stryker

Stryker ENT Navigation System

Instructions for Use

Rx Only

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1. How to Use this Document

1.1. About this Document

This document is the most comprehensive source of information for the safe and effective use of the product. Read this document carefully and keep for future reference. Pay special attention to safety information.

When combined with other medical devices, the user manual of these devices is to be considered as well.

1.2. Contact Information

	Stryker Representative
	+1 269 323 7700
	www.stryker.com

1.3. Definition of Conventions

The following table provides definitions of conventions used in this document.

Convention	Definition
1	Refer to graphic
▶	Instructional step that must be performed.
1.	Instructional steps that must be performed in a sequence.
•/-	Unordered list item

1.4. Definition of Terms, Abbreviations and Symbols

The following table provides definitions of terms used in this document.

Term	Definition
WARNING (signal word)	Highlights a safety-related issue. Comply with this information to prevent patient injury or hospital staff injury.
CAUTION (signal word)	Highlights a product reliability issue. Comply with this information to prevent product damage or malfunction.

The following table provides definitions of abbreviations used in this document.

Abbreviation	Definition
EEC	European Economic Community
EN	European Standard
ISO	International Organization for Standardization
RKI	Robert Koch Institute

The following tables define the symbols used in this document, on the product and on the product label.

EN ISO 7010 Graphical symbols – Safety colors and safety signs – Registered safety signs

Symbol	Name: Definition
 W001	**General warning sign:** to signify a general warning.
 M002	**Refer to instruction manual/booklet:** to signify that the user instruction manual/booklet must be read.
 P007	**No access for people with active implanted cardiac devices:** To prohibit people with active implanted cardiac devices from entering a designated area.

EN ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements

Symbol/number	Name: Definition
 5.1.1	**Manufacturer:** indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
 5.1.2	**Date of manufacture:** indicates the date when the medical device was manufactured.
 5.1.4	**Use-by date:** Indicates the date after which the medical device is not to be used.
 5.1.5	**Batch code:** indicates the manufacturer's batch code so that the batch or lot can be identified.
 5.1.6	**Catalog number:** indicates the manufacturer's catalog number so that the medical device can be identified.
 5.1.7	**Serial number:** Indicates the manufacturer's serial number so that a specific medical device can be identified.
 5.2.7	**Non-sterile:** Indicates a medical device that has not been subjected to a sterilization process.
 5.3.1	**Fragile, handle with care:** Indicates a medical device that can be broken or damaged if not handled carefully.
 5.3.2	**Keep away from sunlight:** indicates a medical device that needs protection from light sources.
 5.3.4	**Keep dry:** indicates a medical device that needs to be protected from moisture.
 5.3.7	**Temperature limit:** indicates the temperature limits to which the medical device can be safely exposed.
 5.3.8	**Humidity limitation:** Indicates the range of humidity to which the medical device can be safely exposed.
 5.3.9	**Atmospheric pressure limitation:** Indicates the range of atmospheric pressure to which the medical device can be safely exposed.

Symbol/number	Name: Definition
 5.4.2	**Do not re-use:** Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.
 5.4.3	**Consult instructions for use:** indicates the need for the use to consult the instructions for use.
 5.4.5	**Caution:** Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

IEC 60417 Graphical symbols for use on equipment

Symbol	Name: Definition
 0623	**This way up:** To indicate correct upright position of the transport package.
 0630	**Stacking limit by mass:** To indicate that the items shall not be vertically stacked beyond the specified number, either because of the nature of the transport packaging or because of the nature of the items themselves.
 2403	**Stacking limit by number:** To indicate that the items shall not be vertically stacked beyond the specified number, either because of the nature of the transport packaging or because of the nature of the items themselves.
 5009	**Stand-by:** To identify the switch position by means of which part of the equipment is switched on in order to bring it into the stand-by condition, and to identify the control to shift to or to indicate the state of low power consumption. Each of different states of power consumption may be indicted using a corresponding color.
 5016	**Fuse:** To identify fuse boxes or their location.
 5017	**Earth; ground:** To identify an earth (ground) terminal in cases where neither the symbol 5018 nor 5010 is explicitly required.
 5019	**Protective earth; protective ground:** To identify any terminal that is intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode.
 5021	**Equipotentiality:** To identify the terminals that, when connected together, bring the various parts of an equipment or of a system to the same potential, not necessarily being the earth (ground) potential, e.g. for local bonding.
 5032	**Alternating current:** To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.
 5134	**Electrostatic sensitive devices:** To indicate packages containing electrostatic sensitive devices, or to identify a device or a connector that has not been tested for immunity to electrostatic discharge.
 5140	**Non-ionizing electromagnetic radiation:** To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.
 5333	**Type BF applied part:** To identify a type BF applied part complying with IEC 60601-1.

Product-Specific Symbols

Symbol	Name: Definition
QTY	**Quantity:** Indicates the number of medical devices in the packaging.
	Note symbol: Used to supplement or clarify information.
GTIN	Global Trade Item Number.

81 FR 38911 FDA Final rule for the use of symbols in labeling

Symbol	Name: Definition
Rx Only	**Caution:** federal law (USA) restricts this device to sale by or on the order of a physician.

Directive 2012/19/EU on waste electrical and electronic equipment (WEEE)

Symbol	Name: Definition
	Indicates that the product must be collected separately and must not be disposed of as unsorted municipal waste.

ASTM F2503-08 Standard practice for marking medical devices and other items for safety in the MR environment

Symbol	Name: Definition
	MR Unsafe: Indicates a product that is known to pose hazards in all MRI environments.

Regulatory marks and logos

Symbol	Definition
CE	Conformity with Annex I of Medical Device Directive 93/42/EEC for Class I.
CE 0197	Conformity with Annex I of Medical Device Directive 93/42/EEC for Class Is, Im, IIa, IIb and III.
	CSA certified for Canada and USA.

2.1. General Safety Information

WARNING

- Potential malfunction. Only use the system if the surgery also can be performed conventionally. Otherwise, a second equivalent product should be available.
- During therapeutic use, it is necessary to ensure visual observation of the systemic effects.
- Intra-operative live images processed by the system may be displayed with a delay. During applications that require realtime-critical imaging, a second monitor must be used. This must be directly connected to the realtime-critical image source.
- Always inspect the product and all system components for damage before each use. Do not use the product if damage is apparent; contact Stryker.
- Do not disassemble, modify, service, or repair this product without the authorization of the manufacturer. Failure to comply may result in substandard performance and/or void the warranty. Contact Stryker for service.
- Ensure regular installation of software updates.
- Do not bend or kink cables, or use cables that are damaged. Position measurements from a system with damaged tool cables may result in possible personal injury.
- Do not use the system in atmospheres with potential for explosion. The system is not protected against explosion.
- Do not block the ventilation slots on the product's bottom and backside.
- Position the product outside the reach of the patient.
- Do not use the device in the environment of a magnetic resonance imaging (MRI) scanner.
- In case of emergency, shut down the product immediately and remove it from patient or staff. Then arrange for the necessary check-ups and repairs conducted by qualified service staff.
- Do not use the system during the discharge of a defibrillator. All navigated instruments must be removed from the patient and the operating area beforehand.
- The system should not be used by users who suffer from dyschromatopsia (color blindness); in particular, red-green impairment or red-green-blindness affect the ability to use the system.
- Navigated instruments are delivered in a non-sterile condition. Before the first use as well as before each following use, the instrument must be processed (cleaned, disinfected, and/or sterilized) according to a validated procedure.
- Only those accessories listed in the manual may be used in combination with the navigation system. When combining medical products, safety is only ensured if:
  - the combination is specified in the respective manuals as a safe combination, or
  - the intended use and the interface specifications of the combined medical products are suited for combination (compare IEC 60601-1).
- Using non-listed instruments and accessories (including cables) will lead to loss of the product conformity.
- The medical electrical devices used in combination must comply with the safety standard IEC 60601-1 and the standard for data handling devices IEC 60950, if applicable. When connecting additional devices to the signal in- and outputs, you are configuring a medical system and will be responsible for making sure that the system meets the requirements of the system standard IEC 60601-1.
- Do not expose or immerse the electrical components of the navigation system to liquids. Do not place liquids on or above the devices. Liquids or other objects penetrating into the device may result in equipment damage, produce a fire or shock hazard.
- Do not use mobile or other phones or portable radio frequency (RF) equipment in the vicinity of medical devices. Devices emitting electromagnetic radiation may interfere with operation of the product.
- Non-observance of the permitted environmental conditions may lead to a decalibration of the measuring system. Should this happen, deviations can occur while measuring.

These deviations can only be remedied with a new calibration by the manufacturer. See Chapter “Technical Specifications.”
- If the device or its accessories are used on a patient who suffers from a disease whose pathogens cannot be eliminated with conventional, standardized procedures, it must be disposed of or processed according to the requirements of the responsible public authority.
- Do not simultaneously touch the patient and any parts of the system—e.g. Electromagnetic Navigation Unit, cart, monitors—except the EM Tools. This may lead to dangerous electrical currents that may harm the patient or operator.
- When using a supporting system (e.g. cart), always connect and power all other devices within the system (e.g. Electromagnetic Navigation Unit, monitor) via the supporting system. Do not connect these other devices directly to wall sockets when using a supporting system.

2.2. Safety Measures for Electromagnetic Measuring Systems

WARNING

- Electromagnetic instruments are highly precise measuring instruments. Restrictions concerning lifetime and handling must be observed. Damaged and inaccurate instruments must be exchanged.
- Do not operate the Field Generator within 200 mm of an installed pacemaker. The magnetic field produced by the may interfere with the operation of the pacemaker. This interference may result in personal injury.
- Do not operate the Field Generator within 10 m of another Field Generator. To do so may contribute to inaccurate position measurement and possible personal injury.
- Do not drop the Field Generator or subject it to impact. Physical damage to the Field Generator may alter its calibration and contribute to inaccurate position measurement and possible personal injury.
- Do not place electromagnetic instruments directly on the Field Generator. Doing so may cause interferences which may produce inaccurate position measurements.
- Do not place the Field Generator Cable inside the measurement volume or wrap it around the Field Generator, as it may create a magnetic interference. This interference can contribute to inaccurate position measurements and possible personal injury.
- Do not place electromagnetic tool cables within 30 mm of the Field Generator Cable. If placed this close – particularly if the cables are parallel to each other – the tool cable may become subject to electromagnetic interference. This interference can contribute to inaccurate position measurements and possible personal injury.
- Do not coil the Field Generator Cable, as it produces enough electric current that a magnetic field will be created when the cable is placed in a circular formation. This magnetic field may disturb the Field Generator’s magnetic field, contributing to inaccurate position measurements and possible personal injury.
- Do not disconnect the Field Generator from the system while using the navigation. In tracking mode, this could result in sparks being generated, and possible personal injury.
- Do not navigate in an unvalidated environment, as it may contain elements that affect navigation functions. The system can be adversely affected by electromagnetic field disturbances from other objects in the room, the close proximity of metal, and the close proximity of another Field Generator. Failure to test for such disturbances will increase the possibility of inaccurate position measurement and possible personal injury.

2.3. Data Privacy Information

WARNING

Connecting the navigation unit to a network/data aggregate can put the patient, the operator, or third parties at risk. Your organization’s risk management should determine, analyze, evaluate, and control these risks to avoid potential damages (see especially ISO 80001-1). Regarding this product, it is necessary to pay special attention to risks regarding the privacy of patient image data and data integrity.

CAUTION

Prior to sending the device for maintenance, remove the data drive so that any private patient data is not shared with Stryker.

The user must adhere to the respective national requirements regarding protection of patient data. The navigation system may only be used by authorized personnel. We recommend protecting the system from unauthorized use by means of a password.

In public hospitals, it is necessary to inform the data protection commissioner about the system.

Due to data security, it is necessary to back up data regularly. Stryker does not assume liability for data loss.

2.4. User Qualifications Information

WARNING

The product is intended solely for use by medical professionals and may only be used by physicians with the corresponding qualifications and the necessary instruction.

Stryker does not assume liability for any diagnoses or interpretations established with the help of this product. The product's user is responsible for acquiring medical knowledge and for its diagnostic and therapeutic consequences.

To ensure the safe and efficient use of the product, the user must be instructed on how to use the product as authorized by the manufacturer and retailer. The medical product's operator must ensure that the user receives such instruction in accordance with the respective local laws, and that the instruction is refreshed at the prescribed intervals. Additionally, the instructions in all accompanying manuals must be respected.

During a surgical operation using the navigation system, the patient must be treated and observed with the usual medical care. This includes the follow-up to the treatment process, the monitoring of vital signs and the state of anesthesia, as well as the maintenance of sterile conditions if required for the operation.

Aside from your own medical skills and knowledge, the operational safety and utility of the product requires correct usage as well as regular cleaning and maintenance.

WARNING

The product may only be used for its intended purpose and in accordance with the following user manual, as well as all current versions of the “Stryker ENT Navigation System” manual.
The user manual is part of the product and must therefore be accessible to personnel at all times. It must be handed over to subsequent owners or users.

3.1. Indications for Use

The Stryker ENT Navigation System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure in the field of ENT surgery, such as the paranasal sinuses, mastoid anatomy, can be identified relative to a CT or MR based model of the anatomy.

Example procedures include, but are not limited to the following ENT procedures:

- Transphenoidal access procedures;
- Intranasal procedures;
- Sinus procedures, such as Maxillary antrostomies, Ethmoidectomies, Sphenoidotomies/ Sphenoid explorations, Turbinate resections, and Frontal sinusotomies;
- ENT related anterior skull based procedures.

3.2. Contraindications

None known.

4.1. For Use With

WARNING

Use only Stryker-approved components, unless otherwise specified.

Article Name	REF
8000-010-003	Electromagnetic Navigation Unit
8000-010-004	Field Generator
8000-010-005	Field Generator Mounting Arm
8000-010-006	Headrest for Field Generator
8000-020-001	Scopis ENT Software
8000-040-001	Patient Tracker Electromagnetic
8000-040-002	Patient Tracker Electromagnetic -10 uses
8000-100-001	Patient Tracker Tabs
8000-050-001	Precision Pointer Electromagnetic
8000-050-002	Pointer Electromagnetic
8000-050-003	Registration Pointer Electromagnetic
8000-050-005	Suction Tube Frazier Electromagnetic
8000-050-006	Suction Tube Eicken Electromagnetic
8000-050-011	Navigation Tool Extension Cable
8000-060-006	Universal Tracker Electromagnetic
8000-060-030	Instrument Clip Electromagnetic, 4 mm
8000-060-010	Instrument Clamp, Forceps
8000-060-011	Instrument Clamp, 2-6 mm
8000-060-012	Instrument Clamp, 6-10 mm
8000-060-013	Instrument Clamp, 10-16 mm

4.2. Planning for Application

The application of the navigation system must be planned before the surgery, as patient image data suitable for navigation are needed.

Defining the Operating Field

Consider the intended uses of the products included in the system. Many products are only intended for use in selected operating fields. The intended uses can be found in the respective product manuals.

Choosing a Patient Tracker and Positioning

Patient trackers serve to reference the patients. They are therefore firmly attached to the patient near the operating area, which enables the localization of the patient. The available Patient Trackers are described in "Preparing Navigated Instruments."

Choosing a Registration Type

Before every application, conduct an image-to-patient registration to determine the position of the patient and to match the patient image data.

The software offers several types of image-to-patient registration:

Landmark	At least three clearly perceptible landmarks are marked in the patient image data and subsequently touched precisely with a pointer on the patient. This type of registration is especially suitable in the presence of artificial landmarks (e.g. bone screws, fiducials) in the operating area and in the patient image data.
Surface	At least three clearly perceptible landmarks are marked in the patient image data and subsequently touched with the precision pointer on the patient. Afterwards the pointer must be moved over the patient's surface to collect more points for the matching. This type of registration is especially suitable when registration only takes place on the skin. For surface registration at least 40 cm^2 of skin near the situs are necessary.
Enhanced Surface	Here a specific path is generated in the patient image data that must be initially moved along on the patient's surface. Afterwards the pointer must be moved over the patient's surface to collect more points for the matching. This type of registration is especially suitable for sinus surgery. For enhanced surface registration at least 30 cm^2 of skin left and right of the nose, as well as the nose itself, are necessary.

Ordering Radiological Image Data

Note the following points, and follow the detailed instructions for acquiring suitable images for navigation in "Recording Radiological Image Data."

- Depending on registration type, it might be necessary to plan and set bone screws around the operating field before ordering radiological image data.
- Existing image data may be used if the patient anatomy has stayed the same. The geometry can significantly change and recording of new images is necessary.
- Image resolution should be set to a slice thickness of less than 1 mm and pixel resolution of 0.5 mm or finer for optimal navigation results. Also consider that the areas needed for image-to-patient registration are included in the scan.
- All common DICOM modalities such as DVT, CT, or MRI can be used.

4.3. Instructions for Functional Endoscopic Sinus Surgery (FESS)

WARNING

The following recommendations are based on clinical experience with the navigation system. However, it is the physician's responsibility to determine the specifics of each operation and to decide in each case for the use of a navigation system.

For use of the navigation system in frontal sinus surgery and functional endoscopic sinus surgery, the following procedure has proven most effective:

1. Request a thin slice CT scan of the operating field. Ensure that the patient's face and nose are completely included. The back of the head, slices above the forehead and below the subnasale are not necessary. Recommended slice thickness < 1 mm, pixel resolution 0.8 mm or finer.

2. Use the enhanced surface registration, which can be used without additional planning.

3. Use the Patient Tracker Electromagnetic on the patient's forehead. Keep sufficient area on the patient's face free of sterile cover. Leave an uncovered area of 0.5 cm vertically between subnasale and nasale and also horizontally to the outer corner of the eyes (Figure 1).

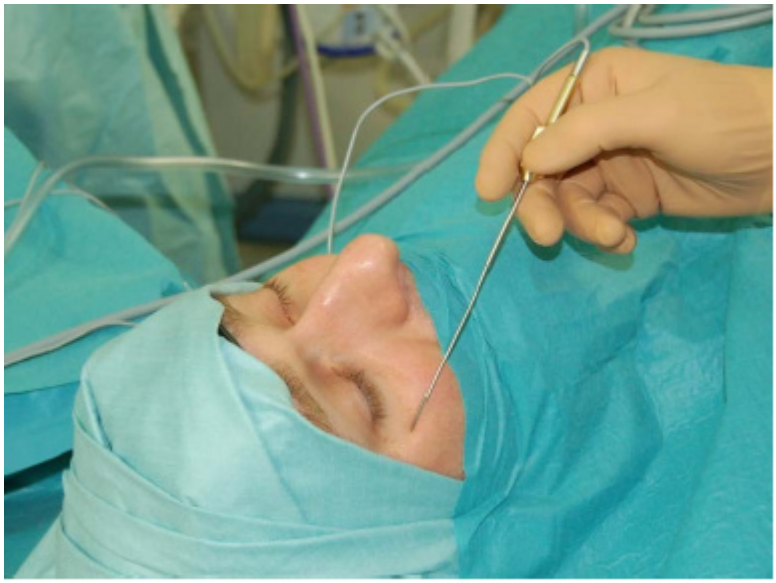


Figure 1 – Recommended Position and Sterile Cover for FESS

4.4. Instructions for Lateral Skull Surgery

WARNING

The following recommendations are based on clinical experience with the navigation system. However, it is the physician's responsibility to determine the specifics of each operation and to decide in each concrete case for the use of a navigation system.

For use of the navigation system in lateral skull surgery, the following procedure has proven most effective:

Landmark registration with 4-5 bone screws is found to be most effective for lateral skull surgery (Figure 2). Usually these screws are placed at the end of a preceding surgery when entry to the lateral skull is exposed. If accuracy is limited to 1 mm, but a surface registration can be performed, if the subnasale, nasion, and canthus are selected as starting points to the operation area. While registering the surface consider that bone structures around the operating area will be included in the registration.

1. Request a thin slice CT scan and ensure that all bone screws or the respective half of the patient's face are completely included. Choose a resolution in which the relevant structures are well visible. In case the data is too large, request the data to be trimmed accordingly.

2. Use the Patient Tracker Electromagnetic and place it on the opposite side of the situs from yourself. If you are being assisted by a second surgeon, the Patient Tracker can be moved correspondingly to the right or to the left. A distance of 7.5 cm is found to be most effective (Figure 3).

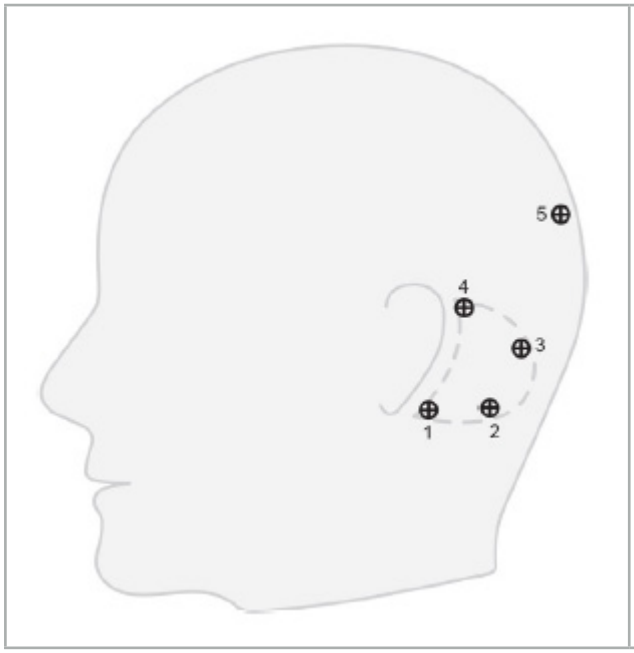


Figure 2 – Recommended Bone Screw Placement for Lateral Skull Surgery

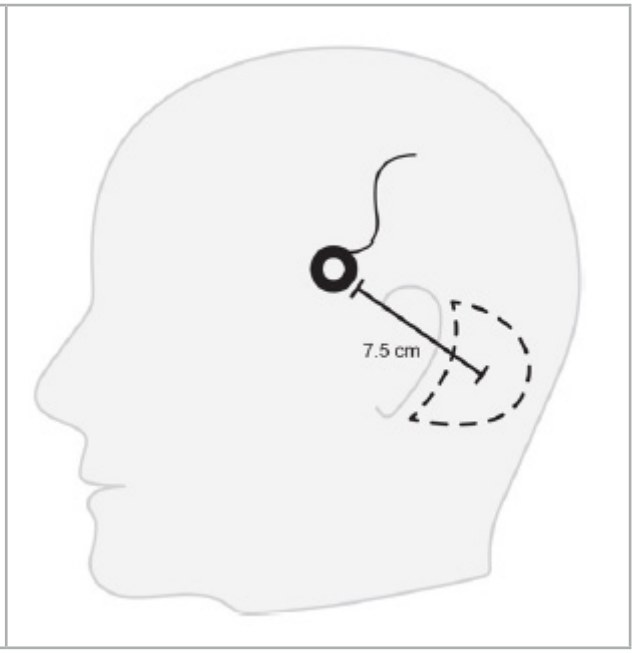


Figure 3 – Positioning of the Patient Tracker Electromagnetic for Lateral Skull Surgery

5. Recording Radiological Image Data

Before acquiring radiological images for your patient, consider the following aspects:

- The radiological volume image data must be compatible with the desired type of patient registration. That means it may be necessary to attach bone screws before the imaging or ensure that certain parts of the face or patient anatomy are visible. See Chapter “Selecting the Patient Registration Type.”
- Navigation is only possible from 3D volume image data that conforms to particular requirements regarding resolution, slice distance/gap, and export format. Refer to the following chapter for specifics.
- Despite support from the standardized DICOM 3.0 interface, problems may occur with the data exchange or the loading of data. Refer to the following chapter.

