OPSB™ Sensor System
Instructions For Use

MANUFACTURER:
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https://opsb.com/ifu

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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 Cycoloy C6600 (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.

CLIINICAL 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.
- Please contact Boston Brace International, Inc. 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., may void the FCC authorization to operate this equipment.

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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. will keep confidential any patient identifying information that comes into its possession. Boston Brace International, Inc. may share and utilize limited or de-identified data with clinical partners of Boston Brace International, Inc. in research and in reporting outcome data to objectively review the impact of brace monitoring. Information regarding Boston Brace International, Inc.'s 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. 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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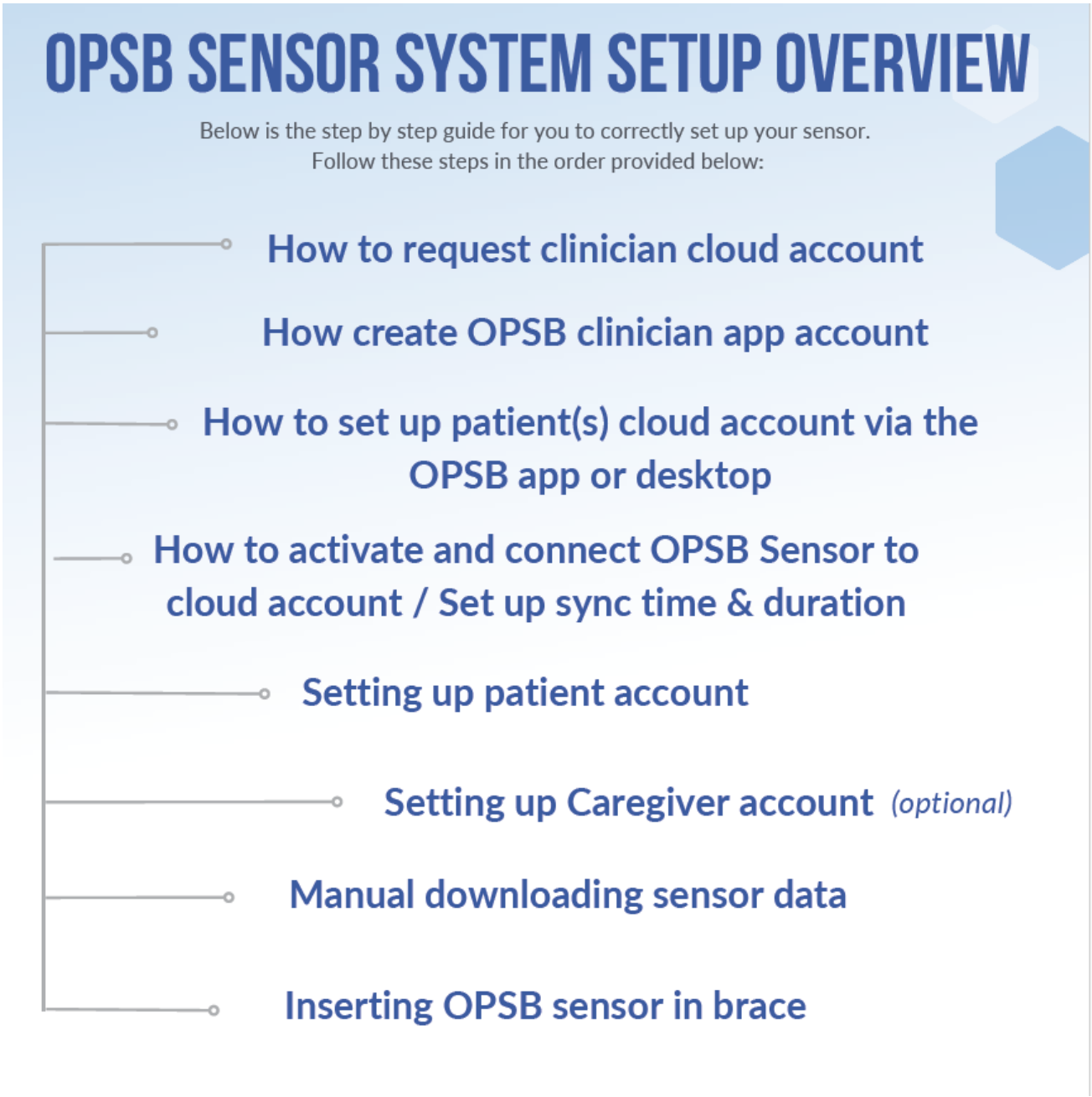
GUIDE FOR SETTING UP THE OPSB™ SENSOR SYSTEM



