Scopis® ENT Software

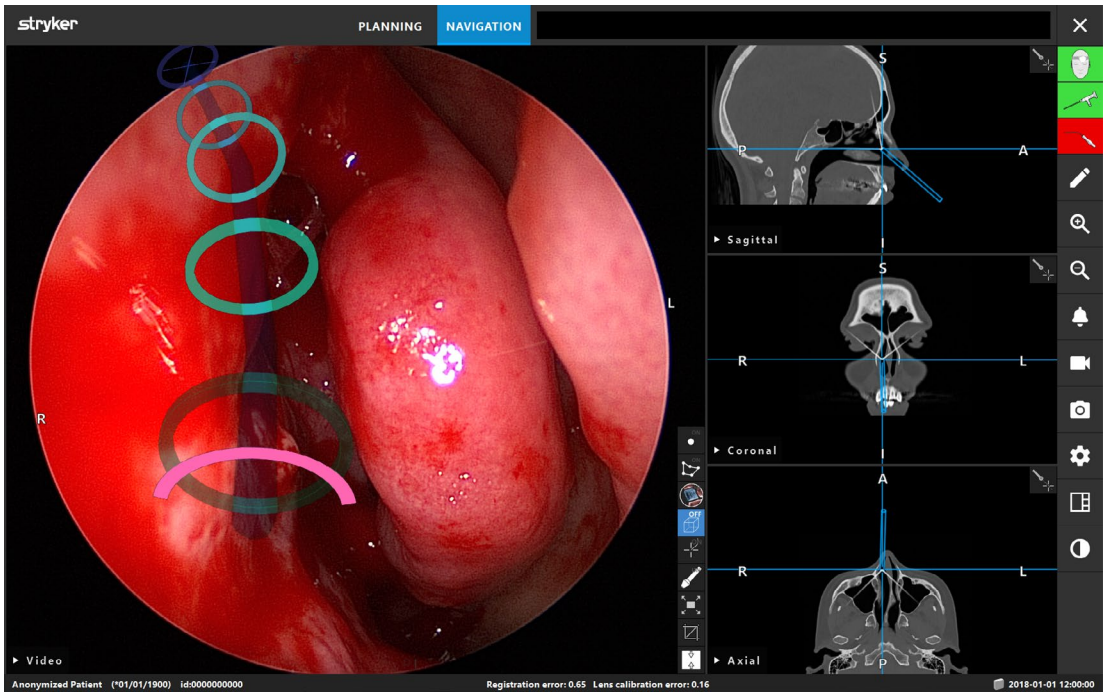
REF 8000-021-001

Scopis® ENT Software with TGS®

REF 8000-021-002

Version 3.6

User manual



Rx Only

EN

Table of Contents

1. Introduction

This document provides information intended to ensure the effective use of the Stryker ENT Navigation System with the Scopis ENT Software, and the Scopis ENT Software with TGS. The document guides you through the steps required to use the system and contains information on features of the application and frequently performed tasks.

1.1. Conventions used in this document

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

Convention	Definition
1.	Step-by-step instruction.
•/-	Unordered list of items or list of actions requiring no special order
Italics	Screen texts (menu commands, file paths, etc.)
“”	References to sections are put in quotation marks
[TGS ONLY]	This tag indicates that the objects, processes or applications in question are only available in Scopis ENT Software with TGS (REF 8000-021-002) and not in Scopis ENT Software (REF 8000-021-001).

1.2. Definition of signs and symbols

The following table provides definitions of signs and symbols used in this document.

Sign	Definition
	General warning sign. Signifies a general warning.
 WARNING	The signal word WARNING indicates a hazardous situation that, if not avoided, could result in death or serious injury.
 CAUTION	The signal word CAUTION indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.
	Note: Used to supplement or clarify information

1.3. Definition of abbreviations

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

Abbreviation	Definition
AR	Augmented Reality
CBCT	Cone Beam Computed Tomography
CD	Compact Disc
CT	Computed Tomography
DICOM	Digital Imaging and Communications in Medicine
DVD	Digital Video Disc
DVI	Digital Visual Interface
EM	Electromagnetic
ENT	Ear, Nose, Throat
FESS	Functional Endoscopic Sinus Surgery
HDMI	High Definition Multimedia Interface
HD-SDI	High Definition-Serial Digital Interface
HIPAA	Health Insurance Portability and Accountability Act
IBM	International Business Machines Corporation
ID	Abbreviation for “identity” or “identification”
IEC	International Electrotechnical Commission
IFAC	International Frontal Sinus Anatomy Classification
IFU	Instructions for Use
ISO	International Organization for Standardization
ISO_IR	ISO International Register of Coded Character Sets
JPEG	Joint Photographic Experts Group
LED	Light Emitting Diode
MAC	Media Access Control
MD	Medical Devices
MOPP	Means of Patient Protection
MR	Magnetic Resonance
MRI	Magnetic Resonance Imaging
PACS	Picture Archiving and Communication System
PAL	Phase Alternating Line
PET	Positron Emission Tomography
RF	Radio Frequency
REF	Product Reference Number
SDI	Serial Digital Interface
S-VIDEO	Separate Video
SPECT	Single-Photon Emission Computed Tomography
STL	Stereolithography
TGS	Target Guided Surgery
UI	User Interface

Abbreviation	Definition
UID	User Interface Design
USB	Universal Serial Bus
UTF	Unicode Transformation Format
VGA	Video Graphics Array

1.4. Definition of terms

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

Term	Definition
Accessories	Instruments and devices used with the Electromagnetic Navigation Unit in order to achieve the intended use of the Stryker ENT navigation system, facilitate its use or enable its functions. For example: Trackers, calibration devices, adapters, etc.
Active instrument	A currently navigated instrument whose position is visualized by the navigation system. If multiple instruments are navigated, the following factors define the choice of the active instrument: Instrument type priority, first-come-first-serve, visibility and the closeness to the patient tracker.
Clamp	An umbrella term which encompasses the following instrument clamps: • Instrument Clamp, forceps • Instrument Clamp, 2 - 6 mm • Instrument Clamp, 6 - 10 mm • Instrument Clamp, 10 - 16 mm
Endoscope calibration	When calibrating an endoscope, the system not only identifies the position of the endoscope camera but also calibrates the endoscopic image in order to enable overlays of planning objects and instrument tool position information onto the endoscopic camera image.
Instrument calibration	In order to be navigated by the system, conventional surgical instruments must be extended by a tracker and then calibrated before use. By means of calibration, the navigation system identifies the position of the instrument tip.
Navigated instrument	An instrument whose position is identified and may be visualized by the navigation system. This is either an instrument with an attached tracker or a tracker itself or an instrument with an integrated electromagnetic sensor.
Navigation system	Same as: Stryker ENT Navigation System
Operator	Any natural or legal person who operates or controls the device or, where this is provided for in national legislation, to whom decisive economic power over the technical functioning of the device has been delegated.
Patient registration	Before every navigated surgery, it is necessary to register the patient. As a result of patient registration, the software determines the position of the patient anatomy and establishes a match between the patient anatomy and the patient image data. There are three different types of registration: *Landmark*, *Surface* and *Enhanced Surface*.
Scopis Navigation Software	An umbrella term which encompasses both Scopis ENT Software and Scopis ENT Software with TGS
Stryker ENT Navigation System	A system that consists of the Scopis software, the Electromagnetic Navigation Unit with the Field Generator, and accessories. See section „For use with“ for further details.

Term	Definition
Tracker	A device with a built-in electromagnetic sensor used by the navigation system to track the position of a patient, a surgical instrument or an endoscope. The position is used to compute navigational information, which is then displayed on the screen. A tracker can be one of the following: • Patient Tracker Electromagnetic • Patient Tracker Electromagnetic-10 uses • Endoscope Tracker Electromagnetic • Universal Tracker Electromagnetic • Instrument Clamp Electromagnetic Sphere • Instrument Clamp Electromagnetic Universal

1.5. Definition of symbols and numbers

The following tables define the symbols used in this document, on the product label, on the products and in related user documentation in compliance with the following standards:

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

Symbols and numbers	Name: Definition
	General warning sign: Signifies a general warning.
	Refer to instruction manual or booklet: Signifies that the user instruction manual must be read.
	No access for people with active implanted cardiac devices: Prohibits 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, labelling, and information to be supplied - Part 1 General requirements.

Symbols and numbers	Name: Definition
 5.1.1	Manufacturer: Indicates the medical device manufacturer as defined in the European Union harmonization legislation.
 5.1.3	Date of manufacture: Indicates the date when the medical device was manufactured.
 5.1.6	Catalog number: Indicates the manufacturer's catalog number so that the medical device can be identified.
 5.4.3	Consult instructions for use: Indicates the need for the user to consult the instructions for use.
 5.1.5	Batch code: Indicates the manufacturer's batch code so that the batch or lot can be identified.

Label-Specific Symbols

Symbols and numbers	Name: Definition
UDI	Unique device identifier
MD	Indicates a medical device, according to European Union harmonization legislation.
UDI	Quantity: Indicates the number of medical devices in the packaging.
GTIN	Global Trade Item Number

21 Code of Federal regulations (CFR), section 801.109(b)(1)

Symbols and numbers	Name: Definition
Rx Only	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

2. Safety information

Refer to user documentation

For safety information related to the application, refer to the safety information document supplied with the application.

For safety information and instructions related to image acquisition, refer to the imaging protocol documents supplied with the application.

For safety information and instructions related to accessories and the Electromagnetic Navigation Unit, refer to the instructions for use supplied with these products.

The surgeon must consider the particular condition of the patient and perform the necessary adjustments if required.

Safety and caution must always be applied before proceeding.

2.1. General safety information

WARNING

- This document is part of the product and must be accessible to personnel at all times. It must be provided to subsequent owners or users.
- The software may only be used for its intended purpose and in accordance with this document and all current versions of the user documentation supplied with the Stryker ENT Navigation System. Read all these documents carefully.
- The healthcare provider performing any procedure is responsible for determining the appropriateness of using the product and for the specific technique for each patient. Stryker, as a manufacturer, does not recommend any specific surgical procedure.
- Use only Stryker-approved products unless otherwise specified. Refer to section „For use with“ for a list of products that are part of the Stryker ENT Navigation System. When using third-party products, follow specifications indicated in the user documentation of the Stryker ENT Navigation System.
- Do not service the system and its accessories. They do not contain any parts the user can service. If service is required, contact your Stryker sales representative.

CAUTION

- Unauthorized modifications of the product are forbidden for safety reasons.
- Use the system for therapeutic applications only if the surgery can also be performed conventionally. Otherwise a second and equivalent system must be available.

- The user or patient must report any serious product-related incident to both the manufacturer and the national competent authority of where the user or patient is established.
- When using third-party products, carefully read and follow instructions provided with those products.

2.2. Cyber security and patient data privacy

WARNING

- Make sure to read the information on cyber security issues (e.g. phishing attacks or USB-based malware) and patient data privacy provided in this document, in the safety information document, and in the security operations manual, and be aware of cyber security defences such as virus scanners and encryption.
- Operators and users must adhere to the respective national requirements regarding protection of patient data (e.g. HIPAA). Only persons authorized by the operator may use the navigation system or the Scopis Planning Software. Protect the system from unauthorized use by means of a password.
- Connecting the Electromagnetic Navigation Unit to a network or USB media can put the patient, the user, or third parties at risk. Your organization's risk management must determine, analyze, evaluate, and control these risks to avoid potential damages (see especially ISO 80001-1). Pay special attention to risks associated with the privacy of patient image data, system and data integrity, as well as system availability.
- Perform changes to the system's configuration in a controlled manner. Create restore points before making changes.
- Changes to the network 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 network.
- User is solely responsible for ensuring timely installation of operating system updates. User failure to install system updates may increase risk of vulnerabilities.
- Use the integrated anti-virus software on the navigation system for on-access and full scans at regular intervals.
- Connect the system only to protected and monitored networks to prevent malicious activity or policy violations. Track MAC addresses and only give known devices access to this network.
- Always use a validated user authentication and authorization scheme such as Windows domain logon to prevent unauthorized access to the navigation system and unauthorized downloads of patient data via media ports.
- If a cyber security attack has been detected, do not use the device until the attack has been responded to adequately and the device integrity has been restored. Do not use a compromised navigation system. Contact Stryker for help.

CAUTION

- The Stryker ENT Navigation System and computers running the Scopis Planning Software only must be used in physically protected areas such as the doctor's personal office or the operating room.
- It is recommended to use only encrypted USB sticks for transferring patient data from and to the navigation system.

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

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

2.3. User group

The product is intended solely for use by healthcare professionals (surgeon/resident, nurse/professional caregiver) educated in computer-assisted surgery and thoroughly familiar with the instructions for use and with the operation of this product.

CAUTION

- To request an additional in-service instruction, contact Stryker.
- The system must not be used by persons who suffer from dyschromatopsia (color blindness), in particular red-green impairment or red-green blindness.

3. For use with

WARNING

Use only Stryker-approved products, unless otherwise specified.

3.1. Software

For information related to compatible software, refer to the table below.

Article Name	REF
Scopis Planning Software	8000-021-005

3.2. Hardware

For information related to compatible hardware, refer to the table below.

Article Name	REF
Electromagnetic Navigation Unit	8000-010-003
Field Generator	8000-010-004
Field Generator Mounting Arm	8000-010-005
Patient Tracker Electromagnetic	8000-040-001
Patient Tracker Electromagnetic-10 uses	8000-040-002
Precision Pointer Electromagnetic	8000-050-001
Pointer Electromagnetic	8000-050-002
Registration Pointer Electromagnetic	8000-050-003
Suction Tube Frazier Electromagnetic	8000-050-005
Suction Tube Eicken Electromagnetic	8000-050-006
Navigation Tool Extension Cable	8000-050-011
Endoscope Tracker Electromagnetic [TGS ONLY]	8000-060-001
Calibration Body Electromagnetic	8000-060-002
Universal Tracker Electromagnetic	8000-060-006
Instrument Clamp, forceps	8000-060-010
Instrument Clamp, 2 - 6 mm	8000-060-011
Instrument Clamp, 6 - 10 mm	8000-060-012
Instrument Clamp, 10 - 16 mm	8000-060-013
Instrument Clamp Electromagnetic Sphere	8000-060-020
Instrument Clamp Electromagnetic Universal	8000-060-021
Instrument Clip Electromagnetic, 4 mm	8000-060-030 (discontinued product)

Note that the product may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Contact your Stryker representative for product availability.

3.3. Disposables

For information related to compatible disposables, refer to the table below.

Article Name	REF
TGS Guidewire	8000-060-009
Patient Tracker Tabs	8000-100-001

3.4. Additional equipment

For information related to additional compatible equipment, refer to the table below.

Article Name	REF
Medical keyboard U.S./international	8000-030-010
Mouse, wired	8000-030-020
Mouse, wireless	8000-030-021
Medical keyboard GER	8000-030-011
Medical keyboard UK	8000-030-012
Medical keyboard ES	8000-030-013
Medical keyboard FR	8000-030-014
Medical keyboard Nordic	8000-030-015
Pro Equipment Cart	8000-030-002

4. Indications for use and contraindications

4.1. 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:

- Transsphenoidal 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

4.2. Intended use

Scopis ENT Software

The Scopis ENT Software is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures together with the Stryker ENT Navigation System. The software application is indicated for any medical condition in which the use of computer-assisted surgery may be appropriate.

Scopis ENT Software with TGS

The Scopis ENT Software with TGS is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures together with the Stryker ENT Navigation System. The software application is indicated for any medical condition in which the use of computer-assisted planning and surgery may be appropriate.

4.3. Contraindications

None known.

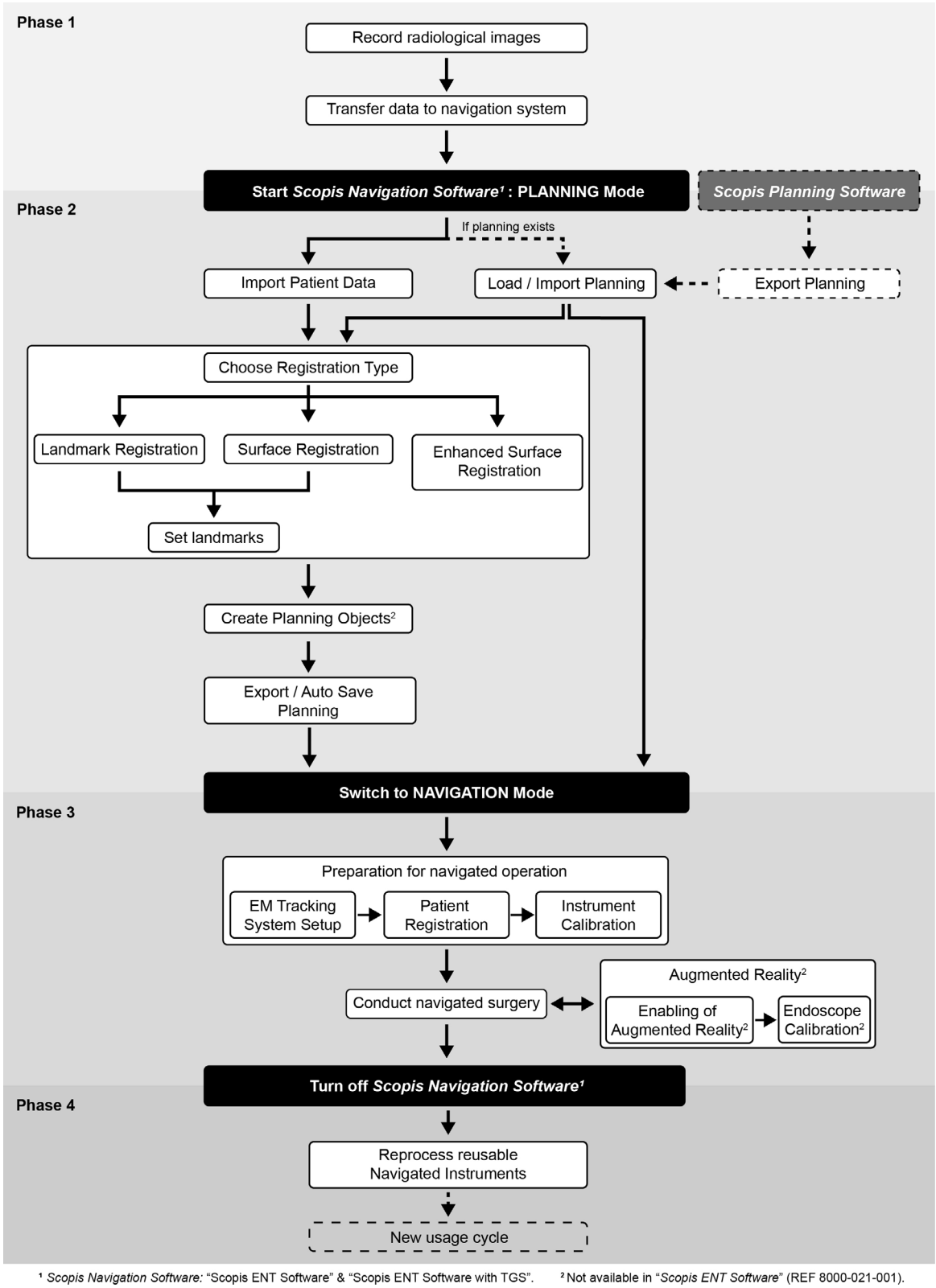
5. Essential performance

5.1. Essential performance features

The essential performance of the Stryker ENT Navigation System with the Scopis ENT Software applications is defined as follows:

- Movements of the instrument position must be updated on the screen within 2 seconds.
- The product detects and visualizes defined navigation positions with an accuracy of at least 2.0 mm in radiological images.

6. Navigated surgery cycle



¹ *Scopis Navigation Software:* "Scopis ENT Software" & "Scopis ENT Software with TGS". ² Not available in "*Scopis ENT Software*" (REF 8000-021-001).

Figure 1 Navigation surgery cycle

The use of the navigation system can be split into 4 phases.

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

Ordering radiological image data

Note the following points, and follow the detailed instructions for acquiring suitable images for navigation in Section „Recording radiological image data“ and in the imaging protocol supplied with the software application.

- 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 should not be older than three weeks, but must only be used if the patient anatomy has stayed the same. However, recording of new images is necessary if suspected that the face geometry has significantly changed.
- Image resolution should be set to a slice thickness and pixel resolution of less than 1 mm or finer for optimal navigation results. Also consider that the areas needed for patient registration are included in the scan.
- Image datasets from modalities such as CT, CBCT and MRI are supported.
- PET or SPECT images can only be used as additional data sets intended for image fusion. The patient registration can not be conducted on PET or SPECT images alone.
- To store the data, use a USB Drive, a PACS (Server), a DVD, or a CD.

Choosing a registration type

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

The software offers three types of patient registration: landmark registration, surface registration, and enhanced surface registration. Refer to Section „Patient registration“ for more information on patient registration.

Choosing a patient tracker and positioning

There are two types of patient trackers that only differ in their maximum use count and serve to reference the patients. Refer to Section „Lifetime of electromagnetic instruments“. They are therefore firmly attached to the patient near the operating area, which enables the localization of the patient. For more details, refer to Section „Field generator setup“.

7. 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. Refer to Section „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 specified in the imaging protocol supplied with the software application. The imaging protocol must be forwarded to your radiology department.
- Despite support from the standardized DICOM interface, problems may occur with the data exchange or data loading.

CAUTION

Compatibility of image data with the navigation system is only ensured if you follow requirements for image data specified in the imaging protocol provided with the software application.

A test data set, provided by the radiology department, must be used to confirm that the exported image data of the device is compatible with the navigation software.

7.1. 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, which will expose the patient to increased radiation.

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

Note that in certain cases the patient registration can only be conducted if bone screws are placed near the operating area as no clearly identifiable anatomical features are present in this area. These screws or specific areas of the face or of the patient's anatomy must be visible from within the image data. Refer to Sections „Selecting the patient registration type“ and „Instructions for lateral skull surgery“.

Eye protection

WARNING

If you use an X-ray eye protection, follow instructions set out in this document and in the imaging protocol. An X-ray eye protection must not rest directly on skin, otherwise the patient registration accuracy may be compromised.

X-ray eye protections can have an impact on the accuracy of the (*Enhanced*) *Surface Registration*. If an eye protection was necessary for the recording of radiological images, the software will try to identify the eye protection to avoid a negative impact on patient registration accuracy. Refer to Section „Optimization of patient image data visualization“.

7.2. Saving data

WARNING

- When saving the data set, make sure to use the correct patient name.
- 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 Stryker recommends using uncompressed data or lossless compression for optimal image quality.

Do not save secondary reconstructions or other image data on the same storage medium. If multiple data sets are created, each data set must be stored in a separate directory and must be stored with a separate series instance UID.

7.3. 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.

7.3.1. DICOM tag IDs and tag names

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
0002,0010	Transfer Syntax UID
0008,0016	SOP Class UID
0008,0018	SOP Instance UID
0008,0020	Study Date
0008,0021	Series Date
0008,0030	Study Time
0008,0031	Series Time
0010,0010	Patient's Name
0010,0020	Patient ID
0020,000E	Series Instance UID
0020,0010	Study ID
0020,0011	Series Number
0020,0032	Image Position (Patient)
0020,0037	Image Orientation (Patient)
0028,0002	Samples per Pixel
0028,0010	Rows

Tag ID	Tag Name
0028,0011	Columns
0028,0030	Pixel Spacing
0028,0100	Bits Allocated
0028,0101	Bits Stored
0028,0102	High Bit
0028,0103	Pixel Representation
7FE0,0010	Pixel Data

7.4. Character set support

7.4.1. Character set descriptions and DICOM defined terms

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
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

8. Introduction to user interface

8.1. UI elements

Message bar

During the entire application, instructions appear in the black upper-right Message Bar to assist you with your current workflow (Figure 2).

Figure 2 Message bar

Pop-up messages

At times the software displays pop-up messages with additional important information. The messages without buttons do not require user interaction. They remain visible for about 60 seconds before they disappear automatically. A mesage provides information e.g. about the software license state, an instruments lifetime etc.

Note that there are different types of pop-up messages, which can be recognized by the respective icons. A yellow triangle signifies warning, a blue circle relates to simple information, and errors are indicated by a red hexagon (see example below).

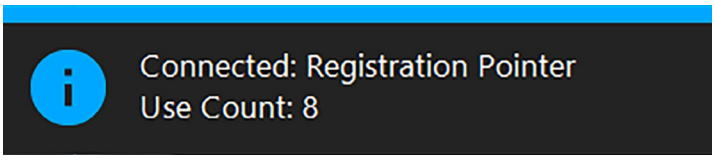


Figure 3 Information pop-up message

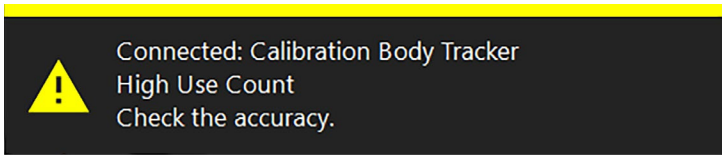


Figure 4 Warning pop-up message

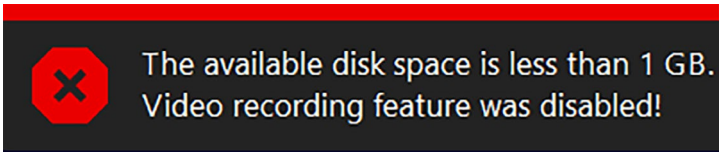


Figure 5 Error pop-up message

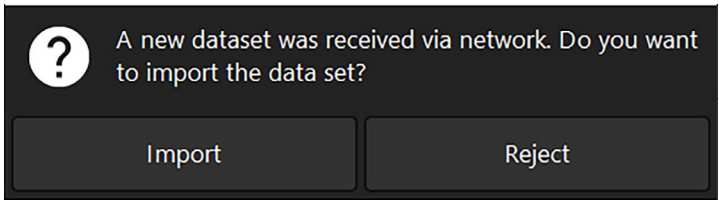


Figure 6 Import pop-up message

Side panel

The side panel is available both in planning as well as in navigation mode of the software. It provides the following functionalities:

	The *Close* button allows you to close the application. The software will not shut down without giving you the option to save any changes made. Refer to section „Close the navigation“.
	The *Import* button allows you to import patient data and previously created plannings. Refer to section „Loading patient image data“.
	The *Image Fusion* button allows you to import additional patient data to fuse with already imported dataset or datasets. Refer to section „Importing additional data sets for image fusion [TGS ONLY]“
	The *Patient Registration* button allows you to choose a *Patient Registration* type if the default *Enhanced Surface Registration* is not desired. Refer to section „Selection of displayed data sets per view“.
	The *Zoom In* button allows you to zoom equally into all cross-section images. Refer to section „Buttons available in cross-section and 3D view types“.
	The *Zoom Out* button allows you to zoom out equally of all cross-section images. Refer to section „Buttons available in cross-section and 3D view types“.
	This button allows you to switch off and on distance notification sound alerts. Refer to section „Message bar“.
	Use the *Start/Stop Screen Recording* button to start a new screen record session and to terminate it. Refer to section „Taking screenshots and screen recordings“.
	The *Take Screenshots* button allows you to make a screenshot of the current screen. Refer to section „Taking screenshots and screen recordings“.
	The *Adjust Settings* button allows you to display the *Adjust Settings* menu to adjust audio and video settings. Refer to section „Configuration settings: video and audio“.
	Use the *View Layout Button* to adjust the view layout or choose a view orientation. Refer to sections „Managing view layouts“ and „Choosing the view orientation“.
	The *Adjusting Gray Level* button opens the menu where you can see and adjust gray scale levels of the visualization of the patient image data. Refer to section „Adjusting gray levels for patient image data“.

8.2. About dialog

Click the application logo in the upper left corner. The software's *About* dialog opens. This dialog provides general information about the software application. Through this dialog, you can access the user manual and view and renew the software licence.

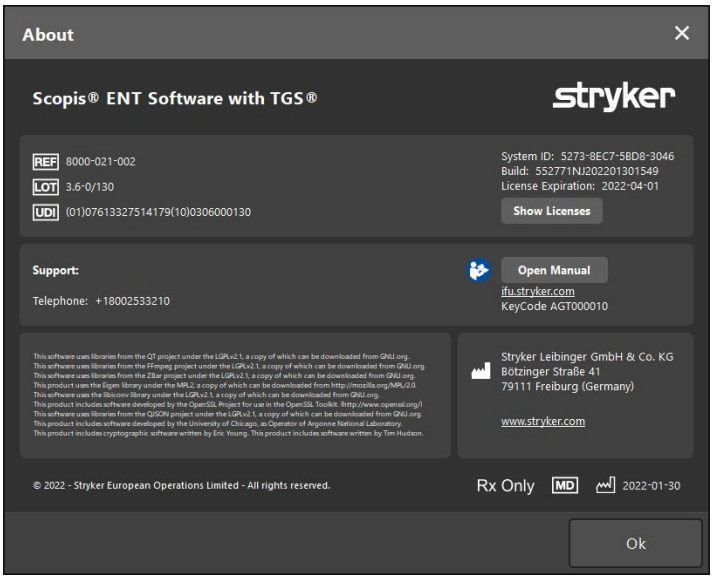


Figure 7 About dialog

8.3. Views

By default, the navigation software shows four windows with different views of the patient image data. These windows 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.

8.3.1. Cross-section image views: axial, coronal, and sagittal

Each respective view – axial, coronal, or sagittal – shows one of the recorded cross-section images.

You can select slices by shifting the blue intersection lines (crosshair). Click the horizontal or vertical line or their intersection and drag until the relevant slice is shown. Alternatively, use the arrow buttons or the mouse wheel.

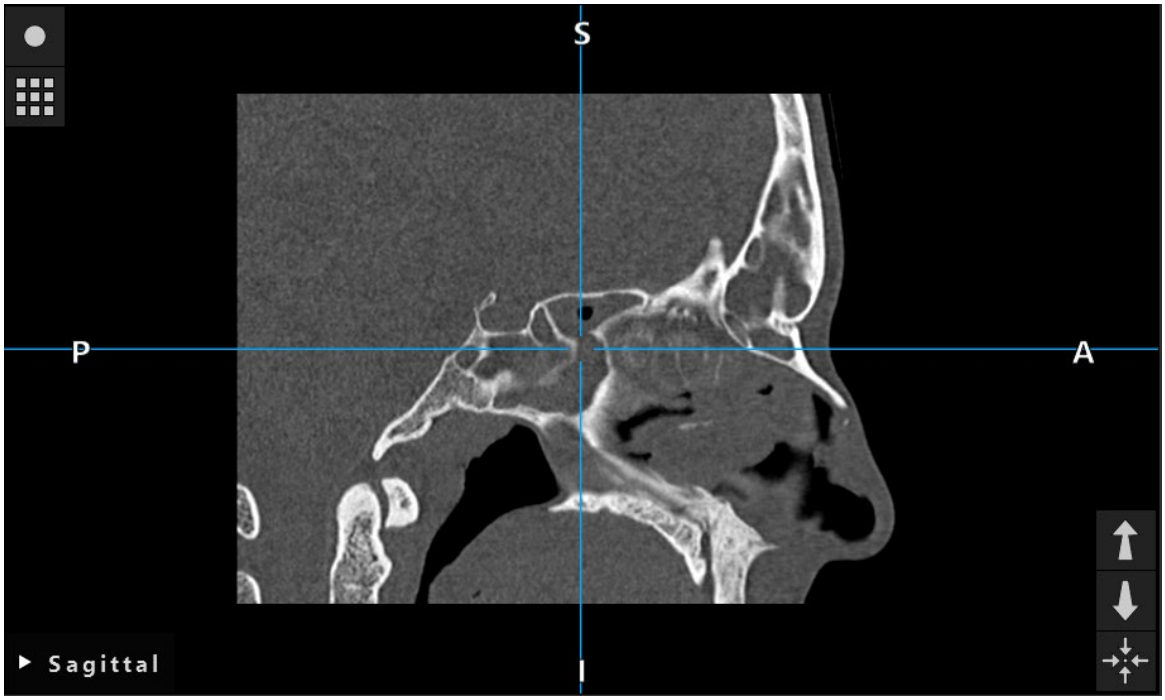


Figure 8 Blue intersection lines

The arrow buttons (Figure 9) allow you to move forward and backward between the cross-section images in the respective views.

Figure 9 Arrow buttons

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

To move the patient image, click in the display and drag until the relevant detail is ideally positioned. During this process, the mouse cursor is shown as a closed hand.

8.3.2. 3D view

In this view, a 3D model of the patient is displayed.

To rotate a 3D model, click the left mouse button in the view, hold the button and move the mouse. The option to rotate a 3D model is only available if the *Move View* function is not activated.

Figure 10 Move view button

The *Move View* function allows you to move the 3D model vertically and horizontally without rotating it. Activate this function by clicking the respective button, then click in the view and drag until the 3D model reaches the desired position. The blue background of the button indicates that the *Move View* function is activated.

To deactivate the function, click the button again. In the deactivated state, the background of the button is gray.

8.3.3. Buttons available in cross-section and 3D view types

In cross-section views, the *Centering* button (Figure 11) allows to center the display of a cross-section on the crossing point of the intersection lines so that these are in the middle of the display. In the 3D view, this button resets all changes related to magnifying, moving, or rotating the model.

Figure 11 Centering button

If you are zooming a cross-section view in or out, the other two cross-section views are zoomed in or out automatically as well. The following buttons allow to zoom a view in or out:

Figure 12 Zoom in / zoom out buttons

Note that these zoom buttons are only available in the 3D view. You may find the zoom buttons for the cross-section views on the right in the side panel.

8.3.4. Inline and probe view

Inline and *Probe* views (Figure 13) also show cross-section images of a 3D data set. The cross-section planes of these views are derived from the orientation given by one of the following options:

- planning path
- navigated instrument

During navigation, the displayed cross-sections are updated according to the spatial direction of the navigated instrument or the planned path.

- *Inline View 1* and *Inline View 2* offer two orthogonal cross-sections along the instrument axis which runs through the tip or planned path.
- *Probe View* dissects both inline views at right angles and displays a cross-section on which the navigated instrument tip or planned path lies.

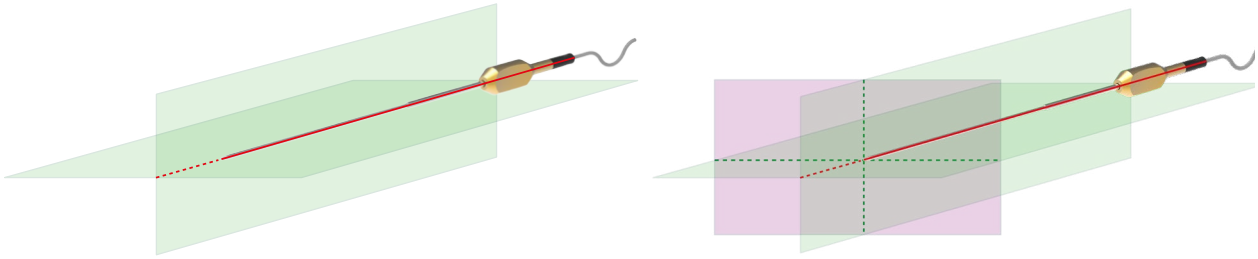
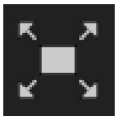


Figure 13 Left: Inline views (green). Right: Inline views (green) and a probe view (magenta)

8.3.5. Video view

This view displays the video image of the camera processor that is connected to the Electromagnetic Navigation Unit.

The following buttons are available in the video view. The first four icons are the four states of one and the same button, and are never all visible at the same time:

	The *Full Screen* button enables you to switch to a full screen view layout to display only the video image. To return to the previous view configuration, click this button again.
	With the *Scale Video* button, you can enlarge the video image so that it fits the maximum dimensions of the video view. Parts of the video image may be cut off in this mode, depending on the aspect ratio of the video view and the video image.
	With the *Fill View* button, you can scale the video image to the minimal dimensions of the video view.
	The *1:1* button displays the video image in its original size ratio.
	The *Crop Video* button enables automatic cropping of endoscopic video images. This function optimizes the displayed image section based on valid image regions detected during the endoscope calibration.

If the video continuously shows a black screen, verify that the endoscope unit is switched on, delivers an image, and is properly connected to the Electromagnetic Navigation Unit with a DVI or SDI cable.

8.3.6. Virtual endoscopy view [TGS ONLY]

In the planning mode, the *Virtual Endoscopy* view displays a virtual endoscopic image that simulates a view along planning objects such as drainage pathways and planning paths. You can move along a path by using the slider (Figure 14).

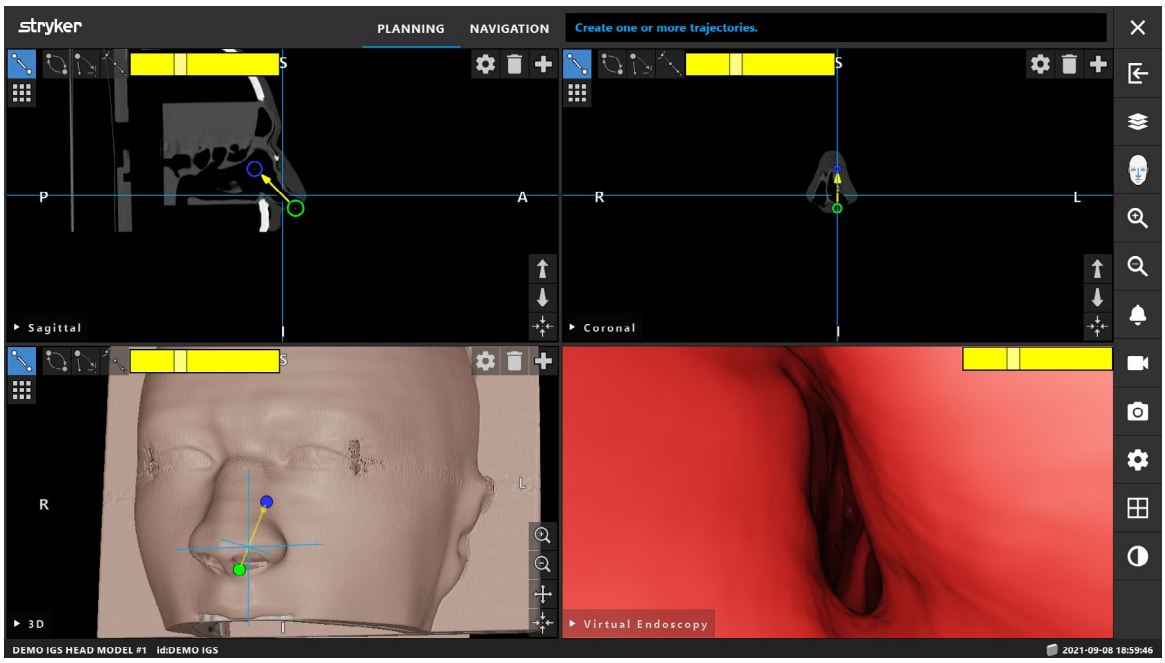


Figure 14 Virtual endoscopy example

8.4. Customizing views

8.4.1. Selecting a view type

You can change the view type in any view window. To change the view type, click the arrow next to the view description in the left bottom corner of the respective view window. The list of the available view types pops up (Figure 15). Select the desired view type for this window. To resize the views, drag the edges of the view.

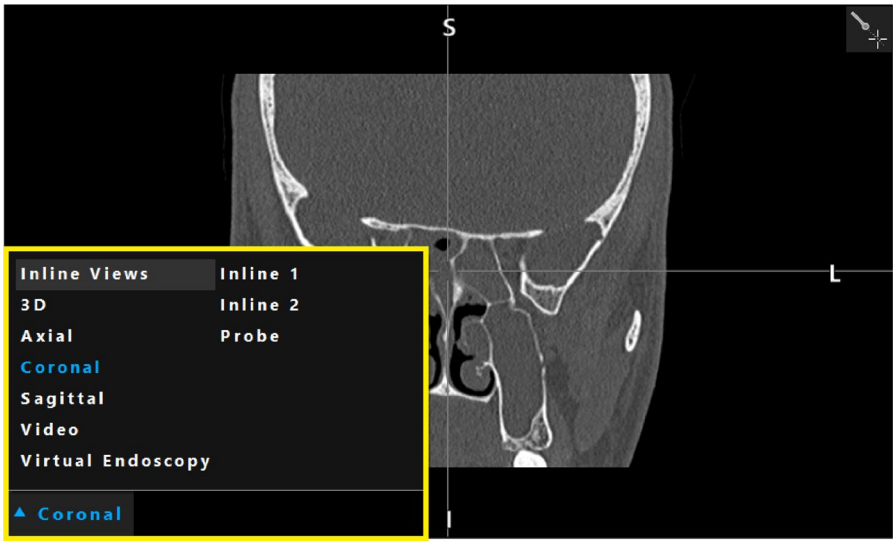


Figure 15 Selecting the view type

The *Virtual Endoscopy* view is only available in the *Scopis* ENT Software with TGS and in the Scopis Planning Software. [TGS ONLY]

8.4.2. Changing crosshair color

Crosshair Color may be adjusted via advanced options menu (refer to Section „Advanced options dialog“). Open one of the options shown in Figure 16.

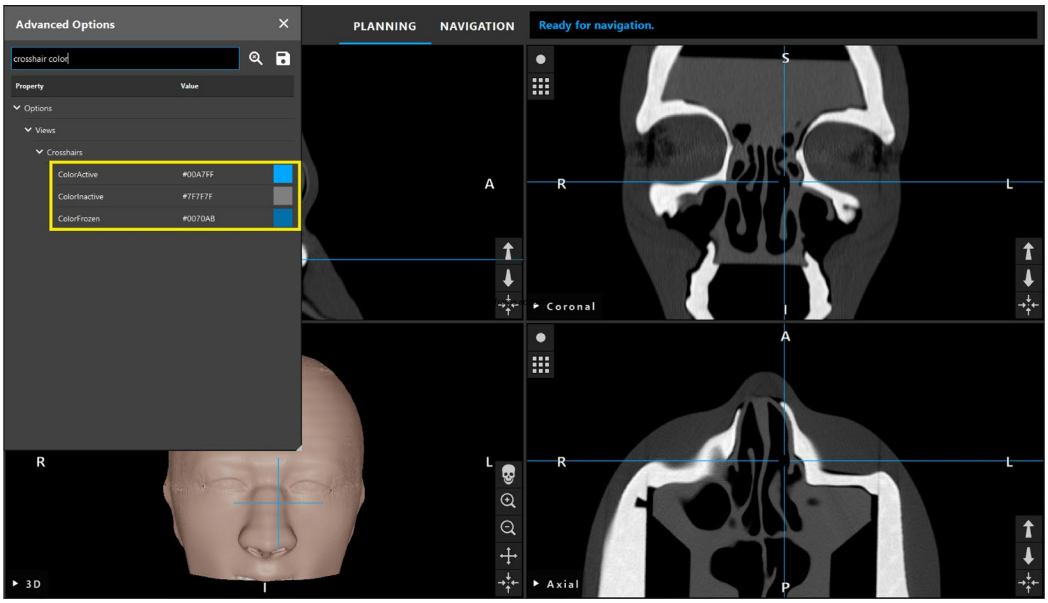


Figure 16 Changing crosshair color

8.4.3. Managing view layouts

Both in planning and navigation mode, the navigation software displays up to six windows with different views of the patient image data.

The *View Layout* menu displays all available layouts. The software application comes with nine predefined layouts as shown in Figure 17.

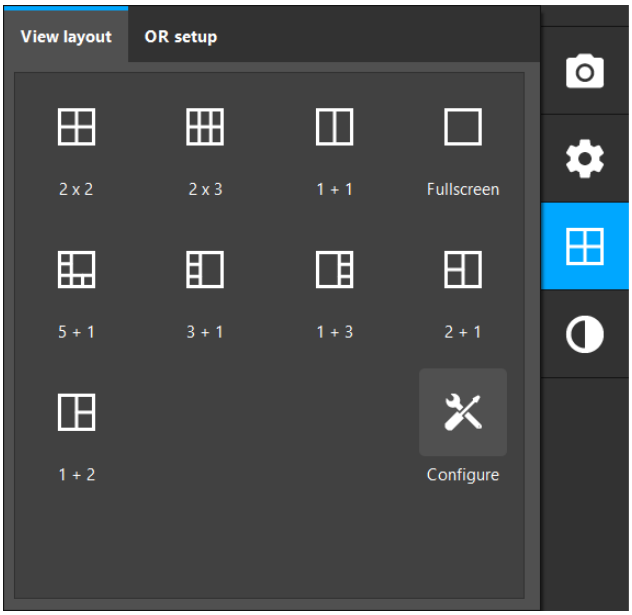


Figure 17 View layout menu

Every predefined layout has a preset view type (coronal, axial, 3D, etc.) in each window.

By default, the patient image data are displayed in four windows arranged 2x2. The default 2x2 layout consists of the following view types: The 3D view and three 2D cross-sectional views (axial, coronal, and sagittal).

By default, the same 2x2 default layout is used for all three phases of the navigated surgery (planning, registration and navigation).

You can switch into any of the available layouts by selecting it in the *View Layout* menu at any time.

You can select the view type individually for each view window regardless of the selected layout: Refer to Section „Selecting a view type“ for more information.

You have the option of creating user-defined layouts. Select a layout with a desired window arrangement and set view types as you wish, then click *Configure* in the *View Layout* menu. The *Configure View Layouts* dialog box appears (Figure 18).

