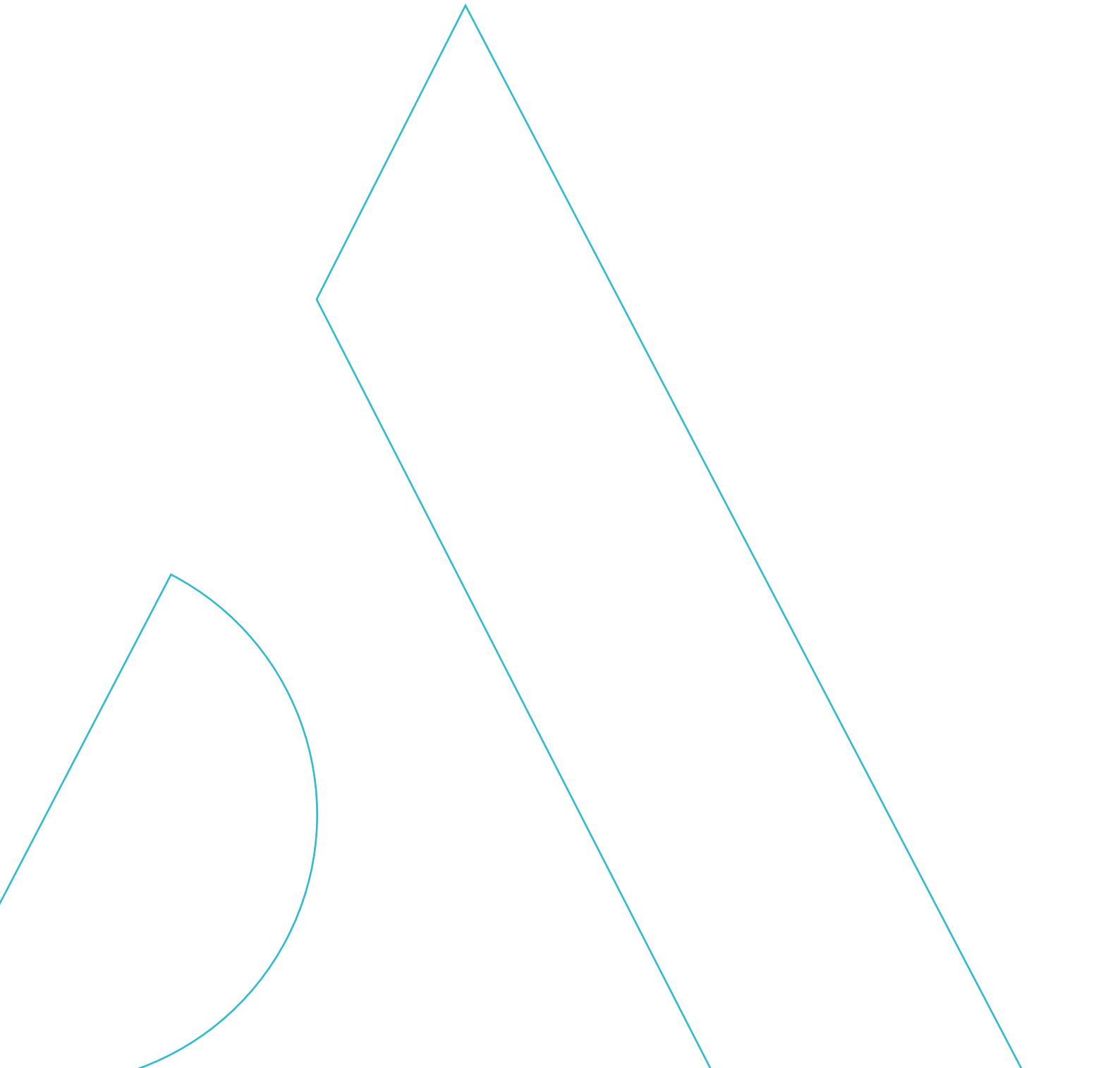
amplivision

amplitude

Surgical Technique

SKN Smart Knee Navigation



Summary

Introduction

- This Surgical Technique Supplement describes the use of the AKN (Advanced Knee Navigation) computer-assisted surgery software for implanting Amplitude's total knee arthroplasty (TKA) systems.

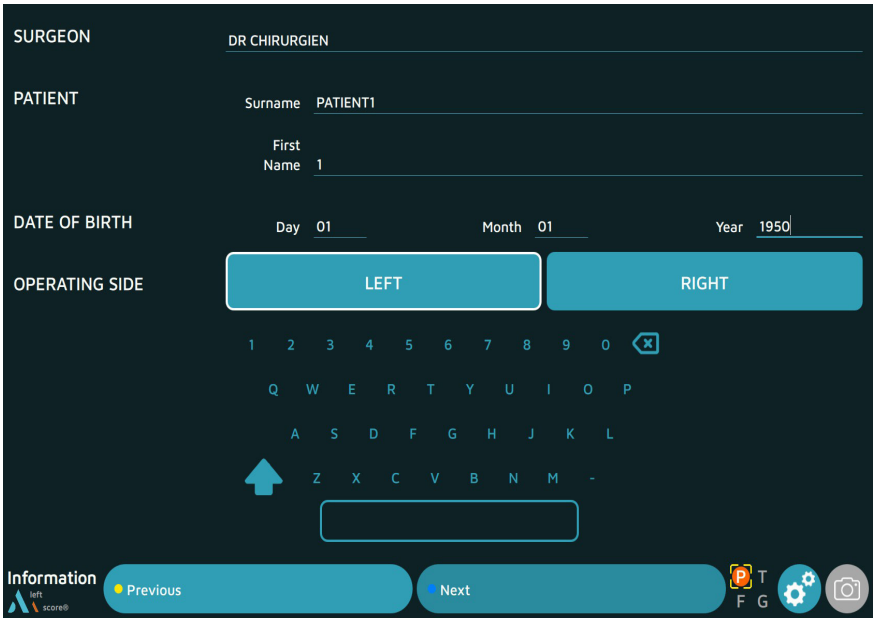
- This software is used to navigate tibial resection and distal femoral resection.

- This surgical technique replaces the following paragraphs from conventional surgical techniques TO.G.009 and TO.G.013 (for SCORE and SCORE II TKAs, 4-in-1 technique), TO.G.002 (for ANATOMIC TKA, 4-in-1 technique), and TO.G.041 (for TRAX CR TKA):
    > The paragraphs on the distal femoral cut
    > The paragraphs on the tibial guides
    > The paragraphs on the tibial cut

Starting the software

On the touch screen

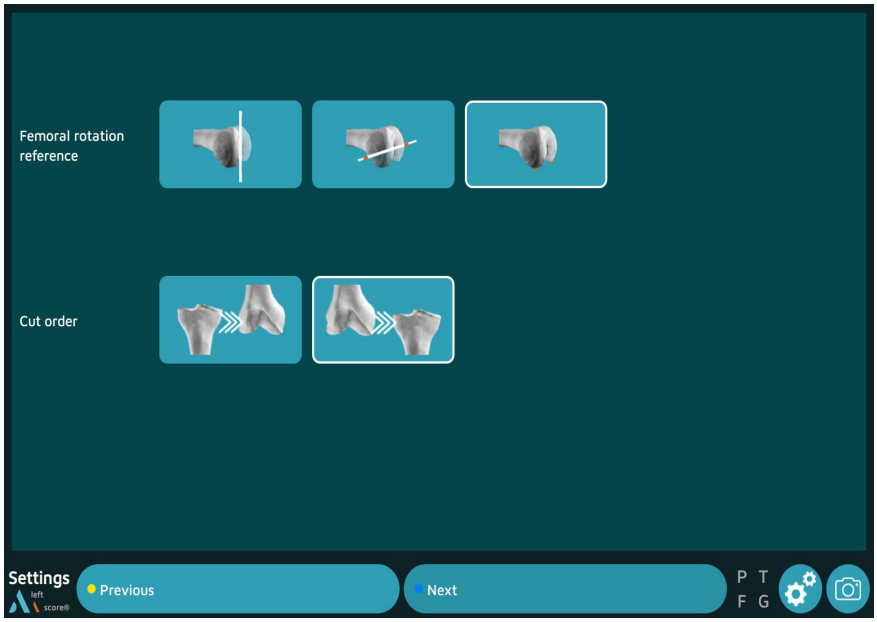
- Select the language.
- Select the knee.
- Select the implant.
- Select the **SKN**.



