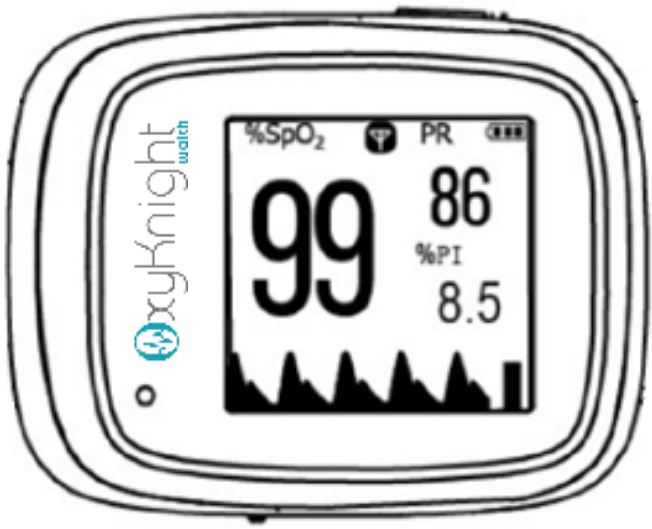


OxyKnight® Watch

User Manual

User Manual for OxyKnight® Watch

Dear Customer,

Thank you for purchasing this quality product. Please read the manual very carefully before using this device. Failure to follow these inst ructions can cause measuring abnormality or damage to the OxyKnight® Watch.

Version of the Manual: Ver 1.0
Issued Date: March 13th, 2020

3502-2640001

Notes:

- Thecontentscontainedinthismanualare subject to change without prior notice.
  Information furnished by **Telomed, Inc.** is believed to be accurate and r eliable. Ho wever, no responsibility is assumed by **Telomed**, Inc. for its use, or any infringements of patents or other rights of third parties that may result from its use.

Instructions for Safe Operation

- Check the device to make sure that there is no visible damage that may affect user's safety and measurement performance. It is recommended that the device should be inspected minimally before each use. If there is obvious damage, stop using the device.
- Necessary service must be performed only by qualified technicians. Users are not permitted to service this

device.

- The OxyKnight® Watch must not be used together with devices and accessories not specified in the User Manual.

Cautions

- Explosive hazard—DO NOT use the OxyKnight® Watch in environment with inflammable gas such as some ignitable anesthetic agents.
- DO NOT use the OxyKnight® Watchwhile the user is under MRI or CT scanning. This device is NOT MRI Compatible.

Warnings

- Discomfort or pain may occur if using the sensor of this device continuously on the same location for a long time, especially for the users with poor microcirculation.
- Misapplication of a SpO_2 probe with excessive pressure for prolonged

periods can induce pressure injury.

- Place the SpO_2 probe on the finger too tightly will cause venous pulse and effect blood circulation, and lead to interstitial edema, hypoxia and inaccurate measurement.
- Biocompatibility tests have been performed on all the applied parts. Hand eczema may occur. Some exceptional allergic users may get anaphylaxis. Stop using immediately and consult a doctor if you have any allergic reaction.
- For the individual users, there should be a more prudent inspecting in the placing process.

  The sensor cannot be placed on the edema and soft tissue.
- The local law should be followed when disposing of the expired device or its accessories.
- DO NOT operate in the environment

where strong electro-magnetic interference exists, such as radiogram, television, radiophone, etc.

- Please pay attention to the SpO 2probe cable and the USB cable to avoid strangulation and choking.

Attentions

- Keep the Watch away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- If the Watch gets wet, please stop using and do not resume using until it is dry and still work properly. When it is carried from a cold environment to a warm and humid environment, please do not use immediately. Allow at least 15 minutes for the Watch to reach ambient temperature.
- DO NOT operate the button with sharp

objects.

- DO NOT use high temperature or high-pressure steam disinfection on the Watch and probes. Refer to related chapter for instructions regarding cleaning and disinfection.
- The intended use of this device is not for therapy purpose.
- The equipment is IP22 with protection against harmful solid foreign objects and ingress of liquid. So that means the equipment is protected against solid foreign objects of 12.5mm and greater and protected against vertically falling water drops when enclosure tilted up to 15°.
- Please pay attention to the effects of lint, dust, light (including sunlight), etc.

Declaration of Conformity

The manufacturer hereby declares that this device complies with the following

standards:

IEC 60601-1:2005+A1: 2012, IEC60601-1-2:2014,IEC60601-1-11:2010, ISO 80601-2-61:2011 and follows the provisions of the council directive MDD93/42/EEC.

