



CRANIAL NAVIGATION SYSTEM NAVIGATION

Version 4.0

Software User Guide
Revision 1.1

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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.

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 - **Kick®** is a registered trademark of Brainlab AG in Germany and/or the US.
 - **Z-touch®** is a registered trademark of Brainlab AG in Germany and/or the US.
-

Non-Brainlab Trademarks

- Microsoft® and Windows® are registered trademarks of Microsoft Corporation in the US and other countries.
 - NVIDIA® is a registered trademark of NVIDIA Corporation in the United States and other countries.
-

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:

- Independent JPEG Group (<https://github.com/uclouvain/openjpeg/blob/master/LICENSE>)
 - libjpeg-turbo (<https://github.com/libjpeg-turbo/libjpeg-turbo/blob/master/LICENSE.md>)
 - libtiff 4.0.4 beta (<http://www.simplesystems.org/libtiff/>)
 - OpenJPEG (<https://github.com/uclouvain/openjpeg/blob/master/LICENSE>)
 - Xerces C++ 3.2.2, developed by the Apache Software Foundation (<http://www.apache.org/licenses/LICENSE-2.0.html>)
-

CE Label



- The CE label indicates that the Brainlab product complies with the essential requirements of Council Directive 93/42/EEC (the “MDD”).
 - **Cranial Navigation 4.0** is a part of **Cranial Navigation System**, which is a Class IIb product according to the rules established by the MDD.
-

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.

Sales in US

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

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.

1.4 Using the System

Intended Use

The Cranial IGS System, when used with a compatible navigation platform and compatible instrument accessories, is intended as image guided planning and navigation system to enable navigated surgery. It links instruments to a virtual computer image space on patient image data being processed by the navigation platform.

Indications for Use

Cranial Navigation 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, including:

Cranial Resection

- Resection of tumors and other lesions
- Resection of skull-base tumor or other lesions

AVM Resection

Intended Patient Population

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

Intended User

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

Place of Use

The Cranial Navigation System shall be used in a hospital environment, specifically, in rooms appropriate for surgical interventions (e.g., operating rooms).

The environmental requirements depend on the navigation platform being used. For more information, refer to the respective **System and Technical User Guides**.

Essential Performance

The Essential Performance is summarized by:

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

Plausibility Review



Warning

Before patient treatment, review the plausibility of all information input to and output from the system.

1.5 Compatibility with Medical Devices

Compatible Non-Brainlab Devices

Medical Device	Manufacturer
Multi-Modality Registration Markers	IZI Medical Products 7020 Tudsbury Road Baltimore, MD 21244 USA

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.

Compatibility with Brainlab Medical Instruments

Navigation is compatible with the following instruments:

- Disposable Reflective Marker Spheres
- Pointer Cranial/ENT (Blunt Tip, with Gauge)
- Reference Clamp Universal
- Skull Reference Array
- Skull Reference Base
- Standard Cranial Reference Array, 4 Markers
- Vario Reference Arm for Mayfield Headholder

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**.

Instruments Intended for Contact with Certain Body Parts or Tissue Types



Warning

Only specified Brainlab instruments are intended for direct contact with body parts or tissue types. For a list of such instruments, refer to the Cranial/ENT Optical Instrument User Guide.

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.

1.6 Compatibility with Software

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.

Microsoft Security Updates for Windows and Driver Updates

Brainlab allows the installation of security patches 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.

See the Brainlab website for more information about settings and a list of Microsoft Security Updates blocked by Brainlab support.

Address: www.brainlab.com/updates

Password: WindowsUpdates!89

Updates

NOTE: Updates to the operating system (hotfixes) 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 hotfixes and will know, for some updates, if problems can be expected. Contact Brainlab support if any problems to operating system hotfixes 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.

NOTE: 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.

1.7 Software Environment and Cybersecurity

Bill of Materials of Integrated Third-Party Software

- dcmtnk – 3.6.0
- Lapack – 3.2.1
- libjpeg – 6b
- libjpeg2k – 2.3.1
- libpng – 1.6.16
- libtiff – 4.0.4 beta
- libturbo-jpeg – 1.4.0
- 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 .NET Framework – 4.5.2
- Microsoft Visual C++ Runtimes 2015 – 14.0.24215.1.1
- NVidia Cg Tool kit – 3.1.0010
- NVidia NVAPI – Release 367
- 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
8765	outgoing	TCP	Communication with tracking camera
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.

1.8 Training and Documentation

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

2 SYSTEM SETUP

2.1 Introduction

Background

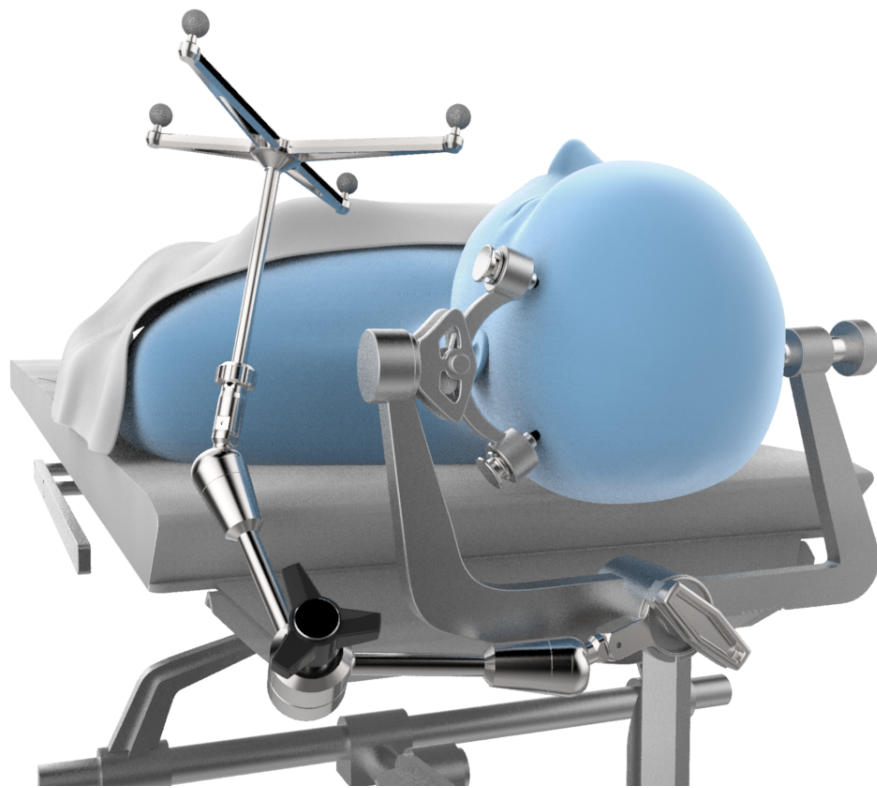


Figure 1

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. Ensure the patient's head is rigidly fixed in the headholder.

Register the patient in the desired position for surgery, as any movement of the patient's head after registration decreases navigation accuracy.

- If the patient's head moves, but the relative position to the reference array stays the same (e.g., the OR table is moved), verify accuracy.
- If the patient's head moves relative to the reference array (e.g., repositioning the patient's head in the headholder, moving the reference array), perform registration again.

2.2 Camera and Monitor Setup

Background

Artifacts caused by reflections, especially during registration, can cause inaccuracies. Ensure light sources or highly reflective items do not affect the camera field of view.

The camera and/or **Z-touch** laser may interfere with other infrared-based OR equipment, such as remote controls, pulse oximeters or IR-sensitive microscopes. Remove other infrared sources from the camera field of view, as they may hinder the camera in detecting **Z-touch**.

How to Set Up the Camera and Monitor

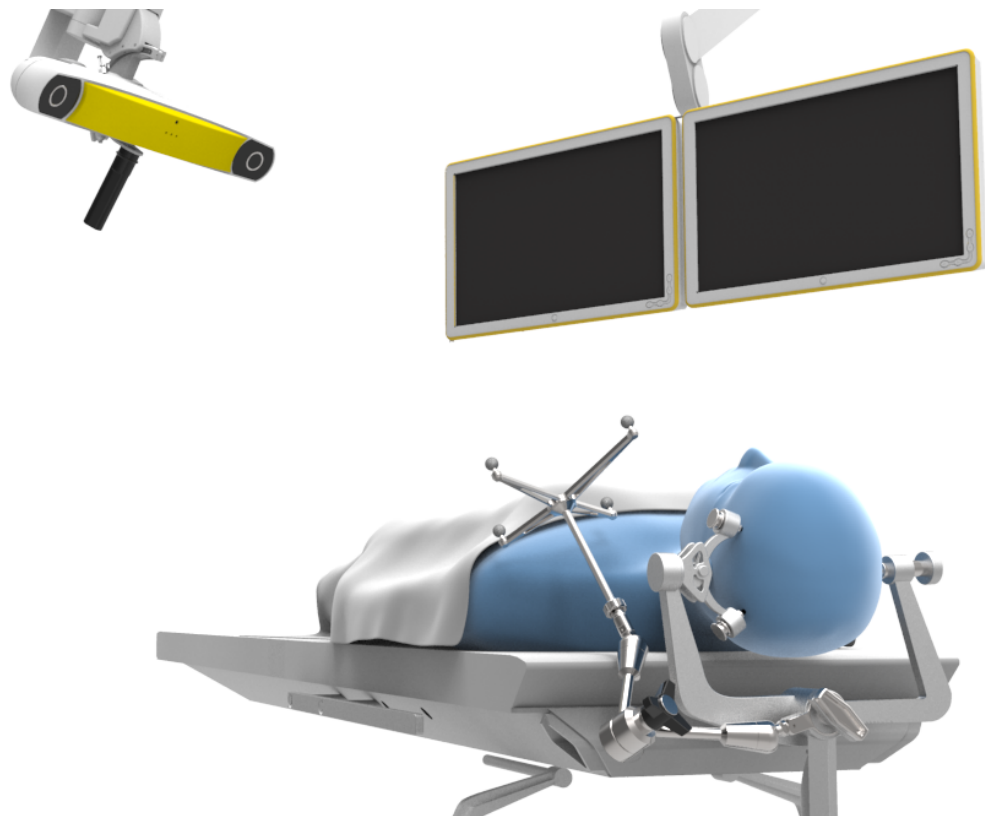


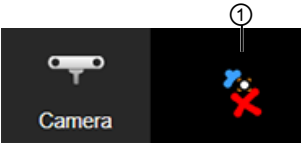
Figure 2

The system setup varies depending on the system used and the type of procedure being performed.

Step

1. Position the camera and monitor while keeping the following points in mind:
 - Select a correct camera position that will work throughout the entire procedure (including registration and navigation).
 - The camera and monitor must not restrict the surgeon during surgery.
 - Avoid major movement of the camera during a procedure. If the camera is moved, you must verify the accuracy again.
 - The camera must have a clear view of the reference array and instruments throughout the procedure, including all registration and navigation procedures. To provide an optimum view, the camera should be approximately 1.2 - 1.8 meters (4 - 6 feet) away from the surgical field.

