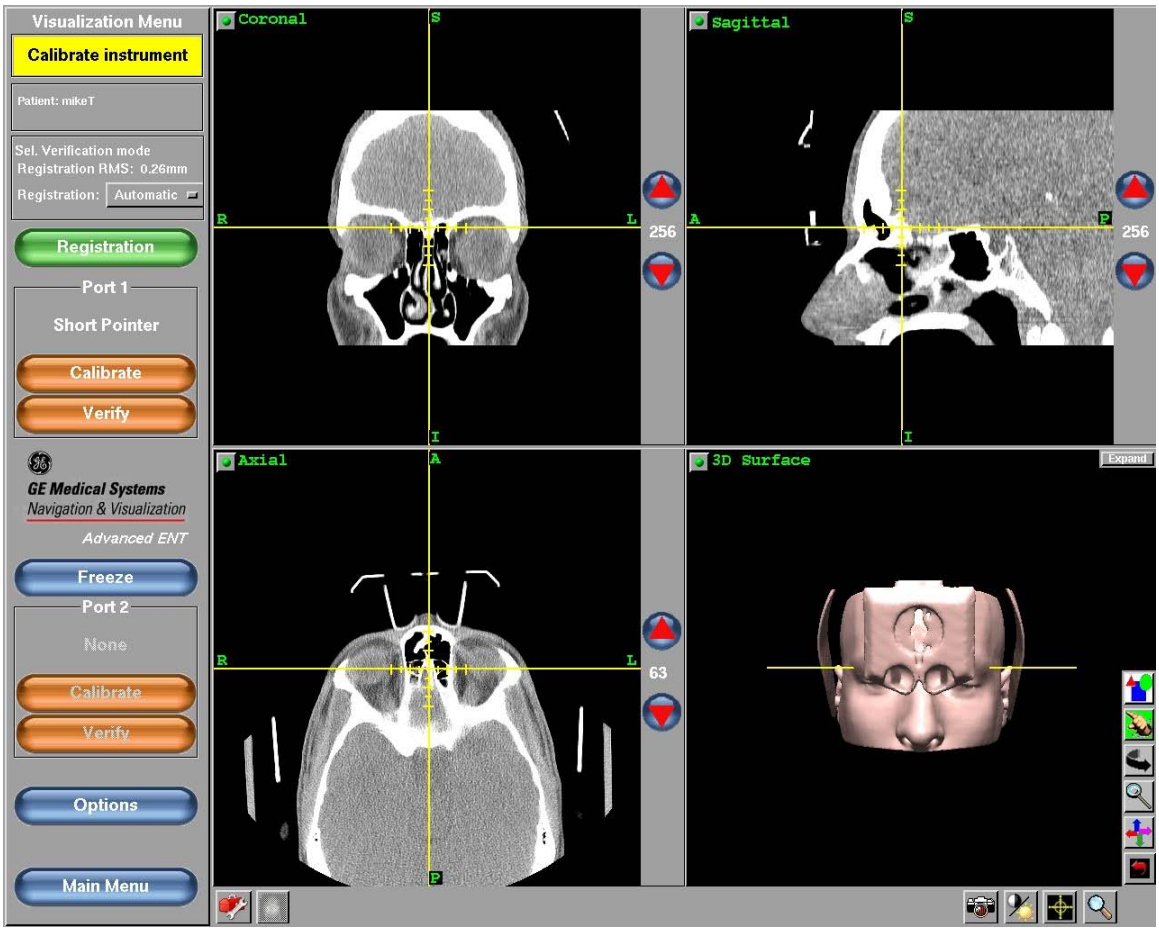
InstaTrak® 3500 Plus

Advanced ENT Application

Operator's Manual



1008214-NAV R3

Revision History

Rev	Date	Comments
R00	June 2005	Manufacturing Release
R3	June 2008	Headset placement changes

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1
INTRODUCTION

Intended Use, Indications & Contraindications, Warnings & Precautions

Intended Use

- The *InstaTrak® 3500 Plus Surgical Navigation System*–**Advanced ENT Application** is intended as an aid to the surgeon to precisely locate anatomical structures in the human body, and to precisely locate the tip and trajectory of surgical instrumentation in reference to those anatomical structures.

Indications for Use

- The *InstaTrak® 3500 Plus*–**Advanced ENT Application** *is indicated for use in surgical procedures* that require precise location of surgical instrumentation with reference to rigid anatomical structures visible on medical images.

Contraindications

- *The* InstaTrak® 3500 Plus Advanced ENT Application *should not be used for any non-ENT or non-skull-base surgical procedures.*
- *The* InstaTrak® 3500 Plus Advanced ENT Application *is contraindicated for skeletally immature patients.*
- *The* InstaTrak® 3500 Plus Advanced ENT Application *should not be used with patients suspected of having Creutzfeld-Jacob disease. Sterilization of cables cannot be guaranteed.*
- *For instruments used with the* InstaTrak® 3500 Plus Advanced ENT Application*, follow the specific contraindications for that device.*

Warnings and Precautions

- *The* InstaTrak®3500 *Plus* Advanced ENT Application *provides information from medical imaging that enhances the information provided to the surgeon. The* InstaTrak® 3500 Advanced ENT Application *should be used only as an adjunct for surgical guidance. It is not a replacement for surgical judgment, expertise, or knowledge of the anatomy. The* InstaTrak® *3500* Plus ***Advanced ENT Application*** *is for use by qualified surgeons only and should not be used by any person not qualified to use this device.*
- *Clinical tracking accuracy is subject to many factors. Navigation should be used only by personnel trained in the use of navigation and experienced with the*

anatomy on which navigation will be used. It is the responsibility of the user to verify tracking accuracy during the procedure to ensure the navigation system is performing adequately. The user should plan the procedure so that it can be safely completed without the use of navigation.

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

- *The safety and effectiveness of the* InstaTrak® 3500 Advanced ENT Application *has not been validated for use on patients who have electronic devices that make an internal, direct connection to the cardiovascular system, brain or central nervous system.*
- *Only persons who have attended the in-service training courses conducted by GE Healthcare Technologies Clinical Training Specialists, should attempt to operate this equipment.*
- *GE Healthcare Technologies also strongly recommends that radiologists and scanner technologists acquaint themselves with the intra-operative use of the* InstaTrak® 3500 Plus *by reading this manual and attending surgery. Radiology and OR personnel are both critical components of the* InstaTrak® 3500 Plus Advanced ENT Application *team.*
- *This manual covers the use of the* InstaTrak® *3500* Plus ***Advanced ENT Application*** *and should be used in conjunction with the* InstaTrak® 3500 Plus *Operator's Manual. The* InstaTrak® *3500* Plus *Operator's Manual contains instructions and information for the basic system platform. Information about any of the features and functions that are common to all of the applications can be found in the* InstaTrak® *3500* Plus *Operator's Manual.*
- *Do not connect any equipment to the system, which is not specifically described in this manual. Whenever AC powered equipment is connected to the system, the user must confirm that applicable Standards for leakage current are met by the interconnected system any any applied parts.*
- *Please follow the warnings and cautions embedded in individual sections of this manual as appropriate. For instruments used with the* InstaTrak® 3500 Plus*, follow the specific warnings and precautions for that device.*

Note: The screen images in this manual are for representation purposes only. The actual images on your display might vary.

Note: No natural latex is used in the manufacture of any of GE Healthcare Technologies products or packaging used for the *InstaTrak® 3500 Plus* system.

Note: This device has been tested for electromagnetic emission and susceptibility in accordance with IEC 60601-1-2.

The InstaTrak 3500® Plus

System Components

The components of the *InstaTrak® 3500 Plus* include

- A high-powered computer,
- A high-resolution touch-screen display,
- A keyboard/mouse, and
- A tracking system.

The patient's CT or MRI images are acquired and sent to the *InstaTrak® 3500 Plus* prior to surgery. The scan is used during the surgical navigation procedure.

The keyboard is used to enter patient identifiers and text. The touch-screen or mouse is used to interact with the display.

The tracking system is used to track the position of the surgeon's instruments.

Note The *InstaTrak® 3500 Plus* uses a specific tracking system. If your System is not equipped with the correct tracking system, the following message appears after attempting to enter the **Visualization Display** for surgical navigation.

Figure 1-1. Incompatible Tracker Message

If this message is seen, the *InstaTrak 3500 Plus* cannot be used for surgical navigation. Contact your GE Healthcare Technologies Representative.

HIPAA Privacy Rule Compliance

The *InstaTrak*® *Plus* Surgical Navigation System is compliant with the Privacy Rule, a Federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 protecting the privacy of individually identifiable health information.

Users of the *InstaTrak*® *Plus* Surgical Navigation System have the option of assigning a password before system operation and to de-identify patient data before copying.

Note: To protect sensitive healthcare information, GE Healthcare Technologies strongly recommends requiring a password to operate the system and de-identifying patient data before transferring or copying to a CD or floppy disk.

2
Pre-Operative

Scanner Compatibility

The **Advanced ENT Application** of the *InstaTrak® 3500 Plus* is designed to interface with any CT or MRI scanner that can output data in the DICOM 3.0 storage class format.

Data Transfer

Before the *InstaTrak® 3500 Plus* may be used in surgery, a CT or MRI scan must be transferred to the system.

If the scanner has the capability to archive DICOM data onto a CD, then the scans can be downloaded onto a CD directly from the scanner or Radiology workstation and then loaded onto the *InstaTrak® 3500 Plus*.

The scans also can be transferred to the system via an Ethernet network. Connectivity must be established between the scanner or Radiology workstation and the *InstaTrak® 3500 Plus* or *ConneCTstat™ Plus* in order to transfer scans in this manner.

There are some basic prerequisites for successful connectivity:

The system uses the DICOM (Digital Imaging and Communications in Medicine) 3.0 standard for network based image transfers. This standard was developed jointly by the American College of Radiology (ACR) and National Electrical Manufacturers Association (NEMA) to facilitate data transfer between medical equipment. Many scanners support this standard by providing a storage or transfer facility to a DICOM-capable device, either directly from the scanner or by means of a workstation. In some cases, older scanners can be made to output DICOM data through the use of third party equipment.

Data may be transferred to either the *InstaTrak® 3500 Plus* or the *ConneCTstat™ Plus* through an Ethernet network connection. The Ethernet port is a twisted pair RJ-45 (10/100 Base-T) connector (no ground connection) located on the back panel of the *InstaTrak 3500 Plus.* The Ethernet capability conforms to the ISO 802.3 standard.

Radiology

Surgical Navigation Systems use information from medical images to aid doctors during surgery. Depending on the surgical procedure, a CT or MRI is obtained using the scanning protocols provided in this Operator's Manual. The axial scan is transferred to the system, where the images are automatically reformatted into coronal, sagittal and three-dimensional views.

Connectivity is the process of establishing communication between the scanner and the *InstaTrak® 3500 Plus.* A GE Healthcare Field Service Engineer works with your network administrator to establish a method for transferring the medical images to the system. Refer to the Service section in the *InstaTrak® 3500 Plus* Operator's Manual for more information about connectivity.

Transferring Scans To the *InstaTrak 3500 Plus*

There are a number of options for transferring scans to the system:

- A *ConneCTstat™ Plus* can be placed in a Radiology Department and connected to your network. Images are transferred to the *ConneCTstat™ Plus* and sent to a CD, which can then be inserted into the *InstaTrak® 3500 Plus*. This enables an outside Radiology group to perform the medical imaging that will be used during surgery.
- The *InstaTrak® 3500 Plus* can be directly connected to the hospital network enabling the scans to be transferred from the scanner to the system, which is connected to the network in the OR. It is also possible to transfer scans between the *InstaTrak® Plus* and the *ConneCTstat™ Plus* via a network connection.
- The *InstaTrak® 3500 Plus* can be transported to the Radiology Department and hooked up to a network connection. Scans are transferred directly from the scanner to the system.
- If the scanner has the capability to archive DICOM data onto a CD, then the scans may be downloaded onto a CD directly from the scanner or Radiology workstation and then loaded onto the *InstaTrak® 3500 Plus*.

The medical images used for surgical navigation must meet specific criteria. GE Healthcare has developed protocols that must be followed in order to ensure high quality images for use with the *InstaTrak® 3500 Plus*. The GE Healthcare Clinical Specialist will work with your CT and/or MRI technologists to ensure that the protocols are understood and followed.

Scanning Protocols

The scanning protocols are designed to meet the following goals:

- Maximize system accuracy during surgery
- Obtain Automatic Registration, when applicable
- Minimize scan time
- Minimize patient radiation exposure
- Optimize image quality

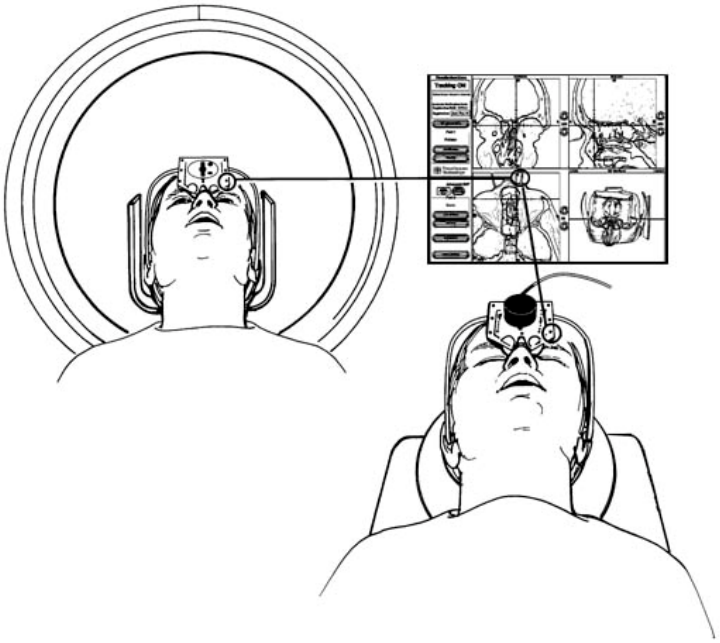


Figure 2-1. Scanning/Surgery

Registration

Registration is the process of aligning the patient scan with the actual physical features of the patient. For a more detailed description of registration, refer to *System Operation* in the *InstaTrak 3500 Plus* Operator's Manual.

A valid registration is necessary in order to use the system for surgical navigation.

Methods

Several different registration options are available with the **Advanced ENT Application** of the *InstaTrak® 3500 Plus*:

- *Automatic Headset* registration - The headset is worn during the scan.
- *Auto Plus* registration – The headset is worn during the scan.
- Fiducial registration - Fiducial markers are placed on the patient before the scan.

  Fast Fiducial ™ is a computer algorithm to determine the position and center of the fiducial marker

- *AccuMatch*™ Surface Registration (if system is equipped) - No markers are placed on the patient.

Registration Methods and Scan Compatibility

- CT: All registration methods may be used

- MRI: Fiducial or *AccuMatch*™ registration only.

Note: The headset contains embedded metal markers and may not be worn during an MRI scan.

Automatic Registration Headset

Headset Selection Guidelines

- For patients 14 years or older, use the Adult Headset
- For pediatric patients under the age of 14, head circumference must be measured to determine the appropriate Pediatric Headset size.
- Measure the head circumference directly above the eyebrows used the tape measure provided in each headset box.

Headset Description	Reorder #	Patient	Head Circumference
Adult	100497	Adults and Children age 14 or over	Greater than 57 cm
Pediatric Large	100948	Large Children	Greater than 52 cm
Pediatric Small	100949	Small Children	Less than 52 cm

Table 2-1. Headset Selection Guidelines

Note: Patients, 14 years or older with a head circumference less than 57 cm, may be better suited for the Pediatric Large Headset. Pediatric patients, less than 14 years with a head circumference greater than 57 cm, may be better suited for using the Adult Headset. We recommend that the surgeon fit the Headset to the patient to ensure proper fit.

WARNING
Some patients may experience discomfort when the Headset *is worn for an extended period of time. Such discomfort should be temporary. Patients with TMJ, impaired circulation, or other conditions that may be aggravated by use of the* Headset*, should be given special consideration. Temporary pain or temporary loss of sensation may be experienced with use of the* Headset.

CAUTION
The use of the Headset *is not recommended on patients less than three (3) years of age unless a proper fit can be determined.*

WARNING
The Headset is a single-use patient item. Using the same Headset on another patient can result in system inaccuracy due to changes in Headset geometry leading to a patient safety hazard.

CAUTION
Prior to scanning, ensure the small metal markers embedded in front and side of the Headset are present. If any markers are missing, do not use the Headset. Automatic registration is not possible if the markers are missing or are not present on the CT scan.

CAUTION

To maximize system and tracking accuracy, the Headset used during the CT scan should be used in surgery. If a surgical fixation device, such as a Mayfield, will be used, ensure that the Headset is positioned exactly as in the CT scanner.

Verification Pad Placement

2 adult verification pads are provided in each Adult Headset box. 2 pediatric verification pads are provided in each Pediatric Small Headset box. 2 adult and 2 pediatric verification pads are provided in each Pediatric Large Headset box. The clinician must select the appropriate Verification Pad for each patient.

The verification pad must be worn during the CT scan for patient comfort and to ensure proper fit of the Headset. Place the verification pad on the patient's nose by aligning the upper center curve of the verification pad with the bridge of the patient's nose.

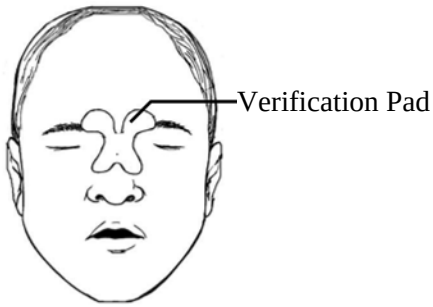


Figure 2-2. Verification Pad Placement

WARNING

The Verification Pad provided with the headset must be used to increase patient comfort and to reduce the possibility of bruising of the skin under the nosepiece of the Headset.

Headset Placement

Select the appropriate Adult, Large Pediatric or Pediatric *Headset*. Gently set the nosepiece on the bridge of nose and place each earpiece into the external ear canals.

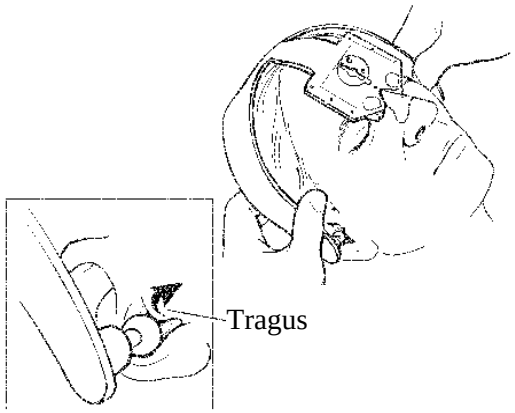


Figure 2-3. Headset Placement

WARNING

Store Headset only in the supplied box. Ensure that the Headset is positioned properly in the box to maintain its shape. Failure to do so can result in system inaccuracy due to changes in Headset geometry.

WARNING

The Headset is a single-use patient item. Using the same Headset on another patient can result in system inaccuracy due to changes in Headset geometry leading to a patient safety hazard.

Fiducial markers are used to correlate the scanned images with the patient. The fiducial markers must be placed on the patient before the scan and must not be moved until after the registration process in surgery is complete.

For best results, wipe the areas on which the fiducials are to be placed with alcohol to remove oil. Place the fiducial markers on the patient according to the placement below.

Note: To ensure registration accuracy, once the fiducial markers are placed they cannot be moved or replaced until the registration process is complete.

CAUTION

If a fiducial marker falls off, it must not be replaced. Replacing a fiducial marker may result in registration inaccuracy.

Fiducial Marker Placement Guidelines

- Place more fiducial markers than necessary in case one or more is displaced. A minimum of four (4) fiducial markers is required for a relevant registration.
- Surround the operative area and do not place too close together
- Apply to areas where the skin is relatively immobile.
- Apply to bony areas. Avoid areas where skin is loose.
- Apply within the medical images scanning range only.
- Do not apply to areas of trauma as swelling may displace their position.
- Do not apply fiducials in a straight line

For best results, GE recommends fiducial marker placement on the following areas:

- Above the eyebrow at the hairline
- Lateral forehead
- Vertex, slightly off the midline
- Asterion (junction of parietal, occipital and temporal bones)
- Above and behind the ear

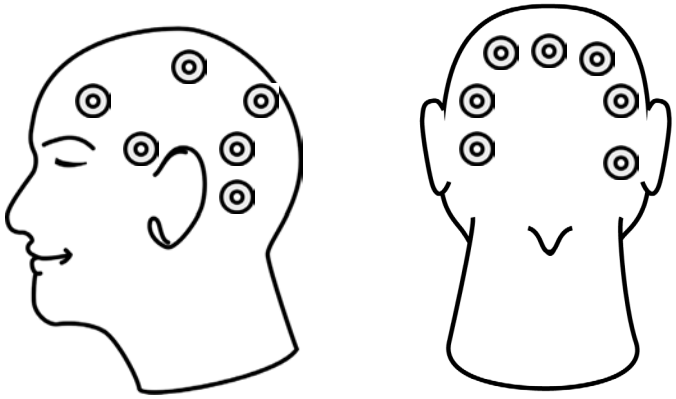


Figure 2-4. Fiducial Marker Placement

CT Scanning Protocol

The following table provides CT scanner guidelines to obtain the best results for use with the *InstaTrak® 3500 Plus*.

Keep all parameters consistent throughout the scan.

Scanning Plane	**Axial**
Patient Position	**Supine**

Gantry Angle	**Zero**
Matrix Size	512
Slice Thickness	1-3mm
Scanning mode	Helical
Table increment	1mm
Algorithm	Standard brain

Table 2-2. Recommended CT Scanner Protocol

CAUTION

Scanner settings listed in bold print indicate that no changes are allowed. All others may be set at the discretion of the user.

Patient Preparation

- Remove all metal from the patient's head
- Place the fiducial markers or the *Automatic Headset* on the patient, as applicable
- Be certain to place the Verification Pad on the patient as directed before placing the *Headset*
- Fiducial markers or the *Headset* are not required if *AccuMatch™ Surface Registration* will be used
- Position the patient on the scanner table for a supine axial scan.

MRI Scanning Protocol

The following table provides MRI scanner setting-guidelines to obtain the best results for use with the *InstaTrak® 3500 Plus*.

Scanning Plane	**Axial**
Patient Position	**Supine**
Data Acquisition	**3D Volumetric**
Matrix Size	256
Slice Thickness	1.5mm

Table 2-3. Recommended MRI Protocol

CAUTION
*Scanner settings in **bold** print indicate that no changes are allowed. All others may be set at the discretion of the user.*

Patient Preparation

- Remove all metal from the patient
- Place fiducial markers on the patient, if applicable
- Position the patient on the scanner table in the supine position

Scanning

- Use a protocol for T1 3D volumetric data or 3D reconstructions
- Scan using 1.5mm slice thickness with contiguous, non-overlapping slices Images must be acquired in the axial plane.
  - If the abnormal area is not clearly visualized, then the protocol should be adjusted to use T2.
- Make certain that all of the requested anatomy appears on the scan
- If fiducial markers are used, all markers must appear on the scan
- If no markers were placed on the patient, the nose, ears, top of the head and the back of the head must appear on the scan.

Note: The GE Healthcare Automatic Headset cannot be used during an MRI scan. If using a MRI scan, fiducial or AccuMatch™ Surface Registration must be performed.

3
GETTING STARTED

HIPAA “Privacy Rule” Compliance

The *InstaTrak® Plus* Surgical Navigation System is compliant with the Privacy Rule, a Federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 protecting the privacy of individually identifiable health information.

Users of the *InstaTrak® Plus* Surgical Navigation System have the option of assigning a password before system operation and to de-identify patient data before copying.

Note: To protect sensitive healthcare information, GE Healthcare Technologies strongly recommends requiring a password to operate the system and de-identifying patient data before transferring or copying to a CD or floppy disk

Transferring Data

Scanner Transfer

The following instructions apply to transferring image data from either a CT or an MRI scanner to either the *InstaTrak® 3500 Plus* or the *ConneCTstat™ Plus.* Refer to *Service* in the *InstaTrak® 3500 Plus Operator's Manual* for more details about connectivity.

Note: The System should be disconnected from the network connection before using in surgery.

- Plug the system into a hospital-grade electrical outlet.
- Plug the network connector into the receptacle marked "Ethernet Port" on the back of the system.
- Turn on the system.
- Wait for the MAIN MENU to appear.

△ ***CAUTION***

Each scan requires approximately one hundred twenty-five (125) images of free disk space. If disk space is unavailable, older scans must be deleted. See System Operation in the InstaTrak® 3500 Plus Operator's Manual for instructions on how to delete images.

Network Transfer

After scanning is done and all reconstructions are complete, initiate the transfer between the scanner and the *InstaTrak® 3500 Plus.* A menu appears showing the transfer status.

To end the transfer of a scan, select an entry while it is being transferred and then select the Cancel button. Any scan that has already been transferred must be deleted manually from the PATIENT DATABASE MENU.

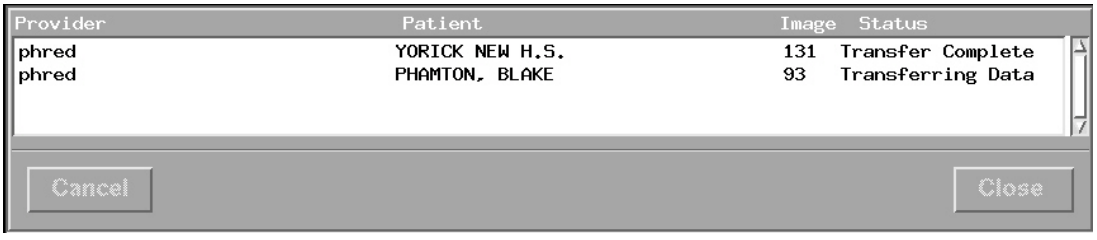


Figure 3-1. Network Transfer Menu

Transferring Between Systems

A scan may be selected and transferred between InstaTrak systems via an Ethernet network. Before beginning the transfer, ensure that both the *InstaTrak® 3500 Plus* or the *ConneCTstat™ Plus* are connected to the hospital network and that both systems have the same AE (Application Entity) Title.

Note: Only one scan may be selected and transferred at a time.

To transfer a scan between systems

- Plug in both systems and turn the power on.
- Select the PATIENT DATABASE button. The PATIENT DATABASE MENU appears.
- Highlight the correct scan.
- Select the **Send Data To**…. button from the PATIENT DATABASE MENU. The TRANSFER DATA MENU appears.
- Select the **Network** button from the TRANSFER DATA MENU. All the DICOM Data Providers that are listed on the DICOM CONFIGURATION MENU appear.
- Select the **Host Name** assigned to the receiving system.
- Select the **Send** button.
- A message appears to confirm the transfer. Select **Yes** to continue or **No** to cancel the process.

