BRAINLAB

AUTOMATIC
REGISTRATION

Version 2.5

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

Feedback

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

Manufacturer

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

1.2 Legal Information

Copyright

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

Brainlab Trademarks

- Brainlab® is a trademark of Brainlab AG.
- **Airo**® is a trademark of Brainlab AG.
- **Curve**® is a trademark of Brainlab AG.
- **Loop-X**® is a trademark of Brainlab AG.

Non-Brainlab Trademarks

- Microsoft® and Windows® are registered trademarks of Microsoft Corporation.
- NVIDIA® is a registered trademark of NVIDIA Corporation.

Patent Information

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

Integrated Third-Party Software

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

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

CE Label

CE 0123   The CE label indicates that the Brainlab product complies with the essential requirements of Council Directive 93/42/EEC (the "MDD").
Automatic Registration is a Class IIb product according to the rules established by the MDD.

Disposal Instructions

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

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

www.brainlab.com/sustainability

Sales in US

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

Report Incidents Related to This Product

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

1.3   Symbols

Warnings

⚠️ **Warning**

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

Cautions

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

Notes

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

Product Symbols

Symbol	Explanation
🏭	Manufacturer
📖	Consult instructions for use
UDI	Unique Device Identifier
MD	Medical Device
℞Only	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

Automatic Registration is a surgical device for image guided surgery intended to be used in combination with compatible Brainlab navigation systems. **Automatic Registration** provides an image registration for intraoperatively acquired 3D CT/CBCT or fluoroscopic images. It consists of the software module **Automatic Registration** and hardware accessories.

Known Contraindications

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

Place of Use

Automatic Registration is intended to be used in an OR environment.

User Profiles

In a spinal context, the intended users are Neuro / Ortho / Spine / Trauma surgeons or their assistants having a 3D image acquisition system (such as a 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.

In a cranial context, the intended users are surgeons or their assistants for neurosurgery or ENT educated according to the indications for use.

Patient Population

In a spinal context, 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).

In a cranial context, 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.

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 Non-Brainlab Scanning Devices

⚠️ **Warning**

Only medical scanning devices specified by Brainlab may be used with Automatic Registration.

For information about compatible models please contact Brainlab support.

Compatible Brainlab Intraoperative Imaging Instruments

Automatic Registration is compatible with:
- **Adhesive Flat Markers** for the scanner
- **Calibration Phantom CT Scanner**
- **Patient Scan Drape**
- **DrapeLink Cranial Reference Unit**
- **Reference Array for Spine Clamps with 3 Marker Spheres**
- **Reference Array for Spine Clamps with 4 Marker Spheres**
- **Registration Matrix CT Spine (Open Surgery)**
- **Registration Matrix CT Spine (Small Incision)**
- **Registration Matrix CT Cranial and Spine (Minimally Invasive)**
- **Supporting Arm for Registration Matrix CT**

Compatible Brainlab Surgical Instruments

Refer to the **Software User Guide** of the IGS system that is using **Automatic Registration** for a list of compatible Brainlab medical instruments.

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

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.

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

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

- *C:\Brainlab, D:\Brainlab, F:\Brainlab, etc.*
- *Be aware that some malware protection software (e.g., virus scanner)C:\PatientData, D: \PatientData, F:\PatientData, etc.*

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

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

Microsoft Security Updates for Windows and Driver Updates

Brainlab allows the installation of security 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.

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

1.6   Software Environment and Cybersecurity

Bill of Materials of Integrated Third-Party Software

- dcmtk - 3.6.0
- Effects 11 - June 7, 2010
- Lapack - 3.2.1
- libjpeg2k - 2.3.1
- libpng - 1.6.16
- libtiff - 4.0.4
- libturbo-jpeg - 1.4.0
- MergeComLib - 5.7.0
- meta - 0.1
- Microsoft Direct 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 Toolkit - 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)
55599	ingoing	TCP	Communication with external scanner (**Loop-X**)
123	ingoing	UDP	Time synchronization with external scanner (**Loop-X**)

Log File Management

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

Cybersecurity Use Environment

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

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

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

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

- Access control measures (e.g., role based) to ensure only authenticated and authorized personnel are allowed access to network elements, stored information, services and applications.
- Network access controls, such as segmentation, to limit medical device communication.
- General patch management practices that ensure timely security patch updates on adjacent devices in the use environment.
- Malware protection to prevent unauthorized code execution on adjacent devices in the use environment.
- Ensure that prescribed maintenance is done as required, including installation of security patches.
- Security awareness training of the users.

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

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

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

Cybersecurity Vulnerability

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

1.7 Training and Documentation

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.

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   INTRODUCTION TO AUTOMATIC REGISTRATION

2.1   Before You Begin

Background

Automatic Registration allows you to register intraoperatively acquired patient data. Therefore, standard registration requiring access to patient markers and/or landmarks is not necessary.

Automatic Registration cannot register pre-operatively acquired data. If pre-operative data is to be used for the initial phase of surgery, use a different registration procedure.

NOTE: For more information about intraoperatively acquired image data refer to the relevant ***Spine & Trauma*** *or* ***Cranial/ENT Software User Guide***.

Checking the Scanner

Ensure the scanner and associated workstations are started and ready for use and that the scanner and the Brainlab system are connected.

Movement During Registration

⚠️ **Warning**

Do not move the patient, reference array, registration matrix or the OR table during the scan. Ensure that the registration process is completed and registration is accurate before moving the patient or the OR table. Otherwise registration cannot be recovered.

⚠️ **Warning**

Do not modify the position of the reference array after starting the registration procedure.

Halting Respirations

⚠️ **Warning**

If applicable for your procedure (e.g., spine procedures), consider halting or reducing patient respirations in order to reduce patient movement for the duration of registration and scan.

Infrared Artifacts

Ensure that highly reflective items and light sources never disturb the camera field of view.

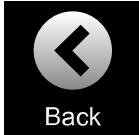# 2.2   General Software Features

Camera App
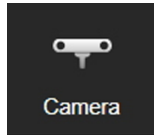
The **Camera** app is an optional feature. The same functionality and buttons for camera motor control as well as the large camera views for adjusting the camera or marker position are available in **Automatic Registration**.

Select **Camera** from **Content Manager** to view any connected devices visible to the camera (e.g., tracker, markers, reflectors) in real-time. Select **Camera** again to close it.

For **Curve** 1.1, **Camera** tracks camera movement, and includes a centralization button. To view the visible devices on a distance graph, expand the **Camera**.

NOTE: For further information on the Camera feature, refer to the relevant Spine & Trauma or Cranial/ENT Software User Guide.

Additional Options

Options	
Back	Returns to the navigation software or the previous step in the workflow.
Home	Returns to **Content Manager**. *NOTE: Refer to the Origin Data Management Software User Guide for more information.*

2.3   Maintenance

Scanner Maintenance

Warning

If the scanner has spent a prolonged period of time unused and without service, the system may fail to function correctly or may become inaccurate. It is recommended to contact Brainlab support and arrange inspections in regular periodic intervals.

Use the scanner test workflow to check accuracy of the scanner calibration. This procedure should be performed by trained technical hospital personnel on a regular basis. The service checks are described at the end of each chapter.

The service check does not replace regular maintenance and inspection performed by Brainlab.

Maintenance

3 AUTOMATIC REGISTRATION – LOOP-X 3D

3.1 Introduction – Loop-X 3D

Background

Ensure **Loop-X** is started and ready for use and that the scanner and Brainlab Navigation Station are connected using the IGS Ethernet port on the connection panel of **Loop-X** and the Intraoperative Data port of the Brainlab Navigation Station.

Follow the instructions on **Loop-X** to bring the system into scan mode.

Patient Selection

You can enter the **Automatic Registration** workflow with or without a selected patient.

If a patient is selected, make sure the same patient is selected on **Loop-X**.

Draping

⚠️ **Warning**
Only drape the patient and scanner with sterile drapes approved for use by Brainlab.

For more information see the **Intraoperative Imaging Cranial Hardware User Guide**, **Spine and Trauma Instrument User Guide** or contact Brainlab support.

How to Enter the Automatic Registration Workflow

The **Automatic Registration** workflow is controlled by **Loop-X** but selected from the Brainlab Navigation Station (e.g., **Curve**, **Kick**).

Step
1. Select **Navigation** from the **Cranial** or **Spine & Trauma** workflow.
2. Perform all steps on **Loop-X** (e.g., select patient and treatment region).
3. On the **Set Scan Parameters** screen, ensure that **Scan with navigation** is enabled on the scanner.
4.   **Automatic Registration** starts automatically on the Brainlab Navigation Station.

3.2 Scan Preparation – Loop-X 3D Data

Scan Preparation

Always perform a collision check before scanning, paying particular attention to the reference array.

Patient Preparation

⚠️ **Warning**

For spinal procedures, make sure the reference array is firmly attached on the spinous process and not to the ligaments in between. It is recommended to perform a lateral scout scan before the actual 3D registration scan and carefully check the position of the clamp.

Follow the sterile draping instructions in the **Intraoperative Imaging Cranial Hardware User Guide** to avoid displacements that may be caused by moving the scanner.

For both cranial and spine procedures, it is recommended to use patient references with four marker spheres.

If applicable for your procedure (e.g., for spine procedures), consider halting or reducing patient respiration in order to prevent movement of the patient for the duration of registration and the scan.

Scan Considerations

- Ensure that the drape does not obstruct the direct line of sight between the camera and scanner markers.
- Send only one CT reconstruction at a time for automatic registration.
- If not configured automatically, the data must be sent to the Brainlab Navigation Station immediately following image acquisition.

How to Prepare for Scanning
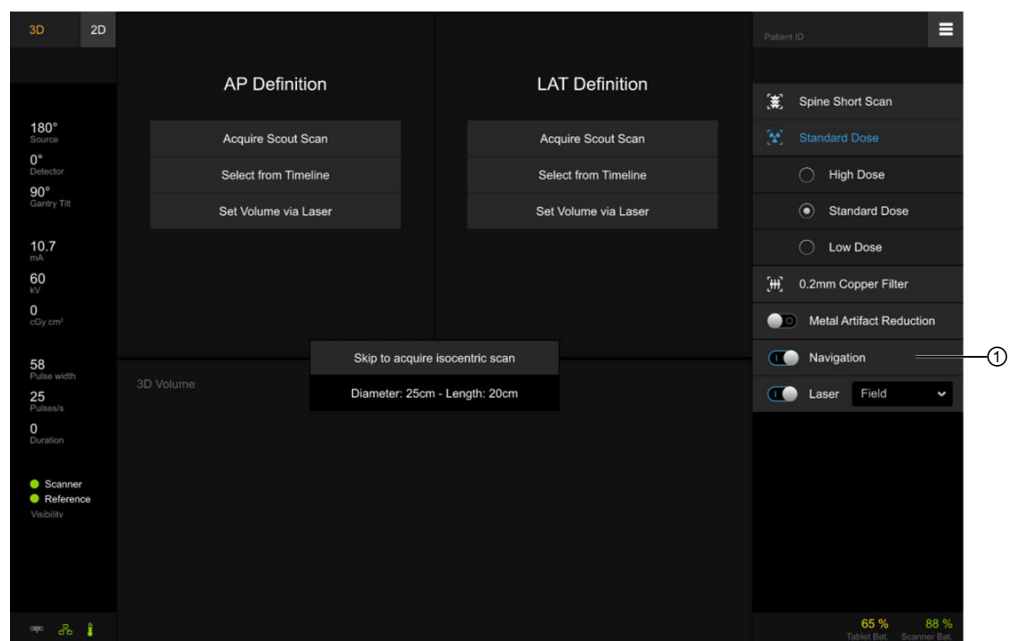
Figure 1

Step	
1.	Connect the network cable.
2.	Enter 3D scan mode and ensure that **Navigation** ① is selected on **Loop-X**. Once the preliminary steps are completed, a green circle appears in front of each of the reminder icons on the display.

How to Adjust the Camera

Figure 2

Step	
1.	Make sure the camera is facing **Loop-X** and all registration markers are visible.
2.	Adjust the camera. • For Brainlab systems with non-motorized camera movement: Use the camera handle to adjust the camera so that the marker spheres are in the center of the camera field of view. • For Brainlab systems with a motorized camera: The camera moves automatically to be focused on the marker spheres. The motorized camera could collide with other devices. Ensure that there are no ceiling-mounted devices in close proximity to the camera.
3.	For Brainlab systems with a motorized camera: You may see directional arrows within the view ①. Use these controls to adjust the camera manually. **Auto Camera** can be toggled on or off ②. When toggled off, the camera must be moved into position manually.
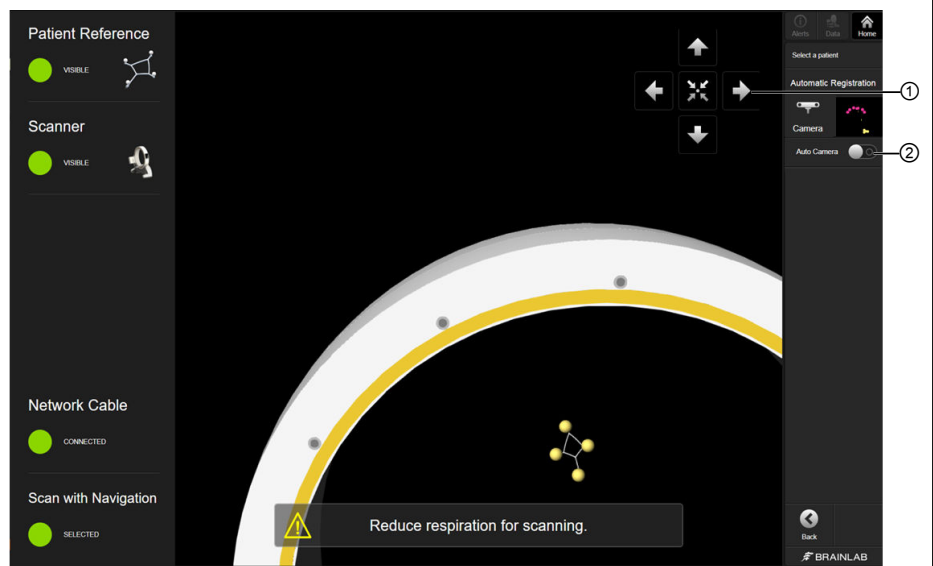
3.3 Image Acquisition – Loop-X 3D Data

Overview

After setting up the patient and scanner, **Automatic Registration** allows you to acquire the 3D scan and send it to the Brainlab Navigation Station.

Precautions

If not configured automatically, the data must be sent to the Brainlab Navigation Station immediately following image acquisition.

Restoring a Registration – Loop-X 3D Data

If the software unexpectedly shuts down during or after performing a patient scan, the previous registration is detected by the software.

Automatic Registration restores the patient data including the registration. The registration must be verified carefully before navigation.

