Dream Sock®

User Manual

Owlet Baby Care Customer Support

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1. General Information

About this Manual

This manual explains how to set up and use Dream Sock. Important safety information pertaining to the Owlet Dream Sock is included and should be read in its entirety. Other applicable safety warnings, cautions and notes appear in this manual where appropriate.

Read through this user manual before using Dream Sock.

Follow the instructions in this manual carefully to ensure proper use of the device. Contact Owlet customer support with any questions.

Intended Use for Dream Sock

Dream Sock is intended for routine, in-home surveillance of healthy infants by measuring oxygen saturation (SpO2) and pulse rate (PR). Dream Sock software analyzes photoplethysmography data to identify instances when the infant's PR and/or SpO2 moves outside a preset range, and provides a notification to the caregiver, prompting them to assess the infant.

The notifications and associated data are intended to supplement the decision by caregivers to seek additional guidance for medical care of the infant. The feature is not intended to replace traditional methods of diagnosis and/or treatment.

Indications for Use for Dream Sock

Dream Sock is indicated for use in healthy infants/children ages 0 to 18 months and weighing between 2.5-13.6kg in the home environment. It is not indicated for use with infants previously diagnosed with chronic cardiovascular and/or respiratory conditions.

Dream Sock is indicated for the detection and notification of hypoxia when measured SpO2 levels fall below 80%, as well as the detection and notification of tachycardia and bradycardia when PR levels are measured above 220 BPM or below 50 BPM, respectively.

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1.1 Manufacturer Information



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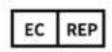
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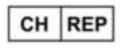




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1.2 Requesting a Paper Manual

Should you want a physical, paper copy of this manual, please email Owlet Baby Care Customer Support requesting you be mailed a physical copy of Dream Sock manual. If requested, Owlet shall provide a physical, paper copy within 7 calendar days.

Owlet Baby Care Customer Support can be emailed at: contact@owletcare.com

2. Safety Information

This section contains important information. Read this section completely. Contact technical support or customer support with any questions. For contact information, see <u>Section 14</u>.

In the event that a serious health and safety event occurs while using the device please immediately contact customer support as well as the applicable competent authority in your geographic area.

2.1 Safety Symbols

For a complete list of symbols, see Section 19



WARNING!

Alert of potentially hazardous situations which, if not avoided, could result in death or serious injury to the baby or Caregiver.



Alert of potentially hazardous situations which, if not avoided, may result in minor or moderate injury to the baby or Caregiver or damage to the equipment or other property.



NOTE:

Provides important information about the product or a specific topic.

2.2 Warnings



WARNING: USE DREAM SOCK AS INDICATED AND REGULATED FOR USE.

WARNING! Always keep the device and accessories out of the reach of children. Small parts including the Sensor and cables are potential choking hazards. Place the Base Station at least 1 meter away from the crib as the cord can pose a strangulation hazard.

WARNING! The mobile device application is not intended to be treated as the primary source of notifications. **The Base Station is the primary source of notifications.** Always keep the Base Station in audible range. Ensure the Base Station can be heard over ambient noises (example: noise machines or televisions). Ensure the Base Station is not covered, as it could muffle alarm sounds.

WARNING! TO PROPERLY USE OUR PRODUCTS AND FOR CARE OF YOUR CHILD: RESPOND PROMPTLY WHENEVER A NOTIFICATION IS PROVIDED, EVEN IF IT RESOLVES.

WARNING! Always check on the baby during high priority alarms to assess the environment and take action as needed.

WARNING! DREAM SOCK IS NOT A SUBSTITUTE FOR ADULT SUPERVISION, GOOD PARENTING PRACTICES OR SAFE SLEEP PRACTICES.

WARNING! Dream Sock is not indicated for use in babies with health conditions. For babies with health conditions, please consult your healthcare professional to determine whether or not Dream Sock is right for your child.

WARNING! Dream Sock is not intended for use with babies older than 18 months old, or weighing less than 2.5kg or above 13.6kg.

WARNING! Use of accessories, transducers and cables other than those specified for use with Dream Sock as described in this document can result in inaccurate readings, degraded performance, or injury.



WARNING! Dream Sock system is single infant/child use only.



WARNING! Remove the Sock and Sensor before bathing.



WARNING! Do not connect Dream Sock to other devices not included with the device.



WARNING! Discontinue use of damaged components of Dream Sock system.

WARNING! Do not transport or store the system in direct sunlight, garages, attics or a hot vehicle or Dream Sock system may be damaged.



WARNING! Dream Sock is not for use in the presence of flammable agents including IPA and other cleaning agents.



WARNING! Pulse Rate and Oxygen ranges are not adjustable and are fixed preset values.

2.3 Cautions



CAUTION. Dream Sock is **NOT** designed for use in moving vehicles.



CAUTION. Keep Sensor out of direct sunlight when in use to minimize interference that may affect performance.

CAUTION. If there is more than one baby in the house using different Dream Sock systems, write the name of each baby on the Sock, Sensor and Base Station to avoid confusion.

CAUTION. Do <u>NOT</u> place any component of Dream Sock system or accessories in any position where it might fall on the baby. Injury could occur.

CAUTION. For security, keep your Owlet Dream App up to date at all times and make sure your mobile device is password protected.

CAUTION. Regularly verify Sock fit. The baby's actual foot size may differ from the provided guidelines and babies grow quickly. Stop using the Dream Sock system when your baby outgrows the largest sock.

CAUTION. Even if your baby meets the age and weight requirements, if all Sock sizes are either too small or too large, discontinue use of the Dream Sock device.

CAUTION. Alternate between feet every 8 hours of use or after recharging the Sensor. Check the child's foot often for any signs of irritated skin.

CAUTION. Dream Sock performance may be affected by foot deformities. Because foot deformities vary widely in nature and severity, we recommend that you consult your pediatrician before use on babies with foot deformities.

CAUTION. Do <u>NOT</u> stretch the straps when fastening. Stretching straps will lead to over tightening and increased risk for skin irritation.

CAUTION. Do <u>NOT</u> fasten the Sensor to the baby's foot using anything other than Dream Sock fabric socks. Injury to the baby's foot may result.

CAUTION. Do <u>NOT</u> use lotions, creams or powders on the feet before applying the Sock and Sensor. Application site must be clean and dry to avoid skin irritation.



CAUTION. Do **NOT** apply the Sock and Sensor to wet skin. Excess moisture may increase the risk of skin irritation.



CAUTION. Verify the Sock and Sensor are dry and free of dirt, hair or other foreign substances before placing it on the



baby.

CAUTION. Do NOT apply the Sock and Sensor too tightly. Too much pressure for long periods can cause a pressure injury.

CAUTION. Always ensure that the Sock with Sensor is placed correctly on the baby's foot. Poor Sock placement may cause skin irritation.

CAUTION. Ensure the abrasive patches of the hook and loop fasteners are not contacting the baby's skin as this may lead to skin abrasion.



CAUTION. Signs of skin irritation or excessive notifications can be an indicator of incorrect Sock size or placement.

CAUTION. If the Sensor windows are pulling away from the foot, the Sock may be too loose. Try tightening the Sock or use a smaller Sock size. Air gaps can cause intermittent readings.



CAUTION. Improper Sock fit or care can lead to injury to the skin.



CAUTION. If you Log Out of the mobile app you will no longer receive push notifications or alarms on your device.

CAUTION. Do **NOT** use caustic or abrasive cleaning agents such as ammonia, bleach or alcohol. Harsh chemicals could damage the Sock or Sensor.

CAUTION. Do <u>NOT</u> submerge the Sensor for any period of time or use a washing machine. The Sensor is water resistant and should only be scrubbed clean.



CAUTION. Use cleaning solutions sparingly to avoid getting any liquid in the enclosure.

CAUTION. A factory reset will completely reset the Dream Sock Base Station and Sensor. You will no longer be able to receive readings or notifications until the device is set up again.



CAUTION. Do **NOT** sit or step on the device as damage may occur.



CAUTION. Avoid positioning the Base Station near devices that emit radio waves.



CAUTION. Do **NOT** service, repair, open, or modify Dream Sock.

CAUTION. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally

CAUTION. Keep Dream Sock clean, free of dust and lint, and away from pets. Exposing the device to dust, lint and pets or pests could damage the device.

CAUTION. Always store the Dream Sock properly when not in use. Pets, pests (insects) or children can damage the device or accessories.

3. Before Using Dream Sock

3.1 Before First Use

Do the following before using Dream Sock for the first time:

- Read this entire user manual (this document).
- Understand the warnings and precautions.
- Set up the Owlet Dream mobile app.
- Fully charge the Sensor.

3.2 Who Should Use Dream Sock?

Dream Sock is indicated for:

- Dream Sock is suitable for routine, in-home surveillance of healthy babies.
- Children ages 0-18 months, weighing between 2.5-13.6kg

The Dream Sock is designed to be used by caregivers in the home environment. All knowledge required to operate the device is provided within the IFU.

3.3 Who Should NOT Use Dream Sock?

Dream Sock is contraindicated for:

- Babies and children with ongoing health conditions. For infants/children with health conditions, caregivers shall consult a healthcare professional to determine whether or not Dream Sock is right for the infant/child.
- Not for infants weighing less than 2.5kg.
- Not for children weighing more than 13.6kg.
- Not for children more than 18 months old.
- Not a substitute for caregiver supervision.

- Not a substitute for safe sleep practices.
- Infants/children who are poorly perfused
- Infants/children who require physician recommended monitoring for chronic cardiovascular and/or respiratory conditions

3.4 Where to use the Dream Sock

Dream Sock is designed for use in the home.



CAUTION. Dream Sock is NOT designed for use in moving vehicles.



CAUTION. Keep Sensor out of direct sunlight when in use to minimize interference that may affect performance.

3.5 Network Requirements

A Wi-Fi network is required to use Dream Sock and Owlet Dream App and allows the hardware to communicate with the mobile device application and cloud servers - information such as Sleep States, Health Notifications and battery status are shared over the network. The mobile device application will not function properly if the Base Station is not able to connect to a reliable Wi-Fi network, A 2.4GHz IEEE 802.11 (b/g/n) Wi-Fi network using WPA2, or similar encryption method is required. Most home routers that operate at 5 GHz will also operate at 2.4 GHz. When connecting your devices, pick the 2.4 GHz connection.

Dream Sock can remember up to 8 Wi-Fi networks making it easy to move the system between locations (i.e., home, grandmother's, babysitter).

To add a new Wi-Fi network to an already set up device, refer to the setup instructions in the Owlet Dream App, Section 5. Account > My Owlet Devices (Select Device) > Change Wi-Fi

NOTE: Dream Sock cannot be used with networks that require authentication via a browser. These include many public networks like those found in hotels and airports.

The Sensor and the Base Station communicate via BLE (Bluetooth® Low Energy) 4.2. This communication is handled automatically, and no additional hardware is required.

4. Dream Sock Overview

4.1 What is Dream Sock



WARNING: USE DREAM SOCK AS INDICATED AND REGULATED FOR USE.

Dream Sock Sensor measures oxygen saturation (SpO2) and pulse rate readings from your child. The Sock connects to the Base Station, and the info is sent from the Base Station to the phone, via the mobile app. The App also provides tips and developmental insights. The Base Station indicates notifications as needed based on the data sent from the Sock.



How the App works

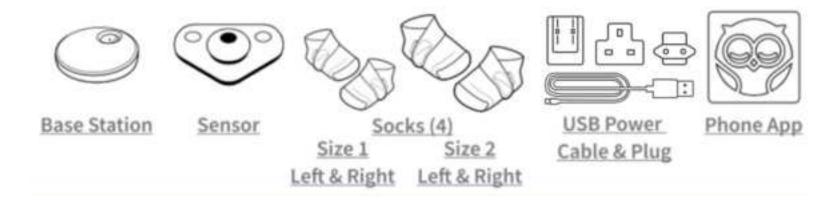
Connect to Wi-Fi: The Base Station sends information to the Owlet cloud via Wi-Fi, and displays this data in the mobile phone application. This enables real-time readings and notifications in the mobile phone application from anywhere. The Base Station will indicate whether or not you have the Sock connected to Wi-Fi.

BLE:

The Sensor and the Base Station communicate via BLE (Bluetooth® Low Energy) 4.2. This communication is handled automatically, and no additional hardware is required.

4.2 Unpacking the Box

Dream Sock box includes the following:



The use life of Dream Sock is defined as 12 months.

The following are available for spare or replacement parts for Dream Sock.

