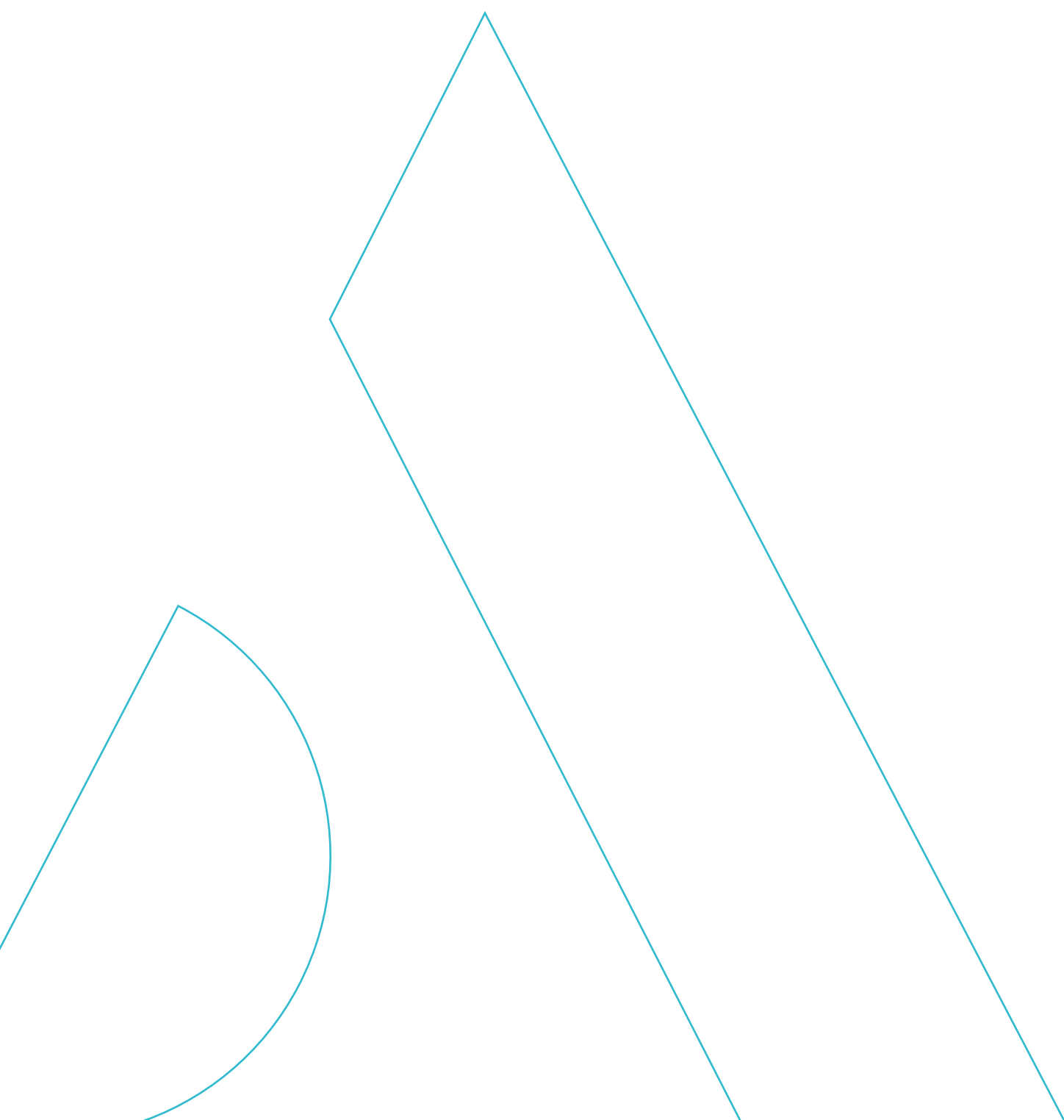




Surgical Technique

AKN (Advanced Knee Navigation)
Dependent cuts with planning Workflow



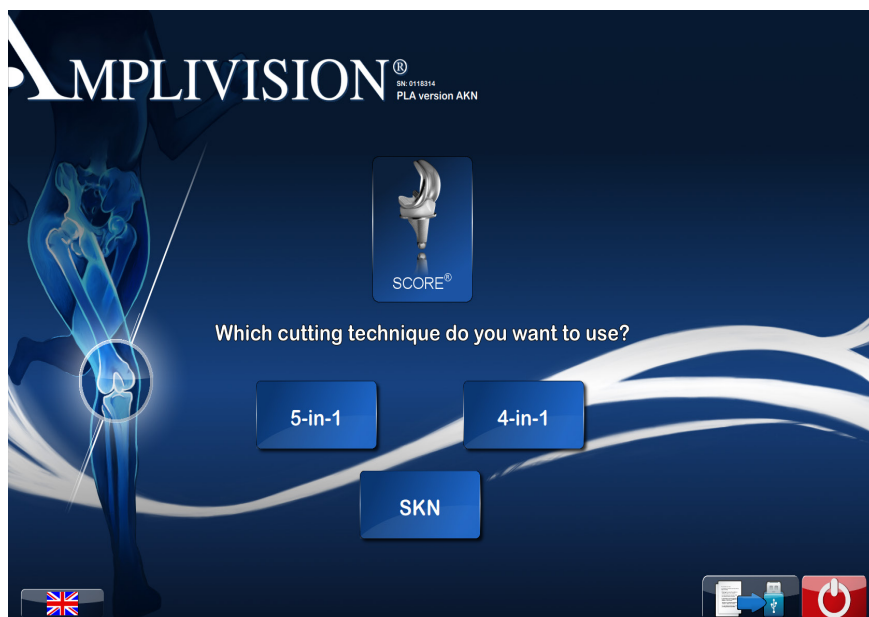
Summary

Introduction.....	4
Starting the software.....	5
User settings.....	6
Set up	10
Tibial registrations	12
Femoral registrations.....	16
Tibial navigation	20
Femoral planning	21
Femoral navigation	24
Trials registration	27
Final test.....	31
Surgery report	32
Powering down the workstation	33
Instrumentation	34
Option	37
Appendix	48

Introduction

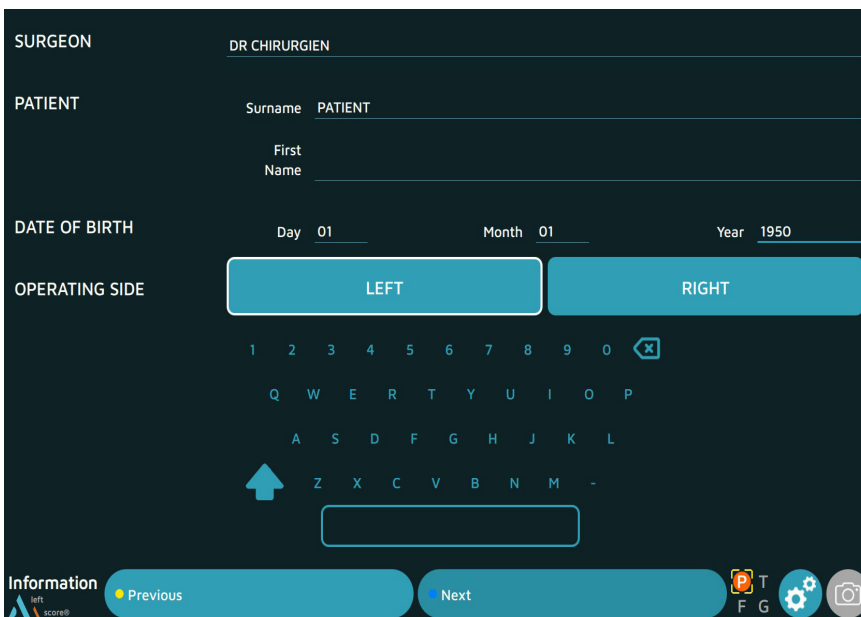
- This Surgical Technique Supplement describes the use of the AKN (Advanced Knee Navigation) computer-assisted surgery software for implanting Amplitude's total knee arthroplasty (TKA) systems.
- This software is used to navigate tibial resection, distal femoral resection and 4-in-1 femoral resections.
- This surgical technique replaces the following paragraphs from conventional surgical techniques:
- For SCORE TKA with conventional 4-in-1 instrumentation: **TO.G.009**
 - > The paragraphs on the distal femoral cut
 - > Paragraphs on the tibial alignment
 - > The paragraphs on the tibial cut
 - > Paragraphs on medio-lateral femoral adjustment, preparation of the inter-condylar notch, tibial preparation, patellar preparation and placement of the final implants.
- For the SCORE II TKA with conventional 4-in-1 instrumentation: **TO.G.009** and **TO.G.013**
 - > The paragraphs on the distal femoral cut
 - > The paragraphs on tibial alignment
 - > The paragraphs on the tibial cut
 - > Paragraphs on medio-lateral femoral adjustment, preparation of the inter-condylar notch, tibial preparation, patellar preparation and placement of the final implants.
- For ANATOMIC TKA with conventional 4-in-1 instrumentation: **TO.G.002**
 - > The paragraphs on the distal femoral cut
 - > The paragraphs on the tibial alignment
 - > The paragraphs on the tibial cut
 - > The paragraphs on the femoral preparation guide, the preparation of the femoral notch, the preparation of the femoral trochlea, the preparation of the postero-stabilization bar, the end of the femoral preparation, the placement of the trial femoral component, the placement of the trial tibial component, the tibial preparation, the patellar preparation, the placement of the final implants.

Starting the software



On the touch screen

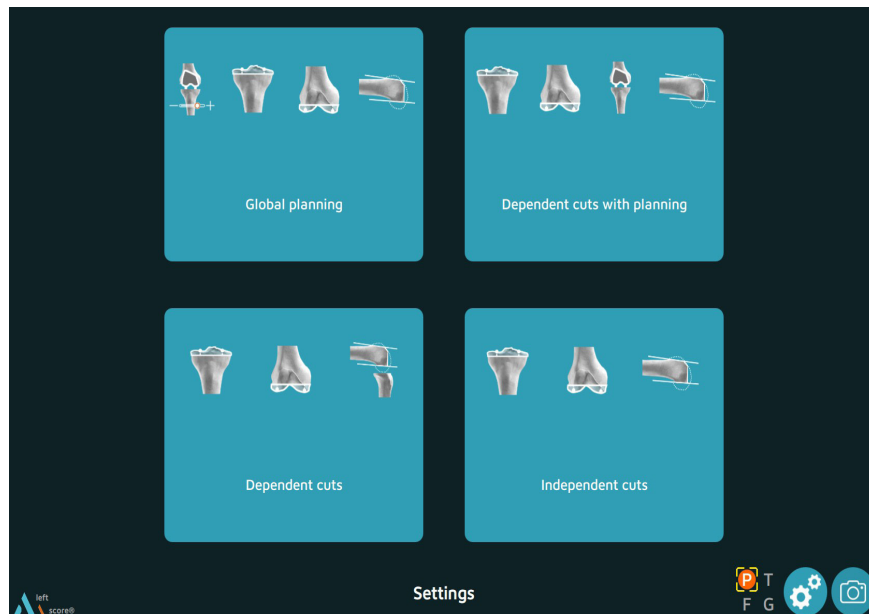
- Select the language.
- Select the knee.
- Select the implant.
- Select the **4 in 1**.



- 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



- Select the «**Dependent cuts with planning**» workflow described in this Surgical technique document.

Description of the 4 workflows:

Global planning

This workflow allows to perform the resections based on Mecanichal alignment (MECA), Kinematic Alignment (KA,rKA) and Functional Alignment (GAPS)

Dependent cuts with planning:

This workflow allows to perform the tibial cut and then simulate the position of the femoral component

Dependent cuts

This workflow allows to perform the distal femoral cut, the tibial cut and then the measurement of the flexion and extension gaps to guide the 4-in-1 cuts

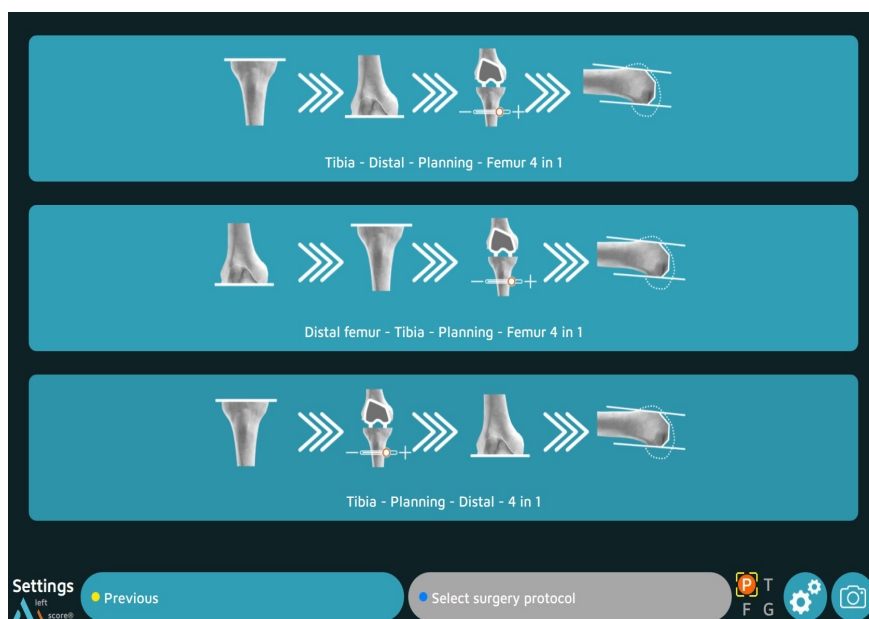
Independent cuts

This workflow allows to perform independent cuts based on bone references

- Press the blue pedal to continue to the next step

User settings

Order of the resections



- Select the cuts order:
 Tibial cut first next Distal femoral cut next Femoral Planning and 4-in-1 femoral cuts*.
 Distal femoral cut first next tibial cut next Femoral Planning and 4-in-1 femoral cuts*.
 Tibial cut first next Femoral Planning next Distal femoral cut and 4-in-1 femoral cuts
 ==> describes in this surgical technique.

**In cases where the distal cut is performed before the femoral planning: the planning is only applicable to 4-in-1 cuts, as the distal cut is already acquired.*

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

User settings

Anatomical registration options



Acquisition order

Tibial registration first or femoral registration first.

Tibial and Femoral surfaces

2 solutions are proposed

Mapping:

- for the femur : a series of 50 points is acquired for each reference.
- for the tibia: the sulcus bottoms are palpated and a reference point is automatically selected for each side (most proximal point).

Morphing: complete registration of the bone surface to reconstruct the femoral and tibial extremities.

TEA (Trans Epicondylar Axis)

Registration of the medial epicondyle and lateral epicondyle to calculate the Biepicondylar axis.

Whiteside line

Registration of the Whiteside line using the probe.

Trochlear line

Registration of a serie of points on the anatomical trochlear to calculate its orientation.

ATT (Anterior Tibial Tuberosity)

Registration of the Anterior Tibial Tuberosity.

Acquire laxity Graph

This allows the option to test ligament laxity before cuts, and to compare it at the end of surgery with the trials or the definitive implants insitu.

Confidence points

Acquisition of a point on the Array Fixation Systems to check their position throughout the surgery.

Cursor calibration

Select this option to calibrate the probe position relative to the screen manually. If the option has not been ticked, the calibration will be done automatically.

