



BabySat™ User Manual

- Rx Only
- HSA/FSA Approved

1-18 months

6-30 lbs

FDA Cleared

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1. General Information

About This Manual

This manual explains how to set up and use the BabySat Monitoring System. Important safety information pertaining to BabySat is included and should be read in its entirety. Other safety warnings, cautions and notes are in this manual where appropriate.

Read through this User Manual before using BabySat.

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

Manual Version: 16.0008/Rev. 5.0

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2. 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 Care+ App)

Owlet Care+ mobile device application used to communicate with the Sensor and the Base Station.

Base Station

The part of BabySat 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 alarms.

Direct Connection

Direct Wi-Fi connection between the Base Station and mobile device on the same network.

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 Care+ App.

Perfused

The passage of blood through the organs and capillaries.

Pulse Oximeter

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

Push Notifications

Messages sent indirectly to your mobile device through Apple's cloud network.

Remote Connection

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

Sensor

The part of BabySat that measures Pulse Rate and SpO2.

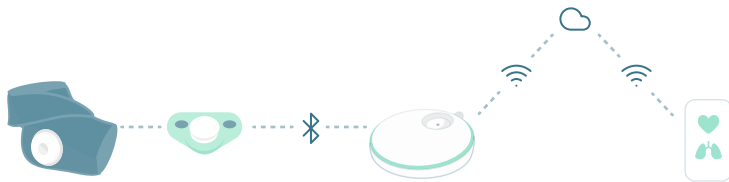
Sock

Fabric sock that the Sensor attaches to.

Wi-Fi

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

3. Introduction to the BabySat™ Monitoring System



3.1 What is the BabySat Monitoring System?

BabySat is a Pulse Oximeter for home use. The Sock secures the Sensor to the baby's foot. The Sensor measures the baby's readings (SpO₂ and Pulse Rate) and transmits the baby's readings to the Base Station. The Base Station monitors the baby's readings and alarms if the readings are outside specific limits. The Base Station also relays the data to the App, which displays the baby's readings and any active alarms.

3.2 Who **Should** Use BabySat? (Indications for Use)

The BabySat pulse oximeter is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO₂) and heart rate. It is indicated for spot-checking and/or continuous monitoring of well-perfused patients greater than one month old and weighing between 6 and 30 lbs., in the home environment.

3.3 Who **Should Not** Use BabySat? (Contraindications)

- Not for patients under 1 month old or weighing less than 6 lbs.
- Not for patients weighing more than 30 lbs.
- Not a substitute for Caregiver supervision.
- Not for use as an apnea monitor.

Rx Only

Federal law (U.S.) restricts the sale of this device to, or by the order of, a physician.

4. Safety Information

This section contains important safety information.

Read this section completely. Contact technical support or customer service with any questions.

4.1 Safety Symbols



WARNING!

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



CAUTION.

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



NOTE.

Provides important information about the product or a specific topic.

4.2 WARNINGS!

WARNING! Always keep the device and accessories out of the reach of children. Small parts including the Sensor are potential choking hazards. Cables are a strangulation hazard.

WARNING! Do **NOT** cover the Base Station or mobile device. Alarm sounds could become muffled and go unnoticed.

WARNING! Single patient use only. Do NOT reuse any BabySat components or accessories with other babies. Use with multiple babies could cause infection.

WARNING! Always disconnect the Sensor from the Base Station before monitoring the baby. Risk of strangulation from cables may result.

WARNING! Ensure that the Base Station can be heard over Ambient Noises such as vacuum cleaners, dishwashers, clothes dryers, televisions, radios, etc.

WARNING! Do NOT service, repair, open, or modify any components of BabySat. Damage to internal parts could affect the safety or performance of the device. Contact customer service for service.

WARNING! Use of accessories, transducers and cables other than those specified for use with BabySat as described in this document can result in incorrect readings, degraded performance, or injury. Do not physically connect the Base Station or Sensor to other devices not included.

WARNING! Do **NOT** apply the Sock and Sensor to damaged or irritated skin. This could result in serious injury to the skin or infection.

WARNING! Immediately discontinue use of BabySat if any components or accessories appear damaged. Contact Owllet.

4.3 CAUTIONS

CAUTION. Always remove the Sock and Sensor from the baby before bathing the baby.

CAUTION. If fluid spills on the Base Station, immediately disconnect the power cord and dry completely. Use cleaning solutions sparingly to avoid getting any liquid in the enclosures. Should liquid enter the USB port, absorb the liquid with a cotton swab and allow the port to dry. Contact customer service if you have any concern about performance.

CAUTION. Check size and fit of the Sock periodically. Improper size or fit can lead to skin irritation.

CAUTION. Keep the Sock, Sensor and Base Station clean, free of dust and lint, and away from pets.

CAUTION. Discontinue use and contact customer service if changes in the performance of BabySat occur.

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

CAUTION. The BabySat monitoring system provided is non-sterile.

CAUTION. BabySat should not be used by Caregivers with vision, hearing, or mental impairments.

CAUTION. Do NOT lean, sit or step on any parts of the device.

CAUTION. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

4.4 ! Notes

NOTE: BabySat is calibrated to display functional Oxygen Saturation of arterial Hemoglobin (SpO2) in the Owlet Care+ App.

NOTE: BabySat does not require calibration by the user.

NOTE: Cold or poorly Perfused tissue may affect the Sensor's performance.

NOTE: The taking of medications that alter blood color, the administration of intravascular dyes (such as methylene blue or indocyanine green and other dyes) or a high level of dysfunctional Hemoglobin in cases of Thalassemia, spherocytosis, MCF (e.g. Carboxyhemoglobin or Methemoglobin) may affect the Sensor's performance.

NOTE: Severe anemia or elevated levels of total bilirubin may affect the Sensor's performance.

4.5 Risks of Using the Sock and Sensor

Skin Irritation: Some babies may develop skin irritation on their feet when using the Sock due to the pressure or friction against the baby's delicate skin. Here is what you can do to help avoid skin irritation:

- Make sure the Sock is correctly sized for the baby and correctly applied.
- For the first two weeks, and after switching to a new Sock size, check the skin under the Sock every 4 hours for any signs of irritated skin.
- Alternate Sock placement between feet at least every 8 hours. If your baby has sensitive skin, alternate every 4 hours. Check skin condition each time you alternate feet.
- Stop use if skin irritation persists. Resume use when the skin irritation is gone.
- Keep the Sock and baby's skin clean and dry.
- Avoid using lotions or powders under the Sock.

Hyperpigmentation: There are some wavelengths of light used by the Sensor that can potentially cause hyperpigmentation (darkening of the skin tone) in the area of skin exposed to the light. This is due to activation of melanin by the light source. This is not an injury to the skin, but a reaction some babies may have. It is more common in children with darker skin tones. There is no treatment necessary for this finding, and gradually resolves over time. If you have questions about any skin changes related to wearing the Sock, please contact customer support.

4.6 Benefits of Using the Device

Benefits of using BabySat include:

- Monitoring a baby's Sleep State, Oxygen Saturation and Pulse Rate can provide helpful health information about the baby's well-being.
- Visual and audible alarm indicators identify when alarm thresholds have been exceeded.

5. Before Using BabySat

5.1 Before First Use


Do the following before using BabySat **for the first time**:


- Read this entire User Manual.
- Understand the warnings and precautions.
- Set up the Owlet Care+ App (Section 7.2).
- Fully charge the Sensor (Section 8.6).

5.2 Operational Environment

BabySat is designed for use in the home.

 **CAUTION.** BabySat is NOT designed for use in moving vehicles.


 **CAUTION.** Keep BabySat away from electrical equipment that emits radio frequencies to minimize radio interference. Radio interference may affect performance.

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

5.3 Network Requirements

A Wi-Fi network is required to use BabySat to allow the Base Station to communicate with the App and cloud servers. Information such as Pulse Rate, Oxygen Saturation, alarms, and battery status are shared over the network. The 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 a 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 2.4GHz connection.

 **CAUTION.** Make sure your router firewall is enabled and your router is password protected. Also password-protect your mobile device and keep the operating system updated.

The Base Station can remember up to 8 Wi-Fi networks making it easy to move the device between locations (i.e., home, grandparents, babysitter).

To add a new Wi-Fi network to an already set up device, refer to the setup instructions in the App.

Account>My Owlet Devices (Select Device)>Change Wi-Fi

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

! NOTE.

