



SHOULDER USER GUIDE



VERASENSE USER GUIDE

VERASENSE for Exactech Equinox Overview	4	Motion Capture	19
Linkstation MINI With Integrated Antenna Option Overview	5	Assessing Stability	20
Linkstation MINI Evaluation Kit Overview	6	Shutting Down VERASENSE for Exactech Equinox	21
VERASENSE Software Application for Shoulder Overview	7	Shutting Down the Linkstation MINI and Linkstation MINI Evaluation Kit	22
Getting Started	8	Warning & Dialog Messages	23
Surgeon Selection	9	Troubleshooting	25
VERASENSE for Exactech Equinox Activation	10	Cleaning & Care	26
Calibration Sequence & Shoulder Selection	11	Additional Features	27
Verify VERASENSE for Exactech Equinox Activation	12	Options Menu	28
Active Monitoring Screen	13	Display Available Menus	29
VERASENSE for Exactech Equinox Insertion	14	OrthoLogIQ Mode (“IQ Mode”)	30
Assessing Loads	15	WiFi Connection Setup	31
Image & Data Capture	16	Selecting the Open Network	32
Calibration Indicators	17	Keyboard Hot-Keys	33
VERASENSE for Exactech Equinox Re-Zero Load	18		

OrthoSensor's VERASENSE for Exactech Equinox delivers data wirelessly to an intra-operative monitor that enables surgeons to make informed decisions on joint tension and implant position in real time.

VERASENSE for Exactech Equinox utilizes proprietary sensor technologies to transmit load data wirelessly. This enables surgeons to make informed decisions regarding joint tension, and implant position with the goal of improving joint performance, shoulder kinetics and patient satisfaction.



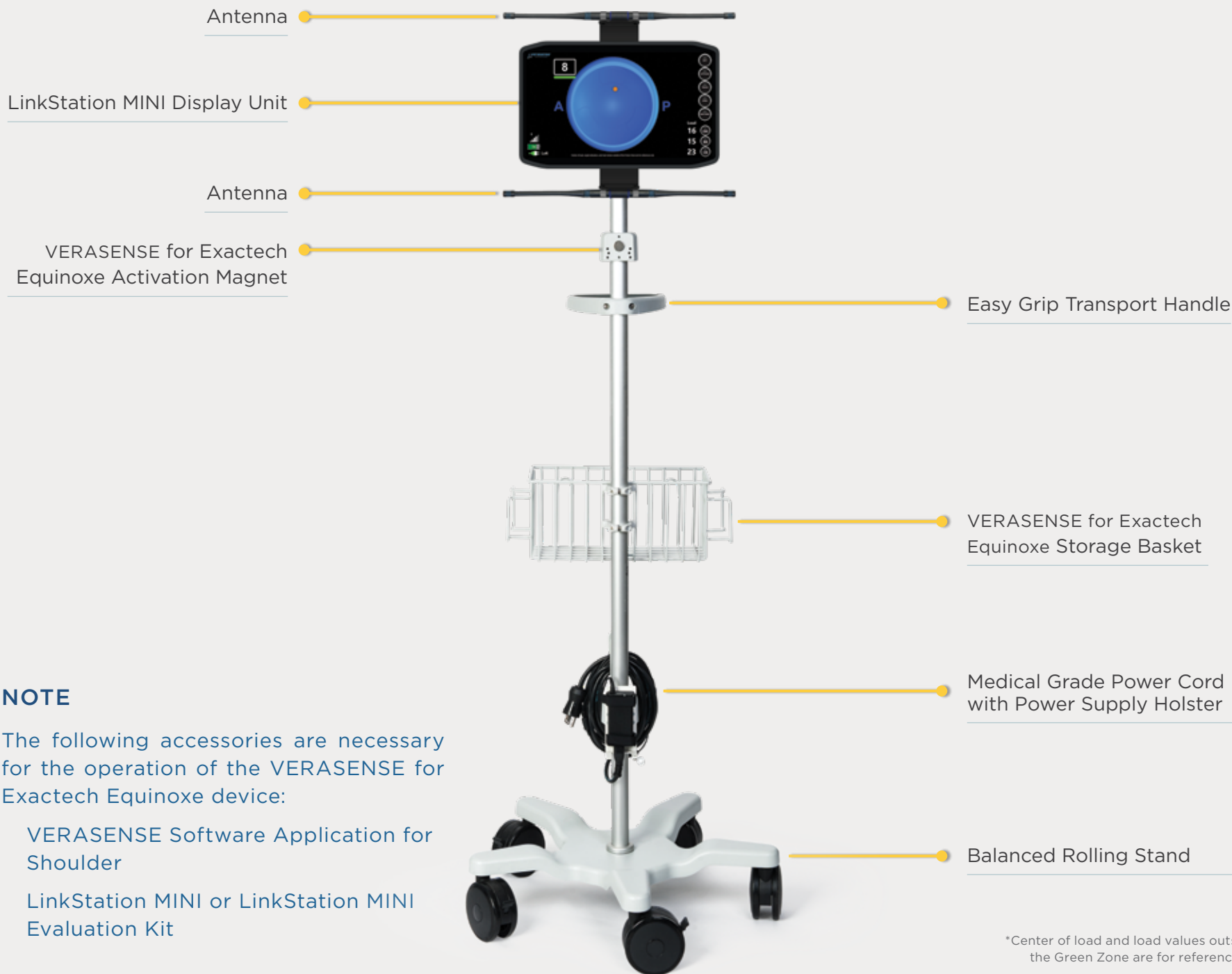
SENSOR-ASSISTED RTSA

VERASENSE for Exactech Equinox enables surgeons to quantify joint stability and improves surgeon skill through real-time, quantified data.

VERASENSE FOR EXACTECH EQUINOXE KEY PRODUCT FEATURES

- Wireless humeral sensor allows unconstrained evaluation of glenohumeral joint stability and kinematics
- Provides dynamic feedback on glenohumeral joint compressive load through the full ROM
- Kinetic tracking* displays load tracking in conjunction with numerical load data to visualize glenohumeral articulation through the full ROM
- Requires no change to surgical work flow
- Low-cost, single use disposable sensor
- Enables intraoperative data capture

