

Label and Packaging, Product, VERASENSE for Exactech Equinox Family

DESCRIPTION

- This document specifies the information that is printed on to the Product Label and packaging assembly requirements for the following family:
VERASENSE for Exactech Equinox

PRODUCT LABEL NOTES

- Create label from: LB-1029 “VERASENSE Label Set Template”
- Record all required information on Device History Record (DHR).
- Print all required information directly onto Label Set blank using laser printer and black ink.
- Print each field per the Field-Description table below. Per the Print column, print either the exact text show, or the information as described.
- Items 8 and 10-12 are repeated on the three peel-off stickers.
- All printed text is to be legible with unaided eye. Printed text shall not overlap.
- Items 5 is GS1-128 single concatenated type one dimensional barcode and human readable printed below barcode as described below:
 - Generation of GS1-128 barcode may be accomplished by several validated software methods, such as specialized software, Excel add-in, or online software.
 - Information encoded into Barcode is particular to an individual sensor following programming and calibration.
 - Encode the following data per the example below (The values on the table for reference only. For the GTIN reference Table #2 and all other use the actual values from work order /route detailed in the table below in the order and formats shown.) Only the values are encoded, not the descriptor in the first column.

Descriptor	Value
GS1 Application Identifier (AI) for Global Trade Identification Number (GTIN)	01
GTIN (must be in a 14 digit format)	00816818021234
GS1 AI for Date of Manufacture	11
Date of Manufacture (six numeric characters)	YYMMDD
GS1 AI for Expiration Date	17
Use by Date (six numeric characters)	YYMMDD
GS1 AI for Lot number	10
Mfg Lot Number (maximum 20 alphanumeric characters)	1234567
GS1 AI for Serial Number	21
Serial Number (maximum 20 alphanumeric characters)	9876543210

- The data is encoded as a single text string of the format below:

010081681802123411YYMMDD17YYMMDD101234567219876543210

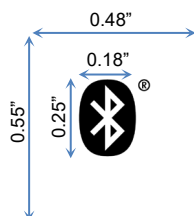
NOTE: For clarity, the numbers representing the AI and numbers representing the date element are shown in bold in the example above.

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- Barcodes symbol sizes

Item	X-dimension			Minimum Symbol Height for Given X mm (inches)			Quiet Zone		Minimum Quality Specification
	Minimum	Target	Maximum	For Minimum X-dimension	For Target X-dimension	For Maximum X-dimension	Left, Right	Above, Below	
5	0.170 (0.0067")	0.495 (0.0195")	0.495 (0.0195")	12.70 (0.500")	12.70 (0.500")	12.70 (0.500")	10X	2X	1.5 /06/660
34	0.170 (0.0067")	0.495 (0.0195")	0.495 (0.0195")	4.76 (0.1875")	4.76 (0.1875")	4.76 (0.1875")	10X	2X	1.5 /06/660

- Human readable format is printed below the barcode in the following format:
(01) 00816818021234 (11) YYMMDD (17) YYMMDD (10) 1234567 (21) 9876543210
- Items 18 and 30 are undefined fields to be used by the Contract Manufacturer for internal tracking (e.g. alphanumeric, 1D barcode, etc...). Print must fit within the specified space.
- Item 13, 22, 32, 41, and 44 contain the document number and revision.
- The specification for the Bluetooth® symbol is as described below:
 - Print the symbol with the size requirements shown below, including the required white space around the figure.
 - Use the highest possible resolution, not going below 16x16 pixels



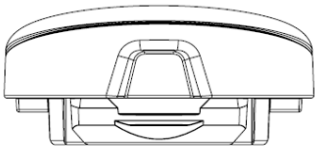
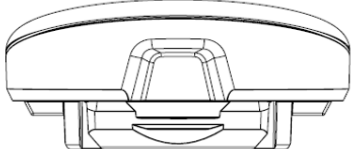
Label and Packaging, Product, VERASENSE for Exactech Equinox Family

Product Label field Descriptions:

