BRAINLAB

BRAINLAB
HIP
Version 6.0

Software User Guide - US Version
Revision 1.1

TABLE OF CONTENTS

SURGERY SETUP

REGISTRATION

1 GENERAL INFORMATION

1.1 Chapter Overview

1.1.1 Contents

Topics Covered

Section	See
Contact Data and Legal Information	Page 10
Symbols	Page 12
Intended Use	Page 13
Compatibility with Medical Devices	Page 18
Training and Documentation	Page 22

1.2 Contact Data and Legal Information

1.2.1 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: (800) 597-5911 Fax: (708) 409-1619	us.support@brainlab.com
Brazil	Tel: (0800) 892-1217	
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 991568-44 Fax: +49 89 991568-811	
Japan	Tel: +81 3 3769 6900 Fax: +81 3 3769 6901	

Expected Service Life

Brainlab provides five years of service for software applications. 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.

Manufacturer

Brainlab AG

Kapellenstr. 12

85622 Feldkirchen

Germany

1.2.2 Legal Information

Copyright

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

Non-Brainlab Trademarks

- CHANA™ is a trademark of Dr. GS Chana, Birmingham, UK.
- Microsoft® and Windows® are registered trademarks of Microsoft Corporation.
- Precimed® is a registered trademark of Precimed.

Integrated 3rd-Party Software

- This software is based in part on the work of the Independent JPEG Group.
- Portions of this software are based in part on the CyberVrml97 package written by Satoshi Konno.

CE Label

$C\mathcal{E}$ 0123

- The CE label shows that **Brainlab hip** complies with the essential requirements of the Medical Device Directive (MDD).
- According to the MDD (Council Directive 93/42/EEC), **Brainlab hip** is a Class IIa 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.

1.3 Symbols

1.3.1 Symbols Used in This Guide

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.

1.4 Intended Use

1.4.1 Using the System

Medical Purpose

Brainlab hip is an image guided surgery system for hip replacement, based on landmark-based registration of femur and pelvis, functioning with different implant vendors and universal implants.

Indications for Use: THR Procedures

The **Brainlab hip** system is intended to be an intraoperative image-guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system, to virtual computer image space either on a patient's preoperative image data being processed by Brainlab IGS platforms, or on an individual 3D-model of the patient's bone, which is generated through acquiring multiple landmarks on the bone surface.

The system is indicated for any medical condition in which the use of stereotactic surgery may be considered to be safe and effective, and where a reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT, X-Ray, or MR-based model of the anatomy. The system aids the surgeon to accurately navigate a hip endoprosthesis to the preoperatively or intraoperatively planned position.

Example orthopedic surgical procedures include but are not limited to:

- Total Joint Replacement
- Minimally invasive orthopedic surgery
- Tumor resection and bone/joint reconstruction

Indications for Use: SR (Surface Replacement) Procedures

The **Brainlab hip** system is intended as an intraoperative image-guided localization system. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on Brainlab IGS platforms. The image data is provided either in the form of preoperatively-acquired patient images or in the form of an individual 3D model of the patient's bone, which is generated by acquiring multiple landmarks on the bone surface.

The system is indicated for any medical condition in which the use of stereotactic surgery may be considered to be appropriate and where a reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT, X-ray, or MR-based model of the anatomy. The system aids the surgeon in accurately navigating a hip endoprothesis to the preoperatively or intraoperatively planned position.

Example orthopedic surgical procedures include but are not limited to:

- Partial/hemi-hip resurfacing

Contraindications

The registration result for supine and lateral patient position is strongly depending on statistical values of the human anatomy. These values are only valid for fully grown adults, otherwise registration could be inaccurate. Hip replacement patients that are not fully grown adults shall not be treated using **Brainlab hip**.

Patients suffering from dysplasia should only be treated using the **Brainlab hip** Express Leg Situation workflow. For patients suffering from dysplasia or other pelvic deformities, it is not possible to register the center of rotation correctly, which could result in inaccurate navigation.

Intended User

The intended users of **Brainlab hip** are surgeons and medical professionals.

Place and Conditions of Use

Brainlab hip is an image guided surgery system that is used in operating rooms. The system consists of parts that can be used multiple times, such as the software, tracking system and computer platform, and parts that are single-use items, such as reflective marker spheres for instruments. Instruments and navigation disposables must be sterile during use. The computer platform and tracking system may be mobile, according to platform specification.

Plausibility Review

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

1.4.2 System Accuracy

Accuracy of Measuring Device

Brainlab hip provides the basic measurement options and corresponding accuracy ranges presented in this section.

Cup Orientation

A prospective clinical validation study was performed to analyze the accuracy of lateral and supine pelvis registration in **Brainlab hip 6.0**. The study included 48 total hip replacement surgeries on patients over 55 years of age. Patients with previous ipsilateral hip surgery affecting the pelvic or acetabular anatomy, pelvic fracture, ipsilateral acetabular fracture and women with childbearing potential were excluded.

The surgical procedure was performed using a **Brainlab Hip 5.1** navigation system, including an epicutaneous acquisition of the anterior pelvis plane (APP) as the basic reference for intraoperative navigation. This reflects an established registration procedure. The final position of the cup was verified based on this registration. Additionally, all landmarks required for **Brainlab hip 6.0** registration procedures were acquired. Based on this information, the verified cup orientation was virtually adapted to the registration methods of **Brainlab hip 6.0**. Post-operative CT scans were performed to determine a gold standard registration by defining the APP points directly on bone. Cup orientation was measured for this reference and then compared to the virtually adapted cup orientation. This enabled a direct comparison of the lateral and supine registration methods in **Brainlab hip 6.0** with the gold standard.

The descriptive statistics (mean ± standard deviation) of the deviations to the gold standard, as well as the percentage of cases within a ±10° safe zone, as defined by Lewinnek et al in *Lewinnek GE, Lewis JL, Tarr R, Compere CL, Zimmerman JR. Dislocations after total hip-replacement arthroplasties. J Bone Joint Surg Am. 1978 Mar;60(2):217-20,* were calculated according to the radiographic definition specified by Murray DW in *The definition and measurement of acetabular orientation. J Bone Joint Surg Br. 1993 Mar; 75(2): 228-32*. The percentages were calculated based on the actual numbers of cases, as well as a statistical calculation where error distribution was modeled as a normal distribution.

- Deviation between gold standard and **Brainlab hip 6.0** lateral registration:
  - Inclination: -1.1° ± 3.1°, statistically 0.25% of the cases were outside the ±10° safe zone
  - Anteversion: 0.9° ± 4.3°, statistically 2.32% of the cases were outside the ±10° safe zone
- Deviation between gold standard and **Brainlab hip 6.0** supine registration:
  - Inclination: 0.5° ± 2.2°, statistically 0.0% of the cases were outside the ±10° safe zone
  - Anteversion: -0.9° ± 3.9°, statistically 1.2% of the cases were outside the ±10° safe zone

The deviation was not outside the safe zone in any of the actual cases. This was true for both lateral and supine registration methods. These results describe the basic accuracy of cup orientation measurement in **Brainlab hip 6.0**.

Pin-Based Leg Situation

According to the results from a cadaver study including 17 hip specimens, the accuracy of leg length and offset measurements using a pin-based femoral reference array in **Brainlab hip** is described as follows:

The accuracy was calculated as the deviation between the post-operative CT analysis and the results determined by **Brainlab hip**. The values are given as mean ± standard deviation.

- Deviation (navigation compared to gold standard based on CT analysis) of leg length changes:
  - 0.74 mm ± 2.4 mm
- Deviation (navigation compared to gold standard based on CT analysis) of changes in global offset:
  - 0.89 mm ± 1.8 mm

These results are documented in *Renkawitz T, Schuster T, Herold T, Goessmann H, Sendtner E, Grifka J, Kalteis T. Measuring leg length and offset with an imageless navigation system during total hip arthroplasty: is it really accurate? Int J Med Robot. 2009 Jun;5(2):192-7*.

Pinless Leg Situation	According to the results from prospective clinical study including 43 clinical cases, the accuracy of leg length and offset measurements using a pinless femoral reference array in **Brainlab hip** is described as follows:

The accuracy was calculated as the deviation between and the changes in leg length and offset as determined by pre- and post-operative X-rays, compared to the results measured by **Brainlab hip**. The values are given as mean ± standard deviation. The results below describe the direct comparison between X-ray measurements and navigation data. Additionally, the results were compensated according to the inherent inaccuracies of the X-ray measurement. The accuracy of the X-ray measurements was assessed based on measurements on the non-treated side in the same clinical cases. This accuracy limit was determined to be 1.1 mm ± 3.5 mm for leg length and 0.2 mm ± 3.4 mm for offset changes.

- Deviation (navigation compared to X-ray analysis) of leg length changes:
  - 0.4 mm ± 3.9 mm
  - After correction according to inaccuracy of X-ray analysis: -0.7 mm ± 1.9 mm
- Deviation (navigation compared to X-ray analysis) of changes in global offset:
  - 0.9 mm ± 4.0 mm
  - After correction according to inaccuracy of X-ray analysis: 0.7 mm ± 2.2 mm

The results are documented in *Wörner M, Sendtner E, Springorum R, Renkawitz T, Poitzsch L, Gneiting S, Schubert M, Haimerl M. Accuracy of computer aided pinless leg length and offset measurements in THA. EFORT 2012, Berlin*.

1.4.3 Potential Side Effects

Additional Incisions

When using **Brainlab hip** navigation, additional skin incisions are needed at the Iliac Crest and the distal femur to securely fixate reference arrays using bone screws.

Alternatively, the pelvis reference array may be fixed cranial to the acetabulum, directly inside the wound to avoid an additional incision. Additionally, the **Pinless Femur Reference Array** may be used to measure leg length and offset changes without the need for additional pins in the femur.

For SR procedures, pins for the femoral reference array are fixated on the proximal femur, directly inside the wound. Therefore, also for these procedures, no additional incision is necessary.

Increased OR Time

When using current navigation techniques an increase of OR time was reported, primarily for the additional effort of registration, e.g., due to a need of patient repositioning.

As **Brainlab hip** uses an indirect reconstruction of the anterior pelvic plane based on landmarks that are accessible in a standard OR setup, there is no additional need to reposition the patient. Thus, the additional OR time is reduced, though it may not be avoided totally.

Other Side Effects

No other side effects are currently known.

1.5 Compatibility with Medical Devices

1.5.1 Brainlab Medical Instruments

Compatible Brainlab Medical Instruments

Brainlab hip is compatible with:

- Adapter for Cup Inserter
- Chana Cup Reamer Handle
- Cup Reamer Adapter "Brainlab"
- Cup Reamer Adapter "DePuy Quickset"
- Cup Reamer Adapter "Precimed EZ-Clean"
- Cup Reamer Adapter "Zimmer Full Hemisphere"
- Curved Cup Impactor Universal (with inserts)
- Disposable Clip-on Remote Control
- Disposable Reflective Marker Spheres
- Disposable Schanz Screws (various sizes)
- Disposable Sterile Touchpen
- Drill Guide
- Drill Guide Tube
  - 2.5 x 45 mm
  - 3.0 x 45 mm
  - 3.2 x 45 mm
  - Rev. 0: 3.0 x 137 mm, 3.2 x 137 mm
  - Rev.A: 2.5 x 150 mm, 3.0 x 150 mm, 3.2 x 150 mm
- Femoral Broach Adapter "DePuy"
- Hip Caliper
- Instrument Calibration Matrix, Rev. 4 (ICM4)
- Instrument Adapter, StarLock Interface
- MI Reference Array Kit, X-Press
- Pinless Femur Reference Array Kit
- Pointer Angled
- Pointer Extended
- Pointer Extended with Sharp Tip
- Pointer Reverse Angled
- Pointer Square Angled
- Pointer Straight Extended
- Stem Position Verification Tool Extended
- Stem Position Verification Tool hip ct

Other Brainlab Instruments

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

⚠

Only use instruments and spare parts specified by Brainlab with Brainlab hip. 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.

1.5.2   Brainlab Medical Software

Compatible Brainlab Medical Software	**Brainlab hip** is compatible with: • Patient Browser 2.1 • Patient Data Manager, comprised of: - Content Manager 1.0 - Interactive DICOM Viewer 1.0 - Patient Browser 3.0
Other Brainlab Software	If you are running software versions other than those specified above, contact Brainlab support for clarification regarding compatibility with Brainlab devices.

Only Brainlab medical software specified by Brainlab may be installed and used with the system.

1.5.3 Non-Brainlab Medical Devices

Compatible Non-Brainlab Medical Devices

Brainlab hip is compatible with medical devices from the following manufacturers:

- Aesculap
- Biomet
- Corin Limited
- Greatbatch Medical
- Precimed
- Smith & Nephew
- Wright Medical Technology
- Zimmer

Other Non-Brainlab Devices

Medical Device	Model	Manufacturer
Power drill	Various, contact Brainlab support.	
3rd-party precalibrated instruments and axis precalibrated instruments	Various, contact Brainlab support.	
Footswitch	Footswitch (USB)	Manufactured by *.steute*

Using medical device combinations which 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.

1.5.4   Non-Brainlab Software

Compatible Non-Brainlab Software   **Brainlab hip** is compatible with:

- Microsoft XP operating system
- Windows 7 operating system

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

Other Non-Brainlab Software

Only software specified by Brainlab may be installed and used with Brainlab hip.

1.6 Training and Documentation

1.6.1 Training

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

Supervised Support
Before using the system for surgical procedures where computer-aided navigation is considered critical, perform a sufficient number of complete procedures with a Brainlab 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.

1.6.2 Documentation

Intended Audience This user guide is intended for all members of the clinical team who use or handle the **Brainlab hip** software or parts thereof.

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

It is important that all users of 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

User Guide	Contents
Software User Guides	• Overview of treatment planning and image-guided navigation • Description of OR system setup • Detailed software instructions
Instrument User Guides	Detailed instructions on instrument handling
Cleaning, Disinfection and Sterilization Guide	Details on cleaning, disinfecting and sterilizing instruments
System User Guides	Comprehensive information on system setup
Technical User Guide	Detailed technical information on the system, including specifications and compliances

2 SOFTWARE OVERVIEW

2.1 Chapter Overview

2.1.1 Contents

Topics Covered

Section	See
Introduction	Page 26
Opening and Closing the Software	Page 29
User Interface	Page 34
Navigating the Workflow	Page 39
Menu and Options Menu	Page 43
System Settings and Information	Page 48
Therapy Reports	Page 53

2.2 Introduction

2.2.1 Overview

General Information

Brainlab hip is a wireless, touchscreen-operated planning and navigation software designed for intraoperative use in hip surgery. It can be installed on a Brainlab navigation system.

⚠

Only use the Brainlab hip software for treatments described in the section "Intended Use" (see page 13). Do not use the software for any other treatments.

Wireless Tracking

The Brainlab navigation system is a wireless, touchscreen-operated surgical navigation system.

Wireless tracking is achieved by a camera unit, attached to the navigation station, that emits and detects flashes of infrared light.
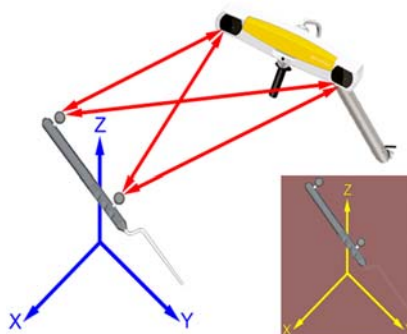
Figure 1

- Reflective elements, affixed to reference arrays on the patient and to instrumentation, reflect the infrared signals back to the camera unit.
- Reflected signals from the reflective marker spheres and discs are captured and digitized by each camera lens from a different angle.
- The software uses the camera input to calculate the relative three-dimensional positions of the instruments and the patient reference arrays.

Touchscreen Display

On the navigation station, database images and 3D bone models are displayed on the touchscreen monitor, and are used to provide localization information during surgery.

Patient Positioning

The patient is positioned in a supine or lateral position and draped. Draping and positioning of patient supports may need to be adapted for lateral positioning as the spinous process of the L5 vertebra must be accessible. The iliac crest must be accessible for registration. The mid-femoral region must also be accessible so that the femoral reference array can be attached if the femur and/or leg situation shall be navigated.

Both camera lenses must have an unobstructed view of the surgical area at all times.

Registration and Navigation	Before beginning navigation, you must register the patient by acquiring landmarks with a pointer on different areas of the bone, as indicated by the software.
	The registration procedure serves two purposes:
	• It concurrently provides the software with reference landmarks on the patient's anatomy relative to the tracked reference arrays.
	• It can allow the software to "morph" a 3D model of the hip that matches the patient's anatomy.
	You must verify the registration before beginning computer-aided navigation.
	During navigation, simultaneous tracking of surgical instruments and reference arrays enables the software to provide real-time information on the location of the instruments relative to the patient's anatomy.
Navigated Instruments	If the selected instrument does not have a tracking array fixed to it, you must attach an instrument adapter. If the instrument is not pre-calibrated, you can use a calibration procedure (see page 142), which allows the software to reference the instrument.
Therapy Reports	The **Therapy Report** button in the menu bar allows you to create a therapy report of the surgery at any time. Therapy reports are saved to the hard drive of the navigation system. See page 53 for more information.

Memory Requirements

System Memory	Response
Only 200-1024 MB memory	A warning message is displayed. • To continue without archiving, press **Proceed** • To cancel startup, press **Cancel**
Less than 200 MB memory	You are prompted to shut down the system.

NOTE: In either case, contact Brainlab support.

External Storage Media	**Brainlab hip** is compatible with CDs and USB flash drives for patient data storage.

2.2.2 Workflow for Hip Procedures

Workflow

```
┌─────────────────────────────────────────┐
│        Preoperative measurements         │───── Preoperative
│  (e.g., ASIS-to-ASIS distance, pelvic tilt) │
└─────────────────────────────────────────┘
                    │
┌─────────────────────────────────────────┐
│   Set up system in OR and enter patient info │
└─────────────────────────────────────────┘
                    │
┌─────────────────────────────────────────┐
│              Select procedure            │
└─────────────────────────────────────────┘
                    │
┌─────────────────────────────────────────┐
│               Drape patient              │
└─────────────────────────────────────────┘
                    │
┌─────────────────────────────────────────┐
│          Attach reference arrays         │
└─────────────────────────────────────────┘
                    │                        Intraoperative
┌─────────────────────────────────────────┐
│         Make incision and prepare bone   │
└─────────────────────────────────────────┘
                    │
┌─────────────────────────────────────────┐
│            Perform registration          │
└─────────────────────────────────────────┘
                    │
┌─────────────────────────────────────────┐
│     Attach instrument adapters and       │
│     calibrate instruments (optional)     │
└─────────────────────────────────────────┘
                    │
┌─────────────────────────────────────────┐
│            Perform navigation            │
└─────────────────────────────────────────┘
                    │
┌─────────────────────────────────────────┐
│       Print and file therapy report      │───── Postoperative
└─────────────────────────────────────────┘
```

2.3   Opening and Closing the Software

2.3.1   Opening the Software

General Information

After turning on the system, **Brainlab hip** is accessed either via **Patient Data Manager** or **Patient Browser**, depending on the system you are using.

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

How to Open the Software (Patient Data Manager)
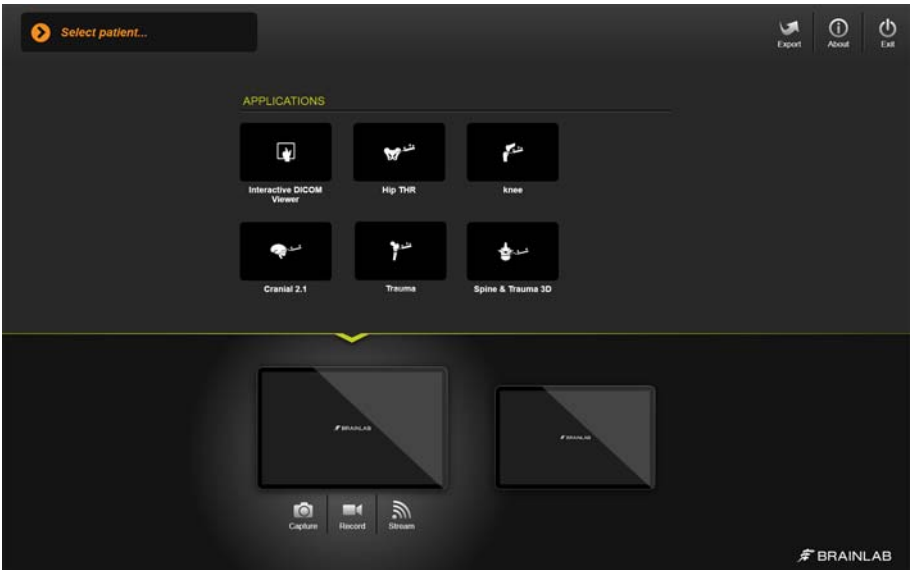
Figure 2

Steps
1.   Turn on the system using the power switch.
2.   Press the hip software icon, then press the desired display.
3.   Patient information is entered during surgery set up (see page 96).

How to Open the Software with Patient Selected (Patient Data Manager)
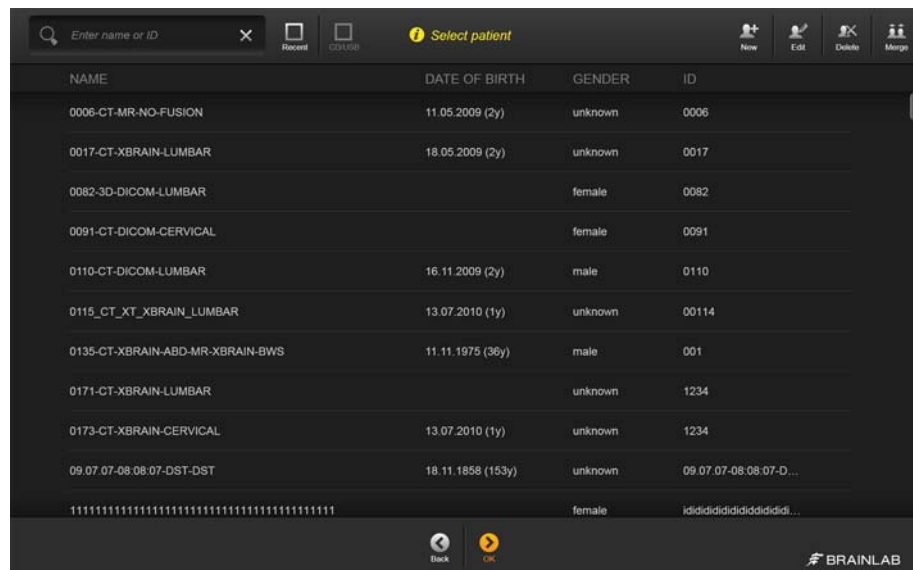
Figure 3

Steps	
1.	Turn on the system using the power switch.
2.	Select existing patient or create patient profile.
3.	Press **Select**.
4.	Press the hip software icon, then press the desired display.

How to Open the Software (Patient Browser)

Steps	
1.	Turn on the system using the power switch.
2.	If more than one software is installed, select **Brainlab hip**.
3.	Patient information is entered during surgery set up (see page 96).

2.3.2   Closing the Software

General Information

Once you have completed all planned steps in your procedure, e.g., after hip function analysis, press **Finish** to close the software.

*NOTE: For information on system shutdown, please see your **System User Guide**.*

Always close the software before shutting down the system. Never use the system power switch to exit the software as data may be lost.

How to Manually Close the Software

Step
Select **Exit** in the menu. The **Exit** dialog opens.

Confirm Verified Implants

After pressing **Finish** or selecting **Exit** from the menu, you must confirm the implants that were used. This ensures that the correct implants appear on the therapy report.
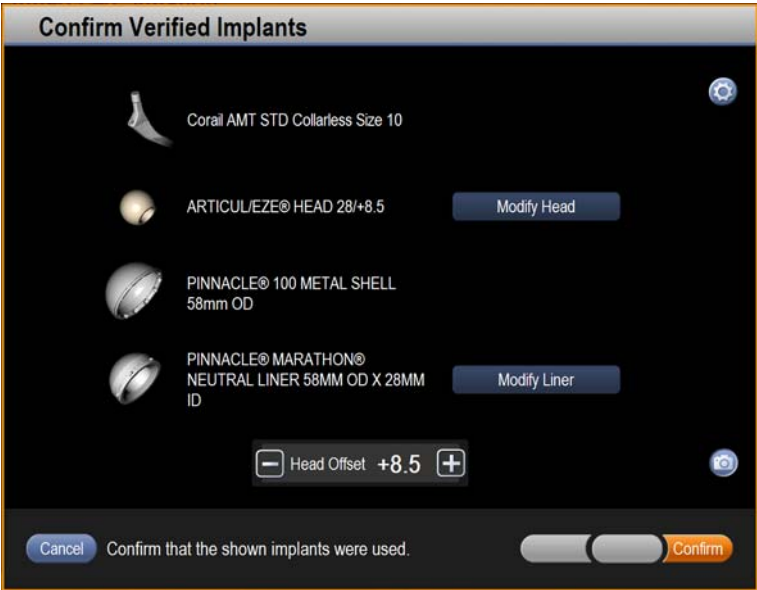
Figure 4

Options
If all implant components are correct, press **Confirm**. The **Exit** dialog opens.
If necessary, modify implant components via the adjacent button (e.g., **Modify Head**, **Modify Liner**).
When all implant components are correct, press **Confirm**. The **Exit** dialog opens.

Exit Dialog
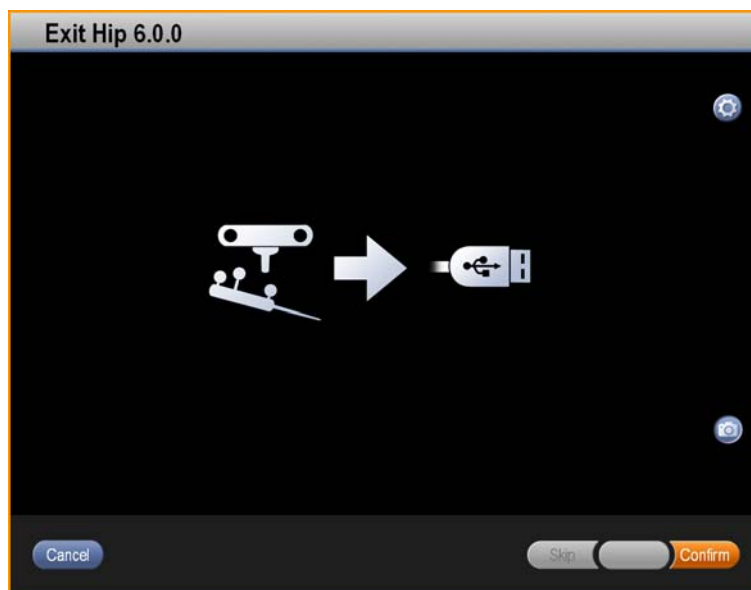
Figure 5

Step
Press **Confirm** to shut down.
Patient data is saved to the navigation system.
*NOTE: If you initiated shutdown, but wish to return to the program, press **Cancel** in the **Exit** dialog.*

Saved Procedure Information

During each procedure, a session folder is generated that contains:

- Registration data
- A long and a short therapy report (PDFs)
- All screenshots acquired during the session

These are saved to the selected storage medium in a session folder labeled with the patient's name and ID.

NOTE: The session folder also contains other files, e.g., the "logfile" and "session file". Do not delete any files from the session folder! They may be important to Brainlab support if the system function needs to be analyzed.

Changes to the Procedure

If you have made any changes to the settings selected during procedure planning, they are shown in orange in the **Procedure Overview** screen.

Figure 6

2.4   User Interface

2.4.1   Main Screen

Types of Interface Pages   The types of interface pages in **Brainlab hip** include:

- Main screens: For planning and navigation
- Dialogs: Windows that give you information, allow you to make choices, or guide you through steps in a workflow
- Alerts and warnings

Main Screen Layout   Some main screen images change depending on the active planning or navigation function. Other main screen elements remain constant.
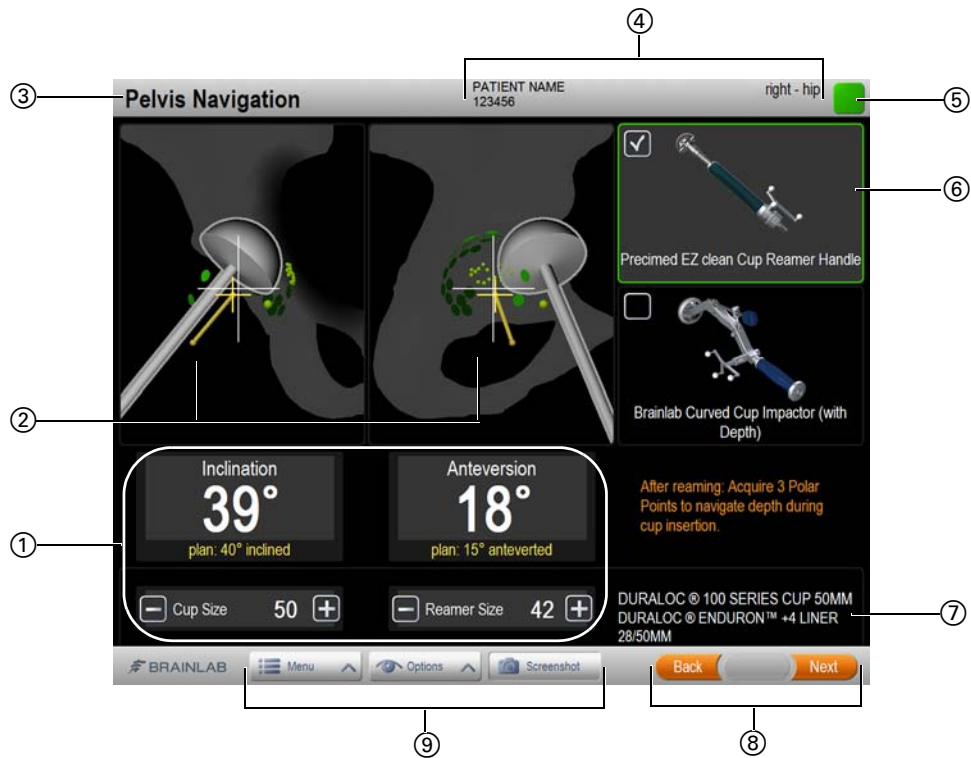
Figure 7

No.	Component
①	Values
②	Planning or navigation views
③	Current step
④	Patient name, ID and treated side
⑤	Camera status indicator
⑥	Selected instrument
⑦	Implant information
⑧	Workflow buttons
⑨	Menu bar

NOTE: All planning, navigation and verification values ① are based on the preoperative situation.

