



Surgical Technique

AKN (Advanced Knee Navigation)
4-in-1 Global Planning



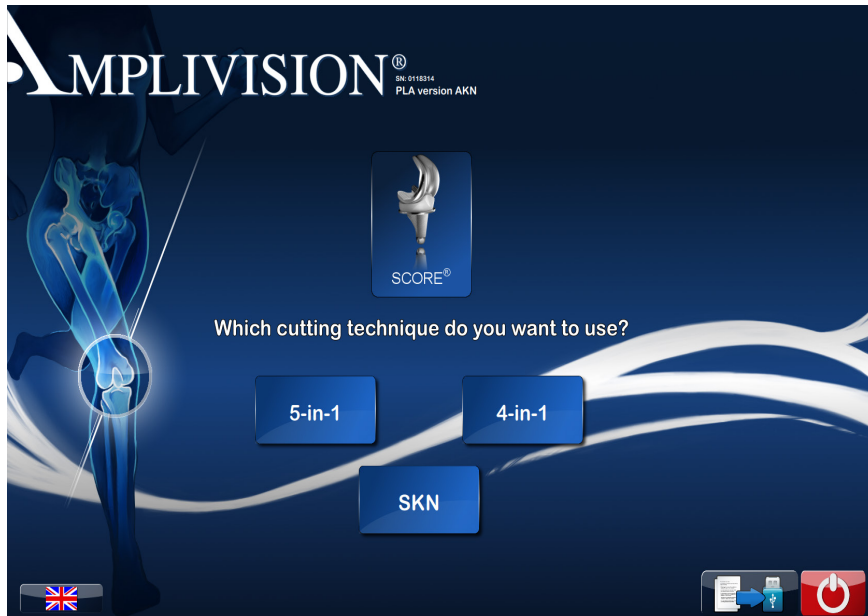
Summary

Introduction	4
Starting the software	5
User settings	6
Set up	10
Tibial registration	12
Femoral registration	16
Planning	20
Tibial navigation	26
Femoral navigation	27
Trials registration	30
Final test	34
Surgery report	35
Powering down the workstation	36
Instrumentation	37
Options	40
Appendix	44

Introduction

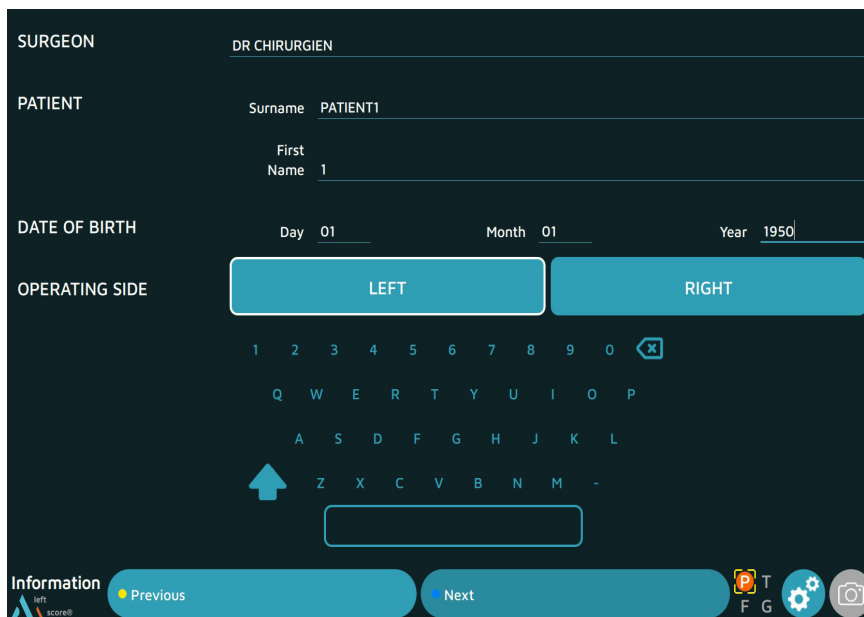
- This Surgical Technique Supplement describes the use of the AKN (Advanced Knee Navigation) computer-assisted surgery software for implanting Amplitude's total knee arthroplasty (TKA) systems.
- This software is used to navigate tibial resection, distal femoral resection and 4-in-1 femoral resections.
- 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
 - > The paragraphs on the 4-in-1 Femoral Resection
 - > The paragraphs on the extension & flexion gap measurement, the femoral sizing, the trials.
- 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
 - > The paragraphs on the 4-in-1 Femoral Resection
 - > The paragraphs on the extension & flexion gap measurement, the femoral sizing, the trials.
- 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 4-in-1 Femoral Resection
 - > The paragraphs on the extension & flexion gap measurement, the femoral sizing, the trials.
- For TRAX CR TKA with conventional 4-in-1 instrumentation: **TO.G.041**
 - > The paragraphs on the distal femoral resection
 - > The paragraphs on the tibial system
 - > The paragraphs on the tibial resection
 - > The paragraphs on the 4-in-1 Femoral Resection
 - > The paragraphs on the extension & flexion gap measurement, the femoral sizing, the trials.

Starting the software



On the touch screen

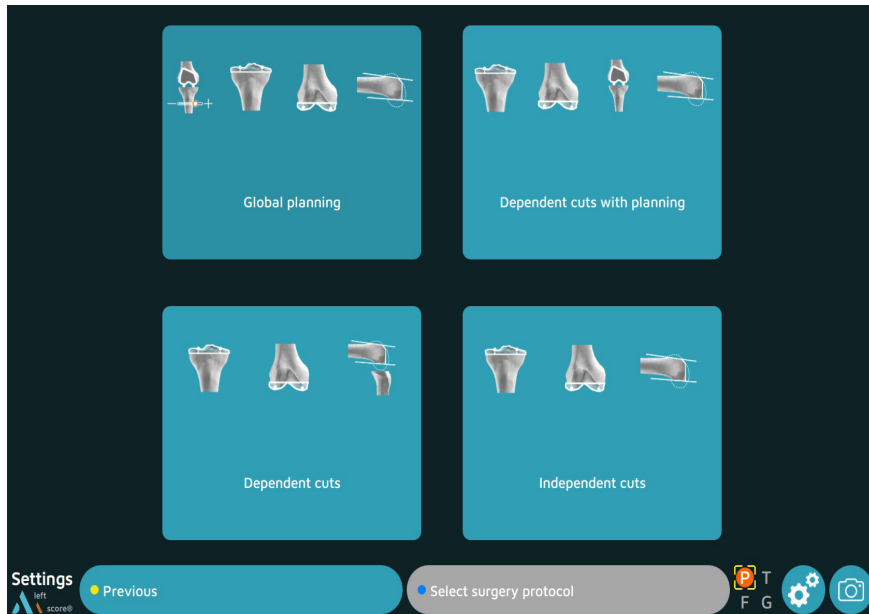
- Select the language.
- Select the knee.
- Select the implant.
- Select the **4 in 1**.



- 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 « **Global 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

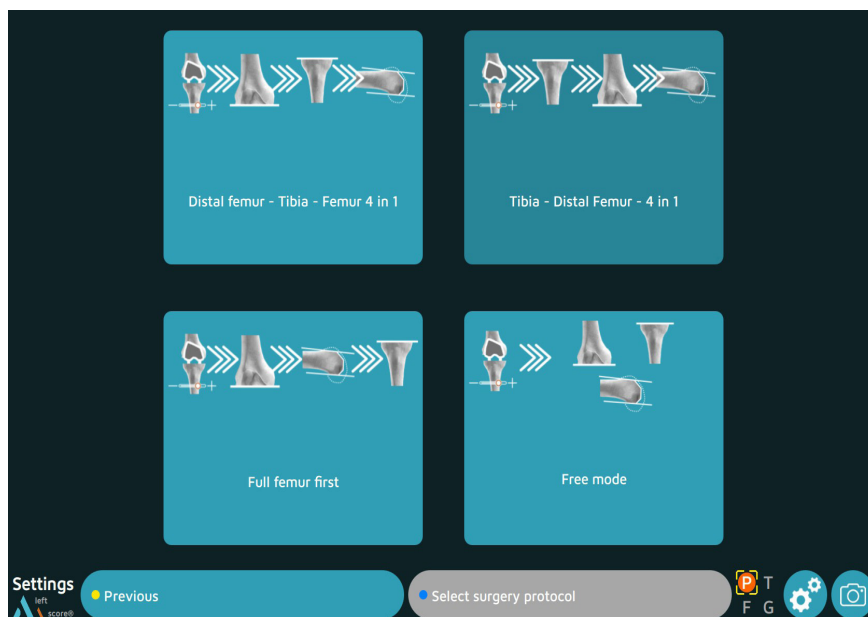
Independent cuts

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 order of the resections:

Distal femoral cut first then tibial cut then 4-in-1 femoral cuts

Tibial cut first then Distal femoral cut then 4-in-1 femoral cuts

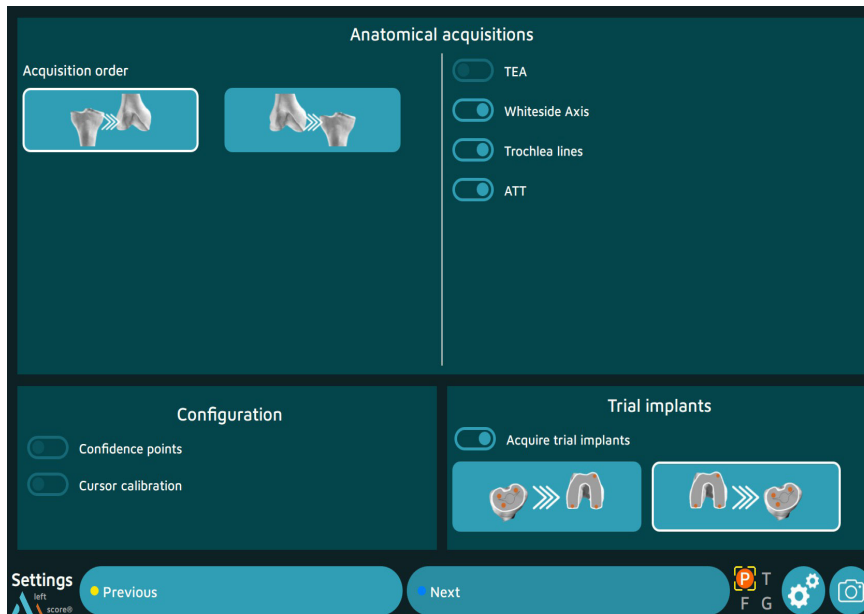
Femoral cuts first then tibial cut

Free mode : the software proposes to perform the closest cut to the guide during manipulation

- Press the blue pedal to continue to the next step

User settings

Anatomical registration options



Registration

Tibial registration first or femoral registration first

TEA Biepicondylar 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

Confidence points

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

Calibrate navigation station position

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 registration

Assessment of the implant trials positioning

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

User settings

Planning options



Preferences

The preferences allows to pre-positioned 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, the tibial resection thickness, the tibial insert thickness

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

Limits for the planning

If the stop to the limits is activated, the software will not go beyond this values for each of the parameters chosen by the surgeon, for the tibial varus/valgus, the femoral varus/valgus, the femoral external rotation and the femoral internal rotation.

This stop to the limits is valid for the kinematic alignment (KA) which will switch to the restricted Kinamtic Alignment (rKA), and for the Fonctionnal Alignment.

