



OMNIBotics™ Total Hip Application

INSTRUCTIONS FOR USE

Manufactured by:

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Standards

This product complies with the standards for medical electrical devices.
See the instructions for use for each system component listed in §1.3 “Associated documents”.

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Commercial Brand

OMNIBotics Bone Morphing™ is a trademark of OMNIlife science, Inc.

Modifications

The information given in this document is subject to modification without notice. We have done our utmost to ensure the accuracy of the information given in this document.

License and guarantee contract

See general sales conditions.

Training options

For safe and effective use of the medical device, the following training courses are recommended:

<i>Name</i>	<i>Reference</i>	<i>Duration</i>	<i>Frequency</i>
OMNIBotics™ Total Hip Application Instructions for Use	IFU-034	2 hours	Annual
OMNIBotics™ Station Instructions for Use	PRAXIM/0112/INMUTI/EN	2 hours	Annual

Table 1 - Description and reference codes for training courses

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1 Introduction

1.1 Purpose of the document

This document provides a set of instructions for use of the **OMNIBotics™ Total Hip Application** (OMNIBotics Total Hip) including use of its instrument kit. This document facilitates set-up of the OMNIBotics Station and its routine use with OMNIBotics Total Hip, as well as basic troubleshooting and maintenance phases. It is intended for any user surgeon, sales representative or hospital staff member that will be assisting a surgical procedure or providing supervision of the system. These personnel should also be trained on the OMNIBotics Station instructions and complete any additional training requirements set by OMNI.

1.2 Conventions




	WARNING: This symbol precedes any hazard involving the health and/or safety of users and patients.
	RECOMMENDATION: This symbol precedes any advice on the use of the system, which has no incidence on the health and/or safety of users and patients.

1.3 Associated documents

- OMNIBotics Station Instructions for Use (PRAXIM/0112/INMUTI/EN)
- OMNIBotics Tracker Kit Instructions for Use (IFU-035)
- CATH HIP INSTRUMENTATION Instructions for Use (IFU-033)

1.4 Special conditions for use

The OMNIBotics Total Hip Application should not be used without first having read the material listed in §1.3 “Associated documents”, and understanding their content.

 <p>Warning!</p>	<p>WARNING: The surgeon is to be thoroughly familiar with this system, implants, instruments, and duly trained in the computer assisted technique prior to performing surgery.</p>
	<p>RECOMMENDATION: Read and understand the entire Instructions for Use and the Associated Documents before using the OMNIBotics Station with OMNIBotics Total Hip.</p>
	<p>RECOMMENDATION: Access to the computer systems contained in the OMNIBotics Station is strictly reserved for personnel authorized by the manufacturer, OMNI.</p>

2 Overview

2.1 Intended Use

The OMNIBotics Total Hip Application is intended for use during stereotaxic surgery to aid the surgeon in locating anatomical structures.

The OMNIBotics Total Hip Application is for use solely with the OMNIBotics Station.

The OMNIBotics Total Hip Application is specifically intended for use in Total Hip Arthroplasty with the following OMNI Hip Systems:

- Apex Modular™ Interface™ Acetabular Cup
- Apex ARC™ Hip Stem (Monoblock and Modular)
- Paragon™ Stem
- Apex K1™ / K2™ Stem



WARNING: In the event that the OMNIBotics Total Hip fails and the surgeon must revert to conventional surgical protocol, make sure that a sterile set of conventional instruments for the Hip System is available before starting any procedure with the system.

Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.

2.2 Contraindications, Warnings, and Precautions

Contraindications :

- Any contraindications outlined for the above listed OMNI Hip Systems

Warnings and Precautions:

- Do not use with procedures or implants other than Total Hip Replacement using the listed OMNI Hip systems
- Surgeon should be duly trained in the computer assisted technique

2.3 Main functions


The main functions of the OMNIBotics Total Hip are the following:

- **Reamer Driver tracking:** Based on pelvic reference frame registration and proprietary OMNIBotics Bone Morphing™ Technology the user can virtually monitor 3D reaming. The system monitors the exact position of the reamer (anteversion, inclination, depth, centering). Compatible Reamer Driver is specific to OMNIBotics Total Hip and is provided as part of the OMNIBotics Total Hip Instruments Kit (for more details, see §4.7).
- **Cup Impactor tracking:** Based on pelvic reference frame registration and reamed surface, the system monitors the exact position of the cup (anteversion, inclination, depth/seating, centering). A cup Impactor dedicated to Apex Modular™ Interface™ Acetabular is provided as part of the OMNIBotics Total Hip Instruments Kit (for more details, see §4.8).
- **Leg length and offset control:** During the computer assisted protocol, the user can control leg length and offset without requiring an array pinned into the femur (for more details, see §4.9).


2.4 System and Accessories

The OMNIBotics Total Hip is part of the OMNIBotics System and must be used with the following system accessories:




- An OMNIBotics Station










PRODUCT CODE	QTY	DESCRIPTION	ILLUSTRATION
NV Series	1	OMNIBotics Station Full Station	








- A modular application software: OMNIBotics Total Hip Software

PRODUCT CODE	QTY	DESCRIPTION	ILLUSTRATION
NS-27004	1	OMNIBotics Total Hip Software	




- A set of instruments: OMNIBotics Total Hip Instrument Kit (HK-00001)

PRODUCT CODE	QTY	DESCRIPTION	ILLUSTRATION
CH-00001	1	CA Hip Instrument Pan	
CH-00011	1	Straight Pointer (P)	
CH-00008	1	Acetabular Array (A)	






CH-00009	1	Reamer Array (R)	
CH-00010	1	Impactor Array (I)	
4148-2000	1	Bone Screw Quick Socket	
4148-1001	4	Self Tapping and Self Drilling Bone Screw, Diameter 4.0mm, 150mm, Thread 45mm	
4148-1002	4	Self Tapping and Self Drilling Bone Screw, Diameter 4.0mm, 120mm, Thread 45mm	
4148-1004	4	Self Tapping and Self Drilling Bone Screw, Diameter 3.2mm, 80mm, Thread 30mm	
4148-1005	4	Self Tapping and Self Drilling Bone Screw, Diameter 3.2mm, 110mm, Thread 40mm	
4149-5000	1	Two Pin Universal Fixation	
CH-00023	1	Two Pin Universal Fixation with Square Drive	
4154-5000	1	Universal Reattachable Joint Ø6.9mm Adaptor	
CH-00016	1	Angled Array Holder	
CH-00017	1	Straight Array Holder	
CH-00012	4	Reference Pin	

CH-00019	2	Dual Wing Screw	
CH-00015	2	Dual Wing Pin	
CH-00018	1	Dual Wing Plate, Posterior	
CH-00024	1	Dual Wing Plate, Anterior	
KS-90033	1	Pin Puller	
CH-00022	1	7mm Square Drive Screwdriver	
CH-00025	1	Dual Wing Plate, Inserter	

Straight Instruments for Apex Modular™ Interface™ Acetabular Cup

PRODUCT CODE	QTY	DESCRIPTION	ILLUSTRATION
CH-00002	1	Straight Reamer Driver	
CH-00003	1	Straight Reamer Stop	
CH-00004	1	Straight Reamer Sleeve	

OVERVIEW

CH-00005	1	Straight Reamer Arm	
CH-00006	1	Straight Impactor Base	
CH-00007	1	Straight Impactor Arm	
CH-00013	1	Straight Impactor Calibration Gage	
9-144	1	3.5mm Hex Driver	

- Some disposables: OMNIBotics Tracker Kit containing single use markers delivered sterile.

PRODUCT CODE	QTY	DESCRIPTION	ILLUSTRATION
RM-10000	1	OMNIBotics Tracker Kit Contains: 20 Sterile Markers (1301-1020) + 1 USB Drive	

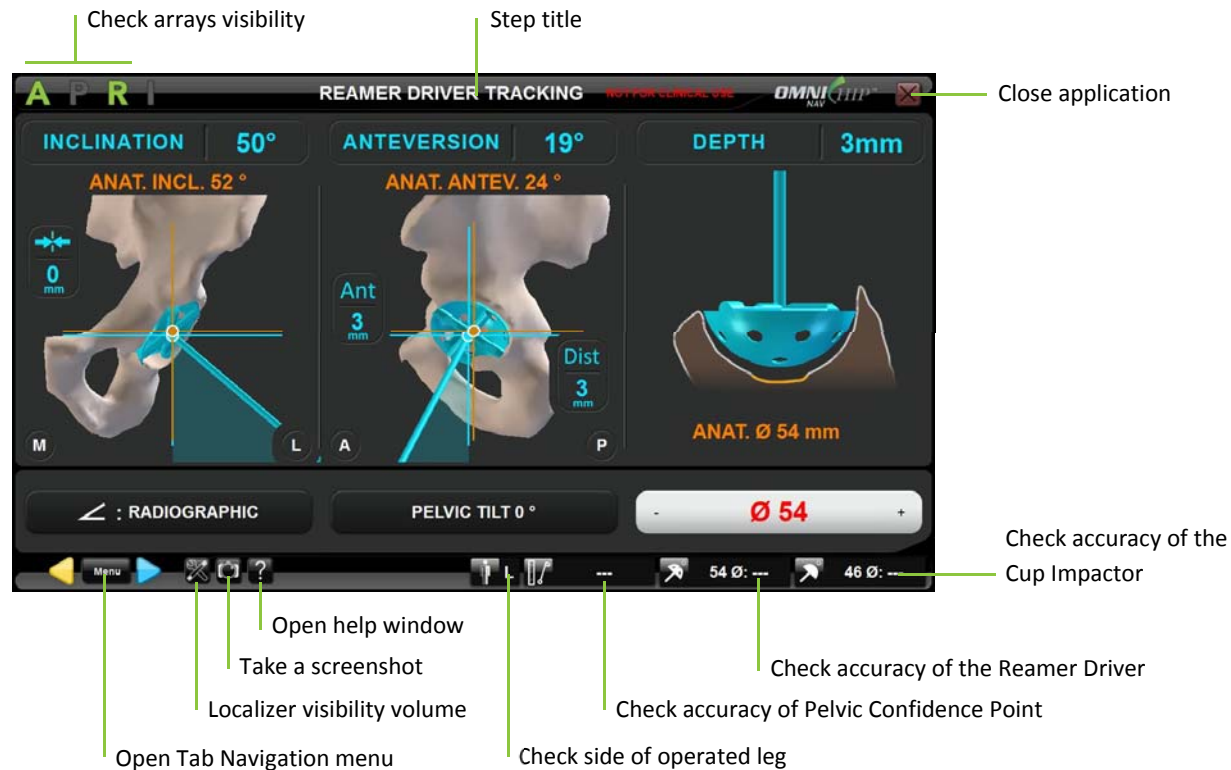
2.5 Accuracy

The global accuracy of the OMNIBotics System with OMNIBotics Total Hip Application as determined in bench test conditions is $\pm 1\text{mm}$ and $\pm 1^\circ$ (see table below) and meets the requirements of ASTM F2554-10 *Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems*.



Accuracy (absolute error) of the OMNIBotics Total Hip Application as measured in bench test conditions		
	Angular [°]	Linear [mm]
Mean	0.14	0.39
Standard Deviation	0.35	0.51
95 th percentile	1	1
Maximum	1	2

2.6 User Interface





During the protocol, the system is controlled via the OMNIBotics Total Hip Software graphical user interface. This interface has been designed and optimized for use on touch screens of the OMNIBotics Station.





Going forward and backward in the workflow:

- Touch  to start an acquisition or to validate a step.
- Touch  to go back to a previous step.

Note: When going back to a previous step, only the step that you go back to needs to be reacquired.





The OMNIBotics Station is equipped with a three switch foot pedal. The use of the blue pedal is equivalent to  forward. The use of the yellow pedal is equivalent to  back. The use of the black switch on the foot pedal is equivalent to  / .

Reviewing or moving to another step in the workflow: Touch  to open the Tab Navigation Menu and select the step to review. Double click the corresponding tab or touch  to go to the selected step (for more details see §5.4).


Checking reference visibility:


The OMNIBotics Total Hip Instrument Kit includes four arrays that are equipped with posts that allow for the attachment of disposable reflective markers. These arrays are A for Acetabulum, P for Pointer, R for Reamer and I for Impactor. The OMNIBotics Total Hip Software indicates which arrays are required during the computer assisted protocol.


Examples:

-  indicates that the Acetabulum array is visible.
-  indicates that the Pointer array is visible.
-  indicates that the Reamer array is required but it is not visible.
-  indicates that the Impactor array is not visible but it is not required.


Note: “INFRARED DETECTED” in the upper part of the screen indicates that the system cannot detect the arrays due to infrared interference.


Checking the localizer visibility volume: Touch  to display the References and Camera screen. This will show the location of the arrays in the localizer visibility volume.


	RECOMMENDATION: Make sure that only one set of arrays (A, P, R and I) is in the camera field of view.
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 **Taking a screenshot:** The current screen will be saved to the report.


Note: Screenshots can be exported to external media (USB drive) at the end of the computer assisted procedure.

 **Help screen:** Displays the Help window and provides detailed information about actions required to complete the current step.


 **Operated hip indicator:** The operated hip is indicated by a letter (L for left, R is for right).

 **Accuracy of acetabulum array position:** Place the ball-tip of the Pointer on the confidence point. The distance between the Pointer tip and the previously registered confidence point position is shown. The distance should remain $0\pm 1.0\text{mm}$ during the entire procedure to ensure the A array is properly secured and fixed to the bone.

Note: The P array and A array must both be visible and is only available after pelvic confidence point registration has been completed.

 **Accuracy of Reamer Driver:** Place the ball-tip of the Pointer in contact with the outer surface of the reamer basket in an area with no teeth. The distance between the Pointer tip and the calibrated reamer surface is shown for the diameter indicated. The distance should be $0\pm 1.0\text{mm}$.

Note: The P array and R array must both be visible and is only available after Reamer Driver calibration has been completed.

 **Accuracy of Cup Impactor:** Place the ball-tip of the Pointer in contact with the outer surface of the trial shell. The distance between the Pointer tip and the calibrated shell surface is shown for the diameter indicated. The distance should be $0\pm 1.0\text{mm}$.

Note: The P array and I array must both be visible and is only available after Cup Impactor calibration has been completed.

 **Close the application:** Closes the navigation software and will prompt to save the navigation report.

3 Starting the system

3.1 Required personnel

No additional staff is required for the operation of the system other than those required for conventional total hip arthroplasty.

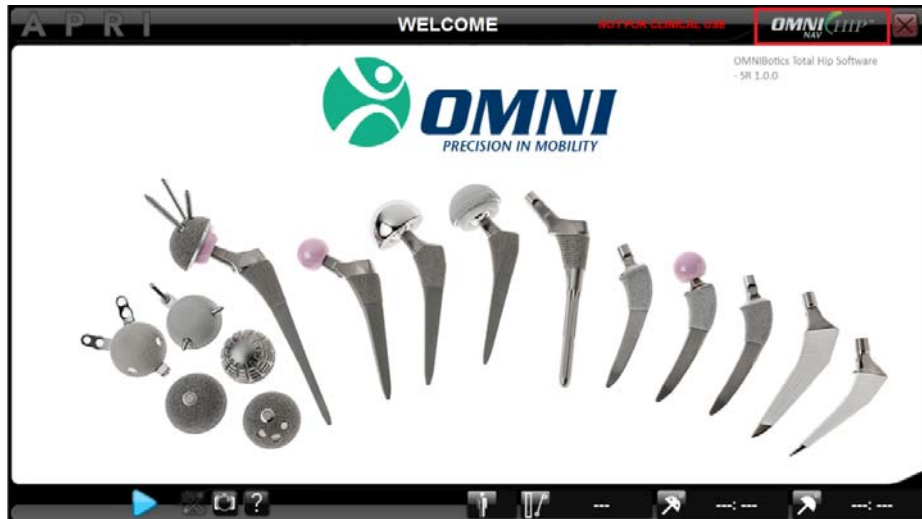
3.2 Preparation of the system


OMNIBotics CATH Hip Instruments (HK-00001) as well as OMNI Hip Systems instruments Kit must be sterilized prior to use. For more information about instrument cleaning, inspection or sterilization refer to IFU-033.

An OMNIBotics Tracker Kit (RM-10000) is required for each use of the system. It contains a box of 20 single use sterile reflective markers dedicated to work with the OMNIBotics Station and OMNIBotics Total Hip. A minimum of 16 markers are required and 4 additional markers are included in case one or more markers are damaged during surgery and require replacement (detaches, soiled, etc.).


3.3 Starting the application

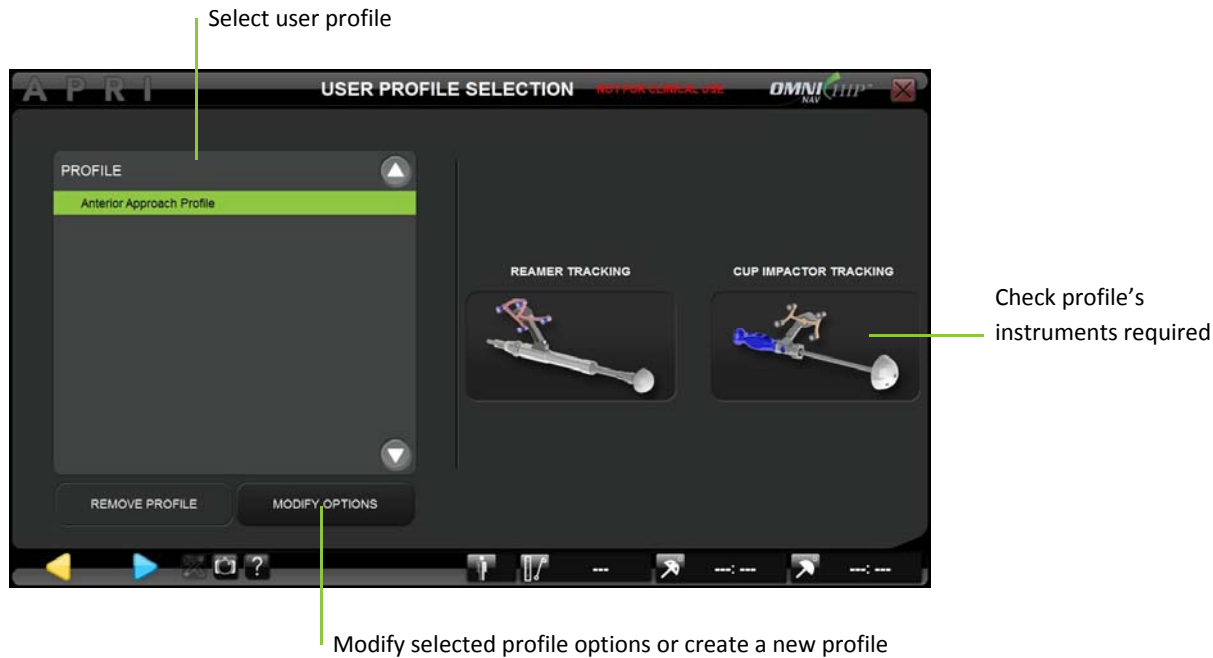
Launching the OMNIBotics Total Hip Software: Turn on the OMNIBotics Station and touch the OMNIBotics Total Hip Software icon on the screen (for more details refer to OMNIBotics Station – Instructions for use). Once the application has started it displays the following “Welcome” screen:



Touch  to go to “User Profile Selection”.

3.4 User profile selection

Select the profile: Touch the name of the profile in the user profile list and verify that the illustrated instruments are the desired instruments for use. If no modification is required to the selected profile then touch  to go to “Patient Information”.

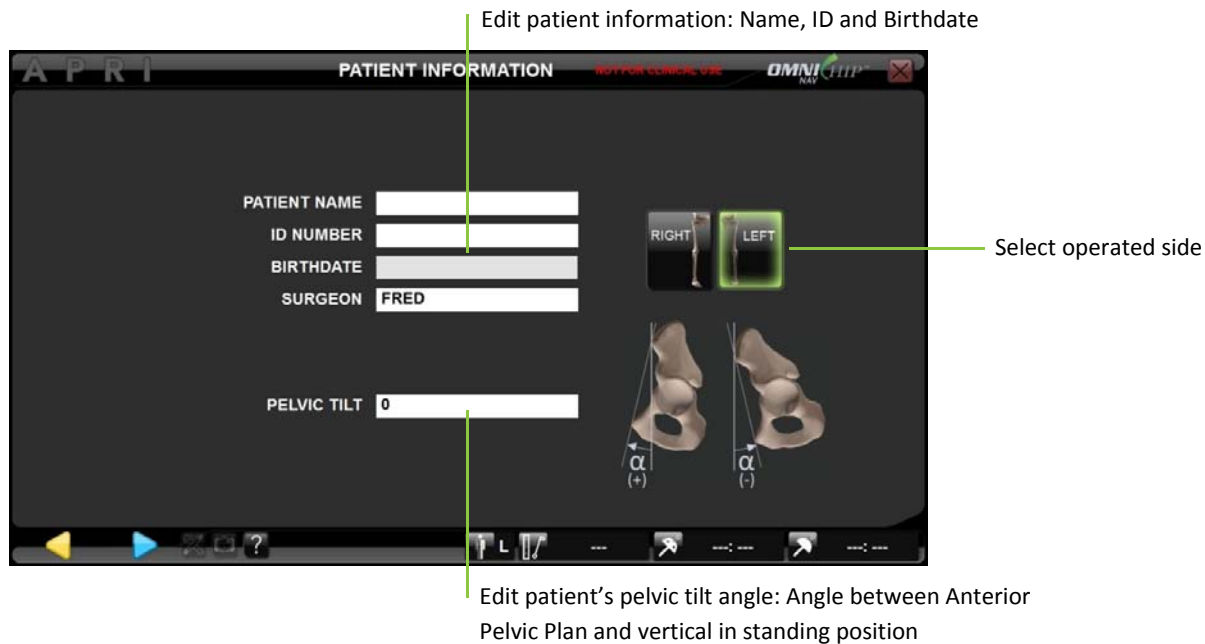


Note: OMNIBotics Total Hip Software is preinstalled on every station with one default profile recommended by OMNI:

- Anterior Approach: This profile is set up for an anterior approach technique using straight instruments. Inclination and Anteversion angles computation relies on the acquisition of the Anterior Pelvic Plane.
- For additional information about predefined profile refer to §5.2.

