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

VERASENSE INSTRUCTIONS FOR USE

DESCRIPTION

VERASENSE provides a means to dynamically balance the knee during primary or revision Total Knee Arthroplasty (TKA).

The VERASENSE device is an intelligent disposable tibial insert that measures dynamic loads in the medial and lateral compartments of the knee and wirelessly transmits the measured load data to the LinkStation MINI or LinkStation MINI Evaluation Kit with VERASENSE Software Application (VSA) installed for surgeon visualization. Individual VERASENSE 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 device:

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

The LinkStation MINI and LinkStation MINI Evaluation Kit displays the measured load data by providing a graphical and numerical presentation of the loads in both the medial and lateral compartments of the knee.

VERASENSE devices are implant system specific due to variations in implant design. VERASENSE is compatible with the following implant systems:

- VERASENSE for Biomet Vanguard
- VERASENSE for Stryker Triathlon
- VERASENSE for Zimmer NexGen
- VERASENSE for Smith & Nephew Legion
- VERASENSE for Smith & Nephew Journey II
- VERASENSE for Zimmer Biomet Persona

Please see Table 3 for the listing of Catalog Numbers for each compatible implant system and sizes.

INDICATIONS

VERASENSE is indicated for any medical condition in which primary or revision Total Knee Arthroplasty (TKA) would be indicated.

For use as a tool for adjustment of the femoral knee implant to reduce instability from flexion gap asymmetry. VERASENSE is sterile, for single patient use.

CONTRAINDICATIONS

- Any active or suspected latent infection in or about the knee joint.
- Refer to Implant Knee 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 knee system IFU for additional precautions.
- Data from VERASENSE is for reference purposes only and should not be the sole basis for surgical decisions.
- The internal components of the VERASENSE device 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 device consists of sophisticated calibrated internal microelectronics. Do NOT directly impact with mallet or other instruments at any time.

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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- Handle VERASENSE device with care when inserting, adjusting shim size or removing from tibial tray.
- Do not forcibly impact femoral implant trial onto the VERASENSE device placed in tibial tray.
- Do not attempt to use the VERASENSE device without selection and use of proper shim and appropriate sized tibial tray.
- When detaching a shim from the VERASENSE device, detach anterior lip first, do not pry off posterior edge.
    - Note: For the VERASENSE for Zimmer Biomet Persona, detach shim by prying on the posterior edge.
- Federal law restricts this device to sale by or on the order of a licensed physician.

USER/PATIENT SAFETY

- VERASENSE device and shim sets are supplied as single-use sterile. Do not reuse or re-sterilize.
- If VERASENSE device or shim set packaging is open or damaged, do not use and immediately return to OrthoSensor.
- Do not use VERASENSE device after the expiration date on the package labeling.
- Do not use the VERASENSE device without a shim attached in the tibial tray for the VERASENSE for Stryker Triathlon Sizes 3-6, VERASENSE for Biomet Vanguard, or VERASENSE for Zimmer Biomet Persona devices.
- Maximum allowable load for the VERASENSE device is 70 lbf per compartment. 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 device 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 device is in place as this may result in damage to the exterior of the device.
- The VERASENSE 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 device or shims.
- Do not use VERASENSE device if it appears to be functioning improperly.
- Observe all warnings generated by the VERASENSE Software Application.

Model	Measurement Load Range	Load Accuracy
VERASENSE for Biomet Vanguard	5-40 lbf per compartment	±3.5 lbf
VERASENSE for Stryker Triathlon		
VERASENSE for Zimmer NexGen		
VERASENSE for Smith & Nephew Legion		
VERASENSE for Smith & Nephew Journey II		
VERASENSE for Zimmer Biomet Persona		

INSTRUCTIONS

1. Confirm the LinkStation MINI or LinkStation MINI Evaluation Kit is setup appropriately outside of the sterile field. Refer to the VERASENSE User Guide or VERASENSE Quick Reference Guides. The LinkStation MINI or LinkStation MINI Evaluation Kit is located outside of the sterile field and the VERASENSE device and shims are used within the sterile field.
2. Determine the specific implant type and size VERASENSE device required. Remove pouched Shims and device from the box. DO NOT OPEN POUCH SEALS.
    a. Do not use if device or shim set packaging has been opened or damaged.
3. Record VERASENSE device serial number (SN) onto patient and hospital records as required.
4. To activate the VERASENSE device:
    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 launches.
        iii. Initialization progress bar appears and completes.

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iv. Prompt to select left or right leg appears.

b. Device may now be removed from magnet.

5. The VERASENSE Software Application will automatically prompt selection of left or right leg. Select the appropriate operative leg.
6. Zero Device
   a. Follow on screen instructions to zero the VERASENSE device.
7. Upon completion of the device initiation process as prompted on the VERASENSE Software Application, pass the sealed pouches to the nurses within the sterile field of the operating room.
8. Open double sealed pouches per hospital protocol (VERASENSE device and shim set).
9. With the VERASENSE device and shims removed from the pouches, apply designated shim to underside of VERASENSE device.