- On the « Information » page, input the required information using the virtual keyboard.
  - Surgeon name
  - Patient name and surname
  - Patient date of birth (optional)
  - Operated side (select right or left)
- To go to the next step, press the blue pedal or Next on the screen.
- To go to the previous step, press the yellow pedal or Previous on the screen.

User settings

Surgical workflows



- Configuring the surgery-related options:

  Three methods can be used to define the femoral rotation reference:

  - Perpendicular to the **AP (sagittal) axis**
  - Using the **trans-epicondylar axis**
  - Using the **posterior condylar axis**

  Order of cuts:

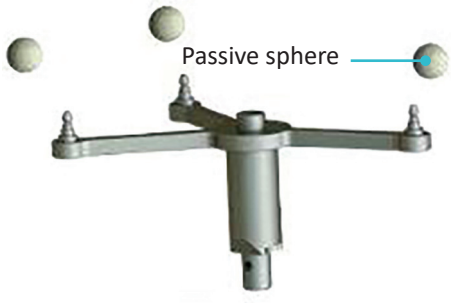
  - Tibial cut first then distal cut
  - Distal cut first then tibial cut

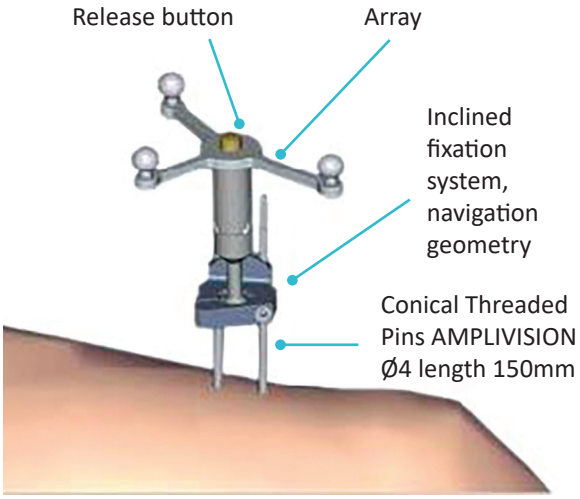
- Press the blue pedal to go to the next step.

Set up

Setting up of the arrays

- Clip the AMPLIVISION sterile Passive spheres to the arrays:
  - 3 for the T array, tibia navigation
  - 3 for the F array, femur navigation
  - 4 for the Probe, knee navigation
  - 3 for the G array, Instrumentation navigation





- The Conical Threaded Pins AMPLIVISION Ø4 length 150mm must be placed on the antero-medial side of the femur and tibia (when the surgeon stands on the lateral side) and must not interfere with tap placement. They can be inserted either percutaneously or through an incision.

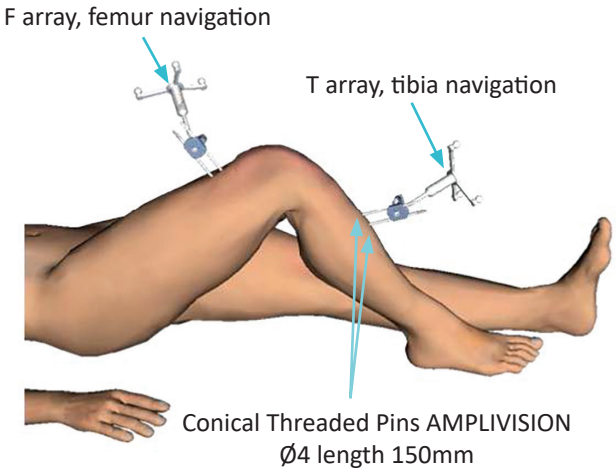
NOTE

If the femoral pin is being inserted percutaneously, make sure the knee is flexed to prevent damaging muscle fibres

- Insert the first pin: go through the proximal cortex and then into, but not through, the distal cortex.
- Place the Inclined fixation system, navigation geometry, on the first pin to get the proper spacing for the second pin.
- Clip the F array on the moveable part of the support, making sure the arrows are aligned correctly. If the array needs to be removed during the procedure, it can be returned to the same position on the support.
- Position the array towards the camera head and lock the fixation support.
- Position and secure the arrays so they are always visible to the camera head, whether the knee is flexed or extended.

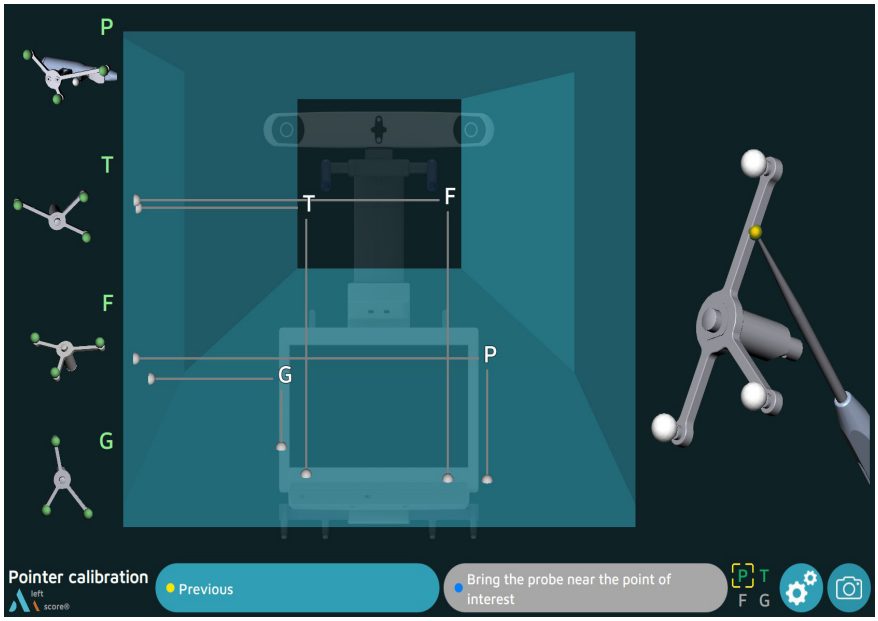
NOTE

There is no need to fix the T array in the tibia if the tibial cut is not navigated. The same applies to the F array if the distal cut is not navigated.



Set up

Setting up of the camera



- Position the camera head so the letters corresponding to the F and T arrays are in the middle of the field of view.

The laser located between the two optical sensors of the AMPLIVISION workstation makes this adjustment easier.

- Confirm that the Probe knee navigation P array is visible.
- On the left side of the screen, a 3D view of the arrays indicates why an array may not be visible:

  > The array will be green if it is fully visible.

  > Any passive sphere that is not visible on an array will be orange, as will the letter associated with this array.

The array's visibility may be compromised by interfering infrared sources (sunlight, hot lights, dirty passive spheres).

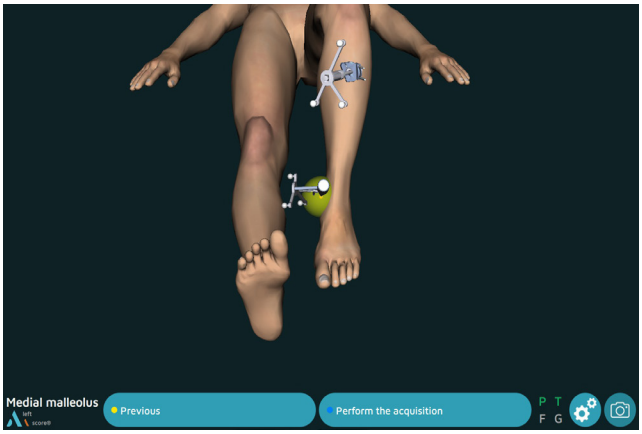
Probe calibration

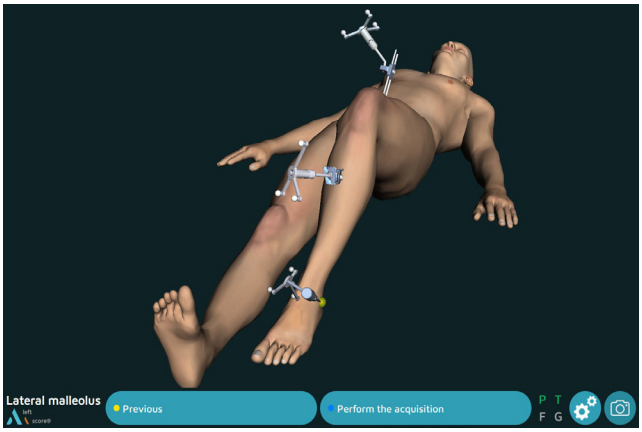
To define exactly the position of the probe tip,

- Calibrate the probe by placing its tip in the conical calibration mark on one arm of the T array
- Press trigger to confirm
- Without lifting the probe tip, change the probe's orientation slightly
- Press the trigger to confirm

Tibial registrations

Ankle center registration





Case where the order of anatomical acquisitions is the **tibia first**.

