A310B Fingertip Pulse Oximeter

Operator's Manual

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Section 1

Safety

Instructions for the Safe Operation and Use of the A310B Pulse Oximeter

Do not attempt to service the A310B Pulse Oximeter. Only qualified service personnel should attempt any needed internal servicing.

Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status and correct alignment at least every 2 hours.

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.

The following reason will cause interference to the testing accuracy of the pulse oximeter.

High-frequency electrosurgical equipment.

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

The patient has hypotension severe vasoconstriction severe anemia or hypothermia.

The patient is in cardiac arrest or is in shock.

Fingernail polish or false fingernails may cause inaccurate SpO2 readings.

1.2 Warnings

WARNING: EXPLOSION HAZARD — Do not use the A310B in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.

WARNING: Do not throw batteries in fire as this may causes them to explode.

WARNING: Do not attempt to recharge normal dry-cell batteries, they may leak. And may cause a fire or even explode.

WARNING: **.**Do not use the pulse oximeter in an MRI or CT environment.

WARNING: Do not modify this equipment without authorization of the manufacturer.

WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.

CAUTION: Keep the operating environment free of dust, vibrations, corrosive, or flammable materials, and extremes of temperature and humidity.

CAUTION: Do not operate the unit if it is damp or wet because of condensation or spills. Avoid using the equipment immediately after moving it from a cold environment to a

CAUTION: Never use sharp or pointed objects to operate the front-panel switches.

CAUTION: The batteries must be taken out from the battery compartment if the device will not be used for a long time.

CAUTION: The device shall only be used if the battery cover is closed.

CAUTION: The batteries must be proper disposed according to local regulation after their use.

CAUTION: The device should keep away from the children, pets and pests to avoid swallowing.

1.3 Definitions and Symbols

Symbol	Description
	Type BF Equipment
	Batch code*
	Date of manufacture*
SN	Serial NO*
	Information of manufacture, including name and address
	Temperature limitation
	Bluetooth Indication
	When the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling

	Follow instruction for use
IP22	Anti-dust& Anti-water class
Warning：	The information you should know to protect patients and medical staff from possible injury
Caution：	The information you should know to protect the equipment from possible damage
Note：	The important information you should know

*Batch code, Date of manufacturer and Serial No are printed on the label on the battery cover.

Section 2

Introduction

2.1 General

This chapter provides a general description of the A310B Pulse Oximeter including:

Brief device description

Product features

2.2 Brief Device Description

The Pulse Oximeter, based on all digital technology, is intended for noninvasive spot-check measurement of functional oxygen saturation of arterial hemoglobin (SpO2). Advanced DSP algorithm can minimize the influence of motion artifact and improve measurement accuracy of low perfusion.

The Oximeter can be used to measure human Hemoglobin Saturation and heart rate through finger. The product is suitable for family, hospital (including clinical use in internist/surgery, Anesthesia, pediatrics, intensive care and etc.) Oxygen Bar, social medical organizations, physical care in sports and etc.

2.3 Product Features

- Lightweight for carrying and Easy-To-Use.
- Manually adjust the direction of interface .
- Color OLED display, simultaneous display for testing value and plethysmogram.
- Low Perfusion : 0.2%. (Advanced DSP algorithm can improve measurement accuracy, under the condition of low perfusion.)
- Visual & Sound alarm function. Real-time spot-checks.
- Wireless Bluetooth for data transmission.
- Low Battery voltage indicator.
- Automatically switch off.
- Standard two AAA 1.5V Alkaline Battery support more than 20 hours continuous work.

●

CAUTION: The device cannot be used to measure the child below 1 years as the test result is not guarantee to accurate.

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

CAUTION: A function tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor.