Item #	Field	Description	Font Size pts (Arial)	Print
1		Print image. See Table 1- Select image based on work order	NA	Fill all available space
2		Sizes accommodated. Table 2.	BOLD 9	Text
3		Programmed Device Model ID Number	BOLD 10	Text
4		Manufacturing Lot Number	BOLD 10	Info
5, 34		1D Bar-Code and Human Readable Interpretation. Select appropriate GTIN per work order.	7	Bar Code and human readable
6		Device Expiration Date = Manufactured date plus 24 months in YYYY-MM-DD format.	BOLD 10	Info
7		Manufacturing Date (date that FTS is preformed, obtained from the DHR) in YYYY-MM-DD format.	BOLD 10	Info
8		See table 2. Select the appropriate description per work order.	BOLD 7	Text
9, 28	Side	See table 2. Select the appropriate side per work order.	BOLD 20	Text
10, 36, 39, 43		Manufacturing Lot Number	BOLD 7	Info
11, 33, 38		Programmed Device Model ID Number	BOLD 7	Info
12, 31, 37, 42		See table 2. Select the appropriate description per work order	BOLD 7	Info
13, 22, 32, 41, 44		Document number and revision	6	Text
14, 29	Type	See table 2. Select the appropriate type per work order.	BOLD 20	
15, 27	Size	See table 2. Select the appropriate size per work order.	BOLD 20	Text
16		See table 2. Select the appropriate description per work order.	BOLD 19	Text
17		Programmed Device Model ID Number	BOLD 9	Text
18, 30, 47, 48		Contract Manufacturer's Internal Tracking Identifier (Optional)	NA	Bar Code
19		See table 2. Select the appropriate description per work order.	BOLD 10	Text
23		Manufacturing Lot Number	BOLD 9	Text
24		See table 2. Select the appropriate description per work order.	BOLD 9	Text
20		FCC ID XNL-ORTHOSNSR8	7	Text
25		Device Expiration Date = Manufactured date plus 24 months in YYYY-MM-DD format.	BOLD 9	Text
26		See table 2. Select the appropriate description per work order.	BOLD 9	Text
40, 45		Device Expiration Date = Manufactured date plus 24 months in YYYY-MM-DD format.	BOLD 7	Text
46		Print Bluetooth® symbol as specified in the product label notes.	NA	Symbol

Label and Packaging, Product, VERASENSE for Exactech Equinox Family

Table 1 DEVICE Images

Item # 1	
Reverse, 38 mm	Reverse, 42 mm
 	 

Label and Packaging, Product, VERASENSE for Exactech Equinox Family

Table #2

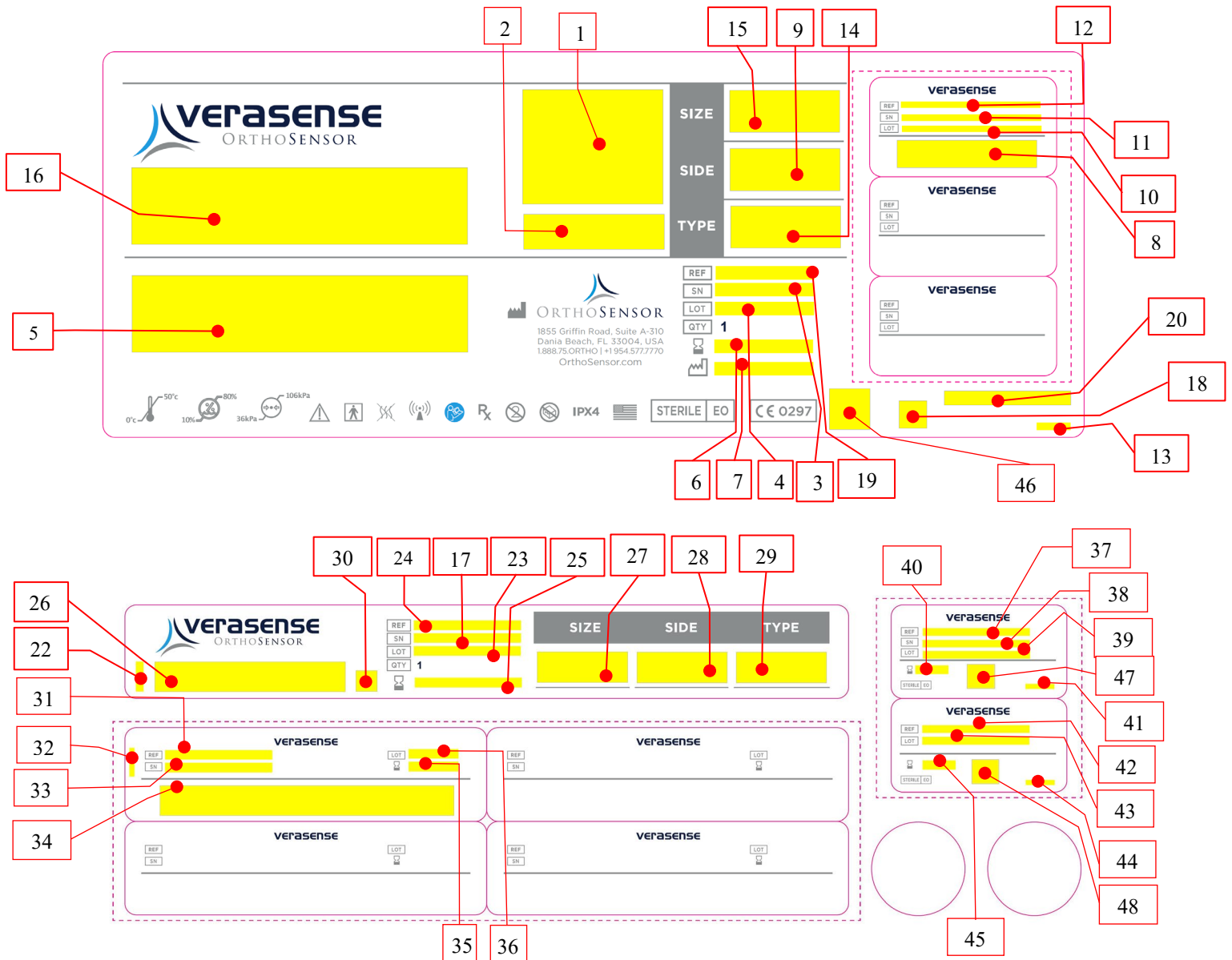
Item 5 GTIN	Item 2	Items 8, 16, 26	Items 12, 19, 24	Items 15 & 27	Items 9 & 28	Items 14 & 29
00816818022055	0 mm, 2.5 mm	VERASENSE for Exactech Equinox Reverse Size 38 mm	EXC-EQRV38	38	N/A	REV
00816818022062	0 mm, 2.5 mm	VERASENSE for Exactech Equinox Reverse Size 42 mm	EXC-EQRV42	42	N/A	REV