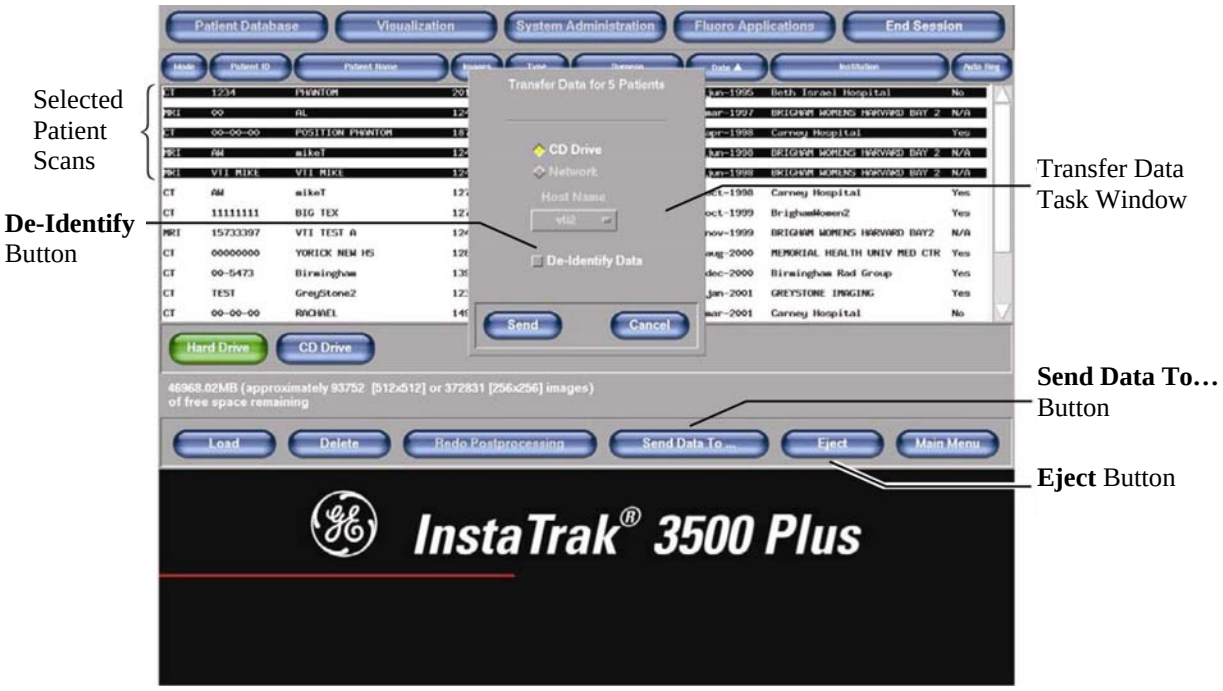


Figure 3-2. Transfer Data Between Systems

Transferring Using a CD

If a *ConneCTstat™ Plus* is in the Radiology Department, the CT or MRI scans can be placed on a blank CD-R for transfer to the *InstaTrak® 3500 Plus.*

To load the CT or MRI scan for viewing or navigation purposes, the scan must first be transferred to the system Hard Drive. Scans cannot be directly loaded from the CD.

Scans may be downloaded onto a CD and viewed on a PC. Refer to the *InstaTrak® 3500 Plus* Operator's manual for more information on the *DICOM CD Viewer*.

Note: The *InstaTrak® 3500 Plus* or *ConneCTstat™ Plus* uses a CD-R that can be written to one time only.

Note: Before copying patient data to a CD, the patient's name can be de-identified. GE Healthcare strongly recommends the de-identification of patient data before copying.

- There are three ways to open the CD drawer:
  - The drawer will open on command when certain message windows are selected.
  - The button is pressed on the CD Drive.
  - The **Eject** button is s elected from the PATIENT DATABASE MENU.
- There are two ways to close the CD drawer:
  - The drawer will close on command.
  - The CD drawer is gently pushed to activate closing. Do not force the CD drawer.

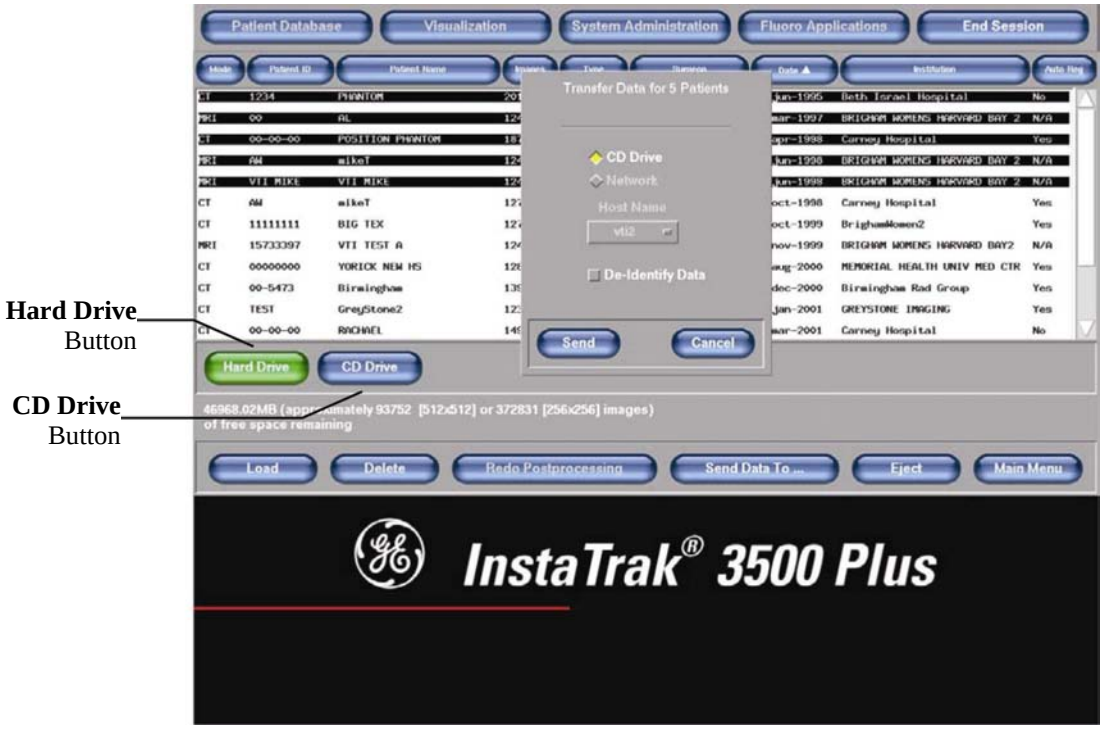


Figure 3-3. Transferring Data Using A CD

Transferring Scans: CD to Hard Drive

- Open the CD drawer and place the CD containing the scan into the drive.
- Close the CD drawer.
- Select the CD Drive button from the PATIENT DATABASE MENU.
- Highlight the desired scan (s). Multiple scans may be copied at the same time as long as all scans are listed consecutively in the PATIENT DATABASE MENU.
- Select the **Send Data To**… button. The TRANSFER DATA MENU appears. Hard Drive is selected automatically.
- Select **Send.**
- A message window appears. Select **Yes** to confirm or **No** to cancel.

After the transfer process is complete, select the **Hard Drive** button to confirm that the scan was successfully transferred.

Hard Drive to CD

From the PATIENT DATABASE MENU, select the desired scan (s). More than one scan can be copied at one time. Snapshots appearing in the database can be included in a series.

- If the scans are listed consecutively, highlight one and drag the cursor to the next until all scans or snapshots to be copied are highlighted.
- If the scans are not listed consecutively, and a keyboard is attached to the system, highlight a scan, then select and hold down the **Control** button on the keyboard. Highlight the other scans or snapshots until all items to be copied are highlighted.
- Select the **Send Data To**…. button from the PATIENT DATABASE MENU. The TRANSFER DATA task window appears. CD Drive is selected automatically.

Note: To remove the patient name from the copied data, select the De-Identify Data button. The De-Identify task window appears allowing you to select a new identifier for the patient.

- Select the **Send** button.
- Select **Yes** to confirm or **No** to cancel the copying process.
- If **Yes** is selected, the CD drawer opens automatically.
- If a blank disk is inserted in the CD drive, select Continue. The CD drawer will automatically close
- Select **Cancel** to cancel the copy process
- Note the amount of data to be copied and verify that there is sufficient space on the CD. You must use a blank CD-R.

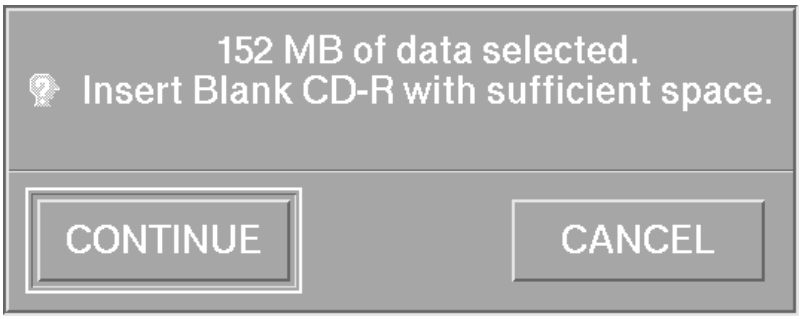


Figure 3-4. Sufficient CD Space Message

- If the highlighted series of scans and snapshots are correct, select **Yes**. The CD copying process begins automatically

Figure 3-5. Confirm CD Copy Message

- When the transfer process is complete, the CD Complete message appears. Select **OK**.

Figure 3-6. CD Complete Message

When the CD copying process is complete and the **OK** button is selected, the CD drawer opens automatically.

To confirm that the scan has been copied onto the CD, close the drawer and select the **CD Drive** button on the PATIENT DATABASE MENU. The copied scans and snapshots appear on the PATIENT DATABASE MENU. To remove the CD, select the **Eject** button.

Auto Registration Verification

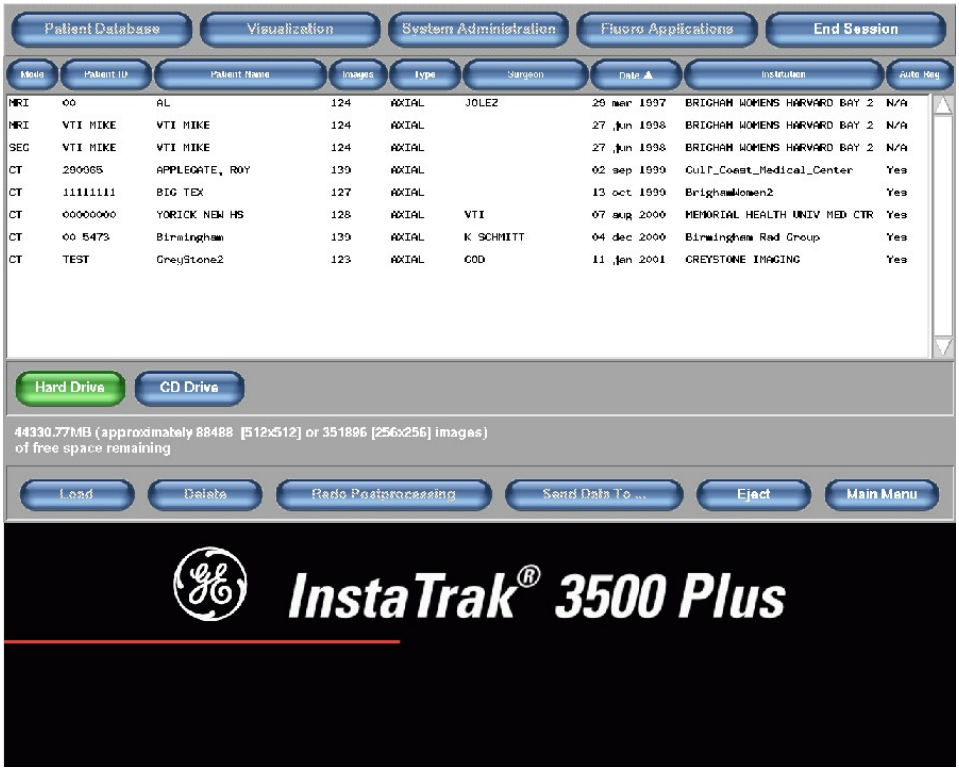


Figure 3-7. Auto Registration Column

If the patient's CT scan was performed using a *Headset*, an automatic registration may be used. To verify that automatic registration may be used:

- From the MAIN MENU, select the **Patient Database** button. The PATIENT DATABASE MENU appears.
  - The Auto Reg column on the far right of the PATIENT DATABASE MENU provides information on the status of *Automatic Headset Registration*.
  - If **Yes** appears in the Auto Reg column, then *Automatic Headset Registration* can be used.
  - If **No** appears in the Auto Reg column, either the *Automatic Headset Registration* was not successful, the *Headset* was not used during the patient scan, or the embedded fiducial markers were not present in the scan volume.

Note: If an Automatic Headset Registration is not possible as indicated by a **No** in the Auto Reg column, an *AccuMatch™ Surface Registration*, automatic fiducial registration (if at least 5 marker balls are present on the patient scan), or fiducial registration (if patient was scanned with fiducial markers) may be performed.

CAUTION

*If dashes appear or anything other than **Yes** or **No** is listed in the Auto Reg column, the scan was not done to protocol and cannot be used in surgery with the* InstaTrak 3500 Plus*.*

Note: The automatic registration status will *not* appear on the CD. The Auto Reg column for the patient scan will display "- - -". To verify automatic registration, check the status of the scan on the hard drive. When the scan is transferred to the Hard Drive, post-processing will reinitiate and the correct auto registration will reappear.

4
Operating Room

Operating Room Setup

HIPAA "Privacy Rule" Compliance

The *InstaTrak® Plus* Surgical Navigation System is compliant with the Privacy Rule, a Federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 protecting the privacy of individually identifiable health information.

Users of the *InstaTrak® Plus* Surgical Navigation System have the option of assigning a password before system operation and to de-identify patient data before copying.

Note: To protect sensitive healthcare information, GE Medical System strongly recommends requiring a password to operate the system and de-identifying patient data before transferring or copying to a CD or floppy disk

Logon and Logout

Since the system contains sensitive patient data, you have the option of requiring users to Logon to the system and to Logout when system use is complete. The Logon process requires a password (default or selected by you) when the system is powered on. When finished using the System, you have the option to logout or shutdown. The System shutdown and logout process is covered in the *Post-Operative* section of this *Operator's Manual* and in the *InstaTrak 3500 Plus Operator's Manual*.

Password Protection

Upon installation, the *InstaTrak® Plus* Surgical Navigation System is protected with a default password. The password is required to operate the system. If desired, you can change or eliminate the password. Since the system contains sensitive patient information, GE Healthcare strongly recommends that the password requirement not be eliminated.

Powering and Logging On To The System

The system should be positioned in the Operating Room so that the surgeon can easily see and reach the display. If the operative area is crowded, the articulating arm can be extended. If you want to interact with the display during the surgical procedure, a sterilizable stylus is supplied or the display can be covered with a sterile drape.

- Plug the system into a grounded hospital grade outlet. Disconnect the system from the network connection, if applicable.
- Turn on the power switch (bottom center of unit). After a short period of time, the Logon menu will appear:

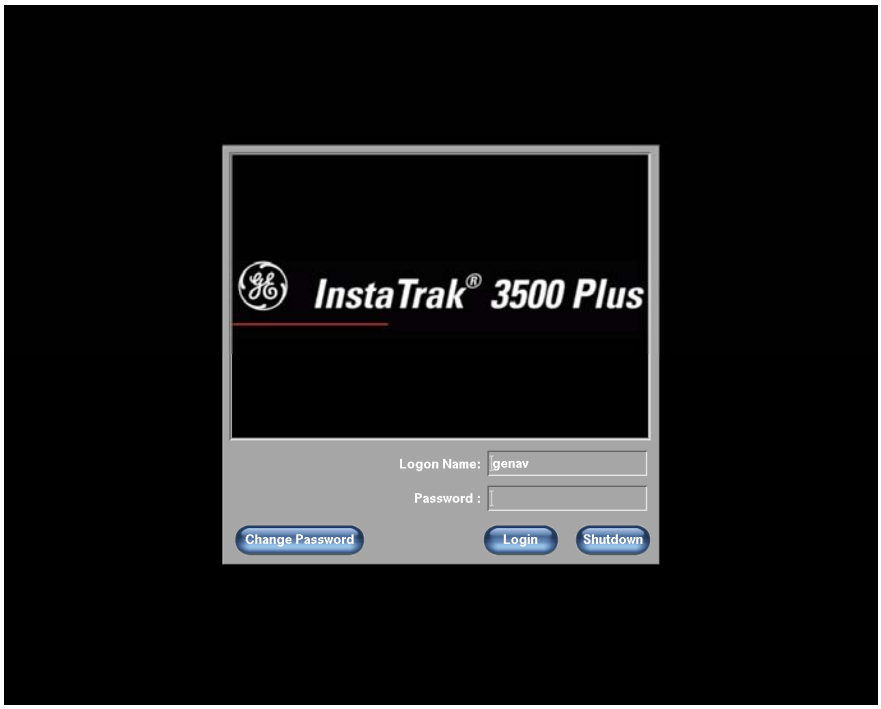


Figure 4-1. Log-on Menu

- The Logon Name is **genav** and appears automatically.
- Enter the password. The default password is **tmp123** but may have been changed by your System Administrator or Biomedical Department.

Note: If you do not know the password, contact your hospital's System Administrator or Biomedical Department.

- When the correct password is entered, the MAIN MENU appears.

Changing The Password

If you want to change the password:

- Select the **Change Password** button. The CHANGE PASSWORD TASK WINDOW appears:

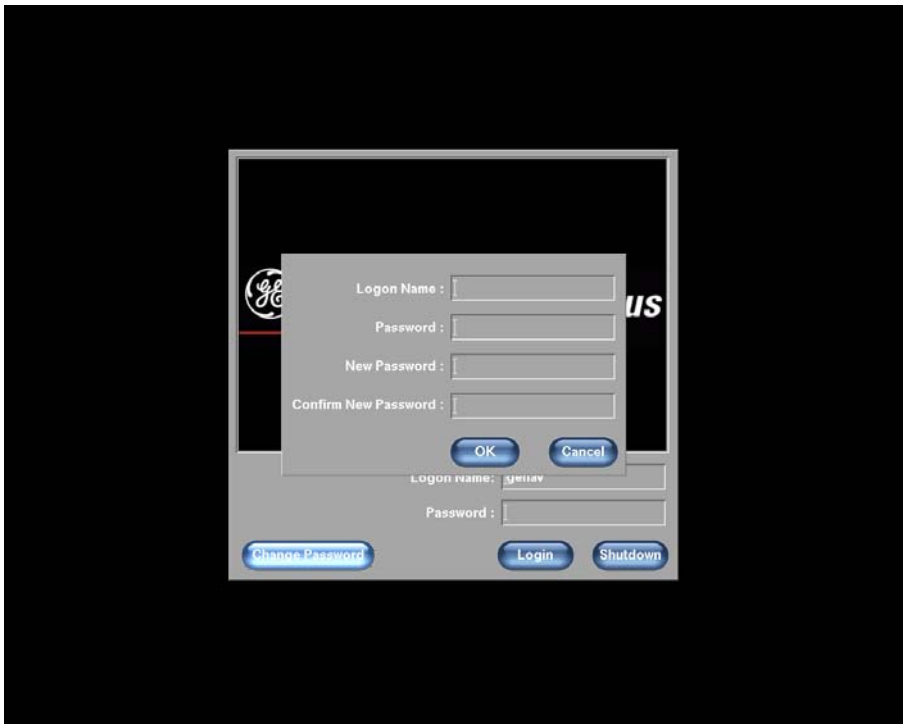


Figure 4-2. Change Password Task Window

Note: To change the password, the current password must be entered. The default password is **tmp123**. If you do not know the password, contact your hospital's System Administrator or Biomedical Department.

- Enter the Logon Name: **genav**, and enter the current and new password. When completed, select **OK**.
- Enter the new password into the LOGIN TASK WINDOW
- Select the **Login** button and the MAIN MENU will appear.

Disabling the Logon Requirement

You have the option to eliminate the Logon-with-password requirement and may choose to retain the patient's name on copied scans and snapshots. To choose these options:

- Select **System Administration** from the MAIN MENU

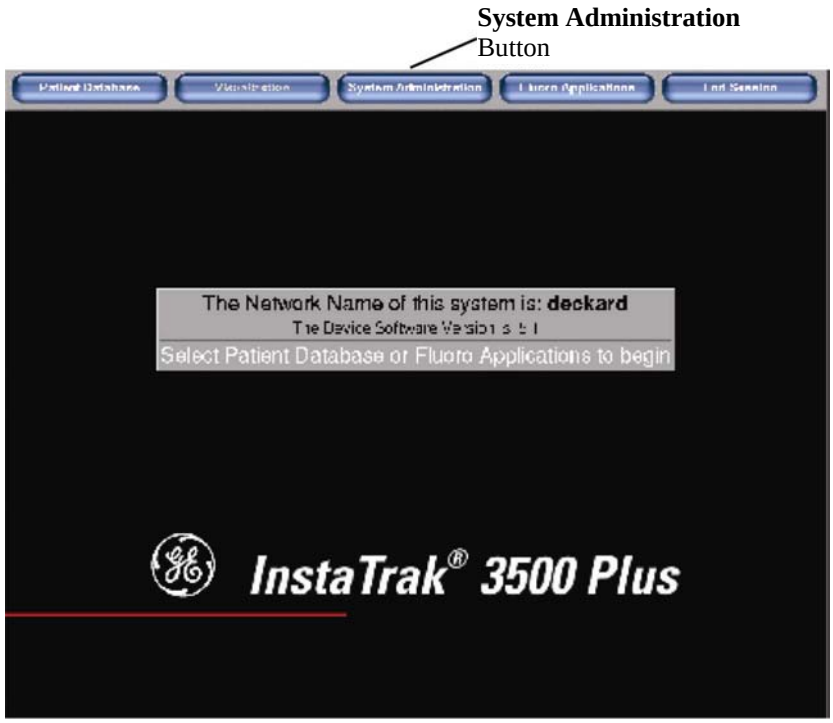


Figure 4-3. System Administration Button

- Select **User Options.** The USER OPTIONS TASK WINDOW appears.

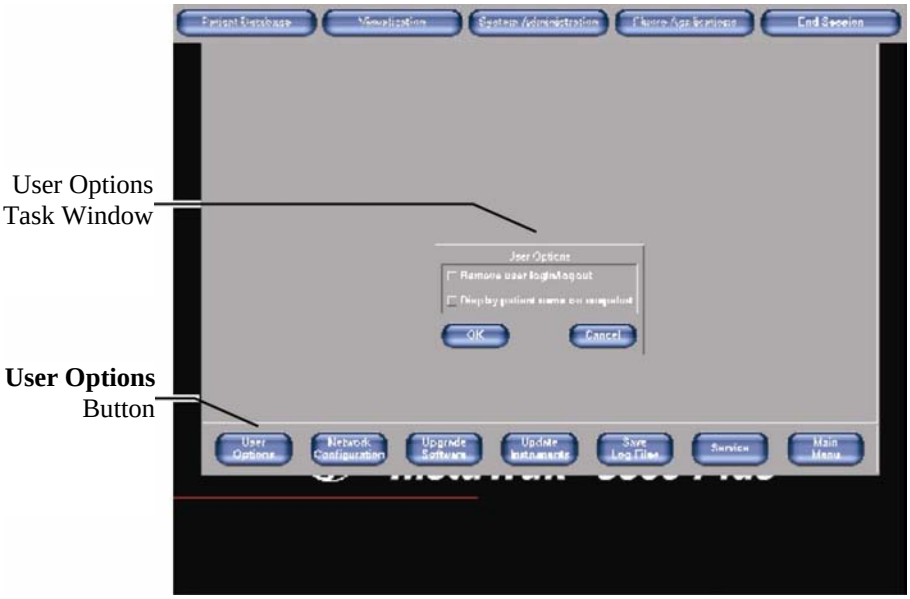


Figure 4-4. User Options

- Select Remove User Login/Logout.

Note: GE Healthcare strongly recommends requiring users to log in and out of the system with a password and not automatically displaying the patient's name on snapshots

Copying Sensitive Patient Data

Patient snapshots can be copied to a floppy disk or CD. Unless the patient identifiers are removed, the snapshots contain the patient name. The patient identifier can be replaced.

Copying snapshots to a Floppy Disk or CD

- Select the snapshot images to copy from the PATIENT DATABASE MENU
- Select the **View Snapshots** button or double-click on the patient's name. The IMAGE PREVIEW MENU appears:

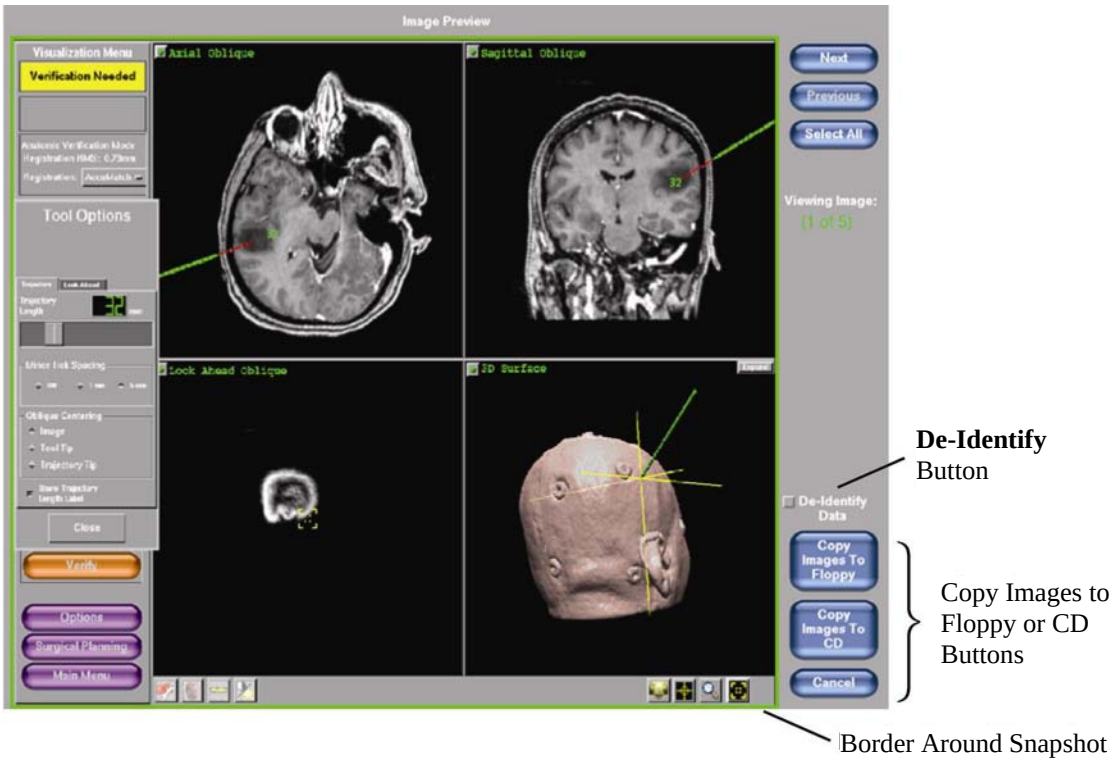


Figure 4-5. Image Preview Menu

- Select anywhere on the image by touching the screen or clicking with the left mouse button. The border of the image turns green meaning that the image is selected.
- Select **Next** or **Previous** to view and choose individual images or **Select All** to copy the entire series.

