Owlet
Dream Sock®

User Manual

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1. General Information **6**
1.1 Glossary 8
2. Safety Information **9**
2.1 Safety Symbols 9
2.2 Warnings 10
2.3 Cautions 12
3. Before Using Dream Sock **15**
3.1 Before First Use 15
3.2 Who Should Use Dream Sock? 15
3.3 Who Should NOT Use Dream Sock? 16
3.4 Where to Use Dream Sock 16
3.5 Network Requirements 16
4. Dream Sock Overview **17**
4.1 What is Dream Sock? 17
4.2 Unpacking the Box 18
4.3 Base Station Overview 19
4.3.1 Base Station Backup Battery 21
4.4 Sensor 22
4.5 Sock 23
5. How to Set Up Dream Sock **24**
5.1 Finding a Home for the Base Station 24
5.2 Set Up the Owlet Dream App 26
5.3 Health Notifications Function 28
5.4 Using the Owlet Dream App and Dream Sock with Multiples 31
6. How to Use Dream Sock **31**
6.1 Sock Size, Fit & Placement 31

6.1.1 Skin Irritation 39
6.2 Base Station Status & Control 40
6.3 Getting Readings and Notifications 41
6.3.1 Notification Color Reference Chart 42
6.3.2 Notification Definitions 43
6.3.2.1 High Priority Notifications 43
6.3.2.2 Medium Priority Notifications 43
6.3.2.3 Low Priority Notification (Technical notification) 44
6.3.2.4 Lavender Notifications 44
6.3.2 Snoozing the Notifications 44
6.4 Turning off Dream Sock 45
6.4.1 Excessive motion 45
6.4.2 How to turn off Dream Sock 45
6.5 Charging the Sensor 45
6.6 When to Discontinue Use of Dream Sock 46
7. Using the Owlet Dream App 46
7.1 Monitoring Sleep with Dream Sock 46
7.2 Display of Live Pulse Rate and Oxygen Saturation Levels 47
7.2.1 Pulse Rate 48
7.2.2 Oxygen Saturation Levels 50
7.3 Sleep Status Indicators 51
7.4 Owlet Dream App Tabs 51
7.5 Understanding History and Session Details 52
7.5.1 Using Oxygen and Pulse Rate History 53
7.5.1.1 Oxygen Trends 54
7.5.1.2 Pulse Rate Trends 55
7.6 Sock Battery Level 55
8. Cleaning 58
8.1 Cleaning the Sock and Sensor 58

8.2 When to Replace the Sock or Sensor 58
8.3 Cleaning the Base Station 59
9. Maintenance **59**
9.1 Sensor Battery Maintenance 59
9.2 Base Station Battery Maintenance 60
9.3 Testing Notification Signal Generation 60
9.4 Turning the Sensor Off and On 61
9.5 Unpairing your Sensor 61
9.6 Pairing your Sensor 62
10. Storage and Disposal **62**
10.1 Storage 62
10.2 Clear Personal Data 63
10.3 Disposal 65
11. Troubleshooting **66**
12. Electro-Magnetic Compatibility **68**
12.1 Electro-Magnetic Compatibility 68
12.2 Emissions 68
12.3 Immunity 69
13. Warranty & Guarantee Information **71**
13.1 Limited Warranty 71
13.2 Satisfaction guarantee 72
14. Service and Support **72**
14.1 When to Contact Your Doctor 72
14.2 Customer Support 72
15. Technical Information **73**
15.1 Peak Wavelengths and Maximum Optical Output of Power 73
15.2 Data Processing Delay 73
15.3 Data Update 73
15.4 Alarm Condition Delay (Time from event to alarm condition) 73

15.5 Alarm Signal Generation Delay (Time from alarm condition to alarm signal) 74
15.6 SpO2 and Pulse Rate Display Ranges and Performance 74
15.7 Equipment Classification 75
15.8 Power 76
16. Theory of Operation 77
16.1 Pulse Oximeter Theory 77
16.2 Calibration Not Required 78
16.3 Functional Oxygen Saturation 78
16.4 Use of Functional Testers 79
16.5 Clinical SpO2 Accuracy Study Report Summary 79
16.6 In-Home Performance Study Report Summary 82
17. Cybersecurity Information 82
17.1 Ensuring Secure Access 82
17.2 Service Unavailability 83
17.3 Detecting Cybersecurity Events 83
17.4 Keeping Your Device Up To Date 83
17.4.1 Owlet Dream App Updates 83
17.4.2 Firmware Updates 84
18. Biocompatibility 85
19. Symbols Glossary 85

1. General Information

About This Manual

This manual explains how to set up and use Dream Sock Monitoring System. Important safety information pertaining to 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

The Owlet Dream Sock is intended to assist caregivers in tracking their child's well-being by monitoring sleep patterns, quality and duration of sleep. When enabled (in-home use on healthy infants only), the Owlet Dream Sock displays pulse rate (PR) and oxygen saturation (SpO2) values and provides a notification in the rare instance that the values move outside of a preset zone.

Indications for Use

The Dream Sock analyzes photoplethysmography data to identify instances when the infant's pulse rate (PR) and/or oxygen saturation (SpO2) moves outside a preset range, and provides a notification to the caregiver, prompting them to assess the infant. The Dream Sock also displays the infant's PR and SpO2 values to the caregiver and displays trends in these measured values, and their relationship to the preset ranges, over time. These PR and SpO2 notifications and displays on the Dream Sock are intended for use in infants who are 1 to 18 months of age and between 6 to 30 lbs.

The Dream Sock is intended for over-the-counter (OTC) use only in a home environment. It is not intended to provide notification for every episode of the unexpected occurrences of elevated or depressed PR or a low SpO2 level; rather, the Dream Sock is intended to provide a notification only when sufficient data are available for analysis. The notifications and associated data can be used to supplement the decision by caregivers to seek additional guidance for medical care of the infant. The Dream Sock is not intended to replace traditional methods of monitoring, diagnosis or treatment.

The Dream Sock is not intended for use with infants previously diagnosed with cardiovascular or respiratory disease or conditions.

Manufacturer Information

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1.1 Glossary

Ambient Light
The light level around the baby. Bright light from lamps, heaters, or direct sunlight can interfere with Sensor performance. A dimly lit room is best.

Ambient Noise
The background sounds which are present at a location. Common ambient sounds include water, birds, appliances, traffic, etc. It is sometimes called the background noise level.

App (or Owlet Dream App)
Owlet Dream mobile device application used to communicate with the Sensor and the Base Station.

Base Station
The part of Dream Sock that is the primary alarming device and audible and visual indicator.

Bluetooth®
Wireless communication method used by the Sensor to talk to the Base Station.

Caregiver
A person who takes care of the baby and applies the Sock with Sensor, checks the in-App readings, and responds to notifications.

Pulse Rate
The number of heart beats per minute (BPM). It is also called the Heart Rate.

Hemoglobin
Part of the blood that carries oxygen throughout the body.

Measurement Light
Light that passes through the baby's skin to measure Pulse Rate and Oxygen Saturation

Oxygen Saturation (or SpO2)
The percent of oxygen available in the baby's blood. It is displayed as %SpO2 in the Owlet Dream App.

Perfused
The passage of blood through the organs and capillaries.

Pulse Oximeter
Medical equipment that uses a non-invasive method to measure and display the Oxygen Saturation in the blood.

Push Notifications
Messages sent indirectly to your mobile device through the Operating System's cloud network.

Remote Connection
The connection of the Base Station to the App is made through remote servers.

Sensor
The part of Dream Sock that measures Pulse Rate and SpO2.

Sock
Fabric wrap that attaches the Sensor to the baby's foot.

Wi-Fi
Wireless network for transferring data between the internet and a mobile device.

Mobile Device
Portable electronic equipment that can connect to the internet, specifically a smartphone.

FDA (Food and Drug Administration)
The Food and Drug Administration is a US government agency that regulates certain food, drug, cosmetic, and medical device products.

Health Notifications
A set of capabilities provided by Dream Sock which displays live and historic Pulse Rate and Oxygen Saturation readings and triggers notifications if the infant wearing the Dream Sock has a Pulse Rate or Oxygen Saturation value that moves outside of preset ranges.

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 Section 14.

2.1 Safety Symbols

WARNING!

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

CAUTION.

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

NOTE:

Provides important information about Dream Sock or a specific topic.

