OrthoSensor, Inc.
1855 Griffin Road
Suite A-310
Dania Beach, FL 33004-2200 USA
www.orthosensor.com

VERASENSE FOR EXACTECH EQUINOXE
INSTRUCTIONS FOR USE

DESCRIPTION

VERASENSE for Exactech Equinoxe provides orthopedic surgeons a tool to measure load and location for adjustment of humeral shoulder implants during total shoulder arthroplasty (rTSA). This device does not make a diagnosis and is not intended to replace a surgeon's clinical judgment.

The VERASENSE for Exactech Equinoxe device is an intelligent disposable humeral insert trial that measures dynamic loads on the humoral shoulder and wirelessly transmits the measured load data to the LinkStation MINI and LinkStation MINI Evaluation Kit with VERASENSE Software Application for Shoulder (VSA-S) installed for surgeon visualization. Individual VERASENSE for Exactech Equinoxe devices are packaged sterile, for single patient use with a shim set for thickness adjustments.

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

- LinkStation MINI or LinkStation MINI Evaluation Kit
- VERASENSE Software Application for Shoulder (VSA-S)

The LinkStation MINI and LinkStation MINI Evaluation Kit displays the measured load data by providing a graphical and numerical presentation of the loads on the humoral insert.

INDICATIONS

The VERASENSE for Exactech Equinoxe is for any medical condition in which reverse Total Shoulder Arthroplasty (rTSA) would be indicated.

For use as a tool for measuring load magnitude and location for adjustment of the humeral shoulder implant. The device does not make a diagnosis and is not intended to replace a surgeon's clinical judgement. The VERASENSE for Exactech Equinoxe is sterile, for single patient use.

CONTRAINDICATIONS

- Any active or suspected latent infection in or about the shoulder joint.
- Refer to Implant Shoulder System IFU for additional contraindications.

PRECAUTIONS

- Read and follow instructions for proper use and interpretation of force data displayed.
- Strict adherence to the indications, contraindications, precautions and user/patient safety for this product is essential.
- Refer to appropriate implant shoulder system IFU for additional precautions.
- Data from VERASENSE for Exactech Equinoxe is for reference purposes only and should not be the sole basis for surgical decisions.
- The internal components of the VERASENSE for Exactech Equinoxe are non-sterile. Immediately discontinue use of device if any cracks, damage, or internal fluid is observed. Failure to observe these warnings may expose patient to non-sterile material.
- The VERASENSE for Exactech Equinoxe consists of sophisticated calibrated internal microelectronics. Do NOT directly impact with mallet or other instruments at any time.
- Handle VERASENSE for Exactech Equinoxe with care when inserting, adjusting shim size or removing from humeral trial tray.
- Do not forcibly impact implant trial onto the VERASENSE for Exactech Equinoxe placed in the humeral tray.
- Do not attempt to use the VERASENSE for Exactech Equinoxe without selection and use of proper shim and appropriate sized humeral tray.
- When detaching a shim from the VERASENSE for Exactech Equinoxe, detach proximal lip first, do not pry off distal edge.
- Federal law restricts this device to sale by or on the order of a licensed physician.

For further information, contact the OrthoSensor Customer Service Center by phone at + 1 954-577-7770 or by e-mail at customerservice@orthosensor.com or go to www.orthosensor.com.

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USER/PATIENT SAFETY

- VERASENSE for Exactech Equinoxe and shim sets are supplied as single-use sterile. Do not reuse or re-sterilize.
- If VERASENSE for Exactech Equinoxe or shim set packaging is open or damaged, do not use and immediately return to OrthoSensor.
- Do not use VERASENSE for Exactech Equinoxe after the expiration date on the package labeling.
- Do not use the VERASENSE for Exactech Equinoxe without a shim attached.
- The measurement load range of the VERASENSE for Exactech Equinoxe is 5 to 40 lbf, with a load accuracy of ±3.5 lbf.
- Maximum allowable load for the VERASENSE for Exactech Equinoxe is 70 lbf. If the physician perceives a difference between the loads displayed on the screen and the physical feel, the physician should either replace the device or continue the procedure using their standard instrumented trial technique and best clinical judgment.

  Note: *Load values between 41-70 lbf are displayed for reference only.*
- Do not impact / hit the VERASENSE for Exactech Equinoxe or any objects in contact with the device as this may result in damage to its exterior casing.
- Do not use a prying device during surgical procedure while the VERASENSE for Exactech Equinoxe is in place as this may result in damage to the exterior of the device.
- The VERASENSE for Exactech Equinoxe device contains non-sterile, non-medical grade internal components. If the device housing is damaged or cracked during the procedure, take appropriate steps to promote patient safety.
- Do not disassemble or otherwise modify the VERASENSE for Exactech Equinoxe or shims.
- Do not use VERASENSE for Exactech Equinoxe device if it appears to be functioning improperly.
- Observe all warnings generated by the VERASENSE Software Application for Shoulder.

