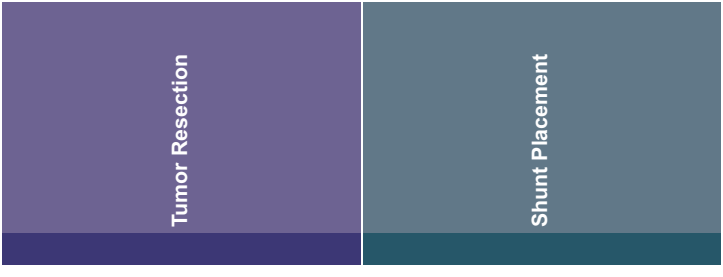
Medtronic

CE 0123 Rx Only

Synergy® Cranial AXIEM™ Pocket Guide



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Contents

Intended Use

Your Medtronic computer-assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT- or MR-based model, fluoroscopic images, or digitized landmarks of the anatomy.

Contraindications

Medical conditions which contraindicate the use of a Medtronic computer-assisted surgery system and its associated applications include any medical conditions which may contraindicate the medical procedure itself.

What effect, if any, the electromagnetic field generated by the Mobile Emitter may have on pregnancy has not been assessed. Surgeons are advised to bear this in mind and use the system judiciously around pregnant women.

Warnings

⚠ **Warning:** The system and its associated applications should be used only by qualified medical professionals who are trained on and familiar with the proper operation of Medtronic computer-assisted surgery systems.

⚠ **Warning:** The system and its associated applications should be used only as an adjunct for surgical guidance. They do not replace the surgeon's knowledge, expertise, or judgement.

⚠ **Warning:** If system navigation seems inaccurate and steps to restore accuracy are unsuccessful, abort use of the system.

⚠ **Warning:** Discard before use any pre-sterilized component whose sterile packaging appears to be compromised.

⚠ **Warning:** Prior to use, examine all components for damage and deterioration. Examine the sterile single-use instruments and trackers for nicks and exposed wire. Do not use any compromised component. Abandon use of any component damaged during the procedure.

⚠ **Warning:** Do not attempt to re-sterilize any component labeled as single-use only.

⚠ **Warning:** Verify that all necessary instrumentation has been properly sterilized before surgery. Refer to the *Equipment Cleaning and Sterilization* sheet (9730713) for cleaning and sterilization instructions. For non-sterilizable components, refer to the *Non-Sterilizable Equipment Cleaning* sheet (9733205).

⚠ **Warning:** Accessory equipment connected to the analog and digital interfaces of the Medtronic computer-assisted surgery system must be certified according to the respective IEC standards (e.g., IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the system standard IEC 60601-1-1. Any person who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible for ensuring that the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, contact technical support or your local representative.

⚠ **Warning:** Some system components may contain batteries. Batteries can explode if mishandled. Do not recharge or disassemble batteries. Do not dispose of batteries in fire. Observe local regulations concerning battery disposal.

⚠ **Warning:** The system is not suitable for use in the presence of a flammable, anesthetic mixture with air or oxygen or nitrous oxide. Position the system at least 25 cm from any source of flammable gas.

⚠ **Warning:** Support the Mobile Emitter whenever you release the locking knob of the Vertek® Articulating Arm. Failure to control the arm when unlocking could result in patient injury if the arm drops unexpectedly.

⚠ **Warning:** Do not bump or reposition the patient reference after registration because such movement will result in inaccurate navigation. If the patient reference moves in relation to the patient anatomy at any time after registration, you must re-register.

⚠ **Warning:** There is currently no effective sterilization method for components that are tainted with the infectious agent that causes Creutzfeld-Jakob Disease (CJD). Therefore, you must discard immediately after surgery any components that come into contact with biologic material from patients who carry or are suspected to carry this infectious agent. As a precaution, drape all non-disposable components that could otherwise come into contact with such material.

Precautions

△ **Caution:** Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

△ **Caution:** The system and its associated applications contain no user-repairable parts. For repair or replacement of any part of the system, contact a technical support representative.

△ **Caution:** The system has been successfully tested against the requirements of IEC 60601-1-2. However, RF interference could hamper its operation or the operation of other nearby electrical devices. If you suspect either of these conditions, move the conflicting equipment farther apart, separate the equipment with an RF barrier, or discontinue use of the system.

△ **Caution:** Do not exceed the recommended electrical ratings for the system. Exceeding the ratings could damage the system.

△ **Caution:** Before moving the system cart, shut down all components, and remove any loose items from the top of the cart.

△ **Caution:** The system mouse and Mobile Emitter are not designed for sterilization and may be damaged if sterilization is attempted.

△ **Caution:** Procedures performed with the Mobile Emitter require use of a surgical bed featuring a radiolucent table top and stainless steel side rails. Nonconforming surgical beds may introduce navigational inaccuracy.

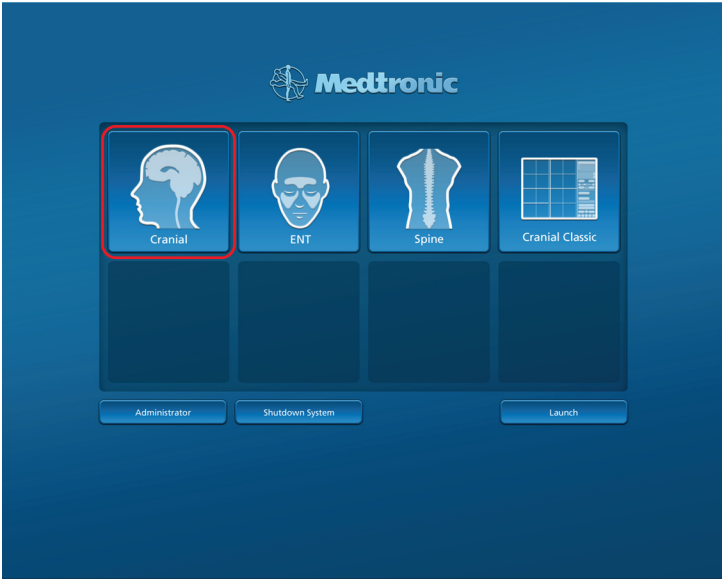
△ **Caution:** Metallic objects in or near the navigation field can degrade navigational accuracy. If metallic distortion causes excessive error, navigation will be disabled. To restore navigation, remove metallic objects from the navigation field.

△ **Caution:** Electrical noise in or near the navigation field can degrade navigational accuracy. If electrical noise introduces excessive error, the system will automatically disable navigation. To restore navigation, remove devices that produce electrical noise (such as electrocautery equipment and electric drills) from the navigation field.

Procedure

Logging In

1. At the login screen, click the **Cranial** icon and then click **[Launch]**.
2. The **Select Surgeon** screen appears.

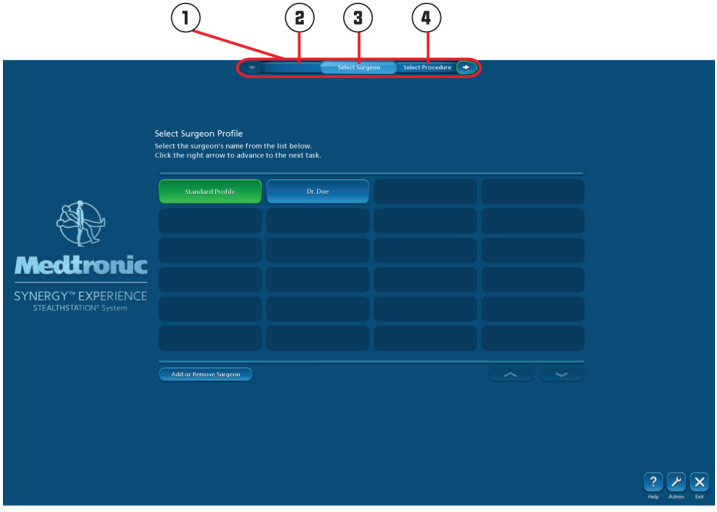

Medtronic
Cranial
ENT
Spine
Cranial Classic
Administrator
Shutdown System
Launch

Selecting a Surgeon

1. Select **Standard Profile** or select a primary surgeon.

   You may add or customize surgeon profiles by clicking **[Add or Remove Surgeon]**. Surgeon profiles allow you to save surgeon-specific preferences such as instruments, navigation options, and view settings.

2. Click  to advance to the next task.



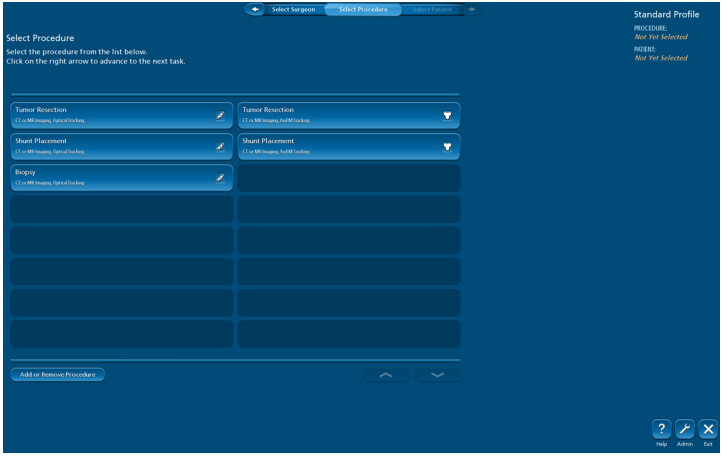
1	The procedure flow bar indicates the current task as well as the previous and next tasks.
2	Previous task
3	Current task
4	Next task

Selecting a Procedure

1. Select the surgical procedure to be performed.

   You may add or customize procedures by clicking **[Add or Remove Procedure]**. Customizing a procedure allows you to save preferences such as tracking method, registration method, and whether to include the **Plan** task.

2. Click  to advance to the next task.


Select Surgeon
Select Procedure
Select Patient
Standard Profile
PROCEDURE:
Not Yet Selected
PATIENT:
Not Yet Selected
Select Procedure
Select the procedure from the list below.
Click on the right arrow to advance to the next task.
Tumor Resection
CT or MR Imaging, Optical Tracking
Tumor Resection
CT or MR Imaging, FiveXM Tracking
Shunt Placement
CT or MR Imaging, Optical Tracking
Shunt Placement
CT or MR Imaging, FiveXM Tracking
Biopsy
CT or MR Imaging, Optical Tracking
Add or Remove Procedure
Help
Admin
Exit

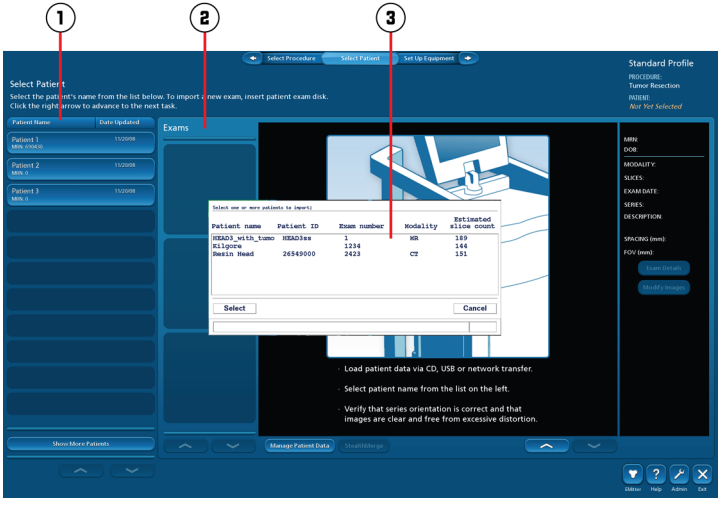
Selecting a Patient

The software displays a list of exams that were previously imported. If your patient's exam is not in the list, use one of three standard methods to import a new exam: CD/DVD-ROM, USB, or DICOM. (Sony brand magneto-optical disc is also an option for importing exams on some systems.) If your patient's exam appears in the list, proceed to page 18.

