BabyO2™

Pulse Oximeter

User Manual

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Website: www.welluehealth.com

Contents

1　Introduction

1.1　Intended use

This Pulse Oximeter is intended to be used for measuring the pulse oxygen saturation (SpO2), pulse rate of adults, children and newborns in home or healthcare facilities environment.

1.2　Contraindications

No contraindications.

1.3　Warnings and Cautions

- DO NOT twist the sensor and the wrap or apply excessive force on them.
- Do not use this device during MRI examination.
- Do not store the device in the following locations: locations in which the device is exposed to direct sunlight, high temperatures or levels of moisture, or heavy contamination; locations near to sources of water or fire; or locations that are subject to strong electromagnetic influences.
- Do not use the device in a combustible environment.
- Never submerge the device in water or other liquids.
- Do not clean the device with acetone or other volatile solutions.
- Do not drop this device or subject it to strong impact.
- The device and accessories are provided non-sterile.
- Do not place this device in pressure vessels or gas sterilization device.
- Do not dismantle the device, as this could cause damage or malfunctions or impede the operation of the device.
- Consult your doctor immediately if you experience symptoms that could indicate acute disease.
- Do not self-diagnose or self-medicate on the basis of this device without consulting your doctor. In particular, do not start taking any new medication or change the type and/or dosage of any existing medication without prior approval.
- Use only cables, sensors and other accessories specified in this manual.
- Prolonged continuous monitoring may increase the risk of

undesirable changes in skin characteristics, such as irritation, reddening, blistering or burns.
- Do not open the device cover without authorization. The cover should only be opened by a qualified service personnel.
- The biocompatibility testing has been performed on the materials in contact with the person in accordance with ISO10993.
- Do not place the SpO2 probe on a finger with edema or fragile tissue.
- Check the SpO2 sensor and cable before use. Do not use a damaged SpO2 sensor.
- Check the SpO2 sensor application site every 6-8 hours to determine the positioning of the sensor and the circulation and skin sensitivity of the patient. Patient sensitivity varies depending on medical status or skin condition. For patients with poor peripheral blood circulation or sensitive skin, inspect the sensor site more frequently.
- The functional tester cannot be used to assess the accuracy of the SpO2 sensor or a device.
- The device has no alarm system.
- The local laws and regulations should be followed when disposing of the device and accessories.
- The battery inside this product cannot be replaced

1.4 Unpacking
- Device (main unit)
- Sensor cable
- Soft wraps
- User Manual
- Data/Charging Cable

2 Overview
Name: Pulse Oximeter
Model: PO5, PO5-1, PO5-2, PO5-3

- Device（main unit）:
  Display device status and testing results.
- Sensor cable:

Connect the sensor and device.
- Soft wraps:
  Secure the sensor and the device.
- Data/Charging Cable:
  Can be charged and data transmission.

3   Using the device and App

3.1   Download App

App name: **ViHealth**

iOS: **App Store**

Android: **Google Play**

Notice: if you have installed the App before, please update it to the latest version.

3.2   Charging

Charge the battery before using.

Connect the device to USB of computer or USB charging adapter with the supplied cable.

After fully charged, the device will power off automatically.

Note: The device cannot be used during charging, and if choosing a third party charging adaptor (Class II), select one that complies with IEC60950 or IEC60601-1.

3.3   POWER ON/OFF

POWER ON:

Press the side button for 2 seconds.

POWER OFF:

3 ways:

- Press the side button for 2 seconds.
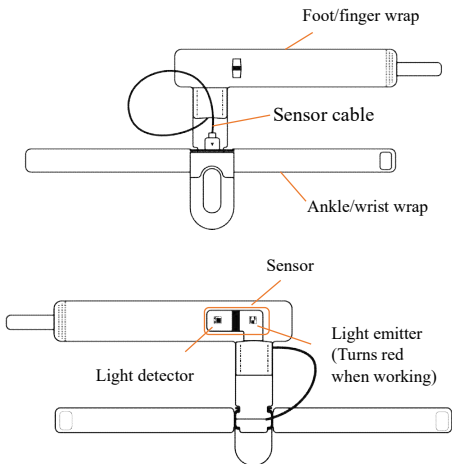- Unplug the sensor cable, it will power off automatically

if not connected to phone for 2 minutes.

