



WayPoint™ Navigator (software version 4.5)

Directions For Use

L011-58 (Rev J1, 2019-07-12)

Contains directions for the following products:

66-WP-NV(4.5), C0239, C0241, C0242, C0243, C0244

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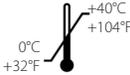
Indications for Use

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

Intended Use

WayPoint™ Navigator 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.	 Authorized Representative in the European Community	 Medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
 Consult the instructions for use.	 European Conformity. This device fully complies with MDD Directive 93/42/EEC and legal responsibilities as a manufacturer are with FHC, Inc., 1201 Main Street, Bowdoin, ME 04287 USA.	 Telephone number
 In reference to "Rx only" symbol; this applies to USA audiences only	 Indicates the temperature limits which the medical device can be safely exposed	 Instructions for end of life disposal
Rx Only Caution- Federal law (USA) restricts this device to sale by or on the order of a physician.	 Software license number	
 Indicates the catalog number		
 Indicates the serial number		

WayPoint™ and microTargeting™ are all trademarks of FHC, Inc.

Warnings and Cautions

-  WARNING: The WayPoint Navigator must be operated by a person that has been trained by an FHC, Inc. authorized representative and has read and understood the Directions For Use (DFU).
-  WARNING: The WayPoint Navigator 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 Navigator software provides no diagnostic function.
-  WARNING: The WayPoint Navigator must be installed by an FHC, Inc. authorized representative. Do not load third party software onto the WayPoint Navigator planning station.
-  WARNING: Discontinue use of the WayPoint Navigator should any damage or erratic function become evident.
-  WARNING: Prior to the first surgery, use of the WayPoint Navigator should be validated by using a Platform phantom. If the phantom does not appear accurate, please contact FHC, Inc. immediately.
-  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. Platform legs must not pass through patient anatomy.
-  WARNING: The data provided by the CranialVault™ Atlas embedded in the WayPoint Navigator software is solely for information. The atlas fusion is directly dependent on imaging quality. While the software will warn you for potential mis-use of the data, it remains the sole responsibility of you to check the fusion before using it.
-  WARNING: The fusion of the atlas registration may be affected if the reference MRI image used is acquired after surgery or contains tumors.
-  WARNING: The primary MRI image for use with the atlas registration should contain no leads, such as a preoperative MRI.
-  WARNING: The MRI image sets used in the module should contain data from below the nose to the top of the head at a minimum.

-  WARNING: The primary CT image sets should contain a range of data at least 15 cm long starting from just under the nose towards the top of the head.
-  WARNING: For FHC microTargeting™ Platform users, the system labeling shall state that CT image sets should contain a range of data that contains the anchors.
-  WARNING: For Leksell® and CRW® frames user, the CT image sets should contain a range of data that contains the localizer rods.
-  WARNING: Missing CT slices may affect the extraction of anchors /frame localizer.
-  WARNING: Very fine resolution image sets may slow down system performance and may not be able to be loaded due to memory constraints.
-  WARNING: Image and atlas fusion may be affected by patient movement during scan, brain shift, and air in the brain.
-  WARNING: The WayPoint Navigator software may be used only with one of these specific frames: microTargeting Platform, FHC Inc; CRW®, Radionics™; Leksell® G-Frame, Elekta.

Rx Only CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

CAUTION: The Cranial Suite workstation is not designed for sterilization.

CAUTION: Do not drop the WayPoint Navigator workstation.

Product Descriptions and System Requirements

The following Navigator licenses are available which enable installation on a fixed number of computers for specific use cases:

C0239 - WayPoint Navigator Software (V4) Starter License

C0241 - WayPoint Navigator Software (V4) Standard License

C0242 - WayPoint Navigator Software (V4) Enterprise License

C0243 - WayPoint Navigator Software (V4) Pay-per-use License

C0244 - WayPoint Navigator Software (V4) Academic License

Licenses must be installed on a computer that meets the following requirements:

<p>Following are the minimum requirements:</p> <p>CPU: Intel Core 2 Duo or equivalent, 2.93+ GHz, 2 GB RAM Disk Space: 3 GB, Integrated Graphics Processor Monitor Resolution: 1152x864 Connection: USB 2.0 or greater OS: Windows XP(SP3) or Windows 7 (SP2+)</p>	<p>Following are the recommended hardware requirements:</p> <p>CPU: Intel I7 or equivalent, 3.4+ GHz, 4 GB RAM Disk Space: 6 GB Graphics Card: 1 GB of VRAM Monitor Resolution: 1920x1080 Connection: USB 2.0 or greater OS: Windows 7 (SP2+)</p>
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Also available

66-WP-NV(4.5) - Laptop with pre-installed starter license

Compatibility

The software is compatible with the following stereotactic systems:

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

CRW™ stereotactic system by Integra Radionics™, Inc.: Refer to the documentation provided by Integra Radionics™, Inc. for details on proper use of the system.

Leksell® stereotactic system (Coordinate Frame G) by Elekta: Refer to the documentation provided by the Elekta for details on proper use of the system.

The software is compatible with the following intraoperative recording systems:

Guideline 4000™ 5.0 and Guideline 4000 LP+™ by FHC, Inc.: Refer to the Guideline system instruction manuals

The software is compatible with the following lead models (please refer to the manufacturer for details):

Medtronic: 3389, 3387, 3391; **Abbott:** 6142, 6143, 6144, 6145, 6146, 6147, 6148, 6149, 6158, 6159, 6160, 6161, 6166, 6167, 6168, 6169, 6170, 6171, 6172, 6173, 6178, 6179, 6180, 6181; **PMT:** 2102-06-091, 2102-08-091, 2102-10-091, 2102-12-091, 2102-14-091, 2102-16-091, 2102-16-092, 2102-16-097, 2102-16-098; **Boston Scientific:** DB-2201; **Ad-Tech:** RD06R-SP05X-000, RD08R-SP04X-000, RD08R-SP05X-000, RD10R-SP03X-000, RD10R-SP04X-000, RD10R-SP05X-000, RD10R-SP06X-000, RD10R-SP07X-000, RD10R-SP08X-000, BF09R-SP61X-0BB; **Integra:** AU4D5L25, AU6D5L25, AU8D5L25, AU10D5L25, AU12D5L25, AU4D10L25, AU6D10L25, AU8D10L25, AU4D10L5, AU6D10L5, AU8D10L5; **Neuropace:** DL-330-10, DL-330-3.5, DL-344-10, DL-344-3.5

The software is compatible with the following Medtronic implantable pulse generator models (please refer to the manufacturer for details):

Solectra™ (7426), Kinetra™ (7428), Activa™ RC (37612), Activa™ PC (37601), Activa™ SC (37602, 37603), Activa™ ENS (37022)

Illustrative Procedure:

System Start-up

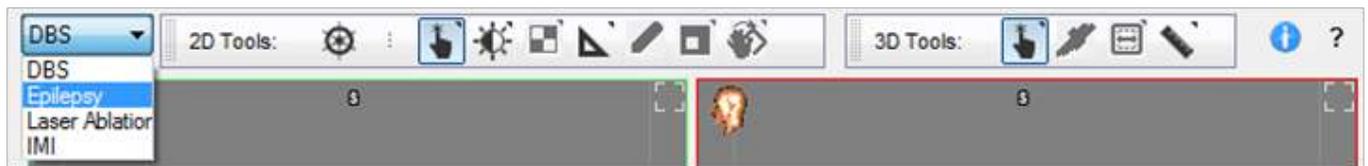
1. Launch WayPoint Navigator application
2. Select a module
3. Select a frame (if applicable)

 **WARNING:** WayPoint Navigator software must be installed before following these steps.

Planning Module

The WayPoint Navigator planning module is used during the planning phase of a surgical procedure and provides the user with the tools and assistance necessary to guide the selection of each trajectory and convert it into stereotactic frame coordinates.