Importing Exams

To import an exam, insert a CD-ROM or a USB drive or push an exam across the DICOM network.

- When you insert a CD-ROM or a USB drive, the system displays the list of exams available to import. Click the patient's name in the list and then click **[Select]**.
- When you push an exam across the DICOM network, the exam automatically appears in the list of imported exams.



1	Patient names
2	Imported exams
3	Exams available to import

If you experience problems while importing an exam, refer to “Exam Import Problems” on page 89 for troubleshooting tips.

Selecting Exams

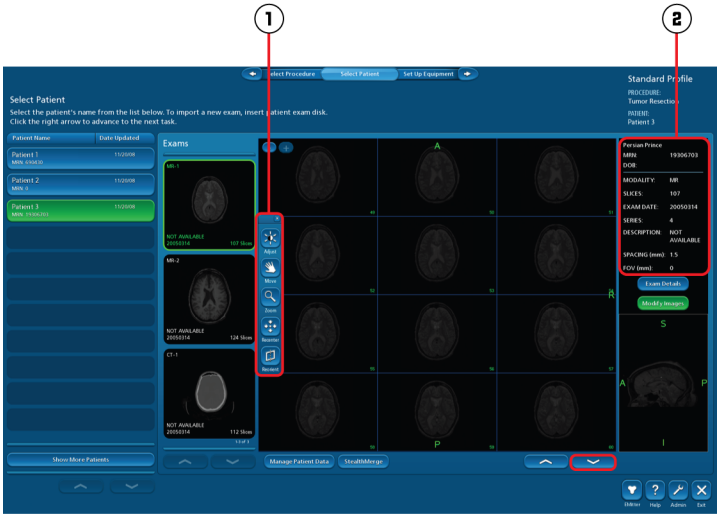
When your patient's name appears in the list of imported exams:

1. Click the patient's name. The software displays all of the exams associated with the patient, preview images from the most recent exam, and exam details for the surgeon's review.

   To browse additional slices, click  on the right side of the screen.
2. If you plan to navigate on an exam other than the most recent one in the list, click that exam in the **Exams** list and preview the images.
3. Confirm that all aspects of the exam are correct including patient data. Make sure that the anatomy of interest is captured in the exam.

   ⚠ **Warning:** Verify that the exam orientation matches the patient's anatomy.

   If you need to adjust level or width, or reorient the images, click **[Modify Images]**.
4. If you plan to merge multiple exams from the same patient, click each exam in the **Exams** list to preview the images and check the orientation.
5. After confirming that everything is correct in the patient's exam(s), click  to advance to the next task.



1	Tools for modifying images
2	Patient data

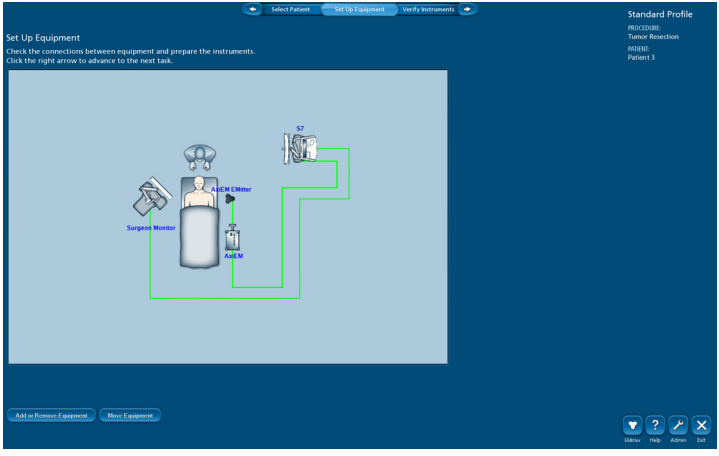
For additional information about the buttons on this screen, see “Buttons” on page 95.

If you want to merge multiple exams from the same patient, see “Using StealthMerge™ Image Registration” on page 62.

Setting Up Equipment

Confirm that the equipment and instruments used for the procedure are present in the OR. Connect the equipment to the Medtronic Navigation Computer-Assisted Surgery System. Connection status links automatically display. Solid green lines indicate verified connections and dashed orange lines indicate unverified connections. Refer to “Troubleshooting” on page 88 for connection troubleshooting tips.

When all connections are verified, click  to advance to the next task.


Select Patient
Set Up Equipment
Verify Instruments
Standard Profile
PROCEDURE:
Tumor Resection
PATIENT:
Patient 3
Set Up Equipment
Check the connections between equipment and prepare the instruments.
Click the right arrow to advance to the next task.
S7
A.I.C.M. CMitter
Surgeon Monitor
A.I.C.M.
Add or Remove Equipment
Move Equipment
Minimize
Help
Admin
Exit

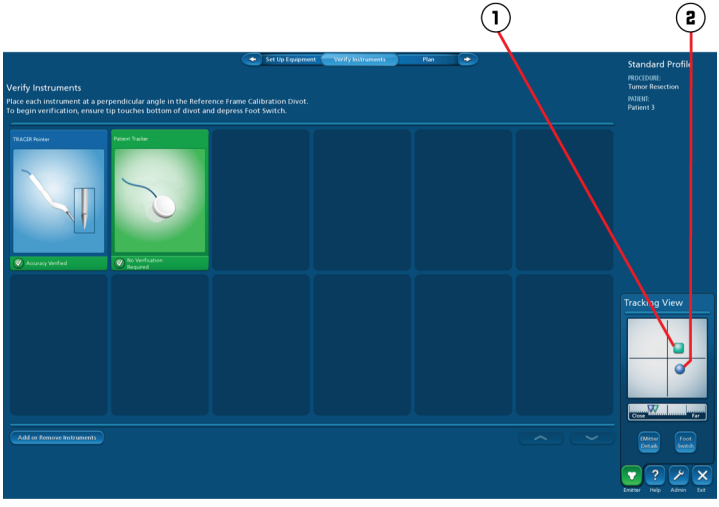
Verifying Instruments

The **Verify Instruments** screen displays the instruments selected for the procedure and indicates whether those instruments are within the emitter's tracking view.

⚠ **Warning:** Physically inspect instruments for any defects. Never attempt to use a bent or damaged instrument.

1. Plug the instrument and patient reference into ports on the AXIEM™ portable unit.

   Note: You do not need to attach the patient reference to the patient at this point in the procedure.
2. Make sure that the correct patient reference is pictured.
3. Click **[EMitter]** and confirm that both the instrument and the patient reference are visible in the **Tracking View**.
4. Repeat this process for each instrument to be used in the procedure.
5. Click  to advance to the next task.



1	Patient reference
2	Instrument

Defining a Surgical Plan

The software automatically creates a three dimensional model using the patient's exam. Verify that the model accurately represents the patient. If you want to modify the 3D model see "Building or Editing 3D Model" on page 64.

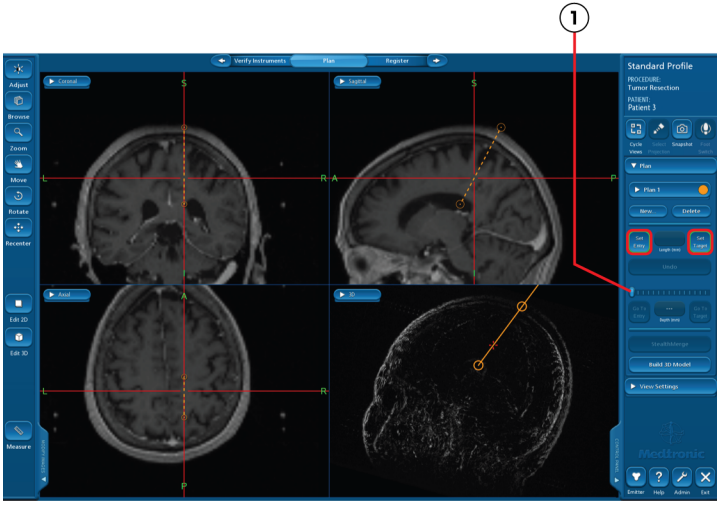
To define a surgical plan:

1. Click **[Browse]** and scroll through slices to find the slice that contains the surgical target.
2. Click a target point in one of the 2D images. Refine its location by clicking in any of the other images.
3. Click **[Set Target]**.
4. Click an entry point on one of the 2D images or on the surface of the 3D model. Refine its location by clicking in any of the other images.
5. Click **[Set Entry]**.
6. Move the plan slider to simulate movement along the plan.

   Click **[Go To Entry]** or **[Go To Target]** to move the crosshairs to either of the two stored points.

   You can click the target and entry points in the 2D images and drag them to define their positions.

   If you move a point by mistake, click **[Undo]** to undo your last change.



①	Plan slider

To create another plan, click **[New]** in the task panel and then repeat the steps above.

To display multiple plans, click **[Show Multiple Plans]** and then click the check box beside each plan that you want to show.

Setting Up the Patient Reference

For a tumor resection, use either option 1 or option 2. For a shunt placement, use either option 1 or option 3.

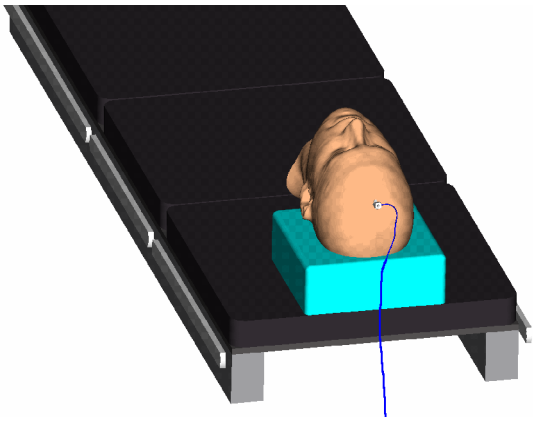
Option 1: Pinless configuration (Tumor Resection or Shunt Placement)

⚠ **Warning:** Before attaching the DRF, carefully examine the patient image data to ensure that the skull thickness and density at the intended attachment site is adequate for securing the DRF and screws, and that no arterial or venous structures lie beneath the site. When fully tightened, the DRF screws penetrate 2.5–3.0 mm below the DRF's lower surface. Therefore, never place the DRF at a site where the skull bone is less than 4.0 mm thick.