Trial implants

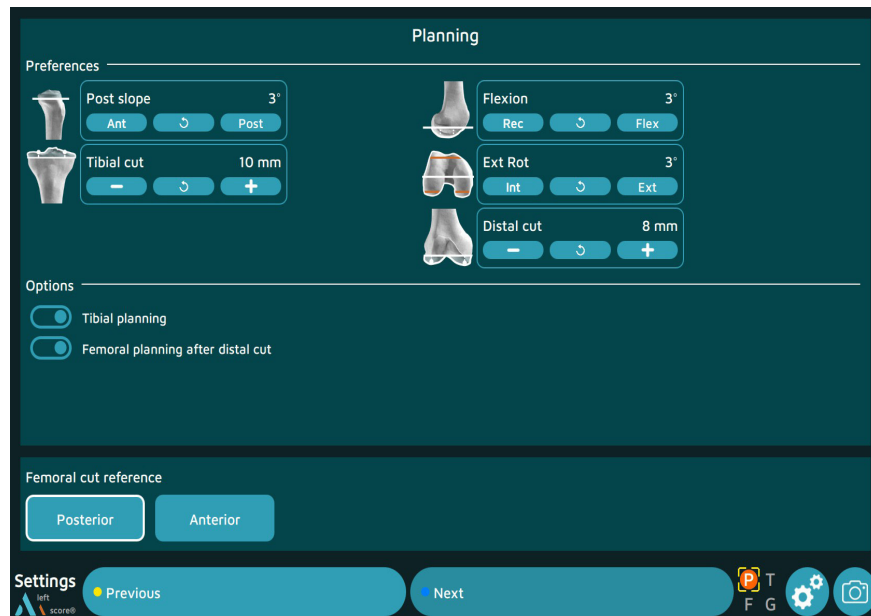
Assessment of the implant trials positionning.

Choice of order for acquiring test implants.

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

User settings

Planning options



Preferences

The preferences allows to pre-positionned the implants reagrding surgeons user settings, during the planning those values can be changed.

For the tibia, it is possible to pre-register the posterior slope and the tibial resection thickness.

For the femur, it is possible to pre-register the flexion, the femoral rotation, the distal resection thickness.

Options

Tibial planning: adds a dedicated screen for planning the tibial cut: cutting height, slope and varus/valgus. Option to return to planning after distal cut.

Femoral cut reference

Choice between the Anterior reference and the **Posterior reference**.

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

NOTE

At the end of the selection of options, it is possible to create a User Profile which will save all the choices of the surgery protocol, and to reuse them automatically during the next navigations of this prosthesis.

NOTE

The workflow describes in this surgical technique include the following choices :

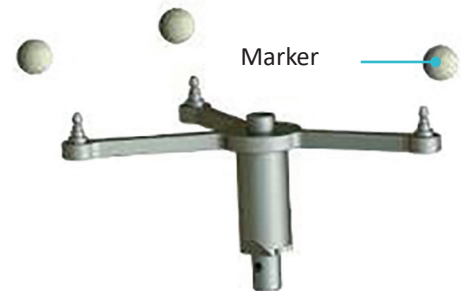
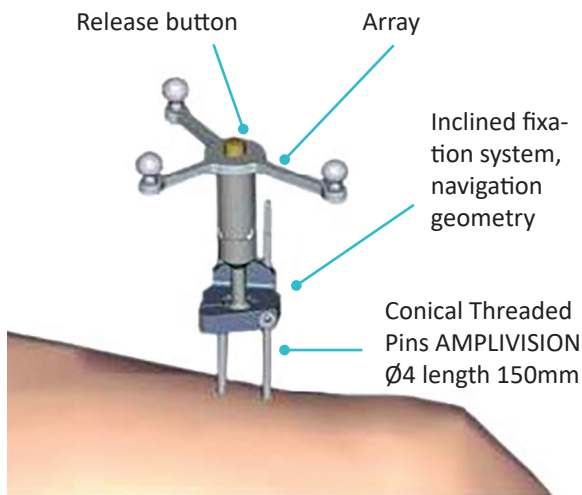
Tibial registration first
Morphing for tibia and femur
Trochlear line
Acquisition of the laxities
Trials registration

Other options are described at the end of the Surgical Technique

Set up

Setting up of the arrays

- Clip the AMPLIVISION sterile Markers (14 per pack) 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

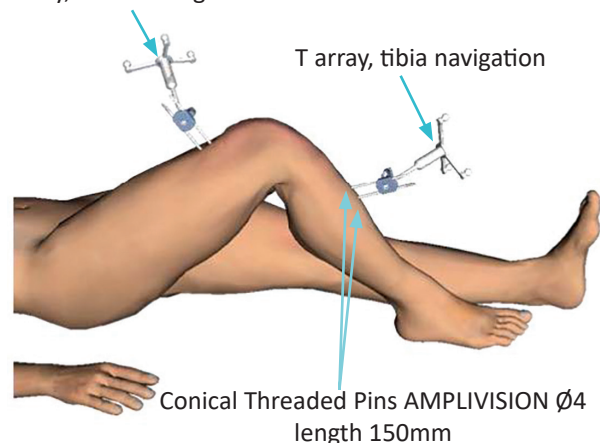
If the femoral pin is being inserted percutaneously, make sure the knee is flexed to prevent damaging muscle fibres

- 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

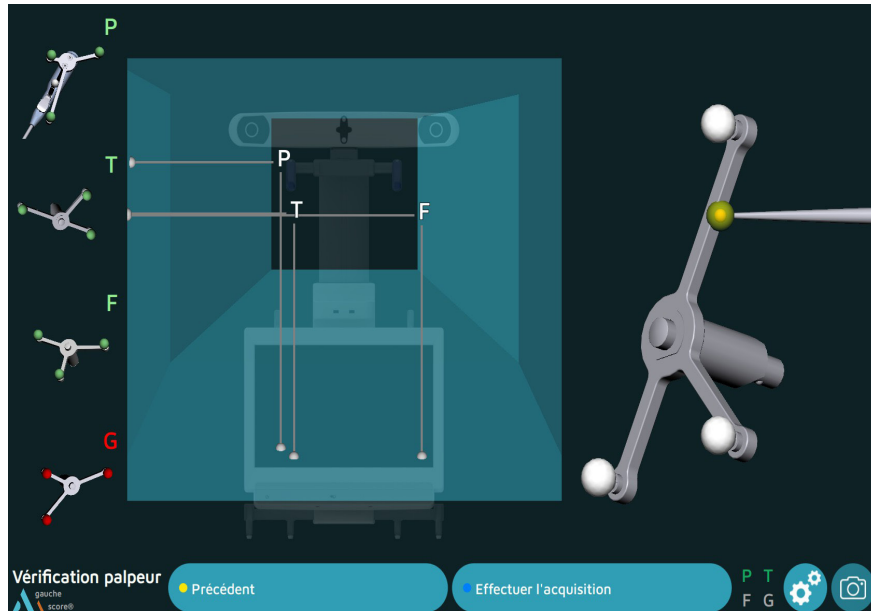
After approaching the joint and exposing the knee, it is important to remove the osteophytes in order to find the right joint surfaces to be palpated for the digitisation of the joint surfaces (otherwise there is a risk of over- or undersizing the size of the implant).

F array, femur navigation



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:
 - Any marker that is not visible on an array will be red, as will the letter associated with this array.
 - The array will be green if it is fully visible.
- The array's visibility may be compromised by interfering infrared sources (sunlight, hot lights, dirty markers).

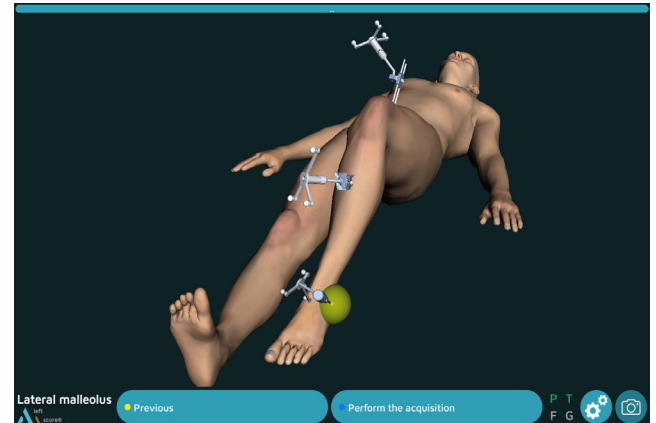
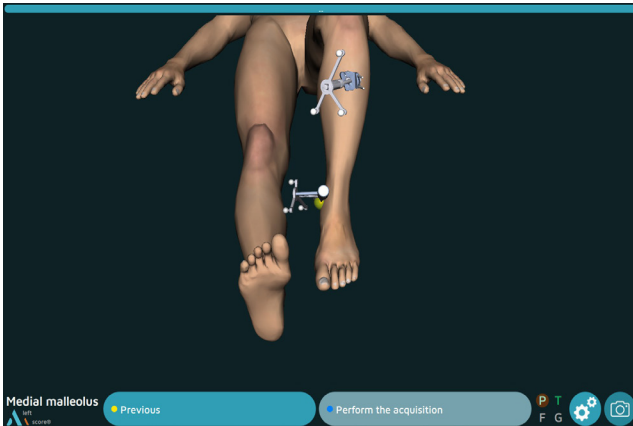
Pointer calibration

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**.

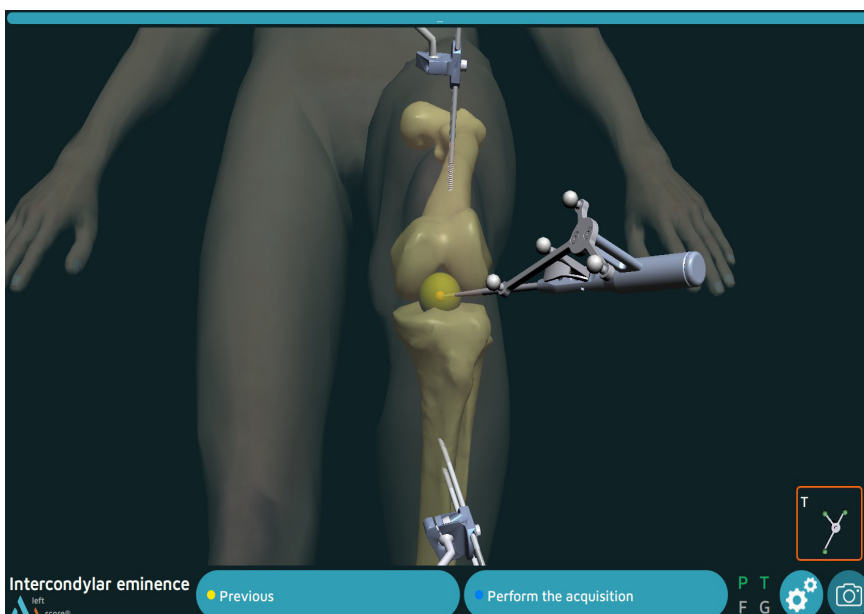
Medial malleolus

- 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.

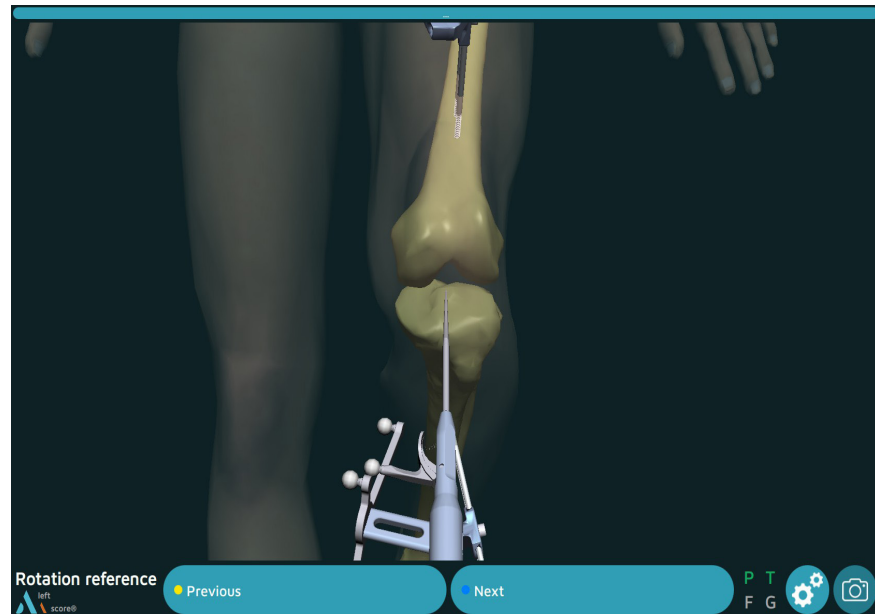
Tibial center registration



- 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

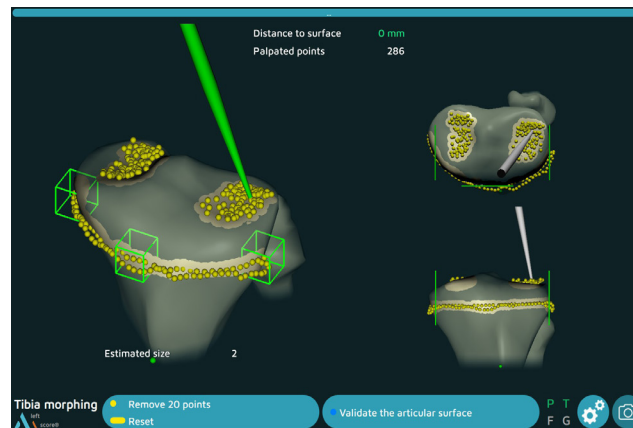
Tibial reference rotation



- 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

Tibial bone surface registration



The goal of this step is to register the tibial bone surface.

- Place the probe tip on the bone surface.
- Press the trigger on the probe: the system will beep to indicate the start and end of the acquisition.
- Hold down the trigger while moving the tip along the surfaces that need to be acquired:
 - Medial and lateral articular surfaces used to determine height of cut.
 - Contour of tibial plateau at the articular surface, as well as at the level of the planned tibial cut.
- Release the trigger to stop the registration.

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 registration.

The system will continuously register points and draw a contour map of the surface in real time. A counter in the upper-left corner shows how many points have been registered.

The software will not proceed to the next step until the anterior part and one of the two lateral parts are green.

NOTE

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

Verification of the contours

Release the trigger and place the probe tip on the registered bone surface. The DISTANCE TO SURFACE value is shown: this distance is the error between the palpated point and the same point on the digitised 3D model (accuracy of contours). The number will be green if this distance is equal to or less than 1 mm, and white if it is not.

Removal of acquired points

The last 20 acquired points can be deleted by pressing the yellow pedal.

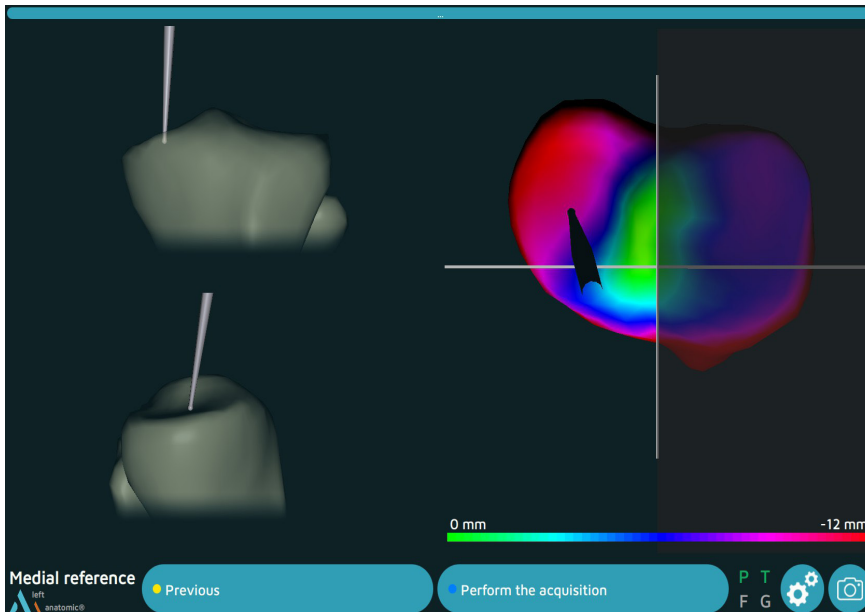
Press and hold down the yellow pedal (for at least 2 seconds) to erase all the acquired points.