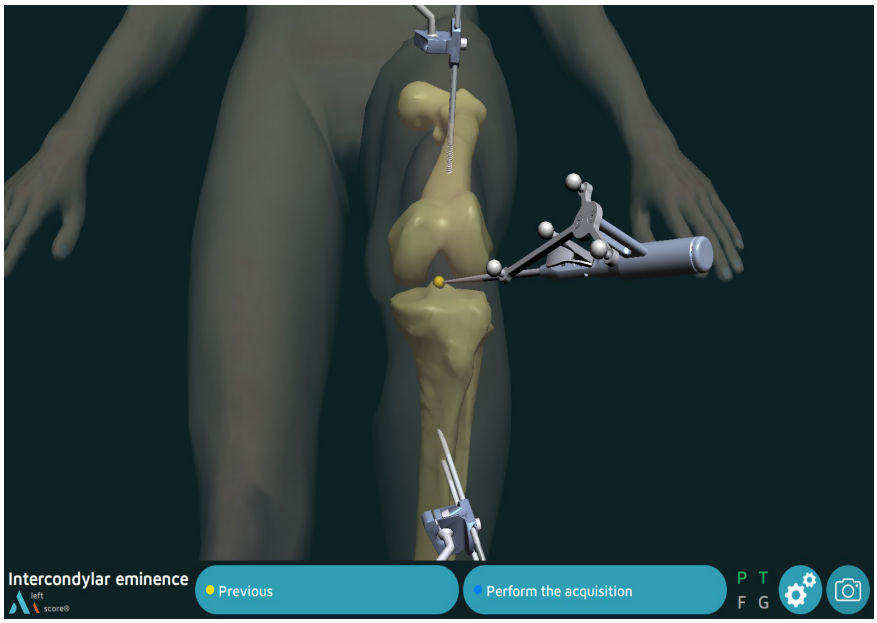
Medial malleolus

- Place the probe tip on the most medial point of the medial malleolus.
- Press the trigger on the probe to confirm.

Lateral malleolus

- Place the probe tip on the most lateral point of the lateral malleolus.
- Press the trigger to confirm.

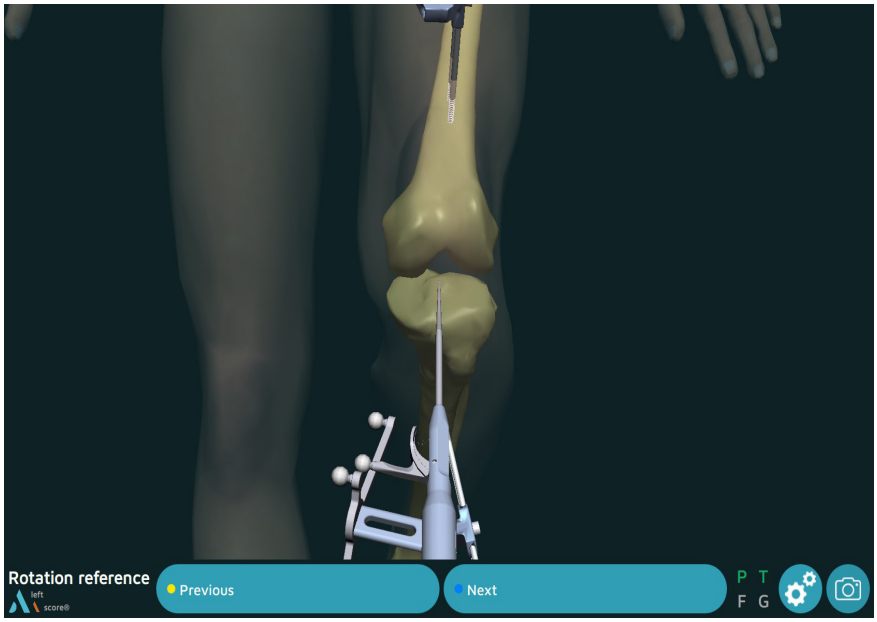
Tibial center registration



- Place the probe tip on the middle of the intercondylar eminence on the axis of the tibial shaft.
- Press the trigger to confirm.

Tibial registrations

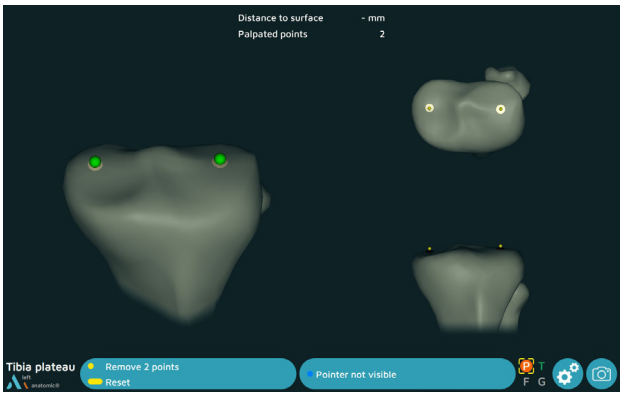
Tibial reference rotation



- Place the probe tip on the intercondylar eminence and turn the body of the probe.
- Once it corresponds to the desired sagittal plane orientation, confirm its position.

Tibial registrations

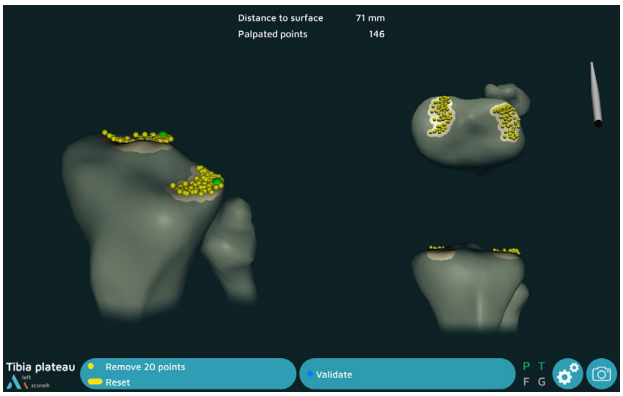
Proximal resection height references



Two options for acquiring the proximal resection height reference:

Acquisition of one point on each tibial plateau:

- Palpate one point on the plateau and validate by pressing the trigger.
- Repeat on the contralateral plateau.
- These two points will serve as references for the proximal resection height in each compartment.



Acquisition of one area on each tibial plateau:

- On each plateau, place the probe tip on the bone surface. Press and hold trigger then move the tip along the surface being acquired.
- At any time, the surgeon may release the trigger, move the probe tip to another location and then press the trigger again to continue the acquisition.
- The last 20 acquired points can be deleted by pressing the yellow pedal.
- Press and hold down the yellow pedal (for at least 2 seconds) to erase all the acquired points
- The most distal points will be calculated automatically and saved as the resection height reference (green points).
- Press the blue pedal to go to the next step.

NOTE

Make sure the probe tip is always in contact with the tibial bone surface when the trigger is pressed

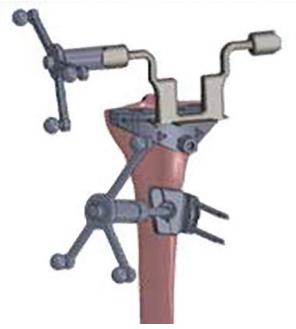
NOTE

It is important to acquire points at the bottom of the plateau, not the ones on the side of it

Tibial navigation

Tibial resection

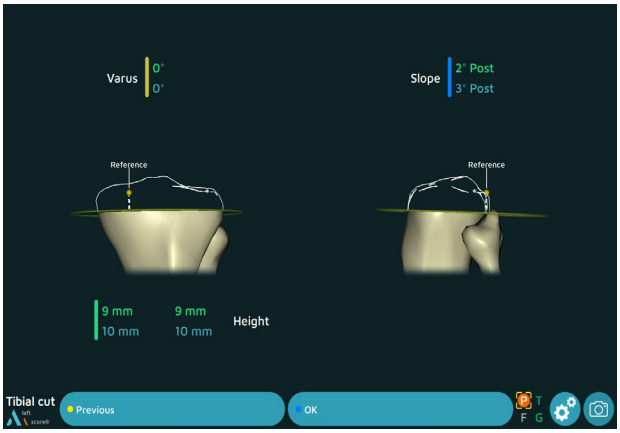
This step can be performed using either the Universal Alignment Guide or the Semi-assisted resection guide.



