ORTHOSENSOR

ORTHOSENSOR™ KNEE BALANCER

USER GUIDE
Device Activation and LinkStation™ Operation

LB-03000-003 Rev A

INTRODUCTION

The OrthoSensor™ Knee Balancer is an intelligent tibial trial that provides intraoperative data to help determine and achieve optimal soft tissue balance and component position during total knee arthroplasty (TKA).

The Knee Balancer is capable of sensing dynamic loads and center of load* in the medial and lateral compartments of the operated knee through a full range of motion with the patella reduced.

When utilized in the trialing phase of TKA the Knee Balancer will sense intercompartmental loads, center of load* as a reference for tibial-femoral contact, tibial tray rotation and flexion angle of the leg*. Data is displayed on a 27" monitor on the OrthoSensor LinkStation™ depicted below.

The OrthoSensor Knee Balancer enables the surgeon to make evidence based decisions regarding soft tissue releases and component position to achieve true balance and stability through a full range of motion.

Key Features

- Provides dynamic intraoperative loads and center of load* in the medial and lateral compartments through full range of motion with the patella reduced.
- *Kinetic Tracking™* feature provides dynamic kinematic tracking in conjunction with load data.
- Displays Tibial Tray Rotation and Knee Flexion Angle*.
- Requires no change to surgical workflow.
- Low cost, single use disposable device.
- Enables data capture in still images or video that may be added to the patient record.

Key Clinical Benefits

- Addresses the leading causes of early implant failure in TKA: instability, malrotation and loosening
- Dynamic intercompartmental load data and Kinetic Tracking enable evidence based soft tissue releases to improve stability.
- Provides intraoperative feedback on tibial component rotation*, center of load* and femoral articulation to facilitate optimal component position.
- Enables reproducible, teachable surgical technique.
- Captures intraoperative data for inclusion in patient record and registries.

ORTHOSENSOR LINKSTATION

*For Reference Only

LINKSTATION SET-UP

STEP 1

Activate LinkStation

Press and hold power button on back of computer to activate.

Confirm surgeon visualization of LinkStation.

Position Transceiver

Ensure Transceiver is connected directly to USB port on back of computer.

Transceiver CANNOT be connected through a peripheral USB hub.

Transceiver should point toward the operating table with antennae oriented in opposite directions at approximately 45º to the Transceiver.

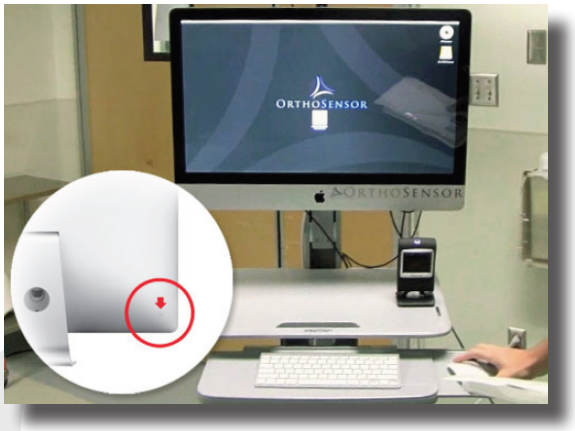
This position promotes optimal communication between the Transceiver and the OrthoSensor Knee Balancer.

Four (4) blue LED lights on the top of the transceiver (FIGURE I) indicate power and communication link with the OrthoSensor Knee Balancer.

LED #1 and LED #2 indicate communication link between Transceiver and the OrthoSensor Knee Balancer. These LEDs will illuminate only after device is activated.

LED #4 indicates that Transceiver is active.

LED #3 is inactive and will not illuminate.



Power switch on back of computer

Optimal Transceiver position with antennae at 45º

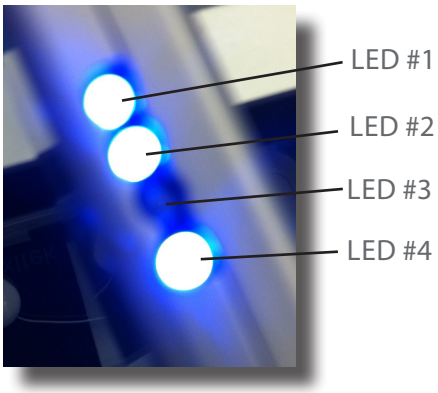


FIGURE I

DEVICE ACTIVATION

STEP 2

Launch Application

Double click the OrthoSensor icon to launch application.