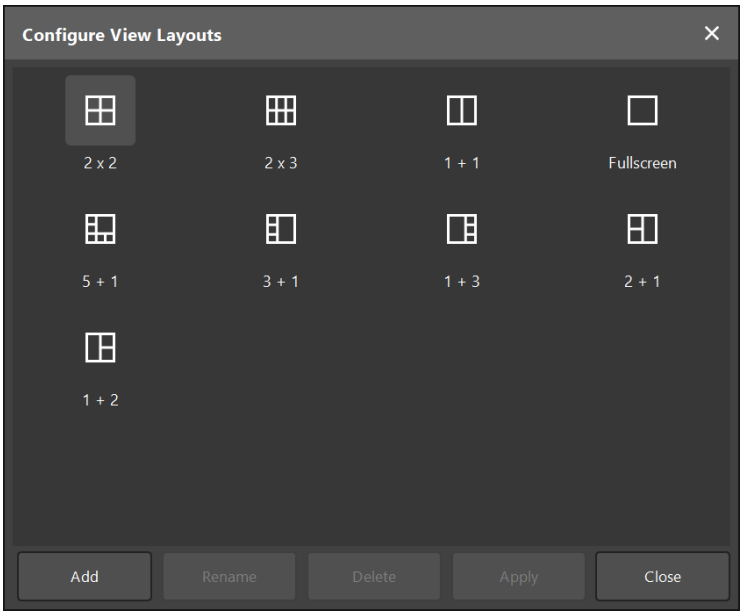


Figure 18 Configure view layouts dialog box

Click *Add* to save the currently displayed window arrangement with the current view types as a new layout. Enter a name for your layout in the *Enter Name* field, then click *OK*. Your new layout now appears among the available layouts.

To switch to any available layout from the *Configure View Layout* menu, select the desired layout and click *Apply*.

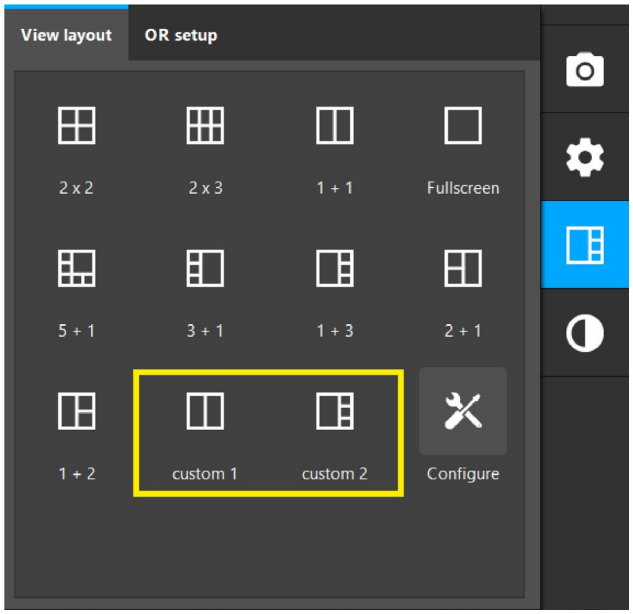


Figure 19 View layout with two user-defined layouts

To delete or rename a user-defined layout, click *Configure* in the *View Layout* menu, then select the desired layout. Click *Delete* to delete the selected layout. Click *Rename* to rename the selected layout.

- It is not possible to delete or rename predefined layouts.
- If you choose *Save as New* or *Overwrite* in the *Save Planning* dialog when closing the program, the currently displayed window arrangement with the current view types will be saved with your planning and applied when you reload the planning.

If the predefined 2x2 default layout doesn't suit your needs, you can set a different layout as the default. This option is available for each phase of the navigated surgery (planning, registration and navigation). A default layout is applied at every software start or when creating a new planning. The default layout is stored with the planning and overwritten if the user changes the layout, with respect to the current phase and planning. To set a new default layout, proceed as follows:

- Choose a layout from the available layouts in the *View Layout* menu.
- Choose desired view type(s) in the respective window(s) if necessary.
- Open the *Advanced Options* dialog (Ctrl + D) and click *Set* at one of the options (Figure 20):
  - *Options > UI > Set default Planning Layout*
  - *Options > UI > Set default Registration Layout*
  - *Options > UI > Set default Navigation Layout*

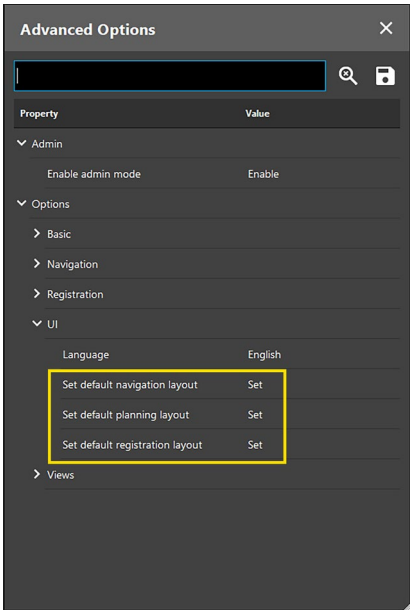


Figure 20 Setting of default view layouts

For more information on the *Advanced Options* dialog, refer to the Section „Advanced options dialog“.

8.4.4. Choosing the view orientation

In the *OR Setup* tab of the *Configure View Layout* menu, you can choose the way the patient image data are displayed. The tab allows you to choose the orientation of the view by switching between the front and the rear view of the patient and between the feet-to-head view and the head-to-feet view of the surgeon. These four view orientation options enable the data display to approximate to the actual spatial setup of a surgery you are conducting.

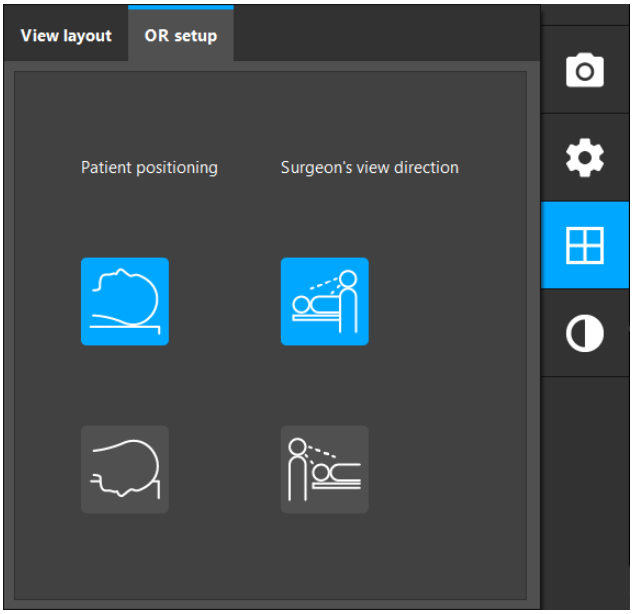


Figure 21 Choosing the view orientation

8.4.5. Adjusting gray levels for patient image data

The *Adjust Gray Level* button on the side panel opens the menu where you can see and adjust gray scale levels of the visualization of the radiological patient image data (axial, sagittal, and coronal).

Numbers after the slash indicate a chosen window width. Numbers before a slash indicate a window level of this window. By default, values are taken from the metadata of the DICOM files of a data set. Adjust the brightness of the image via the window level. The contrast is adjusted via the window width. You can adjust the settings to ensure that the relevant patient image information is displayed optimally.

The *Bone* button applies a window width and a window level that allow a better view of bone structures.

The *Soft Tissue* button applies a window width and a window level that allow a better view of soft tissues.

To apply a window width and a window level of your choice, type the values you want in the respective *Custom* fields. Alternatively, you can use the slider on the left side of the menu.

The entire range of available values varies depending on the modality of the radiological imaging from which the data was acquired.

Additionally, the check box in the left bottom corner enables you to enhance sharpness.

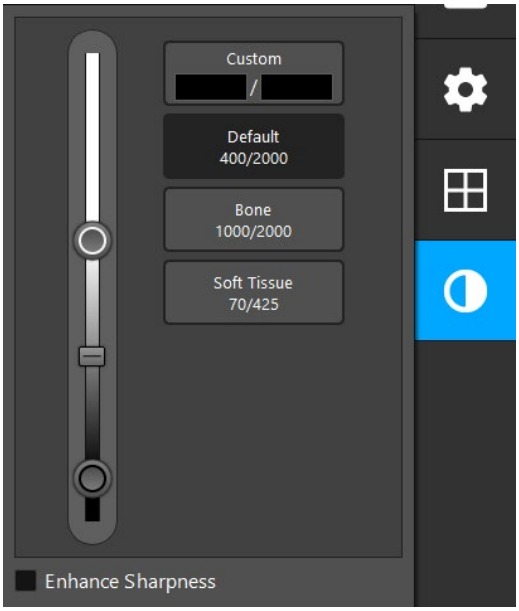


Figure 22 Menu for adjusting gray scale levels

8.5. Configuration settings: video and audio

Use the *Video* tab (Figure 23) of the *Adjust Settings* menu to change the brightness and saturation of the endoscopic video as well as to zoom the video view in or out (up to 2x magnification).

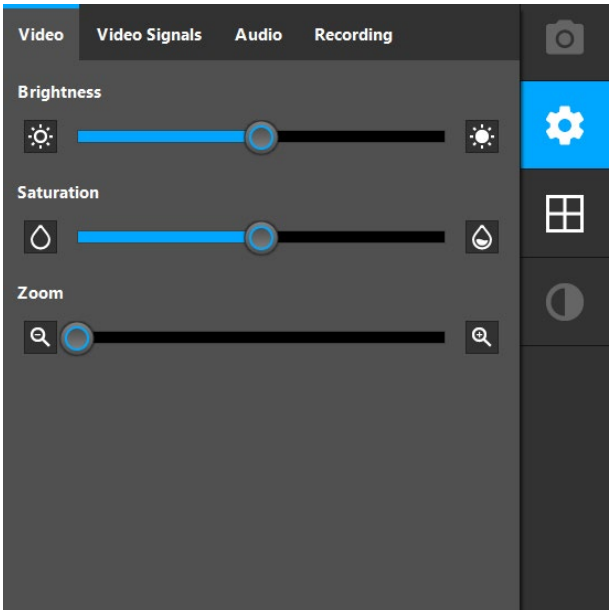


Figure 23 Endoscopic video settings

If several video generating devices are connected, it is possible to select the desired video input in the *Video Signals* tab.

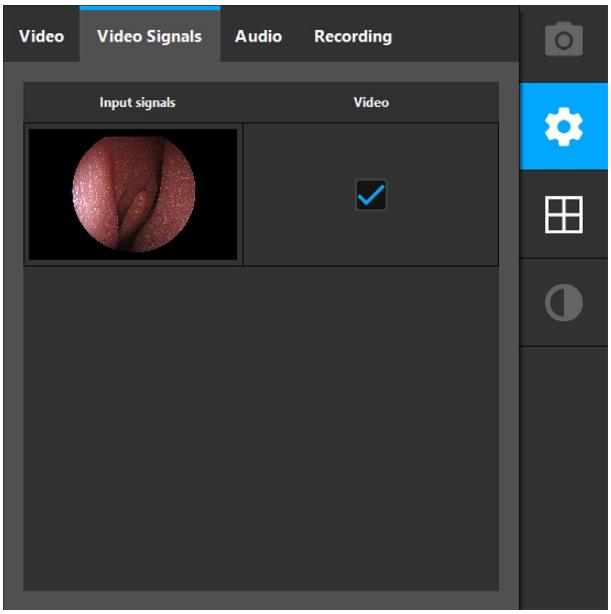


Figure 24 Video signals

If the video display shows the message *No Video Input* make sure that the endoscope is properly connected to the Electromagnetic Navigation Unit.

Use the slider in the *Audio* tab to change the system volume.

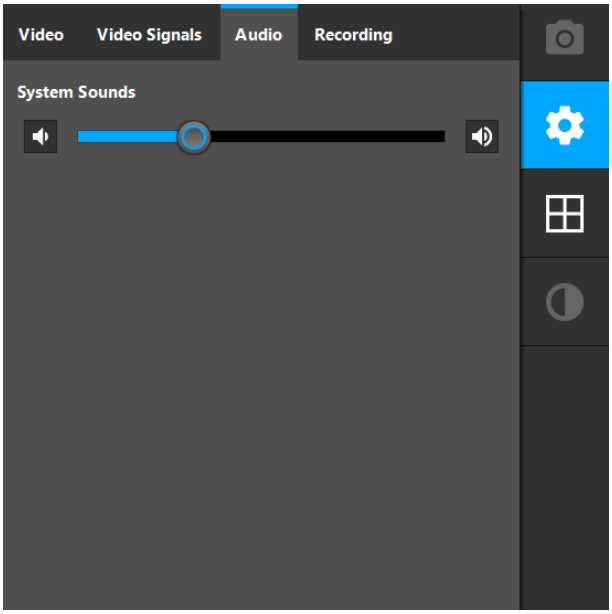


Figure 25 Volume control

The *Recording* tab allows you to choose an audio channel to be used as an audio source during the screen recording. It offers the possibility to add audio comments to video recordings.

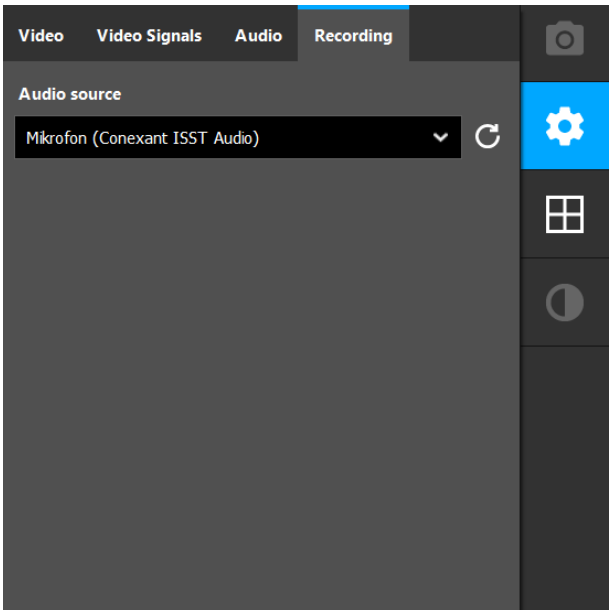


Figure 26 Audio source for recording

9. 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.

9.1. Switching on the navigation system

Switch on the Electromagnetic Navigation Unit by pressing the power button. When switched on, the power button glows green. Then attach the accessories. Refer to the IFU supplied with each instrument.

If you notice undesirable behavior of the navigation software during planning or intra-operatively, restart the software and the navigation unit. On how to reuse an existing patient registration, refer to Section „Reuse a patient registration“

9.2. Starting the navigation software

After switching on the Electromagnetic Navigation Unit, wait until the operating system is ready. Start the software via the shortcut on the *Windows* desktop.

Figure 27 Desktop icon

When starting the software, a user authentication from the *Windows* user is necessary for security reasons (optional, disabled by default).

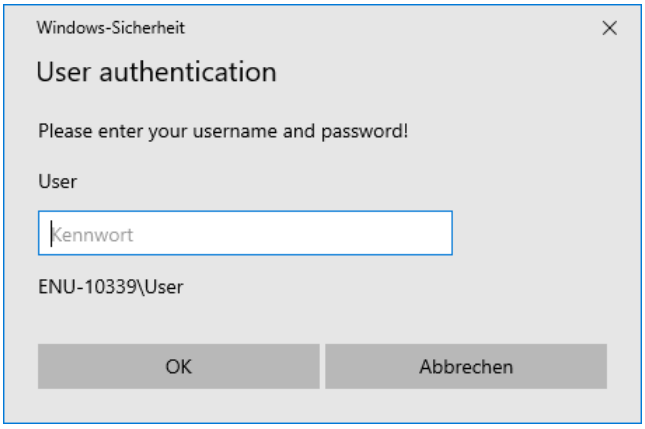


Figure 28 User authentication

After starting the software, a start-up window appears. Subsequently, the application window appears and the *Import* dialog opens.

9.3. Loading patient image data

The *Data Import* dialog opens automatically when the software is started and can also be called manually by clicking the *Load Patient Data* button. Refer to Section „UI elements“.

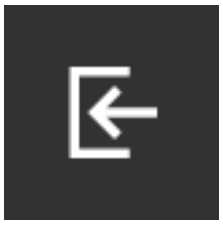


Figure 29 *Load Patient Data* button

CAUTION

If the network connection or the image data server fail or are incorrectly configured, the patient image data may become inaccessible. Upload image data to the navigation system well before an operation so that you can import the data by other means if necessary.

WARNING

- Ensure that you do not use outdated image data. Any considerable discrepancy between the actual condition of the patient during surgery and the patient's condition reflected in the image data (e.g. due to tissue swelling) compromises the accuracy of the system.
- 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.

- Depending on the size of the data sets, 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 data sets, 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, refer to Section „Transmitting image data".

On the left side of the dialog, choose a data source for the import. The *Import* dialog offers different options to search for and load plannings or new patient image data (see Figure 33).

The *Plannings* button shows all plannings created and saved with this software. If you are using the software for the first time or want to plan a new operation, you have to load new patient image data either from a local drive (*Browse* button) or from a removable storage device (*USB* button) or from a DICOM data server (*PACS Server* button). Refer to the following sections for more details. Should a needed data source not show up, contact Stryker.

DICOM data sets with existing plannings are marked with a green checkmark icon, as e.g. in Figure 30.

Study Date	Patient Name	Birthday	Sex	Description	Image device	Slices	Pixel Spacing	Patient ID	Study ID	Series number	Planning
2021-02-26	VISTA^LIGHTSKY...	1977-03-17	M	ANONYMIZED	CT	63	▲ 0.31 mm x 0.31 ...	1450825377	N/A	80292	✓
▲ 2020-11-23	RAYMONDVILLE^...	1960-11-22	M	ANONYMIZED	CT	112	0.49 mm x 0.49 mm	1184948705	N/A	10	✓
▲ 2020-01-06	IOLA^CORNFLO...	2013-06-15	M	ANONYMIZED	MRI	38	▲ 0.47 mm x 0.47 ...	2091349856	N/A	4	✓
yesterday	GENOA^LIGHTSL...	1973-07-02	M	N/A	CT	322	0.42 mm x 0.42 mm	254709687	N/A	1	

Figure 30 Green checkmark icon to identify existing plannings

In the lists of image data sets or plannings, data sets older than three weeks are accompanied by a warning sign, as e.g. in Figure 31.

Last Saved	Patient Name	Birthday	Image device	Study Age	Description
115 minutes ago	VICTORIA^ANTIQUEWHITE	1958-02-19	CT	2 days	ANONYMIZED
4 hours ago	CHARLES CITY^BLUE	2008-05-19	CT	4 days	ANONYMIZED
yesterday	GENOA^LIGHTSLATEGREY	1973-07-02	CT	39 hours	ANONYMIZED
2021-02-26	VISTA^LIGHTSKYBLUE	1977-03-17	CT	10 days	ANONYMIZED
2020-11-23	RAYMONDVILLE^DARKSLATEGRAY	1960-11-22	CT	⚠ 10 months	ANONYMIZED
2020-01-06	IOLA^CORNFLOWERBLUE	2013-06-15	MRI	⚠ 15 months	ANONYMIZED

Figure 31 Warning sign to indicate old patient data

If you attempt to load an outdated (older than three weeks) image data set or a planning based on an image data set older than three weeks, a dialog with a warning appears as shown in Figure 32. If you proceed, be aware that the navigation might not be accurate as the anatomical structure of the patient might differ from the current state.

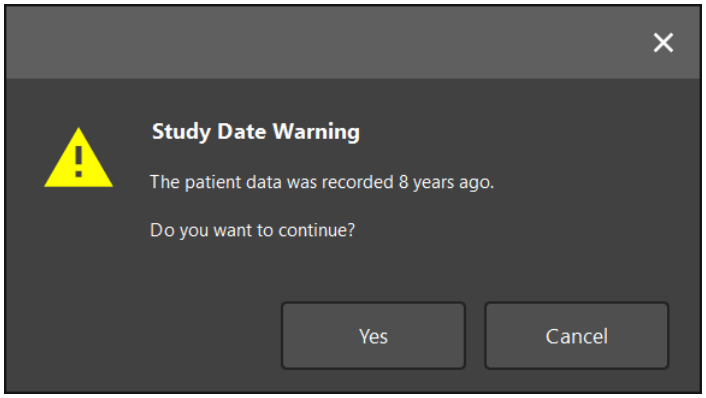


Figure 32 Warning dialog to confirm the import of old patient data

9.3.1. Loading from local drives

To choose and import patient image data from a folder on a local drive, use the *Browse* button.

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. Refer to Section „Exporting the planning“.

Choose the patient from the list and click the *Import* button. When using the browser import function for DICOM data, the *Image Optimization* dialog appears. This step is skipped only if a planning is imported using this function. Refer to Section „Optimization of patient image data visualization“ on how to proceed.

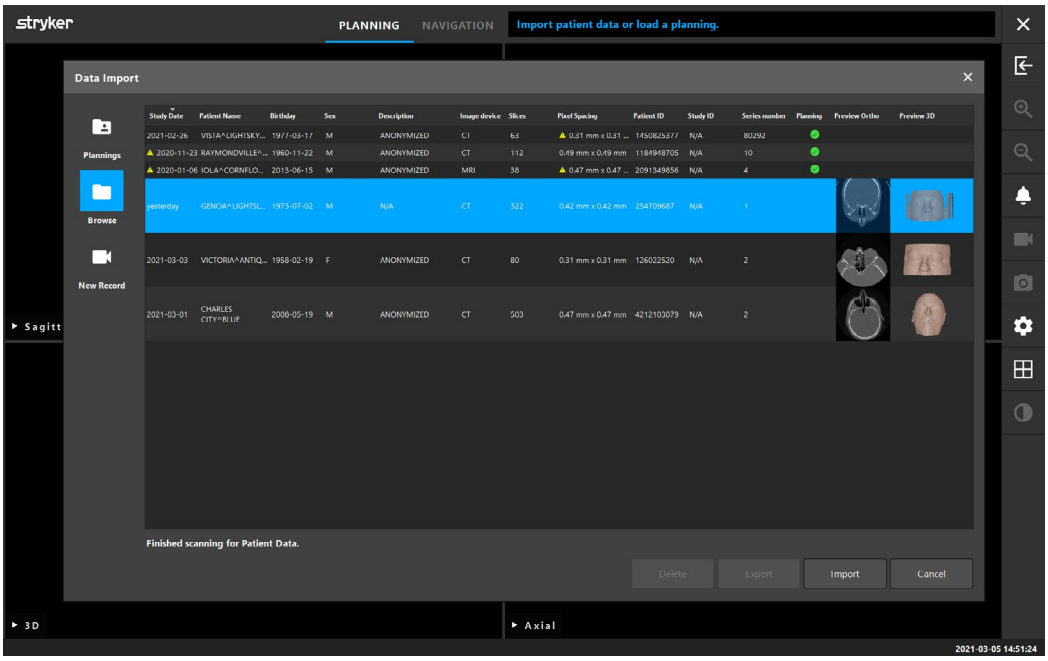


Figure 33 Data import dialog

9.3.2. Receiving from DICOM image data servers

Depending on your configuration, the software can also receive image data sets via DICOM Push.

You can check if the software is ready to receive image data sets by opening the *DicomPush* tab in the *Import* dialog.

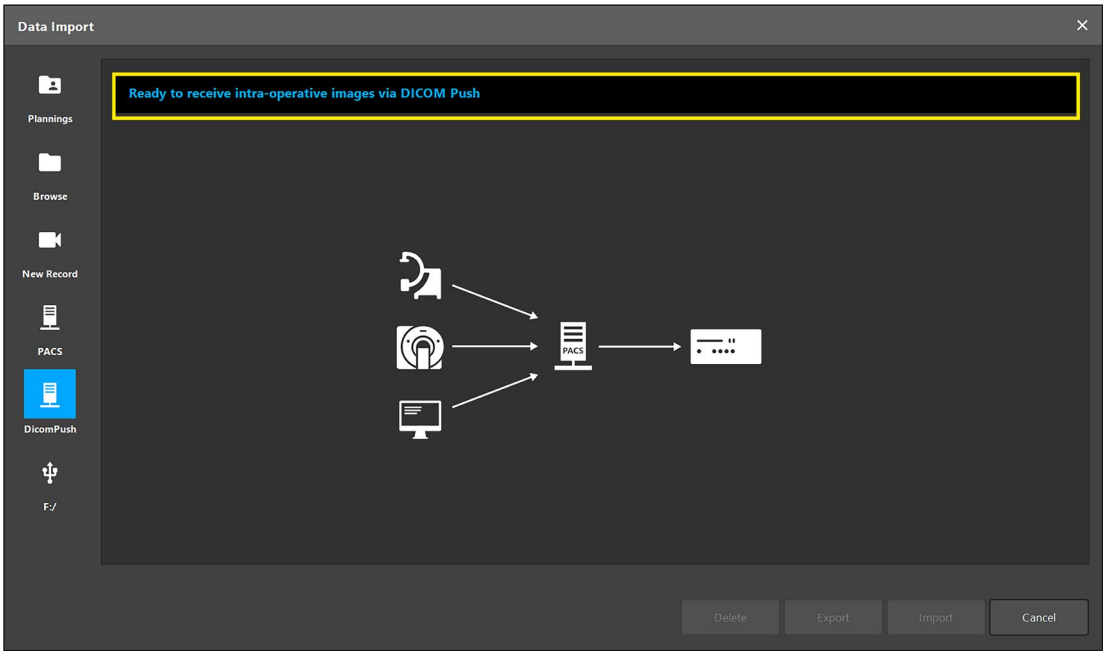


Figure 34 Check if ready to receive image data

When the *DicomPush* tab is open, and a data set is received it is automatically imported. The message in *DicomPush* tab shows that data are being received.

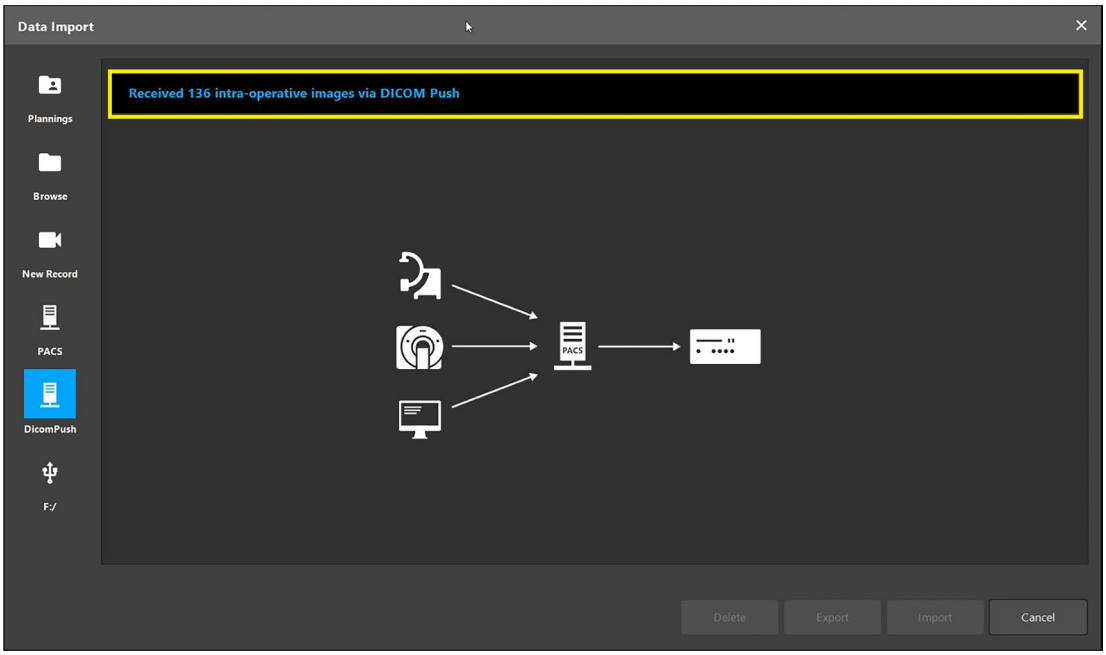


Figure 35 Received image data

Data sets can also be received in the background without the *Import* dialog open. When a data set is received in the background a toast appears with the choice to import or reject the received data set.

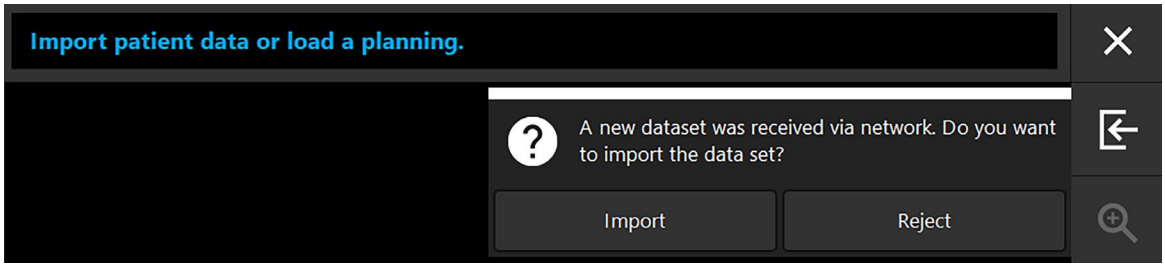


Figure 36 Import or reject a received dataset

When importing a data set via DICOM Push with a planning already open, an option appears to import into a new planning or fuse the new data set with the current planning (Refer to Section „Delete individual plannings via Data Import dialog by selecting a planning from the list of plannings and clicking Delete. A confirmation dialog will appear to confirm the deletion, or“ for more details).

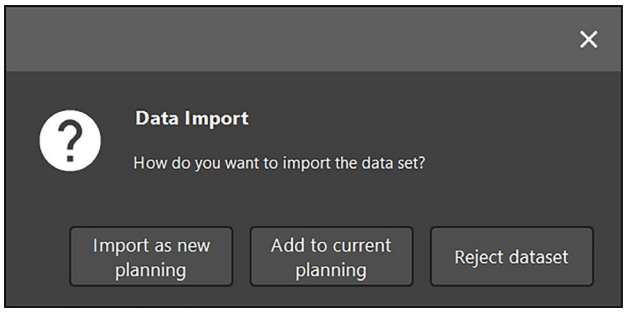


Figure 37 Import options dialog for a received dataset

Contact your local DICOM image data server administrator for configuration details for retreiving DICOM image data.

Refer to the Section „Advanced options dialog“ for more information on the *PACS Configuration* dialog.

9.3.3. Loading from DICOM image data servers

Depending on your configuration, the software can access and load data from a DICOM data server.

If a DICOM image data server is chosen as the data source, the PACS search interface opens (Figure 38). Enter at least the patient name and, preferably, an additional limiting feature, such as the date of birth, the sex, the desired modality, or the date of the study. Then press the *Return* key on the keyboard or click the *Search* button (symbolized by a magnifying glass).

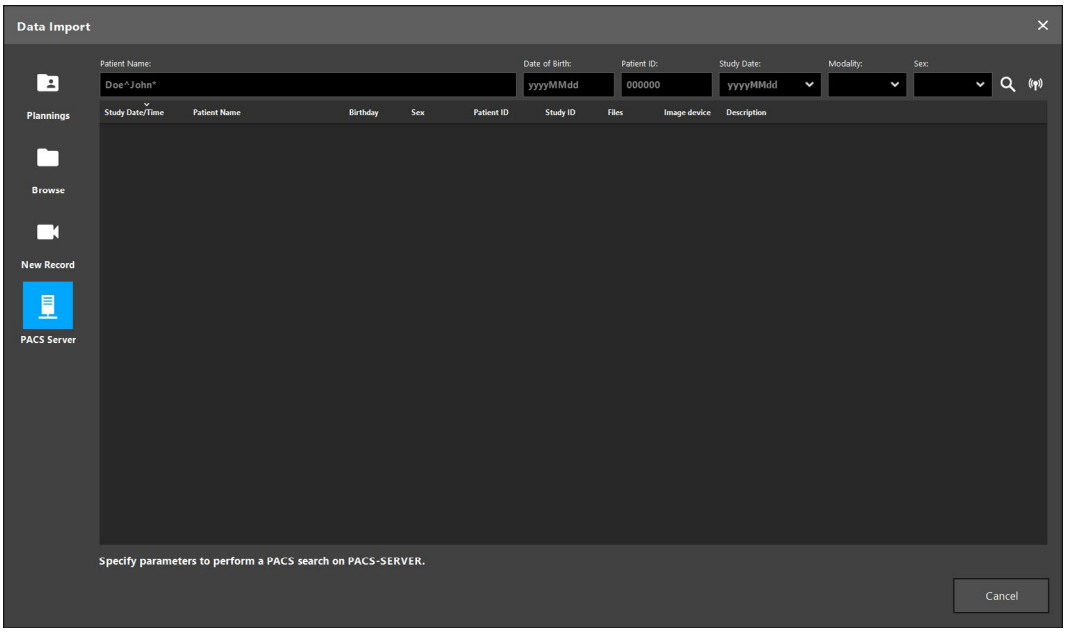


Figure 38 DICOM imaga data search on the PACS server

WARNING

When choosing the data set, make sure to choose the correct image series. Pay special attention to the series number and the quantity of slice images in the series.

- To test the connection to the configured DICOM image server (e.g. when the search request does not provide any results), click the button to the right of the *Search* button. A test signal is emitted and a success message is returned. In case of error, make sure the network cable is connected and in case you still have problems contact your local IT support.
- Use the placeholder symbol * to search for names and dates that cannot be specified exactly.
- Dates must be entered in the format YYYYMMDD, without blank spaces, dots, or hyphens (19651027, for instance).

The search results are shown as a list so that they can be sorted and chosen. Click the *Search* button again to cancel a running search.

Then choose the desired image series from the list and click the *Import* button.

Refer to Section „Advanced options dialog“ and to the *Installation Instructions* supplied with the software application for more information on the *PACS Configuration* dialog.

9.3.4. Loading from removable storage devices (USB)

To connect a removable storage device with image data via USB, use the *USB* button. When using the browser import function for DICOM data, the Image Optimization dialog appears. This step is skipped only if a planning is imported using this function. Refer to Section „Optimization of patient image data visualization“ on how to proceed.

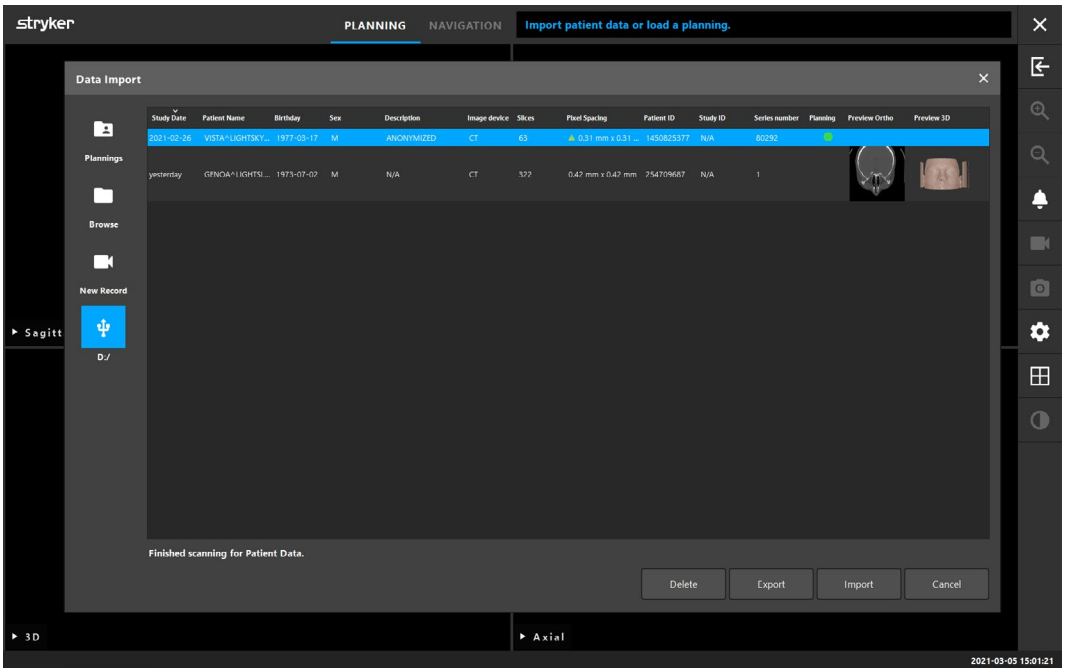


Figure 39 Data import from an external source

9.3.5. Optimization of patient image data visualization

As an intermediate step in importing patient data, an automatic visualization optimization of the image data are carried out. A dialog with four windows showing the patient image data as 2D slice images (axial, sagittal, and coronal) and as a 3D model is displayed during import (Figure 40). In this dialog, you can review automatic image optimization results and adjust the image data to further improve its quality. If the data shows a realistic, correctly oriented (face towards user) and complete representation of the patient, the import can be completed directly via *Finish* without any adjustments.

The visualization of patient data in the 2D cross-section images remains unchanged as the underlying medical data is not changed in this step.

If there is a reason to improve the quality, the following options are available that allow you to adjust the data set manually before finalizing the import:

- *Threshold*: If the skin of the 3D patient model appears incomplete or rough, use the skin and bone sliders of the *Threshold* tab (pre-selected at dialog start-up) to correct the *Thresholds* (Figure 40).
- *Orientation*: The head of the patient must be shown facing forward. Deviations from the ideal orientation can be corrected in the *Orientation* tab (Figure 40).
- *Trim*: 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, unnecessary parts of the volume can be removed with the help of the *Trim* tab (Figure 40).
- *Artifacts*: The head of the patient should not be occluded by eye protection, *CBCT* artifacts or parts of a headrest. If artifacts are visible, they can be removed with the help of the *Artifacts* tab (Figure 40).

We recommend checking these optimization options according to the tab order and making adjustments in each tab if necessary.

A green indicator next to a tab means that this optimization has been carried out. A blue indicator marks the currently active tab.

Artifacts are partially removed automatically, therefore the indicator already shows green when the *Image Optimization* dialog starts. Automatic and manually applied changes can be undone with the corresponding *Reset* button on each tab individually.

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

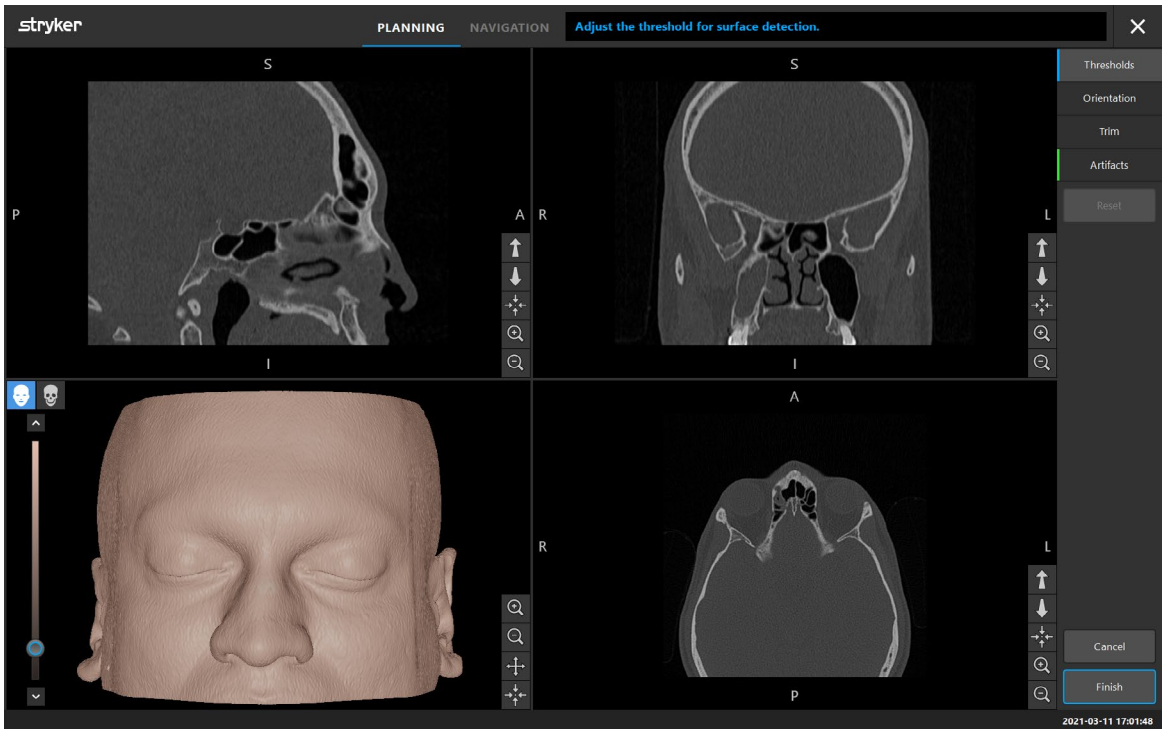


Figure 40 Image optimization dialog at startup

9.3.5.1. Threshold

When the *Threshold* tab is active, a slider is displayed to the left of the 3D patient model. Using the skin slider, set a threshold that defines the boundary between the patient's skin and the air (Figure 41). In addition to the skin slider, also a bone slider is available for CT images. Switch to the bone slider to adjust the threshold that defines the boundary between tissues and bones. Adjust the respective threshold so that the 3D model appears complete and as realistic as possible, and artifacts and gaps in the patient's skin or bone surfaces are avoided or at least minimized. For CT data, the boundary between skin and air is clearly defined, and a white line is drawn across the *Threshold* slider to aid the user. Once you have defined a threshold or the both thresholds correctly, use further functions of the dialog or complete the data import with *Finish*.

Clicking *Reset* discards your changes; the threshold is then reset to the value indicated by the white line on the slider.

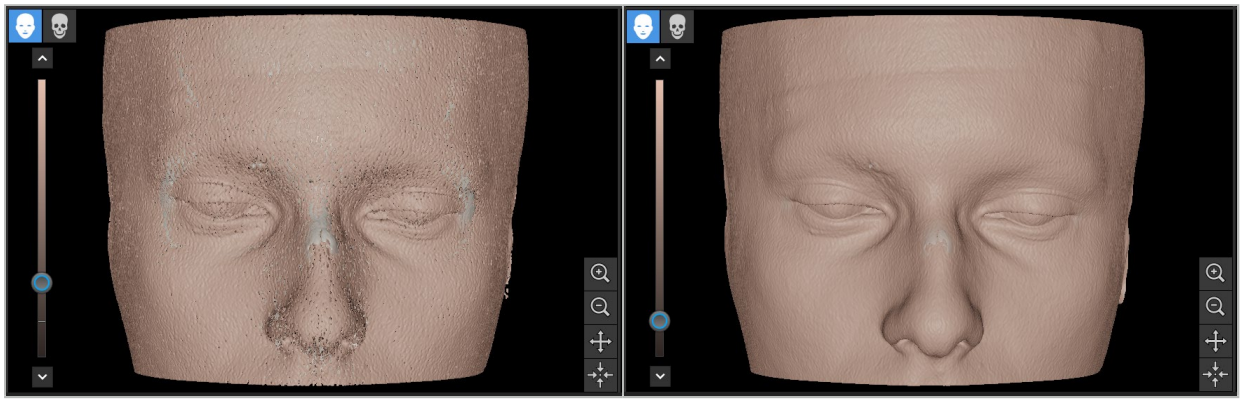


Figure 41 Optimizing threshold values: before (left) and after (right)

9.3.5.2. Orientation

When the *Orientation* Tab is active (Figure 42), six orientation arrow buttons are displayed around the 3D patient view. With these buttons you can rotate the patient's head freely to effect its frontal orientation. The *Reset* button allows to revert all applied orientation changes without resetting changes made in the other tabs. To re-apply the automatic orientation correction, click *Auto*.

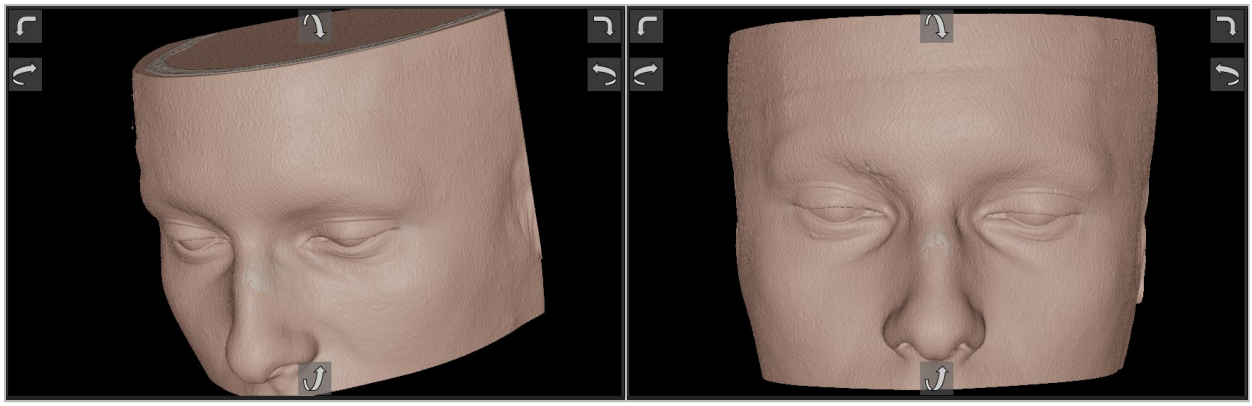


Figure 42 Adjusting orientation: before (left) and after (right)

9.3.5.3. Trim

When the *Trim* tab is active (Figure 43), a white frame is drawn around the area to be used after the import. This area can be adjusted by clicking and dragging one of the corners or edges of the frame. The 3D visualization shows the part of the volume that will be available once the import is completed. The *Reset* button allows to restore the original volume without resetting changes made in the other tabs.

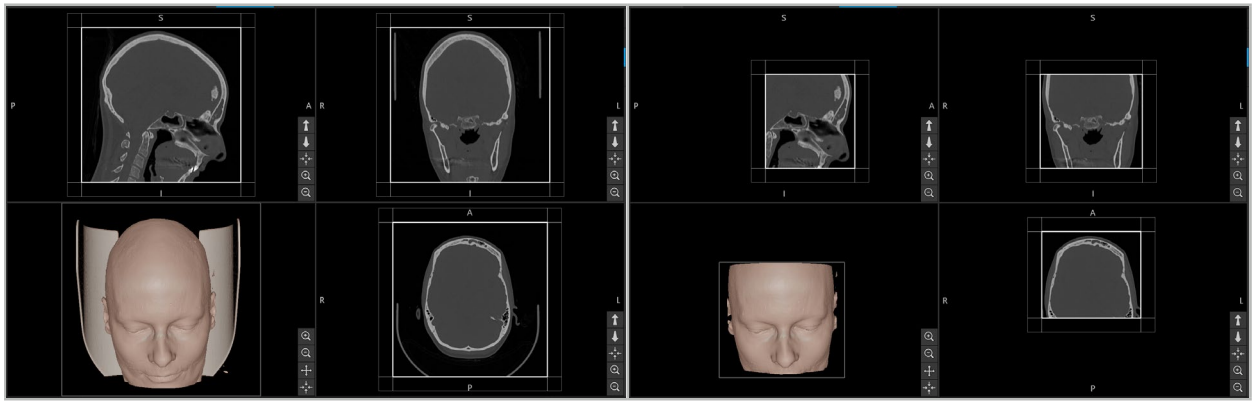


Figure 43 Trimming volume: before (left) and after (right)

If the image data are very large, the image's voxel resolution may need to be reduced in order to load the data set and work fluently with it. By removing some parts of the volume as described here, you can reduce the size of the image, thus ensuring that it is imported in its original voxel resolution.

