Pulse Oximeter

Software version: V1.1
Manual Ver : 1.4
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The pulse oximeter has two types of screen for option.

（1）LED screen

（2）OLED screen

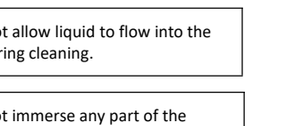
General Description

SpO2 stands for peripheral capillary oxygen saturation. Oxygen saturation is defined as the ratio of oxyhemoglobin (HbO2) to the total concentration of hemoglobin (i.e. Oxyhemoglobin + reduced hemoglobin) present in the blood. It is an important physiological parameter involved in respiration and circulation. The Pulse Oximeter feature herein is small, portable, non-invasive and easy to use. The user only needs to insert a finger into the chamber to measure his/her SpO2 and pulse rate.

Measurement Principle

Oxygenated blood absorbs light preferentially at 905nm (near infrared light), whereas deoxygenated blood absorbs light preferentially at 660nm (red light). A pulse oximeter works by passing a beam of red and infrared light through a pulsating capillary bed and then measure the amount of red and infrared light emerging from the tissues via a sensor. To improve accuracy, the iP900AP uses a proprietary algorithm to collect data from pulsatile arterial blood and excludes local noise from the tissues. The relative absorption of light by oxyhemoglobin (HbO) and deoxyhemoglobin is then calculated according to the Beer-Lambert's law and a quantitative measurement of the users' oxyhemoglobin status i.e. Oxygen saturation level (SpO2) is derived.

Due to the sensitivity of the pulse oximeter, finger should be kept stationary during measurement. It is recommended that you use this device for measurement before or after sports. Do not use for continuous monitoring.



Attention: Do not use any strong dissolving agent such as acetone.

Attention: Do not rub the body of the instrument using materials such as steel wire balls or polished metal objects.

Attention: Ensure that there is no washing liquid on the surface of the instrument.

Caution: Do not allow liquid to flow into the instrument during cleaning.

Caution: Do not immerse any part of the instrument into any liquid.

2. Disinfection

Before measurement with the instrument, wipe the silicon finger pad using a piece of dry soft cloth dipped with 75% medical alcohol. Clean the finger to be measured using the medical alcohol for disinfection purposes before and after use.

⚠ Do not disinfect the instrument by using high-temperature/high-pressure disinfecting gas.

Maintenance and Storage

1. Replace the batteries in time when low voltage lamp is lighted.
2. Clean surface of the fingertip oximeter before it is used in diagnosis for users.
3. Remove the batteries inside the battery cassette if the oximeter will not be operated for a long time.
4. It is best to preserve the product in a place where ambient temperatures is -20℃~70℃ (-4°F～158°F) and relative humidity is 10%-95%.
5. It is recommended that the product should be kept in a dry environment anytime. A wet ambient might affect its lifetime and even might damage the product.
6. Avoid exposure or direct sunlight.
7. Avoid excessive radioactive infrared rays or ultraviolet rays.
   Please follow the law of the local government to deal with used battery.

Technical Specification

1. Display Type:
LED screen
OLED screen

2. SpO2:
Measurement range: 35%-100%
Resolution: 1%
Accuracy: 70%-100%, ±2%; < 70% no definition.

3. Pulse Rate:
Measurement range: 25bpm -250bpm
Resolution: 1bpm

Accuracy : ± 3bpm
Pulse Intensity: Bargraph Indicator (only for OLED screen)

4. Perfusion Index (only for OLED screen):
Measurement range: 0%~50%
Resolution: 1%
Accuracy : 0.1% (0%~1%) ; 1% (1%~20%) ;
>20%no definition.

5. Power Requirements:
Two AAA alkaline Batteries
Power consumption: 30mA(Normal)
Low power indication:
Battery Life: Two AAA 1.5V, 600mAh alkaline batteries could be continuously operated as long as 24 hours.
6. Dimension:
Length: 63mm Width: 36mm Height: 39mm

Weight: 43g (without battery)

7. Environment Requirements:
Operation Temperature: 0℃~50℃ (32°F ~ 122°F)
Storage Temperature: -20℃~70℃ (-4°F ~ 158°F)
Ambient Humidity:≤80%RH, no condensation in operation.
≤93%RH, no condensation in storage

8. Measurement Performance in Low Perfusion Condition:0.3%.

Declaration

EMC of this product complies with IEC60601-1-2 standard. The materials which the user can come into contact have no toxicity and no action on tissues comply with ISO10993-1, ISO10993-5 and ISO10993-10.