During the planning all the values can be changed.

Femoral resection reference

Choice between the Anterior reference and the Posterior reference.

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

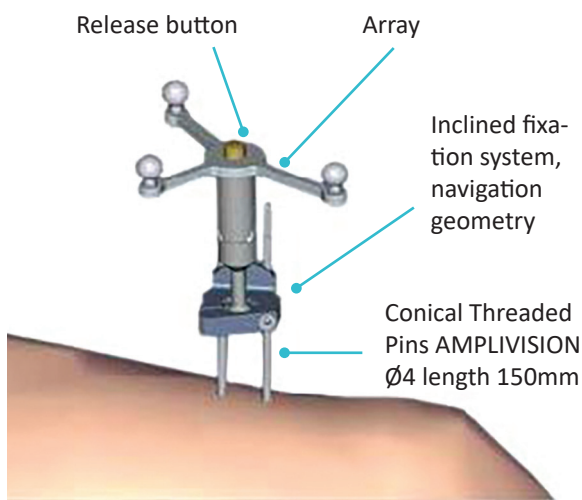
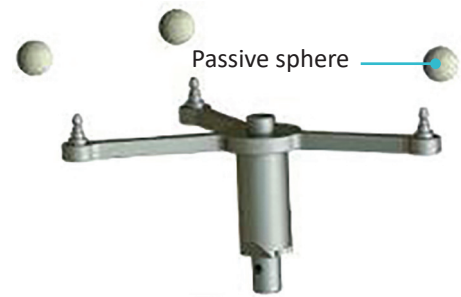
NOTE

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.

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

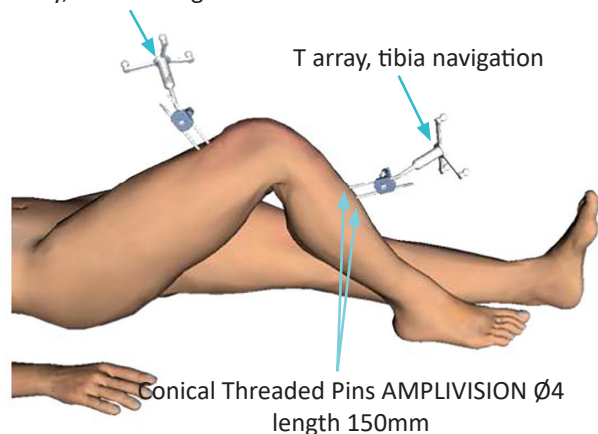
- Insert the first pin: go through the proximal cortex and then into, but not through, the distal cortex.
- Place the Inclined fixation system, navigation geometry, on the first pin to get the proper spacing for the second pin.
- Clip the F array on the moveable part of the support, making sure the arrows 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

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).

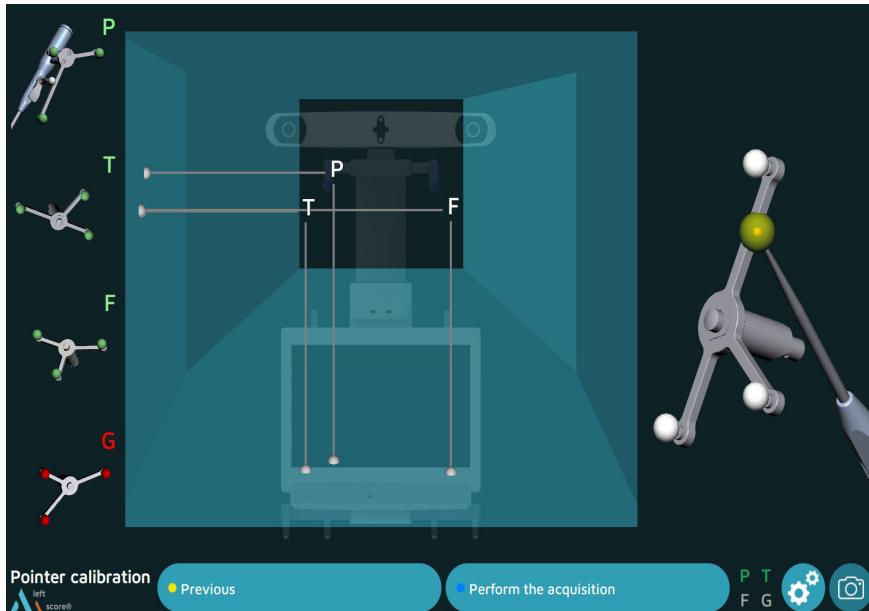
F array, femur navigation

T array, tibia 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 V3 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 passive sphere 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 passive spheres).

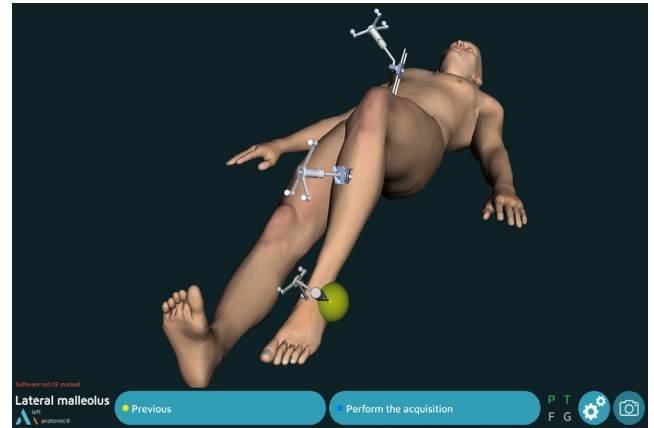
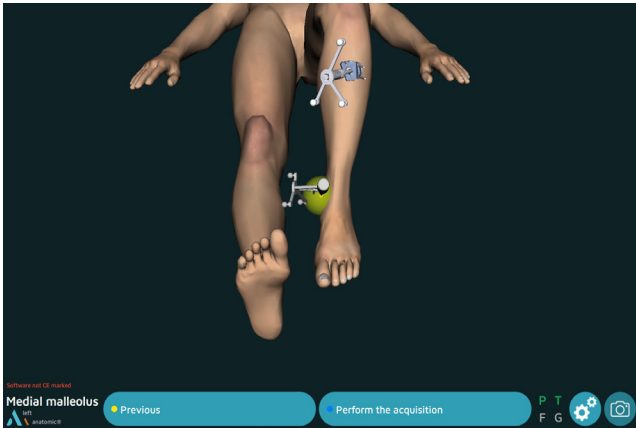
Probe calibration

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**.

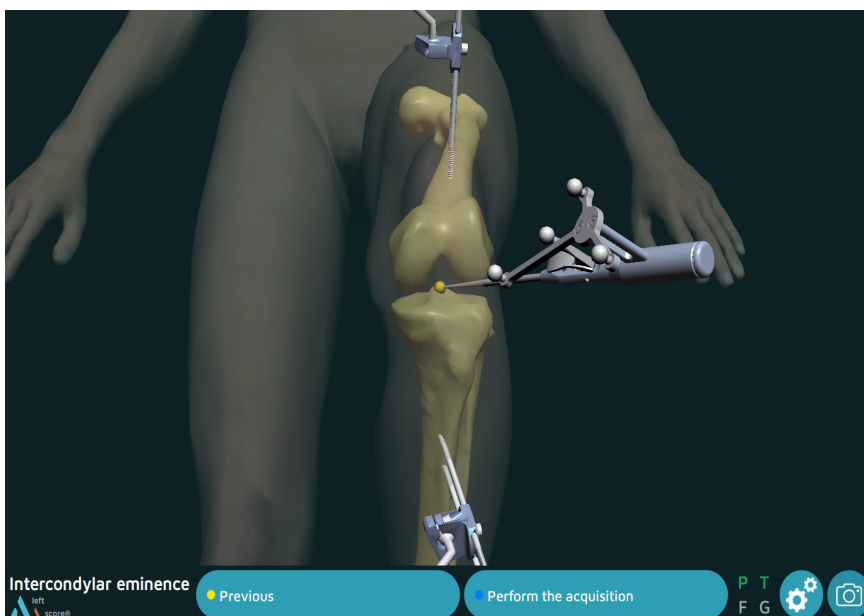
Medial malleolus

- 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

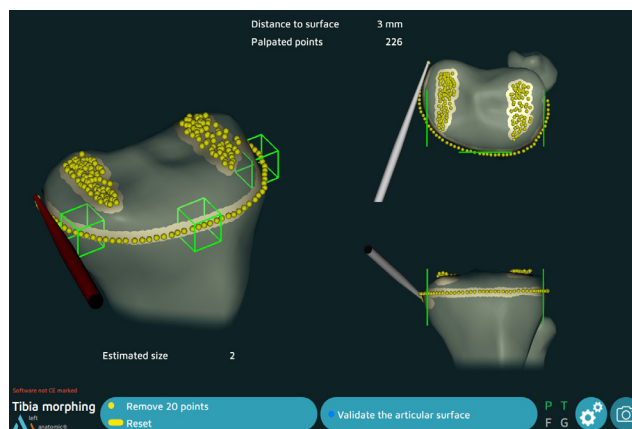
Tibial reference rotation



- 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

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.

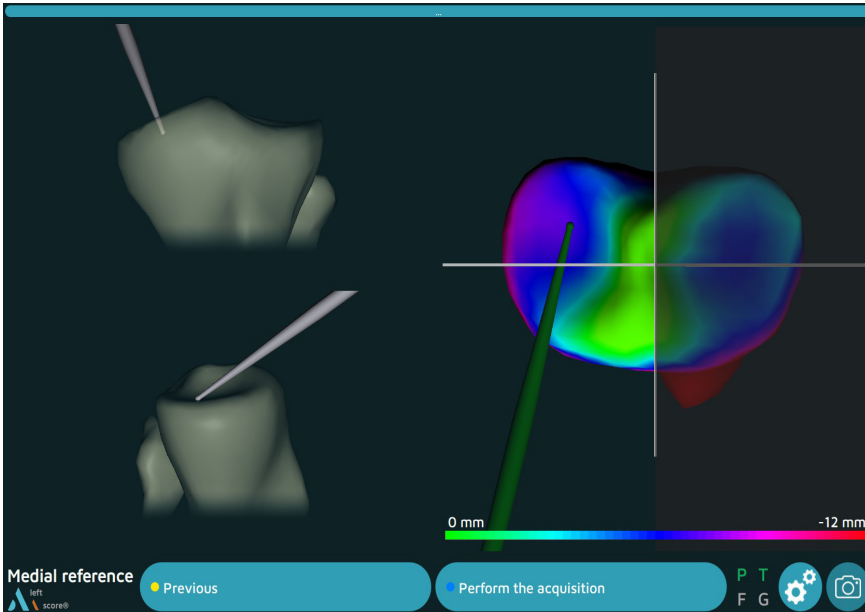
Press and hold down the yellow pedal (for at least 2 seconds) to erase all the acquired points.