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

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.

6. About BabySat

6.1 Unpacking the Box

The BabySat box includes the following:



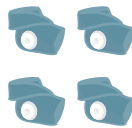
Quick Reference



Base Station



Sensor



Socks (4)



USB Power Cable



USB Plug



WARNING!

Inspect all parts for damage. Do NOT use damaged parts as this could lead to harm. Contact customer service if the box appears damaged or if any parts are damaged or missing.

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

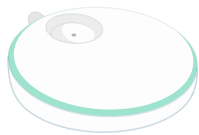
! **NOTE.** Note: Dispose of packaging waste in a responsible manner. Please recycle.

6.2 Base Station

The Base Station is a central component of BabySat. It communicates with the Sensor to obtain the baby's Pulse Rate and Oxygen Saturation readings. The Base Station logs and monitors the baby's data and determines when to create alarms. The Base Station also relays the baby's information to the Owlet server and the Owlet Care+ App so Caregivers can see the information and alarms on their mobile devices.

Base Station Status Indicators

The Base Station has a light ring indicator around its edge which provides information about the Base Station and monitoring status.



Quick Bouncing Green

Sensor is acquiring first Pulse Rate and Oxygen Saturation readings.

Slow Pulsing Green

Pulse Rate and Oxygen Saturation are within prescribed limits.

Solid Cyan (Blue)

Low Priority Alarm (Section 8.5).

Flashing Yellow

Medium Priority Alarm (Section 8.5).

Flashing Red

High Priority Alarm (Section 8.5).

Blinking Orange

Sensor charging on Base Station is paired to a different Base Station.

Solid White

Sensor is plugged in and is fully charged.

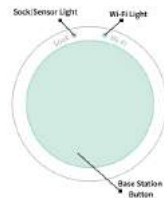
Slow Pulsing White

Sensor is plugged in and is charging.

Blinking White

Sock is not paired to Base Station.

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

(Long press top of Base Station)

Base Station Button

Turn on / off Base Station.

(Long press top of Base Station)

Silence / Resume audible alarms.

(Short, single press)

Base Station Alarm Indicators

The Base Station alarms with visual and audible indicators to inform you when your baby or the BabySat require attention. (See Section 8.5 for details on alarms).



WARNING!

Always keep the Base Station in audible range. Use the Base Station as your source for alarms and check on the baby first. DO NOT rely on mobile device for alarms. The Owlet Care+ App will ONLY alarm when open and the mobile device is unlocked and connected to the same Wi-Fi network as the Base Station. If the App is closed, it may take additional time to receive and display Push Notifications.

Base Station Backup Battery

Base Station contains a backup battery which is designed to alert the Caregiver that main power has been lost while monitoring.

During a power loss, the Base Station will continue monitoring the baby and provide a medium priority audible and visual alarm for at least 2 minutes. However, no data or alarms will be sent to the App.

Restore power to the Base Station to resume monitoring. If power is not restored, the device will power off within 10 minutes. Alarm settings are not affected by power loss. The backup battery charges automatically when the Base Station is plugged in.

The Base Station will not alarm during a power loss if it is already turned off or the Sensor is charging.



CAUTION.

Do not intentionally operate the Base Station on the backup battery.

! NOTE.

Backup battery will sound an alarm for up to 10 minutes, then shut down. If an unexpected power failure occurs, check power connection, restore power or switch to alternative monitoring methods.

6.3 Sensor

The Sensor has light emitters and a detector which measure Pulse Rate and Oxygen Saturation by differential light absorption techniques (see Section 15 for more details). This data, along with information about the data quality and movement metrics, is sent to the Base Station via Bluetooth®.

For the Sensor to function properly, it is positioned and held in a specific location on the foot by a specialized Sock (see Section 8.1).

! NOTE.

Pairing associates a new Base Station and new Sensor. If the Sensor is replaced, you will need to repeat the pairing process with the new Sensor and the Base Station. Contact customer service for support.

Sensor Features

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

Measurement Light Emitter

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

Measurement Light Detector

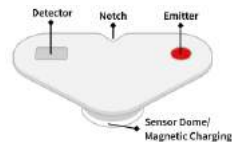
Collects readings.

Sensor Dome/Magnetic Charging

Connects to Base Station for charging.

Notch

Aids in alignment of the Sensor to the Sock.



Sensor Battery

The Sensor is powered using a non-replaceable rechargeable battery. The Sock has 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 keep the Sensor on the Base Station when not in use (see Section 8.6).

Turning off Sensor

See Section 8.8.

6.4 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 and fit to baby's foot see Section 8.1, Sock Size, Fit & Placement.



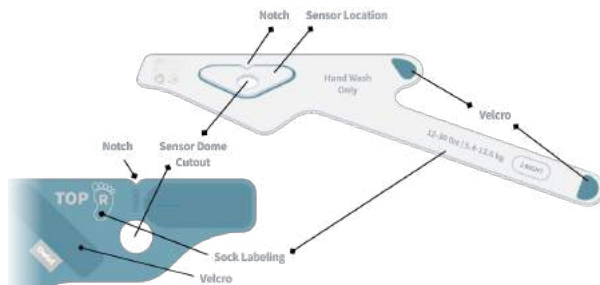
CAUTION.

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



CAUTION.

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



Notch

Aids in proper Sensor and Sock placement.

Sensor Location

Aids in proper placement of Sensor into Sock.

Sensor Dome Cutout

Cutout for Sensor Dome.

Sock Labeling

Indicates Sock size and correct foot.

Hook and loop fastener straps

Secures the Sock on baby.

7 How to Setup BabySat

7.1 Finding a Home for the Base Station

In App: Guide>BabySat Basics> Finding a Home for the Base Station
The Base Station location is essential for proper performance and safety.

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

1. You can always HEAR it

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

2. It will WAKE you up at night

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

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

The Base Station must be within the range of your home Wi-Fi network. Once set up, verify connection using the Wi-Fi light on the bottom of the Base Station or the Owlet Care+ 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 in the same home (within 100 ft. of each other) so they can communicate. But home size and layout may affect signal strength, which may require the Base Station to be placed closer to the Sensor. Check signal strength in the Owlet Care+ App once setup is complete (See Section 7.3).

5. It is away from the crib

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



CAUTION.

Do NOT place Base Station or accessories in any position that might cause it to fall on the baby. Injury could occur.

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

7.2 Setting up the App

The Owlet Care +App communicates with the Base Station using your home Wi-Fi network. The App displays readings, status messages and alarm information and is a vital part of BabySat. The mobile device should always be on and within arm's reach of the Caregiver while monitoring the baby.

The Owlet Care+ App allows you to:

- Control the Base Station remotely
- See real-time readings for Pulse Rate & SpO2
- Receive alarms
- See and modify alarm thresholds

Requirements: Any Apple mobile device with iOS 14 or greater. Not compatible with smart watches.



WARNING!

Always keep the Base Station in audible range. Use the Base Station as your source for alarms and check on the baby first. DO NOT rely on mobile device for alarms. The Owlet Care+ App will ONLY alarm when open and the mobile device is unlocked and connected to the same Wi-Fi as the Base Station. If the App is closed, it may take additional time to receive and display Push Notifications.

! NOTE.

Contact Owlet Baby Care for assistance in setting up, using or maintaining the BabySat device, 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. (See Section 6)

Download the Owlet Care+ App

Before proceeding, download and install the App. The App will guide you step by step through setup.

1. Go to the Apple App store on your mobile device.
2. Search for Owlet Care+ App.
3. Download the App.



WARNING!

Without Push Notifications, the App has no way to provide alarms to the user when closed. Make sure to allow Push Notifications.



CAUTION.

For security, keep your iOS Software and Owlet Care+ App up to date at all times and make sure your mobile device is password protected.

! NOTE. You must have a valid Apple App Store account to download the App.

Finish Setup

After downloading, the App will guide you through:

- Creating an Account
- Account Confirmation
- Enabling Push Notifications
- Device Setup
- Connecting to Wi-Fi
- Registering Base Station
- Sensor Pairing
- Creating a Child Profile
- Safety Tutorial

7.3 Understanding the App

Main Screen Layout and Information

In App: Guide>Additional Help> Understanding the App

The App Home screen shows key information about the health and status of the baby as well as status of the Base Station.

Help Buttons



Press any of the help buttons to get more detailed information about that section.

Device Settings



Press this button to access device settings, including alarm settings.