Before copying the images, you have the option to remove the patient identifier on the copied images. To remove the patient identifier, select **De-Identify Data**.

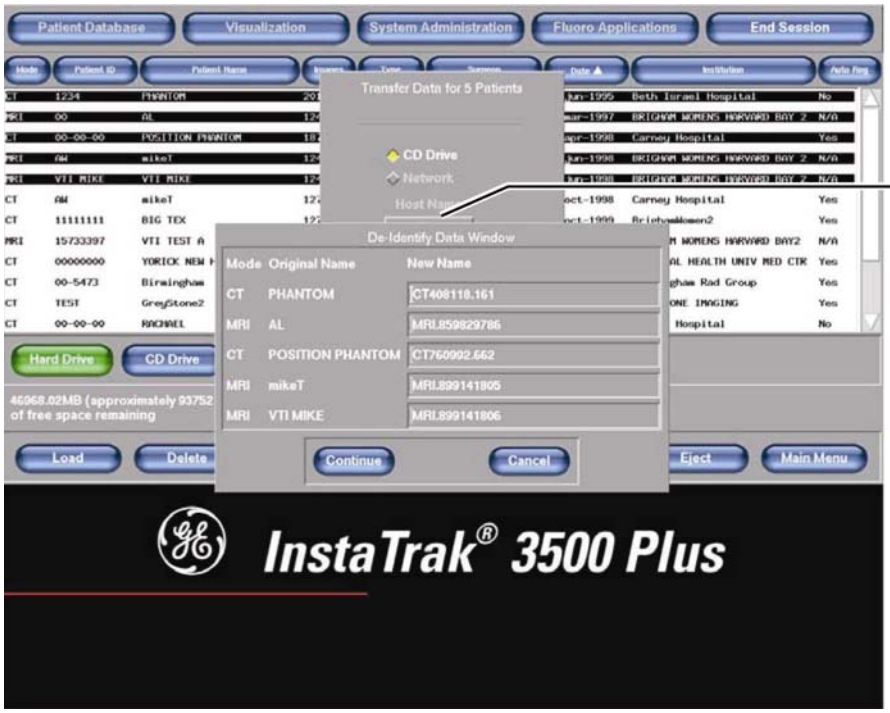


Figure 4-6. De-Identify Data Window

The DE-IDENTIFY DATA WINDOW displays the Original Name and a New Name consisting of pre-selected letters and numbers. If desired, input a New Name.

- When completed, select **Continue**.
- To continue copying, select **Copy Images to Floppy**.

ElectroMagnetic Tracking Guidelines

The *InstaTrak™ 3500 Plus* utilizes an electromagnetic tracking system. For best results, you must be aware of the amount of metal in the operative area and try to eliminate ferrous metal placed between the transmitter and receiver.

Standard operating room equipment and techniques should be used along with the following recommended guidelines for reducing the amount of ferrous metal in the operative area.

- Select a radiolucent OR table whenever possible. If using a metal OR table, place an extra mattress pad on the table.
- Use plastic clips for securing surgical drapes
- Place intubation tube holder and Mayo stand at least 12 inches away from the operative area
- Position the *InstaTrak® 3500 Plus* so that it is at least 3 feet away from the transmitter
- When metal instruments such as a speculum or retractors are required, ensure that they are non-ferrous. Non-ferrous instruments are supplied by GE Healthcare. For more information, see your GE Healthcare Technologies Representative.
- The system displays a message if the field is distorted or excessive metal is detected.

WARNING

Do not ignore any field distortion messages. When the field is distorted or excessive metal is detected, accuracy can be affected that can lead to a patient hazard.

WARNING

When instruments, such as mouth gag, nasal speculum or retractors, are used ensure they are made from low content metal or non-magnetic materials. These instruments may be obtained from GE Healthcare. Failure to use non-magnetic instruments *may decrease accuracy or result in an inoperable system.*

CAUTION

Notify GE Healthcare if any red warning message occurs repeatedly without an apparent cause or cannot be eliminated by the user.

Standard ENT Equipment and Instruments

The following lists equipment and instruments generally used for ENT and skull-base surgical navigation procedures. The list should be used as a guide only.

Figure 4-7. Aspirators

- Headset, Adult or Pediatric
- Aspirator(s):
  - 7 F or 10 F
  - Extended Straight
  - 15 Degree, 45 Degree, 90 Degree
- Debrider Attachment
- Button Probe, non-sterile, if *AccuMatch*™ surface registration is desired
- Transmitter
- One or Two Receivers

Note: GE Healthcare Technologies strongly recommends sterilizing the receivers before use.

Transsphenoidal Procedures

- Automatic Headset, Adult or Pediatric
- Verification Pad, Adult or Pediatric
- Extended Straight Aspirator
- 3M 1010 Steri-Drapes or other clear plastic drape for the Headset
- Button Probe, non-sterile, if *AccuMatch*™ surface registration is desired
- Nasal Speculum, non-ferrous metal

Skull-base Procedures

- Axcess™ System for unrestricted surgical approach. For procedures when the use of the headset is not possible. Refer to the *Axcess System Operator's Manual* for complete details.
- Non-sterile Pointer or Button Probe for registration process
- Nasal Speculum (optional)

Figure 4-8. Button Probe

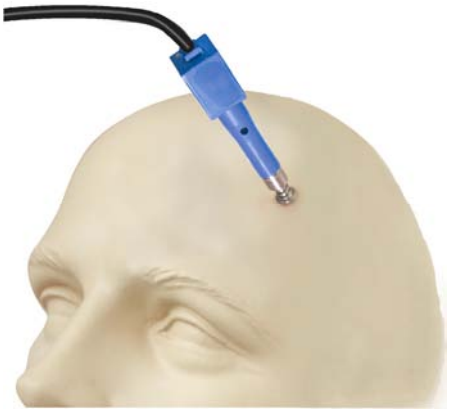


Figure 4-9. Axcess System

General and Optional Equipment and Instruments

- Button Probe if using optional *AccuMatch*™ surface registration
- Calibration Post for calibrating the Gyrus Diego or Stryker Debriders
- Flat Panel Sterile Drape for display
- Fiducial markers if using MRI and fiducial registration is desired

- Camera drape bags for the receiver, if sterilization is not possible
- Composite or S-video cable to connect to endoscope or microscope
- Video Scan Converter/Recorder

Note: No natural rubber latex is used in any GE Healthcare Technologies product or packaging.

WARNING

Only surgical instruments or attachments to instruments supplied or recommended by GE Healthcare will provide the level of accuracy specified by this System. We cannot guarantee the accuracy with instruments that are not recommended by GE Healthcare and using such instruments might compromise the accuracy leading to a potential patient hazard.

CAUTION

Do not connect any equipment that is not specifically described in this manual to the System. Whenever AC powered equipment is connected to the System, the user must confirm that applicable standards for leakage current are met by the interconnected system.

CAUTION

Due to the magnets in the Instruments*, do not put magnetic media, such as a floppy disk, near any of the* Instruments *as the data could be erased.*

Setting Up The InstaTrak 3500 Plus

Refer to *System Operation* in the *InstaTrak® 3500 Plus Operator's Manual* for more detailed instructions.

Note: *Select* refers either to touching the touch screen with a finger or a pointer or clicking with the computer mouse.

WARNING

The Network Connection must be unplugged before the InstaTrak® 3500 Plus is placed in the vicinity of a patient. Not unplugging the network connection could cause a potential patient hazard.

After turning on the *InstaTrak® 3500 Plus* and entering the Logon information, the MAIN MENU appears.

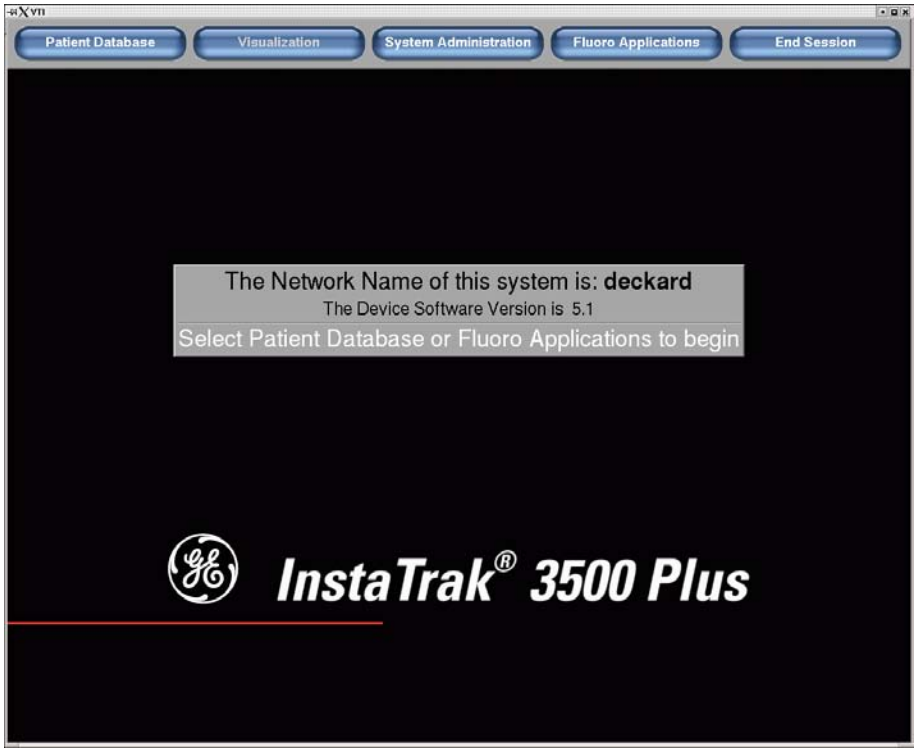


Figure 4-10. Main Menu

- Attach the transmitter and a receiver to the front of the *InstaTrak® 3500 Plus*.

If a video display of the microscope or endoscope camera is desired on the system during the surgical procedure, a connection must be made between the endoscopic camera and the *InstaTrak®3500 Plus* using composite or S-video cable.

To establish the link between the system and the microscope or endoscope camera:

- Plug one end of either a composite cable or an S-Video cable into the appropriate **Video In** connector on the back of the system.
- Plug the other end of the cable into the output on the microscope or endoscopic system.

Loading Images

After selecting the **Patient Database** button from the MAIN MENU, the PATIENT DATABASE TASK WINDOW is displayed.

Figure 4-11. Patient Database Menu with Application Selections

Note: If using a CD as the method for transferring the scans, the scan must be transferred to the Hard Drive before loading.

- Select the patient's scan from the PATIENT DATABASE.
- Select the **Load** button.
- If you are using the mouse, you can also double-click on the scan to load it.

Post processing is the process of formatting the scan and may be required before the scan can be loaded. If so, the Post processing Message appears.

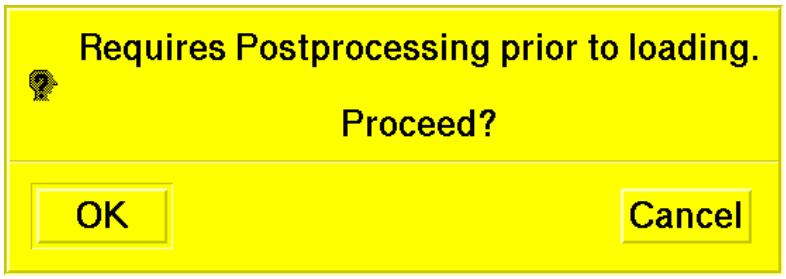
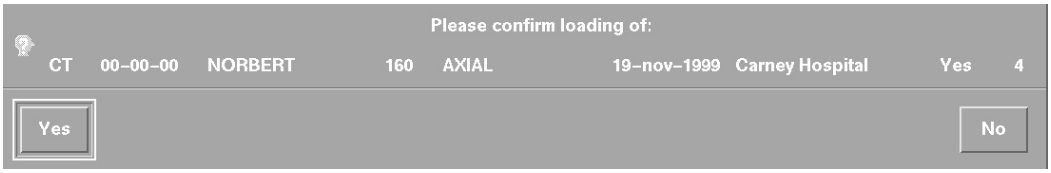


Figure 4-12 Post Processing Required Dialog

- Select **OK** to post process the images. Once post processing is complete, you must select the **Load** button to load the scan.
- Select **Cancel** to stop the post processing procedure.
- Once the **Load** button is selected, a confirmation message will appear. This enables you to verify that the correct scan has been selected.



- Select **Yes** to confirm

Note: Unless *Image Fusion* is available on your *InstaTrak 3500 Plus*, only one scan can be loaded at a time.

- If a scan is already loaded, a message appears to confirm that you will be replacing the existing scan with the new scan.

- Select **Yes** to confirm

Note: Replacing one scan with another will not delete the previously loaded scan.

- Select the correct Application, such as Advanced ENT

The following message appears indicating that the scan is being loaded.

Visualization Display

After loading the patient scan, the VISUALIZATION MENU appears.

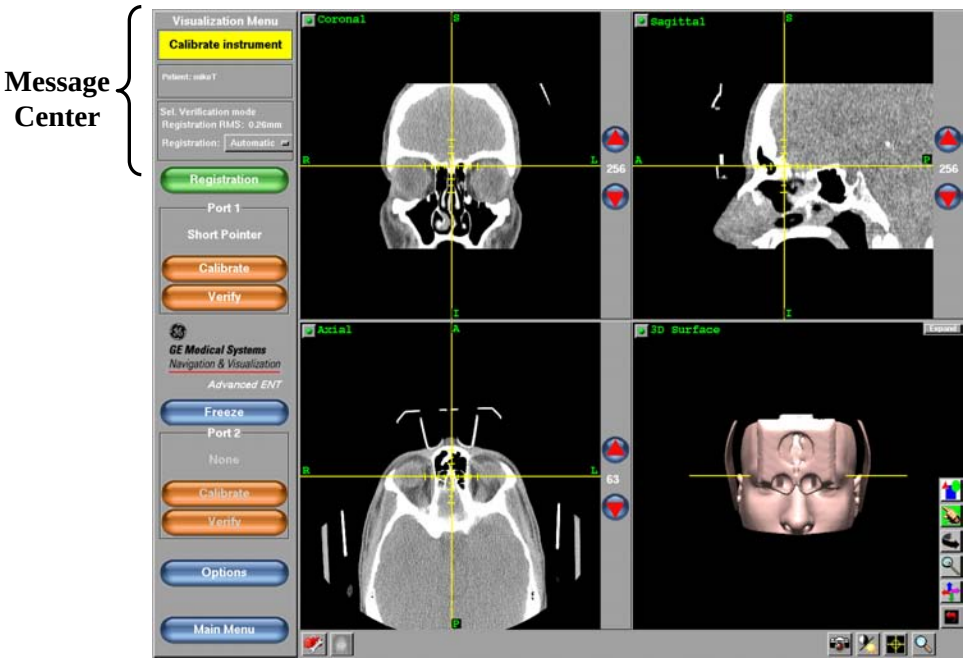
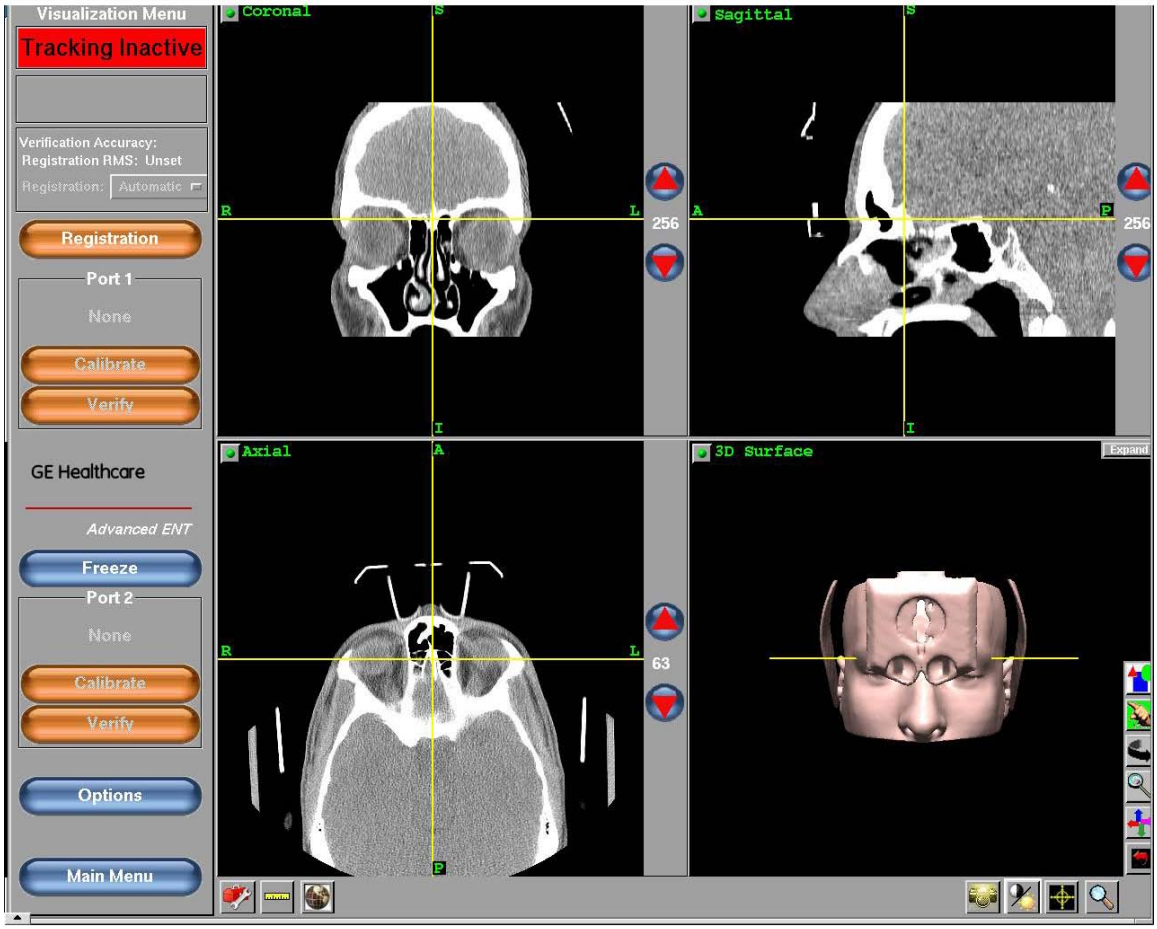


Figure 4-13. Visualization Menu

The **Message Center** displays important or informative messages. The messages indicate tasks that need to be completed in order to initiate tracking or they indicate the status of the system. The message background will be red or yellow depending on the status or severity. Red messages must be responded to immediately and always indicate a severe problem or urgent condition.

The icons on the bottom right of the Display enable quick access to display adjustments.



1 2 3 4

Figure 4-14. Display Adjustment

The icons are:

1. Snapshot
2. Brightness and Contrast
3. Crosshair Adjustment
4. Zoom

Snapshot

The **Camera** icon enables a snapshot to be taken at any time during the procedure. When selected, a bright light indicates that a snapshot is being taken. The snapshot is available in the PATIENT DATABASE and can be stored, viewed, or copied to a floppy disk or CD.

Contrast/Brightness Adjustment

The **Contrast/Brightness** icon enables adjustment to the appearance of the display. To make adjustments, select the contrast/brightness icon. When selected, the IMAGE CONTROLS TASK WINDOW appears on the left side of the display.

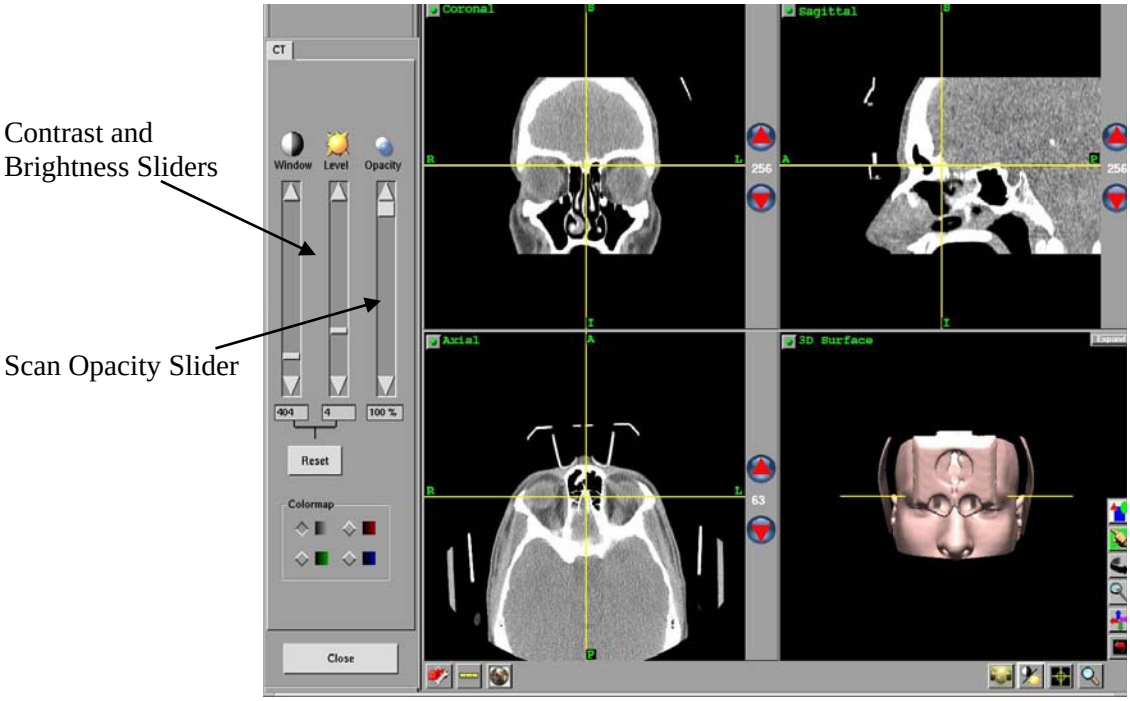


Figure 4-15. Image Picture

- To adjust the contrast and/or brightness of the scan, use the sliders.
- Select **Close** when adjustments are complete.

Note: The Scan Opacity slider and Color Map selector are useful with the *Image Fusion* option. See the *Image Fusion Operator's Manual* for more information.

Crosshair Adjustment

The tip of the surgeon's instrument will appear on the Visualization display's orthogonal views as a crosshair. By selecting the **Crosshair** icon, the appearance can be changed.

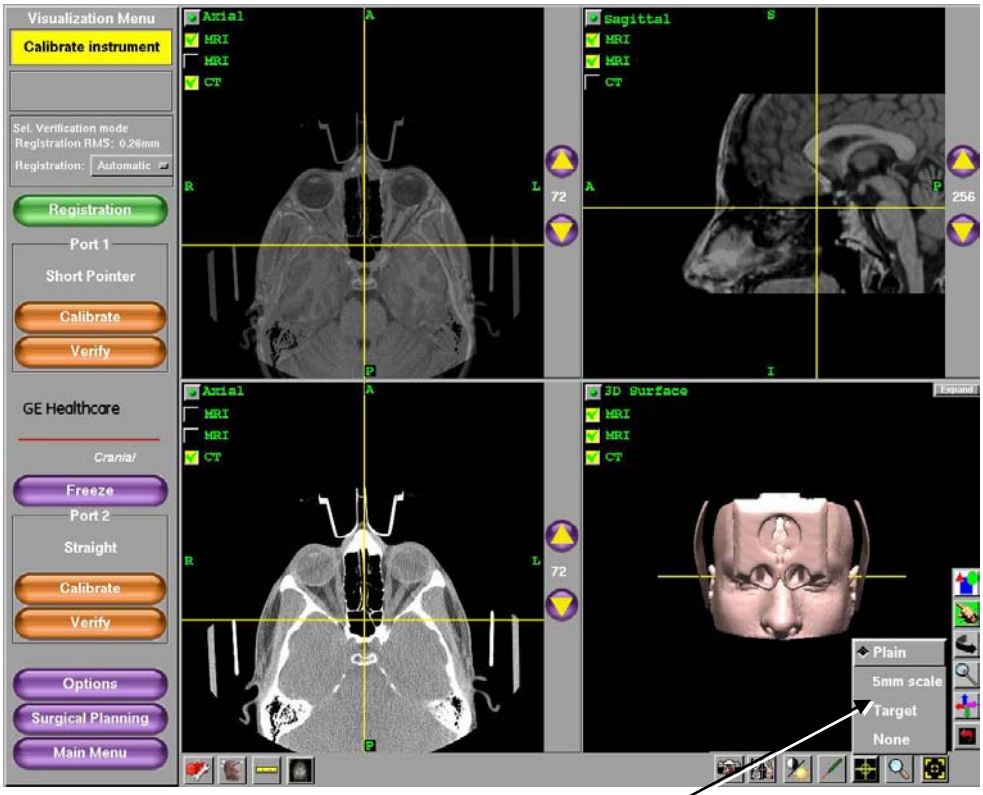


Figure 4-16. Crosshair Adjustment

The **Crosshair Adjustment** choices are:

- 5 mm scale - crosshairs with tick marks every 5 mm
- Plain – crosshairs with no tick marks
- Target – Places a small, yellow cross at the target location
- None - no crosshairs appear on the scan

Zoom Control Adjustment

The displayed scan size can be made larger or smaller by selecting the **Zoom Controls** icon. When the size is selected, all orthogonal displayed views are adjusted.

