eventum Orthopaedics

Accessible innovation designed to improve patient outcomes

Quadsense

Surgical Technique

Overview

The Quadsense System is for use in Total Knee Arthroplasty procedures as a comparative tool to aid surgical decision making in balancing the forces through the patellofemoral joint.

The Quadsense sensor is a single-use device that connects to a re-usable Panel PC. The Quadsense sensor attaches to the patella and provides data in real time to the surgeon on the force through the patellofemoral joint. This data is displayed on the Panel PC.

The Quadsense sensor is used to take readings against the patient's natural anatomy and with the trial implants in situ, providing information on how the force through the patella has changed.

Note: This Surgical Technique should only be read and understood in conjunction with the Quadsense Instructions For Use which contain important information necessary for safe use of Quadsense.

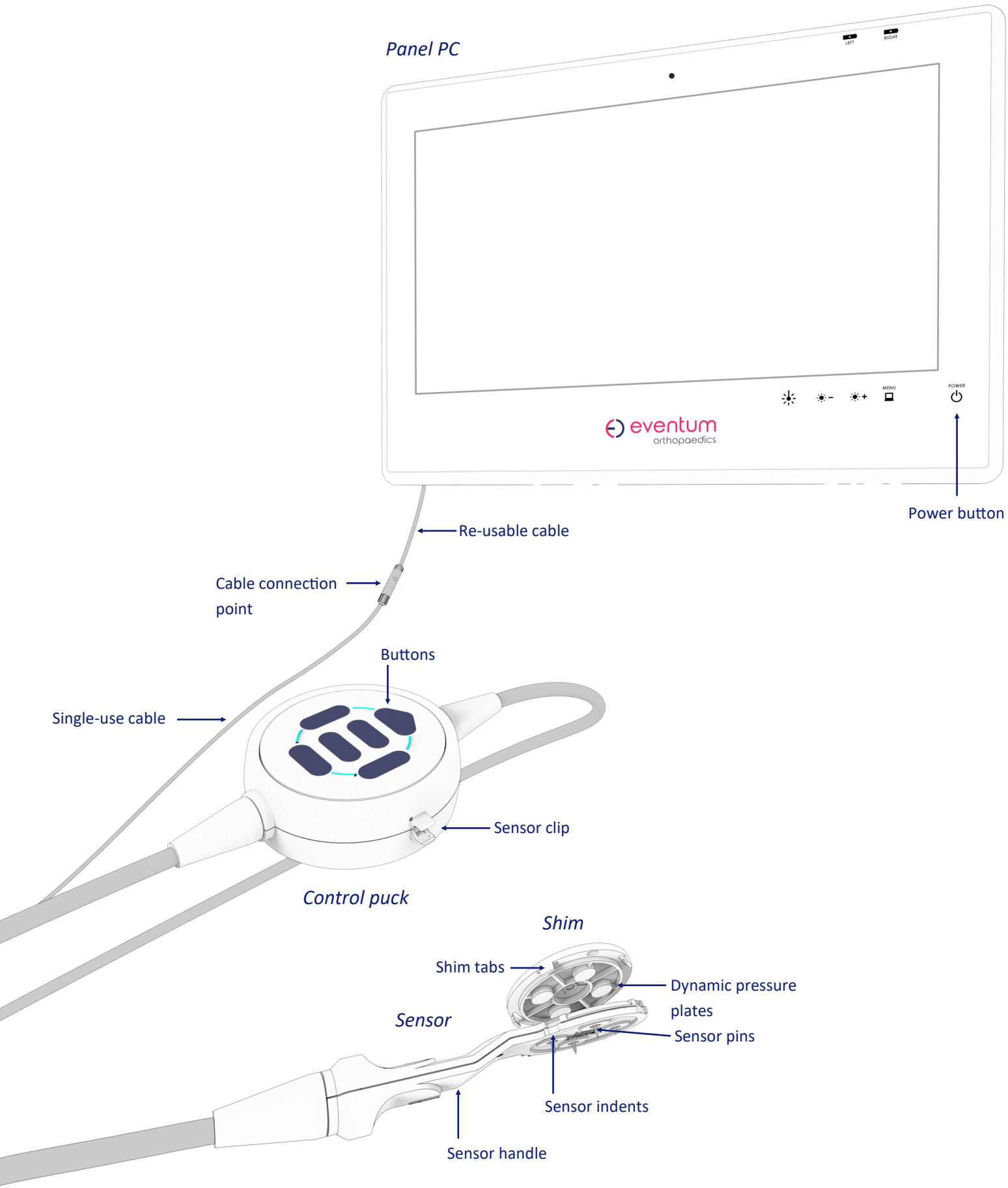
Contents

! The use of Quadsense may add additional operative time as well as increase risk of infection.

! Improper device use may result in adverse surgical decisions and increase risk of soft tissue damage (e.g. Re-cutting may lead to overcutting the patella, fracturing the patella, or compromising patellar component fixation).

The Quadsense System Overview

Figure 1



The Quadsense System: The Control Puck

Figure 2

The left hand side of the Panel PC screen is a visual representation of the buttons on the control puck (Figure 2). Throughout the software workflow, the action of each button will be displayed. Depending on the stage of the workflow, some buttons may be inactive or have a different function than before. If a button is inactive, the Panel PC will display the button as blue with no symbols.

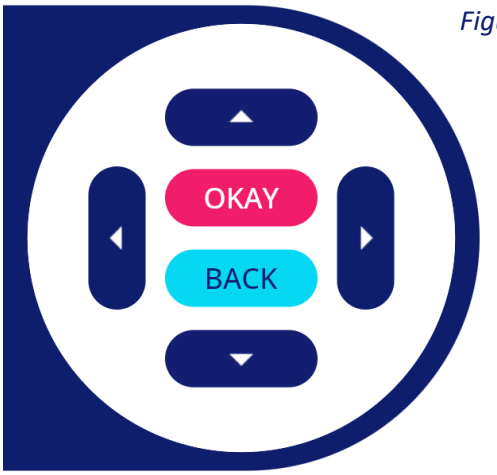


Figure 3a

For example, in Figure 3a, the left, right, top and bottom buttons have small white arrows displayed which indicates that you can move left, right, up and down through an aspect of the workflow. The ‘OKAY’ and ‘BACK’ buttons allow you to move forward and backwards through the workflow, respectively.

