CLEARPOINT

NEURO

ClearPoint 2.0

User's Guide

CE 0344

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: The ClearPoint System can be used in conjunction with MR Conditional, but not MR Unsafe DBS Leads or DBS Leads for which MR Testing was not performed. Placement of MR Conditional deep brain stimulation (DBS) electrodes using the ClearPoint System should be performed in accordance with the instructions for use for such MR Conditional DBS electrodes. The user should carefully review the instructions for use for such MR Conditional DBS electrodes prior to undertaking a procedure with the ClearPoint 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, system accuracy testing will be performed by a trained ClearPoint Neuro Specialist using a calibrated phantom. A minimum of two device placements (ClearPoint Stylet), 1 left side and 1 right side will be performed. The System Installation test shall demonstrate that it can position the tip of the ClearPoint Stylet within 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.**

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

The ClearPoint Workstation is intended for use with the Windows 10 Operating System.

Indications for Use

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 the MRI environment and in conjunction with MR imaging. 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) lead placement. The System is intended for use only with 1.5 and 3.0 Tesla MRI scanners and MR Conditional implants and devices.

Contraindications

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

Security

The ClearPoint Workstation has been pre-configured with operating system security settings to prevent unauthorized access to the system. To ensure secure operation:

- 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 other software on the workstation.
- Do not access the internet from the workstation. Only connect the workstation to a secure, private TCP/IP connection on the hospital network in order to receive images from the scanner.
- Do not turn off, disable, or alter any configuration settings for the Windows Defender Firewall. It has been configured to block unauthorized network traffic flowing onto the workstation.
- Restrict user access to the workstation in order to prevent unintended access. Best practices should be used when configuring user password

policies, including minimum password lengths, password storage encryption, appropriate password complexities (i.e. “strong passwords”), and frequent password renewal periods. Consult HIPAA guidelines for additional information on the best practices for user management.

- Do not modify or alter any system settings related to locking the workstation via the screen saver. The system has been pre-configured to require a password in order to resume workflow after 30 minutes of inactivity.
- Always install the latest security updates and patches for the workstation’s operating system.
- Consider using Windows Encrypted File System (EFS) to keep protected health information stored on the workstation safe. The workstation’s data folder (*C:\ProgramData\ClearPoint\sessions*) stores images from the scanner that contains protected health information. It is suggested that this folder be encrypted in order to prevent unauthorized access.
- Only allow ClearPoint Neuro personnel to install the latest updates and patches for the ClearPoint software. Any software updates will be installed on-site by an employee of ClearPoint Neuro.
- Be cautious when connecting removable media, such as USB drives, to the workstation. The workstation has been configured to also scan removable device for malware and viruses. Do not modify any configuration settings related to the Windows Defender Antivirus.
- Always use the ClearPoint Software’s Session Export (see Using the Session Window Pg. 36) functionality when moving surgical procedure data off of the workstation. Exporting a surgical session in this manner ensures that all data is appropriately anonymized so that no protected health information is exported.

ClearPoint System Procedure Overview

Below is a summary of steps for a ClearPoint System procedure. These steps are separated into six sections: preoperative planning, patient preparation, treatment planning, positioning the cannula, insertion, and closing.

Preoperative Planning

Preoperative planning is an optional step in ClearPoint that provides the ability to plan entry and target points prior to the day of treatment using previously acquired MR or CT images in different frames of reference.

Using any ClearPoint workstation, images are loaded from DICOM media or can be pushed to ClearPoint from PACS or other DICOM archives. The surgeon plans any number of potential trajectories. Once the plan is complete, it can be used on the day or surgery to import the planned trajectories into the coordinate space defined by the treatment day images.

ClearPoint will translate the pre-operative trajectories into the current image volume based on the fusion transformation defined between the pre-operative and current image volumes. The surgeon can then make any adjustments to any of their pre-operatively planned trajectories and continue with the procedure.

Patient Preparation

The patient is prepared for surgery, which may include local or general anesthesia. The surgeon will then position and secure the patient on the scanner table with the desired patient head fixation system and imaging coil(s)[1]. The patient then undergoes appropriate sterilization preparation and draping[2]. The sterile SMARTGrid is positioned over the approximate incision site[3]. Contrast agent may be administered to visualize vasculature. The patient is then moved to the isocenter of the scanner and a whole-head volume scan is acquired.

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1 Refer to manufacturer's Instructions for Use

2 Refer to document: IFU, MR Neuro Procedure Drape

3 Refer to document: IFU, SMARTGrid

Treatment Planning

The whole-head volumetric scan is transferred to the ClearPoint Workstation via DICOM network transfer[4]. Using the workstation software, the surgeon plans a target and trajectory to determine an entry point. This may be completed on-the-fly or through importing a preoperative plan.

The surgeon confirms that the grid has been identified correctly by the software and identifies the SMARTGrid row and column coordinates of the entry point as shown in the image volume.

The patient is then moved out of the scanner to allow direct access to the incision site. The top layer of the SMARTGrid is removed, leaving an underlay grid attached to the patient. The entry point is then identified by matching the grid coordinates of the entry point displayed on the ClearPoint Workstation software to the physical grid on the patient.

At this point, the surgeon may opt to perform an additional step to verify that the entry point has been identified accurately. To do this, a sterile marker is placed at the identified entry point and one or more additional image slabs are acquired. When the workstation displays the new image slabs, the position of the marker can be compared to the planned entry point. This step may be helpful in cases where the scalp is particularly subject to movement relative to the skull.

The Marking Tool is used to mark the location of the entry point[3], and then the grid underlay can be removed and discarded. Using the mark left by the Marking Tool, the surgeon makes an incision and an appropriately sized burr-hole. The surgeon then centers and affixes the SMARTFrame to patient[5]. The optional Hand Controller is then connected to the SMARTFrame and the patient is moved back to the isocenter of the scanner. A second whole-head volumetric scan that includes the SMARTFrame is acquired and transferred to the ClearPoint Workstation. The surgeon reconfirms planning and adjusts due to possible dynamic changes (i.e. brain shift). If desired, the surgeon may opt to acquire additional high-resolution image slabs for better visualization.

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4 Refer to document: ClearPoint 2.0 DICOM Conformance Statement

5 Refer to document: IFU, SMARTFrame MRI-Guided Trajectory Frame, Hand Controller, and Accessory Kit

Positioning the Cannula

In the cannula positioning sections of the ClearPoint software, the workstation provides the user with scan plane parameters necessary to acquire images that the software can use to identify the location of the Targeting Cannula attached to the SMARTFrame. On transferring these images to the ClearPoint Workstation, the software will display the adjustments required to align the Targeting Cannula to the currently selected trajectory.

The angulation of the cannula is adjusted by turning the pitch (blue thumb wheel) and roll (orange thumb wheel) by the specified amount. Adjusting the X (yellow) and Y (green) offset thumb wheels causes the 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 target is clinically acceptable.

Insertion

For procedures that use a Peel-Away Sheath for access to the target site, please see Using a Peel-Away Sheath Pg.17.

If inserting an MRI Conditional device (refer to manufacturer's Instructions for Use), the ClearPoint Workstation provides the option to monitor and evaluate the insertion. This can only be done with a device that can be safely imaged in the MR scanner. If inserting a device that is not safe to be imaged, the patient is moved to the back of the scanner for improved access and the insertion is performed without any further imaging.

For either case, the ClearPoint Workstation provides an insertion depth value that is 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 stop to that point. A guide tube may be used to accommodate devices with different diameters (multiple gauge devices are supported) . The surgeon passes the device manually into the brain to allow for tactile feedback.

If using an MRI Conditional device, scans may be acquired to verify that the device is following the planned trajectory and also to check for hemorrhaging. Using scans taken during or on completion of the insertion, the ClearPoint Workstation also provides measurements between the device tip position and the planned target.

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.17.

Using a Peel-Away Sheath

Once the Stylet/Peel Away Sheath[6] 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. The insertion depth value is then measured on the device to be inserted and the Stop is set. The device is then inserted into the brain through the Peel-Away Sheath. If required by the procedure, the inserted device may then be locked into place and the Peel-Away Sheath removed, leaving the device in position. Complete the procedure according to the device manufacturer's Instructions for Use.

Closing

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

See also: Appendix 1 – Head Fixation Frame, Imaging Coil(s) & MRI Scanner Requirements Specifications

Navigational Accuracy

Results from the company's bench accuracy tests demonstrated that the mean error across device configurations was below 1mm, with the highest standard deviation being 0.30 mm and the highest 99% confidence limit being 0.79 mm. Angular errors were all below 1°, with the highest standard deviation being 0.08° and the highest 99% confidence limit being 0.40°. These observed values are all below the 2mm and 2° accuracy limits for a stereotaxic device intended for general neurological use.

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[6] Refer to document: IFU, SMARTFrame MRI-Guided Trajectory Frame, Hand Controller, and Accessory Kit

Components of the ClearPoint System

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

   Reusable components:

   - Workstation laptop with workstation software
   - Disposable components:
     - SMARTGrid MRI-Guided Planning Grid
     - SMARTFrame, or SMARTFrame XG MRI-Guided Trajectory Frames
     - SMARTFrame Accessory Kit
     - MR Neuro Procedure Drape
   -

2. Other items required:

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

3. Optional items:

   - SMARTFrame Hand Controller
   - SMARTFrame Thumb Wheel Extension Set
   - SMARTFrame Guide Tubes
   - SMARTFrame Scalp Mount Base
   - SmartTwist CLPT Hand Drill
   - SmartTip CLPT Drill Bit Kit
   - ClearPoint MR Monitor
   - ClearPoint Fiducial Marker

Interoperation with MRI Scanner

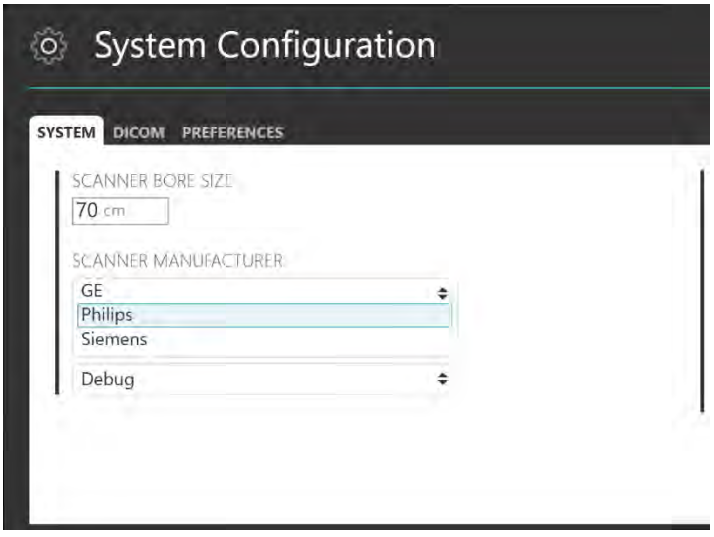
Set up the ClearPoint Workstation in the scanner control room in close proximity to the MR Console. The System is intended for use only with 1.5 and 3.0 Tesla MRI scanners and MR Conditional implants and devices.

The ClearPoint Workstation must be connected to the network to function. The MRI console must be configured to recognize the ClearPoint Workstation as a valid DICOM storage device.

- IP Address (as configured by your site administrator)
- AE Title: SVDBG
- Port: 4467

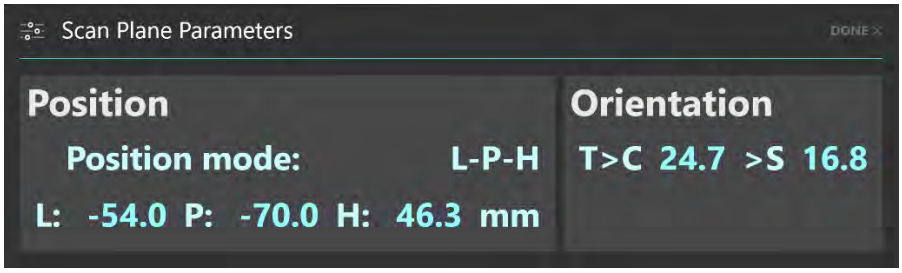
After connecting the ClearPoint Workstation to the scanner for the first time, the System Configuration Dialog (see Configuring System and User Settings Pg. 42) must be used to specify certain information about the scanner, including bore diameter and manufacturer. The bore diameter indicates to the ClearPoint Workstation how much clearance there will be when inserting a device. The scanner manufacturer field determines the format that the ClearPoint Workstation 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 ClearPoint Workstation will provide very specific sets of scan plane parameters that must be manually entered on the user interface of the console used to run the scanner. The Workstation has the ability to show these parameters in a format that is appropriate for only the following three MR scanner manufacturers:

- Siemens Healthcare
- Philips Medical Systems
- GE Healthcare



The parameters shown by the ClearPoint Workstation can then be entered manually on the scanner console used to perform image acquisitions during the procedure. For

example, with Siemens Healthcare scanners, the scan plane parameters are specified as double-oblique values, as 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 any 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. 207.
- Images used to detect the position of the frame's distal tip (ball marker). See Frame Ball Marker Appears Out of Position Pg. 208.
- Images used to detect the position of the targeting cannula. See Adjust Step *Finalize the Cannula Position* Pg. 128.
- Images used to identify the track of the inserted device. See Insertion Track Does Not Appear Straight Pg. 218.

Important Notes for Using Siemens Scanners

Ensuring correct sign and direction

When entering scan plane parameters into the Siemens MR 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 workstation specifies directions based on the positive directions being Left, Posterior, and Head. Any time a negative value is entered on the Siemens 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 ClearPoint Workstation.

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 MR 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 Adjust step (see Adjust Step *Finalize the Cannula Position* Pg. 128) scans to ensure that the cannula slabs 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 interface with 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 MR Console interface, there is a field labeled “Phase Enc Dir” for the phase encoding direction, with an associated drop down for setting a rough direction. This field also has an associated button labeled “…” that opens a dialog for numerically setting the Inplane Rotation. This provides precise control over the phase encoding direction for the scan.

The application provides an Inplane Rotation value in the Adjust step (see Adjust Step *Finalize the Cannula Position* Pg. 128) scan plane parameters to be entered on the Siemens MR Console. This value is calculated to minimize the effects of geometric distortion on accuracy by ensuring that the phase encoding direction lies perpendicular to the long axis of the cannula.

Important Notes for Using Philips Scanners

Ensuring correct slice orientation

When entering scan plane parameters into the Philips 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 ClearPoint Workstation must be entered in the “Geometry” tab on the Philips 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 console interface.

Flipping the scan plane

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

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

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

Important Notes for Using IMRIS Scanners

Entering a Table Position Value

When entering scan plane parameters during the Adjust step (see Adjust Step *Finalize the Cannula Position* Pg. 128) into the IMRIS MR 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 ClearPoint 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. 42).

ClearPoint Workflow

The ClearPoint Workstation application presents the clinical workflow as an ordered set of steps that can be performed in order to complete a neurological procedure. Each workflow step exposes a set of optional tasks that can be invoked to complete a specific, focused activity in the workflow.

Splash Screen

Prior to proceeding with the clinical workflow, the ClearPoint Workstation displays a Splash Screen that can be used to start a new clinical workflow in a new software session, or alternatively, load an existing software session where portions of the clinical workflow have already been completed (see Splash Screen Pg. 79). If starting a new software session, the Splash Screen is used to gather basic information about the procedure, including laterality, target name, device lengths, and type of base mount. If loading an existing software session, the Splash Screen allows specification of which software session to load.

Procedure Workflow

Pre-Op Step

The Pre-Op step allows you to create one or more trajectories using images that were acquired prior to the day of treatment. You may fuse images with different frames of reference in order to supplement the trajectory definition / modification process. 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 pre-operative planning. See Fusion Task *Fusing Images* Pg. 155 for details.

- **Compare**. Perform visual comparison of any two-image series loaded into the workstation for purposes of pre-operative planning. See Compare Task *Comparing Images* Pg. 172 for details.

- **AC-PC**. Review and edit anatomical landmarks needed to define and use Talairach coordinates. See ACPC Task *Reviewing Landmarks* Pg. 160 for details.

- **VOI**. Create or edit volumes of interest within any loaded image series for pre-operative planning purposes. See VOI Task *Defining Volumes* Pg. 163 for details.

Once you continue with the clinical workflow onto the day of treatment steps, any trajectories and/or volumes from this step are imported into the frame of reference of the patient in the scanner during the procedure. This operation is performed by fusing the pre-operative volume with the main day of treatment volume. 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. 85.

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 is placed into the MR scanner).

The Entry step allows you to identify your target(s) and determine the entry point(s) on the patient's head. SMARTGrid(s) are used to localize the position of the frame mount point(s) on the patient based on the entry point(s) planned. If a pre-operative plan was created prior to this step, the ClearPoint Workstation will require that the image volume containing the SMARTGrid(s) be fused with the main image series from the Pre-Op step. This defines a mechanism whereby the pre-operative annotations (including trajectories and anatomical landmarks) can be imported into the frame of 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 the SMARTGrid(s) have been mounted. See Fusion Task *Fusing Images* Pg. 155 for details.

- **Compare**. Perform visual comparison of any two-image series loaded into the workstation for purposes of entry planning. See Compare Task *Comparing Images* Pg. 172 for details.

- **AC-PC**. Review and edit anatomical landmarks needed to use Talairach coordinates. See ACPC Task *Reviewing Landmarks* Pg. 160 for details.

- **VOI**. Create or edit volumes of interest within any loaded image series for trajectory planning purposes. See VOI Task *Defining Volumes* Pg. 163 for details.

- **Grid**. Review and/or edit the positions/orientations of any defined SMARTGrid(s). Create additional SMARTGrids if they were not properly detected in the Entry step. See Grid Task *Editing Marking Grids* Pg. 174 for details.

At this point, the patient position is advanced far enough out the back of the scanner to provide access to their head, and the MRI-visible layer of the SMARTGrid is peeled off. There are two options for mounting the SMARTFrame:

Mounting on the surface of the skull:

If mounting the SMARTFrame 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 SMARTGrid 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 is then centered on the burr hole (using the Centering Tool if a 14mm burr hold is made) and secured to the skull with bone screws.

Mounting on the scalp:

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

Once the frame is mounted, the Hand Controller is attached to the SMARTFrame, and then the patient is returned to the bore of the scanner.

For details, see Entry Step *Locate Mounting Point* Pg. 103.

Target Step

The Target step allows you to refine the anatomical landmarks, targets and trajectories identified in the Entry step after the SMARTFrame(s) have been mounted. At this point in the workflow, the ClearPoint Workstation will require that the image volume containing the SMARTFrame(s) be fused with the image volume containing the SMARTGrid(s), so that annotations defined in the Entry step (including trajectories and anatomical landmarks) can be imported into the frame of reference of the patient with the frames mounted.

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 SMARTFrame(s) have been mounted. See Fusion Task *Fusing Images* Pg. 155 for details.

- **Compare**. Perform visual comparison of any two-image series loaded into the workstation for purposes of trajectory refinement. See Compare Task *Comparing Images* Pg. 172 for details.

- **AC-PC**. Review and edit anatomical landmarks needed to use Talairach coordinates. If the patient has moved in fixation and/or brain shift has occurred after the SMARTFrame(s) have been mounted, these values will require refinement. See ACPC Task *Reviewing Landmarks* Pg. 160 for details.

- **VOI**. Create or edit volumes of interest within any loaded image series for trajectory refinement purposes. See VOI Task *Defining Volumes* Pg. 163 for details.

- **Frame**. Review and/or edit the positions of any defined SMARTFrame(s). Define additional SMARTFrames if they were not properly detected in the Target step. See Frame Task *Editing Frame Markers* Pg. 179 for details.

For details, see Target Step *Finalizing Trajectories* Pg. 115.

Align Step

The Align step allows you to perform a quick, coarse alignment of the cannula to the intended target(s) by iteratively altering its angulation. This workflow serves to position the cannula such that more detailed frame adjustments can be performed in order to align it accurately to the planned target(s) (see Adjust Step Pg. 29).

The following optional tasks are provided by the Align step:

- **Pre-Adjust**. Perform a pre-adjustment of the cannula prior to altering its angulation, in order 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 the user to carry out this task. See Pre-Adjust Task *Pre-adjusting the Cannula* Pg. 185 for details.

- **Compare**. Perform visual comparison of any two-image series loaded into the workstation for purposes of detecting unintended patient / table movement during the cannula alignment process. See Compare Task *Comparing Images* Pg. 172 for details.

- **VOI**. Create or edit volumes of interest within any loaded image series for projected trajectory review purposes. See VOI Task *Defining Volumes* Pg. 163 for details.

For details, see Align Step *Set the Cannula Angulation* Pg. 122.

Adjust Step

The Adjust step allows you to confirm the cannula position / orientation and fine tune it using angulation or X-Y offset adjustments, in order to align it precisely to the intended target(s).

The following optional tasks are provided by the Adjust step:

- **Compare**. Perform visual comparison of any two-image series loaded into the workstation for purposes of detecting unintended patient / table movement during the cannula adjustment process. See Compare Task *Comparing Images* Pg. 172 for details.

- **VOI**. Create or edit volumes of interest within any loaded image series for projected trajectory review purposes. See VOI Task *Defining Volumes* Pg. 163 for details.

For details, see Adjust Step Pg. 29.

Insert Step

The Insert step allows you to monitor, assess and evaluate the accuracy of a device insertion relative to its planned trajectory. **This is an optional workflow step that 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 an IMRIS system, whereby the patient table is moved (causing a frame of reference change) in order to accommodate a device insertion. See Fusion Task *Fusing Images* Pg. 155 for details.

- **Compare**. Perform visual comparison of any two-image series loaded into the workstation for purposes for purposes of detecting unintended patient / table movement during the device insertion process. See Compare Task *Comparing Images* Pg. 172 for details.

- **VOI**. Create or edit volumes of interest within any loaded image series for treatment evaluation purposes (e.g. drug delivery shell definition). See VOI Task *Defining Volumes* Pg. 163 for details.

For details, see Insert Step *Monitor and Assess Device Placement* Pg. 138.

Re-Adjust Step

The Re-Adjust step allows you to correct the position / orientation of the cannula after a device placement has been deemed unacceptable. If the device placement is rejected, the Re-Adjust step will guide you through the workflow for re-adjusting the cannula's position and re-inserting the device.

For details, see Re-Adjust Step *Managing a Device Re-Insertion* Pg. 150.

About this Guide

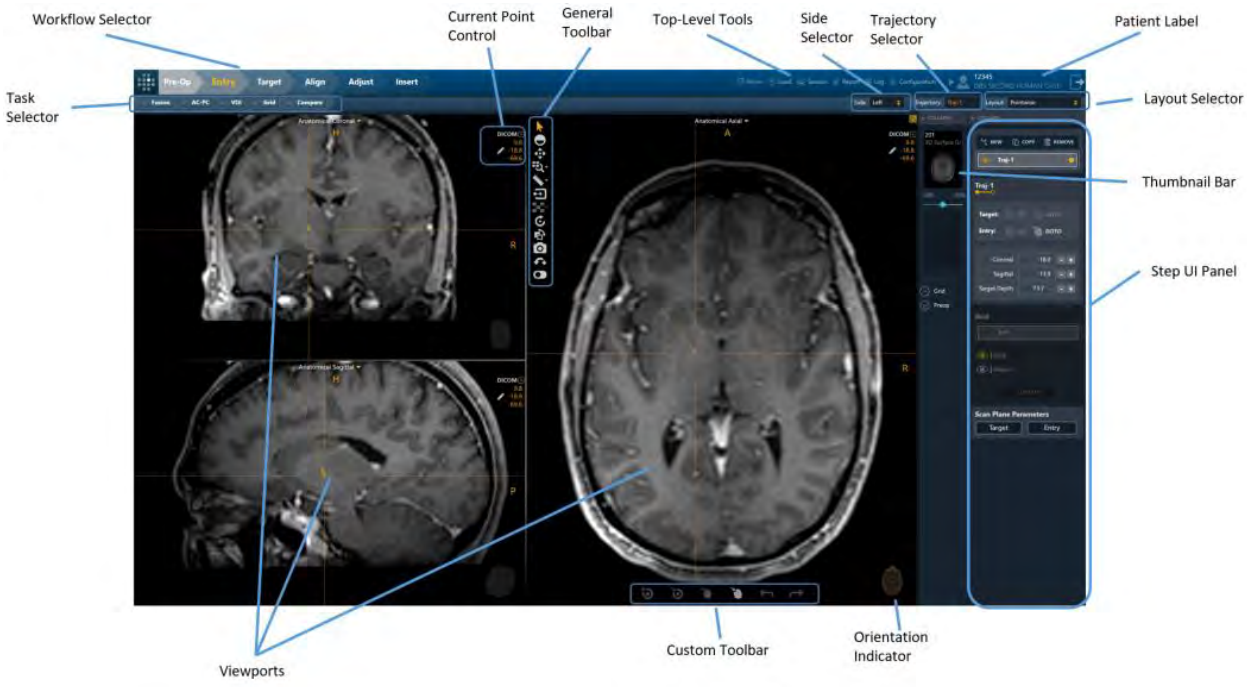
This user's guide assumes that you are familiar with the basic operation of personal computers, such as how to turn them on, how to use the mouse, and how to work in the Microsoft Windows Operating System environment. If you are not familiar with these operations, please refer to the documentation provided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

Application Overview

This chapter describes the general user interface features of the application which consist of the Workflow Selector, the Task Selector, the Patient Label, the Side Selector, the Trajectory Selector, the Layout Selector, the General Toolbar, the Current Point Control, step-specific controls, and the set of top-level tools.



Top-Level Tools

The application has the following top-level tools:

- **Mirror** – Clones the current application window onto the MRI-compatible in-room computer monitor, without compromising the display resolution of the workstation. If a dialog window is being shown it will be cloned instead of the application window, and scaled to fill the in-room monitor to ensure readability. This functionality can be toggled on or off as needed.

- **Load** – An interactive media browser window which allows you to load images into the current session. Loaded files must be encoded in the DICOM format in order to be recognized. Only images with a modality type of MR and CT are supported; all other modality types are restricted from being loaded onto the workstation (see Using the Media Browser Pg. 35).

- **Session** – Allows you to manage the list of software sessions stored on the workstation (see Using the Session Window Pg. 36). Specifically, you can:

    - Edit the current session
    - Create a new session
    - List all sessions for purposes of individualized loading, export, or removal

- **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 Report Window Pg. 39).

- **Log** – Displays the contents of the application log file, including 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 Log Window Pg. 41).

- **Configuration** – Allows you to change system and user-specific settings of the workstation (see Configuring System and User Settings Pg. 42). These settings are divided into 3 separate groupings:

    - System – scanner bore size & manufacturer, system licensing information
    - DICOM – system application entity (AE) title & port number, remote network information for pinging an external entity
    - Preferences – user preferences, such as default annotation colors and target landmark locations

Using the 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** 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.

Note: if you select a slow device with a large amount of DICOM data there can be a delay while reading the data. Data saved to media from a scanner is usually saved with a DICOMDIR directory file which prevents this delay. However, if data loading is taking too long, you can cancel and select a specific sub-folder with just the data of interest.

5. Select one or more image series to load by ticking the checkbox beside each description corresponding to the image series that you wish to load. You may preview the image series by hovering the mouse over the series description.

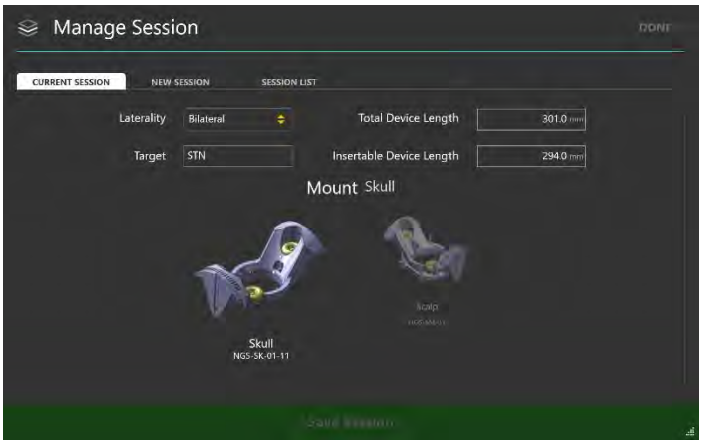
6. Select **Load** at the bottom of the window.

Using the Session Window

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

> **To modify the current session**

1. Select **Session** from the list of top-level tools.
2. A floating window with 3 distinct tabs will appear, providing you with options to manage the list of sessions on the workstation.
3. Select the **CURRENT SESSION** tab.
4. Edit or modify one or more of the properties associated with your current session.



5. Select **Save Session** to save the changes made to your currently loaded session.

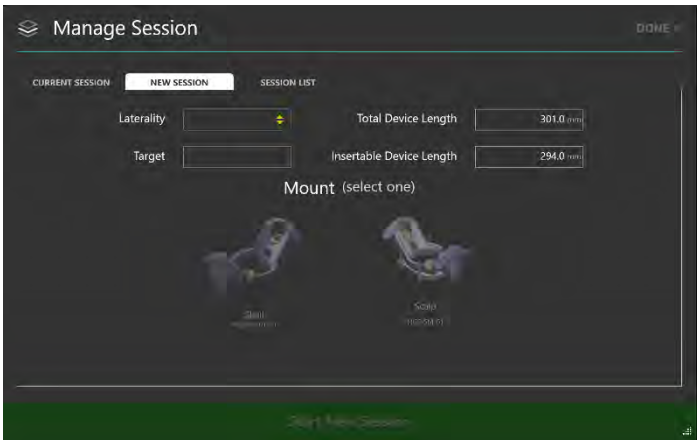
> **To start a new session**

1. Select **Session** from the list of top-level tools.

2. A floating window with 3 distinct tabs will appear, providing you with options to manage the list of sessions on the workstation.

3. Select the **NEW SESSION** tab.

4. Fill in all of the field properties required to create a new session.



5. Select **Start New Session** to close the currently loaded session and start a new session with the field properties listed.

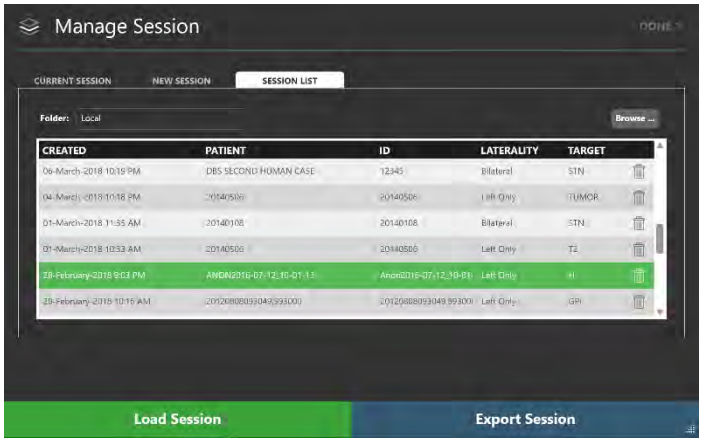
> **To load an existing session**

1. Select **Session** from the list of top-level tools.

2. A floating window with 3 distinct tabs will appear, providing you with options to manage the list of sessions on the workstation.

3. Select the **SESSION LIST** tab.

4. Choose the session that you wish to load from the list of sessions shown.



5. Select **Load Session** to close the currently loaded session and load the session selected in the window.

> To export a session

1. Select **Session** from the list of top-level tools.
2. A floating window with 3 distinct tabs will appear, providing you with options to manage the list of sessions on the workstation.
3. Select the **SESSION LIST** tab.
4. Choose the session that you wish to export from the list of sessions shown.
5. Select **Export Session**.
6. Browse to a location where you would like the selected session to be exported.
7. Select **OK**. The session will be exported in anonymized format to the selected location.

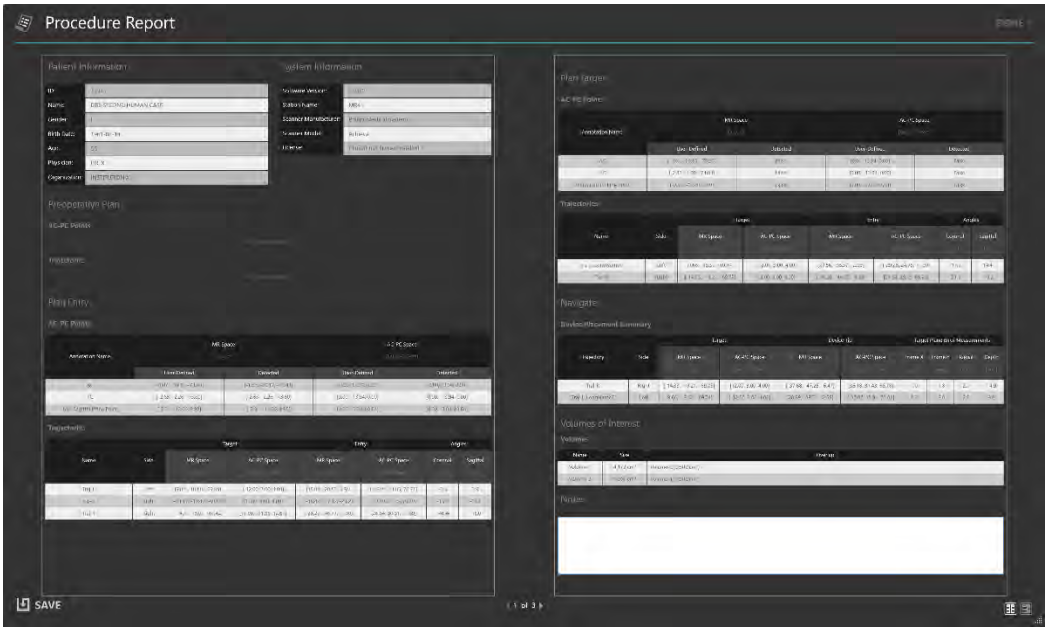
Whenever a session is exported, the patient name and ID within the session will be substituted using the current time stamp when the export process was initiated. For all DICOM image data associated with the session, any header fields that contain protected health information will be blanked out in the physical DICOM image files. This ensures that session data can be shared without the risk of protected health information exposure.

