# VERASENSE USER GUIDE

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OrthoSensor’s VERASENSE delivers evidence-based data wirelessly to an intra-operative monitor that enables surgeons to make informed decisions on soft tissue balance and implant position in real time.

VERASENSE utilizes proprietary sensor technologies to transmit compartmental load data wirelessly. This enables surgeons to make informed decisions regarding soft tissue balance, and implant position with the goal of improving joint performance, knee kinetics and patient satisfaction.

As a result, patients whose knees have been balanced through the use of VERASENSE show statistically significant improvements in joint function, pain, activity level and patient satisfaction.

**VERASENSE KEY PRODUCT FEATURES**

- Provides dynamic intercompartmental loads in the medial and lateral compartments through full ROM with the capsule closed and patella reduced
- Kinetic Tracking* feature displays dynamic kinematic tracking in conjunction with load data to visualize tibiofemoral articulation through full ROM
- Requires no change in surgical workflow
- Low-cost, single-use disposable sensor
- Compatible with multiple knee implant systems
- Enables intraoperative data capture

**KEY CLINICAL BENEFITS**

- Intended to address leading causes of premature implant failure in TKA: mal-alignment and soft-tissue balance related complications
- Dynamic compartmental load data and Kinetic Tracking* enables evidence-based soft tissue releases to improve stability
- Enables reproducible, teachable surgical technique through quantifying surgeon “feel”
- Captures intraoperative data for inclusion in patient EMR, registries or comparative effectiveness studies

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*For Reference Only*
NOTE

The following accessories are necessary for the operation of the VERASENSE device:

- VERASENSE Software Application
- LinkStation MINI or LinkStation MINI Evaluation Kit

*Center of load and load values outside of the Green Zone are for reference only.
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VERASENSE SOFTWARE APPLICATION OVERVIEW

- Center of load and load values outside of the Green Zone are for reference only.

**Verasense Orthosensor.com**

- **Medial/Lateral Indicators**
- **Exit VERASENSE Software Application**
- **Options Menu**
- **Kinetic Tracking**
- **Re-Zero VERASENSE**

**Medial Lateral**
- 23 23 10°
- 22 21 45°
- 21 21 90°

**Positional Data Capture Table**

**Center of Load Indicators**

**Load Values**

**Options Menu**

- **RF/Bluetooth Signal Strength/Channel**
- **VERASENSE Calibration Indicators**
- **VERASENSE Battery Life**
- **Tablet AC/DC**
- **Surgical Side Indicator**

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POWERING ON THE LinkStation MINI

STEP 1
To turn on the LinkStation MINI or LinkStation MINI Evaluation Kit, press the power button located on the left side of the Display Unit.

STEP 2
The VERASENSE Software Application will automatically startup once the Display Unit is powered on.

STEP 3
The plug-shaped AC/DC Power indicator on the bottom left of the screen will show whether the tablet is plugged in and running on AC power or if it is unplugged and running on DC battery power.

⚠️ CAUTION It is recommended to always plug in the Display Unit and operate the system on AC power.

NOTE
Place the LinkStation MINI or LinkStation MINI Evaluation Kit on contralateral side of the operating table for optimal surgeon visibility.
TRANSCEIVER SETUP

- **NOTE** The VERASENSE for Zimmer Biomet Persona communicates with the LinkStation MINI via Bluetooth and the transceiver setup is not required.

**LINKSTATION MINI WITH INTEGRATED ANTENNA OPTION**

**STEP 1**
Ensure the Transceiver Antenna mounting brackets are securely fixed to the back mounting plate of the Display Unit. Also ensure the Transceiver housing is properly fixed to the top mounting bracket.

**STEP 2**
Ensure the Transceiver cable is connected to the USB port on the right of the Display Unit and firmly connected to the Transceiver. Also confirm both antenna cables are securely connected to the Transceiver and the top and bottom mounted Antennas.

**NOTES**
1. LED (1) and LED (2) indicate communication between the Transceiver and VERASENSE. Communication is optimal when both LEDs are illuminated.
2. LED (3) and LED (4) indicate the Transceiver is powered on.
TRANSCIEVER SETUP

- **NOTE** The VERASURE for Zimmer Biomet Persona communicates with the LinkStation MINI or LinkStation MINI Evaluation Kit via Bluetooth and the transceiver setup is not required.