Table of Contents

1.Overview

1.1 Appearance

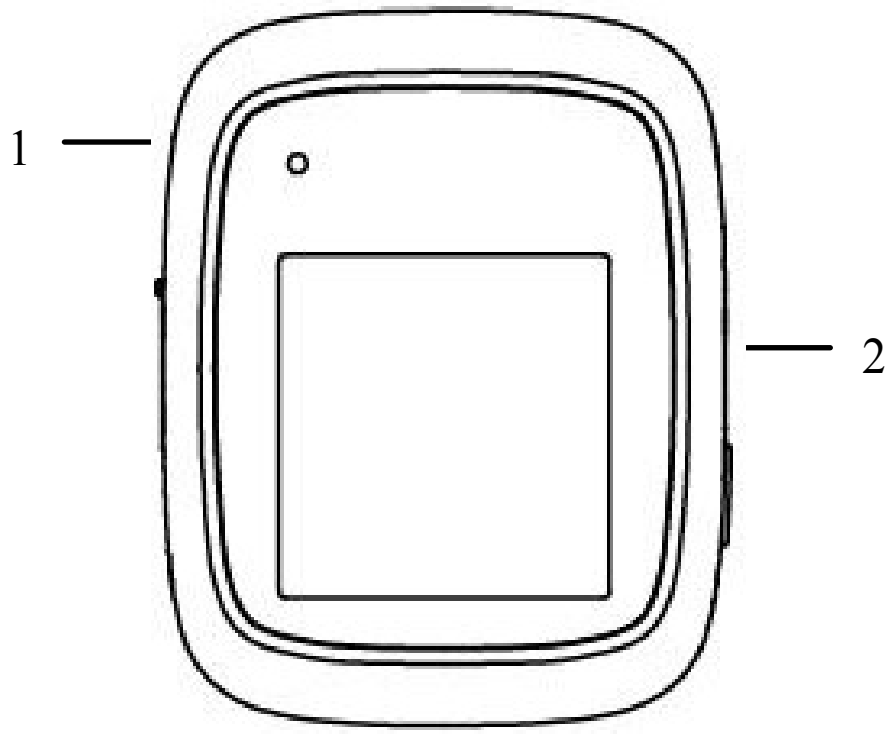


Figure 1 Front view

1. Working status indicator LED.

2. LCD display screen: Display measurement result, Perfusion Index, plethysmograph waveform, etc.

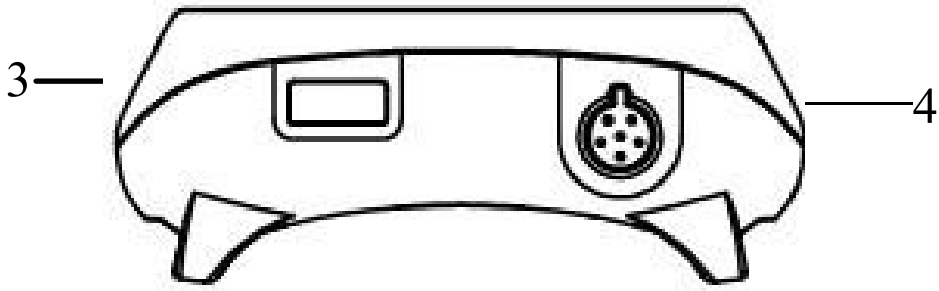


Figure 2 Right side view

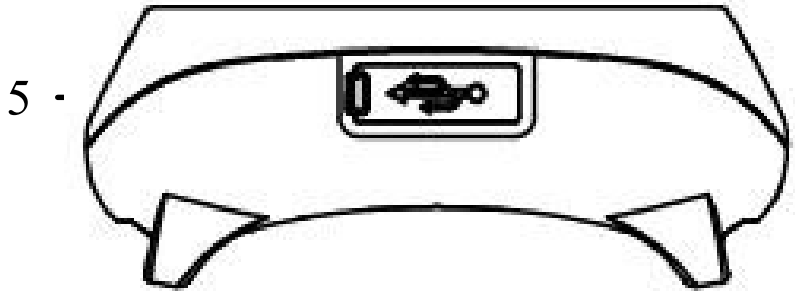


Figure 3 Left side view

3. Power on/off key “ ”: Press and hold to power on/off the device
4. SpO_2 probe connector.
5. Charging Port: Connect with the included USB cable to a 5V power adapter or PC to charge the OxyKnight®Watch

1.2 Product Name and Model

Name: OxyKnight® Watch

Model: OK-10

1.3 Structure

It consists of main unit, SpO_2 probe, acceleration sensor and Bluetooth module.

1.4 Features

- ✧ Bluetooth connectivity (pair with the OxyKnight® Watch App for report and alarm)
- ✧ Lightweight, small in size and easy to wear;
- ✧ 1.44 inch color LCD to display parameters and plethysmogram
- ✧ Body activity recording and analysis function is available;
- ✎ Sleep quality measurement is available; Set
- ✎ ting menu is available;
- ✎ Over-limit alert by vibration of the device. The over limits can be adjusted via the

device menu or Watch APP.

- Convenient to continuously measure and record SpO_2, pulse rate and movement.

1.5 Intended Use

The OxyKnight® Watch is intended for measuring and recording the functional oxygen saturation (SpO_2), pulse rate (PR) and movement. It's applicable forcontinuously tracking of SpO_2, PR and movement while sleeping in hospital, clinics or home.

1.6 Working Environment

Operating temperature: 32-104F

Operating humidity:

15%~93% (non-condensing)

Atmospheric pressure: 70kPa~106kPa

2 Preparation

2.1 Power Supply

- Internal power supply: built-in lithium battery3.7V/500mAh.
- External power supply for charging via USB cable: the power source from USB cable should produce the capacity of 5V DC/1.2A.

2.2 Connection

The illustration of connection among SpO_2 pro be, and OxyKnight® Watch is shown in figure 2.1.