Step	
2.	Plug in and turn on the system. Refer to the platform's System User Guide (e.g., Kick Curve).
3.	Start the software.
4.	Ensure the reference array is visible to the camera. The following view is displayed to indicate whether the array is visible to the camera.



If the array is not visible, adjust the camera distance and angle until the array representation ① is visible.

Camera Display

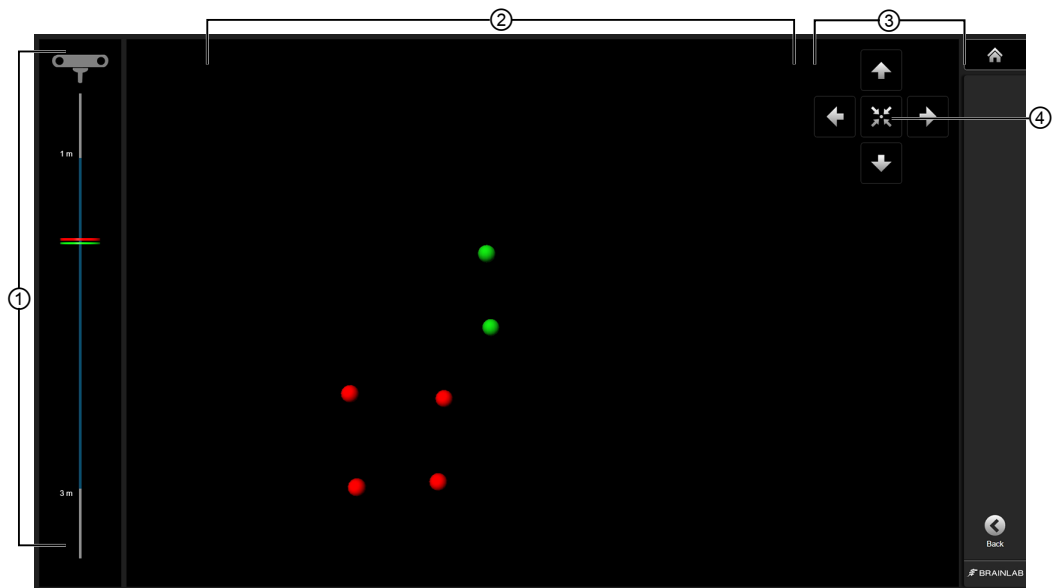


Figure 3

Select **Camera** to open the array representation view.

No.	Description
①	Displays the distance of the instruments and/or reference arrays in relation to the camera. For optimum visibility and accuracy, all marker spheres shall be inside the blue corridor.
②	Displays the position of the instruments and/or reference arrays in relation to the camera.
③	Displays the camera motor control positioning buttons (if available).
④	Used to center the camera. <i>NOTE: Centering the camera takes up to five seconds. A second click deactivates the centering feature.</i>

2.3 Reference Array Setup

Reference Array

Position the reference array so it remains visible for the entirety of the procedure. Consider where any devices may block the line of vision from the reference array. It is helpful to have the camera standing on the same side as where the reference array is attached.

For more accurate navigation, position the reference array as close to the region of interest as possible without interfering with the required surgical space.

Ensure the reference array is firmly attached to the clamp. When using **Reference Clamp Universal**, ensure it is firmly fixed to the headrest.



Warning

Relative movement of the patient's head with respect to the reference array (e.g., movement of the reference array or the patient's head in the headholder) is not allowed during or after registration. If relative movement occurs, you must perform a complete new registration.

Marker Sphere Visibility

Before beginning registration, verify that:

- The reflective marker spheres are securely attached
- The reference array is not bent, especially the pins
- The marker spheres are clean, dry and undamaged
- The marker spheres are not covered by drapes, except for drapes specifically designed by Brainlab for draping reference arrays

2.4 Instrument Accuracy

Verifying Instrument Accuracy

Always verify instrument accuracy prior to use with **Navigation**. You can verify instruments via the reference array divot. For further information, see the **Cranial/ENT Optical Instrument User Guide**.

NOTE: For blunt tipped instruments, be aware that due to the instrument's flat tip, a tip deviation occurs when verifying accuracy.



Figure 4

Each pointer comes in a pointer gauge that serves to prevent pointer damage and ensure maximum pointer accuracy.



Warning

Check pointer accuracy before each use by:

- Ensuring that the pointer tip aligns with the counter pin on the pointer gauge ①
- Placing the tip in the verification point of the reference array (divot) and checking the displayed distance

Pointer ← 0.5 mm → **Verification Point**

3 SOFTWARE OVERVIEW

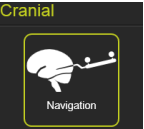
3.1 Software Overview Introduction

Background

Navigation is a touchscreen-based intra-operative navigation software. The software places surgical instruments in a three-dimensional position on anatomical image sets (e.g., MR and/or CT) to support the surgeon during various surgical interventions.

When used together with a planning software, a treatment plan can be prepared separately from the surgical intervention, then transferred to the navigation software for additional reference and support during surgery.






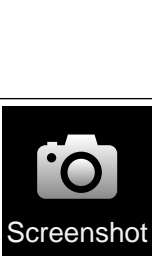
Workflow

Step
1. Select a patient. For more information on patient and data selection, refer to the Origin Data Management Software User Guide .
2.  Select Navigation under the Cranial workflow.
3. Select all appropriate patient data and any defined objects relevant for the procedure. All applications for the dedicated workflow are displayed.


3.2 Navigation and Viewing Functions

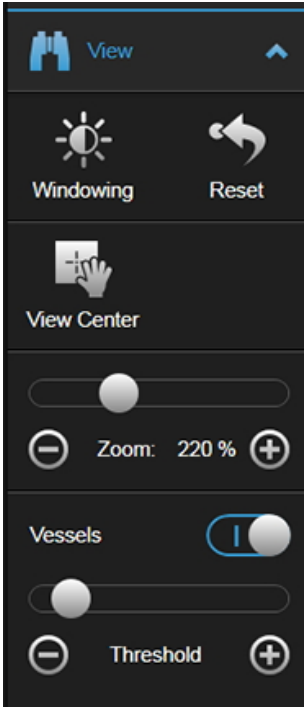


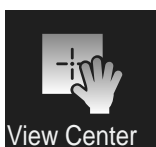

Basic Navigation Functions

The following viewing options are available in all layouts.

Button	Function
 Alerts	Alerts: Displays a list of alerts as soon as the software detects any issues requiring your attention.
 Data	Data: Displays the available layouts, image sets, objects and other content.
 Home	Home: Returns you to Content Manager where you can select a new application or exit completely.
 Camera	Camera: Opens the camera app to display which reference arrays and any pointers or instruments are in the camera field of view.
 Acquire	<p>Acquire: With an available registration, the user can acquire points:</p> <ul style="list-style-type: none"> • On the center of the yellow lines when no instrument is visible. • On the instrument tip when an instrument is visible. <p>If an offset is enabled and the user presses Acquire, the user will acquire a trajectory.</p> <p><i>NOTE: Distance to a visible point is displayed in case you are closer than 8 mm. Distance to a target point of a trajectory is displayed if you are closer than 16 mm.</i></p> <p>The name or color of acquired points and trajectories can be modified in data selection.</p>
 Screenshot	Screenshot: Takes a screenshot of the current view. The screenshot is automatically saved with the patient data.

Viewing Functions

Button	Description
 Freeze	<p>Freeze: Only active if an instrument is visible. Toggle on to freeze the view.</p> <p>The user can scroll through the data set to review current position compared to underlying structures or distance to structures of interest. This is visualized by a distance measurement.</p>

Button	Description
	<p>View menu: Open the menu to access more viewing functions.</p> <p>Zoom: Zoom in or out of a slice. Press the ⊖ and ⊕ symbols or drag the slider:</p> <ul style="list-style-type: none"> • Left to zoom out • Right to zoom in <p>Vessels: Toggle to show or hide vessels. Drag the toggle bar:</p> <ul style="list-style-type: none"> • Left to hide vessels within the craniotomy view • Right to show vessels within the craniotomy view <p><i>NOTE: If contrast agent was detected in the slice set, the Vessels toggle will be active by default. If no contrast agent was detected, the user can manually toggle on Vessels.</i></p>
	<p>Windowing: Adjust the brightness and contrast of a slice.</p> <ul style="list-style-type: none"> • Drag down/up to increase/decrease the brightness. • Right/left to increase/decrease the contrast.
	<p>Reset: Select to go back to the previous windowing setting.</p>
	<p>View Center: Only available in 2D views. It is grayed out unless a registration and an instrument are available.</p> <p>With View Center, you move the crosshair of the tracked instrument to a position off-center. This enables you to adjust which information of the data set is visible in the view (e.g., both the navigated instrument and a deep-seated lesion).</p>
	<p>Scroll buttons: Use the up and down arrows to scroll through the slices.</p> <p><i>NOTE: Scroll buttons appear if the patient was not registered and disappear if a pointer is visible to the camera.</i></p> <p><i>NOTE: The area between the arrows can be used as a scrollbar.</i></p>

Touch Interaction

Touch	Description
Pan (3D views)	Two fingers multitouch only. Touch and drag a slice to the desired location.
Pan (2D views)	Single touch. Touch and drag a slice to the desired location.

Touch	Description
Rotate	Single touch and multitouch. Touch and drag a 3D image to the desired rotation.
Zoom	Multitouch. Pinch inward (zoom out) or outward (zoom in).

Related Links

How to Use Freeze Mode on page 41

Offset Menu

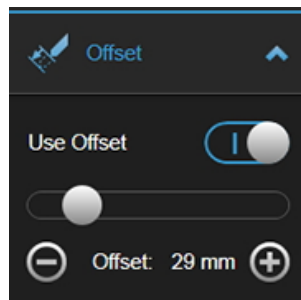


Figure 5

Use Offset allows you to view the anatomy below a pointer or instrument tip by displaying the slice positions at the depth of a virtual tip.

The software automatically sets the default tip offset distance according to the following:

- If you are navigating close to a defined target object, the tip offset is set as the distance from the actual pointer tip to the center of the target object (up to a maximum of 180 mm).
- If no target object is defined or you are not navigating when **Use Offset** is turned on, the tip offset is set to 100 mm.

