Wrist-worn Pulse Oximeter

oCare™ Pro 100

Instructions for Use

Ver. P01A01-1

tBPC HEALTHCARE

Taiwan Biophotonic Corporation

MedNet GmbH
Borkstrasse 10,
48163 Münster, Germany
Tel: +49 (0) 251 322 66-61
Fax: +49 251 322 66-22
Email: ear@medneteurope.com
http://www.mednet-eurep.com

	**CAUTION: The federal laws of USA and the laws of some countries restrict this device to sale by or on the order of a licensed practitioner.**

Trademarks

References to "tBPC" in this manual imply Taiwan Biophotonic Corporation.

References to "this device(s)" or "this product(s)" in this manual imply tBPC's oCare™ Wrist-worn Pulse Oximeter, Model Pro 100.

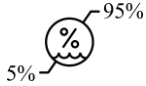
tBPC reserves the right to make changes and improvements to this manual and this product it describes at any time, without notice or obligation.

Safety Symbols

Warnings and cautions noted in this manual and the oCare™ Wrist-worn Pulse Oximeter, Model Pro 100, are indicated by the following marks, designed to prevent accidents caused by erroneous handling of this device.

Table 1: Labeling Symbols

Symbol	Description
	Indicate text consists of warnings or cautions relate to safety. Please read the text carefully and use this device safely.
	Indicate instructions related to actions. Please follow instructions for use.
IP65	No ingress of dust; complete protection against contact (dust tight) Water projected by a nozzle (6.3 mm) against enclosure from any direction shall have no harmful effects
	Indicate a Type BF-Applied Part device that provides a particular degree of protection against electrical shock.
	Indicate separate collection for electrical and electronic equipment (WEEE).
	BLUETOOTH® figure mark.

	Non-ionizing electromagnetic radiation. Equipment includes RF transmitters. Interference may occur in the vicinity of equipment marked with this symbol.
CE 0120	Mark Conformity to European Medical Device Directive 93/42/EEC
EC REP	Indicate authorized representative in the European Community.
SN	Serial number
	The container can and should be recycled
	Temperature limitation
	Humidity limitation
	This way upright
	Fragile, handle with care
	Keep dry
	Manufacturer
	Date of Manufacture

Safety Precautions

Warnings

1. 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.

2. Check the measuring site every 24 hours to determine skin sensitivity of the user. User sensitivity varies depending on medical status or skin condition.

3. Do not use the device for measurement while the watch case is taken off from the watchband for charging purpose.

4. Avoid excessive pressure to the measuring site as this may cause damage to the skin beneath the sensor.

5. No modifications to this device are allowed as it may affect device performance.

6. If allergic to watchband material (thermoplastic silicone vulcanizate) or oCare™ Pro 100 watch case material (polycarbonate), please do not use this device.

7. The Time and Date function are not the primary function of the application. Please do not make any medical

decision based on the Time or Date derived from the device.

8. Tattoos or hairy hairs in the wrist would hinder the measurement accuracy.

9. If this device is damaged in any way, discontinue use immediately.

10. This device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed carefully to verify normal operation.

11. When in fever (body temperature exceeds 40℃), please stop using the device and seek medical attention immediately.

12. Do not use the oCare™ Pro 100 and perform PR/SpO_2 measurement within 48 hours after receiving the photodynamic therapy to avoid the potential skin burn.

13. The use of cable and adaptor other than those listed in this manual may result in increased electromagnetic emission and/or decreased immunity of this device. Make sure the adaptor used complies with IEC 60601-1 Edition 3.1.

14. This equipment complies with International IEC 60601-1-2:2014 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection

against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information specified in this manual.

15. During measurement, do not take off the device and apply the sensor port (the bottom of the watch case) to the eye to avoid the potential eye damage.

16. Do not use this device in a Magnetic Resonance (MR) environment.

17. This device is not defibrillation proof per IEC 60601-1.

18. Do not use the pulse oximeter in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.

Cautions

1. If this device fails to respond as described, refer to

"**Troubleshooting**" section for instruction.

2. Radios and cell phones or similar devices might affect the equipment and should be kept at least 2 meters (6.5 feet) away from equipment.
3. If the oCare™ Pro 100 is being used with wireless communication, use the device within its designated range of approximately 10 meters (spherical radius). Moving outside this range may cause missing or lost data.
4. Refer to the "Care and Maintenance" section for cleaning instructions.
5. Use a detergent that is safe for skin and washable surfaces. Most detergents can be high sudsing, so use sparingly. Wipe with a damp, detergent free cloth to remove residue.
6. A functional tester cannot be used to assess the accuracy of the oximeter.
7. Do not submerge the device in the water.
8. Follow local, state, and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
9. In compliance with the European Directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC, do not dispose of this product as unsorted municipal waste. This device contains WEEE materials; please contact your local distributor regarding take-back or recycling of the device.

10. This device is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Factors that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following:
    - excessive ambient light
    - excessive motion
    - electrosurgical interference
    - blood flow restrictors (arterial catheters, blood pressure cuffs, infusion lines, etc.)
    - anemia or low hemoglobin concentrations
    - improperly applied this device
    - poor pulse quality
    - cardiogreen and other intravascular dyes
    - carboxyhemoglobin
    - methemoglobin
    - dysfunctional hemoglobin
    - venous pulsations
11. Do not perform any testing or maintenance on this device while it is being used to monitor a user.
12. This device is a precision electronic instrument and must be repaired by qualified technical professionals. Field repair of this device is not possible. Do not attempt to open the case or repair the electronics. Opening the case

would damage the device and void the warranty.

13. Portable and mobile RF communications equipment can affect medical electrical equipment.
14. Do not fasten the device too tightly around the patient's wrist. Inaccurate readings and patient discomfort could result.
15. To avoid the risk of confusing or misinterpreting patient data when transmitting data via BLUETOOTH®, verify the device is paired with the correct display unit.
16. The pulse oximeter may not work when circulation is reduced. Warm or rub the wrist when instructed by the device.
17. If any action is not performed during Start-up self-tests, do not use the device.

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 302, Taiwan, declares under its sole responsibility that oCare™ Pro 100, Wrist-worn 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

低功率電波輻射性電機管理辦法。第十二條:經型式認證合格之低功率射頻電機，非經許可，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。第十四條:低功率射頻電機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。前項合法通信，指依電信規定作業之無線電信。低功率射頻電機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。

Contents

List of Figures

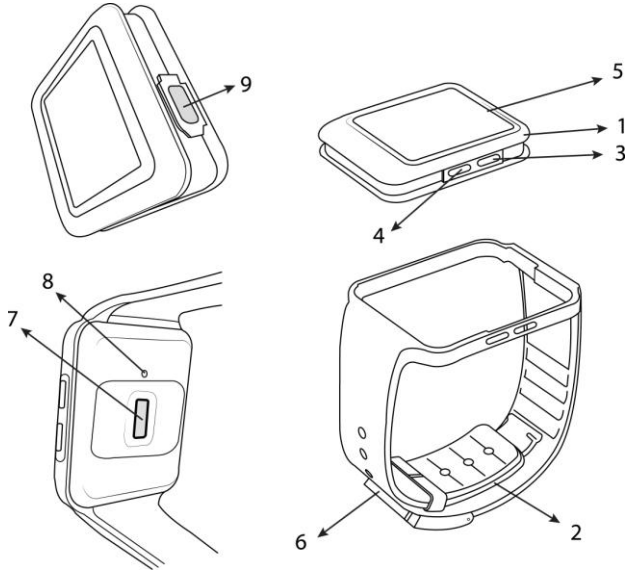
List of Tables

1. Introduction

Intended Use

The tBPC's oCare™ Wrist-worn Pulse Oximeter, Model Pro 100, is a wrist-worn device indicated for use in noninvasive measuring, displaying, and storing functional oxygen saturation of arterial hemoglobin (% SpO_2) 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.

