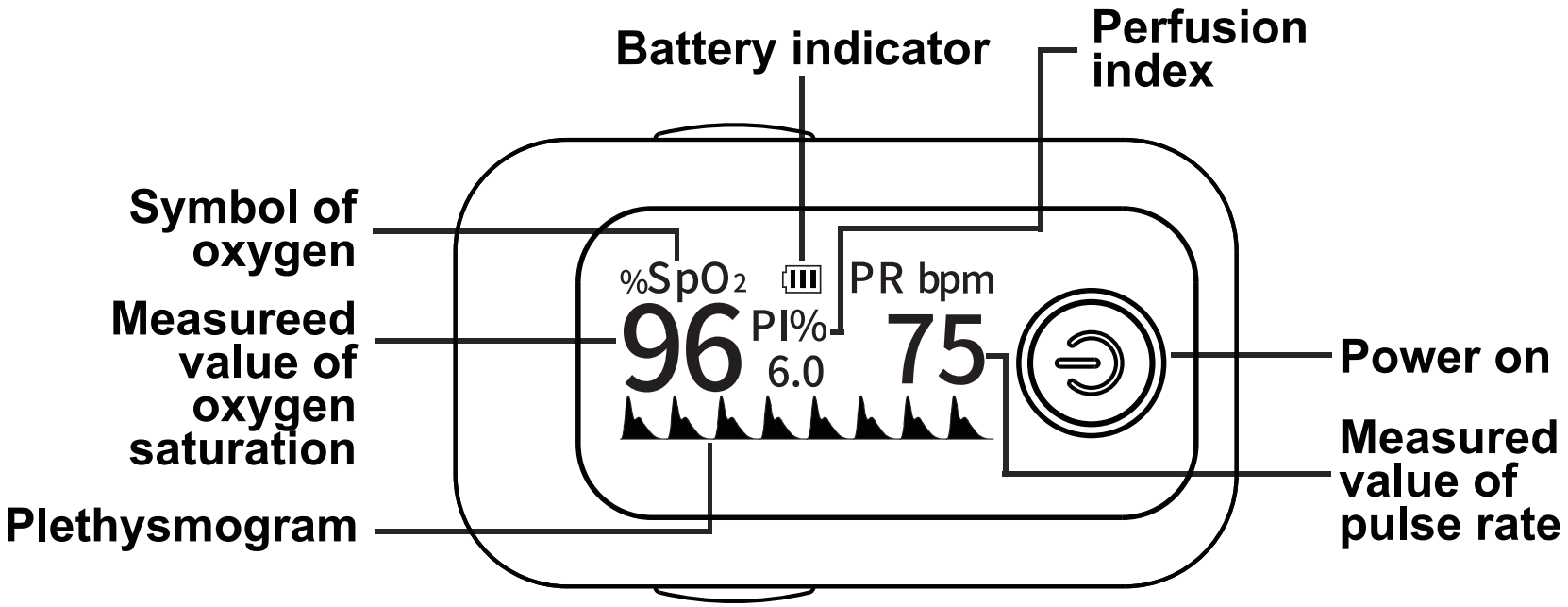
OXILINE

User Guide
PULSE XS Pro

Model: AOJ-70A

Contents

Brief Description of Front Panel



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

General Description

SpO_2 stands for peripheral capillary oxygen saturation. Oxygen saturation is defined as the ratio of oxyhemoglobin (HbO_2) to the total concentration of hemoglobin (i.e.Oxyhe moglobin +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 SpO_2 and pulse rate. PR is pulse rate (bite per min). If the user doesn't have arrhythmia, PR is equivalent to heart rate. Healthy adults generally 60-100 times/min. It is normal for athletes and other