This feature should not cut off important facial parts that are in the surgical field or needed for patient registration. (refer to Section „Selecting the patient registration type“ or the imaging protocol)

9.3.5.4. Artifacts

When the *Artifacts* tab is active, buttons for the following three artifact groups appear in the 3D view: Eye protection, CBCT artifacts and headrests. For each activated artifact group the desired radius for the correction can be adjusted individually with the arrow keys (e.g. < 5.0 mm > in Figure 44). Click the *Remove* button to remove all selected artifact types.

- The artifact removal is required for a successful patient to image registration.
- The visualization of patient data in the 2D cross-section images remains unchanged as the underlying medical data are not changed in this step.

The *Reset* button allows to revert all applied artifact removals without resetting changes made in the other tabs.

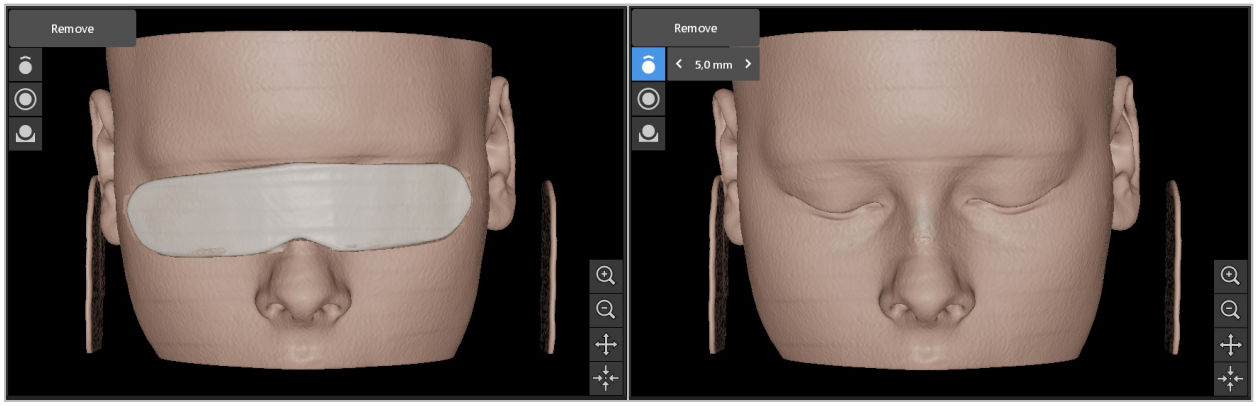


Figure 44 Removing eye protection: before (left) and after (right)

When removing an eye protection, ensure that the eye protection is completely erased from the view and the skin around the eyes is realistic.

Be careful not to set the radius too large to avoid removing part of the face in addition to the eye protection as this will affect patient registration.

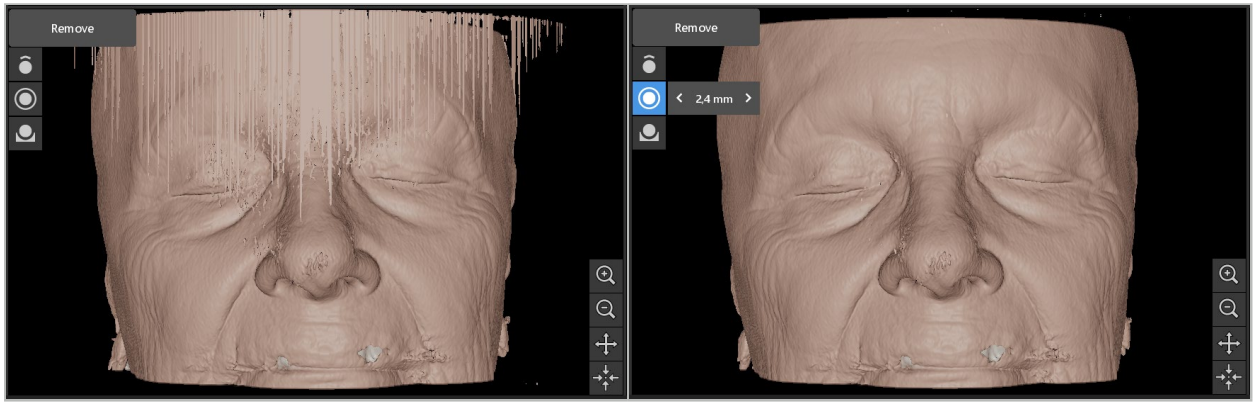


Figure 45 Removing CBCT artifacts: before (left) and after (right)

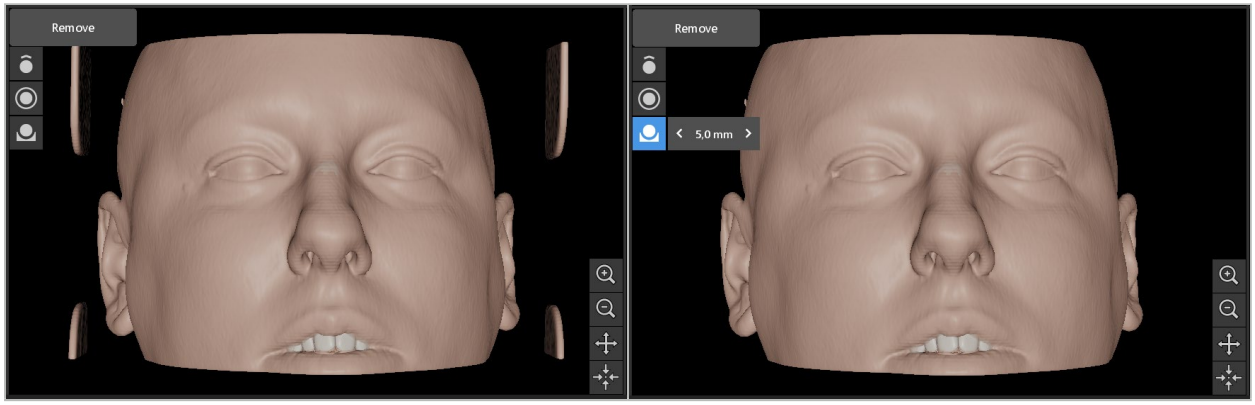


Figure 46 Removing headrest: before (left) and after (right)

WARNING

Ensure that after loading the patient image is accurate enough for the planned application. Check the patient orientation and that the data you have loaded refers to the correct patient and is up to date.

9.3.6. Loading already-imported patient image data

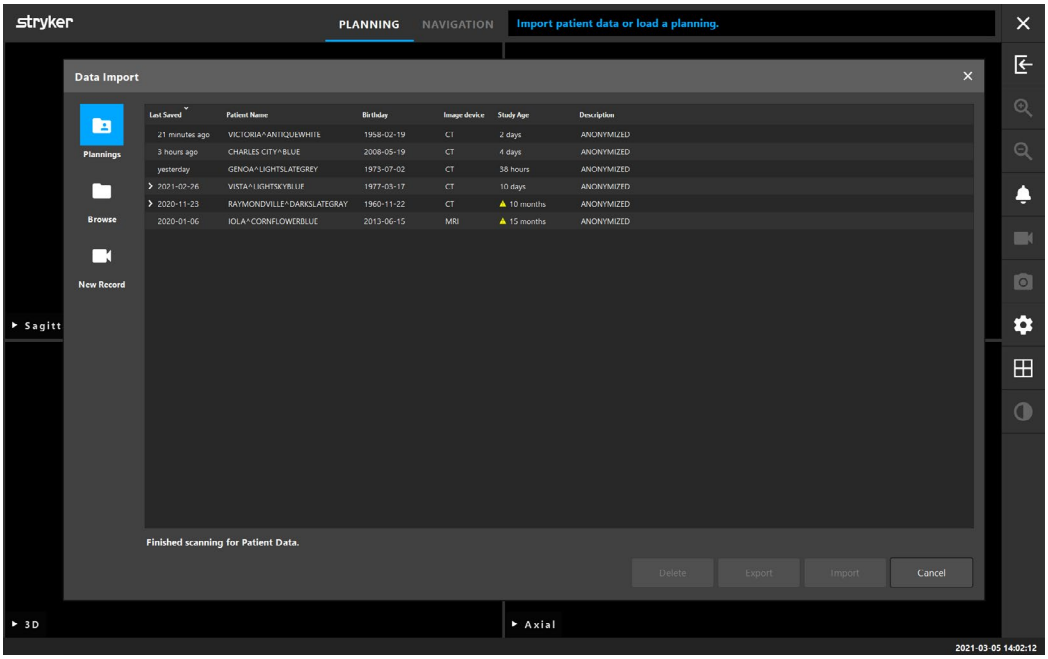


Figure 47 Data import of previously saved plannings

The *Planning* tab of the *Import* dialog displays 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 click the *Load* button. The *Delete* button gives you the option to remove old planning information from the list and free space from your hard drive. You can also select *Export*. Refer to Section „Exporting the planning“.

After loading the patient image data with the planning data, you can proceed with the planning. Refer to the following section for details.

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

9.4. Finalizing patient image data import

After loading, the patient image data are shown as 2D slice images (axial, sagittal, and coronal) and as a 3D model (Figure 48). The status bar shows the patient's name, patient ID, and date of birth as entered by the radiological staff while recording radiological image data. Use this information to verify that you have chosen the correct image data set of the patient.

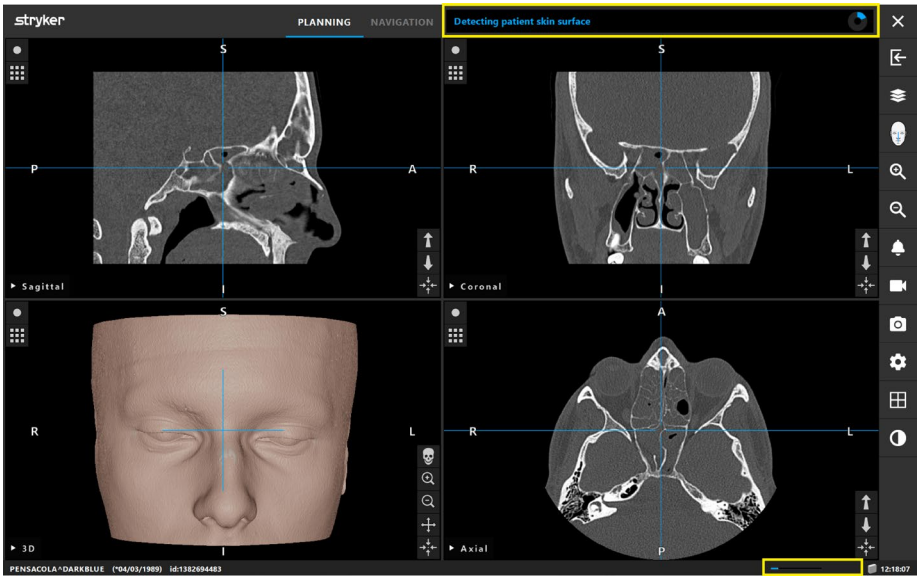


Figure 48 Patient image data after loading: Skin surface detection

If patient image data are imported into the navigation software for the first time, a skin surface model of the patient's skin is computed based on the image optimization steps performed in the *Image Optimization* dialog. This might take up to three minutes (see Figure 49).

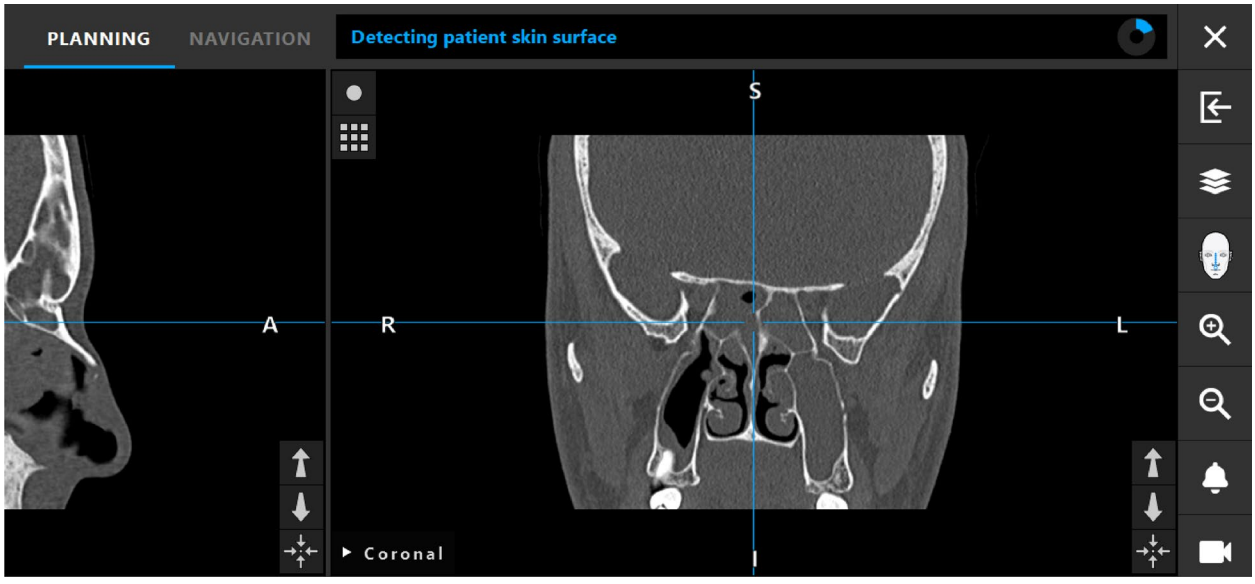


Figure 49 Skin surface detection progress display

After finalizing the patient data import, the skin surface detection is performed while the patient registration can be prepared or planning objects can be defined in the planning mode. You can only enter the navigation mode once the skin surface detection is completed.

9.5. Deletion of patient image data

- Delete individual plannings via *Data Import* dialog by selecting a planning from the list of plannings and clicking *Delete*. A confirmation dialog will appear to confirm the deletion, or

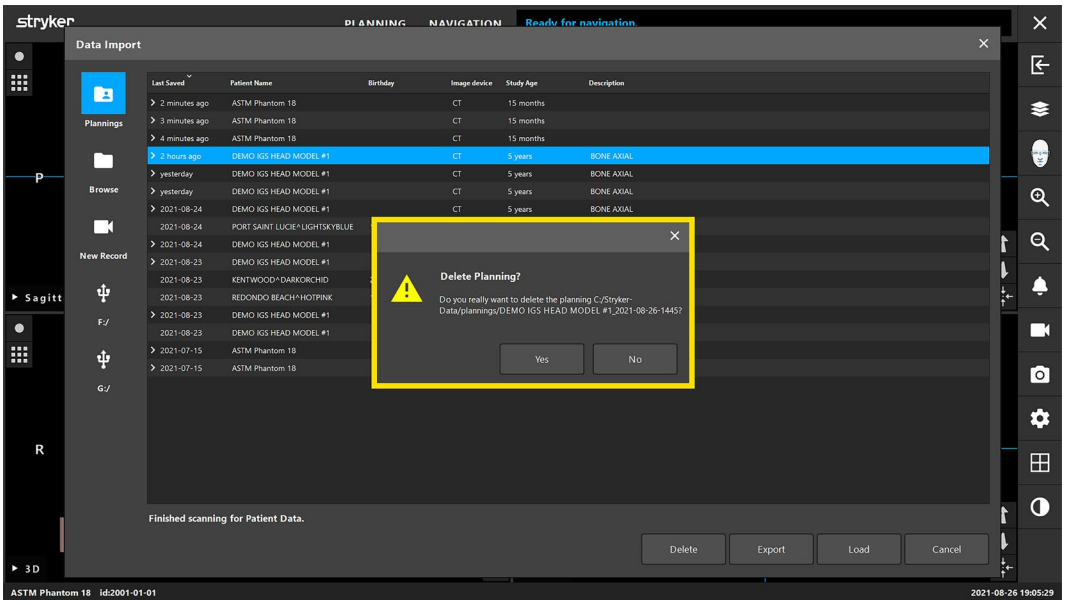


Figure 50 Delete Planning confirmation dialog

- Delete all plannings by manually deleting all directories in the following default path: d:*Stryker-Data**plannings*\ in the Windows File Explorer.

9.6. Importing additional data sets for image fusion [TGS ONLY]

Use the *Image Fusion* function to combine various image data sets. For instance, fusing a CT data set with an MRI data set yields a representation where both bone structures and soft tissues are well visible. Press the *Load Fusion Images* button (left picture below) to open the *Image Fusion* dialog box that shows the loaded image data set.

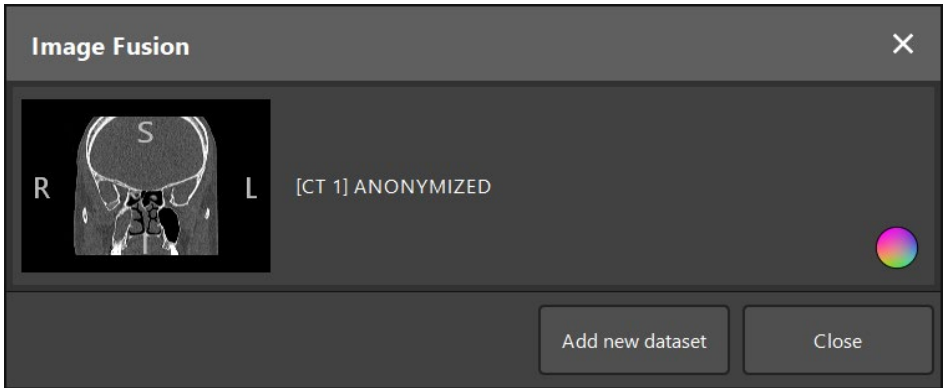


Figure 51 *Image Fusion* button (left) / *Image Fusion* overview dialog (right)

To add further data sets, click *Add new dataset* (Figure 51). A new dialog opens which allows to choose additional image data sets. Refer to Section „Loading patient image data“.

Choose the data set that you want to add. Make sure that the chosen data set refers to the same patient as the one you have already loaded.

Once you have chosen a valid data set, the *Image Registration* dialog box appears after the loading process. Here, the data sets are first preregistered roughly and then matched together precisely.

Optionally, data sets can be colored differently so that they are visually different from each other. To use a two-color scheme, deselect the *Use Monochrome Color Scheme* option (Figure 52).

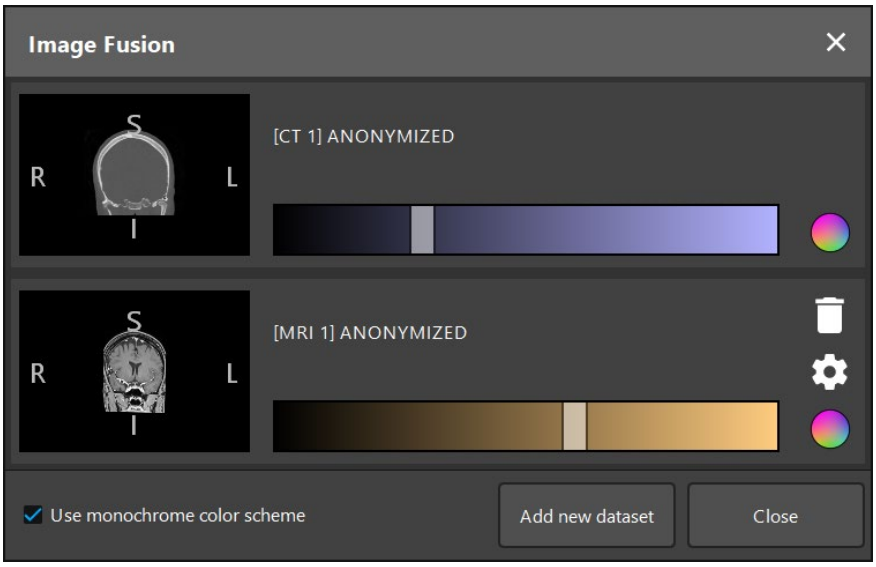


Figure 52 Loaded data sets for image fusion

9.6.1. Approximate image registration

The left view of Figure 53 shows the 3D model of the already loaded data set (referred to as “Reference” from now on), while the right window visualizes the 3D model of the newly added data set (“Target”). The threshold value for skin can be changed with the respective slider next to the Reference or Target data set view. Refer to Section „Optimization of patient image data visualization“, subsection „Threshold“.

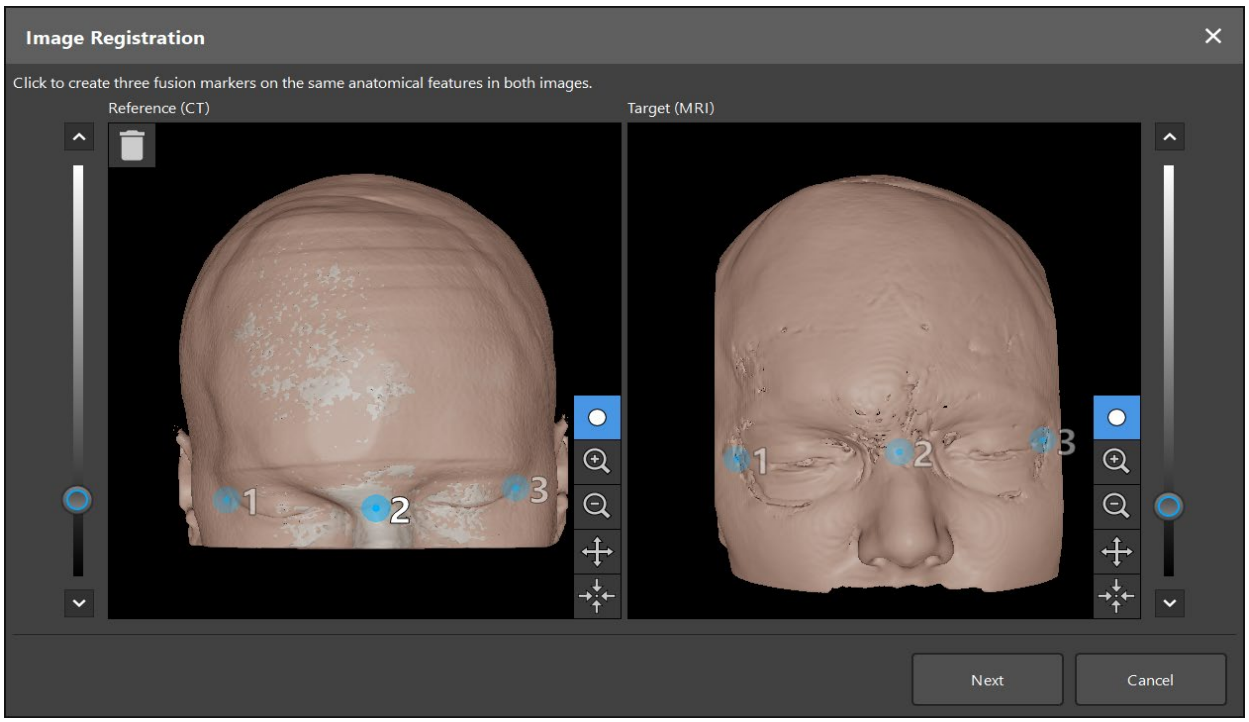


Figure 53 Image registration dialog: approximate image registration

Set the *Threshold* value so that the resulting patient skin surface resembles the skin surface of the reference data set as closely as possible. Then click the patient skin surface to create a colored marker. Move the marker on the patient surface by dragging. Note that it is not possible to position the marker outside the patient surface.

In this manner, create three markers for each of the two images and position them on anatomical structures that are clearly recognizable in both images. Markers with the same number must be positioned on the same anatomical structures in both images, as shown in Figure 53.

Do not place the markers too close together or in a line, as otherwise the registration is less accurate.

9.6.2. Precise image registration

Based on the markers used for the approximate registration, both data sets are made congruent. Check the quality of the registration carefully by observing the fusion image shown as 2D slice images. The target volume is displayed gold-colored, and the reference volume is displayed in violet. This allows to enhance the visibility of the bone structures from *CT* images and the soft tissue from MRI images (Figure 54). If you want to use the grayscale scheme instead, tick the *Use Monochrome Color Scheme* box.

The inherent contrast values of each data set are predefined by the imaging modality and can't be adjusted in this dialog.

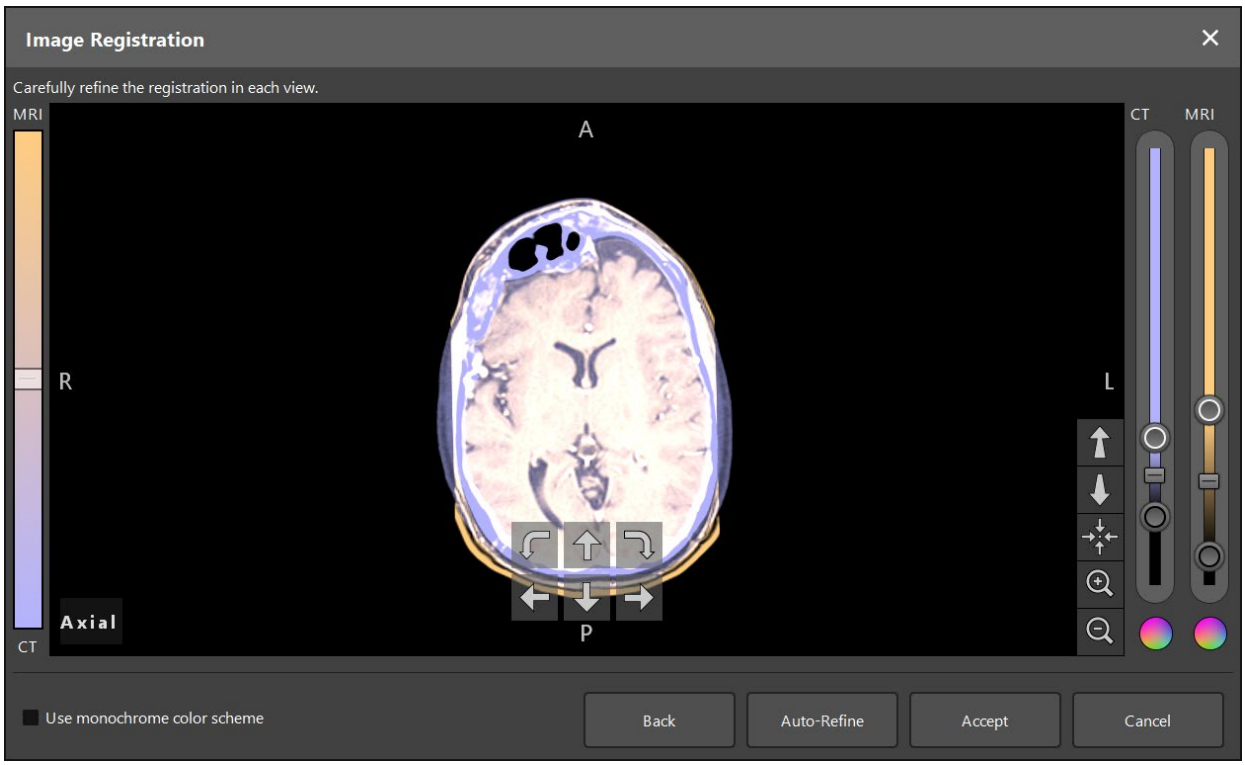


Figure 54 Image registration dialog: Precise registration of data sets

If the approximate registration was too imprecise, you can return to the 3D views by clicking the *Back* button. However, any fine-tuning done in the process is lost.

Use the slider on the left side to change the fusion image composition. It is possible to only show the Reference volume (violet) or the Target volume (gold). If the slider is positioned in the middle, both volumes are shown with maximum intensity.

Clicking the *Auto-Refine* button starts an automatic image registration whereby the two image volumes are matched by the software as precisely as possible. If the approximate registration was accurate enough, the automatic refinement may yield good results. Clicking the *Auto-Refine* button repeatedly can enhance the result.

If the automatic refinement does not lead to an acceptable image registration, conduct a manual registration. With the help of the four movement arrows and two rotation arrows within the image screen move or rotate the target volume so that to reach an optimal congruence between the two volumes in all three views (axial, coronal, and sagittal). When the registration is sufficiently precise, click *Accept*.

WARNING

- Check the image registration carefully in all slices and all views. Inaccurate image registration can cause an incorrect visualization during navigation. In order to check, change the contrast settings temporarily to compare, for example, soft tissue in both data sets.
- When moving the target data set relative to the reference data set, check the position of all created planning objects carefully. All planning objects are attached to the reference data set and do not move when you move the target data set.

9.6.3. Image fusion with PET and SPECT image data

Image data from the modalities Positron Emission Tomography (PET) and Single-Photon Emission Computed Tomography (SPECT) can be imported as additional data sets in order to use a single or combined display of the PET/SPECT image data with the primary CT or MRI image data set during the surgical planning and intraoperative navigation.

When importing PET or SPECT image data, it is strongly recommended that matching CT image data recorded with the same PET-CT or SPECT-CT device, belonging to the same study and stored with the same DICOM Frame of Reference UID is used as a reference data set. This allows an accurate and automatic registration of the possibly low-resolution PET or SPECT image data to the reference data set. Otherwise a manual registration to the reference data sets must be conducted. Refer to Section „Precise image registration“.

When scanning data sources of image data during data import, the system recognizes the modality of the DICOM image data automatically and displays this information in the *Import* dialog Modality column. The PET or SPECT image data are marked “PET” and “SPECT.”

Most image modalities are displayed as grayscale images, unless specified otherwise. PET and SPECT images show metabolic activity in the body and are typically displayed in a false color scheme.

When adding a data set of this modality to the planning, areas of high activity are shown in red, and low activity in blue (Figure 55). Select different color schemes in the color selector accessible via the *Fusion* dialog. Refer to Section „Importing additional data sets for image fusion [TGS ONLY]“.

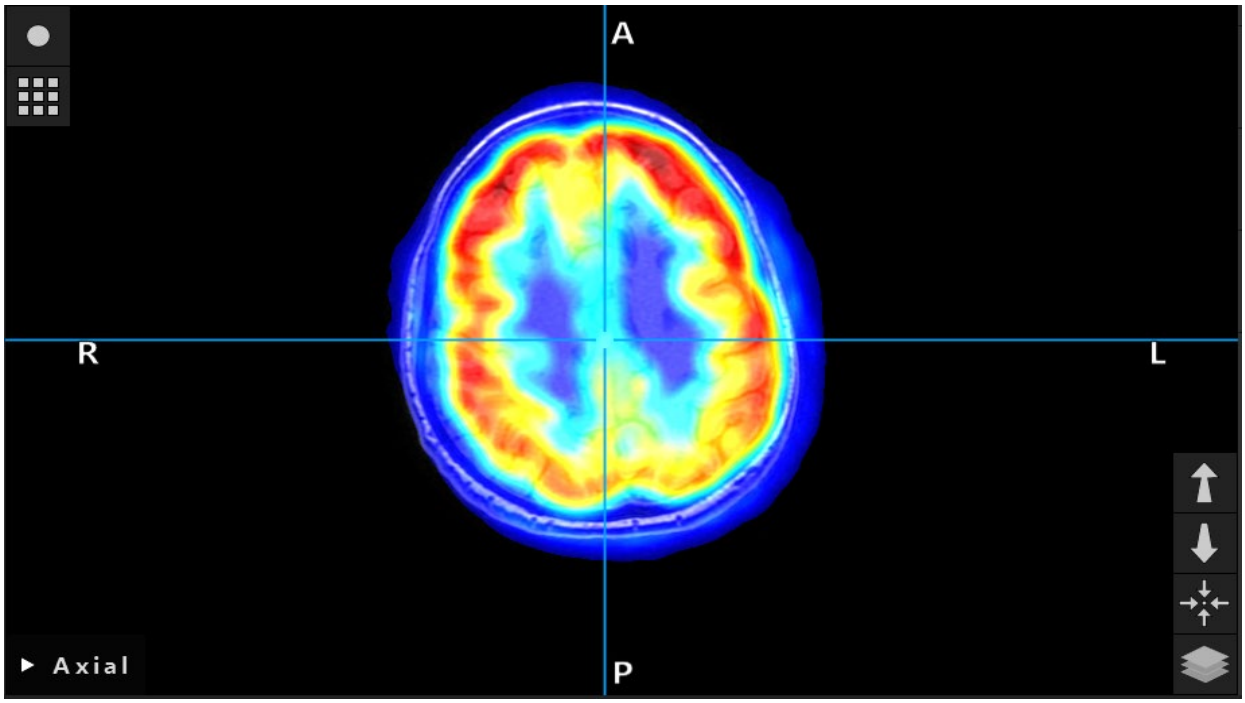


Figure 55 Combined display of CT and color-coded PET image data

Color-coded display of image data is deactivated by default outside the *Image Registration* dialog. To use the false color scheme, remove the check mark from the *Use Monochrome Color Scheme* check box in the *Fusion* dialog (see Figure 52). For better results, you should also change the color of the other data sets in the planning to white, so that they don't influence the perceived color of the SPECT or PET data set.

9.6.4. Configuration options

After the fusion is finished, the view can further be configured in the following ways:

Cross-fading intensity of fusion and reference volume: By default, all data sets are shown in full intensity. However, this can later be changed by means of the contrast menu (Figure 56). Each data set can reduce its weight in the resulting fusion image or be completely deactivated. The gray level window that controls the contrast in different areas of the image can also be adjusted separately for each data set. Refer to Section „Adjusting gray levels for patient image data".

Figure 56 Intensity sliders for image fusion

Additionally, you can select which data sets are fused together for each cross-section view to produce the overall display by clicking the button in the lower right corner of the view. This opens a small menu where you can enable and disable certain data sets (Figure 57). For example, if you have multiple data sets that have an optimal in-slice resolution for some orientations, e.g. sagittal, you might want to prefer this data set to be displayed in the sagittal view.

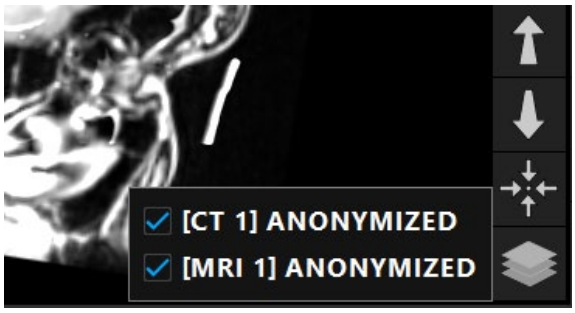


Figure 57 Selection of displayed data sets per view

9.7. Selecting the patient registration type

Before every navigated surgery, it is necessary to register the patient. As a result of patient registration, the software determines the position of the patient anatomy and establishes a match between the patient anatomy and the patient image data.

The software offers three types of patient registration (see Figure 58):

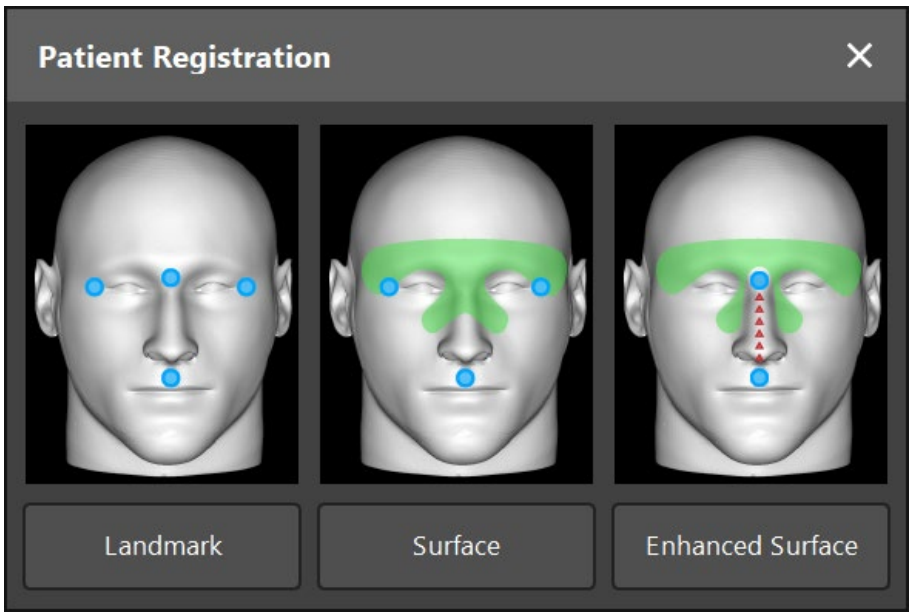


Figure 58 Patient registration dialog

Landmark

At least three and at most five clearly identifiable landmarks are set in the patient image data and corresponding points are 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

Three clearly identifiable landmarks are set in the patient image data and corresponding points are 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 cm^2 of skin near the situs are necessary.

Enhanced surface

For this registration type, a specific path between two landmarks in the patient image data are generated. You must move the pointer along the same path 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 40 cm^2 of skin near the situs are necessary.

By default, the *Enhanced Surface Registration* type is chosen, which enables a direct switch into the navigation mode if the intial path starting at the subnasal towards the nasion is automatically detected by the software.

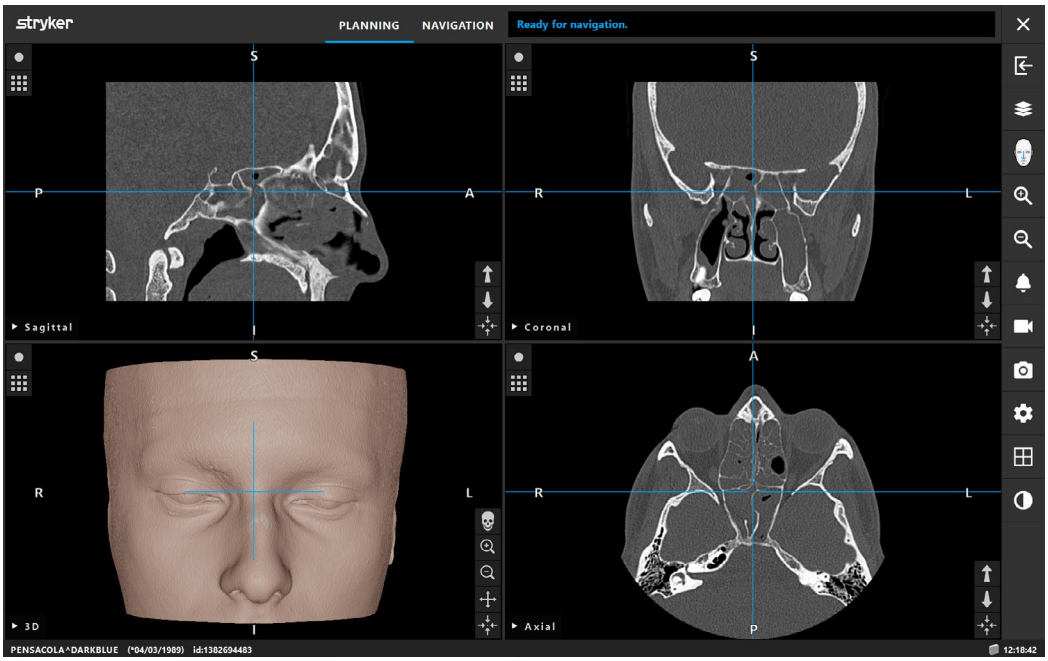


Figure 59 Patient image data after loading: ready for navigation

At times, the required initial path can't be generated automatically and you are asked to configure the patient registration.

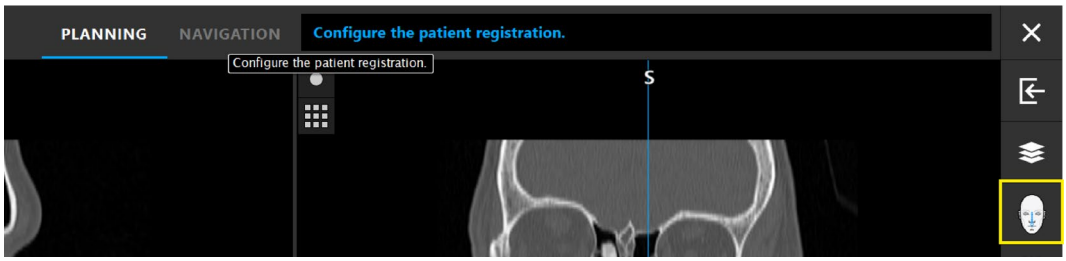


Figure 60 Patient image data after loading: configure patient registration

Clicking the *Patient Registration* button opens the *Patient Registration* dialog box (Figure 58). The *Patient Registration* button changes its appearance depending on the chosen registration type.

9.8. Managing landmarks

9.8.1. Defining landmarks

WARNING

- Landmarks should be positioned on easily recognizable anatomical structures that only move very little when touched with the tip of the pointer. Anatomical landmarks commonly used as registration points are: Lateral canthi, nasion, and subnasale.
- Do not define landmarks on sensitive structures, such as eyes, that might be moved or injured by the tip of the pointer.

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

- The distance between two landmarks should be at least 4 mm.
- The landmarks should be close to the operation area.
- Three landmarks must not be positioned on a single straight line. Landmark positions must define an area of at least 10 cm^2.
- 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 (Refer to Section „Instructions for lateral skull surgery“).

9.8.2. Defining landmarks in the 3D model

To add landmarks to the 3D model, click the place where the landmark should be set (Figure 61, Figure 62).

An added landmark appears as a semi-transparent blue sphere with a small solid center in the 3D view.

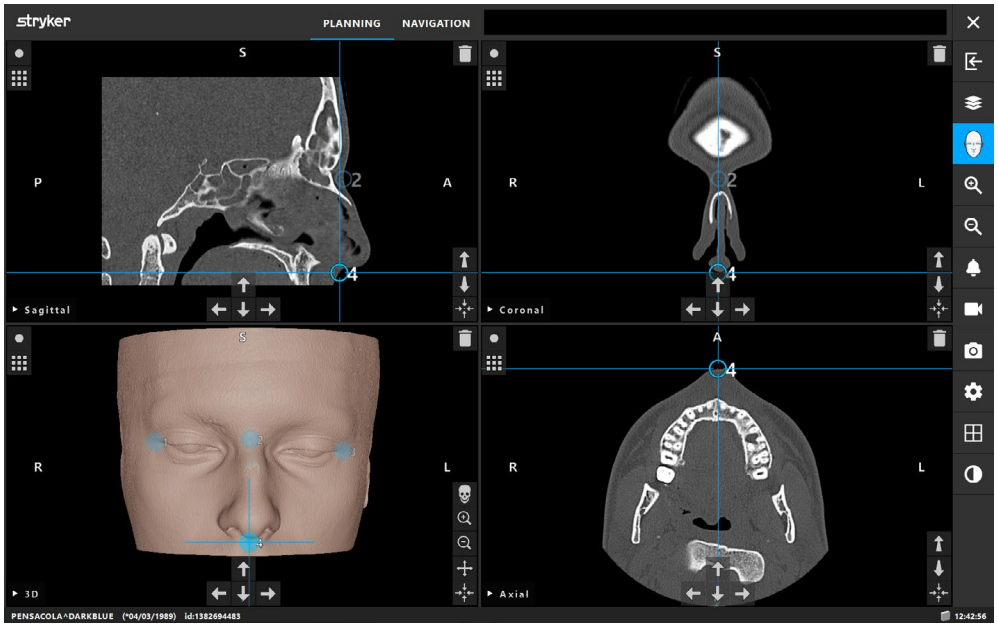


Figure 61 Placing landmarks

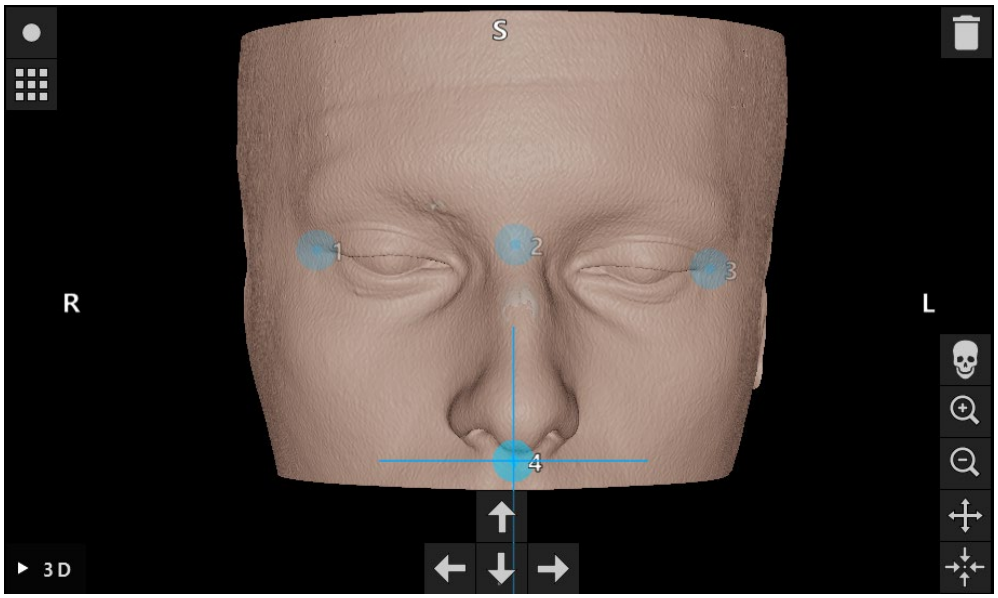


Figure 62 Adding landmarks in the 3D view

Make sure that landmarks are placed directly on the 3D model surface and not outside the 3D model surface.