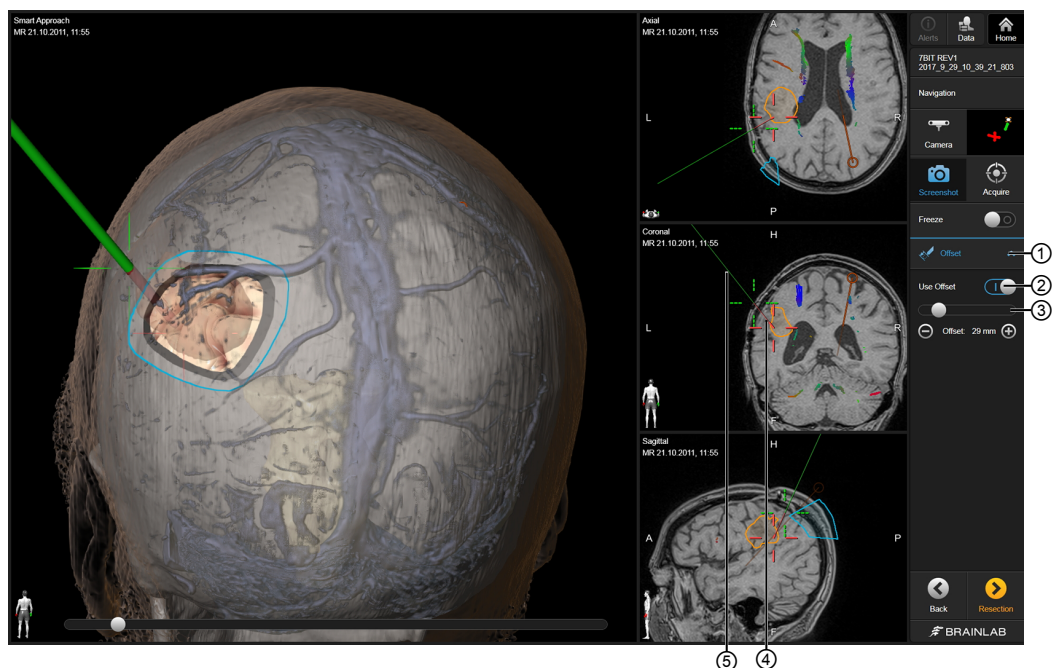


Figure 6

No.	Description
①	Select the arrow to open the Offset drop-down menu.
②	Toggle Use Offset on and off.
③	To shorten or lengthen the offset tip, either: <ul style="list-style-type: none">• Drag the bar to the left and right• Select the ⊖ and ⊕ symbols
④	The actual pointer or instrument is represented by a green line. The actual pointer or instrument tip is represented by a green crosshair.
⑤	The virtual extension is represented by a red line. The virtual tip is represented by a red crosshair.

3.3 Data Menu

Background

The **Data** menu provides access to the available patient data, objects and layouts. Select **Data** to display a list of available content.

Data Menu Layout

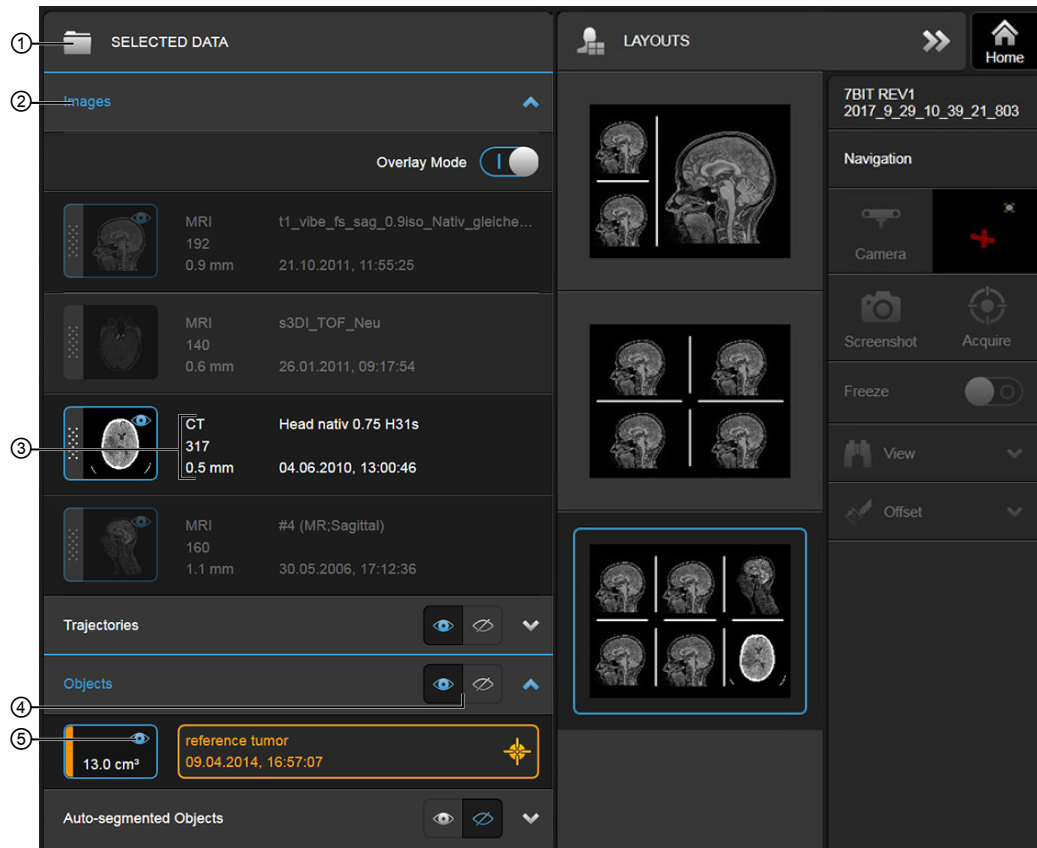


Figure 7

No.	Component	Description
①	SELECTED DATA	<ul style="list-style-type: none"> • Images: Switch between loaded image sets. • 2D DSA Images: Switch between loaded 2D DSA and CIP image pairs (if applicable). • Trajectories: Lists available trajectories. • Objects: Lists available objects, such as the tumor. • Fiber Bundles: Lists available fiber bundles created in Fibertracking. • Points: Lists available points. • Auto-segmented Objects: Lists objects created with Anatomical Mapping. • Rescue Points: Lists rescue points if any were acquired. • Craniotomy: The craniotomy object is created in the Craniotomy menu.

No.	Component	Description
②	Images	If both CT and MR are selected, the software overlays the image sets in the 2D (composition view) and 3D. In Overlay mode, the user can configure which data sets (CT/ultrasound) should be superimposed over a base data set (MR, CT, PET).
③	Scan information	Image information such as name, date, creation time, modality, number of slices and slice distance.
④	Group object visibility	To view/hide all objects, select the open/closed eye buttons.
⑤	Individual object visibility	If an object is visible, it is displayed with a blue border and eye symbol. To hide an object, select the object (box on the left side).

Target Object

If no instrument is visible to the camera, the software initially centers all slice views on the target object. After that, the software jumps to the last panned position.

NOTE: All 2D slice views are centered on the target object if no instrument is visible to the camera. After the pointer disappears, it takes 30 seconds until the 2D views center on the target object.

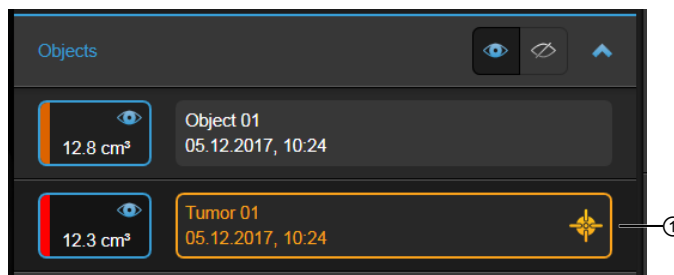


Figure 8

No.	Description
①	The target object is displayed with the target symbol. This applies for objects of type tumor, nidus, malformation and unknown.

Data Dialog

As soon as new intraoperative data is available that is fused to the selected data, the following dialog appears:

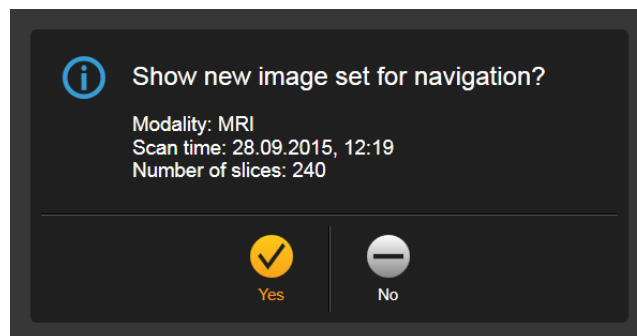


Figure 9

Option	Description
Yes	Shows the image set indicated in the dialog.
No	Continues with the current image set.

NOTE: The data dialog is not shown for new intraoperative ultrasound.

3.4 Drag and Drop Image Set Selection

About Drag and Drop Image Set Selection

Navigation uses default layout filling. This means that **Navigation** fills your layout automatically when you start the application or the resection stage for the first time. You can change the selected data at any time.

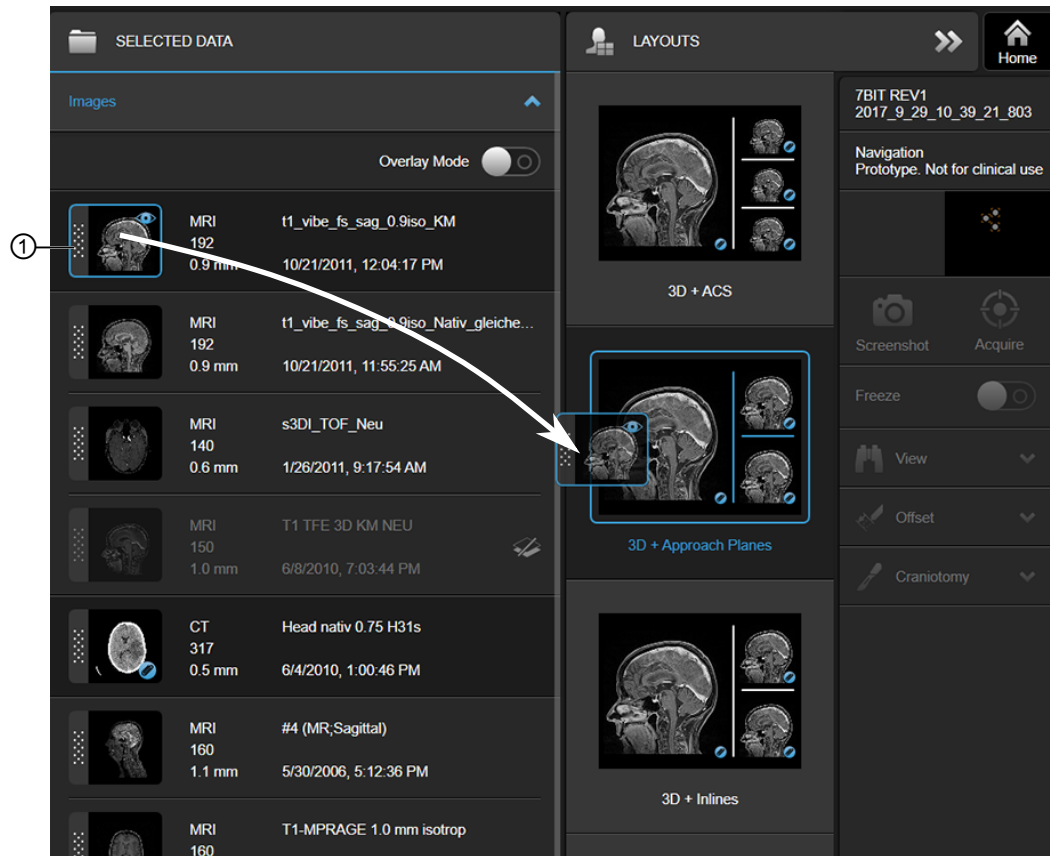


Figure 10

For all layouts, you can change the data sets in a specific layout via the **Data** button. If an image set is marked on the side with a dotted pattern ①, you can drag it into the currently selected layout.