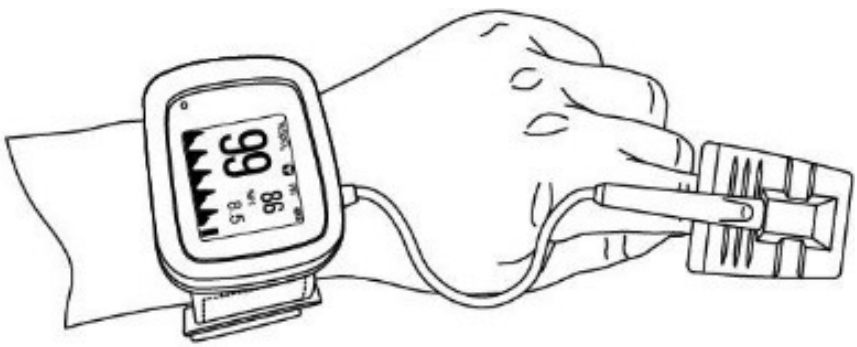


Figure 2.1Oxyknight® Watch with Finger sensor connected

3 Measure Oxygen Level and Pulse Rate

3.1 SpO_2 Measurement

1. Press and hold the power on/off key to turn on the device.

2. ConnecttheSpO2probeto the connector“ ” on the side of the device, the red blinking light from the probe indicates a successful connection. (Note: When disconnecting the connector, be sure pull only the head of the SpO2 connector).

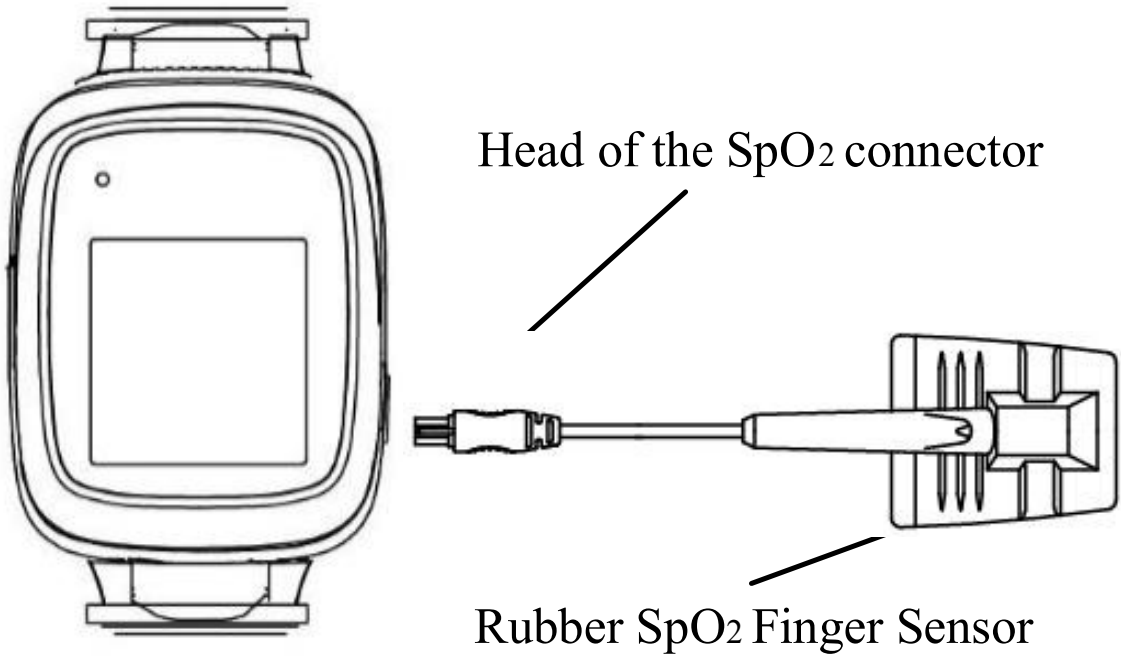


Figure 3.1 SpO2 probe connection

3. Wear the Watch on your left hand.

4. Insert the finger (index finger is preferred, the nail should be not too long) into the probe until the fingernail tip rests against the stop at the

end of the probe (figure3.2). Adjust the finger to be placed evenly on the middle base of the sensor (make sure the finger is in the right position).

Note: If the index finger cannot be positioned correctly, or is not available, another finger can be used.

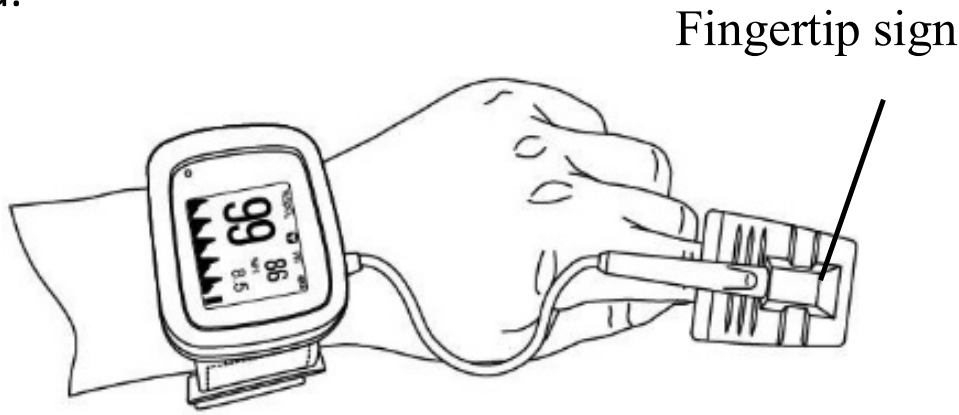


Figure 3.2 Placement illustration

The right placement of probe is as shown in figure3.3A.