2.2 Warnings

 **WARNING: USE DREAM SOCK AS INDICATED AND REGULATED FOR USE.** Components of this product may or may not be a regulated medical device, as determined by the FDA or other regulatory agencies. Dream Sock is not intended to diagnose, cure, treat, alleviate or prevent any disease or health condition.The display and notification of Oxygen Saturation and Pulse Rate is regulated by the FDA. It is important to use the device and notifications as intended and described in this manual. Only a healthcare provider can diagnose a medical condition such as hypoxia (low oxygen saturation levels).

 **WARNING! DO NOT RELY SOLELY ON DREAM SOCK TO ASSESS HEALTH CONDITION OR OXYGEN SATURATION LEVEL.** Focusing solely on a pulse oximeter measurement may give you a false sense of security. Dream Sock does not notify at every unexpected occurrence of an elevated or depressed Pulse Rate or a low Oxygen Saturation level. Dream Sock notifications are intended to identify instances when the infant's Pulse Rate and/or Oxygen Saturation level moves outside a preset range and are provided only when sufficient data are available for analysis. You should seek medical attention if the infant is not feeling well, even if the reading is normal.

 **WARNING! If you have concerns about Oxygen Saturation readings, or if the child's symptoms are serious or getting worse, contact your healthcare provider for guidance.**

 **WARNING! If you have concerns about Pulse Rate readings, or if the child's symptoms are serious or getting worse, contact your healthcare provider for guidance.**

 **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 **three feet** away from the crib, as the cable can pose a strangulation hazard.

 **WARNING! The Base Station is the main source of notifications. DO NOT rely on your mobile device for notifications.** Always keep the Base Station within audible range of the Caregiver. Ensure the Base Station can be heard by the Caregiver over ambient noises (example: noise machines or televisions). Ensure the Base Station is not covered.

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

 **DREAM SOCK IS NOT A SUBSTITUTE FOR ADULT SUPERVISION OR SAFE SLEEP PRACTICES**. Do not rely solely on the notifications to determine if your baby is safe.

 **The Dream Sock Health Notifications function is not intended for use with babies less than one month old or weighing less than 6 pounds.**

 **Dream Sock does not detect, diagnose or reduce Sudden Infant Death Syndrome (SIDS) or sudden unexpected infant death (SUID).**

 **Base Station model OBL 3.0 (model number located at bottom of the Base Station) does not have a backup battery AND WILL NOT NOTIFY IF THE POWER CORD IS UNPLUGGED. Please make sure there is a reliable power connection.**

2.3 Cautions

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

 **CAUTION.** Keep the 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 each Sock, Sensor and Base Station to avoid confusion.

 **CAUTION.** Do **NOT** place any component of the Dream Sock monitoring 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 Dream Sock when the baby outgrows the largest Sock.

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

 **CAUTION.** Alternate Sock between the baby's feet every 8 hours of use and also 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 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 fabric Socks. Injury to the baby's foot may result.

 **CAUTION.** Do NOT use lotions, creams or powders on the baby's feet before applying the Sock and Sensor. The 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 Sock's 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 baby's 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 baby's skin.

 **CAUTION.** If you log out of the Owlet Dream App, you will no longer receive push notifications on your mobile 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 NOT submerge the Sensor for any period of time or use a washing machine to clean the Sensor. The Sensor is water resistant and should only be hand washed using lukewarm running water and diluted, mild, allergen-free detergent.

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

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

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.
- Understand the warnings and precautions.
- Set up the Owlet Dream App.
- Fully charge the Sensor.

3.2 Who Should Use Dream Sock?

Dream Sock is indicated for:

- in-home monitoring.
- healthy babies 1-18 months of age and 6-30 lbs.
- use during baby's sleep.

Dream Sock is an over-the-counter medical device and is not intended to diagnose, cure, treat, alleviate or prevent any disease or health condition.

3.3 Who Should NOT Use Dream Sock?

Dream Sock is **NOT** indicated for:

- babies and children with ongoing health conditions.
- infants weighing less than 6 pounds.
- children weighing more than 30 pounds.
- use as a substitute for Caregiver supervision.
- use as a substitute for safe sleep practices.

3.4 Where to Use 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 with the Owlet Dream App, as it allows the hardware to communicate information such as Sleep States, notifications, and battery status with the app and with cloud servers. The Owlet Dream App 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, which makes it easy to move the system between locations (e.g., primary home, grandmother’s house, babysitter’s house).

To add a new Wi-Fi network to a device that has already been set up, refer to Section 5.

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. Components of this product may or may not be a regulated medical device, as determined by the FDA or other regulatory agencies. Dream Sock is not intended to diagnose, cure, treat, alleviate or prevent any disease or health condition. The display and notification of Oxygen Saturation and Pulse Rate is regulated by the FDA. It is important to use the device and notifications as intended and described in this manual. Only a healthcare provider can diagnose a medical condition such as hypoxia (low oxygen saturation levels).

The Sensor captures readings from the child's foot to track Pulse Rate, Oxygen Saturation, movement and sleep. The Sensor connects and sends data to the Base Station, and the Base Station sends data to your mobile device via the Owlet Dream App. The App also provides tips and developmental insights. The Base Station indicates notifications as needed based on the data sent from the Sensor.

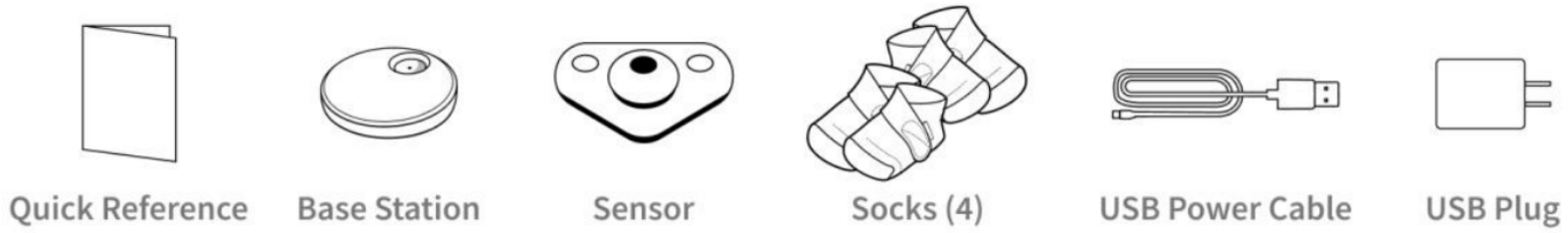
How the Owlet Dream App Works

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

The Dream Sock box includes the following:



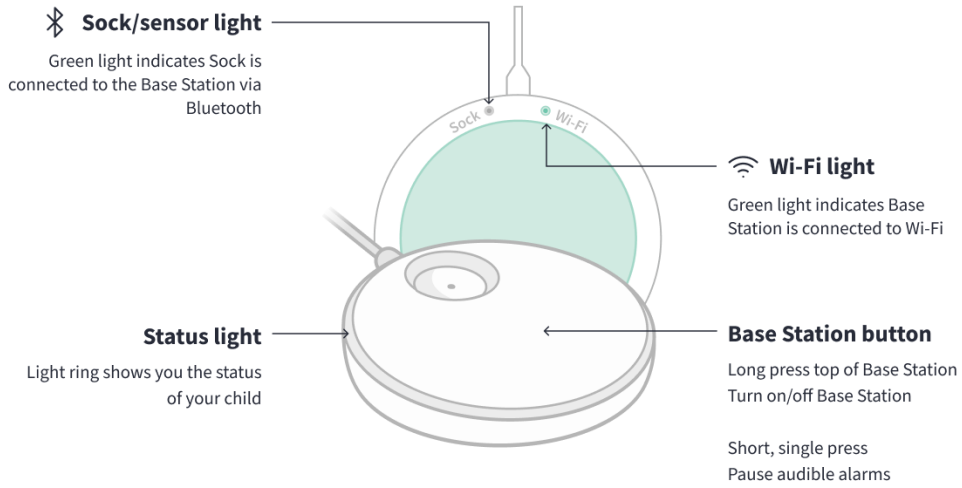
4 Fabric Socks sizes 1 and 2, right and left sock for each size
Sensor
Base Station
USB Power Cable
USB Plug
Quick Reference

Dream Sock is a non-sterile device.

4.3 Base Station Overview

The Base Station is a central component of Dream Sock. 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 the Owlet Server 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.