REF Model Ref. for Dream Sock Component	Component Description	Component Use Life
--	-----------------------	--------------------

20.0177	V3 Fabric Sock Size 1 Left - Mint	3 months
20.0178	V3 Fabric Sock Size 1 Right - Mint	3 months
20.0179	V3 Fabric Sock Size 2 Left - Mint	3 months
20.0180	V3 Fabric Sock Size 2 Right - Mint	3 months
20.0185	V3 Fabric Sock Size 1 Left - Dusty Rose	3 months
20.0186	V3 Fabric Sock Size 1 Right - Dusty Rose	3 months
20.0187	V3 Fabric Sock Size 2 Left - Dusty Rose	3 months
20.0188	V3 Fabric Sock Size 2 Right - Dusty Rose	3 months
20.0181	V3 Fabric Sock Size 1 Left - Bedtime Blue	3 months
20.0182	V3 Fabric Sock Size 1 Right - Bedtime Blue	3 months
20.0183	V3 Fabric Sock Size 2 Left - Bedtime Blue	3 months
20.0184	V3 Fabric Sock Size 2 Right - Bedtime Blue	3 months
OSS 3.0-M1	Sensor	12 months
OBL 3.0-M1	Base Station	12 months
11.0436	USB Power Cable (Manufactured by: Metaline)	12 months
SMI5-5-K-I38-C5 (Base) SMI-EU-3-C2 (EU blade)	USB Plug (Manufactured by: CUI)	12 months

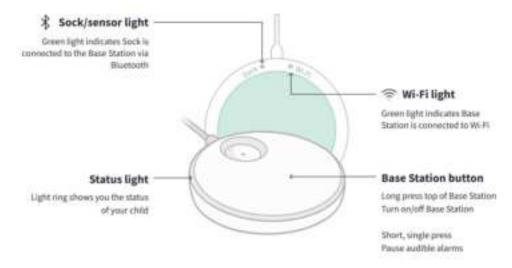
SMI-UK-3-C1 (UK blade)		
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Contact Owlet Baby Care, Inc. customer service for ordering information

4.3 Base Station Overview

The Base Station is a central component of Dream Sock system. It communicates with the Sensor to obtain data. The Base Station logs and monitors the baby's data and determines when to send notifications. The Base Station also relays baby's information to Owlet's servers and the Owlet Dream App so Caregivers can see the information on their mobile devices.

Base Station Features



Sock/Sensor Light

Indicates that the Base Station is communicating properly with the Sensor. Always check that the Sock/Sensor light is lit up whenever monitoring is initiated. The Sensor light on the Base Station will not light up if the Base Station has not yet been paired to the Sensor.

Wi-Fi Light

Indicates that the Base Station is connected to Wi-Fi.

Base Station Button:

(Long press top of Base Station)
Turn on/off Base Station
(Short, single press)
Silence/Resume audible notifications

Base Station Notification Indicators

The Base Station notifies you with visual and audible indicators to inform you of your baby's status. (See <u>Section 6.3.2</u> for details on Notifications)

WARNING! The mobile device application is not intended to be treated as the primary source of notifications. **The Base Station is the primary source of notifications.** Always keep the Base Station in audible range. Ensure the Base Station can be heard over ambient noises (example: noise machines or televisions). Ensure the Base Station is not covered, as it could muffle alarm sounds.

The expected use life of the Base Station is 12 months.

4.3.1 Base Station Backup Battery

Dream Sock Base Station has a built-in backup battery which is designed to alert the Caregiver via a medium priority alarm that main power has been lost while monitoring. Restore power to the Base Station to resume monitoring. If power is not restored, the system will power off after 2 minutes.

- Notification settings will not be reset by power loss and once power is restored, notifications will resume according to your settings.
- The backup battery charges automatically when the Base Station is plugged in.
- The Base Station will NOT notify during a power loss if it is already turned off or the Sensor is charging.
- The typical use of the Base Station backup battery is 12 months.
- The Base Station backup battery is not serviceable.

4.4 Sensor Overview

The Sensor has light emitters and a detector which measures pulse rate, oxygen saturation and movement. This data is sent to the Base Station via Bluetooth.

For the Sensor to function properly, it is positioned and held in a specific location on the foot by a specialized Owlet Sock (see Section 6.1).

NOTE: Pairing associates a Base Station and new Sensor. If the Sensor is replaced, you will need to repeat the pairing process with the new Sensor and Base Station. Contact Owlet Customer Support for assistance.

Sensor Features

The Sensor has a dome-shaped body with an Owlet logo on it. Attached to the Sensor is a flexible fabric sensor with the light emitters and detector. This flexible fabric portion curves around the baby's foot, placing emitters opposite to the detector.

Measurement Light Emitter

Shines LED light through the foot to allow the Sensor to receive accurate readings.

Measurement Light Detector

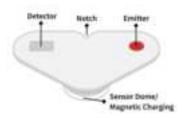
Collects readings.

Sensor Dome/Magnetic Charging

Connects to the Base Station for charging.

Sock Notch

Aids alignment of the Sensor to the Sock.



Sensor Battery

Dream Sock Sensor is powered using a non-replaceable rechargeable battery. The Sensor has up to a 16-hour battery life (when new) and uses convenient drop-and-go charging for an 8-hour charge in just 20 minutes, and full 16-hour charge in only 90-minutes. It is recommended to charge the Sensor at least once a day when the Dream Sock system is being used (see Section 6.5).

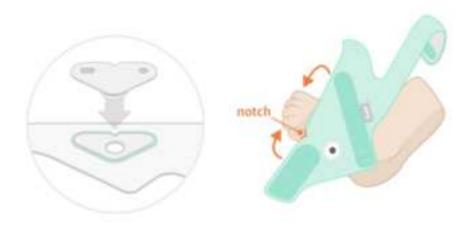
- The typical use life of the Sensor battery is 12 months.
- The Sensor battery is not serviceable.

Turning off the Sensor

See Section 9.4

4.5 Sock Overview

The soft, washable Sock is used to hold the Sensor to the baby's foot in just the right location. The Sock has a location for the Sensor to be inserted. The hole in the sock stretches over the Sensor dome. The Sock also has a notch which should align with the notch in the Sensor. The Sock notch is also used to properly align the Sock to the pinky toe of the foot. Hook and loop straps on the socks are used to secure the Sock to the baby's foot.



To learn more about Sock placement & fit to the baby's foot, see Section 6.1.

• The expected use life of the fabric Sock wrap is 3 months.

CAUTION. Always ensure that the Sock with Sensor is placed correctly on the baby's foot. Poor Sock placement may affect performance.

4.6 USB Power Cable and USB Plug Overview

A USB power cable and USB plug are included with Dream Sock. One end of the USB cable is plugged into the back of the Base Station, and the other end is plugged into the USB Plug. The USB Plug is then plugged into an electrical outlet. This is the power source for the Base Station, including the charging apparatus used for the Base Station backup battery.



WARNING! Use of accessories, transducers and cables other than those specified for use with Dream Sock as described in this document can result in inaccurate readings, degraded performance, or injury.

NOTE: The operator is responsible for checking the compatibility of the Sensor, Base Station, mobile device and any accessories before use.

5. How to Setup Dream Sock

Dream Sock should sit at room temperature for 90 minutes prior to use.

5.1 Finding a Home for the Base Station

WARNING! The mobile device application is not intended to be treated as the primary source of notifications. **The Base Station is the primary source of notifications.** Always keep the Base Station in audible range. Ensure the Base Station can be

heard over ambient noises (example: noise machines or televisions). Ensure the Base Station is not covered, as it could muffle alarm sounds.

The Base Station location is essential for proper performance and safety.

The best location may **NOT** be your baby's room depending on your home. During the day, you may have to **move** the Base Station so you can always hear it. Keep the Base Station where:

1) You can always HEAR and SEE it

The Base Station is the primary source for all notifications, both audible and visual. It should be located so that the Caregiver can see and hear notifications over any background noise.

2) It will WAKE you up at night

The Base Station should be located to wake Caregivers during notifications. The Base Station lights will automatically dim in darker rooms.

3) It can connect to your home Wi-Fi network

The Base Station must be within range of your home Wi-Fi network. Once set up, verify connection using the Wi-Fi light on the bottom of the Base Station or the Owlet Dream App. If the connection is unstable, move the Base Station until the connection is stable.

4) It can talk to the Sensor (within 100 feet)

In most cases, the Sensor and the Base Station just need to be within the same home, within 100 feet of each other, so they can communicate. But home size and layout may affect signal strength, requiring the Base Station to be placed closer to the Sensor.

5) It is away from the crib

Keep the Base Station and cord at least 1 meter away from the crib and out of baby's reach to reduce cord strangulation hazards.

6) It is difficult to disconnect the power cord.

Keep the Base Station in a location where it is difficult to disconnect the power cord from the Base Station.



CAUTION. Do NOT place Dream Sock System in any position that might cause it to fall on the baby. Injury could occur.

If a single location cannot fulfill all of these requirements, the Base Station may need to be moved during the day.

5.2 Setup the Owlet Dream App

The Owlet Dream Mobile Device Application (App) communicates with the Base Station using your home wireless network. The App displays readings, status messages and notification information and is a vital part of the Dream Sock System.



Download the Owlet Dream App

Use the Owlet Dream App to set up your new Dream Sock. After downloading, follow the set up steps in the App, the App will guide you through:

- Creating an account
- Account confirmation
- Device setup
- Connecting to Wi-Fi
- Registering the Base Station
- Sock pairing
- Creating a child profile
- Required learning

The Owlet Dream App allows you to:

- See real-time vital sign readings and baby's status
- Receive notifications
- See and modify the baby's sleep history

Track baby's sleep duration and state

Requirements: Dream Sock requires access to a mobile device running either iOS 14.0 and above or Android 7.0 and above with the Owlet Dream App downloaded; minimum OS versions apply, see app stores for details.

NOTE: Contact Owlet Baby Care customer support for assistance in setting up, using or maintaining Dream Sock or to report unexpected performance and operational issues.

NOTE: The Sensor comes inserted in one of the small Sock sizes. Initial hardware and App setup may be completed using this configuration. Correct Sock size selection should be verified before actual use.

Download the Owlet Dream App

Before proceeding, download and install the Owlet Dream App. The app will guide you step by step through setup. After downloading the Owlet Dream App, you should immediately enable Owlet Dream App push notifications on your mobile device settings.

A 2.4 GHz wireless internet connection is required for live readings in the Owlet Dream App, remote access to the App, and some App features.

Connect to Wi-Fi: The Base Station sends information to the Owlet cloud via Wi-Fi, and displays this data in the App. This enables real-time readings and notifications in the App from anywhere. The Base Station will indicate whether or not you have the Sock connected to Wi-Fi.

NOTE: Other equipment using the same Wi-Fi network may consume excess bandwidth or otherwise interfere with connection to the mobile device. In addition, changes to your network such as hardware replacement/update/upgrade, network configuration or setting changes may result in a lost connection. You should verify a Direct connection when using the Owlet Dream App.

To set up Dream Sock:

Step 1 Download the Owlet Dream App

Available for iOS and Android.

Step 2 Create an account (app screens)

Follow the in-app instructions to create an account. Want to share access to baby's information provided in the Owlet Dream App? We recommend creating a single account that each Caregiver can access.

Step 3: Plug in the Base Station to a power source and place the Sensor onto the charging port on the Base Station Follow the in-app instructions to connect the Dream Sock to Wi-Fi, as well as register and pair the Dream Sock and make updates to the Dream Sock, if necessary.

Step 4: Read and accept safety warnings in the App

These safety warnings must be acknowledged by checking the box in order to move forward in the process.

Step 5: Create a child profile

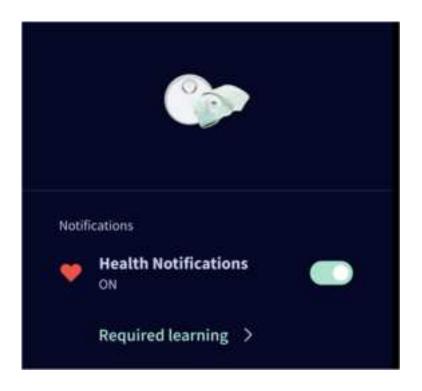
The App will walk you through creating a profile for your child and assigning that profile to an Owlet device.

CAUTION. For Dream Sock to function as intended, as well as for your security, keep your Owlet Dream App up to date at all times and make sure your mobile device is password protected. See Section 17 for more information on Cybersecurity.

5.3 Owlet's Health Notifications



Owlet's Health Notifications allow Caregivers to view live health readings such as Pulse Rate and Oxygen values ("Health Readings") during a monitoring session, as well as get notified via a high-priority notification if Oxygen or Pulse Rate leave preset ranges. These preset ranges are not adjustable, they are fixed preset values. The Pulse Rate Notification will occur when the measured pulse rate goes below 50 BPM (beats per minute) or above 220 BPM. The Oxygen Notification will occur when the measured oxygen level goes below 80%. **New devices have the Health Notifications disabled by default and must be manually enabled.**



Health Notifications can be enabled via the Sock settings in the Owlet Dream App. If the App detects it is disabled, either a message will appear on App launch, a banner will appear on App launch, or a banner will appear while monitoring. Once in Sock settings, the process to enable the Health Notifications will begin by tapping the toggle button. There will then be educational information that is required learning about the Health Notifications and how to respond to each. It is required that the Caregiver tests these Health Notifications prior to completing the required learning.

