

REGISTRATION SOFTWARE SPINE SURFACE MATCHING

Version 1.0

**Software User Guide
Revision 1.0**

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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

Brainlab provides eight years of service for software. During this period of time, software updates as well as field support are offered.

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.

Non-Brainlab Trademarks

Windows® is a registered trademark of Microsoft Corporation in the US 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>)
 - OpenJPEG (<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.libtiff.org/misc.html>)
 - Xerces-C++, developed by the Apache Software Foundation (<https://xerces.apache.org/xerces/>)
-

CE Label



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

Registration Software Spine Surface Matching is a part of the **Spine & Trauma 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.

Product Symbols

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

1.4 Using the System

Intended Use and Indications for Use/Intended Purpose

The **Spine & Trauma Navigation System** is intended as an intraoperative image-guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on a patient's preoperative or intraoperative 3D image data.

The **Spine & Trauma Navigation System** enables computer-assisted navigation of medical image data, which can either be acquired preoperatively or intraoperatively by an appropriate image acquisition system. The software offers screw implant size planning and navigation on rigid bone structures with precalibrated and additional individually-calibrated surgical tools.

The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, the pelvis, a long bone or vertebra can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image and 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy.

Known Contraindications

There are no known contraindications for the use of this device.

Place of Use

The planning tasks shall be performed in an office or in the operating room.
The navigation tasks shall be performed in an operating room/suite.

User Profiles

Neuro / Ortho / Spine / Trauma surgeons or their assistants having a 3D image acquisition system (such as CT or 3D C-arm), or utilizing preoperatively acquired CT / CT like (and potentially fused MR) imaging data in combination with a Brainlab navigation system.

Patient Population

The patient population includes any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, the pelvis, a long bone or vertebra can be identified relative to the acquired image (CT, 3D fluoroscopic image reconstruction).

Clinical Benefit

The **Spine & Trauma Navigation System** provides the following benefits:

- Higher accuracy in placement of screw implants in comparison to conventional techniques
- Reduced radiation dose for the operating staff in comparison to conventional techniques
- Lower (intra-operative and post-operative) complication rate due to misplaced screws in comparison to conventional techniques
- The need for the patient to return to the operating room for revision surgery is reduced or eliminated

Careful Handling of Hardware



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

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

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

- Accessory Package Spine for Anterior/Lateral/Oblique Referencing
 - Accessory Package Spine for Open Surgery (Awls & Probes)
 - Adhesive Flat Markers
 - Auto-Registration Hardware Fluoro 2D / 3D for 3D C-arms
 - Bone Fixator 1-Pin X-Press, Size S, M, L
 - Bone Fixator 2-Pin X-Press
 - Calibration Phantom CT Scanner
 - Chisel Long
 - Chisel Short
 - Disposable Reflective Marker Spheres
 - DrapeLink Reference Unit for C-arm Left, Right
 - Drill Bits with AO Shank
 - Drill Guide Handle with 3 Marker Spheres
 - Drill Guide Handle with 4 Marker Spheres
 - Drill Guide Compact Handle with 4 Marker Spheres
 - Drill Guide Tubes
 - Instrument Adapter Package
 - Instrument Adapter for Surgical Motor System
 - Instrument Calibration Matrix
 - Instrument Reference Unit for Manual Calibration Size ML, L
 - Instrument Reference Unit with 3 Marker Spheres
 - Instrument Reference Unit with 4 Marker Spheres
 - Microscope Tracking Array
 - Pedicle Access Needle Set for Manual Calibration
 - Pointer Extended with Sharp Tip for Spine / Trauma / Hip
 - Reference Array for Spine Clamps with 4 Marker Spheres
 - Reference Array Quick Fastener X-Press
 - Reference Array Y-Geometry X-Press
 - Reflective Disks for Fluoro Registration Kit
 - Skull Reference Array
 - Spine Reference Array for Reference Clamp Carbon (4-Sphere Geometry)
 - Spine Reference Clamp Carbon with Slider
 - Spine Reference X-Clamp Extension 40mm
 - Spine Reference X-Clamp Size S, L
 - Spine Reference Clamp Radiolucent
 - Standard Cranial Reference Array with 4 Marker Spheres
-

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**.

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



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.

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.

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

1.6 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 Camera and Monitor Setup

Setup Considerations

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 laser may interfere with other infrared-based OR equipment, such as remote controls, pulse oximeters or IR-sensitive microscopes.