5.1. Before First Use

WARNING

No radiology images should be recorded from patients until it is verified that the image can be imported to the navigation software.

The following pages should be forwarded on to your radiology department. A test dataset, provided by the radiology department, should be used to confirm that the exported image data of the device is compatible with the navigation software.

5.2. Systems Settings for Computer Tomography (CT)

WARNING

Patient image data with a slice distance or pixel size of more than 1 mm may result in reduced system accuracy. Verify the accuracy by checking the position of well-known anatomical positions.

Use a tilting angle of zero degrees for the gantry while using computer tomography. The dataset must equate a full volume. The volume must not contain gaps, especially not gaps between the sliced images.

Limit the field of view as much as possible.

Make sure that the relevant patient area is fully recorded.

The navigation software works successfully with the following settings:

- Patient positioning: axial to the occlusion plane
- Matrix size: 512 x 512 pixel
- Slice distance/thickness: < 1 mm (≤ 0.5 mm recommended)
- Section size: 150 mm to 180 mm
- Voxel size: 1 mm x 150 mm/512 x 150 mm/512 = 1 mm x 0.3 mm x 0.3 mm
- The patient should be scanned axially

Select the energy of the X-rays (kV) so that a good resolution in the bone area is achieved. Soft tissue windows should not be used.

Make sure that the alignment of the patient corresponds to the settings of the device.

5.3. Radiology Profile for Magnetic Resonance Imaging (MRI)

The navigation software works successfully with the following settings:

- Patient positioning: axial to the occlusion plane
- Transversal (axial) acquisition plane
- Acquisition of 3D volume data (in contrast to 2D multiple slice images)
- Matrix size: at least 256 x 256 pixel – 512 x 512 pixel recommended
- Slice distance: < 1.5 mm (0.8 mm or 0.5 mm recommended)

5.4. Preparing and Scanning the Patient

WARNING

– Make sure that the patient does not move during recording. If the patient moves, the recording is useless and the imaging must be repeated, potentially exposing the patient to increased radiation.
– Recording one area in several partial volumes does not produce usable data.

To avoid artifacts in the acquired images, all prosthetics containing metal (e.g. clasp denture) should be removed if feasible.

Note that certain patient registration types can only be conducted if bone screws are placed near the operating area. These screws or specific areas of the face or of the patient's anatomy must be visible from within the image data. See Chapter "Selecting the Patient Registration Type" for specifics.

5.5. Eye Protection

If using a lens protection, the registration on the patient surface may not be possible, or may not be detected correctly by the software. The following eye protection has proven to be especially suited for a combined use with the navigation system:

Product Name	AttenuRad CT Eye Shield
Manufacturer	F&L Medical Products
Address	1129 Industrial Park Road Vandergrift, PA 15690
Phone	724-845-7028
Fax	724-845-5439

5.6. Saving Data

WARNING

– When saving the dataset, make sure to use the correct patient name and series ID.
– Make sure that the patient orientation is correctly adjusted and saved when creating DICOM data.

The navigation system supports both uncompressed and compressed (JPEG, JPEG 2000) DICOM data, but the manufacturer recommends using uncompressed data for optimal image quality.

Do not save secondary reconstructions or other image data on the same storage medium. If multiple datasets are created, they should be saved under different names (e.g. “Doe, John 3”). Each dataset should preferably be stored in a separate file or must be stored under a separate series ID on a PACS server.

5.7. Transmitting Image Data

Image data for planning and treatment should be provided by your radiologist in DICOM format on a USB drive or other data medium. Alternatively, the system can be configured to communicate directly with your organization’s DICOM image data servers.

When exporting onto a data storage device, the following DICOM tags must be saved with the image data, which happens automatically with typical radiological systems:

Tag ID	Tag Name
0010,0010	PatientName
0020,0010	StudyID
0020,0011	SeriesNumber
0020,0032	ImagePositionPatient
0020,0037	ImageOrientationPatient
0028,0010	Rows
0028,0011	Columns
0028,0030	PixelSpacing
0028,0100	BitsAllocated
0028,0101	BitsStored
0028,0102	HighBit
0028,0103	PixelRepresentation

5.8. Character Set Support

The navigation software supports the following character sets:

Character Set Description	DICOM Defined Terms
Latin alphabet No. 1	ISO_IR 6, ISO 2022 IR 6, ISO_IR 100, ISO 2022 IR 100
Latin alphabet No. 2	ISO_IR 101, ISO 2022 IR 101
Latin alphabet No. 3	ISO_IR 109, ISO 2022 IR 109
Latin alphabet No. 4	ISO_IR 110, ISO 2022 IR 110
Greek	ISO_IR 126, ISO 2022 IR 126
Arabic	ISO_IR 127, ISO 2022 IR 127
Hebrew	ISO_IR 138, ISO 2022 IR 138
Cyrillic	ISO_IR 144, ISO 2022 IR 144

Character Set Description	DICOM Defined Terms
Turkish	ISO_IR 148, ISO 2022 IR 148
Japanese	ISO_IR 13, ISO 2022 IR 13, ISO 2022 IR 87, ISO 2022 IR 159
Thai	ISO_IR 166, ISO 2022 IR 166
Chinese	ISO 2022 IR 58, GB18030, GB2312, GBK
Korean	ISO_IR 149, ISO 2022 IR 149
UTF-8	ISO_IR 192

For the list of character sets supported by DICOM Standard 2011, refer to DICOM 2011 C.12.1.1.2 Specific Character Set.

6. Preparing for a Navigated Surgery

Before conducting navigated surgery, the patient image data must be prepared. To this end, the patient image data must be transferred directly to the navigation system, where the data can be worked on in planning mode.

6.1. Switching On the Navigation System

WARNING

Only connect this device to a mains supply that has a protective earth (PE) connection. Before connecting the power cable to a power outlet, make sure that the correct voltage (100–240 V~/50–60 Hz) is provided, and that the power cables are clean, dry, and undamaged. For the proper installation of the electrical device, consult the respective installation manual.

Switch on the navigation unit by pressing the power button. When switched on, the power button glows green. Then switch on the medical devices used in combination according to their respective manuals.

6.2. Starting the Navigation Software

After switching on the devices, wait until your operating system is ready. Start the software via the shortcut on the Windows desktop. After starting the software, a loading screen appears for a short time. Then the navigation software application screen appears.

6.3. Working in Planning Mode

After starting the software, the Application window appears (Figure 4).

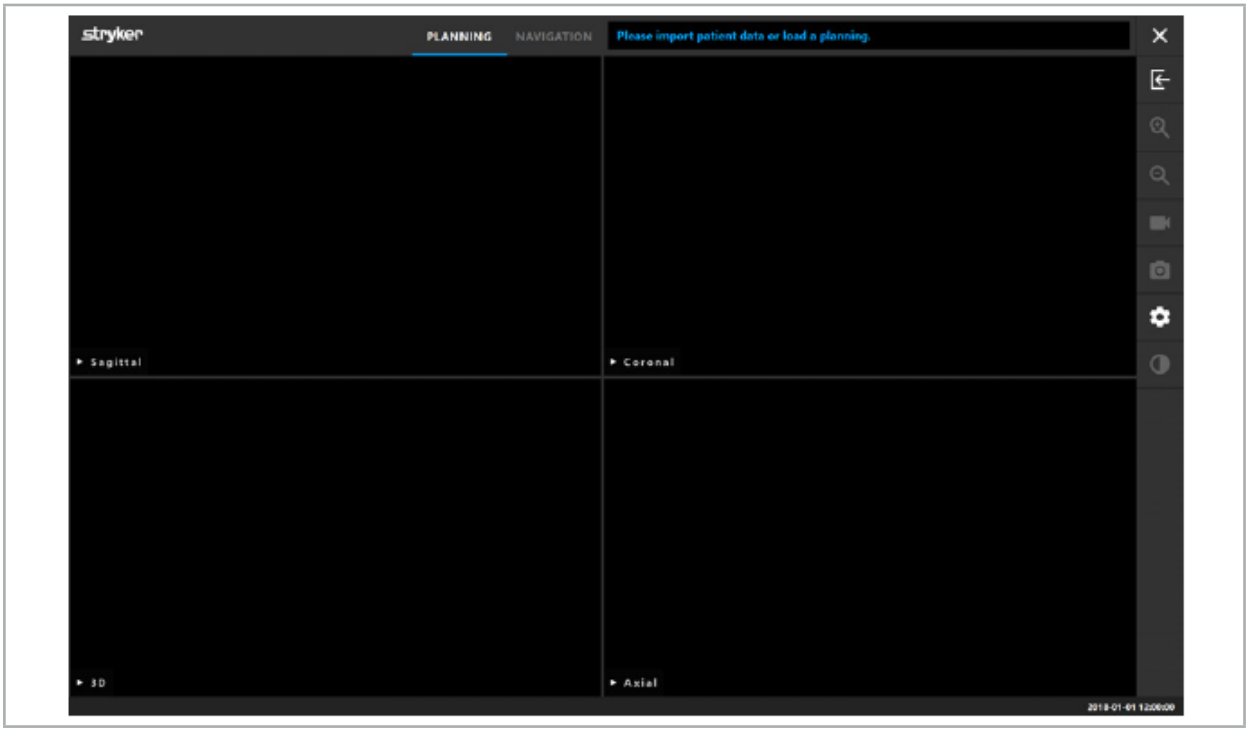


Figure 4 – Application Window

6.4. Basic Requirements for Patient Image Data

- Modality: CT, DVT, MRI, PET, SPECT
- Format: DICOM 3.0
- Storage Media: USB Drive, PACS (Server), DVD, or CD

6.5. Loading Patient Image Data

WARNING

Changes to the network data aggregate can create new risks and should therefore be conducted in a controlled manner. At the very least, attention should be paid to changes to the network configuration and topology, adding and removing additional products, updates and upgrades of systems in the data aggregate.

Press the Loading Patient Data button (Figure 5). The Data Import dialog box appears. On the left side of the dialog, choose a data source for the import. The Plannings button contains all the plannings created and saved with the software.

The USB symbol allows access to data on removable storage devices.

Use the Browse button to choose the folder from which to import the data. Additional folders or DICOM data servers can be chosen depending on configuration.

Should a needed data source not show up, contact Stryker.

If the network connection or the image data server fails or is incorrectly configured, the patient image data may become inaccessible. Image data should be uploaded to the navigation system well before an operation so that you can import the data by other means if necessary.

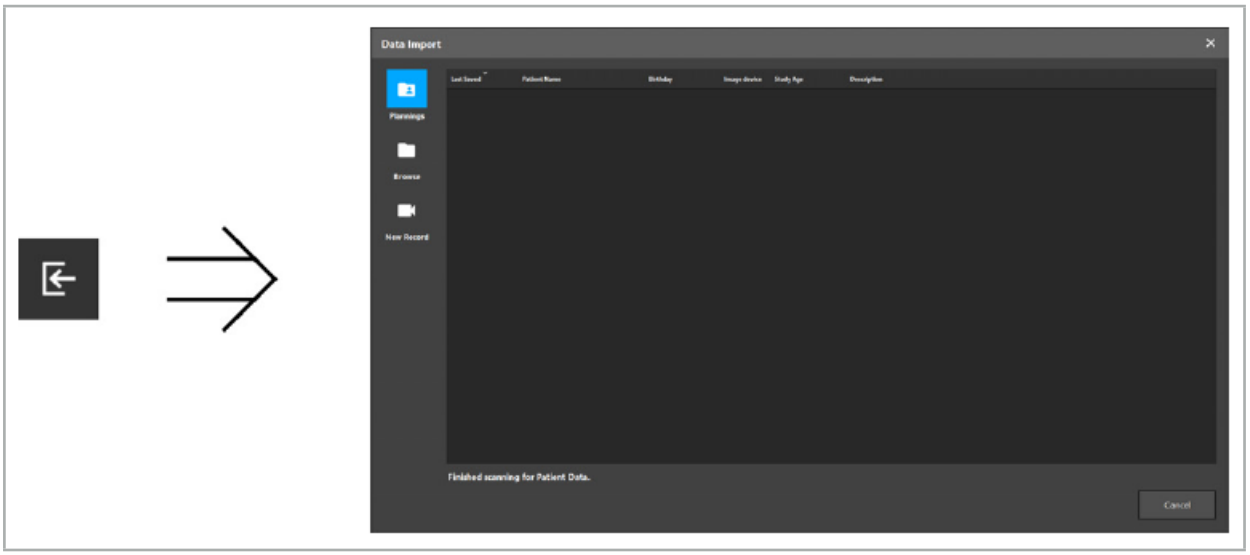


Figure 5 – Data Import

6.5.1. Loading from Disk Drives

After scanning a local data source directory for DICOM compatible data, a selection list of the available patient image data appears. If patient image data was already exported from a planning station, it can be loaded as well. See Chapter “Exporting the Planning.” Choose the patient from the list and press the Import button.

6.5.2. Segmentation of Patient Image Data

After importing the patient image data, the Data Import dialog box appears.

The dialog shows a 3D model of the patient and a slider to the right. Using the slider, set a threshold which defines the boundary between patient and air (Figure 6). Adjust the slider so that the 3D model corresponds as well as possible to the patient, and artifacts and gaps in the patient surface are minimized. For CT data, a dividing line between image and space is clearly defined, and a white line is drawn along the threshold to aid the user. When the threshold is defined correctly, use further functions of the dialog (explained in the following), or complete the step by clicking Ok.

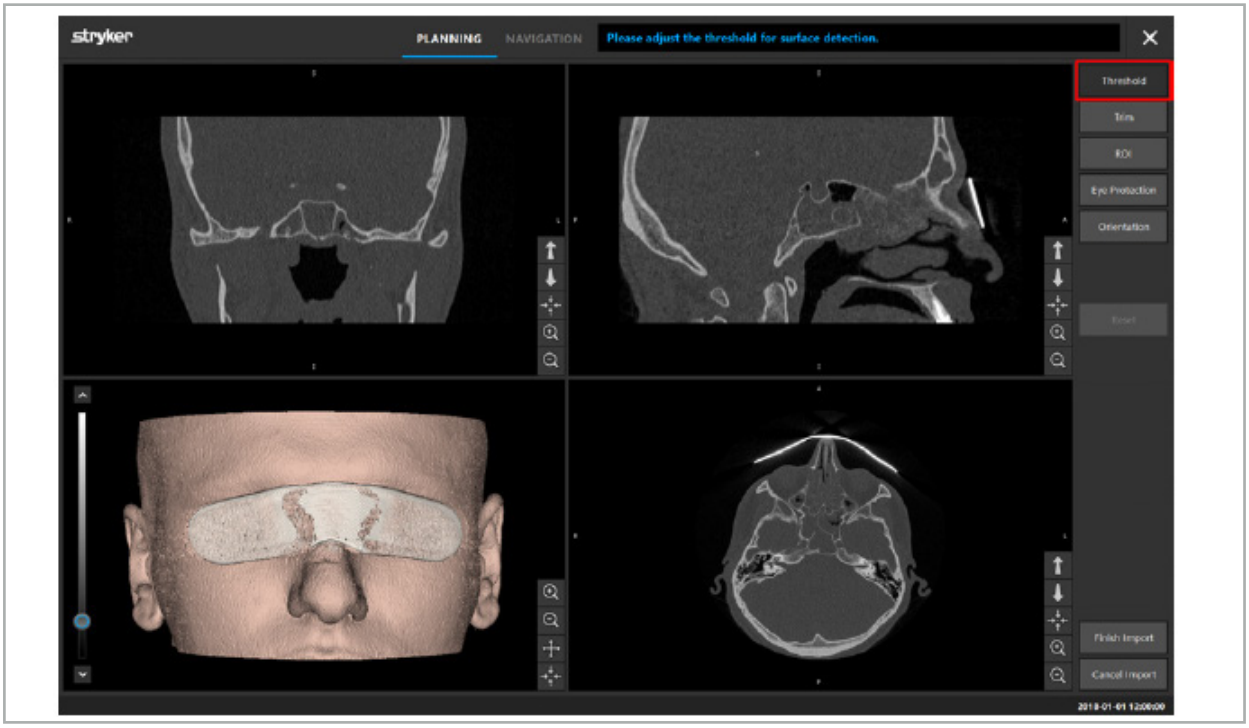


Figure 6 – Choosing the Surface Threshold Value

The head of the patient should be shown facing forward. If not, correct the orientation by pressing the Adjust Orientation button (Figure 7).

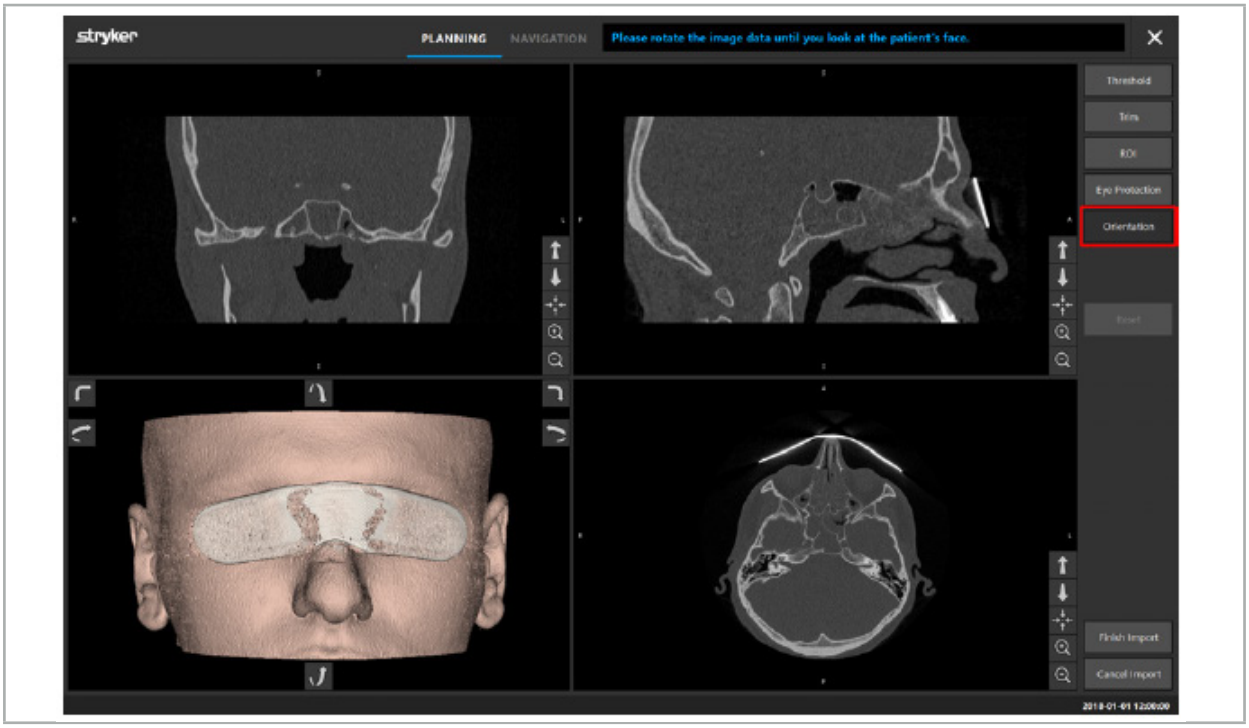


Figure 7 – Adjusting Patient Orientation

If the patient was wearing an eye protection shield during the image scan, this protection can be removed from the 3D model by pressing the Remove Eye Protection button (Figure 8). A dialog to remove the eye protection appears. Adjust the desired radius for the correction with the arrow keys. Then press Remove to remove the eye protection. The Reset button allows the resetting of the original 3D model, including the eye protection.

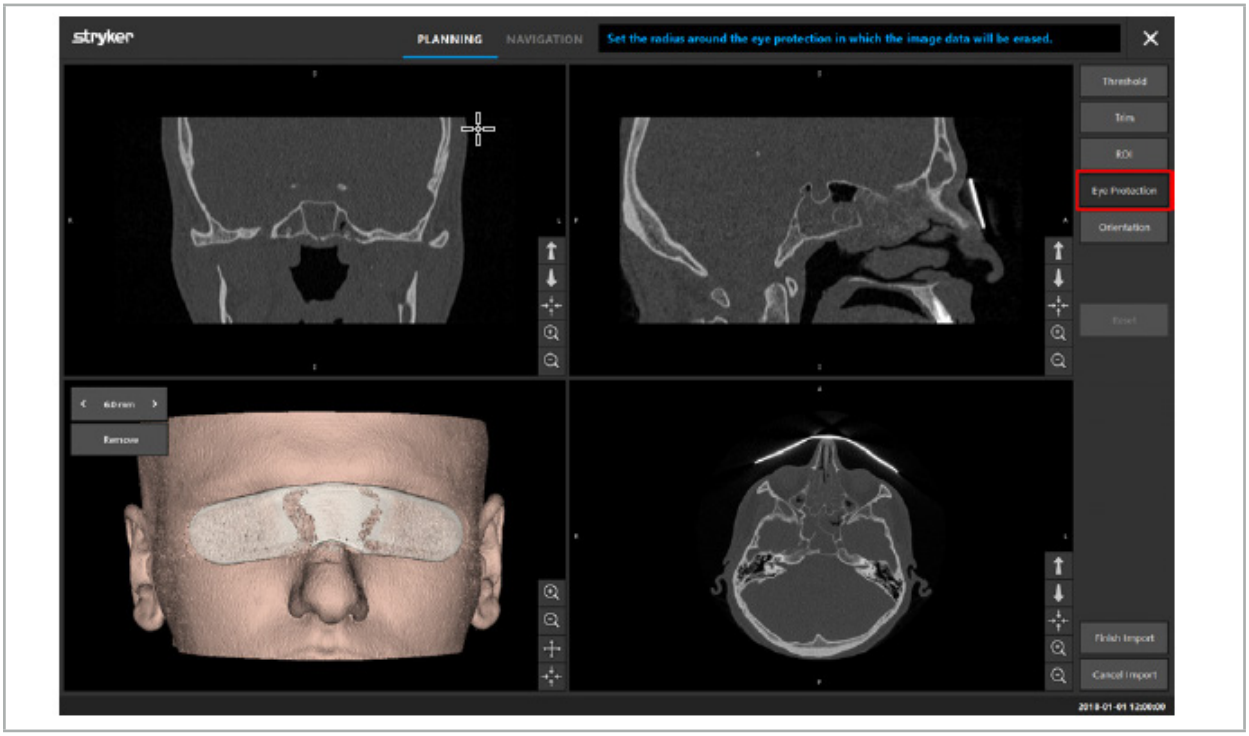


Figure 8 – Removing Eye Protection

WARNING

When removing the X-ray protection shield, it is possible that skin surface particles could also be removed, influencing the patient registration negatively. After the registration, check

the accuracy carefully. Should the deviations be too large, the use of the landmark registration is recommended.