9.8.3. Placing landmarks in 2D cross-section images

To add landmarks to the 2D cross-section images (Figure 63), click the place where a landmark should be set. An added landmark is shown as a blue circle. The size of the circle shows the distance to the slice in which the landmark was defined.

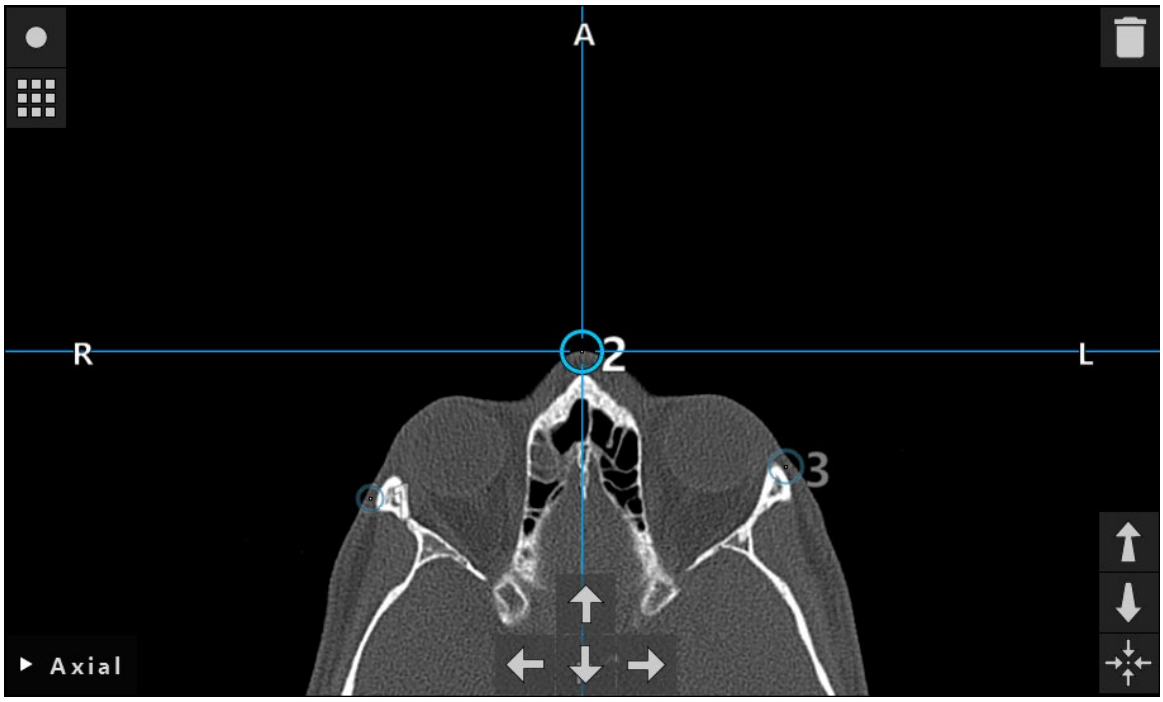


Figure 63 Adding landmarks to an axial view

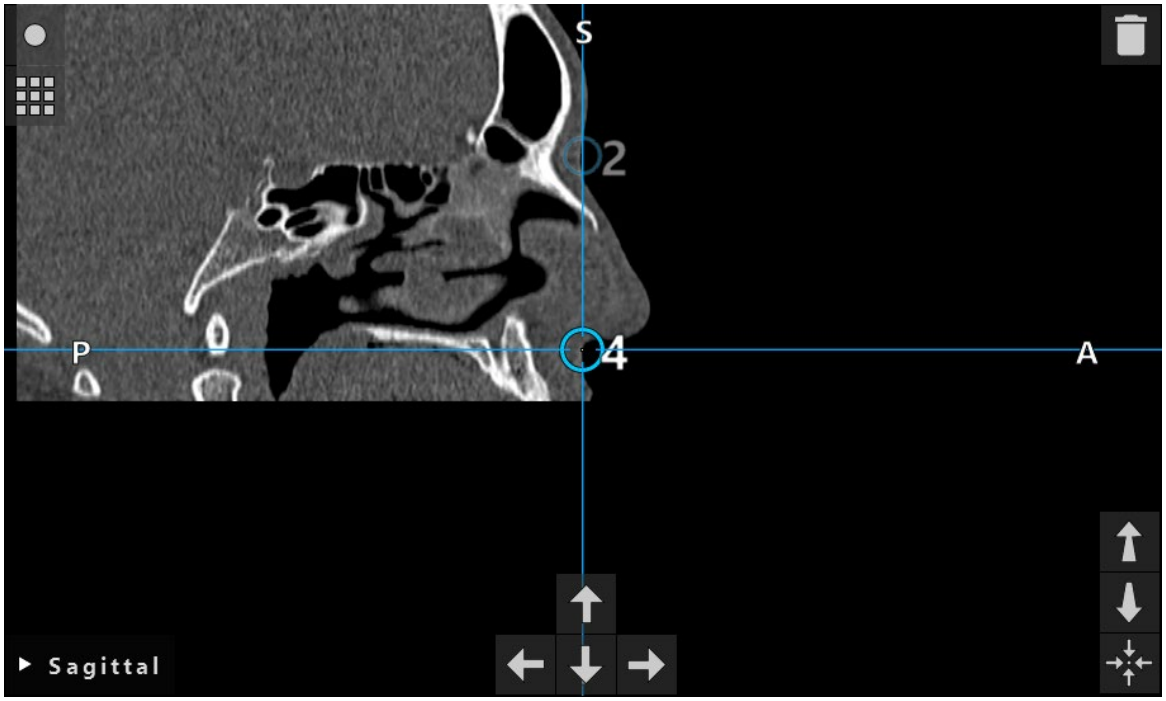


Figure 64 Adding landmarks to a sagittal view

9.8.4. Moving landmarks

The position of existing landmarks can be changed in all views. Click to choose a landmark and drag the landmark to a new position. For precise positioning of the landmarks, use the four additional arrow buttons of the 2D cross-section data. Choose a landmark and move it through the slices of the cross-section data with the help of the four additional arrow buttons.

9.8.5. Removing landmarks

To remove existing landmarks, select the desired landmark and click the *Trash* button in the 3D view or in one of the 2D cross-section views.

Figure 65 Trash button

9.9. Patient registration: landmark

If the *Landmark Patient Registration* type is selected, this is displayed by a corresponding activated symbol (Figure 66).

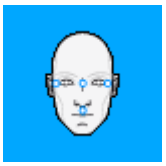


Figure 66 Landmark patient registration type

For the *Landmark Patient Registration* type, it is necessary to place three to five landmarks on easily recognizable anatomical positions in the patient image data. The positions should be chosen so that they can be found and touched precisely with a navigated pointer in navigation mode. The landmarks should not be on the same level or too close together.

9.10. Patient registration: surface

If the *Surface Patient Registration* type is selected, this is displayed by a corresponding activated symbol (Figure 67).

Figure 67 Surface patient registration type

To use the *Surface Patient Registration* type, it is necessary to define three landmarks on easily recognizable anatomical positions in the patient image data (Figure 68). These positions should be easily identifiable so that during navigation you can easily find and touch them on the patient using a navigated pointer with a considerable degree of accuracy.

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

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.

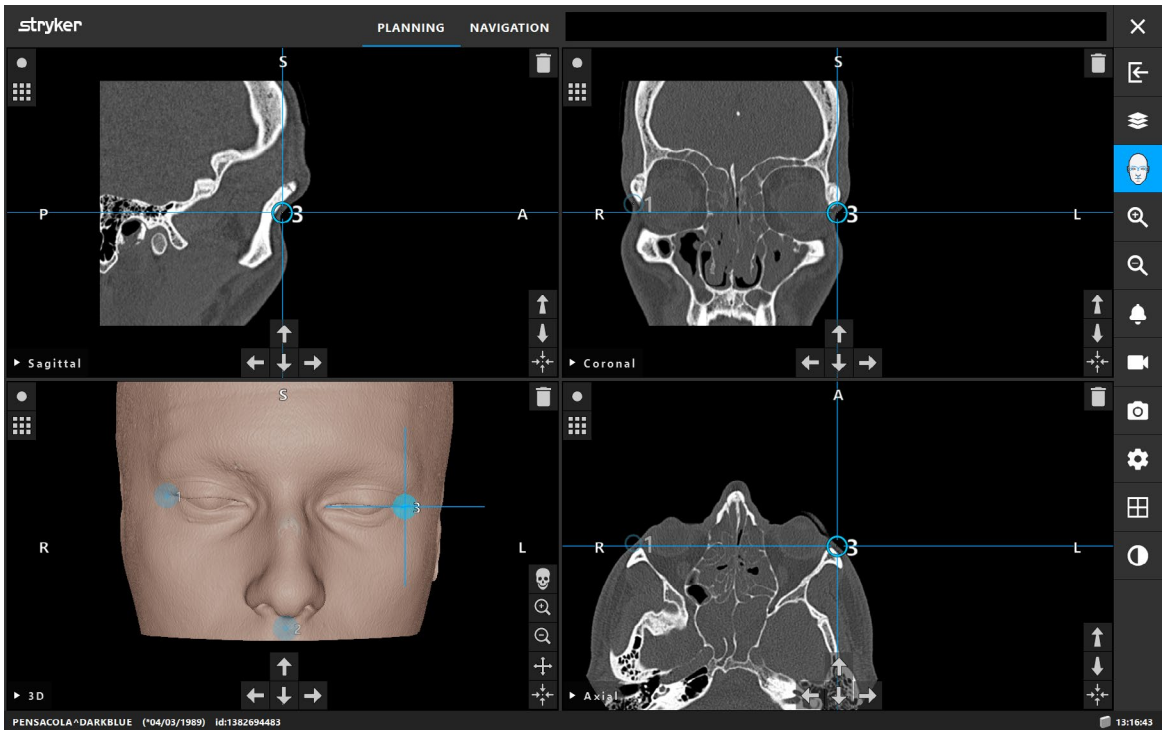


Figure 68 Placing surface landmarks

9.11. Patient registration: enhanced surface

If the *Enhanced Surface Patient Registration* type is selected, this is displayed by the corresponding activated symbol (Figure 69). After the import, the surface is calculated automatically and the two landmarks are set automatically. The *Enhanced Surface Registration* is now selected.

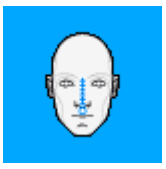


Figure 69 Enhanced surface registration type

A precondition for the *Enhanced Surface Patient Registration* type is the correct recognition of the bridge of the nose and the subnasale (Figure 70).

If the anatomic features (subnasale and nasion) in the patient image data are detected, they are displayed in the 3D model as blue landmarks. The subnasale represents the starting point of a touching path that is shown as a sequence of red triangles directed from the subnasale to the nasion. If the recognition is ideal, the touching path runs along the middle of the nose bridge.

CAUTION

If the subnasale and nasion are not detected correctly, reposition the landmarks in the image. If the subnasale and nasion are not detected at all, place both landmarks in the image manually. If neither helps, choose another registration method.

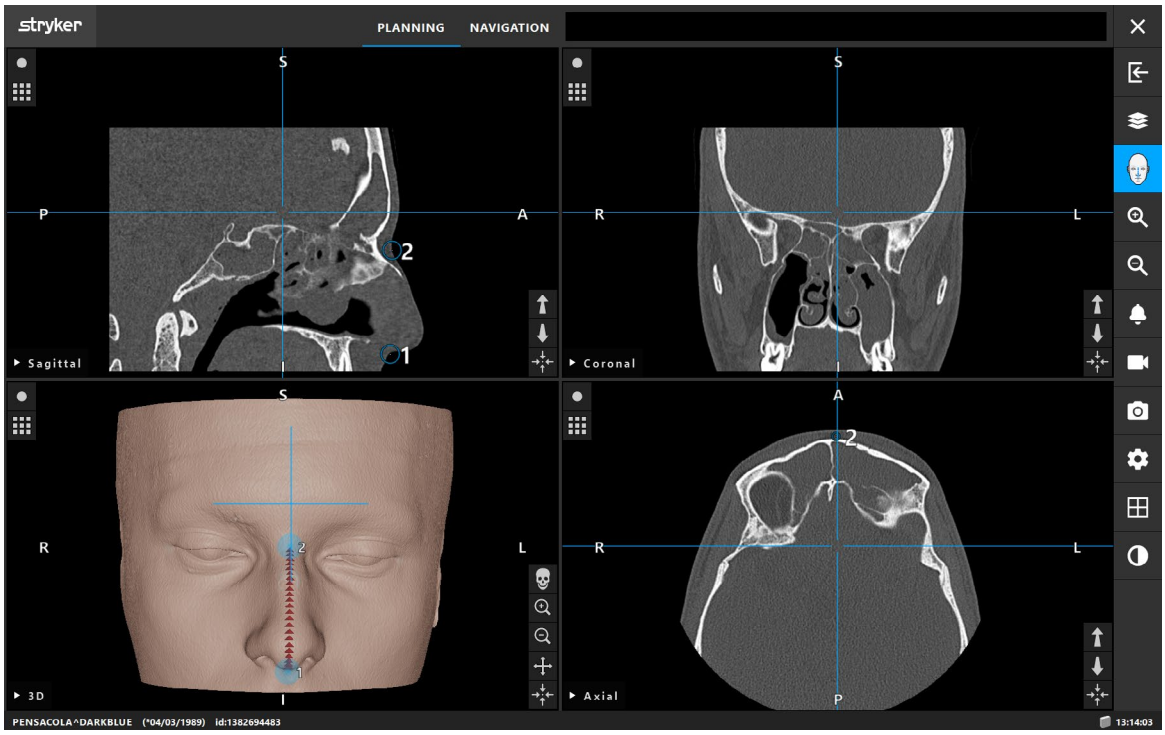


Figure 70 Adjusting/Placing subnasale and nasion landmarks

If the path between the two landmarks is too flat, too short or too long, the software alerts you and does not allow switching to the navigation mode. Correct the landmarks positioning so that a more feasible path is created.

Figure 71 Unsuitable path alerts in the message bar

The advantage of the *Enhanced Surface Patient Registration* type is that landmarks are set in the image automatically. Thus the planning of the registration can be minimized to the loading of patient image data.

If the path can't be generated automatically, place the two landmarks that define the path manually. The message bar will assist you in defining a feasible path.

9.12. Instructions for functional endoscopic sinus surgery (FESS)

For frontal sinus surgery and functional endoscopic sinus surgery, the following procedure is recommended:

1. Request a thin slice CT scan of the operating field (please refer to Section „Navigation surgery cycle“ or the Imaging Protocol).

2. Use the *Enhanced Surface Registration* if possible.

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 between the drape and the points you collect on the patient’s surface (Figure 72).

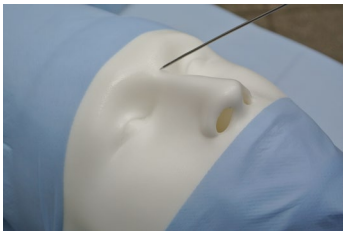


Figure 72 Patient draping and registration for FESS

9.13. Instructions for lateral skull surgery

For middle ear surgery, both *Landmark* and *Surface Registrations* can be used.

Landmark registration

Landmark Registration with 4-5 bone screws is found to be most accurate for middle ear surgery.

1. Place these screws at the end of a preceding surgery when entry to the middle ear is exposed (Figure 73).

2. Request a thin slice CT scan and ensure that all bone screws are completely included. Choose a resolution in which the relevant structures are well visible. In case the data are too large, request the data to be trimmed accordingly or trim the data in the *Image Optimization* dialog. Refer to Section „Optimization of patient image data visualization“.

3. Use the Patient Tracker Electromagnetic and place it on the same side of the head as where the bone screws are placed. If you are being assisted by a physician, 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 74).

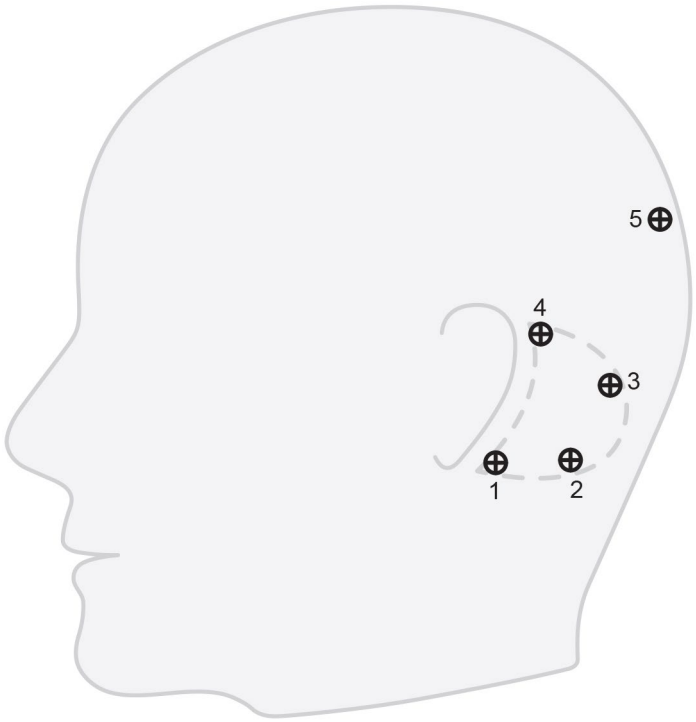


Figure 73 Recommended bone screw placement for lateral skull surgery

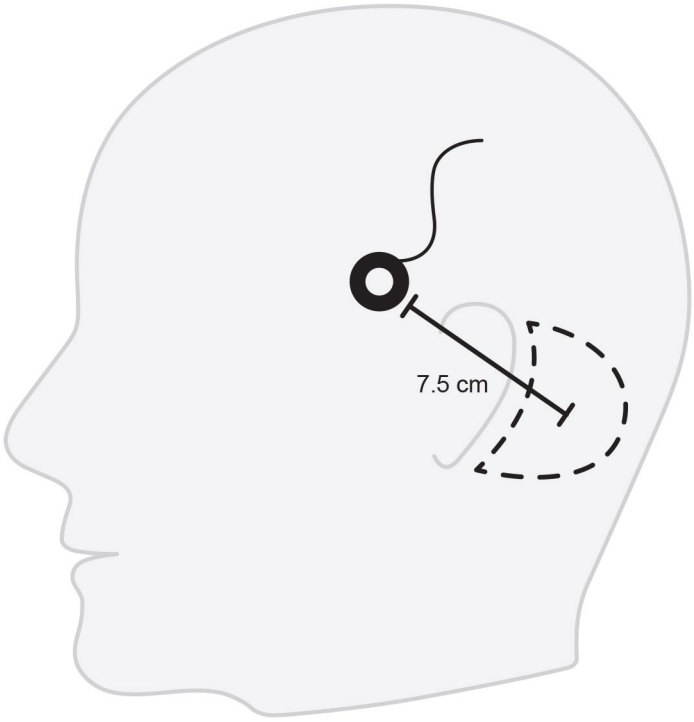


Figure 74 Position of the patient tracker electromagnetic for lateral skull surgery

Surface Registration

A *Surface Registration* is less invasive and is to be preferred if no artificial landmarks such as bone screws are available.

1. Request a thin slice CT scan and ensure that the half of the patient's face is completely included. Choose a resolution in which the relevant structures are well visible. In case the data are too large, request the data to be trimmed accordingly or trim the data in the *Image Optimization* dialog. Refer to Section „Optimization of patient image data visualization".

2. Place registration landmarks on subnasale, nasion, and the lateral canthus of the eye near the surgical situs as starting points for *Surface Registration*.

3. Use the Patient Tracker Electromagnetic or Patient Tracker Electromagnetic - 10 Uses and place it on the opposite side of the situs from yourself. If you are being assisted by a physician, the patient tracker can be moved correspondingly to the right or to the left. A distance of 7.5 cm has been found to be most effective (Figure 74).

4. When collecting surface points, proceed from the initial area (nasion, subnasal, canthus) to the mastoid bone and back. Do not collect points under the ear and on the ear lobe as these are not rigidly connected to the middle ear anatomy.

9.14. Planning objects for navigated surgery [TGS ONLY]

Planning objects extend the patient image information with 3D objects that can be used to support the surgery when used with software that has a navigation mode. There are nine types of planning objects: planning points, target structures, planning paths, cutting lines, segmentations, paranasal sinuses, implants, measurements, and symmetry plane.

When saving a planning, all created planning objects are saved as well. When loading a planning, they are restored.

CAUTION

Limit the quantity of planning objects during planning to a relevant selection. If there are too many planning objects, their visualizations can overlap during the operation, thereby reducing clarity.

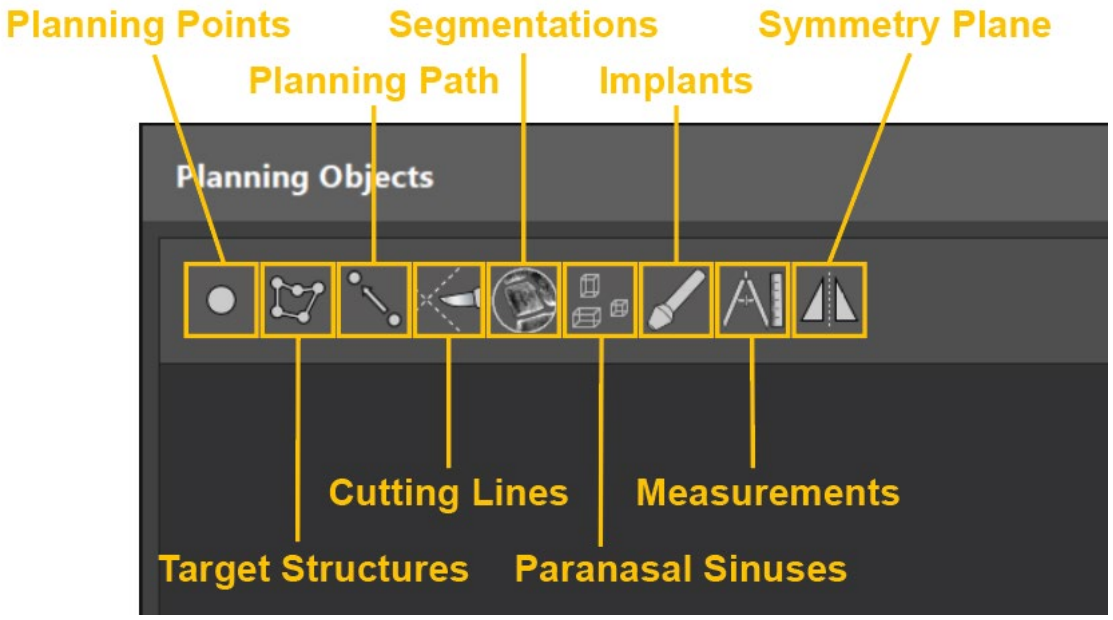


Figure 75 Buttons for different types of planning objects

The following buttons provide general functionalities for planning objects. The buttons can be found either in the large planning object preview button in the *Planning Objects* dialog or in the upper right area of the cross-sectional and 3D views for a selected planning object.

	The *Hide* button is only available in the large preview buttons in the *Planning Objects* dialog. Hides the object or shows the object again. A hidden object is no longer displayed outside of the dialog.
	Clicking the *Trash* button deletes the object. Warning: This operation cannot be undone. When deleting an object in the main view, click to select and highlight the planning object. While the object is selected, the button is shown in the upper right part of the cross-section and 3D views. The button is also available in the top left corner of the *Planning Objects* dialog.
	Clicking this *Configuration* button opens the *Properties* dialog. This dialog allows you to choose various colors, a description, and to activate or deactivate a message during the navigation. Refer to Section „Defining notification distances“. This button is also displayed in the upper right area of the cross-sectional views and 3D view while an object is selected.
	Clicking the *Mirror* button enables you to create a mirror copy of the selected object on the other side of the symmetry plane. Refer to Section „Mirroring of planning objects“. Only available for some objects.
	Clicking the *Export* button enables you to export the object as an STL file. Only available for planning structures, bone segmentations, and implants.
	Clicking the *Add* button enables you to add another planning object of the currently active planning object type without opening the *Planning Objects* dialog (refer to Section „Planning objects dialog“).

9.14.1. Planning object types

Planning points

Planning points are numbered individual points that can be placed in the 3D or the ortho views.

	To create planning points, click the *Planning Points* button in the *Planning Objects* dialog. Then click the large *Plus* button. The dialog closes when the planning points mode is active. Then define a planning point by clicking in the cross-section image view or the 3D view and then refine through point moving (refer to Section „Moving planning objects“) in the cross-section image views. Planning points are shown as white rings in the cross-section image views, and as white spheres in the 3D view.

Planning structures

Planning structures are three-dimensional bodies that are defined through intersections (Figure 76). With the help of planning structures you can mark anatomical structures of interest by marking their borders with points.

	Click the *Planning Structures* button in the *Planning Object* dialog. Then click the big *Plus* button. Click the positions where you want to place the delimiting points. After placing at least three points, they are connected to form a closed region. This procedure needs to be repeated in at least one other slice of the same view (axial, coronal, sagittal) to achieve a 3D view. The regions enclosed in different slices are then automatically combined into a 3D structure.
	To copy an already planned region from one slice into another, first create a region as described above. Then switch to a different slice of the same orientation, and click the button displayed on the left. The previously planned region is now copied into the current slice and can be adjusted according to anatomical structures in the image. It is not necessary to copy existing regions; however, it can save work if only minor adjustments to a region are necessary.

You can define a planning structure in any of the three cross-section views. The entire planning structure must be edited in the same cross-section view, in which the creation was initiated.

Within slices of the same orientation, any number of enclosed regions can be planned. The structure is interpolated between the slices in which regions are planned. To generate a spatial representation, it is necessary to enclose regions in at least two slices.

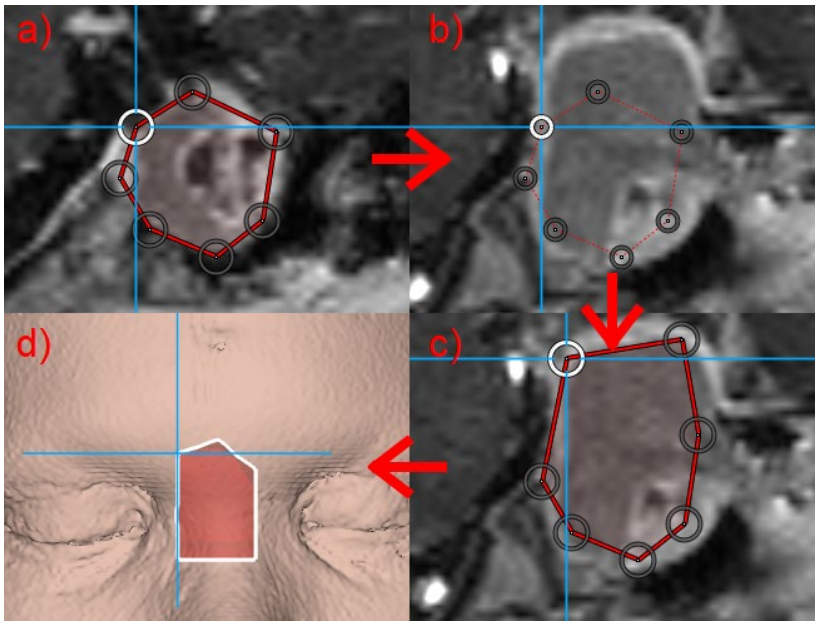


Figure 76 Creation of a planning structure

a - Enclose a region in one slice

b - Change to a different slice. The boundary of the region is displayed by a dotted line

c - Copy the region into the current slice and adjust the points

d - Spatial representation of the planning structure in the 3D view

Planning path

Planning paths are directed linear paths defined by two points (a start point and an end point). Planning paths can be placed in the 3D or the cross-section views (see Figure 77).

To create a planning path, click the *Planning Paths* button in the *Planning Objects* dialog. Then click the large *Plus* button. The dialog closes when the *Planning Paths* mode is active. Then define a planning path by consecutively creating two points. To define a point, click into the cross-section image view or the 3D view and then refine its position through point moving (refer to Section „Moving planning objects“) in the cross-section image views as desired. A connecting path between the points is automatically created.

Additional functionalities allowing to adjust the position of planning points are provided with the following three buttons:

Move the path’s start point along the axis to the patient surface.

Move the path’s start point to the current position.

Swap the path’s end and start positions.

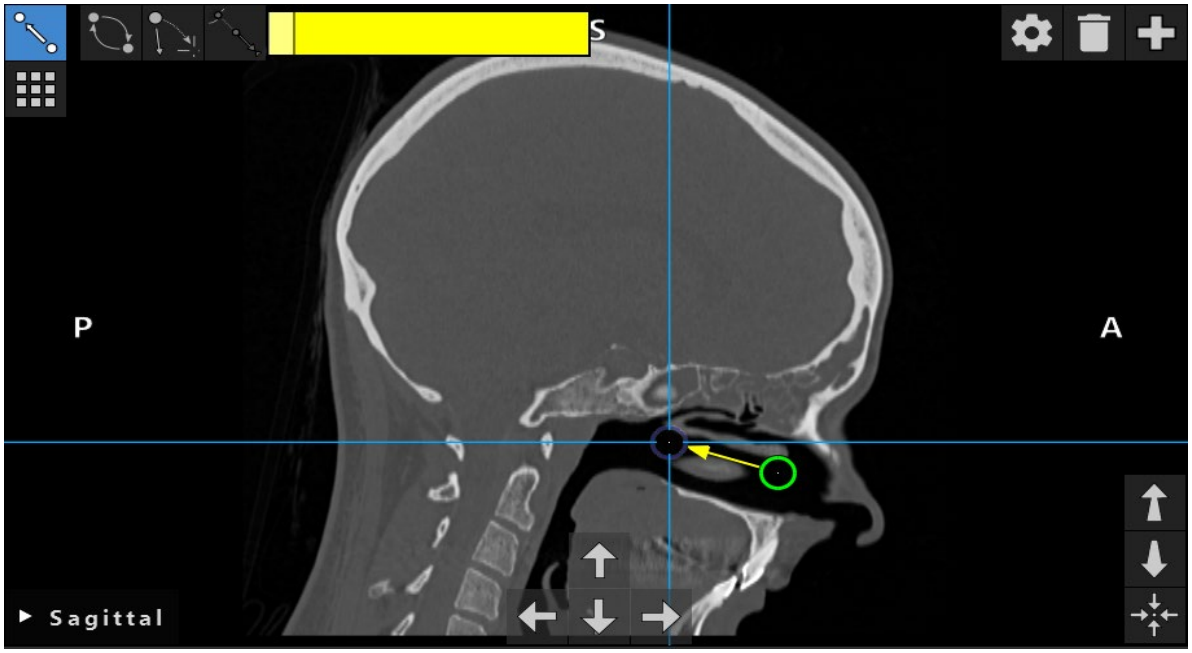


Figure 77 Creating a planning path

Cutting line

A cutting line is a line defined by any number of points placed on the patient's bone structure and provides additional navigation information. This information can be used for severing of the bone along the planned line.

To create a cutting line, click the *Cutting Line* button (Figure 78) in the *Planning Object* dialog. Then click the big *Plus* button. Points of the cutting line can be placed in the 3D view and in any of the cross-sectional views. New points are automatically added to the end of the cutting line. If a new point is placed close to an already existing line segment, it is inserted between existing points.

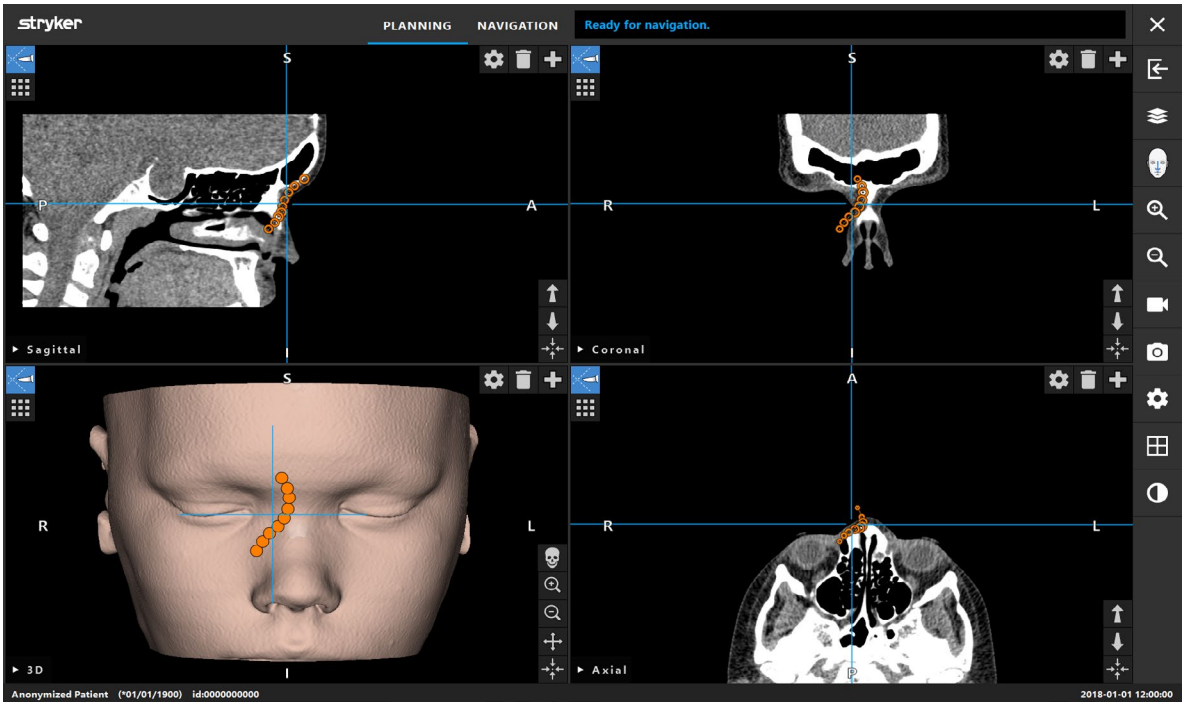


Figure 78 Planning a cutting line

Segmentations

Segmentations mark parts of a patient's bone or soft tissue structure in a different color (Figure 79). Use the slider, to highlight either bone or soft tissue areas for segmentation. Move or rotate these segmentations, or mirror them to the other side of the face along the symmetry plane.

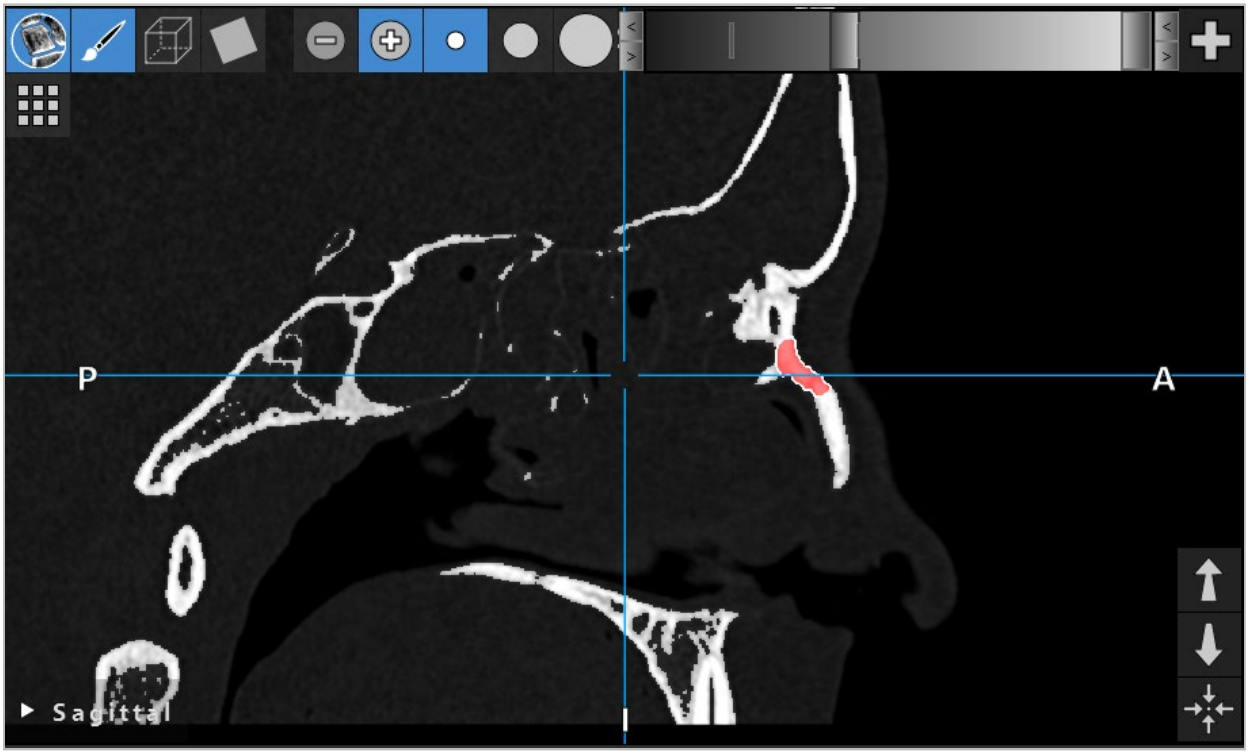


Figure 79 Segmentation of e.g. bone structure

To create a segmentation, click the *Segmentations* button in the *Planning Object* dialog. Then click the big *Plus* button to close the dialog.

In the cross-sectional views, the segmented structures are highlighted. The mouse cursor turns into a colored circle. Click and drag the circle over a highlighted region to mark the areas.

To unmark areas, click the minus sign button. The mouse cursor turns gray. Now click and drag in the views over marked areas in order to unmark them. Alternatively, hold the *Shift* button on the keyboard.

Change the size of the circle by clicking one of the three buttons depicting circles of different sizes. Note that the current zoom level also influences the size of the area that is being marked or unmarked.

To speed up the process, bone or soft tissue structures in neighboring slices are also marked. The depth depends on the zoom level and the size of the mouse cursor.

When you have finished marking the structure, click the blue *Plus Sign* button again in order to leave the marking mode.

The slider widget at the top of the view can be used to adjust the range of densities that can be marked or unmarked. This allows to specifically mark or unmark bone structures or soft tissue.

The slider widget consists of two sliders: The left one defines the minimum density and the right one defines the maximum density that can be marked or unmarked. The sliders can be adjusted by clicking and dragging or by using the arrow buttons on each side of the slider widget. The view is updated immediately to reflect the changes.

Two snap positions for soft tissue and bone are marked for quick selection.

Once the range of densities is selected the *Brush* or *Box* tool can be used to mark or unmark areas.

	Segment an anatomy of interest with activating the *Box* button, by drawing a box around it.
	Click the *Brush* button to use a brush for segmentation.
	Use those three buttons to 1x / 2x / 3x magnify the brush size.
	The *Subtract* / *Add* Buttons are available if the *Brush* or *Box* button is active. Use the buttons to switch between removing / adding voxels to the segmentation.
	With the *Plane* Button you can use a 3D plane to cut away one side of the segmentation.
	A *Flip* button is available if the *Plane* button is active. This button enables you to pick the side of the plane for which the cut away operation should be applied.
	*Threshold* slider

Paranasal sinuses

This function allows highlighting paranasal sinus cells and drainage pathways (see Figure 81 - Figure 84).

	Click the *Paranasal Sinuses* button in the *Planning Object* dialog. Then click the large *Plus* button.

Building blocks mode provides the following functions:

	Box creation function allows you to create and manipulate 3D boxes within the patient image data. This can be used to highlight specific paranasal sinus cells. To create a box, click and hold one point in one of the cross-section views and drag the cursor to a different point. A box is spanned between the two points with a depth proportional to its size. Adjust its size and position by dragging its sides. The shape of boxes can be modified by dragging the box edges as well as corners. As long as boxes are only modified by dragging edges, the box can be modified in all cross-section views via edge or corner dragging. After reshaping a box corner in one view, corners can no longer be reshaped in any of the other views. To create a new box, repeat this process at a different position. Switch between different boxes by clicking them while in this mode.
	Tubes creation (drainage pathways) function allows you to create and manipulate tubes through the image volume. This can be used to highlight drainages in the nasal cavity. Tubes are planned on the basis of building blocks so that not only two but also three dimensional tubes can be planned. To create a new tube, press and hold a mouse button at some point in one of the cross-section views and drag the cursor along a path. You can extend and contract the tube by pressing and holding a mouse button near an endpoint and moving the mouse in the desired direction. The path can be deformed by pressing and holding a mouse button next to it and moving the mouse in the desired direction. To create a new tube, repeat this process at a different position in one of the cross-section views. Switch between different tubes by clicking them while in this mode.
	For this planning object this button has a special function and is also available outside of the *Planning Objects* dialog. This button temporarily hides all previously planned boxes and tubes except for those selected. Clicking the button once more makes all hidden boxes visible again.
	In addition to the object settings described in „Planning objects dialog“, drainage pathways and boxes can be classified directly in correspondence to the IFAC classification (see Figure 80).

Tubes must be created from the inside of the patient to the outside.

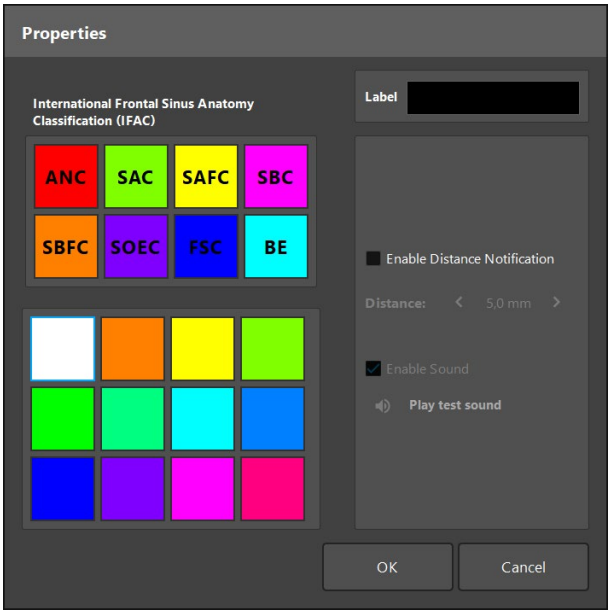


Figure 80 IFAC classification

ANC	Agger Nasi Cells
SAC	Supra Agger Cell
SAFC	Supra Agger Frontal Cell
SBC	Supra Bulla Cell
SBFC	Supra Bulla Frontal Cell
SOEC	Supra Orbital Ethmoid Cell
FSC	Frontal Septal Cell
BE	Bulla Ethmoidalis

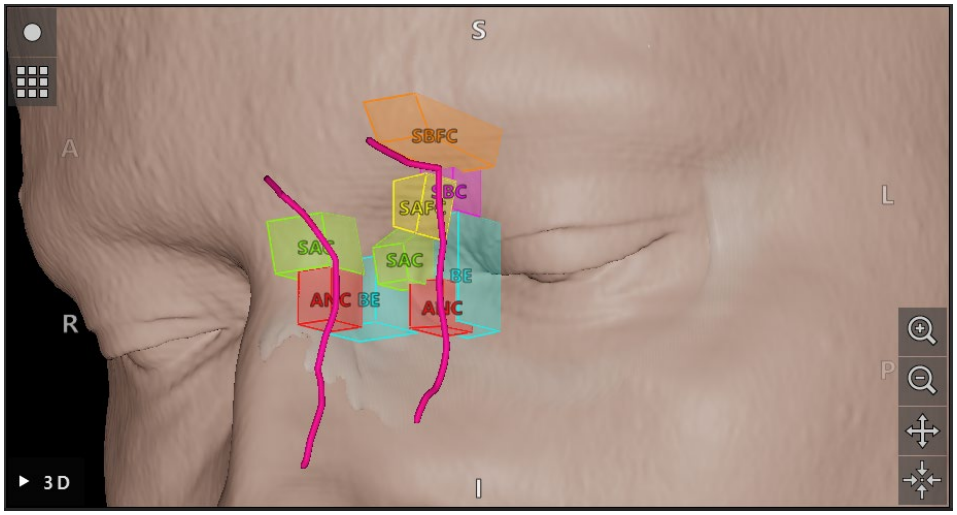


Figure 81 IFAC classified Paranasal Sinuses and drainage pathways in 3D view

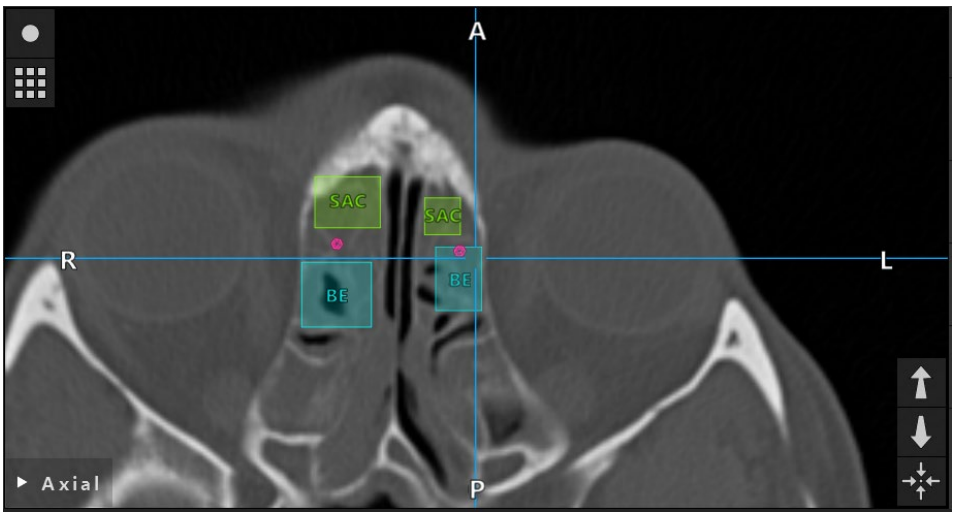


Figure 82 IFAC classified Paranasal Sinuses and drainage pathways in axial view

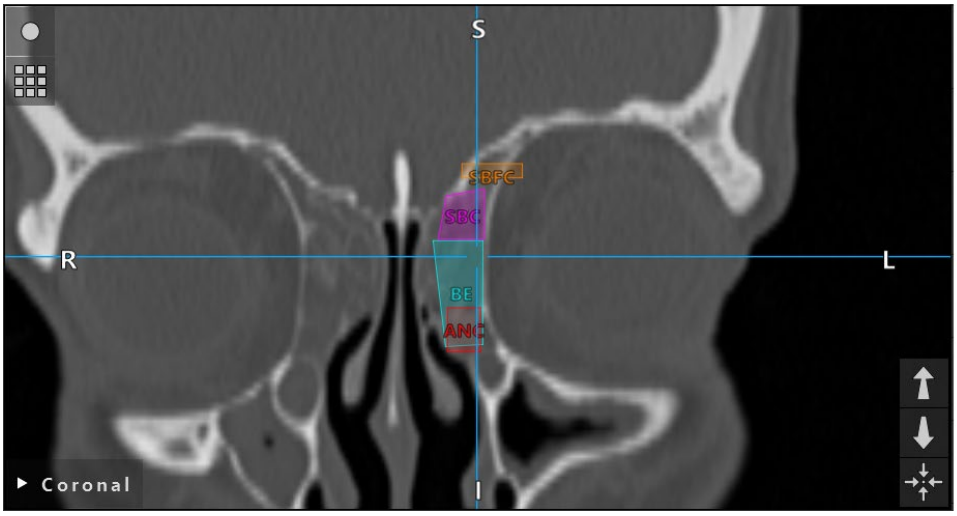


Figure 83 IFAC classified Paranasal Sinuses and drainage pathways in coronal view

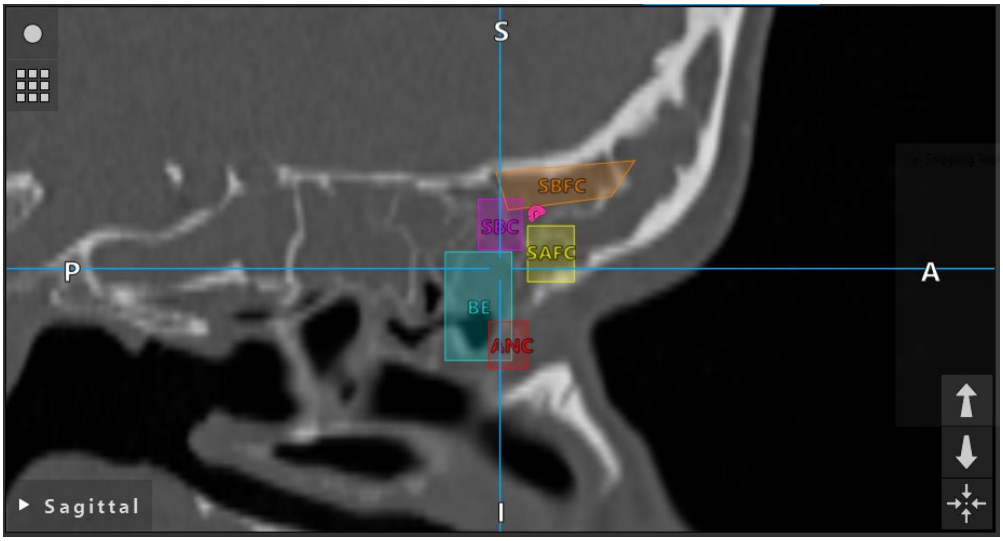
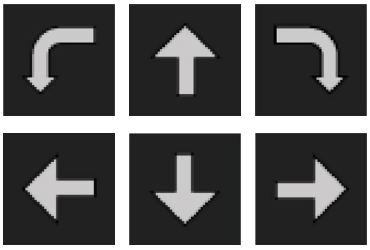


Figure 84 IFAC classified Paranasal Sinuses and drainage pathways in sagittal view

Implants

Implant objects defined using Stereolithography *(STL)* file format can be imported into the navigation software as 3D shapes.