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

Base Station Button:
Turn on/off Base Station
(Long press top of Base Station)

Silence/Resume audible notifications
(Short, single press)

Base Station Notification Indicators
The Base Station notifies you with lights and sound to inform you of the baby's status (See Section 6.3.2 for details on Notifications).

 **WARNING! The Base Station is the main source of notifications. DO NOT rely on the mobile device for 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.

4.3.1 Base Station Backup Battery

 **Base Station model OBL 3.0 (model number located at bottom of Base Station) does not have a backup battery AND WILL NOT NOTIFY IF THE POWER CORD IS UNPLUGGED. Please make sure there is a reliable power connection.**

The Base Station models that are **not** OBL 3.0 (model number located at bottom of Base Station) have a built-in backup battery which is designed to alert the Caregiver 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 if the Sensor is charging.

4.4 Sensor

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 the 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 to pair the new Sensor to the Base Station. Contact Customer Support for assistance.

Sensor Features

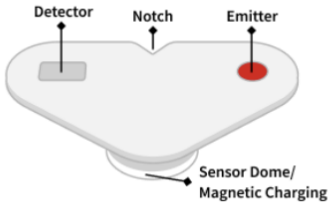
The Sensor has a dome-shaped body with the Owlet logo on it. Attached to the Sensor is a flexible fabric strip with the light emitters and detector. This flexible fabric portion curves around the baby's foot, placing the light emitters opposite the detector.

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.

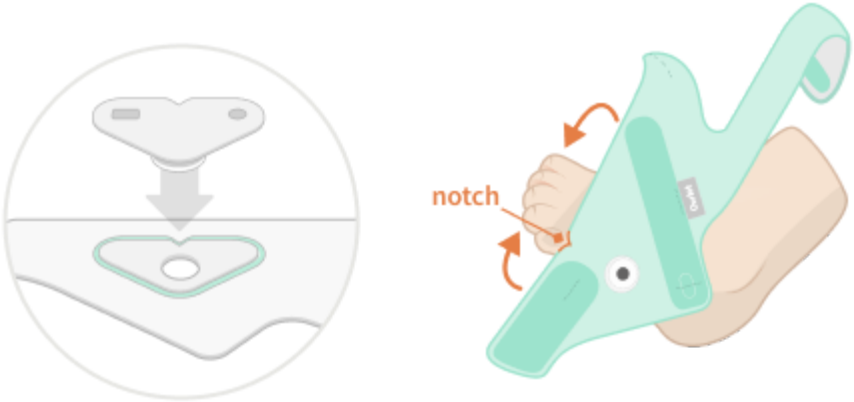


Sensor Battery
The Sensor is powered using a non-replaceable rechargeable battery. The Sensor has up to a 16-hour battery life (when new) and uses convenient drop-and-go charging for an 8-hour charge in just 20 minutes, and full 16-hour charge in only 90-minutes. It is recommended to charge the Sensor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

Turning off the Sensor
See Section 9.4

4.5 Sock

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 fastener straps on the Sock 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.

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

5. How to Set Up Dream Sock

5.1 Finding a Home for the Base Station

WARNING! The Base Station is the main source of notifications. DO NOT rely on the mobile device for 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.

 **WARNING! The Base Station may not perform properly if stored in a location with hotter or colder temperatures than normal.** Prior to use, allow the Base Station to sit at room temperature for at least 15 minutes.

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

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

1) **Caregiver 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 the Caregiver 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 the Caregiver's home Wi-Fi network**

The Base Station must be within range of your home Wi-Fi network. Once Dream Sock is set up, verify Base Station 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 3 feet away from the crib and out of baby's reach to reduce cord strangulation hazards.

 **CAUTION.** Do **NOT** place Dream Sock 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 Set Up the Owlet Dream App

The Owlet Dream 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 Dream Sock.

The Owlet Dream App allows you to:

- See real-time readings* and status of baby
- Receive notifications
- See and modify the baby's sleep history
- Track baby's sleep quality

*Requirements: Dream Sock requires access to a device with iOS 13.0 or later or Android™ 7.0 or later with the Owlet Dream App downloaded; minimum OS versions apply, see app stores for details.

 **NOTE:** Contact Owlet Baby Care, Inc. customer support for assistance in setting up, using or maintaining the Dream Sock system, 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.

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 Owlet Dream 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.

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 Dream Sock to Wi-Fi, to register and pair Dream Sock with the Base Station, and make updates to 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 the Owlet Dream Sock system 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.

5.3 Health Notifications Function

 **WARNING: USE DREAM SOCK AS INDICATED AND REGULATED FOR USE.** Components of this product may or may not be a regulated medical device, as determined by the FDA or other regulatory agencies. Dream Sock is not intended to diagnose, cure, treat, alleviate or prevent any disease or health condition.The display and notification of Oxygen Saturation and Pulse Rate is regulated by the FDA. It is important to use the device and notifications as intended and described in this manual. Only a healthcare provider can diagnose a medical condition such as hypoxia (low Oxygen Saturation levels).

 **WARNING! DO NOT RELY SOLELY ON DREAM SOCK TO ASSESS HEALTH CONDITION OR OXYGEN SATURATION LEVEL.** Focusing solely on a pulse oximeter measurement may give you a false sense of security. Dream Sock does not notify at every unexpected occurrence of an elevated or depressed Pulse Rate or a low Oxygen Saturation level. Dream Sock notifications are intended to identify instances when the infant's Pulse Rate and/or Oxygen Saturation level moves outside a preset range and are provided only when sufficient data are available for analysis. You should seek medical attention if the infant is not feeling well even if the reading is normal.

 **DREAM SOCK IS NOT A SUBSTITUTE FOR ADULT SUPERVISION OR SAFE SLEEP PRACTICES**. Do not rely solely on the notifications to determine if the baby is safe.

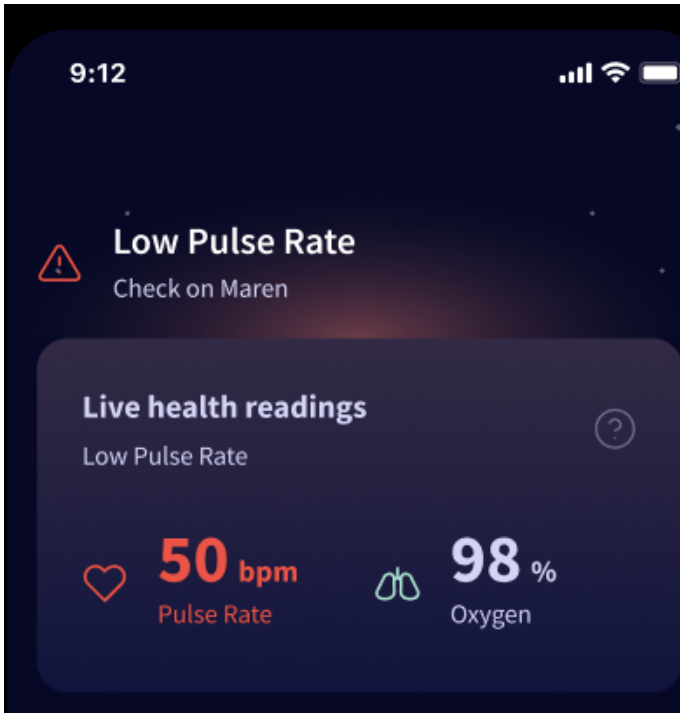
 **The Dream Sock Health Notifications function is not intended for use with babies less than one month old or weighing less than 6 pounds.**

What the Dream Sock Health Notifications function is indicated for

- For in-home surveillance of healthy babies
- For children from 1 month to 18 months of age weighing from 6 to 30 lbs

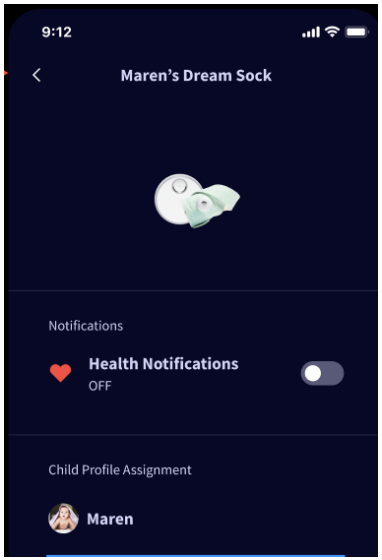
What the Dream Sock Health Notifications function is **NOT** for

- Not for babies and children with ongoing health conditions.
- Not for infants under 1 month old or weighing less than 6 pounds.
- Not for children weighing more than 30 pounds.
- Not for substituting Caregiver supervision.
- Not for substituting safe sleep practices.