Creating/modifying a profile: Touch the profile to modify and touch MODIFY OPTIONS (for more details see §5.3).

3.5 Patient information



Editing patient information: Touch any text input field and use the laptop keyboard to enter the information.

Selecting operated hip side:


- Touch the Right or Left button.

Note: The operated side must be selected before proceeding to the next step.

Setting the Pelvic Tilt Angle:

- Touch the “PELVIC TILT” text input field and use the laptop keyboard to enter an angle between -90° and +90° (for more details – See §6.2).

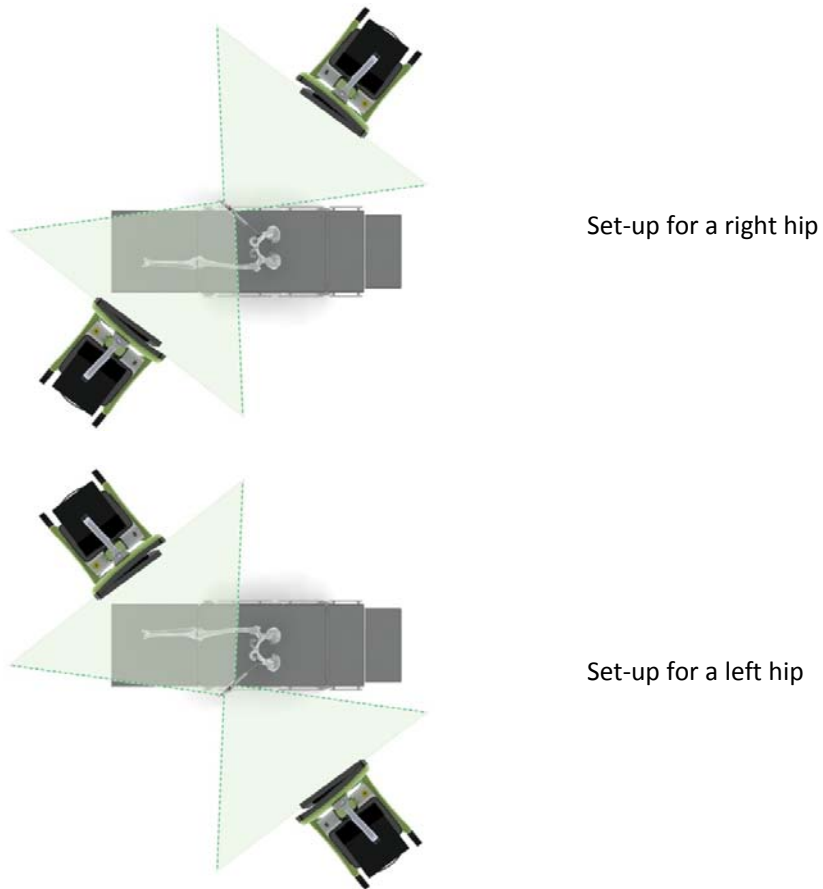
Note: The pelvic tilt angle can be modified later during the Reamer Driver Tracking and/or Cup Impactor Tracking steps.

- Touch  to go to “Pointer Calibration”.

3.6 Positioning the navigation station



Anterior Approach set-up: In the operating room the navigation system can be positioned on either side of the operating table outside the patient environment. It is recommended that the system be set up at foot end on the opposite side of the patient from the surgeon.

The camera should be placed approximately 5 to 6 feet (1.5 to 1.8 meters) from the hip.



3.7 Storage and handling

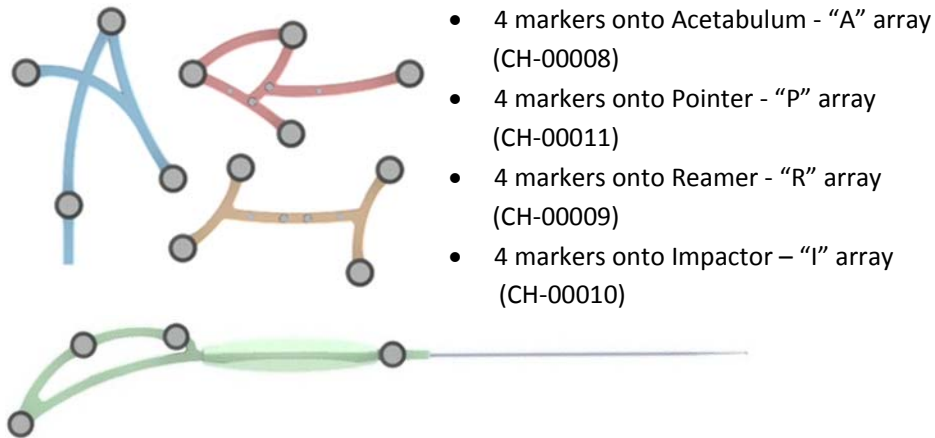
See the instructions for use of the system components listed in §1.3 « Associated documents ».

 Warning!	WARNING: Instruments must be decontaminated and sterilized by autoclave after each use.
 Warning!	WARNING: Loosen all screws before cleaning, decontaminating and sterilizing the instruments.



4 Using the system

4.1 Preparation of arrays

Unpack the OMNIBotics Tracker Kit (RM-10000) which contains one box of 20 Sterile Markers (1301-1020). Attach a marker on each post of the arrays.



Note: The reflective surface of the marker is fragile and sensitive to soiling. They should be handled with care and avoid touching the reflective surface with dirty gloves.

 Warning!	WARNING: The markers must be securely attached to the posts of the arrays. Correct fixation is characterized by a "click".
 Warning!	WARNING: The markers are disposable and single use.

4.2 Preparation of navigation instruments



Verify instruments and screws: Before each use of the system, verify that there is no mechanical play in assemblies or abnormal deformations of instruments and screws. Check all reproducible interfaces. Do not use the system or replace parts if any faults are observed.

See the instructions for use of the system components listed in §1.3 « Associated documents ».

4.3 Tracked Instruments

OMNIBotics Total Hip provides a straight Reamer Driver and a straight Cup Impactor as dedicated tools for acetabulum preparation and cup placement. These instruments are compatible with Apex Modular™ Interface™ Acetabular Cup conventional instrumentation set supplied by OMNI.

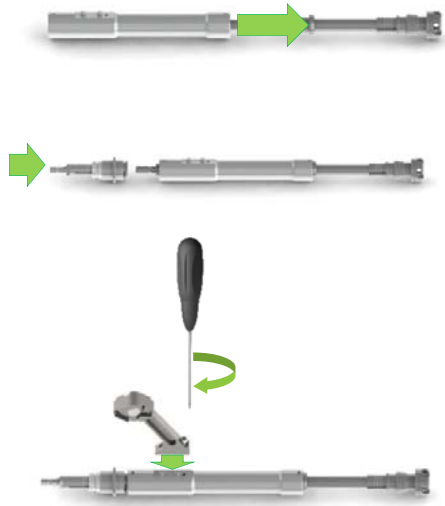
The following instruments require calibration before use with the system:

PRODUCT CODE	DESCRIPTION	SUPPLIER	ILLUSTRATION	COMPATIBILITY
CH-00002 To CH-00005	Straight Reamer Driver with Arm	OMNI		OMNI Acetabular Reamer Kit (HK-60020)
CH-00006 CH-00007	Straight Cup Impactor with Arm	OMNI		Apex Modular™ Interface™ Acetabular Cup



WARNING: Do not leave any sharp instrument (knife, blade, etc...) near the Impactor Arm and Reamer Arm due to the embedded magnets

Assembling the straight Reamer Driver with Sleeve, Stop and Arm:



1. Slide the Straight Reamer Sleeve (CH-00004) over the Straight Reamer Driver (CH-00002).
2. Connect the Straight Reamer Stop (CH-00003) to the back end of the Straight Reamer Driver.
3. Use the 3.5mm Hex Driver (9-144) to secure the Straight Reamer Arm to the Straight Reamer Sleeve. The hex screw should be finger tightened and then rotated another quarter turn to ensure it is completely seated. The arm should be oriented toward the back end of the Straight Reamer Driver.

Note: There is only one way to assemble the Straight Reamer Sleeve with the Straight Reamer Driver as well as there is only one way to assemble the Straight Reamer Arm with the Straight Reamer Sleeve. Once assembled no significant play should be noticeable between the sleeve and the Driver and Driver should rotate freely within the sleeve.

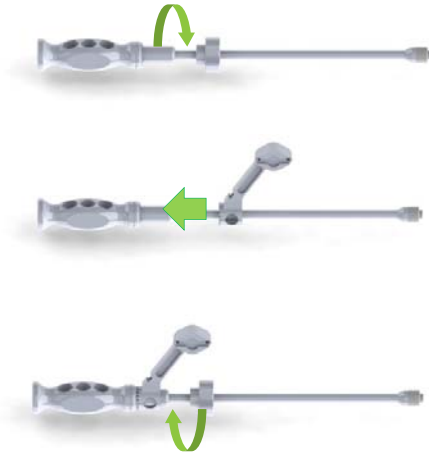
Attaching the “R” array to the Reamer Driver:



Align the two pins in the Reamer Array (CH-00009) with the hole/slot pattern in the Straight Reamer Arm. Bring the “R” Array close to the face of the Arm until the magnetic attachment engages. The Array should sit flush with the face of the Arm and within the corresponding cutouts.

Note: “R” array can be attached to either right or left face of the Reamer Arm depending on the approach and the operated side. In case of mistake it is still possible to change position of the array at any time and software will address new position automatically.

Assembling the Straight Cup Impactor with Arm:



1. Remove the knob from the Straight Impactor Base (CH-00006).
2. Slide the Straight Impactor Arm (CH-00007) over the Straight Impactor Base. The arm should be oriented toward the front end of the Straight Impactor Base.
3. Secure the Straight Impactor Arm to the Straight Impactor Base with the Straight Impactor Base knob. The knob should be finger tightened and then rotated another quarter turn to ensure it is completely seated.

Note: Once assembled the arm should be solid to the Cup Impactor. It is possible to modify the position in rotation of the arm until Cup Impactor Calibration has been performed. If during cup impaction it is required to change the arm position in rotation then it is recommended to recalibrate the Cup Impactor using Menu.

Attaching the “I” array to the Cup Impactor:



Align the two pins in the Impactor Array (CH-00010) with the hole/slot pattern in the Straight Impactor Arm. Bring the “I” Array close to the face of the Arm until the magnetic attachment engages. The Array should sit flush with the face of the Arm and within the corresponding cutouts.

Note: “I” array can be attached to either right or left face of the Impactor Arm depending on the approach and the operated side. In case of mistake it is still possible to change position of the array at any time and software will address new position automatically.

4.4 Instruments calibration



RECOMMENDATION:

- Do not push on or bend the Pointer during calibration.
- The Pointer axis should be approximately aligned with the instrument axis during calibration.
- The ball-tip of the Pointer should be completely inside each cone during calibration.
- Instruments are centered in the visibility volume of the tracking system camera (depth and centering) during calibration.

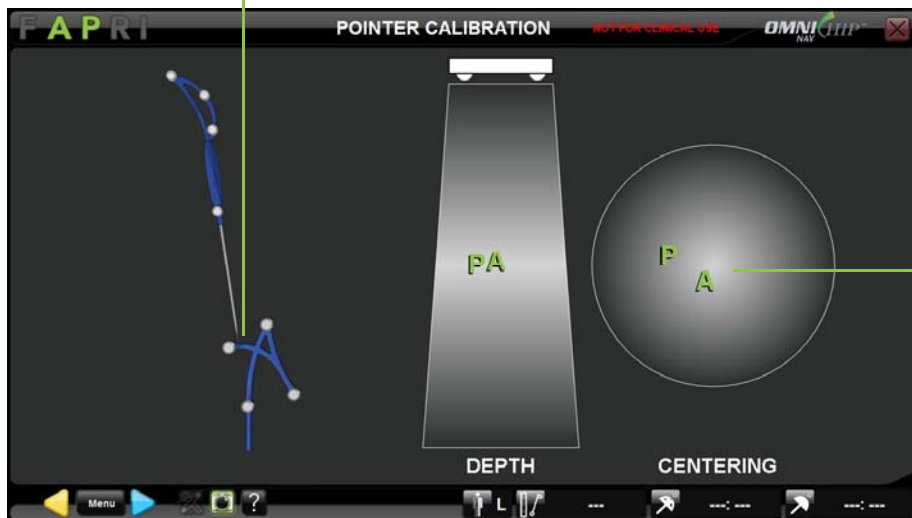


Warning!


WARNING: If any calibrated instrument must be replaced during the procedure then accuracy of the replacement instrument is no longer guaranteed. The replacement instrument must be recalibrated before being used (See §5.4).

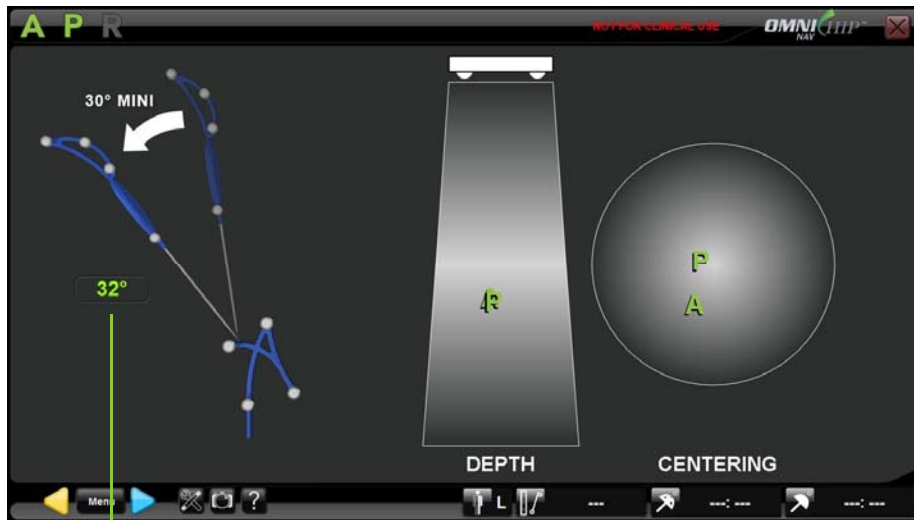
Calibrating the Pointer

Check position of the calibration cone on the A array




Check reference location
in the visibility volume of
the tracking system
camera

- Place the ball-tip of the Pointer (CH-00011) into the calibration cone of the “A” array (CH-00008) and check that A and P are visible to the tracking system then touch  to register the first position of the Pointer.



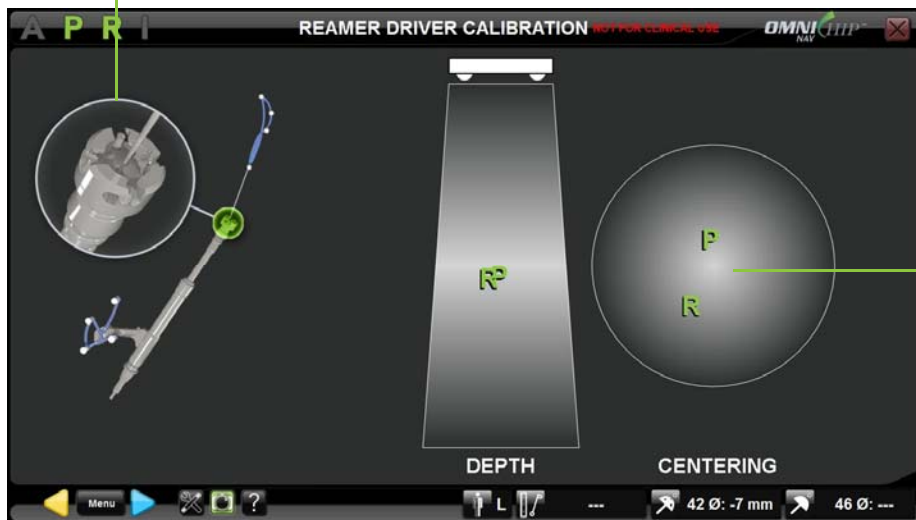
Control Pointer tilt

- Tilt the Pointer by at least 30° and check that A and P are visible then touch  to register the second position of the Pointer.


Note: The software will detect if Pointer tilt angle is at least 30° between the two positions. In such case calibration of the Pointer will be restarted automatically.

Calibrating the Reamer Driver

Check position of the calibration cone on Reamer Driver

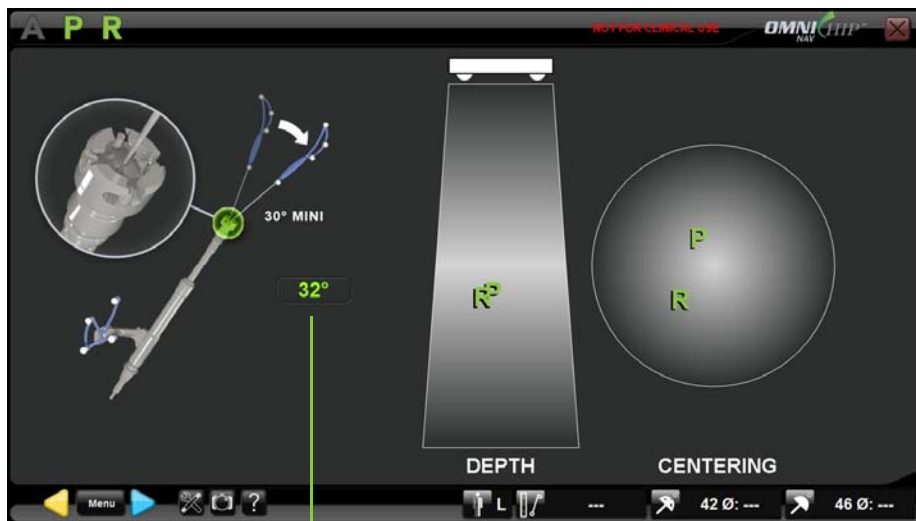


Check reference location
in the visibility volume of
the tracking system
camera


- Place the ball-tip of the Pointer (CH-00011) into the calibration cone of the Reamer Driver (CH-00002) and check that R and P are visible to the tracking system then touch  to register the first position of the Pointer.



RECOMMENDATION: Ensure that the Reamer Sleeve is flush against the front stop of the Reamer Driver when performing the calibration



Control Pointer tilt

- Tilt the Pointer by at least 30° and check that R and P are visible then touch  to register the second position of the Pointer.

Note: The software will detect if Pointer tilt angle is at least 30° between the two positions. In such case calibration of the Pointer will be restarted automatically. The software will also detect if the Reamer Driver is out of calibration by more than 1.5° or 2°.



RECOMMENDATION: If the Reamer Driver is out of angular calibration (error message) then check that the Reamer is correctly assembled (See §4.3) and retry to calibrate the Reamer Driver.



WARNING: If sufficient attempts have been made to correct the issue and error message remains, surgeon may proceed with the understanding that the angular outputs, both anteversion and inclination may be outside of the desired accuracy limits.

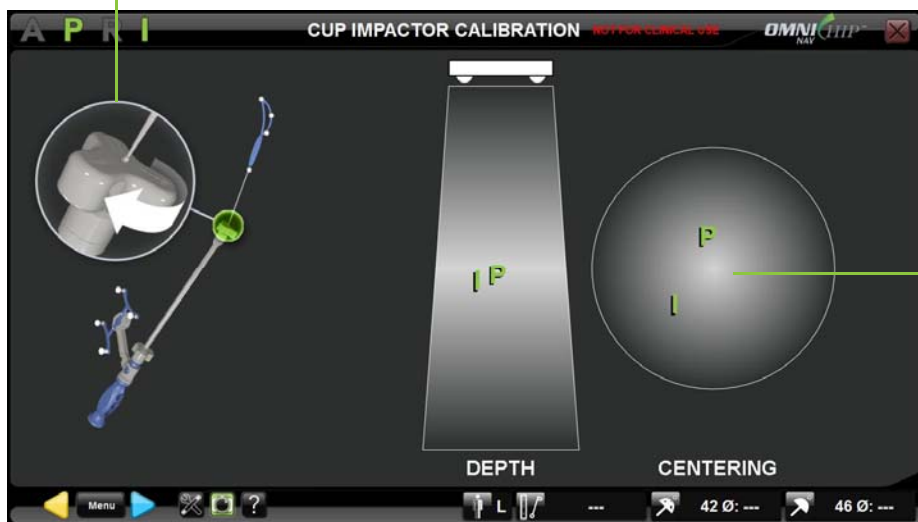
Calibrating the Cup Impactor




Tighten the Straight Impactor Calibration Gage (CH-00013) onto Straight Impactor Base (CH-00006) equipped with Straight Impactor Arm (CH-00005) and Impactor Array (CH-00010).

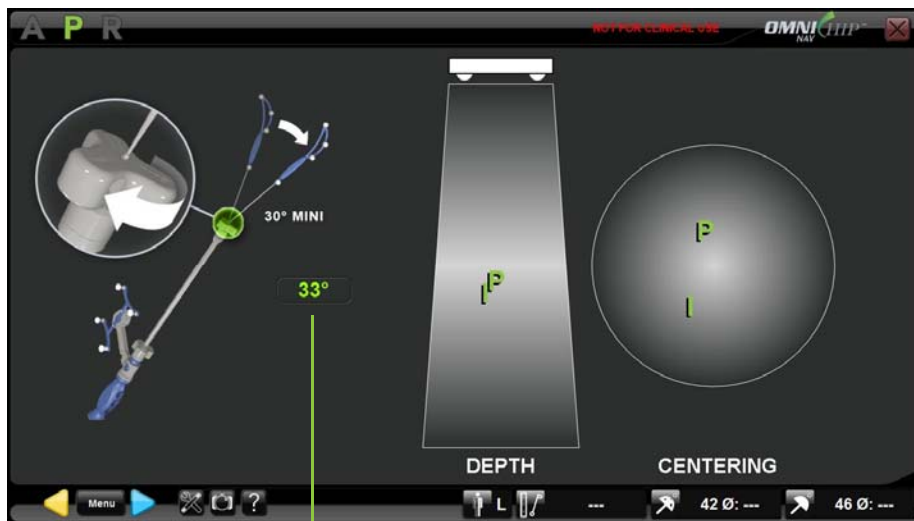
Note: Ensure that the Straight Impactor Calibration Gage is fully seated prior to calibrating the Straight Impactor Base.