STL files can be generated by exporting 3D planning structures, like bone segments and target structure, or using third party STL generating software.

	To import implants, click the *Implants* button in the *Planning Object* dialog. Then click the *Plus* button. A file dialog opens; select the file to be imported. The implant is then loaded by the software and positioned in the DICOM coordinate space of the reference data set.
	To position and/or rotate the implant, use the *Positioning* arrow buttons in each cross-section view.
	*Rotate Implant* button.
	*Recenter Implant* button.
	*Move Implant* button.
	*Center Selected Implant* button.

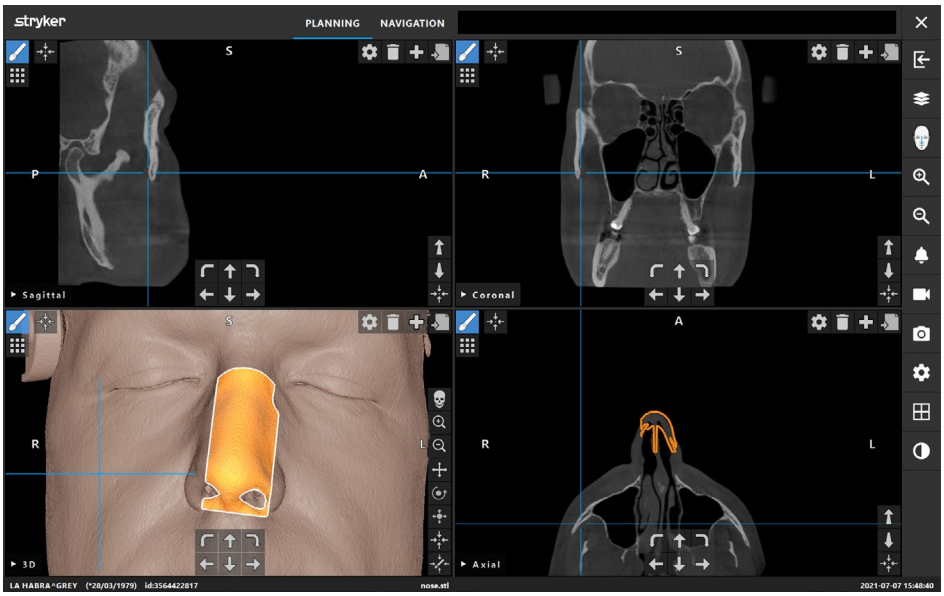


Figure 85 Positioning of an implant

Symmetry plane

The symmetry plane is defined by subnasale, nasion, and sella, and divides the skull into the left and the right half. The symmetry plane is necessary for the mirroring of planning objects. In most cases, the symmetry plane is automatically detected during import. It might be necessary to manually adjust the automatic detected symmetry plane.

To edit the symmetry plane, click the *Symmetry Plane* button in the *Planning Object* dialog. While the *Symmetry Plane* mode is active, a plane is shown in the 3D view. Adjust the symmetry plane by dragging the three object handle points. Note: Only one symmetry plane can be defined.

Measurements

With a measurement planning object, it is possible to measure distances, angles, and areas.

To switch into the measurements mode, click the *Measurements* button in the *Planning Objects* dialog. Then click the big *Plus* button to start the measurement.

In the cross-section views there are three additional buttons with which to select the type of measurement:

	To measure the distance between two points, activate the *Distances* button and click anywhere in the cross-section views at the position where the points can be set.
	To measure an angle, activate the *Angles* button, then click in the view where the measurement should be taken. Complete the measurement by creating two or more points to define the sides of the angle.
	To measure an area, activate the *Areas* button and create two points by clicking. These two points define the main axis. A third point must be created next to this axis and defines an oval, the area of which is displayed. Create a fourth point on the other side of the axis to better fit the measurement to the object that is to be measured.

9.14.2. Planning objects dialog

To open the *Planning Objects* dialog, click the *Planning Objects* dialog button in a cross-section or the 3D view (Figure 86).

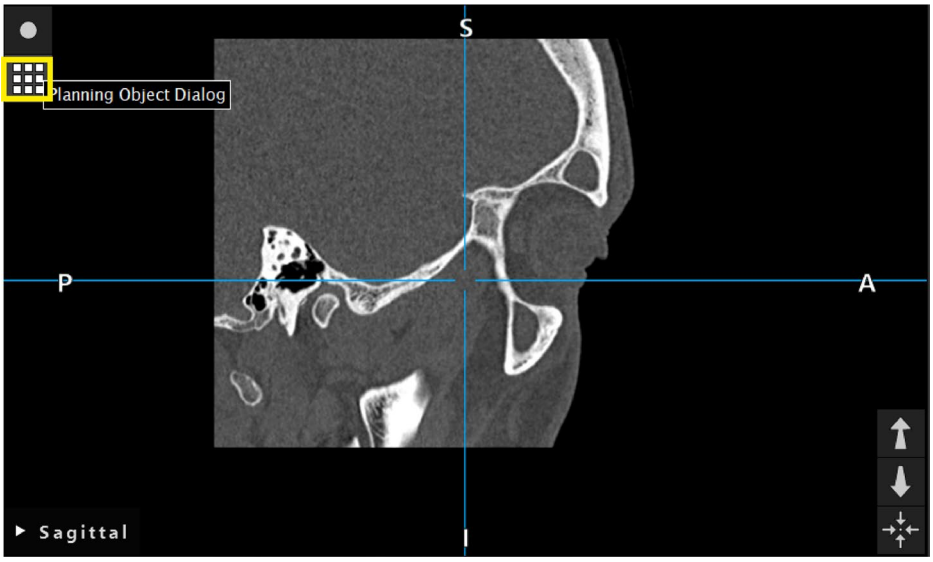


Figure 86 Button for opening the *Planning Objects* dialog

Each planning object is displayed with a small preview around its location on a large button (Figure 87). Clicking the button selects the object; double-clicking selects and also closes the dialog.

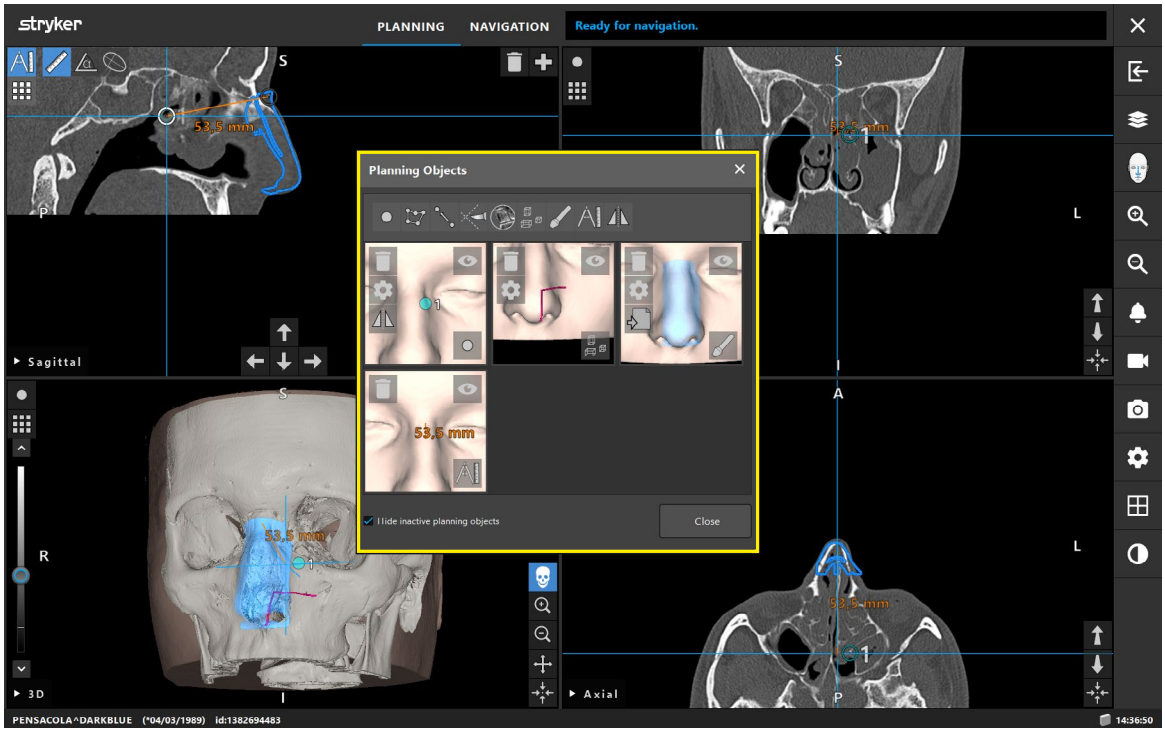


Figure 87 *Planning Objects* dialog

To create a new planning object, first select the type of the object by clicking one of the *Planning Objects* type buttons in the upper taskbar in the dialog (Figure 87). Then click the large *Plus* button in the *Planning Objects* dialog (Figure 88).

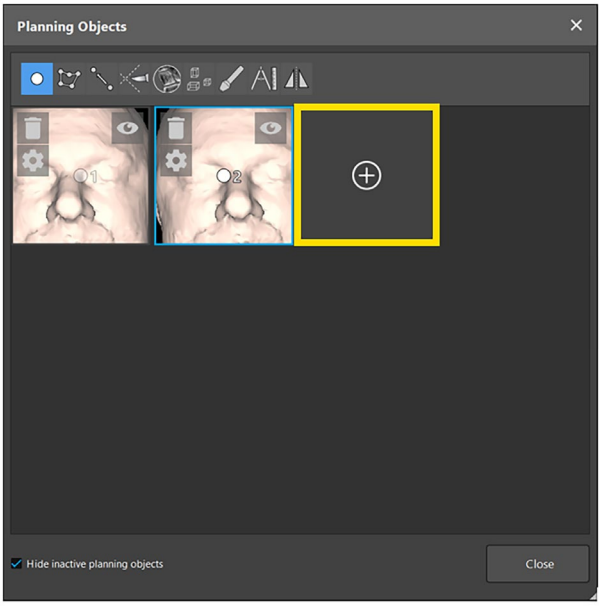


Figure 88 *Create New Planning Objects* button

Alternatively, if a *Planning Objects* type is already active outside the *Planning Objects* dialog, you can click the small *Plus* button in one of the views in order to create a new planning object of the active type. Refer to Section „Planning object types“ for description of the *Plus* button.

When creating a new planning object or selecting an existing one, the software enters a mode where interaction is only possible with objects of the chosen type. The active planning object type is displayed in the top left corner of each cross-section view and 3D view (e.g. Figure 89) and can be toggled off by clicking the button.

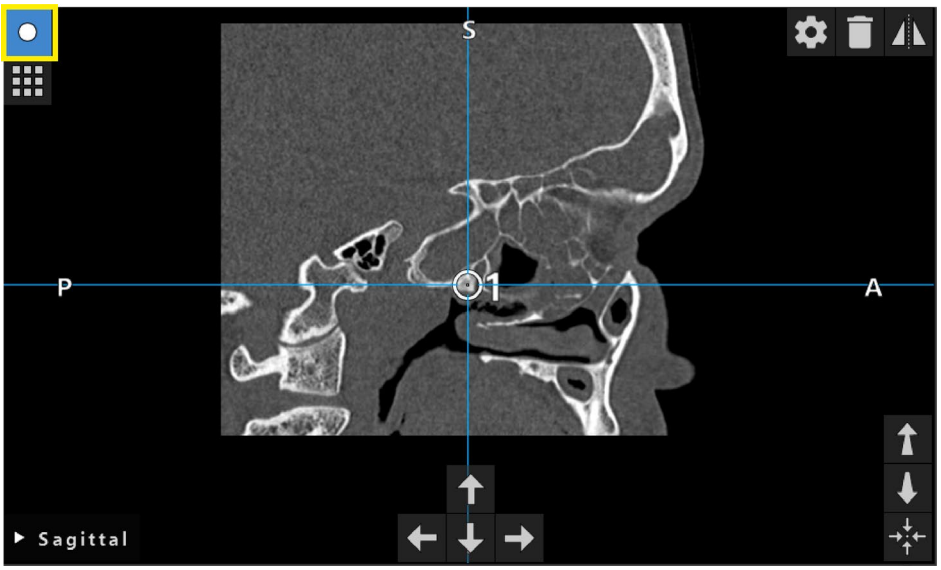


Figure 89 Activated planning point mode

9.14.3. Moving planning objects

While the *Planning Object* mode is active, you can move existing points that are part of this object. Click to select a point; drag to reposition a point. The selected point is highlighted.

Also a precise adjustment function is available for points that are part of a planning object (Figure 90). First activate the mode for the respective planning object and then select the desired point. When selected, points are highlighted and slightly enlarged. Additional arrow buttons for conducting precision adjustment appear in the cross-sectional views. The buttons pointing left, right, up, and down move the point in the image plane.

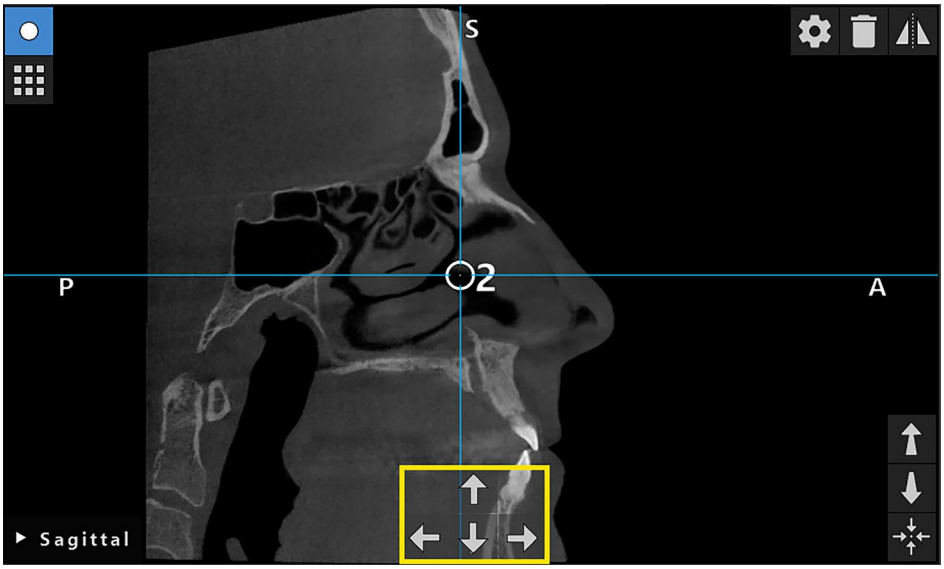


Figure 90 Precise adjustment of planning object points

A selected point of any point-based planning object can be precisely adjusted in all three 2D cross-section views.

9.14.4. Mirroring of planning objects

To mirror existing planning points or planning structures or segmentations, a valid symmetry plane is required. The symmetry plane is automatically determined during import but might require additional manual adjustment. For the description of symmetry planes, refer to Section „Planning object types“.

To mirror a planning object, select the planning object in the *Planning Object* dialog. When an object is selected and a valid symmetry plane exists, a mirror symbol appears in the top left corner of each cross-sectional view as well as in the 3D view (e.g. Figure 90). Activating the mirror symbol causes the point to be mirrored (copied) to the other side of the symmetry plane. The copied planning point is connected to its original. If any of the points moves, its mirrored point moves as well in correspondence with the symmetry plane. The same applies to planning structures. Changes to the structure, e.g. moving, deleting, or adding of border points are also mirrored.

Figure 91 *Mirror Planning Object* button

- If a planning structure is mirrored, the mirrored copy cannot be edited.
- When moving the symmetry plane, all mirrored copies of planning objects move as well. The original points and structures are not moved. If the symmetry plane becomes invalid, all copies are deleted automatically.
- An already mirrored planning point can only be mirrored once, as long as its mirrored copy exists. The same goes for planning structures.

9.14.5. Defining notification distances

Most planning objects can be configured to trigger visual and audible notification signals if the tip of an active instrument comes too close to them. The notification for planning objects may be configured by clicking the *Properties* button in the *Planning Objects* dialog. Refer to Section „Planning objects dialog“.

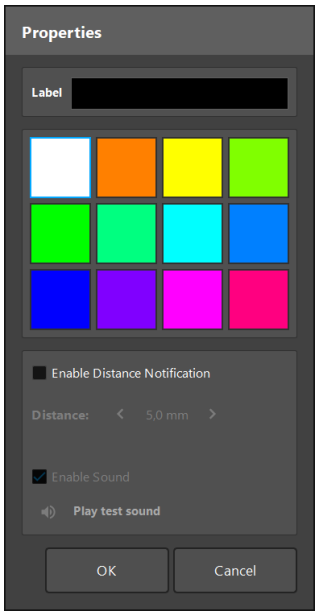


Figure 92 Properties dialog

Figure 93 Toggle notification sounds

An optional user-defined label for planning points can be defined in the *Properties* dialog (Figure 92).

If *Enable Distance Notification* is checked, the planning object is marked as a critical area. In addition, a distance (minimum 3 mm) can be configured as a tolerance boundary. If the distance between the instrument and the critical area is less than the tolerance boundary, a notification sound alerts you. If the instrument is getting very close to the critical structure (< 1.5 mm), the notification sounds are played more frequently.

WARNING

- The notification function can only monitor the distance to critical surgical targets if the navigation is available and accurate. Verify the accuracy of the navigation system and monitor the status display of the system for valid navigation information each time before approaching a critical structure. The notification function is not suitable for general observation of distances if attention cannot be paid to the navigation system.
- If planning objects (e.g. planning points, planning structures or a planning path) are used to measure the distance between the currently navigated instrument and a specific anatomical structure during navigation, it is necessary to set these planning objects at anatomical structures with high precision.
- Make sure that your system is able to play sound. Click *Play Test Sound* in the *Properties* dialog. If you don't hear a sound, verify that the sound settings are switched on and are loud enough in *Windows* settings.

– When using an instrument in the vicinity of an object with notification enabled, quick movements should be avoided. Make sure that the patient registration and instrument calibration are sufficiently accurate.

– Notification sounds can be switched on or off globally or only for single planning objects. To quickly switch off a notification sound, use the corresponding button in the side panel (Figure 93).

9.15. Saving the planning

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

When clicking the *Loading Patient Data* button or the *Close Software* button, a *Save Planning* dialog box appears.

- To overwrite the loaded planning, click *Overwrite*.
- To save the current planning as a duplicate, click *Save as New*.
- To discard the current planning and proceed with either closing the application or importing a new data set, click *Quit without Save* or *Do Not Save* respectively.
- To close the *Save Planning* dialog box and abort the currently executed action, click *Cancel* (Figure 94).

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

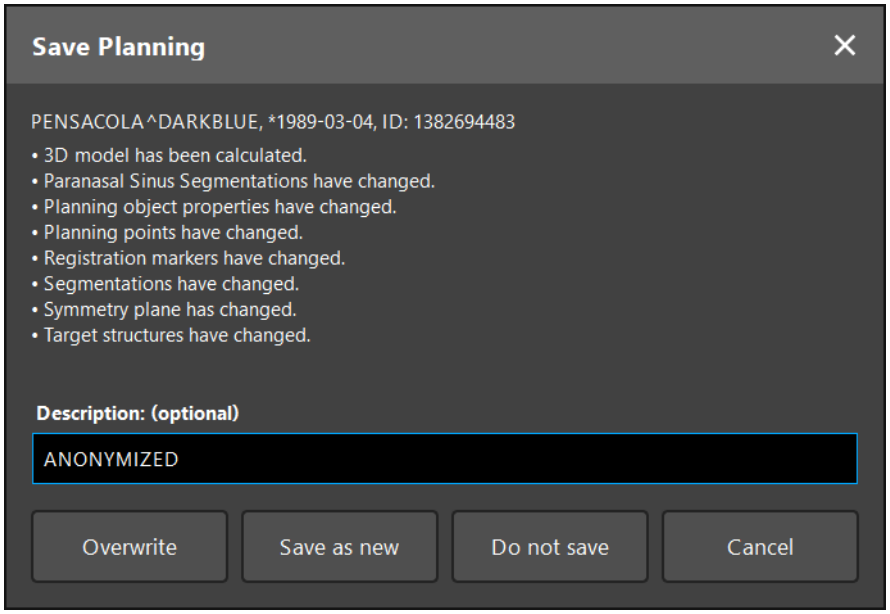


Figure 94 *Save Planning* dialog

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

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

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

9.16. Exporting the planning

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

1. To export a planning or documentation material such as screenshots and videos, open the *Import* dialog, select a planning and click the *Export* button.
2. In the *Export Planning* dialog, choose the target drive desired for exporting (Figure 95).
3. Enter a fitting description for the planning.
4. Click *Export*.

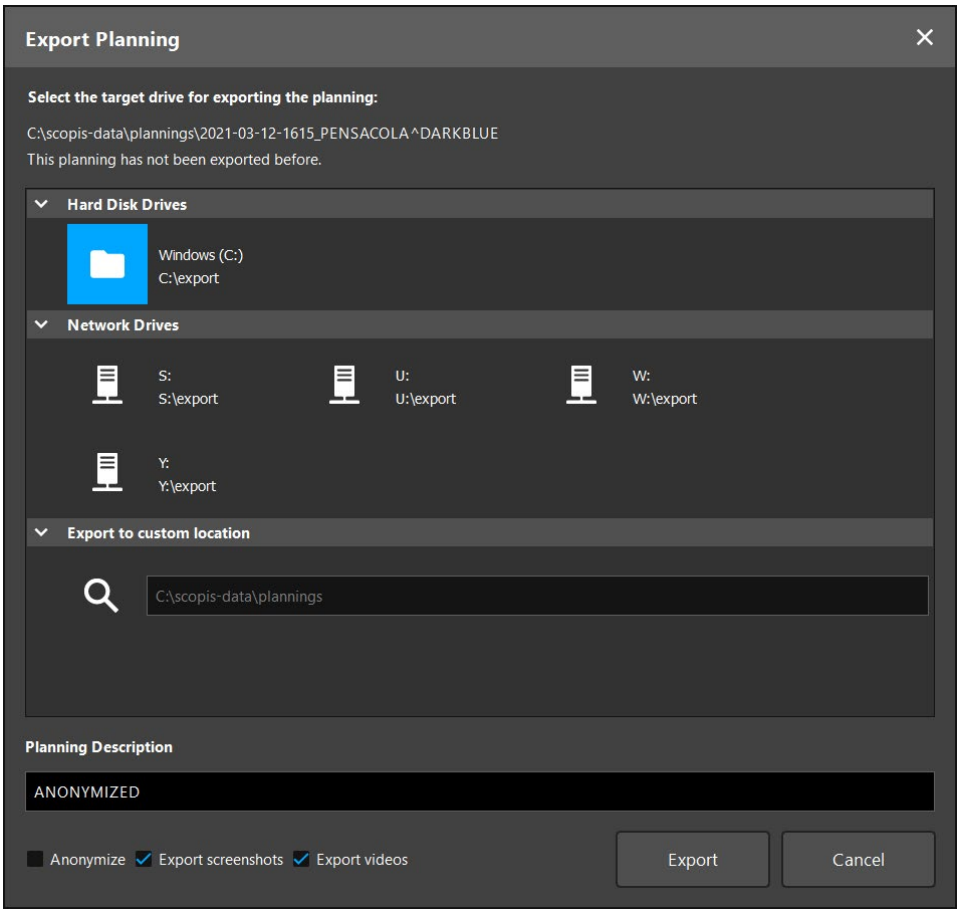


Figure 95 *Export Planning* dialog

The data are stored on the selected drive.

Optionally, you can anonymize the data set as well as export screenshots and videos by using the respective checkboxes at the bottom of the *Export Planning* dialog.

9.17. Taking screenshots and screen recordings

To use the Scopis Navigation Software as a recording tool, a planning without patient data can be created in the *Import* dialog using *New Recording*.

The below buttons are featured on the right side of the user interface. Click the corresponding button to either take a single screenshot or to record the screen (Figure 96).

Figure 96 Screenshot and *Screen Recording* buttons

Plannings with associated screenshots or videos attached can be displayed as a list in the view (Figure 97). Just like plannings, these individual files are opened by double-clicking or clicking the *Load* button, as well as deleted or exported by clicking *Delete* or *Export*.

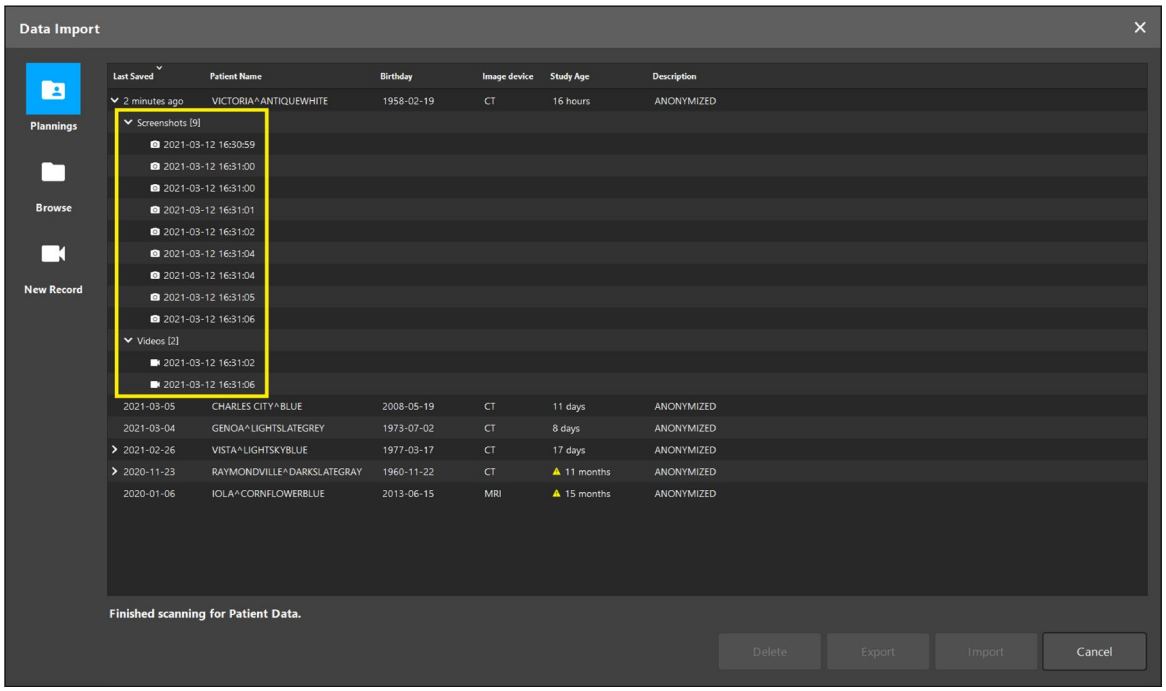


Figure 97 Video and screenshot files attached to a planning

The software automatically creates a screenshot after the Image optimization step during the patient data import. *AutoScreenshots* are listed similar to *Screenshots* and *Videos* as part of the planning.

10.System setup for a navigated surgery

10.1. General functionality testing

CAUTION

Before each use, ensure that all system components are available and operate properly. Inspect all components for loose parts, deformations, damage, and malfunction. Do not use if these conditions exist. Otherwise the surgery may be prolonged or incorrect navigational information may lead to patient injury. If a component requires service, contact your Stryker sales representative.

10.2. Electromagnetic tracking system setup

You need:

- Electromagnetic Navigation Unit with the software application
- Field Generator
- Field Generator Mounting Arm for secure positioning of the Field Generator
- One patient tracker: Either the Patient Tracker Electromagnetic or the Patient Tracker Electromagnetic - 10 Uses
- Patient Tracker Tabs to secure the patient tracker on the patient

To register the patient, you need:

- Precision Pointer Electromagnetic or Pointer Electromagnetic or Registration Pointer Electromagnetic or TGS Guidewire

To navigate, you need:

- at least one surgical instrument that can be tracked by the system either directly or via an attached instrument tracker
- Optionally: Navigation Tool Extension Cable

Refer to Section „For use with“ for a list of compatible products.

10.2.1. Field generator setup

Plug the field generator cable into the socket on the front of the Electromagnetic Navigation Unit (Figure 98).

Figure 98 Connecting the field generator cable to the *Electromagnetic Navigation Unit*

The tracking system uses the electromagnetic field generated by the Field Generator to track the position of the electromagnetic instruments and the patient trackers. Sensors built into the electromagnetic instruments and the patient trackers enable the system to identify their position within the electromagnetic field.

The system identifies the position of the patient tracker and the electromagnetic instruments only within the tracking volume of the Field Generator.

The Field Generator has a tracking volume of 50 x 50 x 50 cm. The tracking volume begins at a distance of 5 cm from the Field Generator (correspondingly, the Field Generator tracking range is from 5 cm to 55 cm).

The optimal tracking volume for patient trackers begins at a distance of 6 cm from the Field Generator and is 20 x 20 x 9 cm large, see the blue rectangle in Figure 99. Place the patient tracker within the optimal tracking volume for optimal tracking results.

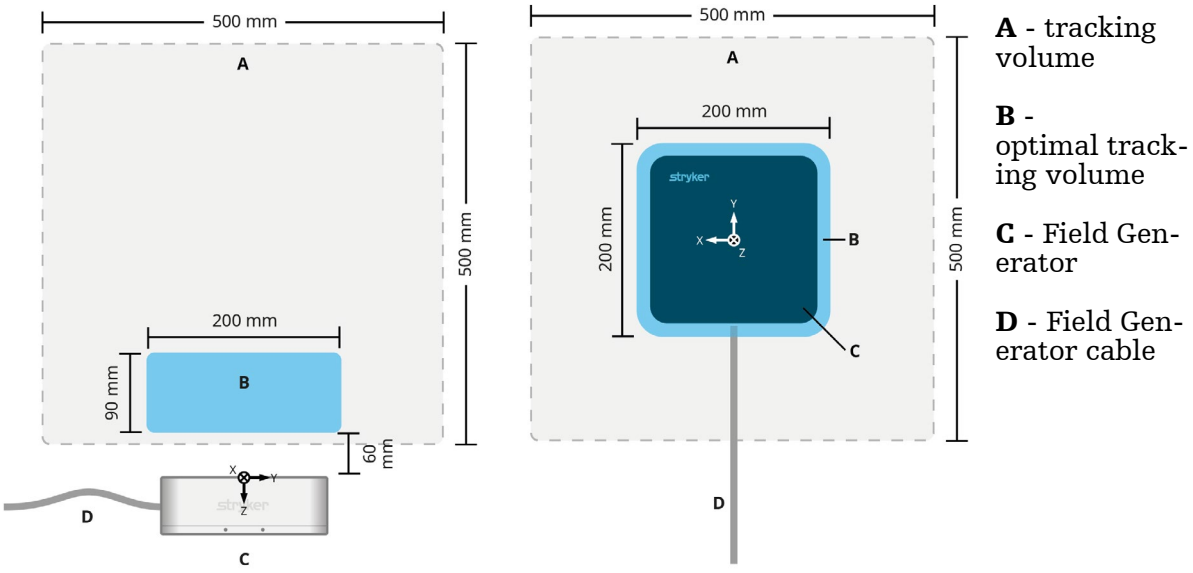


Figure 99 Field generator tracking volume

WARNING

- When positioning the Field Generator, ensure that the patient's anatomy on which you intend to navigate is inside the tracking volume of the Field Generator and ideally within the optimal tracking volume.
- The accuracy of navigated instruments may decrease when a distance of 35 cm or greater between the electromagnetic tracking instrument and the Field Generator is reached.

The tracking reliability decreases with the distance from the Field Generator. Therefore the Field Generator must be positioned as close as possible to the operation area in which the navigated instruments are to be moved. Refer to Figure 100.

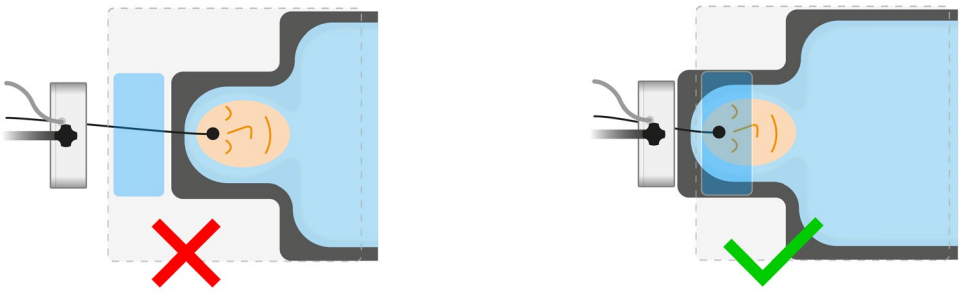


Figure 100 Field generator positioning: Left - too far; right - optimal

The electromagnetic field only begins at a distance of 5 cm from the field generator. To allow navigation throughout the operating area, do not position the Field Generator closer to the operation area than 5 cm. Figure 101 illustrates positioning of the Field Generator when operating on the left side of the patient.

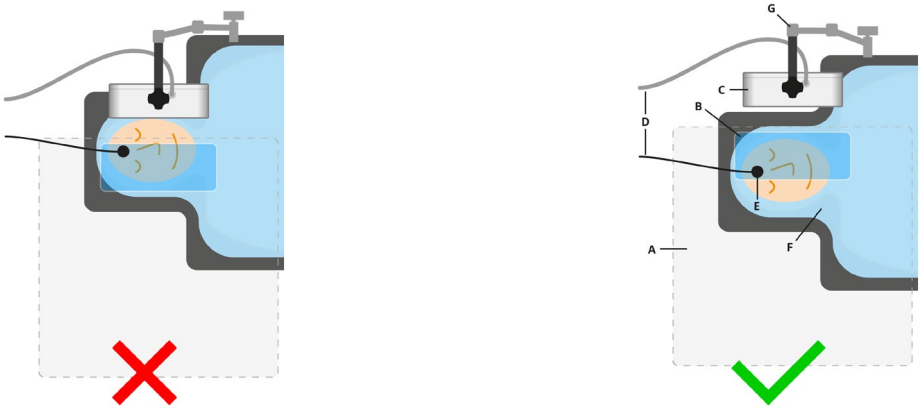


Figure 101 Field generator positioning: Left - too close; right - optimal

Figure 102 shows some possible field generator positions with which a good tracking quality can be achieved.

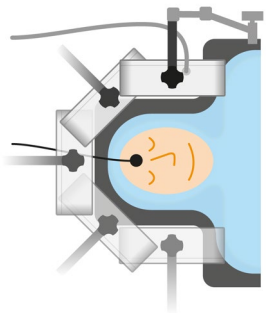
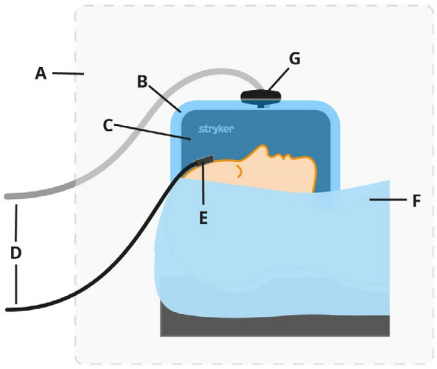


Figure 102 Variants of field generator positioning

Positioning the Field Generator on the side of the patient is usually the most convenient way to ensure optimal tracking results since the operating area largely overlaps with the optimal tracking area.



A - Tracking Area

B - Optimal Tracking area

C - Field Generator

D - Cables

E - Patient Tracker

F - Patient with Cover

G - Field Generator Mounting Arm

Figure 103 Side view of field generator positioning

The software offers visual support for an optimal alignment between the Field Generator and the patient tracker: Refer to the Section „Field generator alignment assistant“.

When using non-sterile products in or near a sterile area, make sure to drape them with a sterile drape.

Interferences with electromagnetic systems

WARNING

- The navigation system can be adversely affected by electromagnetic field disturbances from other objects in the operating room, the close proximity of metal and the close proximity of another Field Generator. Failure to avoid such disturbances may lead to inaccurate position measurement and possible personal injury.
- Make sure that during the application of the navigation system there are no disturbing metals within the tracking volume of the Field Generator, e.g. ferromagnetic metals in conventional surgical instruments. Otherwise the accuracy of the position measurement can deteriorate.
- Do not use mobile or other phones or portable radio frequency (RF) equipment in the vicinity of the navigation system. Devices generating electromagnetic fields may interfere with operation of the product. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) must be used no closer than 80 cm to any part of the navigation system including cables specified by the manufacturer. Electromagnetic disturbances may compromise navigation accuracy and lead to personal injuries.
- Do not place cables of electromagnetic instruments within 30 mm of the Field Generator cable. Placing cables that close to the Field Generator cable, particularly if the cables are parallel to each other, can lead to electromagnetic interferences and compromise navigation accuracy.
- Do not place electromagnetic instruments directly on the Field Generator. Doing so may cause interferences, which may produce inaccurate position measurements.
- Do not expose the system to a high magnetic field such as from a Magnetic Resonance Imaging (MRI) device.

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

1. There are no disturbing substances within 80 cm of the Field Generator. The following materials produce interferences:

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

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

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

2. There are no disturbing items within 80 cm of the Field Generator. Typical objects that cause interferences are:

- Medical devices that require creation of electromagnetic fields to carry out their function
- Electrically driven motors, from drills and shavers
- Field generator cable (excessive amount of cable)
- Electromagnetic Navigation Unit
- Surgical cart with navigation and endoscopy equipment
- Monitors
- Keys, watches, jewelry
- Personal electronics, such as phones

Refer to Figure 104 and Figure 105.

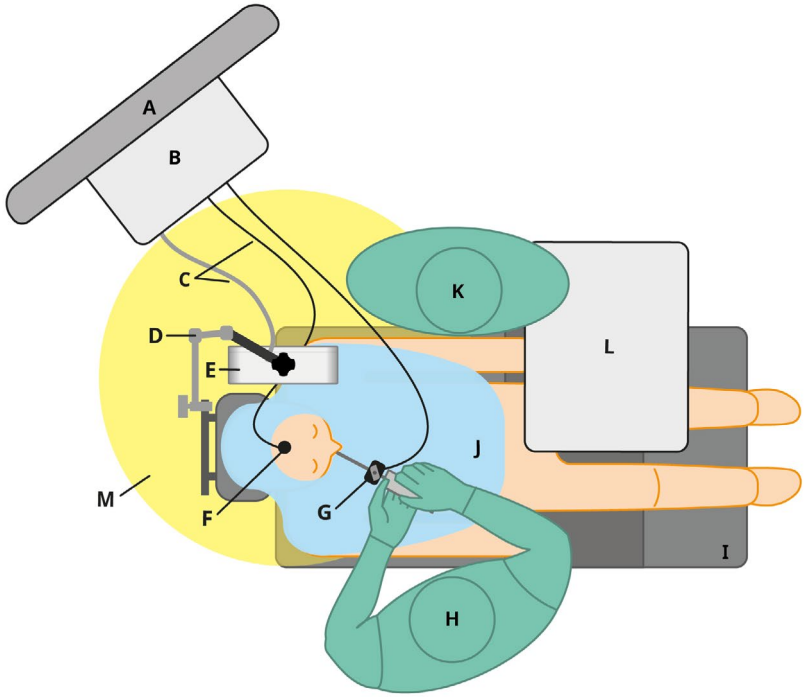


Figure 104 Optimal ENT office setup to avoid electromagnetic interferences

A - monitor

B - Electromagnetic Navigation Unit

C - cables

D - Field Generator Mounting Arm

E - Field Generator

F - Electromagnetic Patient Tracker

G - surgical tool with a tracker

H - surgeon

I - operation chair

J - patient

K - scrub nurse

L - table / tray with surgical tools

M - Field Generator disturbance area

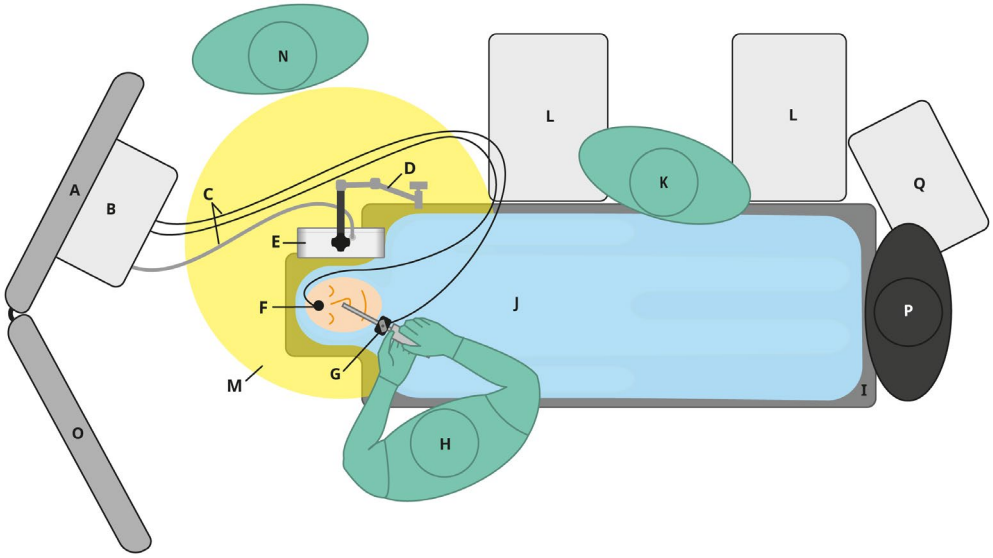


Figure 105 Optimal operating room setup to avoid electromagnetic interferences

A - monitor

B - Electromagnetic Navigation Unit

C - cables

D - Field Generator Mounting Arm

E - Field Generator

F - Electromagnetic Patient Tracker

G - surgical tool with a tracker

H - surgeon

I - operation table

J - patient

K - scrub nurse

L - table / tray with surgical tools

M - Field Generator disturbance area

N - circulator nurse

O - secondary monitor

P - anesthetist

Q - anesthesia apparatus

10.2.2. Patient tracker fixation

Figure 106 Patient Tracker Electromagnetic (REF 8000-040-001) or Patient Tracker Electromagnetic - 10 Uses (REF 8000-040-002)

Mandatory Accessories	REF
Patient Tracker Tabs	8000-100-001

To fix the patient traker on the patient:

1. Clean the intended contact surface on the patient. The contact surface should be intact, 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.

Refer to Figure 107.

