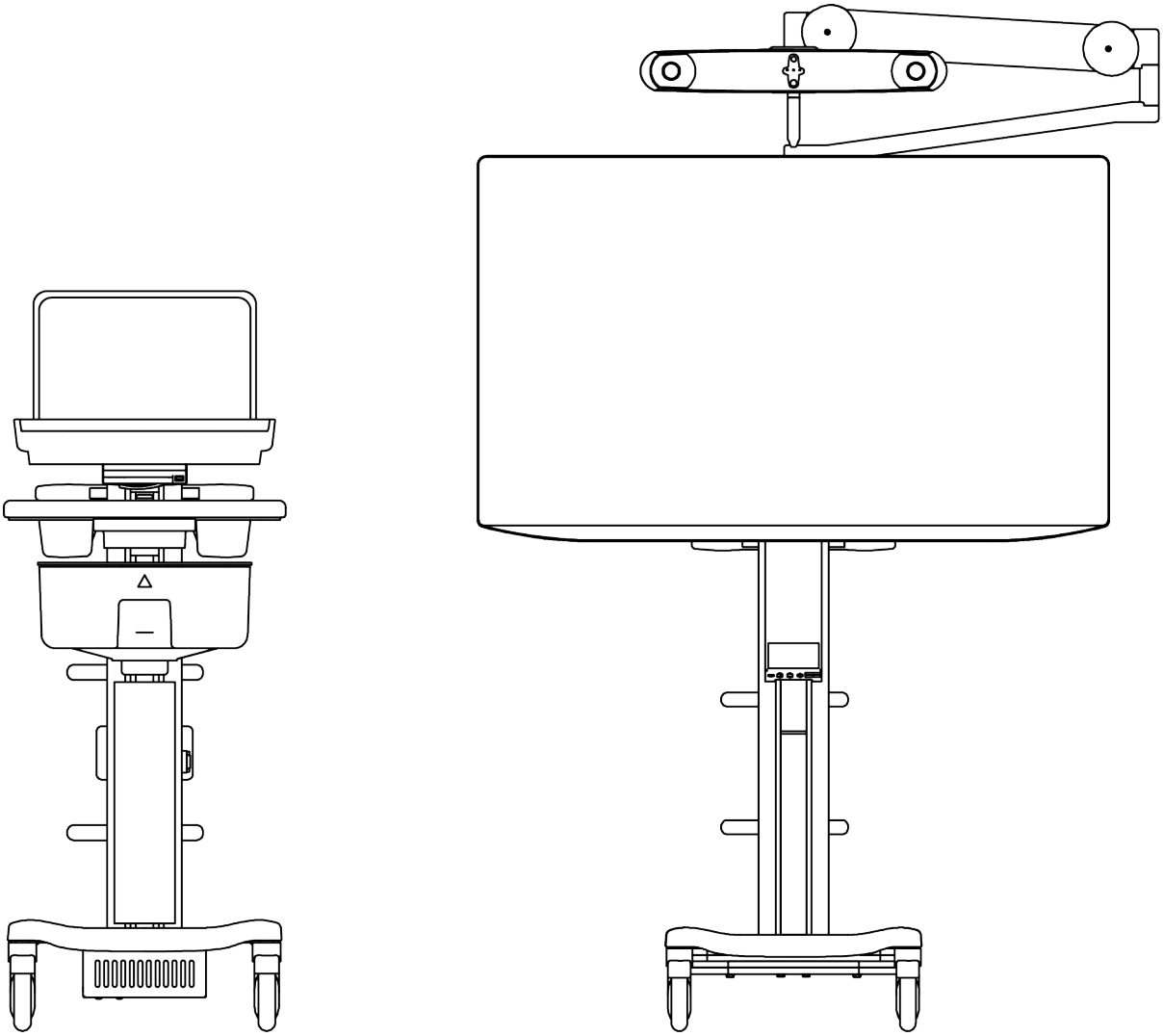
Modus Nav™ 2.2
User Manual

MAN-0655 Revision E



Synaptive

User Manual

Synaptive™ Modus Nav™

SYN-0982
Software version: 2.2

Synaptive

SYN-0982 Basic UDI-DI: 67008200004LP

MAN-0655 – Revision E issued on December 18, 2024.

These instructions for use are also available in electronic form at www.synaptivemedical.com/eIFU. The electronic instructions for use may be viewed on any device that can access the internet and display PDF files. Access to the electronic instructions for use requires a password; to obtain the password, contact Synaptive customer service.

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1.0 Introduction

Synaptive™ Modus Nav™ provides a skilled surgeon the precise tools and information needed to perform accurate and informed neurosurgical procedures. The Modus Nav system consists of hardware for tracking surgical tools and software for planning and monitoring the surgical procedure.

This manual describes the Modus Nav system components and how to use them. Read and become familiar with the information in this manual before using the Modus Nav system.

NOTE: The graphics and medical images in this manual are examples only. The actual design and display on your system may vary.

1.1 Modus Nav Indications for Use

Modus Nav is intended as a planning and intraoperative guidance system to enable open and percutaneous computer assisted surgery. The system is indicated for medical conditions requiring neurosurgical cranial procedures where the use of computer assisted planning and surgery may be appropriate. The system can be used for intra-operative guidance where a reference to a rigid anatomical structure can be identified. The user should consult the “Accuracy Characterization” section of the User Manual to assess if the accuracy of the system is suitable for their needs.

The system hardware and software should be used only by qualified medical professionals who are trained in performing surgery and are familiar with image-guided surgical systems.

1.2 Contraindications for Use

The Modus Nav system should not be used where fiducial structures on the patient cannot be accurately defined to corresponding locations on the image of the same patient.

Modus Nav is not designed as a primary tool for disease detection or diagnosis.

Modus Nav is not designed as a primary tool for assessing therapeutic outcomes.

1.3 Instrumentation Intended Use

1.3.1 Standard and Long Pointer Intended Use

As components of the Modus Nav system, Standard and Long Pointer are intended to be used as pointing tools to enable spatial localization and identification. The system should be operated only by trained personnel such as surgeons and other clinic staff.

1.3.2 Short Pointer Intended Use

As a component of the Modus Nav system, Short Pointer is intended to be used to position a commercially-available trajectory guidance platform in surgical procedures. These procedures may include biopsies or insertion of catheters or electrodes.

1.3.3 Multi-Tool Calibration Device Intended Use

As a component of the Modus platform, the Multi-Tool Calibration Device is intended to be used to calibrate and/or verify tools for navigation and/or positioning of the digital microscope. The Multi-Tool Calibration Device is intended to be used with a tracking camera, software, and a trackable tool.

1.4 Intended Use Environment

The Modus Nav system is intended for use in hospitals, clinics, and other medical institutions.

1.5 Clinical Benefits

Synaptive's tracked surgical instruments integrate with both Modus Nav and Modus V to connect the use of navigation and robotic visualization. Modus Nav's tractography import from Modus Plan provides users the ability to connect pre-planning and operating room visualization of real-time tractography. This integration enables users to automatically match the surgical view to a pre-op trajectory from Plan, or intra-op trajectory from Modus Nav, ensuring consistency and accuracy of the surgical approach and integration of tractography for more procedures[1,2,3,4,5].

1. Jennings et al., The Surgical White Matter Chassis: A Practical 3-Dimensional Atlas for Planning Subcortical Surgical Trajectories. Operative Neurosurgery, 2017
2. Zakaria et al., Automated Whole Brain Tractography Affects Preoperative Surgical Decision Making. Cureus, 2017
3. Kassam, The Operating Room of the Future Versus the Future of the Operating Room. OtolClin N AM, 2017
4. Zarabiet al., Refining Surgical Corridors with Whole Brain Tractography: A Case Series. Cureus, 2017
5. Bonney et al., A Simplified Method of Accurate Postprocessing of Diffusion Tensor Imaging for Use in Brain Tumor Resection. Operative Neurosurgery, 2015

1.6 Product and Safety Symbols

Table 1 ISO 7000 - Graphical symbols for use on equipment - Registered symbols and ISO 15223-1 - Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

Symbol	Title	Reference	Description
	Caution	ISO 7000-0434A	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Manufacturer	ISO 7000-3082	Indicates the medical device manufacturer. The date of manufacture, as well as the name and address of the manufacturer, can be combined in this symbol.
	Date of manufacture	ISO 7000-2497	To indicate the date on which a product was manufactured.
	Sterilized using ethylene oxide	ISO 7000-2501	To indicate that the device is provided sterile and has been sterilized using ethylene oxide.
	Sterilized using steam or dry heat	ISO 7000-2503	To indicate that the device is provided sterile and has been sterilized using steam or dry heat.
	Non-sterile	ISO 7000-2609	Indicates a medical device that has not been subjected to a sterilization process.
	Non-pyrogenic	ISO 7000-2724	On medical devices: to indicate that the product is non-pyrogenic.
	Do not reuse	ISO 7000-1051	To indicate that the item is for single use only and must not be used more than once, for example on packages of medical disposables.
	Catalog number	ISO 7000-2493	To identify the manufacturer's catalog number, for example on a medical device or the corresponding packaging.
	Serial number	ISO 7000-2498	To identify the manufacturer's serial number, for example on a medical device or its packaging.

Table 1 ISO 7000 - Graphical symbols for use on equipment - Registered symbols and ISO 15223-1 - Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied (continued)

Symbol	Title	Reference	Description
	Batch code	ISO 7000-2492	To identify the manufacturer's batch or lot code, for example on a medical device or the corresponding packaging.
	Mass; weight	ISO 7000-1321B	To indicate mass. To identify a function related to mass.
	Do not use if package is damaged	ISO 7000-2606	Indicates a medical device that should not be used if the package has been damaged or opened.
	Fragile; handle with care	ISO 7000-0621	To indicate that the contents of the transport package are fragile and the package shall be handled with care.
	Keep dry	ISO 7000-0626	Indicates a medical device that needs to be protected from moisture.
	Use by date	ISO 7000-2607	To indicate that the device should not be used after the date accompanying the symbol, for example on a medical device or its packaging.
	Humidity limitation	ISO 7000-2620	To indicate the acceptable upper and lower limits of relative humidity for transport and storage.
	Temperature limit	ISO 7000-0632	To indicate the maximum and minimum temperature limits at which the item shall be stored, transported or used.
	Locked.	ISO-7000-1655	To identify the locking control. To indicate that a control is locked. To indicate that the function cannot be changed or adjusted because its operation is locked. To identify the location of a lock.
	Unlocked.	ISO-7000-3305	To identify the control that effects an unlocking function. To indicate that the component or function is in its unlocked state.

Table 2 ISO 7010 - Graphical symbols - Safety colors and safety signs - Registered safety signs

Symbol	Title	Reference	Description
	General warning sign	ISO 7010-W001	To signify a general warning.
	Refer to instruction manual/booklet	ISO 7010-M002	To signify that the instruction manual/booklet must be read.
	Warning: Crushing of hands	ISO 7010-W024	To warn of a closing motion of mechanical parts of equipment.
	No heavy load	ISO 7010-P012	To prohibit the placing of heavy objects on a surface.
	No pushing	ISO 7010-P017	To prohibit pushing against an object.

Table 3 IEC 60417 — Graphical Symbols for Use on Equipment

Symbol	Title	Reference	Description
	Alternating current	IEC 60417-5032	To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.
	Type B applied part	IEC 60417-5840	To identify a type B applied part complying with IEC 60601-1.
	Equipotentiality	IEC 60417-5021	To identify the terminals which, when connected together, bring the various parts of a system to the same potential, not necessarily being the earth (ground) potential (for example, for local bonding).

Table 4 Other Symbols

Symbol	Description
	U.S. Federal law restricts this device to sale by or on the order of a licensed healthcare provider.
	To indicate that the device may not be disposed of in landfill but must be recycled according to the European Waste Electrical and Electronic Equipment (WEEE) directive.

Table 4 Other Symbols (continued)

Symbol	Description
	Does not contain latex.
	Do not move cart when keyboard tray is extended.
	Move cart with keyboard tray docked.

1.7 Warnings and Precautions

CAUTION

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

WARNING: Risk of Patient Death or Permanent Disability Due to Improper Use of the System

Use the system for the indications specified in this user manual only.

WARNING: Risk of Patient Death or Permanent Disability Due to Inaccurate Registration

Improper fixation of the patient's head in the head holder may result in inaccurate registration or loss of registration during the procedure. Follow the manufacturer's recommendations when fixing the patient in the head holder and ensure that the patient's head is properly fixed in the head holder before beginning a procedure.

Patient movement during registration may compromise registration accuracy. Take all reasonable steps to ensure there is no patient movement during registration.

When using Modus Nav, surgical accuracy should be assessed repeatedly throughout the procedure by positioning the navigated instrument tip on an identifiable anatomical landmark and comparing the actual tip location to that displayed by the system.

Abort use of the navigation system if the registration is not accurate and cannot be recovered.

WARNING: Risk of Patient Death or Permanent Disability Due to Inaccurate Fiducial Registration

Symmetrically placed fiducial markers may cause registration to be flipped. Always place the fiducial markers in an asymmetrical pattern around the head.

Fiducial markers may move if excessive pressure is applied to them during registration. Touch the fiducial markers lightly with the Synaptive Standard Pointer during registration.

Using fiducial landmarks on the patient that are not in the same location as those in the patient dataset image will compromise registration accuracy.

Greater distance between the fiducial markers and the surgical site reduces the accuracy of registration. Always place some fiducial markers as close to the surgical site as possible and place additional fiducial markers around the head. Do not place all the fiducial markers in a concentrated area.

WARNING: Risk of Patient Death or Permanent Disability Due to Inaccurate SurfaceTrace Registration

To prevent skin features from shifting, which may adversely affect the accuracy of a SurfaceTrace registration, acquire the pre-operative scan images with the patient in the same position as in the procedure.

The absence of firm structure on the patient's face may adversely affect the accuracy of SurfaceTrace registration.

Medical procedures and equipment (such as the head holder) may distort a patient's facial features in the time between acquiring the pre-operative scan images and the procedure, which may adversely affect the accuracy of SurfaceTrace registration.

Lifting the Synaptive Standard Pointer off the skin surface when tracing may adversely affect the accuracy of SurfaceTrace registration. If you need to adjust the position of the Pointer, finish the current trace and start a new one.

WARNING: Risk of Patient Death or Permanent Disability Due to Loss of Registration

The brain may shift as the dura is opened, which can cause registration to become inaccurate.

The brain may shift as a tool is inserted, which can cause registration to become inaccurate.

WARNING: Risk of Patient Death or Permanent Disability Due to Poor Tracking Accuracy

Tracking accuracy is compromised if the cranial reference is moved relative to the patient. Always attach the cranial reference as described in this manual and take all reasonable precautions to prevent it from being moved during a procedure.

Applying excess lateral force to a tool may deflect the tool tip and compromise tool accuracy.

WARNING: Risk of Patient Death or Permanent Disability Due to Contamination of Sterile Field

Use caution when draping patients and equipment. Always follow the draping instructions in this manual, all applicable draping protocols in use at your site, and protocols for maintaining a sterile field.

The cranial reference may contaminate the sterile field if it is not properly draped.

WARNING: Risk of Patient Death or Permanent Disability Due to Inappropriate Tool Use

Always inspect all tools and instruments for damage prior to surgery. Never use a tool that appears corroded, damaged, bent, or otherwise distorted from its intended shape. If the tool does not meet the inspection criteria, Modus Nav may not function as intended. Always use the Multi-Tool Calibration Device as described in this manual.

To minimize trauma to the brain, never use the BrainPath tracking array as a lever to move brain tissue.

Use caution when applying the point of a Pointer to any tissue. Do not apply pressure sufficient to damage the tissue.

Use caution when handling a Pointer over the patient. Dropping the Pointer may injure the patient.

Collisions between a Pointer and other surgical tools or devices may create metal debris, potentially harming the patient.

Always ensure the tracking spheres are firmly attached to the tool posts before each use. Loose spheres may detach and fall onto the patient.

Do not attach or remove the reflective tracking spheres over the surgical site. Always attach tracking spheres firmly to ensure that they do not fall and injure the patient.

The Pointers and Multi-Tool Calibration Device have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifacts in the MR environment. The safety of the Pointers and Multi-Tool Calibration Device in the MR environment is unknown.

WARNING: Risk of Patient Death or Permanent Disability Due to Incorrect Tool Placement

Using a brain sheath other than the one specified by the plan will result in surgery at an incorrect location and possible damage to areas of the brain outside of the intended location.

When using Standard Pointer to track a NICO BrainPath, always apply the recommended virtual tool tip and verify that Standard Pointer is centered in the obturator and inserted into the obturator as far as it will go. Incorrect Standard Pointer placement may result in surgery at an incorrect location and possible damage to areas of the brain other than the intended location.

WARNING: Risk of Patient Injury During Power Loss Due to Loss of Surgical Tracking

Loss of power to the Modus Nav operator cart will result in loss of tracking capability. Loss of tool tracking capability will result in loss of navigation. To avoid loss of power, it is recommended that you plug the operator and auxiliary carts into an uninterruptible power supply (UPS).

If power to the operator cart is cut off, the laptop will run on battery power for a limited time. If you are able to restore power, the tracking camera restarts automatically (this takes approximately 2 minutes), and tracking automatically resumes in the Modus Nav software application.

If you are not able to restore power to the operator cart, follow your site's established protocols to end the procedure.

WARNING: Risk of Patient Injury Due to Infection

The Pointers and Multi-Tool Calibration Device are not sterile when delivered. The use of non-sterile instruments poses a risk of infection to patients, users, and third parties. Clean and sterilize the Pointers and Multi-Tool Calibration Device before initial use, and before and after every subsequent use, using the cleaning and sterilization instructions accompanying the device.

The materials used in the Pointers have been tested and certified for up to 24 hours of exposure to the patient.

WARNING: Risk of Procedure Delay Due to Loss of Tracking

Infrared sources in the operating room may interfere with tracking camera tracking. Remove any non-Synaptive sources of infrared signals from the operating room before performing a procedure using the tracking camera.

Always ensure the tracking spheres are firmly attached to the tool posts before each use. If tracking spheres are not firmly attached, the tracking camera may not be able to track the tool.

WARNING: Risk of Procedure Delay Due to Loss of Workflow

When performing a navigated surgical procedure using a study that has been processed for planning but that does not contain a plan series, your progress through the Modus Nav workflow will be lost if a version of the study that contains a plan series is pushed to the Modus Nav laptop.

WARNING: Risk of Operator or Patient Injury Due to Laser Light Emission

Do not look directly into the laser-emitting aperture on the tracking camera. The Class 2 laser module on the Position Sensor emits radiation that is visible and may be harmful to the human eye. Direct viewing of the laser diode emission at close range may cause eye damage.

WARNING: Risk of Operator or Patient Injury Due to Laser Light Emission

Take precautions to ensure that people with restricted movement or reflexes (for example, patients undergoing medical procedures) do not look directly into the laser-emitting aperture. Patients undergoing medical procedures may not have normal adverse-effects reflexes (turning away eyes and/or head, closing eyes) due to pharmaceutical influences and/or mechanical restraints. The Class 2 laser module on the Position Sensor emits radiation that is visible and may be harmful to the human eye. Direct viewing of the laser diode emission at close range may cause eye damage.

Use of laser controls or adjustments or performance of laser-related procedures other than those specified herein may result in hazardous radiation exposure.

WARNING: Risk of Patient Death or Permanent Disability Due to Malfunctioning Equipment

Avoid using the Modus Nav system adjacent to other equipment. If this is not possible, observe the Modus Nav system to verify that it operates normally in the configuration in which it will be used. Never stack the Modus Nav system with other equipment.

WARNING: Risk of Operator Injury and Damage to Equipment

The Modus Nav system may be installed, maintained, repaired, and serviced only by qualified Synaptive Medical service representatives. There are no user-serviceable parts in the Modus Nav system.

No modification of the Modus Nav system is allowed.

To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Unplugging the power cord is the means to isolate the Modus Nav carts from the supply mains. Do not position a cart such that it is difficult to unplug.

Use only the cables supplied with Modus Nav by Synaptive Medical. The use of non-approved power cords can result in damage to the Modus Nav system. The use of other accessories, transducers, and cables may result in increased electromagnetic emissions or decreased immunity of this equipment and may result in improper operation. If a cable becomes damaged, contact Synaptive customer service for assistance.

The cables connecting the Modus Nav carts to each other and other equipment are a potential tripping hazard. When positioning the carts for a procedure, always ensure that there is sufficient cable length to allow the cables to reach the floor. Use caution when walking around the carts to avoid tripping over cables.

The laptop enclosure, storage drawer, and patient reference arm all pose a pinch hazard. Use caution when handling these components.

WARNING: Risk of Operator Injury and Damage to Equipment

Before moving a cart, always ensure that all cart casters are unlocked. Push the carts using the cart handles only. Never push on surfaces marked with the Do Not Push symbol. Applying excessive force to the cart or its components may present a tipping hazard.

Do not move the auxiliary cart with the tracking camera arm extended. Collapse the tracking camera arm and lock it in place before moving the cart. If the arm is not locked in place, it may extend unexpectedly and cause the Modus Nav to tip over.

Do not move the operator cart with the storage drawer open.

Use caution when moving Modus Nav system equipment to prevent collisions with people or stationary objects such as equipment, doorways, or walls.

Do not roll the Modus Nav carts over cabling.

The drawer on the operator cart can support a maximum of 3.6 kg (8 lbs). Weight over this limit may cause the drawer to break or the operator cart to tip over during movement.

Do not lean on the operator cart drawer or any other Modus Nav system component.

Fluid spills can irreparably damage the system. Take care when using cleaning agents and always follow the cleaning instructions described in this manual.

Do not use Cidex or other disinfectants to clean any of the Modus Nav components. Use only those cleaning agents described in this manual.

Only those components listed as sterilizable in this user manual may be sterilized.

Use caution when handling the Calibration Device as it can cause injury if dropped.

CAUTION: Risk of Procedure Delay or Damage to Equipment Due to Use of Inappropriate Equipment

The Modus Nav system may be used only with tools and equipment made or validated by Synaptive Medical. Do not bring any trackable instruments not made by Synaptive Medical into the Synaptive tracking camera's field of view. Do not use any tools or equipment not listed in this user manual with the system.

Do not connect any equipment not specified in this manual to the Modus Nav carts.

Modus Nav is not designed to communicate via wireless technology. Do not connect any wireless device to Modus Nav.

CAUTION: Risk of Procedure Delay Due to Loss of Registration

Always lock all casters on the Modus Nav carts to prevent them from moving during the procedure.

CAUTION: Risk of Procedure Delay

Accepting a series with missing slices may prevent you from locating appropriate surgical targets and regions of interest. Before working with a series in a study retrieved from a DICOM server, always review the entire series to ensure that all slices have been retrieved from the server.

CAUTION: Risk of Operator Injury

Wear all necessary personal protective equipment when handling contaminated components and cleaning supplies.

To prevent the risk of operator infection, dispose of the Modus Nav keyboard and mouse properly if they become contaminated.

Inspect the Modus Nav carts prior to use and do not use the system if any electrical enclosures are damaged.

The laptop enclosure and storage drawer on the operator cart and the patient reference arm all pose a pinch hazard.

1.8 Device Lifetime

Modus Nav has an expected lifespan of five years. The Pointers and the Multi-Tool Calibration Device have an expected lifespan of seven years.

1.9 Disposal

No part of the Modus Nav system may be disposed of in landfill.

Dispose of single-use, sterile items (tracking spheres, BrainPath Tracking Array,, and cranial reference drape) as pathological waste.

Before disposing of any Synaptive product, contact Synaptive customer service or your supplier for further information.

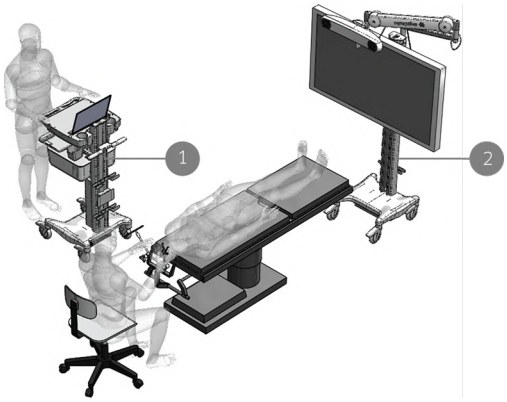
1.10 Synaptive Customer Service Information

For 24-hour access to clinical and technical support, contact Synaptive customer service.

Phone:	1-844-462-7246 (North America)
	1-647-925-3435 (International)
Email:	service@synaptivemedical.com

2.0 Modus Nav Hardware

The Modus Nav system hardware consists of an operator cart holding a laptop running the Modus Nav software and an auxiliary cart supporting the tracking camera and surgeon monitor.



1 Operator cart
2 Auxiliary cart

Other optional carts (not shown in Figure 1) are also available for purchase with Modus Nav. For more information about using optional carts, see the user manual provided with the cart or contact Synaptive Medical.

Figure 1 Modus Nav hardware

2.1 Operator Cart

The operator cart supports a laptop computer running the Modus Nav software.

WARNING: Risk of Patient Death or Permanent Disability Due to Contamination of Sterile Equipment

Do not introduce the Modus Nav laptop into the sterile field.

WARNING: Risk of Operator Injury and Damage to Equipment

The drawer on the operator cart can support a maximum of 3.6 kg (8 lbs). Weight over this limit may cause the drawer to break or the operator cart to tip over during movement.

Do not move the operator cart with the storage drawer open.

Do not lean on the operator cart drawer or any other Modus Nav system component.

Figure 2 Operator cart (front and back views)

1	Computer running Modus Nav software	6	Locking casters
2	Keyboard and mouse	7	Handle
3	Optical drive and USB port	8	Communication port
4	Storage drawer	9	Cable cleat (video cable)
5	Power tray	10	Cable cleat (power cable)

To prevent studies from being pushed to the Modus Nav laptop from a PACS during a procedure (which would negatively affect Modus Nav performance), disconnect the laptop from the network by unplugging the Ethernet cable during procedures.

Use the optical drive and/or USB port on the operator cart to import surgical plans created on a Modus Plan workstation and to copy screen shots or log data from the Modus Nav procedure to a DVD or USB key. **Do not use the USB port for any other purpose.**

Reconnect the mouse or keyboard if the laptop cannot detect either of them, or both.

2.2 Auxiliary Cart

The auxiliary cart supports the tracking camera and a 55” medical-grade monitor connected to the computer on the operator cart.

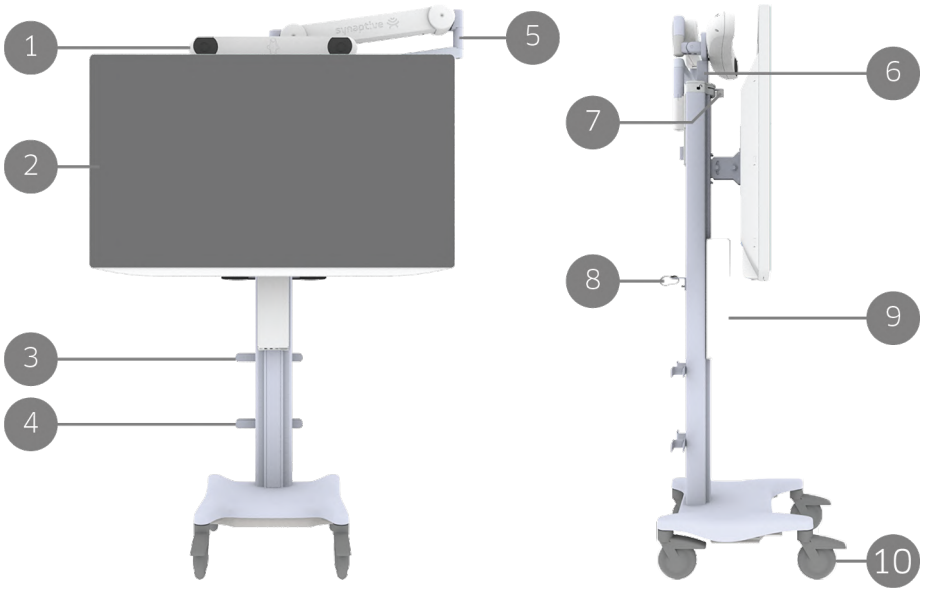


Figure 3 Auxiliary cart (front and side views)

1	Tracking camera	7	Tracking camera arm lock
2	Monitor	8	Handle
3	Cable cleat (monitor power cable)	9	I/O box
4	Cable cleat (camera cable)	10	Locking casters*
5	Tracking camera arm	11	Monitor cover (not shown)
6	Tracking camera handle		

* To prevent the tracking camera from moving during the procedure, all four casters must be locked before turning on the equipment.

For more information about using the auxiliary cart features, see the user manual accompanying your cart.

2.3 Hardware Setup

Set up the Modus Nav carts well in advance of the procedure to verify that there is adequate space in the operating room and sufficient cable length to position the carts as required for the procedure.

WARNING: Risk of Operator Injury and Damage to Equipment

Before moving a cart, always ensure that all cart casters are unlocked. Push the carts using the cart handles only. Never push on surfaces marked with the Do Not Push symbol. Applying excessive force to the cart or its components may present a tipping hazard.

WARNING: Risk of Operator Injury Due to Tripping Hazards

The cables connecting the Modus Nav carts to each other and other equipment are a potential tripping hazard. When positioning the carts for a procedure, always ensure that there is sufficient cable length to allow the cables to reach the floor. Use caution when walking around the carts to avoid tripping over cables.

2.3.1 Cart Positioning

The green volume in Figure 4 below shows the tracking camera's field of view. Although the camera can track instruments anywhere within the indicated volume, the tracking accuracy diminishes toward the margins. For best results, position the tracking camera so that the cranial reference and tracked tools are closer to the center of the volume.

The carts may be positioned in any configuration as long as they are within the recommended distances indicated in Figure 4.

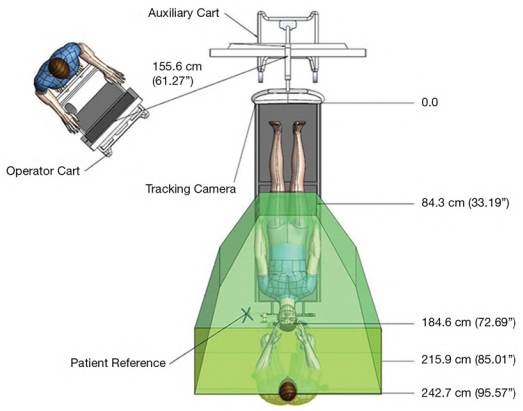


Figure 4 Modus Nav cart position tolerances

2.3.2 Cable Connection

Figure 5 below shows the Modus Nav cart cable connections.

CAUTION: Risk of Damage to Equipment Due to Use of Inappropriate Equipment

Do not connect any equipment not specified in this manual to the Modus Nav carts.

NOTE: The tracking camera on the auxiliary cart is powered by the power tray on the operator cart. To use the tracking camera, the tracking camera cable on the auxiliary cart must be connected to the operator cart and the operator cart must be plugged in to a power source.