If an image set cannot be dragged to a specific section of a layout (e.g., a CIP image into the bottom row of the **Angio + Reconstructions** layout), a prohibition sign is displayed:

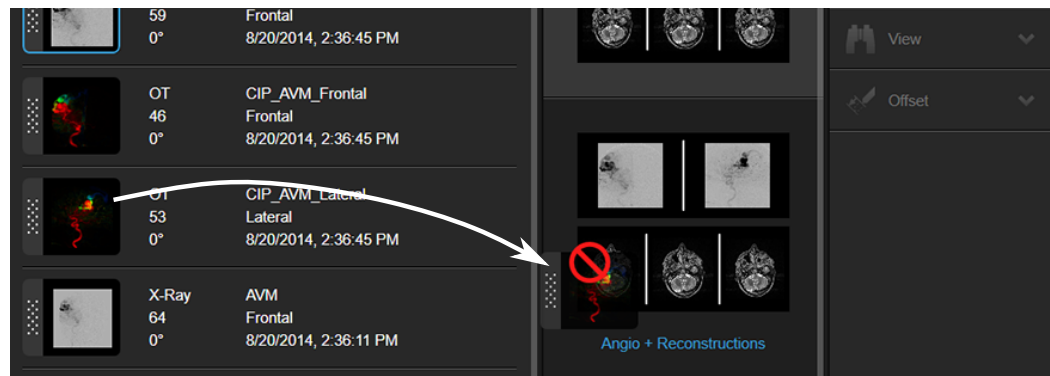
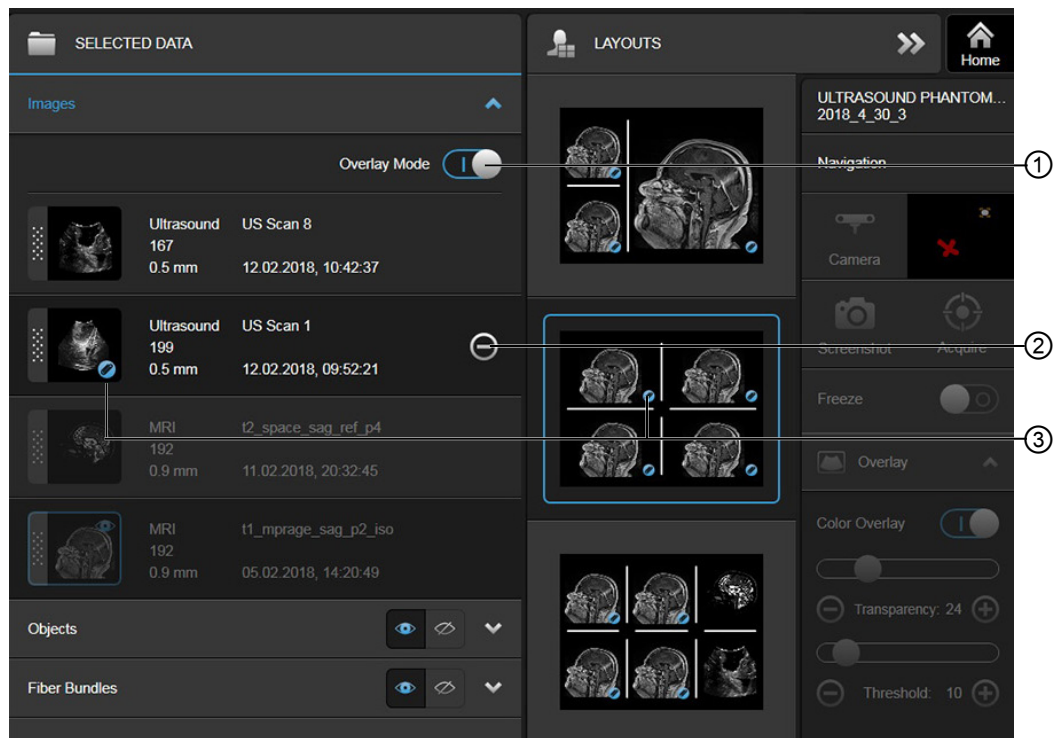


Figure 11

Overlay Mode Editor



No.	Description
①	Overlay Mode toggle: Toggle on to open the Overlay Mode editor.
②	⊖: Indicates that this image set is an overlay. The symbol appears only when Overlay Mode editor has been toggled on and the image set is used as an overlay. By selecting it, the image set is removed as an overlay globally.
③	Paper clip: Indicates that the ultrasound or CT has been set as an overlay. Also displayed in the layout.

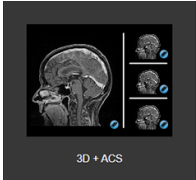

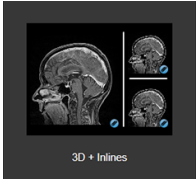
3.5 Layouts

Available Layouts

Select **Data** to open the **Layouts** menu and switch between layouts. The available layouts depend on whether you are in the craniotomy or resection step, your license, and which types of image sets are available.


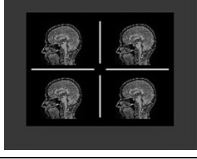
Craniotomy Step

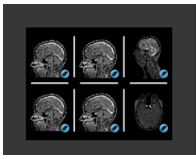
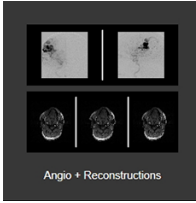
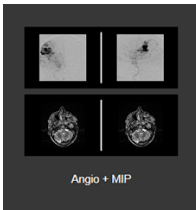
The following layouts are available in the craniotomy step.

Craniotomy Step	
Layout	Description
 <p>3D + ACS</p>	<p>3D + ACS:</p> <ul style="list-style-type: none"> • Left side: 3D view of the patient's head and objects (if applicable). • Right side: Axial, coronal and sagittal slice views.
 <p>3D + Approach Planes</p>	<p>3D + Approach Planes:</p> <ul style="list-style-type: none"> • Left side: 3D view of the patient's head and objects (if applicable). • Right side: Approach plane views.
 <p>3D + Inlines</p>	<p>3D + Inlines:</p> <ul style="list-style-type: none"> • Left side: 3D view of the patient's head and objects (if applicable) • Right side: Two inline views show reconstructions that are in plane with the pointer axis. These are orthogonal to each other.

Resection Step

The following layouts are available in the resection step. Almost all layouts are completely customizable.

Resection Step	
Layout	Description
	<p>3 Views layout:</p> <p>All three views are customizable.</p>
	<p>4 Views layout:</p> <p>All four views are customizable.</p> <p>By default, the reconstructions and the number of data sets displayed is dependent on which data the user had selected before selecting Resection.</p>

Resection Step	
Layout	Description
	<p>6 Views layout: All six views are customizable. By default, the reconstructions and the number of data sets displayed is dependent on which data the user had selected before selecting Resection.</p>
 <p>Angio + Reconstructions</p>	<p>Angio + Reconstructions:</p> <ul style="list-style-type: none"> • Top: Frontal and lateral DSA or CIP image sequences. • Bottom: Axial, coronal and sagittal slice views.
 <p>Angio + MIP</p>	<p>Angio + MIP:</p> <ul style="list-style-type: none"> • Top: Frontal and lateral DSA or CIP image sequences. • Bottom: Coronal and sagittal MIPs.

Changing Reconstructions

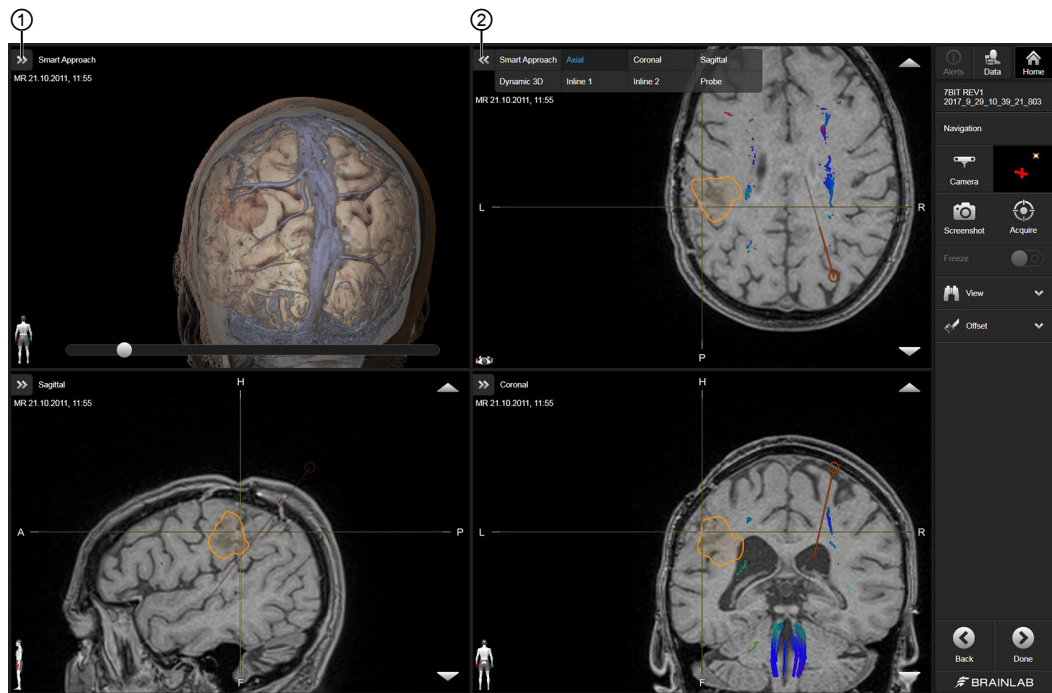


Figure 12

You can change the reconstruction type in nearly all resection step views (except for Angio DSA views and MIP views). To change the reconstruction, select the arrow in the upper left corner of each view ①.

When you select the arrow, a menu opens showing available views ②. In this case, the available options are: **Smart Approach**, **Axial**, **Coronal**, **Sagittal**, **Dynamic 3D**, **Inline 1**, **Inline 2** and **Probe**.

Dynamic 3D View

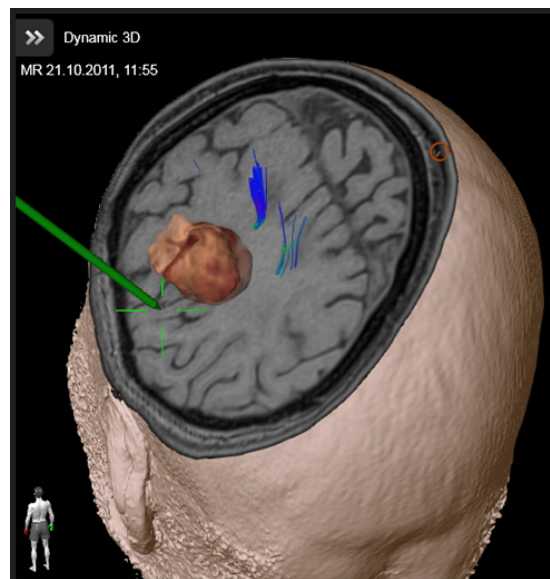


Figure 13

Specifically used with MR image sets, **Dynamic 3D** view shows the data with a cut perpendicular to the instrument plane. The displayed information changes as you move the instrument. In this way, you can visualize the structures surrounding the instrument.

