# SleepImage Fingertip Device

## Model: PO6

## User Manual

This device uses Bluetooth to communicate with the SleepImage Mobile App. The device must be paired with the App to collect and transfer data collected during sleep to the SleepImage System, Software as a Medical Device.

**Download App**

**Name:** SleepImage
**iOS:** App Store
**Android:** Google Play

*Please ensure App is updated to the latest version prior to each use.*

## 1. Introduction

### 1.1. Intended Use

This device is intended to be used by adults for recording plethysmography, oxygen saturation ($SpO_2$) and actigraphy data that is transferred via Bluetooth to the SleepImage App during recording sessions in home or healthcare facilities environment. (EU countries)

This non-invasive device is intended for continuous data collection of plethysmography, functional oxygen saturation of arterial hemoglobin ($SpO_2$), and actigraphy. This portable device is indicated for use in adult patients in home environments and clinical institutions except acute clinical environment. (USA)

This device is indicated for use in continuously measuring and transmitting plethysmography, functional oxygen saturation of arterial hemoglobin ($SpO_2$) and actigraphy for adult patients. It can be used in sleep labs, long-term care, hospitals (except the operating room, ICU) and home use. (For Australia & Canada)

This device can display $SpO_2$ and pulse rate values on its display while in use. No data is stored on this device.

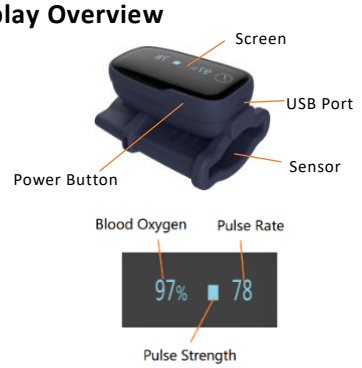
### 1.2. Warnings and Cautions

- Do not use this device during MRI examination.
- Do not use this device with a defibrillator.
- Do not store the device in the following locations: direct sunlight; high temperatures or high levels of moisture, or heavy contamination; locations near to sources of water, fire, lint, or dust; or locations that are subject to strong electromagnetic influences.
- Do not use the device in a combustible environment.
- Never submerge the device in water or other liquids.
- Do not clean the device with acetone or other volatile solutions.
- Do not drop this device or subject it to strong impact.
- The device and accessories are provided non-sterile.
- Do not place this device in pressure vessels or gas sterilization device.
- Do not dismantle the device.
- Consult your doctor immediately if you experience symptoms that could indicate acute disease.
- Do not self-diagnose or self-medicate on the basis of this device without consulting your doctor. In particular, do not start taking any new medication or change the type and/or dosage of any existing medication without prior approval.
- Use only cables, sensors and other accessories specified in this manual.
- Prolonged continuous monitoring may increase the risk of undesirable changes in skin characteristics, such as irritation, reddening, blistering or burns.
- Do not open the device cover.
- The biocompatibility testing has been performed on the materials in contact with the person in accordance with ISO 10993.
- Do not place the device on a finger with edema or fragile tissue.
- Check the display values on the device before use. Do not use a device with no or unlikely values displayed.
- Check the sensor application site before going to sleep, during awakenings and at the end of the sleep test to determine correct positioning of the sensor and the circulation and skin sensitivity of the patient. Patient sensitivity varies depending on medical status or skin condition. This sensor may not be appropriate for patients with poor peripheral blood circulation or sensitive skin.
- The device has no alarm system.
- Local laws and regulations should be followed when disposing of the device and accessories.
- Do not wear the device while it is charging.
- Keep the charging cable away from children. It can cause strangulation.
- Keep the device out of reach of children and pets.
- This device is calibrated to display FUNCTIONAL OXYGEN SATURATION.

### 1.3. Included in Box

- Device, User Manual, Warranty Card, Charging Cable.

## 2. Display Overview




## 3. Using the Device and App

### 3.1. Charging

Charge the battery before using by connecting the device to computer USB or USB charging adapter using the included USB cable. When fully charged, the device will power off automatically.

### 3.2. POWER ON/OFF

Device will turn on automatically by placing a finger in the sensor and turn off automatically by removing a finger from the sensor.

### 3.3. SleepImage App

The device uses Bluetooth to communicate with the SleepImage Mobile App. The device must be paired with the App to collect and transfer data to SleepImage.

**Note: *DO NOT PAIR*** *in settings of your phone.*
Follow the Mobile App Instructions for Use on www.sleepimage.com to download the App and pair the device *before* attempting data collection.

### 3.4. Power ON/OFF

**Power ON:**

The device will turn on automatically when worn.

**Power OFF:**

The device will turn off automatically after removal.

### 3.5 Start recording

Wear the device on index finger of left hand. The device will turn on automatically. **Start the recording in the App to begin data collection.**

**Device fit and other notices:**

- Wear the device on index finger of left hand.
- A proper fit is essential. Try to move the device to find the best fit.
- Avoid wearing the device loose on the finger, which causes inaccurate measure.
- Avoid excessive motion during recording.
- Avoid strong ambient light during recording.
- If the device is removed briefly during a recording session, simply put the device back on to resume recording.