If the contour accuracy is satisfactory, confirm this step and go to the next step.

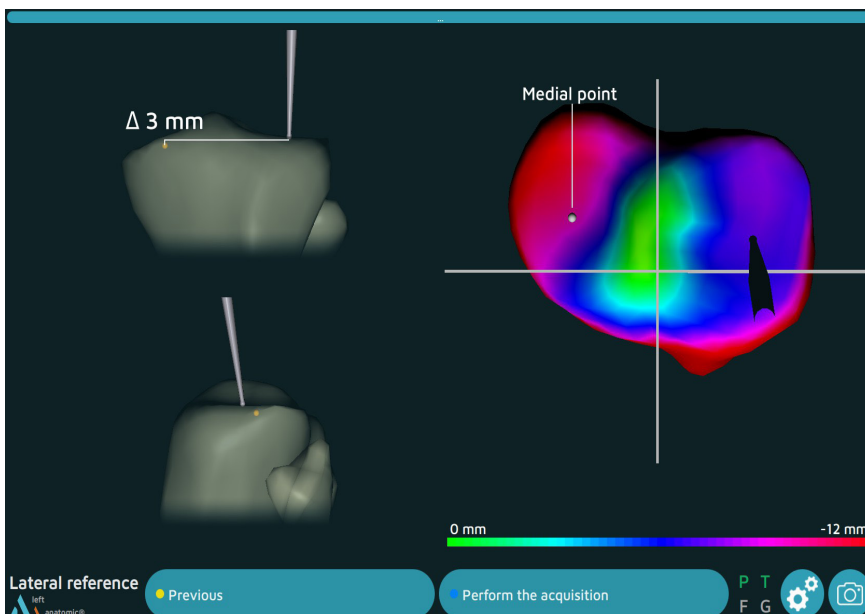


Tibial registrations

Reference points



- Place the probe tip on the medial tibial bone surface.
- Confirm.



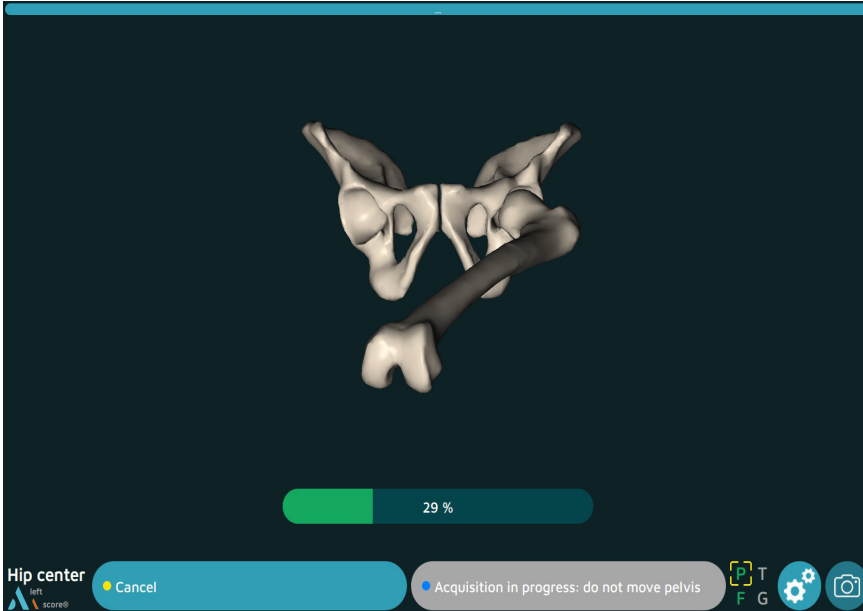
- Place the probe tip on the lateral tibial bone surface.
- Confirm.

NOTE

These 2 points will be used as a reference for the thickness of the tibial resection.

Femoral registrations

Hip center registration



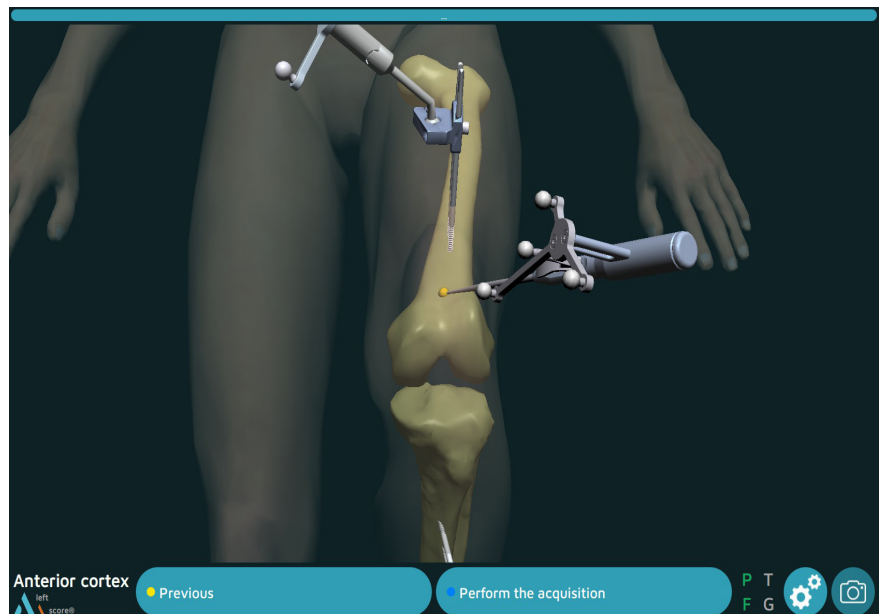
- Extend the patient's leg.
- Grasp the ankle.
- Move the leg in a small circle (15 cm knee displacement), the registration will automatically start.
- Continue the movement until the system has acquired 100% of the points it needs.

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.

Femoral anterior cortex registration

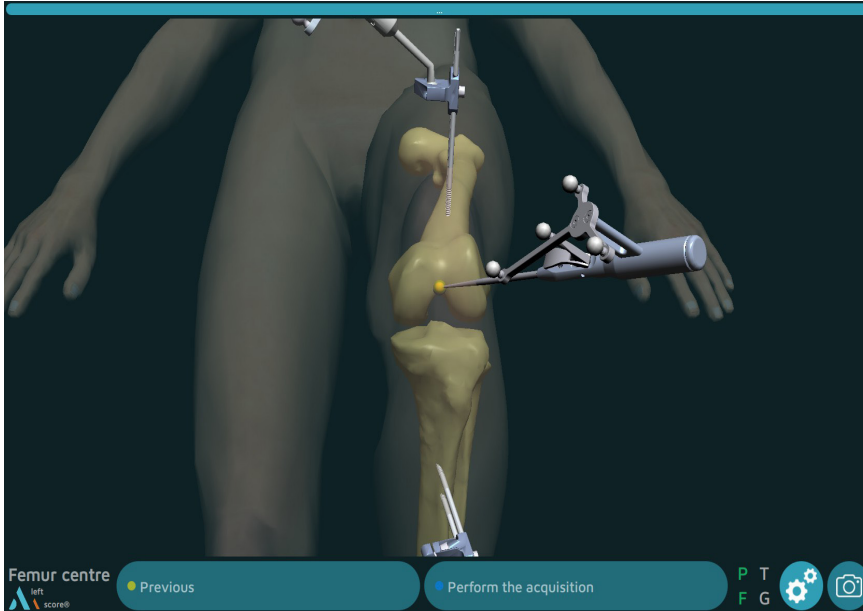
If **Morphing** has been selected:

- Place the probe tip on the anterior femoral cortex.
- Confirm.



Femoral registrations

Top of the intercondylar notch registration



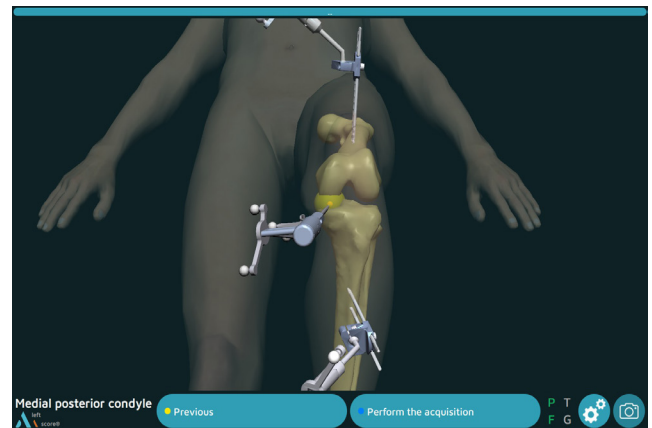
- Place the probe tip at the top of the femur's intercondylar notch and along the femoral shaft axis.
- Confirm.

NOTE

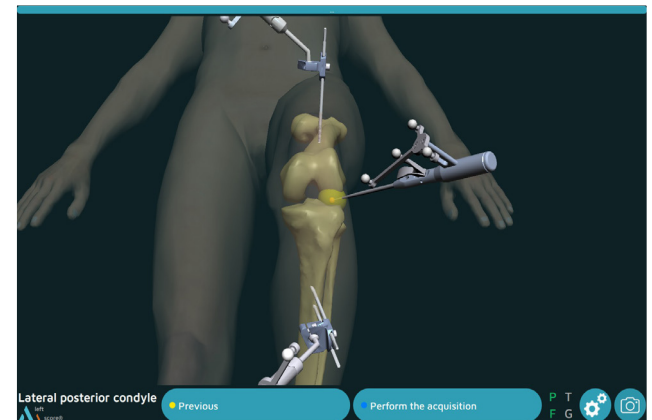
The femoral mechanical axis is calculated using the hip centre and the top of the intercondylar notch.

Posterior condyles registration

- Place the probe tip on the medial posterior condyle.
- Confirm.



- Place the probe tip on the lateral posterior condyle.
- Confirm.



NOTE

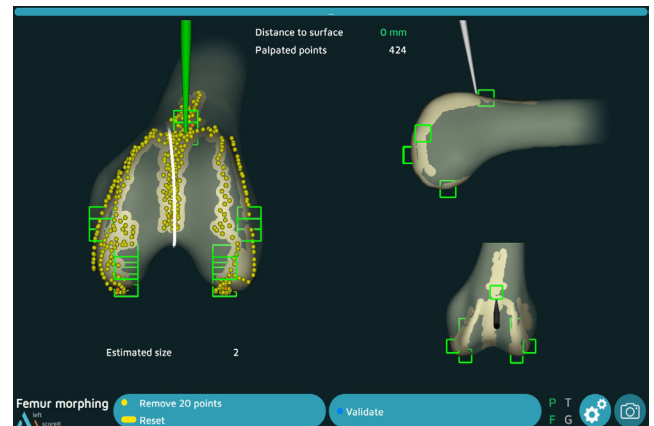
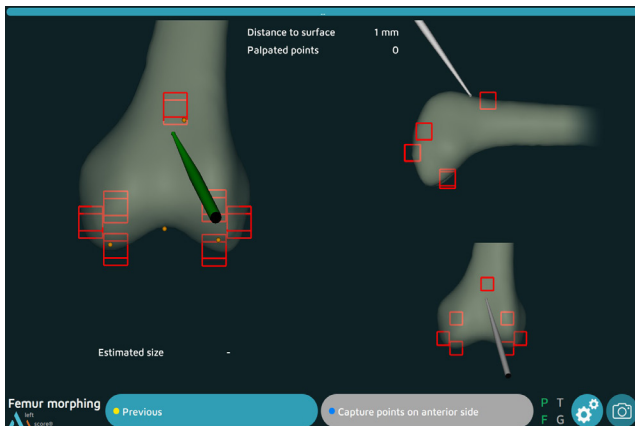
Using the femur's mechanical axis and the posterior condylar axis, the AMPLIVISION system calculates the frontal femoral plane and estimates the sagittal and transverse planes

NOTE

The points at the top of the posterior condyles are recalculated during the condyle digitalisation. The planes are then recalculated to make them more accurate

Femoral registrations

Femoral registration



- The goals of this step are to acquire the femoral bone surface.
- Place the probe tip on the bone surface.
- Press the trigger : the system will beep to indicate the start and end of the acquisition.
- It is best to draw the contour of the femur carefully.
- 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.

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 registration.

The system will continuously register points and draw a contour map of the surface in real time. A counter in the upper-left corner shows how many points have been registered.

The software will not proceed to the next step until the all boxes are registered (in green)

The system will continuously acquire points and draw a contour map of the surface in real time and the matching femoral component size is shown in the lower left part of the screen.

NOTE

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

Verification of the contours

Release the trigger and place the probe tip on the registered bone surface. The DISTANCE TO SURFACE value is shown: this distance is the error between the palpated point and the same point on the digitised 3D model (accuracy of contours). The number will be green if this distance is equal to or less than 1 mm, and white if it is not.

Removal of acquired points

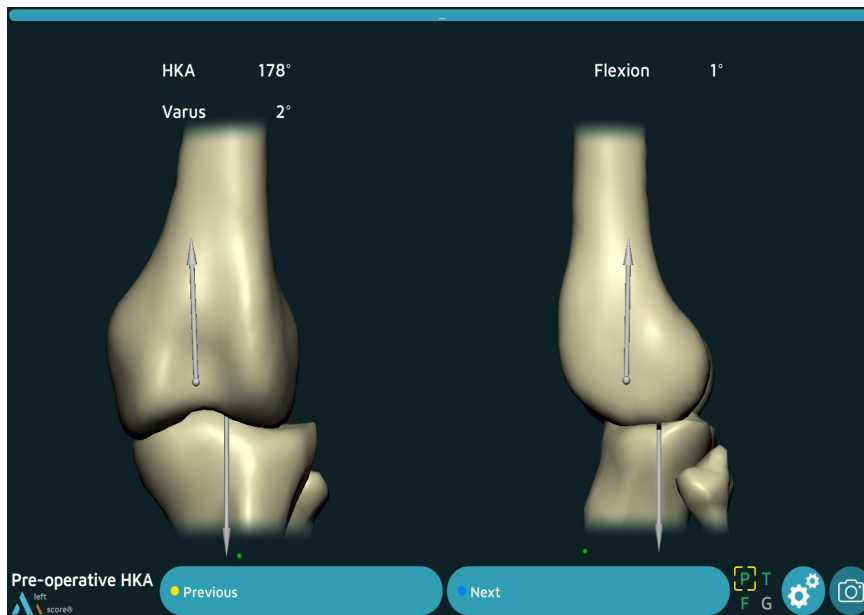
The last 20 acquired points can be deleted by pressing the yellow pedal.

Press and hold down the yellow pedal (for at least 2 seconds) to erase all the acquired points.

If the contour accuracy is satisfactory, confirm this step and go to the next step.

Femoral registrations

Pre-operative alignment



- The software allows to visualize the pre-operative HKA.