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

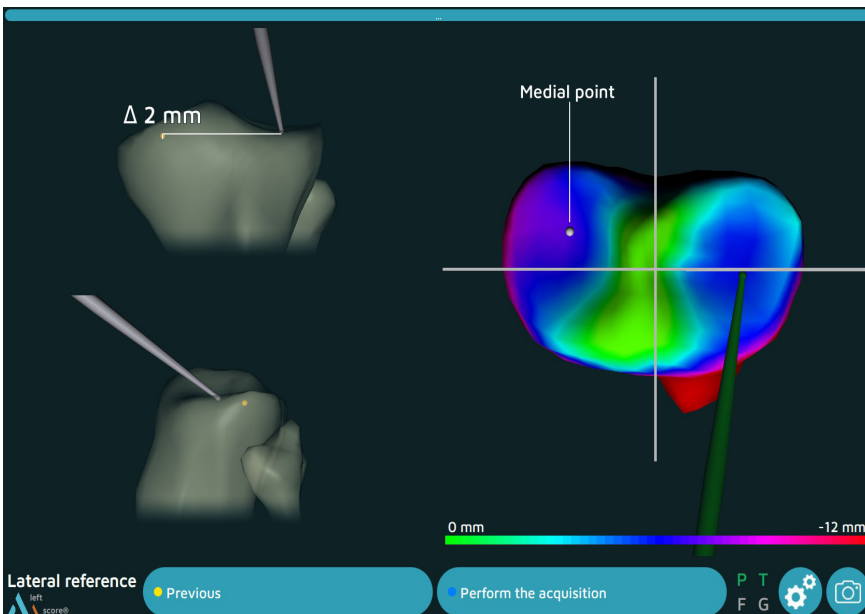


Tibial registrations

Reference points



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



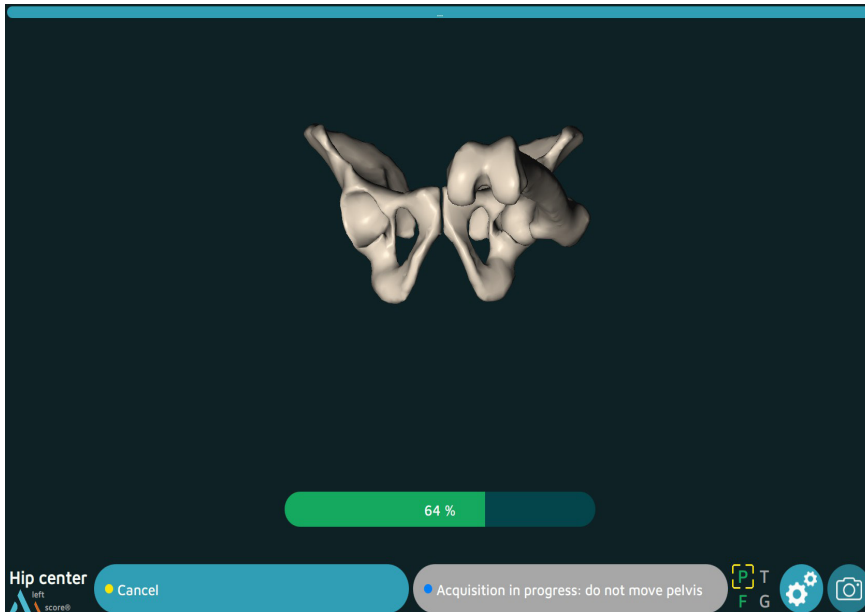
- Place the probe tip on the lateral tibial bone surface
- Confirm

NOTE

Those two points will be used as references to calculate 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.

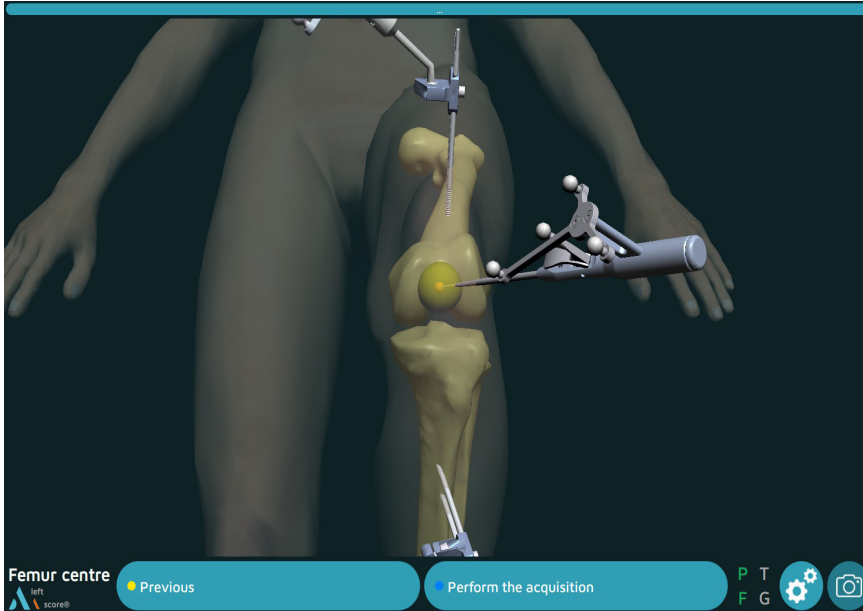
Femoral anterior cortex registration

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



Femoral registrations

Top of the intercondylar notch registration



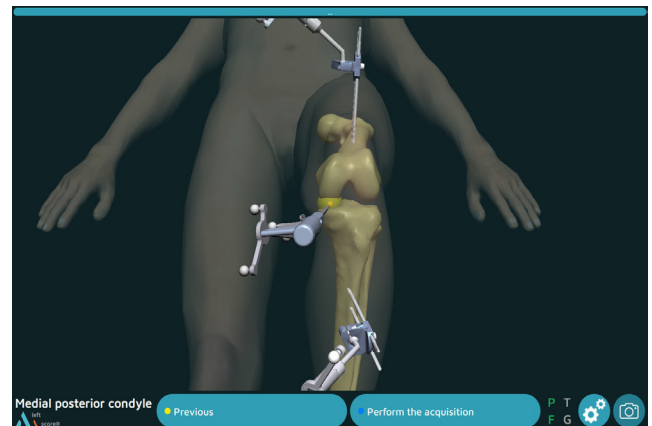
- Place the probe tip at the top of the femur's intercondylar notch and along the femoral shaft axis
- Confirm

NOTE

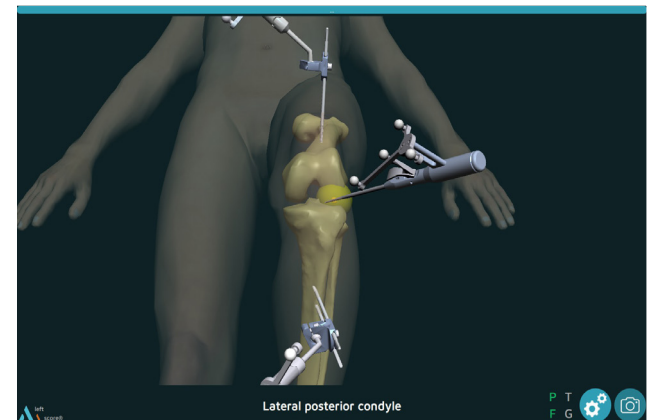
The femoral mechanical axis is calculated using the hip centre and the top of the intercondylar notch.

Posterior condyles registration

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



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



NOTE

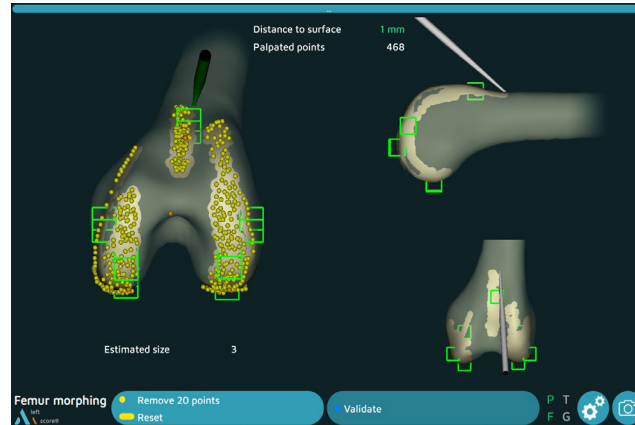
Using the femur's mechanical axis and the posterior condylar axis, the AMPLIVISION system calculates the frontal femoral plane and estimates the sagittal and transverse planes

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 : he 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 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 tibial bone surface when the trigger is pressed

Verification of the contours

Release the trigger and place the probe tip on the registred 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.

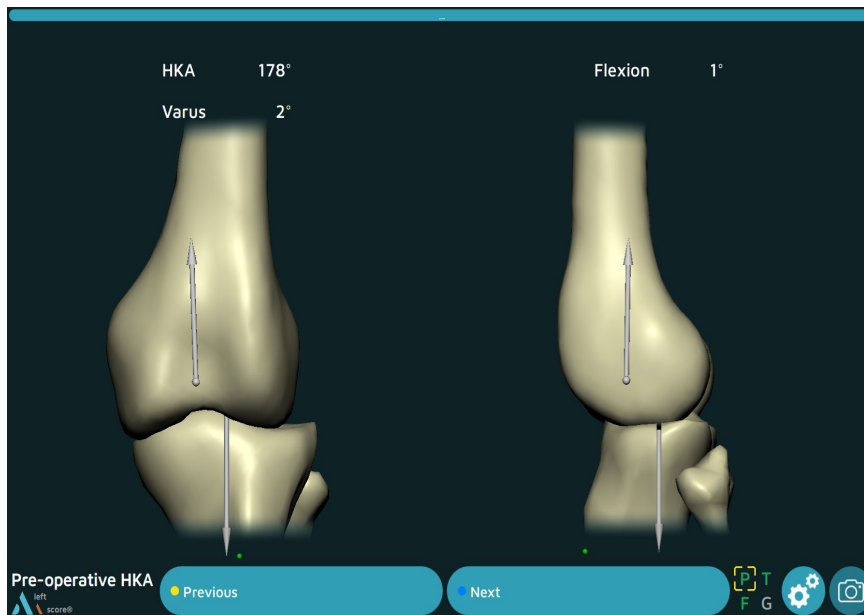
Press and hold down the yellow pedal (for at least 2 seconds) to erase all the acquired points.

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 (Hip Knee Ankle)

Planning

AKN Planning software

The software **Global Planning** proposes 3 surgical alignments to position the implants :

The **Mechanical Alignment** (MECA):

This alignment is proposed by default.

From the user's settings of the surgeon, orientations and height of the resections are calculated to obtain a mechanical axis of 180°: **HKA plan = 180°**.

The curves representing the gaps are the result of those femoral and tibial positioning.

At any time the surgeon can change the values of the height and of the orientation to customize the planning.

The **Kinematic Alignment** (KA ou rKA):

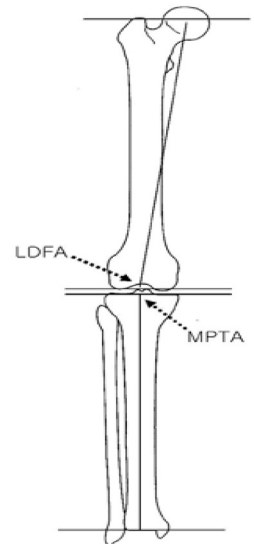
This alignment requires a voluntary action by clicking on the KA button (or rKA if the stops at the limits is activated).

The software proposes to fill in the level of cartilage wear on the distal femoral and proximal tibial compartments. These values of wear allow to calculate the LDFA (Lateral Distal Femoral Angle) and the MPTA (Medial Proximal Tibial Angle).