1. Position the patient on the surgical bed and rest the patient's head in a gel headrest or similar support.
2. Review the other warnings and instructions given in the Package Insert (9660242) which accompanied the sterile, disposable DRF.
3. Select and prepare the attachment site.
4. Make a small scalp incision (14–16 mm) down to the bone at the attachment site.
5. Set the sterile DRF at the site and tighten the screws using the sterile screwdriver (reusable or disposable). Because the screws are self-tapping and self-drilling, no pilot holes are necessary. Make sure the screws are snug, so the DRF cannot

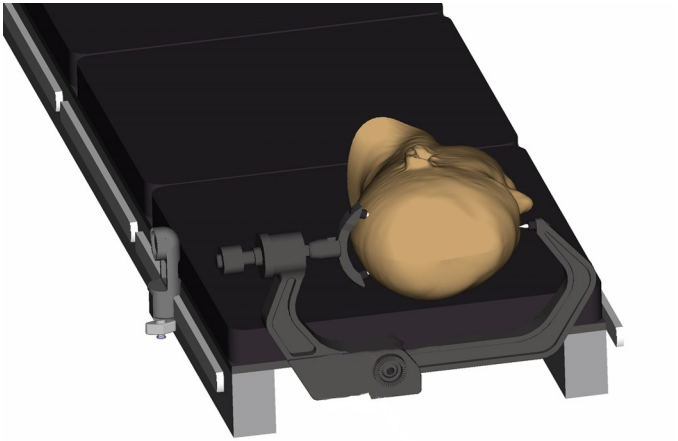
slip or shift at any time during the procedure. However, be careful not to over-tighten the screws.

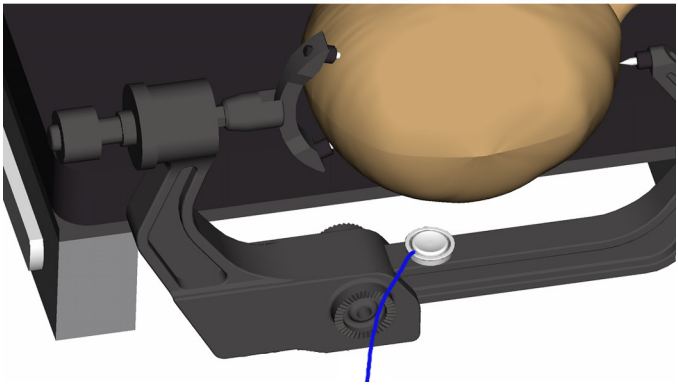
6. Connect the DRF cable to the AXIEM™ portable unit.



Option 2: Pinned configuration (Tumor Resection Only)

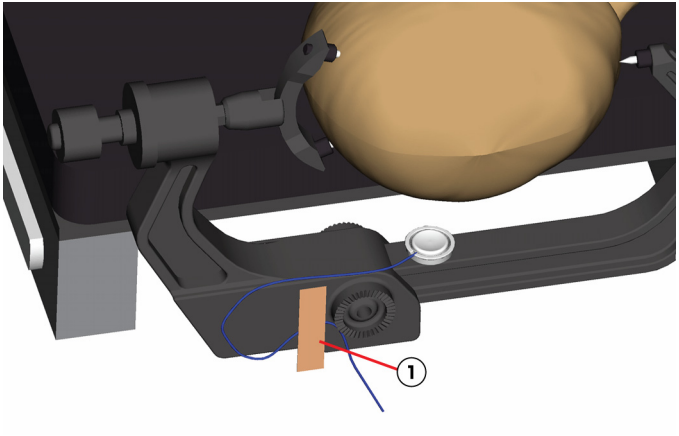
1. Position the patient on the surgical bed and secure the patient's head in the radiolucent skull clamp (for example, Mayfield® A-2004 Headrest System).
2. Review the warnings and other instructions given in the Package Insert (9731659) that accompanied the disposable Patient Tracker.
3. With an alcohol swab, clean the inside of the Patient Tracker Adapter. Also clean a space on the horizontal surface of the adjustable arm on the single-pin radiolucent skull clamp. Choose a space that is free from stickers, labels, and other obstructions.
4. Remove the backing from the adhesive pad on the Patient Tracker. Affix the tracker in the adapter with the tracker cable aligned in the adapter slot.
5. Remove the backing from the adhesive pad on the adapter. Affix the adapter to the space you cleaned.





6. Connect the tracker to any port on the AXIEM™ portable unit.
7. Create a bend in the tracker cable and tape the cable to the skull clamp. This creates a strain relief mechanism that helps prevent the tracker from being dislodged accidentally.
8. Take other necessary precautions to ensure the tracker will not be dislodged accidentally after registration.

   ⚠ **Warning:** After patient registration is complete, avoid altering the position of the tracker relative to the patient. Such movement will result in inaccurate navigation. If the tracker is moved after registration, re-secure it and register the patient again before navigating.



①	Tape the cable to the head holder to create a strain relief.

Option 3: Non-Invasive Patient Tracker (Shunt Placement Only)

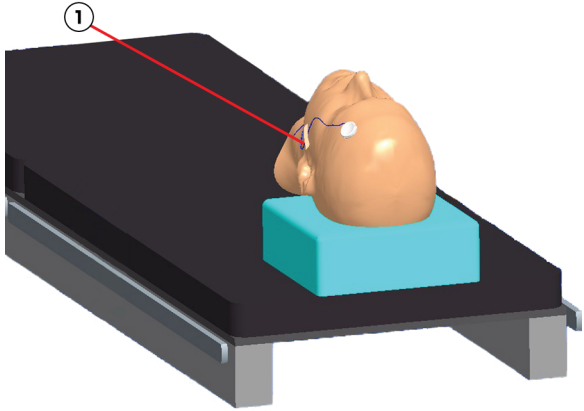
1. Position the patient on the surgical bed and rest the patient's head in a gel headrest or similar support.
2. Review the warnings and other instructions given in the Package Insert (9731659) that accompanied the disposable tracker.
3. Select the site on the patient's skin where you will affix the tracker. The forehead is the recommended application site because it will minimize skin shift.
4. If necessary, shave the site to provide for maximum contact with the patient's skin.
5. Clean the site with alcohol to strengthen adhesion. Allow the site to dry thoroughly before applying the tracker.

   Note: If the patient is diaphoretic, you may want to apply benzoin.
6. Peel away the release liner from the tracker and adhere the tracker to the patient's skin.

   △ **Caution:** If you will acquire images intraoperatively, place the tracker outside potential imaging plane(s) to avoid distortion.
7. Protect the tracker from accidental dislodgement by creating a U-shaped bend in its cable and taping this bend to the patient approximately six inches below the tracker.
8. Connect the tracker cable to the AXIEM™ portable unit.

9. Verify that the tracker is secure and cannot be accidentally dislodged during the procedure.

   ⚠ **Warning:** After patient registration is complete, avoid altering the position of the tracker relative to the patient. Such movement will result in inaccurate navigation. If the tracker is moved after registration, re-secure it and register the patient again before navigating.



1	Tape the cable to the patient to create a strain relief.

Setting Up Mobile Emitter

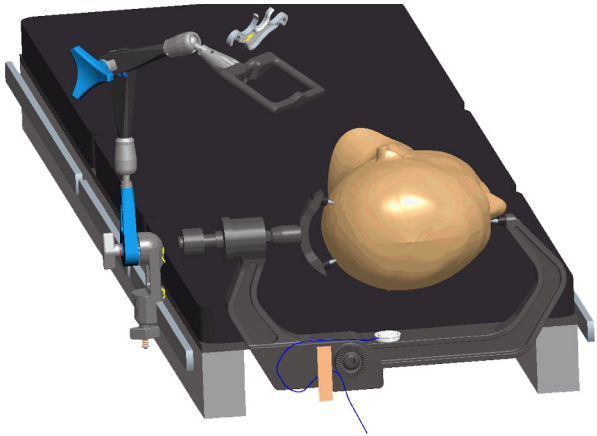
Set up the Mobile Emitter where it will not interfere with the surgeon's access to the patient during surgery.

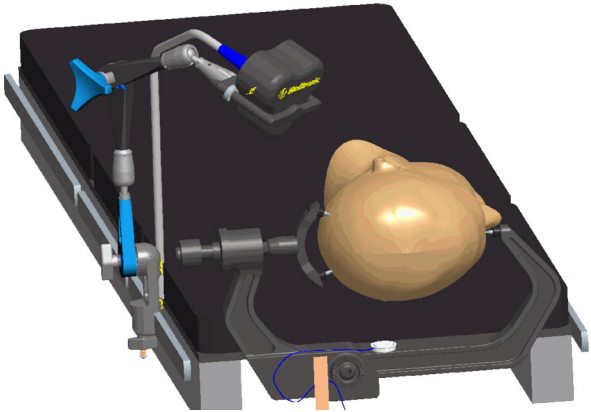
1. Secure the Short Bedrail Adapter to the rail of the surgical bed.

   Note: If the surgeon is right-handed, set up the emitter on the left-hand side. For a left-handed surgeon, set it up on the right-hand side.
2. Connect the Mobile Emitter Holder to the Vertek® Articulating Arm using the Ball Driver.
3. Lock the articulating arm and attach it to the bedrail adapter. Make sure that the starburst teeth mesh together.
4. Snap the Emitter Cable Clip into the emitter holder, as shown.
5. Place the Mobile Emitter in the holder with the Medtronic logo oriented up, as shown. Secure the base of the emitter cable in the cable clip.
6. While supporting the emitter, release the articulating arm locking knob and adjust the position of the emitter.

   Position the emitter about 20 cm above the table pad and about 20 cm from the center of the patient's head. As a general rule, the space between the patient's head and the emitter face should be approximately equal to the width of your fist.

   Aim the emitter at the center of the patient's head as if aiming a flashlight.
7. Tighten the locking knob of the articulating arm.

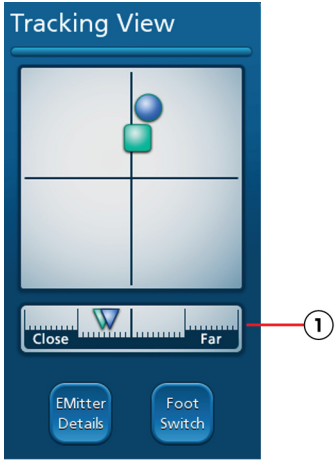




Refining Emitter Aim

1. Connect a registration instrument to any port on the AXIEM™ portable unit.
2. Click  to display the **Tracking View**.
3. Confirm that the system can track the instrument and the patient reference throughout the range of locations required for registration and navigation.
4. Adjust the position of the emitter as required so that the distance and aim indicators for the instrument and patient reference are within range.

   ⚠ **Warning:** Releasing the locking knob of the Vertek® Articulating Arm releases tension on all segments of the arm. Support the Mobile Emitter whenever you release the locking knob of the articulating arm. Otherwise, the emitter could drop unexpectedly.
5. Click  to proceed to patient registration.



①	Distance indicator

Registering

To navigate you must match the patient's exam to the patient's anatomy by using either Tracer™ registration, Touch-n-Go registration, or PointMerge® registration. If you plan to use Touch-n-Go registration refer to page 70. For PointMerge® registration, refer to page 74.

