

Bluetooth 4.0 Pulse Oximeter SA-B06X

FCC Statement

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.
- (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.

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

Precautions

- Do not attempt to maintain the Oximeter unless you are professional engineers. Only professionals with maintenance qualification are allowed to perform interior maintenance as necessary.
- Periodically change the contact position between the Oximeter probe and the finger for a measurement that lasts a long time. Adjust the position of the probe before the measurement lasts two hours, and check the integrity of skin, the blood circulation condition of the finger as well as the position of the finger.
- This product is not applicable to the examination of newborn babies.
- Seek for medical care in time if the measured value goes beyond the normal range while you are sure that the instrument does not malfunction.
- Do not directly expose your eyes to light-emitting components of the Oximeter, as that could cause harm to your eyes.
- For details about clinical limitations and contraindications, please carefully consult relevant medical literatures.

The following factors may cause disturbance to or affect the accuracy of

examination:

- ◆ This product is used in an environment involving high-frequency devices, such as high-frequency electric knives and CT apparatuses.
- ◆ The probe of the Oximeter is placed on the same body part or limb as with blood pressure cuff arterial duct or intravenous injection.
- ◆ The user suffers from hypotension, severe vascular atrophy, severe anemia, or low oxygen.
- ◆ The user is in sudden cardiac arrest or shock state.
- ◆ The finger with nail polish or a fake fingernail may cause wrong readings of pulse oxygen saturation.

Warnings





Warning: Do not use the Oximeter in an environment with any inflammable gases, inflammable anesthetic, or other inflammable substances.

Warning: Do not attempt to charge any common dry battery, as that could cause leakage, fire disaster, or even explosion. Dispose of exhausted batteries in accordance with environment protection regulations.

Warning: Do not use the Oximeter in an MRI or CT environment.

Warning: Do not operate the Oximeter when it is damp with overflow or water vapor condensation. Avoid moving the Oximeter from an excessively-cold environment to a high-temperature moist environment.

Symbol Conventions

Symbol	Description
	BF-type application part
	Caution: Please see this manual.
%SpO2	Symbol of oxygen saturation
bpmPR	Symbol of pulse rate
	Bluetooth symbol
	When end users abandon this product, they must send the product to the collection place for recycling.

Overview

Oxygen saturation is the percentage of oxyhemoglobin (HbO2) that is combined with oxygen against all combinable hemoglobin (Hb). It is an important physiological parameter involved in respiration and circulation. The oxygen saturation of arterial blood in a normal human body is 98%. Oxygen saturation is an important indicator of the oxygen condition in the human body. In general, the normal values of oxygen saturation shall not be lower than 94%. If the measured value of oxygen saturation is lower than 94%, an insufficient supply of oxygen is considered.

The pulse rate is the number of pulse beats per minute. Normally, the pulse rate is

consistent with the heart rate. In general, the pulse rate of every people is 60 to 90 beats per minute.

The Perfusion Index (PI) usually reflects the limb perfusion status of an examined patient, and shows the detection precision of the instrument as well; that is, examination can still be performed even in the low or weak perfusion condition. The PI of a normal human body is 3% or greater.

Working Principles, Expected Usage, and Applicable Scope

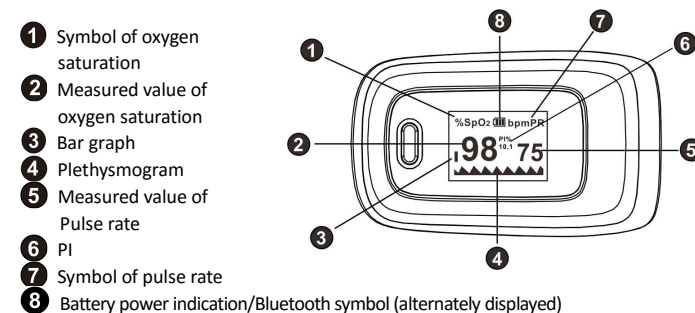
Based on full digital technology, the Finger Pulse Oximeter non-invasively measures the actual content (oxygen saturation) of oxyhemoglobin (HbO2) in arterial blood using the optical transmittance method.