Select the type of procedure in the drop-down menu:



- a. DBS - Deep Brain Stimulation
- b. Epilepsy - SEEG
- c. Laser ablation - LITT
- d. IMI - Radial trajectory

1. Load scans

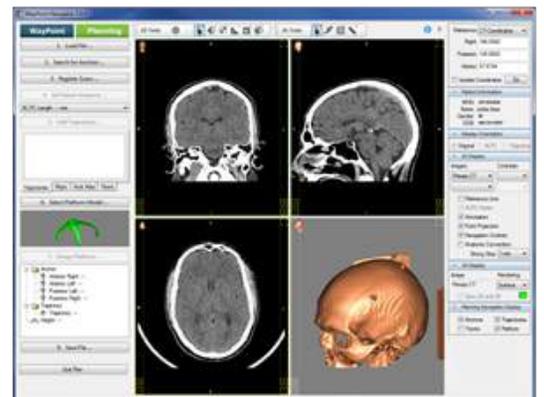
A. Start new plan

1. Click on "Load File..." from the main menu.
2. Click on "Load Primary CT" or "Load Primary MRI." A "Load Scan" dialog opens.
3. Browse for the correct study, and then click "Load."
4. Load additional scans if desired.

 **WARNING:** The first scan loaded for each patient will be the reference scan for the duration of the planning/intra-op session. The primary study must be CT. Secondary studies must be individually registered to the primary CT. 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.

B. Load a previously saved plan

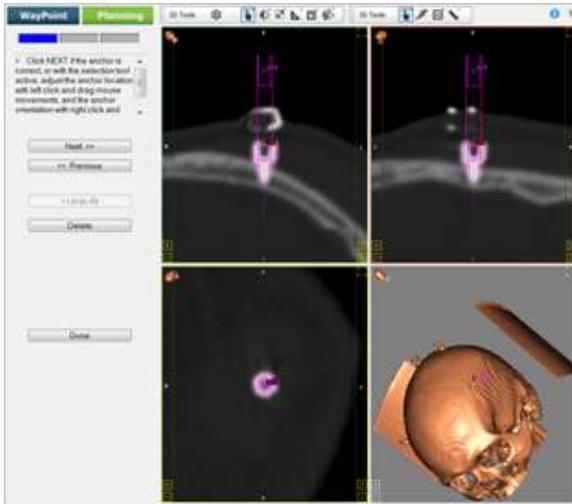
1. Click on "Load File..." from the main menu, then "Load Plan" to open up a dialog showing a history of recently saved plans. Select the correct plan then click "Load", or choose "Load From" to browse for a plan.
2. PWS and ZIP files require that scans exist where they were during planning. PAK files contain copies of source images and we recommend creating one if plans are transferred to another location.
3. When scans are loaded, they are displayed in the 2D and 3D views.



2. Search for anchors/rods

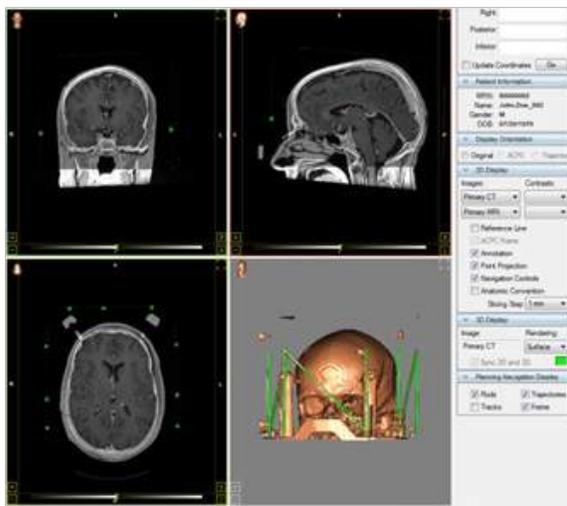
A. Localization of the anchors for the microTargeting Platform

1. Click on "Search for Anchors..." from the main menu.
2. Select "Search Automatically for" option.
3. Select the type of anchors. The system starts searching for the anchors.
4. Visually verify the position of the virtual model for each anchor. Adjust the position and orientation if necessary.
5. Confirm that the number of anchors found by the system is correct.
6. If the number of anchors found is incorrect, click on "Pick up Seed and Search" option to manually locate the anchor(s). Marked anchors will be displayed on the 2D/3D views.



B. Localization of the Rods for Leksell and CRW Frames

1. Click on 'Search for Rods...' from the main menu.
2. Select 'Search Automatically for...' Select the type of rods. The system starts searching for the rods.
3. A dialog message will state the mean squared error (MSE) of the extraction. Acceptable values for MSE need to be <math>< 1\text{mm}</math>. Verify the position of the extracted rods. If rods localization is not correct, clear the rods and use the seed point method to locate them.
4. The rods are displayed in green in the 2D/3D views.



 WARNING: Utilize AC/PC, frame, or trajectory alignment from the Display Orientation control panel to verify a good trajectory path through anatomy.

 WARNING: To visualize the trajectories on the 2D/3D views, check the trajectories in the planning navigation display control panel.

3. Automatic plan generation

This option allows the user to skip steps 4-6 for DBS, Epilepsy, and Laser Ablation procedures.

1. Click "Load File..." from the main menu.
2. Select "Generate Plan."
3. Select a target and click "OK." The system will start generating the plan.
4. Verify the registration, anatomy and trajectories. Registered images, anatomy and trajectories will be displayed in the 2D and 3D views.



WARNING: This software has parameters to safeguard against predictions that are outside reasonable possibility. If targets are preselected outside these parameters, a warning will appear notifying user that the target is out of threshold and to proceed with caution. If the target is outside the warning threshold, the preselected targets will be discarded, and the software will prompt the user to select the target manually.

4. Register scans

When a secondary scan study is loaded, the software prompts the user to register the images immediately. If preferred, the scans can be registered later.

A. Automatic registration

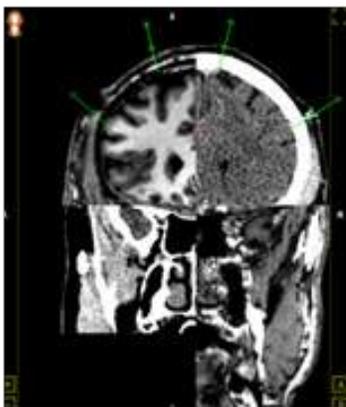
Automatic registration is the preferred method of registration. It does not require additional information or actions because it automatically aligns the CT and MR images using intensity values and merges them to the atlas.

1. Click on "Register Scans..." from the main menu.
2. Select "Register All Images Automatically."
3. Select both "Primary MRI --> Primary CT" and "Primary MRI --> Atlas." Click "OK." The system aligns the images.
4. Verify the registration and visually check the alignment of the images using the "Multi-image Validation" tool (2D tools bar).