Clinical testing is used to establish the SpO2 accuracy. The measured arterial hemoglobin saturation value (SpO2) of the sensor is compared to arterial hemoglobin oxygen(SaO2) value, determined from blood samples with a laboratory CO-oximeter. The accuracy of the sensors in comparison to the CO-oximeter samples measured over the SpO2 range of 70 -100%. Accuracy data is calculated using the root-mean-square(Arms value) for all subjects. Only about two-thirds of PULSE OXIMETER EQUIPMENT measurements can be expected to fall within ±Arms of the value measured by a CO-Oximeter.

Pulse simulator shall be used to assess Pulse rate Accuracy. The measured pulse rate is compared to the preset pulse rate value in simulator. Accuracy data is calculated using the root-mean-square (Arms value) for all subjects.

***DSP algorithm**: Digital signal processor algorithm.

***Low Perfusion:** In physiology, perfusion is the process of a body delivering blood to a capillary bed in its biological tissue. Under the condition of low perfusion, the measurement of non-invasive saturation of pulse-blood oxygen is low-accurate.

***Plethysmograph**: is an instrument for measuring changes in volume within an organ or whole body (usually resulting from fluctuations in the amount of blood or air it contains).

Section 3

Installation,Setup,and Operation

3.1 Description of the Front Panel (as figure 3.1.1)

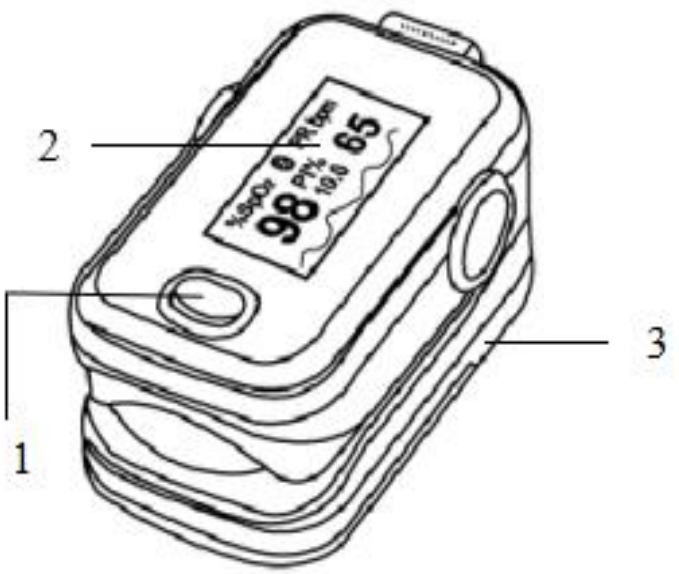


Figure 3.1.1 Parts of front & back panel

Table 3.1.1 Part Definition and Description

Item	Name	Description
1	Power button	Turn on the machine
2	OLED Panel	Display the SPO2/PR data & Plethysmogram,etc.
3	Battery Compartment	

3.2.Display

After switch on, the OLED display of A310B is as follows:

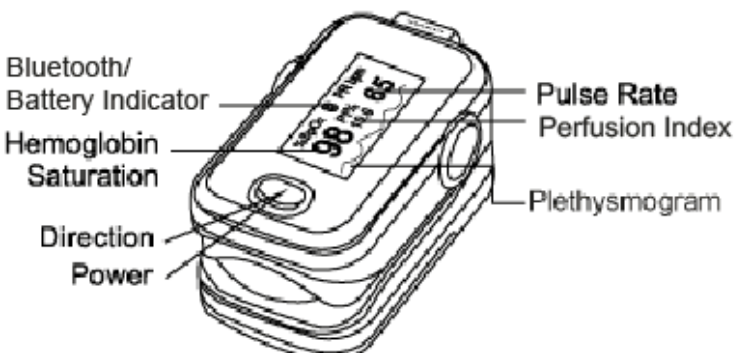


Figure 3.2.1 OLED display

3.3 Parameter setting

When the device is under measuring interface, press the direction button for 1 second in order to enter into menu page(figure 3.3.1 and figure 3.3.2). There are two submenus for choice:

Remind Setup

Press the direction button for 1 second and enter into the Reminder Setup. User can adjust the setting through moving the "*" symbol to the back of the Sound Reminder, Beep , Bluetooth, Restore or Brightness.

