



LEAD **LOCALIZATION**

Version 1.0

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 811	
Japan	Tel: +81 3 3769 6900 Fax: +81 3 3769 6901	

Expected Service Life

Software updates and field support are offered for five years of service for this product.

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 registered trademark of Brainlab AG in Germany and/or the US.

Non-Brainlab Trademarks

Microsoft[®] and Windows[®] are registered trademarks of Microsoft 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:

- Independent JPEG Group (<https://github.com/uclouvain/openjpeg/blob/master/LICENSE>)
 - OpenJPEG library (<http://www.openjpeg.org>) and (<http://www.libjpeg-turbo.org>)
 - Apache Software Foundation (www.apache.org/)
 - Xerces C++ 3.1.1, developed by the Apache Software Foundation (<http://xerces.apache.org/>)
 - libtiff 4.0.4 beta (<http://www.libtiff.org/misc.html>)
 - Portions of this software are based on the work of Sun Microsystems, Inc.
-

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").
 - **Lead Localization** is a Class IIb product according to the rules established by the MDD.
-

Sales in the 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

Lead Localization Intended Use

The **Lead Localization** application suite is intended to be used post-operatively on a (laptop) computer in or outside an operating room to define the position of implanted leads in relation to patient imaging.

Indications for Use

Lead Localization indications for use are the viewing, presentation and documentation of medical imaging, including different modules for image processing, image fusion, atlas assisted visualization and segmentation, intraoperative functional planning where the output can be used e.g., with stereotactic image guided surgery or other devices for further processing and visualization.

Example procedures include but are not limited to:

Review of cranial surgical procedures, such as minimal-invasive stereotactic interventions, biopsy, planning and simulation of trajectories for stimulation and electrode recording.

Intended User

Lead Localization users are healthcare professionals educated for the planning and execution of DBS procedures. These are in general neurosurgeons or neurologists.

Patient Group

There are no demographic, regional or cultural limitations for patients. It is up to the medical professional to decide if the system shall be used to assist a certain treatment. Example procedures are listed in the indications for use.

Place of Use

The intended use environment is a (laptop) computer in a hospital (in office and operating room environment) or a doctor's office. The common use environment is an office environment.

Careful Handling



Warning

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

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 and Software

Global Trade Item Number (GTIN)

Lead Localization 1.0 is identified by GTIN: 04056481006884.

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.

Compatible Non-Brainlab Software

Lead Localization 1.0 is compatible with:

- Microsoft Windows Server 2008/2012
- Microsoft Windows 7
- Microsoft Windows 8.1
- Microsoft Windows 10

For detailed and up-to-date information regarding compatible operating systems, please contact Brainlab support.

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

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) 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.



Warning

Do not download or install updates during treatment planning.

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

Updates



Warning

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.

1.6 Training and Documentation

Brainlab Training

Before using the system, Brainlab recommends that all users should participate in a training program held by a Brainlab 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.

Intended Audience

This user guide is intended for surgeons, neurologists and/or their staff.

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	<ul style="list-style-type: none"> • 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 User Guide	Detailed information on system setup
Technical User Guide	Detailed technical information on the system, including specifications and compliances
System and Technical User Guide	Combines the contents of the System User Guide and the Technical User Guide.

2 SOFTWARE OVERVIEW

2.1 Software Overview Introduction

General Information

Lead Localization is designed to support neurosurgeons in localizing the position of leads in medical imaging data (e.g., these leads are implanted for Deep Brain Stimulation (DBS) therapy).

Typical Workflow

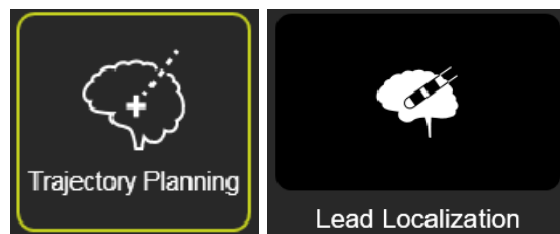



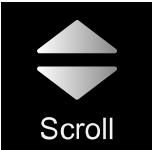
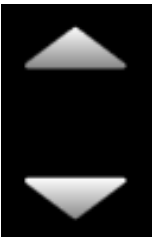


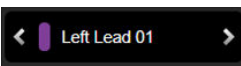
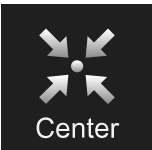
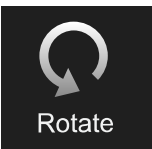

Figure 1

Lead Localization is typically used as a part of the **Trajectory** workflow, and includes the use of both required and optional additional applications. For more information, see the **Software User Guides** for these applications.