Check position of the calibration cone on Cup Impactor Calibration Gage



Check reference location in the visibility volume of the tracking system camera

- Place the ball-tip of the Pointer (CH-00011) into the calibration cone of the Calibration Gage and check that I and P are visible to the tracking system then touch  to register the first position of the Pointer.



Control Pointer tilt

- Tilt the Pointer by at least 30° and check that I and P are visible then touch  register the second position of the Pointer.

Note: The software will detect if Pointer tilt angle is at least 30° between the two positions. In such case calibration of the Pointer will be restarted automatically. The software will also detect if the Cup Impactor is out of axial calibration by more than 1mm or out of angular calibration by more than 1.5° or 2°.



RECOMMENDATION:

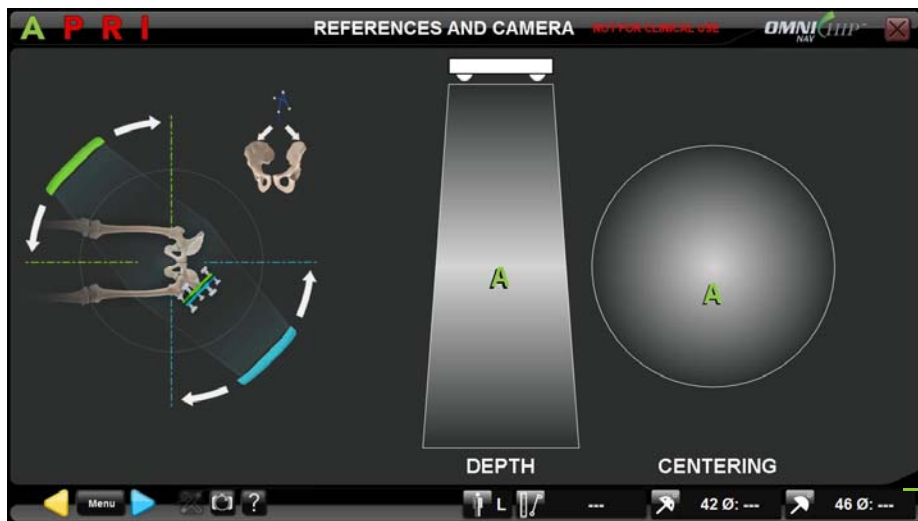
- If the Cup Impactor is out of axial calibration (error message) then check that the Calibration Gage is correctly assembled and retry to calibrate the Cup Impactor.
- If the Cup Impactor is out of angular calibration (error message) then check that the Impactor Arm and array are correctly assembled (See §4.3) and retry to calibrate the Cup Impactor.



WARNING: If sufficient attempts have been made to correct the issue and error message for angular calibration remains, surgeon may proceed with the understanding that the angular outputs, both anteversion and inclination may be outside of the desired accuracy limits.

Controlling tracked instruments calibration:

Accuracy of the Reamer Driver and Cup Impactor calibration can be checked any time during the procedure after the initial calibration is done.



Check accuracy of the Reamer Driver and Cup Impactor calibration

- **Reamer Driver:** With “R” array and 42mm reamer basket attached to the Reamer Driver (See §4.3), place the ball-tip of the Pointer (CH-00011) on the outer surface of the 42mm reamer basket and check accuracy of the Reamer tracking on the screen.
- **Cup Impactor:** With “I” array and 46mm trial shell attached to the Cup Impactor (See §4.3), place the ball-tip of the Pointer on the outer surface of the 46mm trial shell and check accuracy of the cup tracking on the screen.



RECOMMENDATION: Check tracked instruments accuracy before each use.

4.5 References and Camera positioning

General recommendations for Self-Tapping and Self Drilling Bone Screw

- **Required instruments**

The following instruments are required to use the screws:

- Bone screw quick socket (4148-2000)
- Power drill for insertion of bone screws

- **Screw insertion**

Attach the socket to the drill chuck to insert the screw. Choose a screw with the appropriate length for the patient's anatomy. Insert the screw in the socket and drill the screw into the bone. Pull the drill to detach it from the screw once it is sufficiently inserted into the bone. The system is used in the same way to remove the screws.



WARNING: The use of a bone fixation requires the consideration of all the risks linked to this type of device, in particular those regarding the quality of the bone.

- **Usage restriction**



WARNING: Use with a low-speed drill. The screws must not be used if any deformity, signs of damage or an abnormal wear and tear, particularly on the tip, is detected. Such defects may cause the screw to become irreversibly blocked or seized within the instrument that it is intended to be used with.

- **Prion risk**



WARNING: If there is a risk that the patient is infected with Creutzfeld-Jacob disease, the screws must be disposed of appropriately

General recommendations for re-attachable bone fixation - hip

This fixation (4149-5000 and 4154-5000) is used to attach the A array onto the patient's pelvis in such a way that they are visible to the navigation system camera.



RECOMMENDATION:

- OMNI recommends the use of OMNI pins and screws. However, it is possible to use the majority of bone screws with a diameter of between 3 and 4 mm.
- The system can be used in the incision or percutaneously. If the system is used percutaneously, ensure that you prepare the skin in accordance with your usual method.



WARNING: Do not use the instrument if any looseness is detected between the different components once the assembly has been locked together.

Attaching the Acetabular Array to the patient pelvis:

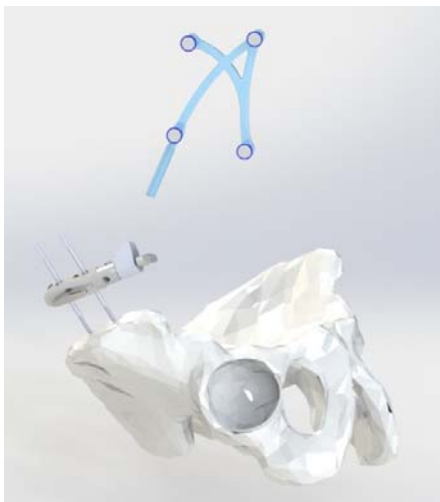
The “A” array (CH-00008) must be securely attached onto the pelvis using the Two Pin Universal Fixation (4149-5000) or using the optional array holders detailed below.

Note: The “A” array can be attached either onto the ipsilateral side or contralateral side of the operated hip.

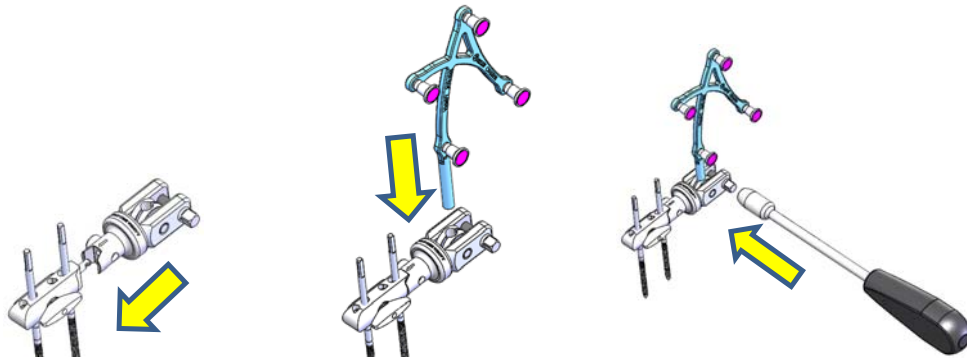


Place the first 4 mm Bone Screw (4148-1001 or 4148-1002) into the iliac crest using the Multi Diameter Quick Socket (4148-2000). Evaluate the placement to avoid conflict with instruments during the acetabulum reaming and femur broaching process.

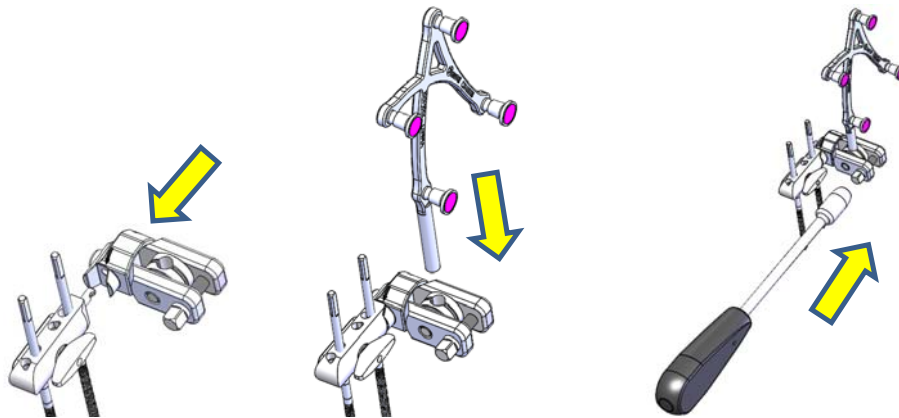
The placement of the second screw can be done using the Two Pin Universal Fixation as a drill guide.



Secure the Two Pin Universal Fixation manually on the two screws by tightening the thumbscrew or the square drive bolt with the 7mm Square Drive Screwdriver (CH-00022). It is important that the bone screws have solid bone fixation and the Two Pin Universal Fixation is firmly clamped onto the screws. Attach the “A” array to the Two Pin Universal Fixation with the Universal Re-attachable Joint Ø6.9mm Adaptor (4154-5000) or Angled Array Holder (CH-00016) or Straight Array Holder (CH-00017). Orient the optical markers of the “A” array toward the station camera and tighten the thumbscrew on the adaptor or the square drive bolt.



Straight Array Holder (CH-00017)

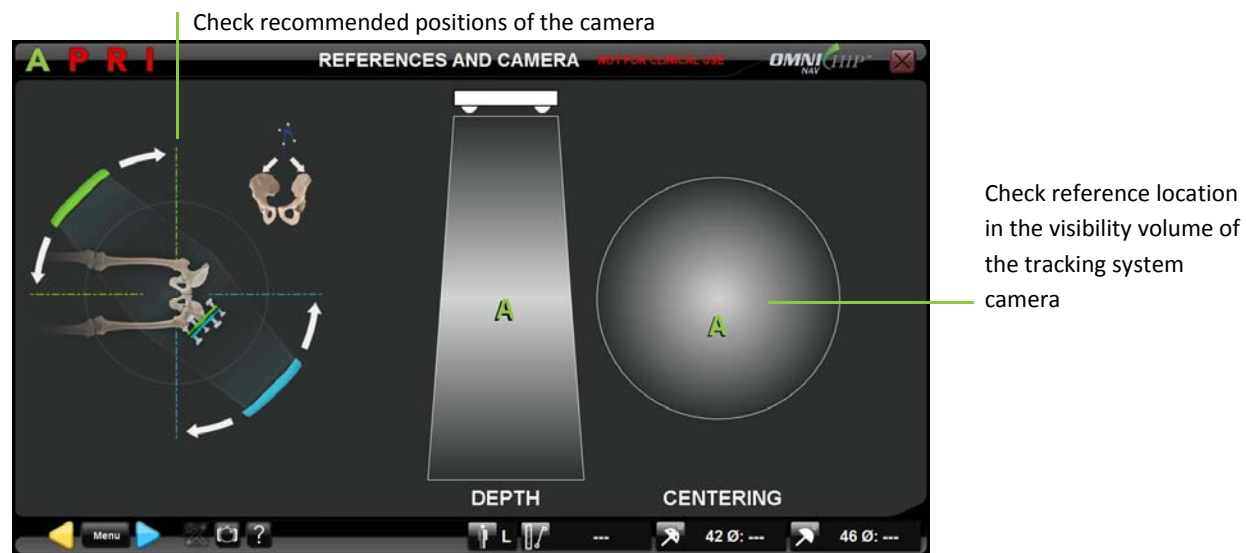


Angled Array Holder (CH-00016)

Optional : Array Holder Assembly Instructions :

- 1) Assemble either an Angled Array Holder (CH-00016) or Straight Array Holder (CH-00017) to Two Pin Fixation (4154-5000 or CH-00023) by pressing the button and aligning the hole with post (black arrow to black arrow)
- 2) Load Acetabular Array (CH-00008) into hole of pivot as shown to left
- 3) Rotate Acetabular Array (CH-00008) to the desired position so that it's visible to the camera and tighten square bolt using the 7mm Square Drive Screwdriver (CH-00022)

Locating the patient array with tracking system camera:



- Check visibility of “A” array (CH-00008) and other arrays on the screen in operative positions. Adjust the orientation of the arrays as necessary and proceed.

	RECOMMENDATION: The A array should be positioned as parallel to the camera face as possible for optimal accuracy.
--	--

- Touch to go to the next step.

	WARNING: The “A array must be securely attached to the pelvis. If the A array is moved after this stage, all patient anatomy registration must be redone.
--	--

4.6 Patient Anatomy Registration

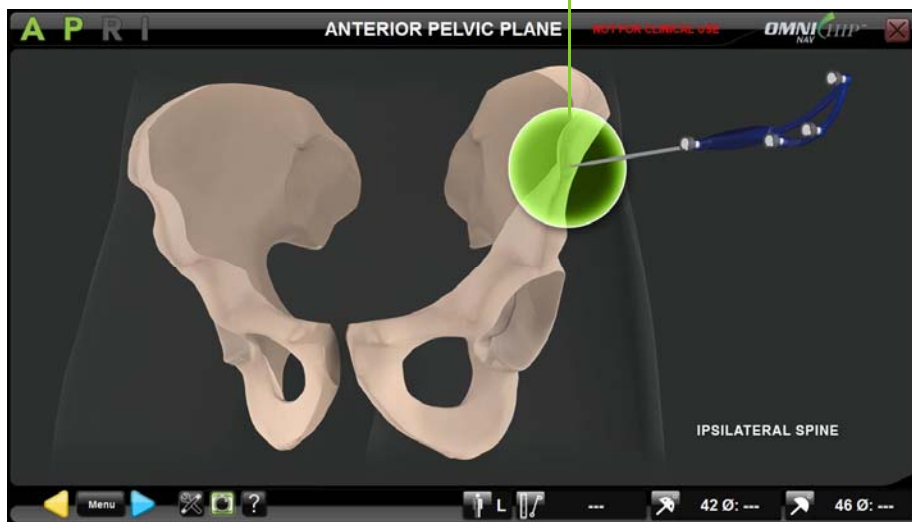
Registering Pelvis Reference Frame:


- Anterior Pelvic Plane



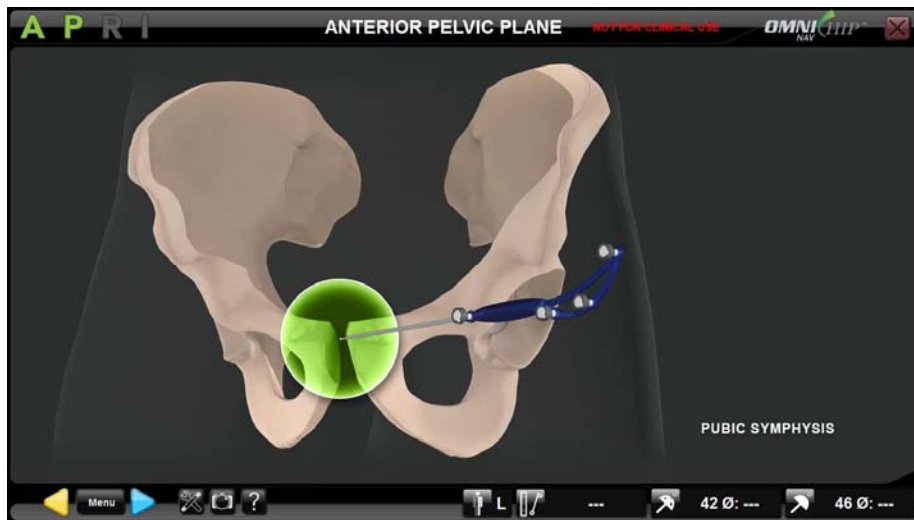
WARNING: Greatest accuracy can be obtained if the landmarks are acquired without soft tissue interference. Excessive soft tissue interference, such as encountered in obese patients, may result in insufficient system accuracy. In such a situation, percutaneous land marking may be required


Check help image for proper anatomical point registration



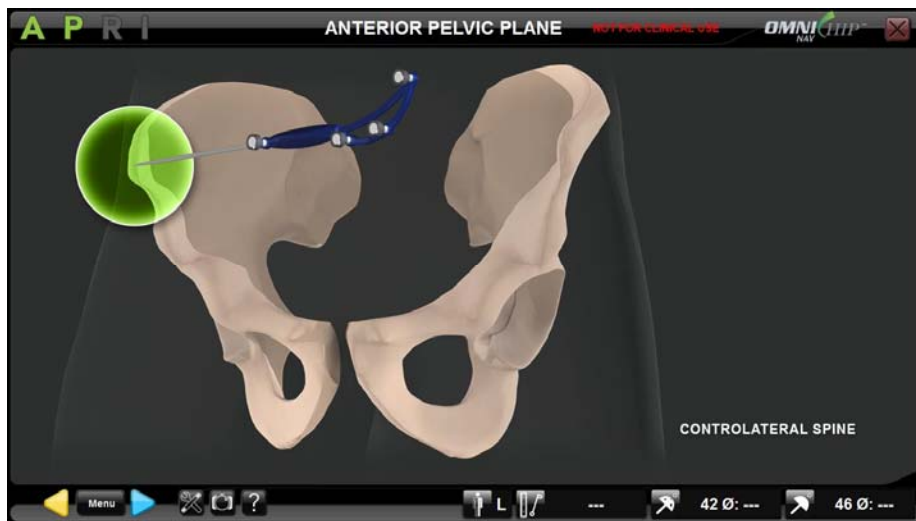
- Place the ball-tip of the Pointer (CH-00011) on the ipsilateral Antero-Superior Iliac Spine.
- Touch  to register the position of this first point.


Note: This point will be used with Pubic Symphysis and contralateral Antero Superior Iliac Spine points to define patient Anterior Pelvic Plane position and to compute Inclination and Anteversion parameters.



- Place the ball-tip of the Pointer on the pubic symphysis
- Touch  to register the position of the second point.

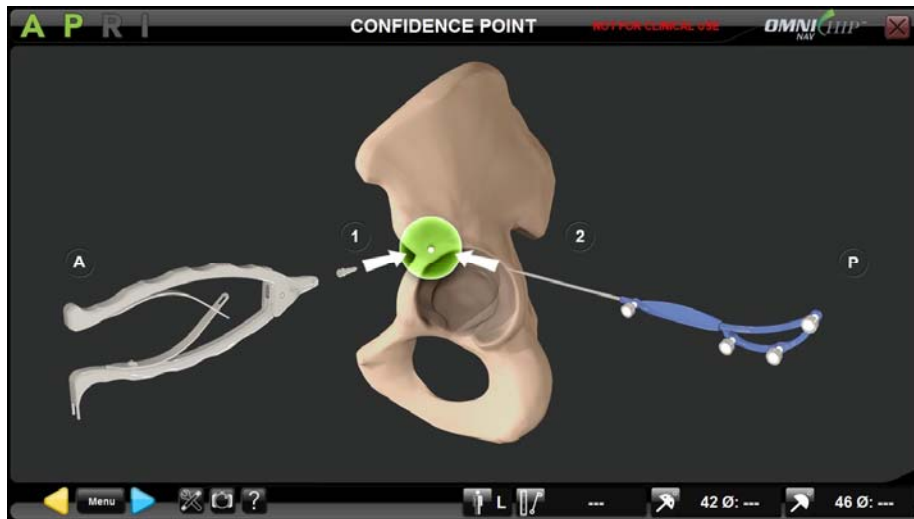
Note: This point will be used with ipsilateral Antero Superior Iliac Spine and contralateral Antero Superior Iliac Spine points to define patient Anterior Pelvic Plane position and to compute Inclination and Anteversion parameters.




- Place the ball-tip of the Pointer on the contralateral Antero-Superior Iliac Spine.
- Touch  to register the position of the third point.

Note: This point will be used with ipsilateral Antero Superior Iliac Spine and Pubic Symphysis points to define patient Anterior Pelvic Plane position and to compute Inclination and Anteversion parameters.

- Pelvic Confidence Point



- Place a Reference Pin (CH-00012) into the pelvis using the Pin Puller (KS-90033).
- Place the ball-tip of the Pointer (CH00011) into the cone onto the head of the Reference Pin.
- Touch  to register the position of the point.

Note: The confidence point can be placed anywhere onto the pelvis but it should remain immobile, secure and accessible throughout the procedure to be used anytime later to check that tracking of the pelvis is accurate and that the Acetabular array didn't move relative to the pelvis. Also the placement of the confidence point should not interfere with any of the acetabular preparation for implant placement. Reference Pin can be replaced by a simple mark on bone if this is a preferred solution.

Registering Femur Reference Frame:

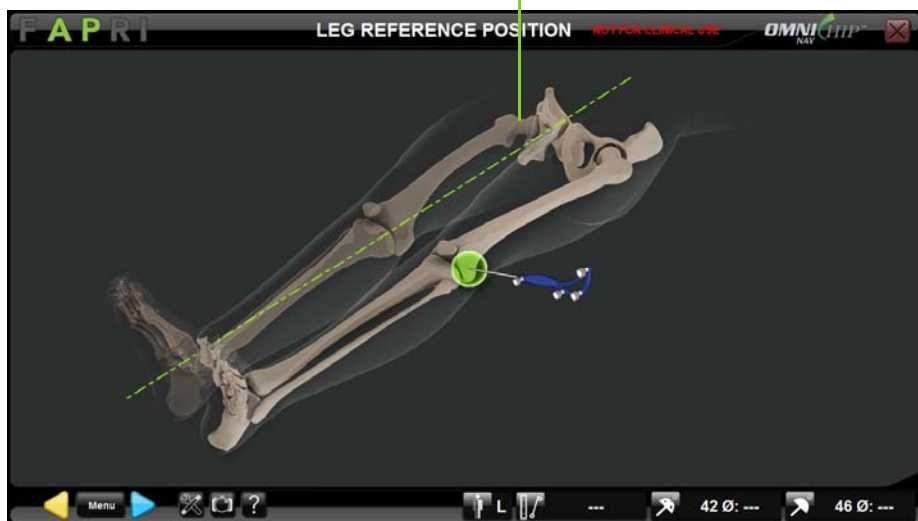
- **Two Reference Points in Neutral Position option**


- Place a Reference Pin (CH-00012) into the greater trochanter using the Pin Puller (KS-90033).
Alternative to placing a reference pin is to make a divot in the bone using the reference pin or a bone screw. To ease finding this spot again, clear the bone of soft tissues in the area of the divot and dip a marking pen in methylene blue and spot it over the divot as an identifier
- Mark a control point with a sterile marking pen on the distal femur at the level of the patella.