Make sure that the 3D model surface does not contain any gaps or artifacts.

When removing the X-ray protection shield, no particles should remain in front of the eyes.

If only a section of the image data is relevant for the procedure, or if a sizable amount of the image data consists of empty space, you can remove unnecessary parts of the volume. For this, click Trim Volume (Figure 9). The dialog now displays the 3D rendering of the image, as well as three slice renderings. A frame is drawn around the volume, enclosing the area to be used after the import. Decrease this area by clicking and dragging one of the corners of the frame. The 3D visualization then shows only the part of the volume that will be available once the import is completed.

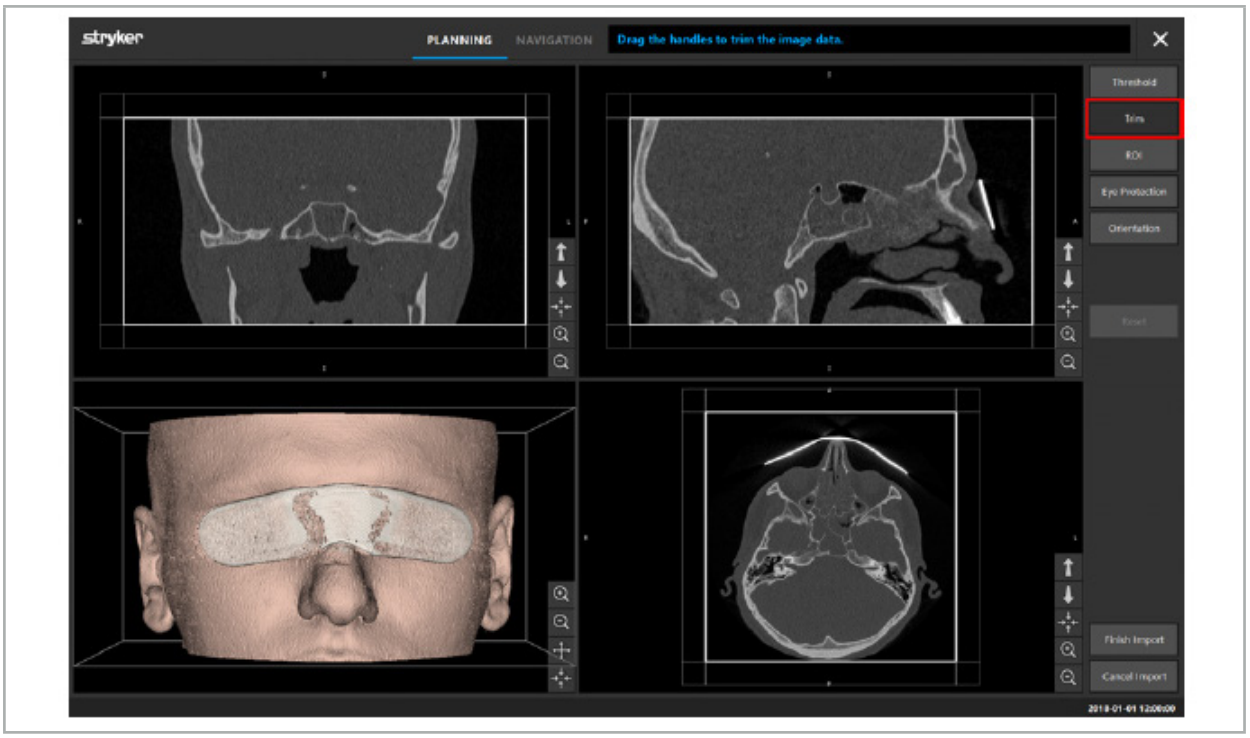


Figure 9 – Trimming Volume

If the image data is very large, the voxel resolution of the image may need to be decreased in order to load it into the computer's memory. The Data Import dialog opens in the trim volume mode and displays a warning message. By removing parts of the volume as described above, the size of the image can be decreased and thus ensure that it imports in its original voxel resolution. It is also possible to continue with the reduced resolution. After loading the image data, it is possible to start with the planning. See Chapter "Selecting the Patient Registration Type."

Depending on the size of the datasets, it can take several minutes to import and load image and planning data.

Only image data in DICOM format can be selected. Should problems occur while loading DICOM datasets, contact the radiologist who carried out the recording, or contact Stryker. For an overview of which DICOM tags must be saved within the export data, see Chapter "Transmitting Image Data."

6.5.3. Loading of Already-Imported Patient Image Data

The PLANNING tab lists already-imported patient image data, including planning information. The information displayed includes patient data and image data, as well as the date of the planning creation and an optional description of the planning.

Choose the desired planning and press the Load button. The Delete Planning button gives you the option to remove old planning information from the list. You can also select Export the Planning. See Chapter “Exporting the Planning.”

After loading the patient image data with the planning data, you can proceed with the planning. To do so, read the following chapter.

If a complete planning was already conducted for the navigation, the NAVIGATION tab allows you to switch to navigation mode and start with the operation.

6.6. Displaying the Loaded Patient Image Data

After loading, the patient image data is shown as 2D slice images (axial, sagittal, and coronal) and as a 3D model (Figure 10). The status bar shows the patient name, date of birth, and the dataset’s session ID. This information is entered by the radiological staff while recording radiological image data and is used to identify the dataset.

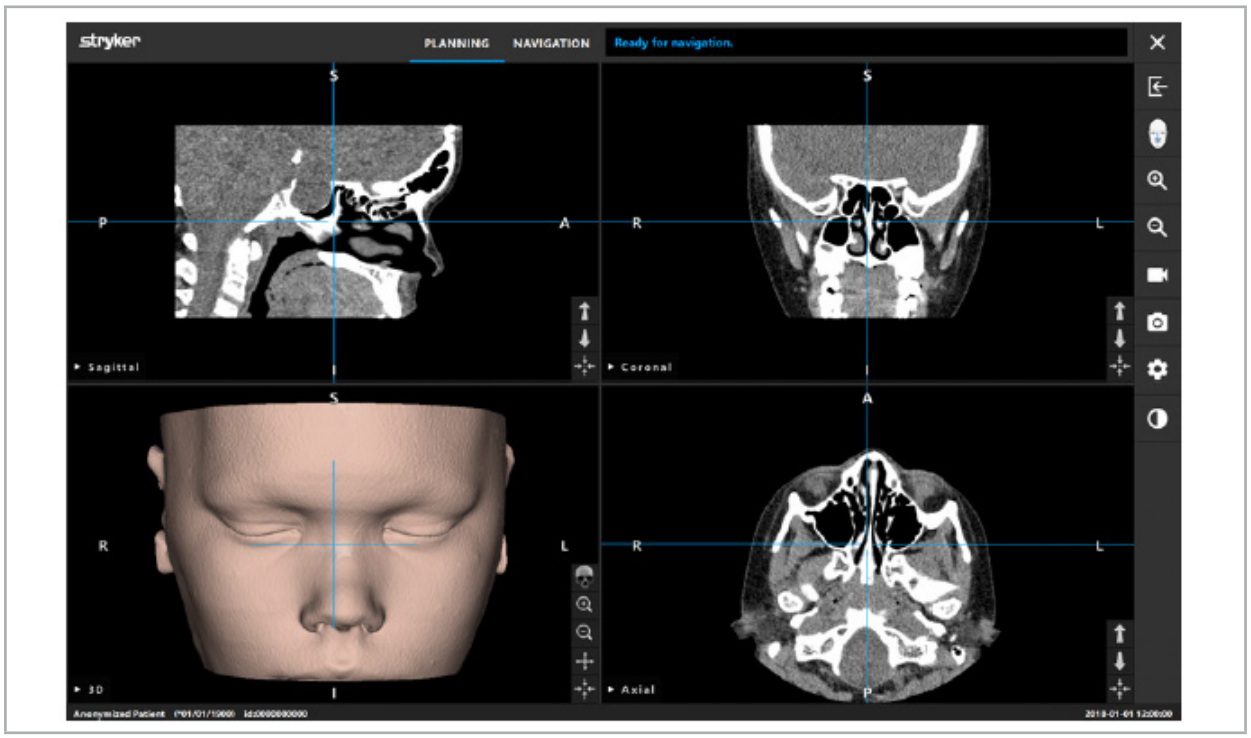


Figure 10 – Patient Image Data After Loading

WARNING

Check all patient image data carefully for accuracy, and make sure that they coincide with the data of the patient that is to be treated.

If you have removed the X-ray protection shield while segmenting the image data, the shield no longer appears in the depiction of the 3D model. The 2D slice images remain unchanged.

6.7. Planning Views

By default, the navigation software shows four windows with different views of the patient image data. These show the 3D model and three 2D cross-section images (axial, coronal, and sagittal).

The following sections explain the respective views as well as functions to adapt these.

6.7.1. Cross-Section Image Views: Axial, Coronal, and Sagittal

Each respective view – axial, coronal, or sagittal – shows one of the recorded cross-section images. The Arrow buttons (Figure 11) are used to move forward and backward between the cross-section images in the respective views.

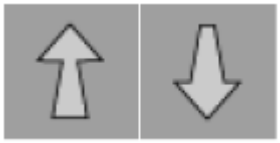


Figure 11 – Arrow Buttons

Figure 12 – Centering Button

Aside from using the Arrow buttons, you can also select slices by shifting the red intersection lines. Click the horizontal or vertical line or their intersection, and drag until the relevant slice is shown.

The Centering button (Figure 12) centers the display of the cross-section on the crossing point of the red intersection lines, so that these are in the middle of the display.

WARNING

If false information is entered regarding the patient position during the imaging process, the labeling of L (left) and R (right) will not be correct in the axial view. Ask your radiologist to save the patient image data again in the correct orientation.

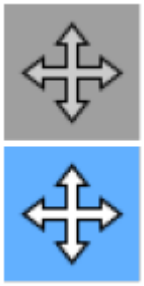
6.7.2. Moving the Patient Image Data

You can move image data horizontally and vertically in the radiological image data views – axial, coronal, and sagittal. Thus, a relevant detail can be moved into the middle of the display, especially when zoomed in.

To move patient image data, click a free space in the display and drag until the relevant detail is ideally positioned. During the process, the mouse cursor is shown as a closed hand. Alternatively, use the touchscreen to move image data.

6.7.3. 3D View

In this view, a 3D model of the patient is displayed. Click in the view and move the button at the same time to rotate the 3D model. Alternatively, use the touchscreen to rotate the model. Adapt the view of the 3D model with the following buttons:

	Zoom in and out of the 3D model by clicking the magnifier buttons. Alternatively, use the touchscreen to zoom in and out.
	Click the Move Model button to move the 3D model vertically and horizontally. The active function is shown by a white highlighted symbol. Click in the view and drag horizontally or vertically until the 3D model reaches the desired position. Deactivate the function by pressing the button again. If this function is deactivated, the 3D model can be rotated. In this state, the background of the button is darkened. Click in the view and drag down in order to rotate the 3D model. Deactivate this function by pressing the button again. Alternatively, use the touchscreen to move the model.
	The Reset button resets all changes related to magnifying, moving, or rotating the model. This function can be activated while in move model or rotate model mode. Alternatively, use the touchscreen to reset.

6.7.4. Inline and Probe View

Inline and Probe views (Figure 13) are based on the instrument orientation: The displayed cross-sections are updated according to the spatial direction of the pointer instrument.

- Inline View 1 and Inline View 2 offer two orthogonal cross-sections along the instrument axis which runs through the centers of the marker spheres and the pointer tip.
- Probe View displays a cross-section through the pointer tip.

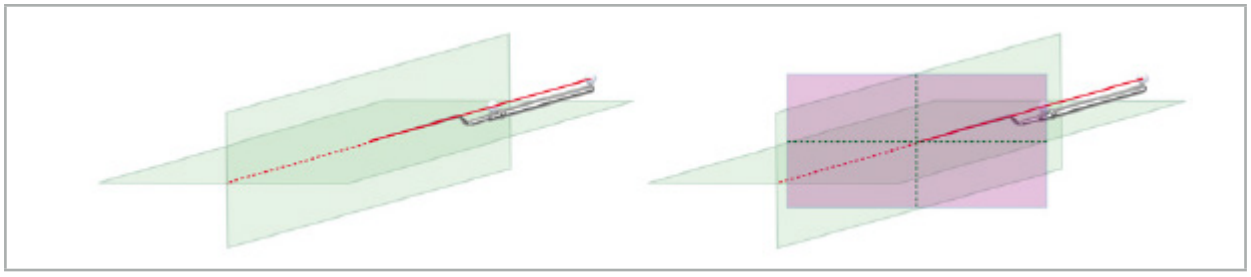


Figure 13 – Inline Views Along the View Axis of the Pointer Instrument (Green, Left), and Probe View as the Cross-Section Through the Pointer Tip (Magenta, Right)

6.7.5. Changing a View Type

Each of the four sub-windows allows for the view type to be switched. To do so, click the red arrow buttons next to the description of the respective view. A list of views is displayed (Figure 14). Choose the view you want to be shown in the window.

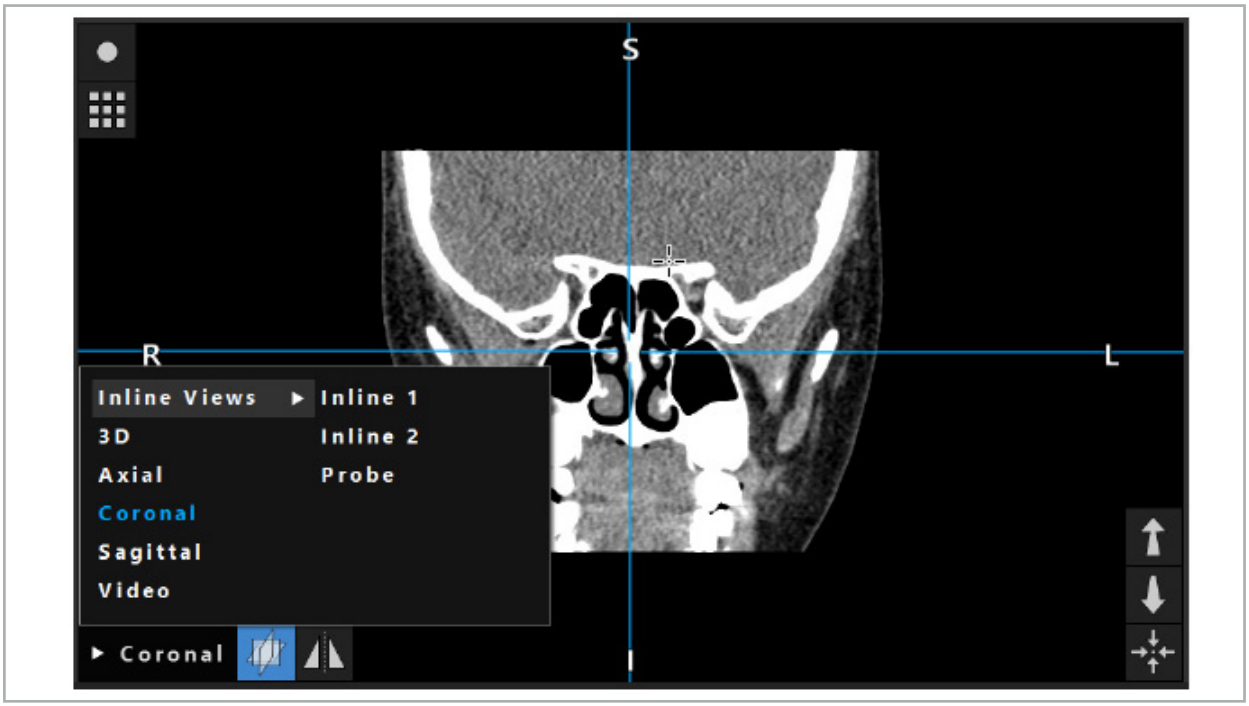


Figure 14 – Changing a View

6.7.6. Adjusting Contrast and Brightness for Patient Image Data and Video

Contrast and brightness of the radiological patient image data (axial, sagittal, and coronal) are adjusted via a slider (Figure 15). The slider is located on the right side of the navigation bar and is activated via the Contrast button. (In software version 1.3.0 or older, the slider is always activated.)

	Activate the slide control for adjusting the contrast via the contrast button.	

The slider has three control elements: the upper element adjusts the brightness, the middle element adjusts the centers of the new set range, and the lower element defines the contrast.

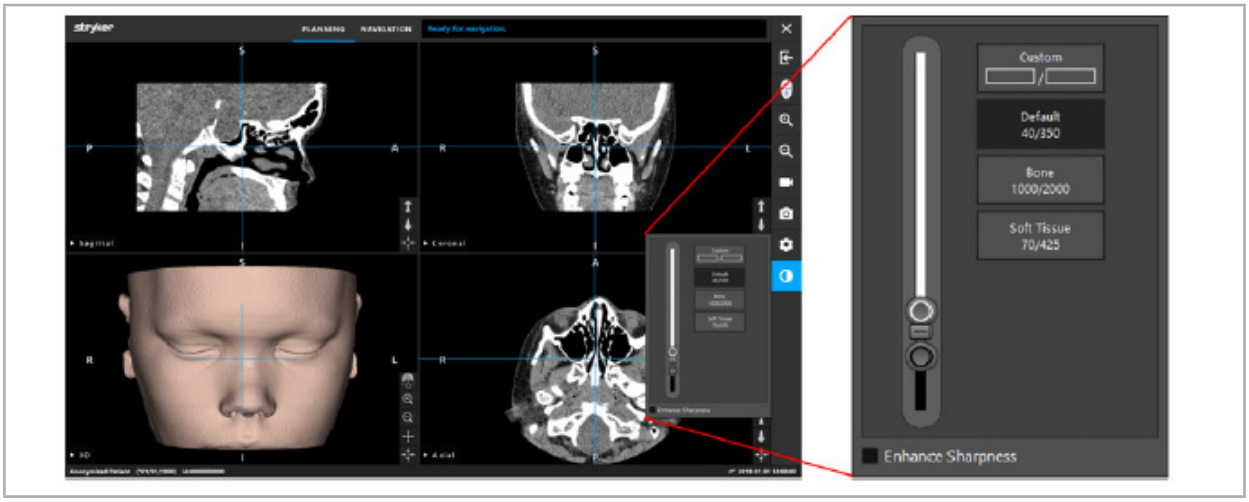


Figure 15 – Slider for Brightness and Contrast

Additionally, next to the slider there are buttons to quickly access predefined gray level window settings. They are given in Hounsfield units and in the form of level/width. The Default window is taken from metadata in the DICOM files of a dataset. The Custom window can be used to enter arbitrary Hounsfield unit values and is updated automatically when changing the slider values.

In addition to altering the display of the patient data, you can adjust the endoscopic video image. For this, switch into the Video tab of the contrast controls (Figure 16). You can change the brightness and saturation of the video, as well as zooming up to 2x into the video image.

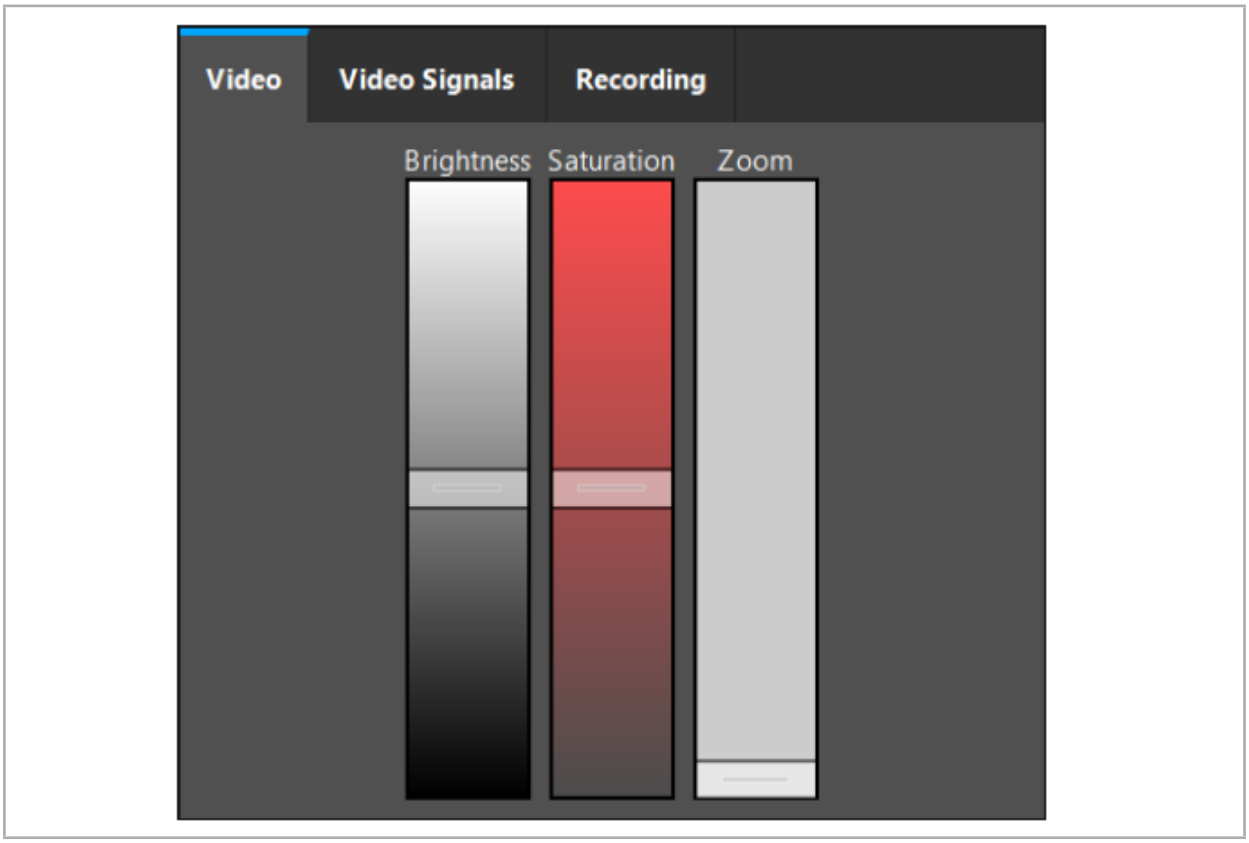


Figure 16 – Adjusting Endoscopic Video

6.7.7. Zooming In and Out in the Patient Image Data

The radiologic patient image data view (axial, sagittal, and coronal) can be zoomed in and out with the magnifier buttons (Figure 17).