Figure 3b

In Figure 3b, only the ‘OKAY’ button is active.

The Quadsense System: Adjustment Shims

The Quadsense single-use device includes four shims that can attach to the sensor to take readings (Figure 4).

Figure 4

The shims have a domed shape and differ in depth (mm) and plane of angle (degrees) (Figure 5).

The shims included are:

Figure 5

6mm shim | 7mm shim | 6mm 2.5 degree shim | 7mm 2.5 degree shim

Neutral angle shims: 0°

Shims with no added angle have a 0 symbol and a straight horizontal line symbol on the surface of the shim.

Angled shims: 2.5°

Figure 6

Shims with a 2.5 marking on the surface, have an angle of 2.5 degrees (Figure 6).

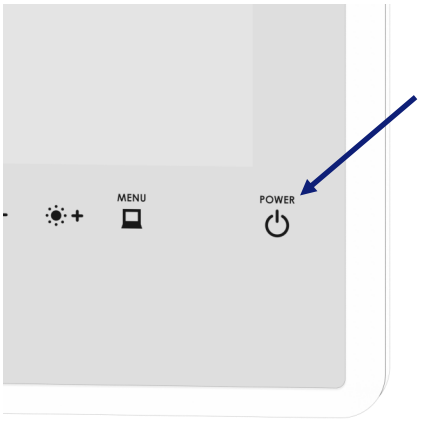
The triangle symbol on the surface of the shim shows the direction of the angle. The thicker side of the triangle is on the thicker side of the shim, and the point of the triangle points to the thinner side of the shim.

Viewing the shim from above, the thicker side of the shim is on the right of the debossed writing when the writing is orientated in a legible manner.

Shims that have an angle can be rotated in four different orientations to change the plane of the angle.

Setting up Quadsense

Figure 7



Position the Panel PC outside of the sterile field on the contralateral side of the operating table, ensuring it is fully visible to the lead surgeon.

Switch on the Panel PC by tapping and holding the power button for three seconds. The power button is located on the bottom right corner of the front of the Panel PC (Figure 7). The symbol will light up once the device is switched on.

The Panel PC is battery powered during the procedure.

The Quadsense sensor is a single-use device. Follow standard hospital procedure for sterile transfer.

Pass the end of the long cable out of the sterile field to be attached to the Panel PC. The sensor and shims will remain in the sterile field at all times.

There is a short cable attached to the Panel PC. Join the long cable from the sensor with the short cable from the Panel PC by positioning the connectors so that the arrows are aligned then gently connecting the two connectors together (Figure 8). Tactile feedback will indicate when the cables are correctly and securely connected.

Figure 8

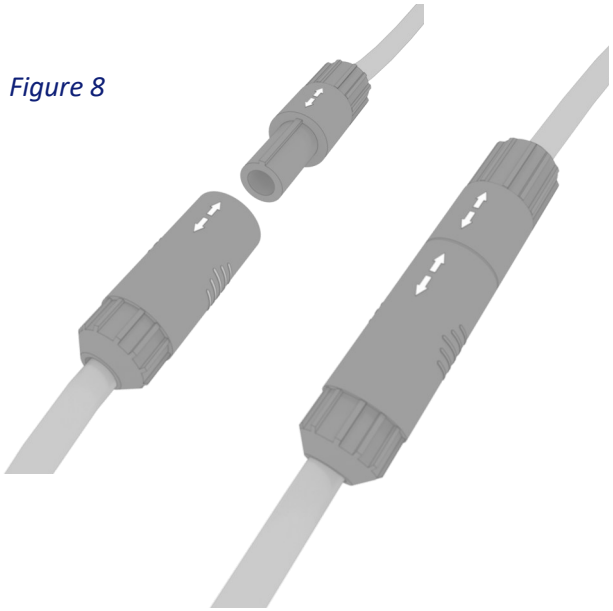


Figure 9

The control puck can be attached to the patient's draped leg. Peel off the sticker from the adhesive back (Figure 9), then stick the control puck to the drape with the buttons facing up.

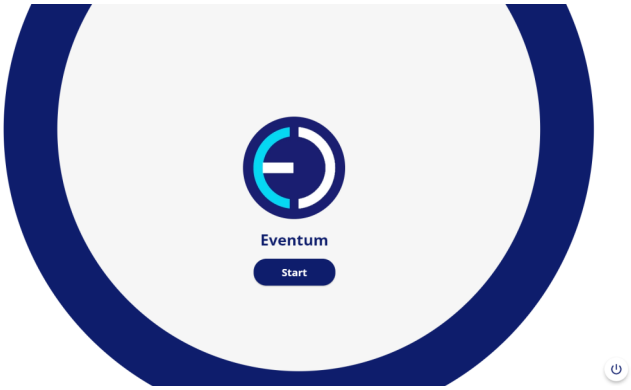
The arrow button should be pointing towards the patients head.

Ensure the control puck is close enough to the knee joint to ensure the cable isn't taut when the sensor is attached to the patella.

Setting up Quadsense

As the Panel PC powers on, the device will automatically load the Quadsense software and connect to the previously authorised WiFi network. Press ‘Start’ to continue (Figure 10).

Figure 10



Select which of the patients knees is to be operated on, left or right (Figure 11). Use the side arrow buttons on the touchscreen or the control puck to select the correct knee, and press okay to select the chosen knee and then press okay to confirm.