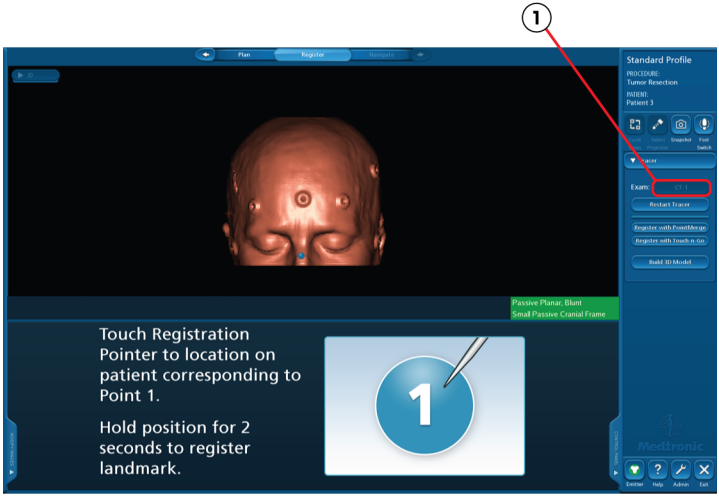
⚠ **Warning:** Do not bump or reposition the patient reference after registration because such movement will result in inaccurate navigation. If the patient reference moves in relation to the patient anatomy at any time after registration, you must re-register.

Performing Tracer™ Registration

If you merged exams, you can change the exam used for registration by clicking the **Exam** drop-down list.

If you need to change the location of the first landmark, click a new location on the 3D model.

1. Touch the registration pointer to landmark 1 on the patient (the tip of the nose or the most anterior point included in the exam) and hold the pointer steady until you hear a verification sound (or press the footswitch).
2. Touch landmark 2 on the patient (the center of the forehead) and hold the pointer steady until you hear a verification sound.
3. Touch landmark 3 on the patient (three centimeters to the patient's left of landmark 2) and hold the pointer steady until you hear a verification sound.



①	Exam drop-down list

4. Place the tip of the instrument on the patient's nose and press and hold the footswitch. Move the tip of the registration pointer lightly around the firm and bony areas of the patient's nose, brow, mastoids, and scalp. Include as many uniquely-shaped areas as possible, but only trace anatomy that is included in the patient exam. Continue until the progress bar indicates 100%.

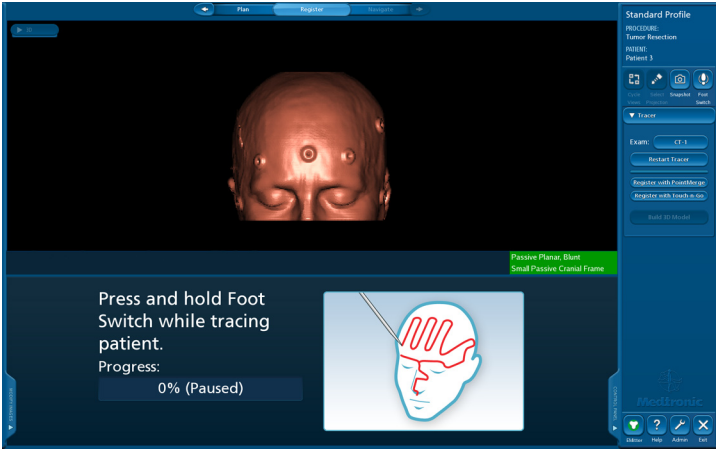
   Gently maintain contact with skin at all times while tracing. If you need to lift the registration pointer to move around an obstruction, release the footswitch before you lift the pointer. Then reposition the pointer before you press the footswitch.

   When **Tracing Progress** reaches 100%, the software matches the points to the 3D model.

   If Tracer™ registration is successful, the software auto-advances to the accuracy verification screen.

   Note: If registration fails, a message displays and the software returns to the first step in Tracer™ registration.

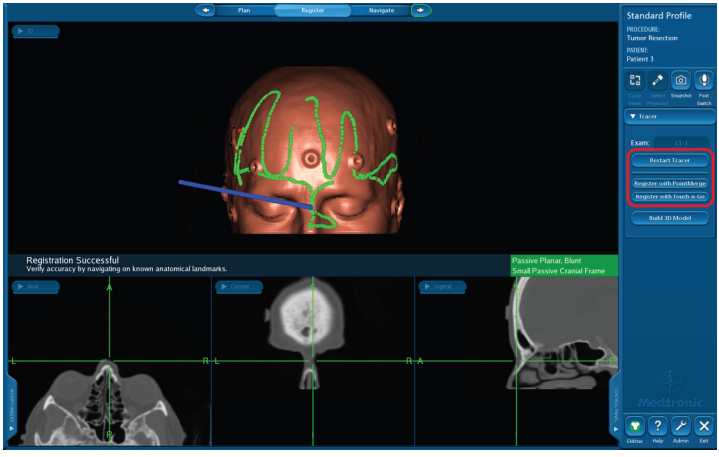
   You can cancel Tracer™ registration at any time by clicking **[Restart Tracer Registration]**. The software returns to the first step in Tracer registration.


Plan
Register
Navigate
Standard Profile
PROCEDURE:
Tumor Resection
PATIENT:
Patient 3
Snapshot
Foot Switch
Tracer
Exam:
CT-1
Restart Tracer
Register with PostMerge
Register with Touch-n-Go
Build 3D Model
Passive Planar, Blunt
Small Passive Cranial Frame
Press and hold Foot Switch while tracing patient.
Progress:
0% (Paused)
Medtronic
Distnav
Help
Admin
Exit

Verifying Tracer™ Registration Accuracy

Check the accuracy of the registration process before continuing. The points shown on the screen are color coded by status. Green points are included in the registration and red points are excluded.

1. Use the registration probe to touch an identifiable point on the patient's anatomy.
2. Compare the location of this point to the centers of the crosshairs in the images.
3. Repeat the process for at least two more points.
4. If you are satisfied with the registration accuracy, click  to advance to the **Navigate** task.

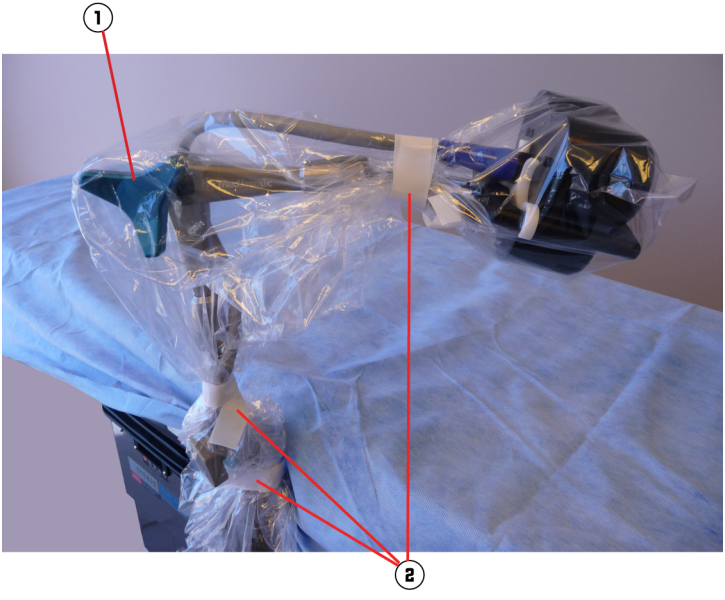


If the accuracy is unacceptable, repeat Tracer™ registration by clicking **[Restart Tracer]**. To change to Touch-n-Go or PointMerge® registration, click **[Register with Touch-n-Go]** or **[Register with PointMerge]**. See “Performing Touch-n-Go Registration” on page 70 or “Performing PointMerge® Registration” on page 74.

Setting Up for Sterile Navigation

1. Disconnect the non-sterile registration instrument and remove it from the surgical arena.
2. Drape the patient and set up the sterile surgical field.
3. Drape the Mobile Emitter, Vertek® Articulating Arm, and Short Bedrail Adapter using the supplied drape (9732571). Cuff the drape using the tabs as shown.

   △ **Caution:** Use care to avoid damaging the drape when re-adjusting the Vertek® Articulating Arm.



1	Leave some slack in the drape around the locking knob to allow for repositioning.
2	Tabs

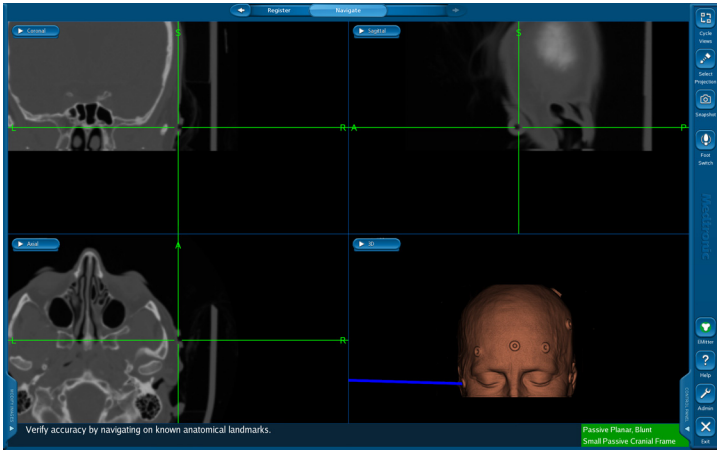
Navigating

During navigation, the software updates the 2D images in real time to reflect changes in the position of the surgical instrument's tip on the anatomy. When navigation is active, the crosshairs display green. When navigation halts, the crosshairs display red.

⚠ **Warning:** Frequently confirm navigation accuracy and system responsiveness during live navigation. Use the probe to touch several bony anatomical landmarks and confirm that the locations identified on the images match the locations touched on the patient. If accuracy degrades, re-register the patient.

The following are optional features in the Navigate task:

- If you want to create accuracy checkpoints, see page 84. If you neglect to establish accuracy checkpoints and the patient reference moves in relation to the patient anatomy at any time after surgery begins, you will have to re-register the patient or abandon use of the system.
- If you want to use tip projection, see page 86.


Register
Navigate
Coronal
Sagittal
Axial
3D
Verify accuracy by navigating on known anatomical landmarks.
Passive Planar, Blunt
Small Passive Cranial Frame

Using Look Ahead View

The look ahead view gives you a preview of the anatomy you will encounter as you advance the pointer along the current trajectory. To display the look ahead view:

1. Click the image view label in the upper left corner of a view to display the list of available views.
2. Select **Look Ahead** from the list.

   The look ahead view displays four probe's eye views, which mimic what you would see if you sighted along the shaft of the instrument. The upper left view shows the plane that is located at the instrument tip, perpendicular to the instrument. The other three views are 5 mm, 10 mm, and 15 mm beyond the instrument tip.