> **To delete a session**

1. Select **Session** from the list of top-level tools.
2. A floating window with 3 distinct tabs will appear, providing you with options to manage the list of sessions on the workstation.
3. Select the **SESSION LIST** tab.
4. Choose the session that you wish to delete from the list of sessions presented.
5. Click the  button.
6. Select **Yes** to confirm removal of the session.

Using the Report Window

When you open the 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, volume of interest measurements, procedure-specific notes and links to any screen captures taken during the procedure.



> To review the report

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

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

> To save the report

1. Select **Report** from the list of top-level tools
2. A floating window will display the report using a single continuous page by default.
3. Select **Save** to save a copy of the currently displayed report. The report will be saved with a unique file name reflecting the time when it was saved. This allows for multiple copies of the report to be saved at different time intervals throughout the procedure.

The application generates two versions of the report when saved: a full version that includes patient information and an anonymous version that can be

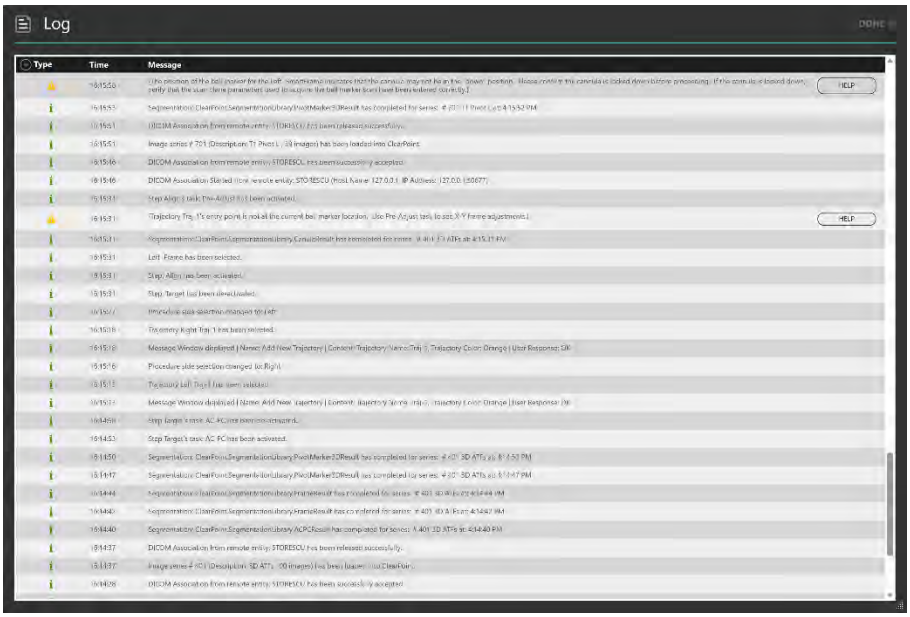
distributed without compromising patient confidentiality. Both versions are saved as individual files in the report folder corresponding to the session.

Using the Log Window

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

> **To review the log**

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



3. Click on the collapsible button beside the **Type** column to filter messages by type: **Information**, **Warning**, **Error**, **Debug**. If you do not see the **Debug** option, use the System Configuration Window to configure the system to show these types of messages (see Configuring System and User Settings Pg. 42).
4. For messages of type **Warning**, select **HELP** to view more information on the specific warning message presented.

Configuring System and User Settings

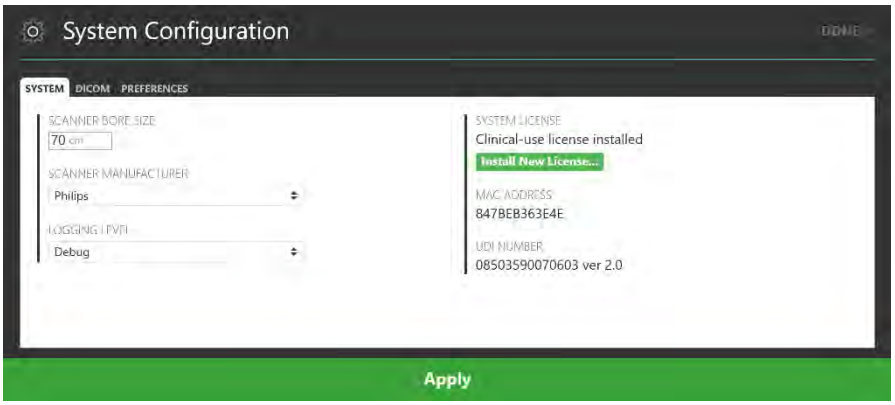
You may configure the system and user-specific settings of the ClearPoint Workstation using the System Configuration Window at any time during program execution.

> To modify system settings

1. Select **Configuration** 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 Splash Screen Pg. 79).

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

3. Select the **SYSTEM** tab to modify the system settings.



4. Modify the following fields, if necessary:

   - Scanner Bore Size – Enter or modify the diameter of the scanner bore in centimeters. The application uses this value along with the total device length entered during the procedure to ensure that for a given planned trajectory, the device can be physically inserted into the SMARTFrame without being obstructed by the scanner's bore.
   - Scanner Manufacturer – Choose an option from the list which represents the manufacturer of the scanner to which the ClearPoint Workstation is connected. For Siemens scanners, indicate whether or not the scanner resides in an IMRIS Surgical Suite (see Important Notes for Using IMRIS Scanners Pg. 24). For GE scanners, specify the number of slices to use for the orthogonal cannula scans.

- Logging Level – Specify the level of logging to be shown. Normal mode will show all messages displayed to you throughout the course of the procedure. Debug mode allows you to see all Normal mode messages plus additional messages used to help troubleshoot problems which may occur with the workstation throughout the course of the procedure.

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. 83).

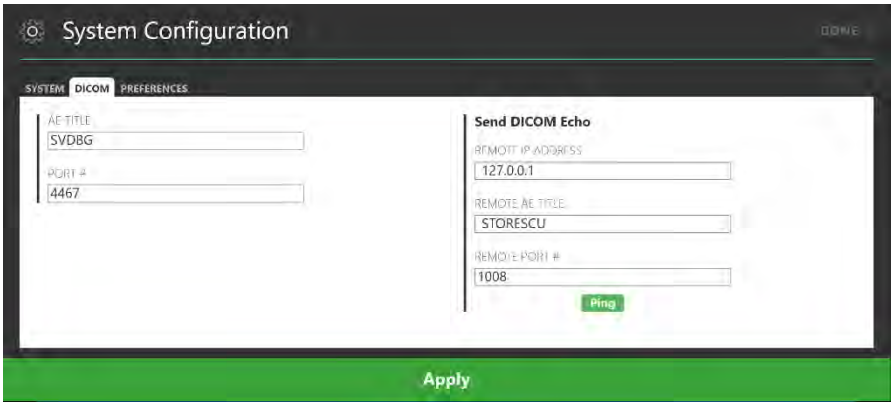
In order for the ClearPoint workstation to receive DICOM images transferred from an image source such as a scanner or PACS, that system will need to be configured with the AE Title and Port Number configured in the ClearPoint software.

> **To modify DICOM settings**

1. Select **Configuration** 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 Splash Screen Pg. 79).

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

3. Select the **DICOM** tab to modify the DICOM settings for the system.



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.

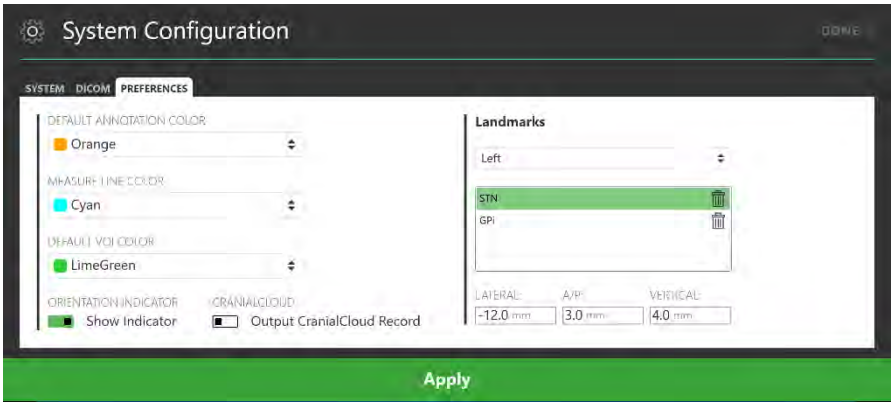
6. You may use the **Ping** button to test DICOM connectivity with the intraoperative scanner. The entity node information (IP Address, Remote AE Title and Remote Port Number) of the scanner will need to be specified prior to testing the workstation's remote DICOM connectivity to it. If images have previously been sent to the workstation successfully, only the port number will be blank and will need to be entered. Otherwise if data has not yet been sent you will need to enter all three values.

> To modify user preferences

1. Select **Configuration** 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 Splash Screen Pg. 79).

2. A floating window with 3 distinct tabs will appear, providing you with the ability to modify the user preferences 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 color to be used to show measure line and measure circle annotations (see Measure Line Tool Pg. 58 and Circle Measure Tool Pg. 59).
- Default VOI Color – Indicate the default color show in the user interface when creating volume of interest annotations.

5. Toggle the **Show Indicator** switch to configure hiding or showing the viewport orientation indicator (see Using the Orientation Indicator Pg. 72).
6. Make any modifications to the target landmarks defined for the system (see Managing Landmarks Pg. 72).
7. Select **Apply** to save the changes made.

Using the Workflow Selector

The Workflow 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 Procedure Workflow Pg. 25 or the chapter for each specific workflow step for full details.

Using the Patient Label

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

> **To review patient information**

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

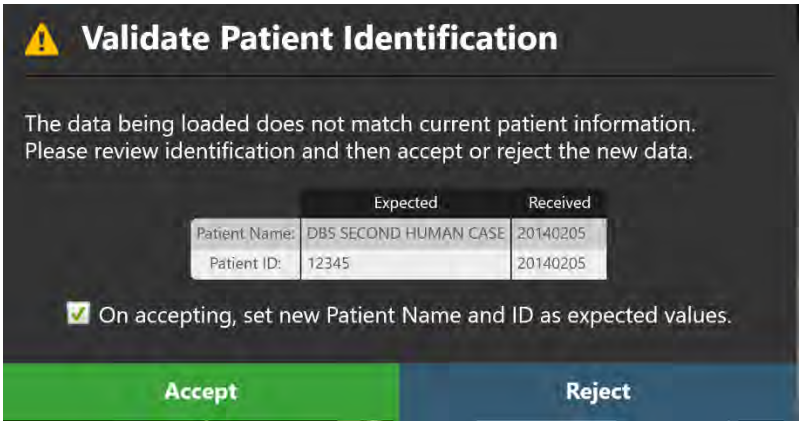
> **To show/hide patient information**

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

Sometimes, there may be discrepancies in either the patient's name, identification number, or both in images received by the scanner. If this scenario arises, the ClearPoint 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 **On accepting, set new Patient Name and ID as expected values** checkbox. Otherwise, untick this checkbox. The images will be loaded into the application, and depending on whether or not the checkbox was ticked, the Patient Label may be updated.

4. If the images received do not correspond to the current patient being treated, select **Reject**. The images just received will be rejected by the workstation and will not be loaded (see Data Rejected by Workstation Pg. 190).

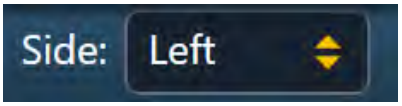
Using the Step-Specific Controls

Each step contains specific user interface controls that are customized depending on the current location 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 entry that is always selected. For bilateral procedures, you can use the Side Selector to specific 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.

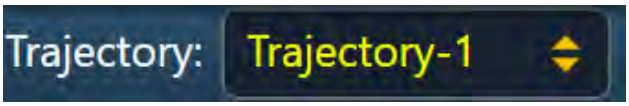


Selecting a Frame

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 entry 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.

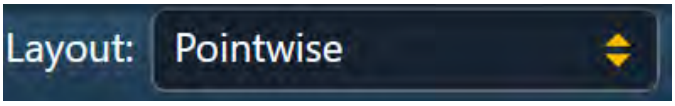
Selecting a Trajectory

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 (in cases where the Side Selector is shown), or the currently selected frame (in cases where the Frame Selector is shown).



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.

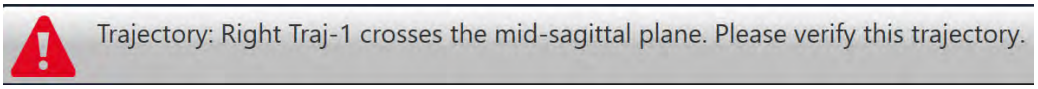


Selecting a Task

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. 155). The list of tasks varies for each step, depending on the workflow requirements needed to complete the step. An optional workflow 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 in order to invoke the task. Only one task can be invoked at any point in time, and will appear as a pop-up window over top of the main application window.

Status Messages

Status messages appear just below the top banner in the main application window, as well as within pop-up 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.

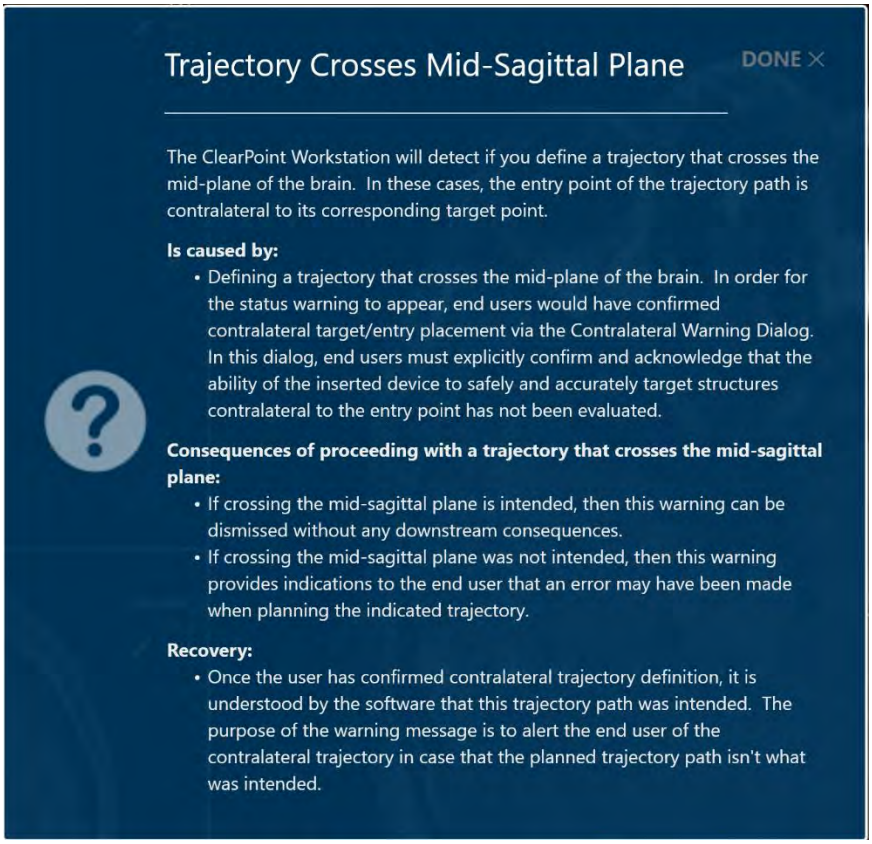


Any time a status message is presented, you have the option of bringing up troubleshooting tips which can help you to resolve the problem(s) encountered. To see a list of all troubleshooting tips provided by the application see Troubleshooting Pg. 189.

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

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

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



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.

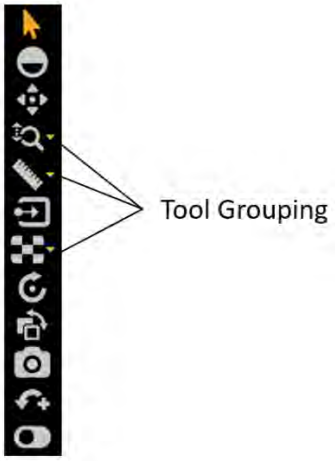
> **To dismiss a status message**

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 the Toolbar

The Toolbar provides the main access to the application's interactive tools. The Toolbar appears inset vertically within the top-left hand corner of the viewport which is currently under the mouse cursor. Some tools within the Toolbar are grouped according to their function, and can be accessed individually by expanding the tool grouping. All of the tools within the Toolbar are also available from the popup menu (see Using the Popup Menu Pg.53). For details on using the interactive tools, see Interactive Tools Pg.54.



> **To select a tool**

1. Left-click on any tool button within the 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

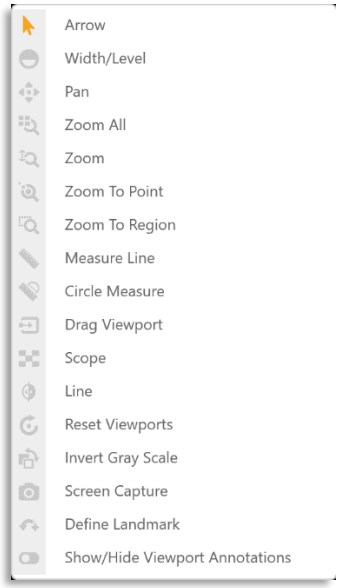
Some steps and tasks provide custom toolbars within their viewports, containing tools that are only relevant in that particular workflow context. These toolbars are orientated horizontally and positioned at the bottom of the viewport currently under the mouse cursor. Unlike the tools contained within the Toolbar, these tools are not accessible via the popup menu, but may be contained within the 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 chapter for each.

Using the Popup Menu

You can right-click a viewport to access a popup menu. The popup menu provides access to viewing functions and review tools.

> **To use the popup menu**

1. Right-click any viewport and select the appropriate option from the popup menu.



Tool Hot Keys

In addition to the Toolbar and the Pop-up Menu, there is also a way to momentarily switch interactive tools using the keyboard.

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

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

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

Interactive Tools

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

Note: When using the Width/Level tool with two series that have been blended together, only the fusion series is affected. To change the width/level for the master series, you must un-fuse the fusion series using the Thumbnail Bar so that no fusion series is selected. In that case, Width/Level changes will only be applied to the master series.

Zoom Tools

There are four separate tools for changing the zoom level.

 **Zoom**

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

 **Zoom All**

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

 **Zoom To Region**

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

3. When you release the mouse button, the application zooms the viewport to show the selected region.

Zoom to Point

1. Do one of the following:

   - From the Toolbar, click the Zoom To Point button.
   - Right-click the desired viewport and click **Zoom To Point**.
   -

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

Pan Tool

Pan an image within a viewport

1. Do one of the following:

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

2. Click and drag the image to change its position in the viewport.

Invert Grayscale Tool

Invert the image grayscale for a negative image display.

1. Do one of the following:

   - From the Toolbar, click the Invert Gray Scale button.

- Right-click any viewport and click **Invert Gray Scale**.
-

2. The application inverts the image grayscale for all current viewports.

3. You can click the button again to return to the original setting.

Measure Line Tool

Measure linear distances on an image

1. Do one of the following:

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

2. Click and drag to draw a line across the span on the image to be measured. The tool will display the current length of the measure line as it is drawn.

3. When you release the mouse button, the measure line and distance value will remain on-screen.

4. Measure lines can be edited by clicking and dragging the end points using either the Measure tool or the default Arrow tool. The distance value will always be shown at the mid-point between the two end points.

5. To delete measure lines, do one of the following:

   - Right-click on the measure line and select **Delete**
   - With the measure line selected, press the DELETE key on the workstation keyboard.
   - Drag the measure line over the  icon positioned in the bottom left corner of the currently selected viewport. This icon appears when you begin dragging the measure line.

6. To move the measurement value from its default location along the measure line, click on the value and drag it away from its current position. If you move the measure line, the measurement value will remain at its position on screen and will not move along with the measure line. If you would like to return the value to its original position, drag it over top of the reticle icon positioned at the mid-point

between the two measure line end points. In this position, the measurement value will move along with the measure line as it is moved.

Circle Measure Tool

Measure the diameter of a circle on an image

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

Image Blend Tools

There are two complimentary tools that can be used in addition to the thumbnail slider bar (see Using Thumbnails Pg. 74) for image blending.

Scope

1. Do one of the following:
   - From the Toolbar, click the Scope button.
   - Right-click the desired viewport and click **Scope**.
   -
2. Click on the viewport where you would like to position the image blend scope.
3. An inset scope window appears centered on the mouse position, showing the fusion image. The master 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 fusion image content followed by the master series content respectively. The number of alternating squares changes as the mouse wheel is rotated. Rotate forward to decrease the number of squares and backwards to increase the number of squares.
6. Click on the  icon to close the scope window

Line

1. Do one of the following:
   - From the Toolbar, click the Line button.
   - Right-click the desired viewport and click **Line**.
   -
2. Click on the viewport where you would like to position a line representing a split fusion view between the master and fusion series.

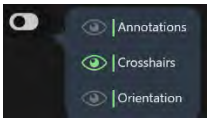
3. A two-dimensional line is drawn on screen. To the left of the line, the master series image content is shown. To the right of the line, the fusion series image content is shown.

4. If you are using a mouse with a mouse wheel, you can rotate the mouse wheel to cause the fusion and master series to change places. If you have not yet clicked on the viewport or have already dismissed the fusion line, rotating the mouse wheel will cause the entire viewport to alternate between the master and fusion series.

5. Click on the icon to dismiss the fusion line, thus showing only the master series image content in the viewport.

Show/Hide Crosshairs, Annotations and Orientation Indicators

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



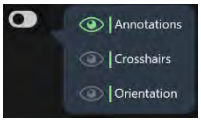
To show or hide crosshairs

1. Do one of the following:

   - From the Toolbar, click the Show/Hide Viewport Annotations button.
   - Right-click any viewport and click **Show/Hide Viewport Annotations**.
   -

2. A pop-out menu appears beside the Show/Hide Viewport Annotations button.

3. Click on the icon in the pop-out menu corresponding to **Crosshairs**.

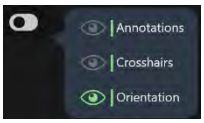


To show or hide annotations

1. Do one of the following:

   - From the Toolbar, click the Show/Hide Viewport Annotations button.
   - Right-click any viewport and click **Show/Hide Viewport Annotations**.
   -

2. A pop-out menu appears beside the Show/Hide Viewport Annotations button.
3. Click on the icon in the pop-out menu corresponding to **Annotations**.



To show or hide orientation indicators

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

Reset Viewports Tool

Reset viewport display parameters

1. Do one of the following:

- From the Toolbar, click the Reset Viewports button.
- Right-click any viewport and click **Reset Viewports**.
  -

2. This will reset the following viewport attributes for all viewports in the current workflow step or task.
   - window width and level
   - zoom
   - pan

Screen Capture Tool

You can capture images of the application screen at any time during the procedure. The tool captures the complete workstation window including the images shown in

the viewports as well as the rest of the application interface. **Protected Health Information is not shown in the captured screen images**. All captured images are included in the final report automatically generated at the end of the procedure (see Using the Report Window Pg. 39).

Capture screen images for report

1. Do one of the following:
   - From the Toolbar, click the Screen Capture button.
   - Right-click any viewport and click **Screen Capture**.
   -
2. A message pop-up will appear in the bottom right corner of the application window, indicating the file location of where the screen capture was saved on the workstation. This message can also be reviewed using the Log Window (see Using the Log Window Pg. 41).

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

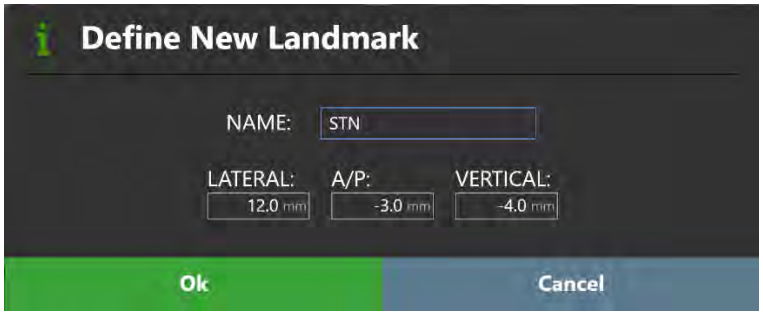
1. Do one of the following:
   - From the Toolbar, click the Drag Viewport button.
   - Right-click any viewport and click **Drag Viewport**.
   -
2. Click and drag an image from one viewport to another. This will cause the images in the source and destination viewports to switch places.

Define Landmarks Tool

Define landmark

Ensure that the Talairach coordinate system has been explicitly reviewed using the ACPC Task (see ACPC Task *Reviewing Landmarks* Pg. 160) prior to using the Define Landmarks Tool.

1. Move the crosshairs (see Changing Crosshair Positions Pg. 66) 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. 72 for details on how to manage landmarks created using the Define Landmarks tool.

Viewport Resizing Tool

The ClearPoint application provides the ability to resize viewports by dragging the border between 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.

Positioning Crosshairs and Editing Annotations

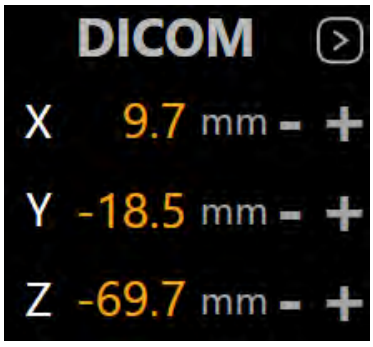
Some viewing layouts provide crosshair annotations (or cross reference lines) defining the intersection point between the coronal, sagittal and axial planes. The crosshairs are defined as follows:

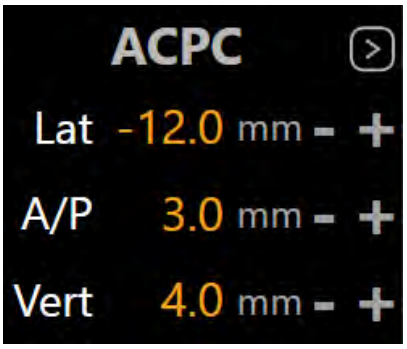
- Axial plane
  - Horizontal line represents intersection with the coronal plane.
  - Vertical line represents intersection with the sagittal plane.

- 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 (Talairach) or MR (DICOM) coordinates by clicking on the label in the header.





Changing Crosshair Positions

> **To change a crosshair position**

1. Select the Arrow tool (see Arrow Tool Pg. 55).
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 viewport's Current Point Control by clicking the icon and editing the points manually. This can be accomplished by typing in new values for one of more of the coordinate fields or using the +/- buttons for each.
- Click on the **landmarks** drop-down below the viewport's Current Point Control to correlate the crosshairs to the anatomical location of the selected landmark (see Managing Landmarks Pg. 72).
- Use the **Go To** buttons in either the step user interface panel or custom toolbars to correlate the crosshairs to the location of a selected annotation.

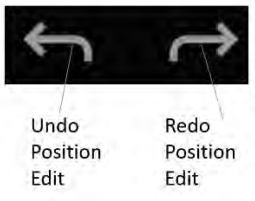
Editing Annotations

> **To modify the position of an editable annotation**

1. Select the Arrow tool (see Arrow Tool Pg. 55).
2. Do one of the following:
    - Change the crosshair location (by any means) to the intended position use the step user interface panel or custom toolbar to click **Set** for the annotation you wish to edit.
    - Click on the annotation in any viewport and drag it to the desired location.

> **To undo position edits associated with an editable annotation**

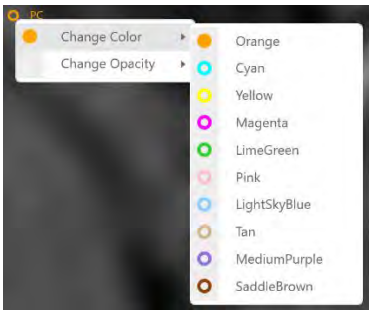
Use the custom toolbar inset within the viewport to undo or redo any number of position changes associated with the editable annotation.



> **To modify the color of an annotation**

1. Right-click on the annotation and select Change Color from the menu:

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



> **To modify the opacity of an annotation**

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

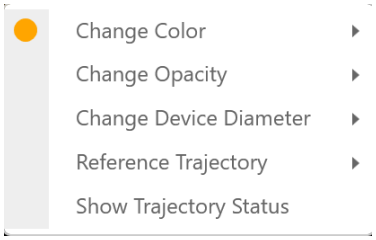
2. Use the slider bar to change the opacity of the annotation.

> **To move the text label for an annotation**

Click on the text label and drag it away from its default location as desired. If you move the annotation after its text label has been moved, the text label will remain at its position on screen and will not move along with the annotation. If you would like to return the text label to its original position, drag it over top of the reticle icon located beside the annotation. In this position, the text value will move along with the annotation as it is moved.

Trajectory Line Context Menu

To display the trajectory line context menu, right-click on the trajectory line of interest. The following options will be provided.



> **To change color**

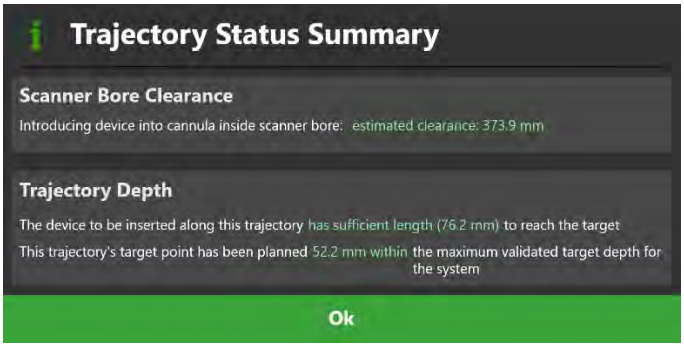
Select a color as you would for any annotation. (see Editing Annotations Pg.67)

> **To change opacity**

Alter the opacity as you would for any annotation. (see Editing Annotations Pg.67)

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

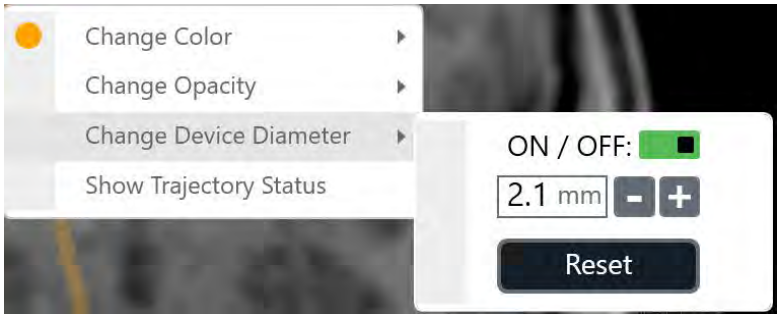
1. Select **Show Trajectory Status** from the context menu.
2. A dialog will display:
   - The scanner bore clearance for the inserted device along the selected trajectory;
   - The amount of device clearance required to reach the trajectory's target;
   - The amount of clearance from the maximum validated target depth for the system;
     -



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

1. Select **Change Device Diameter** from the context menu.

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



3. Select **Reset** to restore the device diameter value to its default value.

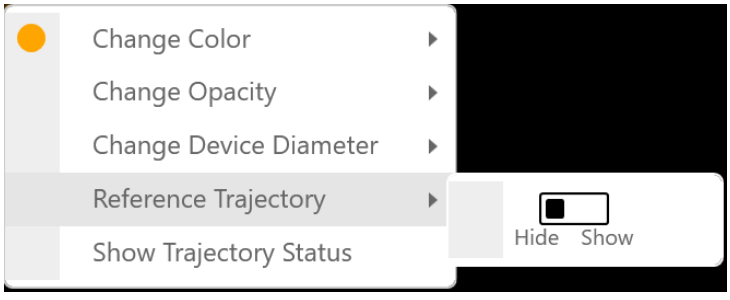
4. Use the **ON / OFF** switch to toggle between displaying the trajectory with a thickness equivalent to the device diameter or not. If set to **OFF**, the trajectory will display as a singular line with no thickness value set.

> **To 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:

Changing a Viewport Orientation

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

> **To change the viewport orientation**

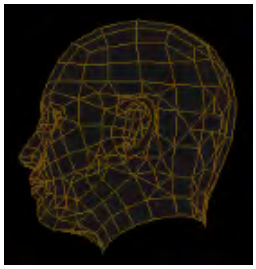
1. Identify the viewport for which you would like to change the orientation.

2. Click on the orientation drop-down control at the top-center of the viewport.

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

Using the 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 user preferences (see Configuring System and User Settings Pg.42).

Managing Landmarks

You can save and manage any number of pre-defined anatomical locations in Talairach space, 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. 160).

2. Use the **Define Landmarks Tool** (see Define Landmarks Tool Pg. 64).

> **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. 160).

2. Locate the Current Point Control and click the icon (see Positioning Crosshairs and Editing Annotations Pg. 65)

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

4. The viewport's crosshairs correlate to the location of the landmark in Talairach space.

> **To modify a landmark**

1. Open the **PREFERENCES** tab in the System Configuration Window (see Configuring System and User Settings Pg.42).

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 System and User Settings Pg.42).