When the Health Notifications function is enabled, Dream Sock allows Caregivers to view live health readings such as Pulse Rate and Oxygen Saturation values during a monitoring session, and notifies Caregivers via a high-priority notification if the baby's Oxygen Saturation 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 Saturation level goes below 80%. **New devices have the Health Notifications function disabled by default and it must be manually enabled.**



Dream Sock Health Notifications function can be enabled via the Sock settings in the Owlet Dream App. If the App detects the Health Notifications function is disabled, a banner is displayed on the Home Page confirming Health Notifications are disabled. Once in Sock settings, you can begin the process to enable the Health Notifications function by tapping the toggle button [to the "on" position]. The Caregiver will then need to complete required learning about Health Notifications and how to respond to each different priority notification. It is required that the Caregiver tests these notifications to complete the enabling process.

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

Dream Sock Health Notifications function also includes historical charts and graphs for 10-minute average Pulse Rate and 10-minute average Oxygen Saturation level, sleep and movement under the history tab.

5.4 Using the Owlet Dream App and Dream Sock with Multiples

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

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

6. How to Use Dream Sock

6.1 Sock Size, Fit & Placement

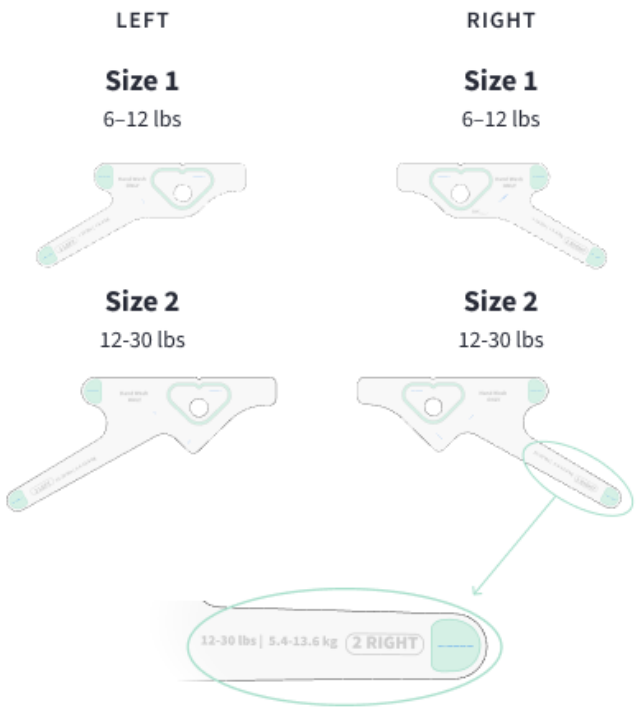
 **WARNING! The Sensor may not perform properly if stored in a location with hotter or colder temperatures than normal.** Prior to use, allow the Sensor to sit at room temperature for at least 15 minutes.

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. Proper Sock size, fit and placement is essential for Dream Sock performance.

Step 1: Take the Sensor off the top of the Base Station
When you take the Sensor off the Base Station, it will display bouncing green lights, indicating that the Sensor is looking for readings from the child. Now it’s time to choose a Sock size and put the Sensor and Sock on the baby’s foot.

Step 2: Choose a Starting Size

Each Dream Sock Monitoring System includes 4 socks - 2 sizes for both left and right feet. Use the guide below to choose a starting Sock size based on the baby’s 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 Dream Sock when the baby reaches 30 lbs or outgrows the largest Sock.

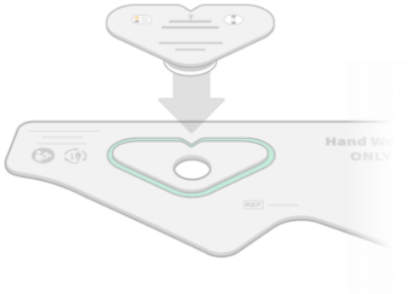
CAUTION. Even if the baby meets the age and weight requirements, if all Sock sizes are either too small or too large, discontinue use of Dream Sock.

CAUTION. Alternate between child's feet every 8 hours of use and also 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 Dome.

Before use, always inspect the Sock and Sensor for damage or excessive moisture and verify that the Sock and Sensor, including the Sensor windows, are clean.



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 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.. 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 the Sock. Injury to the baby's foot may result.

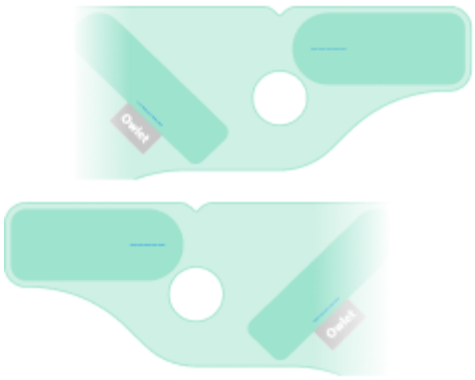
 **CAUTION.** Do NOT use lotions, creams or powders on the baby's feet before applying the Sock and Sensor. Application site must be clean and dry to avoid skin irritation.

 **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.

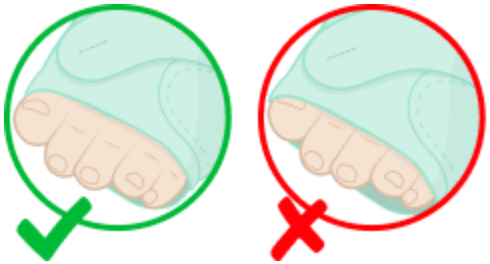
Step 5: Verify Sock Fit & Placement

<u>Match Sock to Foot</u>
Make sure to use the left Sock for the left foot and the 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 baby's skin.
- The Sock should not extend over the toes.



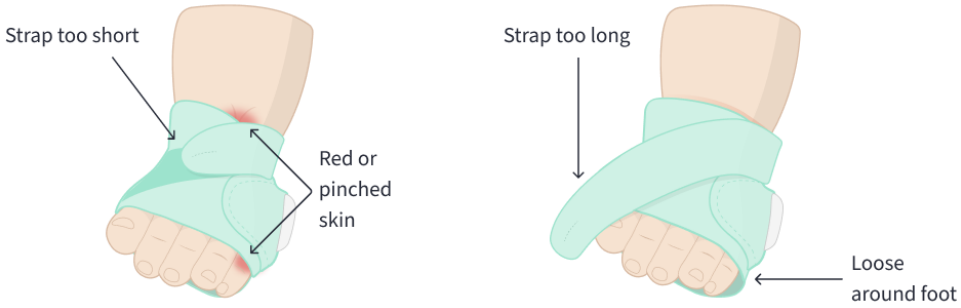
Check Sock Size

Sock too small

If either Sock strap fails to naturally reach the fastener, try a larger Sock size. Do NOT stretch the straps and cinch the Sock too tightly, or it might be uncomfortable for the baby and could result in injury to the baby's skin.

Sock too big

If either Sock 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 the baby'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 and potentially lead to skin irritation, pressure sores or blisters on the baby's foot.

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

Avoiding Skin Irritation

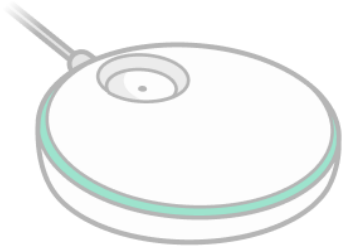
- Always use the *correct size* Sock for the baby. Refer to Section 6.1.
- ***Avoid*** using lotions or powders under the Sock. Keep skin clean and dry.
- Ensure the Sock is positioned and adjusted correctly. Refer to Section 6.1.
- Check skin every 4 hours during the first week of use and after changing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

 **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 the Sock to irritated skin may cause increased damage to the skin.

6.2 Base Station Status & Control

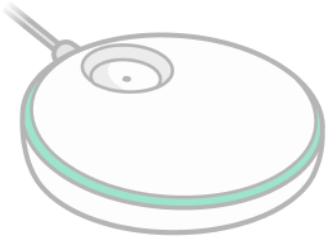


Slow Pulsing Green light

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 the child's readings are out of the normal range, if monitoring is interrupted, or if the child is uncomfortable. There are four different Base Station notification priority types: High Priority Notifications (red), Medium Priority Notifications (yellow), Low Priority Notifications (blue), and Lavender Notifications (lavender). If multiple notifications of different priorities are active at the same time, the Base Station will indicate the highest priority active notification.