Precautions For Use

1 Do not use the pulse oximeter in an MRI or CT environment.

2 **Explosion hazard:** Do not use the pulse oximeter in an explosive atmosphere.

3 The pulse oximeter is intended only as an adjunct in user assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.

4 Check the pulse oximeter sensor application site frequently to determine the positioning of the sensor and circulation and skin sensitivity of the user.

5 Do not stretch the adhesive tape while applying the pulse oximeter sensor. This may cause inaccurate readings or skin blisters.

6 Before use, carefully read the manual.

7 The pulse oximeter has SpO2 alarms; it is not for continuous monitoring.

8 Prolonged use or the user's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.

9 Inaccurate measurements may be caused by autoclaving, ethyleneoxide sterilizing, or immersing the sensors in liquid.

10 Significant levels of dysfunctional hemoglobins (such as carbonxy- hemoglobin or methemoglobin) may cause inaccurate readings.

11 Intravascular dyes such as indocyanine green or methylene blue.

12 SpO2 measurements may be adversely affected in the presence of high ambient light. Shield the sensor area (with a surgical towel, or direct sunlight, for example) if necessary.

13 Excessive user movement may cause inaccurate readings.

14 Venous pulsations may cause inaccurate readings.

15 High-frequency electrosurgical interference may cause inaccurate readings.

16 Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.

17 The user has hypotension, severe vasoconstriction, severe anemia, or hypothermia.

18 The user is in cardiac arrest or is in shock.

19 Fingernail polish or false fingernails may cause inaccurate SpO2 readings.

20 This pulse oximeter is not a medical device and is not intended to diagnose and/or treat any medical condition or disease. It is intended for non-medical use by healthy people to monitor their pulse rate and blood oxygen levels. It is for sports and/or aviation use. People who need SpO2 and pulse rate measurements because of a medical condition should consult with their physician.

Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.

Product Features

- Lightweight, portable and easy to use.
- Dual-color OLED screen shows pulse rate, SpO2, plethysmograph, bar graph and perfusion index; While LED screen shows pulse rate & SpO2.
- Large font display.
- Alarm function.
- Low battery indicator.
- Auto shut down if no signal is detected within15 seconds.
- Low power consumption.

Intended Use

The pulse oximeter is a reusable device and intended for spot-checking of oxygen saturation and pulse rate for use with the finger of adult patients in healthcare environments.

Operation Instructions

1.Install two AAA batteries into battery compartment correctly.
2. Insert one of your fingers into the finger chamber of the pulse oximeter.
Note: The fingernail should be facing the top chamber (which contains the sensor). Finger should also be inserted completely into the chamber. Otherwise, measurement will be inaccurate.
3. Press the power-on button to turn on the pulse oximeter.
4. Finger and body should not tremble during measuring.
5. Read correct data from displayed screen.

Remind Setup	✱
Sound Reminder	on
Beep	off
Demo	off
Restore	ok
Brightness	4
Exit	

Limit Setup	✱
SpO2 Hi	100
SpO2 Lo	94
PR Hi	130
PR Lo	50
+/-	+
Exit	

The following operation is only for OLED screen:
Keep pressing the power on button for a second to enter the setting interface.

Press the power on button once to switch among the settings, keep pressing the button for a second to change the current settings of sounds on or off and other parameters.

Notes:

✧When your finger is inserted into the oximeter, your nail surface must be upward.
✧The results may be wrong if you do not place your finger thoroughly in the oximeter.
✧Please use medical alcohol to clean the silicon touching the finger inside of oximeter, and clean the test finger using alcohol before and after each test. (The silicon inside of the oximeter belongs medical silicon, which has no toxin and no harmful to the skin).

Possible Problems and Resolutions

Problems	Possible reason	Solution
The Oximeter fails to display the blood oxygen saturation levels and/or pulse rate.	1. The finger is not placed between the sensor and the Light Emitting Diode. 2. The user's blood perfusion is too low to be detected.	1. Make sure that the finger is placed right in between the sensor and the Light Emitting Diode. 2. Make sure nothing is restricting your blood flow.
SpO2 or PR is shown unstably	1. The finger is not placed between the sensor and the Light Emitting Diode. 2. The user is moving his/her finger and/or body.	1. Make sure that the finger is placed right in between the sensor and the Light Emitting Diode. 2. Try to stay still during measurement.
The Oximeter can not be powered on	1. The batteries are drained. 2. The batteries are incorrectly installed. 3. The Oximeter is defective and/or damaged.	1. Replace the batteries. 2. Please refer to section 2.8.1 on how to install the battery correctly. 3. Contact the distributor.
The screen are suddenly off	1. If the Oximeter does not detect any signal within 15 seconds, it will automatically power off. 2. The batteries are drained.	1. This is normal. Just turn on the pulse oximeter again. 2. Replace the batteries.