Hardware Overview



1	Watch Case
2	Watchband
3	SWITCH Button
4	ENTER Button
5	LED/Alarm indicator
6	Metal Watch Clasp
7	PR/SpO_2 Sensor Port
8	Thermal Sensor Port
9	Micro USB AB Port

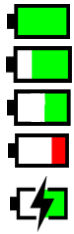
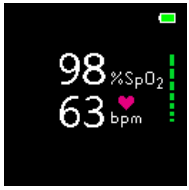
Figure 1. Hardware Overview

Display

The display and symbol/notation are illustrated in **Table 2**.

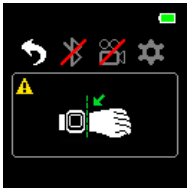
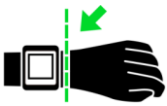
Table 2. Display Symbols and Notations

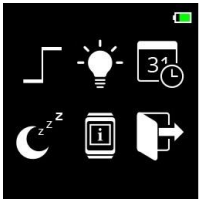
	**Watch Mode Display**
	**Hour Notation** The blue dot indicates the Hour of the time.
	**Minute Notation** The blue square bar indicates the Minute of the time.
	**Second Notation** The white highlight indicates the Second of the time.
AM/PM	AM stands for “Before noon”. PM stands for “After noon”.

2015 Nov 25 Wed	**Date Notation** The notations indicate Year, Month, Date and days of the week.
	**Battery Symbol** - Remaining battery is 75~100% - Remaining battery is 50~75% - Remaining battery is 25~50% - Remaining battery is 3~25% - Battery is charging When remaining battery is less than 25%, the battery symbol flashes. When remaining battery is less than 10%, the device shuts down automatically to preserve the Date/Time setting.
	**Measurement Mode Display**
100 %SpO2	**%SpO_2 Display** This 3-digit display shows percent blood oxygen saturation (% SpO_2). The displayed range is from 0 to 100 % SpO_2. ● When the high (or low) alarm limit is exceeded,

	■ the number turns YELLOW. ■ ▲ (high limit) or ▼ (low limit) symbol is displayed before the number. ● When default high/low alarm limit setting is changed, a decimal point (.) is displayed after the reading as a reminder.
	**Pulse Rate Display** This 3-digit display shows the pulse rate in beats per minute (bpm). The displayed range is from 40 to 240 bpm. Heart sign is added to facilitate the differentiation between pulse rate and SpO_2 value. ● When the high (or low) alarm limit is exceeded, ■ the number turns YELLOW. ■ ▲ (high limit) or ▼ (low limit) symbol is displayed before the number. ● When default high/low alarm limit setting is changed, a decimal point (.) is displayed after the reading as a reminder.

	**Pulse Quality Indicator** The height of the Pulse Quality Indicator reflects the quality of the measured signal. - Long indicator represents strong signal; - Short indicator represents weak signal. The indicator rises and falls with the monitored pulse rate.
--	**Pulse Search Indicator** The dashes are displayed until the measurement readings are stabilized.
	**No Motion Symbol** This symbol indicates excessive movement during measurement is detected.
	**CONTROL Display**
	**Return Symbol** Return to previous MODE.
 	**BLUETOOTH® Symbol** This symbol indicates BLUETOOTH® radio is OFF. This symbol indicates BLUETOOTH® radio is ON, and is also displayed in the

	upper right corner of the display.
 	**Recording Symbol** The symbol indicates the continuous monitoring status is OFF This symbol indicates the continuous monitoring status is ON, and is also displayed in the lower right corner of the display.
	**Setting Symbol** Enter the SETTING menu.
	**MESSAGE Display**
	**Caution Message Symbol** When a caution message is generated (poor signal condition or malfunction), the symbol is displayed in the lower left corner of the display.
	**Poor Signal Condition Symbol** The symbol recommends the user to adjust the device position for better signal reading.

	**Read IFU Symbol** This symbol instructs the user to read the "**Troubleshooting**" for solution.
	**BLUETOOTH® Pairing Request Display** This symbol (in the center) indicates the device receives a BLUETOOTH® pairing request from another master device. A 6-digit passkey is randomly generated and displayed below.
	**BLUETOOTH® Link Symbol** When BLUETOOTH® link is established, the symbol is displayed in the upper left corner of the display.
	**SETTING Display**
	**Alarm Limit Symbol** Enter the PR/SpO_2 high (or low) limit setting.
	**Brightness Setting Symbol** Enter the Brightness setting.

	**Date/Time Setting Symbol** Enter the Date and Time setting.
	**Idle-Time-to-Sleep Setting Symbol** Enter the Idle-Time-to-Sleep setting.
	**About the Device Symbol** See the device model number, device serial number and device software number.
	**Exit Symbol** Return to previous mode.

Unpacking the oCare™ Pro 100

The oCare™ Pro 100 standard kit includes the items listed below. Once the shipping carton is unpacked, verify if these items were received. Contact the carrier immediately if the shipping carton is damaged.

Standard Kit

- oCare™ Wrist-worn Pulse Oximeter, Model Pro 100,
- 1 micro USB cable
- Instructions for Use
- Quick Reference Guide

Lithium-ion Polymer Rechargeable Battery

With battery fully charged, battery life is approximately 118 hours (minimum) when not connected to a BLUETOOTH® device. When connected to a BLUETOOTH® device, battery life varies depending on class of operation. See "**Specifications**" section for detailed battery life information.

The battery symbol shows one of four states: 100%, 75%, 50% and 25% full. Recharge the device when remaining battery is lower than 25%.

When remaining battery is less than 25%

- The low priority alarm is triggered.
- The battery symbol flashes.

When battery reaches very low state (<10%):

- The battery symbol blinks to notify the very low battery status.
- The device ceases all ongoing action (ex. measurement or data syncing).
- The device automatically shuts down to preserve the Date/Time setting.

BLUETOOTH® Wireless Technology

BLUETOOTH® technology allows wireless connections between electronic communications and computing devices. The technology is based on a radio link that offers fast and reliable data transmissions. BLUETOOTH® uses a license-free, globally available frequency range in the ISM band—intended to ensure communication compatibility worldwide.

tBPC's use of BLUETOOTH® wireless technology allows SpO_2 and pulse rate data to be transmitted through a BLUETOOTH® radio to a compatible BLUETOOTH®-enabled device. tBPC's wireless system removes the cable connection from the device, giving patients increased ability to move freely.

To make efficient use of battery life, tBPC's oCare™ Pro 100 uses a BLUETOOTH® radio with a maximum range (spherical radius) of about 10 meters (32.8 feet). Obstacles and other conditions may affect range, and class of operation and connection mode will impact battery life. See "**Specifications**" for detailed battery life information.

The BLUETOOTH® radio contained in the device is compliant to BLUETOOTH® Smart Specification. The supported encryption key size is up to 128 bits and encryption is enforced on all outgoing and incoming data channels.

2. Using oCare™ Pro 100

Charging the Battery

Detach the Watchband

1. Pinch the watch case with one hand, and pull the other side of the watchband with another hand.
2. Separate the watch case with the watchband as illustrated in **Figure 2**.