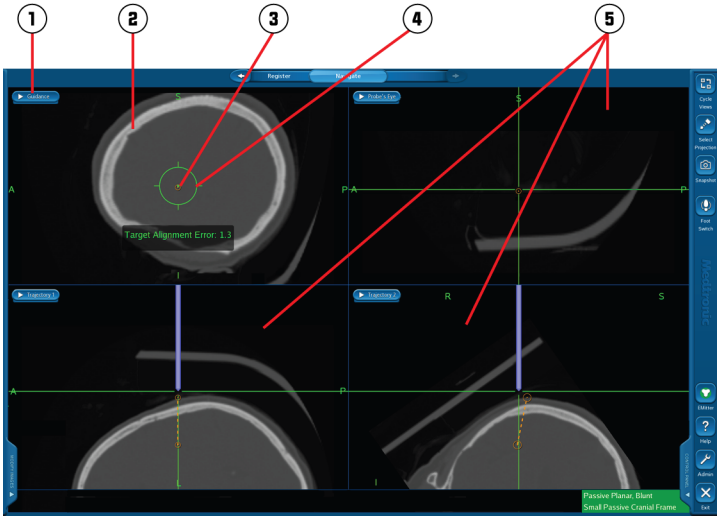

Register
Navigate
Coronal
Sagittal
Axial
Look Ahead
TRACER Pointer
Non-Invasive DRF

Shunt Placement: Guiding the Catheter

⚠ **Warning:** The point identified by the crosshairs in the 2D views represents the **tip** of the instrument.

Note: Using the guidance view is the preferred method for aligning the instrument along the desired trajectory. However, the guidance view is functional only if you have created a surgical plan. (“Defining a Surgical Plan” on page 24.)

1. Replace one of the 2D views with the guidance view. To do this, click the image selection button and select **Guidance** from the list.
2. Replace the other 2D views with **Trajectory 1**, **Trajectory 2**, and **Probes Eye**.
3. Insert the sterile stylet through the sterile catheter.
4. Place the tip of the stylet at the entry point you stored earlier.
5. The guidance view shows the target as a small orange circle. The large green circle represents the aiming area around the probe tip. Use the guidance view to align the center of the aiming circle with the target.
6. As you advance the instrument along the surgical plan, keep the dot centered inside the small circle.



1	Image selection button
2	Guidance view
3	Target
4	Aiming circle around probe tip
5	Trajectory views

Archiving (Optional)

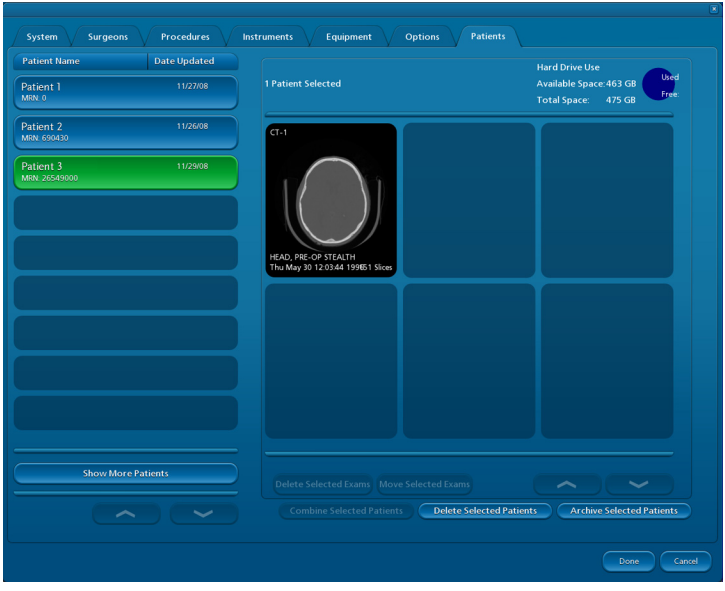
1. Click **[Admin]** and then click the **Patients** tab.
2. Insert a blank CD or a USB drive.
3. Click the patient's name and click **[Archive Selected Patients]**.
4. Select the kind of archive, select the archive media, and click **[OK]**.

Deleting Patients

To delete an unused patient, follow the steps below.

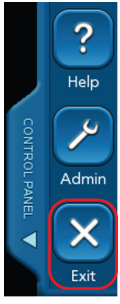
To delete the current patient, return to the **Select Patient** task and then follow these steps.

1. Click **[Admin]** and then click the **Patients** tab.
2. Select a patient.
   - To delete specific exams, click the exams and click **[Delete Selected Exams]**.
   - To delete all of the patient's exams click **[Delete Selected Patients]**.


System
Surgeons
Procedures
Instruments
Equipment
Options
Patients
Patient Name
Date Updated
Patient 1
MRN: 0
11/27/08
Patient 2
MRN: 690430
11/26/08
Patient 3
MRN: 26549000
11/29/08
Show More Patients
1 Patient Selected
Hard Drive Use
Available Space: 463 GB
Total Space: 475 GB
Used
Free
CT-1
HEAD, PRE-OP STEALTH
Thu May 30 12:03:44 1996
51 Slices
Delete Selected Exams
Move Selected Exams
Combine Selected Patients
Delete Selected Patients
Archive Selected Patients
Done
Cancel

Exiting

1. Click the exit button at the bottom of the task panel.
2. Click **[Exit]** to confirm that you want to exit.



Appendixes

A: Standard Equipment

Unless special cleaning or sterilization instructions are noted, follow the standard cleaning and sterilization protocols in the *Equipment Cleaning and Sterilization* sheet (9730713).

AXIEM™ Equipment for Tumor Resection and Shunt Placement

Non-Invasive Patient Tracker (9733674)

When rigidly positioned with respect to the patient's head, the Patient Tracker acts as a continuous point of reference for the Mobile Emitter.

This item is non-sterile and single-use. For more information, refer to the Package Insert which accompanied this item (9731659).

Skull Mounted Patient Tracker (9660202)

When secured to the patient's head using the two bone screws, the DRF acts as a continuous point of reference for the Mobile Emitter.

This item is pre-sterilized and single-use. For more information, refer to the Package Insert which accompanied this item (9660242).

Registration Wand (9660235)

The Registration Wand is a pointing device that can be used to identify the location of points on the patient anatomy.

This item is pre-sterilized and single-use. For more information, refer to the Package Insert which accompanied this item (9660241).

Navigation Pointer (9733365, in Tumor Resection Kit: 9733766)

Use the Navigation Pointer to localize points on the patient anatomy during the Navigate phase of the surgical procedure.

This item is pre-sterilized and single-use. For more information, refer to the Package Insert which accompanied this item (9733365-03).

Tracer™ Pointer (9733367)

Use the Tracer™ Pointer to perform Tracer registration, PointMerge® registration, or as a navigation instrument.

This item is pre-sterilized and single-use. For more information, refer to the Package Insert which accompanied this item (9733367-03).

Touch-n-Go Pointer (9733368)

Use the Touch-n-Go Pointer to identify the locations of the fiducial markers on the patient during Touch-n-Go registration (an optional registration method).

This item is pre-sterilized and single-use. For more information, refer to the Package Insert which accompanied this item (9733368-03).

Emitter Cable Clip (9660245)

Secure the cable running to the Mobile Emitter using the Emitter Cable Clip. The clip attaches to the Mobile Emitter Holder.

This item is non-sterile and single-use.

AXIEM™ Cranial Drape (9732571)

The drape supplied in the procedure kit fits over the Mobile Emitter, Mobile Emitter Holder, Vertek® Articulating Arm, and Short Bedrail Adapter.

This item is pre-sterilized and single-use.

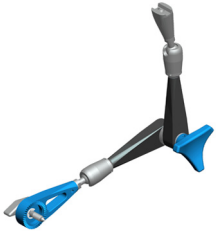
Ball Driver, 1/4” (9731833)

Use the Ball Driver to attach and detach the Mobile Emitter Holder from the Vertek® Articulating Arm.

Short Bedrail Adapter (9732566)

The Short Bedrail Adapter is designed to clamp to the rail of the surgical bed and support the Mobile Emitter Holder.

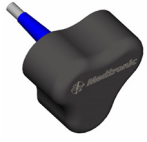
To disassemble for cleaning, refer to the Package Insert which accompanied this item (9732814).



Vertek® II Articulating Arm (9734252)

The Vertek® II Articulating Arm attaches to the Short Bedrail Adapter and supports the AXIEM™ Mobile Emitter Holder. Adjust the position of the articulating arm at the pivot points. All pivot points lock in place with rotation of the locking knob.

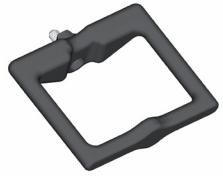
For more information, refer to the instructions which accompanied this item (9733940).



AXIEM™ Mobile Emitter (9731203)

The Mobile Emitter encompasses the patient anatomy and EM devices in a low-energy navigation field, tracking their positions within the field and relative to each other.

Clean this item according to the protocol given in the *Non-Sterilizable Equipment Cleaning* sheet (9733205). Do not submerge or rinse this item.



Mobile Emitter Holder (9731450)

The Mobile Emitter Holder is designed to attach to the Vertek® Articulating Arm and support the AXIEM™ Mobile Emitter upright in the holder.

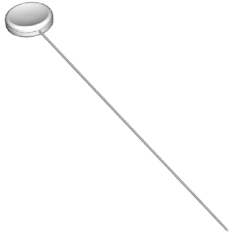
For Tumor Resection Only

Patient Tracker Adapter (9660246)

Use the Patient Tracker Adapter to seat the Patient Tracker to a clean horizontal surface near the base of the radiolucent head rest.

This item is non-sterile and single-use.

For Shunt Placement Only



AXIEM™ Stylet, 1.2mm x 23cm (9733675)

The Stylet is a pointing device that can also be used to place ventric shunts. Any shunt used with the Stylet must be less than or equal to 23.0cm in length and have an inner diameter greater than or equal to 1.2mm.

This item is pre-sterilized and single-use. For more information, refer to the Package Insert which accompanied this item (9660240).

B: Using StealthMerge™ Image Registration

To merge multiple exams from the same patient:

1. While you are in the **Select Patient**, **Plan**, or **Navigate** task, click **[StealthMerge]**.
2. On the left, click all of the exams that you want to merge.
3. On the right, click a reference exam.
4. Click **[Start Merge]**.
5. When each merge completes, **[Verify Merge]** is highlighted. To examine merge accuracy, click **Blend** or **Split-window** and then use the slide controls under the images.
   a. If you determine that the accuracy of the merge is sufficient for the procedure, click **[Verify Merge]**.
   b. If the merge is not aligned correctly, click and drag the merge exam into approximate alignment with the reference exam and click **[Start AutoMerge]**.
   c. If the exam does not contain anatomical images (such as a PET or fMRI), click the **Pre-Merged Exams** tab and select the appropriate anatomical reference exam.

   After you click **[Verify Merge]**, the next merged exam displays for your verification.
6. When you have verified all merges, click **[Done]**.

   When you merge exams, the merged set is always used in the **Plan**, **Register**, and **Navigate** tasks. See “StealthMerge™ Tips” on page 94 if you want to change the merged display in these tasks.