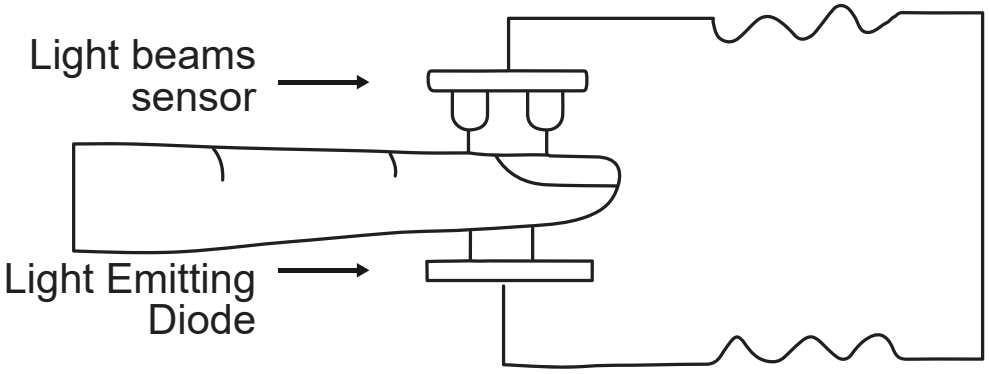
healthy adults with better health to take 50-60 times. PI% refers to the Perfusion Index (PI), and the PIvalue reflects the pulsating blood flow, the greater the pulsating component and the greater the PI value.

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 oximeter 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 (SpO_2) 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. This device is for sports and aviation use only. Not for medical use.



Safety Information

DANGER

Indicates an imminent hazard that, if not avoided, will result in death or serious injury.

Dangers

There are no dangers that refer to the product in general.

WARNING

Indicates a potential hazard or unsafe practice that, if not avoided, will result in death or serious injury.

Warnings

1. Federal (U.S) law restricts this device to sale by or on the order of a physician.

2. Explosive hazard--DO NOT use the equipment in the environment with tinder such as anesthetic.

3. DO NOT use the equipment while the patient is being scanned by MRI or CT.

4. For clinical limitations and contraindications, please carefully review the medical literature.

5. The equipment is NOT intended for neonate and infant, and the patient’s finger thickness should between 8 to 25.4 mm.

6. It is recommended that the equipment should be inspected

before use, when there is obvious damage, stop using the equipment.

7. Discomfort or pain may appear if using the equipment ceaselessly, especially for microcirculation barrier patients, it is recommended that the equipment should not be used on the same finger more than 10 minutes.

8. For some patients who need a more careful examination of the measurement site, the oximeter shall not be placed in edema or fragile organization.

9. The equipment is just a clinical diagnosis auxiliary equipment. The physiological data displayed on the equipment are for reference only and cannot be directly used for diagnostic interpretation.

10. It is not recommended to use the equipment in high frequency environment such as electrosurgical equipment.

11. Do not have the equipment immerged in liquid.

12. Prevent children from swallowing the equipment or its accessories. Children must be accompanied by adult guardian when using products.

13. Please follow local ordinances and recycling instructions regarding disposal or recycling of the equipment and batteries.

CAUTION

Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.

Cautions

The equipment is designed to measure the percentage of arterial oxygen saturation of functional hemoglobin. Factors that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following:

- Excessive light, such as sunlight or direct home lighting
- Moisture in the equipment
- Finger is beyond recommended size range
- Poor pulse quality

- Venous pulsations
- Anemia or low hemoglobin concentrations
- Cardio green and other intravascular dyes
- Carboxyhemoglobin
- Methemoglobin
- Dysfunctional hemoglobin
- Artificial nails or fingernail polish

The light (the infrared is invisible) emitted from the equipment is harmful to the eyes, so the user and the maintenance man should not look at the light.

NOTE

Provides application tips or other useful information to ensure that you get the most from your product.

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

Contraindications

None.

Components

The oximeter consists of probe, electronic circuits, and display and plastic enclosures.

NOTES

- The probe is the hole in the middle of the equipment to which the finger insert.
- The probe is the Applied Part of the equipment.

Product Features

- Lightweight, portable and easy to use.
- OLED screen shows pulse rate, SpO_2, perfusion index.
- Large font display.

- Low battery indicator.
- Auto shut down without use within 15 seconds.

