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1 GENERAL INFORMATION

1.1 Contact Data and Legal Information

Manufacturer

This product is manufactured by Brainlab and exclusively distributed by DePuy Synthes.

Brainlab AG
Kapellenstr. 12
85622 Feldkirchen
Germany

Distributor

DePuy Synthes Sales, Inc.
325 Paramount Drive
Raynham, MA 02767
USA

Support

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

<table>
<thead>
<tr>
<th>Region</th>
<th>Telephone and Fax</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States, Canada, Central and South America</td>
<td>Tel: +1 (866) 473 7823</td>
</tr>
<tr>
<td>Europe, Middle East, Africa</td>
<td>Tel: +32 2 352 16 66</td>
</tr>
<tr>
<td>Asia, Australia</td>
<td>Tel: +65 6827 6154</td>
</tr>
</tbody>
</table>

Expected Service Life

For this product five years of service are provided. During this period of time software updates as well as field support are offered.

Feedback

Despite careful review, this manual may contain errors.

Please contact us at igs.manuals@brainlab.com if you have suggestions as to how we can improve this manual.
1.1.1 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.

Non-Brainlab Trademarks

Microsoft® and Windows® are registered trademarks of Microsoft Corporation in the United States and other countries.

Integrated 3rd-Party Software

- This software is based in part on the work of the Independent JPEG Group.
- This software is based on the work of the Open JPEG Group (for licensing information, see: http://www.openjpeg.org/BSDlicense.txt).
- Portions of the software are based in part on the CyberVrml97 package written by Satoshi Konno.

CE Label

The CE label shows that the Brainlab product complies with the essential requirements of Council Directive 93/42/EEC (the "MDD"). According to the principles set out in the MDD, Fluoro Express is a Class IIb product.

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

Disposal Instructions

Only dispose of electrical and electronic equipment in accordance with statutory regulations. For information regarding the WEEE (Waste Electrical and Electronic Equipment) directive, visit:

http://www.brainlab.com/weee

Sales in the US

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

Warnings

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

Cautions

Cautions are indicated by circular caution symbols. They contain safety-critical information regarding possible problems with the device. Such problems include device malfunctions, device failure, damage to device or damage to property.

Notes

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

Indications for Use

Fluoro Express is intended to be a pre- and 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 pre- or intraoperative image data being processed by a Brainlab Navigation Workstation.

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, a bone structure like tubular bones, pelvic, calcaneus and talus, scapula, or vertebra, can be identified relative to a CT, fluoroscopic, X-ray or MR based model of the anatomy.

Example procedures include but are not limited to:

- Spinal procedures and spinal implant procedures such as pedicle screw placement.
- Pelvis and acetabular fracture treatment such as screw placement or ilio-sacral screw fixation.
- Fracture treatment procedures such as intramedullary nailing or plating or screwing, or external fixation procedures in the tubular bones.

Intended User

The intended users of Fluoro Express are surgeons and medical professionals.

Patient Group

All patients of all ages where a reference to a rigid anatomical structure can be established. For children with an open epiphyseal plate, this structure must not be damaged in order to avoid a negative effect on growth.

Place of Use

The application is to be used in the operating room.

Plausibility Review

Before patient treatment, review the plausibility of all information input to and output from the system.
1.4 Compatibility with Medical Devices

Brainlab Medical Instruments

Compatible Brainlab Medical Instruments

Fluoro Express is compatible with:

- Adapter for Surgical Motor System (SMS)
- Chisel Navigation Package
- Disposable Reflective Marker Spheres
- Drill Guide and Accessories
- Fluoro 3D/2D Registration Kit
- Fluoro Registration Kit (Rev. 2)
- Instrument Adapter Kit, StarLink Interface
- Instrument Adapter Kit, StarLock Interface
- Instrument Calibration Matrix, Rev. 4.0 (ICM4)
- Minimally Invasive Reference Array 3mm, Y-Geometry
- X-Press Bone Fixators (1-Pin, 2-Pin)
- Pointer Extended with Sharp Tip
- Radiolucent Spine Reference Clamp Kit
- Spine Probe Set
- Spine Reference Kit - Anterior/Lateral/Oblique
- Spine Reference X-Clamp
- xSpot (and accessory package)

Other Brainlab Instruments

Additional instrumentation may become available after the release of this manual. Contact support if you have any questions regarding instrument compatibility with Brainlab software.

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

**Other Brainlab Software**

⚠️ Only Brainlab medical software specified by Brainlab may be installed and used with the system.
1.4.2 Non-Brainlab Medical Devices

Compatible Non-Brainlab Medical Devices

<table>
<thead>
<tr>
<th>Medical Device</th>
<th>Model/Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>C-arms</td>
<td>Various, contact support.</td>
</tr>
<tr>
<td>Transparent sterile C-arm drapes</td>
<td>As specified in the Instrument User Guide.</td>
</tr>
<tr>
<td>Threaded 3.0 mm K-wires (for fixation of MIRA-Y 3mm)</td>
<td>Various</td>
</tr>
<tr>
<td>Power drill</td>
<td>Various</td>
</tr>
<tr>
<td>3rd-party precalibrated instruments and axis</td>
<td>Various, contact support.</td>
</tr>
<tr>
<td>precalibrated instruments</td>
<td></td>
</tr>
</tbody>
</table>

Other Non-Brainlab Devices

- A precalibrated instrument can only be used for navigation if it has been activated by support.

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

- Fluoro Registration Kits may only be used with Brainlab-approved C-arms. If you plan on using C-arms, not yet configured with your system, please contact support. Brainlab is not responsible in the event of non-approved C-arm use.
1.4.3 Non-Brainlab Software

Compatible Non-Brainlab Software

Fluoro Express is compatible with:

- Windows 7 operating system
- Windows 8 operating system

*NOTE: For information regarding compatible service packs please contact support.*

Other Non-Brainlab Software

⚠️ Only software specified by Brainlab may be installed and used with Fluoro Express. Do not install third-party software.

Driver Updates

⚠️ Do not install driver updates.
1.4.4 Antivirus and Windows Update Policy

Windows Updates

It is recommended to apply Microsoft updates as they become available. Microsoft updates must be configured as follows:

1. Only install security and critical Microsoft operating system updates.
2. Do not install updates during patient treatment.
3. Deactivate pop-up messages.

Brainlab recommends:
1. Scheduling the download and installation of updates at system shutdown.
2. Testing the system together with a surgeon/physician after an update has been installed.

Antivirus Software Installation

Brainlab recommends protecting the system with state-of-the-art antivirus software. Although the safety and effectiveness of the device is ensured, be aware that this can negatively affect the system performance, e.g., patient data loading. System performance must be verified by support after antivirus software has been installed.

Antivirus Software Configuration

Antivirus software must be configured as follows:

1. Only activate on-access/real-time scan and on-demand/scheduled scan:
   - On-access/real-time scan may be activated permanently.
   - On-demand/scheduled scans must not be activated during patient treatment. It is recommended to schedule full scans at system shutdown.
2. Any other antivirus software feature like browser/email-scanners, additional firewall, etc. must be disabled.
3. The following folders must not be modified by antivirus software:
   - C:\Brainlab, D:\Brainlab and F:\Brainlab
   - C:\PatientData, D:\PatientData and F:\PatientData
5. Deactivate pop-up messages.

Precautions

- Do not download or install antivirus or windows updates during patient treatment.
- Do not reboot antivirus or windows updates during patient treatment.
- The antivirus scanner must be configured in a way that full scans do not occur during patient treatment.
- Brainlab requires that the antivirus scanner does not make any modifications to the Brainlab directories.
1.5 Training and Documentation

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

Supervised Support
Before using the system for surgical procedures where computer-aided navigation is considered critical, perform an adequate number of complete procedures with a Brainlab authorized representative present to provide guidance where necessary.

Responsibility

⚠️ This system solely provides assistance to the surgeon and does not substitute or replace the surgeon’s experience and/or responsibility during its use.
1.5.1 Documentation

**Intended Audience**

This user guide is intended for all members of the clinical team who use the **Fluoro Express** software or related equipment.

**Reading User Guides**

User guides describe complex medical devices and surgical navigation software that must be used with care.

It is important that all users of the system, instruments and software:

- Read the user guides carefully before handling the equipment
- Have access to the user guides at all times

**Available User Guides**

<table>
<thead>
<tr>
<th>User Guide</th>
<th>Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Software User Guides</td>
<td>• Overview of treatment planning and image-guided navigation</td>
</tr>
<tr>
<td></td>
<td>• Description of OR system setup</td>
</tr>
<tr>
<td></td>
<td>• Detailed software instructions</td>
</tr>
<tr>
<td>Instrument User Guides</td>
<td>Detailed instructions on instrument handling</td>
</tr>
<tr>
<td>Cleaning, Disinfection and</td>
<td>Details on cleaning, disinfecting and sterilizing instruments</td>
</tr>
<tr>
<td>Sterilization Guide</td>
<td></td>
</tr>
<tr>
<td>System User Guides</td>
<td>Comprehensive information on system setup</td>
</tr>
</tbody>
</table>
| Technical User Guide              | Detailed technical information on the system, including specifica-
|                                  |    tions and compliances                                       |
2 SOFTWARE OVERVIEW

2.1 Basic Functions

General Information

**Fluoro Express** is a wireless, touchscreen-operated navigation software designed for intraoperative use during spine and trauma surgery. It can be installed on Brainlab navigation systems.