Figure 17 – Magnifier Buttons

6.8. Selecting the Patient Registration Type

Before every application, it is necessary to conduct an image-to-patient registration to determine the position of the patient and to match the patient image data. Clicking the Image-to-Patient Registration button (Figure 18) opens the Patient Registration dialog box (Figure 19).

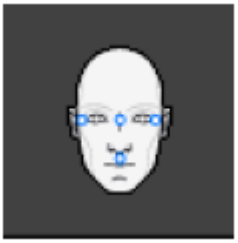


Figure 18 – Image-to-Patient Registration

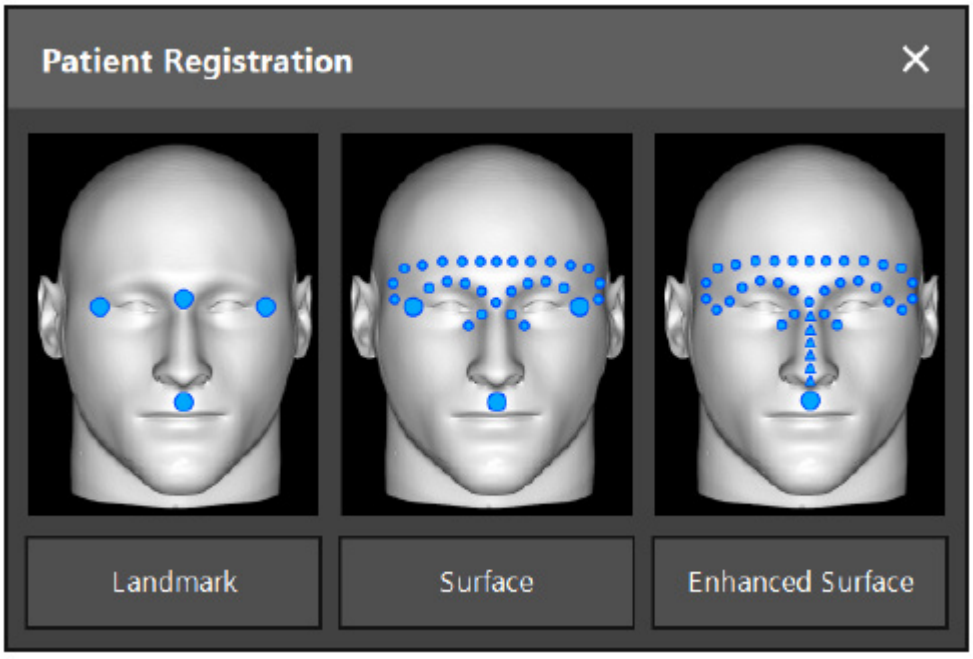


Figure 19 – Selecting Registration Types for ENT

The software offers several types of image-to-patient registration:

Landmark

At least three clearly perceptible landmarks are marked in the patient image data and subsequently touched precisely with a pointer on the patient. This type of registration is especially suitable in the presence of artificial landmarks (e.g. bone screws, fiducials) in the operating area and in the patient image data.

Surface

At least three clearly perceptible landmarks are marked in the patient image data and subsequently touched with a pointer on the patient. Afterwards a pointer must be moved over the patient's surface to collect more points for the matching. This type of registration is especially suitable when registration only takes place on the skin. For surface registration, at least 40 cm2 of skin near the situs are necessary.

Enhanced Surface

Here a specific path in patient image data is generated which must be initially moved along on the patient's surface. Afterwards a pointer must be moved over the patient's surface to collect more points for the matching. This type of registration is especially suitable for sinus surgery. For enhanced surface registration, at least 30 cm2 of skin left and right of the nose, as well as the nose itself, are necessary.

6.9. Image-to-Patient Registration: Landmark

If the landmark image-to-patient registration type is selected, this is displayed by a corresponding activated symbol (Figure 20).

Figure 20 – Landmark Registration Type

For the landmark image-to-patient registration type, it is necessary to place three to five landmarks on prominent places in the patient image data. The places should be chosen so that they can be found and touched precisely with a navigated pointer (pointer instruments) in navigation mode.

6.9.1. Defining Landmarks

WARNING

Do not define landmarks on sensitive structures such as eyes that might be injured by touching with the tip of the pointer.

Landmarks can be defined in the three orthogonal views of the 2D slice images (axial, coronal, and sagittal) and in the 3D model. Pay attention to the following:

- Three to five landmarks can be defined. The distance between two landmarks should be at least 4 mm.

Landmarks should be positioned on prominent anatomical structures which only move very little when touched with the tip of the pointer. Positions on the forehead, the temples, or below the nose are preferred.

- The landmarks should be close to the operation area.
- Three landmarks must not be positioned on a single straight line. Landmark positions must define a plane.
- If artificial landmarks such as bone screws exist in the patient image data, landmarks can be placed upon these structures. The registration with artificial landmarks can enhance the precision of the registration process.

For use in middle ear surgery it is recommended to position three to four bone screws around the situs entry and another screw for reference in 3-4 cm offset (Figure 21).

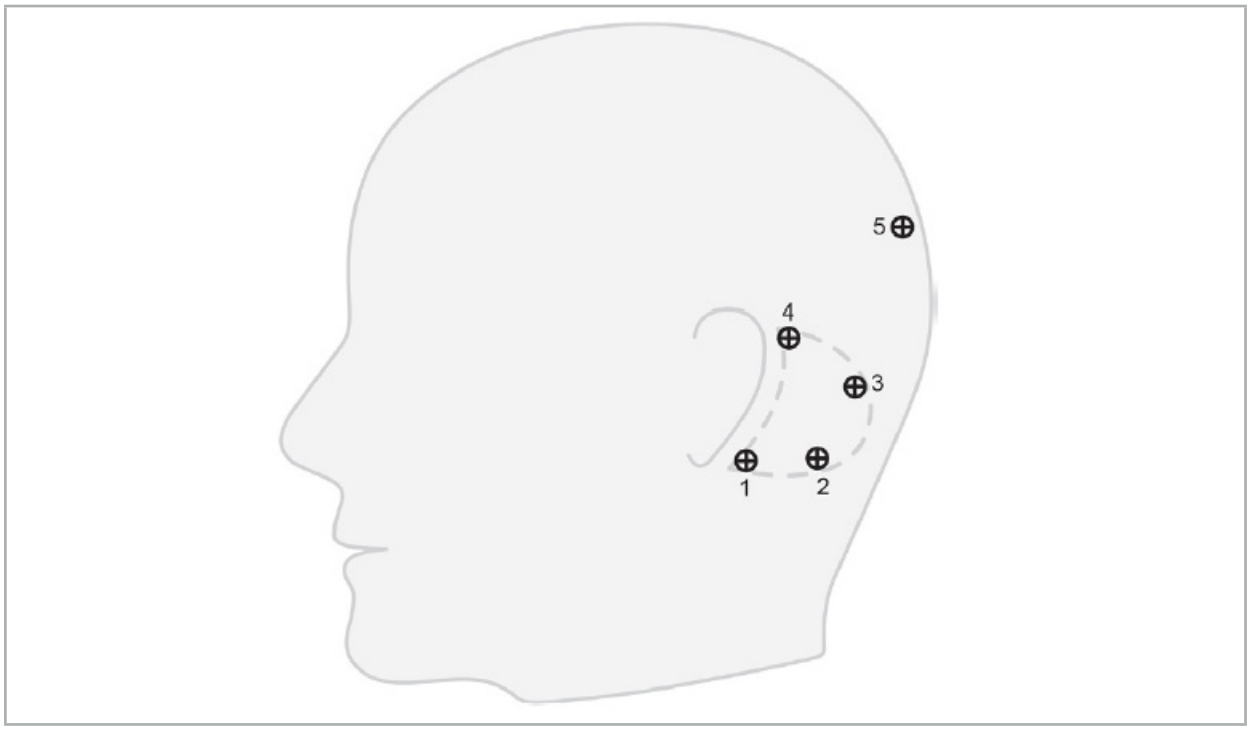


Figure 21 – Recommended Position of Bone Screws

6.9.2. Defining Landmarks in the 3D Model

To add landmarks to the 3D model, click the place where the landmark should be set. Alternatively, use the touchscreen to place new landmarks (Figure 22).

The added and selected landmark appears as a yellow, semi-transparent sphere with a small black center.

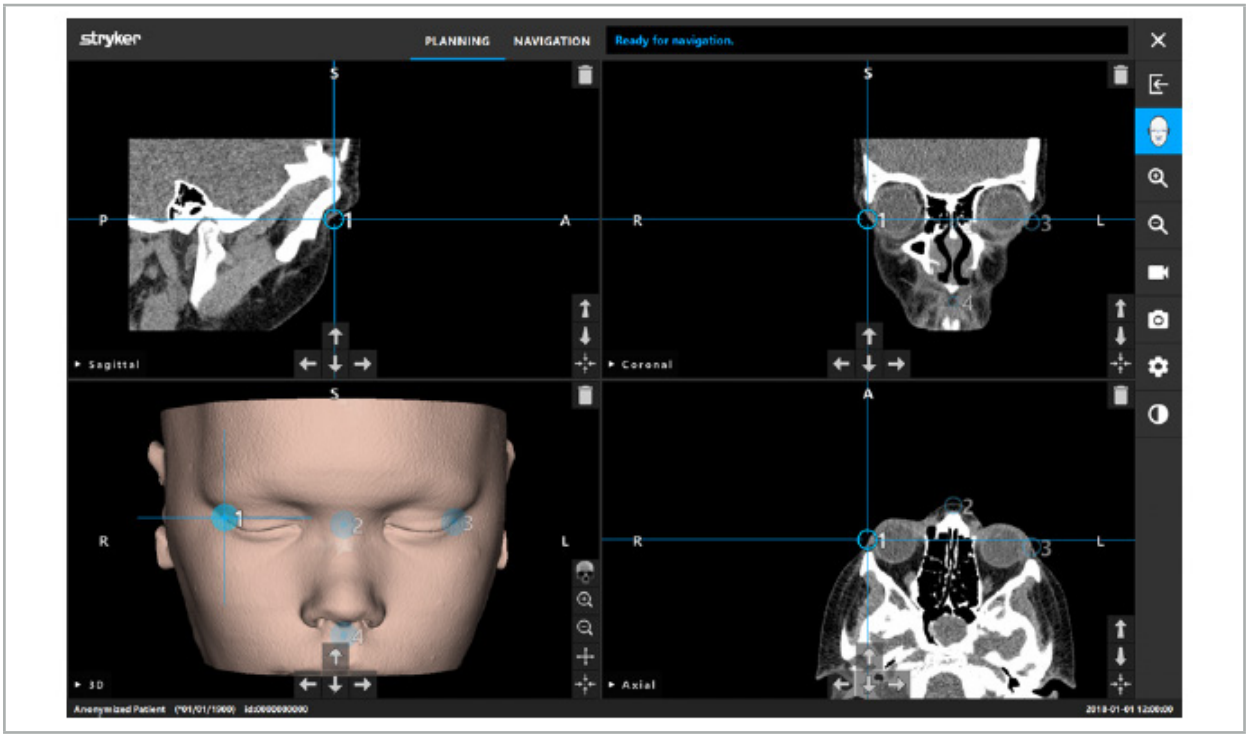


Figure 22 – Placing Landmarks

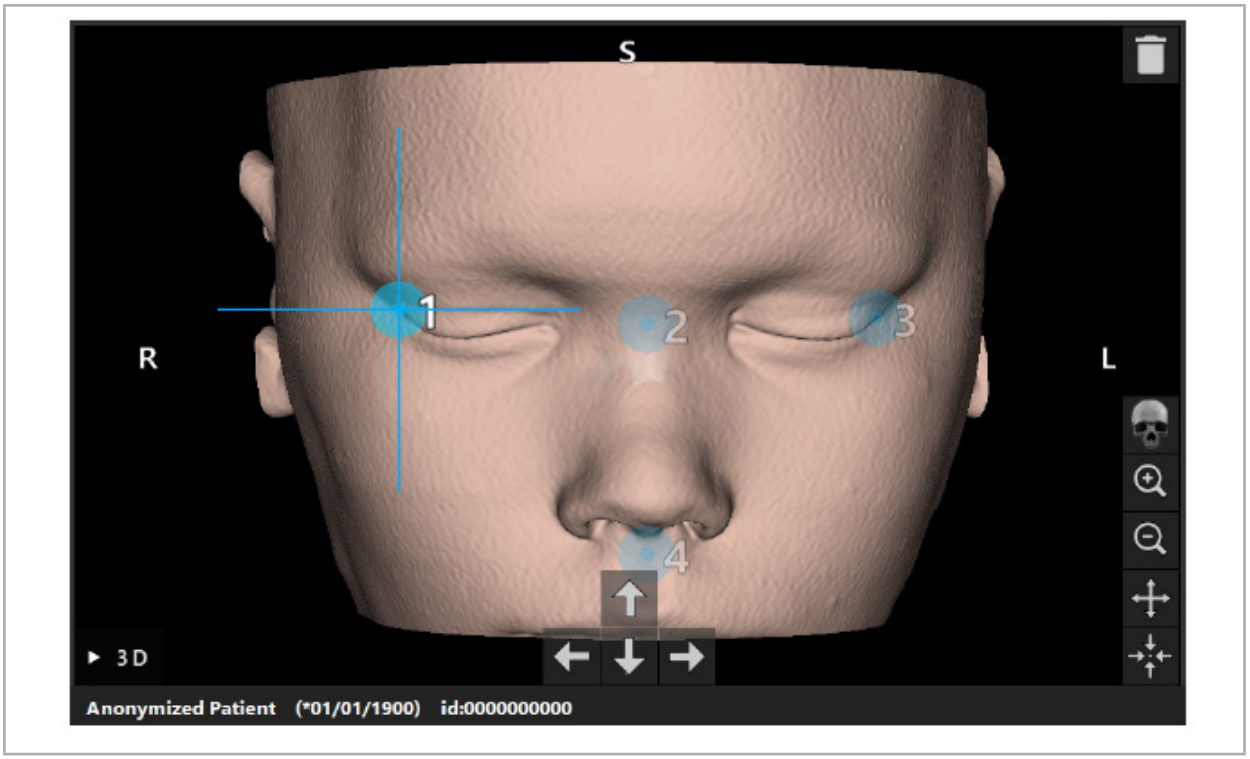


Figure 23 – 3D View

In the 3D view, landmarks can only be placed directly on the 3D model surface. It is not possible to place landmarks outside of the 3D model.

6.9.3. Placing Landmarks in 2D Cross-Section Images

To add landmarks to the 2D cross-section images (Figure 24), click the place where the landmark should be set. Alternatively, use the touchscreen to place new landmarks.

The added and selected landmark appears as a yellow sphere with a target cross.

For further details, see Chapter “Defining Landmarks.”

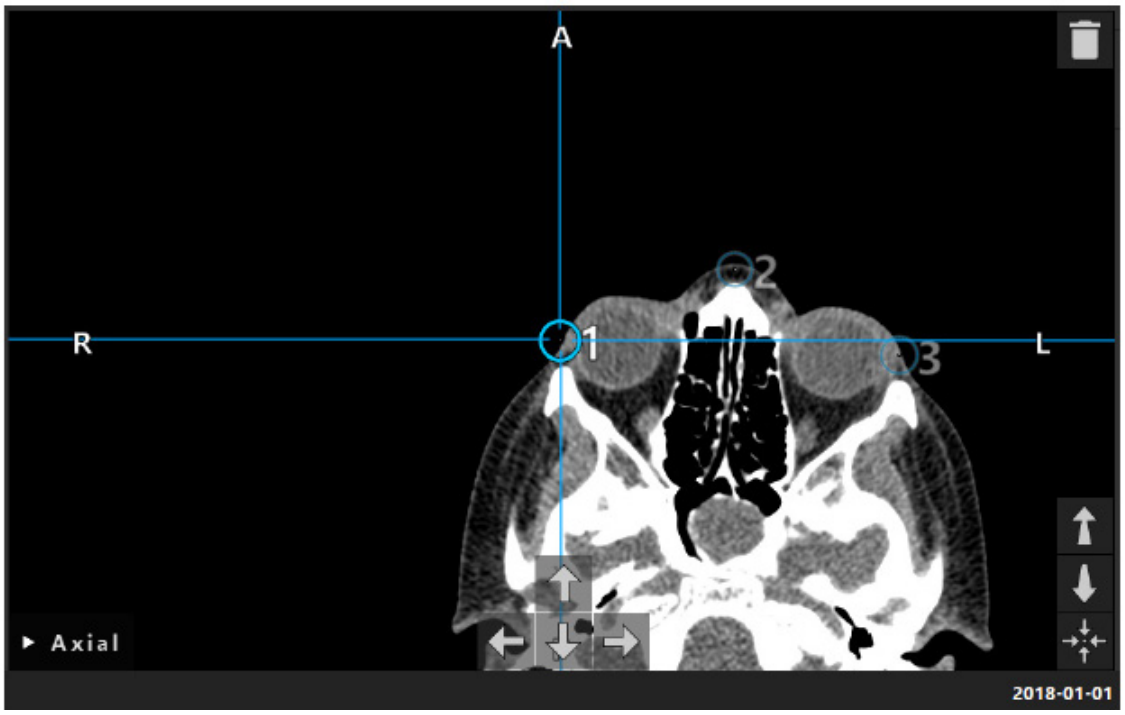


Figure 24 – Adding Landmarks to the 2D Slice Views

6.9.4. Moving Landmarks

The position of existing landmarks can be changed in all views. Click to choose a landmark and drag the landmark to its new position. The selected landmark is shown in yellow. Alternatively, use the touchscreen to position landmarks.

For precise positioning of the landmarks, use the Arrow buttons of the 2D cross-section data. First choose a landmark, which is then shown in yellow. The Arrow buttons in the 2D slice images are now connected to the position of the selected landmark. Move the landmark position through the slices of the cross-section data by pressing the respective Arrow button.

6.9.5. Removing Landmarks

To remove existing landmarks, double-click to select the desired landmark. Alternatively, use the touchscreen to remove landmarks.

6.10. Image-to-Patient Registration: Surface

WARNING

Do not define landmarks on sensitive structures such as eyes that might be injured by touching with the tip of the pointer.

If the surface image-to-patient registration type is selected, this is displayed by a corresponding activated symbol (Figure 25).

Figure 25 – Surface Registration Type

To use the surface image-to-patient registration type, it is necessary to define three landmarks at prominent positions in the patient image data (Figure 26).These positions should be chosen so that they can easily be found and touched in navigation mode using the navigated instrument (pointer instruments) and so they are accurate to a maximum deviation of 10 mm from the landmarks.

The approximate registration by defining three landmarks serves as a first and quick pre-registration, which subsequently must be improved using a surface scan.

For further information on how to define, move, and delete landmarks, see Chapter “Image-to-Patient Registration: Landmark.”

Since only an approximate scanning of the three landmarks is necessary, they can be placed comfortably in the 3D model. A precise adjustment of the landmarks is not necessary.

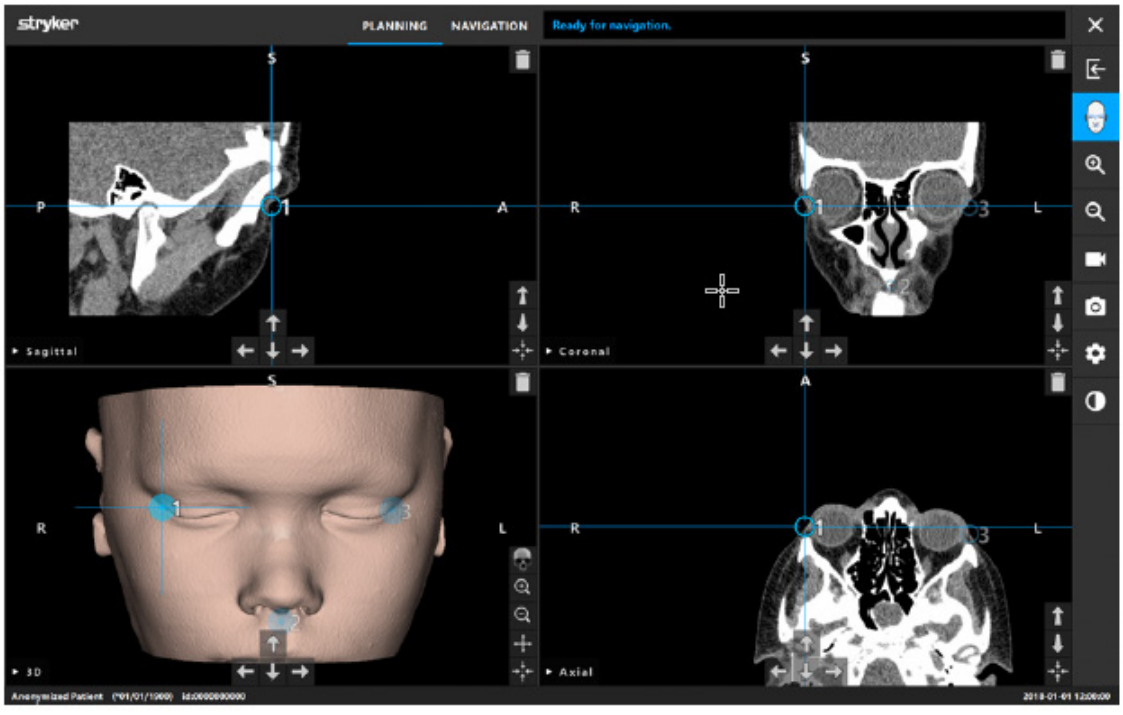


Figure 26 – Placing Surface Landmarks

6.11. Image-to-Patient Registration: Enhanced Surface

If the enhanced surface image-to-patient registration type is selected, this is displayed by a corresponding activated symbol (Figure 27).

Figure 27 – Enhanced Surface Registration Type

A precondition for the enhanced surface image-to-patient registration type is the correct recognition of the ridge of the nose and a point below the nose (subnasal) (Figure 28).

If the anatomic features in the patient image data are detected, they are shown in the 3D model. The subnasale is marked green and represents the starting point of a touching path that is shown as a sequence of red triangles. If the recognition is ideal, the touching path is shown along the middle of the nose bridge.

If the anatomic features are not detected optimally, these can be repositioned by moving the landmarks. For further information on how to define and move landmarks, see Chapter “Image-to-Patient Registration: Landmark.”

