

NavENT

User Manual





NaviENT User Manual
Part No: 990-NE-UMUS Rev D
©2017 ClaroNav Kolahi Inc.



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0086

Caution: U.S. Federal (and Canadian) law restricts this device to sale by or on the order of a licensed medical practitioner.

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1 Indications, Safety and Warnings

1.1 Intended use

NaviENT is a computerized surgical navigation system intended to guide sinus and trans-nasal skull base endoscopic surgery by dynamically presenting the location of the tip of a surgical instrument mapped to a corresponding location in a pre-acquired CT scan of the patient's head. The device is intended for use by a qualified ENT surgeon (otolaryngologist).

NaviENT is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to images of the anatomy. Surgery procedures include but are not limited to the following: transphenoidal procedures, maxillary antrostomies, ethmoidectomies, sphenoidectomies, sphenoid explorations, turbinate resections, frontal sinusotomies, intranasal procedures, intranasal tumor resections, and ENT related skull base surgery.

1.2 Contraindications

Medical conditions which contraindicate the use of NaviENT include any medical conditions which may contraindicate the medical procedure itself, and cases in which the patient CT image does not include forehead area.

The use of NaviENT should be terminated when the accuracy check prior to the initiation of tool guidance has failed. For more details see section 5.8.1.

1.3 Conventions used in this manual

 CAUTION	Cautions are directions which, if they are not followed, can cause damage to the system described in this manual.
 WARNING	Warnings are directions which, if they are not followed, can cause fatal or serious injuries to a user, engineer, patient or any other person or can lead to a mistreatment.

1.4 General warnings



Caution: U.S. Federal (and Canadian) law restricts this device to sale by or on the order of a licensed medical practitioner.

The system and its associated applications should be used only by qualified medical professionals who are thoroughly trained and experienced in performing NaviENT-guided surgery.

NaviENT should be used only as an adjunct for surgical guidance. NaviENT is not a replacement for the surgeon's knowledge, expertise, or judgment.

The user is instructed to perform accuracy checks prior to navigation. If navigation guidance seems inaccurate and recommended steps to restore accuracy are not successful, abort use of the system.

NaviENT should not be used when there are noticeable patient motion artifacts in the CT image or if the CT image does not include any of the patient forehead, dorsum of nose, base of nose and eye laterals.

Inspect all system components before use. If visibly damaged, do not use the system.

Do not attempt to modify or alter the system or any of its components in any way, since doing so can impair its function.

1.5 General cautions



Do not install any other software on the laptop to prevent compromising the system performance.

Do not connect any other equipment to the laptop except the accessories provided (Thunderbolt connection for the tracking camera and DVD drive and an external memory USB drive)

While the laptop computer and the tracking camera may be operated on battery power alone for some period, the tracking system IR LED will remain turned off when operated on battery and therefore performing guidance on battery alone is not recommended. It is also possible that the battery will become fully discharged in the middle of the operation, causing the system to shut down.

When the system is connected to a main power source, make sure it is positioned in a way that would allow for a quick and easy disconnection from the mains, should the need arise.

Verify that all instruments (Registrator, Maxillary and Frontal Seekers, Bayonet Pointer, Calibrator, Silicon strap, Universal Tag, Clamp and thumb screw) have been steam sterilized (Autoclaving) according to the instructions provided in Section 0.

Patient Tracker must be disinfected before surgery following the instructions provided in Section 3.2. Do not heat the Patient Tracker above 80°C (180°F) or attempt to steam-sterilize it, since this may create geometrical distortions which will compromise the system's accuracy.

None of the electronic components of NaviENT is designed for sterilization, and may be damaged if sterilization is attempted. If contact of sterile glove surfaces with electronic components is needed during surgery, use a sterile barrier, such as a sterile disposable nylon sheet.

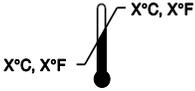
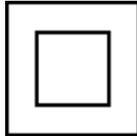
The system has been tested against the requirements of IEC 60601-1-2. However, RF interference could hamper its operation or the operation of other nearby electrical devices. If you suspect either of these conditions, move the interfering equipment away from NaviENT, separate the equipment with an RF barrier, or discontinue use of the system.

Avoid dripping any fluids into or on the laptop computer surface. Disconnect the power; turn the laptop computer off and allow the system to dry if you suspect fluids may have entered any part of the system.

During system operation, maintain the acceptable ranges for temperature and humidity (for details, see Section 1.8)

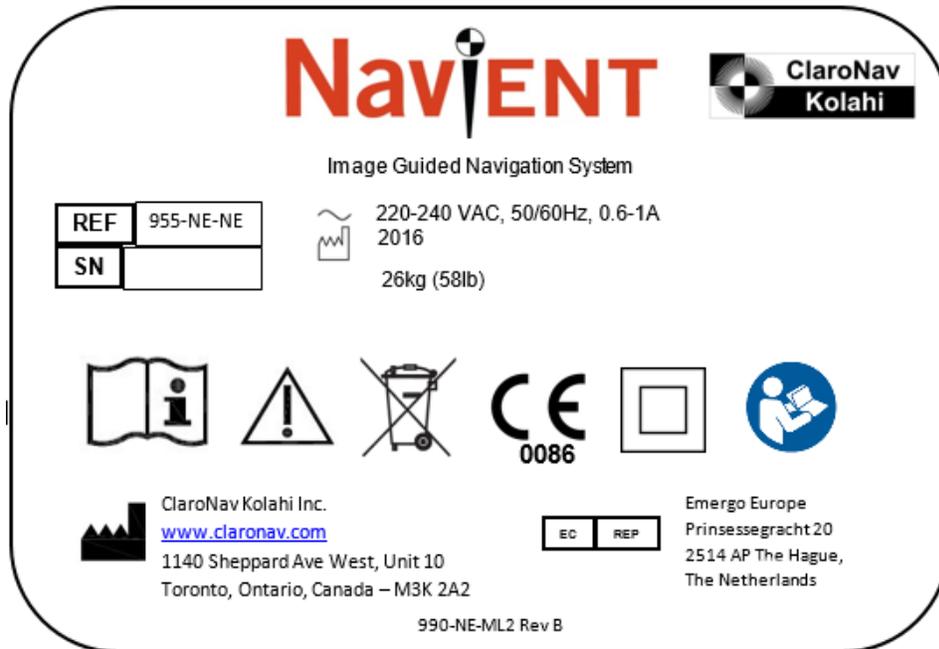
1.6 Device and Label symbols

Symbol	Definition
	Catalogue number
	System serial number
	Follow instructions for use
	Caution, consult documents
	Not suitable for regular trash disposal
	Certification mark
	Manufacturer's name
	Batch code
	Upper temperature limit – Do not store in temperature above 45°C
	Non sterile

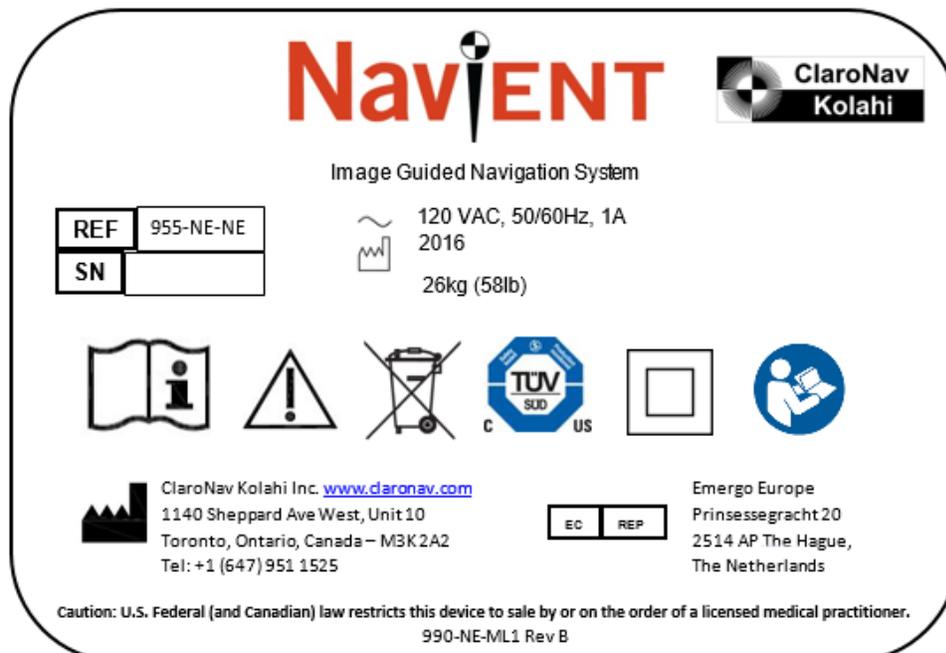
Symbol	Definition
	Re-use is not allowed
	Fragile item, handle carefully
	Do not expose to sunlight
	Humidity limitation
	Atmospheric pressure limitation
	Temperature limitation
	Double insulation (class II device)
	Follow instructions for use
	Do not push the equipment while in use
	Power button

1.7 Safety warnings and compliance labels

The NaviENT system is fitted with a label. This is located at the rear panel of the system.

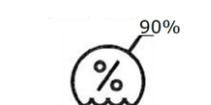
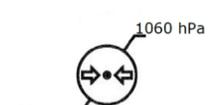


NaviENT label for Europe (top picture) and US & Canada (bottom picture)



1.8 Environmental standards

The following table details the recommended environmental standards required for correct operation of NaviENT.

	Operating temperature	15° to 34°C (59° to 93°F)
	Storage temperature	-25°C to 45°C (-13° to 113°F)
	Humidity	10% to 90% noncondensing
	Atmospheric pressure	700 - 1060 hPa (up to 2000 m)

1.9 Data Security

NaviENT loads patient datasets from external data sources using CD/DVD, USB or a network drive. Only use CD/DVD and USB drives created by secure sources. Do not connect them to the NaviENT laptop if they are not from well trusted sources as it may contain virus or malware and can damage NaviENT laptop. The DVD and USB drives should only include patient scan information generated by the scanning devices.

NaviENT comes with pre-installed Microsoft firewall and provides basic security when the system is connected to the network. Do not connect NaviENT laptop to an unsecure wireless network.

Note: NaviENT is provided with a secure password and user Identification number. It is recommended to change the laptop password at the first use (The default password for the first login is “navient”) and every 6 months afterward and to always lock the NaviENT laptop screen when left unattended.

1.10 General information

Do not drop system components or mishandle them in such a manner as to cause them physical damage. This may impair device function. Even if the component works immediately after being dropped, operational damage may have occurred that may not be observed until some future time.

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

1.10.1 Transport

When moving NaviENT cart, fold the arm into the pole, and fold the tray with the laptop against the folded arm (see the picture). Hold the cart by its handle and wheel it to its new location.

To prevent the cart from rolling down a slope, place both wheels inside the two wheel stoppers provided in the accessories kit, as shown in the picture below.



1.10.2 Laptop Battery Usage and Maintenance

The laptop uses Lithium-Ion rechargeable batteries. For optimal performance, NaviENT should be plugged into a mains power outlet during surgical use, in which case the batteries will not be used to power the laptop.

1.10.3 Cleaning & Disinfection

When cleaning NaviENT, first shut down the computer and unplug the power cable. Use a damp, soft, lint-free cloth to clean the cart and the laptop exterior. Avoid getting moisture in any openings. Do not spray liquid directly on the laptop. Don't use aerosol sprays, solvents, abrasives, or cleaners containing hydrogen peroxide that might damage the surface finish of the parts.

Use a damp cloth soaked with alcohol solution (70% or higher) to disinfect surfaces that may come into occasional contact with liquids during surgery, such as the laptop's keyboard and screen, the camera box and the front pole holding them. In preparation for surgery, ensure that all surfaces that may need to be touched by sterile gloves, such as the tracking camera, the laptop trackpad and the front pole, are covered with sterile sheets.

NaviENT Patient Tracker is a reusable part. Between uses, it should be scrubbed with a wet and soapy brush and thoroughly rinsed with deionized (DI) water to remove any visible residual and dried with a clean, soft cloth. Examine the part for visible soil. If present, repeat cleaning. Once the part is cleaned it should be disinfected using a nylon compatible disinfectant, such as Metricide, Sporox or Cidex. Patient tracker tape strips are single use parts and should be disposed right after using. Place a new tape strip on the Patient Tracker after the Patient Tracker was disinfected.



Do not heat the Patient Tracker above 80°C (180°F). Steam-sterilizing it may damage the part and create geometrical distortions which will compromise the system accuracy in unpredictable ways.

NaviENT Universal Tag Adapter should be mounted on the surgical instrument and sterilized together with it using autoclaving.

1.10.4 Disposal



This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact CKI or your distributor for information concerning the decommissioning of your equipment.

If assistance is desired in the proper disposal of the NaviENT product (including unused disposable accessories and components), after its useful life, please return to CKI or your distributor.

2 Basics

2.1 Principles of operations

NaviENT's guidance function is based on CT image data acquired prior to the procedure, combined with optical measurements of the pose of navigated instruments relative to the patient's head. To enable navigation, the Patient Tracker is attached to the patient's forehead to enable tracking of the patient's head, and the image data is loaded to NaviENT. The image data is then spatially registered with the patient's head by matching landmark locations marked on both the image and the patient, followed by matching a path traced by the user on the patient's face with a model of patient's face surface automatically generated from the image data. Subsequently, NaviENT presents the location of a navigated instrument tip as mapped on the image data through the registration transform.