B. Manual registration

There are three ways to register images manually: by intensity, by image acquisition, or by reference points selected by the user.

1. Click on "Register Scans..." from the main menu.
2. Select "Primary MRI --> Primary CT" from the options.
3. Optional: Manually align the images using the "2D Image Adjust" tool (2D tools bar).
4. Click on "Register by Intensity."
5. Verify the registration and visually check the alignment of the images using the "Multi-image Validation" tool (2D tools bar).



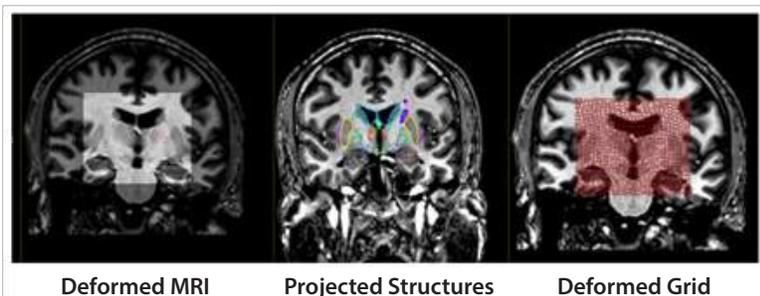
WARNING: Manual image registration only registers image. Separate registration to the atlas is required.

C. Atlas registration

1. Click on "Register Scans..." from the main menu.
2. Select "Primary MRI --> Atlas."
3. Optional: Align the images manually using the "2D Image Adjust" tool (2D tools bar).
4. Check "Global" and "Local."
5. Click "Register."
6. Verify the registration and visually check the alignment of the images using the "Multi-image Validation" tool (2D tools bar).

D. Atlas registration verification

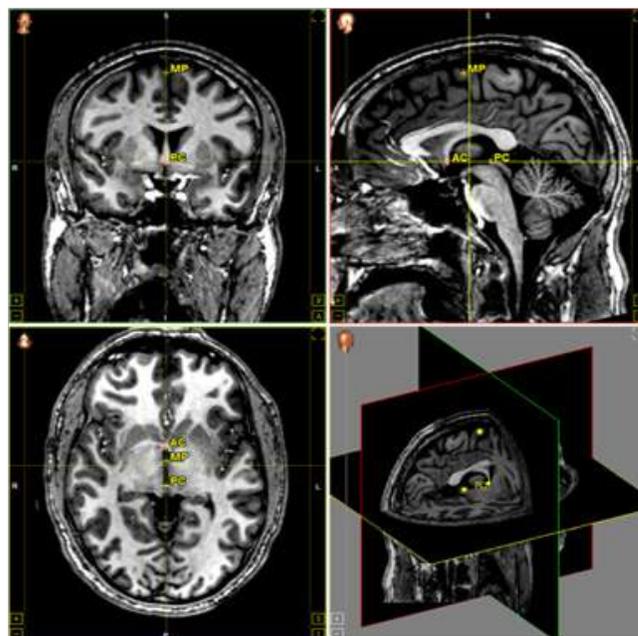
1. Confirm that the corresponding atlas structure aligns with the visible boundaries of the structure in the MR image.



2. Choose "Deformed MRI" to show the atlas registration as an MR image warped to the MR image. Use the "Multi-image Validation" tool (2D tools bar) to visually confirm that the atlas aligns with visible structures in the MR image.
3. Choose "Atlas Anatomy" to show the atlas registration as a set of outlined structures warped to and projected on the MR image. Confirm that the atlas structures align with the visible structures in the MR image.
4. Choose "Deformed Grid" to show the atlas registration as a grid warped to the MR image.

5. Set patient anatomy

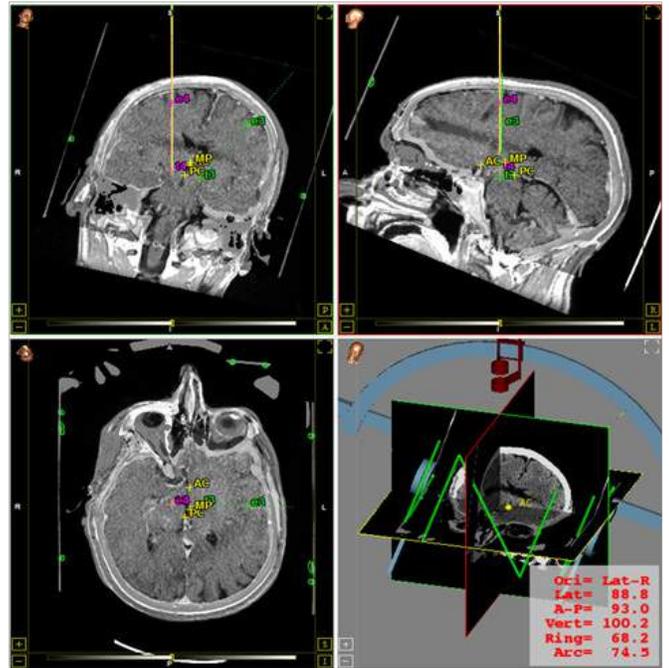
1. Click on "Set Patient Anatomy..." from the main menu.
2. If atlas registration was performed, software will prompt the user to set patient anatomy based on atlas registration. Select "yes" if this is desired, or 'no' to manually set patient anatomy.
3. Verify the patient anatomy and readjust the Anterior Commissure (AC), Posterior Commissure (PC) and Mid-Plane (MP) points if necessary, and select "Done."
4. If atlas registration has not been done, proceed to manually select the AC, PC, and MP reference.



6. Add trajectories

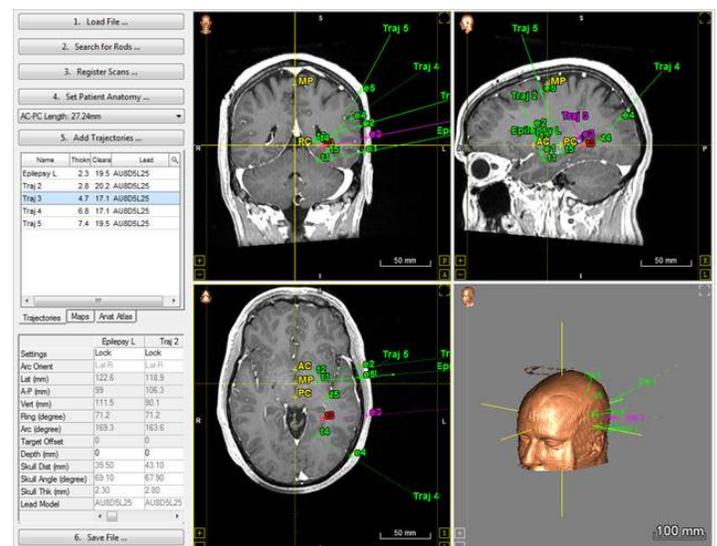
A. DBS

1. Load a trajectory from a saved session.
Or
1. Click on "Add Trajectories..." from the main menu.
2. Move the reference point to the planned target, or select from the default positions for a target type.
3. Select a target type from the drop-down list.
4. Click on "Set" button.
5. Adjust the trajectory entry point by either using the selection tool or entering angle settings.
6. Move the cursor to the target. When satisfied, 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.
7. Click on "Set" button.
8. Type in a descriptive trajectory name, diameter and color then click "Done." Target and entry points can be modified if necessary. Trajectories will be added on the trajectory list under the "Add Trajectory" button.