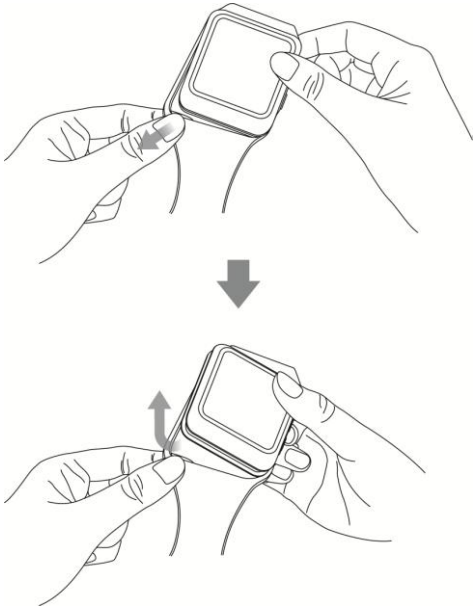


Figure 2. Detach the Watchband

Battery Charge

1. Unplug the anti-ESD (Electrostatic discharge) cover from the micro USB AB port on the watch case.
2. Plug one end of the micro USB cable into the USB port of the AC adaptor.
3. Plug the other end of the micro USB cable into the micro USB AB port of your oCare™ Pro 100 as illustrated in **Figure 3**.
4. While in charging, LED INDICATOR:
   - flashes WHITE every 5 seconds to indicate charging status;
   - stays WHITE (constant ON) to indicate battery full status.
5. If the battery of your oCare™ Pro 100 is completely drained, it takes roughly 3 hours to fully charge the device. While in charging, the LED INDICATOR will not active and the Battery Symbol will not display.
6. Plug the anti-ESD cover back to the micro USB AB port.

NOTE:

1. If you are charging the device for the first time, make sure you charge it for at least 3 hours.
2. This product should not be used in a environment that would cause the electromagnetic interference.
3. During charging, the measurement and BLUETOOTH® radio is disabled for safety consideration.
4. The PR/SpO2 sensor of this product may be flashing during charging when this product is hit by environmental ESD. This is an ESD self-protection of the product and oCare™ Pro 100 will not affect its intended function. The user does not need to concern about it.
5. The power adaptor may be affected by the surge current during the charging of oCare Pro 100. Hence, the charging icon on the screen may be turned off within seconds and on again. The percentage of battery power indicated on the screen may be also slightly changed and returned its indicated value. These situations will be automatically disappear in about one second and do not raise any safety issue. The user does not need to concern about it.

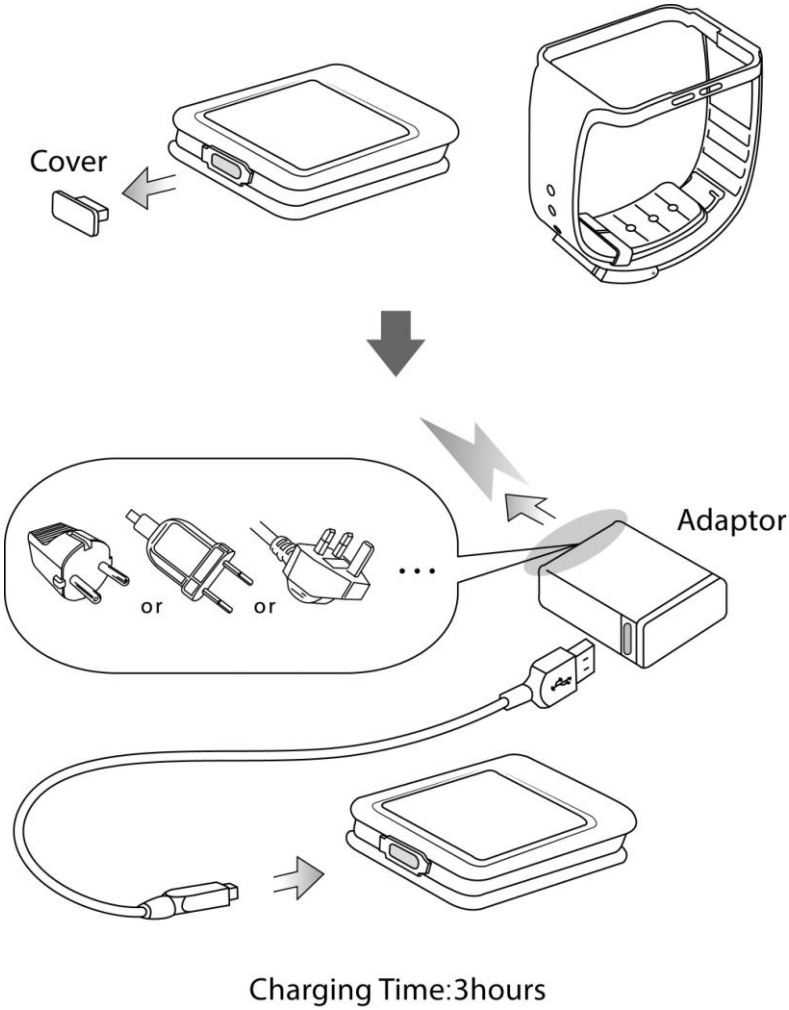


Figure 3. Battery Charge

CAUTION:

1 The Low priority Alarm indicator is triggered when approximately 25% remaining battery is left. The battery symbol starts to flash as a reminder. The low priority ALARM (and flashing of the battery symbol) is dismissed when remaining battery is greater than 25%.

Attach the Watchband

1. Plug the anti-ESD (Electrostatic discharge) cover to the micro USB AB port on the watch case
2. Align the watch case with the watchband as illustrated in **Figure 4**.
3. Insert the buttons into the holes of the watchband all the way to the end.
4. Assemble the watch case with the watchband.
5. Make sure the watchband sits in the trough of the watch case to secure the device.

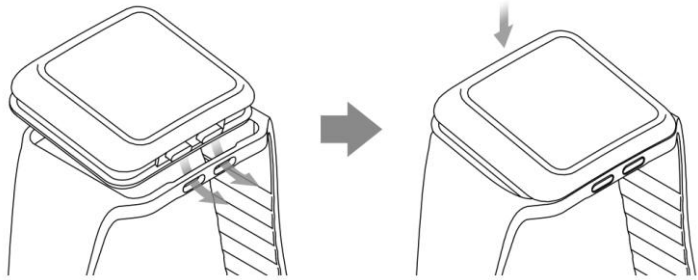


Figure 4. Attach the Watchband

Adjusting the Watchband Length

1. For the first time user, please adjust the watchband length as illustrated in **Figure 5**.
2. Open the metal watchband clasp. The watchband itself is fastened to one end of the clasp in one of the adjustment holes, and it is this end that will be worked on.
3. Pull the watchband from the clasp to remove the pin from the adjustment hole. Move the pin to desired adjustment hole according to your wrist size, and press the pin to secure the adjustment.
4. Make sure the device fit your wrist closely to ensure measurement accuracy.

CAUTION:

If the watchband doesn’t fit your wrist closely, it might hinder the measurement.