The advantage of the enhanced surface image-to-patient registration type is that no landmarks have to be placed. Therefore, the planning can be minimized to the loading of patient image data.

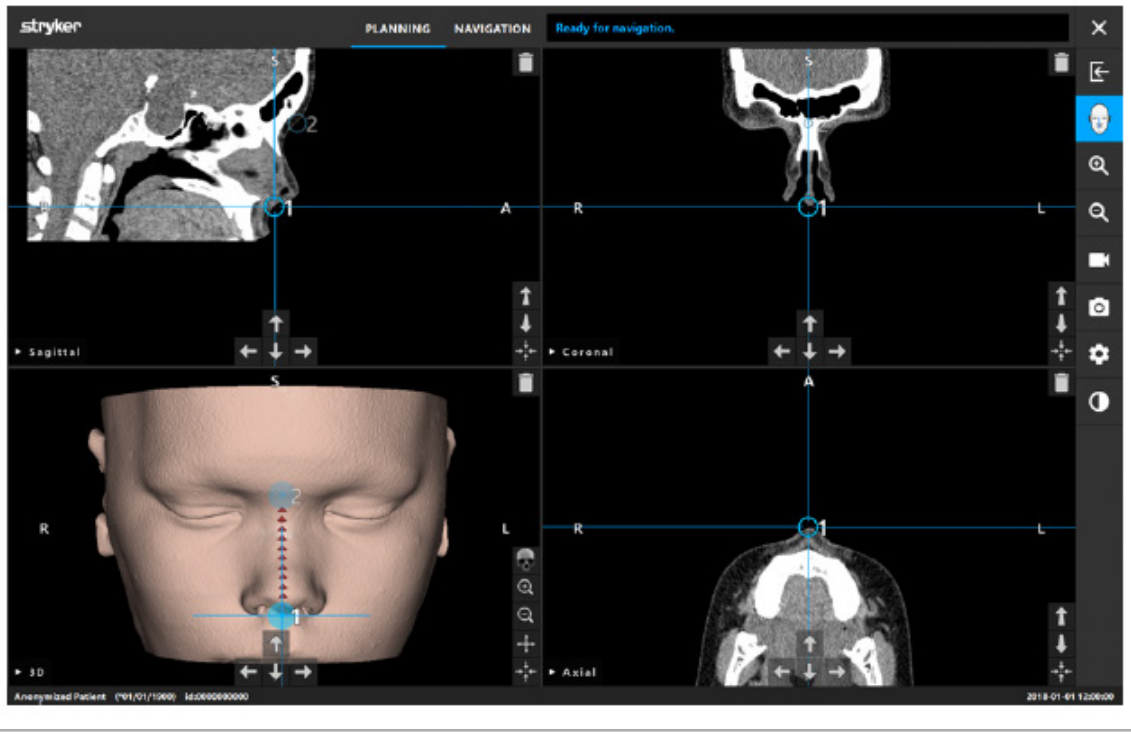


Figure 28 – Image-to-Patient Registration: Enhanced Surface

WARNING

- If the anatomic features are not registered correctly, correct their position first or choose a new registration method.
- Do not define landmarks on sensitive structures such as eyes that might be injured by touching with the tip of the pointer.

If the path between landmark 1 and landmark 2 is too flat, the software emits a warning and does not allow the switch to navigation mode. Correct the positioning of the landmarks so that a path with more profile is created.

6.12. Saving the Planning

If you want to save the planning before proceeding to the navigated operation, press the Loading Patient Data button (Figure 29) or the Close Software button (Figure 30).

Figure 29 – Loading Patient Data

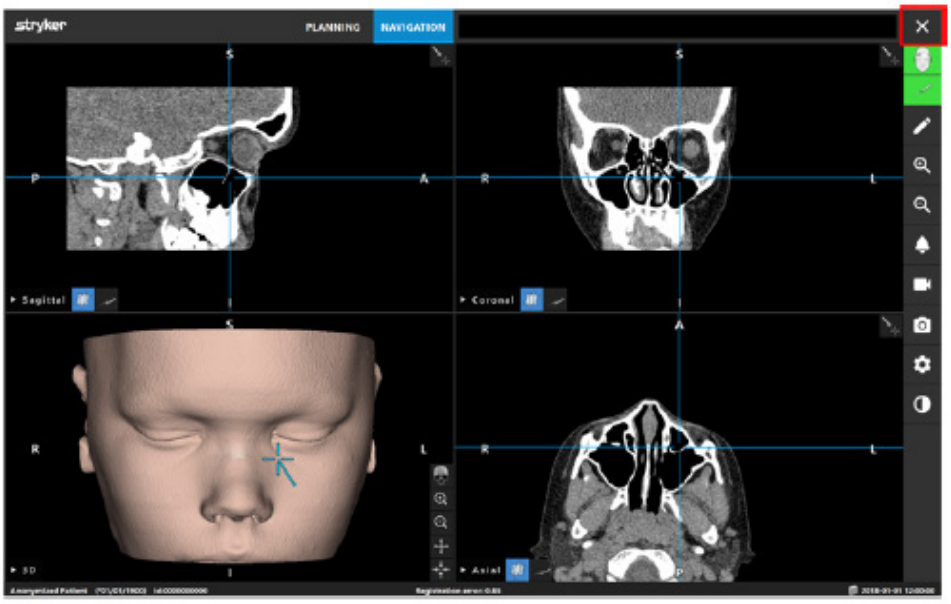


Figure 30 – Close Software

When pressing the Loading Patient Data button, the Save Planning dialog box appears (Figure 31). The dialog box gives you the following options:

- Overwriting the loaded old planning with the current planning with Overwrite.
- Saving the current planning as a new dataset with Save as new.
- Not saving the current planning and showing the Data Import dialog box (Figure 5) with Do not save.
- Closing the Save Planning dialog box without further actions with Cancel.

An optional description of the planning can be entered in the Description field.

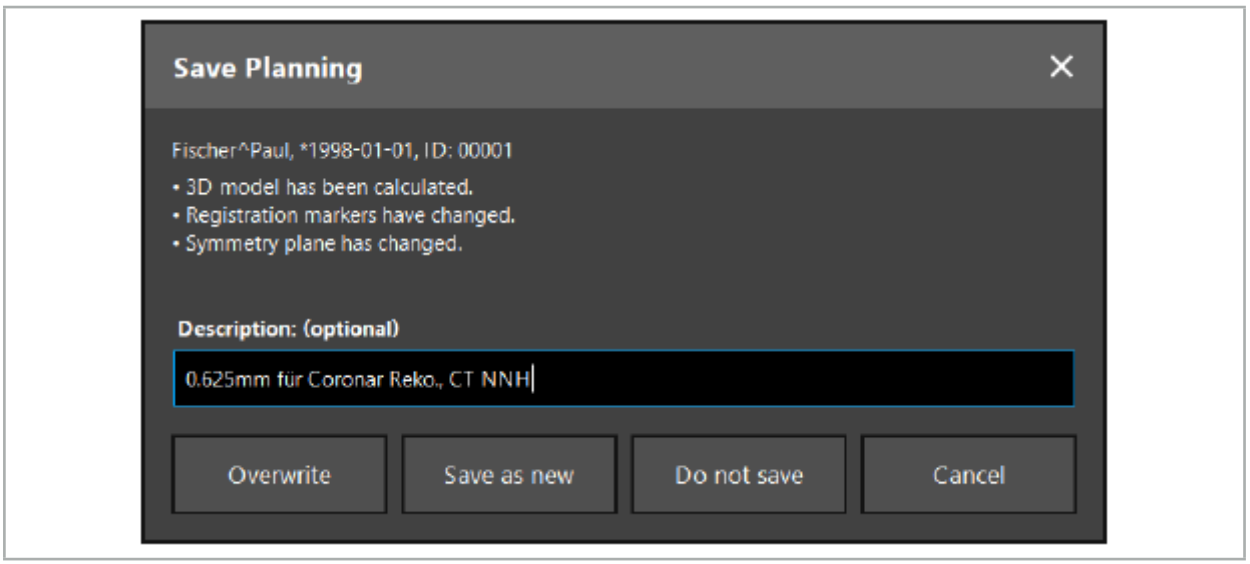


Figure 31 – Save Planning when Loading Patient Data

When pressing the Close Software button, the Save Planning dialog box appears (Figure 32). The dialog box gives you the following options:

- Overwriting the loaded old planning with the current planning with Overwrite.
- Saving the current planning as a new dataset with Save as new.
- Closing the Save Planning dialog box without further actions with Cancel.
- Closing the software without saving the planning with Quit without save.

An optional description of the planning can be entered in the Description field.

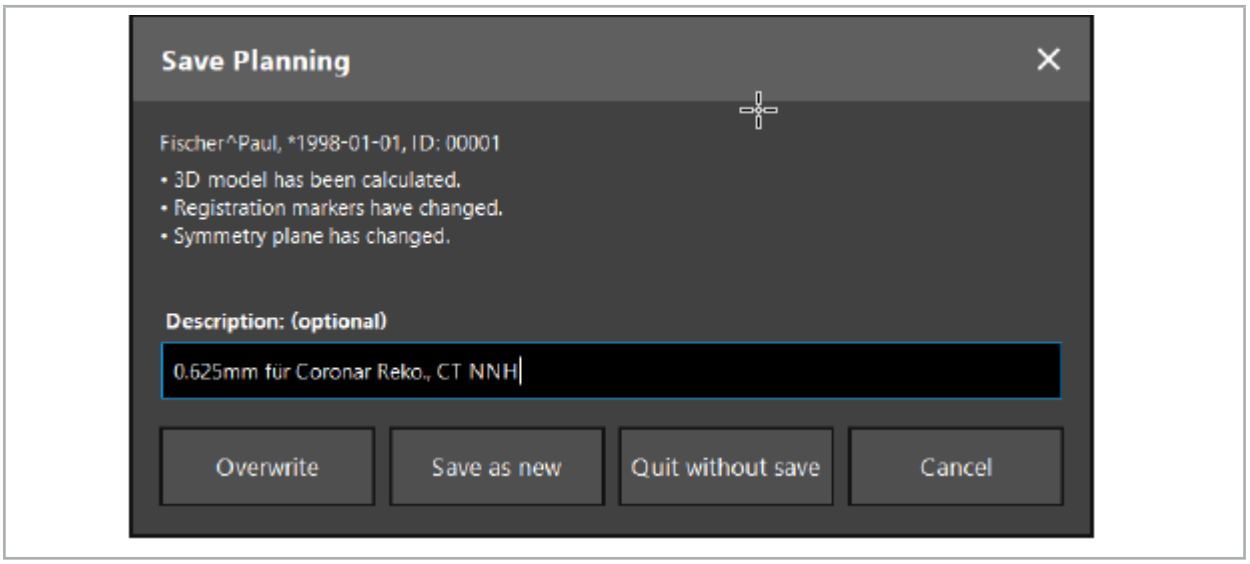


Figure 32 – Save Planning when Closing the Software

The overwrite function completely overwrites a previously saved planning with the current planning.

You can either start the navigated operation directly after the planning, or save the planning and reload it later.

Plannings are saved automatically if you change to navigation mode or conduct a registration.

6.13. Exporting the Planning

Data transfer can be conducted via a USB drive or via a network drive, depending on your hospital's technical situation.

1. After finishing the planning, press the Export button.
2. Choose the target drive desired for exporting (Figure 33).
3. Enter a fitting description for the planning.
4. Press the Export button.

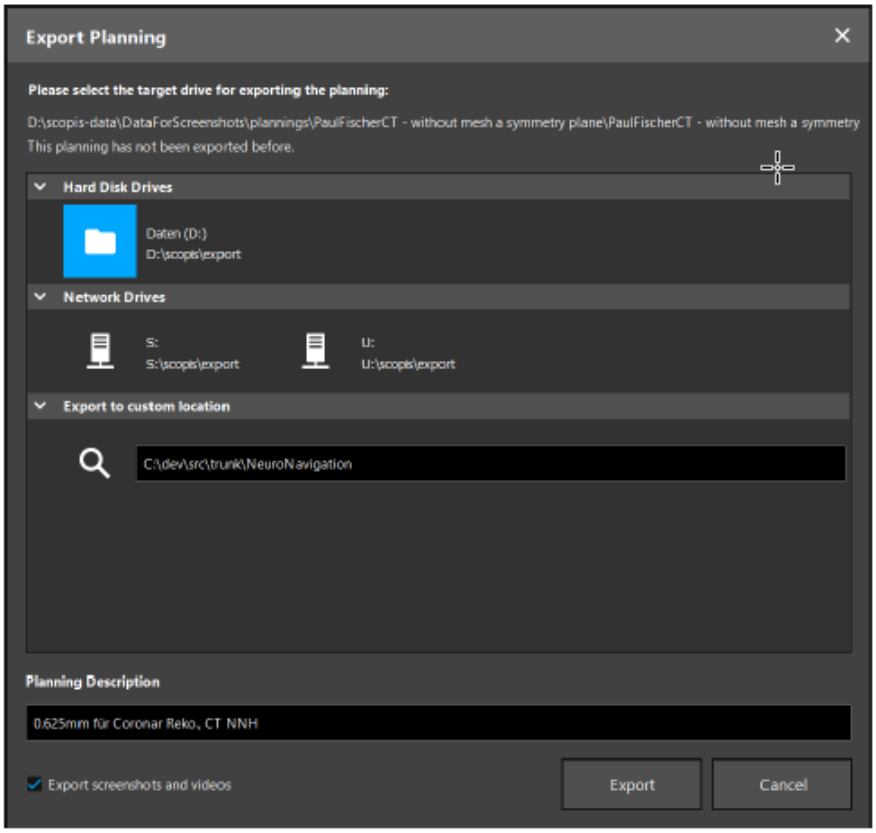


Figure 33 – Export Planning

The data is transmitted to the selected drive. To import the planned data, follow the instructions for importing patient image data "Loading Patient Image Data.´"

6.14. Taking Screenshots and Screen Recordings

The below buttons are featured on the right side of the user interface. Press the corresponding button to either take a single screenshot (Figure 34) or to record the screen (Figure 35).

Figure 34 – Screenshot

Figure 35 – Screen Recording

Plannings with screenshots or videos attached can be displayed as a list in the view (Figure 36). Just like plannings, these individual files are opened by double-clicking or pressing the Load button, as well as deleted or exported by pressing Delete or Export.

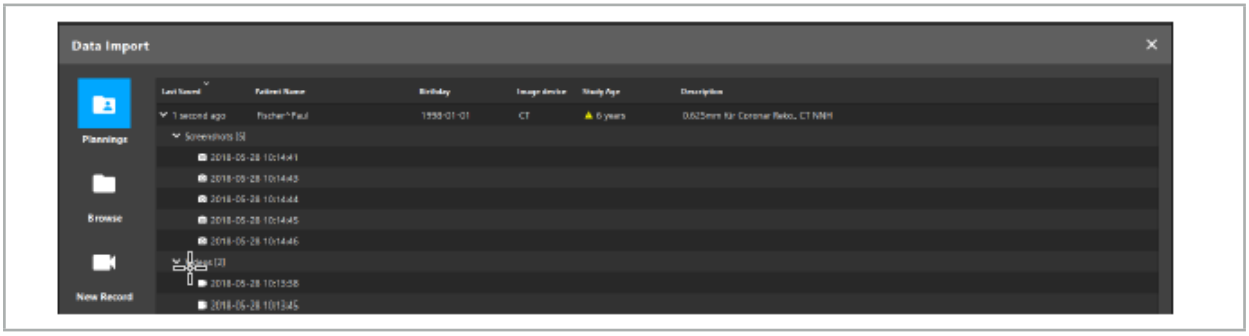


Figure 36 – Video and Screenshot Files Attached to a Planning

The navigation software automatically creates screenshots during navigation whenever the tool is held still near the patient for a short time. These images are shown as “AutoScreenshots” as part of the planning.

If you create a screenshot or screen recording without loading a planning first, the files are saved in the Documentation folder inside the software installation directory. If you load a different planning while a screen recording is in progress, then the video recorded up to this point is saved with the first planning, while the further recording is attached to the new planning.

Depending on the size of the datasets, it can take several minutes to import and load image and planning data.

The navigation software only allows the switch to navigation mode after the planning is completed. This is confirmed with the message, “Ready for Navigation Mode.” Also, the NAVIGATION tab is activated.

7. Pre-operative Setup of a Navigated Surgery

This chapter describes the pre-operative steps necessary to set up the navigation system in the operating theater:

1. Set up the Field Generator near the head of the patient to allow for position measurement of navigated instruments.
2. Prepare the navigated instruments for use.
3. Start the navigation system and load the prepared planning.

7.1. Field Generator

The Field Generator (generator) (Figure 37) is intended for the electromagnetic position measurement of patient and navigated instruments during surgical procedures in which compatible clinical navigation systems are used.

Figure 37 – Field Generator

Field Generator Accessories	REF
Field Generator Mounting Arm	8000-010-005
Headrest for Field Generator	8000-010-006

7.1.1. Application

Connect the plug of the cable to the socket on the front of the navigation unit (Figure 38).

Figure 38 – Connecting the Field Generator Cable to the Navigation Unit

WARNING

While placing the cable, make sure there is no risk of stumbling for operator or a patient.

CAUTION

Never use force to put the plug into the plug socket. Do not flex the cable.

7.1.2. Positioning

Adjust the distance between the generator and the operating area of the patient as follows:

Field Generator: 0.15 m (measuring range: 0.05 m to 0.5 m)

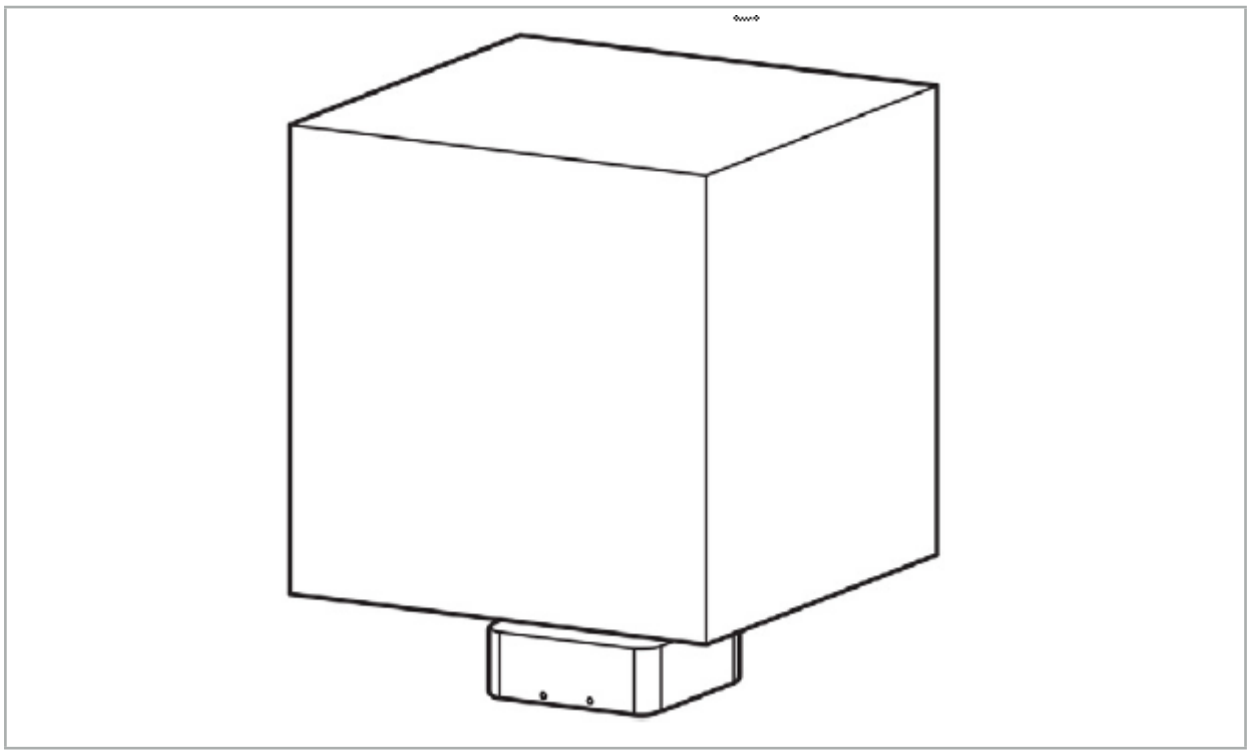


Figure 39 – Measurement Volume: Field Generator

For the positioning of the generator, a mounting arm and headrest are available. The mounting arm is attached to the standard rail and allows the flexible positioning of the generator.

WARNING

The generator is wipe-disinfectable. If the generator is placed close to the sterile area, it has to be covered in a sterile way. The product is not intended for direct patient contact.

Be aware that the use of padding or undersheets increases the distance between the generator and working area. The navigated region has to be inside the measuring volume.

7.1.3. Interferences with Electromagnetic Systems

Electromagnetic measurement systems are susceptible to metals, especially ferromagnetic substances, and electromagnetic fields. Electromagnetic measurement systems can provide precise navigation information only when the following factors are observed:

No disturbing substances within 80 cm (35 inches), neither close to the Field Generator nor between the Field Generator and measuring sensor (navigated instruments). The following materials produce interferences:

- Steel
- Ferromagnetic stainless steel
- Iron
- Aluminum
- Copper

The following materials have only a minimal impact on the measurement precision:

- Stainless steel (Material number: 1.4301, 1.4305, 1.4401, 1.4404)
- Titanium Ti6Al4V
- Cobalt chromium steel

The Field Generator tabletop is an exception. It is shielded against environmental interferences on the opposite side of the measurement volume. Therefore it can be placed directly on the OR table. For all other sides, the specified rules are still valid.

Do not move disturbing items within 80 cm (35 inches) of the Field Generator during or after patient registration. In particular, ensure that the following items are positioned away from the Field Generator:

- Medical devices that require creation of electromagnetic fields to carry out their function
- Electrically driven motors, from drills and shavers
- Field Generator cable
- Navigation unit
- Instrument cart
- Monitors
- Keys, watches, jewelry
- Personal electronics, such as phones

Refer to Figure 40.