Figure 4-17. Zoom Control

The **Zoom Control** choices are:

- 1:1 magnification
- 2:1 magnification
- 4:1 magnification

Display Layouts

Orthogonal Views

Medical scans can be viewed directly on the *InstaTrak® 3500 Plus*. The axial scan is loaded into the system and reconstructed into coronal and sagittal views. The 2D axial, sagittal, and coronal views are termed **orthogonal.**

You can scroll through the scan using the Arrow buttons to view the scan sequentially or click within the two-dimensional (2D) images or the three-dimensional (3D) model to locate a point of interest.

Figure 4-18. Up and Down Arrows

To view a point of interest, position the cursor on an orthogonal image and click with the left mouse button. The other views automatically display the same image point.

If you want to view the scan without the crosshairs, the crosshairs can be removed by selecting **None** from the **Crosshair** icon on the display.

3D Surface Model

The 3D model may be manipulated and adjusted by using the icons on the right of the 3D model.

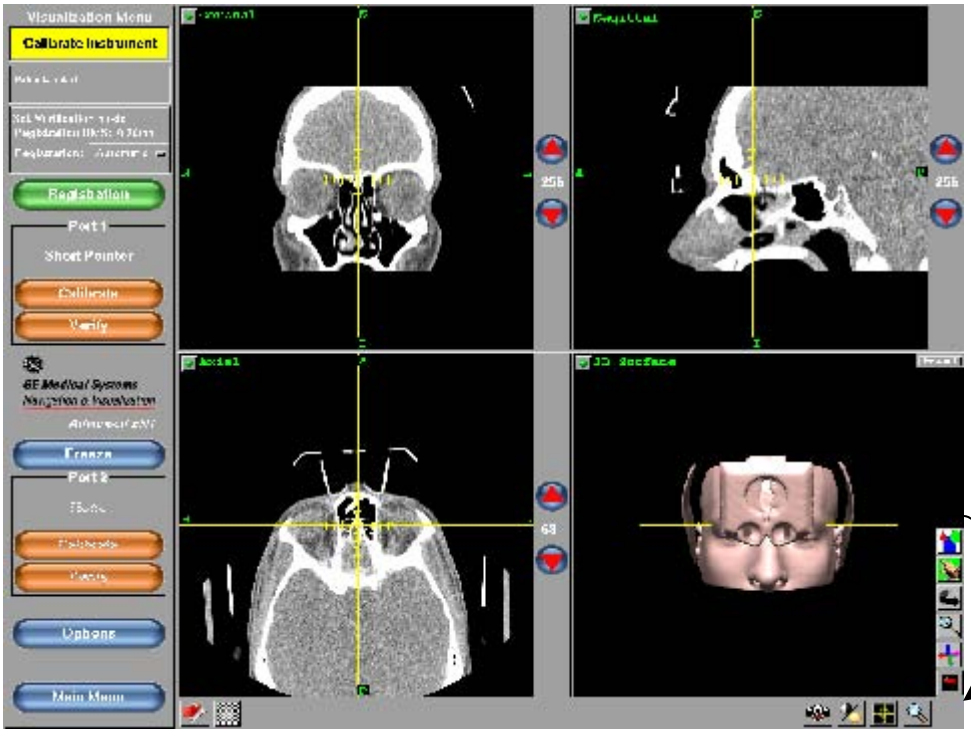


Figure 4-19. Surface Model Adjustment

To access these capabilities, select the icon.

1. **Opacity** of 3D model surface. This button is used most frequently with the Auto-Segmentation. Available with the Cranial Application only.

2. **Point** to quickly view a point of interest on the model.
3. **Rotate** to turn the 3D surface model.
4. **Zoom** to enlarge or shrink the size of the model.
5. **Position** to move the model side-to-side and up and down.
6. **Reset** to quickly adjust the model to default, face-front position.

Expand Button

The 3D model can be expanded to full screen by selecting the **Expand** button at the top right of the 3D model. When the 3D Model is expanded to full screen, the button changes to **Shrink** to exit the full screen mode.

Tracking and Surgical Review Views

Different surgical review or tracking views can be selected for each quadrant. A different view may be selected and changed at any time. The current selection can be seen in the top left of every quadrant. The views selected at the end of the procedure are stored when the *InstaTrak® 3500 Plus* is shut down and displayed during the next use of the system.

To change the view, select the button at the top left of the quadrant. A pull-down menu appears enabling you to change the layout for surgical review or tracking. Each quadrant layout must be changed individually.

Figure 4-20. View Selection Pull Down Menu

Surgical Review Views

Selecting **Surgical Review** enables you to select a view when not tracking. The view can be changed at any time. You can select a view for each quadrant.

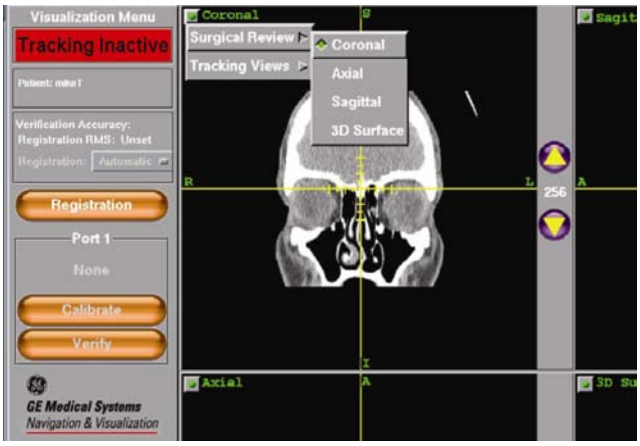


Figure 4-21. Surgical Review Pull Down Menu

The **Surgical Review** view choices are:

- Coronal
- Axial
- Sagittal
- 3D Surface Model

Tracking View Views

Selecting **Tracking View** enables you to select a view for tracking. The view may be changed at any time. You must select a view for each quadrant.

The available **Tracking Views** are determined by the instrument to be used during tracking. You must select either *Probes* or *Instruments* before selecting a **Tracking View**.

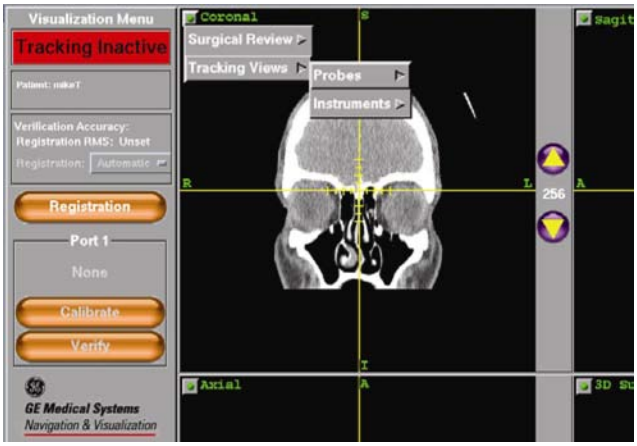


Figure 4-22. Probes or Instruments Pull Down Menu

Probes are any instrument where a trajectory may be displayed. Examples are the pointer. **Oblique Views** are available when *Probes* is selected.

Instruments are any instrument without a trajectory. An example is an *Aspirator*.

If *Probes* are selected, you can choose a **Tracking View** from the pull-down list.

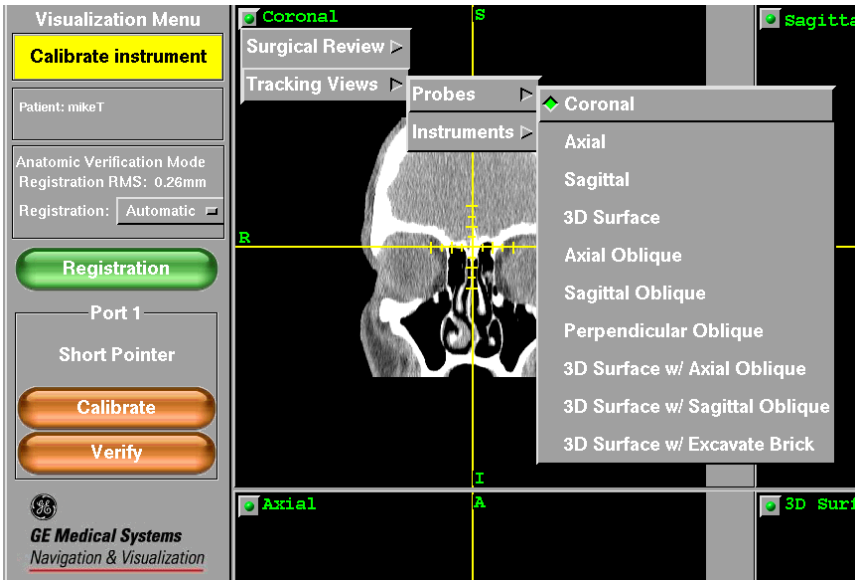


Figure 4-23. Tracking View Pull Down List - Probes

The available **Tracking Views** for *Probes* are:

- Coronal
- Axial
- Sagittal
- 3D Surface
- Axial Oblique
- Sagittal Oblique
- Perpendicular Oblique
- 3D Surface with Axial Oblique
- 3D Surface with Sagittal Oblique
- 3D Surface with Excavate Brick
- Video

If *Instruments* are selected, you can choose a **Tracking View** from the pull-down list.

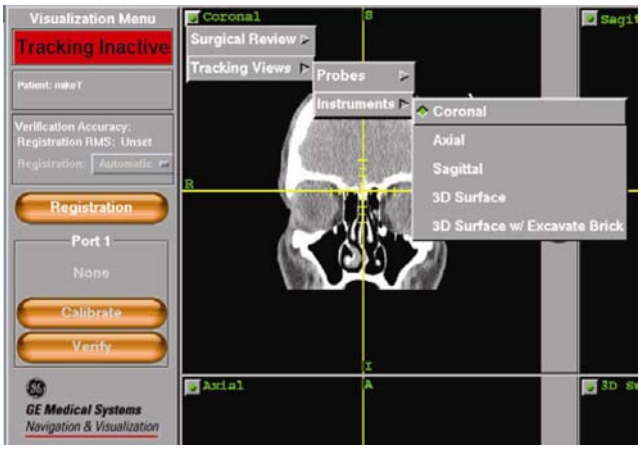


Figure 4-24. Tracking View Pull Down List - Instruments

When **Instruments** is selected, the layout choices are:

- Coronal
- Axial
- Sagittal
- 3D Surface
- 3D Surface with Excavate Brick
- Video

Note: Once the tracking views for either *Probes* or *Instruments* are set, they will automatically appear whenever the applicable instrument is tracked.

Using the Automatic Registration Headset

Attaching Transmitter to the Headset

The *Automatic Registration Headset* may be used for procedures where access to patient anatomy will not be obstructed by use of the Headset. When *AccuMatch*™ surface registration is preferred, the *Headset* can also function simply as a Transmitter attachment device.

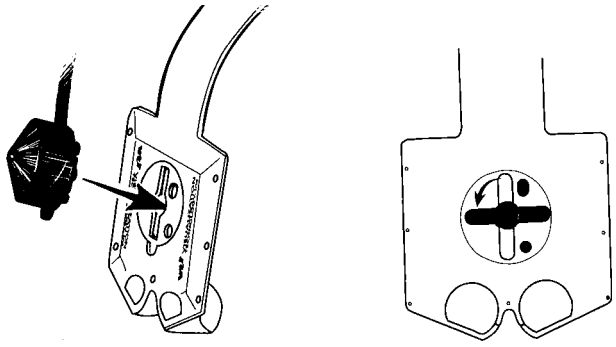


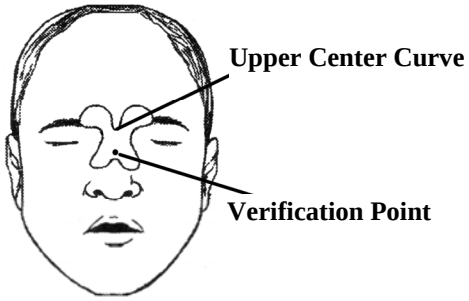
Figure 4-25. Attaching Transmitter to the Headset

- Align the rotating latch on the transmitter to the slot on the Headset.
- Insert the transmitter into the slots in the Headset.
- Secure the transmitter to the Headset by rotating the latch to lock into place of the transmitter.

WARNING
These instructions must be followed for use of the Automatic Headset. Failure to follow these instructions may impact System *accuracy leading to a potential safety hazard.*

Attaching the Verification Pad

The Verification Pad must be used with the Automatic Headset. Two pads are provided in each headset box. The Verification Pad improves patient comfort and system accuracy.

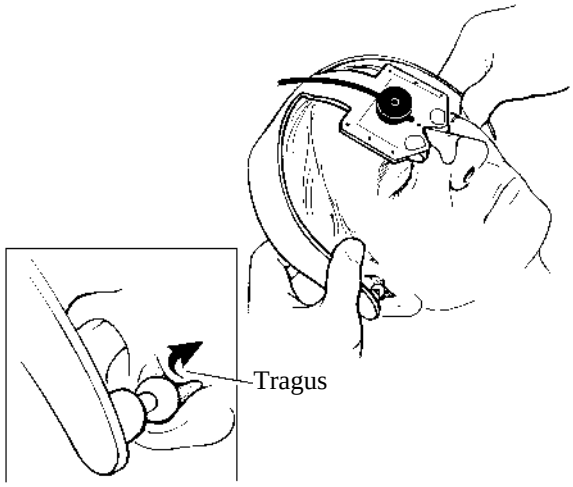


- Place a Verification Pad on the patient's nose after wiping the area to remove dirt and oils.
- Peel the backing from the Verification Pad to expose the adhesive.
- Align the upper center curve of the Verification Pad with the bridge of the patient's nose. Place the verification point on the bony part of the nose. The verification point should be accessible after the headset is in place.

WARNING
To ensure system accuracy the Verification Pad must be used during the CT scan and the surgical procedure.

WARNING
Use the cushioned Verification Pad provided with the Headset to increase patient comfort and to reduce the possibility of bruising to the skin.

Placing the Automatic Headset



- Place the *Headset* on the patient by expanding the earpieces and positioning the nosepiece into the deepest notch of the bridge of the nose. Do not pull or displace the skin
- Align the earpieces over the patient's ear canals and behind the tragus.
- Slowly allow the earpieces to work into the deepest portion of the ear canal. Be sure that any accuracy markers used do not change position as the *Headset* is placed on the patient.

WARNING

If head stabilization is required, ensure that the head frame does not displace, press, or pull on the Headset. *Displacement of the* Headset *may cause system inaccuracy leading to a potential safety hazard.*

WARNING

Some patients may experience temporary *discomfort, pain, or loss of sensation when the headset is worn for an extended period of time. Patients with TMJ, impaired circulation, or other conditions that may be aggravated by use of the headset, should be given special consideration.*

WARNING

A headset must only be used with one patient. Using the same headset with different patients can result in system inaccuracy due to changes in headset geometry resulting in a potential safety hazard.

WARNING

To maximize System *and tracking accuracy, the same headset used during the CT scan should be used in surgery. A Verification Pad must be used if one was used during the CT scan.*

Draping

When draping the patient, use only lightweight plastic draping to avoid displacing the *Headset*. Ensure that the *Lateral Markers* on the side of the *Headset* are easily accessible for registration.

WARNING

When draping the headset prior to surgery, do not allow the draping to distort or pull on the headset. This can result in system inaccuracy leading to a potential safety hazard.

If using *AccuMatch*™ surface registration, an unsterile receiver and Button Probe will be used for the registration process. The receiver used for the surgical procedure, should be sterilized before use. If sterilization is not possible, the receiver must be completely covered with a sterile camera or laser drape bag to maintain sterility. Place the camera

drape bag over the *Receiver*, smooth out any wrinkles in the bag at the attachment point of the *Instrument.*

CAUTION
If tape or other restraining devices are used to help hold the camera drape bag in place, care must be taken not to impede or prevent the exchange of the instruments.

If desired, the *Display Touch Screen* may be fully draped. Draping the *Display Touch Screen* enables the surgeon to interact with the *System* during the surgical procedure.

Using Transmitter Arm Attachment

If using cranial stabilization, the transmitter may be attached to the cranial stabilization system. The transmitter must be securely attached in the surgical field before the registration process can occur. The transmitter can be attached by using one of the three devices available with the *InstaTrak 3500 Plus*:

- Transmitter Attachment Arm for use with the Mayfield® Cranial Stabilization System
- Universal Transmitter Attachment Arm for headframes other than the Mayfield®.
- Automatic Registration Headset

If the surgery is performed using a head frame system, such as the Mayfield, the patient should be positioned before attaching the transmitter.

If the *Headset* will be used, immobilization of the head is not required since the transmitter is attached to the *Headset.*

The patient should not be draped until after the registration process is complete. Transmitter attachment, instrument calibration and registration are performed in a non-sterile environment.

Attaching the Transmitter Arm to the Mayfield® Cranial Stabilization System

GE Healthcare Technologies has designed a transmitter attachment arm that connects specifically to the Mayfield® Cranial Stabilization System.

- Position the patient's head securely in the Mayfield headframe.
- Insert the starburst connecter of the transmitter attachment arm into the starburst connector of the Mayfield.
- Tighten using the handle until the teeth of the connector are locked and the transmitter attachment arm is securely attached.

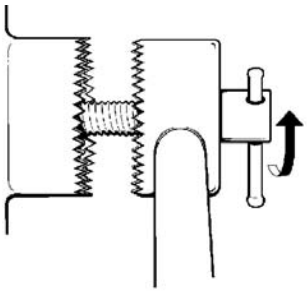


Figure 4-26. Starburst Connector

- Position the transmitter attachment arm so that it will not be intrusive.
- Position the transmitter attachment arm so that the transmitter will be located no more than ten (10) inches away from the surgical site.
- While holding the transmitter *Arm* in the desired location, tighten the two (2) additional clamps. The clamps must be very tight to ensure there is no movement and that the transmitter arm is as rigid as possible.

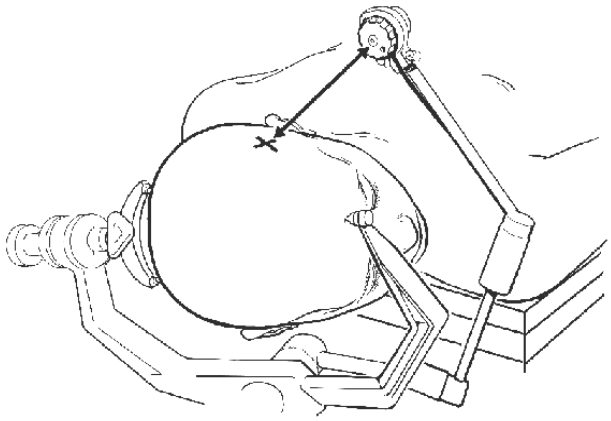


Figure 4-27. Positioning of Transmitter Arm with Transmitter less than 10" from Surgical Site

WARNING

Any movement of the transmitter arm after the registration process will cause inaccuracy that might lead to a potential safety hazard. Ensure that the transmitter arm is securely attached and will not be bumped during the surgical procedure.

Attaching the Transmitter to the Transmitter Arm

The transmitter is attached to the transmitter arm by aligning the transmitter's rotating latch to the slot in the transmitter arm.

Figure 4-28. Align Transmitter Latch with Slot

- Insert the transmitter into the corresponding slot in the transmitter attachment arm

Figure 4-29. Rotate Transmitter Latch to Secure Transmitter

- Rotate the latch on the transmitter to lock it and to prevent it from slipping

CAUTION

If the Transmitter Arm is not completely rigid, registration accuracy might be compromised.

Attaching the Universal Transmitter Arm

The *Universal Transmitter Arm* may be used if a surgical headframe other than the Mayfield® Cranial Stabilization System is used. The *Universal Transmitter Arm* is designed to attach to any headframe or stabilization system.

- Attach the clamp on the Universal Transmitter Arm to the head frame at a point of adequate grip. The transmitter must be positioned within ten (10) inches of the surgical site
- Tighten all of the clamps on the Universal Transmitter Arm.
- Open the latch on the Universal Transmitter Arm and insert the transmitter

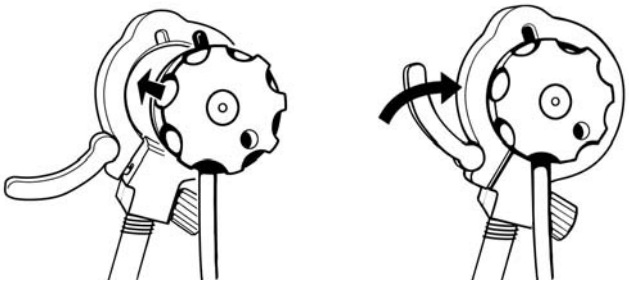


Figure 4-30. Open Latch -- Insert Transmitter -- Close Latch

- Close the latch. If the transmitter does not fit securely, turn the knob on the transmitter arm in small increments to tighten the attachment.

△ ***CAUTION***
Headframes constructed of radiolucent materials may be damaged by over tightening of the universal clamp.

Draping

If using either the transmitter attachment arm for the Mayfield® or the universal transmitter arm, drape the patient in the usual manner, with the following adjustments:

- Place a clear cassette or camera drape bag over the transmitter attachment arm.
- Cut a small hole in the drape to allow access to the transmitter for calibration purposes.

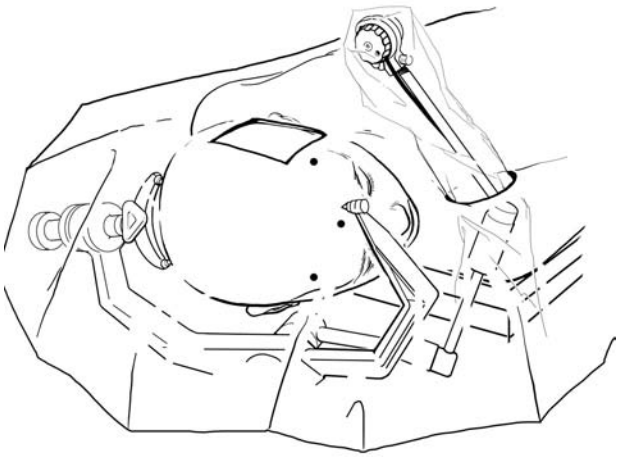


Figure 4-31. Transmitter and Attachment Arm Draping

Attaching an Instrument

Note: All instruments should be sterilized before use.

Note: Multiple sterilization cycles may cause discoloration of the plastic components. This is normal and will not affect the performance of the device.

The *InstaTrak® 3500 Plus* automatically will detect which instrument is attached to the receiver. Confirm that the correct instrument type is indicated before using the instrument. The Button Probe will be identified as a Pointer.

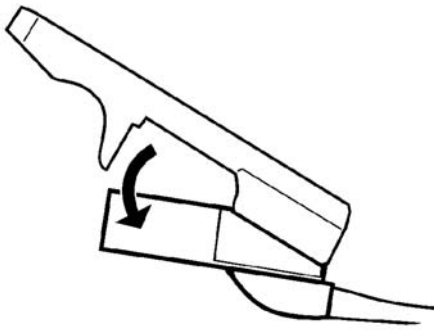
△ ***CAUTION***

Prior to each use, visually inspect all Instruments and docking stations. Discard if they are visually distorted or broken.

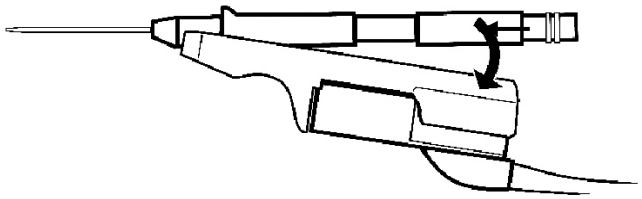
Attaching a Pointer

The pointer is supplied in a sterile package and may be used one time only during surgery. The exception is the Pointer used only for registration purposes. This pointer may be reused but must be cleaned and sterilized between uses as recommended.

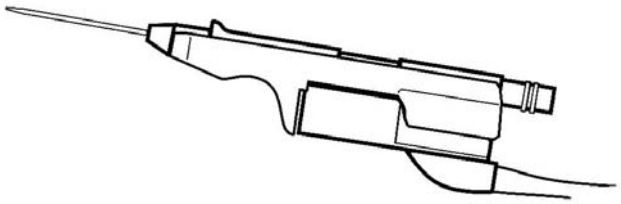
These instructions apply to the pointer and to the button probe and may be followed in any order, that is, the instrument may be attached to the docking station before attaching to the receiver.



- Insert the back of the docking station into the slot on the receiver and gently press until the receiver is locked into the docking station



- Align the notch on the *instrument* with the channel on the docking station. Be certain that the non-functioning suction hole is facing up and magnetic detectors are facing the receiver.



- Snap the *instrument* into the docking station

⚠ ***CAUTION***
Do not use the instrument if the package has been opened or damaged.

Using the Button Probe, P/N 1003632

Note: The following assembly instructions apply only to the Button Probe, P/N 1003632. The newer version of the Button Probe, P/N 1006909, does not require assembly.

The button probe, *P/N 1003632* must be assembled before using.

- Insert the button lever through the button hole.

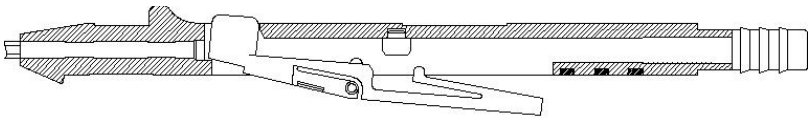
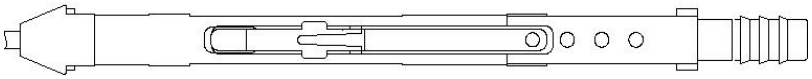


Figure 4-32. Insertion of button lever

- Squeeze the tabs of the button lever then insert the pivot pins into the pivot holes.



- Attach the button probe to the receiver using the instructions for attaching an instrument shown above.

CAUTION
Sterilization of the Button Probe should be limited to ten cycles.

CAUTION
Prior to each use, visually inspect the Button Probe and the docking station. Discard any part that is visually distorted, broken and/or in which the probe is no longer seated securely within the molded handle.

Note: Multiple sterilization cycles may cause discoloration of the plastic components. This is normal and will not affect the performance of the device.

CAUTION
Both versions of the Button Probe and docking station must be cleaned and sterilized prior to each use, if using during the surgical procedure.

Nasal Speculum

When using the *System* in conjunction with a surgical microscope, it is recommended that you use GE Healthcare's Nasal Speculum or other titanium or non-magnetic speculum

CAUTION
For optimal system accuracy, the hinge of the speculum should be positioned away from the patient's nose.

Debrider Attachments

The Debrider Attachment is a device that provides a means of attaching the receiver to almost any of the standard microdebriders being used in sinus surgery. This enables the *InstaTrak 3500 Plus* to track the location of the tip of the microdebrider.

