BRAINLAB

ENT
EM

Navigation Software ENT EM
Version 1.2

Software User Guide
Revision 1.5

TABLE OF CONTENTS

TABLE OF CONTENTS

1 GENERAL INFORMATION

1.1 Contact Data

Support

If you cannot find information you need in this guide, or if you have questions or problems, contact Brainlab support:

Region	Telephone and Fax	Email
United States, Canada, Central and South America	Tel: +1 800 597 5911 Fax: +1 708 409 1619	us.support@brainlab.com
Brazil	Tel: 0800 892 1217	brazil.support@brainlab.com
UK	Tel: +44 1223 755 333	support@brainlab.com
Spain	Tel: +34 900 649 115	
France and French-speaking regions	Tel: +33 800 676 030	
Africa, Asia, Australia, Europe	Tel: +49 89 991568 1044 Fax: +49 89 991568 5811	
Japan	Tel: +81 3 3769 6900 Fax: +81 3 3769 6901	

Expected Service Life

Brainlab provides five years of service for software. During this period of time, software updates as well as field support are offered. If the software remains in service after the end of support, the cybersecurity risks may increase over time.

Feedback

Despite careful review, this user guide may contain errors. Please contact us at user.guides@brainlab.com if you have improvement suggestions.

Manufacturer

Brainlab AG
Olof-Palme-Str. 9
81829 Munich
Germany

1.2 Legal Information

Copyright

This guide contains proprietary information protected by copyright. No part of this guide may be reproduced or translated without express written permission of Brainlab.

Brainlab Trademarks

- Brainlab® is a trademark of Brainlab AG.
- **Curve**® is a trademark of Brainlab AG.
- **Kick**® is a trademark of Brainlab AG.

Non-Brainlab Trademarks

- Diego® is a registered trademark of Gyrus ACMI, Inc.
- Microsoft® and Windows® are registered trademarks of Microsoft Corporation.
- NVIDIA® is a registered trademark of NVIDIA Corporation.

Patent Information

This product may be covered by one or more patents or pending patent applications. For details, see: www.brainlab.com/patent.

Integrated Third-Party Software

This software is based in part on the following work. The full license and copyright notice can be found at the links below:

- DCMTK (https://dicom.offis.de/download/dcmtk/dcmtk366/COPYRIGHT)
- ICU4C (https://github.com/unicode-org/icu/blob/master/icu4c/LICENSE)
- Jansson (https://github.com/akheron/jansson/blob/master/LICENSE)
- Lapack (http://www.netlib.org/lapack/LICENSE.txt)
- libjpeg (http://www.ijg.org/)
- libpng (http://www.libpng.org/pub/png/src/libpng-LICENSE.txt)
- libtiff (http://www.libtiff.org/misc.html), copyright© 1988 - 1997 Sam Leffler and copyright© 1991 - 1997 Silicon Graphics (www.simplesystems.org/libtiff)
- libturbo-jpeg (https://github.com/libjpeg-turbo/libjpeg-turbo/blob/master/LICENSE.md)
- libxml2 (https://opensource.org/licenses/mit-license.html)
- Merge DICOM C/C++ Toolkit 5.7, ICU license, copyright © 1995-2012 International Business Machines Corporation and others. All rights reserved.
- meta (https://github.com/ericniebler/meta/blob/master/LICENSE.md)
- Microsoft dbghelp (https://www.microsoft.com/)
- Microsoft DirectX 3D11 Windows 10 SDK (https://www.microsoft.com/)
- Microsoft Visual C++ Runtimes 2015 (https://www.microsoft.com/)
- NVidia Cg Toolkit (https://launchpad.net/ubuntu/bionic/+source/nvidia-cg-toolkit/+copyright)
- NVidia NVAPI (NVIDIA Corporation, https://www.nvidia.com/)
- PICTools (https://www.componentsource.com/product/pictools-document/licensing)
- OpenJPEG (http://www.openjpeg.org/)
- range (https://github.com/microsoft/Range-V3-VS2015/blob/master/LICENSE.txt)
- Xerces-C++, developed by the Apache Software Foundation (http://www.apache.org/licenses/LICENSE-2.0.html)
- zlib (https://zlib.net/zlib_license.html)

- Portions of this software were originally based on software copyright © 1999, IBM Corporation (http://www.ibm.com)

CE Label

The CE label indicates that the Brainlab product complies with the essential requirements of European Council Directive 93/42/EEC, the Medical Device Directive ("MDD").

CE 0123 According to the principles set out in the MDD, **ENT EM** is a Class IIb product.

NOTE: The validity of the CE label can only be confirmed for products manufactured by Brainlab.

Disposal Instructions

When a medical device reaches the end of its functional life, clean the device of all biomaterial/biohazards and safely dispose of the device in accordance with applicable laws and regulations.

Only dispose of electrical and electronic equipment in accordance with statutory regulations. For information regarding the WEEE (Waste Electrical and Electronic Equipment) directive or relevant substances that could be present in the medical equipment, visit: www.brainlab.com/weee/

Sales in US

US federal law restricts this device to sale by or on the order of a physician.

Report Incidents Related to This Product

You are required to report any serious incident that may have occurred related to this product to Brainlab, and if within Europe, to your corresponding national competent authority for medical devices.

1.3   Symbols

Warnings

⚠️   **Warning**

Warnings are indicated by triangular warning symbols. They contain safety-critical information regarding possible injury, death or other serious consequences associated with device use or misuse.

Cautions

⊙   **Cautions are indicated by circular caution symbols. They contain important information regarding potential device malfunctions, device failure, damage to device or damage to property.**

Notes

NOTE: Notes are formatted in italic type and indicate additional useful hints.

Product Symbols

Symbol	Explanation
Manufacturer symbol	Manufacturer
Consult instructions for use symbol	Consult instructions for use
RxOnly	U.S. federal law restricts this device to sale by or on order of a physician
UDI	Unique Device Identifier
MD	Medical Device

1.4   Using the System

Abbreviated Device Description

The software **ENT EM** and its instrument accessories form a medical device which enables navigated surgery when used with a compatible "IGS platform". The instruments are linked to a virtual computer image space based on patient image data that is being processed by the navigation platform. This allows for the continuous localization of medical instruments in relation to patient anatomy for medical interventions.

Intended Use and Indications for Use

ENT EM, when used with compatible navigation platforms and compatible instrument accessories, is intended as an image-guided planning and navigation software to enable navigated surgery.

The device is indicated for any medical condition in which a reference to a rigid anatomical structure can be identified relative to images (CT, CTA, X-ray, MR, MRA and ultrasound) of the anatomy, such as:

- Intranasal structures and Paranasal Sinus Surgery
    - Functional endoscopic sinus surgery (FESS)
    - Revision & distorted anatomy surgery on all intranasal structures and paranasal sinuses

Known Contraindications

The use of the EM Tracking system within 200 mm of an active implantable or body worn medical device (e.g., ICDs, neurostimulators, cochlear implants) is contraindicated. An installed active implantable or body worn medical device cannot be within 200 mm of an operating EM field generator, since the magnetic field produced by the EM filed generator may interfere with the active implantable or body worn medical device. Not following this rule comprises a contraindication for using EM Tracking in a patient with an active implantable or body worn medical device as the safety of this patient cannot be guaranteed anymore.

Residual Patient Risks

System unavailability:

Brainlab navigation systems are complex devices consisting of software and hardware. A failure of any component in the system may lead to a sudden unavailability of the system. This may lead to abandoning or rescheduling the case, or in some instances continuing the case without navigation. Surgical decisions made after the sudden loss of navigation must be made carefully to avoid damage to critical structures, septal perforations, CSF leak or unintended removal of tissue, which may lead to critical patient injuries, such as blindness, or neurological deficit complications (e.g., motor deterioration, hemiparesis, aphasia) or surgical outcomes that are not according to plan, such as unintended residual tumor.

Extended OR time:

The use of image-guided navigation may increase the procedure time compared to a non navigated procedure due to additional tasks such as system setup and patient registration. The amount of additional time required varies depending on the specific procedure and the experience of the surgeon and surgical staff. In some cases, navigation may actually decrease procedure time. The likelihood of certain surgical complications may increase with extended OR times. These may include meningitis or extracranial infection

Inaccurate navigation:

Inaccurate navigation caused by various factors such as image quality, registration errors, movement of the reference or tracking arrays, bent or damaged instruments, and interference with the tracking system can affect the accuracy of the image-guided navigation system. Surgical decisions made with inaccurate navigation information can cause damage to critical structures, unintended removal of tissue, septal perforations, CSF leaks or surgical outcomes that are not according to plan. These may lead to critical patient injuries, such as blindness, and neurological deficit complications (e.g., motor deterioration, hemiparesis, aphasia).

Place of Use

The EM System is intended to be used inside operating theaters.

The EM System is not intended to be used inside an MR environment.

User Profiles

The intended user profile is defined as follows:

- OR-nurse, neurosurgeons and surgeon's assistants
- Trained Brainlab personnel

Patient Population

There are no demographic, regional or cultural limitations for patients. It is up to the surgeon to decide if the device shall be used to assist a certain treatment.

Careful Handling of Hardware

⊙ **System components and accessory instrumentation are comprised of precise mechanical parts. Handle them carefully.**

1.5   Compatibility with Medical Devices and Software

Compatible Non-Brainlab Devices

Medical Device	Manufacturer
Multi-Modality Fiducial Markers	IZI Medical Products 7020 Tudsbury Road Baltimore, MD 21244 USA
Kick Monitor Drape	Microtek Medical, Inc. 512 Lehmberg Road Columbus, MS 39702 USA
27 Display Drape	
Curve Disposable Sterile Monitor Drape	SPIGGLE & THEIS Medizintechnik GmbH Burghof 14 51491 Overath Germany
Diego Elite	Gyrus ACMI, Inc. 136 Turnpike Road Southborough, MA 01772 USA
Disposable KLS Martin Bone Fixation Screw 1.5 mm x 6 mm, 52170	Gebrüder Martin GmbH & Co. KG A company of the KLS Martin Group KLS Martin Platz 1 78532 Tuttlingen Germany
Drill Bit 1.1 mm, 52126	
Handle for Blades (KLS Martin), 52127	
Screwdriver Blade (KLS Martin), 52171	

Non-Brainlab Devices

⚠️ **Warning**
Using medical device combinations that have not been authorized by Brainlab may adversely affect safety and/or effectiveness of the devices and endanger the safety of the patient, user and/or environment.

Compatible Brainlab Instruments

The following table links the official registered device name to any trade names used in this **Hardware User Guide** or marketing material by identifying the common GTIN / UDI.

UDI-DI	Article No.	Device Name	Trade Name(s)
04056481004866	18099-06	Skull Reference Base EM	**Skull Reference Base EM**
04056481144685	52172	Disposable Skull Reference Bone Fixation Screw 1.5 mm x 6 mm	**Disposable Skull Reference Bone Fixation Screw 1.5 mm x 6 mm**
04056481144708	52174	Skull Reference Screwdriver Handle	**Skull Reference Screwdriver Handle**
04056481144715	52175	Skull Reference Screwdriver Blade	**Skull Reference Screwdriver Blade**

UDI-DI	Article No.	Device Name	Trade Name(s)
04056481144692	52173	Disposable Skull Reference Drill Bit 1.1 mm for Bone Fixation Screw	**Disposable Skull Reference Drill Bit 1.1 mm for Bone Fixation Screw**
4056481005351	55101	Instrument Adapter Clamp (size S)	**Instrument Adapter Clamp (Starlink), Size S**
04056481005344	55102	Instrument Adapter Clamp (size M)	**Instrument Adapter Clamp (Starlink), Size M**
04056481005337	55103	Instrument Adapter Clamp (size L)	**Instrument Adapter Clamp (Starlink), Size L**
04056481005320	55104	Instrument Adapter Clamp (size XL)	**Instrument Adapter Clamp (Starlink), Size XL**
04056481005313	55105	Instrument Adapter Clamp (Blakesley & Rectangular Instruments)	**Adapter for Rectangular Instruments**
04056481005306	55110	Instrument Adapter Clamp (Cylindrical Instruments)	**Adapter for Cylindrical Instruments**
04056481004804	18099-24	EM Patient Reference (2.0)	**Patient Reference EM**
04056481004927	18099-02C	EM Pointer	**EM Pointer**
04056481140410	18099-27	EM Short Pointer	**EM Short Pointer**
04056481004811	18099-23	EM Registration Pointer	**EM Registration Pointer**
04056481004873	18099-05A	Instrument Adapter EM (20 Sterilization Cycles)	**EM Instrument Reference**
04056481001391	55791-01	Pointer Tip (offset 0°, Length 150 mm)	**Pointer Tip (Offset 0°, length 150 mm)**
04056481001377	55791-03	Pointer Tip (offset 30°, length 95 mm; Tip End -70°, 20 mm)	**Pointer Tip (Offset 30°, length 95 mm)**
04056481001360	55791-04	Pointer Tip (offset 0°, length 100 mm; Tip End -90°, 20 mm)	**Pointer Tip (Offset 0°, length 100 mm)**
04056481001353	55791-05	Pointer Tip (offset 0°, length 60 mm)	**Pointer Tip (Offset 0°, length 60 mm)**
4056481001438	55790-65	Suction Maxillary Sinus (charr. 10 With Frazier Tip)	**Suction MS (CH10) Starlink Frazier**
04056481001469	55790-50A	Suction Maxillary Sinus (charr. 8)	**Suction MS (CH8) Starlink**
04056481001452	55790-55	Suction Maxillary Sinus (charr. 8 With Frazier Tip)	**Suction MS (CH8) Starlink Frazier**
04056481001407	55790A	Suction Standard (charr. 10)	**Suction STD (CH10) Starlink**
04056481001421	55790-70	Suction Standard (charr. 10 With Frazier Tip)	**Suction STD (CH10) Starlink Frazier**
04056481001551	55790-05A	Suction Standard (charr. 8)	**Suction STD (CH8) Starlink**
04056481001414	55790-75	Suction Standard (charr. 8 With Frazier Tip)	**Suction STD (CH8) Starlink Frazier**

Other Brainlab Instruments

Additional instrumentation may become available after release of this user guide. Contact Brainlab support if you have any questions regarding compatibility.

Warning

Only use instruments and spare parts specified by Brainlab. Using unauthorized instruments/spare parts may adversely affect safety and/or effectiveness of the medical device and endanger the safety of the patient, user and/or environment.

Instrument Assembly

If any instrumentation is used with this product, ensure that all instruments are correctly assembled according to the instructions within the corresponding **Instrument User Guide**.

Packaging of Sterile Products

Warning

Do not use if the packaging is damaged.

Compatible Brainlab Medical Software

Only Brainlab medical software specified by Brainlab may be installed and used with the system. Contact Brainlab support for clarification regarding compatibility with Brainlab medical software.

Non-Brainlab Software

Only authorized Brainlab employees may install software on the Brainlab system. Do not install or remove any software applications.

Updates

Updates to the operating system or third-party software should be performed outside clinical hours and in a test environment to verify correct operation of the Brainlab system. Brainlab monitors the released Windows security updates and will know, for some updates, if problems can be expected. Contact Brainlab support if any problems to operating system security updates are encountered.

Virus Scanning and Malware

Brainlab recommends protecting the system with state-of-the-art anti-virus software.

Be aware that some malware protection software (e.g., virus scanner) and OS encryption settings can negatively affect system performance. For example, if real-time scans are performed and each file access is monitored, then loading and saving patient data may be slow. Brainlab recommends disabling real-time scans and performing virus scans during non-clinical hours.

Warning

Ensure that your anti-virus software does not modify any Brainlab directories, specifically:

- `C:\Brainlab, D:\Brainlab, F:\Brainlab,` **etc.**
- `C:\PatientData, D:\PatientData, F:\PatientData,` **etc.**

NOTE: Do not download or install updates during treatment planning.

Contact Brainlab support for further information regarding any of these issues.

Microsoft Security Updates for Windows and Driver Updates

Brainlab allows the installation of security updates only. Do not install service packs and optional updates. Verify your settings to ensure updates are downloaded and installed correctly and at a suitable time. Do not update drivers on Brainlab platforms.

For more information about settings and a list of Microsoft Security Updates blocked by Brainlab support, see the Brainlab website (brainlab.com/updates).

1.6   Software Environment and Cybersecurity

Bill of Materials of Integrated Third-Party Software

- DCMTK 3.6.0
- ICU4C 49.1.2
- Jansson 2.7
- Lapack 3.2.1
- libpng 1.6.16
- libtiff 4.0.4 beta
- libturbo-jpeg 1.4.0
- libxml2 2.9.3
- Merge DICOM C/C++ Toolkit 5.7
- meta 0.1
- Microsoft dbghelp 6.3.9600.17209
- Microsoft DirectX 3D11 Windows 10 SDK 10.0.10586.0
- Microsoft Visual C++ Runtimes 2015 14.0.24215.1.1
- NVidia Cg Toolkit 3.1.0010
- NVidia NVAPI Release 367
- OpenJPEG 2.3.1
- PICTools 2.0
- range V3-VS2015
- Xerces-C++ 3.2.2
- zlib 1.2.11

Network Ports

The application uses the following network ports for communication with other applications and/or external devices:

Port	Connection	Type	Description
104	local	TCP	DICOM data exchange
52998-53002	local	TCP	Communication with tracking service (e.g., tracking data, instrument handling)

Log File Management

The log files that can be used for forensic analysis are stored on the local file system. The deletion/archiving of those log files are handled as part of maintenance activities. Access control for log files is in place. The log files are not recycled. The log files are structured and allow parsing by an automated process (e.g., for IDS).

Cybersecurity Use Environment

Cybersecurity considerations were made in accordance with the nature of the device, including the device type and the use environments of the system during its lifetime.

The following common best practice security controls ("security hygiene") in the use environment are expected to be followed, independently of the status of the system (powered on / powered off):

- Good physical security to prevent unauthorized physical access to the system.

If the system is powered on, follow these additional security controls:

- Access control measures (e.g., role based) to ensure only authenticated and authorized personnel are allowed access to network elements, stored information, services and applications.

- Network access controls, such as segmentation, to limit medical device communication.
- General patch management practices that ensure timely security patch updates on adjacent devices in the use environment.
- Malware protection to prevent unauthorized code execution on adjacent devices in the use environment.
- Ensure that prescribed maintenance is done as required, including installation of security patches.
- Security awareness training of the users.

Using the device outside of the intended operating environment may lead to cybersecurity incidents that may affect safety and effectiveness of the device.

Hospital administration is responsible for limiting access to the system and the patient data to appropriate personnel.

Be aware that the screenshot created by the software contains patient-specific data. Saving the screenshot locally thereby saves patient information to the system.

Cybersecurity Vulnerability

If you detect a cybersecurity vulnerability or weakness of the device or if a cybersecurity incident takes place involving the device, contact Brainlab support. Depending on the actual event, Brainlab support will advise which steps to take.

1.7   Training and Documentation

Intended Audience

This user guide is intended for ENT surgeons or their assistants when using a Brainlab navigation system.

Brainlab Training

Before using the system, all users must participate in a mandatory training program held by a Brainlab authorized representative to ensure safe and appropriate use.

Supervised Support

Before using the system for surgical procedures where computer-aided navigation is considered critical, perform a sufficient number of complete procedures together with a Brainlab representative.

Responsibility

⚠ **Warning**
This system solely provides assistance to the surgeon and does not substitute or replace the surgeon's experience and/or responsibility during its use. It must always be possible for the user to proceed without the assistance of the system.

Only trained medical personnel may operate system components and accessory instrumentation.