**LINKSTATION MINI WITH NON-INTEGRATED ANTENNA OPTION**

**STEP 1**
See images for ideal Transceiver arm position.
- Position antennas at 45° to the floor and at least 12" (305 mm) above and 7" (178 mm) out from the display unit.
- Ensure the Transceiver cable is connected to the USB port on the right of the Display Unit.

**LINKSTATION MINI EVALUATION KIT**

**STEP 1**
Attach antennas to Transceiver and mount to tripod. Fully extend tripod legs prior to use.

**STEP 2**
Ensure the Transceiver cable is connected to the USB port on the right of the Display Unit.

**NOTES**
1. LED (1) and LED (2) indicate communication between the Transceiver and VERASURE. Communication is optimal when both LEDs are illuminated.
2. LED (3) and LED (4) indicate the Transceiver is powered on.
SELECT THE SURGEON

STEP 1
Prior to activating VERASENSE, select the surgeon performing the case.

STEP 2
Touch the text box to open a drop down menu of surgeon names.

NOTE: The first name to appear is the surgeon who was selected for the last use of the VERASENSE Software Application.

STEP 3
If the surgeon performing the case does not appear, then select “Surgeon Not Listed” from the drop down menu.

NOTE
Please contact OrthoSensor Customer Service to add a new surgeon to the list.
US ONLY 888.75.ORTHO (888. 756.7846)
US AND INTERNATIONAL +1 954.577.7700
ACTIVATE VERASENSE

STEP 1
Select appropriate VERASENSE size and remove VERASENSE and shims from outer box.
• DO NOT remove from sterile pouch.

STEP 2
Activate VERASENSE by holding it stationary up against the magnet.
NOTE: For the LinkStation MINI only, the magnet is mounted on the roll stand.

STEP 3
DO NOT REMOVE VERASENSE FROM THE MAGNET UNTIL EACH OF THE FOLLOWING ACTIVATION STEPS OCCURS:
• An LED light will illuminate in VERASENSE after approximately one (1) second. The light turns off after approximately four (4) seconds.
• The VERASENSE Software Application will recognize VERASENSE and initializes communication.

NOTE
To optimize battery life, do not activate VERASENSE until just before it is required in the surgical workflow. VERASENSE has a 40 minute battery life.

If channel switching is enabled, then the ACTIVE VERASENSE FOUND dialog will display. Select OK after verifying serial number (SN) with package.
SELECT LATERALITY

- **STEP 1**
  Once the calibration sequence is complete, the SELECT LEG dialog will appear.

- **STEP 2**
  Press either LEFT or RIGHT to match the surgery side.

*Center of load and load values outside of the Green Zone are for reference only.*
**VERIFY VERASENSE ACTIVATION**

**STEP 1**
While in sterile pouch, apply pressure to the VERASENSE condylar surfaces and confirm that loads display on the VERASENSE Software Application.

**STEP 2**
Once activation is confirmed, open the sterile packaging that contains VERASENSE and shims and pass into sterile field using standard sterile technique by hospital personnel.

*Center of load and load values outside of the Green Zone are for reference only.*
STEP 1
Once VERASENSE is passed into the sterile field, it is ready for use during the procedure.

STEP 2
Position the LinkStation MINI or LinkStation MINI Evaluation Kit as close to the sterile boundary as possible and within direct view of the surgeon.

NOTES
1. The ACTIVE MONITORING SCREEN is the main screen of the VERASENSE Software Application.
2. The Communication Signal Strength Indicator is located at the bottom left of the screen VERASENSE Software Application.
   - Reposition the LinkStation MINI or LinkStation MINI Evaluation Kit to troubleshoot poor signal strength.

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VERASENSE INSERTION & SHIM ASSEMBLY

**STEP 1**

Determine desired VERASENSE thickness and attach the appropriate shim as needed.

- **NOTE:** VERASENSE for Zimmer Biomet Persona requires the user to input the selected shim thickness within the VERASENSE Software Application prior to use.