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

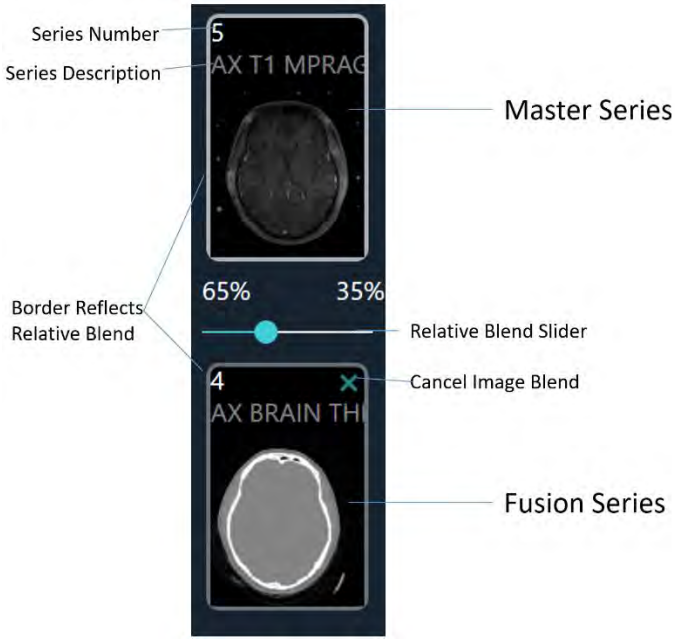
3. Click the  icon.
4. Select **Apply** to save the changes made.

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 appears as a thumbnail image in the Thumbnail bar. These are organized into groups based on the workflow steps in which they were acquired. 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 (or “master”) image series is displayed as the top-most thumbnail within the Thumbnail Bar and is always displayed in the viewing layout. The secondary (or “fusion”) image series is displayed as a child thumbnail under the top-most thumbnail, and will be blended / fused 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.

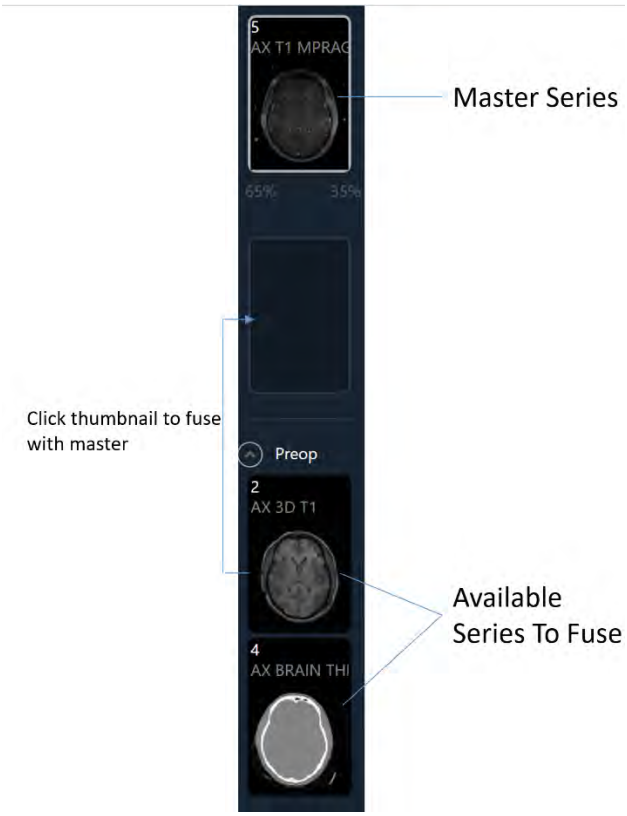
Note: Hovering the mouse over a thumbnail will display a tooltip containing additional information about the image series being represented.



> **To fuse two images**

1. From the grouping of available thumbnails, select one that you wish to fuse with the master image series.

2. Click on the selected thumbnail image.



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

4. Selected thumbnail will now have its corresponding image series blended with the master series in the application viewports.

> **To cancel an image fusion**

1. With an image series selected in the fusion thumbnail slot, click on the ✖ icon.

2. The image series will no longer be blended with the master series in the application viewports.

> **To change the master series image**

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

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

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

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

> **To select an image to display when there are no fusion-related capabilities**

1. From the grouping of available thumbnails, select one that you wish to display in the viewports.

2. Click on the selected thumbnail image.

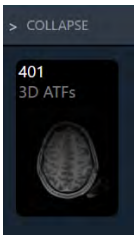
3. Selected thumbnail will now have its corresponding image series displayed in the application viewports.

> **To enable a disabled thumbnail image**

Thumbnails will be disabled if no fusion transform has been defined between it and the master series. The fusion transform is needed to show two series in the same coordinate space and must be set using the Fusion task. See Fusion Task *Fusing Images* Pg. 155 for details.

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

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



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**

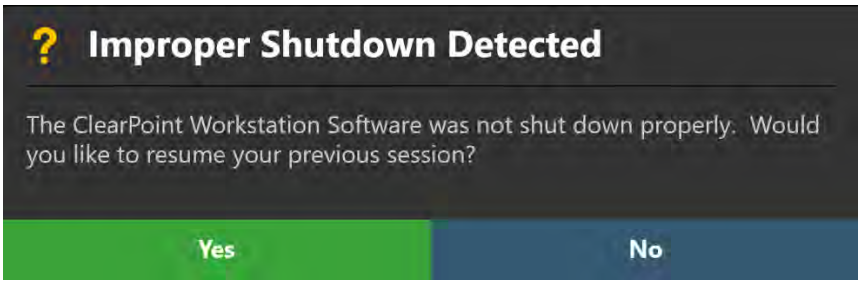
Select from  the far right hand corner of the main application window or from the Splash Screen (see Splash Screen Pg. 79).

Getting Started

This section describes how to get started with the application for either preoperative planning or to initiate / review an interventional treatment session.

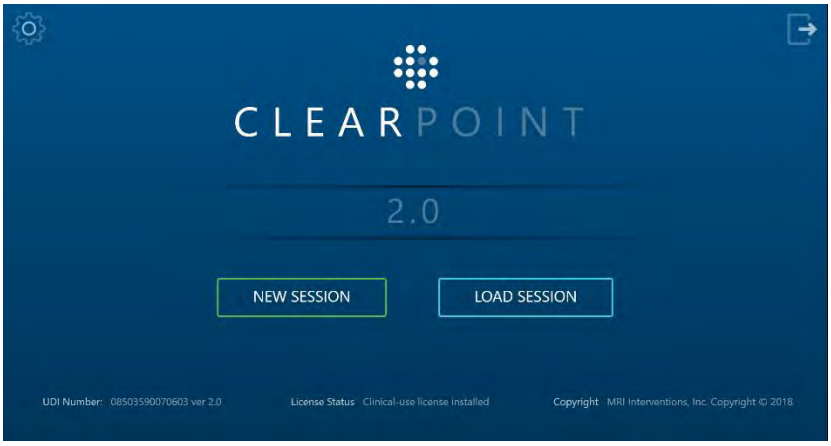
To launch the application, double-click the ClearPoint icon on the Windows desktop.

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.



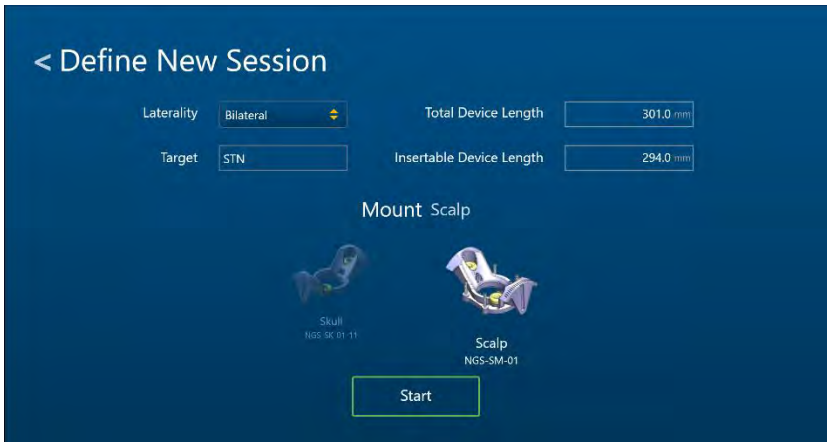
Splash Screen

On starting, ClearPoint will display a Splash Screen that allows you to begin a new session or load an existing one. A session can be used to initiate both a pre-operative plan or proceed with interventional treatment. The Splash Screen also shows the current system licensing status as well as the Unique Device Identification Number associated with the product. Additionally, you can use the Splash Screen to modify the system settings prior to starting or loading a session.



> **To start a new session**

1. Select the **NEW SESSION** button.



2. Fill in all of 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.
   - Target – Specify a name for the target point that you will target during the procedure.
   - Total Device Length - For the device to be inserted into the brain, enter the total rigid length. This value is used to check whether the device will physically fit within the bore of the scanner. This check is not performed preoperatively due to expected differences in patient positioning.
   - Insertable Device Length – For the device to be inserted into the brain, 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 to the patient during the procedure.
-

WARNING: **The correct choice of mounting base affects calculations checking whether the device will clear the scanner bore and whether the device will reach the target. This choice is also important to ensure a viable trajectory.**

Always verify that the hardware reference number and image shown match the hardware you will be using.

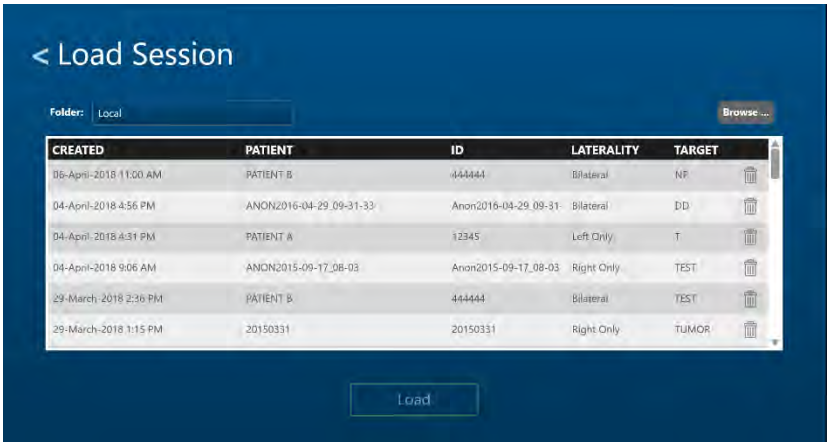
-

3. Select **Start** to begin a new session with the field properties listed. If you do not wish to begin a new session, but instead would like to load an existing session, click the **<** button.

4. After beginning a new session, you can modify the field properties associated with that session at any time during the workflow by using the Session Window (see Using the Session Window Pg. 36).

> To load an existing session

1. Select the **LOAD SESSION** button.



2. Choose the session that you wish to load from the list of sessions shown.

3. Select **Load** to continue with the session selected in the window. If you do not wish to load a session, but instead, would like to start a new session, click the **<** button.

> **To configure the system settings prior to starting a session**

1. Click the  button
2. Configure the system and user settings using the System Configuration Window (see Configuring System and User Settings Pg. 42).

> **To exit the application.**

Click the  button.

DICOM Configuration and Connectivity

In order for the ClearPoint Workstation to receive DICOM images transferred from the intraoperative scanner, the scanner will need to be configured with the AE Title and Port Number set in the application. These values can be set, viewed and edited through the System Configuration Window (see Configuring System and User Settings Pg. 42).

To test DICOM connectivity, use the **DICOM** tab's **Ping** button in the System Configuration Window (see Configuring System and User Settings Pg. 42). If images have previously been sent to the workstation sucessfully only the Port Number will be blank and need to be entered. Otherwise if data has not yet been sent you will need to enter all three values for the remote intraoperative scanner.

Scanner Configuration

Prior to starting an interventional treatment session for the first time, you must specify information about the scanner that will be transferring data to the ClearPoint

Workstation during the procedure. If the workstation connects to different intraoperative scanners within the same institution, this information must be changed each time the connection between the scanner and workstation is changed.

> **To configure the scanner bore size**

Configure the scanner bore size the System Configuration Window's **SYSTEM** tab (see Configuring System and User Settings Pg. 42).

WARNING: **The diameter of the scanner bore that the workstation is connected to is used by the application (along with the Total Device Length) to ensure that for a given planned trajectory in an interventional treatment session, the device can be physically inserted into the SMARTFrame without being blocked by the scanner bore.**

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

> **To configure the scanner manufacturer**

Configure the scanner manufacturer the System Configuration Window's **SYSTEM** tab (see Configuring System and User Settings Pg. 42).

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

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

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.

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

Loading Images

To begin with the clinical workflow, you will need to load image onto the ClearPoint Workstation. Both MR and CT image modalities are supported. Prior to loading data, you will need to choose a workflow step that you wish to begin the workflow from (see Procedure Workflow Pg. 25). If you have started a new session but have not loaded any images yet, you must choose one of the following workflow steps prior to doing so:

- Pre-Op Step (see Pre-Op Step *Setting Preoperative Trajectories* Pg. 85)
- Entry Step (see Entry Step *Locate Mounting Point* Pg. 103)
- Target Step (see Target Step *Finalizing Trajectories* Pg. 115)

To load data you can either push data to the workstation through a DICOM network connection (see DICOM Configuration and Connectivity Pg. 82) or load images from DICOM media (see Using the Media Browser Pg. 35).

Preoperative Planning

This chapter describes how to use the ClearPoint Workstation for preoperative planning.

Preoperative Images

To create a preoperative plan for ClearPoint, you will need appropriate image data (see Loading Images Pg. 84). The Pre-Op workflow step supports image blending for image series in the same or different frame of reference.

> **To load preoperative images**

1. Select the Pre-Op step using the Workflow Selector (see Using the Workflow Selector Pg. 45).

2. Load data onto the ClearPoint Workstation (see Loading Images Pg. 84). If you wish to use Talairach coordinates then at least one pre-operative image set must support accurate identification of the AC and PC landmarks and the mid-sagittal plane.

3. The data will be loaded and displayed in the Pre-Op step. If multiple series are selected for load, the application will select the MR series with largest number slices as the master series. If only CT images are loaded it will select the largest CT series as the master series. The user may select a different master series using the Thumbnail Bar (see Using Thumbnails Pg. 74). 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. 155) to fuse the series together in order to allow for image blending functionality in this step.

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

Pre-Op Step *Setting Preoperative Trajectories*

The Pre-Op workflow step allows you to create a complete pre-operative plan using images that were acquired prior to the day of treatment. You can create a pre-operative plan by defining any number of trajectories into the brain, where each trajectory 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 on pre-operative images.

When images are 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 ACPC (Talairach) coordinate system used by the application to align its viewports to anatomical orientations, while also providing you with the ability to set trajectories relative to this coordinate system.

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

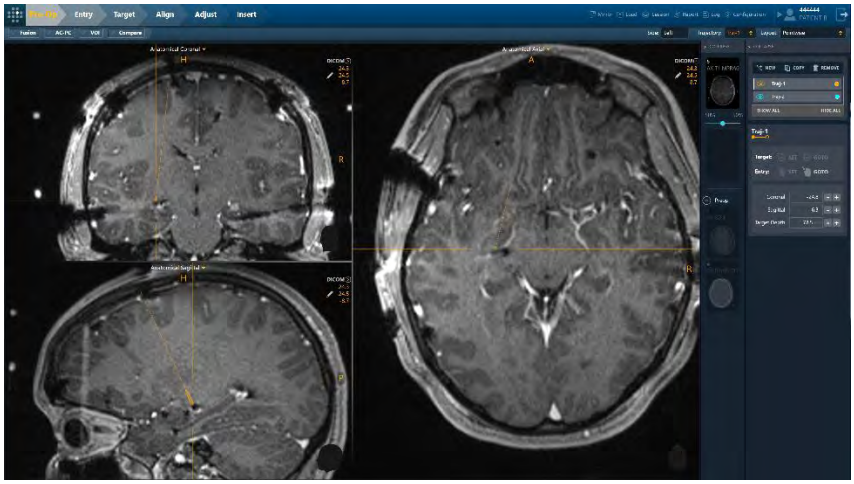
- The Fusion task (see Fusion Task *Fusing Images* Pg. 155) may be used to fuse pre-operative image series that were acquired in different frames of references, for trajectory planning purposes.
- The ACPC task (see ACPC Task *Reviewing Landmarks* Pg. 160) may be used to review and / or modify the anatomical reference points automatically detected by the software. Doing so enables the ability to set trajectories relative to the Talairach coordinate system.
- The VOI task (see VOI Task *Defining Volumes* Pg. 163) may be used to define one or more volumes of interest on pre-operative images for purposes of trajectory planning.
- The Compare task (see Compare Task *Comparing Images* Pg. 172) may be used to compare pre-operative image series in their individual acquisition planes or standard scanner planes.

The Pre-Op step provides 3 viewing layouts that are selectable via the Layout Selector (see Selecting a Viewing Layout Pg. 48): Pointwise, Review and Oblique & Pointwise.

Pointwise Layout

This layout provides you with the ability to create and edit trajectories by editing the associated entry and target annotations individually. The Pointwise Layout provides 3 viewport orientations: **Scanner**, **Anatomical** and **Trajectory** (see Changing a Viewport Orientation Pg. 71):

- Scanner View – Aligns viewports to scanner axes
- Anatomical View – Aligns viewports to ACPC (Talairach) planes.
- Trajectory View – Aligns viewports such that the Trajectory Coronal and Trajectory Sagittal planes are perpendicular and lie along the trajectory and the Trajectory Axial is perpendicular to the trajectory. This option is only functional after at least one trajectory has been defined.

- 

> **To create a new trajectory**

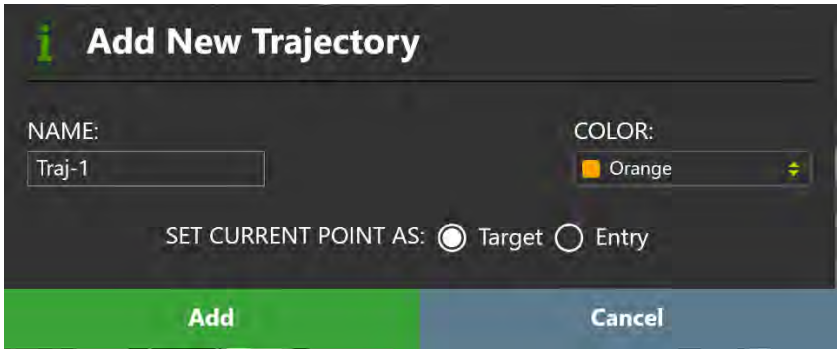
1. Change the crosshair position to a location that you wish to set for either the target or entry point of the proposed trajectory (see Changing Crosshair Positions Pg. 66).

2. Select 

from the step's user interface.

3. A floating window will appear prompting you define the following attributes for the trajectory 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 defined on the same side of the patient's head.
     -
   - Color – Specify a color defining how the trajectory annotation will be displayed in the user interface.
     -
   - Set Current Point As – Indicate whether the current crosshair position should be used to define the target or entry point for the trajectory to be created. For the end point that is not explicitly defined, an appropriate default position will be assigned based on the current step. This end point will need to be edited.
     -



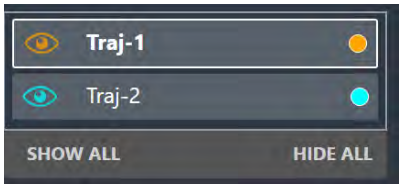
4. Select **Add** to create a planned trajectory in the user interface. Select **Cancel** to cancel the planned trajectory creation.

> **To select a trajectory**

1. Select the trajectory that you wish to work with in the user interface using one of the following methods:

   - Use the Trajectory Selector (see Selecting a Trajectory Pg. 48).

   - Use the step's panel



2. The selected trajectory name will be displayed in the step panel to indicate which one you have selected.

> **To edit a trajectory**

1. Select the trajectory that you wish to edit.

2. Edit the selected trajectory using the following mechanisms:

- Reposition the crosshairs in the viewports (see Changing Crosshair Positions Pg. 66) to a location where you would like to set either the target or entry point. Use the  button in the step's panel or custom toolbar (see Using Custom Toolbars Pg. 52) to set the target point at the current crosshair position. Click the  button in the step's panel or custom toolbar (see Using Custom Toolbars Pg. 52) to set the entry point at the current crosshair position.

- If the viewport is set to the **Trajectory** orientation (see Changing a Viewport Orientation Pg. 71), the following mechanisms can be used to edit the trajectory in **Trajectory Coronal** and **Trajectory Sagittal** viewports:
  - Drag the end point of the trajectory that you wish to edit to a new location within the viewport (see Editing Annotations Pg. 67).
  - Hold down the CTRL key while moving either trajectory end point to constrain the movement to shift along the current direction of the trajectory.
  - Drag in between the trajectory end points (i.e. on the trajectory path cross section) to cause the trajectory's entry point to pivot about its target point.
  - Hold down the ALT key while dragging in between the trajectory end points (i.e. on the trajectory path cross section), 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** orientation (see Changing a Viewport Orientation Pg. 71), the following mechanisms can be used to edit the trajectory in **Trajectory Axial** viewport:
    - Drag the cross section anywhere along the trajectory path to cause the trajectory's entry point to pivot about its target point.
    - If positioned exactly on the target point, drag the cross section to cause the trajectory's target point to pivot about its entry point.
    -

- Change one of the following trajectory properties in the step's panel:
    - Trajectory Angles – Edit **Coronal** and / or **Sagittal** approach angle values to cause the trajectory's entry point to pivot about the currently defined target point in order to make the specified angle with the specified anatomical plane. You can manually enter a new angle value or click the +/- buttons to change the value.

    - Target Depth – Edit the **Target Depth** value 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's panel. You can manually enter a new depth value or click the +/- buttons to change the value.

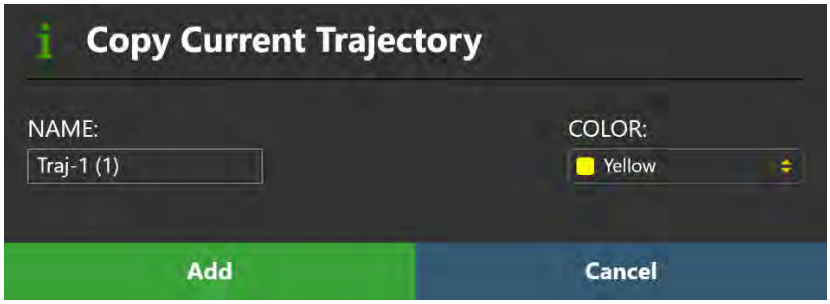
-
-

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

1. Select the trajectory for which you would like to undo or redo edits.
2. Use the custom toolbar in any of the viewports to undo or redo any number of edits made to the trajectory since it was first created (see Editing Annotations Pg. 67).

> **To copy an existing trajectory**

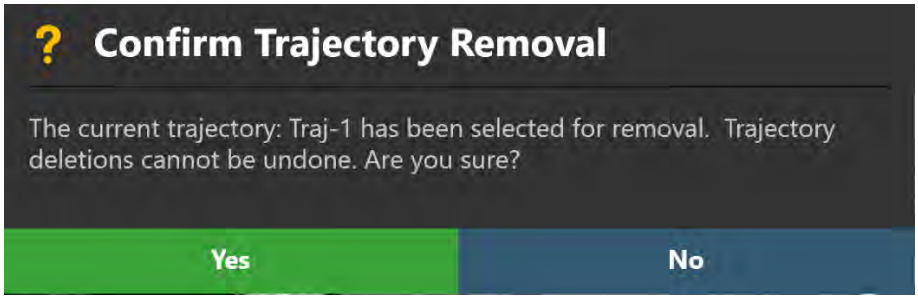
1. Select the trajectory that you wish to copy.
2. Select COPY from the step's user interface.
3. A floating window will appear prompting you define the following attributes for the trajectory to be created.
   - Name – Specify a unique name that will identify the trajectory in the user interface. By default, the name of the trajectory to be copied is used combined with an index number.
     - Note: The application will prevent identical naming of trajectories defined on the same side of the patient's head.
     -
   - Color – Specify a color defining how the trajectory annotation will be displayed in the user interface.
     -



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

> **To remove a trajectory**

1. Select the trajectory that you wish to remove.
2. Select REMOVE from the step's user interface.
3. You will be prompted to confirm whether or not you would like to remove the selected trajectory. Select **Yes** to confirm removal of the trajectory. Select **No** to prevent the selected trajectory from being removed.



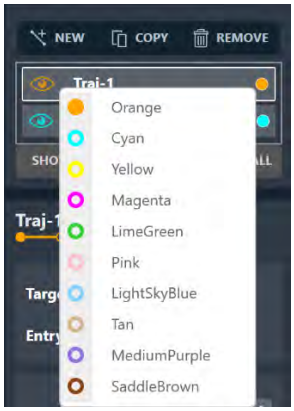
> **To navigate to a trajectory's end points**

1. Select the trajectory that you wish to review.
2. Select to navigate to the selected trajectory's target point, from either the step's panel or the custom toolbar (see Using Custom Toolbars Pg. 52).

3. Select  to navigate to the selected trajectory's entry point, from either the step's panel or the custom toolbar (see Using Custom Toolbars Pg. 52).

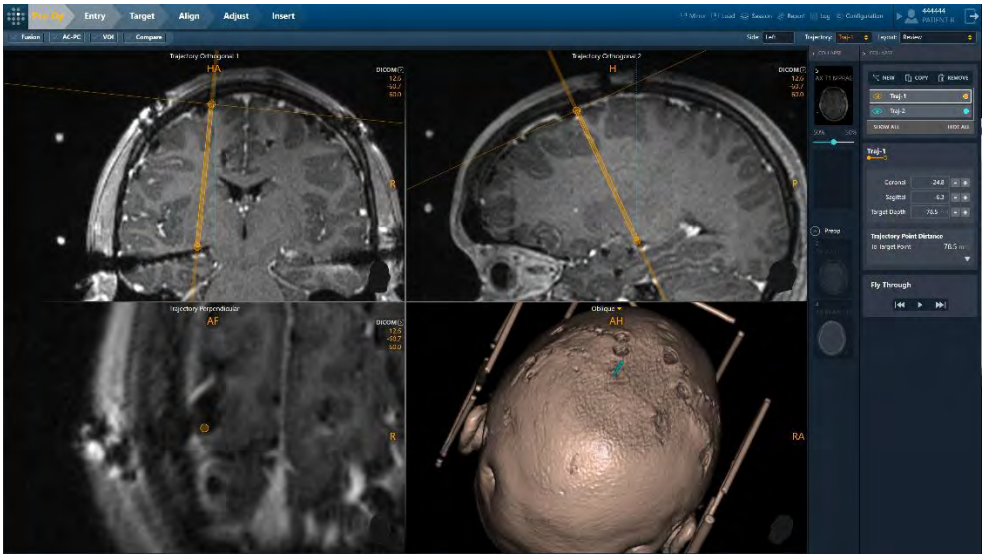
> **To change trajectory properties**

1. Select the trajectory with properties that you wish to change.
2. Use the trajectory line context menu to change the following properties: color, opacity, and device diameter (see Trajectory Line Context Menu Pg. 68).
3. Change the visibility of individual trajectories by clicking on the eye-ball icon () corresponding to the trajectory that you wish to show or hide.
4. Change the visibility of all trajectories for the given side by toggling between **SHOW ALL** and **HIDE ALL**.
5. Change the color of an individual trajectory by clicking on its corresponding colored circle.



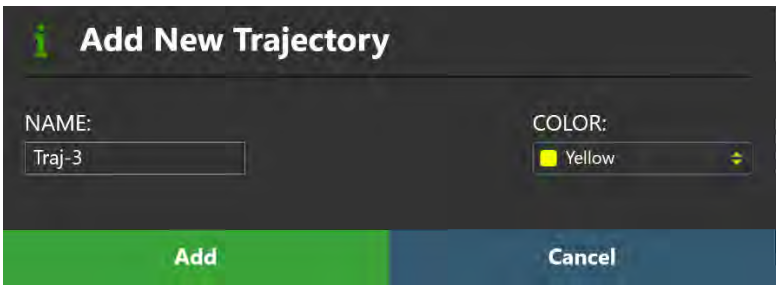
Review Layout

This layout provides you with the ability to create and edit trajectories by visualizing both entry and target annotations at the same time. It also provides a volume rendered view in order to review your planned trajectories in three dimensions. The Review layout provides a single viewing orientation, aligned along the currently selected trajectory, and displays all trajectories defined on the currently selected side.



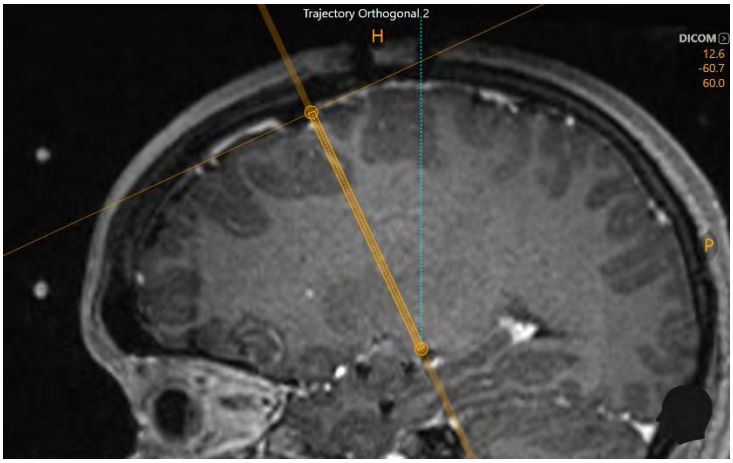
> **To create a new trajectory**

Use the techniques to create a new trajectory, as described in the Pointwise layout (see Pointwise Layout Pg. 86). The floating window prompting you to define the attributes will not include **Set Current Point As** because when creating a trajectory in Review mode, the entry and target points are set simultaneously. Therefore, default locations for both target and entry points will be used when creating a new trajectory in this mode.



> **To select a trajectory**

Use the same mechanisms as described when using the Pointwise layout (see Pointwise Layout Pg. 86). Additionally, you may also select any other trajectory defined on the same side by clicking on the dotted line representing that trajectory.



> **To edit a trajectory**

1. Select the trajectory that you wish to edit.
2. Edit the selected trajectory using the following mechanisms:
    - In the Trajectory Orthogonal 1 and Trajectory Orthogonal 2 viewports:
        - Drag the end point of the trajectory that you wish to edit to a new location within the viewport (see Editing Annotations Pg. 67).
        - Drag the trajectory extension above the entry point to cause the trajectory's entry point to pivot about its target point.
        - Drag the trajectory extension below the entry point to cause the trajectory's target point to pivot about its entry point.
        - Drag in between the trajectory end points (i.e. on the trajectory path cross section) to cause the trajectory's entry point to pivot about its target point.
        - Hold down the CTRL key while moving either trajectory end point to constrain the movement to shift along the current direction of the trajectory.
        - Hold down the ALT key while dragging in between the trajectory end points (i.e. on the trajectory path cross section), to shift the entire trajectory path. This causes both entry and target points to shift by the same amount.
    - In the Trajectory Perpendicular viewport:
        - Drag the cross section anywhere along the trajectory path to cause the trajectory's entry point to pivot about its target point.

- Drag the cross section when positioned above the entry point to cause the trajectory's entry point to pivot about its target point.
- Drag the cross section when positioned below the target point to cause the trajectory's target point to pivot about its entry point.

- Change the trajectory approach angles (**Coronal** / **Sagittal**) and/or **Target Depth** properties associated with the current trajectory, the same as you would using the Pointwise layout (see Pointwise Layout Pg. 86).

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

Use the same mechanisms as described when using the Pointwise layout (see Pointwise Layout Pg. 86).

> **To copy an existing trajectory**

Use the same mechanisms as described when using the Pointwise layout (see Pointwise Layout Pg. 86).

> **To remove a trajectory**

Use the same mechanisms as described when using the Pointwise layout (see Pointwise Layout Pg. 86).

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

1. Select the trajectory that you wish to review.
2. Use the following mechanisms to scroll along the trajectory path to each of the selected trajectory's end points:
    - Drag the horizontal line displayed perpendicular to the trajectory path in **Trajectory Orthogonal 1** or **Trajectory Orthogonal 2** viewports to scroll along the trajectory path.
    - In the **Fly Through** group box, select  to navigate to the selected trajectory's target point.
    - In the **Fly Through** group box, select  to navigate to the selected trajectory's entry point.

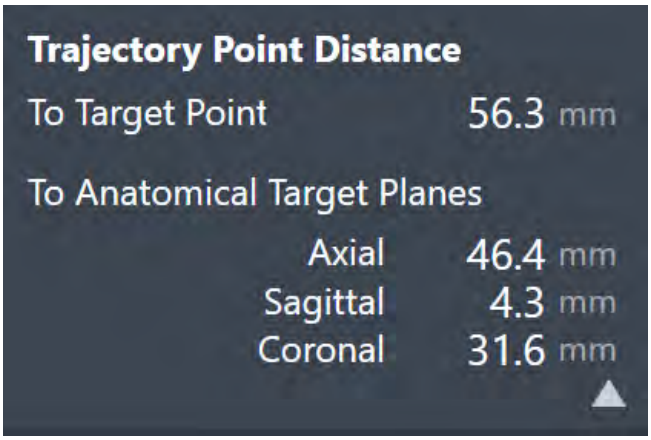
- To automatically scroll from the selected trajectory's entry point to target point using the button in the **Fly Through** group box. To stop automatic scrolling along the selected trajectory path, use the button.

> **To change trajectory properties**

Use the same mechanisms as described when using the Pointwise layout (see Pointwise Layout Pg. 86).

The Review layout also provides several additional measurement values that are not shown in the Pointwise layout:

- To Target Point – 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 coronal 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 sagittal plane passing through the target point. This distance is measured along the left-right axis.



Oblique & Pointwise Layout

This layout combines functionality in Pointwise (see Pointwise Layout Pg. 86) and Review layouts (see Review Layout Pg. 92), providing six viewports that can be used to create, edit or review planned trajectories. The three viewports at the top of the viewing layout are analogous to those trajectory-oblique oriented viewports shown in the Review layout. The three 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 all six viewports, if desired.

> **To create a new trajectory**

Use the same mechanisms as described when using the Pointwise (see Pointwise Layout Pg. 86) and Review (see Review Layout Pg. 92) layouts.

> **To select a trajectory**

Use the same mechanisms as described when using the Pointwise (see Pointwise Layout Pg. 86) and Review (see Review Layout Pg. 92) layouts.

