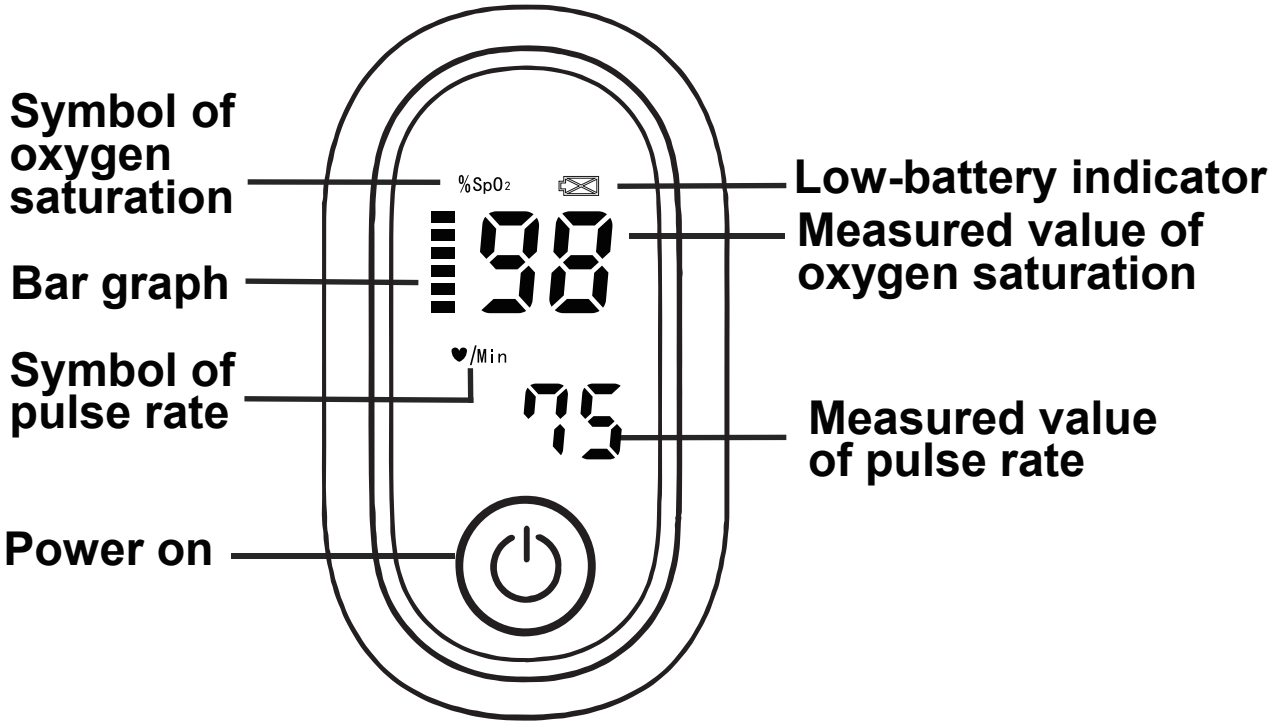
OXILINE

User Guide
PULSE 7S Pro

Model: AOJ-70B

Contents

Brief Description of Front Panel



The pulse bar graph displays corresponding with the user's pulse beat. The height of the bar graph 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. Oxyhemoglobin + reduced hemoglobin) present in the blood. It is an important physiological parameter involved in respiration and circulation. The Pulse 7S Pro 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.

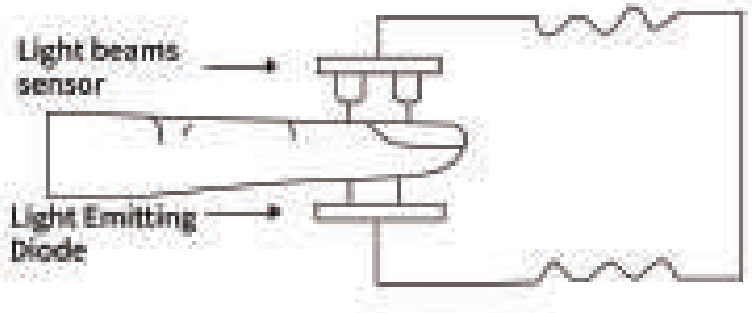
Declaration

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 ISO10993-1, ISO10993-5 and ISO10993-10.