Baby & Device Status

The most important information is shown at the top of the Home screen, including the status of the baby and device. The background color indicates the status or alarm condition at a glance.

The status message(s) on the Home screen provides information about the status or alarm condition. You can press the (?) button for more detailed information about any status displayed on the App. The following table gives the potential status messages and their meaning, for your reference.

Status Messages

Getting Readings: Base Station was recently turned on, and the Sensor is calculating readings.

Receiving readings: The SpO2 and Pulse Rate values are within alarm limits.

One moment...getting readings: The App is loading/trying to connect to the data source.

Sensor Charging Complete: Sensor charging is complete.

Sensor Charging: The Sensor is charging.

Connecting... The App is loading/trying to connect to the data source.

Connecting to base... The App is loading/trying to connect to the data source.

Sensor not paired: No Sensor has been paired with the Base Station. Plug the Sensor into the Base Station.

Wi-Fi disconnected from Base Station: The Base Station is no longer connected to Wi-Fi. Check the router.

App searching for Base Station: The App is having trouble getting new data from the Base Station. Check Wi-Fi connections.

Server error, readings unavailable at this time: The Base Station is linked to a different account, profile or other errors.

Base Station turned off: Base Station is off, and monitoring has been disabled.

LOW SENSOR BATTERY: The Sensor battery has less than 10 minutes remaining.

DATA NOT UPDATING: The data has not updated for more than 30 seconds.

CONNECTION ISSUE: The Sensor is either out of range of the Base Station or the Sensor battery is depleted.

DIFFICULTY GETTING READINGS: The Sensor is not able to get a good reading. Check Sock fit and placement or for excess movement.

POWER LOSS: The Base Station has lost power while monitoring. Restore power.

SOCK PLACEMENT ISSUE: The Sensor is not on the foot or is not close enough to the skin. Check the Sock fit.

HIGH PULSE RATE: A high Pulse Rate has been detected.

HIGH OXYGEN: A high oxygen level has been detected.

LOW PULSE RATE: A low Pulse Rate has been detected.

LOW OXYGEN: A low oxygen level has been detected.

Readings

The readings show real time information about your baby's Pulse Rate and Oxygen Saturation levels.



150 BPM



96% O₂

Pulse Rate



The current Pulse Rate is displayed in beats per minute (BPM). A baby's Pulse Rate is naturally much faster than adults.

SpO₂ (Oxygen Saturation)



SpO₂ (Oxygen Saturation)

Alarm Limits



Current alarm limits are shown on the dials. No value is shown when a particular alarm is disabled.

Movement

When your baby is moving excessively, and the Sensor cannot get readings, these wiggling feet will appear, and the green Base Station lights will bounce back and forth. If movement exceeds 30 seconds, a low priority alarm will be generated. After 4 minutes of continuous movement, a medium priority alarm will be generated.



Movement can impact the quality of readings, so rather than notifying you unnecessarily, the readings and notifications will be momentarily paused until quality readings are obtained again.

Base Station Status & Control

The toggle allows for remote control of the Base Station. Press to toggle monitoring on or off when the Sock is not charging. This feature is only available if you have a Direct Connection.



Base Station: **On, Charged**



Alert Status & Control



This indicates when an audible alert has been paused. Pausing an active alarm is done by pressing the Pause button on the alarm screen or tapping the Base Station one time. The visual indicators will continue while audible alerts are paused.

This pause provides time to the Caregiver to respond to the alarm and resolve the underlying alarm condition. All audible indicators will resume automatically **after 2 minutes** or if a new alarm occurs.

Tapping the toggle will resume the audible alert. This feature is only available if you have a Direct Connection.

Reading Quality



Reading Quality indicates how reliable the oxygen level measurements are and is based on the ratio of Pulse Rate signal to received light signal. If Reading Quality is Poor, BabySat will stop providing values and will display the symbols – or ? in place of Pulse Rate and SpO2 values.

In addition to Reading Quality, BabySat also monitors motion, Ambient Light, and other conditions, and will stop displaying values if they are no longer reliable. BabySat will alarm if readings remain unreliable.

Pulse oximetry readings can be affected by poor contact of the Sensor with the skin. Verify the Sock fit, and that Sensor placement is correct (see Section 8.1).

Reading Quality can also be affected by foot temperature. A cold foot can decrease reading quality. Warm up the foot and recheck the reading in 10-15 minutes.

If after performing these steps the Reading Quality is still Poor, contact Owlet for further guidance. If you are concerned about your baby's health when this issue occurs, contact your healthcare provider for advice.

Sensor Battery Level Status



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


Base Station Connection Status



The Owlet Care+ App can connect to the Base Station either directly over the same Wi-Fi network or remotely through cloud servers. The connection status is indicated by a connection icon and text on the main screen.


They will be one of the following:

Direct

-  The mobile device is talking directly to the Base Station and on the same Wi-Fi network. The App will receive alarms, if active, and can be used to control the Base Station.

! NOTE. Alarm Limits can only be modified with a Direct Connection. See Section 8.5 for more information.

Remote

-  The mobile device is not on the same network. App will show status but will not receive alarms and cannot control the Base Station.

Wait

-  The App is trying to establish a connection to the Base Station.

Disconnected

-  The App is trying to establish a connection to the Base Station.

No network

-  Check your mobile device's connection to the internet.

Alarms Unavailable in App appears in the App when alarms are disabled. To enable alarms, connect the Base Station and App to the same Wi-Fi network and verify Sock placement.



WARNING!

Always use the Base Station as your source for alarms. DO NOT RELY ON MOBILE DEVICE FOR ALARMS!

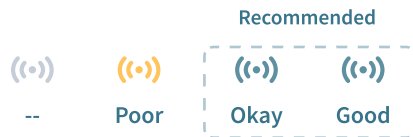
Sensor Range Indicator

 Bluetooth Range 

Good

Indicates the strength of the connection between the Base Station and the Sensor. A Poor connection can affect performance.

Range is affected by distance and building layout. Move the Base Station closer to the baby until you get Good or Okay. If the signal strength gets too low, the Base Station will no longer receive data from the Sensor.



CAUTION.

To ensure good signal strength, position the Base Station so that the range indicator is green (Okay or Good). Do not place the Base Station more than 100 feet from the baby.

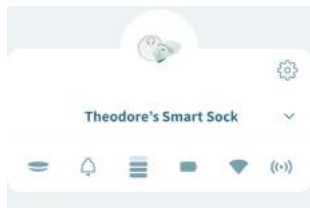
! NOTE.

A medium priority alarm will be generated if the Base Station loses communication with the Sensor.

! NOTE. Always check the range indicator when changing the locations of either the Base Station or the Baby.

Collapsed View

Device details can be collapsed by pressing . When collapsed, key baby information is still visible at the top while other details are represented by icons.



App Tabs

This section is always at the bottom of the Owlet Care+ App and allows you to navigate to the other app screens.



Home

This is the main screen with baby and device details.

Notification History

The History tab (found on the footer of the Home Screen) displays a 30-day notification summary of high and medium priority alarms. Data older than 30 days is automatically discarded. The App must be set up and configured before the alarm history can be collected. Once configured, the history is collected whenever the Base Station is on and connected to a Wi-Fi network with internet access. This log is retained during power loss. Periods when one or more alarms are disabled are not included in the log.



Guide

Find all the guides, tutorials, and the User Manual.

Account

Manage account details and child profiles.

Sections in the Account tab include:

My Account

- My Profile: Personal Information (includes Log Out)
- How-to Videos: Sends to Guide Tab
- Help and Support: Customer Service & Troubleshooting

Child Profiles

- Lists existing child profile with options to edit or add (if a child profile has not already been added).

My Owlet Devices

- Lists existing device with option to add device (if a device has not already been added). Use this section to add additional babies to your account.

Modify Alarm Settings

- Alarm thresholds should only be adjusted to prescribed limits made by a qualified healthcare professional. Instructions on how to update and change alarm settings can be found in Section 8.5.

When the App is Closed, or Mobile Device is Locked



WARNING!

When the mobile device is locked or the App is closed, the mobile device will not provide alarms.

It is important to keep the Base Station within audible range of the Caregiver. If the App is closed when an alarm sounds, open the App to view the alarm.

The App is designed to always keep the mobile device on and the App active unless you close the App or lock (sleep) the mobile device.



WARNING! Keep your mobile device battery charged at all times.