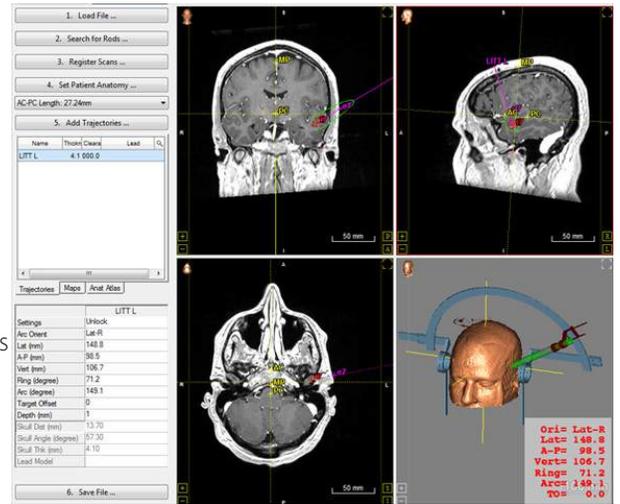
B. Epilepsy

1. Load a trajectory from a saved session.
Or
1. Click on 'Add Trajectories ...' from the main menu.
2. Move the reference point to the planned for the epilepsy target.
3. Click on "Set" button; a trajectory is displayed.
4. Select a recommended lead model for the drop-down list.
5. Set the target-skull distance, trajectory skull angle, and skull thickness by moving the trajectory on the display panels (left click mouse).
6. Click on "Set" button.
7. Type in a descriptive trajectory name, diameter and color then click "Done." Trajectories can be modified if necessary. Trajectories will be added on the trajectory list under the "Add Trajectory" button.
8. Repeat steps 1-7. If the clearance turns red, a conflict exists between the two trajectories and one of the trajectories must be modified.



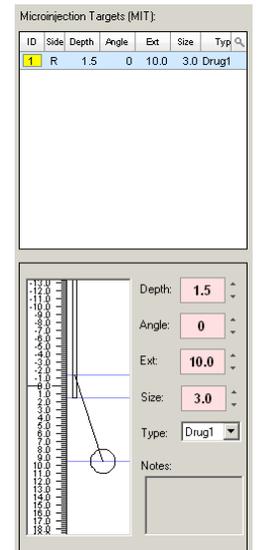
C. Laser ablation

1. Load a trajectory from a saved session.
- Or
1. Click on "Add Trajectories ..." from the main menu.
2. Move the reference point to the planned for the LITT target.
3. Click on "Set" button; a trajectory is displayed.
4. Select a recommended lead model for the drop-down list.
5. Set the target-skull distance, trajectory skull angle, and skull thickness by moving the trajectory on the display panels (left click mouse).
6. Click on "Set" button.
7. Type in a descriptive trajectory name, diameter and color then click "Done." Trajectories can be modified if necessary. Trajectories will be added on the trajectory list under the "Add Trajectory" button.



D. IMI

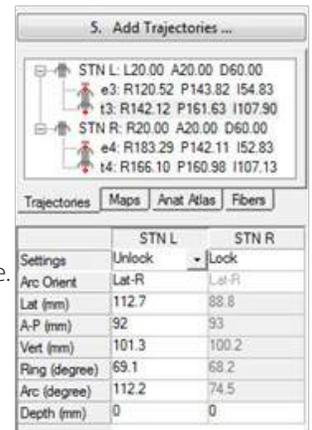
1. Load a trajectory from a saved session.
- Or
1. Click on "Add Trajectories..." from the main menu.
2. Move the reference point to the planned IMI target.
3. Click the "Set" button; a trajectory is displayed.
4. Select "IMI" procedure type from the dropdown menu.
5. Select the IMI trajectory and click "Add Trajectories..." then "IMI..." option.
6. Right click in the Microinjection Targets Window and select a "Add MIT" and select a drug type.
7. Right click on the previously created target and select "Locked" to unlock the target.
8. Select the Depth (mm), Angle, Extension (mm), Volume Size, and Drug Type. Settings can be adjusted by clicking the arrows next to the parameter or double-clicking on the parameter and manually entering a value.
9. Once the settings have been adjusted, lock the MIT to avoid unwanted changes.
10. Right click in the Microinjection Targets Window and select a "Add MIT" to add additional Microinjection Targets.
11. Click "Done" when finished.



7A. Adjust the frame coordinates (Leksell and CRW frames)

Once the trajectories have been defined, the system will generate the frame. The frame and its settings will be displayed in the 3D view. These settings can be adjusted if necessary.

1. In the frame settings table, click on "Lock" and select "Unlock" option.
2. To modify one entry, select the entry, type the new values and hit click "Enter." The user also has the option to obtain frame settings for different mounting orientations. To change frame orientations, click on the drop down list of the frame orientations and choose the desired one.
3. Once the settings have been adjusted, lock the settings again to avoid unwanted changes.
4. For laser ablation, the target offset can be modified.



7B. Platform design (microTargeting Platform)

A. Select platform

1. Set the views to show primary CT as the first image in the 2D display panel.
2. Click on "Select Platform Model..." from the main menu.
3. Select the platform model compatible with the number of anchors and trajectories.

B. Design platform

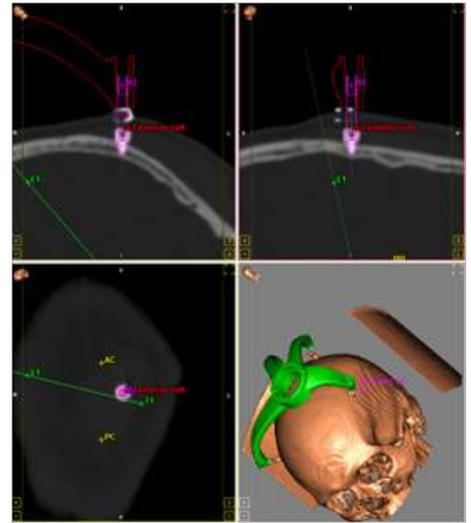
1. Click on "Design Platform" from the main menu.
2. Select "Create Platform..." to have the anchors and trajectories automatically assigned.
3. Select a height for the platform. The system generates the platform. The platform is displayed in the 2D and 3D views.
4. Verify the platform by visually checking 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.



WARNING: Assigning anchors and trajectories manually might be necessary if the proper number of anchors and/or trajectories doesn't match the selected model.



WARNING: To visualize the platform on the 2D/3D views, be sure to check the platform in the planning navigation display control panel.



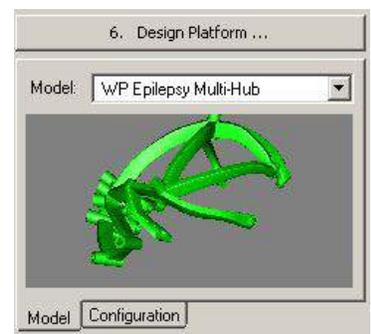
7C. Platform design (microTargeting Multi-Oblique Platform)

A. Select platform

1. Set the views to show primary CT as the first image in the 2D display panel.
2. Select a Multi-Oblique platform model from the "Model" tab of the control below the "Design Platform..." button.