⚠️ Only use Fluoro Express for treatments described in the section page 8 (see page 8). Do not use the software for any other treatments.

Wireless Tracking

Infrared flashes from the camera are reflected by reflective marker spheres on instrument tracking arrays and patient reference arrays. The system uses these reflections to calculate the three-dimensional position of the instrument relative to the reference array. Once image acquisition has been completed, the position of the instrument relative to the patient can be accurately determined and tracked by the system.

Supported Image Format

2D fluoroscopic image(s) of the patient are acquired intraoperatively, and are loaded to the **Fluoro Express** navigation software for navigation.

⚠️ Do not use Fluoro Express for diagnostic imaging purposes.
2.1.1 Opening the Software from the Content Manager

Before You Begin

Before beginning any procedure, ensure that you are familiar with the correct handling of all required instruments and accessories. For detailed information on instrument handling, see your Instrument User Guide.

General Information

After turning on the system, Fluoro Express can be accessed from Content Manager. You can select an existing patient or create a new patient, which loads the patient name and ID to the software. It is not possible to load pre-operative data to the software.

NOTE: It is possible to start the software even if the camera has not yet been connected.

How to Open the Software (Content Manager)

![Figure 2]

**Steps**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Turn on the system using the power switch.</td>
</tr>
</tbody>
</table>
| 2. | Select a patient or create a new patient.  
   
   **NOTE:** Optionally, enter patient information directly in the Fluoro Express software. |
| 3. | Press the [Fluoro Express] icon, then press the desired display. |

Other Options

In the event of a system crash, e.g., due to a power failure, it is possible to restore a previous registration and the acquired images (see page 76).
2.1.2 Switching between the Software and Content Manager

How to Switch to the Content Manager

<table>
<thead>
<tr>
<th>Step</th>
</tr>
</thead>
<tbody>
<tr>
<td>Press the [Home] button in the menu bar.</td>
</tr>
</tbody>
</table>

The Content Manager is displayed.
2.2 User Interface

Overview

In the workflow panel, you can proceed forward or backward through the main steps in the workflow.

Screen Layout

<table>
<thead>
<tr>
<th>No.</th>
<th>Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>①</td>
<td>Back button returns you to the previous step</td>
</tr>
<tr>
<td>②</td>
<td>Current step</td>
</tr>
<tr>
<td>③</td>
<td>Next step</td>
</tr>
<tr>
<td>④</td>
<td>Next button opens the next step</td>
</tr>
</tbody>
</table>

Figure 3
2.2.1 General Buttons

General Information

Various buttons are available on main screens and dialogs, depending on your current step.
- Blue/green shading indicates the button is available
- Yellow shading indicates the button is currently selected
- Gray shading indicates the button is disabled

Common Buttons

<table>
<thead>
<tr>
<th>Button</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Next</td>
<td>Completes the action for the current step and opens the next dialog or main screen.</td>
</tr>
<tr>
<td>Back</td>
<td>Returns you to the previous step.</td>
</tr>
<tr>
<td>Cancel</td>
<td>Exits the current step without saving your settings.</td>
</tr>
<tr>
<td>Close</td>
<td>Exits a dialog and returns you to the previous dialog or main screen.</td>
</tr>
</tbody>
</table>

NOTE: Other buttons with specific functions are described with the corresponding step.
### Tool Bar Buttons

<table>
<thead>
<tr>
<th>Button</th>
<th>Name</th>
<th>Function</th>
<th>See</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Home</td>
<td>Returns to Content Manager</td>
<td>Page 19</td>
</tr>
<tr>
<td></td>
<td>System Settings</td>
<td>Opens the [System] menu for configuring system settings</td>
<td>Page 87</td>
</tr>
<tr>
<td></td>
<td>Precalibrated Instruments</td>
<td>Activates the selection and validation/verification of precalibrated instruments</td>
<td>Page 53</td>
</tr>
<tr>
<td></td>
<td>Instrument Display</td>
<td>Switches between a solid 3D or outlined 2D instrument display</td>
<td>Page 85</td>
</tr>
<tr>
<td></td>
<td>Video brightness</td>
<td>(Available only for analogue C-arm) Controls video brightness and contrast for the C-arm</td>
<td>Page 75</td>
</tr>
<tr>
<td></td>
<td>Swap images</td>
<td>Enables you to change the order of image display in the panels</td>
<td>Page 73</td>
</tr>
<tr>
<td></td>
<td>Zoom/Pan</td>
<td>Enables zoom and pan functions</td>
<td>Page 73</td>
</tr>
<tr>
<td></td>
<td>Flip/Rotate</td>
<td>Enables flip or rotate functions</td>
<td>Page 74</td>
</tr>
<tr>
<td></td>
<td>Brightness/Contrast</td>
<td>Enables brightness or contrast adjustment</td>
<td>Page 74</td>
</tr>
<tr>
<td></td>
<td>Screenshot</td>
<td>Takes a screenshot of the current screen/dialog</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Zoom views in/out</td>
<td>Page 73</td>
</tr>
</tbody>
</table>
2.3 Tracking System

General Information

For successful registration and navigation, the camera must have an unobstructed view of all marker spheres at all times during the surgical procedure.

A camera display in the upper right screen provides real-time feedback about instrument visibility to the camera. Images in the display indicate the relative position of instruments that are visible to both camera lenses.

If you press the camera display, a tabbed window opens in which you can check instrument visibility (see page 25).

Tracking Priority

Up to five arrays can be displayed simultaneously.

The general tracking priority is as follows:

• Calibrated drill in a precalibrated drill guide
• Precalibrated instrument (4-sphere geometry)
• Precalibrated instrument (3-sphere geometry)
• Calibrated instruments
• Visible reference array
• Pointer

Do not use instruments with the same geometry simultaneously (e.g., two precalibrated instruments using the same reference array or two pointers) as the navigation software cannot distinguish between the identical geometrical arrangement of marker spheres on different instruments.

If you are unable to navigate an instrument, check that there are no instruments with a higher priority in the camera field of view.

Interpreting the Camera Display

A camera display is located on all main screens. Colored spheres indicate marker spheres that are visible to both camera lenses.

![Figure 4](image)

<table>
<thead>
<tr>
<th>Sphere Color</th>
<th>Representation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yellow</td>
<td>Active reference array after registration (Y geometry)</td>
</tr>
<tr>
<td>Green</td>
<td>Pointer, precalibrated instruments (StarLock adapter)</td>
</tr>
<tr>
<td>Blue</td>
<td>Fluoro Registration Kits, ICM4</td>
</tr>
<tr>
<td>Purple</td>
<td>xSpot</td>
</tr>
<tr>
<td>Orange</td>
<td>Instrument Adapter Array, SMS adapter</td>
</tr>
<tr>
<td>Sphere Color</td>
<td>Representation</td>
</tr>
<tr>
<td>--------------</td>
<td>----------------</td>
</tr>
<tr>
<td>White</td>
<td>Ambiguous geometries</td>
</tr>
<tr>
<td>Gray</td>
<td>Visible, but unidentifiable instruments</td>
</tr>
<tr>
<td>Gray circles</td>
<td>The marker sphere geometry is only visible to one camera lens and cannot be interpreted</td>
</tr>
</tbody>
</table>

The software detects instruments based on predefined tool geometries provided by reflective marker arrays. Ambiguous marker sphere constellations may cause the system to detect the geometry incorrectly for a short period of time.
2.3.1 Camera Field of View Dialog

General Information
Pressing the camera display opens the tabbed [Camera Field of View] dialog, which identifies the positions of reference arrays and instruments. Check the camera field of view before beginning any registration workflow.

Standard Tab

![Standard Tab Image]

Figure 5

<table>
<thead>
<tr>
<th>No.</th>
<th>Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>①</td>
<td>Visible reference/tracking array</td>
</tr>
<tr>
<td>②</td>
<td>View option tabs</td>
</tr>
</tbody>
</table>

Volume Tab

![Volume Tab Image]

Figure 6
<table>
<thead>
<tr>
<th>No.</th>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>①</td>
<td>Colored spheres</td>
<td>Marker spheres on reference and tracking arrays</td>
</tr>
<tr>
<td>②</td>
<td>Colored rings</td>
<td>Distance of the arrays from camera lenses</td>
</tr>
<tr>
<td>③</td>
<td>Blue cone</td>
<td>Camera field of view</td>
</tr>
</tbody>
</table>

If an instrument tracking array or a reference array is no longer visible to the camera, the spheres for that array disappear from view, indicating that the element can no longer be tracked.

NOTE: The color conventions of the spheres and circles is identical to the camera display (see page 23).

---

### How to Optimize the Camera Field of View

**Steps**

1. In the [Volume] tab, adjust the distance and angle of the camera until the arrays are as close as possible to the center of the blue cone.

2. Hold a pointer to places in the surgical field (where you will likely hold it during the procedure), making sure that the pointer remains visible to the camera.