> To edit a trajectory

Use the same mechanisms as described when using the Pointwise (see Pointwise Layout Pg. 86) and Review (see Review Layout Pg. 92) layouts.

> To undo or redo edits made to a trajectory

Use the same mechanisms as described when using the Pointwise (see Pointwise Layout Pg. 86) and Review (see Review Layout Pg. 92) layouts.

> To copy an existing trajectory

Use the same mechanisms as described when using the Pointwise (see Pointwise Layout Pg. 86) and Review (see Review Layout Pg. 92) layouts.

> To remove a trajectory

Use the same mechanisms as described when using the Pointwise (see Pointwise Layout Pg. 86) and Review (see Review Layout Pg. 92) layouts.

> To navigate to a trajectory's end points

Use the same mechanisms as described when using the Pointwise (see Pointwise Layout Pg. 86) and Review (see Review Layout Pg. 92) layouts.

> To change trajectory properties

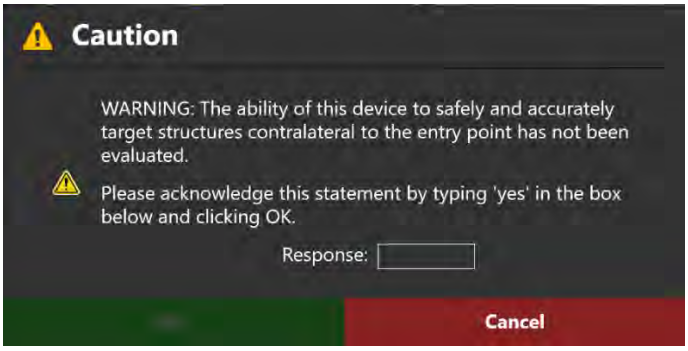
Use the same mechanisms as described when using the Pointwise (see Pointwise Layout Pg. 86) and Review (see Review Layout Pg. 92) layouts.

> To link crosshair locations

1. To link crosshairs between all 6 viewports, click the  button.
2. To un-link crosshairs between all 6 viewports, leaving the top 3 viewports with a different crosshair location than the bottom 3 viewports, click the  button.

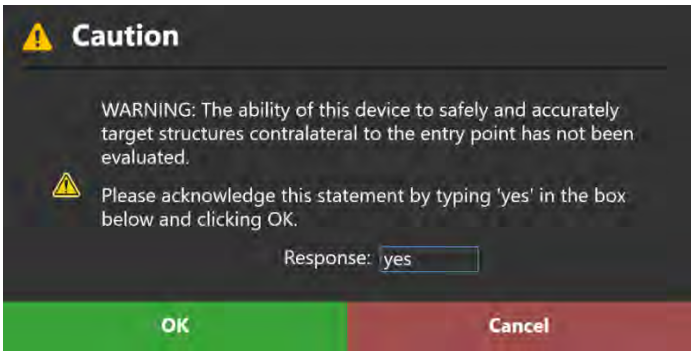
Defining Contralateral Targets

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



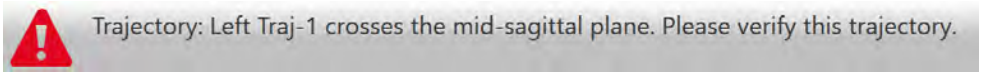
If the edit was inadvertent, select **Cancel** and the change will be discarded.

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

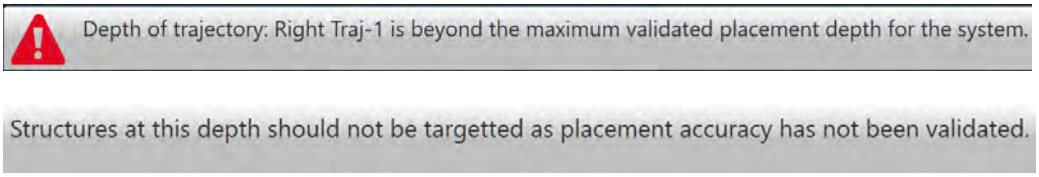


Doing so will enable the **OK** button. Click **OK** to save your updated trajectory.

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 following warning will be displayed in the status area.**



See Trajectory Depth is Beyond Maximum Validated System Depth Pg. 202 for further details.

Localize Mount Points

This chapter describes how to use the ClearPoint Workstation for determining where the SMARTFrame(s) will be mounted. To achieve this, it is necessary to complete trajectory planning so that the intended entry point(s) can be identified on the patient.

Intraoperative Grid Images

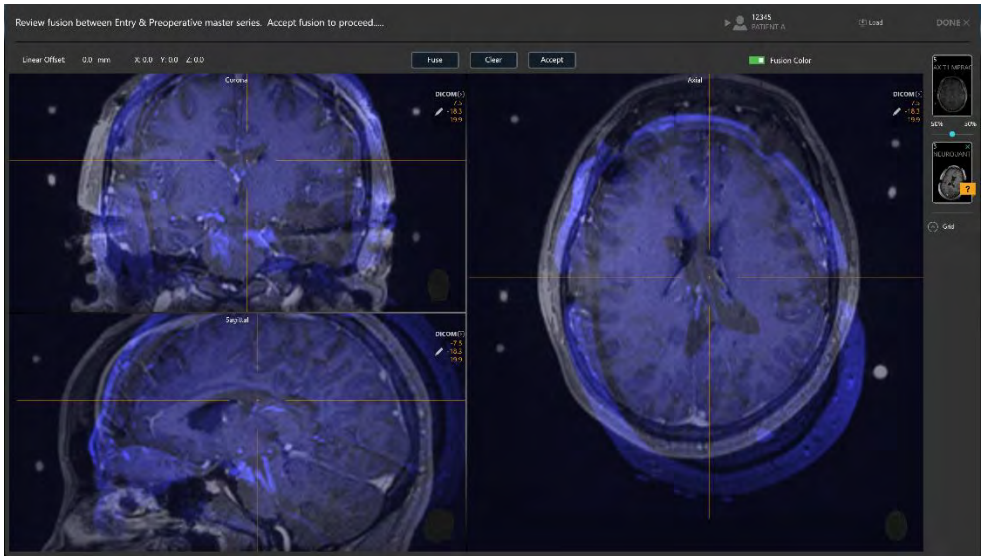
To start an interventional treatment session for ClearPoint, you will need to load image data into either the Entry (see Entry Step *Locate Mounting Point* Pg. 103) or Target (see Target Step *Finalizing Trajectories* Pg. 115) steps. Loading data into the Entry step implies that you will be using the images to identify one or more mount point locations on the patient's head. The Entry step supports image blending for series in the same or different frame of reference.

> **To load intraoperative images used for mount point determination**

1. Select the Entry step using the Workflow Selector (see Using the Workflow Selector Pg. 45).

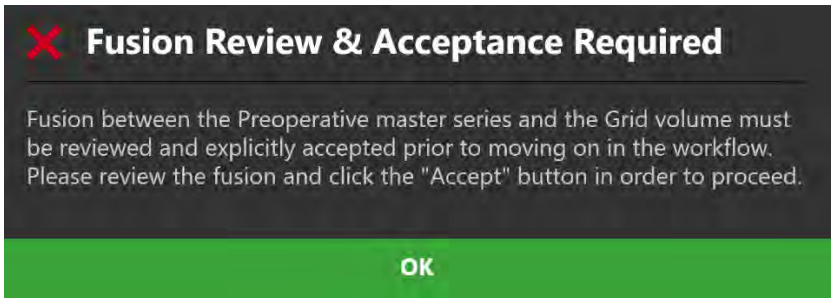
2. Load data onto the ClearPoint Workstation (see Loading Images Pg. 84). At least one image set must support identification of the SMARTGrid(s) and desired entry and target points (i.e. a whole-head image volume with marking grid affixed). If a preoperative plan was not created, at least one image set must also support accurate identification of the AC / PC landmarks and the mid-sagittal plane.

3. If you have created a preoperative plan, the Entry step will prompt you to fuse the master series from the Pre-Op step with each of the image series loaded.



4. Use the pop-up Fusion task (see Fusion Task *Fusing Images* Pg. 155) to fuse the master series from the Pre-Op step with each of the series just loaded into the Entry step.

If you attempt to dismiss the pop-up Fusion task prior to explicitly accepting the fusion between the Pre-Op step's master series and each of the loaded image series, you will be prevented from doing so. The reason for this is that the application must transform the preoperative trajectories and anatomical reference points into the coordinate space defined by the interventional images.



5. After fusing the Pre-Op step's master series with each received image series, the data will be loaded and displayed in the Entry step, and all Pre-Op step trajectories and anatomical landmarks will be imported into the coordinate space defined by the intraoperative images.

6. The application will select the series with the largest number of slices (MR modality preferred over CT modality) and automatically set that as the master series in the Thumbnail Bar (see Using Thumbnails Pg. 74). 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. 155) to fuse the series together in order to allow for image blending functionality in this step.

7. The application will then perform an exhaustive search for all SMARTGrid(s) that may be mounted on the patient from the master series automatically selected. If a preoperative plan was not created prior to loading images into the Entry step, then the application will also automatically detect the anatomical reference points from the master series.

Entry Step *Locate Mounting Point*

The Entry step allows you to import preoperative trajectories and / or plan any number of new trajectories in order to determine mount point locations for the SMARTFrame(s) on the patient's head during the procedure. The same tools provided for trajectory definition, planning, and review in the Pre-Op step (see Pre-Op Step *Setting Preoperative Trajectories* Pg. 85) are also provided in this step.

When images are loaded into the ClearPoint Workstation with the Entry step selected, the application automatically detects the position of any SMARTGrid(s) that are mounted on the patient. Reviewing and verifying the location of these grids within the application ensures correct localization of the mount points required to affix the SMARTFrame(s) on the patient.

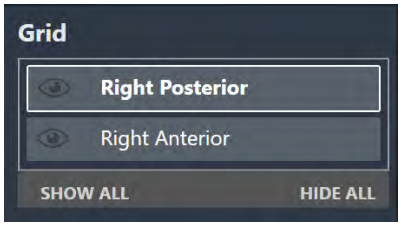
Within the Entry step, you have the option to perform the following workflow-specific tasks:

- The Fusion task (see Fusion Task *Fusing Images* Pg. 155) may be used to fuse additional image series that may be used for trajectory planning or entry point verification purposes that 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. 160) 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.

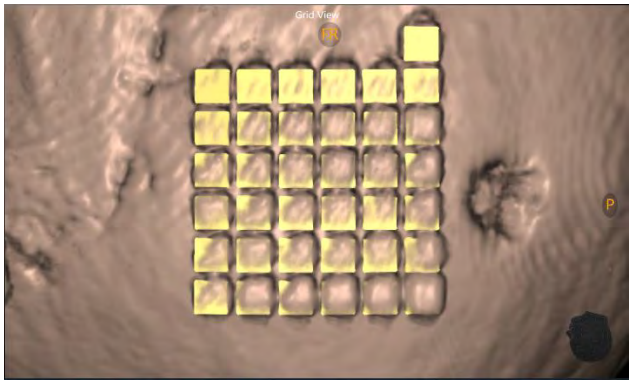
- The VOI task (see VOI Task *Defining Volumes* Pg. 163) may be used to define one or more volumes of interest on intraoperative images for purposes of trajectory planning

- The Compare task (see Compare Task *Comparing Images* Pg. 172) 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. 174) 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 in the Entry step.

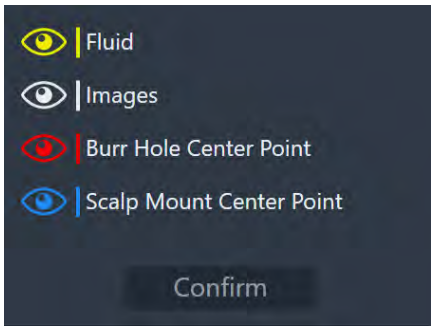
The Entry step is very similar to the Pre-Op step (see Pre-Op Step *Setting Preoperative Trajectories* Pg. 85), but with the following differences:

- The step will automatically search for all SMARTGrids on receiving data for the first time.
- The step will import any preoperative trajectories and anatomical landmarks upon receiving data for the first time.
- In the Review layout (see Review Layout Pg. 92), the following differences exist:
  - A mechanism of selecting the SMARTGrid that you wish to review, verify and define trajectories for is provided.
  - 

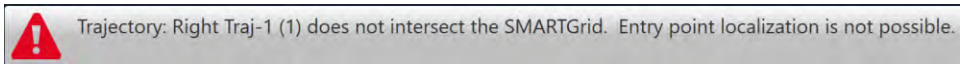
  - An additional 3D viewport is shown illustrating a model of the selected SMARTGrid, aligned along the direction of the marking grid so that it can be reviewed / verified while showing the underlying images used to detect it.



- Additional tools are provided for confirming the marking grid placement, changing the visibility of the grid model, and showing / hiding the mount point locations.



- When creating a trajectory in Pointwise (see Pointwise Layout Pg. 86) or Oblique & Pointwise layouts (see Oblique & Pointwise Layout Pg. 97), the default entry location will be defined automatically by the software at the center of the selected SMARTGrid.
- The step will warn when trajectories don't intersect the selected marking grid. The trajectory line will be drawn in red and the following status message will be shown.



- The step provides scan plane parameters (see Interoperation with MRI Scanner Pg. 18) for the following additional scans:
  - Target - Parameters to acquire a scan that encapsulates target area(s) of the planned trajectories.

-
    - Entry – Parameters to acquire a scan that can be used to verify the mount point(s) after the SMARTGrid(s) have been removed from the patient's scalp.

Reviewing Planned Trajectories

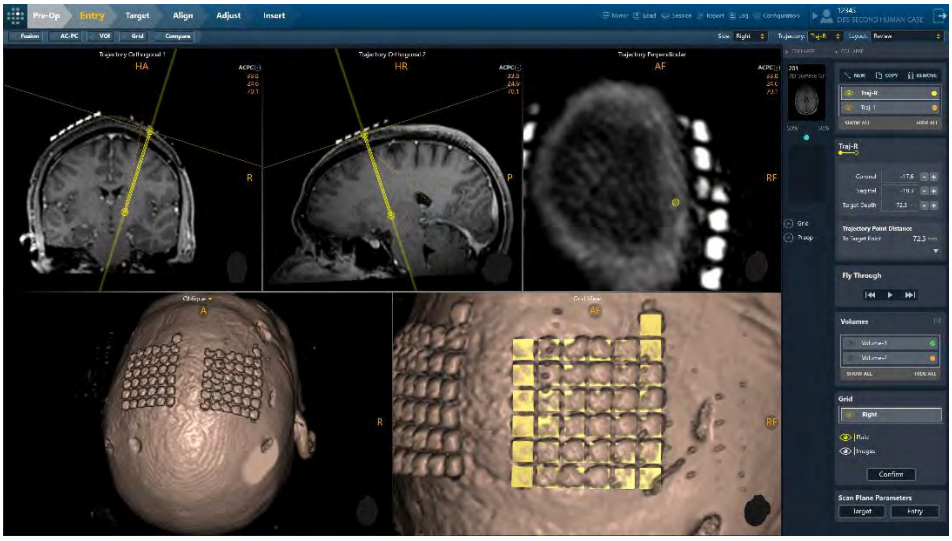
You may use additional scans, such as target or entry slabs, to provide better visualization of structures along the selected trajectory path.

> **To review your planned trajectories**

1. Select any viewing layout (see Selecting a Viewing Layout Pg. 48).
2. Navigate through all defined trajectories using the Trajectory Selector (see Selecting a Trajectory Pg. 48) and use the trajectory tools described in the Pre-Op step (see Pre-Op Step *Setting Preoperative Trajectories* Pg. 85) to review or edit each trajectory. You may also opt to add or remove trajectories as appropriate.
3. If desired, acquire target slabs using the **Target** scan plane parameters to review the target position for one or more trajectories.
4. If desired, acquire entry point slabs using the **Entry** scan plane parameters to verify your mount point positions (see Realizing Mount Points Pg. 110).
5. If you completed the Pre-Op step, use the trajectory line context menu to visually compare changes between the currently selected trajectory and the one that was imported from the Pre-Op step (see Trajectory Line Context Menu Pg. 68).

Locating Mount Points

Use the Entry step's Review layout to locate the SMARTFrame mount points on the patient. The bottom right viewport is used to show a 3D view of the patient with a model representing the currently selected SMARTGrid.



There are two options when mounting the SMARTFrame. You can mount the frame directly on the skull surface after retracting the scalp, or you can mount the frame on the scalp using the optional scalp mount base.

WARNING: **If you are mounting the frame on the skull, mount the frame about the burr hole centering point. If you are using the scalp mount base, mount the frame at the scalp mount centering point.**

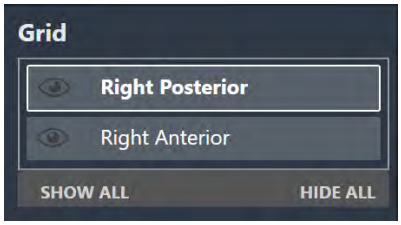
The scalp mount base offsets the frame vertically from the surface of the scalp. This can introduce an offset to the frame mount point in order to be able to align the cannula to the entry and target points. For this reason the Entry step provides two annotations: the burr hole centering point and the scalp mount centering point.

If the SMARTGrid was not detected by the software 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 define a new one using the Grid task (see SMARTGrid Not Found / Detect Incorrectly Pg. 198)

> **To select a grid**

1. Select the Review viewing layout (see Selecting a Viewing Layout Pg. 48).

2. Use the **Grid** group box selector to select a marking grid for which you wish to review, verify and / or define trajectories.



3. The bottom left viewport of the Review viewing layout will align to the selected grid.

   Note: Any trajectories that are defined in the step where the target point is defined first will use the center of the selected grid as its default entry point.

> **To verify grid detection**

1. Select a marking grid whose position / orientation you wish to verify.

   If for any reason the software was unable to detect the position of the SMARTGrid, you will see a warning message and the grid model will not be drawn in the bottom right viewport. You have the option to proceed manually if you are confident of identifying locations on the grid visually.

   If you cannot identify the grid in the volume, you can acquire and blend in additional image slabs which can be used to see the grid. Use the **Entry** scan plane parameters provided in the step to acquire these scans. You may then use the Grid task to attempt to identify the grid in the newly acquired images.

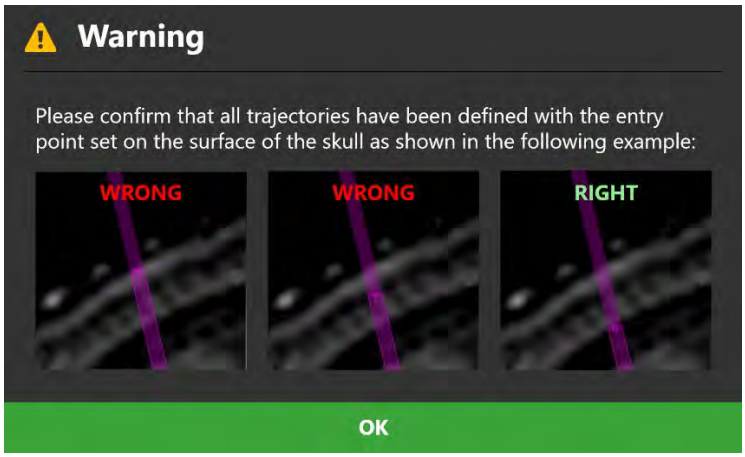
2. Toggle the **Fluid** icon ( ) to show and hide the marking grid model's fluid cells. This can be used to determine if the marking grid model matches up with the underlying images showing the grid acquired from the scan. It is possible for signal attenuation or artifacts in the image volume to cause the application to incorrectly identify the marking grid.

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 software to determine the orientation of the grid to provide correct row and column labels.**

3. Toggle the **Images** icon ( ) to show and hide the underlying images acquired from the scan.

4. Select **Confirm** to verify the position and orientation of the selected marking grid.

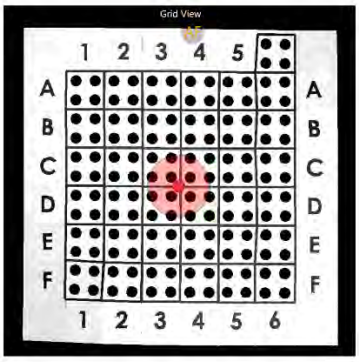
Confirm that entry points for all trajectories intersecting the selected grid have been defined correctly as shown in the dialog below. Failure to set the entry point on the surface of the skull may result in parallax error when identifying the mounting location for the frame.



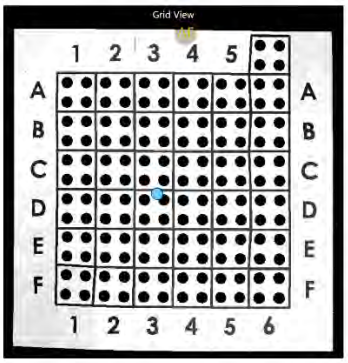
5. If the position and orientation of the selected marking grid does not match up with the underlying images, use the Grid task (see Grid Task *Editing Marking Grids* Pg. 174) to modify its position and orientation accordingly.

> **To find the frame mounting point on the patient**

1. After confirming the selected marking grid's position and orientation, a model of the grid underlay will be displayed in the bottom right viewport, along with the proposed mounting point. If the skull mount was specified when you created (see Splash Screen Pg. 79) or edited (see Using the Session Window Pg. 36) your session, then the **Burr Hole Center Point** will be displayed. If the scalp mount was specified when you created or edited your session, then the **Scalp Mount Center Point** will be displayed.



Burr Hole Center Point



Scalp Mount Center Point

2. You may toggle the display of the **Burr Hole Center Point** using the button regardless of which mount base you have specified in your current session.

3. You may toggle the display of the **Scalp Mount Center Point** using the button regardless of which mount base you have specified in your current session.

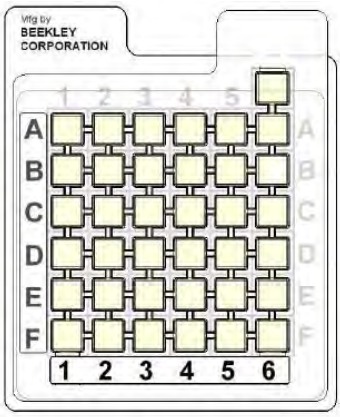
Realizing Mount Points

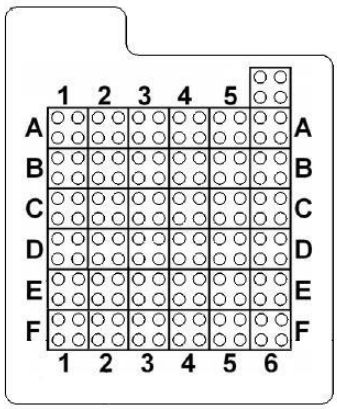
After you have identified the mount point(s) using the ClearPoint Workstation, locate the physical position of the mount point(s) on the patient.

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

1. Move the patient to the back of the scanner bore to provide access to their head.

2. Remove the top layer of the 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**

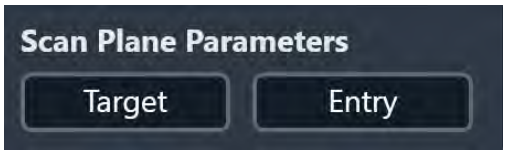
Caution:	**Do not proceed to the next workflow step until all the frame hardware has been mounted (both sides in the bilateral case) and the patient is ready to scan again.**

The Entry step also provides you with the ability to verify the mount points after the SMARTGrid(s) have been removed from the patient. There is a possibility of error in realizing the mount point(s), due to causes such as shift of the patient's scalp in between acquiring the image volume and marking the mount point.

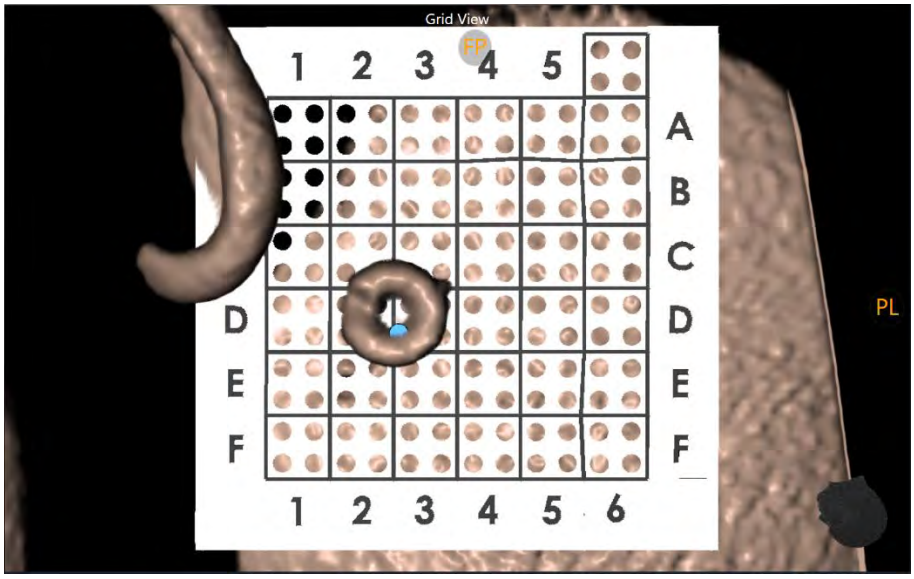
> **To verify the mount point(s) on the patient**

1. After marking the mount point of interest, place a sterile marker that will appear in an acquired MR image directly on the marked mount point.

2. Select the **Entry** scan plane parameters provided in the Entry step to acquire an image slab containing the marker (see Interoperation with MRI Scanner Pg. 18).



3. Load the image slab into the Entry step and compare the marker shown in the image with the annotation shown in the software.



4. If the marker is not within 2 mm of the burr hole center point (for skull mount) or the scalp mount center point (for scalp mount), reposition the marker and re-scan. Repeat as necessary. Use the Measure Line tool (see Measure Line Tool Pg. 58) to determine how far the image marker is from the 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 ClearPoint Workstation, 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 provided with the SMARTGrid to create a recognizable mark on the skull at the desired position for the entry point prior.

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

- Mounting the SMARTFrame — Mount the SMARTFrame according to the Instructions for Use provided. When it is complete, return the patient to the scanner and proceed to the Target step (see TIM _ INSERT LINK).

Scalp mounting:

- Attaching the scalp mount base - Consult the Instructions for Use provide with the scalp mount base.

Finalize Trajectories

This chapter describes how to use the ClearPoint Workstation to finalize the trajectory planning after one or more SMARTFrames has been mounted on the patient.

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

- The SMARTFrames have been mounted.
- The cannula for each frame has been locked in the “down” position.
- The patient has been returned to scanner isocenter.

Intraoperative Frame Images

Loading data into the Target step indicates that you will be finalizing your planned trajectories based on each of the SMARTFrames mounted onto the patient. The Target step supports image blending for series in the same or different frame of reference for purposes of finalizing your trajectories.

> **To load intraoperative images used for trajectory finalization with frames mounted**

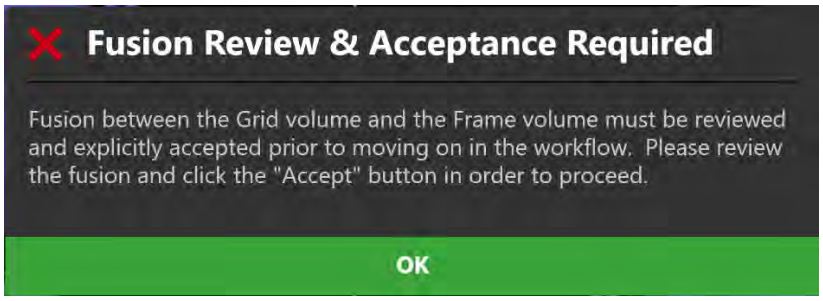
1. Select the Target step using the Workflow Selector (see Using the Workflow Selector Pg. 45).

2. Load data onto the ClearPoint Workstation (see Loading Images Pg. 84). At least one image set must support identification of the SMARTFrames(s) and desired entry and target points (i.e. a whole-head image volume with marking grid affixed). If the Entry or Pre-Op steps were not completed, at least one image set must also support accurate identification of the AC / PC landmarks and the mid-sagittal plane.

3. If you have completed the Entry step, the Target step will prompt you to fuse the master series from the Entry step with each of the image series loaded. This operation is similar to what is performed in the Entry step upon first receiving data (see Intraoperative Grid Images Pg. 101).

4. Use the pop-up Fusion task (see Fusion Task *Fusing Images* Pg. 155) to fuse the master series from the Entry step with each of the series just loaded into the Target step.

   If you attempt to dismiss the pop-up Fusion task prior to explicitly accepting the fusion between the Entry step's master series and each of the loaded image series, you will be prevented from doing so. The reason for this is that the application must transform the trajectories and anatomical reference points defined in the Entry step into the coordinate space defined by the interventional images containing the SMARTFrames.

5. Similar to the Entry step, the Target step will transform all trajectories and anatomical reference landmarks into the coordinate space defined by the intraoperative images containing the frames.

6. Similar to the Entry step, the Target step will automatically select the master series. 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. 155) to fuse the series together in order to allow for image blending functionality in this step.

7. The application will then perform an exhaustive search for all SMARTFrames(s) that may be mounted on the patient from the master series automatically selected. If neither the Pre-Op nor Entry steps have been completed, then the application will also automatically detect the anatomical reference points from the master series.

Target Step *Finalizing Trajectories*

The Target step allows you to finalize your planned trajectories after one or more SMARTFrames have been mounted on the patient. If you have completed the Entry step (see Entry Step *Locate Mounting Point* Pg. 103), then your planned trajectories will be imported upon first loading data into this step. Re-planning of your trajectories may be necessary due to brain shift which may have occurred due to the creation of one of more burr holes on the patient.

Like the Entry step, the Target step is also similar to the Pre-Op step (see Pre-Op Step *Setting Preoperative Trajectories* Pg. 85) in the tools provided for trajectory definition, planning and review. When images are loaded into the ClearPoint Workstation with the Target step selected, the application automatically detects the position of any SMARTFrame(s) that are mounted on the patient. Reviewing and verifying the location of the frame fiducial markers is required to ensure correct definition of each SMARTFrame mounted on the patient.

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

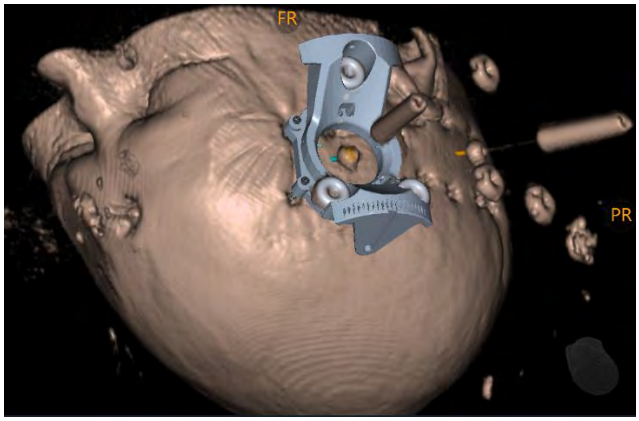
- The Fusion task (see Fusion Task *Fusing Images* Pg. 155) may be used to fuse additional image series that may be used for trajectory planning or frame detection / verification purposes that are not in the same frame of reference as the step's master series. If you load additional image series that are in the same frame of reference as the master series, no action is required.
- The ACPC task (see ACPC Task *Reviewing Landmarks* Pg. 160) may be used to review and / or modify the anatomical reference points automatically detected by the software. If Entry or Pre-Op steps were completed, these locations may need to be modified to account for brain shift that may have occurred as a result of burr hole creation.
- The VOI task (see VOI Task *Defining Volumes* Pg. 163) may be used to define one or more volumes of interest on intraoperative images for purposes of trajectory planning
- The Compare task (see Compare Task *Comparing Images* Pg. 172) 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. 179) may be used review and / or edit the positions of the fiducial markers for any defined

frames mounted on the patient. It can also be used to define additional frames that were not originally detected in the Target step.

The Target step is very similar to the Pre-Op step (see Pre-Op Step *Setting Preoperative Trajectories* Pg. 85), but with the following differences:

- The step will automatically search for all SMARTFrames on receiving data for the first time. If Entry or Pre-Op steps were completed, the entry points of the planned trajectories are used as starting points to search for the SMARTFrames.
- The step will import any trajectories and anatomical landmarks from either the Entry step (if completed) or Pre-Op step (if Entry step not completed) upon receiving data for the first time.
- In the Review layout (see Review Layout Pg. 92), the following differences exist:
  - A mechanism of selecting the SMARTFrame that you wish to review, verify and define trajectories for is provided.
  - 

  - An additional 3D viewport is shown illustrating a model of the selected SMARTFrame so that it can be reviewed / verified while showing the underlying images used to detect it.



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- When creating a trajectory in Pointwise (see Pointwise Layout Pg. 86) or Oblique & Pointwise layouts (see Oblique & Pointwise Layout Pg. 97), the default entry location will be defined automatically by the software at the bottom of the selected frame's targeting cannula.
  -
- The step will warn when trajectories are defined such that their entry points cannot be realized by a SMARTFrame X-Y adjustment. The trajectory line will be drawn in red and the following status message will be shown.
  -
  - 

  -
- The step provides scan plane parameters (see Interoperation with MRI Scanner Pg. 18) for the following additional scans:
  - Target - Parameters to acquire a scan that encapsulates target area(s) of the planned trajectories.
  -
  - Frame – Parameters to acquire a scan that can be used to detect and verify the selected frame's fiducial markers. This allows the software to refine identification of an existing frame or define a new one.

Finalizing Planned Trajectories

You may use additional scans, such as target or frame slabs, to provide better visualization of structures along the selected trajectory path.