If the data transfer fails, scan can be sent again and registration will be restored

Detecting Structures and Registration

The software checks that all necessary marker structures are visible to the camera. Structures in view are listed as **Visible** ① on the left and shown in the camera view ②. Depending on your procedure, you will see one of two screens (cranial or spine).
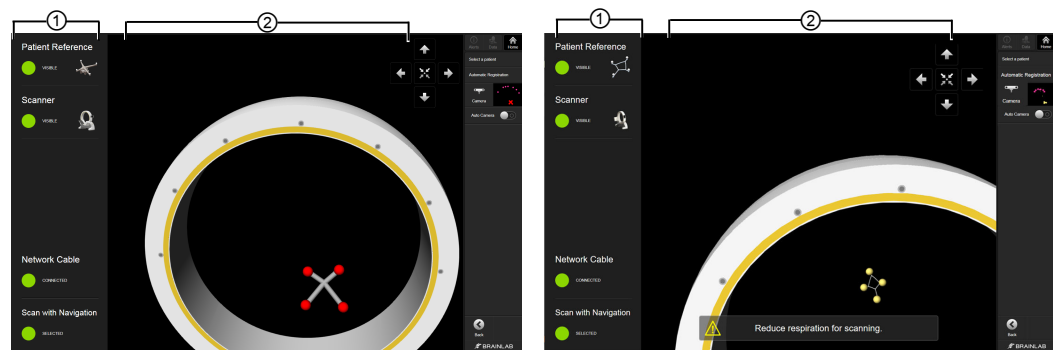
Figure 3

Step
1.   Once all required marker structures are detected by the software, the scanner is ready for registration and scanning. *NOTE: Ensure the marker structures are visible to the camera. Scanning with navigation is not possible unless all markers are visible.*
2.   Always perform a collision check before scanning, paying particular attention to the reference array.
3.   If applicable to your procedure (e.g., for spine procedures), consider halting or reducing patient respiration to prevent movement of the patient before continuing with registration. *NOTE: Only stop the patient's breathing if breathing causes too much array movement.*

Step
4.   After the collision check is done, **Loop-X** is ready to scan.   The scan is performed as long as the **Scan** button remains pressed.
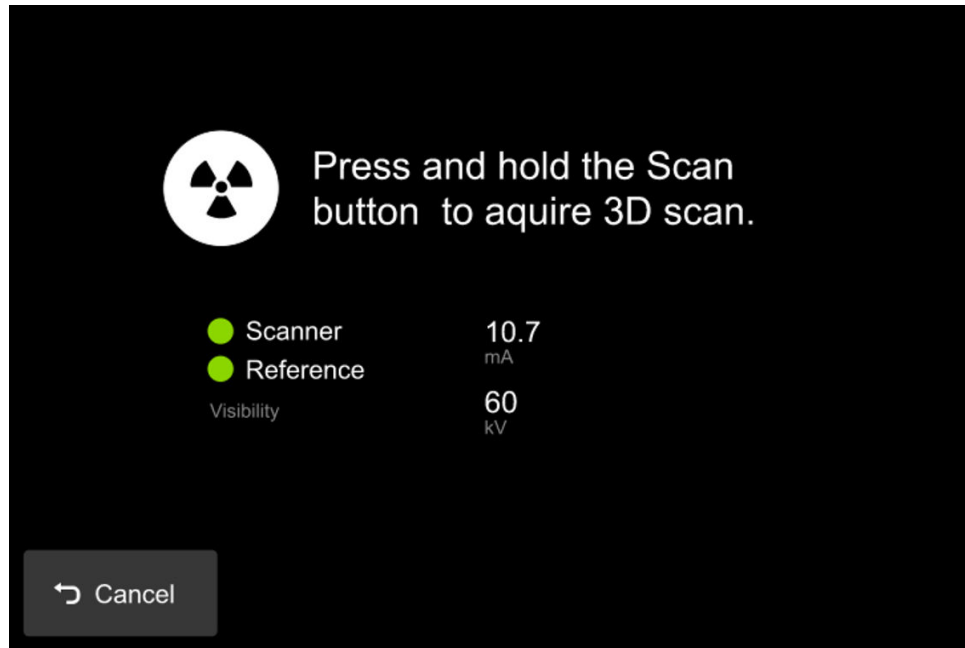
Do not move the patient and/or OR table between the patient registration and end of the scan.

3.4   Accuracy Verification – Loop-X 3D Data

Verifying Automatic Registration

Always verify registration accuracy carefully prior to starting the navigated procedure by holding the pointer or instrument tip to at least three anatomical landmarks and verifying their position in the software.

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

Verify Registration Accuracy – Cranial

Figure 4

Step
1.   Verify automatic registration by touching at least three landmarks with the pointer.
2.   If accuracy is acceptable, select **Yes**.

Verify Registration Accuracy – Spine Standard Procedure

Figure 5

Step	
1.	Hold the instrument on the bony surface of at least three of the following landmarks: • Posterior (on the spinous process) / Anterior (on several locations on the lamina) • Left/Right (on the facet joint or mid-height on the spinous process) • Cranial/Caudal (on the spinous process; first on the cranial and then the caudal part)
2.	Verify that the instrument position displayed on the screen matches the actual position of the instrument on the anatomical landmark.

3.	After verification, two options are available. Select:
	• **Yes** if the registration is accurate, and to proceed to navigation.
	• **No** if the registration is inaccurate, and to clear the current registration. Select either:
	   - **New Scan**: Return to the registration software to acquire a new registration.
	   - **Discard & Exit**: Exit the software and return to **Content Manager**.

Verify Registration Accuracy – Spine Minimally Invasive Procedure

If you are performing a minimally invasive procedure that restricts the verification of at least three landmarks, perform the following accuracy check:

Step	
1.	Insert the instrument into the incision so that it is securely touching an anatomical landmark, reference array clamp or tooth.
2.	Acquire fluoro images of the instrument on the bone: • Lateral fluoro image (cranial/caudal or posterior/anterior registration) • AP fluoro image (cranial/caudal or left/right registration)
3.	Verify that the instrument position displayed on the screen corresponds to the position in the fluoro image.

Step

4.   After verification, two options are available. Select:
      • **Yes** if the registration is accurate, and to proceed to navigation.
      • **No** if the registration is inaccurate, and to clear the current registration. Select either:
          - **New Scan**: Return to the registration software to acquire a new registration.
          - **Discard & Exit**: Exit the software and return to **Content Manager**.

3.5   Service Check – Loop-X 3D

Performing a Service Check
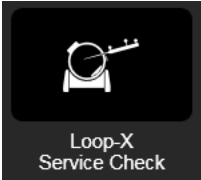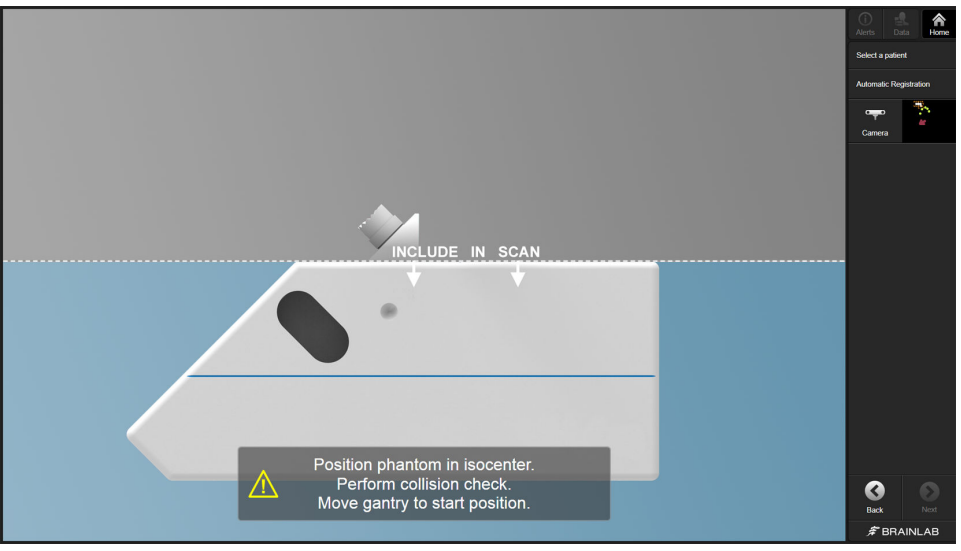
Use the scanner test workflow at any time to check calibration accuracy.

- Perform a calibration accuracy check regularly.
- The service check does not replace regular maintenance and inspection performed by Brainlab.
- The service check shall be performed by technical staff only.

NOTE: Service check is not for patient treatment.

How to Perform a Service Check – Loop-X 3D

Follow these steps to perform a service check to verify calibration accuracy.

Step
1.   Select **Loop-X Service Check** from the workflow.
2. Ensure scanner is connected.   All steps are performed from **Loop-X**.
3. Perform a setup check as described in the software. For instance: • Positioning the phantom in the isocenter   • Performing a collision check
4. Select **Next**.

Step
5.   Ensure all structures are visible to the camera.
6.   Select **Scan** on **Loop-X** to begin the scanning process. Do not move anything until the scan is completed.
7.   **Loop-X** sends the data to the Brainlab Navigation Station. A progress wheel informs you that images are being sent.
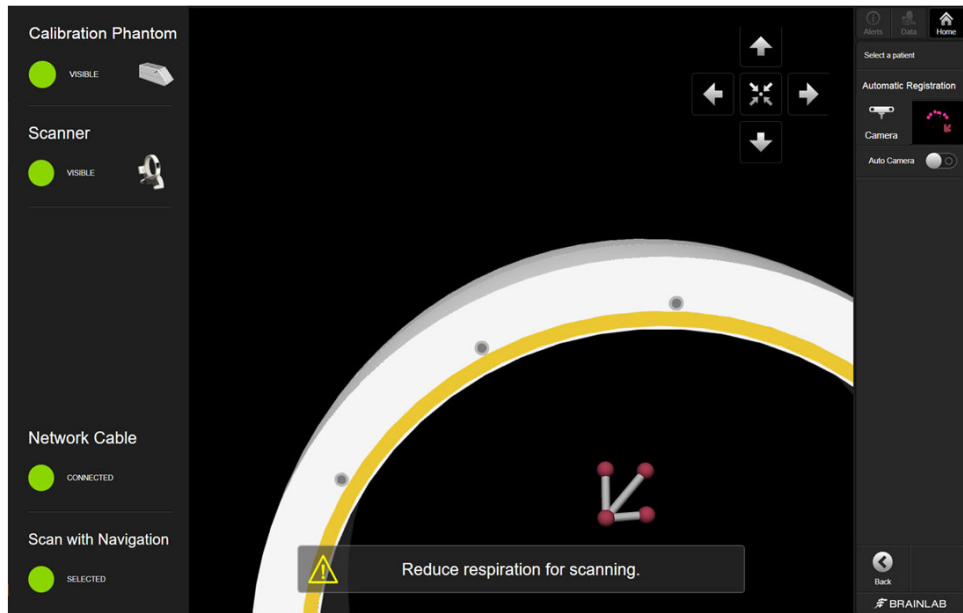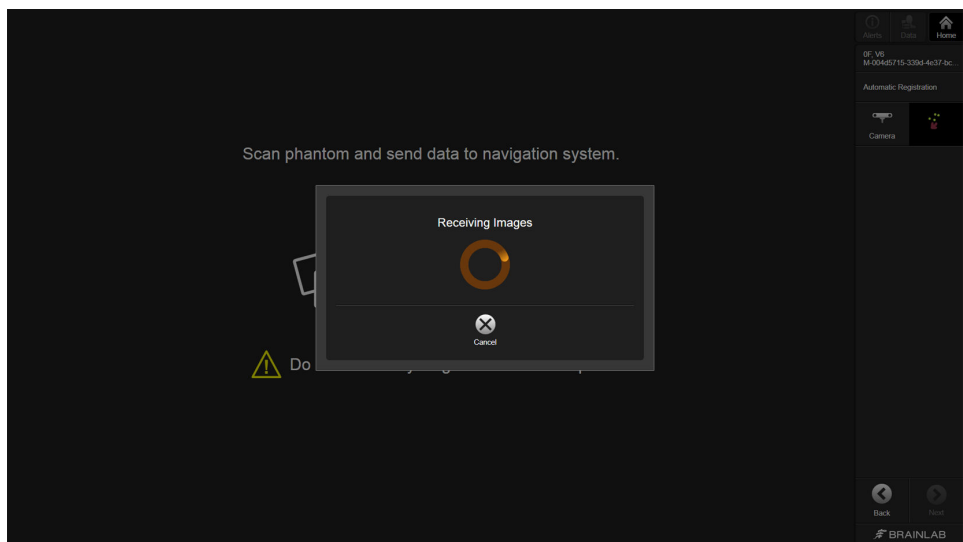
Step
8.   Once the scan is complete, the software informs you if the service check was successful. If it was successful, the following screen is displayed: Select **Next** to complete the service check. If the service check was not successful, the following screen is displayed: Read the information about reasons for failure and resolve them, if applicable.
9.   Select **Next** to complete the service check. If the problem persists, contact Brainlab support.
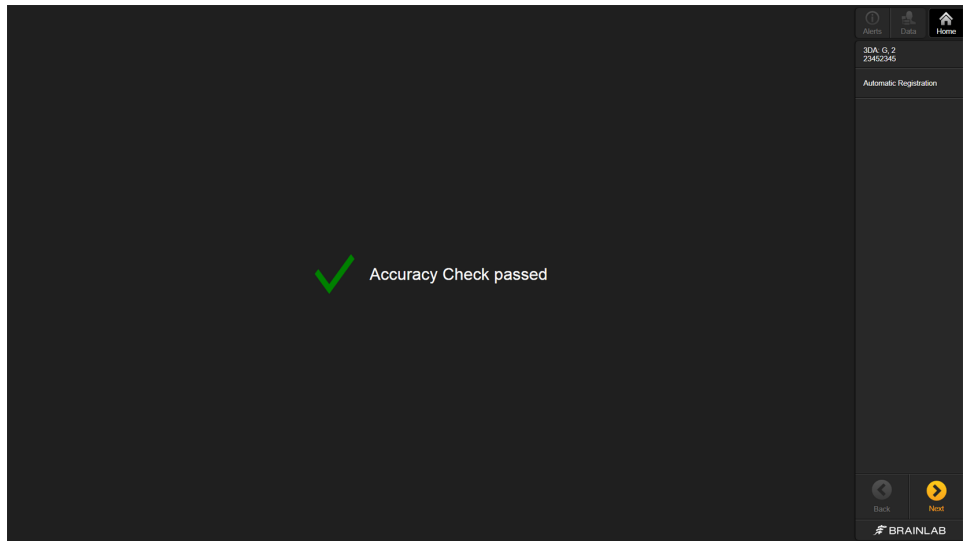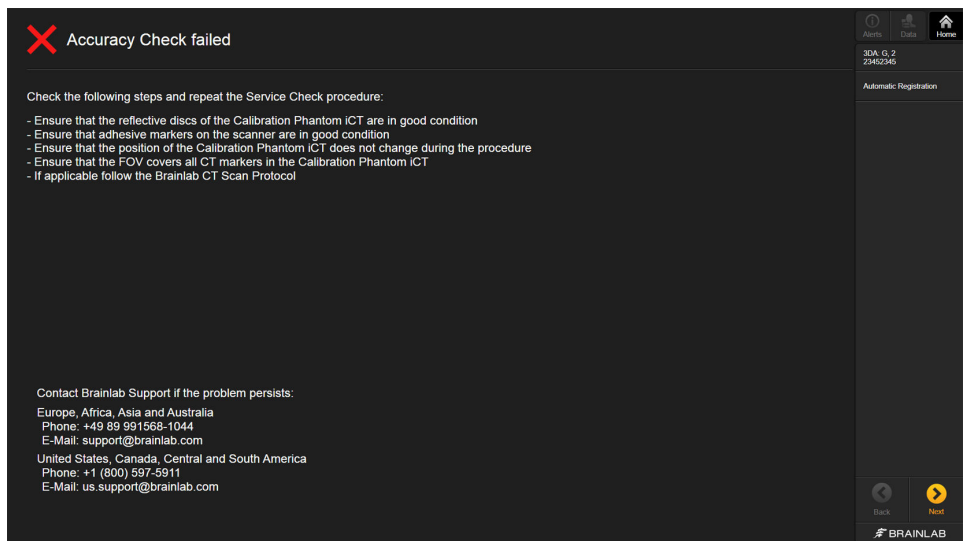
4 AUTOMATIC REGISTRATION – AIRO DATA

4.1 Introduction – Airo

Before You Begin

Ensure **Airo** is started and ready for use and that the scanner and Brainlab system are connected using the IGS Ethernet port on the input panel of **Airo** and the Intraoperative Data port of the Brainlab Navigation Station.

Follow the instructions on **Airo** to bring the system into scan mode. For more information about scan mode or the IGS Ethernet port, see the **Airo Quick Reference Guide**.

Draping

⚠️ **Warning**
Only drape the patient and scanner with sterile drapes approved for use by Brainlab.
For more information see the **Intraoperative Imaging Cranial Hardware User Guide**, **Spine and Trauma Instrument User Guide** or contact Brainlab support.
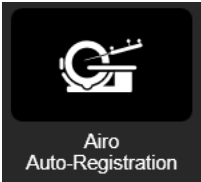
Patient Selection

You can enter the **Automatic Registration** workflow with or without a selected patient.

If a patient is selected, makes sure the same patient is selected on **Airo**.

How to Enter the Automatic Registration Workflow

The **Automatic Registration** workflow is controlled by **Airo** but selected from the Brainlab Navigation Station (e.g., **Curve**, **Kick**).

Step
1. Select **Navigation** from the **Cranial** or **Spine & Trauma** workflow.
2. Perform all steps on **Airo** (e.g., select patient, set start position).
3. On the **Set Scan Parameters** screen, ensure **with** is selected under **Navigation**.

Step	
4.	
	Automatic Registration starts automatically on the Brainlab Navigation Station.

Alternative: How to Enter the Automatic Registration Workflow

Step	
1.	Under **Cranial** or **Spine & Trauma 3D**, select **Navigation**, then **Automatic Registration Airo**.
2.	Perform all steps on **Airo** (e.g., select patient, set start position).
3.	On the **Set Scan Parameters** screen, ensure **with** is selected under **Navigation**.

4.2   Scan Preparation – Airo

Scan Preparation

Always perform a collision check before scanning, paying particular attention to the reference array.

Only scan the part of the anatomy where the reference array is attached. The maximum usable scan length for navigation is 30 cm.

⚠️ **Warning**
Remove all metal items from the region of interest during scanning in order to avoid artifacts.