LINKSTATION MINI WITH INTEGRATED ANTENNA OPTION OVERVIEW



LINKSTATION MINI EVALUATION KIT OVERVIEW



► NOTE

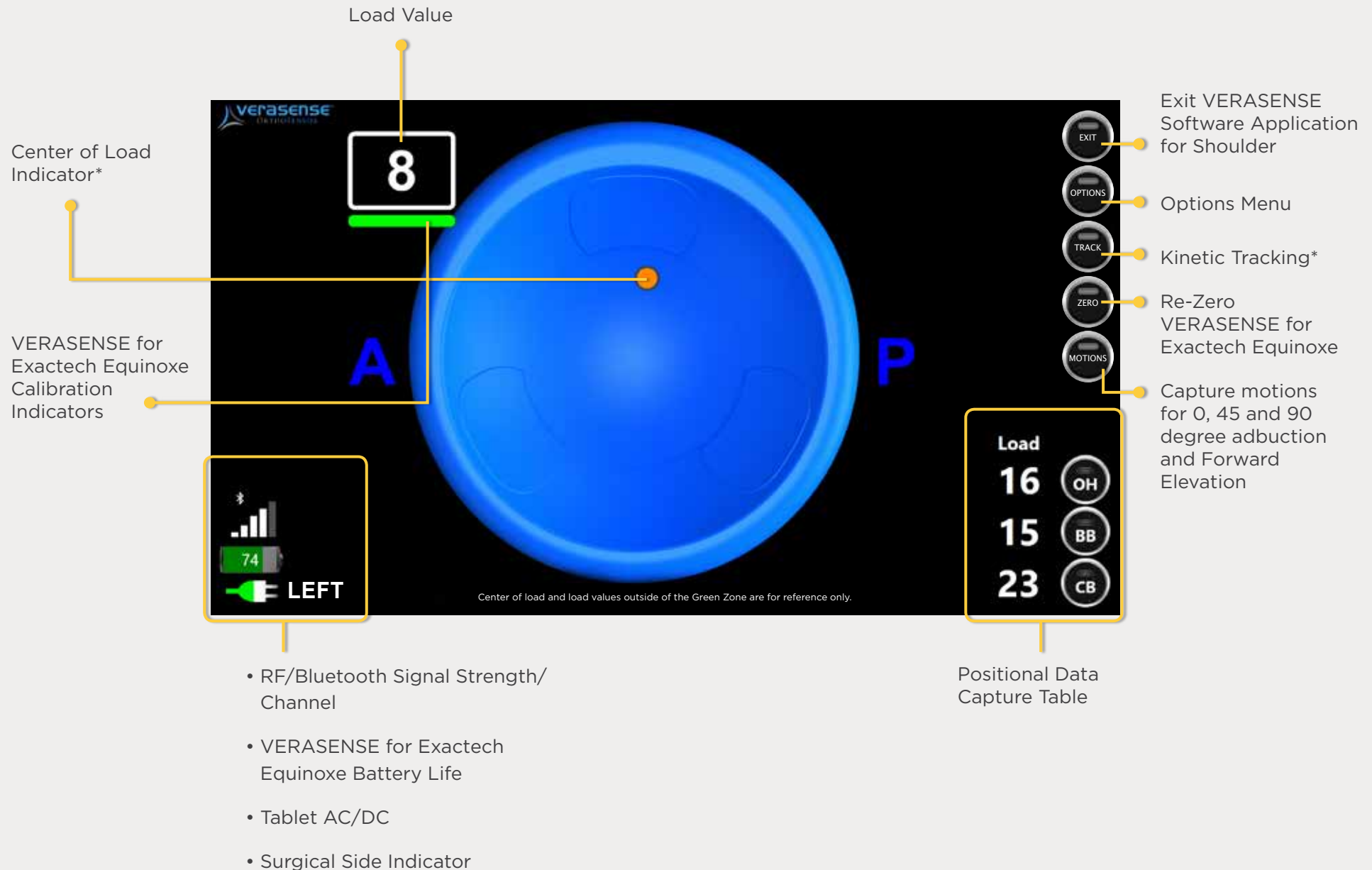
The following accessories are necessary for the operation of the VERASENSE for Exactech Equinox device:

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

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

** Included in the LinkStation MINI Eval Kit, setup not required for use with VERASENSE for Exactech Equinox

VERASENSE SOFTWARE APPLICATION FOR SHOULDER OVERVIEW



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

POWERING ON THE LinkStationMINI

► 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 for Shoulder will automatically startup once the Display Unit is powered on.

► STEP 3

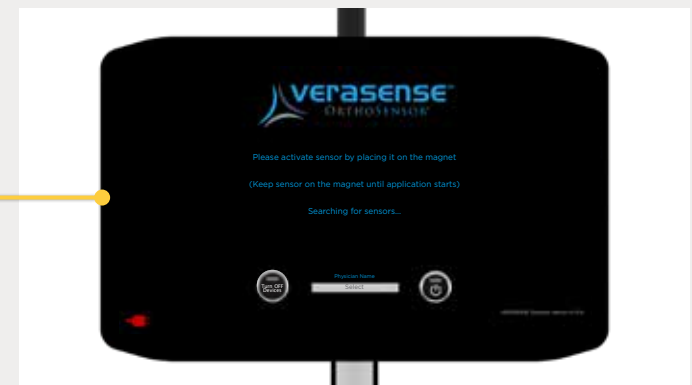
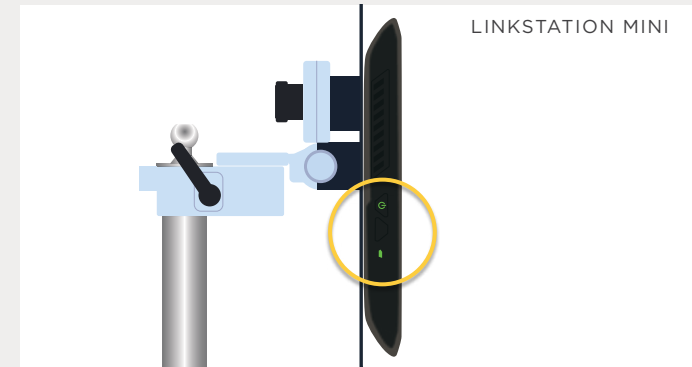
The plug-shaped AC/DC Power indicator on the bottom left of the screen will show whether the tablet is plugged in and running on AC power or if it is unplugged and running on DC battery power.

⚠ 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.

DISPLAY UNIT POWER BUTTON



AC/DC POWER INDICATOR

RED = UNPLUGGED (DC)

GREEN = PLUGGED IN (AC)

SELECT THE SURGEON

▶ STEP 1

Prior to activating VERASENSE for Exactech Equinox, 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 for Shoulder.

▶ STEP 3

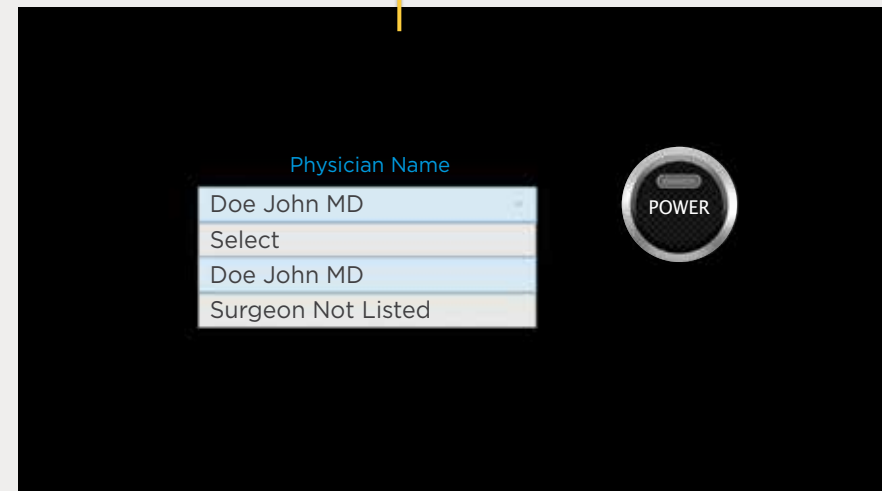
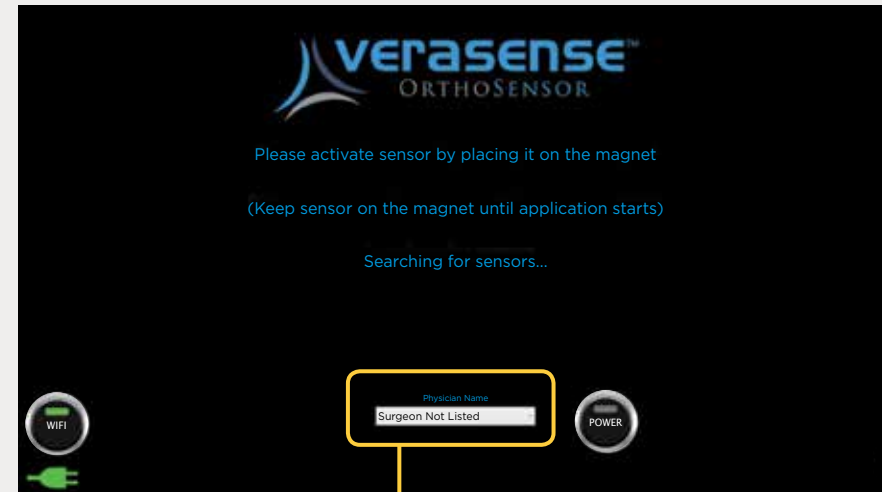
If the surgeon performing the case does not appear, then select “Surgeon Not Listed” from the drop down menu.