Sound Reminder

Press the direction button for 1 second, move the "*" symbol to the back of Sound Reminder, long press the direction button to turn it on/off.

Beep

Press the direction button for 1 second, move the "*" symbol to the back of Beep, long press the direction button to turn it on/off.

Bluetooth

Press the direction button for 1 second, move the "*" symbol to the back of Bluetooth, long press the direction button to turn it on/off.

Restore

When the "*" symbol shown behind "Restore", long press the direction button can be changed to "OK", which causes the device to restore factory data setting.

Brightness

When the "*" symbol shown on "Brightness", long press the direction button to change the Brightness value from 1 to 5.

Limit Value Setting

When the * symbol shown on the Reminder Setup, long press the direction button until enter into the Reminder Limit setup menu(figure 3.3.2). User can press the direction button to select the items. And press the direction button for 1 second to change the data you need.

On the Reminder Limit setup menu page (figure 3.3.2), when the * symbol shown behind the "+/-". Press direction button for 1 second to change the "+" to "-" or change the "-" to "+".

When "+" shows on the right side, press the direction button for 1 second , move the "*" after the Spo2 Hi or PR Hi setting, can increase the value to a higher value (until it reaches to the highest.)

When "-" shows on the right side, press the direction button for 1 second, move the "*" after the Spo2 Lo or PR Lo value setting, can reduce the value to a lower value (untill it reaches to the lowest).

Remind Setup	*
Sound Reminder	on
Beep	off
Bluetooth	on
Restore	OK
Brightness	4
Exit	

Figure3.3.1

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

Figure3.3.2

Note:

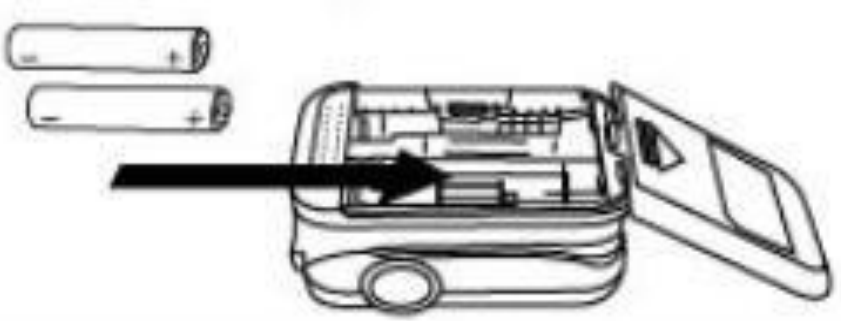
1.The alarm have 1 second delay after the incorrect result being detected.

2. The customer can preset the alarm value to the 98 or 99 to check whether it is normal for alarm setting.

3.4 Operation

3.4.1 Install battery

Installing two AAA batteries into battery cassette in correct polarities and cover it.



WARNING: Do not attempt to recharge normal alkaline batteries, they may leak and may cause a fire or even explode.