Note: High Priority Notifications are for Pulse Rate and Oxygen Saturation and require separate activation of the Health Notifications function within the Owlet Dream App.

6.3.1 Notification Color Reference Chart

Base Station Indicator	Status	Meaning (Notification Condition)	What you should do
 **Flashing Red High Priority**	Low Pulse Rate	Pulse Rate below 50 BPM	Immediately check on your child and see if they are okay. Things to check on are your child's breathing, skin color (are they blue or pale), activity, and alertness. If you have concerns that your child is not okay please seek medical attention.
	High Pulse Rate	Pulse Rate above 220 BPM	
	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 not wiggling or being moved excessively (i.e. swing or being held). It may take 10 – 20 seconds for this alarm to clear once Sensor is repositioned AND the child stops moving. Turn off monitoring until movement stops.
	Power Loss (Not available on Base Station model OBL 3.0)	Base Station has lost line power and is on battery backup.	Check connections and restore power or discontinue use
	Connection Issue	Sensor is out of range of the Base Station, 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.

6.3.2 Notification Definitions

6.3.2.1 High Priority Notifications

See Section 5.3 to learn how to enable Health Notifications function of Dream Sock. The Health Notifications function is optional and needs to be enabled in the App and will remain enabled until they are manually disabled. The Health Notifications function is indicated for, and only to be used with, healthy infants from 1 month of age up to 18 months of age.

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 Saturation goes below 80%.

Note that if multiple conditions occur at the same time that would cause a High Priority Notification to occur, the Owlet Dream App will display all of the conditions triggering the notifications.

 **DREAM SOCK IS NOT A SUBSTITUTE FOR ADULT SUPERVISION OR SAFE SLEEP PRACTICES**. Do not rely solely on the notifications to determine if the baby is safe.

6.3.2.2 Medium Priority Notifications

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 Medium Priority Notification indicates there is a Sock placement issue or the Sock with Sensor has fallen off of the child's foot and was unable to get good readings for at least 60 seconds. A Medium Priority Notification may also indicate the Sock with Sensor 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 to the connection between the Base Station and Sock with Sensor, try not to hold the child with your back facing the Base Station. If Medium Priority Notifications are recurring, move the Sock with Sensor and Base Station closer together to avoid repeated notifications.

6.3.2.3 Low Priority Notification (Technical 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 Low Priority Notification indicates the Sensor battery has 50 minutes of life remaining.

6.3.2.4 Lavender Notifications

During a Lavender Notification, the Base Station will flash lavender and play a tone, and you will receive a push notification in the Owlet Dream App. A Lavender Notification indicates the child has been moving excessively and for an extended period of time. They may need your help going back to sleep.

6.3.2 Snoozing the 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 by clicking the “DISMISS” button on the in-app Notification screen.

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

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

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

6.4.2 How to turn off Dream Sock

To manually turn off the Base Station and end monitoring:

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

1. Pause any active notifications with either the Base Station or the in-app notification screen.

2. Long press the Base Station button 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 and clean, if necessary (see Section 10).
5. Place the Sensor on the Base Station to charge.

6.5 Charging the Sensor

We recommend that you charge the Sensor whenever you are not monitoring. 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 Sensor charging for an 8-hour charge in just 20 minutes, and full 16-hour charge in only 90 minutes.

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

NOTE: The App will indicate if the SENSOR IS CHARGING or Sensor is fully charged only 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 30 lbs.
- The Sock no longer fits properly.
- The Base Station has become damaged and/or has sharp edges

7. Using the Owlet Dream App

7.1 Monitoring Sleep with Dream Sock

After setting up the Dream Sock, the Owlet Dream App Home screen will show key information about the sleep status of the baby, the different sleep states, as well as the status of the Base Station.

The most important information is shown at the top of the Home screen on the Owlet Dream App. Live Status will let you know if the child is asleep or awake, or if they need you. Sleep Session on the App home screen will show the total amount of sleep and number

of wakings for the current sleep session. 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.

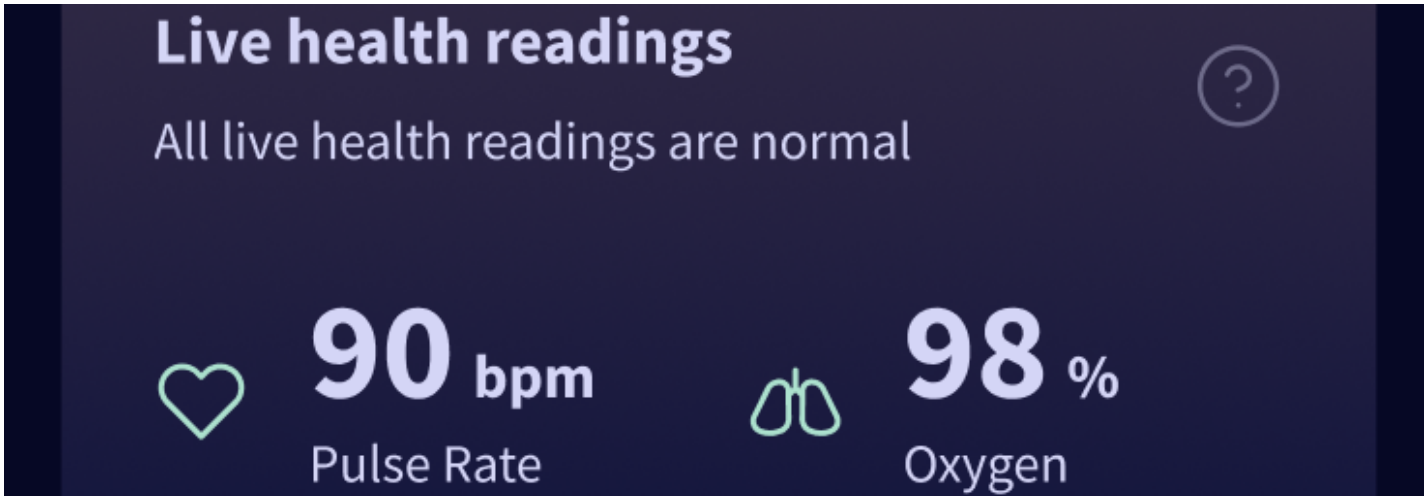
7.2 Display of Live Pulse Rate and Oxygen Saturation Levels

Viewing live Pulse Rate and Oxygen Saturation levels requires the Health Notifications function to be enabled. The readings show real-time information about the baby's Pulse Rate and Oxygen Saturation.

When the Health Notifications function is enabled, Dream Sock will notify Caregivers to critical levels of blood Oxygen Saturation in the baby wearing the Sock with Sensor which may require immediate attention. 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 Saturation 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 Saturation they see on the Owlet Dream App when the Health Notifications function is enabled.

The Owlet Dream App has tooltips that can be used as a quick reference by tapping the help question mark.  The home page 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 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 typical ranges when they are in deep sleep.
- It is very common for infants to have Pulse Rates faster than the typical ranges when they are crying or when they have a fever.

After you set up Dream Sock and connect the App, it is good to get to know how the baby's Pulse Rate normally behaves during routine activities. This will help you recognize anything that is significantly different from the baby's normal range in the future.

For example, the 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 you still may want to check 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 the baby respond to your voice or touch?)
-Temperature (i.e., does the baby feel hot or cool to touch?)

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

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

7.2.2 Oxygen Saturation Levels

Oxygen Saturation levels in healthy infants are similar to adults.

Typically, you will see Oxygen Saturation levels over 90% no matter what activity a baby is doing. Oxygen Saturation levels can vary slightly (within 5%) of the infant's baseline. Infants at high altitude may have slightly lower Oxygen Saturation levels than at sea level, but should still be higher than 90%. Readings from Dream Sock should only be used as an estimate of blood Oxygen Saturation.

After you set up Dream Sock and connect the Owlet Dream App, it is good to get to know the baby's typical Oxygen Saturation levels. Dream Sock will notify if the Oxygen Saturation level falls to 80% or below.

However, there may be times when an infant has an Oxygen Saturation 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 Saturation 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 pink or blue?)
-Breathing (fast or labored?)
-Alertness level (i.e. does the baby respond to your voice or touch?)
-Temperature (does the baby feel hot to touch?)