From this data, the resections height and orientation are calculated to perform a femoral and a tibial resurfacing. The femoral and tibial varus/valgus angles proposed will correspond respectively to the LDFA and MPTA and the thicknesses of the resections will correspond to the thicknesses of the implants : 8 mm for the distal femoral resection and femoral posterior resection, and 10 mm for the tibial resection.

The curves representing the gaps are the result of those femoral and tibial positioning.

At any time the surgeon can change the values of the height and of the orientation to customize the planning.



The **Functional Alignment** (GAPS):

This alignment requires a voluntary action by clicking on the GAPS button.

The software starts to perform a tibial resurfacing (tibial resection is oriented according to the MPTA and height is 10mm), next it is calculating the height and orientation of the femoral resection in order to balance the gaps at 10 mm (corresponding to the thickness of the chosen insert or 10 mm by default) all along the range of motion.

At any time the surgeon can change the values of the height and of the orientation to customize the planning.

Planning

Planning screen

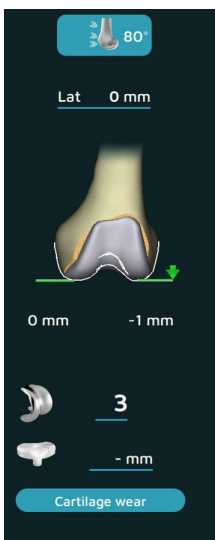
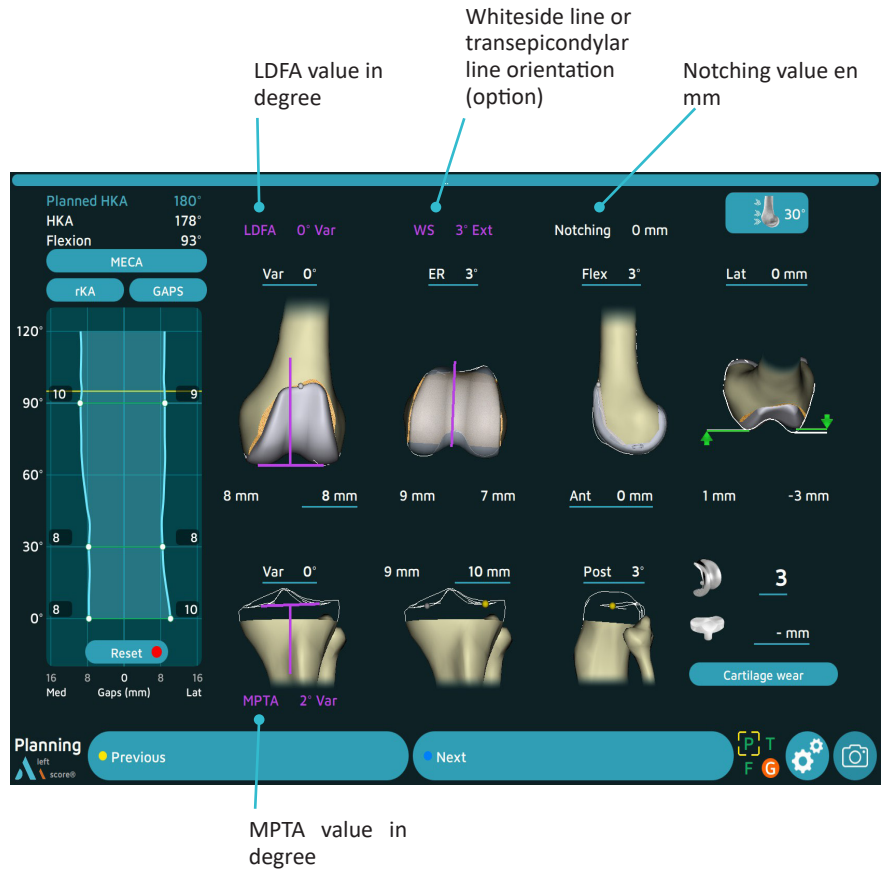
HKA Plan = HKA planned
 HKA = HKA live
 Flexion = angle of flexion of the leg

MECA = button for mechanical alignment
 KA (or rKA) = button for kinematic alignment or restricted kinematic alignment
 GAPS = button for functional alignment
 A button is circled with a white line when the selected software is active without any modification. It is circled in gray when a value is modified.

Ligament gaps curves in mm with specific values at 0°, 30° and 90°

Reset button for gaps registration

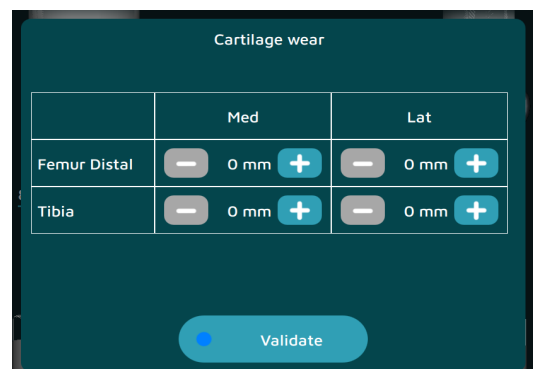
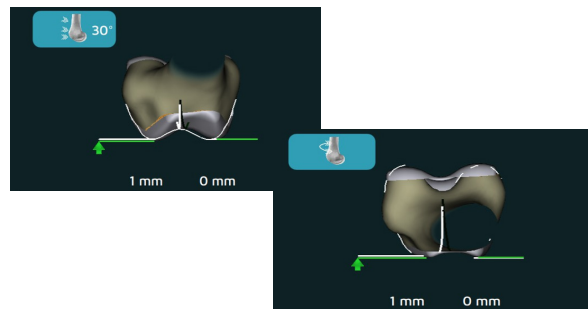
Current step
 Operated side
 Implant name



Trochlear view modification:
 - Free mode associated with leg flexion
 - 30° or 60° or 80° mode

Overhang values of the anatomical flanges versus prosthetic flanges at the different selected angle

Adjustment of the size of the femoral implant
 Adjustment of the tibial implant thickness
 Adjustment of the thickness of the cartilage wear



Planning

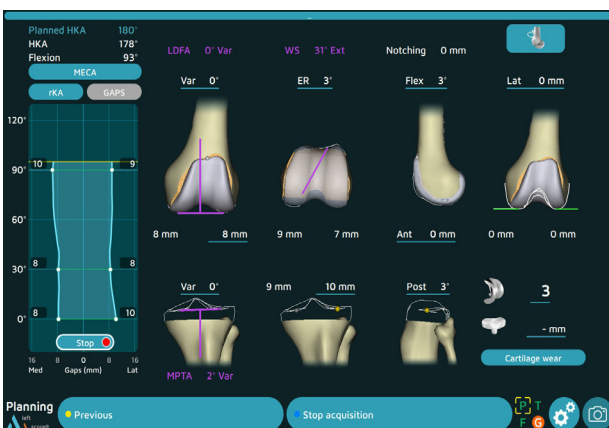
Registration of the gaps



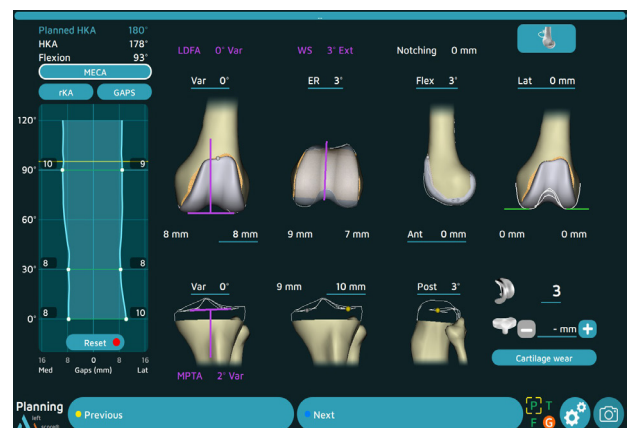
The software allows to assess the ligament gaps all along the rom of extension (ROM).

The registration of this gaps is ready to start upon arrival in the planning screen.

- Start with the knee in extension, forced the varus until full flexion and forced the valgus to come back to the extension
- The maximum gaps values obtained during the extension/flexion cycle will be represented on the graph



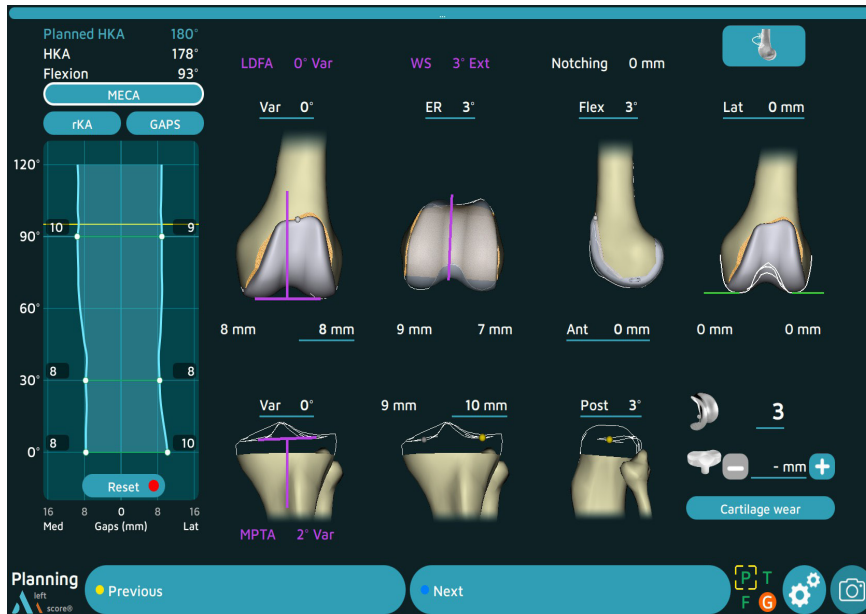
The button **Stop** located under the curve or pressing the blue pedal allows you to stop the registration



The button **Reset** allows to restart an registration of the curves

Planning

Mechanical alignment (MECA)



By default the software proposes orientations of the resections according to the Mechanical Alignment to reach an HKA at 180° ==> **HKA Plan = 180°**.

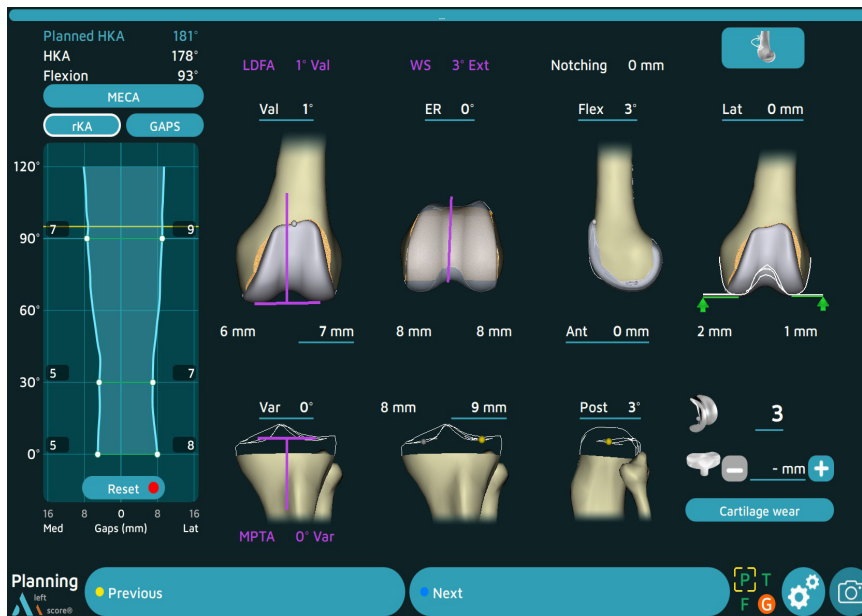
The button MECA is circled with a white line to show that this mode is active.