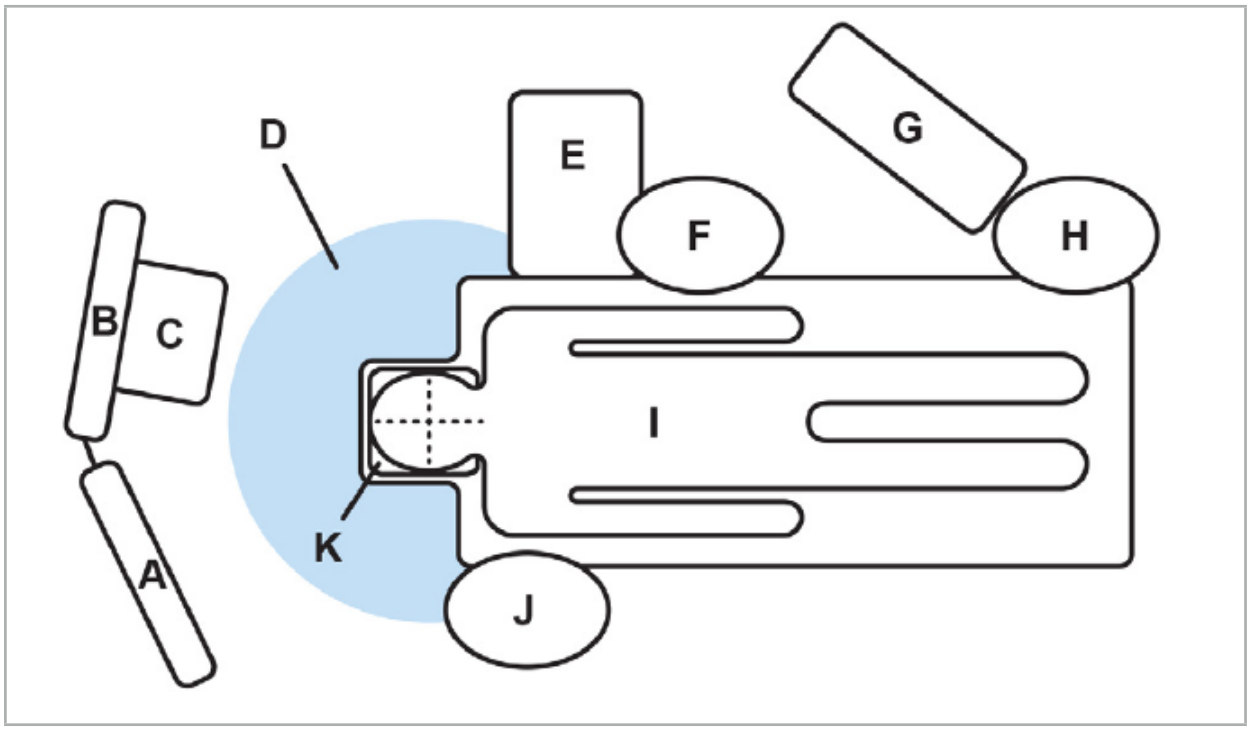


Figure 40 – Optimal Electromagnetic Setup to Avoid Interferences

A - Monitor 1

B - Monitor 2

C - Endoscopy tower

D - Optimal distance of disturbing materials to the Field Generator (80 cm)

E - Table with surgical instruments

F - Surgery nurse

G - Anesthesia apparatus

H - Anesthetist

I - Patient

J - Surgeon

K - Field Generator

Keep these or similar items at a distance of at least 80 cm (35 inches) from each side of the Field Generator to ensure the accuracy of the tool measurement.

WARNING

- Make sure that there are no disturbing metals within the measuring volume of the Field Generator during the application of the navigation system with electromagnetic position measurement; otherwise, the accuracy of the position measurement is significantly reduced.
- Do not operate the Field Generator within 200 mm of an installed pacemaker. The magnetic field produced by the may interfere with the operation of the pacemaker. This interference may result in personal injury.
- Do not operate the Field Generator within 10 m of another Field Generator. To do so may contribute to inaccurate position measurement and possible personal injury.
- Do not drop the Field Generator or subject it to impact. Physical damage to the Field Generator may alter its calibration and contribute to inaccurate position measurement and possible personal injury.
- Do not place the Field Generator Cable inside the measurement volume or wrap it around the Field Generator, as it may create a magnetic interference. This interference can contribute to inaccurate position measurements and possible personal injury.
- Do not place electromagnetic tool cables within 30 mm of the Field Generator Cable. If placed this close – particularly if the cables are parallel to each other – the tool cable may become subject to electromagnetic interference. This interference can contribute to inaccurate position measurements and possible personal injury.
- Do not coil the Field Generator Cable, as it produces enough electric current that a magnetic field will be created when the cable is placed in a circular formation. This magnetic field may disturb the Field Generator's magnetic field, contributing to inaccurate position measurements and possible personal injury.

7.2. Preparing Navigated Instruments

Navigated instruments must be prepared before use.

Patient Trackers provide a reference frame for the patient during surgery. For this purpose, the tracker is fixed onto the patient as near as possible to the operation area.

At least one Patient Tracker and one navigated instrument are necessary for navigation.

Compatible instruments can be found in the following chapters. For information on the calibration and verification of navigated instruments, see Chapter 8.7. in the instructions for use of the ENT Navigation System with TGS.

WARNING

- Navigated instruments are delivered in a non-sterile condition. Before the first use as well as before each following use, the instrument must be processed (cleaned, disinfected, and/or sterilized) according to a validated procedure.
- The product is a high precision instrument. Avoid subjecting it to serious strains, such as heavy impacts. The product cannot be used if there are visible defects. After a heavy impact, the product must be checked for defects and calibrated anew.

Ensure that an unused replacement copy is available for every electromagnetic instrument.

7.2.1. General Functionality Testing

Before each use, check the product for:

- Deformations
- Correct installation and function
- Surface damage (cracks, dents)
- Other damage

Damaged products must not be used.

WARNING

Before using a medical product, assure yourself of its functional safety and proper condition via a visual inspection. Do not use the product If any defects are detected.

7.2.2. Patient Tracker Electromagnetic

The Patient Tracker Electromagnetic (Figure 41) provides a reference for patients. The product is fixed with appropriate accessories onto the intact skin of the patient, thus allowing the localization of the patient without immobilization.

Figure 41 – Patient Tracker Electromagnetic and Patient Tracker Electromagnetic - 10 Uses

Mandatory Accessories	REF
Patient Tracker Tabs	8000-100-001

Application

Refer to Figure 42.

1. Clean the intended contact surface on the patient. The contact surface should be free of fat, dry, and (if possible) free of hairs.

2. Remove one protective film from the adhesive tab, and stick the adhesive tab onto the Patient Tracker underside.

3. Remove the second protective film, and stick the Patient Tracker onto the planned contact surface with the adhesive tab.

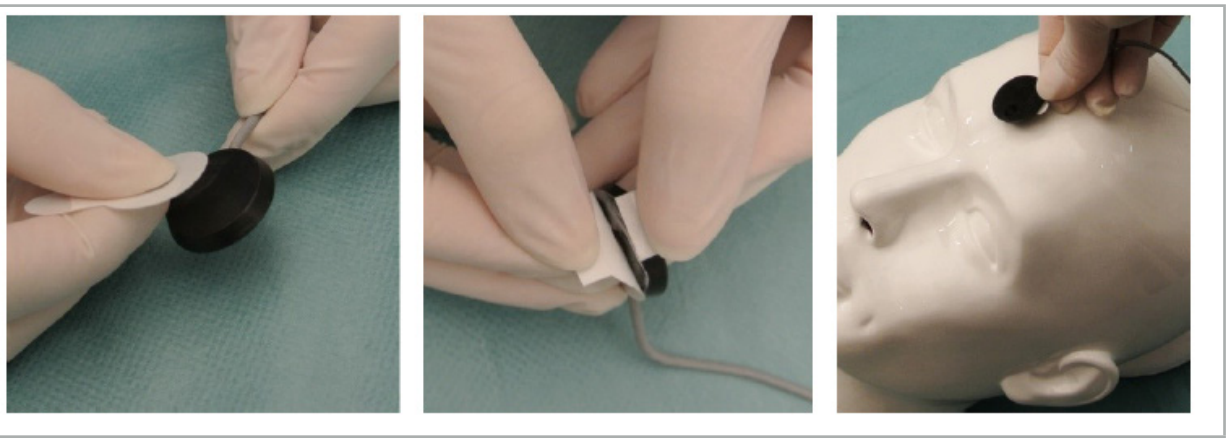


Figure 42 – Fixing Tab to Tracker and Contact Surface

4. If you calibrate instruments using the calibration area of the unsterile Patient Tracker, then it is necessary to cover this with a sterile, transparent drape. Adhesive incision drapes are well suited for this purpose, as they also hold the Patient Tracker in place (Figure 43).

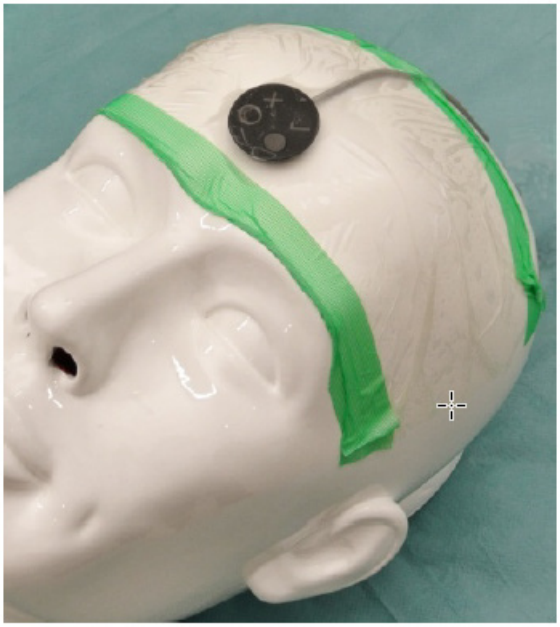


Figure 43 – Fixing the Patient Tracker onto the Patient

WARNING

Make sure not to penetrate the sterile barrier when calibrating through the thin drape.

5. If the calibration area is not needed, the Patient Tracker can be fixed in place with medical adhesive tape and then covered with a surgical drape (Figure 44).

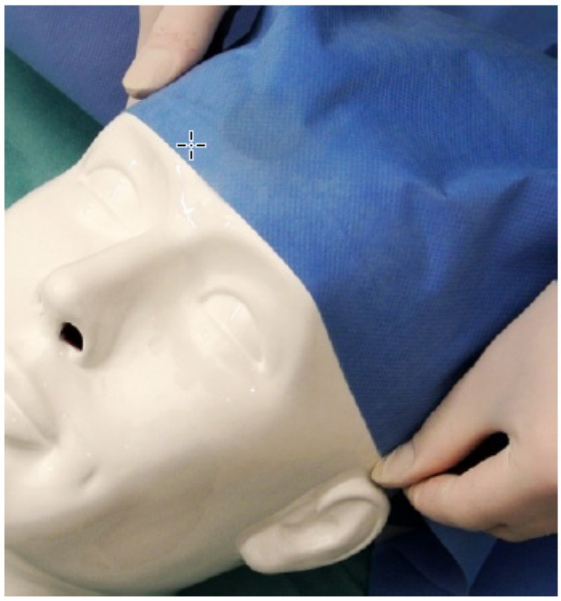


Figure 44 – Cover Patient Tracker

WARNING

Make sure that the Patient Tracker is securely attached to the patient during use, as the navigation would otherwise be inaccurate or useless. If the Patient Tracker moves, the image-to-patient registration must be repeated.

7.2.3. Pointer Instruments

The electromagnetic pointer instruments (Figure 45) are used to touch relevant structures during ENT surgery. Compatible navigations systems are thereby able to locate and navigate the touched structures.

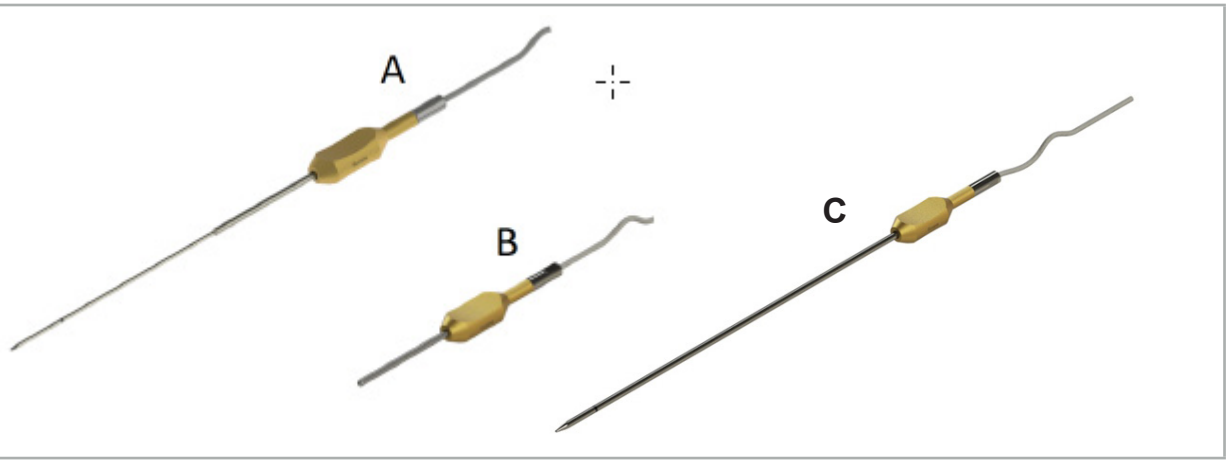


Figure 45 – Pointer Instruments

A - Precision Pointer Electromagnetic (8000-050-001)

B - Registration Pointer Electromagnetic (8000-050-003)

C- Pointer Electromagnetic (8000-050-002)

Description

Precision Pointer Electromagnetic (REF 8000-050-001)

The Precision Pointer Electromagnetic is a pointing device with a tracked tip. The steel tube may be reshaped once per procedure provided that the curvature is not too sharp (i.e. bending must be as spread out as possible) and that the distal 20 mm up to the black ring marking of the instrument remain unbent.

Pointer Electromagnetic (Ref 8000-050-000)

The Pointer Electromagnetic is a pointing device with a tracked tip with a long design for use during endoscopy. The steel tube may be reshaped once per procedure provided that the curvature is not too sharp (i.e. bending must be as spread out as possible) and that the distal 20 mm up to the black ring marking of the instrument remain unbent.

	Precision Pointer EM	Pointer EM
Working length	120mm	175mm
Angle	0°	0°
Diameter	1.5 mm (from tip - 80mm) 2,5mm (80-120mm)	2.7 mm
Flexibility	• Min. bending radius: 1.5 cm • Most narrow section to be bent: 3 cm • Length of flexible section: 6 cm; only to be bent evenly with a total curvature of 90° • Not flexible: First 2 cm of the tip; second tube, in which the tube is adhered	• Min. bending radius: 3 cm • Most narrow section to be bent: 5 cm with a total curvature of 45° • Flexible section length: 10 cm; only to be bent evenly with a total curvature of 90° • Not flexible: tip and end of the tube (each 2 cm)

Registration Pointer Electromagnetic (REF 8000-050-003)

The Registration Pointer Electromagnetic is designed for non-sterile image-to-patient registration on the patient's skin, see Chapter. 8.5.2. Between surgical procedures it is cleaned and disinfected only. For improved registration quality, the pointer tip is broad and rounded, avoiding tissue deformation.

Application

WARNING

Do not bend the distal 20 mm of the Precision Pointer Electromagnetic and the Pointer Electromagnetic.

1. For Registration Pointer Electromagnetic REF 8000-050-003 only: Verify the pointing device is not bent.
2. Conduct a general functionality test. See Chapter "Preparing Navigated Instruments.".

7.2.4. Navigated Suction Tubes

The Frazier and Eicken Electromagnetic (Figure 46) are navigated instruments for ENT surgery. Compatible navigation systems are thereby able to locate and navigate the touched structures.

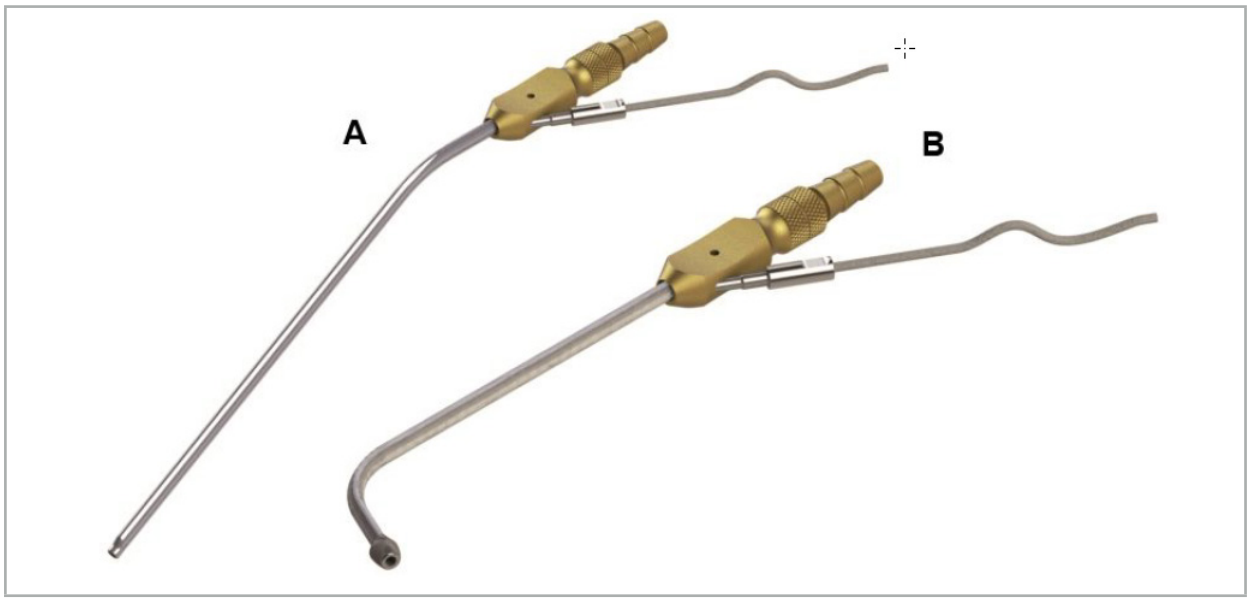


Figure 46 – Navigated Suction Tubes

A - Frazier Electromagnetic (8000-050-005)

B - Eicken Electromagnetic (8000-050-006)

Application

Conduct a general functionality test. See Chapter “Preparing Navigated Instruments.”

CAUTION

Make sure that instruments are not damaged by third party products. Drills and shavers may damage the polymer tubing.

7.2.5. Instrument Clamps

The Instrument Clamps (Figure 47) add a location tracker to surgical instruments. Compatible navigation systems are thereby able to navigate conventional surgical instruments.

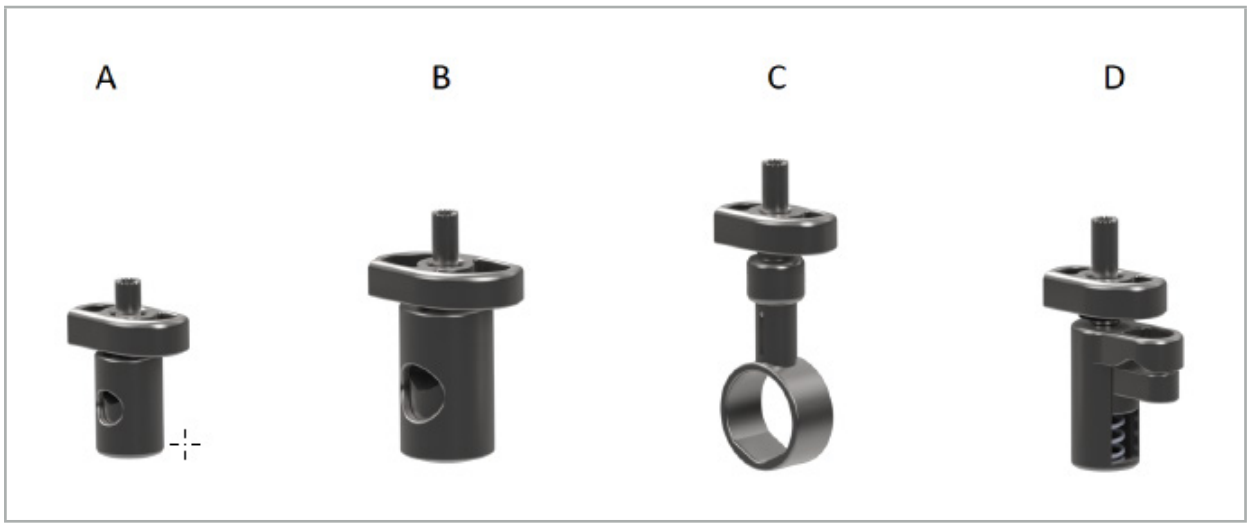


Figure 47 – Instrument Clamps, Individual Parts

A - Instrument Clamp 2-6 mm (8000-060-010) – The Instrument Clamp 2-6 mm is designed for the navigation of instruments with a round or multi-angular profile whose diameter is not larger than 6 mm.

B - Instrument Clamp 6-10 mm (8000-060-011) – The Instrument Clamp 6-10 mm is designed for the navigation of instruments with a round or multi-angular profile whose diameter is not smaller than 6 mm and not larger than 10 mm.

C - Instrument Clamp 10-16 mm (8000-060-012) – The Instrument Clamp 10-16 mm is designed for the navigation of instruments with a round or multi-angular profile whose diameter is not smaller than 10 mm and not larger than 16 mm.

D - Instrument Clamp Forceps (8000-060-013) – The Instrument Clamp Forceps is designed for the navigation of instruments with a round or multi-angular profile whose diameter is not smaller than 5.5 mm and not larger than 10 mm.

The Universal Tracker Electromagnetic (8000-060-006) can be combined with the clamps for electromagnetic navigation.

7.2.6. Suitability of Surgical Instruments

WARNING

Should attachment of the Instrument Clamp affect the functionality or moveability of the instrument or of parts of the instrument, then the instrument cannot be navigated via the Instrument Clamp.

If connected to the Instrument Clamps, numerous surgical instruments can be upgraded to navigated instruments. However, not all instruments are suited for the navigation. The following factors should be considered:

In principle, the navigation system determines the position of the instrument tracker attached to the instrument. The point on the instrument which is to be navigated is taught to your navigation system through a calibration. Only those points on the instrument that are rigidly connected to the instrument tracker should be calibrated. If the instrument is deformed, the precision of the navigation information deteriorates (Figure 48 and Figure 49).