Compatible Microdebriders:

- Gyrus Diego™ Powered Dissector
- Gyrus Turbo 7000
- Smith and Nephew ESSential® Shaver Handpiece
- XOMED® STRAIGHTSHOT®
- XOMED® MAGNUM™
- Stryker® Hummer 2
- Stryker® Hummer TPS debriders
- Linvatec E9000™ High Speed Shaver Handpiece.

Note: The *Debrider Attachment*, along with debrider, must be cleaned and sterilized before use. The Receiver may be sterilized, if desired. Sterilization guidelines may be found in the *InstaTrak 3500 Plus* Operator's Manual. If not sterile, cover the *Receiver* with a sterile camera drape bag.

WARNING

When using the debrider, the system should be used for localizing only. Do not attempt to track with the system while debriding. Tracking while debriding may result in unintended tissue removal.

Gyrus™ Diego™ Powered Dissector

Components

- The Front Ring Assembly consists of the Receiver Attachment, Position Adjustment Arm, Position Adjustment Screw and the Front Ring.
- Back Ring, with attached screw
- Calibration Post
- Allen wrench, with small and large ends

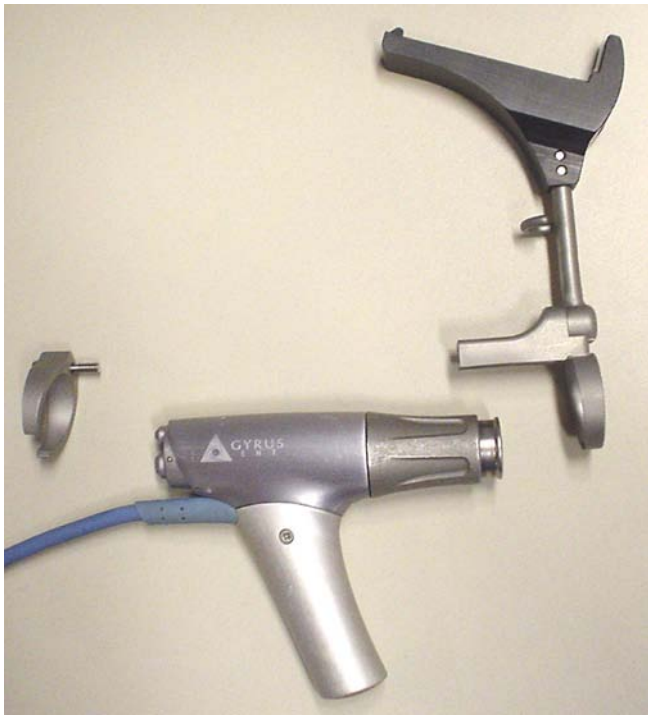


Figure 4-33. Gyrus Diego Powered Dissector, Unassembled

Assembly

- Slide the Front Ring Assembly onto the Gyrus Diego dissector.
- Slide the Back Ring onto the dissector.
- Line up the screw on the Back Ring with the Front Ring Assembly. Use the large end of the Allen wrench to tighten the attached screw until there is no movement between the dissector and the attachment. Verify that the attachment is securely fitted to the dissector by applying a side-to-side force to the attachment. If the *Attachment* is loose, tighten the screw.
- The Gyrus Diego Powered Dissector Attachment may be attached to the Gyrus Diego Powered Dissector in one of three positions: right, left or center. Figure 4-34 shows the attachment in the center position.

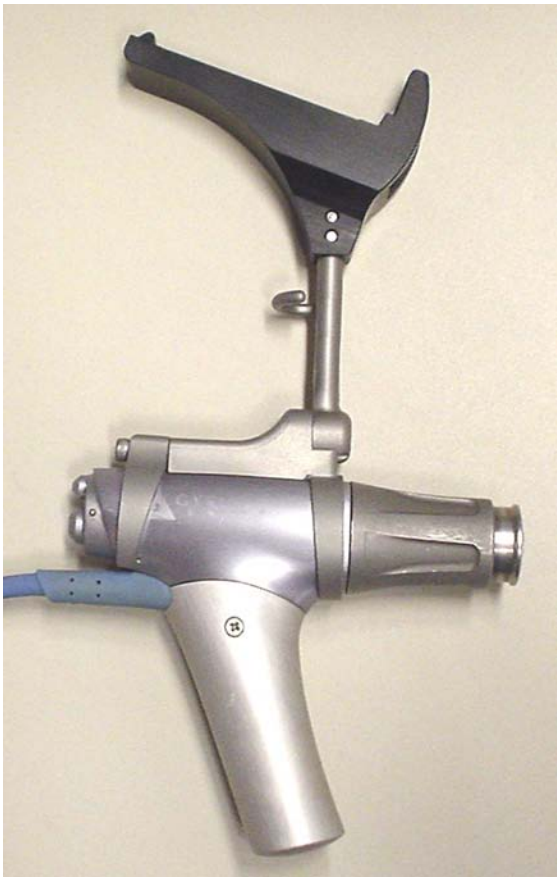


Figure 4-34. Gyrus Diego Powered Dissector, Assembled

To change the position of the Receiver Attachment:

- Remove the Position Adjustment Screw from the Front Ring Assembly by using the small end of the Allen wrench.

- Move the Receiver Attachment into one of the three ratcheted positions.
- Replace the screw into the hole and tighten with the Allen wrench.

After the attachment is firmly connected to the Diego dissector, the receiver may be attached to the *Gyrus™ Diego™ Powered Dissector Attachment*.

- Snap the attachment onto the receiver foot-first in the same manner as attaching the Docking Station to the receiver. The system will automatically detect that a debrider/ dissector is attached.

Disassembly

The *Diego Powered Dissector Attachment* must be removed from the Diego dissector before cleaning and sterilization. The Front Ring Assembly must be removed from the Back Ring, but the Front Ring Assembly may remain as one piece and does not have to be dismantled prior to sterilization.

- Use the large end of the Allen wrench to loosen the screw on the Back Ring. The screw is permanently attached to the Back Ring and may not be removed.
- Slide the Back Ring off of the dissector.
- Remove the Front Ring Assembly.

Gyrus Turbo 7000 Debrider

Figure 4-35. Debrider Attachment to the Gyrus TURBO 7000 Debrider

- Unscrew the knob on the Debrider Attachment to open the clamp. It is not necessary to completely remove the knob from the clamp.
- Attach the Debrider Attachment to the Turbo 7000 Debrider by placing the clamp around the midsection of the debrider, close to the front of the debrider. The word Blade on the Debrider Attachment must face the cutter blade. Position the Debrider Attachment directly above the suction tube.
- Align the knob with the mating threads on the clamp. Turn the knob clockwise to tighten.
- Verify that the Debrider Attachment is securely fitted to the debrider by applying a side-to-side force to the Debrider Attachment. If the Debrider Attachment is loose, tighten the thumbscrew. The Debrider Attachment must not be loose or be able to move.
- Snap the Snap-on Receiver onto the top platform of the Debrider Attachment, similar to attaching the receiver to the Docking Station of an aspirator. The *InstaTrak 3500 Plus* will automatically detect that the debrider is attached to a receiver.

Gyrus (Smith and Nephew) ESSential® Shaver Handpiece

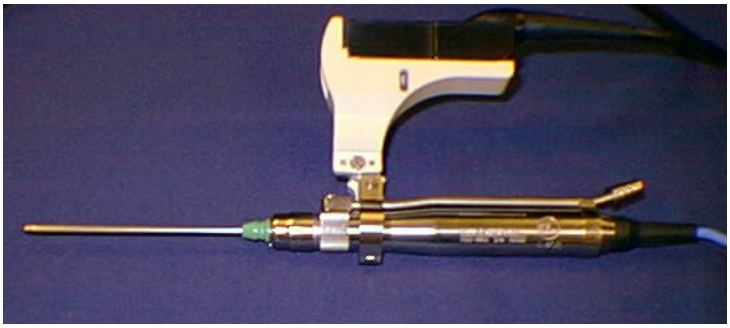


Figure 4-36. Debrider Attachment Attached to the Gyrus ESSential Shaver Handpiece

- Unscrew the knob on the Debrider Attachment to open the clamp. It is not necessary to completely remove the knob from the clamp.
- Attach the Debrider Attachment to the ESSential Shaver Handpiece by placing the clamp around the midsection of the debrider. The word Blade on the Debrider Attachment must face the cutter blade. Position the Debrider Attachment above the suction tube.

XOMED® STRAIGHTSHOT® and MAGNUM™ Debriders

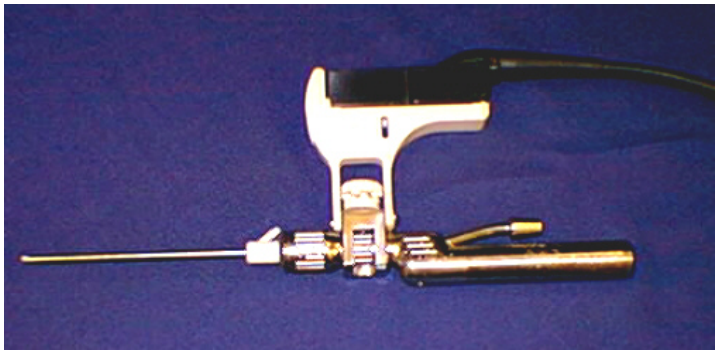


Figure 4-37. Debrider Attachment to the XOMED STRAIGHTSHOT Debrider

- Attach the Debrider Attachment to the STRAIGHTSHOT or MAGNUM Debrider by placing the vise around the midsection of the debrider. The word, Blade, on the Debrider Attachment must face the cutter blade. Position the Debrider Attachment at a comfortable angle on the debrider. The recommended position is forty-five degrees (45°) to the right of the handle with the top indicated by the suction tubing. This position generally allows the least interference with an endoscope during the surgical procedure.
- Press and turn the thumbscrew on the Debrider Attachment clockwise to secure the Debrider Attachment into place. Tighten until the end of the screw fits securely into one of the grooves on the debrider.

Note: To prevent accidental disengagement and movement during use, the thumbscrew is equipped with a positive engagement feature. To turn the thumbscrew, apply downward pressure to the top of the thumbscrew while turning.

- Verify that the Debrider Attachment is securely fitted to the debrider by applying a side-to-side force to the Debrider Attachment. If the Debrider Attachment is loose, tighten the thumbscrew. The Debrider Attachment must not be loose or be able to move.
- Snap the receiver onto the top platform of the Debrider Attachment, similar to attaching the *Receiver* to the Docking Station of an aspirator. The *InstaTrak 3500 Plus* will automatically detect that the debrider is attached to a receiver.

Stryker® Hummer 2 and Hummer TPS debriders:

Figure 4-38. Debrider Attachment to the Stryker Hummer 2 Debrider

Note: In order to attach the debrider attachment to the Hummer TPS debrider the debrider must be modified. The front collar of the Hummer TPS must be replaced with a new front collar similar to another Stryker debrider. If the debrider has not been modified, contact GE Medical Systems Navigation and Visualization for additional information.

- Unscrew the knob on the Debrider Attachment to open the clamp. It is not necessary to completely remove the knob from the clamp.
- Attach the Debrider Attachment to the Hummer 2 or Hummer TPS Debrider by placing the clamp around the midsection of the debrider. The word, Blade, on the Debrider Attachment must face the cutter blade. Position the Debrider Attachment at a comfortable angle on the debrider. The recommended position is thirty degrees (30º) off center of the suction tubing to ensure that the on/off switch can be easily accessed during the procedure.
- Align the knob with the mating threads on the clamp. Turn the knob clockwise to tighten.
- Verify that the Debrider Attachment is securely fitted to the debrider by applying a side-to-side force to the Debrider Attachment. If the Debrider Attachment is loose, tighten the thumbscrew. The Debrider Attachment must not be loose or be able to move.
- Snap the *Receiver* onto the top platform of the Debrider Attachment, similar to attaching the receiver to the Docking Station of an aspirator. The *InstaTrak 3500 Plus* will automatically detect that the debrider is attached to a receiver.

Linvatec E9000™ High Speed Shaver Handpiece

Figure 4-39. Debrider Attachment to Linvatec High Speed Shaver Handpiece

- Unscrew the knob on the Debrider Attachment to open the clamp. It is not necessary to completely remove the knob from the clamp.
- Attach the Debrider Attachment to the E9000 High Speed Shaver Handpiece by placing the clamp around the midsection of the debrider. The word, Blade, on the Debrider Attachment must face the cutter blade. Position the *Debrider Attachment* at a comfortable angle on the debrider. The recommended position is 30º off center of the suction tube to ensure the on/off switch can be used during the procedure.
- Align the knob with the mating threads on the clamp. Turn the knob clockwise to tighten.
- Verify that the *Debrider Attachment* is securely fitted to the debrider by applying a side-to-side force to the Debrider Attachment. If the Debrider Attachment is loose, tighten the thumbscrew. The Debrider Attachment must not be loose or be able to move.
- Snap the *InstaTrak Receiver* onto the top platform of the Debrider Attachment, similar to attaching the receiver to the Docking Station of an aspirator. The *InstaTrak 3500 Plus* will automatically detect that the debrider is attached to a receiver.

Calibration

Calibrating Instruments

Calibration is the process that identifies the position of the tip of the instrument. Every instrument must be calibrated before using it for surgical navigation. The **Calibrate** button on the **VISUALIZATION MENU** remains orange until calibration is completed and then changes to green.

⚠ *CAUTION*

If a non-sterile pointer was calibrated for registration, the sterile pointer should also be calibrated even if the Calibrate button remains green. This action ensures the best accuracy.

To calibrate an instrument*:*

- Place the tip of the instrument in the dimple on the transmitter.

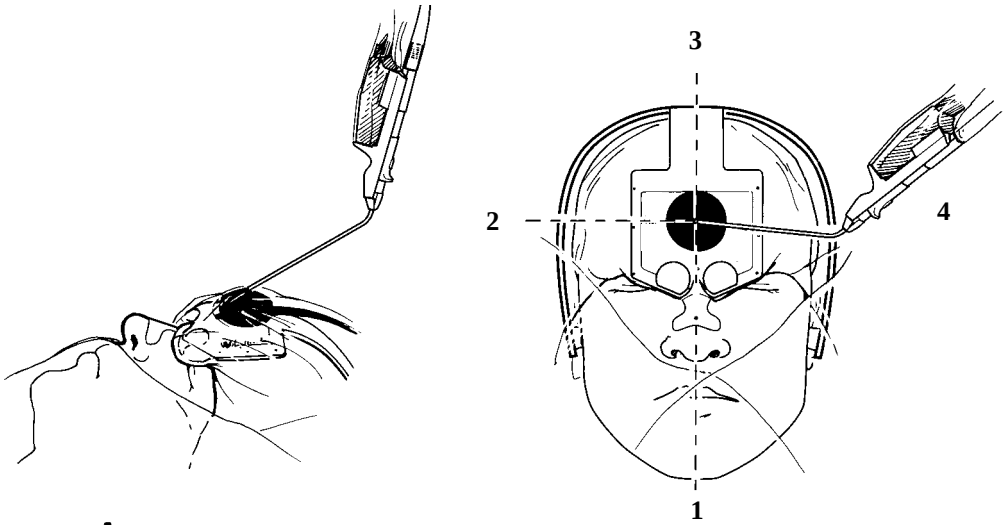


Figure 4-40. Calibration

- Select the **Calibrate** button from the **VISUALIZATION MENU**.
- If calibration is successful on one point, the **Calibrate** button turns green.
- If the following message appears, keep the instrument in the dimple

- Slightly rotate or move the instrument through three (3) additional points. A bell sounds and the cursor moves down the dialog box as each point is accepted.
- When all points are accepted, the **Calibrate** button turns green.

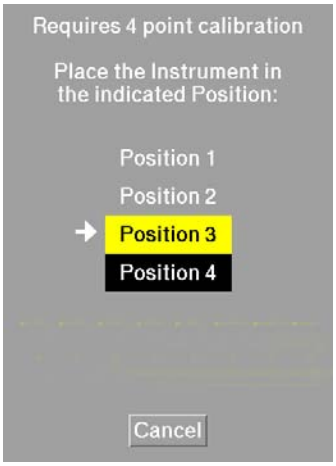


Figure 4-41. 4 Point Calibration Dialog

Note: In order to pass calibration, the instrument tip must be in the transmitter dimple when a point is collected. If desired, place a finger on the instrument tip to ensure that it is held in the dimple.

CAUTION

If a non-sterile pointer was calibrated for registration, the sterile pointer should also be calibrated even if the Calibrate button remains green. This action ensures the greatest accuracy.

Calibrating on Transmitter Dimple

- Turn the dissector to its normal "right-side-up" position
- Place the tip of the dissector into the dimple on the Transmitter, with the dissector held "right-side-up" and at a slight angle, as shown in Figure 4-42.
- Collect 4 points by rotating the Receiver to 9:00, 11:00, 1:00, and 3:00 positions.
- The Receiver cable must not touch the Transmitter during Calibration.

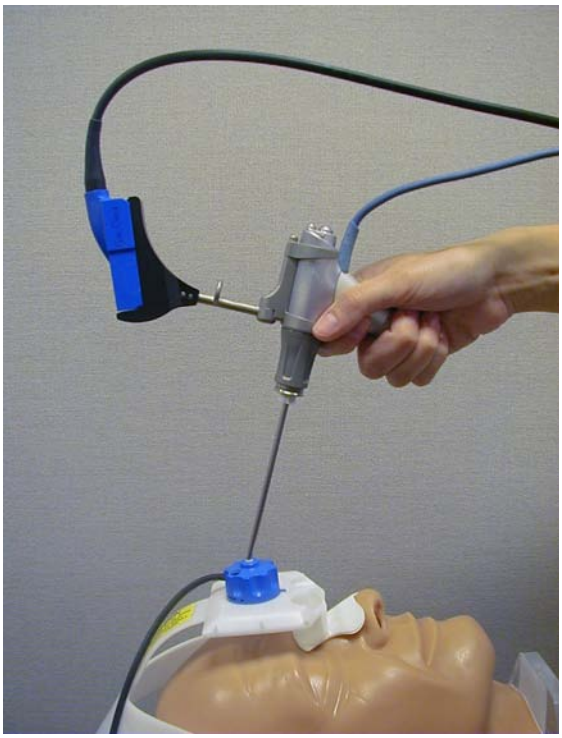


Figure 4-42. Calibrating the Gyrus Diego Powered Dissector

Note: The receiver cable must not touch the transmitter during Calibration.

Note: Calibration for Diego Powered Dissector is similar to the calibration procedure for the *Aspirator*, but the four points should be collected in 60° intervals in two (upper) quadrants (between 9:00 to 3:00).

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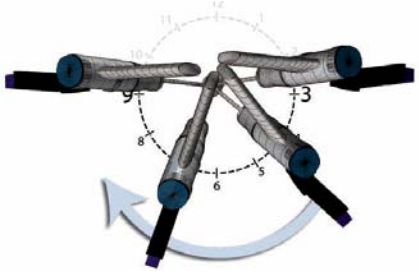


Figure 4-43. Suggested Calibration Points

Stryker Hummer and TPS Debriders

A sterile Calibration Post must be used to calibrate the Stryker debriders when attached to the debrider attachment. Cut a small hole in the Headset draping and insert the sterile Calibration Post into the hole in the transmitter. Turn the sterile Calibration Post slightly to lock into place.

Using the dimple on the sterile Calibration Post, follow the instructions for calibration.

Note: In order to calibrate the debrider attachment on the Stryker debrider, the sterile Calibration Post must be attached to the transmitter.

Registration

Registration is the process of aligning the scan to the patient's physical space. This process enables surgical navigation to be performed accurately.

For more details about registration, refer to *Getting Started* in this manual and to *System Operation* in the *InstaTrak 3500 Plus Operator's Manual*.

There are three methods of registration that may be used with the Advanced ENT Application:

- *AccuMatch*™ Surface Registration
- Fiducial Registration
- Automatic Headset Registration

You must access the REGISTRATION MENU to perform either an *AccuMatch*™ surface registration or a fiducial registration.

You don't have to use the REGISTRATION MENU if you are using the Headset with automatic registration.

Automatic Registration Headset

The *Automatic Registration Headset* can be used for procedures where access to patient anatomy will not be obstructed by use of the device. Registration, the alignment of the images and the patient's anatomy, is done automatically with the Headset. Automatic registration and *Auto Plus* registration may only be obtained through use of the Headset at the time of the scan and in the OR. When *AccuMatch*™ registration is preferred, the Headset may function simply as a transmitter attachment device.

Auto Plus Registration

Auto Plus registration requires that the patient wear the Headset with Lateral Markers during the CT scan and during surgery. Both of the Lateral Markers must be visible on the CT scan and automatic registration must be listed in the **Auto Reg** column as **Yes**.

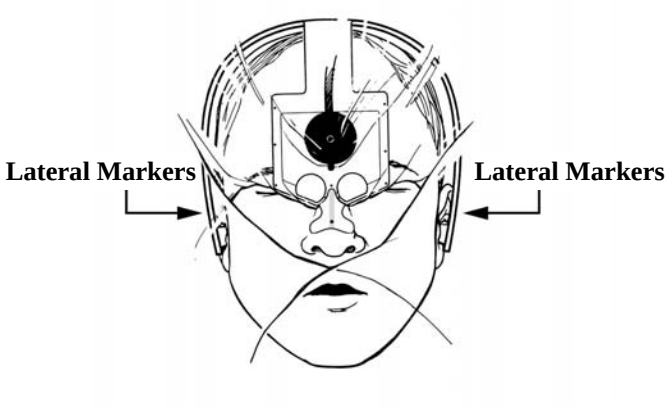


Figure 4-44 Lateral Marker Position

After calibrating and verifying the instrument, an orange message box may appear, indicating that the lateral markers have been identified by the System.

Figure 4-45 Lateral Marker Message

Collecting Lateral Markers

To collect the lateral markers on the Headset:

- Touch the tip of the instrument to one of the lateral markers on the side of the Headset. A bell sounds when the point is collected.
- Touch the other marker. A bell sounds when the point is collected.

If the RMS is less than three (3) mm, the **VISUALIZATION MENU** is displayed and tracking is initiated. If the RMS is greater than three (3) mm, registration is unacceptable and a yellow dialog appears with the option to recollect the markers.

To continue without using the lateral markers, select the **Cancel** button and return to Automatic Registration.

Performing a Fiducial or AccuMatch™ Registration

To perform a fiducial or AccuMatch™ registration you must first calibrate the non-sterile registration pointer. After calibrating, select the **Registration** button. The REGISTRATION MENU appears with Automatic, Fiducial, or *AccuMatch* selected as the method of registration.

Figure 4-46. Use the Registration Button to Select Method

To change the method of registration, select the **Registration Method** button. A pull-down menu appears.

Figure 4-47. Registration Method Pull Down Menu

Select *AccuMatch*™ or Fiducial, as applicable.

Fiducial Registration

A fiducial registration requires that fiducial markers be placed on the patient prior to the scan. The fiducial markers contain a radio-opaque material that shows up on the medical image. These fiducial markers must remain on the patient until the registration process has been completed.

Fast Fiducial Registration is an exclusive GE Healthcare feature where the system software automatically locates the markers on the scan, eliminating the process of identifying the markers manually as in a standard fiducial registration.

The *InstaTrak® 3500 Plus* stores the location of each fiducial marker that is automatically identified on the medical image. The actual physical marker on the patient must be touched with the instrument tip in order to "collect" the point for a valid registration. The system then calculates the registration RMS value.

CAUTION

Fast Fiducial Registration *is not compatible with T2 weighted MR scans because fiducial markers do not show up clearly on the images.*

Fiducial Registration Instructions

Use the following procedure for both the standard fiducial registration and fast fiducial registration methods. The term fiducial applies to the donut type of fiducial marker placed on the patient before the scan.

Note: Before proceeding, rotate the 3-D model so that the majority of the fiducials are visible.

1. After the instrument has been calibrated, select the **Registration** button. If necessary, select **Fiducial** as the registration method.
2. If the system has identified the fiducial markers on the scan, the **Collect Fiducials** message appears automatically, and a *Fast Fiducial Registration* may be performed.

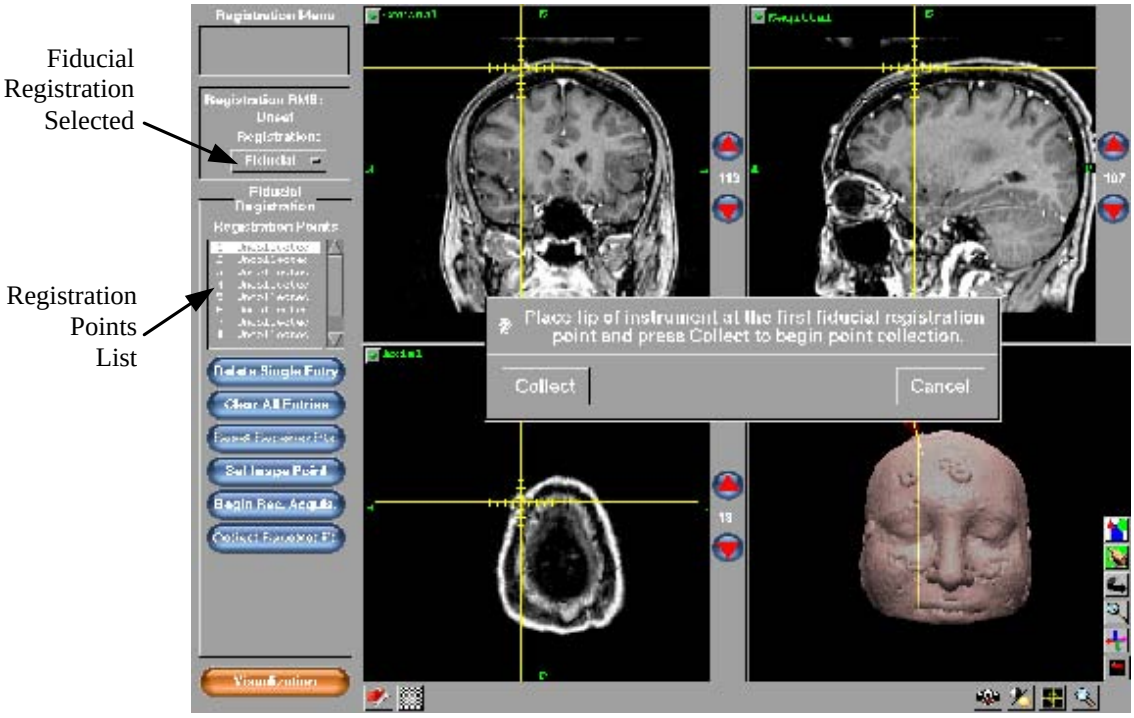


Figure 4-48. Fast Fiducial Registration Display

3. A red arrow points to the first fiducial marker on the 3-D model. The crosshairs are centered on the fiducial and the **Registration Points** List shows all fiducials that were located as *Uncollected*. In this case, skip to Step 13 to continue the registration process.
4. If the **Collect Fiducials** message does not appear, and Number One (1) on the **Registration Points List** is <Insertion Point>, the system was unable to perform a valid registration. The **Fast Fiducial Registration** is not active and a standard fiducial registration must be performed. In this case, follow all instructions to complete the fiducial registration process or to add fiducials to the **Registration Points List**.