▶ 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 FOR EXACTECH EQUINOXE

► STEP 1

Select appropriate VERASENSE for Exactech Equinox size and remove VERASENSE for Exactech Equinox and shims from outer box.

- DO NOT remove from sterile pouch.

► STEP 2

Activate VERASENSE for Exactech Equinox by holding it stationary up against the magnet.

NOTE: For the LinkStation MINI only, the magnet is mounted on the roll stand.

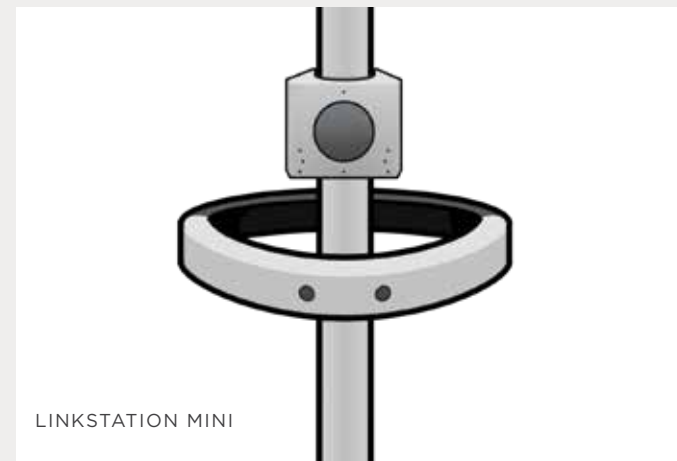
► STEP 3

DO NOT REMOVE VERASENSE FOR EXACTECH EQUINOXE FROM THE MAGNET UNTIL EACH OF THE FOLLOWING ACTIVATION STEPS OCCURS:

- An LED light will illuminate in VERASENSE for Exactech Equinox after approximately one (1) second. The light turns off after approximately four (4) seconds.
- The VERASENSE Software Application for Shoulder will recognize VERASENSE for Exactech Equinox and initializes communication.

► NOTE

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



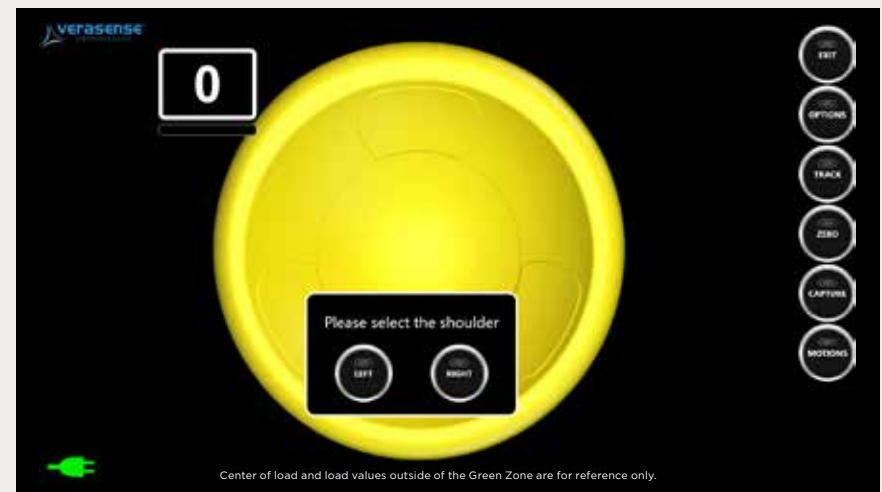
SELECT LATERALITY

▶ STEP 1

Once the calibration sequence is complete, the **SELECT SHOULDER** 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.

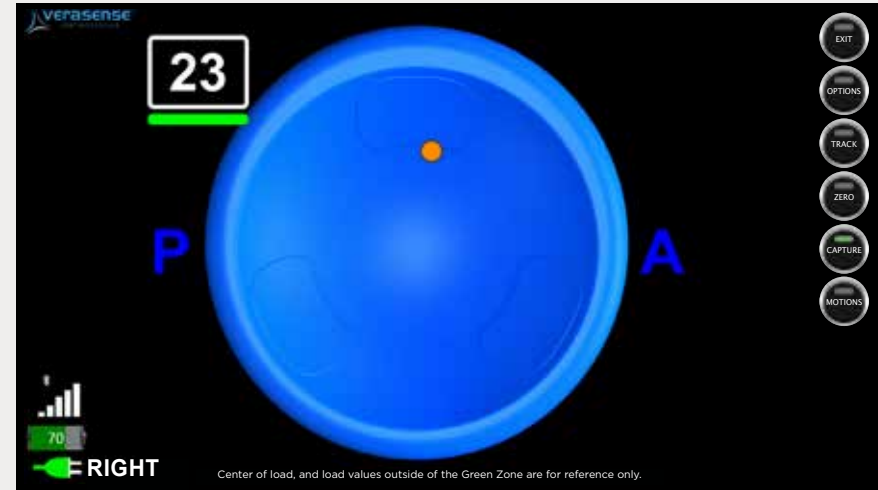
VERIFY VERASENSE FOR EXACTECH EQUINOXE ACTIVATION

▶ STEP 1

While in sterile pouch, apply pressure to the VERASENSE for Exactech Equinox® articular surface on the sensor nodes and confirm that loads display.

▶ STEP 2

Once activation is confirmed, open the sterile packaging that contains VERASENSE for Exactech Equinox® 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.