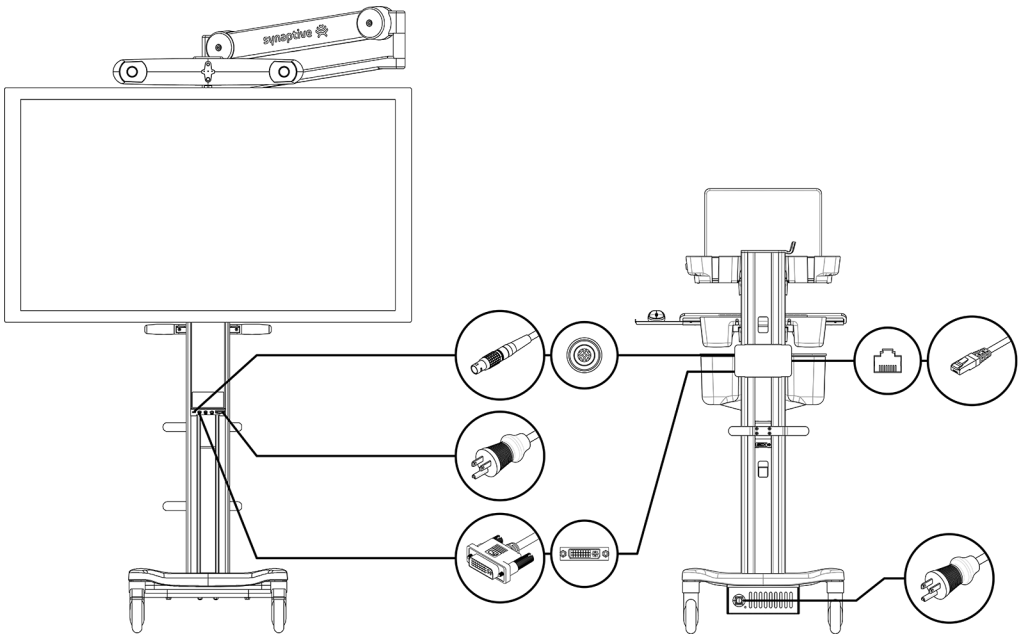


Figure 5 Modus Nav cable connections

2.3.3 Starting and Shutting Down Modus Nav

To start up the Modus Nav system:

1. Connect the tracking camera and video cables as indicated in Figure 5 above.
2. Plug the operator cart and auxiliary cart power cables into a power source.

   NOTE: It is strongly advised that you plug the carts into an uninterruptable power supply (UPS). If you are plugging the carts into wall outlets, the outlets must meet the criteria described in 12.1 System Classification and Specifications on page 122.

   The Modus Nav laptop powers up automatically.
3. Log in using your user name and password. The Modus Nav software application launches automatically.
4. Sign in using your Modus Nav user name and password. For more information about working in the Modus Nav software application, see 5.0 Performing a Procedure with Modus Nav on page 54.

To shut down the Modus Nav system:

1. Close the Modus Nav software application.
2. Click the shutdown icon in the bottom-right corner of the login screen to shut down the laptop.
3. Disconnect the cables connecting the operator and auxiliary carts and unplug both carts from the wall outlets.
4. Wrap all cables around the cable cleats on the carts.
5. Store the Modus Nav system in a secure location.

3.0 Modus Nav Instrumentation

The Modus Nav system uses a stationary cranial reference and tracked tools to provide surgical guidance. The tracked tools must be calibrated and/or verified each time they are used.

NOTE: The tracked tools are separately configured in Modus Nav and may not be available with your system. For information about enabling tracked tools, contact Synaptive customer service.

Modus Nav can track the following Synaptive tools:

- Pointer set

  The Pointer set includes a Standard Pointer, a Long Pointer, a Short Pointer, and a Multi-Tool Calibration Device in a sterilizable storage tray. Two Pointer sets are included with each Modus Nav system. Use one set of tools before, and the other set after, the sterile field has been established for the procedure.

- Tracking Array for NICO BrainPath

  A single-use tracking array that can be attached to a NICO BrainPath sheath. The tracking arrays are provided sterile. Use the Calibration Device included in the Pointer set to verify the tracking array when it is attached to a NICO BrainPath.

- Shunt Stylet

  A single-use Stylet that can be used to place shunts or ventricular catheters. The Shunt Stylet is provided sterile with tracking spheres attached.

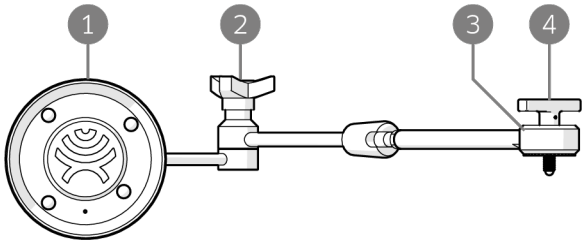
- Trackable Suction

  A surgical suction tool with a tracking array. Trackable Suction is provided with a sterilizable storage tray for sterilizing the tool components. Use the Calibration Device included in the Pointer set to calibrate and verify Trackable Suction.

NOTE: The tracking camera cannot track multiple instances of the same tool simultaneously. Use only one of each tool in the camera's field of view at a time.

3.1 Cranial Reference

The cranial reference allows the Modus Nav system to track the patient's position. For maximum accuracy, position the cranial reference as close to the surgical field as possible.



1 Cranial reference
2 Arm adjustment knob
3 Arm adapter
4 Arm adapter thumbscrew

Figure 6 Cranial reference

3.1.1 Using the Cranial Reference Arm and Adapter

WARNING: Risk of Patient Death or Permanent Disability Due to Poor Tracking Accuracy

Tracking accuracy is compromised if the cranial reference is moved relative to the patient. Always attach the cranial reference as described in this manual and take all reasonable precautions to prevent it from being moved during a procedure.

The arm adapter connects the cranial reference arm to the patient head holder.

To secure the cranial reference to the patient head holder, align the thumb screw on the cranial reference arm with the hole in the patient head holder and turn clockwise to tighten.

NOTE: The cranial reference arm adapter is only supported for use with a Mayfield head holder. The arm and adapter are not MR compatible or CT radiolucent.

To position the cranial reference arm, turn the knob on the arm counter-clockwise to loosen the joints. When the cranial reference is in a suitable position for the procedure, turn the knob on the arm clockwise to fix it in place.

IMPORTANT: Do not over-tighten the arm adjustment knob as this may damage the arm joints. Turn the knob only as far as is necessary to fix the joints in place.

3.1.2 Draping the Cranial Reference

After registration is complete, the cranial reference must be covered with the sterile cranial reference drape supplied by Synaptive Medical (part number SYN-0019).

NOTE: The cranial reference drape is not made with natural latex rubber.

WARNING: Risk of Patient Death or Permanent Disability Due to Contamination of Sterile Equipment

Use caution when draping patients and equipment. Always follow the draping instructions in this manual, all applicable draping protocols in use at your site, and protocols for maintaining a sterile field.

To apply the cranial reference drape:

1. Verify that the thumbscrew and knob on cranial reference arm are tightened securely.
2. Fit the drape ring around the cranial reference plate. Press on the surface of the drape lens to ensure that it is fully flush with the rim of the cranial reference plate. The drape lens must be parallel with the cranial plate and must not be bulging out.
3. Unfold the drape down the length of the cranial reference arm. The drape should cover the entire length of the arm including the adapter that connects it to the head holder.
4. Peel off the backing on the adhesive patches on the plastic strips and use the strips to snug the

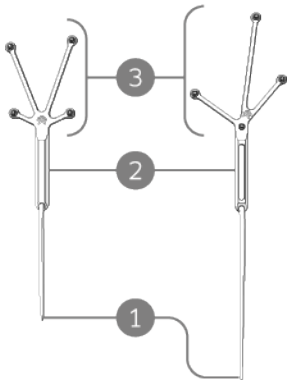
drape around the cranial reference arm.

5. Pull the blue tab to remove the protective cover from the drape lens.

3.2 Pointers

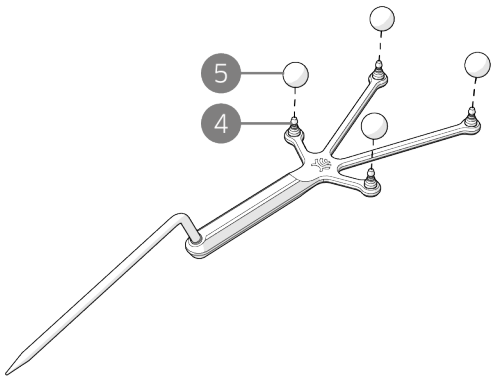
3.2.1 Standard Pointer and Long Pointer

Use Standard or Long Pointer to perform registration and to verify the location of anatomical features during a procedure. Modus Nav tracks the Standard and Long Pointer tip.



1 Tip
2 Handle
3 Tracking array
4 Tracking sphere post
5 Tracking sphere

Standard and Long Pointer features



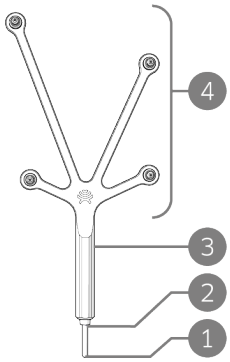
Pointer assembly

The Standard and Long Pointers are also used to navigate the Vycor port tools and can be used to navigate a NICO BrainPath if necessary. For more information, see 5.11.6 Using a Pointer to Navigate the Approach for a NICO Port on page 92.

3.2.2 Short Pointer

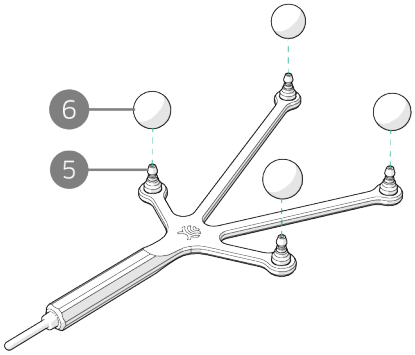
Use Short Pointer to position a commercially-available trajectory guidance platform in surgical procedures such as biopsies or catheter or electrode insertion. Short Pointer is compatible with trajectory guidance platforms that include a 2.6 mm reducing tube.

Modus Nav tracks the "shelf" where the Short Pointer tip meets the handle. For more information, see Important Information About the Trajectory Length When Using Short Pointer on page 96.



1 Tip
2 Shelf (trajectory length is measured from this point)
3 Handle
4 Tracking array
5 Tracking sphere post
6 Tracking sphere

Short Pointer features



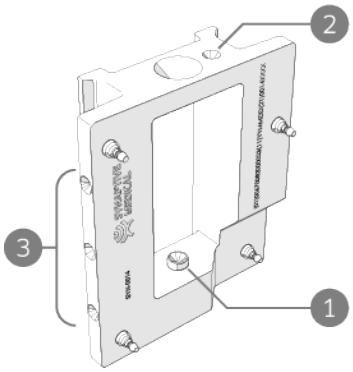
Short Pointer assembly

3.3 Calibration Tools

Before you can use any Synaptive tracked tool with Modus Nav, the tool must be calibrated and verified to ensure that it is not damaged and that it matches the tool selected in the Modus Nav software application. Your Modus Nav system is configured to use either the Synaptive calibration block or Multi-Tool Calibration Device for calibrating and verifying Synaptive tools.

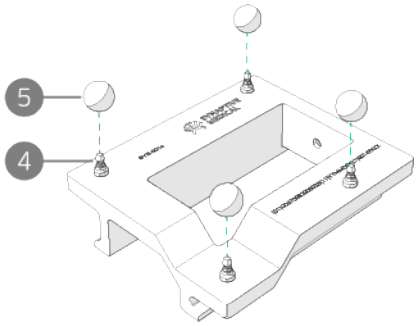
Follow the instructions in the Modus Nav software application to calibrate and verify the Synaptive tracked tools at the appropriate phases in the procedure.

3.3.1 Calibration Block



1 Calibration divot
2 Top verification divot
3 Side verification divots
4 Tracking sphere post
5 Tracking sphere

Calibration block features



Calibration block assembly

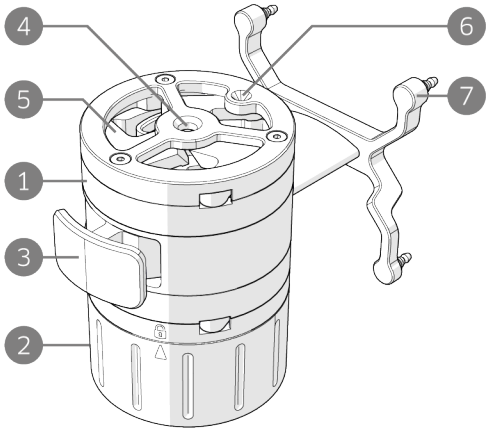
Follow the instructions in the Modus Nav software application to calibrate and verify the Synaptive tracked tools at the appropriate phases in the procedure.

3.3.2 Multi-Tool Calibration Device

WARNING: Risk of Operator Injury or Damage to Equipment

Use caution when handling the Calibration Device as it can cause injury if dropped.

Calibration Device Features



1 Body
2 Removable base
3 Release lever
4 Instrument aperture
5 Holder arms
6 Verification divot
7 Tracking array

Figure 7 Multi-Tool Calibration device features

Calibration Device Assembly

Figure 8 Assembling the Multi-Tool Calibration Device

1 Attach the removable base to the body by aligning the arrow indicator on the base with the "unlock" symbol on the body and rotating the base until the arrow aligns with the "locked" symbol.

2 Attach a tracking sphere to each post. Push the spheres as far down onto the posts as they will go. You should feel the spheres snap into place. Verify that each sphere is securely attached to its post.

NOTE: You must attach new tracking spheres to the sterile Multi-Tool Calibration Device for each procedure.

Calibration Device Inspection

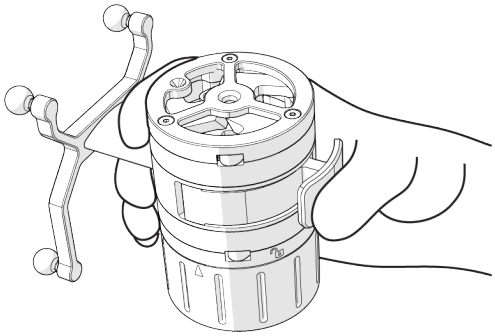
WARNING: Risk of Patient Death, Permanent Disability, or Injury Due to Inappropriate Tool Use

Always inspect the Calibration Device for damage prior to surgery. Never use a tool that appears corroded, damaged, bent, or otherwise distorted from its intended shape. If the Calibration Device does not meet the inspection criteria, Modus Nav may not function as intended.

If the Calibration Device does not meet the criteria listed below, do not use it. Contact Synaptive customer service for assistance.

- The Calibration Device must be free of corrosion
- The Calibration Device must be free of nicks, dents, or cracks
- The tracking array must not be bent or otherwise distorted from its original shape, and the posts for attaching the tracking spheres must be undamaged and perpendicular to the tool
- The release lever must move smoothly and the holder arms must open and close freely when the lever is pressed and released

Holding the Calibration Device



Hold the Calibration Device securely in the palm of your hand with the tracking array between your index and middle fingers.

Use your thumb to squeeze the release lever, which opens the holder arms.

Figure 9 Holding the Calibration Device

3.4 Tracking Array for BrainPath

The Synaptive tracking array for BrainPath allows the Modus Nav system to track the brain sheath throughout the procedure. The tracking array is designed for use with the NICO BrainPort Kit. The BrainPort is also referenced by the manufacturer (NICO) as BrainPath.

Table 5 Compatible BrainPath Products

Diameter	Lengths
13.5 mm	• 50 mm • 50 mm ST-Gold • 60 mm • 75 mm • 95 mm
11 mm	• 50 mm • 60 mm • 75 mm

When the tracking array is attached to a BrainPath tool Modus Nav tracks the distal end of the BrainPath sheath.

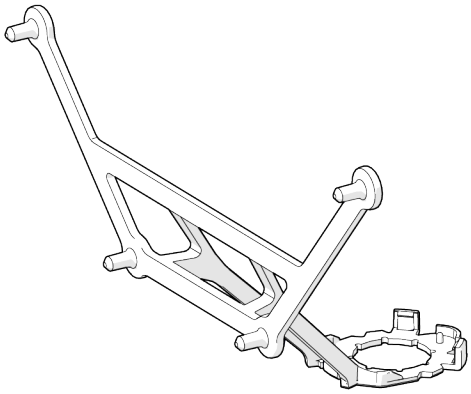


Figure 10 BrainPath tracking array

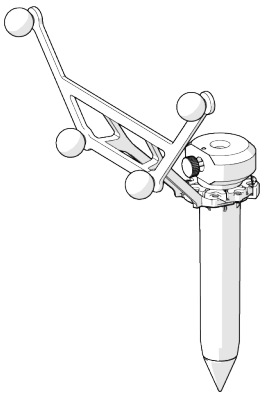


Figure 11 BrainPath tracking array on brain sheath

To attach the BrainPath tracking array to the brain sheath (NICO BrainPath), insert the brain sheath into the tracking array ring and press until the brain sheath lip “snaps” securely to the ring. Attach the tracking spheres immediately before the procedure.

NOTE: A faulty connection between the BrainPath tracking array and the brain sheath (NICO BrainPath) can result in the tool being placed in an incorrect location. Always inspect the BrainPath tracking array to verify that it is correctly fitted to the brain sheath.

The NICO Shepherd’s Hook™ must be attached under the BrainPath tracking array when the brain sheath is in use to ensure the fit.

Handle the BrainPath tracking array by the ring that connects it to the brain sheath, not by the “tree” where the tracking spheres are attached. Handling the BrainPath tracking array by the tree may distort the tool’s shape and compromise tracking accuracy.

The tracking array and tracking spheres are single-use only and must be properly disposed of after each procedure.

Follow the manufacturer's instructions for sterilization or disposal of the NICO BrainPath Kit components.

3.5 Shunt Stylet

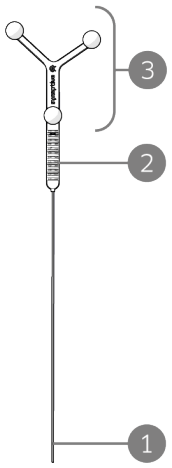


Figure 12 Shunt Stylet features

Use Shunt Stylet with Modus Nav to place shunts or ventricular catheters. Shunt Stylet is compatible with catheters having an inner diameter between 1.3 mm and 1.5 mm. Modus Nav tracks the Shunt Stylet tip.

1 Tip
2 Handle
3 Tracking Array

NOTE: To minimize the possibility of the Shunt Stylet tip deflecting during cannulation, avoid applying lateral force to Shunt Stylet when cannulating.

Shunt Stylet is provided sterile with reflective tracking spheres already attached (the tracking spheres cannot be removed or replaced). It is single-use only and must be properly disposed of after each procedure.

3.6 Trackable Suction

Trackable Suction is a surgical suction tool that can be tracked and localized using other Synaptive products. Modus Nav tracks the tip of the suction tube.

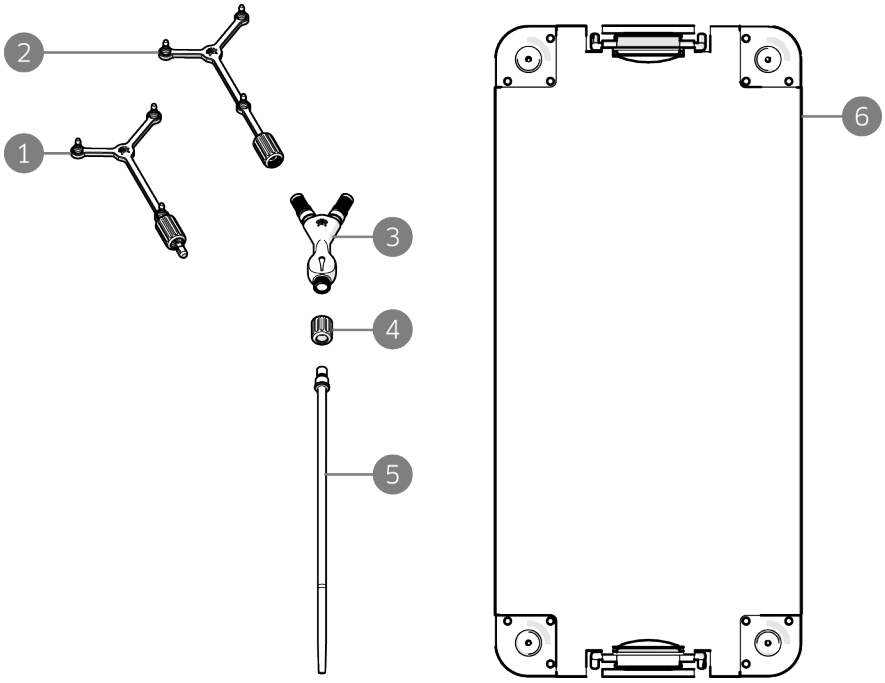


Figure 13 Trackable Suction components

1	Tracking array 1	4	Tube nut
2	Tracking array 2	5	Suction tube (see the user manual accompanying Trackable Suction for a complete list of available suction tube configurations)
3	Handle	6	Sterilizable storage tray (not to scale)

3.6.1 Assembly

NOTE: Make sure that the suction tube and tracking array are fully seated in the handle before tightening the nut. Tighten nuts firmly to ensure the suction tool components stay connected during use.

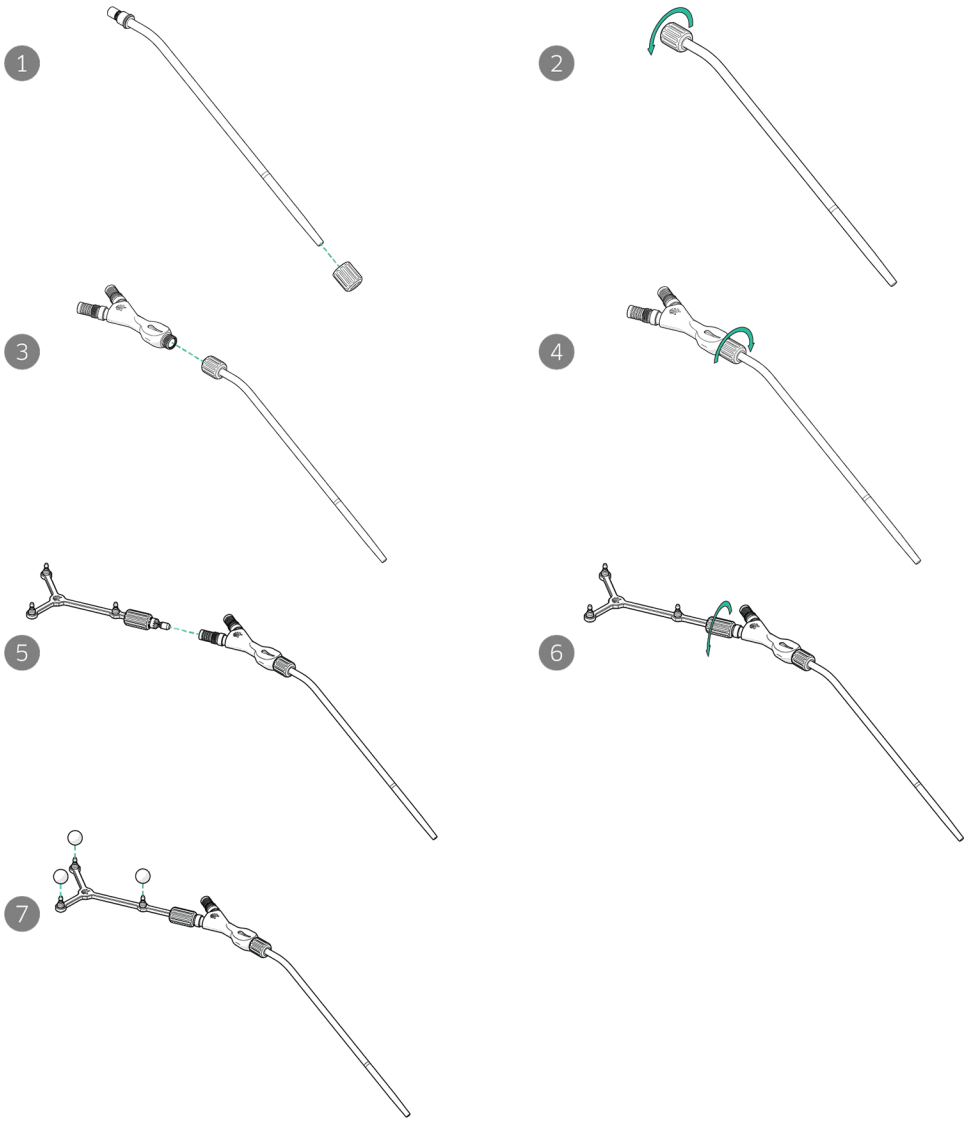


Figure 14 Trackable Suction assembly steps. Reverse these steps to disassemble.

NOTE: The tracking array may be attached to either fitting on the top of the handle.

TIP: In step 5, attach the tracking array to the post furthest from the surgeon's hand and position it so that the tracking array will always be visible to the tracking camera. The surgeon may want to try out different positions before calibrating Trackable Suction.

3.7 Working with Reflective Tracking Spheres

Synaptive trackable tools are tracked using spherical passive reflective markers. In order to track a tool, all the spheres on the tool must be:

- Properly attached

  To attach the tracking spheres to a tool, push them firmly onto the posts on the tool until they stop. You should feel the spheres snap into place. If a sphere is loose, or is not pushed as far as it will go onto the post, the tracking camera may not be able to track the tool.

- Visible to the tracking camera

  To prevent the loss of tool tracking, avoid obstructing the tracking camera's view of the spheres when using a trackable tool.

- Clean

  If the tracking spheres become soiled during use they can be replaced, but be aware of the following points:

  - Do not attempt to replace tracking spheres over the surgical site
  - If you replace a tracking sphere on a calibrated tool, you must re-calibrate the tool before using it again

Perform a visual inspection before using tracking spheres. Do not use the spheres if they, or their packaging, appear damaged.

The tracking spheres are single-use only and must be properly disposed of after each use.

4.0 Modus Nav Software

The Modus Nav software consists of the Study Explorer and procedure workspace.

4.1 About the Study Explorer

Modus Nav opens in the study explorer where you can locate and work with studies.

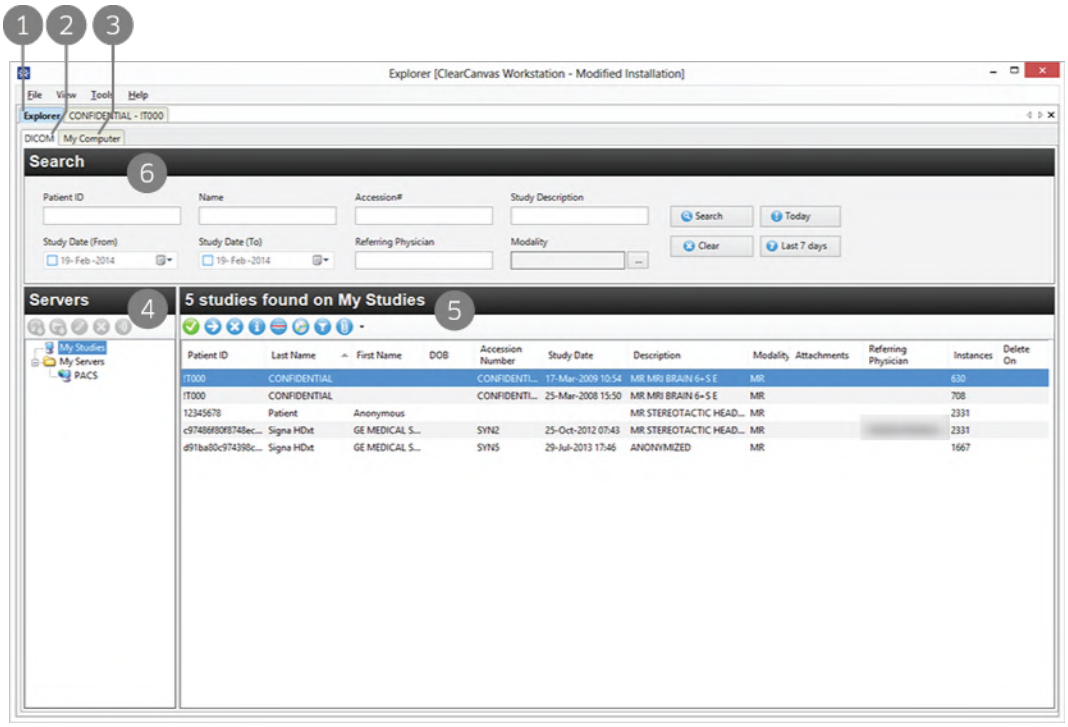


Figure 15 Study explorer interface

1 Explorer tab. If you are working with a study in Investigate mode, you can access the study explorer by clicking the Explorer tab. To access the study explorer from the navigation workspace, click Exit icon.

2 The DICOM tab displays studies in the local database (My Studies) and any remote DICOM servers Modus Nav is configured to communicate with, such as a PACS.

3 The My Computer tab displays an explorer view of the workstation. Use this tab to locate studies on the workstation or to import studies from external media such as a flash drive.

4 The Servers pane lists the local database and the remote DICOM servers Modus Nav is configured to communicate with. For more information about working with servers, see Server Configuration.

5 The Studies pane displays the studies on the selected server.

6 Use the fields in the Search pane to locate studies on the selected server.

4.2 About the Procedure Workspace

The Modus Nav procedure workspace consists of a workflow ribbon, one or more viewports, tracking icons, feature icons, system icons, and the phase panel.

4.2.1 The Workflow Ribbon

The workflow ribbon shows the phases in the Modus Nav workflow.

Figure 16 Workflow ribbon

The phase color indicates the phase state:

- Blue indicates the current phase
- Black indicates the phase is complete (though you can return to a completed phase to add or change values if necessary)
- Gray indicates that the phase has not been started, or that the work in that phase is not complete.

4.2.2 Tracking Icons

The tracked instruments are represented by icons on the left side of the workspace.

 Cranial reference

 Standard Pointer

 Long Pointer

 Synaptive robotic exoscope end effector (optional)

 NICO BrainPath tracking array

 Shunt Stylet

 Short Pointer

 Trackable Suction array 1

 Trackable Suction array 2

 Multi-Tool Calibration Device

 Calibration block

 Align to Trajectory

NOTES:

- The tracked tools are separately configured in Modus Nav. Only the icons for tools that have been configured for use with your system are visible in the software. For information about enabling tracked tools, contact Synaptive customer service.
- The Align to Trajectory feature is only available with the Synaptive robotic exoscope.
- Before you can use the Align to Trajectory feature, a number of conditions must be met. For more

information, see 5.13 Using Align to Trajectory on page 102.

- The Align to Trajectory icon is always red in the Plan Selection phase of no plan workflows.

The icon color indicates the tracking status:

- Green: Instrument is being tracked by the camera and has been calibrated/verified (when applicable)
- Yellow: Instrument is being tracked by the camera but has not been calibrated/verified
- Red: Instrument is not being tracked by the camera or some conditions have not been met

If you are unsure whether a tool is in the tracking camera's field of view, click the tracking camera icon on the left side of the workspace to open the Tracker Calibration dialog.