> **To finalize your planned trajectories for frame alignment**

1. Select any viewing layout (see Selecting a Viewing Layout Pg. 48).

2. Navigate through all defined trajectories using the Trajectory Selector (see Selecting a Trajectory Pg. 48) and use the trajectory tools described in the Pre-Op step (see Pre-Op Step *Setting Preoperative Trajectories* Pg. 85) to review or edit each trajectory. You may also opt to add or remove trajectories as appropriate. Ensure that each trajectory's planned entry point lies within the physical X-Y limits of the frame (see Verifying Frames Pg. 118).

3. If desired, acquire target slabs using the **Target** scan plane parameters to finalize the target position for one or more trajectories (see Interoperation with MRI Scanner Pg. 18).

4. If desired, acquire frames slabs for the selected frame using the **Frame** scan plane parameters in order to verify the frame's position on the patient (see Verifying Frames Pg. 118).

5. If you completed the Entry step, use the trajectory line context menu to visually compare changes between the currently selected trajectory and the one that was imported from the Entry step (see Trajectory Line Context Menu Pg. 68).

Verifying Frames

Use the Target step's Review layout to verify the position and orientation of all SMARTFrames mounted on the patient. This process involves ensuring that the three fiducial markers in the base of the frame, as well as the ball marker at the distal end

of the targeting cannula have been correctly identified by the application. The 3D viewport in the viewing layout displays a model representing the currently selected SMARTFrame, which can be used to verify the position and orientation of its underlying fiducial markers.

> To select a frame

1. Select the Review viewing layout (see Selecting a Viewing Layout Pg. 48).

2. Use the **Frame** group box selector to select a frame for which you wish to review, verify and / or define trajectories.

3. The bottom right viewport of the Review viewing layout will display a 3D model of the frame base selected when you created (see Splash Screen Pg. 79) or edited your session (see Using the Session Window Pg. 36).

   Note: Any trajectories that are defined in the step where the target point is defined first will use the distal marker of the selected frame's targeting cannula as its default entry point.

> To verify frame detection

1. Select a frame whose position / orientation you wish to verify.

   If the software was unable to detect the position of one or more of the SMARTFrames mounted on the patient, you will see a warning message and the frame model will not be drawn in the bottom right viewport.

   In order to proceed with the workflow, you must define the location of each undetected frame in the software. Use the **Frame** scan plane parameters to acquire an image slab containing the selected frame's fiducial markers, and send it to the workstation. Upon receiving the image slab, the application will automatically attempt to identify the frame. You may also use the Frame task to

either manually or automatically identify the frame in any image series loaded with the Target step active.

2. Toggle the frame's visibility icon ( ) in the **Frame** group box to show and hide the frame model shown in the 3D viewport. This process can be used to determine if the frame's base model matches the fiducial markers in the underlying images. It is possible that distortion artifacts or signal attenuation in the image volume may cause the application to incorrectly identify the frame.

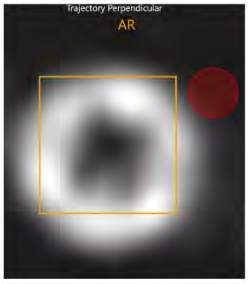
3. Use the slider bar in the **Frame** group box to change the opacity of the frame model shown in the 3D viewport. This process can supplement toggling the visibility of the model to observe if the frame's fiducial markers in the image correctly match the position and orientation of the frame model.

4. Select **Confirm** to verify the position and orientation of the selected frame.

5. A two dimensional square annotation will be drawn in the **Trajectory Perpendicular** viewport representing the physical extents of the frame's X-Y stage. This provides a visual indication on whether or not the planned entry point can be reachable by a SMARTFrame X-Y adjustment.

WARNING: **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.**

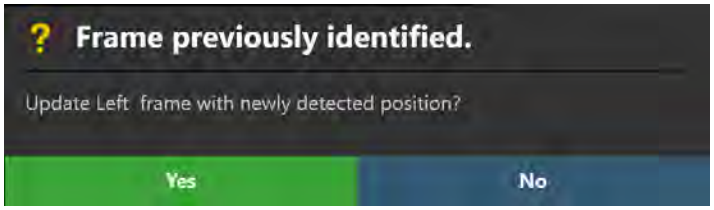
Valid Entry Point
Within X-Y Limits



Invalid Entry Point
Not Within X-Y Limits

6. If the position and orientation of the selected frame's fiducial markers do not match up with the underlying images, use the Frame task (see Frame Task *Editing Frame Markers* Pg. 179) to modify their positions accordingly. Alternatively, acquire frames slabs for the selected frame using the **Frame** scan plane parameters in the step panel and load them onto the workstation. The Target step will automatically detect the new positions of the frame's fiducial markers and will prompt you on whether or not you wish to update the frame with

the newly detected positions. Select **Yes** to update the frame with the newly detected positions. Select **No** to leave the frame's previous position intact.



Caution:	**Each time you update the position of a frame's cannula 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 cannula ball marker position.**

Align and Adjust Cannula

This chapter describes how to use the ClearPoint Workstation to position the cannula so that it is aligned to the desired trajectory.

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

- All planned trajectories have been defined, reviewed and verified.
- Each frame's fiducial markers have been defined, reviewed and verified.
- Each frame's cannula has been locked in the "down" position.

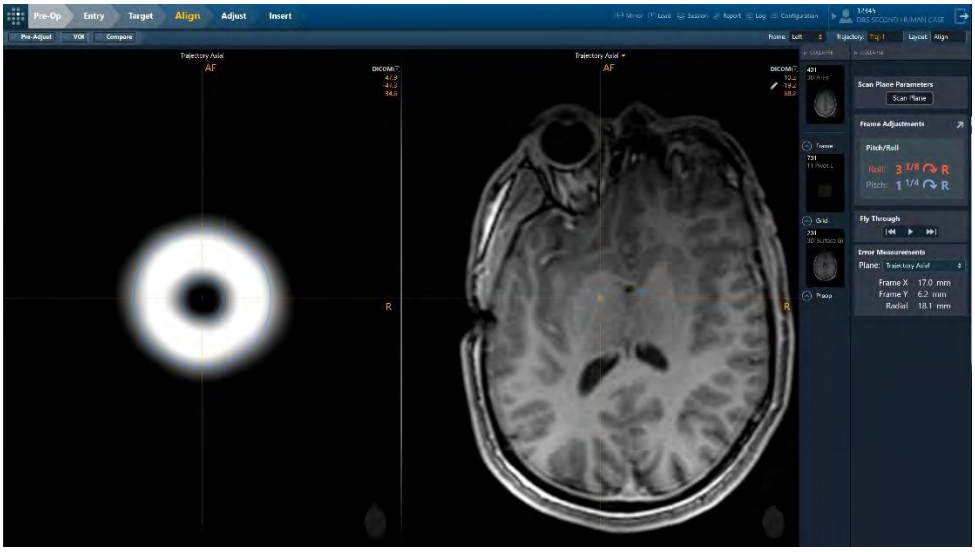
Align Step *Set the Cannula Angulation*

Use the Align step to modify the angulation of the cannula until it is roughly aligned with the planned target point. The required accuracy in this step is simply to align the cannula such that it will fall completely inside the narrow slab that is acquired in the subsequent Adjust step (see Adjust Step *Finalize the Cannula Position* Pg. 128). A projected error value below 2 mm should accomplish this.

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

- The Pre-Adjust task (see Pre-Adjust Task *Pre-adjusting the Cannula* Pg. 185) 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 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.
  •
- The VOI task (see VOI Task *Defining Volumes* Pg. 163) may be used to define one or more volumes of interest on intraoperative images for purposes of trajectory monitoring.
  •
- The Compare task (see Compare Task *Comparing Images* Pg. 172) may be used to compare intraoperative image series in their individual acquisition planes or standard scanner planes.
  •

To roughly align the cannula position to the planned target point, the step is used to acquire a single 2D image through the top end of the cannula with each adjustment to the angulation of the cannula. In instances where acquisition of a 2D slice is prohibited on the scanner, an entire image slab may be alternatively acquired. The Align step uses this acquisition to automatically detect the top end of the targeting cannula on the currently selected frame. The acquired images will be displayed in the left viewport, providing you with the ability to assess the top cannula detection result overlaid on the acquired images. You may override the detection result if the software incorrectly identified the top cannula position.



If the top end of the cannula was acquired as part of the frame (master) volume in the Target step (see Target Step *Finalizing Trajectories* Pg. 115) then the Align step will automatically detect it in order to provide a set of initial frame adjustment instructions prior to the cannula acquisitions.

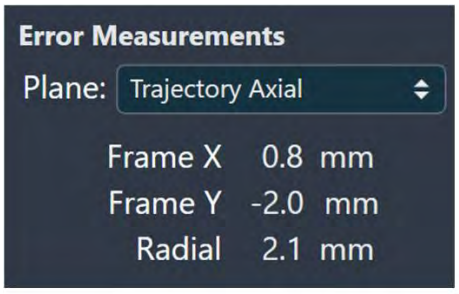
Frame Adjustments Panel

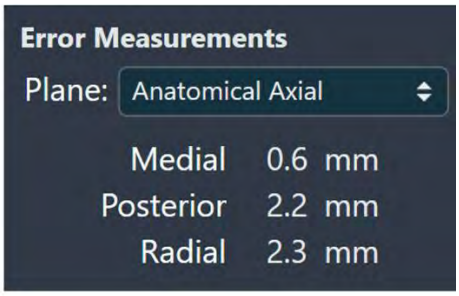
The **Frame Adjustments** panel shows the direction and number of rotations of the pitch and roll knobs required to align the cannula to the target. As the angulation of the cannula changes, so does the associated frame adjustment values. This panel can be expanded to display in a larger floating window for visualization on the in-room monitor.

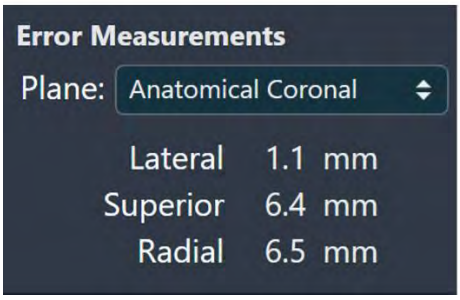
In the above example, the **Frame Adjustments** panel shows that the orange Roll knob should be rotated to the right by 3 and 3/8 turns. The blue Pitch knob should be rotated to the right by 1 and 1/4 turns.

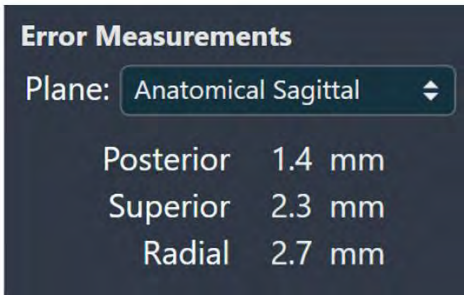
Error Measurements Panel

The **Error Measurements** panel allows you to view how the current cannula projection compares to the planned target on the selected error plane. As the angulation of the cannula changes, so do the associated error measurements.









In the above example, the **Error Measurements** panel shows that the current angulation of the cannula yields a placement that is:

- 2.1 mm away from the target on the **Trajectory Axial** plane. The direction of the error is broken up to show how much is contributed by the X and Y components of the selected frame for the target point of the currently selected trajectory.
- 2.3 mm away from the target on the **Anatomical Axial** plane. The direction of the error is broken up to show how much is contributed in the medial and posterior directions for the target point of the currently selected trajectory.
- 6.5 mm away from the target on the **Anatomical Coronal** plane. The direction of the error is broken up to show how much is contributed in the lateral and superior directions for the target point of the currently selected trajectory.
- 2.7 mm away from the target on the **Anatomical Sagittal** plane. The direction of the error is broken up to show how much is contributed in the posterior and superior directions for the target point of the currently selected trajectory.

The application always defaults to show projected cannula error measurements relative to the **Trajectory Axial** plane in order 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.

Aligning the Cannula

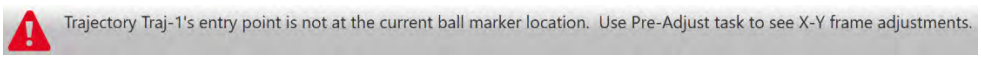
The Align step may be used to roughly align the cannula to the planned target point of the currently selected trajectory.

> **To align the cannula**

1. Select the frame that you wish to align to a planned trajectory (see Selecting a Frame Pg. 48).

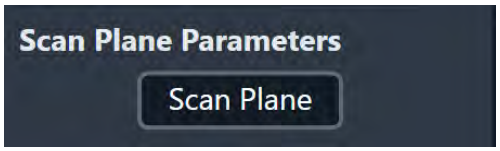
2. Select a planned trajectory associated with the frame (see Selecting a Trajectory Pg. 48).

3. Determine if pre-adjustments of the cannula are required prior to modifying its angulation. The application will display a warning message in cases where cannula pre-adjustments are recommended. Use the Pre-Adjust task (see Pre-Adjust Task *Pre-adjusting the Cannula* Pg. 185) to carry out the appropriate cannula pre-adjustments.



4. Change the viewport orientation to the desired viewing orientation (see Changing a Viewport Orientation Pg. 71).

5. Scan the top of the cannula using the scan plane parameters provided in the step panel (see Interoperation with MRI Scanner Pg. 18).



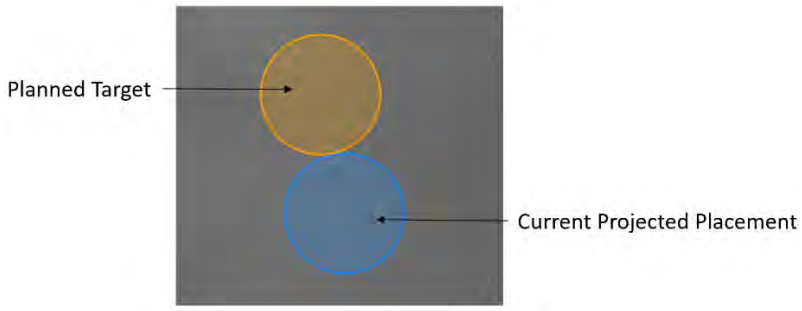
6. Send or load the images onto the workstation.

7. The application will automatically detect the top cannula position from the image(s) received.

With each acquisition, the new position detected for the top of the cannula causes the ClearPoint Workstation to recalculate the projected path that would be followed if a device were to be inserted at the current angulation. This path is extrapolated down to the selected viewport orientation containing the planned target.

8. The application draws annotations onto the target plane in which:

   - A blue circle shows the current projected placement for the device;
   - A circle which matches the color of the planned trajectory shows the planned target;
   -



Note: The diameter of the circles will be drawn to reflect any customization of the device diameter that may have been set earlier when working with the trajectory. Right-click on a circle to further customize the device diameter or to revert to the default device diameter of 2.1 mm.

9. The application displays the resultant error in the **Error Measurements** panel (see Error Measurements Panel Pg. 124).

10. Follow the instructions provided in the **Frame Adjustments** panel to make your adjustments (see Frame Adjustments Panel Pg. 123). The colors in the panel match the color of the knobs on the hand controller and the SMARTFrame.

11. Repeat adjustment and re-acquisition until the residual adjustment is less than a 1/8th turn for both pitch and roll and/or the total predicted error is less than 1.0 mm.

> **To manually override the cannula position**

1. If the top cannula position detected by the software appears incorrect in the left viewport, you may edit its position using the following techniques:

    - Drag the top cannula cross section annotation in the left viewport (see Editing Annotations Pg. 67).

    - Change the crosshair location (by any means) to the intended position and use the **Set Cannula Marker Point** tool () in the step's custom toolbar.

2. To undo any position edits made to the currently selected frame's top cannula position, use the undo / redo tools inset within the custom toolbar (see Editing Annotations Pg. 67).

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

1. In the **Fly Through** group box, select  to navigate to the selected trajectory's target point.

2. In the **Fly Through** group box, select  to navigate to the selected trajectory's entry point.

3. To automatically scroll from the selected trajectory's entry point to target point use the  button in the **Fly Through** group box. To stop automatic scrolling along the selected trajectory path, use the  button.

Adjust Step *Finalize the Cannula Position*

The Adjust step allows you to fine-tune the cannula angulation and position of the SMARTFrame to align it with the desired target point. To do this, use the MR scanner to acquire perpendicular image slabs along the length of the cannula. By identifying the position of the cannula within the image slabs, a projected point is calculated representing the point on the target plane that would be reached if it was inserted at the current position.

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

- The VOI task (see VOI Task *Defining Volumes* Pg. 163) may be used to define one or more volumes of interest on intraoperative images for purposes of trajectory monitoring.
  -
- The Compare task (see Compare Task *Comparing Images* Pg. 172) may be used to compare intraoperative image series in their individual acquisition planes or standard scanner planes.

The Adjust step provides 2 viewing layouts that are selectable via the Layout Selector (see Selecting a Viewing Layout Pg. 48): Adjust and 3D - Adjust.

Adjust Layout

The Adjust layout is used to perform detailed adjustment of the targeting cannula such that it is aligned with the currently selected trajectory's target point.

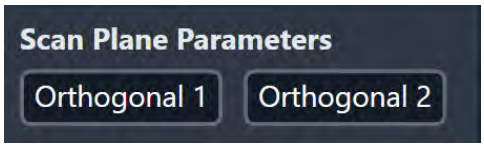
> **To adjust the cannula**

1. Select the frame that you wish to align to a planned trajectory (see Selecting a Frame Pg. 48).

2. Select a planned trajectory associated with the frame (see Selecting a Trajectory Pg. 48) to which you wish to align the cannula.

3. Change the viewport orientation to the desired viewing orientation (see Changing a Viewport Orientation Pg. 71).

4. 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 Scanner Pg. 18).



For Siemens scanners, a Table Position value is shown as part of the scan plane parameters for this step. In the 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. 21.

For IMRIS scanners, a Table Position should not be entered in this step. See Important Notes for Using IMRIS Scanners Pg. 24.

5. Enter the values on the scanner console, scan, and transfer or load the images onto the workstation.

6. On receiving the orthogonal image slabs, the application verifies:

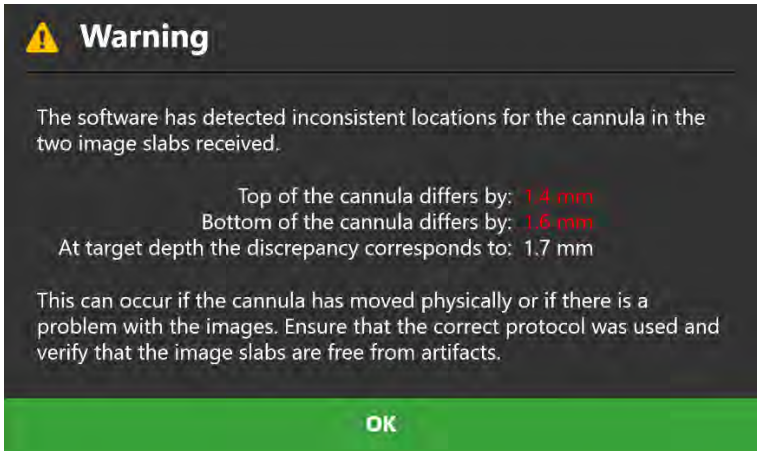
    - That the planned trajectory is contained completely within the slab. If not, the display displays a warning.

    - That the image slab was acquired using the scan plane parameters provided by the step.

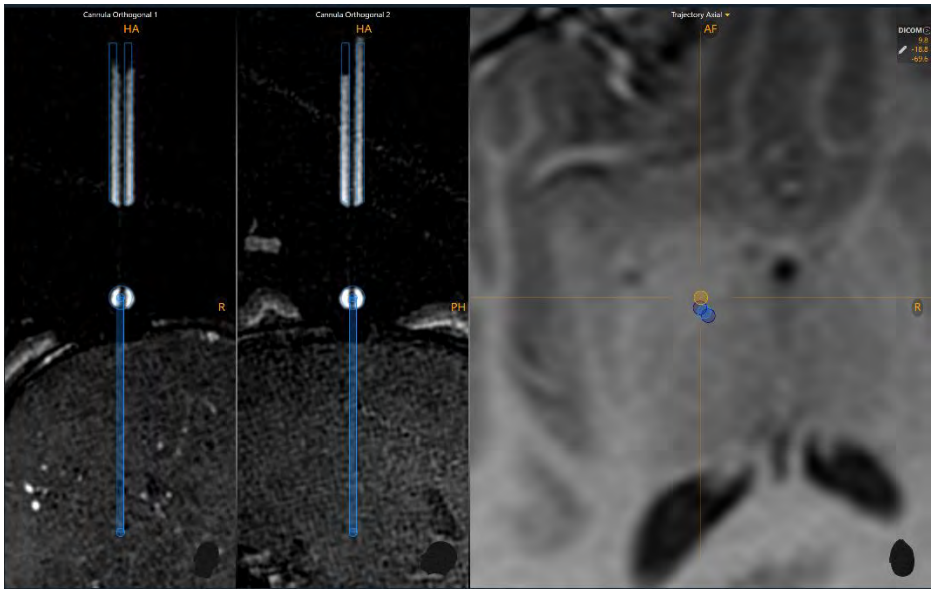
7. Once both slabs have been acquired and sent to the workstation, the software detects the position of the cannula in both image slabs. A check is then performed to verify that the detected positions in the two slabs agree. If they don't agree, this indicates that either the cannula moved between the two scans or, more likely, that the images are affected by geometric distortion.

   To assess the amount of discrepancy between the two image slabs, a warning message is shown with discrepancy measurements at the top of the cannula and at the bottom of the cannula. Numerical values shown in red indicate that they are beyond the configured tolerance. A green value is within tolerance.

   A third value is also provided that 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 distortion on the radial error when the device is inserted.

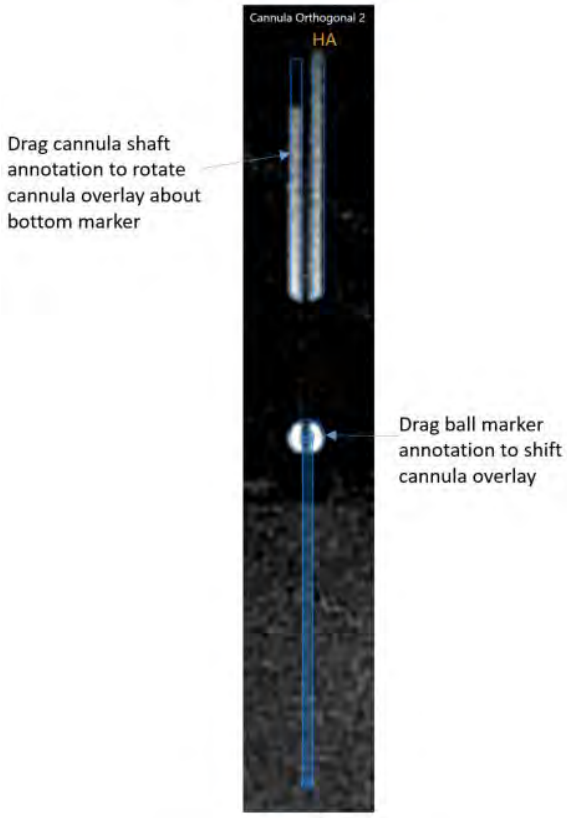


8. Next, the application shows the two slabs with an outline overlay of the cannula, and the projected target.



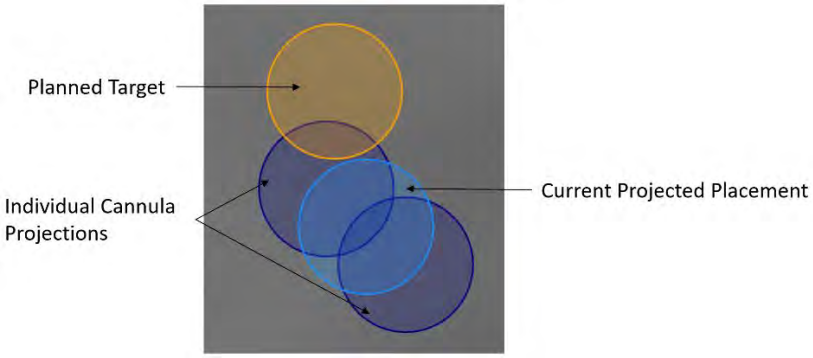
9. In these image slabs, verify that the cannula overlay is perfectly positioned on top of the image of the cannula in the two slabs. If you need to move the overlay:

    - Drag the cross section annotation 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 shaft cross section annotation to align with the upper shaft of the cannula in the underlying images. Fit the overlay 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. 56) and single/multi viewport tool (see Single / Multi Viewport Tool Pg. 63) to ensure the best possible match in both views.
    - To undo any position edits made to the currently selected frame's cannula position, use the undo / redo tools inset within the custom toolbar (see Editing Annotations Pg. 67).



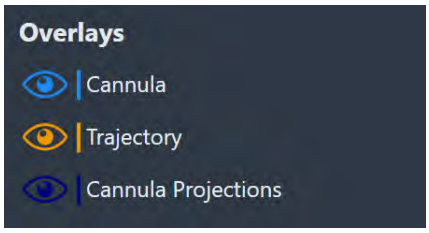
10. The application draws annotations onto the target plane in which:

    - A blue circle shows the current projected placement for the device;
    - A circle which matches the color of the planned trajectory shows the planned target;
    - Two blue circles show the projected placements for the device if the **Orthogonal 1** and **Orthogonal 2** scans are each considered in isolation. This can be useful to understand the difference when there is a discrepancy between the two results. The overall projected placement averages the two results together. Hover the mouse over each blue circle to show which image slab projects that point. A pop-up tooltip will indicate whether it's from the **Orthogonal 1** or **Orthogonal 2** scan.
    -



- *Note: The diameter of the circles will be drawn to reflect any customization of the device diameter that may have been set earlier when working with the trajectory. Right-click on a circle to further customize the device diameter or to revert to the default device diameter of 2.1 mm.*

11. You may toggle the visibility of the target plane annotations using the eyeball icons in the **Overlays** group box.



The position of the overlay is used to determine the projected target on the target plane. Once the overlay has been positioned to match the cannula in the image, the projected target represents the expected result if the device were to be inserted through the cannula. The interface will show the expected error and the necessary roll and pitch or X and Y offset adjustments required to reach the planned target.

12. The application displays the resultant error in the **Error Measurements** panel (see Error Measurements Panel Pg. 124).

13. Follow the instructions provided in the **Frame Adjustments** panel to make your adjustments (see Frame Adjustments Panel Pg. 123). The colors in the panel match the color of the knobs on the hand controller and the SMARTFrame.

Note: If the required X and Y adjustments are too large and are physically impossible, then Pitch/Roll adjustments will be shown. You may toggle displaying X/Y or Pitch/Roll adjustments as desired.

Note: X and Y offset adjustments will result in a change to the entry point.

14. Repeat this procedure (i.e. repeat scan acquisition, positioning of the overlay and the adjustment of the cannula) until the projected target is clinically acceptable.

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

1. In the **Fly Through** group box, select  to navigate to the selected trajectory's target point.

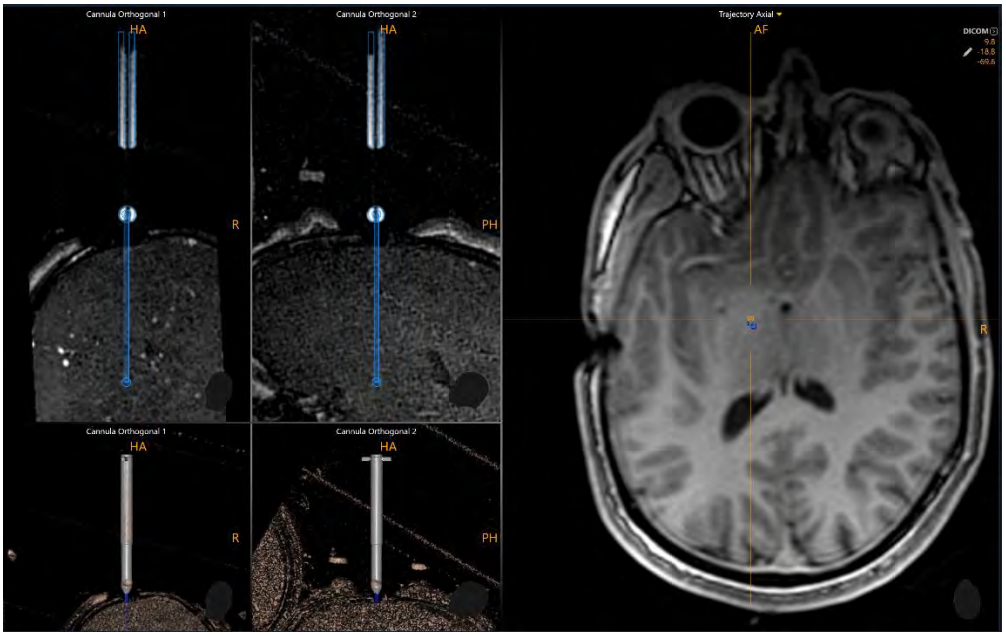
2. In the **Fly Through** group box, select  to navigate to the selected trajectory's entry point.

3. To automatically scroll from the selected trajectory's entry point to target point use the  button in the **Fly Through** group box. To stop automatic scrolling along the selected trajectory path, use the  button.

3D – Adjust Layout

The 3D - Adjust layout is very similar to the Adjust layout, except that it displays two additional 3D views of the cannula slabs to help you assess potential geometric distortion artifacts in the underlying images. These additional views display 3D representations of the image slabs as well as the cannula models to allow for visual comparison between the two.

Caution:	**If the image slab of the cannula does not appear straight, this may indicate that there is a geometric distortion in the acquired images. If this occurs, the images should not be used to align the cannula. You will need to acquire undistorted image slabs in order to accurately align the cannula to the trajectory.**



> **To assess distortion artifacts in the cannula slabs**

1. Use the Window Width/Level tool (see Window Width and Level Tool Pg. 55) to clearly see the cannula model and associated ball marker in the underlying images.

2. Compare the cannula model with the underlying images and assess for any potential geometric distortion artifacts.

Insert Device

This chapter describes how to use the ClearPoint Workstation to monitor and assess the placement of one or more devices into the brain.

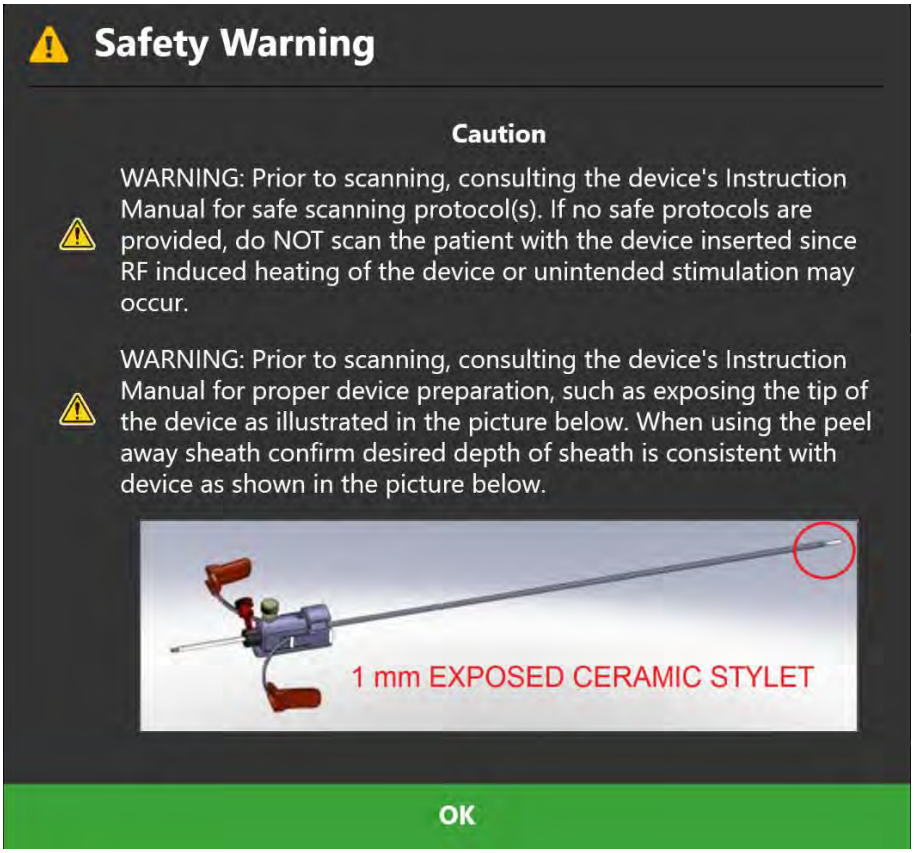
Caution:	**This chapter describes optional workflow that is not required to complete a neurological procedure. It is only to be performed if the manufacturer's instructions for the inserted device provide a safe scanning protocol. If no safe protocols are provided, the procedure must be completed without 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 planned trajectory which you plan to insert the device(s) along must have its associated cannula project to a clinically acceptable position into the brain that has been reviewed and verified.
- The frame's cannula must be locked in the "down" position.
- Safe scanner protocols must be configured on the scanner and verified to be safe for clinical use.

Preparing the Device

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



Measuring Device Depth Stop

Before you insert the device into the cannula, you need to measure and mark the depth.

The depth value required to reach the specified target is provided in the Insert step panel (see Insert Step *Monitor and Assess Device Placement* Pg. 138). If you wish to stop your insertion prior to reaching the target point itself, subtract the desired offset from the values provided and then set the stop (see Depth Stop if using Stylet / Peel-Away Sheath) appropriately. Also, at any point during the insertion, you can acquire a new slab and use the Measure Tool to determine the distance from the tip to the planned target.

At this point, you should introduce the device into the cannula.

As you insert the MRI Conditional device into the brain, you can continue scanning and using the application to evaluate the insertion.

