the  button to discard the region of interest.



4. Use the **Fusion Series ROI** tool in the task's custom toolbar to define a spherical region of interest that will be considered in the selected image series when performing an automatic fusion with the master series. This region should match the anatomical coverage achieved using the **Primary Series ROI** tool from the

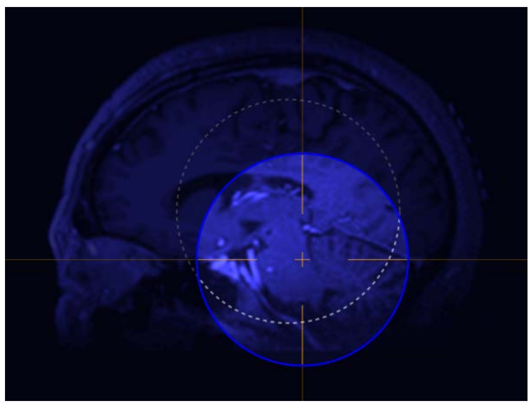
master series. Note that only the image voxels contained within the spherical region of interest on the selected image series will be considered when executing an automatic fusion. To use the **Fusion Series ROI** tool:

- Select the button from the custom toolbar. A spherical region of default size will be drawn on screen. Cross-sections of the region may be visualized in each of the viewports.

- Click anywhere on the colored region of interest cross-sections to re-size the spherical region with respect to the selected series.

- Click and drag the viewport crosshairs (see Using the Viewport Crosshairs Pg. 91) to move the region in the viewports.

- Select the button to accept the region of interest. Select the button to discard the region of interest.



5. Select **Detect Fusion** from the task's control panel.

6. A floating window will display a **Please Wait** message and the task user interface will be blurred.

7. After the automatic fusion completes, the results will be displayed within the viewports. A status message will pop-up indicating that the automatic fusion has completed successfully.

8. Review the resulting fusion between the images (see Reviewing Image Fusions Pg. 219).

9. To clear any defined fusion regions of interest, click the button.

10. If the resulting fusion appears correct, accept the fusion transformation using the task (see Reviewing Image Fusions Pg. 219). If the resulting fusion appears incorrect, you may use a seeded automatic fusion, manual fusion tools (see Manually Editing Image Fusions Pg. 226), or reset the image fusion and use an

unseeded automatic fusion to modify the result until it appears correct. Clear any defined regions of interest when exercising these other methods.

Manually Editing Image Fusions

The Fusion Task may also be used to manually edit the defined fusion transformation between a selected image series and the master series.

> **To manually edit an image fusion**

1. Select the Fusion Task using the Task Selector (see Selecting a Task Pg. 84). (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. If necessary, select an image series to fuse using the Thumbnail Bar (see Using Thumbnails Pg. 86).

3. Use the **Fusion Pan** tool in the task's custom toolbar to pan the selected 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.
    - To make fine-tuned translational adjustments to the fusion transformation, press the LEFT ARROW, RIGHT ARROW, ARROW UP, and/or ARROW DOWN keys to move the fusion series in 0.1 mm increments in the corresponding directions relative to the master series.

4. Use the **Fusion Rotate** tool in the task's custom toolbar to rotate the selected 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.
    - To make fine-tuned rotational adjustments to the fusion transformation, press the LEFT ARROW and/or RIGHT ARROW keys to rotate the fusion image series in 0.1° increments counterclockwise and/or clockwise relative to the master series.

5. 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.

6. Review the resulting fusion between the images (see Reviewing Image Fusions Pg. 219).

7. Once the resulting fusion appears correct, accept the fusion transformation using the task (see Reviewing Image Fusions Pg. 219).

> To reset an image fusion

1. Select the Fusion Task using the Task Selector (see Selecting a Task Pg. 84). (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. If necessary, select an image series to fuse using the Thumbnail Bar (see Using Thumbnails Pg. 86).

3. Select **Clear Fusion** from the task control panel. (Note that selecting **Clear Fusion** will also clear any fusion ROIs defined in the task).

4. The fusion transformation between the selected image series and the master series will be reset to have no offset or rotation.

ACPC Task Reviewing Landmarks

When the ClearPoint Workstation receives a whole-head scan for the first time, it automatically detects and identifies candidate positions for the anatomical reference points.

- AC Point – The center of the Anterior Commissure.
- PC Point – The center of the Posterior Commissure.
- Mid-Sagittal Plane Point – A representative point on the mid-sagittal plane.

Together, these points are used to define the ACPC (anatomical) coordinate system. The application uses this coordinate system to define the **Anatomical** viewing orientation, while also allowing you to reference coordinates in the anatomical coordinate system using the Current Point Control (see Using the Viewport Crosshairs Pg. 91) and the Define Landmarks Tool (see Define Landmarks Tool Pg. 115).

The ACPC Task allows you to review and / or modify the positions of the anatomical locations used to define the anatomical coordinate system. Specifically, the following capabilities are offered within the task:

- Review the currently defined positions of the anatomical landmarks (see Reviewing Anatomical Landmark Positions Pg. 228).
- Edit the position of one or more anatomical landmarks (see Editing Anatomical Landmark Positions Pg. 229).
- Automatically re-detect the positions of the anatomical landmarks on a selected image series (see Re-detecting Anatomical Landmarks Pg. 230).

Reviewing Anatomical Landmark Positions

The ACPC Task may be used to review the anatomical landmark positions defined in the application. These positions are used to define the **Anatomical** viewing orientations shown in the viewports, as well as the ACPC (anatomical) coordinates displayed in the application.

If you use anatomical coordinates for indirect targeting purposes, you must launch the ACPC Task and review the anatomical positions prior to proceeding in the workflow. Otherwise, the ability to plan a trajectory based off anatomical coordinates will not be provided.

> **To review the anatomical landmarks**

1. Launch the ACPC task using the Task Selector (see Selecting a Task Pg. 84).

2. Select the 

button from the custom toolbar (see Using Custom Toolbars Pg. 97) to position the crosshairs on the AC Point.

3. Select the 

button from the custom toolbar (see Using Custom Toolbars Pg. 97) to position the crosshairs on the PC Point.

4. Select the 

button from the custom toolbar (see Using Custom Toolbars Pg. 97) to position the crosshairs on the Mid-Sagittal Plane Point.

5. Review the distance (in millimeters) between the AC and PC points displayed in the task panel.

Editing Anatomical Landmark Positions

If you notice that the anatomically oriented viewports are not aligned to patient anatomy and/or that the positions for the anatomical landmarks are incorrect, you may manually edit the anatomical landmark positions using the ACPC Task.

> **To edit the anatomical landmarks**

1. Select the anatomical landmark that you wish to edit (see Reviewing Anatomical Landmark Positions Pg. 228).

2. Edit the locations of each of the landmarks using the following mechanisms:

   - Reposition the crosshairs in the viewports (see Changing Crosshair Positions Pg. 93) to a location where you would like to set the landmark. Use the corresponding set button in the custom toolbar (see Using Custom Toolbars Pg. 97) to set the landmark location at the current crosshair position.

   - Drag the landmark within any of the task's viewports to a new location within the viewport.

Note: By default, the viewing orientation for the ACPC Task is set to Anatomical, which means that whenever the landmark points change, the three perpendicular anatomical views will re-align to match the new reference positions. Changing the view to Scanner will align the planes to the scanner directions. This can improve visualization if the defined anatomical landmark positions are significantly inaccurate after automated detection and require manual correction.

3. Use the **Undo ACPC Change** and **Redo ACPC Change** tools in the viewport's custom toolbar to undo or redo any changes made to one or more of the anatomical landmarks shown on screen.

   - Select the  button from the custom toolbar to undo a change made to an anatomical landmark shown on screen.

   - Select the  button from the custom toolbar to redo a change made to an anatomical landmark shown on screen.

4. You may edit the color and opacity of the anatomical landmarks using the context menu associated with the corresponding annotations.

5. You may re-position the text labels associated with the anatomical landmarks as desired by clicking and dragging the corresponding label.

Re-detecting Anatomical Landmarks

You may also use the ACPC Task to re-detect the anatomical landmark positions from a selected image series.

Note: The algorithm used to detect the anatomical landmark positions was developed and validated using whole-head T1-weighted MR image series collected with modern high resolution gradient echo sequences. For best results, ensure that a whole-head T1-weighted image series is selected when utilizing this feature in the software.

> **To re-detect the anatomical landmarks**

1. Select the image series for which you would like to detect the anatomical landmarks from. If the series is not selected as either the master or secondary series within the Thumbnail Bar, select that series as the secondary series (see Using Thumbnails Pg. 86).

2. Select **Detect ACPC** from within the thumbnail.

3. A floating window will display a **Please Wait** message and the task user interface will be blurred.

4. The results of the ACPC detection will be reflected in the new positions of the anatomical landmarks shown within the viewports.

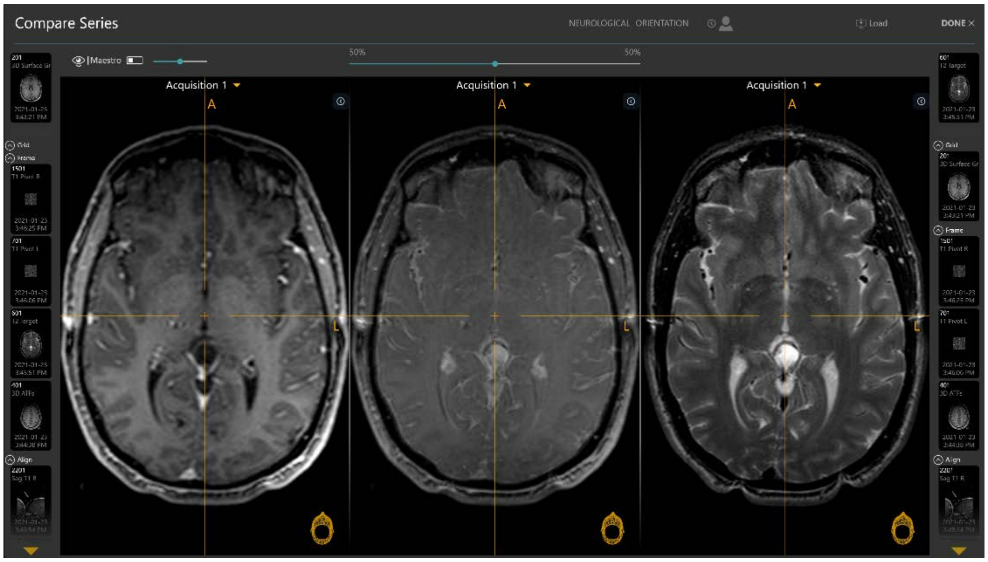
Compare Task Comparing Images

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 several workflow-related needs, such as:

- Visualizing locations between two image series acquired using different scans.
- Viewing one or more scans in the exact orientation in which they were acquired.
- Determining whether the patient has 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.
- Acquisition 2 View – Aligns viewports to the plane where the second image series selected for comparison was acquired.
- Axial View – Aligns viewports to the scanner axial plane.
- Coronal View – Aligns viewports to the scanner coronal plane.
- Sagittal View – Aligns viewports to the scanner sagittal plane.
- 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 Task Selector (see Selecting a Task Pg. 84).
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. You may change the image series selections in each Thumbnail Bar as desired (see Using Thumbnails Pg. 86).
4. Use the slider bar in the task control panel to change the relative weighting of each selected 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 Thumbnail Bar.

> **To change the comparison viewing orientation**

Change the viewport orientation in one of the viewports (see Changing a Viewing Layout Orientation Pg. 90). The orientation of all viewports will match the one just selected.

Overlaying Maestro Brain Regions

You may also overlay brain regions produced from Maestro Brain Model segmentations on images shown in the Compare Task.

> **To overlay brain region segmentations**

1. Launch the Compare task using the Task Selector (see Selecting a Task Pg. 84).
2. Change the visibility of one or more brain regions using the **Maestro** toggle button in the task control panel (see Working with Maestro Brain Regions Pg. 124).

Grid Task Editing Marking Grids

The Grid Task allows you to review and modify the position and orientation of each detected SMARTGrid Planning Grid on one or more scans. Additionally, you may use the Grid Task to remove any marking grids that were mis-detected and/or identify one or more marking grids that were not detected automatically in the Entry Step (see Entry Step Setting Intraoperative Trajectories Pg. 143).

The following operations are provided by the task:

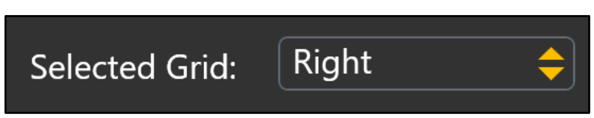
- Review the position and orientation for each marking grid defined in the application (see Reviewing Marking Grids Pg. 235).
- Manually edit the position and/or orientation for each marking grid, in instances where the identified grid does not match up with the physical grid in the underlying images (see Modifying Marking Grids Pg. 236).
- Identify one or more marking grids that were not detected automatically in the Entry Step and/or not yet defined (see Managing Marking Grids Pg. 238).
- Remove marking grids that may not correspond to grids affixed physically to the patient (see Managing Marking Grids Pg. 238).

Reviewing Marking Grids

You may review the position and orientation of each defined marking grid relative to any image series loaded in the Entry Step.

> **To review marking grid detections**

1. Launch the Grid Task using the Task Selector (see Selecting a Task Pg. 84).
2. Use the **Selected Grid** drop-down in the task control panel to select a grid to review.



3. The viewport's orientation will align to the selected grid.

4. Select an image series for which to review the selected grid using the Thumbnail Bar (see Using Thumbnails Pg. 86).

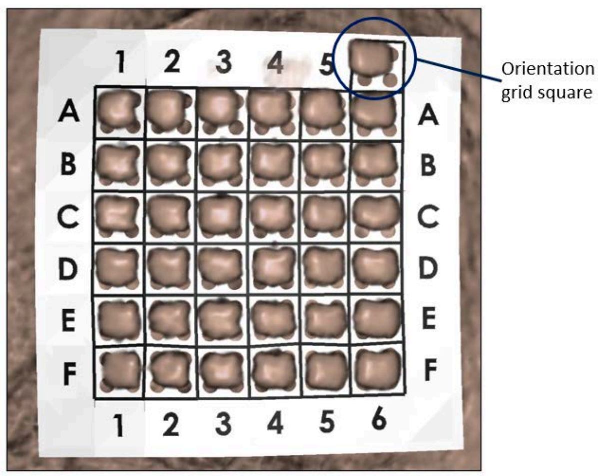
5. Use the **Grid Underlay** toggle switch to control the visibility of the marking grid underlay model.

6. Use the slider bar beside **Grid Underlay** to control the opacity of the marking grid underlay model. Drag to the left to decrease opacity of the underlay. Drag to the right to increase opacity of the underlay.

7. Use the **Grid Fluid** toggle switch to control the visibility of the marking grid fluid cells.

8. Use the slider bar beside **Grid Fluid** to control the opacity of the marking grid fluid cells. Drag to the left to decrease opacity of the fluid cells. Drag to the right to increase opacity of the fluid cells.

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 the correct row and column labels.**



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

Modifying Marking Grids

The Grid Task 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 Entry Step, due to signal attenuation, image artifacts, or other issues in the acquired master series.

> **To manually modify a marking grid**

1. Launch the Grid Task using the Task Selector (see Selecting a Task Pg. 84).

2. Use the **Selected Grid** drop-down to select a grid to modify.

3. Use the **Shift Grid Left** tool in the task's custom toolbar to shift the selected grid one column at a time to the left. To use the **Shift Grid Left** tool:

    - Select the  button from the custom toolbar.
    - The entire grid model shifts one column to the left.

4. Use the **Shift Grid Right** tool in the task's custom toolbar to shift the selected grid one column at a time to the right. To use the **Shift Grid Right** tool:

    - Select the  button from the custom toolbar.
    - The entire grid model shifts one column to the right.

5. Use the **Shift Grid Up** tool in the task's custom toolbar to shift the selected grid one row at a time upwards. To use the **Shift Grid Up** tool:

    - Select the  button from the custom toolbar.
    - The entire grid model shifts one row upwards.

6. Use the **Shift Grid Down** tool in the task's custom toolbar to shift the selected grid one row at a time downwards. To use the **Shift Grid Down** tool:

    - Select the  button from the custom toolbar.
    - The entire grid model shifts one row downwards.

7. Use the **Rotate Grid Right** tool in the task's custom toolbar to rotate the orientation cell (A-6) clockwise 90 degrees from its current position.

    - Select the  button from the custom toolbar.
    - The entire grid model rotates 90 degrees in the clockwise direction, such that the orientation cell (A-6) is positioned to the right of its original position.