**STEP 2**

Insert VERASENSE.

- In a tight knee capsule, it may be necessary to insert the trial tibial baseplate and VERASENSE prior to insertion of the femoral trial. In this instance, reduce the tibia under the femur, then insert the femoral trial.

**CAUTION**

DO NOT utilize excessive force or impact VERASENSE directly with a mallet. Excessive impaction force may damage or negatively impact function of VERASENSE.
ASSESSING LOADS AND BALANCE

**STEP 1**
With VERASENSE inserted, the VERASENSE Software Application will display the position (Contact Points*) and magnitude of the applied loads in the medial and lateral compartments.

**STEP 2**
Data is displayed dynamically through a full range of motion.

**NOTE**
It is recommended to evaluate compartmental loads and joint balance with the patella reduced and the capsule closed.

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**IMAGE & DATA CAPTURE**

- **TWO WAYS TO CAPTURE SCREEN IMAGES AND DATA**
  The VERASENSE Software Application shows EITHER the Simple Capture Button OR the Position Capture Table.

- **SIMPLE CAPTURE**
  - Shown when Position Capture Table isn’t displayed.
  - Captures screenshot when selected.

- **POSITION CAPTURE**
  - Captures screenshot and records load data when 10°, 45°, 90° BUTTONS are selected.
WHAT YOU NEED TO KNOW:

- Calibration Indicators are the color bar displays beneath each M/L load value.
  • Indicate levels of VERASENSE accuracy throughout loading range.

- Center of Load reference points are a consistent color throughout all loading ranges.

- Calibrated load range is within **GREEN ZONE FROM 5 - 40 LBF**. Loads values outside of the GREEN ZONE are for reference only.

- VERASENSE Software Application displays a **VERASENSE OVERLOAD** message when either side goes into the **RED ZONE**.

  - **BLACK** = 0-4 lbf
  - **GREEN** = 5-40 lbf
  - **YELLOW** = 41-70 lbf
  - **RED** = 70+ lbf

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UNDERSTANDING BALANCE

› **CORONAL BALANCE**

Clinical research suggests a load differential between the medial and lateral compartments of less than or equal to 15 LBF through the range of motion is indicative of coronal plane soft tissue balance.*

› **SAGITTAL BALANCE (CR COMPONENTS)**

This is typically determined by a stable end-point during a posterior drawer test, while not exhibiting gross PCL tension leading to excessive rollback or anterior lift-off of the tibial component. The femoral contact points are in the mid-third of the tibial plateau.*

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BALANCE SOFT-TISSUE

Clinical experience combined with information displayed by the VERASENSE Software Application may be used to assist decision making regarding component placement and soft tissue releases to achieve compartmental balance.

NOTES

1. If VERASENSE indicates a compartmental load in excess of 70lbf, reduce shim size if possible or perform initial releases to bring the load below 70lbf. Before performing final release to achieve soft tissue balance, remove VERASENSE and re-zero.

2. If VERASENSE indicates a compartmental load of less than 5 lbf, increase shim size to generate condylar load.

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RE-ZEROING

If VERASENSE experiences elevated loads, a re-zero calibration may be required for accurate load readings. A user can perform a re-zero in two ways:

- **MOTION-CONTROLLED RE-ZERO**
  Hold VERASENSE with superior side (articulating surface) facing the floor for three (3) seconds. Wait for Re-Zero Enabled and Re-Zero Completed messages to display.

- **MENU ZERO BUTTON**
  Remove loaded VERASENSE and then press the Zero Button on the VERASENSE Software Application.

- **CAUTION**
  Always be sure no force is being applied to VERASENSE before performing a re-zero!

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USING THE KINETIC TRACKING FEATURE

Displays dynamic motion of the knee through the full ROM to evaluate joint kinetics

- Extension to flexion roll back evaluation, AP drawer test, Int/Ext rotation laxity, etc.