Patient Tracker attached on patient forehead

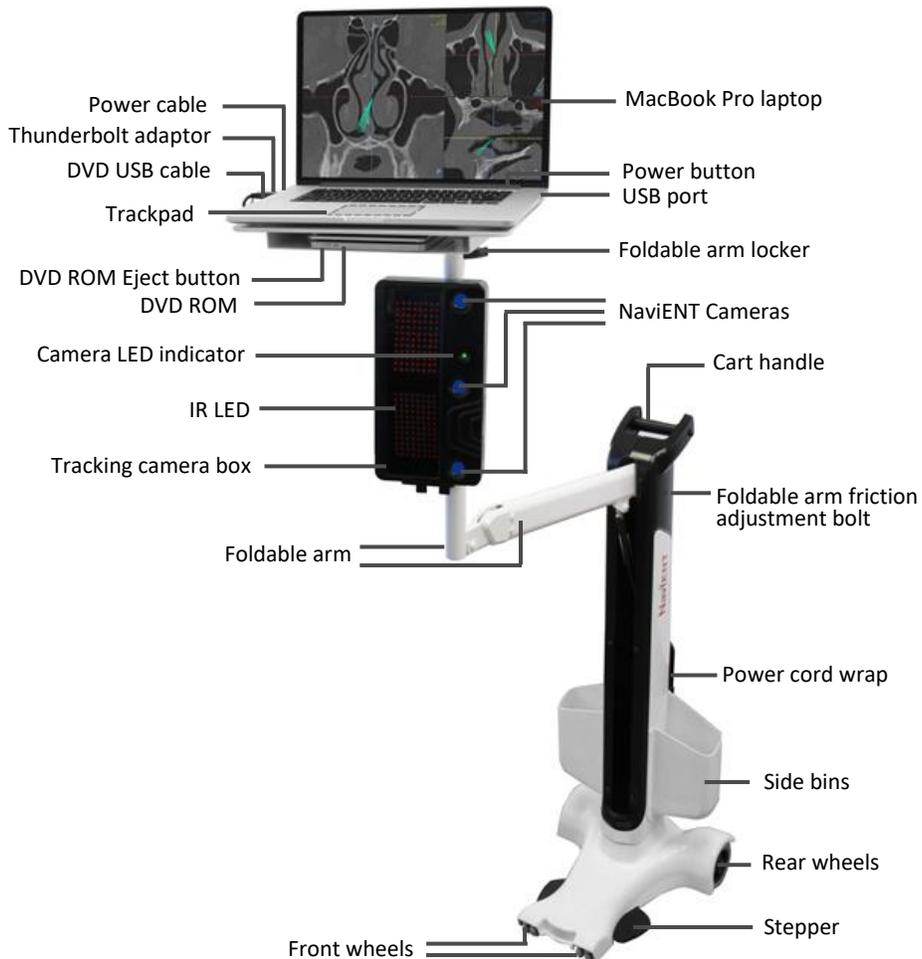
NaviENT provides instruments including Registrator, maxillary seeker, frontal seeker and a bayonet pointer for general identification of anatomical locations. Navigation of other surgical instrument is enabled using a universal tag which can be attached to any surgical instrument; the location of the tip of the instrument relative to the tag is calibrated by placing the tip at a designated location on the Calibrator for a few seconds.

The Tracking Camera box contains a stereoscopic NaviENT camera and an IR light source, both operating in the near infrared (NIR) light spectrum. The tracking software identifies and pin-points the center of checkered-pattern targets, called XPoints, marked on the instruments or the

Patient Tracker. The constellation of XPoints marked on an object, such as an instrument or Patient Tracker, is called a “marker”. Software running on the laptop computer processes the stereoscopic video images captured by NaviENT Camera to detect and triangulate the positions of XPoints. The relative positions and orientations of the detected XPoints are compared to marker templates stored in the computer memory to identify the instrument and its pose relative to the tracker. At least 3 or 4 XPoints need to be detected for a successful marker identification and pose measurement. The location and orientation of the tip of each instrument relative to its XPoints is also stored in the marker template, and is used in mapping the tip to the CT image.

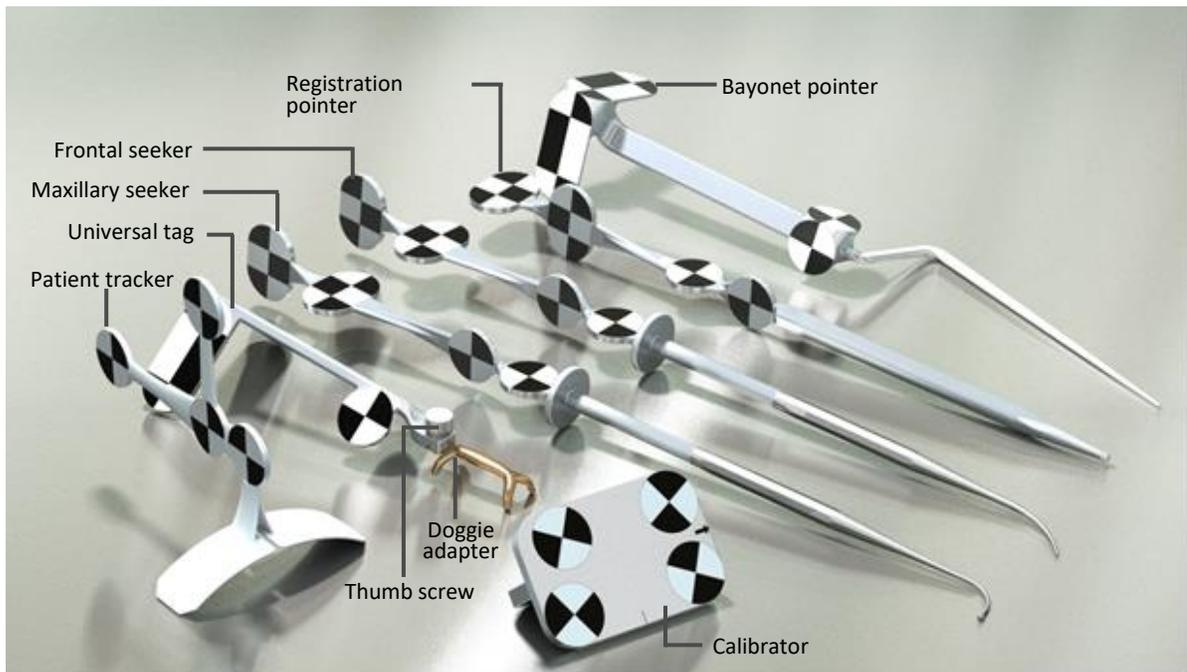
2.2 NaviENT components and accessories

The picture below shows a fully assembled NaviENT system. It includes a MacBook Pro laptop



and a tracking camera mounted on the NaviENT cart. The cart arm can be folded to make it compact and easily portable. The MacBook Pro runs the NaviENT software which displays the position of pre-calibrated instruments superimposed on the pre-operative CT scans. The enclosure below the laptop contains an infra-red (IR) light emitting diodes (LEDs) lighting panel and the NaviENT Camera, a stereoscopic tracking camera, which feeds a video stream to the laptop for further processing.

NaviENT also includes an Instruments kit consisting of a Patient Tracker, a registration pointer (Registrator), Maxillary and Frontal Seekers, Universal Tag, Bayonet Pointer and a tip Calibrator (see picture below).



NaviENT instruments

3 Safety Information

3.1 Preventing navigation inaccuracy

While a properly used navigation system reduces the likelihood of surgical complications, the system is fallible and may occasionally misguide you. The system requires navigation accuracy verification at regular intervals.



NaviENT should not be used to make important surgical decision without first validating its correctness using recognizable surface and landmarks.

To minimize the risk of injury to the patient due to incorrect localization, navigation accuracy must be verified at regular intervals.

You can reduce the likelihood of navigation errors by being aware of the key factors degrading accuracy and acting to minimize or prevent them:

Registration error: Mis-registration is the most common reason for localization errors. Following the registration step, immediately perform an accuracy check, and, in case of doubt, redo the registration (see section 5.8).

Instrument tip calibration error: NaviENT tracks the position of markers (the checkerboard patterns on each tool), rather than the tips of instruments. To map the location of the instrument tip to the CT image volume, NaviENT needs to accurately know the position of the instrument tip relative to the relevant marker. For accurate operation, it is critical that that position would be validated, and, as needed, correctly calibrated.

Patient Tracker movement: Movement of the Patient Tracker relative to the skull will invalidate the registration. When mounting it, ensure that the tag is well attached to the skin and avoid touching it for the duration of the surgery. In case you suspect it may have moved, perform an accuracy check and, as needed, repeat the registration.

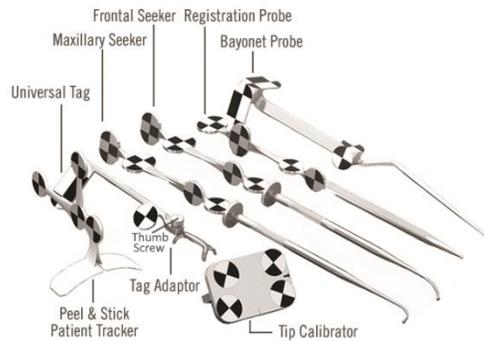
Tracking camera mishandling: The tracking system is a high precision instrument and should be treated carefully. When handling its enclosure, avoid shaking, dropping or mishandling of the device. Do not open the enclosure. In case you suspect the tracking system may not be operating correctly (e.g., following an accidental shock or when marker detection becomes unreliable), you should check tracking system accuracy by performing the R-Fine procedure. The R-Fine application is installed on the NaviENT computer and is activated using a desktop icon (see Appendix A for details).

3.2 Cleaning and Sterilization prior to usage

3.2.1 Cleaning

The following instructions for cleaning must be followed prior to use for the following NaviENT parts:

950-NE-RP Registration Pointer
950-NE-BP Bayonet Pointer
950-NE-FS Frontal Seeker
950-NE-MS Maxillary Seeker
950-NE-TC Tip Calibrator
950-NE-PT Patient Tracker
950-NE-UT Universal Tag
950-NE-UTA Universal Tag Adaptor
950-NE-UTC Universal Tag C-Clamp
950-NE-TS Thumb Screw



Warnings:

- Clean the instruments prior to first use and after each use.
- Before sterilization, disassemble the Universal Tag from its Adaptor or C-Clamp and the thumb screw(s).
- Remove and properly dispose of the single-use silicon tape used for Universal Tag and the Patient Tracker dual sided tape.

Instructions:

1. Promptly and thoroughly rinse the instrument under running tap water to remove any visible soil. This step should be done at the Point-of-Use to prevent the drying of soil on the device surface. A soft-bristled brush or clean cloth may be used to aid in soil removal.
2. Prepare an FDA approved enzyme based detergent according to the detergent manufacturer's recommendations.
3. Immerse the instrument in the enzymatic detergent solution and let it soak for a minimum of two (2) minutes.
4. Thoroughly clean the instrument using a soft-bristled brush and remove all foreign matter.
5. Flush crevices, lumens, and blind holes in the instrument with fresh detergent solution until the solution runs clear.
6. Thoroughly rinse the instrument in deionized (DI) water for a minimum of one (1) minute to remove any residual detergent.
7. Flush crevices, lumens, and blind holes in the instrument with DI water.
8. Dry the instrument with a clean, soft cloth.
9. Examine the instrument for visible soil. If present, repeat cleaning.

3.2.2 Steam sterilization (Autoclave)

The following instructions for sterilization must be followed prior to use for the following NaviENT parts:

950-NE-RP Registration Pointer
950-NE-BP Bayonet Pointer
950-NE-FS Frontal Seeker
950-NE-MS Maxillary Seeker
950-NE-TC Tip Calibrator
950-NE-UT Universal Tag
950-NE-UTA Universal Tag Adaptor
950-NE-TS Thumb Screw
950-NE-ST Silicon Tape

Warnings:

- Instruments must be adequately cleaned prior to sterilization.
- Remove the plastic backing of the silicon tape prior to sterilization.
- Before sterilization, disassemble the Universal Tag from its Adaptor or C-Clamp and the thumb screw(s).

Instructions:

1. Instruments should be individually wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC200 – 510(k) K082554) using sequential envelope folding techniques.
2. Cut silicon tape in pieces of 6inch (15cm) long, remove its plastic backing and wrap them individually.
3. The sterilization process should be done according to the following parameters:
 - Sterilizer Type: Prevacuum
 - Preconditioning Pulses: 4
 - Temperature: 132 °C
 - Exposure Time: 4 minutes
 - Dry Time: 30 minutes

3.2.3 Disinfection

The following instructions for disinfection must be followed prior to use for the following NaviENT parts:

950-NE-PT Patient Tracker

Warnings:

- Remove and dispose the dual sided patient tracker tape

- Patient Tracker must be adequately cleaned prior to disinfection.
- Do not sterilize patient tracker. It will be damaged if heated above 80°C (176°F).

Instructions:

1. Use FDA cleared/CE marked nylon compatible disinfectant, such as Metricide, Sporox or Cidex.
2. Prepare the disinfectant according to the manufacturer recommendation
3. Soak the patient tracker inside the disinfectant for the duration recommended by the manufacturer.