B. Build initial platform

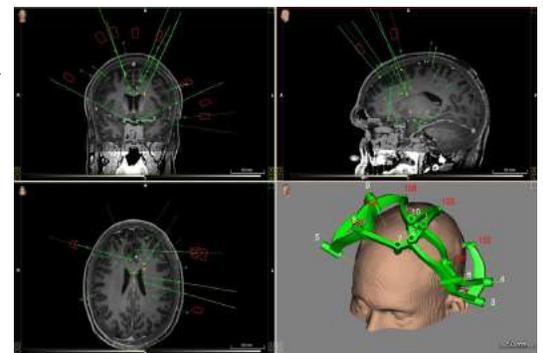
1. Click "Design platform..." then select "Create Platform..."
2. Answer "yes" to initialize connections.
3. Select desired platform height (distance from the outer table of skull to BOTTOM of platform hub).
4. Platform will build, then ask to be verified
 - i. Once verified platform will display in all views if enabled in platform navigation display control panel.
 - ii. Model will switch to "Configuration" tab to show connection table.
 - iii. In the 3D view hubs will be labeled with white numbers starting with "1" and feet labeled with red numbers starting at "101".
 - iv. In the 2D views the platform cross sections will be shown as a red outline.



Select platform

C. Edit platform configuration

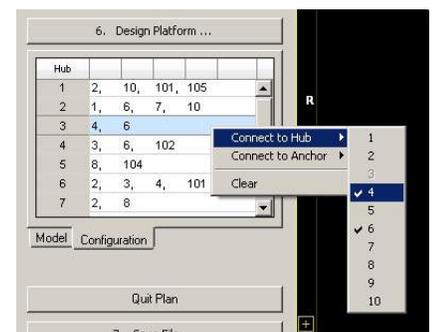
1. Right click on a row in the connections table to edit connections from selected row to other hubs or anchors (feet).
 - i. Once the connection table has been edited the platform in the 3D view will become transparent to indicate it is out of date.



Build initial platform

D. Rebuild platform

1. Click "Design platform...", then select "Create Platform..." to display updated platform.
2. If you are satisfied with the appearance of the platform, select "yes" to verify.



Edit platform configuration

F. Change platform heights (if needed).

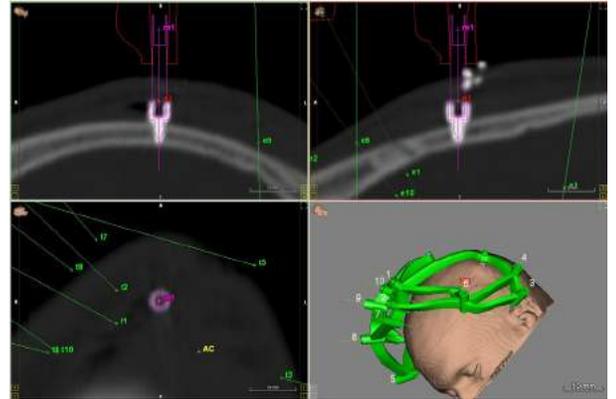
1. Click "Design Platform..." then select "Select Height" then choose new value.
2. Rebuild platform and verify when prompted.

G. Verify platform.

1. For each trajectory, confirm the calculated position of the anchor (shown in cyan outline) properly aligns with the CT image.
2. If additional changes needed, perform, then repeat "F" steps.

 **WARNING:** Assigning anchors and trajectories manually might be necessary if the proper number of anchors and/or trajectories doesn't match the selected model.

 **WARNING:** To visualize the platform on the 2D/3D views, be sure to check the platform in the planning navigation display control panel.



8. Save plan

1. Click on "Save File..." from the main menu. Select "Save Plan" if the plan file and images files will remain in their current location on the planning computer.
2. Select "Pack Plan" if the plan file and image files must be moved together to a different location.
3. Select "Save as Production file" (microTargeting Platform only) to send the platform model to FHC for frame construction.

CAUTION: Save plan or pack file can be done anytime during the planning process.

CAUTION: (Leksell G and the CRW frames) It is recommended to create a .PAK file before moving to the intra-op module. This will allow all images, transformations, and trajectory information to be saved together.

CAUTION: (microTargeting™ Platform) The production file must be sent to FHC at least four working days prior to intended delivery. It is recommended to create a .PAK file as well.

Intraoperative Module

The Cranial Suite Intraoperative module will be used during the surgical phase of a DBS procedure and give the user the tools and assistance to navigate virtually in the patient's brain while annotating experiments. The module will let the user place a virtual lead in the brain corresponding to confirm its location before placement in the patient's brain.

While still in the Pre-Op Module, planning sessions can be ported directly to the Intra-Op module by clicking the "Save..." button and choosing the "Go to Intra-Op Module" option.

Select the type of procedure in the drop-down menu:

I. DBS

The intra-op guidance interface is divided into four different tabs: tracks, data entry, implants, and atlas.

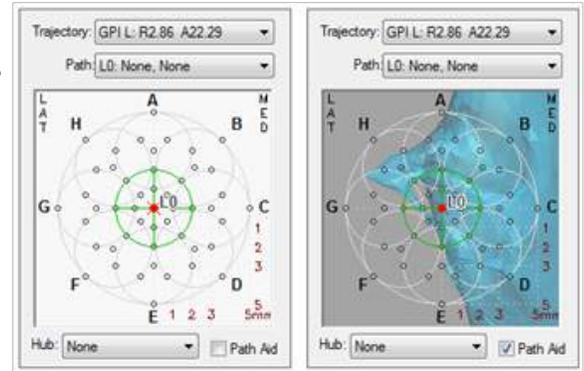
A. Load plan

1. Load an existing plan.
Or
1. Click on "Plan..." from the main menu.
2. Click on "Plan" and select the plan from the list of saved plan and click "Load" or click on "Load from..." and browse to find the saved plan on your computer or network.
3. Scans are displayed in the 2D and /3D views.

B. Tracks tab

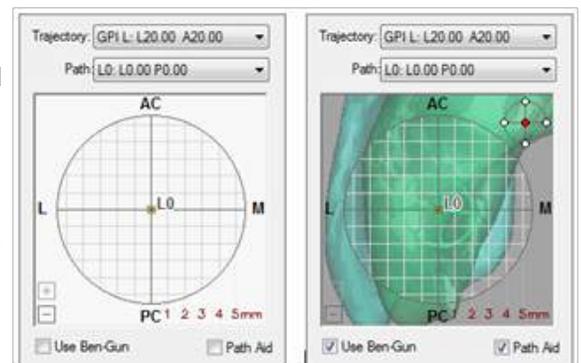
For microTargeting Platform:

1. Select the main trajectory (defined in the planning module) from the drop-down list labeled "Trajectory." The trajectory is highlighted in the center of a green circle (active Ben-Gun) on the path grid guide.
2. To create a parallel path to the initial path, use the Ben-Gun templates (circles on the grid). To create an oblique path, from the hub drop down list, select any of the entry and target offset positioners allowed by the microTargeting Platform system.
3. Select an appropriate path for the selected trajectory. To define a new trajectory path, double click on any of the little circles in the track positions window that denote the available paths. Each new pass will be automatically named incrementally (L0 L1, L2 etc. for left side and R0, R1, R2 etc. for right side).
4. Optional: If desired, enable "Path Aid" by checking the "Path Aid" box. Path aid overlays atlas anatomical structures (selected in the atlas tab) on the chosen electrode trajectory.