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.

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. Don't near active HF surgical equipment and the RFshielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

5. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper

operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

6. Portable RF communications equipment(including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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

8. It is recommended that the equipment should be inspected before use, when there is obvious damage, stop using the equipment.

9. 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.

10. For some patients who need a more careful examination of the measurement site, don't put the adema or injured finger into the oximeter.

11. The equipent 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.

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

13. Do not have the equipment immerged in liquid.

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

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

16. No maintenance or servicing the device when using.

17. Users are NOT permitted to repair the equipment by themselves.
18. There are NO replaceable components in the equipment.

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

Cautions
1. The equipment is designed to measure the percentage of arteral 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 lowhemoglobin concentrations
- Cardio green and other intravascular dyes
- Carboxyhemoglobin
- Methemoglobin
- Dysfunctional hemoglobin
- Artificial nails or fingernail polish

2. 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.
3. When the performance changes(such as: inaccurate measurement or abnormal display), please stop using it immediately and contact the after-sales service personnel in time.

NOTE

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.

Product Features

- Lightweight, portable and easy to use.
- LED screen shows pulse rate, SpO_2.

- Large font display.
- Low battery indicator.
- Auto shut down if no signal is detected 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 at home and healthcare environments. And it is not intended to be used under motion or low perfusion scenarios.

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.

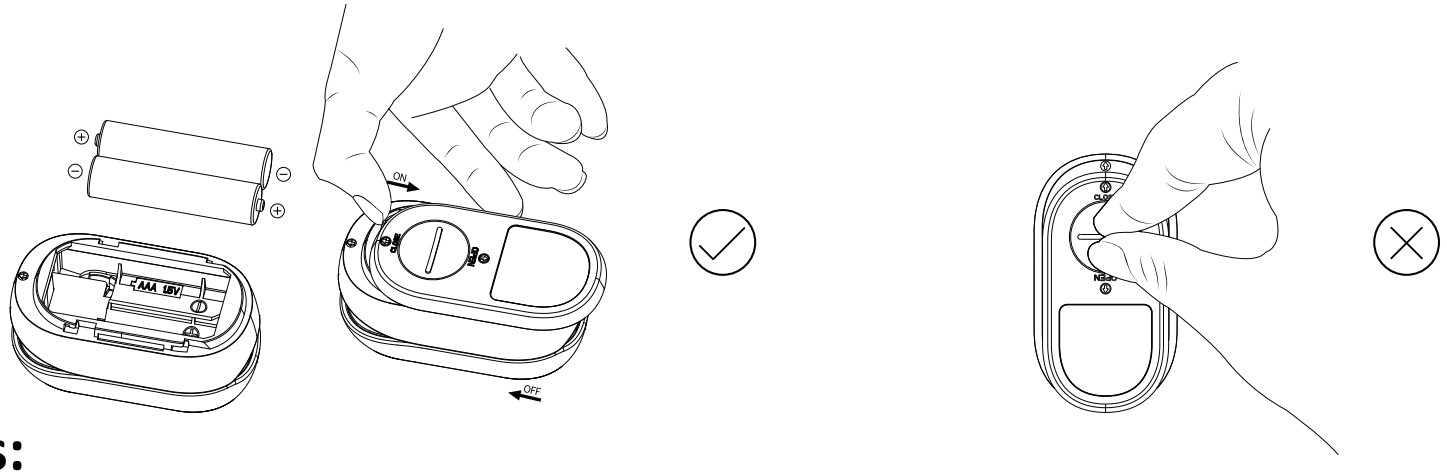
✧ Please use medical alcohol to clean the silicon which touches the finger inside of oximeter, and use alcohol to clean the test finger before and after each test. (The silicon inside of the oximeter belongs to medical silicon, which has no toxins and does no harm to the skin).

