



Neural microTargeting™ Worldwide

WayPoint™ Planner

Directions For Use

L011-43 (Rev E0, 2020-03-10)

Contains directions for the following products:
66-WP-PL

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FHC, Inc. Does not accept liability for injury or damage to equipment that may result from misuse of the WayPoint™ Planner software or of the microTargeting™ Platforms which it produces.

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Indications for Use

WayPoint™ Planner software is part of the WayPoint™ Stereotactic System. The WayPoint™ Stereotactic System is intended for use with commercially available stereotactic systems for neurosurgical procedures which require the accurate positioning of microelectrodes, stimulating electrodes, or other instruments in the brain or nervous system.

Intended Use





WayPoint™ Planner and related software is intended to be used by a neurosurgeon, neurologist or clinical neurophysiologist to plan and monitor positioning of microelectrodes, stimulating electrodes, or other instruments in specific anatomical structures in brain or nervous system.

Symbol Key			
	WARNING / Caution, consult instructions for important cautionary information.		Medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	Consult the instructions for use.		Telephone number
Rx Only	Caution- Federal law (USA) restricts this device to sale by or on the order of a physician.		Authorized Representative in the European Community.
	In reference to "Rx only" symbol; this applies to USA audiences only.		Indicates the serial number so that a specific medical device can be identified.
	Indicates the catalog number so that the medical device can be identified.		

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WARNINGS and Cautions

These warning statements should be read carefully and strictly adhered to.

-  **WARNING:** The WayPoint™ Planner software requires use of WayPoint™ Anchors or other FHC, Inc. approved anchor/ marker system devices. Use with other components or systems is not authorized.
-  **WARNING:** The WayPoint™ Planner software provides no diagnostic function.
-  **WARNING:** Always verify the created platform is built with all parts connected with no parts thinning or twisted. Platform feet must all be properly aligned with their corresponding anchors. Legs must not pass through patient anatomy. Hubs must not overlap or be touching at all.
-  **Caution:** Federal law (USA) restricts microTargeting™ Platforms to sale by or on the order of a physician.

Unauthorized duplication or distribution of the planning software, or any component of the planning software, is prohibited. Alteration of the planning software source code or included files is prohibited.

System Requirements

The WayPoint™ Planner software must be installed on a computer that meets the following requirements:

Following are the minimum requirements: CPU: Intel Core 2 Duo or equivalent, 2.93+ GHz, 4 GB RAM Disk Space: 50 GB, Integrated Graphics Processor Monitor Resolution: 1152x864 Connection: USB 2.0 or greater OS: Windows 10	Following are the recommended hardware requirements: CPU: Intel I7 or equivalent, 3.4+ GHz, 8 GB RAM Disk Space: 100 GB or greater Graphics Card: 1 GB of VRAM Monitor Resolution: 1920x1080 Connection: USB 3.0 or greater OS: Windows 10
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Compatibility

The software is compatible with the following stereotactic systems:

microTargeting Platform: WayPoint Planner software requires use of WayPoint Anchors (4mm and 5mm without post). The following platforms are compatible with Planner: unilateral, 2h2h unilateral, 2h2h bilateral, 2h2b bilateral, epilepsy and multi-oblique platforms.

Accuracy

The software performs precise operations on one or more sets of preoperative scans to determine physical characteristics needed to create or position a stereotactic device to along a planned trajectory or trajectories. These operations are performed with a precision that significantly exceeds the resolution of the input data. Therefore accuracy of the physical trajectory position compared to planned trajectory is determined primarily by the resolution of the input scan(s).

The ability to accurately locate specific anatomical target in relation to the physical frame depends on the proper alignment of the frame CT scan set with one or more MRI scan sets. The software supports multiple methods for registering scans which are selected and visually verified by the user. While incorrect usage of these functions will affect targeting accuracy, the functions do not have any inherent accuracy limitations.

Installation

Before installing The WayPoint™ Planner software, please make sure that you have installed as prerequisite IDL 8.5 (setup "IDL_ENVI53SP1win64.exe"), MATLAB Runtime 9.5 (setup "MCR_R2018b_win64_installer.exe") and .NET Framework 4.7.2 (setup ".NET Framework 4.7.2.exe"). Please use only the previous specified installers, which are the only ones supported by the current version of the application.

The planning software runs on computer systems compatible with the ITT Visual Information Solutions Interactive Data Language, IDL, virtual machine. The virtual machine, MATLAB Runtime and .NET Framework installation files may be included with authorized distribution of the planning software or acquired from ITT Visual Information Solutions, MathWorks and Microsoft.

The machine on which the planning software will be installed should run a 64-bit Windows 10 operating system. To install the planning software, run the setup.exe program from the installation USB card or CD-ROM. The default installation path should not be modified.

After installation is complete, please restart the computer. After reboot is completed, check if there is an icon named microTargeting WayPoint Planner 3.0 on your desktop. Double click on the icon and check if the application starts. Follow the steps in the "Procedure Outline" section to perform a full verification of the software functionality.

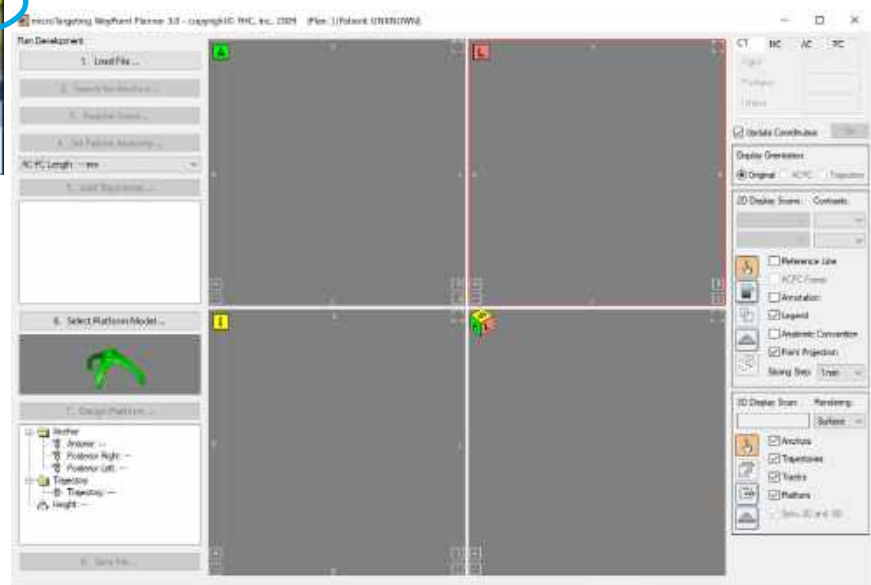
Startup

Start the planning software by running the 'pv.sav' file. At startup, the IDL splash screen may be displayed. Click the 'click to continue' button to advance into the planning software.