OrthoSensor Icon & Application Start Screen

Activate Device

A. Remove appropriate size OrthoSensor Knee Balancer and Shims from box.

Do not remove from sterile pack.

Remove outer box labels and affix to patient documentation as required.

B. Place device directly over round silver magnet on LinkStation with articulating surface facing up.

The LED will illuminate on the articulating surface of the device after approximately one second.

DO NOT MOVE THE DEVICE until you observe the following:

i) LED turns off after approximately four (4) seconds.

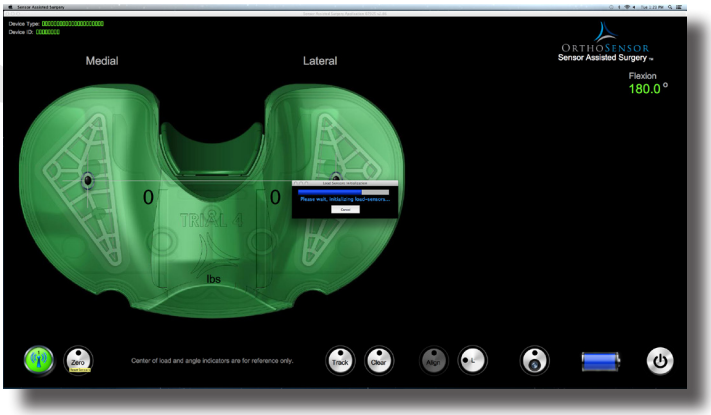
ii) Graphic User Interface (GUI) launches.

iii) Load Sensor initialization progress bar appears and completes.

Initialization takes up to 10 seconds.

Device may now be removed from magnet.