How to Set Up the Camera and Monitor

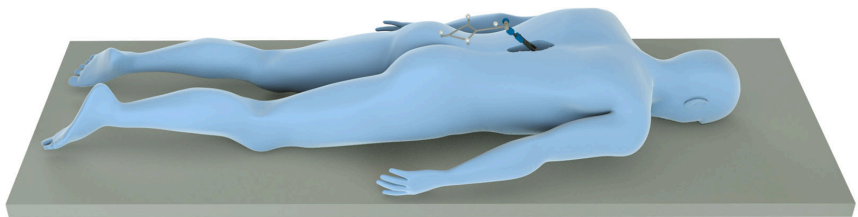
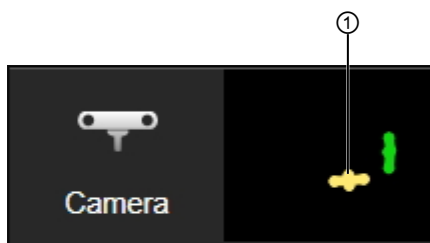


Figure 1

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: <ul style="list-style-type: none"> • Select a camera position that works throughout the entire procedure (including later 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.
2.	Plug in and turn on the system. Refer to the relevant 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

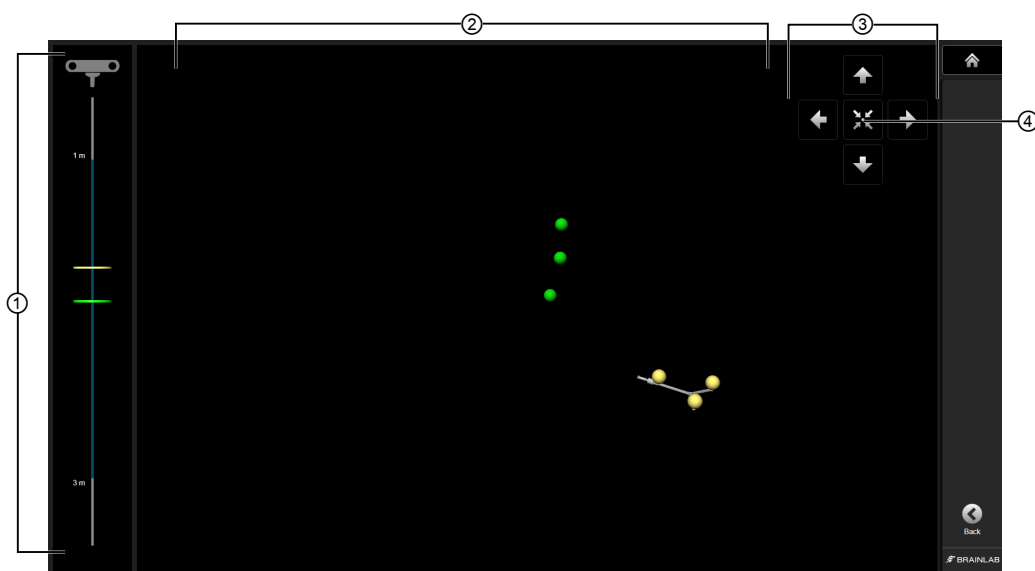


Figure 2

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	Camera motor control positioning buttons (if available).
④	Used to center the camera. <i>NOTE: Centering the camera takes up to five seconds. Select again to deactivate the centering feature.</i>

2.2 Reference Array Setup

Reference Array

Position the reference array so it remains visible for the entirety of the procedure, otherwise matching accuracy may be affected. 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.



The reference array must be attached to the vertebra being treated, and the surface matching registration must be performed on the same vertebra. Otherwise, the registration could be inaccurate.

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.



The marker spheres must be clean and securely attached to the base of the instrument or reference array.

2.3 Using the Pointer

General Information

The **Pointer Extended with Sharp Tip** is used to match a virtual position and 3D representation of a patient's bone in the software to the actual position of the patient's anatomy. It can be used alone or with a **Disposable Clip-on Remote Control**.

This enables the software to provide navigational information during surgery.

When a point is acquired, it means that the software has stored the position of the pointer tip relative to the position of the bone according to the reference array.

By these means, the software:

- Determines the location of the bone structure relative to the reference array.
- Places the acquired landmark in the correct relative position on the 3D bone model.

Pointer Handling

Use only the **Pointer Extended with Sharp Tip** for point acquisition.



Warning

Handle the pointer with extreme care. A bent pointer or a pointer with a broken tip may lead to extreme inaccuracies during patient registration and must not be used. Precalibrated and calibrated instruments cannot be used for registration.

Pointer Accuracy



Figure 3

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

Prior to the operation, use to check that the pointer is not bent.

Check pointer accuracy with the test gauge before each use, ensuring that the pointer tip aligns with the counter pin on the pointer gauge ①.

Standard Pointer Registration

In standard pointer registration, you pivot a calibrated **Pointer Extended with Sharp Tip** to acquire (register) specific landmarks on the patient's bone.

Prepare the surface of the bone before acquiring points. Acquire points directly on the bone surface, not on tissue, otherwise it may lead to inaccurate registration.

If the pointer tip moves away from the bone during point acquisition, points may be acquired “in the air” as well, reducing registration accuracy. During point acquisition, make sure the pointer tip is always directly on the bone in the scanned region.