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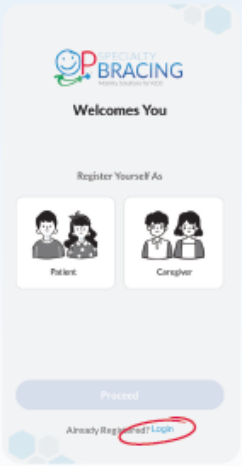
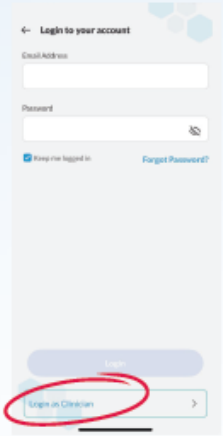
PATIENT REGISTRATION BY CLINICIAN

1 Clinician Login - Download the OPSB APP to your device

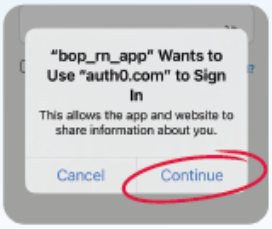
1. Select "Login" located in the bottom right corner.



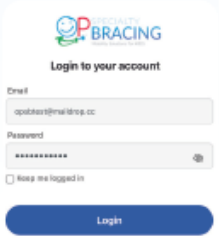
2. At the bottom of the screen, select "Login as Clinician."



3. To sign in, click 'Continue'.

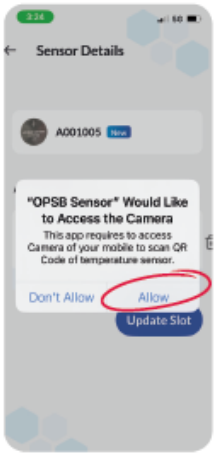


4. Use the same information you provided to create your cloud account for logging in.

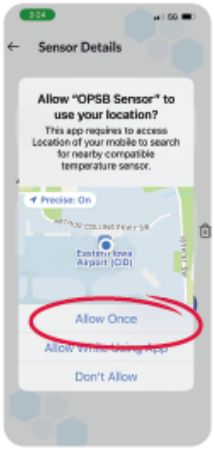


2 Allowing APP Permissions

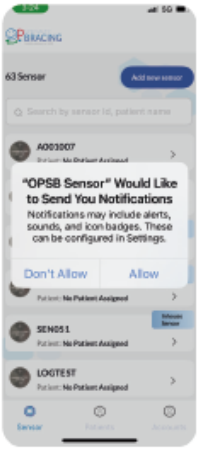
1. Grant camera permissions to scan the sensor's QR code.



2. Choose 'Allow Once' or 'Allow While Using App'

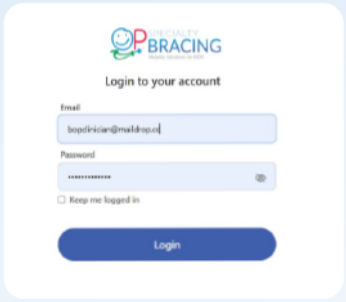


3. Decide whether you wish to receive notifications. *(optional)*

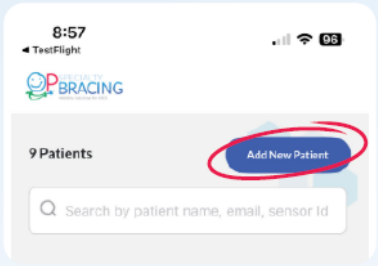


1 OPSB App Patient Account Set Up:

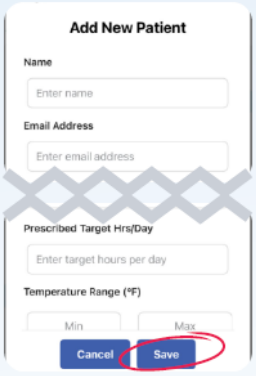
1. Log into your clinician account in OPSB App.