INSTRUCTIONS

1. Confirm the LinkStation MINI or LinkStation MINI Evaluation Kit is setup appropriately outside of the sterile field. Refer to the VERASENSE for Exactech Equinoxe User Guide. The LinkStation MINI or LinkStation MINI Evaluation Kit is located outside of the sterile field and the VERASENSE for Exactech Equinoxe device and shims are used within the sterile field.
2. Determine the specific implant type and size VERASENSE for Exactech Equinoxe required. Remove pouched Shims and device from the box. DO NOT OPEN THE POUCH SEAL.
    a. Do not use if device or shim set packaging has been opened or damaged.
3. Record device serial number (SN) onto patient and hospital records as required.
4. To activate the VERASENSE for Exactech Equinoxe:
    a. With the product still in the sealed pouches, place the device directly over the magnet on LinkStation MINI or LinkStation MINI Evaluation Kit. An LED light will illuminate on the device. Do not move the device until you observe the following:
        i. LED turns off after approximately four (4) seconds.
        ii. VERASENSE Software Application for Shoulder launches.
        iii. Initialization progress bar appears and completes.
        iv. Prompt to select left or right shoulder appears.
    b. Device may now be removed from magnet.
5. The VERASENSE Software Application for Shoulder will automatically prompt selection of left or right shoulder. Select the appropriate operative shoulder.
6. Zero Device
    a. Follow on screen instructions to zero the device.
7. Upon completion of the device initiation process as prompted on the VERASENSE Software Application for Shoulder, pass the sealed pouch to the nurses within the sterile field of the operating room.
8. Open double sealed pouch per hospital protocol (VERASENSE for Exactech Equinoxe and shim set).
9. With the VERASENSE for Exactech Equinoxe and shims removed from the pouch, apply designated shim to underside of the device.

    Note*: The VERASENSE for Exactech Equinoxe shim attaches to the bottom of the device. Attach by inserting the device's distal end into the shim, matching the sensor base geometry, then engage the proximal end snapping mechanism by squeezing the assembly together.*

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Note: *The 0mm or 2.5mm shim must be attached to the device prior to insertion into the humeral component.*

10. To remove the shim, or exchange for another size, simply unsnap the proximal lip of the attached shim and replace.
11. With the VERASENSE for Exactech Equinoxe and shim attached, physician should manually compress / apply load to the device and verify the response on the User Interface prior to placing VERASENSE for Exactech Equinoxe into the humeral tray.
12. Place the VERASENSE for Exactech Equinoxe within humeral tray.
13. Confirm that the VERASENSE for Exactech Equinoxe with shim is fully seated when placed in the humeral tray.
14. Flex the joint throughout its full range of motion to ensure appropriate response on the User Interface.
15. Proceed with rTSA process per physician / hospital protocol.

    Note: *If maximum allowable load of 70 lbf is reached, the VERASENSE for Exactech Equinoxe must be removed from the shoulder joint and "re-zeroed" by pressing the Re-Zero button from the VERASENSE Software Application for Shoulder, Re-Zero enabled will appear on the VERASENSE Software Application for Shoulder, followed by Re-Zero Complete indicating that VERASENSE for Exactech Equinoxe has been reset to zero*.
16. Upon completion of the procedure, deactivate the VERASENSE Software Application for Shoulder by pressing the Exit Button on the User Interface.
17. Dispose of the VERASENSE for Exactech Equinoxe per institutional guidelines for biohazardous medical waste.

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VERASENSE FOR EXACTECH EQUINOXE TROUBLESHOOTING

Table 1		
Issue	**Cause**	**Solution**
VERASENSE for Exactech Equinoxe LED does not light up	VERASENSE for Exactech Equinoxe batteries are dead	Discard VERASENSE for Exactech Equinoxe and replace
VERASENSE for Exactech Equinoxe not transmitting data to LinkStation MINI or LinkStation MINI Evaluation Kit	VERASENSE for Exactech Equinoxe is out of wireless range	Move LinkStation MINI or LinkStation MINI Evaluation Kit closer to VERASENSE for Exactech Equinoxe
		Move LinkStation MINI or LinkStation MINI Evaluation Kit to achieve an unobstructed line-of-sight to the VERASENSE for Exactech Equinoxe field of use
	VERASENSE for Exactech Equinoxe is powered off	Activate with LinkStation MINI or LinkStation MINI Evaluation Kit magnet
	VERASENSE for Exactech Equinoxe device batteries are low	Discard VERASENSE for Exactech Equinoxe and replace
VERASENSE for Exactech Equinoxe breakage	VERASENSE for Exactech Equinoxe applied load is beyond limit	VERASENSE for Exactech Equinoxe internal components are non-sterile and non-medical grade. Ensure patient safety. Discard device and replace.
Lag in reported data	Software latency	Maintain shoulder position until data settles (approximately 5 seconds)