Once the required learning is completed, Health Notifications will be enabled. These notifications will remain enabled until they are manually disabled. The required learning can always be reviewed in the Sock settings.

The Health Notifications also include historical charts and graphs for 10 minute average pulse rate and oxygen levels under the history tab. This tab shows historical charts and graphs for Sleep Indicators as well as Health Readings.

5.4 Using the Owlet Dream App and Dream Sock with Multiples

The Owlet Dream App supports multiple child profiles and Dream Sock systems to allow you to monitor multiple Dream Socks. Be sure to keep your Socks and their assigned Base Stations separated by child to ensure there is no confusion in the event of a notification.

CAUTION. If there is more than one baby in the house using different Dream Sock devices, write the name of the baby on the Sock, Sensor and Base Station to avoid confusion.

6. How to Use Dream Sock

6.1 Sock Size, Fit & Placement

Sock fit refers to the snugness of the Sock on the foot. Sock placement refers to the orientation and alignment of the Sock to the foot.

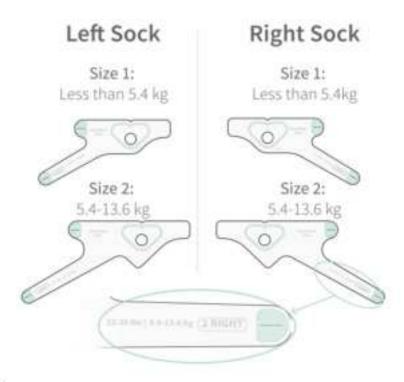
Step 1: Take the Sensor off the top of the Base Station

When you take the Sensor off the charging port, the Base Station will display bouncing green lights, indicating that the Sensor is looking for readings from your child. Now it's time to choose a Sock size and put the Sensor & Sock on your child's foot.



Step 2: Choose a Starting Size

Each Dream Sock includes 4 socks - 2 sizes for both left and right feet. Use the guide below to choose a starting Sock size based on weight. If the starting Sock doesn't fit properly, try different sizes based on actual fit.



CAUTION. Regularly verify Sock fit. The baby's actual foot size may differ from the guidelines above and babies grow quickly. Stop using the Dream Sock system when your baby reaches 13.6kg or outgrows the largest sock.

CAUTION. Even if your baby meets the age and weight requirements, if all Sock sizes are either too small or too large, discontinue use of the Dream Sock device.

CAUTION. Alternate between feet every 8 hours of use or after recharging the Sensor. Check the child's foot often for any signs of irritated skin.

CAUTION. Dream Sock performance may be affected by foot deformities. Because foot deformities vary widely in nature and severity, we recommend that you consult your pediatrician before use on babies with foot deformities.

Step 3: Insert the sensor (if not already attached)

Attach the Sensor to the Sock by lining up the notch on the Sensor with the notch on the Sock. Stretch the hole in the Sock over the Sensor.

Always inspect the Sock and Sensor for damage or excessive water or moisture and verify that the Sock and Sensor, including the sensor windows, are clean and unobstructed before use.



NOTE: Ensure the Sensor is completely inserted into the Sock before use. Discontinue Sock use if you notice any damage to the Sock.

Step 4: Position the Sock

Place the Sock on the corresponding foot (left/right) with the notch on the **outside** of the foot **behind** the pinky toe. The Sock should **NOT** touch the toes.



Secure the fastener from the toe strap (1) around the foot above the toes and then wrap the ankle strap around the back of the ankle and secure it to the top of the foot (2). Do **NOT** stretch when fastening. Let the straps connect naturally without stretching. The Sock should lay flat against the skin without gaps between the Sock and the foot.

CAUTION. Do NOT stretch the straps when fastening. Stretching straps will lead to over tightening and increased risk for skin irritation.

CAUTION. Do NOT fasten the Sensor to the baby's foot using anything other than Dream Sock. Injury to the baby's foot may result.

CAUTION. Do NOT use lotions, creams or powders on the feet before applying the Sock and Sensor. Application site must be clean and dry to avoid skin irritation.



CAUTION. Do NOT apply the Sock and Sensor to wet skin. Excess moisture may increase the risk of skin irritation.

CAUTION. Verify the Sock and Sensor fabric is dry and free of dirt, hair or other foreign substances before placing it on the baby.

Step 5: Verify Sock Fit & Placement

Match Sock to Foot

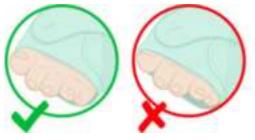
Make sure to use the left Sock for the left foot and right Sock for the right foot. Each Sock is marked with "R" or "L".



Protect Sensitive Parts

• Make sure the abrasive part of the straps is not touching the skin.

Sock should not extend over the toes.



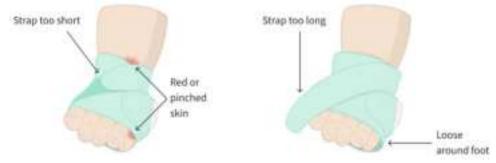
Check Sock Size

Sock too small

If either strap fails to naturally reach the fastener, try a larger Sock size. Do NOT stretch the straps and cinch the Sock too tight or it might be uncomfortable for your child.

Sock too big

If either strap goes past the fastener, try a smaller Sock size. The Sock and straps should be snug against the foot.



Check Straps

Verify the straps are adjusted correctly. Do **NOT** overtighten.

- Straps should lay flat against the skin but not press into the skin.
- Do NOT stretch the straps when fastening this leads to overtightening.



CAUTION. Do **NOT** apply the Sock and Sensor too tightly. Too much pressure for long periods can cause a pressure injury.

CAUTION. Always ensure that the Sock with Sensor is placed correctly on the baby's foot. Poor Sensor placement may cause skin irritation.



CAUTION. Ensure the abrasive portions of the straps are not contacting the baby's skin as this may lead to skin abrasion.



CAUTION. Signs of skin irritation or excessive notifications can be an indicator of incorrect Sock size.

CAUTION. If the Sensor windows are pulling away from the foot, the Sock may be too loose. Try tightening the Sock or use a smaller Sock size. Air gaps can cause intermittent readings.



NOTE: Proper fit is affected by age, weight and foot shape.

Step 6: Check the Base Station

With the Sock now on the baby's foot, check the Base Station. Once it softly pulses green that means your child's readings are being picked up, and the Sock and Base Station are communicating as intended.

6.1.1 Skin Irritation

Incorrect use of the Sock could result in discomfort, potentially leading to skin irritation, pressure sores or blisters on your baby's foot.



CAUTION. Improper Sock fit or care can lead to injury to the skin.

CAUTION. Discontinue use immediately if red marks develop on the foot in the vicinity of the Sensor. Continued use could result in further injury and inaccurate readings. Contact your healthcare provider with any questions.

CAUTION. Check Sensor position and baby's skin condition at least every 8 hours and reposition if necessary. Alternate between feet after every use. If your infant/children has sensitive skin, check and rotate feet every 4 hours. Misapplication of the Sock and Sensor with excessive pressure for prolonged periods can induce pressure injury or skin irritation.

Avoiding Skin Irritation

- Always use the *correct size* Sock for your baby. Refer to <u>Section 6.1</u>.
- Avoid using lotions or powders under the Sock. Keep skin clean and dry.
- Ensure Sock is positioned and adjusted correctly. Refer to Section 6.1.
- Check skin every 4 hours during the first week of use and after changing Sock size.
- Alternate the Socks from left to right about every 2 weeks, or more frequently if redness is noticed.
- Hand wash Sock and Sensor every 2 weeks or when dirty. Dry completely before use.
- Check your child's feet for irritation each time before you apply the Sock. Do NOT apply to a foot with skin irritation,

NOTE: Temporary skin marking from Sock contact is normal if it fades within 8 hours.

What to do if the skin is irritated

- Discontinue use on the affected foot and apply the Sock only to the unaffected foot until irritation resolves completely.
- Contact Owlet Customer Support for one-on-one help with avoiding red marks.
- Inspect the skin under the Sock on the unaffected foot every 4 hours to ensure irritation does not recur.
- If irritation appears on both feet, discontinue use, and consult with your healthcare provider. Re-applying Dream Sock to irritated skin may cause increased damage to the skin.

6.2 Base Station Status & Control



Slow Pulsing Green light

Sock is getting readings



Solid white light

Sock charging on the Base Station is fully charged



Quick Bouncing Green light

Sock is getting initial readings or child is moving



Pulsing white light

Sock is charging



Blinking Orange Light

Sock charging on the Base Station is paired to a different Base Station



Blinking white light

Sock charging on Base Station is not paired to Base station

6.3 Getting Readings and Notifications

The Base Station is designed to notify you with light and sound if your child's readings are out of the normal range, if monitoring is interrupted, or if your child is uncomfortable. There are three different Base Station notification priority types: High (red), Medium (yellow), and Low Priority (blue).

NOTE: High Priority notifications are Health Notifications for Pulse Rate and Oxygen that require separate activation within the Owlet Dream App.

6.3.1 Notification Color Reference Chart

NOTE: When two or more alarms occur at the same time, the highest priority alarm always takes precedence on both the Base Station and the App. If two high priority alarms occur at the same time, both will be indicated. Status message priority for simultaneous medium or low alarms occurs in the order listed below.

Base Station Indicator	Status	Meaning (Notification Condition)	What you should do	
Flashing Red High Priority	Low Heart Rate	Heart Rate below 50 BPM	Immediately check on your child and see if they are	
	High Heart Rate	Heart Rate above 220 BPM	okay. Things to check on are your child's breathing, sk color (are they blue or pale), activity, and alertness. If you have concerns that your child is not okay please seek medical attention.	
	Low Oxygen	Oxygen below 80%		
Flashing Yellow Medium Priority	Difficulty getting readings	Sensor may be placed improperly and not able to provide valid data for the last 90 seconds with no motion, OR there has been no data for 240 seconds and there is excessive motion.	Check the Sensor placement and ensure the child is no wiggling or being moved excessively (i.e. swing or bein held). It may take 10 – 20 seconds for this alarm to clea once Sensor is repositioned AND the child stops moving. Turn off monitoring until movement stops.	
	Power Loss	Base Station has lost line power and is on battery backup.	Check connections and restore power or discontinue use	
	Connection Issue	Sensor has been disconnected from the Base Station for 60 seconds because it is out of range of the Base Station, has lost power or has an internal problem.	Move the Base Station closer to the sensor, or make sure there is nothing blocking the signal between the two. Check the sock battery level in the app.	
Solid Blue Low Priority	Low Sensor Battery	Sensor has 50 minutes or less left of battery life	Place the Sensor on the charger soon.	
Flashing Lavender Notification	Sleep Assist	Your child is moving excessively or has been moving for an extended period of time.	Check on your child, they may need your help falling back to sleep.	

The Base Station generates audible alarm signals with a sound pressure level not more than 85dBA when measured 1 meter from the unit. High (red) priority alarms have a sound pressure level of equal to or greater than 60dBA and less than or equal to 85dBA.

Medium (yellow) and Low priority alarms have a sound pressure level of equal to or greater than 43dBA and less than or equal to 85dBA.

6.3.2 Notification Definitions

6.3.2.1 High Priority Health Notifications (Physiological Alarm)

See <u>Section 5.3</u> to learn how to enable Health Notifications. These Health Notifications are optional and need to be enabled in the App and will remain enabled until they are manually disabled.

During a High Priority Notification, the Base Station will flash red and play a high notification sound, and you will receive a push notification in the Owlet Dream App. The Pulse Rate notifications will occur when the measured pulse rate goes below 50 bpm or above 220 bpm. The Oxygen notification will occur when the measured oxygen goes below 80%.

6.3.2.2 Medium Priority notifications (Technical Alarms)

During a Medium Priority Notification the Base Station will flash yellow and play a medium notification sound, and you will receive a push notification in the Owlet Dream App. A yellow notification indicates there is a Sock placement issue or the Sock has fallen off of your child's foot and was unable to get good readings for at least 60 seconds. A yellow notification may also indicate the Sock is out of range of the Base Station or the signal was blocked for at least 60 seconds. The App will be the best resource to direct you on how to address this notification.

Because the human body can act as a barrier between the base and Sock connection, try not to hold your child with your back facing the Base Station. If yellow notifications are recurring, move the Sock and Base Station closer together to avoid repeated notifications.

The Base Station will sound a medium priority technical alarm when powered up if it doesn't make a connection with the mobile application within 120 seconds after initialization.

When a medium priority technical alarm is present, no high priority alarms will activate until the technical alarm is resolved. When there is a Medium Priority Base Station Power Loss alarm, the Base Station will continue monitoring and alarming until backup power is exhausted or for maximum of 10 minutes before powering down if power is not restored to the Base Station.