Figure 4

Step
<p>Hold pointer tip to the landmark indicated and pivot the pointer slightly around its tip.</p> <ul style="list-style-type: none"> • If the tip moves during pivoting, the point is not acquired. • When a point is acquired, the software indicates the next point to acquire, or opens the next step.

Registration Using the Disposable Clip-on Remote Control

The **Disposable Clip-on Remote Control** enables active patient registration in combination with the **Pointer Extended with Sharp Tip**. For more information on the **Disposable Clip-on Remote Control** see the **Spine and Trauma Instrument User Guide**.

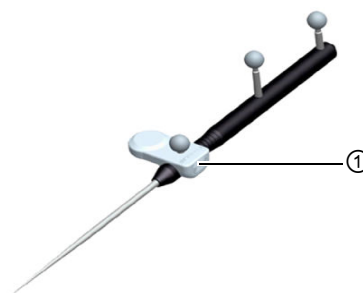


Figure 5

Step
<p>1. Hold pointer tip to the landmark indicated.</p>
<p>2. Press the control button ①.</p> <ul style="list-style-type: none"> • If the tip moves when you press the button, the point is not acquired. • When a point is acquired, the software indicates the next point to acquire.

3 SOFTWARE OVERVIEW

3.1 Introduction to Spine Surface Matching

Background

Registration Software Spine Surface Matching is a touchscreen-based intraoperative registration software. The placement of surgical instruments in a three-dimensional representation overlaid on anatomical image sets, such as CT and/or XT can support the surgeon during various surgical interventions.

Use **Registration Software Spine Surface Matching** to register the patient position relative to the preoperative scans prior to surgical navigation.

How to Open the Software

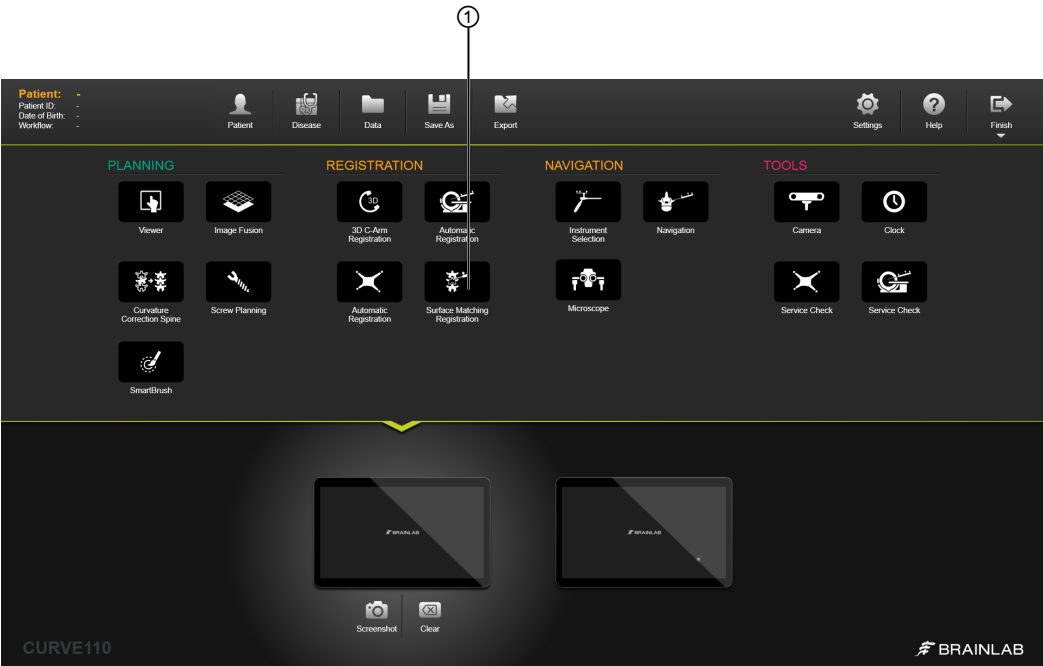


Figure 6

Step
1. Select a patient. For more information on patient and data selection, refer to the Patient Data Manager Software User Guide .
2. Select all appropriate patient data and any defined objects relevant for the procedure. All applications for the dedicated workflow are displayed.
3. Select Registration from the Spine workflow.

Step
4. Select Surface Matching Registration ① from the Registration options.

How to Select a Different Image Set

You can optionally select a different image set from the loaded data.

