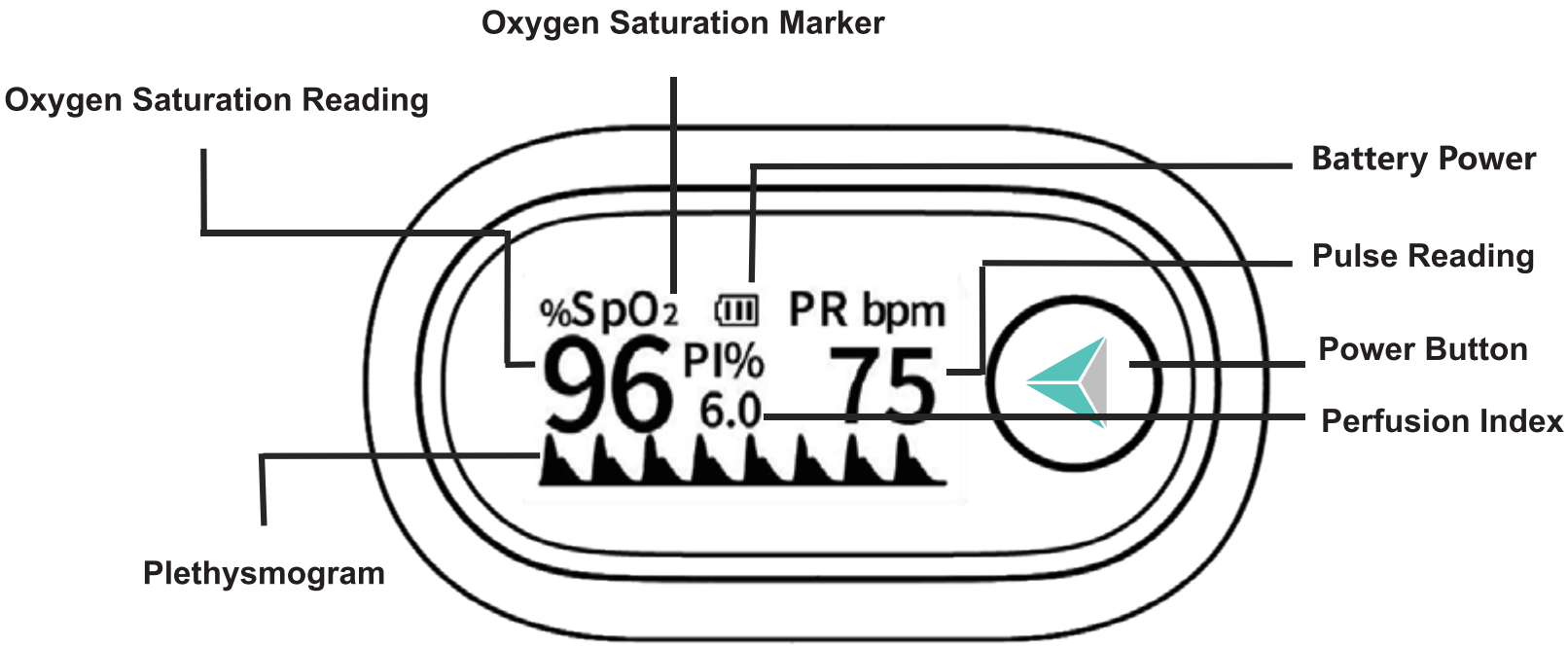
Pulse Oximeter

DISPLAY OVERVIEW



OVERVIEW

The Pulse Oximeter is a portable, non-invasive, simple-to-use device that detects the wearer's SpO2 level and pulse rate in seconds. All the wearer needs to do is slip their finger into the designated chamber to get results in seconds.