Extended OR Time

Brainlab Navigation Systems are sensitive technical equipment. Depending upon OR setup, patient positioning, calculation durations and complexity, surgery duration using navigation may vary. It is up to the user to decide whether a potential prolongation is acceptable for the respective patient and treatment.

Reading User Guides

This guide describes complex medical software or medical devices that must be used with care.

It is therefore important that all users of the system, instrument or software:
- Read this guide carefully before handling the equipment
- Have access to this guide at all times

Available User Guides

NOTE: Available user guides vary depending upon the Brainlab product. If you have questions regarding the user guides you received, please contact Brainlab support.

User Guide	Contents
Software User Guides	• Overview of treatment planning and image-guided navigation • Description of OR system setup • Detailed software instructions
Hardware User Guides	Detailed information on radiotherapy and surgical hardware, typically defined as large complex instruments
Instrument User Guides	Detailed instructions on instrument handling

User Guide	Contents
Cleaning, Disinfection and Sterilization Guide	Details on cleaning, disinfecting and sterilizing instruments
System and Technical User Guide	Detailed information on system setup, technical information on the system, specifications and compliances

1.8   Electromagnetic Immunity and RFID

IEC 60601-1-2 and AIM Standard 7351731

Applicable immunity tests and standards, as well as the used compliance levels are documented in the **System and Technical User Guide** of the corresponding navigation platform used with the **ENT EM** system.

Limitations of ENT EM System

To ensure and maintain basic safety, device function and essential performance the following limitations and precautions need to be taken into consideration:

- Place the **EM Base Station** at least 60 cm away from the **EM Field Generator** as this may affect the tracking volume or the tracking accuracy.
- Place the **Monitor Cart** at least 60 cm away from the **EM Field Generator** as this may affect the tracking volume or the tracking accuracy.
- Do not place any RFID device in close proximity to the **Monitor Cart**. Refer to the corresponding **System and Technical User Guide** for the required distance, depending on the platform.
- Do not place any RFID device in close proximity of the Field Generator. Ensure a distance of at least 1 m is maintained from the **EM Field Generator**
- Do not place any RFID device in close proximity of EM Instruments. Ensure a distance of at least 1 m is maintained from any EM Instruments.

⚠️ **Warning**
Portable RF communications equipment (including peripherals like antenna cables and external antennas) should not be used closer than 30 cm from any part of the Curve Navigation system including cables specified by Brainlab. Otherwise, degradation of the performance could result.

⚠️ **Warning**
Remove all metal jewelry, including piercings, before operating.

⚠️ **Warning**
Do not operate the EM Field Generator within 200 mm of an installed active implant or body worn medical devices (e.g., pacemaker, ICD, neurostimulator, cochlear implant or other). The magnetic field produced by the EM Field Generator may interfere with the operation of active implants.

Phenomena Observed During EMC Testing and RFID

Electromagnetic fields generated by other devices (e.g., power frequency magnetic field) near the electromagnetic navigation field can degrade navigational accuracy:

- If the distortion introduces excessive error, the software will automatically disable the tracking and a red magnet is displayed in the software. To restore navigation, the distortion must be moved away from the navigation field.
- If the system detects a potential distortion, before completely disabling the tracking, the software displays a yellow magnet. If a yellow magnet is displayed, accuracy may be degraded. Verification by comparing the instrument position on the patient's anatomy and the display is crucial. To restore accuracy, remove any metallic, conductive elements or any other source of distortion (e.g., other medical electrical equipment) near the navigation field.

If the minimum separation distances from RFID devices are not maintained, effects such as ghost touches may be observed.

During transient electrostatic discharge (ESD) or electrical fast transients (EFT) phenomena, the device may temporarily lose tracking. Absence of tracking is indicated via the Tracking System status (see related links). The system features automatic recovery that recovers the tracking system within seconds. The process of reestablishing tracking includes all initialization steps to

reestablish tracking without losing previously registered information. In case the automatic recovery takes longer than a few seconds, unplug and replug the **EM Power Data Cable**, connecting the **EM Base Station** to the **Monitor Cart**. For detailed instructions on connecting the **EM Tracking Unit** to the **Monitor Cart**, refer to the corresponding **System and Technical User Guide**.

In case of voltage interruption, the device shuts down and must be restarted manually. The system features a recovery mode where the tracking is reestablished and the patient registration is been reloaded.

2 SYSTEM SETUP

2.1 Getting Started

About System Setup

Correct system setup is required to enable accurate navigation. Set up the system so that it does not hinder the surgeon and position the patient carefully. After registration is performed, the patient and **EM Field Generator** should not be moved.

Animations in the software provide guidance for correctly setting up and positioning the patient and patient reference and verifying the tracking volume.

Once the setup is complete, select **Next**. Attached instruments and references can then be seen in a representation of the tracking volume.

Precautions

⚠️ **Warning**
System accuracy may be affected by the setup. Some metal objects and radio frequency communication equipment may cause interference in the electromagnetic field that can affect tracking accuracy. Always verify system accuracy for the planned procedure upon completing setup. Check the accuracy of the system in different spatial locations in order to verify that the field is not distorted.

⚠️ **Warning**
The electromagnetic field of the EM Field Generator may be disturbed by other nearby equipment leading to increased inaccuracy of the system. Do not use actively powered devices within the tracking volume as they cause interference that affects tracking accuracy.

ⓘ **Do not wind any cables around the EM Field Generator as this can lead to device malfunction.**

Distance Considerations

⚠️ **Warning**
Do not operate the EM Field Generator within 200 mm of an installed active implant or body worn medical devices (e.g., pacemaker, ICD, neurostimulator, cochlear implant). The magnetic field produced by the EM Field Generator may interfere with the operation of these active implants.

⚠️ **Warning**
Place the EM Base Station at least 60 cm from the EM Field Generator, otherwise tracking volume or system accuracy may be affected.

⚠️ **Warning**
Place your Monitor Cart at least 60 cm from the EM Field Generator, otherwise tracking volume or system accuracy may be affected.

Warning

Do not place EM instrument cables within 30 mm of the EM Field Generator cable. If placed this close (particularly if the cables are parallel to each other) the EM instrument cable may become subject to electromagnetic interference leading to compromised system accuracy.

Electrical Conductivity

The electromagnetic field induces current into electrically conductive parts. Remove all conductive objects from the patient (e.g., piercings).

Pairing Function

It is possible to pair the monitor with another monitor (e.g., **Kick, Curve, Buzz**) for additional viewing of the software. For more information, refer to the relevant **System and Technical User Guides** and the **Origin Data Management Software User Guide.**

NOTE: Depending on the quality of the network used, pairing could lead to performance issues during navigation. A direct wired connection between paired systems can improve the performance compared to a local area network connection. If you encounter performance issues, consider deactivating the pairing function in the software.

2.2   EM Tracking Add-on Setup

About the EM Tracking Add-on

The **EM Tracking Add-on** components can be used together with either the **Curve Navigation**, **Curve** or **Kick** navigation systems.

For more information, refer to the **System and Technical User Guide** of the respective platform.

How to Set Up the EM Tracking Add-on with Kick

Figure 1

Step	
1.	Ensure that the EM power supply ④ is turned off.
2.	Connect the EM power supply to a wall outlet.
3.	Connect the **Kick Monitor Cart** ③ to a wall outlet.
4.	Connect the **EM Base Station** to EM power supply and **Kick Monitor Cart**.
5.	Connect the **EM Field Generator** ① to **EM Base Station** ②.

How to Set Up the EM Tracking Add-on with Curve/Curve Navigation
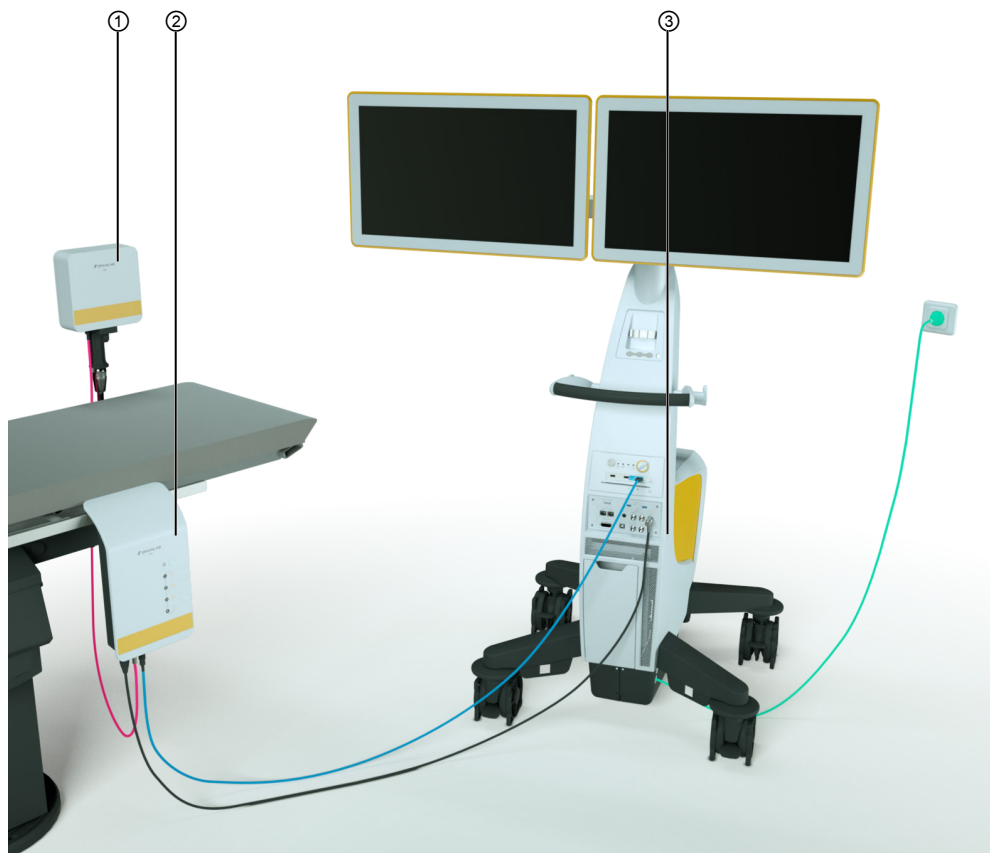
Figure 2

Step	
1.	Connect the **Monitor Cart** ③ to a wall outlet.
2.	Connect **EM Base Station** ② power supply to the camera socket.
3.	Connect the socket of the **EM Base Station** navigation system to the EM tracking USB port in the **Monitor Cart**.
4.	Connect the **EM Field Generator** ① to **EM Base Station**.

*NOTE: The required cables vary depending on if you use a **Curve** or **Curve Navigation 17700** system.*

Fixing EM Base Station

Figure 3

Step
1. Fix **EM Base Station** to **Kick EM** Holder ① (this option is only available for the **Kick** navigation system) or to a rail on the OR table ②. *NOTE: The distance between **EM Base Station** and the field of interest is limited by the instrument cable length. Set up **EM Base Station** so that the instruments reach the field of interest, ensuring there is sufficient slack when connecting cables.*
2. Set up the operating table if necessary. *NOTE: If you must move the OR table after setting up the **EM Tracking Add-on** components, move it extremely carefully. Repositioning or tilting the OR table may cause system components to shift by pulling on the attached cables.*

2.3 Influences on Tracking Accuracy

Influence of Metals

Introducing metal (copper, aluminum, brass, iron, etc.) or portable/mobile radio frequency communication equipment into the electromagnetic field can cause interference and/or distortion that affect tracking accuracy. Therefore, avoid the use of unnecessary metals. Some examples of interference in the operating room include instrument tables, metal parts of OR tables, endoscope towers, retractors, OR lamps, monitors, piercings or watches.

Take into account that other medical equipment can influence system accuracy or reliability due to electromagnetic influences. Consider repositioning other medical equipment if you encounter difficulties. For example, you may need to move **EM Field Generator** away from the metal parts on the operating table and at the same time keep it close to the patient (as described in the section above).

Each time you bring a new instrument into the field, carefully check the accuracy throughout the tracking volume to verify that there is no interference.

Influence of EM Instruments

Ensure that EM instruments are in good shape and are not visibly damaged or bent as this could negatively influence navigation accuracy.

Carefully calibrate instruments attached to **EM Instrument Reference** and verify the calibration accuracy on anatomical landmarks before using the calibrated instrument for surgery. When switching **EM Instrument Reference** to a different instrument, always calibrate the newly attached instrument.

Regularly inspect **EM Instrument Reference** for wear or damage to ensure correct operation. Contact Brainlab support for more information.

Dispose of EM instruments that have reached the maximum reprocessing cycles or expected lifetime, as afterwards accuracy cannot be guaranteed.

2.4 Patient Registration Accuracy

Optimal Scan Modality and Registration Method

For optimal navigation accuracy, use one of the following options:

Options
The **Skull Reference Base EM** as reference.
CT data in combination with one of the following: • Sterile landmark registration • Bone screws as landmarks/registration points when using **Patient Reference EM** attached to **Skull Reference Base EM**.

Accurate Surface Matching Registration

During surface matching registration, acquire points by sliding the **EM Pointer**, **EM Short Pointer** or **EM Registration Pointer** (in ENT mode only in combination with **Skull Reference Base EM**) over distinctive surfaces and bony structures, such as the bridge of the nose and the sides of the eyes.

While keeping the pointer tip constantly in contact with the patient's skin, acquire points on both sides of the patient's head, especially on any accessible area of the upper forehead (region near the bregma). Points should be spread out and cover the widest accessible sterile area possible.

Avoid acquiring points on indistinct areas, the eyebrows or areas where skin has visually shifted. Do not apply pressure to the pointer tip on the patient's skin, as this acquires points deeper than skin level.

Try to register the patient in the desired position for surgery. Major changes in the patient's head or **EM Field Generator** position after registration could lead to increased navigation inaccuracy. If you need to reposition the patient's head during surgery, please verify if the system accuracy is still good enough for your procedure or repeat registration.

Acquire registration points in proximity to the region of interest and in as wide a distribution as possible.

Accurate Landmark Registration

During landmark registration, plan points so that they surround the region of interest.

Acquire points exactly where they were planned. If a point is planned on bone, you may have to apply pressure to the skin surface in order to reach the bone. On the contrary, if the point was planned on the skin, acquire the point on the skin surface and avoid pressing into the skin.

How to Perform a Detailed Verification After Patient Registration

⚠️ **Warning**
The accuracy in the region of interest may differ from the accuracy verified on the skin surface. To estimate the accuracy in the region of interest, verify on various landmarks surrounding the region of interest. Once the region of interest is accessed during the surgical procedure, check that accuracy is still sufficient.

To ensure appropriate accuracy of patient registration:

Step	
1.	Verify in areas where no points were taken during registration.
2.	Verify in multiple widely distributed areas (e.g., on both sides of the face, on the top of the head and in or near to the region of interest).

Step

3.   Verify the following landmarks:
    • Tragi
    • Inion
    • Bregma
    • Teeth in the upper jaw
    • Other typical landmarks including the lateral canthi, nasion or spina nasalis. However, these may display optimistic results when using surface matching, as they are in close proximity to where the registration points are acquired.
 	
NOTE: Always verify accuracy using landmarks. Rotational errors can only be detected when verifying at significant landmarks spread out over the patient's head.

3   SOFTWARE OVERVIEW

3.1   Introduction to ENT EM
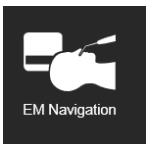
About ENT EM

ENT EM is a touchscreen-based intraoperative navigation software. The placement of surgical instruments in a three-dimensional representation overlaid on anatomical image sets, such as MR and/or CT, can support the surgeon during various surgical interventions.

ENT EM can only be used for ENT treatments. Do not use the software for any other treatments.

ENT EM uses scanned images of the patient that are acquired before surgery is performed. The actual anatomy of the patient could differ from the preoperative image data (e.g., due to resections).

Typical ENT EM Workflow

Step
1. Select the patient.
2.   Select **EM Navigation** from the ENT workflow selection screen.
3. Select patient data.
4. Select reference fixation. Follow the steps shown to perform setup.
5. Perform registration.
6. Perform navigation.
7. Calibrate instruments if necessary.

*NOTE: If the software requires that the patient be selected or changed after the ENT workflow was selected, you are redirected to **Patient Selection** and **Data Selection**.*

*NOTE: To finish the treatment and open a new procedure, select **Finish** and then select **New Treatment**. The system restarts.*

3.2 Starting and Closing the Software and Shutting Down the System

About Starting and Closing the Software and Shutting Down the System

The instructions below describe how to properly start and close the software and shut down the system. For more information see the relevant **System and Technical User Guide**.

How to Start the Software

Step	
1.	Start the system.
2.	Select the patient.
3.	Select **EM Navigation** from the ENT workflow selection screen. *NOTE: Make sure the patient name and ID are correct before loading patient data.*
4.	Select image set.
5.	**Setup Navigation** opens. Follow steps in **Setup Navigation**.

*NOTE: For details on patient and data selection, refer to the **Origin Data Management Software User Guide**.*

How to Close the Software

Step	
1.	Press the home button on the front of the Brainlab system or the home symbol in the software. **Content Manager** opens.
2.	Select **Export** to export the patient data to the selected storage medium or network location. *NOTE: All screenshots acquired during the session using the **Screenshot** button are accessed and saved when you select **Export**.*

*NOTE: For details on saving patient data, refer to the **Origin Data Management Software User Guide**.*

Proper Shutdown

(!) **Always close the software before shutting down the system. Never use the power switch to exit the software, as data may be lost.**

How to Shut Down the System

Step	
1.	After closing the software and saving patient data, remove any attached storage medium.
2.	Select **Finish** in **Content Manager**.
3.	Select **Shut Down**.

NOTE: For more information on system shutdown refer to the relevant **System and Technical User Guide***.*

3.3   Restoring a Session

About Restored Sessions

If the software shuts down unexpectedly, the registration can be restored from the previous session upon restarting the software.
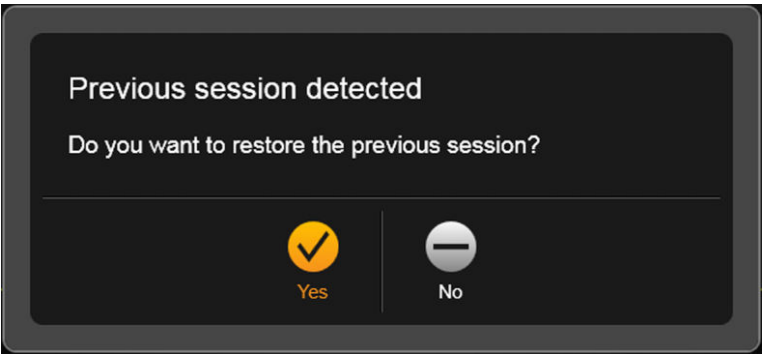
Figure 4

Options
Select **Yes** to restore the previous registration and open the main screen.   *NOTE: Carefully verify restored registrations before continuing.*
Select **No** to start over from **Patient Selection**.

Patient Position

Do not restore a registration if the patient position has changed relative to the **Patient Reference** or **EM Field Generator**.

4 DATA SELECTION

4.1 Introduction to Data Selection

About Data Selection

After the software starts, you are prompted to select patient data.

If more than one image set is loaded, the software automatically selects the best image set for registration.

For more information see the **Origin Data Management Software User Guide**.