Using the Universal Alignment Guide:

- Secure the G array, Instrumentation navigation to the Universal Alignment Guide.
- Position the universal guide's plate in the slot of the Tibial resection guide (or the 4T Tibial Resection Guide - 0°).
- Adjust the positioning until the guide is in the position needed to perform the tibial cut.

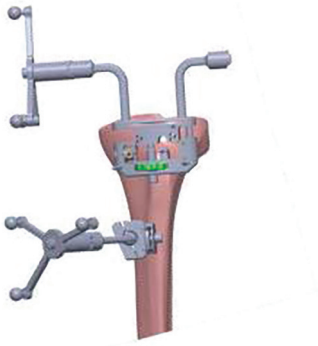
The blue values represent the default targets. White values are real time values. The values are green when they are close to the targets (+/-1 degree or mm).



- Insert 2 Headless pins length 80 mm in the resection guide's «0» holes.
- Remove the Universal Alignment Guide
- Secure the resection guide with 3 Headed pins length 70 mm,
- Perform the tibial cut
- Remove the guide

Using the Semi-assisted resection guide:

- Secure the G array to the Semi-assisted resection guide
- adjust the positioning to get close to the position needed to perfomr the tibial cut.
- Insert a Headless pin length 80 mm in the alignment hole to stabilise the guide



The blue values represent the targets based on the user settings. White values are real time values. The values are green when they are close to the targets (+/-1 degree or mm).

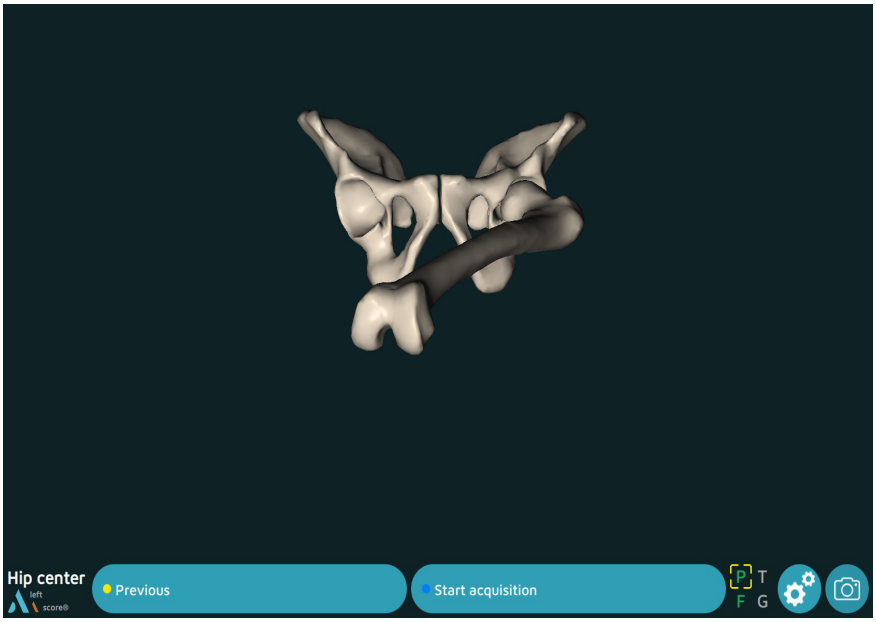
- Insert 2 Headless pins length 80 mm in the guide's «0» holes.
- Secure the semi-assisted guide with 3 Headed pins length 70 mm,
- Perform the tibial cut
- Remove the guide

Acquisition

- Once the tibial cut has been made, check with the Universal Alignment Guide placed on the cut.
- Press the blue pedal to confirm and continue to the next step.

Femoral registrations

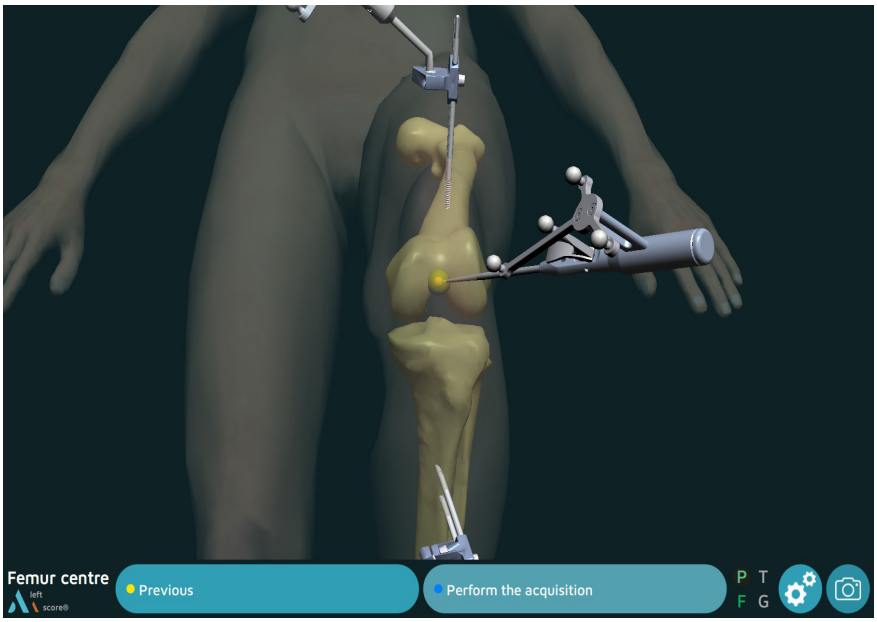
Hip center registration



- Extend the patient's leg
- Grasp the ankle
- Move the leg in a small circle (15 cm knee displacement), the registration will automatically start
- Continue the movement until the system has acquired 100% of the points it needs.

If the result is acceptable, the system automatically goes to the next step.If not, the system will prompt the user to restart the acquisition.

Top of the intercondylar notch registration



- Place the probe tip at the top of the femur's intercondylar notch and along the femoral shaft axis
- Confirm

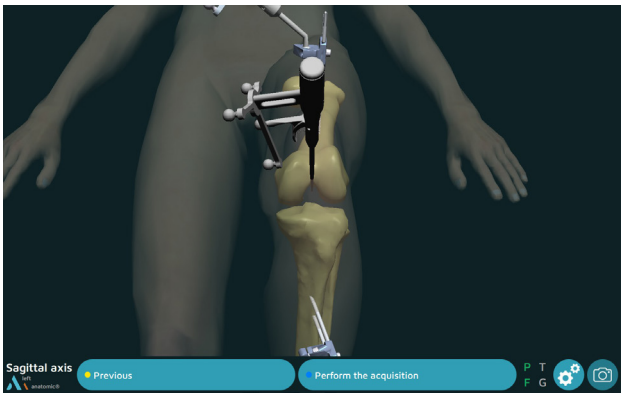
NOTE
The femoral mechanical axis is calculated using the hip centre and the top of the intercondylar notch.

Femoral registrations

Femoral rotation reference

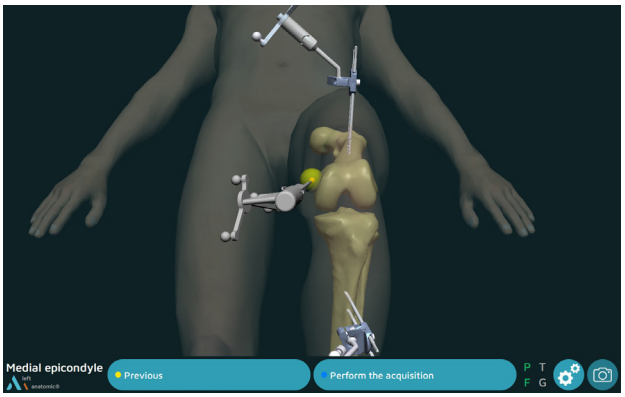
If the acquisition of the **femoral sagittal axis** (Whiteside's line) was selected as a femoral rotation reference:

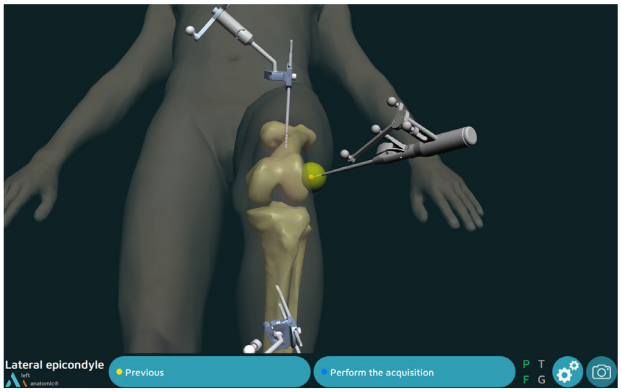
- Place the probe in the middle of the femur and align the body of the probe with the femur's sagittal axis.
- Press the trigger to validate.