6.3.2.3 Low Priority Notifications (Technical Alarms)

Battery Notification

During a Low Priority Notification, the Base Station will be solid blue and play a low notification sound, and you will receive a push notification in the Owlet Dream App. A blue notification indicates the Sock battery has 50 minutes (10% charge) of life remaining, and should be charged in the near future. When this alarm is present, the Base Station will still alarm for other technical and high priority alarms as normal.

Flashing Lavender Notification

When excessive movement is detected, the Base Station will flash lavender to indicate that your baby may not be sleeping well and may require assistance to be re-settled back to sleep. When the Base Station is flashing lavender, you should check on your baby to evaluate their environment and determine if they need assistance in returning to a sleep state.

6.3.3 Snoozing notifications

When there is an active notification of any kind you can snooze the sound for 60 seconds with a short press on the Base Station or in the Owlet Dream App.

Snoozing will only pause the Base Station and App sounds—the light ring will continue to show on the Base Station and details are available in the App. The notification remains in effect until the condition is resolved. If the initiating event ceases while snoozed, the notification will stop.

If a new event occurs while notifications are snoozed, the notification sound will restart.

When notifications/alarms are snoozed on the Owlet Dream App, these alarms are also silenced on the Base Station.

How do I turn the Base Station and monitoring off?

Press down on the Base Station and hold until the green light turns off and you hear a beep.

6.4 Turning off Dream Sock

6.4.1 Excessive motion

Monitoring with the Base Station should be turned off when your baby is active enough to cause repeated motion notifications. Motion notifications can be caused by your baby's movement, such as kicking, crawling or wiggling. Motion notifications can also be caused by carrying, rocking, feeding, or burping your baby. Monitoring can be automatically turned off by placing the Sensor on the Base Station to charge.



Excessive infant/child motion may affect Sensor performance and the accuracy of the measurements

6.4.2 How to turn off Dream Sock

To turn off the Base Station manually and end monitoring:

TO PROPERLY USE OUR PRODUCTS AND FOR CARE OF YOUR CHILD: RESPOND PROMPTLY WHENEVER A NOTIFICATION IS PROVIDED.

- 1. Pause any active notifications.
- 2. Long press the Base Station for 3 seconds until you hear a chirp; and then release.

NOTE: The Base Station light will turn off and there will be a falling chime sound indicating monitoring has ceased.

- 3. Remove Sock and Sensor from baby's foot.
- 4. Visually inspect the Sock and Sensor for soiling & clean if necessary (see Section 10).
- 5. Place the Sensor on the Base Station to charge.

6.5 Charging the Sensor

Charge the Sensor by placing Sensor onto the Base Station. The Base Station pulses white when the Sensor is fully charged. Dream Sock uses convenient drop-and-go charging for an 8-hour charge in just 20 minutes, and full 16-hour charge in only 90 minutes. We recommend that you charge the Sensor by placing it onto the Base Station whenever you are not monitoring or the Sensor is not in storage.

NOTE: The Sensor can be charged while inside the Sock.

NOTE: The Owlet Dream App will only indicate if the Sensor is charging or fully charged while the Sensor is on the Base Station.



6.6 When to discontinue use of Dream Sock

Stop using Dream Sock if:

- Baby has skin irritation on both feet.
- The baby weighs more than 13.6kg
- The Sock no longer fits properly.
- Baby is moving or is in a device that is moving the infant/child (such as a swing or vehicle)

Stop using the Owlet Base Station for the Dream Sock if:

• The Base Station has become damaged and/or has sharp edges.

7. Using the Owlet Dream App

7.1 Tracking Sleep with Dream Sock

The Owlet Dream App Home screen shows key information about the sleep status of the baby, the different sleep states, as well as status of the Base Station.

The most important information is shown at the top of the Home screen on the phone App. The app screen will show the number of wakings and the degree of movement measured from the Dream Sock. There is a gauge to help you understand how much your child is moving, below is the one thing you need to know about your child's sleep status. You can press the question mark button to the right of the sleep status for more detailed information about any status displayed in the app.

7.2 Health Notifications: Owlet's Display of Live Pulse Rate and Oxygen Levels

Viewing live pulse rate and oxygen levels requires Health Notifications to be enabled. The readings show real-time information about your baby's pulse rate and Oxygen Saturation.

Health Notifications will notify Caregivers to critical levels of blood oxygen in the baby wearing the device which may require immediate attention. The Dream Sock will also notify caregivers to extremely low or high pulse rates that require attention. These are High Priority Notifications.

The Owlet Dream App will also display oxygen and pulse rate readings so that Caregivers can check on the status of their child while the Sock and Sensor are worn and monitoring is on. This section is intended to help a Caregiver understand the information on pulse rate and oxygen they see on the Owlet Dream App when Health Notifications are enabled.

The Owlet Dream App has tooltips that can be used as a quick reference by tapping the help question mark. The home pag tooltip has a quick reference table for normal live health readings for children based on age.



7.2.1 Pulse Rate

Infant pulse rates are much faster than those of adults. There are ranges of pulse rates which are generally seen when infants are awake and relaxed, seen in the table below. Pulse rate is displayed in beats per minute (BPM).

Pulse Rates in Healthy Infants By Age*

Age	Typical Pulse Rate range - Awake Infant	
0 to 3 months	123-164	
3 to <6 months	120-159	
6 to <9 months	114-152	
9 to <12 months	109-145	

12 to <18 months	103-140
18 to 24 months	98-135

^{*}Data from: Fleming S, Thompson M, Stevens R, et al. Normal ranges of heart rate and respiratory rate in children from birth to 18 years of age: A systematic review of observational studies. Lancet 2011; 377:1011

While these are typical ranges for awake and relaxed infants, pulse rates can vary with activity. For example:

- It is very common for infants to have pulse rates slower than the range when they are in deep sleep.
- It is very common for infants to have pulse rates faster than the range when they are crying or when they have a fever.

After you set up your device and connect the Owlet Dream App, it is good to get to know how your baby's pulse rate normally behaves during routine activities. This will help you recognize anything that is significantly different in the future.

For example, your baby may normally have a pulse rate of 120 beats per minute when sleeping. If you see a pulse rate of 180 beats per minute, the system will not notify you, but it still may be worthwhile checking on the baby for any signs of discomfort or illness.

Things to check for may include:

- Color of the infant's lips (are they a normal pink, or blue?)
- Breathing (fast or labored?)
- Alertness level (i.e. does your baby respond to your voice or touch?)
- Temperature (i.e. does your baby feel hot or cool to touch?)

You should also check your baby's sleep position and environment to ensure there are no items which may obstruct your baby's breathing.

Even if the notification has not sounded, if you have concerns about your child's health, it is advisable to contact your child's healthcare provider.

7.2.2 Oxygen Levels

Oxygen levels are expressed as a percent of oxygen available in the baby's blood. Oxygen levels are displayed as %SpO2 (functional oxygen saturation) within the Owlet Dream App. Dream Sock is calibrated to display functional oxygen saturation of arterial hemoglobin (SpO2).

Oxygen levels in healthy infants are similar to adults. Typically you will see oxygen levels over 90% no matter what activity a baby is doing. Oxygen levels can vary slightly (within 5%) of the infant's baseline. Infants at high altitude may have slightly lower oxygen levels than at sea level, but should still be higher than 90%.

After you set up your device and connect the app, it is good to get to know your baby's typical oxygen levels. The Owlet device will send a Health Notification if the oxygen saturation level falls to 80% or below.

However, there may be times when an infant has an oxygen level less than 90% but does not yet reach the notification limit of 80%.

The most common reason for this to happen is when a baby is getting sick with a virus that affects their breathing. An observation of an oxygen level between 80 and 90% which lasts for more than a few seconds at a time is a reason to check on the baby for signs of breathing difficulty, including nasal congestion, fast or labored breathing, and wheezing.

Things to check for may include:

- Color of the infant's lips (are they a normal pink, or blue?)
- Breathing (fast or labored?)
- Alertness level (i.e. does your baby respond to your voice or touch?)
- Temperature (i.e., does your baby feel hot or cool to touch?)

You should also check your baby's sleep position and environment to ensure there are no items which may obstruct your baby's breathing.

Even if you have not received a notification, if you have concerns about your child's health, it is advisable to contact your child's healthcare provider. If you have concerns about low or ultra-low oxygen saturation trends, contact your healthcare provider.

7.3 Sleep Status Indicators

The sleep status on the home screen updates every minute to inform you of the status of your child during their sleep session. A sleep session graph will display data after 10 minutes of tracking real-time sleep status indicators, which are shown below.

Sleep Status Indicators

Sleep status indicators show the number of wakings and the degree of movement measured from the sock

- Wakings
 - o The number of wakings in the current sleep session.
- Movement
 - The current status of the baby displayed as still or active. Movement can impact the quality readings.

If excessive movement is detected, the Base Station will flash lavender (See Section 6.3.2.4 for more information on Lavender Notifications).

7.4 Owlet Dream App Tabs

This Section is always at the bottom of the Owlet Dream App and allows you to navigate to the other app screens.



<u>Home</u>

This is the main screen with baby and device details.

Routine History

The History tab in the Owlet Dream App displays your baby's past sleep session readings. Sleep history is available for the past 30 days.

<u>Guide</u>

Find all the guides and tutorials.

Account

Manage account details and child profiles. Access support chats, Also, access Chat and Phone support options. Sections in the Account tab include:

- My Account
 - My Profile: Personal Information (includes Log Out)

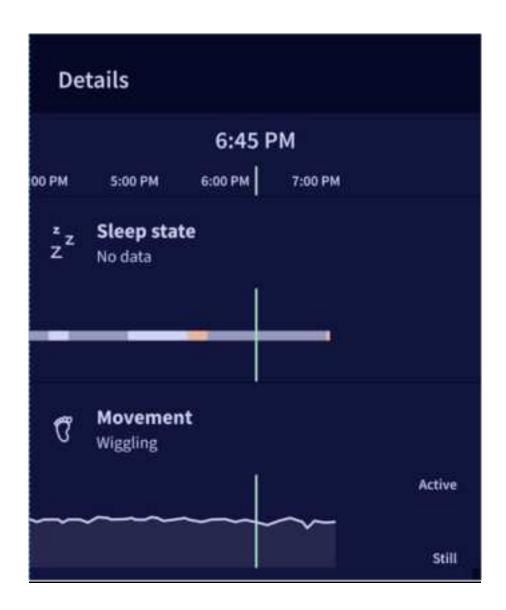


CAUTION. If you Log Out of the mobile app you will no longer receive push notifications or alarms on your device.

- Help and Support: customer support & Troubleshooting
- Child Profiles
 - Lists existing child profiles with options to edit or add
 - Use this section to add a new baby to your account
- My Owlet Devices
 - Lists existing devices with option to add devices.
 - o Use this section to add a new device to your account

7.5 Understanding History and Session Details

Under the history tab, tapping on any previously recorded sleep sessions will take you to the sleep details page for that session. A sleep session is defined as the start of the sleep event to the end of the sleep event. You will see data from sleep status indicators for various metrics recorded during that session for the past 30 days. This feature allows you to have an overall view of the baby's sleep patterns and different sleep status indicators that indicate both sleep state and duration.



Not seeing a sleep session under the History tab?

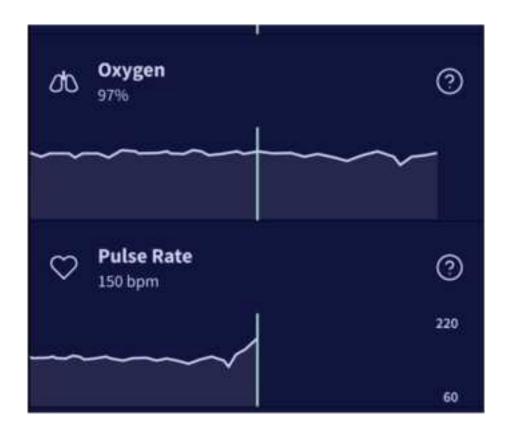
- **Sessions aren't immediate:** It takes 10 minutes before a sleep session is displayed in History. The session is updated every 10 minutes once viewable.
- **Child is not sleeping:** The Sock must detect sleep before it will create a sleep session. If your child is awake, the session will not appear in History.

7.5.1 Using Oxygen and Pulse Rate History

Activating the Health Notifications allows Caregivers to view historical sleep session data and graphs for pulse rate and oxygen. This feature must be turned on following instructions from <u>Section 5.3</u>. Historical graphs give you a full visual of pulse rate and oxygen throughout the sleep session. The graphs allow you to view the 10-minute averages of pulse rate and oxygen.

NOTE: This graph DOES NOT include a historical log of alarms (both physiological and technical) generated by the device.

The Owlet Dream App has tooltips that can be used as a quick reference by tapping the help question mark. The history page tooltips have a quick reference table for normal historical oxygen and pulse rate values for children based on age.