Figure 3.3A

The wrong placement of probe is as shown in figure3.33B/3.3C.

Figure 3.3B Fingertip out

Figure 3.3C Not deep enough

5. The Watch will automatically start measurement in 2 seconds when finger is inserted. The display screen is as shown in figure 3.4. User can read the values and view the waveform form the display screen.

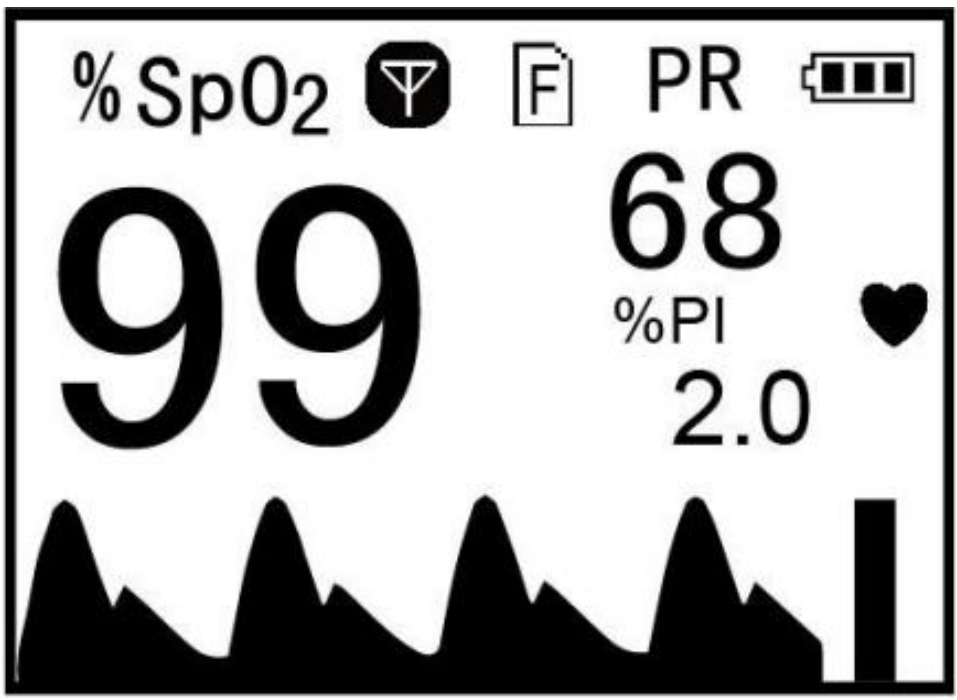


Figure 3.4 SpO_2 measuring screen display

Screen description:

- **"%SpO_2":** SpO_2 label; "99": current SpO_2 value.
- "**PR**": Pulse rate label; "68":current PR value.

- ✧ “%PI”: Perfusion index label; “2.0”: current PI value.
- ✧ “  ”: Pulse beat icon.
- ✧ “  : Pulse strength bar-graph.
- ✧ The displayed waveform is plethysmogram.
- ✧ “  “: Data storage indicator, details see Section 3.4.
- ✧ “  ”: Battery voltage icon.
- ✧ “  ”: Wireless icon. If the wireless (Bluetooth communication) link is setup successfully, the icon will be displayed on the screen; if the icon is flashing, it means device is looking for pairing. If there is no wireless icon, it means the device is not configured with Bluetooth.

Key Operation:

Long press: press and hold the key for over 1 second.

Short press: press the key for less than 1 second

Description for Power indicator:

1) The power indicator is always on during charging.

2) When the screen display is on, the indicator is off.

3) During measuring, short press the power on/off key, then the device will enter power saving mode, turning off the backlight and turning on the power indicator.

Short press the power on/off key again, the power indicator will turn off and device screen display will turn on.

Activate the device during standby status:

When the device is in standby status, then short press power on/off key“[redacted]” can exit from standby status.

3.2 Setting Menu

Double short time press the power on/off key “[redacted]” to enter Menu Setting Screen, as shown in figure3.7.

