

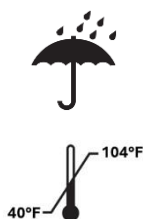
Instructions For Use

OPSB™ Sensor

OPSB™ Sensor System Instructions For Use



MANUFACTURER:
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Prosthetics
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<https://opsb.com/ifu>



Instructions For Use

OPSB™ Sensor

DESCRIPTION

The OrthoPediatrics Specialty Bracing (OPSB) Sensor System is intended to collect and transmit temperature data to aid patients and healthcare professionals (HCP) in their monitoring of a patient's compliance with their HCP's recommended brace or orthosis wear times and pattern. The system consists of the OPSB™ Sensor, software applications (installable on Android and iOS phones), and cloud-based portal. The OPSB Sensor is a wireless accessory used to measure, collect and transmit measured temperature and time data of the Sensor. The OPSB™ Sensor System is intended to be used in a clinical setting as well as outside of the clinical environment.

The OPSB sensor communicates, via Bluetooth, to an OPSB App available for Android and iOS platforms. Each OPSB Sensor has a unique QR code that allows secure synchronization to a corresponding smart phone containing the downloaded OPSB App. Synchronized data is automatically uploaded and stored to a cloud platform for analysis and display to the corresponding smart phone as a visual reward using stars and trophies for reaching wear goals. The cloud platform also allows authorized members of the patient's HCP team, via a secure log in, to remotely monitor the patient's wear times and patterns.

MATERIALS

The OPSB Sensor System is made from Polycarbonate/Acrylonitrile Butadiene Styrene Cyclopy 6600 (Sensor enclosure), FLEXCON 1400U (Sensor label), medical grade polyurethane (clear adhesive Sensor securing mechanism), and includes 3V Lithium coin-cell battery. There are no additional cables, transducers, or accessories.

INDICATIONS FOR USE

The OPSB Sensor System is intended to collect, transmit and store temperature data to monitor a patient's wear time and pattern.

CLINICAL BENEFITS

The OPSB Sensor System provides valuable information regarding compliance with a HCP's recommended brace or orthosis wear time and pattern. Studies on brace and orthosis wear time show that when patients know they are being monitored and they receive a performance report, their adherence to the recommended hours of wear time improves. Achieving the goal is a time to celebrate. If there are some difficulties wearing the brace, then conversations between patient and HCP can be had to help patients meet wear time goals.

CONTRAINDICATIONS

Do not use the OPSB Sensor System in the presence of any contraindication. Contraindications include but are not limited to:

- Material sensitivity documented or suspected.
- Inability to follow treatment protocol and care instructions.

GENERAL SAFETY PRECAUTIONS

- Danger of damage to the OPSB Sensor: Do not attempt to modify or repair the Sensor. This may result in hazardous situations. Do not open the Sensor enclosure.
- Do not use the OPSB Sensor if it shows visible signs of damage, including damage to the QR Code.
- Protect the OPSB Sensor from mechanical shock. Keep the sensor away from; (1) aggressive chemicals or flammable substances, (2) heat sources like radiant heaters or fireplaces, (3) pets or pests, (4) babies and (5) chlorinated water, salt water, sunscreen and DEET based insect repellents.
- Do not use the sensor while bathing, swimming, surfing, or in a hot tub or sauna.

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- Please contact Boston Brace International, Inc dba Boston Orthotics & Prosthetics for all repairs and modifications to the OPSB Sensor. Any unauthorized repairs or modifications to the OPSB Sensor may void the warranty and compliance of the equipment. Changes or modifications made to this equipment not expressly approved by Boston Brace International, Inc dba Boston Orthotics & Prosthetics, may void the FCC authorization to operate this equipment.