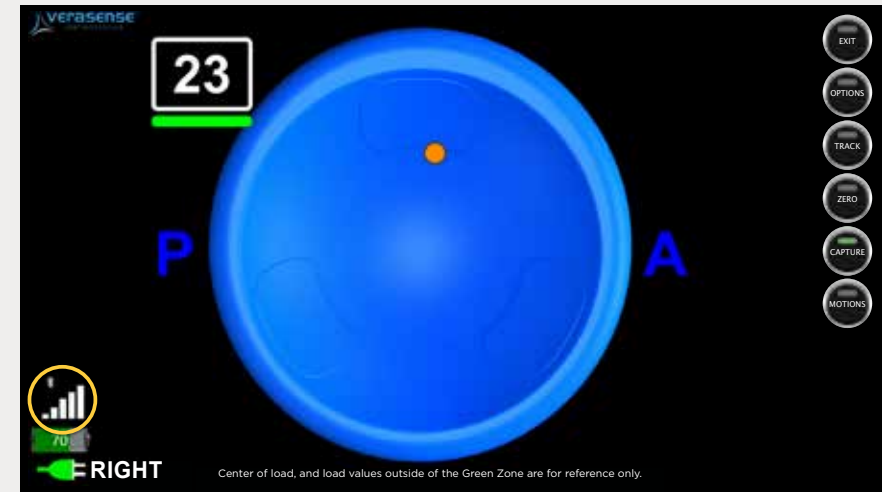
ACTIVE MONITORING SCREEN AND COMMUNICATION STATUS

► STEP 1

Once VERASENSE for Exactech Equinox 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 for Shoulder.
2. The Communication Signal Strength Indicator is located at the bottom left of the screen VERASENSE Software Application for Shoulder.
 - **Reposition the LinkStation MINI or LinkStation MINI Evaluation Kit to troubleshoot poor signal strength.**

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VERASENSE FOR EXACTECH EQUINOXE INSERTION & SHIM ASSEMBLY

▶ STEP 1

Determine desired VERASENSE for Exactech Equinox® thickness and attach the appropriate shim as needed.

▶ STEP 2

Insert VERASENSE for Exactech Equinox®

- To insert the VERASENSE for Exactech Equinox® humeral trial sensor, the underside asymmetric-connecting feature should be appropriately aligned and the liner/tray trials should be pressed together until the C-spring engages. This technique is the same as the standard humeral trial liner insertion and removal, additional details for this can be found in the “EQUINOXE® PLATFORM SHOULDER SYSTEM OPERATIVE TECHNIQUE”



▶ ⚠ CAUTION

DO NOT utilize excessive force or impact VERASENSE for Exactech Equinox® directly with a mallet. Excessive impactation force may damage or negatively impact function of VERASENSE for Exactech Equinox®.

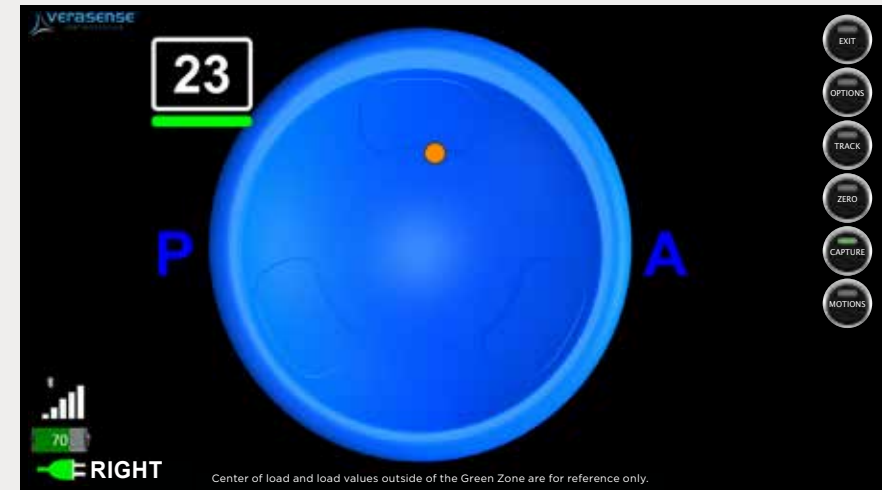
ASSESSING LOADS AND TENSION

▶ STEP 1

With VERASENSE for Exactech Equinox inserted, the VERASENSE Software Application for Shoulder will display the position (contact point*) and magnitude of the compressive loads in the glenohumeral joint.

▶ STEP 2

Data is displayed dynamically through a full range of motion.



▶ NOTE

It is recommended to evaluate glenohumeral load with retractors and other surgical instruments removed and the capsule closed.

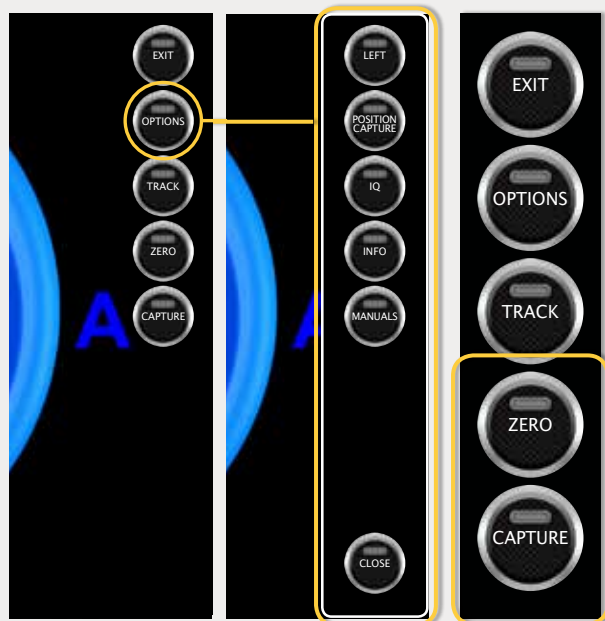
*Center of load and load values outside of the Green Zone are for reference only.

IMAGE & DATA CAPTURE

▶ TWO WAYS TO CAPTURE SCREEN IMAGES AND DATA

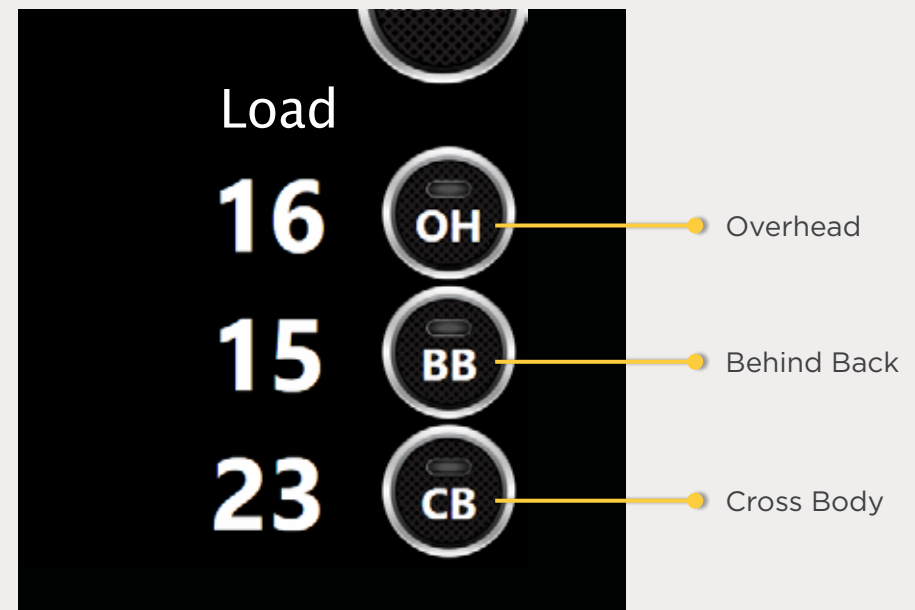
The VERASENSE Software Application for Shoulder shows EITHER the **Simple Capture Button** OR the **Position Capture Table**

▶ SIMPLE CAPTURE



- Shown when Position Capture Table isn't displayed.
- Captures screenshot when selected.