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

Consider accuracy limitations when using Dream Sock. For example, a reported Oxygen Saturation value of 90% may represent an arterial blood saturation of 87 - 93%. Pulse oximeters tend to be less accurate when Oxygen Saturations are less than 80%, at lower levels of perfusion, and during periods of weak or noisy signals. Be aware that multiple factors can affect the accuracy of readings. Review **Factors that may affect performance and accuracy** in Section 15.6 for additional information.

7.3 Sleep Status Indicators

The sleep status on the Owlet Dream App home screen updates every minute to inform you of the status of the child during their sleep session. A sleep session graph will display data after 10 minutes of monitoring and real-time sleep session information is shown below.

Sleep Session Information
Sleep session shows the number of wakings and the total amount of sleep for the current sleep session.

- **Wakings**
  - The number of wakings in the current sleep session.
- **Total Sleep**
  - The total amount of sleep, including light and deep sleep for the current sleep session.

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.

Home
This is the main screen with baby and device details.

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

Guide

Find all the guides and tutorials.

Account

Through the Account tab, you can manage account details and child profiles and access Chat and Phone support options.
Sections in the Account tab include:

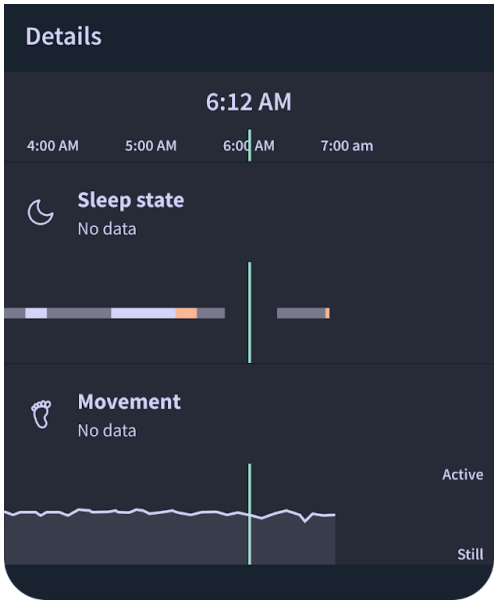
- My Account
    - My Profile: Personal Information (includes Log Out)

CAUTION. If you Log Out of the Owlet Dream App, you will no longer receive push notifications on your mobile 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
    - 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 start of the monitoring session to the end. You will see data from Dream Sock 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 monitoring sessions.

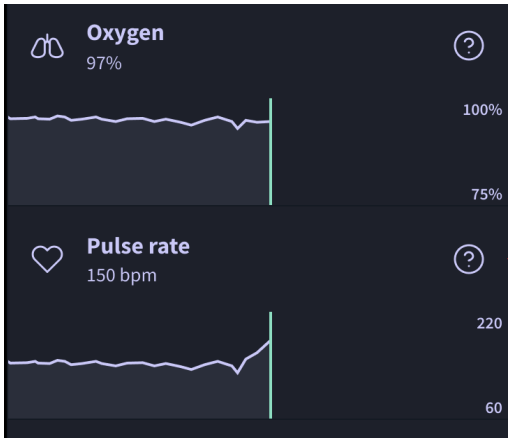


7.5.1 Using Oxygen and Pulse Rate History

Enabling the Health Notifications function allows Caregivers to view historical sleep session data and graphs for Pulse Rate and Oxygen Saturation levels. This feature must be turned on following instructions from Section 5.3. Historical graphs provide a full visual review of Pulse Rate and Oxygen Saturation levels throughout the session allowing you to focus on changes from baseline levels and may be more meaningful than one single measurement. The graphs allow you to view the 10-minute averages of Pulse Rate and Oxygen Saturation.

Measurements should be interpreted thoughtfully considering other signs, symptoms and health history, otherwise the measurement may be misleading.

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 Saturation and Pulse Rate values for children based on age.



NOTE: Oxygen Saturation and Pulse Rate History will only be displayed for time periods where sufficient data is available.

7.5.1.1 Oxygen Trends

Once the Dream Sock Health Notification function has been activated, a graph is available showing a trend of 10-minute averages of Oxygen Saturation readings. The graph will also be presented with an average of the Oxygen Saturation levels measured through the session.

It is expected that an infant should have an Oxygen Saturation level over 90%. However, any prolonged episode of lower Oxygen Saturation levels may show up as a dip in the trend line. 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 Saturation level between 80 and 90% is a reason to check on the baby for signs of breathing difficulty, including nasal congestion, fast or labored breathing, and wheezing.

Additional symptoms to check for may include:
-Color of the infant's lips (are they pink or blue?)
-Breathing (fast or labored?)
-Alertness level (i.e. does the baby respond to your voice or touch?)
-Temperature (does the baby feel hot to touch?)

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

 **WARNING! If you have concerns about Oxygen Saturation readings, or the child's symptoms are serious or getting worse, contact your healthcare provider for guidance.**

7.5.1.2 Pulse Rate Trends

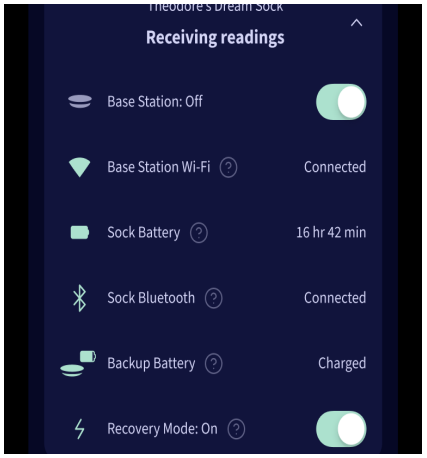
Once the Health Notifications function has been activated, the graph tracking Pulse Rate levels provides a trend of 10 minute averages of Pulse Rate readings. This provides a general review of the pattern of Pulse Rate ranges through a session. It is expected that an infant wearing the Sock with Sensor 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 the 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 the child's average Pulse Rate, it may suggest that the child was uncomfortable, had higher numbers of awakenings, or has an illness developing. It is recommended that you check the child for any signs of illness, and any safety issues in the child's sleep environment.

 **WARNING! If you have concerns about Pulse Rate readings, or the child's symptoms are serious or getting worse, contact your healthcare provider for guidance.**

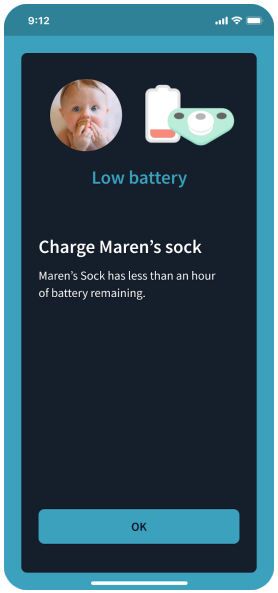
7.6 Sock Battery Level

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



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

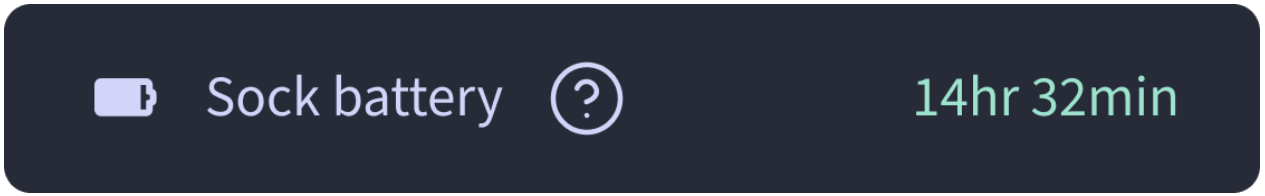
Low Sensor Battery Notification



If your Sensor battery has less than 50 minutes of operation time you will be notified in the Owlet Dream App with a blue notification, and the Base Station will play a sound and light up blue.

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

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 the baby. We recommend washing the **Sock and Sensor at least every week** or more often when visibly soiled.

1. (Optional) Turn off the Sensor (in app, Account>Select Device>Turn off Sensor) see Section 9.4. While the Sensor is water resistant, we recommend turning off the Sensor prior to washing.
2. Gently **hand wash** the fabric Sock and electronic Sensor using lukewarm **running** water and diluted, mild, allergen-free detergent. The Sensor is water resistant and should be washed under running water.

 **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 hand washed under running lukewarm water.

3. Thoroughly rinse with running lukewarm water until no detergent residue remains in the Sock or on the Sensor.
4. Lay or hang the fabric Sock and Sensor to dry. Do **NOT** tumble dry.
5. Visually **inspect** the Sock and Sensor for excessive wear or damage. Replace the Socks as needed.
6. Make sure the Sock with Sensor and the baby's foot are completely dry before use or charging.