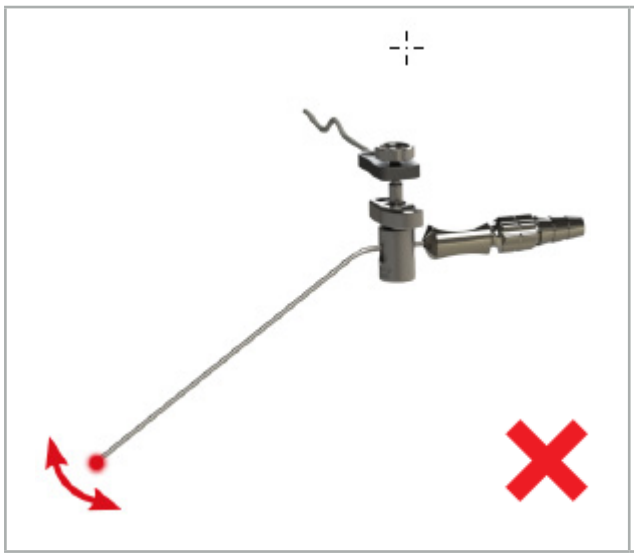


Figure 48 – Instrument with Low Precision

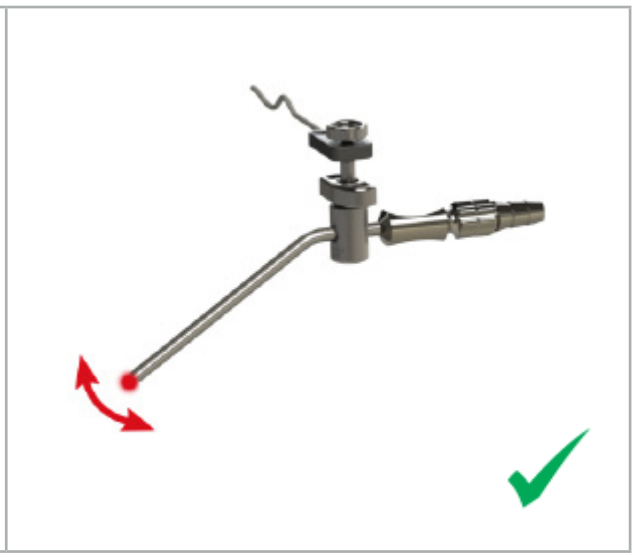


Figure 49 – Instrument with High Precision

The position of the instrument tracker is determined very precisely. However, if the distance between the instrument tracker and the navigated point changes, the precision of the navigated point deteriorates. The closer the instrument tracker is placed to the navigated point, the more precise the navigation information (Figure 50 and Figure 51).

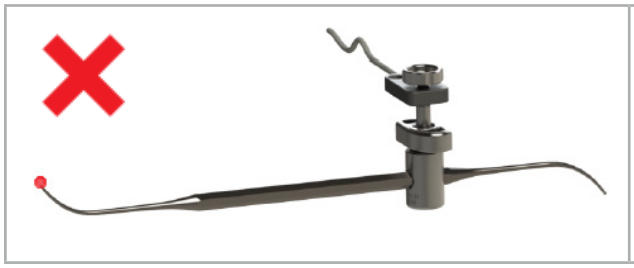


Figure 50 – Instrument with Low Precision

Figure 51 – Instrument with High Precision

Application

Refer to Figure 52.

3. To assemble a clamp, unscrew the fastening nut counter-clockwise.
4. Press the Instrument Clamp together and position it on the instrument.
5. Tighten the fastening nut clockwise until the clamp is rigidly connected with the instrument.

Figure 52 – Fixing the Instrument Clamp to the Surgical Instrument

WARNING

If it is not possible to fix the clamp on the instrument without damaging it, the instrument is not suitable for use. Do not use any tools for tightening the fastening nut.

7.2.7. Using Universal Tracker Electromagnetic

Screw the second knurled screw through the Universal Tracker Electromagnetic so that the knurled screw is loosely connected with the tracker (Figure 53).

Figure 53 – Preparation of Universal Tracker Electromagnetic

7.2.8. Fixing Instrument Tracker to Instrument Clamp

Refer to Figure 54.

1. Attach the Universal Tracker Electromagnetic to the Instrument Clamp.
2. Screw the knurled screw tightly so that the Universal Tracker is rigidly connected with the Instrument Clamp.

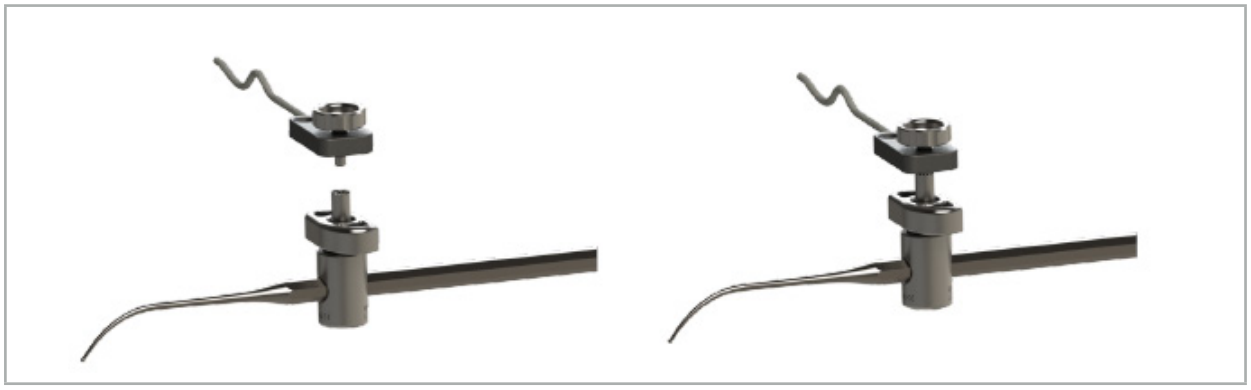


Figure 54 – Preparation of Instrument Clamp and Universal Tracker Electromagnetic

WARNING

- Make sure that the instrument to be navigated is not restrained by the attached Instrument Clamp.
- The Instrument Clamp must be securely fixed to the instrument before beginning with the calibration.

3. Calibrate the instruments. See Chapter “Calibration and Verification of Navigated Instruments.”

4. Test/verify calibration.

WARNING

Make sure the device is securely attached to the surgical instrument because the navigation will otherwise be imprecise and useless. If the device moves, a new calibration is required.

7.2.9. Universal Tracker Electromagnetic

The Universal Tracker Electromagnetic (Figure 55) references patient anatomy or adds an electromagnetic localizer to surgical instruments. For this purpose, the product is attached to compatible adapter, which is securely connected to the patient or the instrument.

Figure 55 – Universal Tracker Electromagnetic

Application

1. Screw the second knurled screw through the tracker so that the knurled screw is loosely connected with the tracker.

2. For instructions for use as an instrument tracker, see Chapter “Instrument Clamps.”

7.2.10. Instrument Clip Electromagnetic, 4 mm

The Instrument Clip Electromagnetic, 4 mm (Figure 56) is intended for the navigation of surgical instruments. The Instrument Clip Electromagnetic, 4 mm is suited for instruments with a cylindrical diameter of 3.9 mm to 4.0 m.

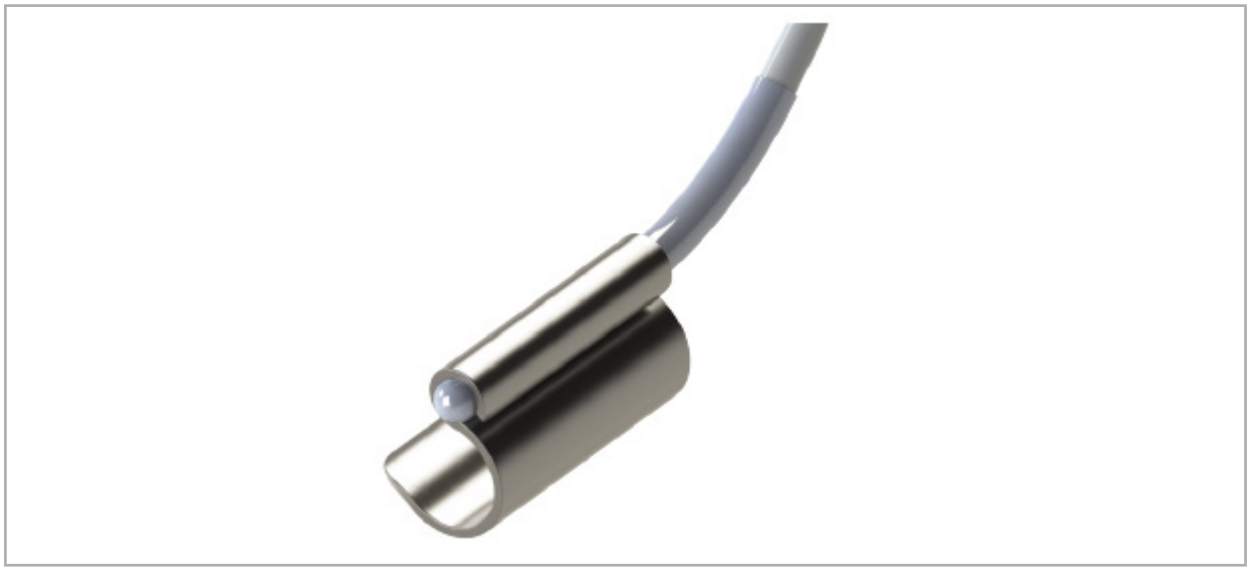


Figure 56 – Instrument Clip Electromagnetic, 4 mm

Application

1. Attach the Instrument Clip Electromagnetic, 4 mm to the suitable instrument you want to navigate. Refer to Figure 57. The Instrument Clip produces a click sound when properly fastened in position.

Figure 57 – Instrument Clip Electromagnetic, 4 mm Attached to a Suitable Instrument

WARNING

- Make sure the device is securely attached to the surgical instrument because the navigation will otherwise be imprecise and useless. If the device moves, a new calibration is required.
- Attach the sensor cable to the instrument at a suitable location using a sterile tape so that the sensor does not move due to unexpected tensile forces.

2. Calibrate the instruments. See Chapter “Calibration and Verification of Navigated Instruments.”

7.2.11. Navigation Tool Extension Cable

The Navigation Tool Extension Cable (Figure 58) is intended for sterile handling of compatible navigated instruments.

Application

1. Connect the plug of the Navigation Tool Extension Cable to one of the electromagnetic instrument ports of the navigation unit.
2. Fix the socket of the Navigation Tool Extension Cable to a sterile location with a sterile tape. Now it is possible to connect electromagnetic instruments to the instrument port in a sterile environment.
3. Conduct a general functionality test. See Chapter “Preparing Navigated Instruments.”

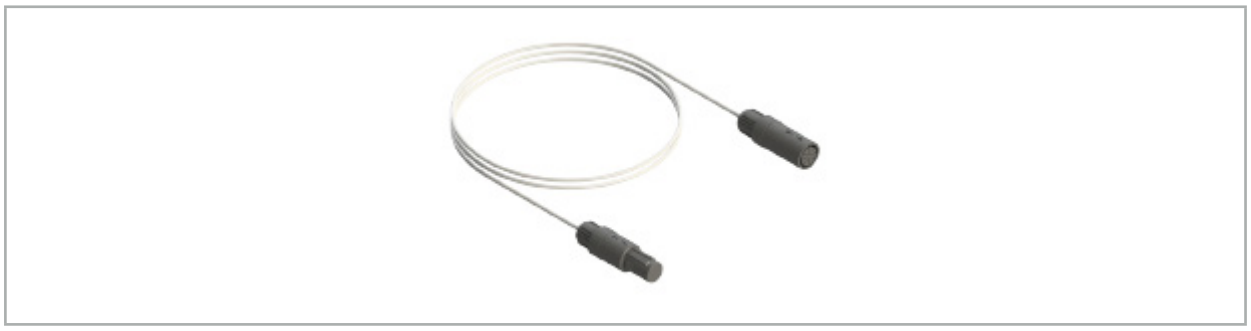


Figure 58 – Navigation Tool Extension Cable

WARNING

Ensure that the instrument connection socket is kept at least 30 cm away from the field generator. Otherwise the transmitted signal may be lost or the accuracy of the instrument may deteriorate.

7.2.12. Connecting Electromagnetic Instruments

Four ports are available at the front side of the navigation unit for connecting electromagnetic instruments. The plug clicks in audibly.

After an electromagnetic instrument is connected to the navigation unit, a dialog box appears showing the use counter of the instrument. See Chapter “Lifetime of Electromagnetic Instruments.”

7.3. Switching On the Navigation System

WARNING

Only connect this device to a mains supply that has a protective earth (PE) connection. Before connecting the power cable to a power outlet, make sure that the correct voltage (100–240 V~/50–60 Hz) is provided, and that the power cables are clean, dry, and undamaged. For the proper installation of the electrical device, consult the respective installation manual.

Switch on the navigation unit by pressing the power button. When switched on, the power button glows green. Then switch on the medical devices used in combination according to their respective manuals.

7.4. Loading Patient Data

1. Press the Loading Patient Data button (Figure 59). The Data Import dialog box appears. On the left side of the dialog, choose a data source for the import. The Plannings button contains all the plannings created and saved with the software.

Figure 59 – Data Import

2. Choose the desired planning and press the Load button.

To switch on the navigation system, see Chapter “Switching On the Navigation System” and “Starting the Navigation Software.”

WARNING

- Do not navigate in an unvalidated environment, as it may contain elements that affect navigation functions. The system can be adversely affected by electromagnetic field disturbances from other objects in the room, the close proximity of metal, and the close proximity of another Field Generator. Failure to test for such disturbances will increase the possibility of inaccurate position measurement and possible personal injury.
- During use of the navigation unit with electromagnetic position measurement, no ferromagnetic material may be within the measurement area of the Field Generator; otherwise, the precision of the navigation may be significantly reduced.

Should the power supply fail briefly during the application, the system must be restarted. The data from a running video documentation is lost.

In the unlikely event that the navigation software or the navigation unit should experience difficulties during planning or intra-operatively, restart the software and navigation unit.

8.1. Starting the Navigation

1. Once the dataset is loaded and patient registration is chosen, the message “Ready for Navigation” appears. The NAVIGATION tab is activated (Figure 61).

Figure 60 – Starting the Navigation

2. Start the navigation mode by pressing the NAVIGATION tab.

The planning data is saved automatically when changing to navigation mode.

8.2. Status Displays

During navigation mode, the status displays of Patient Tracker and navigated instruments are visualized in the taskbar on the right. The status displays visualize the visibility of the Patient Tracker and instruments that are in use with a green or a red background (Figure 61).

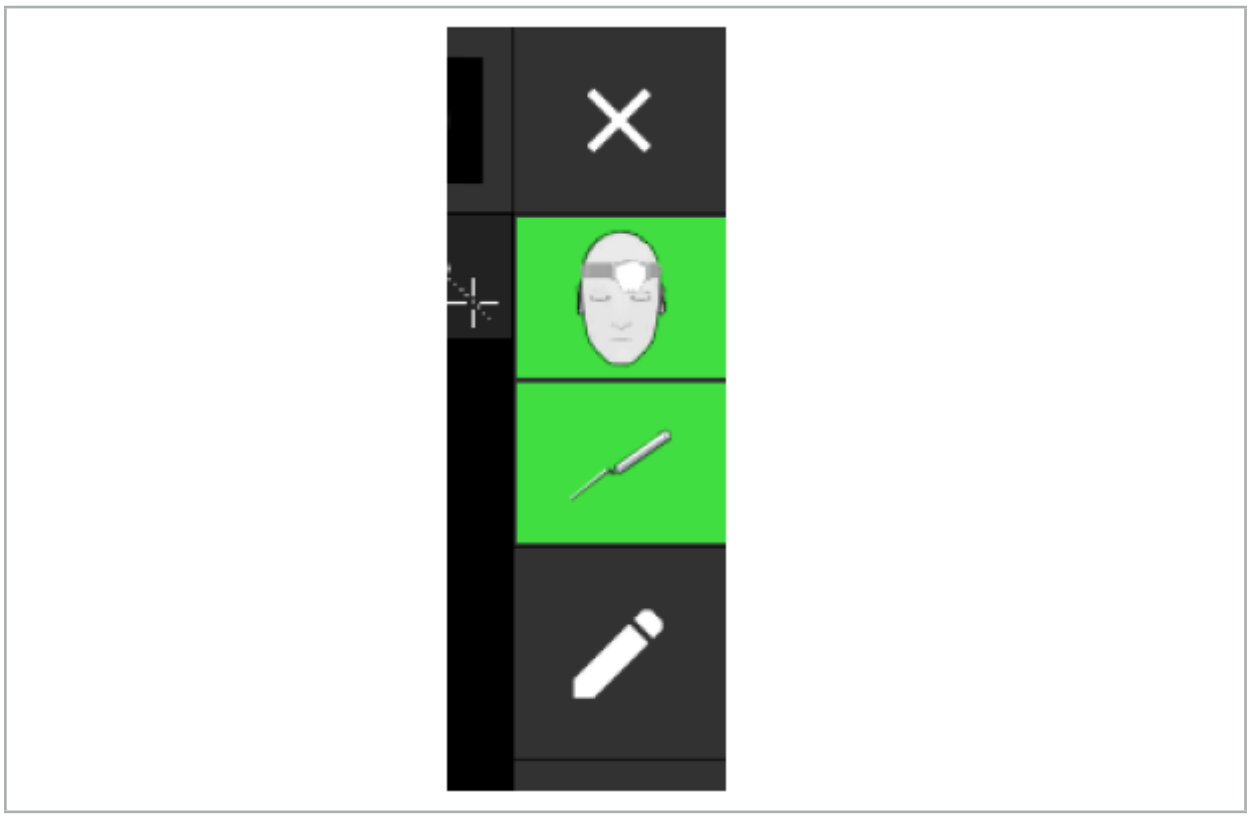


Figure 61 – Status Displays

- The upper status display shows the Patient Tracker that is in use.
- The status display in the middle shows involved imaging systems (endoscope).
- The lower status display shows the navigated instrument in the red cross hair. This can also be an involved imaging system.

8.3. Checklist: Visibility of Navigated Instruments

- The visibility of patient trackers and navigated instruments depends on the following:
- Is the instrument located within the operating range of the measuring system?
- Is the instrument undamaged, or damaged/bent?
- Are there any para- or ferromagnetic substances (iron, steel, aluminum…) within a 20 cm-radius around the Field Generator or between Field Generator and instruments?
- Are there any radiating sources of disturbances (Mobile phones, drills, mills…) within a 100 cm-radius around the Field Generator?

If the Patient Tracker is not visible, the navigated instrument will likewise be shown as not visible.

8.4. Freezing Navigation

Pausing the navigation allows you to view the patient image data manually and to change the planning components in navigation mode without having to return to planning mode.

The Edit button pauses the navigation (Figure 62). Pause mode is indicated by highlighting the icon (Figure 50).

Figure 62 – Navigation Mode

Figure 63 – Pause Mode

Planning data can be edited in pause mode. For this purpose, the buttons for working on the planning objects appear. The operation is the same as in planning mode.

The position within the slice image at the time of suspension is visualized by a grey cross hair. The distance of the current position to this suspended position is shown in the display's upper right corner. Return to the suspended position by using the cross-section view's Centering button. Continue with the navigation by pressing the Cross Arrow button again.

8.5. Conducting the Image-to-Patient Registration

Depending on the type of image-to-patient registration chosen in planning mode, different actions are conducted.

WARNING

Make sure that the Patient Tracker is securely connected to the patient because the navigation will otherwise be imprecise or useless. If the Patient Tracker is moved, a new image-to-patient registration is required.

Refer to the advice window for help.

8.5.1. Image-to-Patient Registration: Landmark

The landmark registration mode can be conducted with the following instruments:

- Precision Pointer Electromagnetic

Application

1. Touch the yellow/green flashing landmark as precisely as possible with a pointer on the patient. Hold the pointer still until you hear a confirmation tone and a new landmark starts flashing.

   WARNING

   Make sure when touching the landmarks on the patient's tissue that you do not exert any force with the pointer, so as to not move the tissue.

2. Repeat procedure until all landmarks are touched (Figure 64).

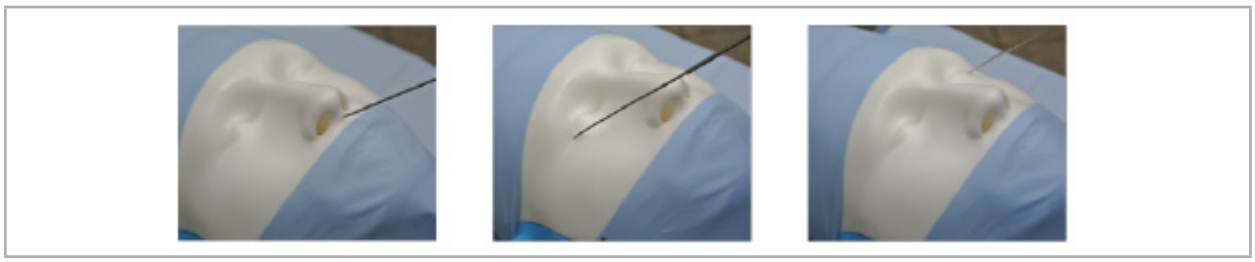


Figure 64 – Registering the Landmarks

3. After successfully touching all landmarks, the advice window shows the message, “Please confirm or increase accuracy.”

   If no sufficient correspondence between touched and planned landmarks is found, the advice window shows the message, “Please check anatomy and retouch landmarks.” The landmarks must be touched again iteratively.

   If no sufficient correspondence is found after several attempts, change to Planning mode and plan the landmarks again.

4. Check and confirm the precision of the image-to patient registration. See Chapter “Verification/Confirmation of the Image-to- Patient Registration.”

8.5.2. Image-to-Patient Registration: Surface

The surface registration mode can be conducted with the following instruments:

Electromagnetic:

- Precision Pointer Electromagnetic
- Registration Pointer Electromagnetic

Application

1. Touch the yellow/green flashing landmark as precisely as possible with a pointer on the patient. Hold the pointer still until you hear a confirmation tone and a new landmark starts flashing.

   WARNING

   Make sure when touching the landmarks on the patient’s tissue that you do not exert any force with the pointer, so as not to move the tissue.

2. Repeat procedure until all landmarks are touched (Figure 65).

3. After successfully touching all landmarks, the advice window shows the message, “Move pointer over surface.”

   If no sufficient correspondence between touched and planned landmarks is found, the advice window shows the message, “Please check anatomy and retouch landmarks.” The landmarks must be touched again iteratively.

   If no sufficient correspondence is found after several attempts, change to Planning mode and plan the landmarks
   again.

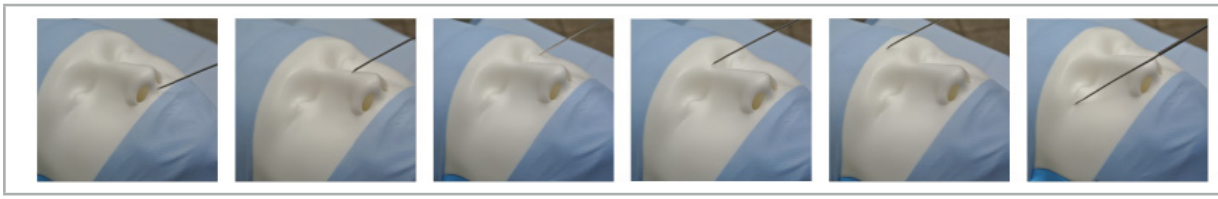


Figure 65 – Recording Point on the Surface

4. Now move the pointer over the surface of the patient in wide curves. The more prominent structures that are moved along, the more precise the registration. A small clock in the advice window indicates the progress of the registration.