Smart Approach View

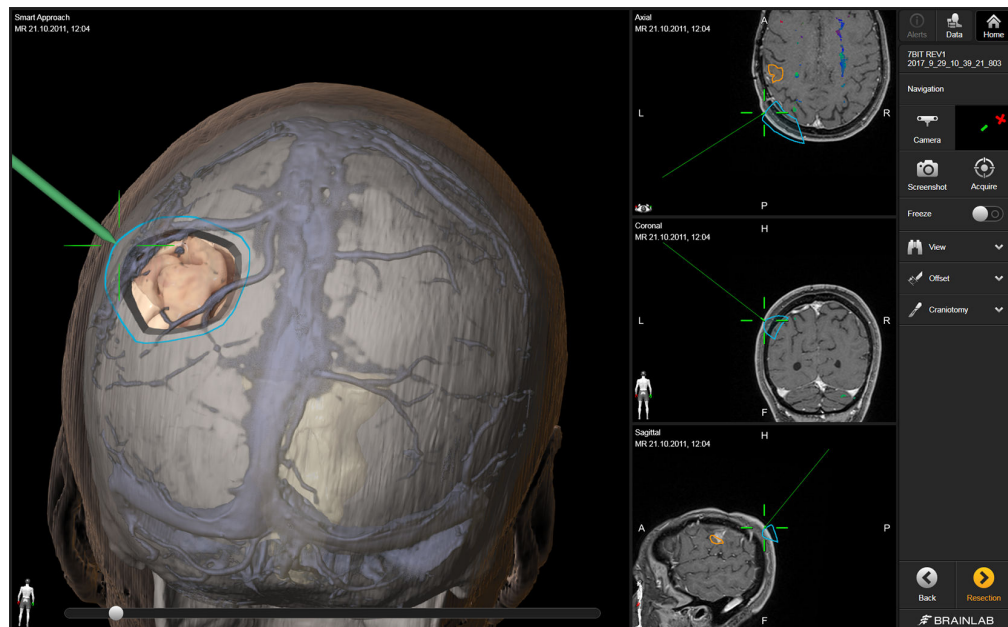


Figure 14

To use **Smart Approach** view, rotate the 3D model so that it reflects the surgeon's view of the patient.

In **Smart Approach** view, move the slider to unpeel the layers of the available compiled information (e.g., skull bone, cerebrum, fibers).

4 NAVIGATION

4.1 Navigation Introduction

Background

If you did not previously perform registration, use **Navigation** to review the selected patient data. If you previously performed registration, use **Navigation** to support you while performing craniotomy and resection. The navigation instrument is displayed within the 2D and 3D views.

Scan Requirements

To ensure sufficient accuracy, scan the patient as described in the **Cranial/ENT Registration and Navigation Scan Protocol**.

Safety Considerations



Warning

The software uses scan images of the patient acquired before surgery. The patient's actual anatomy could differ from the preoperative image data (e.g., due to brain shift or resections).

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



Warning

Verify registration accuracy frequently throughout the entire surgery, especially after the draping procedure (including exchanging an unsterile reference array with a sterile one).

Navigation Workflow

When you start **Navigation**, the software takes you through separate steps that contain the optimal layouts for the craniotomy and resection procedures.

Step
<ol style="list-style-type: none"> 1. Within the craniotomy step: <ol style="list-style-type: none"> a. Rotate the 3D model in the craniotomy layouts to reflect the actual view the surgeon has of the patient's head. b. Plan and perform craniotomy. c. Select Resection to proceed to the resection layouts.
<ol style="list-style-type: none"> 2. Within the resection step: <ol style="list-style-type: none"> a. Define a Rescue Registration (optional). b. Perform resection. c. Select Done to close the application.

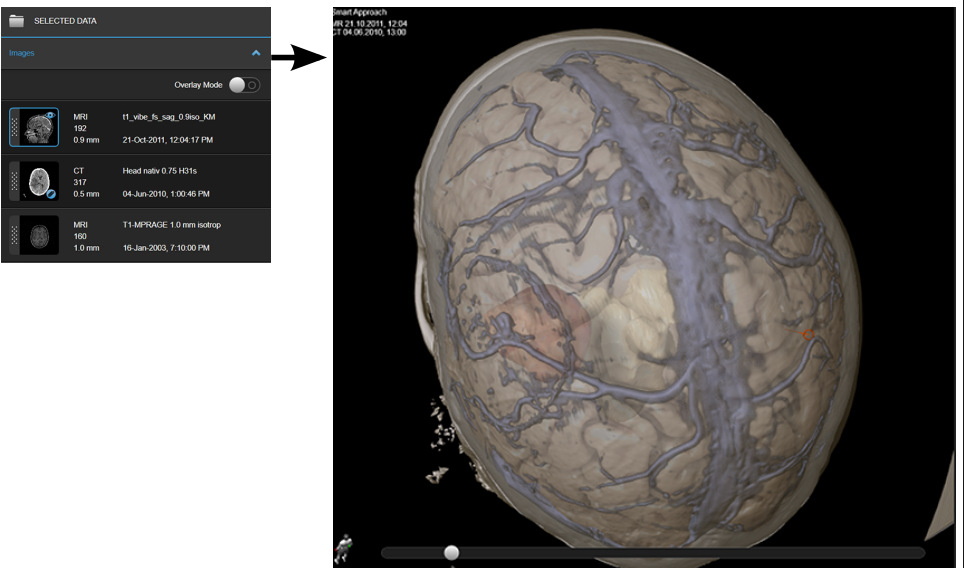
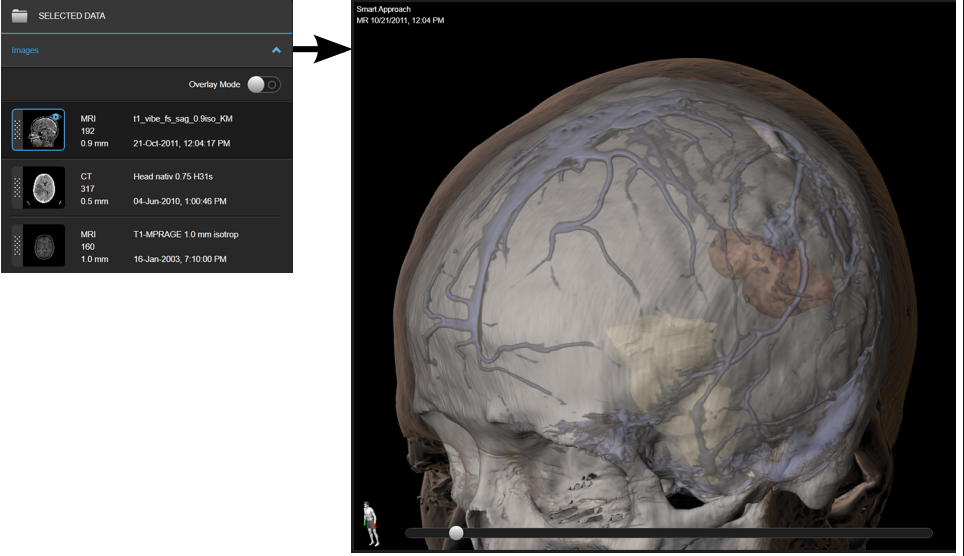
4.2 Craniotomy Step

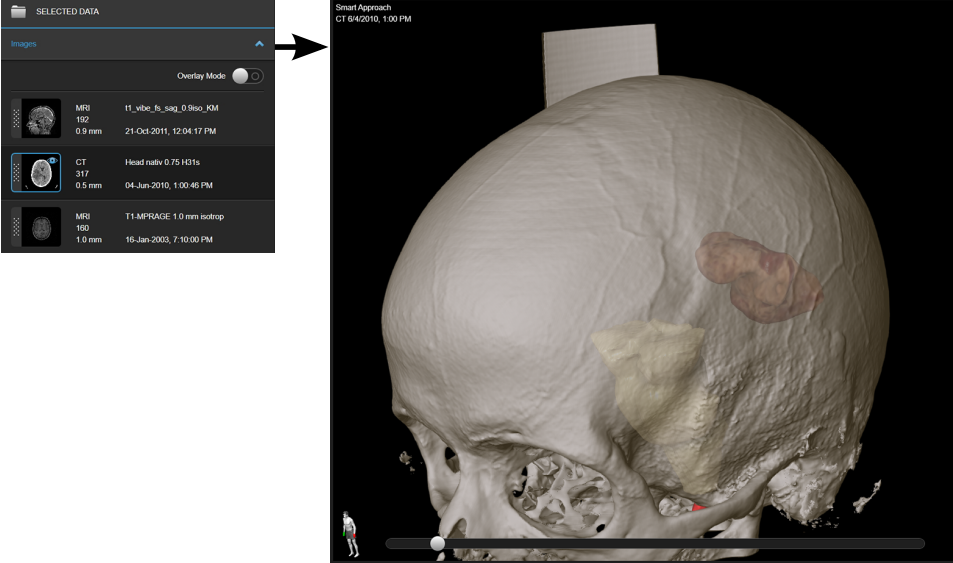
Background

The craniotomy step provides all necessary information for the craniotomy procedure. Select **Data** to switch between the three available layouts.

Image Set Selection for the Craniotomy Step

The 3D view depends on which MRI and CT image sets are selected. There are three cases:

Option	Description
①	 <p>If both MR and CT information is selected (shown with a paper clip icon), the software displays a skin silhouette and a bone reconstruction from the CT and brain reconstruction from the MR.</p>
②	 <p>If an MR image set is selected, the software displays a skin silhouette, a bone reconstruction (depending on Atlas) and a brain reconstruction of the MR data.</p>

Option	Description
③	 <p>If only a CT image set is selected, the software displays a skin silhouette and a bone reconstruction of the CT data but no brain reconstruction.</p>

3D + ACS Layout

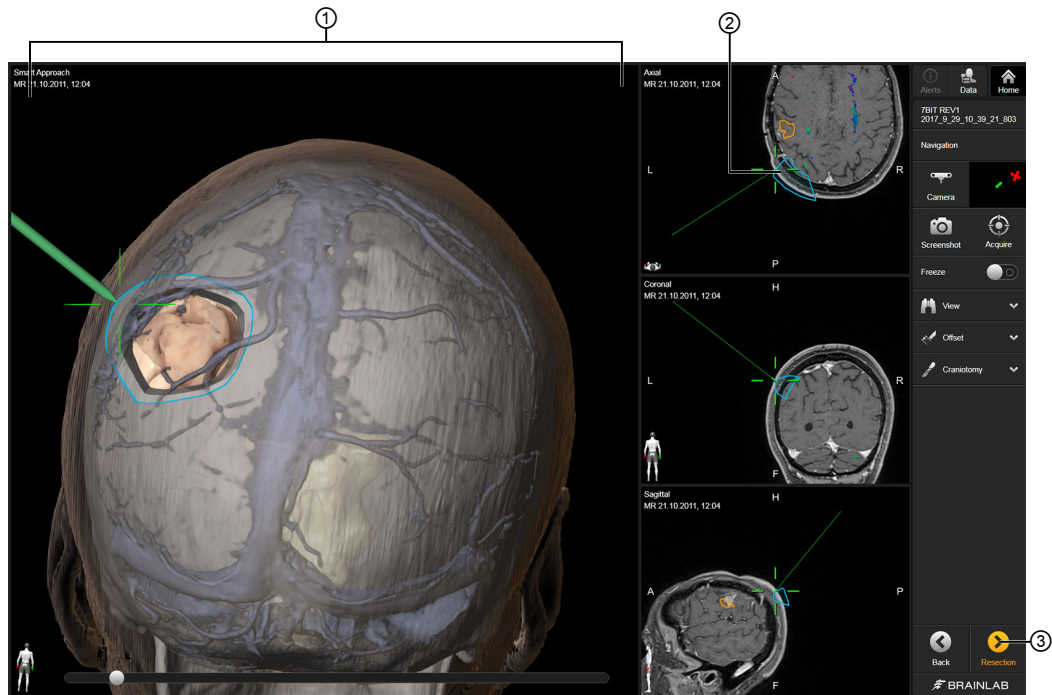


Figure 15

No.	Description
①	Smart Approach view: Rotate the 3D model so that it reflects the surgeon's view of the patient. This view supports you during craniotomy planning.
②	The crosshair marks the position of the instrument tip.
③	Select Resection to open the resection screen.