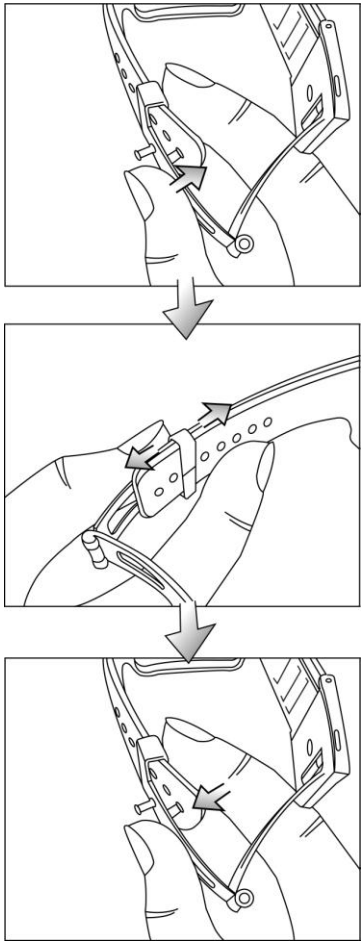


Figure 5. Adjustment of Watchband Length

Wearing the oCare™ Pro 100

1. The oCare™ Pro 100 is worn on the back of the hand, slightly above the wrist bone (ulnar styloid processus) as illustrated in **Figure 6** to provide the best comfort and measurement accuracy.

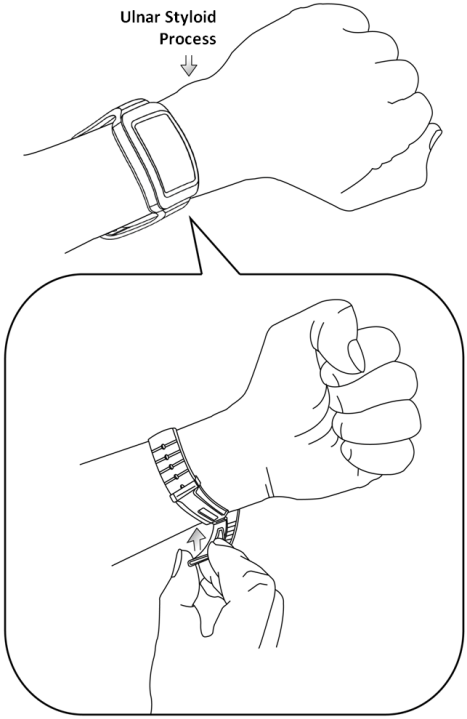


Figure 6. Wearing the oCare™ Pro 100

Taking off the oCare™ Pro 100

1. Pinch the pins on both sides of the metal watch clasp as illustrated in **Figure 7**.

2. Pull the metal watch clasp and take off the device.

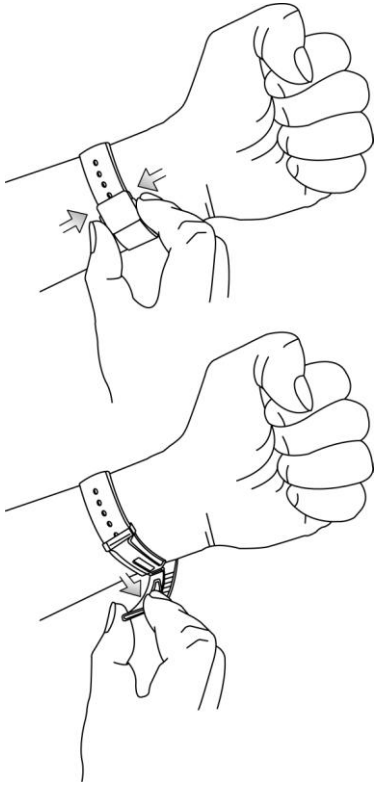


Figure 7. Taking off the oCare™ Pro 100

Startup Sequence and Self-Tests

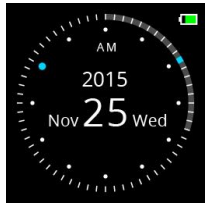
1. Press ENTER buttons for 3 seconds to turn on the device.

2. During Startup sequence, the device will execute self-testing automatically. Check if the following action sequences are performed:

   - Vibrate for 1 seconds.
   - The LED INDICATOR flashes YELLOW one time.

   - The LED INDICATOR flashes BLUE one time.
   - LED INDICATOR flashes WHITE three times
   - The display shows serial number and software version number to indicate the Startup self-tests are completed

3. If not first-time use, the device enters the Watch Mode.



CAUTION:

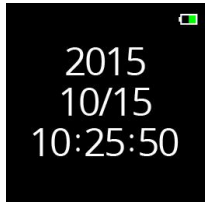
1. If any action is not performed during self-tests, do not use

the device. Contact tBPC customer support for assistance.

Date and Time Setting

Date and Time Setting are prompted only at the first time use.

1 Date setting



1.1 Year setting

1.1.1 Year setting (default: 2010) is indicated by changing color of Year into yellow.

1.1.2 Press SWITCH button to select the current Year (up to 2099; long press to speed up the selection); press ENTER button to accept the setting and move to Month setting.

1.2 Month/Day setting: repeat the same procedure above (Month default: 1; Day default: 1).

1.3 Press ENTER button to move to Time setting.

2 Time setting

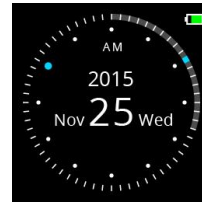
2.1 Hour setting

2.1.1 Hour (default: 00; in 24 hour format) flashes to indicate Hour setting.

2.1.2 Press SWITCH button to select the hour (long press to speed up the selection); press ENTER button to accept the setting and move to Minute setting.

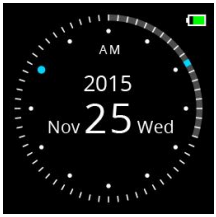
2.2 Minute/second setting: repeat the same procedure above (Minute default: 00; second default: 00).

2.3 Press ENTER button to accept the setting and enter the Watch Mode.

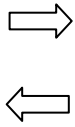


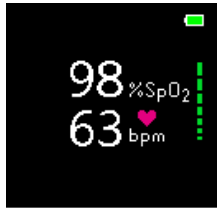
3. Operation and Measurement

The device has two modes in repeated cycle as following:



Watch Mode





Measurement Mode

Device Activation

Press ENTER buttons for 3 seconds to turn on the device.

Sleep Mode

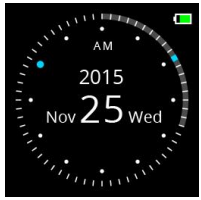
When the criteria of Sleep Mode is met, after the (ex. no activity in 3 minutes), the Sleep Mode is activated according to the setting of the Idle-Time-to-Sleep, and the device

- returns to Watch Mode, and
- turns off the display, and/or

- turns off the BLUETOOTH® radio

Watch Mode

Watch Mode is the home screen of the device with watch functionality.



1 To check the Time or Date, press any button once to wake up from the Sleep Mode.

2 If no button is pressed in designated time, the device enters Sleep Mode.

3 Press SWITCH button once to enter the Measurement Mode whenever needed.

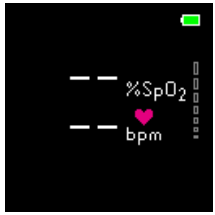
Measurement Mode

The mode is for the monitoring of Pulse Rate (PR) and blood oxygen saturation (SpO_2). Make sure the device is worn properly, as illustrated in **Figure 8,** before starting the measurement.

1 Press SWITCH button once to enter the Measurement Mode (from Watch Mode).

2 Two available options in the Measurement Mode:

2.1 Spot-check



2.1.1 "--" are displayed until the measured reading are stabilized.

2.1.2 Once the reading is stabilized, the PR and SpO_2 values are displayed as right:

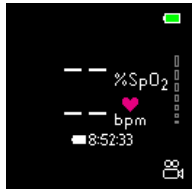
2.1.3 If longer observation of the measurement value is required, go to the Idle-Time-to-Sleep in "**SETTTING**" to extend the setting there.

