eventum Orthopaedics

Accessible innovation designed to improve patient outcomes

Quadsense

Surgical Technique

Overview

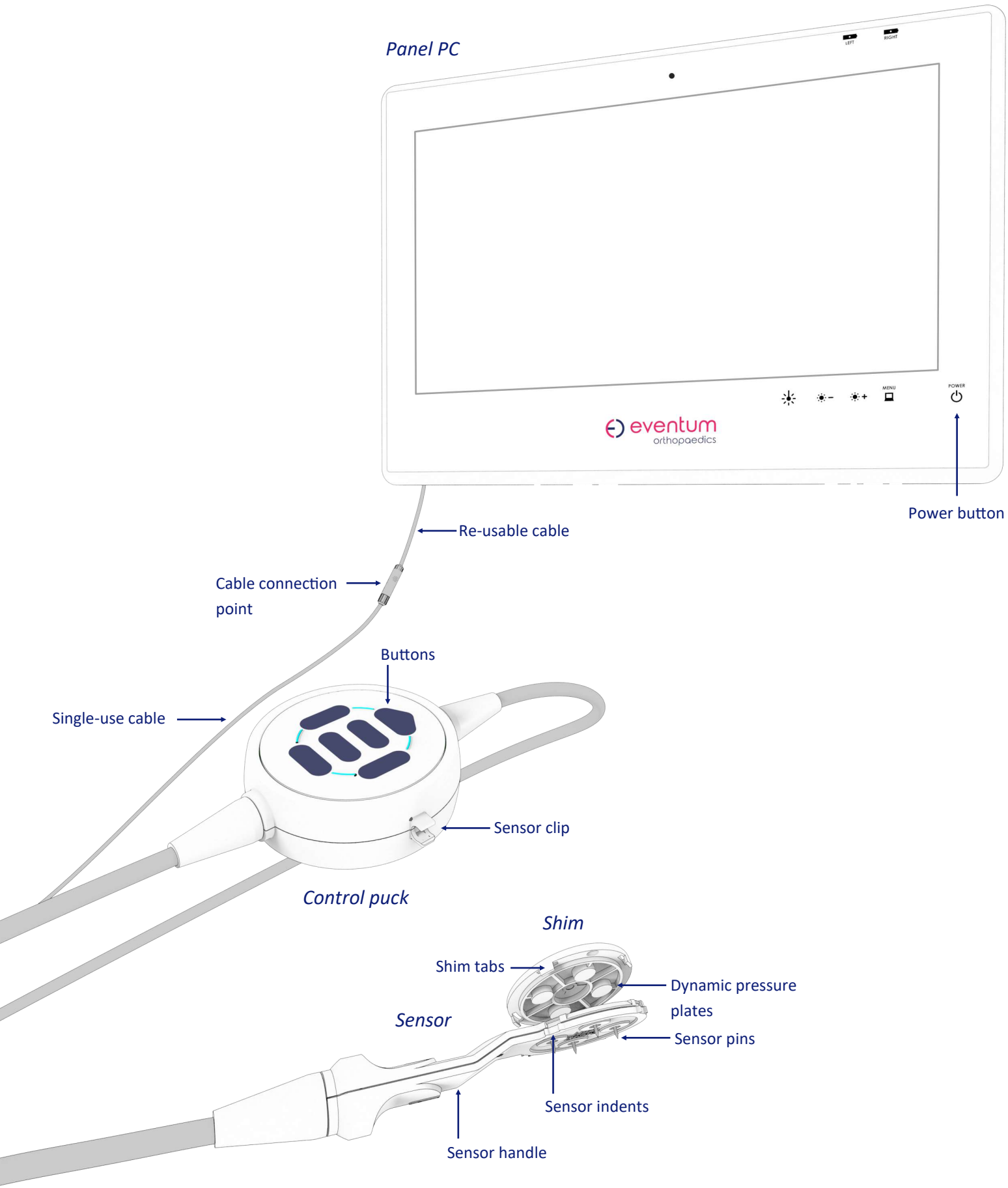
The Quadsense System is intended for use in Total Knee Arthroplasty procedures to aid surgical decision making in balancing the forces through the patellofemoral joint.

The Quadsense sensor attaches to the patella to take readings and multiple adjustment shims are provided that attach to the sensor. There is a control puck within the sterile field that the surgeon can use to navigate the software workflow. The Quadsense sensor provides intra-operative data in real time to the surgeon on the joint reaction force through the patella. The surgeon can then use this information to make adjustments to the patella resection or conduct soft tissue releases.

Contents

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 12 shims that attach to the sensor to take readings.

The shims have a slight dome shape and differ in depth (mm) and plane of angle (degrees).

The shims included are:

Figure 4

- 6mm
- 7mm
- 8mm
- 9mm

- 6mm 1.25°
- 7mm 1.25°
- 8mm 1.25°
- 9mm 1.25°

- 6mm 2.5°
- 7mm 2.5°
- 8mm 2.5°
- 9mm 2.5°

The shim attaches to the top of the sensor. The sensor has four evenly spaced indents around the circumference of the sensor head, and the shim has four small tabs that line up with these sensor indents. When attaching a shim to the sensor, line the tabs up to the indents and press down gently (Figure 5). The shim will give tactile feedback when it is attached. The shims can be attached to the sensor in any of the four orientations where the tabs line up to the indents.