When the App is closed, the mobile device may receive Push Notifications during alarm events. Keep your mobile device volume turned up to hear these Push Notifications. However, since Push Notifications can be delayed by several minutes, do not rely on the Push Notifications as a primary alarm source. Always keep the Base Station within audible range. If the mobile device or App are not available, the Base Station will continue to provide alarms.



WARNING! Always check on the baby during high priority alarms.



WARNING! Always keep your mobile device within 3 feet of you while monitoring the baby. Always keep the Base Station within audible range.

8 How to use BabySat

8.1 Sock Size, Fit & Placement

In App: Guide>BabySat Basics>Sock Placement: How to Get Readings
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 BabySat performance.

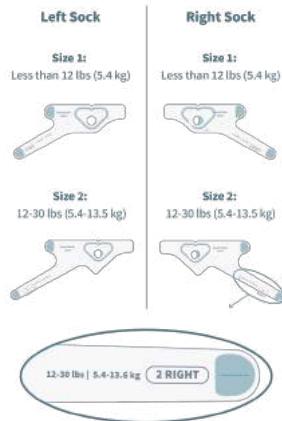
Step 1: Take the Sensor off the Base Station

When you take the Sensor off the Base Station's charging port, the Base Station light will start bouncing green, indicating that the Sensor is looking for readings from your baby, and that it's time to put the Sensor and Sock on your baby's foot.



Step 2: Choose a Starting Size

Each box comes with 4 Socks - 2 sizes for both left and right feet. Use the guide below to choose a starting Sock size based on weight. Then switch Sock size based on actual fit.



WARNING!

Misapplication of the Sock and Sensor with excessive pressure for prolonged periods can induce pressure injury or skin irritation.

**CAUTION.**

Regularly verify Sock fit. The baby's actual foot size may differ from the guidelines above and babies grow quickly. Stop using the device when your baby reaches 30 lbs or outgrows the largest Sock.

**CAUTION.**

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

**CAUTION.**

Alternate Sock between feet every 8 hours of use or after recharging the Sensor. Check the application site often for any signs of irritated skin.

**CAUTION.**

BabySat 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.

Replacement Socks can be purchased from Owlet (see Section 14).

In App: Guide > BabySat Basics>Sock Placement: How to Get Readings
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 BabySat performance.

Step 3: Insert the Sensor (If not already attached)

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

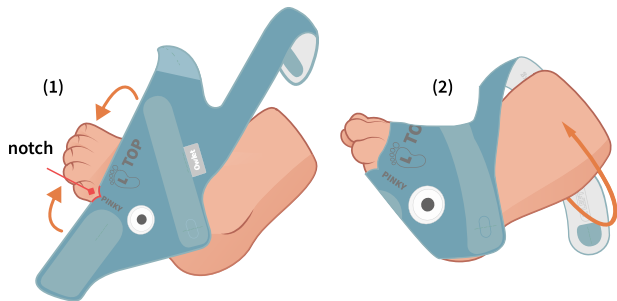
Always inspect the Sock and Sensor for damage or excessive wear and verify that the Sock and Sensor, including the Sensor windows, are clean before use.

**! NOTE.**

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

Step 4: Position the Sock

Place the Sock on the corresponding foot (left/right) with the **notch on the outside** of the foot **behind** the pinky toe. The Sock should **NOT** touch the toes. The word “**TOP**” should be placed on the top of the foot **near the toes** and not at the ankle.



Secure the hook and loop fastener from the toe strap (1) around the foot above the toes and then wrap the ankle strap around the back of the ankle and secure it to the top of the foot (2). Do **NOT** stretch when fastening. Let the hook and loop fastener pieces 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 powder on the feet before applying the Sock and Sensor. Application site must be clean and dry to avoid skin irritation.



CAUTION.

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



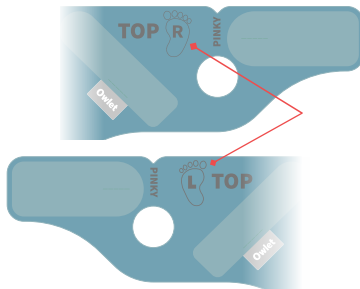
CAUTION.

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

Step 5: Verify Sock Fit & Placement

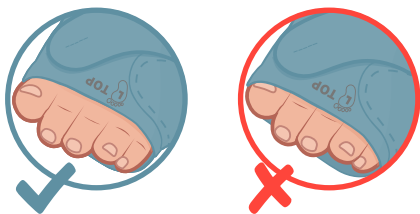
Match Sock to Foot

Make sure to use the left Sock for the left foot and 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 hook and loop fastener is not touching the skin.
- Sock should not extend over the toes.



Check Sock Size

Sock too small

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

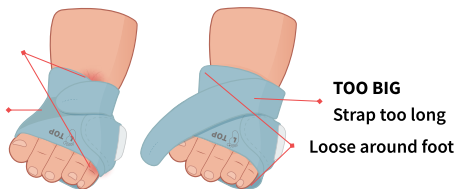
Sock too big

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

TOO SMALL

Red/pinched skin

Strap too short



TOO BIG

Strap too long

Loose around foot

Check Straps

Verify the straps are adjusted correctly. **Do NOT over tighten.**

- 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 patches of hook and loop fastener are not contacting the baby's skin, as this may lead to skin abrasion.



CAUTION.

Signs of skin irritation or excessive alarms 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 between the baby's foot and the Sensor can cause intermittent readings or frequent false alarms.

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

Step 6: Check the Base Station

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

8.2 Skin Irritation

In App: Guide > Caring for your Baby>Avoiding red marks

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



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

Avoiding Skin Irritation

- Select the **correct Sock size** for your baby. Refer to Section 8.1.
- **Avoid** using lotions or powders under the Sock. Keep skin clean and dry.
- Ensure Sock is positioned and **adjusted** correctly. Refer to Section 8.1.
- Check skin every 4 hours during the first week of use and after changing Sock size.

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

- **Alternate** Sock between feet at least every **8 hours**.
- **Hand wash** Sock and Sensor every 2 weeks or when dirty. Dry completely before use.
- **Check** your baby's feet for irritation each time you apply the Sock. **Do NOT** apply Sock to a foot with skin irritation.

If you notice irritation that has persisted from the previous use on that foot, please follow the instructions below.

What to do if the skin is irritated

1. Discontinue use on the affected foot and apply the Sock only to the unaffected foot until irritation resolves completely.
2. If irritation doesn't resolve within 8 hours, contact your healthcare provider to determine if a backup Pulse Oximeter is required.
3. Contact Owlet for one-on-one help with avoiding red marks.
4. Inspect the skin under the Sock on the unaffected foot every 4 hours to ensure irritation does not recur.
5. 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.

8.3 Monitoring with BabySat

After setup is complete, use the following steps to turn on the Base Station and begin monitoring the baby's readings.

1. Disconnect the Sensor from the Base Station.

! NOTE. The Sensor turns on automatically when disconnected from the Base Station.

2. Insert the Sensor into the Sock, if needed.
3. Verify the Sensor is ON (check the red Sensor light).
4. Apply the Sock with Sensor to your baby's foot ensuring proper fit and placement (see Section 8.1, Sock Fit & Placement).
5. Verify the Base Station is ON. The Base Station will automatically turn on when the Sensor is disconnected from the Base Station. If the Base Station is OFF, press the Base Station to turn it on.

! NOTE. The Base Station sounds a rising chime when the Base Station turns on and the Base Station light ring will turn green.

6. Open the Owlet Care+ App on your mobile device.
7. Verify baby's readings are normal.



CAUTION.

Always verify BabySat is monitoring as expected after turning on the Base Station, repositioning the Sock or after clearing alarms.

8.4 Turning off the Base Station

Monitoring with the Base Station should be turned off when your baby is active enough to cause repeated motion alerts or while washing your baby. Monitoring can be automatically turned off by placing the Sensor on the Base Station to charge. To turn off the Base Station manually and end monitoring:

Pause any active alarms.



WARNING!

If an alarm is active, check on the baby and resolve the alarm condition.




Long press the Base Station for 3 seconds until you hear a chirp and then let go **OR** toggle the Base Station toggle on the App.

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

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

8.5 Alarms & Indicators

The Base Station is designed to notify you with light and sound if your baby's readings are out of the normal range or if monitoring is interrupted. There are 3 different Base Station alarm priority types: High, Medium, and Low. Each alarm priority is associated with a different audible indicator to clearly identify the alarm priority to the Caregiver. The following table describes each alarm priority and its visual and audible indicator.