7.5.1.1 Oxygen Trends

Once Health Notification software features have been activated, a graph is available showing a trend of oxygen readings. This provides a general review of the pattern of oxygen levels through a sleep session. It is expected that an infant wearing the Sock should have an oxygen level over 90%. However, any prolonged episode of lower oxygen levels may show up as a dip in the trend line. The graph will also be presented with an average of the oxygen levels measured through the sleep session.

If you observe a change in your child's oxygen patterns, it is recommended that you also check your child for any signs of illness, and any safety issues in your child's sleep environment. You can also look at a live oxygen reading from the sock to determine if there is still a change in oxygen from your child's typical levels.

If you have concerns about your child's health, contact your healthcare provider for guidance. If you have concerns about low or ultra-low oxygen saturation trends, contact your healthcare provider.

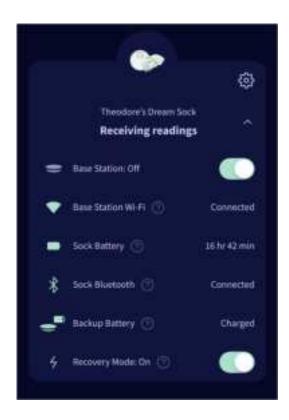
7.5.1.2 Pulse Rate Trends

Once Health Notification software features have been activated, the graph tracking pulse rate levels provides a trend of pulse rate readings. This provides a general review of the pattern of pulse rate ranges through a sleep session. It is expected that an infant wearing the sock may have a lower pulse rate during sleep than during awake hours (for reference of normal awake pulse rates, please see Section 7.2.1). It is normal to see variability in the pulse rate, especially if your child is still waking up during the night. You will also see an average pulse rate for the entire sleep session presented with the graph.

If you observe a large change in your child's average pulse rate, it may suggest that your child was uncomfortable, had higher numbers of awakenings, or has an illness developing. It is recommended that you check your child for any signs of illness, and any safety issues in your child's sleep environment. If you have concerns about your child's health, contact your healthcare provider for guidance.

7.6 Sensor battery level

You can check the Sensor's battery level in the Owlet Dream App.



When the Base Station light is pulsing white the Sensor is charging; when the light is static white the Sensor is fully charged.

Low Sock battery Notification



If your Sensor battery has less than 50 minutes (10% charge) of operation time you will be notified in the DreamApp with a blue notification. The Base Station will play a sound and light up blue.

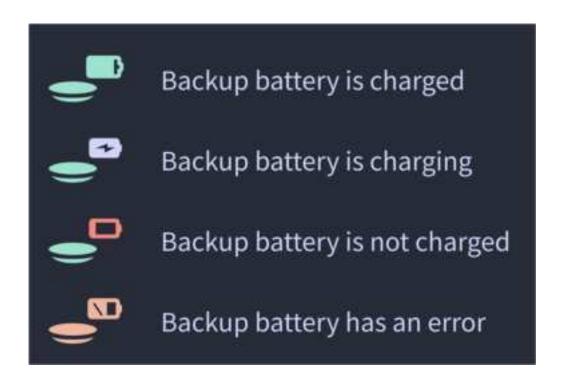
You can also view battery status at any time in the Sensor status screen.

Sensor Battery Level Status



Sensor Battery indicates the available run time remaining. If the Sensor is on the Base Station, it indicates the charging status.

Base Station Backup Battery Status



Backup Battery indicates the current battery status of the Base Station backup battery. If charged, the backup battery will allow the Base Station to immediately notify you with lights and sounds when power has been lost and continue monitoring your child. Wi-Fi connection will be unavailable when operating on backup battery. The backup battery will automatically charge when your Base Station is plugged in. Above is a list of all backup battery statuses.

8. Tips for a Safe Sleep Environment

At Owlet our priority is your baby's wellness. Below are some friendly tips to keep your baby healthy and safe.

sleep on their side or on their stomach is not safe.

• Always place your baby alone and on their back to sleep. Placing your baby to

• Use a crib that meets current safety standards. Use a firm mattress that fits snugly

- in the crib and is covered with only a tight-fitting crib sheet.
- Do not put anything soft, loose, or fluffy in your baby's sleep space. This includes pillows, blankets, comforters, bumper pads, stuffed animals, toys, or any other soft items.
- Use a wearable blanket, or similar type sleeper, instead of traditional blankets to keep your baby safe and warm.
- Room-share instead of co-sleeping. Keep your baby's sleep space separate from, but close to, your bed. This will keep them safe and make feeding easier. Dream Sock does not function properly with co-sleeping. Your body will interfere with the Dream Sock wireless signal.
- Avoid falling asleep with your baby in your bed, couch, or armchair.

- Never allow your baby to sleep on any soft surfaces such as adult or child-sized beds, sofas, chairs, waterbeds, pillows, cushions, comforters, sheepskins, or anything similar.
- Do not use pillows, wedges, or positioners to prop your baby up, keep them on their back, or prevent them from rolling.
- Make sure your baby doesn't get too warm. Use light sleepwear on your baby and keep the room temperature comfortable for a lightly clothed adult.
- Consider offering a pacifier to your baby at naptime and bedtime.
- Educate everyone who cares for your baby about these rules for safe sleep!
- Keep the Base Station and cord away from the crib and out of baby's reach to reduce cord strangulation hazards

8. Cleaning

8.1 Cleaning the Sock and Sensor

Caring for your fabric Sock and Sensor will make it last longer and be more comfortable for your baby. We recommend **cleaning the Sock, and spot cleaning the Sensor, at least every two weeks** or more often when visibly soiled. This helps you avoid irritation to your little one's skin. Follow the steps below to properly turn off your Sock and Sensor, clean and dry Dream Sock, and spot clean its Sensor.

Supplies You Need

- 1. Gentle laundry detergent (use the same mild laundry detergent you use for Baby's clothes).
- 2. Clean and soft-bristled toothbrush.
- 3. Clean, dry towel.
- 4. Sink with a drain plug (you can use a water basin or bowl, too).

What causes skin irritation?

The 3 causes of skin irritation beneath the Sensor include:

- 1. A buildup of dirt, oils, and bacteria from not cleaning the Sensor.
- 2. Using a soap that is drying, irritating, or too harsh for a baby's sensitive skin.
- 3. Not removing all the soap from the Sensor after cleaning.

Turn off the Sensor before cleaning



CAUTION! Turn OFF the Sensor before cleaning.

Follow the below steps to turn off the Sensor to avoid damage during cleaning:

- 1. Unplug the Base Station
- 2. Remove the Sock and Sensor from the baby's foot, if being worn.
- 3. Press and hold the Base Station button while you plug the Base Station back in, keeping constant pressure on the Base Station button until you hear the first chirp.
- 4. Release pressure immediately upon hearing the first chirp from the Base Station. The Base Station will then chirp 4 times in response and the light ring changes to a blinking orange.
- 5. Press the Base Station button once.

 Important: You must click the Base station Button while the ring is blinking orange to properly turn off the Sensor.
- 6. The Base Station single chirps once, the Sock light on the bottom of the Base Station is not illuminated, and the light on the Sensor turns off.
- 7. Watch for the Base Station to turn off completely and you're ready to clean.
- 8. If your Sensor is not turning off, place the Sensor on the base station and repeat these steps.

For an alternative method of shutting the Sensor off, see below:

1. Turn off Sensor (in the Owlet Dream App, Account>Select Device>Turn off Sensor), see Section 9.4.

Cleaning your Sock and Sensor

Your Sock and Sensor rests against your little one's skin for hours at a time, so the potential irritation to Baby's skin from soap exists. Choosing which soap to use is a very important step in your cleaning process. We recommend using whatever laundry detergent you use to clean your little one's clothing since their skin is already accustomed to it.

CAUTION! Avoid using hand soap, antibacterial soap, or dish soap. These can be too drying and irritating on Baby's skin over a long period of time. The most successful approach is creating a sudsy solution of water and familiar laundry detergent, which helps prevent soap from sticking to the sensor.

- 1. Prepare your cleaning solution:
 - a. Create a diluted, soapy solution of water and laundry detergent
 - b. Plug your sink and fill it with cool to lukewarm water (a basin or bowl is also fine).
 - c. Add a small amount of your laundry detergent to the water and mix the solution with your hands.

2. Clean your Sensor:

CAUTION! Do NOT submerge the Sensor for any period of time or use a washing machine. The Sensor is water resistant and should only be scrubbed clean.

- a. Check your Sensor light to ensure it is off. If it is on, ensure you follow the steps above for turning it off. It is important that you only clean the Sensor in the off state.
- b. Separate the Sensor from the Sock.
- c. Do **NOT** submerge the Sensor in the soapy solution. Only the Sock can be submerged.
- d. Scrub the Sensor gently by dipping your toothbrush bristles into the soapy solution, tapping to remove any excess, and brushing the Sensor with the toothbrush in a circular motion.
- e. Rinse the toothbrush clean under running water, tapping to remove the excess.
- f. Use the toothbrush to scrub the Sensor free of residue, again brushing in a gentle, circular motion.
- g. Pause to rinse the toothbrush frequently and completely as you remove the detergent solution from the Sensor, tapping out the excess water each time.

- h. Repeat this "rinse" process as necessary until all dirt and oils are removed from the Sensor. No detergent solution or residue should remain on the Sensor.
- 3. Dry the Sensor:

CAUTION! Do NOT submerge the Sensor for any period of time or use a washing machine. The Sensor is water resistant and should only be scrubbed clean

- a. Gently press the Sensor into a dry towel to remove initial moisture.
- b. Lay the Sensor on the towel and air dry until completely dry. Do **NOT** tumble dry the Sensor.
- c. Visually **inspect** the Sensor for excessive wear or damage.
- 4. Clean your Sock:
 - a. Wash sock on gentle cycle in washing machine
 - b. Lay the Sock flat on a towel or hang the Sock up to dry completely. Do **NOT** tumble dry the Sock.
 - c. Visually **inspect** the Sock for excessive wear or damage. Replace the Socks as needed.

CAUTION! Do NOT autoclave or immerse the Sock or Sensor in liquid or use caustic or abrasive cleaning agents such as ammonia, bleach or alcohol. Harsh chemicals could damage the Sock or Sensor.

8.2 When to Replace the Sock or Sensor

The Sock and/or Sensor should be replaced if:

- Sock is stretched out, fabric is separating or there are holes or rough spots.
- The fabric or Sensor windows are ripped, warped, or otherwise damaged.
- The fastener has been worn and no longer latches properly.
- Multiple cleanings fail to remove visible stains/dirt.
- The Sock or Sensor have come in contact with infectious substances, such as human waste.

For information about replacing the Sock see <u>Section 14</u>.

8.3 Cleaning the Base Station

The Base Station should be cleaned:

- When visibly soiled
- At least once every 30 days
- 1. Turn off monitoring and unplug the Base Station.
- 2. Moisten a soft cloth with a mild cleaning solution.
- 3. Wipe the Base Station with the damp cloth.
- 4. Wipe the Base Station dry or allow it to air dry.



CAUTION! Use cleaning solutions sparingly to avoid getting any liquid in the Base Station enclosure.

9. Maintenance

There are no user serviceable components in Dream Sock, and no calibration is required. Routine maintenance includes:

- Inspecting the device for damage and cleanliness. Do **NOT** use the device if it appears damaged.
- Cleaning the device according to the cleaning instructions found in <u>Section 8</u>.

9.1 Sensor Battery Maintenance

The Sensor battery is non-replaceable and can't be serviced. Sensor battery performance can decrease with age and use. If a fully charged Sensor will not operate for at least 8 hours, it should be replaced.

For long-term storage see <u>Section 10</u>.

9.2 Base Station Battery Maintenance

The Base Station battery is non-replaceable and can't be serviced. For long term storage see Section 10.

The Base Station battery integrity should be tested upon first use and again every three months. The Base Station battery will need to be charged by plugging the Base Station into the wall before first use.

Testing the Base Station Battery

- 1. Charge the Sensor for at least 10 minutes.
- 2. Remove the Sensor from Base Station and then begin monitoring.
- 3. Unplug the Base Station. Verify lost power. Notifications activate and notifications will continue for at least 2 minutes before Base Station turns off. If not, contact Owlet Customer Support to replace the Base Station. Refer to Section 14 of this manual for contact information.

NOTE: The Sensor can be either on or off the baby during this test.

NOTE: The system will sound the medium priority alarm during this test.

9.3 Testing Notification Signal Generation

Caregivers should verify that Dream Sock system produces proper notifications if it has been in storage or at least every 6 months. Preview each notification priority and verify the Base Station and Owlet Dream App notify as expected. Discontinue use and contact Customer Support if notifications do not function as intended.

To test a low priority or medium priority notification, go to the guide tab and tap on the "understanding notification" article. There will be previews for each notification.

To test a high-priority notification associated with Health Notifications, you can test it via the required learning located in the Sock settings.