Product Accessories

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

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:

- Ethanol (70%)

To clean your equipment, follow 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 equipment, follow 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-based cleaners).
- If you spill liquid onto the equipment, contact us or your service personnel.

2. Disinfection

Clean the pulse oximeter before disinfecting it. The recommended 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 the surface of the fingertip oximeter before use.
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 the ambient temperatures is -20℃~50℃ 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 affectits 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: LED
2. SpO_2:
Measurement range: 0%-100%
Display range: 35%-100%
Resolution: 1%
Accuracy: ±2% for 70%-100%; less than 70% is unspecified.
3. Pulse Rate:
Measurementrange: 25bpm-250bpm

Resolution: 1 bpm

Accuracy: ±2 bpm

Pulse Intensity: Bargraph indicator

4. 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.

5.Dimension: 63.5mm (L) X 36mm (W) X 34mm (H)

Weight: 43g (without battery)

6. Environment Requirements: Temperature:10°C-40°C

Humidity (non-condensing): 15%-95%

Atmospheric pressure: 70kPa-106kPa

7. Storage/transportation conditions

Temperature: -20℃-50℃

Humidity (non-condensing): 10%-95%

Atmospheric pressure: 70kPa-106kPa

8. Measurement Performance in Low Perfusion Condition: 0.3%

9. Safety 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

10. Range of the peakwavelengths:RED: 660nm/IR: 905nm

11. Maximum opticaloutput power: 1.2mW

12. Use-life: Two years

Note:

1. SpO_2 and pulse rate accuracy are the essential requirements.

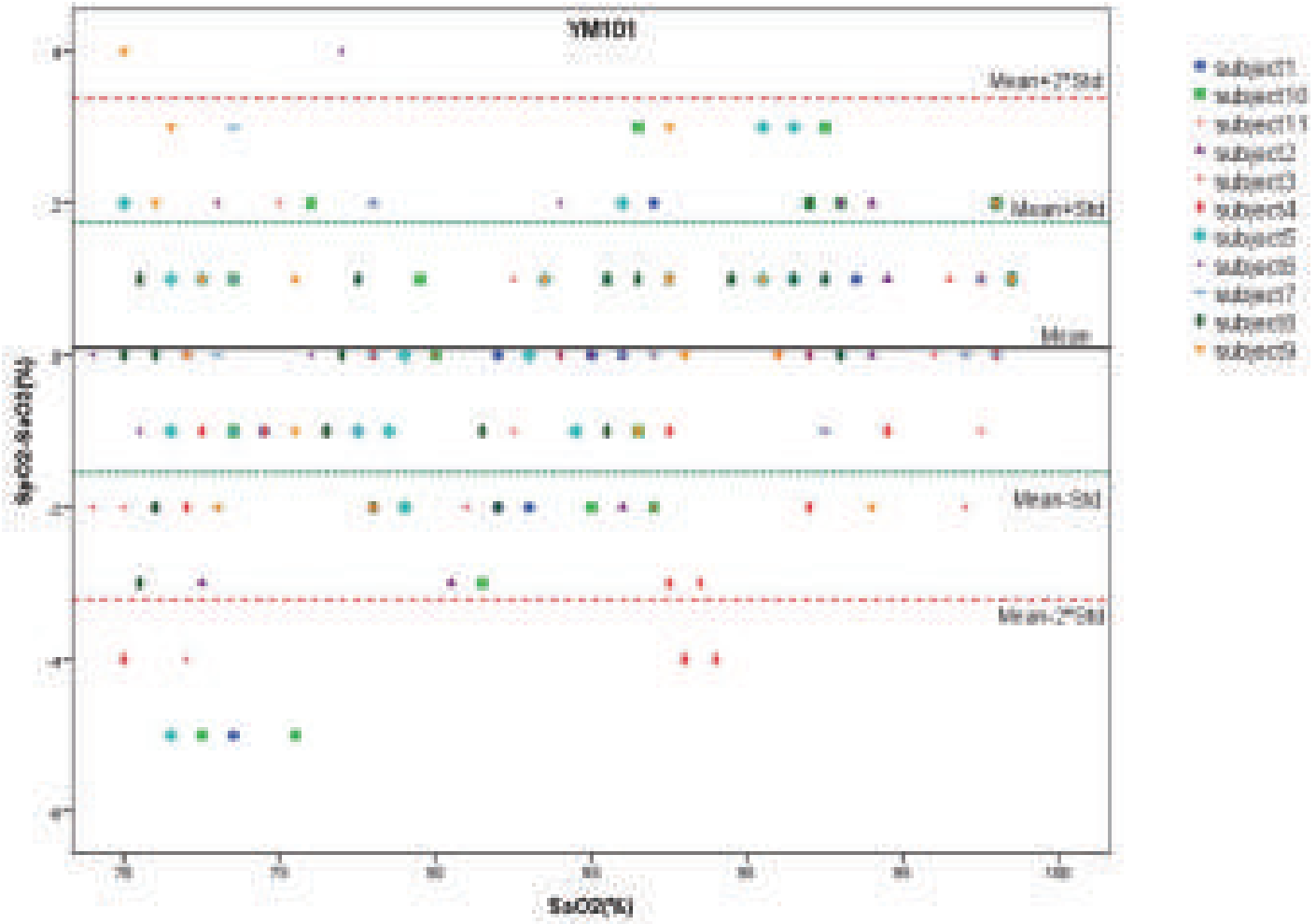
2. There is no alarm that includes the capability to detect an SpO_2 or pulse rate physiological alarm condition is available.