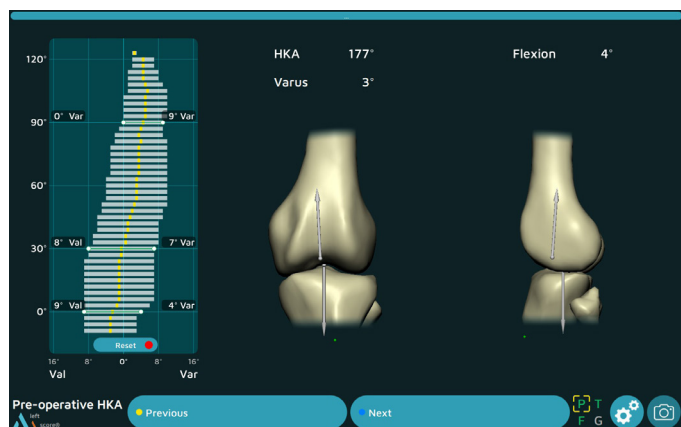
Pre-operative alignment with HKA option with varus/Valgus curves

The software allows the assessment of ligament deformities all along the range of motion (ROM).

- Press the blue pedal to start the acquisition.
- Start with the knee in extension, force varus to full flexion and then force valgus and return to extension.

The maximum and minimum varus/valgus values obtained during the extension/flexion cycle will be displayed on the graph.

A reset button is displayed at the bottom of the graph during recording, and allows to reset the graph if needed.



Tibial navigation

Tibial resection

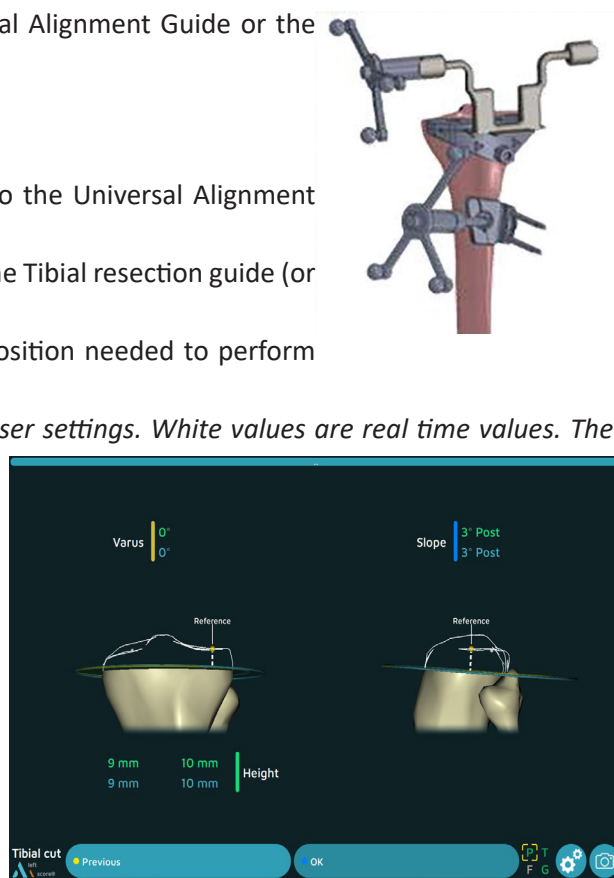
This step can be performed using either the Universal Alignment Guide or the Semi-assisted resection guide.

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.

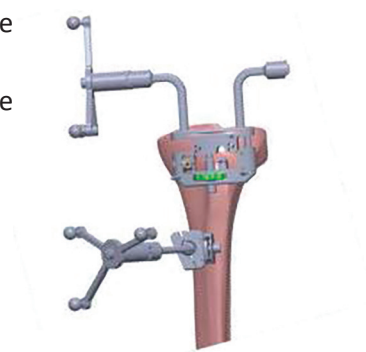
The blue values represent the targets based on the user settings. White values are real time values. The values are green when they are close to the targets (± 1 degree or mm).

- Insert 2 Headless pins length 80 mm in the resection guide's «0» holes.
- Remove the Universal Alignment Guide.
- Secure the 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 perform the tibial cut.
- Insert a Headless pin length 80 mm in the alignment hole to stabilise the guide.
- 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

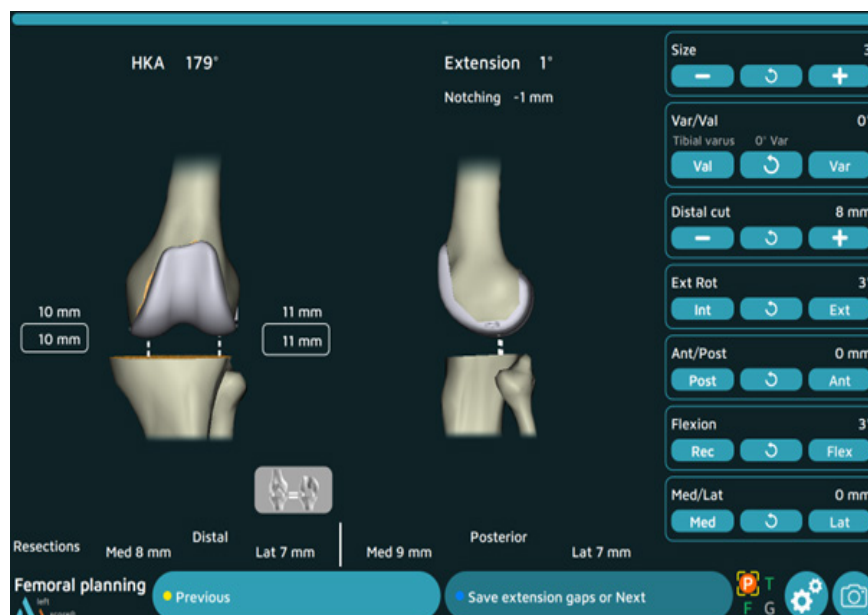
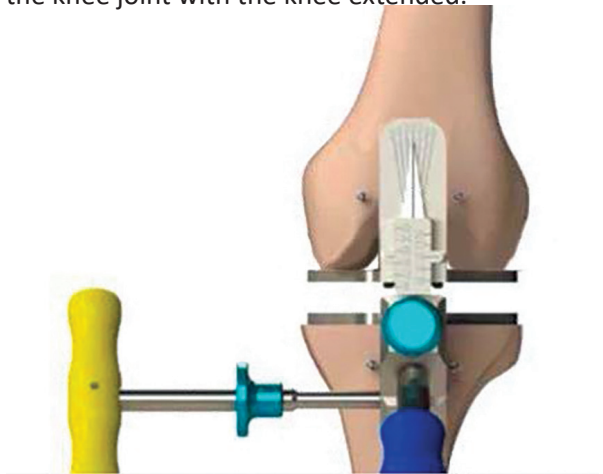
- Once the tibial cut has been made, check with the Universal Alignment Guide placed on the cut.
- Press the blue pedal to confirm and continue to the next step.



Femoral planning

Extension gaps


- This step is available if the **order of cuts** is **Tibial cut first then Planning femur then distal femoral cut then femoral cuts 4 in 1**.
- This protocol allows the user to do the planning (after the tibial cut) of the distal femoral cut as well as the anteroposterior resections, taking into account ligament balancing and gaps in extension and flexion.
- Insert the Extra-articular Ligament Balancer V2 into the knee joint with the knee extended.
- Insert the Snap Screwdriver H5 into the balancer's cog wheel.
- Turn the Snap Screwdriver H5 to operate the distraction mechanism and apply the desired amount of tension. Do not apply excessive distraction, otherwise the knee will flex. The knee must stay extended during the measurements.
- The goal is to have a well-balanced gap on the medial and lateral compartments of 10 mm for a 10 mm tibial insert.
- All of the following values can be adjusted: size, varus/valgus, distal cut height and flectionum/recurvatum (of the distal resection), mediolateral positioning.
- The text area showing the notching value turns into orange as soon as the notching value exceeds 1 mm.
- Once the desired alignment and gaps have been achieved, press the blue pedal to confirm. The gaps in extension then appear in the boxes on either side of the articulation.
- Release the balancer by pressing the blue button, remove it and place the knee in flexion.



Femoral planning

Flexion gaps



- Knee in flexion, Insert the Extra-articular Ligament Balancer V2 into the knee joint.
- Insert the Snap Screwdriver H5 into the balancer's cog wheel.
- Turn the Snap Screwdriver H5 to operate the distraction mechanism and apply the desired amount of tension.
- In this step, it is possible to change the size, the rotation and Antero-Posterior positioning so that the gaps in flexion correspond to the gaps recorded in extension.
- In order to transfer the gaps measured in extension directly to flexion, select the button .
- Once the balance is obtained, press the blue pedal to validate the settings.

NOTE

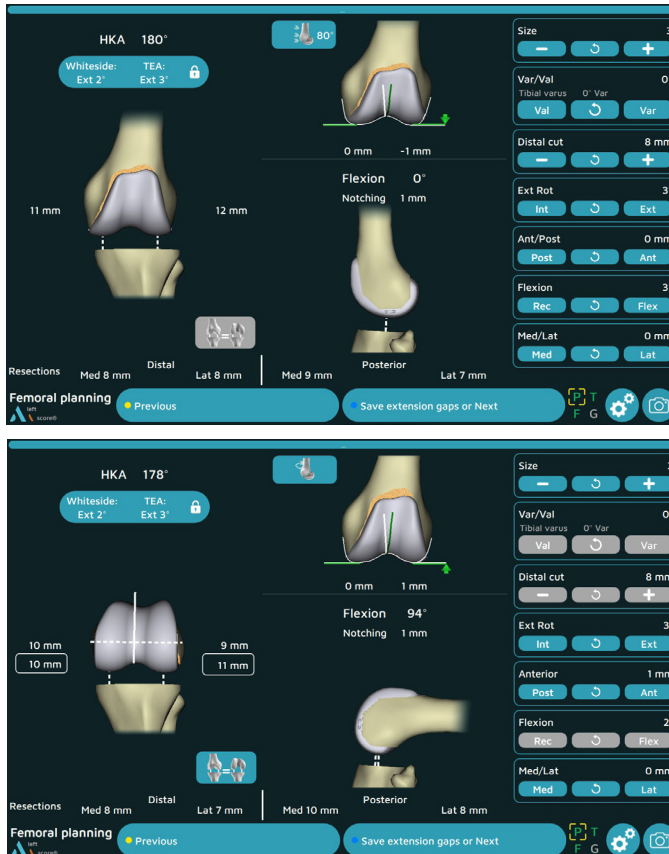
The automatic equalisation only acts on the antero-posterior movement and on the rotation of the femoral implant, and within the limits of 2mm anterior/2mm posterior and 8° external/2° internal rotation.




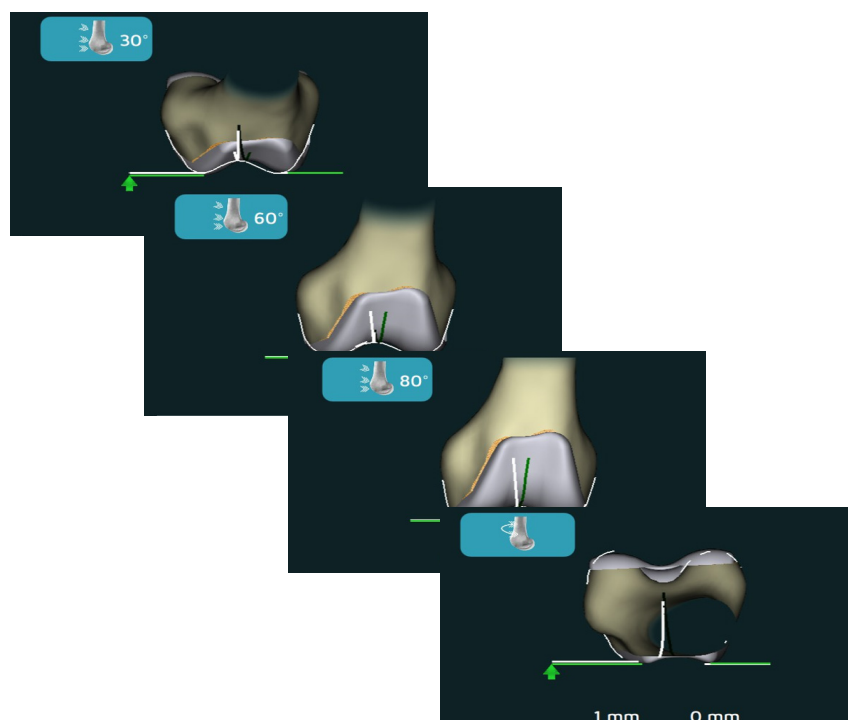
Femoral planning

Trochlear lines

When the Morphing has been chosen:



- This option allows the display of a trochlear view, allowing the visualization of the overthicknesses from different angles. Set the the mediolateral position of the prosthetic condyle according to the prosthetic (in green) and anatomical (in white) trochlea.
- If the implant is positioned above or below the bone femur, the value is indicated (indication for tightening or not the patellar fins).
- This information is shown at 30°, 60°, 80° of flexion as well as a free view showing the values in real time.
- Press the button  to see these four views successively.



Femoral navigation

Distal femoral resection

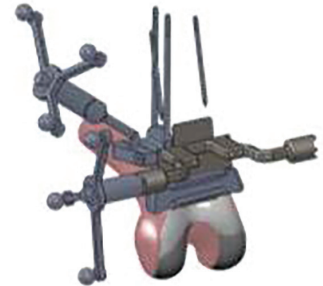
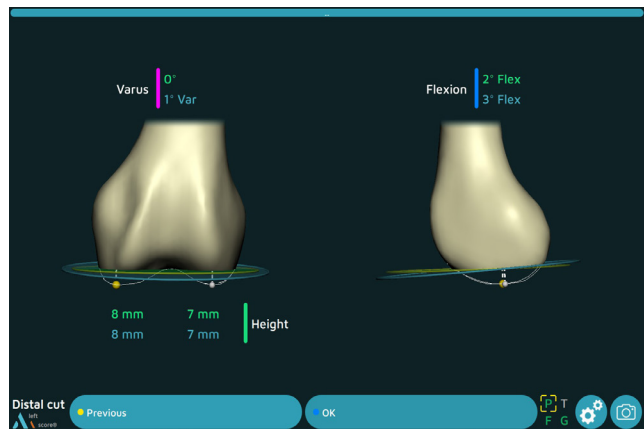
This step can be performed using either the Universal Alignment Guide or the Semi-assisted resection guide.

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.



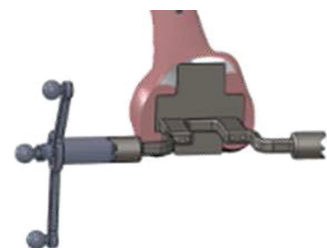
Using the Semi-assisted resection guide :

- 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.
- Once the Semi-assisted 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.



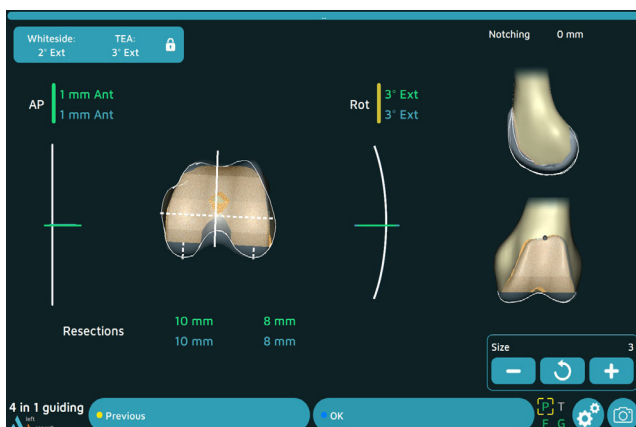
Acquisition

- 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.