3.2.4 Cart cleaning

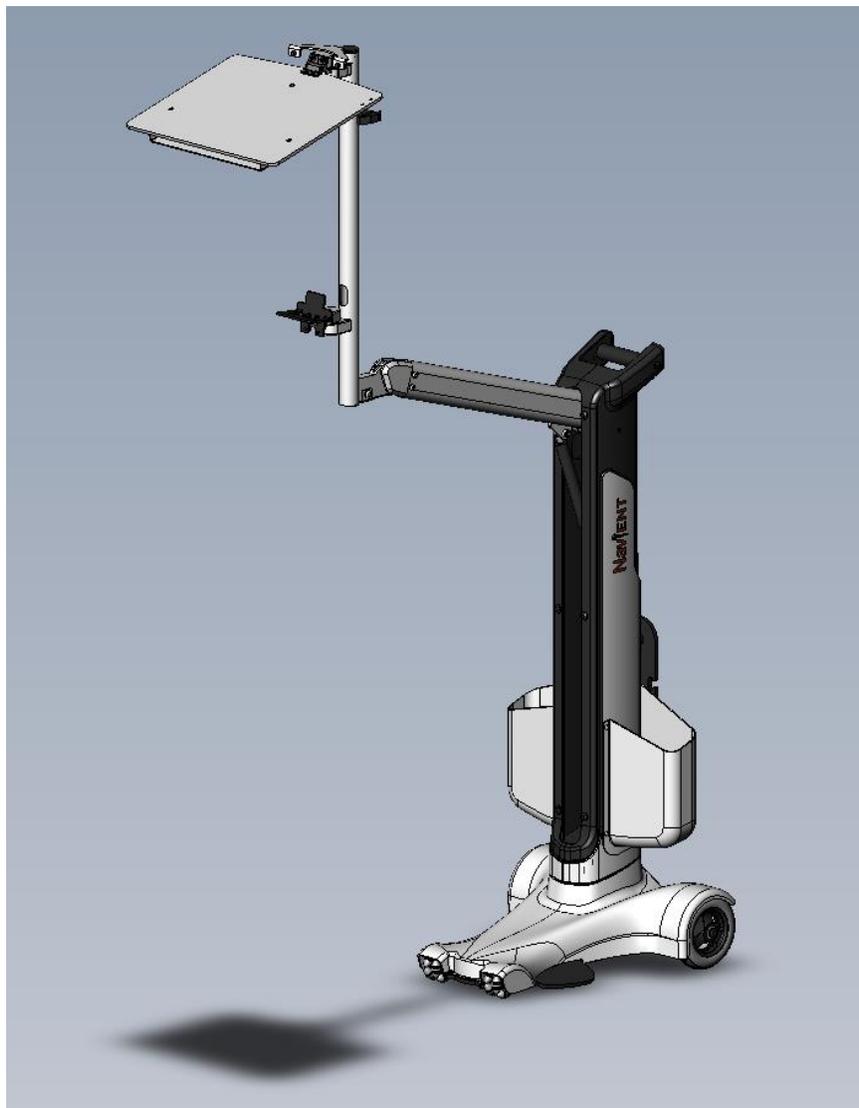
When cleaning the NaviENT cart, first shut down the computer and unplug the power cable. Use a damp, soft, lint-free cloth to clean the cart and the laptop exterior. Avoid getting moisture in any openings. Do not spray liquid directly on the laptop. Don't use aerosol sprays, solvents, abrasives, or cleaners containing hydrogen peroxide that might damage the surface finish of the parts.

Use a damp cloth soaked with alcohol solution (70% or higher) to disinfect surfaces that may come into occasional contact with liquids during surgery, such as the laptop's keyboard and screen, the camera box and the front pole holding them. In preparation for surgery, ensure that all surfaces that may need to be touched by sterile gloves, such as the tracking camera, the laptop trackpad and the front pole, are covered with sterile sheets.

4 Hardware components

4.1 NaviENT cart

NaviENT cart's main purpose is to hold the laptop computer and the tracking camera. The cart is light weight and the arm height can be adjusted. This allows the user to easily position the system in the operating room. The arm is opened by placing a foot over a black tab near the front of the base while pulling the front pole away from the back post. The arm is folded back by pushing it downward. The arm's friction can be adjusted (see Appendix D).



4.2 Tracking system

The Tracking System contains a stereoscopic NaviENT camera and an IR LED light source, both operating in the near infrared (NIR) light spectrum. The tracking system identifies and pin-points checkered marker patterns. It is important to have a clear line of sight between the tracking camera and the targets. The green LED in front of the tracking system indicates its status.



4.3 Laptop computer

The NaviENT software runs on a 15.4" Apple Mac Book Pro laptop. Windows 10 operating system is installed on the laptop. The tracking camera's live video stream is received by the laptop via a thunderbolt port and is processed by the NaviENT application.



4.4 Accessory kit

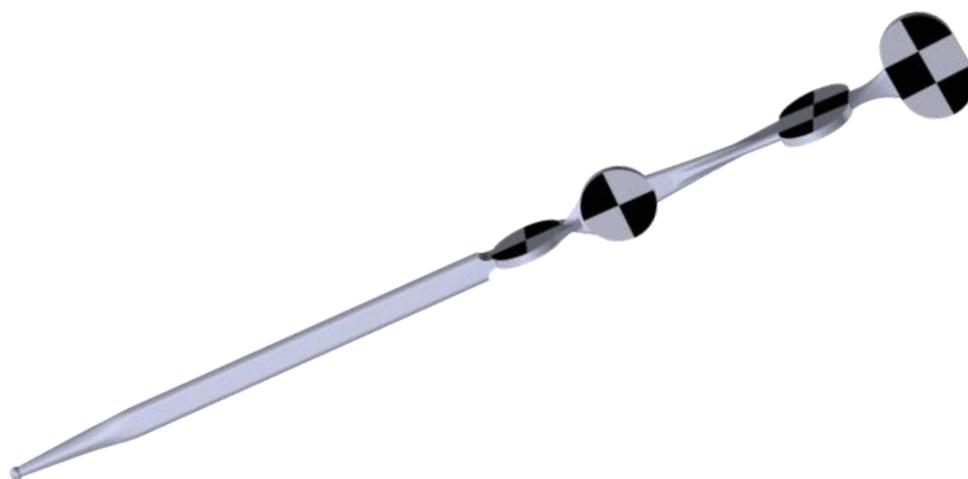
NaviENT system includes a set of accessories. All parts are steam sterilisable except the Patient Tracker. All instruments are marked with black and white patterns which make them trackable by the tracking system. It is important to have a clear line of sight between the tracking system and the targets.



4.4.1 Registrator

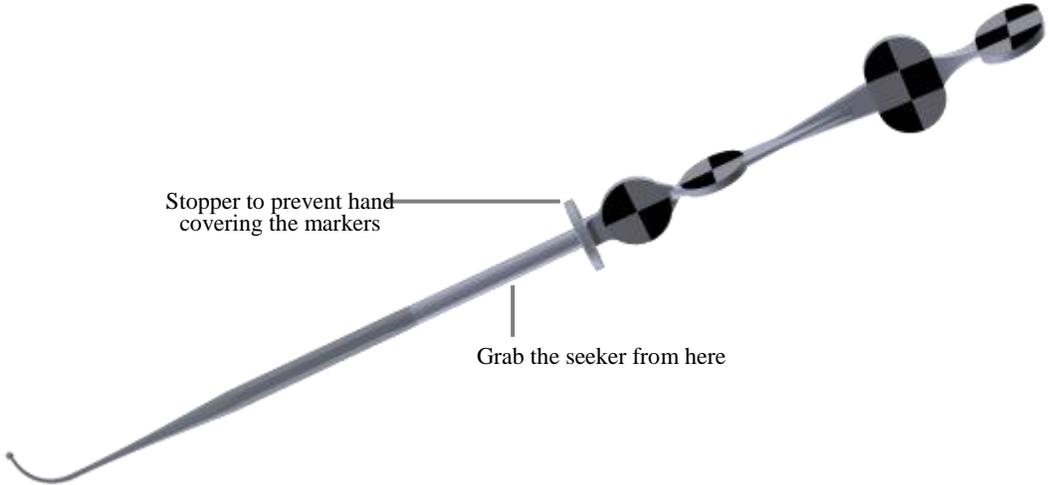
The picture below shows NaviENT registration pointer, called the Registrator. The Registrator is made of aluminium and is marked with black and white patterns that enable it to be detected by the tracking system. During registration, the surgeon touches patient landmarks with the Registrator's tip, and performs the trace registration by gliding the tip on the patient forehead.

Holding the Registrator above the patient's nose activates the floating menu.



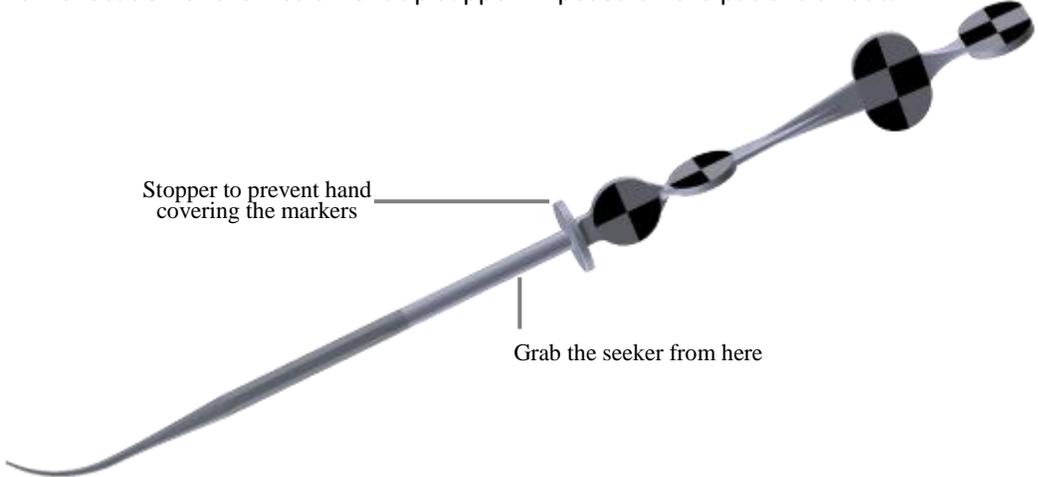
4.4.2 Maxillary Seeker

Picture below shows NaviENT Maxillary Seeker instrument. Maxillary seeker is a common instrument to reach maxillary sinus area. The NaviENT maxillary seeker includes an ergonomic attachment made of aluminium with black and white pattern that enables it to be detected by the tracking system. It is important to have a clear line of sight between the tracking system and the black and white patterns. Once detected, the NaviENT software will display the real time location of the instrument tip super-imposed on the patient CT data.



4.4.3 Frontal Seeker

Picture below shows NaviENT Frontal Seeker instrument. Frontal seeker is a common instrument to reach frontal sinus area. The NaviENT frontal seeker includes an ergonomic attachment made of aluminium with black and white pattern that enables it to be detected by the tracking system. It is important to have a clear line of sight between the tracking system and the black and white patterns. Once detected, The NaviENT software will display the real time location of the instrument tip super-imposed on the patient CT data.



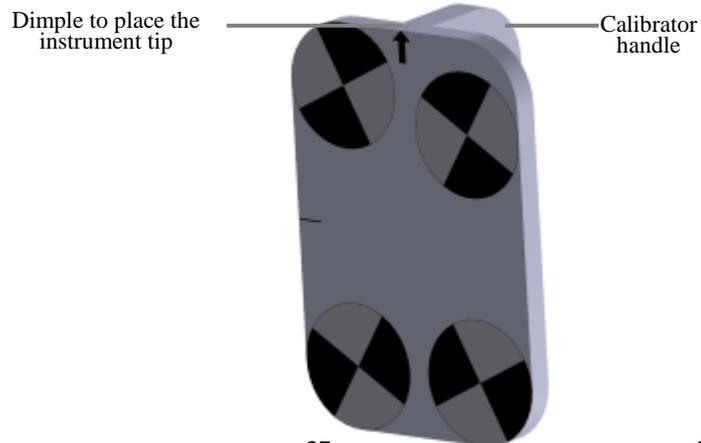
4.4.4 Bayonet pointer

Picture below shows the Bayonet pointer instrument. It is a bayonet shape pointer with a long tip made of stainless steel to allow surgeon to localize internal anatomies. The black and white pattern enables it to be detected by the tracking system. It is important to have a clear line of sight between the tracking system and the black and white patterns. Once detected, The NaviENT software will display the real time location of the instrument tip super-imposed on the patient CT data.



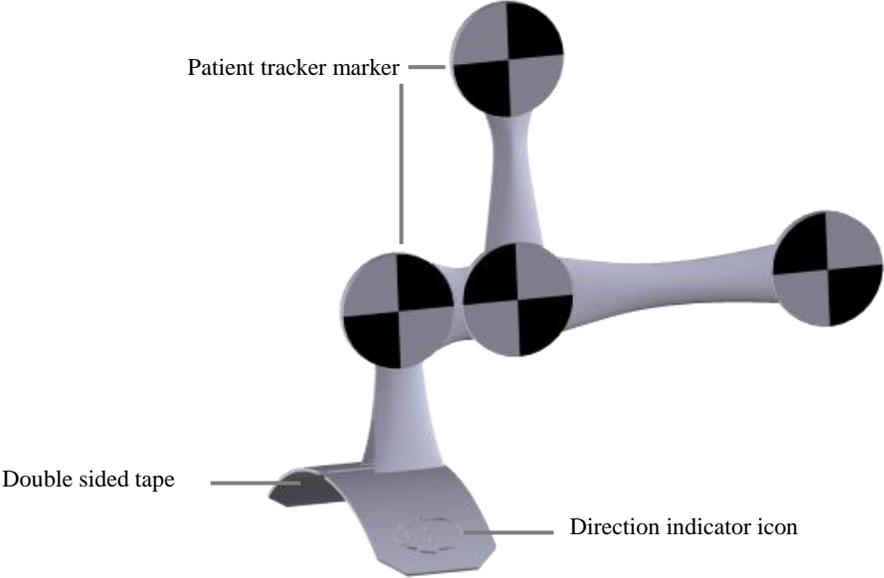
4.4.5 Instrument Tip Calibrator

Picture below shows the Instrument Tip Calibrator. Its main purpose is to calibrate instruments tip and make them trackable. A black and white pattern on the calibrator enables it to be trackable by the tracking system. To calibrate an instrument tip, the tip must be placed on the small dimple on the calibrator and then both the instrument and the calibrator must be presented to the camera. It is important to have a clear line of sight between the tracking system and the black and white patterns. Once both the instrument and the calibrator are detected, the software will display a progress bar indicating the tip calibration process.



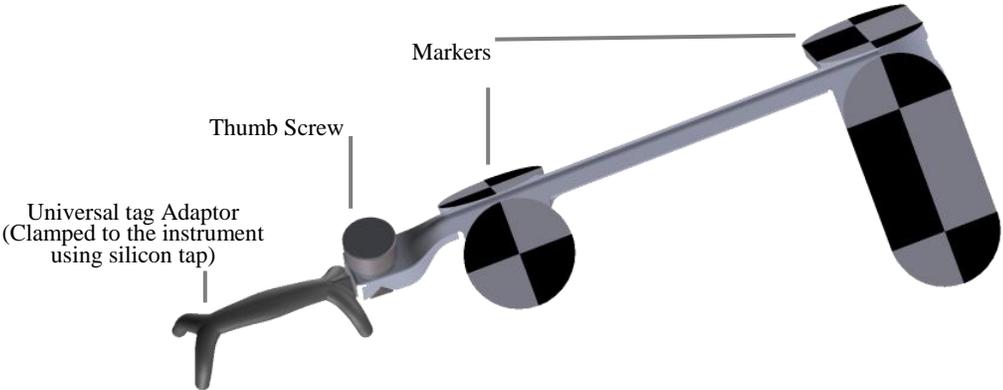
4.4.6 Patient Tracker

Picture below shows the Patient Tracker. It is made of plastic and is attached to the patient forehead with a double sided tape. It remains on the patient forehead for the entire duration of operation. The black and white pattern enables it to be trackable by the camera. It is important to have a clear line of sight between the tracking camera and the black and white patterns. Its main purpose is to locate the spatial location of the patient head.