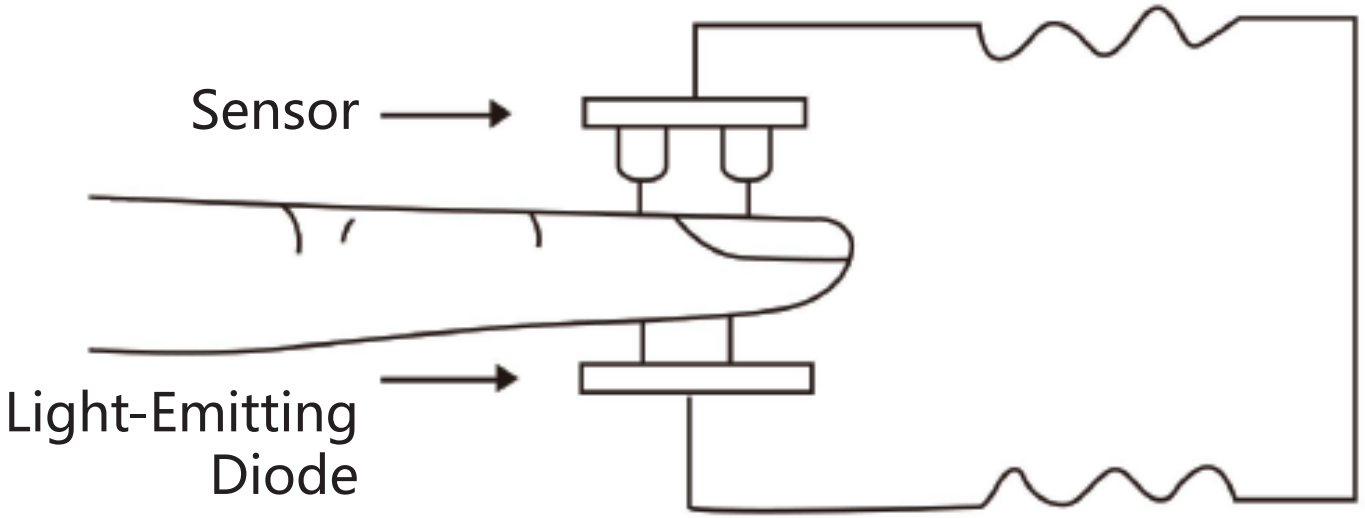
"Peripheral capillary oxygen saturation," or SpO2, is the ratio of oxyhemoglobin (HbO2) concentration to total hemoglobin concentration. The total hemoglobin concentration comprises both oxyhemoglobin and reduced hemoglobin levels in the blood. SpO2 is a vital physiological element of respiration and circulation.

OPERATING PRINCIPLE

Light with a wavelength of 905nm is preferentially absorbed by oxygenated blood (near-infrared light). While deoxygenated blood does the same with red light (wavelength 660nm).

A Pulse Oximeter measures SpO2 by sending red and infrared light beams through a pulsing capillary bed and measuring the amounts of these rays that emerge from the tissues with its sensor.

For greater accuracy, the Pulse Oximeter incorporates a patented algorithm that collects data from pulsatile arterial blood without local noise interference from tissues.



Beer-Lambert's law is then used to derive the numerical value of relative light absorption by total hemoglobin, which is displayed as the oxygen saturation level (SpO2) on the screen.

CAUTION

Due to the pulse oximeter's exceptional sensitivity, the test finger should be kept still during the reading. Measurements are best taken before or after physical activities, not during. We do not recommend using the pulse oximeter for continuous monitoring.

SAFETY INFORMATION

DANGER:

Refers to imminent hazards that could cause death or severe harm if precautions are not taken.
Generally, there are no risks linked with this product.

WARNING: Refers to potential hazards or unsafe practices that could cause death or severe harm if precautions are not taken.

- This device can only be purchased through or on the order of a certified physician under United States federal law.
- Explosive Hazard: Do not use this device within combustible areas.
- Do not use this device while performing an MRI or CT scan on the wearer.
- Please review relevant medical papers carefully for clinical limitations or contraindications.
- The device is not designed for newborns or infants. For reliable readings, the wearer's finger size must be between 8mm and 25.4mm.

- Before each use, the device should be thoroughly inspected. If any damage is identified, kindly discontinue use immediately.

- If the device is mismanaged, the wearer, especially microcirculation barrier patients, may experience discomfort or pain with it.
  Note: This device should not be used on the same finger for more than 10 minutes at a time.

- Avoid using the pulse oximeter on edemas, vulnerable areas, or for high-risk evaluations.

- This device is merely a support clinical diagnostic tool. All data measured by this oximeter are for reference only and should not be relied on for diagnosis.