Figure 5a

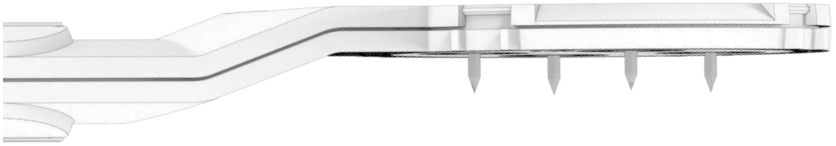


Figure 5b

The Quadsense System: Adjustment Shims

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 (Figure 6). Changing the orientation of the depth shims, with no added angle, should have no affect on sensor readings.

Figure 6

Angled shims: 1.25°, 2.5°

The number symbol on the surface of the shim denotes the degree of angle on the shim e.g. 1.25° and 2.5° (Figure 7).

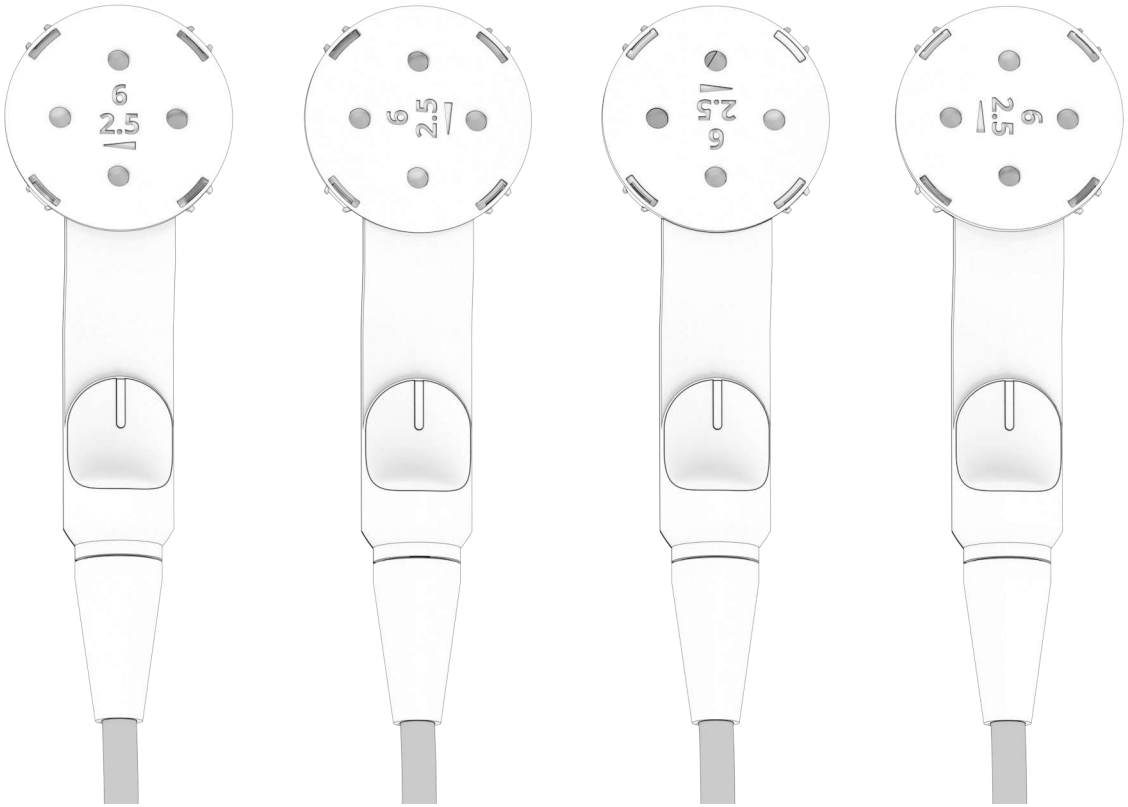
The triangle symbol on the surface of the shim shows the direction of the angle. The thicker side of the triangle is on the thicker side of the shim, and the point of the triangle points to the thinner side of the shim.

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.

Figure 7

Shims that have an angle can be rotated in four different orientations to change the direction of the angle (Figure 8).

Figure 8

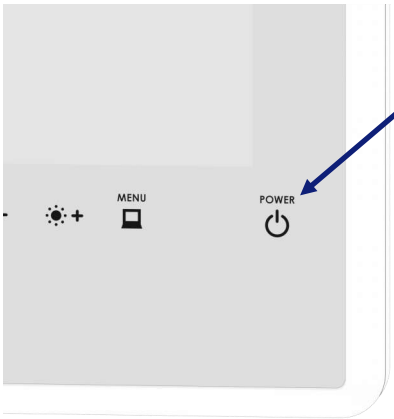


Setting up Quadsense

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 the power button located on the bottom right corner of the front of the Panel PC (Figure 9). The symbol will light up once the device is switched on.

Figure 9



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

Figure 10

A circulating nurse will enter patient details onto the Panel PC for Patient verification, using the touchscreen keypad (Figure 11). This information will include the patients’ forename, surname and the patients date of birth. Press ‘Confirm’ to proceed.