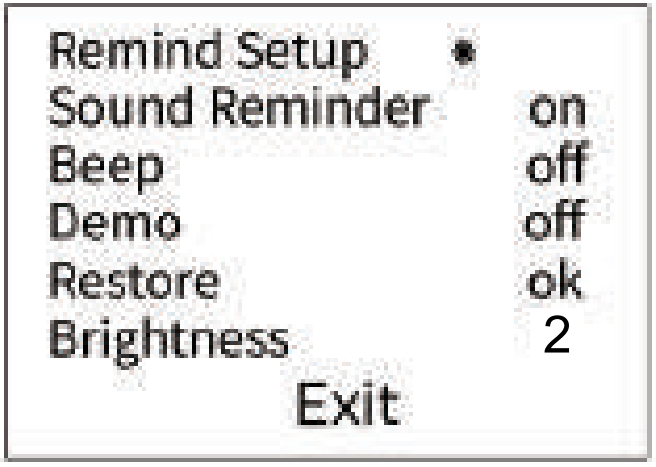
Intended Use

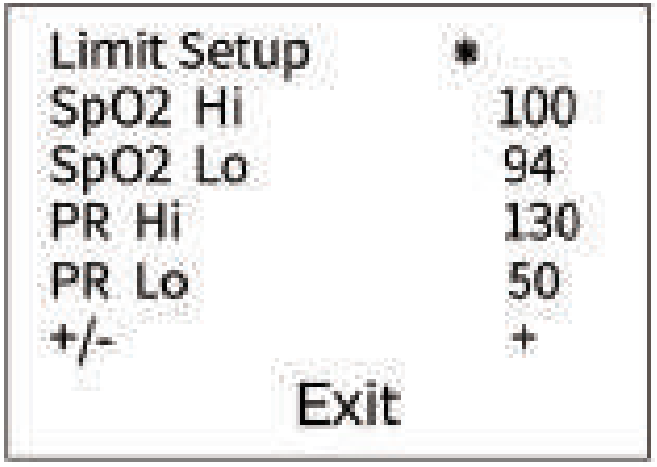
The pulse oximeter is a reusable device and intended for spot-checking of oxygen saturation and pulse rate for use with the finger of adult patients in healthcare environments. And it is not intended to be used under motion or low perfusion scenarios.

Setup

After the oximeter is turned on, press 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.





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.

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.

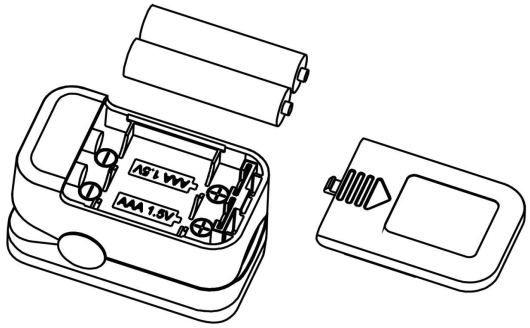
✧ Please use medical alcohol to clean the silicon which touches the finger inside of oximeter, and use alcohol to clean the test finger before and after each test. (The silicon inside of the oximeter belongs to medical silicon, which has no toxins and does no harm to the skin).

Product Accessories

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

Battery Installation

Put 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.

Cleaning and Disinfection

1. Cleaning

Your equipment should be cleaned on a regular basis. If there is

heavy pollution or lots of dust and sand in your place, the equipment should be cleaned more frequently.

Recommended cleaning agents are:

- Mild soap (diluted)
- Ethanol (70%)

To clean your equipmentfollow these rules:

- Shut down the pulse oximeter.
- Clean the display screen using a soft, clean cloth dampened with a glass cleaner.
- Clean the exterior surface of the equipment and probe using a soft cloth dampened with the cleaner.
- Wipe off all the cleaning solution with a dry cloth after cleaning if necessary.
- Dry your equipment in a ventilated and cool place.