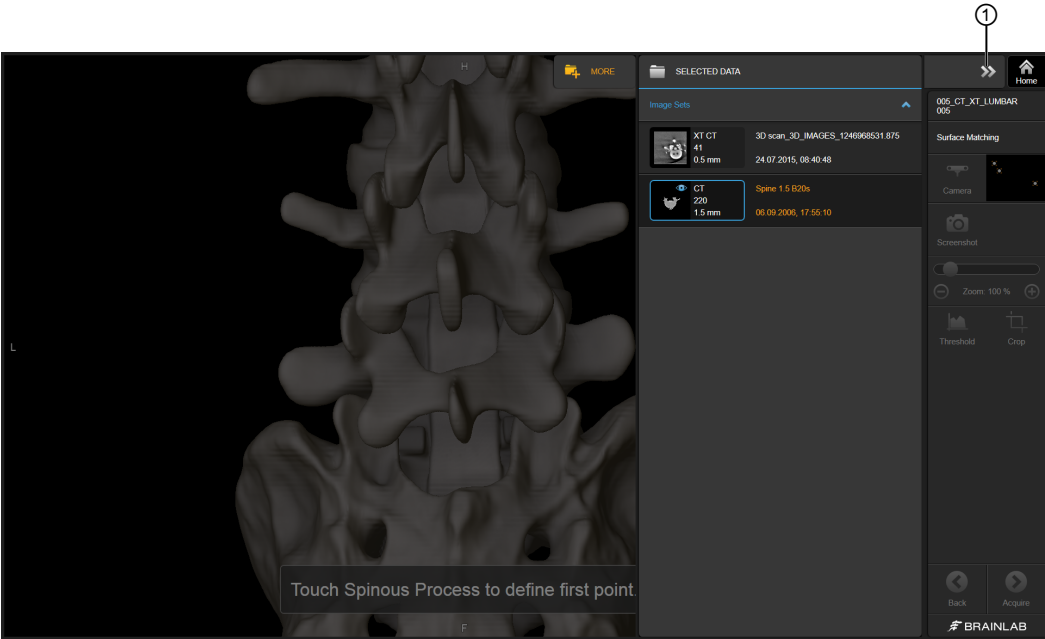








Figure 7

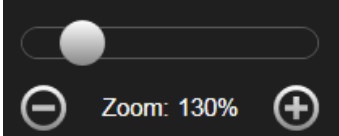
Step
1.  Select the Data button.
2. Select an image set from the SELECTED DATA list. To load additional data, select MORE .
3. Select the arrow button ① to proceed using the selected patient data.

3.2 Navigation and Viewing Functions

Basic Navigation Functions

Button	Function
 Alerts	Displays a list of alerts if the software detects any issues requiring your attention.
 Data	Displays the available image sets.
 Home	Returns you to Content Manager where you can select a new application or exit completely.
 Camera	Opens the camera app to display reference arrays, pointers or instruments in the camera field of view.
 Screenshot	Takes a screenshot of the current view. The screenshot is automatically saved with the patient data.

Viewing Functions

Button	Function	Description
	Zoom in or out of a slice	Press the ⊖ and ⊕ symbols or drag the slider: <ul style="list-style-type: none"> • Left to zoom out • Right to zoom in

4 REGISTRATION OVERVIEW

4.1 Registration Introduction

Background

During registration, the software maps the patient's preoperative image data to the physical anatomy of the patient's spine in its current position.

Correct registration is a key influencing factor for accurate navigation. Registrations must be verified as accurate and suitable for the procedure to ensure reliable navigation accuracy.

Before You Begin

Carefully read all relevant sections in the **Spine and Trauma Instrument User Guide**.

Image Set Requirements

To ensure sufficient accuracy, scan the patient as described in the **Spine and Trauma Scan Protocol**.

The following image set requirements apply for all scans:

- The image set must contain the entire area of interest on the patient's anatomy.
- Must be CT or XT data.



Slice thickness for CT scans must not exceed 2 mm. Refer to the Spine & Trauma 3D Navigation scan protocol for details.

Safety Considerations



Ensure that the patient's anatomy has not changed from the scan. This results in incorrect registration and navigation.

4.2 Bone Threshold and Cropping

Bone Threshold Background

The bone threshold is the value above which the software determines objects in scans to be bone, not tissue.

When the bone threshold is set correctly, no tissue is visible and the bone surface in the images appears smooth and solid, especially in areas where registration points are to be acquired. If the threshold is too low or too high, there will be a discrepancy in the coordinate system between the real bone and the (visible) navigated bone, resulting in inaccurate patient registration.



The quality of the chosen bone threshold influences the accuracy of the matching result. Make sure to set the threshold so that a smooth bone surface is displayed.

Fine-Tuning Bone Threshold

Adjust the threshold as well as possible by making sure that mostly bone, and as little tissue as possible, is visible. Registration may only be carried out if the bone surface is clearly visible.



Inspect the calculated 3D surface model and if the surface is not represented uniformly (e.g., artifacts outside or holes inside anatomical regions are displayed), adjust the bone threshold as necessary.