**STEP 1**
Select the Track Button on the VERASENSE Software Application to enable Kinetic Tracking.

**STEP 2**
To clear and disable tracking, click the Track Button again.

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USE OF VERASENSE DURING CEMENTATION

- VERASENSE can be used during the final cementation process to ensure balance achieved during component trialing is maintained through the end of the procedure.
  - Ensure proper seating of the components, as even a small amount of residual cement mantle can affect joint balance.
  - Assess final poly component thickness for adequate loading.

When impacting the final femoral components be sure not to overload VERASENSE. Re-Zero, if necessary.

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**VERASENSE SHUT DOWN**

- **STEP 1**
  To turn off VERASENSE when the procedure is complete, press the **EXIT button** in the top right corner of the Active Monitoring screen.

- **STEP 2**
  Confirm exit on the pop-up window by pressing **OK**. The “Shutting down VERASENSE” dialog box will open.

**NOTE**

Either the RF or Bluetooth Transceiver will communicate with VERASENSE to power down the device. If communication can no longer be achieved, the “VERASENSE shutdown failed” box will open. Select **EXIT HOME SCREEN** to exit the VERASENSE Software Application.

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After the procedure is complete and VERASENSE has been shut down successfully, shut down the Display Unit by pressing the **POWER BUTTON** and then selecting **OK**.

- This will power the entire Display Unit down.
- In order to restart, the external power button must be pressed.
- **VERASENSE ERROR - UNABLE TO CONNECT**
  Error during the initial connection with starting VERASENSE. Typically due to VERASENSE power loss during connection.

- **INVALID LEG SELECTION**
  Error message if leg selection is the wrong side for an asymmetrical VERASENSE.

- **VERASENSE CALIBRATION ERROR**
  This message will appear if a VERASENSE Software Application error has occurred during the initial VERASENSE calibration while on the Active Monitoring Screen.

- **RF TRANSCEIVER UNPLUGGED**
  Transceiver cable disconnected during active VERASENSE monitoring.

- **VERASENSE CALIBRATION TIMEOUT**
  This message will appear if a calibration error occurs during Activation of VERASENSE.
  - Select **RECALIBRATE** to have the VERASENSE Software Application recalibrate VERASENSE prior to moving to the Active Monitoring Screen.
  - Select **SHUT DOWN VERASENSE** to shut down the current VERASENSE and to exit to the VERASENSE Software Application Home Screen.

- **VERASENSE OVERLOAD DETECTED**
  This message appears when the VERASENSE Software Application detects the VERASENSE condyle load exceeds 70lbs. Re-zeroing of VERASENSE will remove the overload detected dialog box.
ACTIVE VERASENSE FOUND

This message appears when an active VERASENSE is found. If the VERASENSE Software Application is enabled with Channel Switching and the VERASENSE Software Application detects an active VERASENSE, the following dialog box will appear with the active VERASENSE serial number.

SERIAL NUMBER ([SN]) VERASENSE. (The serial number is located on both the VERASENSE box as well as the Tyvek Pouch that VERASENSE is in).

VERASENSE SEARCH - ERROR

This message appears when an error has occurred while the VERASENSE Software Application is searching for active VERASENSE. Select OK and the VERASENSE Software Application will reset and re-establish the search for all active VERASENSE.

VERASENSE DATA TIMEOUT

This message will appear if an error has occurred when handling measured data that is being transferred from VERASENSE.

VERASENSE Error. Unable to connect.

VERASENSE shutdown failed. Try again?

VERASENSE ERROR - UNABLE TO CONNECT

This message may appear when an error has occurred during the initial connection after the identification of VERASENSE and the VERASENSE Software Application is unable to properly obtain the VERASENSE EEPROM data. Typical causes are due to loss of VERASENSE power during activation or reception issues.

VERASENSE SHUTDOWN FAILED

This message will appear if an error has occurred when trying to shutdown VERASENSE from the Active Monitoring Screen. If RETRY is selected, the VERASENSE Software Application will offer additional shutdown attempts. If EXIT HOME SCREEN is selected then the VERASENSE Software Application will close and return to the VERASENSE Software Application Homepage.
TROUBLESHOOTING

VERASENSE

If VERASENSE Light does not turn off during activation:
• Return VERASENSE to the activation magnet to complete the activation sequence.

