

Soosyn Wrist Pulse Oximeter Instructions for Use

Model : ST-50

- * Before use, please be sure to read the original manufacturer's instruction manual and follow the instructions.
- * This product involves the collection, processing and use of personal data and should comply with the regulations of the Personal Data Protection Act.

T01A04-0

01 Intended Use

The Soosyn Wrist Pulse Oximeter, Model ST-50, is a wrist-worn device indicated for use in noninvasive measuring, displaying, and storing functional oxygen saturation of arterial hemoglobin (% SpO₂) and pulse rate (PR). The intended measuring site of this device is the wrist skin surface. It is intended for spot-checking or continuous monitoring of adult patients during no motion conditions, in hospitals, hospital-type facilities, and home environments.

This product includes data storage and data transmission. The collected data can be exported through the APP, and users can obtain the measurement data in the user interface.

02 Principle

Soosyn ST-50 uses a non-invasive pulse oximetry method to measure the functional oxygen saturation in the blood. More specifically, it measures the amount of oxygenated hemoglobin as percentage of functional hemoglobin, including oxygenated hemoglobin (HbO₂) and deoxygenated hemoglobin (Hb). Tissue, muscle and bone normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into measurement of functional oxygen saturation (SpO₂).

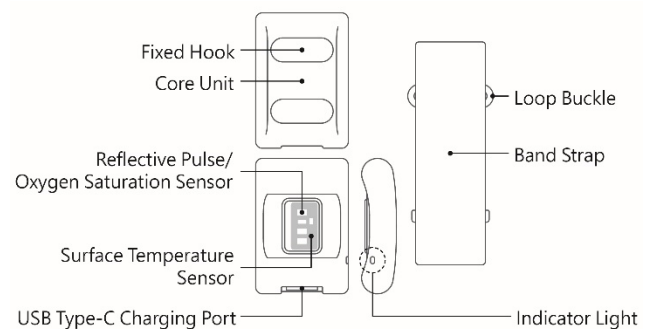
Soosyn ST-50 has a built-in reflective oxygen saturation sensor. It operates on the same optical path principle as a transmissive oxygen saturation sensor, ensuring that the principles of arterial oxygen saturation and heme absorption remain unaffected. Both transmissive and reflective pulsatile oxygen saturation sensors measure the functional oxygen saturation of arterial blood based on the same pulsatile oximetry principle.

03 Product Standard Kit

Soosyn ST-50 standard kit includes the items listed below. Please check the box for these items.

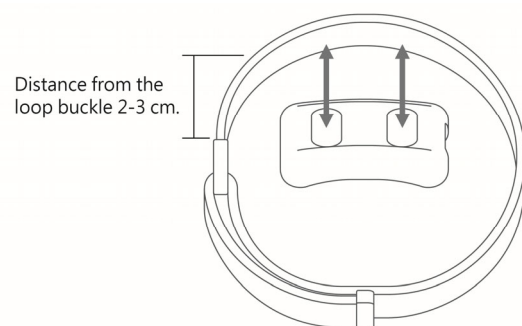
- Soosyn Wrist Pulse Oximeter, Model : ST-50, one unit.
- USB Type-C charging cable, one piece.
- Soosyn Wrist Pulse Oximeter Instructions for Use, one copy.

04 Product Overview



05 Installing/Replacing the Band Strap

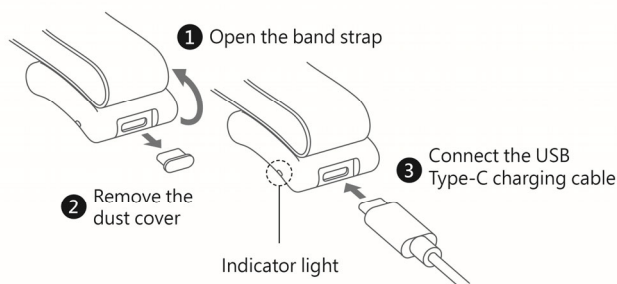
Place the core unit 2 to 3 cm away from the loop buckle of the band strap, then lightly press it with the band strap to secure it in place. To detach the band strap, simply peel it off from the core unit.