Insert Step *Monitor and Assess Device Placement*

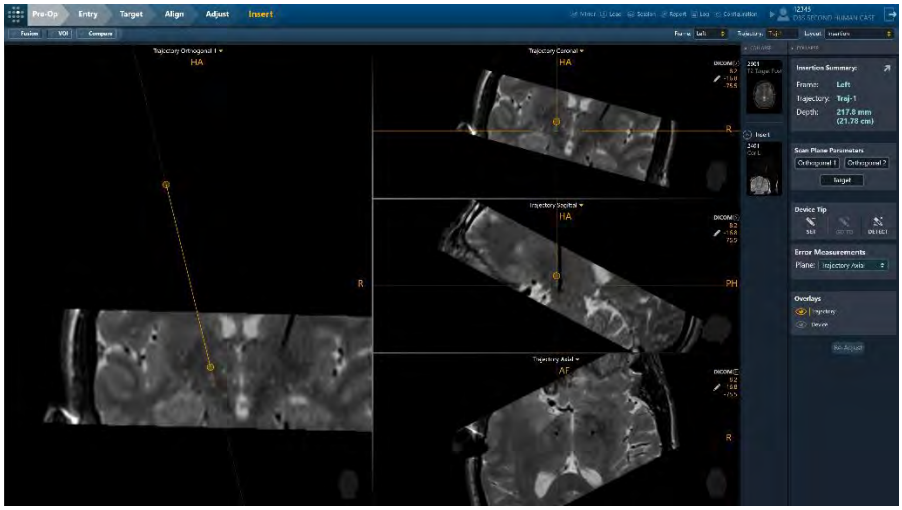
The Insert step allows you to assess partial or completed device insertions into the brain.

Caution:	**This is an optional workflow step. 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.**

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

- The Fusion task (see Fusion Task *Fusing Images* Pg. 155) may be used to fuse additional image series that contain the insert 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. This workflow is typical for IMRIS scanners (see Important Notes for Using IMRIS Scanners Pg. 24).
  -

- The VOI task (see VOI Task *Defining Volumes* Pg. 163) may be used to define one or more volumes of interest on post-insertion / post-operative images for purposes of treatment monitoring.
  -
- The Compare task (see Compare Task *Comparing Images* Pg. 172) may be used to compare post-insertion / post-operative images in their individual acquisition planes or standard scanner planes.
  -
  -



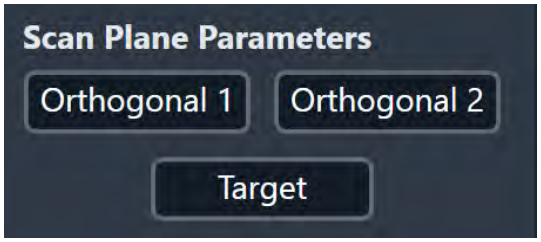
  - The Insert step provides 4 viewing layouts that are selectable via the Layout
  - Selector (see Selecting a Viewing Layout Pg. 48):
  -
- Insertion – Viewing layout specific to the Insert step which allows you to qualitatively or quantitatively assess a partial or completed device insertion.
  -
- Pointwise – Viewing layout similar to other steps (see Pointwise Layout Pg. 86) which allows you to individually set the position of the device tip and compare to the planned trajectory.
  -
- Review – Viewing layout similar to other steps (see Review Layout Pg. 92) which allows you to set the device tip in views orthogonal to the planned trajectory or device paths.
  -
- Pointwise & Oblique – Viewing layout similar to other steps (see Oblique & Pointwise Layout Pg. 97) which allows you to set the device tip in either Pointwise or Review layouts.

Monitor Insertion Progress

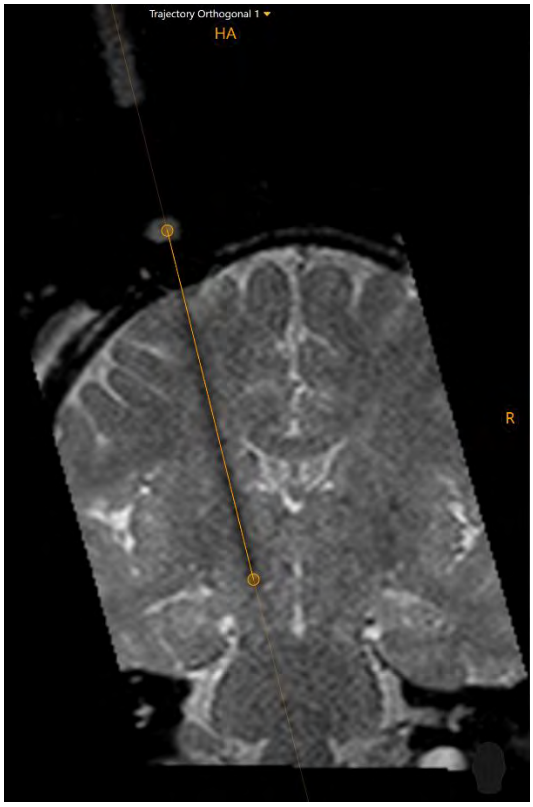
You may use the Insert step to monitor the progress of a device insertion. Scans may be acquired with the device partially inserted to qualitatively or quantitatively assess the projected device path into the brain.

> **To monitor a device insertion**

1. Select the frame for inserting the device. (see Selecting a Frame Pg. 48).
2. From the trajectories associated with the selected frame, select one for insertion. (see Selecting a Trajectory Pg. 48).
3. Use the **Scan Plane Parameters** group box to acquire oblique slabs that are aligned to the planned trajectory. In the Scan Plane Parameters panel, click **Orthogonal 1** and **Orthogonal 2** to obtain scan plane values for the scanner console (see Interoperation with MRI Scanner Pg. 18).



4. Send or load the images onto the workstation.
5. On receiving the orthogonal image slabs, the application verifies that the planned target is contained completely within the slab. If so, the application displays the orthogonal scan data with an overlay graphic indicating the planned trajectory. If not, the application will display a system warning and will not display the data.
6. The application displays the received scans with the trajectory line drawn as an overlay. In the image, the signal void from the inserted device should appear perfectly aligned to the trajectory line.



Caution:	**You should acquire slabs multiple times during the insertion. These images provide assurance that the inserted device is actually following the planned trajectory. Frequent scans may also help with the early detection of hemorrhage.**

The most-recently acquired Orthogonal 1 or Orthogonal 2 slabs will be automatically connected to the viewing layout upon receiving new data. You may change the currently selected image series using the Thumbnail Bar in the step.

Assess Device Placement

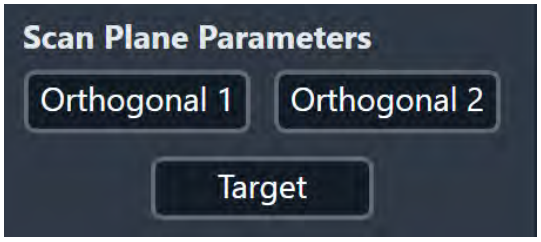
The Insert step may also be used to assess the placement of a partially or fully inserted device.

> **To evaluate the placement of the device**

1. Select the frame used for insertion (see Selecting a Frame Pg. 48).

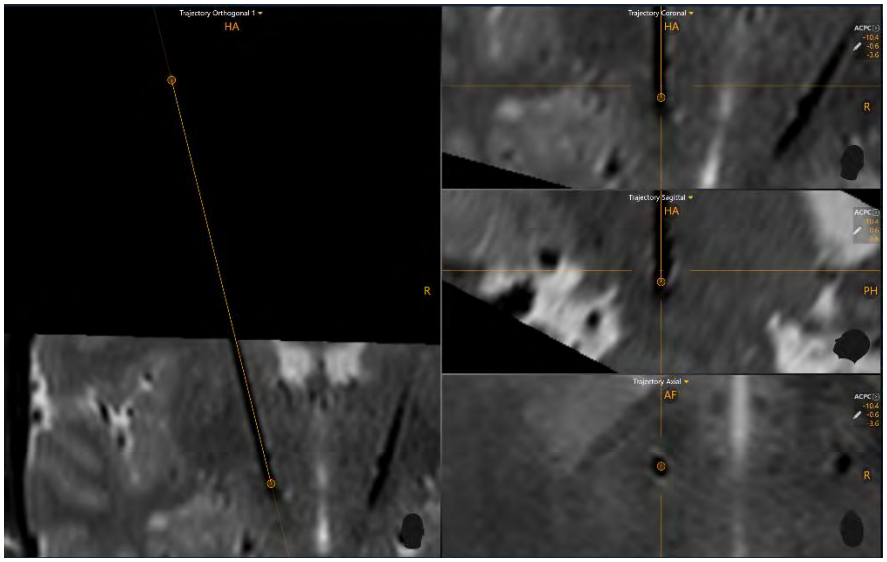
2. Select a planned trajectory used for insertion (see Selecting a Trajectory Pg. 48).

3. Use the **Orthogonal 1** and **Orthogonal 2** scan plane parameters in the **Scan Plane Parameters** group box to acquire oblique slabs that are aligned to the planned trajectory. Alternatively, use the **Target** scan plane parameters to acquire slabs that are centered on the planned target and extend far enough above and below the target level to provide you with the ability to visualize the tip of the inserted device with appropriate anatomical context.



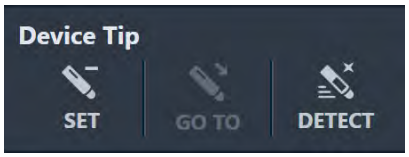
4. Send or load the images onto the workstation.

5. On receiving the scans, the application verifies that the planned target is contained completely within the slab, and if not, will reject the data. The viewing orientation of the layout is automatically set to **Trajectory** in order to assess the placement of the device along the planned trajectory path. The signal void from the inserted device should appear aligned to the trajectory path.



6. Change the viewport orientation to the desired viewing orientation that you would like to use to set the device tip (see Changing a Viewport Orientation Pg. 71).

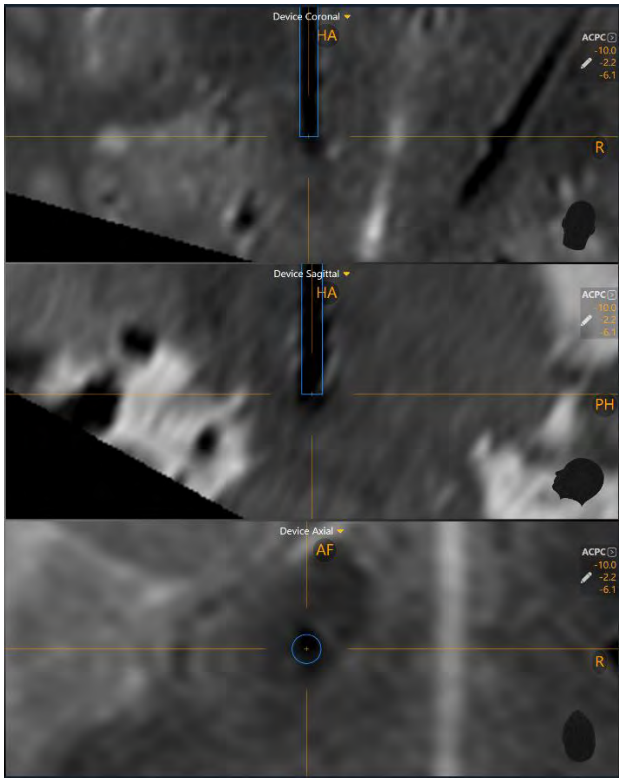
7. You may opt to either manually or automatically identify the tip of the inserted device using the **Device Tip** group box in the step's side panel.



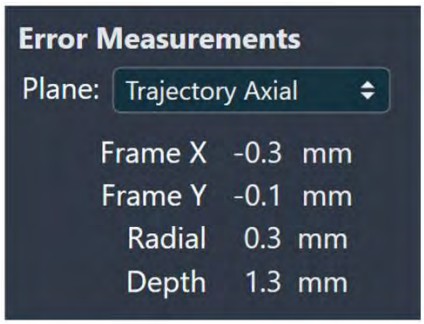
8. To automatically identify the tip of the inserted device in the selected image series, select **DETECT** from the **Device Tip** group box in the step side panel or use **Segment Device Tip** from the custom toolbar. A floating window will display a **Please Wait** message and the task user interface will be blurred.

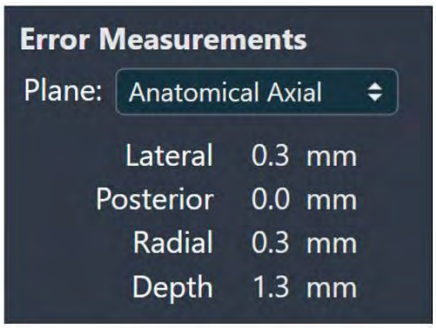
9. To manually set the tip of the inserted device, select **SET** from the **Device Tip** group box in the step side panel or use **Set Device Tip** from the custom toolbar.

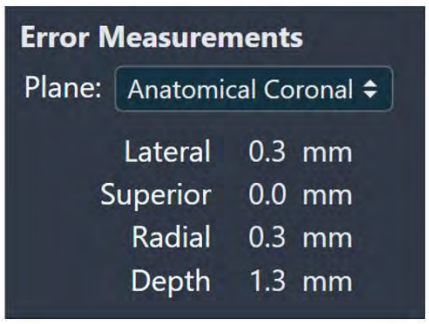
10. After identifying the inserted device tip, the application will automatically change the viewing orientation of the layout to **Device**. The viewports will be oriented along the path of the inserted device. Annotation cross sections of the device will be rendered in the viewports.

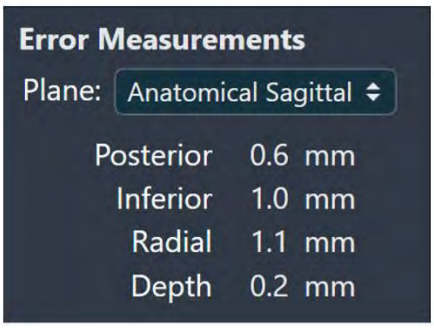


11. Once the tip has been identified, the Error Measurements panel (see Error Measurements Panel Pg. 124) enables you to select one of the following error planes to view error measurements.









For each selected error plane, its in-plane 2D radial error can be decomposed into two components:

- If the selected plane is **Anatomical Axial**, the two axes used for the decomposition 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 for the decomposition 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 for the decomposition are coronal and axial, and the corresponding labels for the error are anterior/posterior, and superior/inferior respectively.
- Insertion Depth – The distance along the device axis between device tip and the intersection of the device axis with the selected anatomical plane through the target (target plane). Negative values indicate that the device is shallow relative to the target plane, positive indicates that it has been inserted past the target plane.
- 2D 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.

> **To review the device tip position**

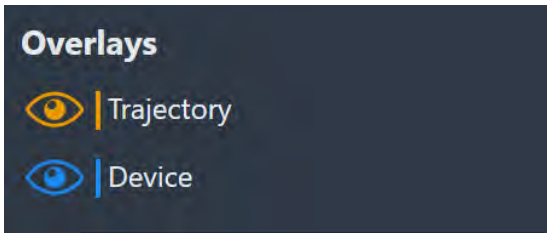
1. Change the viewing layout to the desired layout that you would like to use to review the device tip position (see Selecting a Viewing Layout Pg. 48).

2. Change the viewport orientation to the desired viewing orientation that you would like to use to review the device tip (see Changing a Viewport Orientation Pg. 71).

3. Select an image series for which to review the defined device tip using the Thumbnail Bar (see Using Thumbnails Pg. 74).

4. To reposition your crosshairs on the currently selected device tip, use the **Go To Device Tip** tool from the custom toolbar (see Using Custom Toolbars Pg. 52).

5. You may toggle the visibility of the target and device annotations using the eye ball icons in the **Overlays** group box.



> **To modify the device tip position**

1. Change the viewing layout to the desired layout that you would like to use to modify the device tip position (see Selecting a Viewing Layout Pg. 48).

2. Change the viewport orientation to the desired viewing orientation that you would like to use to set the device tip (see Changing a Viewport Orientation Pg. 71). Use the viewing orientation to review the device tip position.

3. Edit the device tip using the following mechanisms:

   - Reposition the crosshairs in the viewports (see Changing Crosshair Positions Pg. 66) to a location where you would like to set the device tip. Use the **Set Device Tip** in the custom toolbar (see Using Custom Toolbars Pg. 52) to set the device tip at the current crosshair position.

   - If the viewport is set to the **Device** orientation (see Changing a Viewport Orientation Pg. 71), the following mechanisms can be used to edit the device tip in **Device Coronal** and **Device Sagittal** viewports:

- Drag the end point of the device path to a new location within the viewport (see Editing Annotations Pg. 67).
- Hold down the CTRL key while moving the device path end point to constrain the movement to shift along the current direction of the device.
- Drag the device path in between its end points (i.e. on the device path cross section) to cause the device's end point to pivot about the currently selected frame's ball marker.
- Hold down the ALT key while dragging in between the device path end points (i.e. on the device path cross section), to shift the entire device path.
-

- If the viewport is set to the **Device** orientation (see Changing a Viewport Orientation Pg. 71), the following mechanisms can be used to edit the device tip in the **Device Axial** viewport:
  - Drag the cross section anywhere along the device path to cause the device's end point to pivot about the selected frame's ball marker.
  -

4. To undo any position edits made to the currently selected device tip position, use the undo / redo tools inset within the custom toolbar (see Editing Annotations Pg. 67).

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:	**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, you may opt to re-adjust the cannula and re-insert the device (see Device Re-Insertion and Bias Compensation Pg. 148).

> **To reject a device placement**

Select **Re-Adjust** from the step panel

Device Re-Insertion and Bias Compensation

This chapter describes how to use the ClearPoint Workstation to reject a device placement and re-insert the device.

Bias Compensation Determination

If you choose to reject the device placement and re-insert the device, you can use *bias compensation* to correct for a systematic scan distortion.

Prior to using bias compensation, you must first determine whether bias compensation will improve the placement. Points that need to be considered are:

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.

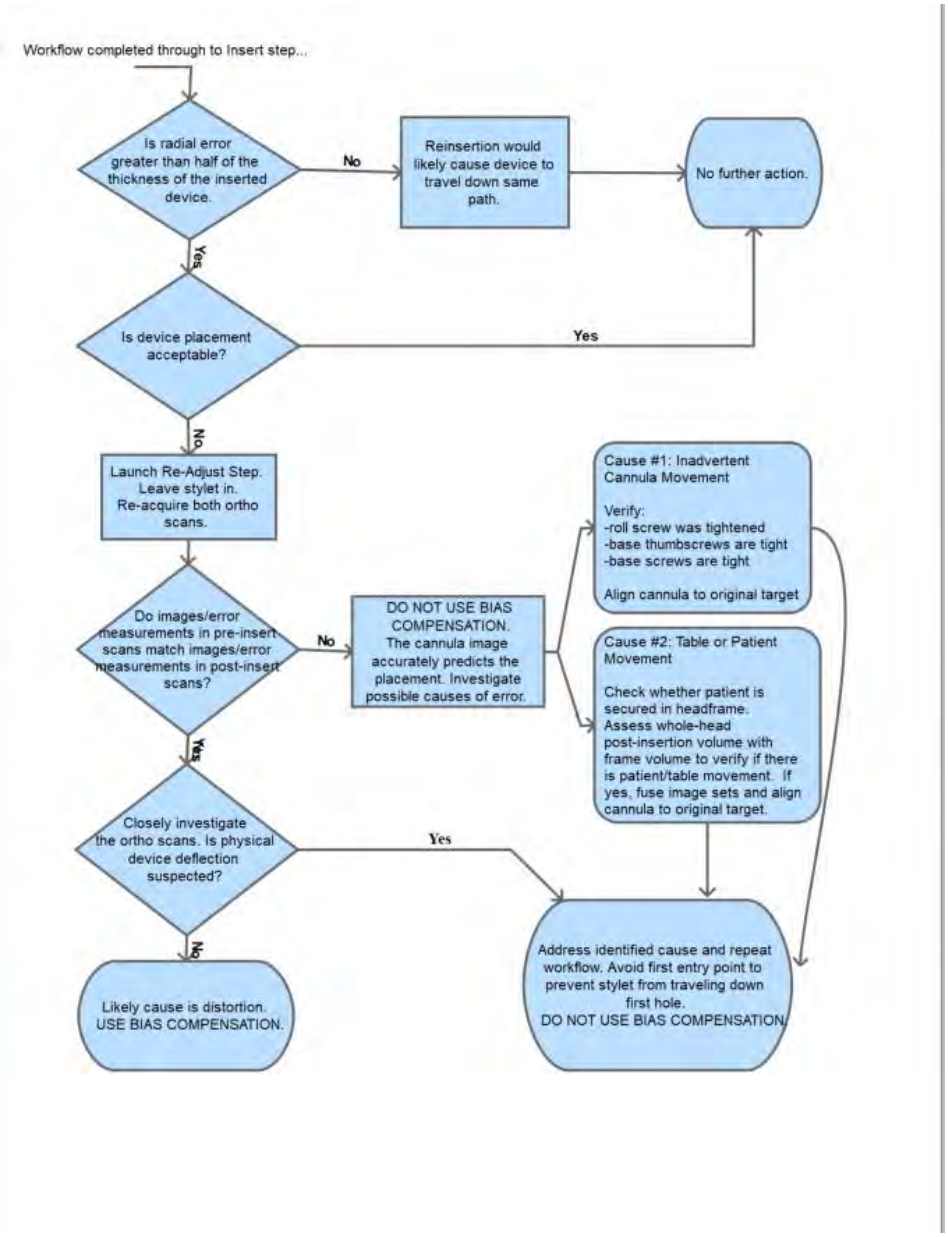
Caution:	**Re-inserting the device introduces the possibility of following a previous insertion track. If necessary, perform a manual X/Y adjustment to ensure that the device will insert along a new track.**

2. What is the source of the error? Possibilities include:

    - Accidental movement of cannula
    - Movement of frame on patient
    - Movement of patient in fixation
    - Movement of table in scanner
    - Device deflection on skull or dura
    - Geometric distortion of images – 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 image volume has been identified.**

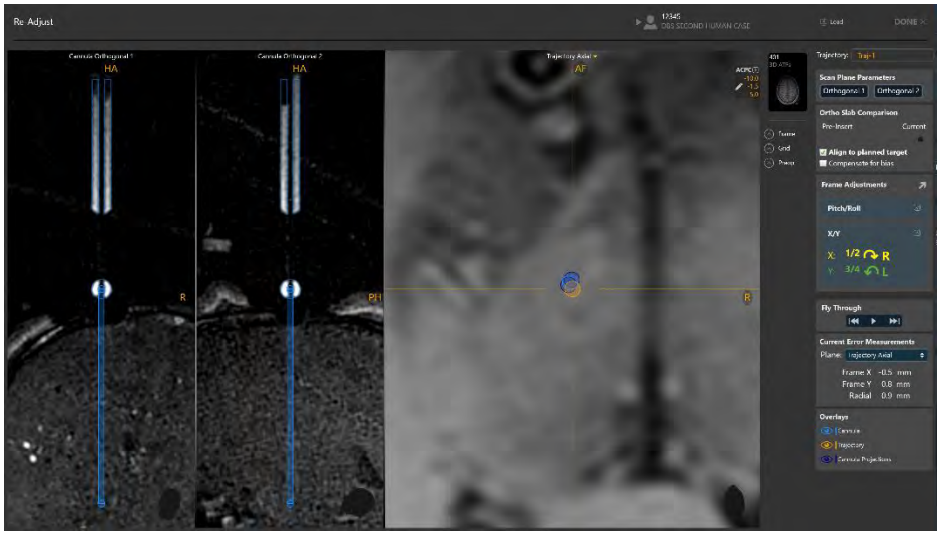
The following flowchart describes how to decide whether bias compensation is appropriate.



Re-Adjust Step *Managing a Device Re-Insertion*

The Re-Adjust step allows you to correct cannula positioning after a device placement has been deemed clinically unacceptable.

Caution:	**You must remove the inserted device prior to performing any further adjustments of the cannula.**

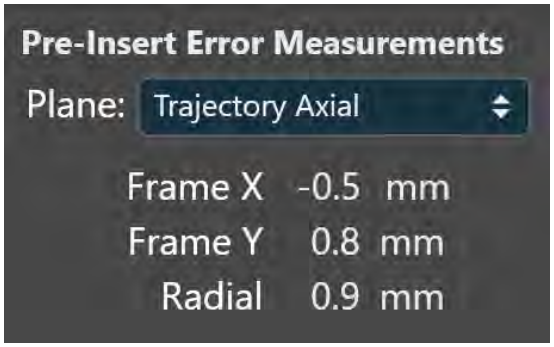
- 

  - The Re-Adjust step provides a viewing layout similar to the Adjust step (see Adjust Step *Finalize the Cannula Position* Pg. 128).

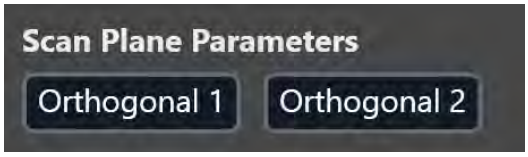
> **To re-adjust the cannula**

1. Launch the Re-Adjust step by selecting **Re-Adjust** in the Insert step (see Accept or Re-Adjust Placement Pg. 147).

2. The viewing layout will display the most recent set of orthogonal cannula scans that were last acquired for the selected trajectory's associated frame. These acquisitions were sent when the Adjust step (see Adjust Step *Finalize the Cannula Position* Pg. 128) was completed for the selected trajectory. The step will display the residual error measurements achieved using these orthogonal cannula scans.



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 Scanner Pg. 18).

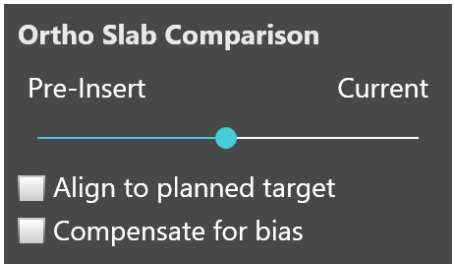


4. Enter the values on the scanner console, scan, and transfer or load the images onto the workstation.

5. On receiving the orthogonal scans, the application performs the same set of operations as described in the Adjust step (see Adjust Step *Finalize the Cannula Position* Pg. 128) in order to detect the current position of the targeting cannula.

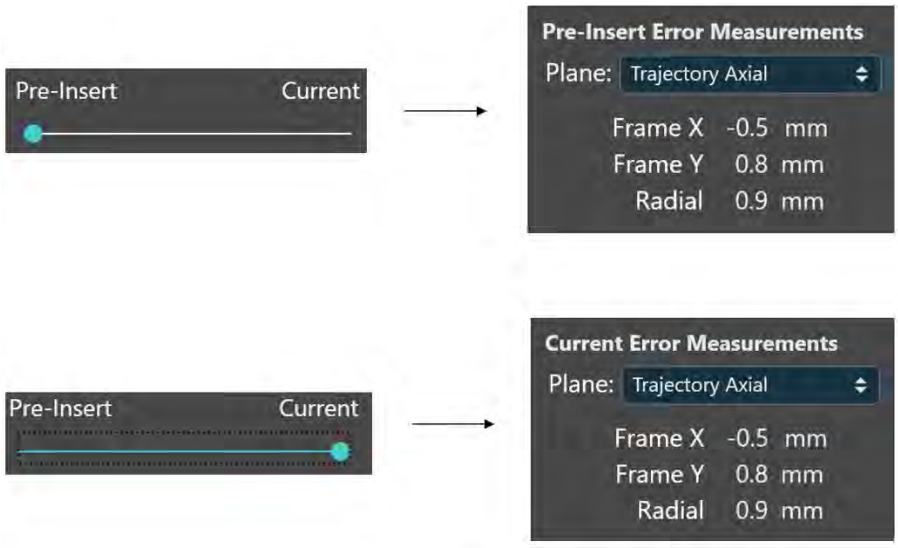
6. Use any of the tools discussed in the Adjust step to review the current position of the cannula and manually position it if necessary (see Adjust Step *Finalize the Cannula Position* Pg. 128).

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:

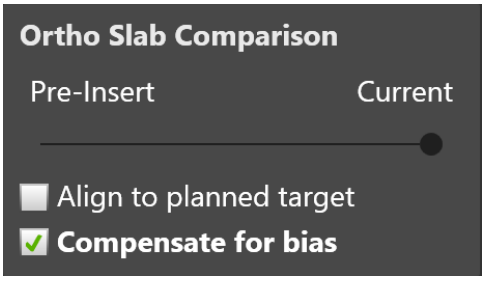
    - If the device placement was caused by inadvertent cannula movement, verify that the frame's roll locking screw, base thumbscrews and base screws have been tightened appropriately. Select the **Align to planned target** checkbox to show the frame instructions required to align the cannula to the originally planned target point (see Frame Adjustments Panel Pg. 123).

    - 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. Select the **Align to planned target** checkbox to show the frame instructions required to align the cannula to the originally planned target point (see Frame Adjustments Panel Pg. 123).

- If the device placement was caused by device deflection, 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. Select the **Compensate for bias** checkbox to show the frame instructions required to align the cannula to the bias compensate target (see Frame Adjustments Panel Pg. 123).



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.

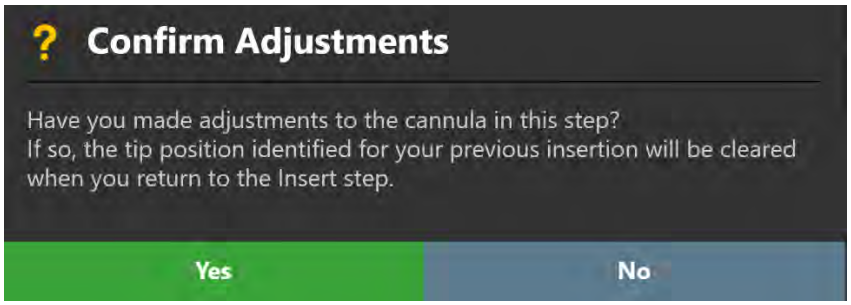
WARNING: **Bias compensation will only work properly when the error to be corrected is a consistent bias rather than random error or a one-time occurrence. When using bias compensation, additional scans are recommended during the subsequent insertion to verify that the inserted device is in fact following the desired trajectory.**

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* Pg. 128.

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.

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 adjustment 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.



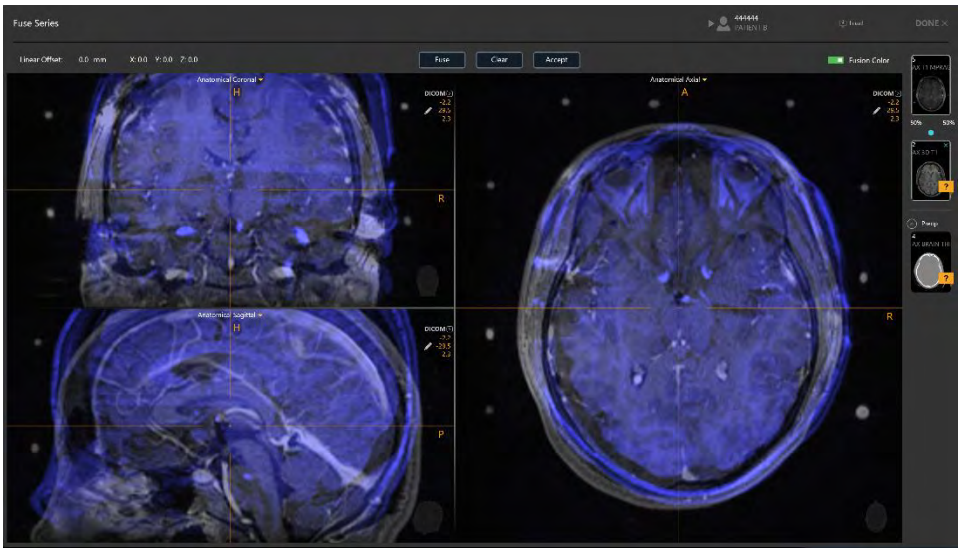
13. Proceed with the insertion of the device (see Insert Device Pg. 136).

Optional Tasks

This chapter 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 different sets of image into a single coordinate system so that they can be blended together regardless of the frame of reference in which they were acquired. If images with different frames of reference are loaded, they will be disabled within the step's Thumbnail Bar until they have been fused with the master series. The ClearPoint Workstation offers you the ability to perform this image fusion automatically using a built in software library, or manually using several tools provided in the Fusion task. Once fused with the master series, any image series will then be available for selection within the Thumbnail Bars for all other steps and tasks.



> **To select an image series to fuse**

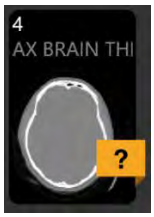
1. Select an image series from the group of thumbnails in the Thumbnail Bar (see Using Thumbnails Pg. 74). The master series will be set automatically based on

the master series defined in the underlying workflow step. You may not change the master series selection in the Fusion task.

2. The image series to fuse will appear in the fusion thumbnail slot and its underlying images will be displayed in color within the viewports as to be easily distinguished from the master series when blended together.

3. To turn off the fusion color, select the **Fusion Color** toggle switch from the task panel. To turn fusion color back on, select the **Fusion Color** toggle switch again.

4. To select a new image series to fuse with the master series, select another image series in the Thumbnail Bar. Any image series that is not registered with the master will display a question mark icon beside the image series thumbnail in the Thumbnail Bar.



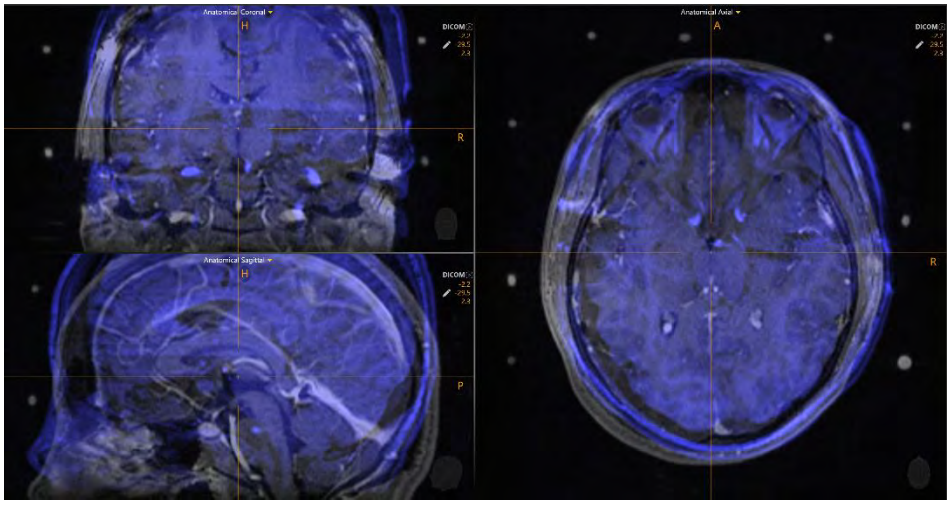
Automatic Fusion

You may use the Fusion task to automatically fuse an image series to the master series.