9.4 Switching the Sensor Off and On

Owlet recommends placing the Sensor on the Base Station when not in use to charge the Sensor and to keep it safe. The Sensor should only be shut-off for cleaning and short or long-term storage.

To power off the Sensor

- 1. Press settings cog on the Home Screen or press Account then select the Owlet Device.
- 2. Press "Turn off Sensor".

The red light in the Sensor will turn off and monitoring will cease.

Turn the Sensor On

The Sensor is turned on when it is removed from the charger. To turn the Sensor on, place it on the Base Station charging port for at least 3 seconds and then remove it.

9.5 Unpairing your Sensor

To unpair your Sensor, follow the steps below:

- 1. Unplug the Base Station and remove the Sock from the baby, if being worn.
- 2. Press and hold the Base Station button while you plug the Base Station back in. Keep pressing the button until you hear the Dream Sock Base Station chirp 4 times. The light ring will change to blinking orange. Release pressure after the chirp is heard.
- 3. Quickly press the Dream Sock Base Station button twice (2). The Base Station ring is blinking orange, otherwise, the Dream Sock Sensor will not properly turn off.

If successful, the Sock light on the bottom of the Base Station will not be illuminated, and the Sensor will NOT turn off. The Base Station will bounce white briefly before the blue disconnection notification sounds.

9.6 Pairing your Sensor

To pair your Sensor, follow the steps below:

- 1. Place the Sensor on the Base Station charging port.
- 2. The Base Station light will transition from bouncing white to solid white once the Dream Sock has paired.
- 3. If there is a blue notification, the Sensor has not successfully paired. Follow the pairing instructions again. Please ensure the charging port is clean and the Dream Sock is making good contact with the charging port.

If successful, the "Sock" light on the bottom of the Base Station will be illuminated. When the paired Sensor is removed from the Base Station, the Dream Sock Base Station light bounces green.

10. Storage and Disposal

10.1 Storage

Care should be taken when placing Dream Sock system into long-term storage to ensure the Dream Sock continues to work properly. Follow the steps below when storing Dream Sock. See Section 16 for more information.

Storage Instructions

- 1. Fully charge the Sensor, and ensure the Base Station backup battery is charged.
- 2. Clear all data (optional, see Section 10.2).
- 3. Power the Sensor OFF (see Section 9.4).
- 4. Unplug the Base Station from the wall outlet.
- 5. Clean Sock, Sensor and Base Station and allow all of them to dry completely (see Section 8).
- 6. Gather power supply and cables.
- 7. Place into original packaging or suitable storage box.
- 8. Store the device in a cool, dry place.

NOTE: To maintain the life of the device, fully charge the Sensor and Base Station every 6 months while in long term storage.

5ymbol .	Specification	Value
-25°C	Storage and Transport Temperature Limits	-25°C to +60 °C
90% S	Storage and Transport Humidity Limits	0% to 90 %, non-condensing. Water vapor pressure not to exceed 50hPa.
500 hPa	Storage Atmospheric pressure Limits	500 hPa to 1060 hPa
5°C -40°C	Operating Temperature Limits	+5°C to +40°C
15%	Operating Humidity Limits	15% to 90 %, non-condensing. Water vapor pressure not to exceed 50hPa.
700 hPa	Operating Atmospheric pressure Limits	700 hPa to 1060 hPa. This pressure range corresponds to a suitable operating altitude up to 3000 meters.

10.2 Clear Personal Data

You can delete your baby's data or delete Dream Sock device from your app account. Deleting the device from your app account will not remove the baby profile and the baby profile will be able to be paired with a different Dream Sock device.

Delete Baby Profile

- 1. Open the Owlet Dream App.
- 2. From the Home Screen click: Account.
- 3. Under the Child Profiles section choose the profile you would like to delete.

- 4. Scroll to the bottom of the baby profile screen and select: Delete Child Profile.
- 5. Verify you would like to delete the profile.

NOTE: Deleting a baby profile cannot be undone. All the data for your baby will be lost.

Delete Owlet Device

- 1. Open the Owlet Dream App.
- 2. From the Home Screen click: Account.
- 3. Under the My Owlet Devices section choose the device you would like to delete.
- 4. Scroll to the bottom of the device information screen and select: Remove Device.
- 5. Verify you would like to delete the device.

Reset Account Password

If you have forgotten your account password, follow the steps below to reset your password.

- 1. From the Owlet Dream App, press "Login" (this is only possible when logged out of account)
- 2. Click "Forgot password?".
- 3. Enter email associated with your account.
- 4. Check email and follow link.
- 5. Enter new password and press "reset".
- 6. Go back to the App and log in with new password.

Forget Memorized Wi-Fi Networks

- 1. Remove the Sensor from the Base Station.
- 2. Disconnect the power cord from the Base Station.
- 3. Press and hold the Base Station button while inserting the power cord into the Base Station.
- 4. Hold the Base Station button until the Base Station light glows orange and you hear 4 beeps (this can take up to 10 seconds).
- 5. Then tap the Base Station button three times (3x).
- 6. Confirm the Wi-Fi light on the bottom of the Base Station is off.
- 7. Pause and wait for 4 beeps.

NOTE: If the sequence is recognized, the Wi-Fi light on the bottom of the Base Station will turn off.

NOTE: If you do not hear beeps, wait 5 seconds and try from step 1 again.

Factory Reset

A factory reset is a complete software reset of Dream Sock hardware to its original settings by erasing all information stored on the device.

- 1. Disconnect the power cord from the Base Station.
- 2. Press and hold the Base Station button while inserting the power cord.
- 3. Hole the Base Station button until light glows orange and you hear 4 beeps (this can take up to 10 seconds).
- 4. Tap the Base Station button 4 times.
- 5. You will hear 4 beeps, Dream Sock (incl. Base Station and Sensor) is now reset.

CAUTION. A factory reset will completely reset the Dream Sock Base Station and Sensor. You will no longer be able to receive readings or notifications until the device is set up again.

NOTE: A factory reset will not remove your data from the cloud server.

NOTE: If you do not hear beeps, wait 5 seconds and try from step 1 again.

10.3 Disposal

Before disposing of Dream Sock, turn off the Sensor (see <u>Section 9.4</u>) and Clear Personal Data (see <u>Section 10.2</u>). Discard Socks and recycle packaging materials, as appropriate.

Dispose of parts with electronic components responsibly. Follow local disposal and recycling laws to protect the environment.

11. Troubleshooting

Use the following troubleshooting guide to resolve problems related to set up, connection, and operation. For information on troubleshooting notifications, including technical notifications, see <u>Section 6.3</u>.

Problem	Possible Causes	Actions
Cannot see Owlet Wi-Fi during setup	Base Station is not turned on	Plug in the Base Station
	Already connected to Wi-Fi network	Check if the Wi-Fi light on the bottom of the Base Station is on. If so, you can skip this step and continue setting up your account in the App.
Cannot see your home Wi-Fi in the Owlet Dream App	Your home router is 5.0 GHz (Owlet only supports 2.4 GHz).	Make sure your mobile device is connected to a 2.4 GHz network (most 5.0 GHz routers also support 2.4 GHz).
Base Station will not connect to your Wi-Fi	Password is incorrect	Double check your Wi-Fi network password
	Base Station is out of range of your Wi-Fi router	Move the Base Station closer to your Wi-Fi router for setup
	Your Wi-Fi is not working	Try restarting your mobile device and reconnecting to your Wi-Fi or reset your Wi-Fi router
	The Wi-Fi requires authentication through a browser or has firewall restrictions	Try a different network
	Your home router is 5.0 GHz (Owlet only supports 2.4 GHz)	Make sure your mobile device is connected to a 2.4 GHz network (most 5.0 GHz routers also support 2.4 GHz)
Unable to log into the Owlet	Forget the password	Reset your password. See Section 12.2

Dream App		
Sensor will not connect to the Base Station	Sensor is out of range of the Base Station	Move the Base Station to a different location
	Other devices are interfering with the Sensor	Move other electronics near the Sensor or the Base Station or move the Base Station to a different location
The Base Station will not register with your Owlet	The Base Station and your mobile device are not on the same Wi-Fi network	Verify that your mobile device is connected to the same Wi-Fi network as the Base Station
Dream App account	The Base Station is disconnected from the Wi-Fi	Check the green Wi-Fi light on the bottom of the Base Station. It should be on. If not, then try reconnecting the Base Station to the Wi-Fi network.
The Base Station is disconnected from the internet	The Base Station is out of range of your Wi-Fi router.	Move the Base Station and the Wi-Fi router closer together. (NOTE: neither Wi-Fi range extenders nor second routers will help.)
	Your home Wi-Fi is not working.	Reset your Wi-Fi router.
App reset and asking to set up the system again	Base Station was registered to a different user account.	The Base Station can only be registered to one account at a time. Use one account for all Caregivers
	A different account was used during login.	Log out of the Owlet Dream App and login with the correct account.

If you are unable to resolve the issue or to report unexpected operations or events, contact Owlet Customer Support. Refer to Section 14 of this manual for contact information.

12. Electro-Magnetic Compatibility

12.1 Electro-Magnetic Compatibility

The Dream Sock is intended for use in the electromagnetic environment of typical homes. The user of the Dream Sock should assure that it is used in such an environment. The Dream Sock contains BLE and Wi-Fi modules which intentionally transmit and receive RF electromagnetic energy in the 2.4 GHz frequency band. Observe the function of other equipment in the vicinity to ensure the Dream Sock does not interfere with the function of other devices. Move the Dream Sock base station further away from any affected device if interference is observed.

Sensor range distance may vary depending on the environment, and can be affected by distance and building lay out. Move the Base Station closer to the baby if the Sensor is out of range. If the signal strength gets too low, the Base Station will no longer receive data from the Sensor.

12.2 Emissions

Emissions Test	Compliance	Electromagnetic environment-guidance	
RF emissions CISPR 11	Group 1	The Dream Sock uses RF energy only for its internal functions. Therefore, its RF emissions are low and are not likely to cause any interference in nearby electronic equipment.	
Conducted emissions CISPR 11	Class B	Suitable for use in all establishments, including domestic environments and those directly connected to other public low-voltage power supply network that supplies buildings used for domestic purposes.	
Harmonic emissions IEC 6100-3-2	Class A		
Voltage fluctuations/flicker emissions IEC 61000-3-3	Compliant		

12.3 Immunity

During the following testing, the Dream Sock will continue to operate within the specification or show an error.

Immunity Test	IEC 60601-2 test level	Compliance level	Electromagnetic environment- guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 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 lines ±1 kV for input/ output lines	±2 kV for power lines ±1 kV for input/ output lines	Mains power quality should be that of a typical home environment.
Surge IEC 61000-4-5	±1 kV differential	±1 kV differential	Mains power quality should be that of a typical home environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0%, 0.5 Periods 0%, 1 Period 70%, 25 Periods 0%, 5 sec	0%, .5 Periods 0%, 1 Period 70%, 25 Periods 0%, 5 sec	Mains power quality should be that of a typical home environment. If continued operation during power mains interruptions beyond that provided by the battery, it is recommended that the system be powered from an

			uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home environment.
Conducted RF IEC 61000-4-6	3 Vrms 6 Vrms in ISM and Amateur Radio Bands	3 Vrms 6 Vrms in ISM and Amateur Radio Bands	The Dream Sock is suitable for the electromagnetic environment of typical homes,
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m 80 MHz to 2.7 GHz	or commercial settings.

13. Warranty & Guarantee Information

13.1 Limited Warranty

LIMITED WARRANTY

We warrant that if you use our products as they are intended, our products will be free from defects in materials and workmanship for a period of 1 year from the date of set up for new products and 6 months for refurbished products. We do not warrant our products against general wear and tear or damage as a result of misuse, modifications or improper maintenance.

If you believe you have received a defective product, we will either repair or replace the defective product or its defective component part(s) in accordance with the terms of this limited warranty. We warranty the replacement for the remaining unexpired period of the original product's warranty.

This limited warranty applies only to the original purchaser of the product and to products purchased directly from us or one of our authorized sellers, unless otherwise prohibited by law. Our products are legitimately sold only by us and our authorized sellers who are required to follow our policies, procedures, and quality control standards. We reserve the right to reject warranty claims for

products purchased from unauthorized sellers, including unauthorized websites. This limited warranty does not warrant that the operation of the product will be uninterrupted or error-free.

Please note: This limited warranty is the only warranty available for our products.

We limit the applicability of implied warranties, including the implied warranties of merchantability and fitness for a particular purpose, to the duration of this limited warranty. To the extent permitted by law, we disclaim all other warranties of any kind. Some States and countries do not allow limitations on implied warranties, so the above limitation may not apply to you. Our sole liability for any defect shall be as set forth in this limited warranty and excludes any claims for incidental or consequential damages. Some States and countries do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you. No person or entity is authorized to make any other warranty on our behalf. This warranty gives you specific legal rights. You may also have other rights which vary from State to State and country to country.