No Patient Selected

If no patient is selected before navigation or registration, you are prompted to select a patient:
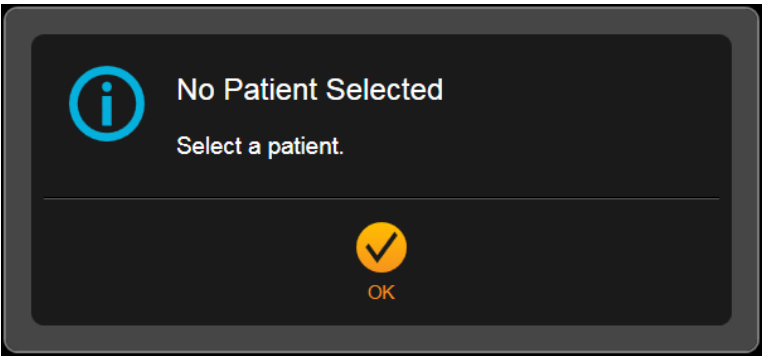
Figure 5

Select **OK** to return to the **Patient Selection** screen.

How to Load Patient Data During a Session

You can load patient data during the session if you started the software without patient data or want to load initial or additional patient data.

Step
1.   Select the home button to open **Content Manager**.
2.   Select **Patient** to load a patient.
3.   Select **Data** to load data.

How to Use Image Fusion

If **Image Fusion** is installed, you can fuse multiple image sets together (e.g., CT and MR data).

Step	
1.	Open **Content Manager** to access the **Image Fusion** software.
2.	If the patient data contains image sets that are not yet fused, the software selects image pairs to be fused automatically. You must select **Accept** or **Decline** to continue.
3.	If you select **Accept**, the images are fused. When fusion is complete, select **Done**.
4.	Select **Decline** to continue without fusing the image sets. For more information, see the **Image Fusion Software User Guide**.

How to Switch the Displayed Image Set with Fused Images
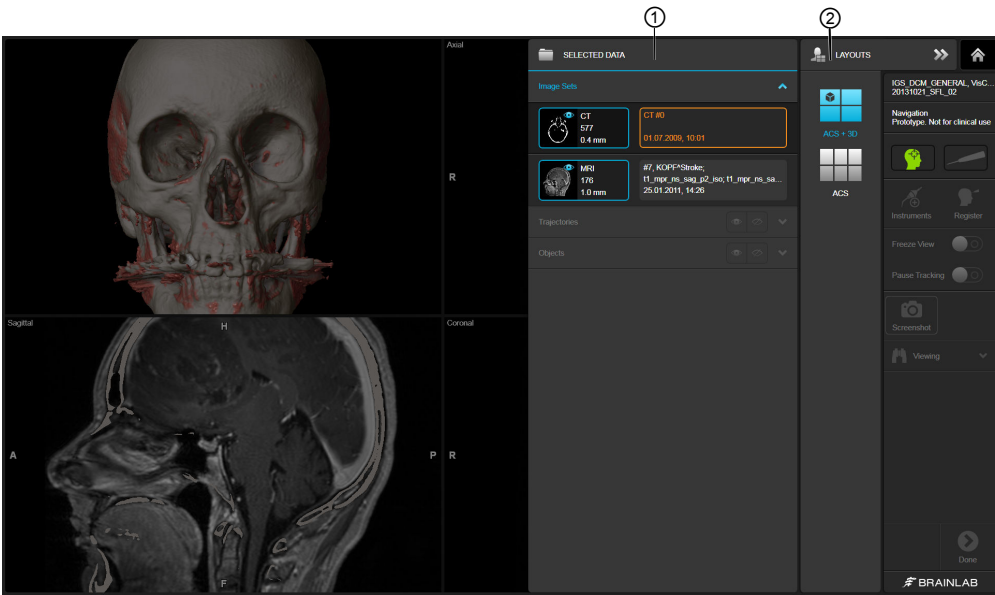
Figure 6

If you loaded fused images, you can change the displayed image set.

Step	
1.	Select the data icon ②. The available image sets are displayed.
2.	Review pairs and select the desired image set under **SELECTED DATA** ①. The currently selected image set is highlighted orange.
3.	Select **Done** to continue. *NOTE: To load additional image sets, select the home button to return to Patient Selection and select additional patient data.*

5 SETUP NAVIGATION

5.1 Select Reference Fixation

About Selecting a Reference Fixation

After starting **ENT EM** and selecting the patient data set, the **Select reference fixation** menu opens. Select the reference fixation method.
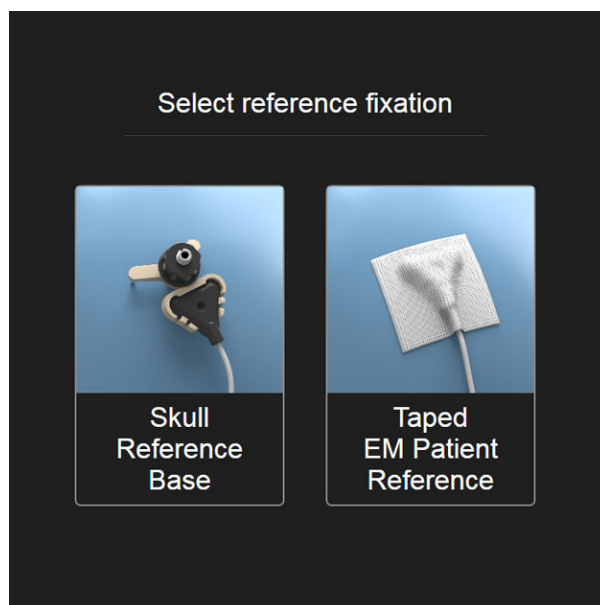
Figure 7

Skull Reference Base EM

If you select **Skull Reference Base EM**, you can either:

- Register before draping
- Register after draping

*NOTE: Attaching the reference to **Skull Reference Base EM** protects the reference from moving during draping and thereby ensures a higher navigation accuracy.*

Taped EM Patient Reference

If you select **Taped EM Patient Reference**, you must register after draping using the sterile **EM Pointer** or **EM Short Pointer**.

*NOTE: If **Taped EM Patient Reference** is selected, the unsterile **EM Registration Pointer** is blocked and cannot be used for registration or navigation.*

5.2   Initial Arrangement

Initial Arrangement Screen
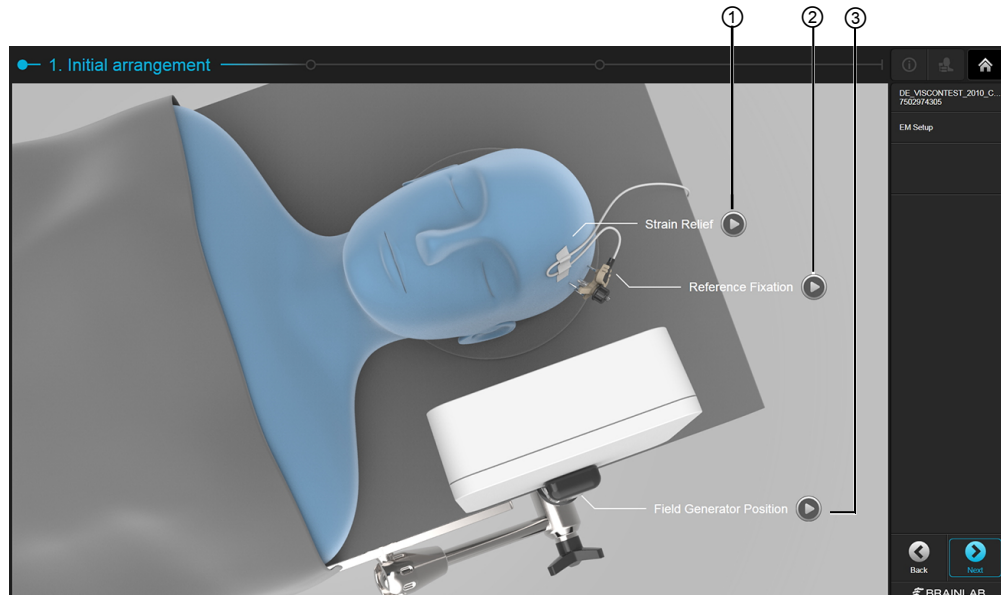
Figure 8
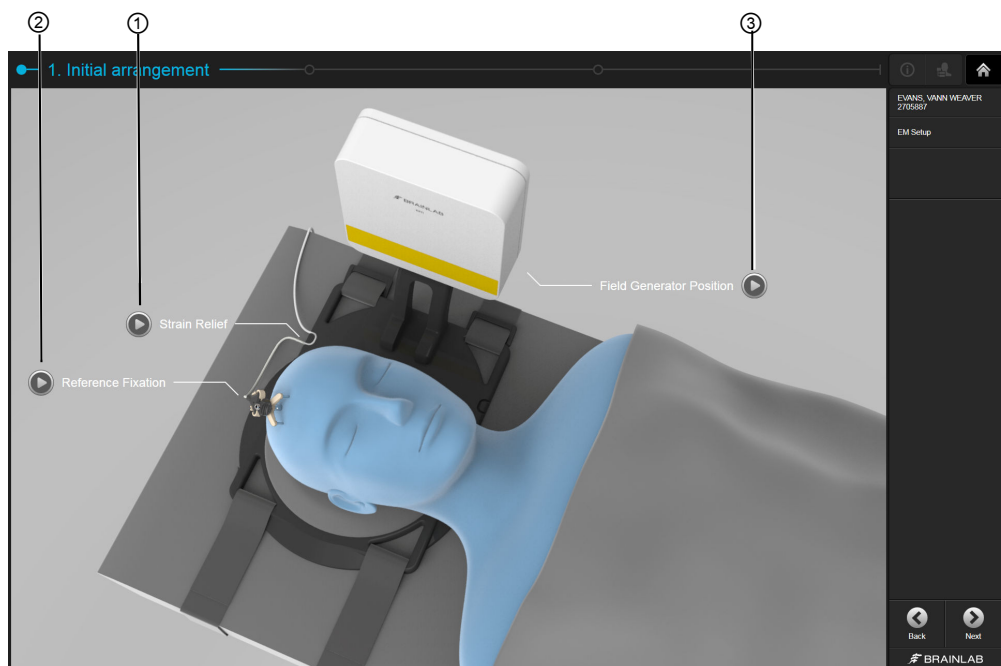
Figure 9

After selecting the reference fixation, the **Initial arrangement** screen opens. Which image is shown depends on the setup. Select the play symbols to start the videos for more information on:

- ① Fixing the **Patient Reference** cable for optimal strain relief
- ② Positioning **Patient Reference**
- ③ Positioning **EM Field Generator**

Attaching the Patient Reference EM

Patient Reference EM can be attached using one of the following methods depending on the registration method used:

- **Skull Reference Base EM**: Available for sterile (after draping) or unsterile (before draping) registration.
- **Taped EM Patient Reference**: Available for sterile registration (after draping).

For best results, place **Patient Reference EM**:

- Close to the region of interest without covering important structures needed for surface registration.
- On a rigid area of the patient's head where skin shift or movement is unlikely such as the forehead and temporal bone region (shave the region, if necessary).
- Inside the tracking volume with the best tracking accuracy (10 - 35 cm from **EM Field Generator** and centered in the xy plane). This allows the system to track the location of the patient's head throughout the procedure.
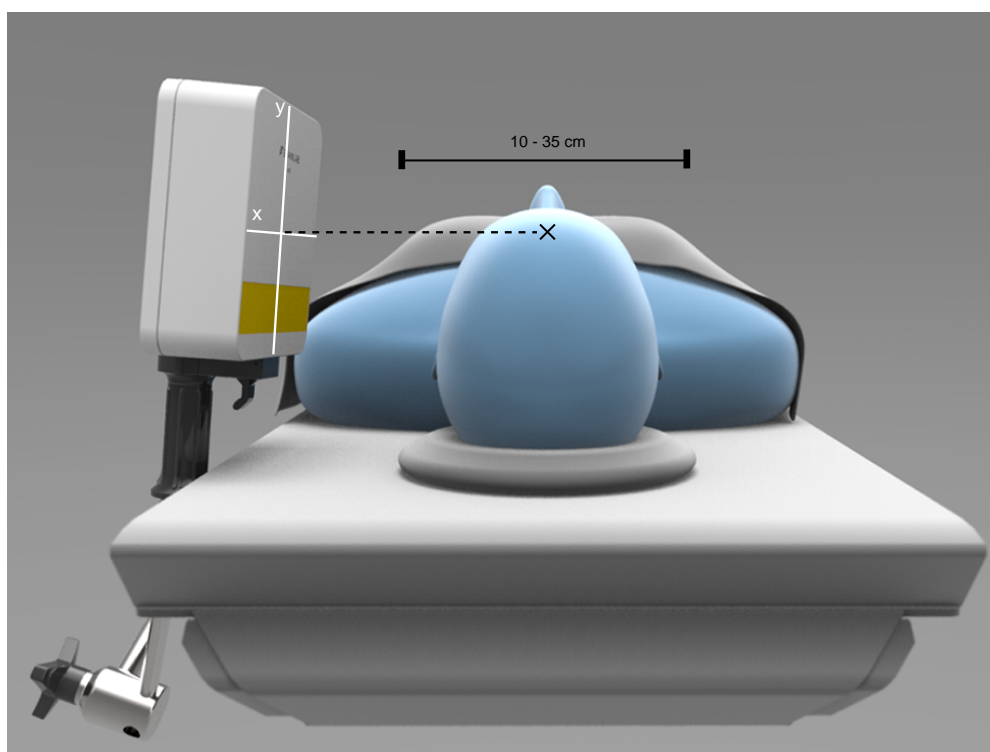
Figure 10

⚠️ **Warning**
Place patient reference 10 - 35 cm from the EM Field Generator and centered in the xy plane. Placing the patient reference too close or too far from the EM Field Generator can lead to decreased accuracy.

ⓘ **Do not cover important structures needed for surface registration with patient reference.**

How to Attach Patient Reference EM with Skull Reference Base EM
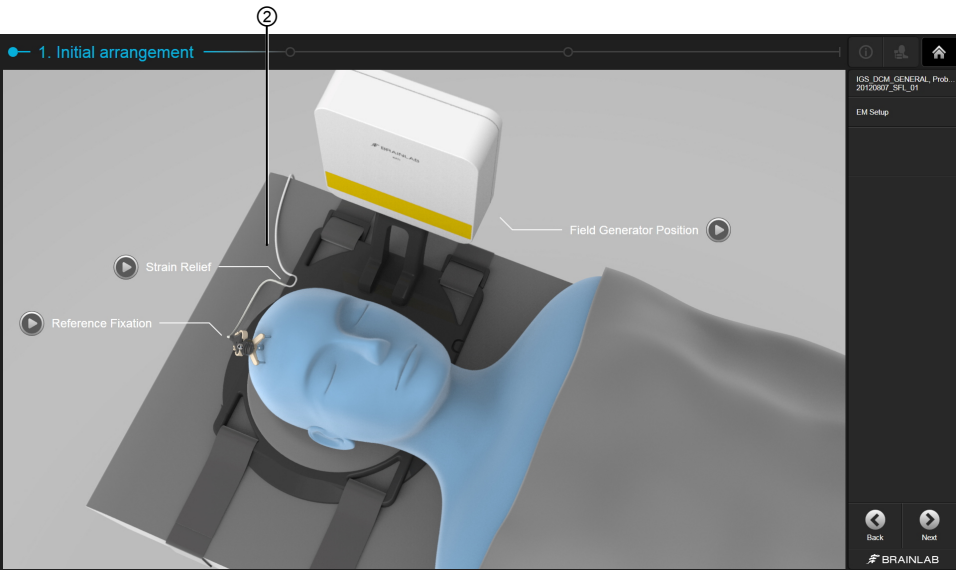
Figure 11

Step
1.   Using the setup tutorial for guidance, position **Patient Reference** inside the navigation volume.
2.   Attach **Patient Reference EM** to **Skull Reference Base EM** ①. **Skull Reference Base EM** must be attached rigidly to the head using a screw. When fully tightened, the screw penetrates 5 mm. Avoid screwing into regions where the skull bone is less than 5 mm thick and avoid screwing on top of venous or arterial structures. Estimate the skull thickness, curvature and quality during planning to estimate the penetration depth of the inserted screw.
3.   If the Positioning Arm is used, form a loop with the **Patient Reference** cable and tape onto the patient's head as illustrated in the software. Fix the cable to avoid unintended movement of the head reference due to accidental cable pulling.
4.   If the Fixation Plate is used, fix **Patient Reference** cable to the patient positioning plate ② as shown to avoid unintended movement of the head reference due to accidental cable pulling.

*NOTE: Sufficient bone density is essential for attaching **Skull Reference Base EM**. As the patient's age or possible diseases (e.g., osteoporosis) could degrade the bone mineral density, inspect the planning data prior to fixing the device.*

NOTE: To avoid fractures, do not apply too much force on the screws. If the screw is so tight that the tube cannot move, loosen the screw half a turn.

⚠️ **Warning**
Do not fasten the tube fixation nut too tightly as this could cause the screw to come out.

⚠️ **Warning**
As soon as the base is securely fixed on the patient's head, do not tighten the nut further as this might damage the bone screw.

⚠️ **Warning**
The surgeon is responsible for ensuring that Skull Reference Base EM is mounted rigidly to a safe and non-sensitive area of the patient's head. Since Skull Reference Base EM is attached through a minimal incision and minor pressure is applied, attachment to critical areas could injure the patient.

⚠️ **Warning**
Take care not to bump into Skull Reference Base EM or pull the cable. This could injure the patient and cause inaccuracies. Re-registration is required if the patient reference was repositioned or accidentally moved after registration.

How to Affix Patient Reference EM with Tape Attachment

Figure 12

Step
1. Using the setup tutorial for guidance, position **Patient Reference EM** inside the navigation volume. ⚠️ **Warning** **If you use the taped Patient Reference EM, you must perform sterile registration (either Landmark or Surface Matching Registration) after draping in order to avoid unintentional movement of the patient reference during registration.**

Step	
2.	Attach **Patient Reference EM** directly to the skin using tape ①.
3.	If Positioning Arm is used, form a loop with the **Patient Reference EM** cable and tape onto the patient's head, as illustrated in the software.
4.	If Fixation Plate is used, fix **Patient Reference EM** cable to the patient positioning plate to avoid unintended movement of the head reference due to accidental cable pulling.

How to Position EM Field Generator with Positioning Arm

Attach **EM Field Generator** to Positioning Arm as described below.