Priority	Visual Indicator	Audible Indicator
High Priority	Flashing Red 	BEEP, BEEP, BEEP, short pause, BEEP, BEEP, long pause BEEP, BEEP, BEEP, short pause, BEEP, BEEP long pause Repeated every 3 seconds
Medium Priority	Flashing Yellow 	BEEP, BEEP, BEEP, long pause Repeated every 3 seconds
Low Priority	Solid Cyan 	Single BEEP Repeated every 60 seconds
Informational Only	None	Additional audible indicators are created to provide feedback to the user. These chime sounds are much quieter and indicate when the Base Station turns on (rising chime) or off (falling chime).

Preview Alarms

Previewing alarms can be done while setting up the App or by going to Guide>BabySat Basics>Alarms: Know What's Going On and using the Preview function for each alarm priority.



WARNING!

Always keep the Base Station in audible range. Use the Base Station as your source for alarms and check on the baby first. DO NOT rely on mobile device for alarms.



CAUTION.

The mobile device must be connected to the same Wi-Fi network as the Base Station to receive alarms.



NOTE.

The highest priority alarm will be displayed on the Base Station. All alarm conditions are detailed in the App.



NOTE.

Previews are only available when Sensor is charging and mobile device is on the same Wi-Fi network as the Base Station.

Alarm Settings (Limits)

BabySat comes with preset, default alarm settings. Pulse Rate (BPM) and Oxygen Saturation alarm settings should only be adjusted to prescribed limits made by a qualified healthcare professional.

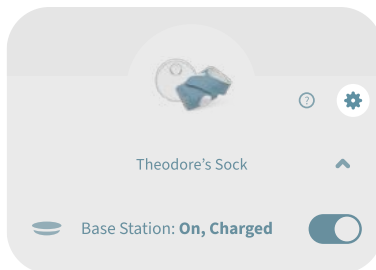


CAUTION.

Consult your qualified healthcare professional about appropriate alarm settings before making any changes.

To Modify Alarm Settings

From the Home Screen, go to Device Settings.



Select “Modify Alarm Settings”.



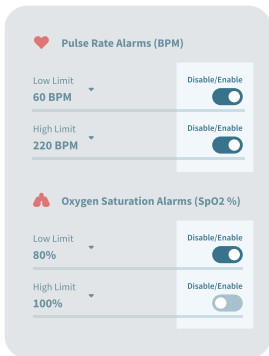
Modify Alarm Settings



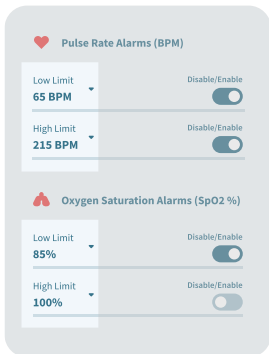
WARNING!

Pulse Rate (BPM) and Oxygen Saturation) alarm settings should only be adjusted to prescribed limits set by a qualified healthcare professional.

Use the toggle to enable or disable each alarm.



Use the drop-down menus to set the limits for each enabled alarm.



CAUTION. When disabled, an alarm will no longer be displayed or sounded.

When done, tap “Confirm Alarm Changes”.



The updated alarm settings will show in the dial.



CAUTION. Lower limits can never be set higher than upper limits and vice versa. If a disabled alarm limit is blocking another one, enable it, adjust the value, and then disable the alarm.



NOTE. Always verify threshold setpoints are set properly by checking the main screen.



WARNING! A hazard can exist if different ALARM PRESETS are used for the same or similar equipment in any single area.



NOTE. Alarm settings are not affected by a power loss and will remain the same.

Alarm Types and Meanings

BabySat produces several alarms based on Sensor and other data when certain alarm conditions have occurred. These alarms are designed to provide physiological and technical alarms to the Caregiver. The following table describes each alarm type, the App Status message, the alarm condition and how the Caregiver should respond. For details on alarm delays and alarm thresholds, refer to Section 16.

! NOTE.

A failure in the Sensor hardware will result in either the SENSOR DISCONNECT alarm or the CHECK SENSOR PLACEMENT alarm.

! NOTE.

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

Alarm Type	App Status Text	Meaning (Alarm Condition)	What you should do
High Priority (Physiological) Alarms	HIGH OXYGEN LEVEL DETECTED!	Oxygen Level has exceeded prescribed limits.	Immediately check on the Baby. Use your experience as a Caregiver to determine if there is a change in the infant's status that may require intervention and follow any directions provided by your healthcare provider.
	LOW OXYGEN LEVEL DETECTED!	Oxygen Level has fallen below prescribed limits.	
	HIGH PULSE RATE DETECTED!	PULSE RATE has exceeded prescribed limits.	Check connections and restore power or discontinue use.
	LOW PULSE RATE DETECTED!	PULSE RATE has fallen below prescribed limits.	
Medium Priority (Technical) Alarms	BASE STATION LOST POWER	Base Station has lost line power and is on battery backup.	Check connections and restore power or discontinue use.
	SENSOR DISCONNECTED FROM BASE STATION	Sensor is out of range of the Base Station, lost power or has an internal problem.	Check the range and Sensor battery status in the App.
	DIFFICULTY GETTING READING	Sensor may be placed improperly and data has not updated for 90 seconds OR there has been excessive movement for over 4 minutes.	Check the Sensor placement and ensure the baby 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 baby stops moving. Turn off monitoring until movement stops.
	CHECK SENSOR PLACEMENT	Sensor has fallen off or is not close enough to the skin.	

Alarm Type	App Status Text	Meaning (Alarm Condition)	What you should do
Low Priority (Technical) Alarms	DATA NOT UPDATING	The data has not updated for 30 seconds. This alarm will change to a Medium Priority alarm if the situation continues.	Wait to see if the situation resolves itself. Check on the baby if it doesn't resolve in 10 to 20 seconds.
	SENSOR LOW BATTERY	Sensor battery is low (10 minutes of charge time or less).	Discontinue use and charge the Sensor.
	DIRECT CONNECTION LOST (APP ONLY)	The App has lost the Direct Connection to the Base Station for more than 10 seconds.	Verify the Base Station and App are connected to the same Wi-Fi network.
	APP NOT CONNECTED (BASE STATION ONLY)	App was not opened within 60 seconds of starting monitoring (once per power cycle).	Open the App while on the same Wi-Fi network as the Base Station.

Pausing and Resuming Audible Alarms

The Caregiver can pause audible alarms using the Base Station or the Owlet Care+ App. This pause provides time for the Caregiver to respond to the alarm and resolve the underlying alarm condition. The visual indicators will continue while audible indicators are paused.

Pausing Audible Alarms



Pausing from the App: Use the Alert toggle in the App.

Pausing from the Base Station: Press down on the Base Station 1 time.

Resuming Audible Alarms



Automatic: Audible alarms resume after 2 minutes if the alarm conditions have not cleared.

Resuming from the Base Station: Press down on the Base Station 1 time.

Resuming from the App: Use the Alert toggle in the App.

! NOTE. If an alarm of equal or higher priority occurs while audible alarms are paused, the audible alarms will automatically resume for all alarms.

! NOTE. App alarm pause and resume controls will only work if the App has a Direct Connection to the Base Station.

Clearing Alarms

All alarms will continue until the underlying alarm condition has stopped or the Base Station is turned off. Depending on the alarm priority, a user acknowledgment of the alarm may also be required. The requirements for clearing an alarm are:

For Alarms to Clear:			
HIGH PRIORITY	UNDERLYING ALARM CONDITION MUST BE RESOLVED	AND	ALARM MUST BE ACKNOWLEDGED WITH A PAUSE COMMAND
MEDIUM PRIORITY			ACKNOWLEDGED BY A PAUSE COMMAND OR 30 SECONDS HAVE ELAPSED
LOW PRIORITY			NO ACKNOWLEDGM ENT REQUIRED

Other Audible Information Indicators

The Base Station produces other audible indicators to provide information during user interaction. When monitoring is turned on, a quiet series of tones rising in pitch are played. A similar tone, decreasing in pitch is played when monitoring is turned off. The Base Station also produces several chirps when the Base Station Button is long pressed.