RECOMMENDATION: Use Coban or equivalent to wrap the knee and mark distal femur control point on the Coban in order to limit movement of skin/tissues relative to the femur.

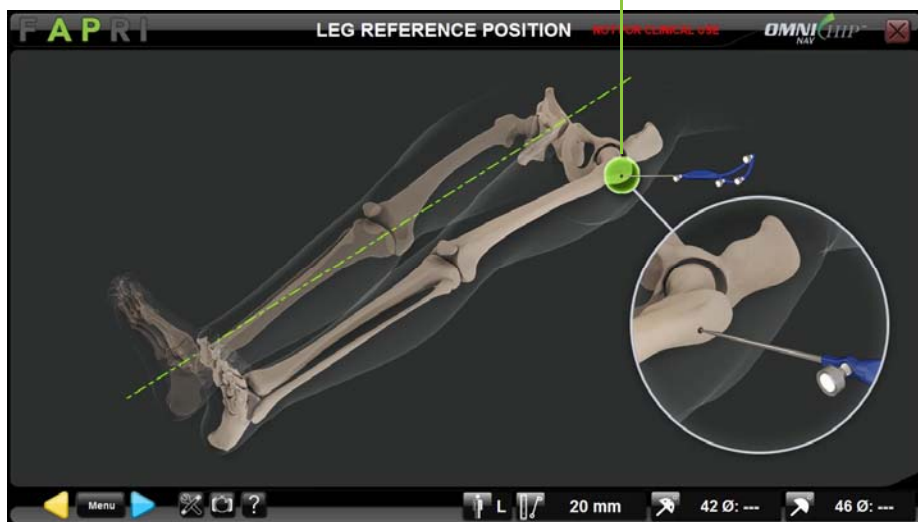
Check help image for proper control point registration




- Place the leg into neutral position. Flexion/extension, adduction/abduction and axial rotation should be within 10° of neutral.
- With leg in neutral position, place the ball-tip of the Pointer (CH-00011) on the distal femur control point.
- Touch  to register the position of the control point.

Note: This point is used for controlling proper leg repositioning before leg length and offset control.

Check help image for proper reference point registration



- With leg in neutral position, place the ball-tip of the Pointer (CH-00011) into the cone onto the head of the Reference Pin.
- Touch  to register the position of the reference point.

Note: This point is used as reference for leg length and offset measurement.

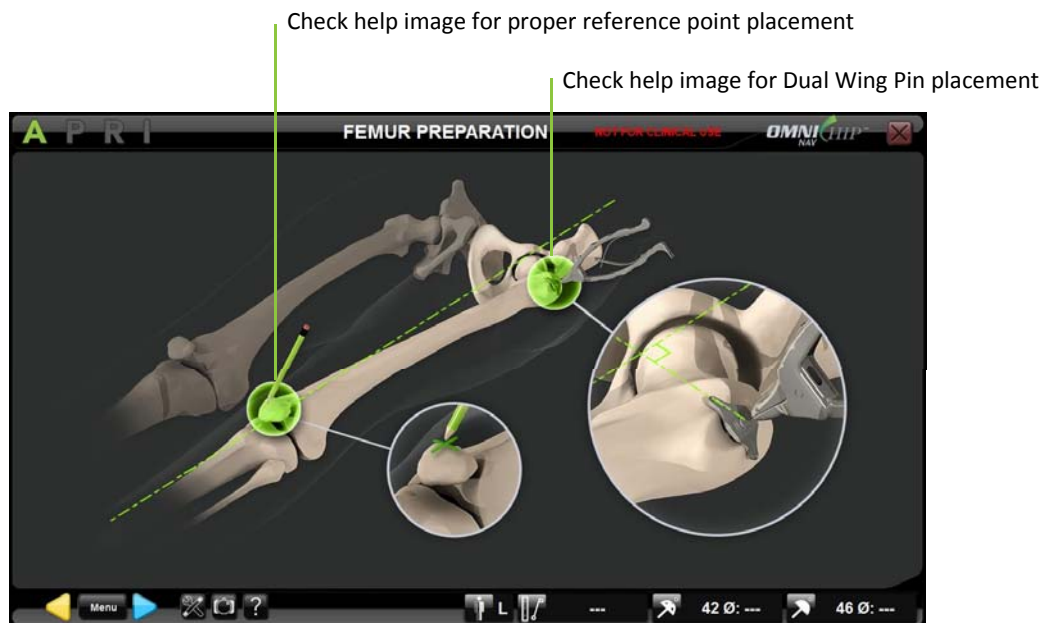


WARNING: The leg must not move during registration of the two reference points or accuracy of the leg length and offset values will be compromised.



WARNING: In this case the leg axial rotation is not registered by software so leg initial position including any initial deformity must be identified to be reproduced during the leg length and offset control step or accuracy of the offset value can be compromised. With two point registration, the leg axial rotation is not be registered by the software. The initial position (with notation of any deformities) must be reproduced during the leg length and offset control step or accuracy of the offset value can be compromised.

Three Reference Points in Neutral Position option



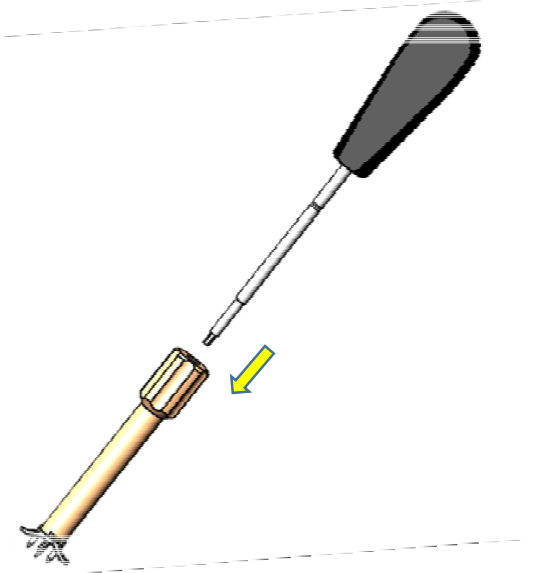
- Place a Dual Wing Pin (CH-00015) into the greater trochanter using the Pin Puller (KS-90033).
Alternative to placing a reference pin is to install a Dual Wing Plate, Anterior (CH-00024) or Dual Wing Plate, Posterior (CH-00018) in the greater trochanter of the proximal femur. Dual Wing Plate should be placed no more than 20° from perpendicular to the Mechanical Axis as shown on next page.
- Mark a reference point with a sterile marking pen on the distal femur at the level of the patella



Dual Wing Plate, Anterior



Dual Wing Plate, Posterior



Dual Wing Plate & Screw Installation Instructions:

- 1) Load Dual Wing Screw (CH-00019) into Dual Wing Plate Inserter (CH-00025) as shown.
- 2) Load either a Dual Wing Plate, Anterior (CH-00024) or Posterior (CH-00018) onto Dual Wing Inserter (CH-00025) tip and rotate clockwise to lock to plate and screw.
- 3) Locate desired location for installation, install by gently tapping the top of the inserter with a mallet. *Note: Dual Wing Plate should be placed no more than 20° from perpendicular to the Mechanical Axis.*
- 4) Load the 3.5mm Hex Screwdriver (9-144) through the inner diameter of the inserter and tighten until the Dual Wing Screw is completely seated on the Dual Wing Plate. If screw is not fully seated on the Dual Wing Plate, additional tightening with the 3.5mm Hex Screwdriver may be necessary. Take care not to overtighten the screw so as not to strip the bone at the bone-screw interface.
- 5) To remove the plate and screw,
 - a. Re-install the Dual Wing Inserter over the Dual Wing Plate
 - b. Load the 3.5mm Hex Screwdriver through the ID of the inserter and loosen the screw by turning the screwdriver counter-clockwise,
 - c. Pull the inserter without rotating it to remove the plate and screw. A little rocking may be necessary.

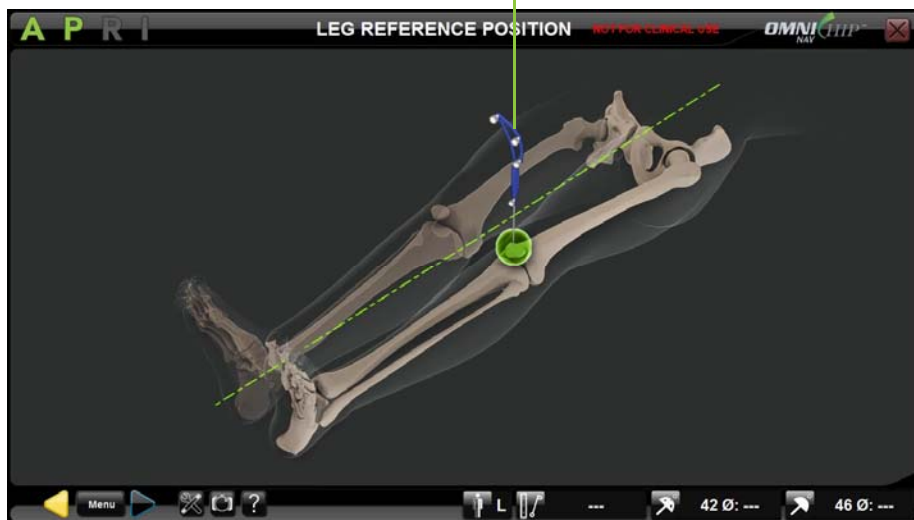



RECOMMENDATION: Use Coban or equivalent to wrap the knee and mark distal femur control point on the Coban in order to limit movement of skin/tissues relative to the femur.



RECOMMENDATION: Dual Wing Pin should be placed as perpendicular as possible to the femur mechanical axis.

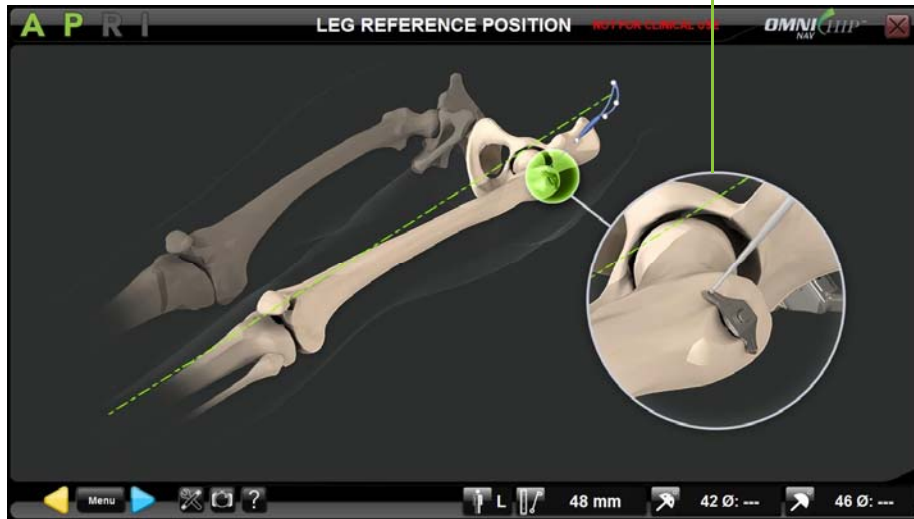
Check help image for proper distal reference point registration




- Place the leg into neutral position relative to the pelvis. Flexion/extension, adduction/abduction and axial rotation should be within 10° of neutral.
- With leg in neutral position, place the ball-tip of the Pointer (CH-00011) on the distal skin reference point marked during Femur Preparation.
- Touch  to register the position of this first reference point.

Note: This point is used for femur reference frame computation with leg in neutral position relative to the pelvis.

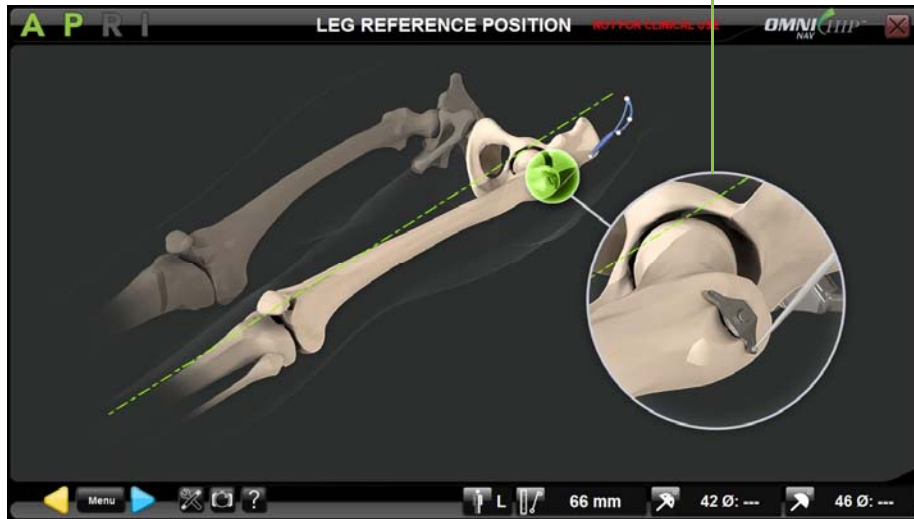
Check help image for proper Dual Wing Pin cone registration




- With leg in neutral position, place the ball-tip of the Pointer (CH-00011) into the anterior cone of the Dual Wing Pin placed into the greater trochanter during Femur Preparation.
- Touch  to register the position of this second reference point.

Note: This point is used for femur reference frame computation with leg in neutral position relative to the pelvis.

Check help image for proper Dual Wing Pin cone registration



- With leg in neutral position, place the ball-tip of the Pointer (CH-00011) into the posterior cone of the Dual Wing Pin placed into the greater trochanter during Femur Preparation.
- Touch  to register the position of this third reference point.

Note: This point is used for femur reference frame computation with leg in neutral position relative to the pelvis.



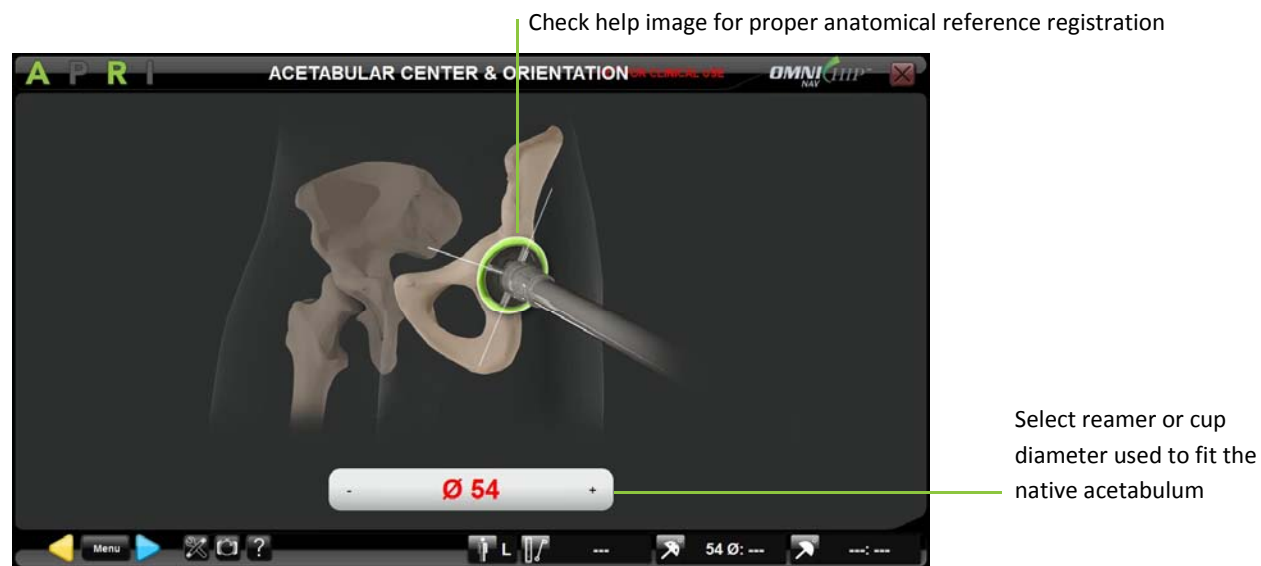
RECOMMENDATION: If the Dual Wing Pin (DWP) registration fails repeatedly because of a distance error between the two points, then check that there is no tissue in the DWP cones. In such case cones can be cleared easily with suction.




WARNING: The leg must not move during registration of the three reference points or accuracy of the leg length and offset values will be compromised.

Registering Acetabulum Anatomy using Reamer and/or Cup Impactor:

- Acetabular Anatomical Center/Diameter & Orientation with Acetabular Fit option



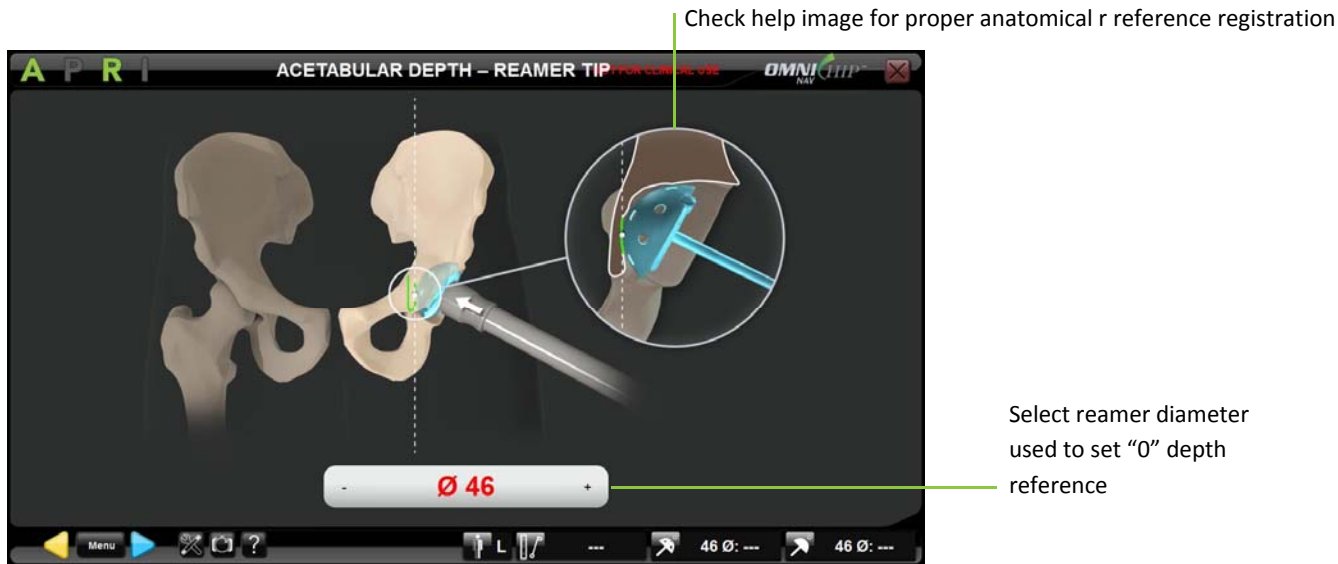
- Select a reamer basket or trial cup that fits the best into the acetabulum and adjust corresponding diameter on the screen.
- Place Reamer Driver equipped with “R” array or Cup Impactor equipped with “I” array in the acetabulum and/or align the peripheral reamer basket or cup with the native rim.
- Touch  to register native acetabulum orientation and/or native acetabulum center and diameter.


Note: The native Acetabulum Center is used as reference for centering control during Reamer Driver Tracking and Cup Impactor Tracking. Native acetabulum orientation is used to assess reamer or cup orientation during Reamer Driver Tracking and Cup Impactor Tracking. Acetabulum Diameter can be used to assess correct reaming diameter during Reamer Driver Tracking.




WARNING: Make sure you selected same instrument diameter on screen as instrument actually used for registering native acetabulum anatomy to avoid risks of implant misplacement.

- **Depth with Reamer Tip option**



- Select a small reamer basket that fits into the acetabulum and adjust corresponding diameter on the screen.
- Place Reamer equipped with "R" array into the acetabulum and start reaming until you reach contact with acetabular medial wall or fossa.
- Touch  to register the position of the medial wall or fossa.

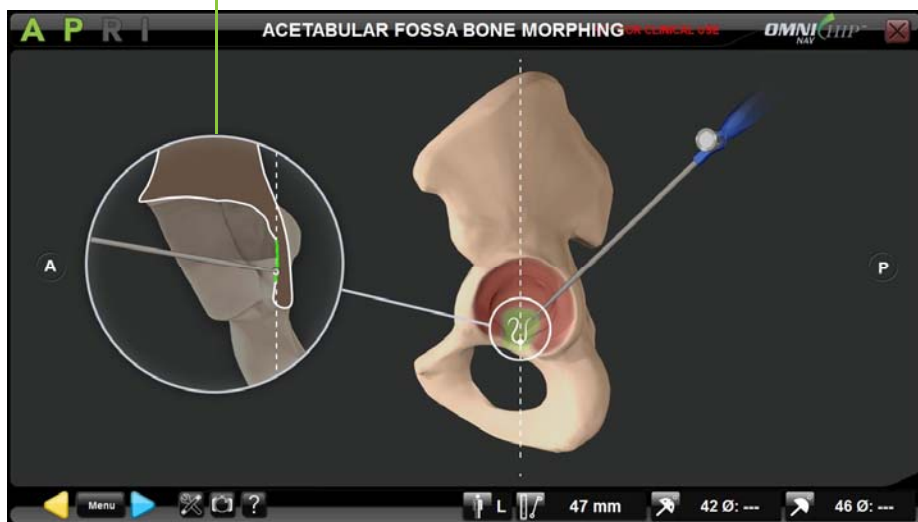
Note: The reamer position is used as the "0" depth reference to control reaming depth during Reamer Driver Tracking.