Femoral navigation

Anterior and posterior resections and chamfers



- Set the 4-in-1 Femoral Resection Guide according to the size indicated by the AMPLIVISION system.
- Secure the G array to the Universal Alignment Guide.
- Place the Universal Alignment Guide in the anterior slot of the resection guide.
- Check the contact of the resection guide with the distal cut and adjust the rotation and the AP position of the resection guide according to the expected values.

The blue values are target values based on the User Settings.

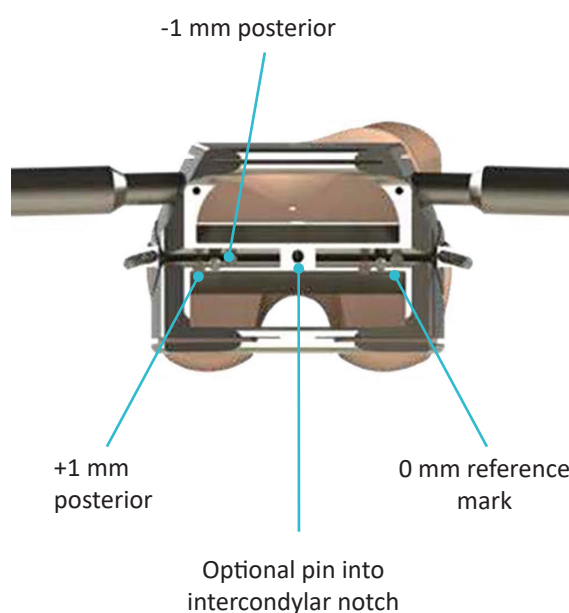
The white values are the real time values.

The values are green when they are close to the targets (± 1 degree or mm).

The text area showing the notching value changes to orange as soon as it is greater than 1 mm.

- Secure the resection guide with 2 Headless pins, $\varnothing 3.2$ length 65 mm into the central holes (neutral position).

- Use the resection gauge to check the anterior cut will not notch the femoral cortex.
- Secure the resection guide at the sides with Headless pin length 80 mm
- Remove the Universal Alignment Guide from the slot
- Perform the anterior and posterior cuts using a medium AMPLITUDE saw blade that matches the instrumentation set and motorized handpiece.
- Remove the distal pins using the pin extractor.
- Perform the 2 chamfer cuts.
- Position the Universal Alignment Guide on the anterior cut and check the cuts.
- Press the blue pedal to confirm and continue to the next step.



Femoral navigation

Femoral preparation guide placement

This step only applies to the ANATOMIC TKA.

For ANATOMIC Knee:

- Choose the same size of Femoral preparation guide as the 4-in-1 resection guide used previously (the planned size is shown on the screen).
- Place the universal handle on the oval clip by simultaneously pushing and turning the handle one-quarter turn.
- Place the probe tip on the conical mark located on the front of the femoral preparation guide. The mediolateral distance between the planned position (blue value) and true guide position will be shown (white or green value).
- Once the guide has been centred in the mediolateral direction, remove the universal handle and secure it with three Headed pins length 30 mm.
- Prepare the femoral trochlea (described in the Conventional Surgical Technique TO.G.002 for ANATOMIC knee).



NOTE

This step is optional. If centring the guide without navigation assistance, skip this step by pressing the blue pedal, probe or on the screen «Perform acquisition».

Placement of the trial femoral component

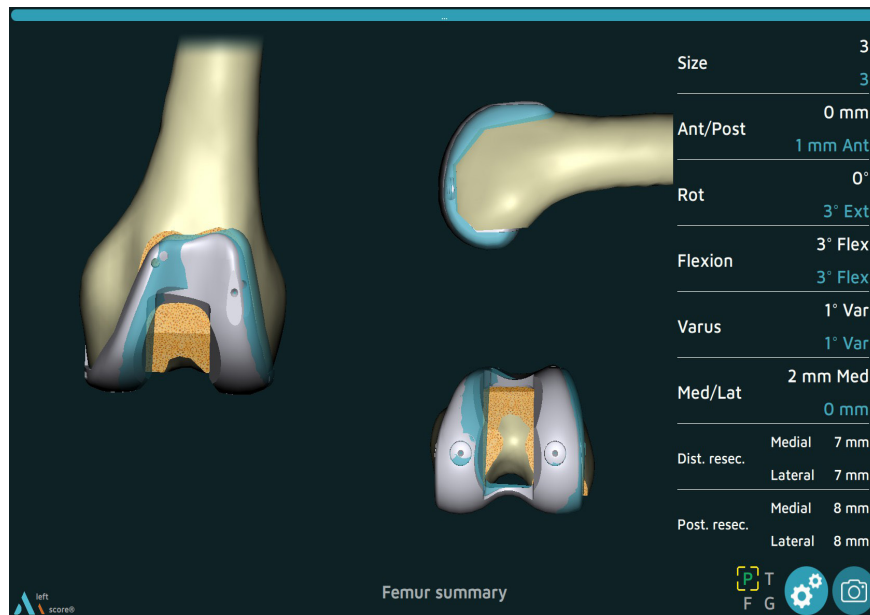
For SCORE, SCORE II and ANATOMIC Knees:

- Select the trial femoral component of the same size as the 4-in-1 resection guide used in the previous steps (the planned size is shown on the screen) and of the same operated side.
- For SCORE and SCORE II TKA: Place the probe tip on the conical mark located on the front of the trial femoral component. The mediolateral distance between the planned position (blue value) and true guide position will be shown (yellow value).
- Impact the trial component using the femoral component impactor until being in contact with the distal resection.
- Mark the entry point for the two pegs with the Drill for peg holes. Insert the 2 Trial pegs for trial femoral component.
- Repeat the validation with the trigger by positioning the probe tip in the other two conical marks (any order).
- For ANATOMIC TKA, do the validation of the 3 conical marks (any order).



Trials registration

Femoral summary

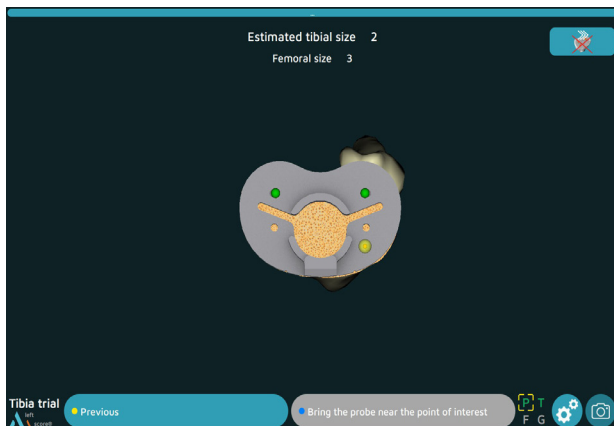


- The trial implant's position (grey) is superimposed over the planned implant position (blue).
- The size and final position of the trial femoral component are shown in white; the planned values are in blue.
- Press the blue pedal to confirm and continue to the next step.

Trials registration

Positioning of the trial baseplate

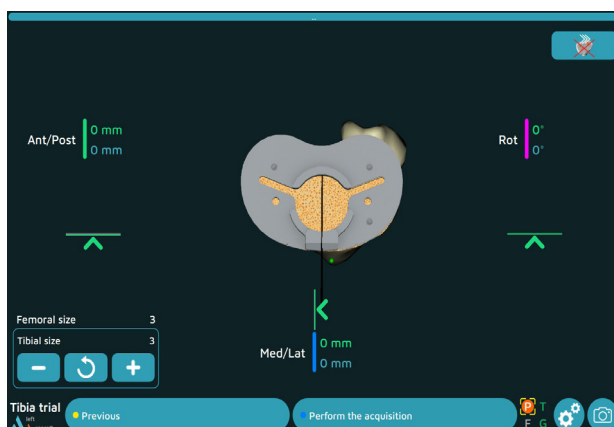
For the SCORE et SCORE II TKAs: 2 possibilities



Acquisition of trial baseplate position using conical calibration marks:

- Select the appropriate tibial baseplate (the estimated size is shown on the screen) and secure it to the universal handle.
- Position and secure the trial baseplate with two, 30-mm long headed pins.
- Using the probe, acquire the position of the three calibration marks located on the baseplate to identify its position on the tibia.

Detection of the G array by the camera



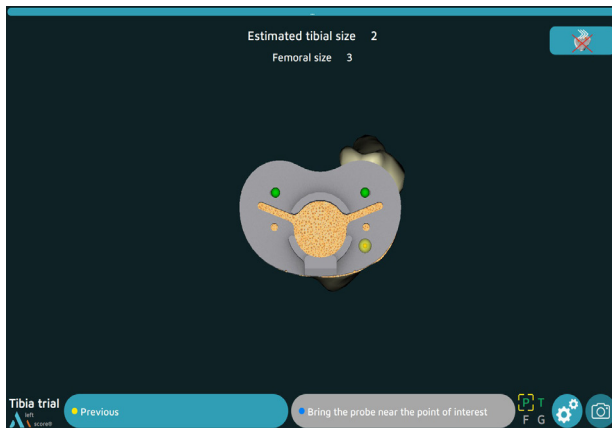
Navigation of trial baseplate position with universal handle:

- Secure the G array support to the universal handle.
- Select the appropriate tibial baseplate (the estimated size is shown on the screen) and secure it to the universal handle.
- Place the trial tibial baseplate on the tibial cut and compare its medio-lateral, anteroposterior and rotational position values. The values will be displayed in green if they are beyond ± 1 mm or $\pm 1^\circ$ from the target values (in blue).
- Use the arrows to adjust the baseplate position to match the planned position.
- Once the trial baseplate's position has been determined, secure the trial baseplate with two Headed pins length 30 mm.
- Confirm its position by pressing the blue pedal.

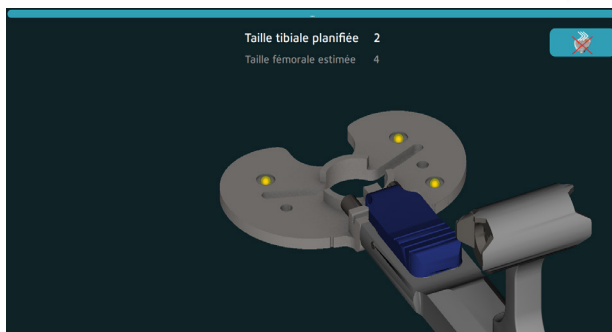
Trials registration

Positioning of the trial baseplate

For the ANATOMIC TKA: 2 options



Detection of the G array by the camera



Acquisition of trial baseplate position using conical calibration marks:

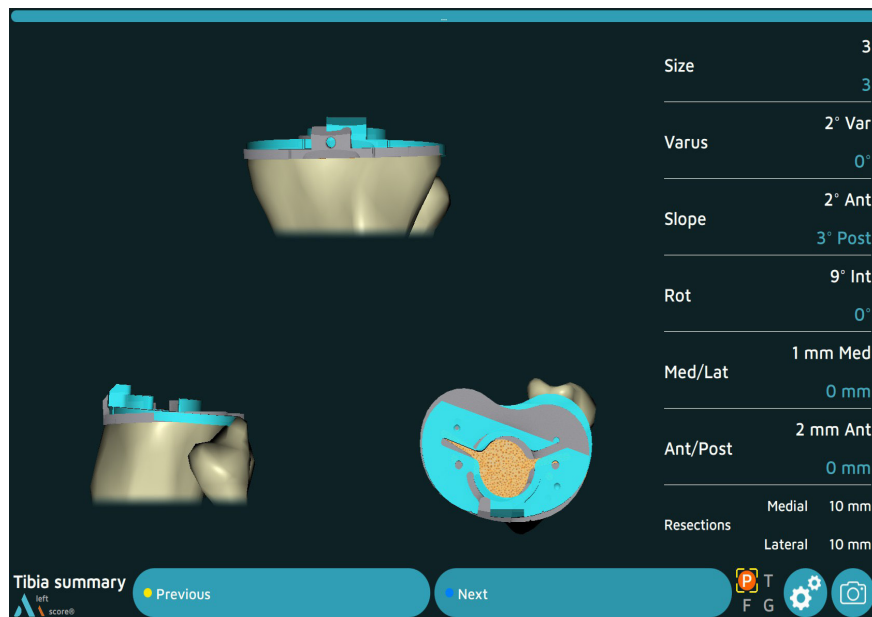
- Select the appropriate tibial baseplate (the estimated size is shown on the screen) and secure it to the baseplate handle.
- Position and secure the trial baseplate with two Headed pins length 30 mm.
- Using the probe, acquire the position of the three calibration marks located on the baseplate to identify its position on the tibia.

Navigation of trial baseplate position with baseplate handle:

- Secure the array support to the baseplate handle, and then attach the G array.
- Select the appropriate tibial baseplate (the estimated size is shown on the screen) and secure it to the baseplate handle.
- Calibrate the handle's position by placing the probe on each of the three calibration marks on the baseplate.
- Place the trial tibial baseplate on the tibial cut and compare its mediolateral, antero-posterior and rotational position values. The values will be displayed in green if they are beyond ± 1 mm or $\pm 1^\circ$ from the target values (in blue).
- Use the arrows to adjust the baseplate position to match the planned position.
- Once the trial baseplate's position has been determined, secure the trial baseplate with two Headed pins length 30 mm.
- Confirm its position by pressing the blue pedal.

Trials registration

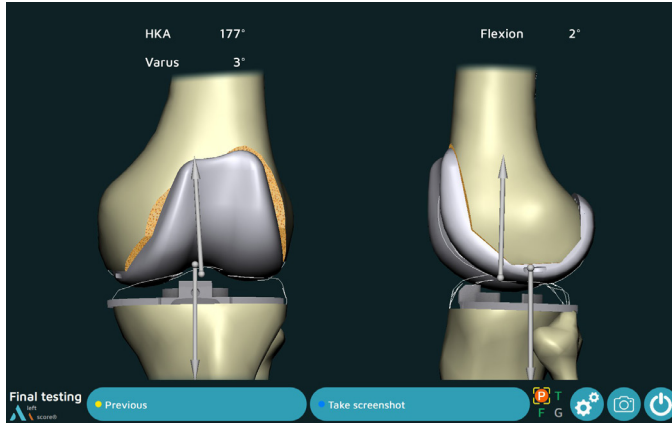
Tibial summary



- The trial implant's position (grey) is superimposed over the planned implant position (blue).
- The size and final position of the implant are shown in white; the planned values are in blue.
- Press the blue pedal to confirm and continue to the next step.

Final test

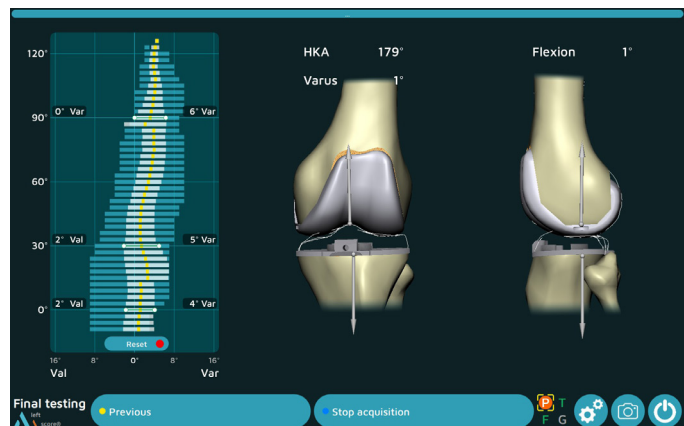
Post-operative alignment



- At this step, the software allows the final HKA and varus to be visualized in real time.
- If the acquisition of the trial implants has been performed, the gaps will be displayed.
- 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 on the Screen click on « Screenshot»).