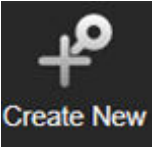
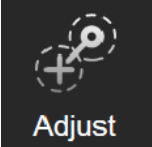
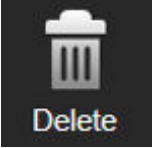

Step
1. Start Lead Localization .
2. Select patient data in Patient Selection .
3. Optional: Fuse image sets using Image Fusion .
4. Optional: Segment structures using Anatomical Mapping .
5. Optional: Create, modify and remove fiber bundles using Fibertracking .
6. Optional: Create, modify and remove objects using SmartBrush .
7. Localize and define leads using Lead Localization .
8. Save as a plan and close Lead Localization .

2.2 Image Viewing Functions

Viewing Functions

Button	Function
 <p>Zoom</p>	<p>Zoom: Activates zoom function to the region of interest. <i>NOTE: Alternatively use Ctrl and the mouse wheel.</i></p>
 <p>Scroll</p> 	<p>Scroll: Activates scroll functions in the displayed reconstruction (plane). For each view and interaction option, there is a dedicated scroll increment:</p> <ul style="list-style-type: none"> • Use the in-view buttons to scroll up/down 1 mm • Drag the mouse pointer within the main view to scroll up/down (zoom level dependent) • Turn the mouse wheel with the mouse pointer over the Inline side view to scroll up/down 0.5 mm in the trajectory direction <p><i>NOTE: Some scroll functions are available independently of Scroll being activated.</i></p>
 <p>Pan</p>	<p>Pan: Pans vertical and horizontal planes. <i>NOTE: Alternatively use Ctrl and the left mouse button to pan.</i></p>
 <p>Windowing</p>	<p>Windowing:</p> <ul style="list-style-type: none"> • Drag left or right across the viewing area to adjust the contrast. • Drag up or down to adjust the brightness.
	<ul style="list-style-type: none"> • Selects the active lead. • Use arrow buttons to toggle between leads.
 <p>Center</p>	<p>Center: Automatically scrolls and pans the reconstruction to display the target/entry (at the center of the view).</p>
 <p>Rotate</p>	<p>Rotate: Rotates the current view.</p> <ul style="list-style-type: none"> • Rotates the 2D reconstruction in relation to other views. • Rotates the 3D reconstruction plane.
 <p>Undo</p>	<p>Undo: Undoes the last change made or multiple consecutive steps.</p>

Trajectories Functions

Button	Function
 Create New	Create New: Creates a new trajectory. Drag the target and entry points to align the trajectory.
 Adjust	Adjust: Enables adjustment of target and entry points.
 Delete	Delete: Deletes the selected lead or trajectory.
 Undo	Undo: Undoes consecutive changes made to the position of target or entry points.

2.3 Data Menu

Using the Data Menu

To access the available patient data and other content (e.g., **Objects**, **Trajectories** and **Fiber Bundles**) or change layouts, select **Data** to open the **Data** menu.