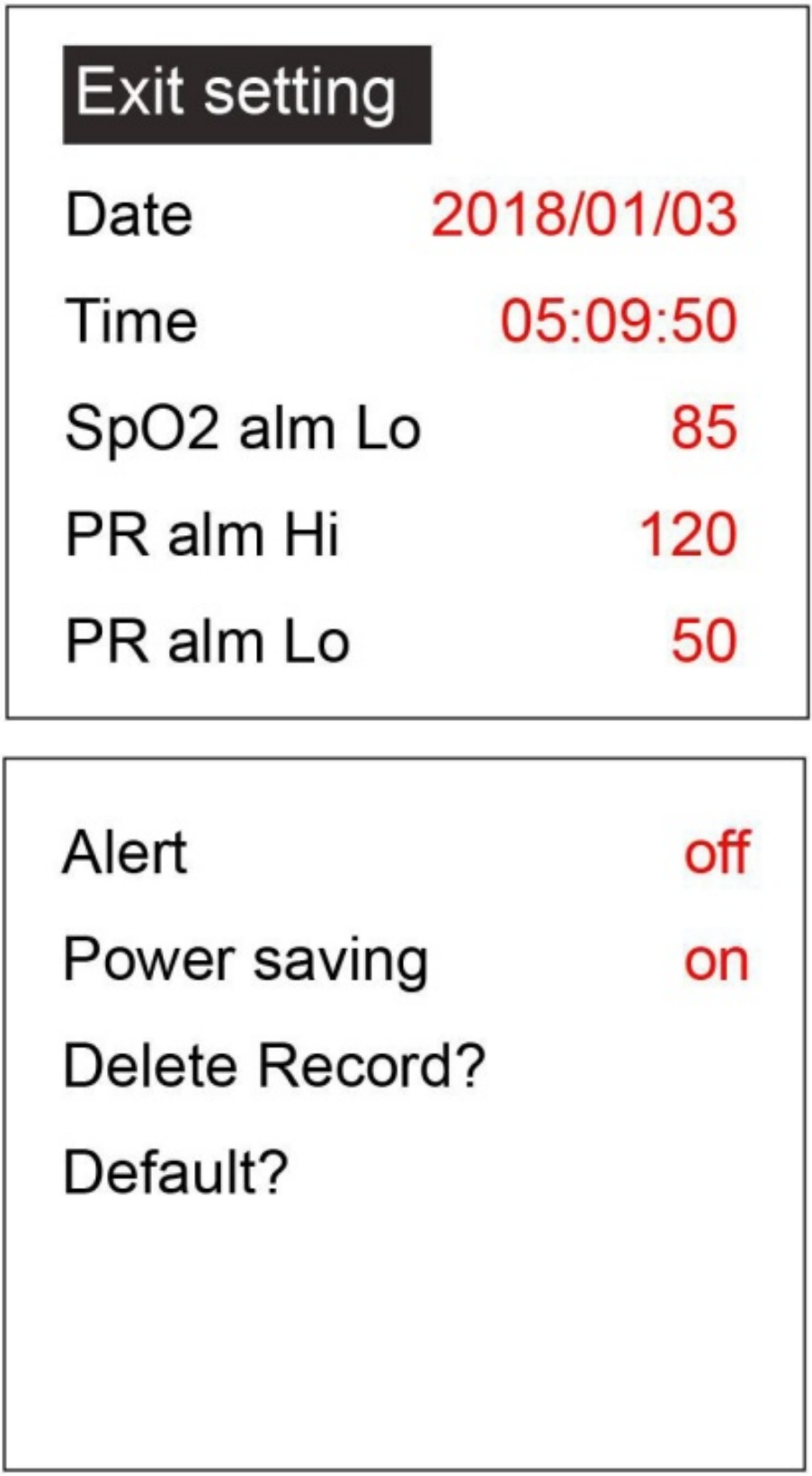

Exit setting
Date 2018/01/03
Time 05:09:50
SpO2 alm Lo 85
PR alm Hi 120
PR alm Lo 50
Alert off
Power saving on
Delete Record?
Default?

Figure 3.7

- ✧ Date: set current date;
- ✧ Time: set current time;
- ✧ SpO2 alm Lo: set SpO2 low limit; Setting range: 85%~100%, default setting:85%;
- ✧ PR alm Lo: set pulse rate low limit; Setting range: 25bpm~99bpm, default setting:50bpm;
- ✧ PR alm Hi: set pulse rate high limit; Setting range: 100bpm~250bpm, default setting: 120bpm;
- ✧ Alert: enable/disable the function of over-limit indication by vibration of the OxyKnight Watch, factory default is “off”.
- ✧ Power saving: turn on/off the power saving mode, factory default is “on”.
- ✧ Delete record: select “Delete record” and long press “ ■■■■ ” key to enter into Deletion Confirmation screen. Then, select “Yes” with

“ [redacted] ” key (short time press), and long pressing “ [redacted] ” key to carry out the deleting action.

- Default: select “Default” and long press” [redacted]” key to enter into Default Setting screen. Then select “Yes” with“ [redacted] ” key (short time press), and long pressing “[redacted]” key to carry out the action of resuming all items to factory setting.

Menu setting operation:

Short time press “[redacted] ” to move the cursor to the item you need to set, and long press “[redacted]” to activate the setting item, then short press it to modify the setting parameter; Next, long press “[redacted]” to confirm the modification and exit from this setting item. At last, move the setting item to “Exit setting” to exit from the setup menu.

3.3 Body Movement Measurement

Wearing the OxyKnight® Watch and making measurement, if you rotate your wrist, then the screen enter into the time indicating screen, as shown in figure 3.8.