If VERASENSE is showing no load values in the knee, or load values are being shown when it has been removed from the knee and no load is being applied:
• Re-Zero VERASENSE.

DISPLAY UNIT

If Display Unit will not turn on, or shuts down inadvertently:
• Ensure the power cord is properly attached to the Display Unit and plugged into a power outlet.

If Display Unit power button is blinking but nothing is happening:
• The Display Unit is in sleep mode. Press the power button to wake up the Display Unit.

ROLL STAND (FOR LINKSTATION MINI ONLY)

If Roll Stand will not roll:
• Check to ensure that the breaks on the casters are disengaged.

WIRELESS COMMUNICATION

If Communication is intermittent:
• Reposition the LinkStation MINI or LinkStation MINI Evaluation Kit as close to the sterile boundary as possible and within direct view of the surgeon.

• Objects such as OR lights, metal tables and mayo stands, and people can potentially interfere with communication.

RF Communication:
• Verify USB cable for the Transceiver is securely plugged into the Display Unit and into the USB port on the bottom of the Transceiver.

• Ensure antennas on the Transceiver are secure and that the line of sight between the Transceiver and VERASENSE is clear.

• All four LED lights on the Transceiver will be illuminated when VERASENSE is communicating assembly.

Bluetooth Communication: (FOR VERASENSE FOR ZIMMER BIOMET PERSONA ONLY)
• If communication cannot be reestablished, complete a force restart of the LinkStation MINI or LinkStation MINI Evaluation Kit by holding the power button on the display unit down for 5 seconds. The system will reboot and automatically reconnect to the device.
CLeaning And Care

Solutions

The following is a list of chemical cleaning solutions that have been successfully tested on the Display Unit & Roll Stand:

- Sani-Cloth HB
- Sani-Cloth Plus
- Super Sani-Cloth
- Cavi Wipes
- Cloro-Wipe Towelette
- 70% Isopropyl Alcohol
- Alcohol Prep Pads
- Tuffie Wipes

Display Unit

Use only a soft, lint-free cloth. Please note: abrasive cloths, towels, paper towels or similar items should not be used as these may cause damage to the Display Unit.

1. Disconnect the Display Unit from any external power sources.
2. Spray approved cleaning solutions onto soft lint-free cloth.
   Do not spray cleaning solutions directly onto equipment or at any openings.
3. Wipe surface until clean.
4. Cleaning of the Display Unit should be performed after each use.

Transceiver

Wipe the Transceiver down with 70% isopropyl alcohol wipes after each use.

Roll Stand (For Linkstation Mini Only)

The Roll Stand may be cleaned with most mild, non-abrasive solutions commonly used in the hospital environment (e.g. diluted bleach, ammonia, or isopropyl alcohol).

Note

The surface finish will be permanently damaged by strong chemicals and solvents such as acetone and trichloroethylene. Do not use steel wool or other abrasive material to clean the Display Unit. Never submerge or allow liquids to enter the Display Unit. Wipe any cleaning agents off the Display Unit immediately using a water-dampened cloth. Dry all Display Unit thoroughly after cleaning.
VERASENSE ADDITIONAL FEATURES

*Center of load and load values outside of the Green Zone are for reference only.
OPTIONS MENU

Left/Right Leg Selection
Open/Close the 10/45/90 Position Capture Table
Open OrthoLogIQ* Web Portal
Open VERASENSE Information Panel
Exit Options Panel

*OrthoLogIQ is only available to those end-users who purchase it pursuant to a separate agreement with OrthoSensor, Inc. OrthoLogIQ is only available in the United States.
## Display Available Manuals