Figure 11

Once the software has identified the patient, it will ask you to select which of the patients’ knees is to be operated on, left or right (Figure 12). 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 12a

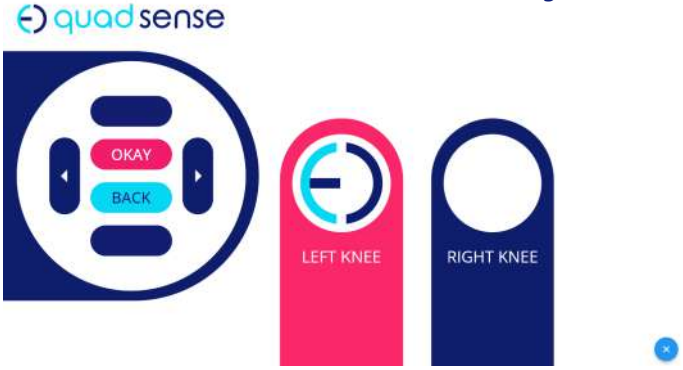
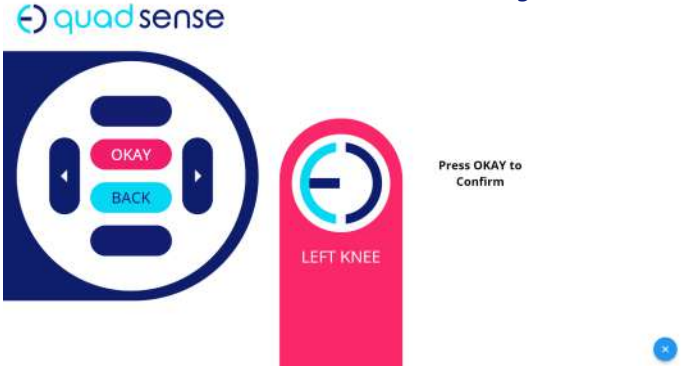


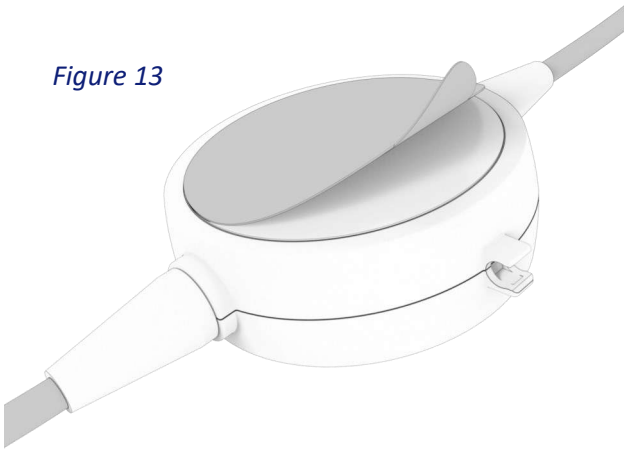
Figure 12b



Setting up Quadsense

The Quadsense sensor is a single-use device. Follow standard hospital procedure for sterile transfer. Layout the sensor device and all shims. The long cable will pass out from the sterile field and connect with the Panel PC via a short, re-usable cable. The sensor and shims will remain in the sterile field at all times.

Figure 13

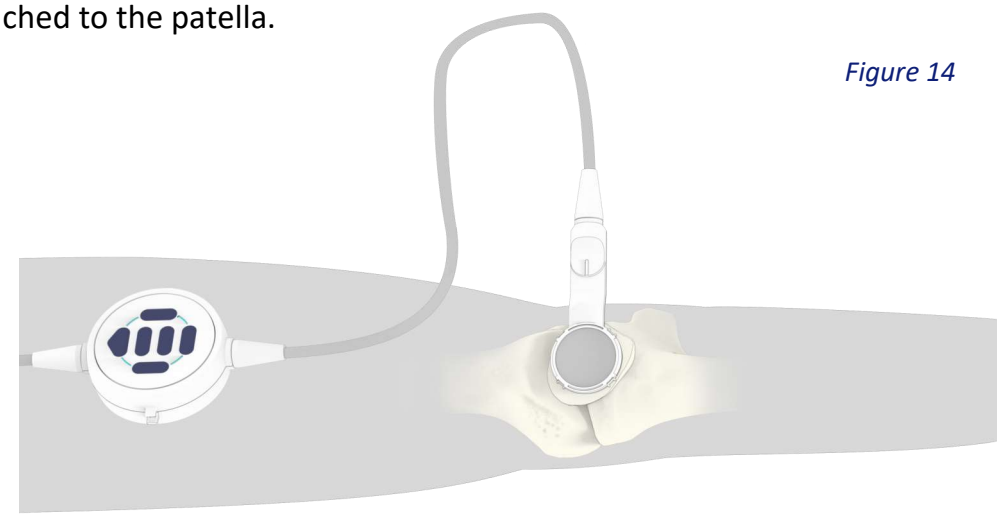


The control puck needs to be attached to the patients draped leg. Peel off the sticker from the adhesive back (Figure 13), then stick the control puck to the drape with the buttons facing up.

The arrow button should be pointing towards the patients head and the short length of cable, attached to the sensor, should be pointing towards the patients feet (Figure 14).