The parameters that are underlined in blue can be modified using the probe.

- Target the probe on the screen
- Move the cursor on the value to be changed, the blue squares appear on both side of the value
- Click on the symbol to change the value
- Check all the parameters and the gaps
- Click on next to perform the resections

Planning

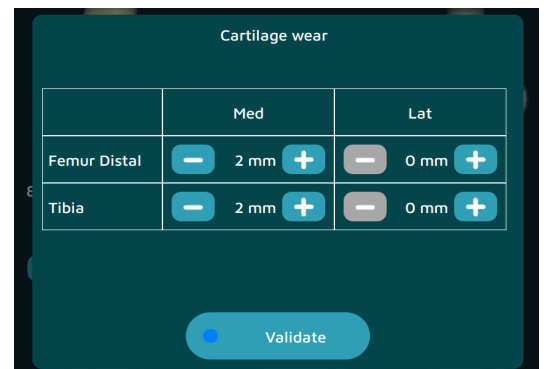
Kinematic Alignment (KA or rKA)



- Click on the button **KA**. The button is circled with a white line.

A pop-up automatically opens and allows to fill in the wear of the cartilage.

- Target the probe on the screen
- Fill in the wear of the cartilage on the different compartments with the button located on both side of the values.
- Confirm



The values of LDFA and MPTA are then recalculated according to these wears and the software modifies the orientations according to these new values : tibial resurfacing (tibial cut height at 10 mm - cartilage wear) et femoral resurfacing (distal and posterior femoral cut heights at 8 mm - cartilage wear). The gaps values are also updated.

The parameters that are underlined in blue can be modified using the probe.

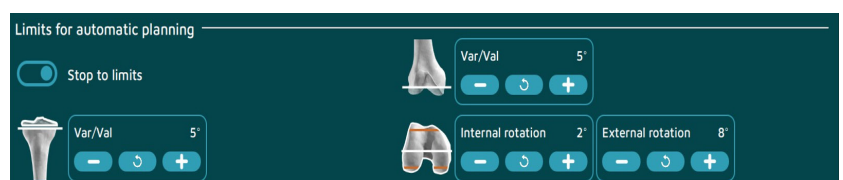
- Target the probe on the screen
- Move the cursor on the value to be changed, the blue squares appear on both side of the value
- Click on the symbol to change the value
- Check all the parameters and the gaps

If a value exceeds a limit previously recorded, it flashes and is displayed in orange.

- Click on next to perform the resections

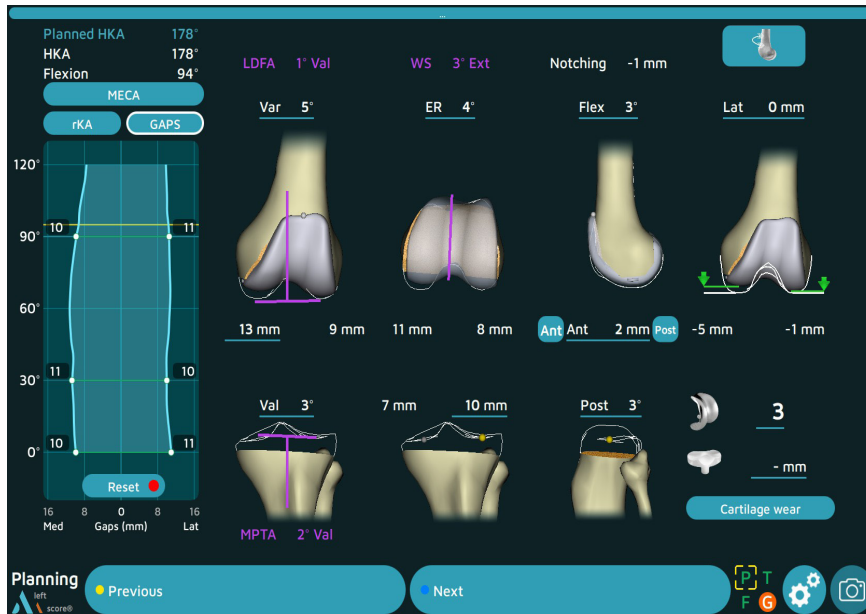
The button indicates rKA in case the limit stops are active in the user settings

The software takes these values into account when calculating the positioning of the tibia (maximum varus/valgus) and the femur (maximum varus/valgus; maximum internal and external rotation).



Planning

Inverse Kinematic Alignment (GAPS)



- Click on the **GAPS** button. The button is circled in white.

Based on a tibial resurfacing (resection oriented on the MPTA and tibial cut height at 10 mm - cartilage wear), the software calculates the femoral cut heights and orientations in order to balance the spaces throughout all the range of motion.

The parameters underlined with a blue line can be modified using the probe.

- Target the probe on the screen
- Move the cursor on the value to be changed, the blue squares appear on both side of the value
- Click on the symbol to change the value
- Check all the parameters and the gaps

If a value exceeds a limit previously recorded, it flashes and is displayed in orange.

- Click on next to perform the resections

NOTE

The GAPS button is grayed out until all ligament spaces are filled in.

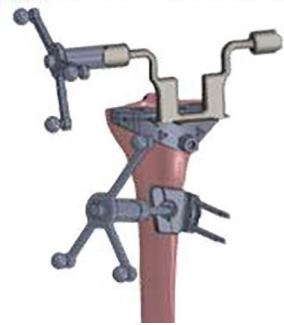
Tibial navigation

Tibial resection

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

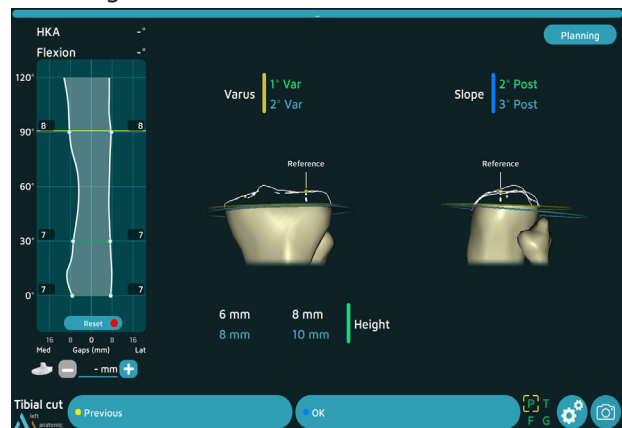
Using the Universal Alignment Guide:

- 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 will be displayed in green if they are beyond ± 1 mm or $\pm 1^\circ$ from the planned values.

- 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

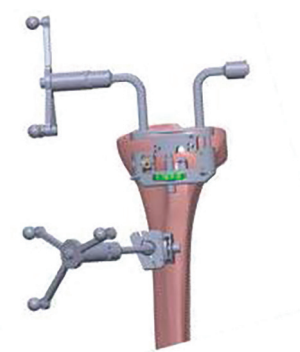


Using the Semi-assisted resection guide:

- 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

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.



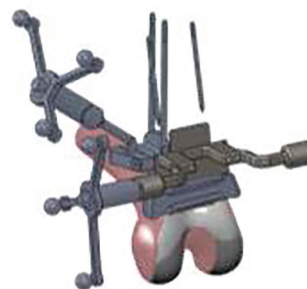
Femoral navigation

Distal femoral resection

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

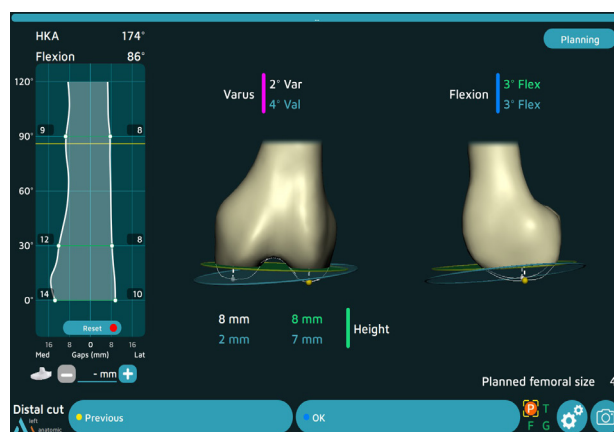
Using the Universal Alignment Guide:

- 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 will be displayed in green if they are beyond ± 1 mm or $\pm 1^\circ$ from the planned values.

- 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.



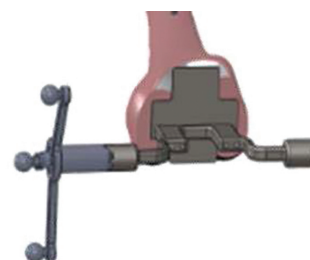
Using the Semi-assisted resection guide :

- 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.



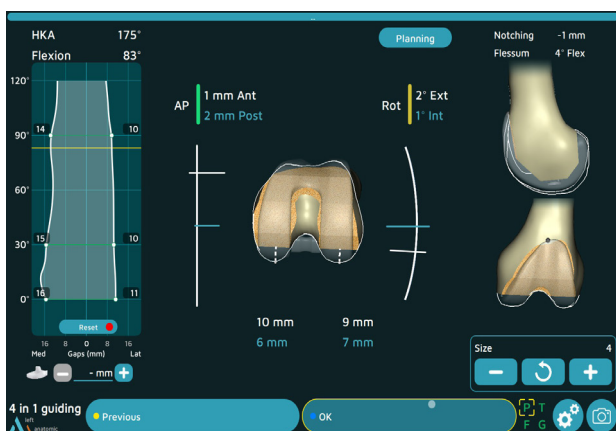
Acquisition

- Once the 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 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.

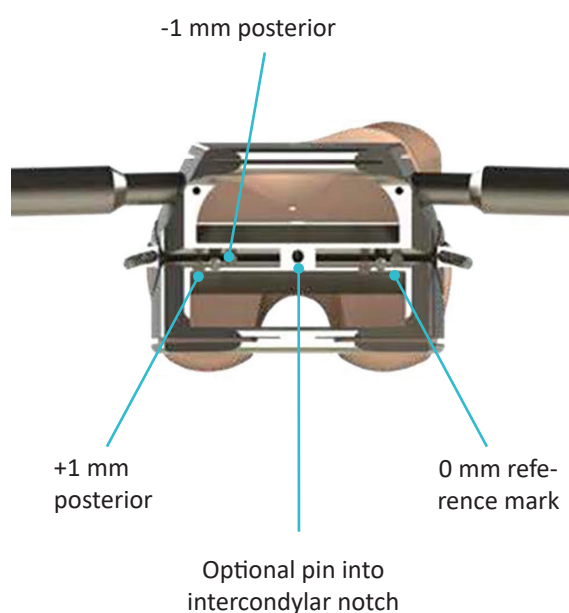
The white values are the real time values.

The values will be displayed in green if they are beyond ± 1 mm or $\pm 1^\circ$ from the planned values.

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

- Secure the resection guide with 2 Headless pins, $\varnothing 3.2$ length 65 mm 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.