8.6 Charging the Sensor

We recommend that you charge the Sensor whenever it is not in use. Charge the Sensor by placing the Sensor onto the Base Station. The Base Station pulses white while charging the Sensor and switches to a solid white when the Sensor is fully charged. BabySat uses convenient drop-and-go charging for an 8-hour charge in just 20 minutes, and full 16-hour charge in only 90 minutes.



WARNING!

Do not attempt to charge the Sensor while the Sensor is on the Baby's foot.

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

! NOTE. The App will only indicate if the SENSOR IS CHARGING or Fully Charged while the Sensor is on the Base Station.

8.7 When to discontinue use of BabySat

Stop using BabySat if:

- The baby has skin irritation on both feet.
- The baby weighs more than 30 lbs.
- The Sock no longer fits properly.

! NOTE. Contact your healthcare provider if your baby has outgrown but the prescription implies that pulse oximetry monitoring should continue.

8.8 Switching the Sensor Off and On

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



To power off the Sensor

1. Press settings cog on the Home Screen or press Account then select the My Owlet Devices.
2. Press “Turn off Sensor”.

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

Turn the Sensor On

The Sensor is turned on when it is removed from the Base Station.

To turn the Sensor on, place it on the Base Station for at least 3 seconds and then remove it.

9 Tips for a Safe Sleep Environment

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

- Always place your baby alone and on their back to sleep. Placing your baby to sleep on their side or on their stomach is not safe.
- Use a crib that meets current safety standards. Use a firm mattress that fits snugly in the crib and is covered with only a tight-fitting crib sheet.
- Do not put anything soft, loose, or fluffy in your baby's sleep space. This includes pillows, blankets, comforters, bumper pads, stuffed animals, toys, or any other soft items.
- Use a wearable blanket, or similar type sleeper, instead of traditional blankets to keep your baby safe and warm.
- Room-share instead of co-sleeping. Keep your baby's sleep space separate from, but close to, your bed. This will keep them safe and make feeding easier. BabySat does not function properly with co-sleeping. Your body will interfere with the BabySat wireless signal.
- Avoid falling asleep with your baby in your bed, couch, or armchair.
- Never allow your baby to sleep on any soft surfaces such as adult or child-sized beds, sofas, chairs, waterbeds, pillows, cushions, comforters, sheepskins, or anything similar.
- Do not use pillows, wedges, or positioners to prop your baby up, keep them on their back, or prevent them from rolling.
- Make sure your baby doesn't get too warm. Use light sleepwear on your baby and keep the room temperature comfortable for a lightly clothed adult.
- Consider offering a pacifier to your baby at naptime and bedtime.
- Educate everyone who cares for your baby about these rules for safe sleep!
- Keep the Base Station and cord **away** from the crib and out of baby's reach to reduce **cord strangulation hazards**.

10 Cleaning

10.1 Cleaning the Sock and Sensor

Caring for your fabric Sock and Sensor will make it last longer and be more comfortable for your baby. We recommend washing the **Sock and Sensor at least every two weeks** or more often when visibly soiled.

1. (Optional) Turn off Sensor (in App, Account>Select Device>Turn off Sensor) (see Section 8.8). 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 such as Tide Free & Gentle. The Sensor is water resistant and should be washed under running water.
3. Thoroughly rinse with running lukewarm water until no detergent residue remains in the fabric.
4. Lay or hang the fabric Sock and Sensor to dry. Make sure the Sock and your baby's foot are completely dry before use or charging. Do **NOT** tumble dry.
5. Visually inspect the Sock and Sensor for excessive wear or damage. Replace the Socks as needed.



CAUTION.

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

10.2 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:

- Sock is stretched out; fabric is separating or there are holes or rough spots.
- The fabric or Sensor windows are ripped, warped, or otherwise damaged.
- The hook and loop 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.

10.3 Cleaning the Base Station

The Base Station should be cleaned:

- When visibly soiled
- At least once every 30 days

To clean the Base Station:

Turn off monitoring (see section 8.4) and unplug the Base Station.

Moisten a soft cloth with a mild cleaning solution.

Wipe the Base Station with the damp cloth.

Wipe the Base Station dry or allow it to air dry.

**CAUTION.**

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

11 Maintenance

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

- Inspecting the BabySat components for damage and cleanliness. Do NOT use it if the components appear damaged.
- Cleaning the Soc, Sensor and Base Station according to the cleaning instructions found in Section 10.
- Charging Sensor battery.

11.1 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 12.

11.2 Base Station Battery Maintenance

The Base Station battery is non-replaceable and can't be serviced. For long term storage see 12.

The Base Station battery should be tested upon first use and again every three months.

Testing the Base Station Battery

1. Charge the Sensor for at least 10 minutes.
2. Remove Sensor from Base Station, begin monitoring.
3. Unplug the Base Station. Verify lost power alarm activates and alarm continues for at least 5 minutes before Base Station turns off. If not, replace the Base Station.



NOTE.

The Sensor can be on or off the baby during Step 3 of this test.



NOTE.

The device will sound the medium priority alarm during this test.

11.3 Testing Alarm Signal Generation

Caregiver should verify that the Base Station produces proper alarms if it has been in storage or at least every 6 months. Preview each alarm priority and verify both the Base Station and App alarm as expected. Discontinue use if alarms do not function as intended.

12 Storage, [Personal Data], and Disposal

12.1 Storage

Care should be taken when placing BabySat into long-term storage to ensure BabySat continues to work properly. Follow the steps below when storing BabySat. 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 it to dry completely (see Section 10).
6. Gather power supply and cables.
7. Place into the original packaging or suitable storage box.
8. Store the Sock, Sensor and Base Station 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.

12.2 Clear Personal Data

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

To delete either, the Owlet Care+ App must be set up and working with your BabySat.

Delete Your Baby's Profile

- Open the Owlet Care+ App.
- From the Home Screen, select: Account.
- Under the Child Profiles section, select the profile you would like to delete.
- Scroll to the bottom of the Child Profiles screen and select: Delete Child Profile.
- Click "Yes" to verify you would like to delete the profile.

! **NOTE.**

Deleting a baby's profile cannot be undone. All the data for your baby will be lost.

Delete Owlet Device from Account

1. Open the Owlet Care+ 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. Click “Yes” to verify you would like to delete the device.

Reset Account Password

If you have forgotten your account password and you are logged out of your account, follow the steps below to reset your password.

1. From the App, press “Login”.
2. Select “Forgot password?”.
3. Enter the email associated with your account.
4. Click the link provided in the email from noreply@owletcare-prod.firebaseio.com.
5. Enter a new password and select “Reset”.
6. Go back to the App and log in with your new password.

Forget Memorized Wi-Fi Networks

1. Remove the Sensor from the Base Station.
2. Disconnect the power cord from the Base Station.
3. Press and hold the Base Station button while re-inserting the power cord into the Base Station.
4. Hold the Base Station button until the light glows orange and you hear 4 beeps (this can take up to 10 seconds).
5. Tap the Base Station button 3 times.
6. Confirm the Wi-Fi light on the bottom of the base is off.
7. You will hear 4 beeps, which will indicate the memorized Wi-Fi Networks have been forgotten.

! **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 again starting from step 1.

Factory Reset

A factory reset of BabySat will erase all information stored on the device and restore BabySat software to its original settings.

1. Disconnect the power cord from the Base Station.
2. Press and hold the Base Station button while re-inserting the power cord into the Base Station.
3. Hold the Base Station button until the 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, which will indicate BabySat has been reset.



CAUTION. A factory reset will completely reset the Base Station and Sensor. You will no longer be able to receive readings, Push Notifications or alarms until BabySat 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 again starting from step 1.

12.3 Disposal

Before disposing of BabySat, turn off the Sensor (see Section 8.8) and clear personal data (see Section 12.2). 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.

13 Troubleshooting

Use the following troubleshooting guide to resolve problems related to setup, connection, and operation. For information on troubleshooting alarms, including technical alarms, see Section 8.5.

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 a Wi-Fi network.	Check if the green Wi-Fi light on the bottom of the Base Station is on. If so, you can skip this step and continue setting up your account in the App.
Cannot see your home Wi-Fi in the Owlet Care+ App	Your home router is 5.0 GHz (BabySat 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 Wi-Fi network.
	Your home router is 5.0 GHz (BabySat 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 App	Forgot the password.	Reset your password. See Section 12.2.
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.