LED illuminated



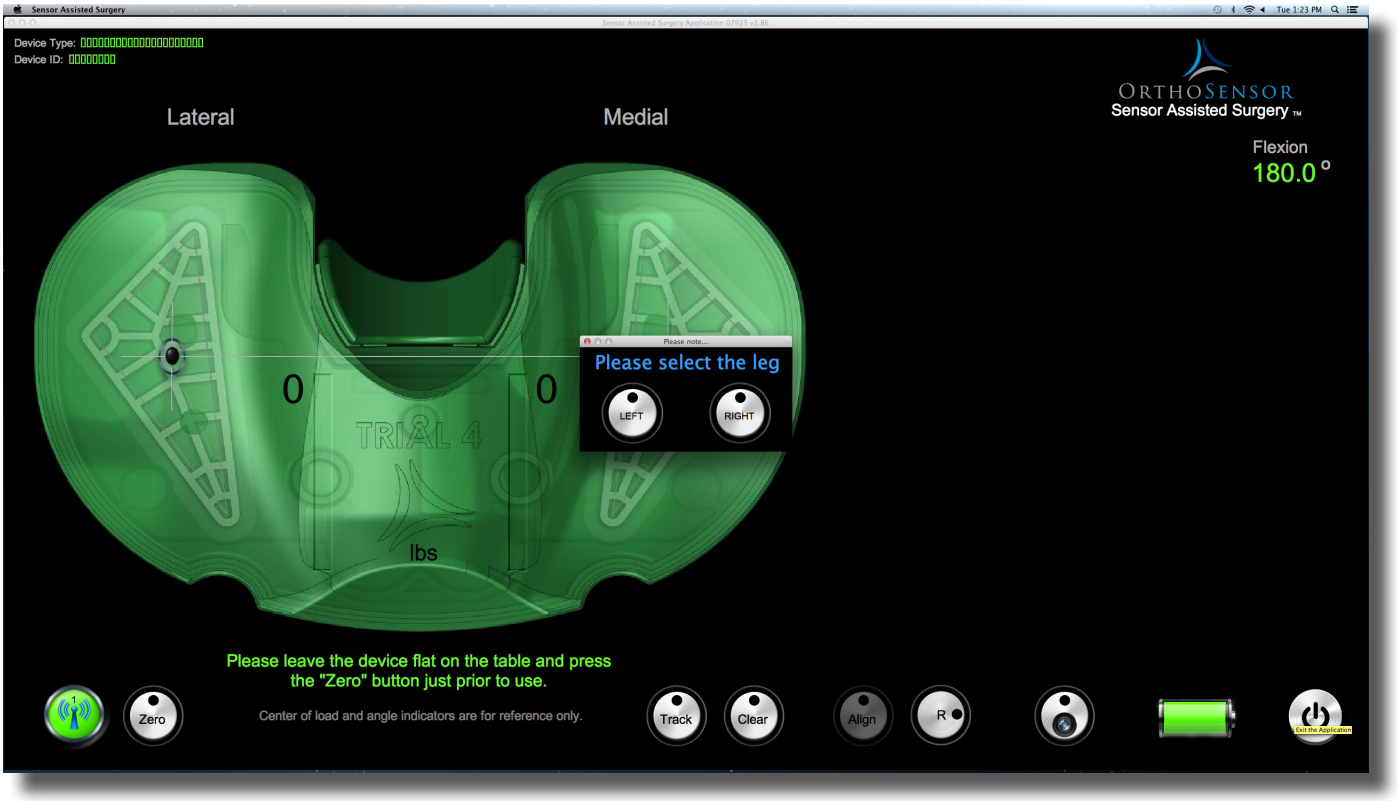
Initialization in progress

LEG SELECTION

STEP 3

Select LEFT or RIGHT leg

The GUI will automatically prompt leg selection.



"ZERO" DEVICE

STEP 4

Zero Device

The OrthoSensor Knee Balancer utilizes an accelerometer to assess component position* and leg flexion angle*.

The "zero" process calibrates the accelerometers to enable these functions and is accomplished in three steps.

Note that the GUI prompts user to execute each step in the "Zero" process.

A. Horizontal Zero, step 1

Place sterile packed device flat on LinkStation shelf

Gently secure medial and lateral edges to ensure device is flat. (FIGURE I)

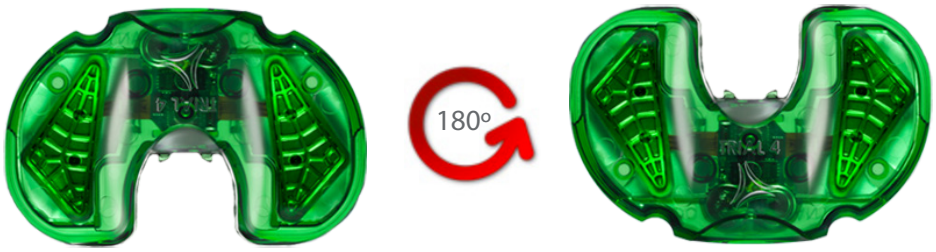
Click the "Zero" button (now flashing red) in the lower left corner of the GUI.

Load Sensor initialization progress bar will appear and complete. Initialization takes up to 10 seconds

FIGURE I

B. Horizontal Zero, step 2

Rotate device 180º and repeat previous step.



*For Reference Only

STEP 4 (continued)

C. Vertical Zero, step 3

Place sterile packed device flat against LinkStation post.

Underside (non-articulating surface) of device should be placed against post with posterior edge pointing toward floor.

Hold device in place and click the "Zero" button.

"Device is Ready for Use" will appear on the GUI indicating completion of the "Zero" process.

NOTE: This step is instantaneous and has no progress bar.

DEVICE READY FOR USE

STEP 5

The OrthoSensor Knee Balancer is now ready for use.

Verify Device Activation

While still in sterile packaging, apply pressure on the device to verify that loads are registering on the GUI. (FIGURE I)

NOTE: If loads do not register then the device may not be fully active and the following steps are recommended:

i) Deactivate device by clicking the Power button in the lower right corner of the GUI.

ii) If device does not shut down, click "OK" to exit or manually quit the GUI (hold Command key down and press the letter Q key). Unplug the transceiver USB cable and re-connect. Re-launch GUI and follow on-screen prompt to shut down active device (if necessary).