2.4.2 Camera Setup

**General
Information**

All steps that you perform during registration and navigation require that the camera has a clear line of sight to the reference arrays and active instrument.

The **Surgery Setup** dialog assists you in correctly placing reference arrays within the camera field of view.

When the first instrument or reference array enters the camera field of view, the **Surgery Setup** dialog opens and **Camera Setup** is selected.

Although you can move and readjust the camera later, setting up the camera properly beforehand can save a lot of time during the surgical procedure.

NOTE: A notification appears if the camera connection to the navigation system is lost or too weak.

Screen Layout
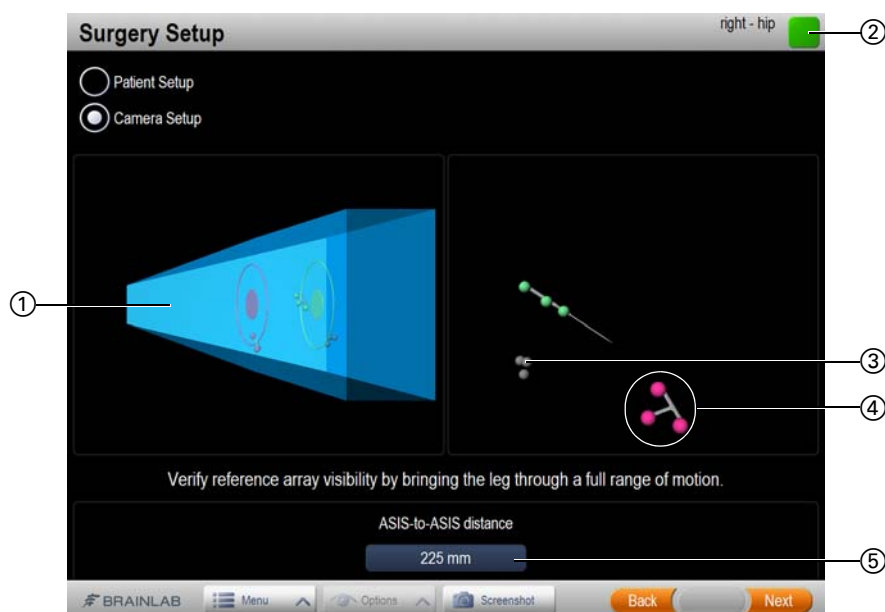
Figure 8

No.	Component	Description
①	Blue cone	3D representation of camera field of view.
②	Camera visibility indicator	Indicates whether all necessary instruments/reference arrays are visible (green) or not (red).
③	Gray spheres	Instrument or reference array that is only partially visible or cannot be identified by the software.
④	Colored spheres	Reference and tracking arrays within the camera field of view.
⑤	ASIS-to-ASIS distance	Press this button to make changes to the ASIS-to-ASIS distance you entered (see page 98). *NOTE: If you have selected pelvic tilt, a button is available here for adjusting pelvic tilt.*

How to Optimize the Camera Field of View

Step
In the **Surgery Setup** dialog, adjust the camera so that all reference arrays and registration kits are within the blue cone, ideally in the middle.

NOTE: If an instrument or reference array is no longer visible to the camera lenses, the corresponding sphere disappears from view.

Camera Visibility Indicator

The camera visibility indicator identifies the visibility of instruments and reference arrays to the camera. The camera display also acts as a button to open the visibility display.

Status	Visibility to the Camera
	All instruments and reference arrays necessary for the current step are visible.
	One or more instruments or reference arrays are not visible. *NOTE: The letter indicates which required hardware is not visible (i.e., I = instrument, P = pelvis array, F = femur array.)*

2.4.3 Visibility Display

General Information

For successful registration and navigation, the camera must have an unobstructed view of instruments and reference arrays.

The visibility display gives you real-time feedback about the visibility of instruments and reference arrays to the camera. Images in the display indicate the relative position of instruments and reference arrays visible to both camera lenses.

NOTE: We recommend that you check the visibility display before beginning any registration or navigation step.

Screen Layout
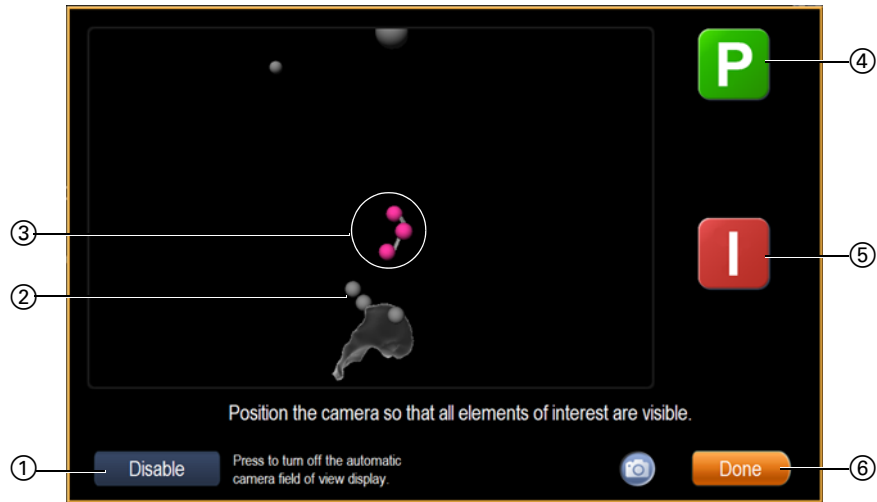
Figure 9

No.	Component
①	Disable/Enable button
②	Only partially visible or unidentifiable instrument or reference array
③	Visible reference arrays
④	Indicator identifying that the necessary reference array is visible.
⑤	Indicator identifying that the necessary instrument is not visible.
⑥	Done button

How to Open and Close the Display

Steps	
1.	• The visibility display automatically opens five seconds after a necessary instrument or reference array disappears from the camera field of view. • You can open the display manually at any time by pressing the camera visibility indicator.
2.	• Once all required instruments and/or reference arrays are returned to the camera field of view, the display disappears. • You can close the display manually by pressing the **Done** button ⑥.

Camera View Sphere Colors

Color	Instrument/Array
Magenta	Pelvis reference array (**T** geometry)
Yellow	Femur reference array (**Y** geometry)
Green	Pointers
Dark blue	Calibrated instruments, the **ICM4** or other tracking arrays
Light purple	Uncalibrated instruments, **Pinless Femur Reference Array**
Gray	Instrument or reference array that is only partially visible or cannot be identified by the software

Tracking Array Ambiguity

⚠

The software detects instruments based on predefined geometries of their tracking arrays. Ambiguous marker sphere constellations may cause the system to detect geometries incorrectly for a short period of time.

How to Disable the Visibility Display

Steps	
1.	Press the camera visibility indicator. The visibility display opens.
2.	Press the **Disable** button ①. The display disappears and the visibility display is now disabled.

How to Re-Enable the Visibility Display

Steps	
1.	Press the camera visibility indicator. The visibility display opens.
2.	Press the **Enable** button ①. The display disappears and the visibility display is again enabled.

2.5   Navigating the Workflow

2.5.1   Using Workflow Buttons

General Information

Workflow buttons allow you to proceed forward or backward through a workflow, such as a registration procedure. They appear in the lower right-hand corner of the screen.

- Buttons with blue outlines and text are enabled.
- Buttons with gray outlines and text are disabled.
- When a function is not available for a certain step, the corresponding button is not shown.

Workflow Buttons
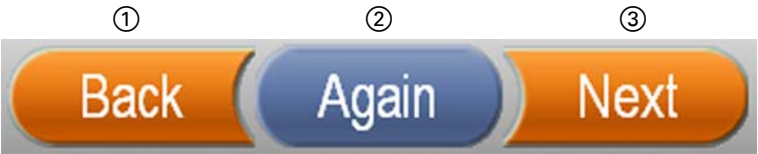
Figure 10

No.	Button	Description
①	Back	Goes to the previous registration or navigation step.
②	Center button	Offers a function specific to the current dialog (e.g., "Again" or "Reset").
③	Next/Accept	Takes you to the next step of planning, registration or navigation, and confirms entries.

Proceeding to the Next Step

The **Next** button ③ appears on dialogs and main screens. It always takes you to the next planned step in the procedure.

Returning to Previous Steps

To return to a previous dialog or main screen, press **Back** ①.

You can also re-enter a step via the **Go to...** menu.

Opening Other Steps

To open a step that is not directly before or after your current step, select the **GOTO** button in the **Menu**.

2.5.2 Clip-on Remote Control

Use of Clip-On Remote Control

The **Clip-on Remote Control** enables active patient registration in combination with a calibrated pointer.

A check box is located on any page where it is possible to use the **Clip-on Remote Control**. Select/ deselect the check box to enable/disable the functionality. The **Clip-on Remote Control** can also be activated via the **System** menu (see page 52).

For more information on using the **Clip-on Remote Control** for patient registration, see page 103.

2.5.3 Using a Footswitch

Using a Footswitch If you are using a footswitch to navigate through the software, buttons that can be controlled by the footswitch are highlighted with a colored border.

Figure 11

The colored border corresponds to the three colors on the foot pedals as described in the following table.

Pedal	On screen/dialog	Function
Left (yellow)	Any dialog with max. 3 main buttons	Like the **Back** button, which is highlighted in yellow.
	Any dialog with more than 3 main buttons, e.g., planning screens	If highlighted in yellow, currently activated for footswitch control.
Center (black)	Any dialog with max. 3 main buttons	Generally, like the **Reset**/center button.
	Any dialog with more than 3 main buttons, e.g., planning screens	Toggles between buttons.
	Any	Hold down for an extended time to take a screenshot.
Right (blue)	Any dialog with max. 3 main buttons	Like the **Next** button, which is highlighted in blue.
	Any dialog with more than 3 main buttons, e.g., planning screens	If highlighted in blue, currently activated for footswitch control.

NOTE: The footswitch works as soon as the cable is connected to the system. If the footswitch is not working, check the cable connection. The software provides no warning of footswitch connection failure, however the footswitch-controlled buttons do not appear highlighted.

2.5.4   Go to... Menu

General Information   The **Go to...** menu allows you to navigate the workflow steps. The **Go to...** menu is accessed via the **Menu** (see page 43).

The functions that are accessible from the **Go to...** menu depend on the procedure plan and the progress of the workflow. Buttons and tabs for functions which are not in the procedure plan or for which prerequisite steps have not yet been performed are disabled.

Screen Layout

Figure 12

No.	Component
①	Buttons for accessing registration, planning and navigation functions, listed in the order that steps are performed: • An arrow and orange outline indicate the selected function. • A green checkmark indicates that the step is completed. • Grayed out functions are not available.
②	Tabs from which you can access a particular step.
③	Preview field showing an image and description of the selected function.

2.6   Menu and Options Menu

2.6.1   Overview

Menu   The **Menu** remains the same for all screens and during all procedure steps. Options that are not
available in the current step are grayed out.
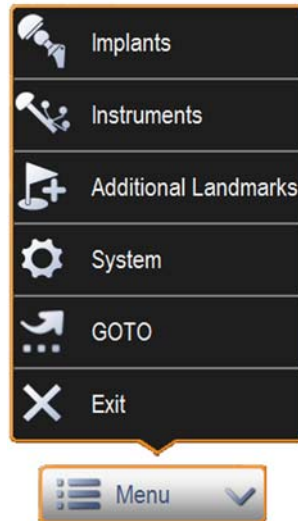
Figure 13

No.	Component	Explanation	See
①	Implants button	Opens implant selection.	Page 67
②	Instruments button	Opens instrument selection.	Page 70
③	Additional Landmarks button	Opens dialog where additional landmarks can be acquired.	Page 146
④	System button	Opens System menu.	Page 48
⑤	GOTO button	Opens Go to... menu.	Page 42
⑥	Exit button	Opens the Exit dialog.	Page 31

Options Menu (Example)	The **Options** menu changes to screen-specific options and procedure steps. If a screen does not offer any options, the button is disabled.

To enable an option, press the check box or button.

Check box features are:

- Checked when enabled
- Unchecked when disabled

Button features are:

- Orange when enabled
- Black when disabled
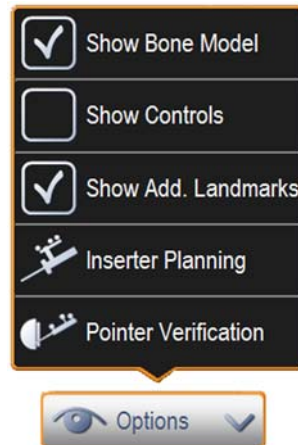
2.6.2   Additional Registration and Planning Options

Inserter Planning	Use cup inserter to define the planned cup orientation. For more information, see page 150.
Polar Points	Acquire polar points after cup reaming. For more information, see page 154.
Pointer Verification	After cup insertion, verify the cup using the pointer instead of the cup inserter. For more information, see page 157.
Dynamic Notching Warning	Switch on/off dynamic warning that notching may occur in the current position of the femoral component in SR workflows. Available during **SR Femur Head Planning** and **SR Pin Insertion** steps.
Impingement Analysis	Switch impingement analysis on/off during the Intraoperative ROM step. For more information, see page 178.

2.6.3   View Options

Show Bone Model	Show/hide bone model to better visualize implant and landmark information.
	Available on all screens that display a bone model.

Show Additional Landmarks	Show/hide additional landmarks.
	Available on all screens with navigation views.

Show Controls

Figure 14

Show ①/hide ② the additional controls for translational parameters of the cup implant.

Available during **Functional Cup Planning**, **Cup Planning**, **Cup Reaming**, **Cup Insertion** and **Cup Verification** steps.

Show Tilt Correction
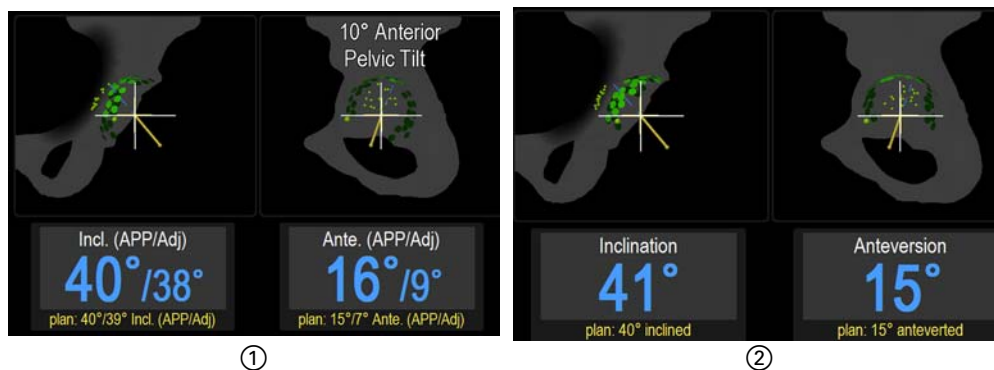
Figure 15

Show ①/hide ② additional display of cup orientation angles corrected by pelvic tilt. Whether shown or hidden, standard cup orientation angles are always shown as well.

Available during **Functional Cup Planning**, **Cup Planning**, **Cup Reaming**, **Cup Insertion** and **Cup Verification** steps.

Show Head Points	Show/hide head points in SR views to better visualize surface bone model and implant information.
	Available on the **Neck Axis (SR)**, **SR Femur Head Planning**, **SR Pin Insertion**, **SR Pin Verification**, and **SR Implant Verification** screens.

Dynamic Views	Provides the option to scroll through the bone model slices by using the pointer, i.e. slice selection is updated according to the current position of the pointer. Available during **SR Femur Head Planning**.
Flip Views	Flip the femur views in SR workflows to adapt to the surgeon's preferred position in the OR (anterior or posterior to the patient). Available on the **Neck Axis (SR)**, **SR Femur Head Planning**, **SR Pin Insertion**, **SR Pin Verification**, and **SR Implant Verification** screens.

2.7 System Settings and Information

2.7.1 System Menu

System Info Button

The **System Info** button opens a dialog showing the software and database version information. It also provides access to **Screenshots** and **Settings** options.

All settings shown below are accessed via the **System Info** button or by selecting **System** in the **Menu**.

2.7.2 Screenshots

General Information
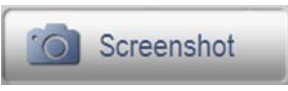
The software automatically saves screenshots of certain planning and registration steps.

You may take additional screenshots at any time. These are saved as .png files.

You can preview saved screenshots directly from the program.

NOTE: All automatically and manually taken screenshots are included in the patient's file, which is saved at system shutdown.

How to Take Screenshots

Step	
	Press one of the **Screenshot** buttons to create a screenshot of the current screen.
	The monitor flickers briefly to indicate that a screenshot has been taken.
	Screenshots are saved in the procedure file and the therapy report.

NOTE: Alternatively, use the footswitch to take a screenshot (see page 41).

Anonymized Data

Patient name and ID are automatically removed from all screenshots taken with **Brainlab hip**. If screenshots are created with **Patient Data Manager** or other applications, those screenshots are *not* anonymized.

Viewing Screenshots
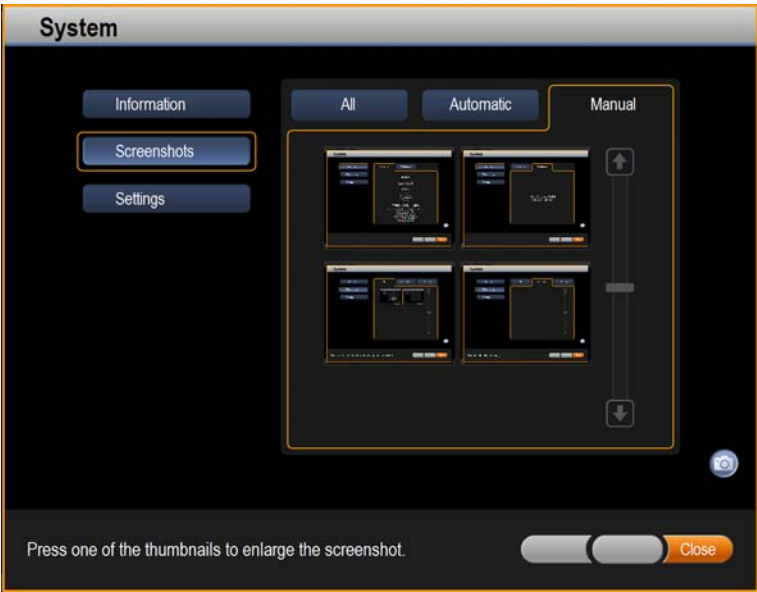
Figure 16

Options
To view all screenshots, select the **All** tab.
To view screenshots that the software generated automatically, select the **Automatic** tab.
To view screenshots you took manually, select the **Manual** tab.

Previewing Screenshots

Options
To scroll through stored screenshots, press arrows at either end of the scrollbar.
To view a screenshot as a full screen, press thumbnail of desired screenshot.
To return to thumbnail views of all screenshots, press anywhere on the screenshot view screen.
To close the **System** menu, press **Close**.

2.7.3 Settings

**How to Adjust
System Sounds**
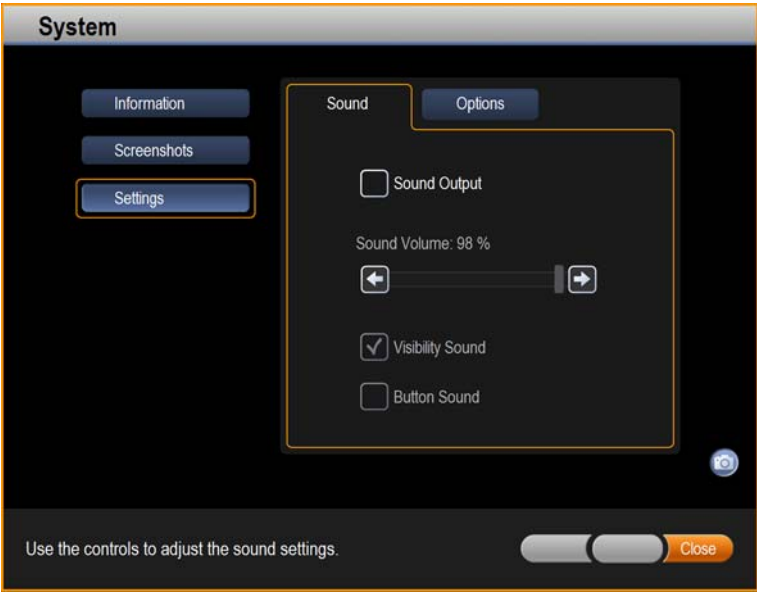
Figure 17

Options
Activate or deactivate system sounds with the **Sound Output** check box.
Activate or deactivate sounds when a reference array is not visible to the camera, with the **Visibility Sound** check box.
Activate or deactivate button sounds with the **Button Sound** check box.
Use the slider bar to adjust system sound volume.

**System Sound
Information**

Sounds are produced by the software to provide feedback to the user. Sounds will be audible, e.g., when a button is pressed, when points are acquired, when an instrument is successfully calibrated, etc.

In addition, a "humming" sound is audible when all required instruments and reference arrays are visible to the camera. This indicates that everything is correct and you may proceed.

How to Select Interface Language   The **Language** tab under **Settings** allows you to select the language of the software interface.
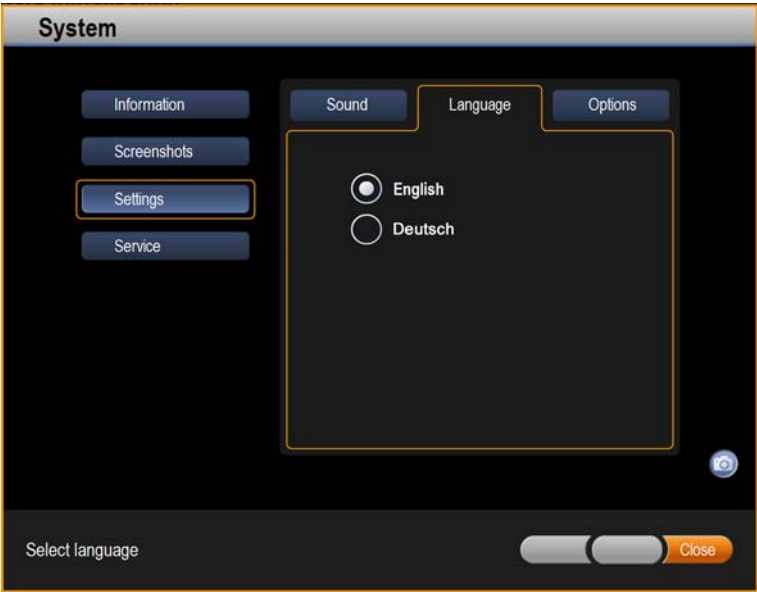
Figure 18

Steps
1. Select the **Language** tab.
2. Press the button for your desired language.
3. Press **Close** to apply your settings and close the **System** menu.

How to Activate Clip-On Remote Control
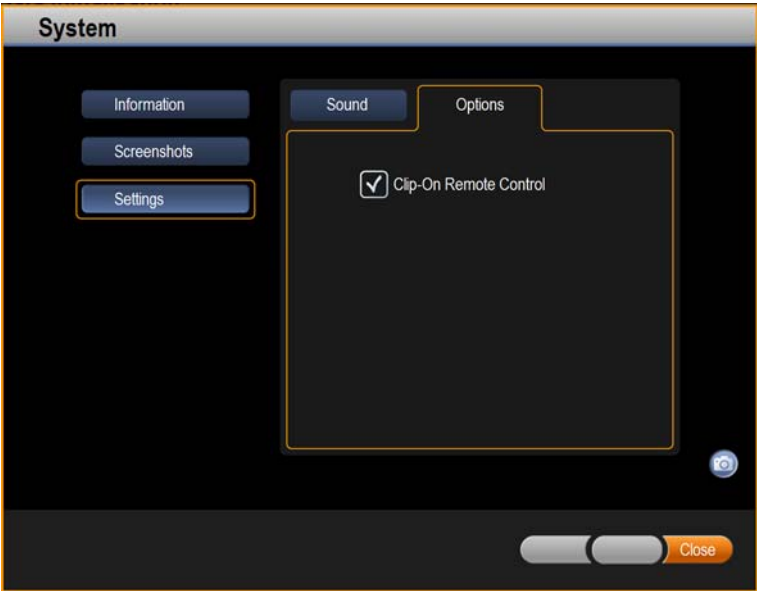
Figure 19

In the **Options** tab under **Settings** use the check box to activate/deactivate **Clip-On Remote Control** functionality.

*NOTE: The activation/deactivation of the **Clip-On Remote Control** is also possible via a check box on all point acquisition screens.*

2.8 Therapy Reports

2.8.1 Overview

General Information

When you close the software, it generates therapy reports for the session (PDFs).

Report	Data Contained
Long therapy report	• Procedure data and selected software settings • The time at which various steps were completed • Screenshots generated both automatically and manually during the procedure
Short therapy report	The same data as the long therapy report, but excluding screenshots

Saved Therapy Reports

Interim therapy reports are saved to the navigation system while the program is running. The final therapy report is saved to the navigation system upon shutdown.

Screenshots

- Screenshots are displayed in the therapy report according to the time at which they were taken.
- Automatic screenshots are updated to display the most recent version of the workflow step and are labeled as "automatic" in the therapy report.
- Manual screenshots are labeled as "manual" in the therapy report.

2.8.2   Therapy Report Information

General Data

Section	Contents
Therapy Report Header	• Patient name and ID • Gender
General Information Data	• Name and address of the hospital or clinic where the operation was performed • Names of the operating surgeon and assisting surgeon (filled out by the surgeon)
Surgical Procedure Data	• Treatment date • Treatment side • Date and procedure start and end time • Patient position • Selected workflow • Navigation steps • Acetabular rim points • Acetabular orientation • Femoral anteversion • ASIS distance

Additional Therapy Report Sections

The following sections always appear in therapy reports. The exact content depends on your workflow and procedure type:

- Navigation thresholds
- Planned implant data
- Pelvis verification
- Femur verification
- Impingement analysis (Intraoperative ROM)
- Leg situation

3 PROCEDURE PLANNING

3.1 Chapter Overview

3.1.1 Contents

Topics Covered

Section	See
Getting Started	Page 56
Creating a Procedure Plan	Page 63
Procedure Plan Setup	Page 64

3.2 Getting Started

3.2.1 Preoperative ASIS-to-ASIS Measurement

General Information

If you are performing a lateral procedure with cup navigation, you must use the Brainlab **Hip Caliper** to measure the ASIS-to-ASIS distance of the pelvis prior to surgery on intact skin. This information is required for pelvis definition and navigation of hip implants.

The **Hip Caliper** can be used on obese patients, however the soft tissue layer should be pulled away from the ASIS landmarks during measurement.

If, for any reason, the **Hip Caliper** cannot be used for ASIS-to-ASIS measurement, only the Express Leg Situation workflow may be used. Express Leg Situation does not require ASIS-to-ASIS measurement.

The Hip Caliper shall only be used on intact skin.

How to Measure the ASIS Distance
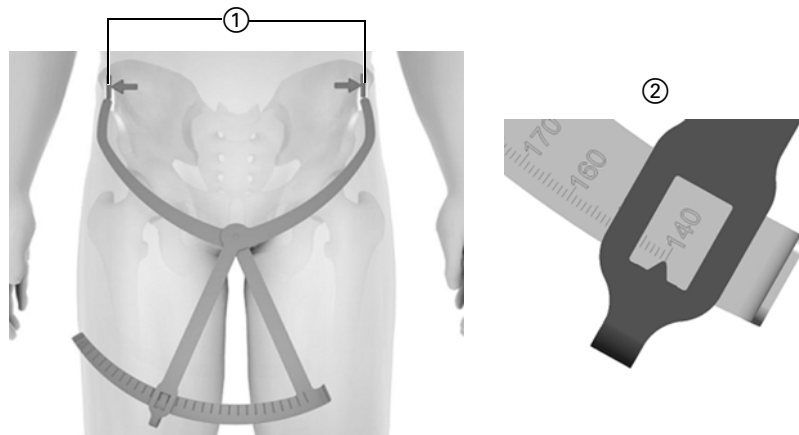
Figure 20

Steps	
1.	Define two distinctive ASIS landmarks ①. *NOTE: The landmark on the treated side must be acquired in the exact same position in the subsequent registration step (see page 114).*
2.	Place the center of the **Hip Caliper** markers on top of the landmarks ①. *NOTE: For obese patients, pull soft tissue away from the ASIS landmarks in order to reduce the amount of soft tissue included in the measurement.*
3.	Note the value displayed in the inspection window ②. This value is entered during software setup (see page 98).