Figure 11a

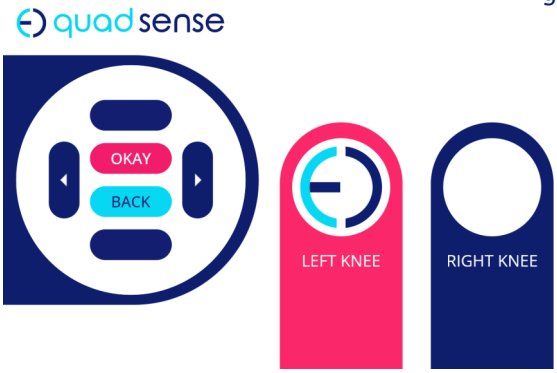
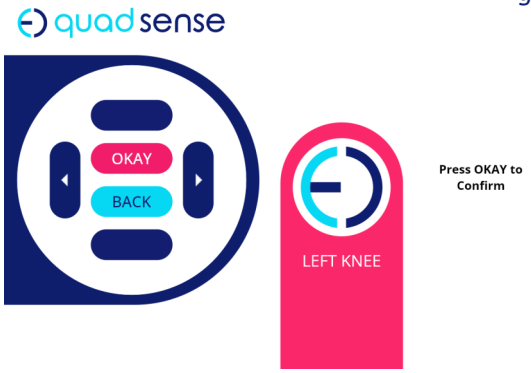


Figure 11b



Conservative Patella Resection

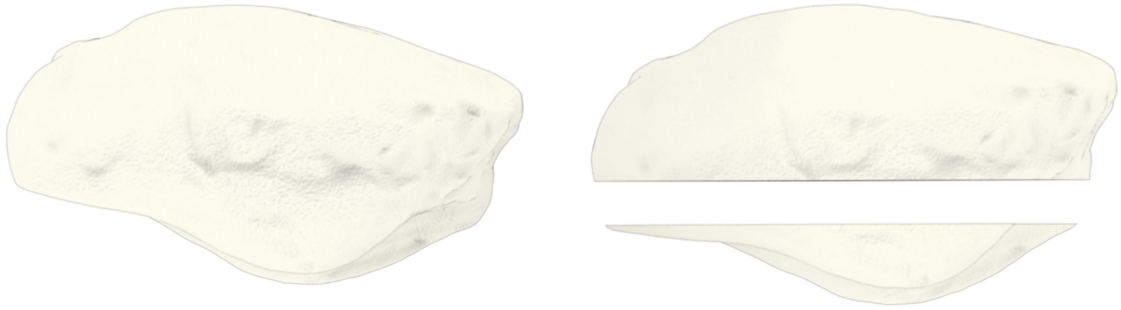


Figure 12

A flat surface of cancellous bone is needed for the sensor to attach to the patella. An appropriate patella resection should be made to accommodate the sensor.

Place the leg in extension and evert the patella by at least 90 degrees.

Carefully remove the soft tissue from the patella apart from the insertions of the quadriceps and patella tendons.

Measure the total thickness of the patella using a calliper to ensure the patella will not be over-resected, risking patella fracture. Ensure that the patella is measured where the apex is highest.

Clamp the patella and resect, following the methodology of the surgical tools and guides used.

Unclamp the patella.

Remeasure the patella with a calliper.

The surgeon may decide to accommodate for any articular wear and alter resection depth.

! A resection that reduces the thickness of the patella to 12mm or less could risk patella fracture.

Attaching the Sensor to the Patella

The sensor has a flat surface mounted with three small metal pins. The pins allow the sensor to attach to the patella and remain secure whilst taking readings.

Remove the protective cover from the sensor to reveal the pins (Figure 13).

Mount the sensor on the flat resected surface of the patella (Figure 14).

Figure 13

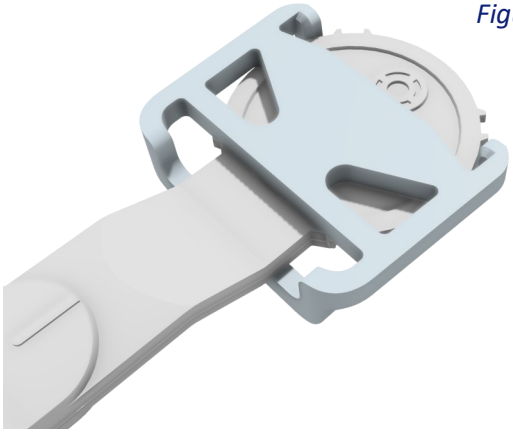


Figure 14

The sensor should be central on the flat patella surface with the metal pins inserted into the patella bone. When the patella is everted, the cable should be directed towards the surgeon and the handle should be perpendicular to the joint (Figure 15). The underside of the sensor should be flush with the bone and stable (Figure 16).

When the patella has been reverted to it's natural position, the cable should be coming out on the medial side of the knee, perpendicular to the joint.

Correct

Figure 15a

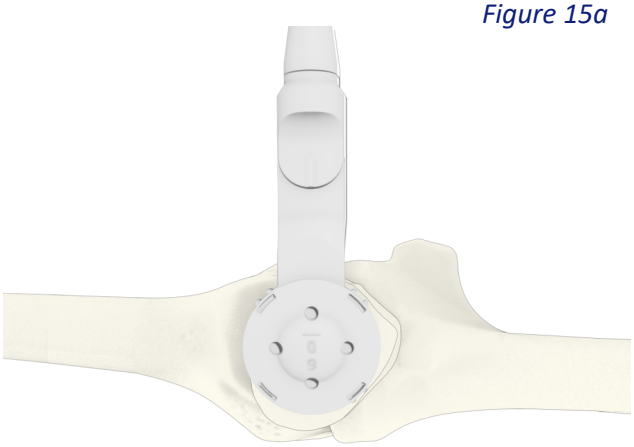
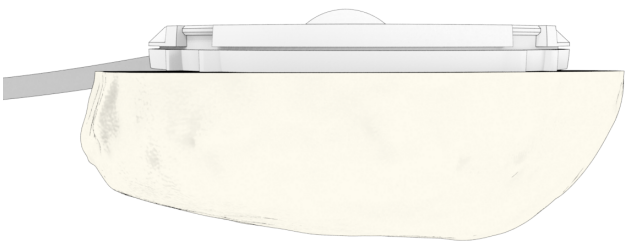