The tracking volume starts 5 cm from **EM Field Generator** (the side facing the patient's face) and transitions into a region of maximum accuracy. Accuracy is lower in the first 5 cm of the tracking volume. Therefore, to achieve optimum accuracy, the field of interest should be 10 - 35 cm from the **EM Field Generator** front face.
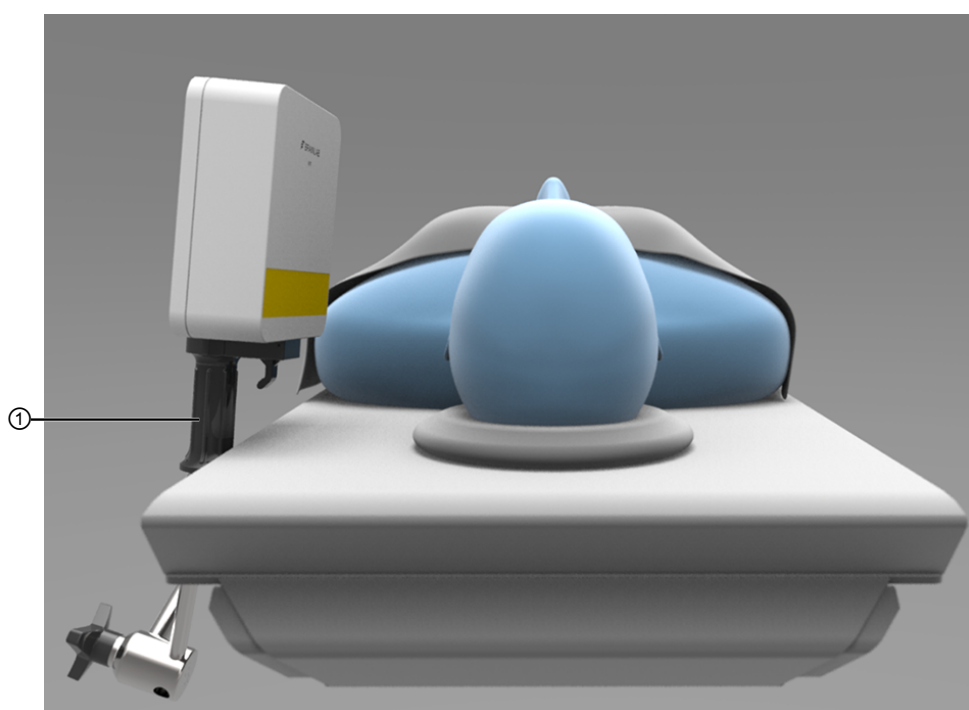
Figure 13

Step	
1.	Attach the Positioning Arm ① to the OR table so that **EM Field Generator** faces the patient's head.
2.	Attach system cables.

*NOTE: For further information on system setup and system cables refer to the relevant **System and Technical User Guides**.*

How to Position EM Field Generator with Fixation Plate

Attach the **EM Field Generator** to Fixation Plate as described below.

The tracking volume starts 5 cm from **EM Field Generator** (the side facing the patient's face) and transitions into a region of maximum accuracy. Accuracy is lower in the first 5 cm of the tracking volume. Therefore, to achieve optimum accuracy, the field of interest should be 10 - 35 cm from the **EM Field Generator** front face.
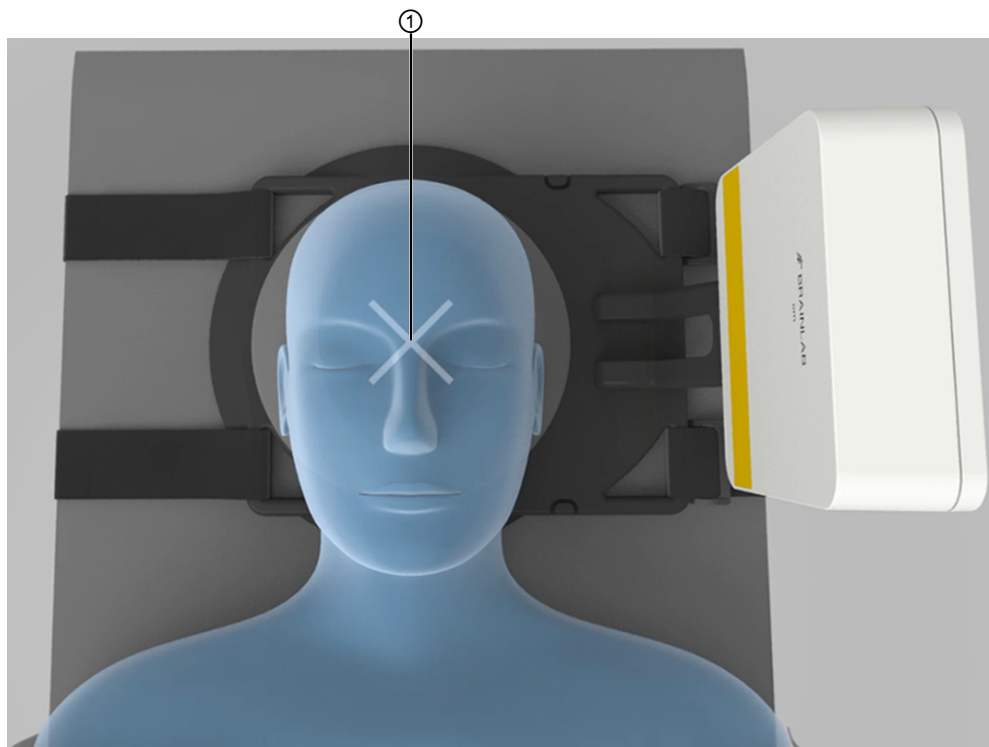
Figure 14

Step
1.   Attach the Fixation Plate to the OR table so that the cross of the base plate ① is located where the patient's head will be placed and **EM Field Generator** faces the patient's head.
2.   Attach system cables.

*NOTE: For further information on system set up and system cables refer to the relevant **System User Guides**.*

5.3   Positioning

How to Position the Patient's Head

Position the head optimally within the tracking volume. The software guides you to find the optimal position.
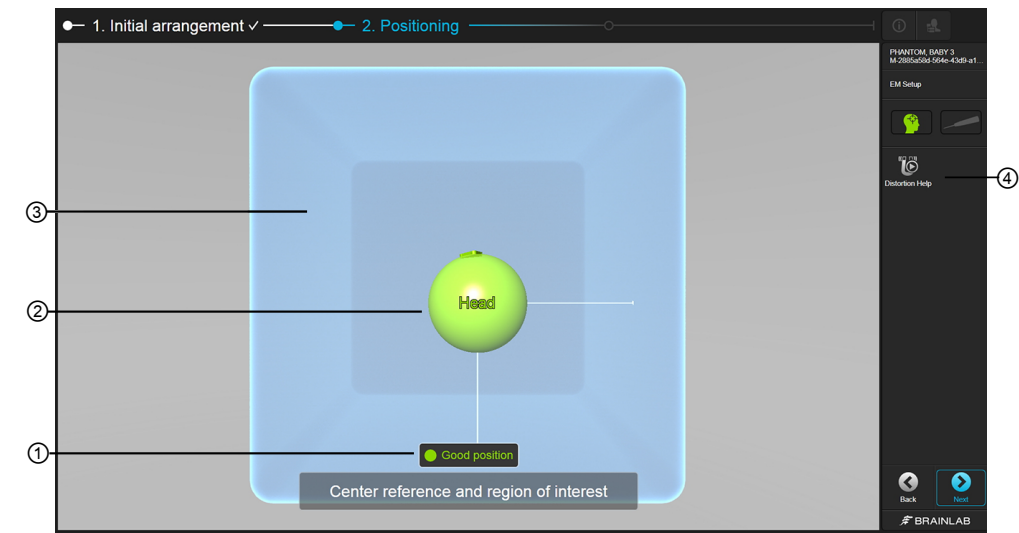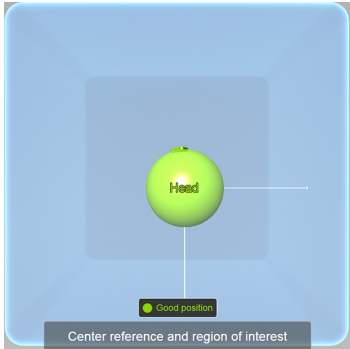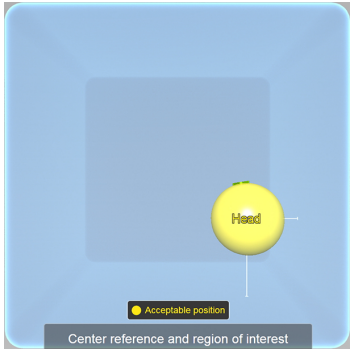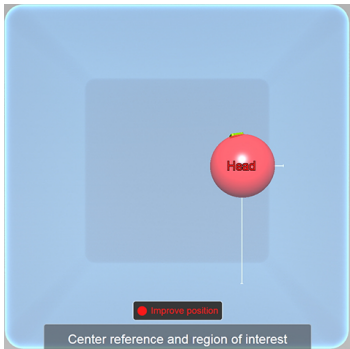
Figure 15

No.	Component
①	Head position indicators: • Green: Good position • Yellow: Acceptable position • Red: Improve position
②	Sphere: Patient's head representation
③	Tracking volume representation *NOTE: References should be inside this representation during the procedure.*
④	Select **Distortion Help** to correct distortion.

NOTE: During accuracy verification, the patient reference and instrument representations are not shown. Instead, the distance between the pointer tip and the reference verification point is displayed.

Head Position Indicators

Indicator	Explanation
	The patient's head is in the tracking volume in an optimal position.
	The patient's head is in the tracking volume in an acceptable, but not optimal position.
	The patient's head is in the tracking volume in an unacceptable position. You must improve the head position to be able to continue to the next step.

5.4   Verify Field

About Field Distortion

Field distortion reduces tracking accuracy. The software helps you to verify that no field distortion is present.
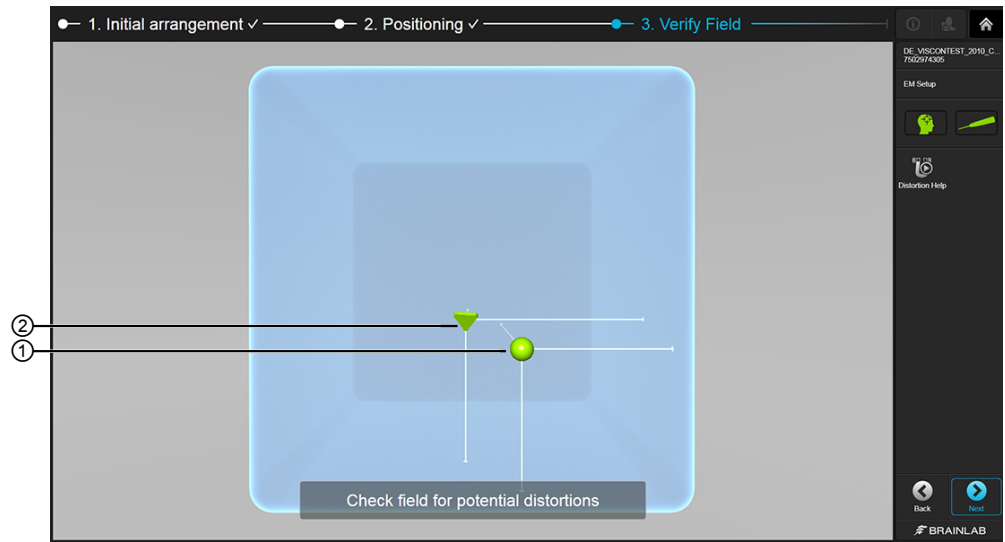
Figure 16
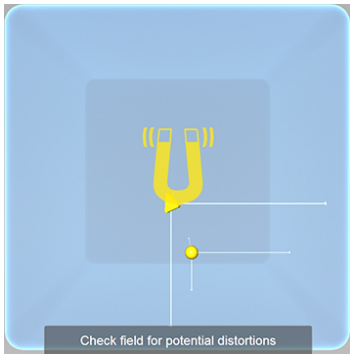
No.	Component
①	Pointer representation
②	Patient reference representation

Field Distortion Indicators

To check for field distortion, run the pointer through the entire tracking volume. If any field distortion indicators are displayed on the screen, there is likely to be a field distortion close to or directly in the field.

*NOTE: For more information on possible causes of EM field distortion, see the relevant **System User Guides**.*

Indicator	Explanation
	There is minor field distortion affecting the pointer only or the pointer is too close to the border of the tracking volume.

Indicator	Explanation
Check field for potential distortions	There is minor field distortion affecting the pointer and patient reference.
Check field for potential distortions	There is major field distortion. The pointer and patient reference can no longer be detected.

5.5   EM Tracking Accuracy

General Information

ENT EM solely provides assistance to the surgeon and does not substitute or replace the surgeon's experience and/or responsibility. Nevertheless, appropriate accuracy of the system is essential for its performance.

Adherence to the recommendations in this section is critical for ensuring EM tracking accuracy.

Clinical Recommendation

Do not rely on the navigation system for procedures that require an accuracy of better than 3 mm.

Various factors may significantly affect system accuracy. Appropriate setup and handling, as well as careful accuracy verification, are essential for successful navigation.

Technical Performance

ENT EM is tested on a phantom to ensure that its mean location error is ≤ 2 mm (with a mean trajectory angle error ≤ 2.0 degrees).

Essential Performance

The Essential Performance is summarized by:

• Providing accurate display of instrument's position relative to registered DICOM patient image data.

Verifying Accuracy

Periodically verify registration accuracy throughout the procedure by comparing the position of the instrument or pointer displayed in the image views to the actual point on the patient's anatomy.

Use of Appropriate Scans

Ensure that appropriate patient scans are used. Do not use distorted MRI scans for registration. If available, use 3D distortion correction for all scans.

Acquire the image set(s) used for registration according to the Brainlab scan protocols.

Possible sources of error include MRI headphones pressing into the skin during the scan or tubes and tape on the patient, which alter the skin surface.

For surface matching registration, compare the patient's face with the 3D reconstruction. Avoid areas that differ between the patient's actual anatomy and the 3D software reconstruction.

Patient Reference Position

Position patient reference on a rigid area, as close to the region of interest as possible. The closer the reference is mounted to the actual region of interest, the more accurate the procedure.

Ensure that the reference is inside the most accurate region of the tracking volume, ideally placed in front of **EM Field Generator** at a distance of 10 - 35 cm.

Correct Draping Procedure

Be careful not to move the registered patient, patient reference or **Skull Reference Base EM** during the draping procedure after registration, as this could lead to decreased navigation accuracy. Regularly verify system accuracy.

The taped patient reference could move unintentionally during draping. Therefore, perform sterile registration (either landmark or surface matching) after patient draping or use **Skull Reference Base EM**.

Minimizing Changes to Patient Field and EM Field Generator Position

Avoid changes to the position of the patient's head or **EM Field Generator** after registration.

Changes in the setup could lead to decreased navigation accuracy. Before beginning registration, ensure that the patient is in the desired position for surgery.

If it is necessary to reposition the patient's head during surgery, verify that system accuracy is still sufficient or repeat registration.

EM Tracking Accuracy
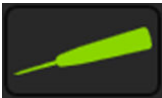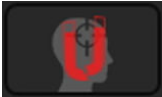
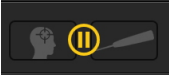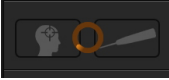# 6 TRACKING

6.1 Tracking System

About the Tracking Volume

For successful registration and navigation, the instruments must be inside the tracking volume.

Use the tracking volume indicators to check whether an instrument or reference is inside the tracking volume, with sufficient accuracy, as well as if there is any interference (e.g., due to metals, electric razors, debriders or another field generator).

Instrument/Patient Reference Status

Indicator	Explanation
	Pointer/patient reference is in the tracking volume with no interference detected.
	Pointer/patient reference is in the tracking volume, but tracking accuracy is low due to: • Interference (for more information, see the relevant **System and Technical User Guides**) • Instrument or patient reference not being located in the center of the navigation volume. Ideally, instruments should be centered in the navigation field and not located within the outer borders.
	Pointer, instrument or patient reference is in the tracking volume, but tracking accuracy is insufficient.
	Pointer, instrument or patient reference is not attached or attached but not located within the tracking volume.

Tracking System Status

Indicator	Explanation
	There is an error with the tracking system. It is currently not available.
	The tracking system has been paused.
	The tracking system is warming up.

6.2   Tracking Instruments

Tracking Priority for Navigation

The software updates the navigation views based on the position of the instrument with the highest priority. Lower priority instruments are displayed but are not used by default to update the views.

Instruments in the center of the tracking volume have a higher priority than instruments located at the borders of the tracking volume. For instruments located in the center, the following priorities apply:

1. **EM Pointer** or **EM Short Pointer**
2. **EM Registration Pointer**
3. **EM Instrument Reference**

NOTE: To update the navigation views to the position of a lower priority instrument, remove the instruments of higher priority from the tracking volume.

Tracking Priority for Registration

1. **EM Registration Pointer** (only in combination with the **Skull Reference Base EM**)
2. **EM Short Pointer**
3. **EM Pointer**

Tracking Latencies

Check for tracking latencies by comparing the movement of instruments on the screen compared to the actual instrument.

Information in the navigation screen may be delayed compared to your actual tracked instrument. If the navigation display is slow, keep the visible data to a minimum.

How to Pause Tracking

To temporarily stop generating the EM field (e.g., during neuromonitoring), you can use **Pause Tracking**.

Step
1.   Select **Pause Tracking** under **Navigation**.
2.   Activate **Pause Tracking** by moving the slider to the right.   *NOTE: To use **Pause Tracking**, the monitor must be connected to the system.*

*NOTE: When **Pause Tracking** is activated, the **Pause** symbol appears in the tracking status.*

7 REGISTRATION INFORMATION

7.1 Patient Registration

About Patient Registration

Patient registration enables the software to map the patient's preoperative image data to the physical anatomy of the patient's head. Registration is usually performed in a sterile environment.

The software uses preoperative scan images of the patient. The patient's actual anatomy could differ from the preoperative image data (e.g., due to resections). Make sure that for registration and navigation the patient's anatomy is the same as what is visible in the image set.

Registration Methods

Method	Explanation
Surface Match	Acquire the patient's skin surface using **EM Pointer**, **EM Short Pointer** or **EM Registration Pointer** (in ENT mode, only in combination with **Skull Reference Base EM**).
Landmark	Register markers worn by the patient during scanning or preplanned landmarks in the image set.

NOTE: Surface matching is the default registration method. If you wish to switch to landmark registration, select **Landmark** *from the drop-down menu on the registration screen.*

Data Cannot be Used for Registration

If a patient was selected but no data was selected, the following pop-up appears:
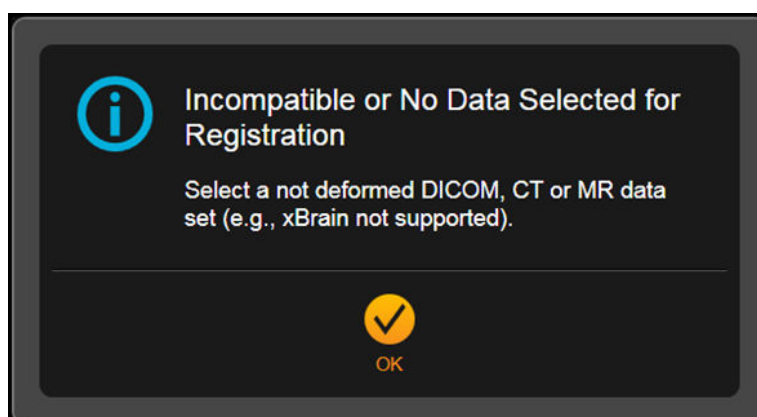

Figure 17

Select **OK** to be redirected to patient or data selection, as relevant.

*NOTE: In rare cases, the selected patient data does not match the scan protocols. For more information on suitable data, refer to the **Origin Data Management Software User Guide**.*

Restoring a Registration

If the software shuts down unexpectedly, the registration from the previous session can be restored.

7.2   Pointers for Registration

Pointers for Sterile and Unsterile Registration

Figure 18

For sterile registration, use **EM Pointer** ① or **EM Short Pointer** ②.

Figure 19

For unsterile registration, use **EM Registration Pointer** with **Skull Reference Base EM**.

Do not use **EM Registration Pointer** in combination with the non-invasive taped **Patient Reference EM**. If the non-invasive taped **Patient Reference EM** is used, you must use the **EM Pointer** for registration after draping.

Do not use EM pointers on the patient's eyes.

Warning

The EM pointers are not intended to be used in an MR environment. Do not expose the device to a high magnetic field, such as a magnetic resonance imaging (MRI) scanner, as it may become magnetized. Tracking with a magnetized device may result in incorrect navigation and possible personal injury.