StealthMerge
Select Exams
Merge Exams
Merge Exam:
MR-2 (NOT AVAILABLE)
Reference Exam: CT-1
Patient: Patient 3, 19306703
Blend
Split-window
Adjust
Browse
Zoom
Move
Recenter
Reorient
Axial
Coronal
Sagittal
AutoMerge
Pre-Merged Exam
Verify Merge
Verify merge accuracy using the Blend/Split-window controls. If merge is accurate, click "Verify Merge."
If the merge is not accurate, click and drag the merge exam to approximate alignment. Click "Start AutoMerge" to continue the merge process.
Start AutoMerge
Reset Merge
Verify Merge
Done
Cancel

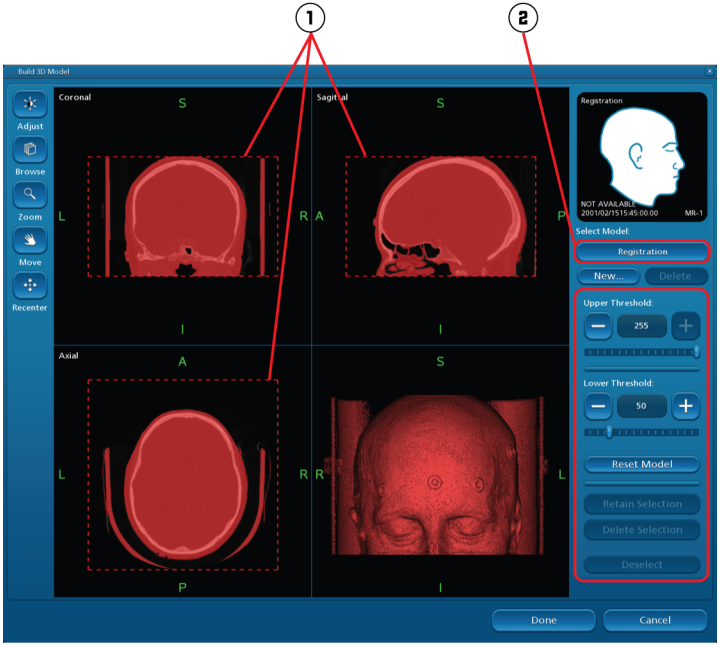
C: Building or Editing 3D Model

To prevent an unintended registration change or deletion, the **Registration** model can only be viewed in the **Register** task. The model that appears by default in the **Plan** and **Navigate** tasks is based on the exam you selected in **Select Patient**, but it is not the **Registration** model. If you want to view a different model in the **Plan** or **Navigate** tasks, you must build a new model.

To build a new 3D model or edit an existing model:

1. Click **[Build 3D Model]**.
2. Click the **Select Model** drop-down list to select an existing model, or click **[New]**.

   If you clicked **[New]**, select a model type, select the exam, name the model, check **Use for Registration** if you are building a skin model that you plan to use for registration, and click **[OK]**.
3. Reposition the dashed clipping lines in each 2D view so that they closely surround the anatomy that you are modeling.



①	Clipping lines
②	Select model drop-down list

4. Adjust the threshold to highlight only the anatomy that you want to model.

   The model updates automatically.

   - To return the threshold settings to their default values, click **[Reset Model]**.
   - To retain only a portion of the model, click the object you want to retain and then click **[Retain Selection]**.
   - To delete a portion of the model, click the object you want to delete and then click **[Delete Selection]**.

5. Build all of the skin, bone, and tumor models that you want to view in the **Plan** and **Navigate** tasks, and then click **[Done]**.

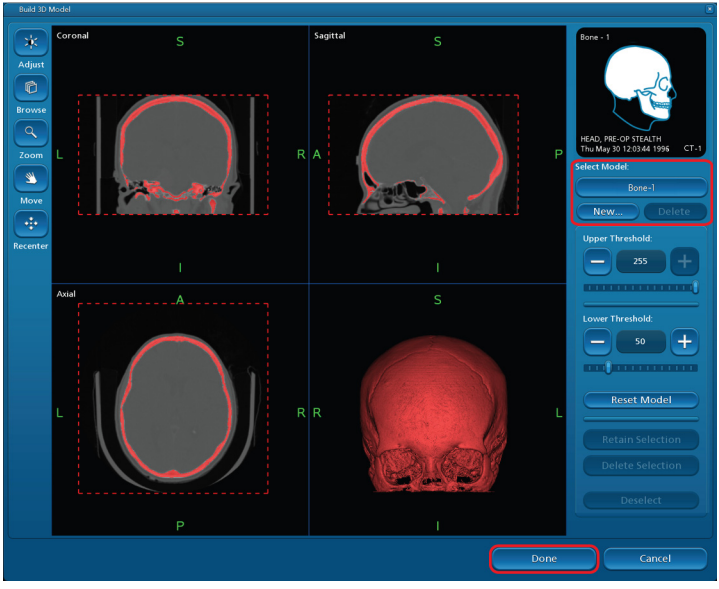
   To display your new models in the **Plan** and **Navigate** tasks:

   a. Click **[Edit 3D]**.

   b. Click the exam that has a layer number in the upper-right corner, and click **[Remove]** to remove the default model from the **Composite View**.

   c. Click the **View Models** tab, click the model that you want to display in **Plan** and **Navigate**, click **[Add]** to add it to the **Composite View**, and click **[Done]**.

   See “Adjusting 2D Images or 3D Models” on page 68 for additional information about the **Composite View**.


Build 3D Model
Adjust
Browse
Zoom
Move
Recenter
Coronal
S
L
I
Sagittal
S
R A
P
I
Axial
A
L
P
S
R R
L
I
Bone - 1
HEAD, PRE-OP STEALTH
Thu May 30 12:03:44 1996
CT-1
Select Model:
Bone-1
New...
Delete
Upper Threshold:
255
Lower Threshold:
50
Reset Model
Retain Selection
Delete Selection
Deselect
Done
Cancel

D: Adjusting 2D Images or 3D Models

If you only need to adjust the level and width of images, click **[Adjust]**. To make more advanced adjustments, such as rendering style and colormap of 2D images or 3D models, click **[Edit 2D]** or **[Edit 3D]**.

1. In the **View Exams** tab or the **View Models** tab, click an exam or a model.

   If no models display in the **View Models** tab, click **[Cancel]** and then click **[Build 3D Model]** to build a model.
2. Adjust the exam modality, rendering style, colormap, level, or width. The changes appear in the **Selected View** window.
3. Click **[Add]** to add the **Selected View** to the **Composite View**.

   The **Composite View** is a preview of all the adjustments that you have added.

   When you add a model to the **Composite View**, a layer number appears in the upper-right corner of the model. The layer number indicates placement in the **Composite View** (for example, layer 2 appears on top of layer 1).
4. Adjust the blend level of the exam or model.
5. Click **[Done]**.

   The composite image displays in the **Plan** and **Navigate** tasks.

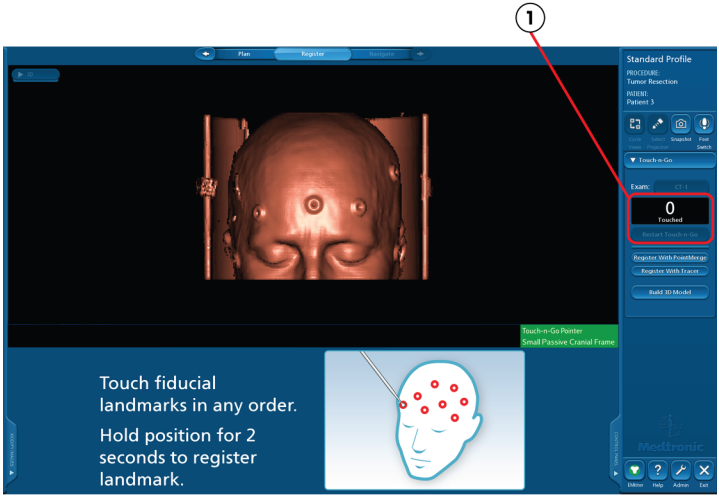
①	Layer numbers

E: Performing Touch-n-Go Registration

1. Click **[Touch-n-Go]**.
2. Confirm that **Touch-n-Go Pointer** is the instrument name displayed in the lower right corner of the image area. If necessary, verify the Touch-n-Go pointer.
3. If you merged exams, you can change the exam used for registration by clicking the exam button.
4. Hold the tip of the Touch-n-Go Pointer in the center of one of the fiducials for two seconds or until the **Touched** counter increments by one. The order in which you record the fiducials is not important. Repeat this process for the remaining fiducial points, or until you are satisfied with the predicted maximum error displayed.

   To proceed to navigation you must have touched at least four fiducial points and the predicted maximum error must be less than 5.0 mm.

   You may re-record any fiducial point in the same way you first recorded it. When you re-record a fiducial point, the **Touched** counter does not increment.
5. When finished, click  to advance to the **Navigate** task to verify registration accuracy.

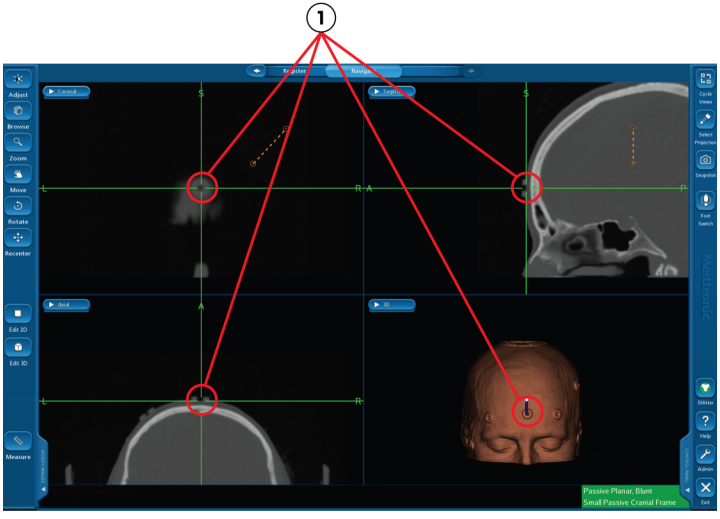


①	Touched fiducial counter

Verifying Touch-n-Go Registration Accuracy

1. In the **Navigate** task, use the registration probe to touch an identifiable point on the patient's anatomy.
2. Compare the location of this point to the centers of the crosshairs in the images.
3. Repeat the process for at least two more points.
4. If you are satisfied with the registration accuracy, proceed with navigation (page 46).

   If the accuracy is not acceptable, click the left arrow and then click **[Restart Touch-n-Go]**, **[Register with Tracer],** or **[Register with PointMerge]** to repeat the registration process.



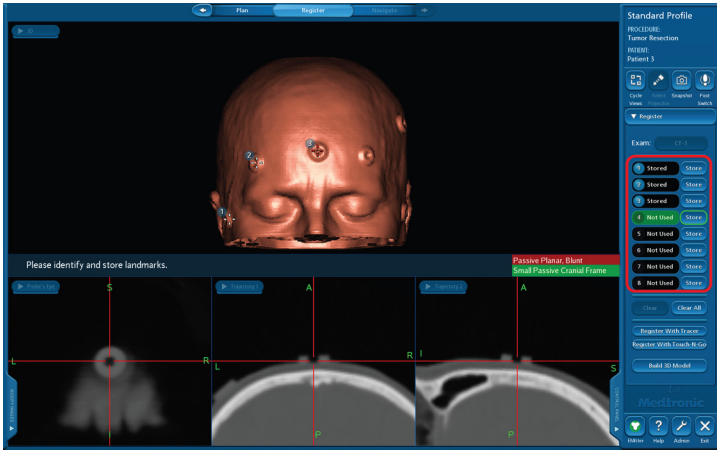
1	Make sure that the point you touch on the patient matches the point displayed in all views.