For example, customers in some jurisdictions may have additional rights under applicable national legislation such as the Australian Consumer Law or national laws implementing EC Directive 99/44. This limited warranty does not affect any such rights. https://owletcare.com/pages/warranty

13.2 Satisfaction guarantee

Every Owlet product comes with a 30-night Peace of Mind Guarantee. If you aren't 100% satisfied with your product, you can return it within 30 days of purchase. (Only applies to purchases from owletcare.com)

14. Service and Support

14.1 When to Contact Your Doctor

For any medical questions or concerns contact a healthcare professional.

14.2 Customer Support

For assistance in setting up, using, or maintaining Dream Sock or to report unexpected operation or events, contact Owlet Customer Support, at the following:

Owlet Baby Care Customer Support may be reached at the following:

Owlet Baby Care, Inc.

3300 N Ashton Blvd, Suite 300

Lehi, UT 84043 USA

Toll Free: +1 (844) 334-5330 Email: <u>contact@owletcare.com</u> Chat: owletcare.com/chat

www.owletcare.com

In the App, go to Account > Help and Support to contact our Customer Support team via in-app chat, email and phone, or go to http://support.owletcare.com/. For more tips view the Guide Tab in the Owlet Dream App.

If you have any concerns regarding functionality, contact Owlet Baby Care Customer Support.

15. Technical Information

15.1 Peak Wavelengths and Maximum Optical Output of Power

The peak infrared LED wavelength shall fall within 924nm to 937nm at time of manufacture. The peak red LED wavelength shall remain within 649nm to 657nm at time of manufacture. This information may be useful to clinicians.

The below are the maximum optical output of power of the Sensor emitters:

Blue emitter: 20mW
Green emitter: 11mW
Red emitter: 13mW
Infrared emitter: 10mW
Total of all emitters: 54mW

The Dream Sock emits radiation for medical diagnostic purposes in the form of infrared light, this radiation is non-ionizing electromagnetic.

15.2 Data Processing Delay

In normal operation, the average processing delay for the Sensor is 5 seconds. Upon start-up, the data processing delay is 10 to 15 seconds to initialize the signal processing chain.

15.3 Data Update

The Sensor transmits data to the Base Station every second. This includes Pulse Rate, Oxygen Saturation, movement metrics, battery charge, signal quality and reading quality. If the Sensor is having difficulty determining valid data, a low priority alarm is generated when the data update period to the Base Station exceeds 30 seconds. NOTE: Alarm conditions are transmitted immediately by the Base Station to the App with almost no delay (assuming the App is up and running).

15.4 Alarm Condition Delay (Time from event to alarm condition)

The alarm condition delays are detailed in the following table. Delays vary by alarm type. All noted times include the data processing delay, the data update delay and transmission time to the base station.

Alarm	Alarm Condition	Alarm Condition Delay
High Priority	Oxygen has dropped below the Low Oxygen Threshold (80% SpO2)	10 seconds
	Pulse Rate has fallen below the Low Pulse Rate Threshold (50 bpm)	10 seconds
	Pulse Rate has exceeded the High Pulse Rate Threshold (220 bpm)	10 seconds
Medium Priority	Sensor is disconnected from the base station for 60 seconds (connection issue) ¹	60 +/- 3 seconds
	Sensor is not able to provide valid data for more than 90 seconds and there is no excessive movement OR the Sensor is not able to provide valid data for more than 4 minutes and there is excessive movement	90 +/- 5 seconds (no excessive motion) 4 mins +/- 5 seconds (excessive motion)

	(Difficulty getting reading) ¹	
	Sensor has fallen off the baby (check sensor placement) ¹	60 +/- 3 seconds
	Base Station has lost power	Less than 5 seconds
Low Priority	Sensor battery is low (Approximately 50 minutes or less)	Less than 5 seconds

¹ Sensor has a 120 second delay when removed from Base Station which must be met for these conditions to occur.

15.5 Alarm Signal Generation Delay (Time from alarm condition to alarm signal)

The Base Station controls the alarms and there is no measurable delay in signal generation within the Base Station or in sending the data to the mobile device. There is less than a 3 second delay in signal generation by the App when connected to the Base Station.

15.6 SpO2 and Pulse Rate Display Ranges and Performance

The SpO2 determined by the Sensor shall be accurate to within ±3% Arms over a range of 70% to 100% oxygen saturation under motion and non-motion conditions.

The pulse rate determined by the Sensor shall be accurate to within ±3 bpm over a range of 30 bpm to 300 bpm under non-motion conditions.*

NOTE: *Established by a study comparing the OSS 3.0 Base Station pulse rate to a calibrated Fluke Pro Sim 8 with SPOT SpO2 Simulator.

NOTE: Because pulse oximeter equipment measurements are statistically distributed, only about two-thirds of pulse oximeter equipment measurements can be expected to fall within ± Arms of the value measured by a co-oximeter

Factors that may affect performance

- Improper Sock placement and/or fit may affect performance. Refer to <u>Section 6.1</u> for fitment information.
- Excessive motion will cause the Sensor to pause transmitting readings.
- Powders, creams, or lotions applied to the baby's foot may cause skin irritation and trouble getting data.
- Electrical equipment that emits radio frequencies may interfere with the Dream Sock's performance. Refer to <u>Section 12</u> for further details.
- Direct sunlight on the baby's foot may affect performance. Owlet recommends the Sock be shaded from direct sunlight.
- Excessively bright direct lighting may cause trouble getting data.

15.7 Equipment Classification

Symbol	Description	Specification
	Protection against electric shock	Class II (Power adapter)
★	Degree of protection against electric shock	Type BF Applied Part (Sensor)
IP22	Liquid Ingress Protection Rating of Base Station	Indicates the device is protected against: 1) solid foreign objects of 12.5 mm and greater, and

		2) water ingress of vertically falling water drops when the device is tilted up to 15°
IP35	Liquid Ingress Protection Rating of Sensor	Indicates the device is protected against: 1) solid foreign objects of 2.5 mm and greater, and 2) water ingress of low pressure jets of water from all directions

15.8 Power

Unit	External Power Requirements	Internal Power	Specifications
Sensor	Re-Charging: Base Station coin cell with a nominal voltage	Operating Time (new): 16 hours	
		of 3.8V and a capacity of 60mAh.	Recharge Time: 2 hours
Base Station	Power adapter with a voltage of 5V and a current 1.0 A. Supplies electrical isolation on all poles. Rechargeable Li-ion Polymer Battery with a nominal voltage of 3.7V and a capacity of 30mAh.	Operating Time: 10 minutes	
		•	Recharge Time: 3 hours

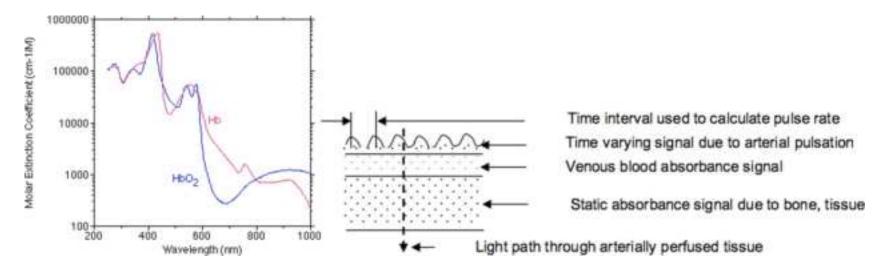
16. Theory of Operation

16.1 Pulse Oximeter Theory

The Dream Sock device measures functional Oxygen Saturation of arterial Hemoglobin (SpO2) and Pulse Rate. Pulse oximetry measurements are based on two physiological principles:

- The differences in optical absorbance properties between oxyhemoglobin (HbO2, oxygenated blood) and deoxyhemoglobin (Hb, non-oxygenated blood)
- The volume (and therefore light absorption) of arterial blood changes due to heart pulsation as it is distributed in tissue throughout the body.

A Pulse Oximeter determines the saturation of arterially Perfused tissue by sequential illumination with the red and infrared wavelengths of light via light emitting diodes (LED's). Refer to the figure below. The time-varying signal passing through the tissue is measured from a photodiode detector many times per second, and the differences between the maximum and minimum absorbance due to pulsation are used to determine the saturation, and the pulsation time period is used to calculate the Pulse Rate.



16.2 Calibration Not Required

As described above, the light absorption properties of Hemoglobin vary with wavelength. The Pulse Oximeter technology used in the Dream Sock device requires no ongoing calibration because the specified wavelengths used in the LED light sources have been selected to be within the calibration range required for the measurement.

16.3 Functional Oxygen Saturation

The Dream Sock is calibrated and clinically tested to measure functional Oxygen Saturation of arterial Hemoglobin based on reference measurements of fractional Oxygen Saturation with a laboratory co-oximeter using arterial blood samples obtained from healthy adult volunteer test subjects.

Functional Oxygen Saturation can be expressed as the following formula:

% Functional Saturation =
$$100 \times \frac{\% Fractional Saturation}{100 - (\% COHb + \% MetHb)}$$

(where % COHb represents % Carboxyhemoglobin and % MetHb represents % Methemoglobin)

If the level of dysfunctional Hemoglobin is high (i.e., high level of carboxyhemoglobin or methemoglobin), the accuracy of the functional saturation measurement may be reduced.

16.4 Use of Functional Testers

A functional tester cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter monitor.

16.5 Clinical SpO2 Accuracy Study Report Summary

Dream Sock has been clinically evaluated for SpO2 accuracy in 18 healthy adult volunteers providing informed consent within an institutionally approved clinical study protocol per the method of ISO 80601-2-61:2017 Clause 201.12.1.101.2. The demographics of subjects included 9 males and 9 females (age: 22-37 yrs., weight: 106-194 lbs., height:59-73", BMI: 19-28). The subject pool included 2 Black / African Americans, 8 Asians, 7 Caucasians and 1 subject of Hispanic / Latino ethnicity. Skin tones ranged from Type I to Type VI on the Fitzpatrick scale. Motion was added by placing one of the subject's arms on a machine that simulates rubbing and touching motions, at 2 to 4 Hz at an amplitude of 1 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 1 to 3 cm. All subjects completed the study without incident.

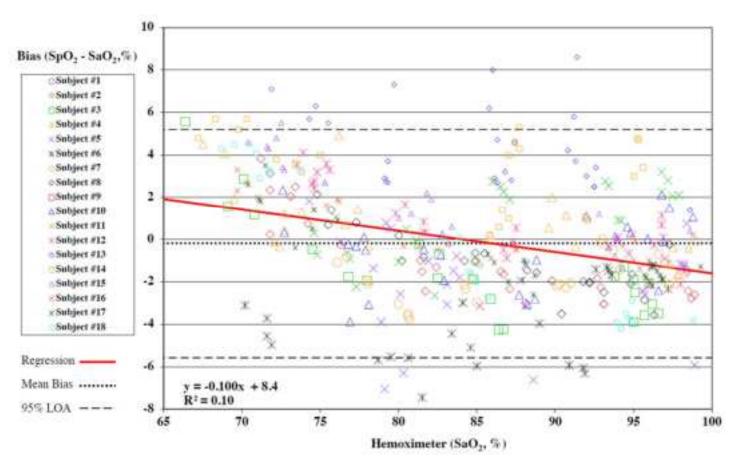
Arterial blood samples measured by co-oximeter (SaO2) are the reference method for simultaneously obtaining Dream Sock values (SpO2). Skin pigmentation of the study subjects included at least three darkly pigmented subjects.

SpO2 accuracy results obtained from this clinical study are provided numerically in the following table and graphically on the next diagram.

SpO2 Accuracy Analysis Range	Non-motion Study Results	Motion Study Results
70% to 100%	± 2.72 % Arms	± 2.63 % Arms
70% to 80%	± 3.05 % Arms	± 3.11 % Arms
80% to 90%	± 2.66 % Arms	± 2.24 % Arms
90% to 100%	± 2.46 % Arms	± 2.54 % Arms

Results of the clinical study demonstrate the Dream Sock meets established criteria for SpO2 accuracy (in non-motion conditions) for the range 70% to 100% SaO2 per the referenced standards.

Non-Motion SpO2



Pooled results from eighteen subjects showing error between Dream Sock readings and Co-Oximeter blood gas measurements, under no motion conditions. Upper and lower 95% limits of agreement (LOA) are shown.

17. Cybersecurity Information

17.1 Ensuring Secure Access

17.1.1 Strong password creation

- Do not use personal information (IE: Email, Username, Birthday, etc). This kind of information is often publicly available and can make your password easily guessable.
- Use a complex password. A minimum of 8 characters that combine numbers, symbols, and both uppercase and lowercase letters.
- Avoid using words that are in the dictionary.
- Avoid using the same password for each account.
- Do not share your password.
- Random passwords are the strongest to use.