Patient Preparation

⚠️ **Warning**
For spinal procedures, make sure the reference array is firmly attached on the spinous process and not to the ligaments in between. It is recommended to perform a lateral scout scan before the actual 3D registration scan and carefully check the position of the clamp.

Do not drape the scanner. Only drape the patient.

Only use drapes compatible with **Airo** as listed in the **Intraoperative Imaging Cranial Hardware User Guide**.

Follow the sterile draping instructions in the **Intraoperative Imaging Cranial Hardware User Guide** to avoid displacements that may be caused by moving the scanner.

If applicable for your procedure (e.g., for spine procedures), consider halting or reducing patient respiration in order to prevent movement of the patient for the duration of registration and the scan.

If a post-scan table rotation of 90° to 180° is required, only use 4-marker reference arrays.

How to Connect the Scanner with the Brainlab Navigation Station

Depending on your procedure, you will see one of two screens (e.g., cranial on the left) displaying successful connection between **Curve** and **Airo**.
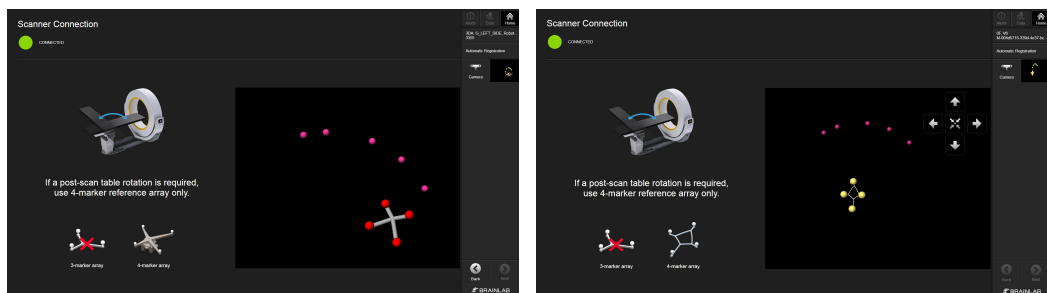
Figure 6

Step
On **Airo**, select **Next**. The **WELCOME** screen is displayed. See the **Airo Quick Reference Guide** for more information.

Welcome Page – Airo
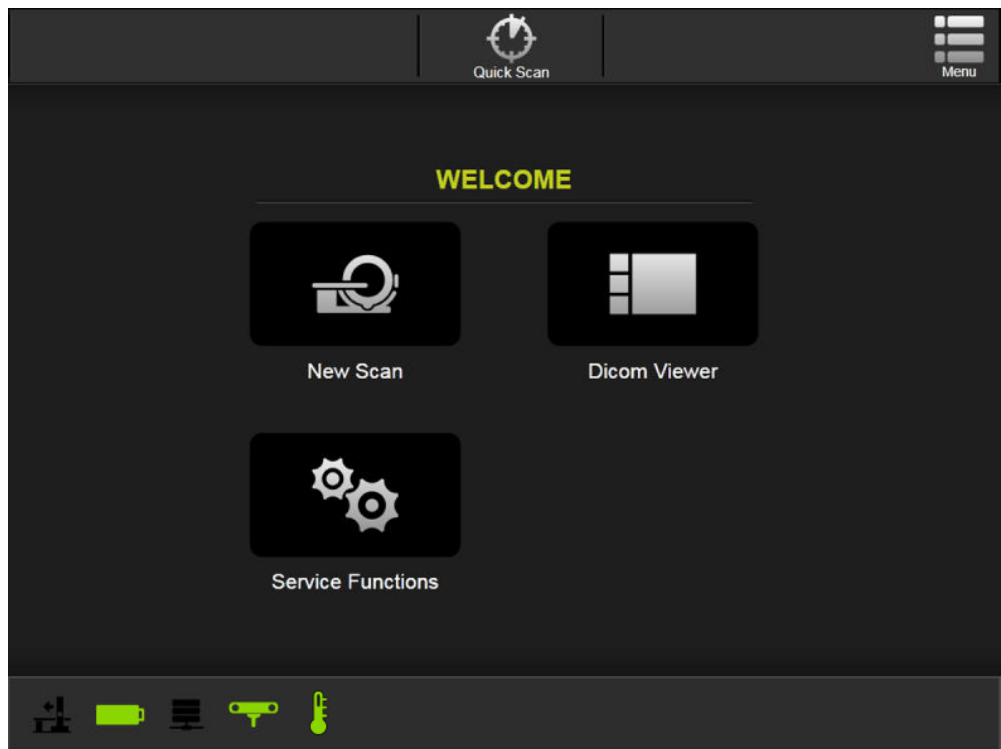
Figure 7

Options
New Scan starts the new scan workflow.
DICOM Viewer displays existing scans stored on **Airo**.
Service Functions displays service options (see the **Airo Quick Reference Guide**).

Patient Data – Airo

When **New Scan** is selected on the **WELCOME** screen, you are prompted to select patient data. For more information, see the **Airo Quick Reference Guide**.
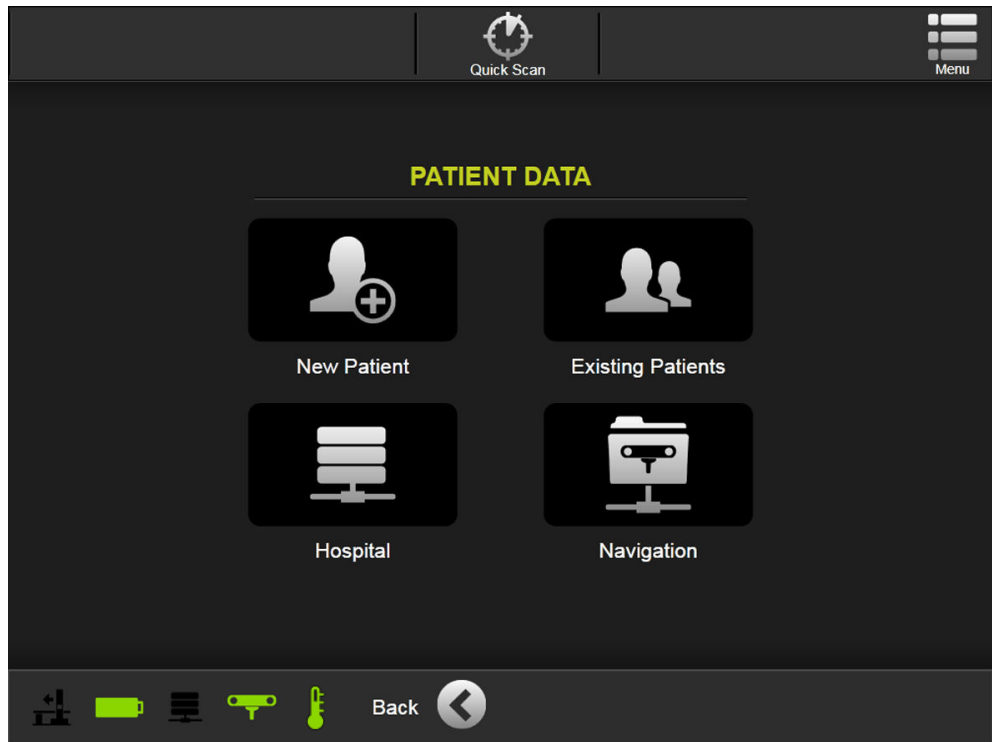
Figure 8

Options
New Patient adds a new patient.
Existing Patients displays existing patients stored on **Airo**.
Hospital displays patients sent from the main hospital server to **Airo** via the modality worklist.
Navigation displays a worklist showing the currently selected patient on **Curve**.

4.3   Confirming Ring Rotation – Airo

Airo: Confirming Ring Rotation for Imaging

The typical OR setup requires you to put the camera at the base of the table. Therefore, the scan direction must move away from the base, as shown below.

How to Confirm Ring Rotation – Airo
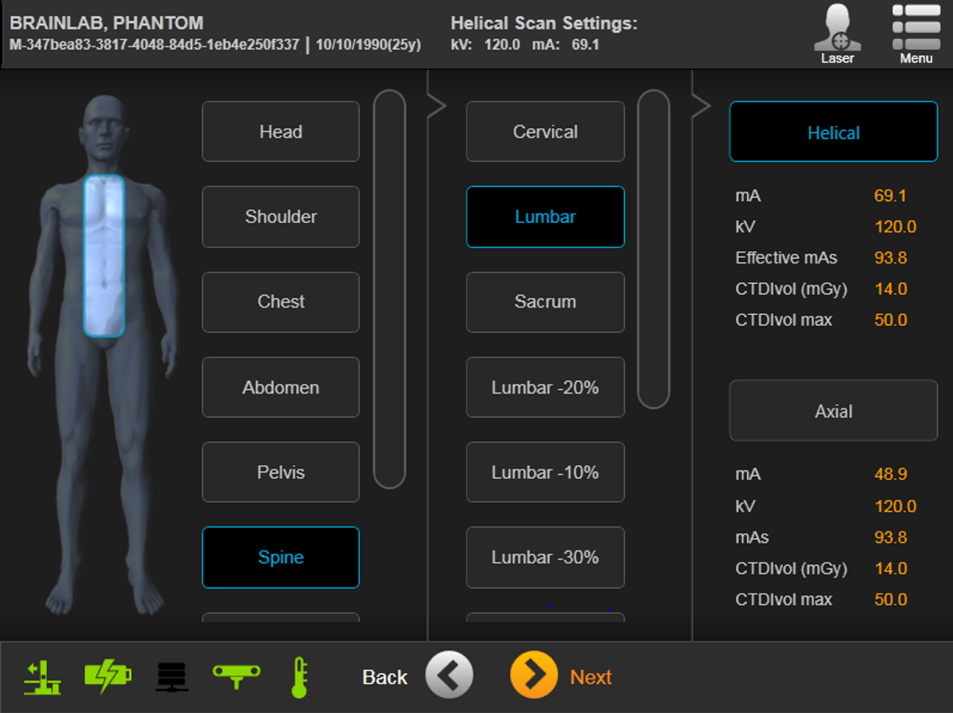
Figure 9

Step	
1.	Confirm the ring rotation in relation to the camera.
2.	To confirm the scan will move away from the base, select **Next**.

How to Select the Exam Region – Airo

Step
1. Follow the workflow to select the examination region and scanning mode (e.g., **Spine** > **Lumbar** > **Helical**).
2. Select **Next**. The **Set Scan Parameters** screen opens.

Step
3. Select your parameters using **Kernel** and **Field of View**. Under **Navigation** select to perform a scan **with** or **without Automatic Registration**.
4. Select **Next**. The system automatically verifies if the setup is ready for navigation and displays a warning if the system state is invalid.
5. The **Verification of image guided surgery setup** screen appears.
6. Select **Next**.
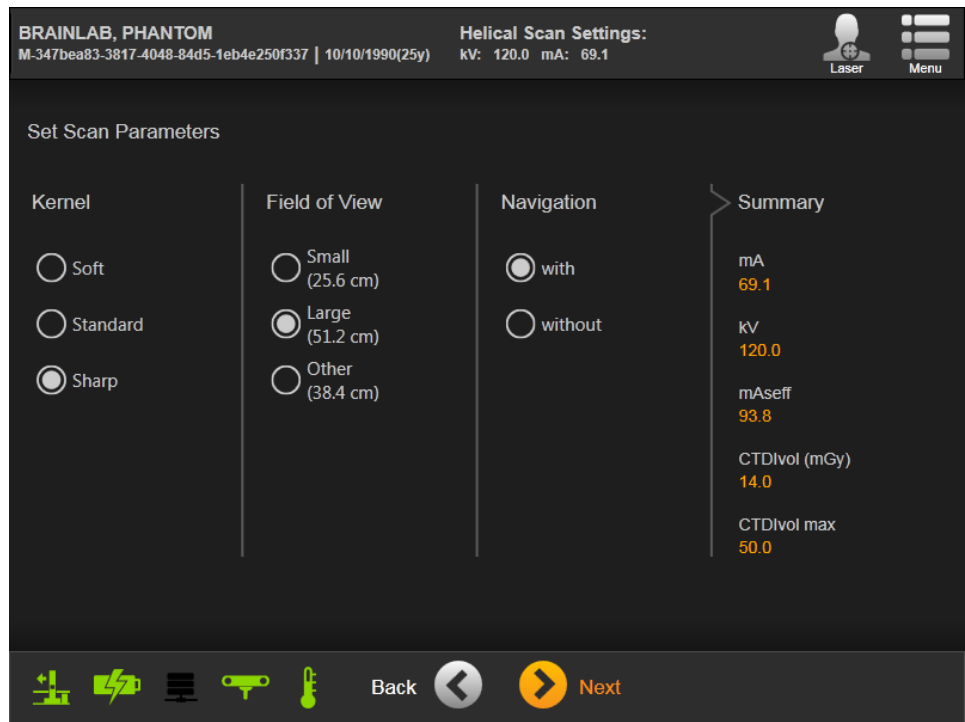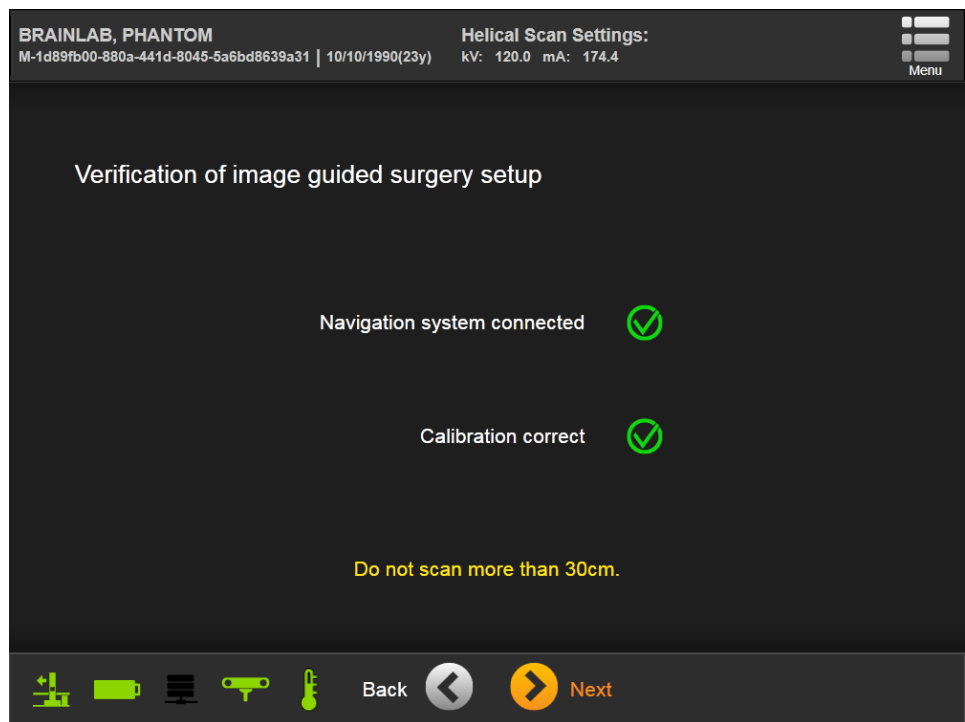
How to Adjust the Camera on Curve

Figure 10

Step
1.   After selecting the examination region on **Airo**, the camera on **Curve** automatically adjusts.
2.   Make sure the camera is facing **Airo** and all registration markers are visible.   *NOTE: This feature is only available on **Curve** systems with a motorized camera.*   The camera moves automatically and might collide with other devices. Ensure that there are no ceiling-mounted devices in close proximity of the camera.
3.   **Auto Camera** can be toggled on or off ②.   With some systems, you may see directional arrows within the view area ①. If toggled off, use these controls to adjust the camera manually.
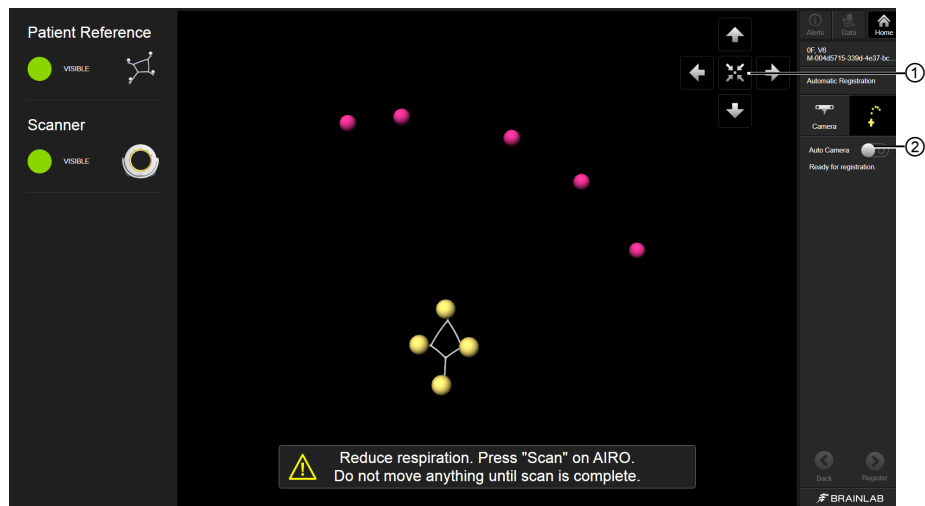
No Auto Camera Available

If **Auto Camera** is not included in your system, the toggle will not appear on your toolbar.