• Even with sensor cable connected, it will power off automatically if no working for 10 minutes.

3.4   Placement Guide before working

To ensure that the measurement is performed normally, please follow the steps below to wear the device.

**1)   Plug the sensor cable into the device**

Foot/finger wrap

Sensor cable

Ankle/wrist wrap

Sensor

Light emitter (Turns red when working)

Light detector

2）Secure the sensor(For newborn)

A.   Place the foot wrap on the foot (either foot works), with the sensor part running on the outside edge of

6
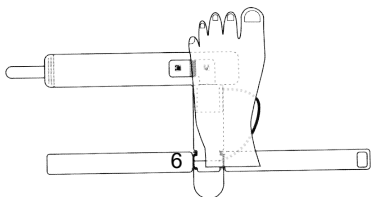
the foot. The device should be oriented to the baby's leg.

B. Put the foot wrap around the foot and attach the velcro securely with no gap between the foot wrap and the baby's skin. **The light emitter and the light detector should be opposite to each other on the two sides of the foot.**

Light detector
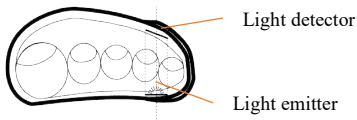
Light emitter

Note:

For the right foot, the Light Emitter should be on the top; for the left foot, the Light Emitter should be on the bottom.

C. Put the ankle wrap around the ankle, attach the velcro to secure the device.
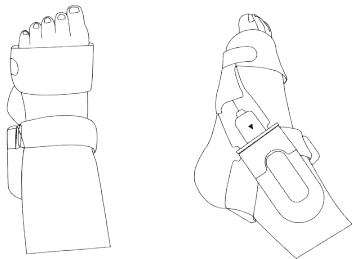
3) Secure the sensor (For adult/child)

A. Tie the finger wrap with the sensor to the finger of the appropriate size.

B. The sensor cable should run along the direction of the palm.

C. The light emitter and the light detector should be opposite to each other on the two sides of the finger.

D. Put the finger wrap around the finger and attach the velcro securely with no gap between the finger wrap and the skin.

E. Plug the sensor cable into the device.

F. Put the wrist wrap around the wrist, attach the velcro to secure the device.

3.5 Start working

After the placement, press the side button for 2 seconds to power on. There should be red light inside the soft wrap.

After displaying time and battery, you can change the reminder settings with side button (usually you can do nothing). You can also change the settings in App (illustrated later). It's easier to set in App.

Oxygen level   Pulse rate

20:03

98% ▌116

Pulse bar
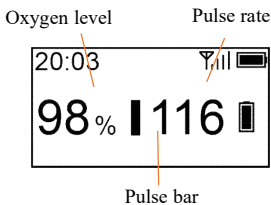
After a few seconds, readings will be displayed on the screen.

If the screen display "poor signal", please check if the sensor has been positioned and secured properly.

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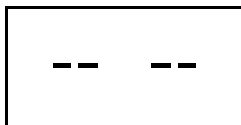
When the above symbol displays on device screen, it indicates the readings is unavailable right now.

When at rest, there will be readings in a few seconds. If you can't get readings for a long time, it may be caused by:

- Improper sensor placement
- Frequent movement
- Foot or finger is too cold

Run App to connect the device, you can check the real-time readings in App Dashboard. (The detail of using App will be illustrated later)

Notice:
- If the working time is less than 2 minute, the data will not be saved.
- Motion may cause readings unavailable. Readings recover very soon at rest.
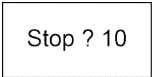- Please avoid strong ambient light condition.