2. Select '**Add New Patient**.'

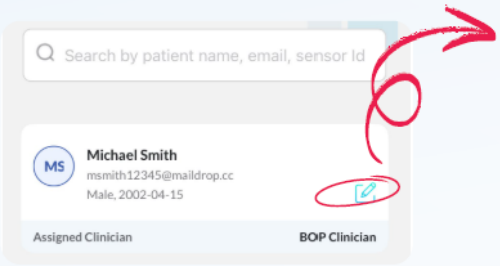


3. Enter all of patient's information and click '**Save.**'

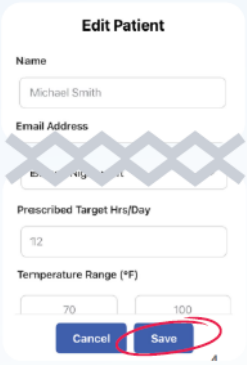


**The email address entered will be used to send the six digit code for the patient login section of the app.*

4. All patient's information can be easily edited by clicking the pencil icon.



5. Click '**Save**' once done.



Additionally, patients can be added via the web portal. To access the Clinician Cloud, go to https://us-app.opsb.com.

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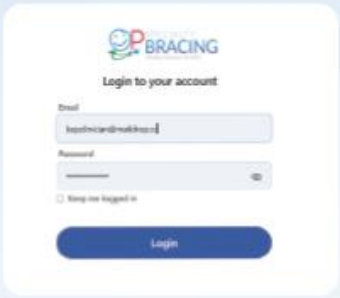
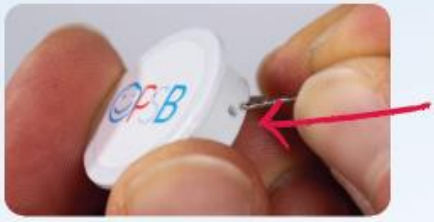
ADDING SENSOR TO PATIENT ACCOUNT BY CLINICIAN

1 Clinician: Assigning the OPSB Sensor

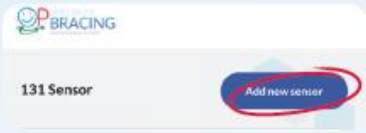
1. Log into your clinician account in OPSB App.



2. Activate the sensor by inserting the pushpin into the small opening.



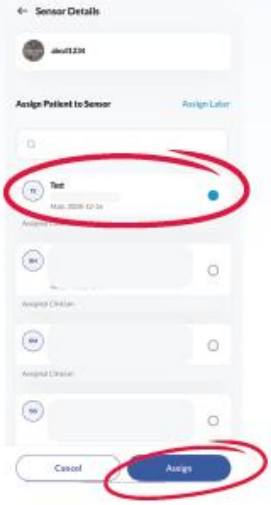
3. Select 'Add New Sensor.'