4.4 Image Acquisition – Airo

Overview

After setting up the patient and scanner, **Automatic Registration** allows you to acquire scanning data and send it to the Brainlab Navigation Station.

Scanner Start Position – Airo
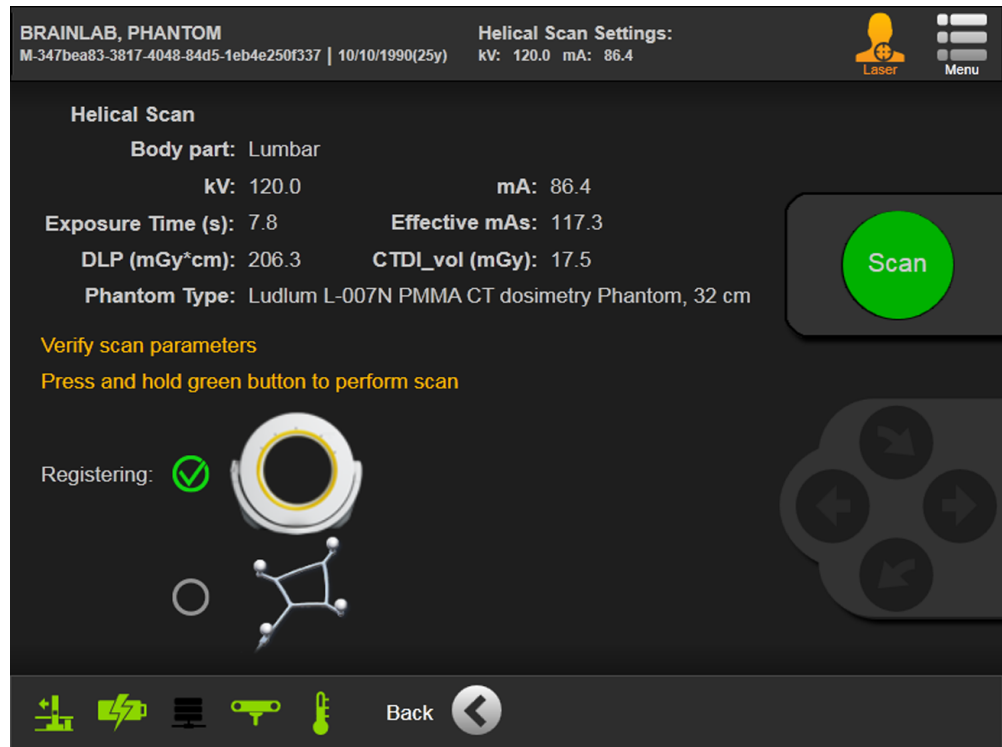
Figure 11

Step	
1.	Follow the workflow to verify scan parameters on **Airo** (see **Airo Quick Reference Guide**) until the scanner has moved to the start position of the helical/axial scan.
2.	Wait until the camera has finished adjusting.

Detecting Structures and Registration

The software checks that all necessary marker structures are visible to the camera.
Structures in view are listed as **Visible** ① on the left and shown in the camera view ②. Depending on your procedure, you will see one of two screens (e.g., cranial on the left).
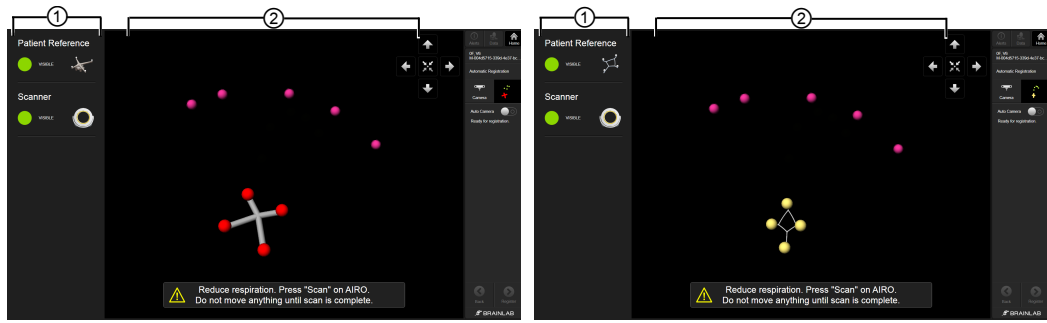
Figure 12

Step	
1.	Once all required marker structures are detected by the software, the scanner is ready for registration and scanning. *NOTE: Ensure the marker structures are visible to the camera. Scanning is possible without all structures detected, but registration cannot be performed.*
2.	If applicable to your procedure (e.g., for spine procedures), consider halting or reducing patient respiration to prevent movement of the patient before continuing with registration. *NOTE: Only stop the patient's breathing if breathing causes too much array movement.*
3.	Select and hold **Scan** on **Airo**. The scan is performed as long as the scan button is selected. *NOTE: The maximum usable scan length for navigation is 30 cm.*

Do not move the patient and/or OR table between the patient registration and end of the scan.

Consider halting or reducing patient respiration in order to prevent movement of the patient (spinal procedures only) for the duration of registration and scanning.

Always perform a collision check before scanning, paying particular attention to the reference array.

⚠ **Warning**
Ensure that no wrinkles are covering the markers on the patient scan drape during spinal procedures. Flatten the wrinkles on the drape above the markers.

Scan Considerations

Registration always takes place before scanning.

⚠ **Warning**
If a post-scan table rotation is required, only use a 4-marker reference array.

⚠ **Warning**
Ensure that no wrinkles are covering the markers on the patient scan drape. Flatten the wrinkles on the drape above the markers.

Performing a Helical or Axial Scan – Curve

Step	
1.	Once the scan is complete, allow respiration if you have reduced it.

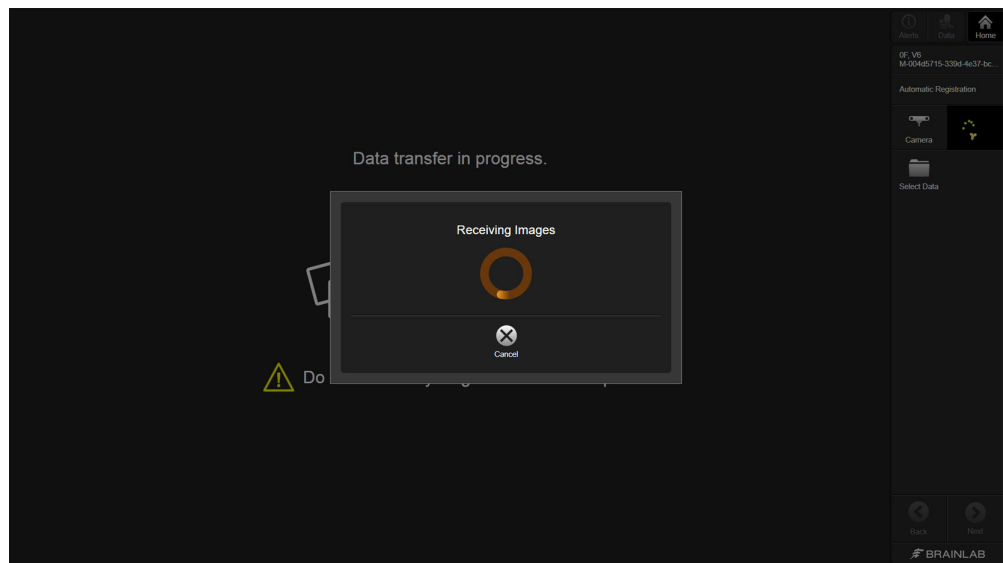| Step |
| --- |
| 2. This screen shows that data is prepared for sending.

 |
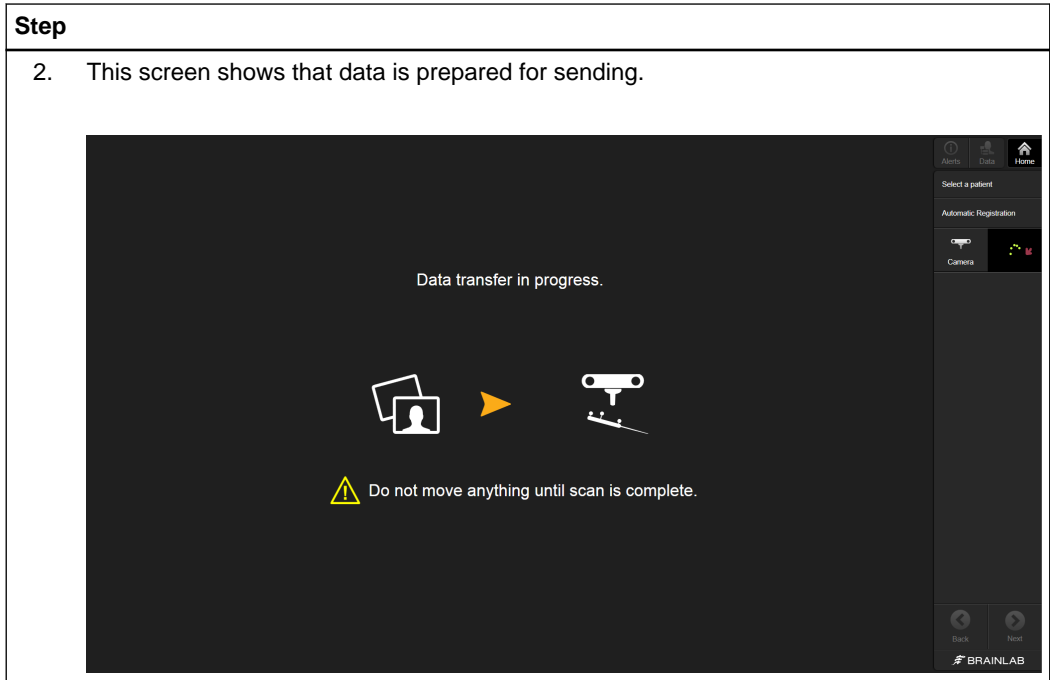
Receiving Data – Curve

Figure 13

Step
1. The data is sent from the scanner to the Brainlab Navigation Station. The software indicates it is receiving images. *NOTE: If images are not sent automatically from the scanner, send them manually.*
2. Verify the registration.

Restoring a Registration – Airo

If the software unexpectedly shuts down during or after performing a patient scan, the previous registration is detected by the software.

Software User Guide Rev. 1.1 Automatic Registration Ver. 2.5

Automatic Registration opens automatically and restores the patient data including the registration. The registration must be verified carefully before navigation.

4.5 Accuracy Verification – Airo

Verifying Automatic Registration

Always verify registration accuracy carefully prior to starting the navigated procedure by holding the pointer or instrument tip to at least three anatomical landmarks and verifying their position in the software.

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

Verify Registration Accuracy – Cranial

Figure 14

Step
1.   Verify automatic registration by touching at least three landmarks with the pointer.
2.   If accuracy is acceptable, select **Yes**.

Verify Registration Accuracy – Spine Standard Procedure

Figure 15

Step	
1.	Hold the instrument on the bony surface of at least three of the following landmarks: • Posterior (on the spinous process) / Anterior (on several locations on the lamina) • Left/Right (on the facet joint or mid-height on the spinous process) • Cranial/Caudal (on the spinous process; first on the cranial and then the caudal part)
2.	Verify that the instrument position displayed on the screen matches the actual position of the instrument on the anatomical landmark.

3.	After verification, two options are available. Select:
	• **Yes** if the registration is accurate, and to proceed to navigation.
	• **No** if the registration is inaccurate, and to clear the current registration. Select either:
	   - **New Scan**: Return to the registration software to acquire a new registration.
	   - **Discard & Exit**: Exit the software and return to **Content Manager**.

Verify Registration Accuracy – Spine Minimally Invasive Procedure

If you are performing a minimally invasive procedure that restricts the verification of at least three landmarks, perform the following accuracy check:

Step	
1.	Insert the instrument into the incision so that it is securely touching an anatomical landmark, reference array clamp or tooth.
2.	Acquire fluoro images of the instrument on the bone: • Lateral fluoro image (cranial/caudal or posterior/anterior registration) • AP fluoro image (cranial/caudal or left/right registration)
3.	Verify that the instrument position displayed on the screen corresponds to the position in the fluoro image.

Step

4.   After verification, two options are available. Select:
      • **Yes** if the registration is accurate, and to proceed to navigation.
      • **No** if the registration is inaccurate, and to clear the current registration. Select either:
         - **New Scan**: Return to the registration software to acquire a new registration.
         - **Discard & Exit**: Exit the software and return to **Content Manager**.

4.6   Service Check – Airo

Performing a Service Check
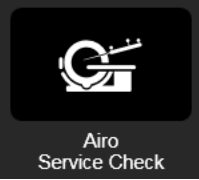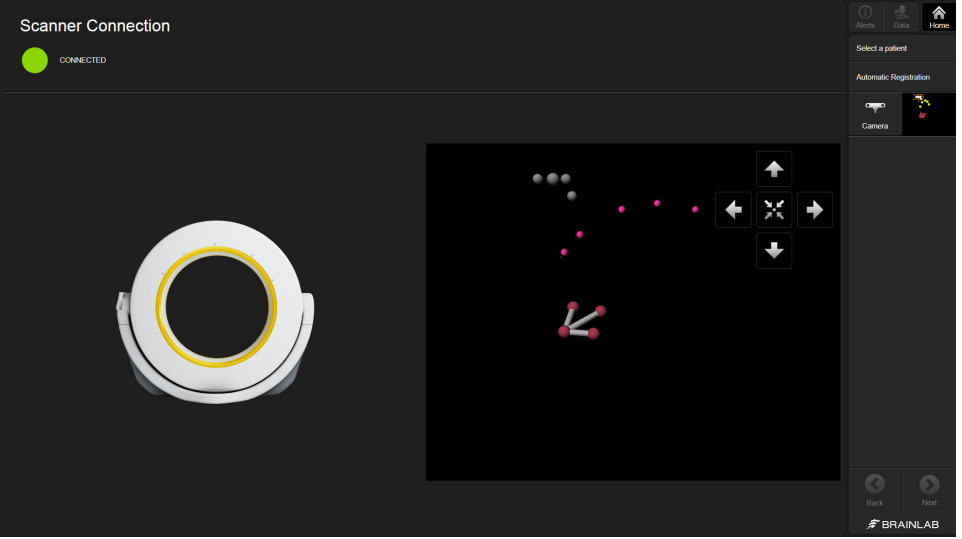
Use the scanner test workflow at any time to check calibration accuracy.

- Perform a calibration accuracy check regularly.
- The service check does not replace regular maintenance and inspection performed by Brainlab.
- The service check shall be performed by technical staff only.

NOTE: Service check is not for patient treatment.

How to Perform a Service Check – Airo

Follow these steps to perform a service check to verify calibration accuracy.

Step
1. Select **Airo Service Check** from the workflow.
2.   Ensure scanner is connected.
3.   Select **Next**. All steps are performed from **Airo**.

Step

4. Perform a setup check as described in the software. For instance:
    • Positioning the phantom in the isocenter
    • Performing a collision check
    • Moving the gantry to the start position
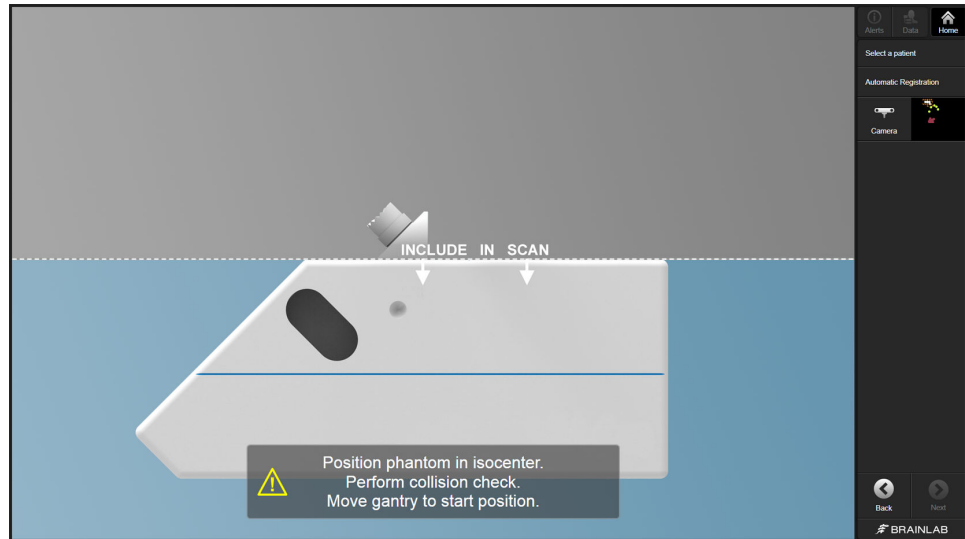
5. Select **Next**.
6. Ensure all structures are visible to the camera.
7. Select **Scan** on **Airo** to begin the scanning process. Do not move anything until the scan is completed.