2.1.4 If no button is pressed in designated time, the device enters Sleep Mode.

2.2 **Continuous Monitoring** (for longer period of monitoring)

2.2.1 Activate the continuous monitoring function in the "**CONTROL"** (please refer to "**CONTROL"** for details).

2.2.2 symbol is displayed in the lower right corner of the display as a reminder.



2.2.3 Lasting recording time would be estimated and displayed below the dash lines shortly for information purpose.

2.2.4 LED INDICATOR flashes WHITE every 5

seconds to indicate the continuous monitoring status after Sleep Mode is activated.

2.2.5 To wake up from Sleep Mode, press any button once to turn on the display in Continuous Monitoring.

2.2.6 To stop the continuous monitoring, go to "**CONTROL"** and deactivate the continuous monitoring.

2.3 Press SWITCH button once and return to Watch Mode after measurement.

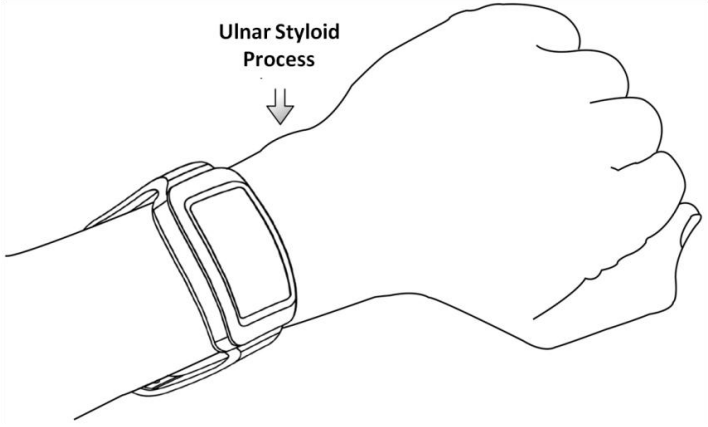


Figure 8. Position Adjustment during Measurement

CAUTION:

1 In order to get fast and accurate results,

- Make sure the device sit on your wrist skin, **slightly above the wrist bone** (ulnar styloid processus), as illustrated in **Figure 8**.
- 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).

2 When PR/SpO_2 high (or low) limit is exceeded,

- Medium priority alarm is activated (refer to **Table 4** for details). Address the patient condition immediately.
- The PR/SpO_2 number on the display turns YELLOW.
- The device takes the measurement continually until the medium alarm condition is resolved.

3 When PR/SpO_2 high (or low) limit is changed from default, a decimal point (.) is displayed after the reading as a reminder.

4 If PR/SpO_2 results do not show in designated time, the low priority alarm is triggered and the ⚠ symbol is displayed (in the lower left corner of the display) to indicate the situation. Please adjust the watch position (slightly above the wrist bone or ulnar styloid processus) for better signal

reading. If the situation persists, please refer to "**Troubleshooting**" section for instruction.

5 When technical alarm is triggered, low priority alarm is activated (refer to **Table 4** for details). Address the device condition immediately.

6 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.

NOTE:

1 The device measures, collects, and stores up to 72 hours of SpO_2 and pulse rate data with a 1-second data collection rate.

2 When the memory is full, the device overwrites the oldest existing data with the new data.

3 Syncing data in memory does not clear memory.

4 During normal measurement conditions the averaging time is 8 seconds. During conditions such as those caused by low perfusion, interference, the algorithm automatically extends the amount of data required beyond 8 seconds.

5 If the signal from the sensor is inadequate, the last measured SpO_2 and pulse rate values freeze for 25 seconds, and are then replaced with dashes.

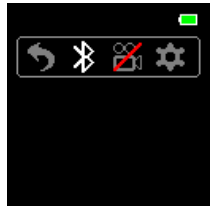
CONTROL and MESSAGE

CONTROL

1. Press ENTER button any time to enter **CONTROL** menu.
2. Press SWITCH button to select the target symbol (the color of the unselected one turn dark), and

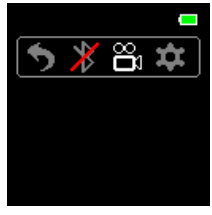
2.1 **Return**

2.1.1 Press ENTER button to return to previous MODE.



2.2 **BLUETOOTH®**

2.2.1 Press ENTER button to activate/deactivate the BLUETOOTH® radio.



2.3 **Continuous Monitoring**

2.3.1 Press ENTER button to activate/deactivate the continuous monitoring function.

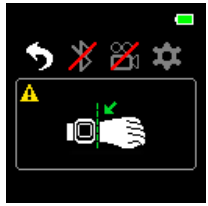
2.4 **SETTING**

2.4.1 Press ENTER button to enter the "**SETTING"** menu.

MESSAGE

1. When ⚠ symbol is displayed (on the lower left corner of the display), press ENTER button can switch to the message directly.

2. There are two types of messages:



- Poor Signal Condition

  Suggest the user to adjust the device position as illustrated in **Figure 8** for better signal reading.

- Malfunction

  Refer the user to " **Troubleshooting**" for instruction.

NOTE:

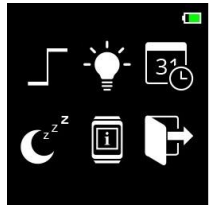
1 ⚠ symbol disappears when the situation is resolved.

SETTING

The setting of the device can be adjusted here.

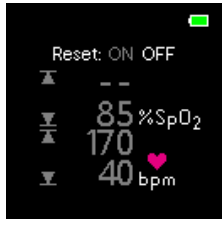
Select ⚙ in "**CONTROL"** and press ENTER button to enter the SETTING menu:

- PR/SpO_2 Alarm Limit Setting
- Brightness Setting
- Date/Time Setting
- Idle-Time-to-Sleep Setting
- About the Device
- Exit



Press SWITCH button to select the target symbol (the color of the selected symbol would change), and press ENTER button to enter the lower menu.

PR/SpO_2 Limit Setting



RESET ON/OFF

- Press ENTER button to switch to SpO_2 high limit setting, or
- Press SWITCH button to turn ON the RESET menu (the default settings would be displayed), and press ENTERE button to enter the RESET menu

1 Press SWITCH button to select:

- "✓(in GREEN)": restore all settings to factory default value.
- "X (in RED)": about the reset process.

2 Press ENTER button to accept the selection and return to "**SETTING"** menu.

SpO_2/PR high (or low) limit

1 Press SWITCH button to select the target setting for the SpO_2 high limit, and press ENTER button to accept the setting and move to SpO_2 low limit setting.

2 Repeat the same process above for SpO_2 low limit, PR high limit and PR low limit.

3 Once the PR low limit is set, press ENTER button to accept the settings and return to "**SETTING**" menu.

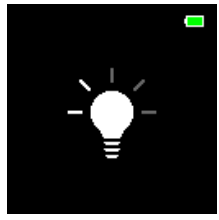
NOTE:

The table below shows the range and default value of the PR/SpO_2 limits:

Parameter	Ranges	Defaults
SpO_2 High Limit	86~100%, with 1% step size	Off
SpO_2 Low Limit	85~95%, with 1% step size	85%
PR High Limit	75~250bpm, with 5bpm step size	170bpm

PR Low Limit	40~110bpm, with 5bpm step size	40bpm

Brightness Setting



- Press SWITCH button to move among five brightness settings.
- Once preferred brightness setting is selected, press ENTER button to accept the setting, and return to "**SETTING**" menu.

Date/Time Setting

Please refer to "**Date and Time Setting"** for adjustment instrucitons.

Idle-Time-to-Sleep Setting

If longer observation of the measurement value is required, adjust the setting here to accommodate for that purpose. Remember to adjust the setting back to 3 minutes for battery conservation and better performance.