4. Scan the Sensor QR Code.

5. Type in your patient's name.

6. Select your patients '**Name**,' then click '**Assign**.'

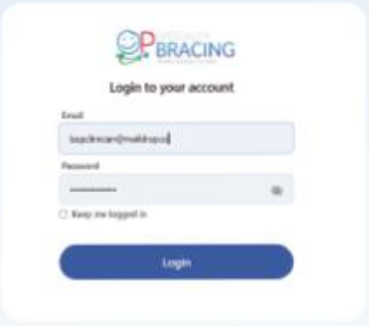


7. Sync Time and Duration.

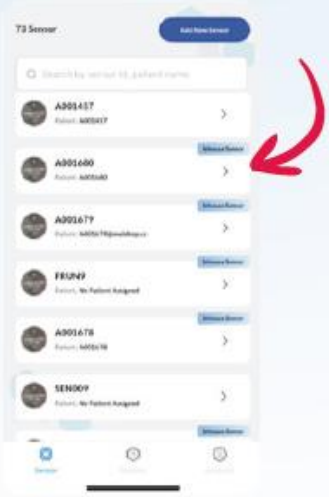
- The default slot time (12 PM EST) and duration (30 mins) are assigned to sensor and will need to be adjusted during the patient/parent set up.
- Patient/caregiver will have the ability to change default sync time and duration when initial onboarding and throughout the use of the sensor and app.

MANUAL DATA SYNC VIA CLINICIAN APP

1. Log into your clinician account in OPSB App.

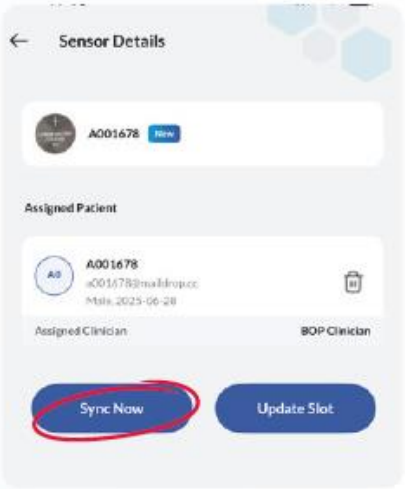


2. Type in patient name or sensor serial number to locate sensor.
   - Click on sensor

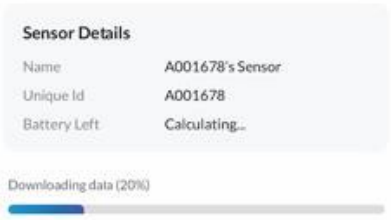


3. Use push pin to wake up Sensor so it's available for syncing.

4. Click 'Sync Now.'



5. Syncing will begin after a few moments.



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NOTE: Recommendation is to have Patient sign up on their own phone. If Patient doesn't have a phone, then Caregiver should download the OPSB™ app & sign in as Patient.

THE PATIENT APP ACCOUNT MUST BE SETUP FIRST IN ORDER FOR THE SYNCING TO OCCUR.

SETTING UP PATIENT APP INSTRUCTIONS

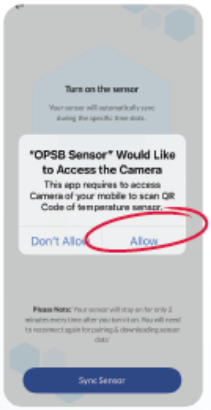
1 Setting Up APP on a Patient Device

1. Download the OPSB App off the App Store or Google Play store.

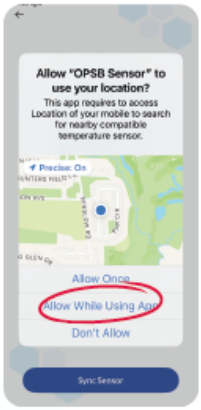
OPSB Sensor

2 Allowing APP Permissions on iOS

1. Allow camera permissions to scan the sensor QR Code.



2. Choose 'Allow Once' or 'Allow While Using App.'



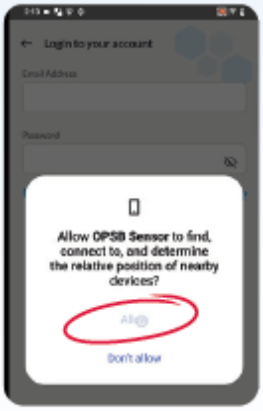
3. Choose 'Allow' to give Bluetooth access to device.

2 Allowing APP Permissions on Android

1. Allow camera permissions while using the App' to scan the sensor QR Code.

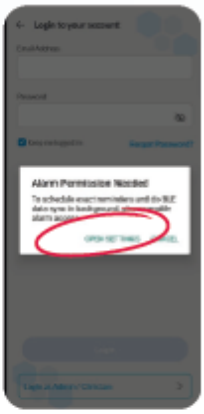
2. Choose **Precise** 'While Using App.'