5. Scroll through the patient's images and 3D model to identify a fiducial marker.

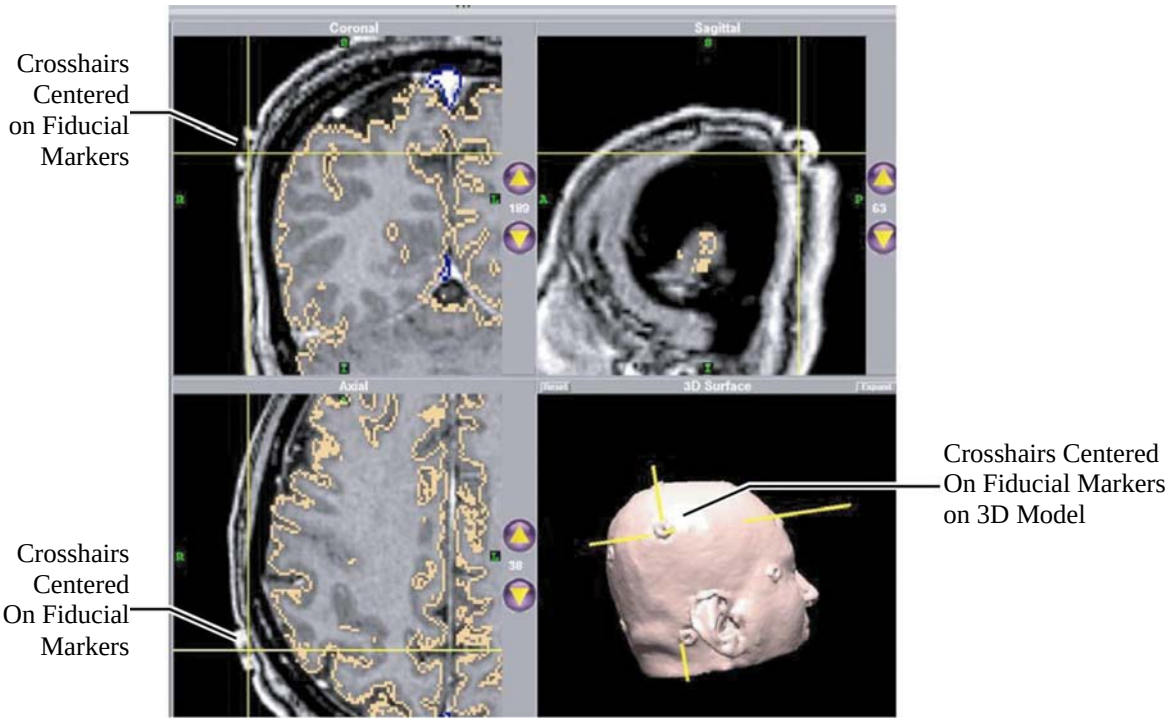


Figure 4-49. Identifying Fiducial Markers with 4:1 Magnification

6. Place the crosshairs in the center of the first fiducial location on the images. Alignment can be checked in all three planes axial, coronal and sagittal or on the 3D model. Adjust the crosshair position until the center of the crosshairs appears in the center of the fiducial marker on each one of the orthogonal images.

Note: Select 4:1 magnification for a more precise selection during this step.

Note: As points are collected, the System automatically highlights the applicable "insertion point" on the list. If an insertion point is reselected manually, the automatic process is inactive and the cursor must be moved manually from that point on.

7. Select the **Image Point** button. The Insertion Point List now states:
   a. Uncollected
   b. <insertion point>
8. Locate the second fiducial marker and center the crosshairs.
9. Select the **Image Point** button. The **Insertion Point List** now states:
   a. Uncollected
   b. Uncollected
   c. <insertion point>
10. Continue this process until all fiducials seen on the scan are listed in the **Insertion Point List** as Uncollected.

11. Select the **Begin Rec. Acquis**. (Begin Receiver Acquisition) button. The Collect Fiducials message appears and a red arrow points to the fiducial marker on the 3D Model.

12. *Fast Fiducial Registration* instructions resume at this point.

CAUTION

If more than seven (7) fiducial markers were placed and are identified by the System, you must *collect them in the order indicated by the position of the Red Arrow on the Display. If seven (7) or less fiducial markers were identified by the System, and no markers were skipped, you may collect the fiducial markers in any order.*

13. Gently place the pointer in the center of the first fiducial on the patient. Be careful not to depress the surface of the skin.

    a. A high-pitched bell sound indicates that the point was successfully collected.

    b. A lower-pitch tone indicates that the system was unable to collect the point.

If there is motion of the instrument or excessive metal interference during a point collection, the following messages appear and the point is not collected. Select **OK** to remove the message.

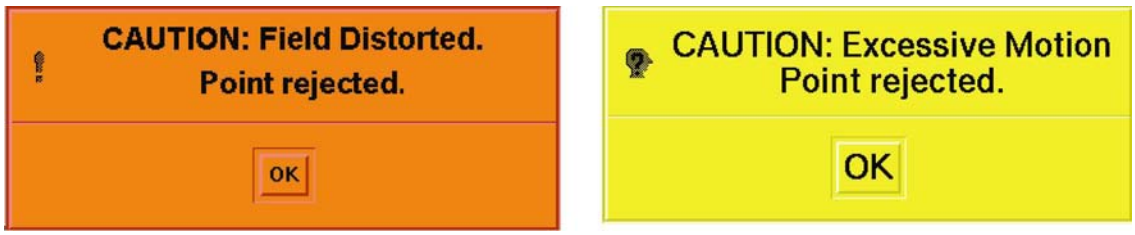


Figure 4-50. Field Interference Messages

The point may be recollected. Place the instrument tip on the center of the fiducial marker, but reposition the receiver in order to reduce metal interference. Select the **Collect Receiver Pts**. button.

14. Continue this process until all the fiducials are listed in the **Insertion Point List** as collected. Ensure that points are collected only once.

WARNING

It is important that a point is collected only once. Collecting the same point twice may cause system inaccuracies that could lead to a potential patient safety hazard.

15. The system calculates the best fit of the image point positions and the actual patient locations. This value can be seen in the Registration RMS. If the Registration RMS is acceptable, RMS < 3 mm, you will automatically proceed to the **Visualization Menu** to continue with the procedure.

16. If the registration is unacceptable, RMS > 3mm, the following dialog appears:

Figure 4-51. Registration Unacceptable Message

a. Select **Yes** to recollect the receiver points by touching the center of the fiducial marker with the tip of the instrument.
b. To repeat the entire process, select the **Reset Receiver Pts** button to return all of the image points to Uncollected.
c. If **No** is selected, the Registration RMS appears on the menu and a residual distance in millimeters is listed for each insertion point. If one or more of the values is significantly higher than the other points, and there are enough fiducials listed (four [4] are required for a valid registration), entries may be deleted. To delete points, select the entry, and then select **Delete Single Entry**. The system recalculates the Registration RMS.

Figure 4-52. Registration Unacceptable - Retry Message

17. In rare instances the selected points cannot determine a registration because the information is mathematically indeterminate. This occurs if the points are too close together or are positioned in a straight line. If at least four (4) registration points cannot be collected, a valid registration may not be possible.
18. When the registration process is complete, select the **Visualization** button to return to the VISUALIZATION MENU and continue with the procedure.

AccuMatch™ Surface Registration

AccuMatch™ Surface Registration is an optional feature. If your system is equipped, the REGISTRATION MENU will list AccuMatch as one of the available methods of registration. If your system is not equipped, the REGISTRATION MENU will list AccuMatch, but the button will be disabled.

If the patient was not scanned with fiducial markers or the headset, the AccuMatch registration may be used as an alternate registration process.

A Button Probe is used to perform an AccuMatch registration. Before beginning the registration process, the Button Probe must be calibrated and the transmitter must be securely attached to the patient using either the headset or one of the transmitter attachment arms.

Guidelines for AccuMatch Registration

- Scan must include anatomical landmarks (nose and ears).
- Collect points in areas where bone is in close proximity to the skin surface and where the skin is relatively immobile.
- Do not collect points on surface areas of trauma, loose skin (cheeks, previous craniotomy sites) or movable parts (mandible).

CAUTION

AccuMatch™ Surface Registration is highly dependent on user technique, which may result in System accuracy variations.

To perform an AccuMatch Registration:

1. After the button probe has been calibrated, select the **Registration** button. The REGISTRATION MENU appears.
2. If the **Collect/Cancel** message appears, select **Cancel**
3. Select **AccuMatch** from the pull-down Registration menu.
4. The AccuMatch SURFACE REGISTRATION MENU appears with the 3-D model displayed on the full screen.

Figure 4-53 . AccuMatch Registration Menu

AccuMatch Registration process consists of three (3) steps:

1. *Find* - Three (3) points are placed on the 3D model using the mouse.
2. *Touch* - The corresponding three (3) points are touched on the patient.

Note: An RMS number appears after the Touch process is complete. The RMS reflects the correlation of the three points as set on the 3D model and touched on the patient. If this RMS is greater than fifteen (15), a message appears indicating that the registration process must be repeated.

3. *Paint* - A series of lines are "painted" on the surface of the patient's skin.

Note: A new RMS replaces the previous RMS in the upper left corner of the screen. The new RMS reflects the correlation of the patient's scan with the *AccuMatch Registration* point collection.

Step #1 - Find

- Select the **Find** button.
- Using the mouse, find three (3) points on the 3D Model. These three (3) points should surround the area of surgical interest and be as widely dispersed as possible while still on a single rigid anatomical structure.

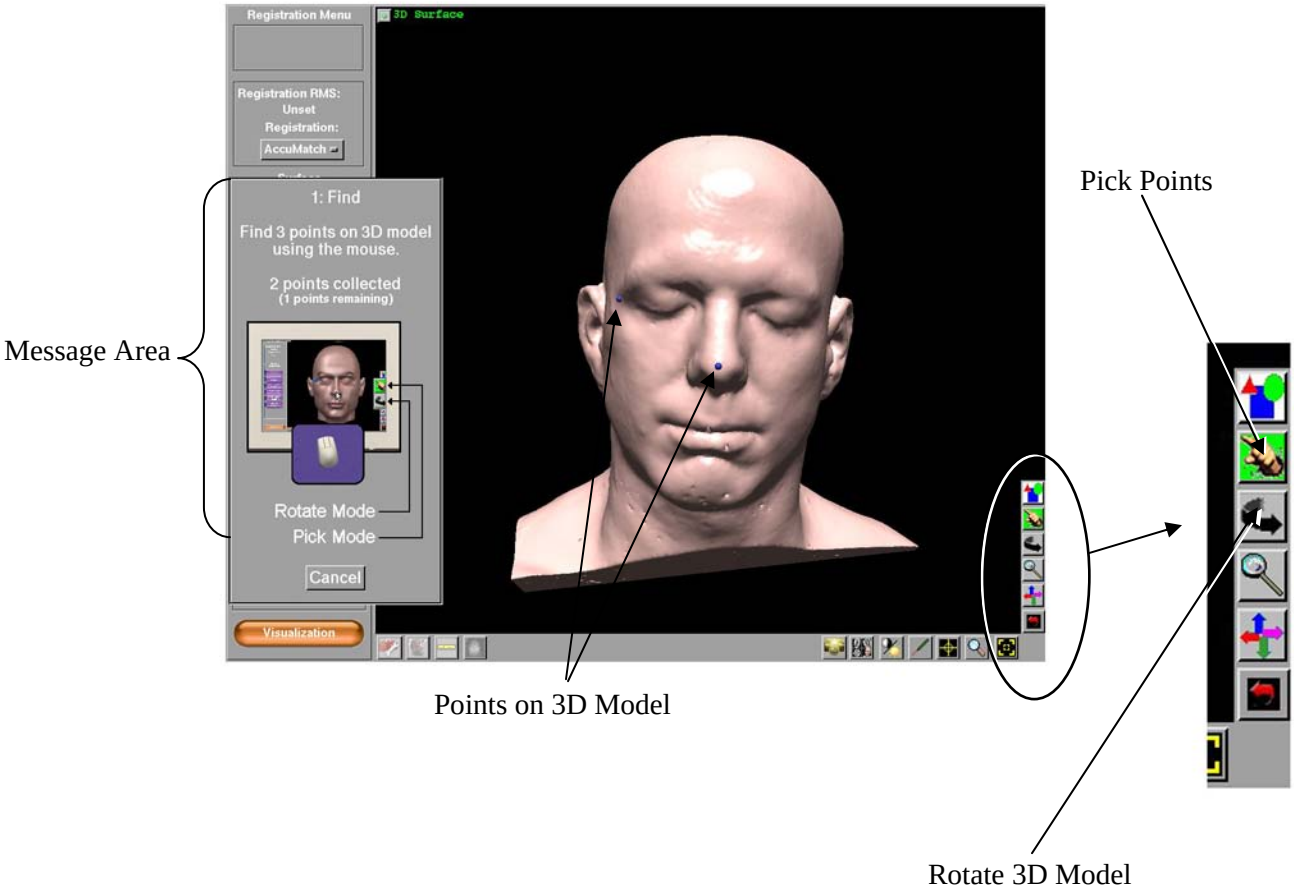


Figure 4-54. AccuMatch Registration - Find

- The 3D model may be adjusted by selecting the **Rotate 3D Model** button on the right of the screen. Select the **Pick Points** button to return to picking points.
- Place the point by positioning the cursor and clicking with the left mouse button. An audible bell sounds and a blue sphere appears at the selected location.
- Repeat for the two (2) other desired points. Each time a point is set the message area is updated to show how many points have been set and how many more points are needed.

Step #2 - Touch

After the three (3) points have been set, the TOUCH MENU appears automatically.

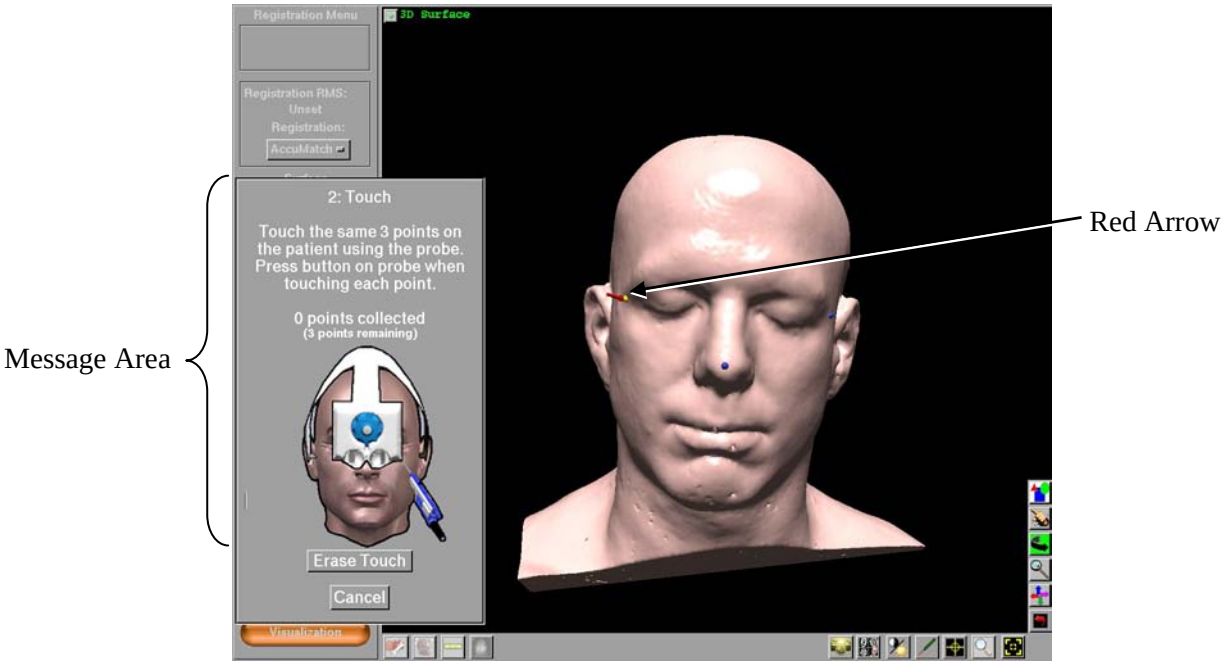


Figure 4-55. AccuMatch Registration - Touch

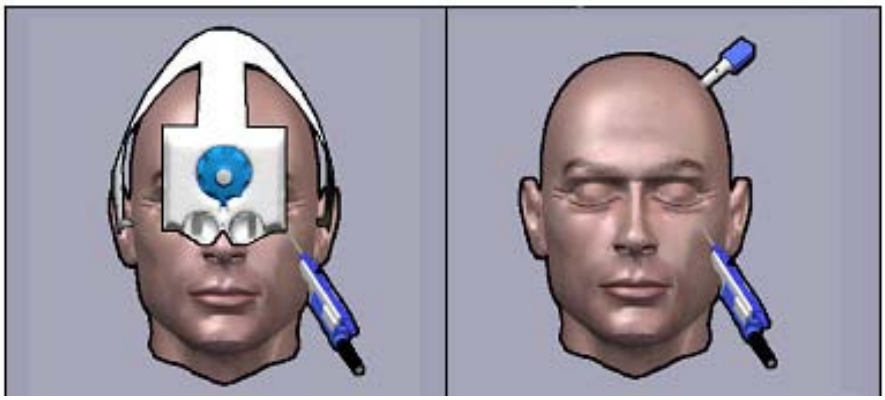
- Using the Button Probe, touch the same three (3) points on the patient. A red arrow indicates the point that should be touched.
- Touch the tip of the Button Probe lightly on the corresponding surface point on the patient and press the button on the Button Probe.
- A bell sounds and the yellow sphere at the end of the red arrow turns green. The next point to be collected is indicated by a red arrow with yellow sphere.

Note: The button on the Button Probe must be depressed to collect the points for an AccuMatch Registration. Do not press the button unless the tip of the Button Probe is on the skin surface.

Note: The image you see in the Message Area depends on which application you are working with and what type of transmitter you are using. The figure below shows the differences.

Headset Transmitter Pin Transmitter

Touch



- An RMS number appears. The RMS reflects the correlation of the three points as set on the image and touched on the patient. If this RMS is greater than fifteen (15), the registration process must be repeated.

RMS After Touch Step

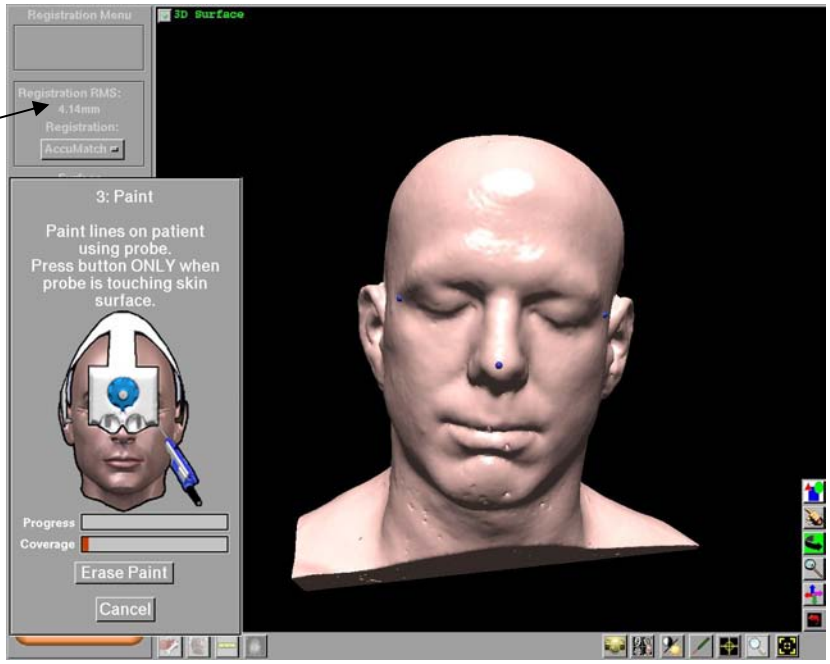


Figure 4-56. AccuMatch Registration – Touch Complete

Step #3 - Paint

When the three **Touch** points have been collected, the PAINT MENU appears.

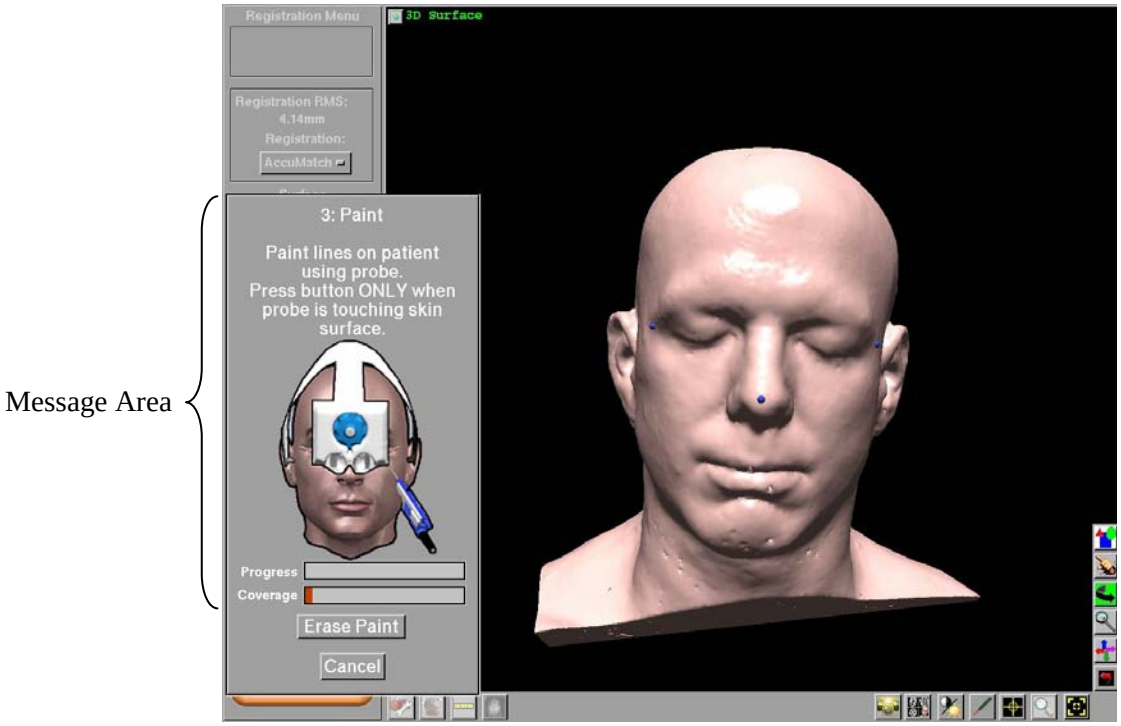
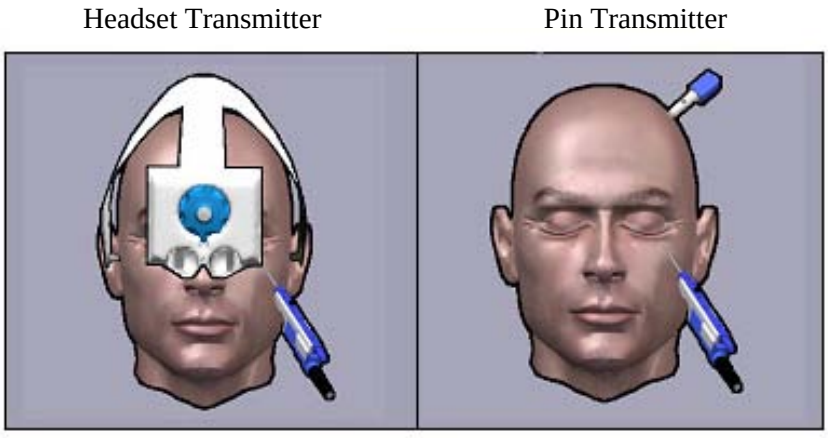


Figure 4-57. AccuMatch Registration - Paint

Note: The image you see in the Message Area depends on which application you are working with and what type of transmitter you are using. The figure below shows the differences

Paint



- Paint a series of lines on the surface of the patient's skin with the Button Probe.
- Place the tip of the Button Probe lightly on the surface of the patient's skin. Push the button on the Button Probe and hold it down while moving the tip of the Button Probe lightly over the skin surface. Press the button only when the tip of the Button Probe is touching the patient.

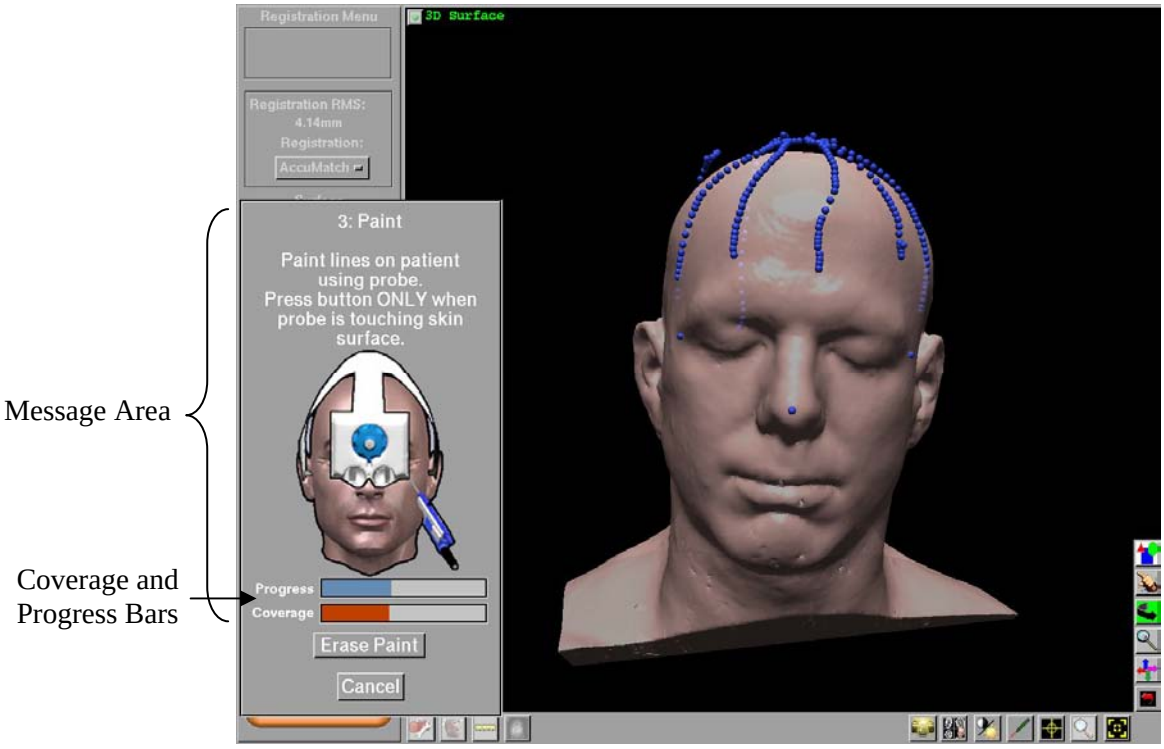


Figure 4-58. AccuMatch Registration – Paint Lines

- Blue spheres appear on the 3D Model indicating where you are drawing the lines. The 3D model is slightly transparent so that all the collected points can be visualized.
- Lines should be drawn around the area of surgical interest and in as large a surface area as the medical images allow (lines can only be drawn in areas that are within the scanning range). Keep in mind that the back of the patient's head was resting on a sponge or on a table during the scan, so do not paint lines in this area, if possible.