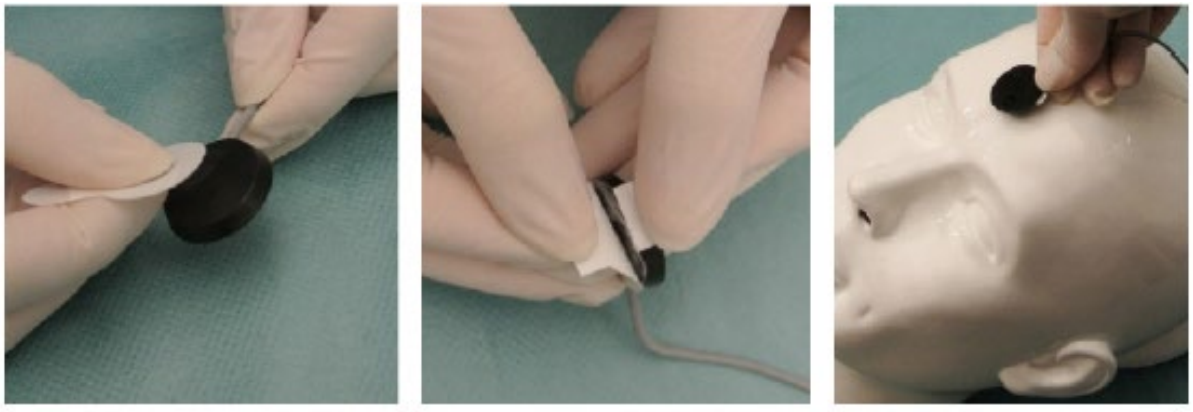


Figure 107 Fixing tab to tracker and contact surface

4. If you plan to use the calibration area of an unsterile patient tracker for instrument calibration, make sure to cover the patient tracker with a sterile transparent drape. Adhesive incision drapes are well suited for this purpose, as they also hold the patient tracker in place (Figure 108).

Figure 108 Fixing the patient tracker onto the patient

5. If the calibration area of the patient tracker is not needed, the patient tracker can be fixed in place with medical adhesive tape and then covered with a surgical drape (Figure 109).

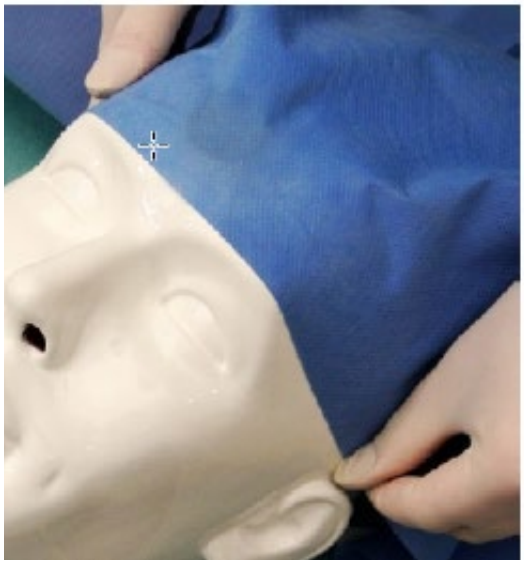


Figure 109 Cover patient tracker

When draping, only cover the necessary skin areas. Depending on the chosen *Patient Registration* type various areas are used for registration such as the forehead and eye area.

WARNING

- Ensure that the patient tracker does not move with respect to the patient. If the patient tracker has moved, the system displays inaccurate positional information of the instruments. If the patient tracker has moved, the patient registration must be repeated.
- If you suspect that the patient tracker has moved, touch some anatomical structures with the instrument and ensure that the touched anatomical structures match the visualization.

10.2.3. Preparing navigated instruments

Electromagnetic instruments must be prepared before use. Refer to the instructions for use supplied with the respective device for detailed information on pre-assembly, reprocessing and correct handling of the device.

Keep in mind that electromagnetic instruments may have a restricted number of uses; refer to Section „Lifetime of electromagnetic instruments“ for more information.

WARNING

Have a replacement available for each electromagnetic instrument and reorder replacement electromagnetic instruments in time based on expected surgery schedule.

10.3. Starting the navigation mode

Once the data set is loaded and the *Patient Registration* type is chosen the message *Ready for Navigation* appears. Then the *Navigation* tab can be activated (Figure 110).

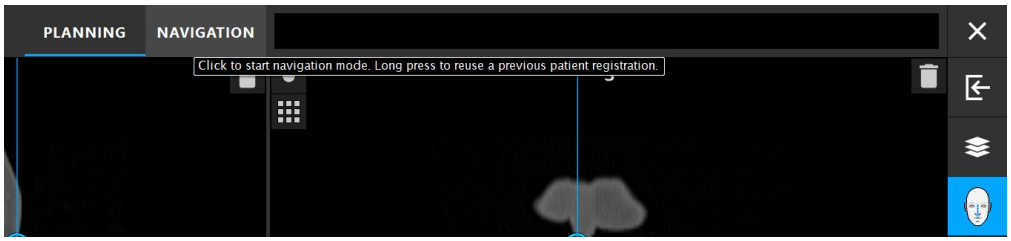


Figure 110 Starting the navigation

Start the navigation mode by clicking the *Navigation* tab.

Long press to reuse a previous patient registration. Refer to section „Reuse a patient registration“.

- The planning data are saved automatically when changing to navigation mode.
- It is recommended to create all necessary planning objects before switching into the navigation mode. During navigation, you can edit planning objects in the edit mode.

10.4. Connecting electromagnetic instruments

CAUTION

Do not unplug any electromagnetic instrument from the Electromagnetic Navigation Unit while initialization is in progress.

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

The current status of the initialization is displayed in the *Initializing Tracking System* information dialog (Figure 111).

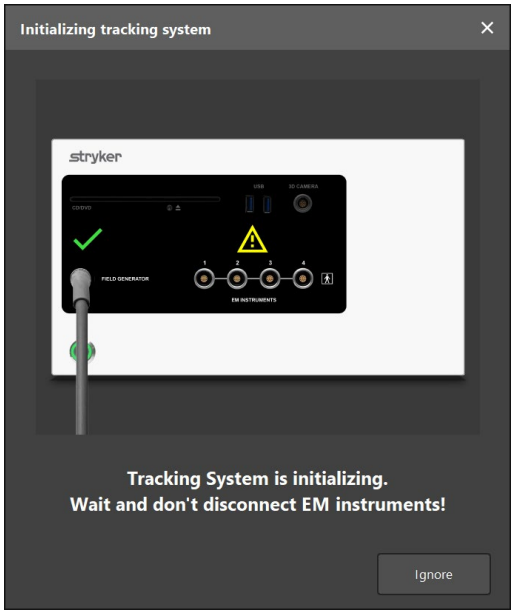
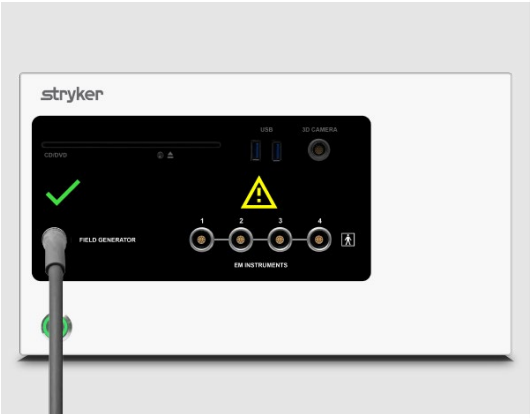
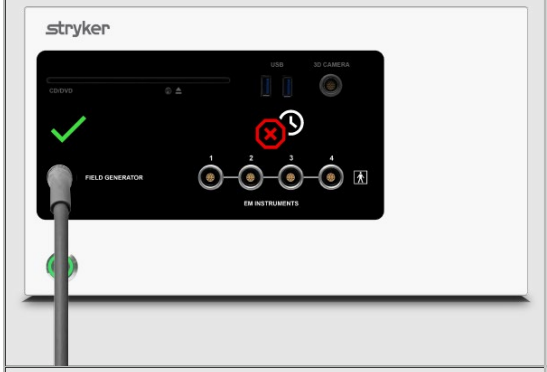


Figure 111 *Initializing Tracking System* information dialog

All possible status displays are shown and explained next:

	Instruments are currently being initialized.
	A defective or broken instrument is plugged into a port and should be removed. An info text with the port number of the affected instrument is displayed.
	An expired instrument is plugged into a port and must be removed. An info text with the port number of the affected instrument is displayed.
	All connected instruments were successfully recognized and initialized.

After an electromagnetic instrument is connected to the Electromagnetic Navigation Unit, a pop-up notification showing the use count of the instrument appears. Refer to Section „Lifetime of electromagnetic instruments“.

10.5. Instrument visibility and status

10.5.1. Instrument status indicators

In the navigation mode, the status of the patient tracker and navigated instruments is visualized in the side panel on the right. The status indicators show the visibility of the patient tracker and instruments that are in use (Figure 112).

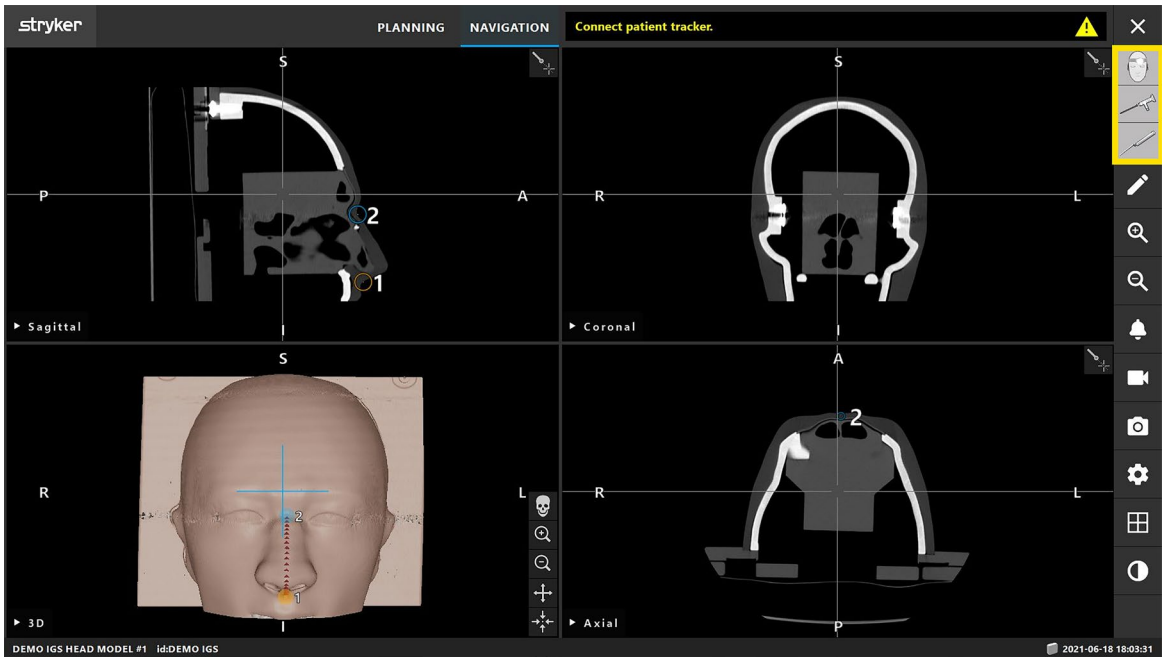


Figure 112 Instrument status indicators

- The upper status indicator shows the patient tracker that is in use.
- The status indicator in the middle shows the tracker attached to the calibrated endoscope.
- The lower status indicator shows the active instrument whose position is also displayed in the crosshairs.

The meaning of colors and symbols used in the status indicators is as follows:

green	instrument visible		
red	instrument not visible		
gray	instrument not connected or defective, including the following special cases:	 sensor coil broken	 expired (maximum number of uses reached)

In addition to the color feedback, also a pop-up message describing the current status of the instrument appears to the left of the status indicators. Refer to Figure 113 and to Section „Lifetime of electromagnetic instruments“

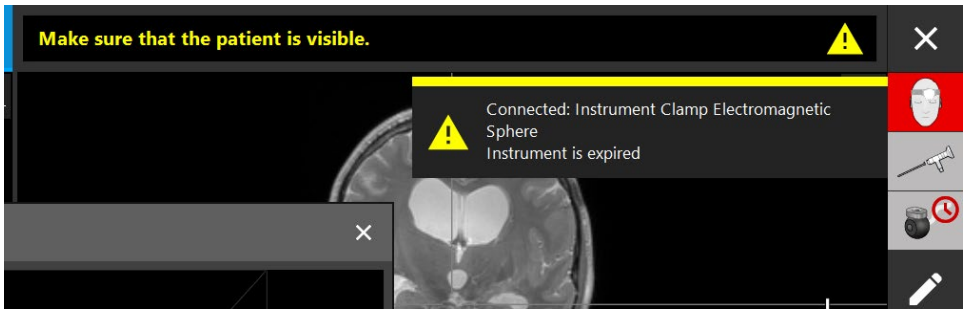


Figure 113 Expired instrument pop-up message

10.5.2. Instrument visibility

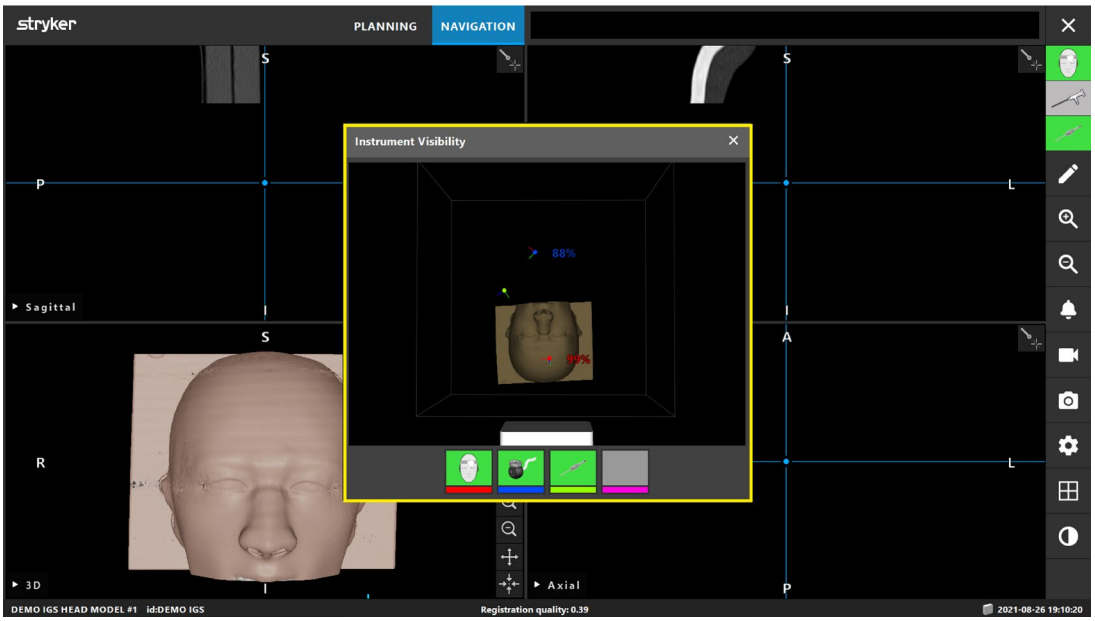


Figure 114 Instrument visibility dialog

The visibility of patient trackers and navigated instruments depends on the following:

- Is the instrument located within the tracking area of the Field Generator?
- Is the instrument damaged?
- Are there any para- or ferromagnetic substances (iron, steel, aluminum…) within an 80 cm-radius of the Field Generator or between the Field Generator and instruments?
- Are there any radiating sources of disturbances (mobile phones, drills, mills…) within an 80 cm-radius around the Field Generator?

For more details, refer to Section „Field generator setup“.

In addition to the status indicators, the visibility of the instruments can be monitored in the *Instrument Visibility* dialog (Figure 114). To open this dialog, click the patient tracker status indicator. Alternatively, the Field Generator icon at the bottom right can also be clicked to open this dialog in the planning mode. In the *Instrument Visibility* dialog, each instrument is represented by a square *Instrument Information* button divided into two colored areas. Refer to Figure 115.

Figure 115 Instrument Information buttons in the *Instrument Visibility* dialog

In the 3D image, each instrument is represented by a point of the same color as the bar in the instrument button of the respective instrument. This point visualizes the position of the corresponding instrument within the tracking volume. Percentage of the same color indicates the tracking quality in percent.

Each bar at the bottom of an instrument button has its own color so that a specific color is associated with each instrument. The larger colored area of an instrument button indicates the current status of the instrument; here, colors have the following values:

gray	instrument not connected or defective (including expired instruments and instruments with broken sensor coil)
green	instrument visible, tracking quality good
yellow	instrument visible, tracking quality acceptable
orange	instrument visible, tracking quality poor
red	instrument not visible (connected, but out of the tracking volume)

For functioning instruments, the displayed color varies on the scale between green, yellow and red depending on the actual tracking quality.

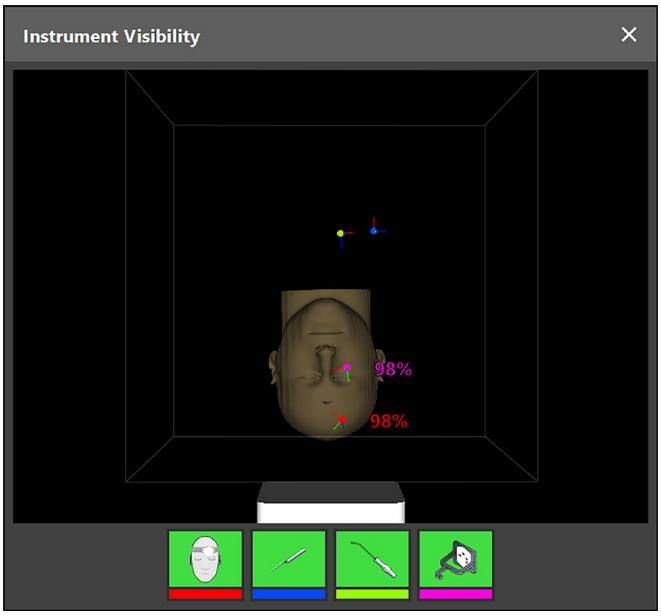


Figure 116 Instrument visibility and tracking quality in 3D image

Clicking the instrument button displays a dialog box with further information on the selected instrument.

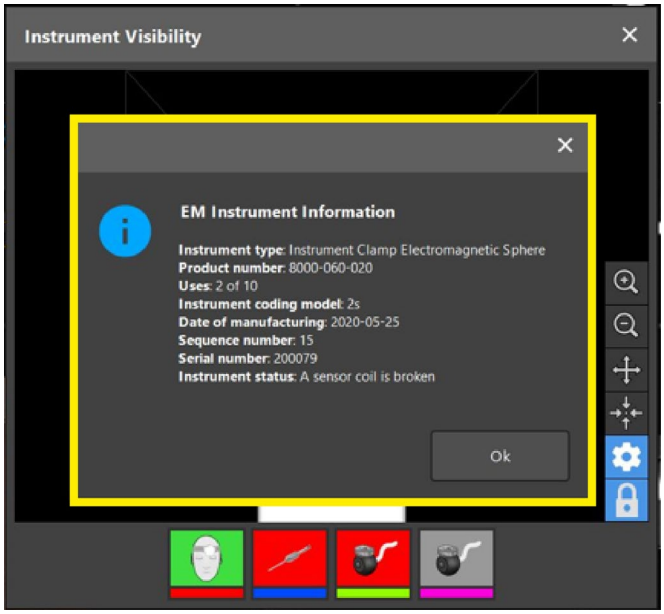


Figure 117 *Instrument Information* dialog box

10.6. Field generator alignment assistant

The optimal positioning of the Field Generator relative to the patient tracker is essential for the accuracy of the navigation system.

In case the positioning of the Field Generator relative to the patient tracker is not optimal when you enter the navigation mode, the *Field Generator Alignment* dialog (Figure 118) opens up automatically. The *Field Generator Alignment* dialog provides visual feedback and assists in adjusting the patient tracker to *Field Generator* alignment to achieve high tracking accuracy. It depends on the situation in the operating room, whether it is easier to reposition the Field Generator or the patient or the patient tracker.

The dialog does not appear if the accuracy is sufficient. Once it appears, it will close automatically if the alignment has been corrected.

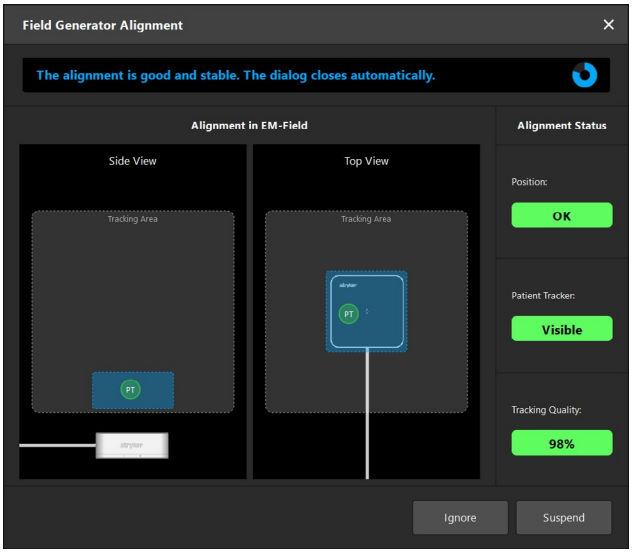


Figure 118 Alignment dialog before patient registration

If the alignment between the Field Generator and the patient tracker changes after patient registration its position or orientation (more than 35mm divergence, rotation by more than 15 degrees, or decreased tracking quality), the dialog re-appears. Once you have corrected the alignment, the dialog closes automatically (Figure 119).

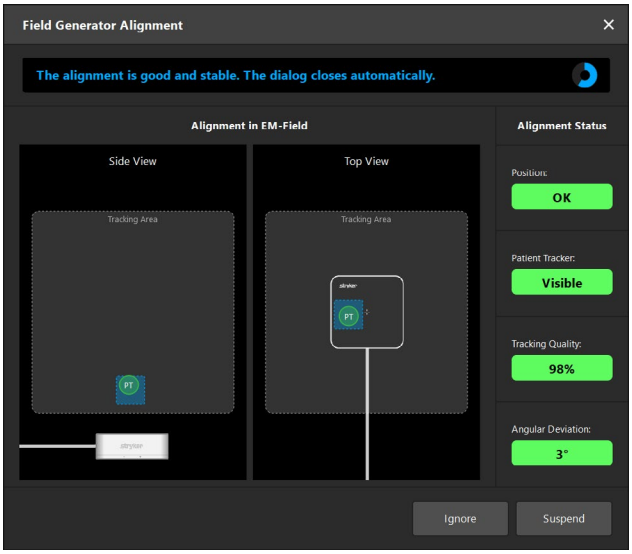


Figure 119 Intraoperative Alignment dialog

The dialog contains two planar views (a side view and a top view) showing the disposition of the *Field Generator* and the patient tracker (a circle). The gray rectangles labeled *Tracking Area* indicate the maximum tracking volume. The patient tracker must be within this area in order to be visible to the tracking system. For optimal tracking results, the patient tracker must be in the smaller subarea depicted as a blue rectangle. Before registration, the blue rectangle corresponds to the default optimal tracking area; after registration, the blue rectangle corresponds to a smaller area around the patient tracker where it should stay for optimal tracking results. As long as the patient tracker is placed correctly, the circle representing the tracker is green; otherwise the circle is red.

The dialog can be suspended for a few seconds with a click *Suspend*.

With *Ignore* the dialog can be disabled for the course of the surgery. Since the dialog provides guidance both before and after patient registration, a dialog ignored during registration may appear again during navigation.

WARNING

- Do not choose to ignore a tracking quality of less than 95% if you can adjust the alignment between the Field Generator and the patient tracker. Tracking quality under 90% is not recommended for navigation.
- Do not choose to ignore a patient tracker position outside of the optimal tracking volume if you can adjust the alignment between the Field Generator and the patient tracker.
- After patient registration, do not choose to ignore an angular deviation of more than 15° and a position deviation of more than 35 mm if possible. An angular deviation of more than 30° is not recommended for navigation.

Status indicators for alignment guidance

Position: Classification of the patient tracker position relative to the electromagnetic field of the Field Generator.

green	**OK**	Patient tracker is inside the optimal tracking volume.
red	**Too far**	Patient tracker is outside the optimal tracking volume. Adjust the position of the Field Generator or the patient tracker to bring the patient tracker into the optimal tracking volume
gray	**Undefined**	Make sure a patient tracker is connected and within the tracking volume.

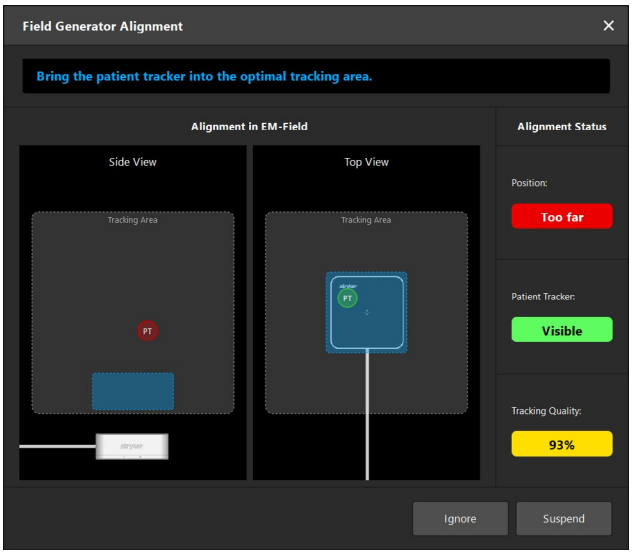


Figure 120 Patient tracker outside the optimal tracking volume

Patient tracker visibility status

green	**Visible**	Patient tracker is connected to the tracking system and visible.
red	**Invisible**	Patient tracker is outside the maximum tracking volume. Adjust the position of the Field Generator or the patient tracker to bring the patient tracker into the optimal tracking volume.
gray	**Disconnected**	Make sure the patient tracker is connected and within the tracking volume.

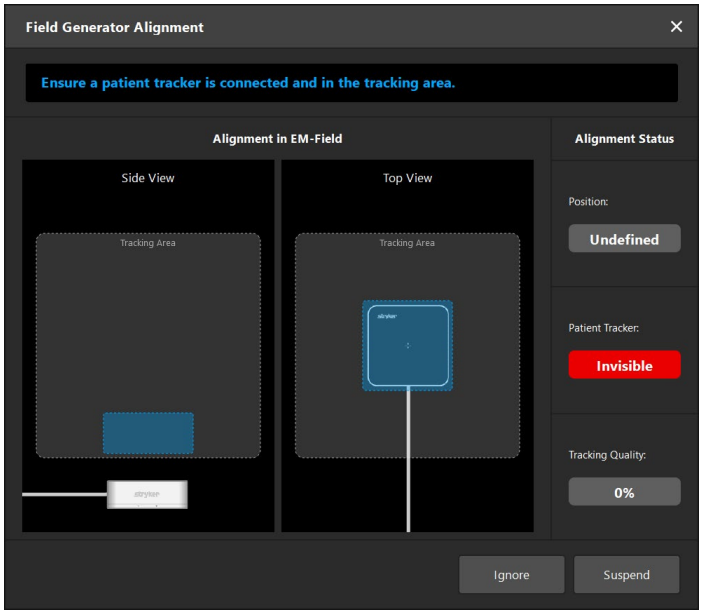


Figure 121 Patient tracker invisible (before registration)

Tracking Quality: Quantitative indicator of the tracking quality of the patient tracker

	95 – 100 %	Tracking quality is good.
	90 – 94 %	Tracking quality is acceptable. Adjust the position of the Field Generator or patient tracker to bring the patient tracker into the optimal tracking volume. If the position status shows *OK*, check for electromagnetic field disturbances.
	1– 89%	Tracking quality is poor. Adjust the position of the Field Generator or patient tracker to bring the patient tracker into the optimal tracking volume. If the position status shows *OK*, check for electromagnetic field disturbances. If disturbances in the field can be ruled out, try replacing the patient tracker.
	0%	Make sure the patient tracker is connected and within the tracking volume.

Angular Deviation (only after patient registration): The angular deviation of the patient tracker with respect to the registered position

	0 – 15 °	The angular deviation is within the tolerated range.
	16 – 30 °	The angular deviation exceeds the recommended range and can affect navigation accuracy. Move the Field Generator to its initial position or register the patient anew.
	31 – 180 °	The angular deviation is too high to ensure sufficient navigation accuracy. Move the Field Generator to its initial position or register the patient anew.
	0 °	Make sure the patient tracker is connected and within the tracking volume.

All status indicators must be green for optimal tracking accuracy.

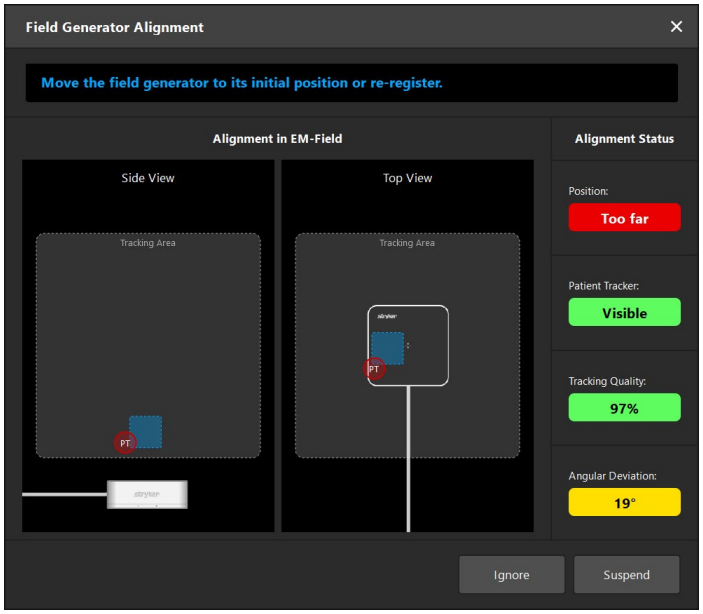


Figure 122 Patient tracker outside optimal tracking volume and high angular deviation.

10.7. Edit mode

Click the *Edit* button to pause the navigation (Figure 123) and switch into the edit mode. You are in the edit mode if the button is highlighted (Figure 123).

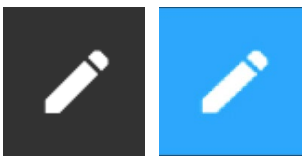


Figure 123 Edit button (inactive), left; *Edit* button (switched on), right

In the edit mode, you can view the patient image data and change the planning components and planning data without having to return to the planning mode. For this purpose, the buttons for working on the planning objects appear. The workflow is the same as in the planning mode. Refer to Section „Preparing for a navigated surgery“ for more information on how to work in the planning mode.

The position within the slice image at the time of suspension is visualized by a dashed blue cross-hair. When you click to another position a second solid blue crosshair is shown. The distance between both cross-hairs is shown in the message view. To return to the suspended position, use the cross-section view's *Centering* button. To continue with the navigation, click the *Edit* button again.

If no planning action is carried out with the navigation application for a few seconds, the navigation application automatically returns to the navigation mode.

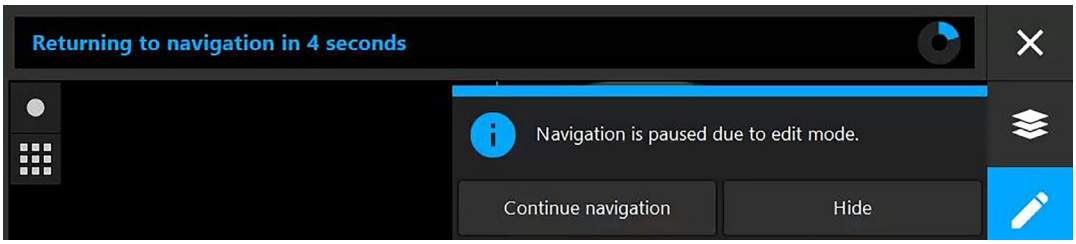


Figure 124 Automatic return to navigation mode

10.8. Calibration of surgical instruments

Conventional (sensorless) surgical instruments can be tracked by the system if they are equipped with one of the following trackers:

- Universal Tracker Electromagnetic (using one of the four Instrument Clamps)
- Instrument Clamp Electromagnetic Sphere
- Instrument Clamp Electromagnetic Universal
- Instrument Clip Electromagnetic, 4 mm (product discontinued)

If connected to a tracker, numerous surgical instruments can be upgraded to navigated instruments.
The closer the instrument tracker is placed to the navigated point, the more precise the navigation information.

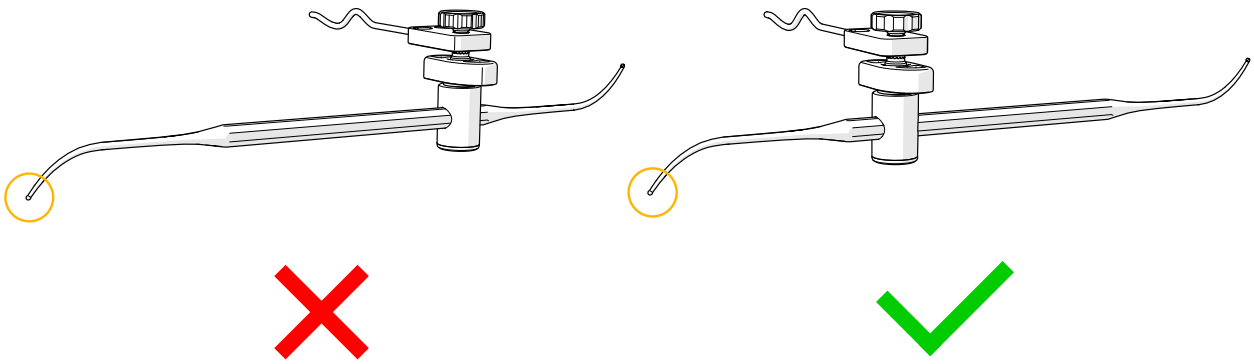


Figure 125 Instrument with low precision (left) / Instrument with high precision (right)

Surgical instrument calibration is different from endoscope calibration, for which refer to Section „Calibration of rigid endoscopes [TGS ONLY]".

In order to be recognized by the system, conventional surgical instruments must be calibrated before use. By means of calibration, the navigation system identifies the position of the instrument tip. After ending the surgery, the information received from calibration is deleted. The instrument calibration requires interaction with a calibration area. Calibration areas are integrated into the following instruments:

- Calibration Body Electromagnetic
- Patient Tracker Electromagnetic – 10 Uses
- Patient Tracker Electromagnetic

A calibration area consists of a calibration cone and a calibration plane (Figure 126).

Figure 126 Calibration areas (cone and plane) exemplified on the base of the tracker

WARNING

Be careful when using the patient tracker for calibration. Do not exert force as otherwise you could unintentionally shift the patient tracker or damage the sterile drape.

10.9. Interaction areas

Patient trackers have interaction areas. These are marked with a cross “x” and a hook “✓.” If these areas are touched with an instrument, the following happens:

If a dialog box is opened (please note that this does not work for all dialogs):	✓	Touching the hook confirms the displayed software dialog
	X	Touching the cross rejects the displayed software dialog
In the navigation mode:	X	Long holding discards the current patient registration

Figure 127 Interaction areas (hook and cross)

10.10. Calibration Procedure

WARNING

- The clamp and tracker must be rigidly attached to the instrument before beginning with the calibration.
- Make sure that the clamp and the tracker are rigidly attached to the surgical instrument during navigation. Otherwise the navigation becomes inaccurate and useless. If the device moves or is repositioned relative to the surgical instrument, calibrate the surgical instrument new.
- Conduct calibration each time you attach a tracker to an instrument. If you remove a tracker from an instrument after calibration and attach the same tracker to another instrument, be sure to calibrate this instrument. Otherwise the navigation information becomes incorrect. The system does not detect a replacement of instruments.
- Do not exert force when calibrating surgical instruments.

The *Instrument Calibration* dialog appears automatically if an instrument with an attached tracker is held visibly in the vicinity of one of the instruments with a built-in calibration area (Figure 126), e.g. Calibration Body Electromagnetic.

Refer to Figure 128 and Figure 129.

1. Move the instrument to be calibrated and the instrument with a built-in calibration area into the tracking volume of the navigation system.
2. Slowly and perpendicularly move the tip of the instrument into the calibration cone and hold it still.
3. Calibration is conducted automatically. A progress wheel indicates the progress. The step is complete when you hear a confirmation tone.

Place the instrument tip into the calibration cone with the instrument axis perpendicular to the calibration cone and hold the instrument still. Through this step the system identifies the instrument tip and axis.

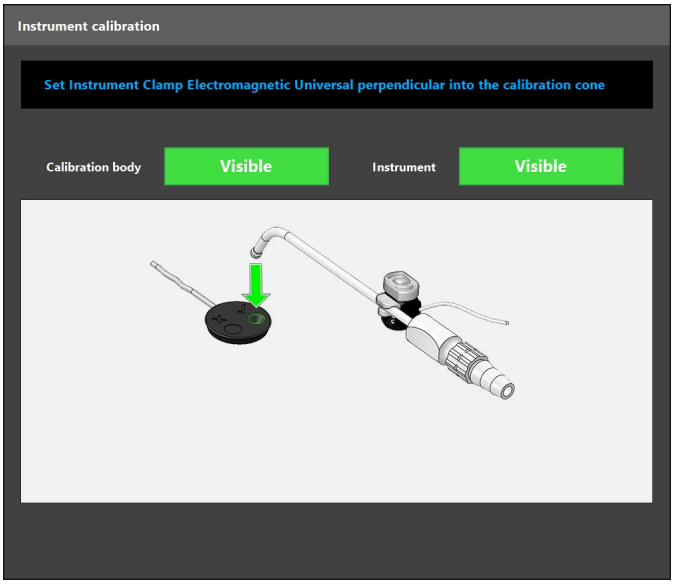


Figure 128 Calibration step 1: holding the instrument tip into the calibration cone

4. Move the instrument towards the calibration area with the tip axis perpendicular to the calibration area and hold the instrument still.

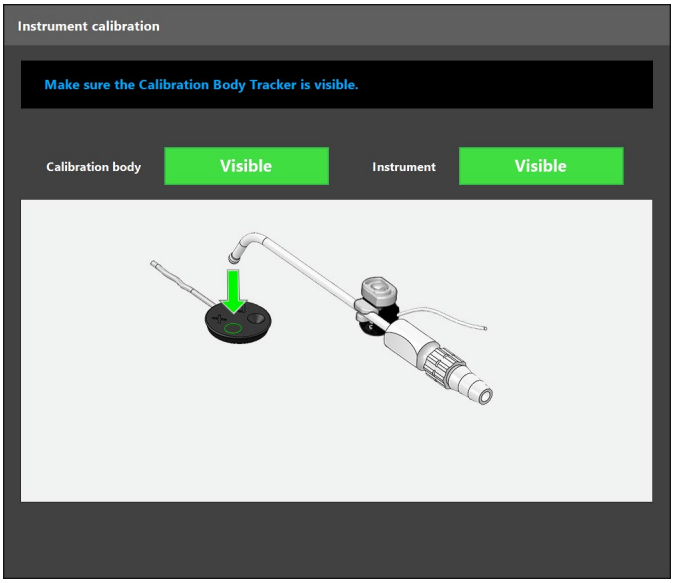


Figure 129 Calibration step 2: holding the instrument tip to the calibration plane

5. A progress wheel indicates the progress. Calibration is finished when you hear a confirmation tone.

WARNING

- Check the accuracy of the calibration carefully before using the instrument. To do so, touch an anatomical structure with the calibrated instrument and compare the touched structure with the visualization displayed by the software application. Should the deviation be too big, repeat the calibration.
- Do not change the position of the instrument tracker on the clamp after calibration. Otherwise the navigation information deteriorates. If the position of the instrument tracker has changed (e.g. it has been rotated), calibrate the surgical instrument anew.
- The calibration of an instrument may become incorrect if it is dropped, bent, or damaged.

10.11. Resetting an Instrument Calibration

Cancelling a previous calibration and conducting a new one is necessary in the following situations:

- you want to use the same tracker for a different instrument
- a tracker has moved (e.g. slipped, rotated) on the calibrated instrument
- you have noticed that the conducted calibration is inaccurate (displayed instrument position differs from its actual position)

There are three ways to reset a calibration.

1. A calibration can be reset by clicking the instrument status indicator of the active instrument tracker and confirming the following dialog as shown in Figure 130:

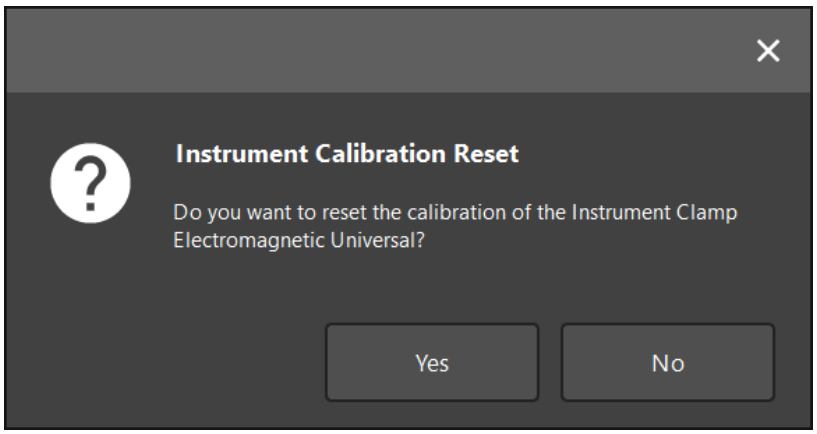


Figure 130 Confirm the reset of the instrument calibration

2. A calibration can be reset by holding an active tracker upside down on top of the patient tracker as shown below (Figure 131). Alternatively, the status icon of the tracker can be clicked to open the reset dialog.

Figure 131 Hold the tracker up-side down over the patient tracker to reset calibration

This method of calibration reset does not apply to the Endoscope Tracker Electromagnetic.

3. Bringing the Calibration Body Electromagnetic and a tracker near each other (ca. 4 cm) within the tracking volume automatically starts a new calibration.

10.12. Calibration of rigid endoscopes [TGS ONLY]

Note that Endoscopes can generally be used and navigated without image calibration when using universal trackers. Then, an instrument calibration is sufficient. If the Endoscope Tracker Electromagnetic is used, image calibration is required but instrument calibration isn't.

When calibrating an endoscope, the system not only identifies the position of the endoscope camera but also calibrates the endoscopic image in order to enable overlays of planning objects and instrument tool position information onto the endoscopic camera image.

To calibrate an endoscope, you need:

- Calibration Body Electromagnetic

For navigating rigid endoscopes, the following trackers are available:

- Instrument Clamp Electromagnetic Sphere
- Instrument Clamp Electromagnetic Universal
- Endoscope Tracker Electromagnetic
- Universal Tracker Electromagnetic (using one of the four Instrument Clamps)

Rigid endoscopes are supported depending on the selected tracker.

Preliminary check of endoscopes

Before starting calibration, check the following:

- Is the tracker securely fastened to the endoscope?

WARNING

Make sure that the tracker is rigidly attached to the endoscope before you begin with the calibration. Ensure that the bayonet cap of the Endoscope Tracker Electromagnetic or the screw of the Universal Tracker Electromagnetic, or the Instrument Clamp Electromagnetic Sphere/Universal is completely fastened and is not moveable in relation to the endoscope.

- Is the endoscope securely fastened to the endoscope camera?

WARNING

Before calibration, make sure that the endoscope is rigidly attached to the endoscope camera. Check that the endoscope rests tightly in the endoscope camera fastener. The endoscope must not rotate in relation to the endoscope camera during use.

Endoscope settings

Adjust zoom and focus to an area of 5 mm to 25 mm in front of the lens.

Calibration procedure

To calibrate an endoscope with an attached Endoscope Tracker Electromagnetic:

1. Slide the endoscope with the attached tracker through the guidance grooves of the Calibration Body Electromagnetic (Figure 132).

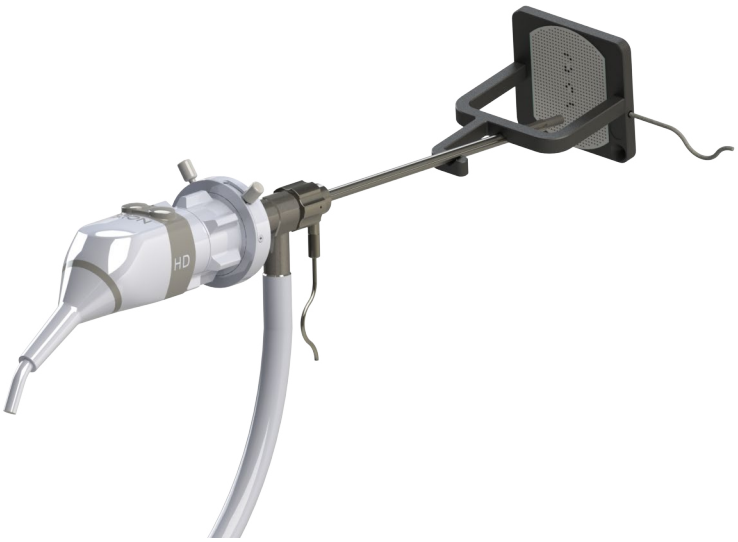


Figure 132 Navigated endoscope in guidance grooves

2. Move the endoscope and the calibration area into the measuring volume of the navigation system. The *Endoscope Calibration* dialog opens.

   The *Endoscope Calibration* dialog is shown only if both the endoscope and the Calibration Body Electromagnetic are detected by the navigation system in the tracking volume.

3. Slowly move the endoscope backward and forward inside the Calibration Body Electromagnetic until the displayed yellow bars turn green (Figure 133 - Figure 135). Refer to the message bar for directions.