3. Press [OK] to close the [Camera Field of View] dialog.

---

### 2D Tab

The [2D] tab identifies the visibility of marker spheres to the individual camera lenses, from the surgeon’s point of view.

**Figure 7**

<table>
<thead>
<tr>
<th>No.</th>
<th>Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>①</td>
<td>Left camera lens view</td>
</tr>
<tr>
<td>②</td>
<td>Right camera lens view</td>
</tr>
</tbody>
</table>
2.4 System Accuracy

Marker Spheres
To enable navigation tracking, reflective marker spheres must be attached to reference and tracking arrays.

- Verify that the surfaces of all Reflective Marker Spheres are in good condition prior to each case. In order to provide the highest precision, make sure that the reflective surface is not peeling.

- To ensure accurate navigation, the camera lenses must have an unobstructed view of the instrument marker spheres at all times.

- If a reference array cannot be detected by the camera, verify that the marker spheres are clean, dry and undamaged, and that the reference array is not bent.

Reference Arrays
Reference arrays must remain securely attached to the bone at all times.

<table>
<thead>
<tr>
<th>Safety Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>If an array moves or becomes unstable, verify the accuracy and re-attach if necessary.</td>
</tr>
<tr>
<td>If the accuracy decreases or if any array must be re-attached, repeat fluoroscopic registration before performing navigation.</td>
</tr>
</tbody>
</table>

- Ensure that the relevant reference arrays for each procedure are securely attached to the correct bone segment and visible to the camera at all times.

- Do not use an adapter of the same geometry on more than one instrument at the same time. Otherwise, the system will not be able to identify the instrument.

- Navigated instruments have different priorities assigned. If several navigated instruments are in the camera field of view, the information displayed in the navigation views may depend on the visible instrument with the highest priority.

Instrument Calibration
If an instrument is not precalibrated, it must be calibrated with the ICM4 before use. Precalibrated instruments must be validated and verified via the [Precalibrated Tools] dialog.
3  GETTING STARTED

3.1 Workflow

Before You Begin

Before beginning any procedure, ensure that you are familiar with the correct handling of all required instruments and accessories. For detailed information on instrument handling, see your Instrument User Guide.

Standard Workflow

- Set up system, start application, connect C-arm
- Drape patient, make incision, prepare bone surface
- Select C-arm
- Instrument selection and calibration*
- Attach reference array
- Acquire and verify fluoro image(s)
- Navigation

NOTE: Some procedures may not include all of the above steps.

*This step may be performed at any time during the procedure.
3.2 Operating Room Setup

General Information

OR setup varies depending on the procedure, room layout and which navigation system is used. In any case, ensure that:

- The camera and monitor do not restrict the movement of the OR team
- The camera has a clear view of reference arrays and instruments

See your System User Guide for detailed information on system transport and setup.

OR Setup Example

![Figure 8](image)

<table>
<thead>
<tr>
<th>No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>①</td>
<td>Touchscreen</td>
</tr>
<tr>
<td>②</td>
<td>Camera</td>
</tr>
<tr>
<td>③</td>
<td>Nurse</td>
</tr>
<tr>
<td>④</td>
<td>Surgeon</td>
</tr>
<tr>
<td>⑤</td>
<td>C-arm</td>
</tr>
</tbody>
</table>

How to Set Up the OR

Steps

1. Move the system into the desired position.
2. Position the camera at the foot or head end of the operating table at a distance of approximately 2 m (6.5 feet) from the surgical field. Point it at the bone to be operated upon.
3. Drape system as necessary (e.g., camera handle) (see System User Guide).
4. Drape the C-arm and registration kit as necessary (see Instrument User Guide).
5. Adjust the monitor to a position convenient for and accessible by the surgeon or assistant.
Steps
6. Plug in the system components.

Attaching Registration Kits and Correction Plate

<table>
<thead>
<tr>
<th>Registration Kit</th>
<th>C-arm Draping Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoro Registration Kit Rev. 2.0</td>
<td>Drape the C-arm as usual, then mount the registration kit.</td>
</tr>
<tr>
<td>Fluoro 3D/2D Registration Kit</td>
<td>Mount the registration kit to the C-arm before draping.</td>
</tr>
<tr>
<td>xSpot Correction Plate</td>
<td>Mount the correction plate to the C-arm before draping.</td>
</tr>
</tbody>
</table>

NOTE: The Fluoro Registration Kit Rev. 2 can also be used without a drape.

For detailed information on Fluoro Registration Kit and xSpot Correction Plate handling, see page 57 and your Instrument User Guide.

C-arm Connection

Either an analog or a digital C-arm can be connected to the system.

<table>
<thead>
<tr>
<th>C-arm Type</th>
<th>Connection to the System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analog C-arm</td>
<td>Via video cable</td>
</tr>
<tr>
<td>Digital C-arm</td>
<td>Via crossover LAN cable</td>
</tr>
</tbody>
</table>

Make sure that the respective cable connecting the navigation system to the C-arm is plugged in, and that the correct video input is selected before beginning image acquisition.
If an error message appears during image acquisition informing you that the C-arm connection has been interrupted, check the cable connection.

C-arm Startup

<table>
<thead>
<tr>
<th>Step</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plug in and turn on the C-arm as described in the manufacturer’s user manual.</td>
</tr>
</tbody>
</table>

Keep the draped C-arm and the attached Fluoro Registration Kit sterile throughout the surgical procedure.

Establishing Visibility

Make sure that instrumentation is visible from all relevant surgical positions.

Prior to surgery, position the camera so that both lenses have a clear and unobstructed view to the markers spheres on the tracking arrays. They must be visible to the camera at all times during registration and navigation, otherwise tracking is not possible.
3.3 Procedure Setup

Patient Identification

How to Enter Patient Name

If you did not select or create a patient in Content Manager, you must enter patient name and ID.

![Patient Name Entry](image)

**Figure 9**

**Steps**

1. Enter the patient name using the touchscreen keyboard.
2. Use the right arrow button ① or press in the ID field to move cursor.
3. Enter the patient ID.

**NOTE:** Unless anonymized (see page 90), all screenshots saved during the procedure are labeled with patient name and ID.
3.3.1 C-arm Selection

General Information

If more than one C-arm is configured, you are prompted to select a C-arm after entering patient information.
To add or remove a C-arm, or to change C-arm settings, contact support.
NOTE: If only one C-arm is configured, this dialog does not appear.

How to Select the C-arm

How to Change C-arm Selection

If you wish to later change your C-arm selection, it must be accessed via the [Fluoro Tools] menu (see page 92).
3.4 Reference Array Attachment

General Information

The Y-geometry reference array is necessary for allowing the system to track the location and movement of the bone throughout the procedure and navigate the instrument on the fluoro image(s).

Reference kits supported by Fluoro Express are listed on page 9.

For detailed information on handling and attaching reference arrays, see your Instrument User Guide.

Ensure that the reference array is securely attached to the correct bone segment and visible to the camera at all times.

Attachment for Screw Fixation

Attach the Y reference array to the bone to be treated.

If you are performing an SI Screw procedure, attach the array to the side of the pelvis that is fused to the sacrum:

• If the right sacroiliac joint is fractured, the reference array must be attached to the left iliac crest so that the reference array has a fixed spatial position with regard to the sacrum.
• Where there is no significant displacement between the iliac crest and the sacrum, it is possible to attach the reference array on the same side as the fracture.

Ensuring Secure Attachment

Securely tighten all reference array screws before scanning the patient or performing patient registration. If there is any movement of the reference array during patient registration you must re-register, otherwise registration will be incorrect.

Do not open any of the angular adjustment screws of the reference array once patient registration has been completed.

Make sure that the reference array(s) is (are) tightly attached to the patient's bone. Any movement of the array(s) will improperly affect the measurement coordinate system and lead to an incorrect display of the instrument. This is a hazard to the patient. However, do not damage the patient's bone while attaching the array(s).
Ensuring Sufficient Space

- Take the size of the surgical instruments into account when placing the reference array. Sufficient space should be available to enable incision and drilling without moving the array.

- Make sure that the position of the reference array will not hinder the surgeon before attaching it to the relevant bone structure.
4 CALIBRATING INSTRUMENTS

4.1 Calibration

Before You Begin

Read your Instrument User Guide before handling Brainlab instruments.

Calibration

For the system to navigate an instrument, its axis and diameter must first be calibrated, then verified using an instrument calibration matrix (ICM4).

For calibration and use, the instrument must have an adapter with marker spheres attached.

When to Calibrate

For best results, calibrate or validate instruments directly prior to use. The calibration dialog opens when the system detects both the marker spheres of an instrument and the ICM4 in the camera field of view.

NOTE: This is true also when the precalibrated instruments tab is open.

Best Practices for Calibration

To minimize the possibility of errors due to incorrect instrument handling, perform instrument calibration directly prior to use.

Use the largest possible tracking array on the instrument adapter. This maximizes calibration accuracy.

Attach tracking array so that the longest arm of the array is in line with the instrument axis.

Verify the accuracy of the instrument calibration during surgery by touching the instrument to known anatomical landmarks, and confirming that these are correctly displayed on the screen.