4.4.7 Universal tag

Universal tag is designed to be attached to a shaver or endoscope instruments and enable them to be trackable by the tracking system. It does not contact patient. A silicon tape is used to attach the tag to the surgical instruments. Once attached, the user will need to go through the instrument tip calibration process. Once calibrated, the NaviENT software will display the real time location of the instrument tip super-imposed on the patient CT data.



4.4.8 Silicone Tape

It is a self-adhesive strong tape which is used to attach the universal tag to the surgical instruments like shaver and endoscope. Prior to use it should be steam sterilized. Cut silicon tape in pieces of 6inch (15cm) long, remove its plastic backing and wrap them individually and sterilize them according to section 3.2.

Silicon tape is a single use part and should be disposed after the use.



Silicon tape is steam sterilizable



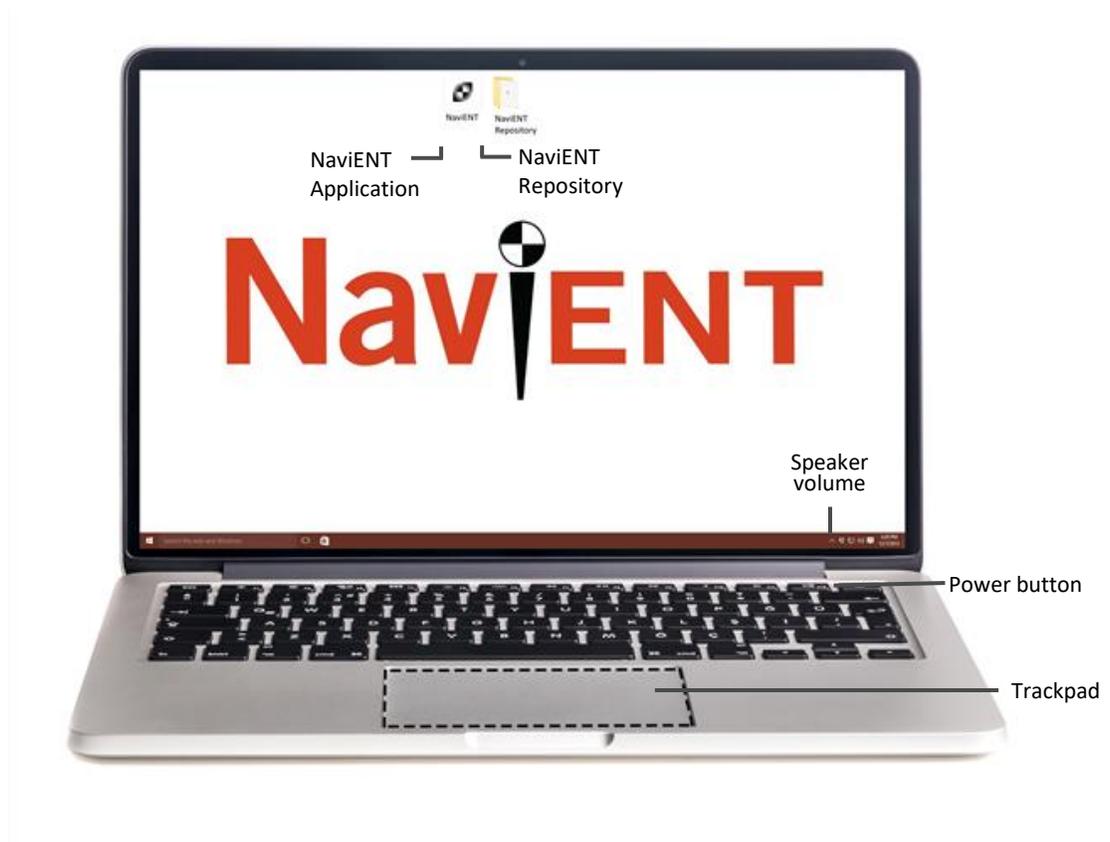
Silicon tape warped for sterilization

5 Software Workflow

5.1 Workflow overview

NaviENT software has been pre-installed on the MacBook Pro laptop. The shortcut for the **NaviENT** application and the **NaviENT Repository** folder are placed on the desktop (see picture below). Use the laptop trackpad to place the cursor over the NaviENT application icon, and then double click the trackpad to run the software.

NaviENT Repository is a folder where the NaviENT application stores all imported datasets locally. Section 5.3 explains importing patient scan data from CD/DVD to the repository and loading it to the application for guidance.



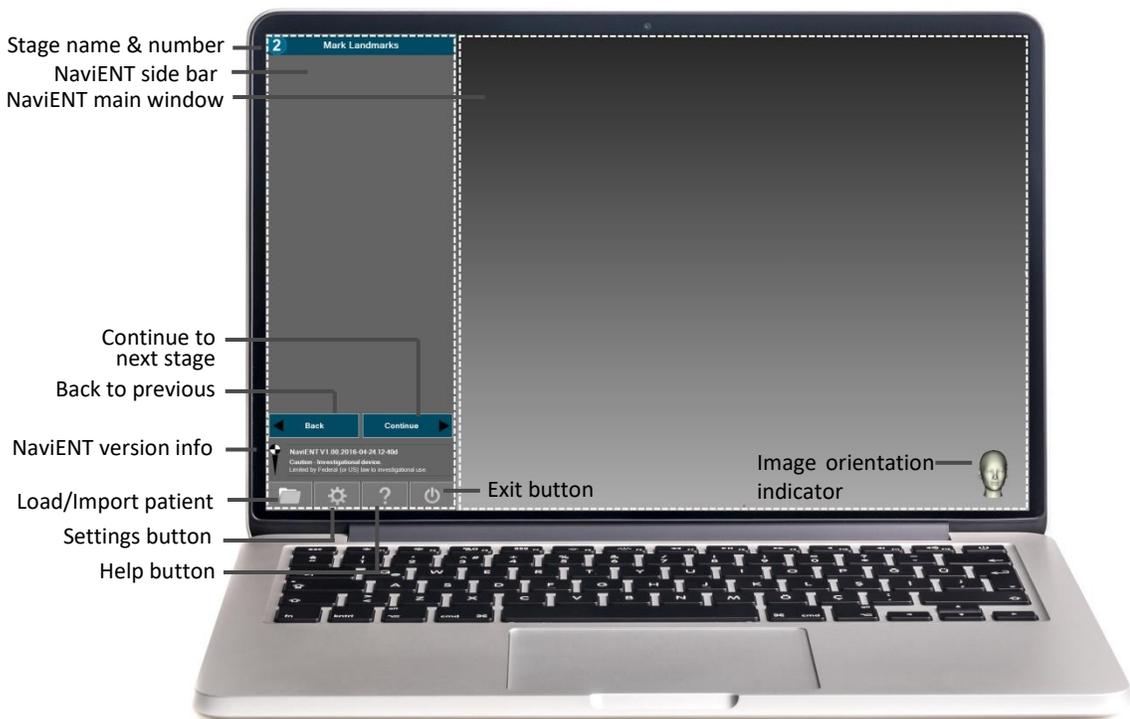
NaviENT software operation proceeds sequentially through 5 stages, or screens:

1. **Verify:** Load the image volume, verify and explore its contents.
2. **Mark Landmarks:** Mark easily identifiable anatomical landmarks on 3D-rendered views of the patient's skin.
3. **Set Up:** Stick the Patient Tracker to the patient's forehead, set up the tracking system position and verify the instruments' tip calibration accuracy.
4. **Register:** Using registrator, point to the marked landmarks on the actual patient's skin, then trace a path on the patient's face to refine the registration.
5. **Navigate:** Observe the position of the tip of various instrument in the image volume.

5.2 User Interface overview

Picture below shows the common user interface (UI) elements of the NaviENT application. The UI has two main components:

- **Main window:** reserved to show patient data
- **Sidebar:** reserved to show stage specific instructions and tracking camera video



On the top of the sidebar it shows the current stage number and name, the area below is reserved for displaying stage specific instructions and tracking system live video. Use **Back** and **Continue** buttons to navigate between stages. Four buttons are displayed at the bottom of the side bar at all stages:

- **Load/Import:** Opens a data browser window and enables loading a new data from the repository or importing a new data to the repository.
- **Settings:** Displays NaviENT application settings window (see section **Hata! Başvuru kaynağı bulunamadı.**).
- **Help:** opens up a new window with detailed information about current stage.
- **Exit:** closes the application.

5.3 Patient data loading and importing

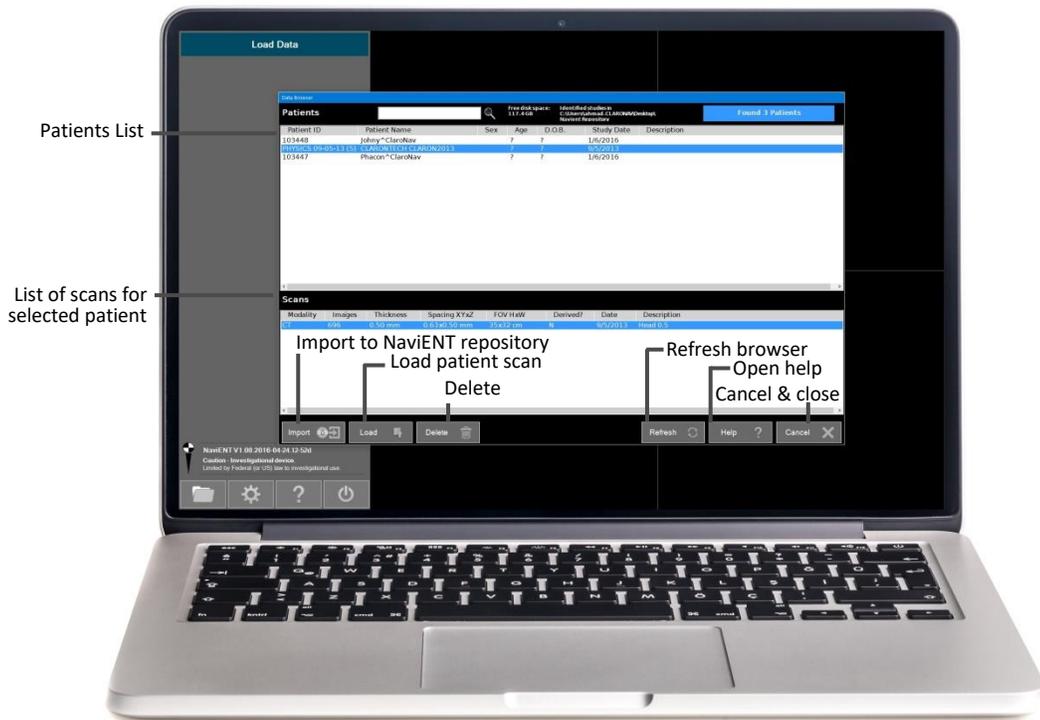
When started, NaviENT displays a “splash” screen that provides the software version number and license information. It then opens the data browser window, allowing the user to load, import and delete patient image data. The data browser window can also be initiated from the **Load/Import** button on the bottom of the NaviENT sidebar.

NaviENT stores all imported patient scans on a desktop folder called **NaviENT Repository**. The user can load patient data from the repository or import data from other locations or devices (like CD or DVD and USB drives) to the repository.

5.3.1 Loading data

The **Data Browser** searches through the **NaviENT Repository** folder and shows the search results in two panes. On the top pane it lists the patient information for all patients for which some DICOM-formatted images were found. The browser auto selects the first discovered patient, but the user can click on other rows to change that selection. On the pane below, the discovered image series (slice stack) for the selected patient are shown.

The user can select the desired series and load it with a click on the **Load** button or with a double click on the corresponding row in the lower pane. The loading automatically triggers the advancement to the **Verify** stage.

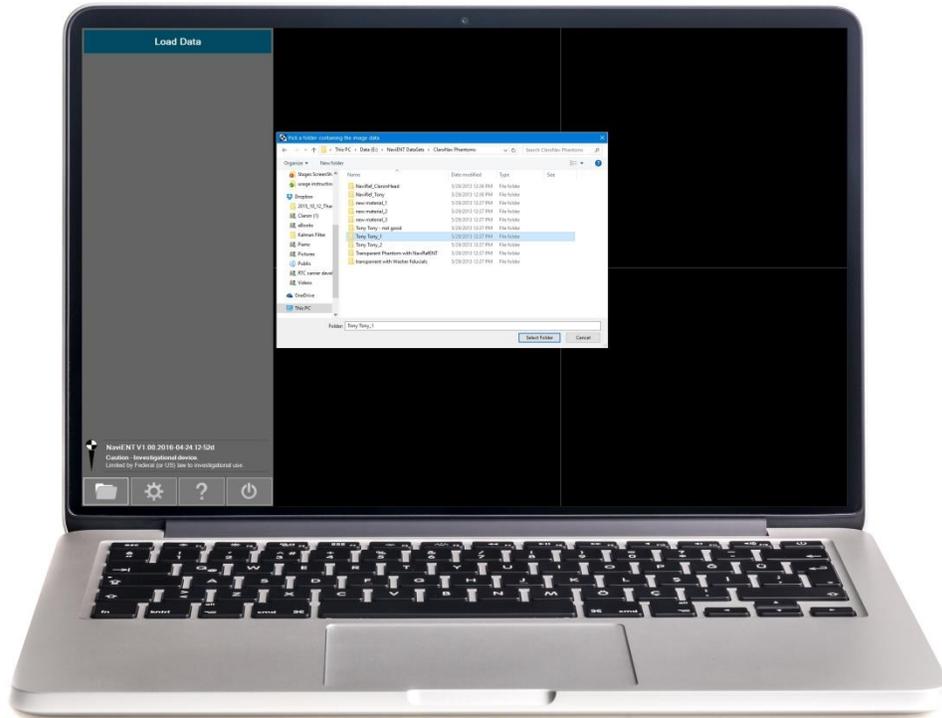


- **Import button:** Enables importing a new dataset from devices like CD or DVD and USB drives to the **NaviENT Repository**.
- **Load:** Loads the selected patient scan and shows 3D and 2D views.
- **Delete:** Deletes the selected patient data.
- **Refresh:** Refreshes the Data Browser window.
- **Help:** Opens up help window
- **Cancel:** closes the Data Browser window.