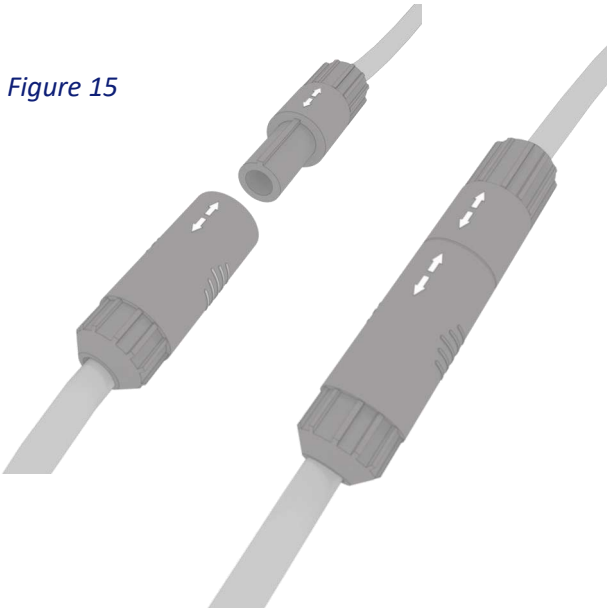
Ensure the control puck is close enough to the knee joint to ensure the wire isn't taut when the sensor is attached to the patella.

Figure 14



There is a short cable attached to the Panel PC, and a long cable with the sensor device. The end of the short re-usable cable and the long single-use cable need to be joined together. Hold the ends of each cable and line up the arrows on the grey connector ends so that they align in a straight line (Figure 15). Gently connect the two cables together, ensuring the arrows are aligned. Tactile feedback will inform the user when the cables are correctly and securely connected.

Figure 15



Conservative Patella Resection

Figure 16

To mount the sensor on the articular side of the patella, a flat surface is needed. A 6mm resection is needed to accommodate the sensor and first shim (Figure 16). A 6mm resection can be achieved using Eventum's Depth and Angle Adaptors.

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 is not over-resected and 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 thickness of the patella using the same reference point should be 6mm less than the initial measurement.

Note: The surgeon can decide to accommodate for any articular wear by making a smaller resection.

Caution: A resection of 6mm from a patella that is 18mm thick or less could risk patella fracture.

Attaching the Sensor to the Patella

The sensor has a flat surface mounted with four small metal pins (Figure 17). The pins allow the sensor to attach to the patella and remain secure whilst taking readings.

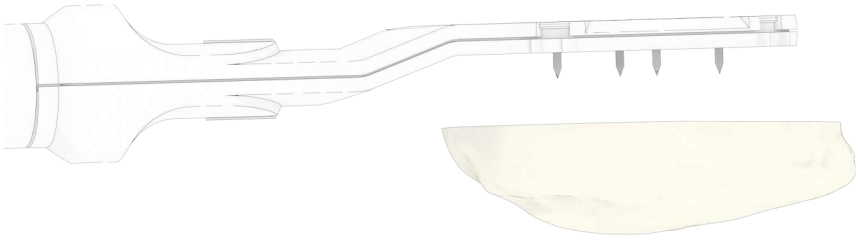
Figure 17

Remove the protective cover from the sensor to reveal the pins.

Mount the sensor on the flat resected surface of the patella (Figure 18).

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 19). The underside of the sensor should be flush with the bone and stable (Figure 20).

Figure 18



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 19a

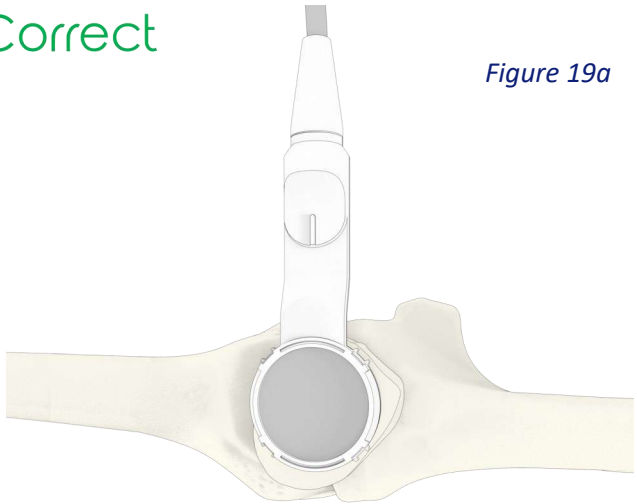
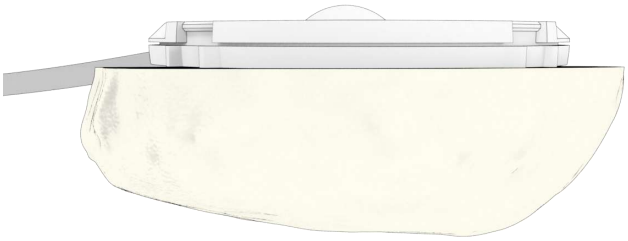