Figure 16a



Incorrect

Figure 15b

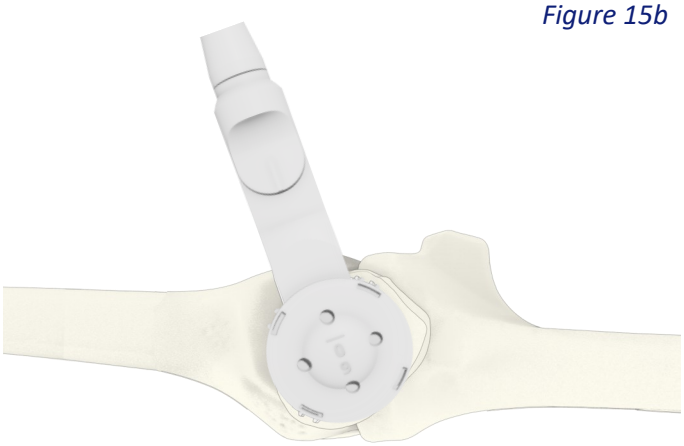
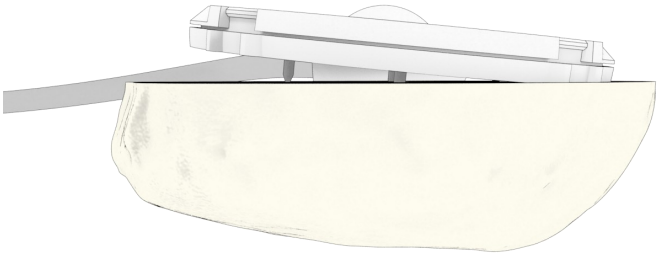


Figure 16b



Initial Sensor Reading

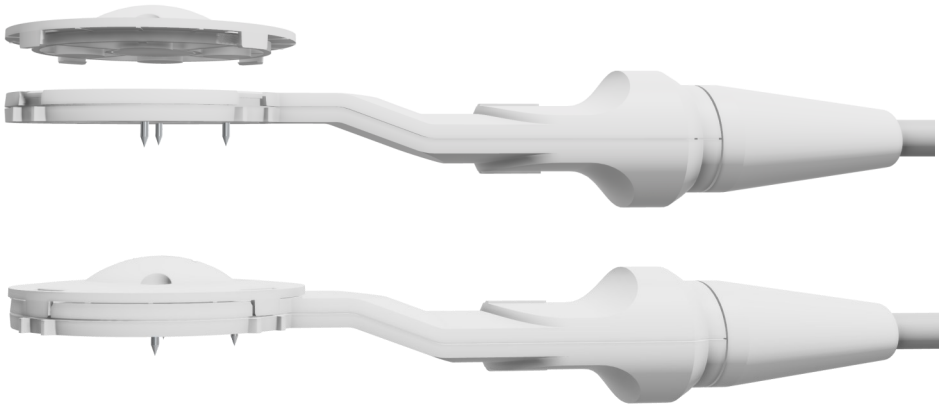
Figure 17

For the first sensor reading, a shims needs to be attached to the sensor.

We recommend using the 7mm shim with a neutral angle. This shim has the symbol ‘7’ and ‘0’ on the surface (Figure 17). This refers to a shim of 7mm depth with no added angle.

Attach the chosen shim to the sensor by lining up the four tabs on the bottom edges of the shim, to the four indents on the edges of the sensor (Figure 18). The shim should click on with tactile feedback, and be secure.

Figure 18

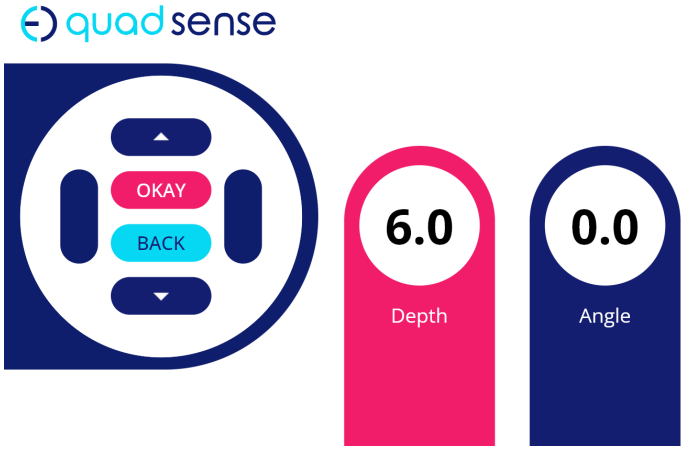


The shim used for this reading must be registered on the software.

The software automatically presents the dimensions 6.0mm depth and 0.0 degree angle (Figure 19).

The depth can be changed by pressing the top button to increase depth, or the bottom button to decrease. Once the depth is set to the correct value, press okay. Complete the same methodology for the angle. Press okay to confirm.

Figure 19



Initial Sensor Reading

Revert the patella and place the leg in extension.

Press the button on the control puck to start the reading (Figure 20).

Figure 20

Move the leg through full flexion extension at a consistent pace, at a minimum three times (Figure 21). The leg should be flexed to the same flexion angle each time. Twelve seconds are allotted to take the reading.