Unsterile EM Registration Pointer

If you selected **Taped EM Patient Reference**, you are only allowed to use the sterile **EM Pointer** or **EM Short Pointer**. If you try to plug in **EM Registration Pointer**, a pop-up message appears instructing you to use the sterile **EM Pointer** or **EM Short Pointer**.

Before You Begin

Carefully read the EM pointer chapter in the corresponding Instrument User Guide. Verify that the **EM pointer** is functioning properly by checking accuracy.

Warning

Perform registration under sterile conditions and after patient draping to avoid patient reference movement leading to inaccurate navigation. Alternatively, use Skull Reference Base EM to firmly attach the reference.

Warning

EM pointers are highly accurate and sensitive medical instruments. If a pointer is dropped (even if it is in the storage case), verify the calibration accuracy as described or contact Brainlab for advice on how to proceed.

Do not expose EM pointers to X-radiation as this could damage the device.

Only use EM Pointer, EM Short Pointer and EM Registration Pointer in combination with devices that are released for use with the Brainlab EM navigation system.

NOTE: When using EM pointers for registration, take care that the tip does not injure the patient. Blood vessels, eyes and other sensitive areas are not suitable for landmark registration.

Appropriate Areas for Point Acquisition

- Do not use the pointers on soft tissue that may shift position (e.g., loose skin).
- To ensure optimum accuracy, acquire points on both sides of the patient's face.
- Generally, bony structures with a surface that does not change during anesthesia are appropriate for point acquisition.

NOTE: The mandible is not an acceptable bony structure for point acquisition as the position may move relative to the patient reference.

8 SURFACE MATCHING REGISTRATION

8.1 Introduction to Surface Matching Registration

About Surface Matching Registration

With surface matching registration, you acquire specific surfaces of the patient's head using **EM Pointer**, **EM Short Pointer** or **EM Registration Pointer**.

The software uses a surface matching algorithm to match the patient's anatomy to the preoperative CT/MR images. Only anatomical surface points included in the CT/MR image sets can be acquired and used by the surface matching algorithm. Do not acquire points in areas that are not rigid compared to the CT or MR scan (e.g., around the chin).

An advantage of surface matching registration is that CT/MR markers are not required.

Image Set Requirements

- The image set must contain the area to be acquired on the patient's anatomy, including the entire nose.
- The slice thickness for the surface matching image should not exceed 3 mm.
- To achieve highest registration quality, use MR T1, CT, or CTA image sets.
- Using MR T2 image sets may lead to reduced registration quality.

Data Quality Insufficient
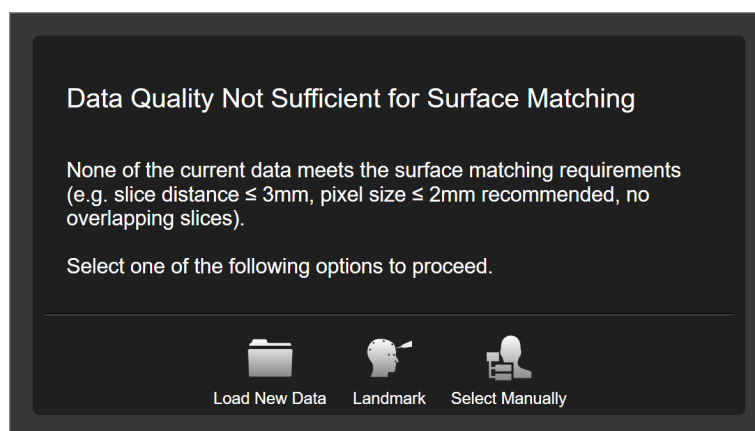
Figure 20

If data quality is not sufficient for surface matching, a dialog opens. Select one of the following options to proceed.

Options	
Load New Data	Redirects to **Patient Data Selection**
Landmark	Starts landmark registration
Select Manually	Opens **Data Selection** in the sidebar. In this case, you may select the data, but the quality will be inferior.

NOTE: Only scan the anatomical regions that are to be included in the image set for surface matching registration. Refer to the Brainlab scan protocol for information on suitable image sets.

NOTE: Surface matching registration is more likely to fail if used with rotational angiography, C-arm or Cone Beam CT image sets. It is recommended to perform surface matching registration in MR or CT image sets first, and then use automatic image fusion to fuse other image types.

NOTE: When the 3D reconstruction shows a result that is extremely different from the patient skin surface, you can change the threshold by selecting the threshold button in the software.

Image Set Selection

The software automatically selects the image set most sufficient for **Surface Matching Registration**. If you do not wish to register using the automatically selected image set, select a different image set under **Selected Data**. For more information, see the **Origin Data Management Software User Guide**.

NOTE: Any previous registrations are lost if you select a new image set.

Interrupting the Registration

If registration is interrupted for any reason, registration must be performed again.

NOTE: Registrations are automatically deleted after 24 hours.

Typical Surface Matching Registration Workflow

The software guides you through registration based on anatomical landmarks and the patient position relative to **EM Field Generator**.

Step
1. Verify the surface of the 3D reconstruction.
2. Acquire three anatomical landmarks as instructed by the software.
3. Acquire surface matching points using **EM Pointer**, **EM Short Pointer** or **EM Registration Pointer**.
4. Verify registration accuracy.

8.2   Activating Surface Matching Registration

About Activation

Select **Next** after finishing the **Setup Navigation**. Surface matching registration opens automatically as the default.

Patient Registration Screen

The software automatically selects the best image set for registration. If needed, you can switch to a different loaded image set by selecting the data icon.
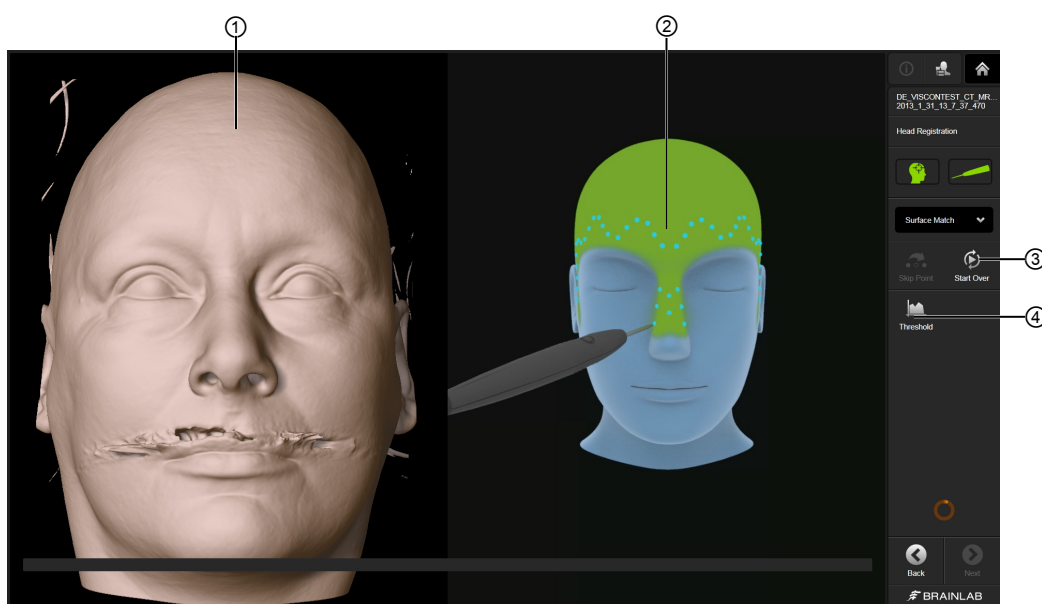

Figure 21

No.	Component
①	3D reconstruction of the image set. Use this reconstruction to verify the surface.
②	The green area on the 3D model indicates the ideal area in which to acquire surface matching points. The animation demonstrates how to move the pointer across the surface to achieve best results.
③	Press **Start Over** to start registration over.
④	Select **Threshold** to open the skin threshold dialog.

Verifying the 3D Surface

Before beginning registration, examine the surface of the 3D reconstruction to determine whether it is suitable for surface matching registration.

Check that:
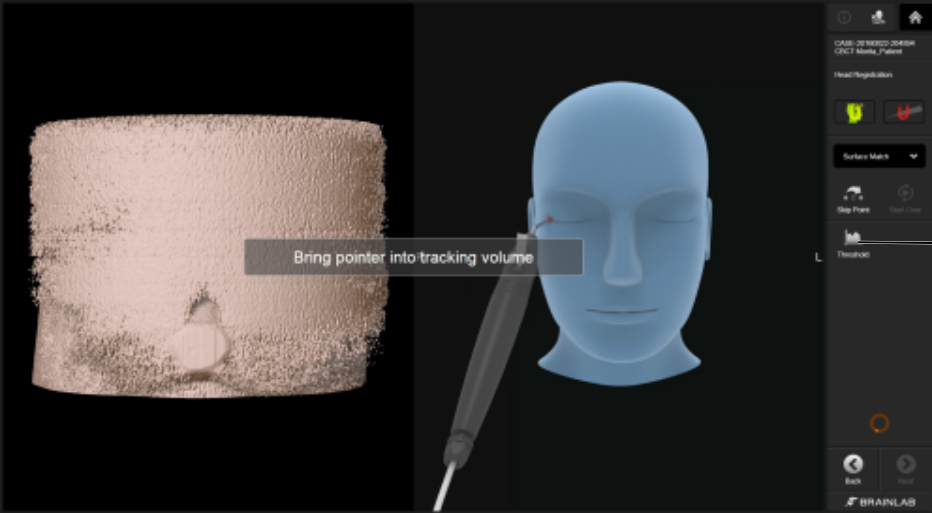
- The surface of the face is clearly visible.
- The skin surface is smooth without breaks or major artifacts.
- The 3D reconstruction resembles the patient.
- Tubes, tape and other devices that may change the appearance of the face after scanning are identified.
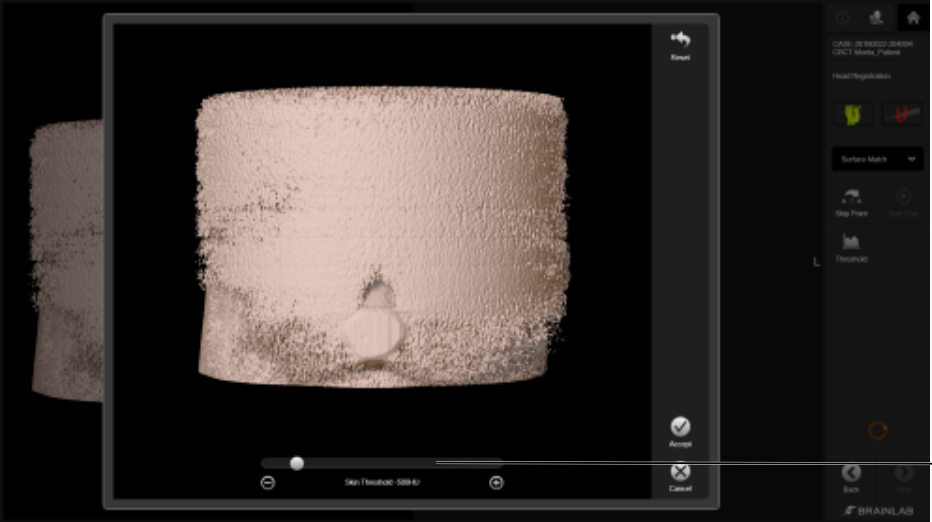
NOTE: Be aware that skin shift may have occurred during scanning due to the patient fixation device.

How to Change the Threshold

If the skin surface cannot be properly visualized (e.g., when using Cone Beam CT), select **Threshold** to adjust as needed.
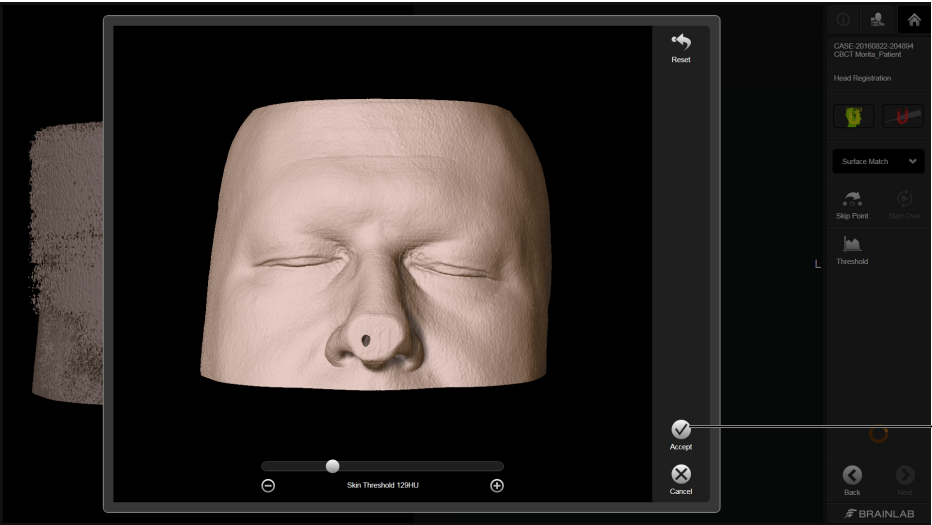
Step	
1.	Select **Threshold** ① from the toolbar.
2.	In the dialog that opens, adjust the slider ② to visualize the skin surface as necessary.

Step
3.   When the visualization is correct, select **Accept** ③ to continue with the procedure. Select **Cancel** or **Reset** to cancel or repeat the process.

8.3 Performing Surface Matching Registration

Before You Begin

Avoid acquiring points in areas where the patient's anatomy may be different from the image set (e.g., swollen areas of the face or skin shift due to a different patient position). This may result in incorrect registration and navigation.

How to Acquire the First Points
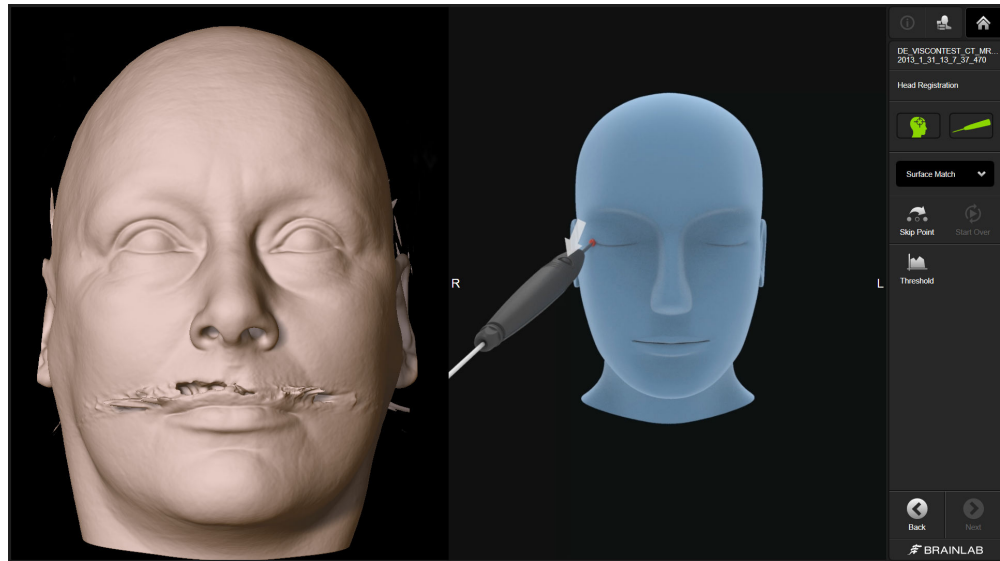
Figure 22

Four registration points are identified by the software in a defined order:

- Canthus lateralis right
- Nasion
- Canthus lateralis left
- Inion

Three of these points must be acquired. If a point is not accessible due to patient positioning, press **Skip Point** to proceed to the next point.

*NOTE: To restart registration from the beginning, select **Start Over**. All points that were already acquired are deleted.*

How to Acquire Skin Surface Points

Figure 23

Step	
1.	Hold the pointer inside the tracking volume.
2.	Gently hold the pointer against the patient's skin and move it around in the green area of interest ②. *NOTE: Hold the pointer at an angle between 40 - 60° to the skin surface to ensure accurate registration. If the angle is too steep, the pointer will easily get stuck in surface irregularities and if the angle is too flat, the tool-tip may hover over the skin surface.*
3.	Press the pointer control button to begin point acquisition. Keep the control button pressed while sliding the pointer tip along the green area, keeping in constant contact with the patient's skin. The points appear on the 3D reconstruction ①. It is recommended to also acquire points on the upper forehead if the area is not draped during registration. *NOTE: During point acquisition, keep the pointer tip in constant contact with the patient's skin. Do not apply pressure with the pointer tip on the patient's skin, as this could dent the skin and cause the system to acquire points deeper than skin level.* *NOTE: If the pointer tip loses contact with the patient's skin, select* **Start Over** ③ *to start skin surface acquisition over.*
4.	As more points are acquired, a progress bar ④ fills and you hear an audible tone. *NOTE: Acquiring points too quickly during registration may lead to inaccuracies.*
5.	Once sufficient points are acquired, the software proceeds to verification. Verify registration accuracy in the screen that opens. *NOTE: The number of points required to proceed automatically can be configured. Contact Brainlab support for more information.*

How to Pause Skin Surface Acquisition

Step
Release the control button on the **EM Pointer** or **EM Short Pointer** to pause skin surface acquisition. To restart acquisition, press the control button again. *NOTE: You can also use **EM Registration Pointer** in cranial mode for an unsterile registration.*

8.4   Surface Matching Registration Accuracy

Possible Reasons for Decreased Navigation Accuracy

Accuracy may vary within the tracking volume, depending on the distance between the instrument and **EM Field Generator**.

To ensure sufficient accuracy, the image set (e.g., CT, MR) must be suitable for stereotactic navigation procedures and 3D correctness must be ensured. Scan the patient as described in the Brainlab scan protocol.

⚠️ **Warning**
Due to possible distortions in MR image sets, navigation accuracy may be decreased at the point of interest, even if the registration has been satisfactorily verified.

⚠️ **Warning**
Verify accuracy close to the region of interest, but not directly on registered landmarks. Be aware that navigation accuracy can be degraded in areas where accuracy was not verified due to error propagation.

If a Match Cannot Be Found
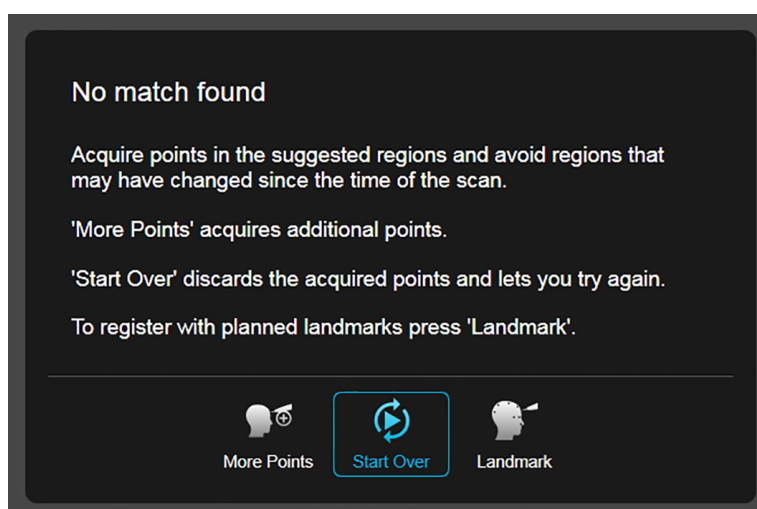
Figure 24

After acquiring additional points, the corresponding dialog opens if the software still cannot find a match.