If the acquisition of the **trans-epicondylar axis** was selected as a femoral rotation reference:

- Place the probe on the medial epicondyle and press the trigger to validate this point.
- Repeat on the lateral epicondyle.
- The trans-epicondylar axis will be calculated using these two points.





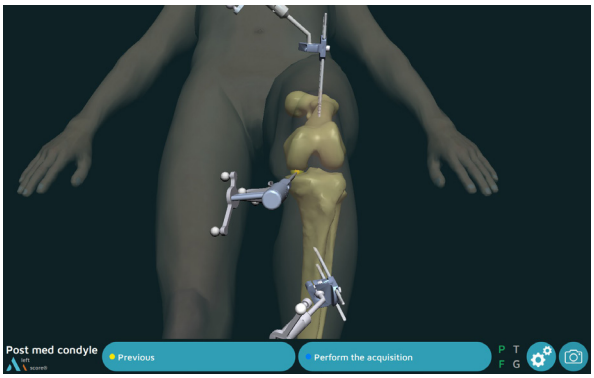
Femoral registrations

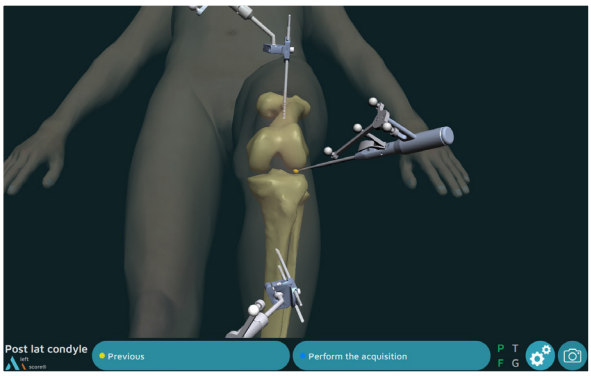
Femoral registration

If the acquisition of the **posterior condylar axis** was selected as a femoral rotation reference:

- Place the probe tip at the top of the medial posterior condyle and confirm; do the same for the top of the lateral posterior condyle.

- The posterior condylar axis will be calculated using these two points





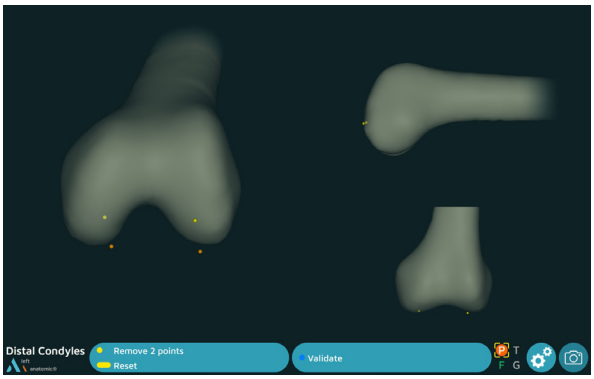
Femoral registrations

Femoral registrations

Two options for acquiring the distal resection height reference:

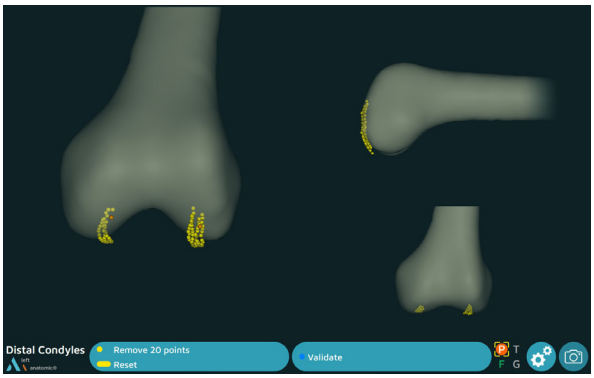
Acquisition of one point on each of the distal condyles:

- Place the probe on the condyle and press the trigger to validate.
- Repeat on the contralateral condyle.
- These two points will serve as references for the distal resection height.



Acquisition of one area on each distal condyle:

- On each distal condyle, place the probe tip on the bone surface. Press and hold trigger then move the tip along the surface being acquired.
- At any time, the surgeon may release the trigger, move the probe tip to another location and then press the trigger again to continue the acquisition.
- The last 20 acquired points can be deleted by pressing the yellow pedal. Press and hold down the yellow pedal (for at least 2 seconds) to erase all the acquired points.
- The most distal points will be calculated automatically and saved as the distal resection height reference.



NOTE

Make sure the probe tip is always in contact with the femoral bone surface when the trigger is pressed

Femoral navigation

Distal femoral resection

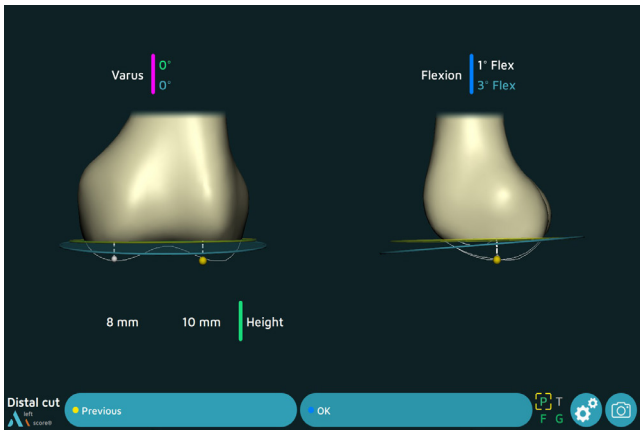
This step can be performed using either the Universal Alignment Guide or the Semi-assisted resection guide.

Using the Universal Alignment Guide:

- Secure the G array to the Universal Alignment Guide.
- Position the alignment guide's plate in the Distal Resection Guide 8 mm's slot.

The blue values represent the targets based on the user settings. White values are real time values. The values are green when they are close to the targets (+/-1 degree or mm).

- Insert 2 Headless pins length 80 mm in the resection guide's «0» holes.
- Remove the Universal Alignment Guide
- Secure the guide with two converging Headless pins length 80 mm,
- Perform the distal cut
- Remove the resection guide.



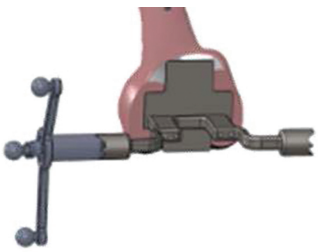
Using the Semi-assisted resection guide :

- Secure the G array to the Semi-assisted resection guide.
- Adjust the positioning to get close to the position needed to perform the distal cut. Place a Headless pin length 80 mm into the alignment hole to stabilise the guide.

The blue values represent the targets based on the user settings. White values are real time values. The values are green when they are close to the targets (+/-1 degree or mm).

- Once the resection guide's position is set, without validating the sequence, put two Headless pins length 80 mm in the guide's «0» holes.
- Secure the Semi-assisted resection guide, perform the distal cut and remove the guide.

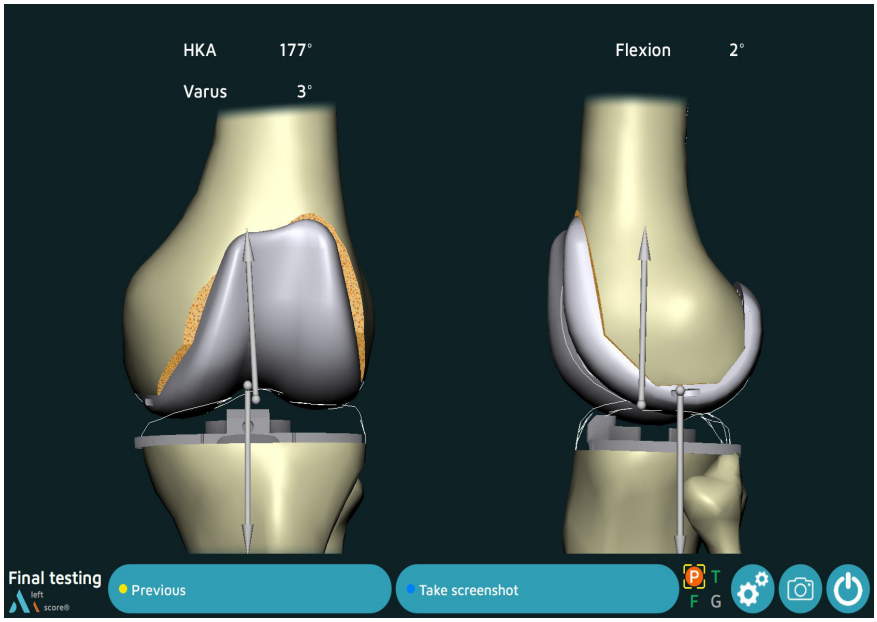
Acquisition



- Once the femoral distal cut has been made, check with the Universal Alignment Guide placed on the cut.
- Press the blue pedal to confirm and continue to the next step.