- * Please use the official band strap. Using third-party band straps may affect the performance of the Soosyn ST-50 or cause skin irritation.

06 Charging

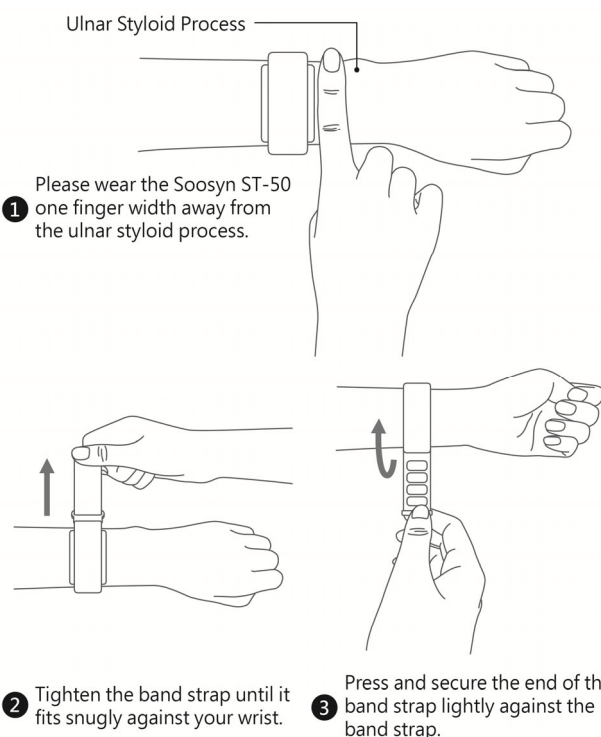
- 1 Open the band strap.
- 2 Remove the dust cover.
- 3 Use the included USB Type-C charging cable to connect the core unit to a power source.



- * Please make sure to charge it before use.
- * During charging, the indicator light flashes orange. When the indicator light turns off, it means charging is complete.
- * After removing the charging cable, please reattach the dust cover to the charging port.

07 Wearing the Soosyn ST-50

- 1 Please wear the Soosyn ST-50 one finger width away from the ulnar styloid process, as shown in the figure below, to ensure maximum comfort and measurement accuracy.
- 2 Tighten the band strap until it fits snugly against your wrist.
- 3 Press and secure the end of the band strap lightly against the band strap.



08 Device Operation and Measurement

- (1) Before use, please connect the USB Type-C charging cable to charge, and wait until the indicator light turns off to indicate that charging is complete.
- (2) Connect the power using a USB Type-C charging cable to wake up and reset the device.
- (3) After turning on the device, please refer to the previous section 07 "Wearing the Soosyn ST-50" for the correct way to wear the device. Once the device is properly worn, the indicator light will flash green, and the device will automatically start measuring. During the measurement process, please remain still, and when the indicator light goes out, it indicates that the device has started measuring.
- (4) After removing the Soosyn ST-50, Soosyn ST-50 will automatically stop measuring.
- (5) After the device is turned on, if there is no measurement activity or no wireless device connection, the device will automatically enter sleep mode and turn off the indicator light after 30 seconds of inactivity.
- (6) For detailed information, please refer to the description in Table 1 below.

| Device Status | Indicator Light Status | Description |
|---------------|------------------------|--|
| Charging | Orange light flashing | Charging in progress. The light turns off when fully charged. |
| Wearing | Green light flashing | Measuring physiological signals. The light turns off after 20 seconds. |
| Error | Orange light solid | Malfunction detected. Please contact the manufacturer for repair. |
| Standby | Green light solid | Exited sleep mode. The green light remains solid. (Returns to sleep mode after 30 seconds of no skin detection.) |
| | No light | Out of power/in sleep mode. (Insert a Type-C cable to connect the power to wake up/reset the device.) |

Table 1 Indicator Light Description

09 Monitor Real-Time Data

The SoosynCare APP (hereinafter referred to as the APP) is intended for use by medical professionals. Its main function is to monitor physiological data in real-time. Please install the APP on your phone before use.