Instrument Types

For calibration purposes, instruments are categorized as:

• Pointed tip (e.g., awls, probes)
• Flat-tipped (e.g., drill guides, tubes)
• Screws
• Chisels
Flexible or Bent Instruments

- Do not calibrate bent or curved instruments. The result will be inaccurate. Flexible instruments must be calibrated and used together with a drill guide and you must rely only on the depth information.

- Only rigid instruments, on which an instrument adapter can be fixed, can be calibrated and used for navigation.

  NOTE: See page 46 for more information on the calibration of flexible instruments.

Proper Handling of Instrument Adapters

- If you mount new spheres on an adapter, pointer or patient reference array, ensure that the marker fits flush to the ICM4.

- Tighten all instrument adapter screws securely before beginning calibration.

- Do not change the position of the instrument adapter tracking array during surgery. Any movement of the array will result in inaccurate instrument tracking, which could be hazardous to the patient.

- If you remove an instrument adapter from one calibrated instrument to use on a different instrument, you must perform a new calibration.

Canceling Calibration

You can cancel calibration at any time by pressing [Cancel] on a calibration dialog.
4.1.1 Using the ICM4

General Information

The Instrument Calibration Matrix, Rev. 4.0 (ICM4) is used to:

- Calibrate and verify instruments and implants
- Validate and verify precalibrated instruments

The ICM4 calibrates the instrument axis, shaft length, and tip diameter (or width for chisels).

ICM Features for Spine and Trauma Instrument Calibration

![Figure 12](image)

<table>
<thead>
<tr>
<th>No.</th>
<th>Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>V-inset</td>
</tr>
<tr>
<td>2</td>
<td>Reference plane 2</td>
</tr>
<tr>
<td>3</td>
<td>Reference plane 3</td>
</tr>
<tr>
<td>4</td>
<td>Calibration receptacles (examples)</td>
</tr>
<tr>
<td>5</td>
<td>Reference plane 1</td>
</tr>
<tr>
<td>6</td>
<td>Reference plane 4 (not visible in image)</td>
</tr>
<tr>
<td>7</td>
<td>Pivot points</td>
</tr>
</tbody>
</table>

V-inset

Use the V-inset (1) to calibrate instruments with long shafts, or any instrument whose shaft does not fit snugly into one of the calibration receptacles.

If you use the V-inset, check the diameter result carefully. The value is calculated based on the instrument shaft.

**Do not calibrate conical instruments using the V-inset. This results in the incorrect display of the instrument axis.**

Receptacles

The calibration receptacles (5) are the best choice for calibrating shorter instruments that have tips which do not reach reference plane 4 (6) when the instrument is positioned in the V-inset.
Always use the receptacle of the smallest possible diameter into which the instrument fits. Otherwise, calibration may be inaccurate. Only use the 30 mm receptacle if the tip of the instrument does not fit into the other ones. Failure to do so may result in highly inaccurate calibration.

Reference Planes

The **ICM4** has four reference planes. They can be identified by the numbers etched on them. Use reference plane 1 or 2 to calibrate the tips of chisels and flat-tipped instruments.

Pivot Points

There are two pivot points 🇵 🇲 on the **ICM4**, one on the side and one on the bottom. Use these to calibrate the tips of pointed instruments.
4.1.2 Instrument Adapters

General Information

For the system to navigate an instrument it must be fitted with adapter and calibrated and verified using the ICM4.

The [Calibration] dialog opens when an instrument fitted with an instrument adapter and the ICM4 are held in the camera field of view.

Required Instrument Adapters

<table>
<thead>
<tr>
<th>No.</th>
<th>Adapter</th>
<th>Required for:</th>
</tr>
</thead>
<tbody>
<tr>
<td>①</td>
<td>StarLink</td>
<td>Standard tools: Pointed tool, screw, drill, chisel</td>
</tr>
<tr>
<td>②</td>
<td>Adapter for Surgical Motor System</td>
<td>Flexible tools: K-wire, drill bit</td>
</tr>
</tbody>
</table>

Figure 13
4.1.3 Calibration Workflow

Overview

Below is an overview of the instrument calibration steps. More detailed instructions for individual steps are on the following pages.

<table>
<thead>
<tr>
<th>Steps</th>
<th>See</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Hold the instrument and ICM4 in the camera field of view.</td>
<td>Page 43</td>
</tr>
<tr>
<td>The [Calibration] dialog opens.</td>
<td></td>
</tr>
<tr>
<td>2. Calibrate the instrument in the V-inset or a receptacle of the ICM4.</td>
<td>Page 43</td>
</tr>
<tr>
<td>This calibrates the axis and defines initial calibration values for both the shaft diameter and tip.</td>
<td></td>
</tr>
<tr>
<td>3. Verify the accuracy of the calibration results.</td>
<td>Page 48</td>
</tr>
<tr>
<td>You may need to perform additional steps to improve the calibration precision of the tip and diameter.</td>
<td></td>
</tr>
<tr>
<td>4. If the axis and tip calibration are both good (low angle and distance deviations and correct diameter are displayed on the screen), accept calibration and continue to navigation.</td>
<td>Page 47</td>
</tr>
<tr>
<td>If axis calibration is not accurate enough, a warning recommends that you repeat the initial calibration. If you accept a low accuracy, you must proceed with caution.</td>
<td></td>
</tr>
<tr>
<td>• If the tip calibration accuracy is low, you should perform additional tip calibration.</td>
<td></td>
</tr>
<tr>
<td>• To correct a miscalculated diameter (or set a chisel width), you can manually define the diameter or chisel width.</td>
<td></td>
</tr>
<tr>
<td>NOTE: After any additional calibration, verify the calibration results again.</td>
<td></td>
</tr>
</tbody>
</table>

Calibration of Screws

To calibrate a screw, insert it in the screwdriver you will be using to navigate its placement, and calibrate them together. See page 42 for more information on screw calibration.

If a screwdriver has been calibrated with a specific screw and is later used with a different screw, it must be recalibrated.
4.1.4 Automatic Calibration

General Information

Automatic calibration becomes activated by holding an instrument fitted with the appropriate tracking array, together with the **ICM4** in the camera field of view. Perform calibration using either the V-inset or a receptacle. The [Instrument Calibration] dialog shows the progress of your calibration.

How to Use the V-inset

![Figure 14](image)

<table>
<thead>
<tr>
<th>Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Place the shaft of the instrument into the V-inset on the top of the <strong>ICM4</strong>, ensuring that it touches reference plane 4 (see page 39).</td>
</tr>
<tr>
<td>1. <strong>NOTE</strong>: If you use the V-inset to calibrate an instrument, and the tip of the instrument does not touch reference plane 4, you will have to perform further steps to calibrate the instrument tip (see page 50).</td>
</tr>
<tr>
<td>2. Rotate the instrument approximately 45° along its long axis within the V-inset. The software calculates the instrument diameter and trajectory, and opens the [Verify Calibration] dialog (see page 48).</td>
</tr>
</tbody>
</table>

How to Use a Receptacle

![Figure 15](image)
### Steps

<table>
<thead>
<tr>
<th>Steps</th>
<th>Insert the tip of the instrument into the receptacle of the smallest possible diameter.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>NOTE: The tip must touch the bottom of the receptacle and fit snugly. A loose fit will result in inaccurate calibration.</td>
</tr>
<tr>
<td>2.</td>
<td>Rotate the instrument along its long axis. The software calculates the instrument calibration and trajectory and opens the [Verify Calibration] dialog.</td>
</tr>
</tbody>
</table>

Following automatic detection of the receptacle, verify that the detected receptacle is the correct one. If the wrong receptacle was detected, perform tip calibration or press [Back] to repeat calibration using manual calibration.

### Next Steps

<table>
<thead>
<tr>
<th>Options</th>
<th>If the calibration accuracy is low, the [Low Calibration Accuracy] warning opens (see page 47). Follow the steps for low calibration accuracy (see page 47). If calibration is accurate, verify calibration (see page 48). Press [Manual] to switch to manual calibration using the receptacles (see page 45). NOTE: This can be useful if you encounter difficulty, e.g., with thin or non-rigid instruments. Press [Cancel] to close the dialog and exit the calibration.</th>
</tr>
</thead>
</table>
4.1.5 Manual Calibration

General Information

Use manual calibration for tools that cannot be calibrated using automatic calibration, e.g., flexible or non-rigid tools.

How to Perform Manual Calibration

Steps

1. Select the instrument diameter by pressing the corresponding receptacle in the manual [Instrument Calibration] dialog. Select the smallest diameter into which the instrument fits.
2. Insert the tip of the instrument into the receptacle.
3. Hold the instrument completely still until calibration is complete and the verification dialog opens.

Other Options

Options

To return to automatic calibration, press [Back].
To exit or restart calibration, press [Cancel].
4.1.6 Flexible Instrument Calibration

General Information

The below steps outline the calibration of flexible instruments, e.g.:

- K-wires (e.g., for guiding cannulated nails and/or screws)
- Drill bits

*NOTE: In the following information, “flexible instrument” refers to either of the above examples.*

How to Calibrate Flexible Instruments

Flexible instruments must be calibrated and used with a drill guide. Otherwise calibration would be highly inaccurate.