How to Set the Bone Threshold

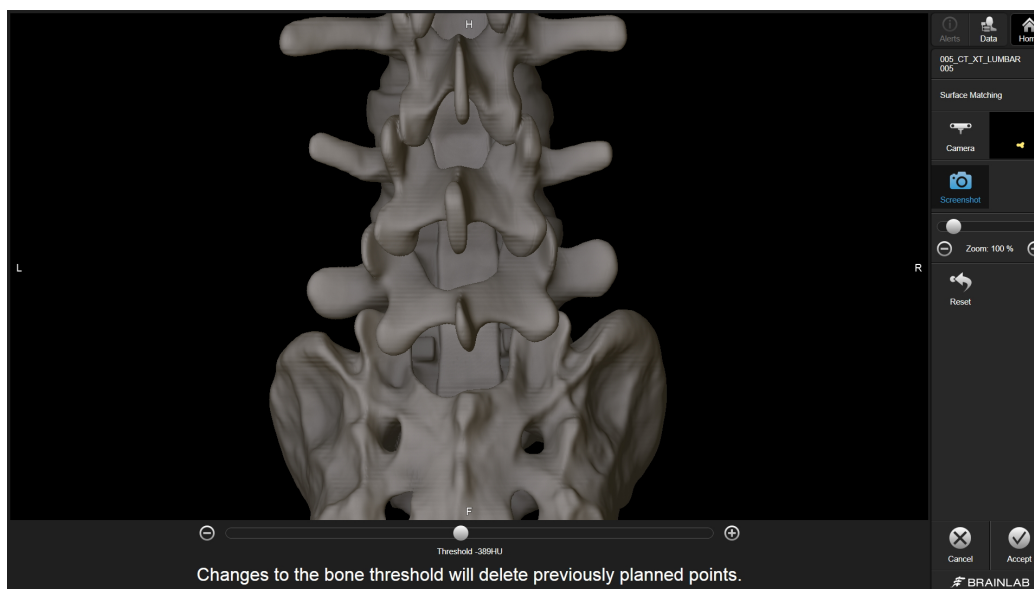


Figure 8

Step
1. Select the Threshold button from the toolbar.
2. Use the slider bar to increase/decrease the bone threshold. <i>NOTE: Select Reset to reset to the bone threshold as originally calculated by the software.</i>
3. Select Accept to proceed.

How to Crop Images

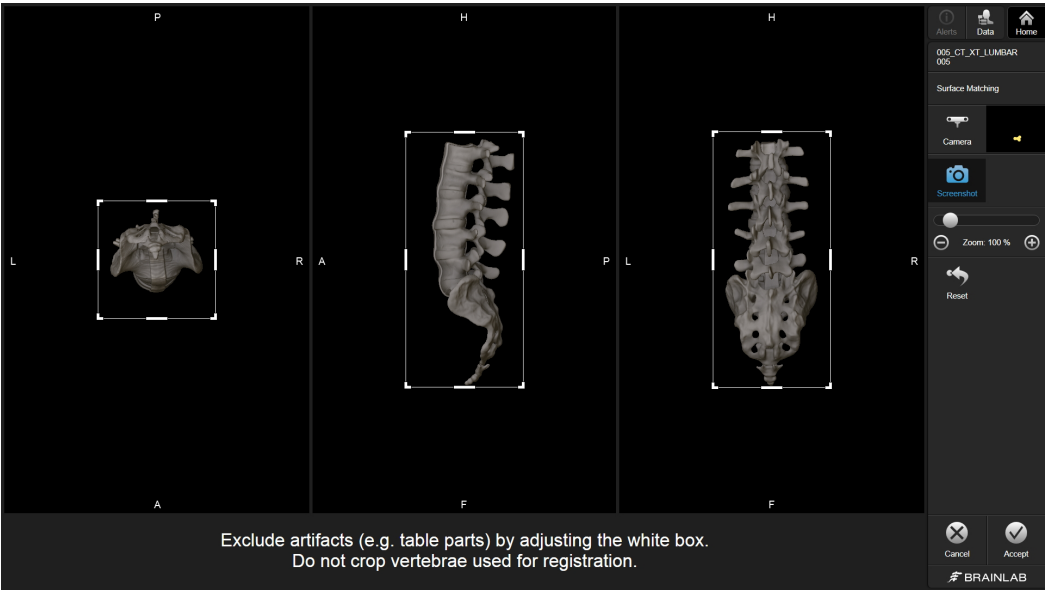


Figure 9

Step
1. Select the Crop button from the toolbar.
2. Adjust the sides of the white box to exclude any artifacts (e.g., the table), being sure not to exclude any part of the vertebra of interest .
3. Select Accept to proceed.

5 SURFACE MATCHING REGISTRATION

5.1 Background

General Information

In surface matching registration, you define the bone you are operating on, then the software guides you to acquire points on the patient's vertebra; first in specific regions, then wherever you can best acquire them on the bone.

The software matches the acquired points to a preoperatively acquired CT scan to establish a coordinate system for navigation.



All points for surface matching must be acquired on the same bone structure. The planned regions and acquired points must be on the same level on the screen and on the patient.



Only proceed with surface matching if the corresponding bone surface can be clearly identified in the scan.

Preparation of the Surgical Site

Registration Software Spine Surface Matching is only intended for spinal procedures.



Prepare the surgical site so that points can be acquired directly on the bone surface. Points not acquired directly on the bone could result in inaccurate registration.