To avoid damage to the equipmentfollow these rules:

CAUTIONS

- Always dilute according the manufacturer's instructions or use lowest possible concentration.
- Do not immerse the equipment in liquid.
- Do not pour liquid onto the equipment or accessories.
- Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-basedcleaners).
- If you spill liguid onto the equipment, contact us or your service personnel.

2. Disinfection

Clean the pulse oximeter before disinfecting it. The recommend-ed disinfectant is ethanol 70%. Disinfection steps are the same

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

⚠ Never use ETO or formaldehyde for disinfection.

Maintenance and Storage

1.Replace the batteries in time when low battery indicator flashes.
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°°C~50℃ (-4°F~122°F) and relative humidity

is 10%-95%.
5. It is recommended that the product should be keptin a dry environment anytime. A wet ambient might affect its lifetime and even might damage the product.
6. Avoid exposure to direct sunlight.
7. Avoid excessive radioactive infrared rays or ultraviolet rays.
8. Please follow the law of the local government to deal with used battery.

Specification

1. Display Type: OLED screen
2.SpO_2:
Measurement range: 35%-100%
Resolution: 1%

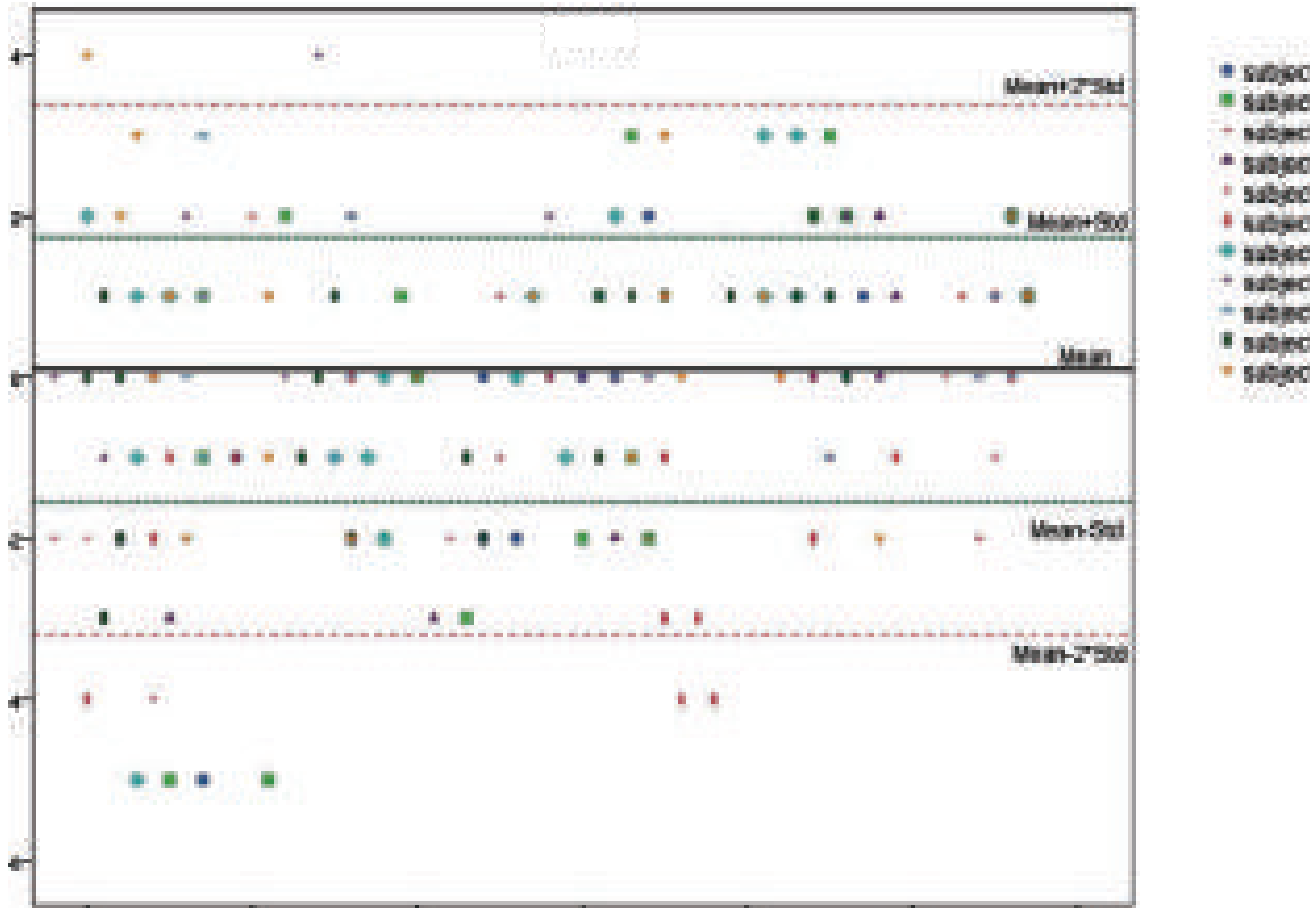
Accuracy:
100%-90%, ±2%; 90%-80%, ±2%;
80%-70%, ±2%; 100%-70%, ±2%;
0%-69% unspecified.
3. Pulse Rate:
Measurement range: 25bpm-250bpm
Resolution: 1bpm
ccuracy: ±2bpm
Pulse Intensity: Bar graph indicator
4. Perfusion Index:
Measurement range: 35%-100%
Resolution: 1%
Accuracy: 0.1% (0%~1%); 1%(1%~20%); >20% no definition.
5. Power Requirements: Two AAA alkaline Batteries
Power consumption: 30mA (Normal)