3.2.2 Preoperative Pelvic Tilt Measurement

How to Measure Pelvic Tilt

If you plan to use pelvic tilt adjustment with the software, measure the pelvic tilt preoperatively.

For more information on pelvic tilt, see page 77 and page 183.

Steps	
1.	Measure the pelvic tilt of the patient, i.e., the angle that the frontal body plane deviates from the anterior pelvic plane in a sagittal projection, using, e.g., lateral X-rays.
2.	This value is entered during software setup (see page 99).

3.2.3   Welcome Dialog

Screen Layout   The first dialog you see when the software opens is the **Welcome** dialog.
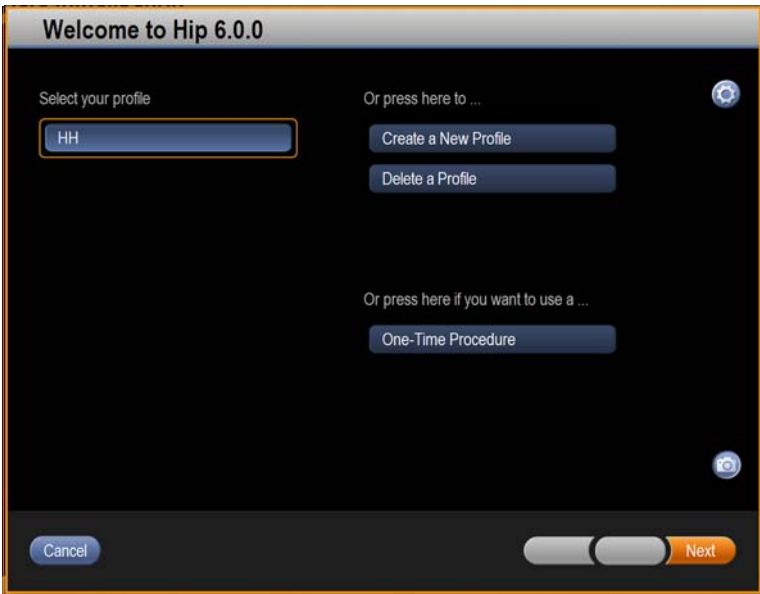
Figure 21

Options
To open your user profile, select your user name and press **Next**.   *NOTE: If no user profiles are available, no user names appear.*
To create a new user profile, press **Create a New Profile**.
To delete user profiles, press **Delete a Profile**.
To proceed without using a user profile, select **One Time Procedure**.   *NOTE: No procedure preferences are saved.*
If you wish to exit the program, press **Cancel**.

3.2.4   Creating and Deleting User Profiles

General Information

A user profile is connected to a procedure plan. Therefore, creating a new user profile also includes creating a procedure plan.

How to Create a User Profile

① ②
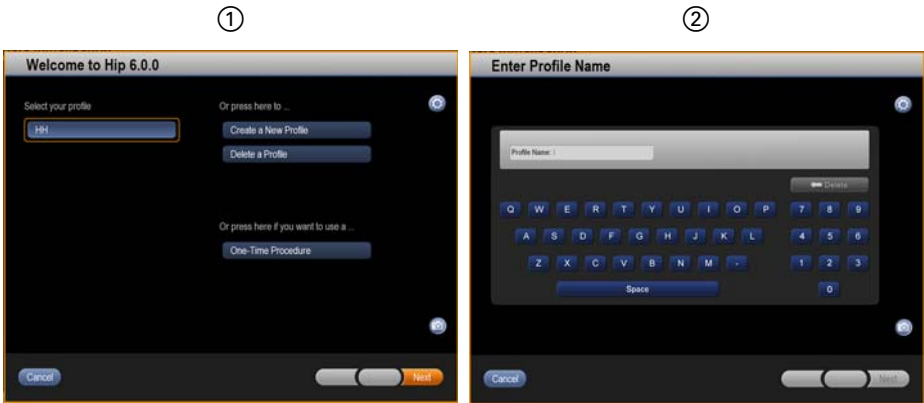
Figure 22

Steps	
1.	In the **Welcome** dialog, press **Create a New Profile** ①. The **Enter Profile Name** dialog opens ②.
2.	Enter a profile name on the virtual keyboard.
3.	Press **Next.** The **Set Up Procedure** dialog opens.

*NOTE: The **Next** button remains disabled until text is entered in the **Profile Name** field.*

How to Delete Users

Figure 23

Steps	
1.	In the **Welcome** dialog, select **Delete a Profile**. The **Delete Profile** dialog opens.
2.	Select the profile you wish to delete. *NOTE: Proceed with caution. You cannot undo deletion of a user profile!*
3.	Press **Delete**. The user profile is deleted.
4.	Repeat steps 2 and 3 for all profiles you wish to delete.
5.	Press **Close** to return to the **Welcome** dialog.

Modify Profile
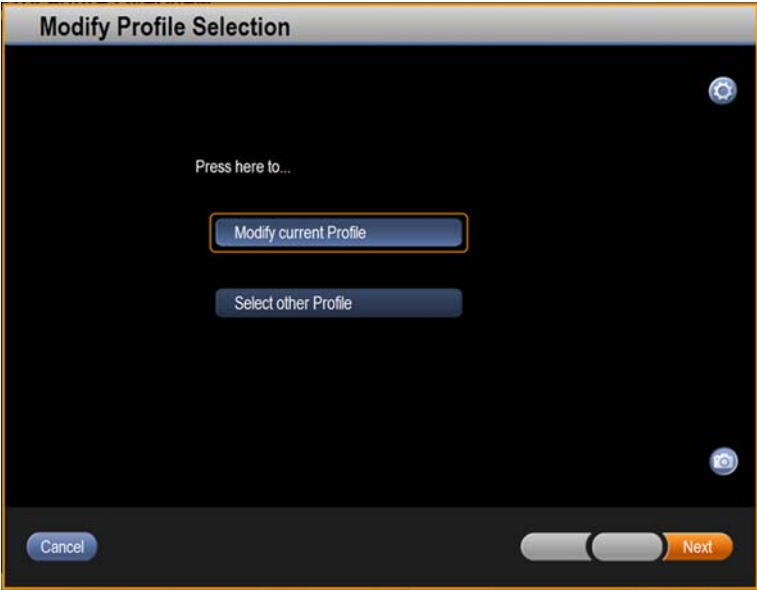
Figure 24

Options
To make changes to the current user profile, press **Modify current Profile**.
To select a different user profile, press **Select other Profile**.

3.2.5 Choosing an Existing Procedure

General Information

After selecting or creating the user profile, you are prompted to choose your procedure.

How to Choosing a Procedure
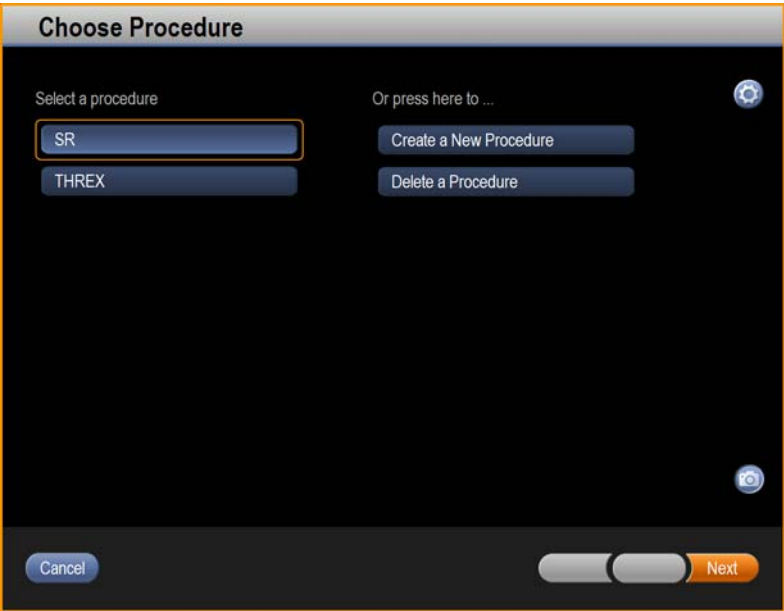
Figure 25

Options
Select an existing procedure from the left column.
Select corresponding button to create a new procedure.
Select corresponding button to delete a procedure.

3.3   Creating a Procedure Plan

3.3.1   Overview

General Information

The procedure planning functionality enables you to plan surgical procedures preoperatively.

When you create a new user profile, you are prompted to create a procedure plan. One procedure plan can be saved per user profile. A procedure plan defines preferred, or commonly used, surgical workflows and registration steps.

You can make changes to a procedure plan before beginning a procedure, and if desired, save your changes for subsequent procedures.

How to Create a Procedure Plan

Steps		See
1.	Select patient position (**Supine** or **Lateral**).	Page 66
2.	Select the implants you will use.	Page 67
3.	Select the workflow (workflow selection is limited by the selected implants).	Page 64
4.	Select optional navigation steps.	Page 69
5.	Select instruments.	Page 70

3.4 Procedure Plan Setup

3.4.1 Workflow Selection

General Information

Some of the following procedure planning steps may not apply to your procedure, depending on your selected implants, registration method and workflow. The dialogs that are not applicable to your procedure are skipped.

After completing a procedure planning step, the software opens the dialog for the next step.

Surgical Workflows

Your implant choice determines which procedures are available. Explanations of the registration, planning and navigation workflows associated with these selections are given in the following chapters.

Brainlab hip supports the following surgical workflows:

- THR Procedures
  - Cup and Stem
  - Cup Only
  - Express Leg Situation
- SR Procedures
  - Head Only

Be sure that before you select a workflow you are familiar with all applicable registration and navigation steps. Failure to do so may result in incorrect implant placement and patient injury.

How to Select a Workflow
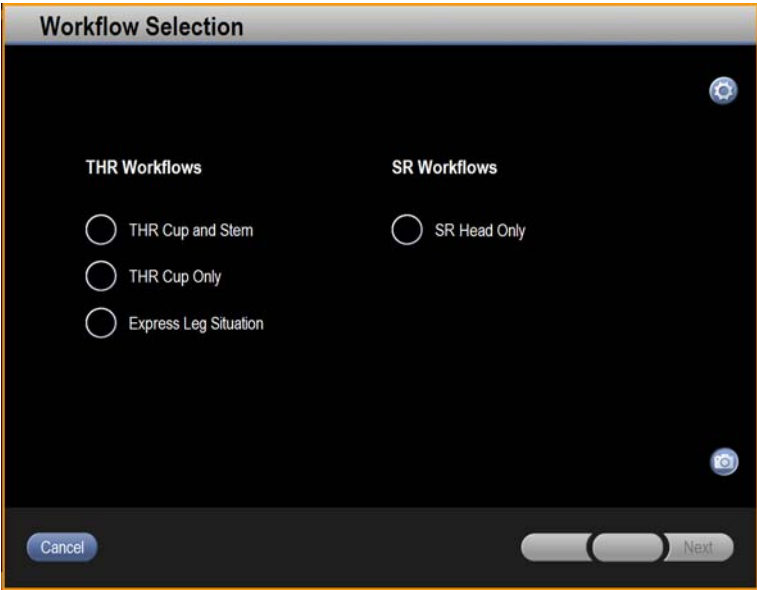
Figure 26

Steps
1.   Select the surgical workflow you wish to use for this procedure.
2.   Press **Next** to continue.

3.4.2 Patient Position

General Information

In this step you select the position the patient will be in during surgery.

How to Select Patient Position
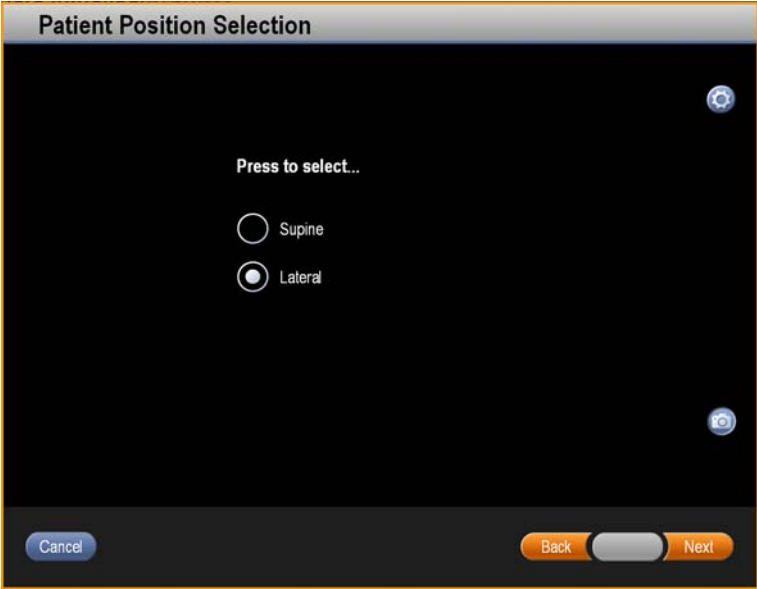
Figure 27

Steps
1.   Select the position (**Supine** or **Lateral**) that the patient will be in during surgery.
2.   Press **Next**.

3.4.3   Implants Selection

General Information

On this dialog you select:

- The implant product line
- The implant system components
- The component attributes

NOTE: Once a bone has been registered, you can also change or modify the implants via the **Menu** *(see page 43).*

⚠

Be sure that the implants you select are the implants you will actually use. The verification values provided after implant insertion are calculated based on the selected implants, and will otherwise be inaccurate.

⚠

Make sure that the individual implant components are compatible and fit appropriately with each other. An incorrect combination of implant components could result in severe patient injury.

Available Implants

All implants authorized by your license can be accessed through the **Implants** dialog.

NOTE: If you have any questions regarding access to implants that are not in your license, contact Brainlab support.

How to Select Implants
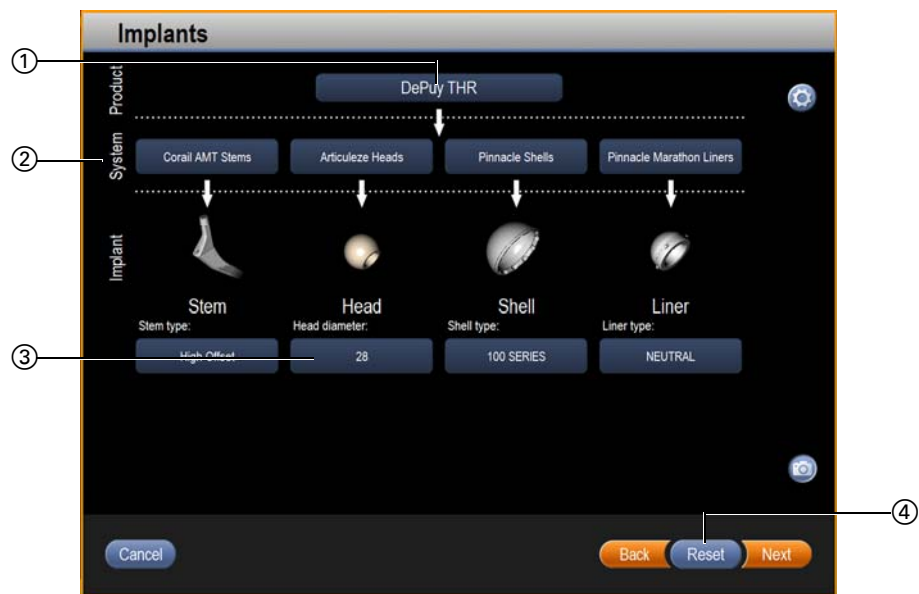
Figure 28

Steps	
1.	Ensure that the product line ① and implant systems ② are correct.
	To make adjustments, press the relevant button and select correct implant.
2.	Ensure that the implant component attributes ③ are correct.
	To make adjustments, press the relevant button and make necessary changes.
3.	• To proceed with the selected implants, press **Next**.
	• To reset the implants and attributes to the initial selections, press **Reset** ④.

3.4.4 Optional Navigation Steps Selection

General Information

In the **Optional Navigation Steps** dialog you select the surgical steps for which you wish to use computer-aided navigation. Only steps that are optional and compatible with the procedure appear here.

The options available depend on the selected registration workflow, implants and patient position.

How to Select Optional Navigation Steps
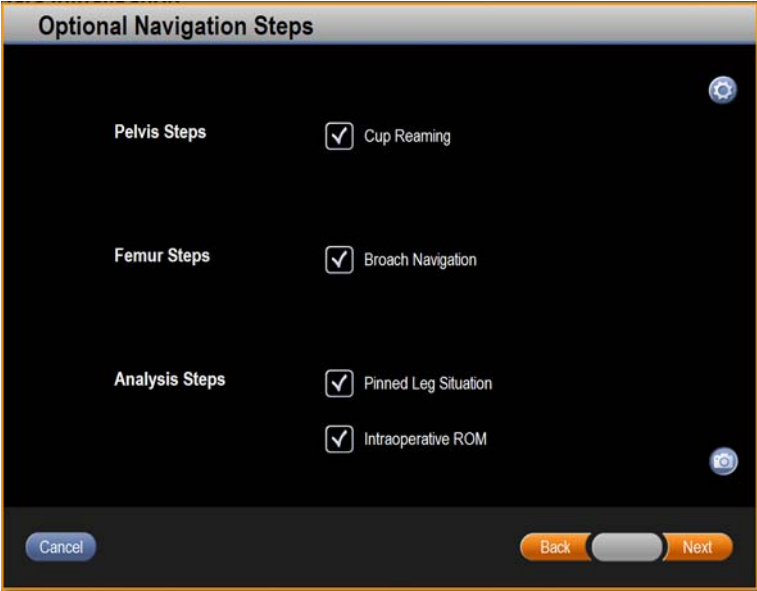
Figure 29

Steps
1.   Press the check box for all steps for which you wish to use computer-aided navigation.
2.   Press **Next** to continue.

Optional Steps Depending on Workflow

	THR	SR
Pelvis steps	Cup Reaming	
Femur steps	Broach Navigation	Implant Verification
	Final Implant Verification	
Analysis steps	Pin-Based Leg Situation	
	Pinless Leg Situation	
	Intraoperative ROM	

NOTE: Not all of the above options may appear. Selected workflow, implants and patient position affect which optionally navigation steps are available.

3.4.5 Instruments Selection

General Information

The **Instruments** screen displays instruments that are compatible with the currently selected implants and workflow.

It is not required to select instruments in this dialog, however, you can save time by selecting and verifying instruments before starting navigation. Otherwise the corresponding instrument selection dialog will open directly before starting each navigation step.

Instruments may later be selected, changed or modified via the **Menu** (see page 43).

NOTE: The selected implants and workflow determine which instruments to select. In some cases, certain steps discussed in this section are not applicable.

Verifying Instruments

Via the **Instruments** screen, you are able to select instruments for verification:

- Broach axis of the broach handle
- Drill guide length, using a pointer (SR workflows)
- Cup inserter tool tip with mounted cup implant, using pointer

For more information on verification of precalibrated instruments, see page 143.

Screen Layout
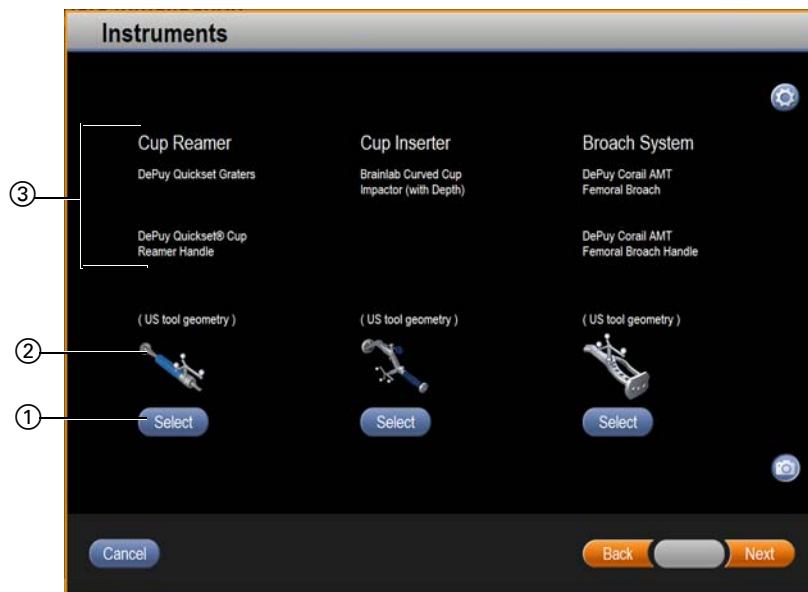
Figure 30

No.	Component
①	Select button: Opens dialog for selecting/exchanging instruments
②	Image of selected instrument
③	Information on the selected instrument

**How to Select Cup
Reamer and Handle**
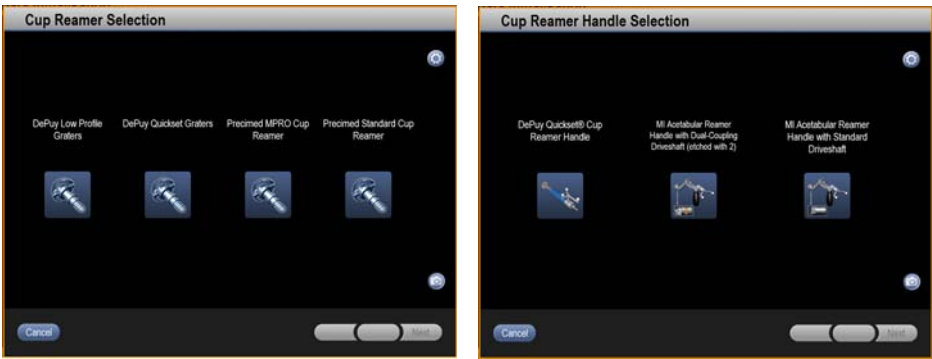
Figure 31

Steps	
1.	Under **Cup Reamer** on the **Instruments** dialog, press **Select**.
2.	In the **Cup Reamer Selection** dialog, press the icon for the desired cup reamer head.
3.	If the **Cup Reamer Handle Selection** dialog opens, press the icon for the desired cup reamer handle.
	The **Instruments** dialog reopens and displays the selected cup reamer.

**Cup Reamer
Calibration**

All cup reamers and handles supported by **Brainlab hip** are precalibrated with a specific adapter.

During calibration you are therefore only required to select a reamer head, and in certain cases, a reamer handle, before confirming the calibration.

How to Select the Cup Inserter
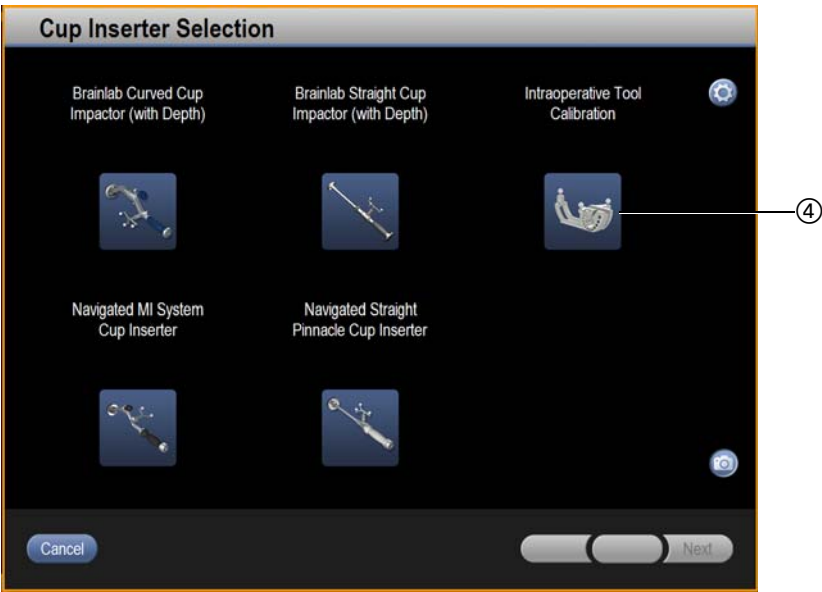
Figure 32

Steps
1.   Under **Cup Inserter** on the **Instruments** dialog, press **Select**.
2.   In the **Cup Inserter Selection** dialog, press the icon for the desired cup inserter. The **Instruments** dialog reopens and displays the selected cup inserter.

*NOTE: During cup inserter selection, you may opt to perform manual calibration with the **ICM4** ①. For more information on calibration, see page 142.*

How to Select the Broach Handle
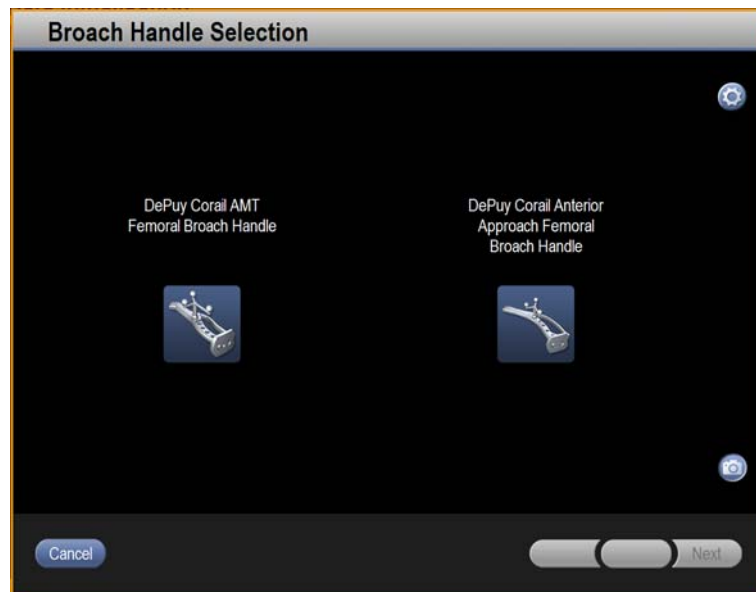
Figure 33

Steps
1.   Under **Broach System** on the **Instruments** dialog, press **Select**.
2.   If prompted, select desired broach handle.

NOTE: The broach approach is detected by the software as soon as the broach becomes visible to the camera and is brought in close proximity to the proximal femoral shaft axis.

How to Select the Drill Guide

Figure 34

Steps
1.   Under **Drill Guide** on the **Instruments** dialog, press **Select**.
2.   In the **Drill Guide Selection** dialog, press the icon for the desired **Drill Guide**. The **Instruments** dialog reopens and displays the selected **Drill Guide**.

3.4.6 Acetabular Rim Points

General Information

If prompted, you can chose to acquire the acetabular rim points during registration.

These points help morph the bone model. They are also shown during cup planning to give you additional points of reference to orient the implant.

If rim points are not acquired during pelvis registration, the bone model may not necessarily correspond to actual patient anatomy with respect to the acetabular rim.

How to Select Whether to Acquire Rim Points
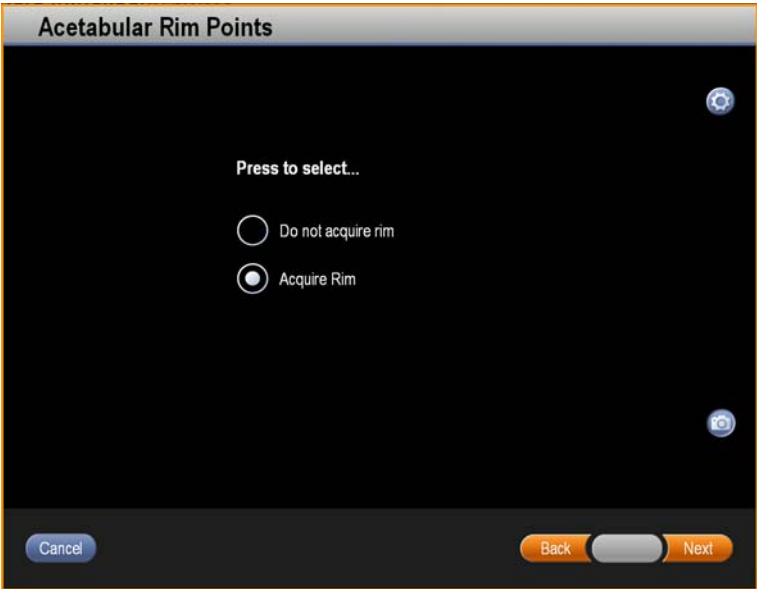
Figure 35

Steps	
1.	Select whether you will acquire points on the acetabular rim (**Acquire Rim**) or not (**Do not acquire rim**).
2.	Press **Next**.

3.4.7   Acetabular Orientation

**General
Information**

If prompted, select the method by which the software calculates acetabular orientation:

Acetabular Orientation	Angle Calculations
Operative Definition	• Cup anteversion is calculated as the angle between the longitudinal axis and the acetabular axis, as projected onto the sagittal plane. • Cup inclination is calculated as the angle between the acetabular axis and the sagittal plane.
Anatomical Definition	• Cup anteversion is calculated as the angle between the transverse axis and the acetabular axis, as projected onto the transverse plane. • Cup inclination is calculated as the angle between the acetabular axis and the longitudinal axis.
Radiographic Definition	• Cup anteversion is calculated as the angle between the acetabular axis and the coronal plane. • Cup inclination is calculated as the angle between the longitudinal axis and the acetabular axis, as projected onto the coronal plane.