Repeat device activation and "zero" process detailed steps 2-4 again to fully activate device.

Open Sterile Packaging

Once activation is confirmed, open sterile packed device and shims and pass into the operative field using standard sterile technique. (FIGURE II)

FIGURE I

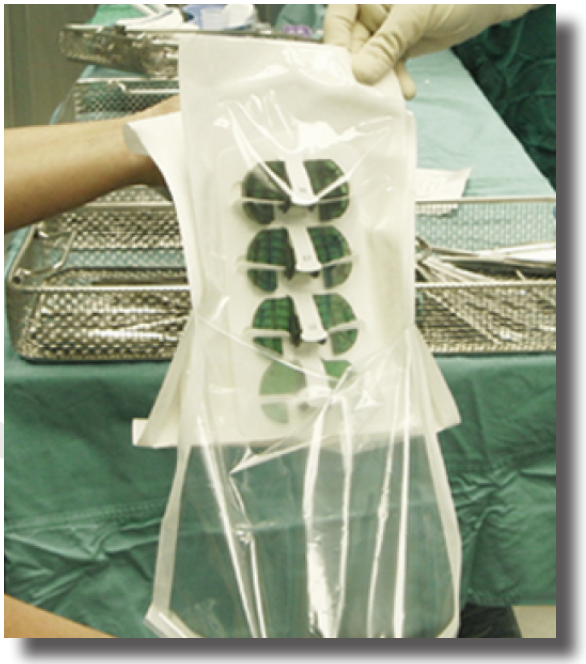


FIGURE II

ATTACH SHIMS

STEP 6

The OrthoSensor Knee Balancer is packaged with four (4) shims to enable use of trial inserts with 9mm, 11mm, 13mm and 16mm thickness.

A shim must be affixed to the underside of the device prior to insertion into the tibial tray.

Affix Shim

Affix appropriate size shim to underside of device by sliding it posterior to anterior. (FIGURE I)

Shim Exchange

To exchange shim size, unsnap it from anterior portion of the device and replace with desired size. (FIGURE II)