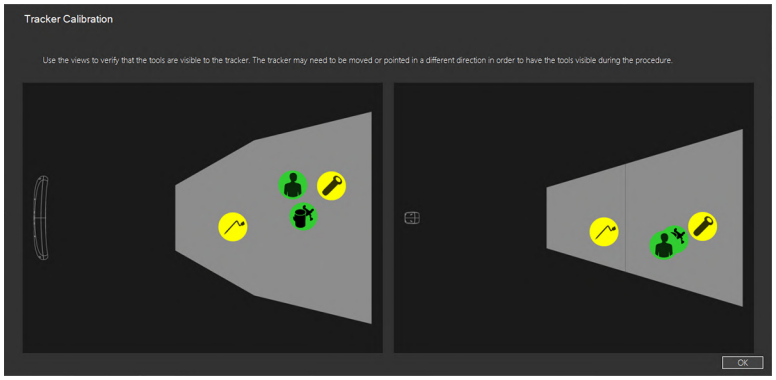


Figure 17 Tracker Calibration dialog

Tracking When Connected to the Synaptive Robotic Exoscope

The Synaptive robotic exoscope temporarily disables tracking during IR fluorescence visualilzation to prevent image artifacts from the tracking camera. When this occurs, the tracking camera icon changes to indicate that tracking is paused and that tool location data is not available.

If the Synaptive robotic exoscope shuts down while tracking is paused, you must restart the Modus Nav system to re-enable tracking.

4.2.3 Feature Icons

Use the rescue points feature to capture anatomical points in the event that you need to recover a lost registration. This icon is displayed in one of three colors:

- Black: Registration recovery cannot be performed. This may be because:
  - The tracking camera is not available
  - The Pointer tool is not calibrated
  - No registration has been accepted
- White: Rescue points can be defined or redefined.
- Green: Rescue points have been used to recover the registration.

The icon is displayed with a check mark when rescue points have been defined.

For more information, see 5.10 Registration Recovery on page 84.

In the Approach and Resection phases, click this icon to freeze or resume navigation.

NOTE: Navigation automatically resumes if you explode or restore a viewport, switch the hanging protocol, move to a different phase in the workflow, or open the tracking camera view.

To capture a screen shot of the viewports, click the camera icon. To access your screen shots, in the Modus Nav Explorer window click **Tools** > **Explore Screen Captures**. A Windows Explorer window opens where you can view your screen shots and save them to a USB drive.

NOTE: To maintain the privacy of the patient's protected health information, before capturing a screen shot use the Show/Hide Overlays tool to hide the DICOM data displayed in the viewports.

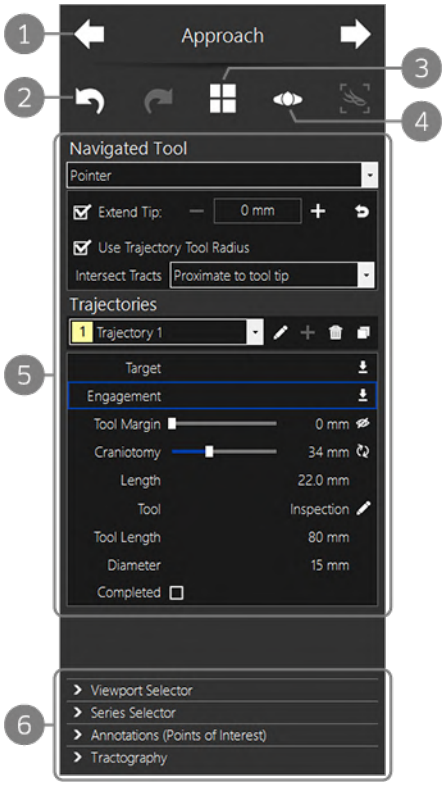
4.2.4 System Icons

Click the volume icon to adjust the Modus Nav laptop volume.

A battery icon appears in the Modus Nav workspace if the Modus Nav laptop is unplugged or is not receiving AC power for some other reason. A warning message is also displayed indicating that performance will be affected when the Modus Nav laptop is running on battery power.

4.2.5 The Phase Panel

The phase panel contains information and options relevant to the task you are currently performing in the phase.



1 Click the **Previous** and **Next** arrows to move between phases. Note that the **Next** arrow does not become available until you have completed all required tasks for the current phase.

2 Undo and redo icons.

3 Change layout icon. Click to change the viewport layout in the workspace. For more information, see 4.3.1 Custom Viewport Layouts on page 45.

4 Change the patient orientation in the viewports.

5 Task area. This area displays information, options, and actions relevant to the current phase.

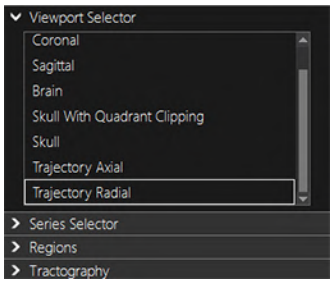
6 View options. For more information, see 4.2.6 View Options on page 38.

Figure 18 Phase panel in the Approach phase

4.2.6 View Options

Use the view options in the phase panel to change the information displayed in the viewports. Note that the view options available in the phase panel are limited to those that are appropriate to the phase you are currently working in.

Viewport Selector Options



The Viewport Selector option contains a list of anatomical views that can be displayed in the viewports.

To display a view, select the viewport you want to see it in and then select a view option from the **Viewport Selector** list.

NOTE: You can also change the view by right-clicking a viewport and selecting from the Select View options in the context menu.

Figure 19 Viewport Selector list

Series Selector Options

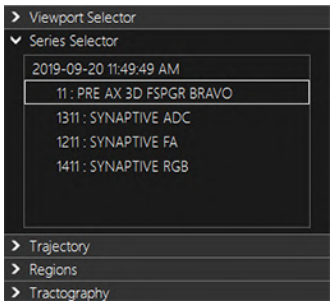


Figure 20 Series Selector list

The Series Selector option contains a list of series that can be displayed in the viewports. The list includes the series in the plan study as well as merged series (for more information about merging series, see 5.6 Merged Series Phase on page 65). Right-click on a series name and select **Show Series Details** from the context menu to see information about the series.

To display a series, select the viewport you want to see it in and then select a series from the **Series Selector** list. To apply the series to all the viewports, right-click on the series name and select **Apply to all Viewports** from the context menu.

NOTE: You can also change the series by right-clicking a viewport and selecting from the Select Series options in the context menu.

Regions Options

The Regions options become available when one or more regions have been added to the series.

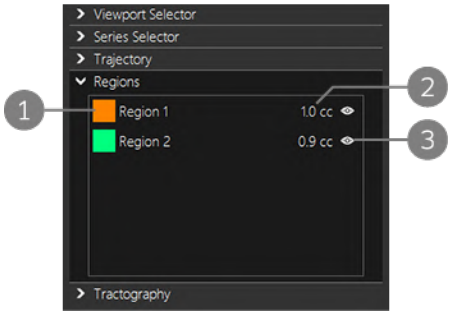


Figure 21 Regions overlay options

1 Displays each region you created in the Segmentation phase.

2 Displays the region volume in cubic centimeters (cc).

3 Click the show/hide icon to show or hide this region in the workspace.

NOTE: You can also toggle the visibility of regions by right-clicking on the region name and selecting an option from the context menu.

To change the region's color, click on the colored square and select a new color from the options that appear. To change the region's name, double click on the name and enter a new one.

Tractography Options

NOTE: Modus Plan is required to generate tractography for use in Modus Nav.

The Tractography overlays options are available if you accepted the tractography in the Review phase.

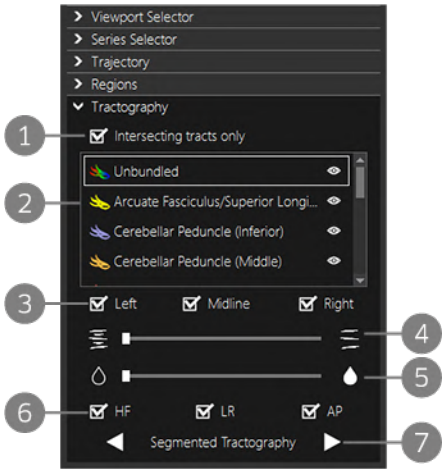


Figure 22 Tractography options

1 Select the **Intersecting tracts only** option to show only those tracts that intersect a trajectory. (This option becomes available when a trajectory has been created.) The size of the area considered for tract intersection is based on the size of the tool you have selected for the trajectory. When reviewing tract intersection for the trajectory, always verify that you have the correct tool selected.

2 Any tract bundles that have been created for this series are displayed here.

TIP: Right click on the name of a tract bundle and select Show only this bundle to view the bundle in isolation in the viewports.

3 Show tracts based on the brain hemisphere.

4 Move this slider to adjust the number of unbundled tracts displayed in the viewports based on their FA value and length. As the slider moves to the right, only longer tracts are displayed.

NOTE: This only applies to unbundled tracts. Tracts in bundles are not affected by this slider.

5 Move this slider to adjust how the tracts are displayed in the viewports based on the degree of free water correction.

NOTE: Free water correction is a separately licensed feature and may not be available on your Modus Nav system. For more information about the free water correction feature, see your Modus Plan user manual.

6 Show tracts based on direction. Select the options to show or hide tracts running in the Head-Foot (HF), Left-Right (LR), or Anterior-Posterior (AP) direction.

7 Click the arrows to toggle between viewing the whole brain tractography and segmented tractography (tract bundles).

NOTE: Modus Nav retains the last specified tractography culling slider positions in the Approach and Resection phases. When you move between these phases, a notification appears indicating that some tracts are not being displayed due to the tractography culling settings. Before proceeding, verify that the tractography complexity setting is appropriate for the work you will be doing in the phase.

Annotations (Points of Interest)

The Annotations (Points of Interest) overlay options appear in the Approach and Resection phases. Use these options to mark points of interest in the viewport images. The annotation points are added at the location of the navigated tool tip (or virtual tip, if a virtual tip has been applied).

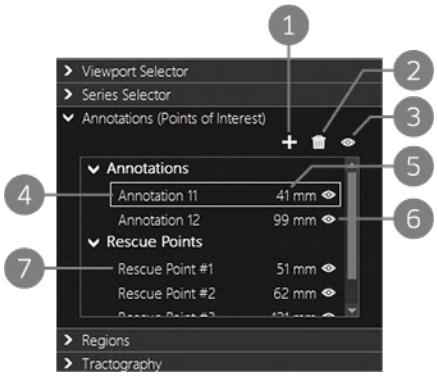


Figure 23 Annotations overlay options

1 Add an annotation. Click this icon to add an annotation at the location of the navigated tool tip (or virtual tip)

2 Delete the selected annotation.

3 Show/hide all annotations in the viewports.

4 Annotations are listed here. Double-click on an annotation to rename it.

5 The distance between the annotation point and current location of the navigated tool tip is displayed here.

6 Show/hide this annotation in the viewports.

7 If you defined registration rescue points in the Registration phase, they are listed here. Note that you cannot rename registration rescue points.

Annotations appear in the viewports. Click and drag an annotation label to move it if it is obscuring the image.

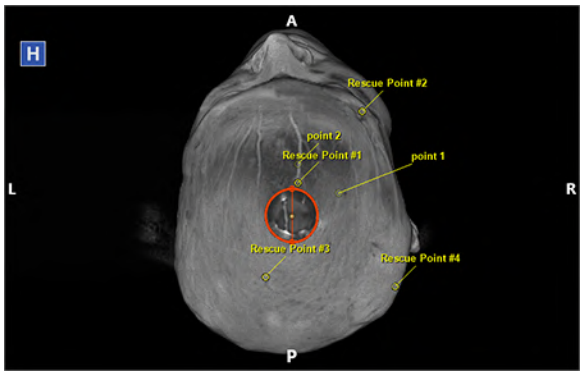


Figure 24 Annotations in viewport

NOTE: In viewports showing a 2D image, annotations only appear when the tool is on the same slice as the annotation point.

4.2.7 Modus Nav Viewports

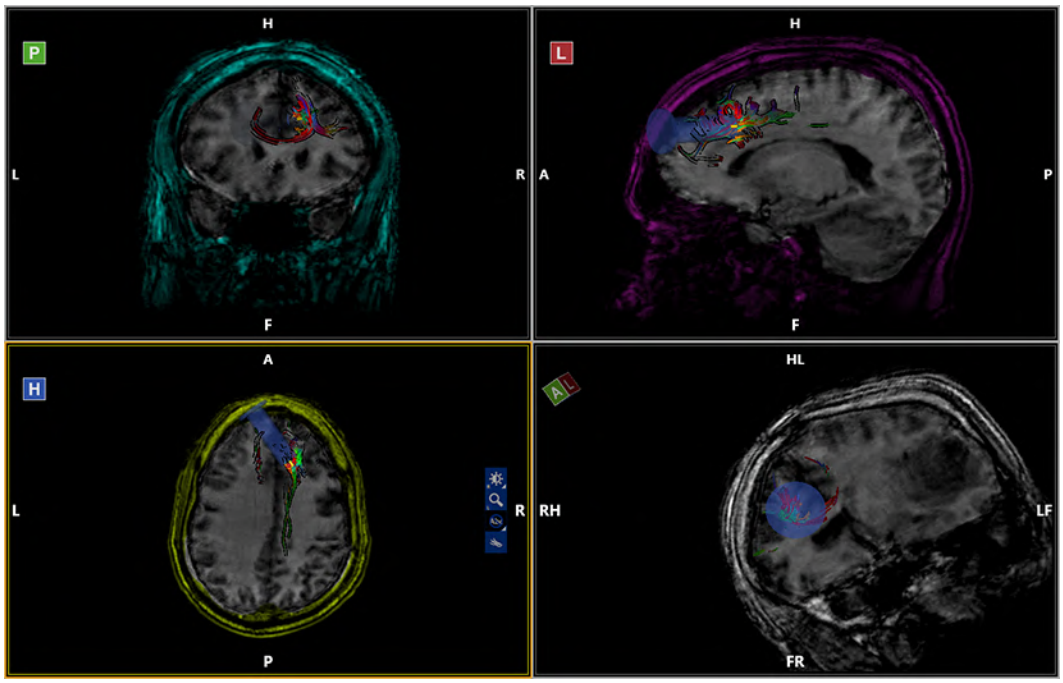


Figure 25 Viewports in the Resection phase

The viewports display one or more views of your image series. Modus Nav has preset viewport layouts for each workflow phase but you can create and save custom layouts if you need them (for more information, see 4.3.1 Custom Viewport Layouts on page 45). The viewports in some phases display image artifacts like regions and tract bundles created in Modus Plan.

NOTE: Use careful clinical judgment when using a series with image artifacts, as these may occlude anatomical features.

The tools available in each phase appear in the active viewport.

TIPS:

- **To expand a viewport to fill the whole workspace, double-click in the viewport or press the X key on the keyboard. Double-click or press the X key again to restore the viewport to its original size.**
- **Right-click in the viewports to display a context menu that allows you to perform other tasks like toggling on and off the brain mask and craniotomy visualizations.**

4.2.8 Viewport Tools

The tools applicable to the tasks in each phase appear in the active viewport. The tools available depend on the task you will perform in that viewport. For example, the Rotate tool is only available in viewports that contain a solid volume rendering of the anatomy.

You can also access tools and options applicable to the active viewport by right-clicking in the viewport and selecting them from the context menu that appears.

Tools that involve using the mouse can be assigned to a mouse button. For more information, see 4.2.8.1 Assigning a Tool to a Mouse Button on page 45.

NOTE: For more detailed information about the viewport tools, see the Modus Plan User Reference Guide.

Table 6 Viewport Tools

	Tool	Description
	Stack	Click and drag the mouse to stack through the slices and volumes in the series. • Drag the mouse up or down to decrease or increase the slice index. • Drag the mouse left or right to stack through volumes. Alternatively, you can also use the mouse scroll wheel to stack.
	Radial Stacking	Click in the image and drag the mouse up or down to stack around an axis. Alternatively, you can also use the mouse scroll wheel to stack radially. **NOTE: To quickly jump to the nearest orthogonal view in a radially stacked image, right-click in the image and select Snap to Nearest Plane. To switch to the alternate orthogonal view, right-click in the image (in orthogonal view) and select Snap to Perpendicular Plane.**
	Trajectory Stacking	Click in the image and drag the mouse up or down to stack through image slices perpendicular to a trajectory. This tool is only available when a valid target and engagement point have been created for a trajectory and the Position slider is selected in the phase panel. For more information, see 5.8.1 About the Position Slider on page 74.
	Window/Level	Click and drag the mouse in the image to adjust the window contrast and brightness. • Drag the mouse left or right to adjust the window (contrast) value. • Drag the mouse up or down to adjust the level (brightness) value. If window/level presets have been configured, click and hold on tool to select a preset. **IMPORTANT: The window/level settings may cause sulci to appear wider and deeper than they are.**
	Pan	Click and drag the mouse to move the image in any direction in the viewport.

Table 6 Viewport Tools (continued)

	Tool	Description
	Zoom	Zoom in or out of the image. The zoom level is applied to all 2D viewports. • Drag the mouse up to zoom in. • Drag the mouse down to zoom out. **NOTE: Your system may be configured to reverse these directions.** Click and hold on this tool to select a discrete magnification factor.
	Rotate	Click and drag the mouse to rotate a 3D solid view.
	Reset	Click to reset the image to its original parameters (zoom, pan, flip, rotation).
 	Hide Overlays / Show Overlays	Click to hide the viewport overlays. When this tool is active, it changes to the Show Overlays tool. Click it to show the viewport overlays. Click and hold on this tool to select specific overlay elements to show or hide.
 	Toggle Region Graphics	Click to hide or show regions that you have created. Click and hold on this tool to select a specific region display option to show or hide.
	Toggle Tractography	Click to show the tract information in the image in all viewports. Click again to hide the tracts.
	Ruler	Draws a line on the image and displays its length.
	Spatial Locator	Adds persistent crosshairs to all viewports.
	Add	Use the Add tool to add fiducial markers to register and in the Trajectories phase to add a target and engagement point.
	Set Location	Click to move an existing fiducial marker, a target, or engagement point to the current spatial locator position.
	Toggle Extracted Surface	Click to show a translucent image of the skin surface in the viewport. When this tool is active, click it again to hide the skin surface. **NOTE: This tool is only available in viewports that contain a 3D solid view. This tool is not available in the Merged Series phase. The extracted skin surface view is not available for gantry-tilted series.**

When the lower-right corner of a tool icon is a white triangle, click and hold on the tool icon to open a context menu with additional options for using the tool.

Figure 26 Zoom tool context menu

4.2.8.1 Assigning a Tool to a Mouse Button

By default, certain tools are mapped to the left and right mouse buttons in each workflow phase, but many tools can be temporarily assigned to a mouse button.

To assign a tool to a mouse button, click the tool in the toolbar with the mouse button you want to use. Clicking in the image with that mouse button now performs the function associated with the tool.

Figure 27 Tools assigned to mouse buttons

When a tool has been assigned to a mouse button, the toolbar icon for the tool is highlighted and displays the letter corresponding to the mouse button it has been assigned to (left, right, middle, and others). For mouse devices with five buttons, the buttons on the left and right edges of the mouse are indicted by the numbers 4 and 5.

4.3 Common Tasks

Each phase in the Modus Nav workflow is designed to facilitate specific tasks in a navigated surgical procedure, but some tasks can be performed in many phases.

4.3.1 Custom Viewport Layouts

Each workflow phase has a preset hanging protocol that displays content in the viewports appropriate to complete the tasks in that phase, but you can adjust the viewport layouts and contents and save your changes as custom viewport layouts if you prefer. To access the custom viewport layout features, click the **Change layout** icon in the phase panel.

NOTE: The custom viewport layout features are only available in some workflow phases.

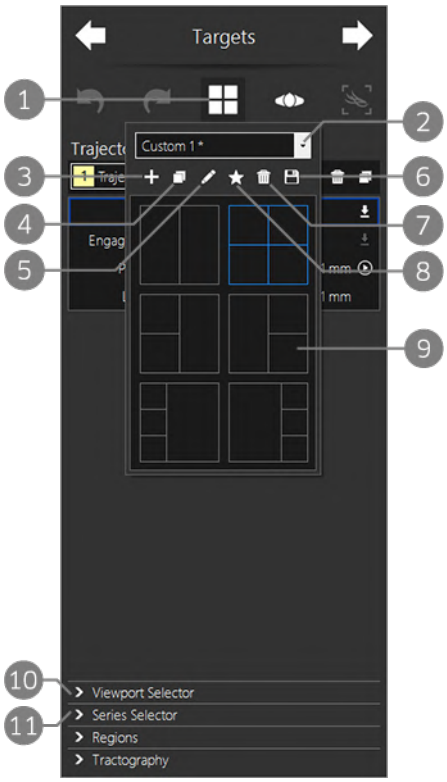


Figure 28 Custom viewport layout features

1 **Change layout** icon.

2 Available viewport layouts. This list contains the preset layouts available for the current workflow phase as well as any layouts you have created. Select a layout from the list to view it in the workspace.

NOTE: The default layout for the current workflow phase is shown in bold text.

3 Create a new custom viewport layout.

4 Copy the current viewport layout into a new custom viewport layout.

5 Rename the currently selected custom viewport layout.

6 Save the current viewport layout as a new custom viewport layout.

NOTE: If you do not save the layout, it is not saved when you exit the planning workflow and will not be available for future planning.

7 Delete the currently selected custom viewport layout.

8 Set the currently selected viewport layout as the default layout for this workflow phase.

9 Viewport layouts. Select a layout to display in the workspace.

10 Viewport Selector options. For more information, see Viewport Selector Options on page 38

11 Series Selector options. For more information, see Series Selector Options on page 39.

Creating a New Custom Viewport Layout

To create a new custom viewport layout:

1. Click the **Change layout** icon in the phase panel.
2. Click the **New** icon (item 3 in Figure 28 above).
3. Select a viewport layout from the viewport layouts options (item 9 in Figure 28 above).
4. Use the **Viewport Selector** options to populate the viewports with the anatomical views you want to see in this layout. You can also right-click in a viewport and select the content to display from the **Select View** options in the context menu.

   NOTE: The viewports always open with the primary series displayed. You cannot save alternate series as part of a custom viewport layout.
5. Click the **Save** icon (item 6 in Figure 28 above).
6. In the **Custom Layout Name** dialog, enter a name for this viewport layout and then click **OK**.

Creating a Custom Viewport Layout by Copying

You can also create a new custom viewport layout by copying an existing viewport layout.

1. Click the **Change Layout** icon in the phase panel.
2. Select the viewport layout you want to use as a starting point from the viewport layouts list.

3. Click the **Copy** icon (item 4 in Figure 28 above). Modus Nav creates a new custom viewport layout with a default name.
4. Use the **Viewport Selector** options to populate the viewports with the anatomical views you want to see in this viewport layout. You can also right-click in a viewport and select the content to display from the **Select View** options in the context menu.
5. Click the **Save** icon (item 6 in Figure 28 above).
6. In the **Overwrite Custom Layout** dialog, click **Overwrite**.
7. If you want to change the name of the new custom viewport layout from the default, click the **Rename** icon (item 5 in Figure 28 above). In the **Custom Layout Name** dialog, enter a name for this viewport layout and then click **OK**.

Modifying a Custom Viewport Layout

You can modify any custom viewport layout you have created. You cannot modify the preset viewport layouts that come with Modus Nav. To modify a custom viewport layout:

1. Click the **Change Layout** icon in the phase panel.
2. Select the viewport layout you want to modify from the viewport layouts list.
3. Use the **Viewport Selector** options to populate the viewports with the anatomical views you want to see in this viewport layout. You can also right-click in a viewport and select the content to display from the **Select View** options in the context menu.
4. Click the **Save** icon (item 6 in Figure 28 above).
5. In the **Overwrite Custom Layout** dialog, click **Overwrite**.

Setting a Default Viewport Layout

To set a viewport layout as the default layout to display in the current workflow phase:

1. Click the **Change Layout** icon in the phase panel.
2. Select the viewport layout you want to set as the default from the viewport layouts list.
3. Click the **Set as Default** icon (item 8 in Figure 28 above).

Deleting a Custom Viewport Layout

You can delete any custom viewport layout you have created. You cannot delete the preset viewport layouts that come with Modus Nav. To delete a custom viewport layout:

1. Click the **Change Layout** icon in the phase panel.
2. Select the viewport layout you want to delete from the viewport layouts list.
3. Click the **Delete** icon (item 7 in Figure 28 above).
4. In the confirmation dialog that appears, click **Yes**.

4.3.2 Changing the Color of Visualizations

You can change color of regions and tract bundles (if they were created in Modus Plan) and trajectories.

To change a region color:

1. Expand the **Regions** section of the Overlays options in the phase panel.
2. Click on the color beside a region and then select a new color from the palette that appears.

Figure 29 Selecting a new region color

A series containing very large region volumes may take longer to load. The system loads the coarse surface first, then the refined surface with a higher resolution in the background. If the surface is clinically relevant for the procedure, wait until the refined surface is loaded before proceeding to the Approach or Resection phase. You can check the status in the Regions overlays section. When the system has finished loading the refined surfaces, the "Refining surfaces" status message disappears.

Figure 30 Regions - Refining surfaces

To change a tractography bundle color:

1. Expand the **Tractography** section of the Overlays options in the phase panel.
2. Click on the color beside a tract bundle and then select a new color from the palette that appears.

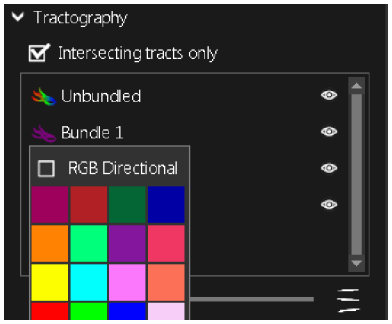


Figure 31 Selecting a new bundle color

NOTES:

- The "Unbundled" label in the Tractography overlay represents all tracts that do not belong to any bundle. You cannot edit the name and color of unbundled tracts.
- You can select RGB Directional in the Tractography overlay to better visualize the tracts in the 3D solid view. RGB Directional shows which direction the tracts are going, or at what point the direction is changing.

To change the color of a trajectory:

1. In the phase panel, click the edit icon beside the trajectory drop-down list.
2. In the Edit Properties dialog that opens, click on the color block and select a new color from the palette that appears.

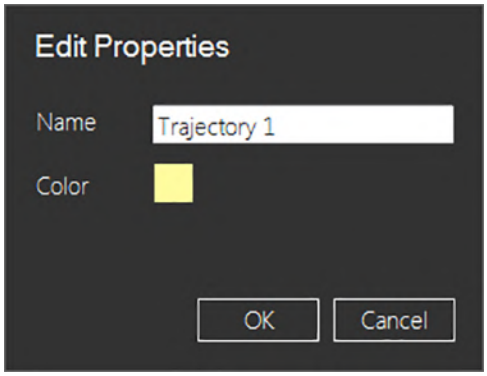


Figure 32 Edit Properties dialog

4.3.3 Toggling Trajectory Visibility

In the Trajectories, Approach, and Resection phases, Modus Nav shows all trajectories by default. If you want to hide the trajectories that are not currently active, right-click in a viewport and select **Show Only Active Trajectory** from the context menu.

To show all the trajectories in the plan again, right-click in a viewport and select **Show All Trajectories**.

4.3.4 Adjusting the Brain's Cortical Surface Visualization

You adjust the opacity of the translucent cortical surface visualization to better view regions and tracts.

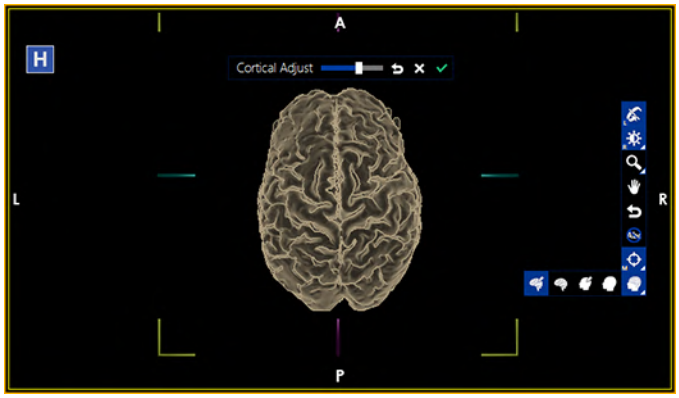


Figure 33 Adjusting the cortical surface visualization

This feature is only available when all the following conditions are met:

- The primary series is a T1 (the cortical surface is always generated from the primary series)

  NOTE: Cortical surface adjustment works better on pre-contrast T1 series.
- The study is processed and contains a brain mask
- The brain mask is accepted
- The viewport contains a 3D solid view
- The primary series is displayed in the viewport; if a merged series is overlaid on the primary series, you can toggle the cortical surface visualization on and off but you cannot adjust it

To adjust the cortical surface visualization:

1. Select the 3D solid viewport.
2. Click and hold on the **Show Extracted Surface** tool.

   Figure 34 Tool icons for adjusting the cortical surface visualization
3. Select the **Adjust Cortical Surface** icon.
4. In the toolbar that appears, drag the slider until you get your desired cortical surface view.

   You can also:
   - Click the reset icon (curved arrow) to reset the slider to its original position (if you have made adjustments).
   - Click the cancel icon (x) to discard any adjustments that you have made (and have not accepted by clicking the checkmark icon).
5. When done, click the checkmark icon to accept your adjustments.

4.3.5 Adjusting the Extracted Skin Surface

The quality of skin surface extraction is impacted by the quality of the scan images. Always carefully review the extracted skin surface and, if necessary, manually refine or adjust it to improve the head mask in

low skin intensity images. This provides a more accurate surface for registration using the SurfaceTrace feature.

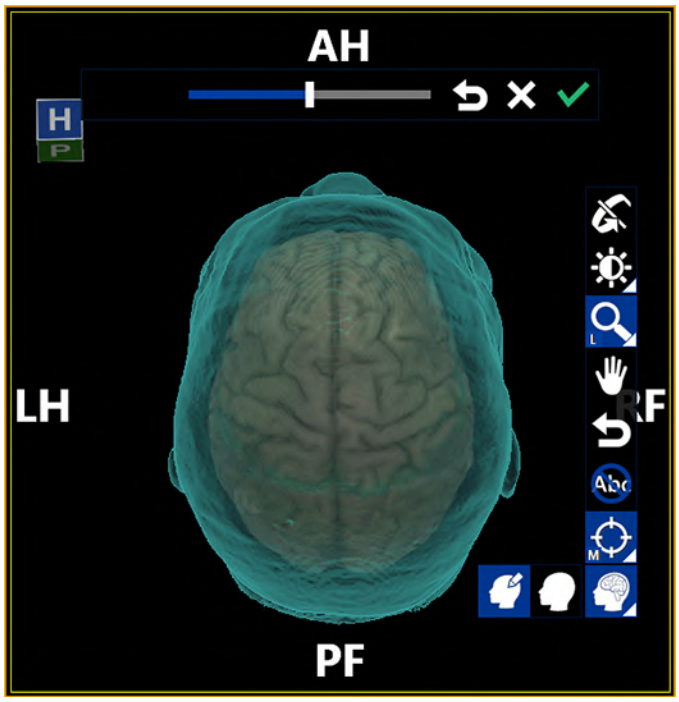


Figure 35 Adjusting the skin surface visualization

NOTES:

- **This feature is not available on a series processed in versions of Plan before 1.5.**
- **Do not over-smooth the surface as it will negatively affect the registration. Only smooth to correct the surface if necessary and only smooth as much as required.**

This feature is only available when all the following conditions are met:

- The primary series is a T1 (the extracted skin surface is always generated from the primary series)
- The study is processed
- The viewport contains a 3D solid view
- The primary series is displayed in the viewport; if a merged series is overlaid on the primary series, you can toggle the skin surface visualization on and off but you cannot adjust it

To refine the skin surface visualization:

1. Select the 3D solid viewport.
2. Click and hold on the **Show Extracted Surface** tool.

Figure 36 Tool icons for adjusting the skin surface visualization

3. Select the **Adjust Skin Surface** icon.
4. In the toolbar that appears, drag the slider to adjust the skin surface as necessary.