Low battery indication: When the battery voltage is 1.9V±0.2V, the oximeter will shut down.
Battery Life: Two AAA 1.5V, 600mAh alkaline batteries could be continuously operated as long as 24 hours.
6. Dimension:
63mm (L) X 39mm (W) X 36mm (H)
Weight: 38g (without batteries)
7. Environment Requirements:
Temperature: 10°C-40°C
Humidity (non-condensing): 15%-95%
Atmospheric pressure: 70kPa-106kPa
8. Storage/transportation conditions
Temperature: -20°C-50°C
Humidity (non-condensing): 10%-95%
Atmospheric pressure: 70 Kpa-106 kPa

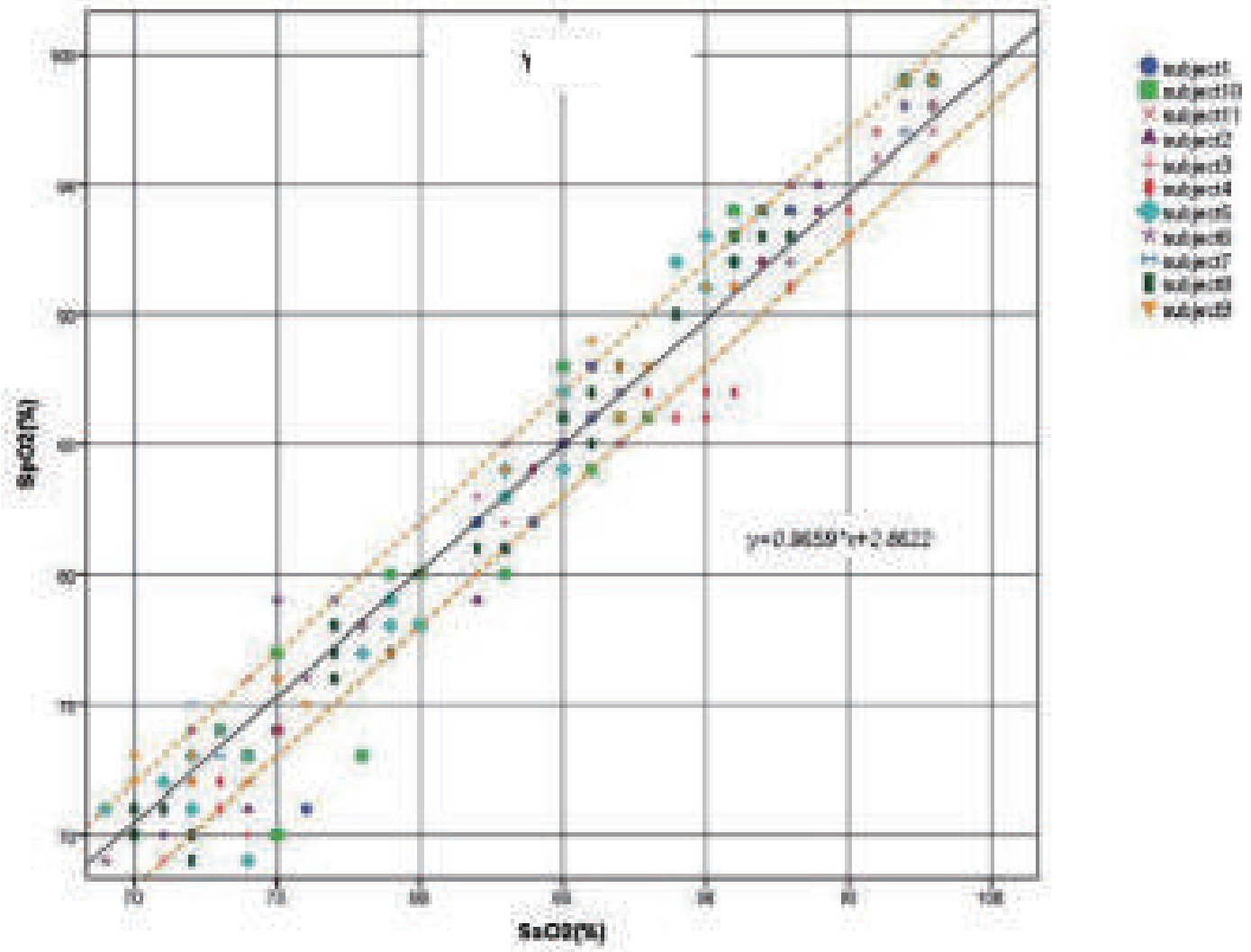
9. Measurement Performance in Low Perfusion
Condition: 0.3%
10. Classification
Type of protection against electric shock:
Internally powered equipment
Degree of protection against electric shock:
Type BF-Applied part (non-defibrillation proof)
Operating mode: Spot checking
Degree of protection against hazards ofexplosion: IP22
Application type: Fingertip oximeter
11. Lifespan: Two years

⚠ **Note: SpO_2 and pulse rate accuracy are the essential requirements.**

Graphical Plot of All Sampled Data Points



Bland-Altman graph for SpO_2-SaO_2



The regression line of the measured data

Assessing the Validity of a SpO_2 Reading

You can check the quality of the pleth wave and the stability of the SpO_2 values on the Patient Monitor to assess whether the sensor functions properly and whether the SpO_2 readings are valid. Always use these two indications simultaneously to assess the validity of a SpO_2 reading.

NOTE:

1. The SpO_2 accuracy has been validated in human studies against arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements arestatistically distributed, only about two-thirds of the measurements can be expected to fall within the specified accuracy compared to CO-oximeter measurements. The volunteer population in the studies composed of local healthy men and women from age 18

to 46, with variations of skin pigmentations.
2. The pulse rate accuracy is obtained by comparison to the pulse rate generated with an arterial oxygen simulator (also an electronic pulse simulator).
3. Generally, the quality of the SpO_2 pleth wave reflects the quality of the light signals obtained by the sensor. A wave of poor quality manifests a decline of the signal validity. On the other hand, the stability of the SpO_2 values also reflects the signal quality. Different from varying SpO_2 readings caused by physiological factors, unstable SpO_2 readings are resulted from the sensor's receiving signals with interference.
The problems mentioned above may be caused by patient movement, wrong sensor placement or sensor malfunction. To obtain valid SpO_2 readings try to limit patient movement.