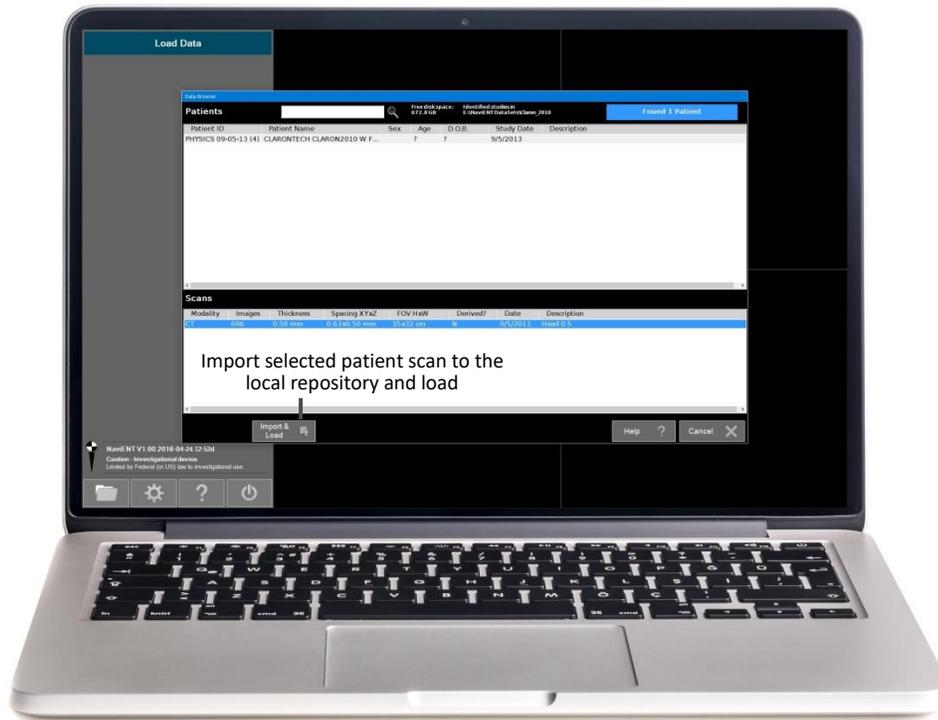
Note: Always load the most recent patient data (recommended less than 6 month old) with largest slice number (200 or more) and smallest slice spacing (1mm or less). NaviENT will show warning messages if the data is more than 2 years old or if it has slice spacing of more than 2mm or if the number of slices are less than 30 slices.

5.3.2 Importing Data

The user can import patient data from CD, DVD or USB drives to the repository. Click on the Import button to open up the folder browser. Select the device that you want to import the data and browse and select the patient data folder.



Click **Select Folder** to return to the Data Browser form. Data Browser will display all scans found under the selected folder. Select the scan that you want to import and click on **Import & Load** (see picture below). It will import the patient data to the local **NaviENT Repository** and then will load the data from the repository.



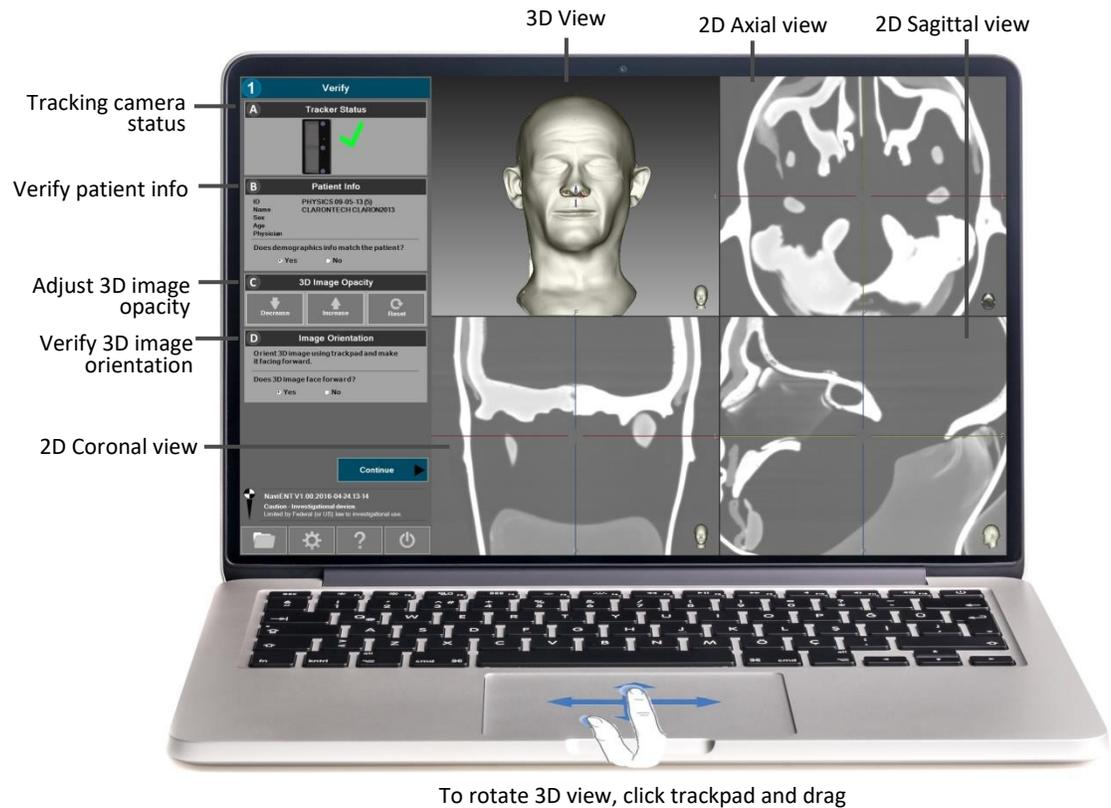
Note: Once data is imported, it will be copied to the **NaviENT Repository** folder on the desktop. A warning message will be displayed if you try to reimport the same data twice. Once imported, the imported data will be displayed in the Data Browser window.

5.4 Stage 1: Verify

Once the CT data is loaded, the application will proceed to the “Verify” stage. It displays the 3D dataset as well as 2D axial, coronal and sagittal reformatted slice views and allows the user to rotate, zoom and explore the data. The main goal of this stage is to:

- A. **Verify tracking camera:** A green checkmark will be displayed next to the tracking system image if the tracking system is activated. Otherwise a “Red” sign along with a troubleshoot button will be displayed.
- B. **Patient info:** The user must confirm that the image dataset belongs to the current patient. This can be done by visually inspecting/matching the patient and the 3D dataset. Brief information of the patient like ID, Name, Age, Gender and physician name are also displayed on the sidebar.

- C. **3D Image Opacity:** use the arrow buttons to adjust the opacity of 3D image so that the patient skin can be clearly visible.
 - a. **Lower opacity** if there is noise or artifacts on the 3D image.
 - b. **Increase opacity** if skin is eroded and bony structure is visible.
- D. **Image orientation:** The patient 3D image must be facing forward as displayed below. As needed, use the trackpad to rotate by dragging as illustrated below. This initial orientation will be used as reference for proper presentations in the following stages, for example in orienting the coronal and sagittal cut planes.

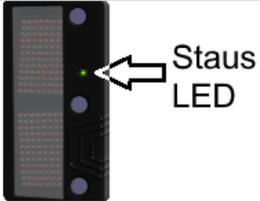


To rotate 3D view, click trackpad and drag

Note 1: It is recommended to adjust 2D contrast in stage 1. Use the toolstrip buttons on the top left hand side of each 2D viewport to adjust the windowing level of the 2D CT images.

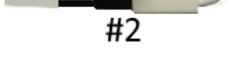
Note 2: A troubleshooting window will show up if the tracking system is inactive. Follow the instructions displayed in the troubleshooting window (picture below) to resolve the issue.

What is the tracking camera LED status?
Depending on the tracking camera status LED, follow the instructions stated under A, B, or C



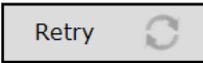
A. If LED is off
Check the connection cables (as shown):

1. Thunderbolt adaptor to laptop
2. Thunderbolt adaptor to firewire cable
3. Firewire cable to camera back



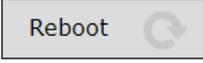
After connecting the cables, if the status LED is on:

1. Click Retry button to test connection.
2. If Tracker is still inactive, follow instructions B



If the issue still persists, please contact technical support.

B. If LED is constant bright green
First check the tracking cable connections to the laptop, white adaptor and camera and then reboot the laptop. Click the reboot button, and after reboot, re-login with default password "navient" and restart NaviENT.



To avoid this from happening again, please do not remove the white adapter cable from the laptop.

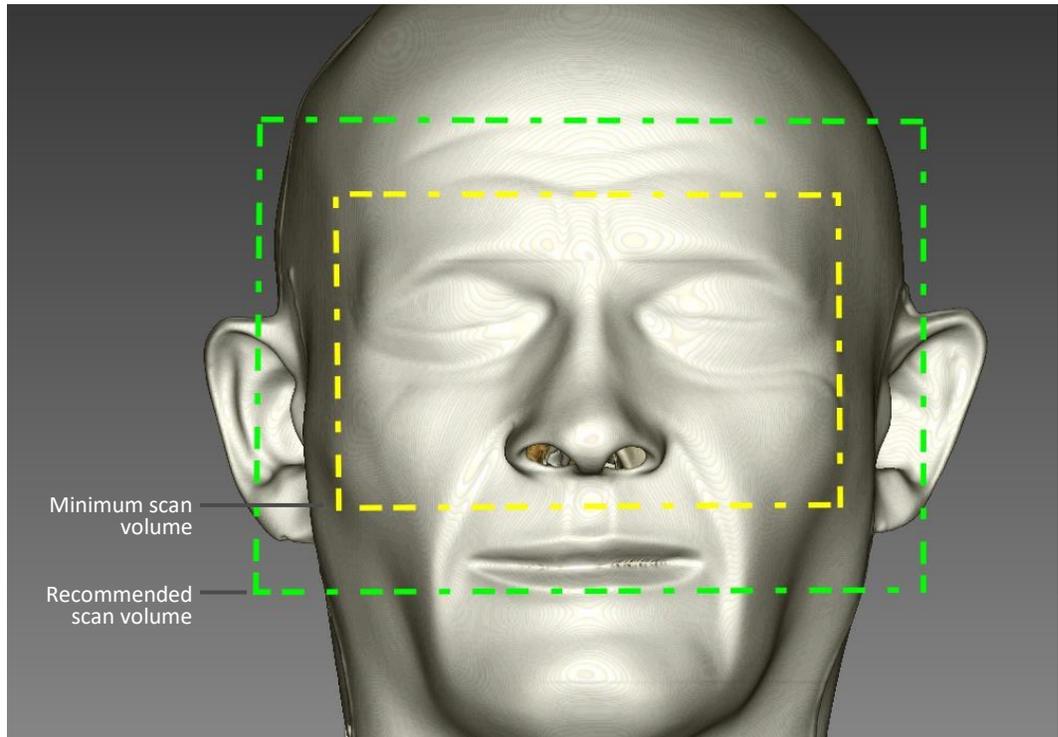
if the issue still persists, please contact technical support.

C. If LED is blinking
Blinking LED is an indication of a hardware issue, please contact technical support.



Important Note: The Patient CT scan must be taken according to instructions provided by NaviENT CT Scanning instructions:

1. These anatomical regions must be visible in the patient scan: forehead, dorsum of nose, base of nose and eye laterals. In the image below the yellow region is the minimum scan volume that can be used by NaviENT. The green region shows the recommended volume.



2. Use square pixels of 0.25mm x 0.25mm – 0.5mm x 0.5mm
3. Use constant slice thickness of 0.5mm – 1.0 mm
4. Axial slices are preferred (Helical scans are also acceptable).
5. Scan contiguous, non-overlapping slices.
6. No motion artifacts or no gantry tilt.
7. Archive the exam from the scanner to a CD or DVD
8. The scan should be uncompressed when saved (non zipped)
9. The scan should be Multi-File DICOM
10. The CD should only contain DICOM data
11. Save scan data into one folder only

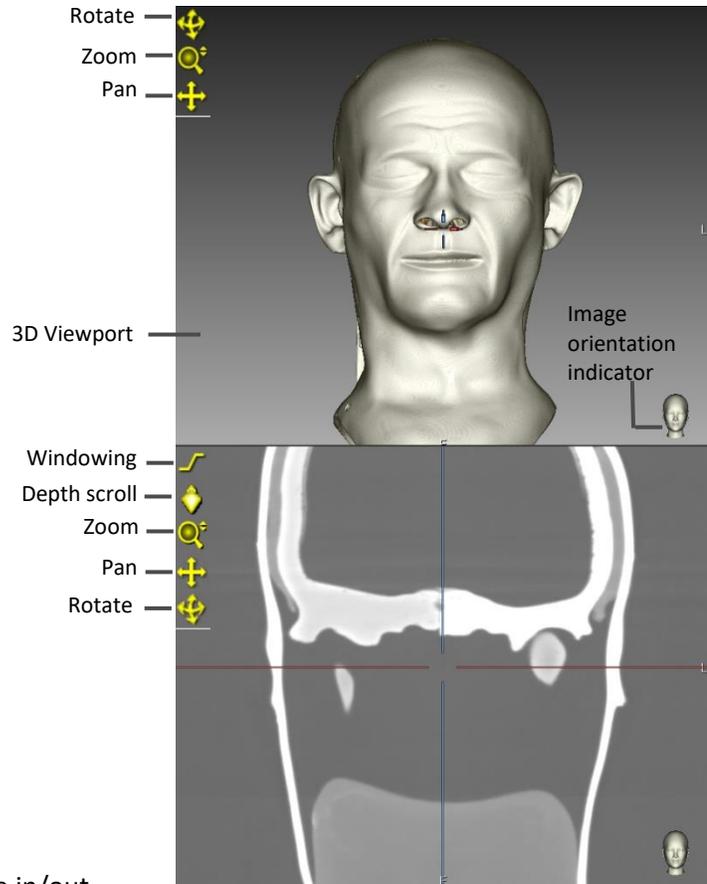
Refer to NaviENT CT Scanning instructions for a comprehensive CT Scanning instructions.