The planning software will start in the DBS mode by default. To change to epilepsy mode, please run the set_msdriver.bat script located at <root_directory>\multi-oblique.



IDL Splash Screen



Initial Planning Software Screen

Procedure Outline - Task Buttons

Numbered 'Task Buttons' guide the user through a planning session. When clicked, buttons expand to menus, shown below. Tasks required in a CT-MR planning are shown below in bold.

1. Load File

- Load Plan
- Load Primary CT**
- Load MR-1**
- Load MR-2
- Load More Scans
- Clear All
- About Planner

2. Search for Anchors

- Search Automatically for**
- Pick up Seed and Search
- Verify
- Clear All

3. Register Scans

- Register All Images Automatically**
- MR1 > CT**
- MR2 > CT
- Clear All

4. Set Patient anatomy

- Set**
- Verify
- Modify AC
- Modify PC
- Modify MP
- Clear All

5. Add Trajectories

- Add**
- Modify Target
- Modify Entry
- Rename
- Delete
- Mirror
- Clear All

6. Select Platform Model

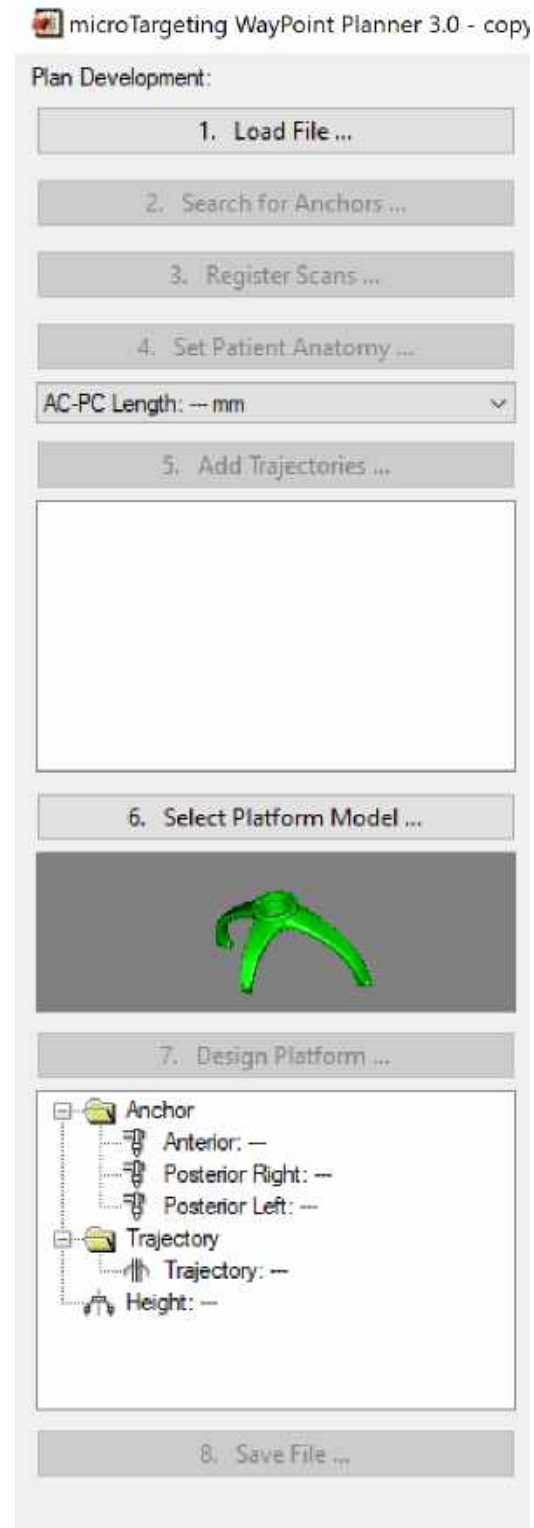
(Choose from list of available models)

7. Design Platform

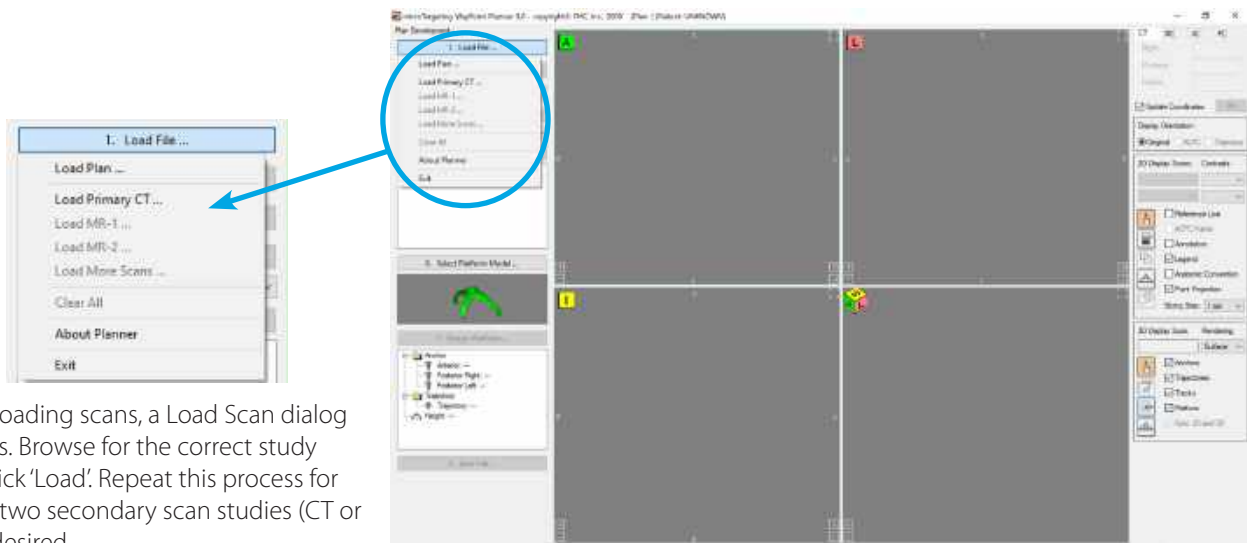
- Create Platform
- Verify Platform
- Assign All Anchors
- Assign Trajectories
- Select Height