8. Use the **Rotate Grid Left** tool in the task's custom toolbar to rotate the orientation cell (A-6) counter-clockwise 90 degrees from its current position.

    - Select the  button from the custom toolbar.

- The entire grid model rotates 90 degrees in the counter-clockwise direction, such that the orientation cell (A-6) is positioned to the left of its original position.

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

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

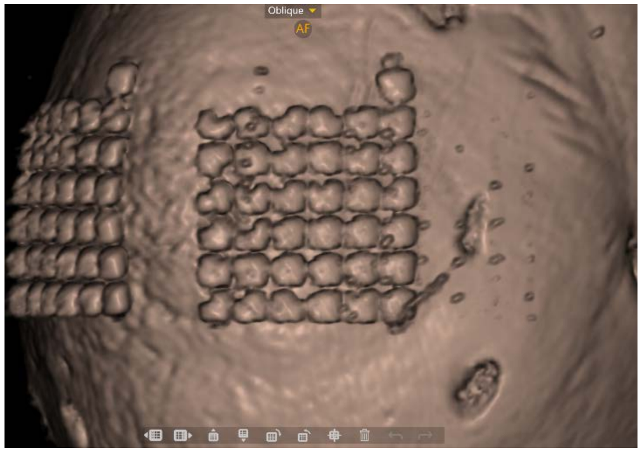
- Select the  button from the custom toolbar to undo a change made to the selected grid shown on screen.
- Select the  button from the custom toolbar to redo a change made to the selected grid shown on screen.

Managing Marking Grids

You may also use the Grid Task 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**

1. Launch the Grid Task using the Task Selector (see Selecting a Task Pg. 84).
2. Select an image series from the Thumbnail Bar (see Using Thumbnails Pg. 86) to use to detect the new marking grid.
3. Rotate the view such that it is perpendicular to the center of the non-identified grid that you wish to detect.



4. Select the  button from the task's custom toolbar.

5. A floating window will display a **Please Wait** message and the task user interface will be blurred.

6. The newly detected marking grid will be shown in the viewports.

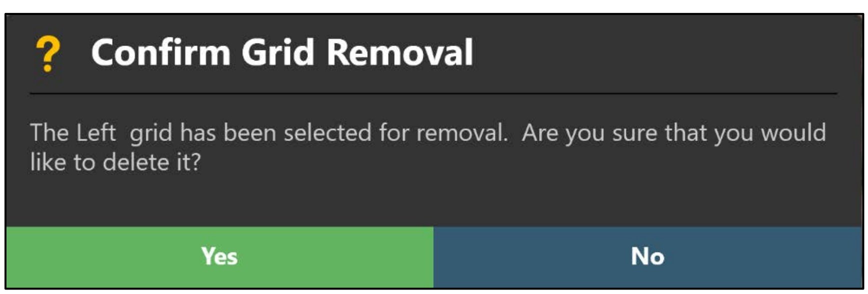
> **To delete a marking grid**

1. Launch the Grid Task using the Task Selector (see Selecting a Task Pg. 84).

2. Use the **Selected Grid** drop-down to select a grid to remove.

3. Select the  button from the task's custom toolbar.

4. You will be prompted to confirm the removal of the grid before proceeding. Select **Yes** to proceed with removal of the selected grid. Otherwise, choose **No** to leave the selected grid intact.



Frame Task Editing Frame Markers

The Frame Task may be used to review and modify the location of the fiducial markers associated with each SMARTFrame trajectory frame identified by the application. These fiducial markers include the three markers embedded in the base of the frame, as well as the ball marker embedded within the distal tip of its corresponding targeting cannula. You may also use the Frame Task to remove any frames that were mis-detected and/or identify one or more frames that were not detected automatically in the Target Step (see Target Step Finalizing Trajectories Pg. 159).

The following operations are provided by the task:

- Review the position of the fiducial markers within each frame defined in the application (see Reviewing Frame Markers Pg. 240).
- Manually edit the position of the fiducial markers for each frame defined in the application (see Modifying Frame Markers Pg. 242).
- Search for one or more frames that were not detected automatically in the Target Step (see Managing Frames Pg. 244).
- Remove application frames that may not correspond to frames physically mounted on the patient (see Managing Frames Pg. 244).

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 Target Step.

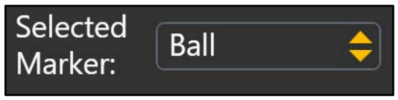
> **To review frame markers**

1. Launch the Frame Task using the Task Selector (see Selecting a Task Pg. 84).
2. Use the **Selected Frame** drop-down to select a frame whose fiducial markers you would like to review.

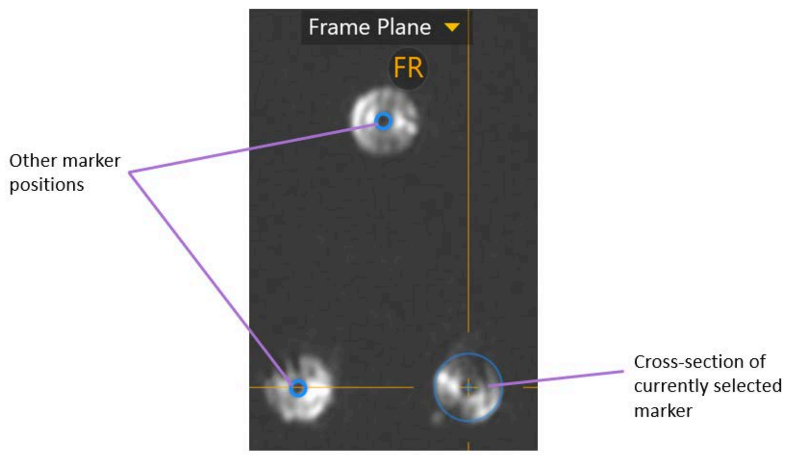
3. The viewport's orientation will align to the plane created by the three frame markers located in the base of the selected frame.

4. Select an image series for which to review the selected frame using the Thumbnail Bar (see Using Thumbnails Pg. 86).

5. Use the **Selected Marker** drop-down to select the individual fiducial marker associated with the current frame that you would like to review. You may also click directly on the marker that you wish to review in the 3D viewport to change the marker selection.

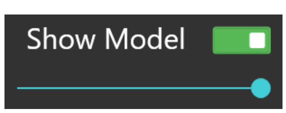


6. The crosshairs within the linked viewports will correlate to the center of the selected marker. The application will display blue annotations representing the cross section of the selected marker in each of these viewing planes, as well as point annotations representing the other markers. The 3D viewport will highlight the selected marker in blue within the frame base model displayed.



7. If you move the crosshair position away from the selected marker, you can use the **Go To Marker Point** button () in the task's custom toolbar to re-correlate the crosshairs back to its defined location (see Changing Crosshair Positions Pg. 93).

8. Use the **Show Model** toggle switch to control the visibility of the frame base model. You may use this mechanism to determine if the frame fiducial markers in the underlying images agree with the frame base model rendered in the viewport.



9. Use the slider bar underneath the **Show Model** switch to control the opacity of the frame base model. Drag to the left to decrease opacity of the frame base model. Drag to the right to increase opacity of the frame base model.

10. Repeat the above steps for each frame detected by the application.

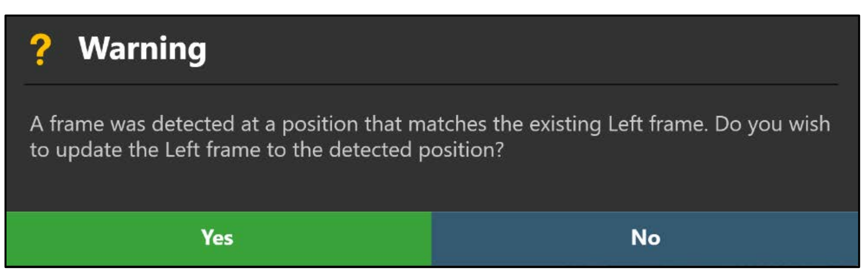
Modifying Frame Markers

The Frame Task 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 Target Step, due to signal attenuation, image artifacts, or other issues in the acquired scan.

Caution: **The base markers are used by the software to determine the location of the frame. If marker positions are defined incorrectly, then incorrect values may be provided for device adjustment instructions. Additionally, in the CT Workflow, incorrect depth values may be given for insertion if the base markers are not defined correctly.**

> **To automatically edit the frame markers**

1. Launch the Frame Task using the Task Selector (see Selecting a Task Pg. 84).
2. Use the **Selected Frame** drop-down to select a frame whose fiducial markers you would like to edit.
3. Select an image series to automatically re-detect the selected frame's fiducial markers from using the Thumbnail Bar (see Using Thumbnails Pg. 86).
4. Select **Re-Detect Current Frame** from the task control panel to automatically re-detect the frame's fiducial markers from the selected image series.
5. A floating window will display a **Please Wait** message and the task user interface will be blurred.
6. You will be prompted prior to updating the frame's fiducial marker positions with the ones just detected by the application. Select **Yes** to update the currently selected frame's fiducial marker positions with the ones detected by the application. Otherwise, select **No** to leave the currently selected frame's fiducial marker positions intact.

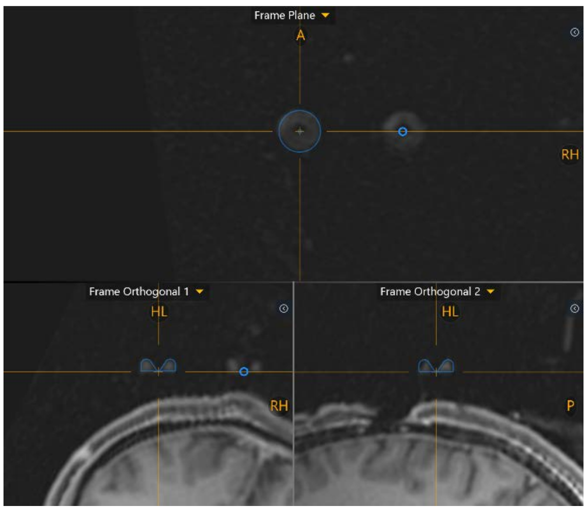


> **To manually edit the frame markers**

1. Launch the Frame Task using the Task Selector (see Selecting a Task Pg. 84).

2. Use the **Selected Frame** drop-down to select a frame whose fiducial markers you would like to edit.

3. Use the **Selected Marker** drop-down to select the individual fiducial marker associated with the currently selected frame that you would like to edit.



4. To modify the position of the selected fiducial marker:

   - With the Arrow Tool selected (see Arrow Tool Pg. 99), click and drag the blue outline to match the cross section of the physical fiducial marker displayed in the images.

   - Move the crosshairs (see Changing Crosshair Positions Pg. 93) to the physical center of the currently selected fiducial marker. Use the **Set Marker** tool () in the task's custom toolbar to set the position of the currently selected marker at the position of the crosshairs.

   - Alternatively, move the crosshairs (see Changing Crosshair Positions Pg. 93) to the physical center of the fiducial marker displayed in the images and select the appropriate **Set Marker** button in the task control panel:

     - **Set Marker 1** – Sets the position of frame marker 1 at the current crosshair location.

     - **Set Marker 2** – Sets the position of frame marker 2 at the current crosshair location.

- **Set Marker 3** – Sets the position of frame marker 3 at the current crosshair location.
- **Set Ball Marker** – Sets the position of the cannula ball marker at the current crosshair location.

5. To modify the position of an unselected fiducial marker:
    - Move the crosshair position such that one or more of the unselected fiducial markers intersect the viewing plane. Note that unselected fiducial markers will appear as point annotations within the viewport.
    - Hover the mouse over the point annotation of interest. A tooltip will appear identify the fiducial marker that the point annotation corresponds to.
    - With the Arrow Tool selected (see Arrow Tool Pg. 99), click and drag the point annotation such that it corresponds to the physical center of the fiducial marker that it corresponds to in the images.
    - Note that the unselected fiducial marker that was edited now becomes the selected fiducial marker.
6. To undo or redo any position edits made to the currently selected frame's fiducial markers:
    - Select the button from the custom toolbar to undo a position edit made to a fiducial marker associated with the currently selected frame.
    - Select the button from the custom toolbar to redo a position edit made to a fiducial marker associated with the currently selected frame.

Managing Frames

You may also use the Frame Task to manage the frame defined in the application. Specifically, you can:

- Detect one or more frames from any selected image series. Two mechanisms are provided for automatic frame detection:
    - Local Search – will only search for a frame's markers within a small region centered on the current position of the viewport crosshairs or existing entry point locations.
    - Broach Search – will search the entire image series for the frame markers.

- Delete any existing frames.

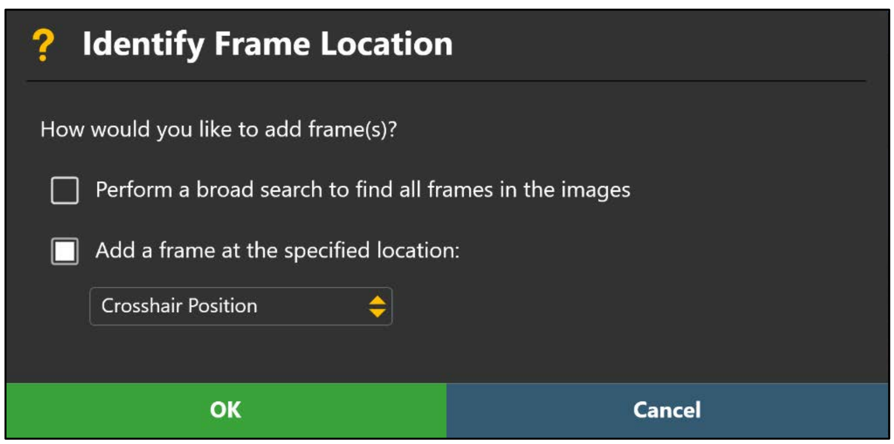
> **To automatically detect new frames**

1. Launch the Frame task using the Task Selector (see Selecting a Task Pg. 84).

2. Select an image series from the Thumbnail Bar (see Using Thumbnails Pg. 86) to use to detect one or more new frames.

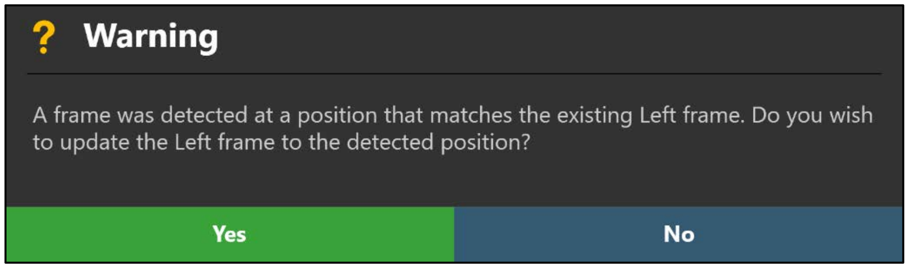
3. Select **Add Frame(s)** from the task control panel.

4. Select how you would like the application to identify one or more new frames. Use the **Perform a broad search to find all frames in the images** checkbox to search the entire image series for sets of frame markers corresponding to one or more frames. Use **Add a frame at the specified location** to perform a local search for frame markers around the vicinity of the current crosshair position or existing entry point locations. Select **OK** to search for one or more frames using the selected method. Otherwise, select **Cancel** to terminate searching for the frame markers in the selected image series.



5. A floating window will display a **Please Wait** message and the task user interface will be blurred.

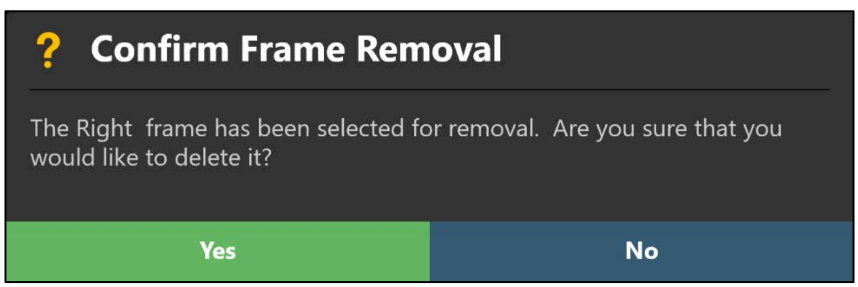
6. If the application detects a frame that corresponds to a frame that you have already defined, you will be prompted to update the existing frame with the newly detected marker positions. Select **Yes** to update the existing frame with the marker positions just detected by the application. Otherwise, select **No** to leave the existing frame's marker positions intact.