  Do not use the device in high-frequency situations, such as rooms

- containing electrosurgical equipment.

- Do not submerge the oximeter in water or any other liquid.

- The thermometer is not a toy. No parts should be played with or swallowed by children. Children should not be allowed to take measurements without proper aid.

- Kindly follow local legislation and recycling guidelines when disposing of and recycling this device and its components.

CAUTION: Refers to potential hazards or risky practices that, if not avoided, may cause minor injuries or product/property damage.

The pulse oximeter is designed to determine the percentage of arterial oxygen saturation in functional hemoglobin. Factors that may lower its performance or accuracy level include, but are not limited to:

- Obstructions: Do not use the pulse oximeter on the same arm as a blood pressure cuff, arterial catheter, or infusion line(s) (IVs).
- Excessive light, such as direct home lighting or sunlight.
- Presence of moisture in the device.
- Finger size outside the specified size range.
- Poor pulse rate/strength.
- Venous pulsations.
- Anemia or low hemoglobin concentrations.
- Presence of cardio-green or other intravascular dyes.
- Presence of carboxyhemoglobin.
- Presence of methemoglobin.
- Dysfunctional hemoglobin.
- Artificial nails or fingernail polish.

WARNING: The light from the oximeter (visible infrared) is harmful to the human eyes. Avoid prolonged exposure to the eyes.

CONTRAINDICATIONS

None

COMPONENT OUTLINE

The pulse oximeter consists of a probe, electronic circuits, an OLED screen, and plastic enclosures.

PROBE

It is the compartment (opening) in the oximeter into which the finger is inserted and placed. It is a functional piece of the oximeter.

FEATURES OF THE LAZLE PULSE OXIMETER

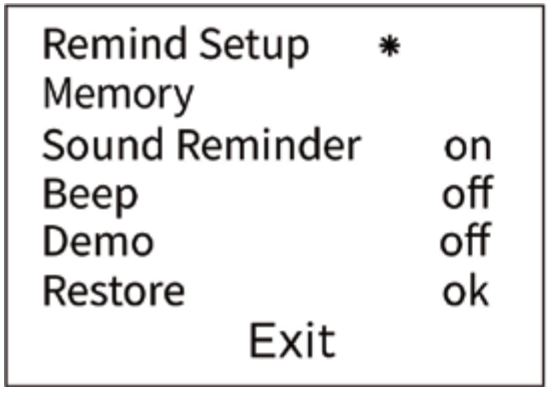
- A lightweight, portable, simple-to-use device.
- An OLED screen that displays pulse rate, SpO2, and perfusion index measurements clearly.
- A memory function with up to 50 SpO2 and pulse rate storage slots.
- A large font display.
- A low battery indicator.
- Automatic power down after 15 seconds of inactivity.

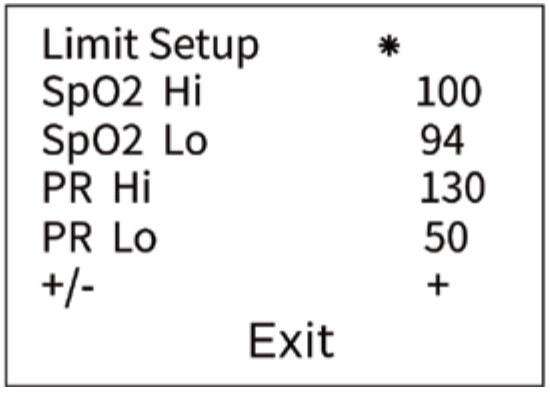
INDICATIONS FOR USE

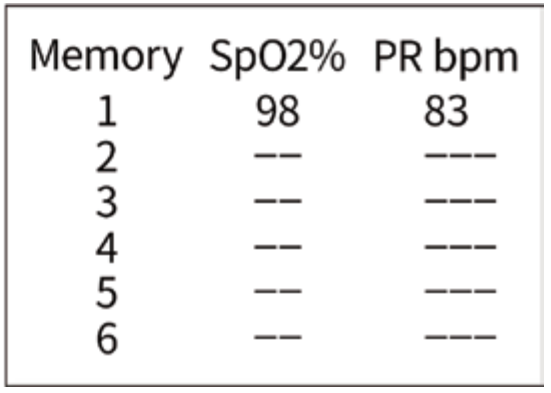
The Pulse Oximeter is a reusable device designed for spot-checking oxygen saturation levels and pulse rates through the finger of ADULT patients in healthcare environments. It is not indicated for use under motion or low perfusion scenarios.