Post-operative alignment with HKA option with varus/flexion curves

- The software allows the assessment of ligament deformities all along the range of motion (ROM) with trial or final implants.
- Press the blue pedal to start the acquisition.
- Start with the knee in extension, force varus to full flexion and then force valgus and return to extension.
- The maximum and minimum varus/valgus values obtained during the extension/flexion cycle will be displayed on the graph (light grey curve) and superimposed on the preoperative alignment (dark grey curve).
- A recording indicator is displayed at the top of the graph during recording and closes automatically when recording is completed.

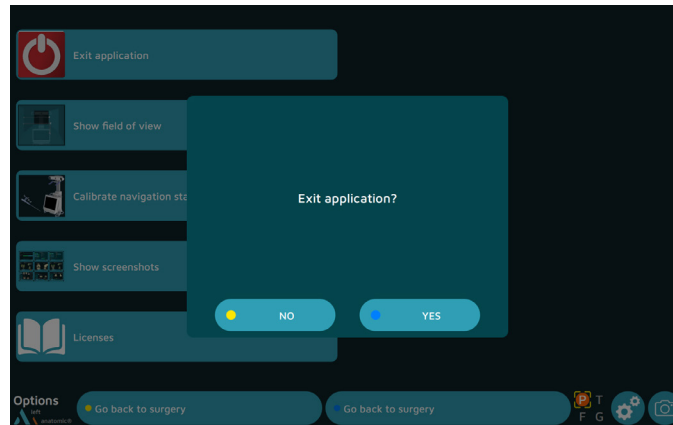



All navigation steps have been completed.

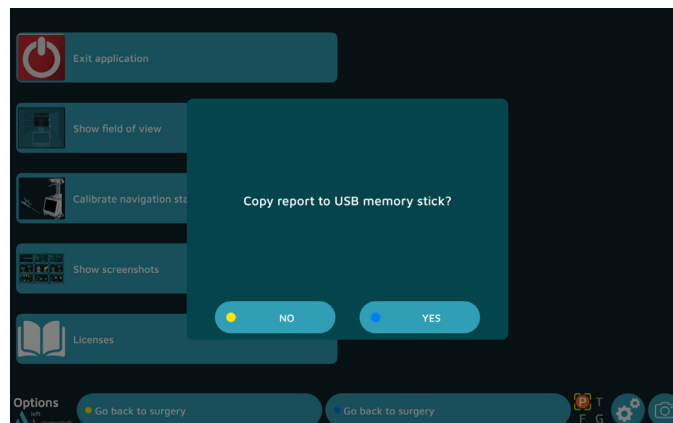
Refer to the following Surgical Techniques documents: TO.G.009 for SCORE, TO.G.013 for SCORE II and TO.G.002 for ANATOMIC for the following steps:

- Femoral preparation
- Tibial preparation
- Patellar preparation
- Positioning 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.



Power off button

Instrumentation

- In addition to the mechanical instrumentation described in the Surgical Technique documents TO.G.009 for SCORE, TO.G.013 for SCORE II and TO.G.002 for ANATOMIC), the following are required:
 - AMPLIVISION Navigation Station
 - Sterile, single-use markers (14 per pack)
 - The [Instrumentation Set for TKA 4in1 \(Navigated\): 2-0299946](#)

Sterile Markers (14 per pack) (Product No. 3-0400902) :

- The arrays must be equipped with markers to be visible to the camera. These markers 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):

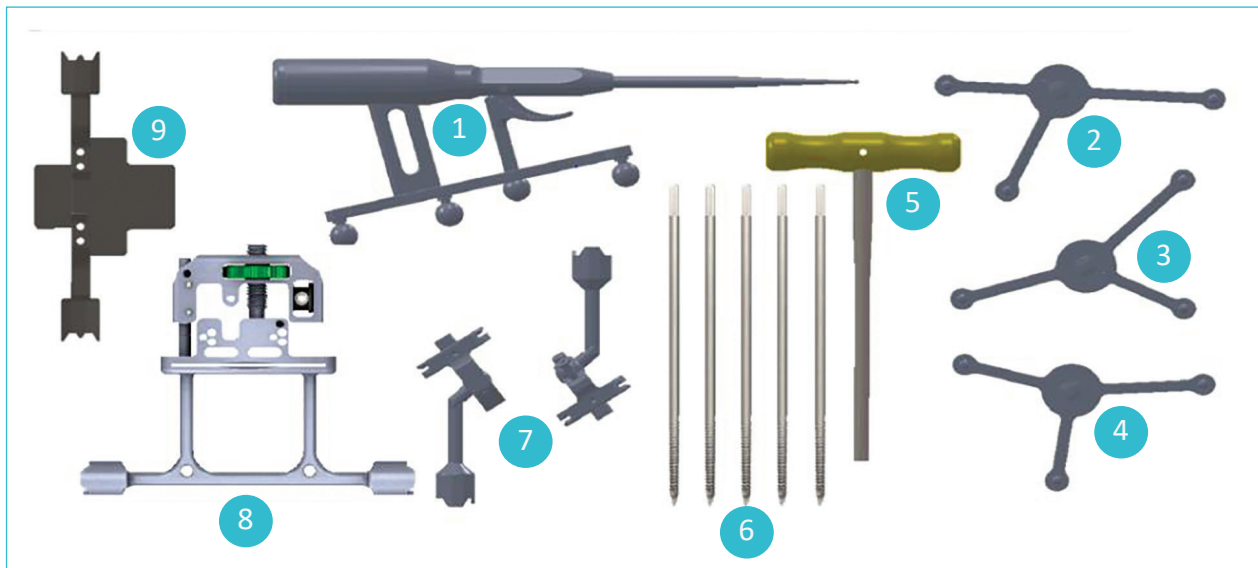
- 4 Single-use Conical Threaded Pins AMPLIVISION Ø4 length 150mm, are available upon request. They are inserted in the femur and the tibia and array fixation supports are placed on these pins which are inserted in the femur and the tibia.



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



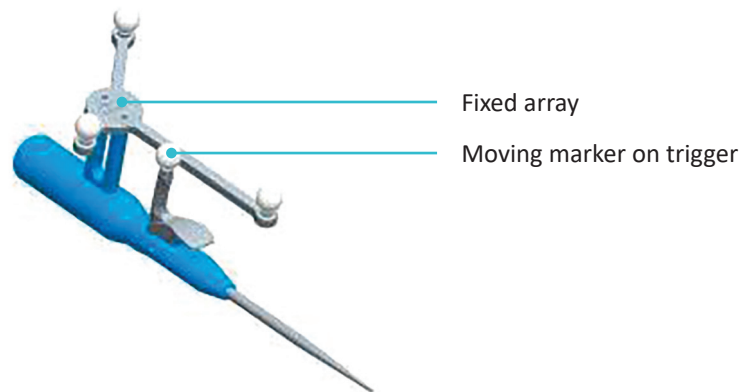
Item	Name	Reference	Qty
1	Probe knee navigation	2-0215700	1
2	T array, tibia navigation	2-0215800	1
3	F array, femur navigation	2-0117400	1
4	G array, Instrumentation navigation	2-0117500	1
5	H5 Screwdriver	2-0200800	1
6	Conical Threaded Pins AMPLIVISION Ø4 length 150mm	2-0235500	5
7	Inclined fixation 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 markers, 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.

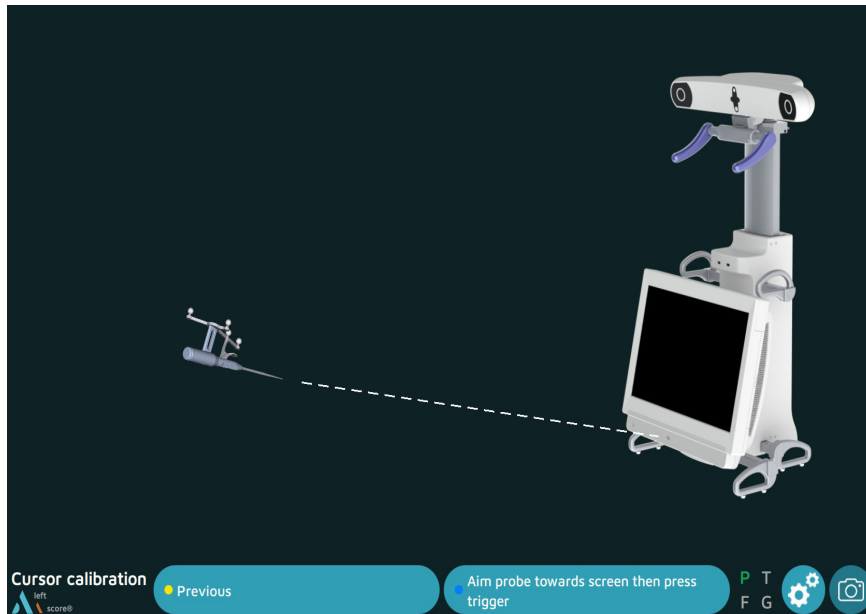


Universal guide:

- 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.



Option : calibration of the screen



- From this step on, the AMPLIVISION system can be controlled with:
 - the pedal,
 - the touchscreen of the AMPLIVISION workstation.
 - the probe: target the center of the AMPLIVISION screen with the probe and press the trigger to confirm.
- The system will capture screenshots when:
 - the user validates a step,
 - the user presses the screen capture button at the bottom right corner of the screen.

NOTE

If screen calibration is not initially selected, the station position is set by default.

NOTE

The user must make sure the arrays used in this step are fully visible.

The camera position may be recalibrated at any time:

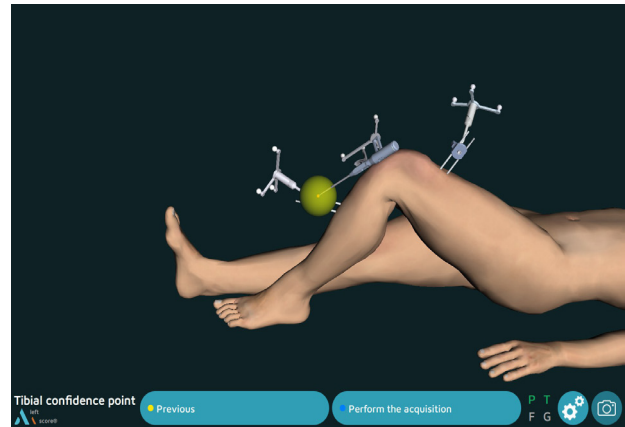
- Press the «Options» button.
- Press the «Calibrate AMPLIVISION workstation position» button.
- Validate the new position; the system will automatically return to the current surgical step.

Option : reference points on arrays

Tibial reference point on the array

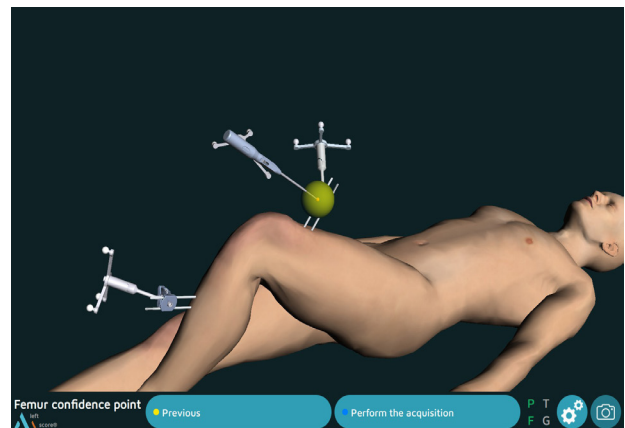
This step validates the final position of the T array on its fixation support. At any point during the procedure, the surgeon can check if the array position has changed by using this reference point.

- Place the probe tip in one of the two conical calibration marks on the T array support
- Confirm.



Femoral reference point on the array

- Place the probe tip in one of the two conical calibration marks on the F array support
- Confirm.



At any time during the procedure, place the probe tip on the previously acquired tibia and/or femur reference point. The words « Femur OK » and/or « Tibia OK » will appear in the lower right corner of the screen if the array has not moved relative to its support.

If the array has moved, the surgeon can continue the procedure without navigation or return to the reference point step.

NOTE

If during the procedure there is any doubt as to whether the arrays will hold up to the initial acquisitions, continue the procedure with the conventional technique.

NOTE

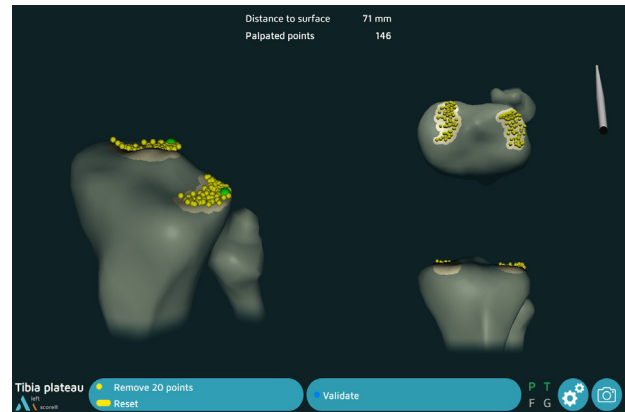
There is no way to check if the array–fixation support combination has moved. If in doubt, continue the procedure without navigation

Option : tibial registrations

Tibial bone surface registration

If **Mapping** has been chosen:

- 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).



NOTE

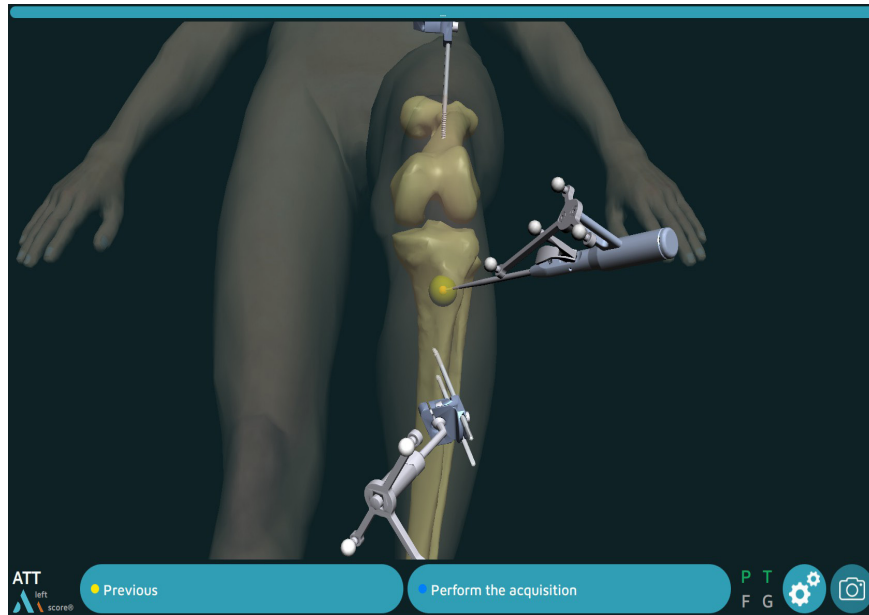
It is important to acquire points at the bottom of the plateau, not the ones on the side of it

NOTE

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

Option : tibial registrations

Anterior Tibial Tuberosity (ATT)



- Acquire one point with the Probe tip on the medial aspect of the anterior tibial tuberosity (ATT).
- Press the trigger to confirm.

Option : femoral registrations

Femoral anterior cortex registration

If **Mapping** has been chosen:

- It is necessary to enter a series of at least 50 points.