7. The results of the frame detection will be reflected in the new frame(s) defined within the viewports. Review the fiducial marker results appropriately using all viewports (see Reviewing Frame Markers Pg 240).

> **To delete a frame**

1. Launch the Frame Task using the Task Selector (see Selecting a Task Pg. 84).
2. Use the **Selected Frame** drop-down to select a frame you wish to delete.
3. Select the  button from the task's custom toolbar.
4. You will be prompted to confirm the removal of the frame before proceeding. Select **Yes** to proceed with removal of the selected frame. Otherwise, choose **No** to leave the selected frame intact.



Pre-Adjust Task Pre-adjusting the Cannula in an MRI Workflow

During an MRI Workflow, the Pre-Adjust Task may be used to iteratively make X/Y adjustments on a frame prior to alignment such that its cannula ball marker can be positioned at the location of the planned entry point. Utilizing this task may be necessary to ensure that the device to be inserted will enter the brain at the desired entry point. The Pre-Adjust Task is only available when executing an MRI Workflow (see MRI Workflow Pg. 39). During an MRI Workflow, the task can be activated in the Target (see Target Step Finalizing Trajectories Pg. 159) and Align (see Align Step Set the Cannula Angulation Pg. 168) steps, prior to alignment of the targeting cannula.

For similar functionality in a CT Workflow, follow the “Target and Entry” frame adjustment instructions in the Adjust (CT Workflow) step (see Adjust Step Finalize the Cannula Position in a CT Workflow Pg. 188).

Upon activating the Align Step in an MRI Workflow, if the position of the ball marker is such that it does not agree with the desired entry point, you will be warned that a cannula pre-adjustment may be required. See Selected Trajectory Needs Pre-Adjustment Pg. 300 for details.

If pre-adjustments are made prior to cannula alignment, then any further X/Y adjustments made later in the workflow will cause the cannula’s ball marker to be re-positioned. If you require the position of the ball marker to remain fixed after pre-adjustment, it is advised to only realize Pitch/Roll adjustments when further aligning the targeting cannula.

The following functionality is provided by the Pre-Adjust Task:

- Prescribing the frame adjustments required to align the cannula’s ball marker to the selected trajectory’s entry point (see Prescribing Cannula Pre-Adjustments Pg. 248).
- Specifying the scan plane parameters needed to acquire a localized scan of the cannula ball marker (see Acquiring Ball Marker Scans Pg. 248).
- Reviewing and/or modifying the current position of the cannula ball marker based on the acquired ball marker scans (see Reviewing the Ball Marker Position Pg. 249).
- Reviewing and comparing the desired and actual trajectory paths based on the ball marker position (see Reviewing Actual and Desired Trajectory Paths Pg. 251).

Prescribing Cannula Pre-Adjustments

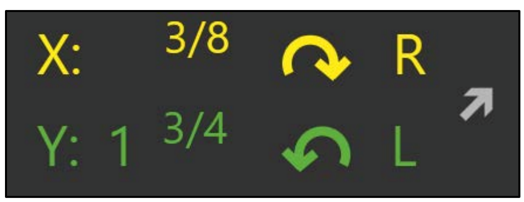
You may use the frame adjustments prescribed in the Pre-Adjust Task to make physical adjustments on the corresponding frame such that its ball marker is positioned on the planned entry point. In order for these pre-adjustments to be prescribed, there must be a difference between the planned entry point of the selected trajectory and the defined position of the ball marker in the application. This scenario will arise if you have made edits to the planned entry point in the Target Step (see Target Step Finalizing Trajectories Pg. 159).

> **To make a cannula pre-adjustment**

1. Launch the Pre-Adjust Task using the Task Selector (see Selecting a Task Pg. 84).

2. Make note of the frame and associated trajectory used to prescribe the pre-adjustments of the cannula in the task control panel.

3. Using the prescribed pre-adjustments displayed in the task control panel, make the adjustments on the physical frame mounted on the patient. You may expand the pre-adjustments using the button so that they can be displayed larger if you are using an external in-room monitor (see Mirroring the External Monitor Pg. 67).



It is recommended that you acquire at least one follow-up scan of the ball marker after performing a frame pre-adjustment to ensure that the adjustment was made correctly.

Acquiring Ball Marker Scans

The Pre-Adjust Task provides the ability to acquire a localized scan of the selected frame's ball marker instead of a whole head scan, so that guidance can be provided regarding its proximity to the planned trajectory's entry point in a time efficient manner.

> **To acquire scans of the cannula ball marker**

1. Launch the Pre-Adjust Task using the Task Selector (see Selecting a Task Pg. 84).
2. Select **Scan Plane** from the task control panel to bring up scan plane parameters that you must enter on the MRI Scanner Console to acquire a localized scan of the targeting cannula's ball marker.
3. Enter the values on the MRI Scanner Console, scan and transfer or load the images onto the workstation.
4. On receiving the scan of the ball marker, the application verifies that the cannula's ball marker is contained completely within the scan to ensure that the correct images were transferred.
5. If the application accepts the scan, it will search for the ball marker from the images received. A floating window will display a **Please Wait** message and the user interface will be blurred while the application searches for the ball marker in the scan.

With each new acquisition, the application updates the position for the cannula ball marker. Doing so allows the application to recalculate the frame adjustments required to position the ball marker at the planned entry point.

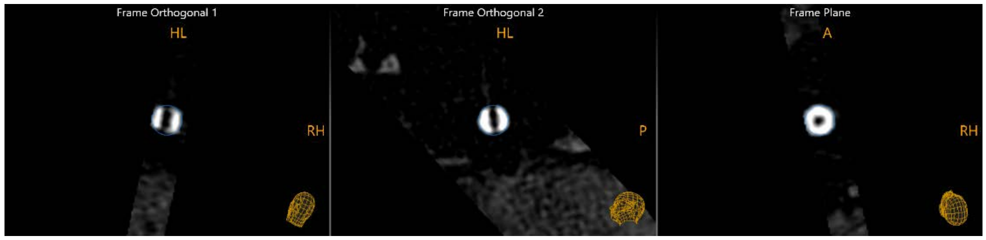
6. If the application succeeds in detecting the cannula ball marker from the scan, it will overlay two-dimensional cross-sections of the ball marker at the location where it detected its position, in the top row of viewports in the viewing layout. If the application failed to detect the ball marker position from the scan, a warning will be issued (see SMARTFrame Ball Marker Not Found Pg. 287).

Reviewing the Ball Marker Position

You may use the Pre-Adjust Task to review the detection results for the cannula ball marker in the most recently acquired scan containing the ball marker.

> **To review the cannula ball marker position**

1. Launch the Pre-Adjust Task using the Task Selector (see Selecting a Task Pg. 84).
2. Observe the graphic cross sections of the cannula ball marker overlaid on the acquired scan in the **Frame Orthogonal 1**, **Frame Orthogonal 2**, and **Frame Plane** viewports.



3. Verify that the outlines of the ball marker overlays match up with signal from the ball marker in the scan. If the graphic outlines do not match up with the underlying images, proceed to manually modify the position of the ball marker.

> **To automatically edit the cannula ball marker position**

1. Launch the Pre-Adjust Task using the Task Selector (see Selecting a Task Pg. 84).

2. Select **Re-Detect Ball Marker** from the task control panel to automatically re-detect the frame's ball marker from the most recently acquired ball marker scan for the selected frame.

3. A floating window will display a **Please Wait** message and the task user interface will be blurred.

4. If the application succeeds in detecting the cannula ball marker from the scan, it will modify the two-dimensional cross-sections of the ball marker at the location where it detected its position, in the top row of viewports in the viewing layout. If the application failed to detect the ball marker position from the scan, a warning will be issued (see SMARTFrame Ball Marker Not Found Pg. 287).

> **To manually modify the cannula ball marker position**

1. If the ball marker position detected by the application appears incorrect in the top row of viewports, you may edit its position using the following techniques:

   - If the crosshairs are not positioned on the ball marker, use the **Go To Ball Marker Point** tool ( ) in the task's custom toolbar (see Using Custom Toolbars Pg. 97).

   - Drag the ball marker cross section in any of the **Frame Orthogonal 1**, **Frame Orthogonal 2**, and **Frame Plane** viewports so that it aligns with the signal from the cannula ball marker.

   - Change the crosshair location to the center of the cannula ball marker signal in the image (see Changing Crosshair Positions Pg.

93) and use the **Set Ball Marker Point** tool () in the task's custom toolbar (see Using Custom Toolbars Pg. 97).

2. To undo or redo any position edits made to the currently selected cannula ball marker position:

   - Select the button from the custom toolbar to undo a position edit made to the ball marker cross section shown on screen.

   - Select the button from the custom toolbar to redo a position edit made to the ball marker cross section shown on screen.

Reviewing Actual and Desired Trajectory Paths

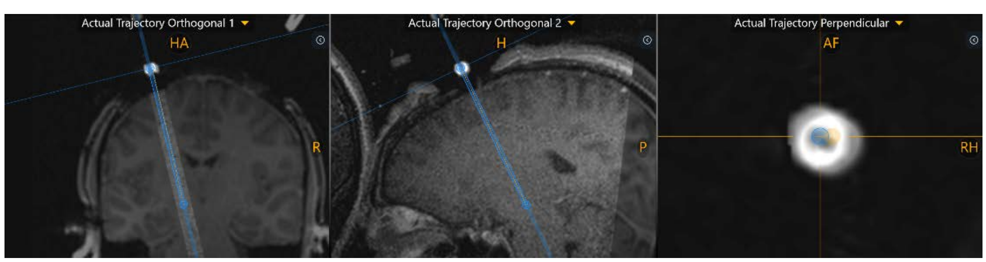
The Pre-Adjust Task provides you with the ability to review the trajectory path based on the current ball marker position (known as the "actual trajectory path"), as well as the planned trajectory path (known as the "desired trajectory path"). The trajectory's entry point planned in the Target Step (see Target Step Finalizing Trajectories Pg. 159) represents the desired location where you would like the device to enter the brain on insertion. The actual entry point is reflected by the position of the ball marker. The purpose of the Pre-Adjust Task is to modify the position of the cannula ball marker to match the desired trajectory path.

> **To review the actual trajectory path**

1. Launch the Pre-Adjust Task using the Task Selector (see Selecting a Task Pg. 84).

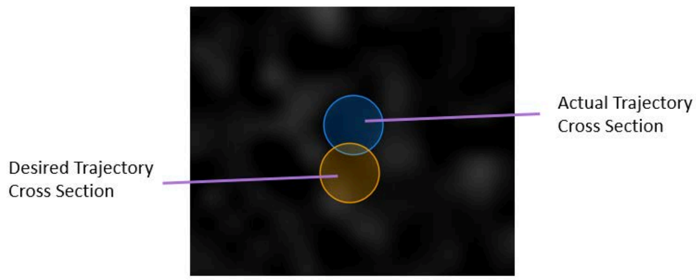
2. Change the orientation of the viewing layout to: **Actual Trajectory** (see Changing a Viewing Layout Orientation Pg. 90).

3. Observe the blue graphic annotations overlaid on the scans in the bottom row of viewports: **Actual Trajectory Orthogonal 1**, **Actual Trajectory Orthogonal 2**, and **Actual Trajectory Perpendicular**. These blue graphics represent the actual trajectory path, from planned target point to current position of the ball marker, for which the device would enter the brain.



4. In the **Actual Trajectory Orthogonal 1** and/or **Actual Trajectory Orthogonal 2** viewports, use the Fly Through Line (see Fly Through Line Pg. 94) or Image Scroller (see Image Scroller Pg. 95) to scroll through the actual trajectory. In the **Actual Trajectory Perpendicular** viewports, use the Image Scroller to scroll through the actual trajectory.

5. Observe the projected cross section of the planned ("desired") trajectory in the bottom row of viewports. Visually compare the residual difference between the desired and actual trajectories.



> **To review the desired trajectory path**

1. Launch the Pre-Adjust Task using the Task Selector (see Selecting a Task Pg. 84).

2. Change the orientation of the viewing layout to: **Desired Trajectory** (see Changing a Viewing Layout Orientation Pg. 90).

3. Observe the graphic annotations overlaid on the scans in the bottom row of viewports: **Desired Trajectory Orthogonal 1**, **Desired Trajectory Orthogonal 2**, and **Desired Trajectory Perpendicular**. These graphics represent the desired trajectory path, from planned target point to planned entry point position as set in the Target Step (see Target Step Finalizing Trajectories Pg. 159).

4. In the **Desired Trajectory Orthogonal 1** and/or **Desired Trajectory Orthogonal 2** viewports, use the Fly Through Line (see Fly Through Line Pg. 94) or Image Scroller (see Image Scroller Pg. 95) to scroll through the desired trajectory. In the **Desired Trajectory Perpendicular** viewports, use the Image Scroller to scroll through the desired trajectory.

5. Observe the projected cross section of the actual trajectory in the bottom row of viewports. Visually compare the residual difference between the desired and actual trajectories.

> **To set the desired entry point at the actual entry point**

1. Launch the Pre-Adjust Task using the Task Selector (see Selecting a Task Pg. 84).

2. Change the orientation of the viewing layout to: **Actual Trajectory** (see Changing a Viewing Layout Orientation Pg. 90).

3. Review and verify that the actual trajectory path is anatomically viable on the loaded image series.

4. Select **Set Entry at Ball Marker** from the task control panel.

This operation sets the entry point of the planned trajectory to the position of the ball marker. This means that there will be no residual difference between the planned entry point and the ball marker, so therefore the prescribed pre-adjustments will reset to 0.

5. The desired entry point will be matched to the actual entry point. This has effectively changed the entry point of the planned trajectory to the location of the cannula ball marker.

6. Select **Undo Set Entry at Ball Marker** from the task control panel to undo setting the desired entry point to the actual entry point. This effectively changes the entry point of the planned trajectory back to its original location.

Preview Frame Task Visualizing Frames Prior to Mounting

The Preview Frame Task may be used to visualize one or more frames positioned on the patient prior to frame mounting. This functionality may be useful during trajectory planning, either preoperatively or intraoperatively after the marking grids have been affixed, to discern how the frame(s) may be positioned on the patient. In instances where multiple frames are intended to be mounted on the patient, the functionality provided in this task may be useful for determining how close in proximity the frames can be positioned on the patient without colliding with one another. This task is only available for use in the Pre-Op (see Pre-Op Step Setting Preoperative Trajectories Pg. 128), Entry (see Entry Step Setting Intraoperative Trajectories Pg. 143), and Mount (see Mount Step Mounting Frames Pg. 149) steps.

The following functionality is provided by the Preview Frame Task:

- Displaying a scene which illustrates how the frames (including base and tower) for each trajectory may be positioned on the patient (see Visualizing the Frames Pg. 254).
- Modifying the in-plane orientation of the frames to allow for better flexibility in visualizing how they may be positioned on the patient (see Rotating the Frames Pg. 256).
- Prescribing frame adjustment instructions that can be used to pre-align each frame's targeting cannula to a selected trajectory prior to imaging the frame intraoperatively (see Prescribing Pre-Alignment Frame Adjustments Pg. 257).

Visualizing the Frames

The Preview Frame task displays a three-dimensional scene illustrating the selected image series, planned trajectories, and frame models (bases and towers) for each trajectory. This view may be used as a planning tool to understand how the frames may be positioned on the patient.

> **To visualize the frames prior to mounting**

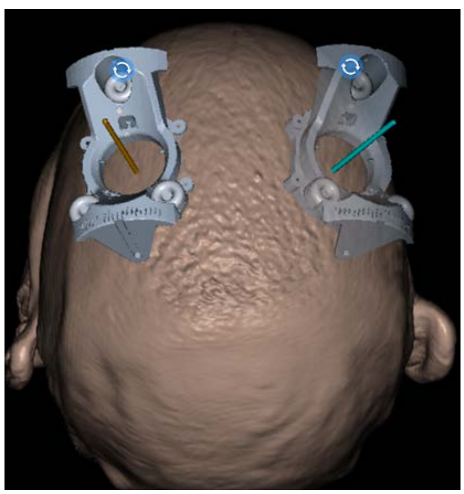
1. Launch the Preview Frame task using the Task Selector (see Selecting a Task Pg. 84).
2. Select a whole-head volumetric image series on which to visualize the frames using the Thumbnail Bar (see Using Thumbnails Pg. 86).
3. The application will display a three-dimensional scene rendering a volumetric view of the selected image series, each of the planned trajectories defined,

and a frame model for each currently selected trajectory in the underlying step.