Non-Navigated 3D + Approach Planes Layout

The non-navigated views in the **Approach Planes** layout are 2D slices cut through the center of the tumor (target object) and angled to the surgeon's view of the patient's head. **Approach Plane 1** is the vertical cutting plane and **Approach Plane 2** is the horizontal cutting plane.

Therefore, before using the **Approach Planes** layout, you must first create a target object in **SmartBrush** and rotate the 3D model to reflect the surgeon's view of the patient.

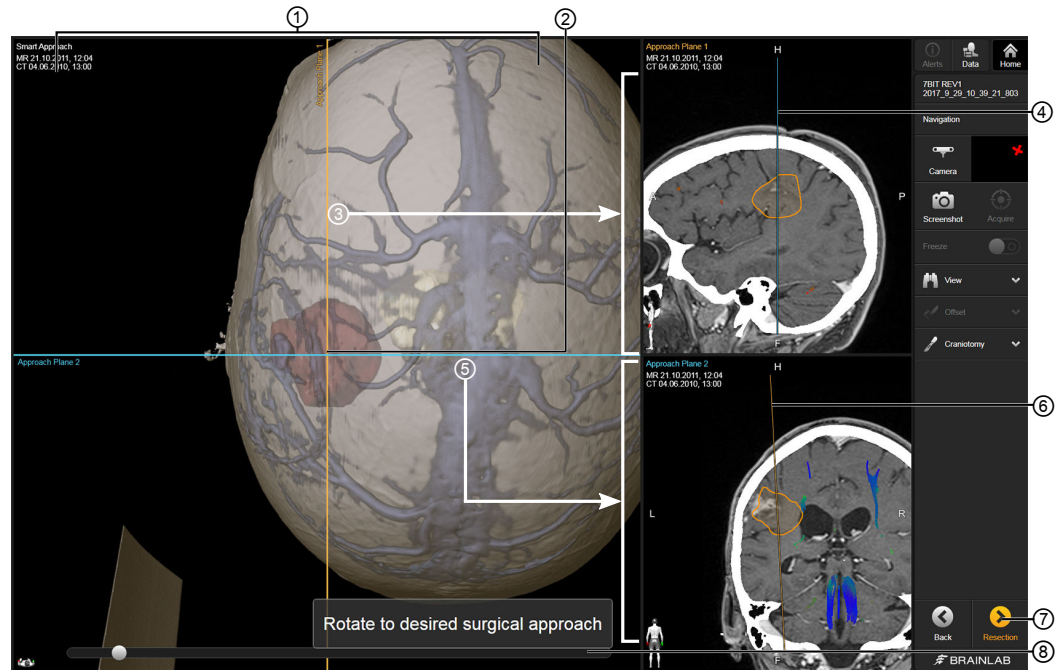


Figure 16

No.	Description
①	Smart Approach view: Rotate the 3D model so that it reflects the surgeon's view of the patient. This view supports you during craniotomy planning and is used to define the approach planes.
②	If no instrument is visible, the Approach Planes intersect in the center of the target object.
③	The 2D slice through Approach Plane 1 is shown in the upper right side.
④	The reference line for the cutting plane of Approach Plane 2 .
⑤	The 2D slice through Approach Plane 2 is shown in the bottom right side.
⑥	The reference line for the cutting plane of Approach Plane 1 .
⑦	Select Resection to open the resection step.
⑧	Smart Approach view slider: Drag the slider to see the view dynamically.

Navigated 3D + Approach Planes Layout

During navigation, the **Approach Planes** move parallel to the default view (when there is no instrument visible to the camera) to intersect at the instrument tip instead of the center of the target object. The angle of the instrument is not taken into consideration as the orientation of the patient's head stays the same.

The **Approach Plane** views can help define the tumor borders for the craniotomy. As soon as one of the **Approach Plane** views no longer passes through the tumor, it is also hidden in the respective **Approach Plane** view.

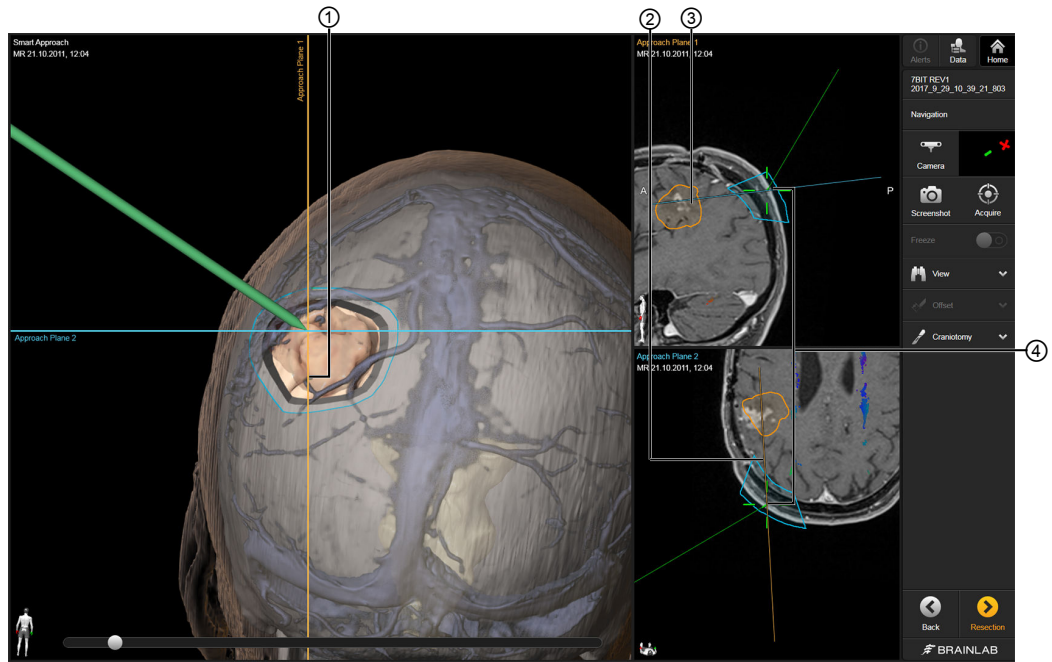


Figure 17

No.	Description
①	<p>Smart Approach view: When a pointer or instrument is visible to the camera, the approach planes intersect at the instrument tip. In this example:</p> <ul style="list-style-type: none"> • Approach Plane 1 intersects the tumor (to the left side). • Approach Plane 2 intersects the tumor (at the top).
②	The 2D Approach Plane 1 view intersects the tumor.
③	The 2D Approach Plane 2 view intersects the tumor.
④	The instrument tip is displayed by a crosshair in the 2D slice views.

3D + Inlines Layout

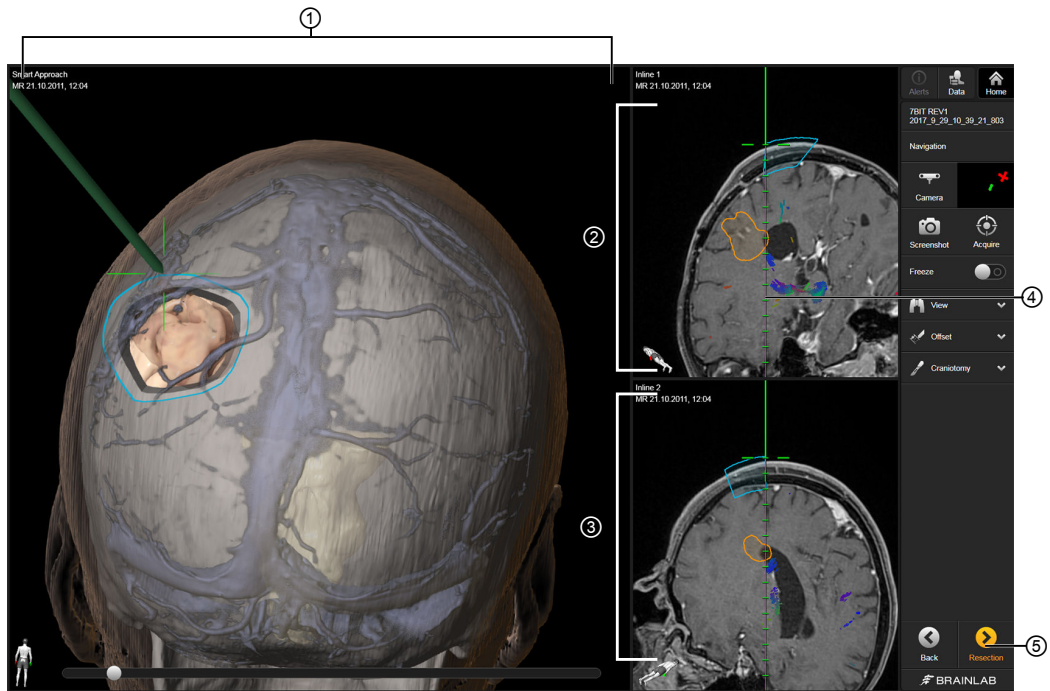


Figure 18

No.	Description
①	A 3D view of the data set. In the Smart Approach view, you can rotate the 3D model so that it reflects the surgeon's view of the patient. Move the view slider to unpeel the layers.
②	Inline 1: Displays a reconstruction plane spanned by the instrument axis in a vertical direction.
③	Inline 2: Displays a view perpendicular to the Inline 1 view.
④	A prolongation of the instrument is shown in the 2D views.
⑤	Select Resection to open the resection step.