▶ POSITION CAPTURE



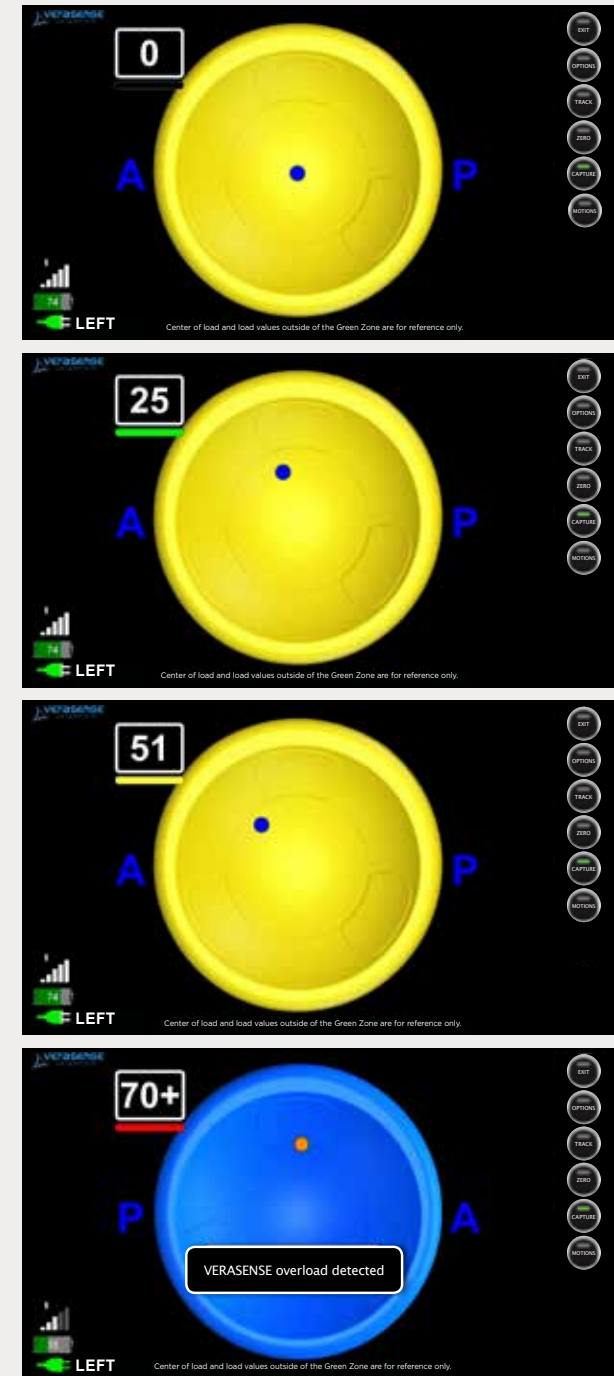
- Captures screenshot and records load data when **0, 45 and 90** **BUTTONS** are selected.

WHAT YOU NEED TO KNOW:

- ▶ Calibration Indicators are the color bar displays beneath the shoulder load range.
 - Indicate levels of VERASENSE for Exactech Equinox 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**. Load range outside of the GREEN ZONE are for reference only.
- ▶ VERASENSE Software Application for Shoulder displays 70+ and a **VERASENSE OVERLOAD** message when in the **RED ZONE**.

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

*Center of load and load range outside of the Green Zone are for reference only.

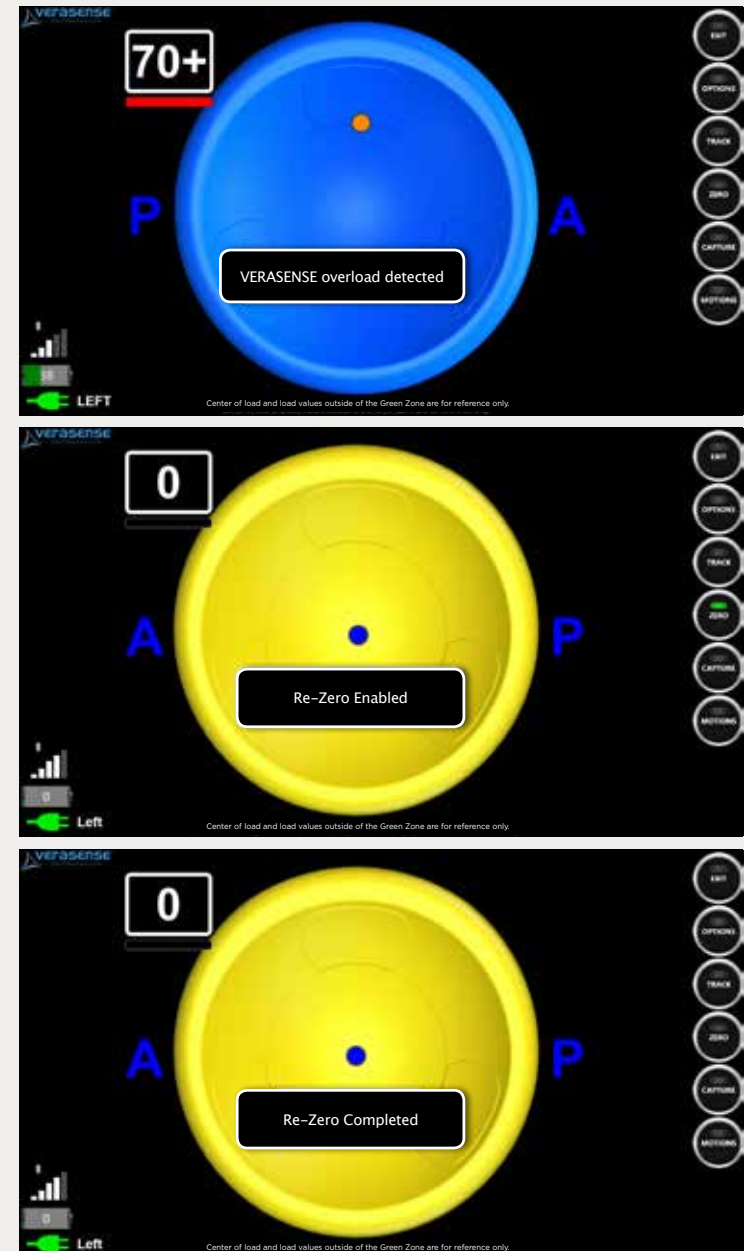


RE-ZEROING

If VERASENSE for Exactech Equinox experiences elevated loads, a re-zero calibration may be required for accurate load readings. A user can perform a re-zero as follows:

► MENU ZERO BUTTON

Remove loaded VERASENSE for Exactech Equinox and then press the Zero Button on the VERASENSE Software Application for Shoulder.



USING THE MOTION TRACKING FEATURE

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

► STEP 1

Select the Track Button on the VERASENSE Software Application for Shoulder to enable Kinetic Tracking.

► STEP 2

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

Press **Track** to turn on/off kinetic tracking



Kinetic Tracks are displayed as grey lines that trace contact point movement*

► NOTE

Center of Load trace color map can be modified in the option screen.

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

ASSESSING STABILITY

VERASENSE for Exactech Equinox quantifies the stability of the shoulder by measuring and recording the trace of the Center of Load and Maximum Load during prescribed motions. Motion traces are recorded for internal/external rotation of the humerus at 0, 45, & 90 degrees of abduction (elbow at 90 degrees flexion) as well as shoulder forward elevation.