- Press SWITCH button to move among five Idle-Time-to-Sleep setting: 3 minutes, 10 minutes, 30 minutes, 120

minutes, and Never.

- Once preferred Idle-Time-to-Sleep is selected, press ENTER button to accept the setting and return to upper menu.

About the Device

- The screen displays the model number, software version # and serial number.
- Press ENTER button to go back to "**SETTING**" menu.

Exit

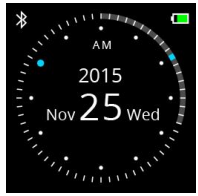
Press ENTER button to return to Watch Mode.

Data Transmission

The device has BLUETOOTH® radio for downloading the stored data to other devices for the purpose of analysis or archive.

BLUETOOTH® Pairing Request

Before the device can be connected with other BLUETOOTH® master device, the devices must be paired.



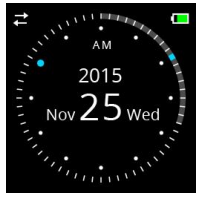
1 Turn on the BLUETOOTH® radio in CONTROL. The ᛒ symbol is displayed (on the upper left corner of the display) to indicate BLUETOOTH® radio ON status.

2 When prompted with BLUETOOTH® pairing request from other master device (within 10-m radius), the device generates a random 6-digit passkey on the display.

3 Enter the 6-digit passkey into the other BLUETOOTH® master device.

BLUETOOTH® Connection

Once paired, the device will automatically connect to the BLUETOOTH® master device when receives BLUETOOTH® connection request.



1. Once the BLUETOOTH® connection is established, ⇄ symbol replaces the ᛒ symbol.
2. Start the data downloading process on the BLUETOOTH® master device.

3. BLUETOOTH® radio is turned off automatically after data uploading completed.
4. Press SWITCH button once to enter the Watch Mode whenever needed.

NOTE:

1 If BLUETOOTH® link is not established in designated time, the device enters Sleep Mode to conserve the battery.

2 The last two paired master devices are memorized for quick BLUETOOTH® connection.

3 The BLUETOOTH® master device and oCareTM Pro 100 shall stay within 10 meter radius range during BLUETOOTH® connection.

4 The BLUETOOTH® master device shall support BLUETOOTH® 4.0.

5 During measurement, PR and SpO_2 value and data/time of the recorded PR/SpO_2 value are saved at one-second interval in non-volatile memory. Shut down of the device would not affect the completeness of the data.

Device Shut Down

Press ENTER buttons for 3 seconds to shut down the device.

4. Alarm

Alarm Indication

The alarm condition is indicated by visual ALARM INDICATOR as described in **Table 3** below. The operator could be patient, caretaker or medical personnel.

Table 3. Characteristics of ALARM INDICATOR

Alarm Priority	Color	Flashing Frequency
Medium	YELLOW	0.4Hz
Low	BLUE	Constant (ON)

Alarm Limits

Two types of alarm are present, physiological and technical (refer to **Table 4** and **Table 5** below for details). The flashing ALARM INDICATOR occurs when the alarm condition is exceeded.

Table 4. Physiological Alarm – Medium Priority

Parameter	Ranges	Defaults
SpO_2 High Limit	86~100%, with 1% step size	Off

SpO_2 Low Limit	85~95%, with 1% step size	85%
PR High Limit	75~250bpm, with 5bpm step size	170bpm
PR Low Limit	40~110bpm, with 5bpm step size	40bpm

Note:

1. The low limit must be set below the high limit setting. While the high limit is set equal to or below the low limit, the low limit will automatically be adjusted to the next setting below the newly entered high limit setting.
2. When default alarm setting is changed, a decimal point (.) is displayed after the reading as a reminder.
3. When PR/SpO_2 high (or low) limit is exceeded,
   - Medium priority alarm is activated.
   - The PR/SpO_2 number on the display turns YELLOW.

Table 5. Technical Alarm – Low Priority

Parameter	Condition
Low Battery	Remaining battery is less than 25%
Poor Signal Condition	Poor signal, determined by the algorithm, for more than 25 seconds
Malfunction	Malfunction detected

NOTE:

1 Alarms are prioritized so that high priority alarms

overwrite low priority alarms.

2 For multiple alarms, lower priority alarms would also be displayed.

3 Alarm system still operates during adjustment of alarm limit.

WARNING:

1. To ensure the alarm limits are appropriate to the monitored patient, check the alarm setting each time before use.
2. Do not change the alarm limit before consulting the medical advice.
3. Alarm condition (physiological and technical), alarm limits, date/time of occurrence are saved in non-volatile memory. The alarm data is kept intact during powered down.
4. When the alarm data is full, the device overwrites the oldest existing alarm data with the new alarm data.
5. When the battery is in very low state (<25%), the alarm system is not expected to repeat alarm signals indefinitely.
6. If a low battery condition occurs, immediately discontinue patient monitoring and charge the device.

5. Care and Maintenance

The device's expected service life is 2 years.

Cleaning the Watch Case

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.

Cleaning the Watchband

Wipe the Watchband with a soft cloth dampened with 70~75% alcohol or water whenever needed. Dry with a soft cloth, or allow to air dry.

NOTES:

1. 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.

Storing

Store the device within the stated environmental conditions. See "**Specifications**" section for additional information.

6. Support and Warranty

Support

For information about the oCare™ Wrist-worn Pulse Oximeter, Model Pro 100 (oCare Pro 100) and its accessories, contact your local sales representative or distributor first. For the contact information of sales representative or distributor in your area, contact Taiwan Biophotonic Corporation (tBPC). Please take a moment to have the device serial number ready if you have to contact tBPC with technical service issues or if you have any questions regarding the use or performance of your pulse oximeter. A return material authorization (RMA) number is required before returning any product to tBPC. To obtain this RMA number, contact tBPC at:

Taiwan Biophotonic Co.,

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

Hsinchu County, 30261, Taiwan

Tel. No. : + 886-3-667-0888

Fax No. : + 886-3-667-0222

E-mail: serv@tbpchc.com

Website: www.tbpchc.com

Warranty

Taiwan Biophotonic Corporation (tBPC) warrants to the purchaser of the oCare™ Wrist-worn Pulse Oximeter, Model Pro 100 (oCare Pro 100) for a Limited Warranty Period of 1

(one) year from the date of purchase under normal use. tBPC shall, at its sole discretion, remedy defects in materials or workmanship free of charge either by a) repairing, or b) replacing, any oCare Pro 100, found to be defective, subject to the terms and conditions of this Warranty, for which tBPC has been notified by the purchaser by serial number that there is a defect, provided said notification occurs within the Limited Warranty Period. This Warranty is only valid and enforceable in the country of purchase, unless local law stipulates otherwise. Processing of all warranty claims will be handled by the distributor of tBPC for the geographic area where the purchase was made. A return shipping and handling fee may be applied for all returns.

As a condition of this Warranty, the warranty registration must be completed within 20 days of the purchase date at www.tbpchc.com or sales@tbpchc.com.

All non-warranty work shall be performed according to tBPC standard rates and charges.

This Warranty does not cover:

1 a)normal wear and tear, b) defects caused by rough handling, or c) defects or damage caused by misuse, contrary to intended or recommended use or alteration of the tBPC's product such as moisture or water damage sufficient to affect the proper function of the product, and damage to the product case or visible cracking of the face.

2 Instruction for Uses or any third-party items.

This Warranty is not enforceable if:

1 tBPC's product has been used in ways other than the intended use.