Final test

Post-operative alignment



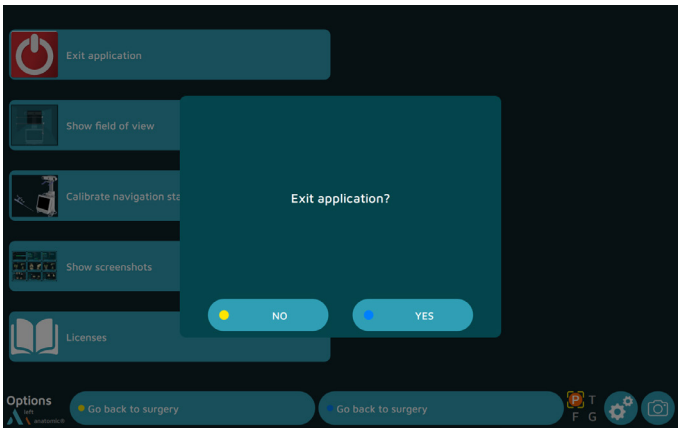
- At this step, the software allows the final HKA and varus to be visualized in real time.
- In this step, it is possible to record the information that appears on the screen (regardless of the degree of flexion) using the blue pedal (or the blue arrow).

All navigation steps have been completed.

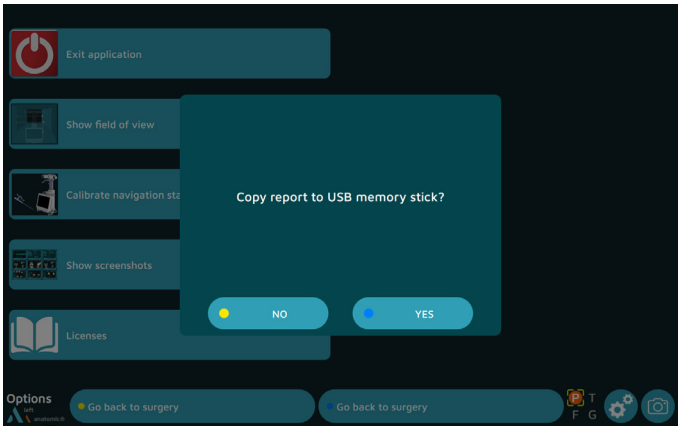
Refer to the following Surgical Techniques documents: TO.G.009 for SCORE, TO.G.013 for SCORE II, TO.G.002 for ANATOMIC and TO.G.041 for TRAX CR for the following steps:

- Femoral preparation
- Tibial preparation
- Patellar preparation
- Postioning of final implants

Surgery report

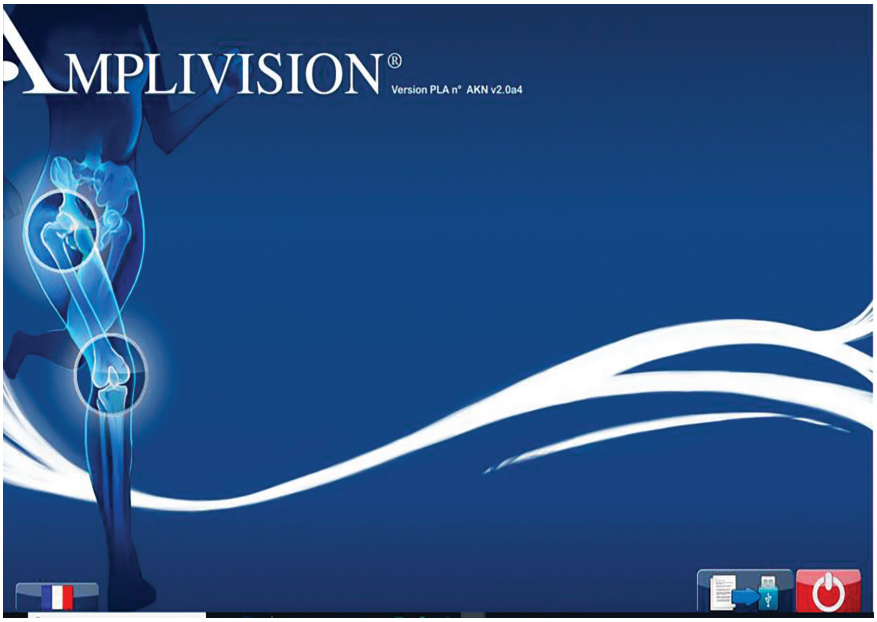


- Press the button to exit the application.
  - It is directly available after the last step of the « Post-operative alignment » procedure or
  - It can be found on the « Options » page at any point during the procedure.
- The message « Do you really want to exit? » will appear. Press « Yes » to confirm.
- The message « Copy report to USB drive? » will appear.
- Indicate whether you want to create a backup copy of the surgery report by pressing the « Yes » or « No » button.



- A message will appear asking you to insert a USB drive. Insert the USB drive in the slot close to the screen and confirm that you would like to backup the report.
- In the surgery report, a file named « report.html » contains the following elements:
  - Patient name and surgeon name
  - Bone contour maps
  - Bone resection pages
  - Implant size and position planning pages
  - Postoperative validation pages.

Powering down the workstation



- Press the button at the the lower right corner of the screen.
- Confirm that you want to shut down the system.
- The system will shut down.
- Refer to the AMPLIVISION NO205 (AMPLIVISION V3) or NO114 (AMPLIVISION V2) User Manual for instructions on how to store the workstation.

Instrumentation

- In addition to the mechanical instrumentation described in the Surgical Technique documents TO.G.009 for SCORE, TO.G.013 for SCORE II, TO.G.002 for ANATOMIC and TO.G.041 for TRAX CR), the following are required:
  - AMPLIVISION Navigation Station
  - NDI Passive Spheres
  - The Instrumentation Set for TKA 4in1 (Navigated): 2-0299946

NDI Passive Spheres - 30 pheres (2x15) (Product No. 8800966)

NDI Passive Spheres - 15 spheres (5x3) (Product No. 8800738)

- The arrays must be equipped with passive spheres to be visible to the camera. These passive spheres are attached through the nipples on the array (3 for the F, T and G arrays and 4 for the probe P).

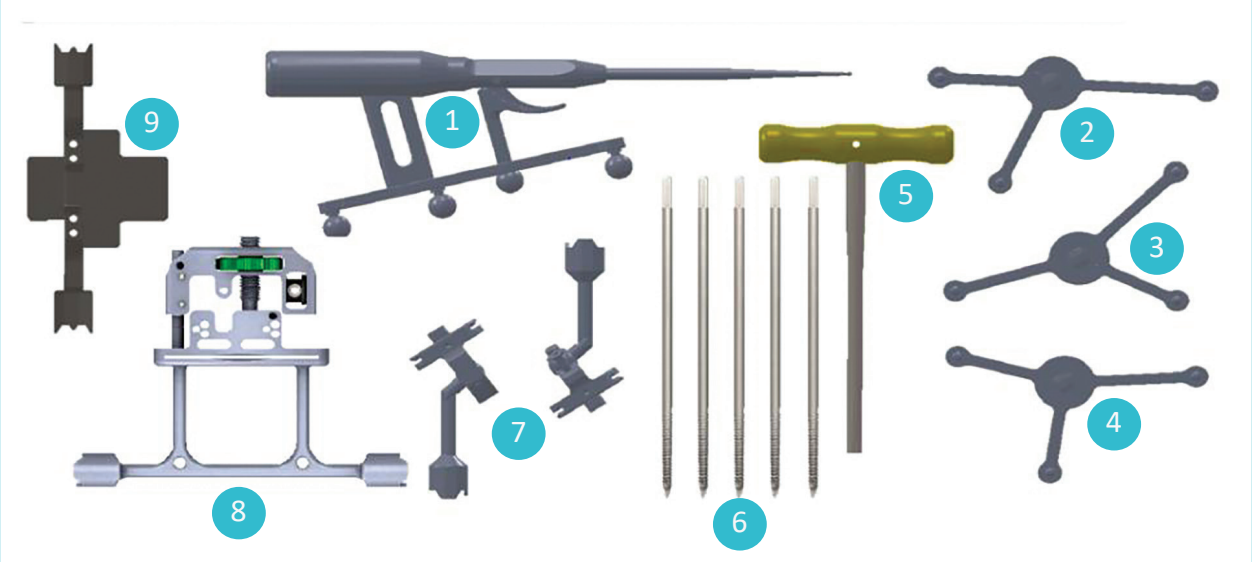
Single-use Conical Threaded Pins AMPLIVISION Ø4 length 150mm (Product No. 2-0252200):