3.4.2 Turn the Pulse Oximeter on

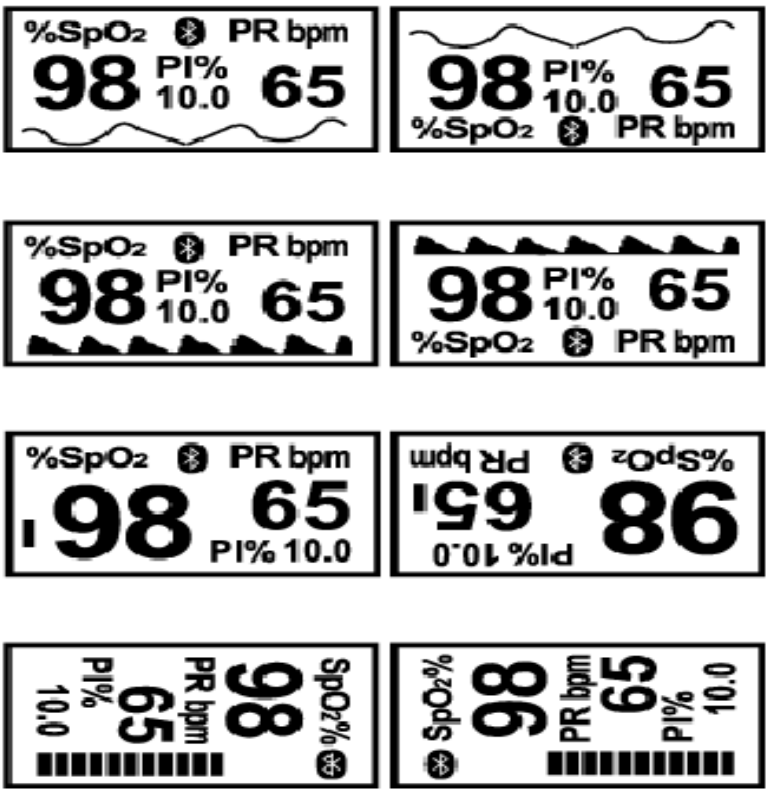
Put one of fingers into rubber hole of the oximeter (it is best to put the finger thoroughly) with nail surface upward**,** then releasing the clamp.

Press power button to turn the Pulse Oximeter on. The oximeter will be automatically powered off when no finger in the device for longer than 16 seconds.

3.4.3 Read correspondent data from display screen.

3.4.4 *Display Description of OLED*

The display interface of “OLED” can rotate four directions with six different display modes after pressing the power button for less than 0.5s. It is shown as below:



Note:

1.when battery power is at lowest level, the battery capacity indicates symbol of " " in OLED, remind users of replacement of battery.

2. The pletismogragh can been regarded as correct if the wave is fluctuated regularly.

3.4.5 Date Transmission

1. The current measurement will transmit to the App automatically. after data transmission successfully, the measurement

flashing for 8s, then the device will power off automatically. If there is no Bluetooth connection over 1 min, the device will power off automatically and the data will not be

stored.

If there is no reading, the device will power off automatically.

Notes:

With the Bluetooth 4.0 to transmit the data to App.

The transmission distance is 10 m at most.

Section 4

Cleaning and Disinfection

4.1 Cleaning

Cleaning the machine once every day. Switch off the power and take out the batteries before cleaning, Cleaning exterior surface (OLED display screen included) of the unit with a dry and soft cloth. Use 75% density of medical alcohol to clean the surface and use dry fabric with little alcohol to avoid alcohol permeates into the device.

4.2 Disinfection

Disinfecting the machine after using by the patient if multiple patient use the machine in the hospital.

Use 75% density of medical alcohol to clean the surface that contacting with the patient.

***CAUTION*:** Don't use strong solvent. For example, acetone.

***CAUTION*:** Never use an abrasive such as steel wool or metal polish.

***CAUTION*:** Do not allow any liquid into the product, and do not immerse any parts of the device into any liquids.

***CAUTION*:** Avoid pouring liquids on the device while cleaning.

***CAUTION*:** Don't remain any cleaning solution on the surface of the device.

Section 5

Troubleshooting and Maintenance

5.1 Maintenance

Replace the batteries timely when battery indication is low.

Clean surface of the Pulse Oximeter before it is used in diagnosis for patients.

Remove the batteries inside the battery cassette if the oximeter will not be operated for a long time.

It is better to preserve the product in a place where ambient temperature is -10-50℃ and humidity is 15%-80%.

Regular inspection to make sure that no obvious damage existed to affect the safety and performance of device.

No flammable substance, overtop or lower temperature and

humidity existed in operation conditions.