2 The sealed enclosure of tBPC's product has been opened or it has been otherwise tampered with.

3 tBPC's product was not purchased from an authorized tBPC distributors.

4 tBPC does not warrant that the operation of the device will be uninterrupted or error free, or that the device will work with any hardware or software provided by a third party.

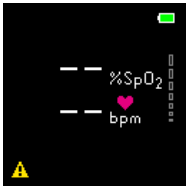
DISCLAIMER/EXCLUSIVITY OF WARRANTY:

This Warranty constitutes the only responsibility and obligation of Taiwan Biophotonic Corporation (tBPC) to repair or replace materials or components. tBPC makes no other express or implied warranties, arising by operation of law or otherwise, or any warranty of merchantability or fitness for a particular use or purpose whether or not the use or purpose has been disclosed to tBPC in specifications, drawings or otherwise, and whether or not tBPC's products are specifically designed and/or manufactured by tBPC for the purchaser's use or purposes, except for the limited warranty stated above. tBPC will not be responsible for any indirect, incidental, special, consequential, or punitive damages or other loss, including, but not limited to, damage to or loss of other property or equipment and personal injuries, whether to purchaser or others. tBPC shall in no event be liable to the purchaser for any amount in excess of the cost of replacement of tBPC's products.

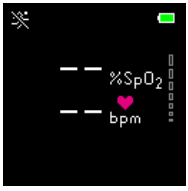
7. Troubleshooting

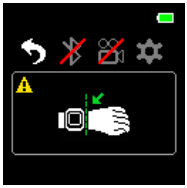
When caution message is displayewd or encounter a problem, check the corresponding solutions below, and follow the instruction correctly.

Table 6. Troubleshooting

Caution Messages or Problems	Possible Cause	Possible Solution
No PR/SpO_2 value 	Premature determination of malfunction	If no PR/SpO_2 value shown in 25 seconds, follow the troubleshooting below for solution.
	Wrist skin is cold	Warm (or rub) the device application site to increase the blood circulation.
	Wear the device incorrectly	Adjust the watchband position slightly above the wrist bone or ulnar styloid processus as illustrated in Fig. 8, and make sure the device fit closely but

		comfortably on the wrist.
	Excessive ambient light	Adjust the watchband so that the device fits closely on the wrist, and avoid excessive ambient light while taking the measurement.
	Tattoo or hairy hairs under the device measurement site	Make sure the device measurement site is free of tattoo or hairy hairs.
	Possible interference from blood flow restrictors (arterial catheters, blood pressure cuffs, infusion lines, etc.)	Reduce or eliminate the restriction.
	Other causes	Press SWITCH button to re-enter the Measurement Mode. If the incident remains, press ENTER buttons for 3 seconds to shut

		down the device. If the problem persists after reboot, contact local distributor for assistance.
Motion symbol displayed 	Excessive user movement during measurement	Keep the device-worn lower arm HORIZONTAL and STILL while taking the measurement.
Battery symbol flashes 	Battery is low	Charge the device as illustrated in Figure 3.
ALARM INDICATOR flashes YELLOW	Medium priority alarm is triggered	Address the patient condition immediately.
ALARM INDICATOR flashes BLUE	Low priority alarm is triggered	Assess/address the device condition immediately.
Caution	Wear the device	Adjust the

message shown 	incorrectly	watchband position slightly above the wrist bone or ulnar styloid processus as illustrated in Figure 8, and make sure the device fit closely but comfortably on the wrist.
Caution message shown 	Hardware malfunction detected	Press ENTER buttons for 3 seconds to shut down the device. If the error message persists after reboot, contact local distributor for assistance.
Device is not responding	Software malfunction occurred	Press SWITCH and ENTER buttons for 10 seconds to reboot the device.
Device can't activate	Battery is depleted	Charge the device as illustrated in Figure 3. If the device still can't be activated after charging, contact local

		distributor for assistance.
Device enters Sleep Mode during measurement	Sleep Mode is activated during measurement	Enter "**SETTING**" to extend the Idle-Time-to-Sleep setting.
Device can't start the continuous recording during measurement	Remaining battery is less than 10%	Charge the battery full, and then enter the continuous recording.
Devices can't pair	Device is out of BLUETOOTH® range	Verify device is in BLUETOOTH® range while being paired (approximately 10 meters [32.8 feet] spherical radius).
	Radio frequency interference (ex. microwave)	Conduct the pairing process away from possible interference source.
	BLUETOOTH® radio has timed out	Turn the BLUETOOTH® radio ON again in "**CONTROL**".

BLUETOOTH® and Continuous Monitoring function is disabled in "**CONTORL"**	Device is charging	Conduct the measurement or data upload process after charging.
Device automatically shuts down	Battery is depleted	Charge the device as illustrated in Figure 3.
Device battery runs out quickly	Idle-Time-to-Sleep is set to "Never"	Change the Idle-Time-to-Sleep setting in "**SETTING"**, to 3 minute to conserve the battery consumption.

If these solutions do not correct the problem, please contact local distributor or Taiwan Biophotonic Corporation at +(886) 3-667-0888.

8. Technical Information

Specifications

Performance

Measuring Wavelength @ Maximum Output Power[a]	Green:530nm@6.9mW maximum Red: 655 nm @ 3.8 mW maximum Infrared: 940 nm @ 1.7 mW maximum
Oxygen Saturation Display Range	0-100 %SpO_2
Pulse Rate Display Range [Beats/Minute]	40-240 bpm
Oxygen Saturation Accuracy Oxygen Saturation Measuring Range Non-motion	 70-100 %SpO_2 $\pm$ 3 %SpO_2
Pulse Rate Accuracy Pulse Rate Measuring Range Non-motion	 40 -240 bpm $\pm$ 3 bpm

a. This information is especially useful for clinicians performing photodynamic therapy.

System

Interface Connectivity	BLUETOOTH® 4.0
Memory Type Capacity @ Data Storage Rate	 Non-volatile Up to 72 hours @ one-second interval

Electrical

Power Supply	Input DC 5V, 400mAh, Lithium Ion Polymer Rechargeable Battery
Battery Charging Port	Micro USB AB Type
Charging time	3 hrs
Power Consumption	Approximate 24 hours with 4 Spot Check measurement/day (under sleep mode) Approximate 8 hours with continuous recording (under sleep mode)

Physical Characteristics

Watch Case Dimension (L x W x H)	48 mm x 42 mm x 14 mm (1.89 in. x 1.65 in. x 0.55in.)
Weight Watch Case Watchband	 25 g (0.88 oz) 33 g (1.16 oz)
Watch Case Watchband	Polycarbonate Thermoplastic Silicone Vulcanizate
Enclosure Degree of Ingress Protection	IP65 No ingress of dust; complete protection against contact (dust tight) Water projected by a nozzle (6.3 mm) against enclosure from any direction shall have no harmful effects
Usable Life	2 years (under normal usage)
Display	Type: OLED 4 Directions Display Resolution: 128 x 128 (RGB)

Environmental Condition

Operating Condition	● A temperature range of 10 ℃ to 40 ℃ (50 ℉ to 104 ℉) ● A relative humidity range of 10 % to 93 %, non-condensing; ● An atmospheric pressure range of 760 hPa to 1,060 hPa. (altitude: 0 ~3,000m)
Storage/Transportation Condition	● A temperature range of -40 ℃ to 70 ℃ (-40 ℉ to 158 ℉) ● A relative humidity range of 5 % to 95 %, non-condensing; ● -40 ℃ (-40 ℉) without relative humidity control;