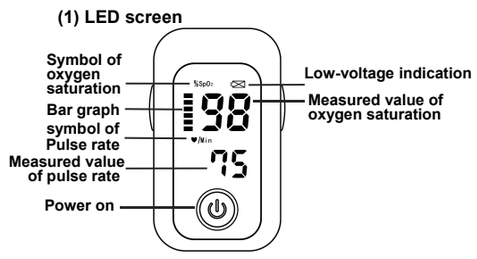
There are no user-serviceable parts inside the oximeter. The cover should only be removed by qualified service personnel.
If you are uncertain about the accuracy of any measurement, check the user's vital signs by alternate means; then make sure the oximeter is functioning correctly.
Do not spray, pour, or spill any liquid on the oximeter, itsaccessories, connectors, switches, or openings in the enclosure as this may damage the oximeter.

Guidance and manufacturer's declaration-electromagnetic emissions-for all EQUIPMENT and SYSTEMS

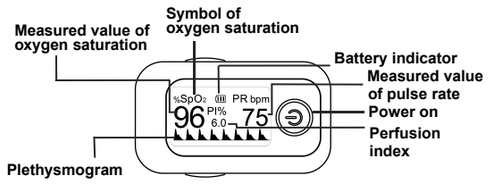
Guidance and manufacturer's declaration – electromagnetic emission		
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Pulse Oximeter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The Pulse Oximeter is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply. network that supplies buildings used for domestic purposes.

Brief Description of Front Panel

(1) LED screen



(2) OLED screen



The pulse bar graph displays corresponding with the user's pulse beat. The height of the bar graph shows the user's pulse strength.

Product Accessories

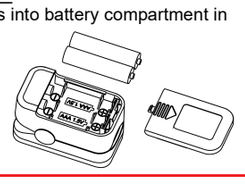
1. Pulse oximeter*1 pc
2. User manual*1 pc
3. Lanyard*1pc

Battery Installation

1. Put the two AAA batteries into battery compartment in correct polarities.

Notes:

✧ Battery polarities should be correctly installed. Otherwise, damage may be caused to the device.



✧ Please remove the batteries if the Oximeter will not be used for a long time.

Installing the Lanyard

Thread the thin end of the lanyard through the lanyard hole, and thread the coarse end of the lanyard through the thin end of the lanyard, and tighten the lanyard.

Cleaning and Disinfection

1. To clean the instrument, power off and remove the batteries first. Then clean the outer surface of the instrument (including the screen) using a piece of dry soft cloth dipped with 75% medical alcohol. Do not immerse the unit in alcohol!

Symbol Definitions

Symbol	Definition
	Type BF equipment
	Attention, consult accompanying documents.
%SpO2	Oxygen saturation
♥/Min	Pulse rate
	Symbol for the marking of electrical and electronics devices according to Directive 200296/EC. The device, accessories and the packaging have to be disposed of waste correctly at the end of the usage. Please follow Local Ordinances or Regulations for disposal. Note: The Oximeter is applied to this regulation.

Note：The illustration used in this manual may differ slightly from the appearance of the actual product.

FCC STATEMENT

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.

FCC Radiation Exposure Statement:
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment .
This transmitter must not be co located or operating in conjunction with any other antenna or transmitter.

Use your mobile phone to test the Bluetooth function, download "nRF Connect" on an Android phone, as shown in Figure 3, download it on an iPhone

1.

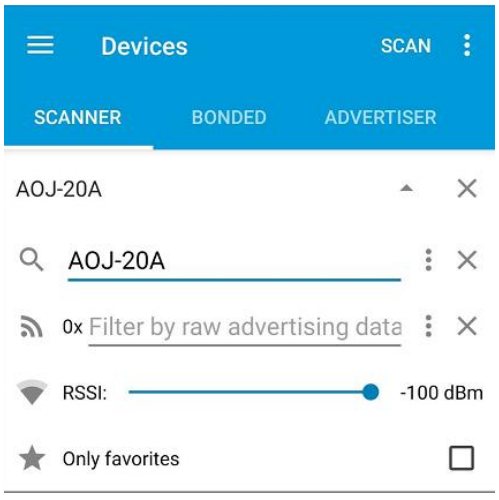
"LightBlue", As shown in Figure 4;