### 3.6. Stop recording

After waking, Stop the recording in the App and remove the device which will automatically turn itself off.

### 3.7. Data Upload

After the recording is stopped in the App, the recording will upload to SleepImage. If study does not upload, check Troubleshooting in the SleepImage App Instructions for Use on www.sleepimage.com.

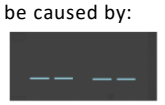
### 3.8. How to Check Battery level

Touch the power button to switch the display between showing readings, battery level and last four digits of the device's serial number (SN).

### 3.9. Unavailable Symbol

When this symbol displays on device screen, it indicates the readings is unavailable, which may be caused by:

- Excessive movement;
- Poor signal;
- Finger is too cold.



## 4. Maintenance

### 4.1. Time & Date

Device time automatically syncs from your mobile device.

### 4.2. Cleaning

Use a soft cloth moistened with water or alcohol to clean the device surface.

### 4.3 Recycling

Disposal of the device and its accessories must be done in accordance with local regulations for recycling.

## 5. Troubleshooting

| Problem | Possible Cause | Possible Solution |
|---|---|---|
| **Device does not turn on or no response** | Battery may be low. | Charge battery and try again. |
| | Device may be damaged. | Please contact your local distributor. |
| **The app cannot find or pair with the device** | The device is off. | Turn on device. |
| | Bluetooth cannot work without location permission (Android) | Allow location access. |
| | The Bluetooth of your phone is off. | Turn on the Bluetooth in the phone. |
| | Your mobile device may not meet the minimum specifications required. (See www.sleepimage.com for information). | |

## 6. Guide to Symbols

| Symbol | Description |
|---|---|
| | Manufacturer |
| | Date of manufacture |
| SN | Serial number |
| | Indicates a medical device that is not to be disposed of as unsorted municipal waste. |
| | Follow Instructions for Use. |
| | Type BF Applied Part |
| | No alarm system |
| MR | MRI unsafe. Presents hazards in all MR environments as device contains strongly ferromagnetic materials. |
| IP22 | Resistant to liquid ingress |
| CE 0197 | CE marking |
| EC REP | Authorized representative in the European community. |
| UK CA | UKCA marking. |
| UK REP | Authorized Representative in the United Kingdom. |
| FC | This product complies with the rules and regulations of the Federal Communication Commission. |
| | Non-ionizing radiation. |
| IC | This device contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's license-exempt RSS(s). |
| | Temperature limitation. |
| | Humidity limitation. |
| | Atmospheric pressure limitation. |
| | Our products and packaging can be recycled, don't throw them away! Find where to drop them off on the www.quefairedemesdechets.fr site (Only applicable for French market) |

## 7. Specifications

| Environmental | Operating | Storage |
|---|---|---|
| **Temperature** | 5 to 40°C | -25 to 70°C |
| **Relative humidity (noncondensing)** | 10% to 95% | 10% to 95% |
| **Barometric** | 700 to 1060hPa | 700 to 1060hPa |
| **Protection against electric shock** | Internally powered equipment | |
| **Degree protection against electrical shock** | Type BF | |
| **Electro-magnetic compatibility** | Group I, Class B | |
| **Degree of dust & water resistance** | IP22 | |
| **Weight** | 28 g | |
| **Size** | 38×30×38 mm | |
| **Battery** | 3.7Vdc, Rechargeable Lithium-polymer | |
| **Charge requirement** | 5VDC, Max. 80mA | |
| **Charge time** | 2-3 hours | |
| **Battery life** | 12-14 hours for typical use | |
| **Wireless** | Bluetooth 4.0 BLE | |
| **$SpO_2$ range** | 70% to100% | |
| **SpO2 accuracy (Arms)** | 80-100%: ±2%, 70-80%: ±3% | |
| **Pulse Rate range** | 30 to 250 bpm | |
| **Pulse Rate accuracy** | ±2 bpm or ±2%, whichever is greater | |
| **Wavelength / Max emission power** | 660nm/940nm, 0.8mW/1.2mW | |
| **Recorded parameters** | $SpO_2$, Pulse Rate, Plethysmography, Actigraphy | |
| **Data storage** | No data is stored on the device | |
| **Frequency range** | 2.402 – 2.480 GHz | |
| **Max RF power** | -10 dBm | |
| **Expected service life** | 3 Years | |

## 8. FCC Statement

FCC Warning:
FCC ID: 2ADXK-4708
Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
This device complies with part 15 of the FCC Rules. Operation is subject to the following 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.
Note: 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 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.
The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

## 9. IC Caution

IC:29845-S001
This device contains license-exempt transmitter(s)/ receiver(s) that comply with Innovation, Science and Economic Development Canada's license-exempt RSS(s). Operation is subject to the following two conditions:
(1) This device may not cause interference.
(2) This device must accept any interference, including interference that may cause undesired operation of the device.
Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

## 10. Electromagnetic Compatibility

The device meets the requirements of IEC 60601-1-2.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