3. Choose 'Allow' to give Bluetooth access to device.



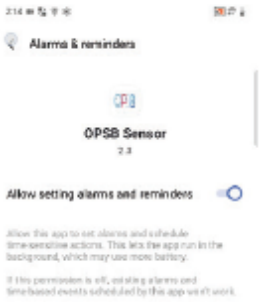
Alarm permissions are needed to enable auto syncing of the data.

4. Click 'Open Settings.'



5. Click on 'OPSB Sensor.'

6. Click 'Allow setting alarms and reminders' slider.



7. Setting will now say OPSB Sensor 'Allowed.'

8. Navigate back to the OPSB App and continue the set-up process.

9. 'Allow' sensor to send notifications.

3 Patient: Setting Up the Patient Account

1. Open app and click 'Patient.'
   - To awaken the sensor, insert the push pin into the small hole.

2. Scan the sensor QR code.
   - Or click 'Pair via bluetooth'
   - Select your sensor ID from the list
   - Click "Yes it's me" once the patient's name appears

3. A 6-digit code will be sent to the provided email, please enter it here to verify.

4. Set the password for your account.

5. End-user License agreement. Must select the top box and sign to proceed.

6. Set the sync slot and duration (time sensor is available to sync) and select 'Save.'

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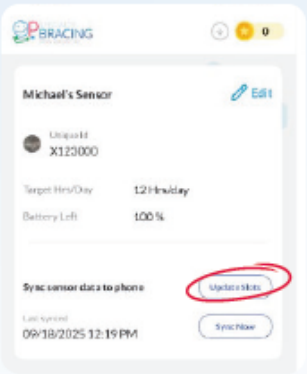
UPDATING SYNC TIMES

4 Updating sync times

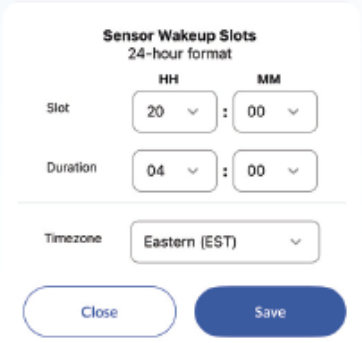
1. Open OPSB Sensor app and login.

2. See bottom bar click on sensor tab.

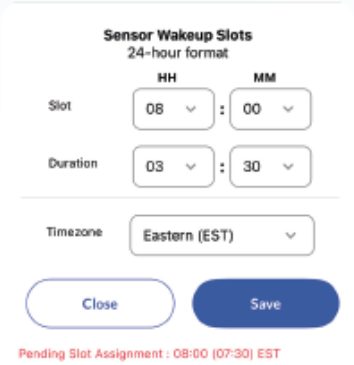
3. Click 'Update Slots' to change sync times and duration.



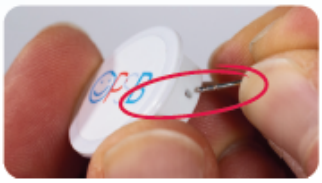
4. Update slot and duration time.



5. Updated time will change at next current sync time.

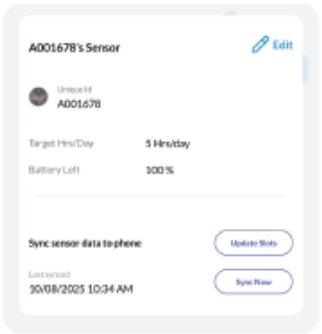


6. Auto download of the sensor.
   - Press the pin hole button
   - Click 'Sync Sensor'



5. Click 'Sync Sensor.'

7. Confirm the sensor has synced.
   - Click 'Sensor' at the bottom of screen to review
   - Note the date and time of the last sync