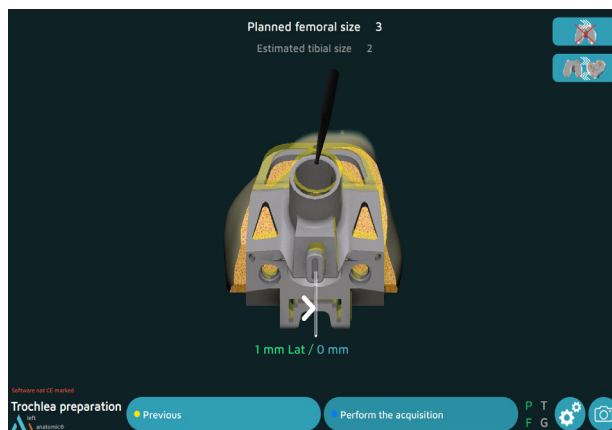
Femoral navigation

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 (yellow value) will be shown (yellow 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).



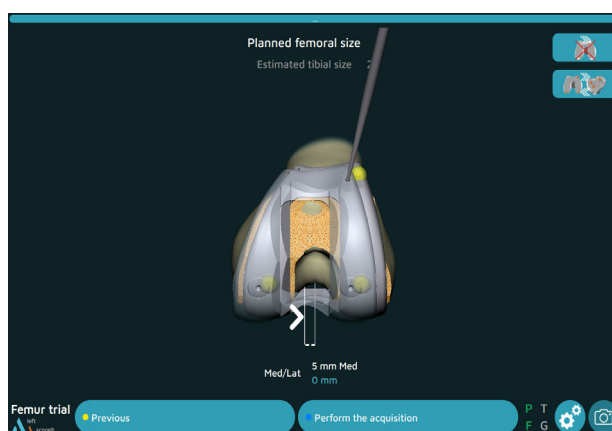
NOTE

This step is optional. If centring the guide without navigation assistance, skip this step by pressing the blue pedal, probe or blue button.

Placement of the trial femoral component

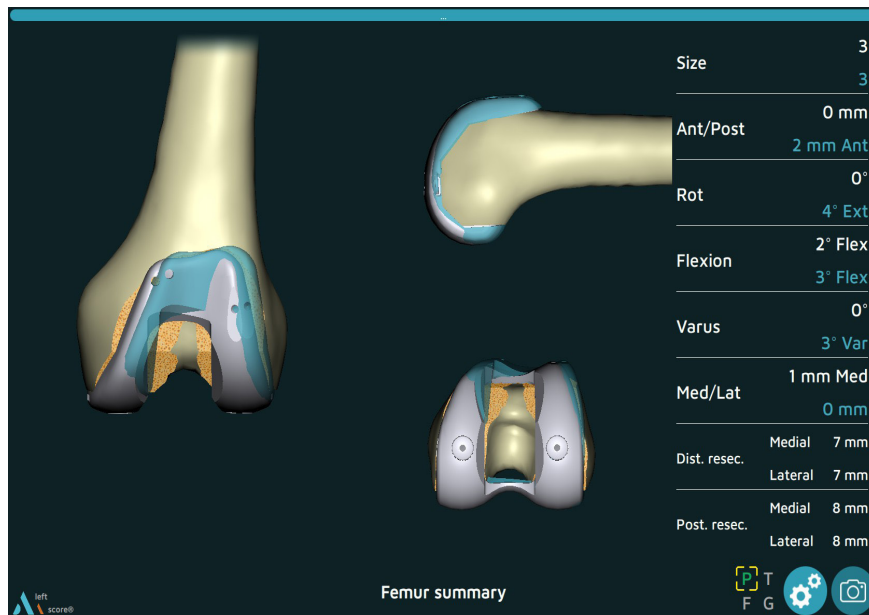
For SCORE, SCORE II, ANATOMIC and TRAX CR Knees:

- 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, SCORE II and TRAX CR TKAs: 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 (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

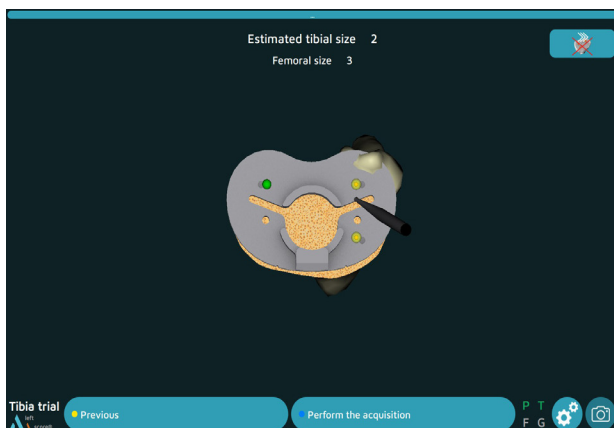


- The trial implant's position (grey) is superimposed over the planned implant position (blue).
- The size and final position of the trial femoral component are shown in white; the planned values are in blue.
- Press the blue pedal to confirm and continue to the next step.

Trials registration

Placement of the trial tibial baseplate

For the SCORE and SCORE II TKAs: 2 options



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



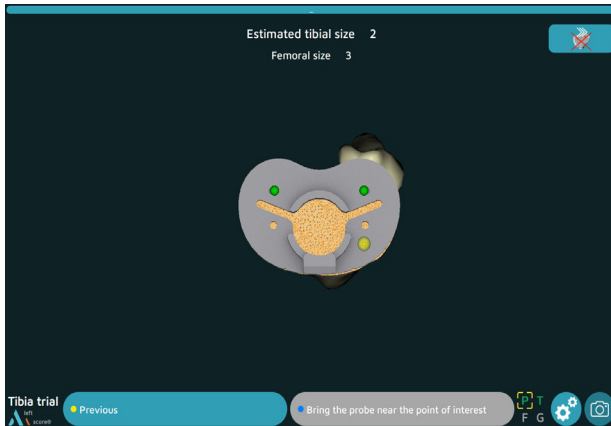
Navigation of trial baseplate position with universal handle:

- 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.

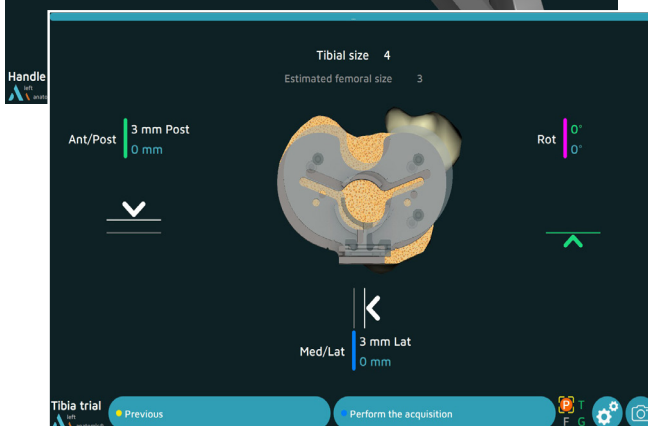
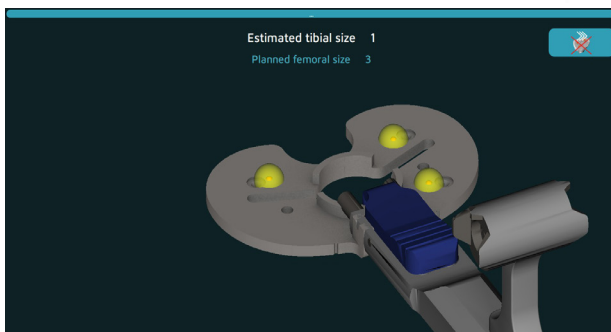
Trials registration

Placement of the trial tibial baseplate

For the ANATOMIC and TRAX CR TKAs: 2 options



Detection of the G array by the camera



Acquisition of trial baseplate position using conical calibration marks:

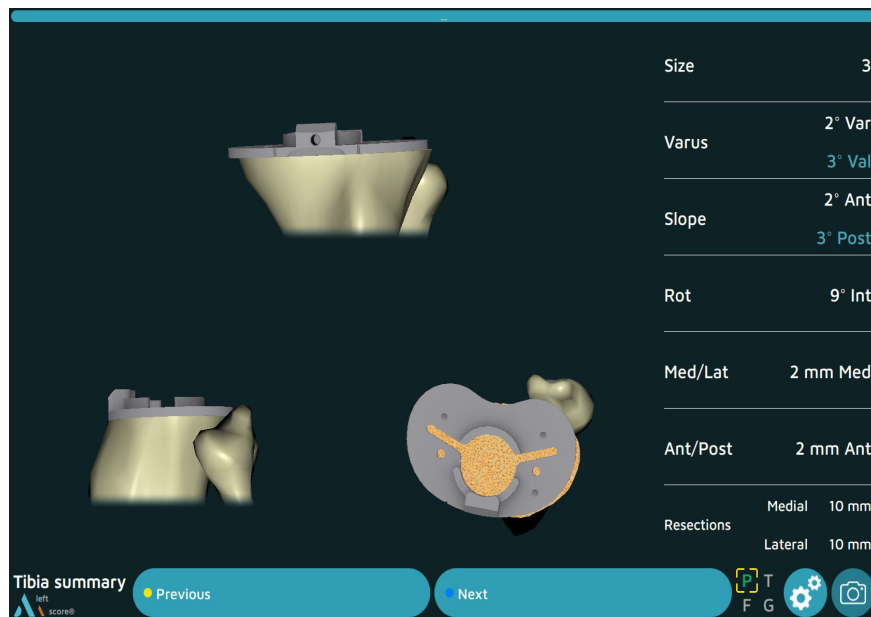
- Select the appropriate tibial baseplate (the estimated size is shown on the screen) and secure it to the baseplate handle.
- Position and secure the trial baseplate with two Headed pins length 30 mm.
- Using the probe, acquire the position of the three calibration marks located on the baseplate to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



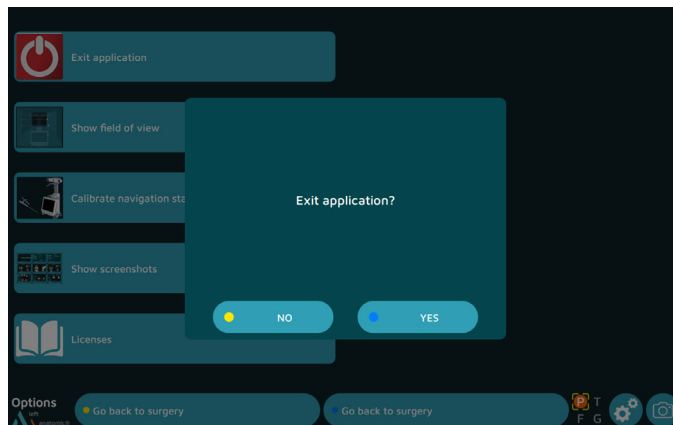
- At this step, the software allows the final HKA and varus to be visualized in real time.
- If the acquisition of the trial implants has been performed, the gaps will be displayed.
- In this step, it is possible to record the information that appears on the screen (regardless of the degree of flexion) using the blue pedal (or the blue button).


All navigation steps have been completed.