NOTE: When selecting the appropriate item, please ensure it is the correct side, size and type per the work order.

Label and Packaging, Product, VERASENSE for Exactech Equinox Family

PRODUCT LABEL REFERENCE FIGURES

1. Blank label is shown below with the required print fields highlight:



Label and Packaging, Product, VERASENSE for Exactech Equinox Family

2. Below is an example of the completed Label with all fields completed and the barcodes with encoded information. Appendix 1 includes an example label for each item listed in Table 2.

				SIZE 38												
VERASENSE for Exactech Equinox Reverse Size 38 mm				SIDE N/A												
		TYPE REV														
				<table border="1"> <tr><td>REF</td><td>EXC-EQVR38</td></tr> <tr><td>SN</td><td>510845011</td></tr> <tr><td>LOT</td><td>20568</td></tr> <tr><td>QTY</td><td>1</td></tr> <tr><td>EXP</td><td>2020-01-18</td></tr> <tr><td>EXP</td><td>2018-01-18</td></tr> </table>	REF	EXC-EQVR38	SN	510845011	LOT	20568	QTY	1	EXP	2020-01-18	EXP	2018-01-18
REF	EXC-EQVR38															
SN	510845011															
LOT	20568															
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EXP	2020-01-18															
EXP	2018-01-18															
(01) 00816818022055 (11) 180118 (17) 200118 (10) 20568 (21) 510845011		1855 Griffin Road, Suite A-310 Danla Beach, FL 33004, USA 1888.75.ORTHO +1 954.577.7770 OrthoSensor.com														
0°C 50°C 10% 80% 106kPa 36kPa 0+0 STERILE EO CE 0297																

		<table border="1"> <tr><td>REF</td><td>EXC-EQVR38</td></tr> <tr><td>SN</td><td>510845011</td></tr> <tr><td>LOT</td><td>20568</td></tr> <tr><td>QTY</td><td>1</td></tr> <tr><td>EXP</td><td>2020-01-18</td></tr> </table>	REF	EXC-EQVR38	SN	510845011	LOT	20568	QTY	1	EXP	2020-01-18	<table border="1"> <tr><td>SIZE</td><td>38</td></tr> <tr><td>SIDE</td><td>N/A</td></tr> <tr><td>TYPE</td><td>REV</td></tr> </table>	SIZE	38	SIDE	N/A	TYPE	REV
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SN	510845011																		
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TYPE	REV																		

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<table border="1"> <tr><td>REF</td><td>EXC-EQVR38</td></tr> <tr><td>SN</td><td>510845011</td></tr> <tr><td>LOT</td><td>20568</td></tr> <tr><td>EXP</td><td>2020-01-18</td></tr> </table>	REF	EXC-EQVR38	SN	510845011	LOT	20568	EXP	2020-01-18		<table border="1"> <tr><td>LOT</td><td>20568</td></tr> <tr><td>EXP</td><td>2020-01-18</td></tr> </table>	LOT	20568	EXP	2020-01-18
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SN	510845011													
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REF	EXC-EQVR38								
SN	510845011								
LOT	20568								
EXP	2020-01-18								
STERILE EO									