SpO_2 measurement principle:

The Pulse Oximeter is a lightweight, portable health oximeter for use in the home or in healthcare facilities. SpO_2

measurement technology is based on developed photoelectron method, the circuit design and calculation software was developed by Shenzhen Viatom Technology Co., Ltd. The SpO_2 sensor receives the optical signal from the red light and infra-red light through the finger. Insert the finger into the oximeter, there are two emitting tube (red light diodes and infrared diodes) located on the inner upside of the sensor and they can emit red light and infrared; There is the receiving end located on the inner downside of the sensor, and it can transmit the red light and infrared into the pulse signal through finger. The MCU receives the pulse signal, gets the frequency signal by counting, processes its digital signal, and finally gets the measured SpO_2 value. The PR is averagely calculated by above peak intervals of PR waveform.

3.6   Stop working & sync data

Unplug the sensor cable, the countdown on the screen will begin.

Stop ? 10

During the countdown, if you plug the sensor cable again, the record will be resumed.

After the countdown, the **data will be ready for sync**.

Notice:

- If the working time is less than 2 minute, there will be no data saved
- If the device power off during working, the data should have been saved.

Sync data:

- After the countdown, run App to sync data; If App has already opened, go to History page to sync data.
- **You can also sync data later.** The built-in memory can

store 4 sessions. The oldest will be overwritten by the 5th. Please sync data to your phone in time.

Notice: The built-in memory can store 4 sessions, up to 10 hours for each. It will start the next session automatically after 10 hours monitoring.

3.7   Screen wake up / change display

During measurement, the screen will go off automatically for saving power; you can press the side button to wake up the screen or change display.

3.8   Bluetooth Connection

The device Bluetooth will be enabled automatically after it's turned on.

To establish a Bluetooth connection,

1) Power on the device.
2) Make sure the phone Bluetooth is enabled.
3) Run the App.
4) Allow the App to use Bluetooth.

Notice:

● **DO NOT PAIR** in the settings of your smartphone.

3.9   Add a new device

For the initial use, you need to add a new device.

1) Turn on device, run App, select <BabyO2>;
2) Follow the App instruction to add the new device.

3.10   App Dashboard

In App Dashboard, you can view:

- Real-time oxygen Level, heart rate;
- Near term trends of oxygen level, heart rate and motion.
- PI (Perfusion Index). If too weak (being red), please check if the sensor has been positioned and secured properly.
- Bluetooth signal. If too weak, place phone closer to the device.
- Device battery level
- Reminder info
- Help info

3.11   Audio reminder in Device

You can configure it in **App-Settings** when your device is connected to App.

- You can **switch on or off** the reminder.
- You can adjust the volume of the reminder.
- You can adjust the **Threshold**.

The reminder will stop when oxygen level recover, or you can press the side button to stop it.

3.12   Audio reminder in App

You can configure it in **App-Settings**.

- You can **switch on or off** the reminder.
- You can adjust the **Threshold**.

The volume is same as your phone's volume.

The Reminder works only when your phone stayed in Dashboard and not locked.

The Reminder in Dashboard will be activated when the oxygen level fall below the pre-set value (Threshold).

The Reminder will stop when the oxygen level recover. You can press the Mute icon on Dashboard to mute.

3.13   View Report

In App->History,

- Tap an item in the list, you can check the detailed report, which includes analysis results and diagrams.
- Slide an item to left, you can delete it.

3.14   App Offline Mode | Multiple Devices

If you enter App Offline Mode, you can view history data, in App Settings->Select Device, you can select device **if you have multiple devices**. In this Mode, device is not connected so you cannot sync data or set device.

4   PC software

PC Software: O2 Insight Pro

Download from: www.getbabytone.com

Enter top menu: Support->PC Software

Install the software on windows (win 7/8/10) or Mac OS(10.13 or above).