F: Performing PointMerge® Registration

Store Landmarks

Select and store up to eight landmarks on the images.

1. Click **[Register with PointMerge]**.
2. If you merged exams, you can change the exam used for registration by clicking the exam button.
3. Click an identifiable anatomical landmark or a fiducial on the skin model, refine the position of the selected point in the 2D images, and then click **[Store]** beside **1**.
4. Click another identifiable point on the skin model and then click **[Store]** beside **2**.
5. Continue clicking the landmarks and **[Store]** buttons until you have selected seven or eight well-distributed landmarks. A minimum of four landmarks is required.

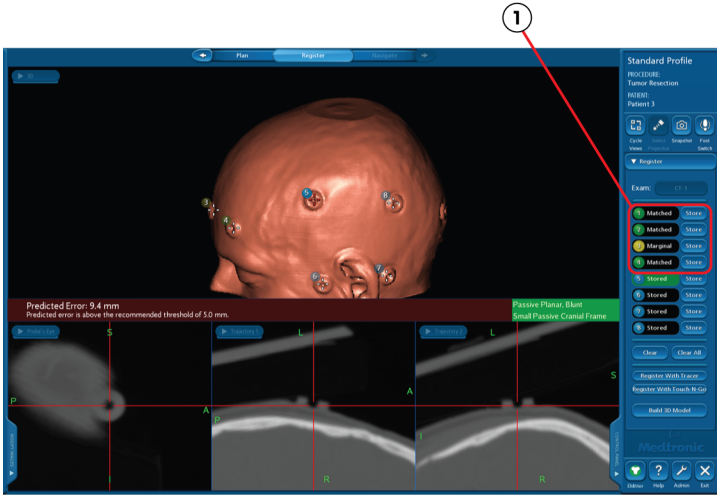

Plan
Register
Navigate
Standard Profile
PROCEDURE:
Tumor Resection
PATIENT:
Patient 3
Circle Views
Select Probe/Tip
Snapshot
Foot Switch
Register
Exam:
CT-1
1 Stored
Store
2 Stored
Store
3 Stored
Store
4 Not Used
Store
5 Not Used
Store
6 Not Used
Store
7 Not Used
Store
8 Not Used
Store
Clear
Clear All
Register With Tracer
Register With Touch-N-Go
Build 3D Model
Please identify and store landmarks.
Passive Planar, Blunt
Small Passive Cranial Frame
Probe's Eye
Trajectory1
Trajectory2
Medtronic
Utilities
Help
Admin
Exit

Touching Landmarks

Touch the landmarks on the patient.

1. Place the tip of the registration probe on the patient at the first landmark. Hold the probe steady until you hear the confirmation sound. The circle around number **1** turns green.
2. The system automatically advances to the next landmark on the list, and the skin model auto-rotates to display the next landmark.
3. Repeat this process for the remaining landmarks.

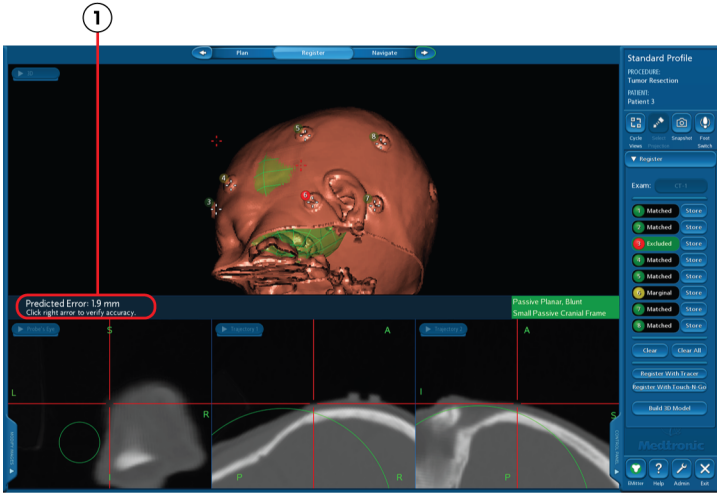
   Note: If a landmark changes to red, it is inaccurate and excluded from the registration. If a landmark changes to yellow, it is marginally accurate, and you may want to refine it. After you have touched the first four landmarks, you can refine a previously touched landmark by holding the probe tip on it for two seconds. Note that the least accurate landmark used in the registration will always be marked **Marginal**. This is normal.



1	Touched landmarks

The system displays a numerical predicted error value. If the predicted error value exceeds 5.0 mm, the system will not allow you to proceed to the **Navigate** task. In that case, re-register the patient.

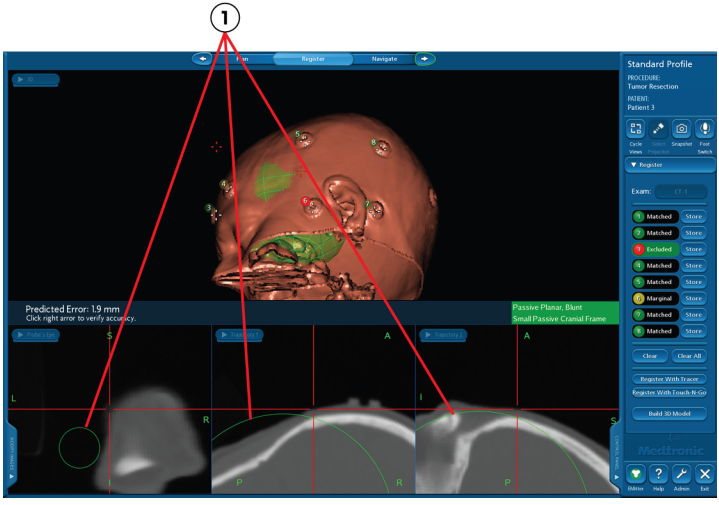
Note: Clicking **[Clear All]** one time clears all of the touched points and selects the first landmark in the list. Clicking **[Clear All]** two times clears all of the stored landmarks.



①	Predicted error value

Sphere of Accuracy

As soon as you match the fourth landmark, the software displays a sphere of predicted accuracy on the 3D model as well as three green and yellow circles on the three orthogonal views. The circles are cross sections of the sphere of accuracy. As you match more landmarks, the system may refine the sphere of accuracy. Within the green circles, localization error is estimated to be 1 mm or less. Within the yellow circles, localization error is estimated to be 2 mm or less. Make sure that the surgical area of interest lies inside the circles.



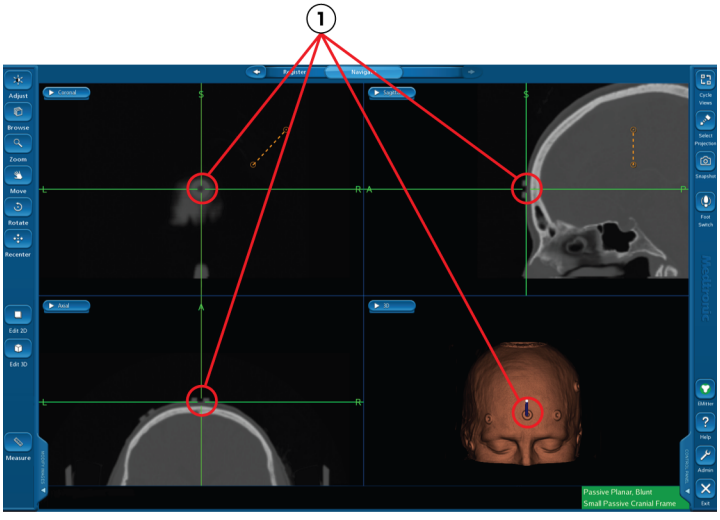
①	Cross-sections of the sphere of predicted navigation accuracy: Within the green circles, localization error is estimated to be 1 mm or less.

Verifying PointMerge® Registration Accuracy

Click  to advance to the **Navigate** task to verify registration accuracy.

1. In the **Navigate** task, use the registration probe to touch an identifiable point on the patient's anatomy.
2. Compare the location of this point to the centers of the crosshairs in the images.
3. Repeat the process for at least two more points.
4. If you are satisfied with the registration accuracy, proceed with navigation (page 46).

   If the accuracy is not acceptable, click  and then click **[Restart PointMerge]** to repeat the registration process or click **[Register with Tracer]** to use Tracer™ registration.



1	Make sure that the point you touch on the patient matches the point displayed in all views.

G: Creating Accuracy Checkpoints (Optional)

⚠ **Warning:** If you neglect to establish accuracy checkpoints and the patient reference moves in relation to the patient anatomy at any time after surgery begins, you will have to re-register the patient or abandon use of the system.

1. Create four fixed, identifiable points on the anatomy in the sterile field.
2. Click **[Control Panel]** and then click **[Create Checkpoints]**.
3. Place the sterile registration instrument on the first point and hold it steady for 2 seconds or press the footswitch. Listen for the confirmation sound.
4. Store three more accuracy checkpoints in the same manner.

   When you have touched four checkpoints, the **[Realign Registration]** button becomes active.
5. At any time during the procedure, return the registration instrument to any of the accuracy checkpoints and observe the reported **Distance to Checkpoint** displayed in the lower-left corner of the screen. A distance in excess of 2 mm indicates a potential shift in the position of the anatomy in relation to the patient reference. In these situations, carefully re-evaluate navigational accuracy by touching several anatomical points. If inaccuracy persists, click **[Realign Registration]** and then re-register the patient using the accuracy checkpoints as landmarks.


Register
Navigate
Coronal
Sagittal
Axial
3D
Standard Profile
PROCEDURE:
Tumor Resection
PATIENT:
Patient 3
Cycle Views
Select Image Set
Snapshot
Fast Switch
Plan
View Settings
Create Checkpoints
Touched
Touched
Touched
Touched
Realign Registration
Cancel Realignment
Medtronic
Dictionr
Help
Admin
Exit
Passive Planar, Blunt
Small Passive Cranial Frame

H: Using Tip Projection

The tip projection feature allows you to localize at a point along the current instrument trajectory but beyond the instrument tip, as if the selected instrument were longer than it is.

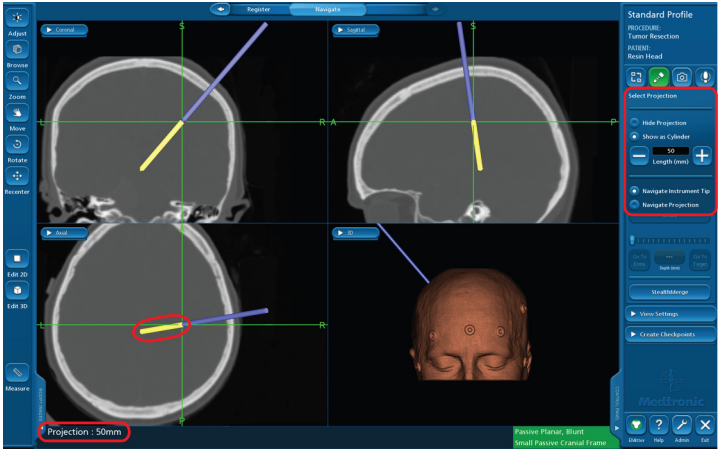
To enable the projection feature:

1. Click **[Select Projection]** in the task panel.
2. Click **[Show Projection]** and then use the plus and minus buttons to adjust the length of the projection.
3. Select either **Navigate Instrument Tip** or **Navigate Projection**.