DEVICE SPECIFIC WARNINGS

- Do not attach the OPSB Sensor directly to the body, or to other parts of the brace not intended for Sensor attachment.
- To prevent skin irritation or direct skin contact, always wear a clean, dry garment.
- Harsh cleaners, such as bleach, are not recommended as the OPSB Sensor is in close contact with the skin while installed in the brace.
- Do not submerge the OPSB Sensor in water or cleaning liquids.
- Do not put the OPSB Sensor into a mechanical washer or dryer.
- Avoid misusing the OPSB Sensor as damage to the Sensor may cause battery fluid leak, which may lead to chemical burn. Do not touch a battery leakage. If you are exposed to battery leakage, wash the affected area thoroughly with clean water.
- Avoid potentially damaging circumstances: (1) do not drop the device, (2) do not damage the device, (3) do not connect to other devices, (4) do not put the device in contact with sharp objects.
- Avoid danger of electromagnetic interference: Do not use the OPSB Sensor close to MRI or CT facilities. Do not use the OPSB Sensor closer than 30 cm to a short wave, microwave or high frequency surgical device.
- Signal interference may be experienced if sensor is used within 30cm of another wireless device. See FCC Compliance Statement for more information.
- Sensor contains small parts, which could present a choking hazard.
- Apps (Android / iOS) are downloaded to the user's personal property and any vulnerabilities with the mobile devices are the responsibility of the user.
- App (Android / iOS) downloads must be made by and supervised by an adult, such as the patient's guardian where applicable.
- Loss of active Wi-Fi or cellular connection could impact data transfer.
- Patient data available through the Sensor, App and cloud platform can include name, date of birth, brace type, body temperature, and wear times. Boston Brace International, Inc dba Boston Orthotics & Prosthetics will keep confidential any patient identifying information that comes into its possession. Boston Brace International, Inc dba Boston Orthotics & Prosthetics. may share and utilize limited or deidentified data with clinical partners of Boston Brace International, Inc dba Boston Orthotics & Prosthetics. in research and in reporting outcome data to objectively review the impact of brace monitoring. Information regarding Boston Brace International, Inc dba Boston Orthotics & Prosthetics Privacy Policy may be found at: <https://www.bostonoandp.com/privacy-policy/>
- Patients may request deletion of their data from the cloud platform at any time by submitting a request to Boston Brace International, Inc dba Boston Orthotics & Prosthetics through the Contact Us page: <https://www.bostonoandp.com/contact/>
- Patient data is stored in a third-party cloud platform. Data breaches, including cybersecurity attacks, can cause loss, damage, or unauthorized disclosure of patient data and impact the availability and accuracy of patient data. Patients and HCP are responsible for maintaining alternative sources and copies of patient data
- User credentials, including the names and contact information of patients, guardians, HCP, and authorized researchers are stored in the third-party cloud platform. Data breaches, including cybersecurity attacks, can cause loss, damage, or unauthorized disclosure of user credentials.

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GUIDE FOR SETTING UP THE OPSB SENSOR SYSTEM

1. Patient registration by clinician/admin

Patient Registration

- ① Log into Cloud application using Clinician credentials
- ② Create a new patient, and fill in all fields

Note: Email field cannot be edited after initial patient creation, use an email you can access

2. Adding Sensor to patient account by clinician/admin

Add Sensor to Patient

- ③ Download OPSB Sensor app from Apple or Google Play store
- ④ Click "Already registered? Login" button, and then Login using Clinicians or Admin credentials
- ⑤ On the home page, click "add new sensor"
- ⑥ Push the pin-hole button to wake up the sensor
Note: The sensor will stay awake for 2 minutes, this process should take under 2 minutes
- ⑦ Allow camera permissions, and scan the QR code on the sensor
- ⑧ Select the patient which was created on the portal during step 2 and click on Assign
- ⑨ Set the measurement interval to 15 minutes
- ⑩ Set the time slots for when the sensor will connect to the app
Note: Times should be chosen for when the patient will be in proximity to their phone to allow for syncing of data
- ⑪ Click Save to allow the app to sync with the sensor, this may take a few seconds