 <p>Warning!</p>	<p>WARNING: Make sure you selected same instrument diameter on screen as instrument actually used for registering depth reference plane to avoid risks of over reaming the acetabulum.</p>
--	---

Registering Acetabulum Anatomy using Bone Morphing:

- **Depth with Fossa Bone Morphing option**

Check help image for proper anatomical surface registration



- Place the ball-tip of the Pointer on the acetabular fossa.
- Touch  to start Bone Morphing acquisition
- Glide the ball-tip of the Pointer on the fossa surface until the green bar fills up and acquisition completes automatically.

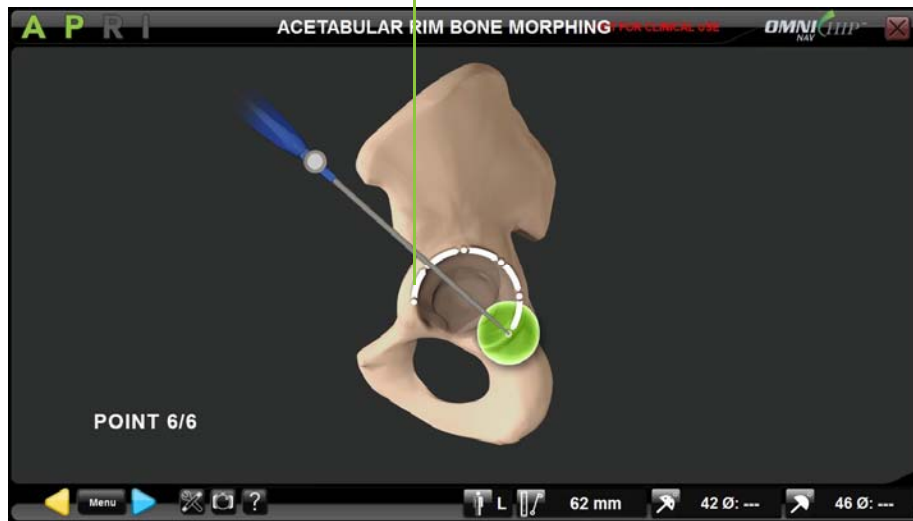
Note: The fossa Bone Morphing is used to assess the reamer's depth during Reamer Driver Tracking and Cup Impactor Tracking. It is important to keep the ball-tip of the Pointer in constant contact with the bone during morphing acquisition.




RECOMMENDATION: Remove osteophytes and the fat pad contained in the acetabular fossa before starting the Bone Morphing surface acquisitions process.

- **Acetabular Anatomical Orientation with Rim Bone Morphing (6 points) option**

Check help image for proper anatomical surface registration



- Place the ball-tip of the Pointer on the acetabular rim.
- Touch  to register the position of this first point.
- Repeat the same process for the five other points required for acetabular rim registration

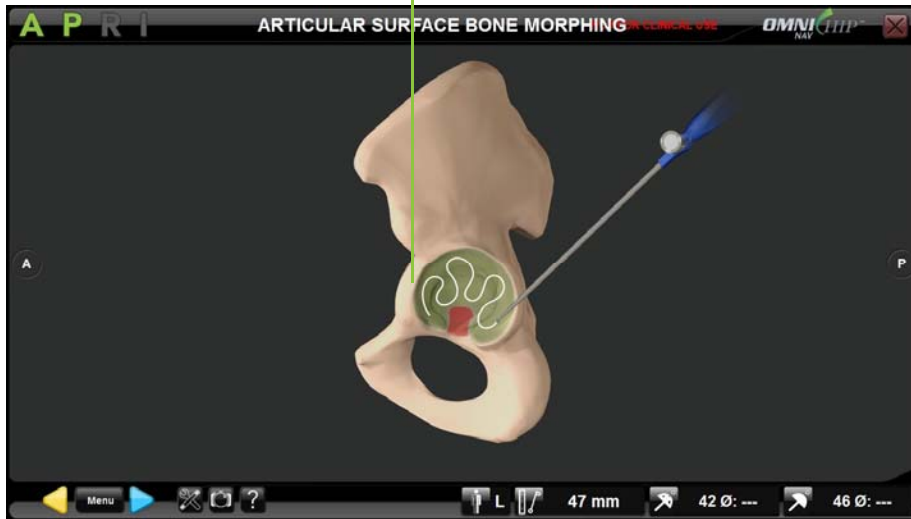
Note: These points are used to complete the Bone Morphing of the acetabulum, to compute the anatomical orientation of the native acetabulum and to assess reamer or cup orientation during Reamer Driver Tracking and Cup Impactor Tracking. The six points should be registered all around the rim.




RECOMMENDATION: Remove osteophytes before starting the Bone Morphing surface acquisitions process.

- **Acetabular Center/Diameter with Articular Surface Bone Morphing option**

Check help image for proper anatomical surface registration



- Place the ball-tip of the Pointer on the articular surface of the acetabulum.
- Touch  to start Bone Morphing acquisition
- Glide the ball-tip of the Pointer on the articular surface until the green bar fills up and acquisition completes automatically.

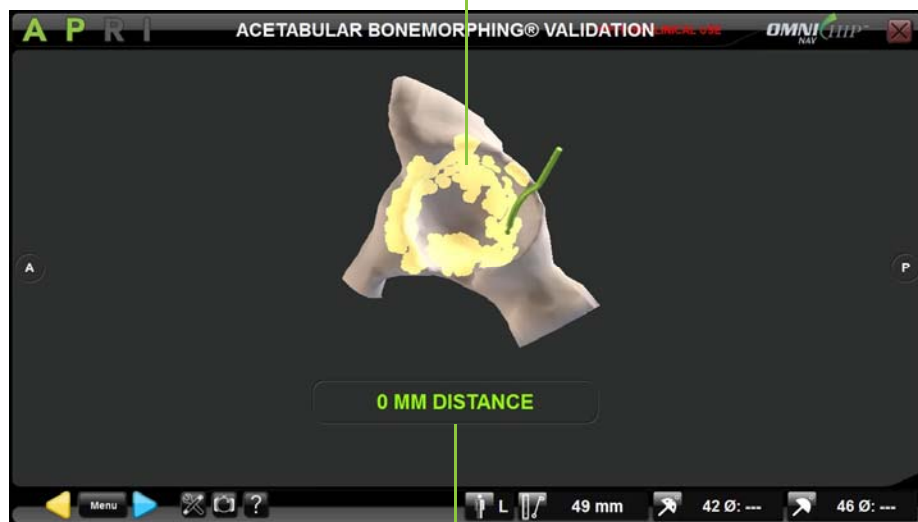
Note: The rim Bone Morphing is used to compute the geometrical center and diameter of the native acetabulum and to assess reamer or cup position during Reamer Driver Tracking and Cup Impactor Tracking. It is important to keep the ball-tip of the Pointer in constant contact with the bone during morphing acquisition.




RECOMMENDATION: Remove osteophytes before starting the Bone Morphing surface acquisitions process.

Validating the Bone Morphing reconstruction:

Check part of the reconstructed bone surface corresponding to accurate points



Check distance from the Pointer ball-tip to the reconstructed bone surface

- Place the ball-tip of the Pointer (CH-00011) on part of the bone you want to check. The value indicated on the screen below the bone model represents the distance between the Pointer and the bone model. Check that the distance is less than or equal to 1.0mm in this key area.
- Touch  to validate the generated 3D model of the bone.

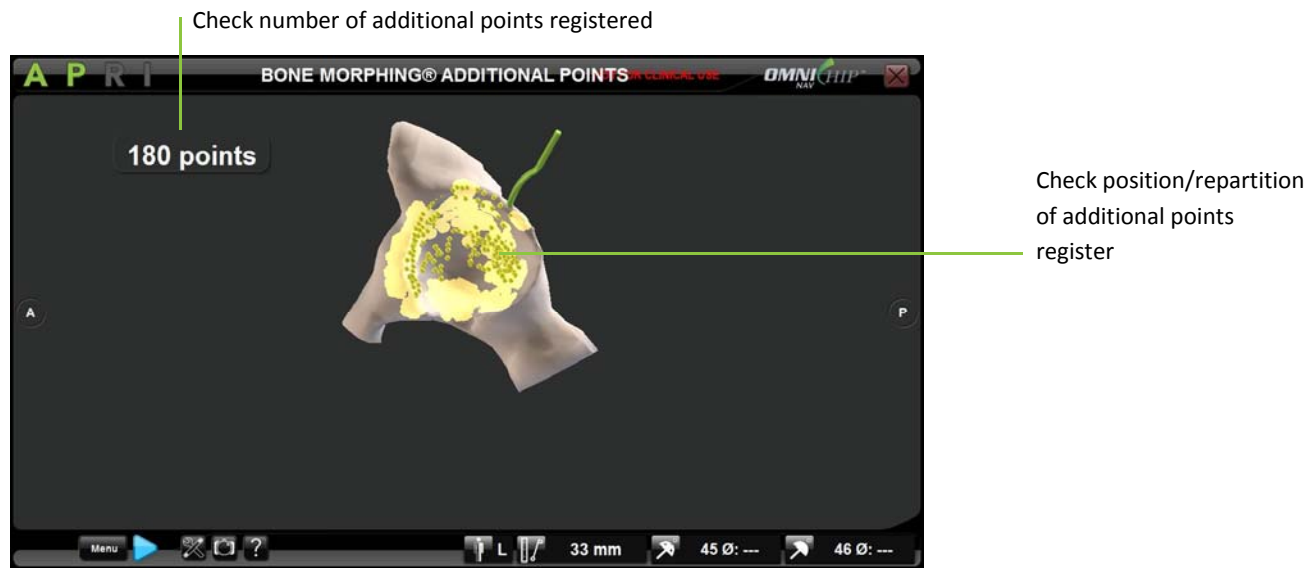
Note: Areas of the model displayed in yellow are corresponding to areas where points have been collected during the registration of the fossa, rim and articular surface




Warning!


WARNING: In case of atypical patient anatomy, particular attention must be paid during the accuracy verification stage using the pointer.

Adding points to the Bone Morphing:





- From Bone Morphing validation page touch **Menu** to open Tab Navigation Menu directly on “Bone Morphing Additional Points” tab.
- Touch **GO** to go to “Bone Morphing Additional Points” step.
- Touch  to start the additional point acquisition.

Note: It is important to keep the ball-tip of the Pointer in constant contact with the bone during morphing acquisition.

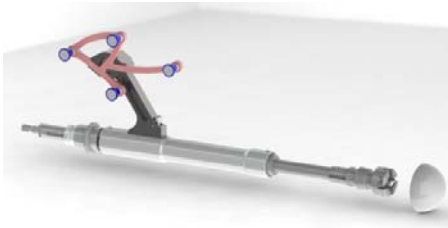
- Touch  to stop the additional point acquisition.

4.7 Reamer Driver Tracking

Straight Reamer Driver has been specifically designed for navigation of acetabular preparation

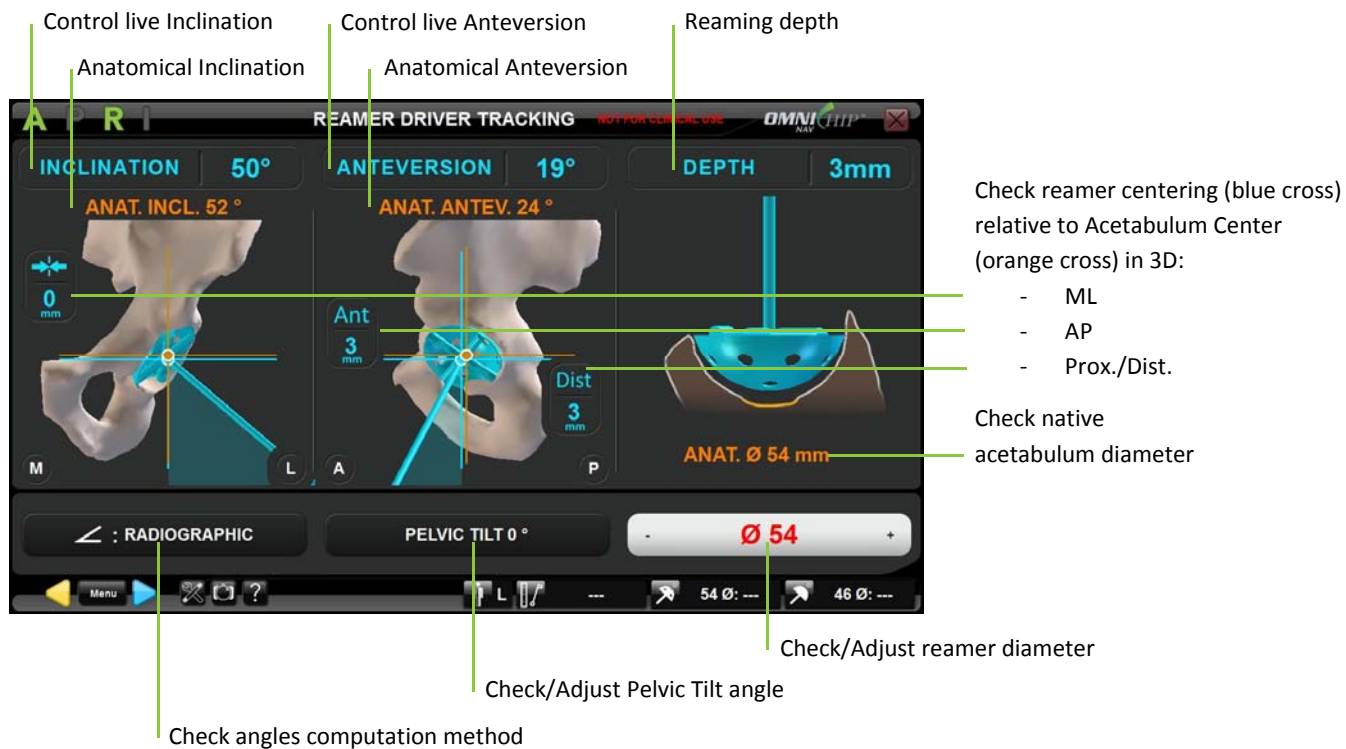
 Warning!	WARNING: Before the navigation of the Reamer, it is strongly recommended to check that the “A” array has not moved by placing the Pointer (CH-00011) on the confidence point. If the displayed distance (See §2.6) from the Pointer to the confidence is more than 1.0mm, the “A” array may have moved. Accuracy is no longer guaranteed and the pelvis/acetabulum should be re-registered.
 Warning!	WARNING: The pelvic model displayed during the entire protocol does not correspond to the patient anatomy and should not be considered as a diagnostic image. Only the landmarks digitized on the pelvis correspond to the patient anatomy.

Reamer assembly with the straight reamer Driver




Connect the first reamer basket to the Straight Reamer Driver (CH-00002) equipped with the R array (CH-00009) then connect the Reamer Driver to the power tool.

Note: The Straight Reamer Driver is compatible with OMNI Acetabular Reamer Kit (HK-60020) and has a Zimmer-style connection to the power tool.



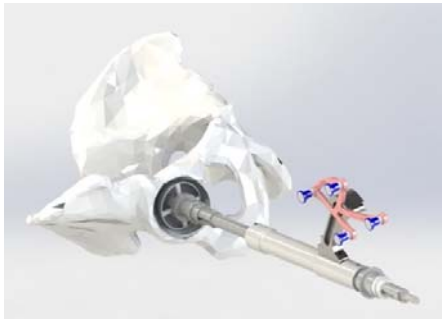
Note: The anatomical inclination/anteversion, diameter and centering, depth values are options. They are displayed only if that option has been registered.


Set the reamer diameter to the size of the reamer being used: Touch the parameter button to be adjusted then touch +/-.

	<p>WARNING: Make sure you select and update reamer diameter on screen as you change actual reamer size for reaming the acetabulum to avoid risks of over reaming and/or implant mal-positioning.</p>
---	---

Control the reaming process:

- Position of the Reamer Driver equipped with first reamer diameter and the “R” array into the acetabular cavity.
- Align Reamer inclination and anteversion angles.
- Start reaming.



- Monitor depth and centering of the reaming.
- Adjust the reamer diameter on screen each time the reamer basket size is being changed on the tracked Reamer Driver.
- Touch  to record the final position of the last reamer basket used.



Note: The final position of the reamer is used as reference for the seating of the cup. If no reamer final position has been registered (both A and R red on screen) than cup position will be controlled relative to medial wall/fossa reference.



WARNING: Make sure you don't record reamer position before actual end of the reaming process or then make sure you record actual final position of the reamer before moving forward, otherwise seating information could be inaccurate.

4.8 Cup Impactor Tracking

The Straight Cup Impactor has been specifically designed for navigation of Apex Modular™ Interface™ Acetabular Cup

 Warning!	WARNING: Before the navigation of the cup, it is strongly recommended to check that the “A” array has not moved by placing the Pointer (CH-00011) on the confidence point. If the displayed distance (See §2.6) from the Pointer to the confidence point is more than 1 mm, the “A” array may have moved. Accuracy is no longer guaranteed and the pelvis/acetabulum should be re-registered.
 Warning!	WARNING: The pelvic model displayed during the whole protocol doesn’t correspond to the patient anatomy and should not be considered as a diagnostic image. Only the landmarks digitized on the pelvis correspond to the patient anatomy.

Cup assembly with the Straight Cup Impactor



Tighten a trial shell or a cup implant onto Straight Impactor Base (CH-00006) equipped with the I Array (CH-00010).

Note: Ensure that the Straight Impactor Calibration Gage is fully seated prior to calibrating the Straight Impactor Base.

Navigated Inclination
 Anatomical Inclination
 Navigated Anteversion
 Anatomical Anteversion
 Seating or Depth

INCLINATION 48°
ANTEVERSION 21°
SEATING 1mm

ANAT. INCL. 52°
ANAT. ANTEV. 24°

Lat 5 mm
 Ant 1 mm
 Dist 4 mm
ANAT. Ø 54 mm

Check cup centering (blue cross) relative to Acetabulum Center (orange cross) in 3D:
 - ML
 - AP
 - Prox./Dist.

Check native acetabulum diameter

Check angles computation method
 Check/Adjust Pelvic Tilt angle
 Check/Adjust cup diameter

RADIOGRAPHIC
PELVIC TILT 0°
Ø 54

Set the cup diameter to the size of the cup being used: Touch the parameter button to be adjusted then touch +/-.

 Warning!	<p>WARNING: Make sure you selected same cup diameter on screen as trial shell or cup actually used for impaction to avoid risks of implant mal-positioning.</p>
---------------------	--

USING SYSTEM


Control the cup impaction:

- Position of the Cup Impactor equipped with the cup and the “I” array into the acetabular cavity.
- Align cup inclination and anteversion angles.
- Start Impacting.



- Monitor seating/depth of the cup.

Note: The reference for the seating of the cup is the registered final position of the reamer. If no reamer final position has been registered than depth will be displayed.

- Touch  to record the final position of the cup.

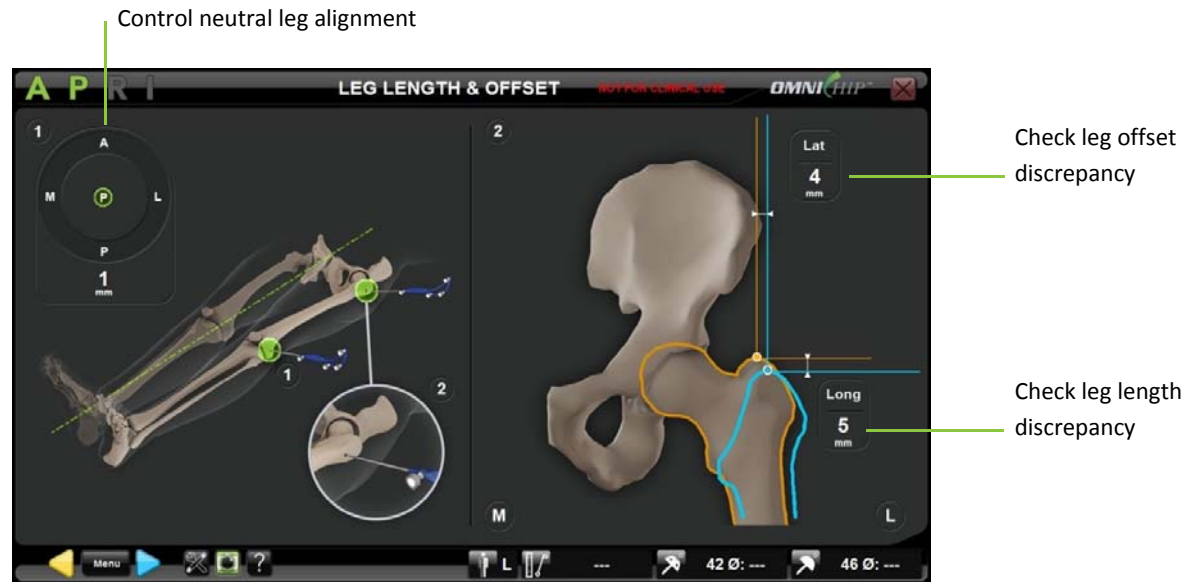
Note: The final position of the cup is required for Leg Length and Offset control with the Three Reference Points in Neutral Position option (For more details - See §6.4).



WARNING: Make sure the trial/implant is tightened all the way until it is flush with the Straight Impactor Base stop. Otherwise centering and seating/depth information could be inaccurate.

4.9 Leg length and offset control

Two Reference Points in Neutral Position option:



- **Check leg neutral position (1):**

- Reduce hip joint
- Bring leg back into neutral position
- Control axial rotation of the leg visually to reproduce the leg reference position axial rotation.



WARNING: In this case the leg axial rotation is not controlled by software so it must be carefully controlled or accuracy of the offset value can be compromised.

- Place the ball-tip of the Pointer (CH-00011) back on the distal skin marker. The leg is in original neutral position when the green “P” is in the middle of the circle and distance to the reference point is less than 8mm.

- **Check leg length and offset (2):** Without moving the leg from checked neutral position, place the ball-tip of the Pointer on the proximal bone marker

Note: Repeat steps (1) and (2) until expected leg length and offset reconstruction is achieved after changing trial and/or final implants.



WARNING: The leg must not move between steps (1) and (2) or accuracy of the leg length and offset values will be compromised.


- **Record final leg length and offset:** Touch .

Three Reference Points in Neutral Position option:

Check help image for proper distal reference point registration




- **Register Leg Final Position:**

- Reduce hip joint
- Place the ball-tip of the Pointer (CH-00011) on the distal skin reference point marked during Femur Preparation.
- Touch  to register the position of this first reference point.