Data Menu Layout

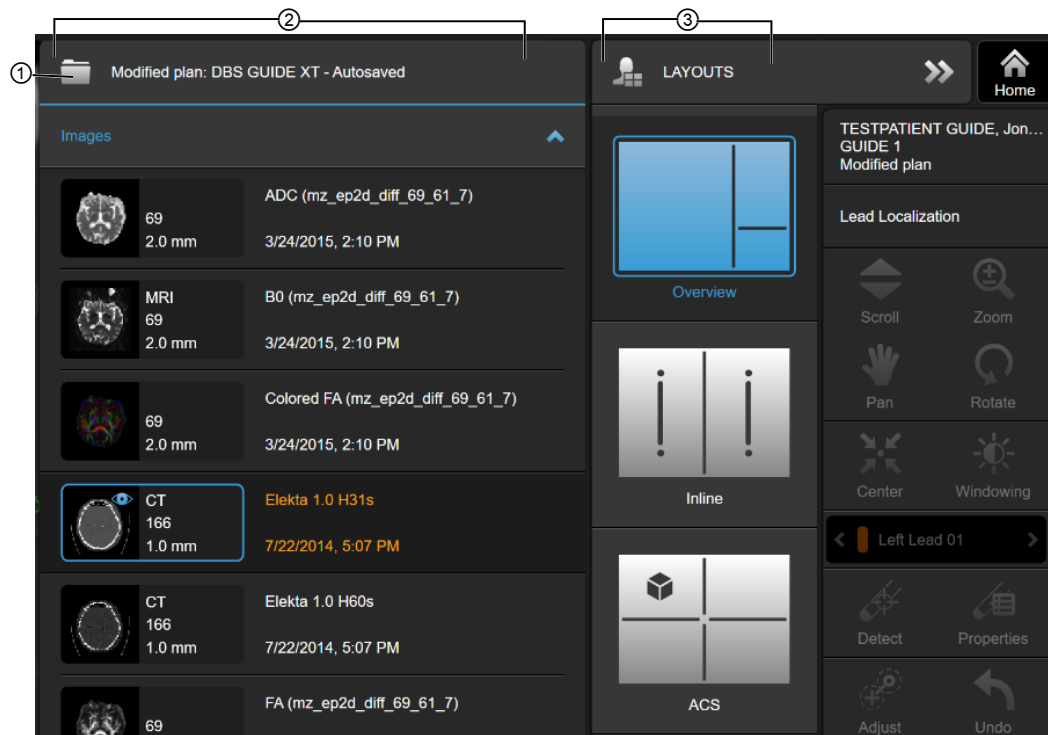


Figure 2

No.	Description
①	The selected plan status and name is displayed within the Data menu.
②	View and select available patient data
③	Switch between available layouts

Data Menu: Images

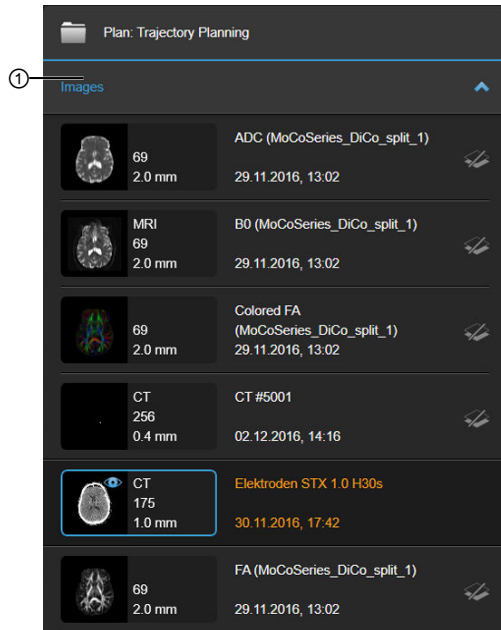


Figure 3

In the **Images** drop down ①, you can select the images to display in the views.

Data Menu: Objects

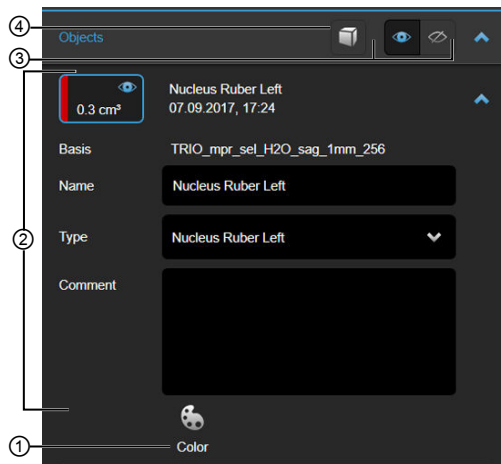


Figure 4

Objects may include auto-segmented or drawn objects.

No.	Component
①	Color selection

No.	Component
②	Object characteristics: <ul style="list-style-type: none"> • Basis • Name assigned to the object • Type • Comment
③	Show/hide all objects (in 3D view) <i>NOTE: You can also show/hide individual objects. When outlined in blue, an object is set to visible.</i>
④	Toggle 2D/3D objects (in 3D view)

Data Menu: Trajectories

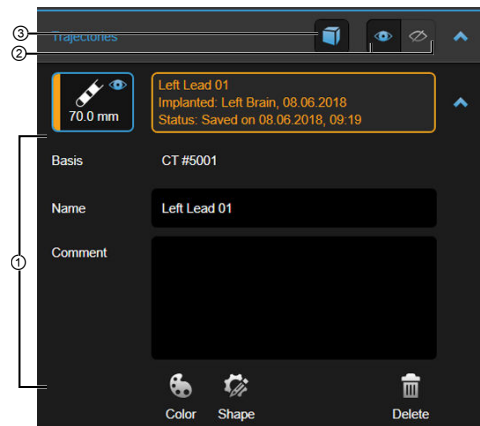


Figure 5

No.	Component
①	Lead characteristics: <ul style="list-style-type: none"> • Basis • Name • Comment
②	Show/hide leads/trajectories
③	Toggle 2D/3D leads/trajectories (in 3D view)