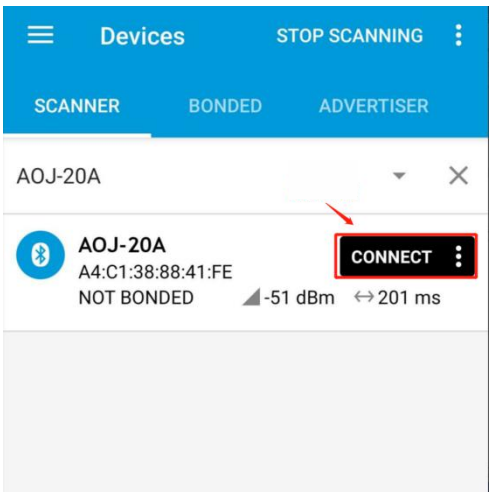
nRF Connect

LightBlue® Explorer

F3 F4

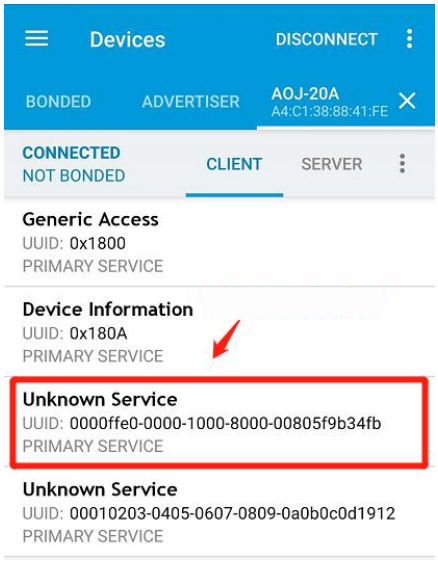
2. Take nRF Connect as an example. After entering the APP, open Bluetooth and fill in the filter Bluetooth name "AOJ-20A", as shown in Figure 5. Pull down to refresh and you will only see the name "AOJ-20A". If there are more than one, select For the device with the strongest signal, you can also enhance the RSSI to -60dBm filtering, click CONNECT to connect, as shown in Figure 6;



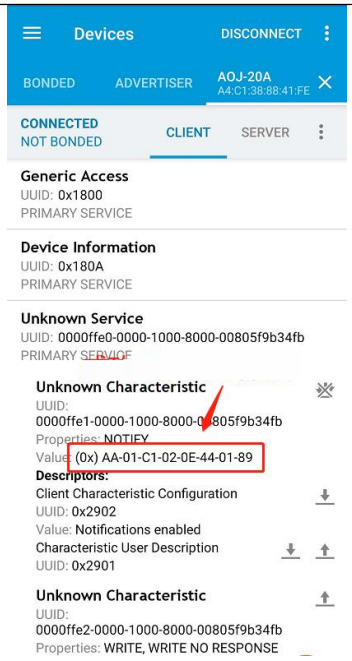


F5 F6

Turn on the Bluetooth receiving service, as shown in Figure 7; perform a normal measurement and check the received Bluetooth data, as shown in Figure 8;