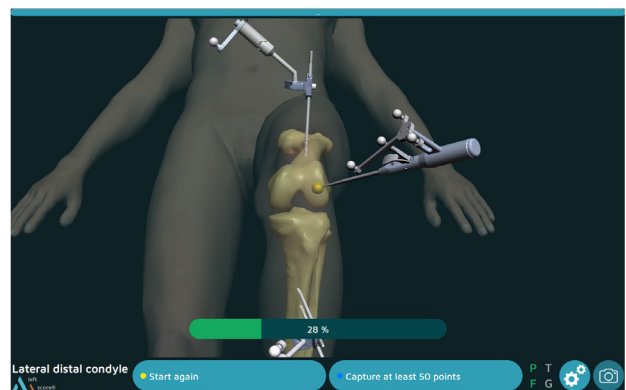
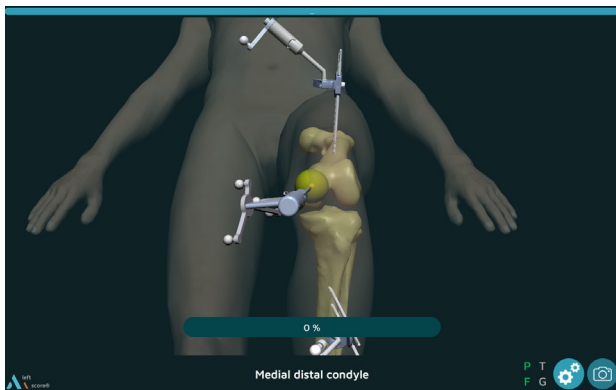
Option : femoral registrations

Femoral bone surface registration

Medial and lateral distal condyles

If **Mapping** has been chosen:

- Place the probe tip on the medial distal bone surface. Press and hold trigger then move the tip along the surface being acquired.
- The most distal points will be calculated automatically and saved as the distal resection height reference.
- Repeat on the contralateral condyle.



NOTE

It is important to acquire the points in the central area of the distal condyles while avoiding any peripheral osteophytes.

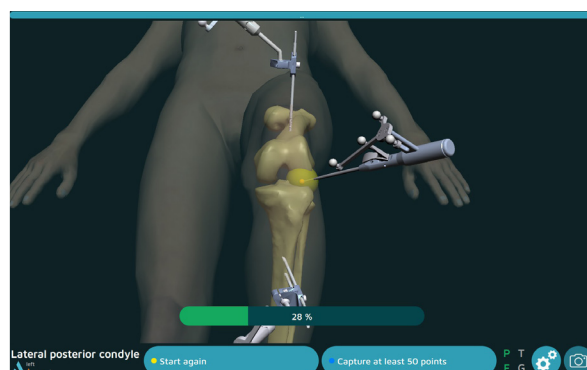
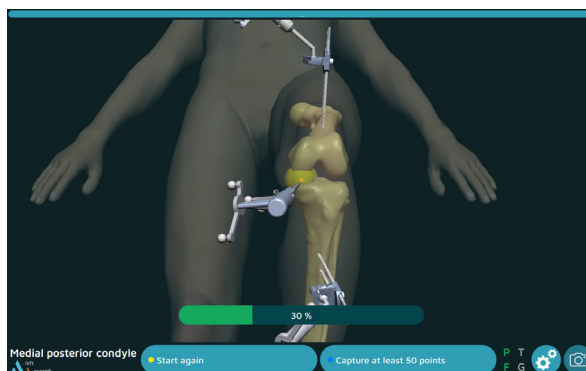
Option : femoral registrations

Femoral bone surface registration

Medial and lateral posterior condyles

If **Mapping** has been chosen:

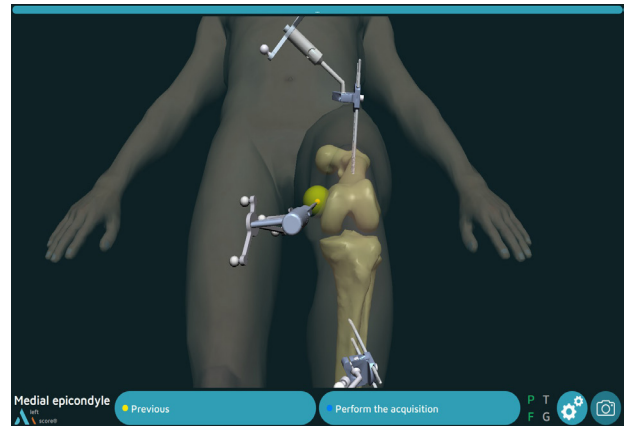
- Place the probe tip on the medial posterior bone surface. Press and hold trigger then move the tip along the surface being acquired.
- The most posterior points will be calculated automatically and saved as the posterior resection height reference.
- Repeat on the contralateral condyle.
- At any time, the surgeon may release the trigger, move the probe tip to another location and then press the trigger again to continue the acquisition.
- Pressing the yellow pedal will erase all the acquired points.



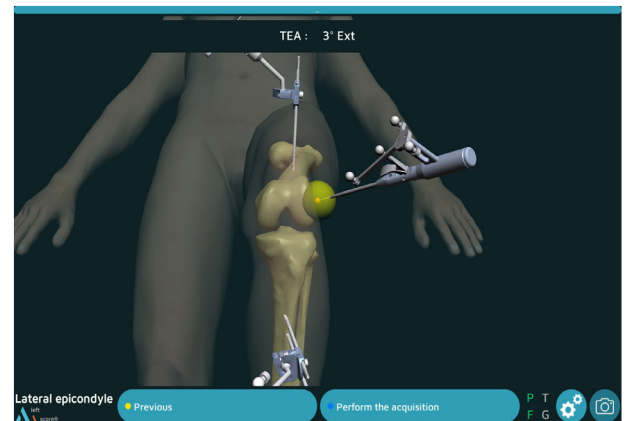
Option : femoral registrations

Transepicondylar axis registration

- Place the probe tip on the medial epicondyle
- Confirm



- Place the probe tip on the lateral epicondyle
The angle between the transepicondylar axis and the posterior condyles is displayed.
- Confirm



Whiteside line registration



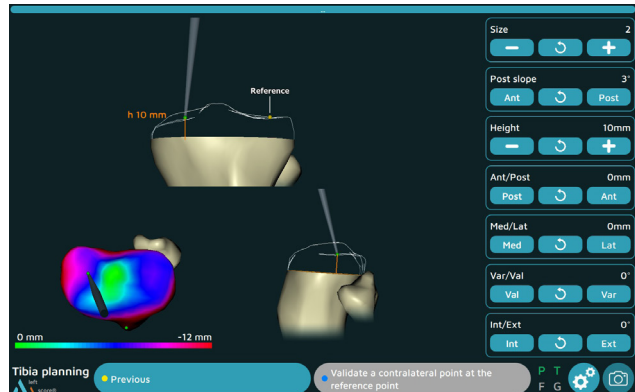
- Place the probe tip following the whiteside line : the angle between the Whiteside line and the posterior condyle is displayed
- Confirm

Option : tibial planning

Reference point for tibial resection height

If **Morphing** has been chosen and the Tibial planning option selected:

- Select and acquire the reference point from which the cutting height will be defined with the probe: for example a point on the healthy side.
- Select and acquire a contralateral point to know the distance to the cutting height reference point.
- It will display the difference between the two points in millimetres.



NOTE

A heat map helps to appreciate the relief of the joint surfaces: the healthiest areas (highest points) are in green tones, and the most worn areas (lowest points) are in red tones.

Tibial planning

- Before making the tibial cut, a suggested tibial baseplate size and position are given.
- All the potential adjustments to the position of the tibial baseplate are shown on the right side of the screen.
- Use the +/- keys on the touchscreen to adjust the size and position of the implant, as needed.
- Press the white button in the middle to return to the default value.
- Validate the plan once the desired changes (if any) have been made.

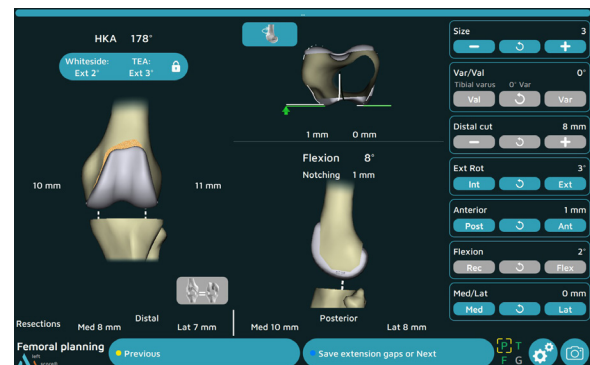
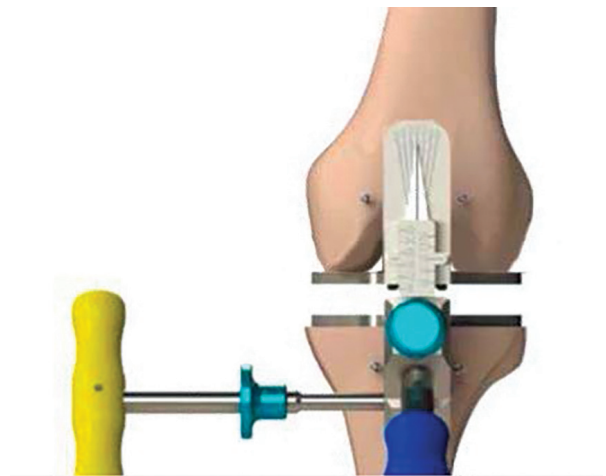


Option : femoral planning after distal cut

- This step is available in the case where the **order of cuts** chosen is **Tibial cut first then Distal femoral cut, then Femoral planning after distal cut and then 4-in-1 Femoral cuts and Distal femoral cut first then Tibial cut, then Femoral planning after distal cut and then 4-in-1 Femoral cuts.**
- This protocol allows to do the planning (after the tibial cut and the distal femoral cut) the anteroposterior resections taking into account the ligament balancing and the gaps in extension and flexion.

Extension gaps


- Insert the Extra-articular Ligament Balancer V2 into the knee joint with the knee extended.
- Insert the Snap Screwdriver H5 into the balancer's cog wheel.
- Turn the Snap Screwdriver H5 to operate the distraction mechanism and apply the desired amount of tension. Do not apply excessive distraction, otherwise the knee will flex. The knee must stay extended during the measurements.
- The goal is to have a well-balanced gap on the medial and lateral compartments of 10 mm for a 10 mm tibial insert. It is possible to adjust all the following values: size and mediolateral positioning.
- The parameters in dark grey cannot be modified because the distal femoral cut has already been performed: varus/valgus, distal cut height and flexum/recurvatum.
- The text showing the notching value changes to orange as soon as it is greater than 1 mm.
- Once the desired alignment and gaps have been achieved, press the blue pedal to confirm.
- Release the balancer by pressing the blue button, remove it and place the knee in flexion.

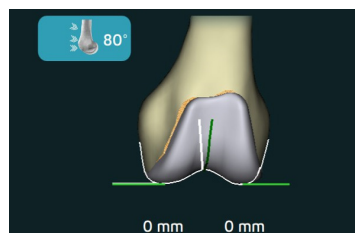
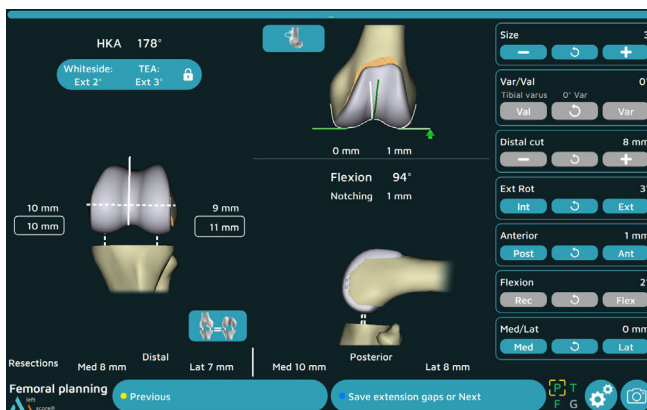


Option : femoral planning after distal cut

Flexion gaps



- Knee in flexion, Insert the Extra-articular Ligament Balancer V2 into the knee joint.
- Insert the Snap Screwdriver H5 into the balancer's cog wheel.
- Turn the Snap Screwdriver H5 to operate the distraction mechanism and apply the desired amount of tension.
- In this step, it is possible to change the size, the rotation and Antero-Posterior positioning so that the gaps in flexion correspond to the gaps recorded in extension.
- In order to transfer the gaps measured in extension directly to flexion, select the button .
- Once the balance is obtained, press the blue pedal to validate the settings.



If the option Trochlea Lines has been chosen :

An addition view allows the display of a trochlear view, allowing the visualization of the over-thicknesses from different angles.

NOTE

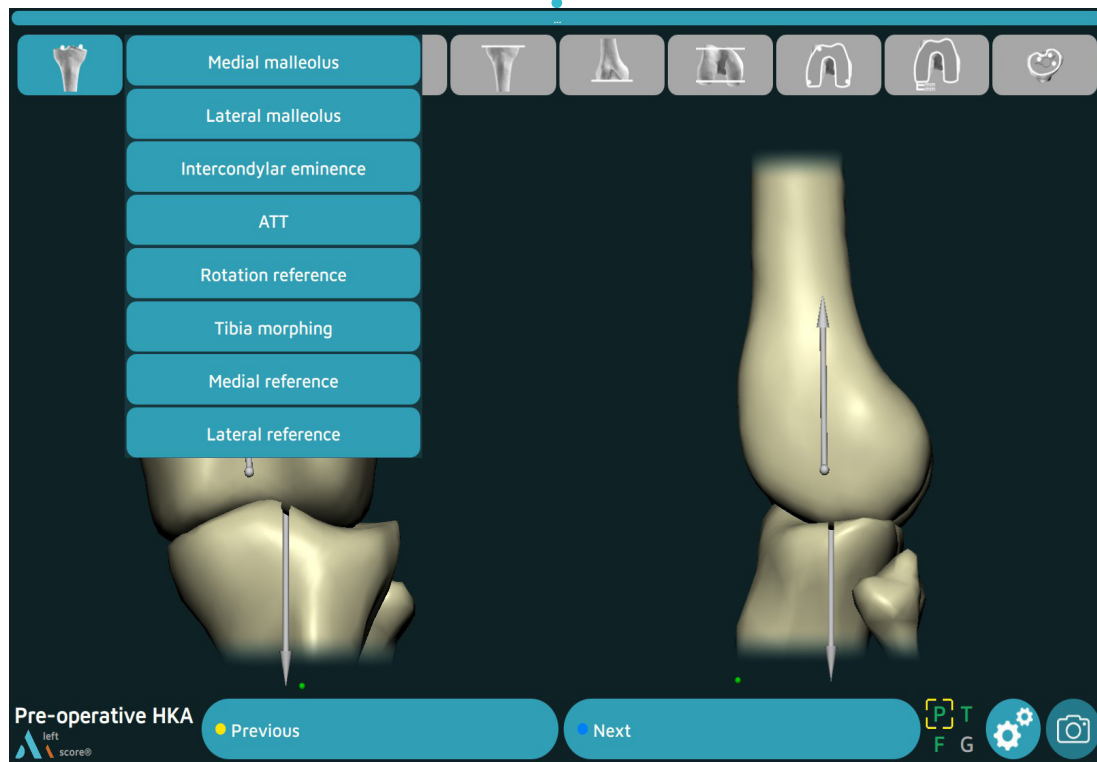
The automatic equalisation only acts on the antero-posterior movement and on the rotation of the femoral implant, and within the limits of 2mm anterior/2mm posterior and 8° external/2° internal rotation.