   You can also:
   - Click the reset icon (curved arrow) to reset the slider to its original position (if you have made adjustments).
   - Click the cancel icon (x) to discard any adjustments that you have made.
5. When done, click the checkmark icon to accept your adjustments.

4.3.6 Using the Virtual Tip Feature

The virtual tip feature displays an extension of the tool graphic in the viewports. Modus Nav treats this extension as though it were part of the tool and shows the slices and tractography intersection at the virtual tip of the tool. This provides a way to "look" ahead of the tool. For the Standard and Long Pointers, the tracts displayed depends on the tract intersection option selected in the phase panel:

- When the **Proximate to tool tip** option is selected, Modus Nav displays only the tracts that intersect with the first 5 mm of the virtual tip, if one is set
- When the **Along entire length of tool** option is selected, Modus Nav displays the tracts that intersect with the entire tool, including with the virtual tip
- When the **From tool tip to target** option is selected, Modus Nav displays the tracts that intersect with the path from the tool tip, or virtual tool tip, to the target

For NICO BrainPath tools, Modus Nav displays all tracts that intersect with the tool anywhere along its length.

NOTE: The accuracy of the displayed tractography intersection degrades as the virtual tool tip length increases.

In the Resection phase, the virtual tip is displayed with a crosshairs in the viewport showing the images from the perspective of the tool.

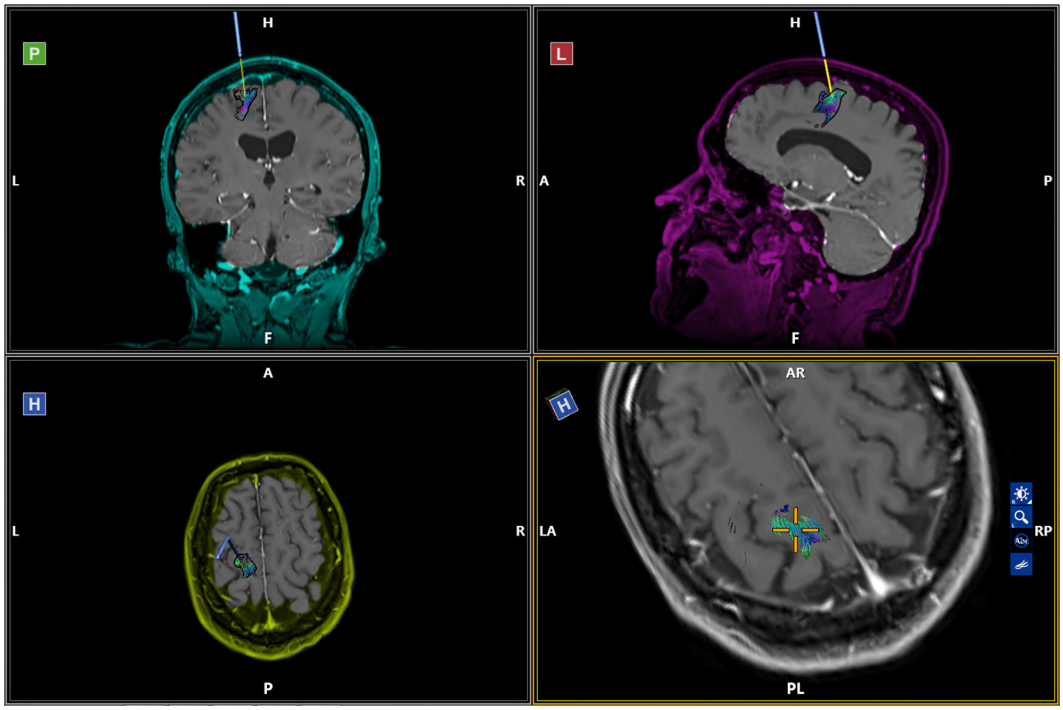


Figure 37 Virtual tip feature in the Resection phase

You can adjust the virtual tip length for each tracked tool individually. You can also specify different virtual tip lengths for the tools in the Approach and Resection phases. Modus Nav remembers your virtual tip length for each tool in each phase.

NOTE: Modus Nav uses the length of the BrainPath sheath as the length of the BrainPath tool. The distance the obturator extends past the opening of the sheath is indicated by the virtual tip. By default, Modus Nav sets the virtual tip length for the BrainPath tool to the distance the obturator extends past the opening of the sheath of the tool selected for this procedure: 15 mm for NICO BrainPath tools and 7 mm for the NICO BrainPath Gold tools. These are the recommended virtual tip lengths for these tools.

5.0 Performing a Procedure with Modus Nav

The Modus Nav software application guides a surgeon through a navigation-assisted surgical procedure. If a plan for the procedure was created in Modus Plan, Modus Nav displays the trajectory and craniotomy specified in the plan. If no plan exists for the procedure, you can create a target and engagement point on an image series in Modus Nav. In both cases, Modus Nav provides views and tools to help accurately reach the target location.

5.1 Logging In and Out of Modus Nav

When the Modus Nav operator cart is connected to a power outlet, the Modus Nav laptop powers up automatically. For more information about connecting the Modus Nav carts, see 2.3 Hardware Setup on page 21.

To log in to Modus Nav:

1. Log in to the Modus Nav laptop using your user name and password.

   Modus Nav launches automatically.
2. Log in to Modus Nav using your Modus Nav user name and password.

NOTE: For help with user names and passwords, contact your system administrator.

To close Modus Nav when the procedure is complete:

1. Close the software application.
2. Click the shutdown icon in the bottom-right corner of the login screen to shut down the laptop.

NOTE: Modus Nav automatically saves your navigation workflow data when you close a study. That data is available when the study is opened again in Modus Nav. You can also save your work using the CTRL + S keyboard shortcut.

5.2 Importing a Study

You must import the study or studies you want to use for the Modus Nav procedure. Studies may be on a DICOM server or on a CD, DVD or a USB flash drive.

5.2.1 Importing from a DICOM Server

NOTE: Modus Nav must be configured to communicate with the DICOM server where the study you want to import is located and must have network access to the DICOM server. For information about configuring Modus Nav to communicate with a server, see the Modus Plan User Reference Manual.

To retrieve a study from a DICOM server:

1. Connect the Modus Nav navigation cart to the network using the Ethernet cable supplied with the Modus Nav system.
2. In the Servers pane on the Explorer tab, select the server you want to retrieve from.
3. Select the study or studies you want to import in the studies pane (use the search fields to locate them if necessary).

   NOTE: To select multiple studies hold down the SHIFT key or CTRL key when clicking in the studies pane.
4. Click **Retrieve** in the study pane toolbar.

   A notification dialog appears indicating that the retrieval process has begun. You can view the progress of the retrieval in the Activity Monitor.

CAUTION: Risk of Procedure Delay Due to Missing Data

Accepting a series with missing slices may prevent you from locating appropriate surgical targets and regions of interest. Before working with a series in a study retrieved from a DICOM server, always review the entire series to ensure that all slices have been retrieved from the server.

5.2.2 Importing from a CD, DVD, or USB Flash Drive

Use the My Computer tab to locate and import study data stored on an external media source such as a CD or USB flash drive.

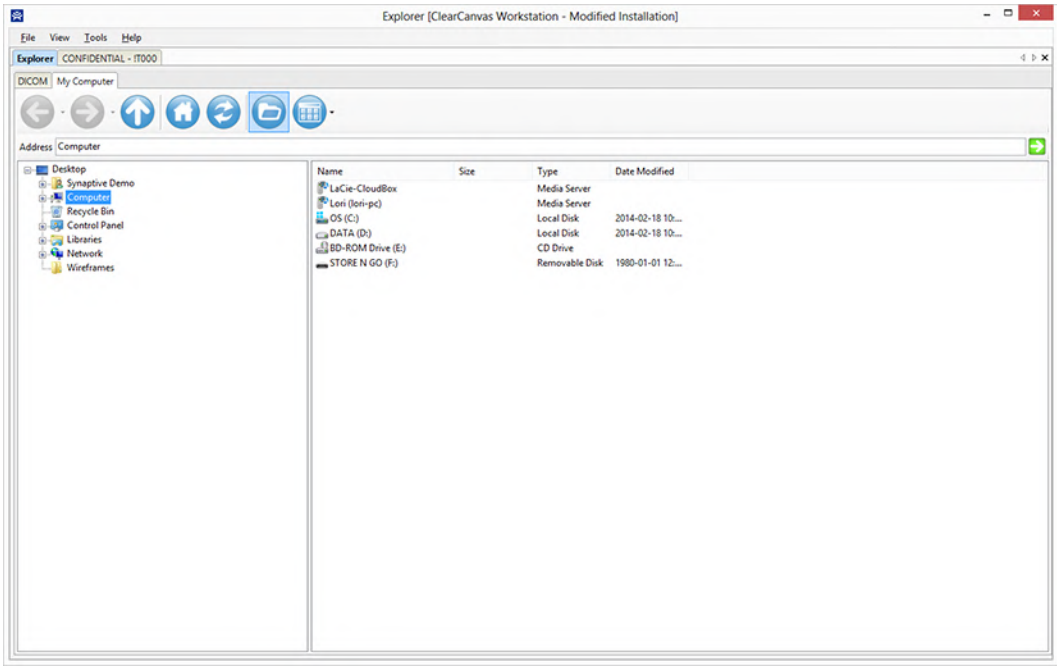


Figure 38 My Computer tab

To import a study from a CD, DVD, or USB flash drive:

1. Insert the CD, DVD or USB flash drive into the optical drive or USB port on the Guide operator cart.
2. If you want to import all the files on the CD, DVD or USB flash drive, select **Yes** in the dialog that appears.

   If you want to import only some of the files, select **No** and continue to the next step.
3. On the Explorer tab, click the **My Computer** tab.
4. In the tree view on the left, navigate to the location of the study.
5. In the right pane, right-click on the folder or individual image you want to import and select **Import.**

5.3 Processing a Study

If you want to use a study for the procedure that has not previously been processed by Modus Plan, you can manually process the study.

To process a study, right-click on the study in the My Studies list and select **Process Study** from the context menu.

NOTE: Processing may take up to 30 minutes to complete. It is not possible to cancel processing once it has started. You will not be able to open the study in Modus Nav until processing is complete.

When the study has been processed, you can either open it in Modus Plan to create a plan or open it in Modus Nav and begin a navigated procedure without a plan.

NOTES:

- **If you do not open the processed study in Plan and accept the processed data (the brain mask, diffusion data, and tractography), that data will not be available in Modus Nav.**
- **Duplicate processed data may be available for navigation. If there are duplicate series and you delete one of them, you might get a message for the missing series.**

On rare occasions during processing, Modus Nav may misidentify the series in the study (for example, identifying a T1 series as a T2 series). If this occurs, you can manually change the classification of the series.

1. In the Study Explorer, right-click on the affected study and select **View Series Details**.
2. In the Series Details dialog that appears, right-click on the series that you want to reclassify and select **Define MR Protocol**.
3. Select the appropriate series type.

NOTE: Using a T2 weighted MR series for processing may reduce the quality of surface extraction and surface registration.

5.4 Opening a Study

To open a study in the My Studies list, double-click on it. In the Workflow Study Launcher dialog, click the mode you want to open the study in.

NOTE: The Plan and Investigate modes may not be available depending on your configuration.

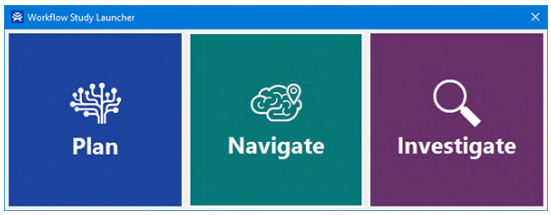


Figure 39 Workflow Study Launcher dialog

- To create a plan for the procedure using this study, click **Plan**. For information about creating a plan, see the Modus Plan User Reference. Note that it is possible to use Modus Nav without first creating a plan in Modus Plan.
- To start a Modus Nav procedure, click **Navigation**.

  NOTE: If you are opening a workflow created from the previous version of Modus Plan containing regions with non-uniform slice spacing on the primary series, these regions will not be available. A message appears when you open this study in Modus Nav. You may continue opening the study without the regions.
- To review the series in the study, click **Investigate**.

5.5 Review Phase

If a plan for the procedure created in Modus Plan, use the Review phase to verify that the plan is appropriate. If no plan exists, use the Review phase to verify that the quality of the scan images and registered visualizations (brain mask, diffusion data, and tractography) in the series you will use for the procedure is sufficient to navigate accurately. At a minimum, you must indicate that you accept the image quality. It is not necessary to accept the brain mask and the diffusion and tractography registrations, but if you do not accept them, they will not be available in subsequent workflow phases.

NOTE: At any point during the planning workflow, you can return to the Review phase and revoke your acceptance of the image data and the visualizations. However, if you do so you will lose any data you created in subsequent phases that was based on the data revoked. Modus Nav displays a warning message informing you of what will be lost when you change your acceptance of a plan or other image data.

CAUTION: Risk of Data Loss

Once you start work in Modus Nav on a study for which no plan exists, you should not later create a plan for that study. If you close the study you started work on and re-open it to start working with a plan, you will lose any work you had done prior to closing the study.

5.5.1 Reviewing a Plan

If a plan for the procedure was created in Modus Plan, the plan series opens automatically in when you open the study in Modus Nav.

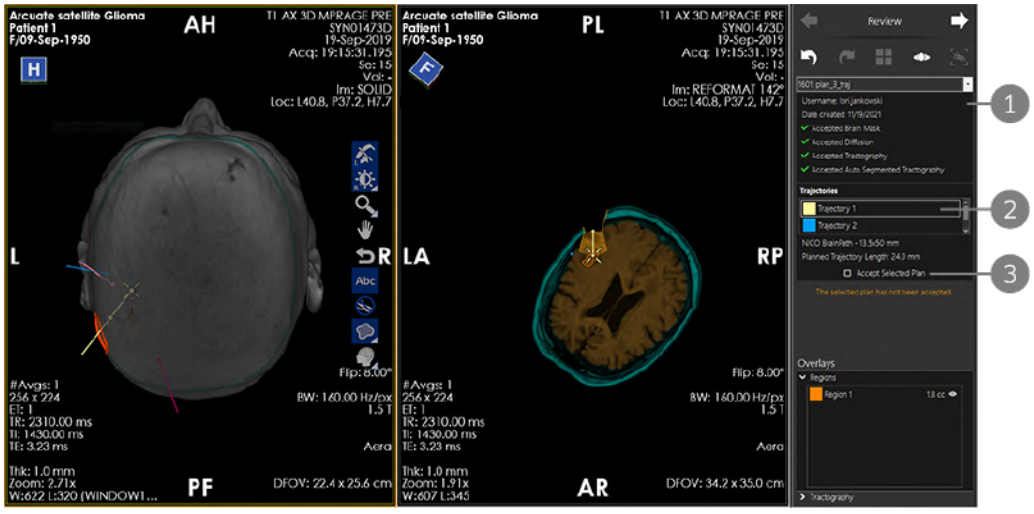


Figure 40 Workspace in the Review phase for a procedure with a plan

1 Details about the plan appear here. Review this information to verify that you have the correct plan selected.

2 The trajectories in the plan are displayed here. Select a trajectory to display it in the viewports.

3 When you have reviewed the plan, click **Accept Selection** in the phase panel.

If no plan exists, follow the steps in the sections below to review a series for navigation.

NOTES:

- If a plan from a previous version of Modus Plan has regions on a series with non-uniform slice spacing, these regions will not be displayed in Modus Nav.
- Modus Plan only exports 2D window/level values. If you select a plan that has user-defined window/level adjustments in the primary and merged series, you can view both the user-defined and the default window/level in Modus Nav. Select a viewport and then press the F2 key to switch between these views. A plan with a user-defined window/level has "Plan" added to the window/level values in the viewport overlay.

5.5.2 Reviewing the Primary Series and Brain Mask Quality

To be useful during a navigated procedure, the primary series image quality should be sufficient to clearly show the structures that are the target of the procedure.

The brain mask indicates the margins of the brain in the scan images. In the scan images, the brain is highlighted in brown and the skull and other areas outside the brain are cyan.

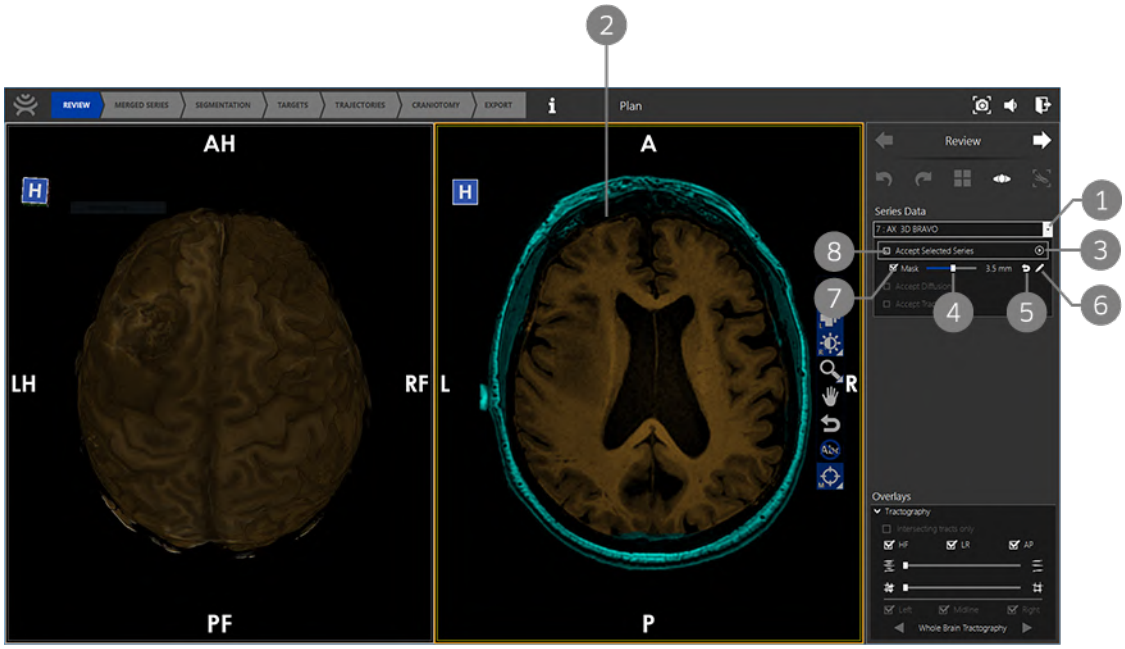


Figure 41 Workspace for reviewing image quality and the brain mask

1 Select the series you want to review. Series that have enhancement such as tractography associated with them appear in bold text in the list.

2 Stack through the images in the viewport and evaluate the quality of the images and the accuracy of the brain mask.

3 Optionally, click the **Play** icon to animate stacking through the slices.

4 If necessary, adjust the **Mask** slider to dilate or erode the brain mask until it more closely corresponds to the brain surface.

5 Reset the **Mask** slider to its original position.

6 Optionally, click the **Edit** icon to make specific edits to the brain mask. For more information, see 1.0 Editing the Brain Mask on page 1.

7 If the brain mask is inadequate, even after making adjustments, clear the **Toggle Brain Mask** checkbox to proceed without using a brain mask.

8 When you are satisfied that the image quality is acceptable and the brain mask is adequate (or you have decided not to use a brain mask for this plan), click the **Accept selected series** checkbox to proceed.

IMPORTANT:

- **Accepting poor quality series may impede location of appropriate surgical targets and regions of interest.**
- **Accepting an image series with low resolution will impact navigation accuracy.**
- **Accepting a brain mask that excludes part of the brain may result in a trajectory that originates beneath the surface of the brain.**
- **Accepting a brain mask that includes part of the skull may result in diffusion tracts located outside of the brain.**

To review the series for image quality and brain mask accuracy:

1. In the right viewport, stack through the images to ensure that they are sufficient for your intended procedure.

   If the image quality is not adequate or the scan does not cover the whole head, use a different series. If another series has already been processed, select that series from the **Series Data** list; if not, follow the instructions in section 5.3 Processing a Study on page 56 to process another series.

2. Review the accuracy of the brain mask and adjust if necessary:
   a. In the right viewport, stack through the images and verify that the brain mask has been accurately generated.
   b. If necessary, adjust the **Mask** slider in the phase panel to dilate or erode the brain mask until it more closely corresponds to the brain surface, or click the **Edit** icon to edit only specific areas of the brain mask.

      This will set the default brain mask for the rest of the planning phases.

      NOTE: The brain mask does not need to correspond exactly to the brain tissue on all slices. In the Trajectories phase, you will be able to further dilate or erode the brain mask to improve its accuracy in the areas relevant to the procedure before you specify an engagement point.

   If the brain mask is not adequate, even after making adjustments, try using another series or another study. For information, see section 5.3 Processing a Study on page 56. If no other series or study is available, clear the **Toggle Brain Mask** checkbox to proceed without a using a brain mask.
3. If you are satisfied with the image quality and brain mask (or are willing to proceed without brain mask), click the **Accept selected series** checkbox.

To hide the brain mask visualization, right-click in one of the viewports, and then select **Toggle Brain Mask**.

5.5.3 Diffusion

During processing, Modus Nav creates three diffusion series: Apparent Diffusion Coefficient (ADC), Fractional Anisotropy (FA) and an RGB color map. (For diffusion tensors with high anisotropy, the major eigenvector direction is generally assumed to be parallel to the direction of white matter tract. This is often represented using an RGB (red-green-blue) color map to indicate the eigenvector orientations.)

When you have accepted the primary series, the workspace updates with four viewports to help you evaluate the diffusion data. The top-left viewport displays the primary series, the top-right and two bottom viewports display different visualizations of the diffusion data.

Stack through the slices to verify the quality of the diffusion data. You can also click the Play icon in the phase panel to animate stacking through the slices in the series. If the diffusion data is not perfectly registered to the anatomy, you can still accept it and adjust it when you review the tractography data. For more information, see 5.5.4 Tractography on page 62.

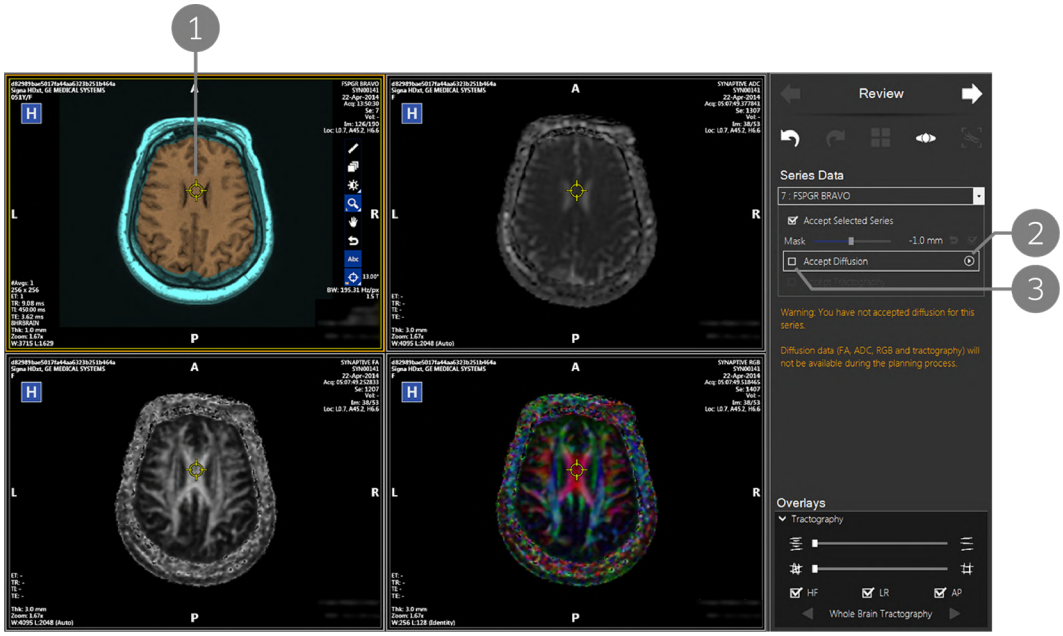


Figure 42 Workspace for reviewing diffusion data

1 Use the Spatial Locator to follow anatomical structures in the viewports.
2 Optionally, click the Play icon to animate stacking through the slices.
3 If the diffusion data is adequate, click the **Accept Diffusion** checkbox.

IMPORTANT: Accepting series with poor registration will lead to inaccuracy in plans and surgery.

NOTE: By their nature, diffusion scans represent anatomy differently than T1 scans. In some cases, this may cause the diffusion data to appear to be incorrectly registered to the anatomy. In the ADC image on the right below, the margin of the tumor appears to extend beyond the margin indicated in the T1 scan on the left, however this is a characteristic of ADC visualizations.

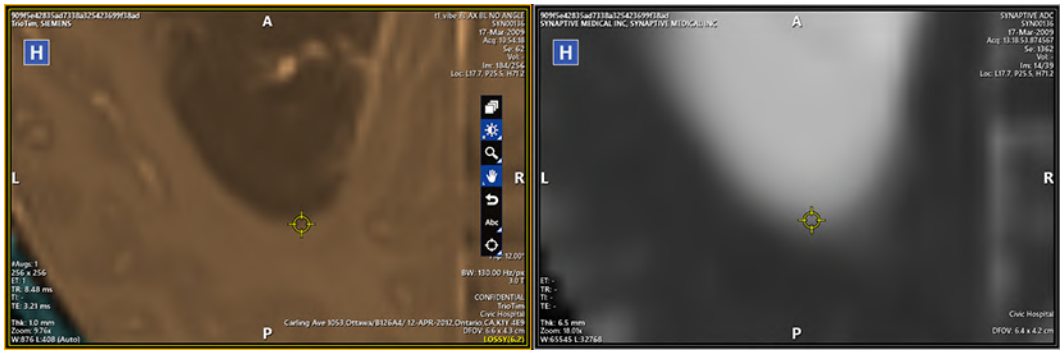


Figure 43 Comparing the lesion margin in the T1 and ADC series

Use careful clinical judgment and look for very clear anatomical structures when evaluating the diffusion data.

5.5.4 Tractography

When you have accepted the diffusion data for the series, the workspace updates with four viewports to help you evaluate the tractography data generated for this series.

NOTE: If during processing Modus Nav detects that the image data in the primary series is of poor quality or is incomplete (for example if part of the head is missing), tractography data will not be generated for the series.

IMPORTANT:

- **Tract information displayed in Modus Nav is based on diffusion data; it does not necessarily correspond to nerve bundles.**
- **The diffusion tract colors are based on the axes of the scanner. If the patient's head is not aligned with the scanner, the colors will not map to the patient axes. If necessary, you can change the tract RGB coloring to match the patient's orientation instead of the scanner's orientation. For more information, see Adjusting the Tractography Registration on page 63.**

If the tractography does not appear to be correctly registered to the anatomy, you can move it or scale it to correct the issue. For more information, see Adjusting the Tractography Registration below.

When you are satisfied that the tractography data registration is adequate, click the **Accept Tractography** item in the phase panel.

NOTE: If the automatic tractography segmentation feature is enabled on your Modus Nav system, see Working with Automatically Segmented Bundles in the Review Phase on page 1.

Figure 44 Workspace for reviewing tractography

1 Use the Window/Level tool to reduce the brightness in this view (right-click and drag down). This will hide the brain tissue and reveal the tractography. Rotate the view to review the tracts from all angles.

2 It can be easier to view the tracts in 2D slice mode. Stack through the slices in this viewport to view the tracts overlaid on the anatomy.

3 Optionally, click the Play icon to animate the images in the viewports. The solid image in the left viewport rotates and the 2D image in the right viewport stacks through the slices.

4 Click to show or hide the tractography adjustment controls.

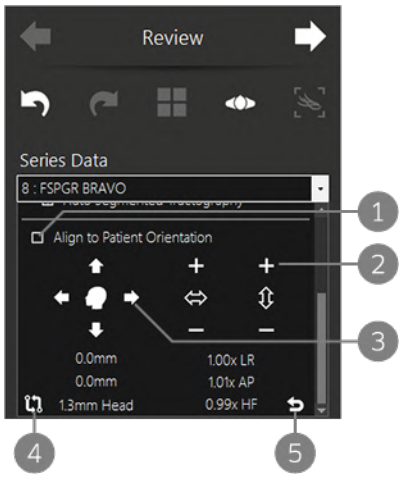
5 When you are satisfied that the tractography data is adequate, click the **Accept Tractography** checkbox.

IMPORTANT: Accepting series with poor registration will lead to inaccuracy in plans and surgery.

Adjusting the Tractography Registration

To adjust the tractography registration:

1. In the phase panel, click the Tractography Adjustment Controls icon. The tractography adjustment controls appear in the phase panel.



1 Select this option to change the tract RGB coloring to match the patient's orientation instead of the scanner's orientation (for example if the scan was oblique or if the patient's head was not aligned with the scanner). For more information, see Important Information about Diffusion Tensor Calculations below.

2 Click the + and – icons to scale the tracts horizontally or vertically relative to the active viewport.

3 Click the arrows to move the tractography up, down, left or right relative to the active viewport.

4 Click and hold to "snap" to the original tractography position. Release the mouse button to jump back to your adjusted tractography.

5 Click to discard all your adjustments and reset the tractography.

Figure 45 Tractography adjustment controls

2. When you are satisfied that the tractography is correctly registered to the anatomy, click the the **Accept Tractography** checkbox.

NOTE: When you adjust the tractography, the diffusion data on which the tractography is based is also adjusted to match your changes. When you accept adjusted tractography, a confirmation dialog appears requiring you to accept these changes.

TIP: Zoom in on the image in the viewport to see the effect of your tractography adjustments more clearly.

NOTE: Noise in the diffusion scan images may cause tractography to appear outside of the brain. Do not attempt to correct this using the tractography adjustment controls. Use the sliders on the Tractography overlay options in the phase panel to remove stray tracts caused by noise. For more information, see Tractography Options on page 39.