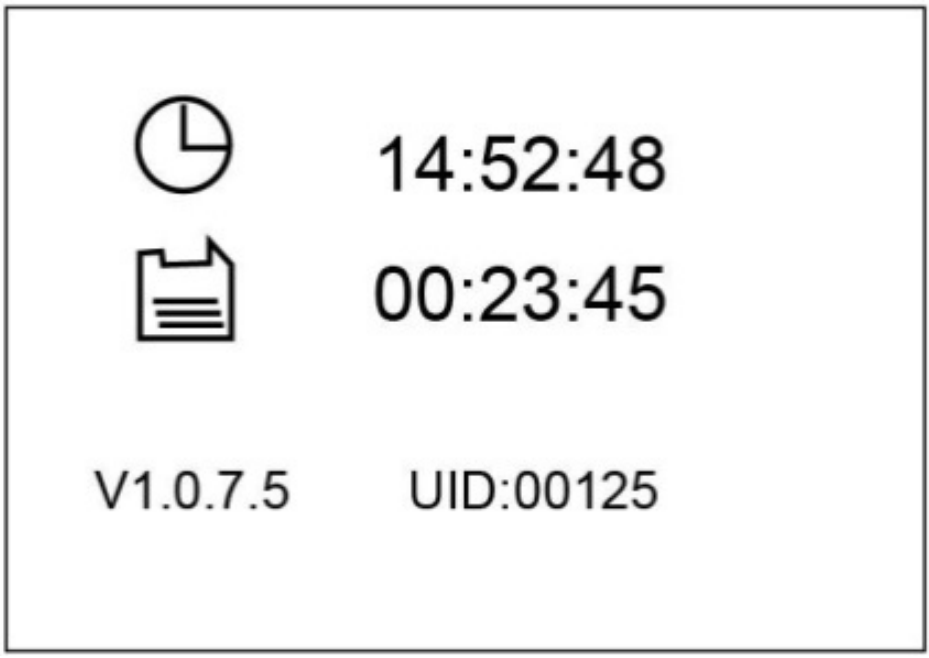
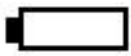


Figure 3.8

- ✧ “14:52:48”: the current time.
- ✧ “00:23:45”: the measuring duration up to now.
- ✧ “V1.0.7.5”: the software version.
- ✧ “UID 00125”: unique ID for the device.

3.4 Additional Information

- During measurement, if the memory is full, then icon "  " appears on the screen, and the device will not store the following measured data again.
- If "  " appears on the screen, it indicates that battery power is not enough, please charge the battery. If you keep on using it, after a while the OxyKnight Watch will be off.
- Do not make measurement when the OxyKnight Watch is charging.
- Avoid shaking finger as possible as you can during measurement.
- Do not wrap wet finger or put wet finger directly into sensor.
- Do not let anything block the emitting light from device.
- Using enamel or other makeup on the nail may affect the measuring accuracy.
- If the first readings appear with poor plethysmogram (irregular or not smooth),

Wait for a while for the more values.

- The measurement records will not be lost, and the settings will not be changed if the power supply of the Oximeter is interrupted. After connecting the power again and turn on the Oximeter, it will resume to normal working.

4 Technical Specification

A. Display Mode: 1.44 inch color LED display

B. SpO_2measurement

Transducer: dual-wavelength LED

LED wavelength:

Red light: 660nm, Infrared light: 905nm

Maximal optical output power: less than 2mW maximum average

Measuring range: 0~100%

Display range: 0~100%

Measuring accuracy: *Arms* value (defined in ISO 80601-2-61) is not greater than 3% for SpO_2 range from 70% to 100%.

Data update: <10s

C. Pulse Rate measurement

Measuring range:30bpm~250bpm

Measuring accuracy: ±2bpm or ±2%

(whichever is greater)

Resolution: 1bpm

D. Perfusion Index Display Range:

0.2%~20%

E. Preset alert limits

SpO_2 Low alert limit: 85%

PR high alert limit: 120bpm

PR low alert limit:50bpm

F. Power Supply:

Built-in lithium battery: 3.70V/500mAh

Operating current: ≤90mA

Continues working time (display is off while measuring continues): about 15 hours

G. Operating environment

Operating

temperature:41~104F

H. Operating humidity:

15%~93% (non-condensing)

Atmospheric pressure: 70kPa~106kPa

I. Performance under low perfusion condition

The accuracy of SpO_2 and PR measurement still meets the specification described above when the modulation amplitude is as low as 0.6%.

J. Resistance to ambient light interference:

The accuracy of SpO_2 and PR measurement still meets the specification described above when the device is tested by SpO_2 simulator (Fluke Biomedical Index 2 series) while setting the emulating interference of sun light and 50Hz/60Hz fluorescent light.

K. Over-limit alert by visible display: If the measured SpO_2, PR, RR exceeds the preset alert limit value, then visible alert should be available.

L. Dimensions: D 56mm× W 44mm×H 16mm

Net Weight: about 45g

M. Bluetooth function

Frequency band: 2.4GHz

Working profile: BLEV4.0

5 Classification

The type of protection against electric shock: Internally powered equipment.

The degree of protection against electric shock: Type BF applied part.

The degree of protection against harmful ingress of liquids: IP22.