Data Menu: Fiber Bundles

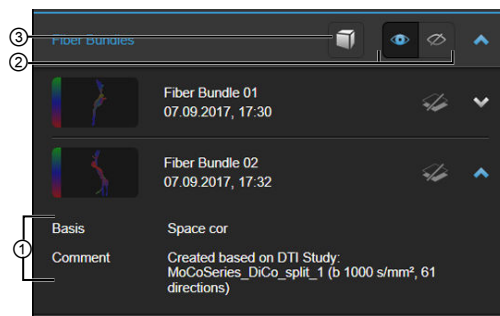


Figure 6


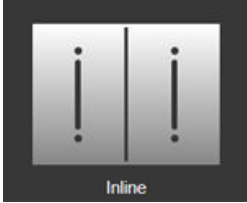

No.	Component
①	Fiber bundle characteristics: <ul style="list-style-type: none">• Basis• Comment
②	Show/hide fiber bundles
③	Toggle 2D/3D fiber bundles (in 3D view)

2.4 Layouts

Available Layouts

Select **Data** to open the **Layouts** menu and switch between layout views.

By switching between **Overview**, **Inline** and **ACS** layouts, you have different visualization options for reviewing the leads.

Layout	Description
 <p>Overview</p>	<p>Overview: The Overview layout combines a large view showing an axial, coronal or sagittal reconstruction in combination with an Inline and a Perpendicular view.</p>
 <p>Inline</p>	<p>Inline: Use the Inline layout to scroll through the data set for verification purposes</p>
 <p>ACS</p>	<p>ACS: ACS layout displays the axial, coronal or sagittal views, as well as a perpendicular view.</p>

Overview Layout

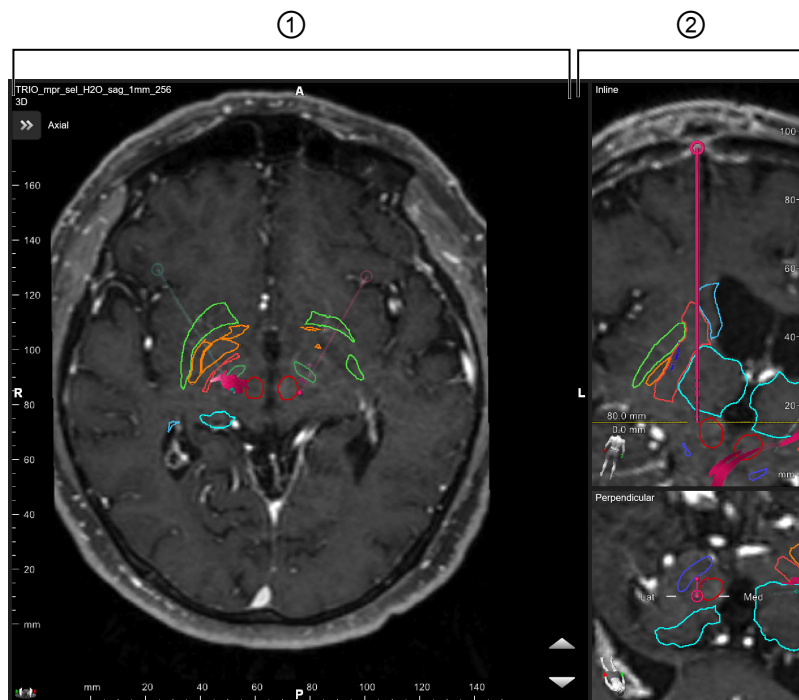


Figure 7

No.	Component
①	3D view: Switch between axial, coronal or sagittal views. <i>NOTE: Use the Rotate function to dynamically switch between axial, coronal or sagittal views.</i>
②	<ul style="list-style-type: none"> • Inline view: The yellow depth line is adjustable. Changes are reflected in the Perpendicular view. • Perpendicular view