- 4 Single-use Conical Threaded Pins AMPLIVISION Ø4 length 150mm, are available upon request. They are inserted in the femur and the tibia and array fixation supports are placed on these pins which are inserted in the femur and the tibia.

Not all devices presented in this Surgical Technique may be registered in your country. Please contact your Amplitude Sales Representative for availability.

Instrumentation

Instrumentation set for TKA 4in1 (Navigated) 2-0299946



Item	Name	Reference	Qty
1	Probe knee navigation	2-0215700	1
2	T array, tibia navigation	2-0215800	1
3	F array, femur navigation	2-0117400	1
4	G array, Instrumentation navigation	2-0117500	1
5	H5 Screwdriver	2-0200800	1
6	Conical Threaded Pins AMPLIVISION Ø4 length 150mm	2-0235500	5
7	Inclined fixation system, navigation geometry	2-0117200	2
8	Semi-assisted resection guide	2-0232500	1
9	Universal Alignment Guide	2-0229000	1

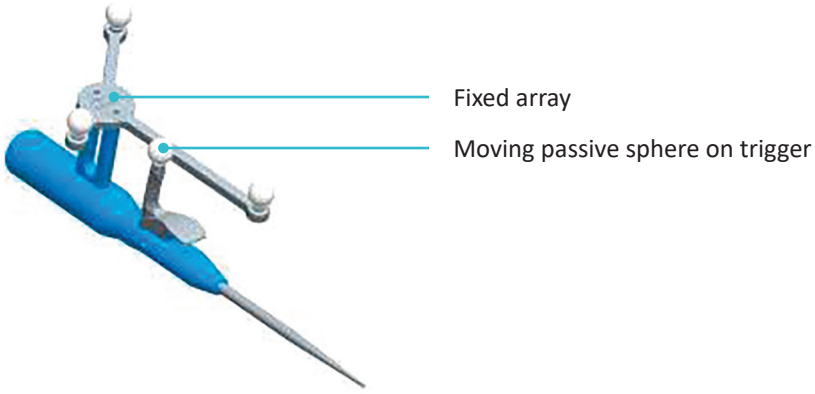
Instrumentation

Instruments

Probe knee navigation:

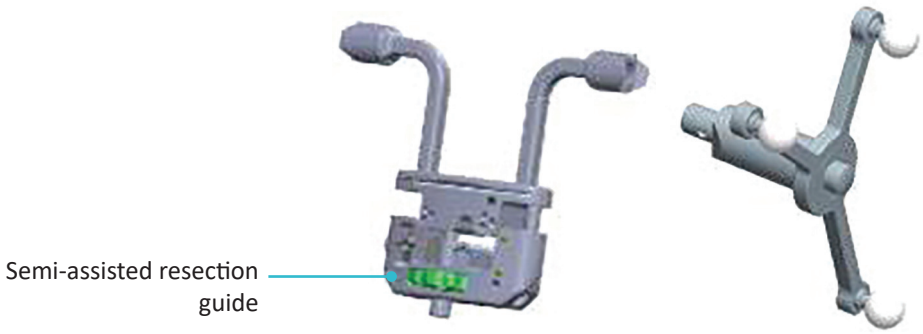
- This instrument is used to acquire specific points and areas on the patient's anatomical structures.

  It is also used to remotely control certain active elements on the screen. The probe must be fitted with four passive spheres, one of them being on the trigger.



Semi-assisted resection guide:

- The semi-assisted resection guide is used to make the distal cut and the tibial cut, once its position has been established. There are two attachment points for the G array (one on each side). The array can only be assembled in one direction into each attachment point.

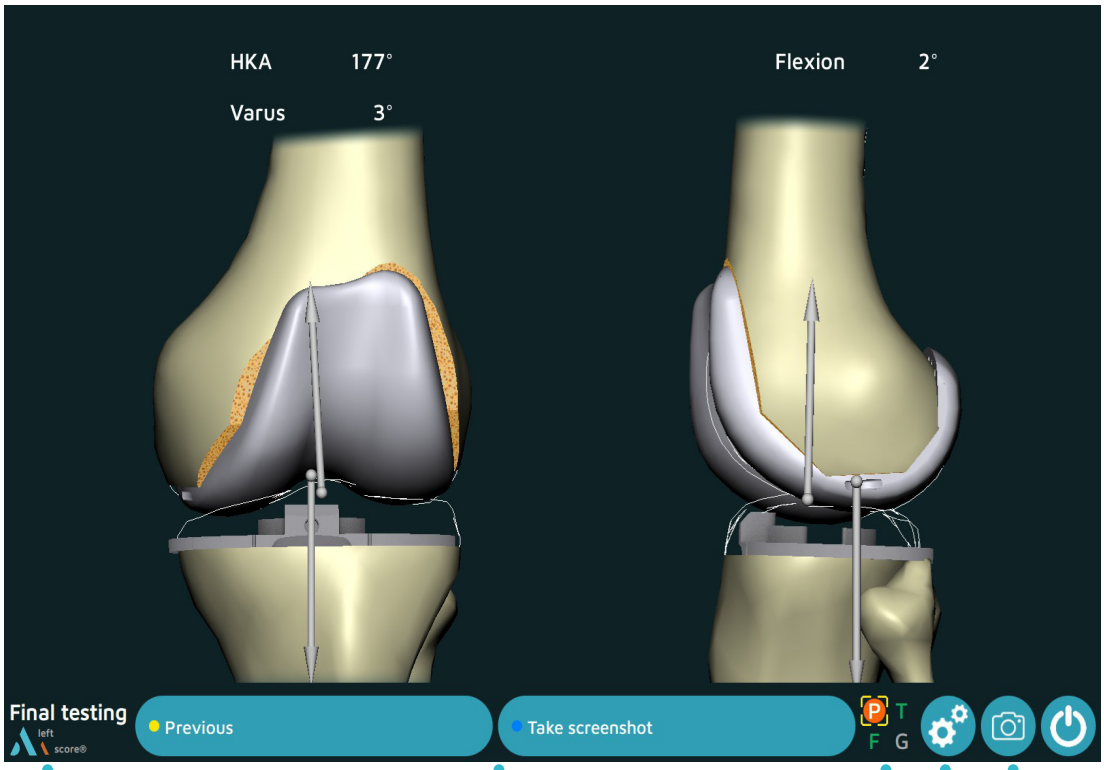


Universal guide:

- The universal alignment guide is inserted into slots in the resection guide to navigate the position of these guides. It is also used to acquire the cuts once they have been made. There are two attachment points for the G array (one on each side). The array can only be assembled in one direction into each attachment point.