For CRW and the Leksell-G frames:

1. Select the main trajectory (defined in the planning module) from the drop-down list labeled "Trajectory." The trajectory is highlighted in the center of the path grid guide.
2. Select an appropriate path for the selected trajectory. To define a new path, double click anywhere in the circular guide. Select one of the 2 options: "Move both target and entry points" or "Move only the target point." Minimum resolution achievable between passes is 0.5mm.
3. Each new pass will be automatically named incrementally (L0, L1, L2 etc. for left side and R0, R1, R2 etc. for right side).
4. The frame coordinates of the current passes for the left and right side are shown on the frame setting table. By default the settings are locked. Numbers may be rounded or modified by unlocking the setting and typing in a new value.
5. Optional: If desired, enable "Path Aid" by checking the "Path Aid" box. Path aid overlays atlas anatomical structures (selected in the atlas tab) on the chose electrode trajectory.



x-y grid view

Track Coordinates:

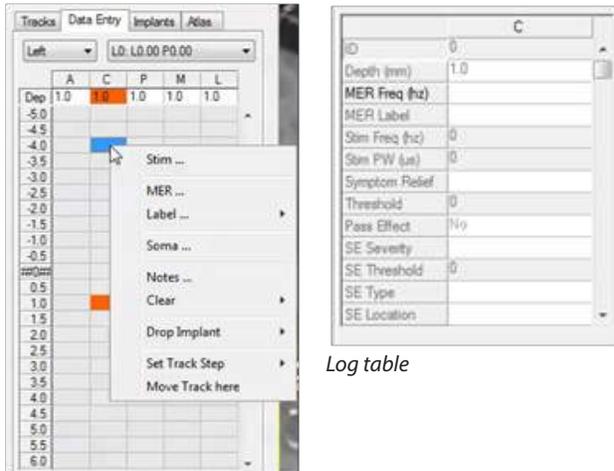
1. Once selected, the probes can be moved virtually. The user may set step size at 0.1, 0.5 or 1mm. The depth of the probe may be adjusted manually or by scrolling up or down with the mouse. The depth is relative to the planned target. Negative values are above target (superior to target) while positive values are below target (inferior to target).
2. The track coordinates provides user with the coordinates of the tip of the probe in a selection of reference coordinate systems: CT, MC, AC, and PC. The user may visualize all available track positions in the 2D and 3D views by selecting the "show available track positions" checkbox.



Step-depth and track coordinates panel

C. Data entry tab

The data entry tab provides an interface to collect data related to the current position of the track tip. Choose a trajectory and path from available trajectories and paths using the two drop-down menus immediately below the tabs. Right-click on any cell in the data entry table to bring up the options for data entry.



Data entry table

Labels:

1. Right-click on the lower-right highlighted cell and choose the "Label..." option to mark a cell as part of an anatomical region. Highlighted adjacent cells can label multiple cells at once.
2. Select a label from the options list. The labeled cell(s) will be colored in the data entry table, and colored tubes at the labeled section will be displayed on the 2D and 3D views. The labels will be saved in the data log with the surgery data and printed on the Intra-Op Report.

Notes:

1. Right-click on a cell to add notes.
2. Click on "Notes" from the options list.
3. Enter the notes in the box then click "OK." A mark (note ID) will be added on the cell in the data entry table. Notes will be saved with the surgery data and visible at the bottom the log table.

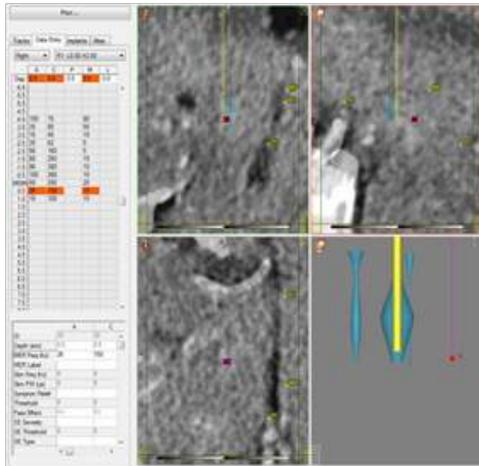
MER (Microelectrode Recording)

Manual recording:

1. Right-click on any cell in the data entry table and select "MER" from the options.
2. Select "Manual" from the drop-down in the MER entry data window.
3. Set all the parameters (histogram shape, sync tracks). Data from a maximum of 10 tracks may be manually entered - five on each side.
4. Assign tracks to each side/path before entering MER data in the text boxes. Ensure that the depth is accurately recorded. After entering data, press the "Enter" button. The depth field automatically readjusts to a value defined by the set step size (sync tracks checked). If at any time the user would like to enter data for a depth that is not accommodated within fixed step size, the depth may be manually entered. Data recorded will be displayed on the data entry table. Values will be drawn (histogram shape) in the 2D and 3D views. The data are reported in the log data table. All recordings will be written in the Intra-op report.

Automatic entry:

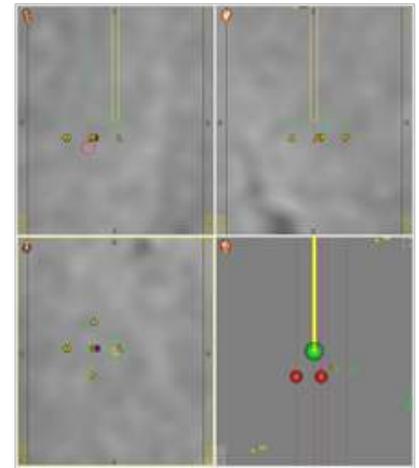
1. Right-click on any cell in the data entry table and select “MER” from the options.
2. Select “Guideline” or “MicroGuide” from the drop-down in the MER entry data window.
3. Enter the IP address of the host and ensure the port selection is set at 2567.
4. Set all the parameters (histogram shape, sync tracks).
5. Map MER tracks to channels on the Guideline.
6. Press the “Start Data Streaming” (Guideline) or “Acquire MER Data from server” (MicroGuide) button.
7. Once the connection is established, map channels from the Guideline to a particular side. If channels were not mapped to tracks on the Guideline system, Navigator will prompt the user to map channels to the appropriate tracks. Data are streamed and entered into the data entry table. Values will be drawn (histogram shape) in the 2D and 3D views.



 **WARNING:** Data visualization is for reference only. Do not solely rely on it for targeting purposes.

Stimulation recording:

1. Right-click on the cell in the data entry table at the location of the stimulation.
2. Select “Stim...” from the options.
3. In the stimulation entry data window, set up the parameters (Pulse Width (μ s), the frequency (Hz), impedance (kOhms), the stimulation mode (Current or Voltage), and the amplitude (mA or V depending of the stimulation mode)).
4. Enter the symptoms, side effects, and mood changes observed during the stimulation. To enter side effects, right click in the side effect box and make the appropriate selections. If mood based symptoms are being analyzed, make the appropriate selections via the slider bar. Add notes if desired.
5. Press the “Save and Start New” button. Note that multiple events may be recorded at a single depth.
6. Stimulation result appears in the 2D and 3D views as bubbles. The stim bubble is generated per the legend that can be viewed by checking the “Stim Legend” checkbox in the surgical navigation display control panel.