Figure 21a

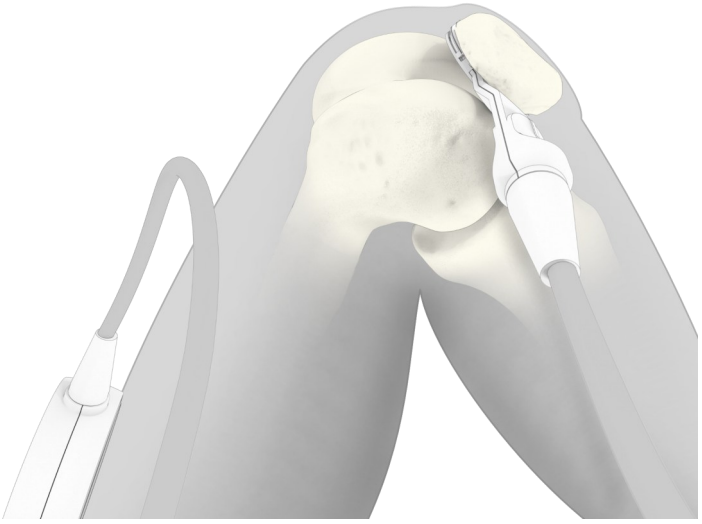
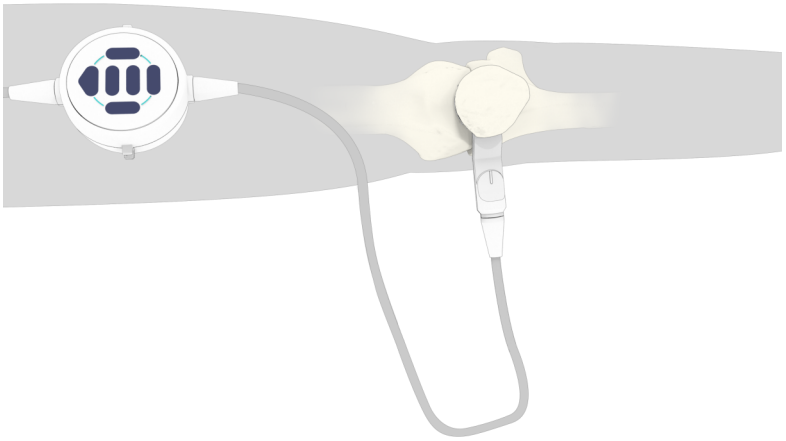


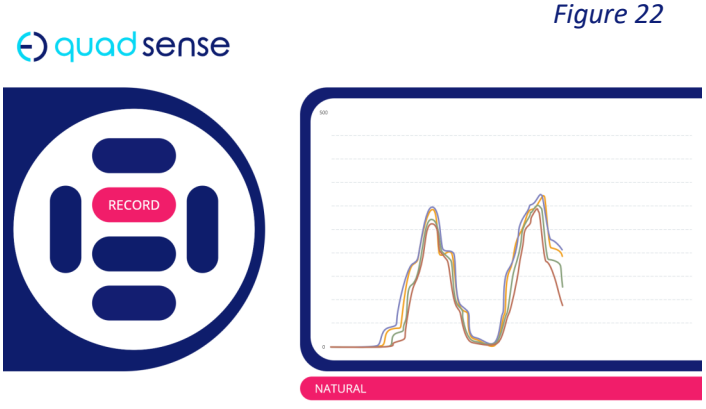
Figure 21b



As the reading takes place, the results will appear on the Panel PC in the form of a graph (Figure 22).

Once the reading is complete, the patient's leg can be placed back in the surgeon's preferred position.

Figure 22



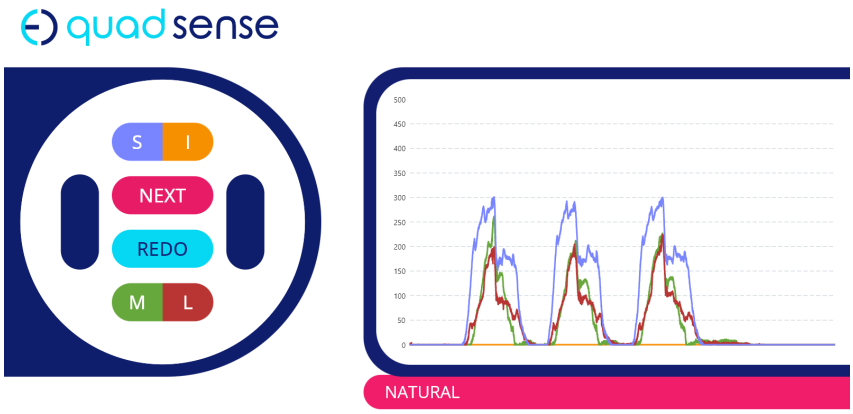
Interpreting a Reading

The results of the reading will appear as a graph with four different coloured lines, see Key 1 (Figure 23). The lines represent the load measured through the four sensors located superiorly, laterally, inferiorly and medially on the patella surface. The buttons on the depiction of the control puck show what each coloured line represents.

Figure 23

KEY 1

Line colour	Sensor
Blue	Superior
Yellow	Inferior
Green	Medial
Red	Lateral



The y axis is relative load, and the x-axis is time. If the leg is moved through flexion extension consistently three times, there should be 3 distinct peaks of similar height.

The top and bottom buttons of the puck allow you to toggle on and off different loads.
The S I button can be pressed so that only the superior and inferior loads are visible (Figure 24a).
Likewise, the M L button causes only the medial and lateral loads to be visible (Figure 24b).

To display all four graph lines, press the buttons that relates to the current two visible lines.
If the superior and inferior loads are visible, press the S I button to display all four loads.
Likewise, if the medial and lateral loads are visible, press the M L button to display all four loads.