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

8.2 When to Replace the Sock or Sensor

The Sock should be replaced every 3 months to reduce the risk of skin irritation.

The Sock and/or Sensor should be replaced if:

- The Sock is stretched out, the fabric is separating or has 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.

For information about replacing the Sock see Section 14.

8.3 Cleaning the Base Station

The Base Station should be cleaned:

- When visibly soiled
- At least once every 2 weeks

1. Turn off monitoring and unplug the Base Station. (Section 9.4 Turning the Sensor Off)
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

Dream Sock contains no user-serviceable components, and no calibration is required. Routine maintenance includes:

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

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 Section 10.

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 it 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 begin monitoring.
3. Unplug the Base Station.
4. Verify lost power.
5. Notifications will continue for at least 2 minutes before Base Station turns off. If not, replace the Base Station.
6. Reestablish power or discontinue monitoring.

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

NOTE: The system will sound the Medium Priority Notification during this test.

9.3 Testing Notification Signal Generation

Caregivers should verify that Dream Sock produces proper notifications if it has been in storage for at least every 6 months (See Sectio 10.1 Storage). Preview each notification priority and verify that 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, Medium Priority, or Lavender Notification, go to the guide tab in the Owlet Dream App and tap on the "Health Notifications" article. There will be previews for each notification.

High Priority Notifications can be tested via the required learning located in the Sock settings on the Home or Account tab.

9.4 Turning 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 turned off for cleaning and short-term or long-term storage.

Turning the Sensor Off

1. In the Owlet Dream App, press the settings cog  on the Home Screen or navigate to the Account tab then select the Owlet Device.
2. Press “Turn off Sensor”.

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

Turning 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 Sensor.
2. Press and hold the Base Station button while you plug the Base Station back in. Keep pressing the button until you hear the Base Station chirp 4 times. The light ring will change to blinking orange. Release pressure after you hear a chirp.
3. Quickly press the Base Station button twice (2x). Ensure the Base Station light ring is blinking orange, otherwise, the Sensor will not properly turn off.

If successful, the 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 Sensor 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 Sensor 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 Base Station light bounces green.

10. Storage and Disposal

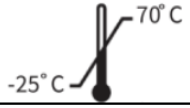
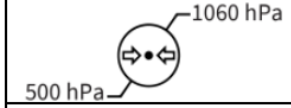
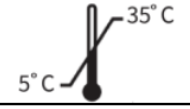
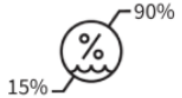
10.1 Storage

Care should be taken when placing Dream Sock into long-term storage to ensure 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.
2. Clear all data (optional, see Section 12.2).
3. Power the Sensor OFF (see Section 8.8).
4. Unplug the Base Station from the wall outlet.
5. Clean Sock, Sensor and Base Station and allow 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.

Symbol	Specification	Value
	Storage and Transport Temperature Limits	-25°C to +70 °C
	Storage and Transport Humidity Limits	0% to 90 %, non-condensing. Water vapor pressure not to exceed 50hPa.
	Storage Atmospheric pressure Limits	500 hPa to 1060 hPa
	Operating Temperature Limits	+5°C to +40°C
	Operating Humidity Limits	15% to 90 %, non-condensing. Water vapor pressure not to exceed 50hPa.
	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 from your Owlet Dream App account. Deleting Dream Sock from your App account will not remove the baby profile and the baby profile will be able to be paired with a different Owlet 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 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 the link.
5. Enter a new password and press “Reset.”
6. Go back to the app and log in with the 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 button while inserting the power cord into the Base.
4. Hold the Base button until the base light glows orange and you hear 4 beeps (this can take up to 10 seconds).
5. Then tap the Base button three times (3x).
6. Confirm the Wi-Fi light on the bottom of the base 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 is now reset.

CAUTION. A factory reset will completely reset the 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 Section 9.4) and Clear Personal Data (see Section 10.2). 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 setup, connection, and operation. For information on troubleshooting notifications, including technical notifications, see Section 6.3.

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 Owlet Dream App.
Cannot see your home Wi-Fi in the 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	Forgot 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 Dream App account	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.
	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 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 18 of this manual for contact information.

12. Electro-Magnetic Compatibility

12.1 Electro-Magnetic Compatibility

Dream Sock is intended for use in the electromagnetic environment of typical homes. The user of Dream Sock should assure that it is used in such an environment. 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 Dream Sock does not interfere with the function of other devices. Move Dream Sock base station further away from any affected device if interference is observed.

12.2 Emissions

Emissions Test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	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 networks that supply 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 Dream Sock continued to operate within specifications (including accuracy and alarm functionality) or show an error. It will alarm if the Base Station cannot communicate with the Sensor due to electromagnetic interference.

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	Dream Sock is suitable for the electromagnetic environment of typical homes, or commercial settings.
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m 80 MHz to 2.7 GHz	

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.

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: contact@owletcare.com
Chat: owletcare.com/chat
Available Monday-Saturday 7 AM- 9 PM MST
www.owletcare.com

In the Owlet Dream 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 App.

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

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 notification 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
	The data has not updated for more than 90 seconds and there is no excessive movement OR the data has not updated for more than 4 minutes and there is excessive movement (Difficulty getting reading)[1]	90 +/- 5 seconds (no excessive motion) 4 mins +/- 5 seconds (excessive motion)
	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 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 Pulse Rate to a calibrated Fluke Pro Sim 8 with SPOT SpO2 Simulator.

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 and accuracy of Dream Sock

- Improper Sock placement and/or fit may affect performance and accuracy. Refer to Section 6.1 for information on Sock placement and fit.
- Performance and accuracy may be affected by poor circulation, variations in skin pigmentation and/or skin thickness, as well as skin temperature.
- 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 performance and accuracy of Dream Sock. Refer to Section 12 for further details.
- Direct sunlight on the Sensor may affect performance and accuracy. Owlet recommends the Sensor be shaded from direct sunlight.
- Excessively bright direct light on the Sensor 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	Normal operation: none Re-Charging: Base Station	Rechargeable Coin type Li-ion coin cell with a nominal voltage of 3.8V and a capacity of 60mAh.	Operating Time (new): 16 hours
			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

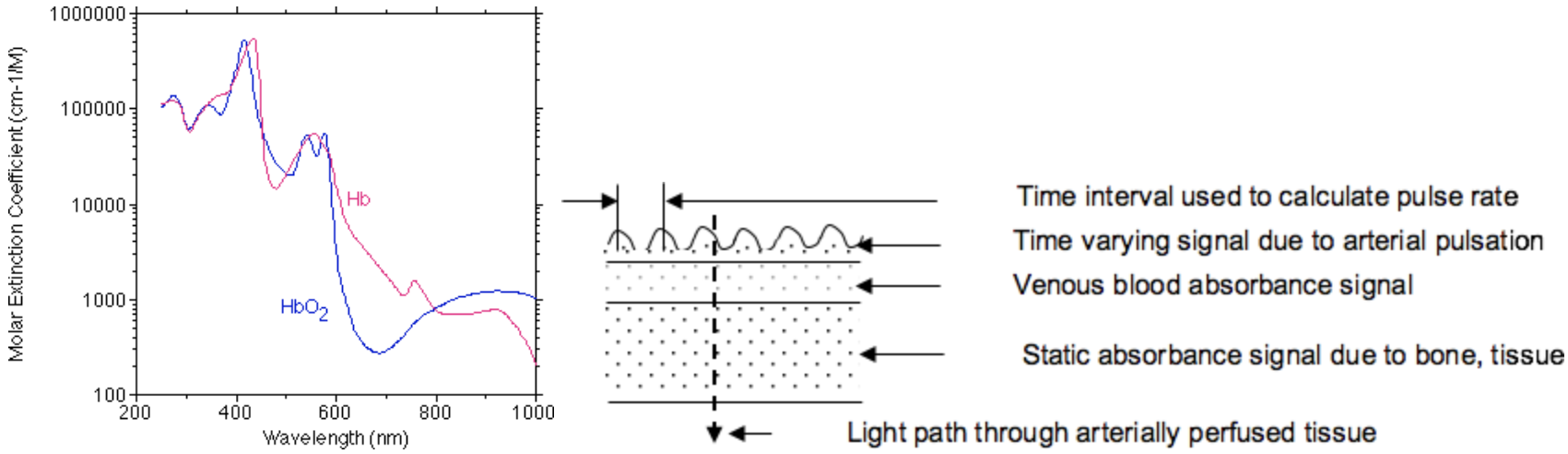
16. Theory of Operation

16.1 Pulse Oximeter Theory

Dream Sock 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 (LEDs). 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 Dream Sock 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

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:

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

(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 80601-2-61:2011 Part 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.