							
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REF	DWG-07000-060						
LOT	510845011						
EXP	2020-01-18						
STERILE EO							

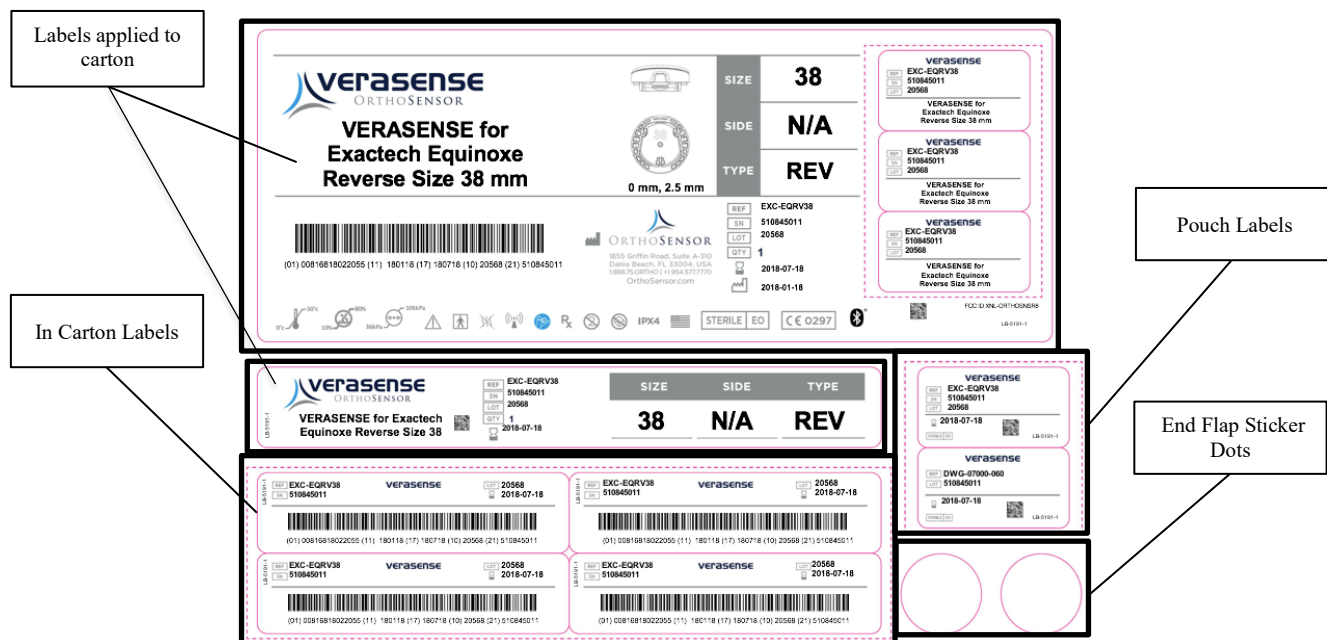
Label and Packaging, Product, VERASENSE for Exactech Equinox Family

PACKAGING ASSEMBLY NOTES

- See separate Bill of Materials, VERASENSE for Exactech Equinox for Item description.
- Refer to Contract Manufacturer's Quality System for:
 - Part Inspection requirements
 - Functional testing requirements
 - Part handling and cleanliness
 - Packaging and Labeling
 - Traceability and Documentation requirements
- Contract Manufacturer's Quality System shall meet or exceed the requirements per the Quality Agreement established with the Contract Manufacturer.
- Contract Manufacturer's internal Tracking & Identification labels are permissible on all components per the following:
 - Labels are permitted on: Box, Envelope, Bags, IFU and Addendum, Product Label, and on the outer Pouch of the Pouched Sensor and Shim-Set.
 - Labels are not permitted on any Inner Pouch, or on any VERASENSE or Shim surfaces.
 - Labels must be permanent, and printed with indelible ink. Maximum label size is 1.0" x 0.5".
 - Labels should be located near a corner, or in an innocuous location, and not obscure any other marking or lettering.

PACKAGING ASSEMBLY PROCEDURES

1. Build per Bill of Materials, VERASENSE for Exactech Equinox and Router/Work Instruction.



Label and Packaging, Product, VERASENSE for Exactech Equinox Family

2. If the device is for Design Verification Testing (DVT)
 - a. Add DVT-build number to the end of descriptions in fields 16 & 26.
 - b. Do not enter information in the following fields: 4, 5, 6, 7, 8, 10, 11, 12, 18, 23, 25, 30, 33, 35, 36, 39, 40, 42, 45, 47, 48.