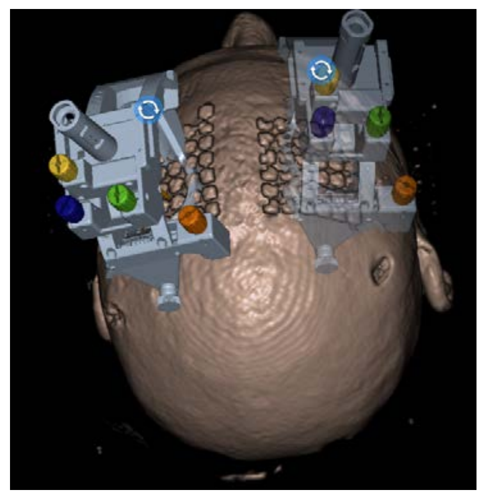
When activating the task from the Pre-Op Step (see Pre-Op Step Setting Preoperative Trajectories *Pg. 128**), the Preview Frame task will display the frame base model for each trajectory by default, positioned at the entry point of the corresponding trajectory.*

When activating the task from the Entry Step (see Entry Step Setting Intraoperative Trajectories Pg. 143*) or the Mount Step (see* Mount Step Mounting Frames *Pg. 149**), the Preview Frame task will display the frame base model and corresponding tower for each trajectory by default, positioned at the frame mount position computed by the application.*

Ensure that any planned entry points are set on the skull surface to achieve accurate representation of the frame model on the patient images.



From Pre-Op Step



From Entry & Mount Steps

4. You may use the **OVERLAYS** group-box in the task control panel to toggle the visibility of the following elements in the displayed scene:

    - **Images** – Allows for toggling the displayed image series on and off.

    - **Trajectories** – Allows for individually toggling each planned trajectory on and off.

    - **Frames** – Allows for toggling each frame model on and off. Optionally, you may individually toggle each frame tower model on and off. (Note that each planned trajectory will have a corresponding frame model, and that by default, only the currently selected trajectories from the underlying step will have their frame models visible upon first activating the task).

5. Use the Arrow Tool (see Arrow Tool Pg. 99) to rotate the selected image series and associated annotations to better visualize the frame(s) at different viewing orientations.

6. Change the orientation of the viewing layout to better visualize the frame model(s) at different viewing orientations (see Changing a Viewing Layout Orientation Pg. 90).

Rotating the Frames

Within the three-dimensional scene provided by the Preview Frame task, the application also provides the ability to apply an in-plane rotation to each frame model. This provides you with the means to explore and assess different orientations of the frame base(s) on the patient, prior to mounting. This assessment may be useful in instances where multiple frames are planned to be mounted on the patient in close proximity.

> **To manually edit the orientation of a frame model**

1. Launch the Preview Frame task using the Task Selector (see Selecting a Task Pg. 84).

2. Select an image series on which to visualize the frames using the Thumbnail Bar (see Using Thumbnails Pg. 86).

3. Select the frame whose orientation you would like to edit by hovering the mouse over the model.

4. To modify the orientation of the frame model just selected:

   - With the Arrow Tool selected (see Arrow Tool Pg. 99) click and drag the handle rendered on each frame base model to apply an in-plane rotation.

   - Clicking and dragging to the right will apply a clockwise in-plane rotation to the frame model. Clicking and dragging to the left will apply a counterclockwise rotation to the frame model.

> **To undo or redo edits made the orientation of a frame model**

Use the **Undo Preview Frame Edit** and **Redo Preview Frame Edit** tools to undo or redo any in-plane orientation changes made to the selected frame:

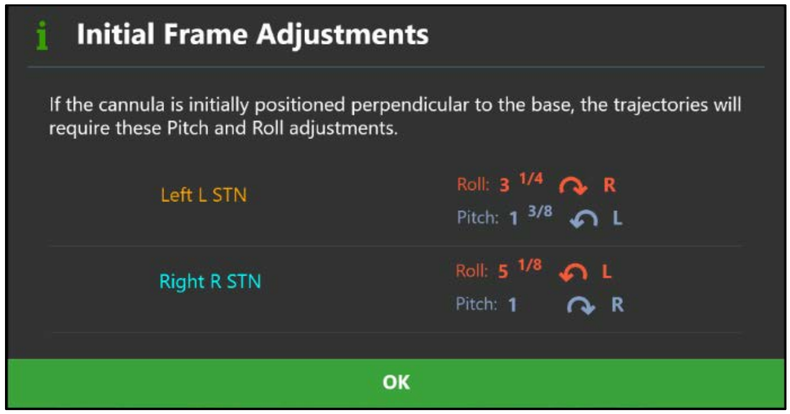
- Select the  button from the custom toolbar to undo an orientation change made to the selected frame model.
- Select the  button from the custom toolbar to redo an orientation change made to the selected frame model.

Prescribing Pre-Alignment Frame Adjustments

The Preview Frame task can also be used to prescribe frame adjustments to pre-align a given frame's targeting cannula to a selected trajectory path prior to intraoperative imaging. Making the prescribed pre-alignment adjustments is performed after the frames have been mounted but before a whole-head scan of the patient with frames affixed is acquired. For this reason, display of pre-alignment frame adjustments is only offered when the Preview Frame task is activated from the Entry (see Entry Step Setting Intraoperative Trajectories Pg. 143) and Mount (see Mount Step Mounting Frames Pg. 149) steps.

> **To make a frame pre-alignment adjustment**

1. Launch the Preview Frame task using the Task Selector (see Selecting a Task Pg. 84).
2. Select **Initial Frame Adjustments** in the task control panel.
3. A window will appear displaying the prescribed pre-alignment adjustments to align each frame to its corresponding trajectory(ies).



When mounting the frame, ensure that its physical orientation on the patient matches that of the frame model as visualized in the viewports as closely as possible (see Visualizing the Frames *Pg. 254**). The orientation of the frame model affects the pre-alignment adjustments that are displayed.*

4. Using the pre-alignment adjustments displayed, make the adjustments on the physical frame mounted on the patient. Ensure that the cannula is positioned as close as perpendicular to the base as possible prior to making the prescribed pre-alignment frame adjustments.

Note: If a trajectory is defined such that it exceeds the angular limits of its associated frame, the software will change the color of the frame tower model to red, present the pre-alignment frame adjustments within a red box, and will present a warning message (see Planned Trajectory May Exceed Frame Angular Limits *Pg. 285**). This indicates that the defined trajectory may not be possible later in the workflow using this frame mount. If the desired trajectory will necessarily exceed the angular limits of the frame, edit the trajectory of interest and/or reposition the selected marking grid on the patient so a better frame mount can be identified.*

Mount Point Task Reviewing and Refining Mount Points

The Mount Point Task provides a mechanism to review the prescribed frame mount location for a given trajectory by modeling the expected position and orientation of the corresponding scalp mount base prior to frame mounting. This functionality may be used to visualize whether the mount location prescribed by the application in the Mount Step (see Mount Step Mounting Frames Pg. 149) will result in optimal frame positioning relative to the planned entry point, based on how the bone screw tips are positioned relative to the surface of the skull.

If the initial projected position and orientation of the scalp mount base does not appear correct relative to the skull, the Mount Point Task provides the ability to refine the position of the scalp mount base. Accurately repositioning the base relative to the patient skull yields a new mount point location that will better achieve the planned entry point, reducing the total amount of XY adjustment required when subsequently adjusting the frame.

Utilization of this task to refine the mount point may be particularly helpful in instances where the curvature of the grid is not a good analog for the curvature of the skull. For example, this may occur for extreme posterior entry points at the base of the skull, especially when combined with a thick patient scalp.

Caution:	**Any modifications made to the scalp mount base model in the Mount Point Task causes the scalp mount point prescribed by the application in the Mount Step to change. Please review the updated scalp mount position upon returning to the Mount Step and confirm the updated mount point position is appropriate.**

The Mount Point Task is only accessible in the Mount Step (see Mount Step Mounting Frames Pg. 149) and if the scalp mount base is selected in the session (see Starting a New Session Pg. 60).

The following functionality is provided by the Mount Point Task:

- Reviewing the prescribed mount point position, by modelling how the scalp mount base will be positioned on the patient (see Reviewing the Mount Point Position Pg. 259).

- Modifying the mount point position, by modelling how the scalp mount base screws are anchored into bone on images of the patient prior to frame mounting (see Modifying the Mount Point Position Pg. 262).

Reviewing the Mount Point Position

You may use the Mount Point Task to review the mount point prescribed by the application for each trajectory path selected in the Mount Step (see Mount Step Mounting Frames Pg. 149). This can be accomplished by modelling how the scalp mount base may be positioned on the patient based on the location of the prescribed mount point. To assess the viability of the prescribed mount point, you should review how each of the scalp mount base screws may be anchored into the patient's skull on images acquired prior to mounting the frame. This should provide appropriate anatomical context for whether the prescribed mount point will achieve the planned entry point.

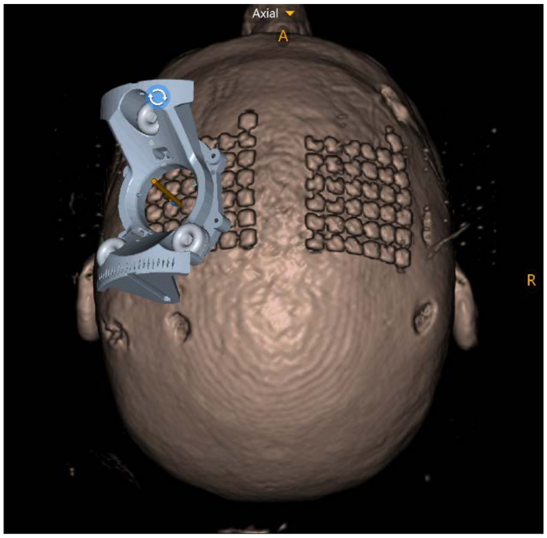
> **To review the mount point position**

1. Launch the Mount Point Task using the Task Selector (see Selecting a Task Pg. 84).

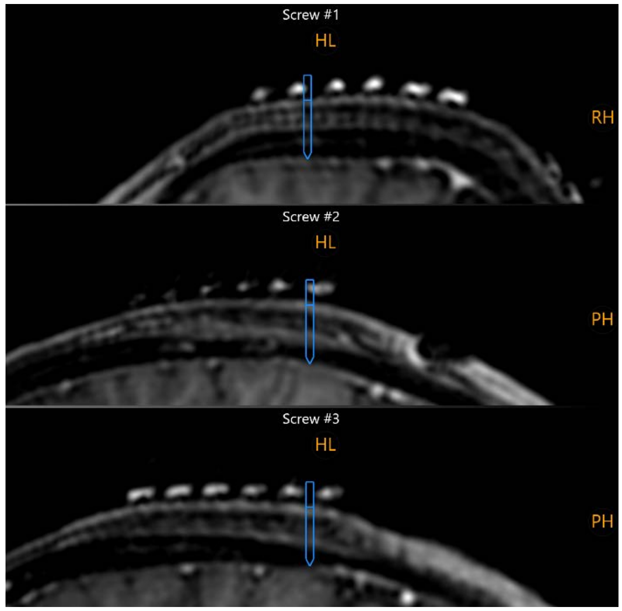
2. Select a trajectory whose mount point location you would like to review using the menu in the task control panel.

3. If necessary, select an additional image series for blending with the master series using the Thumbnail Bar (see Using Thumbnails Pg. 86).

4. The application will display a three-dimensional model of the frame base positioned at the currently prescribed mount point location on the selected image series in the right-most viewport.



5. Cross sections for each of the bone anchor screws will be overlaid on the selected image series in the three viewports on the right-hand side. A horizontal line graphic will be drawn on each screw cross section indicating where the bottom of the frame base would be located once the screw is fully seated into the patient. The label for each viewport indicates which bone anchor screw is being displayed: **Screw #1**, **Screw #2**, and **Screw #3**.

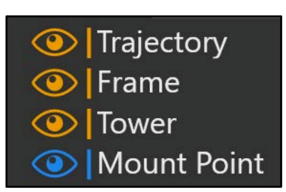


6. Review all views and ensure that the rendering of the scalp mount base correctly models how it will be positioned on the patient's skull. To do this:

   - Use the Arrow Tool (see Arrow Tool Pg. 99) to rotate the three-dimensional viewport and assess whether the scalp mount base model is fully seated on the patient's scalp, based on the selected images being viewed. If a portion of the base is positioned off the patient's scalp, this suggests that the prescribed mount point position may not be optimal for the planned trajectory.

   - Assess the position of the bone anchor screw cross sections in each of the right-most viewports. Verify that the tip of each screw cross section is seated into the patient's skull. You may also use the horizontal line graphic associated with each bone anchor screw to understand where the frame base will sit vertically relative to the patient's scalp. If one or more bone screw cross sections are not seated into the patient's skull, or if they are too deep and penetrate completely through the skull, this indicates that the prescribed mount point position may not be optimal for the planned trajectory.

7. Use the annotation toggle buttons in the task control panel to toggle the visibility of the currently selected trajectory, frame, frame tower and/or associated mount point.



Modifying the Mount Point Position

The Mount Point Task provides the ability to manually revise the mount location for the frame originally prescribed by the application in the Mount Step (see Mount Step Mounting Frames Pg. 149). This can be accomplished by changing the position of each of the scalp mount base's bone anchor screws, such that the entire frame model can be positioned properly on the patient's skull. The scalp mount base model can be raised, lowered, or tilted to better conform to the patient anatomy shown in the underlying images. Once the model has been optimally positioned, the mount point is automatically updated to match the new position of the model.

> **To manually edit the mount point position**

1. Launch the Mount Point Task using the Task Selector (see Selecting a Task Pg. 84).
2. Select a trajectory whose mount point location you would like to edit using the menu in the task control panel.
3. If necessary, select an additional image series for blending with the master series using the Thumbnail Bar (see Using Thumbnails Pg. 86).
4. To shift the vertical position of the frame base model away from the patient's skull, click **Raise Frame** from the task control panel. This will iteratively move the position of the entire base by 0.5 mm upward along the planned trajectory path.

5. To shift the vertical position of the frame base model towards the patient's skull, click **Lower Frame** from the task control panel. This will iteratively move the position of the entire base by 0.5 mm downward along the planned trajectory path.
6. To tilt / pivot the frame base model about its center of rotation:
   - For the bone anchor screw of interest, select **Up** from the task control panel to raise the screw away from the patient's skull. This will pivot the frame base model by raising that screw by 0.5 mm increments away from the patient's skull. The other screws will be lowered as the base pivots.
   - For the bone anchor screw of interest, select **Down** from the task control panel to lower the screw towards the patient's skull. This will pivot the frame base model by lowering that screw by 0.5 mm

increments towards the patient's skull. The other screws will be raised as the base pivots.

7. Iteratively modify the position of the bone anchor screws until the entire frame model is positioned such that each screw is positioned within the bone of the patient's skull as shown on the images.

8. To modify the orientation of the frame base model on the surface of the head:

    - With the Arrow Tool selected (see Arrow Tool Pg. 99) click and drag the handle rendered on each frame base model to apply an in-plane rotation.

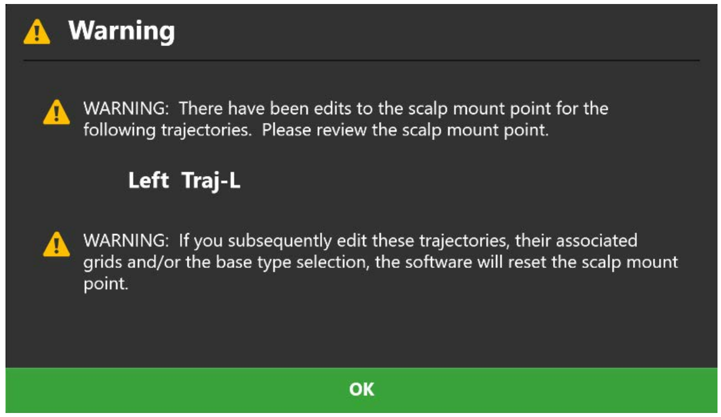
    - Clicking and dragging to the right to apply a clockwise in-plane rotation to the frame base model. Clicking and dragging to the left will apply a counterclockwise rotation to the frame base model.

9. Once all modifications have been made to the position of frame, review its final position and orientation as displayed on the patient images (see Reviewing the Mount Point Position Pg. 259).

10. Select **DONE** in the task panel to close the task window.

11. If modifications have been made to the frame base model for one or more trajectories, the application will notify you that the underlying frame mount point has been changed.