Options
To acquire more points, select **More Points**. The registration dialog opens. Any additional points are indicated with a different color.
To restart registration, select **Start Over**. All points already acquired are deleted.
To switch to landmark registration, select **Landmark**.

If Registration is Found

When registration is successful, the registration verification screen opens.

Figure 25

Step
1. Hold the pointer to known anatomical landmarks (e.g., nasion, most lateral orbital points) and verify that the position of the pointer displayed in the image views corresponds with the actual point on the patient's anatomy. *NOTE: Verify accuracy at multiple anatomical landmarks, especially in the region of interest as it may differ from the accuracy verified on the skin surface. If the region of interest is not accessible, verify areas as close as possible to the region of interest.*
2. Hold the pointer to various points on the patient's skull and verify that the displayed distance from the virtual pointer tip to the patent's skin corresponds to the actual pointer position. *NOTE: Distance measurement is shown when the pointer tip is within 8 mm of the calculated surface.*
3. If the verified registration is acceptable, select **Yes** to continue with the procedure.

Improvement Options

Step
1. If the registration is unacceptable after visual verification, select **No** on the registration verification screen.
2. The **Improvement Options** dialog opens.

| Step |
| --- |
| 3.   Select an option to continue:
    • **More Points**: Acquire ten additional surface points. Any previously acquired surface points are retained, and considered in the calculation.
    • **Start Over**: Start registration over.
    • **Landmark**: Switch to landmark registration.
*NOTE: If a significant deviation is observed during visual verification, it is recommended to select **No** and/or check pointer accuracy.* |

Using More Points
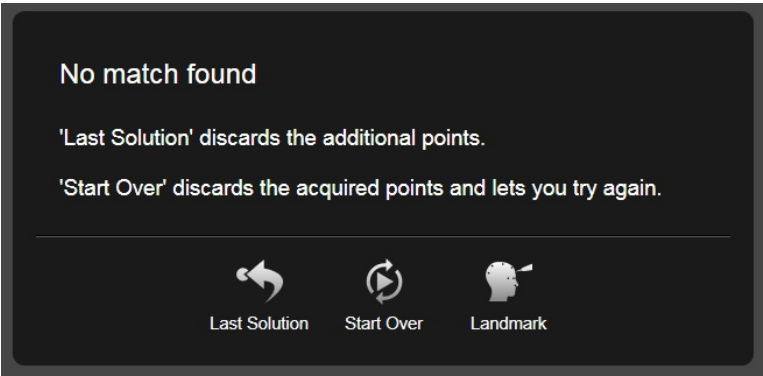
Figure 26

If **Surface Matching Registration** was successful but during verification the result was not optimal, you can add **More Points** to improve it.

After adding more points, two scenarios are possible:

Options
The algorithm finds a match, and the verification screen opens. You can now toggle between the two registrations with the **Last Solution** toggle (see below).
The algorithm does not find a match. This means the additional points did not help the software to improve the registration, and the **No match found** pop-up is displayed.

*NOTE: If you select **Last Solution**, you return to the verification page of the previous solution. The additional points are discarded and the previous registration is shown.*

Using Last Solution to Compare Registrations

If you select **More Points** from the **Improvement Options** and a match is found, the software displays the verification page of both registrations: the original one, and the additional points.

The **Last Solution** toggle is activated on the toolbar. You can now toggle between the two successful registrations and compare them.
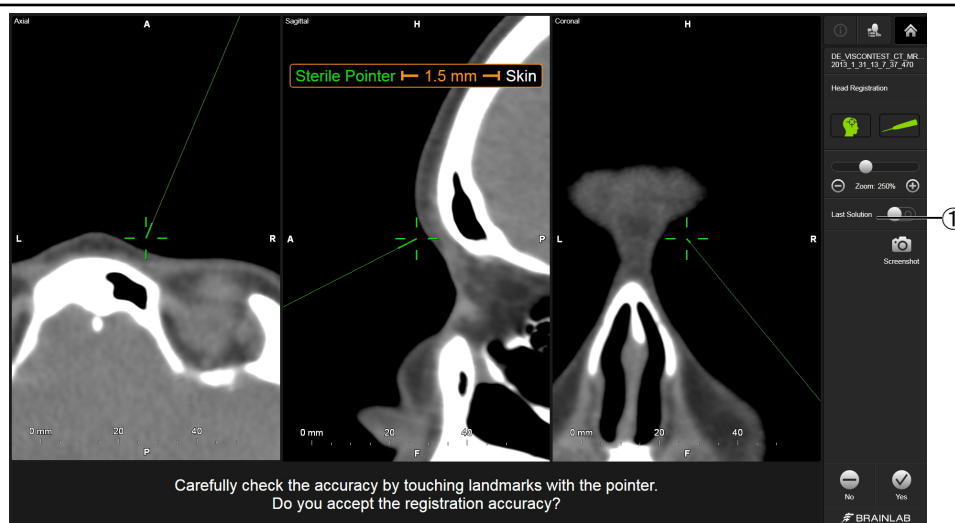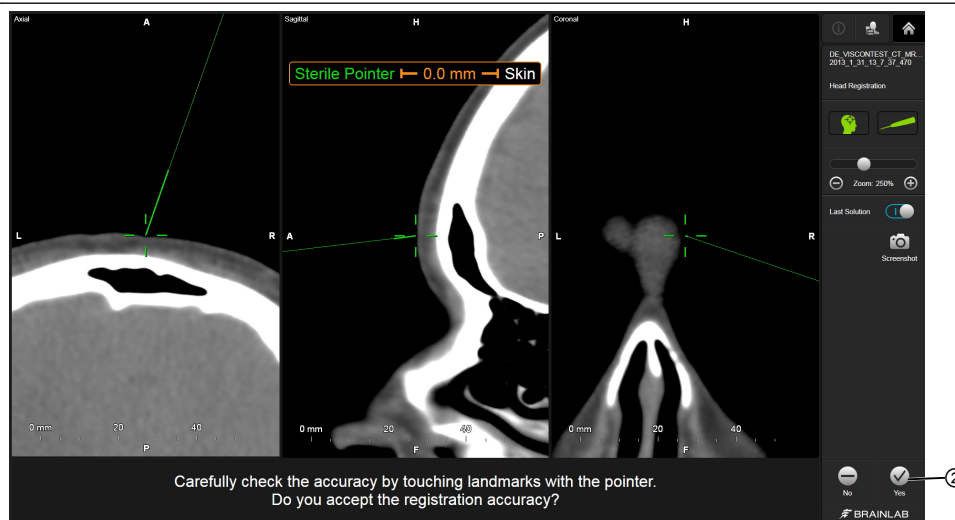
Step
1. Toggle **Last Solution** on the toolbar ① to compare the two registrations.
2. If one of the registrations is acceptable, select **Yes** to continue ②. If neither is satisfactory, select **No** to go back to **Landmark** or **Start Over**. Improve the registration again until a satisfactory result is achieved.

9 LANDMARK REGISTRATION

9.1 Introduction to Landmark Registration

About Landmark Registration

With **Landmark Registration**, you acquire specific surfaces of the patient's head using **EM Pointer**, **EM Short Pointer** or **EM Registration Pointer**.

First, you plan registration points in the preoperative image set, with or without the use of fiducial markers. You then acquire the same points on the patient's anatomy. The software correlates the image set to the actual patient anatomy.

Only anatomical surface points included in the CT/MR image sets can be acquired and used by the landmark algorithm. Do not acquire points in areas that are not rigid compared to the CT or MR scan (e.g., around the chin).

NOTE: For detailed information on positioning fiducial markers on the patient, see the manufacturer's user guide.

Image Set Requirements

The image set must contain the area to be acquired on the patient's anatomy, including the entire nose.

To achieve highest registration quality, use MR T1, CT or CTA image sets.

Using MR T2 image sets may lead to reduced registration quality.

NOTE: Refer to the Brainlab scan protocol for information on suitable image sets.

Image Set Selection

The software automatically selects the image set most sufficient for **Landmark Registration**. If you do not wish to register using the automatically selected image set, select a different image set under **Selected Data**. For more information, see the **Origin Data Management Software User Guide**.

NOTE: Any previous registrations are lost if you select a new image set.

Interrupting Registration

If registration is interrupted for any reason, registration must be performed again.

NOTE: Registrations are automatically deleted after 24 hours.

Typical Landmark Registration Workflow

Step	
1.	If it is not your default registration method, switch to **Landmark** registration.
2.	Plan registration points.
3.	Register points in the order defined by the software.
4.	Verify registration accuracy.

9.2 Activating Landmark Registration

About Activation

This section describes how to manually plan registration points (fiducial markers or landmarks).

How to Open Landmark Registration

Surface Match is the default registration method (if available). Therefore, you must manually change to **Landmark** registration.

The point-planning screen opens when you select **Landmark**, prompting you to plan points.
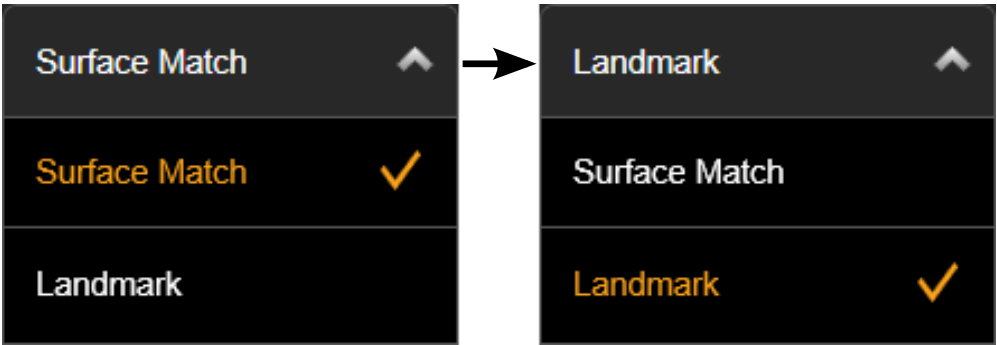
Figure 27

Step
1.   Select **Surface Match** to open the drop-down menu.
2.   Select **Landmark** from the drop-down menu.

Patient Registration Screen
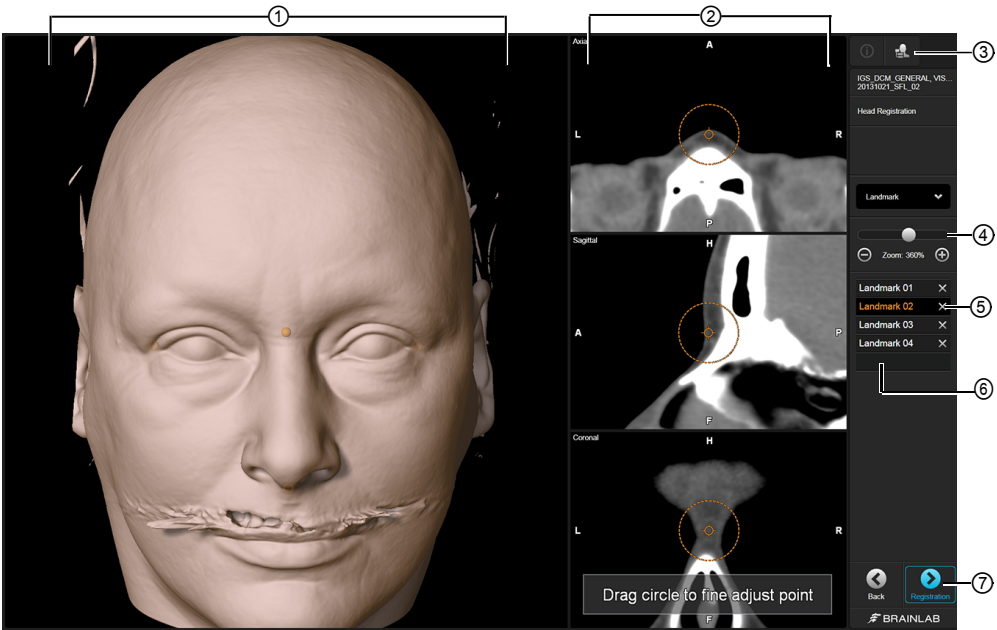
Figure 28

No.	Component	Explanation
①	3D model	Manually add registration points by pressing on the 3D model.
②	**Axial**, **Coronal** and **Sagittal** (ACS) views	Finely reposition planned points by dragging the circled crosshair in the ACS views.
③	Data	If more than one data/image set is available, press this button to select the data set you wish to use for landmark registration.
④	Zoom	Zoom in on the registration points by sliding the bar or pressing the minus or plus symbols.
⑤	Delete	Delete points by selecting the point and pressing the **X** next to it.
⑥	Point list	List of planned points.
⑦	**Registration**	• Active if four or more points are defined. • Opens the **Registration** screen and applies the planned points. *NOTE: If you plan points too close together or in a row, registration is not accurate. You will not be able to proceed.*

Verifying the 3D Surface

Before beginning registration, examine the surface of the 3D reconstruction to determine whether it is suitable for landmark registration.

Check that:

- The surface of the face is clearly visible.
- The skin surface is smooth without breaks or major artifacts.
- The 3D reconstruction resembles the patient.
- Tubes, tape, and other devices that may change the appearance of the face after scanning are identified.

NOTE: Be aware that skin shift may have occurred during scanning due to the patient fixation device.

Changing the Threshold

If the skin surface cannot be properly visualized (e.g., when using Cone Beam CT), go back to **Surface Match** registration and use the **Threshold** function.

9.3 Planning Registration Points

Optimal Registration Point Positioning

To achieve an optimal registration of fiducial markers or landmarks:

- Spread the fiducial marker/landmark positions around the head, as widely distributed as possible and not in a line.
- Avoid placing fiducial markers/landmarks in a symmetric structure (e.g., in a row or regular shape).
- Avoid areas with loose skin.
- The fiducial marker/landmark positions should surround the region of interest.

Types of Registration Points Planning

In registration points planning, you can:

- Plan landmarks: Anatomical or artificial (e.g., splints, implanted screws, etc.)
- Plan fiducial markers that are visible in the image set.

All registration points planned in the navigation software are displayed in orange on the screen.

9.4   Planning Anatomical Markers

About Planning Registration with Anatomical Markers

This section describes how to manually plan anatomical landmark points.

How to Select Points

Step
Press the desired point on the 3D model or in the point list. The point is highlighted in the list and is shown filled in the views.

How to Reposition Points

Step	
1.	Select the desired point.
2.	In the ACS views, drag the circled crosshair to the exact desired location of the registration point.

How to Delete Points

Step
Press the **X** in the point list next to the point you wish to delete.

9.5   Planning Fiducial Markers

About Planning Registration with Fiducial Markers

This section describes how to manually plan registration points using fiducial marker semi-automatic detection.

Use of Fiducial Markers

At least four landmarks are required for registration. When using fiducial markers, it is recommended to attach six or seven markers to the patient to ensure a sufficient number of landmarks in case markers fall off.
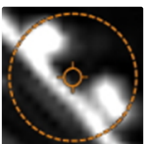
(!)   **The patient should not remove the fiducial markers. Do not leave small children or disoriented patients with attached fiducial markers unattended to avoid risks of swallowing markers.**

How to Add Fiducial Markers Using Semi-automatic Detection

Press directly on the 3D view to enable the semi-automatic detection feature. When you press a marker in the view, a registration point is placed directly in the center.

NOTE: Semi-automatic detection can only be used with compatible fiducial markers.

Step
1.   In the point planning screen, press a fiducial marker in the 3D view. The 3D model rotates until the fiducial marker is in the front. *NOTE: If needed, drag the 3D view to make adjustments to the 3D model rotation.*
2.   Press the fiducial marker. A registration point (indicated by a circle) is placed in the center of the fiducial marker.
3.   In the ACS views, ensure that the registration point is placed in the center of the fiducial marker. Use the zoom feature to verify that the registration point has been placed correctly.

NOTE: Check the position of each fiducial marker in the axial, coronal, and sagittal views.

How to Register Fiducial Markers

Step
Press **Registration**. The software prompts you to register the points.

9.6 Performing Landmark Registration

Registration Techniques

When using a pointer for landmark registration, the registration technique depends on the type of point to be registered.

Registration Point	Technique
Fiducial markers	Place the pointer tip in the center of each **Multi-Modality Donut Registration Marker**, making sure that the tip touches skin, then press the button on the **EM Pointer** or **EM Short Pointer**. You can also use **EM Registration Pointer** with **Skull Reference Base EM**. *NOTE: Do not apply pressure to the skin, as the point should be acquired on the skin's surface.*
Landmarks	Hold the pointer tip to the landmark, then press the pointer button. *NOTE: Do not apply pressure to the skin, as the point should be acquired on the skin's surface.*
Bony landmarks	Gently press the pointer tip until the bony landmark is reached, then press the pointer button. *NOTE: Without injuring the patient, apply enough pressure so that the point is acquired on the bone, and not on the skin's surface.*

About Points

Points must be registered in the order defined by the software.

Warning

Perform registration under sterile conditions and after patient draping if possible to avoid patient reference movement leading to inaccurate navigation.

Verify pointer accuracy if the pointer is dropped or otherwise physically damaged before continuing with navigation.

Before you Begin

Avoid acquiring points in areas where the patient's anatomy may be different from the image set (e.g., swollen areas of the face or skin shift due to a different patient position). This may result in incorrect registration and navigation.

How to Acquire Points
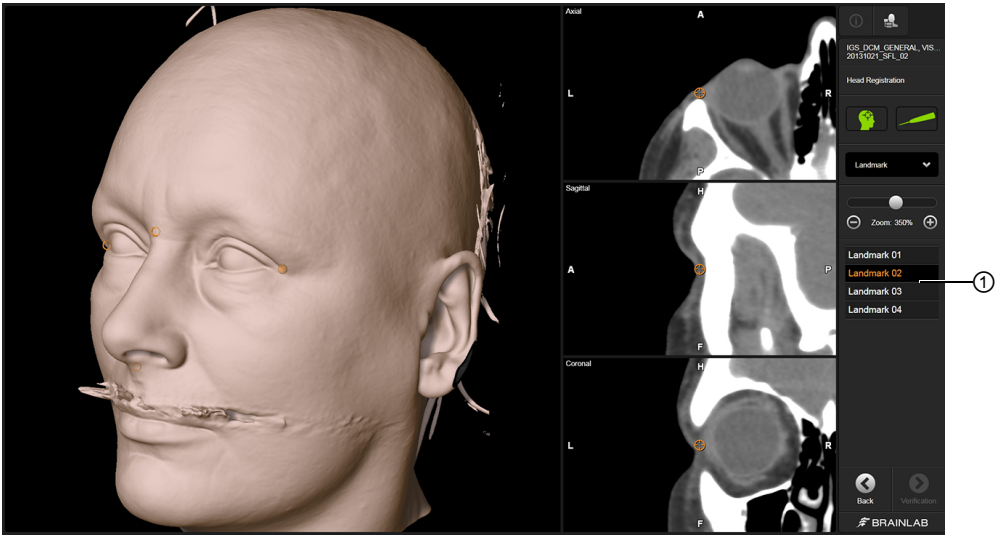
Figure 29

Step	
1.	Use **EM Pointer**, **EM Short Pointer** or **EM Registration Pointer** to register points sequentially as indicated by the software. *NOTE: If a marker/landmark is not accessible (e.g., due to the surgical set up), you can skip a point by selecting the next point in the point list ①.*
2.	Register a minimum of four points or register all points in the list.
3.	Select **Verification**. Verify registration accuracy in the dialog that opens.