Stimulation results in 2D/3D views



Stim legend

Somatotopy recording:

The system will allow associating a nucleus, body part and type of somatotopic recorded to the current position of the tip of a track.

1. Right-click in the data entry table at the relevant location.
2. Select the "Soma..." from the options.
3. In the somatotopy window, select the path and depth and the nucleus, location and type.
4. Click on "Save and Start New." Repeat for other locations if desired.
5. Click on "Exit" to log and save the entries. The data are reported in the log data table and the somatotopic label written on the cell in the data entry table.

 **WARNING:** Lower limit for current/voltage amplitude that may be registered is 0.1mA/0.1V. If lower stimulation amplitudes are used, make notes in the stimulation event form.

Drop implant:

At any time of the surgery, the user can virtually drop an implant to visualize its position in the 2D and 3D views.

1. Right-click on the cell in the entry data table where to drop the implant.
2. Select the "Drop Implant" from the options.
3. Select the manufacturer, the type of lead and its alignment (center, top, or bottom of the lead related to the depth of the dropping point).
4. Enter a name for the implant. The lead model is displayed in the 2D and 3D views. The system switches to the implant tab where the dropped implant is displayed.

D. Implant tab

1. In the implant view or the 2D and 3D views, scroll-wheel the mouse to move the implant along the trajectory.
2. When the final position is set, right-click on the lead model in the implant view and select 'FEP' (final electrode position) to lock the implant to its final position.
3. Stimulation events through the lead may be recorded in a fashion similar to that described in the stimulation data entry section. To denote polarity of applied stimulus, left-click on the box in front of the lead contacts and choose desired polarities.



E. Save session/plan

At any time during the surgery, the session can be saved.

1. Click on "Plan..."
2. Select "Save..." if the plan file and image files will remain in their current location on the planning (.pio file).
3. Click "Pak..." if the plan file and image files must be moved together to a different location (.pak file).

F. Generate report

The report will include the patient's info (MRN, name, DOB, gender, surgery info (surgeon, neurologist, electrophysiologist, date of surgery), frame/platform, target, paths, FEP, all recordings (MER, Stim, Soma, label, notes).

1. Click on "Plan..."
2. Select "Generate Report" in the options.
3. Fill the "Surgery Information" form.
4. Select name and location for the report and click "Save." The report (in PDF format) opens.

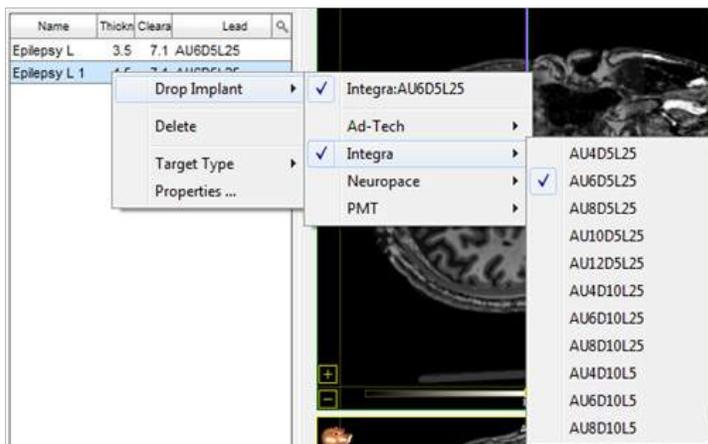
II. Epilepsy

The intra-op guidance interface for epilepsy is divided into three different tabs: trajectory, implant, and atlas.

A. Trajectory

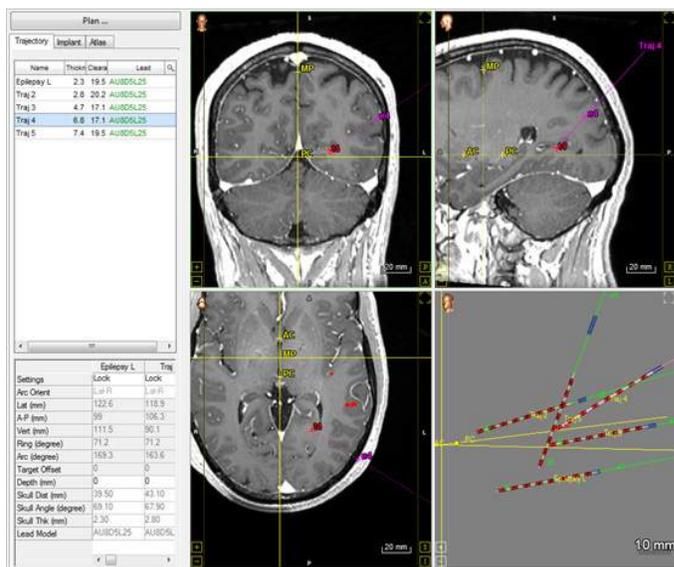
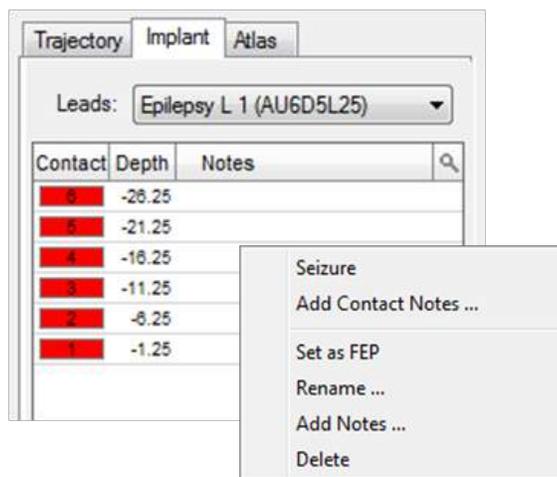
After the plan has been loaded, the trajectories are listed in the trajectory panel – name, thickness, clearance and lead.

1. Right click on the trajectory and select the implant from the drop-down lists to be dropped.
2. Either confirm the trajectory selected in the planning module or select a new one. The implant is shown on the four display views. The lead now appears in green in the trajectory panel.



B. Implant

1. In this panel, all the contacts of the dropped lead are listed with their depth. Right click on a contact, a menu appears.
2. Set as FEP, set the lead to its final position (a check mark is added), to remove as FEP click on the check mark to remove it,
3. Click on 'Add Contact' notes to add a specific note for the contact.
4. Click on 'Rename' to modify the name of the implant.
5. Click on 'Delete' to remove the lead and all its settings.



Follow-up Module

The Cranial Suite Post-Operative module will be used during the programming phase of a DBS procedure and give the user the tools and assistance to guide the selection of the optimal programming parameters for each lead placed in a patient's brain.

I. Select the type of procedure

A. Load images

1. Load an existing plan.

Or

1. Click on "Load File..." from the main menu.
2. Click on "Load Primary CT."
3. A "Load Scan" dialog opens. Browse for the correct study, and then click "Load."
4. Click on "Load File..." from the main menu.
5. Click on "Load Primary MRI."
6. A 'Load Scan' dialog opens. Browse for the correct study, and then click 'Load.' Both images are displayed in the 2D and 3D views.



WARNING: Post-operative CT image sets used in registration should have been acquired after the brain has settled from shifts due to surgery. Missing CT images at the distal end of the lead may affect the quality of the lead registration.