View Intention

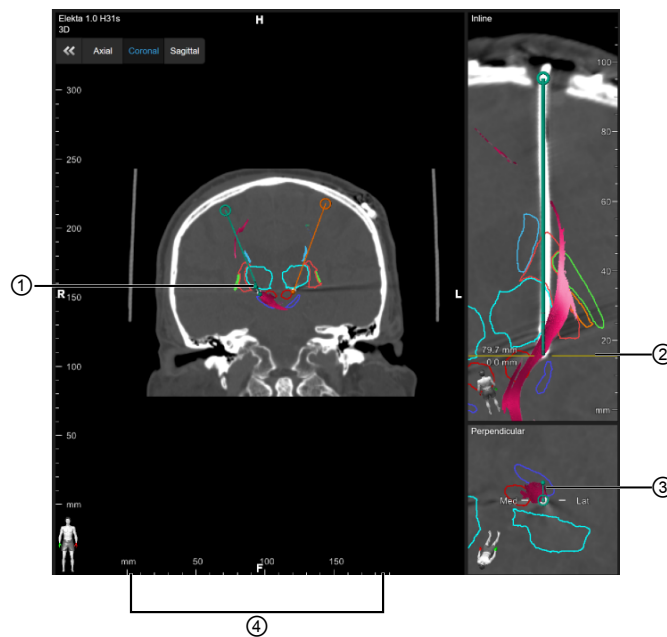


Figure 8

In the **Inline** and **Perpendicular** views:

- Rotation made in one view, is reflected in the other
- Objects are shown in 2D
- The medial/lateral directions are identified in the **Perpendicular** view

In the **3D** view:

- The dot ① represents the intersection of the yellow line ② with the lead in the **Inline** view
- The ruler ④ is only visible in the **3D** view when you are in-plane with axial, coronal or sagittal orientations

For directional leads, the orientation is represented by a directional marker ③.

Lead Display

An intersection point is the point in 3D space where the lead axis intersects the displayed reconstruction plane.

An intersection point is displayed:

- Beyond entry
- Between target and entry
- Beyond target

When the depth position is placed on the target point, after selecting **Center**, the intersection point indicates the exact position of the target.

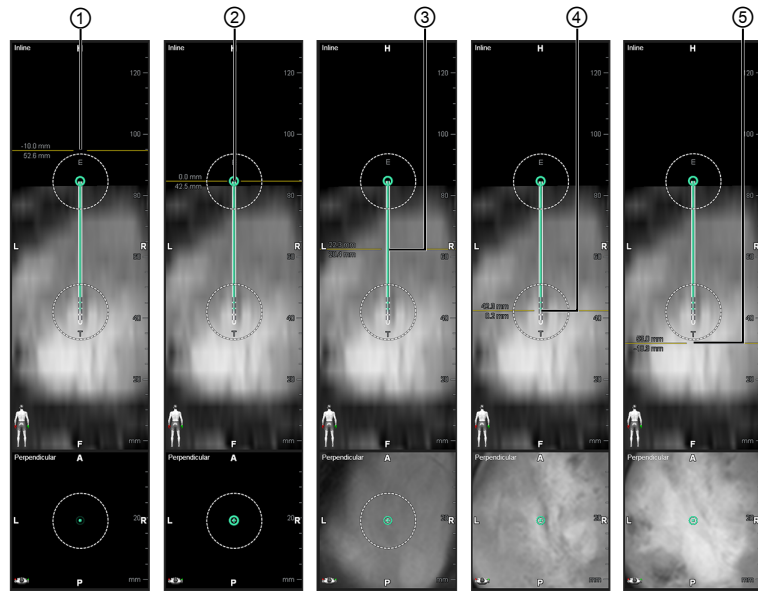


Figure 9

No.	Explanation
①	The intersection point is beyond entry
②	The intersection point is the entry
③	The intersection point is between the target and entry
④	The intersection point is the target
⑤	The intersection point is beyond the target

Inline Layout

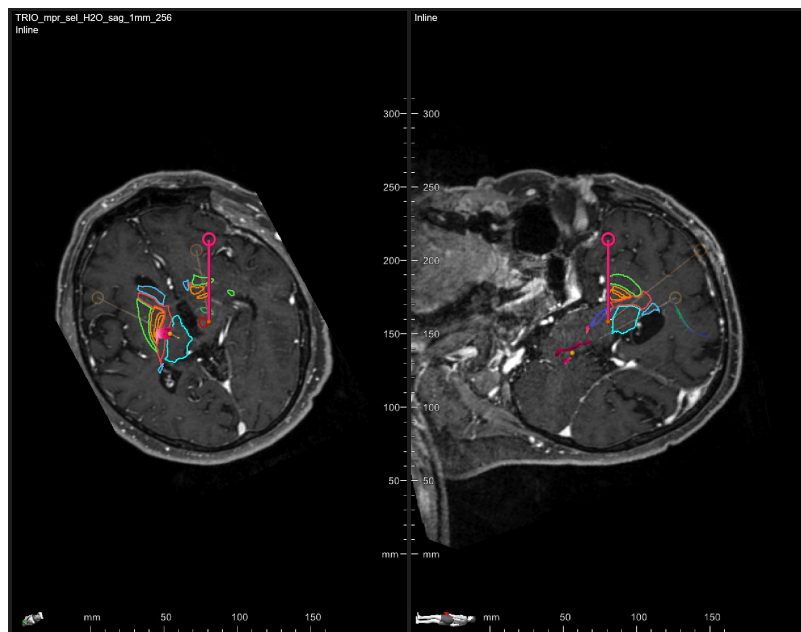


Figure 10

Inline layout allows you to compare the trajectory path in two views aligned to the path, where one view is orthogonal to the other.