Caution:	**Any modifications made to the scalp mount base model in the Mount Point Task causes the scalp mount point prescribed by the application in the Mount Step to change. Please review the updated scalp mount position upon returning to the Mount Step to confirm the updated mount point position is appropriate.**



If additional edits are made to a planned trajectory (see Editing Trajectories to Localize Mount Points Pg. 145) or associated marking grid (see Modifying Marking Grids Pg. 236) after modifications to the mount point location have been made using this task, then any mount point modifications will be cleared. The application does this because editing the trajectory and/or associated marking grid will necessarily cause the mount point location to change, and therefore any previous edits are no longer valid. In these cases, you must launch the Mount Point Task after making the trajectory / marking grid edits to review and/or modify the mount point location again.

Any modifications made to the scalp mount base model in the Mount Point task will also necessarily affect any pre-alignment frame adjustments prescribed in the Preview Frame task (see Preview Frame Task Visualizing Frames Prior to Mounting Pg. 254). If modifications to the scalp mount base model were made after displaying pre-alignment frame instructions, ensure that the Preview Frame task is re-activated and pre-alignment frame instructions are re-displayed.

Maestro Task Segmenting Brain Structures

The Maestro Task provides a mechanism to automatically segment a set of brain structures from suitable / compatible MRI scans loaded into the application. The task utilizes a shape-constrained deformable model provided by the ClearPoint Maestro Brain Model to adapt, identify, label, and quantify the volume and shape of brain structures visible in a loaded MRI scan. This functionality may then be used throughout the workflow to visualize brain anatomy.

Note: Access to the Maestro Task is controlled by the license installed on the workstation. The application will prevent you from performing automatic brain structure segmentations unless the installed license provides feature-based access *to the Maestro Task. If you have not been granted a valid license to access the Maestro Task and wish to automatically segment brain structures from scans loaded on the workstation, please contact your clinical sales representative.*

The results from the ClearPoint Maestro Brain Model must be explicitly verified in the Maestro Task using the visualization tools provided. Once the results have been verified and accepted, the segmented brain regions and their associated measurements may be displayed in other workflow steps and tasks to assist with planning exercises. The Maestro Task is available for usage in the Pre-Op (see Pre-Op Step Setting Preoperative Trajectories Pg. 128), Entry (see Entry Step Setting Intraoperative Trajectories Pg. 143) and Target (see Target Step Finalizing Trajectories Pg. 159) steps.

Caution:	**For safety reasons, always visually confirm the brain region segmentation results provided by the ClearPoint Maestro Brain Model prior to dismissing the Maestro Task. This can be accomplished by examining the detected brain region results overlaid on the original scan using the viewports provided in the Maestro Task.**

The following functionality is provided by the Maestro Task:

- Automatically segment a set of brain structures on a selected image series (see Segmenting Brain Regions Pg. 266).
- Review the segmented brain region results overlaid on a selected image series (see Reviewing Segmented Brain Regions Pg. 269).
- Clear any brain region segmentation results previously detected on a given image series (see Clearing Segmented Brain Regions Pg. 270).

Segmenting Brain Regions

You may use the Maestro Task to exercise a fully automatic segmentation of brain structures on any suitable image series loaded into the application.

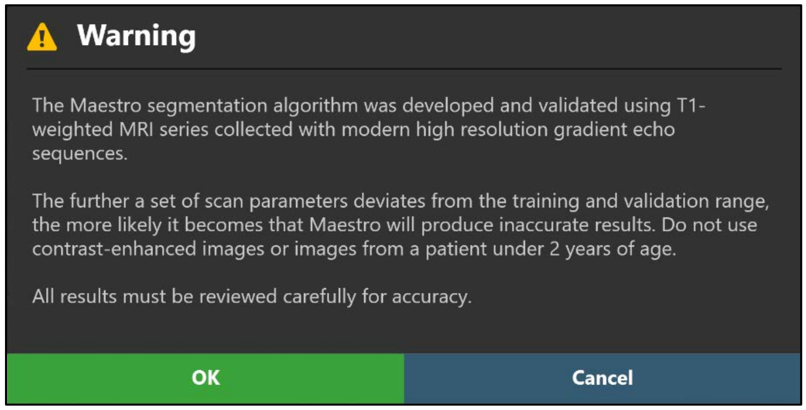
Note: The Maestro segmentation algorithm was developed and validated using non-contrast enhanced T1-weighted MR image series collected with modern high resolution gradient echo sequences. The training data was used to optimize internal, non-editable parameters of the Maestro algorithm. When segmenting image series whose MR scan parameters match those of the training and validation data, Maestro is expected to produce accurate segmentations. For image series with parameters outside the training and validation range, Maestro is still capable of computing accurate segmentations. However, these segmentations must be reviewed carefully for accuracy. The further a set of scan plane parameters deviates from the training and validation range, the more likely it becomes that Maestro will produce inaccurate results. See Appendix 2 – Image Acquisition Parameters for Maestro Training and Validation Datasets *for a table describing the range of specific image sequence parameters used to train and validate the Maestro segmentation algorithm.*

Note: The application will prevent you from initiating an automatic brain region segmentation using image series that were not acquired using an MRI scanner and/or have properties that make them invalid input for the detection algorithm. See Unable to Perform Maestro Segmentation *Pg. 278* *for additional details.*

> **To initiate an automatic brain region segmentation**

1. Launch the Maestro Task using the Task Selector (see Selecting a Task Pg. 84).
2. Select an image series for which to initiate the automatic brain region segmentation using the Thumbnail Bar (see Using Thumbnails Pg. 86). It is suggested that the series with the highest image resolution be selected.
3. Select **Start Maestro Segmentation** to start the ClearPoint Maestro Brain Model segmentation on the selected series.
4. Note the safety warning and ensure that the selected scan meets the following criteria (also refer to Appendix 2 – Image Acquisition Parameters for Maestro Training and Validation Datasets):
    - Acquired on an MRI scanner using a high-resolution gradient echo sequence.
    - T1-weighted without the use of contrast agents.

- Acquired on a patient older than 2 years of age.

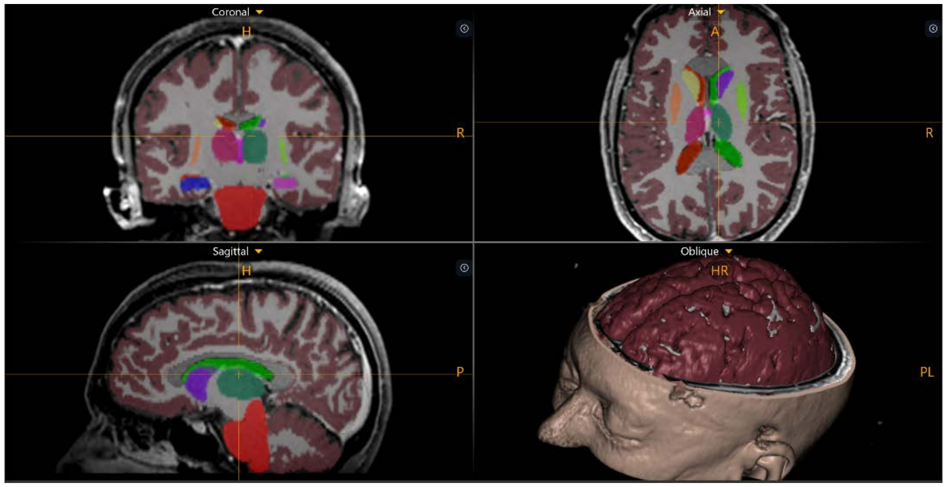


Caution: **Be sure to only initiate automatic brain region segmentations using scans that meet the criteria required by the ClearPoint Maestro Brain Model. Scans that are outside of the training range used for the detection algorithm may produce results that are inaccurate. Carefully review and verify all brain region segmentation results by visually examining their positions overlaid on the image series used to initiate the segmentation. See Appendix 2 – Image Acquisition Parameters for Maestro Training and Validation Datasets for further information.**

5. Select **OK** to start the automatic brain structure segmentation. Otherwise, choose **Cancel** to cancel initiation of the segmentation.

6. A floating window will display a **Please Wait** message and the task user interface will be blurred while the application performs the brain region segmentation.

7. After several minutes of data processing, the segmented brain region results will be displayed in the application viewports. If the segmentation could not return a result, the application will warn the user (see Unable to Perform Maestro Segmentation Pg. 278 for additional information).

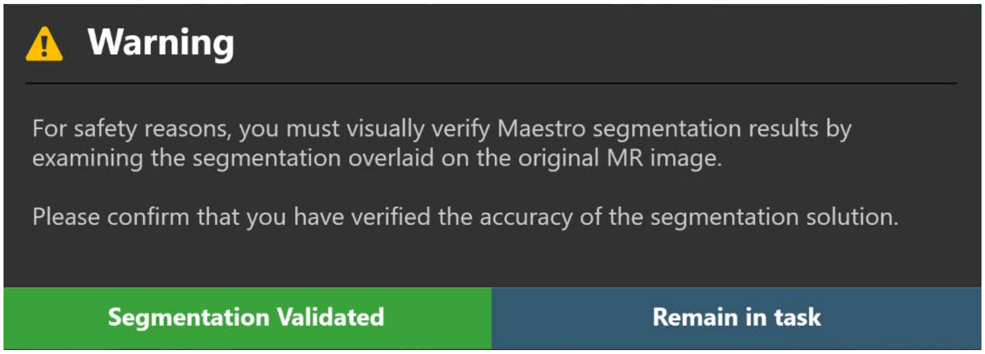


8. Always use the viewports to visually inspect the results of the ClearPoint Maestro Brain Model. This can be achieved by visually examining the position of each segmented brain region overlaid on the selected image series. Use the slider control beside the **Maestro** toggle button in the task panel to change the opacity of the segmented brain structures relative to the original grayscale image (see Working with Maestro Brain Regions Pg. 124). This tool enables you to compare the color-coded overlay corresponding to each segmented brain region with the original grayscale image. Individual segmented brain regions can be more closely examined by adjusting the zoom level in each viewport (see Zoom Tools Pg. 100) and visualizing the regions at different slice positions (see Image Scroller Pg. 95). Doing so allows you to more carefully inspect whether the tissue boundaries identified by the ClearPoint Maestro Brain Model match the boundaries visible in the source image series. Switching to a single viewport (see Single / Multi Viewport Tool Pg. 114) and zooming in (see Zoom Tools Pg. 100) provide the optimal visual setup for use of the **Maestro** slider control (see Working with Maestro Brain Regions Pg. 124). You may also inspect the 3D viewport containing three-dimensional representations of each segmented brain region overlaid with the original grayscale image series. After performing a detailed review of the segmentation results of the ClearPoint Maestro Brain Model, you may determine if the results appear accurate. In instances where the segmentation results do not appear accurate, proceed to clear the results, and select another scan to use for the automatic brain region detection (see Clearing Segmented Brain Regions Pg. 270).

9. After you have reviewed the segmentation results and confirmed the accuracy of the computed segmentation, you may close the Maestro Task.

Caution: **For safety reasons, always visually confirm the brain region segmentation results provided by the ClearPoint Maestro Brain Model. When closing the Maestro Task, the application will prompt you to explicitly confirm that you have verified the**

accuracy of the segmentation prior to proceeding in the workflow.



Reviewing Segmented Brain Regions

You may review the detection of each segmented brain region overlaid on any image series loaded into the application.

When verifying the accuracy of the segmentation results, it is best to visualize the segmented brain regions on the original image series used to exercise the automatic detection as well as on any additional image series that clearly define the structures and boundaries of interest.

> **To review segmented brain regions**

1. Launch the Maestro Task using the Task Selector (see Selecting a Task Pg. 84).

2. Select the image series that you wish to review the segmented brain regions against using the Thumbnail Bar (see Using Thumbnails Pg. 86).

3. Visually review each segmented brain region in each of the application viewports. Scroll through each viewport (see Image Scroller Pg. 95) and/or modify the cross hair position (see Changing Crosshair Positions Pg. 93) to visually review each segmented brain region at different slice positions within the selected image series. Individual segmented brain regions may be more closely examined by adjusting the zoom level in each viewport (see Zoom Tools Pg. 100).

4. Use the **Maestro** toggle button to control the visibility of one or more segmented brain regions (see Working with Maestro Brain Regions Pg. 124). This may help compare the segmented result with the signal from the underlying structure in the selected image series.

5. Use the slider bar beside the **Maestro** toggle button to control the opacity of the segmented brain regions displayed in the application viewports (see Working with Maestro Brain Regions Pg. 124). Using the **Maestro** slider bar allows you more carefully inspect whether the tissue boundaries identified by the ClearPoint Maestro Brain Model match the boundaries visible in the selected image series. Switching to a single viewport (see Single / Multi Viewport Tool Pg. 114) and zooming in (see Zoom Tools Pg. 100) provide the optimal visual setup for use of the **Maestro** slider control.

6. Review the volume measurements for one or more segmented brain regions using the Maestro toggle button in the task panel (see Working with Maestro Brain Regions Pg. 124).

7. Use the 3D viewport in the Maestro Task to inspect the three-dimensional representations of each segmented brain region overlaid with the selected image series.

Clearing Segmented Brain Regions

In instances where the segmentation results returned by the ClearPoint Maestro Brain Model do not appear accurate, you may clear the unwanted segmentation defined in the application.

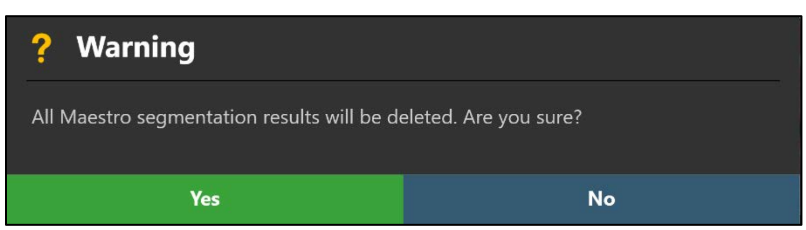
Note: Only one set of segmentation results produced by the ClearPoint Maestro Brain Model can be displayed in each session. If you wish to exercise the brain region segmentation on a different image series, any existing segmentations will be cleared prior to exercising the new brain region segmentation.

> **To clear a brain region segmentation**

1. Launch the Maestro Task using the Task Selector (see Selecting a Task Pg. 84).

2. Select **Delete Segmentation Results** from the task control panel.

3. You will be prompted to confirm the removal of the segmentation prior to proceeding. Select **Yes** to proceed with the deletion of the current segmentation. Otherwise, choose **No** to leave the current segmentation intact.



Troubleshooting

This section describes how to troubleshoot problems that you may encounter on the ClearPoint Workstation. This content is also contained as integrated help topics within the application whenever a warning message is displayed. See Status Messages Pg. 84 for details on how to view integrated help content within the application.

DICOM Association Lost

The DICOM connection between the ClearPoint 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 Window if images from the scanner can be written to removable media.

Data Rejected by Workstation

The series just received by the ClearPoint Workstation has been deemed invalid due to the condition(s) indicated by the warning message. This indicates that the acquisition just sent has some type of problem that is preventing it from being loaded into the workstation.

Can be caused by:

- Images received do not meet the requirements of DICOM conformance of the software. They could be missing DICOM header information that is required in order to be displayed in the software (e.g., patient name/id, series date/time, etc.).
- Patient information associated with incoming images do not match patient information of current session and the user has declined to accept them as equivalent.
- Modality of incoming images are not supported by the software.
- Using a temporary license in a clinical setting. When using a temporary license, the software will reject recent acquisitions unless the word ‘TEST’ is embedded in the patient name.
- Images received are older than previously loaded data. This can indicate the incorrect data has been sent to the software.
- Images received do not conform to the restrictions of the workflow step receiving the data.

Consequences of data rejected by the workstation:

- If data is rejected by the workstation, it will not be available for viewing or loading. Read the data rejection message carefully to determine the cause and make the necessary corrections prior to acquiring the images again.

Recovery:

- Depending on the cause for the image rejection, the recovery can be quite different. Analyze the rejection message carefully to understand why the data is being rejected in the first place.
- Regardless of the cause, if you are seeing this message then there is something inherently invalid about the image acquisition just made, so please review the

acquisition carefully with the imaging technician to ensure that all parameters were entered correctly. Try sending the data again after making the necessary corrections.
- If you do not fully understand the rejection message, please contact the software team for further assistance.

Failed to Load Data into Workstation

The series just received could not be loaded into the ClearPoint Workstation due to the condition(s) indicated by the warning message.