Note: If the RMS for the three (3) Touched points was very high (> fifteen [15]), look at the screen during the painting process to verify that the blue lines are appearing generally in the correct areas on the 3D model. If not, select **Cancel**, then **Erase All**, and restart the process.

- The blue spheres on the 3D model may appear to be above or below the surface of the skin (spheres below the surface appear lighter blue). After the final registration calculation, the spheres will realign themselves on the skin surface.
- The **Progress Indicator** appears. A blue bar moves from left to right to indicate how many points are being collected. The **Progress Indicator** must be completely filled in before the registration can be calculated.
- The **Coverage Indicator** appears. A bar changes colors as the lines are drawn, indicating the percentage (%) of the surface area that is being covered. The registration is calculated even if the points were collected on a

small surface area. Tracking accuracy is directly related to the percentage of the coverage: if a large surface area is covered, accuracy will be acceptable in a larger area. If points are collected in a small area, tracking accuracy will be acceptable only in that area where the points were collected.

  - Red: Low percentage of coverage.
  - Partial Green: Adequate percentage of coverage.
  - All Green: Good percentage of coverage.
- An audible bell sounds twice when enough points have been collected. If the button on the button probe is still depressed after the bell sounds, a message appears to indicate that the collection process is complete.

When all the lines have been drawn, the system calculates the registration.

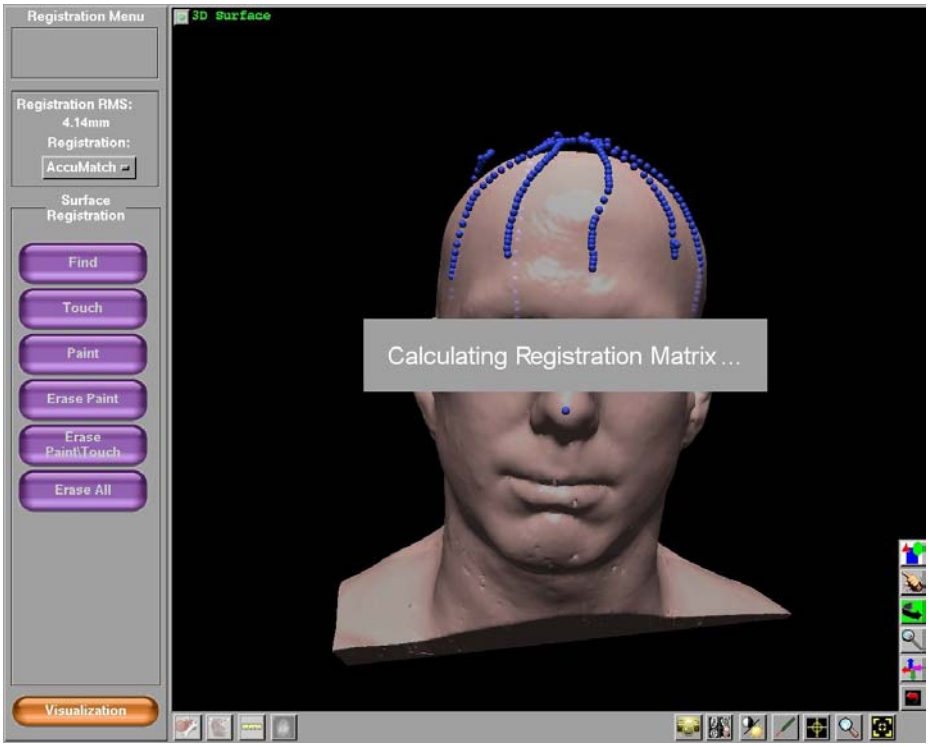


Figure 4-59. AccuMatch Registration - Calculation

The spheres on the 3D model turn either red or green, and move around on the 3D model. As the registration is calculated, the spheres align themselves with the skin surface.

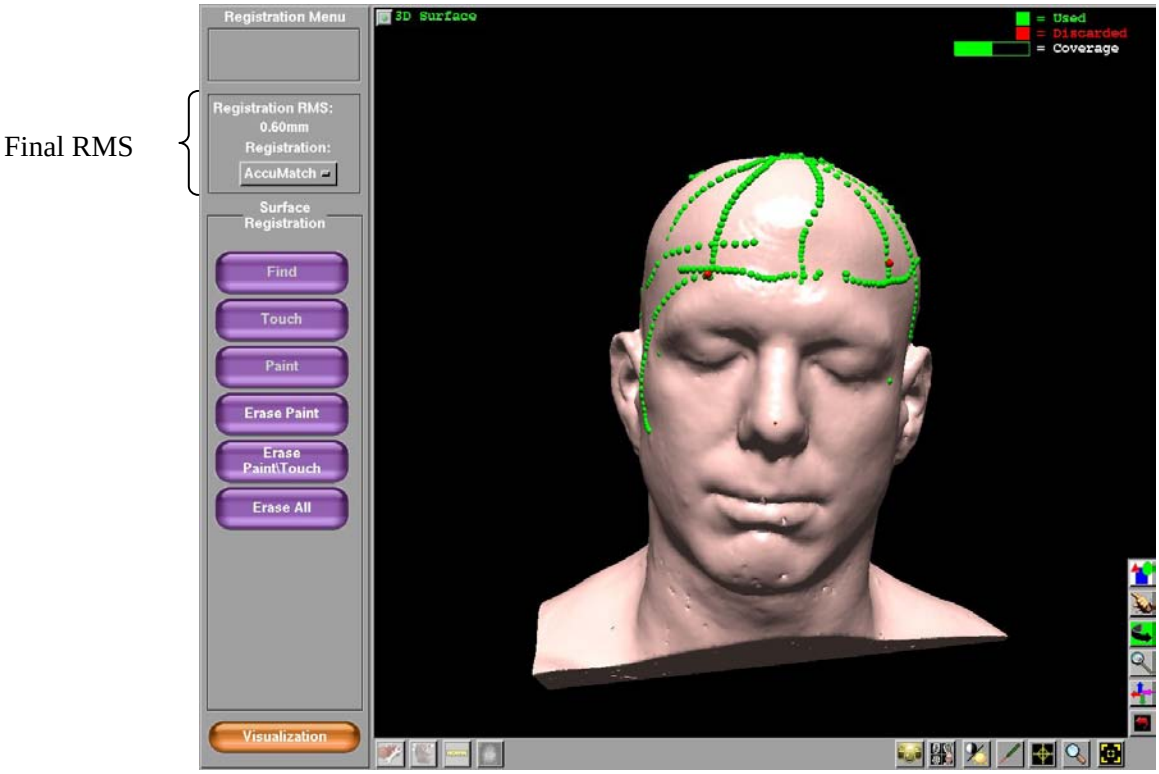


Figure 4-60. AccuMatch Registration - Complete

- Green spheres indicate points used for the registration matrix.
- Red spheres indicate discard or unusable points.

When the calculation is complete, a final RMS replaces the previous RMS in the upper left corner of the screen.

- If the *AccuMatch Registration* is acceptable, RMS less than 1, the system returns to the VISUALIZATION MENU automatically.
- If the RMS greater than or equal to 1, anatomical points should be checked to determine if the system accuracy. If not accurate, the *AccuMatch Registration* should be repeated.
- If a red Warning message appears indicating that the registration was unsuccessful, the *AccuMatch Registration* must be repeated.

Deleting Points

There are several different ways to delete points during each step of the *AccuMatch™ Registration* process.

1. On each of the message windows there is an **Erase** button. Selecting this button deletes only that part of the process and automatically returns to the previous step.

a. **Erase Find** - Selecting this button deletes the points that were set on the 3D model.

b. **Erase Touch** - Selecting this button deletes the points that have been set on the patient, but not the three (3) points that were set on the 3D model. The Touch message remains on the screen and the points can be recollected.

c. **Erase Paint** - Selecting this button removes only the lines that have been drawn on the surface of the patient's skin and not the three point pairs. The Paint message remains on the screen and the lines can be redrawn.

2. The **Cancel** button can be selected from any of the menus. Selecting this button deletes only that part of the process and automatically returns to the *AccuMatch™ Registration* MENU. Only one button is highlighted, indicating the next step to be taken. Select the highlighted button to continue the registration process.

a. **Find** message - The Find button on the *AccuMatch™ Registration* MENU will be highlighted. Select Find to start the *AccuMatch™* Registration process.

b. **Touch** message - The Touch button on the *AccuMatch™ Registration* MENU will be highlighted. The three (3) points that were set from the Find menu will remain on the screen. Select the Touch button to continue the registration process.

c. **Paint** message - The Paint button on the *AccuMatch™ Registration* MENU will be highlighted. The three (3) pairs of points that were found and touched will remain on the screen. Select the Paint button to Paint the lines on the surface of the patient's skin.

There are a series of **Erase** buttons on the main *AccuMatch™ Registration* MENU.

Figure 4-61. *AccuMatch™ Registration* Menu

- **Erase Paint** - Select this button to delete only the lines that have been painted on the surface of the patient's skin. The three (3) pairs of points that were found and touched remain. The Paint message appears on the screen. Continue with the registration process by painting lines on the surface of the patient's skin.
- **Erase Paint/Touch** - Select this button to remove the lines that were drawn as well as the three (3) points that were touched. The three (3) points that were found on the 3D model remain. The Touch message appears on the screen. Continue with the registration process by touching the three (3) points on the surface of the patient's skin.
- **Erase All** - Select this button to delete all points that were found, touched or painted. Select the Find button to restart the *AccuMatch Registration* process.

It is also possible to delete points by using only the button probe.

- Place the tip of the button probe into the dimple on the transmitter and push the button.
- The following message appears. The **OK** button is highlighted.

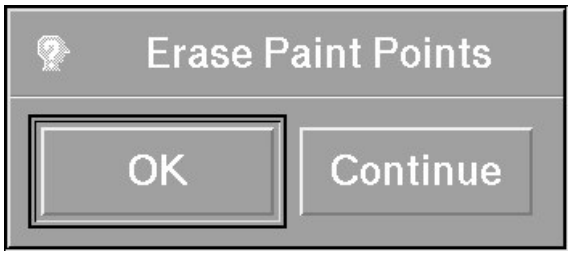


Figure 4-62 Erase Paint Points

- To select **OK**, keep the tip of the button probe in the transmitter dimple and press the button. The points are deleted and the system returns to the previous step in the process.
- To select **Continue**, remove the tip of the button probe from the transmitter dimple and press the button. The **Continue** button is highlighted. Place the tip of the button probe in the transmitter dimple and press the button. The points are not deleted and the process continues.
- To activate the function buttons on the message windows: Place the tip of the button probe into the transmitter dimple and press the button on the button probe.
- To toggle between buttons on the message windows: Press the button on the button probe while the probe is not in the transmitter dimple.

CAUTION

The Transmitter must be rigidly attached or system accuracy may be compromised.

CAUTION

Points should be collected on a single rigid anatomical structure.

CAUTION

Do not depress the surface of the patient's skin during point collection or system accuracy may be compromised.

WARNING

When using AccuMatch™ Registration*, assess system accuracy using anatomical landmarks prior to use. Do not use the system if the anatomical landmark location is determined to be outside the surgical volume. Such use could result in a potential safety hazard.*

Tracking

Tracking is the active function of the *InstaTrak 3500 Plus*. Tracking is automatically initiated following the completion of registration, calibration and verification when the instrument enters the surgical volume.

As the instrument moves, the computer calculates the position of the tip and displays the location in the axial, coronal, sagittal and the 3D Model views. As tracking takes place, the computer updates the crosshair cursor to the corresponding location on the patient's scan.

If the instrument is removed from the surgical volume and the **Full Screen Video** is disabled, the system displays the last image coordinate clicked. If a coordinate has not been selected, the system displays the center of the volume.

WARNING
Do not use the System for tracking when electro-surgical devices are active.

CAUTION
Test the strength of the ball attachment at the tip of each instrument before using. Apply a force to the instrument tip that is greater than the force used during the procedure. If the ball becomes detached, do not use the instrument and report the event to GE Healthcare immediately.

CAUTION
Notify GE Healthcare if any red warning message occurs repeatedly without an apparent cause or cannot be eliminated by the user.

Freeze Function

During tracking the display can be paused or frozen. Freeze can be initiated by selecting the **Freeze** button on the VISUALIZATION MENU

Figure 4-63 Freeze Button

When the **Freeze** button is selected, the following message appears. Select **Continue** to return to tracking or **Snapshot** to take a picture.

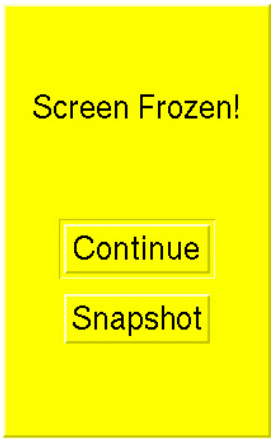


Figure 4-64 Freeze Screen Message

Taking a Snapshot

A view of the system screen can be captured to a TIF (Tagged Image File Format) graphics file and then downloaded to a floppy disk or a CD. Refer to *System Operation* in the *InstaTrak® 3500 Plus Operator's Manual* for instructions for using the Snapshot feature.

Options Menu

The OPTIONS MENU is entered by selecting the **Options** button from the VISUALIZATION MENU.

Note: The Options button can be selected only when Tracking is OFF.

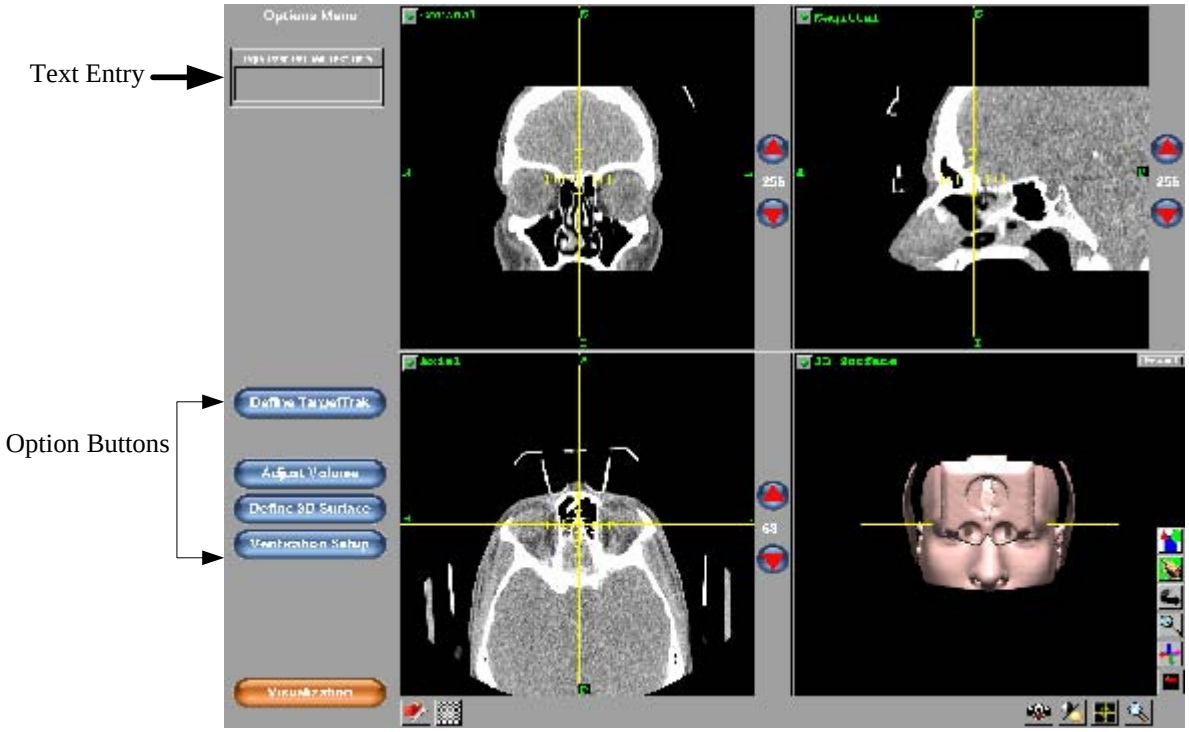


Figure 4-65. Options Menu

User Defined Text

At any point prior to or during surgery the user can enter text in the box located in the upper left hand corner of the OPTIONS MENU. To enter text:

- Move the cursor to the **Type User Defined Text Here** box. The Virtual Keyboard appears if a physical keyboard is not attached to the system.
- Enter the desired text.
- To remove the Virtual Keyboard from the screen, select the **Dismiss** key located on the lower right of the Virtual Keyboard.
- Select the **Visualization** button to return to the VISUALIZATION MENU. The text appears in the upper left hand corner of the screen.

Define TargetTrak

TargetTrak enables the user to pre-operatively select a point on the scan that appears during tracking. Once selected, the target appears as a green bulls-eye on the scan and a green sphere on the 3D Model when the instrument tip is positioned within twenty (20) mm of the selected target point. To define a target:

- Select the **Define TargetTrak** button
- Place the cursor on the target area on the scan and select the Identify Location button.

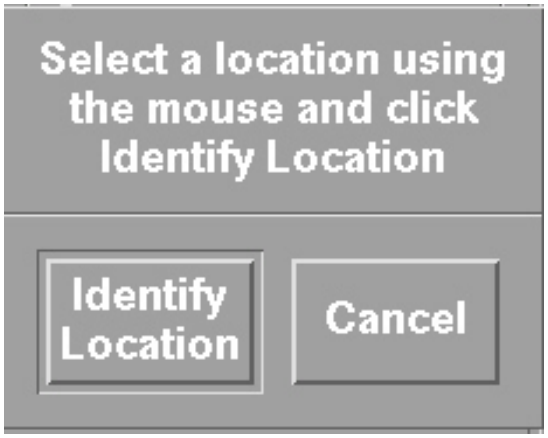


Figure 4-66 Define TargetTrak Message

- Select the **Visualization** button to return to the VISUALIZATION MENU.

Note: When the system is shut down or another scan is loaded the defined target will be lost.

Adjust Volume

A bell is used for notification during calibration, verification, and registration. To adjust the volume of the bell:

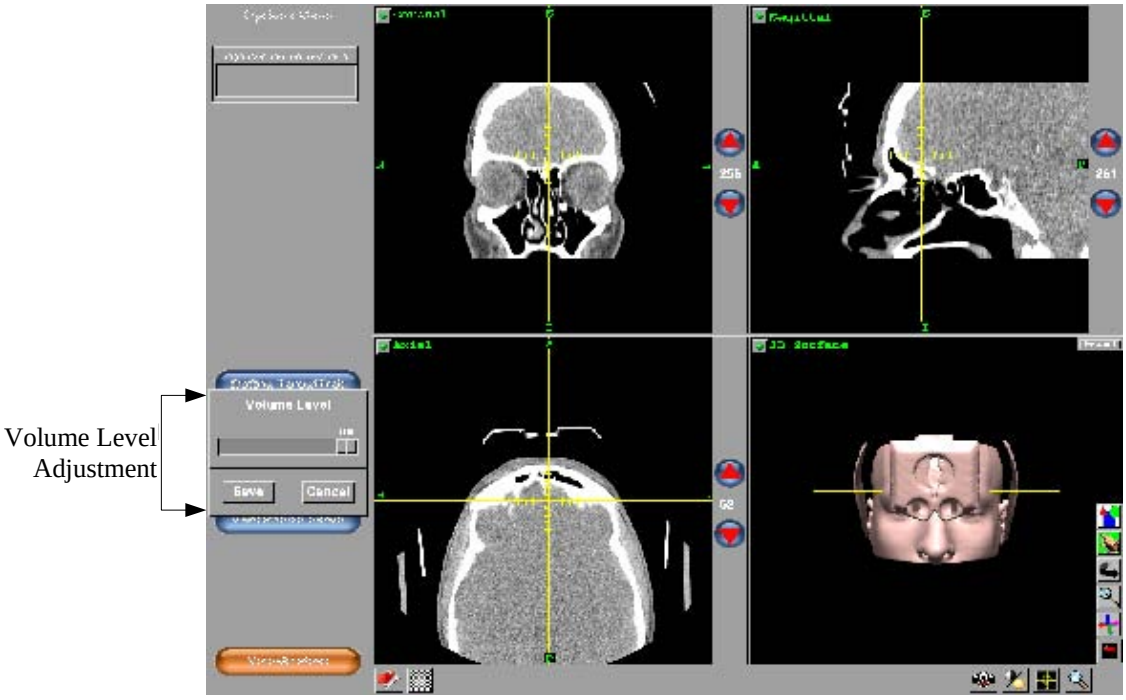


Figure 4-67. Adjust Volume Task Window

- Select the **Adjust Volume** button.
- Move the slider for the desired volume.
- Select **Save.**

Define 3D Surface

The 3D model is generated automatically by the system on the skin surface of the medical images. To re-define the skin surface or to choose the bone surface, select **Define 3D Surface** button.

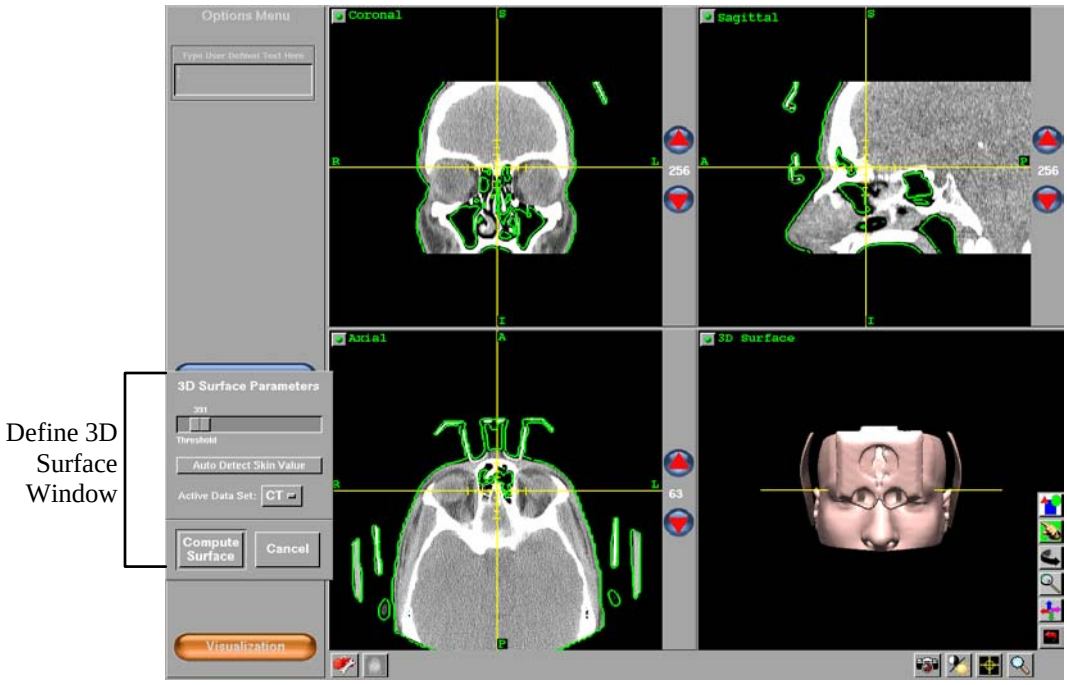


Figure 4-68. Define 3D Surface Task Window

To change the threshold value for 3D model generation:

- Adjust the slider bar until the desired area is completely outlined by a green line on all three of the orthogonal views.
- Select the **Compute Surface** button.

Verification

Verification is the process of checking the accuracy of the alignment between the medical images and the patient. The **Verify** button remains orange and tracking cannot take place until a verification point has been set and the attached instrument has been verified. The **Verify** button turns green after the verification setup process has been successfully completed.

In addition to checking anatomical landmarks regularly, it is recommended that verification take place at the following times during surgery:

- Before critical decisions.
- After any force to the transmitter or transmitter attachment arm.
- At designated intervals indicated by the timer.
- After changing instruments.

The **Verification Needed** message appears:

- When a previously verified instrument is removed and then reattached to the receiver.
- When the Timer interval has expired.
- When any change occurs, such as exiting and then reentering the VISUALIZATION MENU.

WARNING

The acceptable System accuracy range is 0-3mm. If the accuracy is not acceptable see the Troubleshooting Guide in the InstaTrak® 3500 Plus Operator's Manual before continued use of the System.

CAUTION

Before verifying, confirm that the correct patient's images are loaded and that the proper instrument type is selected.

Verification Modes

There are three types of Verification available with the *InstaTrak 3500 Plus*: Anatomic, Drift and Accuracy. The system defaults to the Anatomic Verification mode, but another type may be selected.

Anatomic

An anatomical point on the patient is selected prior to surgery. This **Verification Point** may be touched periodically during surgery, but tracking will continue uninterrupted. Verification will be acceptable if the **Verification Point** remains within three (3) mm of the original point. Anatomic Verification indicates if any changes to system accuracy

have occurred since the start of the procedure, but does not measure the absolute accuracy of the system.

Drift

An anatomical point on the patient is selected prior to surgery. This **Verification Point** must be touched periodically during surgery or tracking cannot continue. Verification will be acceptable if the **Verification Point** remains within three (3) mm of the original point. Messages appear each time that verification occurs, showing numbers that indicate how far the **Verification Point** has moved from the original point. **Drift Verification** indicates if any changes to system accuracy have occurred since the start of the procedure, but does not measure the absolute accuracy of the system.