3. Data update duration is not applicable since it is not intended to be connected with other device to display the reading

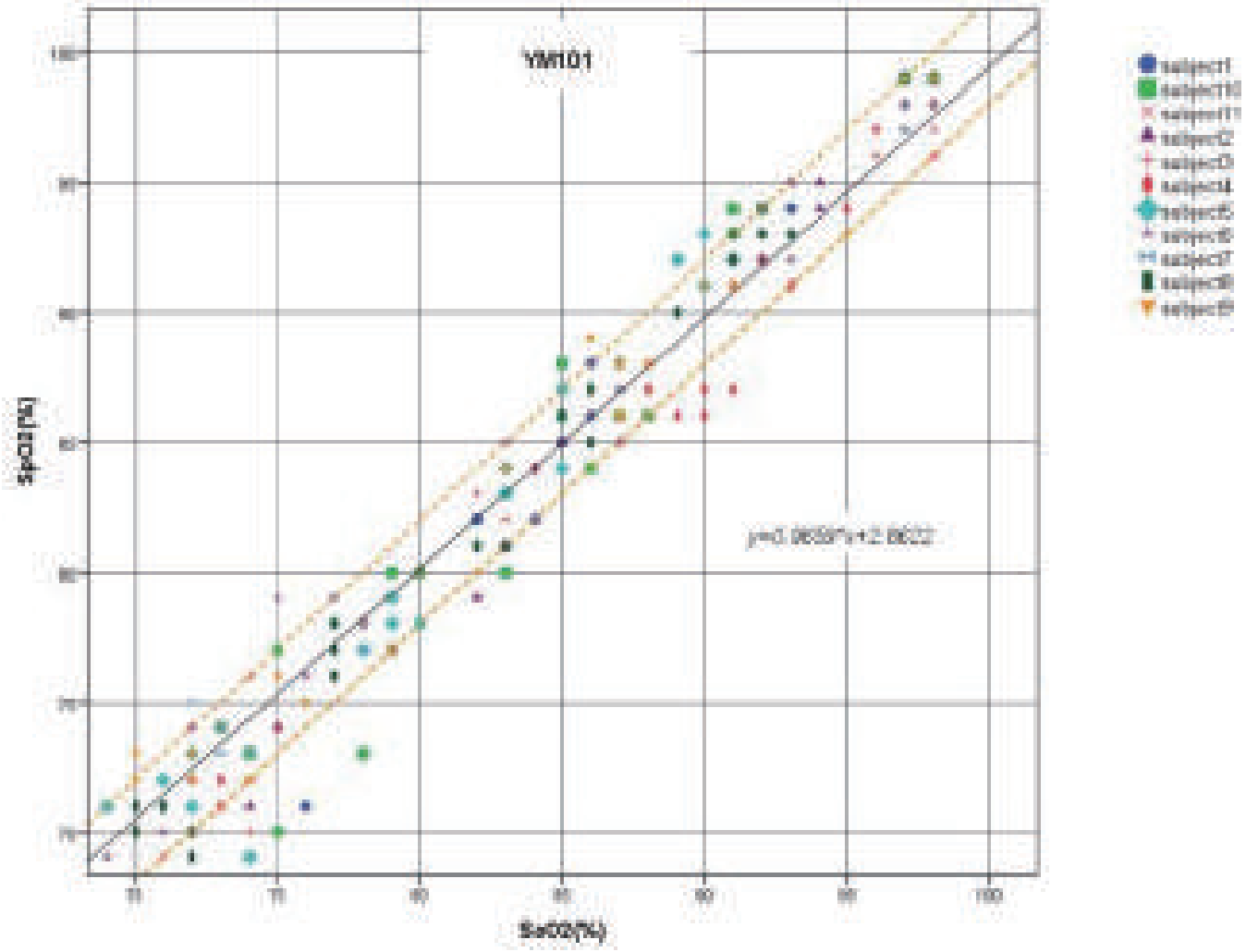
4. The oximeter is for spot checking, frequency of use is not applicable.