Note: This point is used for final femur reference frame computation relative to the pelvis. At this point, leg doesn't need to be in neutral alignment relative to the pelvis.

Check help image for proper Dual Wing Pin cone registration




- With leg in same position, place the ball-tip of the Pointer (CH-00011) into the anterior cone of the Dual Wing Pin placed into the greater trochanter during Femur Preparation.
- Touch  to register the position of this second reference point.

Note: This point is used for final femur reference frame computation relative to the pelvis. At this point, leg doesn't need to be in neutral alignment relative to the pelvis.

Check help image for proper Dual Wing Pin cone registration



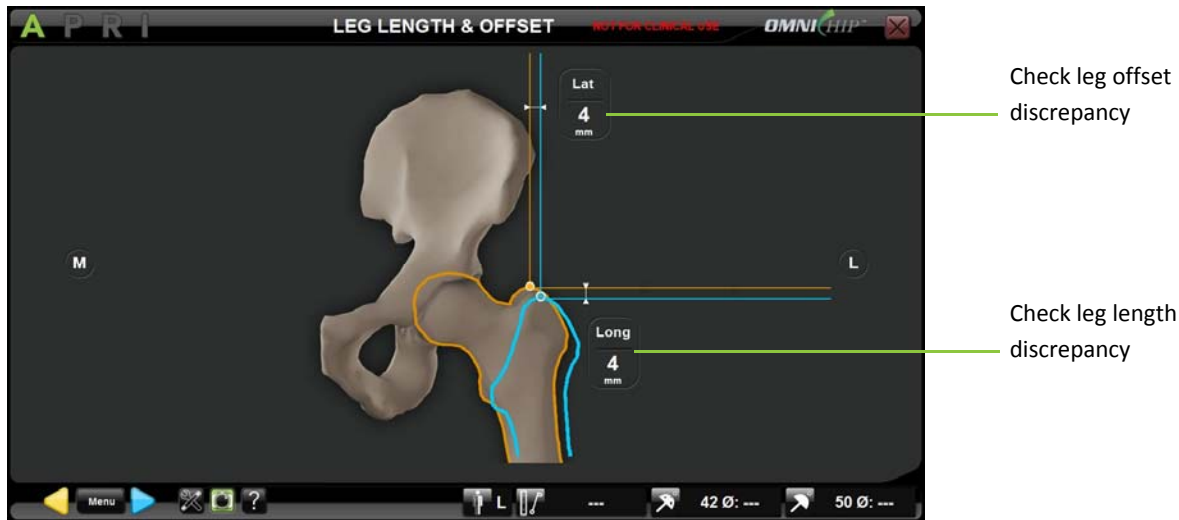
- With leg in same position, place the ball-tip of the Pointer (CH-00011) into the posterior cone of the Dual Wing Pin placed into the greater trochanter during Femur Preparation.
- Touch  to register the position of this third reference point.



Note: This point is used for final femur reference frame computation relative to the pelvis. At this point, leg doesn't need to be in neutral alignment relative to the pelvis.



WARNING: The leg must not move during registration of the three reference points or accuracy of the leg length and offset values will be compromised.

- Check Leg Length and Offset:

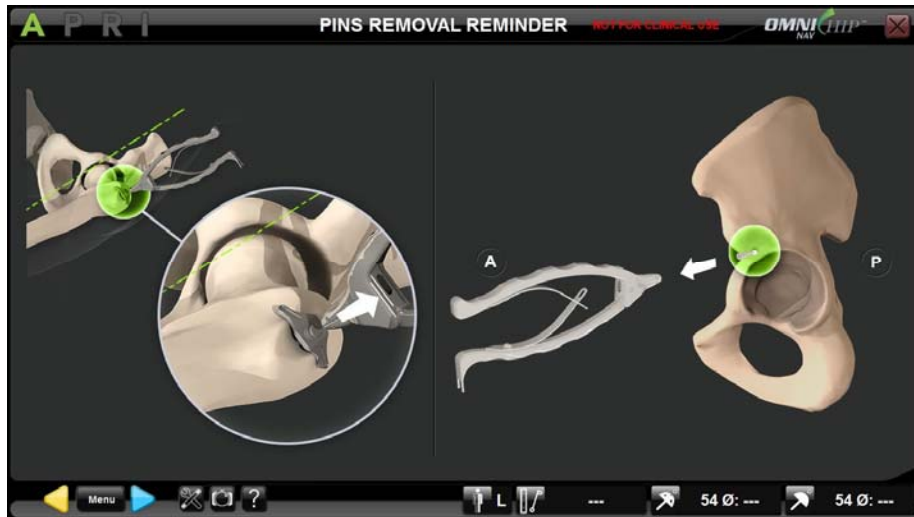



- Touch  to go back to Leg Final Position registration if required.
- Touch  to record the leg length and offset.

Note: Go back and forth between Leg Length and Offset control page and Leg Final Position registration until expected leg length and offset reconstruction is achieved after changing trial and/or final implants.

4.10 Pins removal reminder

At the end of the procedure, the system will remind you to remove all pins used for marking the confidence point or reference point(s) for leg length and offset control.



- Touch  to acknowledge that all pins have been removed from the patient.
- Touch “Confirm” in the pop-up message.



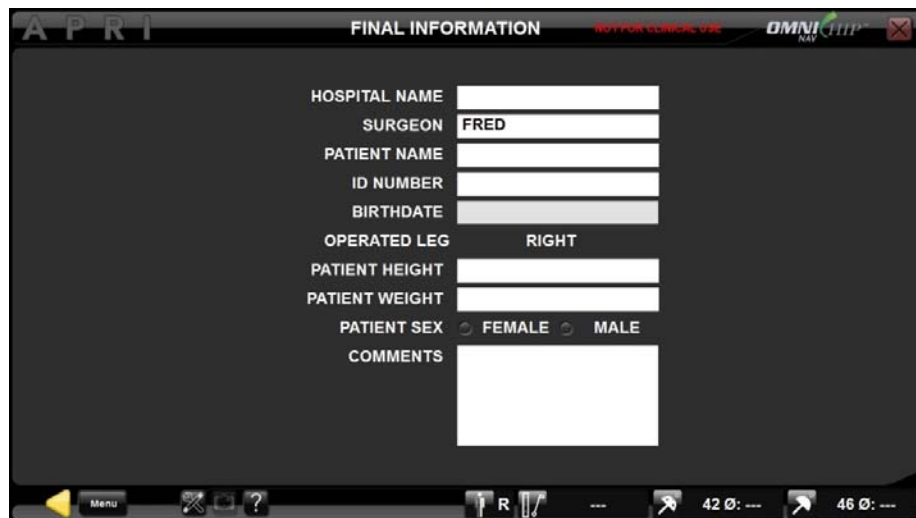
RECOMMENDATION: Do not acknowledge “pins removal” page until all pins have actually been removed from the patient in order to avoid risk of leaving these pins in the patient.

4.11 Navigation report

Adding information to the report

Using the last screen of the procedure additional information can be added or edited to the report.

- Use the touchscreen or laptop trackpad to select the item to be edited.
- Use the laptop keyboard to type in information.



The screenshot shows a software interface titled "APRI FINAL INFORMATION" with a "NOT FOR CLINICAL USE" warning and "OMNI" branding. The interface contains several input fields for patient information:

HOSPITAL NAME	
SURGEON	FRED
PATIENT NAME	
ID NUMBER	
BIRTHDATE	
OPERATED LEG	RIGHT
PATIENT HEIGHT	
PATIENT WEIGHT	
PATIENT SEX	<input type="radio"/> FEMALE <input type="radio"/> MALE
COMMENTS	

At the bottom of the screen, there is a navigation bar with icons for Menu, a close button, a help button, and a status bar showing "R", "42 0: ---", and "46 0: ---".

Note: Patient Health Information edited here will be included in the PDF report generated by the system but it will not be saved onto the system. At the end of the procedure it is possible to save the PDF report containing this information onto a USB key before it is permanently erased from the system.

Saving the navigation report to a USB key:

- At the end of the navigation protocol touch the “Exit” button.
- Insert a USB key into the laptop.
- Touch “Confirm” to record the navigation report.

Note: The navigation report includes a printable PDF report and an XLS sheet. The XLS sheet contains the numerical data for measurements performed during the navigation in a simple form. The navigation report folder also contains screenshots of all steps of the navigation protocol and all the manual screenshots saved during the navigation protocol (See §2.6).

5 Workflow Customization and Tab Navigation

5.1 Definitions

Navigation protocol = Computer Assisted Surgical Protocol

Step:

The OMNIBotics Total Hip Software workflow is composed of a succession of steps. The user can navigate through steps using blue or yellow buttons or Menu.

Parent step:

A step that must be performed before another step can be accessed.

Children step:

A step that must be performed after another step has been performed (or validated).

Group:

Most steps belong to a predefined group of steps.

OMNIBotics Total Hip Software groups are the following:

- Instrument Calibrations
- Pelvis Registration
- Femur Registration
- Acetabulum Anatomy
- Leg Length & Offset

Steps that are alone are considered as a group (group of 1 step). Examples: Reamer Driver Tracking, Cup Impactor Tracking.

Linear Workflow:

Default succession of steps as defined in a default profile or customized by the user in his user profile.

Nonlinear Workflow:

During a procedure it is possible to move out of the linear workflow to skip certain steps or redo steps generating a nonlinear workflow.

5.2 Default profiles

OMNIBotics Total Hip Software is delivered pre-installed with one default profile corresponding to recommended linear workflow:

Anterior Approach

This default profile corresponds to a hip anterior approach technique using Straight Reamer Driver for acetabular preparation and Straight Cup Impactor for Apex Modular™ Interface™ Acetabular Cup.

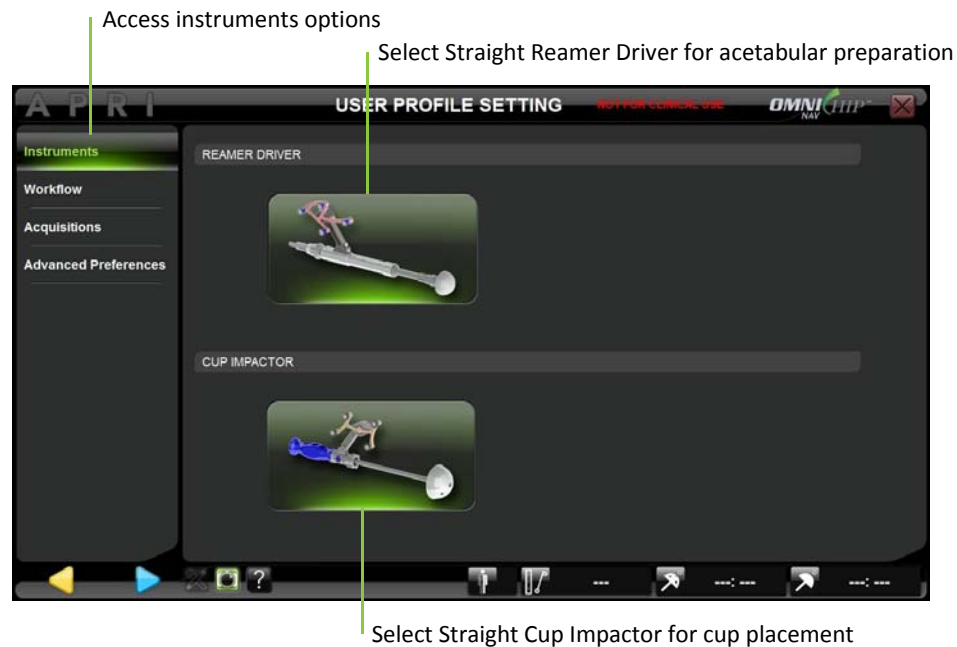
It includes the followings groups/steps:

- Patient Information (See §3.5)
- Instrument Calibrations (See §4.4)
- Reference & Camera positioning (See §4.5)
- Pelvis Registration with Anterior Pelvic Plane option (See §4.6)
- Femur Registration with Three Reference Points in Neutral Position option (See §4.6)
- Acetabulum Anatomy Registration using Reamer and/or Impactor (See §4.6)
- Reamer Driver Tracking (See §4.7)
- Cup Impactor Tracking (See §4.8)
- Leg length & Offset control (See §4.9)

5.3 Customized user profile setting

The user has access to several options and parameters which enables the customization of profiles according to the instruments used and individual surgical techniques. Once a profile has been defined, the navigation protocol will follow a linear workflow corresponding to the profile.

Accessing the User Profile setting options: On “User Profile Selection” page, touch the name of the profile to modify and touch MODIFY OPTIONS button (see §3.4). The default options correspond to the options of the profile selected. The options can be modified to create a profile corresponding to each surgical technique.



Overview of User Profile Setting options:

Instruments

Reamer Driver - Straight Reamer Driver
Cup Impactor - Straight Cup Impactor

Workflow

Optional steps
Reamer Driver Tracking
Cup Impactor Tracking
Leg Length and Offset

Acquisitions

Pelvis Registration - Pelvic Anterior Plane
Femur Registration - Femur Referential
Two Reference Points in Neutral Position
Three Reference Points in Neutral Position
Acetabular Anatomy - Depth
Disabled
Reamer Tip
Fossa Bone Morphing
Acetabular Anatomy - Anatomical Orientation
Disabled
Acetabular Fit (Reamer or Cup)
Rim Bone Morphing
Acetabular Anatomy - Center/Diameter
Disabled
Acetabular Fit (Reamer or Cup)
Articular Surface Bone Morphing

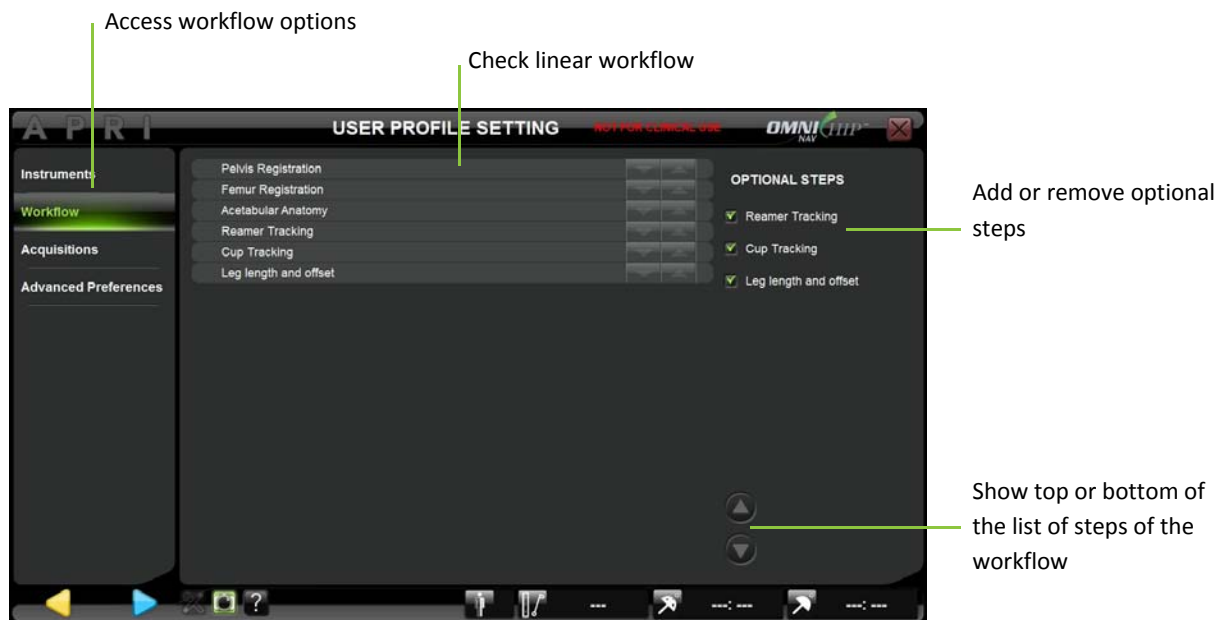
Advanced Preferences

Computation Method
Operative
Radiographic
Anatomic
Sound Guidance
Disabled
Before Acquisition
During Acquisition
Before & During Acquisition
Pelvis Model
Show Generic Model
Show Morphed Model

Modifying the instrument options: Touch “Instruments” tab and select the preferred instrument options.

Note: The following options are currently available:

- Acetabular preparation with Straight Reamer Driver (See §4.7)
- Cup placement with Straight Cup Impactor (See §4.8)

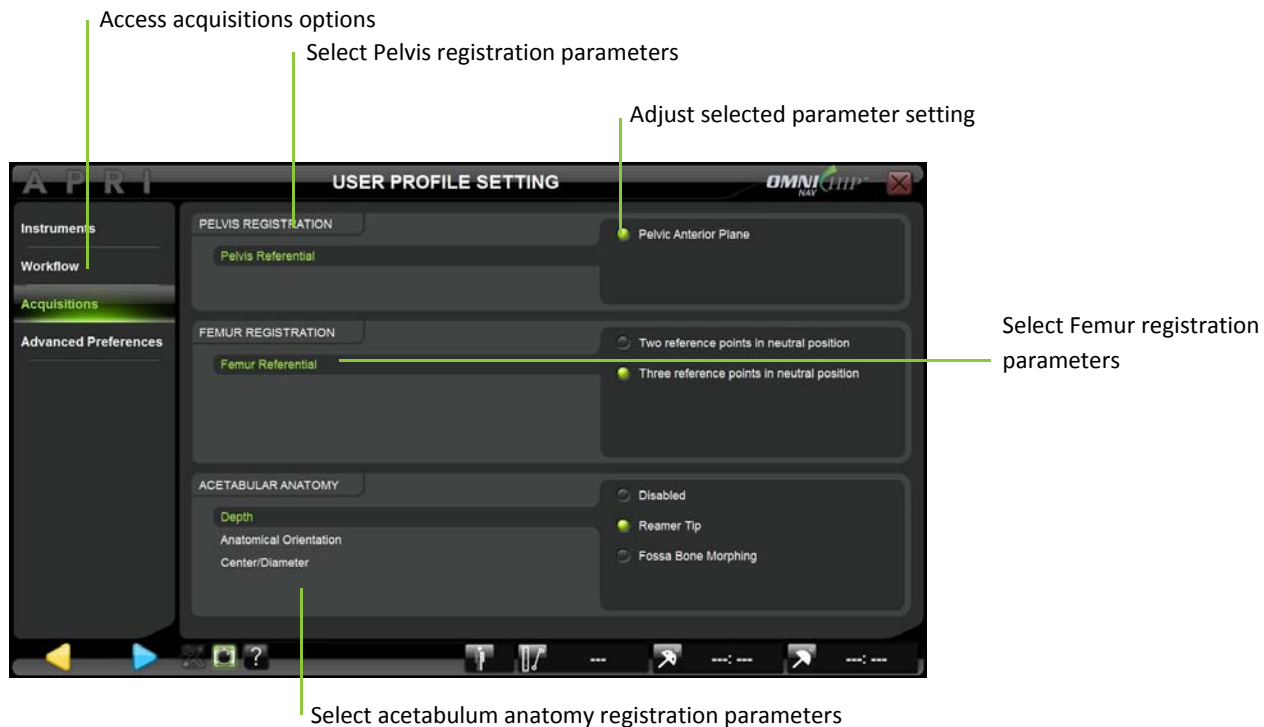


Modifying the workflow options: Touch “Workflow” tab to view the current workflow (corresponding to the profile selected initially) presented at a group level.

- Add or remove the following optional steps by simply checking or unchecking them in the list:
 - Reamer Tracking (See §4.7);
 - Cup Tracking (See §4.8);
 - Leg Length & Offset (See §4.9);

Note: The first few preparation steps (Patient Information, Instruments Calibrations and Reference & Camera) are not represented as they must be performed before any protocol regardless of profile selection.

Note: In this application groups cannot be moved up or down in the workflow.



Modifying the acquisitions options: Touch the “Acquisitions” tab and select the registration parameter to view or modify it.

The pelvis acquisition parameters are the following:

- Pelvis reference frame: Anterior Pelvic Plane

The femur acquisition parameters are the following:

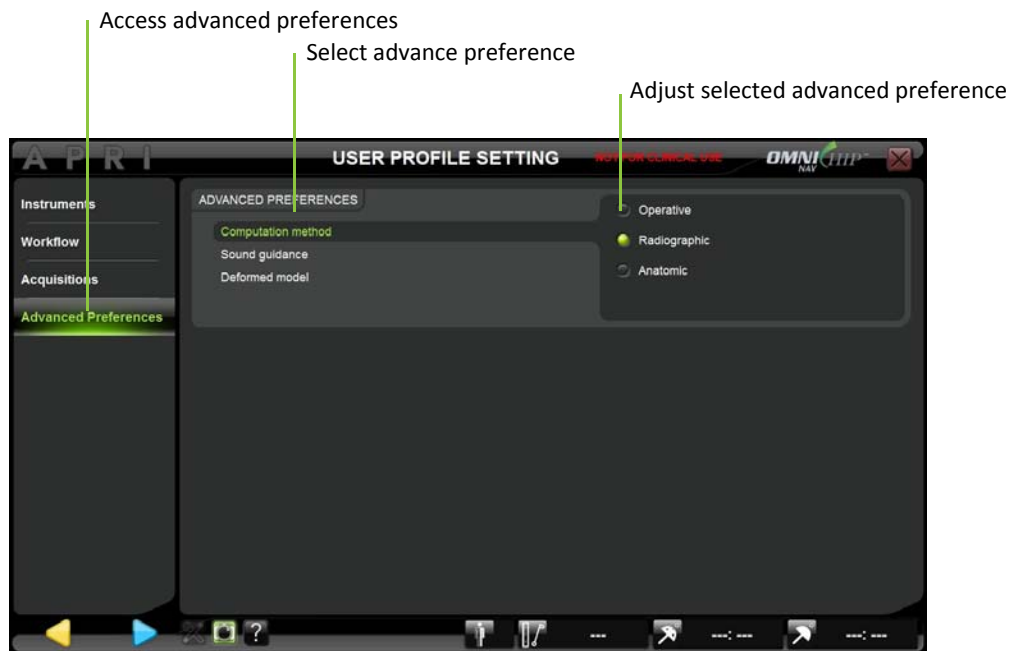
- Femur reference frame: Two Reference Points in Neutral Position or Three Reference Points in Neutral Position

Note: The femur reference frame option cannot be modified once the procedure has started (i.e. these options are not currently available via the Tab Navigation Menu).