Step
8.   **Airo** sends the data to the Brainlab Navigation Station.   A progress wheel informs you that images are being sent.
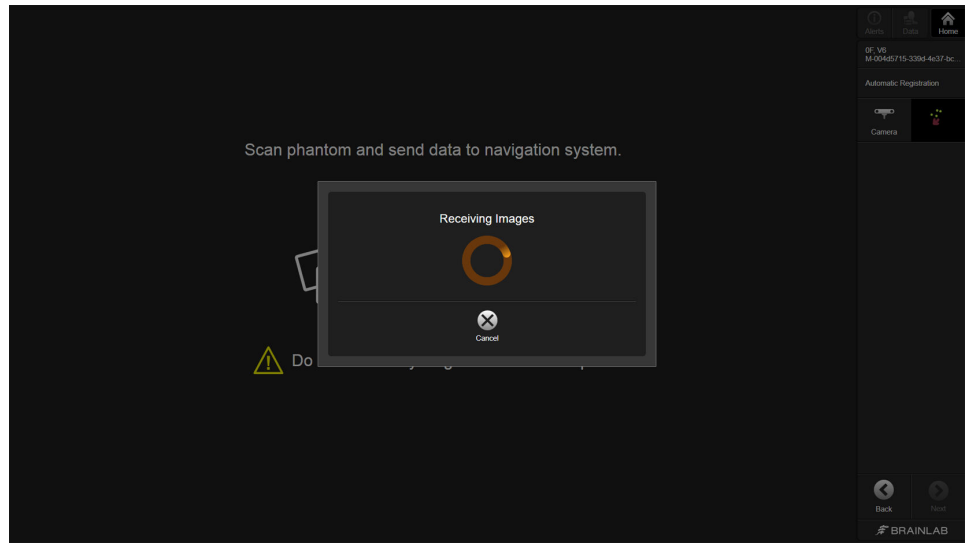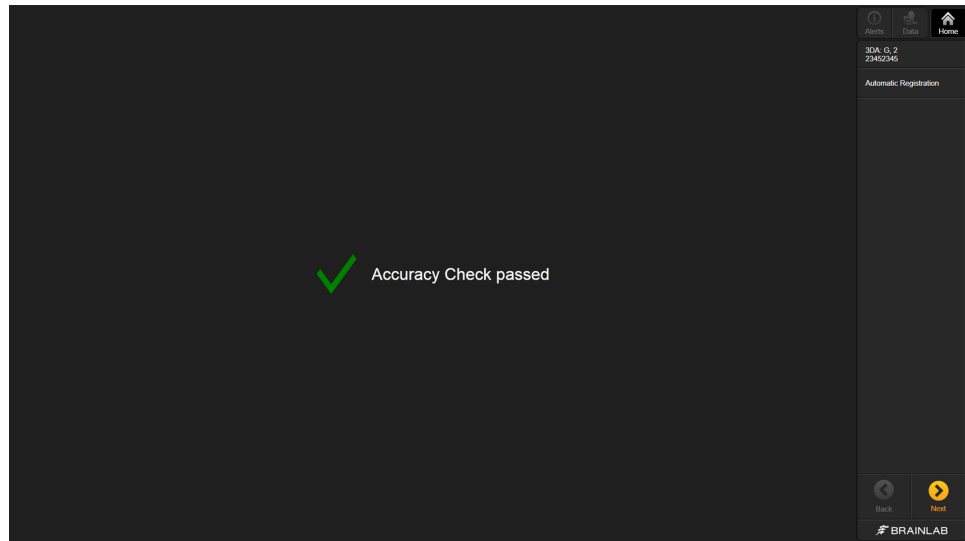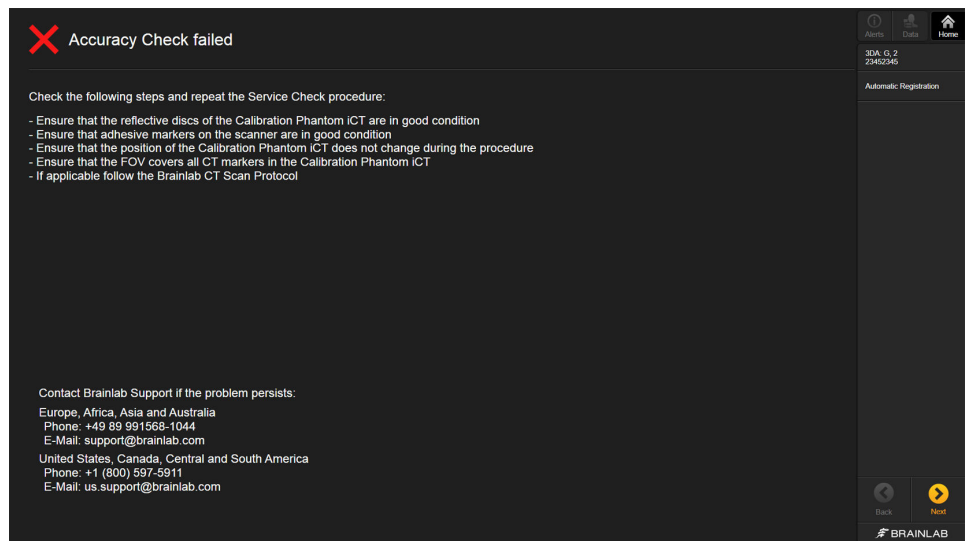
Step
9.   Once the scan is complete, the software informs you if the service check was successful. If it was successful, the following screen is displayed: Select **Next** to complete the service check.   If the service check was not successful, the following screen is displayed: Read the information about reasons for failure and resolve them, if applicable.
10.   Select **Next** to complete the service check. If the problem persists, contact Brainlab support.

5 UNIVERSAL AUTOMATIC REGISTRATION

5.1 Introduction – Universal Workflow

Draping
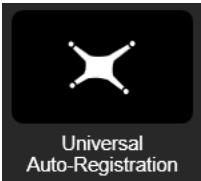
⚠️ **Warning**
Only drape the patient with sterile drapes approved for use by Brainlab.

For more information see the **Intraoperative Imaging Cranial Hardware User Guide**, **Spine and Trauma Instrument User Guide** or contact Brainlab support.

How to Enter the Automatic Registration Workflow

Step
1. Select **Navigation** from the **Cranial** or **Spine & Trauma** workflow.
2.   Select **Automatic Registration**.

Scan Considerations

⚠️ **Warning**
The Registration Matrix CT must be in the scanner's field of view (e.g., via scout scans). This is essential for a successful registration.

Only perform scans according to the relevant scan protocol.

Scan Preparation

⚠️ **Warning**
Always perform a collision check before scanning, paying particular attention to the reference array and Registration Matrix.

⚠️ **Warning**
Remove all metal items from the region of interest during scanning in order to avoid artifacts.

Altering Data

Do not alter image data on the scanner in any way (e.g., rotation, flipping, contrast, magnification). Make sure that the original DICOM information is sent directly to the Brainlab Navigation Station for registration without delay, otherwise the automatic registration cannot be performed.

5.2   Cranial Registration – Universal

Patient Preparation

Follow the sterile draping instructions in the **Intraoperative Imaging Cranial Hardware User Guide** to avoid displacements that may be caused by moving the scanner.

How to Prepare the Patient – Cranial

Follow the steps as prompted on screen to prepare for scanning.
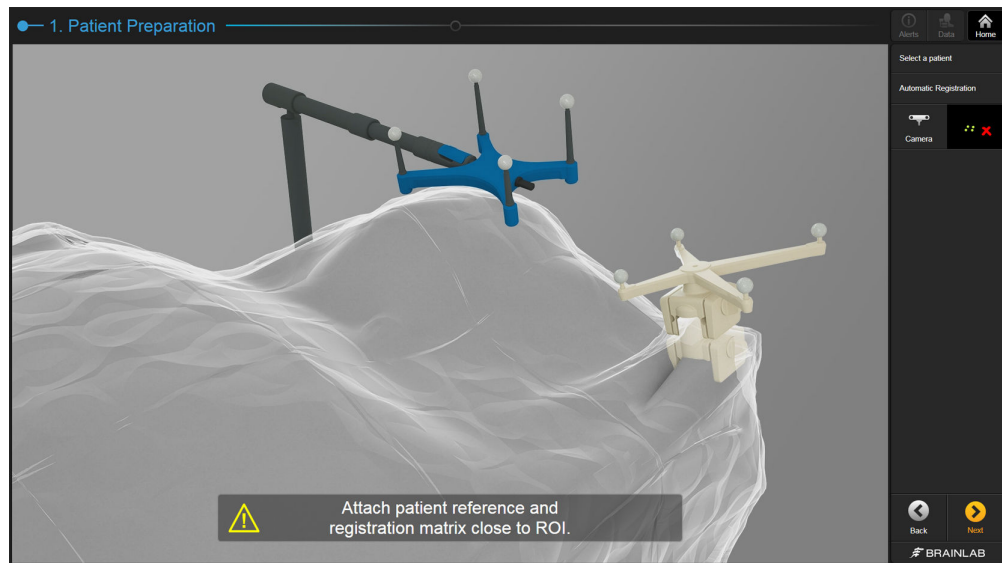
Figure 16

Step	
1.	Attach **Patient Reference** and **Registration Matrix CT** close to the ROI, as shown in the software.
2.	Select **Next**. Refer to the **Cranial/ENT Software User Guide** for more information.

How to Attach the Supporting Arm

Step	
1.	Drape the patient.
2.	Attach and fixate **Supporting Arm for Registration Matrix CT** to the operating table side rail. *NOTE: **Supporting Arm** is not sterile.*
3.	Attach **Registration Matrix CT** to **Supporting Arm** and fixate it by closing the lid.
4.	Adjust **Supporting Arm** in order to place **Registration Matrix CT** close to the ROI, as shown in the software.

How to Perform a Setup Check – Cranial

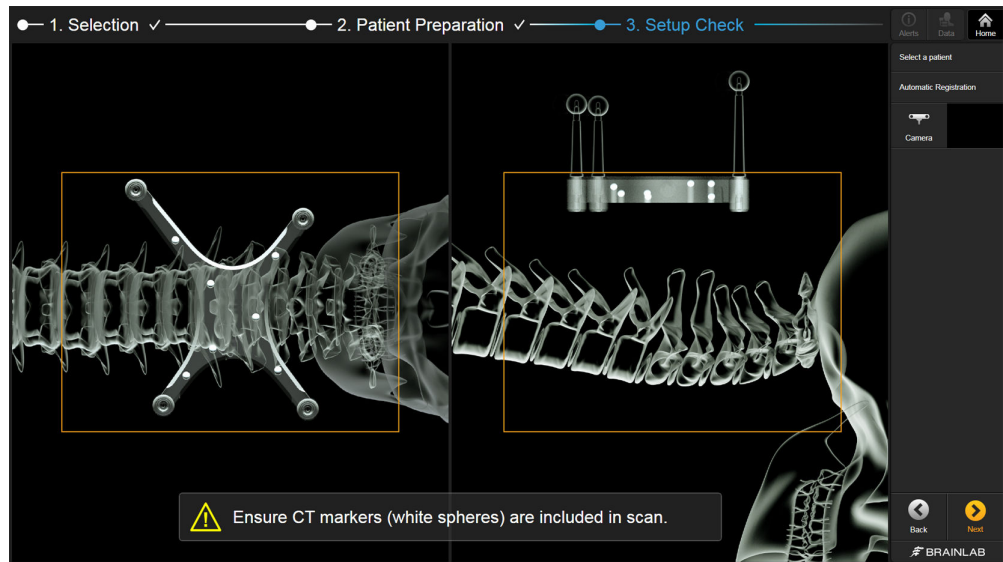CT markers appear as white spheres on the scan.
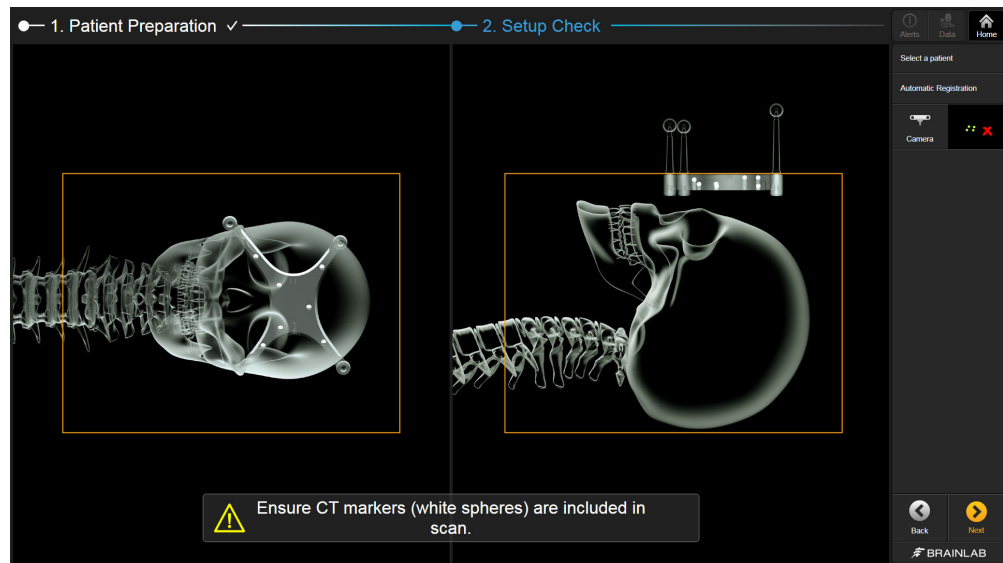
Figure 17

Step	
1.	Use scout scans to adjust the 3D volume on your scanner, similar to the example in the software.
2.	Ensure all CT markers within the **Registration Matrix** will be included in the scan.
3.	Perform a collision check. Pay attention that the **Registration Matrix** and patient reference arrays do not move.
4.	Select **Next**.

5.3   Spinal Registration – Universal

Patient Preparation

It is recommended that **Registration Matrix CT** be affixed to the patient (e.g., with sterile tape).

Follow the sterile draping instructions in the **Intraoperative Imaging Cranial Hardware User Guide** to avoid displacements that may be caused by moving the scanner.

How to Select the Registration Matrix
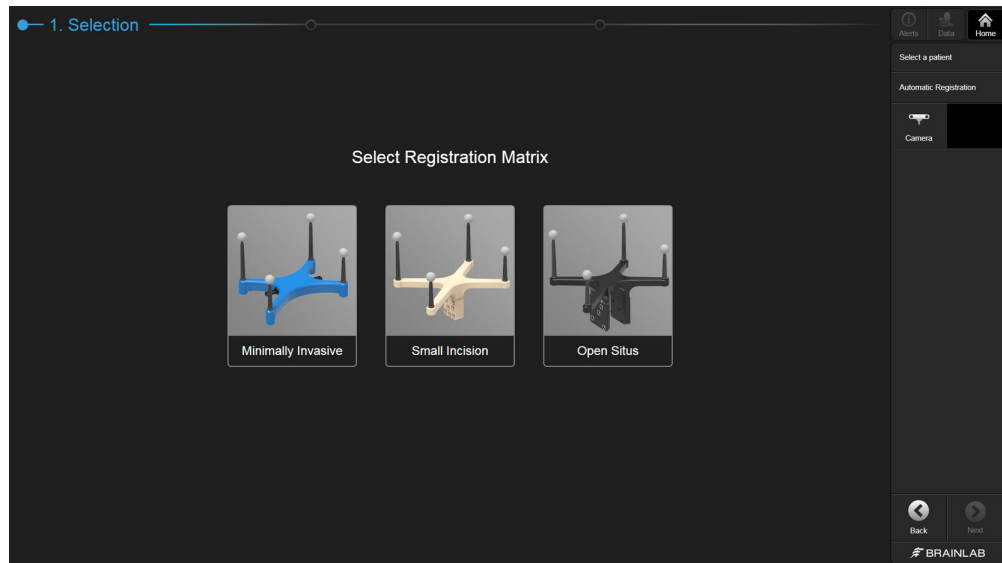
Figure 18

Step
Select the **Registration Matrix** appropriate for your procedure: • **Minimally Invasive** • **Small Incision** • **Open Situs** For cervical spine procedures, select **Minimally Invasive** only.