The Finger Pulse Oximeter measures the blood oxygen saturation and pulse rate of a human body via finger artery. It is applicable to a wide range of fields, such as families, hospitals (including operation rooms of the departments of internal medicine and surgery, the department of anesthesiology, the department of paediatrics, and intensive care rooms), oxygen bars, social medical care institutions, and sports & health. Use this instrument for measurement before or after sports.

You are not advised to use this instrument during sports activities. It is applicable to patients 15 to 60 years old. Do not use it for continuous care for patients.

Schematic Diagram of Display

The following figure shows the information display on the OLED screen of the Oximeter in normal detection state:



Power-On Key/Functional Key Operations

After powering on the Oximeter, hold the power-on key/functional key for about one second. The Oximeter shows a parameter setting interface. Press or hold the power-on/functional key to perform corresponding operations. Hold it to set an item, or press it to switch an option or switch the display mode. Press means no more than 0.5 seconds, while Hold means more than 0.5 seconds.

Alert Sound Setting

Hold the power-on key/functional key while the Oximeter is in powered-on state. Parameter setting interface 1 is displayed, as shown in the following figure. Move

"*" to the corresponding option, and hold the functional key to set **Alm to on** and set **Beep to off**. When **Alm** is set to **on** and the measured values of the blood oxygen saturation and pulse rate go beyond the upper limit or lower limit, the Oximeter gives off an alert sound. When **Alm** is set to **off** and the measured values go beyond the limit, the Oximeter will not give any alert sound. When **Beep** is set to **on**, a tick will be heard along with pulse beats during pulse rate measurement. When **Beep** is set to **off**, no sound will be output along with pulse beats during pulse rate measurement. While the "*" symbol stays on the **Restore** option, hold the functional key to restore factory settings.

Brightness Setting

On parameter interface 1, press the functional key to select the **Brightness** option and then hold the functional key to set the brightness to a value ranging from 1 to 5. The greater the value, the greater the brightness of the screen.

Power saving function

The ADF-B06 has a power saving feature. It can save power through reducing screen brightness automatically. During measurement the brightness will reduce to level 1 automatically after 150 seconds without pressing the function key, to make it recover to original brightness please press the function key.

Alert Range Setting

On parameter interface 2, press the functional key to switch between options. On this interface, you can set the upper limit and lower limit of **SpO2 Alm** and **PR Alm**. While the "*" symbol stays on the +/- option, hold the functional key to set the option to + or -. In + mode, select the corresponding option and hold the functional key to increment the upper or lower limit; in - mode, hold the functional key to decrement the upper or lower limit. Move "*" to the **Exit** option, and hold the functional key to return to the monitoring interface.

V2.01.F	*
Alm setup	on
Alm	off
Beep	off
Demo	ok
Restore	4
Brightness	
Exit	

Interface 1

V2.01.F	*
Sounds Setup	
SpO2 Alm Hi	100
SpO2 Alm Lo	94
PR Alm Hi	130
PR Alm Lo	50
+/-	+
Exit	

Interface 2

Operation Guide

Switch on the power supply of the pulse

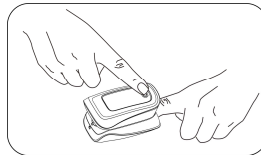
Oximeter

Stick one finger completely into the rubber pad cavity of the Oximeter, keep the fingernail surface upward, and release the clip.

Then press the power key to power on the Oximeter.

If you do not yet completely insert your finger into the cavity, the measurement result may be inaccurate.

Do not vibrate your finger during measurement. Preferably, ensure that your body does not move. After the readings become stable, read the measured values of



oxygen saturation and the pulse rate on the screen.

The Oximeter will automatically shut down 10 seconds later after your finger leaves away.