Figure 20a



Incorrect

Figure 19b

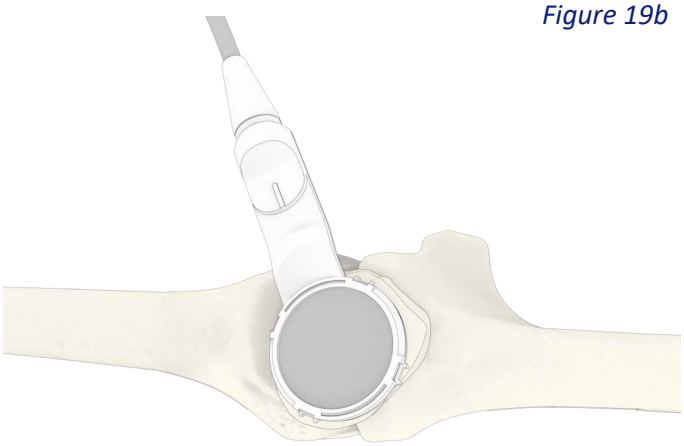
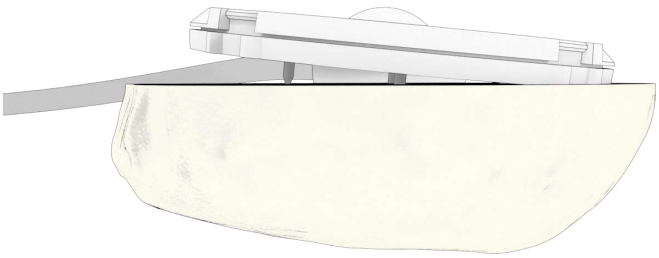


Figure 20b



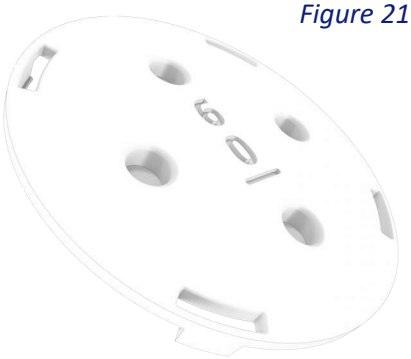
COLLECT
COMPARE
CORRECT

Initial Sensor Reading

For the first reading, the 6mm shim needs to be attached to the sensor.

First select the shim that has the symbol ‘6’ and ‘0’ on the surface (Figure 21). This refers to a shim of 6mm depth with no added angle.

Figure 21



Before the shim is attached to the sensor, the shim must be registered on the software, using the control puck.

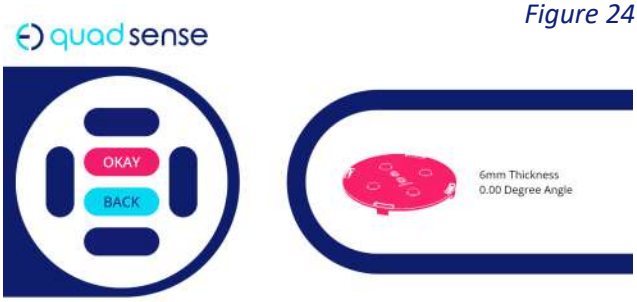
When this animation is displayed on the Panel PC, the software is ready for you to scan a shim (Figure 22).

Figure 22

The shim can be scanned by holding still against the centre of the control puck for a few seconds (Figure 23). The Panel PC will confirm the dimensions of the shim once the scan is complete (Figure 24).

Figure 23

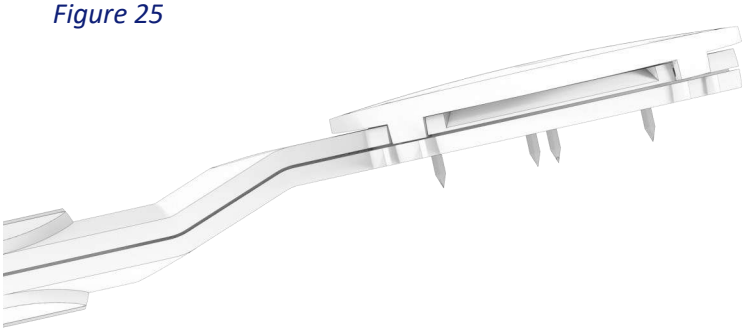
Figure 24



Note: There is a manual mode for inputting shim dimensions. See troubleshooting for further instructions.

Attach the 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 25). The shim should click on with tactile feedback, and be secure.

Figure 25



COLLECT
COMPARE
CORRECT

Initial Sensor Reading

Revert the patella and place the leg in extension.

Press the button on the control puck to start the reading (Figure 26).

Figure 26

Move the leg through full flexion extension at a consistent pace three times (Figure 27). The leg should be flexed to the same flexion angle each time. Twelve seconds are allotted to take the reading.