8. Save File

- Save As Production File**
- Unlock Design for Adjustment
- Save Plan
- Pack Plan



Task 1: Loading Files

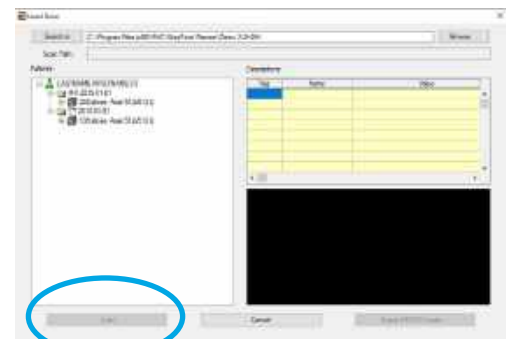


When loading scans, a Load Scan dialog appears. Browse for the correct study then click 'Load'. Repeat this process for one or two secondary scan studies (CT or MR) if desired.

Task #1: Loading Files

NOTE: The primary study must be CT. Secondary studies must be individually registered to the primary CT (see task 3).

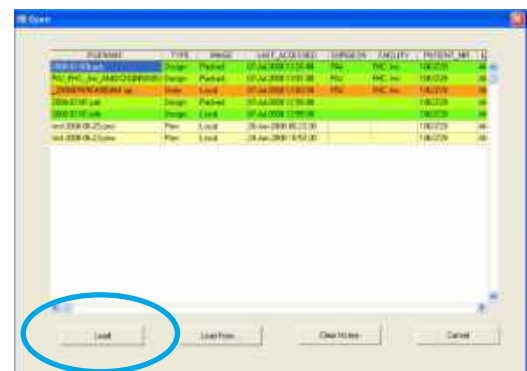
NOTE: Scan studies must be DICOM3.0+, and be contiguous with no X or Y movement, uniform Z increment throughout, (CT with slice thickness 1 mm or less and with all anchors completely within the field of view), with no missing slices, and zero gantry tilt.



Load Scan dialog

When loading a previously saved plan, an Open Plan dialog appears. The dialog shows a history of plans. Select the correct plan then click 'Load', or choose 'Load From' to browse for a plan.

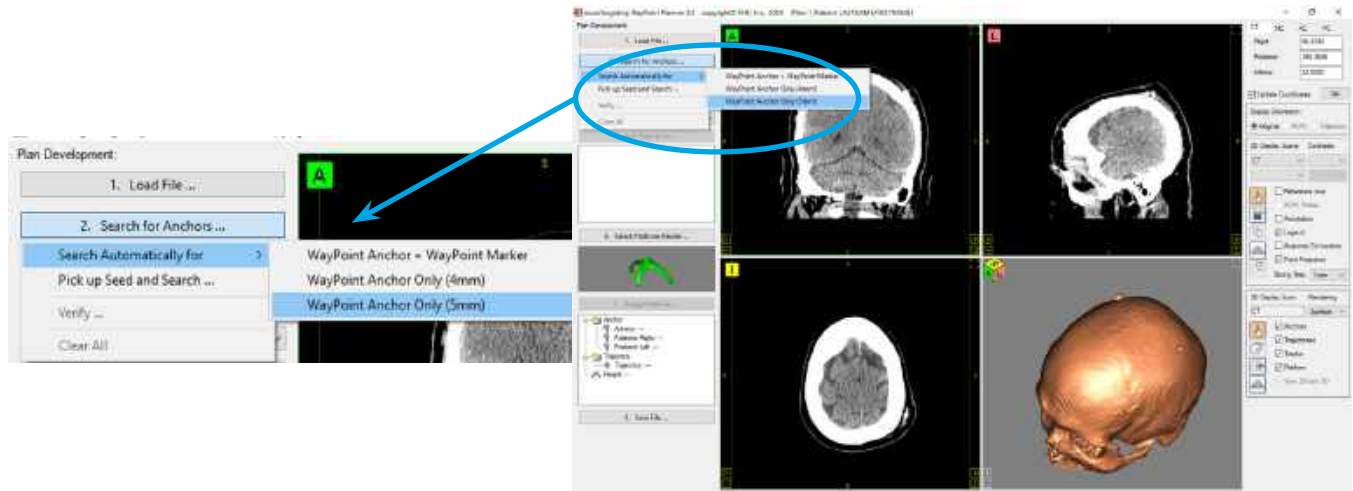
PWS and ZIP files require that scans exist where they were during planning. PAK files contain copies of source images and are recommended if plans are transferred to another location (see step 8 Save File).