5.4.1 Tool strips buttons

All viewports include tool strip buttons that enable basic image manipulations like rotation, zoom, pan, scroll and modifying windowing levels. Bring the mouse cursor to the top left corner of the viewport to reveal the toolstrip buttons. Picture below shows tool strip buttons on the 3D and 2D viewports:

- **Windowing:** changes the windowing width and level of the images and is available only on 2D viewports. In order to change windowing width/level, drag the mouse left/right (width, or contrast) or Up/Down (level, or intensity).
- **Depth Scroll:** scrolls the slice in/out along the depth dimension of the view. Available only on 2D viewports. In order to scroll, drag the button up/down.
- **Zoom:** Zooms in and out the images and is available in both 3D and 2D viewports. In order to zoom in/out the image, drag the Zoom button up/down.
- **Pan:** Pans the images and is available in both 3D and 2D viewports. In order to pan the image, drag the button in the direction you wish to pan.
- **Rotate:** Rotates patient image and is available in both 3D and 2D viewports. In order to rotate the image, drag the button in the direction you wish to rotate.

Note: A single left click on a button will reset the parameters it controls to their default value.

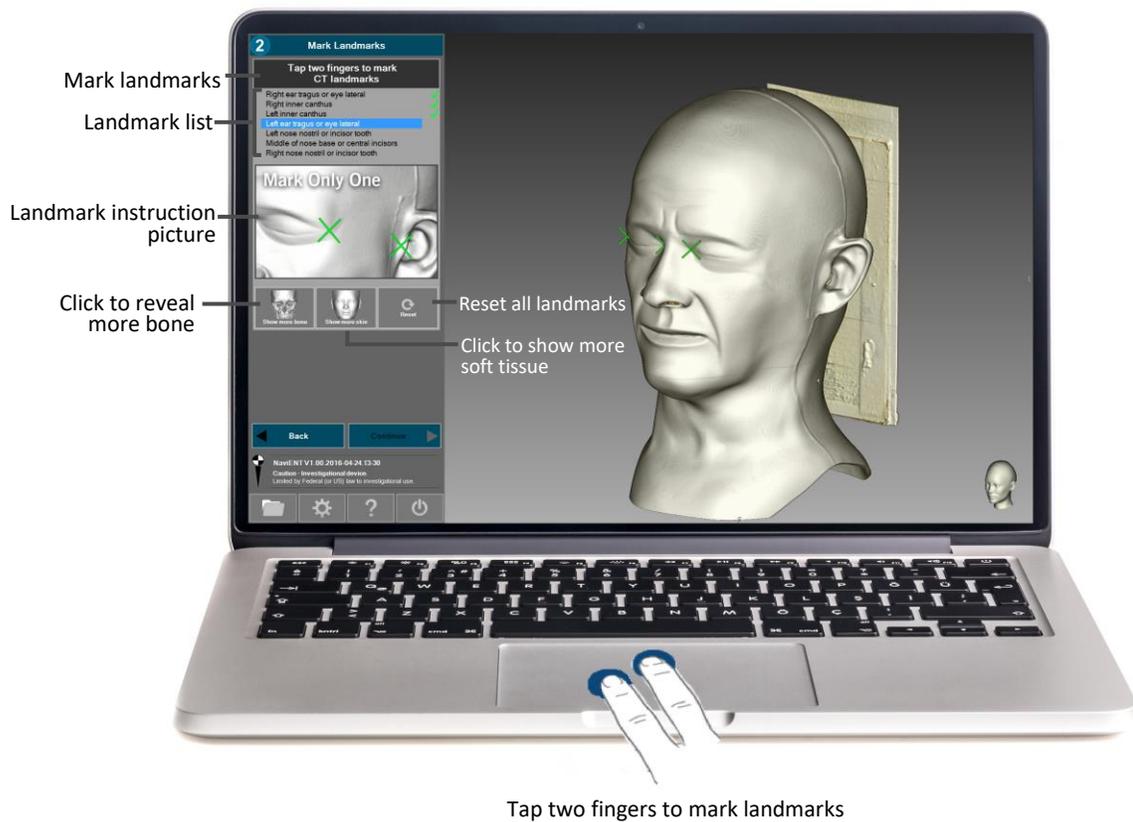


5.5 Stage 2: Mark Landmarks

In this stage, 7 anatomical landmarks are listed, with one “current” landmark highlighted and illustrated in the picture box below the list. The user needs to use trackpad and tap two fingers (or right click with a mouse) to mark each landmark. Once all landmarks were marked, the **Continue** button will be activated enabling to proceed to the next stage.

5.5.1 How to mark CT landmarks

1. Identify which landmark is highlighted in the list and pay attention to the illustration. The 3D image is automatically rotated so that the landmark is facing the viewer, but you can adjust the rotation manually.
2. Place the cursor over the landmark location in the 3D image and tap two fingers, as displayed below, to mark the landmarks.
3. The software will automatically highlight the next landmark until all landmarks have been marked, in which case the “Continue” button would become enabled.

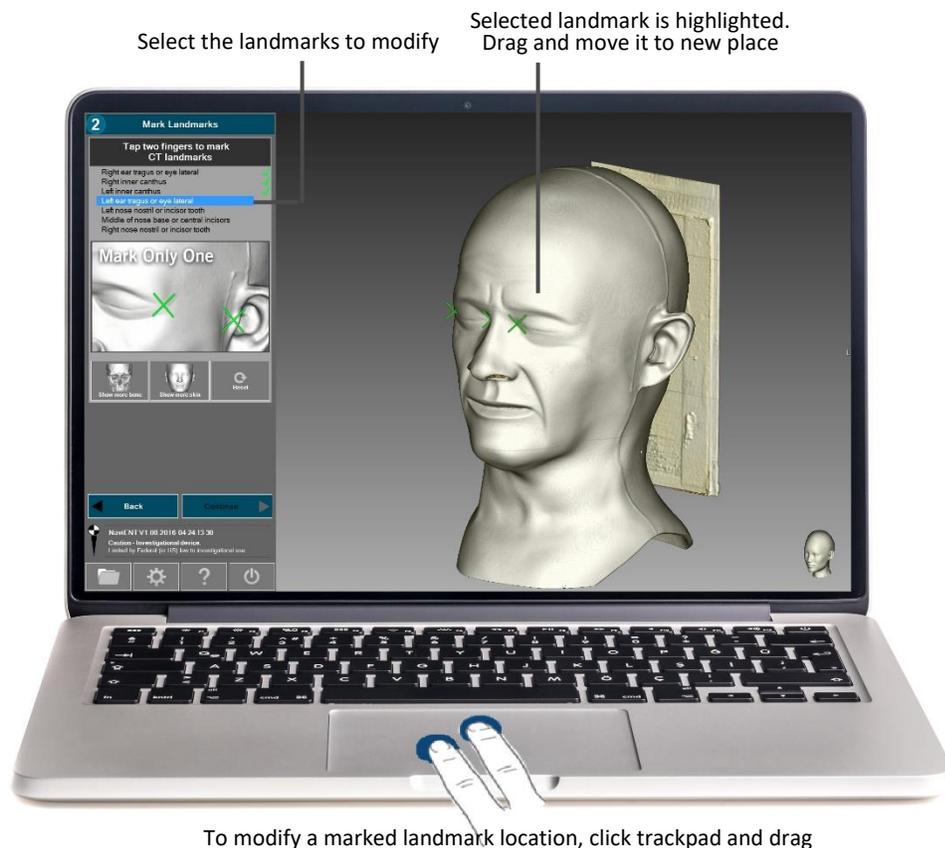


- **Show more bone button:** every click on this button will reveal more bony structure. Use this button if you need to reveal teeth to be marked as a landmark
- **Show more skin button:** every click on this button will show more skin and soft tissues, reversing the effect of the “Show more bone” button.
- **Reset Landmarks button:** clicking on this button will reset all marked landmarks to the “unmarked” state.

5.5.2 How to modify marked landmarks

To move a marked landmark:

1. From the Landmarks list select the landmark that you need to modify
2. Once selected, the corresponding cross bar on the main window will be highlighted
3. Bring the mouse cursor close to the highlighted landmark and drag the cross bar. Release once you are on the right spot.
4. If necessary, use tool strip buttons to rotate, zoom or pan the image.



5.6 Stage 3: Set-Up

This stage is designed to help the user with setting up the patient, positioning the tracking system and verifying/calibrating the instruments tips. The live video from tracking system is displayed in the side panel. It helps the user to orient and re-position it toward the field. A proper warning/instruction will be displayed on the live video if it is not positioned properly.

5.6.1 Tasks to be done in this stage

1. **Verify tracking system:** Make sure the tracking system is active and the live video is displayed. Follow the troubleshooting instruction if it is inactive.
2. **Attach the Patient Tracker:** Stick the Patient Tracker to the patient's forehead. Follow the instruction in section A of the main UI.
3. **Verify the Patient Tracker:** Position the tracking system so that it detects the Patient Tracker. Once detected, patient tracker detection indicator will turn to a green checkmark.
4. **Position and orient the tracking system:** Follow the instruction in section B of the main UI and place the camera at 100cm-120cm far from the Patient Tracker. The tracking system must be facing to the Patient Tracker. Follow any orientation adjustment instructions shown over the video image, if any.
5. **Verify Instruments tip:** present the instruments to the tracking camera one by one and verify the tip accuracy in the magnified window (Section C of the UI).
6. **Calibrate Instruments tip:** If the tip appears in the video misaligned with the overlaid cross-hair indicator, follow instruction in section 5.6.2 to recalibrate the tip.

Click on **Continue** or use the floating menu to proceed to the next stage.



5.6.2 Checking and calibrating an instrument tip

In the **Set Up** stage a zoomed in image of the tip is displayed on the right sidebar panel. It provides visual feedback to verify the accuracy of the tip calibration. If the tip is not overlaid on the center of the hair cross then tip calibration is necessary.

NaviENT package includes a calibrator block that allows tip calibration. Simply place the tip of the instrument (or any surgical tool with a universal tag clamped on it) on the dimple and present the calibrator and the instrument to the tracking camera. A progress bar will pop up showing the tip calibration progress. It typically takes a few seconds to complete the calibration. Once the tip calibration is complete verify the accuracy of the tip by looking at the tip zoomed in window.



5.6.3 Floating menu

From this stage forward the user can interact with the software using gesture based commands. Simply hold the Registrator pointer tip above the patient nose to enable the gesture based window. The Registrator tip will control the mouse cursor. The floating menu is available in Stages 3, 4, and 5 and provides stage specific options as following:

- Stage 3 (Setup): **Activate, Register**
- Stage 4 (Register): **Activate, Restart Landmarks, Restart Trace, Back, Continue**
- Stage 5(Navigate): **Accuracy Troubleshoot, Reregister, Recompute, Set Up**



- **Activate Circle:** Using the Registrator, move the cursor inside the **Activate** circle and wait for the progress bar. Once it is activated, you can proceed with selecting other circles.
- **Register:** This will proceed to the **Registration Stage**. Simply bring the cursor (Registrator tip) inside this circle and wait for the progress bar to complete.

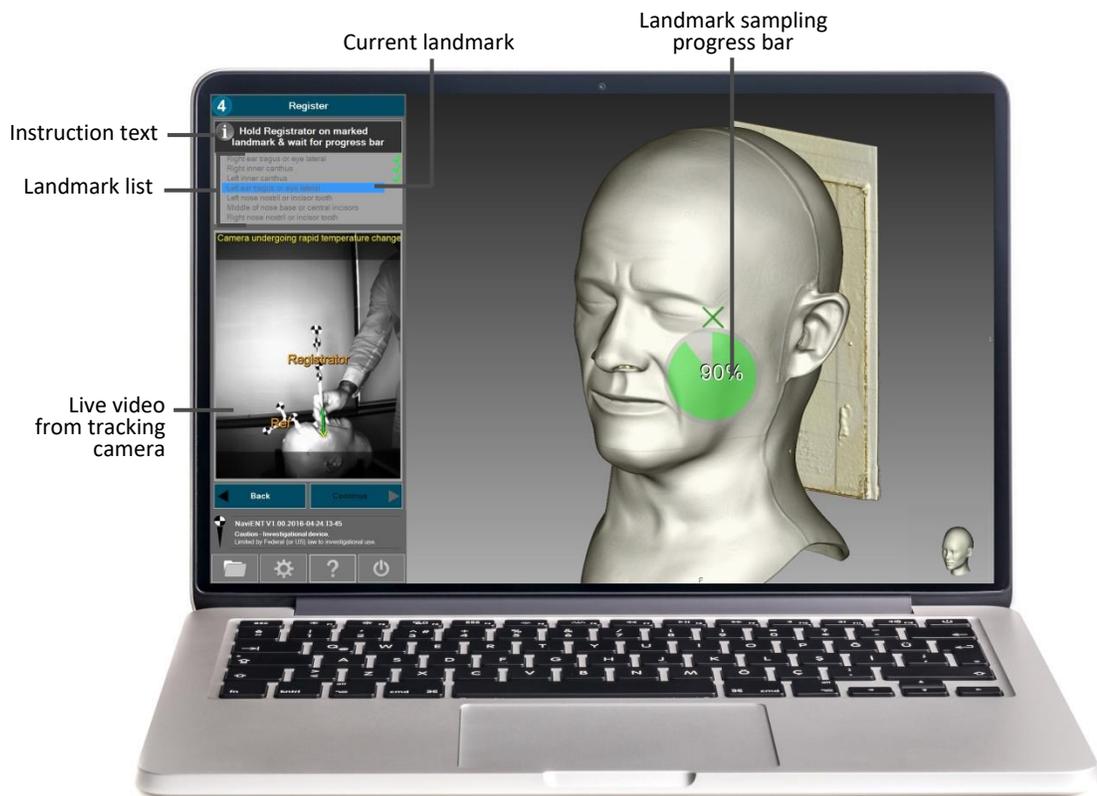
5.7 Stage 4: Register

To allow registration, you need to establish a frame of reference for the patient's head by attaching the Patient Tracker to the patient's forehead using a fresh dual-sided tape strip.