3. Patient onboarding

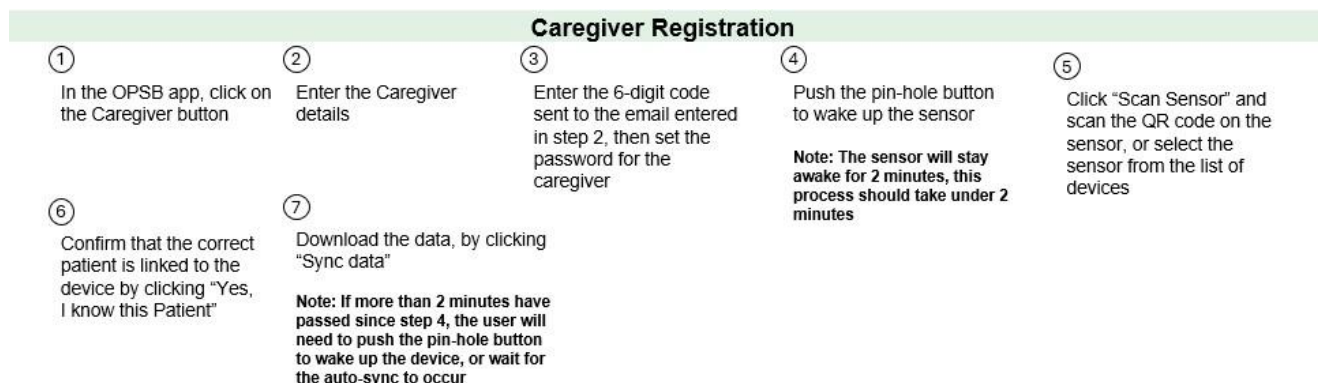
Patient Onboarding

- ① In the OPSB Sensor app, click on the Patient button
- ② Push the pin-hole button to wake up the sensor
Note: The sensor will stay awake for 2 minutes, this process should take under 2 minutes
- ③ Click "Scan Sensor" and scan the QR code on the sensor, or select the sensor from the list of devices
- ④ Confirm that the correct patient is linked to the device by clicking "Yes, its me"
- ⑤ Enter the 6-digit code sent to the email entered in step 2
- ⑥ Set the password for the patient
Note: this password will be used to login to view and download sensor data
- ⑦ Download the data, by clicking "Sync data"
Note: If more than 2 minutes have passed since step 2, the user will need to push the pin-hole button to wake up the device, or wait for the auto-sync to occur

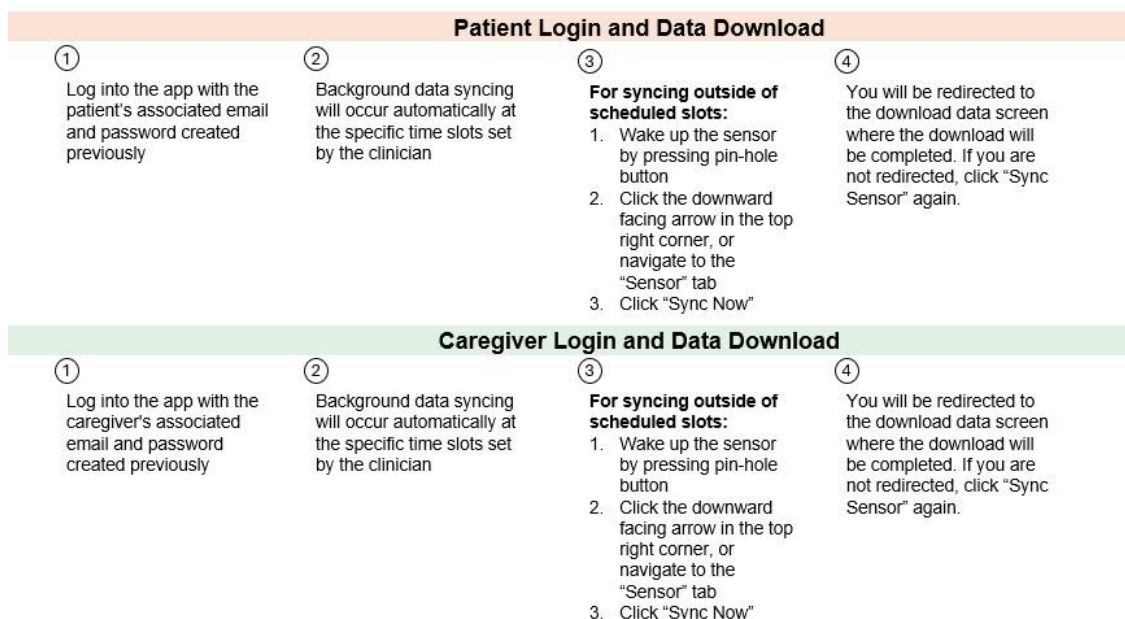
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4. Caregiver registration