17.1.2 Avoid using free public Wi-Fi to connect

17.1.3 Keep your data safe

- Verify the network you are using
- Use a VPN, if possible
- Enable a firewall
- Use antivirus software

17.2 Service Unavailability

Should there be a critical disruption in service from our dependencies or services that impacts user availability, the user will be made aware.

17.3 Detecting cybersecurity events

Cybersecuritiy is a priority at Owlet. We have a team that is dedicated to ensuring the continued security of our products and services. Our products have logging enabled so that we can investigate suspected issues. If you suspect an issue, please contact us: https://support.owletcare.com/hc/en-us/categories/360003108872

17.4 Keeping your device up to date

It is important to keep your devices up to date with manufacturer updates, whether it be your phone, computer, or application - including ours! If there is an update available, please ensure you download it and use the latest version that is available. If a security vulnerability is found in our device, security updates will be pushed in new releases, please make sure your Owlet application is up to date as well.

Any potential vulnerability concerns may be reported as outlined in Owlet's Vulnerability Disclosure Policy: https://owletcare.com/pages/vulnerability-disclosure-policy

17.4.1 Owlet Dream App Updates

Owlet regularly releases updated versions of the Owlet Dream App. It is important that you download the latest version of the Owlet Dream App on your iOS or Android device. Owlet Dream App updates are downloaded directly through the Apple App Store or Google Play Store. You should regularly check the respective store to see if Owlet has released an updated version of the Owlet Dream App.

17.4.2 Firmware Updates

Owlet will periodically release updated firmware for your Dream Sock device. When a new version of firmware is released by Owlet, your Dream Sock will automatically be updated with the new firmware.

When your Dream Sock device's firmware is updating, the status in the Owlet Dream App will say 'Update in Progress' where it normally says 'Getting readings', 'Readings are normal', etc.

While a firmware update such as this is in progress, you should NOT unplug the Base Station or remove the Sensor from the Base Station while the device updates. If the Base Station is not plugged in and the Sensor is not charging on the Base Station, then the firmware update will be stalled. If you remove the Sensor from being charged on the Base Station while a firmware update is in progress, your Dream Sock unit and Sensor will function correctly, but the firmware update will stop, and won't begin again until the Sensor is placed back on the Base Station.

When the firmware update is complete, the 'Update in Progress' message will no longer be displayed within the Owlet Dream App. On average, firmware updates take roughly 15-20 minutes to complete.

If you encounter any issues during a firmware update, please contact Owlet Baby Care Customer Service.

Owlet Baby Care Customer Support

Toll Free: +1 (844) 334-5330 Email: <u>contact@owletcare.com</u> Chat: http://owletcare.com/chat

17.4.3 Security updates

In order to ensure the security of your device any required or routine security updates will be provided to your device for two years from the date of registration of the device.

18. Biocompatibility

The materials that come into contact with the infant/child have undergone extensive biocompatibility testing and comply with ISO 10993-1, ISO 10993-5, ISO 10993-10 and ISO 10993-23. Dream Sock is not made with natural latex rubber or DEHP plasticizers. No

additional precautionary measures for infants, children, pregnant or nursing mothers are required for contact with the materials of Dream Sock. Precautions for proper application still apply.

19. Clinical and Safety Information

19.1 Expected Clinical Performance and Benefits

The expected clinical performance associated with the Dream Sock + Health Notifications is as follows:

- Alarm performance >70% sensitivity and >50% PPV for clinically actionable physiologic conditions (hypoxia <80% SpO2, tachycardia >220BPM, and bradycardia <50BPM) assessed against clinical data obtained through the use of other diagnostic tools under healthcare provider oversight.

The expected clinical benefits associated with the Dream Sock + Health Notifications are as follows:

- Dream Sock is intended to provide accurate recognition and detection of the occurrence of hypoxia (<80% SpO2), tachycardia (>220BPM), and bradycardia (<50BPM) in the home environment, assessed against clinical data obtained through the use of other diagnostic tools under healthcare provider oversight. The associated outcome parameter for this benefit is the successful diagnostic notification of the applicable physiological states (hypoxia, bradycardia, tachycardia).
- Dream Sock is intended to display historical trends of vital sign parameters (pulse rate and oxygen saturation) to a user population traditionally not afforded at-home longitudinal monitoring. This display equips caregivers with biomedical data that can be utilized to help inform healthcare decisions. Clinically relevant outputs associated with this benefit would be achieved through demonstrated predictable and reliable use and usability.

19.2 Safety Information

Dream Sock + Health Notifications is designed and manufactured under a full Quality Management System in accordance with EN ISO 13485:2016 +A11:2021. Dream Sock + Health Notifications has been developed in accordance with the following safety and performance standards:

Standard No.	Title
ISO 80601-2-61:2017	Medical Electrical Equipment - Part 2-61: Particular Requirements for Basic Safety And Essential Performance Of Pulse Oximeter Equipment
EN 60601- 1:2006/A1:2013/A2:2021	Medical electrical equipment Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015 + Amendment 1:2021	Collateral standard: Electromagnetic Compatibility - Requirements and Tests
EN 60601-1-6:2010 + Amendment 1:2015	Collateral Standard: Usability including IEC 62366: Application of usability engineering to medical devices
IEC 60601-1-8:2006 + Amendment 1: 2012 + Amendment 2: 2020	Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-1-11:2015 + Amendment 1: 2020	Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment
IEC 62366-1:2015 + AMD1:2020	Medical devices - Application of usability engineering to medical devices
BS EN ISO 14971:2019 + A11:2021	Medical devices - Application of risk management to medical devices

Standard No.	Title
ISO 20417:2021	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
IEC 62304:2006 + Amendment 1: 2015	Medical Device Software – Software Life Cycle Processes
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and Testing within a Risk Management Process
ISO 10993-5:2009	Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
ISO 10993-10:2021 BS EN 10993-10:2021	Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
ISO 10993-11:2017	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
BS EN ISO 10993-11:2018	biological evaluation of medical devices — Fart 11. Tests for systemic toxicity
(EN) ISO 10993-23:2021	Biological evaluation of medical devices — Part 23: Tests for irritation

Hereby, Owlet Baby Care, Inc. declares that Dream Sock is in compliance with Regulation (EU) 2017/745, UK MDR (2002) and UK PSTI (2022). The full text of the EU and UK Declaration of Conformity is available at the following internet address: https://owletcare.com/pages/ce-compliance

20. Symbols Glossary

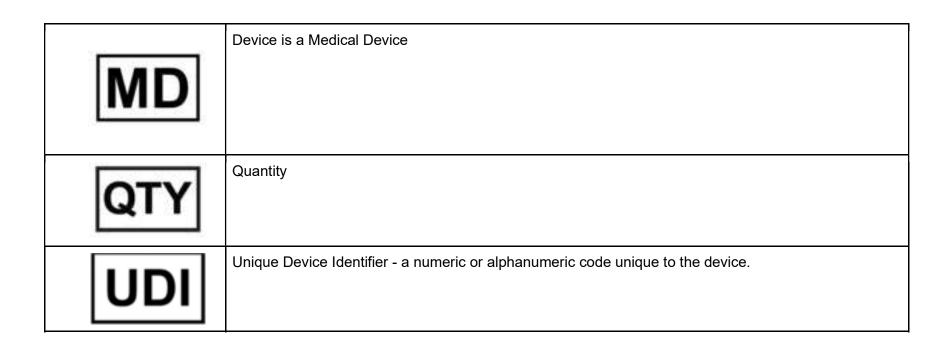
Symbol	Meaning
Ti	Operating Instructions - Indicates the operating instructions, user manual or instructions for use (IFU).
	Manufacturer - Indicates the medical device manufacturer.
\mathbb{Z}	Manufacture Date - Indicates the manufacturing date of the labeled component.
SN	Serial Number - Indicates the device serial number of the component.
REF	Model Reference - Indicates the model reference number of the component.
LOT	Lot Reference – Indicates the manufacturer's batch or lot code.
	Do not use if the package is damaged or opened.

Ť	Keep Dry - Indicates a medical device that needs to be protected from moisture.
1	Temperature Limit - Indicates the temperature limits to which the medical device can be safely exposed.
%	Humidity Limits - Indicates the range of humidity to which the medical device can be safely exposed
6.0	Atmospheric Pressure Limits - Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
★	Type BF Applied Part - Indicated patient isolation from electrical shock
	Mandatory action: Follow instructions for use.
(1m)	Single Patient – multiple use
IP22	Indicates the device is protected against: 1) solid foreign objects of 12 mm and greater, and 2) water ingress of vertically falling water drops when the device is tilted up to 15°

IP35	Indicates the device is protected against:
	solid foreign objects of 2.5 mm and greater, and water ingress of low pressure jets of water from all directions
A	Attention to Proper Disposal of Electronics- Indicates to follow local laws in the disposal or recycling of the device and/or its accessories.
	Class II Equipment - Indicates electrical equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided.
	Warning! - Warnings alert of potentially hazardous situations which, if not avoided, could result in death or serious injury to the patient or user.
<u>^</u>	Caution - Precautions alert of potentially hazardous situations which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property.
!	Note - Provides important information about the product or on a specific topic.
400	UDI (Unique Device Identifier) (01) GTIN (11) Expiration Date (21) Serial Number

$\left(\left(\left(\begin{array}{c} \bullet \\ \blacksquare \end{array} \right) \right)$	Non-ionizing electromagnetic radiation - Equipment includes RF transmitters; interference may occur in the vicinity of equipment marked with this symbol.
===	Direct Current Rating
NON	Device is Non-Sterile
LANEX	Not made with Natural Rubber Latex
	Strangulation Warning - Always keep the base station at least 1 meter away from your baby's crib because the cord can pose a strangulation hazard.
	Recycle
PET	Polyethylene terephthalate, also called PET, is the name of a type of clear, strong, lightweight and 100% recyclable plastic. Unlike other types of plastic, PET plastic is not single-use it is 100% recyclable, versatile, and made to be remade.

%SpO ₂	Functional Oxygen Saturation of arterial Hemoglobin.
UKRP	UK Responsible Person - The UK Responsible Person acts on behalf of the non-UK manufacturer to carry out specified tasks in relation to the manufacturer's obligations
υĸ	UKCA Marking - The UKCA marking is the product marking used for products being placed on the market in Great Britain (England, Scotland and Wales). 0086 refers to the Approved Body number for BSI.
EC REP	EU Authorized Representative. An authorized representative is defined as being any natural or legal person established within the European Union who has received and accepted a written mandate from a manufacturer located outside the EU, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under the Regulations.
CE	CE Marking - CE Marking is product marking used for products being placed on the market in the European Economic Area (EEA). 2797 refers to the Notified Body number for BSI.
2707	Importer - An importer is defined as being any natural or legal person established in EU/UK/Switzerland that places a device from a third country on the EU/UK/Swiss market.
CH REP	CH Representative - The Swiss Authorized Representative acts on behalf of manufacturers located outside of Switzerland to ensure compliance with applicable Swiss medical device requirements.



IFU-SOCK4 - Instructions for Use, Revision 8.0

Team Role Assignment Signature Date

Product Manager	Michelle Smith	
Program Manager	Karsten Shumway	
QA Representative	Mikayla Jensen	
RA Representative	Cydney Ryan	

Revision History

Revision	Modified By	Description of Change
1.0	Perry Nickerson / Cydney Ryan	Initial Release
2.0	Perry Nickerson / Cydney Ryan	 Added maximum optical output of power for Sensor emitters. Added flammable warning statement. Added nonadjustable preset ranges warning statement. Added audible alarm sound pressure ranges. Added MD, QTY, UDI and PET symbols and definitions. Added descriptions of USB Plug and USB Cable.

3.0	Perry Nickerson	Information / language added to align IFU with LRS-SOCK4 requirement SOCK4LRS_192 - SOCK4LRS_202
4.0	Perry Nickerson	Updates to 16.5 Clinical SpO2 Accuracy Study Report Summary section.
		Updated notifications with Physiological and Technical descriptions.
5.0	Cydney Ryan	Updated Expected Clinical Benefits, Safety, and Clinical Performance section to align with CER
		Updated table in 6.3.1.
		Heart rate changed to pulse rate throughout.
6.0	Kristin Young	Updated warning regarding the base station as the primary source of alerts
		Added section 8 Tips for sleep
		Updated Clinical Performance and benefits to align with Clinical Evaluation
7.0	Michelle Smith	Updates per CAPA61 action items and other EU/UK launch prep minor updates (mobile app screens aligned

		with EU/UK product, intended use typographical errors fixed, other small grammatical changes). Added Required PSTI language to section 17.
8.0	Cydney Ryan	Updated Table in Section 16.5 to match data from RPT-M3-034 Rev 1.0; Updated component PNs in REF table to include Dusty Rose and Bedtime Blue. Legal edits throughout doc to refer to trade name appropriately. Language added to cover Android.