Can be caused by:

- Images received do not conform to the restrictions of the workflow step or task loading the data. Some scans are required to include specific regions of the patient anatomy or mounted hardware.
- Scan plane parameters entered incorrectly
- Images are not from the currently selected side of the patient
- Incorrect image fusion
- Incorrect identification of mounted hardware
- Image transfer failure resulting in corrupted and/or incomplete set of images
- 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.

Recovery:

- Depending on the cause for the data not being loaded, the recovery can be quite different. Analyze the warning message carefully to understand why it was not loaded.
- Review the acquisition with the imaging technician to ensure that all parameters for the position and orientation of the images were entered correctly and that the correct imaging sequence was selected. Verify that the scan appears correct on the scanner console. Review carefully to ensure that it contains all the expected contents. If any error is identified in the entered scan parameters, reacquire the images.
- Verify that image fusions were performed correctly and that all mounted hardware has been identified correctly.
- 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.

MR Scanner Bore Size Not Configured

During an intraoperative MRI-guided procedure, if the MR scanner bore size has not been set in the ClearPoint Workstation System Configuration Dialog, then every time an image series is received by the workstation, a warning message concerning the bore size will be shown. In an MRI Workflow, the software uses the MR scanner bore size in combination with the Device Length value (inputted when a new session is created) to ensure that for a given trajectory path, the device can be physically inserted into the SMARTFrame without being blocked by the scanner bore (see Trajectory May Cause Device to be Obstructed by MR Scanner Bore). Without this information, the software will not be equipped with the data it needs to provide this warning for a given trajectory path. The MR scanner bore size is only relevant to those intraoperative procedures utilizing MRI guidance and only needs to be configured once, unless the MR scanner for which the workstation interacts with physically changes.

Is caused by:

- MR scanner bore size not specified in the System Configuration Dialog (‘SYSTEM’ tab) when an MRI Workflow is being performed.

Consequences if the MR scanner bore size is not configured:

- If the software is not aware of what the MR scanner bore size is, it is unable to warn about potential bore collisions prior to the device being inserted during an MRI Workflow.

Recovery:

- Use the System Configuration Window to specify the MR scanner bore size (see ‘SYSTEM’ tab).

Failed to Detect AC-PC Points

In rare circumstances, the ClearPoint Workstation may fail to detect one or all the AC, PC and MSP positions in the selected scan. If this error occurs, you must manually define these positions in the AC-PC task.

Can be caused by:

- Attempting to detect AC-PC landmarks on data other than T1-weighted MR images.
- Attempting to detect AC-PC landmarks on an image series with very few images.

Consequences of failing to detect AC-PC points:

- Several computations in the software rely on the AC, PC and MSP points, so you will be unable to continue in the clinical workflow without experiencing significant problems until these points are defined.

Recovery:

- Verify that the series selected for AC-PC landmark detection is a T1-weighted MRI scan encompassing the entire patient's head. If the image series selected for AC-PC landmark detection is not a T1-weighted whole head scan, please load a scan which meets these criteria.
- If the failure still occurs, you can manually define the AC, PC and MSP points in the AC-PC task prior to proceeding with the clinical workflow.

AC Set Posterior to PC

The AC-PC task may warn that the AC point is set posterior to the PC point, and this may indicate that your AC-PC coordinate system is defined incorrectly. If you see this warning message, carefully review your AC and PC points, and ensure that they are set correctly.

Otherwise, if this message appears when your AC-PC points are correct, then it indicates a more significant problem. This message is shown whenever the selected AC and PC point positions don't agree with the patient orientation that was entered on the scanner console. So, if the AC-PC points are correct, then the scanner must have the patient orientation set incorrectly. For example, if the patient orientation entered on the scanner console was Head-First Supine (HFS) and the patient was actually Head-First Prone (HFP), then the Anterior-Posterior direction will be reversed.

Can be caused by:

- AC and PC points set incorrectly by user
- Incorrect patient orientation entered on the scanner console

Consequences of AC-PC points set incorrectly:

- If the AC-PC points are set incorrectly by the user, the anatomical viewing planes may appear incorrect.
- If the patient orientation was set incorrectly on the scanner, all patient orientation labels (HF/LR/AP) shown in the software will be incorrect because they reflect the patient orientation entered on the scanner. This increases the risk of left/right confusion when planning trajectories.

Recovery:

- Ensure that AC-PC points are set correctly if edited manually.
- If patient orientation is set incorrectly, re-acquire the whole head volume of interest using the correct patient orientation and start a new session.

Mid-Sagittal Plane Point Too Close to AC-PC Line

This warning message is displayed when the position of the mid-sagittal plane (MSP) point is set such that it is less than 20 mm from the AC-PC line. This condition indicates that the MSP may have been set incorrectly. Please verify its location prior to proceeding with the workflow.

Is caused by:

- Mid-sagittal plane point is set within 20 mm of the AC-PC line.

Consequences of setting the MSP too close to the AC-PC line:

- The software uses the AC, PC and MSP points to compute a transformation matrix that is used to align the viewports to an anatomical orientation. If the MSP point is set too low towards the AC-PC line, this could create a drastic rotational component that may not produce desirable anatomical viewing orientations.
- If the anatomical views appear correct and you receive this warning, it can safely be dismissed if placement of the MSP point is satisfactory.

Recovery:

- Review the position of the MSP point to ensure that it has been set correctly. Recall that the MSP represents another location on the anatomical mid-sagittal plane. To set the MSP point, select any other point that is superior to AC/PC points and lying on the patient’s anatomical mid-sagittal plane.
- If the MSP has been set correctly even if it is within 20 mm of the AC-PC line, the warning can be safely dismissed.

Mid-Sagittal Plane Point Set Below AC-PC Line

The ClearPoint Workstation has detected that the position of the mid-sagittal plane (MSP) point has been set inferior to the AC-PC line. This condition may indicate that the MSP has been set incorrectly or that an incorrect patient orientation was initially set on the scanner.

Can be caused by:

- Mid-sagittal plane point is set inferior (in foot direction) to AC-PC line
- Incorrect patient orientation entered on the scanner console

Consequences of setting the MSP below the AC-PC line:

- The software uses the AC, PC and MSP points to compute a transformation matrix that is used to align the viewports to an anatomical orientation. If the MSP point is set below the AC-PC line, this will cause the anatomical views to be flipped upside down.
- If the patient orientation was set incorrectly on the scanner, all patient orientation labels (HF/LR/AP) shown in the software will be incorrect because they reflect the patient orientation entered on the scanner. This increases the risk of left/right confusion when planning trajectories.

Recovery:

- Review the position of the MSP point to ensure that it has been set correctly. Recall that the MSP represents another location on the anatomical mid-sagittal plane. To set the MSP point, select any other point that is superior to AC-PC points and lying on the patient's anatomical mid-sagittal plane. Do not set the point inferior to the AC-PC points.
- If patient orientation is set incorrectly, re-acquire the whole head volume of interest using the correct patient orientation and start a new session.

Unable to Perform Maestro Segmentation

This error indicates that the Maestro brain segmentation cannot be completed, and no result can be generated. See the ClearPoint User's Guide for details on requirements when selecting data for Maestro segmentation.

Can be caused by:

- Selecting non-MR data. Other modalities such as CT or Secondary Capture (SC) are not supported.

- Selecting MR image data that has been encoded as 8-bit. Only 16-bit data is supported.
- Too few images in the series. The image data should include the entire head.

Consequences:

- Brain structures will not be segmented from the selected image series.

Recovery:

- Select suitable MRI data and retry the Maestro segmentation.

SMARTGrid Not Found / Detected Incorrectly

The ClearPoint Workstation software has failed to detect the indicated SMARTGrid present in the whole-head scan of the patient.

Can be caused by:

- Loss of fluid in the grid
- Whole-head volume scan cuts off part of the grid
- Insufficient signal in the grid caused by poor coil placement (MR images only)
- Imaging artifacts that obscure the grid
- Grids overlapping one another in a bilateral case

Consequences if the SMARTGrid is not detected by the software:

- The default entry point for a trajectory path is not set at the center of the marking grid. Instead, it will be defined straight up (superior) from the target point.
- The Entry step will not display a 3D model of the grid in its "Review" layout. Manual modification of the position/orientation of the grid is required to proceed with marking the entry point.
- The scalp mount centering point cannot be calculated. If you are using the scalp mount base and/or accurately hitting your entry point is important, then you will need to ensure that the grid is properly defined in the software.

Recovery:

- Use the Grid task to manually modify the position/orientation of the grid that was detected incorrectly.
- If the grid is not detected at all, use the Grid task to automatically search for it in a more localized area of interest. This can be accomplished by rotating the grid view to "look along" the axis of the grid and then clicking the "Segment Grid" button. For a bilateral procedure be sure to position the view angle so that you are looking at the grid from the side to which the grid belongs. Otherwise, the grid may be identified as belonging to the other side of the head.

- If performing an MRI Workflow, use the scan plane parameters in the Entry step to acquire a localized slab containing the grid of interest. Send the acquisition to the workstation and use the Grid task to detect the grids in this acquisition using the “Segment Grid” button.
- If the above mentioned techniques fail to detect the grid and accuracy at the entry point is not crucial, you can manually work out which grid element contains the entry point. Note: If you are using the scalp mount base, this is not an acceptable recovery mechanism because the scalp mount centering point will never be prescribed by the software.

Trajectory Does Not Intersect SMARTGrid

The trajectory listed in this warning message does not intersect a SMARTGrid, making entry point localization on the marking grid impossible. If you wish to use the SMARTGrid to assist in localizing this trajectory's entry point, make changes to the trajectory to ensure it correctly intersects a marking grid or re-mount the grid.

Can be caused by:

- Planned trajectory does not physically intersect a grid.
- Trajectories imported from Pre-Op do not initially intersect a grid.
- Trajectories transformed incorrectly due to incorrect image fusion between Pre-Op master series and whole head grid volume.

If the trajectory does not intersect grid:

- The default entry point is not set at the center of the grid.
- The burr hole center point will not be rendered on the grid view.
- The scalp mount centering point cannot be calculated.
- The trajectory will be colored in red to indicate that entry point localization is not possible.

Recovery:

- Ensure that the software’s detection of the grid is correct. If not, make manual corrections to the position/orientation of the grid using the Grid task.
- Verify that the image fusion between the master series in the Pre-Op step and the whole head grid volume was performed correctly. If there are issues with the fusion, make the necessary corrections and subsequently edit the trajectory such that it intersects the grid of interest.
- Re-position the grid on the patient if necessary to allow for the planned trajectory to intersect it. This will involve acquiring a new scan which includes the re-positioned grid. The Grid task may then be used to detect its modified position from the newly acquired scan.

- Make corrections to the planned trajectory, if possible, such that it will intersect the grid.

Trajectory May Cause Device to be Obstructed by MR Scanner Bore

The trajectory path mentioned in the warning message has an angulation such that insertion of the device during the MRI-guided procedure may be obstructed or blocked by the MR scanner bore. The software uses the ‘MR SCANNER BORE SIZE’ variable in the System Configuration Dialog as well as the ‘Total Device Length’ specified when starting a new session to determine whether the planned trajectory may cause the device to be blocked by the scanner bore during insertion of the device in an MRI Workflow.

In addition to indicating that the planned trajectory may cause a bore collision with the device during insertion inside the MR scanner bore, the software also provides specific values for device clearance from the bore (in millimeters) in the following instances:

1. When the device is inserted inside the bore.
2. When the device is inserted into the targeting cannula down to the entry point prior to returning the patient into the bore.
3. When the device is inserted all the way to target depth prior to returning the patient into the bore.

If the planned trajectory will not cause a bore collision during device insertion, the distance value indicates how much clearance the device will have before striking the bore. If the planned trajectory will cause a bore collision during device insertion, the distance value indicates how much extra length the device has after striking the bore. The purpose in showing these values is to provide guidance as to how far the device needs to be introduced to clear the MR scanner bore on re-introducing the patient.

Is caused by:

- Defining a trajectory that will cause the device to be obstructed by the MR scanner bore during insertion.

Consequences of proceeding with a trajectory that may cause device to be obstructed by the MR scanner bore:

- During device insertion under MRI guidance, 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 under MRI guidance, including inserting a portion or all 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 an MRI Workflow to prevent further problems later in the workflow.
- Use the Trajectory Status dialog (exercised by right clicking the trajectory annotation) to view the device clearance measurements in an MRI Workflow. 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 during an MRI Workflow 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 the device being inserted during this procedure will not be long enough to reach the target point of the trajectory path mentioned in this warning message. The software uses the ‘Device Insertable Length’ parameter specified when starting a new session as well as the length of planned trajectory (with appropriate frame base vertical offset) to determine whether the device can reach the target point. If this message is shown, it is strongly recommended that changes to the planned trajectory are made to allow the device to reach its target during the insertion stage.

In addition to providing this indication, the software will also indicate the ‘short-fall’ or ‘gap’ distance (in millimeters). This represents how much extra distance is required to reach the target if in fact the device is too short to reach it.

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 device to not reach 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 to prevent further problems later in the workflow.
- Use the Trajectory Status dialog (exercised by right clicking the trajectory annotation) 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 system accuracy has only been validated to a maximum insertion depth 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. Note that in cases where the frame has not been mounted, the software will compute the projected position of the ball marker based on the frame base selected.

Consequences of proceeding with a trajectory that exceeds the maximum validated system depth:

- Since the ClearPoint system has not been validated at depths greater than 125 mm, you may experience higher device placement errors at the target. Factors, such as reduced image quality may come into play more readily at these increased insertion depths.

Recovery:

- It is strongly encouraged to use planned trajectories that do not exceed the maximum validated system depth of 125 mm. Do not use planned trajectories that exceed this depth.

Trajectory Crosses Mid-Sagittal Plane

The ClearPoint Workstation will detect if you define a trajectory that crosses the mid-plane of the brain. In these cases, the entry point of the trajectory path is contralateral to its corresponding target point.

Is caused by:

- Defining a trajectory that crosses the mid-plane of the brain. In order for the status warning to appear, end users would have confirmed contralateral target/entry placement via the Contralateral Warning Dialog. In this dialog, end users must explicitly confirm and acknowledge that the ability of the inserted device to safely and accurately target structures contralateral to the entry point has not been evaluated.

Consequences of proceeding with a trajectory that crosses the mid-sagittal plane:

- If crossing the mid-sagittal plane is intended, then this warning can be dismissed without any downstream consequences.
- If crossing the mid-sagittal plane was not intended, then this warning provides indications to the end user that an error may have been made when planning the indicated trajectory.

Recovery:

- Once the user has confirmed contralateral trajectory definition, it is understood by the software that this trajectory path was intended. The purpose of the warning message is to alert the end user of the contralateral trajectory in case that the planned trajectory path isn't what was intended.

Scalp Mount Centering Point Not On the Grid

This warning message is displayed when the required scalp mount point does not intersect the grid.

Is caused by:

- Trajectory does not intersect grid.
- Trajectory intersects skull at a steep enough angle that the required mount point does not intersect grid.
- Projected orientation of base does not conform to skull surface.
- Trajectory transformed incorrectly due to incorrect image fusion between Pre-Op master series and whole head grid volume.

Consequences:

- No guidance can be provided for mounting the frame.

Recovery:

- A trajectory must be planned that lies well onto the grid such that the mount point can be localized. This can be done either by altering the trajectory or repositioning the grid and acquiring a new scan.
- Verify that the image fusion between the master series in the Pre-Op step and the whole head grid volume was performed correctly. If there are issues with the fusion, make the necessary corrections and edit the trajectory such that it intersects the grid of interest.
- Review the orientation of the frame relative to the skull and correct as needed in the Mount Point task.

Planned Trajectory May Exceed Frame Angular Limits

The planned trajectory specified may exceed the angular limits of its associated SmartFrame. This means that the trajectory may not be realizable if the frame base is mounted as shown in the Preview Frame or Mount Point task.

Can be caused by:

- The trajectory has been planned at an inclination that is too extreme to the skull surface, and therefore falls outside the physical pitch and/or roll limits of the frame shown in the Preview Frame or Mount Point task.
- Images of the grid may be subject to image distortion and/or artifacts, causing the software to incorrectly compute the frame location and/or orientation shown in the Preview Frame or Mount Point task.
- Poor grid adhesion to the head may cause the software to incorrectly compute the frame location and/or orientation that is shown in the Preview Frame or Mount Point task.

Consequences of the trajectory being beyond angular limits of the frame:

- This indicates that the trajectory cannot be realized if the frame base is mounted as shown in the Preview Frame or Mount Point task. Proceeding in the workflow may result in a need to replan and potentially re-mount the frame to achieve a viable trajectory.
- This can also indicate that distortion and/or other artifacts may be present in the acquired images which may have affected the computation of the frame's location and orientation that is shown in the Preview Frame or Mount Point task.