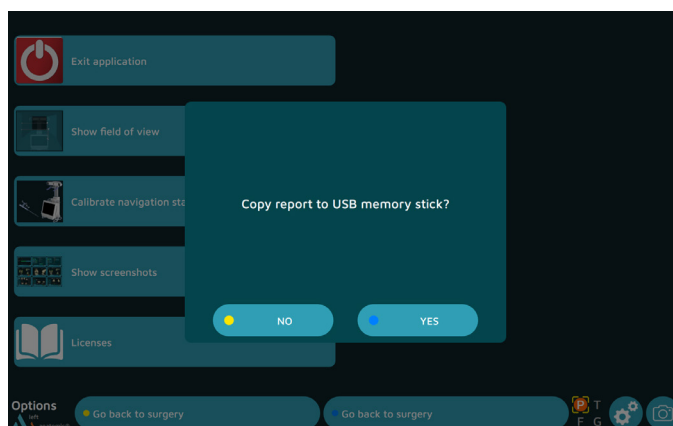
Refer to the following Surgical Techniques documents: TO.G.009 for SCORE, TO.G.013 for SCORE II, TO.G.002 for ANATOMIC and TO.G.041 for TRAX CR for the following steps:

- Femoral preparation
- Tibial preparation
- Patellar preparation
- 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.

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 sets 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.

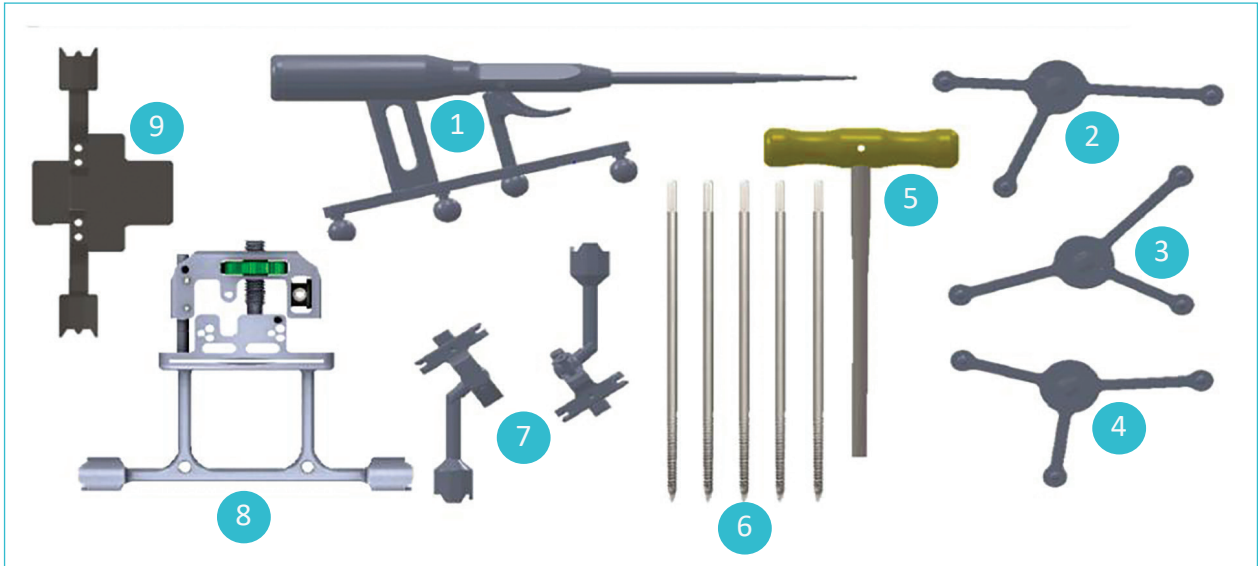


Not all devices presented in this Surgical Technique may be registered in your country. Please contact your Amplitude Sales Representative for availability.

Instrumentation

Instrumentation set for TKA 4in1 (Navigated)

2-0299946



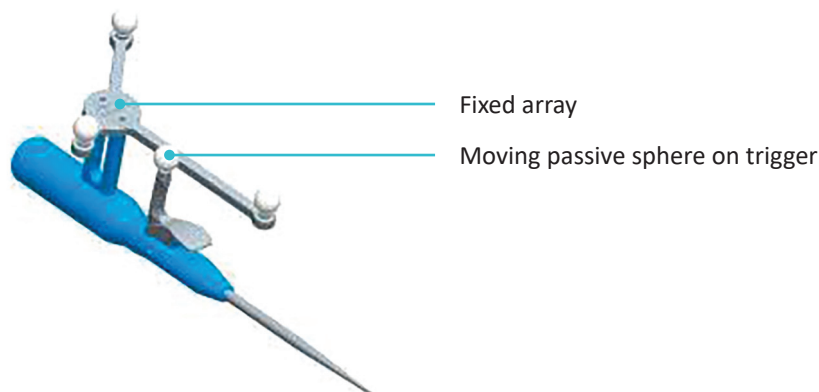
Item	Name	Reference	Qty
1	Probe knee navigation	2-0215700	1
2	T array, tibia navigation	2-0215800	1
3	F array, femur navigation	2-0117400	1
4	G array, Instrumentation navigation	2-0117500	1
5	H5 Screwdriver	2-0200800	1
6	Conical Threaded Pins AMPLIVISION Ø4 length 150mm	2-0235500	5
7	Inclined fixation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

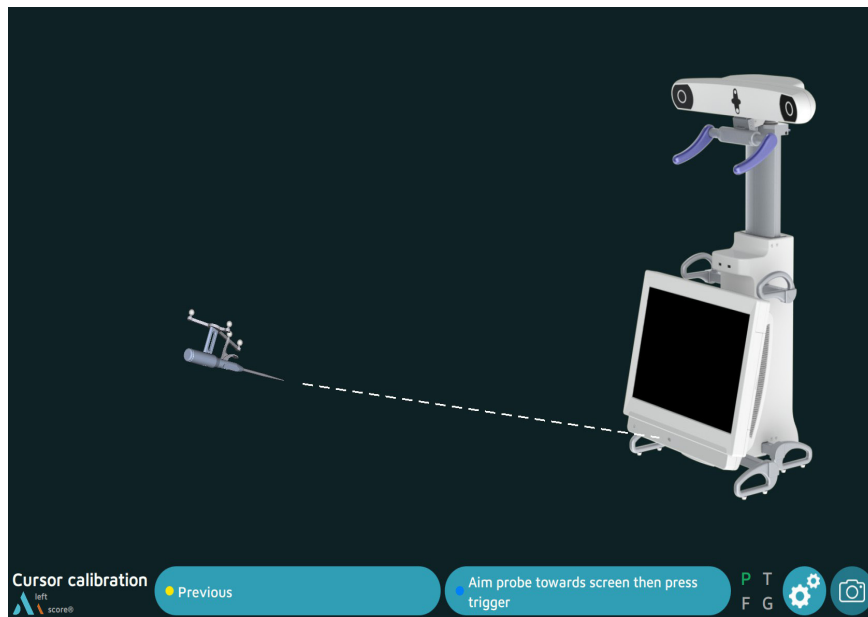


Universal guide:

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.



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 lower-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:

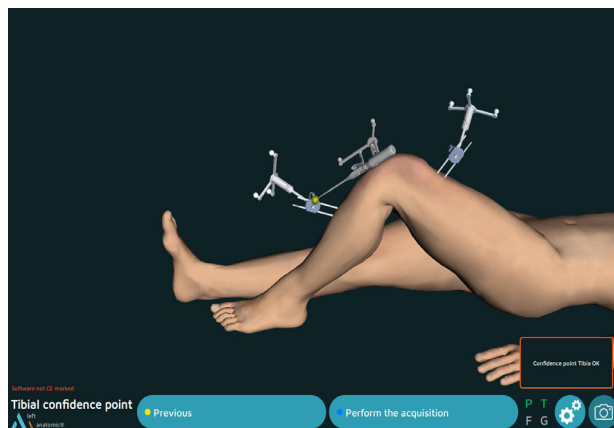
- Press the «Options» button.
- Press the «Calibrate AMPLIVISION workstation position» button.
- Validate the new position; the system will automatically return to the current surgical step.

Option : reference points on arrays

Tibial reference point on the array

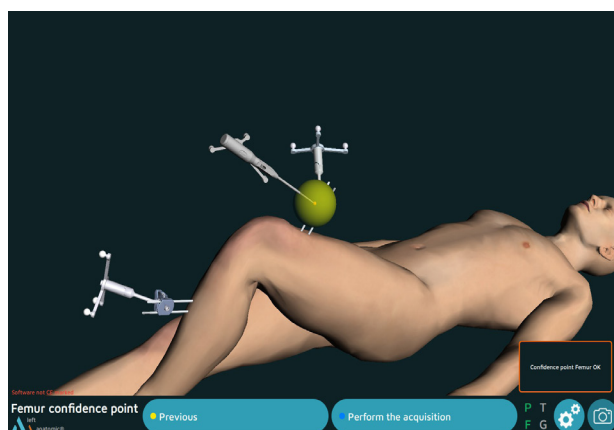
This step validates the final position of the T array on its fixation support. At any point during the procedure, the surgeon can check if the array position has changed by using this reference point.

- 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.

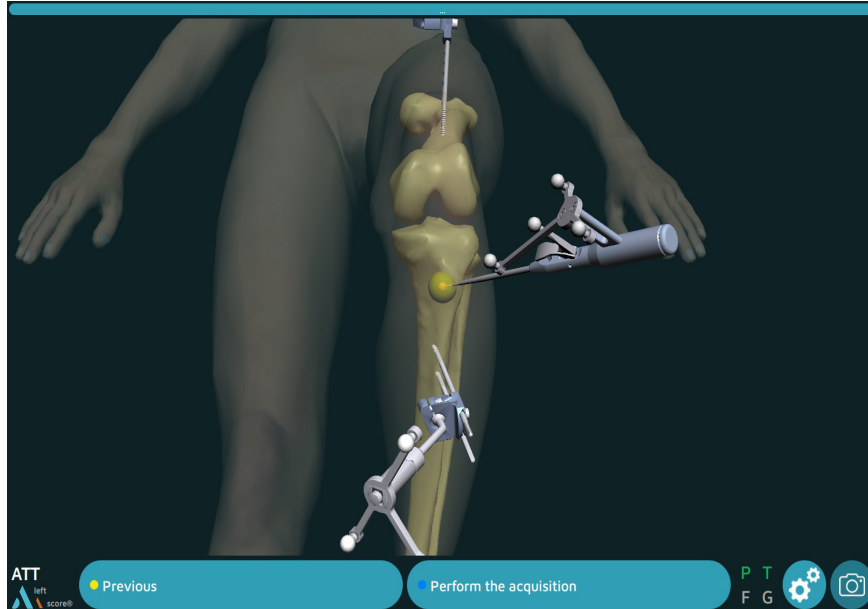
NOTE

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 : Anterior Tibial Tuberosity (ATT)

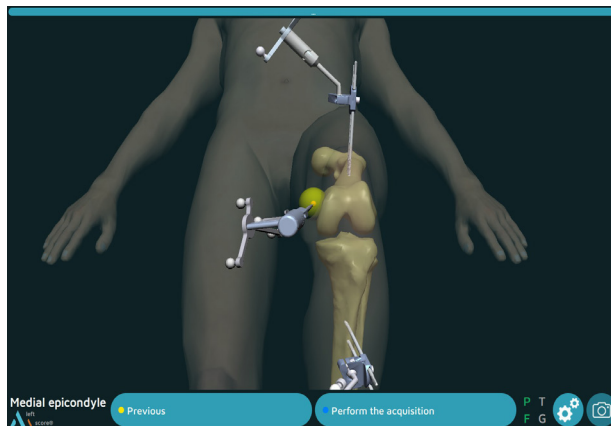


- Acquire one point with the Probe tip on the medial aspect of the anterior tibial tuberosity (ATT).
- Press the trigger to confirm.