**How to Select the
Acetabular
Orientation
Definition**
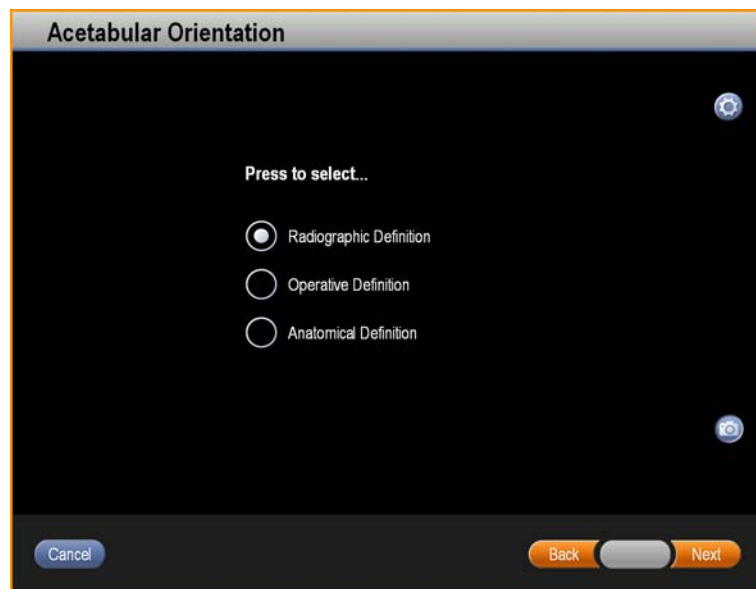
Figure 36

Steps
1.   Select the definition you wish to use to calculate acetabular orientation.
2.   Press **Next**.

3.4.8 Selecting Pelvic Tilt Adjustment

General Information

Pelvic tilt is an optional feature that must be enabled by Brainlab support. Contact Brainlab support for more information.

Entering a pelvic tilt value does not affect the registration result. In addition, standard cup orientation values displayed during planning and navigation are not affected. The both of the below values displayed simultaneously:

- Standard cup orientation angles according to the anterior pelvic plane.
- Cup orientation angles in reference to the frontal body plane, as defined by the selected pelvic tilt.
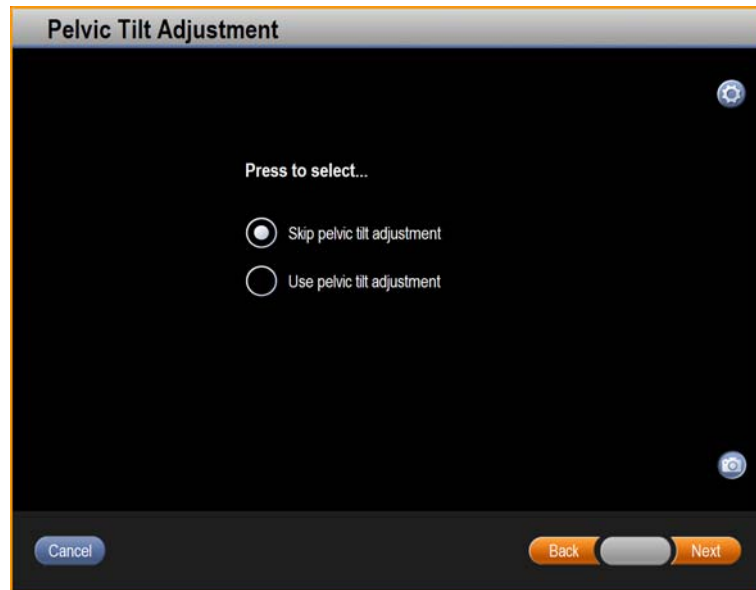
Figure 37

For more information on pelvic tilt, see page 57, page 99 and page 183.

3.4.9 Femoral Antetorsion Reference

General Information

If prompted, select the method by which the software calculates the femoral antetorsion angle. The steps of the registration workflow vary, depending on your choice.

Method	Registration Steps
Epicondyles	• Acquire medial and lateral epicondyle points. • Acquire piriformis fossa. The software uses the epicondyle points to define the epicondylar axis and its midpoint.
AEP (Ankle, Epicondyles, Piriformis Fossa)	• Acquire medial and lateral epicondyle points. • Acquire mid-ankle point (mid-point of the anterior ankle). • Acquire piriformis fossa. The software uses these points to calculate a sagittal reference plane, which is used in the calculation of antetorsion.

How to Select the Femoral Antetorsion Reference
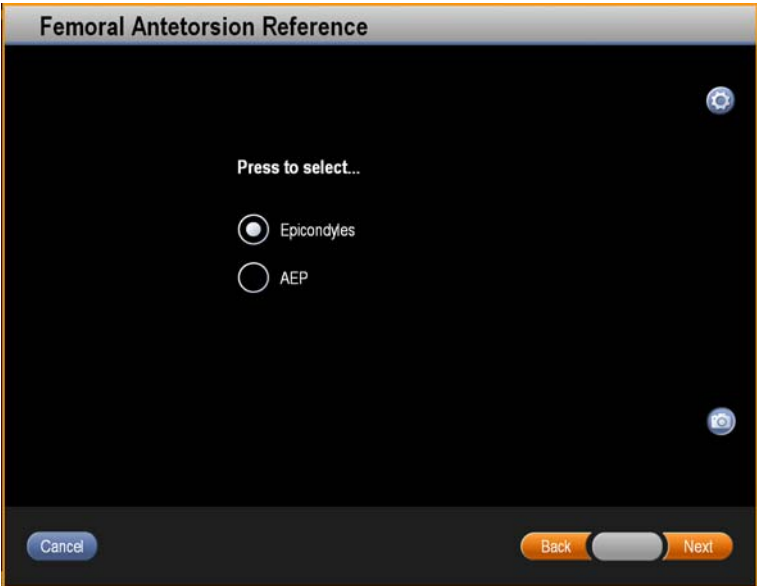
Figure 38

Steps	
1.	Select the femoral antetorsion reference wish to use to calculate the femoral antetorsion angle.
2.	Press **Next**.

3.4.10   Navigation Threshold

General Information

In this step you set ranges around the implant orientation angles, within which you want to stay when navigating an instrument.

During navigation, if the angle of the instrument is outside of the desired threshold range, the corresponding angle meter on the navigation screen turns red as a visual warning.

How to Select the Navigation Threshold
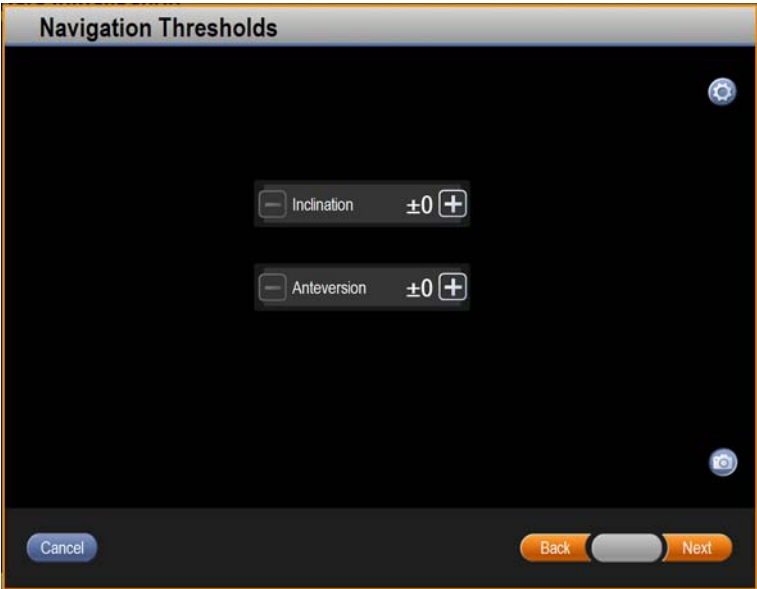
Figure 39

Steps
1.   Use the **+**/**-** buttons to set the thresholds for each angle.
2.   Press **Next**.

3.4.11 Reviewing the Procedure Plan

Reviewing the Procedure Plan

Once you have selected a plan or created a new one, the **Procedure Overview** screen opens. Review the settings selected for the procedure.

Figure 40

Options
To modify procedure plan, press **Modify**.
To use procedure plan as it is, press **Next**.

3.4.12 Modifying a Procedure Plan

General Information

You can modify a procedure plan at any time prior to starting registration. You can make modifications in a plan just for one use, or save your modifications for use in subsequent procedures.

If you save modifications that you make, you overwrite the procedure plan.

NOTE: It is not possible to rename a procedure plan. If you wish to give a procedure plan a new name, you must create a new procedure plan with that name.

How to Modify a Procedure Plan
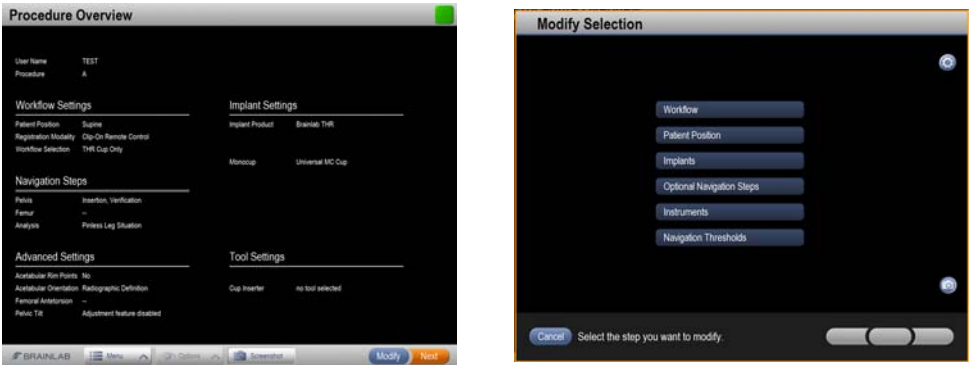
Figure 41

Steps	
1.	On the **Procedure Overview** screen, press **Modify**. The **Modify Selection** dialog opens.
2.	Press the button for the topmost planning step that you wish to change.
3.	In each dialog that opens, make the modifications you wish, then press **Next** or **Accept** to proceed.

4 SURGERY SETUP

4.1 Chapter Overview

4.1.1 Contents

Topics Covered

Section	See
System Setup	Page 84
Using Reference Arrays	Page 87
Software Surgery Setup	Page 95

4.2   System Setup

4.2.1   Operating Room Setup

Before You Begin   The information given here is in preparation for surgery. If you are only doing preoperative planning, it is not necessary to perform these steps.

A descriptive video is shown in the software to demonstrate the recommended OR setup for your procedure.

General Information   The exact OR setup varies depending on the patient position and navigation platform.

Regardless of which platform is used:

- The camera and monitor should not restrict the work of the surgeon.
- The camera should have a clear view of the reference arrays during all registration and navigation steps.

Example OR Setup - Lateral Position   Possible OR setup for surgeries with the patient in the lateral position, for systems with a separate camera:
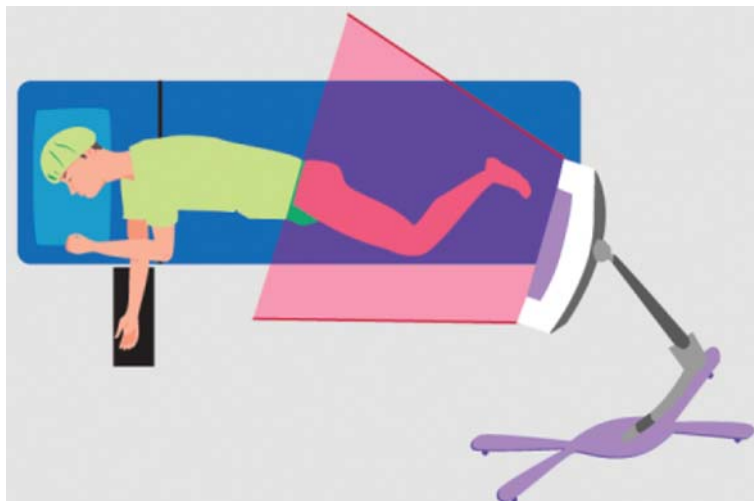
Figure 42

Patient Position	Camera Position	Camera Direction
Lateral	Foot of Table	Ventral to dorsal
	Head of Table	

NOTE: Alternatively, the camera may be positioned at the side of the table, facing the dorsal to ventral or ventral to dorsal direction.

Lateral Patient Position Consideration   When performing a procedure in lateral position, the most caudal spinous process (L5) must be accessible to the surgeon, and must be contained within the sterile field. The software contains a descriptive video to aid with proper set up to allow for registration of the L5 vertebra.

Example OR Setup - Supine Position

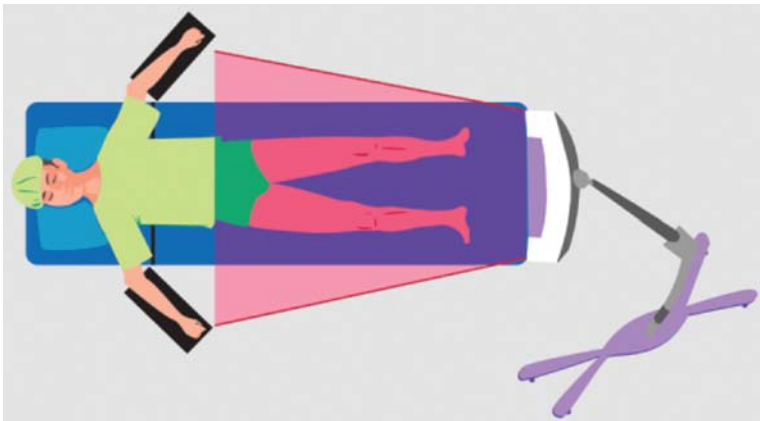Possible OR setup for surgeries with the patient in the supine position, for systems with a separate camera:

Figure 43

Patient Position	Camera Position	Camera Direction
Supine	Foot of Table	Treated side to non-treated side
		Non-treated side to treated side

4.2.2 General Hardware Setup

How to Set Up the Camera

Steps	
1.	Position camera approximately 2 m (6.5 ft) from the surgical field in a position appropriate for the registration modality.
2.	Drape camera handle to allow for intraoperative camera adjustment.
3.	Adjust camera so that the lenses have an unobstructed view of all reference arrays in the surgical field. After software start up, use the software to verify that the camera detects all arrays.

⚠

Camera lenses must have an unobstructed view of the reflective marker spheres on patient reference arrays and active instruments at all times during registration and navigation.

How to Set Up the Monitor

Step
Place the monitor in a position convenient for and accessible by the surgeon.

*NOTE: For information on sterile touchscreen use, see the relevant **System User Guide**.*

How to Position Footswitch

Steps	
1.	Position footswitch under the operating table in a location convenient for and accessible by the surgeon.
2.	Verify that cable connection between footswitch and the system is secure and does not interfere with movement or positioning of other surgical devices.

NOTE: The software provides no warning of footswitch connection failure, however the footswitch-controlled buttons do not appear highlighted (see page 41).

MR Safety   For information on MR safety, see your **System User Guide.**

Next Step   Once the above steps are complete, plug in and turn on the system.

4.3   Using Reference Arrays

4.3.1   Overview

Handling Reference Arrays   For detailed information on reference arrays and marker spheres, see the **Instrument User Guide.**

⚠

Reference arrays are sensitive medical devices. Handle them gently.

⚠

Do not apply any force or torque to a reference array, especially once it is attached to the patient.

⚠

There is the potential that reference arrays may loosen during steps with high impact, such as hammering during cup insertion or broaching. It is recommended to remove the reference array using the quick fastener (see page 89) before performing these steps and then reattach for the verification of tool position. Additionally, it is recommended to check the stability of the reference arrays after performing steps with high impact.

When to Attach Reference Arrays   A reference array must be attached to a bone before the bone can be registered.

- Attach the pelvis reference array before setting up the camera. This allows you to check that the position of the array is appropriate before starting registration.
- Attach the femur reference array before any registration step that requires the array.
  - If registration and navigation of the surgical procedure will both be with the patient in the supine position, the femur reference array may be attached any time after a sterile field has been established.

Using Correct Reference Array Geometry   The software identifies the bone by the geometry of the attached reference array.

- The **Y** geometry reference array tracks the femur.
- The **T** geometry reference array tracks the pelvis.

⚠

Make sure to only attach the Y geometry reference array to the femur and the T geometry reference array to the pelvis. Movement of the leg during the procedure must be taken into consideration when attaching the reference arrays to the relevant bone structure.

Non-invasive Pinless Femur Reference Array   The **Pinless Femur Reference Array** has a unique asymmetrical **Y** geometry ("SMS geometry") It is designed to eliminate the need for inserting fixation pins into the femur, and can be used in various procedures.

Optional in the following workflows (if pinless leg situation is selected):

- THR Cup and Stem
- THR Cup Only

Required in:

- Express Leg Situation

Optimizing Reference Array Position	Ensure that the camera views the pelvis and femur reference arrays positioned side by side and neither blocks the camera's view of the other. Adjust camera to ensure reference array visibility at all times during the procedure and in all relevant OR positions. Use **Surgery Setup** dialog to ensure that reference array geometries do not overlap (see page 35).

Position the camera in such a way that all active patient reference arrays can be clearly seen by the camera lenses. Reference arrays must be visible to the camera lenses at all times that tracking is necessary.

Ensuring Sufficient Operating Space	

Make sure that the position of the reference arrays will not hinder the surgeon's work, before attaching them to the relevant bone structure.

Take the size of the implants and the surgical instruments into account when placing the reference arrays. Sufficient space should be available to enable incision, implant positioning, and reaming or drilling without moving the reference arrays. If these is a collision with a reference array during implantation, navigation will be inaccurate.

Marker Sphere Visibility	Reflective marker spheres must be securely affixed to instruments and reference arrays.

To ensure visibility, use only clean, dry marker spheres. Marker spheres are for one-time use only.

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

Reflection Artifacts	

Artifacts caused by reflections - especially during registration - can cause inaccuracy. Make sure that light sources or items which are highly reflective do not affect the camera field of view.

Movement of Reference Arrays

If a reference array moves during surgery relative to the referenced bone structure, reattach the array. You must then re-register the bone.

⚠

Do not move the reference array relative to the patient's anatomy during the procedure otherwise reference to the bone is lost. Any movement may affect the entire measurement coordinate system, leading to incorrect instrument display and injury to the patient.

⚠

All reference array screws must be tightly secured before patient registration.

⚠

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

Removal of Reference Array with Quick Fastener
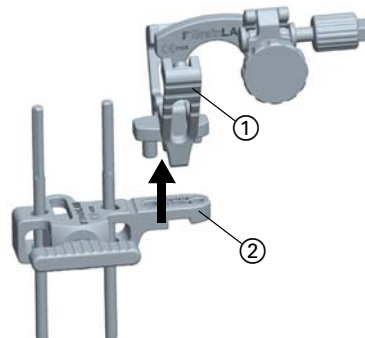
Figure 44

Steps
1.   Maintaining sterility, remove reference array from its bone fixator by pinching the sides of the quick-fastener clamp ① together and lifting the array free from the attachment block ②. *NOTE: Take care not to dislodge the fixation pins.*
2.   Place the array in a safe place where it will remain sterile.

⚠

When removing the reference array, do not open the adjustment screws. Otherwise, the angle of the array will be different when you reattach it later. This would result in inaccurate registration and navigation, and could lead to severe patient injury.

4.3.2   Pelvis Reference Array Positioning

General Information

The pelvis reference array may be attached either:

- To the iliac crest (recommended), or
- Laterally above the acetabular edge of the hip joint to be treated

It is easier to achieve a good line of sight if the reference array is positioned on the iliac crest. In this case the **"2-Pin", X-Press** reference array kit is generally used. For this the surgeon makes an extra incision.

How to Attach the Array ("2-pin", X-Press): Steps 1-6

Figure 45

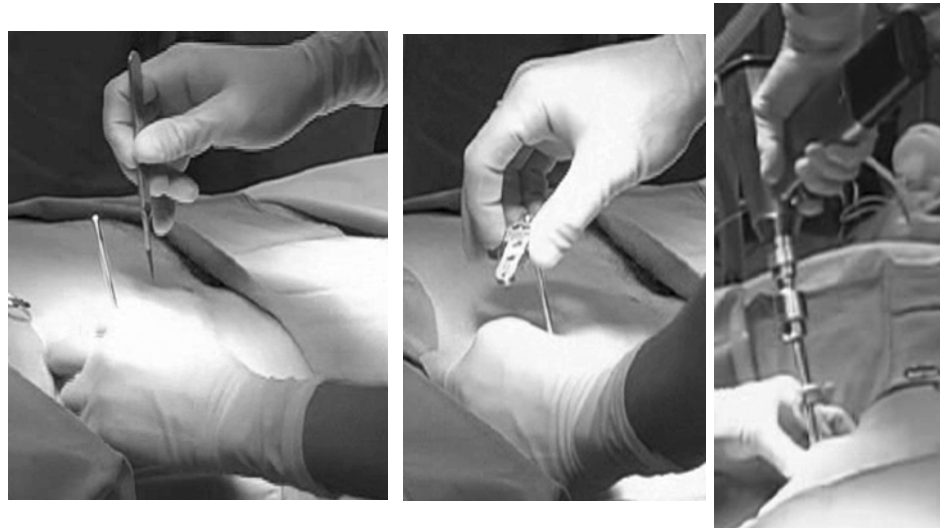| Steps	
1.	Place the patient in a lateral position, treatment side up on the operating table.
2.	Affix anterior and posterior patient positioners, ensuring that the L5 vertebra is accessible.
	A point must be acquired on the L5 vertebra, so the surgeon must have access to it.
3.	Prepare the skin over the treated side hip for sterile placement of the pelvis reference array.
4.	Make a small stab incision.
5.	Set an automatic drill to a low speed and drill a small hole through the stab incision so that the fixation pin for the reference array can be conveniently positioned.
6.	Insert fixation pin according to the usual procedure.
	NOTE: Fixation pins should not be placed near the ASIS point, as this point is required for registration.

Steps 7-11

Figure 46

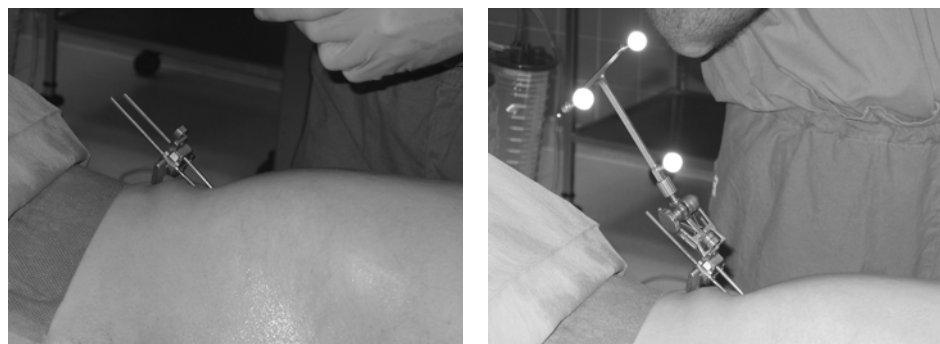| Steps	
7.	Make a second incision for the second fixation pin.
8.	To ensure accurate insertion of the second fixation pin, attach the drill template provided with the **MI Reference Array Kit Hip, X-Press** to the first fixation pin.
9.	Drill a hole for the second fixation pin and insert it.
10.	Attach the bone fixator and secure it with the fixation screw.

Figure 47

Step	
11.	Attach pelvis reference array. Remember that the reference array must be visible to the cameras in both the supine and lateral position.
	If applicable, use camera field of view to avoid problems during acquisition of L5.

**Attachment Beside
the Acetabulum**

Figure 48

If you attach the pelvis reference array above the acetabular edge, it is important to angle the Schanz screw away from the acetabulum so that the reamer will not hit the screw.

The bone fixator should be positioned at an angle so that the femur does not obstruct the visibility of the array in deep flexion. In general, the array should be angled in the medial direction (towards the mid-line) and towards the camera for better visibility.

*NOTE: Do not attach the **Bone Fixator "2-Pin", X-Press** to the acetabulum.*

4.3.3 Femur Reference Array Positioning

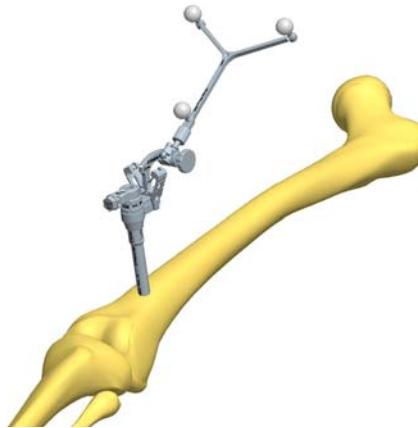**Positioning Femur
Reference Array for
THR Procedures**

Figure 49

For pin-based THR procedures, attach the femur reference array to the distal femur. Exact position may vary depending on your dislocation (luxation) method and camera position. Consider these factors and the space required for the surgical procedure before attaching the array.

Femoral luxation requires the femur to be put in flexion, adduction, and internal rotation. Therefore, depending on the operating position (supine or lateral), the optimal orientation of the femur reference array varies.

- Supine position: tilt femur reference array in the medial direction and toward the camera.
- Lateral position: tilt femur reference array in the lateral direction and slightly toward the camera.

**Positioning Femur
Reference Array for
SR Procedures**

Figure 50

Position the bone fixator on the lesser trochanter or trochanteric ridge.

Attach the femur reference array to the bone fixator and use the adjustment screws to angle the array so that it will be visible to the camera both before and after luxation.

How to Position Pinless Femur Reference Array	The **Pinless Femur Reference Array** (SMS geometry) is used for THR Cup Only and THR Cup and Stem procedures in which you perform pinless leg situation analysis, and is required for the Express Leg Situation workflow.

The array is attached differently depending on patient position:

- Lateral position: Array is attached laterally on the femur (as shown below).
- Supine position: Array is attached on the anterior femur.

Regardless of position, the **Pinless Femur Reference Array** must be attached as far distally as possible on the treated side femur.
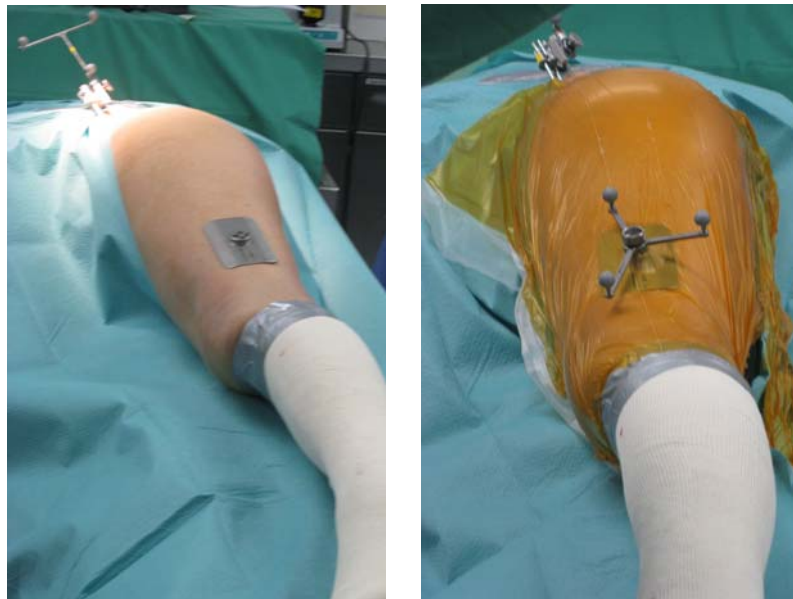

Figure 51

Steps	
1.	Position the plate of the **Pinless Femur Reference Array** as far distally as possible on the treated side femur, ensuring there is a solid base on the leg.
2.	Use a standard sterile adhesive drape to affix the femur plate firmly to the leg.
3.	Once plate is securely affixed to the leg, use the sharp tip of the array to puncture the drape and attach reference array to the plate.

More Information   For more information on reference arrays, see your **Instrument User Guide**.

4.4 Software Surgery Setup

4.4.1 Overview

General Information

The **Surgery Setup** steps in the software are specific to the surgery you are about to perform. They cannot be saved as part of a procedure plan.

⚠

Before beginning any procedure, make sure you are familiar with the correct handling of all required Brainlab instruments and accessories.

Software Surgery Setup Steps

The software prompts you to perform certain steps specific to the surgery, which cannot be saved to a procedure plan. Before you start registration, you must:

- Enter the patient's information
- Identify the treatment side to the software
- Check the camera setup for the procedure

4.4.2 Patient Information

General Information

The patient name and ID that you enter here appear on the therapy report and on all main screens.

How to Enter Patient Information

Figure 52

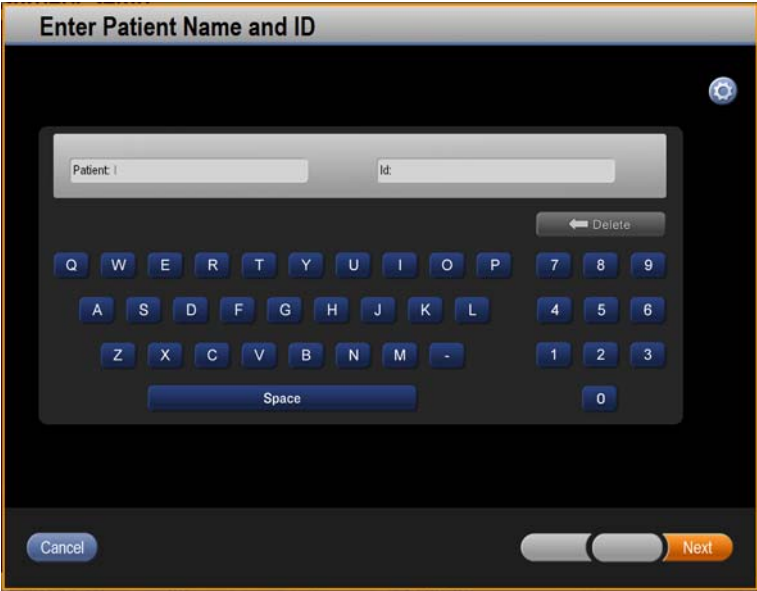| Steps |
|---|
| 1. Enter patient's name by pressing the keys on the virtual keyboard. |
| 2. Press the **ID** field and enter the patient's ID by pressing keys on the virtual keyboard. |
| 3. Press **Accept**. |

*NOTE: If you have started the software via **Patient Data Manager** with a loaded patient, the patient name and ID are already entered and this dialog is skipped.*

SURGERY SETUP

4.4.3 Additional Patient Data

General Information

You must identify the treatment side and patient gender. After the selections are made, you may not change it without restarting the program.