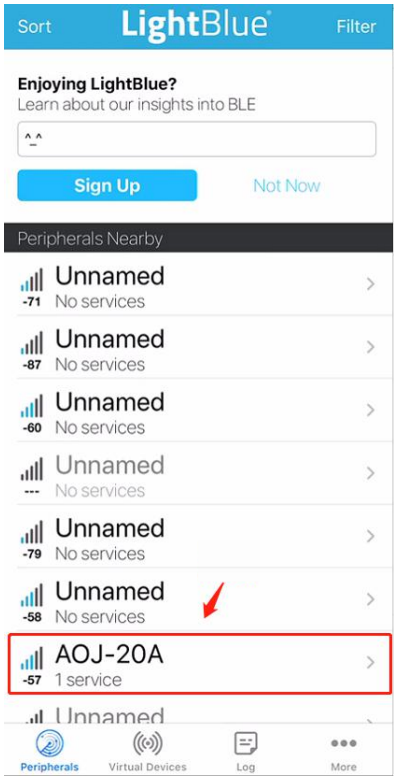


F7

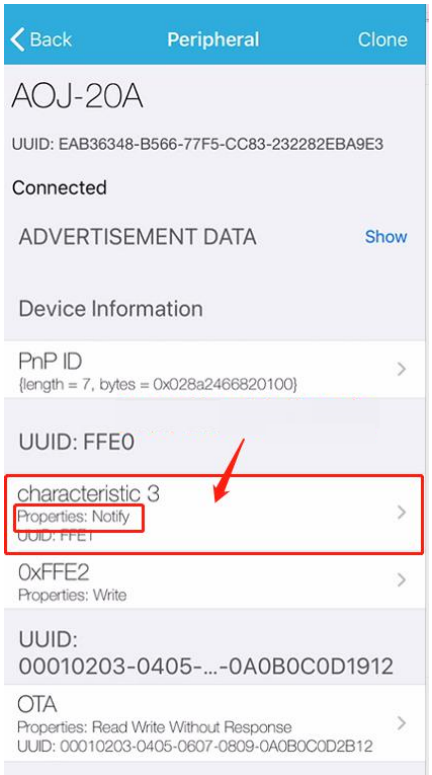


F8

3.For LightBlue, after entering the APP, turn on Bluetooth, pull down to refresh and find the device with the name "AOJ-20A". If there are more than one, select the device with the strongest signal. You can also adjust the Filter to -60dBm and click connect, as shown in Figure 9. Show; turn on the Bluetooth receiving service, as shown in Figure 10;

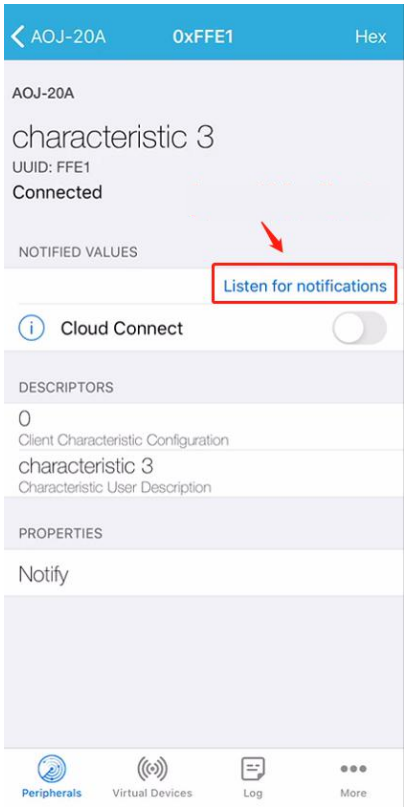


F9

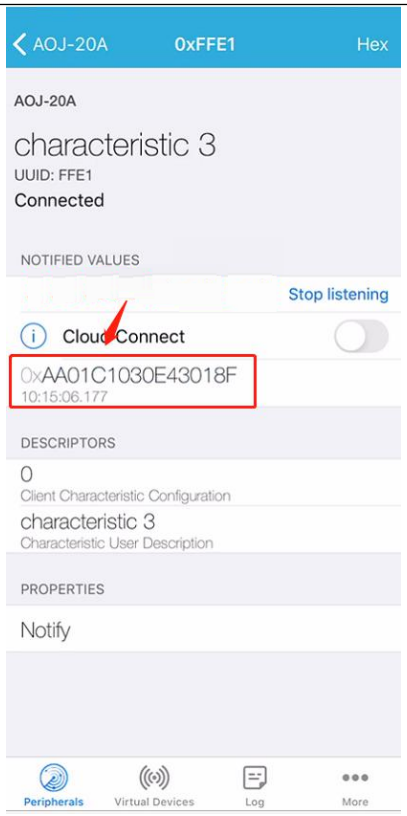


F10

Turn on the Notify data monitoring switch Listen for notifications, as shown in Figure 11; take a normal measurement and check the received Bluetooth data, as shown in Figure 12;


AOJ-20A
0xFFE1
Hex
AOJ-20A
characteristic 3
UUID: FFE1
Connected
NOTIFIED VALUES
Listen for notifications
Cloud Connect
DESCRIPTORS
0
Client Characteristic Configuration
characteristic 3
Characteristic User Description
PROPERTIES
Notify
Peripherals
Virtual Devices
Log
More

F11


AOJ-20A
0xFFE1
Hex
AOJ-20A
characteristic 3
UUID: FFE1
Connected
NOTIFIED VALUES
Stop listening
Cloud Connect
0xAA01C1030E43018F
10:15:06.177
DESCRIPTORS
0
Client Characteristic Configuration
characteristic 3
Characteristic User Description
PROPERTIES
Notify
Peripherals
Virtual Devices
Log
More

F12