How to Draw a Craniotomy Object

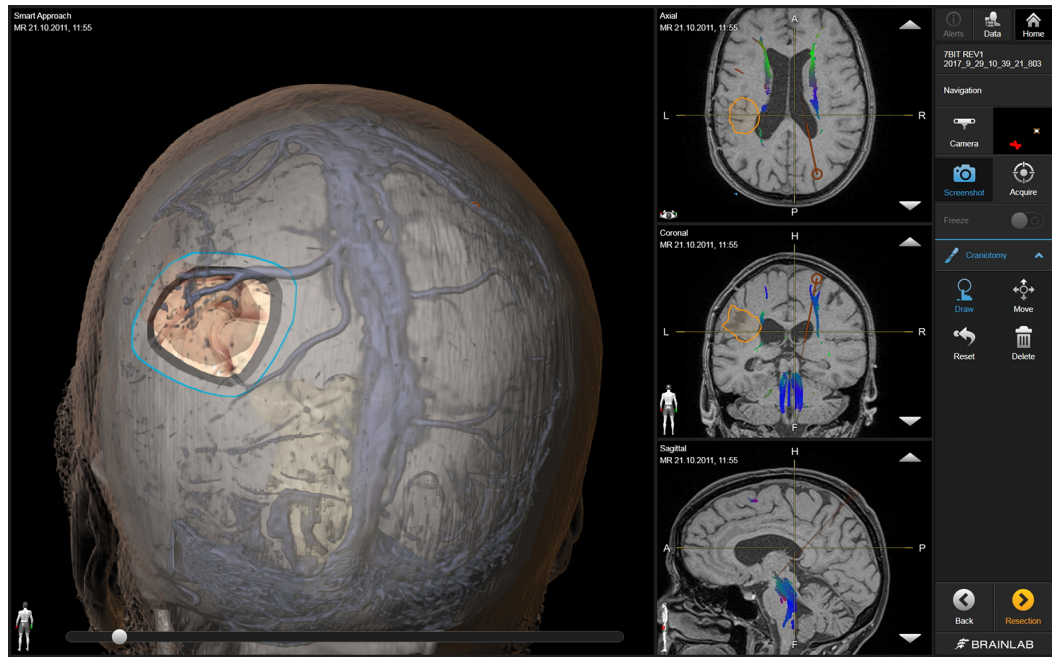
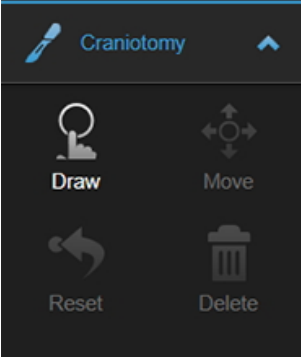


Figure 19

In the craniotomy step, you can draw a craniotomy object. Open the **Craniotomy** menu by selecting the arrow.

You can only create one craniotomy object at a time.

Step	
1.	 <p>Open the Craniotomy menu. When first opened, only Draw is active.</p>
2.	Select Draw or pivot a pointer within 5 mm of the skin to begin drawing an object.
3.	As soon as you start drawing, other menu options become available. You can now Move , Reset or Delete a craniotomy object.

How to Use Freeze Mode

During navigation, it may be useful to freeze the view (e.g., in order to check the distance from the pointer to the **View Center**).

Step
1. Navigate to the desired angle and view.

Step

2. Toggle on **Freeze**.

3.

A lock symbol ② appears in the upper right of each view and the instrument appears frozen in the image.
4. To check the distance, pan the 2D view of your choice.
5. The distance from the pointer to the set **View Center** is displayed ①.

4.3 Resection Step

Background

After selecting **Resection** in the craniotomy step, you are asked to define a **Rescue Registration**. Afterwards, the **Resection** step opens.

Select **Data** to switch between the available layouts described below.

NOTE: The available layouts depend on your license and the available data sets (e.g., the angio layouts are only visible if a pair of DSA/CIP images are available).

Define a Rescue Registration



Figure 20

Option	Description
Yes	Opens Rescue Registration
No	Continues to the resection step

For more information on rescue points, refer to the **Registration Software User Guide**.

3 Views Layout

This layout is completely customizable via drag and drop.

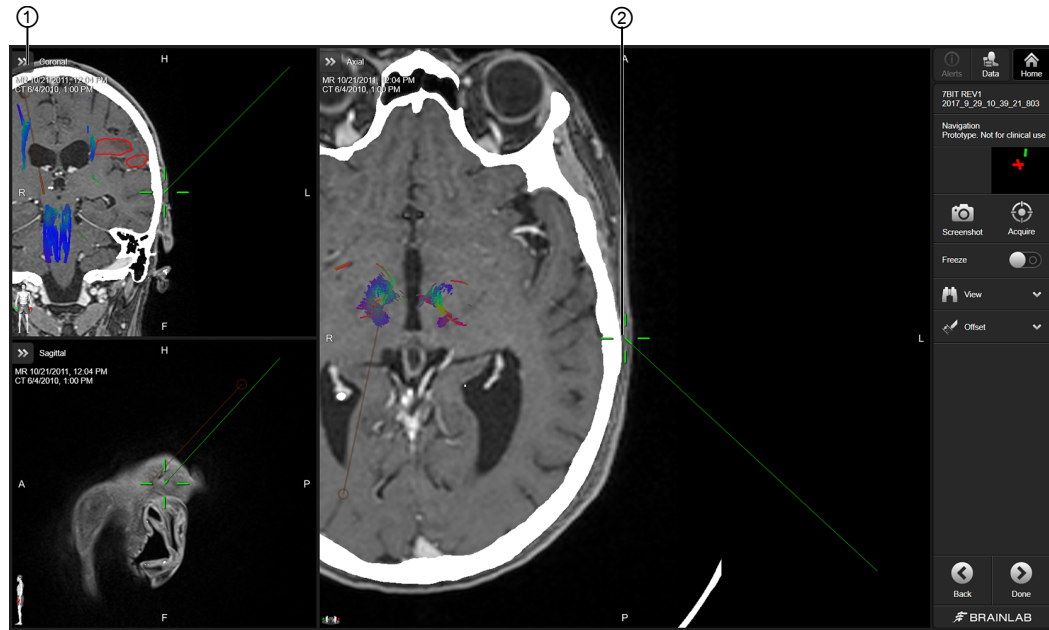


Figure 21

No.	Description
①	In any view pane, select the arrow in the upper left to select a view (e.g., Coronal).
②	The crosshair marks the position of the instrument tip.

4 Views Layout

This layout is completely customizable via drag and drop.

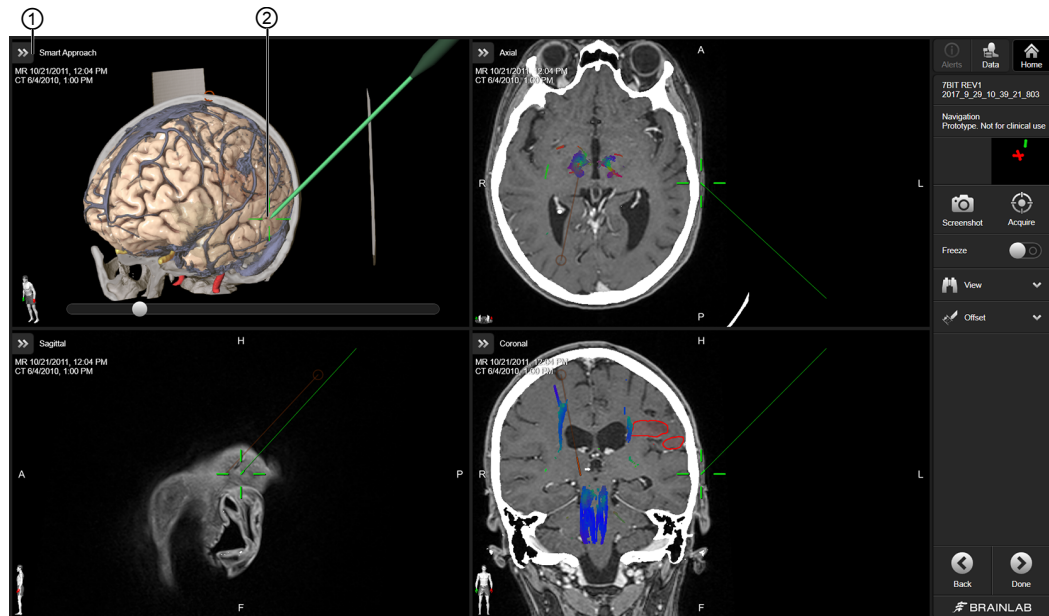


Figure 22

No.	Description
①	In any view pane, select the arrow in the upper left to select a view (e.g., Smart Approach).

No.	Description
②	The crosshair marks the position of the instrument tip.

6 Views Layout

This layout is completely customizable via drag and drop.

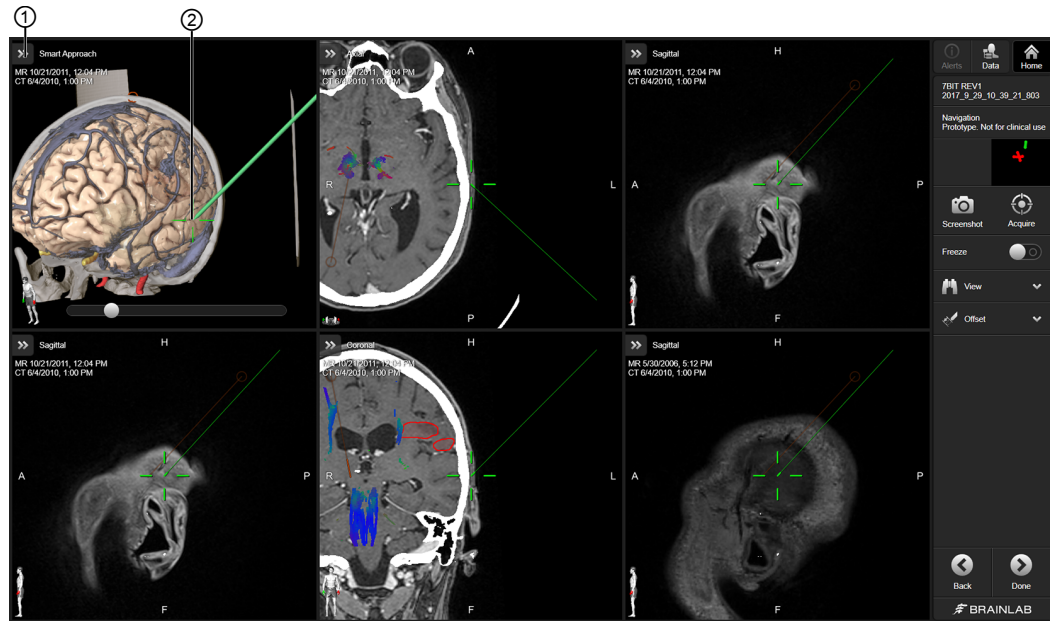


Figure 23

No.	Description
①	In any view pane, select the arrow in the upper left to select a view (e.g., Smart Approach).
②	The crosshair marks the position of the instrument tip.

Angio Layouts in the Resection Step

Angio data provides additional information about vessels in the area of interest. The angio layouts connect vascular flow information with anatomical information.

Select **Data** to switch between the two available layouts described below.

You can drag and drop content into both layouts.