Connect device via Bluetooth 4.0

Prior to first use, download and install "Andesfit" application to your

device. (Bluetooth 4.0 capabilities) For details, see

quick start guide for the phone / tablet.

About the Display

Continuously press the functional key in the monitoring process. The monitored data and the display mode will be cyclically displayed on the OLED screen in two different ways (large fonts and plethysmogram) and four directions, as shown in the following figure.

Replace the batteries when the battery capacity is insufficient and the symbol () flickers on the screen.

Cleaning

Power off the instrument and remove the batteries before cleaning. Ensure that the appearance of the instrument is neat, dust-free, and dirt-free. Clean the outer surface of the instrument (including the OLED screen) using 75% medical alcohol and a piece of dry soft cloth.

Caution: Avoid liquid flowing into the instrument during cleaning.

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

Disinfection

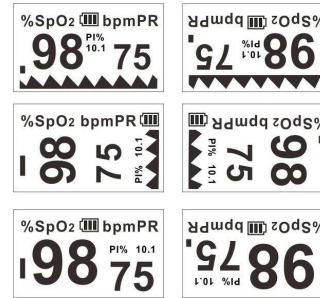
Before measurement with the instrument, wipe the rubber finger pad using a piece of dry soft cloth dipped with 75% medical alcohol. Clean the finger to be measured using the medical alcohol for disinfection purposes before and after use.

Maintenance

- Remove the batteries from the battery slot and properly store them if you do not plan to use the Oximeter for a long period of time.
- Store the Oximeter between 14 and 122°F (-10 to +50°C) and at humidity levels no greater than 93%.
- Periodically check the Oximeter for damage.
- Avoid using the Oximeter in an environment with inflammable gases or using it in an environment where the temperature or humidity is excessively high or low.
- Check the accuracy of the oxygen saturation and pulse rate readings by using an appropriate calibration apparatus.

Technical Specifications

- Dimensions: 62.0 mm (Width) × 37.0 mm (Depth) × 32.0 mm (Height)
Weight: 42.5 g (including the height of the two AAA dry batteries)
- Peak wavelength range of the light emitted from the probe: red light 660 nm ± 3; infrared light 905 nm ± 5.
- Maximum optical output power of the probe: 1.2 mW for infrared light (905



nm).

- Bluetooth module: 4.0 (single-mode)
- Normal working condition

Working Temperature	5°C to 40°C (41°F to 104°F)
Relative Humidity	15% to 80%, non-condensing
Atmospheric Pressure	70 kPa to 106 kPa
Rated Voltage	DC 3.0 V

- Default values and conditions of alert

Parameter	Value
Oxygen saturation	Upper limit: 100 Lower limit: 94
Pulse rate	Upper limit: 130 Lower limit: 50
Alert condition	When the alert switch is on and the actual measured value goes beyond the preset alert parameter range, the Oximeter gives an alert sound.

- Technical parameters

Parameter		Value
Display range	Oxygen saturation	35% to 100%
	Pulse rate	25 bpm to 250 bpm
Resolution	Oxygen saturation	1%
	Pulse rate	1 bpm
Measurement precision	Oxygen saturation	±2% (70% to 100%) No requirement (≤ 69%)
	Pulse rate	±2 bpm
Alert range	Oxygen saturation	Upper limit: 50% to 100% Lower limit: 50% to 100%
	Pulse rate	Upper limit: 25 bpm to 250 bpm Lower limit: 25 bpm to 250 bpm
Alert error	Oxygen saturation	± 1% of the preset value
	Pulse rate	The greater of ±10% of the preset value and ±5 bpm
PI	Weak PI	Min. 0.2%

Safety Type

Anti-electric-shock type: internal power supply device

Anti-electric-shock degree: BF-type application part

Waterproof grade: IP22

Storage and Transportation

Packaged products should be stored in well-ventilated rooms without corrosive gas and with an ambient temperature of -10 to +50°C, a relative humidity lower than 93% (without condensation), and an atmospheric pressure of 50–106 kPa.



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