Example labels for Size 38 DVT build

 VERASENSE for Exactech Equinox Reverse Size 38 mm DVT-1 0 mm, 2.5 mm		SIZE	38	verasense REF EXC-EQRV38 SN 510845011 LOT verasense REF EXC-EQRV38 SN 510845011 LOT verasense REF EXC-EQRV38 SN 510845011 LOT							
		SIDE	N/A								
		TYPE	REV								
 1855 Griffin Road, Suite A-310 Dania Beach, FL 33004, USA 1.888.75.ORTHO +1 954.577.7770 OrthoSensor.com		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td>REF</td><td>EXC-EQRV38</td></tr> <tr><td>SN</td><td>510845011</td></tr> <tr><td>LOT</td><td></td></tr> <tr><td>QTY</td><td>1</td></tr> </table>		REF	EXC-EQRV38	SN	510845011	LOT		QTY	1
REF	EXC-EQRV38										
SN	510845011										
LOT											
QTY	1										
 FCC ID XNL-ORTHOSNR8											

 VERASENSE for Exactech Equinox Reverse Size 38 mm DVT-1		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td>REF</td><td>EXC-EQRV38</td></tr> <tr><td>SN</td><td>510845011</td></tr> <tr><td>LOT</td><td></td></tr> <tr><td>QTY</td><td>1</td></tr> </table>	REF	EXC-EQRV38	SN	510845011	LOT		QTY	1	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th>SIZE</th> <th>SIDE</th> <th>TYPE</th> </tr> <tr> <td style="font-size: large;">38</td> <td style="font-size: large;">N/A</td> <td style="font-size: large;">REV</td> </tr> </table>	SIZE	SIDE	TYPE	38	N/A	REV	verasense REF EXC-EQRV38 SN 510845011 LOT verasense REF SN LOT STERILE EO
REF	EXC-EQRV38																	
SN	510845011																	
LOT																		
QTY	1																	
SIZE	SIDE	TYPE																
38	N/A	REV																
verasense REF EXC-EQRV38 SN 510845011 LOT verasense REF SN LOT STERILE EO		verasense REF EXC-EQRV38 SN 510845011 LOT verasense REF SN LOT STERILE EO																

Label and Packaging, Product, VERASENSE for Exactech Equinox Family

Example labels for Size 42 DVT build



VERASENSE for
Exactech Equinox
Reverse Size 42 mm DVT-1

SIZE 42

SIDE N/A

TYPE REV

0 mm, 2.5 mm



1855 Griffin Road, Suite A-310
Dania Beach, FL 33004, USA
1.888.75.ORTHO | +1.954.577.7770
OrthoSensor.com

REF	EXC-EQRV38
SN	510845011
LOT	
QTY	1

0°C 50°C 10% 80% 36kPa 106kPa



STERILE EO

CE 0297



FCC ID XNL-ORTHOSENSOR8

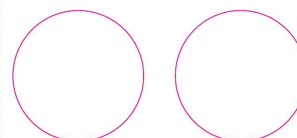
LB-5191-3

 VERASENSE ORTHOSENSOR VERASENSE for Exactech Equinox Reverse Size 42 mm DVT-1	<table border="1"> <tr><td>REF</td></tr> <tr><td>SN</td></tr> <tr><td>LOT</td></tr> <tr><td>QTY</td></tr> </table>	REF	SN	LOT	QTY	EXC-EQRV42 510845011 1	<table border="1"> <thead> <tr> <th>SIZE</th><th>SIDE</th><th>TYPE</th></tr> </thead> <tbody> <tr> <td>42</td><td>N/A</td><td>REV</td></tr> </tbody> </table>	SIZE	SIDE	TYPE	42	N/A	REV
REF													
SN													
LOT													
QTY													
SIZE	SIDE	TYPE											
42	N/A	REV											