Angio + Reconstructions Layout

This layout is customizable via drag and drop. 2D DSA views are always assigned as a pair.

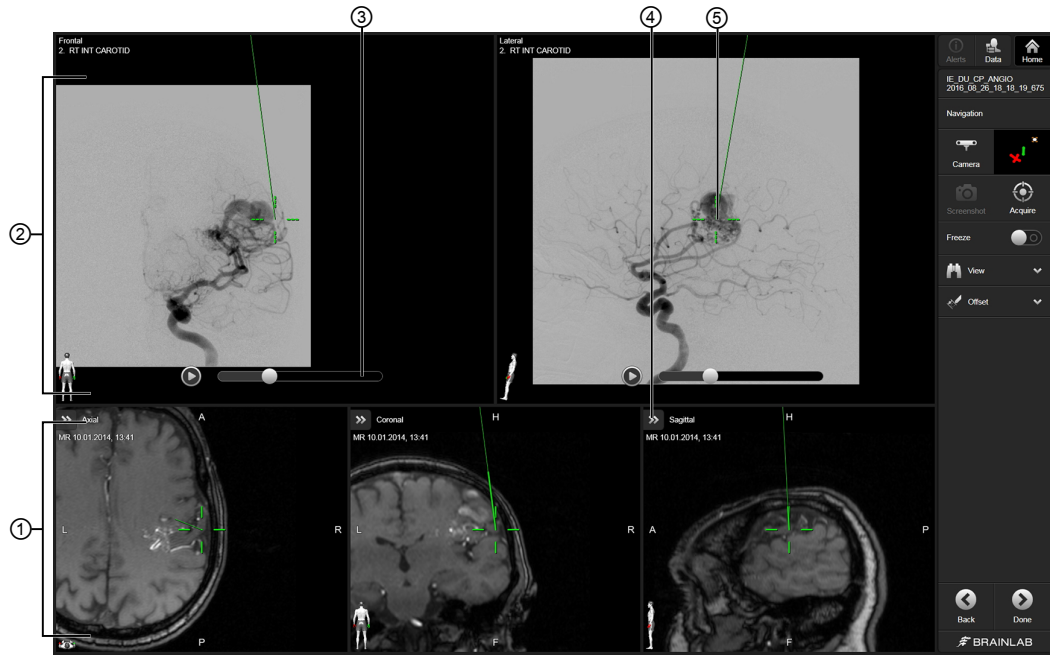


Figure 24

No.	Description
①	Drag and drop the required data sets into the layout. All views are customizable.
②	Drag and drop the required data sets into the layout. Views display frontal and lateral DSA image sequences. You can also display other content (e.g., Points , Trajectories , Objects).
③	Select the Play arrow or adjust the slider on Movie Player Control to view the entire DSA image sequence.
④	Configure the view by selecting the arrow buttons.
⑤	The crosshair marks the position of the instrument tip.

Angio + MIP Layout

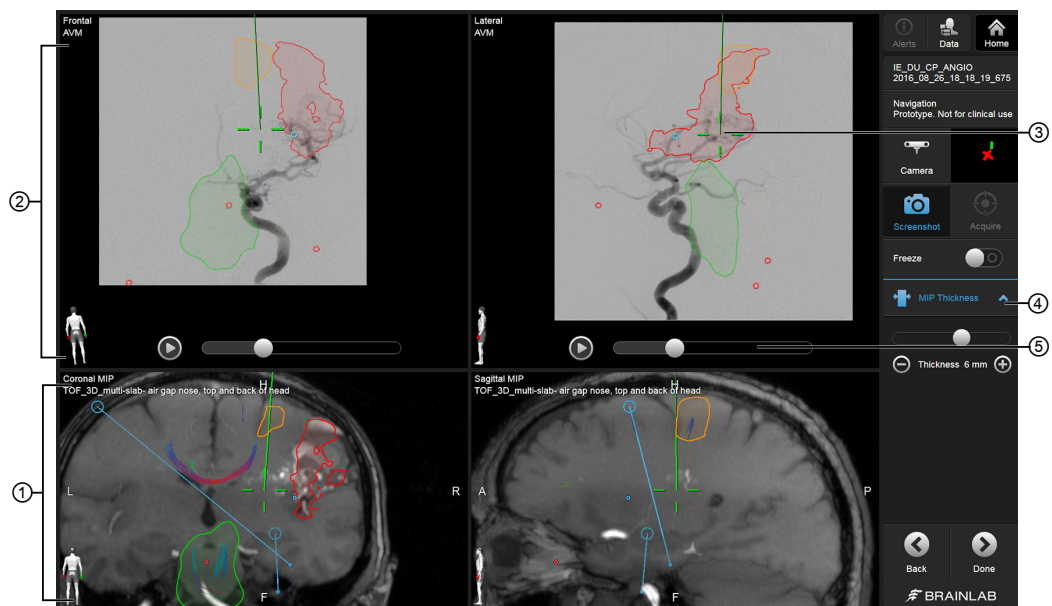


Figure 25

No.	Description
①	Drag and drop the required data sets into the layout. Views display coronal and sagittal slice views.
②	Drag and drop the required data sets into the layout. Views display frontal and lateral DSA images. You can also display other content (e.g., Points , Trajectories , Objects).
③	The crosshair marks the position of the instrument tip.
④	The MIP Thickness menu enables you to set or change the MIP thickness.
⑤	Select the Play arrow or adjust the slider on Movie Player Control to view the entire DSA/CIP image sequence.

MIP Thickness Menu

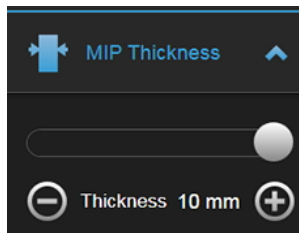


Figure 26

Available only when an **Angio + MIP** layout is active, the **MIP Thickness** menu allows you to set or change the MIP thickness. Drag the slider or press the ⊖ and ⊕ symbols to set a thickness of the MIP reconstruction. Values range from 0 - 10 mm.

NOTE: A maximum intensity projection (MIP) is a volume visualization for 3D data which projects the voxels with the maximum intensity along the viewing direction in the visualization plane. The MIP view shows structures with the highest contrast (e.g., vessels).

*NOTE: By default, **MIP Thickness** is set to 0, which represents a standard reconstruction of your selected slice thickness.*

4.4 Ultrasound Overlays

Background

Although **Navigation** cannot acquire ultrasound scans itself, intraoperative scans acquired by **Ultrasound Navigation** are made available to **Navigation**. For further information, see the **Ultrasound Navigation Software User Guide** and the **Origin Data Management Software User Guide**.

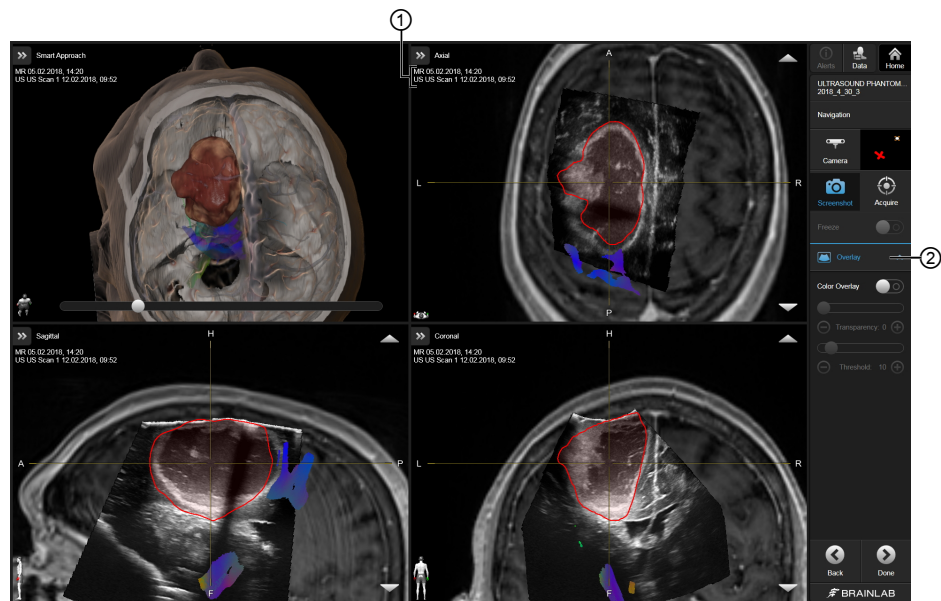
If you have ultrasound data, you can view it in **Navigation** and/or overlay it on existing MR/CT data sets. Ultrasound can be dragged into any layout and can be viewed as an overlay in any 2D view.

NOTE: If an ultrasound has been added to a layout but cannot be viewed, the name will still appear in the view.

About Intraoperative Scans Acquired with Ultrasound Navigation

The initial ultrasound scan is automatically displayed as an overlay on top of all views in the current layout. Subsequent ultrasound scans replace the older scans in the views in which they are shown as an overlay (the sequence number is appended to the scan name).

Before acquiring consecutive ultrasound scans, you can adapt where the ultrasound overlays are shown via **Data** and the **Overlay Mode** editor.



No.	Description
①	The names of each displayed image set appear below the view arrow. If an ultrasound is displayed, the scan's sequence number is also displayed.
②	Select Overlay to access Threshold and Transparency tools.

Adjusting Overlays

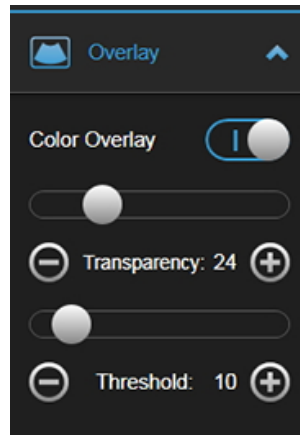


Figure 27

To view a color overlay of an ultrasound over another image set, select the arrow to open the **Overlay** menu and toggle on **Color Overlay**.

To view the overlay in black and white, toggle off **Color Overlay**.

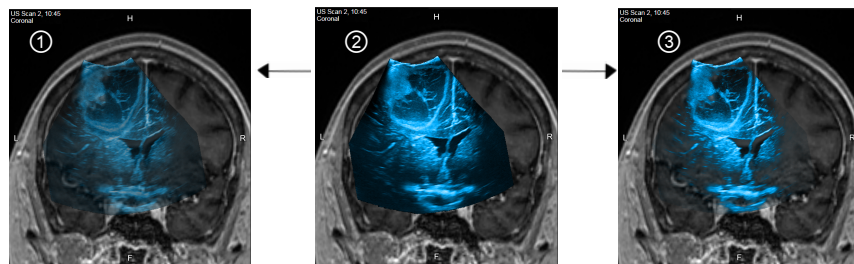


Figure 28

When **Color Overlay** is active, you can adjust the transparency and/or threshold of a scan ② to better see objects and contours. Press the ⊖ and ⊕ symbols or drag the slider to:

- Adjust **Transparency** to make the ultrasound scan less opaque ①.
- Adjust **Threshold** to gradually blend out dark areas ③.

To change which data is shown as an overlay, go to **DATA** and toggle on the **Overlay Mode** editor.

Related Links

Overlay Mode Editor on page 30

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