Accuracy

A marker is placed on the patient prior to the scan. This **Verification Point** must be touched periodically during surgery or tracking cannot continue. Verification will be acceptable if the **Verification Point** remains within three (3) mm. Messages appear each time that verification occurs, showing numbers that indicate how far the **Verification Point** has moved from the originally set point. Accuracy Verification provides the only direct measurement of system accuracy.

Verification Setup

A Verification Point must be selected and then set at the beginning of the surgical case in order to use the *InstaTrak 3500 Plus.* The Verification Point is used as a reference point to check system accuracy.

The VERIFICATION MENU is entered in two ways:

- By selecting the orange **Verify** button
- From the Options Menu by selecting the **Verification Setup** button

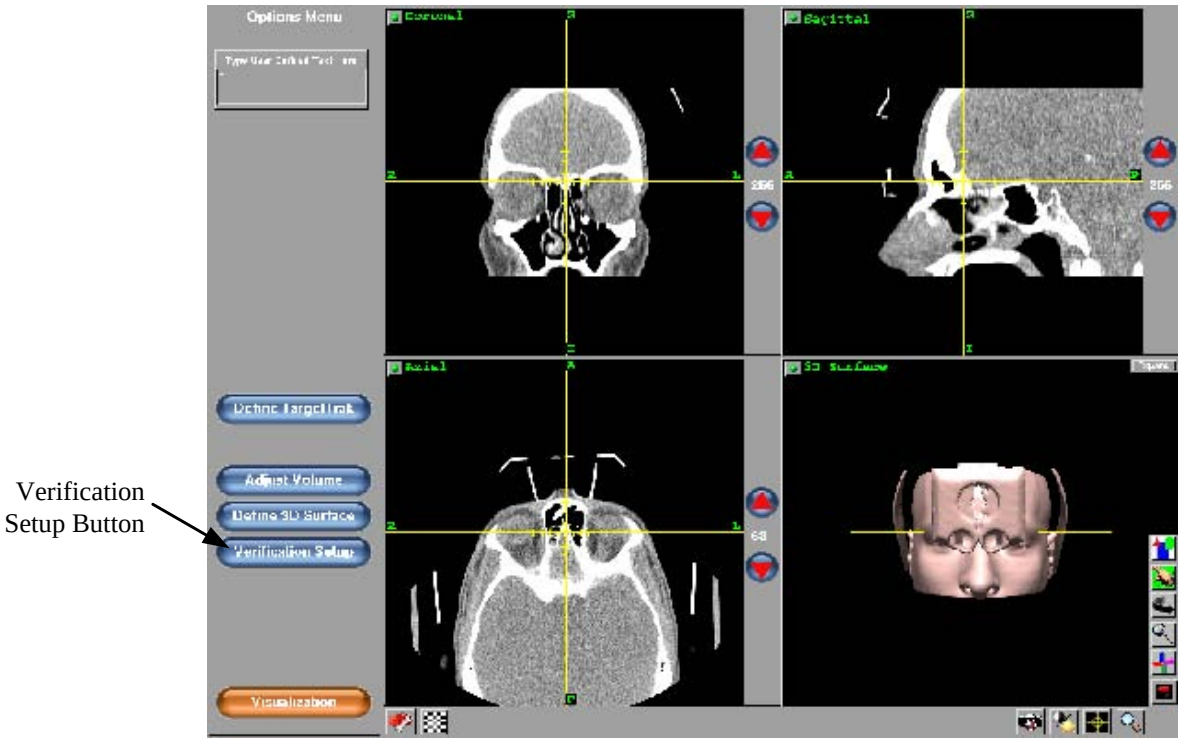


Figure 4-69. Verification Setup Button

After selecting the **Verification Setup** button, the VERIFICATION MENU appears.

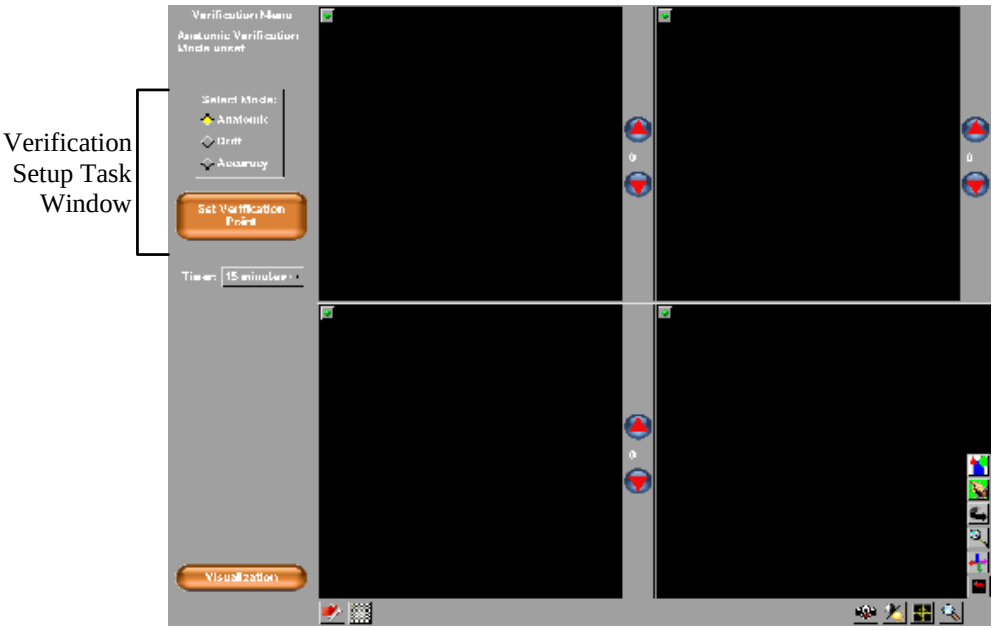


Figure 4-70. Verification Setup Task Window

A timer is provided to determine the intervals between Verification reminder messages. Refer to *Verification Timer* in the *InstaTrak 3500 Plus Operator's Manual* for more details.

Anatomic Verification

Anatomic mode is selected automatically as the default. To change, select Drift mode or Accuracy mode.

The crosshairs type may be changed at this point.

To set the Verification Point:

- Place the instrument tip on the Verification Point on the patient
- Select the **Set Verification Point** button. The system automatically returns to the VISUALIZATION MENU.

To change the selected **Verification Point:**

- Place the tip of the instrument on the Verification Point.
- Select the **Set Verification Point** button. A message appears confirming that the previous Verification Point is being replaced.
- Select **Yes** to continue or **Cancel** to keep the previous point. The system automatically returns to the VISUALIZATION MENU.

Accuracy Verification

To use Accuracy Verification, a radio opaque marker must have been placed on the patient during the scan and must still be in place on the patient in surgery.

To Set the Verification Point:

- Select the Accuracy mode.
- Center the crosshairs on the Verification Point on the scan image.
- Select the **Set Image Point** button. When the point is set, the system automatically returns to the VISUALIZATION MENU.
- Place the instrument on the Verification Point and select Verify.

To Verify during surgery:

When the Verify message window appears or you want to re-verify:

- Place the instrument tip on the Verification Point.
- Select **OK** on the message window or the **Verify** button on the VISUALIZATION MENU.

The system displays a green, Verification Successful message with the accuracy and the amount of drift. Select **OK**. If the Verification accuracy is above three (3) mm, a RED warning message will be displayed.

WARNING

The acceptable System accuracy range is 0-3mm. If the accuracy is not acceptable see the Troubleshooting Guide in the InstaTrak 3500 Plus Operator's Manual before continuing use of the System.

Drift Verification

To Set the Verification Point

- Select the Drift mode.
- Place the instrument tip on the Verification Point on the patient and select the Set Verification Point button. When the point is set, the *InstaTrak® 3500 Plus* automatically returns to the VISUALIZATION MENU.

After returning to the VISUALIZATION MENU, place the instrument on the Verification Point and select Verify.

To Verify during surgery:

When the Verification timer has expired, an instrument is reattached, or the VISUALIZATION MENU is reentered, a message appears stating that Verification must be performed before Tracking can continue.

- Place the instrument tip on the Verification Point
- Select **OK**.

  If the Verification point is within three (3) mm of the original point, a green, Verification Successful message appears with the number in millimeters. Select **OK** to continue.

  If the Verification Point is more than three (3) mm from the original point, a red Verification Unsuccessful message appears. Select **Cancel** to return to tracking, or place the instrument tip on the Verification Point and select **Verify** to continue the Verification procedure.

  When the instrument tip is placed on the Verification Point while Tracking is active, a red twenty (20) mm diameter bull's eye with a three (3) mm center appears on the scan images. If the center of the crosshairs appears within the solid red center of the bulls-eye, then Verification accuracy is within three (3) mm of the original Verification Point. The diameter of this bulls eye decreases as the bull's eye moves away from the Anatomic Point. If the Verification accuracy is greater than three (3) mm, a red warning message is displayed.

To change the selected Verification point:

- Re-enter the VERIFICATION MENU
- Place the instrument on the Verification Point
- Select Verify
- Place the tip of the instrument on the Verification Point
- A message appears confirming the replacement of the original Verification point select **Yes** to continue or **No** to cancel.

Video Controls

If video is selected as a tracking view, a device using video, such as an endoscope or microscope, can occupy one of the quadrants on the Display. The video can be adjusted through the Video Controls menu.

To access the VIDEO CONTROLS MENU, select the Options button from the VISUALIZATION MENU, and then select the Video Controls button.

The image quality of the Video picture that is seen on the *InstaTrak 3500 Plus* may be adjusted by using the slider bars marked Attributes

There are four factors that may be adjusted from zero (0) to two hundred fifty-five (255): Brightness, Contrast, Hue and Saturation. As each attribute is adjusted, the Video image changes on the screen. The settings are saved automatically.

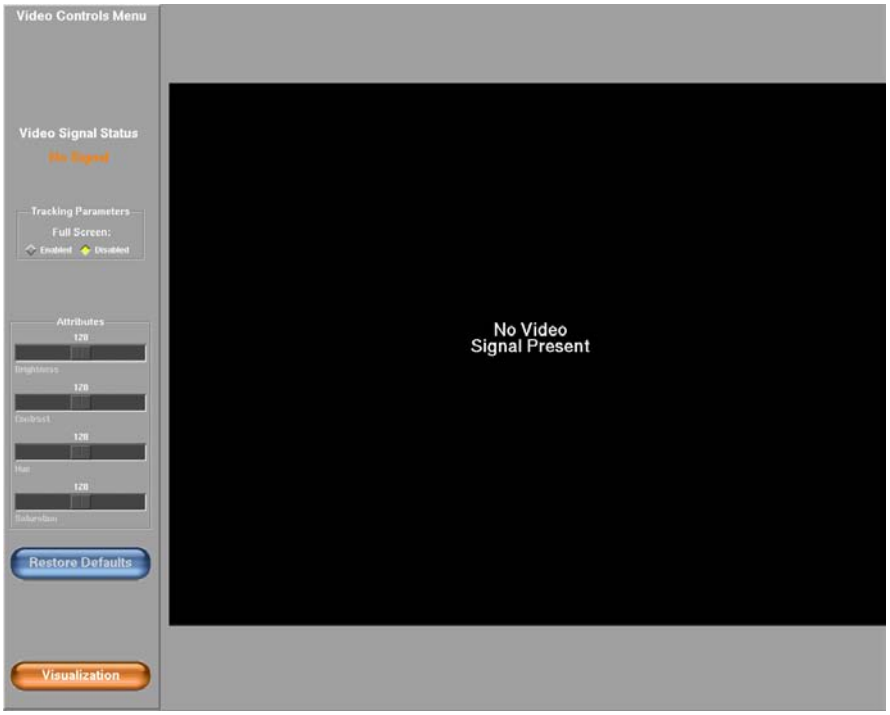


Figure 4-71. Video Controls Menu

While Tracking is inactive, the video image can be shown on the display.

Select Enabled: The video appears as full screen when tracking is off.

Select Disabled: When tracking is off, the screen displays the three orthogonal views and the 3D model. The crosshairs remains in the last position that was set.

Figure 4-72. Full Screen Video Display

The **Right Mouse** button is reserved for video control while tracking is inactive and the Full Screen Video option is enabled. Clicking the **Right Mouse** button when video is being displayed causes the full screen video picture to be toggled on and off.

If a Video Signal is not detected by the system, the VIDEO CONTROLS MENU or clicking the **Right Mouse** button displays the message “No Video Signal Present”.

If the VIDEO CONTROLS MENU indicates “No Signal,” be sure that the device’s video is connected properly to the system.

Note: To access the **Calibrate** and **Verify** buttons when the full screen video view is enabled, either click the **Right Mouse** button or select the **Close** button to remove the video display.

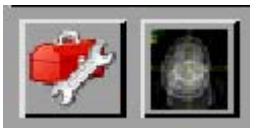
Note: The **Calibrate** and **Verify Status** buttons on the full screen view are only labels and do not function as calibrate and verify buttons.

Selecting the **Restore Defaults** button returns the video attributes to the factory settings.

5
Procedural Capabilities

Procedural Capabilities

The icons on the bottom left of the Display enable you to access procedural capabilities, such as trajectory guidance and Image Fusion.



1 2

Figure 5-1 Procedural Capabilities Icons

The icons are:

1. Tool Options
2. Image Fusion

Note: Image Fusion is an optional feature.

Tool Options

To enter the Tool Options Task Window, select the **Tool Box** Icon.

The **Tool Options** choices enable you to tailor the display when using an instrument with a trajectory, such as a pointer.

Trajectory

Trajectory enables you to adjust the length of the trajectory on Instruments such as the pointer.

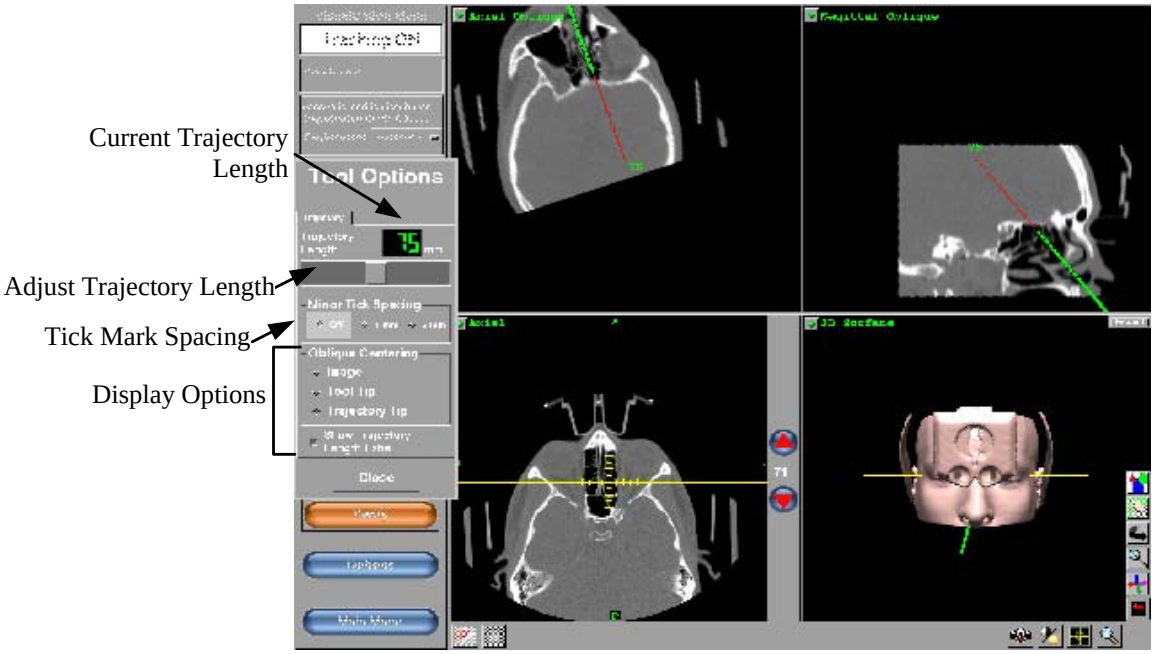


Figure 5-2. Tool Options Task Window

The following adjustments can be made in the Tool Options Task Window.

Trajectory Length – the length of the trajectory can be adjusted from 1 mm to 150 mm using the **Trajectory Length** slider bar. The current length of the trajectory is displayed above the slider bar. To select the length for the trajectory:

- Select the slider bar and move it until the desired length is displayed.

WARNING

It is recommended that the Trajectory be limited to a maximum of 100 mm.

Minor Tick Mark Spacing - The trajectory is marked with major tick marks every 10 mm. Minor tick marks can be turned off or spaced at 1 mm or 5 mm. To select the spacing for minor tick marks:

- Select the appropriate checkbox
  - Off
  - 1 mm
  - 5 mm

To magnify the tick marks , use the **Zoom Control** icon at the bottom right of the display.

Oblique Centering

The **Oblique Centering** selection can be used to determine the image component to be centered within the display window when the **Oblique Views** are selected. The choices are:

- Image
- Tool Tip
- Trajectory Tip

To change the component to be centered, select the appropriate box.

Show Trajectory Length Label

Although the length of the trajectory is displayed in the **Trajectory Task Window**, it is helpful to show it at the end of the trajectory. To show the selected trajectory length, select **Show Trajectory Length Label**.

WARNING

When using Instruments with trajectory guidance, it is recommended that the Trajectory length be limited to 100 mm.

Image Fusion

Image Fusion is the process of taking two or more patient scans and fusing them. *Image Fusion* is an optional feature for the *InstaTrak® 3500 Plus Advanced ENT Application*.

For more information on *Image Fusion*, see the *Image Fusion Operator's Manual*.

6
POST-OPERATIVE

Post-Operative Checklist

Refer to the *InstaTrak 3500 Plus Operator's Manual* for more details and instructions for all post-operative procedures.

- Remove the draping from the patient.
- Remove the headset and Verification Pad from patient, if applicable.
- Remove the Transmitter from the Transmitter Attachment Arm or the headset.
- Remove the pointer or the button probe from the receiver(s).
- Dispose of all single-use items.
- Clean and sterilize any reusable items. Refer to the *Cleaning and Sterilization Addendum (#1007295-NAV)* for instructions.

The Button Probe

The Button Probe may be sterilized up to ten (10) cycles.

⚠ ***CAUTION***
Sterilization of the Button Probe should be limited to ten cycles.

The Button Probe, P/N 1003632

The button probe, P/N 1003632 requires disassembly for cleaning and sterilization.

Note: The following disassembly directions are only for the *Button Probe*, P/N #1003632. The *Button Probe*, P/N #1006909 is a one-piece design and does not require disassembly.

To disassemble the Button Probe:

- Remove the Button Probe from the Docking Station
- Remove the button lever by gently squeezing the tabs on the sides of the Button Probe until the pivot pins disconnect from the pivot holes.

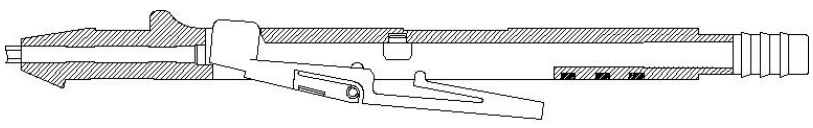


Figure 6-1. Button Probe - P/N 1003632

CAUTION

Prior to each use, visually inspect the Button Probe and the docking station. Discard any part that is visually distorted, broken and/or in which the probe is no longer seated securely within the molded handle.

Note: Multiple sterilization cycles may cause discoloration of the plastic components. This is normal and will not affect the performance of the device.

Detaching the Transmitter From the Mayfield Transmitter Attachment Arm

- Remove the draping from the patient.
- Remove the patient's head from the Mayfield headframe.
- Unscrew the "starburst" attachment of the transmitter Attachment Arm from the Mayfield headframe.
- Remove the transmitter from the transmitter Attachment Arm for the Mayfield Stabilization System
  - Turn the latch on the back of the transmitter until it is aligned with the slot on the Attachment Arm
  - Remove the transmitter from the Attachment Arm

Figure 6-2. Removing Transmitter from Attachment Arm

The transmitter attachment arm can be cleaned, but sterilization is not necessary, since the transmitter is completely covered with a sterile drape.

Detaching the Transmitter From the Universal Transmitter Attachment Arm

- Remove the draping from the patient.
- Loosen the clamps on the Universal Attachment Arm.
- Remove the attachment arm from the headframe.
- Remove the transmitter from the Universal Attachment Arm

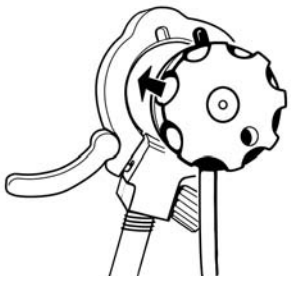


Figure 6-3. Removing the Transmitter from the Universal Attachment Arm

- Open the latch on the attachment arm to release the transmitter.
- Remove the transmitter from the attachment arm.

Removing the Headset

- Remove the draping from the patient.
- Remove the earpieces of the headset from the patient's ears and gently lift the headset off the patient's head.
- Remove the Verification Pad from the patient's nose, if applicable.
- Remove the transmitter by turning the latch on the back of the headset until it lines up with the slot.

Detaching the Transmitter and Receiver(s) from the System

- Firmly grasp the transmitter and receiver(s) connector where it is inserted into the system.
- Pull the connector straight out from the front panel of the system. Do not pull on the cables.

- Attach the soaking cap tightly to the transmitter and receiver(s) before cleaning and sterilization.

CAUTION

Do not pull on the cables to remove the Transmitter and Receivers from the System. This can greatly shorten the cable life span. Pull on the connector, not the cable.

Removing the Instrument from the Receiver

- Pull the pointer or button probe straight up out of the Docking Station to remove.
- Lift up the tab on the Docking Station to remove from the receiver.

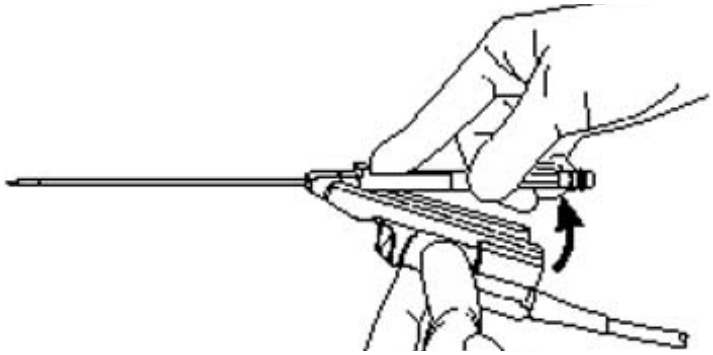


Figure 6-4. Removing Pointer from the Docking Station

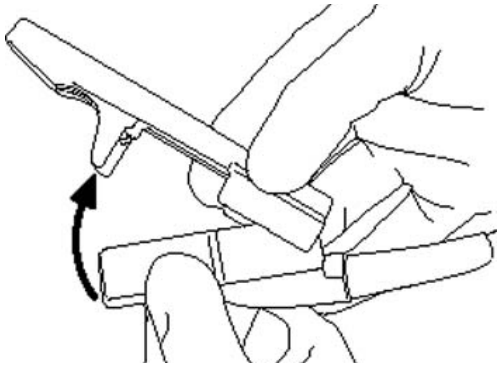


Figure 6-5. Removing Docking Station from Receiver

Shutting Down the System

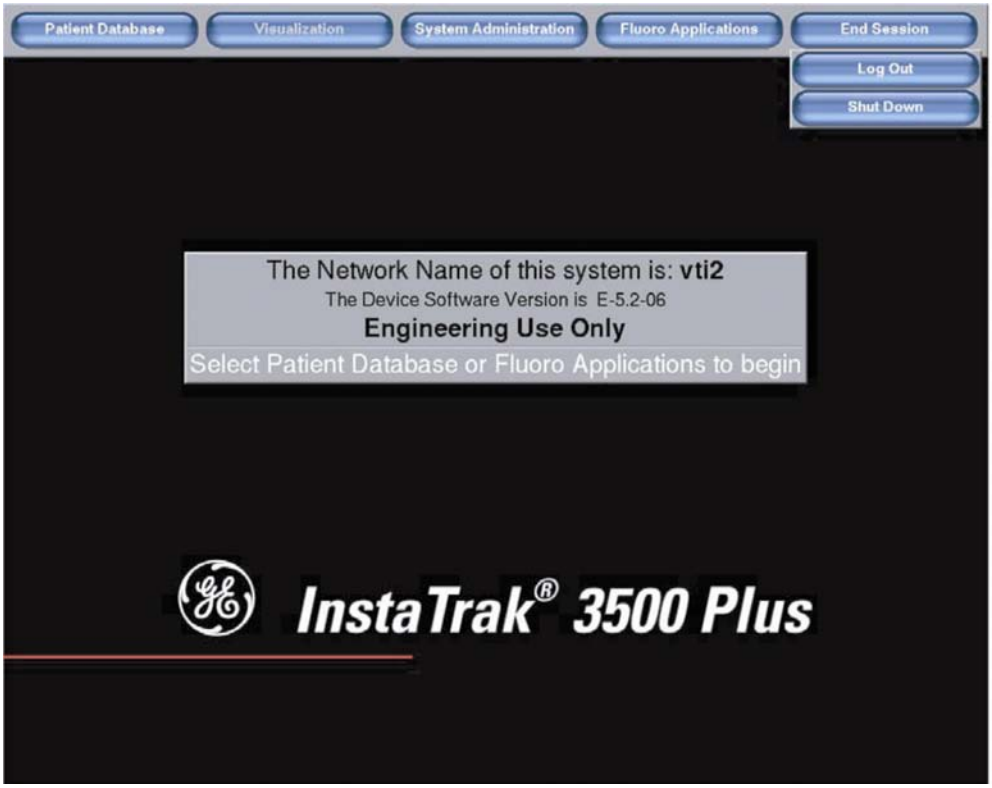
When the procedure is complete, the System must be shut down using the proper powering-off process.

CAUTION

Turning the power off without using the shutdown process may result in technical problems with the System.

To properly shut the System down:

- Go to MAIN MENU
- Select **End Session**
- Select **Log Out** or **Shut Down**



End Session, Log Out, and Shut Down Buttons

Figure 6-6. System Shutdown

Logging Out of the System

Logging out of the system enables you to lock the screen and system use. The system remains on and scans can be transferred to it if the system is connected to the network.

To log out of the system, select the Log Out button from the MAIN MENU. The system will remain locked until you log back in.

Shutting Down the System

Shutting down the system enables you to power it off. When the system is shut down, scans cannot be transferred to it.

To shut down the system, select the **Shut Down** button from the MAIN MENU. You can also shut down the system from the Log In Display.

After selecting the **Shut Down** button, a message appears asking you to validate the shut down.

Figure 6-7. Confirm Shutdown Message

Select **Yes** to begin the shutdown process. When the message, "Power Off" appears on the Display, you can turn the system off. Select **No** to cancel the shutdown process.

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