ACS Layout

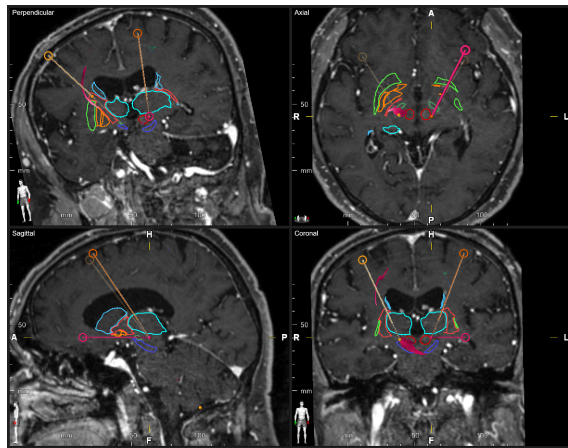


Figure 11

When panning the views, a white crosshair indicates the view center. When scrolling the views, a yellow crosshair shows the intersection of the current trajectory with the reconstruction plane.

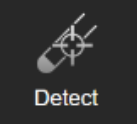
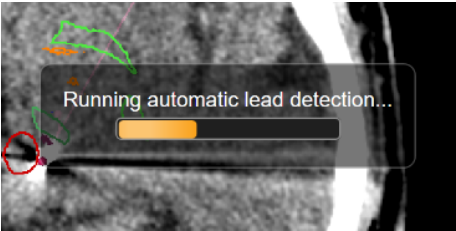
3 USING LEAD LOCALIZATION

3.1 Getting Started with Lead Localization Software

Getting Started

Before you can adjust lead or trajectory position or create 3D shapes, you must first detect leads and define orientation.

How to Detect Leads

Step	
1.	 Select Detect in the main menu.
2.	 A progress bar fills. Leads are detected and assigned names and colors.

Optional: How to Define Leads

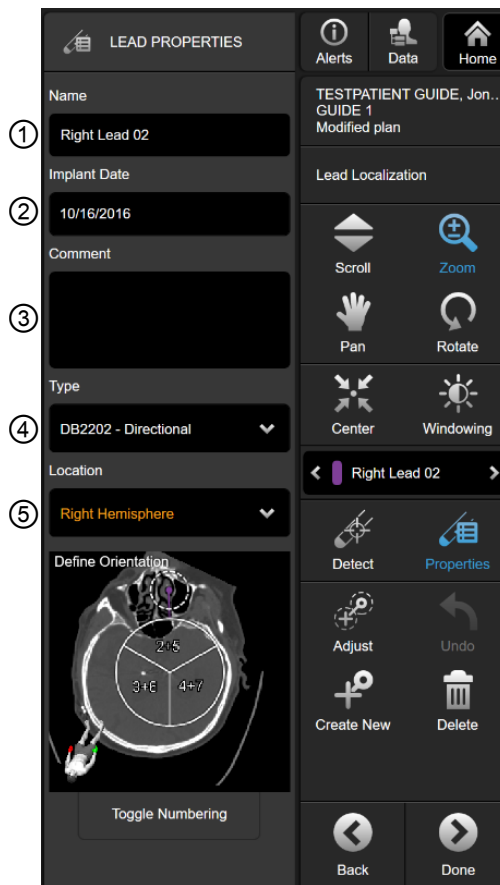
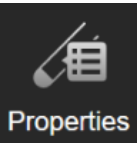


Figure 12

Specific lead models can be defined by assigning the model type and various additional parameters. Based on these parameters, a corresponding lead model is visualized and the lead can be utilized in other applications that interpret this information.

Step	
1.	 Select Properties .
2.	Optional: Edit the automatically assigned lead Name ①.
3.	Optional: Edit the automatically assigned Implant Date ②.
4.	Optional: Enter a Comment ③.
5.	Required: Select lead Type ④.
6.	Required: Select Location ⑤ in which the lead is situated.
7.	Optional: Select a different lead and repeat lead definition.

NOTE: Brainlab recommends naming and assigning different colors to distinguish between different leads, trajectories, objects, etc.