How to Select Treatment Side and Patient Gender

Figure 53
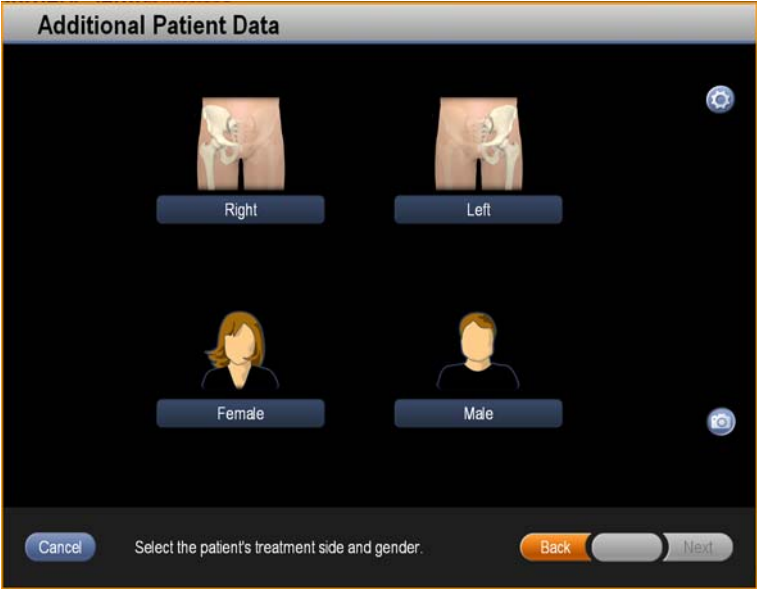
Steps
1.   Select treatment side.
2.   Select patient gender.
3.   Press **Next**.

*NOTE: If you have started the software via **Patient Data Manager** with a loaded patient, the gender is pre-selected by the software and cannot be changed.*

How to Enter ASIS-to-ASIS Distance

Figure 54

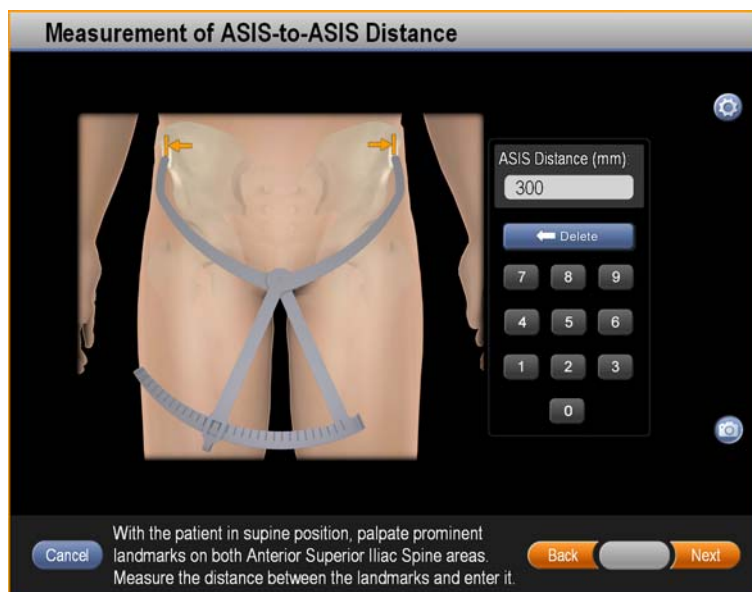| Steps	
1.	Use the number buttons on the screen to enter the distance (in mm). *NOTE: Only the relevant numbers are enabled on the number pad. A limitation is built in to the software so that impossibly high numbers cannot be entered.*
2.	Press **Next**.

*NOTE: If needed, it is possible to change the ASIS-to-ASIS distance before starting surgery from the **Surgery Setup** screen (see page 100).*

How to Enter Pelvic Tilt
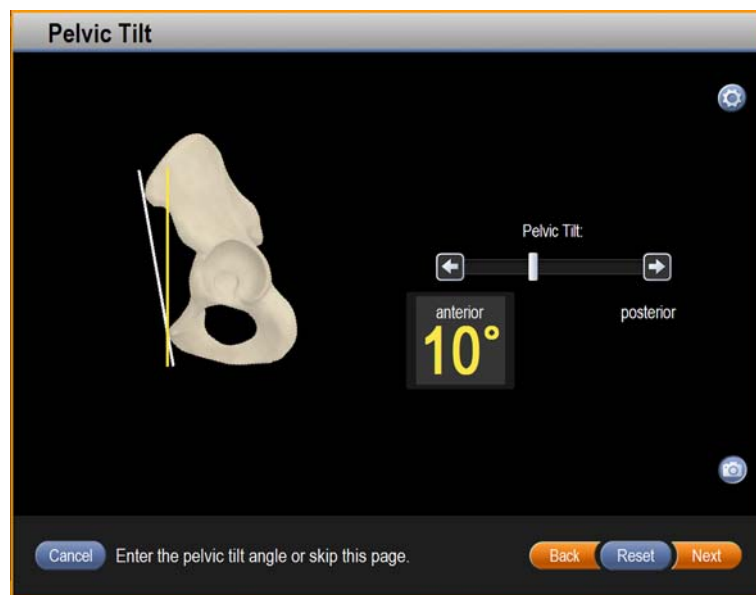
Figure 55

Options
Press the **anterior** or **posterior** arrow button to enter the desired degree of pelvic tilt.
To proceed without entering a pelvic tilt, press **Skip**.
Press **Reset** to discard entered pelvic tilt. The enables the **Skip** button.

*NOTE: If needed, it is possible to change the pelvic tilt angle before starting surgery from the **Surgery Setup** screen. For more information on the pelvic tilt feature, see page 57, page 77 and page 183.*

4.4.4　Surgery Setup Screen

How to Complete Surgery Setup

The **Setup Surgery** is the last screen before proceeding to surgery.

- When **Camera Setup** is selected, you can verify that the reference arrays are visible to the camera (see page 35).
- When **Patient Setup** is selected, a video of correct reference array positioning is shown.

Before pressing **Next** to proceed, ensure that the information you have entered is correct and that reference arrays are correctly attached.
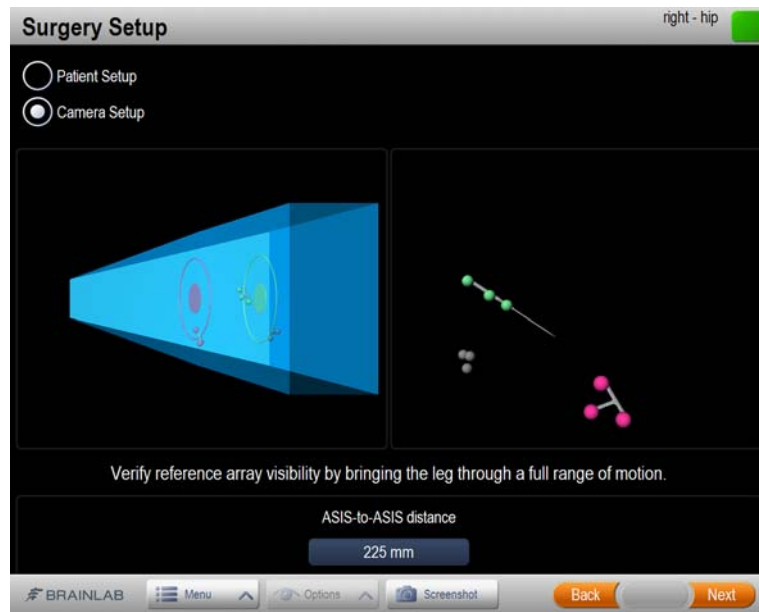

Figure 56

Software User Guide Rev. 1.1 Brainlab hip Ver. 6.0 - US Version

5 REGISTRATION

5.1 Chapter Overview

5.1.1 Contents

Topics Covered

5.2   Using Pointers in Registration

5.2.1   Overview

General Information

Registration is the process by which you match the virtual position and 3D representation of a patient's bone in the software to the actual position of the patient's anatomy.

This enables the software to provide navigational information during surgery.

Pointer-based Registration

In pointer-based registration, you use a calibrated pointer to acquire (register) landmarks and bone surfaces on the patient's femur and/or pelvis.

The software uses the acquired points to morph a 3D bone model of the corresponding bone that matches the patient's anatomy.

Pointer-based registration may entail:

- Pivoting the pointer or using the **Clip-on Remote Control** on specific landmarks on the bone.
- Sliding the tip of the pointer over bone surfaces.

Additional registration steps that does not require a pointer is aligning the leg, allowing the software to register the relative positions of the pelvis and femur.

⚠

Set registration points as accurately as possible. Otherwise, planning and navigation will be inaccurate.

Supported Pointers

The following pointers can be used to acquire and verify registration points:

- **Pointer Extended with Sharp Tip**
- **Pointer Extended**
- **Pointer Angled**
- **Pointer Reverse Angled**
- **Pointer Square Angled** (for hip resurfacing procedures)
- **Pointer Straight Extended**

⚠

The Pointer Angled, Pointer Reverse Angled and Pointer Square Angled have the same marker sphere geometry. Because the software is unable to distinguish between these pointers, ensure that they are not in the camera field of view simultaneously.

Handling Pointers

The accuracy of patient registration depends on the precision and accuracy of pointer calibration.

*NOTE: For more information on handling pointers, see your **Instrument User Guide** and **Cleaning, Disinfection and Sterilization Guide**.*

Standard Pointer Registration

In standard pointer registration, you pivot a calibrated pointer to acquire (register) specific landmarks on the patient's bone.

Figure 57

Step
Hold pointer tip to the landmark indicated and pivot the pointer slightly around its tip.
• If tip moves during pivoting, the point is not acquired.   • When a point is acquired, the software indicates the next point to acquire, or opens the next step.

Registration Using the Clip-on Remote Control

The **Clip-on Remote Control** enables active patient registration in combination with a calibrated pointer. For more information on the software control functions, see page 40.
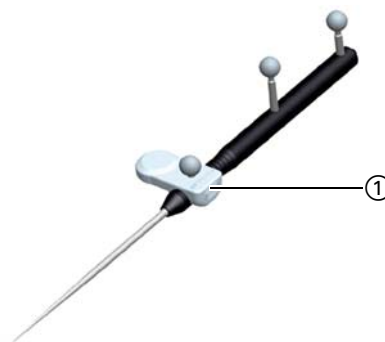

Figure 58

Steps	
1.	Hold pointer tip to the landmark indicated.
2.	Press the control button ①. • If tip moves when you press the button, the point is not acquired. • When a point is acquired, the software indicates the next point to acquire, or opens the next step.

5.2.2 Pointer Registration of Bone Surfaces

General Information

Pointers are also used to register bone surfaces.

The region on the bone where points are to be acquired is highlighted in green, and a progress bar indicates the status of completion of acquisition.

The software only registers points that are a certain distance from other points, i.e.:

- 2 mm for points acquired in the acetabular fossa
- 5 mm for points acquired in the acetabular cavity
- 1.5 mm for points acquired on the femoral head and neck (SR procedures)

Pausing Point Acquisition

If you are using the **Clip-on Remote Control** in surface registration dialogs, you may pause acquisition of the area by pressing the control button.

Undoing Point Acquisition

You may repeat acquisition of the area by pressing **Again**.
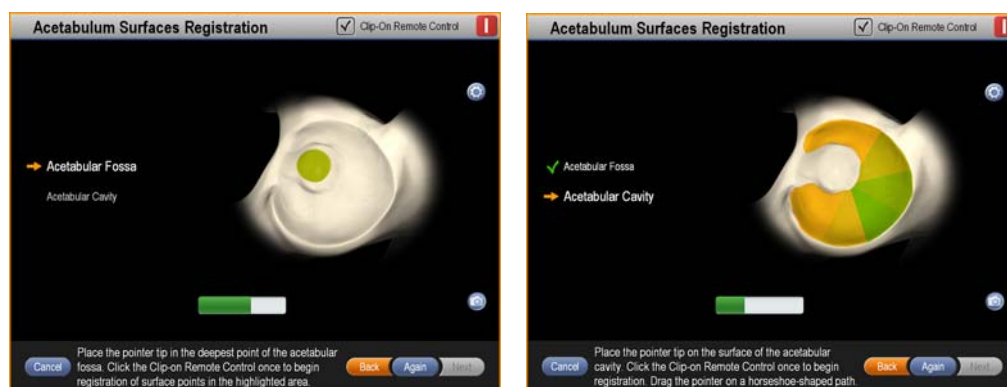
How to Register Bone Surfaces

Figure 59

Steps
1. Hold pointer tip steady on the bone within the highlighted region. Pivot pointer slightly or press the control button of the **Clip-on Remote Control** to start acquisition.
2. Slide pointer tip over the bone surface within the green area until the progress bar is complete.   Cover as wide an area as possible within the highlighted region. Recommended techniques are to move outward in a spiral, or to make an "S" shape back and forth across the area.

Considerations During Bone Surface Registration

⚠

When acquiring points on bone surfaces, be sure to acquire the points in as wide an area as possible. Otherwise, navigation could be inaccurate. For best results, acquire points on all sides of the cavity wall and so that the entire area is green in the software.

⚠

Make sure that the pointer tip stays on the bone during surface area acquisition. If the pointer tip leaves the bone, points in the air may be acquired, reducing registration accuracy.

5.3 Registration Accuracy Check

5.3.1 Overview

General Information	Accuracy checks are a means to verify that the system is maintaining an accurate representation of the patient's bone structure. This is conducted through and the comparison of the points acquired during registration, to the patient's actual anatomy.
	In the registration accuracy check views, the following are represented:
	• Green dots: Acquired landmarks
	• Darker shaded or spotted areas: Acquired surfaces
	• Grey dots: Previously acquired points
	Further, this step allows you to check that the software has generated an accurate bone model representation of the patient's pelvis.
Accuracy Check in the Femur SR Workflow	A mandatory accuracy check appears in the Femur SR workflow.
	In all other workflows, accuracy checks can be performed on the planning/navigation screen, or via the **Go to...** menu (see page 106).
When to Check Registration Accuracy	You can check registration at any time. It is recommended to check registration accuracy:
	• At regular intervals during the procedure.
	• Any time when there is a possibility that a reference array has moved (i.e., if it has been jarred or has come loose).
	• If you have restored a registration session after an inadvertent system shutdown.

<div align="center">⚠</div>

Verify system accuracy by defining three anatomical landmarks before beginning the procedure, and compare the position shown on the navigation station to the actual position.

<div align="center">⚠</div>

If a reference array has changed position relative to the bone, do not try to reestablish the array's position using an accuracy check.

What To Do If Accuracy is Poor	If registration accuracy is poor or has worsened considerably, check that the reference arrays on the bone are secure and all clamps and nuts on the array and bone fixator are tight.
	If there are no contraindication for re-registration (see page 131), re-register the bone.

5.3.2 Checking Registration Accuracy

How to Check Accuracy

Steps	
1.	On any navigation or planning screen, hold the pointer tip to landmarks on the bone, (e.g., acquired points or landmarks made with an electric knife.)
2.	Verify that the location shown on the screen correlates with the actual pointer tip position.

How to Check Accuracy via the Go to... Menu
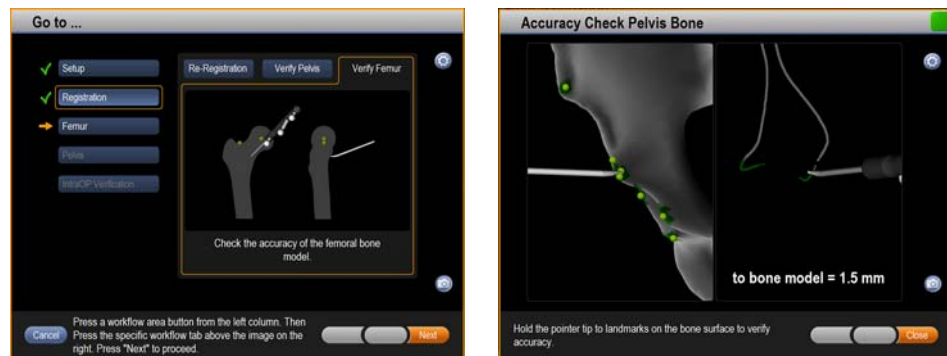
Figure 60

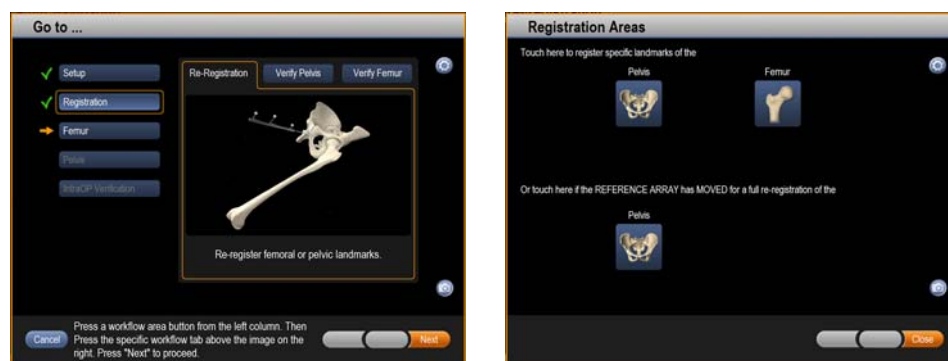| Steps	
1.	Press the **GOTO** button in the **Menu** to open the **Go to...** menu.
2.	In the **Go to...** menu, select **Registration**.
3.	Press **Verify Pelvis** or **Verify Femur** tab as needed.
4.	Press **Next** to open the **Accuracy Check Pelvis Bone/Femur Bone** dialog.
5.	Hold pointer tip to landmarks on the bone, and verify that the position of the pointer tip displayed on the screen correctly corresponds to the selected landmark. The distance between the pointer tip and the nearest acquired point is displayed.
6.	Press **Close** to return to the **Go to...** menu.

How to Re-Register

Figure 61

Steps	
1.	Press the **GOTO** button in the **Menu** to open the **Go to...** menu.
2.	Select **Registration**.
3.	In the preview area, select the **Re-Registration** tab.
4.	Press **Next** to open the **Registration Areas** dialog.
5.	Press the icon for the registration area you wish to re-register. The first registration area for that bone opens.
6.	• If you are re-registering a certain area, press **Next** until you reach the correct registration dialog. Once you have re-registered the area, the next dialog opens. • If you select to fully re-register a bone, all previously acquired points will be deleted and all areas must be re-registered. *NOTE: Re-registration of leg alignment is not possible.*
7.	Perform the step(s) on each dialog that opens. When re-registration of that area is complete, the **Accuracy Check** dialog opens.
8.	Verify the bone model accuracy and press **Next** to continue.

Next Step

Options
To register or re-register another area, use the **Go to...** menu and select the icon for that area.
If you are finished re-registering, press **Close** in the **Registration Areas** dialog.

5.4   Registration Workflows

5.4.1   Overview

General Information

The following registration workflows are available:

- THR procedures (see page 111):
  - Cup and Stem
  - Cup Only
  - Express Leg Situation
- SR procedures (see page 112):
  - Head only

Definitions

A "registration workflow" is a series of steps that you complete to register an area. The registration workflow varies depending on the procedure plan.

You cannot begin navigation on an unregistered bone.

NOTE: Some steps in the registration workflows are not part of any specific anatomical area for registration.

⚠

Set registration points as accurately as possible. Otherwise, planning and navigation will be inaccurate.

Possible Workflow Combinations

Workflow	Pelvis Reg. Method	Femur Reg. Method	Pin-based Leg Align.	Pinless Leg Align.	Acquire Acetab. Rim	Acquire Mid-Ankle Point
Cup and Stem	Standard	Femur Standard	Required	Not possible	Optional	
Cup Only	Standard	N/A	Optional			N/A
Head Only	N/A	Femur SR	Not possible			
Express Leg Situation	Standard Express Leg Situation Registration		N/A	Required	Not possible	

Initial Registration Workflow

When you start registration (by pressing **Next** after **Surgery Setup**), you enter the initial registration workflow. The software opens each consecutive registration step for all registration areas necessary for your procedure plan.
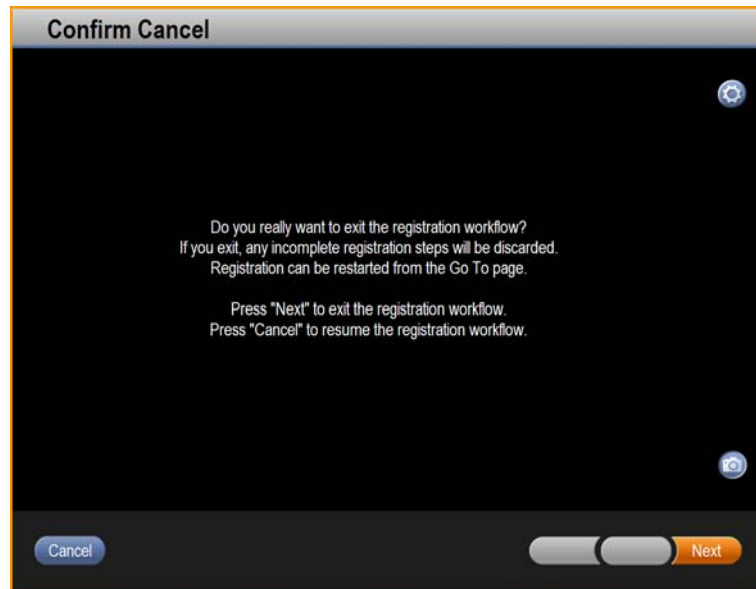
Exiting the Initial Workflow

Confirm Cancel

Do you really want to exit the registration workflow?
If you exit, any incomplete registration steps will be discarded.
Registration can be restarted from the Go To page.

Press "Next" to exit the registration workflow.
Press "Cancel" to resume the registration workflow.

Cancel

Next

Figure 62

To exit an incomplete registration workflow, press **Cancel** on the current page and then confirm by pressing **Next** on the **Confirm Cancel** dialog.

All registered points are discarded when you exit the workflow.

5.4.2 Anatomical Areas for Registration

Definition

An "anatomical area for registration" is a bone or bone region that must be registered in order to perform navigation. In some cases you must register multiple areas to complete the registration of a bone.

The areas for registration depend on the procedure plan.

If you follow the initial workflow, the software prompts you to complete all registration steps. If you exit the workflow, you will need to use the **Go to...** menu to access the registration steps that are incomplete.

Pelvis

To register the pelvis, you are prompted to acquire the following landmarks/areas:

- L5 spinous process (lateral position only)
- ASIS treated side
- ASIS non-treated side (supine position only)
- Inferior Peak of the Psoas Valley
- Acetabular fossa
- Acetabular cavity
- If your procedure plan includes the acetabular rim, acquire four additional acetabular rim points.

These points are used to size the bone model and calculate the frontal pelvic plane and the midsagittal plane, from which the initial cup implant orientation is calculated.

Acetabulum registration is essential to shape the pelvis bone model and determine the center of rotation (COR) of the hip joint.

Once you have acquired these points, the pelvis is registered and the pelvis bone model should be verified on the cup planning/navigation screen or via the **Go to... menu**.

Femur Registration in THR Procedures

To register the femur registration for THR procedures, acquire the following:

- Medial and lateral epicondyle points, used to calculate the midpoint of epicondylar axis
- Piriformis fossa
- Mid-ankle point (not in all workflows)

NOTE: To complete femur registration, you must also register the acetabulum. The center of the femoral head is calculated from the surface points you acquire in the acetabulum.

Femur Area in SR Procedures

To register the femur for SR procedures, you acquire points to define the COR of the femoral head, the neck axis, and the shaft axis.

- The center of the femoral head is calculated from the surface points acquired on the femoral head.
- The neck axis is calculated from the center of the femoral head and the acquired neck surface points.
- The shaft axis is calculated from the acquired lateral mid-neck point, and the midpoint of the acquired medial and lateral epicondyle points.

Leg Alignment

The leg alignment step:

- Is required for analysis of leg situation post-operatively.
- Is a required step in Cup and Stem and Express Leg Situation workflows.

NOTE: If you are re-entering a workflow that calls for leg alignment, you are prompted to re-register the leg alignment before continuing with registration.

5.4.3 THR Registration Workflows

Pelvic Registration Calculations The software uses the below workflows to calculate the midsagittal and frontal pelvic planes. The software references these planes for cup planning and navigation.

Cup and Stem Workflow

Registration Steps	See
Register pelvis landmarks.	Page 113
Store leg alignment.	Page 120
Register epicondyles.	Page 123
Register mid-ankle point.	Page 124
Register piriformis fossa.	Page 125
Register acetabulum (fossa and cavity).	Page 117
Register inferior peak of the Psoas Valley.	Page 118
Register acetabular rim (optional).	Page 118

Cup Only Workflow

Registration Steps	See
Register pelvis landmarks.	Page 113
Store leg alignment (if *pin-based* leg situation analysis is planned).	Page 120
Store leg alignment and acquire proximal femur landmark (if *pinless* leg situation analysis is planned).	Page 122
Register acetabulum (fossa and cavity).	Page 117
Register inferior peak of the Psoas Valley.	Page 118
Register acetabular rim (optional).	Page 118

Express Leg Situation Workflow

Registration Steps	See
Store leg alignment and acquire proximal femur landmark.	Page 122
Acquire anterior and posterior acetabular rim points.	Page 119

5.4.4   SR Registration Workflow

**Head Only
Workflow**

Registration Steps	See
Register the epicondyles.	Page 123
Register lateral mid-neck and sizing points.	Page 127
Register the proximal femur: • Femoral head • Anterior neck • Inferior neck • Posterior neck • Superior neck • Notching zone	Page 127
Verify femur bone model.	Page 105

5.5 Pelvis Registration Steps

5.5.1 Overview

General Information

Using the pelvis landmarks and points on the acetabular rim, the software calculates the frontal and midsagittal planes, on which the inclination and version angles are projected. These points are also used to size the bone model.

The steps presented in this chapter may not be relevant for all workflows. For information on which steps are relevant for your selected workflow, see the registration workflow tables starting on page 111.

Post-Registration

After pelvis registration is complete, neither the ASIS-to-ASIS distance nor the pelvic tilt values may be changed.

5.5.2 Lateral Pelvis Registration
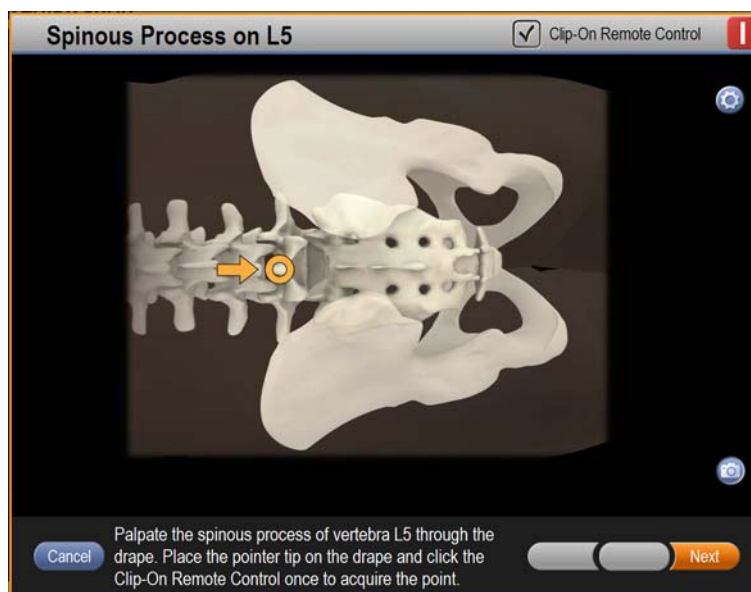
How to Register the L5 Spinous Process

Figure 63

Steps	
1.	On top of the sterile drape, palpate the along the spine from cranial to caudal. Locate the spinous process of the most caudal lumbar vertebra (L5). *NOTE: Due to possible lumbar lordosis, use only the most caudal lumbar vertebra for registration, otherwise registration may be inaccurate.*
2.	Hold the pointer tip to the center of the spinous process and acquire the point.

If the L5 vertebra is deformed or difficult to palpate:

Steps	
1.	Palpate both posterior iliac spine landmarks, locating the mid-point between them.
2.	Hold the pointer tip to the mid-point and acquire the point.

⚠

Take care not to puncture the sterile drape during L5 registration. It is recommended to use the Clip-On Remote Control for this step to avoid drape damage. If the drape is very thin and/or without plastic coating, use multiple drape layers to cover the patient's lumbar spine.