Problem	Possible Causes	Actions
-	Other devices are interfering with the Sensor.	Move other electronics away from the Sensor and/or the Base Station, or move the Base Station to a different location.
The Base Station will not register with your Owlet Care+ 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 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 device 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 App and login with the correct account.
Base Station turns cyan after rebooting and turning on	The App Not Connected alarm is showing.	Open the App and establish a Direct Connection with the Base Station.
The App shows Remote Connection when device and Base Station are on the same Wi-Fi network	Multiple Devices are connected via Direct Connection.	Turn off the App on other devices that may be connected via Direct Connection. Only 2 devices can be connected via Direct Connection at a time.
Base Station turns cyan after rebooting and turning on	Setup is incomplete.	Finish setup or uninstall and then reinstall the App.

If you are unable to resolve the issue, or would like to report unexpected issues or events, contact Owlet. Refer to Section 21 of this manual for contact information.

14 Parts and Accessories

The following replacement or spare parts are available for BabySat.

Model Ref.	Item Description	Service Life
11.0035	Sock Small Left	3 months
11.0036	Sock Small Right	3 months
11.0037	Sock Large Left	3 months
11.0042	Sock Large Right	3 months
OSS 3.0-M1	Sensor	12 months
OBL 3.0-M1	Base Station	17 months
11.0046	USB charging cable	12 months
12.0202	Power adapter	12 months

Contact Owlet for ordering information (See Section 21).

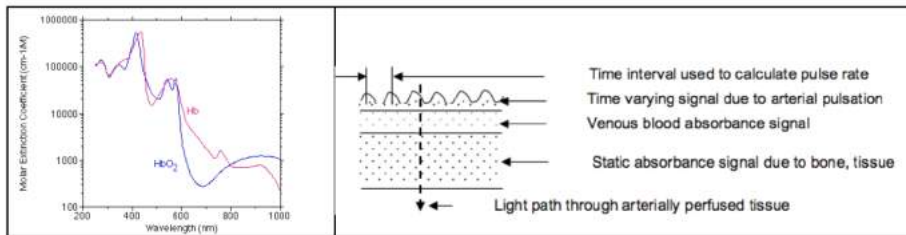
15 Theory of Operation

15.1 Pulse Oximeter Theory

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

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

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



15.2 Calibration Not Required

As described in Section 15.1, the light absorption properties of Hemoglobin vary with wavelength. The Pulse Oximeter technology used in BabySat 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.

15.3 Functional Oxygen Saturation

Pulse Oximeter 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:

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

(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.

15.4 Use of Functional Testers

Some third-party functional testers can be used by trained biomedical staff to verify the functionality of Pulse Oximeters. These functional testers typically operate by adjustments to the optical pathway and allow the user to set various simulated values of saturation and Pulse Rate. While such functional testers are useful for verifying function, they are not able to assess clinical accuracy. An evaluation of the accuracy of a SpO₂ measurement generally requires a clinical study. See the section below for more information on clinical accuracy.



CAUTION.

A functional tester cannot be used to assess the accuracy of a Pulse Oximeter probe or a Pulse Oximeter monitor. If you have any concerns regarding functionality, contact Owlet.

15.5 Clinical SpO₂ Accuracy Study Report Summary

SpO ₂ 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

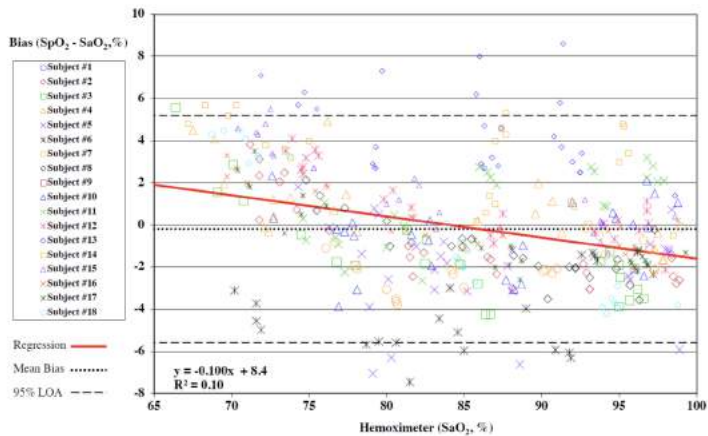
BabySat has been clinically evaluated for SpO₂ accuracy in 18 healthy adult volunteers providing informed consent within an institutionally approved clinical study protocol per the method of ISO 80601-2-61:2011 Part 201.12.1.101.2. The demographics of subjects included 9 males and 9 females (age: 22-37 yrs., weight: 106-194 lbs., height:59-73", BMI: 19-29). There were 7 Caucasian subjects, 8 Asian subjects, 2 Black subjects, and 1 Hispanic subject. 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. There was no significant difference in accuracy as measured by Arms with the applied motion simulation. All subjects completed the study without incidence.

Arterial blood samples measured by co-oximeter (SaO₂) are the reference method for simultaneously-obtained BabySat Pulse Oximeter values (SpO₂). Of the total number of study subjects, at least three or 15% subjects with darkly pigmented skin were included.

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

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

Non-Motion SpO2



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

16 Technical Information

16.1 Data Processing Delay

In normal operation, the average data processing delay for the Sensor is 5 seconds.

Upon startup, the data processing delay is 10 to 15 seconds to initialize the signal processing chain.

16.2 Data Update

The Sensor transmits data to the Base Station every second. This includes Pulse Rate, Oxygen Saturation, movement metrics, battery charge, signal quality and reading quality. If the Sensor is having difficulty determining valid data, a low priority alarm is generated when the data update period to the Base Station exceeds 30 seconds.

!

NOTE.

Alarm conditions are transmitted immediately by the Base Station to the App with almost no delay (assuming the App is up and running).

16.3 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	Meaning (Alarm Condition)
High Priority	The Oxygen value has dropped below the Low Oxygen threshold. (LOW OXYGEN)	8 seconds ¹
	The Oxygen value has exceeded the High Oxygen threshold. (HIGH OXYGEN)	8 seconds ¹
	Pulse Rate has fallen below the Low Pulse Rate threshold. (LOW PULSE RATE)	8 seconds
	Pulse Rate has exceed the High Pulse Rate threshold. (HIGH PULSE RATE)	8 seconds
Medium Priority	Base Station has lost power.	1 to 2 seconds
	Sensor is disconnected from the Base Station (range) for 60 seconds. (CONNECTION ISSUE)	60 +/- 3 seconds
	The data has not updated for more than 90 seconds and there is no movement OR the data has not updated for more than 4 minutes and there is movement. (DIFFICULTY GETTING READING)	90 +/- 5 seconds ² (no movement) 4 minutes +/- 5 seconds (escalated movement alarm)
	Sensor has fallen off the baby. (CHECK SENSOR PLACEMENT)	60 +/- 3 seconds

- 1 An additional 5-second delay may occur if signal quality drops and then recovers as the Sensor reinitializes the oxygen readings.
- 2 These two alarms are mutually exclusive. The low priority alarm sounds first after 30 seconds and will escalate to a medium priority alarm if the issue is not resolved. These alarms can only be cleared with valid data and no movement.

16.4 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.

16.5 Alarm Thresholds and Volume

Alarm Type	Factory Default Value	Adjustment Range	Step Value
Low Oxygen Saturation Alarm Limit	85% SpO2	50-95%	1% SpO2
High Oxygen Saturation Alarm Limit	OFF (100% when enabled)	85-100%, OFF	
Low Pulse Rate Alarm Limit	75 BPM	30-110 BPM	1 BPM
High Pulse Rate Alarm Limit	200 BPM	75-275 BPM	
Alarm Sound Pressure Level	Low priority: 55-60 dBA* High/Medium Priority: 60-65 dBA* (*measured at 1 meter)	Not adjustable	Not applicable

Alarm thresholds should only be altered by a healthcare professional. These values can be modified through the Modify Alarm Settings menu in the Owlet Care+ App (see section 8.5). Alarm volumes are fixed and cannot be adjusted.

- !** **NOTE.** The alarm limit settings are retained in the event of a power interruption.
- !** **NOTE.** Without the App, the alarm thresholds cannot be modified.

16.6 SpO2 and Pulse Rate Performance

Parameter	Specification
SpO2 range	1% to 100%
Pulse Rate range	30 to 300 beats per minute (bpm)
SpO2 Accuracy (70% to 100%)	No Motion: $\pm 3.0\%$ Arms Motion: $\pm 3.0\%$ Arms
Pulse Rate Accuracy*	No motion: ± 3 bpm Arms Motion: ± 5 bpm Arms

! NOTE.