HOW TO SET UP THE DEVICE

With the device powered on, press the power button for 1 second to access the "settings" area.
TAP the power button repeatedly to browse through the settings and LONG PRESS to modify any setting.







USING THE OXIMETER

- Correctly insert the two AAA batteries into the battery compartment and put back the battery cover.
- Insert a single finger, palm up, into the probe.

Note:

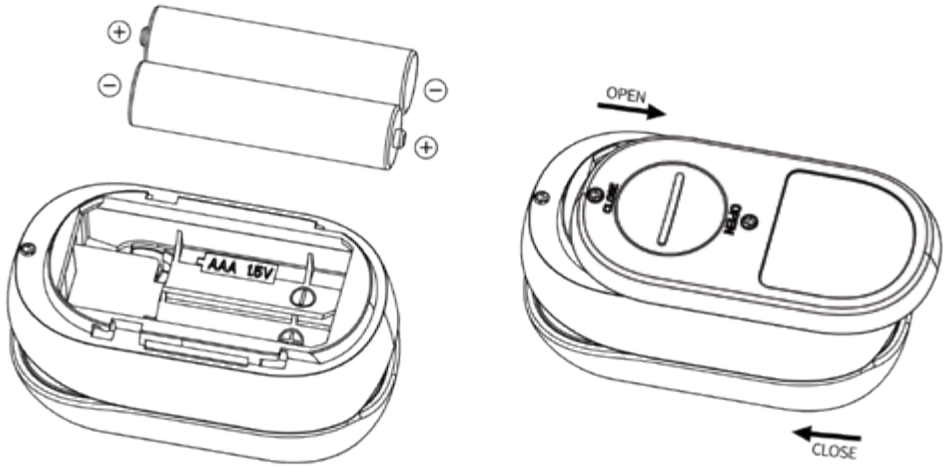
- The front of the finger should be facing the device's roof (top chamber with the senor).
- For reliable readings, insert the finger as deeply as possible into the probe.
- Press the power button once, to turn on the pulse oximeter.
- The wearer should be completely still while the pulse oximeter reads.
- Interpret the information displayed on the screen correctly.
- Before and after taking a reading, please wipe the silicone within the probe and the test finger with medical-grade alcohol.
- The silicone of the pulse oximeter is medical-grade and safe for human use.

IN-BOX CONTENT

- x1 Pulse Oximeter
- x1 User Manual
- x2 AAA Battery

BATTERY INSTALLATION

- Properly place the two AAA batteries in their correct polarities in the slots.



Note:

- Installing the batteries wrongly may damage the device.
  If the device will be inactive for a long while, please take out the batteries to avoid damaging the device.

CLEANING AND DISINFECTION

Cleaning

- The device should be thoroughly cleaned regularly and more frequently if its environment is heavily polluted (e.g., with fumes), dusty, or sandy.
- The recommended cleaning agents of the Pulse Oximeter include:
  - Diluted mild soap.
  - 70% Ethanol.

To clean the Pulse Oximeter:

- Power off the device.
- Wipe the screen with a soft, clean cloth moistened with a non-corrosive glass cleaner.
- Wipe the device, including the probe, with a soft clean cloth moistened with any of the recommended cleaning agents.
- Wipe the device with a soft, clean, dry cloth, and store it in a cool, dry, well-ventilated place.

To avoid damaging the device, please adhere to the following instructions:

- Always dilute the cleaning agent to the manufacturer's instructions or the least effective concentration.
- Do not immerse the oximeter in any liquid.
- Do not pour any form of liquid into this device or its parts.

- Do not use abrasive materials, such as steel, wool, silver polish, or erosive cleaners, such as acetone or acetone-based fluids, on the device or its parts.
- If liquid is accidentally spilled in/on this device, kindly contact us or an authorized technician before using the device.