5.4 Procedures with Registration Matrix Minimally Invasive

How to Perform Spinal Registration

Follow these steps to perform spinal registration using **Registration Matrix CT** for minimally invasive procedures.

How to Prepare the Patient
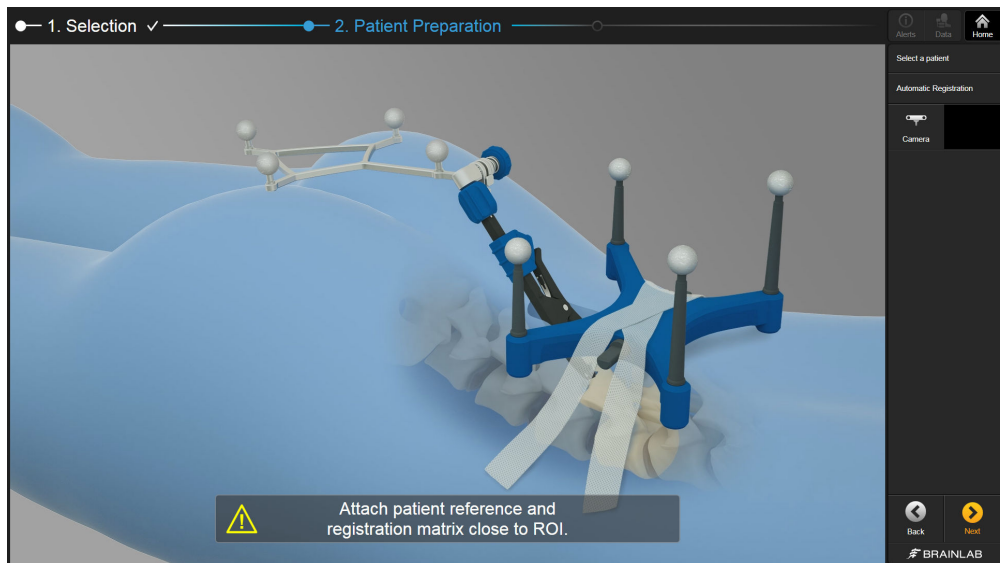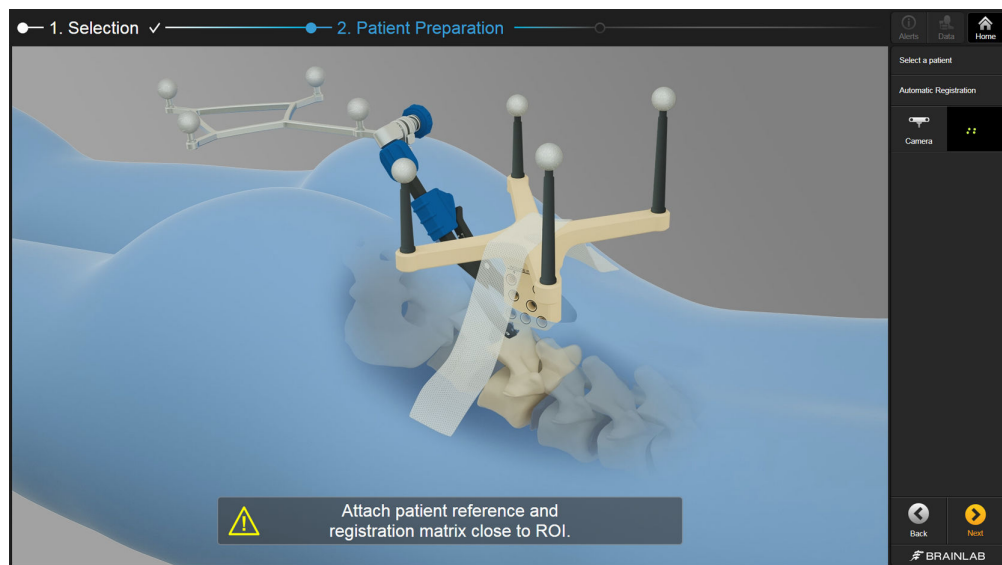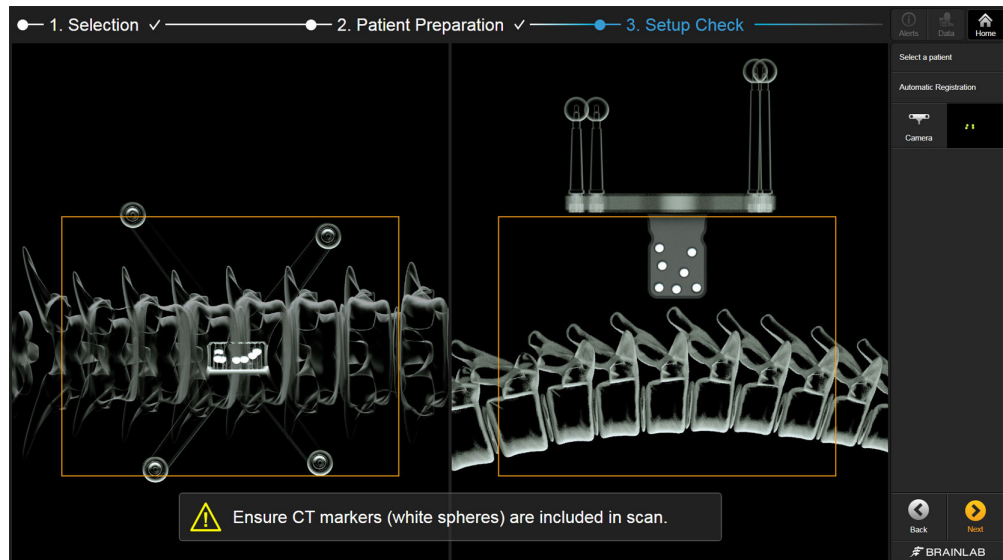

Figure 19
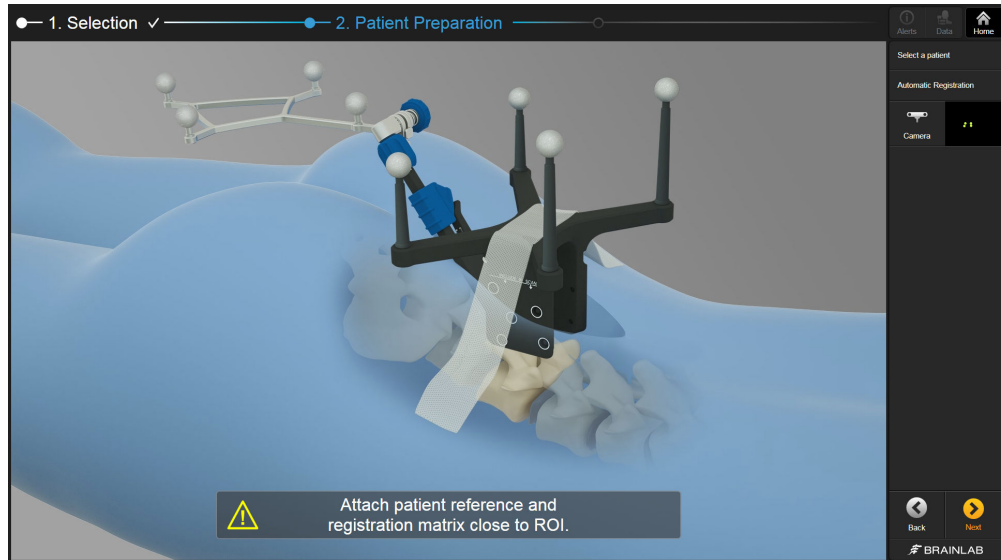
Step	
1.	Attach **Patient Reference** and **Registration Matrix** close to the ROI, as shown in the software. Ensure **Registration Matrix** is properly affixed to the patient (e.g., using sterile tape).
2.	Select **Next**.

How to Perform a Setup Check – Minimally Invasive

Registration Matrix CT is shown in two views depending on the selected anatomical region (e.g., here for minimally invasive spine procedures).

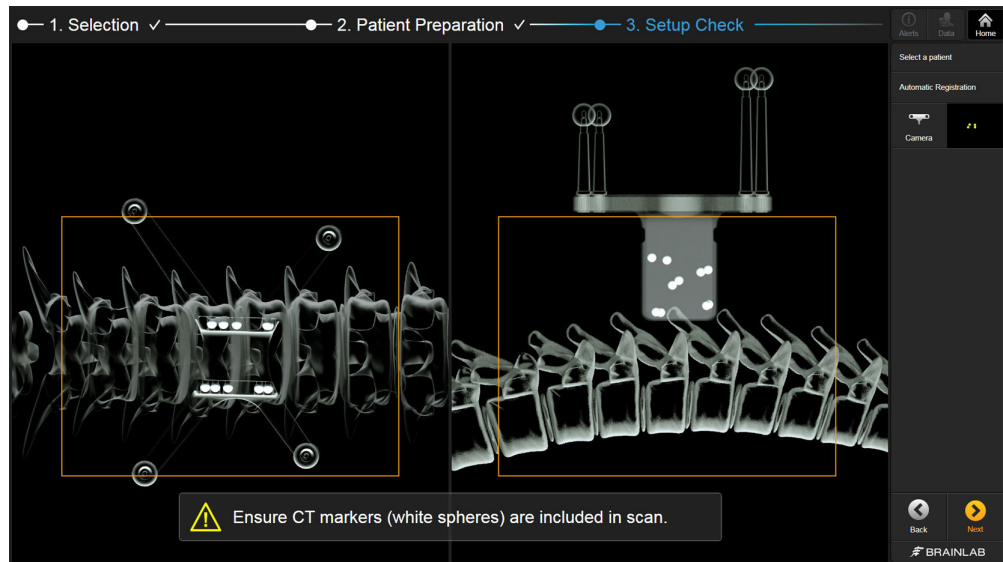CT markers appear as white spheres on the scan.

Figure 20

Step
1.   Use scout scans to adjust the 3D volume on your scanner, similar to the example in the software.
2.   Ensure all CT markers within the **Registration Matrix** will be included in the scan.
3.   Perform a collision check.   Pay attention that the **Registration Matrix** and patient reference arrays do not move.
4.   Select **Next**.

5.5 Procedures with Registration Matrix Small Incision

How to Perform Spinal Registration

Follow these steps to perform spinal registration using **Registration Matrix CT** for small incisions procedures.

How to Prepare Patient – Small Incision

Figure 21

Step	
1.	Attach **Patient Reference** and **Registration Matrix** close to the ROI, as shown in the software. Ensure **Registration Matrix** is properly affixed to the patient (e.g., using sterile tape).
2.	Select **Next**.

How to Perform a Setup Check – Small Incision

The **Registration Matrix** is shown in two views.

CT markers appear as white spheres on the scan.

Figure 22

Step
1.   Use scout scans to adjust the 3D volume on your scanner, similar to the example in the software.
2.   Ensure all CT markers within the **Registration Matrix** will be included in the scan.
3.   Perform a collision check. Pay attention that the **Registration Matrix** and patient reference arrays do not move.
4.   Select **Next**.

5.6 Procedures with Registration Matrix Open Situs

How to Perform Spinal Registration

Follow these steps to perform spinal registration using **Registration Matrix CT** for open situs procedures.

How to Prepare Patient – Open Situs

Figure 23

Step	
1.	Attach **Patient Reference** and **Registration Matrix** close to the ROI, as shown in the software. Ensure **Registration Matrix** is properly affixed to the patient (e.g., using sterile tape).
2.	Select **Next**.

How to Perform a Setup Check – Open Situs

Registration Matrix CT is shown in two views.

CT markers appear as white spheres on the scan.

Figure 24

Step
1.   Use scout scans to adjust the 3D volume on your scanner, similar to the example in the software.
2.   Ensure all CT markers within the **Registration Matrix** will be included in the scan.
3.   Perform a collision check. Pay attention that the **Registration Matrix** and patient reference arrays do not move.
4.   Select **Next**.

5.7 Structure Detection – Universal

Detecting Structures

⚠ **Warning**

Always perform structure detection prior to scanning.

After the collision check, the scanner is in the position where structures can be acquired.

The following information will describe how to detect structures for cranial procedures or for spinal procedures using any of the three **Registration Matrices CT**.

How to Detect Structures for Registration – Cranial

The software checks that all necessary marker structures are visible to the camera. Structures in view are listed as **Visible** ① on the left and shown in the camera view ②.
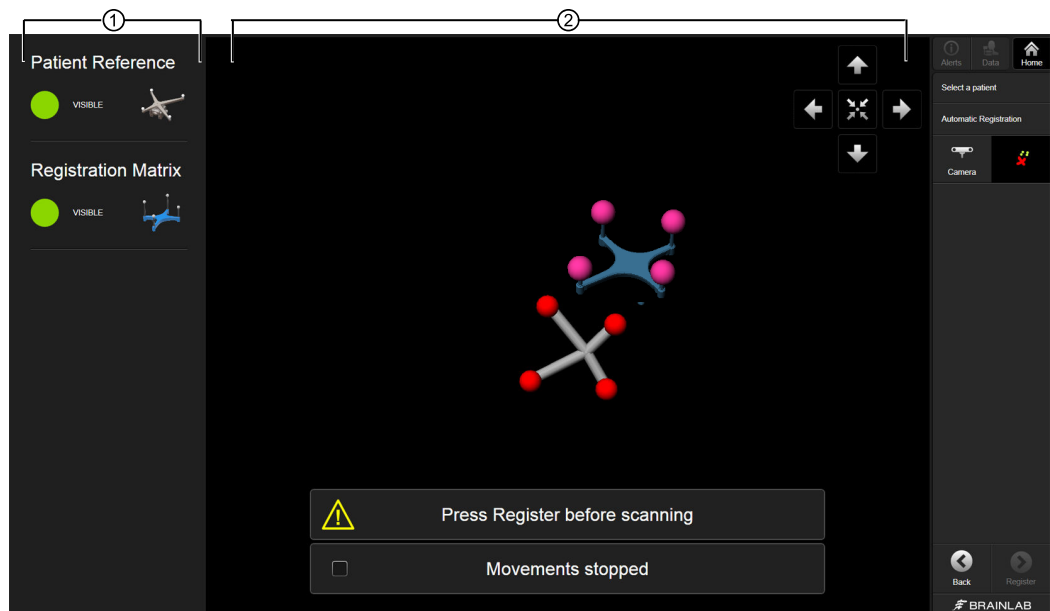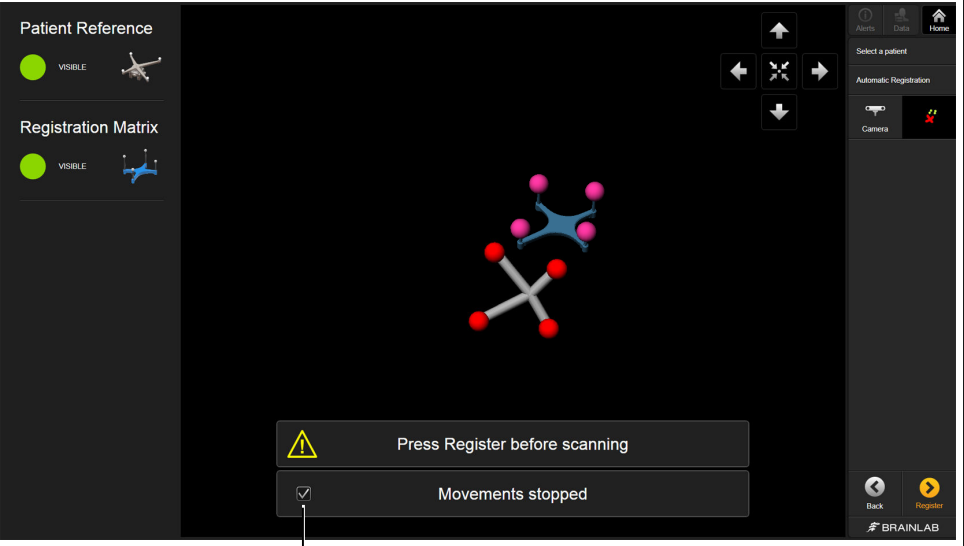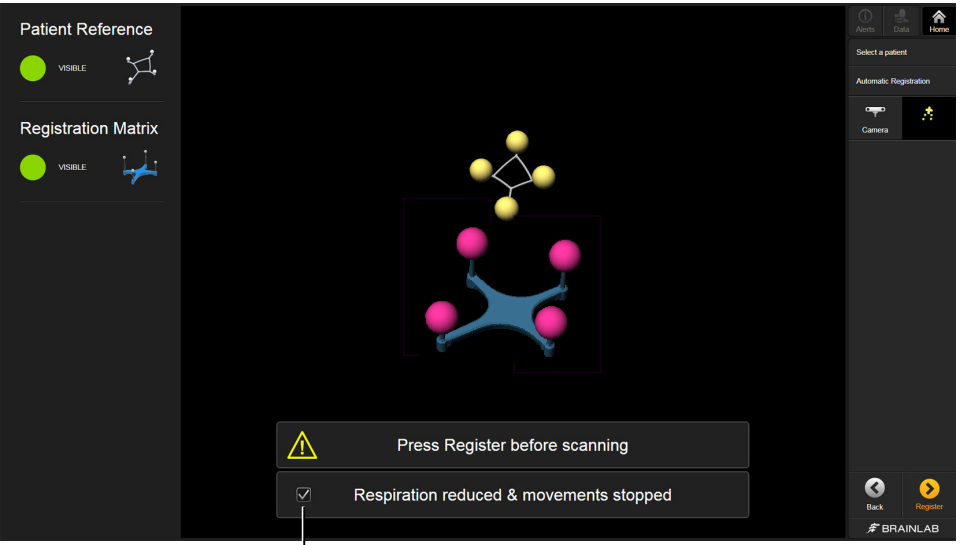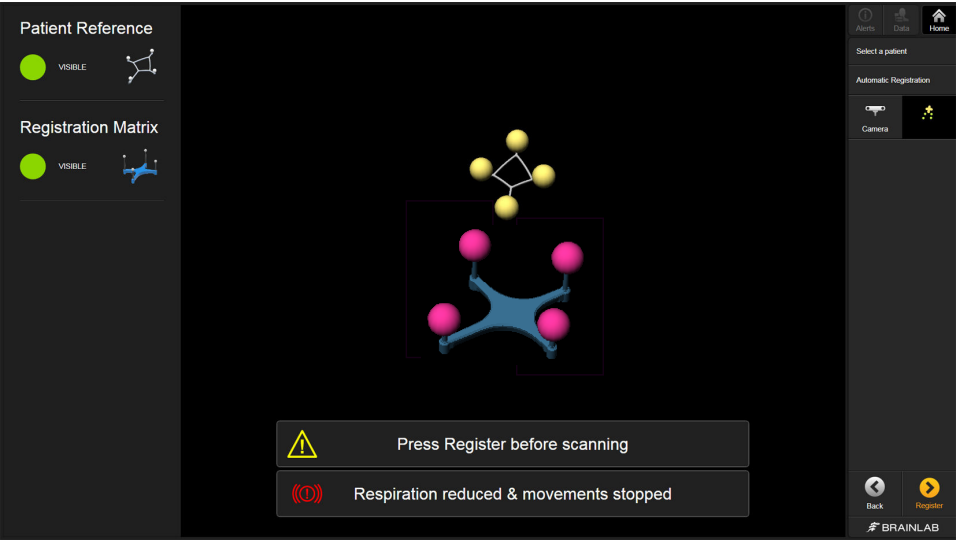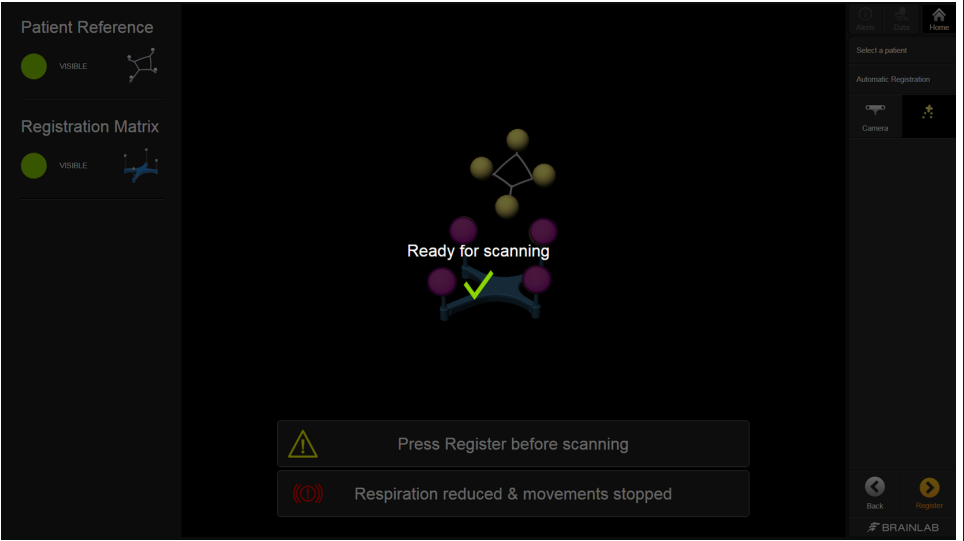