> **To exercise automatic fusion**

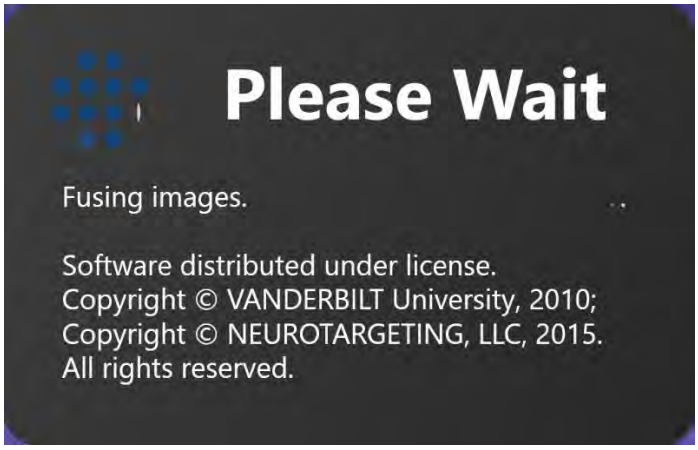
1. Launch the Fusion task using the Task Selector (see Selecting a Task Pg. 49)

2. Select an image series to fuse using the Thumbnail bar (see Using Thumbnails Pg. 74).

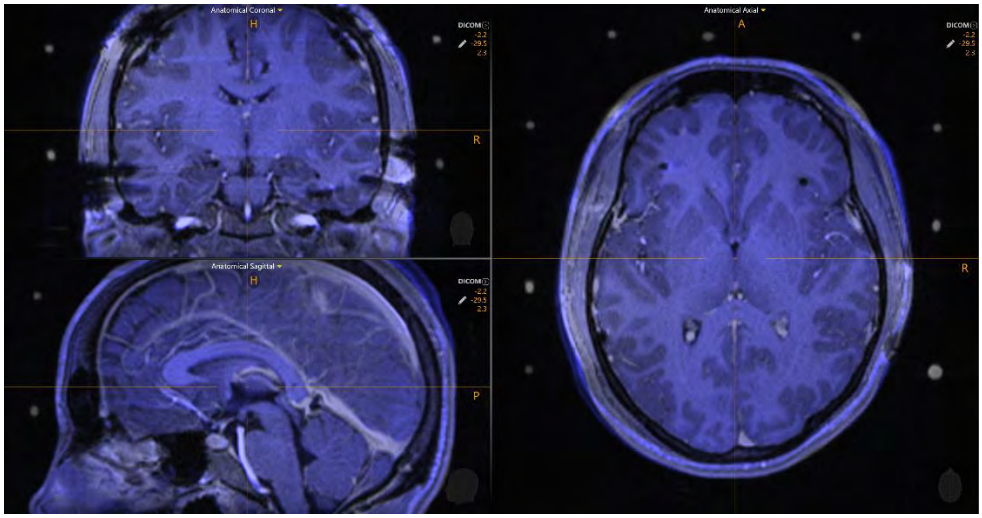


3. Select **Fuse** from the task panel.

4. A floating window will display a **Please Wait** message and the task user interface will be blurred.



5. After the automatic fusion completes, the results will be displayed within the viewports. A status message will pop-up indicating that the automatic fusion process has completed successfully.



> **To review the fusion result**

1. Use image blend tools (see Image Blend Tools Pg. 60) within the task's viewports to review the automatic fusion result.

2. Review the fusion offset values in the task panel, to understand the linear distance differences (in millimeters) found between the two images series once registered.

3. If the resulting fusion appears correct, select **Accept** from the task panel. A checkmark icon will appear beside the image series thumbnail in the Thumbnail bar.

4. If the resulting fusion appears incorrect, you may use the manual fusion tools (see Manual Fusion Override Pg. 159) to modify the result until it appears correct within the viewports. After your manual adjustments have been completed, select **Accept** from the task panel.

5. If the resulting fusion appears incorrect and you wish to reset it to what it was before exercising an automatic fusion, select **Clear** from the task panel.

Manual Fusion Override

The Fusion task may also be used to either override an automatic fusion result or manually define a fusion between two image sets.

> **To manually override a fusion result**

1. Use the **Fusion Pan** tool in the task's custom toolbar to pan the fusion series (i.e. introduce a translational component to the fusion transformation) relative to the master series. To use the **Fusion Pan** tool:
    - Select the  button from the custom toolbar
    - Click and drag the fusion image to change its position relative to the master.
2. Use the **Fusion Rotate** tool in the task's custom toolbar to rotate the fusion series (i.e. introduce a rotational component to the fusion transformation) relative to the master series. To use the **Fusion Rotate** tool:
    - Select the  button from the custom toolbar
    - Click and drag the fusion image to change its orientation relative to the master.
3. Use the **Fusion Undo** and **Fusion Redo** tools to undo or redo any changes made to the fusion shown on screen.
    - Select the  button from the custom toolbar to undo a change to the fusion shown on screen.
    - Select the  button from the custom toolbar to redo a change to the fusion shown on screen.

> **To review an override fusion**

Use the same techniques outlined when reviewing an automatic fusion result (see Automatic Fusion Pg. 156.

ACPC Task *Reviewing Landmarks*

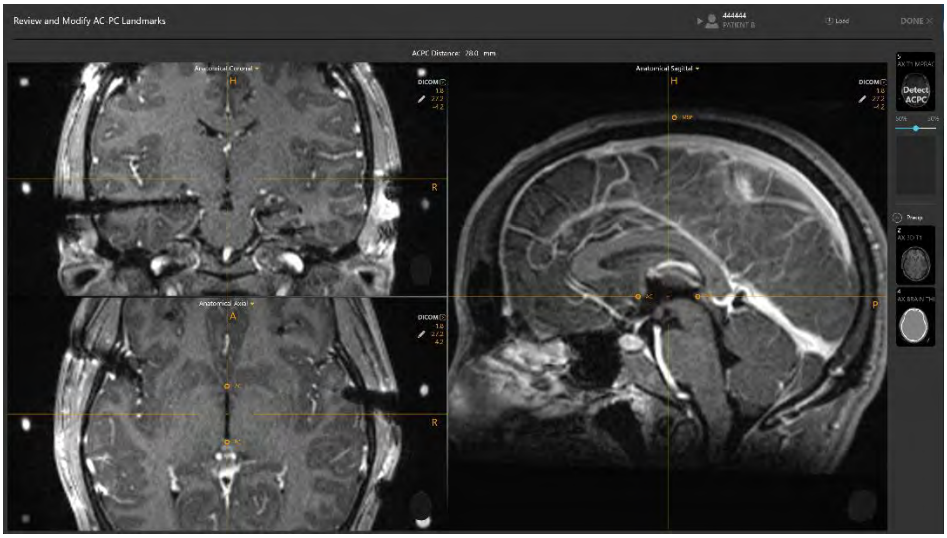
When the ClearPoint Workstation receives images for the first time, it automatically detects and identifies candidate positions for the anatomical reference points.

- 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 (Talairach) coordinate system. The application uses this coordinate system to define the **Anatomical** viewing orientation, while also allowing you to reference coordinates in Talairach space using the Current Point Control (see Positioning Crosshairs and Editing Annotations Pg. 65).

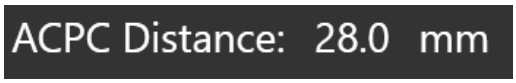
The ACPC task allows you to review and / or modify the positions of the anatomical landmarks used to define the Talairach coordinate system. Its viewing layout provides 2 viewport orientations: **Scanner** and **Anatomical** (see Changing a Viewport Orientation Pg. 71):

- Scanner View – Aligns viewports to scanner axes
- Anatomical View – Aligns viewports to ACPC (Talairach) planes.



> **To review the anatomical landmarks**

1. Launch the ACPC task using the Task Selector (see Selecting a Task Pg. 49).
2. Select the AC button from the custom toolbar (see Using Custom Toolbars Pg. 52) to position the crosshairs on the AC Point.
3. Select the PC button from the custom toolbar (see Using Custom Toolbars Pg. 52) to position the crosshairs on the PC Point.
4. Select the MSP button from the custom toolbar (see Using Custom Toolbars Pg. 52) 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.



> **To edit the anatomical landmarks**

1. Select the anatomical landmark that you wish to edit.
2. Edit the locations of each of the landmarks using the following mechanisms:

- Reposition the crosshairs in the viewports (see Changing Crosshair Positions Pg. 66) to a location where you would like to set the location of the landmark. Use the corresponding set button in the custom toolbar (see Using Custom Toolbars Pg. 52) 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 (see Editing Annotations Pg. 67).

-

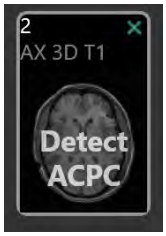
*Note: By default the viewing orientation is set to **Anatomical**, which means that whenever the landmarks points change, the three perpendicular anatomical views re-align to match the new reference positions. Changing the view to **Scanner** will align the planes to the scanner directions. This can improve visualization if very large corrections are required to the detected AC-PC landmarks.*

3. To undo any positional edits made to any of the landmarks, use the undo / redo tools inset within the custom toolbar (see Editing Annotations Pg. 67).

4. You may edit the color, opacity and / or position of the text labels as desired (see Editing Annotations Pg. 67).

> **To re-detect the anatomical landmarks**

1. Select the image series to use to detect the anatomical landmarks. If the series is not selected as either the master or fusion series within the Thumbnail Bar, select that series as the fusion series.



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.

VOI Task *Defining Volumes*

The VOI task may be used to create or edit volumes of interest within any loaded image series on the ClearPoint Workstation. After defining a volume, it will be visible in all subsequent workflow steps to assist in the trajectory planning or frame alignment process. Definition and subsequent editing of volumes can only be performed using the **Scanner** viewing orientation.

Volume Creation

The VOI task allows you to create new volumes of interest based on a grouping of voxels that you can define through the following means:

- Automatic Detection (see Automatic Volume Detection Pg. 165)
- Semi-automatic Detection (see Semi-Automatic Volume Detection Pg. 167)
- Manual definition using volume editing tools (see Volume Editing Pg. 168)

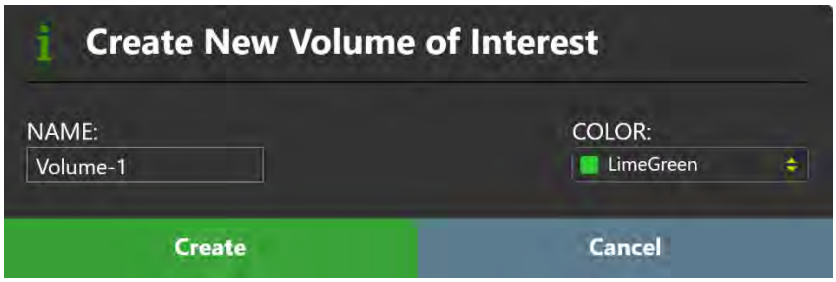
> **To create a volume**

1. Launch the VOI task using the Task Selector (see Selecting a Task Pg. 49).
2. Create a region of voxels that you wish to associate with the volume of interest that you are defining. You can create these regions automatically (see Automatic Volume Detection Pg. 165), semi-automatically (see Semi-Automatic Volume Detection Pg. 167) or manually (see Volume Editing Pg. 168).

3. Select 

from the task panel.

4. A floating window will appear prompting you define the following attributes for the volume to be created.

   - Name – Specify a unique name that will identify the volume in the user interface.
     - Note: The application will prevent identical naming of volumes.
     -
   - Color – Specify a color defining how the volume will be displayed in the user interface.
     -
     

     -
     -

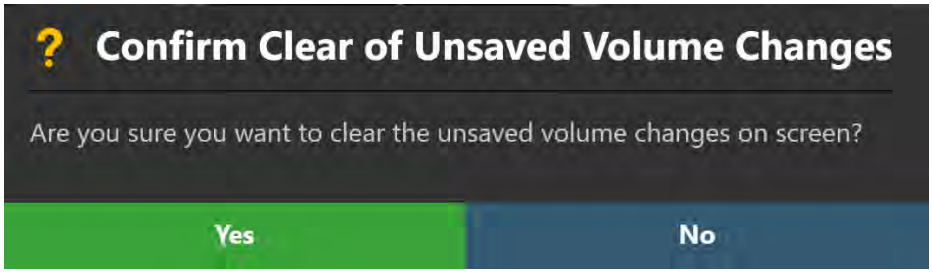
5. Select **Create** to define a volume in the user interface. Select **Cancel** to cancel the volume creation.

> **To clear volume voxels**

1. If you wish to discard the grouping of voxels associated with creating a new volume of interest, select 

from the task panel.

2. You will be prompted on whether or not you would like to clear the voxel grouping.



3. Select **Yes** to clear all associated voxels and any **VOI Box** annotations. Select **No** to leave associated voxels on screen.

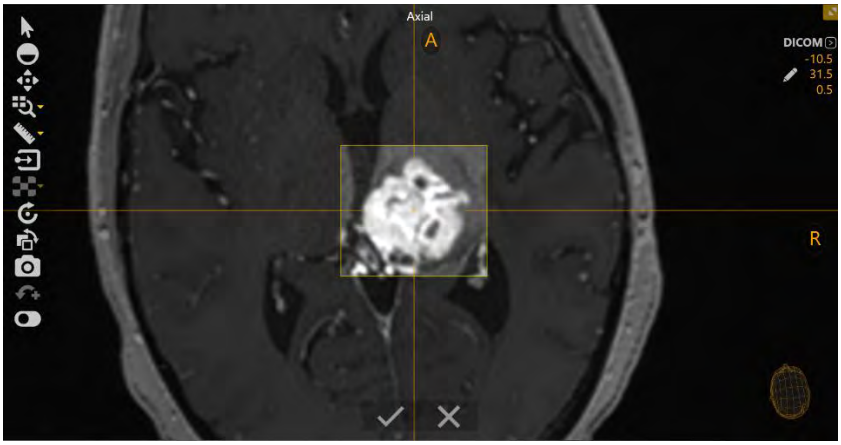
Automatic Volume Detection

You may use the VOI task to automatically identify a grouping of similar-intensity voxels from a three-dimensional rectangular region defined within any image series loaded into the application.

> **To automatically define a volume**

1. Use the **VOI Box** tool in the task's custom toolbar to define a three-dimensional rectangular region around the volume of interest for which you would like to define. To use the **VOI Box** tool:

   - Select the  button from the custom toolbar.
   - Click and drag the mouse over the image to select a rectangular region.

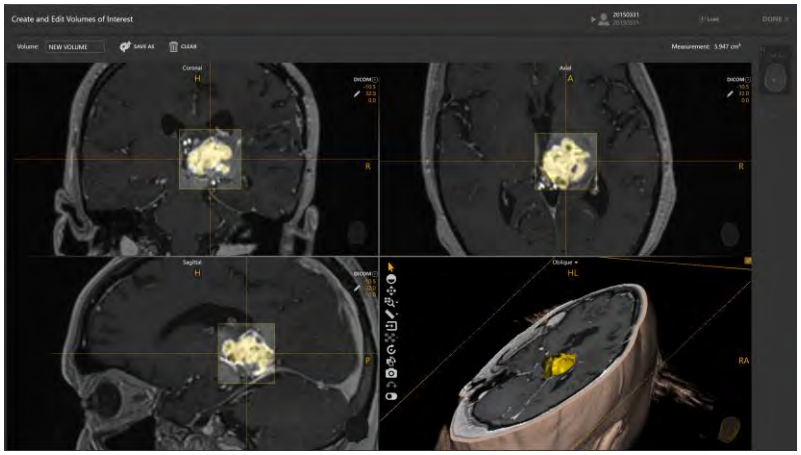


   - After you have finished editing the rectangular region, click the  button to accept the region. Alternatively, you may click the  button to remove the rectangular region entirely and prevent the application from attempting to search the region for a volume.
   - A floating window will display a **Please Wait** message and the task user interface will be blurred.

2. Select the  button from the custom toolbar to automatically detect a grouping of similar-intensity voxels from the volume within the rectangular region.

3. A floating window will display a **Please Wait** message and the task user interface will be blurred.

4. The automatically detected voxel grouping result will appear on screen within the rectangular region defined.



5. Use the **Volume Brush** tool in the task's custom toolbar to make any edits to the grouping of associated voxels (see Volume Editing Pg. 168).

6. Create a volume of interest using the grouping of voxels (see Volume Creation Pg. 163).

7. If you wish to discard the detected volume result, clear the associated voxels (see Volume Creation Pg. 163).

Semi-Automatic Volume Detection

You may also use the VOI task to semi-automatically fill in voxel regions from a three-dimensional rectangular region defined within any image series loaded into the application.

> **To semi-automatically define a volume**

1. Use the **VOI Box** tool in the task's custom toolbar to define a three-dimensional rectangular region around the volume of interest for which you would like to define (see Automatic Volume Detection Pg. 165)

2. Use the **Volume Paint Can** tool in the task's custom toolbar to fill in voxels associated with the volume of interest that you wish to define. To use the **Volume Paint Can** tool:

    - Select the  button from the custom toolbar.
    - Click the mouse over an area of the image that corresponds to a region within the volume of interest you would like to edit. Doing so will automatically fill in connected voxels of similar intensity within the volume of interest.
    - Continue to click within regions of the volume of interest in order to fill in additional voxels.

3. Use the **Volume Brush** tool in the task's custom toolbar to make any edits to the grouping of associated voxels (see Volume Editing Pg. 168).

4. Create a volume of interest using the group of voxels defined (see Volume Creation Pg. 163).

5. If you wish to discard the group of voxels defined, you may clear them appropriately (see Volume Creation Pg. 163).

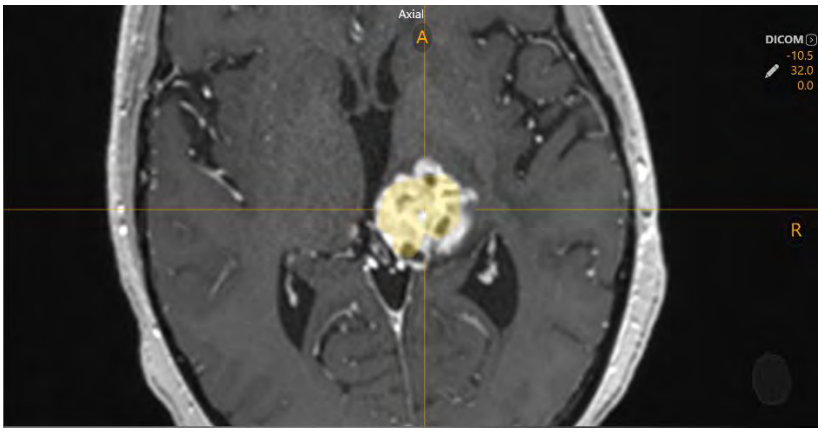
Volume Editing

The VOI task may be used to edit an existing volume or to manually define a new one. Editing a volume involves changing the grouping of voxels associated with the volume of interest. Manually creating a new volume involves defining a group of voxels associated with the volume of interest.

> **To manually define a volume**

1. Use the **Volume Brush** tool in the task's custom toolbar to define a grouping of voxels using a spherical brush of fixed size. To use the **Volume Brush** tool:

    - Select the  button from the custom toolbar.
    - Click and drag the mouse over the areas of image that correspond to the volume of interest that you wish to identify. Doing so will fill in voxels corresponding to the volume of interest.



    - Hold down the CTRL key and rotate the mouse wheel to change the size of the spherical brush.

2. Use the **Volume Eraser** tool in the task's custom toolbar to remove voxels associated with the volume of interest you are defining, using a spherical eraser of fixed size. To use the **Volume Eraser** tool:

    - Select the  button from the custom toolbar.
    - Click and drag the mouse over the areas of the image that contain previously defined voxel groupings. Doing so will remove those voxels from the grouping.

- Hold down the CTRL key and rotate the mouse wheel to change the size of the spherical eraser.

3. Create a volume of interest using the group of associated voxels defined (see Volume Creation Pg. 163).

4. If you wish to discard the group of voxels defined, you may clear them appropriately (see Volume Creation Pg. 163).

> **To edit an existing volume**

1. Select the volume that you wish to edit using the drop-down selector in the task panel.

2. Select 

from the task panel.

3. The grouping of voxels associated with the volume will be displayed within the viewports.

4. Edit the group of voxels using the **Volume Brush** or **Volume Eraser** tools.

5. Use the custom toolbar in any of the viewports to undo or redo any number of edits made to the grouping of voxels while the volume is being editing (see Editing Annotations Pg. 67).

6. Select 

to save the edits made to the grouping of voxels associated with the selected volume. Select 

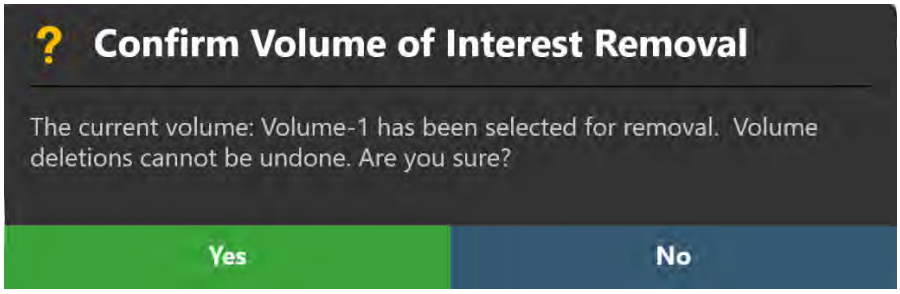
to discard these edits.

7. The volume will be displayed in the viewports using the color for which it was defined.

> **To delete an existing volume**

1. Select the volume that you wish to remove using the drop-down selector in the task panel.

2. You will be prompted on whether or not you would like to remove the defined volume.



3. Select **Yes** to remove the volume of interest from the application. Select **No** to leave the selected volume of interest intact.

Volume Review

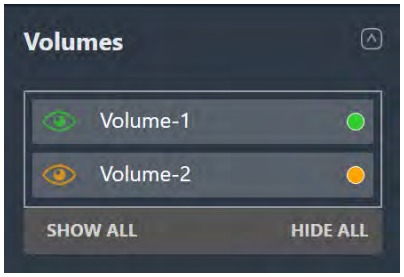
Volumes created using the VOI task may be reviewed and have their properties changed in various places throughout the application.

> **To review a volume using the VOI task**

1. Launch the VOI task using the Task Selector (see Selecting a Task Pg. 49).
2. Select the volume that you wish to review using the drop-down selector in the task panel.
3. Observe the volume measurement value in the task panel.

> **To review a volume within a step**

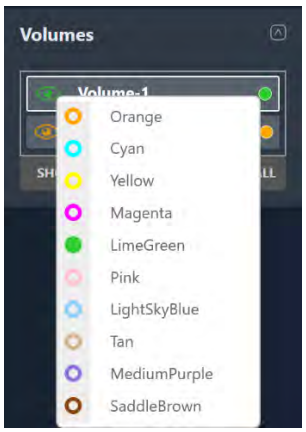
1. If one or more volumes have been defined using the VOI task, a group box will be displayed on the step panel showing the list of volumes.



2. To change the position of the crosshairs such that they are centered on the volume that you wish to review, select the volume from this group box.

> **To change volume properties**

1. Identify the volume with properties you wish to change.
2. You may edit the color and opacity of the volume as desired (see Editing Annotations Pg. 67).
3. Change the visibility of individual volumes by clicking on the eye-ball icon () corresponding to the volume that you wish to show or hide.
4. Change the visibility of all volumes by toggling between **SHOW ALL** and **HIDE ALL**.
5. Change the color of an individual volume by clicking on its corresponding colored circle.



> **To review volumes using the procedure report**

1. Open the Report Window (see Using the Report Window Pg. 39).
2. Navigate to the **Volumes of Interest** section.

3. Observe the volume measurements for each volume, as well as any measurement overlap between other volumes defined in the application.

Compare Task *Comparing Images*

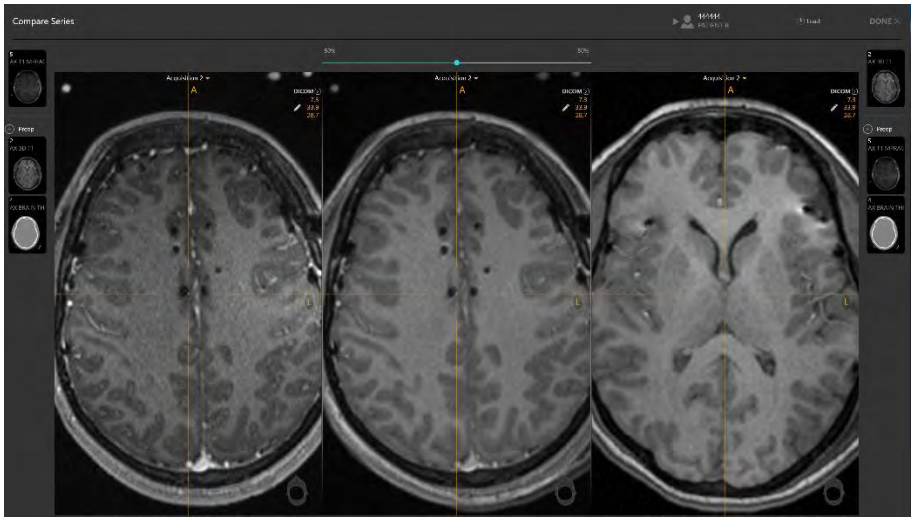
The Compare task offers the ability to visually compare two image series, side-by-side in different viewing orientations. This functionality may be useful for a number of workflow-related needs, such as:

- Visualizing locations between two image series acquired using different pulse sequences (e.g. comparing T1 and T2 weighted images).
- Viewing one or more scans in the exact orientation in which they were acquired.
- Determining whether or not the patient has moved within fixation between two scans.
- Determining whether or not the table has inadvertently moved between two scans.

The Compare task offers the following viewing orientations in its layout:

- Acquisition 1 View – Aligns viewports to the plane where the first image series selected for comparison was acquired in.
  -
- Acquisition 2 View – Aligns viewports to the plane where the second image series selected for comparison was acquired in.
  -

- 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.



> **To compare two image series**

1. Launch the Compare task using the Task Selector (see Selecting a Task Pg. 49).
2. Select the first image that you want to include in the comparison from the Thumbnail Bar on the left-hand side of the task panel (see Using Thumbnails Pg. 74).
3. The first image series selected will appear in the left and center viewports.
4. Select the second image that you want to include in the comparison from the Thumbnail Bar on the right-hand side of the task panel (see Using Thumbnails Pg. 74).
5. The second image series selected will appear in the right viewport, and blended with the first image series in the center viewport.
6. Use the slider bar in the task panel to change the relative weighting of each image series in the center viewport.

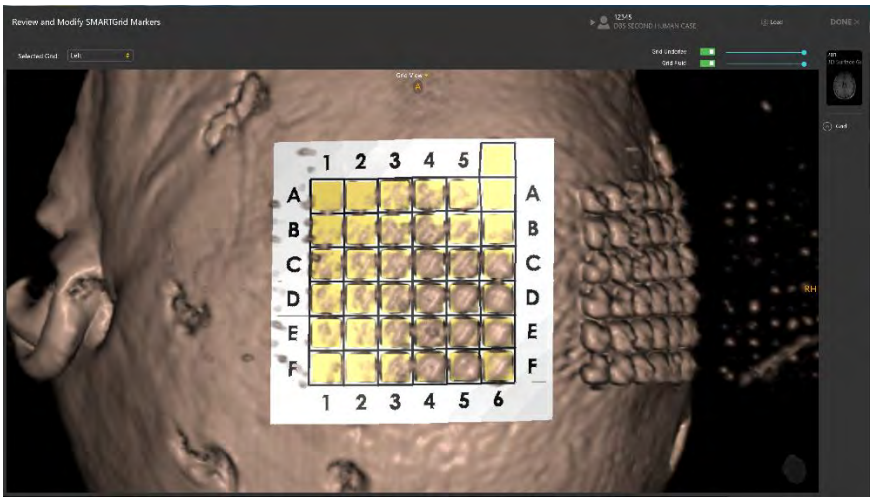
> **To change the comparison viewing orientation**

Change the viewport orientation in one of the viewports (see Changing a Viewport Orientation Pg. 71). The orientation of all viewports will match the one just selected.

Grid Task *Editing Marking Grids*

The Grid task may be used to perform the following operations as it relates to managing SMARTGrid(s) defined in the Entry step (see Entry Step *Locate Mounting Point* Pg. 103):

- Review the position and orientation for each marking grid in the Entry step (see Review Marking Grids Pg. 175)
- Manually edit the position and / or orientation for each marking grid in the Entry step (see Modify Marking Grids Pg. 175).
- Identify one or more marking grids that were not detected automatically in the Entry step and / or not yet defined (see Marking Grid Management Pg. 177).



Review 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 a marking grid**

1. Launch the Grid task using the Task Selector (see Selecting a Task Pg. 49).
2. Use the **Selected Grid** drop-down 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. 74).
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.

Modify 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 SMARTGrid(s) in the Entry step, due to signal attenuation, image artifacts, or other issues.

> **To modify a marking grid**

1. Launch the Grid task using the Task Selector (see Selecting a Task Pg. 49).
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 by 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 by 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.

9. To undo any position or orientation edits made to any of the grids, use the undo / redo tools inset within the custom toolbar (see Editing Annotations Pg. 67).

10. After grid modifications are completed, return to the Entry step. Note that the modifications made are reflected in the grid representations shown in the step.

Marking Grid Management

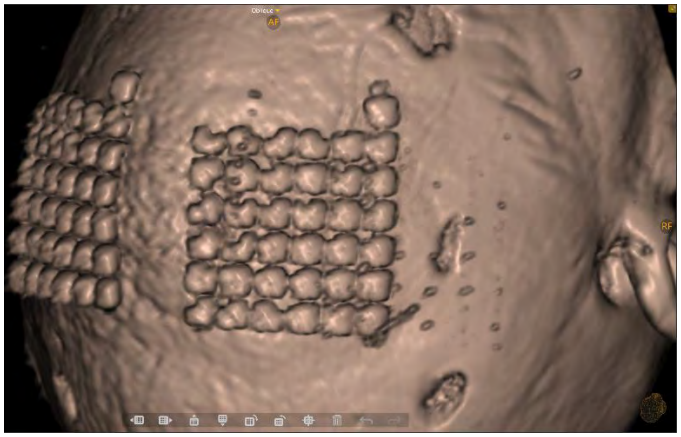
You may also use the Grid task to manage the marking grids defined in the application. Specifically, you can detect one or more marking grids from any selected image series and / or delete any existing marking grids presently defined.

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

1. Launch the Grid task using the Task Selector (see Selecting a Task Pg. 49).

2. Select an image series from the Thumbnail Bar (see Using Thumbnails Pg. 74) 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 results of the grid detection will be reflected in the new grid defined within the viewports.

7. After a new grid has been defined, return to the Entry step to observe the new grid representation shown in the step.

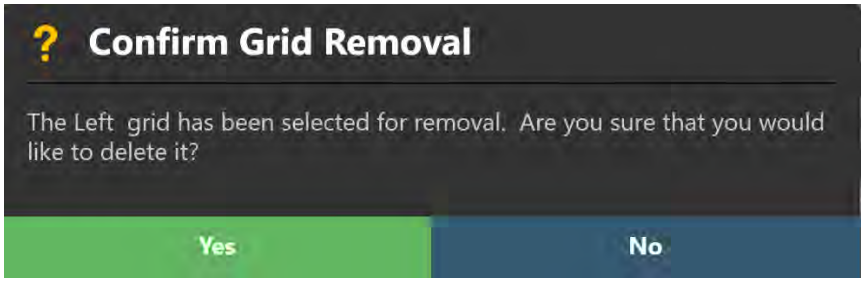
> **To delete a marking grid**

1. Launch the Grid task using the Task Selector (see Selecting a Task Pg. 49).

2. Use the **Selected Grid** drop-down to select a grid to remove. This could be due to improper identification or potential grid duplication.

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.

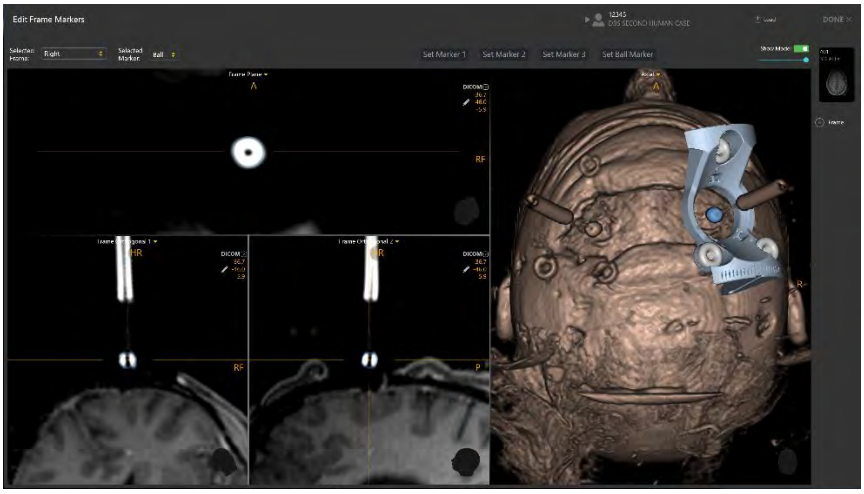


5. Return to the Entry step to observe that the previously existent marking grid is now removed.

Frame Task *Editing Frame Markers*

The Frame task may be used to perform the following operations for managing the SMARTFrame(s) defined in the application. Each SMARTFrame consists of a set of fiducial markers: three donut-shaped markers located in the base of the frame as well as the ball marker embedded within the distal tip of the targeting cannula.