Disinfection

We recommend properly wiping the oximeter before disinfecting it. The recommended disinfecting agent is 70% ethanol, and the steps to be taken are the same as detailed in the section “Cleaning.”

Do NOT attempt to disinfect this device with high-temperature/high-pressure disinfecting gases. Never use formaldehyde or ETO on this device.

MAINTENANCE AND STORAGE

- Always replace the battery as soon as the low battery indicator flashes.
- Always wipe the oximeter with a soft, clean, dry cloth before use.
- Always uninstall the batteries if the oximeter will be inactive for long periods.
- The pulse oximeter is best stored within temperatures between -20°F - +70°F (-4°F - +158°F) and relative humidity between 10% - 95%.
- Always store the device in a cool, dry place, as wet environments may reduce its shelf-life and measurement accuracy.
- Protect this device from direct sunlight, extreme light, and heat.
- Protect this device from excessive radioactive infrared and ultraviolet rays.
- Kindly adhere to local laws and regulations on the disposal of used batteries.

SPECIFICATIONS

- Display Type: OLED screen

- SpO2:
  Range: 35% - 100%
  Resolution: 1%
  Accuracy: 100%-90%, ±2%; 90%-80%, ±2%; 80%-70%, ±2%; 100%-70%, ±2%; 0% -69%, unspecified

- Pulse Rate:
  Range: 25bpm - 250bpm
  Resolution: 1bpm
  Accuracy: ±2bpm
  Pulse Intensity: Pulse Meter Indicated

- Perfusion Index (Only for OLED Screen):
  Range: 0% - 50%
  Resolution: 1%
  Accuracy: 0.1% (0% - 1%); 1% (1% - 20%); > 20%, no definition

- Power Requirements:
  Type: Two AAA alkaline batteries
  Power Consumption: 30mA (Normal)
  Low Battery Indication
  Battery Life: Two AAA 1.5V, 600mAh alkaline batteries that can be continuously used for as long as 24 hours

- Dimensions:
  Length: 63mm
  Width: 36mm
  Height: 34mm
  Weight: 38g (without batteries)

- Optimum Operating Conditions:
  Temperature: 10℃ - 40℃
  Humidity (non-condensing): 15% - 95%
  Atmospheric Pressure: 70kPa - 106kPa

- Optimum Storage/Transportation Conditions:
  Temperature: -20℃ - +50℃
  Humidity (non-condensing): 10% - 95%
  Atmospheric Pressure: 50kPa - 106kPa

- Operating Efficiency with Low Perfusion Conditions: 0.3%
  Classification
  Type of Protection against Electric Shock:
  - II (Internally-Powered Equipment)
  - Type BF-Applied Part (Defibrillation-Proof)
  - Mode of Operation: Spot-Checking
  - Degree of Protection against Explosion Hazards: IP22
  - Shelf-Life: 2 years

Note: SpO2 and Pulse Rate Accuracy are the most essential parameters.