Surface Matching Workflow

Step
1. Open Surface Matching Registration .
2. Optional: Adjust the bone threshold as needed.
3. Define the vertebra level (three points).
4. Acquire 20 points on the vertebra.
5. Verify registration.

5.2 Level Definition and Point Acquisition

General Information

You define the relevant vertebra level by identifying three landmarks and then acquiring 20 points in the region of interest.

Define the landmarks as precisely as possible on the image. The closer the match, the better the registration accuracy.

How to Define the Level

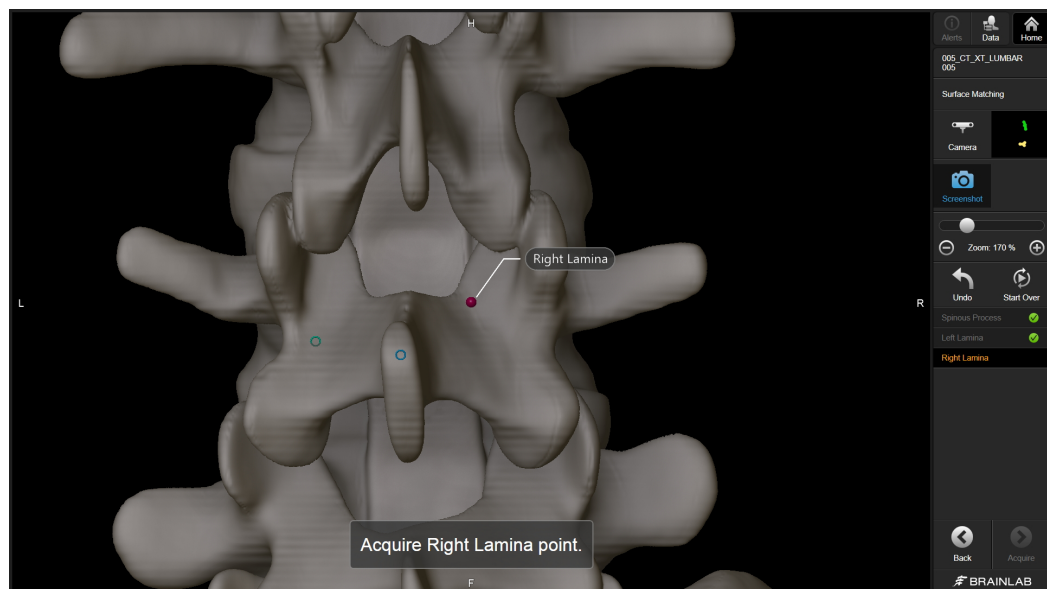


Figure 10

Step
1. Plan a point on the spinous process.
2. Plan a point on the left lamina.
3. Plan a point on the right lamina.
4. Make any necessary fine adjustment to the points by selecting a point and moving it to the center of the relevant anatomical landmark.
5. Select Acquire to begin point acquisition.

NOTE: Verify that the points are planned on the vertebra of interest.

How to Acquire Points



Acquire points in more than one plane, at different depths and over as large an area of the bone as possible. If necessary, additional points may be acquired after the first matching result.



During registration, the pointer is displayed in the software. This visualization is intended for rough orientation only and may not reflect the precise, actual position.