Open Plan dialog

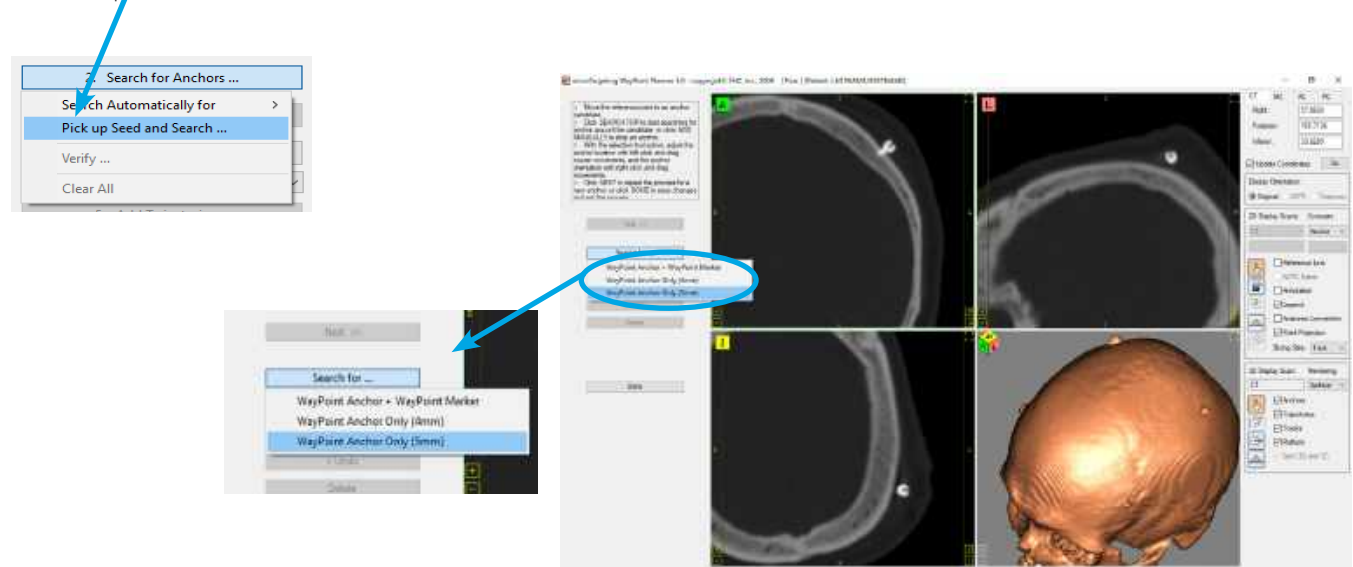
Task 2a: Search for Anchors

Click button #2, 'Search for Anchors...', to search automatically for anchors by anchor type. Contact FHC if the desired anchor type is not listed. CT must be displayed as the primary scan study to access the anchor search.



Task #2a: Search for Anchors

A dialog message will state the number of anchors that the software finds. If any anchors are not found automatically, select the 'Pick up Seed' method to add them.



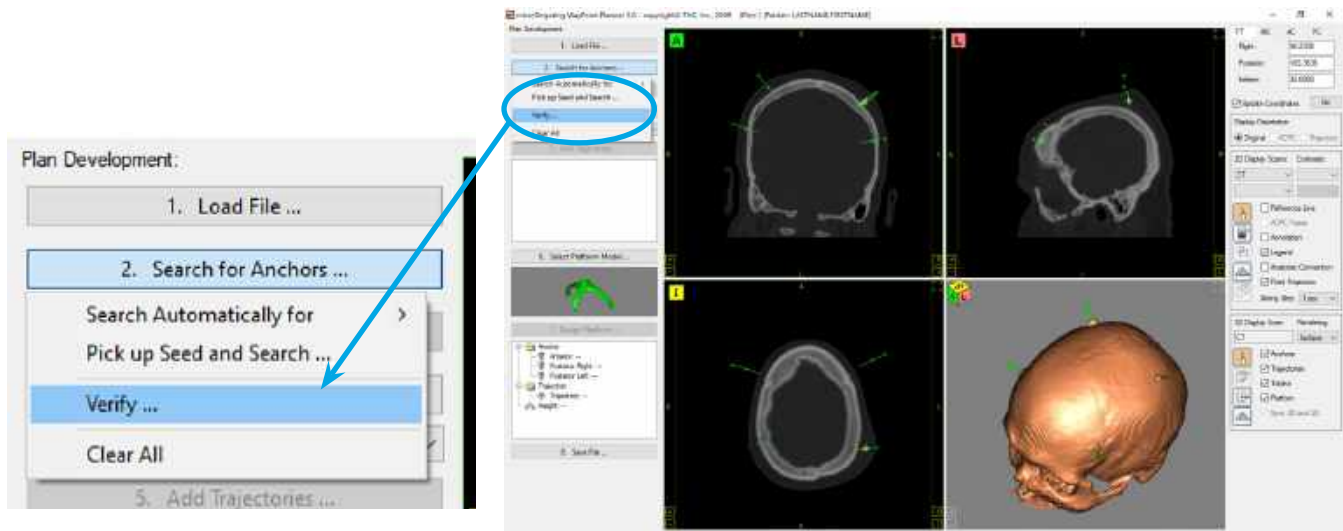
In the 'Pick up Seed' method process, the software will prompt for the user to move the reference point to an anchor site (top center of the anchor head) and click a button to search for a specified anchor type. If no anchor is found, the user may manually add the anchor with the selection tool while in the 'Pick up Seed' method process. Anchor location/orientation may be adjusted using left /right mouse click and drag with the selection tool active either now or during anchor verification (see task 2b).

For the best visual display of anchors, check the 2D display option 'point projection'. Task 2a requires the primary CT to be selected in the first 2D display scans list.

NOTE: Always carefully verify anchor position and orientation, whether found automatically or by the seed method (see task 2b).

Task 2b: Verify Anchors

Click button #2, 'Search for Anchors...' to 'Verify' and adjust, if necessary, anchor position and orientation.



Task #2b: Verify Anchors

Each found anchor will be outlined for verification. The plane of the 2D views, when verifying anchors, is the plane of the displayed anchor.

With the selection tool active,

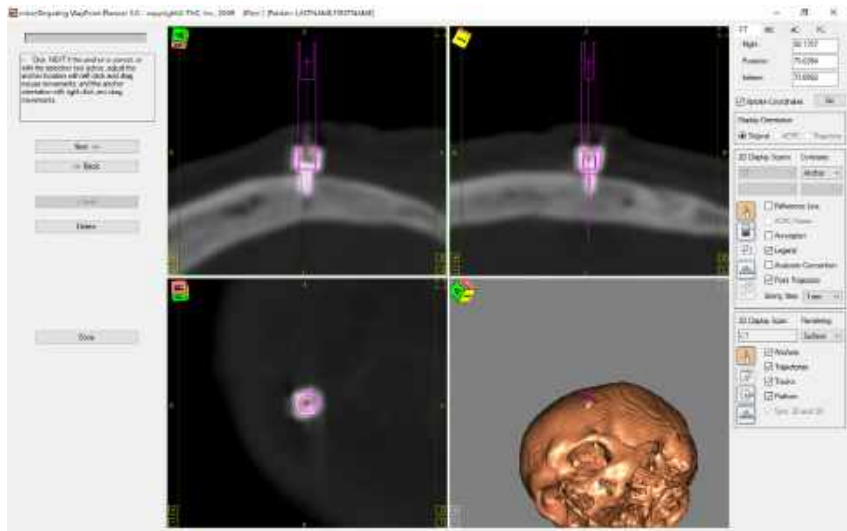
...left click in the panels to move the anchor's location point, which is the top center of the anchor,

...right click to move the orientation point, which is the point in space near the top of the outlined column.