**How to Acquire the
Treated Side ASIS
in Lateral Position**

Figure 64

Step
Acquire the treated side ASIS point at the exact point that was used for the preoperative ASIS distance measurement (see page 56).

5.5.3 Supine Pelvis Registration
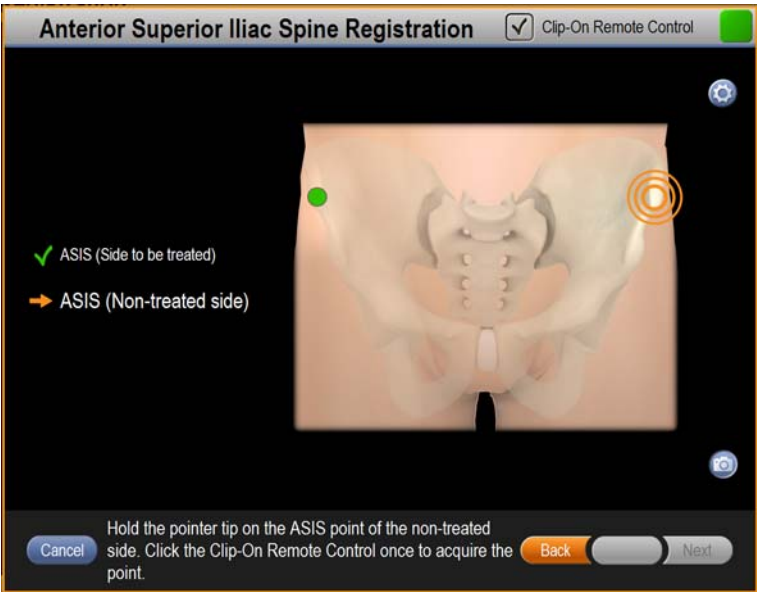
**How to Register the
ASIS Points in
Supine Position**

Figure 65

Steps	
1.	Hold the pointer tip to the treated side ASIS point and acquire the point. *NOTE: Once a point is acquired, the arrow indicates the next point to acquire.*
2.	Acquire the non-treated side ASIS point.

5.5.4 Acetabulum Surfaces Registration

General Information

Registering the acetabular surfaces entails acquiring the bone surface of:

- The acetabular fossa
- The acetabular cavity

These points are used to shape the bone model, calculate the COR of the hip joint, and calculate the initial depth and size of the cup implant. The COR is also used to morph and size the femur bone model.

Before performing these steps, we recommend that you perform femoral head resection to enable maximum access to the inner acetabulum.

⚠️

The pointer tip must not leave the bone surface when acquiring these regions. If it leaves the bone, points in the air may be acquired, causing errors in the bone model calculation. Should the pointer tip leave the bone surface, stop acquisition and press Again.
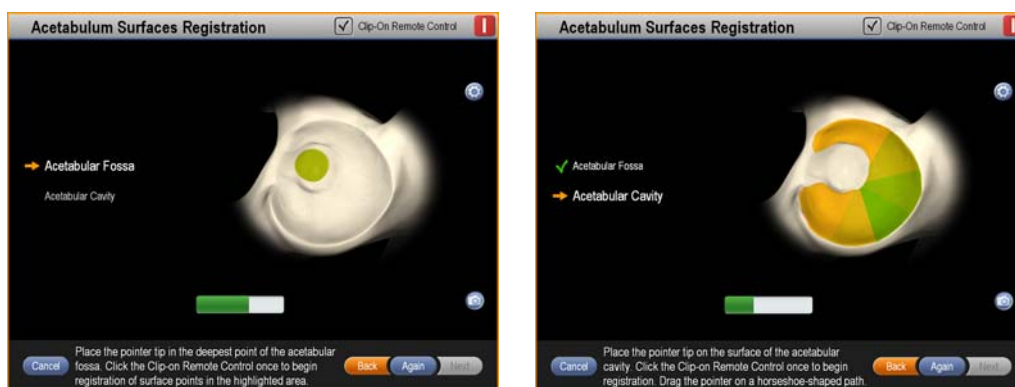
How to Register Acetabulum Surfaces

Figure 66

Steps	
1.	Hold pointer tip on the bone surface in the acetabular fossa and acquire a point. The first point initiates surface registration.
2.	Slide pointer tip along the surface of the acetabular fossa, covering as wide an area as possible within the region. The shading in the region reflects the number of points acquired there. When the shading is dark green and the progress bar is full, sufficient points have been acquired.
3.	Hold pointer tip to the bone surface in the acetabular cavity and acquire a point. The first point initiates surface registration.
4.	Slide pointer tip along the surface of the acetabular cavity, covering as wide an area as possible within the region. The shading in the region reflects the number of points acquired there. When the entire region is shaded dark green and the progress bar is full, sufficient points have been acquired. The software updates the bone model, then opens the next dialog.

*NOTE: To undo all acquired points and reacquire them, press **Again**.*

5.5.5 Acquisition of Points on Acetabular Rim

General Information

If acquiring the acetabular rim is a planned part of the procedure, the corresponding dialog(s) open. Acquiring the acetabular rim is an optional step in some procedures.

To register the rim of the acetabulum, you acquire five or six points. The highlighted text tells you where to acquire each point.

These points help morph the bone model and are shown during cup planning to give you additional points of reference to orient the implant.

How to Acquire Acetabular Rim Points

If the colored section is green, this indicates that the angular distance is sufficient (20°-120° from the previously acquired point) and the point may be acquired. If the colored section is red, it indicates an insufficient angular distance, as it is too close to the previously acquired point.
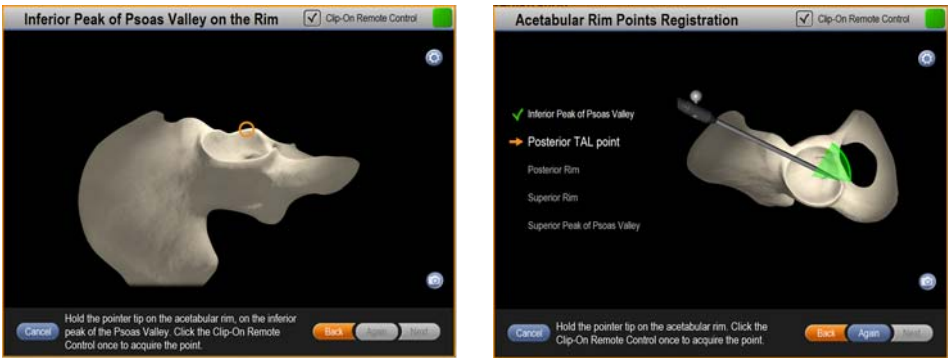

Figure 67

Steps	
1.	Acquire the inferior peak of Psoas Valley.
2.	Acquire the posterior TAL point.
3.	Acquire a point on the posterior rim.
4.	Acquire a point on the superior rim.
5.	Acquire the superior peak of Psoas Valley.

How to Acquire Rim for Express Leg Situation

Acetabular registration in the Express Leg Situation workflow comprises acquiring two opposing points on the acetabular rim to provide an approximate definition of the COR.
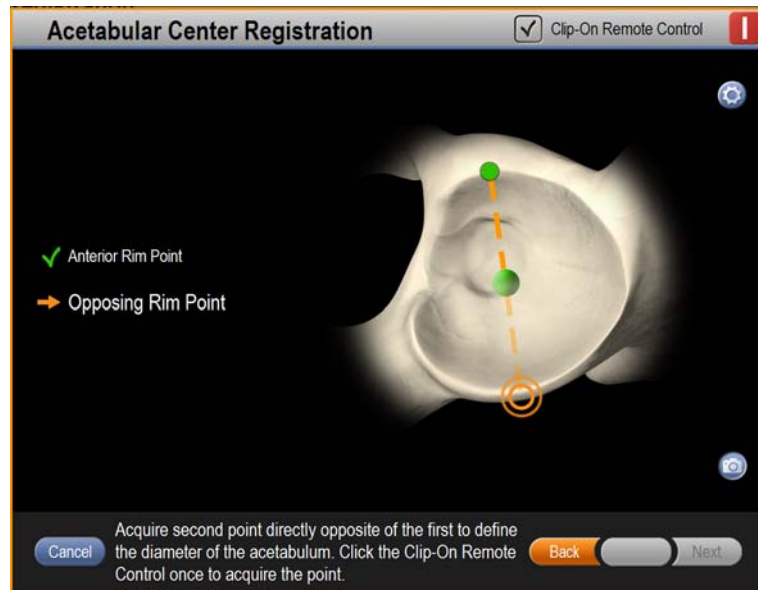

Figure 68

Steps
1. Acquire the anterior rim point, as identified by the software.
2. Acquire the opposing rim point, directly opposite the first point.

5.6 Leg Alignment

5.6.1 Pin-Based Leg Alignment

General Information

The registered alignment of the preoperative leg is used as a basis for calculation of the post-operative leg situation.

This step is required for Cup and Stem workflows.

For Cup Only THR workflows, you are only prompted to perform leg alignment if navigation of the postoperative leg situation was selected during procedure planning.

NOTE: Both a femur and pelvis reference array are required for registering leg alignment and post-operative leg alignment. If your procedure otherwise does not require both reference arrays, it is not possible to include this step in your procedure plan.
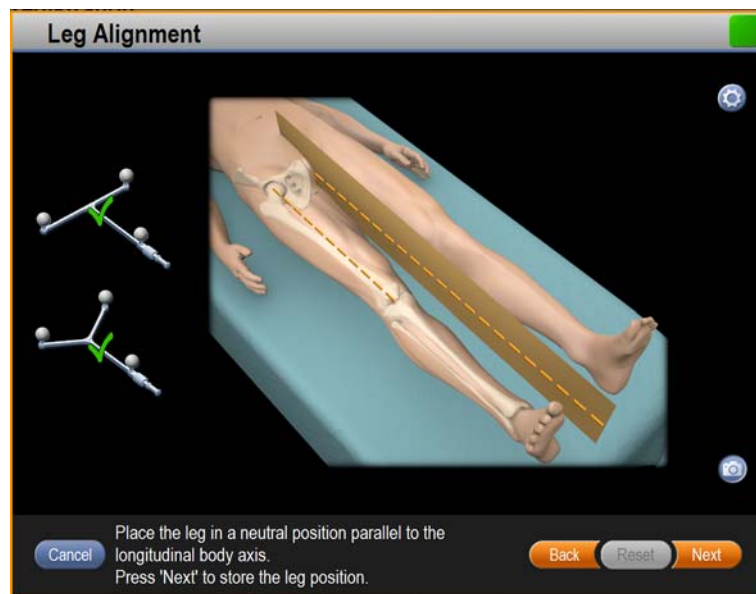
How to Perform Leg Alignment, Supine Position

Figure 69

Steps	
1.	Hold patient's leg in a neutral position, parallel to the body's midsagittal and frontal planes. The leg should not be flexed, extended, adducted, abducted or rotated. *NOTE: The status bars only indicate whether the reference array is visible to the camera, not that the leg is in the correct position.*
2.	Once the leg is correctly positioned, press **Next** to store the position and proceed. *NOTE: If either of the reference arrays is not visible to the camera, the corresponding status bar turns red and the **Next** button is disabled.*

How to Perform Leg Alignment, Lateral Position

If you are performing a procedure with the patient in the lateral position, the leg must be held at a 90° angle.
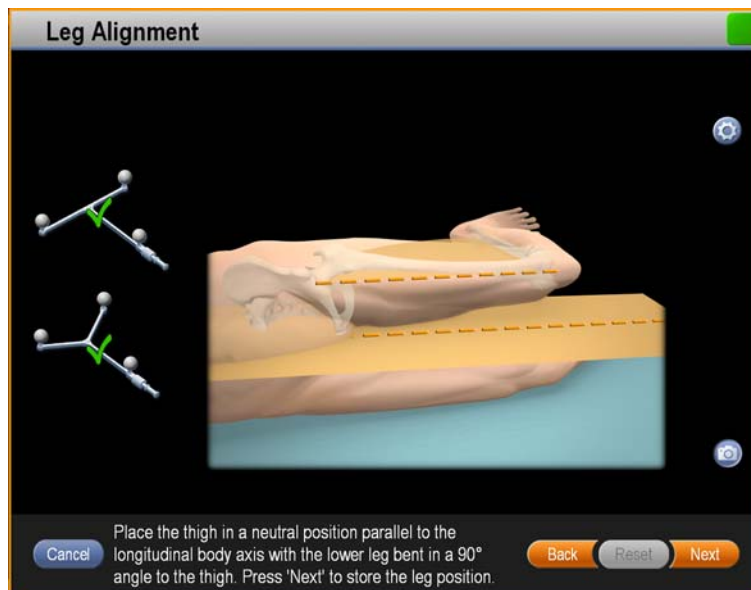

Figure 70

Steps	
1.	Hold patient's femur in a neutral position, parallel to longitudinal body axis (i.e., hip is not flexed, abducted/adducted or internally/externally rotated). Flex patient's leg 90° at the knee to prevent internal or external rotation errors. *NOTE: The status bars only indicate whether the reference array is visible to the camera, not that leg is in the correct position.*
2.	Once the leg is correctly positioned, press **Next** to store the position and proceed. *NOTE: If either of the reference arrays is not visible to the camera, the corresponding status bar turns red and the **Next** button is disabled.*

NOTE: You may optionally align the legs in a knee-to-knee position with a cushion or towels (approximately 5-10 cm thick) between the knees. This can assist with re-aligning the leg after trial reduction, even when the pelvis is moved during surgery. If necessary, some cushion or towels may be removed to reproduce correct leg alignment.

Other Options

Options
To repeat leg alignment and store a new position, press **Reset**. This is only possible if you are repeating this step.

5.6.2 Pinless Leg Alignment

General Information

You must store the leg alignment and acquire a proximal femur landmark when using a **Pinless Femur Reference Array** in the following procedures:

- Cup Only THR
- Express Leg Situation

These steps are used to verify that the reference array has not shifted relative to the femur, as well as to calculate leg length and combined pelvic and femoral offset.

If your procedure plan includes using a **Pinless Femur Reference Array**, the software automatically opens the appropriate dialogs.

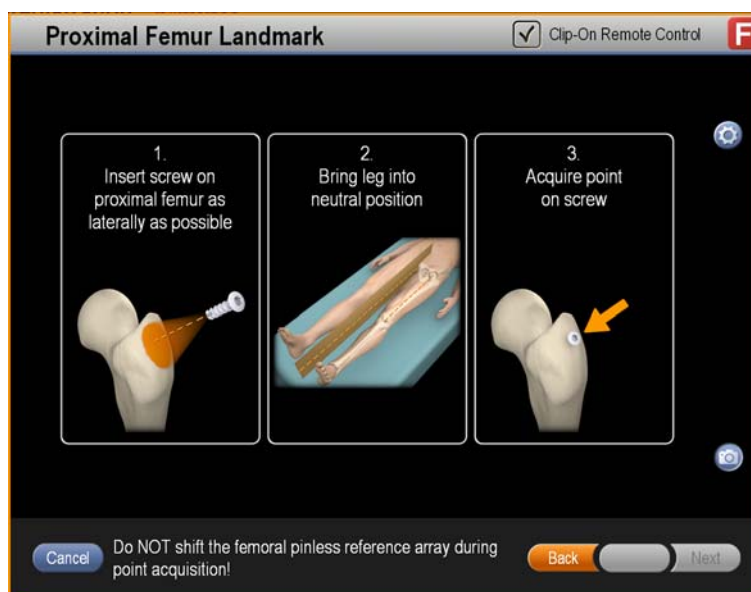**Storing Leg Alignment and Acquiring Proximal Femur Landmark**

Figure 71

Steps	
1.	Insert a unicortical screw on the proximal femur, as laterally as possible.
2.	• Supine position: Bring the patient's leg into neutral position. • Lateral position: Hold patient's femur in a neutral position, parallel to longitudinal body axis (i.e., hip is not flexed, abducted/adducted or internally/externally rotated). Flex patient's leg 90° at the knee to prevent internal or external rotation errors.
3.	Keeping the patient's leg in the relevant position, acquire a point on the screw.

NOTE: In the lateral position, you may optionally align the legs in a knee-to-knee position with a cushion or towels (approximately 5-10 cm thick) between the knees. This can assist with re-aligning the leg after trial reduction, even when the pelvis is moved during surgery. If necessary, some cushion or towels may be removed to reproduce correct leg alignment.

⚠

Ensure that the Pinless Femur Reference Array does not move during initial leg alignment and point acquisition. Movement of the reference array may result in inaccurate navigation and postoperative results.

5.7 Femur Registration Steps

5.7.1 Epicondyles Points Registration

General Information
The software uses the epicondyle points to define the epicondylar axis and its midpoint, from which it calculates the mechanical axis of the femur.

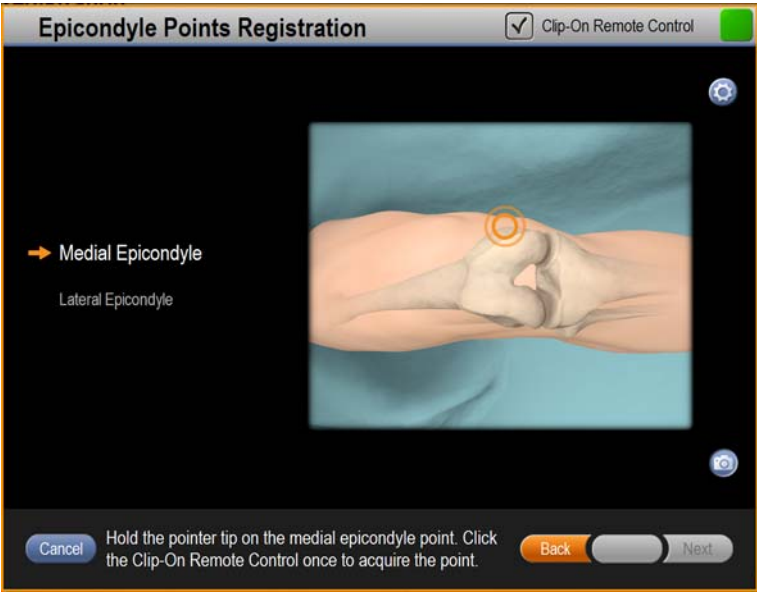**How to Register the Epicondyles**

Figure 72

Steps
1. Hold pointer tip to the medial epicondyle and acquire the point.
2. Hold pointer tip to the lateral epicondyle and acquire the point.   The next dialog opens.

5.7.2 Mid-Ankle Point Registration

General Information

You acquire this point if your procedure plan calls for the calculation of femoral antetorsion by AEP.

The mid-ankle point is used along with the piriformis fossa/COR and the epicondyle midpoint to calculate the sagittal AEP plane, which is used to calculate the orientation of the femur implant.

⚠️

It is important when acquiring these points, that the knee is in 90° flexion and the tibia is held in a neutral position with no valgus or tibial axis torque.

How to Register the Mid-Ankle Point

Figure 73

Steps
1.   Hold patient's leg with the knee in a 90° flexed position.
2.   Hold pointer tip to the mid-ankle point and acquire the point.

5.7.3   Piriformis Fossa Registration

General Information

The piriformis fossa point defines the proximal point of the femur shaft axis, and is one of the points that defines the native neck axis orientation. The registration of the piriformis fossa helps size the bone model.

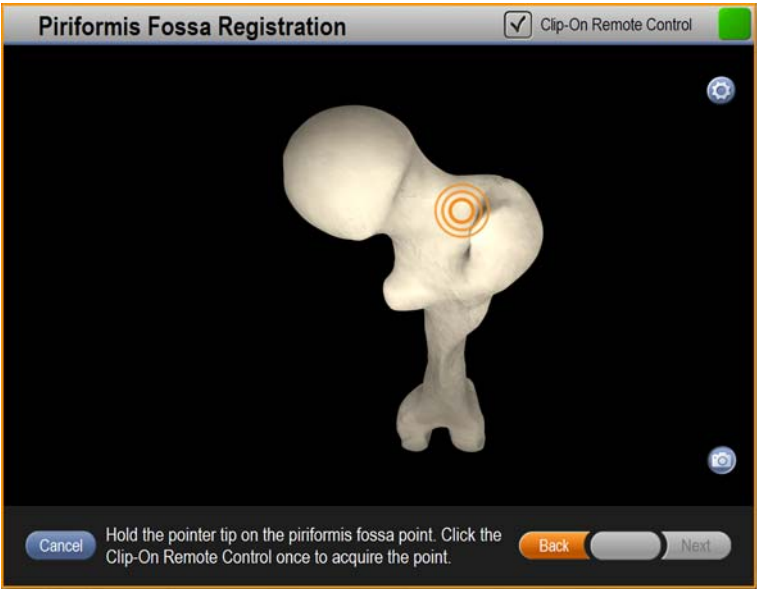**How to Register the Piriformis Fossa**

Figure 74

Step
Hold pointer tip to the piriformis fossa and acquire the point.
The next dialog opens.

5.7.4 Lateral Mid-Neck and Sizing Points for SR Workflows

About the Lateral Mid-Neck Point	The lateral mid-neck point is used for sizing the femur bone model. This point defines the proximal end point of the shaft axis, and is also used to define the femoral neck axis in the axial direction. The initial implant position and orientation is collinear to the neck axis.
	If this point is not correctly acquired, the calculated neck axis and implant position may not be accurate.
About the Sizing Point	This is a reference point at the head-neck junction. As the rim of the implant must meet the head-neck junction, this point is used for initial implant positioning.
	This point also defines the position where the initial implant size is measured when using the "Fit to Neck" algorithm. If not correctly acquired, implant position calculated with the "Fit to Neck" algorithm may not be accurate.

How to Register the Lateral Mid-Neck and Sizing Points

Figure 75

Steps
1. Hold pointer tip on the lateral mid-neck point and acquire the point.
2. Hold pointer tip on the sizing point and acquire the point.

5.7.5   Proximal Femur Registration for SR Workflows

General Information	In the pointer-based femur registration workflows, you are prompted to acquire the following areas on the bone surface of the proximal femur:

- Femoral head
- Anterior neck
- Inferior neck
- Posterior neck
- Superior neck
- Notching zone

Registration Safety and Accuracy

Before beginning registration, remove osteophytes as far as possible. Registration on bone areas with osteophytes severely affects notching calculations.

Ensure that the pointer remains on the bone at all times during point acquisition, and avoid acquiring points in the air, on thick tissue, or in areas where osteophytes are located. Otherwise, the femoral model calculation, notching calculation, and calculation of the implant size will be inaccurate.

During registration, it is essential that each set of points is acquired only at the location specified in the relevant dialog. Otherwise, the femoral notching calculation and femoral planning as a whole will be inaccurate.

Femoral Head

The points acquired on the femoral head determine its center. This center point defines the neck axis and mechanical axis, which is used for leg situation analysis.

Acquiring points over a broad area of the femoral head improves the accuracy of the bone model, and accuracy of the calculation of the COR and the implant size. Along with the lateral mid-neck point, the femoral head surface points are used to define the femoral neck axis in the axial direction.

To acquire additional head points, press the button in the registration dialog.

You may acquire 30 additional points. To acquire more points, press the button again until sufficient points are acquired.

Neck Points

The software prompts you to acquire points in four specific areas on the femoral neck to generate the femoral bone model. After acquiring each area, the highlighted step shifts to the next area and the bone model rotates to display the area to be acquired.

These points are used, along with the lateral mid-neck point and the center head point, to calculate the initial neck axis. The neck points are also used to calculate initial head implant size when using the "Fit to Neck" algorithm. The points acquired here help to calculate whether femoral notching is likely to occur.

Notching Zone

You are prompted to acquire points in this area to ensure that sufficient points have been acquired on the neck in a critical area of the bone where notching is most likely to occur.

| Correct Acquisition of Head Points | For best results, slide the pointer completely around the circumference of the head, then spiral up toward the pin insertion point. |

The head points should be acquired in as wide a region as possible. Otherwise, navigation could be inaccurate.

| Correct Acquisition of Neck Points | The neck points should be acquired in the medial part of the indicated neck region in an area of about 1 cm. Do not acquire them too close to the head-neck junction, nor too far lateral, near the greater trochanter. |

To ensure accurate notching calculation, the points should be acquired in areas where notching is likely to occur, such as the superior-anterior neck region.

To ensure accurate implant sizing, the neck points must be acquired correctly in the below pre-defined areas.
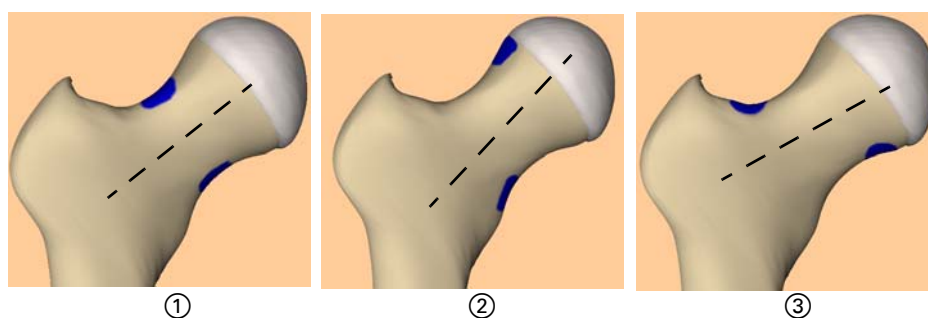
Figure 76

No.	Result
①	**Correct result**: Points are acquired where notching is most likely to occur, e.g. in the medial part of the neck region in an area of about 1 cm.
②	**Neck axis angle too steep**: Points are acquired too far superior (head neck junction) and too far inferior (where the neck almost meets the shaft).
③	**Neck axis too low**: Points are acquired too far lateral (close to the greater trochanter) and too close to the inferior head neck junction.

It is essential that each set of points is acquired only at the location specified in the relevant dialog. Points in different sets should not overlap. Otherwise, the femoral notching calculation and calculation of the neck axis will be inaccurate.

How to Register the Proximal Femur

Figure 77

Steps	
1.	Hold pointer tip to the surface of the femoral head, and pivot the pointer slightly around its tip or press the **Clip-on Remote** to start acquisition.
2.	Slide the pointer tip over the femoral head. For best results, slide the pointer completely around the circumference of the head, then spiral up toward the pin insertion point.
	When the progress bar is complete the dialog indicates the next area to acquire.
	NOTE: Optionally, acquire additional head points using the button described on page 127.
3.	Hold pointer to the bone surface of the highlighted area on the femoral neck and pivot it slightly to start acquisition.
4.	Slide the pointer over the highlighted area to acquire it.
	When the progress bar is complete the dialog indicates the next area to acquire.
5.	Repeat steps 3 and 4 for each area as it becomes highlighted.
	*NOTE: If you acquired points outside the highlighted region in any step, a warning screen opens. If this happens or if you wish to undo all acquired points and reacquire them, press **Again**.*

⚠️

If the pointer leaves the bone surface in any of these steps, stop acquiring the area and press Again to restart.

5.8   Restoring Registration and Re-Registration

5.8.1   Restoring Registration

**General
Information**

If the system is inadvertently shut down, e.g., due to a power failure, and you have already complet-ed registration, you can restore the previous registration.

Upon restarting after an inadvertent shutdown, the **Restoration of Patient Data** dialog opens.

**How to Restore a
Previous Session**

Figure 78

Steps	
1.	You are asked via **Patient Data Manager**/**Patient Browser** if you wish to restart the soft-ware. Press **Restart**/**Yes** to open **Brainlab hip**.
2.	When the software prompts you to restore patient data, press **Use**.
3.	Verify registration accuracy before proceeding.

⚠️

**After restoring a session, always confirm registration accuracy in the verification dia-
log.**

Other Options

Options
To use the software, but not restore patient data, press **Delete**.
The data is saved before the previous registration is deleted.
To close the software, press **Cancel**.

5.8.2   Re-Registration

General Information

If the position of a reference array changes relative to the bone intraoperatively, you must re-register the bone before you can continue.

You may also wish to re-register a bone to improve registration accuracy.

NOTE: If you cancel a re-registration, the original registration is restored.

Contraindications for Re-Registration

- If the patient has been repositioned so that registration points can no longer be accurately acquired, you will not be able to re-register.
- If you must fully re-register due to reference array movement, navigated leg alignment/leg situation analysis is no longer available and cannot be reacquired. In the case of a THR femur navigation, all of these steps are disabled as the initial center of the femoral head cannot be defined via initial leg alignment.
- If the patient's anatomy has changed substantially after initial registration (e.g., due to reaming, luxation or femoral head resection), re-registration is not possible. In that case, continue the procedure without software-aided navigation.

6 PLANNING AND NAVIGATION OVERVIEW

6.1 Chapter Overview

6.1.1 Contents

Topics Covered

Section	See
Planning and Navigation with Brainlab hip	Page 134
Navigation Workflows	Page 137
Intraoperative Tracking	Page 140
Navigation Functions	Page 144

6.2 Planning and Navigation with Brainlab hip

6.2.1 Overview

General Information

The **Brainlab hip** planning, navigation and verification screens fluidly move between steps.

Screens shift between the various tasks depending on which instrument is in the camera field of view.

Furthermore, planning, navigation and verification steps can be activated via the **Menu** (including the **Go to... menu**) and the **Options** menu (see page 43).

Implant Planning

Implant planning screens allow you to make adjustments to the planned position, size and orientation of the implants. Carefully check and adjust the implants before beginning navigation.

If you change implants, use the planning screens to verify that they are correctly sized and positioned.

⚠️

Use the acquired points (shown in the images) to plan the implants. The bone model is displayed for visualization only.