To use the software,

1) Turn on device, connect the device to PC USB port with the supplied Cable. **Don't connect device to App** when you want to connect to PC Software.
2) Run the PC software, click the **Download** button to

download data from the device

With the PC software, you can view and print report, which can also be exported as PDF or CSV files.

5   Maintenance

5.1   Time & Date

After connection with App, device time will sync from your phone time automatically.

5.2   Cleaning

Clean the device with a soft, dry cloth with 75% alcohol.

Clear the wrap with water. Water temperature should be lower than 104°F (40°C)

Clean the sensor carefully with cloth soaked 75% alcohol, if it is dirty or dusty.

Note: The device is a non-sterile medical device and does not contain any sterile or degradable component thus the device is not subject to the shelf-life requirements.

6   Troubleshooting

| Problem	Possible Cause	Possible Solution
No readings on screen	The sensor is not positioned and secured properly	Check if the sensor has been positioned and secured properly
	Baby is moving frequently	It will recover when at rest
Device does not	Battery may be low.	Charge battery and try again.

turn on or no response	Device might be damaged.	Please contact your local distributor.
The app cannot find the device	The Bluetooth of your phone is off.	Turn on the Bluetooth in the phone.
	The device Bluetooth is off.	Turn on device
	The App is not allowed to use Bluetooth	Allow the App to use Bluetooth
	For **Android**, Bluetooth cannot work without location permission	Allow location access

7   Specifications

Environmental	Operating	Storage
Temperature	5 to 40°C	-25 to 55°C
Relative humidity (noncondensing)	10% to 80%	10% to 93%
Barometric	700 to 1060hPa	700 to 1060hPa
Protection against electric shock	Internally powered equipment	
Degree protection against electrical shock	Type BF	
Electro-magnetic compatibility	Group I, Class B	
Degree of dust & water resistance	IP22	
Weight	31g	

	(main unit with band and sensor)
Display	OLED
Size	49×27×14 mm (main unit)
Battery	5Vdc, Rechargeable Lithium-polymer
Charge time	2 hours
Battery life	16 hours for typical use
Wireless	Bluetooth 4.2 BLE
Oxygen level range	0% to 100%
Oxygen level Accuracy (Arms)	70-100%:±2%, 0%-69%:Undefined
A functional tester or SpO2 simulator can be used to determine the pulse rate accuracy.	
Heart Rate range	20 to 250 bpm
Heart Rate accuracy	±2 bpm or ±2%, whichever is greater
Wavelength / Max emission power	660nm/940nm, 0.8mW/1.2mW
SpO2 data update period	1s
Reminder	Triggered by low oxygen level
Recorded parameters	Oxygen level, Heart Rate
Data storage	4 sessions, up to 10 hours for each
Frequency range	2.402 – 2.480 GHz
Max RF power	-5.15 dBm
Expected service life	5 years
Mobile App for iOS	iOS 9.0 or above, iPhone 4s/ iPad 3 or above
Mobile App for android	Android 5.0 or above, with Bluetooth 4.2 BLE

8 Symbols

Symbol	Description
![Manufacturer]	Manufacturer
![Date]	Date of manufacture
SN	Serial number
![WEEE]	Indicate separate collection for electrical and electronic equipment (WEEE).
![Follow IFU]	Follow Instructions for Use.
![Type BF]	Type BF Applied Part
![No alarm]	No alarm system
![MR unsafe]	MRI unsafe. Presents hazards in all MR environments as device contains strongly ferromagnetic materials.
IP22	Resistant to liquid ingress
$C\,\epsilon$	CE marking
EC | REP	Authorized representative in the European community
![FCC]	This product complies with the rules and regulations of the Federal Communication Commission.

Symbol	Description
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation

FCC Statement

FCC Warning:

FCC ID: 2ADXK-4728

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) this device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-Consult the dealer or an experienced radio/TV technician for help.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure

condition without restriction.

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Model: PO5, PO5-1, PO5-2, PO5-3

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