The plane of the displayed anchor will adjust to the new location/orientation settings and be redrawn.

The display orientation should not be toggled and the displayed slice should not be panned in this process.

Adjust as necessary to center the image of the anchor within the drawn outline.



Anchor Verification

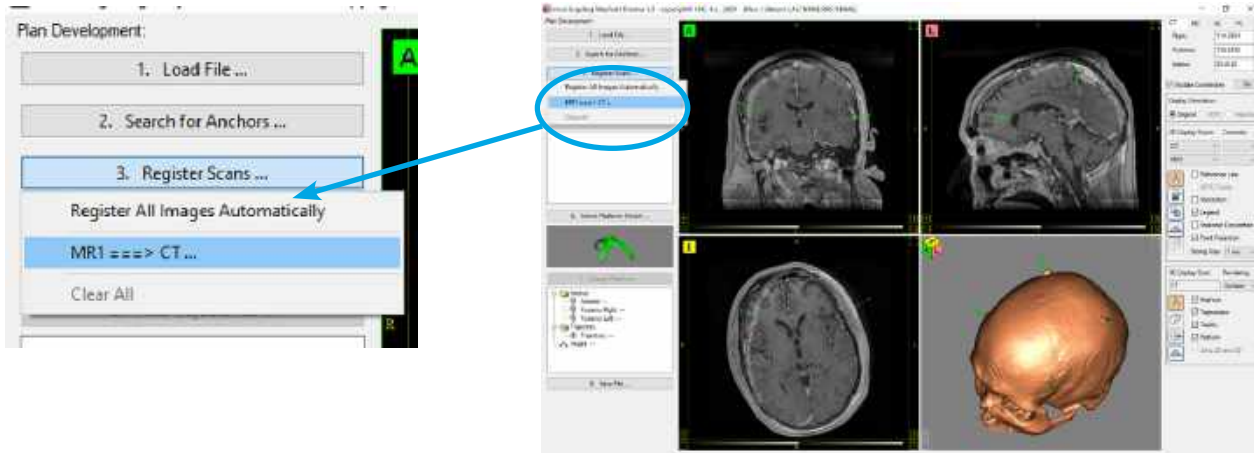
NOTE: The verification outline must be centered on anchors in all three 2D views, with its axis centered on and parallel to the axis of the anchor.

NOTE: If using marking devices such as locator pins, the orientation point of the verification outline must be set to the center of the marking device.

Task 3: Register Scans

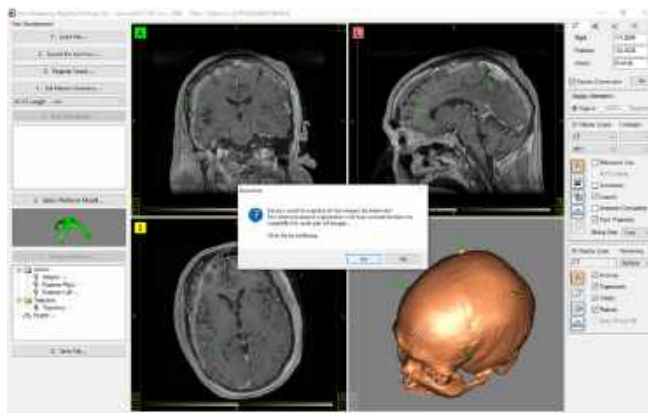
When a secondary scan study is loaded, the software prompts the user to register it. The user may register the images immediately or choose to register all images later before completing the plan.

Scan studies MUST be registered with the primary CT before being used in planning. If a study hasn't been registered, do it now. With CT and the secondary scan study displayed (see 2D display scans), click button #3, 'Register Scans...' and select the choice describing the scans to be registered to enter the registration process.



Task #3: Register Scans

The registration process includes methods to register by hand, by intensities, or by point matching. When multiple scans have been loaded, the 'Register All Images Automatically' button may be selected to merge all images. Be sure to verify each merge individually.



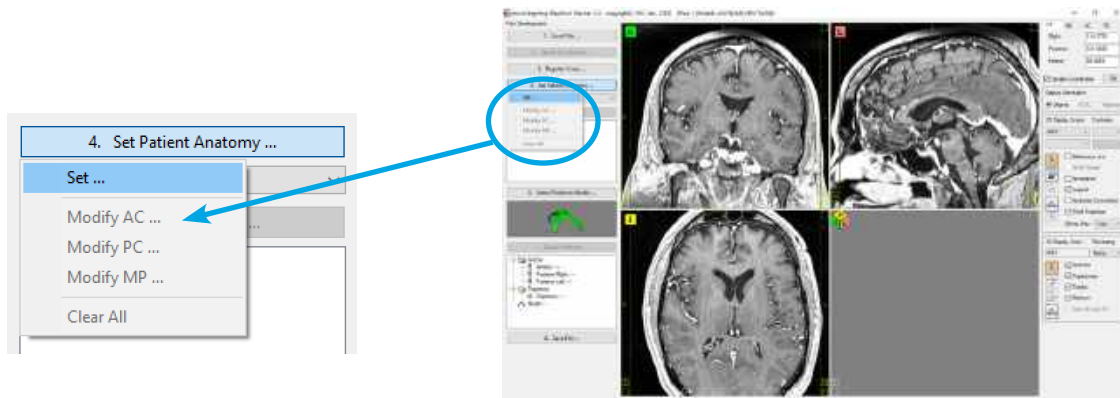
Multiple Scan Merge



Two Methods of Merge Verification

Task 4: Set Patient Anatomy

Click button #4, 'Set Patient Anatomy...' to begin the process of setting patient anatomy.