5. There will be no reading if the oximeter is not well fitted.

Graphical Plots of 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 are statistically 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. And the accuracy cannot be assessed by a function tester.

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.

Troubleshooting

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 8 seconds without any operations.	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 shacking 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.

Appendix 1 EMC Information

Guidance and manufacturer's declaration-Electromagnetic emission		
The Pulse 7S Pro is intended for use in the electromagnetic environment described below.		
Emissions	**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 emissions 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.

Harmonic emissions IEC61000-3-2	N.A.	N.A.
Voltage fluctuations/flicker emissions IEC61000-3-3	N.A.	

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 Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±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 %.

Electrical fast transient/burst IEC 61000-4-4	Not applicable	Not applicable	
Surge IEC 61000-4-5	Not applicable	Not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable	

Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC61000-4-6	Not applicable	Not applicable	
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	
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 Pulse Oximeter should assure that it is used in such an environment.

Radiated RF IEC 61000-4-3 (Test specifications for ENCLOSURE POR	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	IEC 60601-1-2 Test Level (V/m)	Compliance level (V/m)
	385	380 –390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27	27

T IMM UNIT Y to RF wirel ess com muni catio ns equi pme nt)	450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviati on 1 kHz sine	2	0.3	28	28
	710 745 780	704 – 787	LTE Band 13, 17	Pulse modula tion 217 Hz	0,2	0.3	9	9
	810 870	800 – 960	GSM 800/90 0, TETRA 800, iDEN	Pulse modula tion 18 Hz	2	0.3	28	28

	930		820, CDMA 850, LTE Band 5					
	1720	1700–1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28	28
	1845							
	1970							

	2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	28
	5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0.3	9	9
	5500							
	5785							

Possible Problems and Resolutions

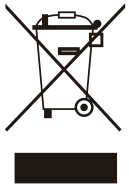
Problems	Possible reason	Solution
The Oximeter fails to display the blood oxygen saturation levels and/or pulse rate.	1. The finger is not placed between the sensor and the Light Emitting Diode. 2. The user's blood oxygen is too low to be detected.	1. Make sure that the finger is placed right in between 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. Install the battery correctly. 3. Contact the distributor.

The screen is suddenly off.	1. Without use, the oximeter will be automatically shutdown 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. Do not spray, pour, or spill any liquid on the oximeter, its accesso-ries, connectors, switches, or openings in the enclosure as this may damage the oximeter.

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 2002/96/EC.
	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
	Manufacturer

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

Manual version: A0

Software version: V1.0

Revision date: 2021-09

Manufactured for:
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Miami, FL 33127

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Made in China

Manual version: A0
Software version: V1.0
Revision date: 2021-09
Oxiline Pulse 7S Pro

RoHS