The acetabulum anatomy acquisition parameters are the following:

- Depth: Disabled or Reamer Tip or Fossa Bone Morphing
- Anatomical Orientation: Disabled or Acetabular Fit or Rim Bone Morphing
- Center/Diameter: Disabled or Acetabular Fit or Articular Surface Bone Morphing

Note: The acetabulum anatomy options cannot be modified once the procedure has started (i.e. these options are not currently available via the Tab Navigation Menu).



Computation Method: Touch the “Advanced Preferences” tab and select Computation Method option. Then select preferred Computation Method “Operative” or “Radiographic” or “Anatomic” (For more details see §6.3).

Note: It is possible to change the computation method during Reamer Driver Tracking (§4.7) and Cup Impactor Tracking (§4.8) steps

Sound Guidance: Touch “Advanced Preferences” tab and select Sound Guidance option. Then select the preferred sound guidance setting: “Before acquisitions” or “During acquisitions” or both.


- If “Before acquisitions” is selected: a “hum” will be audible before each acquisition (calibrations and registrations) as soon as all necessary arrays (A, P, R or I) are visible and as long as the acquisition is not started.
- If “During acquisitions” is selected: a “tac-tac” will be audible during each continuous acquisition (Bone Morphing surfaces registration) as soon as the acquisition is started and all necessary arrays (A, P, R, or I) are visible and as long as acquisition is not yet completed.

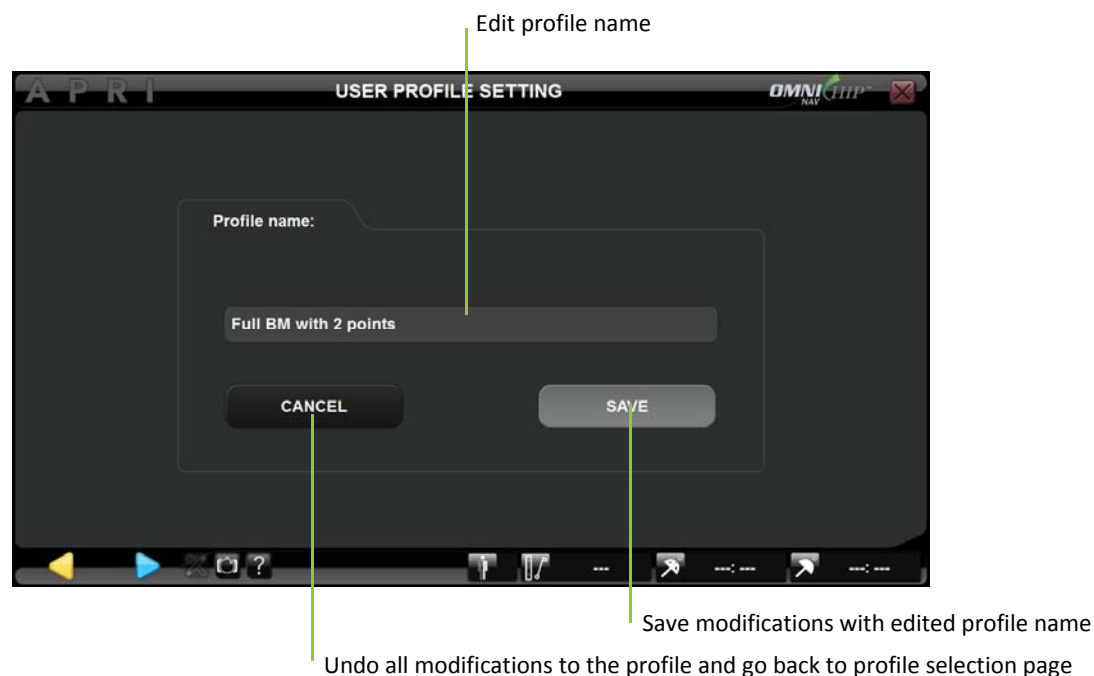
Note: the system will always provide the following sound guidance in addition to Sound Guidance options:

- A validation sound will be emitted at the end of each acquisition or calculation to signify that it was successfully completed.
- A warning sound will be emitted each time the system detects an error. In most of the cases this will go with a warning message.

Pelvis Model: Touch the “Advanced Preferences” tab and select Pelvis Model option. Then select preferred Pelvis Model “Show generic model” or “Show morphed model” (For more details see §6.6).

Saving a customized user profile:

- Touch  any time after the last modification to the profile selected initially.



- Give the profile a new name using the keyboard or leave the existing profile name to replace it.

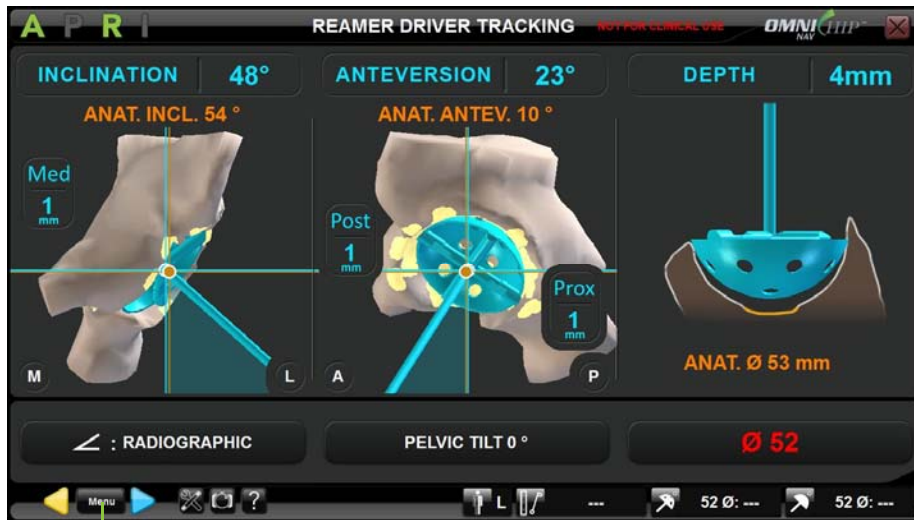
Note: Default profiles are protected (i.e. a customized profile cannot be saved with the same name as a default profile). If a default profile is selected to create a customized profile, a new profile name must be given to save the modifications.

- Touch the “Save” button to save the modified profile with the given profile name.

Note: Once saved the profile can be selected during future sessions. It is possible to save multiple customized profiles. Each profile must be given a unique profile name.

5.4 Tab Navigation menu

The Tab Navigation menu is a graphical interface giving access to steps or groups of the linear workflow following rules defined in next section (§5.5).

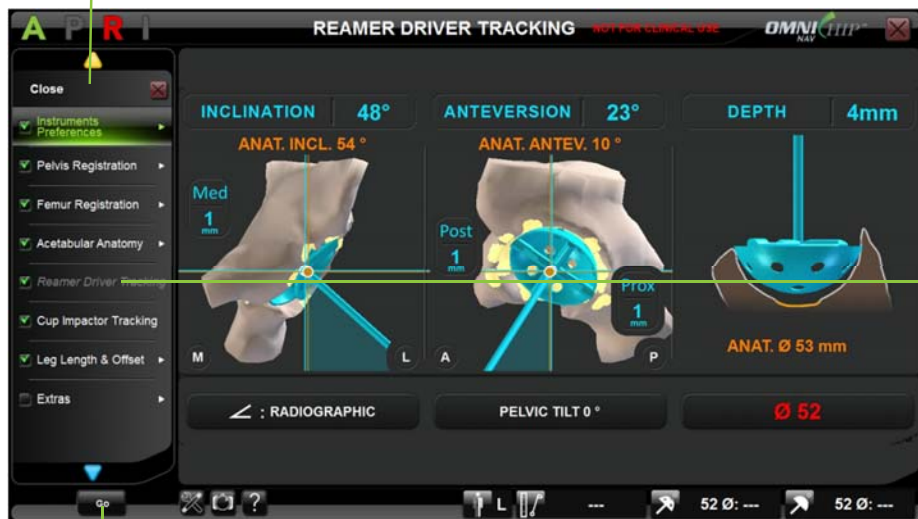


Open Tab Navigation menu

Navigating within the Tab Navigation Menu with touch interface:

- Touch **Menu**. The Menu opens on left hand side of the screen and gives access to the following tabs:
 - Instrument preferences
 - Pelvis Registration
 - Femur Registration
 - Acetabular Anatomy
 - Reamer Driver Tracking
 - Cup Impactor Tracking
 - Leg Length & Offset
 - Extras

Close Tab Navigation Menu



Select the tab to open or step to go to.

Open selected tab or Go to selected step

- Touch any tab with a ▶ to open sub level.
- Touch upper tab with a ◀ to return to upper level.
- Touch any step tab (tab with no sub level) to see a preview or a screenshot of the corresponding step.
- Double tap any step tab or touch **GO** to go to the selected step. See §5.5 for more details about Tab Navigation.



Warning!

WARNING: Using Tab Navigation to go to any step in the protocol will modify the workflow.

If the user moves to any step with parent steps then the system will require the parent steps before reaching the targeted step.

If the user moves to any step with children steps then the system will require the child steps after the targeted step before going back to linear workflow.

- Double tap the “Close” tab to close the menu with no incidence on the workflow.

Navigating within the Tab Navigation Menu with station’s foot pedal:

- Step on the center black foot switch to open the Menu from any step.
- Step on the blue foot switch to move one selection down in the Menu.
- Step on the yellow foot switch to move one selection up in the Menu.
- Step on the center black button to open the sub level of any selected tab with a ►.
- Step on the center black button to return to the upper level from upper tab with a ◀.
- Step on the center black button to “GO” to the step corresponding to the selected tab.

Instrument Preferences tab

This tab gives access to the following sub levels or steps:

- Calibration
 - Pointer
 - Reamer Driver Calibration
 - Cup Impactor Calibration

Calibrate or re-calibrate any or all instruments listed during a procedure.

Pelvis Registration tab

This tab gives access to the following sub levels or steps:

- Anterior Pelvic Plane
Go to all anterior pelvic plane acquisitions.
- Confidence Point
Go to the pelvis confidence point acquisition.

Femur Registration tab

This tab gives access to the following sub levels or steps:

- Leg Reference Position
Go to all leg reference position acquisitions (Two Reference Points in Neutral Position or Three Reference Points in Neutral Position depending on option selected in User Preferences – See §5.3)

Acetabulum Anatomy tab

This tab gives access to the following sub levels or steps:

- Depth
 - Reamer Tip
 - Fossa Bone MorphingGo to any of the acquisitions listed if option selected in User Preferences (See §5.3)
- Anatomical Orientation
 - Acetabular Fit
 - Rim Bone MorphingGo to any of the acquisitions listed if option selected in User Preferences (See §5.3)
- Center/Diameter
 - Acetabular Fit
 - Articular Surface Bone MorphingGo to any of the acquisitions listed if option selected in User Preferences (See §5.3)
- Bone Morphing Validation
Check or go to the acetabulum Bone Morphing (3D model) validation if option selected in User Preferences (See §5.3)
- Bone Morphing Additional Points
Acquire additional points for acetabulum Bone Morphing if option selected in User Preferences (See §5.3)
- Bone Morphing All
Go to all acetabulum Bone Morphing acquisitions.

Reamer Driver Tracking tab

Check or go to the Reamer Driver tracking step.

Cup Impactor Tracking tab

Check or go to the Cup Impactor tracking step.

Leg Length & Offset tab

This tab gives access to the following sub levels or steps:

- Leg Final Position (if Three Reference Points in Neutral Position option selected in User Preferences - See §5.3)
Go to the all leg final position acquisitions.
- Leg Length and Offset
Check or go to leg length and offset control step.

Extras tab

This tab gives access to the following steps:

- References and Camera
Go to the References and Camera step.
- Final Information
Check or go to the Final Information step.

5.5 Using Tab Navigation

Returning to a previous step in the linear workflow:



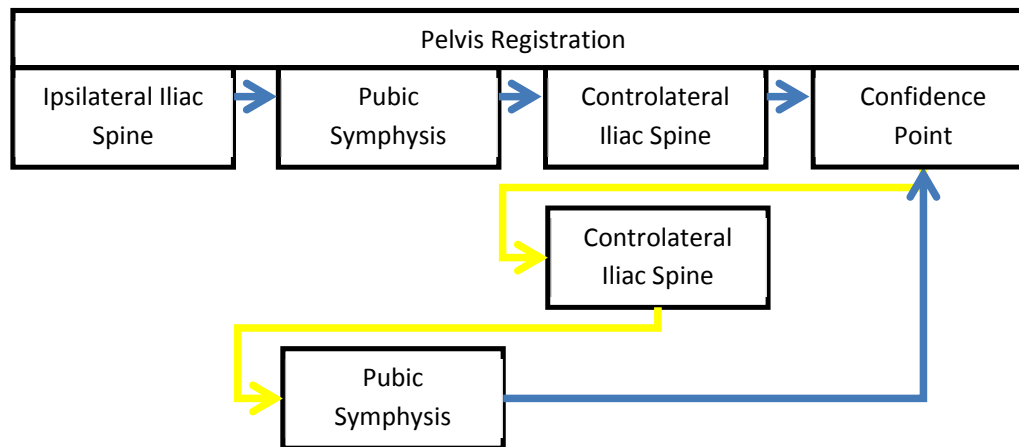

- Touch  multiple times until the desired step is reached.
- Touch  to redo a step and return to the current step in the linear workflow.

FIG.1



Note: Going back in the workflow using  is limited to groups. However, it is possible to return to a previous group if first step of the new group is not yet validated.

In the example below, it is possible to return to the Instruments Calibration group as long as Reference and Camera has not been validated (Fig. 2.1).

FIG.2.1

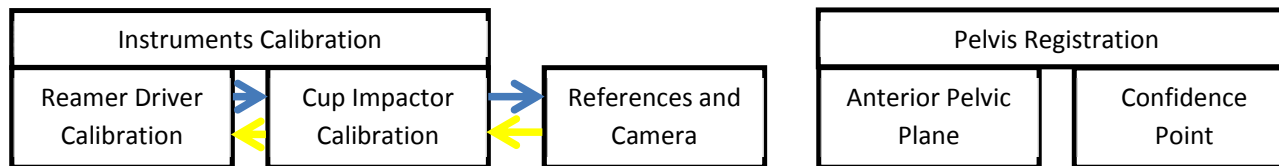
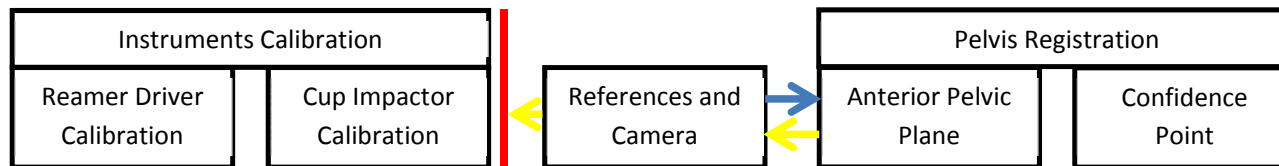


FIG.2.2



Advancing to a step:

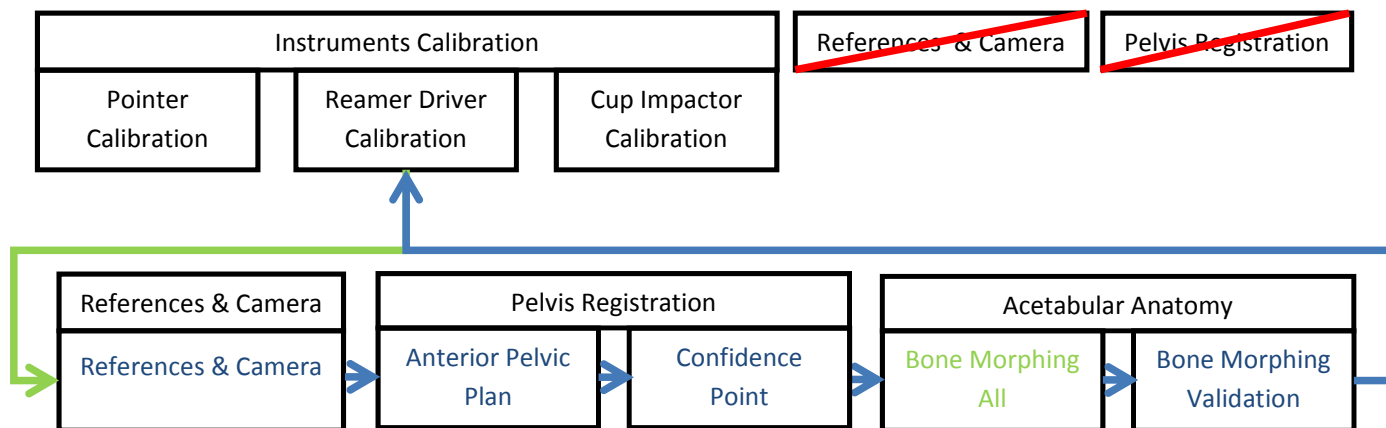
- Select the step you want to advance to in the Menu and touch “Go”.

Note: Advancing to a step with Tab Navigation will include both the parent steps (usually generating inputs necessary to the specified step) and children steps (usually control steps) if necessary.

In the example below, the user wants to perform Acetabular Bone Morphing before calibrating Reamer Driver and Cup Impactor

- Jumping to Bone Morphing All with Tab Navigation requires the Pelvis Registration to be completed which requires Reference and Camera step to be validated.
- After Bone Morphing All: Bone Morphing Validation will be performed immediately.

FIG.3



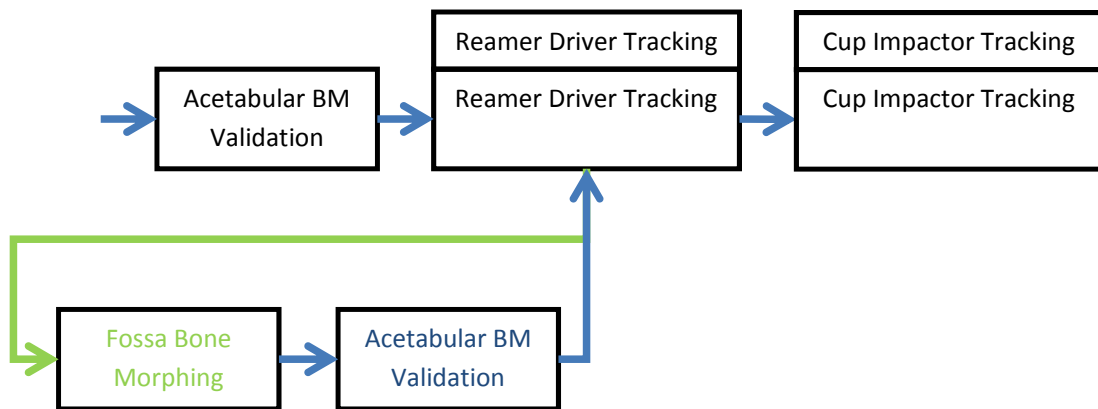
Redoing a step:

- Select the step to redo in the Menu and touch “Go”.

Note: Redoing a step with Tab Navigation will include some children steps (usually control steps) if necessary before coming back to linear workflow.

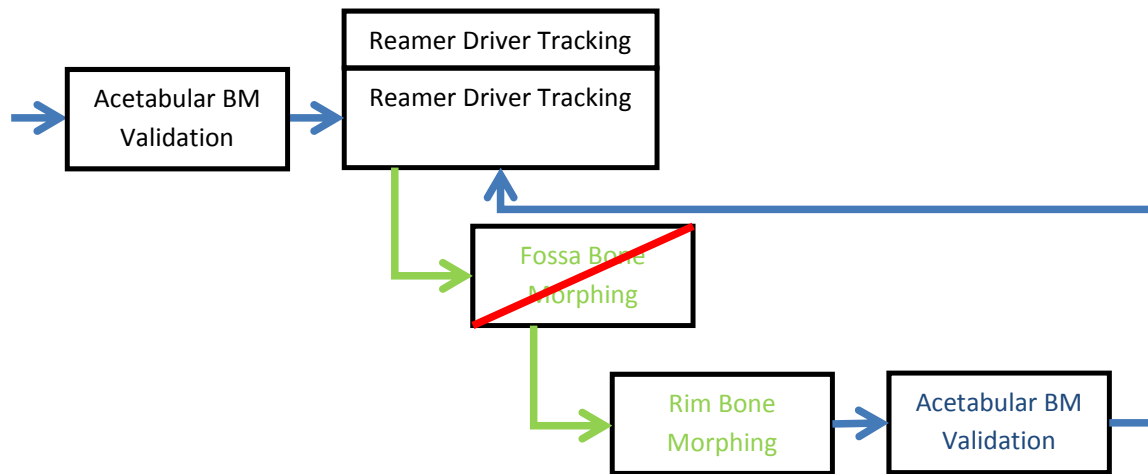
In the example below, the user wants to reacquire the Fossa Bone Morphing during Reamer Driver Tracking. It will require the new Bone Morphing data to be validated before returning to Femur Planning.

FIG.4



From a step accessed with Tab Navigation, it is also possible to move immediately to a new step with Tab Navigation with no impact on the workflow.

FIG.5



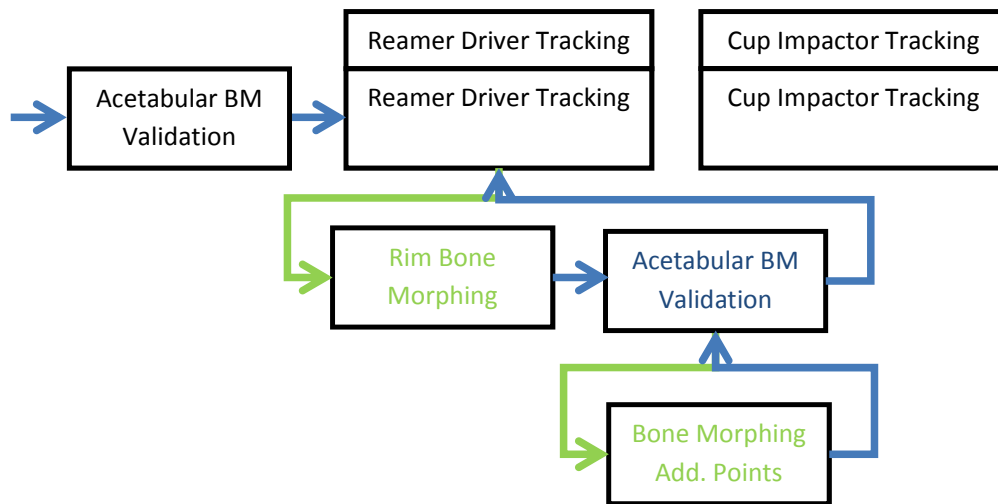
WARNING: It is no longer possible to return to the linear workflow using Tab Navigation if the first step after Tab Navigation jump has been completed. In this case, the user must complete successive steps (rest of the group or children) before returning to the linear workflow.