Appendix A

Screen layout



Current step
Operated side
Implant

Button next and previous

Visibility of each array:
Green - visible
Orange - not visible

Menu : Options

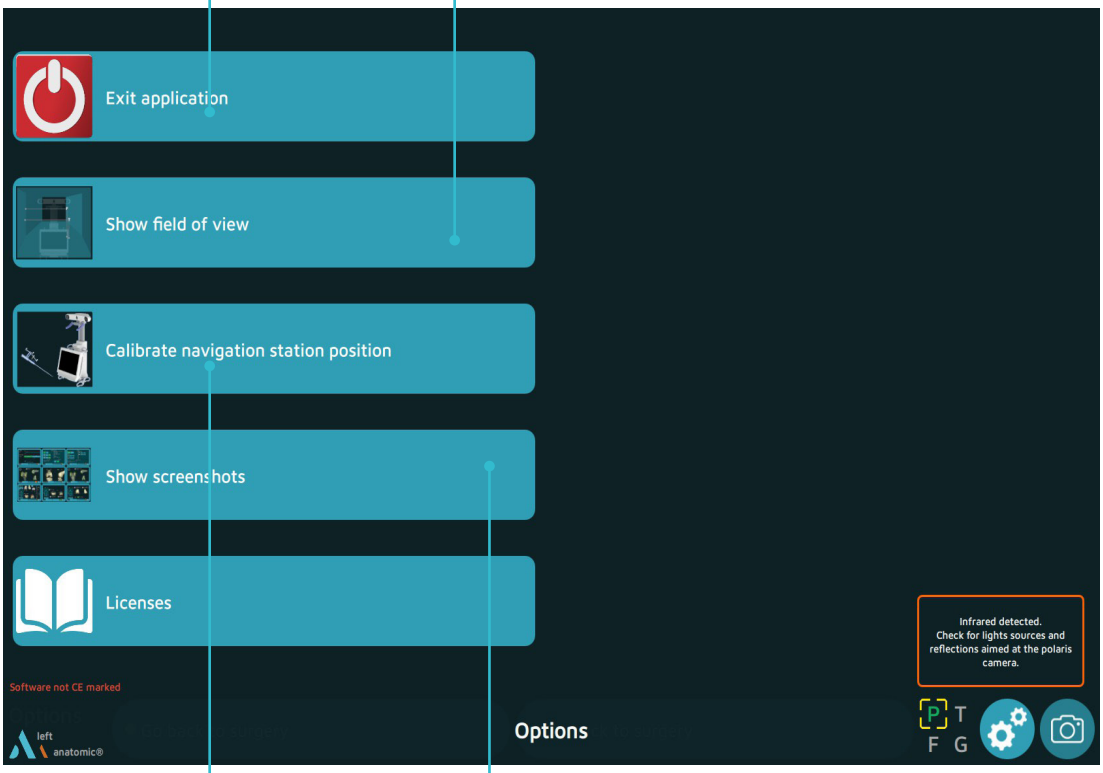
Screenshot

Appendix B

Menu Options

«Exit Application» button

Show camera field of view to locate arrays



Reset navigation station position relative to surgeon position

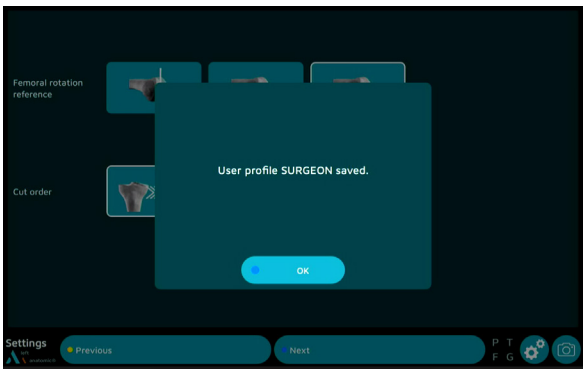
View all the validated steps during the surgery

Appendix C

User profile

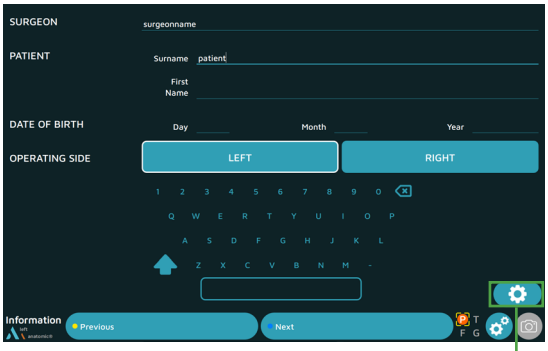
Saving a user profile

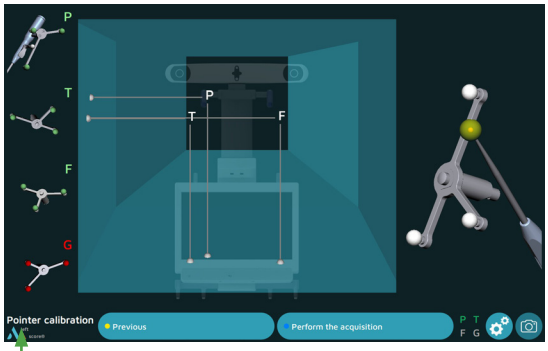
- Once the surgery-related options have been selected and the surgical workflow chosen, a saving of the user profile on a USB key is automatically launched.

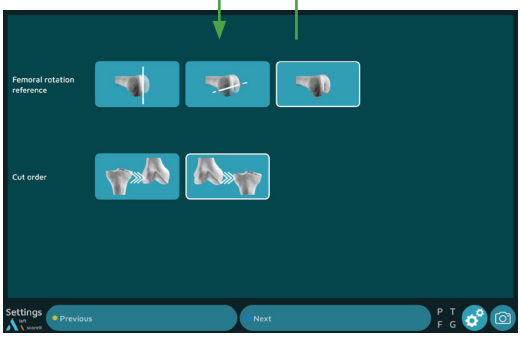


- The following will be saved on the USB key:
  - The surgeon's name,
  - The selected workflow and the order of the cuts
  - All the selected options

Working with a user profile







Options that can be changed

- In future surgical procedures with navigation, plug in the USB drive to automatically load the surgeon's name and preferences.
- At this point, the software will go from the « Information » page to the «Camera Setup» page and will skip the «Surgery-related options» page.

- To change a saved parameter, press the button at the lower right corner of the «Information» screen.

Appendix D

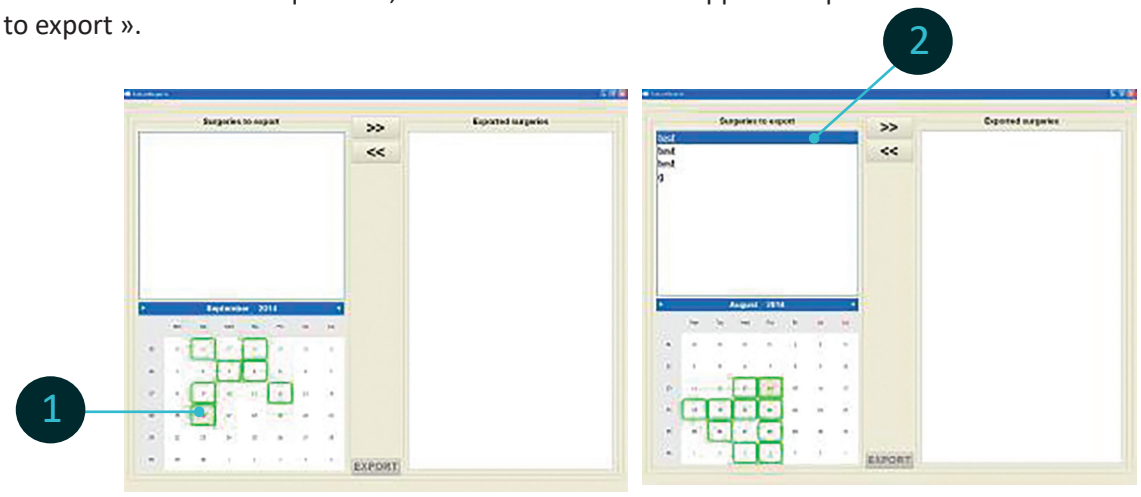
Opening a saved surgery report

If a saved surgery report is not transferred to a USB drive, it can still be retrieved at a later date.

- Turn on the AMPLIVISION workstation
- When the AMPLIVISION welcome screen appears, press the button on the lower right of the screen

- The message « Do you want to extract patient data? » will appear. Press « OK ».
- A calendar will appear. The dates on which surgery reports were saved will be highlighted in green. Select the dates corresponding to the procedure(s). For each date, AMPLIVISION lists available reports in the « Surgeries to export » window.

interventions. Pour chaque date, l'AMPLIVISION liste les rapports disponibles dans la fenêtre « Surgeries to export ».



- Use the touch screen to select the reports to be exported and then press the button to move them to the « Exported surgeries » window.
- Insert the USB drive and press the button to copy these reports to it. A message will appear when the operation is complete.

NOTE

To ensure confidentiality, the exported reports are saved in an encrypted file format, « Report001.amplitudereport » on the USB drive.
Contact AMPLITUDE to obtain access to the desired report

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Reference: TO.G.050/EN/C