   Note: The VERASENSE for Zimmer Biomet Persona device shim attaches to the top of the device. Attach by inserting the devices anterior tab into the anterior loop on the shim, engage the posterior snapping mechanism by squeezing the assembly together. Input the selected shim thickness within the VERASENSE Software Application.

   Note: Once the product is removed from the pouch, the application of the initial shim, if applicable, relates to devices without mounted shims (VERASENSE for Stryker Triathlon Sizes 2 & 7, VERASENSE for Zimmer NexGen, VERASENSE for Smith & Nephew Journey II, and VERASENSE for Smith & Nephew Legion). Apply desired shim to all VERASENSE for Stryker Triathlon 3-6, VERASENSE for Biomet Vanguard, and VERASENSE for Zimmer Biomet Persona devices prior to use.
10. To remove the shim, or exchange for another size, simply unsnap the anterior lip of the attached shim and replace.

    Note: VERASENSE for Zimmer Biomet Persona shim is removed by distracting the posterior aspect of the device from shim. This releases the posterior snapping mechanism.
11. With the VERASENSE device and shim attached, physician should manually compress / apply load to the device and verify the response on the User Interface prior to placing VERASENSE device into the tibial tray.
12. Place VERASENSE within tibial tray.
13. Confirm that the VERASENSE device with shim is fully seated when placed in the tibial tray.
14. Flex the joint throughout its full range of motion to ensure appropriate response on the User Interface.
15. Proceed with TKA process per physician / hospital protocol.

    Note: If maximum allowable load of 70 lbf is reached in either compartment, the VERASENSE device must be removed from the knee joint and “re-zeroed” by holding VERASENSE with superior side (articulating surface) facing the floor for three (3) seconds, Re-Zero enabled will appear on the VERASENSE Software Application, followed by Re-Zero Complete indicating that VERASENSE has been reset to zero; or Re-Zero button from the VERASENSE Software Application by Pressing the Re-Zero button.
16. Upon completion of the procedure, deactivate the VERASENSE Software Application by pressing the Exit Button on the User Interface.
17. Dispose of the VERASENSE device per institutional guidelines for biohazardous medical waste.

    Note: VERASENSE for Zimmer Biomet Persona contains lithium batteries, thus special disposal instructions should be taken in the state of California, USA. The device cannot be incinerated.

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VERASENSE TROUBLESHOOTING

Table 1		
Issue	**Cause**	**Solution**
VERASENSE device LED does not light up	VERASENSE device batteries are dead	Discard VERASENSE device and replace
VERASENSE Device not transmitting data to LinkStation MINI or LinkStation MINI Evaluation Kit	VERASENSE device is out of wireless range	Move LinkStation MINI or LinkStation MINI Evaluation Kit closer to VERASENSE device
		Move LinkStation MINI or LinkStation MINI Evaluation Kit to achieve an unobstructed line-of-sight to the VERASENSE device field of use
	VERASENSE device is powered off	Activate with LinkStation MINI or LinkStation MINI Evaluation Kit magnet
	VERASENSE device batteries are low	Discard VERASENSE device and replace
VERASENSE device breakage	VERASENSE device applied load is beyond limit	VERASENSE device internal components are non-sterile and non-medical grade. Ensure patient safety. Discard device and replace.
Lag in reported data	Software latency	Maintain knee 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 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 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 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 Biomet Vanguard, Stryker Triathlon, Zimmer NexGen, Smith & Nephew Legion, and Smith & Nephew Journey II comply with Part 95 of the FCC rules. These devices may not interfere with stations operating in the 400.150–406.000 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.

The VERASENSE for Zimmer Biomet Persona 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 – Table 7 in the attachments section, which document the intended use environment and EMC compliance levels of VERASENSE.

VERASENSE is intended for use in the electromagnetic environment specified in this IFU.

ADDITIONAL WARNINGS

- Only use the accessories supplied with the VERASENSE. 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 VERASENSE.
- WARNING: No modification of this equipment is allowed.
- Modification is only allowed by the manufacturer of this equipment
- 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 Stryker Triathlon, Zimmer NexGen, Biomet Vanguard, Smith & Nephew Journey II, and Smith & Nephew Legion Devices: Internally Powered by Energizer 362/361 battery

VERASENSE for Zimmer Biomet Persona Devices: Internally powered by Renata CR1216 MFR FH 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	Regulatory and Marketing Services-UK, LTD 28 Trinity Road, Nailsea, Somerset BS48 4NU United Kingdom	
Australia Sponsor	PharmaDev Consulting Pty Ltd. Level 12 95 Pitt Street Sydney NSW 2000 Australia	