A yellow extension from the end of the instrument model visually indicates the projection. When **Navigate Projection** is enabled, the crosshairs are located at the end of the projection and displayed distances (like distance to target) are measured from the end of the projection. This holds true even when a microscope interface is the selected instrument.

⚠ **Warning:** Remember that the end of the projection is not the same as the tip of the instrument. The projection indicates the location to which you could travel by advancing along the current trajectory. Turn off the projection when you want to localize at the tip of the probe or focal point of the microscope.

To turn off tip projection, click **[Select Projection]** and then click **[Hide Projection]**.

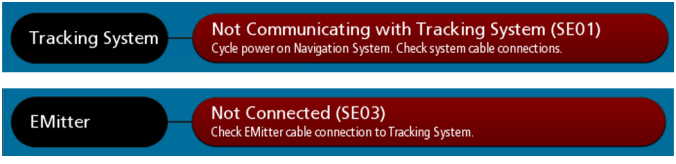

Register
Navigate
Standard Profile
PROCEDURE:
Tumor Resection
PATIENT:
Resin Head
Coronal
Sagittal
Axial
3D
Adjust
Browse
Zoom
Move
Rotate
Recenter
Edit 2D
Edit 3D
Measure
Select Projection
Hide Projection
Show as Cylinder
50
Length (mm)
Navigate Instrument Tip
Navigate Projection
Go To Entry
Depth (mm)
Go To Target
StealthMerge
View Settings
Create Checkpoints
Medtronic
Utilities
Help
Admin
Exit
Projection : 50mm
Passive Planar, Blunt
Small Passive Cranial Frame

I: Troubleshooting

Connection Problems

If the AXIEM™ system or the Mobile Emitter's connection will not verify on the **Setup Equipment** screen, click **[EMitter]** and then click **[EMitter Details]**.

If the AXIEM™ system or emitter displays red status, read the error message and follow the troubleshooting steps below.



Error Message	Troubleshooting Steps
Cycle power on Navigation System. Check system cable connectors.	Exit the software, turn off the system cart, wait 30 seconds, and turn on the cart. Restart the software and allow at least 15 seconds for the software to establish communication with the tracking system and emitter.
Check EMitter cable connection to Tracking System.	Make sure the Mobile Emitter cable is securely connected.

Exam Import Problems

Find the symptom in the table below and follow the troubleshooting steps:

Symptom	Troubleshooting Steps
You imported an exam across the DICOM network and slices are missing.	Remove the exam: Click **[Admin]** and then click the **Patients** tab. Select the exam you want to remove and click **[Delete Selected Exam(s)]**. Ask radiology to push the exam again. A status indicator appears in the upper left corner of the screen to show the number of exams and slices received.
You need to move an exam from one patient name to another.	Click **[Admin]** and then click the **Patients** tab. Select the patient, select the exam to move, and click **[Move Selected Exams]**. Click the drop-down menu under **Select Patient Name**. Select the patient's name, or select **New Patient** and enter a new name and medical record number. Click **[OK]** and then click **[Done]**.
You need to change the exam modality.	Click **[Exam Details]**, click the **MODALITY** drop-down list, and select the correct modality.
Error: *Exam name* does not contain valid data for navigation. Check scanner settings and/or re-import the exam.	If you receive the same message when you re-import the exam, call for technical support.

Symptom	Troubleshooting Steps
Error: *Exam name* contains gantry tilt and cannot be used for navigation.	Re-scan the patient without using gantry tilt. If you have questions about re-scanning the patient, call for technical support.
Error: *Exam name* does not contain the minimum number of images needed for navigation.	Ask radiology to reformat the scan to comply with the Imaging Protocol (9732379).
Error: *Exam name* does not contain contiguous slices and cannot be used for navigation.	Ask radiology to reformat the scan to comply with the Imaging Protocol (9732379).
Warning: *Exam name* is a non-axial scan. Please verify that the orientation is labeled correctly.	If the orientation is incorrect, click **[Modify Images]**, click **[Reorient]**, and correct the orientation.
Warning message that includes “This may affect navigation accuracy.”	Ask radiology to reformat the scan to comply with the Imaging Protocol (9732379).
You are importing exams from a CD or USB drive that contains archived Synergy® Cranial exams and the patient’s name is not in the list.	Click **[Search for More]**.

Define Surgical Plan Tips

Find the goal in the table below and follow the steps:

Goal	Steps
To drag a target or entry point in the 2D images	Click the plan name or click the plan in the 2D images to select it and then move the target or entry point.
To delete a plan	Click on the plan name in the task panel and click **[Delete]**.
To change the exam modality	Click **[Exam Details]**, click the **MODALITY** drop-down list, and select the correct modality.
To display dots instead of crosshairs in 2D views	Click **[Admin]** and click the **Options** tab. In the **Crosshair Visibility** section, click **Off**. Click **[Done]**. Alternatively, press the <F4> key to toggle between crosshairs and dots.

3D Model Tips

Find the goal in the table below and follow the steps:

Goal	Steps
To delete a 3D model	Select the model and click **[Delete]**. You cannot delete the registration (**Reg**) model.
To set a different skin model as the registration model	Click the **Select Model** drop-down list, select a model, click **[Use for Registration]**, and click **[OK]**.

Instrument Problems

Click **[EMitter]** and then click **[EMitter Details]**. Check the error message for the instrument and follow the troubleshooting steps below:

Error Message	Troubleshooting Steps
No Signal	Make sure that the instrument is no more than 50 cm (20 in) from the front of the Mobile Emitter. Make sure that the instrument is at least 6 cm away from the emitter. Move any metal objects farther away from the instrument.
No Signal - EMitter Communication Error	Allow at least 15 seconds for the software to establish communication with the tracking system and emitter. If red status remains, call for technical support.
Poor Signal	Move the instrument so that it is visible in the **Tracking View**. Move any devices that emit electromagnetic noise (such as electric drills and electrocautery devices) away from the instrument. Unplug the instrument from the system and plug it back in. Move any metal objects farther away from the instrument.
Incompatible instrument	Go back to the Setup Equipment task, click **[Add or Remove Instruments]**, and add the instrument.
Undefined instrument	Call for technical support.

Error Message	Troubleshooting Steps
Duplicate Patient Reference	Unplug the unused Patient Tracker from the AXIEM™ system.

Additional Instrument Problems	Troubleshooting Steps
An instrument is plugged into a port and it does not display as red or green in the tracking details.	Unplug and re-plug the instrument. If the problem persists, try a new instrument.
All instruments display red status.	Check for interference around the Mobile Emitter. Make sure that no cables are draped over the emitter.

StealthMerge™ Tips

When you merge exams, the merged set is always used in the **Plan**, **Register**, and **Navigate** tasks.

Goal	Steps
To view only one of the merged exams	Click **[Edit 2D]**, click an exam that you do not want to view, and click **[Remove]**. Repeat this process until the **Composite View** contains only the exam you want to view.
To navigate on an exam that is not part of the merged set	In the **Navigate** task, click **[StealthMerge]** and add the exam to the merged set. If you do not want to add the exam to the merged set, move that exam under a different patient name. Then select that patient in the **Select Patient** task.
To unmerge exams	Delete the exams and re-import them.

J: Buttons

All Tasks

The following buttons display in all software tasks.

The left arrow returns to the previous task.

The right arrow advances to the next task.

[EMitter] opens the Tracking View window. (This button is disabled in the **Select Surgeon** and **Select Patient** tasks.)

[Help] displays relevant help information.

[Admin] opens an Admin window in which you can choose system options.

[Exit] exits the software.

[EMitter Details] displays connection status for the navigation system, emitter, patient reference, and instruments. Click **[EMitter]** to display the **[EMitter Details]** button.

Select Patient, Plan, or Navigate

The following buttons display in the **Select Patient**, **Plan**, or **Navigate** tasks.

[Modify Images] opens a new group of buttons which allow you to modify level, width, magnification, and image orientation as well as recenter and move images.

[Adjust] adjusts brightness and contrast. Click **[Adjust]**, click in an image and drag the mouse up, down, left, or right. Up and down increase and decrease brightness. Right and left increase and decrease contrast.

[Zoom] magnifies an image. Click **[Zoom]**, click on an image, and drag the mouse up to increase the image size. Drag down to decrease the image size.

[Move] changes the cursor to a hand. Click the hand on an image and drag to move images.

[Recenter] returns the crosshairs to the centers of the images.

[Edit 2D] allows you to adjust the level, width, rendering style, and colormap of exams and to blend merged exams for display in **Plan** and **Navigate**.

[Reorient] corrects the orientation of images from the scanner.

[Browse] scrolls through image slices. Click this button, click on an image, and drag the mouse up or down.

[Cycle Views] cycles through the presets in **View Settings.**

[Edit 3D] allows you to adjust the level, width, rendering style, and colormap of 3D models and to blend multiple models for display in **Plan** and **Navigate**.

[Snapshot] captures a snapshot of the screen and stores it with the exam.

[Select Projection] allows you to extend the instrument's tip on the 2D and 3D images.

[Rotate] allows you to rotate the 3D model. Click on the 3D model and drag in the direction that you want it to rotate.

[Measure] displays the distance in millimeters between any two selected points on an image.

The image selection button allows you to select the content in each view. Click this button and choose from the drop-down list (Axial, Coronal, Sagittal, 3D, Video, or Off).

[StealthMerge] allows you to merge multiple exams from the same patient. (This button is enabled when you purchase a StealthMerge™ license.)

[Manage Patient Data] allows you to move, archive, and delete exams.

[View Settings] allows you to configure your image display area.

The layout buttons change the screen layout to display 1, 2, 3, or 4 views.

The preset buttons allow you to save view settings in the surgeon profile. When you have selected a layout for the image display area and selected content for each view, click **[Set]** on one of the preset buttons.

Setup Equipment

The following button displays in the **Setup Equipment** task.

[Move Equipment] allows you to change equipment placement on the screen. Click **[Move Equipment]**. When the **Move Equipment** window opens, click the piece of equipment that you want to move. Placement options (blue squares) appear. Click the appropriate placement and click **[Done]**.

K: Symbols

The following symbols may appear on system equipment, system packaging, or in this document.

The device complies with European Directive MDD 93/42/EEC.

Classified by Underwriters Laboratories Inc. with respect to electric shock, fire, mechanical, and other specified hazards only in accordance with UL2601-1/CAN/CSA C22.2 NO.601.1. Control number 87HJ

When found in this guide, this symbol means: “Warning! Failure to observe could result in injury or death.” When found on equipment, this symbols means: “Attention: consult accompanying documentation.”

Caution! Failure to observe could result in damaged equipment, forfeited time or effort, or the need to abort use of the system.

$\mathbf{R_x}$ **Only**

Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

Power on. Connect to main power.

Power off. Disconnect from main power.

Use by date specified

Single use only. Do not reuse.

Quantity

Sterilized using ethylene oxide.

Non-sterile

Do not sterilize

Mobile Emitter must not be used in ambient temperatures greater than 33°C (92°F).

Protective Earth (Ground)

Do not allow contact with patient. Temperature may exceed limits.

Notes