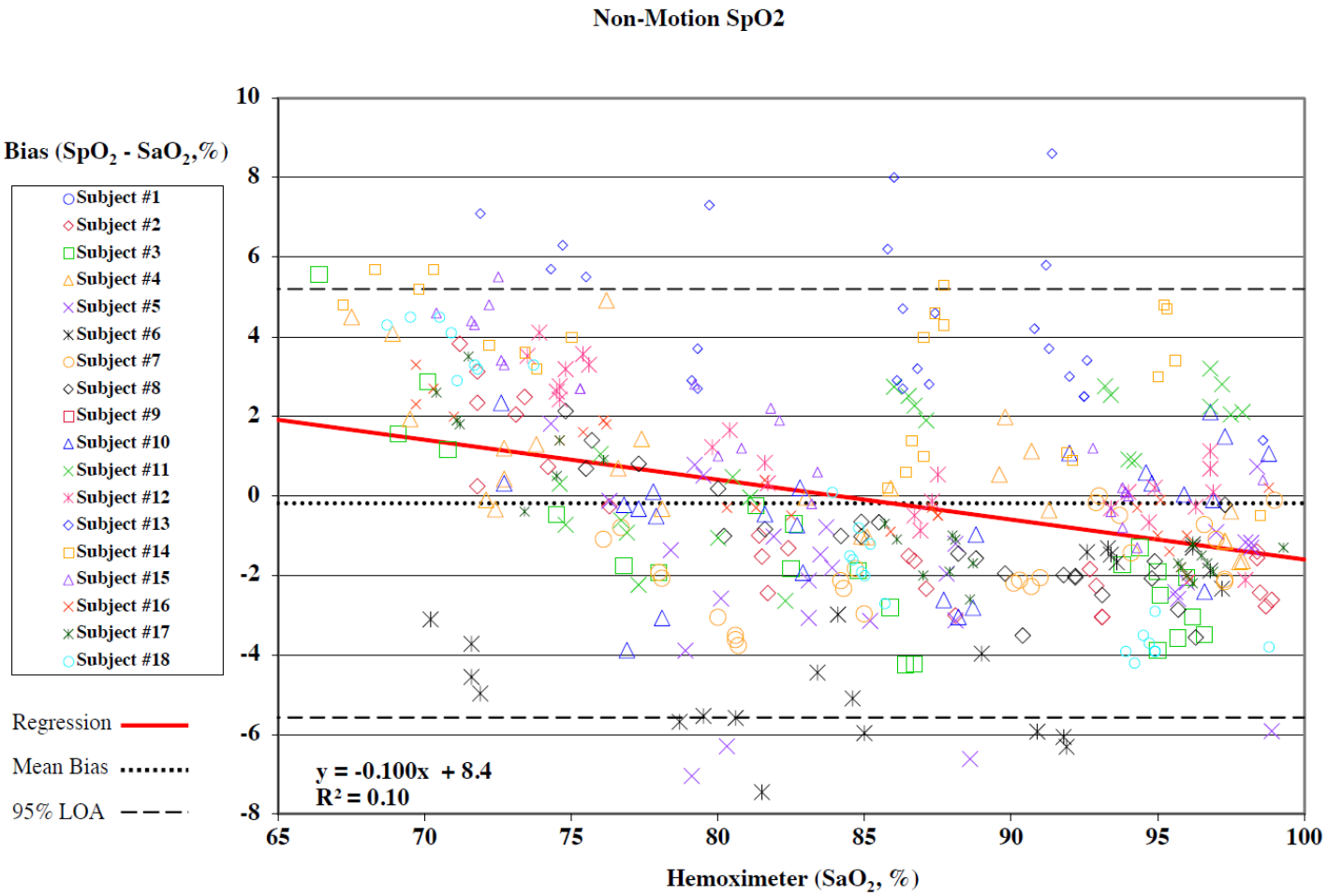
Arterial blood samples measured by co-oximeter (SaO2) are the reference method for simultaneously-obtained Dream Sock values (SpO2). Skin pigmentation of the study subjects included at least three darkly pigmented subjects.

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%	± 2.67 % Arms	± 2.22 % Arms
90% to 100%	± 2.46 % Arms	± 2.63 % Arms

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



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.

16.6 In-Home Performance Study Report Summary

Owlet conducted a prospective study in 35 infants between 1 and 18 months of age wherein the accuracy of Dream Sock was evaluated relative to an FDA-cleared pulse oximetry device. 71.4% of the study subjects were male. The mean weight of subjects was 17.2 lbs with a range of 9.5 to 26 lbs. Fitzpatrick scores (a measure of skin tone/pigmentation) were primarily 2 (27/35, 77.1%), with 5 subjects (14.3%) having scores of 5 or 6.The SpO_2 and PR average root mean square (A_{RMS}) values, a measure of agreement, were 2.16% with a 95% confidence interval of 1.89% to 2.42% and 3.53 with a 95% confidence interval of 3.08 to 3.98, respectively. There were no differences seen in accuracy dependent on age, sex, or Fitzpatrick score. During infant behaviors (i.e., wiggling, feeding) associated with the highest motion levels, the mean SpO2 A_{RMS} value was 2.39% with 95% confidence interval 1.73% to 3.05%; PR mean A_{RMS} during highest motion conditions was 5.02 with 95% confidence interval of 3.38 to 6.56.

No serious adverse events were observed during the study.

17. Cybersecurity Information

17.1 Ensuring Secure Access

Secure your account by creating a strong password:

- Do not use personal information (e.g., email, username, birthday, etc).
- 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.

Avoid using free public Wi-Fi to connect the App to the Base Station.

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 via the email assigned to their account.

17.3 Detecting Cybersecurity Events

Cybersecurity 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 Dream App is up to date as well.

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 mobile device. Owlet Dream App updates can be downloaded directly through the Apple App store or Google Play™ store. You should regularly check the appropriate application 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. When a new version of firmware is released by Owlet, your Base Station and/or Sensor will automatically be updated with the new firmware.

When your firmware is updating, the status in the Owlet Dream App will indicate ‘Update in Progress’.

While a firmware update is in progress, you should NOT unplug the Base Station or remove the Sensor from the Base Station. 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, Dream Sock 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 in the Owlet Dream App will no longer be displayed. On average, firmware updates take roughly 15-20 minutes to complete.

If you encounter any issues during a firmware update, please contact Owlet.

Owlet Customer Support may be reached at the following:
Toll Free: + 1 (844) 334-5330
Available Monday-Friday 10am-8pm EST
Email: contact@owletcare.com
Owlet will respond within 1-2 business days
Chat: owletcare.com/chat
Available Monday-Friday 10am-12am EST

Owlet Baby Care, Inc.
3300 Ashton Blvd., Suite 300
Lehi, UT 84043 USA
+1 (844) 334-5330
www.owletcare.com

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 Sock 4. Precautions for proper application still apply.

19. Symbols Glossary

Symbol	Meaning
	Operating Instructions - Indicates the operating instructions, user manual or instructions for use (IFU).
	Manufacturer - Indicates the medical device manufacturer.
	Manufacture Date - Indicates the manufacturing date of the labeled component.
	Serial Number - Indicates the device serial number of the component.
	Model Reference - Indicates the model reference number of the component.

	Lot Reference – Indicates the manufacturer’s batch or lot code.
	Do not use if the package is damaged or opened.
	Keep Dry - Indicates a medical device that needs to be protected from moisture.
	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
	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.
	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: 1) solid foreign objects of 2.5 mm and greater, and 2) water ingress of low pressure jets of water from all directions
	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.

	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.
	UDI (Unique Device Identifier) (01) GTIN (11) Expiration Date (21) Serial Number
	Non-ionizing electromagnetic radiation - Equipment includes RF transmitters; interference may occur in the vicinity of equipment marked with this symbol.
	Direct Current Rating
	Device is Non-Sterile
	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
	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.
	Device is a Medical Device
	Quantity

	Unique Device Identifier - a numeric or alphanumeric code unique to the device.