- Review the position of the fiducial markers within each frame defined in the application (see Review Frame Markers Pg. 180).
- Manually edit the position of the fiducial markers for each frame defined in the application (see Modify Frame Markers Pg. 181).
- Search for one or more frames that were not detected automatically in the Target step (see Frame Management Pg. 183).



The Frame task can be accessed from within the Target step (see Target Step *Finalizing Trajectories* Pg. 115). The viewing layout for the Frame task provides you with the ability to set, edit, or review the locations of the three donut-shaped frame markers as well as the cannula ball marker for each frame defined in the application, both in cross sectional and three-dimensional views. It also provides 3 viewport orientations: **Scanner**, **Anatomical** and **Frame** (see Changing a Viewport Orientation Pg. 71):

- Scanner View – Aligns viewports to scanner axes
- Anatomical View – Aligns viewports to ACPC (Talairach) planes.
- Frame View – Aligns viewports to the plane defined by the three donut-shaped markers in the base of the currently selected frame. This option is only functional after at least one frame has been defined.

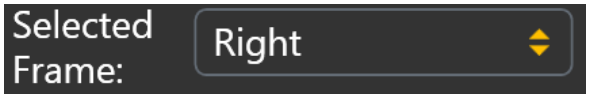
Review Frame Markers

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. 49).

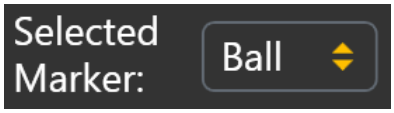
2. Use the **Selected Frame** drop-down to select a frame whose fiducial markers you would like to review.



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. 74).

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. 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** buttons () for each marker in the task's custom toolbar to re-correlate the crosshairs back to the location of the selected marker (see Changing Crosshair Positions Pg. 66).

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.

Modify Frame Markers

The Frame task also allows you to explicitly 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.

> **To manually edit the frame markers**

1. Launch the Frame task using the Task Selector (see Selecting a Task Pg. 49).
2. Use the **Selected Frame** drop-down to select a frame whose fiducial markers that 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. Edit the position of the selected fiducial marker in the linked viewports by dragging the marker's cross section annotation in any of the viewports (see Editing Annotations Pg. 67).
5. 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 (see Editing Annotations Pg. 67).
6. Use the **Set Marker** buttons in the task's panel to individually set the position of any of the currently selected frame's marker. These buttons are useful if you wish to set a frame marker without selecting it as the current marker:
    - 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.
7. To undo any position edits made to any of the currently selected frame's fiducial markers, use the undo / redo tools inset within the custom toolbar (see Editing Annotations Pg. 67).
8. After frame fiducial marker modifications are completed, return to the Target step. Note that the modifications made are reflected in the frame representations shown in the step.

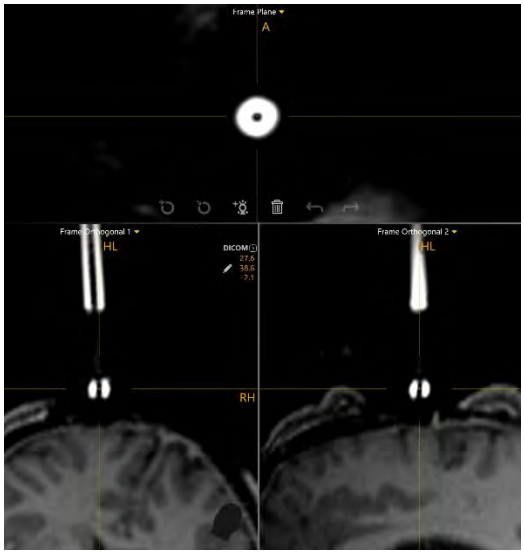
Frame Management

You may also use the Frame task to manage the SMARTFrames 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.
  - Broach Search – will search the entire image series for the frame markers.
- Delete any existing frames.

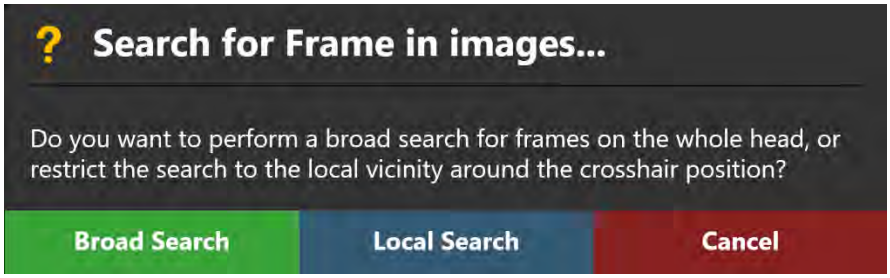
> **To automatically detect a new frame**

1. Launch the Frame task using the Task Selector (see Selecting a Task Pg. 49).
2. Select an image series from the Thumbnail Bar (see Using Thumbnails Pg. 74) to use to detect the new frame.
3. Decide what type of search mechanism that you would like to use: Local or Broad. If using a local search, position your crosshairs at or near the position of the ball marker of the frame you wish to detect. If using a Broad search, no action is required.



4. Select the  button from the task's custom toolbar.

5. Select the type of automatic frame marker detection mechanism that you would like to use. Select **Broad Search** to search the entire image series for the frame markers. Select **Local Search** to search for the frame markers within a small region determined by the position of the current viewport crosshairs. Select **Cancel** to terminate searching for the frame markers in the selected image series.



6. A floating window will display a **Please Wait** message and the task user interface will be blurred.

7. The results of the frame detection will be reflected in the new frame defined within the viewports. Review the fiducial marker results appropriately using all viewports (see Review Frame Markers Pg. 180).

8. After a new frame has been defined, return to the Target step to observe the new frame representation shown in the step.

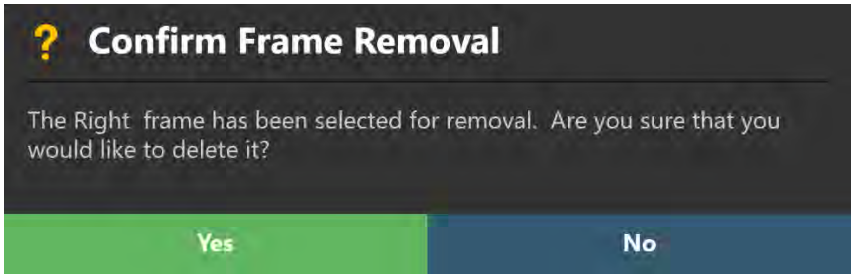
> **To delete a frame**

1. Launch the Frame task using the Task Selector (see Selecting a Task Pg. 49).

2. Use the **Selected Frame** drop-down to select a frame to remove. This could be due to improper identification or potential frame duplication.

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.

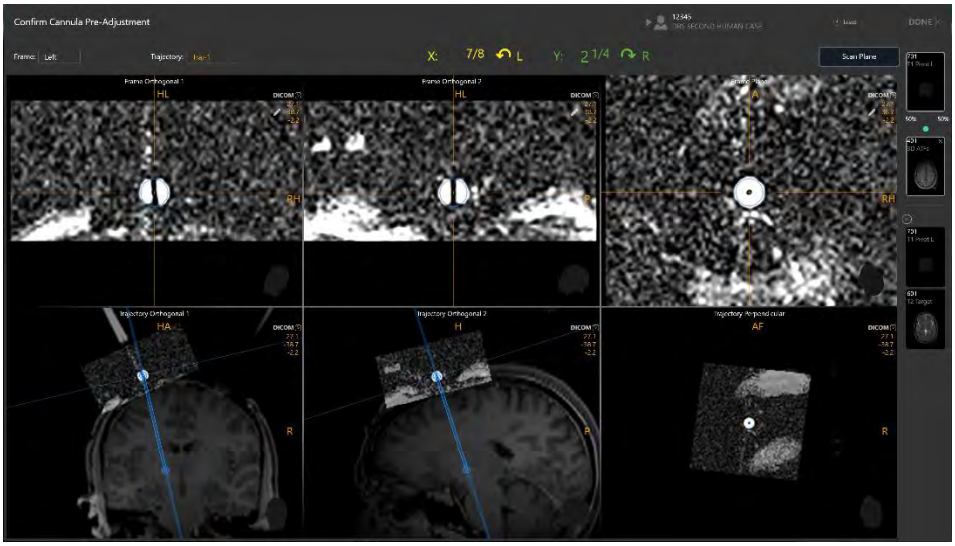


5. Return to the Target step to observe that the previously existent frame is now removed.

Pre-Adjust Task *Pre-adjusting the Cannula*

You can use the Pre-Adjust task to iteratively make X-Y adjustments on the currently selected frame in order to align its cannula ball marker with the planned entry point. The task will provide the X-Y adjustment instructions required in order to position the ball marker at the planned trajectory entry point. In order to verify the pre-adjustments made, the task supplies a set of scan plane parameters that can be used to acquire one or more image slabs containing the ball marker of the currently selected frame. Upon loading the image slabs containing the ball marker, the Pre-Adjust task will automatically detect the new position of the ball marker, display the updated / realized trajectory, and show the new set of X-Y adjustments required to align the ball marker with the planned entry point. This process can be repeated until the ball marker is positioned at the planned entry point.

The Pre-Adjust task is only available for selection in the Align step (see Align Step *Set the Cannula Angulation* Pg. 122) and should be performed prior to attempting to adjust the angulation of the cannula to a planned trajectory.



> **To perform a cannula pre-adjustment**

1. Launch the Pre-Adjust task using the Task Selector (see Selecting a Task Pg. 49).

2. Observe the X and Y adjustments shown in the task panel. These are the adjustments required to align the cannula ball maker to the planned entry point of the selected trajectory.

3. Follow the instructions provided to make your adjustments. The colors in the panel match the color of the knobs on the hand controller and the SMARTFrame

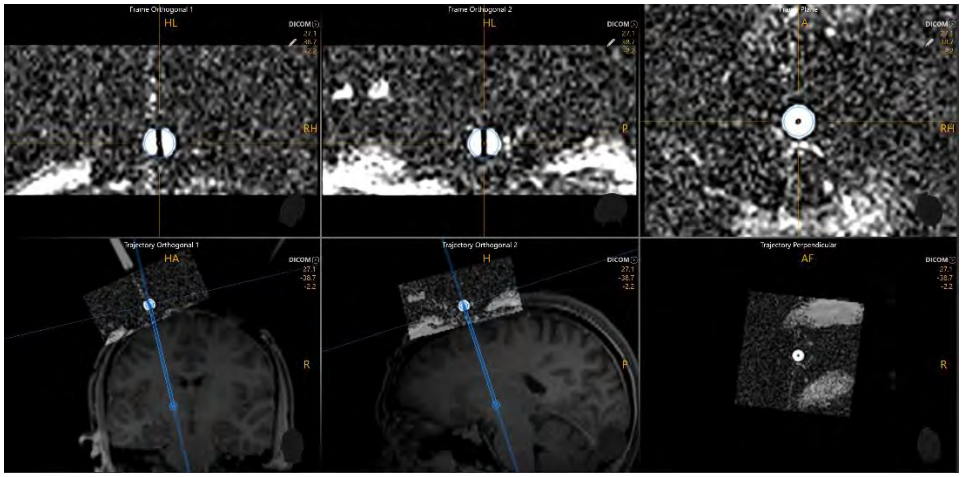
4. Scan the ball marker using the scan plane parameters provided in the task panel (see Interoperation with MRI Scanner Pg. 18).

5. Send or load the images onto the workstation.

The application will automatically detect the ball marker position from the image(s) received. With each acquisition, the new position detected for the cannula ball marker will be used by the ClearPoint Workstation to recalculate the frame adjustments required to position the ball marker at the planned entry point.

6. The application will display the ball marker acquisition images in the first row of viewports. The updated trajectory path will be displayed in the second row of viewports, which shows the master series from the Target step blended with the

ball marker acquisition. This allows the realized trajectory path to be visualized against the underlying images.



7. Follow the instructions provided in the task panel to make your adjustments. The colors in the panel match the color of the knobs on the hand controller and the SMARTFrame.

8. Repeat adjustment and re-acquisition until the residual adjustment is less than a 1/4 turn for both X and Y stages on the selected frame.

> **To manually override the cannula ball marker position**

1. If the cannula ball marker position detected by the software appears incorrect in the top row of viewports, you may edit its position using the following techniques:

    - Drag the ball marker cross section annotation in any of the viewports on the top row (see Editing Annotations Pg. 67).

    - Change the crosshair location (by any means) to the intended position and use the **Set Ball Marker Point** tool ( ) in the step's custom toolbar.

    -

2. To undo any position edits made to the currently selected frame's ball marker position, use the undo / redo tools inset within the custom toolbar (see Editing Annotations Pg. 67).

> **To review realized trajectory**

1. Review the ball marker detection result in the top row of viewports. The crosshairs for these top viewports will correlate to the center of the ball marker. The application will display blue annotations representing the cross section of the ball marker in each of these viewing planes.

2. If you move the crosshair position away from the ball marker, you can use the **Go To Ball Marker Point** button () in the task's custom toolbar to re-correlate the crosshairs back to the location of the ball marker (see Changing Crosshair Positions Pg. 66).

3. Review the updated trajectory path as a result of the task's detection of the ball marker in the bottom row of viewports. The blue trajectory path represents the path from the planned target point to the current position of the ball marker. This trajectory is only editable by sending updated scans of the ball marker to the task.

4. Drag the horizontal line displayed perpendicular to the trajectory path in **Trajectory Orthogonal 1** or **Trajectory Orthogonal 2** viewports to scroll along the trajectory path.

5. You may change the image series blended with the ball marker series using the Thumbnail Bar on the right-hand side of the task panel (see Using Thumbnails Pg. 74).

Troubleshooting

This chapter 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. 49 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 a 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.).
- A workflow step has not been selected.
- 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 non-clinical license in a clinical setting. When using a non-clinical 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 MR 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. This indicates a serious problem with the images just received or a critical error of the software.

Can be caused by:

- Images received are corrupted and/or incomplete
- Byte encoding of images are invalid

Consequences of failure to load images into workstation:

- If the workstation is unable to load the images just received, then they cannot be viewed within the software application. Either changes need to be made to the acquisition received or the software needs to be restarted.

Recovery:

- This may indicate a serious problem with the data sent to the workstation. Review the acquisition with the MR technician and ensure that it can be viewed on the scanner console. Attempt to resend the series if there aren't any problems with the acquisition itself.
- This may also indicate a serious problem with the software. Attempt to restart the software and resend the series.

Data Received Older Than One Hour

The series just received has an acquisition time stamp that is older than one hour from the current time when the data was received. During intra-operative procedures, it is unlikely that breaks between data acquisitions will be extremely

lengthy, unless problems were encountered during the procedure. 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 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 series just received has an acquisition time stamp that is older than data previously loaded into the application. This effectively means you are viewing images that are 'out of date'. The images must be reviewed carefully so that appropriate clinical decisions can be made based on when this data was acquired.

Is caused by:

- Images just received are older than previously loaded data. The software analyzes the DICOM header tags: (0008, 0021) – Series Date and (0008, 0031) – Series Time to make this determination.

Consequences of data received being older than previously loaded data:

- Some workflow steps will allow the series to still be loaded if it is older than previously loaded data. However, you should take caution in using this data because it is effectively 'out of date' when compared to data loaded into the session.
- Other workflow steps will prevent data from being loaded if it is older than previously loaded data. The reason for this is to prevent providing instructions or performing calculations based on data that is not current.

Recovery:

- For those steps that still allow older data to be loaded, the warning message can be safely dismissed, providing the user is aware of the fact that they are loading older data. Please carefully review the images and understand that other images have been loaded that are newer than this series.
- For those steps that prevent older data from being loaded, the only remedy is to acquire a new series and send it to the workstation.

Busy Indication Window Dismissed by User

During a time intensive operation, the ClearPoint Workstation's busy indication window has been dismissed by pressing the ESC key. The busy indication window is used by the software to indicate that a time intensive, background computation/operation is being performed and that it is in the user's best interest to allow it to complete fully before proceeding. Some examples are: searching for a SmartGrid, performing an image fusion, detecting AC/PC, searching for a volume of interest, etc. If the busy indication window is dismissed, the software will still attempt to complete the background operation, but will return control of the UI back to the user so that they can continue through the workflow.

Is caused by:

- Pressing the ESC key while the software is performing a time intensive operation.

Consequences if busy indication window is dismissed:

- The software may lag in performance after the window is dismissed while it tries to complete the operation/computation of interest.
- Suggestion is to give the software a minute or two to complete processing prior to proceeding with the workflow.

Recovery:

- The ability to dismiss the busy indication window is provided to allow the user to proceed with the workflow if the software gets stuck during a time intensive operation. This is extremely unlikely and should never occur, but it provides this ability so that the user can proceed through the workflow if necessary.
- If the ESC key is accidentally pressed with the busy indication window showing, allow the software a minute or two to complete its background processing prior to proceeding with the workflow.

Scanner Bore Size Not Configured

If the scanner bore size has not been set in the ClearPoint Workstation System Configuration Dialog, then every time a series is received by the workstation, a warning message concerning the scanner bore size will be shown. The software uses the bore size in combination with the 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 Scanner). Without this information, the software will not be equipped with the data it needs to provide this warning for a given trajectory path. The scanner bore size only needs to be specified once and does not need to change unless the scanner for which the workstation interacts with physically changes.

Is caused by:

- Scanner bore size not specified in System Configuration Dialog ('SYSTEM' tab)

Consequences if the scanner bore size is not configured:

- If the software is not aware of what the scanner bore size is, it is unable to warn about potential bore collisions prior to the device being inserted.

Recovery:

- Use the System Configuration Window to specify the scanner bore size (see 'SYSTEM' tab).

Failed to Detect AC-PC Points

In extremely rare circumstances, the ClearPoint Workstation may fail to detect one or all of the AC, PC and MSP positions in the whole-head scan. If this occurs, it is a very serious problem, because the AC-PC detection algorithm was designed to always return a non-empty result. If this error occurs, you must manually define these positions in the AC-PC task.

Can be caused by:

- Extreme failure in AC-PC detection algorithm
- Loading series data that is not expected by the workstation
- Attempting to detect AC-PC points from a very thin slab
- Software application corruption

Consequences of failing to detect AC-PC points:

- In most instances, failing to detect the AC-PC points indicates a very serious software failure. Several computations in the software rely on AC-PC points being defined, so you will be unable to continue in the clinical workflow without significant problem until the AC-PC points are defined.

Recovery:

- Suggest re-starting the software and attempting to send the data again.
- If the failure still occurs and you are able to manually define the AC, PC and MSP points in the AC-PC task, do so in order to continue with the clinical workflow.

AC Point 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, there are two very serious results:
    1) 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.

2) Automatic detection of the marking grid or frame in the whole-head volume will consistently fail, even when the hardware is perfectly clear in the images.

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 fairly 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 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, there are two very serious results:
    1) 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.
    2) Automatic detection of the marking grid or frame in the whole-head volume will consistently fail, even when the hardware is perfectly clear in the images.

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.

SMARTGrid Not Found / Detect 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
- Incorrectly defined AC, PC or MSP points (see AC Point Posterior to PC)
- Patient orientation was entered incorrectly on scanner
- 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 order 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.
- 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.
- Ensure that AC, PC and MSP points are set correctly. If not set correctly, use the AC-PC task to correct their positions and re-exercise the grid segmentation in the Grid task 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.

Failed to Segment Volume of Interest

The ClearPoint Workstation software has failed to detect a volume of interest from within the box area that you defined. This means that the grayscale intensity of the volume you are interested in within the box area does not differ significantly enough from its surrounding structures.

Can be caused by:

- Grayscale brightness within acquired image not sufficient/drastic enough within the volume
- Box region drawn does not fully encapsulate volume
- Volume of interest is incredibly small when compared to the box region.

Consequences if the volume of interest is not detected by the software:

- If the software is unable to automatically detect the volume you are interested in, you will be forced to use the 'Volume Brush' tool to manually define your volume.

Recovery:

- Ensure that the box region that you used to tell the software where to search for the volume has been defined correctly. If the box cuts off the volume in any way, please re-draw the box and try again.

- Additional scans can be acquired to provide increased grayscale contrast of the volume when compared to surrounding structures and the software can be used to re-detect the volume in these acquisitions.
- The "Volume Brush" tool can be used to manually define the regions of the volume if automatic detection fails.

Trajectory May Cause Device to be Obstructed by Scanner

The trajectory path mentioned in the warning message has an angulation such that insertion of the device during the procedure may be obstructed or blocked by the scanner bore. The software uses the '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 or not the planned trajectory may cause the device to be blocked by the scanner bore during insertion.

In addition to indicating that the planned trajectory may cause a bore collision with the device during insertion inside the 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 in order to clear the scanner bore on re-introducing the patient.

Is caused by:

- Defining a trajectory that will cause the device to be obstructed by the scanner bore during insertion.

Consequences of proceeding with a trajectory that may cause device to be obstructed by the scanner bore:

- During device insertion, the surgeon may not be able to insert the device into the patient. This depends on the rigidity/flexion of the device to be inserted as well as the possible options for inserting the device into the patient.
- The surgeon may have to explore other options for device insertion, including inserting a portion or all of the device with the patient outside of the scanner bore.

Recovery:

- Warning up front about potential device obstruction is key to ensuring that problems do not manifest during the device insertion stage. Ensure that this

warning is taken seriously during trajectory planning in order to prevent further problems later in the workflow.

- Use the Trajectory Status dialog (exercised by right clicking the trajectory annotation) to view the device clearance measurements. This will indicate the various options for device insertion that will be available to you at the time of insertion.
- Do not use a planned trajectory that has the potential to cause device obstruction. Plan an alternate trajectory for which bore obstruction is less likely to occur (i.e. significant bore clearance).

Device is Not Long Enough to Reach Target

This warning message indicates that 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 or not the device can reach the target point. If this message is shown, it is strongly recommended that changes to the planned trajectory are made in order 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 in order 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 has the ability to guide a device to an intended target in the brain with in-plane errors less than 1.5 mm, however this has only been validated at maximum insertion depths of 125 mm. Insertion depths greater than 125 mm are not endorsed and if attempted, may result in higher device placement errors. If you receive this warning, make changes to the planned trajectory such that the maximum validated system depth will not be exceeded.

Is caused by:

- Defining a trajectory whose length causes the maximum validated system depth (125 mm) to be exceeded. 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 image distortion may come into play more readily at these increased insertion depths.

Recovery:

- It is strongly encouraged to 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.

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
- Incorrectly defined AC, PC, or MSP points (see AC Point Posterior to PC)

- Patient orientation was entered incorrectly on scanner
- Fluid loss in one or more frame markers
- Image artifacts, such as wrapping/ghosting, cause multiple frame markers to appear on top of one another in the 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:

- Use the scan plane parameters in the Target step to acquire a frame slab. Send acquisition to the workstation in order 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 'Segment Frame' button, and selecting 'Local Search'.
- Ensure that AC, PC and MSP points are set correctly. If not set correctly, use the AC-PC task to correct their positions and re-exercise the frame segmentation in the Frame task using the 'Segment Frame' button (either 'Broad' or 'Local' search techniques can be used).

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:

- Ball marker not completely contained within the volume
- Incorrectly defined AC, PC, or MSP points (see AC Point Posterior to PC)
- Patient orientation was entered incorrectly on scanner
- Fluid loss in ball marker

- 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:

- 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 in order to ensure accurate detection. 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 clinical 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 the frames are being stored correctly so that the cannula is upright and air won't rise into the ball marker.
- If there are no bubble issues with the ball marker and automatic detection still fails, 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 clinical 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 (using 'Local' or 'Broad' search techniques) or manually define any undefined markers.
- 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 distortion / artifacts which cause frame markers to appear in different physical locations than they actually are

Consequences of leaving incorrectly set frame markers inconsistent with their hardware specifications:

- Depending on how far off the markers are from one another, this can significantly impact a number of very important 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 very important to ensure that the frame markers have been set correctly, since the software uses their position to make a number of very important computations, including frame adjustments and whether or not to display other warning messages about the frame. Modify frame marker positions if they appear incorrect relative to the underlying images.

- If 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.

Frame Cannula Not Locked Down

The ClearPoint Workstation has detected that the selected SmartFrame's cannula may not be locked in the 'down' position. 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 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 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 Out of Position).

Consequences of selected frame cannula not in locked 'down' position:

- 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

Adjust-step pair of 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.

Frame Ball Marker Appears Out of Position

The ClearPoint Workstation has detected that the selected SmartFrame's ball marker appears lower than it should be relative to the frame markers.

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.

Consequences of selected frame's ball marker out of position:

- 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 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
    - 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 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.

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 in order 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 distortion and/or artifacts, causing the software to warn that the trajectory is beyond the frame's physically X-Y limits even though it may not be.

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. In order 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 in order to realize the planned target through the alternate entry point.

- This can also indicate that there are distortion or other 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.
- Analyze the images used to detect the position of the frame. 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.

Trajectory Not Close Enough to SMARTFrame

The trajectory listed in this warning message is not close enough to a SmartFrame in order 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

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 updated scans 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.

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 position 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 distortion/artifacts cause one or more frame markers to appear in locations where they are not located physically

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.
- 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) Update 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. frame slab segmentation, manual definition of frame markers in the Frame task, etc.).

DICOM Frame of Reference UID Has Changed

In the DICOM header information for the images just received, the scanner has assigned a new frame of reference identifier (UID). This may indicate that the coordinate system has been changed, however, in some cases scanners may assign a new identifier without a measurable change to the coordinate system.

Can be caused by:

- Scanner restart
- Change to landmarking on scanner

Consequences of loss of frame of reference:

- If the coordinate system has not changed there are no consequences.

- If the coordinate system has changed, new images will not be aligned with previous images. Subsequent planning, measurements, and adjustments may be inaccurate as a result.

Recovery:

- 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, dismiss the status message. It will not be shown for subsequent scans unless the Frame of Reference UID changes again.
- If the images are misaligned, you will need to acquire a new volume and fuse it with your previous whole-head scan.
- If the images are not suitable for accurately assessing alignment, acquire a new scan large enough to compare with your previous 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.

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 software 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 middle 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. 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 actually is.

Consequences of needing to make a pre-adjustment:

- This is part of the normal clinical 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 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. 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 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 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 Adjust step if the top cannula marker for the selected frame is not defined. If data is sent to the 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 most recently sent series in the Adjust step.

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 sent to 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 sent, then the software will return the last known position of the cannula.
- 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.

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 fairly large residual error in the frame alignment steps.

- Positional inconsistencies of the cannula in the orthogonal slabs in the Adjust step.
- 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, ensure that the correct pulse sequences and associated scan plane parameters are used. In particular:
    - If 3D error correction is available on the scanner, ensure that it was turned on and that the 3D-corrected series was sent
    - If the scanner supports table-movement verify that the Table Position value was entered correctly.
    - For Siemens scanners, ensure that the direction of phase encoding has been set correctly using the “InPlane Rotation” angle provided by the 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

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 geometric distortion artifacts are present in the acquired images or that physical device deflection may have occurred.

Can be caused by:

- Geometric image distortion artifacts which make the device signal void appear non-straight in the acquired images
- Deflection of the device during insertion
- Device broke during insertion, causing it to bend

Consequences of detected device track not appearing straight:

- This warning message can be dismissed without any direct consequences. Users can choose to define the location of the device tip on the set of acquired images that caused the warning to appear. However, it is strongly recommended against doing this since the images themselves 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 or not the device track is actually curved (use 'Device View'). Attempt to distinguish between potential geometric distortion and physical device deflection.
- If you acquired a large volume in order 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 scanner is likely to have minimal geometric distortion.
- 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.
- Geometric image distortion artifacts which make the device signal void appear non-straight in the acquired images.

Consequences of failure to detect device track:

- Users are still able to set the device tip manually so there are no real software consequences.

Recovery:

- If the software fails to detect the device track but you are still able to see the signal void in the acquired images, you may set the device tip manually using the 'Set Device' button in the Insert step. You should only use this approach if you a can confirm that the device track appears straight in the acquired images.

- Always review the detected device tip position, even if the segmentation succeeds.
- If the device track does not appear in the acquired images and/or the insertion slab is too thin, re-acquire a new scan and assess the tip position on that scan.

VOI Box Drawn Outside the Limits of the Images

This warning message is displayed when any portion of the VOI box extends outside the current series. The VOI box must be defined entirely inside the bounds of the images for it to be usable.

Is caused by:

- VOI box drawn outside the limits of the images.

Consequences of having the VOI box outside the limits of the images:

- When extending outside the limits of the images, the VOI box cannot be used.

Recovery:

- Edit the VOI box to be inside the limits of the images or cancel the box to clear it.

Appendix 1 – Head Fixation Frame, Imaging Coil(s) & MRI Scanner Requirements Specifications

Head Fixation Requirements Specification

A suitable head fixation frame for use 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.

Imaging Coil(s) Requirements Specification

Suitable Imaging Coil(s) for use 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 FOV must include the volume of the patients head plus a distance of 152.4cm 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 a 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.

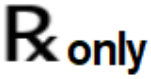
MRI Scanner Requirements Specification

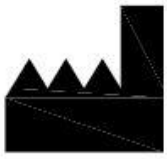
A suitable MRI scanner for use with the ClearPoint must meet the following requirements:

Field Strength	1.5T or 3T
Bore Diameter	60-70cm
Pulse Sequences	T1, T2, Fast Spine Echo, Gradient Echo
Imaging Modes	2D, 3D
Field of View (FOV)	30cm minimum
Slice Thickness	1 mm or less
Repetition Time (TR)	20ms minimum
Echo Time (TE)	3ms minimum
Flip Angle	up to 90°

Measuring Matrix	512 X 512 minimum

SYMBOL	DEFINITION	SYMBOL	DEFINITION
	Consult instructions for use Consulte las instrucciones de uso Consulter le mode d'emploi Consultare le istruzioni per l'uso Gebrauchsanweisung beachten Zapoznać się w instrukcji użytkowania Se brugsvejledningen Zie de gebruiksaanwijzing Se bruksanvisningar Consultar as instruções de utilização Consulte as instruções de uso		Keep away from sunlight Mantenga el producto lejos de la luz solar Tenir à l'abri de la lumière Tenere al riparo dalla luce solare Vor Sonnenlicht schützen Przechowywać w miejscu nienarażonym na działanie światła słonecznego Må ikke udsættes for sollys Buiten direct zonlicht bewaren Skydda mot solljus Manter fora do alcance da luz solar Mantenha longe da luz solar
	Catalogue number Número de catálogo Numéro de référence Numero di catalogo Artikelnummer Numer katalogowy Katalognummer Catalogusnummer Katalognummer Número de encomenda Número de catálogo		Keep dry Mantenga el producto seco Garder au sec Conservare in luogo asciutto Trocken aufbewahren Przechowywać w suchym miejscu Skal holdes tør Droog bewaren Håll torrt Manter seco Mantenha seco
	Batch code Código de lote Code du lot Codice del lotto Fertigungslosnummer Kod partii Batch-kode Partijnummer Satskod Designação do lote Código do lote		Manufacturer Fabricante Fabricant Produttore Hersteller Producent Producent Fabrikant Tillverkare Fabricante Fabricante
	Medical Device Dispositivo médico Dispositif médical Dispositivo medico Medizinprodukt Wyrób medyczny Medicinsk anordning Medisch hulpmiddel Medicinsk utrustning Dispositivo médico Dispositivo Médico		Date of Manufacture Fecha de fabricación Date de fabrication Data di produzione Herstellungsdatum Data produkcji Produktionsdato Fabricagedatum Tillverkningsdatum Data de Fabrico Data de fabricação

SYMBOL	DEFINITION	SYMBOL	DEFINITION
	MR Unsafe No apto para MR Non compatible avec l'IRM Non sicuro per RM Nicht MR-sicher Niebezpieczny w środowisku RM MR-usikker MR-onveilig Ej säker för MR Não em RM Incompatível com RM		Authorized Representative Representante autorizado Représentant agréé Rappresentante autorizzato Bevollmächtigter Vertreter Autoryzowany przedstawiciel Autoriseret repræsentant Vertegenwoordiger Auktoriserade representant Representante autorizado Representante Autorizado
	Do not use if the product sterilization barrier or its packaging is compromised No usar si la barrera de esterilización del producto o el empaque están dañados Ne pas utiliser si la barrière stérile du produit ou son emballage est compromis Non utilizzare se la barriera di sterilizzazione del prodotto o il suo imballaggio sono compromessi Bei beschädigter Verpackung nicht verwenden Nie używać, jeśli bariera sterylizacyjna produktu lub jej opakowanie jest uszkodzone Må ikke benyttes, hvis produktets steriliseringsbarriere eller emballage er brudt Niet gebruiken als de sterilisatiebarrière of de verpakking van het product aangetast is Använd inte om produktens steriliseringsskydd eller förpackningen är skadad Não utilizar caso a barreira de esterilização se encontre comprometida ou a embalagem se apresente danificada Não utilizar caso a barreira de esterilização se encontre comprometida ou a embalagem se apresente danificada		Prescription Device Dispositivo de uso con receta Dispositif sur ordonnance Dispositivo su prescrizione Verschreibungspflichtiges Medizinprodukt Z przepisu lekarza Receptpligtigt udstyr Hulpmiddel op voorschrift Receptbelagd utrustning Sujeito a receita médica Somente sob prescrição



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