Open the APP and enter the username and password, which are provided and set by the medical institution, as shown in Figure 1. Click to enter the APP homepage, as shown in Figure 2.

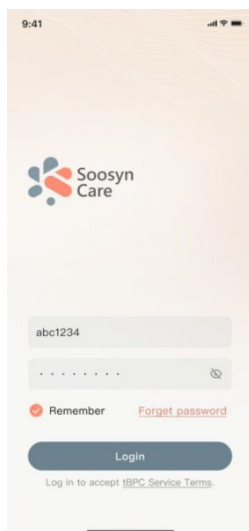


Figure 1

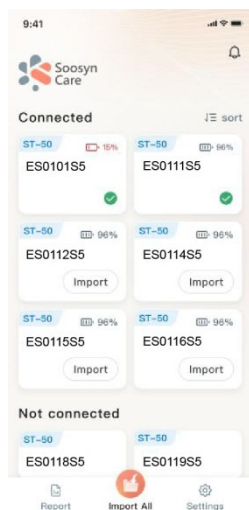


Figure 2

● Monitor Real-Time Data

- (1) Monitor real-time data during measurement.
- (2) Select the serial number of the connected device (for example, device serial number ES0101S5) to enter the device's content page, then click on "Real Time".
- (3) If the physiological values exceed the upper or lower limits, the parameter will be displayed with a red border and an alert sound.
- (4) The upper and lower limits can be adjusted on the "Settings" page.

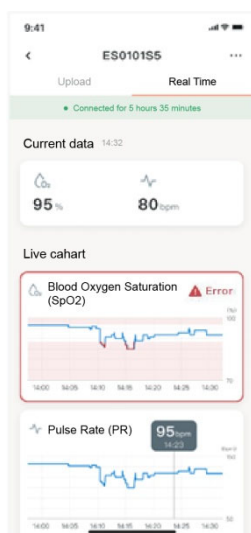


Figure 3

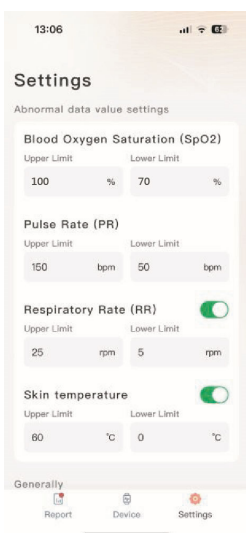


Figure 4

10 Care and Maintenance

- Wipe the Watch case with a soft cloth dampened with 70~75% alcohol or water. Do not use undiluted bleach or any cleaning solution other than those recommended here, as permanent damage could result. Dry with a soft cloth, or allow to air dry. Clean once per week or more frequently if worn by multiple users.
- Mild detergents, such as hand or dish washing liquid detergents, dissolve dirt and grease. To clean washable surfaces, use in a solution of warm water.
- Operating Condition
 - A temperature range : 10 °C~40 °C.
 - A relative humidity range : 10 %~93 %, non-condensing.
 - An atmospheric pressure range : 1013.2 hPa~700 hPa. (altitude: 0 ~3,000m)
- Storage/Transportation Condition
 - A temperature range : -40 °C~70 °C.
 - A relative humidity range : 5 %~95 %, non-condensing.
 - Without relative humidity control, -40 °C (-40 ° F) .

11 Warnings and Cautions

- *Please make sure that the device is worn on the wrist, one finger-width away from the ulnar styloid process.*
- *Keep the device-worn lower arm horizontal and still while the device is taking the measurement.*
- *Do not perform the measurement while the blood flow is restricted (ex. taking blood pressure).*
- *Tattoo or hairy hairs in the sensor site would interfere with the measurement. Please switch hand or shave off the hairs on the sensor site to ensure the best measurement accuracy.*
- *Do not use the Soosyn ST-50 and perform PR/SpO2 measurement within 48 hours after receiving the photodynamic therapy to avoid the potential skin burn.*
- *Follow local, state, and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.*
- *This device is intended only as an adjunct device in user's health assessment and is not intended for use in the diagnosis, cure, treatment, or prevention of disease or other medical conditions. It must be used in conjunction with other methods of assessing clinical signs and symptoms.*
- *Check the measuring site every 24 hours to*

determine skin sensitivity of the user. User sensitivity varies depending on medical status or skin condition.