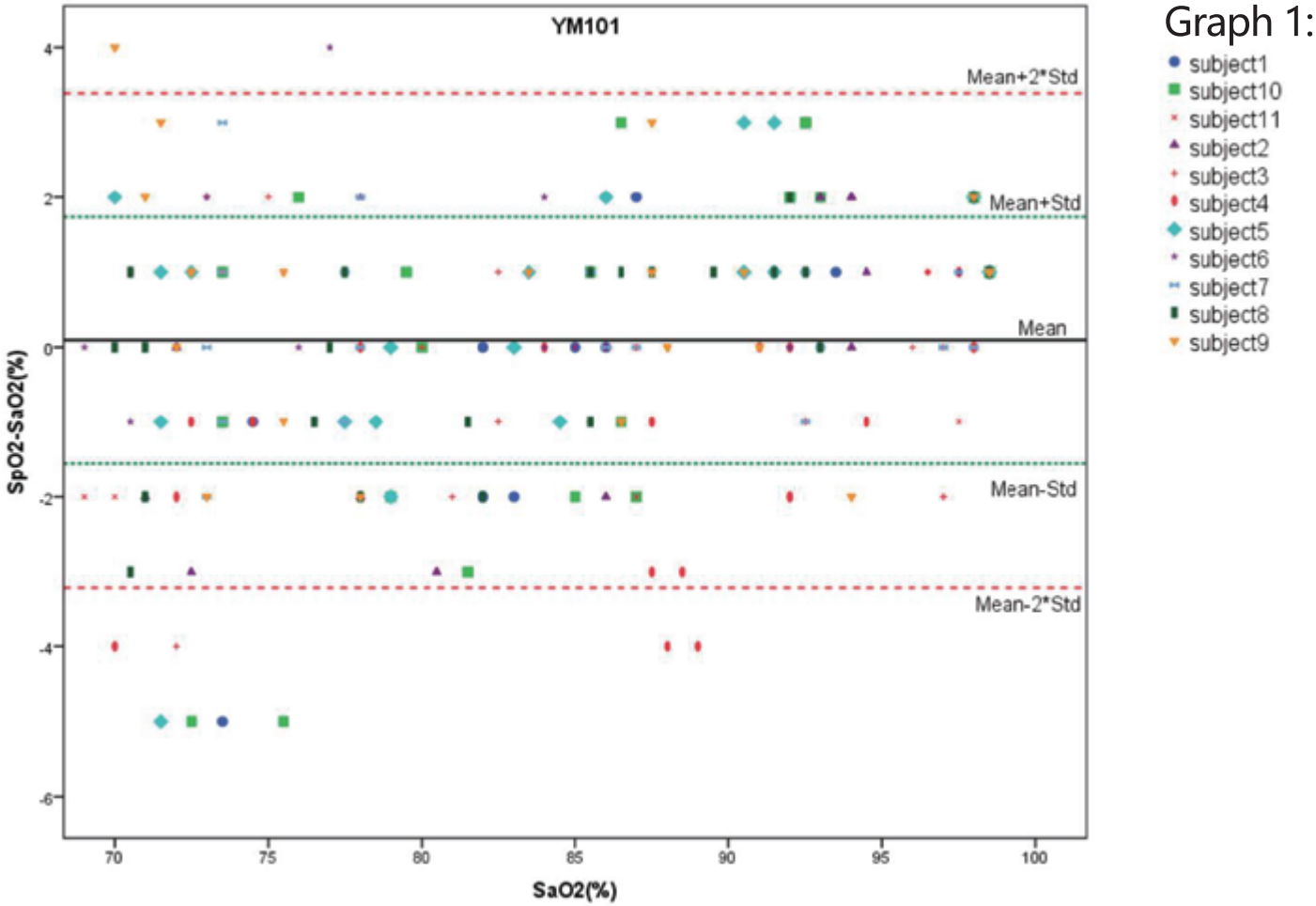


Figure 7: Bland-Altman Graph of SpO2-SaO2 (%)