NaviENT registration process has two stages, landmark based registration followed by trace registration refinement. Both operations are designed to be conducted without touching the trackpad or keyboard. The Registrator pointer must be used for registration. Holding the Registrator pointer tip above the patient nose will activate the floating menu that enables switching to the next/previous stages. You could also reset the registration process using the floating menu (See section 5.7.3).

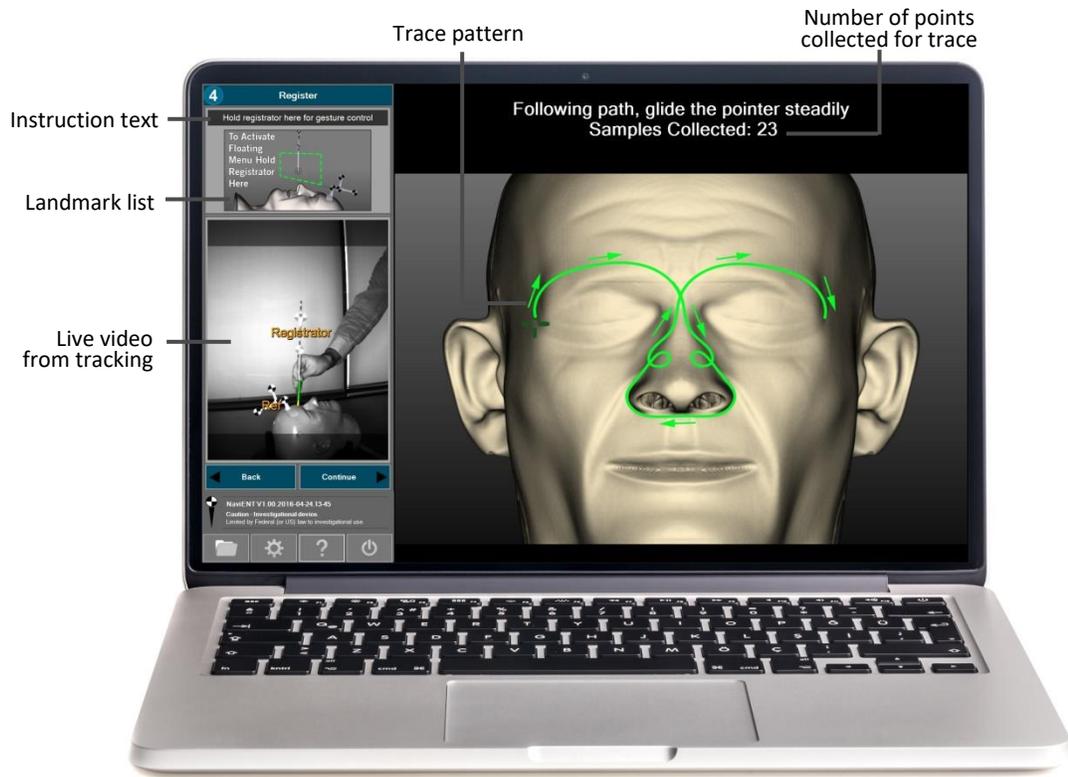
5.7.1 Landmark Based Registration

In this stage the user will be provided with visual and audio feedback to identify patient landmarks corresponding to the CT landmarks displayed on the sidebar panel. Holding the Registrator pointer tip still on the patient landmarks will activate the sampling progress bar. It is very important to hold the Registrator tip as close as possible to the corresponding landmark shown on the 3D image.



5.7.2 Trace Registration

Once the landmark registration is complete, the instruction for trace registration will be presented. Hold the Registrator tip next to the eye lateral right or ear tragus right (depending on which landmark was selected in the stage Mark Landmarks) and wait for the progress bar. Once progress bar is complete, the user needs to slowly glide the Registrator pointer around the patient forehead and nose area. It normally takes less than a minute to complete the process. Once it is done the application will proceed to the next stage.

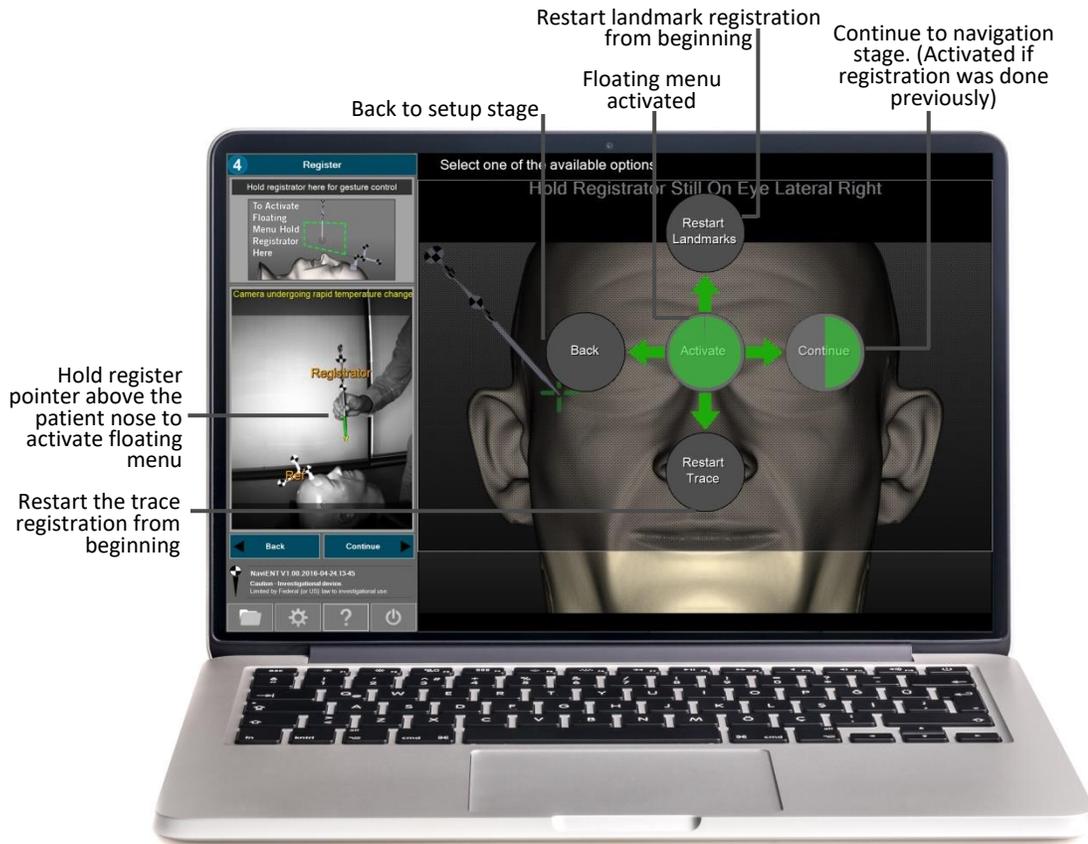


Note: By default the software will go through trace based registration, the user can decide to skip it (by selecting **Continue** circle in the floating menu or clicking on **Continue** button in the side bar). A few reasons to skip trace based registration are:

- Patient scan doesn't cover the forehead area
- Patient scan is low resolution or has large slice spacing
- Patient scan has significant motion artifacts
- Patient scan is very old and doesn't look like the real patient.
- Trace registration fails or degrades the registration accuracy.

5.7.3 Floating menu

The user can interact with the software using gesture based commands. Simply hold the Registrator tip above the patient nose to enable the floating menu.



- **Activate Circle:** Using the Registrator move the cursor inside the **Activate** circle and wait for the progress bar. Once it is activated, you can proceed with selecting other circles.
- **Restart Landmarks:** This will restart Landmarks registration from beginning. Simply bring the cursor (Registrator tip) inside this circle and wait for the progress bar to complete
- **Restart Trace:** this will restart trace registration from beginning. Simply bring the cursor (Registrator tip) inside the circle and wait for the progress bar to complete.
- **Back Circle:** moves back to the **Set-Up** stage
- **Continue Circle:** this will be activated if the registration was completed before. If activated the software will proceed to the **Navigation** stage.

5.8 Stage 5: Navigate

This stage starts with presenting accuracy check instructions. If the accuracy is not satisfactory then user can activate the floating menu to repeat the registration. If the accuracy is satisfactory then full screen navigation can be continued.

5.8.1 Accuracy Check

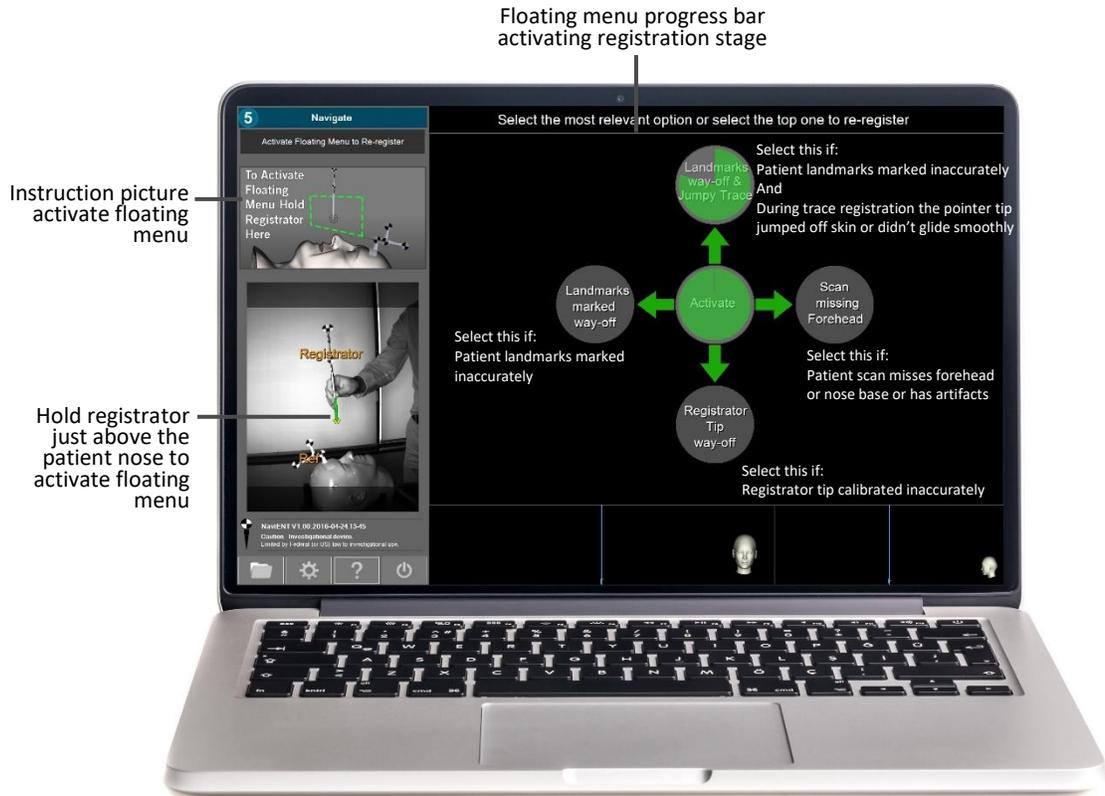
When entering the navigation stage, an instruction for accuracy check will be displayed on the sidebar. Use the Registrator and follow the instruction for the accuracy check. Slowly glide the Registrator pointer around the nose bridge area and make sure the Registrator tip is displayed on the right location. The green safe zone circle around the Registrator tip can help you to decide if the accuracy is acceptable. The safe zone circle radius is 3mm.



Important Note: The registration must be repeated if the registration check shows an unacceptable registration error. Use the floating menu (see section 5.8.2 below) to go back to the registration stage. Use only landmark based registration if the trace based registration fails. Landmark based registration should be used as the last option and should be followed by accuracy check. If the accuracy is still not as expected, consider terminating the use of NaviENT for guidance.

5.8.2 Floating menu

Hold the Registrator tip above the patient's nose to show the floating menu. It displays common inaccuracy root causes and helps the user to take proper action to troubleshoot it. The Registrator tip controls the cursor. Move the cursor inside the **Troubleshoot Accuracy** circle and wait for the progress bar.



The four main common inaccuracy root causes are:

- Patient landmarks marked inaccurately
- During trace registration the registrator tip jumped off the skin or didn't glide smoothly
- Patient scan misses forehead or nose base or has artifacts
- Registrator tip calibrated inaccurately

The floating menu provides 4 options to choose from.