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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:	VERASENSE for Stryker Triathlon	XNL-ORTHOSNSR1	402.0 - 405.0 MHz	GFSK	1.83 nW
	VERASENSE for Biomet Vanguard	XNL-ORTHOSNSR2	404.3 - 404.3 MHz	GFSK	3.314 nW
	Transceiver	XNL-ORTHOSNSR3	401.05 - 405.55 MHz	GFSK	N/A
	VERASENSE for Zimmer NexGen	XNL-ORTHOSNSR5	404.3 - 404.3 MHz	GFSK	1.31 µW
	VERASENSE for Smith & Nephew Journey II				
	VERASENSE for Smith & Nephew Legion				
	VERASENSE for Zimmer Biomet Persona	XNL-ORTHOSNSR7	2402 - 2480 MHz	GFSK	1.26mW
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

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Table 3 – Catalog Numbers			
VERASENSE Device Model	**VERASENSE Catalog Number**	**Size**	**Compatible Implant System Catalog Number**
VERASENSE for Biomet Vanguard	BMT-VGCR 63	63/67	32-483720, 32-483722, 32-483724, 32-483726, 32-483728
	BMT-VGCR 71	71/75	32-483740, 32-483742, 32-483744, 32-483746, 32-483748
	BMT-VGCR 79	79/83	32-483760, 32-483762, 32-483764, 32-483766, 32-483768
	BMT-VGPS 63	63/67	32-483820, 32-483822, 32-483824, 32-483826, 32-483828
	BMT-VGPS 71	71/75	32-483840, 32-483842, 32-483844, 32-483846, 32-483848
	BMT-VGPS 79	79/83	32-483860, 32-483862, 32-483864, 32-483866, 32-483868
VERASENSE for Stryker Triathlon	SYK-TRCR 02	2	5530-T-209, 5530-T-211, 5530-T-213, 5530-T-216
	SYK-TRCR 03	3	5530-T-309, 5530-T-311, 5530-T-313, 5530-T-316
	SYK-TRCR 04	4	5530-T-409, 5530-T-411, 5530-T-413, 5530-T-416
	SYK-TRCR 05	5	5530-T-509, 5530-T-511, 5530-T-513, 5530-T-516
	SYK-TRCR 06	6	5530-T-609, 5530-T-611, 5530-T-613, 5530-T-616
	SYK-TRCR 07	7	5530-T-709, 5530-T-711, 5530-T-713, 5530-T-716
VERASENSE for Zimmer NexGen	ZMR-NGCRCH34	C-H/3-4	00-5971-030-10, 00-5971-030-12, 00-5971-030-14, 00-5971-030-17
	ZMR-NGCRCH56	C-H/5-6	00-5971-040-10, 00-5971-040-12, 00-5971-040-14, 00-5971-040-17
	ZMR-NGCRCH70	C-H/7-10	00-5971-050-10, 00-5971-050-12, 00-5971-050-14, 00-5971-050-17
	ZMR-NGPSCD34	C-D/3-4	00-5961-030-10, 00-5961-030-12, 00-5961-030-14, 00-5961-030-17
	ZMR-NGPSEF34	E-F/3-4	00-5961-032-10, 00-5961-032-12, 00-5961-032-14, 00-5961-032-17
	ZMR-NGPSEF56	E-F/5-6	00-5961-040-10, 00-5961-040-12, 00-5961-040-14, 00-5961-040-17
VERASENSE for Smith & Nephew Journey II	SNN-JRNYBCS12-L	1-2 Left	74027221, 74027222, 74027223, 74027224, 74027225
	SNN-JRNYBCS12-R	1-2 Right	74027211, 74027212, 74027213, 74027214, 74027215
	SNN-JRNYBCS34-L	3-4 Left	74027241, 74027242, 74027243, 74027244, 74027245
	SNN-JRNYBCS34-R	3-4 Right	74027231, 74027232, 74027233, 74027234, 74027235
	SNN-JRNYBCS56-L	5-6 Left	74027261, 74027262, 74027263, 74027264, 74027265
	SNN-JRNYBCS56-R	5-6 Right	74027251, 74027252, 74027253, 74027254, 74027255
	SNN-JRNYBCS78-L	7-8 Left	74027281, 74027282, 74027283, 74027284, 74027285
	SNN-JRNYBCS78-R	7-8 Right	74027271, 74027272, 74027273, 74027274, 74027275
	SNN-JRNYCR12-L	1-2 Left	74025621, 74025622, 74025623, 74025624, 74025625
	SNN-JRNYCR12-R	1-2 Right	74025611, 74025612, 74025613, 74025614, 74025615
	SNN-JRNYCR34-L	3-4 Left	74025641, 74025642, 74025643, 74025644, 74025645
	SNN-JRNYCR34-R	3-4 Right	74025631, 74025632, 74025633, 74025634, 74025635
	SNN-JRNYCR56-L	5-6 Left	74025661, 74025662, 74025663, 74025664, 74025665
	SNN-JRNYCR56-R	5-6 Right	74025651, 74025652, 74025653, 74025654, 74025655
	SNN-JRNYCR78-L	7-8 Left	74025681, 74025682, 74025683, 74025684, 74025685
	SNN-JRNYCR78-R	7-8 Right	74025671, 74025672, 74025673, 74025674, 74025675
VERASENSE for Smith & Nephew Legion	SNN-LGNPS12	1-2	71453201, 71453171, 71453202, 71453172, 71453203
	SNN-LGNPS34	3-4	71453211, 71453173, 71453212, 71453174, 71453213
	SNN-LGNPS56	5-6	71453221, 71453175, 71453222, 71453176, 71453223
	SNN-LGNPS78	7-8	71453231, 71453177, 71453232, 71453178, 71453233
	SNN-LGNCR12	1-2	71453101, 71453181, 71453102, 71453182, 71453103
	SNN-LGNCR34	3-4	71453111, 71453183, 71453112, 71453184, 71453113
	SNN-LGNCR56	5-6	71453121, 71453185, 71453122, 71453186, 71453123
	SNN-LGNCR78	7-8	71453131, 71453187, 71453132, 71453188, 71453133
VERASENSE for Zimmer Biomet Persona	ZBH-PSNCRCD39-L	C-D/3-9 Left	42-5170-004-10, 42-5170-003-03, 42-5170-003-13, 42-5279-003-00, 42-5279-003-01, 42-5279-003-02, 42-5279-003-03, 42-5279-003-04
	ZBH-PSNCRCD39-R	C-D/3-9 Right	42-5270-004-10, 42-5270-003-03, 42-5270-003-13, 42-5279-003-00, 42-5279-003-01, 42-5279-003-02, 42-5279-003-03, 42-5279-003-04
	ZBH-PSNCREF311-L	E-F/3-11 Left	42-5170-005-10, 42-5170-005-05, 42-5170-005-15, 42-5279-005-00, 42-5279-005-01, 42-5279-005-02, 42-5279-005-03, 42-5279-005-04
	ZBH-PSNCREF311-R	E-F/ 3-11 Right	42-5270-005-10, 42-5270-005-05, 42-5270-005-15, 42-5279-005-00, 42-5279-005-01, 42-5279-005-02, 42-5279-005-03, 42-5279-005-04
	ZBH-PSNCRGH712-L	G-H/7-12 Left	42-5170-006-10, 42-5170-007-07, 42-5170-007-17, 42-5279-007-00, 42-5279-007-01, 42-5279-007-02, 42-5279-007-03, 42-5279-007-04
	ZBH-PSNCRGH712-R	G-H/7-12 Right	42-5270-006-10, 42-5270-007-07, 42-5270-007-17, 42-5279-007-00, 42-5279-007-01, 42-5279-007-02, 42-5279-007-03, 42-5279-007-04