- *Do not use this device for measurement while charging.*
- *Avoid excessive pressure to the measuring site as this may cause damage to the skin beneath the sensor.*
- *No modifications to this device are allowed as it may affect device performance.*
- *If allergic to Soosyn ST-50 band strap material (nylon) or device case material (polycarbonate), please do not use this device.*
- *During measurement, do not take off the device and do not look directly at the sensor light port (lower end of the device case) to avoid possible eye damage.*
- *Do not use this device in a Magnetic Resonance (MR) environment or in the presence of flammable anesthetics or anesthetic gases.*

Declaration of Conformity with USA FCC for Electromagnetic Compatibility

Taiwan Biophotonic Co. of 4F-1, 6-1, Section 2, Biomedical Road, Zhubei City, Hsinchu County 302058, Taiwan, declares under its sole responsibility that Soosyn ST-50, Wrist Pulse Oximeter, to which this declaration relates, 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.

Federal Communications Commission (FCC) Notice

This device has been tested and found to comply with the limits for a class B digital device, pursuant to part 15 of the USA FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions, it may cause harmful interference to radio or television reception, which can be determined by turning the device 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 distance between the device and the receiver.
- Connect the device to an outlet on a circuit different from the outlet where the receiver is

connected

- Consult the dealer or an experienced radio/TV technician for assistance.
- RF Exposure: For body worn operation, to maintain compliance with USA FCC RF exposure guidelines, uses only accessories that contain no metallic components. Use of other accessories may violate FCC RF exposure guidelines and should be avoided.
- FCC RF Radiation Exposure Statement: This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
- The USA FCC requires the user to be notified that any changes or modifications to this device that are not expressly approved by Taiwan Biophotonic Co. may void the user's authority to operate the device.
- 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 of the device.

NCC 警語

取得審驗證明之低功率射頻器材，非經核准，公司、商號或使用者均不得擅自變更頻率、加大功率或變更原設計之特性及功能。

低功率射頻器材之使用不得影響飛航安全及干擾合法通信；經發現有干擾現象時，應立即停用，並改善至無干擾時方得繼續使用。

前述合法通信，指依電信管理法規定作業之無線電通信。

低功率射頻器材須忍受合法通信或工業、科學及醫療用電波輻射性電機設備之干擾。

12 Technical information (performance)

- Measurement Wavelength
500 nm ~ 1000 nm
- Oxygen Saturation Display Range
0% ~ 100% SpO₂
- Pulse Rate Display Range (Beats/Minute)
40 bpm ~ 240 bpm
- Oxygen Saturation Measuring Range, Oxygen Saturation Accuracy
70% ~ 100% SpO₂, ±3% SpO₂
- Pulse Rate Measuring Range, Pulse Rate Accuracy
40 bpm ~ 240 bpm, ±3 bpm

13 Product Specifications

Model : ST-50

Band Strap Material : Nylon

Core Unit Material : Polycarbonate

Dimension : 43.7 x 29.2 x 8.8 mm

(Height excluding the optical sensor area)

Battery Type : Li-Polymer Rechargeable Battery

Battery Capacity : 250mAh

Storage Space : 128MBit

Ingress Protection Ratings : IP64

Wireless Connection : 2.4GHz

Sensors : Six-Axis IMU, Reflective Pulse/Oxygen
Saturation Sensor, Surface Temperature
Sensor

Charging Port : USB Type C

Charging Power : DC 5V/1A



Soosyn Care APP : Supports the latest version of Android, backward compatible with Android 10, and the latest version of iOS, backward compatible with the two previous device versions.

14 Manufacturer/Medical Device Info.

Manufacturer/Medical Device Supplier Name :

Taiwan Biophotonic Corporation

Manufacturer's address :

4F-1, No. 6-1, Section 2, Shengyi Rd., Zhubei City,
Hsinchu County 302058, Taiwan

Medical device supplier's address :

4F-1, No. 6-1, Section 2, Shengyi Rd., Zhubei City,
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