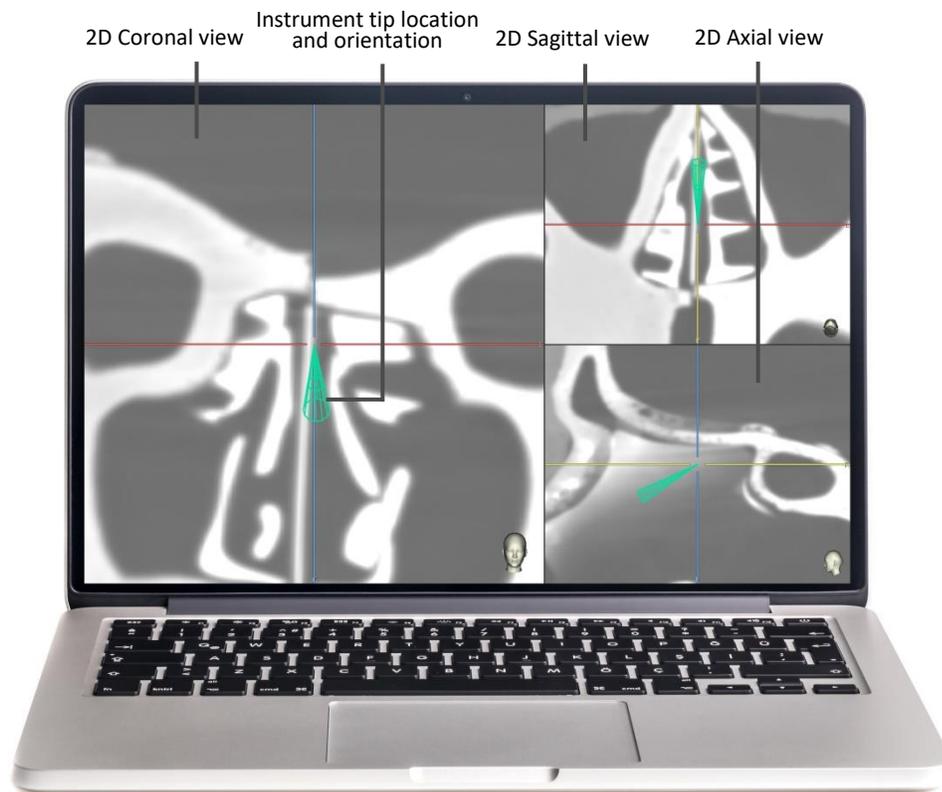
- Top Circle:** Select this if both issues A and B are applicable. It will activate **Register** stage and will require the user to repeat both landmark based registration and trace based registration.
- Left Circle:** Select this if only issue A is applicable. It will activate **Register** stage and will repeat only landmark based registration.

- **Right Circle:** Select this if only issue C is applicable. It will re-compute registration. It will use only landmark based registration and will skip trace registration.
- **Bottom Circle:** Select this if only issue D is applicable. It will return to the **Set Up** stage to verify the accuracy of the registrator tip.

5.8.3 Navigation

In the Navigation stage, the user is presented with three viewports. By default, a 2D sagittal view is displayed in the larger viewport, and the axial and coronal viewports are displayed in two smaller viewports. The user can modify the viewports configuration in the settings. A cone representation of the pointer stem is shown when any trackable instrument is detected inside patient vicinity.

When a navigated tool and the reference marker are both being tracked, the sidebar control panel will be hidden to maximize the viewports size. The smart zoom feature will zoom up the region that the pointer tip is navigating. However if the tool or reference marker are not being tracked, the sidebar panel will be displayed along with the live video images. This would help user to identify why the navigation is inactive.



5.9 Settings

NaviENT Settings form allows customizing and configuring NaviENT application settings. Following application properties are customizable:

- **Collage Layout:** Adjusts the navigation window layout. The default layout is set to **Coronal Axial Sagittal** with Coronal displayed in a large viewport and Axial and Sagittal displayed in two smaller viewports. To change the layout, select the radio button next to the layout and click on “Save & Close”.

The screenshot shows the 'Navigation' settings window. It is divided into two main sections: 'Navigation Layout' and 'General Options'.

Navigation Layout:

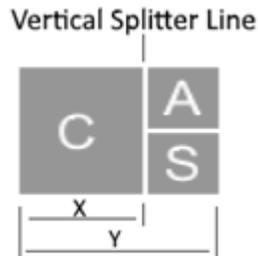
- There are two main layout categories: **2 x 2** and **1 x 3**.
- 2 x 2:** Includes options for 'Axial Coronal Sagittal' (A, C, S in a 2x2 grid) and 'Sagittal Axial Coronal' (S, A, C in a 2x2 grid).
- 1 x 3:** Includes options for 'Coronal Axial Sagittal' (C, A, S in a 1x3 row) and 'Coronal Sagittal Axial' (C, S, A in a 1x3 row).
- The 'Coronal Axial Sagittal' option is currently selected.
- A 'Vertical Splitter Fraction (0...1)' is set to 0.60.

General Options:

- SmartZoom (with a magnifying glass icon)
- Zoom in window size (mm): 60
- Zoom out window size (mm): 100
- Accuracy check instruction display duration (sec): 20
- Accuracy check SafeZone circle radius (mm): 3
- Mute Registration Sound (with a speaker icon)
- Record Sessions to video file (with an 'Open Folder' button)

At the bottom of the window are three buttons: 'Restore Default', 'Save & Close', and 'Cancel'.

- **Vertical splitter Fraction:** Sets the ratio of the width of the large window to the entire main window (x/y in the diagram below).



- **SmartZoom:** Enables/disables automatic zooming feature. When the navigation instrument tip is still, it automatically zooms in to show magnified region surrounding the tip location.
- **Zoom in/out window size (mm):** Determine the size of surrounding area to be displayed when it is zoomed in or zoomed out.
- **Record Session to Video File:** Records the entire session as a video file and stores it on the disk. Click on the folder icon to open the **NaviENT Recordings** folder.
- **Accuracy Check instruction display duration:** the duration to which the accuracy check instruction will be displayed in the Navigation stage.
- **Accuracy Check safe zone circle radius (mm):** determines the size of the safe green zone displayed around the Registrator tip to help measuring the registration accuracy.
- **Mute Registration Sound:** mutes or unmutes the sound feedback played while collecting registration points.
- **Restore Default:** Restores the default manufacturer settings.
- **Save & Close:** Stores all the changes permanently. It will restore the next time that application launches.
- **Cancel:** Ignores the changes and closes the settings window.

6 Service and Support

If support is needed, contact us by:

Email:

- support@claronav.com

Website:

- <http://www.claronav.com/contact/>

Phone:

- (US & Canada): 1-647-951-1525
- Toll Free: 1 (844) 628-4336
- Contact your local representative

Fax:

- 1-647-951-1524

Regular Mail:

ClaroNav Kolahi Inc.
1140 Sheppard Avenue West, Unit 10
Toronto, Ontario, Canada, M3K 2A2

Authorized representative:

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Appendix A: The R-Fine Application

The tracking camera is specifically designed to preserve for a long time the high precision of its optical calibration performed at the factory. But its accuracy can suffer from undesired hardware changes for a variety of reasons, such as environmental stresses or rough handling. R-Fine provides a fast and intuitive method to evaluate the camera's calibration accuracy and the possibility to refine the calibration, if required. NaviENT application will remind the user to perform R-Fine every 12 months.

R-Fine operates by detecting a special AccBar marker (included in the NaviENT accessory kit). The AccBar must be placed by the user in a number of different regions and orientations, as guided by the software using semi-transparent image overlays. Once correctly positioned, the AccBar's coordinates are sampled accuracy analysis.

R-Fine Quick Guide

Upon opening the R-Fine application, the user is presented with a semi-transparent image of the AccBar tool. The user must position and orient the tool as shown on the screen.

- A *Yellow* guide is shown when the camera cannot detect the bar.
- A *Red* guide is shown when the bar is detected but not in the correct position.
- A *Green* guide is shown when the bar is positioned and oriented correctly.

Try to overlap AccBar with the guide



Sometimes it is required to move the bar towards or away from the camera



The bar must be oriented as depicted



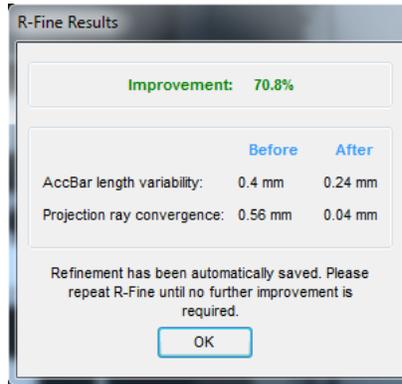
In this orientation the bar is held pointing towards the camera



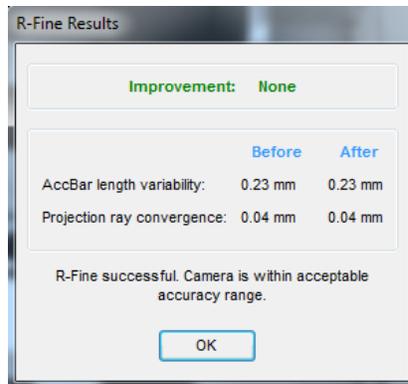
After all samples have been collected, the R-Fine application will determine whether the camera is out of alignment or not. The application will automatically update the calibration file if the

improvement is greater than 10%. In this scenario, the refinement process should be repeated until the improvement seen is less than 10%. If the improvement is greater than 10% after 3 consecutive attempts, please contact support. This is an indication that the camera is out of calibration

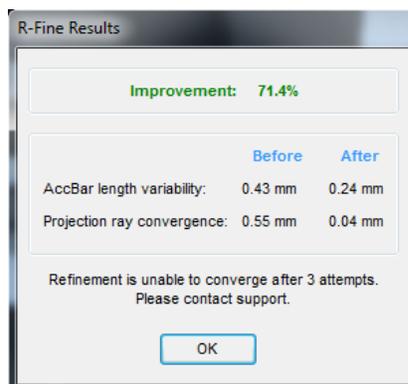
Improvement is greater than 10%. Repeat R-Fine procedure.



Improvement is less than 10%. Refinement is successful.



Improvement is greater than 10% for 3 consecutive tries. Contact support.



Appendix C: Troubleshooting Guide

The various error messages are described and explained here, as well as the possible causes and solutions.

Message	Explanation	Resolution
Another copy of NaviENT is running. Please wait for it to terminate, then restart	You are allowed to only execute a single instance of the NaviENT application at a time	Close the running application or wait for it to exit and then retry
Camera may be out of calibration. Running R-Fine every 12 months is highly recommended	For optimal navigational accuracy the NaviENT camera needs to be calibrated every 12 months	Click "Yes" to run R-Fine or "No" to ignore (not recommended). See <i>Appendix A: The R-Fine Application</i>
Could not start ScreenCaptureServer.exe, please check your installation	Unable to start video recording capabilities	Restart the machine and try again. If the problem persists then contact CKI.
Low resolution warning, spacing is more than 1.0mm. Navigation accuracy may be degraded	The spacing between voxels should be less than 1.0mm.	Use extra caution when navigating and perform accuracy checks by touching visible nearby structures prior to navigation.
Import failed, Invalid path	You may be trying to import data from the main NaviENT data repository (where it already resides), or from a directory that is not accessible, such as one on a network drive or portable medium that is not currently mapped.	Correct the problem with the path and try again.
Import failed. At least 100 slices are required	NaviENT is able to process datasets with 100 or more slices	Refer to NaviENT <i>CT Scanning Instructions</i>
Import failed. There is not enough disk space to import. Do you want to delete data from the repository	Disk is full	In order to continue existing datasets need to be deleted
Directory exists, overwrite patient data?	The data being imported already exists in the data repository	Select Yes to overwrite the existing data and plans file. Select No to cancel import.
Error mapping drive	There is an issue with mapping	Please check the drive path

Message	Explanation	Resolution
	the indicated drive	and user credentials (if required)
Slice stack loading warning. More than one stack of slices found in the folder.	The dataset may be corrupted (e.g. missing or damaged files), or multiple scans are stored in the same folder.	The application will open the data and it is recommended that the user verify the patient data is complete by browsing through the slices
Tracking camera error. Please disconnect and reconnect the camera then wait a few seconds	The MT camera has been either disconnected or there is a communication error	Restart the application and if the application is still unable to connect to camera then restart the computer
Confirm delete, Permanently delete all data of the selected patient(s) from the repository?	Deleting a dataset from the NaviENT repository	Selecting "Yes" will remove the data from the repository
There is not enough disk space	The location that you are exporting the data to does not have enough disk space	Free some space and try again
Directory exists, Overwrite patient data?	The data being exported already exists in the destination folder	Selecting "Yes" will overwrite the destination folder
Adjust camera, move Right/Left/Up/Down/Closer/Further	In order to obtain optimal accuracy, Forehead Tag needs to be within the camera field of view	In case the markers are outside the bounds the application will warn the user to adjust the camera accordingly
Camera operating outside verified temperature range	The camera may be heating up	The cause for the rise in temperature should be investigated, once the issue is mitigated wait for the camera to cool down before continuing
Navigation inactive	During navigation if the forehead tag or the navigation pointer are not detected (for any reason e.g. line of sight interruption) the application will show the side bar with live camera video.	Check if something is obstructing the FOV. Make sure there is direct line of sight between the navigation pointers and the camera box.

Appendix D: Adjusting the cart arm's joint friction

When open, the cart's arm should allow for easy, yet stable, adjustment of the height of the front pole holding the laptop and camera box. The stability of the pole's height is controlled by friction in the joint connecting the arm to the back post. This friction may be adjusted by turning a screw located on the post's left side, which can be accessed through a hole in the plastic cover, as shown below.

Insert the supplied 1/8" Allen key through the hole and turn the screw clockwise to tighten it.



Appendix E: Electrical Safety and EMC Declarations

Manufacturer's Declaration for NaviENT (ME System)

EN 60601-1-2:2007 Table 1 Requirements:

The ME System is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Equipment is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This System is intended for use by healthcare professionals only. This Equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the System or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

EN 60601-1-2:2007 Table 2 Requirements:

The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.			
Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not Applicable	Mains power quality should be that of a typical commercial/residential or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial/residential or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 $U_T = 240 \text{ Vac}$ and 120 Vac	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial/residential or hospital environment. If the user of the Equipment requires continued operation during power mains interruptions, it is recommended that the System be powered from an uninterruptible power supply or a battery.
Power frequency (50 Hz/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial/residential or hospital environment.

EN 60601-1-2:2007 Table 4 Requirements:

The ME System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.			
Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	<p>Portable and mobile RF communications System should be used no closer to any part of the System including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a should be less than the compliance level in each frequency range^b</p> <p>Interference may occur in the vicinity of known RF transmitting devices and System marked with the following symbol:</p> 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
<p>a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the System is used exceeds the applicable RF compliance level above, the System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the System.</p> <p>b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

EN 60601-1-2:2007 Table 6 Requirements:

Recommended separation distances between portable and mobile RF communications System and the ME System			
<p>The ME System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ME System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications System (transmitters) and the ME System as recommended below, according to the maximum output power of the communications System.</p>			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			