5. After successfully registering, the advice window shows the message, “Please confirm or increase accuracy.”

6. Check and confirm the precision of the image-to patient registration. See Chapter “Verification/Confirmation of the Image-to- Patient Registration.”

8.5.3. Image-to-Patient Registration: Enhanced Surface

The enhanced surface registration mode can be conducted with the following instruments:

Electromagnetic:

- Precision Pointer Electromagnetic
- Registration Pointer Electromagnetic

Application

1. Touch the yellow/green flashing landmark as precisely as possible with a pointer at the patient. Hold the pointer still until you hear a confirmation tone.

2. Move along the initial path until you hear a further confirmation tone.

3. Now move the pointer over the surface of the patient in wide curves. The more prominent structures that are moved along, the more precise the registration. A small clock in the advice window indicates the progress of the registration.

   Ideally, the touching curve should be distributed over both halves of the face equally and contain bony areas such as the cheekbone, forehead, and nose bridge.

   If the surface touching cannot be completed successfully after a few minutes, the enhanced surface type image-topatient registration should be started again.

4. After successfully registering, the advice window shows the message, “Please confirm or increase accuracy.”

5. Check and confirm the precision of the image-to patient registration. See Chapter “Verification/Confirmation of the Image-to- Patient Registration.”

8.6. Verification/Confirmation of the Image-to-Patient Registration

The navigation software allows the completion of the conducted image-to-patient registration once a sufficient algorithmic accordance is reached. The advice window shows the following message, depending on which type of image-to-patient registration is conducted:

Landmark	Surface	Enhanced Surface
“Please confirm or increase accuracy.”	“Hold point to confirm.”	“Hold point to confirm.”

Verification of the System Precision

1. To check the precision, touch one or several of the patient's prominent anatomic structures (e.g. tooth gaps in the upper jaw, nose tip and creases) with a pointer and compare it to the visualized position.

2. If the correspondence (accuracy) is acceptable, hold the pointer in a position on the patient's surface until the progress display appears in the advice window and turns completely green. A confirmation tone signals the successful end of the image-to-patient registration.

3. If the correspondence (accuracy) is not acceptable, repeat the image-to-patient registration. See Chapter "Resetting the Image-to-Patient Registration.".

4. After finishing the image-to-patient registration, the 3D view switches automatically to the Video view.

WARNING

- Verify the visualization of the instrument position on several anatomic structures after the registration and repeat this during the surgery. If deviations are too large, conduct a new image-to-patient registration.
- Deviations between patient image data and reality due to old or modified image data, for instance because of tissue swelling, can severely deteriorate the precision of the system. Thoroughly check if the patient image data are suitable for navigation, e.g. by touching prominent anatomical structures.
- If the image-to-patient registration was not performed in a sterile manner, and therefore the non-sterile Patient Tracker was later exchanged for a sterile one, the verification of the image-to-patient registration must be repeated.
- Start with the navigated operation only after confirming the precision of the image-to-patient registration.
- Make sure that the Patient Tracker is securely attached to the patient during use, as the navigation would otherwise be inaccurate or useless. If the Patient Tracker moves, the image-to-patient registration must be repeated.

8.7. Resetting the Image-to-Patient Registration

To reset the Image-to-Patient Registration the following options are available:

- Hold an already registered/verified instrument at the interaction area "x" of the patient tracker until the progress bar in the advice windows is full. If the patient tracker does not have an interaction area "x", the registration cone of the patient tracker or calibration body can be used alternatively for resetting the Image-to-Patient Registration. Hold an already registered/verified instrument at a plane calibration area until the progress bar in the advice windows is full.

- Switch to planning mode and then again to navigation mode.

8.8. Visual Checking of the Navigation Information

If the accordance between the navigated instrument position shown on the screen and the real position on the patient is not sufficient, repeat the image-to-patient registration. If no sufficient accordance is reached even after conducting the imageto- patient registration repeatedly, continue the surgery without support of the navigation system.

Note that the navigation system is an aid to orientation, whose precision can be influenced by errors in handling, the recording of images, or other technical errors. The conventional view of the surgery site remains most important for conducting the surgery.

WARNING

Each treatment process may only be performed if the visual observation of the systemic effects is assured.

8.9. Virtual Extension of the Tool Axis

During navigation, you can virtually extend the axis of the tool you are using by clicking the button in the top right corner of the view. This opens a slider which allows you to choose a distance. The displayed tool position is then moved by this amount along the tool axis. A visual guide originating from the actual instrument position should help you estimate how far away certain features in the image volume are from the current tool position (Figure 66).

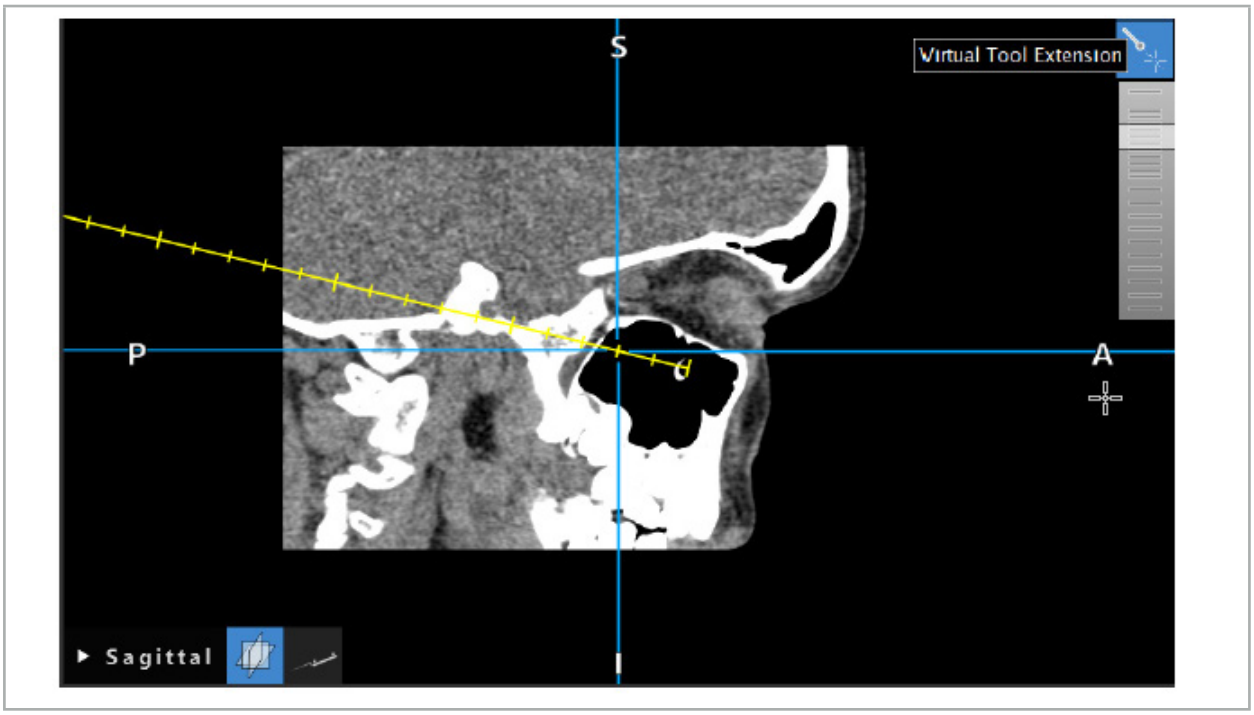


Figure 66 – Navigating with Extended Tool Axis

Moving the displayed cross position in most cases also changes which slice in the volume is displayed. The tool axis is normally not completely located within this slice. Only the cross position is guaranteed to be part of the displayed slice view.

8.10. Recording an Operation without Patient Image Data

The navigation software provides the option to record screenshots and screen recordings of the endoscopic video feed during an operation, even if volumetric image data of the patient does not exist or for some reason cannot be used. Planning and navigation features are unavailable, but it is still possible to display and record the endoscopic video image.

To use the navigation software without patient data, select New Record from the Data Import dialog. See Chapter “Loading Patient Image Data.” You are asked to enter some general information that is associated with the record, like name and date of birth of the patient. After filling out the fields, press Create to use the record.

You cannot enter the navigation mode, but you can take screenshots and recordings as usual. These are associated with the record that can be found under Plannings in the Data Import dialog.

9. Post-operative Procedures

After the navigated surgery is finished, take the following post-operative steps:

1. Shut down the navigation system.
2. Detach the generator with mounting arm from the operating room table.
3. Remove the Patient Tracker.

9.1. Closing the Navigation Mode

To end the navigation mode, do either one of the following steps (Figure 67):

1. Press the PLANNING tab to switch to planning mode.
2. Press the End Software button to end the navigation software.

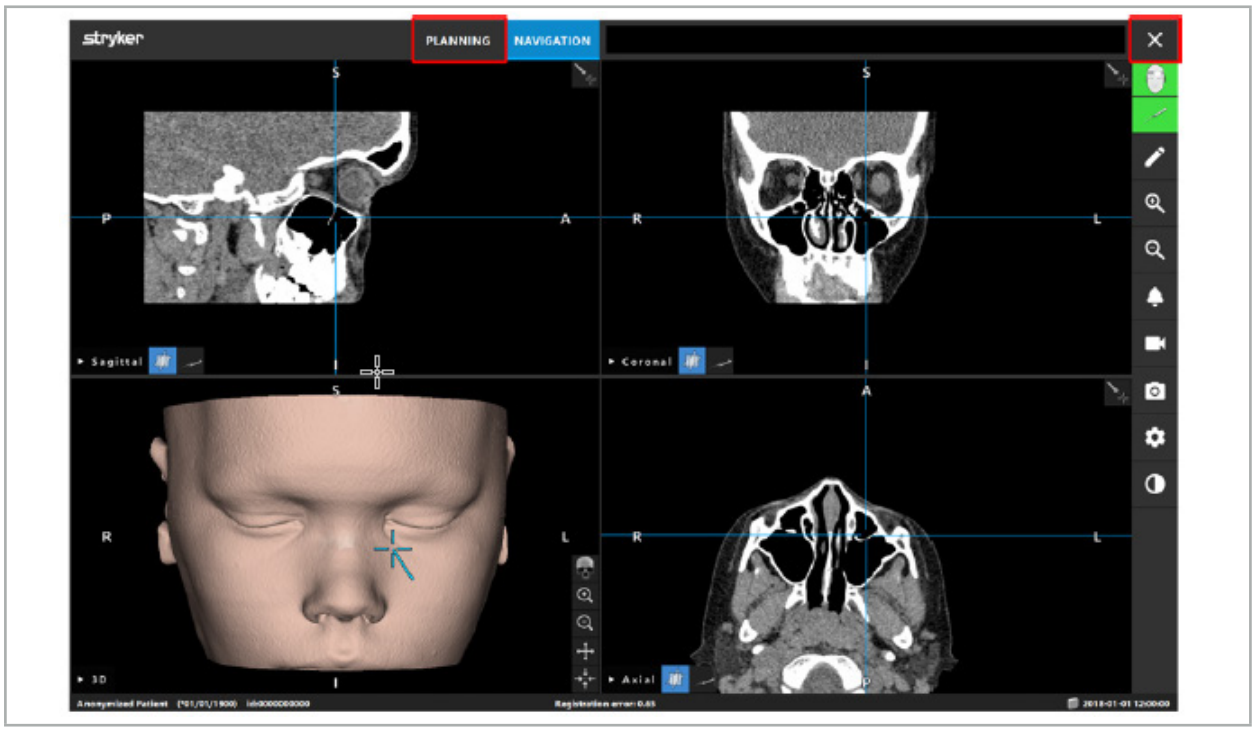


Figure 67 – Closing the Navigation Mode or Software

9.2. Closing the Navigation Software

1. To close the navigation software, press the End Software button.
2. If planning data changed since the last automatic saving, the Save Planning dialog appears, giving you the option to save the planning data before closing the software.

9.3. Switching off the Navigation System

1. To safely end the operation of the navigation system, close all opened windows and shut down the computer by clicking the Windows button and then selecting Shut Down in the submenu that appears.
2. After the computer is shut down, turn off the navigation unit with the On/Off button. After the navigation unit is turned off, the green LED on the On/Off-button switches off.

CAUTION

For full disconnection from the electricity grid, the power plugs must be pulled out of the socket or the power supply removed in some other suitable way.

After using the electromagnetic system, make sure that instruments that cannot be sterilized again are disposed of.

Regarding additional post-operative steps such as disassembly, reprocessing, and storage of the individual instruments and devices, see the respective manuals.

9.4. Detachment of the Field Generator and Mounting Arm

1. First remove the generator by unscrewing it from the mounting arm.
2. Remove the mounting arm from the standard rail by turning the rail screw handle counter-clockwise.

9.5. Detachment of the Patient Tracker

1. Remove any secondary fixation from the Patient Tracker.
2. Carefully remove the Patient Tracker from the patient skin.
3. Remove the tab from the tracker, and dispose of the tab.
4. Do not reuse the tab.

10. Maintenance

WARNING

The device must only be used if it is checked and maintained regularly according to the respective legal requirements and directives.

CAUTION

- If operating or adjusting devices other than those indicated in this manual are used, or other operation procedures are used, this can lead to dangerous radiation exposure.
- Stryker holds no liability for the equipment's operational safety if the product is opened, repaired, or modified without authorization. All guarantees during the warranty period thereby cease to exist.

The user is required to maintain a medical equipment logbook including information about conducted repairs and maintenance work, as well as types of work done, the company that has conducted the repairs, and other relevant information.

Navigation systems need a regular maintenance checkup by the manufacturer every two years and regular routine checkups by the operator/user. These maintenance checkups are necessary to ensure the safe and reliable use of the product.

During the warranty time of two years, starting from the handover to the end customer, any changes to and/or repairs of Stryker products may only be conducted by staff authorized by Stryker, and only original spare parts may be used.

Refer to the REF and serial numbers when making enquiries or ordering spare parts.

After warranty time has run out, arrange how to conduct maintenance work with your respective Stryker representative. Specific service agreements are available for maintenance.

Even though the operator does not conduct maintenance work himself, he is still responsible for ensuring that all required maintenance work is conducted before the product is used on the patient.

11.1. Transport

WARNING

- Before transporting the components of the navigation system, it is necessary to process them in such a way that contamination is ruled out. To achieve this, all components must be reprocessed (cleaning/disinfection/sterilization) according to the instructions provided.
- The instruments may only be sent back to the manufacturer in a cleaned, disinfected, and sterilized condition. Sharp or pointed components need to be sent back in a protected state.

CAUTION

Prior to sending the device for maintenance, remove the data drive so that any private patient data is not shared with Stryker.

For transport advice, refer to the components' specific manuals.

11.2. Disposal

For disposal advice, refer to the specific manuals of the components.

For technical data of the specific products named in this manual, refer to the individual manuals for these products.

12.1. Environmenal Conditions

Environmental Limitations	Operation
Temperature:	between 10 °C and 30 °C
Relative humidity:	30 % to 75 %
Atmospheric air pressure:	between 80 kPa and 106 kPa

12.2. Essential Performance Features

- The product detects and visualizes defined navigation positions with an accuracy of at least 2 mm in radiological images.
- The delay produced in processing the incoming real-time video image data must not exceed 250 ms.
- No undetected data corruption.
- No unnoticed freezing of the instrument display.
- No unnoticed freezing of the incoming real-time video image data.

12.3. Compatible Imaging Systems

The navigation software can import image data in DICOM 3.0 standard. This standard is supported by all of the marketrelevant manufacturer's devices.

The list of compatible systems includes at least devices by:

Philips	Tomoscan M/EG R4.0
Siemens	Somatom 4+, 4+ Volume Zoom
Marconi	Picker PQ 2000, PQ 5000
Morita	3D Accuitomo

Before first use of the navigation system in the clinical routine, check system compatibility by importing a test image.

Should problems occur while loading image datasets, contact the manufacturer.

13. Routine Checkups

Before each use, check that all necessary maintenance work is carried out in accordance with local policy and procedure. Before use, check the device functionality and inspect the product components for outer defects.

Before each use, check the instruments for:

- Correct assembly and function
- Cracks
- Surface damage
- Loose parts
- Other damage

Check the product feed cable and connecting cable routinely for damages. Order spare parts if necessary.

14. Lifetime of Electromagnetic Instruments

The electromagnetic instruments contain delicate electronics whose useful lifetime is limited due to reprocessing and sterilization. When plugging in an instrument, the number of uses is indicated as follows (Figure 68):

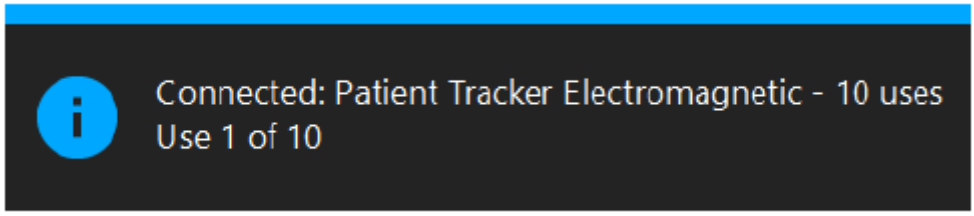


Figure 68 – Use Counter

The use counter automatically increases for the connected instrument when entering navigation mode. The counter increases only once during a surgery. Accordingly, it is possible to unplug and plug in again an instrument during a surgery. If the wrong patient image data are loaded, it is possible to change to the right one within 30 minutes after the beginning of navigation without increasing the use counter again.

Depending on the country-specific regulatory requirements, the number of uses can be restricted. The system automatically disables the instruments after reaching the maximum number of uses and displays the following warning (Figure 69):

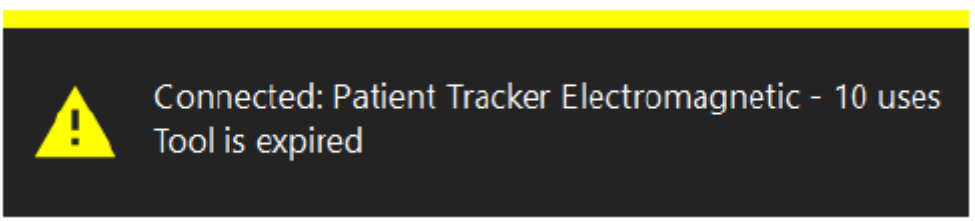


Figure 69 – Use Cycles Exceeded

If the number of uses is not restricted due to country-specific regulatory requirements, the following warning is displayed when the recommended number of uses is exceeded (Figure 70):

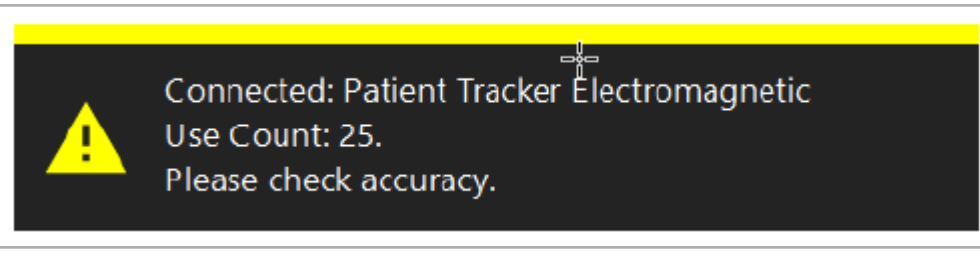


Figure 70 – Consider Number of Use Cycles

WARNING

- To maintain accurate use counting, always connect electromagnetic instruments at least once to the navigation unit during navigated surgery if they are taken from sterile packaging. If resterilizing instruments without connecting them to the navigation unit during surgery, the use counter may become inaccurate to indicate the actual number of reprocessing cycles experienced by the instruments. Inaccurate use counting may lead users to use instruments which have exceeded their useful life.
- Always keep replacement electromagnetic instruments at hand and reorder in time based on expected surgery schedule.

The user carries full responsibility for the use of instruments that have exceeded the recommended number of use cycles.

15. Special Application Instructions for Instruments

As long as other materials are not specified explicitly, the instruments delivered by Stryker or bought additionally are made out of stainless steel or a titanium alloy.

In order to avoid corrosion, instruments made out of stainless steel may not be stored on base metal surfaces (chromed surfaces) or close to chemicals, as the transmission of flash rust cannot be totally excluded. Due to their composition, the instruments are not suited to be used together with other magnetically sensitive medicine products (MRI), devices, or instruments.

The instruments guide electricity and must not be placed between the patient and a respective power source in order to avoid electrical shocks.

The products are sensitive to pushing, throwing, dropping, use of steel brushes and abrasives, as well as heavy exertions of force. It is therefore absolutely necessary to treat the products with care.

16.1. Devices

Endoscope camera unit:

- Outputs: DVI / SDI / HD-SDI / 3G-SDI / S-VIDEO / VGA
- Resolution: minimum PAL 768 x 572 - maximum 1080p60
- Endoscopic image delay in combination with 60 Hz medical monitor: maximum 50 ms
- Camera unit according to IEC 6060-1 and provides 2 MOPP to the camera
- Lightsource according to IEC 60601-1 and provides 2 MOPP towards the patient

Camera head:

- Resolution: PAL (752(H) x 582(V)) or higher

Endoscopes:

- Diameter: 4 mm
- Visual angle: 0° / 30° / 45°
- Default bayonet connector

Medical monitors:

- Inputs: DVI or HDMI
- Resolution: 1280 x 1024 or higher, 1920 x 1080 recommended
- Colors: 16.7 million colors
- Maximum delay of 50 ms in combination with an endoscope camera unit
- Medical grade
- Fulfills IEC 60950 or IEC 60601-1

The device is compatible with the following monitors:

- 240-031-020 VisionPro
- 240-031-050 4K Display

Keyboard/mouse (medical or hygiene grade):

- Connector: USB 2.0 or higher
- IBM Compatible

The device is compatible with the following:

- 8000-030-010 Medical keyboard U.S./international
- 8000-030-020 Mouse, wired
- 8000-030-021 Mouse, wireless
- 8000-030-011 Medical keyboard GER
- 8000-030-012 Medical keyboard UK
- 8000-030-013 Medical keyboard ES
- 8000-030-014 Medical keyboard FR
- 8000-030-015 Medical keyboard Nordic

The device is compatible with the following cart:

- 8000-030-002/KU.2763.903 Pro Equipment Cart

CAUTION

When moving the cart with its components:

- The monitor must be turned 90° degrees sidewards.
- The cart with all components may only be slowly pulled by the handle in a backwards direction. When being pulled over any threshold—including cables or hoses—the speed of movement must be reduced significantly.

For further information, please review the relevant user instructions of the cart and its components.

Should you have questions regarding compatible devices and products, contact Stryker.

16.2. Disposables

Accessory	REF
Patient Tracker Tabs	8000-100-001

stryker

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U.S. Patents: www.stryker.com/patents

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