ROTATIONAL STABILITY

STEP 1

Position the arm at the shown adduction angle, with the elbow bent to 90°.

STEP 2

With the arm in a neutral rotational position, press the angle trace button to begin the recording.

STEP 3

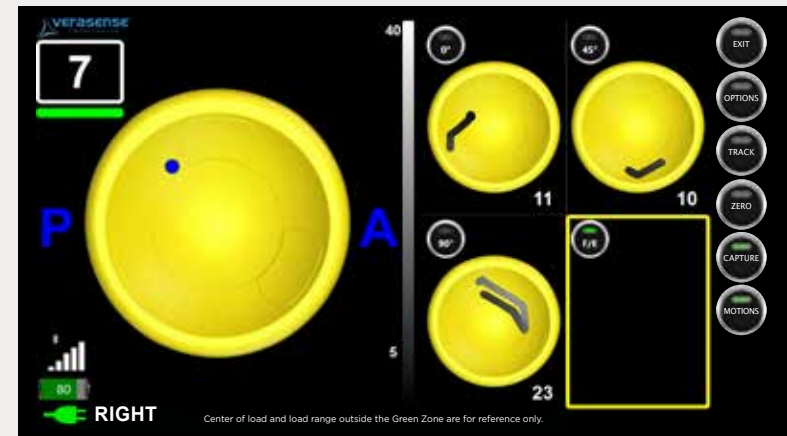
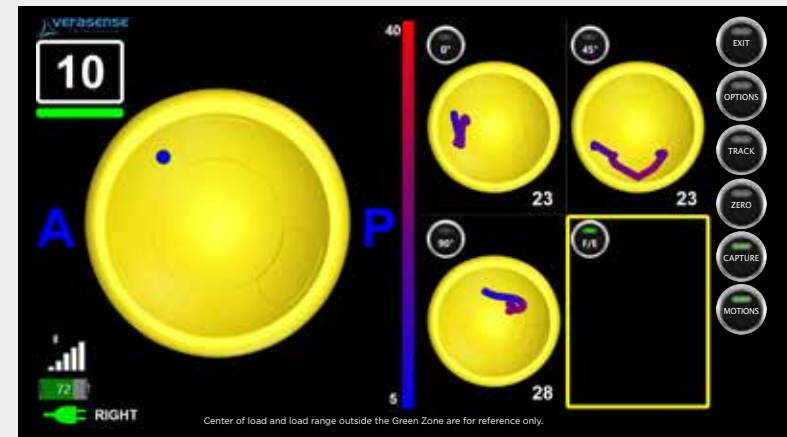
Slowly internally and externally rotate the arm to the limits of motion.

STEP 4

Return the arm to the neutral position and, press the angle trace button to end the recording. The system will advance to the next position automatically.

FORWARD ELEVATION STABILITY

- Repeat steps 2-4 but with the arm moving from flexion to extension.



Any test can be repeated by selecting the trace image and repeating steps.

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

VERASENSE FOR EXACTECH EQUINOXE SHUT DOWN

► STEP 1

To turn off VERASENSE for Exactech Equinox when the procedure is complete, press the **EXIT** button in the top right corner of the Active Monitoring screen.

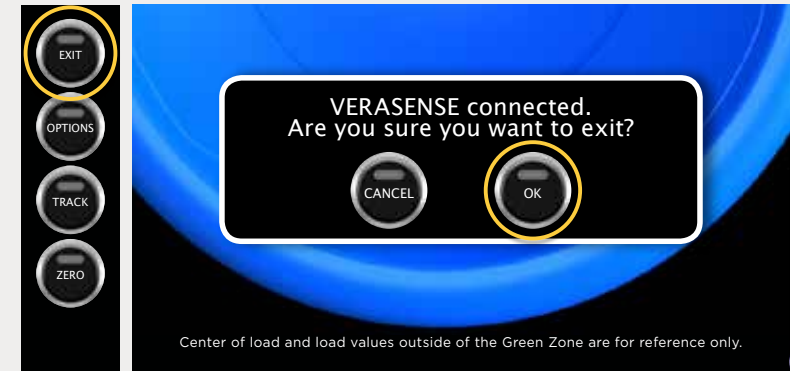
► STEP 2

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

► NOTE

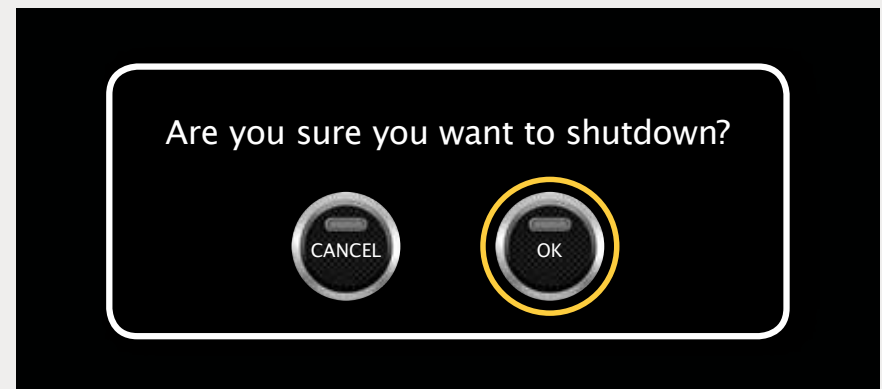
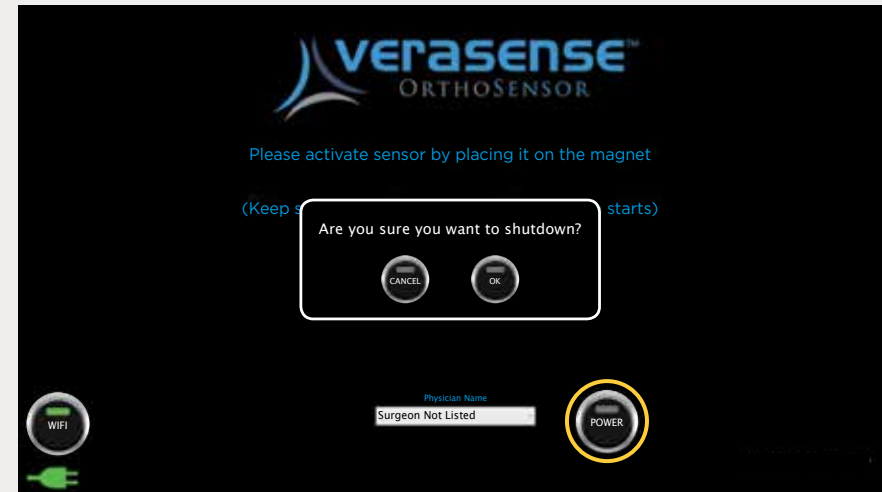
The VERASENSE for Exactech Equinox will communicate via Bluetooth to power the device down. If communication can no longer be achieved, the “VERASENSE shutdown failed” box will open. Select **EXIT HOME SCREEN** to exit the VERASENSE Software Application for Shoulder.

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



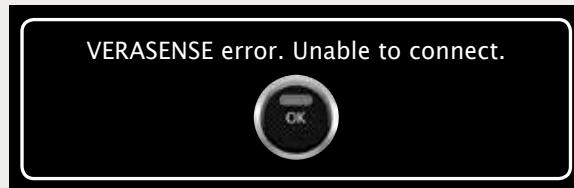
LINKSTATION MINI AND LINKSTATION MINI EVALUATION KIT SHUTDOWN

- ▶ After the procedure is complete and VERASENSE for Exactech Equinox 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.