Figure 25

Step
1. Ensure that the camera is positioned so that the **Registration Matrix** and the patient reference array are centered in the camera field of view.   *NOTE: If a marker structure is not visible or is removed from view, it will appear grayed out on the left, and **Register** will be inactive. All necessary structures must be visible before you can continue.*

Step	
2.	Confirm that no movement of the **Registration Matrix** and patient reference will occur after selecting **Register** by selecting the **Movements stopped** check box ①.
3.	**Register** becomes active and the **Movements stopped** warning is displayed with a red symbol. After this step, do not move **Registration Matrix** or patient reference array until the scan is finished.
4.	Select **Register** prior to starting the scan.
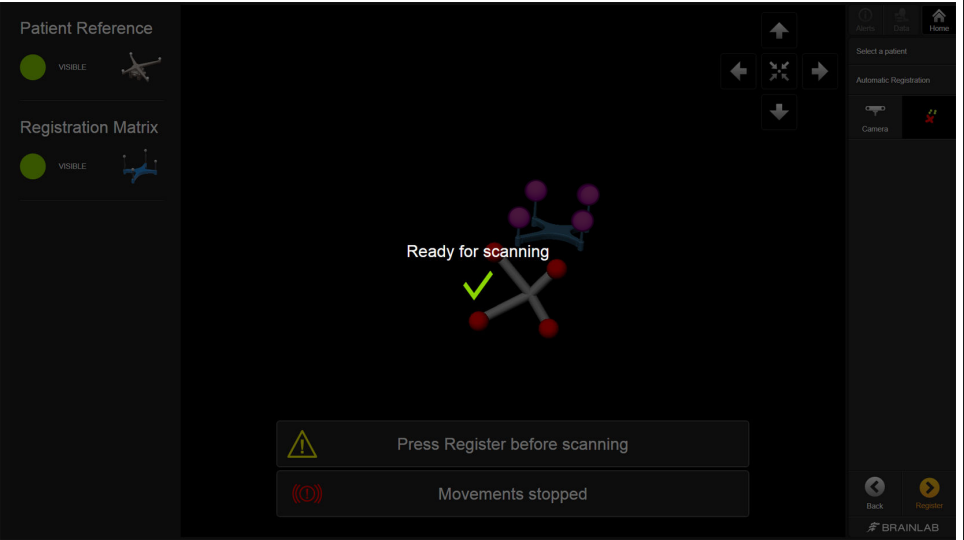
Step	
5.	The system is now ready for scanning. The **Movements stopped** warning remains visible. Always perform registration before scanning.

How to Detect Structures for Registration – Spinal

The software checks that all necessary marker structures are visible to the camera. Structures in view are listed as **Visible** ① on the left and shown in the camera view ②. This example shows the **Registration Matrix** for thoracolumbar and cervical spine procedures:
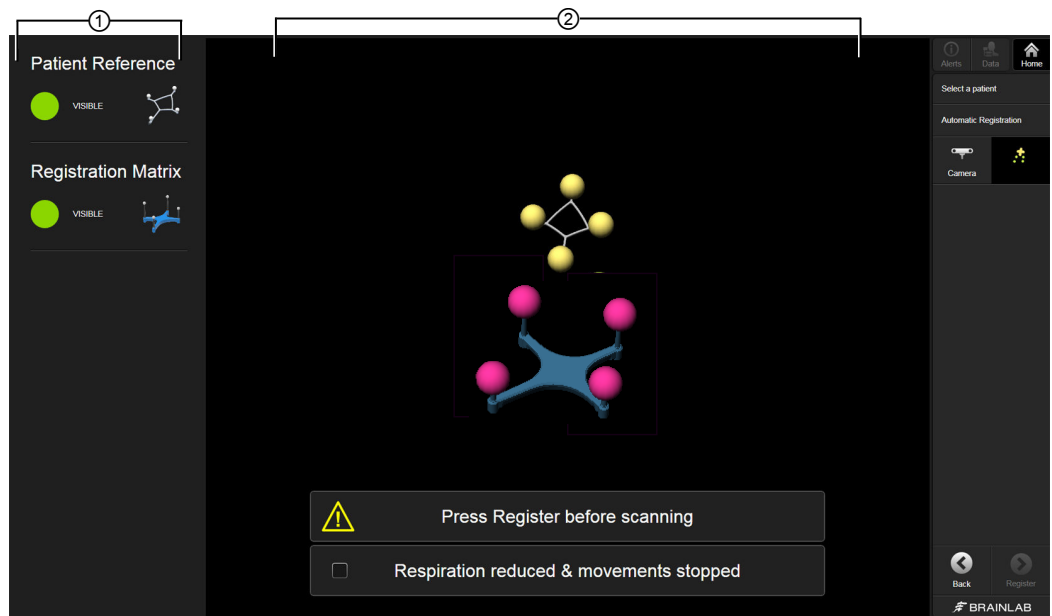
Figure 26

Step	
1.	Ensure that the camera is positioned so that the **Registration Matrix** and the patient reference array are centered in the camera field of view at all times. *NOTE: If a marker structure is not visible or is removed from view, it will appear grayed out on the left, and **Register** will be inactive. All necessary structures must be visible before you can continue.*

Step	
2.	Consider halting or reducing patient respiration to prevent movement of the patient.
3.	Confirm that no movement of the **Registration Matrix** and patient reference will occur after selecting **Register** by selecting the **Respiration reduced & movements stopped** check box ①.
4.	**Register** becomes active and the **Respiration reduced and movements stopped** warning is displayed. After this step, do not move **Registration Matrix** or patient reference array until the scan is finished.
5.	Select **Register** to start the scan.

Step
6. The system is now ready for scanning. The **Respiration reduced & movements stopped** warning remains visible. Always perform registration before scanning.

5.8 Image Acquisition – Universal

Overview

After setting up the patient and scanner, **Automatic Registration** allows you to acquire intraoperative patient data and send it to the Brainlab Navigation Station.

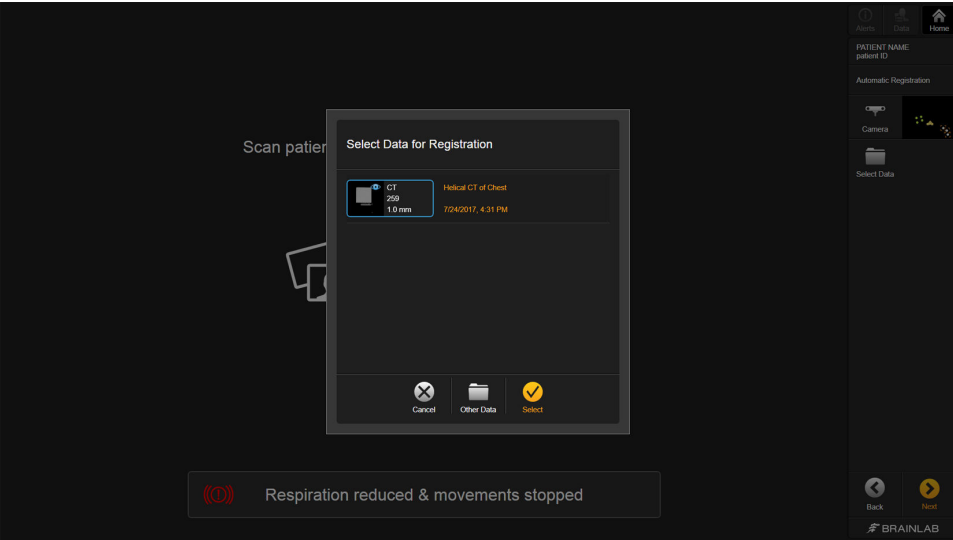**How to Scan the Patient and Select Data – Universal**
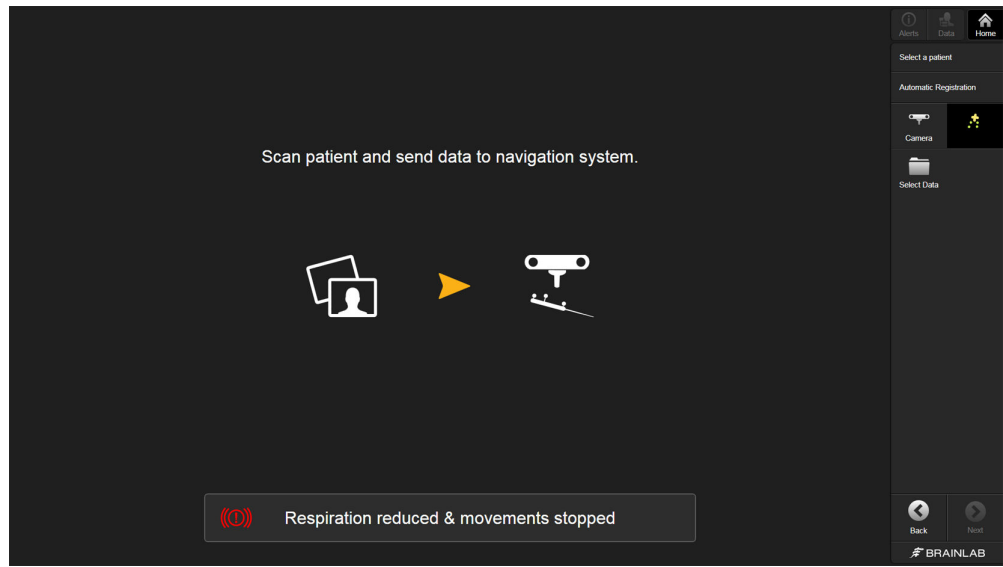
Figure 27

Step
1. Acquire the 3D scan according to the scan protocol and send the data to the Brainlab Navigation Station (DICOM node). The software detects if data is received and calculates the registration.
2. If there is no DICOM node for Brainlab navigation configured on your scanner, use **Select Data** ① on the toolbar to select the correct patient data for registration (e.g., via PACS).
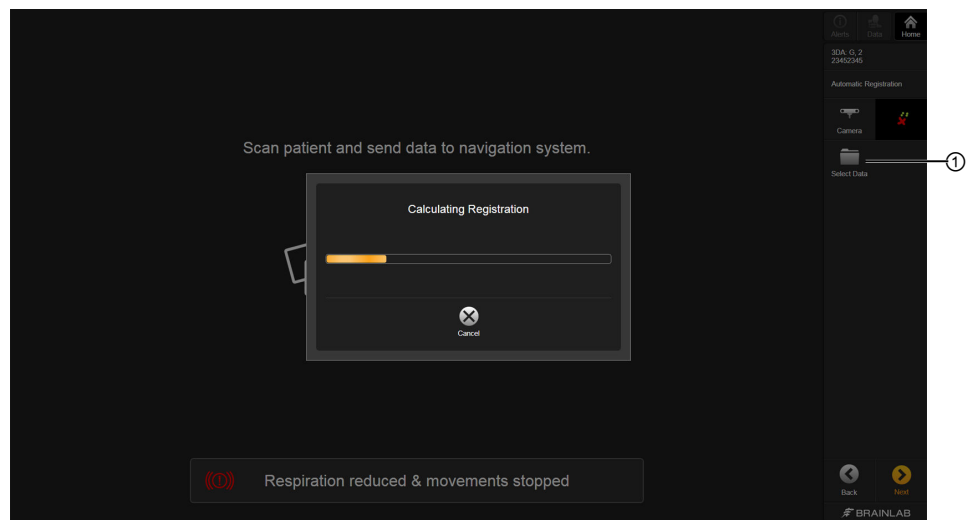
Step	
3.	Select your image set from the dialog box that opens. If the desired scan is not listed here, the **Other Data** button opens **Patient Selection** in **Content Manager**. *NOTE: Refer to the **Origin Data Management Software User Guide** for more information.*
4.	Select **Next**.

5.9   Accuracy Verification – Universal

Verifying Automatic Registration

Always verify registration accuracy carefully prior to starting the navigated procedure by holding the pointer or instrument tip to at least three anatomical landmarks and verifying their position in the software.

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

Verify Registration Accuracy – Cranial

Figure 28

Step
1.   Verify automatic registration by touching at least three landmarks with the pointer.
2.   If accuracy is acceptable, select **Yes**.

Verify Registration Accuracy – Spine Standard Procedure

Figure 29

Step
1. Hold the instrument on the bony surface of at least three of the following landmarks: • Posterior (on the spinous process) / Anterior (on several locations on the lamina) • Left/Right (on the facet joint or mid-height on the spinous process) • Cranial/Caudal (on the spinous process; first on the cranial and then the caudal part)
2. Verify that the instrument position displayed on the screen matches the actual position of the instrument on the anatomical landmark.