Established by a study comparing Pulse Rate measured using BabySat to a calibrated Fluke Biomedical ProSim™ 8 Vital Signs Simulator with SPOT Light SpO2 Simulator. Brand and trade names remain the property of their respective owners. Usage does not imply an endorsement.

! NOTE.

Because Pulse Oximeter equipment measurements are statistically distributed, only about two-thirds of Pulse Oximeter equipment measurements can be expected to fall within \pm Arms of the value measured by a co-oximeter.

Factors that may affect Sensor performance

- Improper Sock placement and/or fit may affect Sensor performance. Refer to Section 8.1 for Sock fit and placement information.
- 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 under the Sock may cause skin irritation and trouble getting data.
- Electrical equipment that emits radio frequencies may interfere with performance of [BabySat/the Sensor]. Refer to Section 17 for further details.
- Direct sunlight on the baby's foot may affect performance of the Sensor. Owlet recommends that Sensor be shaded from direct sunlight.
- Excessively bright direct lighting on the Sensor may cause trouble acquiring data.

16.7 Physical and Mechanical Specifications

Accessory	Dimensions	Weight	Baby Contact	Materials
Sock (Small)	7.18L x 3.89W inches (18.24 x 9.88 cm)	0.14 oz. (4 grams)	Yes	nylon/spandex fabrics
Sock (Large)	9.01L x 4.31W inches (22.89 x 10.94 cm)	0.21 oz. (6 grams)		nylon/spandex fabrics
Sensor	1.39 x 2.16W x 0.46H inches (3.53 x 5.48 x 1.16 cm)	0.28 oz. (8 grams)	Yes	nylon/spandex/ ABS/stainless steel/polyurethane
Base Station	2.4L x 2.4W x 0.7H inches (6.1 x 6.1 x 1.78 cm)	1.41 oz. (40 grams)	No	Enclosure: ABS/acrylic/silicon

The materials that contact the baby have undergone extensive biocompatibility testing and comply with ISO 10993-1:2009. BabySat is not made with natural latex rubber or DEHP plasticizers.

16.8 Storage, Transport and Operating Conditions

Symbol	Specifications	Value
	Storage and Transport Temperature Limits	-25°C to +60 °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.



CAUTION..

Do not transport or store the Sock, Sensor and/or Base Station in direct sunlight. Avoid storage in garages, attics or hot vehicles as it may be damaged.

! NOTE.

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

16.9 Measurement Wavelengths and Output Power

Information about wavelength range can be useful to clinicians.

Light	Range of Peak Wavelengths	Max Output Power
Red	649 to 657 nm red	<10 mW
Infrared	924 to 937 nm infrared	<10 mW

16.10 Transmitters



Accessory	Frequency Band	Modulation Scheme	Effective Radiated Power
Base Station Wi-Fi	2412 - 2462MHz	DSSS	Average: 11.4 dBm, Max: 18 dBm
Base Station BLE	2402 - 2480MHz	GFSK	Average: 12.5 dBm, Max: 19 dBm
Sensor BLE	2402 - 2480MHz	GFSK	Average: 0 dBm, Max: 8 dBm

16.11 Power

! NOTE. If power is disrupted, BabySat will sound a medium priority alarm for 2 minutes. If power is not restored, BabySat will safely power down.

Unit	External Power Requirements	Modulation Scheme	Specification
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

16.12 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



CAUTION.. BabySat is not suitable for use with defibrillation.

16.13 Safety Standards

BabySat has been tested to meet the following safety standards:

Standard	Specification
IEC 60601-1:2005 + A1:2012 EN 60601-1:2006 + A1:2013 ANSI/AAMI ES60601-1:2005 + C1:2009 + A1:2012 + A2:2010 CAN/CSA C22.2 No. 60601-1:14	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014 + A1:2020 EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-8:2006 + A1:2012 + A2:2020 EN 60601-1-8:2007 + A1:2012 +A2:2021 ANSI/AAMI/IEC 60601-1-8:2006 + A1:2012 + A2:2021 CAN/CSA C22.2 No. 60601-1-8:08 AMD 2	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, test and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-1-11:2015 + A1:2020 EN 60601-1-11:2015 + A1:2020 ANSI/AAMI HA60601-1-11:2015 + A1:2021 CAN/CSA C22.2 No. 60601-1-11:15 (IEC 60601-1-11:2015+A1:2020, MOD)	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in home healthcare environment – Consolidated Version
ISO 80601-2-61:2017 EN ISO 80601-2-61:2019 CAN/CSA C22.2 No. 80601-2-61-2021	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of Pulse Oximeter equipment
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and Testing within a Risk Management Process

Standard

IEC 62133-2:2017 + A1:2021

Specification

Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

17 Electro-Magnetic Compatibility

17.1 Electro-Magnetic Compatibility

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



WARNING!

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of BabySat, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.



WARNING!

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



WARNING!

Use of accessories, transducers and cables other than those specified for use with BabySat as described in this document can result in incorrect readings, degraded performance, or injury.

17.2 Emissions

Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	BabySat 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	
Harmonic emissions IEC 61000-3-2	Class A	Suitable for use in all establishments, including domestic environments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compliant	



17.3 Immunity

During the following testing BabySat will continue to operate within specification or show an error.




Immunity Test	Compliance level	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, 4, 8, 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	Mains power quality should be that of a typical home environment.
Surge IEC 61000-4-5	±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%, .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 device be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home environment. Power frequency magnetic fields from appliances in the home are not expected to affect the device. Keep BabySat away from sources of high levels of power line magnetic fields (in excess of 3A/m) to reduce the likelihood of interference.
Conducted RF IEC 61000-4-6	3 Vrms 6 Vrms in ISM and	BabySat is suitable for the electromagnetic environment of typical homes.









Immunity Test	Compliance level	Electromagnetic environment - guidance
-	Amateur Radio Bands	
Radiated RF IEC 61000-4-3	10V/m80 MHz to 2.7 GHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	27 V/m 380-390 MHz, 28 V/m 430-470 MHz, 9 V/m 704-787 MHz, 28 V/m 800-960 MHz, 28 V/m 1700-1900 MHz, 28 V/m 2400-2570 MHz, 9 V/m 5100-5800 MHz	

18 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.
Rx only	Prescription Use Only - Federal law (U.S.) restricts the sale of this device to, or by the order of, a physician.
	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.

Symbol	Meaning
	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.
	Audible alarms are silenced.
	Audible alarms are enabled and will sound during an alarm.
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.

Symbol	Meaning
	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
	FCC Declaration of Conformity - Certifies that the electromagnetic interference from the device is under limits approved by the Federal Communications Commission.
	SGS Listed - SGS Listing Mark for Canada and the United States.
	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.

Symbol	Meaning
	Not made with Natural Rubber Latex
	Strangulation Warning - Always keep the Base Station at least three feet away from your baby's crib because the cord can pose a strangulation hazard.
%SpO ₂	Functional Oxygen Saturation of arterial Hemoglobin.
	Recycle
	Direct Connection from mobile device to Base Station has been established. See Section 7.3.
	The mobile device is not on the same network and talks remotely to the Base Station through the Owlet cloud servers. See Section 7.3.
	A connection is not available as the Base Station is offline or the App has no internet. See Section 7.3
	Movement detected. While the Sensor is designed to work with movement, excessive movement will lead to alarms. See Section 7.3.
	Wi-Fi Network Connection

19 Warranty Information

19.1 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 purchase for new products and 6 months for refurbished products. We do not warrant our products against general wear and tear or damage because 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.

20 Caution Regarding Modifications

Changes or modifications to BabySat not expressly approved by Owlet void the limited warranty and the user's authority to operate the equipment. ONLY use the supplied power adapter. Failure to do so may void our limited warranty.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the manufacturer's instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: Reorient or relocate the receiving antenna. Increase the separation between the equipment and receiver. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. Consult the dealer or an experienced radio/TV technician for help.

This product contains FCC ID numbers 2AIEP-OSS1B and 2AIEP-OBS1B. This device complies with Part 15 of FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

21 Service and Support

21.1 When to Contact a Healthcare Professional

For any medical questions or concerns contact a healthcare professional.

21.2 Customer Service

Owlet Customer Service 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 daysChat: owletcare.com/chat

Available Monday-Friday 10am-12am EST

Owlet Baby Care, Inc.

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www.owletcare.com