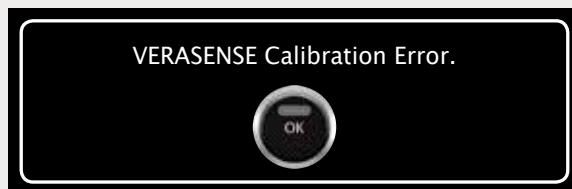
▶ VERASENSE ERROR - UNABLE TO CONNECT

Error during the initial connection with starting VERASENSE for Exactech Equinox. Typically due to VERASENSE power loss during connection.



▶ VERASENSE CALIBRATION ERROR

This message will appear if a VERASENSE Software Application for Shoulder error has occurred during the initial VERASENSE for Exactech Equinox calibration while on the Active Monitoring Screen.



▶ VERASENSE CALIBRATION TIMEOUT

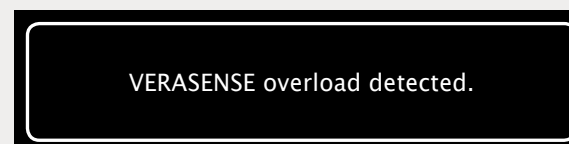
This message will appear if a calibration error occurs during Activation of VERASENSE for Exactech Equinox.

- Select **RECALIBRATE** to have the VERASENSE Software Application for Shoulder recalibrate VERASENSE for Exactech Equinox prior to moving to the Active Monitoring Screen.
- Select **SHUT DOWN VERASENSE** to shut down the current VERASENSE for Exactech Equinox and to exit to the VERASENSE Software Application for Shoulder Home Screen.



▶ VERASENSE OVERLOAD DETECTED

VERASENSE for Exactech Equinox overload condition in loads exceed 70lbf. Re-Zero should be performed.



▶ ACTIVE VERASENSE FOUND

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

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



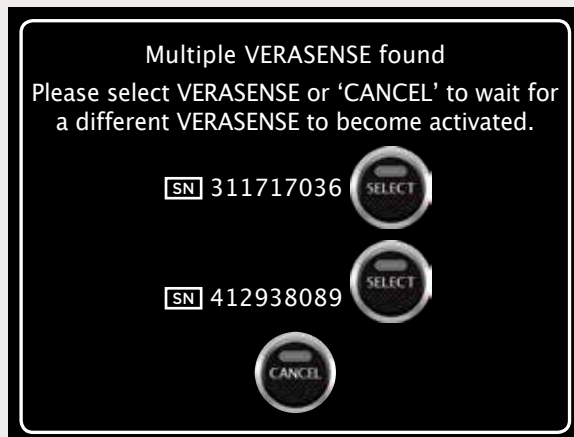
▶ VERASENSE SEARCH - ERROR

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



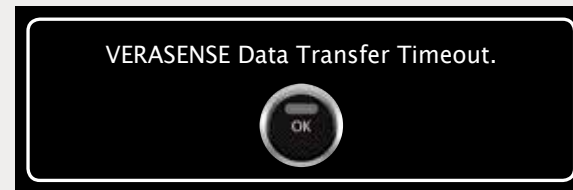
▶ MULTIPLE VERASENSE FOUND

VERASENSE for Exactech Equinox selection message when multiple VERASENSE for Exactech Equinox sensors are active. Choose desired VERASENSE for Exactech Equinox by serial number (SN) listed on box.



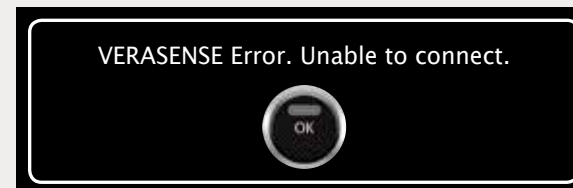
▶ VERASENSE DATA TIMEOUT

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



▶ VERASENSE ERROR - UNABLE TO CONNECT

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



▶ VERASENSE SHUTDOWN FAILED

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



TROUBLESHOOTING

▶ VERASENSE

If VERASENSE for Exactech Equinox light does not turn off during activation:

- Return the VERASENSE for Exactech Equinox to the activation magnet to complete the activation sequence.

If VERASENSE for Exactech Equinox is showing no load values in the shoulder, or load values are being shown when it has been removed from the shoulder and no load is being applied:

- Re-Zero VERASENSE for Exactech Equinox.

▶ 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.

Bluetooth Communication:

- 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.

► TRANSCIVER

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

The diagram illustrates the navigation flow for the Options Menu on the OrthoSensor VERASENSE interface. It consists of two panels. The left panel shows a vertical stack of buttons: EXIT, OPTIONS (highlighted with a yellow circle), TRACK, ZERO, and CAPTURE. A yellow line connects the OPTIONS button to the right panel. The right panel is a sub-menu with a yellow border, containing buttons: LEFT, POSITION CAPTURE, IQ, INFO, MANUALS, and CLOSE. Yellow lines connect each of these buttons to descriptive text on the right. Below the right panel, a screenshot of the 'Side: Left' information screen is shown, featuring an OK button.

- EXIT
- OPTIONS
- TRACK
- ZERO
- CAPTURE

- LEFT
- POSITION CAPTURE
- IQ
- INFO
- MANUALS
- CLOSE

Left/Right Shoulder Selection

Open/Close the 0/45/90 Position Capture Table

Open OrthoLogIQ* Web Portal

Open VERASENSE for Exactech Equinox Information Panel

Open VERASENSE for Exactech Equinox User Manuals

Side: Left
Device ID: 512193013
Device Type: OrthoSensor VERASENSE

OK

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.