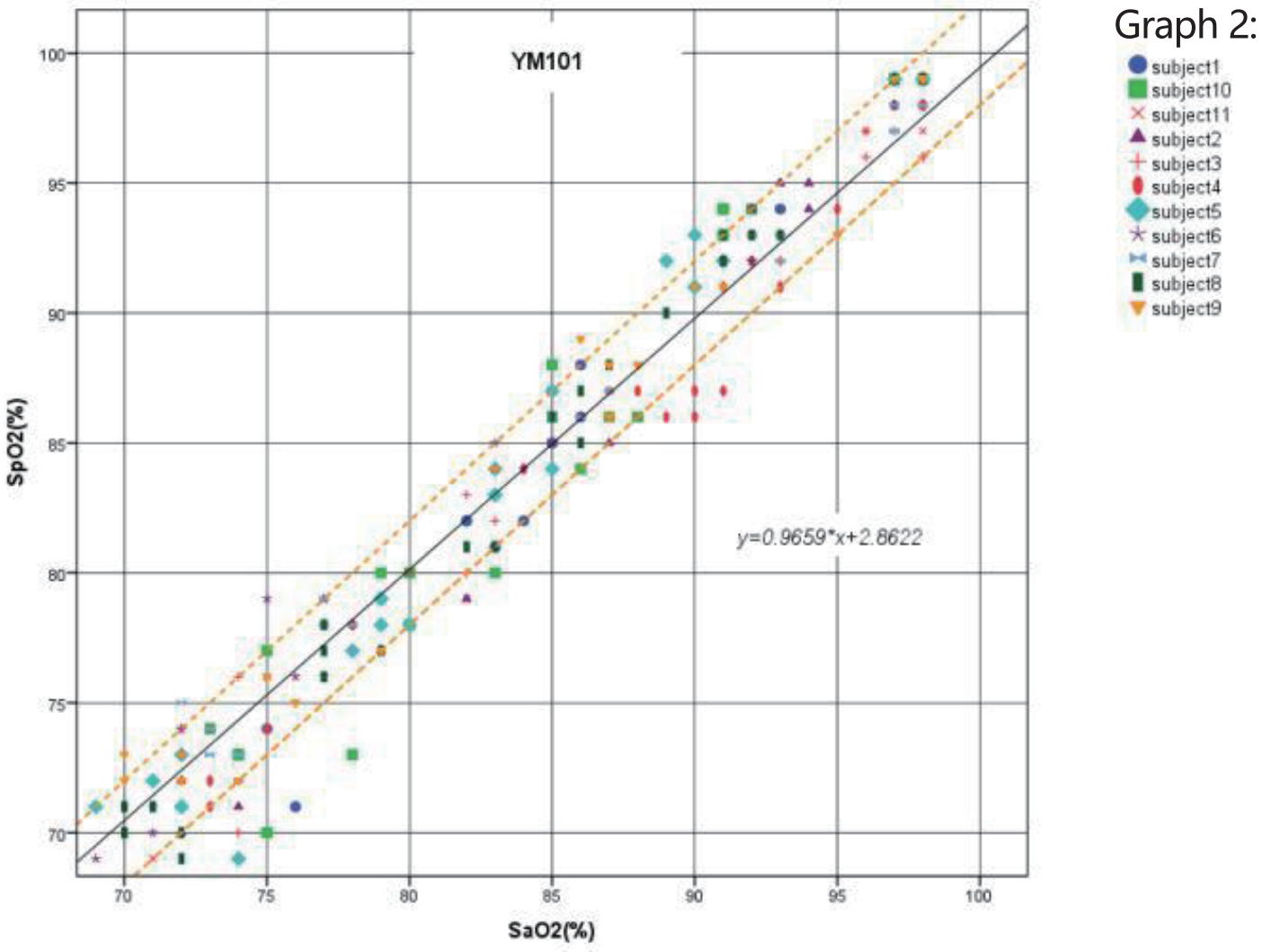


Figure 8: A Regression Chart of the Measured Data

ASSESSING THE VALIDITY OF AN SPO2 MEASUREMENT

The accuracy of the sensor and SpO2 measurements can be validated on a patient monitor by concurrently analyzing the quality of the pleth wave and the stability of the SpO2 values.

Note:

SpO2 Accuracy

The SpO2 accuracy of the pulse oximeter has been validated in human trials by comparing its measurements to those acquired by the Co-oximeter on arterial blood samples.
When pulse oximeter values are statistically dispersed, around two-thirds of the results should fall within the Co-oximeter determined accuracy range.

Pulse Rate Accuracy

The pulse rate was validated by comparing the measured values to those generated by an arterial oxygen simulator (electronic pulse simulator).

The quality of the SpO2 pleth wave is, in general, a reflection of the quality of the light signals received by the sensor. Thus, a low-quality wave signals a decrease in signal validity.

The consistency of the SpO2 values indicates the presence or absence of interference. Thus, oscillations could be caused by interference with the signal channel or physiological factors.

Interference could be due to movement while the oximeter is measuring, incorrect finger or sensor placement, or a defective sensor. For better consistent and correct SpO2 results, limit movement during measurement.

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.

ERROR AND TROUBLESHOOTING

Warning

- Servicing and internal maintenance of this oximeter must be done by qualified service personnel ONLY.
- Owners/Users of this device and non-authorized technicians are not to repair, service, or dismantle this oximeter.
- Besides the batteries, there are NO replaceable components in this device.

ISSUE	POSSIBLE CAUSE	SOLUTION
Failure to Power On.	The battery power is depleted.	Replace with new, powered batteries.
	The batteries are not correctly placed.	Reposition the batteries correctly following the section “BATTERY INSTALLATION.”
	The oximeter is damaged.	Contact an authorized dealer.