Electro-Magnetic Compatibility:

Group I, Class B

6 Packing List

1. Main unit x 1
2. Finger Sensor x 1
3. USB Charging Cable x 1
4. Quick guide x 1

7 Repair and Maintenance

7.1 Maintenance

The service life (not a warranty) of this device is 5 years. In order to ensure its long service life, please pay attention to the maintenance.

- Please charge the device when low battery voltage indicator lightens.
- Please clean the surface of the device before using. Use cloth with alcohol to wipe the device first, and then let it dry in air or wipe it dry.
- There commended storage environment of the device:

  Ambient temperature: -4F~140F, relative humidity 10%~95%, atmospheric pressure: 50kPa~107.4kPa.
- The oximeter is calibrated in the factory before sale, there is no need to calibrate it during its life cycle. However, if it is necessary to verify its precision routinely, the

user can do the verification by means of SpO_2 simulator, or it can be done by contacting our customer service.

⚠ **High-pressure / high temperature sterilization cannot be used on the device.**

⚠ **Do not immerse the device in liquid.**

7.2 Cleaning and Disinfection

- Surface-clean sensor with a soft gauze by wetting with a solution such as 75% isopropyl alcohol, if low-level disinfection is required, use a 1:10 bleach solution. Then surface-clean with a damp cloth and dry with a piece of cloth.
- Clean the wristband with soapy water. Please detach the wristband from the oximeter firstly. (Refer to Appendx for detailed disassembly method)

Caution: Do not sterilize by irradiation steam, or ethylene oxide.

Do not use the sensor if it is damaged.

7.3 Storage and Transportation

If the device will not be used for long period of time, wipe it clean and keep it in the packaging, which shall be kept in a dry and good ventilation place free from dust and corrosive gases.

Storage environment:

Ambient temperature: -4~140F

Relative humidity: 10%~95% (non-condensing)

Atmospheric pressure: 50kPa~107.4kPa

Transportation:

The device should be transported by land (vehicle or railway) or air in accordance with the contractual terms.

Do not hit or drop it with force.

8. Troubleshooting

Trouble	Possible Reason	Solution
The $SpO_2$and Pulse Rate display instable	1. The finger is not placed far enough inside. 2. The finger is not wrapped correctly	1. Place the finger correctly inside and try again. 2. Wrap the finger properly and make the emitter focus on receiver
Cannot turn on the device	1. Low battery voltage 2. The device is malfunctioning.	1. Please charging. 2. Please contact the local service center.
Fragmental SpO_2 waveform	1. Your finger is out of proper location in the probe. 2. Blood flow in the finger blocked. 3. Extreme movement	1. Adjust your finger location properly. 2. Make sure there is no object may occlude the blood flow. 3. Extreme movement may cause invalid measuring result.

Appendix

A Common Knowledge for SpO_2 Measurement

1 .Meaning of SpO_2

SpO_2 is the saturation percentage of oxygen in the blood, so called O_2 concentration in the blood; it is defined by the percentage of oxyhemoglobin (HbO_2) in the total hemoglobin of the arterial blood. SpO_2 is an important physiological parameter to reflect the respiration function; it is calculated by the following method:

$$SpO_2 = HbO_2 / (HbO_2 + Hb) \times 100\%$$

HbO_2 are the oxyhemoglobins (oxygenized hemoglobin), Hb are those hemoglobins which release oxygen.

2 .Principle of Measurement

Based on Lamber-Beer law, the light absorbance of a given substance is directly proportional with its density or concentration. When the light with

certain wavelength emits on human tissue, the measured intensity of light after absorption, reflecting and attenuation in tissue can reflect the structure character of the tissue by which the light passes. Due to that oxygenated hemoglobin (HbO_2) and deoxygenated hemoglobin (Hb) have different absorption character in the spectrum range from red to infrared light (600nm~1000nm wavelength), by using these characteristics, SpO_2 can be determined. SpO_2 measured by this oximeter is the functional oxygen saturation -- a percentage of the hemoglobin that can transport oxygen. In contrast, hemoximeters report fractional oxygen saturation – a percentage of all measured hemoglobin, including dysfunctional hemoglobin, such as carboxyhemoglobin or metahemoglobin.

Clinical application of pulse oximeters: SpO_2 is an important physiological parameter to reflect the re spiration and ventilation function, so SpO_2 measurement used in clinical becomes more popularly, such as monitoring the user with serious respiratory disease, the user under anesthesia

during operation, premature and neonate. The status of SpO_2 can be determined in time by measurement and find the hypoxemia user earlier, thereby preventing or reducing accidental death caused by hypoxia effectively.