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LB-519-3	REF EXC-EQ RV42	VERAsense	LOT 510845011
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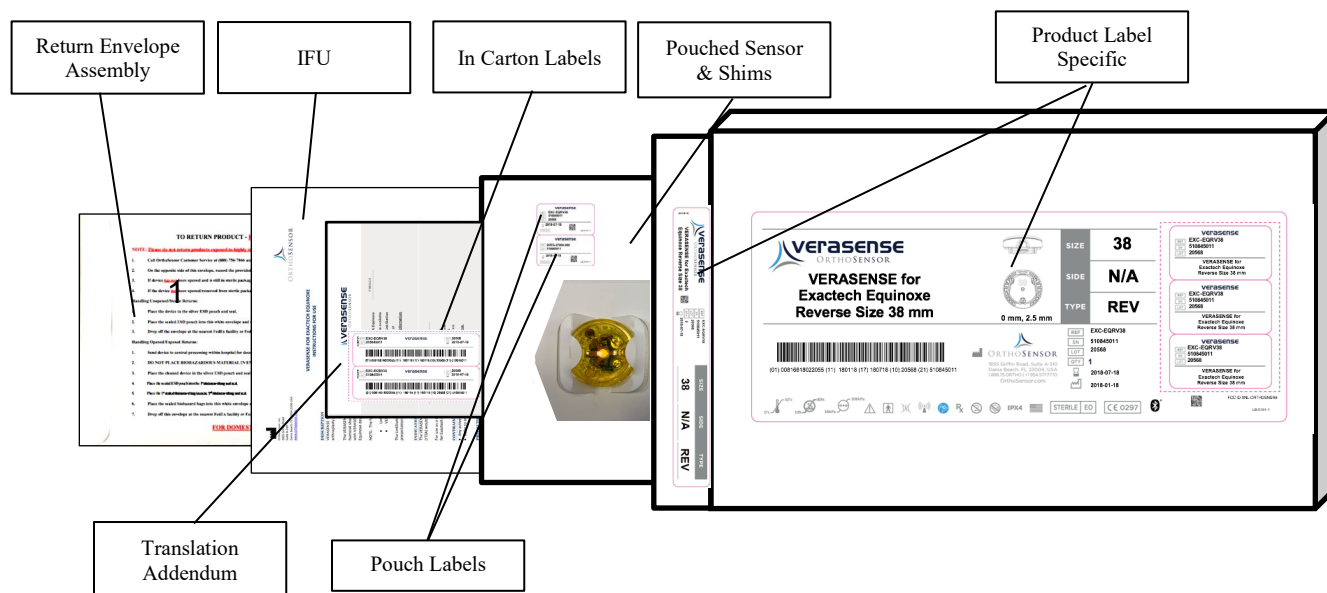
VERASENSE	
REF	EXC-EQRV42
SN	510845011
LOT	
	
STERILE	SD
LB-S191-3	

VERASENSE	
REF	
LOT	
	
STERILE	SD
LB-S189-0	



Label and Packaging, Product, VERASENSE for Exactech Equinox Family

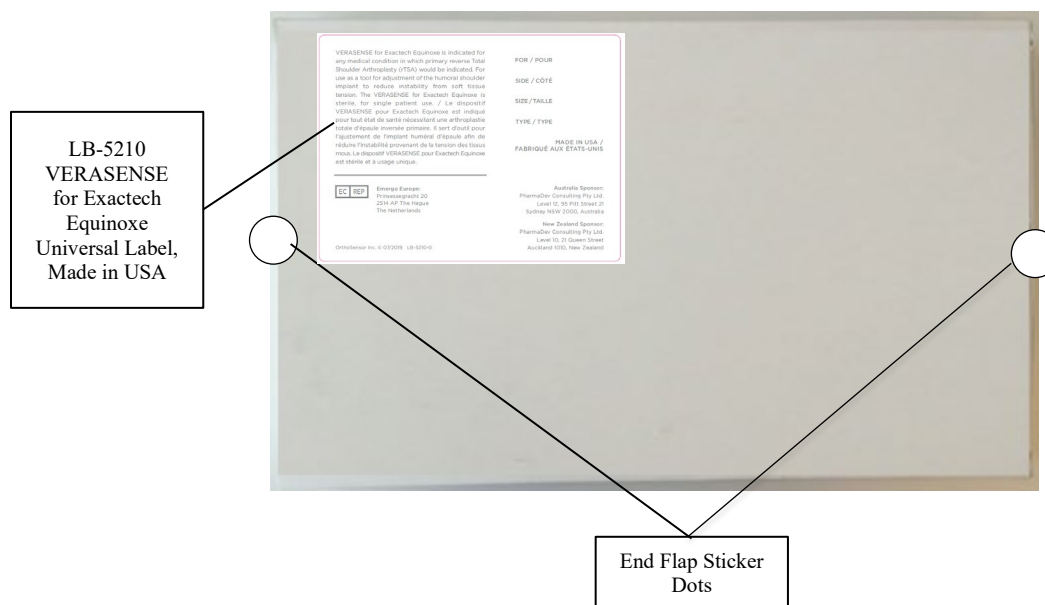
3. With the box oriented as shown below, place contents into box in the order shown below: Return Envelope on bottom, followed by Instructions-for-Use, Translation Addendum, In-Carton Labels, Pouched Shim-Set, and the Pouched Sensor on top.
 1. Insert Pouched Shim-Set and Pouched Sensor clear side up, and the factory sealed end going into the box first.
 2. Do not bend, wrinkle or distort pouches when inserting into product box.