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Attachments:

- **Guidance and Manufacturer's Declaration - Electromagnetic Compatibility (EMC)**: The VERASENSE device and accessories have been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices to IEC 60601-1-2:2007. Refer to the tables below.

Table 4 - Guidance and manufacturer's declaration – electromagnetic emissions

The VERASENSE is intended for use in the electromagnetic environment specified below. The customer or the user of the VERASENSE should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The VERASENSE uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The VERASENSE is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Not applicable	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Not applicable	

Table 5 - Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The VERASENSE are intended for use in the electromagnetic environment specified below.
The customer or the user of the VERASENSE should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the VERASENSE requires continued operation during power mains interruptions, it is recommended that the VERASENSE be powered from an uninterruptible power supply or a battery.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

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Table 6 - Guidance and manufacturer's declaration – electromagnetic immunity

The VERASENSE is intended for use in the electromagnetic environment specified below.
The customer or the user of the VERASENSE should assure that it is used in such an environment.

Immunity test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the VERASENSE and accessories, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** Not applicable
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz Where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitter, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the VERASENSE is used exceeds the applicable RF compliance level above, the VERASENSE should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the VERASENSE.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than not applicable.

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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Table 7 - Recommended separation distances between portable and mobile RF communications equipment and the VERASENSE

The VERASENSE is intended for use in an electromagnetic environment in which RF disturbances are controlled. The customer or the user of the VERASENSE can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and VERASENSE as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** **m**		
	150 kHz to 80 MHz $d = [3.5 / V_1] \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	Not applicable	0.12	0.23
0.1	Not applicable	0.38	0.73
1	Not applicable	1.2	2.3
10	Not applicable	3.8	7.3
100	Not applicable	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 - At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 – These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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