### Exit to VERASENSE Active Monitoring Screen

- Exit
- Options
- Track
- Info
- Capture

### Page Up / Page Down Buttons

- Manual

### Opens & Displays the appropriate manual when selected.

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Description</th>
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<tbody>
<tr>
<td>05000-001</td>
<td>LinkStation MINI1 With Power cord for United States and Canada</td>
<td>1</td>
</tr>
<tr>
<td>05000-002</td>
<td>LinkStation MINI2 With Power cord for Australia and New Zealand</td>
<td>1</td>
</tr>
<tr>
<td>05000-003</td>
<td>LinkStation MINI3 With Power cord for Continental Europe</td>
<td>1</td>
</tr>
<tr>
<td>05000-004</td>
<td>LinkStation MINI4 With Power cord for United Kingdom and Ireland</td>
<td>1</td>
</tr>
<tr>
<td>05000-005</td>
<td>LinkStation MINI5 With Power cord for Italy</td>
<td>1</td>
</tr>
<tr>
<td>05000-006</td>
<td>LinkStation MINI6 With Power cord for Switzerland</td>
<td>1</td>
</tr>
<tr>
<td>05000-007</td>
<td>LinkStation MINI3 With Power cord for South Korea</td>
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<tr>
<td>05000-410</td>
<td>With power cord for United States and Canada</td>
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<tr>
<td>05000-411</td>
<td>With power cord for Continental Europe &amp; South Korea</td>
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<tr>
<td>05000-412</td>
<td>With power cord for United Kingdom and Ireland</td>
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<tr>
<td>05000-413</td>
<td>With power cord for Italy</td>
<td>1</td>
</tr>
<tr>
<td>05000-414</td>
<td>With power cord for Switzerland</td>
<td>1</td>
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</tbody>
</table>

**NOTE:** The following accessories are necessary for the operation of the VERASENSE device: VERASENSE Software Application and LinkStation MINI.
ORTHOLOGIQ MODE ("IQ MODE")

Browser Controls
- Back/Forward
- Home

Open/Close Digital Keyboard

Exit to VERASENSE Software Application
- If user exits IQ mode, browser will minimize and can be reopened with IQ button.

*OrthoLogIQ is only available to those end-users who purchase it pursuant to a separate agreement with OrthoSensor, Inc. OrthoLogIQ is only available in the United States.
WIFI CONNECTION SETUP

The WIFI Button in the lower left-hand corner will indicate the connection status of the VERASENSE Software Application:

- **GREEN** = WIFI Connected
- **RED** = WIFI Not Connected

**STEP 1**
Select the WIFI button to connect the VERASENSE Software Application to a wireless network or to acknowledge a network access policy for a connected (green) network.

- On the WIFI Network Configuration Screen, a list will populate with the names of all available networks.

**STEP 2**
Use the **UP** and **DOWN** arrows to scroll through the list of available networks.

**NOTE**: If desired network is not shown, please select the **RE-SCAN** button to repopulate the network list.

**STEP 3**
Select the desired WIFI network by touching the appropriate network box.
SELECTING THE OPEN NETWORK

STEP 1
After selecting the appropriate WIFI network, enter the Network Security Key:

• Press the KEYBOARD button to open the virtual keyboard.
• Select the Network Security Key field and enter key.
• Press the CONNECT button.

NOTE: If the WIFI network does not have a Network Security Key, select the CONNECT button to proceed.

STEP 2
To confirm a successful WIFI network:

• The connect WIFI network will appear in GREEN.
• Is Connected = True
• On the right portion of the screen, the OrthoLogIQ* login page will appear.

NOTE
If the selected network requires acceptance of a local internet access policy, a pop-up window will appear in the right-hand side of the WIFI Configuration Screen. Enter the required policy information.

To exit to the Home Screen, select the CLOSE button in the bottom left corner.

*OrthoLogIQ is only available to those end-users who purchase it pursuant to a separate agreement with OrthoSensor, Inc. OrthoLogIQ is only available in the United States.
KEYBOARD HOT KEYS

STEP 1
Press the top left corner of the screen to open the digital keyboard.

• Works on both the VERASENSE Software Application Activation and Active Monitoring screens.

STEP 2
“Hot-keys” have been designated for added features:

• U - Initiate the utilization data upload to cloud. Select OK once the upload is complete.

• I - Open IQ mode. Allows user to access OrthoLogIQ once VERASENSE has been shutdown.

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OrthoSensor is the technology leader in the development of intelligent orthopaedic solutions that provide real-time intraoperative data to surgeons and hospitals. OrthoSensor intelligent orthopaedic solutions utilize proprietary sensor technologies with the goal of improving healthcare outcomes and potentially reducing the cost of treating musculoskeletal disease.

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