3. Factors affecting SpO_2 measuring accuracy (interference reason)

- ✧ Intravascular dyes such as indocyanine green or methyleneblue.
- ✎ Exposure to excessive illumination, such as surgical lamps, bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight.
- ✎ Vascular dyes or external used color-up product such as nail enamel or color skin care.
- ✎ Excessive user movement
- ✎ Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line

- Exposure to the chamber with High pressure oxygen
- There is an arterial occlusion proximal to the sensor
- Blood vessel contraction caused by peripheral vessel hyperkinesias or body temperature decreasing

4. Factors causing low SpO_2 Measuring value (pathology reason)

- Hypoxemia disease, functional lack of HbO_2
- Pigmentation or abnormal oxyhemoglobin level
- Abnormal oxyhemoglobin variation
- Methemoglobin disease
- Sulfhemoglobinemia or arterial occlusion exists near sensor
- Obvious venouspulsations
- Peripheral arterial pulsation becomes weak
- Peripheral blood supply is not enough

B Wristband Installation and Disassembly

Introduction:

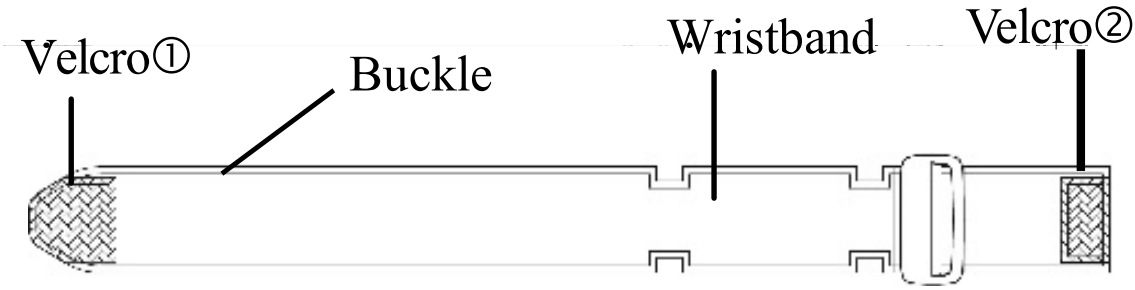


Fig. A

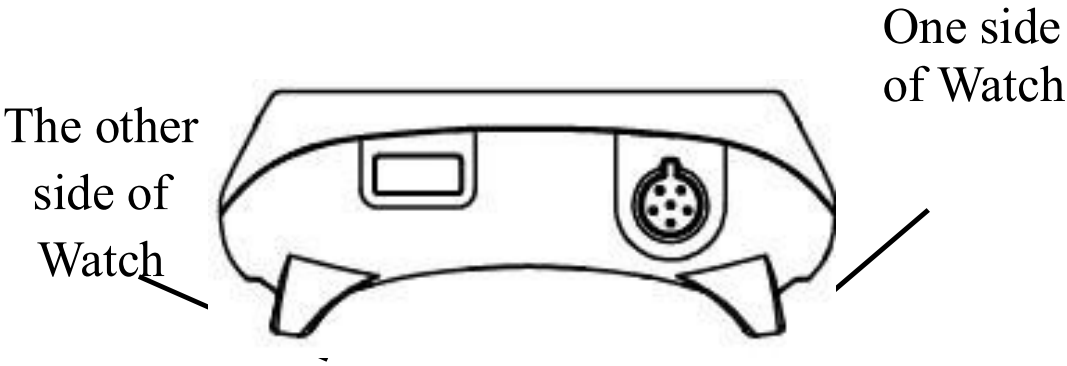


Fig. B The side of the OxyKnight® Watch

Installation Procedure:

Step 1: Insert the wristband to the OxyKnight® Watch from one side to the other side, as shown in Fig. C.

Fig. C

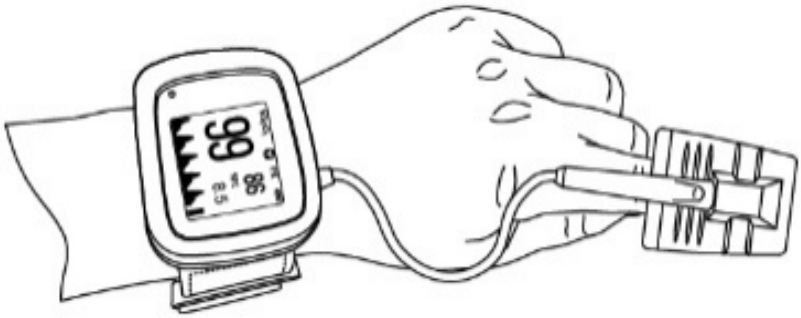
Step 2: Put the Watch on the wrist, and stick the Velcro to the inner side of wristband, press the wristband to make the Velcro stick to the inner side of wristband firmly, as shown in Fig. D.

Fig. D

Fig. E

Step 3: Bring the wristband out from the buckle, and fold back the wristband, as shown in Fig.E. Then press the Velcro to make it stick to the

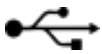
outer side of wristband firmly, as shown in Fig.F.



Disassembly: The process of wristband disassembly is similar to the installation method, but with reverse procedure.

Watch before cleaning the wristband.

C Key of Symbol

Symbol		Description
Symbols on the enclosure		With Type BF applied part
		See User Manual
		Data interface
	SN	Serial number
		No alarm
		Do not litter at will
		Life span
Symbols on the screen	**%SpO_2**	The oxygen saturation
	%PI	Perfusion Index
	PR	Pulse rate
		Respiration rate

		Pulse beat
		Wireless
		Pulse strength bar-graph
		Low battery voltage
		Memory full
		Memory error

Note: the above symbol may appear on your device.

Telomed, Inc.

5975 Shiloh Rd., Suite 114

Alpharetta, GA 30005

Tel: 1-800-86 4-5788

Email: info@telomedllc.com

Website: www.telomed.us