Note: Generic image used above for illustration.

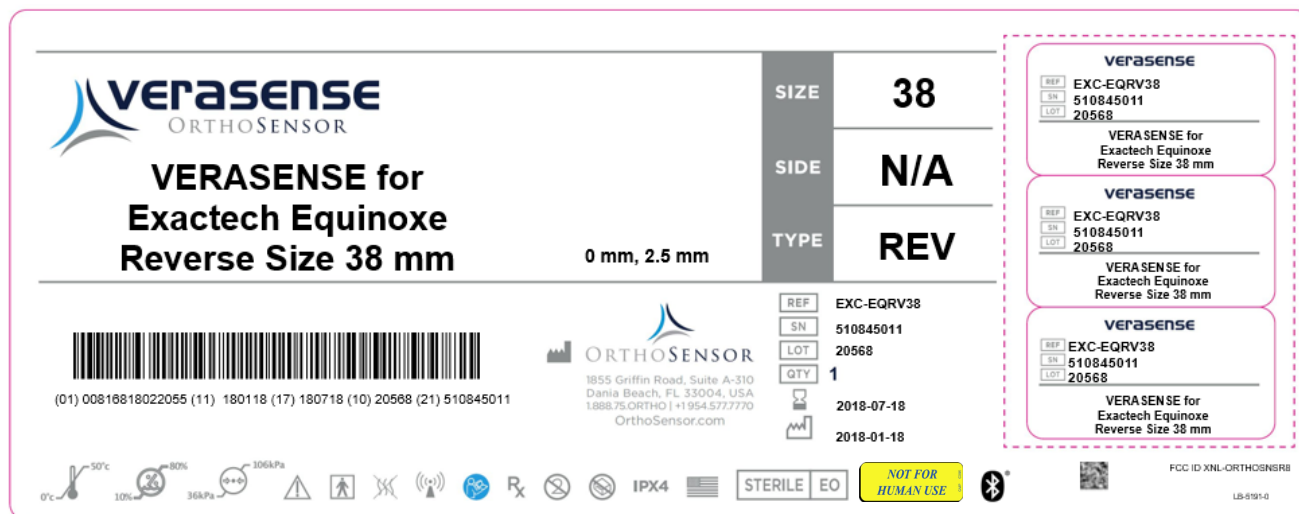
4. Affix End Flap Labels as shown below. Label Barcode IDs shall be traceable to the Device Model ID number.

Back of Box

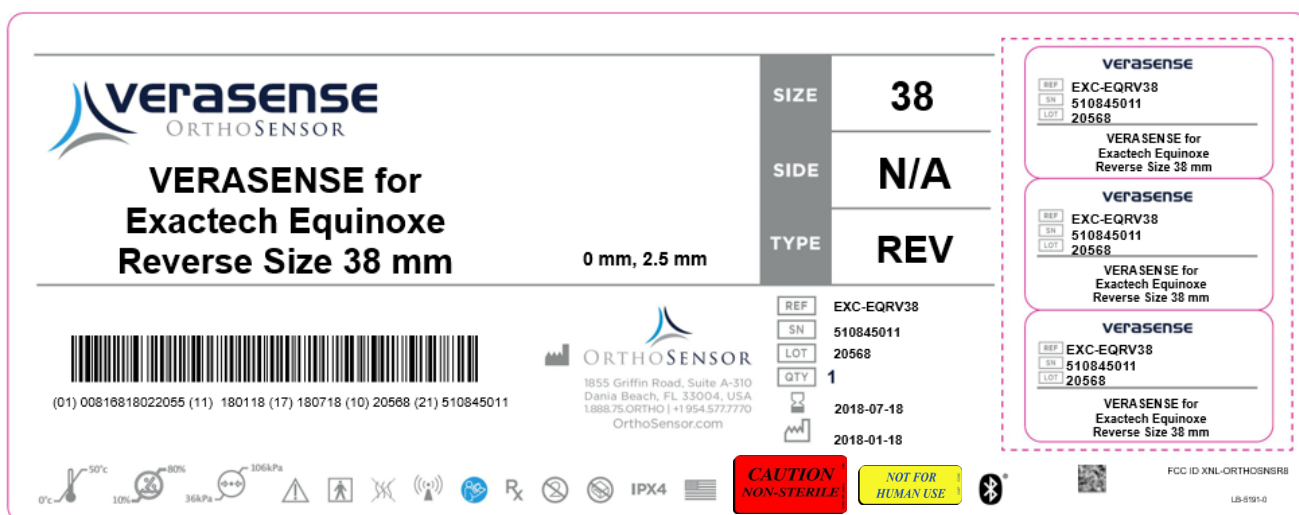


Label and Packaging, Product, VERASENSE for Exactech Equinox Family

5. If device was sterilized and is Not For Human Use, affix the “NOT FOR HUMAN USE” label over the  symbol on the Product Label as shown below.