Important Information about Diffusion Tensor Calculations

Diffusion tensor calculations involve vendor-specific private DICOM tag encodings of gradient direction vectors, which can be affected by a large number of user configurable scanner settings (for example, direction of scan, in-plane phase encoding direction, scan orientation, etc.). For best results, follow the Synaptive MR scan recommendations (listed in document MKT-0008). Contact Synaptive customer service if you experience any issues or have any concerns. For contact information, see 1.10 Synaptive Customer Service Information on page 18.

To correct cases where the patient's orientation does not match the scanner's orientation, select the **Use patient orientation** option in the tractography adjustment tools to have Modus Nav recalculate the RGB values based on the orientation of the patient's head. Figure 46 below shows an example of before and after recalculation.

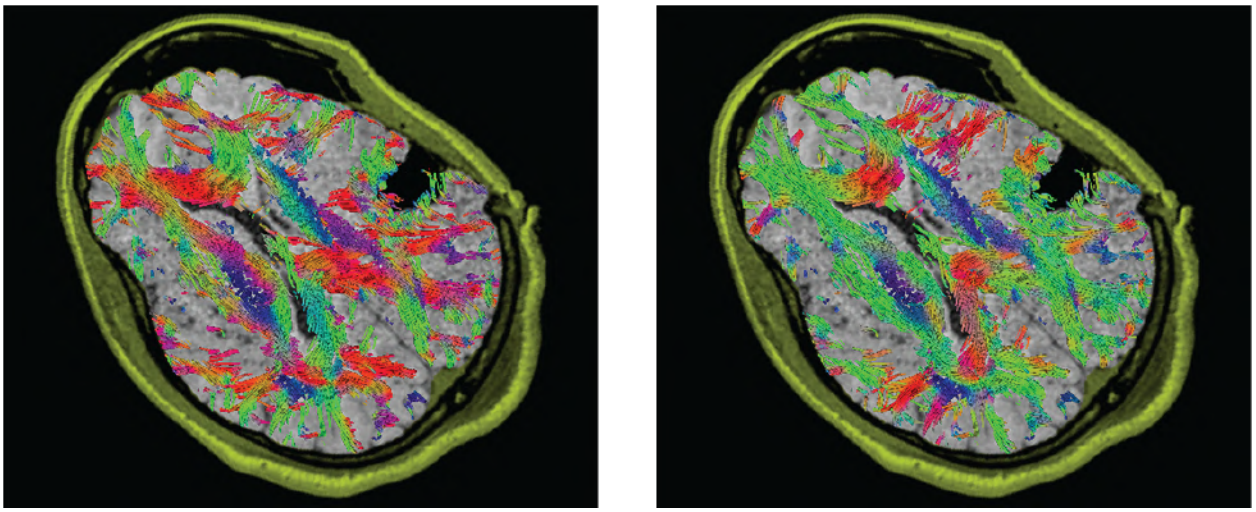


Figure 46 RGB coloring based on scanner axes (left) and based on patient orientation (right)

5.6 Merged Series Phase

If there are other series pertinent to the procedure, including series in other modalities, you can merge them with the primary series for the procedure.

The Merged Series workspace consists of four viewports. Three viewports display a 2D slice view of the anatomy in coronal, sagittal, and axial orientations. The fourth viewport displays a solid view (except in the spyglass comparison mode).

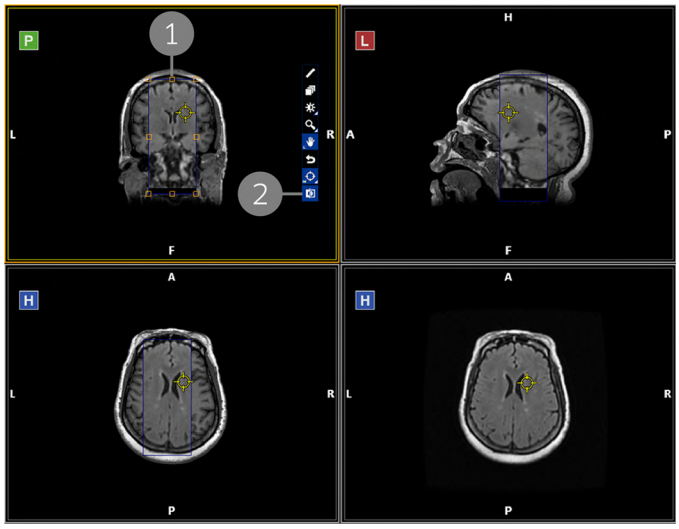
There are two ways to see the merged series overlaid on the primary series:

- Use the spyglass comparison mode

  -or-

- Use the color blend comparison mode

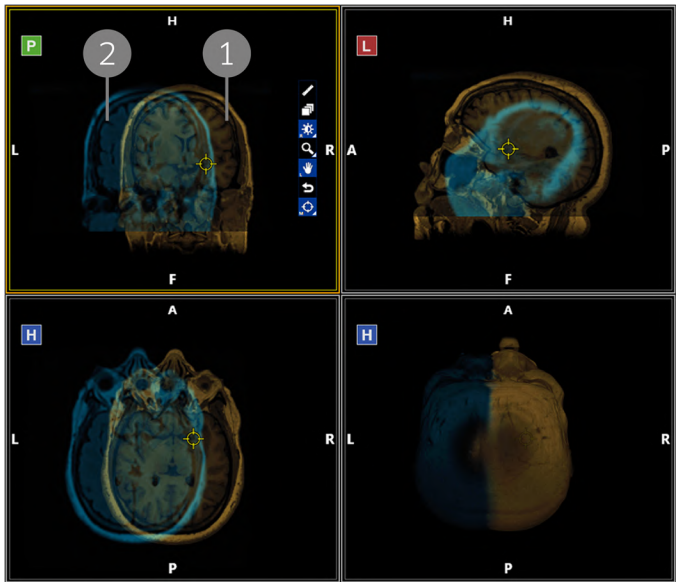
In the spyglass comparison mode, the merged series is displayed in a window overlaid on the primary series. You can adjust the size or shape of the overlay window by clicking and dragging the "handles" on the sides and corners of the window. To adjust the window/level values of the merged series, change the window/level values in the 2D view displayed in the bottom right viewport.



1 Merged series overlay window
2 Show/Hide Series Comparison Graphic. This tool shows or hides the overlay window.

Figure 47 Spyglass comparison mode

In the color blend comparison mode, the merged series has a different color from the primary series. The following example shows a manually adjusted merged series.



1 Primary series (amber)
2 Merged series (blue)

Figure 48 Color blend comparison mode

5.6.1 The Merged Series Phase Panel

The Merged Series phase panel displays the list of series that you have merged with the primary series.

Figure 49 Merged Series phase panel

1 Add a merge series.

2 Delete the selected series.

3 Toggle between spyglass and color blend comparison modes. Click to show the merged series overlay window.

4 List of merged series according to the study date and time, arranged in ascending order. Select a series to see it overlaid on the primary series in the viewports.

TIP: Right-click a series from the list to view the details of the original series where it is merged from.

5 Link window/level. Click this icon to link the adjustments made to the window and level values to the primary or merged series. This item only applies to color blend mode.

6 Drag the slider to adjust the intensity of images. The default opacity is 50% for the primary series and 50% for the merged series. This item only applies to color blend mode.

7 Click to reset the merged series color blending. This item only applies to color blend mode.

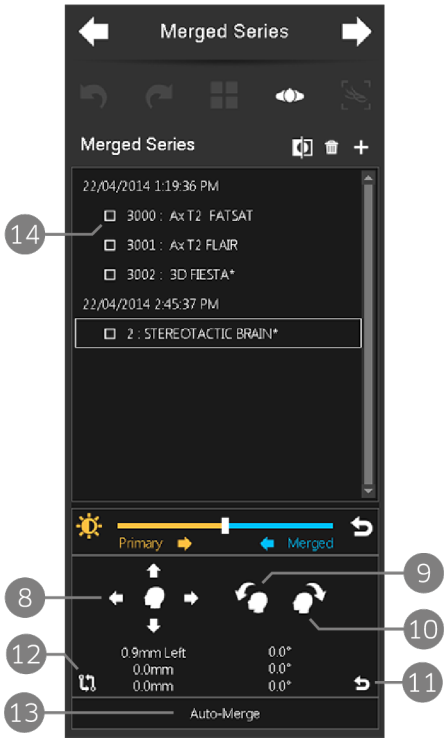


Figure 50 Merged Series phase panel, continued

8 Click the arrows to move the overlaid merged series up, down, left, or right relative to the active viewport.

9 Click the icon to rotate the overlaid merged series counter-clockwise.

10 Click the icon to rotate the overlaid merged series clockwise.

11 Click to discard all your adjustments and reset the merged series position.

12 Click and hold on this icon to temporarily restore the original merged series overlay position. Release the mouse button to reapply your adjustments.

13 Auto-Merge. Click this icon to automatically align the merged series to the primary series. This icon is enabled after you have made manual adjustments, or if the merge was done using the same frame of reference.

14 Select the checkbox to accept the series and make it available in subsequent phases.

5.6.2 Merging Series

To merge one or more series with the primary series:

1. In the phase panel, click the **Add a series** icon to open a list of available studies.
2. In the Merge Prior Series dialog, select the study that contains the series you want to merge.

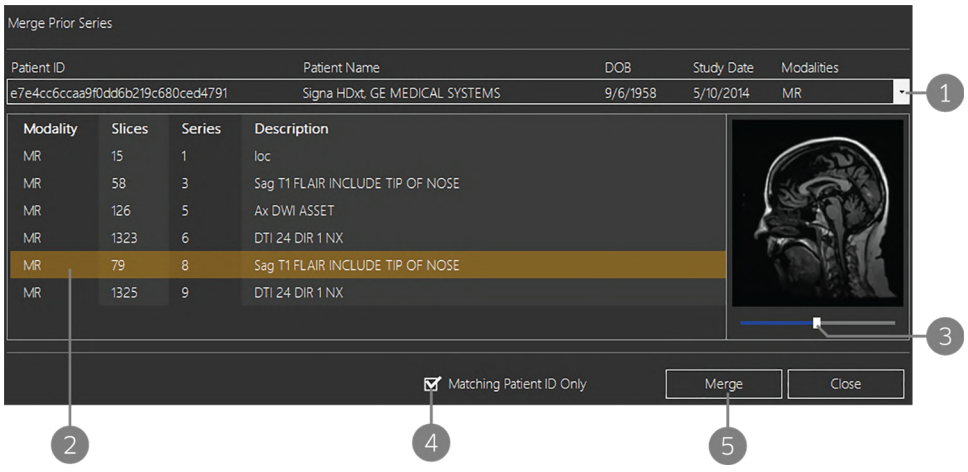


Figure 51 Merge Prior Series dialog

1 Study list. Select the study that contains the series you want to merge.
2 Series list. Click on one or more series to select them for merging.
3 The preview window displays thumbnails of the images in the series. Move the slider to stack through the images in the series.
4 By default, the study list contains only studies that match the Patient ID of the primary series. Deselect this option to view all the studies in the local database.
5 Merge button. Click to merge the selected series into the plan series.

CAUTION: Risk of Patient Injury

If you deselect the **Matching Patient ID Only** checkbox, the list of available studies contains all studies in the local database, including studies from other patients. Modus Nav does not perform any verification to ensure that the study you select is for the same patient as the plan study. Merging a series from the wrong study may negatively impact clinical decisions.

If you select a study that does not match the Patient ID of the plan study, Modus Nav displays a notification message when you merge the study. Review the patient information in the merge study carefully to ensure that you have selected the correct study.

3. Click on one or more series to select them for merging, and then click **Merge**.

   TIP: Hold down the CTRL key to select multiple studies.

   The merged series appear in the phase panel.

4. Click the name of a merged series to view it overlaid on the primary series in the viewports. The viewports show the primary series (amber) blended with the merged series (blue).

   Carefully review the accuracy of the merge. If the merged series is not correctly aligned with the primary series, you can do the following:

   - Manually adjust the alignment. Use the alignment controls (items 8, 9, and 10 in Figure 50 on page 68) to move or rotate the merged series.
   - Automatically adjust the alignment. Click the **Auto-Merge** button (item 13 in Figure 50 on page 68) to automatically adjust the alignment of the merged series to the primary series.
     - If the primary series and the series to be merged have the same frame of reference, the two series will be immediately overlaid in the viewports.
     - If the primary series and the series to be merged have a different frame of reference (for example, merging series of the same patient from two different studies), the system will do the registration first before merging, which may take longer. Registration only happens once for this type of merging.

   NOTES:

   - **If you intend to use the merged series for registration, the merge series must be correctly aligned to the primary series. The registration, and visualizations such as trajectories, tractography, regions, and crainotomies, will not be accurate if the merge series is not correctly aligned to the primary series.**

- **Merging color series to the primary series is only possible if a series with the same frame of reference has already been merged. You cannot use the Auto-Merge feature for the color series.**
- **The system does not support merging of gantry-tilted series.**

5. Select the checkbox (item 14 in Figure 50 on page 68) to accept the series and make it available in subsequent phases.

5.7 Fiducials Phase

In the Fiducials phase, indicate the location of the fiducial markers in the image series.

NOTE: The Fiducials phase is only required if you will be registering the patient to the plan series images using fiducial registration. If you will be using SurfaceTrace registration, click the phase you want to proceed to (Trajectories or Registration) in the workflow ribbon.

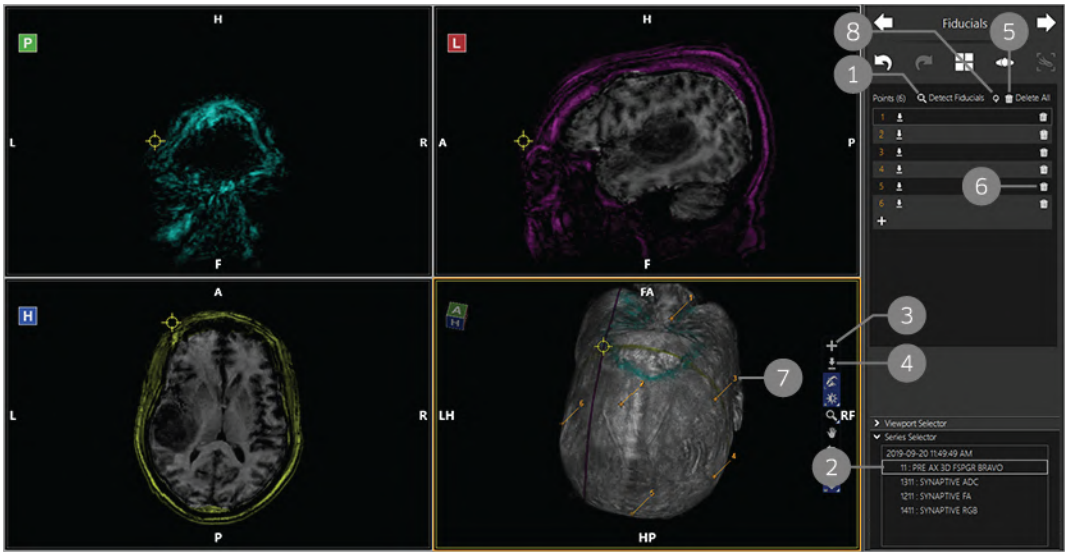


Figure 52 Workspace in the Fiducials phase

1 Click this icon to detect fiducials automatically.

2 If you want to use a merged series to mark the fiducial locations, select the series you want to use from the Series Selector list.

3 Mark a fiducial point at the current spatial locator position. You can mark up to 12 fiducial points.

4 Move the selected fiducial point to the current spatial locator position.

5 Delete all fiducial points.

6 Delete an individual fiducial point.

7 Fiducial points are indicated by number in the solid view.

8 Click this icon to order the fiducial points so that they follow a logical pattern around the head. The numbering starts at the back of the head and proceeds clockwise around the head.

NOTE: This icon only becomes available when you have placed at least two fiducial points.

Once you have ordered the fiducial points, this icon changes to a "reverse" icon. Click the icon to order the fiducials counter-clockwise around the head.

There are two ways to indicate the location of the fiducial markers: detecting them automatically and placing them manually.

5.7.1 Detecting Fiducials Automatically

To automatically detect the fiducial markers in the image, click **Detect Fiducials** in the phase panel. Always review the fiducial marker locations detected by Modus Nav and adjust or remove them if necessary.

NOTES:

- **Modus Nav is configured at installation with the type of fiducials most commonly used at your site. To obtain accurate automatic fiducial detection results, you must use the configured fiducials. For more information, contact Synaptive customer service.**
- **Modus Nav displays a maximum of 12 fiducial points. If the auto-detect feature detects more than 12 fiducial points, Modus Nav displays the best 12 (where "best" is defined as those candidates that most closely match the expected fiducial shape).**

5.7.2 Locating Fiducials Manually

To manually indicate the location of the fiducial markers:

1. In the viewports, move the spatial locator to the center of a fiducial marker in the image. An easy way to do this is to place the spatial locator close to the fiducial in the solid view (displayed in the bottom right viewport) then use the orthogonal views in the other three viewports to position the spatial locator at the exact center of the fiducial marker.
2. In the phase panel, click the **Add** icon to add the location of the fiducial at the current spatial locator position.
3. Repeat this process to mark the location of each fiducial marker you want to use in the registration process. Click the **Add** icon to add more fiducials if necessary.

   You can add up to 12 fiducials and you must add at least five fiducials to complete fiducial registration later in the Registration phase. Fiducials cannot be placed within 20 mm of an existing fiducial. For more information see 9.0 Fiducial Placement Guidelines on page 116.

NOTE: The fiducial marker locations must be specified accurately to ensure accurate registration.

To manually place fiducial points on anatomical landmarks without the use of fiducial markers:

1. Use the solid view to add fiducial points.
2. Move the spatial locator to a landmark point, and then click the **Add Fiducial** tool in the viewport toolbar.
3. Repeat this process to add at least five fiducial points for use in the registration process.

NOTE: Ensure that the selected fiducial points are placed in the desired locations.

5.7.3 Moving or Deleting a Fiducial Marker Location

To adjust the location of a fiducial marker:

1. In the phase panel, select the fiducial you want to adjust.
2. In the viewports, move the spatial locator to the new position.
3. Click the **Set Fiducial** icon in either the viewport or the phase panel.

To delete a fiducial marker, click the trash can icon beside the fiducial in the phase panel.

5.8 Trajectories Phase

If you did not create a plan for this procedure in Modus Plan you can create a trajectory in the Trajectories phase. If you want to create an intraoperative trajectory, you can do that in the Approach phase. For more information, see 5.11.12 Acquiring an Intraoperative Trajectory on page 99.

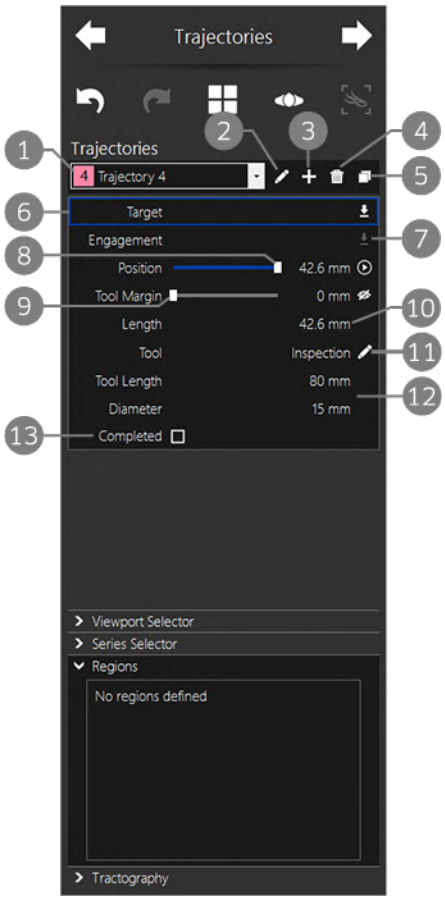


Figure 53 Trajectories phase panel (after a trajectory has been created)

1 Trajectories that have been created for this series (either in Modus Plan or Modus Nav) appear in this list. Select a trajectory from the list to view it in the viewports.

2 Edit properties for the selected trajectory. Click to edit the trajectory name and color.

3 Add a trajectory. Click to add a trajectory with the target at the current spatial locator position. Modus Nav creates a default engagement point for the trajectory which you can adjust (see item 7 below). This option is also available as a tool in the active viewport.

4 Delete this trajectory.

5 Create a new trajectory by copying the selected one.

6 Click **Target** to adjust the target location for this trajectory. When the locator is at the desired location, click the **Set target point** icon to place the target there.

7 Click Engagement to adjust the engagement point for this trajectory. When the locator is at the desired location, click the **Set engagement point** icon to place the engagement point there.

8 Adjust the **Position** slider to simulate moving along the trajectory. For more information, see 5.8.1 About the Position Slider on page 74.

9 Add a margin to the tool graphic in the viewports. Use the slider to view the potential tract intersections over a larger area of the anatomy. The margin is an extension of the tool's radius.

10 Modus Nav displays the trajectory length in millimeters (mm).

11 Click this icon to open the Tool Selection dialog.

12 The dimensions of your selected tool are displayed here.

13 Optionally, click this checkbox to indicate that the trajectory has been navigated. Completed trajectories are displayed with a check mark beside their name in the Trajectories list.

To create a trajectory:

1. In the viewports, move the Target locator to the target location, then click the **Add a trajectory for this target point** icon.
2. Move the Engagement Point locator to the engagement point location on the surface of the brain, and then click the **Set engagement point** icon.
3. If desired, move the **Position** slider to simulate moving along the trajectory, or click the play icon to view an animated "fly-through".
4. Click the pencil icon beside the Tool item in the phase panel to open the Tool Selection dialog.

   Select a tool type from the list on the left, then select or enter the tool specifications in the options on the right.

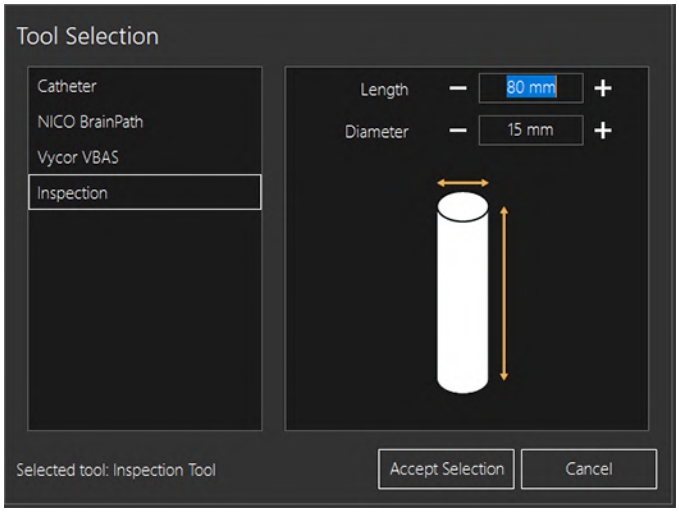


Figure 54 Tool Selection dialog

NOTES:

- **If you select a NICO or Vycor tool that is shorter than the trajectory, Modus Nav displays a notification recommending that you select a longer tool.**
- **Ensure that the tool you want to use is physically available for the procedure.**

To change the target or engagement point, select the target or engagement point in the phase panel, move the locator to the new location, and then click the **Set target point** or **Set engagement point** icon. You can also change the target point by adjusting the Position slider until the locator is in the desired position then clicking the **Set target point** icon.

NOTE: The accuracy of the navigation information Modus Nav provides in the Approach phase depends on the correct placement of the target and engagement points. The target must be placed within the brain volume and the engagement point must be placed on the brain surface. Adjust the images as necessary so that you can clearly see the margin where the brain meets the skull. For example, it may be necessary to adjust the window/level settings to hide other objects in the images such as a head holder or cushioning used to support the patient during the scan.

If you have selected a planned trajectory, the trajectory is locked in Modus Nav and you cannot edit it, but you can duplicate and update this trajectory if you want to acquire an intraoperative trajectory. To acquire an intraoperative trajectory, select **Target** or **Engagement** in the phase panel, move the locator to the new postion, and then click **Set target point** or **Set Engagement point**. A new trajectory is created with "IntraOp" appended to its name to distinguish it from the original planned trajectory.

NOTES:

- **It is possible to have two trajectories with the same name. The planned trajectory is highlighted in the drop-down list, prefixed with "PLAN" in the trajectory name.**
- **The trajectories defined in a previous version of Plan may have a different name, for example, "Target #" when loaded into the current version of Modus Nav. You cannot rename planned trajectories in Modus Nav. You can only rename new or copied trajectories.**

5.8.1 About the Position Slider

Use the Position slider to simulate the movement of the tool along the selected trajectory. When the slider is at its leftmost point (0 mm), the tool is at the engagement point; at its rightmost point, the tool is at the target point. The tool's distance from the engagement point is displayed beside the slider (in mm).

Click the play icon beside the Position slider to animate flying through the trajectory. The animation begins at the skin surface and continues until the tool is 10 mm past the target.

When the Position slider is selected, the Stack viewport tool in 2D views changes to the Trajectory Stack tool. Use this tool to stack through images perpendicular to the trajectory.

5.9 Registration Phase

There are two ways to register the scan images to the patient anatomy:

- SurfaceTrace registration, which involves moving the tracked Pointer tool over the patient's body to define a surface. Modus Nav matches that surface to the surface extracted from the scan images.
- Fiducial registration, which involves touching the tracked Pointer tool to fiducial markers (or other physical landmarks) on the patient's body. Modus Nav matches those points to the points defined in the Fiducials phase.

You can perform both types of registration in the Registration phase. You can also switch between the two types of registration if necessary. For more information, see 5.9.4 Changing the Registration Method on page 83.

5.9.1 Pointer Calibration and Verification

You can use either Standard Pointer or Long Pointer to perform the registration. Before you can register the images to the patient, Modus Nav must calibrate and verify the Pointer. The calibration and verification steps are the same for both Pointers.

1. Squeeze the release lever on the Calibration Device to open the holder arms.
2. Insert the Pointer tip into the Calibration Device aperture as far as it will go. Orient the Pointer so that its tracking array is roughly in the same plane as the Calibration Device tracking array.
3. Release the release lever on the Calibration Device to close the holder arms around the Pointer.

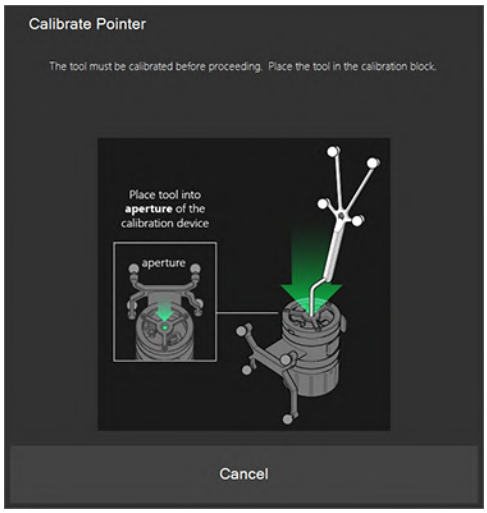


Figure 55 Calibrate Pointer dialog

4. Hold the Calibration Device so that its tracking array is visible the tracking camera and wait for Modus Nav to indicate that calibration is complete.
5. When the calibration process is complete, squeeze the release lever to open the holder arms and remove the Pointer from the Calibration Device aperture.
6. Place the tip of the Pointer in the verification divot on the top of the Calibration Device. Orient the Pointer so that its tracking array is roughly in the same plane as the Calibration Device tracking array.

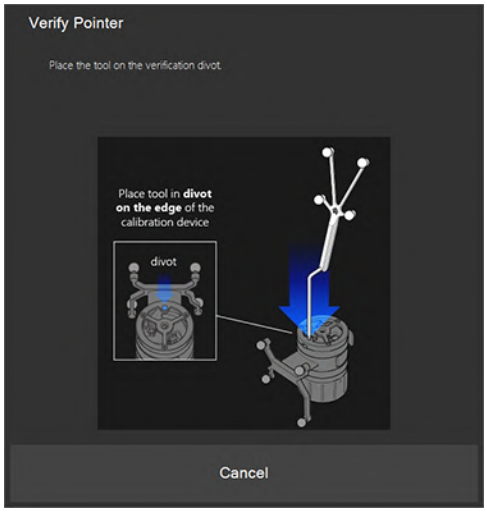


Figure 56 Verify Pointer dialog

7. Hold the Calibration Device and the Pointer so that their tracking arrays are visible to the tracking camera and wait for Modus Nav to indicate that verification is complete.

If Modus Nav detects that the Pointer was not positioned properly in the Calibration Device, an error message is displayed. Verify that you have positioned the Pointer correctly and attempt to calibrate or verify the tool again. If you still receive an error message, the tool may be damaged. Try again using another Pointer.

5.9.2 SurfaceTrace Registration

WARNING: Risk of Patient Death or Permanent Disability Due to Inaccurate SurfaceTrace Registration

To prevent skin features from shifting, which may adversely affect the accuracy of a SurfaceTrace registration, acquire the pre-operative scan images with the patient in the same position as in the procedure.

The absence of firm structure on the patient's face may adversely affect the accuracy of SurfaceTrace registration.

Medical procedures and equipment (such as the head holder) may distort a patient's facial features in the time between acquiring the pre-operative scan images and the procedure, which may adversely affect the accuracy of SurfaceTrace registration.

Lifting the Synaptive Standard Pointer off the skin surface when tracing may adversely affect the accuracy of SurfaceTrace registration. If you need to adjust the position of the Pointer, finish the current trace and start a new one.

CAUTION: Risk of Patient Injury Due to Inappropriate Tool Use

Use caution when applying the point of the Synaptive Standard Pointer or Long Pointer to any tissue. Do not apply pressure sufficient to damage the tissue.

SurfaceTrace registration involves moving the tracked Pointer tool on the patient's skin to create traces. The traces are matched to the extracted surface of series selected for registration.

To reduce the amount of time required to find that match, you must perform an initial landmark registration to indicate the patient's general orientation before performing the SurfaceTrace registration.

NOTE: The scan images used during registration must be MR T1 scans or CT scans that meet the Synaptive recommendations (listed in documents MKT-0008 and MKT-0538). This also applies if you perform a SurfaceTrace registration on a merged series. For best results, use a series that does not contain fiducials, ghosting, or other image artifacts that distort the appearance of the skin surface.

In the unlikely event that Modus Nav has misidentified your T1 scan as a T2 scan and will not allow you to perform a SurfaceTrace registration, you can manually change the classification of the series. For more information, see 5.3 Processing a Study on page 56.