Recovery:

- Analyze the images used to identify the grid. It may be necessary to acquire additional scans to reduce distortion/artifacts in the acquired images, and re-segment the grid using the Grid task. If the grid has visibly not conformed to the shape of the skull, then the frame may not be shown correctly relative to the skull surface.
- If the frame is not shown correctly relative to the skull surface, re-affix the grid and use the Grid task to re-segment the grid or use the Mount Point task to correct the orientation and/or mount point of the frame so that screw tips are anchored into bone.
- If the trajectory is too steeply inclined relative to the skull surface, you may be able to find an orientation of the frame that causes the trajectory to be achievable by rotating the frame base in either the Preview Frame or Mount Point task. Otherwise, the trajectory will need to be replanned at an inclination that is closer to being perpendicular to the skull surface.

SMARTFrame Not Found / Detected Incorrectly

The ClearPoint Workstation software has failed to detect the indicated SMARTFrame present in the whole-head scan of the patient. Either the frame has not been detected at all, or it has been detected in an incorrect position.

Can be caused by:

- Frame markers not completely contained within the volume
- 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 acquired frame volume

Consequences if the SMARTFrame is not detected by 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.
- Any trajectories defined for the frame of interest will not have their entry points defined within the X-Y limits of the frame.
- You will be prevented from moving on in the workflow with this frame selected until it has been defined in the software.

Recovery:

- If performing an MRI Workflow, use the scan plane parameters in the Target step to acquire a frame slab. Send the acquisition to the workstation to trigger automated detection of the frame.
- Manually set the marker positions using the Frame task.

- Use the Frame task 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, clicking the ‘Add Frame(s)’ button, and selecting ‘Add a frame at the specified location’.

SMARTFrame Ball Marker Not Found

The ClearPoint Workstation has failed to detect the indicated SMARTFrame’s ball marker present in the whole-head scan of the patient. This message may be shown in combination with the ‘SMARTFrame Not Found’ message (see SMARTFrame Not Found / Detected Incorrectly) or may appear independently, if the frame markers were in fact detected.

Can be caused by:

- Frame markers not completely contained within the volume
- Fluid loss in ball marker (MR images only)
- Image artifacts, such as wrapping/ghosting, cause multiple ball markers to appear on top of one another in the acquired frame volume

Consequences if the SMARTFrame ball marker is not detected by the software:

- The software must be aware of the position of the frame’s ball marker, otherwise it cannot prescribe any adjustment instructions to align the frame of interest to the desired trajectory path.
- You will be prevented from moving on in the workflow with this frame selected until its ball marker has been defined/identified by the software.

Recovery:

- If performing an MRI Workflow, ensure that there are no significant bubbles in the ball marker. Any bubble in the ball marker must be less than 25% of its total size to ensure accurate detection in MR images. If you detect a significantly large bubble in the marker, take steps to remove the bubble and/or replace the frame entirely. It is strongly advised not to proceed with the MRI Workflow in cases where a significant bubble in the ball marker exists.
- If you decide to replace the frame entirely, ensure to send the defective tower back to ClearPoint Neuro for investigation. Afterwards, please also verify that existing frames in inventory are being stored correctly as per the manufacturer’s guidelines.
- If you have taken steps to remediate the automatic ball marker detection and the software still fails to find its location, use other recovery mechanisms specified in: SMARTFrame Not Found / Detected Incorrectly

SMARTFrame Frame Markers Not Defined

The SMARTFrame listed in this warning message has one or more markers that have not been defined yet. The software is unable to provide frame instructions until all frame markers have been defined.

Is caused by:

- Frame not detected correctly or not at all (see SMARTFrame Not Found / Detected Incorrectly).

Consequences of not all frame markers defined:

- The software will be unable to provide frame adjustment instructions for any trajectories associated with this frame.
- Users should not proceed with the selected workflow unless all frame markers for all frames have been defined correctly.

Recovery:

- Use the Frame task to either re-detect the frame of interest or manually define any undefined markers.
- If performing an MRI Workflow, use the scan plane parameters in the Target step to acquire a frame slab for the interested frame. Send the frame slab to the Target step so that automatic detection of the frame can occur.

SMARTFrame Markers Inconsistent with Hardware Specifications

The ClearPoint 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 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 several 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 Frame task. It is important to ensure that the frame markers have been set correctly, since the software uses their position to make several computations, including frame adjustments and whether to display other warning messages about the frame. Modify frame marker positions if they appear incorrect relative to the underlying images.
- If you are performing an MRI Workflow and the frame markers positions appear correct relative to the underlying images, acquire a frame slab where distortion artifacts will most likely be minimized. Send this frame slab to the Target step or Frame task so that the frame can be re-detected. 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.

Frame Cannula Not Locked Down

The ClearPoint Workstation has detected that the selected SMARTFrame's cannula may not be locked in the 'down' position during an MRI Workflow. The cannula should be set correctly on first mounting the frame and must be locked in the down position prior to adjusting the cannula. If it is necessary to retract the cannula to the 'up' position during the course of the MRI-guided procedure, always ensure to return the cannula back to the 'down' position. **Failure to do so can result in an insertion that is deeper than planned.**

Can be caused by:

- The selected frame's cannula is physically not locked in the 'down' position. If this is the case, it must be corrected before proceeding with the MRI Workflow.
- Image Distortion and/or artifacts in the images used to detect the position of the frame markers or the cannula. This results in the software detecting a position for the selected frame's ball marker which makes it appear as though the cannula is not in the locked 'down' position, even though it is. (For other causes see also Frame Ball Marker Appears Too Low).
- Incorrect image fusion between the scans used to define the frame markers and ball marker.

Consequences of the selected frame's cannula not in locked 'down' position:

- In an MRI Workflow, the software uses the cannula position to compute insertion depth values. If the cannula is physically in the 'up' position when adjusting the frame, then the computed depth value would be based on that position. If the cannula is subsequently in the ‘down’ position at the time of insertion (as may happen when using an XG frame) then the insertion depth provided by the software will result in a deeper insertion than planned which may harm the patient.

- If the cannula is confirmed as being physically locked down despite the message, that indicates that there is error in the detected position of the cannula 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 cannula being left in the ‘up’ position, ensure that it is correctly locked ‘down’ and then acquire at least one more pair of orthogonal cannula scans before proceeding with the insertion. That will ensure that the computed depth value is based on the cannula in the ‘down’ position.
- If the cannula is properly locked ‘down’ 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. 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.
- If the cause for this warning was due to incorrect image fusion between the ball marker and frame marker scans, verify that the fusion was performed correctly and that all mounted hardware has been identified correctly.

Frame Ball Marker Appears Too Low

The ClearPoint Workstation has detected that the selected SMARTFrame’s ball marker appears lower than it should be relative to the frame markers during an MRI Workflow.

Can be caused by:

- Inadvertent patient movement between the Target step 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 ball marker was detected incorrectly in the most recently received images of the frame.

- The most recently received images of the selected frame's ball marker were subjected to image distortion/artifacts that caused its position in space to not reflect where it is located physically.
- Incorrect image fusion between the scans used to define the frame markers and ball marker.

Consequences of the selected frame's ball marker being too low:

- This indicates that detection of the selected frame's frame markers and/or ball marker 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 Target step, re-acquire an entire frame volume and register this to the Target master series. Proceed with frame alignment after this has been accomplished.
- Otherwise, if the cause is due to inconsistent ball marker positions on subsequent frame scans, then analyze all frame scans to rule out any MR-based artifacts in the acquired images. Ensure that the correct scan protocols and associated parameters were used, in particular:
    - If 3D error correction is available on the MR scanner, ensure that it was turned on and that the 3D-corrected series was sent
    - If the MR scanner supports table movement, verify that the Table Position value was entered correctly.
    - For Siemens MR scanners, ensure that the direction of phase encoding has been set correctly using the 'InPlane Rotation' angle provided by the ClearPoint 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
- 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.
- If the cause for this warning was due to incorrect image fusion between the ball marker and frame marker scans, verify that the fusion was performed correctly and that all mounted hardware has been identified correctly.

Trajectory Not Within X-Y Limits of the Frame

The selected trajectory specified in the warning message is not within the X-Y limits of its associated SMARTFrame. This means that the trajectory may not be realizable using further X-Y frame adjustments. Frame re-mounting or exercising a set of pitch and/or roll adjustments may be necessary to realize the planned trajectory and/or position it such that further X-Y adjustments can be made.

Can be caused by:

- The trajectory being defined is physically outside the X-Y limits of the frame in its current position.
- Images of the frame used to identify its position are subject to image artifacts, causing the software to warn that the trajectory is beyond the frame’s physical X-Y limits even though it may not be.
- Trajectories transformed incorrectly due to incorrect image fusion between the whole head frame volume and the master series from the previous step.

Consequences of selected trajectory being beyond X-Y limits of the frame:

- This indicates that the planned entry point cannot be realized with the frame in its current position. To realize the entry point, the frame may need to be re-mounted. If an alternate entry point is acceptable then pitch and/or roll adjustments may be used to realize the planned target through the alternate entry point.
- This can also indicate that there are image artifacts which may have affected the software’s understanding of where the frame is.

Recovery:

- In some instances, pitch and/or roll adjustments may still allow for the planned target to be realized without a large change to the entry point, especially if the planned entry point is only slightly outside the X-Y limits.
- If performing an MRI Workflow, it may be necessary to acquire frame slabs in order to reduce distortion/artifacts in the acquired images.
- In cases where a specific entry point is desired and/or further pitch and roll changes cannot be made, re-mounting of the frame may be necessary.
- Verify that the image fusion between the master series in the Target step and the previous step was performed correctly. If there are issues with the fusion, make the necessary corrections and subsequently edit the trajectory so that it is correct.

Frame Ball Marker Too Far Away From Frame Markers

The ClearPoint Workstation has detected that the selected SMARTFrame's ball marker is too far from the frame markers.

Can be caused by:

- Incorrect manual modification of the ball marker’s position.

- Incorrect image fusion between the series used to define the frame markers and ball marker.
- Image artifacts which cause the frame markers and/or ball marker to appear in different physical locations than they actually are.

Consequences of the selected frame's ball marker being too far away from the frame markers:

- When edits are made to the selected frame's ball marker in the Frame or Pre-Adjust task (MRI Workflow), any trajectories whose entry points are within 5 cm of the frame's mechanical center of rotation will have their entry points updated to reflect the new position of the frame's ball marker. If the ball marker is defined such that it is no longer close to the mechanical center of rotation of the frame, the software will be unable to synchronize any trajectory entry points with the edited ball marker position. Any edits to the ball marker will not result in updates to the corresponding trajectory entry points.
- In the Adjust or Re-Adjust step (MRI Workflow), if the ball marker is defined such that it is not close to the mechanical center of rotation of the frame, the prescribed frame adjustments may be incorrect or unrealistic. The projected error may be incorrect as well.
- This can also indicate that there may be artifacts in the acquired images which cause the frame markers and/or ball marker to appear in different physical locations.
- During an MRI Workflow, the scan plane parameter prescription for frame slabs may be incorrect.

Recovery:

- Carefully review the position of the ball marker using tools in the Frame or Pre-Adjust task (MRI Workflow), or in the Adjust or Re-Adjust step (MRI Workflow). Ensure that the ball marker is within 5 cm of the mechanical center of the corresponding frame. Make any corrections to the ball marker position as necessary.
- If the cause for this warning was due to incorrect image fusion between the ball marker and frame marker scans, verify that the fusion was performed correctly and that all mounted hardware has been identified correctly.

Trajectory Not Close Enough to SMARTFrame

The trajectory listed in this warning message is not close enough to a SMARTFrame to allow frame adjustment instructions to be provided by the software. This most likely means that one or more frames were not detected correctly, one or more frames were mounted incorrectly, or the planned trajectory was defined erroneously.

Can be caused by:

- Frame not detected correctly or not at all (see SMARTFrame Not Found / Detected Incorrectly)
- Planned trajectory is not physically close enough to a frame
- Gross error in mounting the frame
- Incorrect image fusion

If the trajectory is not close enough to a frame:

- The trajectory will be colored in red to indicate that frame instructions cannot be provided for this trajectory.
- Frame instructions in later frame alignment steps will not be shown.

Recovery:

- Ensure that the software's detection of all frames is correct. If not, make manual corrections to the frames' position/orientation in the Frame task.
- If the error was due to mis-positioning of the frame, then re-position the frame correctly based on the planned entry point. Acquire an updated scan of the frame and use the Frame task to re-detect its position/orientation.
- Make corrections to the planned trajectory, if possible, such that it will intersect the frame in its current position.
- Verify that image fusions were performed correctly and that all mounted hardware has been identified correctly.

SMARTFrame Ball Marker Defined On Opposite Side of Head

The SMARTFrame listed in this warning message has its ball marker reside on the opposite side of the patient's head relative to one or more of its frame markers. It is suggested that the positions of all frame markers are reviewed prior to proceeding with the current workflow.

Can be caused by:

- Frame placed close to mid-sagittal plane.
- Frame mounted on opposite side of head from defined procedure laterality.
- Image artifacts cause one or more frame markers to appear in locations where they are not located physically.
- Incorrect image fusion between the ball marker scan and previously acquired scans loaded into the application.

If the ball marker is found on the opposite side of the head:

- Users can dismiss this warning if this is well understood and/or intended. This will cause no software-related consequences if the message is dismissed.

Recovery:

- It is suggested that the user confirm the position of all frame markers in the Frame task to ensure that frame detection succeeded without error.
- Verify that the image fusion between the ball marker scan and previously acquired scans was performed correctly. If there are issues with the fusion, make the necessary corrections and re-detect / re-define the ball marker position.
- If the ball marker is in fact located on the opposite sides of the mid-sagittal plane, the user can proceed without any further action.
- If this message is concerning to the end user, they may opt to change the location of their mid-sagittal plane point using the AC-PC task to resolve this warning.

SMARTFrame Markers Defined on Opposite Side of Head

The SMARTFrame listed in this warning message has one or more markers which reside on opposite sides of the patient's head when compared to the other frame markers. It is suggested that the positions of all frame markers are reviewed prior to proceeding with the current workflow.

Can be caused by:

- Frame placed close to mid-sagittal plane.
- Frame mounted on opposite side of head from defined procedure laterality.
- Image artifacts cause one or more frame markers to appear in locations where they are not located physically.
- Incorrect image fusion between the scan used to define the frame markers and previously acquired scans loaded into the application.

If one or more frame markers are found on the opposite side of the head:

- Users can dismiss this warning if this is well understood and/or intended. This will cause no software-related consequences if the message is dismissed.

Recovery:

- It is suggested that the user confirm the position of all frame markers in the Frame task to ensure that frame detection succeeded without error.
- Verify that the image fusion between the scan used to define the frame markers and previously acquired scans was performed correctly. If there are issues with the fusion, make the necessary corrections and re-detect / re-define the ball marker position.
- If frame markers are in fact located on opposites sides of the mid-sagittal plane, the user can proceed without any further action.
- If this message is concerning to the end user, they may opt to change the location of their mid-sagittal plane point using the AC-PC task to resolve this warning.

Entry Point(s) Updated to Match Ball Marker

During trajectory planning in the Target step, the ClearPoint Workstation has automatically set the entry points of all trajectories associated with the given SMARTFrame to the newly detected/defined ball marker. Please take the time to review all trajectories to ensure that all entry points associated with the indicated frame are correct.

Can be caused by:

- Re-detection of the frame with trajectories already set in the Target step
- Modification of the frame's ball marker position in the Frame task, either through automatic or manual definition.

Consequences of allowing all trajectory entry points to be set at the ball marker:

- The ClearPoint Workstation automatically sets all entry points to the newly defined ball marker as a precaution to ensure that all entry points are within the X-Y limits of the frame. This means that all trajectories associated with the frame will have their entry points set at the ball marker. In most cases, this is desirable, however, there may be cases where surgeons would like to keep their entry point fixed, regardless of the frame position. It is advised to review all trajectories to ensure that entry point definition is correct.
- Those trajectories associated with other frames will not have their entry points automatically modified in this instance.

Recovery:

- This warning message serves to notify the user that the entry points for those trajectories associated with the frame have been modified to lie on the ball marker. If you see this warning message, then it is strongly suggested that you review all trajectories to ensure that the entry point location for each trajectory has been defined correctly.
- Any updates to the frame's ball marker position with associated trajectories will trigger this message, so please be aware to review all trajectories anytime this occurs (e.g., new frame segmentation, manual definition of frame markers in the Frame task, etc.).