<table>
<thead>
<tr>
<th>Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Select a Brainlab drill guide with the appropriate guide tube diameter and verify it for navigation.</td>
</tr>
<tr>
<td>2. Insert the flexible instrument into the Brainlab drill guide.</td>
</tr>
<tr>
<td>3. Calibrate the length of the flexible instrument using an attached Adapter for Surgical Motor System.</td>
</tr>
</tbody>
</table>

*NOTE: Select the [Calibrate Others] tab if the [Select PCI] dialog opens first.*

Ensure that the selected drill guide shown on the screen matches the actual drill guide you are using.

Always verify calibration accuracy before beginning navigation (see page 48).
4.1.7 Low Calibration Accuracy

General Information

The low calibration accuracy warning opens after automatic calibration if the software detects “play” in the instrument axis during calibration. This may occur if:

- The reference array being used is too small.
- The instrument adapter is not tightly affixed to the instrument.
- Marker spheres on the instrument adapter or ICM4 are dirty, wet, or not properly attached.
- The instrument was calibrated using a receptacle that is too large in diameter.

Options

If you are using a chisel or flat-tipped instrument or want to improve calibration accuracy, press [Back] and repeat calibration.

To improve the result, follow these recommendations:

- If possible, use a larger tracking array on the instrument adapter.
- Tighten the adapter connection to the instrument.
- Check the marker spheres on the ICM4 and the adapter. Make sure they are clean, dry, and tightly screwed onto their pins.

If you are calibrating a screw or sharp-tipped instrument and want to proceed with the present calibration, press [Next].

This activates an additional calibration step.

If you want to exit calibration, press [Cancel].

Important Low Accuracy Information

⚠️ It is not possible to accept low calibration accuracy for a chisel or flat instrument. If the warning appears, you must repeat calibration, otherwise additional tool tip calibration is not possible.

⚠️ If a low calibration accuracy warning appears after calibration, carefully review the calibration result in the [Verify Calibration] dialog (see page 48).
4.1.8 Calibration Verification

General Information

Always verify that calibration is accurate. The [Verify Calibration] dialog allows you to check the results. From this dialog you can also:

- Correct the results by specifying the diameter (pointed or flat-tipped instruments) or width (chisels)
- Improve calibration accuracy using tip calibration

Verification Procedure

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pointed tool</td>
<td>Place the tip of the instrument on reference plane 2 or 4, and in either of the pivot points</td>
</tr>
<tr>
<td>Screw</td>
<td>Place the tip of the chisel on the plane in which it was calibrated.</td>
</tr>
<tr>
<td>Drill / flexible tool</td>
<td>Hold the chisel either perpendicular to the plane, or at approximately a 45° angle to the plane.</td>
</tr>
<tr>
<td>Chisel</td>
<td>Place the tip of the chisel on the plane in which it was calibrated.</td>
</tr>
</tbody>
</table>

Verify Calibration Dialog

![Verify Calibration Dialog](image)

No. Component

<table>
<thead>
<tr>
<th>No.</th>
<th>Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>①</td>
<td>Tip Selection button</td>
</tr>
<tr>
<td>②</td>
<td>Re-calibrate Tip button</td>
</tr>
<tr>
<td>③</td>
<td>Calibrated diameter, angle and distance deviation</td>
</tr>
</tbody>
</table>
How to Verify Calibration

**Steps**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Hold the instrument steady in a receptacle or the V-inset, or&lt;br&gt;Hold the tip to a reference plane or pivot point.</td>
</tr>
<tr>
<td>2.</td>
<td>Check that the displayed diameter is correct, and that the deviation of the axis ([Angle]) and deviation of the tip ([Distance]) are minimal.</td>
</tr>
<tr>
<td>3.</td>
<td>If the angle and distance deviations are low and the diameter is correct, press [Next].</td>
</tr>
</tbody>
</table>

**Other Options**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Options</td>
<td></td>
</tr>
<tr>
<td>Hold the instrument still for five seconds to take a screenshot.</td>
<td></td>
</tr>
<tr>
<td>To repeat calibration, press [Back].</td>
<td></td>
</tr>
<tr>
<td>To improve tip calibration of a sharp tip instrument, press [Re-calibrate Tip] and pivot in one of the pivot points.</td>
<td></td>
</tr>
<tr>
<td>To correct a diameter, size, or width calibration, press [Tip Selection] to open another dialog where you can choose the tip and adjust dimensions.</td>
<td></td>
</tr>
<tr>
<td>• To exit calibration or repeat calibration, press [Cancel].</td>
<td></td>
</tr>
<tr>
<td>• The dialog closes five seconds after the ICM4 is removed from the camera field of view.</td>
<td></td>
</tr>
</tbody>
</table>
4.1.9 Additional Tip Calibration

General Information

Tip calibration improves the axis calibration, and is especially useful if the instrument:
- Was not correctly calibrated initially
- Was calibrated using the V-inset, but the tip of the instrument did not touch reference plane 4

**NOTE:** Tip calibration is mandatory for chisels and flat instruments.

Calibration Checklist

- Always check that the length of the calibrated instrument is correct. If it is not, perform tip calibration.
- Only use the colored ICM4 regions indicated by the software for tip calibration.
- If the instrument is moved parallel to its axis during calibration, the tip will not be calibrated. It is then necessary to perform tip calibration.
- When calibrating short instruments which do not reach the bottom of the receptacle (or reference plane 4 when calibrating using the V-inset), you must perform tip calibration.

How to Calibrate Tips of Pointed Instruments and Screws

![Figure 19](image)

**Steps**

1. In the [Select Tool Tip] dialog, press [Pointed] or [Screw] as required.
2. Enter the diameter and screw length, as required, then press [Next].
   
   **NOTE:** To measure the diameter of the shaft, you can hold the instrument up to the ruler on reference plane 2 of the ICM4.
3. Pivot the instrument tip or screw in a pivot point of the ICM4.
   
   Once tip calibration is complete, the verification dialog reopens, displaying the new values.
4. Verify the calibration.
How to Calibrate Tips of Flat-tipped Instruments

Figure 20

Steps

1. In the [Select Tool Tip] dialog, press [Flat].

2. Enter the diameter, then press [Next].
   
   NOTE: To measure the diameter of the shaft, you can hold the instrument up to the ruler on reference plane 2 of the ICM4.

3. Hold the tip of the instrument flat against reference plane 1 or 2 until the verification dialog reopens.

4. Verify the accuracy of the calibration by holding the tip of the instrument on the plane in which it was calibrated.


How to Calibrate Tips of Chisels

Figure 21
<table>
<thead>
<tr>
<th>Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. In the [Select Tool Tip] dialog, press [Chisel].</td>
</tr>
</tbody>
</table>
| 2. Enter the diameter and chisel width, then press [Next].  
   **NOTE:** To measure the diameter of the shaft, you can hold the instrument up to the ruler on reference plane 2 of the **ICM4**. |
| 3. Hold the tip of the chisel flat against reference plane 1 or 2 until the verification dialog re-opens. |
| 4. Verify the accuracy of the calibration by holding the tip of the chisel on the plane in which it was calibrated.  
   **NOTE:** Hold the chisel either perpendicular to the plane, or at angle of approximately 45° to the plane. |
4.2 Precalibrated Instruments

General Information

**Fluoro Express** supports the navigation of selected Brainlab and 3rd-party precalibrated instruments. The dimensions and axes of these instruments are stored in the software database. To enable navigation, the instrument must be equipped with an instrument adapter with a 3 or 4 marker sphere geometry.

For information on use, cleaning, disinfection and sterilization of 3rd-party precalibrated instruments, see the user manuals provided by the instrument manufacturer.

Before using precalibrated instruments, check that the actual instrument you are using is displayed in the software, and verify instrument accuracy using the ICM4.

Accuracy and Validation

Instruments must be validated before each use. After validation, the instrument may be used for the rest of the procedure or until instrument or tracking array is changed.

If the instrument verification indicates a loss of accuracy, re-validate the instrument.
4.2.1 Accessing Precalibrated Instruments

How to Select a Precalibrated Instrument

Steps

1. Press the [Precalibrated Instrument] button in the menu bar, or hold the pre-calibrated tool together with the ICM4 in the camera field of view.

   Select the instrument manufacturer (e.g., Brainlab).

   NOTE: If you have already used a precalibrated instrument during the procedure, the [Used Tools] tab opens by default.

2. Select instrument from the list.

   NOTE: You can identify your instrument using the part number engraved on the side of the instrument.

3. If prompted, check the accuracy of the precalibration (see page 55).

Changing Instruments

To change to a different precalibrated instrument, repeat the above steps. Do not use a precalibrated instrument without first selecting it in the software.

The name and manufacturer of the selected precalibrated instrument are displayed in the main window.

If an instrument was calibrated and the same reference geometry is used for another instrument afterwards, the new instrument has to be calibrated again.

NOTE: It is not possible to track two identical geometries at the same time (e.g., identical tracking arrays attached to two different instruments).
4.2.2 Accuracy Check for Precalibrated Instruments

When to Perform an Accuracy Check

After you first select a precalibrated instrument (p.54), a dialog opens prompting you to perform an Accuracy Check.