Declaration

EMC of this product complies with IEC60601-1-2 standard. The materials which the user can come into contact with have no toxicity and no action on tissues comply with SO10993-1, ISO10993-5 and ISO10993-10.

Troubleshooting

WARNINGS

- Necessary maintenance must be performed by qualified service personal ONLY.
- Users are NOT permitted to repair the equipment by themselves.
- There are NO replaceable components in the equipment.

Trouble	Possible Reason	Solution
The equipment can't be turned on.	The battery is drained away or almost drained away.	Please replace battery.
	The battery installation is incorrect.	Install the battery over again.
	The malfunction of the equipment.	Please contact the local service center.

The display is off suddenly.	The equipment is set to shut down automatically in 15 seconds without use.	Normal
	The battery is almost drained away.	Please replace battery
The SpO_2 and Pulse Rate are not displayed stably.	The thoroughfare from photo detector to light emitting diode was sheltered by some objects.	Check and clean the inside of the probe especially the two windows of sensors.
	The finger is shaking or the user is moving.	The user needs to keep still.

	The finger is not placed inside deep enough.	Place the finger properly and try again.
	The finger's size is too big or too small.	Select the correct size finger to measure.
	Excessive ambient light.	Avoid the excessive ambient light irradiation.
	Pulse rate value of the cyclical fluctuations.	If the measurement is proper, the user might has arrhythmia. Please consult with the doctor.
The SpO_2 and Pulse	The finger is not properly positioned.	Place the finger properly and try again.

Rate can’t be displayed normally.	The patient’s SpO_2 is too low to be detected.	Try again, go to a hospital for a diagnosis if you are sure the equipment works all right.
Pulse sound can’t be turned off.	The key is bad.	Check the key and press again.
	The press time is not right.	Make sure the press time is 2-3 seconds.

Appendix 1 EMC Information

Guidance and manufacturer's declaration-Electromagnetic emission		
Pulse Oximeteris intended for use in the electromagnetic environment specified below. The customer or the user of the Model Pulse XS Pro (AOJ-70A) Pulse Oximeter should assure that it is used in such an environment.		
Emissions	**Compli-ance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	The Pulse Oximeteruses 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 emissions CISPR 11	Class B	The Pulse Oximeteris 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.
Harmonic emissions IEC61000-3-2	N.A	
Voltage fluctuationsl flicker emissions EC61000-3 -3	N.A	

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 Pulse Oximeter should assure that it is used in such an environment.		
Immunity test	IEC60601 test level	Electromagnetic environment-guidance
Electros tatic discharge (ESD) IEC 61000-4 -2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/M, 50/60 Hz	30A/M, 50/60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level			

Guidance and manufacturer's declaration-electromagnetic immunity
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.

Immunity test	IEC 60601 test level	Com-pliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the Pulse XS Pro, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation

Radiated RF IEC 61000-4-3	outside ISM bandsa 10V/m 80 MHz to 2.7 GHz	10 V/m	distance $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80MHz to 800MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800MHz to 2.7GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF

			transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These quidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6795 MHz; 13553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz 3,5 MHz to 4,0 MHz 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to18,17 MHz 21,0 MHz to 21,4 MHz 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHZ.
b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 27 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.
c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios.

amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Pulse XS Pro is used exceeds the applicable RF compliance level above, the Pulse XS Pro should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as
re-orienting or relocating the Pulse XS Pro.
d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Test Frequency (MHz)	**Band a) (MHz)**	**Service a)**	**Modulationb)**	**Max. power (W)**	**Distance**	**Immunity Test Level (V/m)**

385	380-390	TETRA 400	Pulse modula-tion b) 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM c)	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modula-tion b) 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900,	Pulse modula-tion b) 18 Hz	2	0.3	28
870						

930		TETRA 800, iDEN 820, CDMA 850, LTE Band 5				
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; 820, LTE Band 1,3,4,25; UMTS	Pulse modula-tion b) 217 Hz	2	0.3	28

2450	2400-2570	Bluetooth, WLAN, 802.11b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11a/n	Pulse modulation b) 217 Hz	0.2	0.3	9
5500						
5785						
NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the MEEQUIPMENT or ME SYSTEM may be reduced to1m. The 1 m test distance is permitted by IEC61000-4-3.						