Frame Ball Marker Not Within X-Y Limits of the Frame

The ClearPoint Workstation has detected that the selected SMARTFrame's ball marker has been edited such that it is not within the X-Y limits of the frame during an

MRI Workflow. This means that the ball marker's position may not agree with the corresponding position of the frame markers.

Can be caused by:

- Inadvertent patient movement between the scan used to detect the frame markers and that used to detect the ball marker.
- 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 ball marker was detected incorrectly in the most recently received images of the ball marker.
- The most recently received images of the selected frame's ball marker were subjected to image distortion/artifacts that caused its position in space to not reflect where it is located physically.
- Incorrect manual modification of the frame markers' or ball marker's position.
- Incorrect image fusion between the scan used to detect the ball marker and that used to detect the frame markers.

Consequences of the selected frame's ball marker being beyond the X-Y limits:

- This indicates that detection of the selected frame's markers and/or its ball marker is not consistent based on previous acquisitions. This will involve some investigation to determine which images are the source of the discrepancy.
- Scan plane parameter prescription for frame slabs may be incorrect.

Recovery:

- Carefully review the position of the ball marker and frame markers. Make any corrections to the frame markers or ball marker as necessary.
- If the patient has inadvertently moved between frame acquisitions, then return to the Target step, re-acquire an entire frame volume and register this to the Target master series. Proceed with frame alignment after this has been accomplished.
- Verify that the image fusion between the scan used to detect the ball marker and the scan used to detect the frame markers was performed correctly. If there are issues with the fusion, make the necessary corrections and re-detect/re-define the ball marker position.
- Otherwise, if the cause is due to inconsistent ball marker positions on subsequent frame scans, then analyze all frame scans to rule out any artifacts in the acquired images. Ensure that the correct scan protocols and associated parameters were 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
    - Take all possible steps to reduce noise in the scan
- If, after checking all scans and associated parameters for correctness, you still encounter this warning, then proceed with caution since distortion artifacts may be present in the images.

DICOM Frame of Reference UID Has Changed

For the single image just loaded, the software has detected a new frame of reference identifier (UID) when compared to previously received images. This may indicate that the coordinate system has changed, however, in some cases scanners may assign a new identifier without a measurable change to the coordinate system.

In a CT Workflow, **do not attempt to load individual images**. Only acquire whole head scans that can be correctly registered to previous scans. In an MRI Workflow, the following applies.

Can be caused by:

- Patient re-positioning within the scanner
- Scanner restart
- Scanner table movement
- Change to landmarking on scanner
- Change to geometric distortion correction settings used by the scanner during image acquisition

Consequences of loss of frame of reference:

- If the coordinate system has not changed there are no consequences.
- If the coordinate system has changed, the newly loaded image as well as any subsequent image series in that frame of reference will not be aligned with previous images.

Recovery:

- In instances where the frame of reference changes for an image series with more than one image, the software application automatically prompts you to fuse the images using the Fusion task prior to proceeding with the workflow. However, in cases where a single image is loaded with a different frame of reference than previous acquisitions, the software will not prompt you to fuse the images because it will be difficult to do so for a single image. Instead, this warning serves as a prompt to fuse additionally acquired images in the same frame of reference as the single image when loaded into the application.
- For the next image acquisition made after loading the single image, use the Compare task to check whether the new images are aligned with your most recent whole-head scan. If the images are aligned correctly, you may proceed with the workflow without any further action. Otherwise, if the images are misaligned, you will need to fuse them with your most recent whole-head scan.

- If the images are not suitable for accurately assessing alignment with your most recent whole-head scan, acquire a new scan large enough to compare with the most recent whole-head scan.

No Trajectories Defined for Selected Frame

The user has navigated to a frame alignment step and selected a SMARTFrame for which there are no trajectories defined. This means that the software is unable to provide instructions to align the frame to a planned trajectory.

Is caused by:

- One or more trajectories are not associated with the selected frame

Consequences of attempting to proceed in workflow when no trajectories are defined for a given frame:

- Software cannot provide instructions to align the selected frame to a planned trajectory because there are none associated with it.

Recovery:

- Go back to the Target step and ensure that one or more trajectories are associated with the selected frame. It is possible that one or more of your planned trajectories are associated with another frame, so it's best to review all trajectories at this point.

Failed to Detect SMARTFrame Upper Cannula Marker

The ClearPoint Workstation was unable to automatically identify a position on the upper cannula from the most recently sent series in the Align step during an MRI Workflow.

Can be caused by:

- Loss of fluid in cannula
- Incorrect scan plane parameters
- Excessive noise in acquired image(s)
- Insufficient NMR signal at the position where the cannula is being imaged.
- Cannula images have been clipped, cutting off a portion of the cannula cross section.

- Acquired images are subject to image distortion and/or artifacts, causing the software to fail on cannula cross-section detection.

Consequences of proceeding without defining the upper cannula marker:

- If the upper cannula marker has not been defined in the MRI Workflow for the selected frame, the ClearPoint Workstation will not be able to provide any frame adjustment instructions. Additionally, users will not be able to proceed to the Adjust step for further frame adjustment instructions unless the upper cannula marker is defined.
- If the ClearPoint Workstation fails to detect the upper cannula marker after it has been initially defined for a given frame, then the software will use the last known position of the cannula to prescribe frame instructions.
- In all cases, if the graphic overlay representing the cannula does not correspond to the physical position of the cannula in the image, **the frame instructions and error values will be incorrect**.

Recovery:

- If the cannula cross section can be seen in the 'Trajectory Axial' viewport, then you may define it manually using the 'Set Marker' tool within the viewport.
- If the cannula cross section cannot be seen in the 'Trajectory Axial' viewport and you are unsure where to set the upper marker position, then use the Scan Plane Parameters button to confirm the parameters and acquire another set of cannula images.
- If excessive noise is causing the cannula 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 cannula detection to fail, attempt to acquire multiple images of the top of the cannula and send the entire set to the ClearPoint Workstation. The software will select the first image from the slab and exercise the cannula detection from that image.

Selected Trajectory Needs Pre-Adjustment

The ClearPoint Workstation has detected that the selected trajectory's entry point is not coincident with the selected SMARTFrame's ball marker during an MRI Workflow. If end users are concerned with accuracy at their entry point, they are advised to use the Pre-Adjust task to make the necessary X/Y adjustments to align the selected frame's ball marker to the planned entry point.

Can be caused by:

- Planned trajectory in Target step has an entry point that is not physically aligned with the selected frame's ball marker. This can happen if users choose to modify their entry point away from the default location defined by the selected frame's mechanical center of rotation.

- Image distortion/artifacts present in the scan(s) used to detect the frame. It is possible that these artifacts may cause the selected frame's ball marker to not appear where it is physically located. This causes the software to store the position of the ball marker in a location that does not reflect physically where it is.

Consequences of needing to make a pre-adjustment:

- This is part of the normal MRI Workflow, however, is not mandatory to make a frame pre-adjustment. If users are not concerned with entry point accuracy, they can choose to proceed with the MRI Workflow without making a frame pre-adjustment.

Recovery:

- If entry point accuracy is important to you, then you should carry out the frame adjustments provided by the Pre-Adjust task and acquire at least one additional ball marker scan to confirm that the adjustments have been made successfully. You can then iteratively adjust the position of the ball marker until it is aligned at the planned trajectory's entry point.
- You can also choose to ignore this warning if entry point accuracy is not of major concern. Exercising use of the Pre-Adjust task is strictly optional.

SMARTFrame Upper Cannula Marker Not Defined

The selected SMARTFrame does not have its upper cannula position defined in the software during an MRI Workflow. Alignment of this frame cannot begin until the position corresponding to the top of its targeting cannula is identified / defined. Most often, this message indicates that the Align step in the MRI Workflow has not been successfully completed for the selected frame.

Is caused by:

- The position of the selected frame's top cannula location has not been defined. This means that the Align step in the MRI Workflow has not been completed for this frame.

Consequences of selected frame top cannula marker not defined:

- Users will not be able to proceed with frame adjustment in the MRI Workflow (Adjust step) if the top cannula marker for the selected frame is not defined. If data is sent to the Adjust step, it will be rejected with this reason. Users will also be warned of this upon frame selection.

Recovery:

- Return to the Align step for the selected frame and complete it by defining the position of the top cannula marker. Either this will be detected automatically by the software or can be defined manually in the left-most viewport.

Failed To Identify Cannula From Orthogonal Slab

The ClearPoint Workstation was unable to automatically identify the cannula from the orthogonal slab loaded in the Adjust step during an MRI Workflow.

Can be caused by:

- Loss of fluid in cannula
- Incorrect scan plane parameters
- Orthogonal cannula slab has been clipped by the edge of the slab. This can occur if the cannula slab is made too thin or the cannula has not been well aligned in the Align step prior to acquiring the orthogonal slab.

Consequences of orthogonal slab cannula detection failure:

- If the software fails to detect the cannula in only one of the two series loaded in the application, then it will effectively only use the segmentation results from the series that succeeded.
- If the software fails to detect the cannula in both of the series loaded, then the last known position of the cannula will be used.
- In all cases, if the graphic overlay representing the cannula does not correspond to the physical position of the cannula in the image, **the frame instructions and error values will be incorrect**.

Recovery:

- Ultimately, it is your responsibility to ensure that the automatic detection of the cannula has been performed correctly. To do this, zoom in on the cannula in the Orthogonal 1 and Orthogonal 2 views and verify that the 2D graphic overlay produced by the software matches up with the cannula in the underlying images. If they do not match up, manually modify the position of the 2D graphic overlay in one or both views to better align with the cannula in the underlying images. You may also wish to change layouts to view 3D representations of the cannula. This may help in visualizing the position of the cannula relative to the acquired slab.
- If cannula detection failures continue to persist, consider increasing the size of the orthogonal slabs to rule out unnecessary clipping of the targeting cannula.
- Ensure that fluid within both the ball marker and targeting cannula shaft are sufficient. The software has specific knowledge about the physical dimensions of the cannula and associated ball marker, so if these components do not appear clearly in the acquired images, the software will have no way to automatically

detect them reliably. If there are fluid problems within these components, consider replacing the frame.

- Check that the scan plane parameters for the orthogonal cannula scans are correct.

Failed To Identify Cannula

The ClearPoint Workstation was unable to automatically identify the cannula from the most recently acquired scan during a CT Workflow.

Can be caused by:

- Excessive image noise or artifacts near the cannula
- Field of view does not include the area of the cannula

Consequences of cannula detection failure:

- If the software fails to detect the cannula, then the software will not update the position of the cannula overlay relative to the image.
- In all cases, if the graphic overlay representing the cannula does not correspond to the physical position of the cannula in the image, **the frame instructions and error values will be incorrect**.

Recovery:

- The simplest recovery is to manually adjust the cannula overlay to match the visible portion of the cannula. Use visualization tools such as Width/Level and Zoom to ensure that the overlay in both views is precisely aligned to the image of the cannula.
- Introducing a CT-visible aiming device such as a ceramic stylet into the cannula and advancing it down to just above the skin level can help alleviate field of view limitations on subsequent scans.
- If the field of view is still insufficient for manual alignment of the overlay to the cannula, you will need to correct the field of view. Ensure that subsequent scans will include the cannula up to the XY stage, and then re-acquire the images.

Frame Cannula Not Sufficiently Aligned to Trajectory Pre-Insertion

If the currently selected SMARTFrame is not aligned within 1.5 mm of the selected trajectory prior to insertion, then the 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 cannula to the planned trajectory, and that it should be addressed prior to insertion.

Can be caused by:

- Leaving a significant residual error in the frame alignment steps.
- Positional inconsistencies of the cannula in the orthogonal slabs loaded in the Adjust step during an MRI Workflow.
- Changing Trajectory selection without adjusting the cannula

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 cannula positions in the orthogonal cannula slabs in an MRI Workflow, 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 loaded
    - 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 ClearPoint 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 acquired scan

Insertion Track Does Not Appear Straight

The ClearPoint Workstation has determined that the detected signal void left by the device appears to be curved. This could indicate that image artifacts are present in the acquired images or that physical device deflection may have occurred.

Can be caused by:

- Image 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.
- In an MRI Workflow, this warning may indicate that the acquired images could be subject to geometric distortion artifacts that may impact the position of the device tip, potentially invalidating final placement errors.

Recovery:

- Review the images and analyze whether the device track is physically curved (use ‘Device View’). Attempt to distinguish between image artifacts and physical device deflection.
- If performing an MRI Workflow and a large image volume was used to assess device tip placement, consider acquiring a small slab that includes the area immediately around the device tip. A small slab centered at the iso-center of the MR scanner is likely to have minimal geometric distortion.
- If performing an MRI Workflow, ensure that 3D distortion correction is enabled on the scan protocol used to acquire the insertion slab.

Failed to Detect Inserted Device Track

The ClearPoint 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.

- Image 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’ button in the Insert step.
- 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 slab is too thin, re-acquire a new scan and assess the tip position on that scan.

Appendix 1 – MRI Scanner & Equipment Requirements Specifications

MRI Head Fixation Requirements Specification

A suitable head fixation frame for use during MRI-guided procedures with the ClearPoint 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.

MRI Imaging Coil(s) Requirements Specification

Suitable Imaging Coil(s) for use during MRI-guided procedures with the ClearPoint 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 once it has been placed on the patient's skull. Refer to SMARTFrame MRI Guided Trajectory Frame, Hand Controller, and Accessory Kit Instructions for Use for specifications.

Field of View (FOV)

The imaging FOV must include the volume of the patients head plus a distance of 15.24cm superior to the patients head to include the SMARTFrame. For a typical patient this would be a cylindrical volume of approximately 17.8cm in diameter by 30cm in length.

Image Quality:

- Signal to Noise Ratio (SNR):

  The SNR at the center of an imaging coil(s) used for an MRI-guided ClearPoint 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 during MRI-guided procedures with the ClearPoint System must meet the following requirements:

Field Strength	1.5T or 3T
Bore Diameter	60 cm of greater

Appendix 2 – Image Acquisition Parameters for Maestro Training and Validation Datasets

The table below describes the range of MRI sequence parameters used in the training and validation datasets of the ClearPoint Maestro Brain Model.

Training Data		FA	FS	ST	SX	SY	TE	TR	TI
Philips	min	8	1.5	1.2	0.94	0.94	3.09	6.72	0
	max	9	3.0	1.2	1.05	1.05	4.01	8.62	0
Siemens	min	8	1.5	1.2	1.00	1.00	2.88	2300.00	900
	max	9	3.0	1.2	1.35	1.35	3.79	3000.00	1000
GE	min	8	1.5	1.2	0.94	0.94	2.83	6.62	400
	max	11	3.0	1.2	1.09	1.09	4.44	10.40	1000

Validation Data		FA	FS	ST	SX	SY	TE	TR	TI
Philips	min	8	1.5	1.2	0.94	0.94	3.16	6.80	0
	max	8	3.0	1.2	1.00	1.00	4.00	8.61	0
Siemens	min	8	1.5	1.2	1.00	1.00	2.91	9.70	200
	max	10	3.0	1.25	1.25	1.25	4.00	3000.00	1000
GE	min	8	1.5	1.2	0.94	0.94	2.84	6.62	900
	max	8	3.0	1.2	1.02	1.02	4.10	10.20	1000

Table 1: Image Acquisition Parameters for Training and Validation Datasets. FA: Flip Angle (degrees), FS: Field Strength (Tesla) ST: Slice Thickness (mm), SX: Pixel X-Size (mm), SY: Pixel Y-Size (mm), TE: Echo Time (ms), TR: Repetition Time (ms), TI: Inversion Time (ms)

Appendix 3 – CT Scanner & Equipment Requirements Specifications

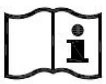
CT Head Fixation Specifications

Usage of a suitable head fixation frame is at the discretion of the surgeon performing the procedure.

CT Imaging Requirements Specification

Field of View (FOV)

The scanner should support 3D volumetric image acquisitions with a minimum field of view of 20 cm.

SYMBOL	DEFINITION	SYMBOL	DEFINITION
	Consult instructions for use		Keep away from sunlight
REF	Catalogue number		Keep dry
LOT	Batch code		Manufacturer
	MR Unsafe		Date of Manufacture
	Do not use if the product sterilization barrier or its packaging is compromised	Rx only	Prescription Device
MD	Medical Device	EC REP	Authorized Representative

Manufactured by:

ClearPoint Neuro, Inc.
6349 Paseo Del Lago
Carlsbad, CA 92011
USA
949-900-6833

EC REP

Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

www.clearpointneuro.com/eifus