Define Orientation

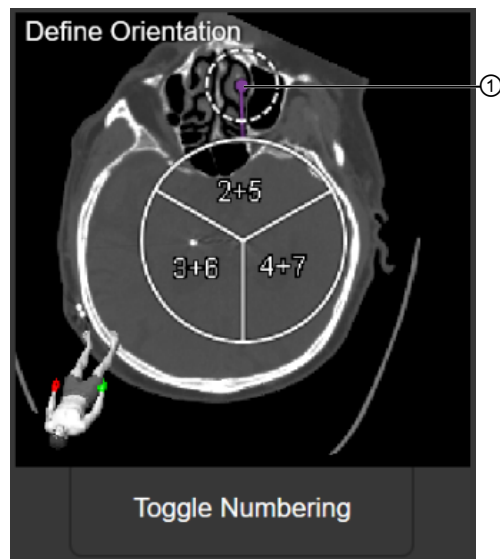


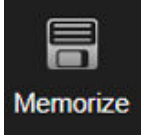
Figure 13

If you have defined a directional lead, the **Define Orientation** view opens. Drag the orientation marker ① to rotate the orientation.

Select and hold **Toggle Numbering** to display how the contact numbering would be if connected to the other IPG port.


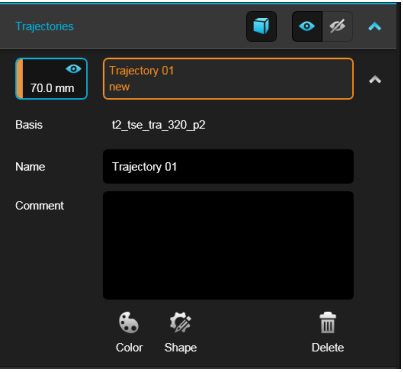
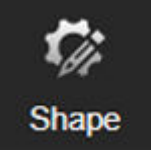
3.2 Creating 3D Shapes

Memorize Function

Button	Function
	Saves modified parameters to use as default settings for later use.

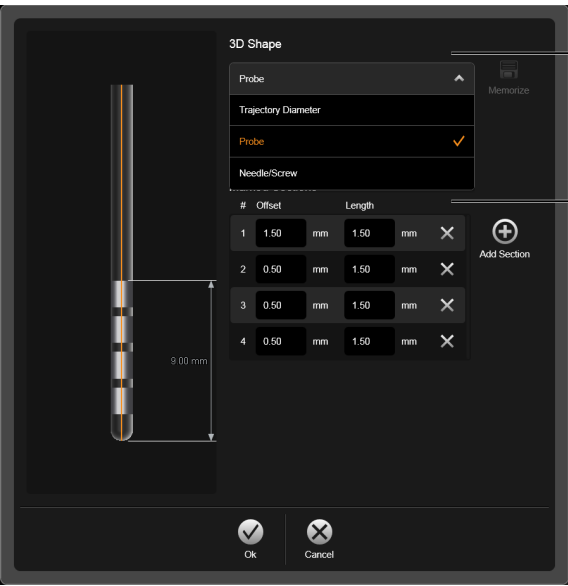
How to Create 3D Shapes

You can assign the type, shape and characteristics of an instrument as a visual aid for positioning the target and entry of an abstract trajectory.

Step	
1.	 <p>Open the Data menu.</p>
2.	 <p>Open the Trajectories drop down.</p>
3.	Select a trajectory and open it by selecting the down arrow.
4.	 <p>Select Shape.</p>

Step

5.



Select a **3D Shape** type from the drop-down menu ①.
The **3D Shape** shown on the left changes to match your selection.

6. Select **OK**.

Related Links

3.1.1 Optional: How to Define Leads on page 26

How to Adjust Shape Parameters

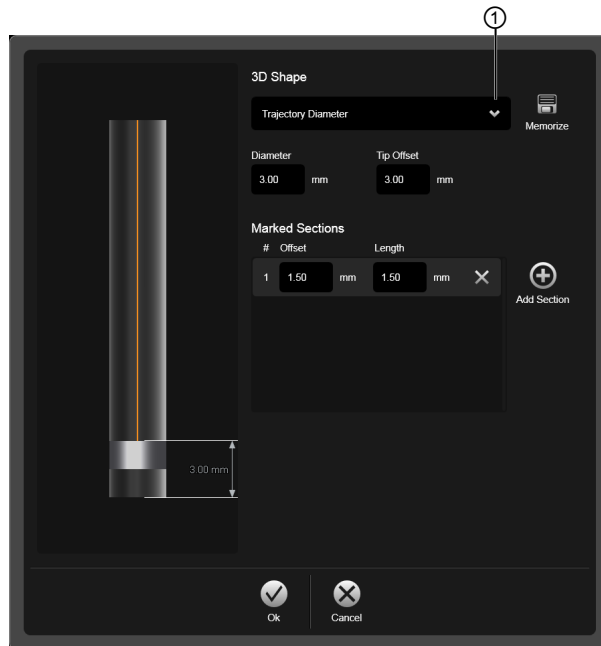



Figure 14

Each **3D Shape** type has parameters that can be adjusted.