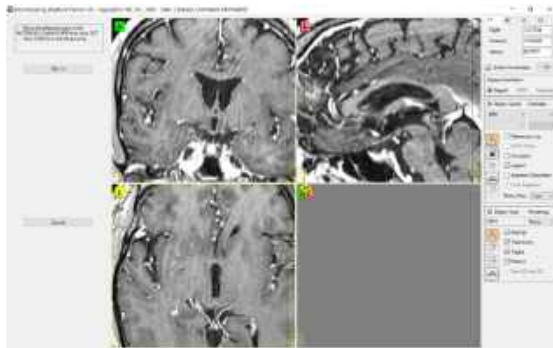


Task #4: Set Patient Anatomy

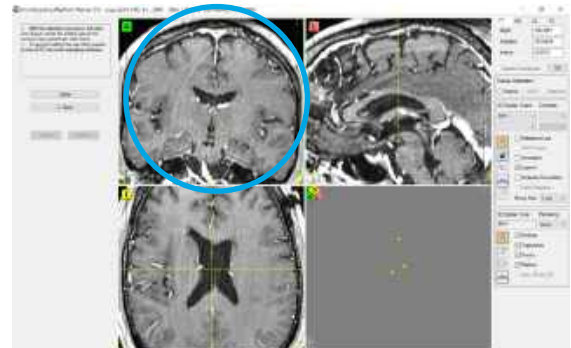
In this process Anterior Commissure (AC), Posterior Commissure (PC) and a midplane reference are set sequentially. Set the display to show reference lines and the scan study and zoom level to desired settings then

1. Move the reference point to the AC then click 'Set'.
2. Move the reference point to the PC then click 'Set'.
3. Click and drag the ACPC frame's upper vertical axis into alignment with the patient's middle plane then click 'Done'.

Once AC, PC and middle plane reference are set, they may be verified or modified using the menu under button #4.



(1., 2.) Set AC then PC using the reference point.



3.) Set Mid Plane reference by clicking, with the selection tool active, and dragging upper vertical axis of ACPC frame in the coronal panel.

NOTE: Register and verify registration of secondary scan studies with the primary CT before setting patient anatomy (see task #3).

NOTE: Precise locations of AC, PC and a middle plane reference point are required for accurate functional targeting, and are also used to create platforms with track offsets parallel and orthogonal to patient

Task 5: Add Trajectories

Click button #5, 'Add Trajectories...' to begin the process of creating a trajectory.

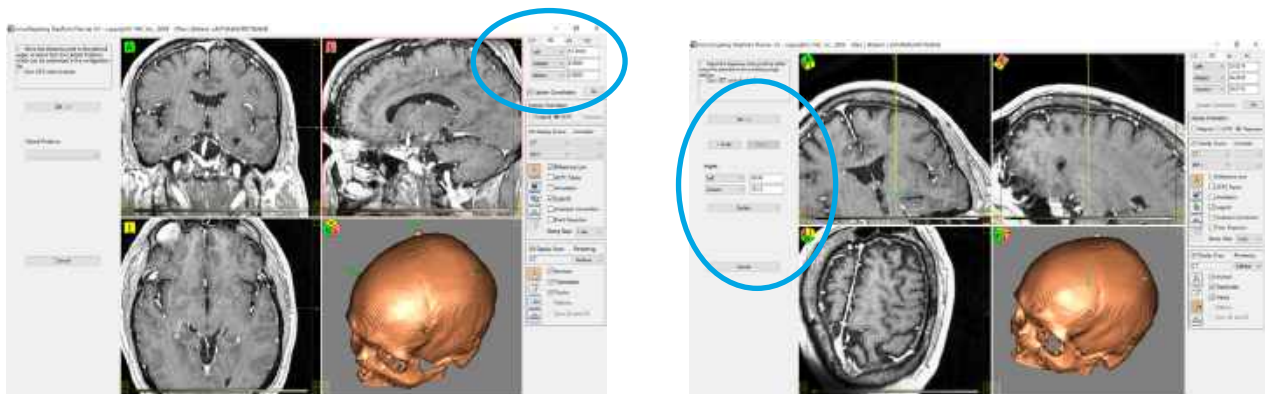


Task #5: Add Trajectories

In this process Target, Entry, and Trajectory Name are set sequentially. Set the display to show reference lines and the scan study and zoom level to desired settings then

1. Move the reference point to the Target then click 'Set'. The CT/MC/AC/PC fields may be utilized to locate a functional target. Check the 'Update Coordinates' box to have the values always correspond with the current reference point. Use the 'Go' button to ensure typed values have been accepted.
2. Click in the views, with the selection tool active, or update angle values to move the Entry, then click 'Set'. Note that slices may be panned without moving the entry; the entry point is indicated by the drawn trajectory line, not necessarily by the cross hairs of the reference lines. Utilize ACPC frame or trajectory alignment display orientation options to verify a good trajectory path through anatomy. 'Undo' and 'Redo' buttons allow a number of candidate entry sites to be evaluated.
3. (not shown) Type in a descriptive trajectory name, then click done.

Once Target, Entry and Trajectory Name are set, they may be verified or modified using the menus under button #5. A selected trajectory may be 'mirrored' to assist in creating a bilateral; target, entry and path should always be verified as desirable.

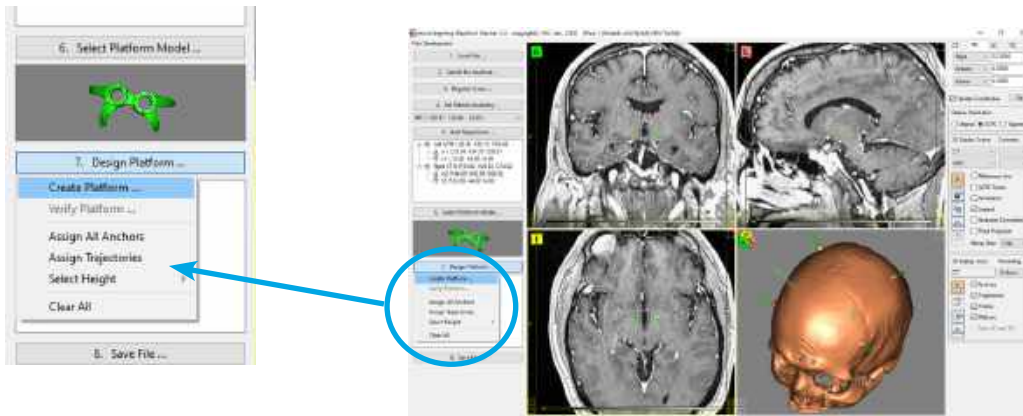


1.) Set Target using the reference point; CT tab fields may be used to enter offset to target values.

2.) Set entry by clicking with the selection tool active or enter angles; reference lines do not necessarily point at entry.

Tasks 6 and 7: Platform Design

Task buttons #6 and #7 are used to set platform design parameters.