You can repeat the Accuracy Check (for a previously selected precalibrated instrument) by holding the precalibrated instrument together with the ICM4 into the Camera Field of View. The dialog opens automatically.

Accuracy Check

The Accuracy Check process checks that the accuracy of the precalibrated instrument is within the necessary tolerance range.

How to Perform an Accuracy Check for Precalibrated Instruments

Steps

1. When the [Accuracy Check] dialog opens, follow the instructions in the dialog.

   • If the dialog indicates that the accuracy check was successful, visually check the accuracy in the viewers and then press [Next].
   • To exit, press [Cancel].

2. If you want to select another Instrument press [Change Instrument].
Unsuccessful Accuracy Check

If the check was not successful, e.g., if the instrument is bent or damaged, [Next] is not enabled. In this case you can press [Help], which opens a troubleshooting page.

Figure 24

<table>
<thead>
<tr>
<th>Step</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete the checks identified in the software, then press [Back] to repeat the accuracy check.</td>
</tr>
</tbody>
</table>
5  FLUORO IMAGE ACQUISITION

5.1  Required Instrumentation

General Information

Registration of fluoroscopic images allows the system to calculate the three-dimensional position of the image relative to attached reference arrays, thereby enabling the navigation of instruments. The used registration kit 'xSpot' is automatically detected by the software when it is in the camera field of view.

For detailed information on the instrumentation presented in this chapter, see your Instrument User Guide.

Before You Begin

The patient should be positioned on the operating table, and draped in the usual manner.

Unless draped, instrumentation used to perform registration must be sterile.

Supported Image Formats

<table>
<thead>
<tr>
<th>Image Type</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>2D patient images</td>
<td>Acquired for navigation using a C-arm.</td>
</tr>
<tr>
<td></td>
<td>NOTE: Contact support for information on approved C-arms.</td>
</tr>
<tr>
<td>Calibration images</td>
<td>Enable registration by providing additional information to the software</td>
</tr>
<tr>
<td></td>
<td>when the tungsten markers (see page 60) were covered during fluoro</td>
</tr>
<tr>
<td></td>
<td>image acquisition (see page 69).</td>
</tr>
</tbody>
</table>

Acquisition Instrumentation

Fluoroscopic images are registered via:

- A Fluoro Registration Kit mounted to the C-arm (Rev. 2 shown below), or
- xSpot with Correction Plate mounted to the C-arm
Draping Information

- The Fluoro Registration Kit (Rev. 2) can be used sterile or draped.
- The Fluoro 3D/2D Registration Kit must be draped using the drape specified in the Instrument User Guide.
- xSpot must be sterile and the Correction Plate must be draped.

*NOTE: For information on compatible drapes, see your Instrument User Guide or contact support.*
5.1.1 Pointer Usage

General Information

Fluoro Express supports the Pointer Extended with Sharp Tip for verifying acquired fluoroscopic images.

Correct Pointer Usage

Use only the Pointer Extended with Sharp Tip for all Fluoro Express registration and navigation steps.

Verify that the pointer is not bent or damaged by using the counter pin in the sterilization tray. Using damaged pointers or instruments could lead to inaccuracy during patient registration and navigation, causing severe patient injury.
5.1.2 Handling Registration Kits

Registration Kit Attachment

Fluoro Registration Kits must be attached the C-arm as described in your Instrument User Guide.

Ensuring Sufficient Space

<table>
<thead>
<tr>
<th>Registration Kit</th>
<th>Attachment Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoro Registration Kit (Rev. 2)</td>
<td>• The lower calibration plate can be removed after acquiring a calibration image.</td>
</tr>
<tr>
<td></td>
<td>• The upper ring must remain attached throughout the procedure.</td>
</tr>
<tr>
<td>Fluoro 3D/2D Registration Kit</td>
<td>• The 2D registration ring can be removed after acquiring a calibration image.</td>
</tr>
<tr>
<td></td>
<td>• The 3D registration ring must remain attached throughout the procedure.</td>
</tr>
</tbody>
</table>

The Fluoro Registration Kits should not come into contact with the patient at any time during use.

To prevent patient injury and/or damage to instruments, ensure that sufficient space is provided between the Fluoro Registration Kit, patient and reference array(s) prior to image acquisition.

Reflective Marker Discs

The Fluoro Registration Kits are equipped with integrated reflective marker discs. Ensure that at least five marker discs are visible when acquiring images.

Tungsten Marker Visibility

![Figure 26](image)

At least four of the large markers in the circle, plus the large marker that lies outside of the circle, must be detected by the software.

If some of the markers are blocked from view, (e.g., by metal retractors) you may also need to acquire calibration images in order to successfully register the fluoroscopic images (see page 69).

Remove unnecessary metallic objects (e.g., instruments) from the X-ray field of view, so that the image can be correctly acquired.
Reference arrays must be visible at all times.

Next Steps

Once the Fluoro Registration Kit has been attached to the C-arm, you can begin image acquisition.

Always make sure that the Fluoro Registration Kit is securely attached to the C-arm and that the marker discs are fully inserted before beginning fluoroscopic registration.
5.1.3 Handling xSpot

General Information

xSpot is a mobile registration tool, used for acquiring registrable 2D images. xSpot is not attached to the C-arm and must be held by the surgeon during image acquisition.

When using a C-arm with a conventional image intensifier, the Correction Plate must be attached to the C-arm.

For detailed information on xSpot handling, see your Instrument User Guide.

Correction Plates are not compatible with flat panel C-arms.

Sterility

xSpot must be sterilized before acquiring images of the affected side.

xSpot and Accessories

![Diagram of xSpot components](Figure 27)

<table>
<thead>
<tr>
<th>No.</th>
<th>Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Rubber bands (small, large)</td>
</tr>
<tr>
<td>2</td>
<td>Plastic receptacle</td>
</tr>
<tr>
<td>3</td>
<td>xSpot head</td>
</tr>
<tr>
<td>4</td>
<td>Stops</td>
</tr>
<tr>
<td>5</td>
<td>Disposable reflective marker spheres</td>
</tr>
<tr>
<td>6</td>
<td>Handle</td>
</tr>
<tr>
<td>7</td>
<td>Plastic clips</td>
</tr>
<tr>
<td>8</td>
<td>Correction plates (9”, 12”)</td>
</tr>
<tr>
<td>9</td>
<td>Adhesive pad</td>
</tr>
</tbody>
</table>

NOTE: It is not possible to use xSpot for registration with a 6” C-arm.
Proper Use

*xSpot* head must be completely within the X-ray beam when a fluoroscopic image is acquired. Use stops located on the top and sides of *xSpot* to position the head in the center of the beam and keep it steady.

Press *xSpot* gently against the image intensifier or stabilize it on the patient or table for best registration quality.

All four marker spheres must be visible to the camera during image acquisition.

*NOTE:* Use sterile adhesive tape ① to protect the drape from damage due to pressing *xSpot* against the image intensifier.
5.2 Successful Image Acquisition

Marker Sphere Visibility

To ensure that all instruments are clearly visible to the system and to facilitate accurate registration, check the reflectivity of all marker spheres.

Reflective marker spheres must be securely attached to the relevant surgical instruments.

To ensure visibility, use only clean, dry marker spheres.

Camera Positioning

The camera must be positioned so that both lenses have an unobstructed view of the surgical area and reference arrays at all times during the procedure, in all relevant OR positions. For more information on the camera field of view, see page 25.

To ensure accurate patient registration, check that reflective discs and reflective marker spheres are not obstructed from the camera field of view.

Position the camera so that the Fluoro Registration Kit, patient reference arrays and instruments can be clearly seen by the camera lenses. Reference arrays must be visible to the camera lenses at all times, otherwise, tracking is not possible.

Infrared artifacts caused by reflection can influence the accuracy of the optical navigation system. Please make sure that all items, which are highly reflective or sources of infrared light do not disturb the camera's view.
5.2.1 Tips for Successful Image Acquisition

C-arm Use

Keep movement of the C-arm and the patient to a minimum during image acquisition.

⚠️ Do not modify images on the C-arm monitor (for example, by magnifying, flipping, etc.) before acquisition is confirmed.

⚠️ Before acquiring new images with the C-arm, ensure that the image acquisition screen is shown on the monitor. Otherwise, the navigation software will not detect the acquired images.

C-arm Positioning

Figure 29
The cone of rays must overlap during image acquisition (see example above).

Re-attached or Adjusted Reference Arrays

⚠️ If the position of a reference array is adjusted following image acquisition, delete the fluoroscopic images and acquire new ones. Otherwise planning and navigation accuracy can not be guaranteed.

⚠️ If the accuracy decreases or if a reference array must be reattached following registration, you must repeat registration before proceeding to navigation. Relative movements cannot be compensated for or displayed by the system, and could result in inaccurate navigation information and severe patient injury.
5.3 Performing Image Acquisition

Required Images

At least one fluoro image must be acquired, up to maximum four images.