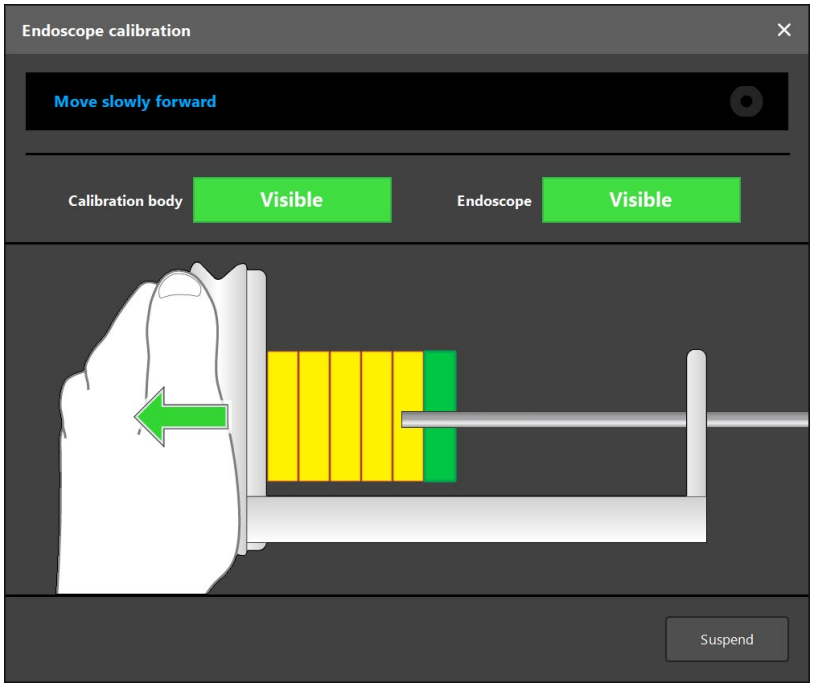


Figure 133 *Endoscope calibration* - move slowly forward

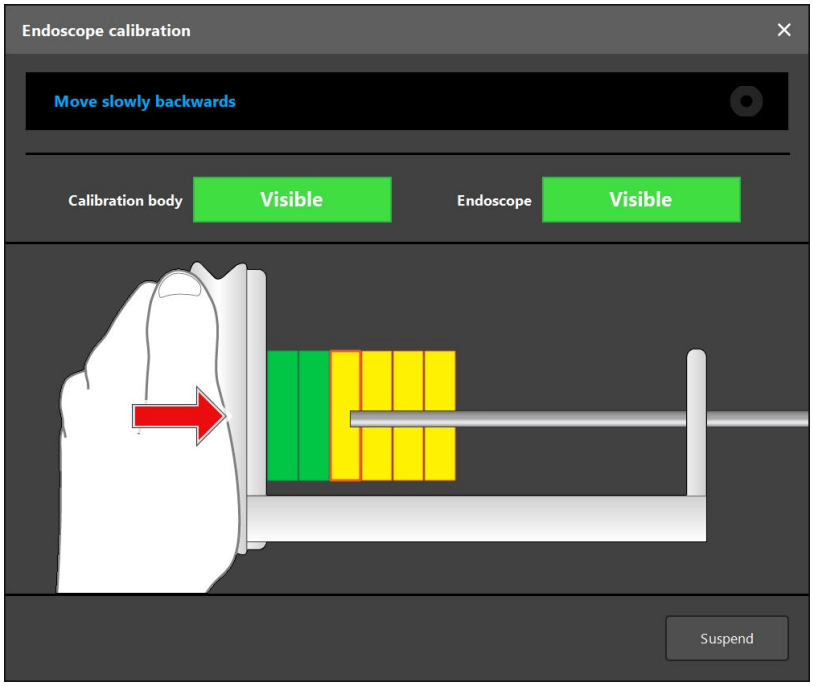


Figure 134 *Endoscope calibration* - move slowly backwards

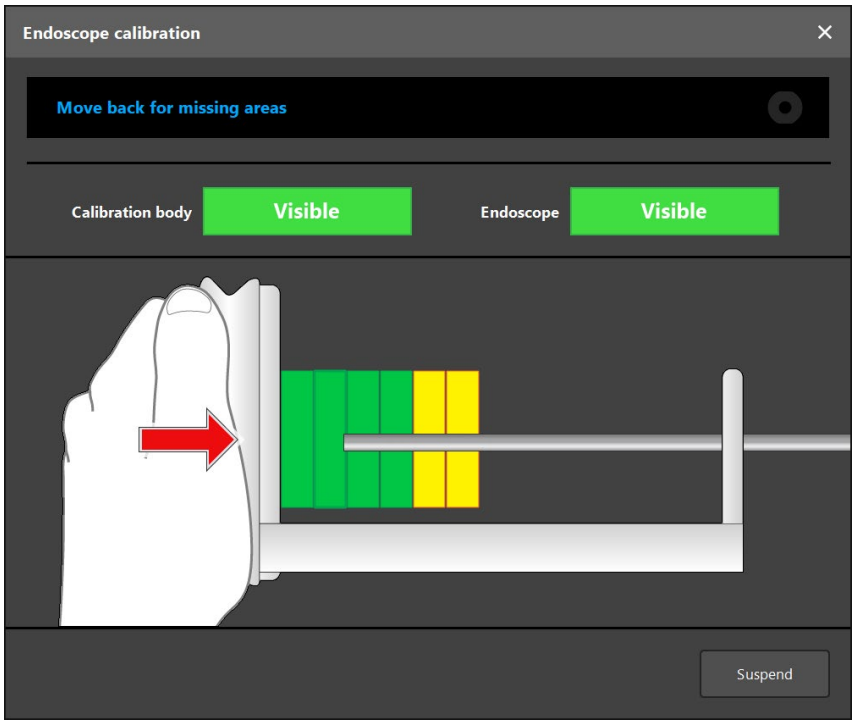


Figure 135 *Endoscope calibration* - move back for missing areas

4. If the calibration pattern is not recognized during calibration, adjust the zoom, focus, and if applicable brightness so that the calibration pattern is clearly recognized (Figure 136). Refer to the message bar for suggested improvements.

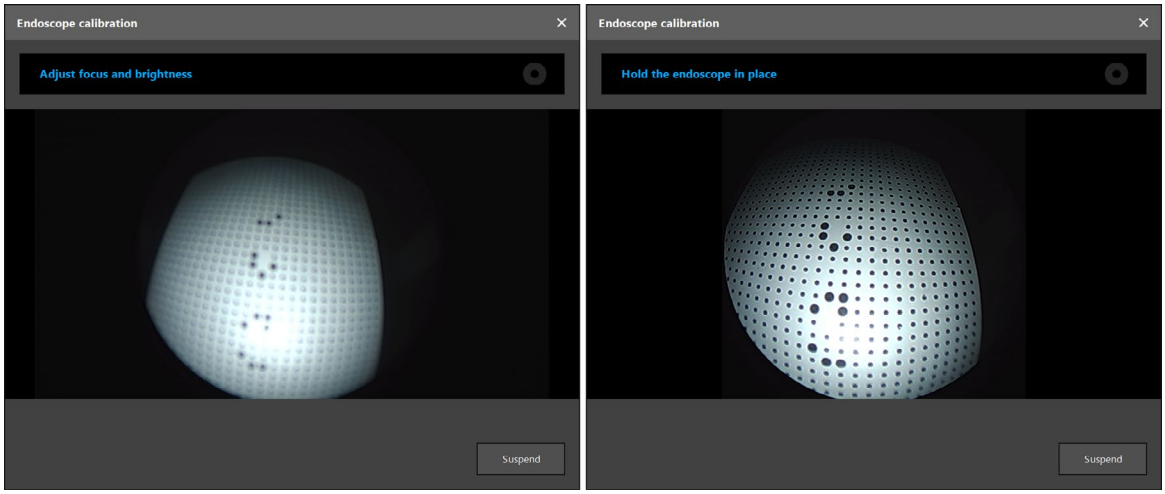


Figure 136 Calibration dialog: Left – image defocused and overexposed; right – optimal image

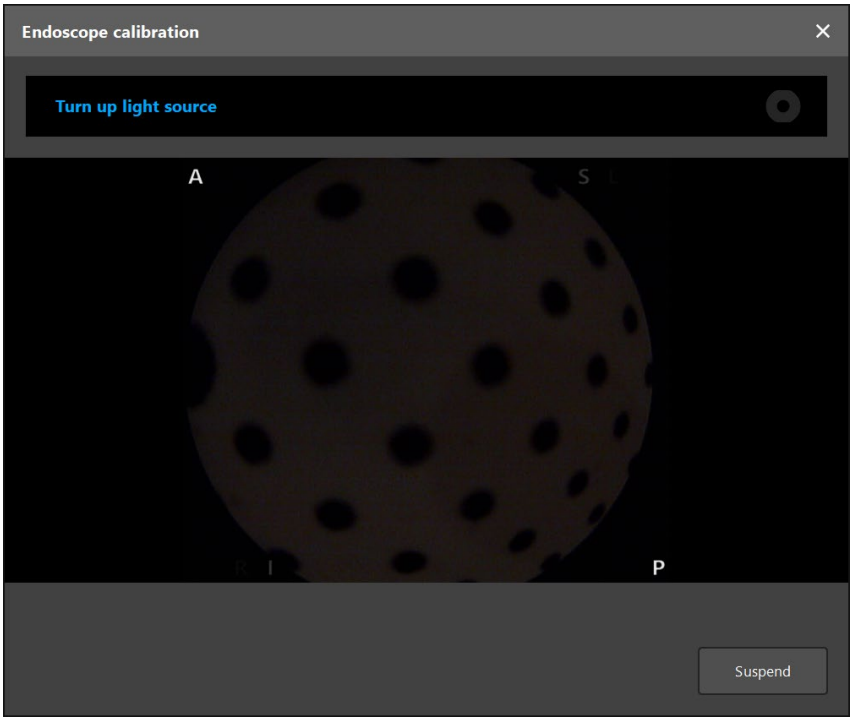


Figure 137 Endoscope calibration - image too dark

5. If the instrument is moving too much relative to the calibration body, the dialog box will alert you to get a stable view of the calibration pattern. Refer to the message bar for suggested improvements.

6. After collecting enough calibration data points, the software processes the calibration (Figure 138).

Figure 138 Computing calibration

In rare cases, the system may inform you via a dialog box that the calibration cannot be calculated. Possible reasons might be that the endoscope was twisted during the calibration, or that zoom or focus were altered. After closing the dialog, conduct a new calibration with the correct settings.

WARNING

- After endoscope calibration, check that the overlay accuracy in the video image is sufficient. Checking the overlay accuracy is only possible if you have created planning points on easily recognizable anatomical locations. Point the endoscope camera at these locations and ensure that the intended position of the planning objects matches their visualized position. If the deviation does not meet your expectations on the accuracy, conduct the endoscope calibration again.

- If any changes are made to the endoscope after calibration, calibration must be repeated. Changes to the endoscope (adjusting zoom, focus, twisting of the endoscope in relation to the endoscope camera, movement of the attached tracker, etc.) will lead to inaccurate endoscope navigation.

Note that endoscope calibration is necessary if a different optic is used (0°, 30°, 45° etc.)

Discarding calibration

You can discard a calibration at any time by separating the endoscope from the calibration body and keeping them apart until the *Calibration* dialog disappears.

Discarding a calibration allows you to start a new calibration.

Calibrating an endoscope with the instrument clamps

To navigate an endoscope that is not compatible with the Endoscope Tracker Electromagnetic, the following parts need to be attached to the endoscope: The Instrument Clamp Electromagnetic Sphere or the Instrument Clamp Electromagnetic Universal or the Universal Tracker Electromagnetic with clamp.

At first calibrate the endoscope as a regular surgical instrument following the procedure described in Section „Calibration of surgical instruments“ and then calibrate the endoscopic image.

Be careful not to damage the endoscope when inserting it into the cone of the Calibration Body Electromagnetic.

11. Patient registration

The procedure depends on the type of patient registration that you have chosen in the planning mode. Refer to Section „Selecting the patient registration type“ for more details.

WARNING

- After data import, verify that the actual skin surface matches the skin surface displayed in the data set. If any deviations are apparent, avoid these areas during surface registration or enhanced surface registration. If no satisfactory registration accuracy can be achieved, use the landmark registration.
- Ensure that the patient tracker does not move with respect to the patient. If the patient tracker moves, the system displays inaccurate positional information of the instruments. If the patient tracker moves, the patient registration must be repeated.
- If you suspect that the patient tracker has moved at any time after registration, touch some anatomical structures with the instrument and ensure that the touched anatomical structures match the visualization.

You need one of the following instruments to conduct registration:

- Precision Pointer Electromagnetic
- Pointer Electromagnetic
- Registration Pointer Electromagnetic (not for the Landmark Registration)
- TGS Guidewire

Defining landmarks

WARNING

- Landmarks should be positioned on easily recognizable anatomical structures that only move very little when touched with the tip of the pointer. Anatomical landmarks commonly used as registration points are: Lateral canthi, nasion, and subnasale.
- Do not define landmarks on sensitive structures, such as eyes, that might be moved or injured by the tip of the pointer.

Conducting registration

WARNING

- Make sure that you actually touch the patient surface with the tip of the instrument while recording the points.
- When touching the landmarks on the patient‘s tissue with the pointer, avoid exerting too much force or moving the tissue.

11.1. Patient registration: landmark

Application

1. Touch the flashing landmark as precisely as possible with a pointer on the patient. Hold the pointer still until you hear a confirmation tone, or the process wheel in the message view is complete and a new landmark starts flashing (see Figure 139).

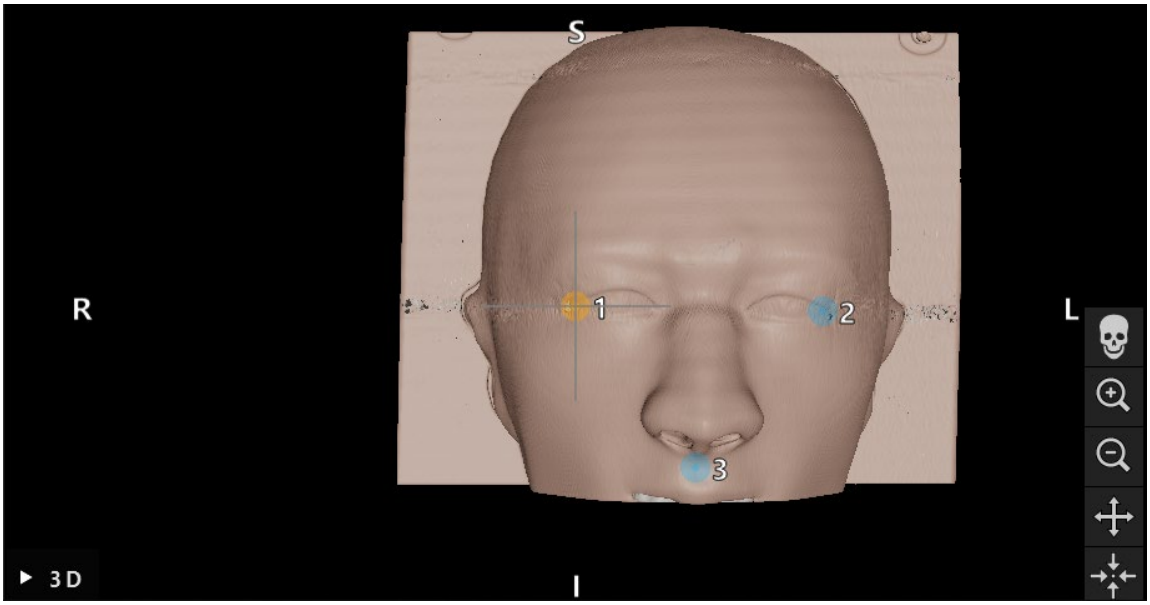


Figure 139 Touch landmark 1 on patient

2. Repeat procedure until all landmarks are touched (Figure 140).

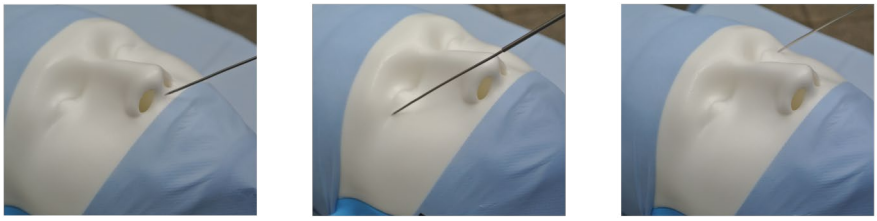


Figure 140 Registering the landmarks

3. After successfully touching all landmarks, the advice window shows the message, “Please confirm or increase accuracy.” (see Figure 141)

– 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.

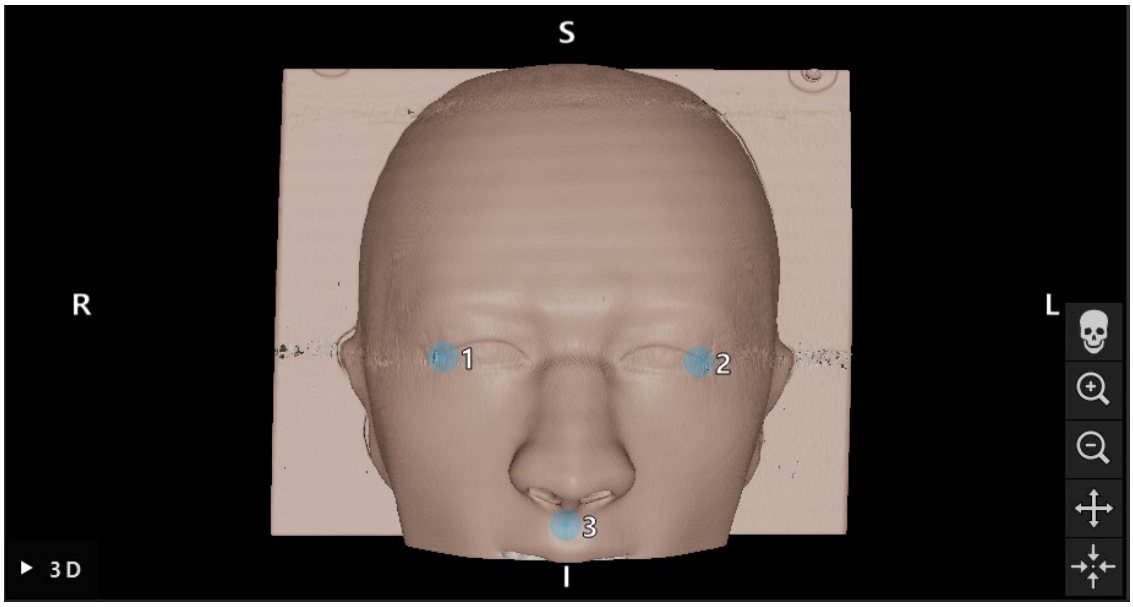


Figure 141 Confirm or increase accuracy

4. Check and confirm the precision of the patient registration through holding the pointer on the surface in one position distant from touched landmarks until the progress wheel is completed. Refer to Section „Confirmation and verification of the patient registration“.

11.2. Patient registration: surface

Application

1. Touch the 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 (see Figure 142.)

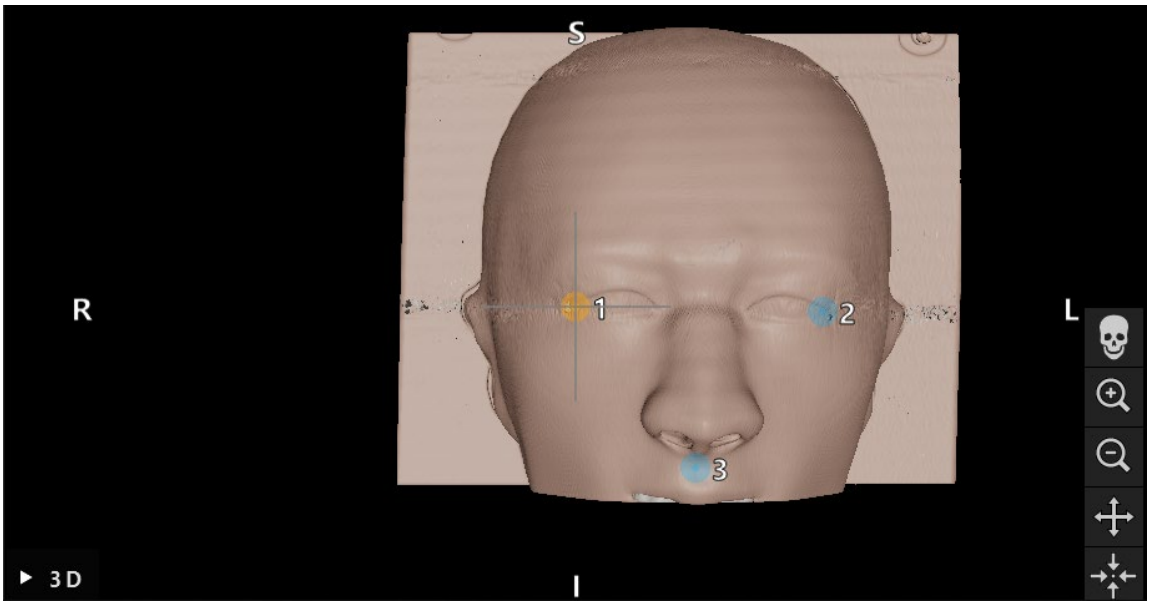


Figure 142 Touch landmark 1 on patient

2. Repeat procedure until all landmarks are touched (Figure 143).

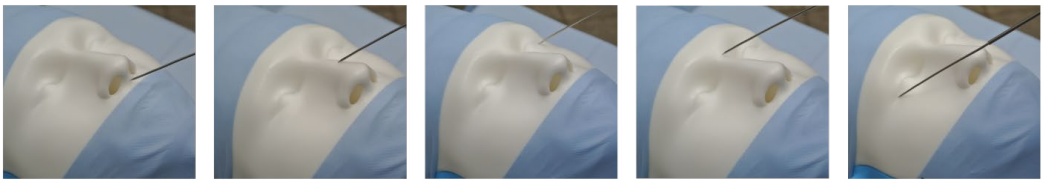


Figure 143 Recording points on the surface

3. After successfully touching all landmarks, the advice window shows the message, *Move pointer over surface* (see Figure 144).

– 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 the surface touching cannot be completed successfully after a few minutes, the surface type patient registration should be started again.

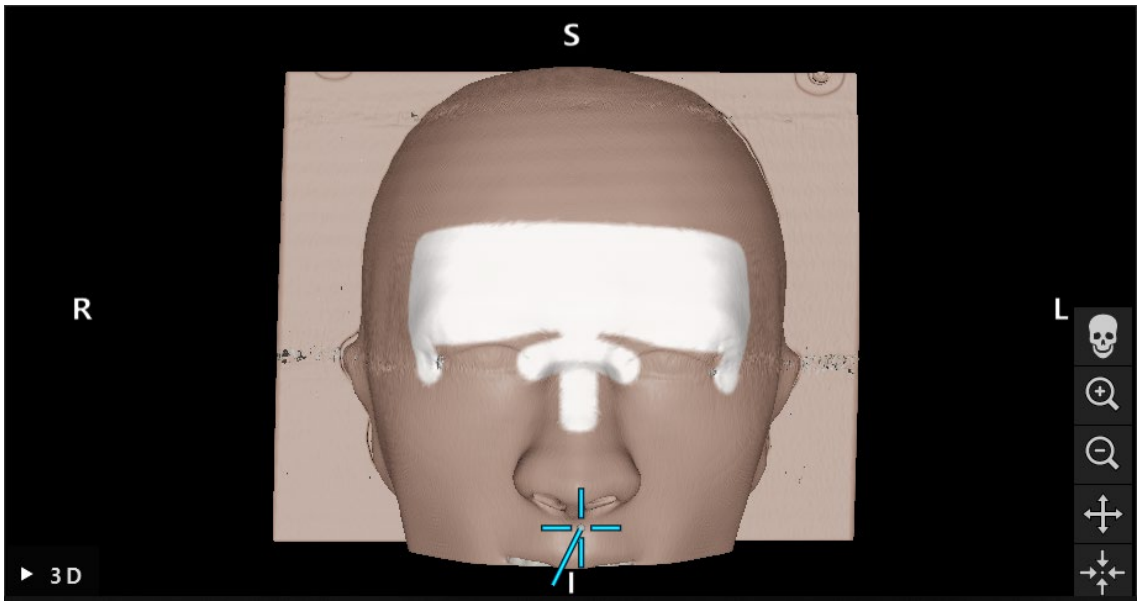


Figure 144 Move pointer over surface

4. Now move the pointer over the surface of the patient in wide curves. The more bony structures that are moved along, the more precise the registration (see Figure 145). A small progress wheel 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 only bone areas such as the cheekbone, forehead, and nose bridge. In case of CT data, the 3D view highlights suitable areas in the face with white color.

– In no sufficient correspondence is found after several attempts, change to planning mode and plan the landmarks again.

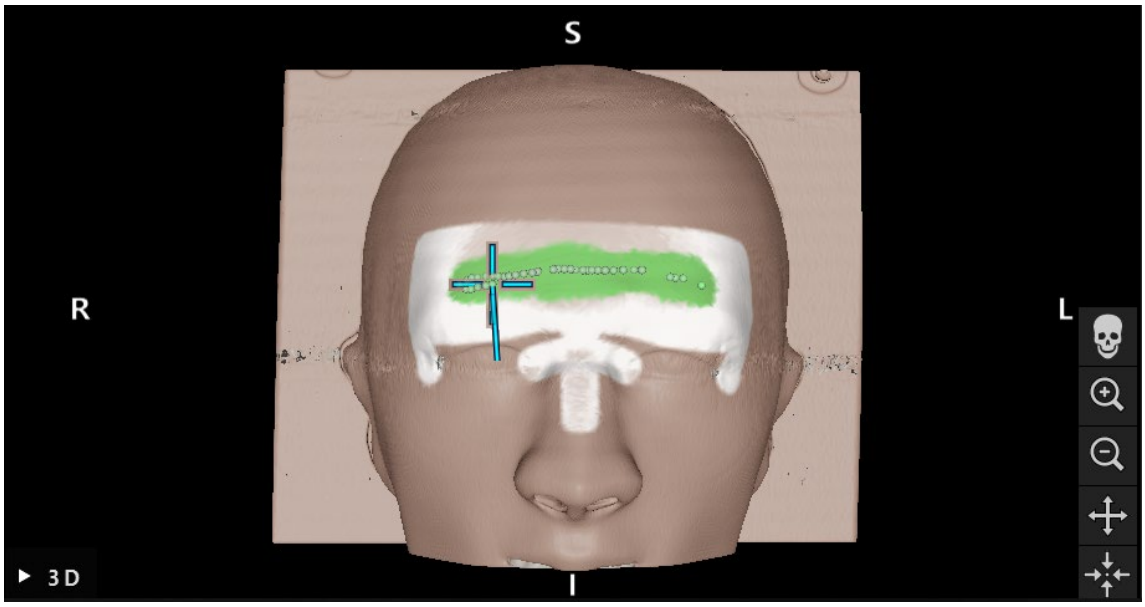


Figure 145 Move pointer over surface

5. After successfully registering, the advice window shows the message, *Hold pointer to confirm.*

6. Check and confirm the precision of the image-to *Patient Registration*. Refer to Section „Confirmation and verification of the patient registration“.

11.3. Patient registration: enhanced surface

CAUTION

If the subnasale and nasion are not detected correctly, reposition the landmarks in the image. If the subnasale and nasion are not detected at all, place both landmarks in the image manually. If neither helps, choose another registration method.

Application

1. Touch and hold the marker on landmark 1 still until you hear a confirmation tone.

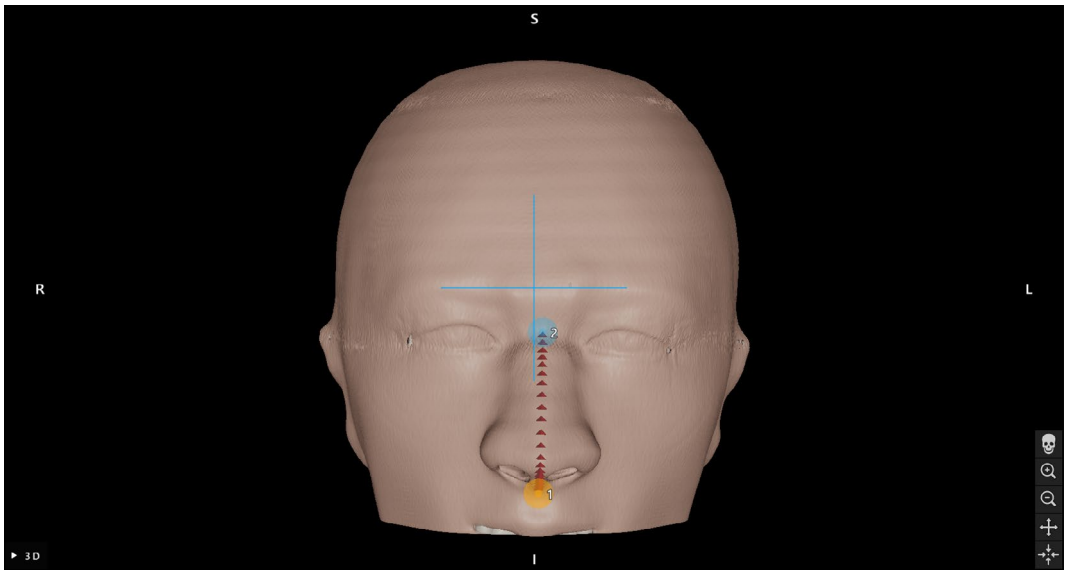


Figure 146 Touch and hold marker

2. Move pointer along the directed highlighted path until you hear a further confirmation tone.

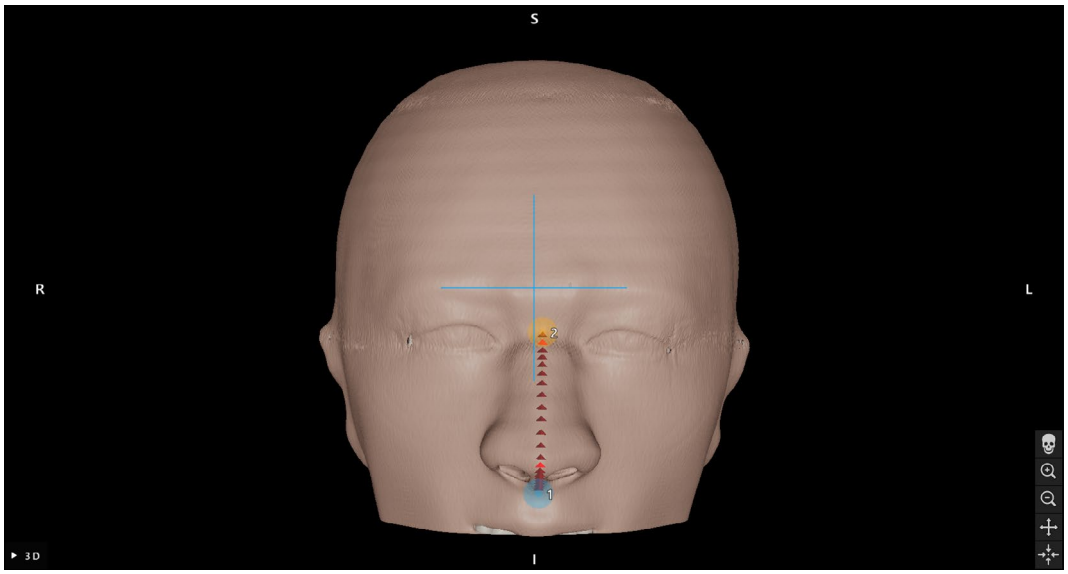


Figure 147 Move pointer along highlighted path

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 progress wheel 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. In case of CT data, the 3D view highlights suitable areas in the face with white color. Areas for which sufficient amount of points were collected are colored in green. Refer to Figure 149.

– If the surface touching cannot be completed successfully after a few minutes, the enhanced surface type *Patient Registration* should be started again.

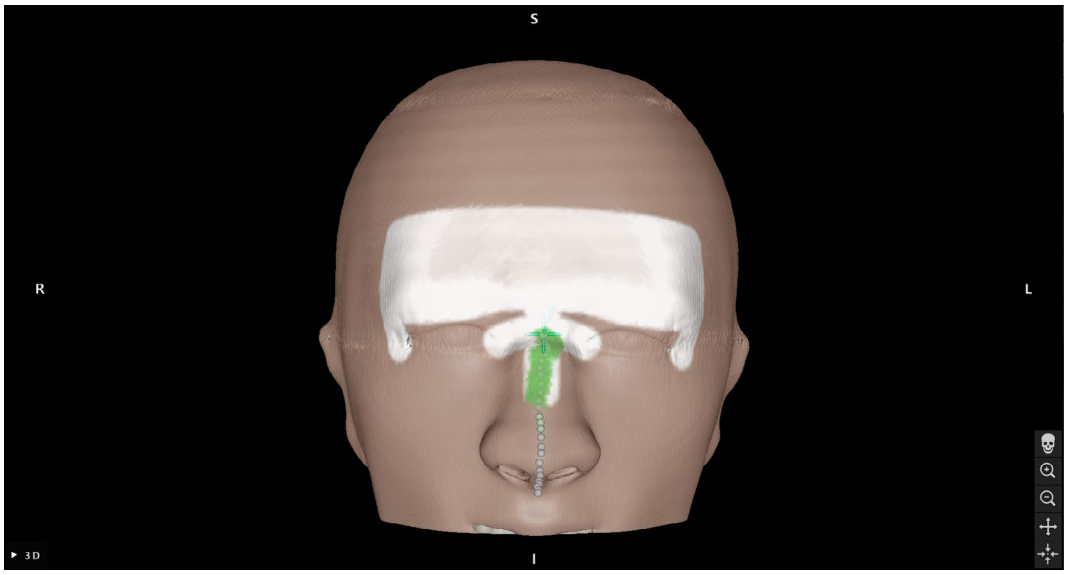


Figure 148 Move pointer over surface

4. After successfully registering, the advice window shows the message, *Hold point to confirm.*

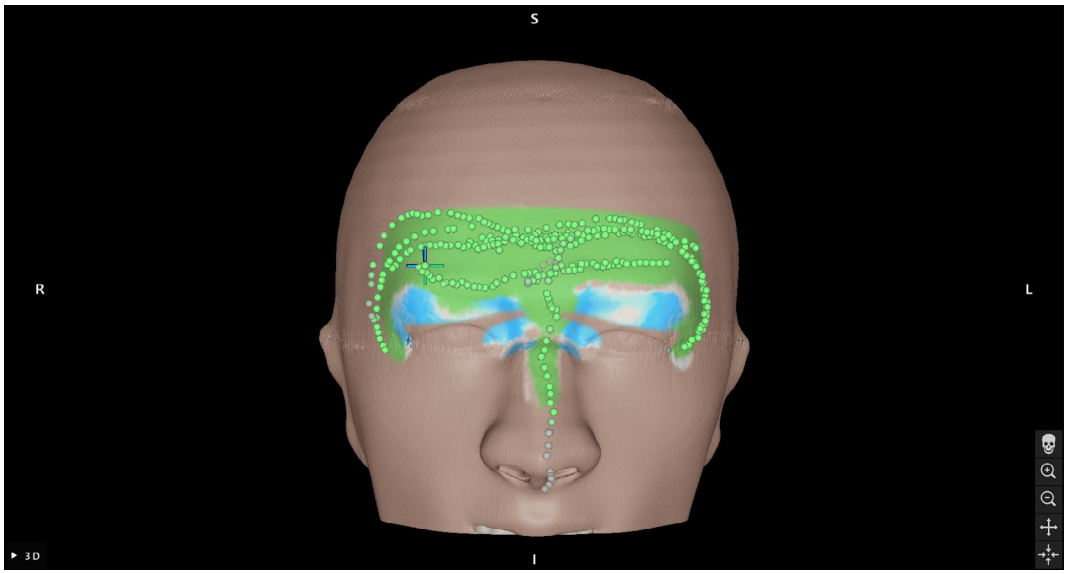


Figure 149 Hold pointer to confirm

5. Registering can be improved when points are displayed in the blue-blinking area (This area is only displayed when enough points have been recorded).

6. Check and confirm the precision of the patient registration. Refer to Section „Confirmation and verification of the patient registration“.

11.4. Confirmation and verification of the patient registration

WARNING

- Be aware that the accuracy of the navigation is mainly dependent on the accuracy of the registration. If prompted by the system, only proceed if the displayed registration error matches your clinical requirements.
- Verify the visualization of instrument position on several anatomical structures after registration and repeatedly during surgery. If deviations do not meet your expectations on the accuracy of the system, perform the patient registration again.
- Ensure that the landmarks you use for registration verification are sufficiently spaced apart, clearly identifiable, close to the relevant anatomy and immovable relative to the anatomy of interest.

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

Landmark	Surface	Enhanced Surface
Confirm or increase accuracy.	*Hold pointer to confirm.*	*Hold pointer to confirm.*

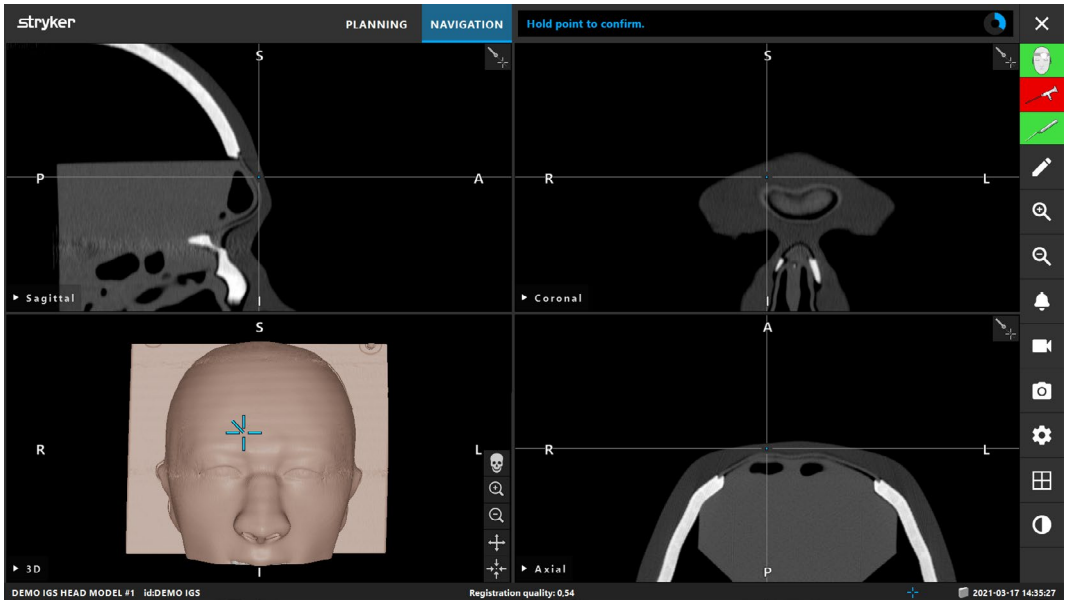


Figure 150 Registration completion

Verification of the system accuracy

1. To check the accuracy, touch one or several of the patient’s prominent anatomical structures (e.g. tooth gaps in the upper jaw, nasion or bony structures) with the instrument used for the patient registration and compare it to the visualized position.

Do not use suction tubes or instruments with attached trackers for system accuracy verification.

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

3. If the correspondence (accuracy) is not acceptable, repeat the patient registration. Refer to Section „Reset the patient registration".

4. After finishing the patient registration, the 3D view switches automatically to the *Video View* if a video signal is detected.

11.5. Interoperative patient registration adjustment

The patient registration can be adjusted intraoperatively.

To perform a patient registration adjustment after registration in navigation mode touch one of the patient's prominent anatomical structures with a pointer instrument. Hold the instrument and switch to edit mode. Create a planning point at the position of the touched anatomical structure with a maximum distance of 10 mm to the crosshair.

The registration can only be offset by a maximum distance of 10 mm.

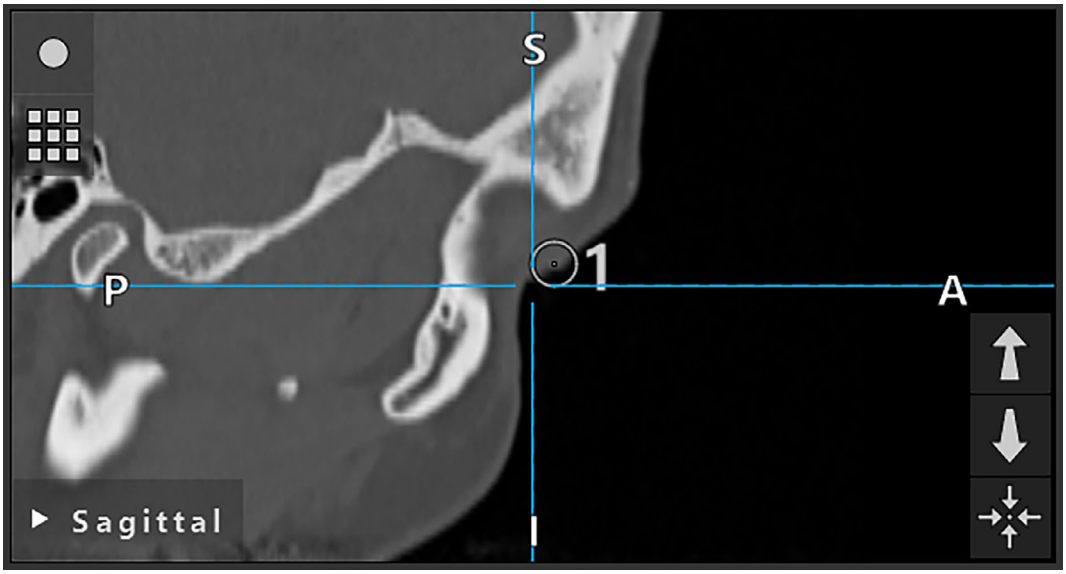


Figure 151 Planning point for patient registration adjustment

Click the *Patient Registration* button. An additional option *Adjust Registration* appears. Click *Move by XX mm* to apply the registration adjustment.

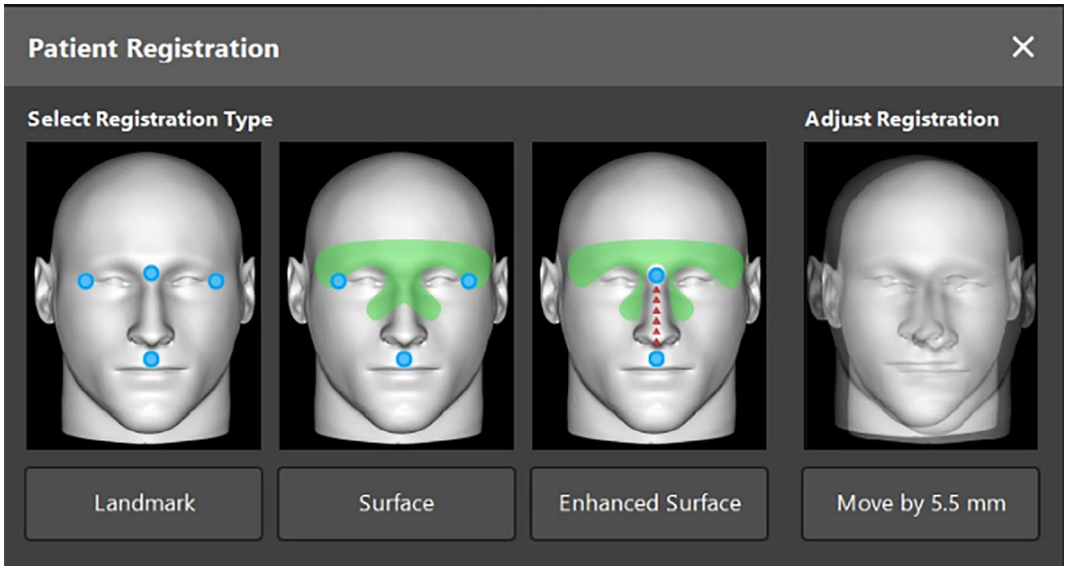


Figure 152 Patient Registration dialog - adjust registration

The selected offset is applied to the active registration immediately. Navigation automatically continues and no further confirmation is required.

11.6. Reset the patient registration

To reset a patient registration, the following options are available:

- Hold a pointer or the TGS Guidewire at the interaction area “x” of the patient tracker until the progress wheel in the advice window is full.

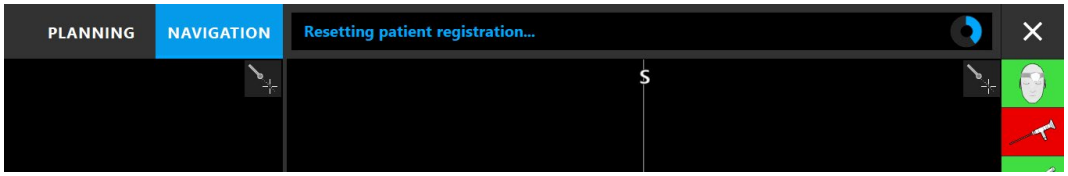


Figure 153 Resetting patient registration

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

11.7. Reuse a patient registration

After you perform the patient registration, the results are stored with the planning and can be reused repeatedly without the need to perform the registration procedure again. In order to reuse a patient registration, you must be in the planning mode, press and hold the left mouse button on the *Navigation* tab until the *Reuse Patient Registration* dialog appears.

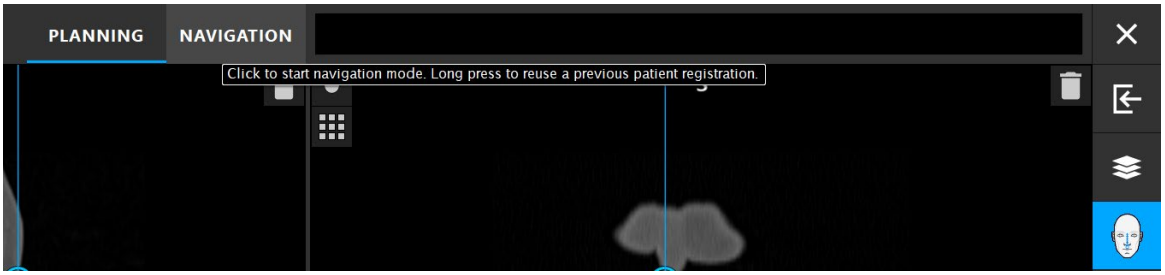


Figure 154 Press and hold the *NAVIGATION* tab to reuse a registration

The software will offer up to five most recent patient registrations in the following dialog as a list of buttons. The registration creation time, the quality and type of registration as well as the instrument used for registration are indicated on each registration button. Use this information to identify a registration you want to reuse. To abort selection click *Cancel* or close the dialog window and perform a manual registration.