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative to FM modulation, 50% pulse modulation at 18Hz may be used because while it dose not represent actua modulation, it would be worst case.

Recommended separation distances between portable and mobile RF communications equipment and Arm Blood Pressure Monitor

The Pulse Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controed. The customer or the user of the models Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the models Pulse Oximeter as recommended below. according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V1}\right]\sqrt{P}$	**80 kHz to 800 MHz** $d = \left[\frac{3.5}{E1}\right]\sqrt{p}$	**800 kHz to 2.7 GHz** $d = \left[\frac{7}{E1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3

100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where Pisthe maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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.

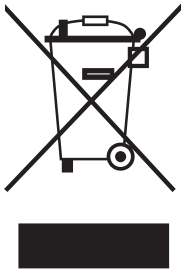
SpO_2 or PR is shown unstably.	1. The finger is not placed between the sensor and the Light Emitting Diode. 2. The user is moving his/her finger and/or body.	1. Make sure that the finger is placed right in between the sensor and the Light Emitting Diode. 2. Try to stay still during measurement.
The oximeter 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 install the battery correctly. 3. Contact the distributor.

The screen is suddenly off.	1. Without use, the device will automatically power off within 15 seconds. 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, its accessories, connectors, switches, or openings in the enclosure as this may damage the oximeter.

Symbol Definitions

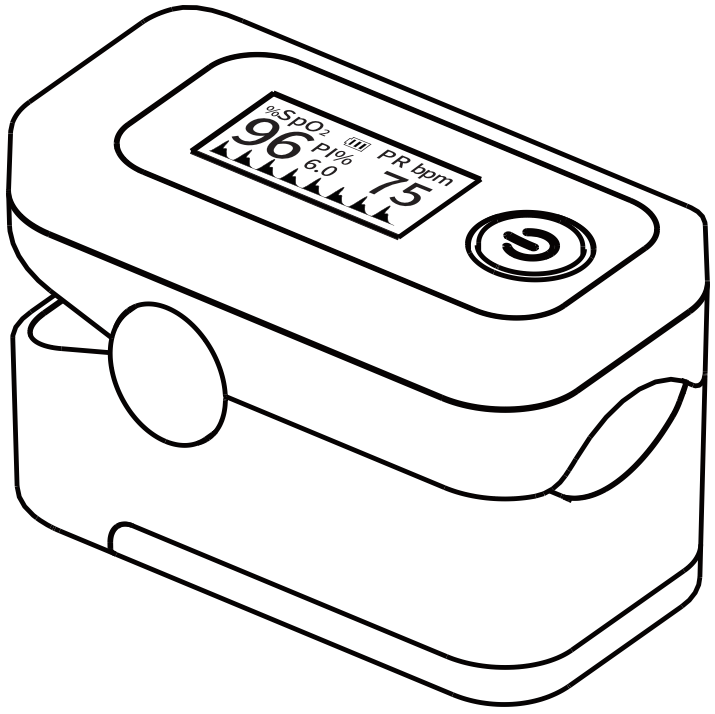
Symbol	Definition
	Type BF equipment
	Attention, consult accompanying documents.
% SpO_2	Oxygen saturation
 **/Min**	Pulse rate

	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.
	The device has no Alarm System
	Caution, Consult Accompanying Documents
IP22	Degree of Protection Provided by Enclosures per IEC60529

	Date of Manufacture
SN	Serial Number
RoHS	RoHS mark
CE	CE mark

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

Manual Version: 1.0
Revision Date: 2021/08/08



Manual version: A0
Software version: V1.0
Revision date: 2022-09

Manufactured for:
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Made in China

Manual version: A0
Software version: V1.0
Revision date: 2022-09
Oxiline Pulse XS Pro