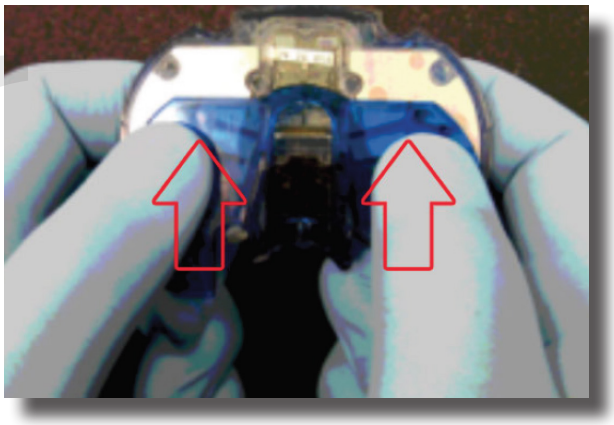


FIGURE I

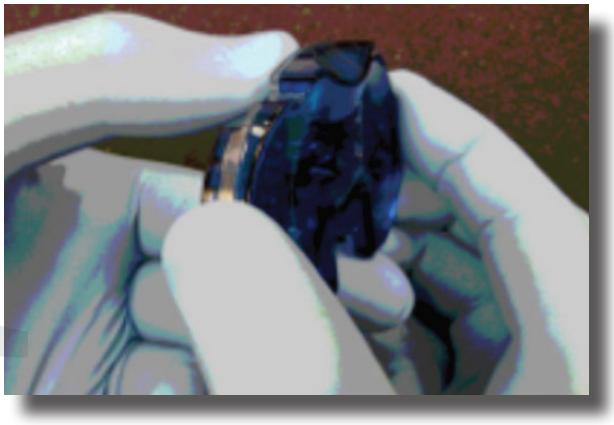
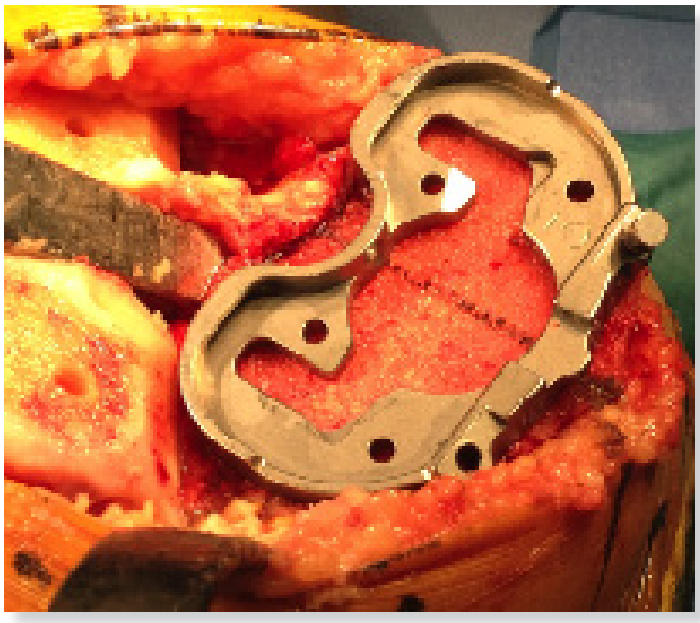


FIGURE II

SET TIBIAL ROTATION

STEP 7

Select and position appropriate size Trial Tibial Tray to achieve maximum tibial plateau coverage. The tibial tubercle mid-middle 1/3 is marked and a single anterior pin is inserted to allow rotational adjustments and maintain medial-lateral position.



Tibial trial with anterior medial pin inserted, PCL to medial 1/3 tibial tubercle is marked

DEVICE INSERTION

STEP 8

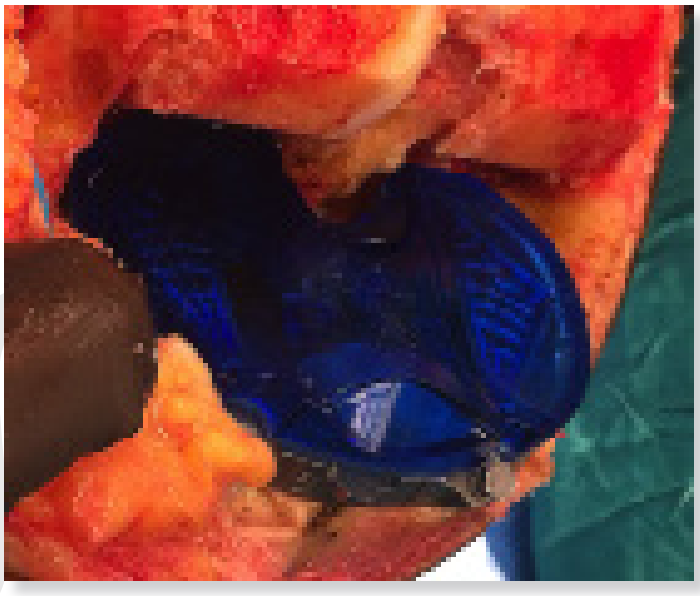
The OrthoSensor Knee Balancer is inserted with appropriate sized shim affixed to replicate the thickness of the selected trial insert.

In a tight knee it is often necessary to insert the tibial baseplate and the OrthoSensor Knee Balancer prior to insertion of the femoral trial.