***Note**: Should any of the issues above arise please contact OrthoSensor Customer service at + 1 954-577-7770 for return or replacement assistance.*

DECONTAMINATION OF PRODUCT RETURNED FOR COMPLAINT INVESTIGATION

This section applies to all VERASENSE for Exactech Equinoxe devices intended to be returned for complaint investigations. Any device that has been opened/removed from sterile packaging and exposed to biohazardous material must be sent to central processing within the hospital for decontamination according to this procedure prior to transport to OrthoSensor. The following guidelines have been proven effective for cleaning VERASENSE for Exactech Equinoxe devices but are not guaranteed to result in a safe handling environment or sterilized devices.

***Note:** Should a device be clearly marked as having been used on a patient with HIV or infectious disease of equivalent risk, the device must not be decontaminated but rather documented and destroyed.*

Decontamination Procedure:

1. Create cleaning solution in labeled cleaning container by combining 2 ounces (59 mL) of ENZOL Enzymatic detergent (or equivalent*) per gallon (3.8 L) of warm water.
2. Soak device(s) for 5 minutes. If necessary, use brush to clean any dried-on material.
3. Thoroughly rinse device(s) with clean running water. Dry device(s) and place on clean absorbent pad.
4. Fill labeled disinfection container with enough Cidex OPA solution (or equivalent*) to cover device(s) completely.
5. Immerse device(s) in solution and soak for 15 minutes. Ensure that all devices are 100% covered by the solution.
6. Remove device(s) and rinse for at least one minute with a large volume of clean water. Dry device(s) and place decontaminated parts on clean absorbent pad.

*If equivalent agent is used, it is recommended to follow manufacturer's instructions for creating cleaning and disinfectant solutions. Once this procedure has been carried out, devices may be packaged in the enclosed return envelope and transported per instructions on return envelope.

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VERASENSE FOR EXACTECH EQUINOXE DEVICE SPECIFICATIONS

This 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.

The VERASENSE for Exactech Equinoxe complies with Part 95 of the FCC rules. This device does not interfere with stations operating in the 2402-2480 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.

Modification of this device may void the user's authority to operate the equipment under the FCC rules above.

This equipment has been tested and found to comply with IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

This equipment has been tested and found to comply with the EMC limits for the Medical Device Directive 93/42/EEC (EN 60601-1-2). No essential performance was identified and tested. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates and uses radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, 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 device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) is connected.
- Consult OrthoSensor for help.

For additional safety information, see Table 4 which documents the EMC compliance levels of VERASENSE for Exactech Equinoxe.

VERASENSE for Exactech Equinoxe is intended for use in a professional healthcare facility environment.

> ***Note:*** The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to make mitigation measures, such as relocating or re-orienting the equipment.

ADDITIONAL WARNINGS

- Only use the accessories supplied with the LinkStation MINI or LinkStation MINI Evaluation Kit. This includes the USB cable, power cord, mounting fixtures, etc.
- Do not power the transceiver from any device other than the provided LinkStation MINI or LinkStation MINI Evaluation Kit.
- Do not connect any other devices to the display unit input/output ports other than those supplied with the LinkStation MINI or LinkStation MINI Evaluation Kit.
- WARNING: No modification of this equipment is allowed.
- Modification is only allowed by the manufacturer of this equipment.
- WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no close than 30 cm to any part of the VERASENSE for Exactech Equinoxe and accessories, including cables specified by the manufacturer. Otherwise, degradation of performance of this equipment could result.
- Transceiver cleaning and disinfection instructions: wipe transceiver down with 70% isopropyl alcohol wipes after each use.

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IEC 60601-1 Medical Electrical Equipment Classification for Protection Against Electrical Shock

Sensor: Internally powered (3.1 V dc)

VERASENSE for Exactech Equinoxe Devices: Internally powered by Energizer 362/361 battery

LinkStation MINI / LinkStation MINI Evaluation Kit:

T**ransceiver:** Class II USB powered and intended to be connected to the USB port of the LinkStation MINI display unit (5 V dc)

Display Unit: Class III (65W universal 3-pin jack, 100-240V, 1.5A, 50-60Hz)

EQUIPMENT NOT SUITABLE FOR USE IN THE PRESENCE OF A FLAMMABLE ANAESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR CONTINUOUS FLOW OF NITROUS OXIDE.

CONTINUOUS OPERATION WITH SHORT-TIME LOADING.