Selected Implants

The selected implants are displayed in the bottom right corner of planning screens. To change implants or implant attributes, access the **Implant** dialog via the **Menu** (see page 67).

Implant Compatibility	If the software detects an incompatibility between implant components, the **Implant Info** dialog opens between the registration and implant planning steps in order to restore a valid implant selection.
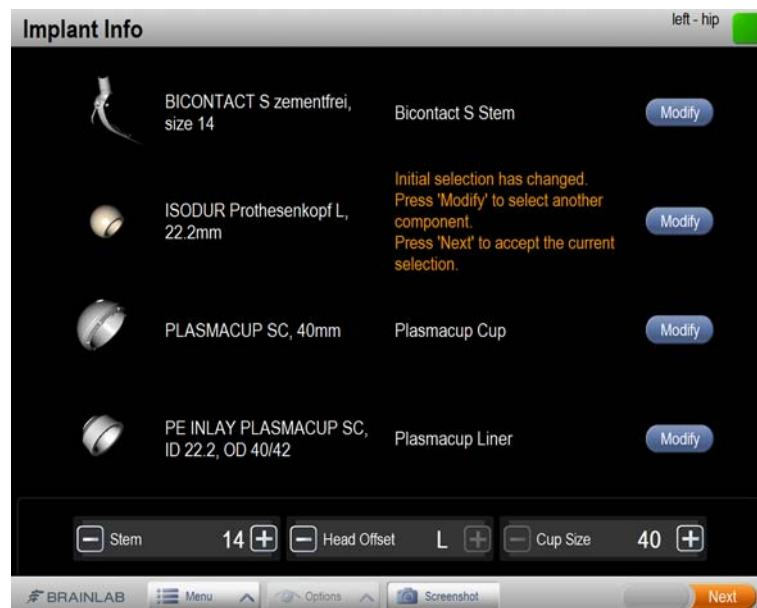
Figure 79

Steps	
1.	• To accept the suggested changes to the implant component(s), press **Next**. You are returned to the planning screen. • To modify changes, press **Modify** next to the relevant component. The **Implant** dialog opens.
2.	• Make any desired changes (see page 67), or • Press **Close** to save changes and return to the **Implant Info** dialog.
3.	Press **Next** to continue with planning.

⚠

Make sure that individual implant components are compatible and fit appropriately with each other. An incorrect combination of implant components could result in severe patient injury.

Selected Instruments	The selected instruments are displayed in the corner of planning screens. To change instruments, or if one or more instruments were not selected during procedure planning, access the **Instruments** dialog via the **Menu** (see page 70).

⚠

Make sure that you only select the instruments that you are actually using. Using instruments other than the ones selected can cause inaccurate navigation and patient injury. Instrument selection can be changed at any time via the Menu (see page 43).

How to Select an Instrument for Verification

Steps	
1.	Press **Verify** ① under the instrument you wish to verify. *NOTE: If no instrument has been selected this button is disabled.*
2.	Follow the steps for verification on page 143.

6.3 Navigation Workflows

6.3.1 THR Navigation Workflows

Overview

In THR Cup and Stem and Cup Only workflows, all registration and planning is complete before navigation begins. The software identifies the instrument in the camera field of view and opens the relevant navigation screen based on that.

Cup and Stem Workflow

Workflow Steps	See
Cup planning	Page 148
Cup reaming (optional)	Page 153
Polar points acquisition (optional)	Page 154
Cup insertion: • Calibrate and confirm cup inserter (if not precalibrated) • Navigate cup insertion	Page 155
Cup verification: • Verification (either with a cup inserter or by acquiring points) • Check verification results	Page 157
Broach navigation (optional): • Select broach size • Navigate broaching • Store broach position (in order to verify trial implant position)	Page 161
Trial leg situation (optional, depending on selected implants)	Page 174
Femur implant verification (optional, depending on selected implants): • Verification (with a **Stem Position Verification Tool**) • Check verification results	Page 163
Leg situation analysis (optional)	Page 174
Intraoperative ROM analysis (optional)	Page 177

Cup Only Workflow

Workflow Steps	See
Cup planning	Page 148
Cup reaming (optional)	Page 153
Polar points acquisition (optional)	Page 154
Cup insertion: • Calibrate and confirm cup inserter (if not precalibrated) • Navigate cup insertion	Page 155
Cup verification: • Verification (either with a cup inserter or by acquiring points) • Check verification results	Page 157
Leg situation analysis (optional)	Page 174

Express Leg Situation Workflow

The Express Leg Situation workflow that comprises minimal registration steps and allows you to determine the postoperative difference in leg length and combined pelvic and femoral offset without navigating the surgical procedure.

Workflow Steps	See
Pinless leg alignment	Page 122
Acquire anterior and posterior acetabular rim points.	Page 119
Perform surgical procedure without navigation	
Leg situation analysis	Page 174

6.3.2   SR Planning and Navigation Workflow

Head Only Workflow

Workflow Steps	See
Femur registration	Page 123
Neck axis planning	Page 166
Head planning	Page 167
Pin insertion/verification: • Calibrate Drill Guide (if not precalibrated) • Navigate pin insertion	Page 169
Head verification (optional): • Verification • Check verification results	Page 170

6.4 Intraoperative Tracking

6.4.1 Patient Tracking

Reference Arrays

The entire navigation coordinate system of the software depends on accurate referencing of the patient's anatomy. Therefore, proper positioning and stability of reference arrays are critical to the functioning of the software.

For information on positioning reference arrays, see "Using Reference Arrays" on page 87.

Positioning Reference Arrays

Before beginning the surgical procedure, make sure to attach the relevant reference array(s): Y geometry reference array to the femur and the T geometry reference array to the pelvis. Movement of the leg during the procedure must be taken into consideration when attaching the reference arrays to the femur and pelvis.

Reference Array Movement

If a reference array changes position relative to the bone, or the array becomes unstable, check its accuracy, and re-attach it if necessary.

If a reference array must be re-attached, re-register the patient before proceeding to navigation. Keep in mind that for some registration steps, it is not possible to re-register (see **Contraindications for Re-Registration** on page 131).

Do not move reference arrays relative to the patient's anatomy during the procedure. Any movement may affect the entire measurement coordinate system, leading to incorrect instrument display and injury to the patient.

Verifying Registration Accuracy

If you re-register or replace a soiled or damaged marker sphere on a reference array, verify registration accuracy before performing any navigated procedure.

*NOTE: For more information on Disposable Reflective Marker Spheres, see your **Instrument User Guide**.*

6.4.2　Instrument Tracking

Instrument Adapters

Instrument adapters with reflective marker spheres allow the software to track surgical instruments.

⚠

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.

⚠

Make sure the instrument you are working with and the instrument you have selected in the Brainlab navigation software are the same. If an instrument other than that selected in the software is used, it cannot be accurately navigated!

Instrument Visibility

If the camera view of a tracked instrument is obstructed, the visibility indicator signals that the instrument is not visible (see page 36). The status bar will turn green once all necessary reference arrays and instruments are returned to the camera field of view.

If an instrument remains invisible to the camera for longer than two seconds, it will disappear from the camera display.

⚠

Plan OR set up prior to surgery. To ensure accurate registration and navigation, the camera lenses must have an unobstructed view of the instrument marker spheres at all times.

⚠

Make sure that the instrument displayed on the navigation screen matches the actual instrument you are using. Using an instrument other than the one selected in the software will cause inaccurate navigation and could cause severe patient injury.

Automatic Detection by the Software

In the **Cup Navigation** screen, the software automatically detects the instrument (reamer or inserter) when it enters the camera field of view, as long as the attached tracking arrays differ. The currently selected tool is highlighted in a colored frame.

Instrument Calibration

Many instruments are precalibrated, and must simply be selected so that the software knows which calibration to use.

Instruments that must be calibrated by the surgeon can be calibrated prior to navigation using the **ICM4** (see page 142). You are prompted if calibration is necessary.

6.4.3   Instrument Calibration

General Information

If you have selected instruments that are not precalibrated, the software prompts you to perform calibration and verification before they can be navigated. The calibration dialog opens right before the given instrument is needed.

*NOTE: For more detailed information on instrument calibration, see the **Instrument User Guide**.*

How to Calibrate Instruments
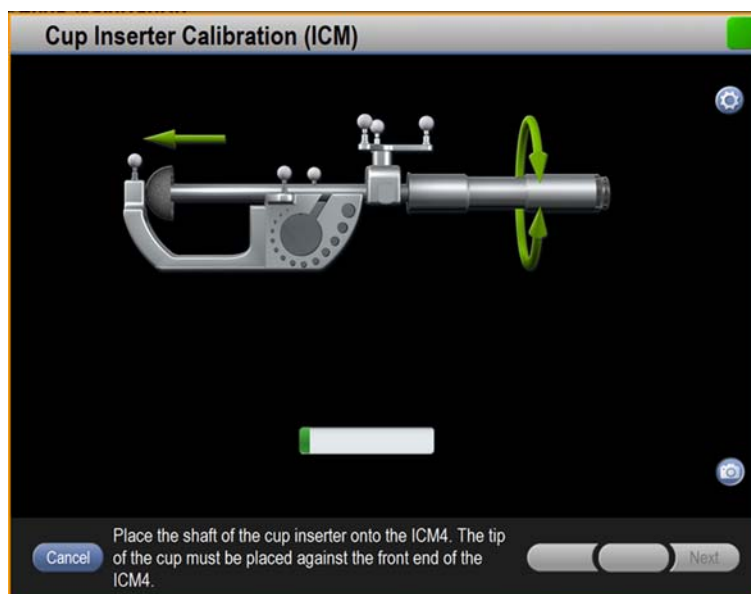
Figure 80

Steps	
1.	When the calibration dialog opens, place the instrument shaft into the V-inset on the top of the **ICM4** with the tip touching the front of the **ICM4**.
2.	Hold instrument and **ICM4** in the camera field of view and rotate the instrument handle gently back and forth. The system calibrates the trajectory and tip of the instrument and opens the **Verify Instrument Calibration** dialog.

NOTE: The status of the calibration procedure is indicated by a progress bar. This bar resets any time the software detects a shift in the rotational center of the instrument, indicating that it is not stable.

How to Verify Instruments

The below procedure is to verify:

- The accuracy of instrument calibration, or
- The accuracy of precalibrated instruments.
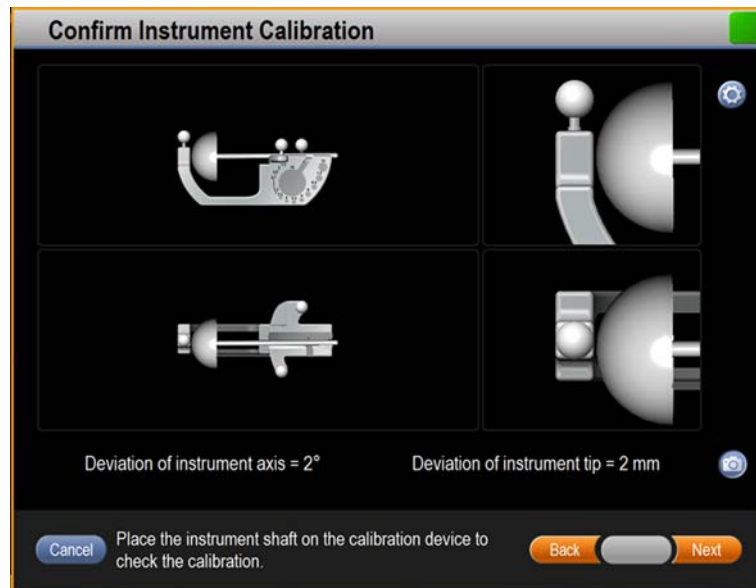
Figure 81

Steps	
1.	Place the instrument shaft into the V-inset on the top of the **ICM4** with the tip touching the front of the **ICM4**.
2.	Verify that the deviation of instrument axis and instrument tip corresponds with the actual position of the instrument on the **ICM4**.
3.	Press **Close** when you have finished verifying the instrument.

6.5   Navigation Functions

6.5.1   Overview

General Information

You can activate any navigation step in the procedure plan from the **Go to...** menu, once you have completed the registration of the appropriate bone(s).

You can also cancel out of a navigated procedure and access it later through the **Go to...** menu (see page 42).

How to Access Navigation Functions via the Go to... Menu
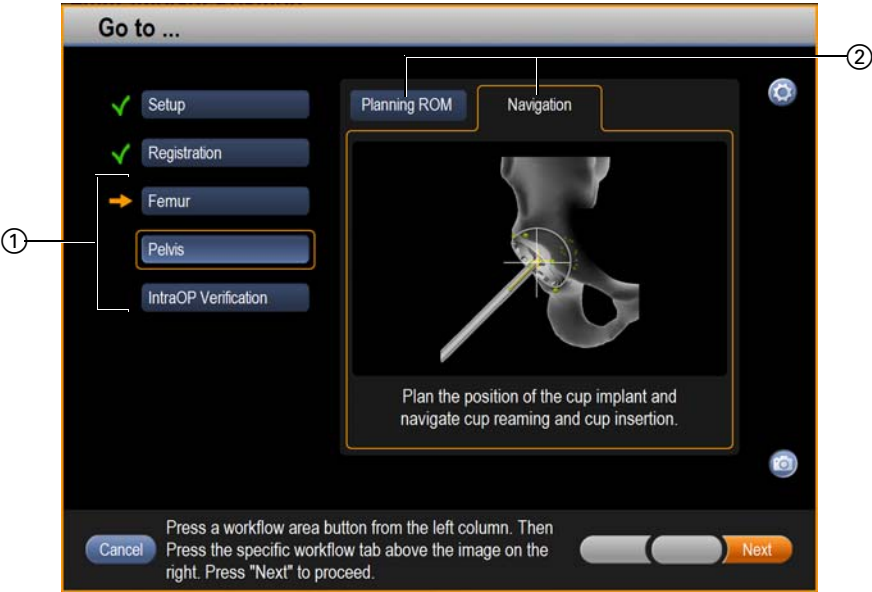
Figure 82

Steps	
1.	Press the **GOTO** button in the menu bar.
2.	In the **Go to...** menu, press the **Femur**, **Pelvis** or **IntraOP Verification** ① button as needed.
3.	Press the tab ② for the procedure you wish to navigate.
4.	Press **Next**.

NOTE: You can only select buttons or tabs for pelvis or femur navigation if you have completed registration of the corresponding bone structure. Otherwise the buttons are disabled.

6.5.2 Available Navigation Functions

General Information	If a function does not appear in the **Go to...** menu, it is either not part of the procedure plan or it is not available with your current license.
	If the button for a function is disabled, you have not yet completed necessary prerequisite steps (e.g., registration of necessary areas) to enable that function.
Pelvis Navigation Options	If planned, after pelvis registration, you can navigate the following procedures:
	• Cup reaming
	• Cup insertion
	• Cup verification
Femur Navigation Options	If planned, after femur registration, you can navigate the following procedures:
	• THR:
	- Broaching
	- Stem Verification
	• SR:
	- Pin Insertion/Verification
	- Head Verification
Analysis Navigation Options	If planned, after registration of both the pelvis and the femur, you can perform intraoperative range of motion (ROM).
	If planned, after registration of the pelvis and alignment of the femur axis you can perform a leg situation analysis.

6.5.3 Acquiring Additional Landmarks

General Information

Once at least one bone has been registered, you can acquire additional landmarks. Once acquired these points appear in all navigation and planning screens unless you remove or hide them via the **Options** menu (see page 44).

The buttons for removing additional landmarks are enabled once a point is acquired.

How to Acquire Additional Landmarks

Figure 83

Steps	
1.	Select **Additional Landmarks** via the **Menu**.
2.	Select where to acquire points: • **Points on Pelvis** • **Points on Femur** • **Points to Instrument** *NOTE: **Points to Instrument** allows you to acquire landmarks in relation to a predefined instrument/reference array. This information is saved in the log files. Contact Brainlab support for more information.*
3.	Hold pointer tip to the landmark and pivot the pointer slightly around its tip or press the **Clip-on Remote Control**. The distance between the last two acquired points is shown.
4.	You can optionally remove all or just the last acquired point with the designated buttons.

How to Show/Hide Additional Landmarks

Step
Select/deselect the **Show Add. Landmarks** check box in the **Options** menu (see page 44).

7 PELVIS STEPS

7.1 Chapter Overview

7.1.1 Contents

Topics Covered

Section	See
Cup Planning	Page 148
Cup Reaming	Page 151
Cup Insertion	Page 155
Cup Verification	Page 157

7.2 Cup Planning

7.2.1 Overview

General Information

The cup planning screen shows the selected cup implant initially aligned in the bone model according to the landmarks and surfaces you acquired during registration.

The functions available on the cup planning screen vary depending on your procedure.

NOTE: If elements do not appear on your screen, your planning selections or license do not enable that feature.

Displayed Angles

The default cup position shown during cup planning, cup reaming and cup insertion screens is set at 15° radiographic anteversion and 45° radiographic inclination (as defined by the Lewinnek target), with a +/- 10° "safe zone."

The orientation angles are converted to the other corresponding definitions if operative or anatomical cup orientation angles were selected (see page 76).

Cup Planning Options

On the cup planning screen you can manually adjust:

• Cup implant position: The horizontal and vertical position of the cup implant, as well as its depth within the acetabulum
• Cup implant orientation: The inclination and anteversion of the cup
• Cup implant size

For workflows that include pelvis registration and cup navigations, you can use a cup inserter to plan the initial cup alignment, then make manual adjustments (page 150).

Default Values

The default inclination and anteversion values differ depending on the acetabular orientation definition selected during procedure planning. Default values are based on Lewinnek et al *(14. Lewinnek GE, Lewis JL, Tarr R, Compere CL, Zimmerman JR. Dislocations after total hip-replacement arthroplasties. J Bone Joint Surg. Am A 1978;60(2):217-220.).*

Radiographic is used as the default acetabular orientation definition. Other definitions may be used by selecting it in your procedure plan (see page 76). For more information on acetabular orientation, see page 182.

Acetabular Orientation Definition	Default Values
Radiographic	• 40° inclination • 15° anteversion
Operative	• 38° inclination • 19° anteversion
Anatomical	• 42° inclination • 23° anteversion

Standard Cup Planning

Figure 84

Steps	
1.	Use the following information to plan the cup implant: • Angle meters ② : for inclination and anteversion • White crosshair ③ : center of rotation • Green fossa points ④ : to adapt the medial-lateral position • Initial depth ⑤ : for the distance to the polar points
2.	Hide the bone model via the **Options** menu at least once, in order to better visualize the fossa points.
3.	If necessary, adjust cup size ① .

NOTE: If you have entered a pelvic tilt (see page 99), the values are shown both with and without pelvic tilt adjustment.

Planning with a Cup Inserter

This option is only available in Cup and Stem and Cup Only workflows.
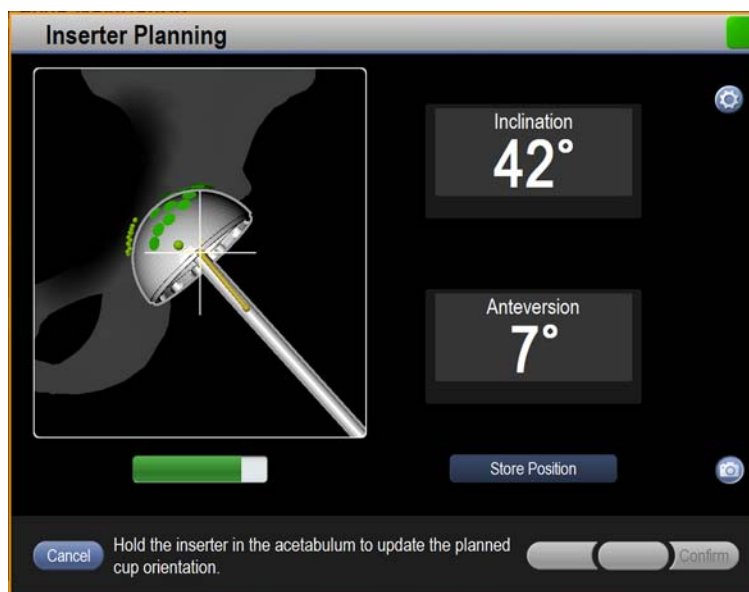
Figure 85

Steps	
1.	Select **Inserter Planning** from the **Options** menu (see page 44).
2.	Hold the inserter steady in the acetabulum at the same angle and position you will use when inserting the cup. Once the progress bar has filled, the calculation is complete, and the software returns you to the cup planning screen with the inclination and anteversion values stored.
3.	Optionally, press **Store Position** to store position before progress bar is complete. The software returns you to the cup planning screen with the inclination and anteversion values stored.

Other Options

Options
To restore the cup to its original position, size, and orientation, press **Reset** on the main planning/navigation screen.

7.3 Cup Reaming

7.3.1 Overview

General Information

Reaming is an optional navigation step. If reaming is planned in the procedure, you can later decide not to navigate it.

Bone Model

The bone model may not necessarily correspond with actual patient anatomy with respect to the medial all of the acetabulum. Use the acquired points to navigate reaming.

Reamer Angle and Head (Grater) Size

In navigated reaming, the software guides you to the correct angle and position.

Initial reaming should be performed with a reamer head diameter 8 mm smaller than the planned cup size. Subsequent reaming should continue with reamer head size increasing in increments of 1-2 mm.

⚠

Check that you have selected the correct reamer size before performing this step. Using an inappropriate reamer size could result in damage to the acetabular structure or transfixion of the pelvis. Whenever you increase the reamer head size, make sure to update it in the software.

Cup Reamer Selection and Calibration

All cup reamers supported by **Brainlab hip** are precalibrated with a specific adapter. The software knows the calibration for the reamer once you have selected it in the software.

For calibration you must therefore select the reamer head, and in certain cases, the reamer handle.

Reamer Visibility

⚠

The camera lenses must have an unobstructed view of the markers spheres on the cup reamer adapter at all times during cup reamer navigation.

7.3.2   Checking Cup Reamer Adapter

Checking the Adapter

The cup reamer adapter is critical to proper navigation of the cup reamer. Make sure that it is in good order and properly affixed to the cup reamer before you begin cup reaming.

*NOTE: For more information on the **Cup Reamer Adapter**, see your **Instrument User Guide**.*

⚠

Check that the Cup Reamer Adapter is attached with the arrow pointing towards the patient, i.e., towards the head of the cup reamer.

⚠

Make sure that both the counter and adjustment nuts on the reamer adapter are properly tightened before navigation.

Checking Adapter Marker Spheres

Make sure that:

- Each marker sphere is screwed onto its pin on the **Cup Reamer Adapter** so that no gap appears between the marker sphere and base of the pin.
- All marker spheres on the **Cup Reamer Adapter** are clean, dry and undamaged.
- If you replace any marker spheres, recalibrate/verify the instrument before proceeding with navigation.

7.3.3　Cup Reaming Navigation

**How to Navigate
Cup Reaming**

Figure 86

Steps	
1.	Bring the reamer into the camera field of view.
	Verify that the depicted reamer ④ is the reamer you are using.
2.	Verify that the reamer diameter shown in the **Reamer Size** controls ① is the diameter you are using. Use the controls to adjust the diameter if necessary.
	Any time you change the reamer head size, adjust the diameter accordingly
	NOTE: Recalibration of the reamer handle is not required in this case.
3.	Use the meters ② and views ③ to navigate reamer to the planned position.
	The large green fossa points can be used to position the reamer in the medial-lateral position.
	Hide the bone model via the **Options** menu at least once, in order to better visualize the fossa points.
4.	Ream the acetabulum according to standard practice.
	If applicable, a notice ⑤ indicates that you acquire polar points after reaming (see page 154).

NOTE:　The displayed angular values are based on the anterior pelvic plane and mid-sagittal plane defined during registration. The calculated values may appear to be inaccurate if you normally calculate these angles using body planes or the table plane. This may be corrected by using the pelvic tilt feature (see page 77).

7.3.4 Acquiring Polar Points

General Information

After cup reaming you may be prompted to acquire polar points in the area where the pole of the final cup shall be positioned. Polar points provide depth information for the reamed acetabulum.

After successful polar point acquisition, the distance between the pole of the planned cup and the polar points is shown in the **Cup Planning** screen.

Polar point registration is only available with certain implants. Contact Brainlab support for more information.

How to Acquire Polar Points
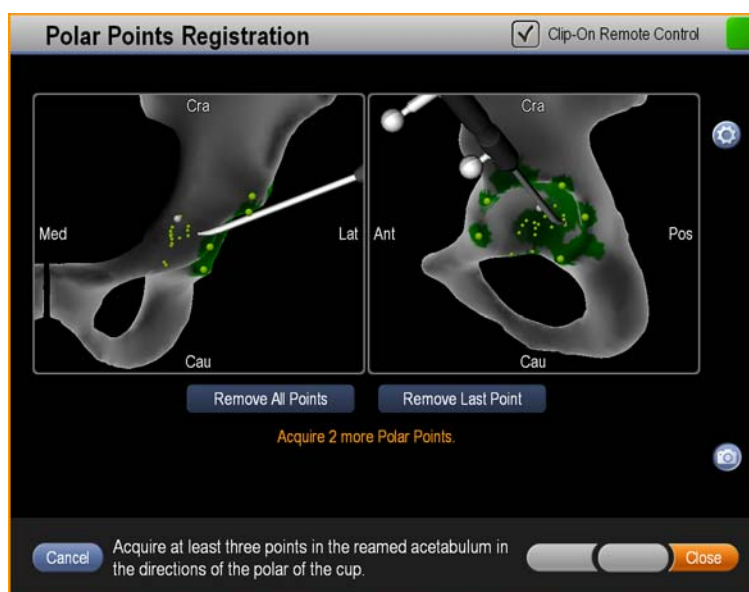
Figure 87

Steps	
1.	Hold the pointer tip to the reamed area of the acetabulum and acquire a point.
2.	Acquire three points the reamed acetabulum in the polar direction of the cup. The dialog closes after three points are acquired.
3.	• Press **Remove All Points** to remove all acquired polar points. • Press **Remove Last Point** to remove the most recently acquired polar point.

*NOTE: You may change or reacquire polar points via the **Options** menu.*

7.4 Cup Insertion

7.4.1 Overview

General Information

Before the actual cup implant is inserted, confirm that the selected cup size and implant parameters are correct. The plan should be updated accordingly if the implant size is changed.

NOTE: The term "cup inserter" is used in the software and this manual to refer to instruments variously known as cup inserters, introducers, positioners, and impactors.

Before You Begin

The cup should be positioned using the anatomy as a reference, and aligned with the bone.

The software does not take into account possible cement thickness when planning the cup depth; only press-fit (non-cemented cups) can be planned and navigated.

Make sure that you have selected the correct cup size before performing this step. Using an inappropriate cup size could result in damage to the acetabular structure or transfixion of the pelvis.

**How to Navigate
Cup Insertion**

Figure 88

Steps	
1.	Bring the cup inserter into the camera field of view.
	Verify that the indicated inserter ⑤ is the one you are using.
2.	Verify that the cup size displayed ① matches the implant you are inserting.
3.	While holding the cup inserter in the camera field of view, use the navigation views ④ and meters ③ (including planned angles ②) to position the cup inserter in the planned orientation and position.
4.	If polar points were acquired, depth information is provided ⑥ to identify how well the cup implant is seated on the reamed acetabular floor. Depth information is the distance between the polar region of the cup (according to the current position) and the acquired polar points (see page 154).
	NOTE: Depth information is displayed when the cup is positioned within 10° of the planned inclination/anteversion.
5.	Insert the cup according to the manufacturer's instructions.
6.	Press **Store Position** to store/verify final cup position.

NOTE: If you have entered a pelvic tilt (see page 99), the values are shown both with and without pelvic tilt adjustment.

⚠

When hammering the cup inserter, check the marker spheres and reference arrays at regular intervals to make sure that they are securely attached.

⚠

The instrument adapter must remain attached to the inserter during calibration and navigation.

7.5 Cup Verification

7.5.1 Confirming Cup Verification Results

General Information

Once you complete cup insertion the software displays the values of the stored cup inserter position. The results displayed depend on your procedure.

Verification results are saved in the therapy report.

⚠

Be sure that the implant you selected is the implant you have actually used. The verification values provided are calculated based on the selected implants, and will otherwise be inaccurate.

⚠

Always check that the implant components are correctly positioned.

How to Perform Cup Verification by Acquiring Points

An optional step to verify the cup orientation by acquiring points on the cup implant is available via the **Options** menu.
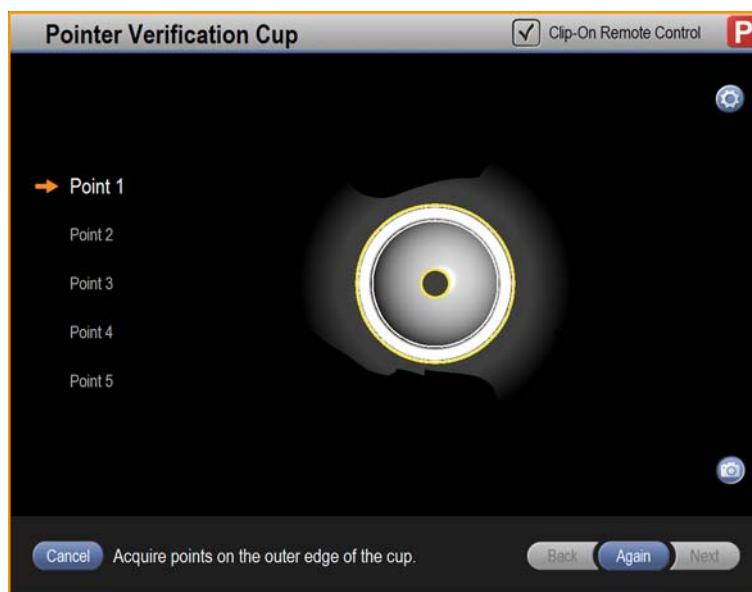
Figure 89

Step
Select **Pointer Verification** in the **Options** menu.
Use a pointer to acquire five points along the rim of the cup as indicated by the highlighted text.
NOTE: Once complete, the cup verification screen opens. This step only verifies the cup orientation, not cup position.