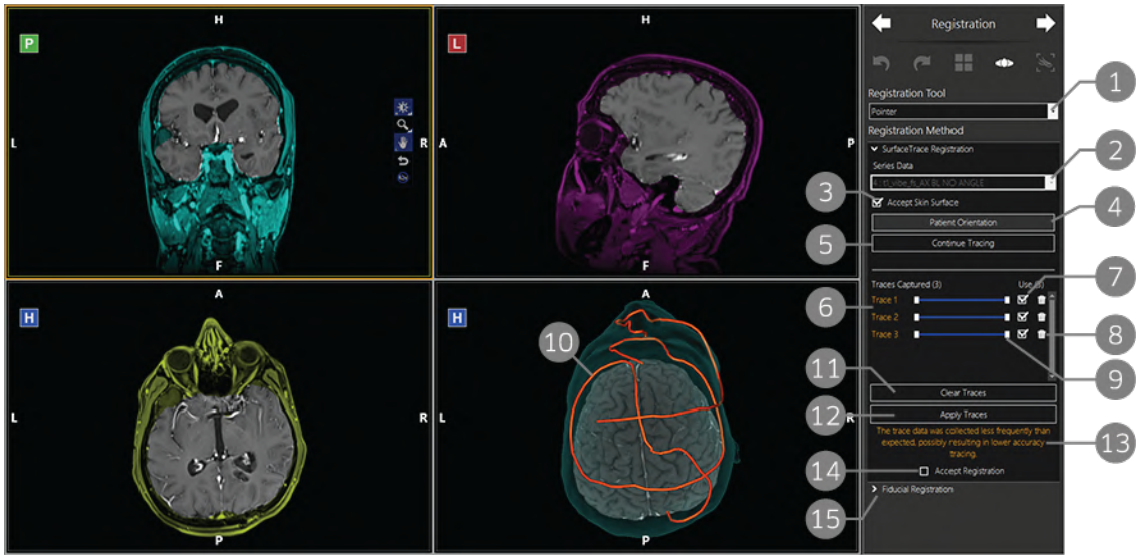


Figure 57 Registration phase workspace when performing SurfaceTrace registration

1 Select the tool you want to use to perform the registration.

2 Click the drop-down arrow to select a series for SurfaceTrace registration. You can select a primary series or a merged series (if available).

3 Click the **Accept Skin Surface** checkbox to accept the skin surface. Skin surface adjustment will not be available after the skin surface is accepted, so adjust the skin surface first if necessary. For more information, see 4.3.5 Adjusting the Extracted Skin Surface on page 50.

The Skin surface must be accepted before you can enable the Align to Trajectory feature. For more information, see 5.13 Using Align to Trajectory on page 102.

4 Click the **Patient Orientation** button to capture at least three initial landmark points.

5 This button has three states:
- **Start Tracing**: Click to start creating traces
- **Stop Tracing**: Click to stop creating traces
- **Continue Tracing**: Click to create additional traces after you started and then stopped creating traces

6 Traces that have been captured are listed here. Click on a trace to view it highlighted in blue in the viewports.

7 Select or clear the checkboxes to include or exclude a trace from the registration. Only selected traces are included in the registration calculations.
8 Delete the trace.
9 Move the sliders to trim off the leading or trailing ends of the trace.
10 Traces are displayed and overlaid on the extracted skin surface by default.
11 Click the **Clear Traces** button to clear the checkboxes for all traces.
12 Click the **Apply Traces** button to register the traces to the extracted skin surface.
13 Information about the SurfaceTrace registration process appears here. This may include a warning message if Modus Nav detects that your traces do not cover enough of the head to create an accurate registration.
14 Click the checkbox to accept the registration. Note that this checkbox is only available when traces have been applied.
15 Click the **Fiducial Registration** drop-down arrow to show the fiducial registration panel. For information about performing fiducial registration, see 5.9.3 Fiducial Registration on page 80.

NOTE: The Undo/Redo feature is not available during SurfaceTrace registration.

5.9.2.1 SurfaceTrace Registration Tips

For best results when performing a SurfaceTrace registration:

- Hold the Pointer tool at a slight angle to the skin surface.
- Trace with light pressure on firm bony anatomy including the nose, brow, scalp, and any other unique features.
- Avoid tracing on soft, fleshy areas such as the cheeks or areas where there are fatty deposits under the skin.
- Keep the pressure and speed consistent as you move the Pointer tool.
- Avoid lifting the Pointer tool off the skin surface in the middle of a trace. If you need to adjust your hold on the Pointer tool, finish the current trace and start a new one.
- Create traces over as much of the head as possible, keeping the following guidelines in mind:
  - Avoid tracing over or around areas that are not included in the scan image (for example, avoid the top or bottom of the head if it is cut off in the scan image).
  - Avoid tracing over areas that are different on the patient than in the scan image (for example, the area behind the ears may not be visible in the scan images because the padding used during the scan may have compressed the ears against the head).

  If your traces do not cover enough of the head, Modus Nav displays a warning message.

5.9.2.2 Performing SurfaceTrace Registration

Before performing a SurfaceTrace registration, always review the pre-operative scan images and note any areas where the images do not match the current state of the patient (for example, fiducials that are present in the scan image but have fallen off the patient, or places such as the bottom of the head that are cut off in the scan images). Avoid these areas when creating traces.

To perform a SurfaceTrace registration:

1. Adjust the skin surface if necessary, and then select the **Accept Skin Surface** checkbox.
2. In the phase panel, click **Patient Orientation**.

3. Capture at least three patient orientation landmark points.

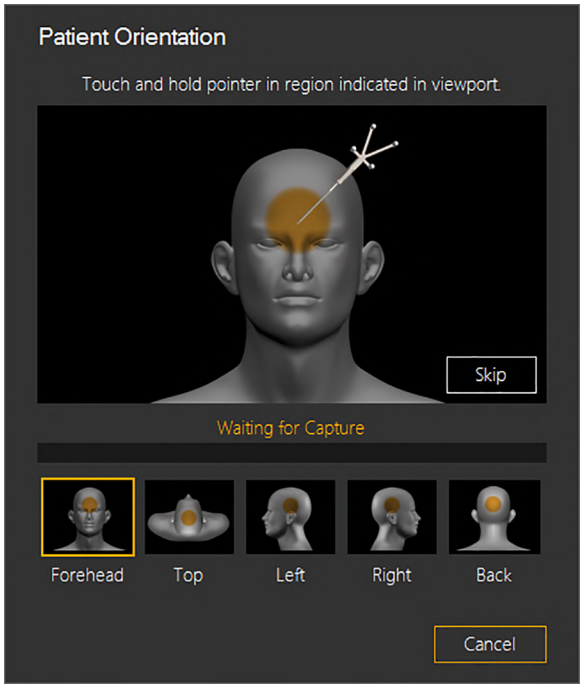


Figure 58 Capturing SurfaceTrace landmarks

   a. Hold the tip of Standard Pointer or Long Pointer anywhere on the patient's forehead with the tracking spheres facing the tracking camera. A progress bar indicates that Modus Nav is capturing the location and a tone sounds when the capture is complete. Or, if you don't want to capture the forehead landmark, click **Skip** to move to the next landmark.

   b. Repeat this process until you have captured at least three landmark points.

4. Click **Start Tracing** in the phase panel.
5. Place the Pointer anywhere on the patient's head and hold it still for a moment with the tracking spheres facing the tracking camera. Modus Nav plays a beeping sound to indicate that it is registering the current location of the Pointer. When the beep pitch rises, start moving the Pointer over the patient's head to create the trace.
6. To finish the trace, hold the Pointer still for a moment with the tracking spheres facing the tracking camera, or quickly pull the Pointer away from the patient. Using the second method may create a "tail" at the end of the trace where Modus Nav captured the Pointer moving away from the patient. If necessary, use the sliders in the phase panel to trim off this "tail".

   NOTE: If the Modus Nav tracking camera briefly loses sight of the tracking spheres on the Pointer, for example because you turned the tool away from the camera while tracing, Modus Nav automatically ends the current trace. To start a new trace, orient the Pointer so that the tracking spheres face the tracking camera and hold the Pointer still until the Modus Nav notification sound indicates that tracing can begin.

7. Repeat steps 4 and 5 to create as many traces as necessary to accurately register the patient anatomy to the images.
8. When you are finished capturing traces, click **Stop Tracing** in the phase panel.

9. In the viewports, review the traces that you have captured. If you don't want to use a trace in the registration process, clear the checkbox for that trace in the phase panel. You can also click **Clear All** to clear the checkboxes for all traces.

   If you want to create more traces, click **Continue Tracing** in the phase panel and repeat steps 4 and 5.

10. When you are satisfied with the traces, click **Apply Traces** in the phase panel. Modus Nav registers the traces to the skin surface extracted from the scan images and displays the proposed registration in the viewports.

11. Assess the accuracy of the registration by moving the Pointer over the surface of the patient's head and observing the Pointer graphic in the viewports. The Pointer graphic should appear to closely follow the surface of the patient's skin. You can also touch the Pointer to specific, easily-recognizable bony anatomical points. Examples of easily-recognizable bony anatomical points include the Nasion, Medial to Inner Canthus, and Lateral to Outer Canthus.

    If the the Pointer graphic does not appear to follow the surface of the head in the images, you can improve the accuracy by adding more traces. Click **Continue Tracing** in the phase panel and repeat steps 4 and 5 to add more traces then click **Apply Traces** to update the registration based on your new traces.

12. When you are satisfied with the quality of the registration, click the **Accept Registration** checkbox (item 11 in Figure 57 above) to proceed to the next phase.

    NOTE: If necessary, you can adjust the registration even after you have accepted it by clearing the Accept Registration checkbox. To add or remove traces from an accepted registration, click Start Tracing in the phase panel and follow steps 5 through 12 above.

5.9.3 Fiducial Registration

Fiducial registration involves touching the tracked Pointer tool to fiducial markers (or other physical landmarks) on the patient's body. Modus Nav matches those points to the points defined in the Fiducials phase.

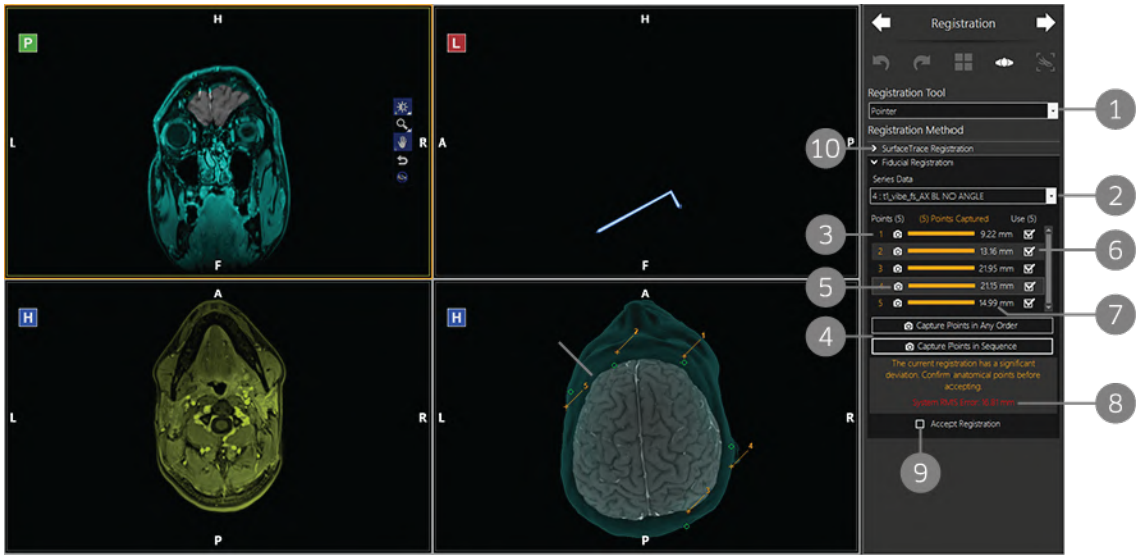


Figure 59 Registration phase workspace when performing fiducial registration

1 Select the tool you want to use to perform the registration.
2 Click the drop-down arrow to select a series for fiducial registration. You can select the primary series or a merged series (if available).
3 Points that you have marked in the Fiducials phase are listed here.
4 Select whether to capture points in sequence or in any order.
5 Recapture a point.
6 Clear the checkbox to exclude a point from being included in the registration.
7 Error for the point (displayed when at least five points have been captured).
8 Combined RMS error for all captured points (displayed when at least five points have been captured). A warning message appears here if the combined RMS error is greater than 5 mm.
9 Click the checkbox to accept the registration.
10 Click the **SurfaceTrace Registration** drop-down arrow to show the SurfaceTrace registration panel. For more information, see 5.9.2 SurfaceTrace Registration on page 76.

Register the images to the patient by placing the tip of the Pointer tool in the center of each fiducial on the patient and holding it while Modus Nav captures the location.

There are two ways to capture the fiducial points: in the order they are listed in the phase panel or in any order.

NOTES:

- **In between capturing points, turn the Pointer tool away from the tracking camera or cover the reflective markers until you are ready to register the next fiducial. Holding the Pointer tool motionless in front of the tracking camera may cause Modus Nav to incorrectly register the current location of the tool as a fiducial marker point. If this occurs, click the Undo icon in the phase panel to remove the point.**
- **To minimize the risk that the patient has been moved during registration, you must capture each fiducial point within five minutes of capturing the previous one.**

WARNING: Risk of Patient Death or Permanent Disability Due to Inaccurate Registration

Fiducial markers may move if excessive pressure is applied to them during registration. Touch the fiducial markers lightly with the Synaptive Standard Pointer during registration.

5.9.3.1 Capturing Fiducial Points in Order

To capture the fiducial points in the order they are listed in the phase panel:

1. Click **Capture Points in Sequence** in the phase panel.
2. Touch the fiducial indicated in the viewports with the Synaptive Standard Pointer or Long Pointer tool with the tracking spheres facing the tracking camera. For greatest accuracy, place the tip of the Pointer tool directly in the center of the fiducial toroid.

   A progress bar indicates that Modus Nav is capturing the location and a tone sounds when the capture is complete.

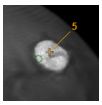
3. Repeat step 2 until you have captured all the fiducial points. Or, if you do not want to use a fiducial point for registration, double-click on the next fiducial point in the sequence. You must register at least five points.

   When four registration points have been captured, the Pointer tool graphic appears in the viewports.

4. If you skipped one or more fiducial points:
   a. When you have captured all the points you want to use for registration, click **Stop Capturing** to end the registration process.
   b. Clear the checkbox beside each fiducial point you did not capture.

5. Review the registration error values. For more information, see 5.9.5 About Registration Error on page 83.

   If the error for an individual point is too high, click the camera icon beside that point to recapture the point, or deselect the checkbox beside the point to exclude that point from the registration calculation.

   When at least five points have been captured, Modus Nav displays the locations where you touched the patient as green circles in the images. You can use these circles to determine the direction to move to improve the registration for a particular point.

   NOTE: When you recapture a point, Modus Nav recalculates the registration for all points. Always review the error values for all points after recapturing a point.

6. Assess the accuracy of the registration by moving the Pointer over the surface of the patient's head and observing the Pointer graphic in the viewports. The Pointer graphic should appear to closely follow the surface of the patient's skin. You can also touch the Pointer to specific, easily-recognizable bony anatomical points. Examples of easily-recognizable bony anatomical points include the Nasion, Medial to Inner Canthus, and Lateral to Outer Canthus.

   If you are satisfied with the quality of the registration, click the **Accept Registration** checkbox to proceed to the next phase.

5.9.3.2 Capturing Fiducial Points in Any Order

To capture the fiducial points in any order:

1. Click **Capture Points in Any Order** in the phase panel.
2. Register a fiducial by touching it with the Synaptive Standard Pointer or Long Pointer tool with the tracking spheres facing the tracking camera. For greatest accuracy, place the tip of the Pointer tool directly in the center of the fiducial toroid.

   A progress bar indicates that Modus Nav is capturing the location and a tone sounds when the capture is complete.

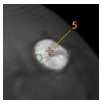
3. Repeat step 2 until you have captured all the fiducial points you want to use for registration. You must register at least five points.

   NOTE: If the points you captured are not sufficiently accurate for Modus Nav to create a registration, you will not be able to proceed. You must either capture additional fiducial points, recapture the selected points, or perform a SurfaceTrace registration.

When at least four registration points have been captured, the Pointer tool graphic appears in the viewports.

4. If you skipped one or more fiducial points:
   a. When you have captured all the points you want to use for registration, click **Stop Capturing** to end the registration process.
   b. Clear the checkbox beside each fiducial point you did not capture.
5. Review the registration error values. For more information, see 5.9.5 About Registration Error on page 83.

   If the error for an individual point is too high, click the camera icon beside that point to recapture the point, or deselect the checkbox beside the point to exclude that point from the registration calculation.

   When at least five points have been captured, Modus Nav displays the locations where you touched the patient as green circles in the images. You can use these circles to determine the direction to move to improve the registration for a particular point.

   NOTE: When you recapture a point, Modus Nav recalculates the registration for all points. Always review the error values for all points after recapturing a point.
6. Assess the accuracy of the registration by moving the Pointer over the surface of the patient's head and observing the Pointer graphic in the viewports. The Pointer graphic should appear to closely follow the surface of the patient's skin. You can also touch the Pointer to specific, easily-recognizable bony anatomical points. Examples of easily-recognizable bony anatomical points include the Nasion, Medial to Inner Canthus, and Lateral to Outer Canthus.

   If you are satisfied with the quality of the registration, click the **Accept Registration** checkbox to proceed to the next phase.

5.9.4 Changing the Registration Method

You can switch easily between the two Modus Nav registration methods and even create a registration using both methods. You can only accept one registration, however. If you switch to the other registration method after you have accepted a registration, your acceptance of that registration will be cleared and any recovery points you created based on that registration will be lost. Modus Nav does retain the data for that registration, however, so you can re-accept it if necessary.

To switch between registration methods, in the phase panel click the drop-down arrow that corresponds to the type of registration you want to perform.

5.9.5 About Registration Error

Modus Nav handles registration error differently for each type of registration.

SurfaceTrace Registration Error

Modus Nav does not provide any measure of the quality of a SurfaceTrace registration. However, Modus Nav always displays a message warning you to assess the quality of the registration by verifying anatomical points before accepting the registration.

Fiducial Registration Error

During fiducial registration, when five points have been captured, Modus Nav displays the error for each registration point and a combined RMS error for all the points. The error for individual points is the distance between the DICOM coordinates of the fiducial marker as it was specified in the Fiducials phase and the DICOM coordinates of the registration point location as it was registered with the Pointer tool. The combined RMS (root mean square) error for all points is the mean error of all the individual registration point errors.

If the combined RMS error for all points is greater than 5 mm, Modus Nav displays a warning message when you attempt to proceed to the next phase. In all cases, Modus Nav displays a warning message instructing you to assess the quality of the registration by verifying anatomical points using the interactive display before accepting the registration.

5.10 Registration Recovery

Use the Modus Nav registration recovery feature to define and use "rescue points" in the event that you lose your registration (for example if the cranial reference is accidentally moved relative to the patient).

5.10.1 Defining Rescue Points

Rescue points are physical indicators on the patient. A common way to create rescue points is to drill small holes in the skull around the craniotomy. To use the Modus Nav registration recovery feature, you must create four rescue points on the patient. It is recommended that these points be at least 2 cm apart and not collinear.

When you have created the rescue points on the patient, you must define them in Modus Nav. To define rescue points:

1. Click the registration recovery icon on the left side of the Modus Nav workspace.
2. In the Registration Recovery dialog, click **Define Rescue Points**.

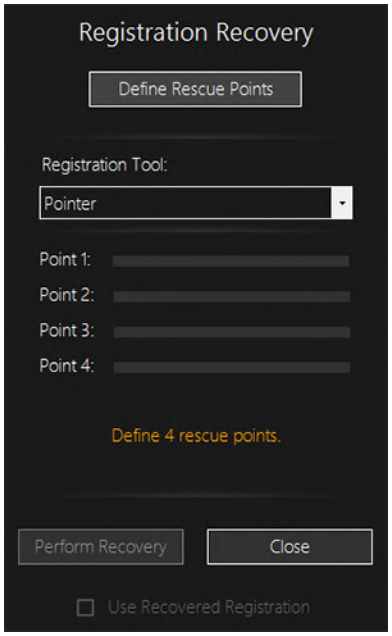


Figure 60 Registration Recovery dialog

3. Select the Pointer you want to use to define the rescue points from the Registration Tool drop-down list.
4. Place the tip of the Pointer tool on the first rescue point with the tracking spheres facing the tracking camera and hold it still. Modus Nav displays a progress bar and plays a sound as the rescue point is being captured.
5. Place the tip of the Pointer tool on the next rescue point and repeat this process until you have captured all four rescue points.

   NOTE: It is imperative that you remember the order in which you captured the rescue points. If you need to use them to recover a registration, you must follow the same order when performing the new registration.
6. When you have captured all four rescue points, click **Close**.

NOTE: If, after defining your rescue points, you return to the Registration phase re-register the patient to the scan images, Modus Nav discards your rescue points. You must follow the steps above to recapture the rescue points.

For fiducial registrations, if you clear your acceptance of the registration by deselecting one of the captured fiducial points, Modus Nav discards your rescue points. This is the case even if you subsequently reselect the fiducial point and re-accept the same registration. Even though the original registration did not change, you must still follow the steps above to recapture your rescue points. Note that this is not the case for SurfaceTrace registrations. If you make temporary changes to the traces but do not ultimately change the registration, your rescue points will not be discarded.

5.10.2 Using Rescue Points to Recover Registration

To use your defined rescue points to recover registration:

1. Click the registration recovery icon on the left side of the Modus Nav workspace.
2. In the Registration Recovery dialog, click **Perform Recovery**.

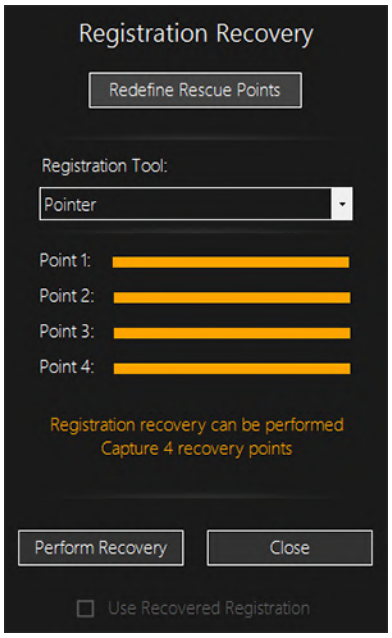


Figure 61 Registration Recovery dialog

3. Select the Pointer you want to use to perform the recovery from the Registration Tool drop-down list.
4. Place the tip of the Pointer tool on the first rescue point you defined with the passive reflective markers facing the tracking camera and hold it still. Modus Nav displays a progress bar and plays a sound as the rescue point is being captured.
5. Place the tip of the Pointer tool on the next rescue point and repeat this process until you have captured all four rescue points.

   NOTE: It is imperative that you register the points in the same order that you defined them in.
6. Assess the accuracy of the recovered registration by moving the Pointer tool over the surface of the patient's skull and observing the Pointer tool graphic in the viewports. The Pointer tool graphic should appear to closely follow the surface of the skull.
7. If you are satisfied with the accuracy of the recovered registration, click **Close** to continue the procedure with navigation based on the recovered registration.

   If you are not satisfied with the accuracy of the recovered registration, clear the **Use Recovered Registration** checkbox and click **Close**. You can either proceed with your original registration or return to the Registration phase and attempt to create a new, more accurate registration.

5.11 Approach Phase

Use the Approach phase for procedures that involve navigating a defined trajectory created in Modus Plan or in Modus Nav (either in the Trajectories phase or intraoperatively). In the Approach phase, Modus Nav displays information to help you align a tracked tool at the engagement point for a trajectory and cannulate to the trajectory's target point.

When evaluating the approach, you may discover that the engagement point specified for the trajectory is not appropriate. If this occurs, you can specify a new engagement point in this phase. For more information, see 5.11.11 Setting a New Engagement Point on page 99.

5.11.1 Working in the Approach Phase

Use the Approach phase to align a tracked tool to a trajectory and cannulate to the trajectory's target.

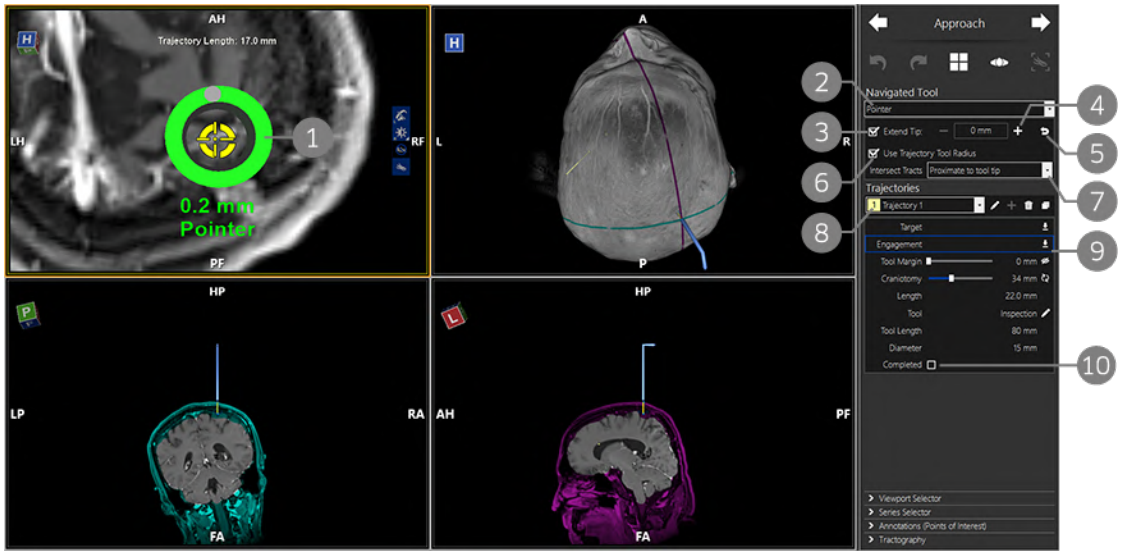


Figure 62 Workspace in the Approach phase showing tool positioned correctly to reach the target

1 Use the tool graphic in the viewports to align the tool on your trajectory. The gray dot on the rim of the tool graphic indicates the orientation of the tracking spheres.

NOTE: In most cases, you cannot navigate more than one tool at a time. Modus Nav displays only the tool graphic corresponding to the tool selected from the Navigated Tool list (item 2). The exception to this rule is the tracking array for the NICO BrainPath which is always rendered in the viewports, even when another tool is selected from the Navigated Tool list.

2 Select the tool to display in the viewport from the **Navigated Tool** list. When you are performing the approach, the tool selected here must match the tool defined for the trajectory.

3 Use the **Extend Tip** feature to view the tractography immediately in front of the tracked tool.

4 Modus Nav displays a default virtual tip length for the tool you are tracking but you can adjust this if necessary. Click the + or - icons to increase or decrease the length of the virtual tip. Click and hold on the icons to accelerate the rate at which the length changes.

5 Reset to the default virtual tip length for the selected tool.

6 Indicate whether to show intersecting tracts in the viewport based on the tool defined for the currently selected trajectory or the selected navigated tool (item 2 above).

NOTE: This option is disabled when the selected navigated tool is a NICO BrainPath port.

7 Options for displaying the tractography that intersects the tool or trajectory, or both. The options available depend on the selected navigated tool (item 2 above).

NOTE: By default, the tractography intersections are displayed using the trajectory tool.

8 Trajectories that have been created for this procedure appear in this list. To view a trajectory in the viewports, select it from the list.

9 Use this section for updating or defining an intraoperative trajectory. For more information, see 5.11.12 Acquiring an Intraoperative Trajectory on page 99.

10 Optionally, click this checkbox to indicate that the trajectory has been navigated. Completed trajectories are displayed with a check mark beside their name in the Trajectories list.

NOTE: If you move the active tool out of the tracking camera's field of view for more than a couple of seconds, Modus Nav recognizes this action and reverts to displaying the last stable location of the tool in the viewports.

5.11.2 Calibrating a Sterile Pointer

If you need to switch to using a sterile Pointer, you must calibrate the sterile Pointer before using it. To calibrate a sterile Pointer, click the appropriate Pointer icon on the left side of the screen. Position the Pointer in a sterile Calibration Device and follow the on-screen prompts. For more information, see 5.9.1 Pointer Calibration and Verification on page 75.

Before using the sterile Pointer, verify that it is being navigated accurately by placing the Pointer tip on the skull surface and observing the Pointer tool graphic in the software viewports. The tool graphic should appear to touch the skull surface at the correct location in the viewport.

NOTE: If you are calibrating a Pointer that has already been used in the procedure, verify that it is free of biomass before inserting it into the Calibration Device.

5.11.3 Aligning the Navigation View to the Surgeon's Position

By default, the navigation view in the Approach phase viewports is oriented from the perspective of a surgeon holding the tool with the tracking spheres facing directly forward (at the surgeon's "12 o'clock"). In this scenario, when the surgeon moves the tool to their left, the tool graphic in the viewport also moves to the left.

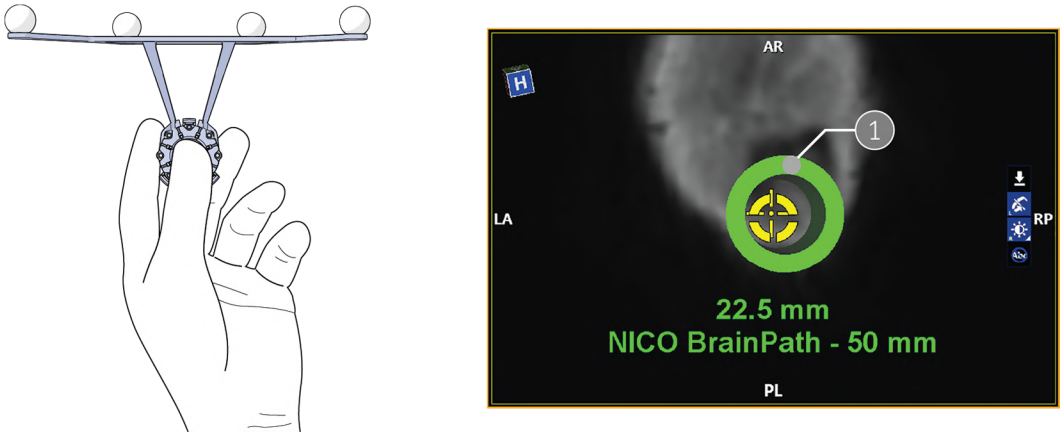


Figure 63 Surgeon holding tool with tracking spheres at their 12 o'clock

1 By default, Modus Nav orients the navigation viewport so that the gray indicator dot is at the 12 o'clock position. This is appropriate when the surgeon is holding the tool with the tracking spheres at their 12 o'clock.

In many cases, however, the location of the surgical target and the layout of the operating room may require the surgeon to hold the tool with the tracking spheres rotated away from 12 o'clock. In this scenario, the graphics displayed in the Modus Nav viewport would not correspond directly to the surgeon's hand movement. For example, when the surgeon moves the tool to their left, the tool graphic in the viewport may move up or down instead of to the left.

To accommodate this diversity in surgeon positions, use the Rotate tool to rotate the view in the navigation viewport to match the surgeon's current situation. The gray dot on the rim of the tool graphic indicates the orientation of the tracking spheres on the tool. Rotate the view until the dot is in the same position relative to the surgeon as the tracking spheres on the tool. For example, if the surgeon is holding the tool so that the tracking spheres are at their 3 o'clock, rotate the view so that the gray dot is at the 3 o'clock position.