WARNING: The primary MR image set should contain no leads. A preoperative MR image set is recommended for use as the primary MR image set. The quality of the image and atlas registration may be affected by the following circumstances:

- The MR image set was taken after DBS or resection surgery.
- The patient has brain tumors.
- The patient has metallic brain implants.
- The patient moved during scanning.
- The position of the brain has shifted due to air entering the brain during DBS surgery.

B. Register images and atlas

Automatic registration:

Automatic registration is the preferred method of registration. It does not require additional information or actions because it automatically aligns the CT and MR images using intensity values and merges them to the atlas.

1. Click on "Register Scans..." from the main menu.
2. Select "Register All Images Automatically."
3. Select both "Primary MRI --> Primary CT" and "Primary MRI --> Atlas." Click "OK." The system aligns the images.
4. Verify the registration and visually check the alignment of the images using the "Multi-image Validation" tool (2D tools bar).

Manual registration:

There are three ways to register images manually: by intensity, by image acquisition, or by reference points selected by the user.

1. Click on "Register Scans..." from the main menu.
2. Select "Primary MRI --> Primary CT" from the options.
3. Align manually the images using the "2D Image Adjust" tool (2D tools bar) - optional.
4. Click on "Register by Intensity."
5. Verify the registration and visually check the alignment of the images using the "Multi-image Validation" tool (2D tools bar).



WARNING: Manual image registration only registers images; it requires separate registration to the atlas.

Atlas registration:

1. Click on "Register Scans..." from the main menu.
2. Select "Primary MRI --> Atlas."
3. Optional: Manually align the images using the "2D Image Adjust" tool (2D tools bar).
4. Check "Global" and "Local."
5. Click "Register."
6. Verify the registration and visually check the alignment of the images.

Atlas registration verification:

Confirm that the corresponding atlas structure aligns with the visible boundaries of the structure in the MR image.

1. Choose "Deformed MRI" to show the atlas registration as an MR image warped to the MR image. Use the "Multi-image Validation" tool (2D tools bar) to visually confirm that the atlas aligns with visible structures in the MR image.
2. Choose "Atlas Anatomy" to show the atlas registration as a set of outlined structures warped to and projected on the MR image. Confirm that the atlas structures align with the visible structures in the MR image.
3. Choose "Deformed Grid" to show the atlas registration as a grid warped to the MR image.

C. Set patient anatomy

1. Click on "Set Patient Anatomy..." from the main menu.
2. Select "Set..." from the options.
3. If atlas registration was performed, software will prompt the user to set patient anatomy based on atlas registration. Select "yes" if this is desired, or 'no' to manually set patient anatomy.
4. Verify the patient anatomy and readjust the Anterior Commissure (AC), Posterior Commissure (PC) and Mid-Plane (MP) points if necessary, and select "Done."
5. If atlas registration has not been done, proceed to manually select the AC, PC, and MP reference.

II. DBS

D. Search for leads

Automatic search:

1. Click on "Search for Leads..." on the main menu.
2. Select "Search Automatically for" option.
3. Select the lead model from the options. The lead(s) will be displayed in the lead list view. The system will return the number of leads found.
4. Verify the lead(s). Visually confirm that the lead outline aligns well to the lead artifact in the CT image.

Lead verification:

1. Click on "Search for Leads..." on the main menu.
2. Click on "Search for Leads..." on the main menu.
3. Select "Verify."
4. Select the "Pointer" tool from the 2D tools bar.
5. Drag the lead to its correct location.
6. Right-click and drag the lead to change its orientation.

Pick up seed and search:

1. Select "Pick up Seed and Search" from the options. The "Search Lead" menu will open.
2. Select the lead model type placed in the patient's brain from the options. (Click on "Search" for an automatic search).
3. Place the cursor and click on (an approximate) the lead position in the 2D views.
4. Click on "Add Manually."
5. Enter a name for the lead and click "OK."
6. Visually confirm that the lead outline aligns well to the lead artifact in the CT image.
7. Adjust the position of the lead model (right-click to translate, left-click to rotate) if necessary.
8. Click on "Done" when satisfied with the lead position. The lead will be displayed in the lead list view.
9. Click on "Undo All" to cancel all the adjustments.
10. Click on "Delete" to remove the new lead.

CAUTION: Check "Lead" in the "Display Orientation" control panel to better see the alignment of the lead and the model.

E. Annotate lead

1. Select a lead from the lead list view and click on the "Program" button in the main menu. For a new patient, an information form needs to be completed.
2. Click on "Add Session." If the INS Serial number is new, a new device will be created and the system will prompt the user to confirm that the type of the new device is correct.
3. Click "Yes" to continue or "No" to cancel and modify the session information. If it has been confirmed that the type of device is correct, the programming workspace opens.
4. In the "Create Setting" box, set up the parameters for the lead, the stimulation, the efficacy, and the rate panels.
5. Save recording.
6. Repeat these steps for any additional stimulation recordings.
7. Click on "Done" to save the session.

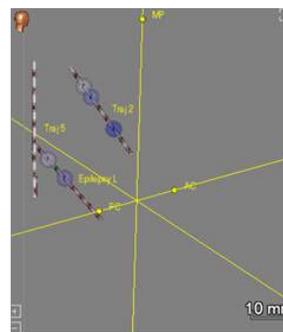
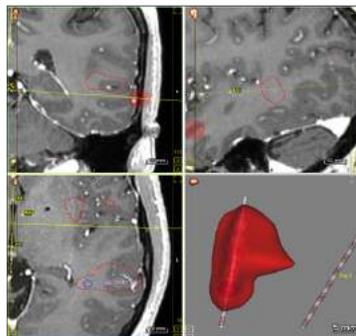
To review the history of the recordings, click on the "Screening History" tab and then click on the "Update History" button.

To view all the sessions (past and current), click on the "Sessions" tab. Session information can be edited.

II. Epilepsy

A. Epilepsy implants records

1. Record on an implant and contact, seizure type, time and notes, physiological label.
2. Visualize on the 2D and 3D views the seizure over time.
3. With the drawing tool, mark the contours of areas where the seizures spread on multiple slices. Interpolate and generate a 3D Mesh.
4. Click on "Update Volume" to get the volume of the meshes.
5. Optional: The Mesh can be exported and imported to another module.



Epilepsy L (AU8D5L25)				
C	Seizure	Time	Label	Notes
6				
7	Onset	0		
8			Sensory	
5	Early Spread	1		
4				
3				
2				
1				

Time: 0

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.

To allow for the targeting of structures that are not visible using traditional 1.5T and 3T MR images, the software supports registrations to a proprietary atlas database. Two different algorithms can be selected by the user to align patient scans to the atlas. Once aligned, the structures included in the atlas can be outlined on the patient scans and visually verified by the user for accuracy. The software includes a unique deformable atlas registration method that accounts for unique patient anatomy. As with CT/MR registration, use of these functions will affect targeting accuracy. However, the functions themselves do not have any inherent accuracy limitations.

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 Navigator 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.

Workstation maintenance

The WayPoint Navigator workstation must be inspected each year by an FHC authorized representative. Contact FHC for more information on service agreements.

End-of-Life System Disposal



Return the WayPoint Navigator to FHC for proper end-of-life disposal. Please contact an FHC factory authorized representative to arrange a return.

System Support

For 24/7 technical support, please contact FHC at +1-207-666-8190, or 1-800-326-2905 (toll free in US and Canada).