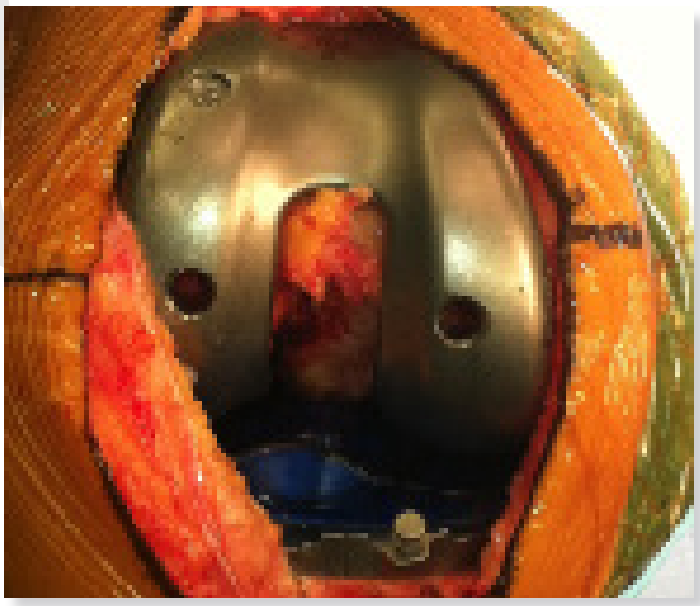
In this instance, reduce the tibia under the femur, then insert the femoral trial with minimal impaction force.

NOTE: Excessive impaction force may damage or negatively impact function of the OrthoSensor Knee Balancer.

Do not utilize excessive force or impact the Knee Balancer directly with a mallet.



OrthoSensor Knee Balancer (size 5) inserted on the tibial plate with anterior pin inserted.



Femoral trial inserted over tibial trial and OrthoSensor Knee Balancer, size 5. Anterior pin inserted.

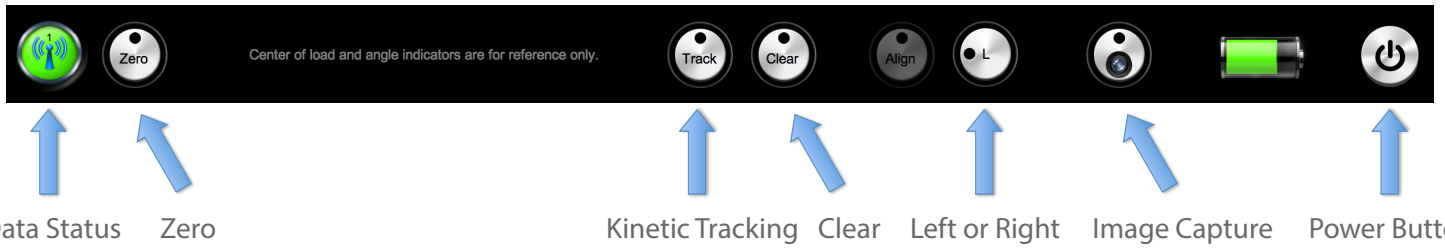
ADDITIONAL FEATURES

KINETIC TRACKING™

The Kinetic Tracking function displays dynamic kinematic motion of the knee with applied loads as well as maximum and minimum load values through the complete range of motion.

To enable Kinetic Tracking click the "Track" button located on the bottom edge of the GUI.

NOTE: Click the "Clear" button immediately after the "Track" button to reset max/min load values.



AUTO ZERO FEATURE

The OrthoSensor Knee Balancer will automatically re-zero process if it detects residual load of greater than three (3) lbs. when resting idle outside of the knee to maintain accuracy for the duration of the procedure.

The Knee Balancer detects that it is outside of the knee if it records a flexion angle of 180º (the equivalent of resting on a table or flat surface) for seven (7) seconds.

BATTERY LIFE

The OrthoSensor Knee Balancer has a battery life of 40 minutes.

DEVICE DEACTIVATION

The OrthoSensor Knee Balancer may be deactivated utilizing the "Power" button in the lower right corner of the GUI.

IMAGE CAPTURE

The Image Capture button (camera lens icon) will capture a screen shot and save to the desktop screen on the LinkStation computer .

OrthoSensor Customer Service
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OrthoSensor™ (www.orthosensor.com) is the technology leader in development of intelligent orthopedic devices that provide real-time data to surgeons and hospitals during and after surgery. OrthoSensor intelligent orthopedic devices utilize advanced sensor and communication technologies to improve healthcare outcomes and reduce the cost of treating musculoskeletal disease.

The device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) This device must accept any interference received, including interference that may cause undesired operation.
This requirement has been tested and found to comply with the limits for Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.
This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipments into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.
Changes/modifications not approved by the responsible party could void the user's authority to operate the equipments.

ORTHOSENSOR

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