Figure 27a

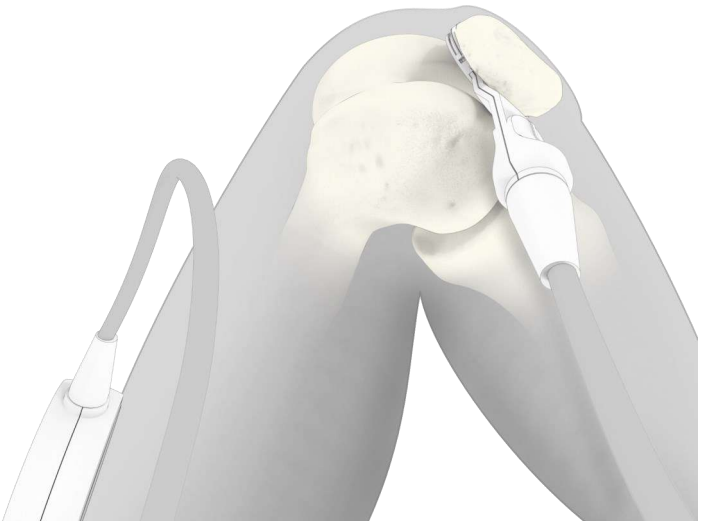


Figure 27b

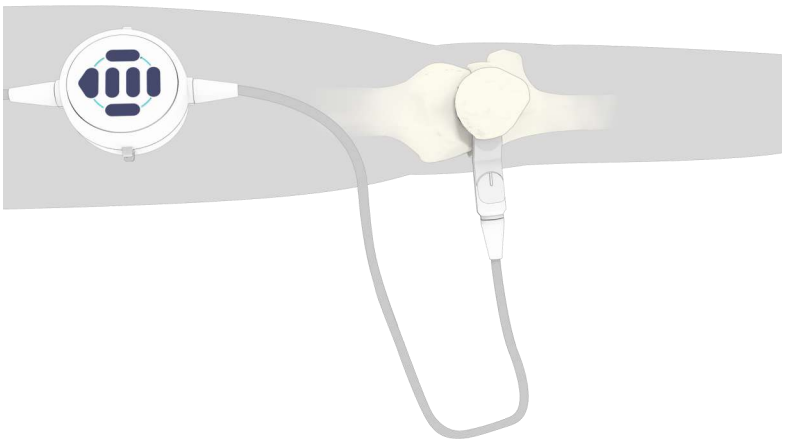
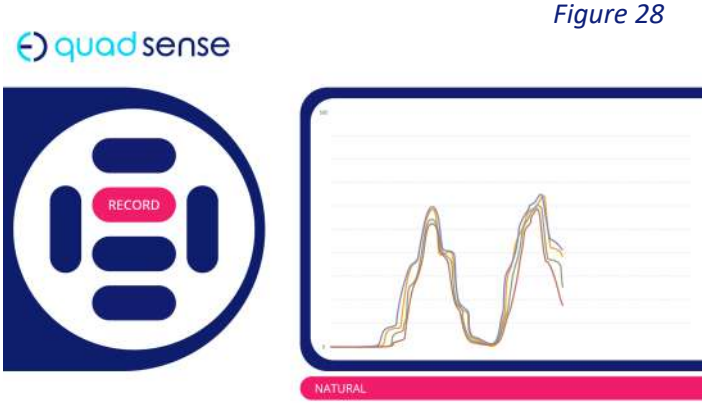


Figure 28

As the reading takes place, the results will appear on the Panel PC in the form of a graph (Figure 28).

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



COLLECT
COMPARE
CORRECT

Interpreting a Reading

The results of the reading will appear as a graph with four different coloured lines, see Key 1 (Figure 29). 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 29

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 30a).
Likewise, the M L button causes only the medial and lateral loads to be visible (Figure 30b).

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 30a

Figure 30b

Reviewing the Initial 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 31a) or you ran out of time and did not complete three flexion extension cycles (Figure 31b) etc.

Figure 31a

Figure 31b

COLLECT
COMPARE
CORRECT

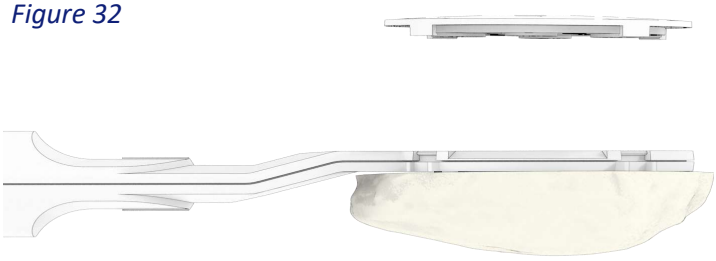
Removing the Sensor from the Patella

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 6mm shim from the sensor and place the shim with the sterile device components (Figure 32).

Figure 32

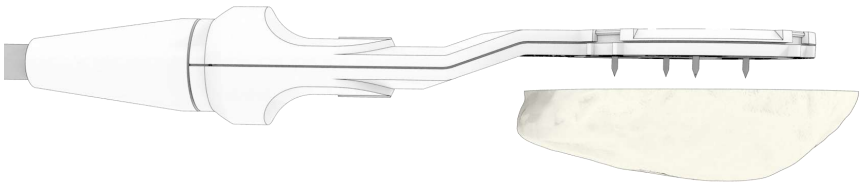


Mark the position of the sensor at the indents using methylene blue (Figure 33). This should allow the surgeon to better position the senor in the same place, for subsequent readings.

Figure 33

Gently remove the sensor from the patella by holding the handle close to the sensor and pulling vertically, away from the patella (Figure 34).

Figure 34



COLLECT
COMPARE
CORRECT

Removing the Sensor from the Patella

Attach the sensor to the clip on the side of the control puck (Figure 35, Figure 36). The clip should give tactile feedback when the sensor is secure.