Tasks #6 and #7: Platform Design

Set the views to show primary CT, then use task button #6 to choose a platform model compatible with the type, number and orientation of implanted anchors. A thumbnail image of the chosen model is displayed.

Use task button #7 to assign anchors and trajectories, set the platform height, and then to create the platform design. Select the 'Create Platform' button to have anchors and trajectories assigned automatically. A platform height will still need to be chosen. Assign anchors and trajectories manually, if necessary, by selecting each in turn and right clicking on the line item in the data tree under task button #7 and choosing the assignment option.

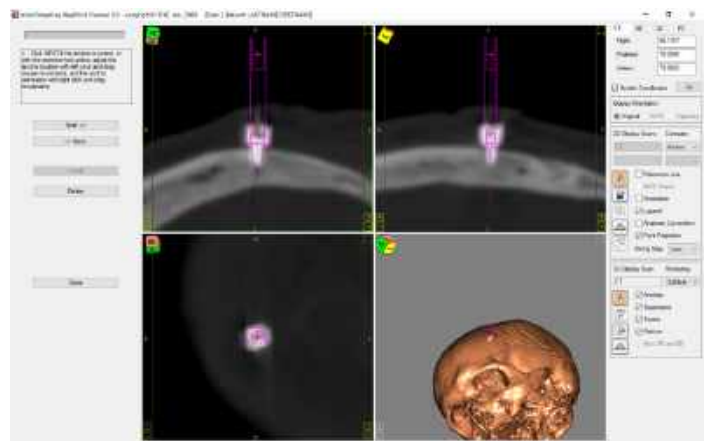
A designed platform will be displayed in the 3D views and have its outline traced in the 2D view panels. Use skin level thresholding of the primary CT for the 3D reconstructed view to verify platform proximity to patient anatomy.



Use task button #7 to verify platform feet rest squarely on the anchors. The software will display each anchor, in turn, with the platform design drawn in the views. The display orientation should not be toggled and the displayed slice should not be panned in this process.

If the platform is undesirable, task button #8 allows it to be unlocked for adjustment.

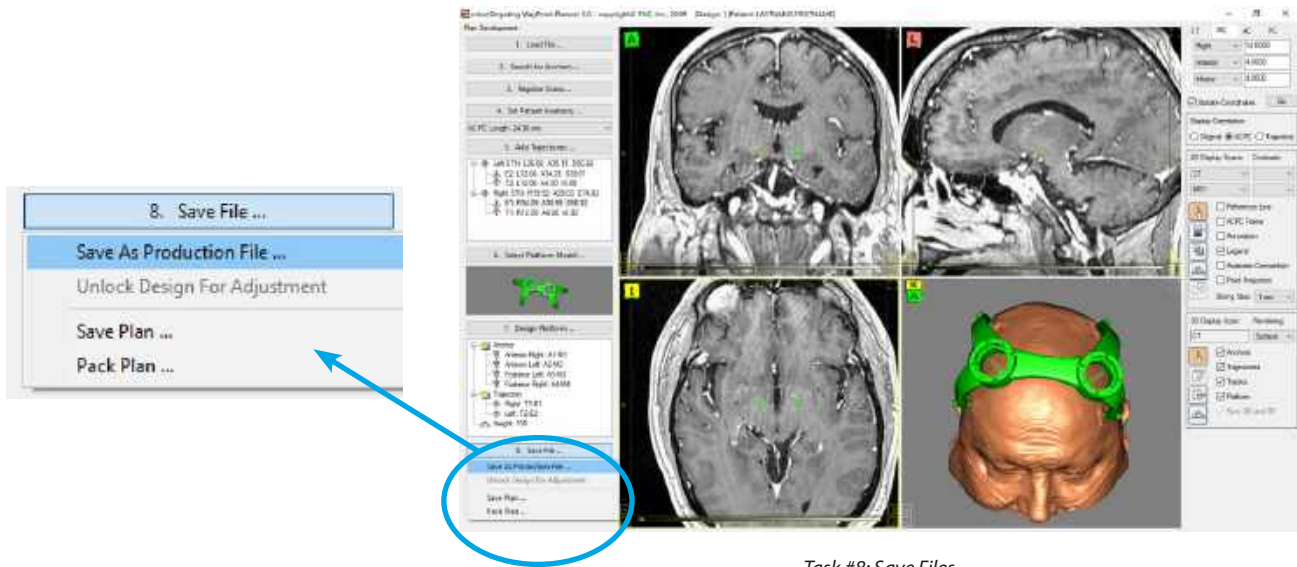
⚠ WARNING: Always verify the created platform is built with all parts connected with no parts thinning or twisted. Platform feet must all be properly aligned with their corresponding anchors. Legs must not pass through patient anatomy. Hubs must not overlap or be touching at all.



Platform foot/anchor verification

Task 8: Save Files

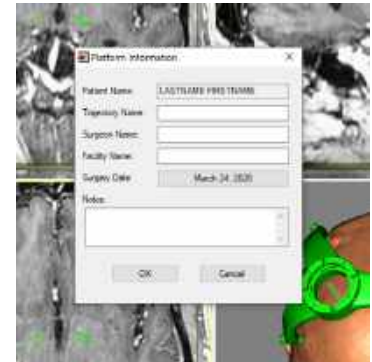
After verifying the platform design, click button #8, 'Save File...' and choose 'Save As Production File...' to create the production file necessary to build the physical device.



Task #8: Save Files

A standard 'Save As' dialogue will pop up, which will allow the Production File to be saved in the location of the user's choice. A 'Platform Information' dialog is used for entry of additional information necessary for proper production of the physical device.

The patient name is automatically entered into the dialog. A descriptive trajectory name, which will be printed on the physical device, should be entered. Surgeon name, facility and surgical date must be entered to ensure the device is built and delivered correctly.



Platform Information Dialog



Production File Confirmation Dialog

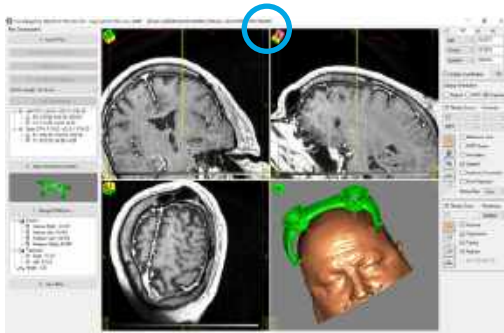
A confirmation dialog appears after creation of the production file. The dialog shows the path and filename of the production file. The production zip file name is in date / time format for easy identification.