Auditory Software Cues

Step
Each time you register a point, the software emits a beep.
If you attempt to register the point more than once, the software emits a different tone. The point is not re-registered.

Visual Software Cues

Figure 30

Prespecified points for registration are listed in the software.

Step
Register a point as it is listed in the software.
Next to each point, a check mark indicates that the point is registered.

How to Add Points

Step
To plan additional points, select **Back**. The **Planning Points** screen opens.

How to Repeat Registration

Step
To repeat registration of a point, select the point from the point list ①, then re-acquire it.

9.7 Landmark Registration Accuracy

Possible Decreased Navigation Accuracy

To ensure sufficient accuracy, the image set must be suitable for stereotactic navigation procedures and 3D correctness must be ensured. Check the position of each fiducial marker for Landmark Registration in the axial, coronal and sagittal views. Scan the patient as described in the Brainlab scan protocol.

⚠️ **Warning**
Due to possible distortions in MR image sets, navigation accuracy may be decreased at the point of interest, even if registration has been verified as satisfactory.

⚠️ **Warning**
Verify accuracy close to the region of interest, but not directly on registered landmarks. Be aware that navigation accuracy can be degraded in areas where accuracy was not verified due to error propagation.

⚠️ **Warning**
Accuracy may vary within the tracking volume, depending on the distance between the instrument and EM Field Generator.

If Registration Cannot be Found

If no registration is found due to insufficient accuracy, a corresponding dialog opens.
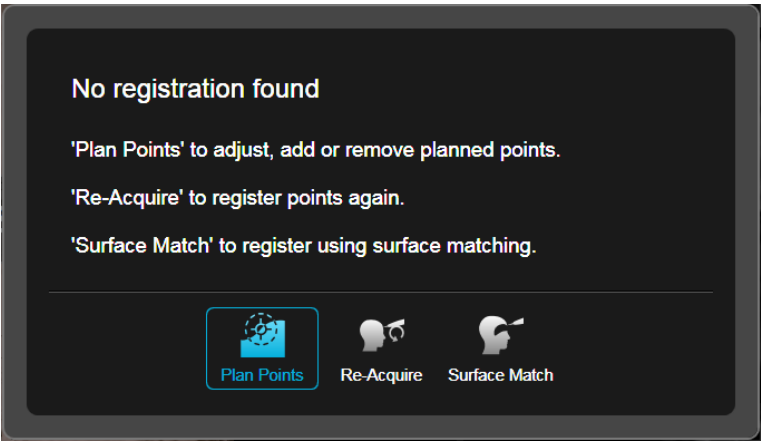
Figure 31

Options
To adjust, add or remove points, select **Plan Points**. The planning points screen opens.
To repeat registration, select **Re-Acquire**.
To exit **Landmark** registration and perform surface matching registration, select **Surface Match**.

If Registration is Found

When registration is successful, the registration verification screen opens.

Figure 32

Step
1.   Hold the pointer to known anatomical landmarks (e.g., nasion, most lateral orbital points) and verify that the position of the pointer displayed in the image views corresponds with the actual point on the patient's anatomy.   *NOTE: Verify accuracy at multiple anatomical landmarks, especially in the region of interest as it may differ from the accuracy verified on the skin surface. If the region of interest is not accessible, verify areas as close as possible to the region of interest.*
2.   Hold the pointer to various points on the patient's skull and verify that the displayed distance from the virtual pointer tip to the patent's skin corresponds to the actual pointer position.   *NOTE: Distance measurement is shown when the pointer tip is within 8 mm of the calculated surface.*
3.   If the verified registration is acceptable, select **Yes** to continue with the procedure.

10 NAVIGATION FUNCTIONS

10.1 Configuring Navigation Views

About Navigation Views

After completing registration verification, the navigation screen displays the patient's anatomical information in a 3D model, (upper left) as well as axial, coronal and sagittal (ACS) views. If you place the pointer on the patient's head, the 3D view is cropped perpendicular to the pointer axis. In this way, you can visualize the structures beyond the pointer.
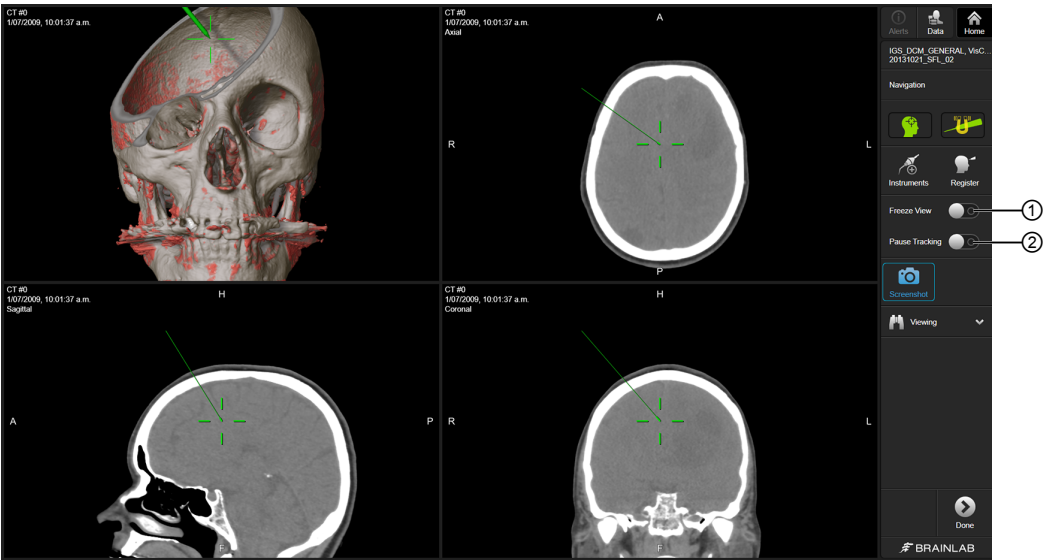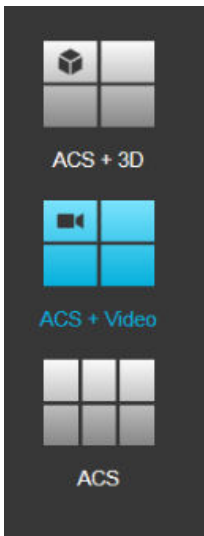
Figure 33

Options	
Freeze View	Slide ① to freeze the displayed slices and reconstructions. You can continue to navigate the instrument while slices and reconstructions remain frozen.
Pause Tracking	Slide ② to turn off the **EM Field Generator** (e.g., during neuromonitoring).

Available Layouts

Select the data icon to open the **Layouts** tab to choose from the available layout views.

Options
ENT EM displays two different navigation data reconstruction views. When video is connected, a third view becomes available that depicts video images. Select the required navigation view from the sidebar.

Video Content

- If a video source is connected to the navigation system, video content is displayed instead of a 3D model. Select the **ACS + Video** or **Inline + Video** layout to display the video content.
- If an endoscope is connected and navigation has been inactive (no instruments in the navigation field) for a defined period of time, the single video view screen maximizes automatically. As soon as navigation begins (an instrument enters the navigation field), the single video view screen minimizes.
- The display of video images may be delayed if the system is being used to full capacity.
- It is recommended to display video images on a separate, additional monitor, in particular for critical interventions.

The navigation views and video images are not suitable for diagnostic use as they could appear distorted. Colors are not calibrated and image resolution is insufficient for diagnostic use. Color image injection from external devices may display the objects in a different color as seen on the navigation screen. It is recommended to use context information (e.g., size and position) for identifying objects.

Spatial and depth perception is restricted when using 3D views. Navigating solely using volume rendering views could lead to misinterpretation in some cases. Verify critical decisions in 2D reconstruction views first.

Image Quality

If the view displays an image set that contains a broken image slice, a corresponding message is displayed.

The navigation views display data reconstructions. These images are interpolated and therefore may appear to have a different or higher resolution than the original image set. Information from adjacent planes may be displayed in the current reconstruction plane.

Additionally, axial, coronal, and sagittal reconstructions may differ from the true axial, coronal, and sagittal image orientation due to the patient position in the scanner or a manipulated image alignment.

Image Labeling

Depending on the displayed image, views are labeled with the image orientation:

Label	Orientation
A	Anterior

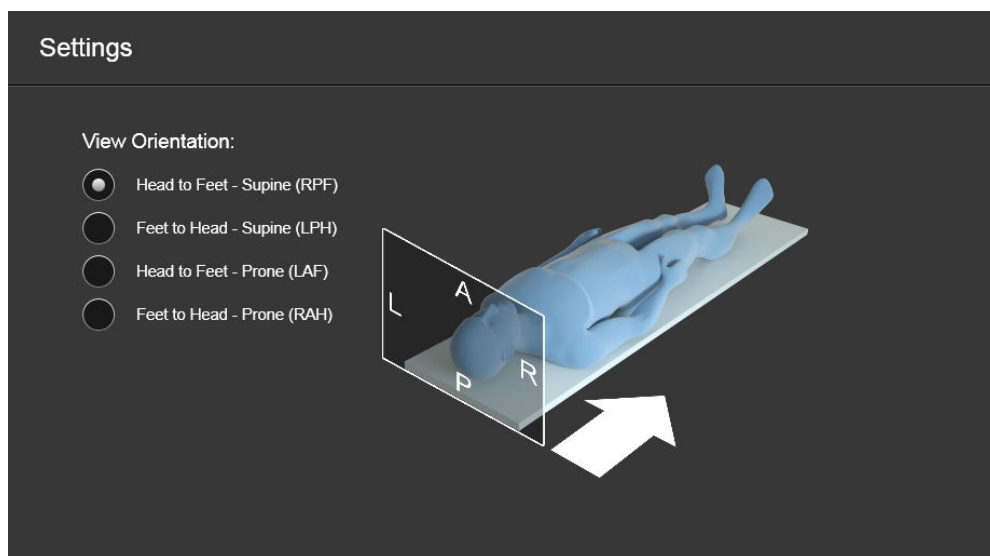| Label	Orientation
P	Posterior
L	Left
R	Right
H	Head
F	Foot

View Orientation

Figure 34

The default view orientation is the supine position, from head to feet. The orientation can be changed at any time in **Content Manager**.

For more information on changing the view orientation, refer to the **Origin Data Management Software User Guide**.

Instrument Display

When the navigated instrument is in the tracking volume, the instrument representation is displayed in the navigation views. The instruments are displayed in the navigation views in different colors.
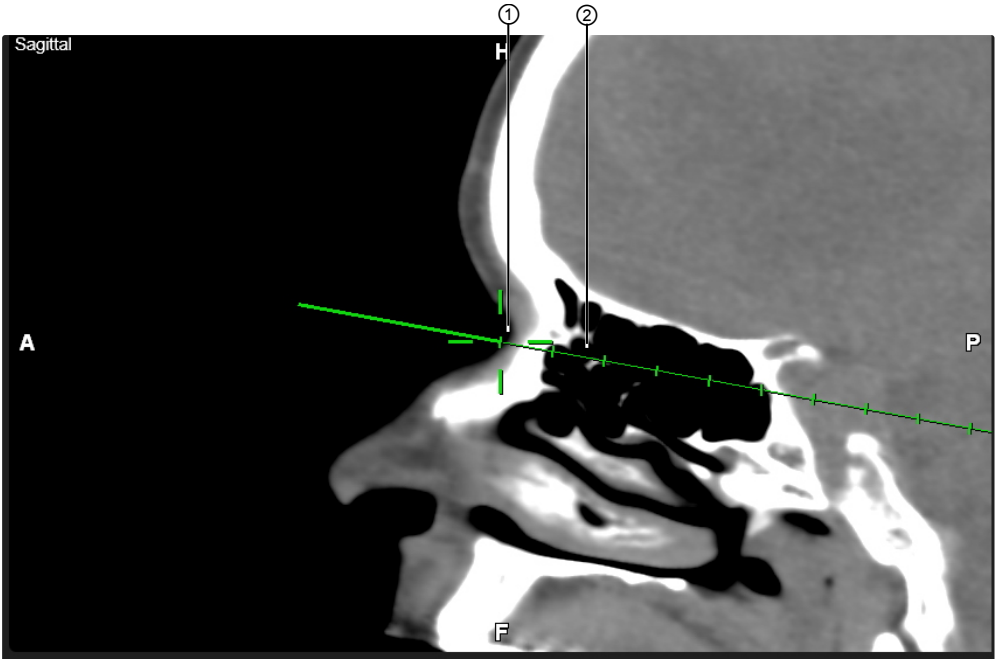
Figure 35

No.	Component
①	The crosshair indicates the instrument tip.
②	When the **EM Pointer**, **EM Short Pointer** or navigated instrument is inline with the view (the instrument axis is in the image plane), a prolongation of the instrument is shown. The prolongation is shown in 2D view.

10.2   Additional Functions

How to Use the Pointer Remote Options

In the navigation mode, access the remote options by pushing the pointer button.

Figure 36

Options	
Short click	Toggles between options and activates the function once selected.
Long click	Opens the remote menu or selects the desired option.
Freeze View	Freeze the displayed slices and reconstructions. You can continue to navigate the instrument while slices and reconstructions remain frozen.
Screenshot	Saves the screenshot to the patient to be exported to an external storage medium or network location via **Content Manager**. *NOTE: Screenshots can also be viewed in other Brainlab software (e.g., **Viewer**) when the relevant patient data is loaded.* The patient name appears on each screenshot. To maintain patient confidentiality, restrict screenshot access to the relevant medical personnel. Contact Brainlab support for more information on how to configure the system so that the patient information does not appear in screenshots.
Instruments	Returns you to the **Instruments** mode without exiting the navigation workflow.
Register	Returns you to the **Register** mode without exiting the navigation workflow.

Pointer Remote Control on Dual Monitor Systems

If you are using a dual monitor system (e.g., **Curve**), the software decides automatically which monitor is being controlled by the remote control.

You can tell which monitor software is being controlled by the following hints:

- Buttons are only active (blue) on the monitor that is being controlled ①.
- A text message appears indicating that the non-controlled monitor is waiting for a process to finish ②.

Figure 37

Display Priority of Applications

In most cases, prioritized remote applications will appear on the prioritized monitor. Occasionally the application will appear on the secondary monitor.

Priority of Remote-Controlled Applications	
Registration takes priority over:	• Setup • Navigation • Instruments
Instruments takes priority over:	• Setup • Navigation
Navigation takes priority over:	• Setup

How to Use Auto-Zoom

The Auto-Zoom feature doubles the zoom factor of the displayed images when the navigated instrument is held steady in the same position. That zoom factor remains as long as the instrument is navigated slowly.

If the instrument is moved quickly or removed from the tracking volume, the default zoom factor returns.

10.3   Verifying Navigation Accuracy

Instrument Accuracy

Instrument accuracy is confirmed by checking the distance between the instrument tip and a known position (e.g., a verification point).

How to Verify Instrument Accuracy with EM Pointer or EM Short Pointer

Figure 38

Step
Hold **EM Pointer** or **EM Short Pointer** tip in the **EM Instrument Reference** verification point.
The distance between the instrument tip and the verification point is displayed in the navigation screen.

*NOTE: **EM Pointer** or **EM Short Pointer** accuracy can also be checked by holding the tip to known anatomical landmarks.*

How to Verify Instrument Accuracy with EM Registration Pointer

Figure 39

Step
Hold **EM Registration Pointer** tip in the **Patient Reference EM** verification point.
The distance between the instrument tip and the verification point is displayed in the navigation screen.

11 INSTRUMENTS

11.1 Instrument Settings

Before You Begin

Some instruments must be calibrated and verified before you can use them. The calibration dialog box provides information about sterilization cycles and calibration status for the instruments currently connected.

How to Access Instrument Information
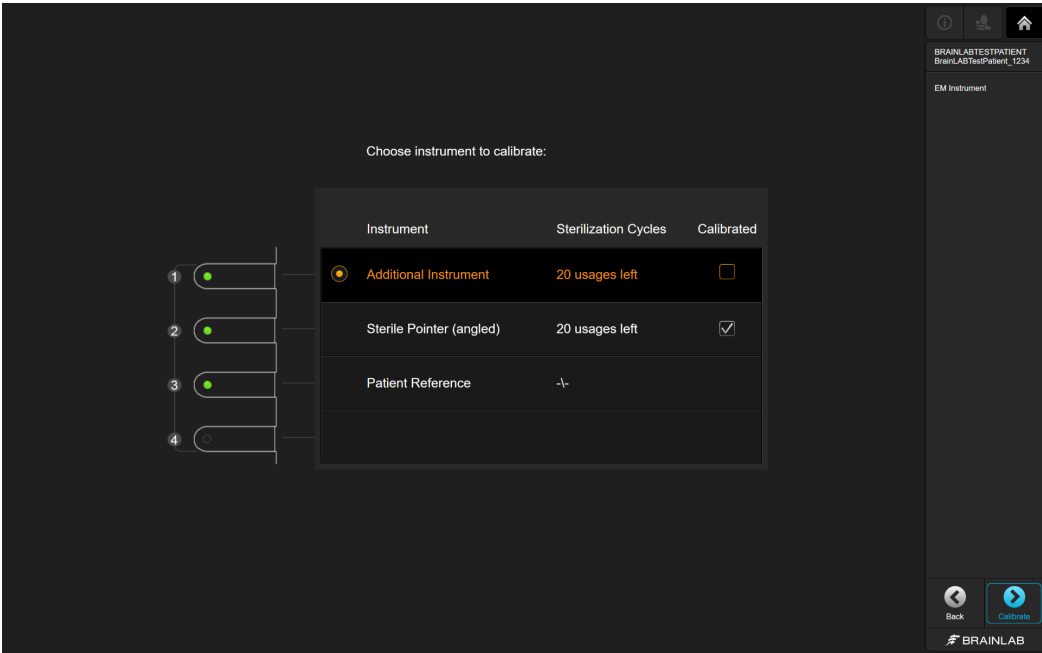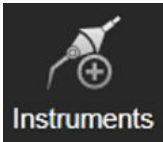
Figure 40

Step	
	Select **Instruments**. Information regarding the number of remaining reprocessing cycles, calibration status and connected instrument port is displayed.

11.2 Information About Instrument Status

Instrument Status Information
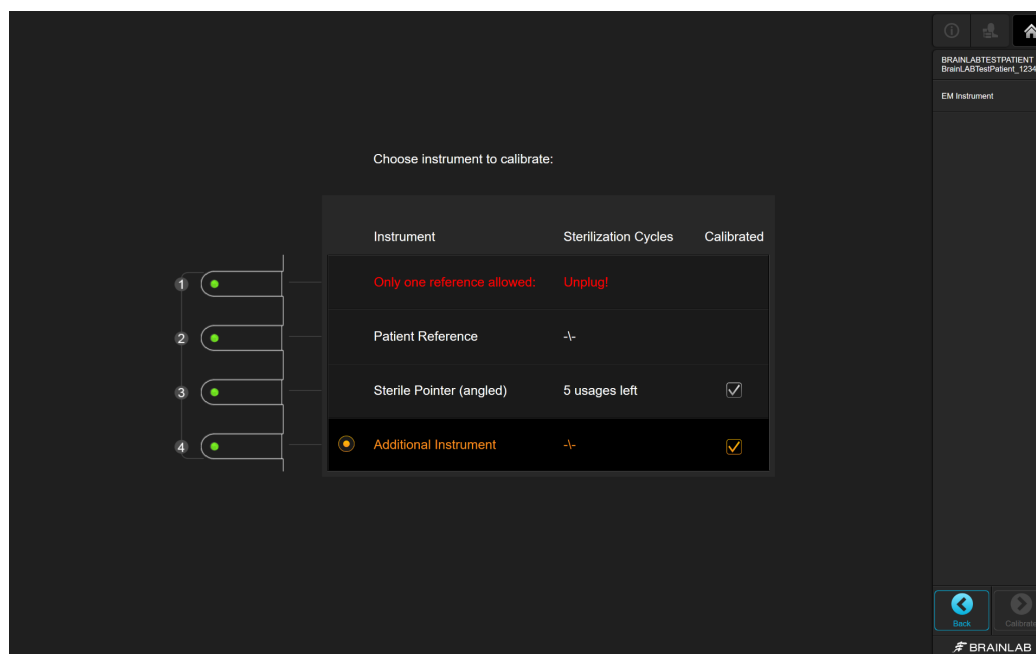
Figure 41

When an instrument is plugged in, the software provides information about how many times that specific instrument has been used or whether it has been calibrated. You can access this information by selecting **Instruments** on the toolbar or by selecting **OK** on an instrument-related dialog.