SETTING UP CAREGIVER ACCOUNT

Optional

1 Setting Up APP on a Different Device

1. Download the OPSB App off the App Store or Google Play store.

2 Allowing APP Permissions

1. Allow camera permissions to scan the sensor QR Code.

2. Choose 'Allow Once' or 'Allow While Using App.'

3. Choose 'Allow' to give Bluetooth access to device.

3 Syncing the Caregiver Account

1. Click 'Caregiver' then 'Proceed'
   - You will be directed to an information screen
   - Enter caregiver details
     - Email will need to be unique from 'Patient' account


2. A 6-digit code will be sent to the 'Caregiver' email please enter it here to verify.

3. Set password.

4. To awaken, push a pin in small hole on the side.
   - Click 'Scan Sensor'


5. Scan the sensor via QR code.
   - Or click 'Pair via bluetooth'
   - Select your sensor ID from the list

6. Select "Yes, I know this Patient" once the patient's name appears.

4 Download Data from Sensor

1. Download data from the sensor first. To begin download:
   - Press the pin hole button again

2. Click 'Sync Sensor.'

3. Confirm the sensor has synced.
   - Click 'Sensor' at bottom of screen to review
   - Note the date and time of the last sync

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INSTALLING SENSOR INTO BRACE OR ORTHOSIS

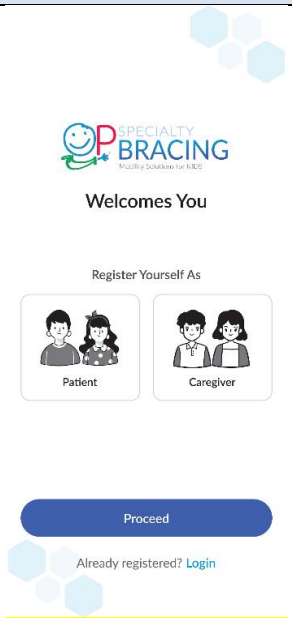
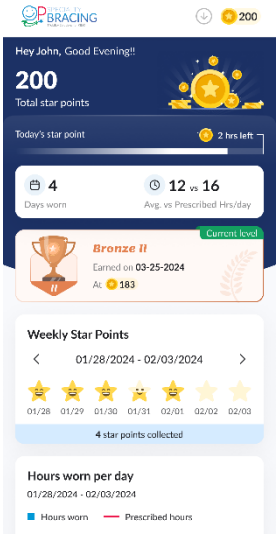
Additional Sensor System Information

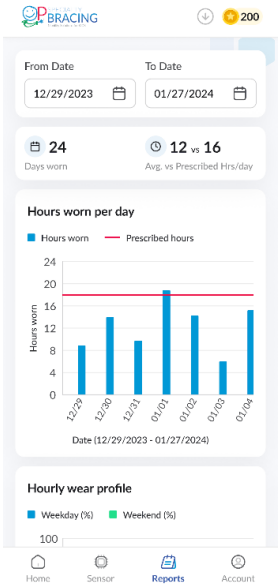
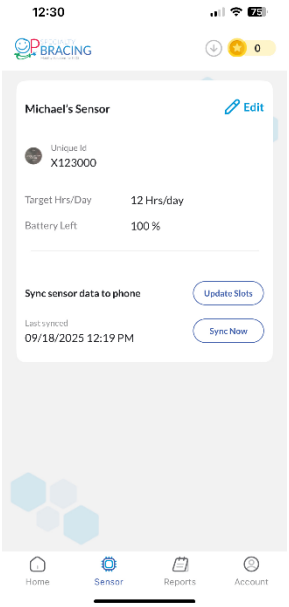
1. **Operating modes**
   a. The OPSB™ Sensor will support two types of low power modes: (1) Power Down Mode where powering on ("wake-up") is allowed only by pin-hole button press, and (2) Sleep Mode, where wake-up is allowed by wake-up pin-hole button press or the pre-set sync schedule (as determined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