5. Logging in after registration



6. Installing sensor into brace or orthosis

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STEPS	IMAGE
<p>If the orthosis includes a pre-drilled hole, then install the OPSB Sensor by placing the Sensor in the pre-drilled hole so that the Sensor snaps into place.</p>	 <p>1. Place the awoken sensor in the brace hole.</p> <p>2. Installed sensor should look like this</p> 
STEPS	IMAGE
<p>If the brace or orthosis does not include a pre-drilled hole, a member of the HCP team will drill a 21mm through the brace or orthosis utilizing an appropriate drill bit. Then install the OPSB Sensor by placing the Sensor in the hole so that the Sensor snaps into place.</p>	 
<p>Once OPSB Sensor is positioned in the brace or orthosis, cover the Sensor with clear adhesive Sensor securing mechanism provided.</p>	 <p>1. Peel off clear adhesive back</p> <p>2. Peel corners off</p> <p>3. Final sensor installed into brace</p>

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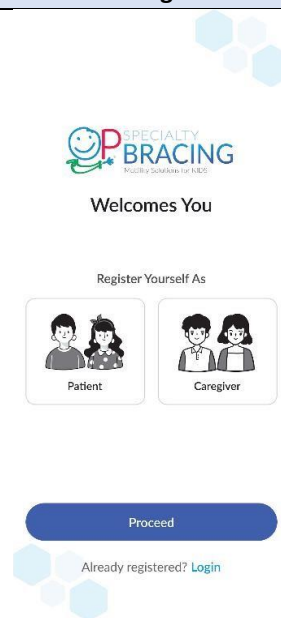
7. Operating modes

- The OPSB Sensor will support two types of low power modes: (1) Power Down Mode where powering on (“wake-up”) is allowed only by pin-hole button press, and (2) Sleep Mode, where wake-up is allowed by wake-up pin-hole button press or the pre-set sync schedule (as determined by your HCP).
- The OPSB Sensor will support two types of Bluetooth Low-Energy Modes: (1) BLE-discovery mode, and (2) BLE-off mode.
- The App will download data from the Sensor when the sensor is within 1-meter of the mobile device.

8. Performing standard functions

- After successfully connecting the OPSB Sensor to the OPSB App on a mobile device, the user will be able to view their earned star points based on sensor wear time data and their actual wear time compared to their target wear time.
- Additionally, after successfully connecting the OPSB Sensor to the OPSB App on a mobile device, the user can: (1) Navigate to the sensor tab or click the gray arrow to download sensor data to the APP, (2) Navigate to the reports screen to view all data and brace wear-trends, or (3) Navigate to the accounts tab to view or modify their account settings.

9. Using the OPSB App (Android / iOS):

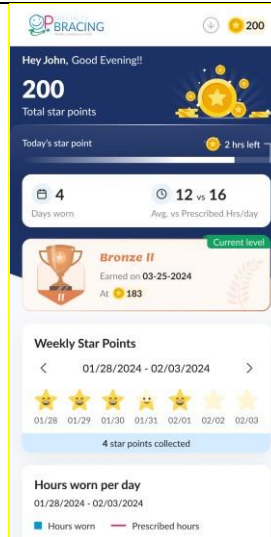
Using the App (Android / iOS)	Image
<p>Figure 1, login screen:</p> <p>New users will proceed through the patient or caregiver workflow to create their account and connect with the Sensor. Existing users will proceed to the “login” screen and use their previously created credentials to enter the App.</p>	

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Figure 2, home screen:

The Home screen displays the Sensor data, and all earned star points. Star points are earned once the patient reaches their target hours goal for the day. From this screen, the patient/caregiver can download the most recent Sensor data to the App.



Using the App (Android / iOS)

Figure 3, reports screen:


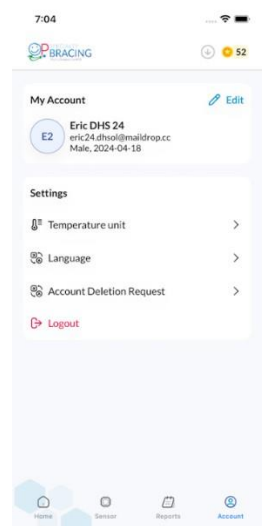
The Reports screen displays all sensor data for the selected date range.