Displayed Message	Explanation
Instrument	Shows you which instruments, patient references or pointers are currently connected. The item with the circle next to it is the one currently selected for calibration.
Sterilization Cycles	Shows how many more times a pointer or instrument can be used. If this is not relevant for the instrument plugged in, **-\-** is displayed.
Calibrated	A check mark indicates whether the pointer or instrument has been calibrated.
No usages left:	The instrument indicated may not be used. To continue with the procedure, you must unplug this instrument and connect a different one.
Unplug!	You may not use this instrument (e.g., because you can only plug in one **EM Patient Reference** at a time, it is damaged, or no longer has any usages left).
Instrument is damaged:	Unplug the instrument and connect a different one.
Tool not initialized:	Initialization of the instrument failed. Unplug the instrument and try connecting it again.
Invalid Tool Combination:	This instrument combination is invalid. Unplug the indicated instrument and connect a different one.
Only use with Skull Reference Base EM	**EM Registration Pointer** can only be used with **Skull Reference Base EM**.

Displayed Message	Explanation
Disposable Stylet not allowed:	**EM Disposable Stylet** is not allowed in ENT procedures.
Unsterile pointer:	Displayed with **Invalid Tool Combination**. You may not use this pointer in this procedure.
Only one reference allowed	You may not use this patient reference because you can only plug in one **EM Patient Reference** at a time.

12 CALIBRATION

12.1 Introduction to Calibration

About Calibration

Instruments that are not pre-calibrated must be calibrated and verified for navigation.

The following types of instruments require an instrument reference to perform calibration and verification:

- Clamps
- Multiple Tip Pointers
- Suction Tubes
- Diego Elite

These instruments are calibrated using the **EM Pointer** or **EM Short Pointer** pivot point.

NOTE: For information on instrument references, see the corresponding Instrument User Guide.

Opening the Calibration Dialog

There are two ways to open the calibration dialog:

- If you are in navigation mode and plug in an instrument reference, the calibration dialog opens.
- To calibrate an instrument before registration, plug in the instrument reference and place the instrument inside the tracking volume. The calibration dialog opens.

Instruments for Calibration

To ensure suitable calibration accuracy, only use the compatible instruments listed in this user guide. For more information, see the relevant Brainlab Instrument User Guides or manufacturer instructions for use.

Do not attempt to calibrate instruments that are not approved for use with the software.

How to Activate Calibration

Figure 42

Step
1.   Connect the instrument reference and hold the instrument inside the tracking volume. The calibration dialog opens.
2.   Select the instrument for calibration in the dialog.
3.   Select **Calibrate**. *NOTE: Ensure that all instrument adapter screws are securely tightened.* ⚠   **Ensure that only the instrument to be calibrated is in the tracking volume.** *NOTE: Carefully read all relevant sections in the corresponding Instrument User Guide.* *NOTE: **EM Pointer**, **EM Short Pointer**, **EM Registration Pointer** and **EM Disposable Stylet** are all pre-calibrated instruments.*

12.2   Performing Calibration

Calibration with the Pivot Point on EM Pointers
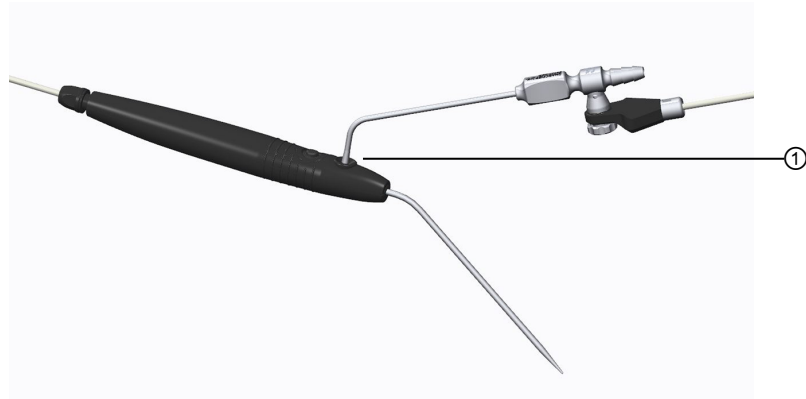
Figure 43

Perform the calibration and verification of compatible pointer tips and suction tubes using the **EM Pointer** or **EM Short Pointer** pivot point ①.

NOTE: Check that all instrument reference screws are securely tightened before calibrating.

NOTE: The instructions in this chapter apply to all pointers compatible with this software.

How to Calibrate
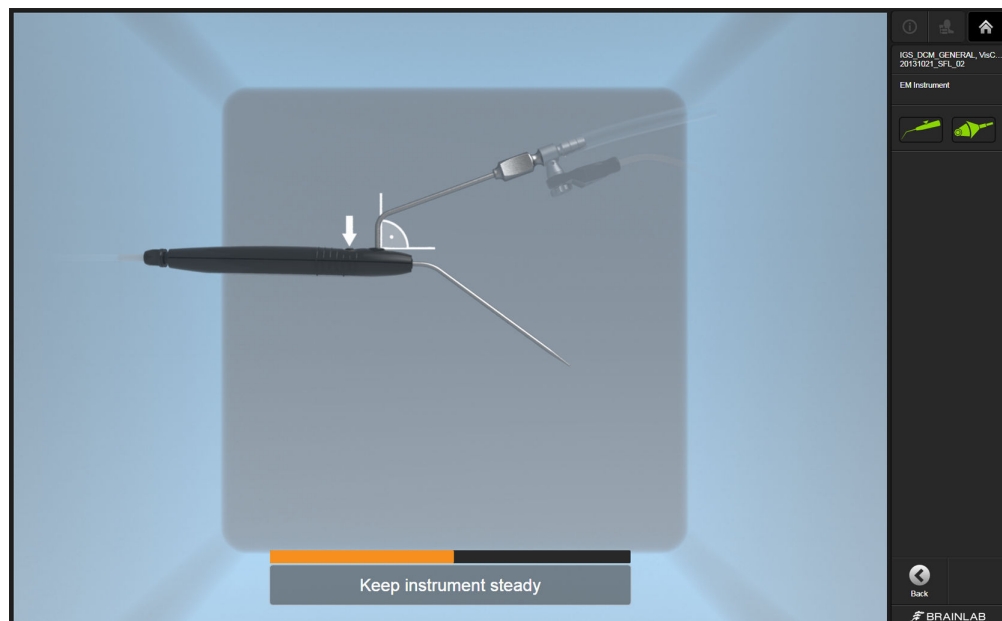
Figure 44

Step
1. Hold the instrument with **EM Instrument Reference** attached in a reliable area of the navigation volume.

If you are calibrating the instrument for the first time, the instrument calibration dialog opens automatically.

The dialog prompts you to bring **EM Pointer** or **EM Short Pointer** and additional references into the tracking volume.

If instruments are not inside the tracking volume, the software displays information so you can quickly resolve the problem:
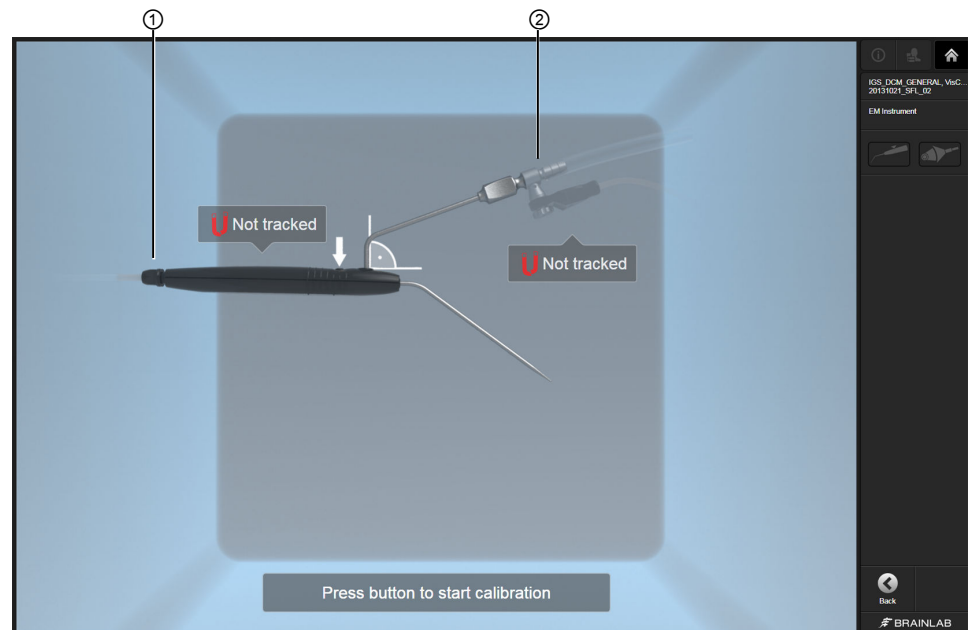
In this example, neither **EM Pointer** ① nor **EM Instrument Reference** ② is visible.
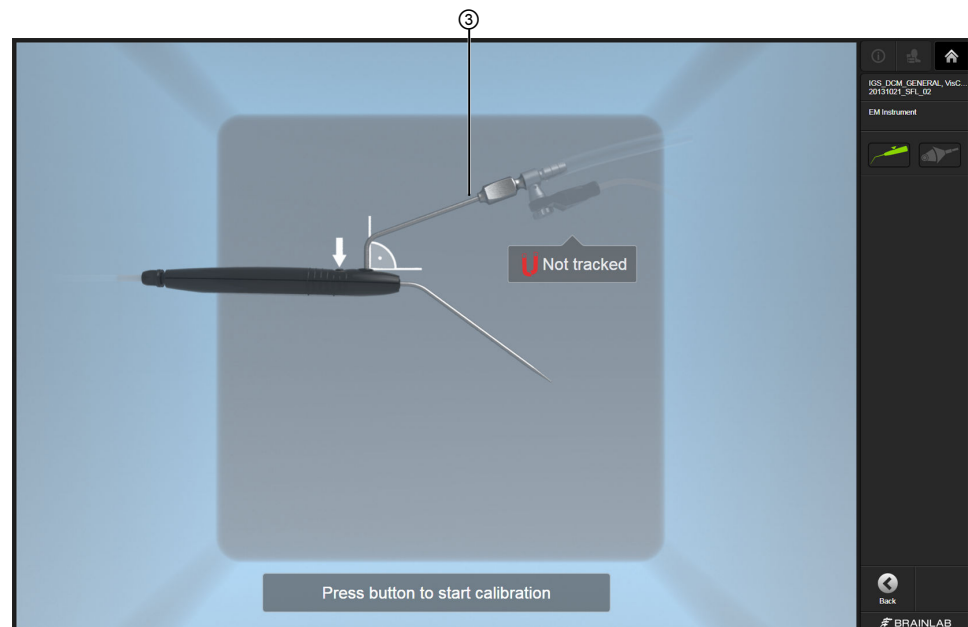
In this example, **EM Instrument Reference** ③ is not visible.

Step	
2.	Place the instrument tip on the pivot point, then push the button briefly, as shown on the screen. Keep instrument steady Hold the instrument steady for a few seconds as the progress bar fills.
3.	Keeping the pointer and instrument held together, rotate the instrument a minimum of 50° relative to the starting point until the curved progress bar fills and the tone has stopped sounding. *NOTE: Ensure that the instrument tip remains perpendicular to the pivot point.* *NOTE: For best calibration results, begin by holding the instrument and the **EM Pointer/EM Short Pointer** at 180°.* *NOTE: Both the instrument and **EM Pointer** or **EM Short Pointer** should be in the optimal EM tracking area (see above).* Rotate instrument and keep it vertical
4.	 Keep instrument steady Hold the instrument tip steady for a few seconds on the pivot point as the progress bar fills.
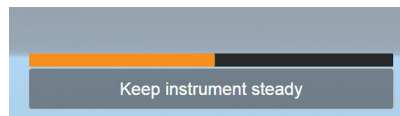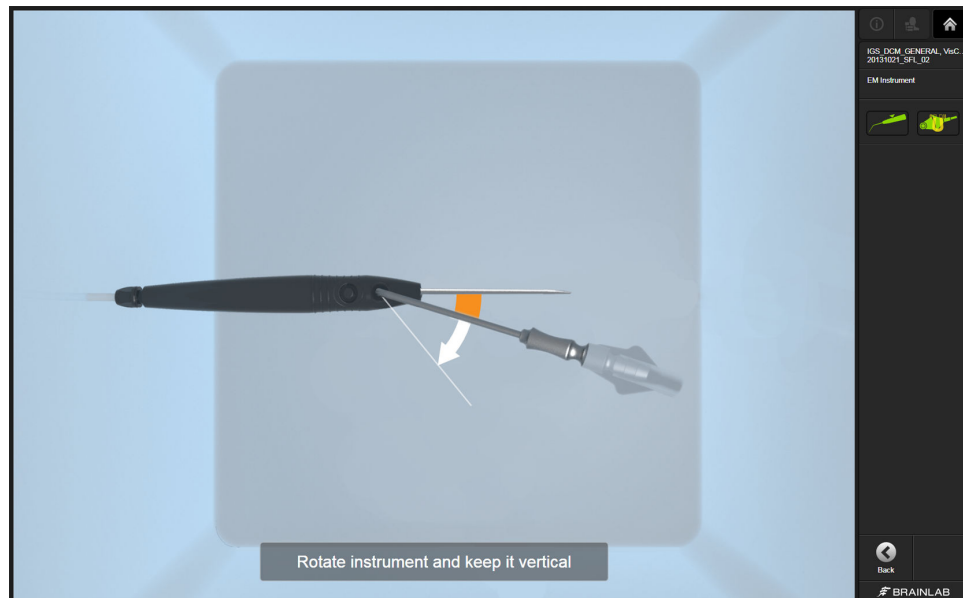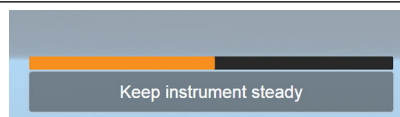
Step
5.   If calibration fails, a corresponding dialog opens.   Read the suggestions on why the calibration did not work. Select **OK** and start calibration again.
6.   If calibration was successful, the calibration result verification page is displayed.   The distance to verification point is shown, and you are asked to accept or refuse the result. *NOTE: **Yes** is activated when you hold the calibrated instrument close to the pivot point for at least 2.5 seconds.*
7.   If the calibration result is satisfactory, select **Yes**. The navigation screen opens and you can navigate using the new instrument.
8.   If the calibration result is not satisfactory, select **No**. Calibration starts again.
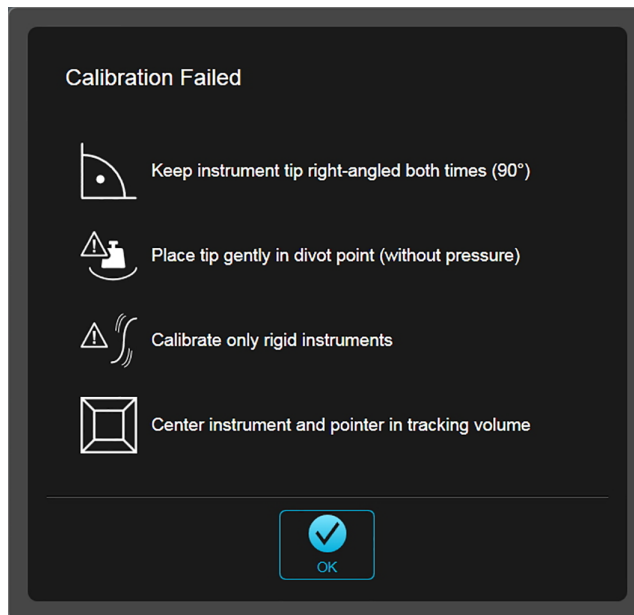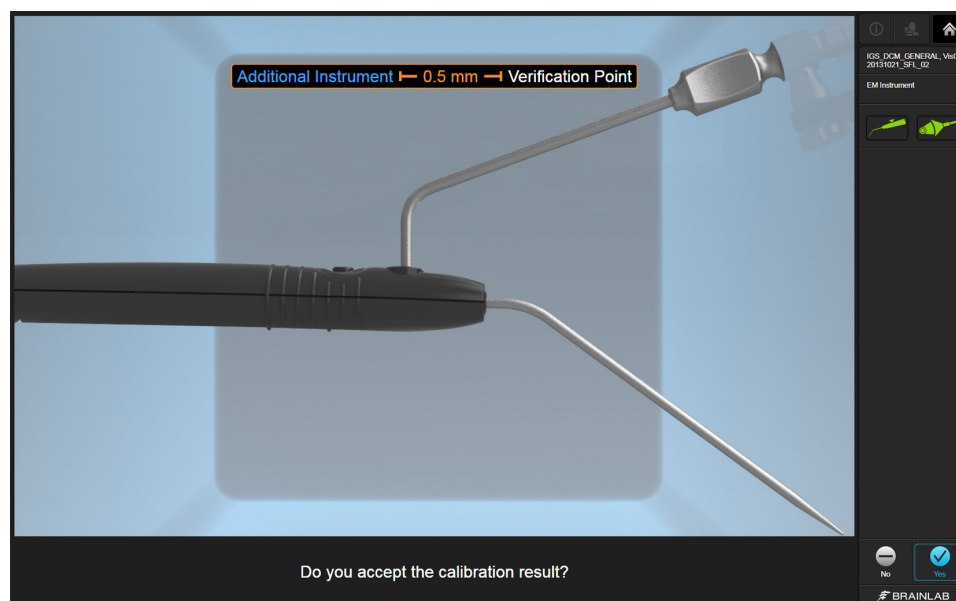
Calibration Failed

Calibrate instruments by holding the pointer and instrument reference inside the most reliable region of the tracking volume, otherwise calibration may fail.

Calibration fails if:

- The instrument and **EM Pointer** or **EM Short Pointer** were not held in a reliable region of the tracking volume.
- Instruments containing materials that cause electromagnetic interference are used.
- Accuracy is insufficient.
- Additional instruments are located in the magnetic field, causing decreased tracking accuracy.
- The calibrated instrument is too long. In this case, the following information pop-up occurs.

12.3   After Calibration

Calibration Verification

To verify the accuracy of the instrument calibration during surgery, repeatedly point the calibrated instrument to known anatomical landmarks and verify the position displayed on the screen.

Exchanging the Instrument or Instrument Reference

Do not exchange or reposition the instrument reference after calibration. This will lead to an incorrect instrument display and navigation inaccuracy. Always recalibrate an instrument reference if it has been exchanged or repositioned.

Exchanging an instrument tip (e.g., **Multiple Tip Pointer** tips) requires a new instrument calibration.

INDEX

BRAINLAB

brainlab.com

CE 0123