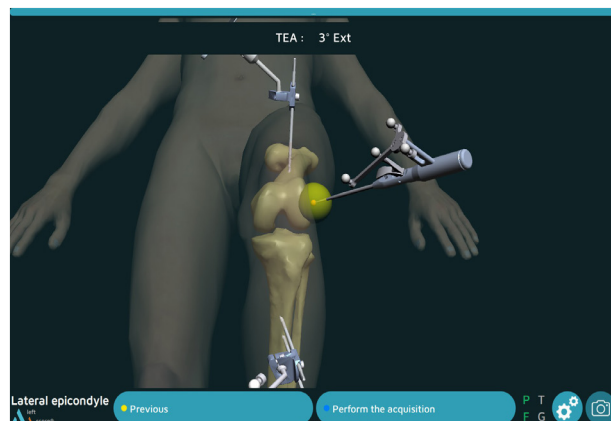
Option : femoral rotation

Transepicondylar axis registration

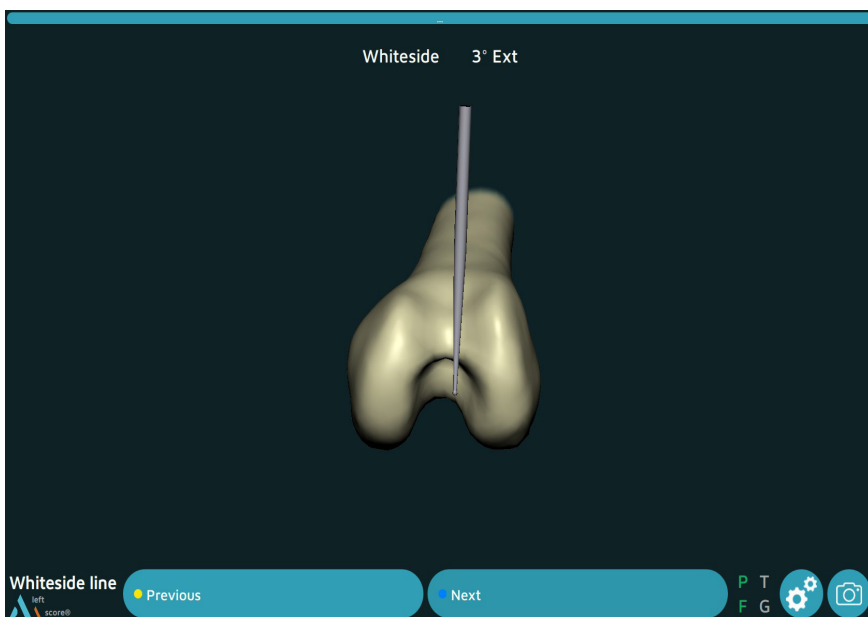
- Place the probe tip on the medial epicondyle
- Confirm



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



Whiteside line registration



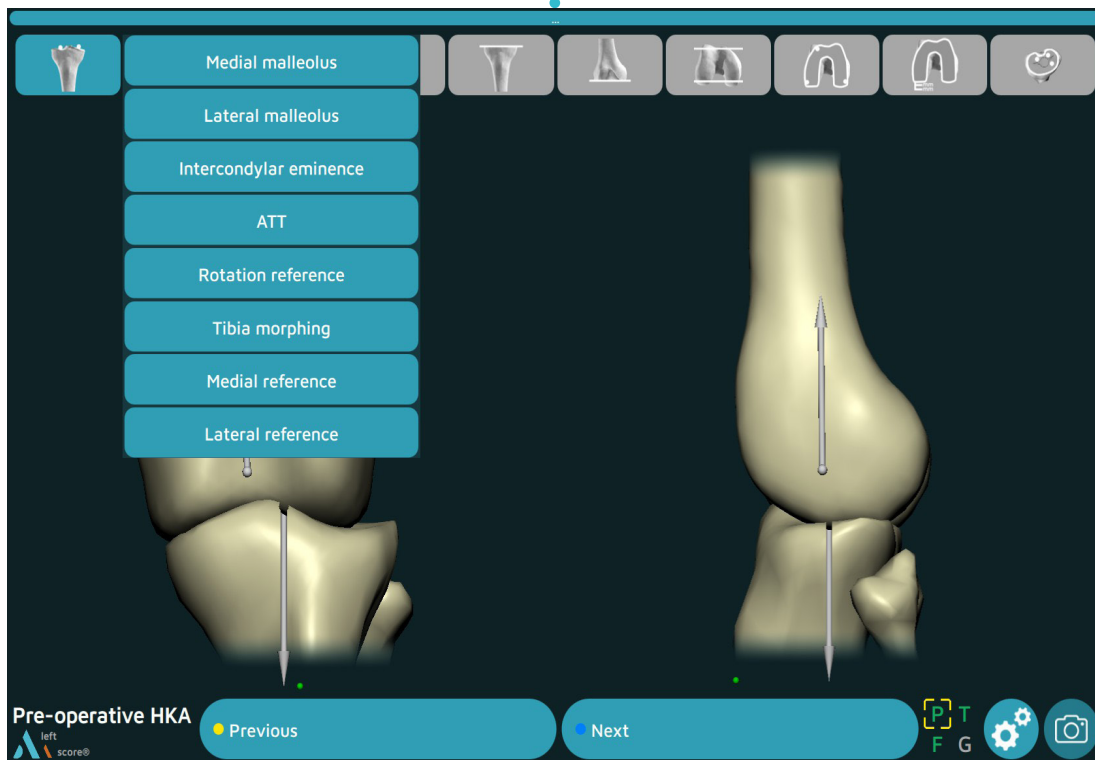
- Place the probe tip following the whiteside line : the angle between the Whiteside line and the posterior condyle is displayed
- Confirm

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

«Exit Application» button

Show camera field of view to locate arrays

Exit application

Show field of view

Calibrate navigation station position

Show screenshots

Licenses

Software not CE marked

left anatomic®

Options

Infrared detected. Check for lights sources and reflections aimed at the polaris camera.

P T F G

Reset the cursor calibration

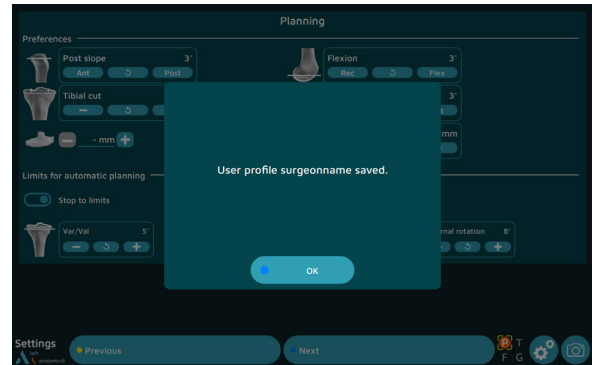
View all the validated steps during the surgery

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



- 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.

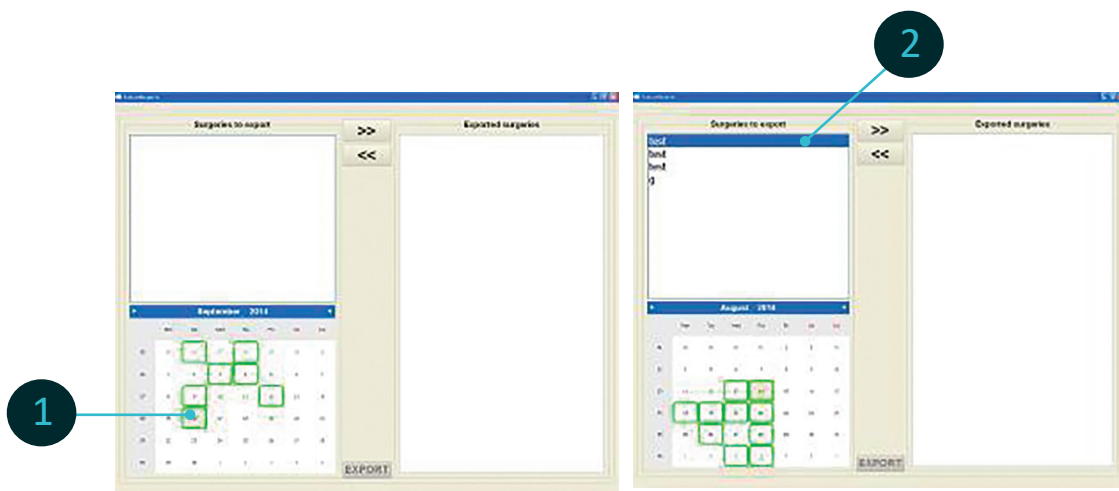


Appendix D

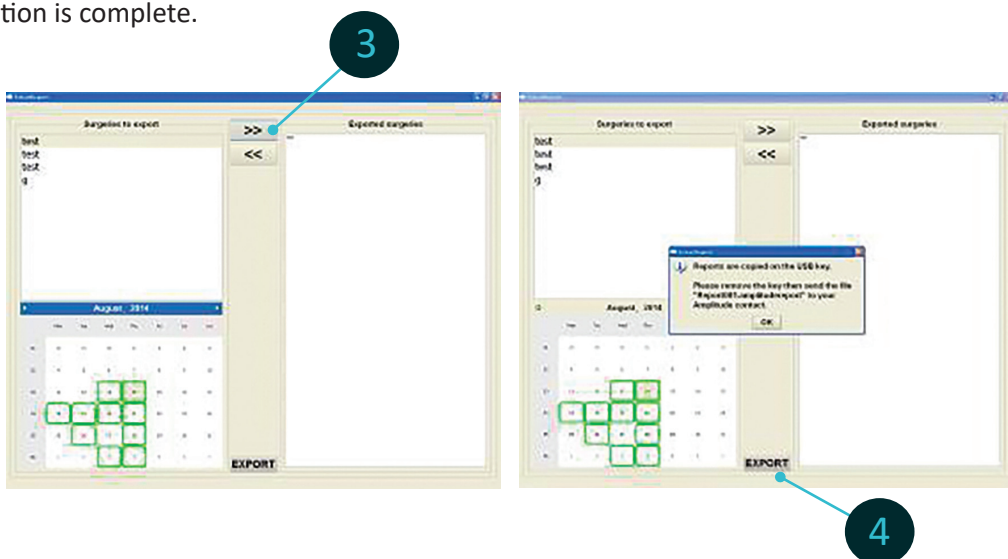
Opening a saved surgery report

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.



- 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

NOTES





Customer Service – France:

Porte du Grand Lyon,
01700 Neyron – France
Phone: **+33 (0)4 37 85 19 19**
Fax: +33 (0)4 37 85 19 18
E-mail: amplitude@amplitude-ortho.com

Customer Service – Export:

11, cours Jacques Offenbach,
ZA Mozart 2,
26000 Valence – France
Phone: **+33 (0)4 75 41 87 41**
Fax: +33 (0)4 75 41 87 42

www.amplitude-ortho.com

Reference: TO.G.047/EN/C