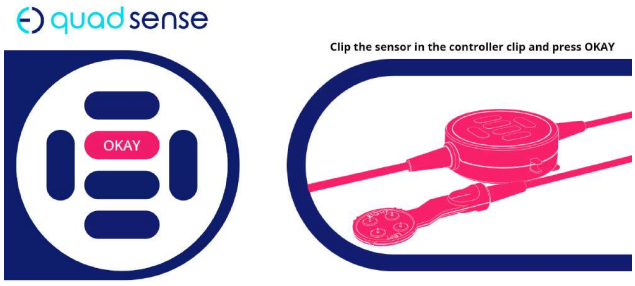


Figure 35

Figure 36a

Figure 36b

Proceed with the knee replacement following preferred surgical workflow.

Taking a Second Reading

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 37, Figure 38).

Figure 37

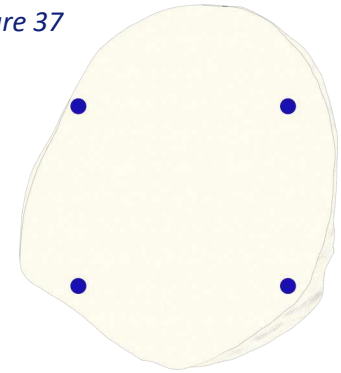


Figure 38

Select the 6mm shim with no angle.

Figure 39

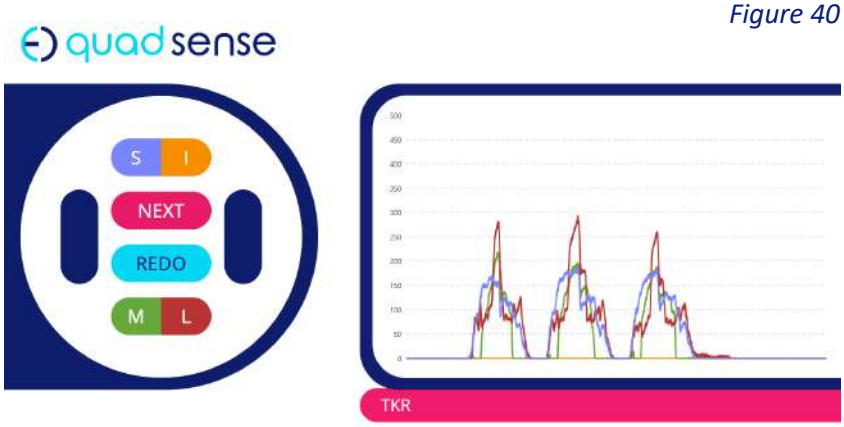
Scan the 6mm shim on the control puck by holding against the centre of the puck surface (Figure 39). Once the control puck registers the shim, the Panel PC will display the confirmation screen with the shim dimensions. If the shim dimensions on screen match the chosen shim, press the okay button on the control puck to move forward.

Attach the 6mm 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 40).

Figure 40



The TKR 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 41).

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

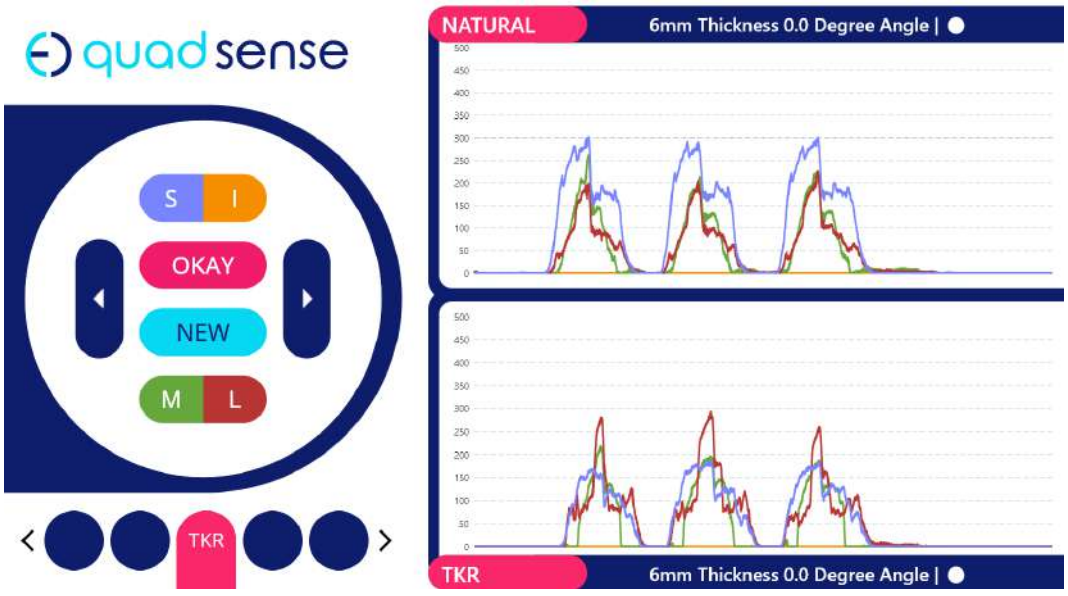
When comparing the two graphs, you may notice that:

- 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 41



The TKR Reading

The difference between the two graphs represents the change to the joint reaction force in 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.

Using an Angled Shim

An angled shim can be attached to the sensor for a reading.

Select the desired shim (Figure 42) and scan against the control puck (Figure 43).

Figure 42

Figure 43

Once the shim has registered on the control puck, the Panel PC will display the dimensions of the shim. If the dimensions on the Panel PC match the chosen shim then press okay on the control puck to proceed.