Figure 24a

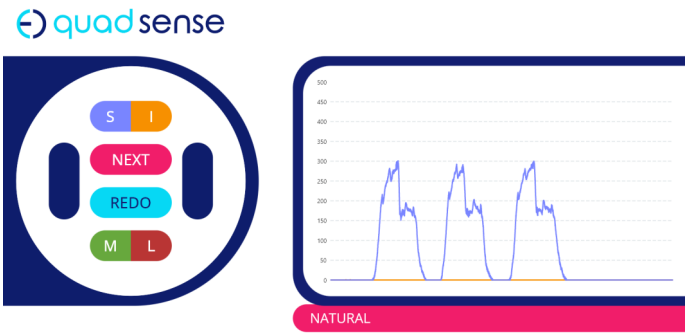
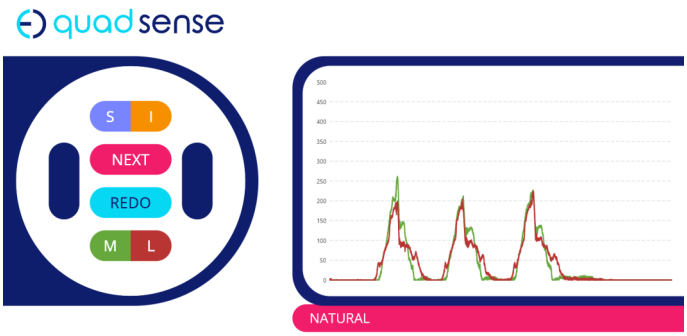


Figure 24b



Interpreting a Reading

Check to see if you are satisfied with the initial reading.

This reading will be stored and used as a reference point for subsequent readings.

If the reading results are not satisfactory then you can opt to redo the reading. You may choose to redo the reading if the three flexion peaks are inconsistent (Figure 25a) or you ran out of time and did not complete three flexion extension cycles (Figure 25b) etc.

Figure 25a

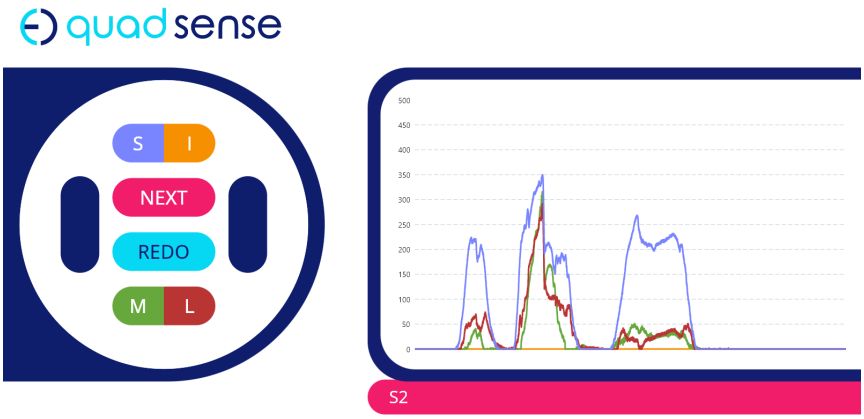
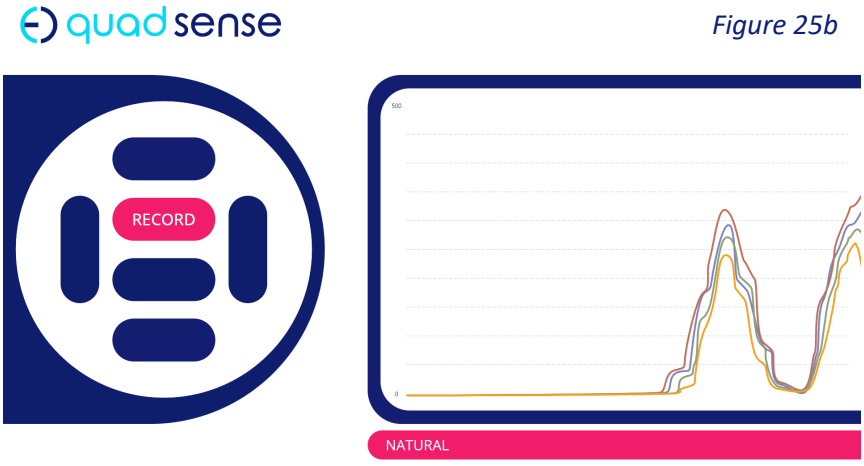


Figure 25b



Removing the Sensor from the Patella

If the sensor reading is satisfactory then remove the sensor from the patella following the steps below.

Evert the patella to at least 90 degrees.

Remove the shim from the sensor and place the shim with the sterile device components (Figure 26).

Figure 26

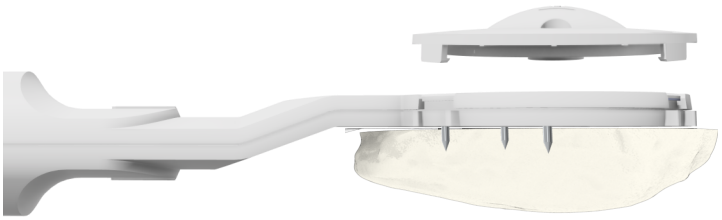


Figure 27

Mark the position of the sensor at the indents using preferred technique, e.g. with methylene blue (Figure 27). This should allow for easier positioning of the sensor in the same place, for subsequent readings.

Gently remove the sensor from the patella by holding the handle close to the sensor and pulling vertically, away from the patella (Figure 28).

Figure 28

Removing the Sensor from the Patella

Attach the sensor to the clip on the side of the control puck (Figure 29, Figure 30). The clip should give tactile feedback when the sensor is secure.