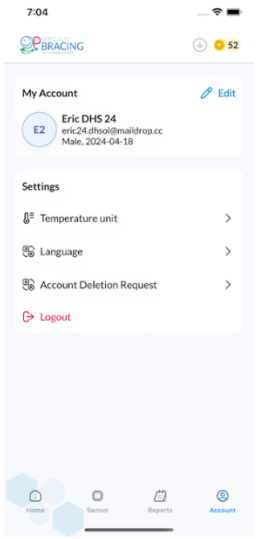
2. **Performing standard functions**
   a. After successfully connecting the OPSB™ Sensor to the OPSB™ App on a mobile device, the user will be able to view their earned star points based on sensor wear time data and their actual wear time compared to their target wear time.

b. 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.
c. To update the sensor sync times, the user can navigate to the sensor tab, click the “Update Slots” button. Here, the user can modify the sensor sync time, and the duration that the sensor will remain awake for when syncing.

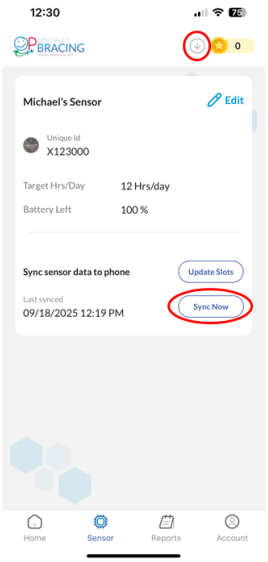
3. Using the OPSB™ App (Android / iOS) -- Logging in after Registration

Using the App (Android / iOS)	Image
Figure 1, login screen: 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 (email/password) to enter the App.	
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. **Background Data Syncing** will occur automatically at the specific time slots set by the clinician, **IF the APP remains open (in the background OR prior to the sync times)**	

Using the App (Android / iOS)	Image
Figure 3, reports screen: The Reports screen displays all sensor data for the selected date range.	
Figure 4, sensor screen: 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 parent/caregiver can download the Sensor data to the App and adjust the sync time and duration.	

Using the App (Android / iOS)	Image
Figure 5, account screen: 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. through the Contact Us page: https://www.bostonoandp.com/contact/.	

4. Display indicators and icons

Display Indicator and icons	Image
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. **For syncing outside of scheduled time slots:** Awaken the sensor by pushing a pin in the small hole on the side of the sensor. Click “Sync Sensor”.	

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. Patients should contact their HCP in relation to the operation of the OPSB™ Sensor System. When necessary, HCP may contact Boston Brace International, Inc. Please refer to the Instructions for Use for the brace or orthosis being used with the OPSB™ Senor 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. at 1-800-262-2235.
- If a patient, user, or HCP becomes aware of the malfunction of the OPSB™ Sensor System or any component of the OPSB™ Sensor System, please immediately report such event to Boston Brace International, Inc.

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

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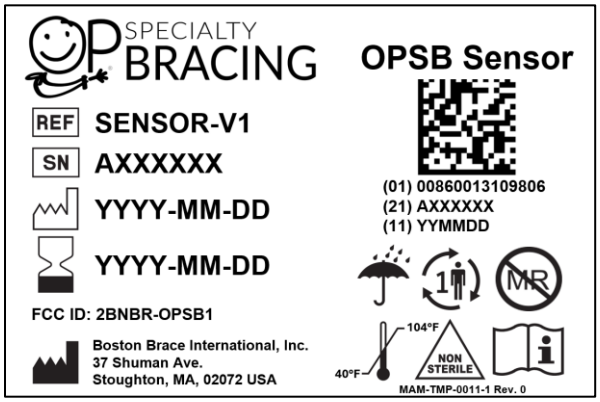
SYMBOL LEGEND

Symbol	Meaning	Symbol	Meaning
	Manufacturer		Date of manufacture
REF	Catalog number	SN	Serial number
	Single Patient, Multiple Use	NON STERILE	Non-sterile
	Consult Instructions for Use or Consult Electronic Instructions for Use	MR	MR Unsafe
104°F 40°F	Temperature limit	MD	Medical Device

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.
- 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.

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

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						

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