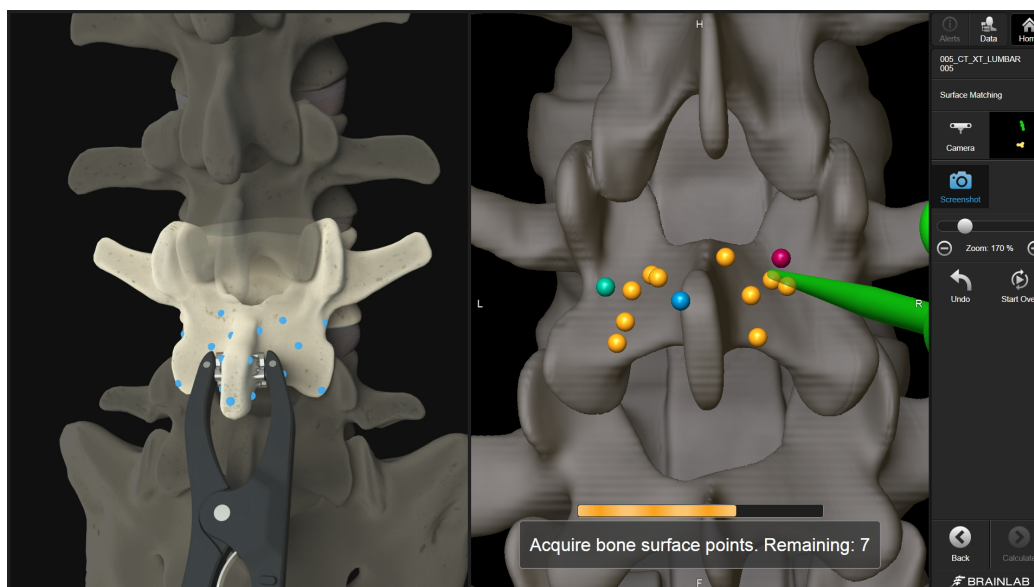


Figure 11

Step	
1.	Use the pointer or Clip-on Remote Control to acquire each of the three landmarks you defined during level definition. Ensure that you acquire points on the same vertebra that was defined in level definition. The defined landmarks are highlighted in blue, green and red.
2.	Acquire 17 additional points at various positions on the vertebra of interest. Be sure to acquire the points at different depths. <i>NOTE: Points that are too close together are not accepted by the software.</i>
3.	A progress bar indicates how many points have been acquired. Once complete, the verification screen opens. Verify the registration accuracy.

*NOTE: Pressing **Undo** deletes the most recently acquired point. Pressing **Start Over** deletes all acquired points.*

Related Links

Registration Verification Introduction on page 31

Left / Right Swap Detection

If the left and right lamina were accidentally swapped during level definition, the **Left / Right Swap** dialog opens.

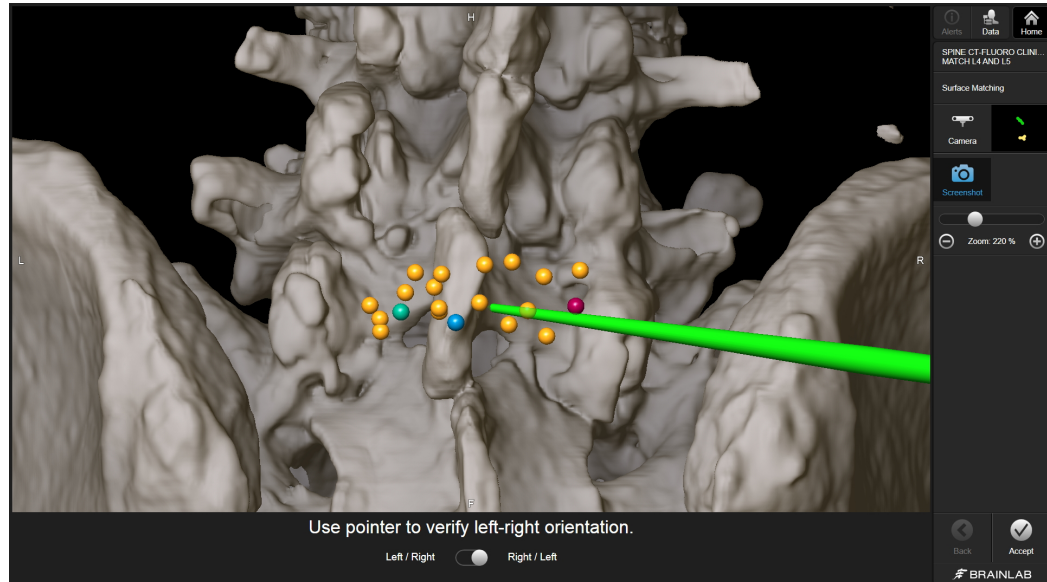


Figure 12

Step	
1.	Slide the button to Left / Right or Right / Left as required.
2.	Verify the orientation of the bone model by placing the pointer to anatomical landmarks and checking that the pointer position in the software matches the actual position on the patient's anatomy.
3.	Press Accept . <i>NOTE: The Accept button is only enabled once the pointer has entered the camera field of view.</i>

NOTE: If the left and right lamina were not actually switched, verify the correct orientation in the views and press **Accept**.

6 REGISTRATION VERIFICATION

6.1 Registration Verification Introduction

Background

After registration, with the pointer or navigated instrument and the reference array in the camera field of view, the registration verification screen opens.

Safety Considerations

Due to error propagation, navigation accuracy may be less accurate in some areas, so thorough verification is important.

Verify accuracy at multiple anatomical landmarks, especially in the region of interest. If the region of interest is not accessible, verify in areas as close as possible to the region of interest.

6.2 Accuracy Verification

Safety Information

Always verify registration accuracy by holding the pointer or instrument tip to at least three anatomical landmarks and verifying their position in the software. If registration accuracy is insufficient, it is recommended to re-register.



Verify that the registration is at the correct level on the patient and data set. Accuracy must be checked on the treated bone structure.

Troubleshooting: Poor Accuracy Values

Cause of Poor Accuracy	How to Avoid/Correct
Movement of the reference array	<ul style="list-style-type: none"> • Make sure all screws on the reference array are tight before beginning registration and do not loosen them during or after registration. • Make sure the array is securely attached to the bone. • Do not apply pressure or torque to the array during or after registration.
Improper setting of the bone threshold	<ul style="list-style-type: none"> • Set the threshold carefully to exclude all soft tissue. • If necessary, reset the threshold and begin registration again.
Acquisition of points outside of the data set	Acquire points only on the bone to be operated on.
Damage to the pointer	<ul style="list-style-type: none"> • Before using any pointer, check that the tip lines up with the calibration mark in the pointer gauge. • Do not use a damaged or bent pointer.