Figure 64 Surgeon holding tool with tracking spheres at their 3 o'clock

1 Use the Rotate tool to rotate the viewport so that it corresponds to the orientation of the tool relative to the surgeon.

2 In this case, because the surgeon is holding the tool with the tracking spheres at their 3 o'clock, the viewport is oriented so that the gray dot is also at 3 o'clock.

5.11.4 Using the Alignment Viewport

Use the alignment viewport in the top left of the workspace to position the tool tip at the engagement point and orient it to the trajectory. This viewport shows a target-centric view of the tool's position relative to the target. The tool tip is indicated in the viewport by the crosshairs, the target point is indicated by a white broken circle, and the tool end is indicated by a solid circle. When the crosshairs is positioned in the broken circle and the solid circle is green, the tool is positioned and aligned correctly.

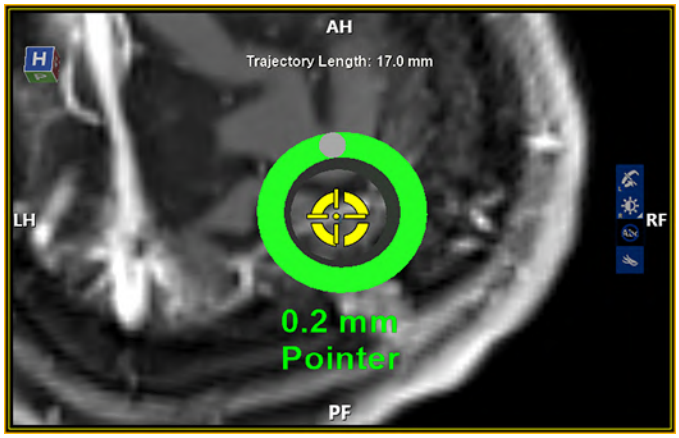


Figure 65 Alignment viewport when approaching to a target

Observe this viewport as you cannulate and keep the solid green circle concentric with the yellow broken circle to stay on the planned trajectory. Watch the distance to target notification text in the viewport. This text changes color to indicate the status of the approach:

- Green: Tool is on the planned trajectory.
- Yellow: Tool tip has reached the target.

  If you are using a port tool, advance the sheath by the **Virtual Tip** distance to position the opening of the sheath at the target. When the sheath has reached the target, secure it with the Shepherd's Hook and remove the obturator.
- Red: Tool is off the planned trajectory or is past the target.

NOTE: When you are using Standard Pointer, Long Pointer, Shunt Stylet, a Synaptive Trackable Suction tool, or a port tool, the alignment viewport displays your alignment along the length of the trajectory. When you are using Short Pointer, the alignment viewport displays your alignment to the target point only.

5.11.5 Using a NICO BrainPath Port

NOTE: Consult the instructions for use provided with the NICO BrainPath port for complete information about using that product.

To use a NICO BrainPath port with Modus Nav:

1. Remove the Synaptive port tracking array from the sterile packaging and attach tracking spheres to the tracking array.
2. Attach the port tracking array to the NICO BrainPath sheath.

3. In the Modus Nav software application, select the port you are using from the **Navigated Tool** drop-down list.

   NOTE: Modus Nav cannot distinguish between the 11x50 and 13.5x60 NICO BrainPath products. If you select one of these options from the Navigated Tool drop-down list, but are actually using the other, Modus Nav will successfully verify the tool, but the intersecting tract data displayed in the viewports will not be represented correctly.

4. Follow the prompts to verify the BrainPath:
   a. Place the tip of the BrainPath obturator in the verification divot on the top of the Calibration Device. Orient the port so that its tracking array is roughly in the same plane as the Calibration Device tracking array.

      NOTE: Modus Nav cannot verify the port if the tracking array is not properly attached to the BrainPath sheath, if the sheath is not held firmly against the obturator, or if the tracking array marker tree is deformed. To avoid deforming the tracking array marker tree, hold the assembled BrainPath tool by the body of the sheath, not by the tracking array.

   b. Hold the Calibration Device and BrainPath so that their tracking arrays are visible to the tracking camera and wait for Modus Nav to indicate that verification is complete.

      If Modus Nav detects that the port was not positioned properly in the Calibration Device, an error message is displayed.

      NOTE: If a port verification attempt fails, Modus Nav discards all previous port verifications. For example, if you successfully verify a 50 mm port, then attempt to verify a 60 mm port and that verification fails, you cannot use the 50 mm port until you re-verify it.

   c. Before using the port tool, verify that it is being navigated accurately by placing the tip of the obturator on the skull surface and observing the port tool graphic in the software viewports. The tool graphic should appear to touch the skull surface at the correct location in the viewport.

5. In the phase panel, verify that the **Virtual Tip** value is set correctly for the type of BrainPath you are using:
   - NICO BrainPath: 15 mm
   - NICO BrainPath ST-Gold: 7 mm

6. To navigate using the BrainPath, hold it so that its tracking array is visible to the tracking camera. The tool graphic appears in the Modus Nav viewports.

Important Information about Using the Virtual Tip Feature When Tracking a NICO BrainPath Port

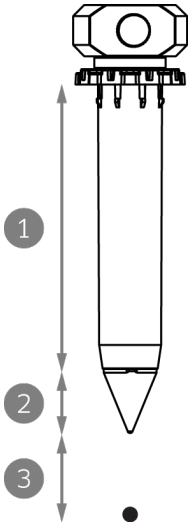


Figure 66 Distances when tracking a NICO BrainPath tool

1 Tool length
2 Virtual tip length
3 Distance to target

When tracking a NICO BrainPath tool, Modus Nav uses the length of the BrainPath sheath as the length of the BrainPath tool. The distance the obturator extends past the opening of the sheath is indicated by the virtual tip. In the Approach phase, the "distance to target" indicated in the viewports is the distance between the target and the virtual tip of the BrainPath tool.

To position the opening of the sheath at the target, the virtual tip length must be set to the distance the obturator extends past the opening of the sheath. Modus Nav sets this distance automatically based on the selected tool for this procedure; if you change it, for example to view the tractography beyond the tip of the tool, you must reset it back to the default before completing the approach.

NOTE: When using the BrainPath tool, once you have advanced the sheath to the target and secured it with the Shepherd's Hook, you may want to set the virtual tip length for the BrainPath tool to 0 mm so that the viewports display the slices at the opening of the sheath rather than those ahead of the tool by the virtual tip length.

5.11.6 Using a Pointer to Navigate the Approach for a NICO Port

If necessary, you can use the Standard or Long Pointer with a NICO BrainPath port to navigate the approach:

1. In the Modus Nav software application, select Standard Pointer or Long Pointer from the **Navigated Tool** drop-down list. If the Pointer you are using has not been verified yet. Follow the prompts to verify it. For more information, see 5.9.1 Pointer Calibration and Verification on page 75.
2. Set the **Virtual Tip** value to the appropriate length for the port tool you are using:

Product	Port Diameter	Port Length	Standard Pointer Virtual Tip	Long Pointer Virtual Tip
NICO BrainPath	13.5 mm	50 mm	15 mm	15 mm
		60 mm	15 mm	15 mm
		75 mm	15 mm	15 mm
		95 mm	29 mm	15 mm
	11 mm	50 mm	15 mm	15 mm
		60 mm	15 mm	15 mm
		75 mm	19 mm	15 mm
NICO BrainPath ST-Gold	13.5 mm	50 mm	7 mm	7 mm

3. Insert the Pointer into the aperture in the obturator and secure it with the set screw.

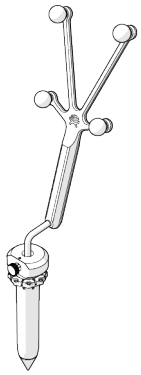


Figure 67 Standard Pointer in obturator situated in brain sheath

4. To navigate, hold the Pointer with the port attached so that its tracking array is visible to the tracking camera. The tool graphic appears in the Modus Nav viewports.

5.11.7 Using a Pointer to Navigate the Approach for a Vycor VBAS Port

You must use the Standard or Long Pointer to navigate the approach with a Vycor VBAS port:

1. In the Modus Nav software application, select Standard Pointer or Long Pointer from the **Navigated Tool** drop-down list. If the Pointer you are using has not been verified yet. Follow the prompts to verify it. For more information, see 5.9.1 Pointer Calibration and Verification on page 75.
2. Set the **Virtual Tip** value to the appropriate length for the Pointer you are using:
   - Standard Pointer: 1 mm
   - Long Pointer: 2 mm

Note that these virtual tip values apply to all Vycor VBAS models.

3. Assemble the Vycor device according to the manufacturer's instructions.
4. Insert the Pointer as far as it will go into the aperture in the alignment clip and secure it with the lock nut.

   NOTE: To ensure accurate navigation, the Pointer must be centered and properly seated in the cup at the bottom of the introducer and locked securely.
5. To navigate, hold the Pointer with the VBAS device attached so that its tracking array is visible to the tracking camera. The tool graphic appears in the Modus Nav viewports.

NOTE: Vycor tools have an oval profile and a flared opening at the collar but because there is no way to adjust their rotation in the viewports, Modus Nav displays them with a straight cylindrical tool graphic. The outer diameter of the tool graphic cylinder is the length of the wider axis of the Vycor tool you have selected (not including the extent of the flaring at the collar). The inner diameter of the cylinder is the length of the shorter axis of the tool.

5.11.8 Using Short Pointer

To use Short Pointer in Modus Nav:

1. Follow the manufacturers instructions for preparing the stereotactic alignment device and fixing it to the patient.

   TIP: If you have planned a trajectory for this procedure, you can use Standard Pointer to locate your planned engagement point and position the stereotactic alignment device accordingly.
2. Attach tracking spheres to the Short Pointer tracking array.
3. In the Modus Nav software application, select **Short Pointer** from the Navigated Tool drop-down list.
4. Follow the prompts to verify Short Pointer:
   a. Place the tip of Short Pointer in the verification divot on the top of the Calibration Device. Orient Short Pointer so that its tracking array is roughly in the same plane as the Calibration Device tracking array.

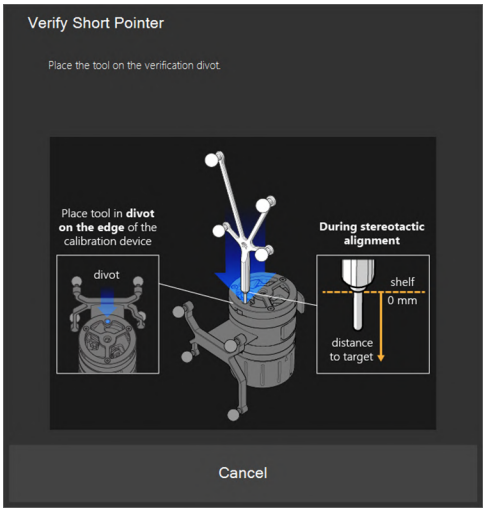


Figure 68 Verify Short Pointer dialog

b. Hold the Calibration Device and Short Pointer so that their tracking arrays are visible to the tracking camera and wait for Modus Nav to indicate that verification is complete.

5. Secure Short Pointer in the stereotactic alignment device. Orient Short Pointer so that its tracking array is visible to the tracking camera.
6. Do one of the following.

   If you have **not** already created a trajectory for this procedure:

   a. In the Modus Nav software application, use the Virtual Tip feature to add a virtual offset to the tool graphic of sufficient length to reach the target location.

   b. Orient the stereotactic alignment device until the Short Pointer virtual tip is located at your desired target point in the viewports. It may be necessary to adjust the Virtual Tip value in the phase panel.

   c. Lock the reducing tube in place.

   d. In the Modus Nav software application, click the **Add a trajectory** icon. A new trajectory is created and the trajectory length is displayed in the phase panel.

   If you **have** already created a trajectory for this procedure:

   a. Use the top left viewport to orient the stereotactic alignment device so that Short Pointer is aligned to the planned target. For more information, see 5.11.4 Using the Alignment Viewport on page 90.

      NOTE: If it is difficult to align Short Pointer to the target, extend the Virtual Tip until it reaches the target point.

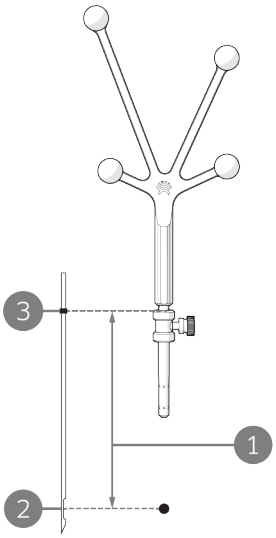
   b. When Short Pointer is aligned to the planned target, lock the reducing tube in place.

   c. In the phase panel, click the **Set Engagement Point** icon. This sets the engagement point at the shoulder of Short Pointer and Modus Nav recalculates the trajectory length.

7. On the biopsy needle, measure the distance of the trajectory length (as displayed in the phase panel) from the middle of the cutting window and mark it with a marker or a stopper on the needle.

8. Remove Short Pointer from the reducing tube and insert the biopsy needle until the marked location reaches the top edge of the reducing tube.
9. Secure the needle in the reducing tube and take the biopsy sample.

Important Information About the Trajectory Length When Using Short Pointer



Modus Nav measures the trajectory length from the "shelf" where the Short Pointer tip meets the tool body. When Short Pointer is insterted into a reducing tube as far as it will go, the "shelf" touches the top of the reducing tube. To determine how far to insert the biopsy needle into the reducing tube, measure the trajectory length from the center of the cutting window.

1 Trajectory length (as shown in Modus Nav)
2 Center of biopsy needle cutting window
3 Biopsy needle stopper

Figure 69 Trajectory length on biopsy needle

5.11.9 Using Shunt Stylet

To use Shunt Stylet with Modus Nav:

1. Remove Shunt Stylet from the sterile packaging.
2. In the Modus Nav software application, select Shunt Stylet from the Navigated Tool drop-down list.
3. Follow the prompts to verify Shunt Stylet:
    a. Place the tip of Shunt Style in the verification divot on the top of the Calibration Device. Orient Shunt Stylet so that its tracking array is roughly in the same plane as the Calibration Device tracking array.

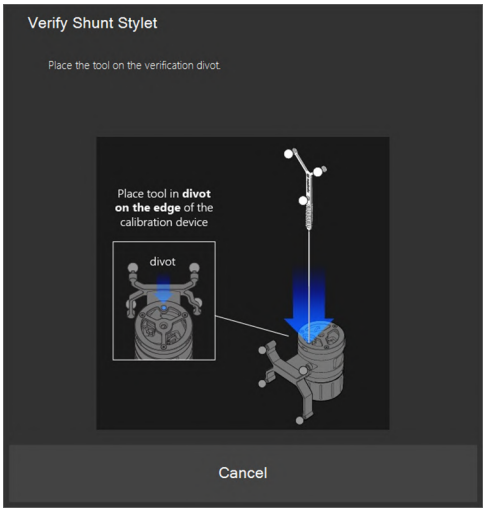


Figure 70 Verify Shunt Stylet dialog

b. Hold the Calibration Device and Shunt Stylet so that their tracking arrays are visible to the tracking camera and wait for Modus Nav to indicate that verification is complete.

4. Trim the desired catheter to an appropriate length and place catheter over Shunt Stylet.
5. To navigate using Shunt Stylet, hold it so that its tracking array is visible to the tracking camera. The tool graphic appears in the Modus Nav viewports.

NOTE: The Shunt Stylet tip can deflect during cannulation. As much as possible, minimize the amount of lateral force applied to the tool when cannulating.

5.11.10 Using Trackable Suction

To use Trackable Suction with Modus Nav:

1. Assemble Trackable Suction. For more information, see 3.6.1 Assembly on page 32.
2. If you are using a malleable suction tube, bend the suction tube to your desired angle. Malleable tubes are marked with a "malleable" pictogram below the handle attachment (). They may be bent anywhere between the pictogram and the thick straight line near that tip (the bendable area is indicated by item 1 in Figure 71).

Figure 71 Malleable suction tube markings

Do not bend in the area indicated by item 2 in Figure 71.

3. In the Modus Nav software application, select **Trackable Suction 1** or **Trackable Suction 2** from the Navigated Tool drop-down list (depending on whether tracking array 1 or tracking array 2 is attached to Trackable Suction).
4. Follow the prompts to calibrate and verify Trackable Suction:

a. Squeeze the release lever on the Calibration Device to open the holder arms.

b. Insert the Trackable Suction tip into the Calibration Device aperture as far as it will go. Orient Trackable Suction so that its tracking array is roughly in the same plane as the Calibration Device tracking array.

c. Release the release lever on the Calibration Device to close the holder arms around Trackable Suction.

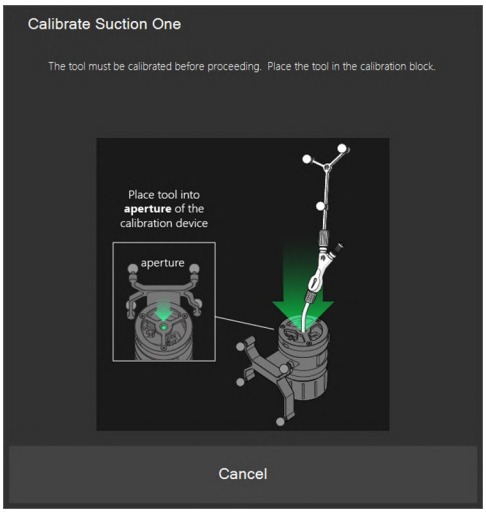


Figure 72 Calibrate Suction dialog

d. Hold the Calibration Device so that its tracking array is visible the tracking camera and wait for Modus Nav to indicate that calibration is complete.

e. When the calibration process is complete, squeeze the release lever to open the holder arms and remove Trackable Suction from the Calibration Device aperture.

f. Place the tip of Trackable Suction in the verification divot on the top of the Calibration Device. Orient Trackable Suction so that its tracking array is roughly in the same plane as the Calibration Device tracking array.

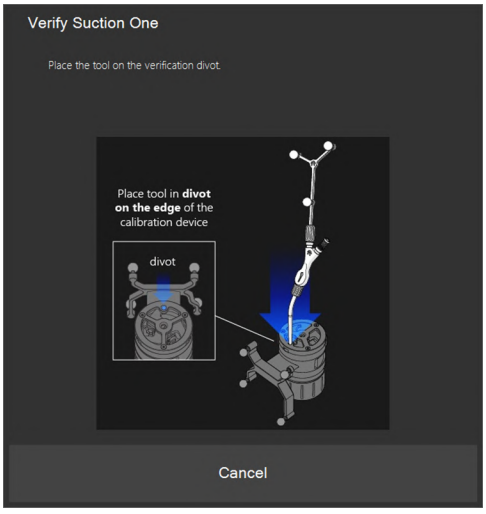


Figure 73 Verify Suction dialog

g. Hold the Calibration Device and Trackable Suction so that their tracking arrays are visible to the tracking camera and wait for Modus Nav to indicate that verification is complete.

5. To navigate using Trackable Suction, hold it so that its tracking array is visible to the tracking camera. The tool graphic appears in the Modus Nav viewports.

IMPORTANT: To maintain accurate calibration, you must re-calibrate Trackable Suction any time you change the suction tube attached to the handle, bend or alter the malleable suction tube, or adjust the position of the suction tube or marker tree relative to the tool handle. To re-calibrate, click the Trackable Suction icon on the left side of the workspace that corresponds to the tracking array attached to Trackable Suction.

NOTE: If you have calibrated the Trackable Suction tool in the Synaptive robotic exoscope software, then you connect Modus Nav to the Synaptive robotic exoscope, you must recalibrate the Trackable Suction tool before continuing to use it.

5.11.11 Setting a New Engagement Point

If it is necessary to specify a new engagement point, move the tip of a tracked tool to the location that you want to set as the new engagement point and click **Set engagement point** in the phase panel.

CAUTION: Risk of Patient Injury

If you set a new engagement point, your original craniotomy location, craniotomy size, and tool selection may no longer be valid. Always review these selections and adjust them if necessary. Modus Nav does not change the craniotomy from your plan based on your new engagement point.

5.11.12 Acquiring an Intraoperative Trajectory

Use the Trajectories features in the Approach phase panel to acquire a new trajectory during the procedure.

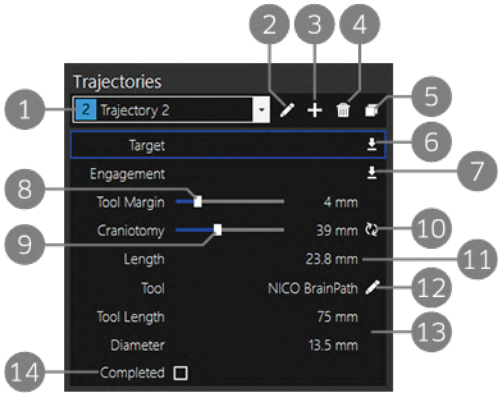


Figure 74 Trajectories features in the Approach phase panel

1 Trajectories that have been created for this procedure appear in this list. To view a trajectory in the viewports, select it from the list.
2 Edit the trajectory name or color. Note that this option is not available for trajectories that were created in Modus Plan.
3 Use this feature to create a new trajectory by defining a new target and engagement point. For more information, see Creating a New Trajectory on page 101.
4 Delete the selected trajectory. Note that you cannot delete trajectories that were created in Modus Plan.
5 Use this feature to create a new trajectory by duplicating an existing trajectory then changing the target or engagement point. For more information, see Duplicating an Existing Trajectory on page 101.
6 Set target point. Click this icon to place a target point at the current location of the navigated tool's virtual tip.
7 Set engagement point. Click this icon to place an engagement point at the navigated tool's physical tip (if you are creating a new trajectory) or virtual tip (if you are updating an existing trajectory).
8 Add a margin to the tool graphic in the viewports. Use the slider to view the potential tract intersections over a larger area of the anatomy. The margin is an extension of the tool's radius.

   NOTE: This slider is disabled when you are viewing tract intersections for the navigated tool (that is, when the **Use trajectory tool radius** option is **not** selected in the phase panel (item 6 in Figure 62 on page 87).
9 Use the slider to adjust the craniotomy size for a new trajectory. For more information, see Adjusting the Craniotomy for a New Trajectory on page 101.
10 Reset the craniotomy to the default size created by Modus Nav.
11 Modus Nav displays the trajectory length in millimeters (mm).
12 Click this icon to open the Tool Selection dialog.
13 The dimensions of your selected tool are displayed here.
14 Optionally, click this checkbox to indicate that the trajectory has been navigated. Completed trajectories are displayed with a check mark beside their name in the Trajectories list.

Updating an Existing Trajectory

To relocate the target or engagement point of an existing trajectory:

1. In the phase panel, select the tool you want to use to relocate the target or engagement point from the Navigated Tool drop-down list.

   NOTE: You cannot update a trajectory using Shunt Stylet.
2. If the tool has not already been calibrated and/or verified, calibrate and/or verify it now.
3. Targets and engagement points are relocated to the position of the tool's virtual tip, so position the tool's physical tip as necessary then use the **Extend Tool Tip to Virtual Location** feature in the phase panel to extend the tool's virtual tip until it is located where you want the target or engagement point to be placed.
4. In the phase panel, under Trajectories:
   - To set the new target point, select Target, and then click the **Set target point** icon

     or
   - To set the new engagement point, select Engagement, and then click the **Set engagement point** icon

   NOTE: If the trajectory you modified was originally created in Modus Plan, a new trajectory is created from the original planned trajectory. The new trajectory is named using the following

convention: "IntraOp <plan name> <trajectory name> <a-z>" to differentiate from the original planned trajectory and any other trajectories copied from the same original trajectory.

Duplicating an Existing Trajectory

To create a new trajectory by duplicating an existing trajectory, select the trajectory you want to duplicate from the Trajectories list and click the **Copy the selected trajectory** icon. You can then modify the target or engagement point of the new trajectory as described above.

Creating a New Trajectory

To create a new trajectory:

1. In the phase panel, select the tool you want to use to create the new trajectory from the Navigated Tool drop-down list.

   NOTE: You cannot create a new trajectory using a port tool or Shunt Stylet.
2. If the tool has not already been calibrated and/or verified, calibrate and/or verify it now.
3. The target for the new trajectory will be created at the position of the tool's virtual tip, so position the tool's physical tip at your desired engagement point and use the **Extend Tool Tip to Virtual Location** feature in the phase panel to extend the tool's virtual tip until it is located where you want the target to be placed.
4. Under Trajectories in the phase panel, click the **Add a trajectory for this target point** button.

   A new trajectory is created.

Adjusting the Craniotomy for a New Trajectory

When you create a new trajectory, Modus Nav creates a craniotomy of the recommended default size. Review and adjust the craniotomy as needed. After adjusting the craniotomy, physically check for critical anatomy along the trajectory, and adjust the trajectory as needed.

NOTE: You cannot adjust the craniotomy for trajectories created in Modus Plan, or new trajectories created by duplicating a trajectory created in Modus Plan.

5.12 Resection

The viewports in the Resection phase are designed to help you orient the anatomy to the plan series images. One viewport shows the plan images from the perspective of the tool at its current position. The other viewports show orthogonal views.

When the Pointer tool is in the tracking camera’s field of view, it appears in the viewports.

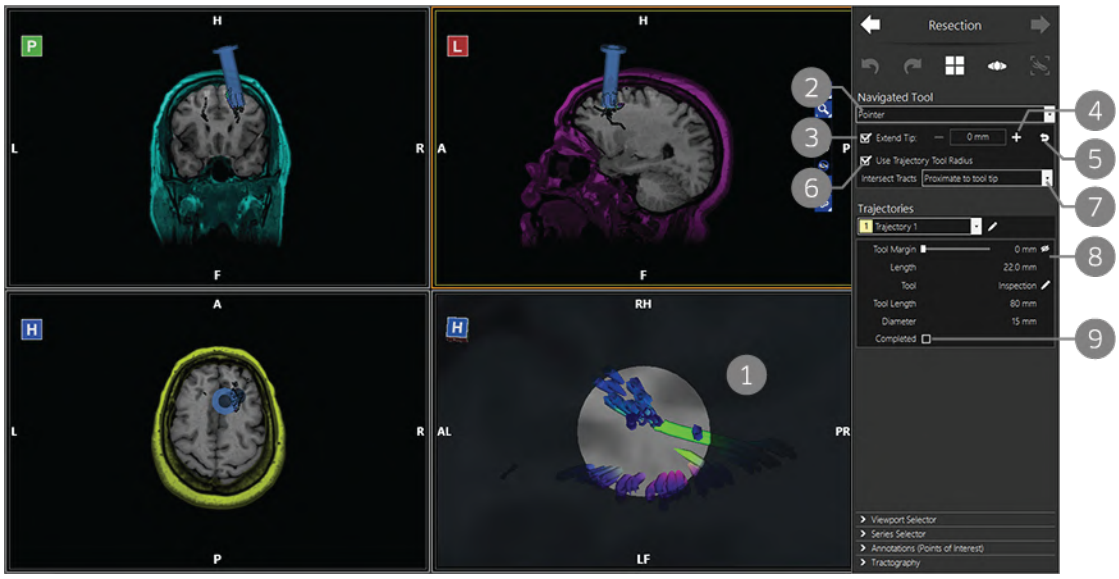


Figure 75 Workspace in the Resection phase

1 One viewport shows the plan images from the perspective of the tool at its current position. Zoom in or out on this viewport to show more or less detail.

2 Select the tool to display in the viewports.

3 Use the Extend Tool Tip to Virtual Location feature to view the slices and tractography ahead of the tracked tool.

4 Click the + and - icons to adjust the length of the virtual tip. Click and hold on the icons to accelerate the rate at which the length changes.

5 Reset to the default virtual tip length for the selected tool.

6 Indicate whether to show intersecting tracts in the viewport based on the tool defined for the currently selected trajectory or the selected navigated tool (item 2 above).

NOTE: This option is disabled when the selected navigated tool is a NICO BrainPath port.

7 Options for displaying the tractography that intersects the tool or trajectory, or both. The options available depend on the selected navigated tool (item 2 above).

8 Information about the trajectory your are navigating appears here.

9 Optionally, click this checkbox to indicate that the trajectory has been navigated. Completed trajectories are displayed with a check mark beside their name in the Trajectories list.

The virtual tip length is set to 0 mm by default in this phase. To show the tractography ahead of the tool in the viewports, click the + icon to increase the virtual tip length by your desired amount.

NOTE: If you move the active tool quickly out of the tracking camera's field of view, Modus Nav recognizes this action and reverts to displaying the last stable location of the tool in the viewports.

5.13 Using Align to Trajectory

The Align to Trajectory feature makes information about a trajectory in the tracking camera's field of view available to other systems connected to Modus Nav. The trajectory consists of the information describing the target point, engagement point, and skin surface as they are defined in Modus Nav.

The trajectory information is only available when the following conditions are met:

- The plan or primary series is accepted
- The patient reference is visible
- A valid trajectory is selected
- The registration is accepted
- The Align to Trajectory feature is enabled

IMPORTANT: The Align to Trajectory feature will not work if there is no extracted skin surface (for example, the primary series is a T2 scan) and if there is a CT scan merged from a previous version of Plan.

To use the Align to Trajectory feature:

1. Click the **Align to Trajectory** tool on the left side of the workspace.
2. In the Configure Align to Trajectory dialog, select the **Enable Align to Trajectory** checkbox.

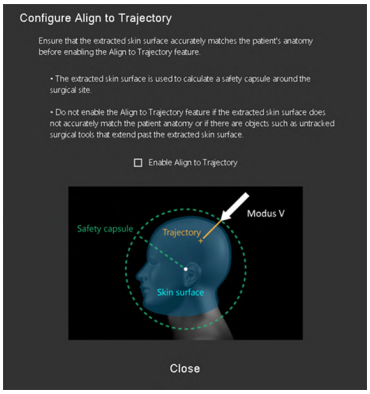


Figure 76 Configure Align to Trajectory dialog

3. Click **Close**.

   The Align to Trajectory icon turns green, indicating that information about the trajectory currently selected in Modus Nav is now available to other systems.

6.0 System Maintenance

6.1 Cleaning

If necessary, clean the Modus Nav hardware components as described below.

Clean and sterilize the Modus Nav instrumentation as described in the cleaning and sterilization instructions provided with each tool.

NOTE: Immediately following a procedure, rinse the sterilizable components as needed to remove visible contaminants and debris. Do not let contaminants dry before cleaning.

The tracking spheres, BrainPath Tracking Array, and cranial reference drape are single-use items and cannot be cleaned.

CAUTION: Risk of Operator Injury and Damage to Equipment

Do not use Cidex or other disinfectants to clean any of the Modus Nav components. Use only those cleaning agents described in this manual.

To prevent the risk of operator infection, dispose of the Modus Nav keyboard and mouse properly if they become contaminated.

Table 7 Hardware Cleaning

Component	Cleaning Instructions
Cart surfaces	Cart surfaces may be cleaned with the following solutions: • Water • Mild Soap Solutions • Hydrogen Peroxide Solution, 3% • Iodine Solutions • Bleach Solutions, 10% • Isopropyl Alcohol Solutions, 70%, 91% • Cavicide® Steel wool or other abrasive material should never be used to clean the carts. Never submerge or allow liquids to enter a cart or components on the cart. Doing so may irreparably damage the system. Wipe cleaning agents off surfaces immediately using a water-dampened cloth. Dry surfaces thoroughly after cleaning.