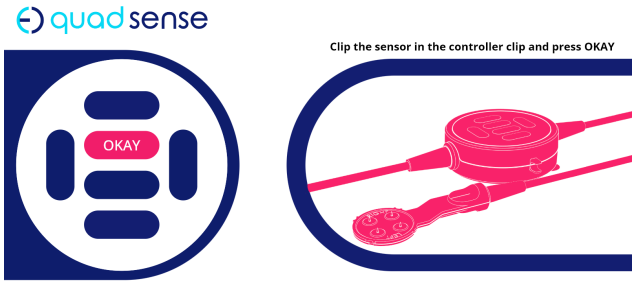


Figure 29

Figure 30a

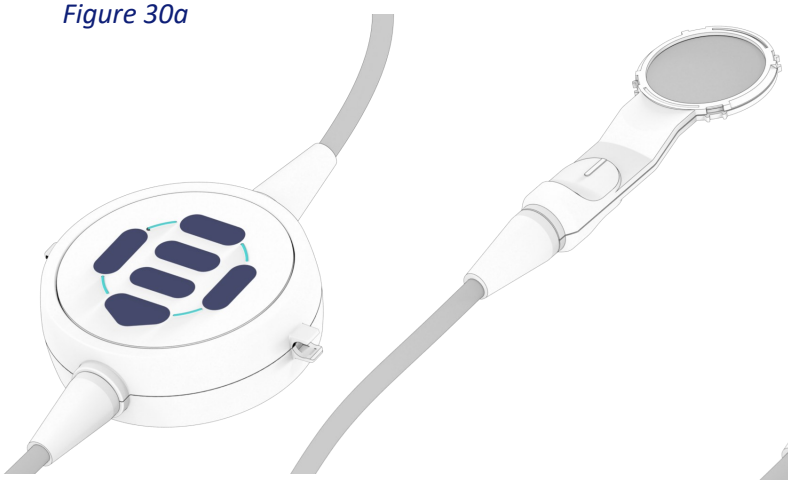


Figure 30b

Proceed with the knee replacement following preferred surgical workflow.

Comparison Sensor Reading

The comparison sensor reading should be taken against the resurfaced knee with the femoral and tibial trial implants in situ.

Evert the patella to at least 90 degrees.

Place the sensor on the patella in the same position using the markings, from the methylene blue, as an aid (Figure 31, Figure 32).

Figure 31

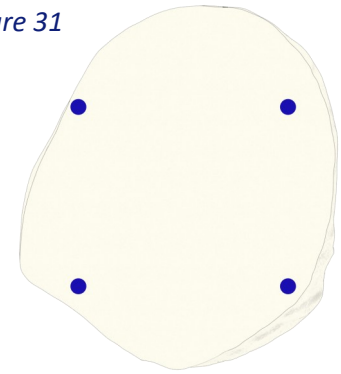
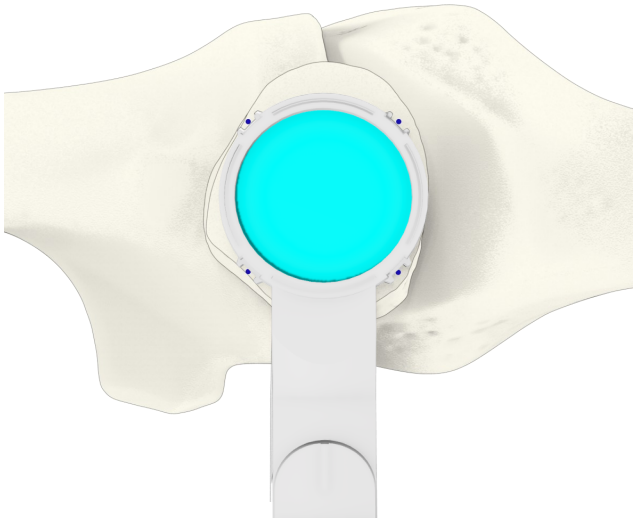


Figure 32



Select the same shim used for the initial reading.

The software will again ask for the dimensions of the shim used. Input the shim dimensions then press okay to confirm and move forward.

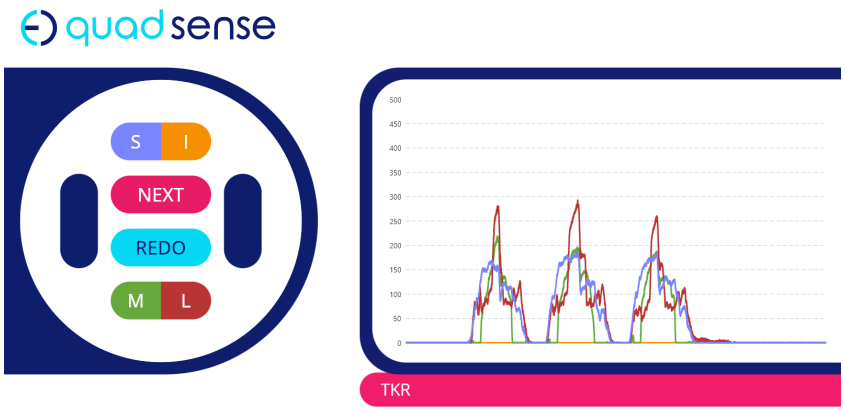
Attach the shim to the sensor, ensuring the tabs line up to the indents.

Revert the patella to it's native position.

Press the record button on the control puck to start the reading.

Move the patient's leg through full flexion extension three times at a consistent pace and consistent flexion angle (Figure 33).

Figure 33



Comparison Sensor Reading

The results from the latest reading should appear as a graph on screen.

If you are satisfied with the graph (e.g. the three flexion peaks are consistent) then press the okay button on the control puck to proceed. If the reading is not satisfactory, press the redo button on the control puck to retake the reading.

The Panel PC should now display two similar graphs; the top graph showing the initial reading and the bottom graph showing the latest TKR reading (Figure 34).

Both graphs display data on equivalent axis, allowing for easier comparison.

When comparing the two graphs, you may notice that:

- The peaks of different load traces change in height
- The proportion of different loads to each other have changed

Any difference on the x-axis is caused by time since the reading started and pace (speed) of readings.

The top and bottom buttons on the control puck can be used to toggle on and off load traces.

Figure 34

Additional Sensor Readings

The difference between the two graphs represents the change to the force through the patellofemoral joint caused by the knee replacement.

The graphs displayed on the Panel PC can be an aid in decision making for the next step.

Multiple different shims are provided with Quadsense that can be used during readings with the aim to achieve reading output similar to the initial graph.

Once you have chosen a shim you would like to take a reading with, press the ‘new’ button on the control puck.

Enter the shim dimensions onto the Panel PC, following the same methodology as previously used.

Attach the shim to the sensor in the desired orientation.

Press the record button on the control puck and take a new reading as done before.

If the reading is satisfactory press okay on the control puck to move forward.

Using an Angled Shim

When using an angled shim to take a sensor reading, the dimensions and direction of the angle need to be entered onto the Panel PC.