Image Acquisition Screen Layout

<table>
<thead>
<tr>
<th>No.</th>
<th>Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>①</td>
<td>Views</td>
</tr>
<tr>
<td>②</td>
<td>Visibility indicators (see page 66)</td>
</tr>
</tbody>
</table>

Visibility Indicators

The software automatically recognizes which Fluoro Registration Kit / xSpot is being used. Visibility indicators ① on the image acquisition screen identify if the reference array and Fluoro Registration Kit / xSpot are visible to the camera.
- Green with check mark: visible to camera
- Red: not visible to camera

All visibility indicators must be green in order to enable image acquisition. If one or more visibility indicators are red, a clicking noise is heard until all required hardware is visible to the camera.
If an image is acquired when a required piece of hardware is not visible to the camera, a warning tone is heard and a corresponding icon is displayed in the view. Reacquire these images with all required hardware visible to the camera.

How to Acquire Patient Images

![Figure 32](image)

<table>
<thead>
<tr>
<th>Steps</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Ensure that the reference arrays and <strong>Fluoro Registration Kit / xSpot</strong> are visible to the camera lenses (i.e., visibility displays are green, see page 66), and no instruments are in the camera field of view.</td>
</tr>
<tr>
<td>2.</td>
<td>Generate an image of the relevant bone structure with the C-arm.</td>
</tr>
</tbody>
</table>
| 3. | Wait until the image is transferred to the navigation system and displayed in the image acquisition views. A confirmation tone can be heard.  
   **NOTE:** If you are using a Ziehm digital C-arm, the gray arrow icon 🔄 indicates that you must manually transfer the image from the C-arm to the system. |
| 4. | Press the blue hand icon ⚱ to assign the image to the relevant view. |
| 5. | • If image acquisition is successful, verify the image (see page 71).  
   • If image acquisition is not successful, a corresponding error message appears. You must reacquire the image. |
| 6. | If necessary, use the manipulation options provided in the menu bar to enhance image quality (see page 73).  
   If the image is suitable, repeat steps 1-5 until all images have been acquired. |

If a pointer or instrument is in the camera field of view during acquisition (see page 71), or if manipulation mode is switched on (see page 73), images cannot be transferred to the application.
**xSpot Shake Warning**

Figure 33

*xSpot* must be held still when acquiring images. If *xSpot* was moved during acquisition, the image cannot be registered and the above shake warning icon appears. Repeat acquisition holding *xSpot* stable (see page 63).

**xSpot Registration Failed Warning**

If a *Registration Failed* warning appears during image acquisition, the corresponding image cannot be registered.

Remove any obstructive (e.g., metal) objects and check and/or correct the possible causes. After correction, image acquisition must be repeated.

- Registration markers of *xSpot* could not be detected in image or image could not be registered for navigation:
  - Position *xSpot* directly under the image intensifier
  - Slightly change the position/orientation of *xSpot*
- Registration markers of the *Correction Plate* could not be detected:
  - Ensure that the *Correction Plate* is correctly mounted and positioned
  - Ensure that correct C-arm is selected in the software

**Invalid Images**

<table>
<thead>
<tr>
<th>Step</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Trash Can] (If an image is invalid and cannot be used, press the [Garbage] button in the view to remove the image.)</td>
</tr>
</tbody>
</table>

---

Performing Image Acquisition

Fluoro Express Ver. 3.2 / Software User Guide Rev. 1.0 / DePuy Synthes
5.3.1 Calibration Images

General Information

Calibration images are used to aid patient image registration, if an image does not contain sufficient information.

*NOTE: Calibration images are not available when using xSpot.*

Before You Begin

- Calibration images should ideally be acquired prior to beginning surgery.
- Reference arrays do not have to be attached during calibration image acquisition.
- Ensure that the lower calibration plate of the Fluoro Registration Kit is securely attached before acquiring calibration images.

Before acquiring a calibration image, ensure that all unnecessary objects between the X-ray source and the image intensifier are removed.

Even if image segments obscured by the marker discs are reconstructed, it may not be possible to restore smaller objects that were obscured, e.g., K-wires or screw tips may appear distorted.

How to Acquire Calibration Images

- Press the [Calibration Images] button ① in the [Image Acquisition] screen.

*NOTE: Calibration image acquisition can also be accessed via the [Fluoro Tools] menu (see page 92).*

1. Acquire image with the C-arm and press [Next] to register the image.
2. After successful image registration, press [Next] to confirm the image.
3. Repeat steps 1-3 for all desired C-arm positions.

*Do not modify images on the C-arm monitor (for example, by magnifying, flipping, etc.) before acquisition is confirmed.*

---

Figure 34

**Steps**


*NOTE: Calibration image acquisition can also be accessed via the [Fluoro Tools] menu (see page 92).*

2. Acquire image with the C-arm and press [Next] to register the image.
3. After successful image registration, press [Next] to confirm the image.
4. Repeat steps 1-3 for all desired C-arm positions.

*Do not modify images on the C-arm monitor (for example, by magnifying, flipping, etc.) before acquisition is confirmed.*
After acquiring calibration images, do not change the position of the Fluoro Registration Kit on the image intensifier. If the Fluoro Registration Kit is, for example, rotated, tilted, or shifted vertically, the calibration image must be reacquired.

### Next Steps

<table>
<thead>
<tr>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Press [Close] to return to the [Image Acquisition] screen where you can acquire fluoroscopic images of the patient.</td>
</tr>
<tr>
<td>Press [Next] to take another calibration image.</td>
</tr>
<tr>
<td>If image registration is not successful, press [Back] on the warning page to return to the main screen and acquire another calibration image.</td>
</tr>
</tbody>
</table>
5.3.2 Fluoroscopic Image Verification

General Information

Once image acquisition is complete, the images must be verified. Help text on the lower right of the screen indicates when verification mode is active. When [Image Verification] mode is active, further images cannot be acquired.

Always confirm registration accuracy in the fluoro views by holding the tip of the pointer to known anatomical landmarks and verifying their position on the monitor.

How to Verify Images

<table>
<thead>
<tr>
<th>Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Ensure that the reference arrays are visible to the camera ①, then hold pointer in the camera field of view to activate image verification.</td>
</tr>
<tr>
<td>2. If necessary, use the manipulation mode buttons ② to adjust the quality and position of the image within the view (see page 73).</td>
</tr>
</tbody>
</table>
Steps

3. Hold the pointer tip to known anatomical landmarks on the bone structure or to areas of the reference array visible in the fluoro image.

4. Ensure that the pointer on the screen correlates with the actual pointer position.

5. • Once all images have been verified, press [Next] to proceed.
   • Remove pointer from the camera field of view to re-enable image acquisition.

NOTE: To avoid unnecessary C-arm re-positioning, it is recommended to verify image accuracy after each image is acquired and before the C-arm is moved.

Factors Affecting Accuracy

⚠️ The level of distortion may be higher at the edges of the acquired images. For this reason, you should also verify accuracy in these areas if they contain structures of interest.

⚠️ Before accepting fluoroscopic images in the navigation software, ensure that they are accurate and show the required bone structure.

⚠️ Ensure that the C-arm, drape and/or registration device (e.g., Fluoro Registration Kit or xSpot) do not partially cover the reference geometries, otherwise inaccuracies will occur. Always verify image accuracy after acquisition.

Confirming Verification

When all images have been acquired and before you can proceed to planning and navigation, the [Image Verification] dialog opens. You must confirm the accuracy of all images that shall be used.

![Image Verification](Figure 37)

Options

If all images are accurate, press [Next].

If one or more images have not been verified, press [Back] to verify the images on the acquisition page.
5.3.3 Image Manipulation Mode

**General Information**

Manipulation mode is available after image acquisition, and on any main screens featuring fluoro image views. Using the three manipulation mode buttons, various image properties can be adjusted.

To use the manipulation mode, press the relevant button, then press the image you wish to manipulate. To turn manipulation mode off, press the button again.

When manipulation mode is active, further images cannot be acquired.

**Swap Images**

![Swap Images Image]

Enables you to swap images between the four display panels.

<table>
<thead>
<tr>
<th>No.</th>
<th>Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>①</td>
<td>Click arrow to swap with the image the panel indicated by the arrow.</td>
</tr>
</tbody>
</table>

**Pan/Zoom**

[Pan]: Move finger along the pan slider bars or elsewhere on the image to shift image position.

[Zoom]:
Pressing the "[+]" button magnifies the view (maximum value: 300%).
Pressing the "[-]" button reduces the view (minimum value: 30%).
Performing Image Acquisition

Figure 39

<table>
<thead>
<tr>
<th>No.</th>
<th>Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>①</td>
<td>Pan slider bars</td>
</tr>
<tr>
<td>②</td>
<td>Zoom buttons</td>
</tr>
</tbody>
</table>

Flip/Rotate

- **[Flip]**: Press the [Flip] button to mirror the image at its vertical center axis.
- **[Rotate]**: Press the curved arrow buttons or move finger along rotation slider bar or elsewhere in the image to rotate the image clockwise or counter-clockwise.

Figure 40

<table>
<thead>
<tr>
<th>No.</th>
<th>Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>①</td>
<td>Curved arrow buttons</td>
</tr>
<tr>
<td>②</td>
<td>Rotation slider bar</td>
</tr>
<tr>
<td>③</td>
<td>Flip button</td>
</tr>
</tbody>
</table>

Brightness/Contrast

- **[Brightness]**: Move finger upward to increase, or downward to decrease brightness.
- **[Contrast]**: Move finger right to increase, or left to decrease contrast.
**Video Brightness/Contrast (with Analog C-Arm)**

(Available only when using an analog C-arm)

Click to open video settings. You can adjust the brightness and contrast of images received from the C-Arm. Images must be re-acquired for the changes to take effect.