3. After verification, two options are available. Select:
• **Yes** if the registration is accurate, and to proceed to navigation.
• **No** if the registration is inaccurate, and to clear the current registration. Select either:
  - **New Scan**: Return to the registration software to acquire a new registration.
  - **Discard & Exit**: Exit the software and return to **Content Manager**.

Verify Registration Accuracy – Spine Minimally Invasive Procedure

If you are performing a minimally invasive procedure that restricts the verification of at least three landmarks, perform the following accuracy check:

Step
1. Insert the instrument into the incision so that it is securely touching an anatomical landmark, reference array clamp or tooth.
2. Acquire fluoro images of the instrument on the bone: • Lateral fluoro image (cranial/caudal or posterior/anterior registration) • AP fluoro image (cranial/caudal or left/right registration)
3. Verify that the instrument position displayed on the screen corresponds to the position in the fluoro image.

Step

4.   After verification, two options are available. Select:
      • **Yes** if the registration is accurate, and to proceed to navigation.
      • **No** if the registration is inaccurate, and to clear the current registration. Select either:
         - **New Scan**: return to the registration software to acquire a new registration.
         - **Discard & Exit**: exit out of the software and return to **Content Manager**.

5.10   Service Check – Universal

Performing a Service Check
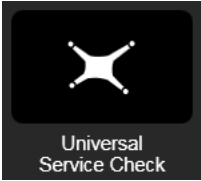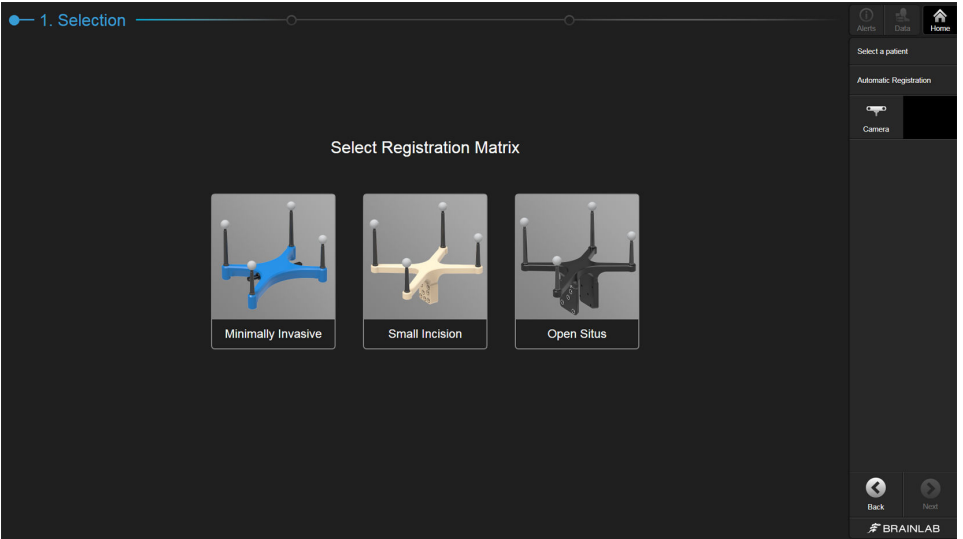
Use the scanner test workflow at any time to check the accuracy of the scanner and the **Registration Matrix** (e.g., if a structure has been moved, bumped or dropped).
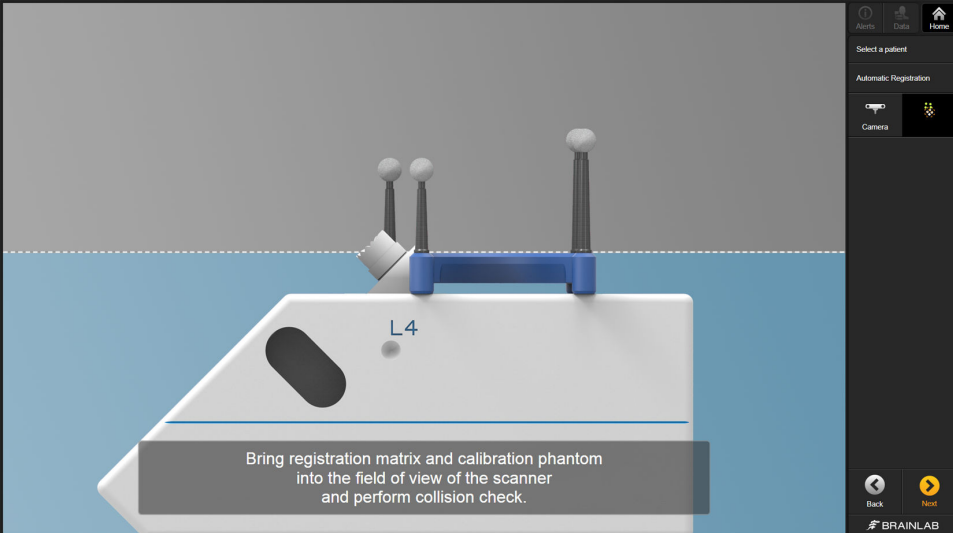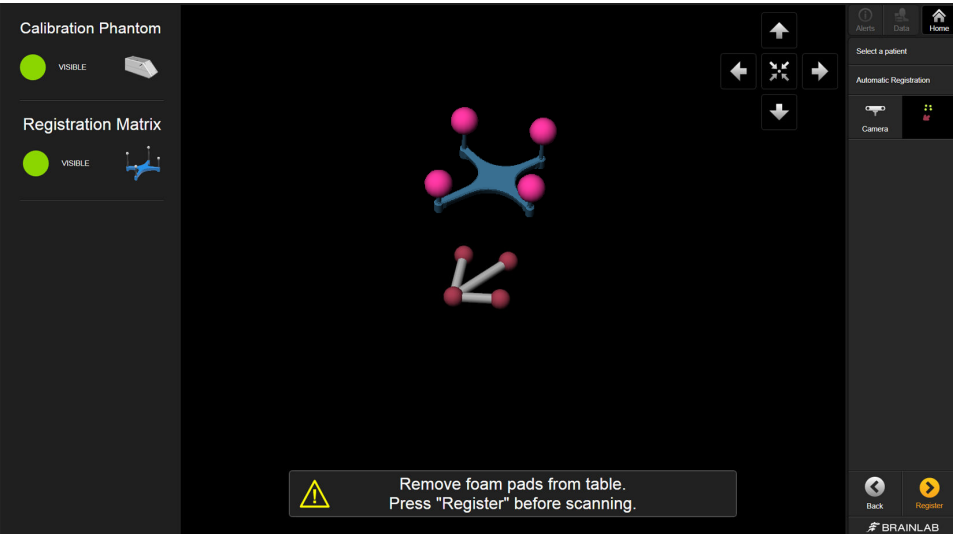
- Perform a service check regularly.
- The service check does not replace regular maintenance and inspection performed by Brainlab.
- The service check shall be performed by technical staff only.
- Not for patient treatment.

It is recommended that your technical staff use this workflow to verify the **Registration Matrix** after 30 sterilization cycles.

How to Perform a Service Check

Follow these steps to perform a service check to verify registration accuracy. The screenshots are exemplary for the Minimally Invasive **Registration Matrix**.

Step
1.   Select **Universal Service Check** from the workflow under **Tools**.
2.   Select the **Registration Matrix** you want to verify.

| Step |
|---|
| 3. Perform a setup check as described in the software. For instance:
    • Bringing **Registration Matrix** and calibration matrix into the scanner's field of view
    • Performing a collision check
    • Removing cushions and foam pads from the OR table, if applicable

 |
| 4. Select **Next**. |
| 5. Ensure that all structures are in the camera view.

 |
| 6. Select **Register** to continue. |
| 7. Select **Next** to scan the phantom. |

Step
8.   Either the software detects that it is receiving data or you can select data manually by selecting **Select Data** from the toolbar.
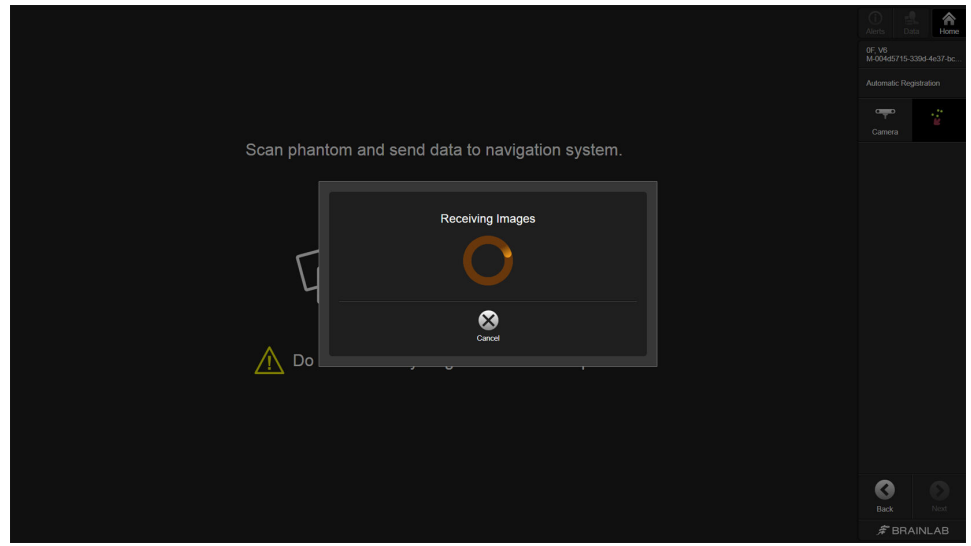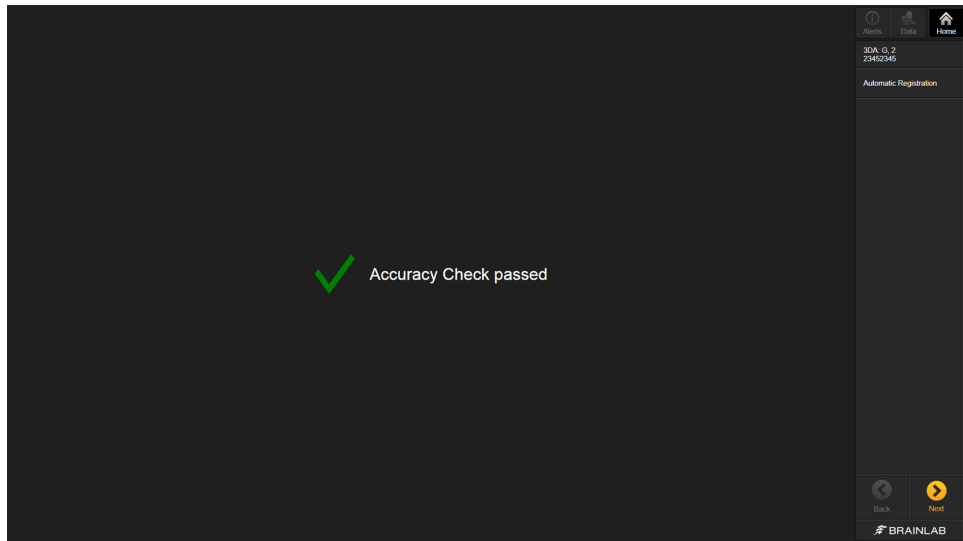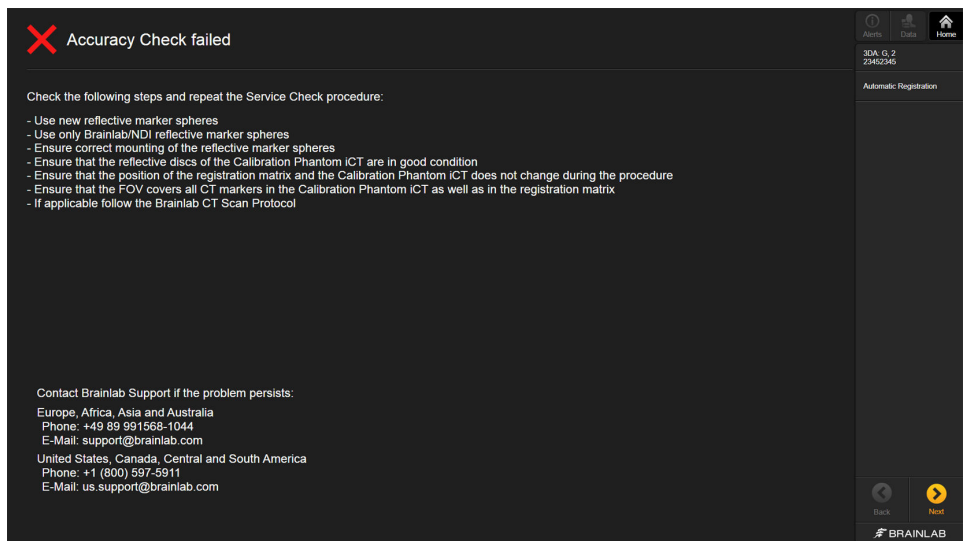
Step
9. Once the scan is complete, the software informs you if the service check was successful. If it was successful, the following screen is displayed: Select **Next** to complete the service check. If the service check was not successful, the following screen is displayed:
10. Read the information about reasons for failure and resolve them, if applicable.
11. Select **Next** to complete the service check. If the problem persists, contact Brainlab support.
12. If applicable, repeat this procedure to verify the remaining **Registration Matrices**.

6   ACCESSORIES

6.1   Adhesive Flat Markers

General Information

Adhesive Flat Markers are used to reference compatible scanners during registration.

NOTE: The information provided here does not substitute the scanner manufacturer's user guide.

Product Information

Figure 30

Name	Scanners	Draping	Article No.
Adhesive Flat Markers (10 PCS)	• **Airo** • **Loop-X** • Siemens CT scanners • Siemens Artis Zeego	Drape the C-arm	19144

Ensuring Navigation Accuracy

Registration	Placement
Before	Markers are attached to the scanner by Brainlab support.
During	Markers must be visible to the camera at all times.
After	Markers do not have to remain in the camera's field of view. Move the scanner back to its parking position or adjust the camera accordingly.

NOTE: The adhesive flat markers on the scanner must not be covered by wrinkles of the sterile drape or other objects.

⚠ **Registration accuracy depends on the condition of the adhesive flat markers. Verify prior to use that the reflective surface of all flat markers is in good condition and not peeling.**

6.2 Calibration Phantom CT Scanner

General Information

The **Calibration Phantom CT Scanner** (19148) is used to verify the accuracy of the automatic image registration of CT and angio data with Brainlab software applications.
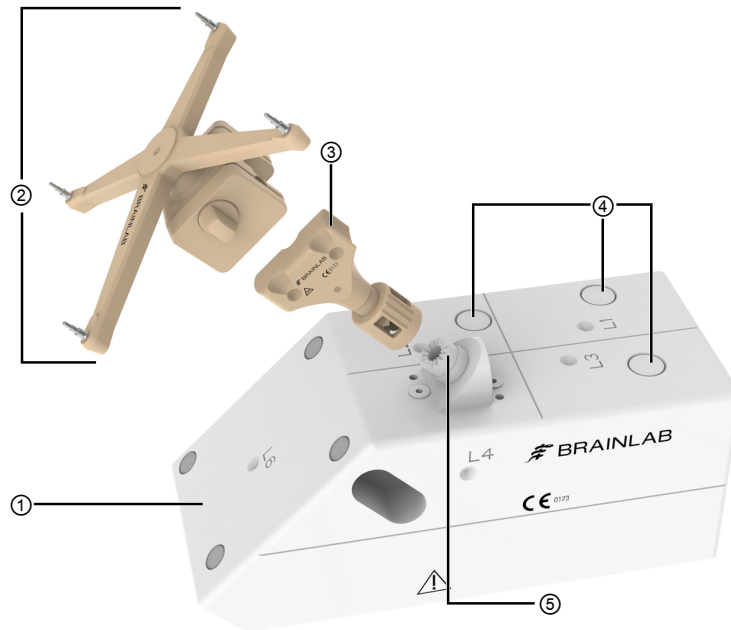
Components

Figure 31

No.	Component	Article No.
①	**Calibration Phantom CT Scanner**	19148
②	**DrapeLink Reference Array Cranial**	19152-02
③	**DrapeLink Interface for iCT Calibration Phantom**	19142-06
④	Notches (used as landmarks for verification)	n/a
⑤	Connector (interface for reference array attachment)	n/a

How to Assemble and Scan the Phantom

Step	
1.	Attach the respective reference array ① onto the connector ②.
2.	Attach three **Disposable Reflective Marker Spheres** to the reference array.
3.	Place the phantom on the table and align the scanner laser guides to the crosshair on top of the phantom.
4.	Perform a scan according to the instructions in the **Software User Guide**.

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