Compliance

Biocompatibility	The device is in compliance with ISO 10993-1, ISO 10993-5 and ISO 10993-10
EMC	IEC 60601-1-2:2014, Class B.
Classification per IEC 60601-1	

Type of Protection	Internally Powered (Battery Power)
Degree of Protection	Type BF-Applied Part
Mode of operation	Continuous

Alarm

Alarm Type	Low Battery Malfunction Poor Signal Condition High/Low SpO_2 (PR)
High/Low SpO_2 (PR) alarm range	SpO_2 high limit: 86~100 %SpO_2 SpO_2 low limit: 85~95 %SpO_2 PR high limit: 75~250 bpm PR low limit: 40~110 bpm
Medium priority	ALARM INDICATOR: YELLOW Alarm flashing frequency: 0.4 Hz
Low priority	ALARM INDICATOR: BLUE Alarm flashing frequency: Constant (ON)

Wireless Transmitter

BLUETOOTH® Compliance:	BLUETOOTH® Smart
Operating Frequency:	2.4 to 2.483 GHz
Operating Range:	10-meter (32.8-foot) radius indoors (under normal usage)
Network Topology:	Point-to-Point
Operation:	Slave
Antenna Type:	Internal
Modulation Type:	Frequency Shift Keying Frequency Hopping Spread Spectrum
Band Width:	1 MHz

NOTE:

1. The device has been validated for no motion accuracy in human clinical studies on sick and healthy adult volunteers in the range of 70-100% SpO_2 against a laboratory co-oximeter.
2. The device has been validated for pulse rate accuracy in the range of 40~240bpm in bench top testing against a simulator.

Displayed Values

SpO_2

Update the last 8-beat moving average of the functional oxygen saturation at one-second interval.

Pulse Rate

Update the last 8-beat moving average of the pulse rates at one–second interval.

Principles of Operation

oCare™ Pro 100 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 (HbO_2) and deoxygenated hemoglobin (Hb). Blood vessels, tissue 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 (SpO_2).

Pulse oximetry is based on the following two principles:

(1) Oxygenated hemoglobin and deoxygenated hemoglobin have different optical absorbance in red and infrared wavelength range (spectrophotometry).

(2) The volume of arterial blood in the tissue is periodically changed with the heart beating. Therefore, the amount of light absorbed by the changing volume of arterial blood is also changed as well (photoplethysmography**)**.

oCare™ Pro 100 is built with a reflectance oximetry sensor, which consists of two or more light emitting diodes (LEDs) and one or more photodiode light detector (PDs) located side by side. Light beams are shone from LEDs through the skin to the arteriolar bed of the tissue. The arteriolar bed absorbs variable amounts of light during the pulsations. Changes in light absorption during the pulsing cycle are measured by the PDs as scattered lights are reflected back from the pulsating arteriolar bed. Because oxygenated hemoglobin (HbO_2) and deoxygenated hemoglobin (Hb) have different optical absorbance in red and infrared wavelength range, the beam of infrared light is absorbed more by HbO_2; the other beam of red light is less absorbed by oxygenated blood and more strongly absorbed by Hb.

The light absorbed by the blood also varies with the volume variation in the arteriolar bed. During systole, light absorption and blood volume increase to their maximum due to a new pulse of arterial blood enters the arteriolar bed. During diastole, light absorption and blood volume reach their minimum. Pulse oximetry determines the SpO_2 on the difference between

maximum and minimum light absorption measured at systole and diastole. It focuses on light absorption by pulsating arterial blood, eliminates the effect of non-pulsating absorbers such as tissue, bone and venous blood.

By calculating the ratio of absorbance of Hb and HbO_2 at red and infrared beams during the arterial pulsing respectively, oCare™ Pro 100 determines functional oxygen saturation of arterial blood. The pulse wave of photoplethysmography measured by the changing optical absorption, also leads to determine the pulse rate.

There are two common types of pulse oximetry sensor, referred to as transmission mode and reflectance mode. The transmission oximetry sensor is configured with LED and PD positioned on opposing surfaces of the tissue (i.e. finger, earlobe), then the PD detects predominantly forward scattered light transmitted through a tissue. In the reflectance oximetry sensor, LED and PD are located on the same side and the sensor is applied to one surface of the tissue (i.e. finger, forehead and wrist), so that the PD measures the scattered light that is reflected from the pulsating arteriolar bed. The terms transmittance and reflectance refer to the geometry of pulse oximetry and are not related to the principle of pulse oximetry and how the light is absorbed by the hemoglobin. Both transmission and reflectance pulse oximetry sensor measure the functional oxygen saturation of arterial blood by the same principal of pulse oximetry.

Manufacturer's Declaration

Taiwan Biophotonic Corporation hereby declares that the oCareTM Pro 100 is in compliance with the essential requirements and other relevant provisions of IEC 60601-1-2:2014.

The oCare™ Pro 100 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the oCare™ Pro 100 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the oCare™ Pro 100 as recommended below, according to the maximum output of the communications equipment.

Table 7. Recommended Separation Distances

This table details the recommended separation distances between portable and mobile RF communications equipment and the oCare™ Pro 100.

This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Users of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the device as recommended below, according to maximum output power of the communications equipment.

	Separation Distance According to Frequency of Transmitter		
Rated Maximum Output Power of Transmitter, W	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.73
1	1.2	1.2	2.3
10	3.7	3.7	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency

of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTES:

1. At 80 MHz and 800 MHz, the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 8. Electromagnetic Emissions

The oCare™ Pro100 is intended for use in the electromagnetic environment specified below. The customer or user of the monitor should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 2	This oCare™ Pro 100 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class B	The oCare™ Pro 100 is suitable for use in establishments, including diagnostic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions. IEC 61000-3-2	N/A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	N/A	

Table 9. Electromagnetic Immunity

This oCare™ Pro 100 is intended for use in the electromagnetic environment specified below. The customer and/or user of the oCare™ Pro 100 should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common	N/A	Mains power quality should be that of a typical commercial or hospital

	mode		environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	±5% UT (>95% dip in U_T) for 0.5 cycle ±40% UT (60% dip in U_T) for 5 cycles ±70% UT (30% dip in U_T) for 25 cycles <5% UT (>95% dip in U_T) for 5 seconds	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency (50/60Hz) Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the AC mains voltage before application of the test level.

Table 10. Guidance and Manufacturer's Declaration - Electromagnetic Immunity

This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.			
Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	**Recommended Separation Distance** $d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 3 V/m	80 MHz to 800 MHz, $d = 1.17\sqrt{P}$ 800 MHz to 2.7 GHz, $d = 2.33\sqrt{P}$ where P is the maximum output power rating of the

			transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the symbol: 

NOTES:

1. At 80 MHz and 800 MHz, the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the oCare™ Pro 100 is used exceeds the applicable RF compliance level above, the oCare™ Pro 100 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

9. Parts and Accessories

For more information about tBPC oCare™ accessories, please contact your local distributor, or tBPC at +(886) 3-667-0888. This information is also available on tBPC's website: www.tbpchc.com.

PART NAME
Watchband (Large) – Black (fits 165~205cm wrists)
Watchband (Large) – White (fits 165~205cm wrists)
Watchband (Medium) – Black (fits 145~185cm wrists)
Watchband (Medium) – White (fits 145~185cm wrists)
Micro USB cable – Black

Taiwan Biophotonic Corporation
4F-1, No. 6-1, Section 2, Shengyi Rd., Zhubei City,
Hsinchu County 30261, Taiwan
Tel. No. +886-3-667-0888
Fax No. +886-3-667-0222
E-mail: serv@tbpchc.com
Website: www.tbpchc.com

Ver. P01A01-1