Image



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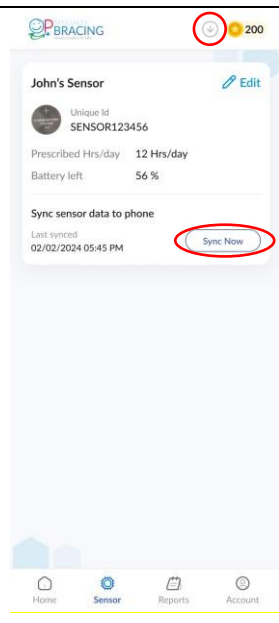
<p>Figure 4, sensor screen:</p> <p>The Sensor screen displays the Sensor's unique ID, the patient's target wear time in hours per day, and the remaining battery percentage. From this screen, the guardian/caregiver can download the Sensor data to the App.</p>	
<p>Using the App (Android / iOS)</p>	<p>Image</p>
<p>Figure 5, account screen:</p> <p>The Account screen displays the account details of the patient, and allows the patient to modify the App settings and to request deletion of their OPSB App account and all their stored data. Patients may request deletion of their data from the cloud platform at any time by submitting a request to Boston Brace International, Inc dba Boston Orthotics & Prosthetics through the Contact Us page: https://www.bostonoandp.com/contact/.</p>	

1.1 DISPLAY INDICATORS AND ICONS

<p>Display Indicator and icons</p>	<p>Image</p>
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<p>The down-arrow and “Sync Now” buttons identified in the image on the right are used to initiate the data download process with the Sensor if syncing data outside of the scheduled sync window.</p>	
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POSSIBLE ADVERSE EFFECTS

Patients should be advised to consult their HCP team immediately if experiencing any of the following:

- Skin irritation
- Pressure sores
- Pain, discomfort, or abnormal sensations due to the presence of the sensor

PATIENT COUNSELING

These Instructions for Use and all risks and benefits of the OPSB Sensor System based on individual patient factors should be fully explained to the patient by their HCP. Patient should contact their HCP in relation to the operation of the OPSB Sensor System. When necessary, the HCP may contact Boston Brace International, Inc dba Boston Orthotics & Prosthetics. Please refer to the

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Instructions for Use for the brace or orthosis being used with the OPSB Sensor System for important information regarding the instructions, warnings, precautions, and possible adverse effects of the brace or orthosis.

MRI SAFETY INFORMATION

The OPSB Sensor System is magnetic resonance (MR) unsafe and should remain outside magnetic resonance imaging (MRI) scanner rooms.

STERILIZATION INFORMATION

The OPSB Sensor System cannot be sterilized via steam, gamma, ETO, or x-ray. The OPSB Sensor System is provided nonsterile and does not require sterilization before use.

CLEANING INSTRUCTIONS

Clean the outside of the OPSB Sensor with 70% rubbing alcohol. The Sensor should be allowed to air dry. Do not use a heat source for drying.

STORAGE AND HANDLING

Avoid exposing the OPSB Sensor to extreme temperatures. The ideal temperature range is 40°F to 104°F. Please see the above Precautions and Warnings for other storage and handling instructions.

REUSE / USE LIFE

All parts of the OPSB Sensor were designed to be used by a single patient, multi-use under normal use conditions and as instructed by a clinical care provider. The OPSB Sensor has a shelf life of two (2) years. After first powering on, the OPSB Sensor has a useful life of one (1) year.

SAFE DISPOSAL

When the OPSB Sensor reaches the end of useful life, recycle or dispose of the equipment according to appropriate local and regional regulations. Do not dispose of the Sensor in household refuse.

IMPORTANT STATEMENT

- The OPSB Sensor System manufacturer and distributor are not liable for cases of material damage or personal injury caused by misuse of the Sensor or non-compliance with these Instructions for Use. Normal use is defined as a single user following intended use.
- Instructions for Use (IFU) are available in English in paper copy as well as at <https://opsb.com/ifu>. To obtain additional copies of the paper IFU, please call Customer Service Group at Boston Brace International, Inc dba Boston Orthotics & Prosthetics. at 1800-262-2235.
- If a patient, user, or HCP becomes aware of a malfunction of the OPSB Sensor System or any component of the OPSB Sensor System, please immediately report such event to Boston Brace International, Inc dba Boston Orthotics & Prosthetics.