Multiple jumps:

It is not necessary to wait until returning to the linear workflow before moving to a different step with Tab Navigation.

In the example below, the user wants to redo the Rim Bone Morphing during Reamer Driver Tracking step. It will require the new Bone Morphing data to be validated before returning to the Reamer Driver Tracking step. When viewing the Acetabular Bone Morphing model, the user decides to add some points to the Bone Morphing model to improve points coverage in the articular surface area.


FIG.6



	<p>RECOMMENDATION: The user should try to complete all steps following a jump with tab navigation (i.e. returning to the initial step where the user was before jumping to another step with Tab Navigation menu in order to avoid an unexpected workflow).</p>
--	--

Returning to a previous step in the non-linear workflow:

Going back in a group of step initiated by a jump with Tab Navigation is possible.

In the example below, the user decides to redo the Pelvis Registration / Anterior Pelvic Plane. During this sequence the user can touch  to go back to any acquisition step in this sequence.


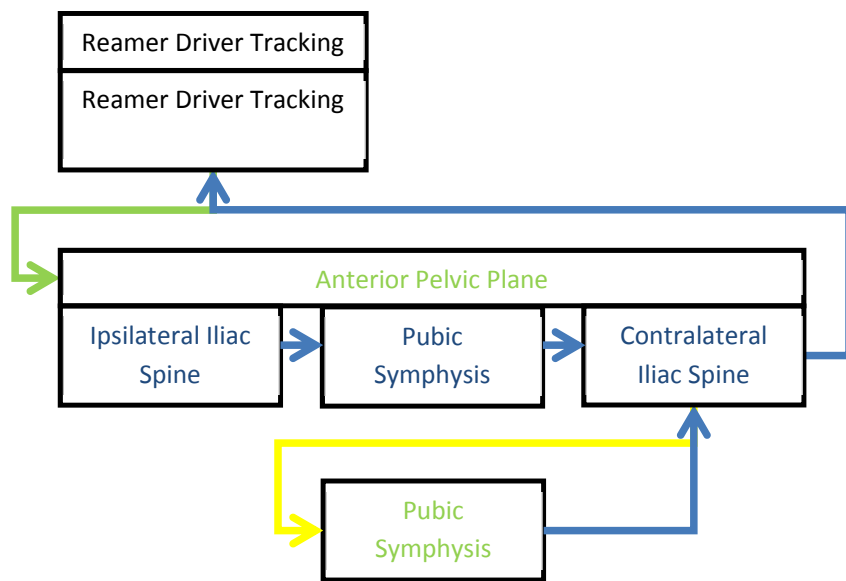
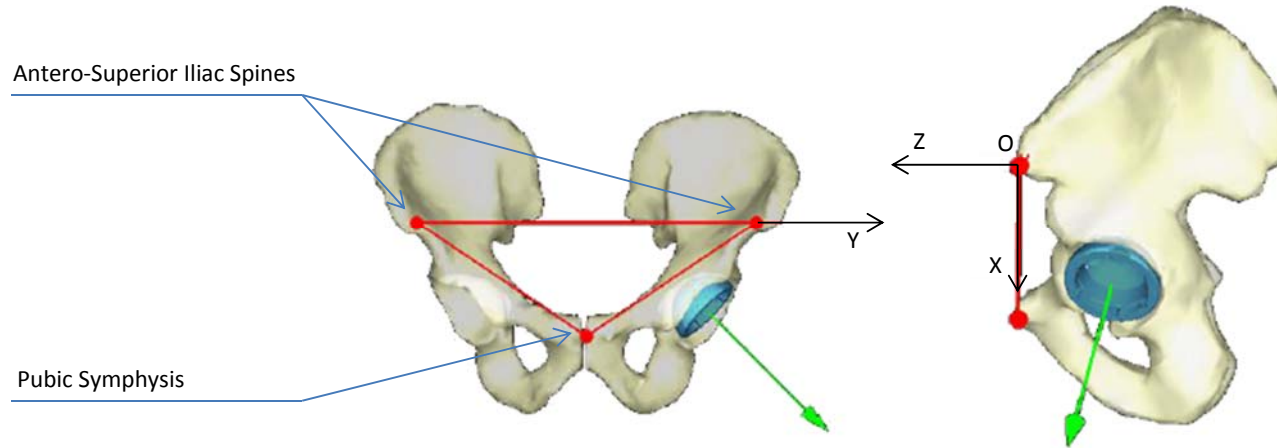
Note: Once 1st step of the sequence is completed it is no longer possible to return to the Reamer Driver Tracking step using . The user should complete all successive steps to reach Femur Planning.

FIG.7



6 Technical notes

6.1 Pelvis Registration: Anterior Pelvic Plane



The anterior pelvic plane is the reference for the computation of inclination and anteversion angles. It is defined by the two antero-superior iliac spines and the pubic symphysis.

Patient Transverse Axis:

This axis (Oy) is defined by the line joining the two iliac spines.

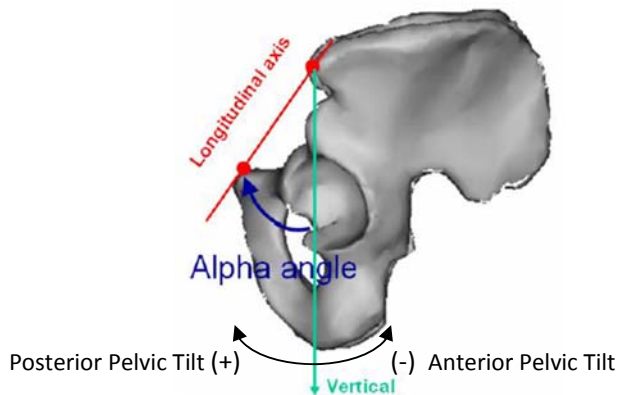
Patient Longitudinal Axis:

This axis (Ox) is defined by the pubic symphysis and its perpendicular projection on the transverse axis. This axis corresponds to the vertical. In case of patient pelvic tilt, a correction has to be taken into account, this is the purpose of the pelvic tilt angle described in §6.2.

Frontal plane (xOy):

This plane, which defines the frontal view, is the plane passing through the transverse axis and the longitudinal axis.

6.2 Pelvic Tilt



Pelvic Tilt Angle Definition

The pelvic tilt angle (α) is the angle that allows a correction between the longitudinal axis of the anterior pelvic plane and the true vertical axis.

How to measure the Pelvic Tilt Angle

The pelvic tilt angle (α) associated to the patient's pelvis can be determined on a lateral X-ray. This X-ray must be done so that the two antero-superior iliac spines are superimposed.

The pelvic tilt angle (α) is measured from the true vertical axis to the longitudinal axis of the anterior pelvic plane it must be oriented (+/-):

- Posterior Pelvic Tilt: $\alpha > 0$
- Anterior Pelvic Tilt: $\alpha < 0$

How to use the Pelvic Tilt Angle

If the pelvic tilt angle (α) is used, the anterior pelvic plane reference frame will then be rotated by α degrees around the transversal axis. The computation of the inclination / anteversion angles will be done in the anterior pelvic plane corrected by the pelvic tilt angle (α).

To set the pelvic tilt angle (α) see §3.5.



RECOMMENDATION: It is recommended to set accurately the pelvic tilt angle. Correcting anterior pelvic plane with respect to the true vertical axis by one degree modifies the operative anteversion angle by one degree.

6.3 Computation Method for Inclination and Anteversion angles

Three different methods exist for the computation of the anteversion and inclination angles:

Method:	Operative	Radiographic	Anatomical
What each method corresponds to:	Angles as viewed by the surgeon in the OR, (i.e. using an alignment tower)	Angles as viewed on a post-operative coronal plane X-ray Anteversion based on the ellipse formed by the contour of the cup	True anatomical definition of anteversion and inclination angles, valid for both normal and dysplastic hips
Inclination (blue angles):	Angle between Reamer / Impactor axis and sagittal plane	Angle between patient's longitudinal axis and Reamer / Impactor axis projected onto the coronal plane	Angle between Reamer / Impactor axis) and patient's longitudinal axis
Anteversion (purple angles):	Angle between patient longitudinal axis and Reamer / Impactor axis projected on sagittal plane	Angle between the Reamer / Impactor axis and the coronal plane	Angle between patient's transverse axis and Reamer / Impactor axis projected onto the transverse plane

Selection of the computation method is described in Customized user profile settings (See - §5.3).

6.4 Femur Registration

Two different options are proposed for the registration of the femur and computation of leg length and offset parameters:

- Two Reference Points in Neutral Position
- Three Reference Points in Neutral Position

The selection of the registration option is done as described in Customized user profile settings (See - §5.3).

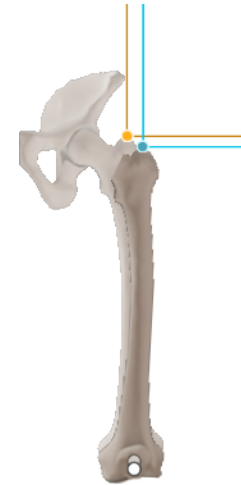
Two Reference Points in Neutral Position

This option requires placing the leg in neutral position relative to the pelvis during both the leg reference position registration process and the final leg length and offset control process.

One distal point is used to control that final leg position is equivalent to reference position in terms of Flexion/Extension and Abduction/Adduction. Axial rotation is not controlled by software in this case.

Leg length: Distance between the proximal reference point in leg reference position and the proximal reference point in leg final position along the patient's longitudinal axis.

Leg offset: Distance between the proximal reference point in leg reference position and the proximal reference point in leg final position along the patient's transverse axis.



Three Reference Points in Neutral Position

This option allows a true 3D registration of the femur reference frame in both leg reference and final positions via a three reference points registration process.

It requires placing the leg in neutral position relative to the pelvis only for the leg reference position registration process.

During the leg length and offset control step the leg length and offset are computed comparing the cup center virtual position in leg reference position and cup center actual position in leg final position.

Leg length: Distance between the cup center virtual position in leg reference position and cup center actual position in leg final position along the patient's longitudinal axis.

Leg offset: Distance between the cup center virtual position in leg reference position and cup center actual position in leg final position along the patient's transverse axis.



6.5 Acetabular Bone Morphing

The aim of Bone Morphing is the intraoperative reconstruction of the patient anatomy 3D model. The system needs to collect data on the anatomical surface to compute this reconstruction.

The reconstruction process starts with an acquisition stage in which points are digitized on the bone surface. The surface points are acquired using the Pointer which needs to slide over the whole surface covering as large an area as possible. It is strongly recommended that all osteophytes are removed before starting the bone surface acquisition process.

Fossa and Articular Surface Bone Morphing acquisition

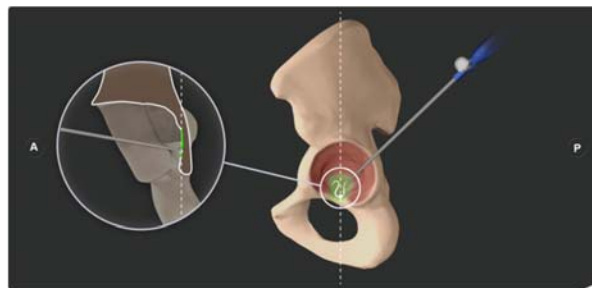
These acetabular surfaces are acquired locally to guarantee accurate anatomical parameter computation (Depth and Center/Diameter). Once the acquisition is started, the Pointer must not be lifted from the bone surface until the end of the digitization of the current zone. Each zone is digitized separately. To start the acquisition of a zone, place the Pointer on the bone surface and press the blue pedal. Then slide the Pointer over the bone surface covering the entire area of the zone. In order to achieve the highest accuracy possible, the key point of this acquisition process is the homogeneity of the digitized points in the different zones. The computation process prefers that the surface digitization is as homogenous as possible, with a roughly equal spread of points across the zone.

When the acquisition of a zone is completed, the protocol passes to the following zone automatically.

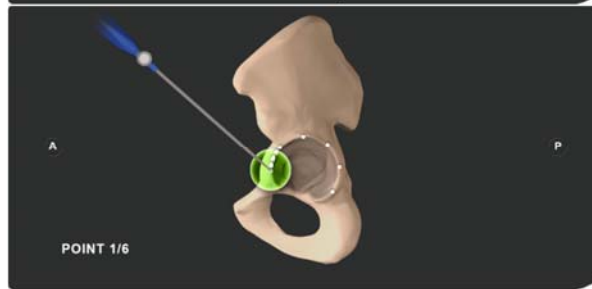
Rim Bone Morphing acquisition

This surface is acquired locally via six individual points to guarantee accurate anatomical parameter computation (Anatomical Orientation). Once the acquisition is started, the Pointer is moved from point to point until the end of the digitization of the current zone. To start the acquisition of that zone, place the Pointer on the rim edge and press the blue pedal. Then move to next point and repeat the same registration process. In order to achieve the highest accuracy possible, the key point of this acquisition process is the homogeneity of the digitized points along the acetabular rim. The computation process prefers that the rim digitization is as homogenous as possible, with a roughly equal spread of points from acetabular anterior notch to posterior acetabular notch.

When the acquisition of this zone is completed, the protocol passes to the following zone automatically.



1. Acetabular Fossa



2. Acetabular Rim



5. Acetabular Articular Surface

When the computation is completed then you access a stage to check the accuracy of the reconstruction (see §4.6).

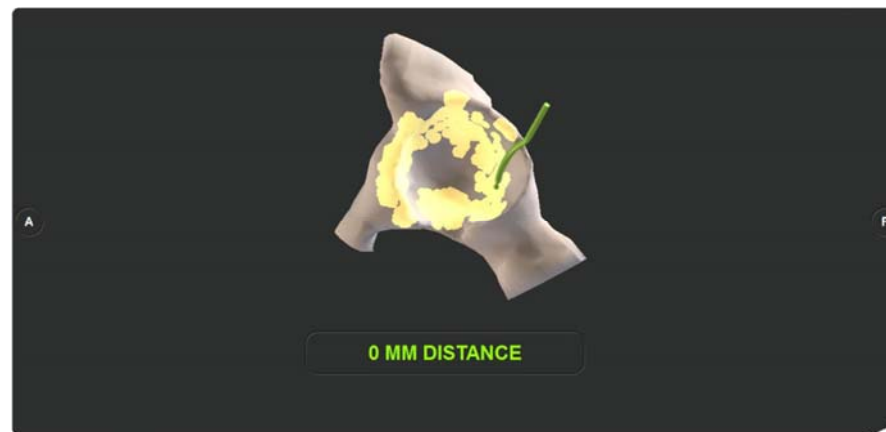
Bone Morphing Validation

The reconstructed bone model is displayed on the screen and the user is asked to slide the Pointer over the patient's actual bone surface again. The distance between the locally reconstructed model and the actual surface can then be checked.

If the accuracy of the reconstruction is satisfactory, i.e. less than 1.0mm in the areas used for anatomical parameters computation, the Pointer is displayed in green and you can validate with the blue pedal. If the accuracy is not satisfactory:

- Go back with yellow button to restart some acquisitions from the start
or
- Use Tab Navigation Menu to add new points to enrich the acquisitions in the areas where you wish to have more accuracy (recommended).

If additional points are added to increase the accuracy, the points that have already been acquired will not be lost. The acquisition is enhanced with the new acquired points and a new Bone Morphing computation is performed.



6.6 Pelvis Model display modes

Two different options are proposed for the display of the pelvis model during Reamer Driver Tracking and Cup Impactor Tracking steps:

- Show generic model
- Show morphed model

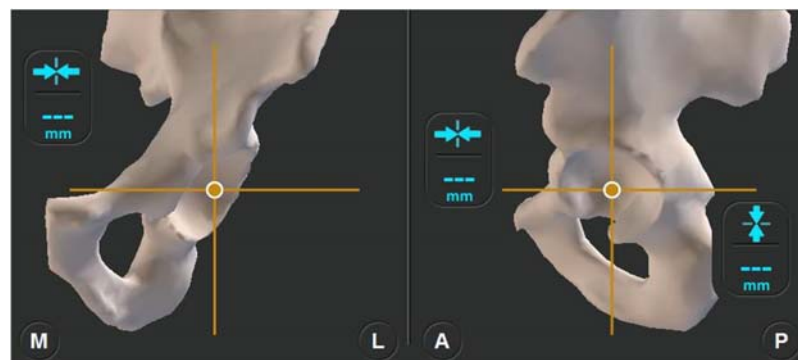
The selection of the registration option is done as described in Customized user profile settings (See - §5.3).

Show generic model

A full generic hemi-pelvis will be displayed during Reamer Driver Tracking and Cup Impactor Tracking steps.

This option doesn't require any Bone Morphing registration of the acetabulum.

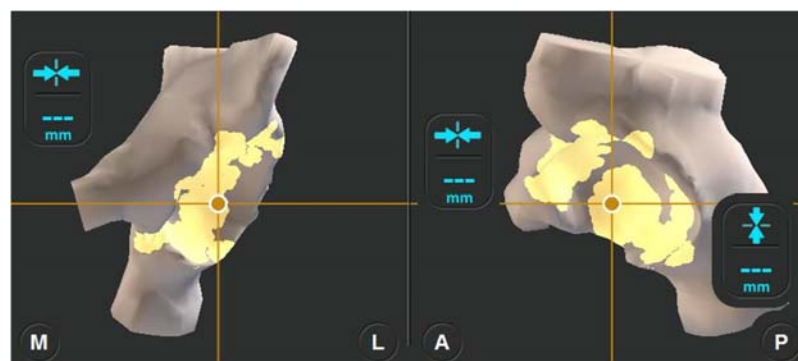
This option can be selected even if Bone Morphing options have been selected for computing native acetabulum anatomical orientation or center/diameter.



Show morphed model

The acetabular bone model reconstructed via Bone Morphing is displayed during Reamer Driver Tracking and Cup Impactor Tracking steps.

This option requires Bone Morphing registration of the acetabulum and it can be selected if Bone Morphing options have been selected for computing native acetabulum anatomical orientation or center/diameter.



7 Troubleshooting

PROBLEM	DIAGNOSIS	SOLUTION
One of the arrays is no longer visible to the system, even if it is in front of the camera.	<ul style="list-style-type: none"> ➤ One of the markers is soiled or out of position. ➤ Disturbance caused by another source of light. 	<ul style="list-style-type: none"> ➤ Check that the markers on the array are clean and clipped correctly. Change defected markers if necessary and recalibrate the instrument. ➤ Change the position and orientation of the camera.
An error message appears at the beginning of the application reporting that the camera is not connected properly.	Problem with the camera connection.	<ul style="list-style-type: none"> ➤ Check the camera connection plug. ➤ Restart the system. ➤ If the problem persists, call maintenance.
An error message appears at the beginning of the application reporting that the camera requires warm-up time.	Camera is out of specified operating temperature range or not yet warmed up.	Wait for a couple of minutes for camera to be warmed up (Power LED I stops flashing) and retry. Next time, start station a few minutes before starting protocol.
An array is not visible and/or the system displays "INFRA-RED DETECTED" in the upper part of the screen	The system detects infra-red interference which blocks the visibility of the arrays.	<ul style="list-style-type: none"> ➤ Check that no one is in front of camera or directly interfering with camera. ➤ Adjust any surgical lights that may be directly shining on the array or camera. ➤ Modify slightly the position of the camera to reduce interferences.
The anatomic data no longer correspond to reality (inclination and anteversion angles, reamer or cup centering, depth, etc...).	Check that the acetabular array is not moving or have not moved using the pelvic confidence point.	<ul style="list-style-type: none"> ➤ If hip neck has been cut and the acetabular arrays has moved, the surgeon must go back to Pelvis Registration with Tab Navigation Menu or revert to conventional surgical protocol but leg reference position is lost and leg length and offset cannot be controlled relying on the system anymore. ➤ If not, it is possible to reattach the array and to go back to full registration with Tab Navigation Menu.
Nothing happens when any pedal is pressed.	Problem with the foot pedal connection.	<ul style="list-style-type: none"> ➤ Check the foot pedal connection plug. ➤ If the problem persists, call maintenance. <p>NB: It is possible to perform the procedure using</p>

		buttons on the touchscreen
Nothing happens when the blue pedal is pressed or the blue arrow is touched.	The arrays necessary for the stage are not visible.	Make the arrays visible.
Tab Navigation Menu does not jump directly to the selected step.	Selected step requires some parent steps to be performed before (necessary inputs)	➤ Perform required steps until you reach initially selected step.
After performing some step with Tab Navigation Menu, system does not go back directly to initial workflow.	Steps performed via Tab Navigation require some children steps to be performed before going back to initial workflow as their input data have been modified.	➤ Perform required steps until you get back to initial workflow.
Software is not more responsive to any actions for more than a couple of seconds	Software crash or freeze	➤ Reboot the system and restart the application. Proceed to registration following the linear workflow or use Menu to access quickly to last performed step. Or ➤ Complete case with conventional instruments
No value is displayed when controlling tracked instrument calibration accuracy (Reamer Driver or Cup Impactor)	<ul style="list-style-type: none"> ➤ The arrays necessary for the stage are not visible. ➤ The instrument is not calibrated or the array is attached to a calibrated side of the instrument. 	<ul style="list-style-type: none"> ➤ Make the arrays visible. ➤ Calibrate that side of the instrument using Menu or swap the array to the other side of the instrument.

Refer also to associated documents (See - §1.3)

8 Maintenance and monitoring

The software does not require any specific maintenance.

See the instructions for use of the system components listed in §1.3 « Associated documents ».