Next Steps

Options
If the accuracy is satisfactory, press Yes . <i>NOTE: The Yes button is inactive unless the pointer/instrument and reference array are visible.</i>
Press No for registration improvement options.
To redo any part of the registration process, press Add Points or Replan Points .
To exit registration, press Discard & Exit . The registration is not saved.

How to Verify Registration Accuracy

Following successful registration, you are prompted to perform a visual accuracy check.

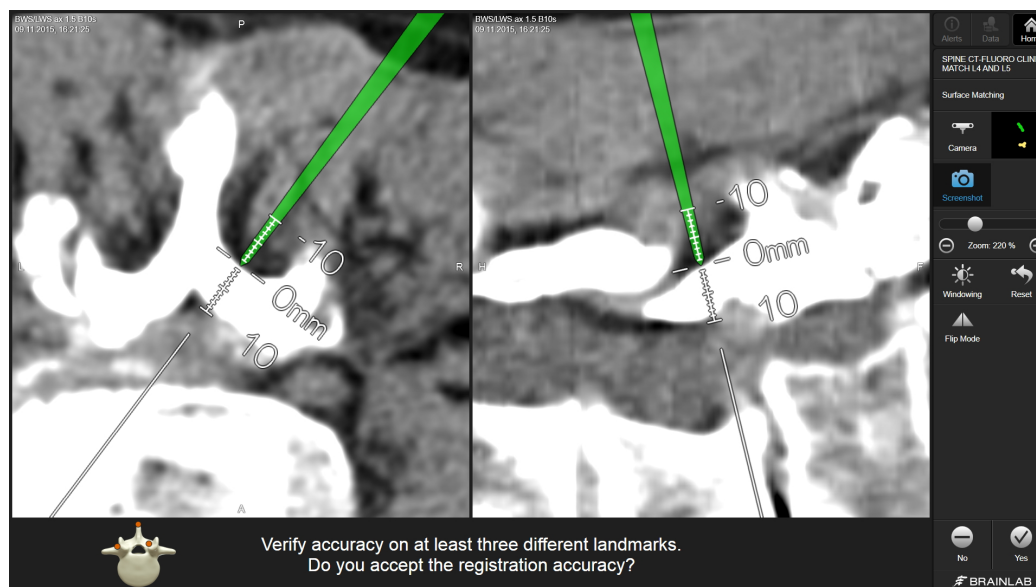


Figure 13

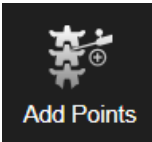
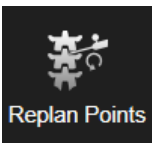
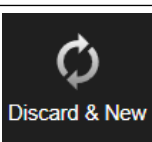
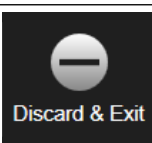
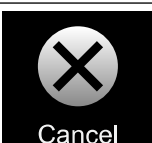
Step
<p>1. Verify the accuracy by holding the pointer or instrument tip to, at least, the following landmarks:</p> <ul style="list-style-type: none"> a. Posterior/anterior: <ul style="list-style-type: none"> - On the posterior part of the spinous process. Make sure to verify directly on the bone, not on the supraspinous ligament. - At several locations on the bony surface of the lamina. b. Left/right: <ul style="list-style-type: none"> - On the left side of the spinous process at approximately mid-height and then on the right side. - On the left and right facet joint (ideally within the joint space) if accessible. c. Cranial/caudal: <ul style="list-style-type: none"> - On the cranial side of the spinous process and then on the caudal part. <p>Carefully decide if the determined accuracy is suitable for the current procedure. Do not apply force to the pointer or instrument during verification.</p>
<p>2. For each verification point, compare the position of the pointer on the patient to the position displayed at the navigation system.</p>
<p>3. Alternatively, verify accuracy by holding the pointer carefully to the tips of the reference clamp (all directions can be verified: posterior/anterior, left/right and cranial/caudal) or to a tooth of the reference clamp, if accessible.</p>

6.3 How to Improve Registration Accuracy

Background

If the registration is determined to be unacceptable, the **No Match Found** dialog opens. Alternatively, if you observe a significant deviation during visual verification, check pointer accuracy and/or select **No**. Select one of the displayed **Improvement Options** to continue.

Improvement Options for Surface Matching Registration

Option	Description
 Add Points	Opens the registration dialog to acquire 10 additional points, which are indicated with a different color.
 Replan Points	Opens the level definition step, to re-plan and re-acquire the spinous process, left lamina and right lamina.
 Discard & New	Discards the registered points and opens a new registration.
 Discard & Exit	Discards the registered points and closes the software.
 Cancel	Closes the dialog.

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