CUSTOMER SUPPORT

- Contact Us at customerservice@bostonoandp.com
Telephone: 1-800-262-2235

SYMBOL LEGEND

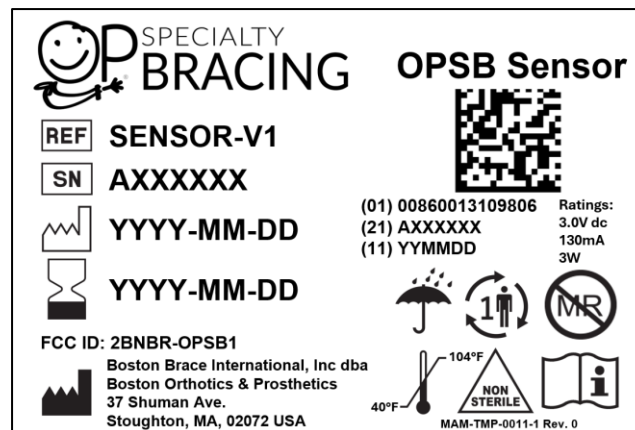
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Symbol	Meaning	Symbol	Meaning
	Manufacturer		Date of manufacture
	Catalog number		Serial number
	Single Patient, Multiple Use		Non-sterile
	Consult Instructions for Use or Consult Electronic Instructions for Use		MR Unsafe
	Temperature limit		Medical Device
	Type BF applied part		

SENSOR LABELING

The following label is found on the rear side of the OPSB Sensor Packaging. The label measures 3 inches by 2 inches.



SAFETY

- 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 take mitigation measures, such as relocating or re-orienting the equipment.
- The sensor was successfully tested for compliance with the following tests: Radiated Emission, Electrostatic Discharge, Immunity to Radio Frequency Electromagnetic Fields, Proximity fields from RF wireless communications equipment, and Power Frequency and Magnetic field Test.

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- There are no deviations from any standards used.
- No maintenance is needed to ensure basic safety and essential performance.

BATTERY RATING

- 3.0v dc, 130mA, 3W

FCC COMPLIANCE STATEMENT

FCC ID: 2BNBR-OPSB1. Changes or modifications to this product not expressly approved by the party responsible for compliance could void the electromagnetic compatibility (EMC) and wireless compliance and void the user's authority to operate the equipment. **This device complies with Part 15 of the FCC Rules. Operation is subject to the following conditions: (1) this device may not cause harmful interference, (2) this device must accept any interference received, including interference that may cause undesired operation.**

This equipment has been tested and found to comply with the limits for Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, 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: (1) reorient or relocate the receiving antenna, (2) increase the separation between the equipment and receiver, (3) connect the equipment into an outlet on a circuit different to that to which the receiver is connected, and (4) consult the dealer or an experienced radio/TV technician for help.

Any changes or modifications not expressly approved by the party responsible for Compliance could void the user's authority to operate the equipment. The OPSB Sensor (Antenna) maintains a 5mm separation distance from the body, it qualifies for an exemption from SAR measurement requirements. Please affix OPSB Sensor on body as instructed in this manual for maintaining the separation distance.

Compliance Standards

Guidance and Manufacturer's Declarations – Electromagnetic Emissions	
IEC 60601-1-2:2014+A1:2020	
Emission Test	Home Healthcare Environment
Radiated Emission	CISPR 11, Class B, Group 1
Guidance and Manufacturer's Declarations – Electromagnetic Immunity	
Immunity Tests	Home Healthcare Environment
Electrostatic Discharges (IEC 61000-4-2)	Contact Discharge: ±8kV Air Discharge: ±15kV
RF electromagnetic fields (IEC 61000-4-3)	80MHz-2700MHz, 10V/m, 80%, 1kHz
Proximity fields from RF wireless communications equipment (IEC 61000-4-3)	Refer Note
power frequency magnetic fields (IEC 61000-4-8)	30 A/m

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Test Specifications for Enclosure Port Immunity to RF Wireless Communications Equipment

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 – 390	TETRA 400	Pulse Modulation 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRs 460	FM ±5 kHz deviation 1kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse Modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse Modulation 18Hz	2	0.3	28
870						
930						
1720	1700 – 1990	Bluetooth, WLAN, 802.11 b/g/n, LTE Band 7	Pulse Modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217 Hz	2	0.3	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0.2	0.3	9
5500						
5785						