Table 7 Hardware Cleaning (continued)

Component	Cleaning Instructions
Tracking camera	Use a 70% isopropanol solution and a soft lint-free cloth to remove smudges from the enclosure and illuminator covers. Do not use any paper products for cleaning as they may scratch the illuminator filters. To clean the position sensors: 1. Remove dust from each illuminator filter and lens using a photographic lens duster brush. Gently wipe the surface in one direction only by pulling the brush across the surface. 2. Continue cleaning the remainder of the position sensor, taking care not to wipe debris into the illuminator filter or lenses. To clean the video camera window: 1. Use a photographic lens duster brush or an air puffing lens cleaner to gently remove any dust and particles from the window. Do not use pressurized air. 2. Use a clean, dry, microfibre lens cleaning cloth to remove marks from the window. Wipe gently in a circular motion over the window. 3. If necessary, wipe the window with a 70% isopropanol solution and a lens cleaning cloth. A standard lens cleaning solution can also be used. The cloth should be slightly damp, not wet. **NOTE: When wiping the window with a cloth or duster brush, use a circular motion and sweep up and away from the window to draw dust and debris out of the enclosure. Do not wipe dust, debris, or cleaning solution towards the edges of the window. An accumulation around the edges of the window can impact the quality of the image from the video camera. An air puffing lens cleaner is useful for removing dust and debris from the edges of the window.**
Monitors	Prior to cleaning, turn off the monitor and disconnect it from its power source. Clean monitor surfaces with a 50 to 70 v/v% concentration of isopropyl alcohol or a 76.9 to 81.4 v/v% concentration of ethanol using a swab method. Wipe gently (using less than 1 N force). Stubborn stains may be removed with a soft cleaning cloth dampened with mild detergent using a swab method and then clean using the above chemical solution. To prevent scratches, do not use unnecessary force to rub the monitor surfaces. Do not keep the monitor surfaces in contact with a rubber or vinyl resin product for a long period of time as this may damage the surface.

Table 7 Hardware Cleaning (continued)

Component	Cleaning Instructions
Monitor cover	The monitor cover may be cleaned with most mild, non-abrasive solutions commonly used in hospital environment (e.g., diluted bleach, ammonia, or alcohol solutions). The surface finish will be permanently damaged by strong chemicals and solvents such as acetone and trichloroethylene. Steel wool or other abrasive material should never be used. Wipe cleaning agents off surfaces immediately using a water-dampened cloth. Dry surfaces thoroughly after cleaning.
Cranial reference and arm	Cleaning: Thoroughly wipe all exterior surfaces with a lint-free cloth that has been dampened with vinegar (distilled white vinegar, 5% acidity) or an Ammonia-based glass cleaner. Remove residual detergent by wiping all exterior surfaces with a lint-free cloth dampened with distilled water. Disinfecting: Wipe all exterior surfaces with a lint-free cloth dampened with 80% Ethyl Alcohol. Allow the unit to air dry.

CAUTION

Synaptive Medical makes no claims regarding the efficacy of the listed chemicals or processes as a means for controlling infection. Consult your hospitals' infection control officer or epidemiologist.

6.2 Inspection

Inspect the Modus Nav components regularly to verify that they are in proper working order. Do not use any component that does not meet the inspection criteria listed in Table 8 below or that appears damaged in any way. Contact Synaptive customer service for assistance (see 1.10 Synaptive Customer Service Information on page 18).

Inspections should be carried out only by trained personnel.

Table 8 Inspection Criteria

Component	Inspection Schedule	Inspection Criteria
Carts	Before each use	• Wheels roll smoothly when casters are unlocked • All casters lock securely

Table 8 Inspection Criteria (continued)

Component	Inspection Schedule	Inspection Criteria
Cables	Before each use	• Cables bend and straighten without creasing • No fraying or cracks anywhere on the length of the cable • Connectors are clean and show no signs of corrosion on connector pins
Pointers and Calibration Device	Before each procedure	• No evidence of corrosion • No nicks, dents or cracks • Posts for attaching the tracking spheres are free of damage and perpendicular to the tracking array • Pointer is not bent or otherwise distorted from its original shape
Trackable Suction	Before each procedure	• Damage to suction tube tip • Cracks in weld seams • Corrosion • Posts for attaching the tracking spheres are free of damage and perpendicular to the tracking array
Sterilizable storage trays	Before each procedure	• Brackets are not broken or deformed • Latches close securely • No evidence of corrosion
Single-use components	Before use	• Visually inspect for damaged packaging • Visually inspect components before use
Tracking camera arm	Annual	• Move the Tracking Camera arm through its entire range of motion. The Tracking Camera should maintain its position at every point in the travel of the arm. Contact Synaptive Service if it does not.

6.3 Consumables

The following parts are consumable/disposable products available from Synaptive Medical. To order parts contact salesorders@synaptivemedical.com.

Table 9 Consumables

Part	Part Number	Recommended Minimum Available on Hand
BrainPath tracking array	SYN-0015	10
Tracking spheres	SYN-0533	1 box of 48 (12 trays of 4 in box)
Cranial reference drape	SYN-0019	10
IZI Multi-Modality Fiducial Markers *	SYN-0528	250

*** Beekley PinPoint® Multi-Modality fiducial markers are also supported for use with Modus Nav, but they are not available from Synaptive Medical. Contact a Beekley Medical product supplier to obtain PinPoint® Multi-Modality fiducial markers.**

6.4 Replaceable Components

To replace any component of the Modus Nav system, contact Synaptive customer service (see 1.10 Synaptive Customer Service Information on page 18). To order Modus Nav consumables (drapes, tracking spheres, and tracking arrays) see 6.3 Consumables above.

Table 10 Operator and Auxiliary Carts

Name	Part Number
Modus Nav Operator Cart	SYN-0982
Auxiliary Cart - 3D Monitor Cart 55" with Camera	SYN-0907
Auxiliary Cart - 3D Monitor Cart 55"	SYN-0906
Auxiliary Cart - 3D Monitor Cart 31" with Camera	SYN-0793
Auxiliary Cart - 3D Monitor Cart 31"	SYN-0794
Auxiliary Cart - Camera Cart	SYN-0621

Table 11 Synaptive Instrumentation

Name	Part Number
Patient Reference	SYN-0021

Table 11 Synaptive Instrumentation (continued)

Name	Part Number
Standard Pointer	SYN-0642
Long Pointer	SYN-0975
Short Pointer	SYN-0559
Trackable Suction Set Standard	SYN-0657
Trackable Suction Set Malleable	SYN-0783
Calibration Block	SYN-0014
Multi-Tool Calibration Device	SYN-0755
Sterilizable Storage Tray for Pointers and Multi-Tool Calibration Device	SYN-0754
Sterilizable Storage Tray for Standard Pointer and Calibration Block	SYN-0596

Table 12 Software

Name	Part Number
Modus Nav Laptop	SYN-0971
Modus Nav Software	SYN-0867
Modus Plan Software	SYN-0866

6.5 Hard Drive Space Maintenance

The Modus Nav system should not be used to permanently store data. Use a system such as a PACS to archive data.

To ensure there is always enough space on the hard drive for a new study to be imported, you should regularly delete old studies from the Modus Nav laptop.

To delete a study from the laptop, in the Study Explorer right-click on the study and select **Delete**.

To configure Modus Nav to automatically delete older studies from the laptop:

1. On the menu bar in the Study Explorer select **Tools** > **System Configuration**. The System Configuration dialog appears.
2. In the tree view on the left side of the dialog, select **Local** > **Study Storage**.

3. In the list of options on the right side of the dialog, under Automatic Study Deletion, select the **Delete Studies** checkbox and specify how long Modus Nav should leave a study in the local database before deleting it.
4. Click **OK**.

7.0 Keyboard Shortcuts

Table 13 Keyboard Shortcuts

Keystroke	Function
CTRL + Left Mouse	Pan
CTRL + Right Mouse	Rotate (only applicable in solid views)
CTRL + Middle Mouse	Window/Level
CTRL + Scroll	Zoom
CTRL + S	Save
CTRL + Z	Undo
CTRL + Y	Redo
O	Toggle text overlays
X	Explode/Unexplode
S	Assign mouse button to Stack
R	Assign mouse button to Rotate (only applicable in solid views)
P	Assign mouse button to Pan
W	Assign mouse button to Window/Level
Z	Assign mouse button to Zoom
L	Toggle locator visibility
,	Zoom out
.	Zoom in
Page Up	Stack up
Page Down	Stack down
Arrow Keys (Up/Down/Left/Right)	Window/Level

Table 13 Keyboard Shortcuts (continued)

Keystroke	Function
CTRL + Arrow Keys (Up/Down/Left/Right)	Pan
F2	Return to default window/level values

8.0 Troubleshooting

8.1 Troubleshooting Problems

Table 14 Problems and Possible Solutions

Problem	Possible Solutions
Software does not display on auxiliary cart monitor.	• Set the Modus Nav laptop to clone display automatically.
No power on monitor.	• Check monitor power connection. • Check power switch on back of monitor.
No video signal to monitor (when monitor is powered on).	• Verify that the cable connecting the monitor to the Modus Nav operator cart or other system is securely connected at both ends.
Tracked tools are not recognized by the tracking system.	• Ensure tracking camera has power and the transfer cable is connected between the Auxiliary Cart and Modus Nav operator cart. • Ensure tracking spheres are clean and properly attached to the tool. • Use the tracker calibration function in the Modus Nav software application to identify the positions of all tracked tools. Move the tracking camera so that all tools are inside the viewable volume. For more information, see 4.2.2 Tracking Icons on page 35.

Table 14 Problems and Possible Solutions (continued)

Problem	Possible Solutions
Tracked tools cannot be verified or calibrated.	• Verify that the tracking spheres are properly attached to the tool. • For the BrainPath tracking array, verify that the tracking array is properly attached to the brain sheath. • Ensure that all tracking spheres are visible to the tracking camera when holding the tool and Calibration Device in front of the camera. • Ensure that no other tracked tools are visible to the camera during the verification/calibration process. • Tool or Calibration Device may be deformed (possibly due to being dropped). Try with another tool and Calibration Device.
Keyboard or mouse become unusable.	• Disconnect and reconnect the keyboard and/or mouse. • Open the laptop enclosure on the operator cart and use the laptop keyboard and/or track pad.

9.0 Fiducial Placement Guidelines

If you are using fiducial registration, fiducial markers must be placed prior to image acquisition and remain affixed to the patient for the duration of image acquisition and during registration. Instruct the patient to not move during image acquisition and not to remove or alter the fiducial markers prior to, during, or after the image acquisition.

Use standard MR-compatible adhesive fiducial markers such as IZI Multi-Modality Fiducial Markers. If a fiducial marker falls off after the image acquisition, leave it off. Do not attempt to re-affix the fiducial marker.

NOTE: A minimum of five fiducial markers are required to perform fiducial registration using Modus Nav. It is recommended that you place at least seven fiducial markers on the patient prior to image acquisition to ensure that at least five are available at the time of registration.

Fiducial markers must be placed on firm skin around the head (for example, mastoid process, zygomatic arch).

For best results, follow these steps when placing fiducial markers:

1. Shave a small area of hair at the location where the fiducial marker will be placed.

   NOTE: If the patient is diaphoretic, applying an adhesive is allowed.
2. Remove the paper backing from the fiducial marker and place the marker on the prepared area.
3. Using an indelible marker, mark the center of each fiducial.
4. Place 7-10 fiducial markers around the head, spread out over as much of the surface of the head as possible. The minimum supported distance between fiducials is 20 mm.

   Distribute the fiducial markers in non-coplanar and asymmetrical locations.

   NOTE: To help the surgeon confirm the patient orientation in the images, place two fiducial markers close to one another on one side of the head.
5. When positioning the patient in a head holder, confirm that the fiducial markers have not shifted from their original locations.
6. Image the patient using a scan protocol that meets the Synaptive MR scan recommendations (listed in document MKT-0008).

10.0 Cybersecurity Considerations

10.1 Secure System Configuration

10.1.1 Anti-Virus

A default anti-virus software application (Windows Defender) is deployed during initial configuration of your system. It is possible to replace this application with your Institution's approved anti-virus software.

For performance reasons, the following directory and its children should be added as an exception to any configured anti-virus application:

C:\ProgramData\Synaptive Medical\ClearCanvas Workstation General

Consult your Synaptive Support representative for further details.

10.1.2 Firewall

The default Windows firewall is deployed and enabled during initial configuration of your system. It is recommended that you replace this application with your Institution’s approved firewall software. The following firewall exceptions are required:

- ClearCanvas.Desktop.Executable.exe
- ClearCanvas.Server.ShredHostService.exe

To enable DICOM communication to the Modus Nav system, port 104 must be open for TCP send/receive.

10.2 User Profiles and Permissions

10.2.1 Domain Membership

It is possible to attach the device to your institution’s Windows Domain. However, it is recommended that a very lightweight policy be applied, which does not conflict with the unique security and safety provisions of the device.

Consult your Synaptive Service representative for more details.

10.2.2 Default User Profiles

- Admin user

  The system is deployed with a local administrator account, named “Admin”. This account has sufficient permissions to enable software configuration, update, and management.

It is recommended that access to this account be restricted to users who are responsible for maintaining the operation of the system.

- Operator user

  The system is deployed with a default local user account, named “Operator”. This account is configured for general use of the system, and is restricted from software install or update. Additional accounts may be configured for you during initial installation of the system.

10.2.3 Recommendations Regarding User Accounts and Permissions

- User accounts

  It is recommended that a minimum number of user accounts be enabled for the system. If individual user accounts must be configured, they should be Domain accounts so that account and authentication settings are consistent for each user.

- Administrator accounts

  General users should not be provided with administrator privilege on the Synaptive system.

- Password management

  Authentication policy should be adjusted to match your institution's guidelines.

10.3 Device Configuration and Restrictions

10.3.1 Removable Media

Removable media, such as USB and DVD, can be vectors for malicious software. By default, these devices are accessible to all users. Apply access restrictions to these devices consistent with your institution’s security policies.

10.3.2 Wireless Communications

Modus Nav does not require use of Wireless communications. It is recommended that wireless devices (802.11 and Bluetooth) be disabled for all users of the system. No wireless device should be connected to Modus Nav.

10.3.3 Data Encryption

The Windows file system can be configured to encrypt data. This may be a useful precaution to protect patient data stored on the Modus Nav system. Note, however, that the use of encryption can have a significant adverse effect on the performance of the system. If you enable data encryption tools, it is recommended that you evaluate their impact on computer and software performance.

10.3.4 Audit Logging

It is recommended that Windows audit logging be configured to capture account “logon events” or audit “logon attempts”. See https://technet.microsoft.com/en-us/library/cc952128.aspx for details.

10.3.5 Use of a Trusted Network

Modus Nav uses the industry standard DICOM protocol for transferring image data. In typical configurations, this protocol does not provide a secure means of data transport. For this reason, Modus Nav should only be used on trusted networks.

10.4 Windows Update

10.4.1 Minimum Supported Patch Level

Modus Nav supports a minimum Windows patch level which will be provided to IT Operations at the time of installation or upgrade.

10.4.2 Maximum Supported Windows Patch Level

Modus Nav is periodically validated for compatibility with new Windows updates. The current support level is available through your Synaptive Service representative.

10.4.3 Update to Supported Windows Patch Level

Synaptive is responsible for providing timely updates for Modus Nav systems.

10.5 System Storage

When not in use, Synaptive systems should be turned off and stored in a secure location.

11.0 HIPAA Compliance

Supporting your institution to maintain compliance with the Health Insurance Portability and Accountability Act (HIPAA) is important to us. Modus Nav provides several features and capabilities which enable this.

NOTE: Modus Nav is not intended as a long-term store for protected health information (PHI), and periodic removal of historical information is recommended. The application can be configured to do this automatically after a defined period of time.

1. Access Control - Unique User Identification

   Modus Nav may be used in emergency situations. For this reason, the requirement for unique login has been relaxed to enable rapid access to system functions. However, the intended use environment is an Operating Room, which has limited and well-monitored access.

   It is anticipated that the Modus Nav system will be stored in a physically secure location while not in use.

2. Access Control - Emergency Access

   Modus Nav may be used in emergency situations. For this reason, the requirement for unique login has been relaxed to enable rapid access to system functions.

3. Access Control - Automatic Logoff

   In normal use, Modus Nav may operate for several hours without direct user interaction. For this reason, automatic logoff is neither configured nor recommended for this system.

4. Access Control - Encryption and Decryption

   Modus Nav supports any AES based disk-level encryption.

   NOTE: Modus Nav does not ship with encryption enabled by default.

5. Audit Controls

   Modus Nav implements a DICOM-compliant audit logging system.

6. Integrity

   Modus Nav integrates data review in the procedure workflow. In the first step in the workflow, Modus Nav displays patient information and study data and requires the user to confirm the data is correct and appropriate for the intended clinical use. This information, along with standard practices adopted in the OR to confirm data correctness, facilitates confirmation of data integrity.

7. Authentication

   A user profile with two-factor authentication and elevated permissions exists for the purpose of a Synaptive Authorized Service Provider.

   Modus Nav may be used in emergency situations. For this reason, the requirement for unique login has been relaxed to enable rapid access to system functions. The intended use environment is an

Operating Room, however; processes can be implemented to identify staff members who may contact PHI during the course of the procedure.

8. Transmission Security

   Modus Nav transmits and receives data using the DICOM protocol. This protocol is inherently insecure and care should be taken to ensure that it is not used across public networks.

9. Protection Against Malware

   Modus Nav is installed with a default anti-virus and firewall enabled. Administrators may replace or configure these components to comply with their security policy.

12.0 Specifications

12.1 System Classification and Specifications

Classification: Class 1 Equipment, Type B Applied Part

Mode of Operation: Continuous Operation

Degree of Protection Against Ingress of Water: IPX0

Mains supply: 100-240 V, 50/60 Hz, 350 VA

12.2 Essential Performance

The essential performance criteria of Modus Nav are that:

- The system must display the location of tracked surgical instruments relative to a set of radiological images, within the accuracy criteria stated in 13.0 Accuracy Characterization on page 130
- The system must be able to recover in a timely manner from a prolonged loss of mains power

The electrical system of Modus Nav is divided between two major components: the operator cart and the auxiliary (visualization) cart. The operator cart contains the computer and video outputs and the auxiliary cart contains the external display and tracking camera. There are no critical components on the operator cart. The essential performance criteria of the auxiliary cart are that:

- The monitor shall display an image and maintain its selected video orientation
- The camera shall transmit consistent data about the location of tracked tools

Electromagnetic disturbances outside the electromagnetic environment described in section 12.7 can negatively impact the essential performance of Modus Nav. Degradation of essential performance will be observed by a reduction in navigational accuracy.

12.3 Cable Specifications

Table 15 Operator Cart Cable Specifications

Cable	Specifications
Power cord *	20 ft (3 x 14 AWG) with C13 and NEMA 5-15P hospital grade connectors 20 ft with C13 and JIS 8303 connector 20 ft with C13 and DK-2-8A hospital grade connector 20 ft with C13 and CEE7/7 connector 20 ft with C13 and BS1363/A connector 20 ft with C13 and AS/NZS 3112:2000 hospital grade connector 20 ft with C13 and SEV 1011 Type 12 connector
Video cable	25 ft shielded cable with DVI-D Duel link connector, male to male
Ethernet cable	25 ft cable (4 UTP x 24 AWG) with RJ-25 connector, male to male

* The specific power cord supplied with your Modus Nav system is dependent on regional power specifications.

NOTE: Additional cables are supplied with the auxiliary cart. For information about those cables, see the user manual accompanying your cart.

WARNING

Use only the cables supplied with Modus Nav by Synaptive Medical. The use of non-approved power cords can result in damage to the Modus Nav system. The use of other accessories, transducers, and cables may result in increased electromagnetic emissions or decreased immunity of this equipment and may result in improper operation. If a cable becomes damaged, contact Synaptive customer service for assistance.

12.4 Tracking Camera Laser Specifications and Standards

The positioning laser on the tracking camera is a Class 2 laser with a wavelength of 635 mm and a maximum output of 1 mW. The positioning laser conforms to the following standards:

- ANSI Z136.1 (2007)
- IEC 60825-1 (2007)
- FDA/CDRH 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007

12.5 Certifications

Modus Nav is certified to the following standards:

- IEC 60601-1-2: 2014 (4th edition)
- CAN/CSA C22.2 No. 60601-1: 2014-03
- ANSI/AAMI ES60601-1:2005/A1:2012-08
- CB SCHEME CERTIFICATION

All Modus Nav Systems are designed and manufactured in an ISO:13485 registered facility that is routinely audited by medical device regulators under the Medical Device Single Audit Program (MDSAP).

12.6 Permissible Environmental Conditions

Operate, store, and transport the Modus Nav system components only under the following conditions.

Table 16 Permissible Environmental Conditions

	Operating	Storage	Transport
Ambient temperature	16° C – +30° C	-10° C – +50° C	-10°C – +50° C
Relative humidity (non-condensing)	10% – 70%	10% – 90%	10% – 90%
Atmospheric Pressure	89 kPa – 102 kPa	89 kPa – 102 kPa	89 kPa – 102 kPa

12.7 Electromagnetic Environment Information

The Modus Nav system requires special precautions regarding electromagnetic compatibility and must be installed and used according to the electromagnetic compatibility information described in the tables below.

Portable and mobile RF (radio frequency) communications equipment can affect the performance of the Modus Nav system.

WARNING

The operating room may present sources of electromagnetic energy which may create disturbances greater than the recommended electromagnetic environment described in this section.

If Modus Nav will be used alongside potential sources of EM that exceed the recommended electromagnetic environment, the system should be observed to verify normal operation and no degradation in essential performance.

Users should periodically evaluate navigational accuracy throughout the procedure. If a degradation is observed that is the result of an electromagnetic disturbance, RF emitters in use around Modus Nav should be turned off or moved away from Modus Nav. If the source cannot be found and Modus Nav continues to operate with degraded essential performance, discontinue use of Modus Nav and contact Synaptive support.

Table 17 Electromagnetic Environment (Emissions)

The Modus Nav system is intended for use in the electromagnetic environment specified below. The customer or the user of the Modus Nav system should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The Modus Nav system 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 Modus Nav system 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 equipment 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 equipment or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Table 18 Electromagnetic Environment (Immunity)

The Modus Nav system is intended for use in the electromagnetic environment specified below. The customer or the user of the Modus Nav system should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 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	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	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 = 120 Vac	0% U_T (100% dip in U_T) for 0.5 cycle 0% U_T (100% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 30 cycles 0% U_T (100% dip in U_T) for 5 sec	0% U_T (100% dip in U_T) for 0.5 cycle 0% U_T (100% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 30 cycles 0% U_T (100% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial/residential or hospital environment. It is recommended that the Modus Nav system be powered from an uninterruptible power supply or a battery.
Power frequency (50 Hz/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial/residential or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Table 19 Electromagnetic Environment (Conducted/Radiated)

The Modus Nav system is intended for use in the electromagnetic environment specified below. The customer or the user of the Modus Nav system should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM/Amateur Radio bands inside 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM/Amateur Radio bands inside 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Modus Nav system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz RF communication equipment inside 80 MHz to 6 GHz	3 V/m 80 MHz to 2,7 GHz RF communication equipment inside 80 MHz to 6 GHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 Mhz to 2.5 GHz $d = 2.3\sqrt{P}$ 800 Mhz to 2.7 GHz 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). See Table 20 below for the calculated separation distances for Modus Nav. 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].

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.

Table 19 Electromagnetic Environment (Conducted/Radiated) (continued)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
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 Equipment is used exceeds the applicable RF compliance level above, the Modus Nav 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 Modus Nav system. b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 20 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the System

The Modus Nav system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Modus Nav users can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Modus Nav system as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz - 80 MHz $d = 1.2\sqrt{P}$	80 MHz - 800 MHz $d = 1.2\sqrt{P}$	800 MHz - 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.24 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

Table 20 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the System (continued)

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.

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.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Modus Nav system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

13.0 Accuracy Characterization

The tables in the sections below summarize the Modus Nav system accuracy for various positions within the tracking camera's field of view. Accuracy testing was conducted with tools calibrated using both the Synaptive calibration block (SYN-0014) and Multi-Tool Calibration Device (SYN-0755).

All tests were conducted using CMM measurements of the measurement phantom as truth data and a CT scan of the same phantom was used in the software to simulate clinical workflow. The CT scan had a slice thickness of 0.625 mm and the CMM has a single point accuracy of 0.024 mm. The "Clinical Setup" and "Worst Case Setup" headings indicate the location of the measurement phantom relative to the tracking camera in its field of view.[1]

The Modus Nav system is accurate to within 2 mm and 2 degrees of the physical tip of the tracked tool. When a virtual tip is applied to the tracked tool, the accuracy of the virtual tip degrades as the virtual tip length increases.

13.1 Accuracy Measurements After SurfaceTrace Registration

13.1.1 Tools Calibrated With Multi-Tool Calibration Device

13.1.1.1 Registration With Standard Pointer

Table 21 Positional Accuracy

Navigated Tool	Clinical Setup		Worst Case Setup	
	Mean Error (mm)	Standard Deviation (mm)	Mean Error (mm)	Standard Deviation (mm)
Standard Pointer	1.29	0.37	0.66	0.31
Long Pointer	1.57	0.23	1.13	0.31
Short Pointer	0.41	0.16	1.21	0.49
Suction One	1.05	0.33	1.26	0.48
Suction Two	1.28	0.37	1.11	0.41
Port	1.53	0.28	0.65	0.33

[1] Contact Synaptive Medical for the detailed test procedure and designs for a measurement phantom suitable for conducting such tests.

Table 22 Angular Accuracy

Navigated Tool	Clinical Setup		Worst Case Setup	
	Mean error (°)	Standard Deviation (°)	Mean Error (°)	Standard Deviation (°)
Standard Pointer	0.84	0.18	0.77	0.15
Long Pointer	0.77	0.12	0.46	0.09
Short Pointer	1.12	0.17	0.93	0.22
Suction One	1.22	0.31	0.71	0.28
Suction Two	0.86	0.23	0.52	0.18
Port	0.57	0.02	0.51	0.21

13.1.1.2 Registration With Long Pointer

Table 23 Positional Accuracy

Navigated Tool	Clinical Setup		Worst Case Setup	
	Mean Error (mm)	Standard Deviation (mm)	Mean Error (mm)	Standard Deviation (mm)
Standard Pointer	0.53	0.20	1.61	0.27
Long Pointer	0.59	0.19	1.39	0.44
Short Pointer	0.60	0.22	1.08	0.40
Suction One	1.20	0.48	1.71	0.76
Suction Two	0.64	0.25	1.27	0.50
Port	0.65	0.27	1.65	0.48

Table 24 Angular Accuracy

Navigated Tool	Clinical Setup		Worst Case Setup	
	Mean error (°)	Standard Deviation (°)	Mean Error (°)	Standard Deviation (°)
Standard Pointer	0.46	0.17	0.33	0.20
Long Pointer	0.39	0.12	0.38	0.10
Short Pointer	0.95	0.17	0.86	0.19
Suction One	0.85	0.31	0.48	0.23
Suction Two	0.48	0.23	0.48	0.22
Port	0.88	0.21	0.86	0.22

13.1.2 Tools Calibrated With Calibration Block

13.1.2.1 Registration With Standard Pointer

Table 25 Positional Accuracy

Navigated Tool	Clinical Setup		Worst Case Setup	
	Mean Error (mm)	Standard Deviation (mm)	Mean Error (mm)	Standard Deviation (mm)
Standard Pointer	0.49	0.25	0.90	0.33
Port	0.70	0.22	1.12	0.37

Table 26 Angular Accuracy

Navigated Tool	Clinical Setup		Worst Case Setup	
	Mean error (°)	Standard Deviation (°)	Mean Error (°)	Standard Deviation (°)
Standard Pointer	0.33	0.12	1.10	0.12
Port	1.16	0.16	0.69	0.23

13.2 Accuracy Measurements after Touch Point Registration

13.2.1 Tools Calibrated With Multi-Tool Calibration Device

13.2.1.1 Registration With Standard Pointer

Table 27 Positional Accuracy

Navigated Tool	Clinical Setup		Worst Case Setup	
	Mean Error (mm)	Standard Deviation (mm)	Mean Error (mm)	Standard Deviation (mm)
Standard Pointer	0.76	0.21	1.07	0.36
Long Pointer	1.01	0.17	1.40	0.27
Short Pointer	1.11	0.08	1.30	0.24
Suction One	1.05	0.33	1.59	0.42
Suction Two	1.28	0.37	1.36	0.38
Port	1.53	0.28	1.20	0.38

Table 28 Angular Accuracy

Navigated Tool	Clinical Setup		Worst Case Setup	
	Mean error (°)	Standard Deviation (°)	Mean Error (°)	Standard Deviation (°)
Standard Pointer	0.45	0.17	0.45	0.18
Long Pointer	0.77	0.12	0.15	0.07
Short Pointer	0.75	0.17	0.63	0.22
Suction One	1.22	0.31	0.47	0.23
Suction Two	0.86	0.23	0.31	0.18
Port	0.57	0.02	0.58	0.22

13.2.1.2 Registration With Long Pointer

Table 29 Positional Accuracy

Navigated Tool	Clinical Setup		Worst Case Setup	
	Mean Error (mm)	Standard Deviation (mm)	Mean Error (mm)	Standard Deviation (mm)
Standard Pointer	0.90	0.12	1.43	0.36
Long Pointer	0.88	0.14	1.60	0.208
Short Pointer	0.72	0.06	1.07	0.23
Suction One	1.69	0.50	1.81	0.47
Suction Two	1.11	0.25	1.55	0.44
Port	0.84	0.24	1.58	0.39

Table 30 Angular Accuracy

Navigated Tool	Clinical Setup		Worst Case Setup	
	Mean error (°)	Standard Deviation (°)	Mean Error (°)	Standard Deviation (°)
Standard Pointer	0.34	0.17	0.44	0.17
Long Pointer	0.28	0.11	0.16	0.08
Short Pointer	1.06	0.17	0.82	0.22
Suction One	0.72	0.31	0.48	0.23
Suction Two	0.36	0.22	0.31	0.17
Port	0.98	0.22	0.63	0.22

13.2.2 Tools Calibrated With Calibration Block

13.2.2.1 Registration With Standard Pointer

Table 31 Positional Accuracy

Navigated Tool	Clinical Setup		Worst Case Setup	
	Mean Error (mm)	Standard Deviation (mm)	Mean Error (mm)	Standard Deviation (mm)
Standard Pointer	0.0.88	0.15	1.12	0.35
Port	1.10	0.14	1.31	0.38

Table 32 Angular Accuracy

Navigated Tool	Clinical Setup		Worst Case Setup	
	Mean error (°)	Standard Deviation (°)	Mean Error (°)	Standard Deviation (°)
Standard Pointer	0.31	0.14	0.48	0.12
Port	1.00	0.16	0.35	0.18