The production file must be sent (email to mtplatform@fh-co.com) to the manufacturer at least four working days prior to intended delivery.

Task Button #8 may be used to save a plan at any point during the planning. Use the 'Save Plan' choice if the planning and scans will remain in their current location on the planning computer. Choose 'Pack Plan' if the planning and scans are to be moved together to a different location. A copy of scans is made with the Pack Plan option.

Display Options

The main viewing panels of the planning software may be set up to show coronal, axial, sagittal and 3D reconstruction simultaneously or with any one of the views filling the display area. Clicking the 'maximize' button on a view panel toggles the view state.



Four Panel Display



Single Panel Display

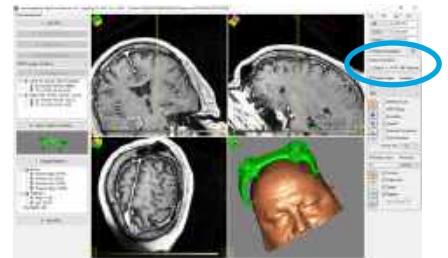
The images in the main viewing panels may be aligned in their original orientation, aligned with ACPC (after patient anatomy is set, see task #4), or with a selected trajectory (once trajectories are created, see task #5). The alignment selection is made by clicking on the appropriate option button in the 'Display Orientation' group.



Original Alignment



ACPC Alignment



Trajectory Alignment



Additional Display Options:

The lower right panel of the screen contains dropdown lists, tool buttons (see display tools), and other display option check boxes.

2D Display Scans allow choice of loaded scan studies for display. With CT, preset contrast options are available. Only two studies may be displayed simultaneously.

'Slicing Step' determines the distance between slices when scrolling through a slice stack in a 2D panel. Scrolling is done using the mouse wheel, if present, or by clicking and dragging up/down in the area along inside the right portion of each 2D panel.

The 3D display is determined by the top choice under 2D display scans. Rendering defaults to surface when a CT is displayed and to none when an MR is displayed. Rendering options include 'none', 'surface', and 'slice'.

Check boxes turn on or off display features.

Display Tools

Non button tools:

Reference lines. Dragging a reference line in any 2D scan moves the current reference point in all of the views. The current reference point is always in the same location of the scan volume in every view.

Patient anatomy and trajectory lists. Clicking on AC, PC or MP in the dropdown list under Task #4 moves the current reference point to the corresponding location in the scan views (patient anatomy must be set first). Clicking on entry or target lines in the data tree under Task #5 moves the current reference point to the corresponding entry or target (trajectory must be set first).

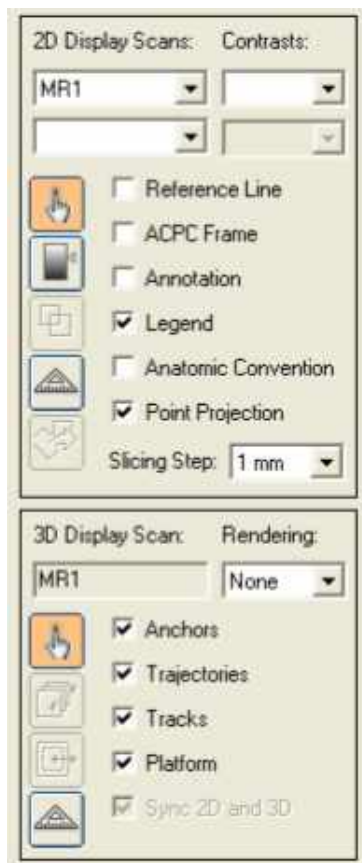
CT/MC/AC/PC tab. When the 'Update Coordinates' box is checked, entering new values in any field of the tab moves the current reference point to the corresponding location in the scan views. When updated, the fields give coordinates for the current reference point in the scan views.

Slice Scrolling is done using the mouse wheel (if present) with the cursor over a 2D panel, or by clicking and dragging up/down in the area along inside the right portion of each 2D panel. The distance between slices when scrolling is set by the 'Slicing Step' parameter, see 'Display Options'. Clicking [A], [P], [L], [R], [S], [I] moves the reference point anterior, posterior, left, right, superior or inferior a distance equal to the slicing step, which is set in a dropdown list in the 2D Display Scans group (see additional display options).

Zooming is done by clicking and dragging up/down in the area along inside the left portion of each 2D panel. Clicking [+] and [-] zooms in/out in steps.

Blend Bar. On the bottom part of each 2D panel is a bar which allows blending between the two scans displayed. Clicking and dragging the mouse from left to right adjusts the level of blend.

Tool Buttons: Tool buttons allow left / right mouse button click functionality in the 2D and 3D view panels.



2D Tools

1. Selection / Pan
 - This tool is normally used to move the reference point to a selected position; it may also be used to select anchors or trajectories for manual assignment in platform design.
2. Brightness, Contrast / Preset Brightness, Contrast
 - When two studies are displayed left click-drag affects the top scan selection and right click-drag affects the bottom scan selection.
 - When a single study is displayed, a right click over a 2D panel with this tool active opens a context menu with contrast presets.
3. Checkerboard/Patch
 - Checkerboard/Patch is available only when two scan studies are displayed simultaneously.
4. Measure Length/Measure Angle
5. Translate Scan / Rotate Scan
 - Translate/Rotate is available only in the scan registration process.
 - Right click with the 'Ctrl' key pressed to move the rotation point.

3D Tools

1. Selection / Rotate
2. Slice / Rotate
3. Surface Threshold/Surface Rendering
4. Measure / Rotate

System Maintenance and Repair

Software maintenance

Software troubleshooting:

The software generates log files and saves them locally for use in troubleshooting by trained personnel.

Crash and data recovery:

The system is able to recover from a crash of the software and to load the case/session until the point the system crashed.

System updates:

The WayPoint Planner notebook computer runs on the Windows™ operating system. If the computer is going to be connected to a hospital network, other information technology devices, or the internet, then the Windows, Anti-Virus and other installed software should be allowed to automatically download and install updates and security patches on a monthly basis. Contact your hospital's IT department for specific updating requirements.

Disposal:

Dispose of the WayPoint Planner according to hospital protocol.