5.2 Troubleshooting

Table 5.2.1 troubleshooting

Problems	Possible Reason	Resolutions
Oxyhemoglobin or heart rate can not be shown normally	1. Finger is not plugged correctly. 2. Patient’s perfusion is too low to be measured.	1. Retry by plugging the finger 2. Try some more times, if you can make sure about no problem existing in the product, Please go to a hospital timely for exact diagnosis
Oxyhemoglobin or heart rate is shown unstably	1. Finger might not be plugged deep enough 2. Finger is trembling or patient's body is in movement status	1.Retry by plugging the finger 2.Try not to move, Let the patient keep calm.
Oxyhemoglobin or heart rate is abnormal and cause alarm	1. Finger is not plugged correctly. 2. Patient’s SPO2&PR is abnormal.	1. 1. Retry by plugging the finger 2. go to the hospital for further examination.

The oximeter can not be powered on	1. Power of batteries might be inadequate or not be there at all 2.Batteries might be installed incorrectly 3.The Oximeter might be damaged	1. Please replace batteries 2.Please reinstall the batteries 3.Please contact with local customer service center
he screen are suddenly off	1.The product is automatically powered off when no signal is detected longer than 8 seconds 2.Power quantity of the batteries is exhausted.	1.Normal 2.Replace the batteries

Section 6

Specification

Fingertip Pulse Oximeter Specifications:

Physical Characteristics

Machine:

Dimensions -60 mm (L) x 36mm (W) x28mm (D)

Weight -approx: 50 g（including 2 x AAA battery）

Color box:

Dimensions-80mm(L)x60mm(w)x55mm(D)

Gross Weight: 70g

Outer carton:

Dimensions-440mm (L) X340mm (W) X290mm (H)

Gross Weight: 8.7 kg

Classification ：

Anti-electric Shock Type：Internally powered equipment

Anti-electric Shock Degree：Type BF equipment

EMC：Type B

Mode of operation: Continuous Operation

Enclosure Degree of ingress protection: IP22

IP22 means shell of this product can withstand the water dropping to the surface when the shell deviate 15 degree from horizontal surface.

Power

Internal:	2xAAA 1.5v alkaline battery
Power Consumption	Smaller than 30mA(Normal)

Environmental:

Operating Temperature:	5 ℃ to 40 ℃
Storage Temperature:	–10 ℃ to 50 ℃
Relative Humidity:	15% to 80% non-condensing
Air Pressure	86Kpa-106Kpa

Alarm default value:

Parameter	**Value**
Hemoglobin saturation:	Upper limit: 100/ bottom limit:94
Pulse rate:	Upper limit: 130 /bottom limit:50

Electronics Parameters:

Parameter		**Value**
Hemoglobin saturation display		35-100%
Pulse rate Display		30-250 BPM
Resolution	Hemoglobin Saturation	1%
	Pulse rate	1 BPM

Measure Accuracy:	Hemoglobin Saturation	±3% (70%-100%) Unspecified (<70%)
	Pulse rate	±1 BPM
PI	Display	0-20%
	Resolution	0.1%
	Measure Accuracy	0-1%: 0.1% 1-20%: 1%

Probe LED Specification;

	Wave Length	Radiant Power
RED	660±2 nm	1.8 mW
Infra RED	905±2 nm	2.0 mW

FCC Statement

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.

§ 15.19 Labeling requirement.

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.

§ 15.21 Information to user.

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

Specific Absorption Rate (SAR) information:

This product meets the government's requirements for exposure to radio waves. The guidelines are based on standards that were developed by independent scientific organizations through periodic and thorough evaluation of scientific studies.

The standards include a substantial safety margin designed to assure the safety of all persons regardless of age or health.

Body-worn Operation

This device was tested for typical body-worn operations. To comply with RF exposure requirements, a minimum separation distance of 5mm for body worn must be maintained between the user's body, including the antenna. Third-party belt-clips, holsters, and similar accessories used by this device should not contain any metallic components. Body-worn accessories that do not meet these requirements may not comply with RF exposure requirements and should be avoided. Use only the supplied or an approved antenna