6. If the device and/or shim were not sterilized:
- Affix a “CAUTION NON-STERILE” sticker on the outer pouch of the pouched sensor and shim-set, where indicated below.
 - Affix a “CAUTION NON-STERILE” sticker over the  symbol on the Product Label as shown below.



Label and Packaging, Product, VERASENSE for Exactech Equinox Family

REVISION HISTORY

Rev	Description	Date
0	Initial Release.	1/17/2019
1	Added device images to Table 1. Updated example images in the Product Label Reference, Appendix, and Packaging Assembly Procedures sections.	4/9/2019
2	Added packaging instructions for translation addendum and universal label.	7/31/2019
3	Changed shelf life from 6 months to 24 months	8/16/2019

Label and Packaging, Product, VERASENSE for Exactech Equinox Family

APPENDIX 1: Example Labels



VERASENSE for Exactech Equinox® Reverse Size 38 mm




0 mm, 2.5 mm

SIZE	38
SIDE	N/A
TYPE	REV



(01) 00816818022055 (11) 180118 (17) 200118 (10) 20568 (21) 510845011



1855 Griffin Road, Suite A-310
Dania Beach, FL 33004, USA
1.888.75.ORTHO | +1 954.577.7770
OrthoSensor.com

REF	EXC-EQRV38
SN	510845011
LOT	20568
QTY	1
	2020-01-18
	2018-01-18

VERASENSE	
REF	EXC-EQRV38
SN	510845011
LOT	20568
VERASENSE for Exactech Equinox® Reverse Size 38 mm	

VERASENSE	
REF	EXC-EQRV38
SN	510845011
LOT	20568
VERASENSE for Exactech Equinox® Reverse Size 38 mm	

 50°C
 80%
 36kPa
 106kPa

















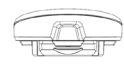

FCC ID: XNL-ORTHOSENSOR

LB-6191-3

 VERASENSE for Exactech Equinox Reverse Size 38 mm		<table border="1"> <tr><td>REF</td><td>EXC-EQRV38</td></tr> <tr><td>SN</td><td>510845011</td></tr> <tr><td>LOT</td><td>20568</td></tr> <tr><td>QTY</td><td>1</td></tr> </table>  2020-01-18	REF	EXC-EQRV38	SN	510845011	LOT	20568	QTY	1	<table border="1"> <thead> <tr> <th>SIZE</th><th>SIDE</th><th>TYPE</th></tr> </thead> <tbody> <tr> <td>38</td><td>N/A</td><td>REV</td></tr> </tbody> </table>	SIZE	SIDE	TYPE	38	N/A	REV
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VERASENSE	
REF	EXC-EQRV38
SN	510845011
LOT	20568
 2020-01-18	
	
STURILE ED LB-5191-3	

Label and Packaging, Product, VERASENSE for Exactech Equinox Family

				SIZE	42
VERASENSE for Exactech Equinox Reverse Size 42 mm				SIDE	N/A
		0 mm, 2.5 mm		TYPE	REV
				REF	EXC-EQVR42
(01) 00816818022062 (11) 180118 (17) 200118 (10) 20568 (21) 510845011		1855 Griffin Road, Suite A-310 Dania Beach, FL 33004, USA 1.888.75.ORTHO +1 954.577.7770 OrthoSensor.com		SN	510845011
				LOT	20568
				QTY	1
				EXP	2020-01-18
				EXP	2018-01-18
					
					
					

		REF	EXC-EQVR42
		SN	510845011
		LOT	20568
		QTY	1
		EXP	2020-01-18
VERASENSE for Exactech Equinox Reverse Size 42 mm		SIZE	42
		SIDE	N/A
		TYPE	REV

	
REF	EXC-EQVR42
SN	510845011
LOT	20568
EXP	2020-01-18
	
	
	
	

REF	EXC-EQVR42	VERASENSE	LOT	20568
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SN	510845011		EXP	2020-01-18
				
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REF	EXC-EQVR42	VERASENSE	LOT	20568
SN	510845011		EXP	2020-01-18
				
(01) 00816818022062 (11) 180118 (17) 200118 (10) 20568 (21) 510845011				

	
REF	DWG-07000-061
LOT	510845011
EXP	2020-01-18
	
	
	
	