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Table 2 – Symbols		
Type:	Do not re-sterilize	
	Single Procedure use / Do not re-use	
Prescription:	By Prescription Only	
Sterility:	Sterilized using ethylene oxide	
Manufacturer:	OrthoSensor, Inc. 1855 Griffin Road Suite A-310 Dania Beach, FL 33004-2200 USA	
Date of Manufacture:		
Made in USA		
Device Type:	Type BF (sensor only)	
Caution:		
Use:	Do not use if package is damaged	
	Non-pyrogenic	
	Non-ionizing Radiation	
	Ingress Protection Rating	
	Consult User Guide	
	Bluetooth® Symbol	
Shelf Life:	Use-by date	
Identification:	Batch Code	
	Serial number	
	Quantity	
	Catalog number	
Authorized Representative in the European Community	Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	
Australia Sponsor	PharmaDev Consulting Pty Ltd. Level 12 95 Pitt Street	

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	Sydney NSW 2000 Australia				
New Zealand Sponsor	PharmaDev Consulting Pty Ltd. Level 10 21 Queen Street Auckland 1010 New Zealand				
CE Mark and Notified Body Number	CE 0297				
	Model	FCC ID	Frequency band	Modulation	EIRP
FCC ID:	Transceiver	XNL-ORTHOSNSR3	401.05-405.55 MHz	GFSK	N/A
	VERASENSE for Exactech Equinoxe	XNL-ORTHOSNSR8	2402 - 2480 MHz	GFSK	6.1 µW
Operating Range:	6.5 ft [2m] Unobstructed				
Power Supply:	Internally powered at less than 3.3 VDC				
Battery Life:	40 minutes (approximate)				
Temperature Limit:	**Operation**	37°C 15°C	**Storage**	50°C 0°C	
Relative Humidity:		100%, submersion 30%		80%, non-condensing 10%	
Atmospheric Pressure:		106 kPa 47 kPa		106 kPa 36 kPa	

Table 3 – Catalog Numbers

VERASENSE Device Model	VERASENSE Catalog Number	Size	Compatible Implant System Catalog Number
VERASENSE for Exactech Equinoxe	EXC-EQRV38	38	320-38-00, 320-38-03, 321-38-00, 321-38-03
	EXC-EQRV42	42	320-42-00, 320-42-03, 321-42-00, 321-42-03

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Table 4 - Guidance and manufacturer's declaration – Electromagnetic Immunity and Emissions	
The VERASENSE for Exactech Equinoxe and accessories have been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices to IEC 60601-1-2:2014.	
Emissions/Immunity Test	**Compliance Level**
RF Emissions CISPR 11	Class A, Group 1
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact discharge ± 2, 4, 8 & 15kV air discharge
Radiated RF Immunity IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% at 1 kHz
Immunity to Proximity Fields from RF wireless communication equipment IEC 61000-4-3	28 V/m
Conducted Immunity IEC 61000-4-6	0.15 - 80 MHz 3 Vrms & 6Vrms in ISM Band 1 kHz, AC Mains
Electrical fast transient/burst IEC 61000-4-4	± 2 kV AC Mains 5kHz & 100 kHz
Magnetic Immunity IEC 61000-4-8	30 A/m
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T .5 cycle 0% U_T 1 cycle 70% U_T 25 cycles 0% U_T 5 Sec

ORTHOSENSOR

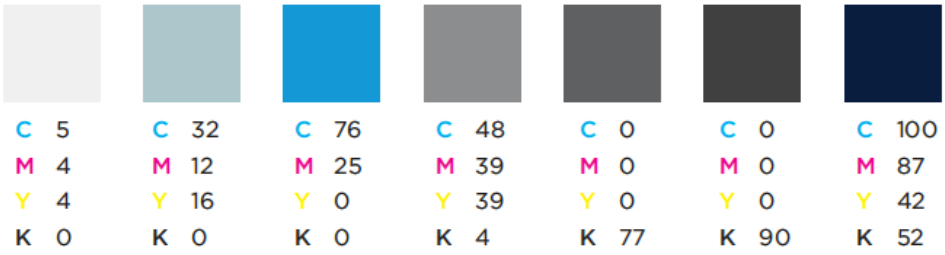
FOR REFERENCE ONLY

Material: White, 24# Paper

Measurements: 8.5” x 11”

Specs: 4/4 CMYK
Double sided print; letters out
Trim, staple upper left corner and fold to 5.5” x 8.5”

Process Colors:



C 5	C 32	C 76	C 48	C 0	C 0	C 100
M 4	M 12	M 25	M 39	M 0	M 0	M 87
Y 4	Y 16	Y 0	Y 39	Y 0	Y 0	Y 42
K 0	K 0	K 0	K 4	K 77	K 90	K 52