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

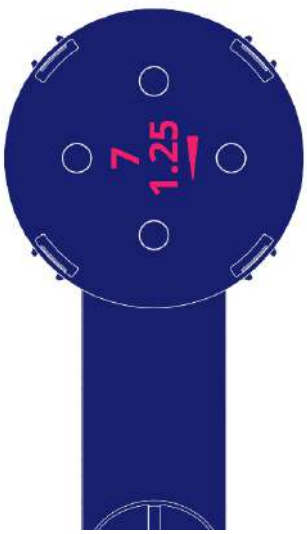
Input the orientation of the shim onto the Panel PC using the arrow buttons on the puck.

For example, a reading can be taken with the 7mm 1.25 degree shim, with the shim orientated so that the thicker side is on the lateral edge of the patella (Figure 44a). Use the arrow buttons on the control puck to change the orientation of the shim on the Panel PC to match the orientation of the shim attached to the sensor (Figure 44c). In this example, the required button is indicated with an arrow (Figure 44b).

Figure 44a

Figure 44b

Figure 44c



COLLECT
COMPARE
CORRECT

Reviewing Multiple Readings

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

Hold the chosen shim still against the centre of the control puck and wait for the shim to register and be confirmed on the Panel PC.

Attach the shim to the sensor in the desired orientation. If the shim is an angled shim, input the orientation of the shim on the sensor onto the Panel PC, using the buttons on the control puck.

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.

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 45).

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 45a

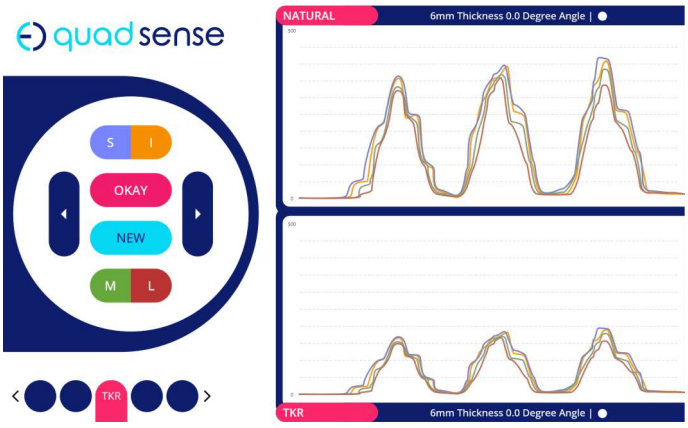
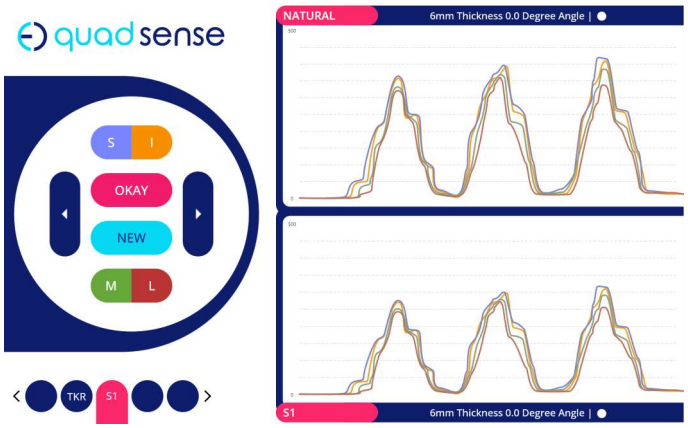


Figure 45b



<u>Navigating the readings</u>

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 46).

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.

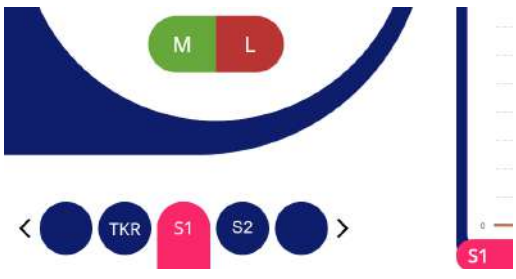


Figure 46

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.

With this information, the surgeon may choose to perform an additional patella resection to achieve the load through the patella femoral joint displayed in the chosen graph.

Caution: The patella has already been resected by 6mm. Ensure that any subsequent resections do not reduce overall patella thickness to less than 12 mm, putting the patella at risk of fracture.

Table 1 demonstrates a patella resection, after an initial 6mm resection, that would accommodate for a 9mm or 10mm implant, based on a reading chosen by the surgeon.

Table 1

	Additional patella resection	
Shim used in chosen reading	9mm implant	10 mm implant
6mm	3mm	4mm
7mm	2mm	3mm
8mm	1mm	2mm
9mm	0	1mm

Scenario: a 6mm patella resection, an initial reading taken with a 6mm shim, using a 9mm implant.

If the surgeon selects a reading with a 7mm shim, a resection of 2mm would accommodate for a 9mm implant.

If the shim was an angled shim, resect the patella at the indicated depth, at a plane of angle indicated by shim orientation.

After referring to the shim dimensions on the caption of the graph, press okay on the control puck to confirm. The data will now be sent to the cloud and 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, using the sensor data.

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 tapping the power button.

Refer to the IFU for cleaning, storage and maintenance instructions.

Device Components

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