Appendix A

Screen layout

Operative workflow

- Click on the blue area to display the steps of the surgery
- Click on the desired step (the accessible steps are in green)
- Modify the desired parameters in the chosen step
- Validate
- The flow will resume at the current step



Current step
Operated side
Implant

Button next and previous

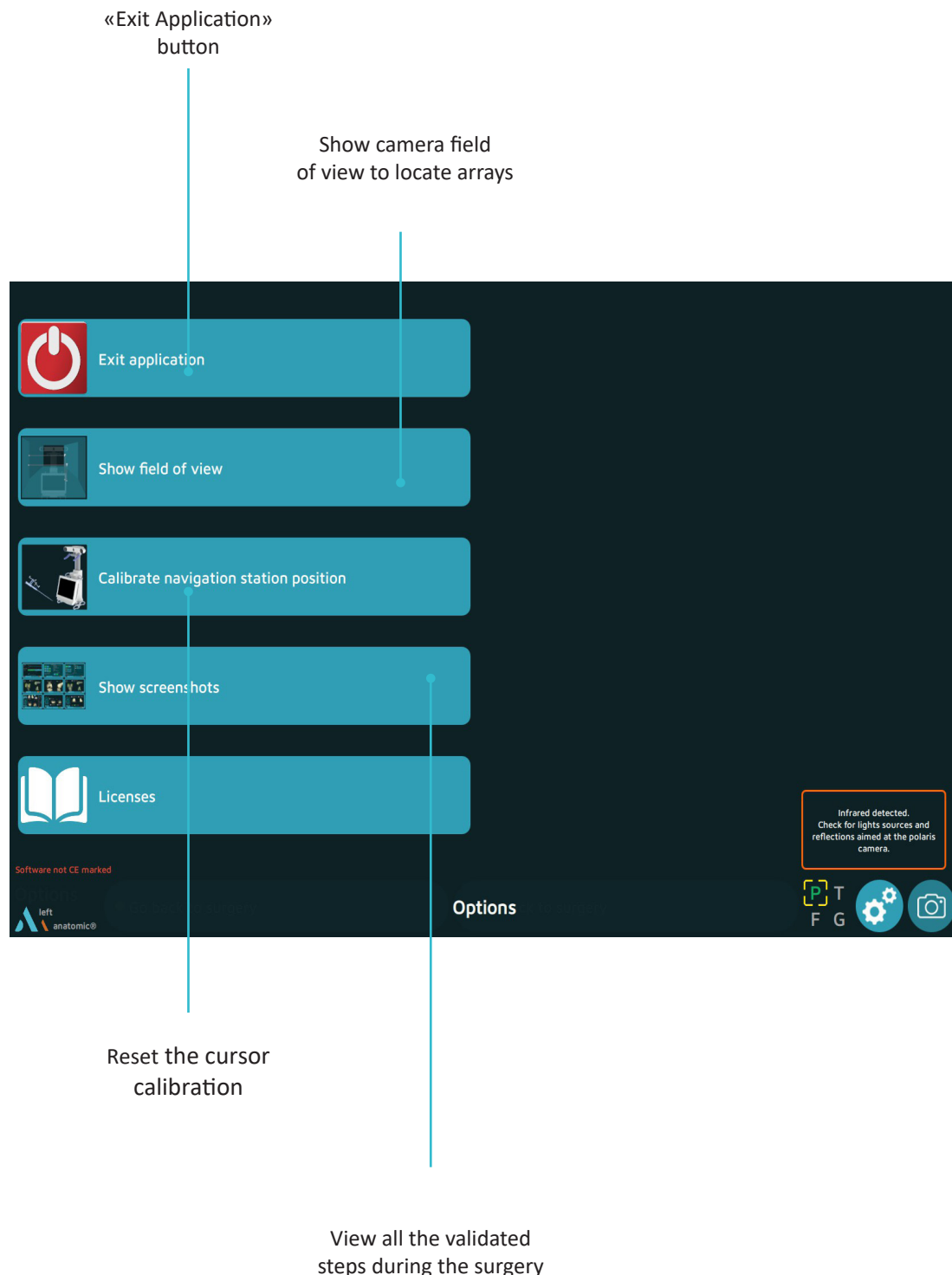
Screenshot

Menu : Options

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

Appendix B

Menu Options

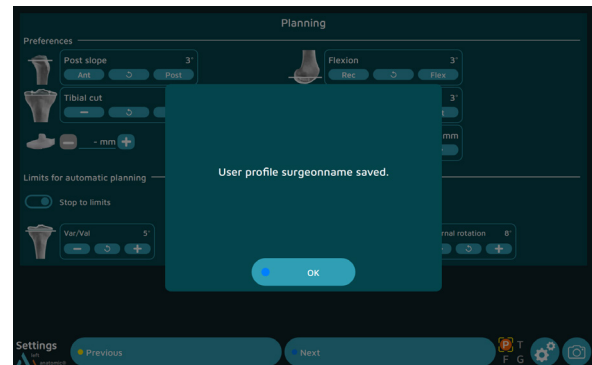


Appendix C

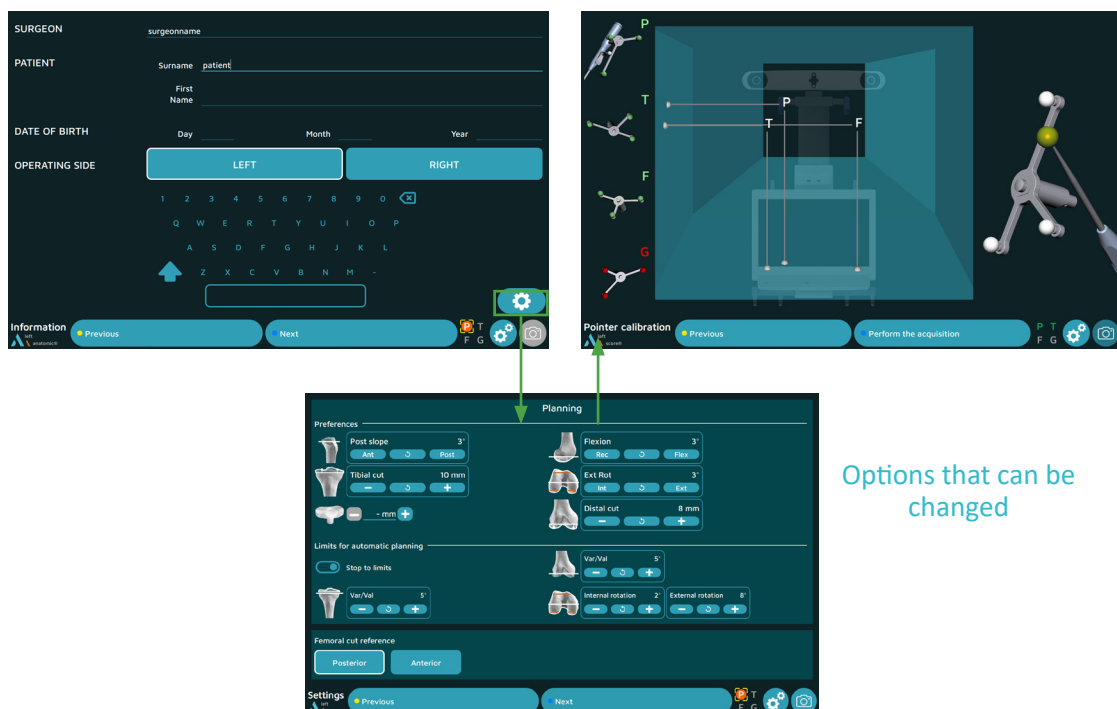
User profile

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.

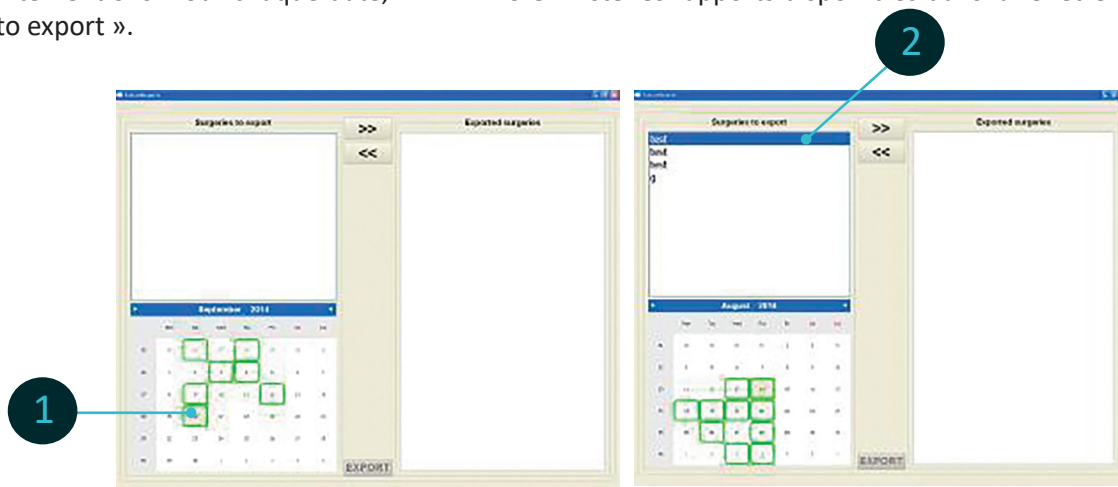
Appendix C

Opening a saved surgery report

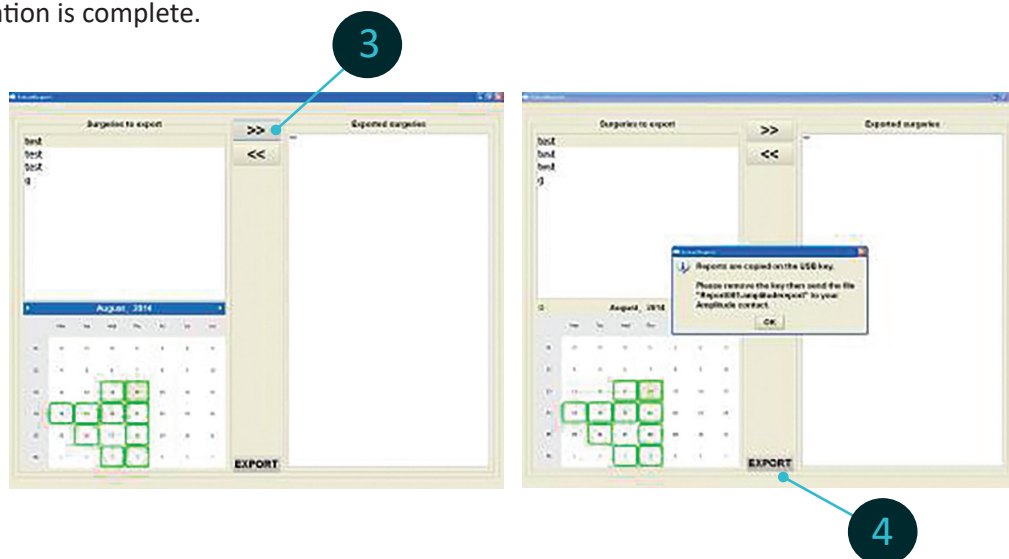
If a saved surgery report is not transferred to a USB drive, it can still be retrieved at a later date.

- 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.

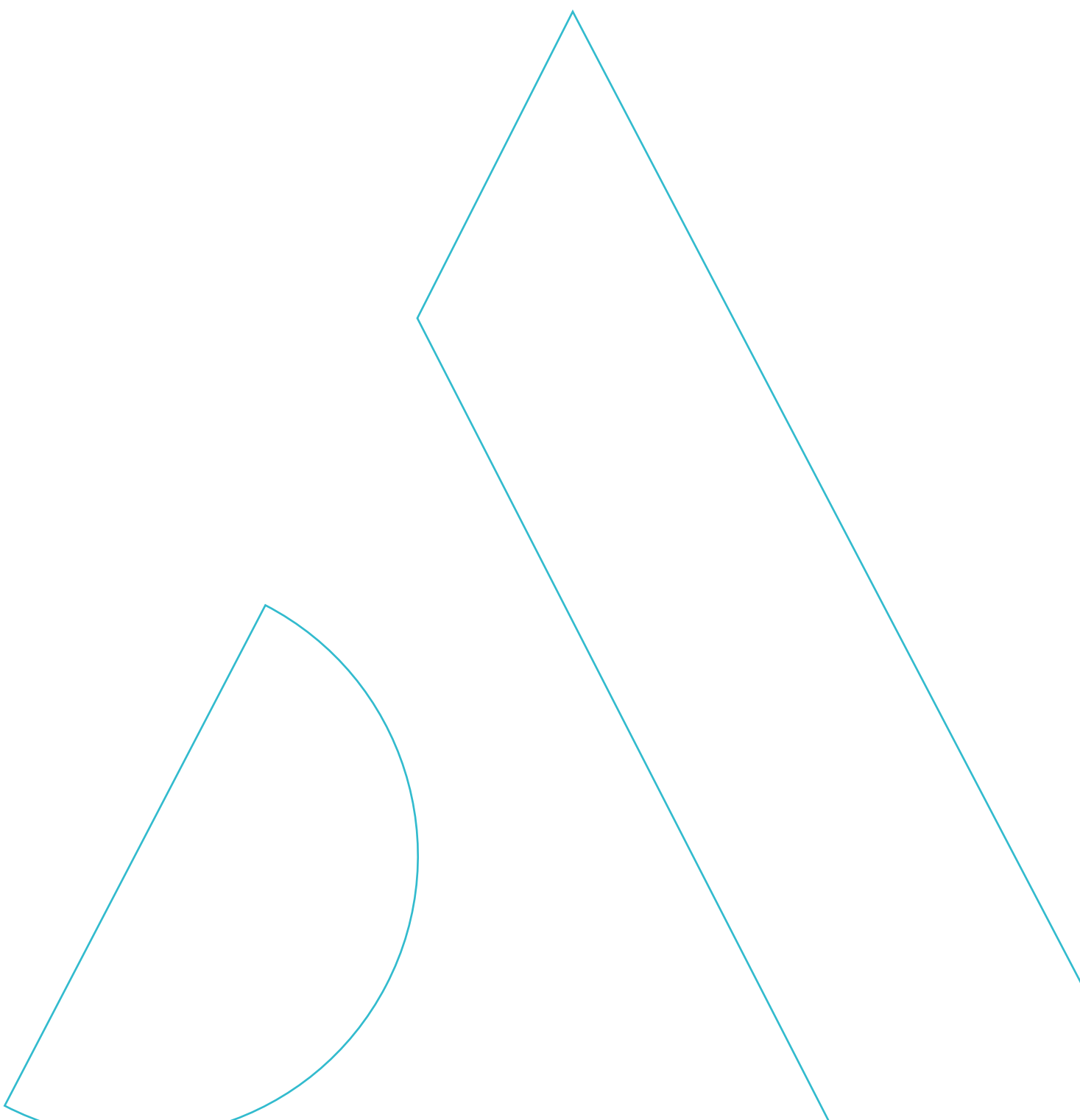


NOTE

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

This image shows a blank sheet of white paper designed for taking notes. At the top left corner, the word "NOTES" is printed in a large, bold, blue font. Below the title, the page is filled with horizontal black lines, providing a structured space for writing. The lines are evenly spaced and extend across the width of the page.







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Reference : TO.G.046/EN/A