**How to Confirm
Cup Verification
Results**

Figure 90

Steps
1.	Check verified translational parameters ①, angles ② and depth information ④ (if polar points were acquired). *NOTE: The translational parameters are shown/hidden via **Additional Controls** in the **Options** menu.*
2.	Select the used liner from the available compatible liners ③.
3.	• Press **Next** to accept the cup positioning results and continue, or • Press **Clear Position** ④ to repeat cup verification

NOTE: If you have entered a pelvic tilt (see page 99), the values are shown both with and without pelvic tilt adjustment.

8 FEMUR STEPS

8.1 Chapter Overview

8.1.1 Contents

Topics Covered

Section	See
Femur Implant Planning THR	Page 160
Broach Navigation	Page 161
Head Planning SR	Page 165
Pin Navigation SR	Page 169

8.2 Femur Implant Planning THR

8.2.1 Overview

**General
Information**

On the **Femur Implant Position** screen, the position of the femur implant is shown aligned relative to the bone model, so that the CCD angle of the implant projects the neck axis of the implant onto an interception point with the calculated COR of the femur head.

Each femur implant in the implant database has a defined shaft axis encoded in the software.

Full femur implant planning is not possible in pointer-based registration, since only three registration points define the femur:

• The COR of the femoral head
• The piriformis fossa
• The midpoint of the epicondylar axis

After registration of the femur, you can adjust the stem size and head offset.

**How to Plan Femur
Implant Position**

Figure 91

Steps
1.   Adjust stem size, head offset and broach size as required ①.
2.   Press **Next** to update the treatment plan with the new implant settings.

8.3 Broach Navigation

8.3.1 Implant Insertion and Verification

Precautions

The displayed femoral antetorsion does not consider the built-in antetorsion of an implant.

If you use reflective marker spheres on, or in the vicinity of oscillating or vibrating instruments, or when hammering the broach handle, check the marker spheres at regular intervals to ensure that they are securely attached.

How to Navigate Broaching

Figure 92

Steps	
1.	Bring the broach into the camera field of view. Verify that the indicated broach ④ is the one you are using.
2.	Use the **Broach** size controls ① to adjust the size, if necessary.
3.	Make sure that the stem size and head offset displayed match those of the implant you are inserting. If you change the stem size or head offset, use the **Stem** and **Head Offset** controls ① to update the software accordingly.
4.	Use the views ③ and meters ② to navigate broaching. The meters show change in leg length, medial/lateral position and torsion based on the current broach position.
5.	• Press **Next** to proceed to femur implant verification (see page 163). • Press **Store Position** ⑤ to store final position and confirm results (see page 164).

*NOTE: The **Store Position** and **Next** buttons are only enabled when broach and stem size match. Similarly, leg length and medial/lateral information are only given when broach and stem size roughly match.*

8.3.2 Verification of Femur Implant Position

General Information

Once it has been positioned, you can verify the femur implant position.

Femur implant verification allows you to check that the final femur implant position is acceptable. The results are included in the therapy report and are confirmed in the next step (see page 164).

Instruments for Verification

Femur implant verification can be performed with:

- **Stem Position Verification Tool hip ct**
- **Stem Position Verification Tool Extended**

How to Verify Femur Implant Position
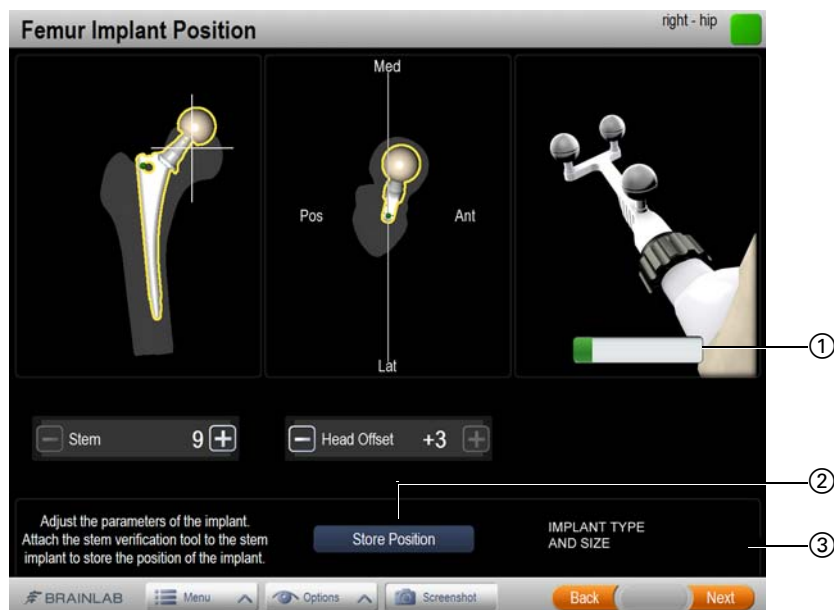
Figure 93

Steps	
1.	Check that the selected femur implant ③ matches the implant that was actually used.
2.	Place the appropriate **Stem Position Verification Tool** and sleeve onto the taper of the femur implant.
3.	Make sure the femur reference array and **Stem Position Verification Tool** remain steady in the camera field of view until the progress bar fills ①. Alternatively, use the **Store Position** button ②.

8.3.3 Confirming Femur Implant Position

**Femur Implant
Verification Results**

Figure 94

Steps
1. Check that the selected femur implant ③ matches the implant that was actually used.
2. Select the correct head offset ②.
3. Check that leg length, antetorsion and medial/lateral values ① are acceptable.
4. Press **Next**.

⚠

Be sure that the implant you selected is the implant you will actually use. The verification values provided are calculated based on the selected implants, and will otherwise be inaccurate.

⚠

Always check that the implant components are correctly positioned.

**How to Clear the
Stored Position**

Steps
1. Press **Clear Position** to delete the stored broach position.
2. Re-navigate the broach to the desired position.
3. Press **Store Position** to store the new broach position. *NOTE: You may adjust the broach and press the **Clear/Store Position** button as much as needed. Each time the **Store Position** button is pressed, the previous position is overwritten.*

8.4   Head Planning SR

8.4.1   Overview

General Information

Head planning comprises two steps:

- Planning the neck axis
- Planning the head implant

About Neck Axis Planning

In this step you adjust the calculated neck axis position to fit the anatomy of the femur neck.

The software calculates an initial neck axis position for the implant based on points you acquired. In neck axis planning you adjust the neck axis position manually or using the pointer to the optimal position. The adjusted neck axis is the starting basis for initial head implant positioning.

There is no need to repeat registration if you change the neck axis. Adjustments made on this screen correct initial implant position and/or size.

⚠

It is necessary to check and adapt the initially calculated neck axis. Check the planned neck axis against preoperative templating, in particular regarding neck shaft angle.

About Head Planning

The **Head Planning** screen shows cross-sectional "virtual slice" views through the femoral head and head implant with the implant size and position based on the acquired head surface points, the planned neck axis and the neck shaft angle.

On this screen you can scroll through "virtual slices" of the bone model to check the position of the implant.

You can manually adjust the position of the head implant or change the algorithm by which the implant is positioned.

8.4.2   Neck Axis Planning

**How to Plan the
Neck Axis**

Figure 95

	Steps
1.	Use the adjustment controls ④ to position the yellow planning axis ③ so that it passes through the COR of the hip joint and the center of the femur neck.
2.	Use the **Show Bone Model** check box in the **Options** menu to toggle the bone model off at least once during planning to verify that the planned axis is aligned accurately according to the acquired points.
3.	Hold a pointer in the camera field of view alongside the femur head and neck, parallel to the neck axis, to cross-check plausibility of the axis position. The pointer appears in the views and the pointer angle is displayed ②.
4.	Optionally, align the pointer to the desired neck shaft angle. Press the **Store Neck Shaft Angle** button to store the planning axis to the pointer angle.
5.	Press **Next** to apply your changes to the neck axis and continue to head planning. *NOTE: If you wish to return the axis to its original position, press **Reset**.*

⚠

Plan the neck axis to best fit the acquired points (green dots), not the bone model contours.

8.4.3   Head Implant Planning

How to Plan Head Implant

Figure 96

Step
Use the controls to adjust head size ①, neck shaft angle ② and implant position ③ as needed.

NOTE: Version information is related to the initially planned neck axis orientation, not to a neutral rotation of the femur (e.g., condyle axis).

⚠

Plan the implant to best fit the acquired points (green dots), not the bone model contours.

Fit to Neck Algorithm

The software initially positions the implant using a "Fit to Head" algorithm.

An alternate algorithm, "Fit to Neck", positions the implant based on the acquired neck points and so that the opening plane of the implant is aligned with the head-neck junction (the sizing point).

Options
To position and size the implant based on the "Fit to Neck" algorithm, press **Fit To Neck** ④.
To return the position and size of the implant to those based on the "Fit to Head" algorithm, press **Fit to Head** ④.

Scrolling Through Virtual Slices

You can change the level of the cross-sectional views through the bone model.

Options	
	To scroll through the virtual slices of the bone model, press the stack-scrolling arrows. As you scroll, section level lines transiently appear to show you the level of the virtual cross-section.
To return the views to their original slice level, press the **Reset Views** button ⑤.	

Notching Risks   There are two possible situations when the software displays an alert that the position of the planned implant presents a potential notching risk:

- When points are acquired outside of the position of the planned implant. This may indicate that the implant is not positioned optimally.
- When there are insufficient neck points for the software to determine a certain notching risk. Proceed with care when positioning the implant so as not to notch the bone.

When moving the pointer over the head surface, the pointer tip appears red if a notching risk is identified.

8.5 Pin Navigation SR

8.5.1 Pin Insertion and Verification

**How to Navigate
Pin Insertion/
Verification**

Figure 97

	Steps
1.	Using feedback from the angle meters ①, the target crosshairs ③ and the views ② on the **Femur Navigation** screen, align the drill guide (blue line and crosshair) with the planned axis for pin insertion (yellow line and crosshair).
2.	Perform pin insertion according to standard practice.
3.	Press **Store Axis** ④ to store/verify final drill guide position.
4.	Remove the **Drill Guide**.

*NOTE: If you did not select SR Head Verification during procedure planning, verify the values displayed after pressing **Store Axis**. To accept press **Next**, to repeat press **Clear Axis**.*

8.5.2   Head Verification

How to Verify Head Implant

Figure 98

Steps	
1.	Slide the **Stem Verification Tool hip ct** over the surface of the head implant until progress bar is full.
2.	Check that the displayed values are sufficient ①.
3.	• To accept, press **Finish/Next**. • To repeat verification, press **Clear Position** ②.

8.5.3 Confirming SR Verification Results

Screen Layout

Figure 99

Steps
1.   Compare the planned head implant position values to the verified values.
2.   • If the values are satisfactory, press **Finish**/**Next**.   • If the values are not satisfactory, press **Clear Position** to repeat verification.

⚠

Be sure that the implant you selected is the implant you will actually used. The verification values provided are calculated based on the selected implants, and will otherwise be inaccurate.

⚠

Always check that the implant components are correctly positioned.

9 ANALYSIS STEPS

9.1 Chapter Overview

9.1.1 Contents

Topics Covered

Section	See
Leg Situation Analysis	Page 174
Intraoperative Range of Motion	Page 177

9.2 Leg Situation Analysis

9.2.1 Overview

Standard Leg Situation Analysis	Leg situation analysis allows you to determine intraoperatively the difference in leg length and combined pelvic and femoral offset between the preoperative situation and the situation after joint reduction. Leg situation analysis is possible in the following workflows: • Cup Only • Cup and Stem This function is only enabled once the pelvis is registered and you have performed leg alignment during registration. The results of the leg situation analysis are saved in the therapy reports.
Trial Leg Situation Analysis	Trial leg situation analysis is an optional step in workflows that include leg situation analysis. Trial leg situation analysis is performed identically to final leg situation analysis.
Pinless Leg Situation Analysis	Pinless leg situation analysis is a required step in Express Leg Situation procedures and an optional step in Cup Only procedures performed with a **Pinless Femur Reference Array**. This function allows you to non-invasively determine the difference in leg length and combined pelvic and femoral offset following implant placement. During this step you reacquire the proximal femur landmark that was acquired during registration. *NOTE: If the **Pinless Femur Reference Array** loosens, valid leg situation analysis cannot be performed. No re-registration of the femur is possible once registration is complete.*

9.2.2 Leg Situation - Standard Femur Reference Array

**How to Perform
Standard Leg
Situation Analysis**
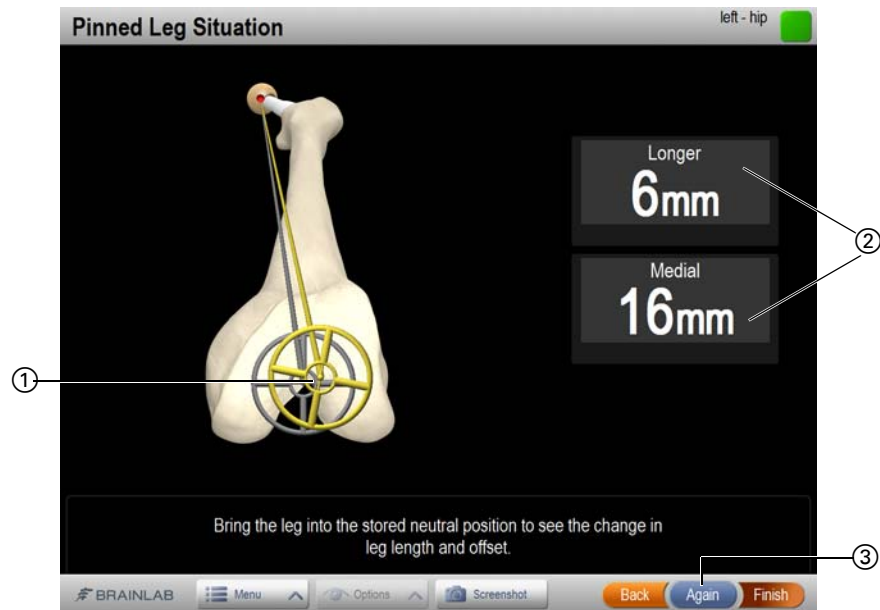
Figure 100

Steps	
1.	Bring the femur into the neutral position stored during leg alignment so that the centers of the crosshairs ① meet. When the crosshairs are sufficiently aligned (within 5° of stored leg alignment), the active crosshair turns green.
2.	Hold the leg steady for 2-3 seconds, until the change in leg length and offset values are displayed ②.
3.	• Press **Finish**. • If you wish to repeat leg situation analysis, press **Again** ③.

NOTE: For information on the calculation of leg length and offset, see page 185.

9.2.3 Leg Situation - Pinless Femur Reference Array

How to Perform Pinless Leg Situation Analysis
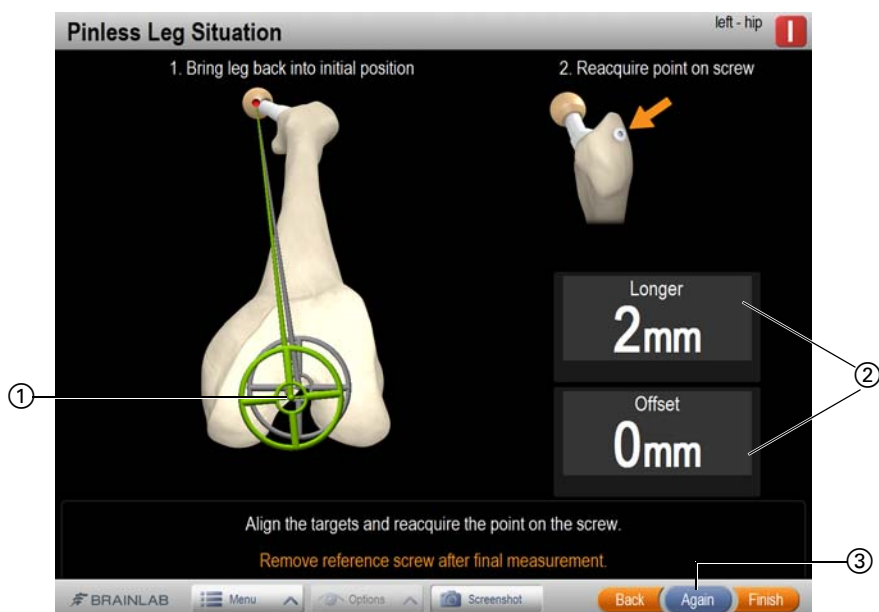
Figure 101

Steps	
1.	Bring the femur into the neutral position stored during leg alignment so that the centers of the crosshairs ① meet.
	When the crosshairs are sufficiently aligned (within 5° of stored leg alignment), the active crosshair turns green.
2.	While holding the femur in the stored neutral position, reacquire the proximal femur landmark as accurately as possible with a pointer.
	The change in leg length and offset are displayed ②.
3.	• Press **Finish**. • To repeat, press **Again** ③.
4.	Remove screw that was used for proximal femur landmark acquisition.

*NOTE: For information on the calculation of leg length and offset with the **Pinless Femur Reference Array**, see page 186.*

⚠

Ensure that the Pinless Femur Reference Array does not move when re-navigating the leg into the stored leg alignment position. Movement of the reference array may result in inaccurate postoperative results.

⚠

The screw used for registering the proximal femur landmark must be removed after reacquisition.

Pinless Leg Situation Warning Message

If the software detects a large shift in the postoperative measurement (a shift larger than 20 mm), a warning message is displayed indicating the result may not be sufficiently accurate.

This can occur due to an active clinical decision to create a large change, because the post operative point was taken inaccurately or because the reference array has been moved.

9.3 Intraoperative Range of Motion

9.3.1 Overview

General Information

Intraoperative range of motion (ROM) analysis allows you to determine and record the current ROM values with the implanted components in place. Optionally, you can measure impingement values to identify motions that could lead to hip dislocation.

The calculated ROM values are related to the pelvic planes, i.e., alignment of the femur with the pelvic planes is used as a neutral position (0° flexion/extension, 0° abduction/adduction, 0° internal/external rotation). This may differ from the common practice of judging motion with regard to the patient's coronal body plane. In a standing or lying position, the pelvic tilt respective to the patient's coronal body plane influences the calculated result.

When to Perform Intraoperative ROM

Though it is usually performed after the procedure, ROM analysis can be carried out at any time after the registration of the pelvis and femur.

Screen Layout
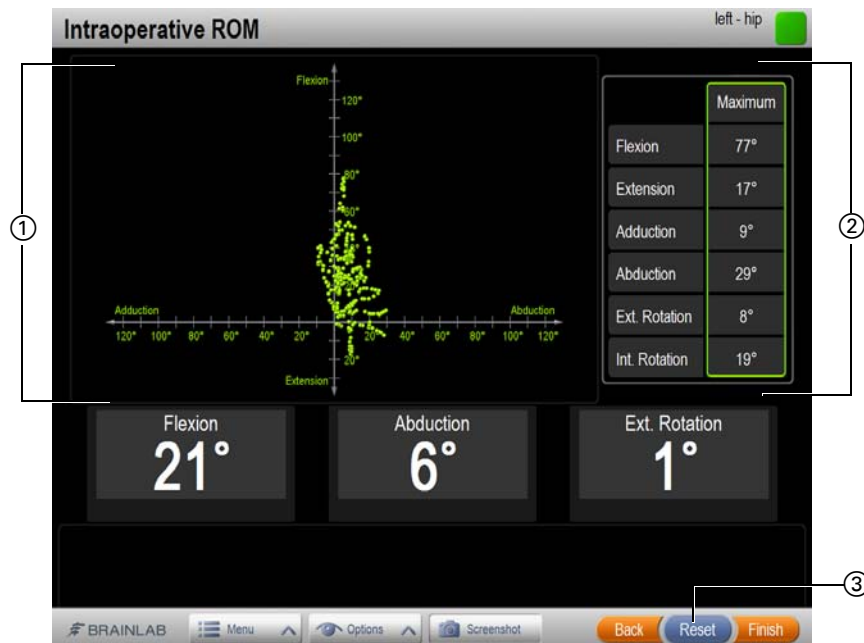
Figure 102

Steps	
1.	Start with the femur in the neutral position stored during leg alignment.
	Rotate the leg in the joint, using the full ROM. The graph displays a 2D point cloud of the registered ROM ①.
2.	The maximum detected values are displayed in the table ②.
3.	• Press **Finish**. • If you wish to repeat ROM analysis, press **Reset** ③.

**How to Perform
Impingement
Analysis**

Figure 103

Steps	
1.	Select **Impingement Analysis** in the **Options** menu.
2.	After locating the COR, move the patient's leg to test maximal ranges of movement using standard intraoperative ROM testing procedures.
3.	When the displayed ROM values identify an impingement: • Press **Accept Impingement** ① to add these values to the therapy report and continue with the impingement analysis • Press **Clear Impingement** ② to clear the current impingement values and continue with the impingement analysis • Press **Reset** ③ to reset the point cloud and begin a new analysis *NOTE: Impingement values are recorded as red dots in the point cloud.*
4.	Repeat steps 1-2 until you have tested all movements of interest.

10 APPENDIX

10.1 Chapter Overview

10.1.1 Contents
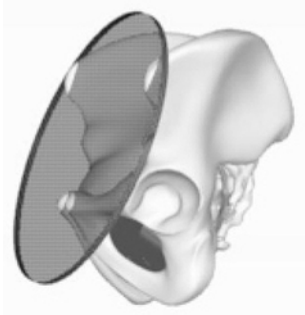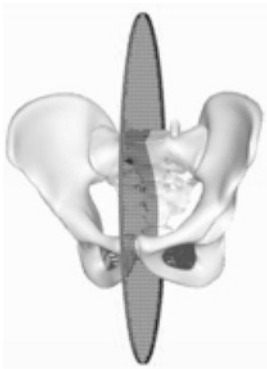
Topics Covered

Section	See
Important Planes and Angles	Page 180
Leg Length and Offset Measurement	Page 184
Supported Implants	Page 187

10.2   Important Planes and Angles
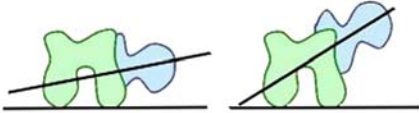
10.2.1   Planes

Pelvic Planes

Plane	Description
Anterior Pelvic Plane	 Figure 104 The anterior pelvic plane is defined by the anterior superior iliac spines (left and right) and the pubic tubercles. The anterior pelvic plane determines the angle of cup anteversion.
Mid-sagittal Plane	 Figure 105 The mid-sagittal plane bisects the pelvis as shown above. • The mid-sagittal plane determines the cup inclination angle (also known as cup abduction). • The current position of the anterior pelvic plane, together with the mid-sagittal plane is used as a basis for all calculations.

10.2.2   Angles
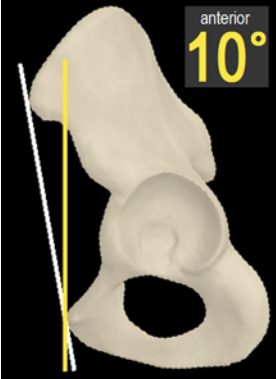
Femur Angles

Angle	Description
Femoral Antetorsion	 Figure 106 Antetorsion is the angle between the femoral neck axis and the axis of either the posterior condyles or the epicondyles of the femur. The AEP is an approximation of the posterior condyle axis.
CCD (*Centrum-Collum-Diaphysis*)	 Figure 107 The CCD angle or neck shaft angle, is the angle between the femoral neck axis and the femoral shaft axis.

Pelvis Angles

Angle	Description
Cup Anteversion (Radio-graphic)	Figure 108 Cup anteversion is the solid angle between the anterior pelvic plane and the cup axis. **Brainlab hip** references cup anteversion using the pelvic reference planes, rather than the standard body axis. This allows positional changes to be accurately tracked. The frontal body plane may deviate from the anterior pelvic plane, especially in the supine position. The absolute value of the cup anteversion therefore depends on the patient's position. *NOTE: For more information on acetabular orientation, see page 76 or Murray DW. The definition and measurement of acetabular orientation. J Bone Joint Surg Br. 1993 Mar; 75(2): 228-32.*
Cup Inclination (Radio-graphic)	Figure 109 Inclination is the solid angle between the mid-sagittal plane and the cup axis. The angles of cup anteversion and cup inclination are used to describe the angular orientation of the cup axis.

**Pelvis Angles
(Continued)**

Angle	Description
Pelvic Tilt	Pelvic tilt is the deviation between frontal body plane (yellow line) and anterior pelvic plane (white line) in a sagittal projection. Figure 110 • Anterior pelvic tilt: ASIS points lie more anterior than pubis points in relation to the frontal body plane. • Posterior pelvic tilt: ASIS points lie more posterior than pubis points in relation to the frontal body plane.

10.3   Leg Length and Offset Measurement

10.3.1   Overview

Measurement of Leg Length and Offset

Brainlab hip only measures changes in intraoperative leg length and offset. Differences between the treated and non-treated sides are not given. The surgeon must assess which leg length and offset changes are to be achieved.

NOTE: Measurements taken with X-rays have limitations. Misalignments of the leg (e.g., abduction, internal/external rotation, different femoral antetorsions) in imaging can compromise the accuracy of conventional pre-operative measurements, e.g., comparison between treated and non-treated sides. Additionally, inconsistent position of the femoral head within the acetabulum may compromise the measurements, as no precise definition of leg length and offset is available in these cases. For example, a decentralization/subluxation of the femoral head may present itself on an anteroposterior X-ray, but correct itself in the same patient lying on the operative table. Such differences must always be considered when comparing the results of the software with measurements on anteroposterior X-rays.

10.3.2   Pin-Based Leg Length/Offset Measurement

Preoperative Situation	• Surgeon places leg in a neutral position. • **Brainlab hip** stores a transformation matrix of the pelvis reference array to the femur reference array.
Postoperative Situation	• Surgeon repositions leg in a neutral position. • **Brainlab hip** stores a transformation matrix of the pelvis reference array to the femur reference array again.
Calculation	• **Brainlab hip** transforms the acetabular center of rotation into the femur coordinate system, based on the preoperative transformation matrix. • **Brainlab hip** transforms this point (COR in the femoral coordinate system) back into the pelvis coordinate system based on the postoperative transformation matrix. • The difference vector is decomposed into its components parallel to femur medial-lateral axis (leg offset) and cranial-caudal axis (leg length).

10.3.3 Pinless Leg Length/Offset Measurement

General Information

With pinless leg situation, **Brainlab hip** calculates total leg length and offset by monitoring the overall change in the position of a reference point located on the proximal femur. The position of the reference point is registered once prior to dislocation of the hip joint, and then again with the implants in place and the hip reduced. These measurements are an accumulation of leg length and offset changes caused by the femoral and acetabular implant components. It does not calculate information about pure femoral offset.

Measuring Leg Length and Offset

For these calculations, a reference axis ① is defined by the acetabular rim points ② and the **Pinless Reference Array**. This reference axis is used to assess the differences in the position of the proximal femoral point (③ and ⑥), which is marked by the **Proximal Reference Screw** to reproduce its position for pre- and postoperative measurements. The postoperative measurement ⑥ can be repeated as often as wished, (i.e., during intraoperative implant trialing and to confirm the measurement with the final implants in place).
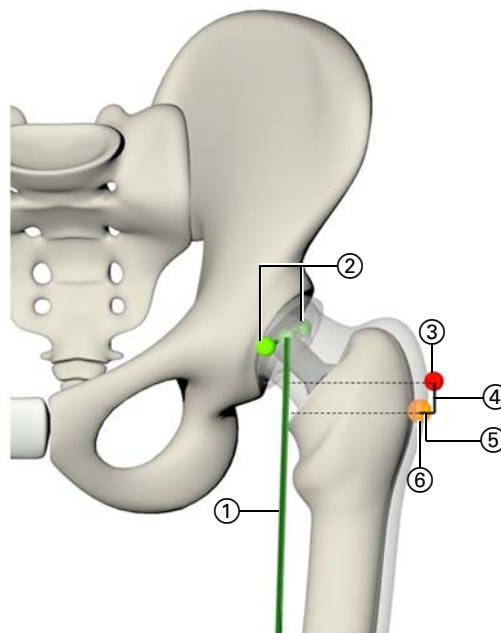
Figure 111

Leg length changes ④ are calculated as the shift of the proximal femoral point along the reference axis (i.e., cranial-caudal shift of the proximal point when projected onto the reference axis).

Offset changes ⑤ are calculated as the change in the distance of the proximal femoral point to the reference axis. This addresses the total offset caused by both the femoral and acetabular implant components, as the reference axis is defined relative to the stable pelvic coordinate system, and is not influenced by the postoperative shift of the center of rotation on the femoral side.

10.4 Supported Implants

10.4.1 Supported Implant Systems

General Information

Your software license determines which implants are available for use with your system.

Brainlab hip supports implants from the following manufacturers:

- Aesculap
- Biomet
- Corin Limited
- Smith & Nephew
- Wright Medical Technology
- Zimmer

Supported Implants

INDEX

W