Select the desired shim and input the shim dimensions onto the software. Use the top and bottom button on the control puck to change the depth, if needed, and then press okay. Use the same buttons to change the angle and press okay.

Attach the shim to the sensor in the preferred orientation for plane of angle.

If the shim selected is an angled shim, the software will ask you to input the orientation of the shim on the sensor. This is done using the outside buttons on the control puck.

Example

A patient is having a Total Knee Replacement on their left knee.

With the trial implants in situ, the surgeon decides to take a reading with the 6mm 2.5 degree shim, with the shim orientated so that the thicker side is on the lateral edge of the patella (Figure 35a).

Once the shim dimensions have been entered into the software, the orientation of the shim needs to be entered. To inform the software the shim is orientated with the thicker side on the lateral side, press the button on the control puck indicated with the arrow (Figure 35b). The shim displayed on the Panel PC will now be in the same orientation as the shim attached to the sensor (Figure 35c).

Figure 35a

Figure 35b

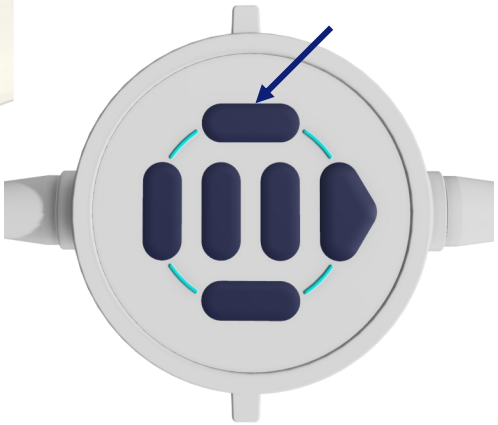
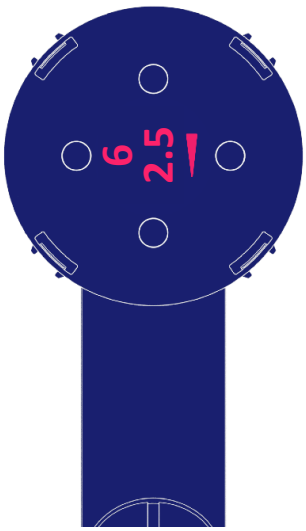


Figure 35c



Reviewing Multiple Readings

The Panel PC will display the results from the latest reading in a graph at the bottom of the screen, where the TKR reading was previously (Figure 36).

The left and right buttons on the control puck allow you to toggle between TKR and any additional readings.

The surgeon can take as many readings as they like.

Figure 36a

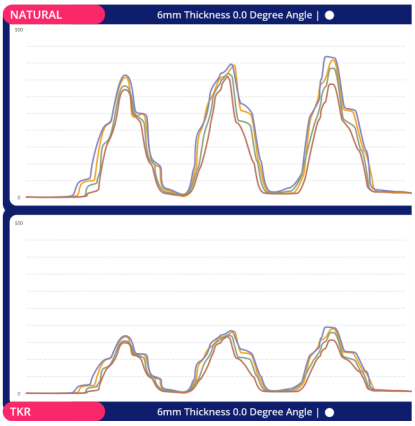
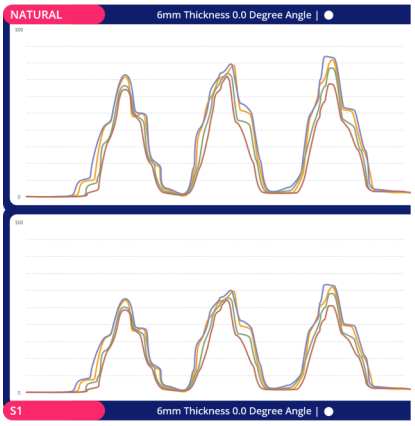


Figure 36b

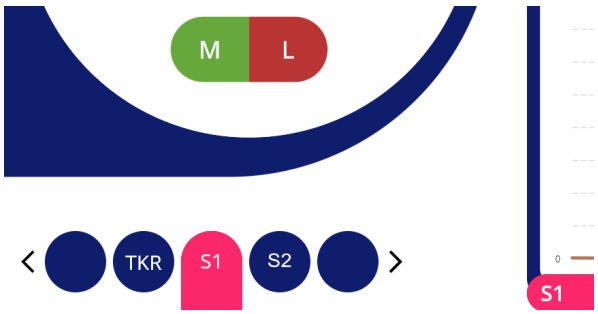


Navigating the readings

Each time a new reading is completed, it will appear on the graph screen with a label at the bottom describing the dimensions (and orientation) of the shim used. In the left corner, there is an icon for each reading in which TKR represents the second reading and subsequent icons represent subsequent readings (Figure 37).

Subsequent icons are labelled S'n' where n represents the number of the reading, and increases in increments of 1 every time a new reading is completed.

Figure 37



Additional Patella Resection

Using the left and right buttons on the control puck, toggle to the reading that is determined to match closest to the natural reading. Press the okay button on the control puck to select and then press okay to confirm.

The caption of the selected graph describes the dimensions of the shim used in that reading. The thickness (mm) and angle of the shim will be depicted as the corresponding number. If the shim is an angled shim, the direction of the angle when the shim was attached to the sensor will be displayed in the form of an arrow that may be orientated in one of four directions.

! Ensure that any subsequent resections do not reduce overall patella thickness to less than 12 mm, putting the patella at risk of fracture.

After referring to the shim dimensions on the caption of the graph, press okay on the control puck to confirm. The Panel PC will display the confirmation screen.

The patella has now been resected at a depth and angle determined by the surgeons decision making.

Proceed with patella implant positioning and trialling.

Disassembly Instructions

Detach the single-use cable from the short re-usable cable, at the connection point, by gently pulling the two grey connectors away from each other. The short re-usable cable will remain with the Panel PC.

Remove the control puck from the patients draped leg and dispose of the sensor device and all shim components following standard hospital protocol.

Power down the Panel PC by holding the power button.

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