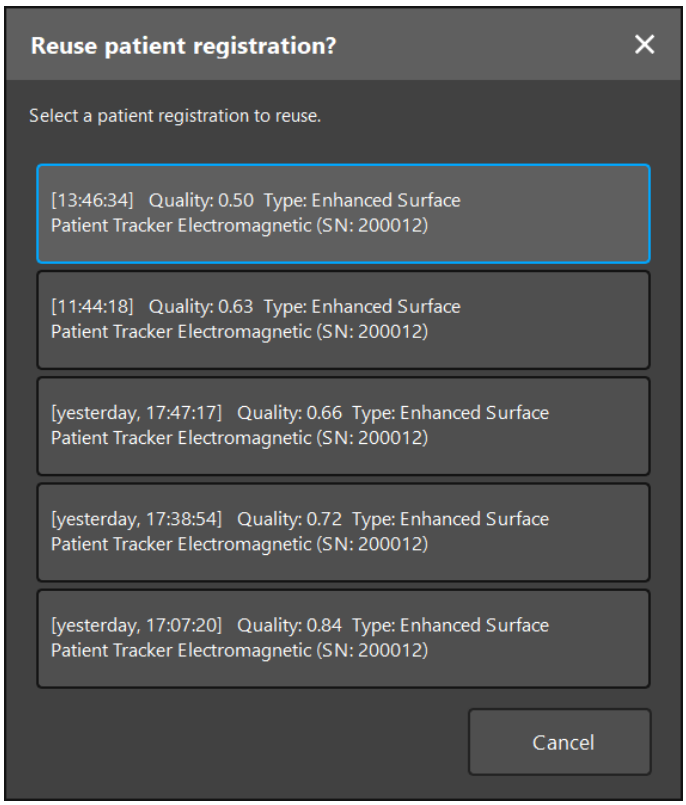


Figure 155 Select a patient registration to reuse

After a patient registration was selected to be reused the precision of the patient registration must be verified and confirmed. Refer to Section „Confirmation and verification of the patient registration“.

- Patient registrations can only be reused within 24 hours after the original registration has been performed. Older patient registrations are no longer available.
- A patient registration is linked to the patient tracker used for the registration and can only be reused with the same patient tracker.
- Patient registrations are tied to a specific planning. If there are multiple planning files with the same patient data, the patient registration can only be reused if the same planning was loaded that was used to perform the original registration.
- In order to modify the current planning after you have already performed a patient registration, e. g. to create a new *Planning Object*, it is not necessary to switch back to planning mode. Instead, you can pause the navigation in order to retain the current patient registration, refer to Section „Edit mode“.

12.Navigation

12.1. Reliability of the navigation information

WARNING

Start with the navigated surgery only after confirming the accuracy of the patient registration.

If the accordance between the navigated instrument position shown on the screen and the real position on the patient is not sufficient, repeat the patient registration. If no sufficient accordance is reached even after conducting the 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 visual observation of the surgical site remains most important for conducting the surgery.

WARNING

- Never rely exclusively on the displayed distance information during surgery but use your tactile feeling within the operation area as well. The system detects and visualizes defined navigation positions with an accuracy of at least 2 mm in radiological images.
- If the navigation system does not appear to be accurate and your attempts to improve the system accuracy fail, do not rely on the navigation system.
- If a navigational accuracy error is suspected, confirm the instrument's position using intraoperative imaging or switch to a non-navigated surgical method.
- The displayed video images from the endoscope camera can be affected by a time lag. Never rely exclusively on the video information; also make use of your tactile feeling in the operation area.
- For minimal video delay, make sure you directly connect the endoscope module with the Electromagnetic Navigation Unit, and the Electromagnetic Navigation Unit with the monitor.

12.2. Visualization of the navigated instrument position

Each navigated instrument has a navigation point, whose position is tracked by the navigation system. This navigation point is shown as a colored crosshair in all 2D cross-section views. Each cross-section view (axial, sagittal and coronal) is shown so that their slice runs through the instrument navigation point.

Visualized position at the navigated instrument:

Precision Pointer Electromagnetic	pointer tip
Pointer Electromagnetic	pointer tip
TGS Guidewire	tip of the guidewire
Registration Pointer Electromagnetic	center of the registration ball
Suction Tubes Electromagnetic	the axis of the sensor tube extended to the tip of the suction tube

Figure 156 Sensor tube and tracked position (yellow cross)

If multiple navigated instruments are detected by the tracking system simultaneously, the system shows the position of only one instrument, e.g. the active instrument. The active instrument is an instrument visible in the tracking volume. Sensorless surgical instruments navigated by means of attached trackers yield a lower tracking accuracy than the navigation instruments with built-in sensors and have a lower priority in becoming the active instrument. If no tracker or instrument is detected by the system, the navigation pauses and visualizes the last known and visible position of a navigated instrument.

The navigated position is visualized in the cross-section views by means of a crosshair which is shown colored if the navigated information is valid. Crosshair colors can be customized, refer to Section „Advanced options dialog“. The crosshairs are shown in gray if:

- The position of the patient tracker or of the instrument cannot be tracked
- The patient image registration is not completed and confirmed.
- Disturbance of the tracking data of the patient tracker or of the instrument has been detected

12.3. Virtual extension of the instrument axis

This function is not available for endoscopes, instrument trackers and Instrument Clamps Electromagnetic.

During navigation, you can virtually extend the axis of an instrument you are using by clicking the button in the top right corner of the view (Figure 157). This opens a slider that allows you to choose the length of the virtual axis extension. The visual representation of the instrument axis is then extended to the according length. The yellow line is a visualization aid originating from the actual instrument position and should help you estimate how far away certain features in the image volume are from the current instrument position (Figure 157).

In Advanced Options (refer to Section „Advanced options dialog“) you can change the visualization of the virtual instrument extension via the Advanced Options (refer to section „Advanced options dialog“) setting *Extend instrument extension*. If deactivated, the virtual instrument extension is displayed as a line from the instrument tip to the center of the crosshair. If activated, the line is extended beyond the crosshair. Deactivated by default (Figure 158).

The currently displayed slice shows the plane on which the virtually repositioned instrument tip is located. The virtually repositioned instrument tip is shown in the crosshair. The actual position of the instrument tip is the starting point of the yellow line and marked with a separate cross. The both points are connected by the yellow line representing the extended instrument axis.

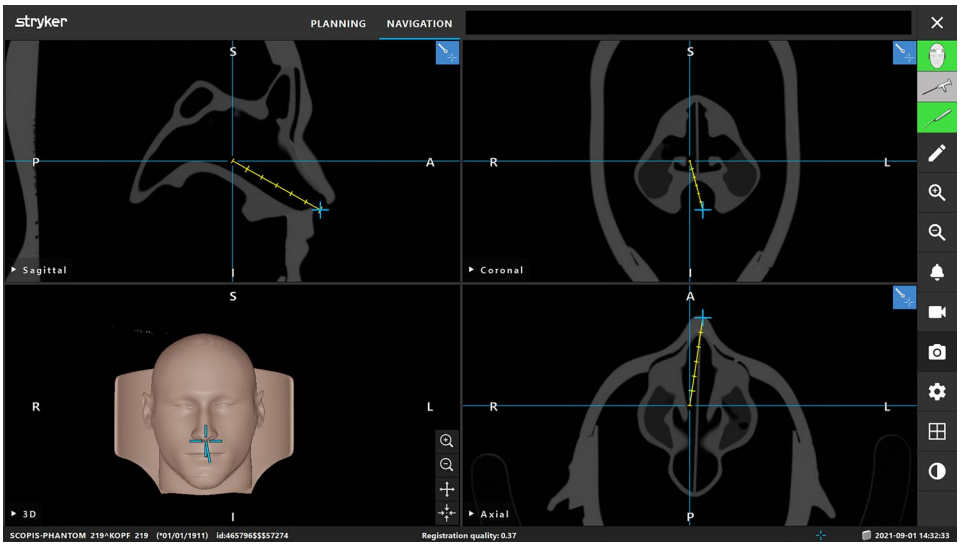


Figure 157 Navigating with *Virtual Instrument Extension* enabled

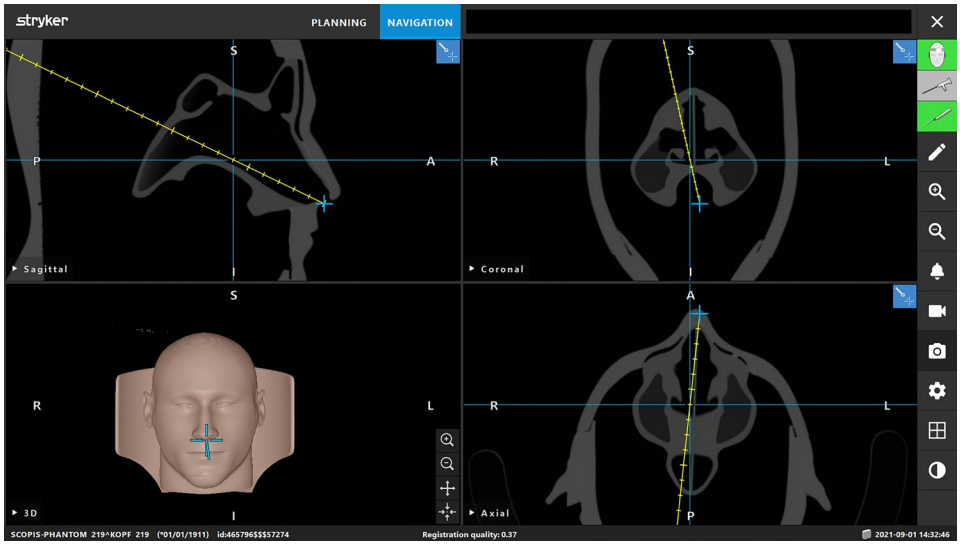


Figure 158 *Extend instrument extension* option activated

To get a simple directional projection directly from the instrument tip, along the instrument axis, without extending the instrument, set the *Virtual Instrument Extension* slider to zero and activate the *Extend instrument extension* option through the *Advanced Options* Dialog (refer to Section „Advanced options dialog“).

12.4. Augmented reality [TGS ONLY]

The navigation software supports the technology of augmented reality (AR), which enables overlay planning objects onto the endoscopic camera image in correct position and in real time. However, the overlay of AR information is only possible if all of the following requirements are met:

- Planning objects to be visualized are created.
- A patient tracker is attached to the patient, and a patient registration is conducted.
- The camera processor of the endoscope is connected to the Electromagnetic Navigation Unit.
- The endoscope is connected with a tracker. Refer to Section „Calibration of surgical instruments“.
- Image calibration was carried out for the endoscope. Refer to Section „Calibration of rigid endoscopes [TGS ONLY]“

WARNING

– Be aware that the displayed position of the planning objects may differ from their actual position.

– Be aware that the display of augmented reality information depends on the accuracy of the patient registration and of the calibration of the endoscopic imaging system. Therefore the accuracy of the augmented reality overlays is lower than the accuracy of the navigation data displayed in the cross-section view.

– The augmented reality overlays of planning objects block and reduce visibility onto the surgical site in the endoscope image and might thus reduce accuracy when handling instruments. If overlays cause inconvenience to you during the surgery, you can deactivate the visualization of individual planning object types in the video view.

12.4.1. Distance orientation guide

If augmented reality is active, the software shows the distance between the navigation point of the active instrument and the selected *Planning Object*.

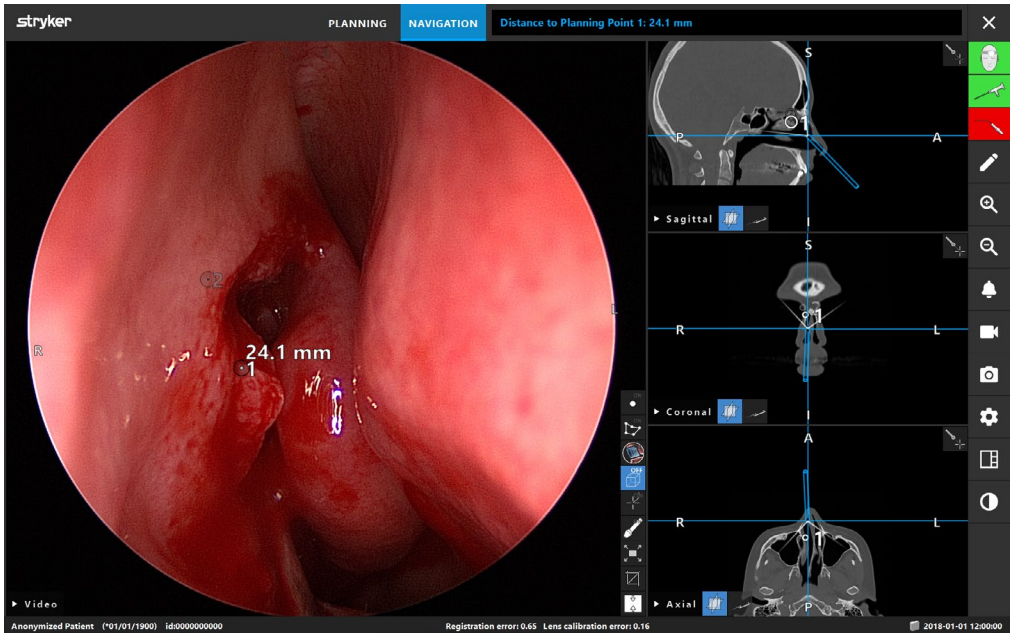


Figure 159 Distance orientation guide

Point the endoscope toward a planning point to select one. The point that is closest to the tip of the endoscope and visible in the endoscope image is selected.

In Figure 159, only planning point 1 is visible to the endoscopic camer. Hence, this point is selected. The selected point is highlighted in the cross-section views and is marked with a white middle point in the endoscope image.

Similar to the planning point object, distance measurements are also available for other types of planning objects, e.g. *Target Structures* (see Figure 160).

Refer also to „Planning objects for navigated surgery [TGS ONLY]“.

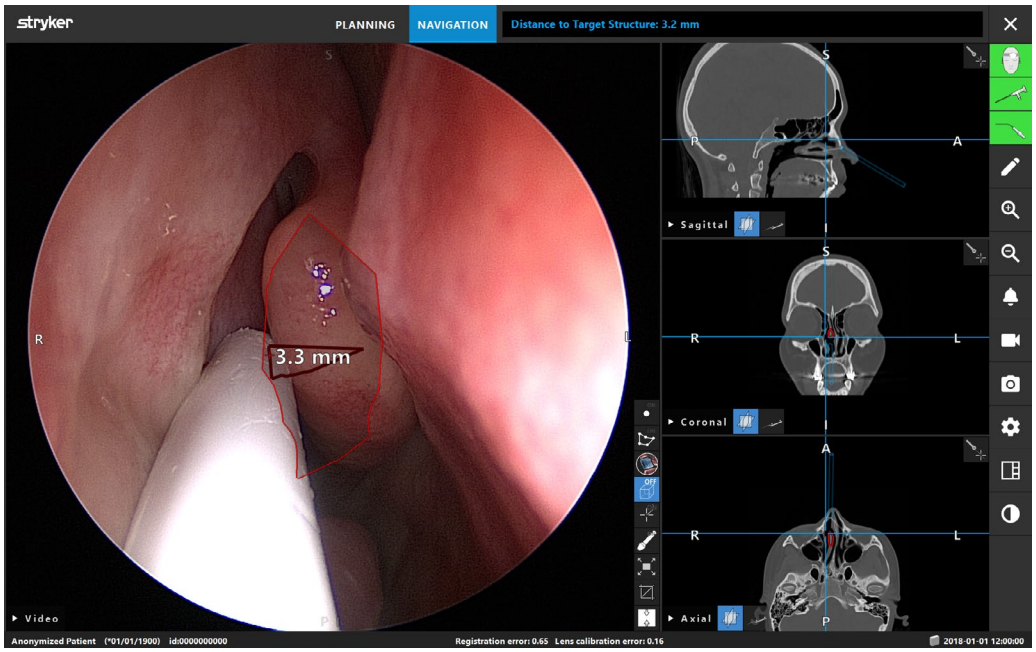


Figure 160 Distance to the planning structure

12.4.2. Navigating with target guided surgery

A planned drainage pathway is shown in the video image view as a line. Refer to Section „Planning objects for navigated surgery [TGS ONLY]“. A series of concentric circles situated at a distance of 5 mm from the line indicate the allowed deviation when moving along the path with an instrument. The pink circle visualizes the actual current instrument tip position along the path. If the tip is too far away from the path, this circle is shown as a segment in the direction of the instrument.

If you move an instrument along this path or trajectory, the circles behind the instrument tip fade out. You can then see how much of the path is already covered.

Furthermore, the distance between the instrument tip and the path end is shown. If the instrument tip is in front of the entry point of the path, the distance is shown to this entry point.

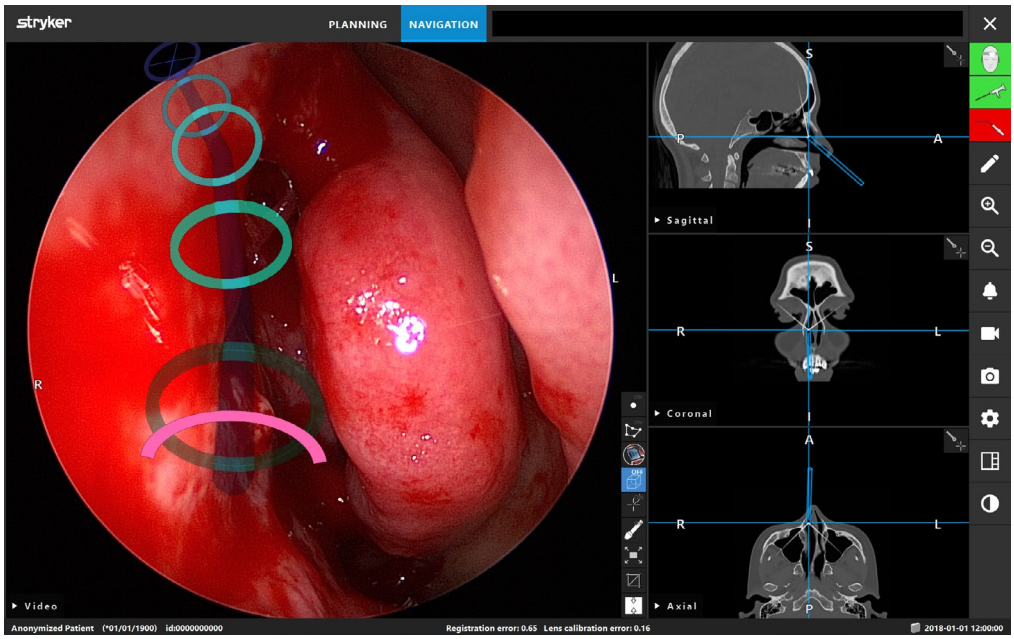


Figure 161 Augmented reality view of drainage pathway

WARNING

The position of the circles indicating a planned pathway in the video view may be less accurate than the accuracy of navigation data in the cross-section views and should only be used as a rough indication of the instrument tip position. Therefore, the instrument tip position in the cross-section views should also be visually monitored during navigation.

12.5. Virtual endoscopy (virtual reality)

Both during planning and navigation, a virtual endoscopic view can be activated in the view selection menu *Virtual Endoscopy* (Figure 162).

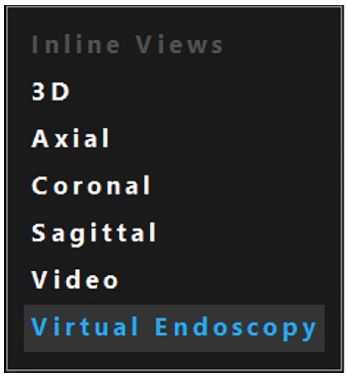


Figure 162 Activate virtual endoscopic view

This feature enables a visualization of the patient anatomy comparable with a real endoscopic view. Planning objects are shown similarly to how they are already known from the *Augmented Endoscopic view.*

In planning mode, this feature provides a visualization along drainage pathways and planning paths. You can move along a path by scrolling or using the slider. Refer to Section „Virtual endoscopy view [TGS ONLY]“ for more information on how to use this feature in the planning mode.
During navigation, you can select the virtual view origin as desired via the setting „prioritize endoscope“, which can be accessed through the *Advanced Options* dialog (refer to Section „Advanced options dialog“ for more details). You can switch back and forth between the endoscope view and the currently active instrument view (the latter is active by default).

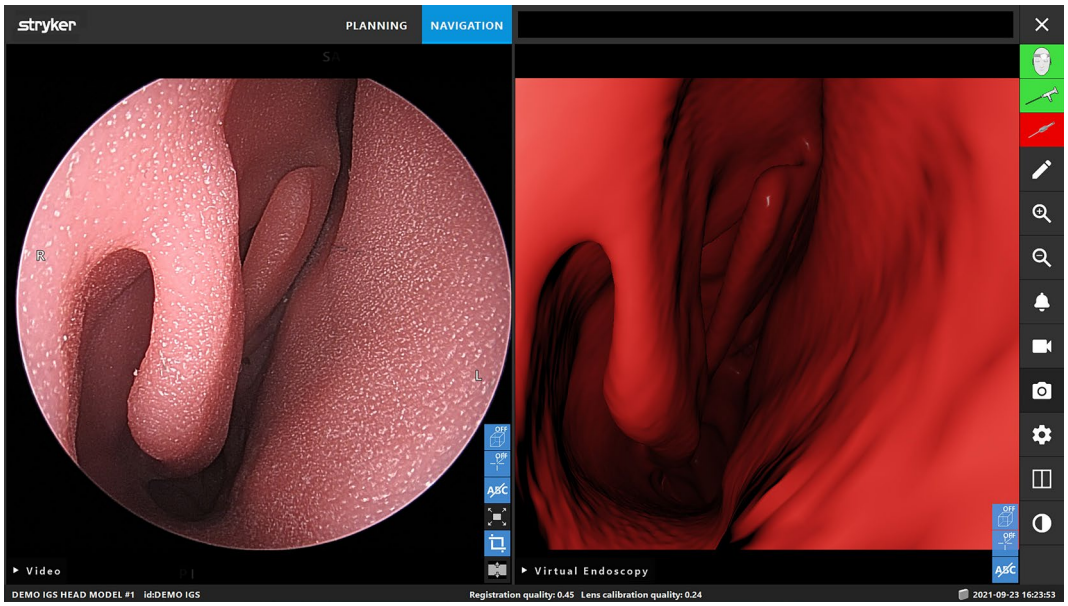


Figure 163 Actual endoscopic view vs. endoscopic virtual reality

If planning objects are created, they can be displayed as overlays in the virtual endoscopy view, similar to the overlays of planning objects in the video view using AR. (see Figure 164).

In contrast to AR (refer to Section „Augmented reality [TGS ONLY]“), the overlay of planning objects on the virtual endoscopy view does not require the endoscope to be calibrated.

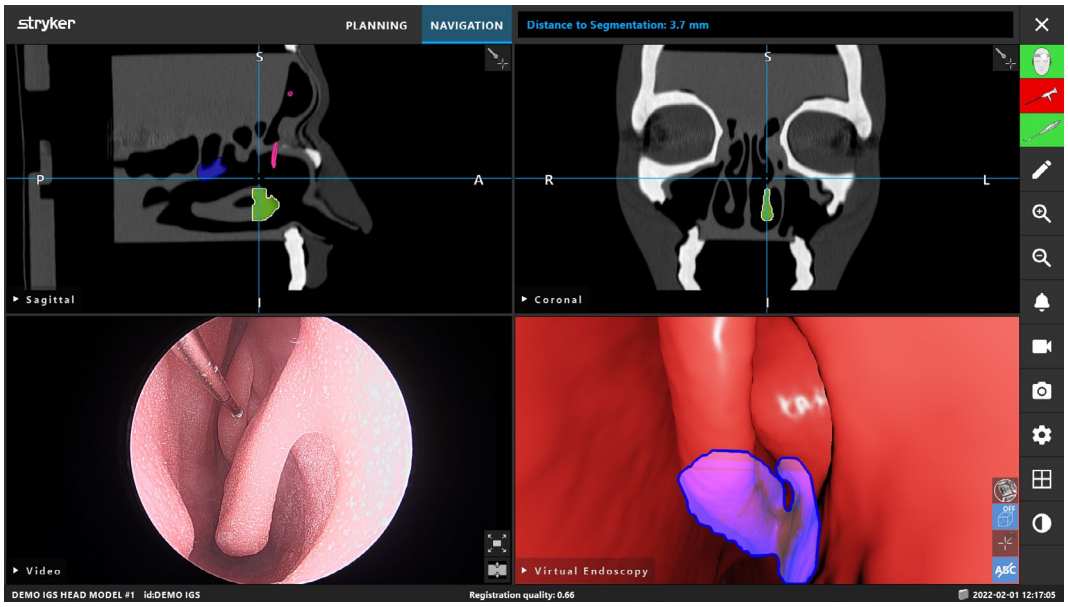


Figure 164 Planning objects displayed as overlays in virtual endoscopic view

12.6. Close the navigation

12.6.1. Close the navigation mode

Do either one of the following steps:

1. Click the *Planning* tab to switch to planning mode.
2. Click the *Close Software* button to end the navigation software.

12.6.2. Close the navigation software

Click the *Close Software* button.

Figure 165 Closing software button

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. Refer to Section „Saving the planning“.

12.6.3. Switch off 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. After the navigation unit is turned off, the green LED on the *On/Off* button of the Electromagnetic Navigation Unit switches off.

- 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.
- Pulling the plug to “switch off” can damage the unit and the operating system.

13. Recording an OP without patient image data

The navigation software provides the option to take screenshots and screen recordings of the endoscopic video feed during an operation, even if radiological 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. Refer to Section „Loading patient image data“. You are asked to enter some general information that is associated with the record as e.g. the patient's name and date of birth (see Figure 166). After filling out the fields, click *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 is listed under the *Plannings* tab of the *Data Import* dialog.

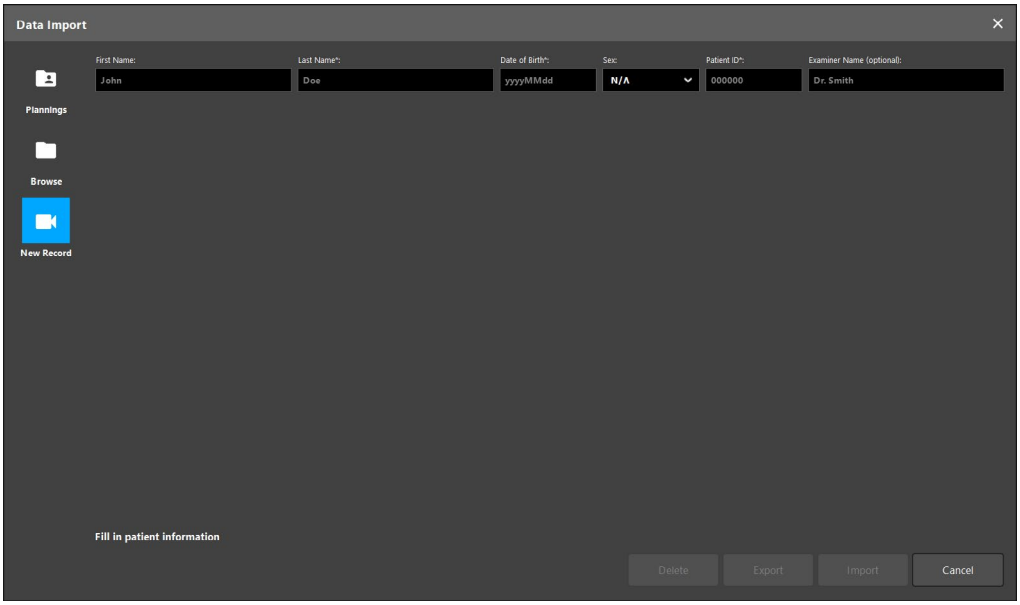


Figure 166 Fill in patient information to start recording

14. Lifetime of electromagnetic instruments

The electromagnetic instruments contain delicate electronics whose useful lifetime is limited due to reprocessing and sterilization. When you plug in an instrument, a message indicating the number of uses appears. For an example, refer to Figure 167:

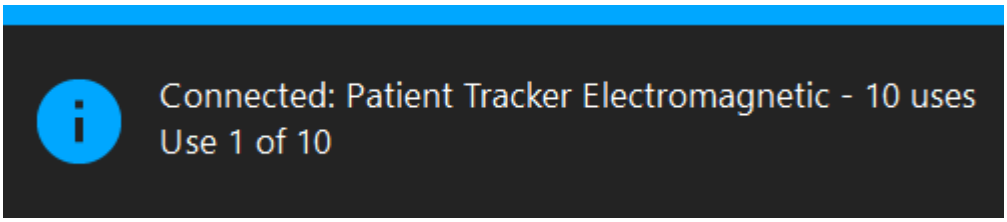


Figure 167 Use counter

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 correct image data within 30 minutes after the beginning of navigation without increasing the use count again.

The number of uses of an electromagnetic instrument can be restricted. The system automatically disables the instrument after reaching the maximum number of uses and displays the following warning (Figure 168):

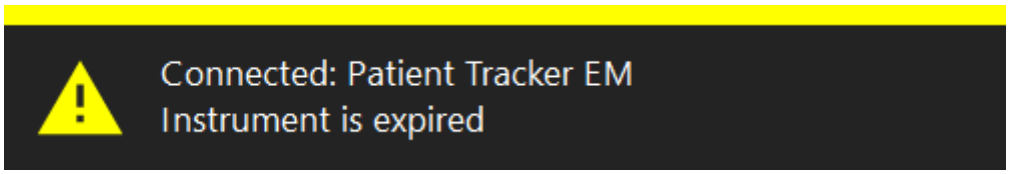


Figure 168 Use cycles exceeded

If the number of uses is not restricted, the following warning is displayed when the recommended number of uses is exceeded by a factor of 2 (Figure 169):

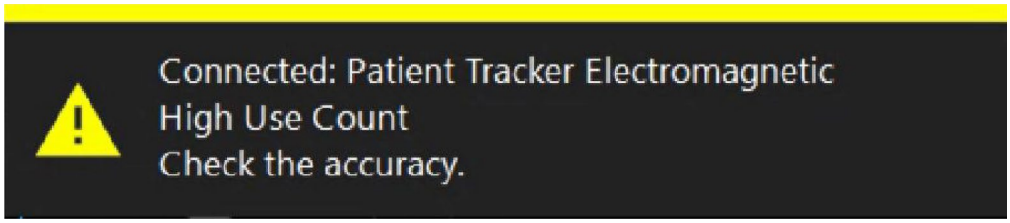


Figure 169 Consider number of use cycles

CAUTION

At the end of the navigated surgery, make sure that accessories that cannot be sterilized again are disposed of.

15. Other compatible components

Endoscope camera unit:

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

Endoscopes:

- Rigid endoscopes
  See section „10.12. Calibration of rigid endoscopes [TGS ONLY]“ for information on available endoscope trackers. For navigating rigid endoscopes of diameter 4 mm, length of 180 mm and default bayonet connector, the use of the Endoscope Tracker Electromagnetic (REF 8000-060-001) is recommended. Refer to Instructions for Use of Instrument Clamps and Instructions for Use of Instrument Clamps Electromagnetic for specifications of more supported diameters.
- Straight forward or forward-oblique optics with 0° / 30° / 45° between shaft axis and viewing direction.

Medical monitors:

- Inputs: DVI, HDMI or Display Port
- Resolution: 1920 x 1080 (Full HD)
- Colors: 16.7 million colors
- Maximum delay of 50 ms when used in combination with an endoscope camera unit
- Medical grade
- Fulfills IEC 62368-1 or IEC 60601-1

Keyboard/mouse (medical or hygiene grade):

- Connector: USB 2.0 or higher
- IBM compatible

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

16. Keyboard shortcuts for navigation software

The navigation software allows the use of keyboard combinations (shortcuts) for easy handling of the navigation software.

Shortcut	Function
Ctrl+D	Show *Advanced Options* dialog (refer to section „Advanced options dialog“)
Ctrl+L	Open log file in *Windows Explorer*
Ctrl+Shift+L	Open current log file
Ctrl+Alt+M	Reset cursor positions
Ctrl+T	Show the *Instrument Visibility* dialog (refer to section „Instrument visibility“). [TGS ONLY]
Ctrl+Q	Show the *Field Generator Alignment* dialog (refer to section „Field generator alignment assistant“)
F2	Take a screenshot
F5	Resize view to fullscreen
F8	Open *Report an Issue* dialog
F10	Open the *System Compatibility Details* dialog.

17. Report an issue

Case report

If you encounter an issue with the software, press F8 to display the *Report an Issue* dialog any time during the application. This dialog is not directly sending any information to Stryker. To report an issue:

1. Provide your contact information so we can reach out in case of queries regarding the reported issue.

2. Use the *Issue Description* box to provide as much context and detail on the discovered software issue as possible.

3. With the date/time picker, select the time frame in which the issue occured.

4. With unchecking/checking the checkbox *Add Planning* you can decide if a planning that might be related to the occured issue should be attached to the issue report (using this feature is recommended).

By default screenshots are not saved with a planning. However, if desired, check the checkbox to include screenshots. Be aware that case reports generally do not export videos.

5. Export the issue report to your storage device of choice.

6. Upload the issue report to the official Stryker website or contact your Stryker sales representative to provide the issue report to Stryker.

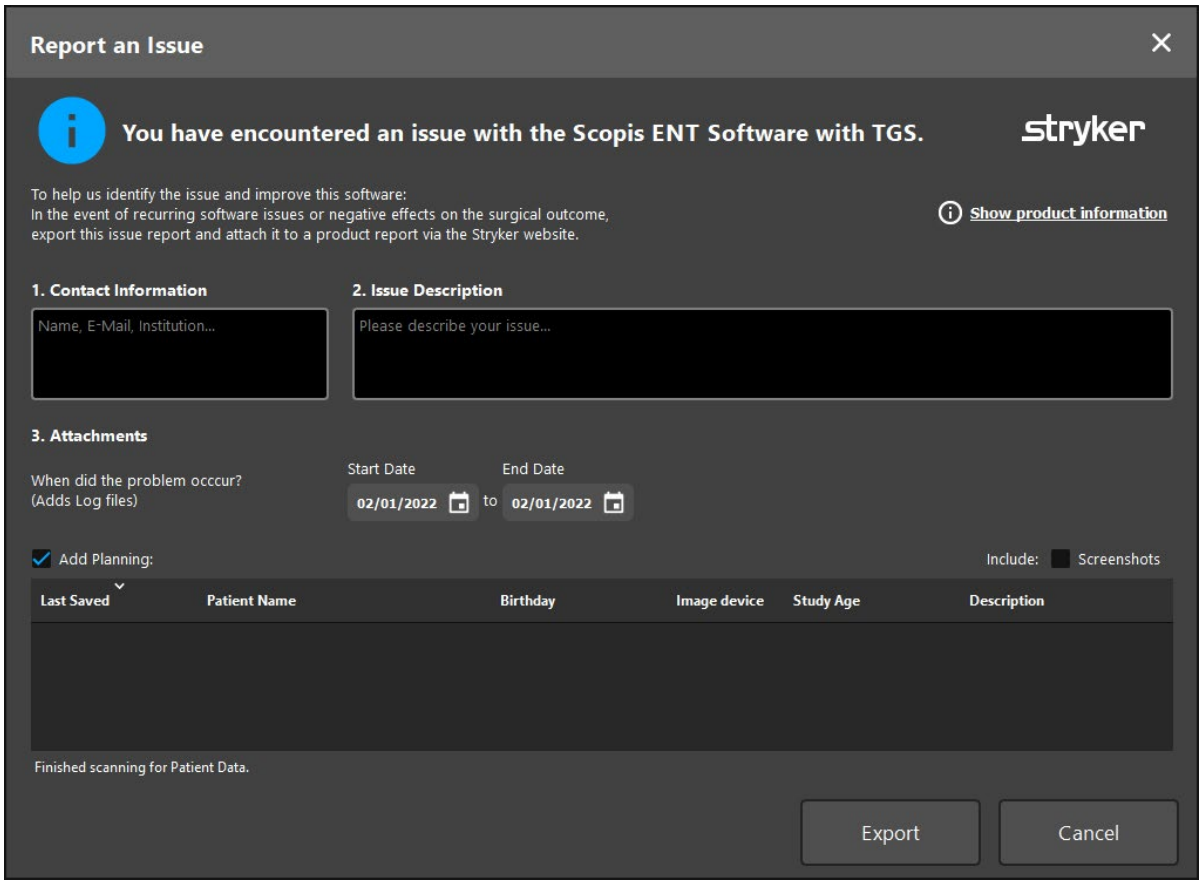


Figure 170 *Report an Issue* dialog (case report)

Bug report

In case the software has spotted an internal issue and has stopped working, the *Report an Issue* dialog is displayed automatically with the most recent plannings suggested as attachments. Proceed as with a case report (see above). Select one planning that might stand in connection with the issue and might help us to resolve the issue and attach screenshots if available.

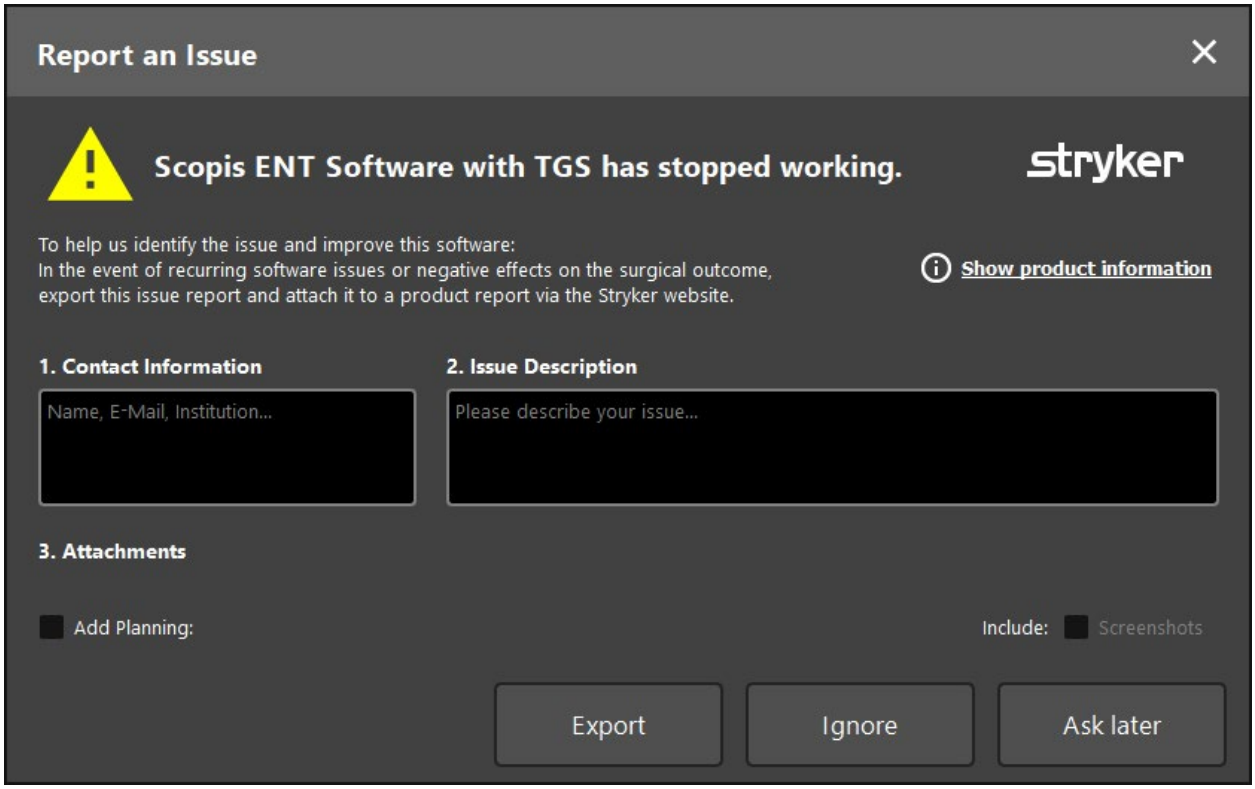


Figure 171 Report an Issue dialog (bug report)

18. Advanced options dialog

The navigation software offers additional user settings that can be accessed via the *Advanced Options* dialog (Figure 172). The *Advanced Options* dialog can be opened with Ctrl + D.

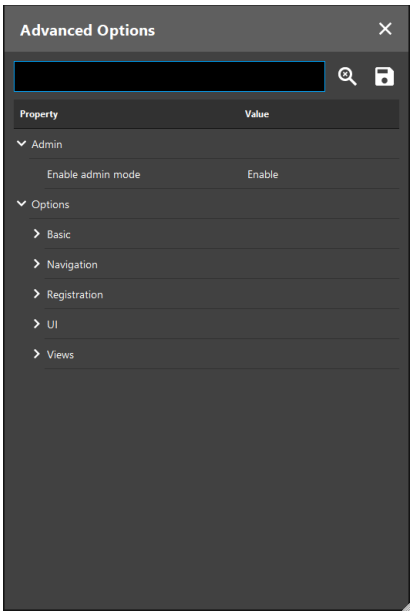


Figure 172 *Advanced Options* dialog

Option	**Function**
Admin	
Enable admin mode	Gives access to additional, restricted options. With “Enable” a prompt asks for the password or authentication code.
Options > Basic	
Reset user settings	With „Reset“ all user defined settings can be reset to the status of the software installation.
Options > Basic > PACS	
Open config dialog	Opens the *PACS Configuration* dialog. Refer to section „Loading from DICOM image data servers“ in this document and refer to the *Software Installation Instructions* supplied with the software application for detailed information. The *PACS* configurations shown in the dialog can only be changed in admin mode. The *PACS Configuration* dialog is only available if the software has been started with admin rights.
Options > Basic > IFU	
Language	Select the preferred language of this user manual document. The application language is used as default user manual language.

Option	Function
Options > Navigation	
Draw distance line	Draws a distance line in the orthographic views from the object to the current pointer position.
High contrast line width	Define the line width with one of the following values: [0, 1, 2, 3]. Default value: 1. A line width of 0 causes no line to be displayed.
Options > Registration > Surface	
Sound for bad positions	Activate acoustic feedback for poor registration positions. Deactivated by default.
Sound for good positions	Activate acoustic feedback for good registration positions. Deactivated by default.
Colorize surface points by registration error	If enabled, the collected points of a surface scan are colored based on their distance to the surface mesh. Deactivated by default.
Options > UI	
Set default planning layout	Overwrites the default planning layout with the current planning layout. Default layouts will be applied at every software start. Refer to section „Managing view layouts“.
Set default navigation layout	Overwrites the default navigation layout with the current navigation layout. Default layouts will be applied at every software start. Refer to section „Managing view layouts“.
Set default registration layout	Overwrites the default registration layout with the current registration layout. Default layouts will be applied at every software start. Refer to section „Managing view layouts“.
Language	Select one of the available user interface languages from a drop-down menu. Changing this setting requires a restart of the software.
Options > Views	
Extend instrument extension	If deactivated, the virtual instrument extension is displayed as a line from the instrument tip to the center of the crosshair. If activated, the line is extended beyond the crosshair. Deactivated by default.
Resizable views	Enables resizing views by drag-and-drop. Drag the grid outline of a view until it is the size you want. To apply the changes, restart the software. Activated by default.

Option	Function
Linear interpolation	Apply linear interpolation in orthographic views. Activated by default.
Draggable	Views can be swapped by dragging a view selection menu onto another view. Changing this setting requires a restart of the software.
Options > Views > Crosshairs	
Crosshair inner (empty) radius	Adjust the size of the inner empty cross section of the slices. Default value: 10 Valid values [-inf, inf]
Crosshair outer (solid) radius	Adjust the size of the outer solid cross section of the slices. Default value: -1 Valid values [-inf, inf]
Color-Active	Change the color of the active crosshairs. Default color: #00A7FF (light blue)
Color-Inactive	Change the color of the inactive crosshairs. Default color: #7F7F7F (gray)
Color-Frozen	Change the color of the frozen crosshairs. Default color: #0070AB (dark blue)
Dynamic scrolling	For activated dynamic scrolling, the crosshair is always in the center of the view. If deactivated, the crosshair moves with the instrument tip. Activated by default.
Clip to border	If activated, the view is moved when the crosshairs get close to the view border. Otherwise, the crosshairs can move outside of the view. Inactive by default. Note: This setting has no effect if “Dynamic scrolling” is activated.
Options > Views > VirtEndo	
Prioritize endoscope [TGS ONLY]	When enabled, the virtual endoscopy view will prioritize the endoscope over the active navigated instrument. Inactive by default.

19. Operating System Update

The operating system of the Stryker ENT Navigation System has the capability to download and install operating system updates (internet connection required).

By default the installation of updates requires manual confirmation/action in order to ensure system availability during the use of the system.

Since operating system updates can have an impact on the system performance, it is strongly recommended to perform a system test after the installation of operating system updates.

To ensure that the navigation system works normally after installing operating system updates the following steps are recommended:

WARNING

Operating system updates can have an impact on the navigation system performance. Check the performance of the navigation system after each operating system update according to the steps described below.

Action	Expected result
1. Reboot the system	System boots normally to *Windows* desktop or login screen.
2. Start the navigation software	Software starts without a warning.
3. Load existing planning or import dataset	Patient data are visualized in 2D and 3D.
4. Switch to navigation mode (Field Generator connected)	No error dialog shown. The *Navigation* tab is pulsing smoothly without stutter or lagging.
5. Connect a video source (e.g. endoscope), if available	*Video View* shows the input video signal.

Enabling Technologies

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