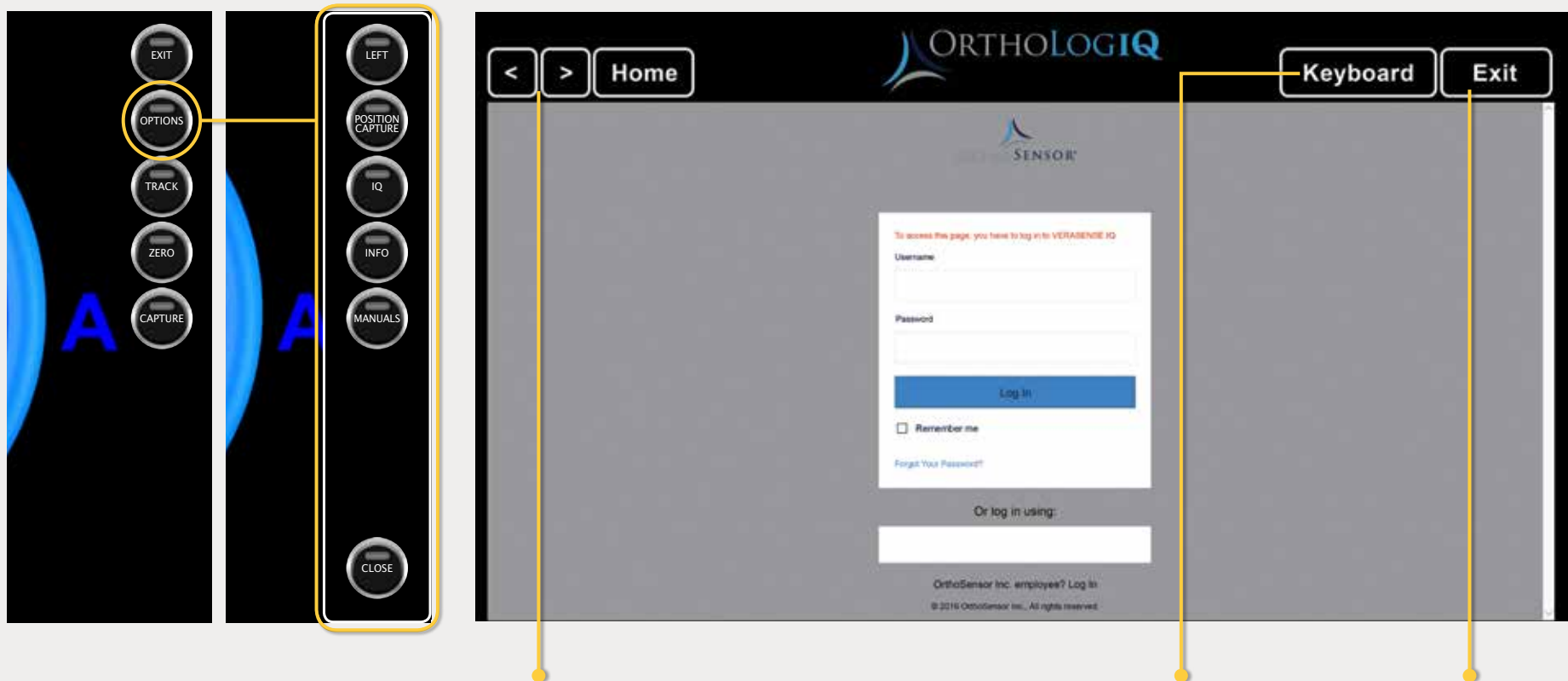
DISPLAY AVAILABLE MANUALS

Exit to VERASENSE Active Monitoring Screen

Page Up / Page Down Buttons

Opens & Displays the appropriate manual when selected.

ORTHOLOGIQ MODE (“IQ MODE”)



Browser Controls

- ▶ Back/Forward
- Home

Open/Close
Digital
Keyboard

Exit to VERASENSE
Software Application
for Shoulder

- ▶ 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 for Shoulder:

GREEN = WIFI Connected

RED = WIFI Not Connected

▶ STEP 1

Select the WIFI button to connect the VERASENSE Software Application for Shoulder 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.

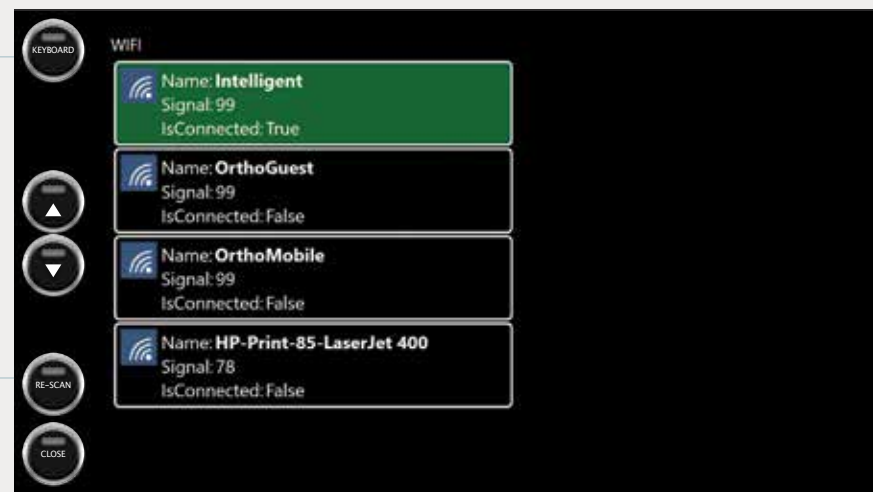
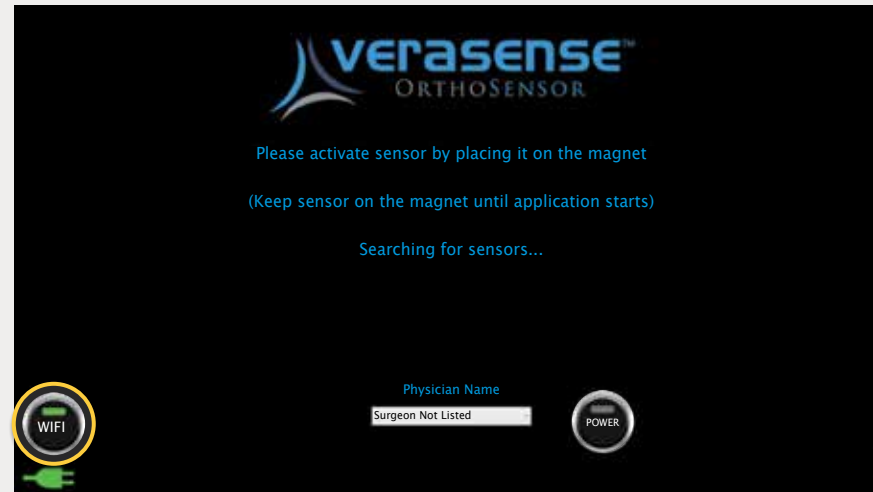
▶ STEP 2

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.

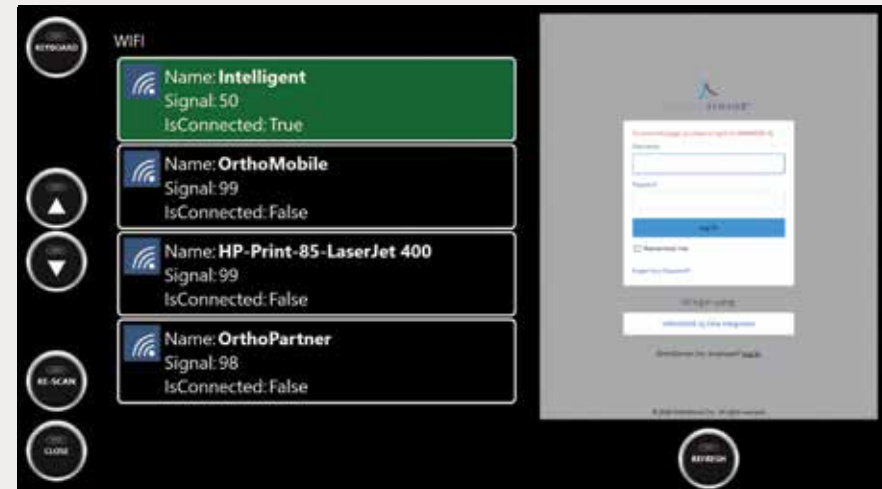
NOTE: If the WIFI network does not have a Network Security Key, select the **CONNECT** button to proceed.



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 for Shoulder 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 for Exactech Equinox has been shutdown.



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

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This image shows a single sheet of white paper with horizontal blue ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.



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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		VERASENSE for Exactech Equinox
IN STORAGE		LinkStation MINI & LinkStation MINI Eval. Kit
		VERASENSE for Exactech Equinox
RELATIVE HUMIDITY IN OPERATION		LinkStation MINI & LinkStation MINI Eval. Kit
		VERASENSE for Exactech Equinox
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