<table>
<thead>
<tr>
<th>No.</th>
<th>Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>①</td>
<td>Brightness slider bar</td>
</tr>
<tr>
<td>②</td>
<td>Contrast slider bar</td>
</tr>
</tbody>
</table>
5.4 Restoring Fluoroscopic Registration

General Information

In the event of a system crash, e.g., due to a power failure, you can restore a previous registration and the acquired images. Alternatively, you may re-register the patient.

NOTE: The software may take up to two minutes to restore the session.

How to Restore the Session

After restarting the software, the [Restore Session] dialog opens.

![Figure 42: Restore Session Dialog](image)

<table>
<thead>
<tr>
<th>Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.  In the [Restore Session] dialog, verify that the correct patient information is displayed.</td>
</tr>
<tr>
<td>2.  Ensure that reference arrays have not been moved since the registration to be restored was completed.</td>
</tr>
</tbody>
</table>
| 3.  • Press [Restore] to restore the most recent patient data. The [Patient Preparation] dialog opens (see page 77).  
• To open a new procedure and acquire new images, press [Close] and restart the software. |
Patient Preparation Dialog

If you restore the most recent patient data, you must confirm that the reference arrays have not moved.

<table>
<thead>
<tr>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>If the reference arrays have not moved, select [Yes], then press [Next].</td>
</tr>
<tr>
<td>If the references have moved, or if you are unsure of the registration accuracy, select [No (discard data)], then press [Next].</td>
</tr>
<tr>
<td>Image acquisition is started.</td>
</tr>
</tbody>
</table>

Figure 43
6 FLUORO EXPRESS NAVIGATION

6.1 Navigation

General Information

With Fluoro Express, images can be acquired and navigated without specifying a bone or procedure.

Before You Begin

Before beginning navigation, ensure that:

- The fluoro images provide an adequate view of the region of interest.
- The bone segments are correctly set.
- All required instruments have been calibrated (see page 37).
- Precalibrated instruments have been selected and validated/verified.

Workflow Steps

Image acquisition

Navigation

Figure 44

How to Navigate with Fluoro Express

Figure 45
### Steps

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Acquire and verify up to four fluoro images on which you will navigate.</td>
</tr>
<tr>
<td>2.</td>
<td>Using the indicator ⚪ for guidance, navigate the required instrument on the fluoro images while performing procedure according to standard practice. Three views are available (see below).</td>
</tr>
<tr>
<td>3.</td>
<td>When navigation is complete, press [Next]. The [Close Application] dialog opens.</td>
</tr>
</tbody>
</table>

### View

<table>
<thead>
<tr>
<th>View</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trajectory Only</td>
<td>Displays only the trajectory of the instrument.</td>
</tr>
<tr>
<td>Full Screw</td>
<td>Displays the space and position occupied by the screw. You can adjust the length and diameter ⚪ of the screw to match the one you are using.</td>
</tr>
</tbody>
</table>

[Diagram of Full Screw view showing adjustment options]
Partial Screw

Displays the space and position occupied by the screw, but only showing the tip and part of the screw's body.

You can adjust the length and diameter of the screw is the display to match the one you are using. In addition, you can also set the **Partial Length** to control how much of the screw's body is displayed.

**WARNING:**

If only one fluoroscopic image is available for a specific region, proceed with extreme care when placing screws.

If an instrument has an inaccurate trajectory, the virtual tip extension of the instrument will also be inaccurate.

**View Tabs**

If more than two images have been acquired, can choose between navigating with four views or two views (upper or lower two) displayed. You can also maximize each image to full screen. **NOTE:** View tabs are only visible if the number of acquired images is larger than two.
Figure 46
6.2 Flexible Tool Navigation

General Information

The below steps outline the navigation of flexible tools, e.g.:

• K-wires (e.g., for guiding cannulated nails and/or screws)
• Drill bits

*NOTE*: In the following information, “flexible tool” refers to either of the above examples.

Before You Begin

<table>
<thead>
<tr>
<th>Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Calibrate the length of the flexible tool using an attached <strong>Adapter for Surgical Motor System</strong> (see page 46).</td>
</tr>
<tr>
<td>2. Select a Brainlab drill guide with the appropriate guide tube diameter and verify it for navigation (see page 53).</td>
</tr>
<tr>
<td>3. Insert the flexible tool into the Brainlab drill guide.</td>
</tr>
</tbody>
</table>

Ensure that the selected drill guide shown on the screen matches the actual drill guide you are using.

Always verify calibration accuracy before beginning navigation (see page 48).

If you are concerned that the actual path of the flexible tool may have deviated from its projected path, verify the actual position by acquiring additional fluoro images.
6.2.1 Navigation of Flexible Tools

Flexible Tool Navigation Views

When you begin drilling, the software shows the position of the drill guide on the fluoro images. The actual path that the flexible tool takes depends on how steadily the drill is held in position.

⚠️ If you are concerned that the actual path of the flexible tool may have deviated from its projected path, verify the actual position by acquiring additional fluoro images.

How to Navigate

<table>
<thead>
<tr>
<th>Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. After incision and soft tissue preparation are complete, pre-drill the entry point.</td>
</tr>
<tr>
<td>2. Align the drill guide with the required trajectory.</td>
</tr>
<tr>
<td>3. Drill the flexible tool into the bone via the pre-drilled entry point, using the navigation views and depth indicator.</td>
</tr>
</tbody>
</table>

Bending of Flexible Tools When Drilling

Clinically relevant bending can occur because flexible tools can:

1. Be deviated by cortical bone:

![Figure 47](image_url)

Figure 47

1. Be bent by perpendicular force exerted on the drill guide:

![Figure 48](image_url)

Figure 48

Next Step

Once the flexible tool has been successfully navigated, remove the drill guide and continue with your procedure.
6.3 Instrument Representation

2D/3D Instrument Representation

Figure 49
The navigated instrument can be displayed either in 3D ① or 2D ②.

How to Switch the Instrument Representation

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Icon]</td>
<td>In the menu bar, press the [Instrument Display] button to switch the instrument representation as required. The button is then activated.</td>
</tr>
<tr>
<td>![Icon]</td>
<td>To switch back to the default instrument representation, press the [Instrument Display] button again.</td>
</tr>
</tbody>
</table>
7 SYSTEM SETTINGS

7.1 System Menu

General Information
The [System Menu] provides access to general information and system controls including:

- Software version and Brainlab service numbers
- Settings for sounds and language
- Fluoro tools

How to Access the System Menu

<table>
<thead>
<tr>
<th>Step</th>
</tr>
</thead>
<tbody>
<tr>
<td>Press the [System] button to open the [System Menu].</td>
</tr>
</tbody>
</table>

**NOTE:** Pressing [Close] on any tab closes the [System Menu].

7.1.1 Software Information

How to Access Software Information

Figure 50

Step

Select [Software Info].

The window displays the software version and Brainlab contact details.
7.1.2 Adjusting Sound and Language Settings

Overview

The [Settings] option allows you to:
• Adjust sounds emitted by the software during the procedure
• Select the language of the software interface
• Anonymize screenshots

How to Access Sound Settings

<table>
<thead>
<tr>
<th>Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Select [Settings].</td>
</tr>
<tr>
<td>2. Select the [Sound] tab.</td>
</tr>
</tbody>
</table>

System Sound Options

Options

To activate /deactivate system sounds, e.g., when a button is pressed, press the [Sound Output] check box.

*NOTE: Warning sounds cannot be deactivated.*

To adjust the sound volume, use the slider bar or arrow buttons.
How to Adjust Language Settings

Steps
1. Select [Settings].
2. Select the [Language] tab.
3. Press the button for your desired language.

How to Anonymize Screenshots

Steps
1. Select [Settings].
2. Select the [Options] tab.
3. To anonymize all screenshots, enable the [Anonymize Screenshots] check box.
   All screenshots of the main screens will contain a gray bar rather than patient data.
   
   NOTE: Any screenshots acquired before enabling this option still contain patient data.
Unless screenshots are anonymized, the patient name and ID appear on all screenshots. To maintain patient confidentiality, ensure that access to screenshots is restricted to the relevant medical personnel.
### How to Access Fluoro Tools

![Fluoro Tools Menu](image)

**Figure 53**

| Step | Select [Fluoro].
The window displays the available fluoro tools. |
|------|--------------------------------------------------|

### How to Select C-arm

C-arm selection is only available if more than one C-arm is configured.

<table>
<thead>
<tr>
<th>Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Press the [C-arm Selection] button.\nThe [Select C-arm] dialog opens.</td>
</tr>
<tr>
<td>2. Press the icon of the C-arm you will use.\n<strong>NOTE:</strong> For more information, see page 33.</td>
</tr>
</tbody>
</table>

### How to Access Calibration Image Acquisition

<table>
<thead>
<tr>
<th>Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Acquire calibration images as described on page 69.</td>
</tr>
</tbody>
</table>

**Warning:** Calibration images are not available when using xSpot.
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