Step	
1.	Select a 3D Shape type from the drop-down menu ①.
2.	 Use Add Section to add a new marked section to the 3D Shape .
3.	Amend the parameters as appropriate to your surgical application, e.g.: <ul style="list-style-type: none">• Diameter• Tip Offset• Offset• Length
4.	Select Ok .

3.3 Adjusting Lead/Trajectory Position

Overview

You can reposition the target and entry points of the lead interactively within the views by dragging the point to the desired location.

How to Adjust Target and Entry Points

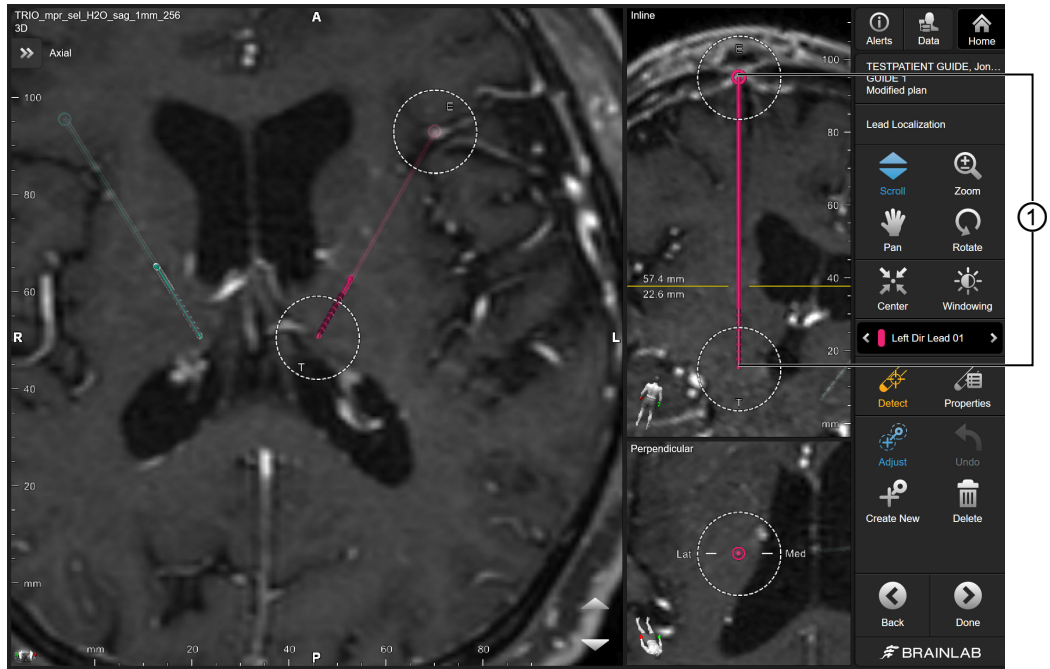
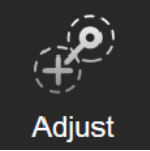


Figure 15

Step	
1.	 <p>Select Adjust to enable the adjustment of target and entry points.</p>
2.	<p>Drag the target/entry points ① to reposition them.</p>

How to Remove Trajectories

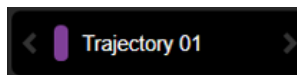
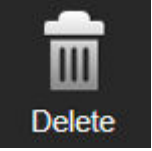


Figure 16

Step	
1.	<p>Select the trajectory in the toolbar or in the Data menu.</p>


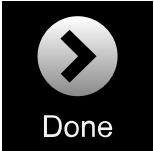

Step	
2.	 Select Delete . The trajectory is removed.

3.4 Saving and Closing the Software

Saving and Closing

To save or close the software, perform one of the following tasks.

Save or Close the Software

Button	Function
 <p>Back</p>	<p>Returns you to the previous step and discard changes.</p>
 <p>Done</p>	<p>Select Done to perform the following:</p> <ul style="list-style-type: none"> • Save your existing task • Close Lead Localization • Open another application <p><i>NOTE: A warning message appears if you select Done before reviewing all leads.</i></p>
 <p>Home</p>	<p>Select Home to save changes and return to Content Manager. The application runs in the background, so you can continue where you left off.</p>

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