The display suddenly goes off.	The device powers down, by default, after 15 seconds of detecting no physiological signs.	This is normal. Simply power on the oximeter again.
	The battery power is depleted.	Replace with new, powered batteries.
The SpO2 and Pulse Rate values flickering on the display screen.	Interference between the light-emitting diode and the sensor.	Properly clean the probe, especially the upper and low screens.
	The finger is not stable, or the wearer is moving.	Ensure the wearer stays still during the measurement.

	The finger is not placed deep enough within the probe.	Reposition the finger, this time deeper.
	The finger is not correctly positioned (not placed between the sensor and the Light Emitting Diode).	Reposition the finger, ensuring it is placed right between the sensor and the Light Emitting Diode.
	The finger size is too large or too small.	Ensure the wearer's finger is within the recommended size range (check section "SAFETY INFORMATION").
	Pulse rate value of cyclical fluctuations.	The measurement is normal. The wearer has arrhythmia.
The SpO2 and Pulse Rate values are not displayed at all or solidly.	The finger is not correctly positioned (not placed between the sensor and the Light Emitting Diode).	Reposition the finger, ensuring it is placed right between the sensor and the Light Emitting Diode.

	The wearer's SpO2 level is too low.	Try taking another measurement, or see a doctor if confident of the device's accurate operation.
	The wearer's blood perfusion rate is too low.	Ensure there are no restrictions obstructing the wearer's blood flow.
Oximeter cannot be muted.	The power button is bad.	Check the button and try again.
	The power button was not pressed as directed (The press time is not right).	Ensure the press time is 2-3 seconds.

Note:

- There are no parts of this oximeter that can be serviced by the user or unauthorized personnel. Disassembly of this device should be done ONLY by qualified service personnel.
- Alternative, functional method(s) can be used to verify the accuracy of the obtained vital results.
- Do not spray, spill, or pour fluids on/into the oximeter, its accessories, connectors, switches, and opening. This might damage the device or reduce its measurement accuracy.

The Pulse Oximeter can be used in the listed electromagnetic environments. The owner or wearer of this device is assured of its safety when used in the stipulated environments.		
Emissions	**Compliance**	**Electromagnetic environment guidance**
RF Emissions CISPR II	Group 1	The Pulse Oximeter can be used in the listed electromagnetic environments. The owner or wearer of this device is assured of its safety when used in the stipulated environments.

RF Emissions CISPR II	Class B	The Pulse Oximeter can be used in all establishments, including homes and buildings directly connected to public low-voltage power supply networks
Harmonic Emissions IEC61000-3-2	N.A.	
Voltage Fluctuations/ Flicker Emissions IEC61000-3-3	N.A.	

Guidance and manufacturer's declaration on electromagnetic immunity			
The Pulse Oximeter can be used in the following electromagnetic environments. The owner or wearer of this device is assured of its safety when used in the stipulated environments.			
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 wooden, concrete, or made of ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.

Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50/60Hz	30 A/m 50/60Hz	The power frequency of magnetic fields should be at similar levels as in a typical commercial or hospital environment.
NOTE: UT is the A.C. mains voltage before applying the test level.			

Guidance and manufacturer is declaration on electromagnetic immunity

The Pulse Oximeter can be used in the following electromagnetic environments. The owner or wearer of this device is assured of its safety when used in the stipulated environments.

Immunity Test	IEC 60601 test level	Com-pli-ance level	
Conduct-ed RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz 6Vrms 150 kHz to 80MHz Outside ISM bands	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the AOJ-70 series Pulse Oximeter, including cables, than the recommended separation distance, as calculated from the transmitter frequency equation.
Radiated RF	10 V/m	10 V/m	

IEC 61000-4-3	80MHz to 2.7 GHz		Recommended Separation 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 power output rating of the transmitter in watts (W) according to the manufacturer of the transmitter and d is the recommended separation distance in meters (m).

			The field strengths of fixed RF transmitters determined from electromagnetic site surveys should be lower than the compliance levels in each frequency range. Interference may occur within vicinities of equipment marked with the symbol: 

Note:

→ At ranges between 80 MHz and 800 MHz, the higher frequency applies.

→ These guidelines may not apply in all situations. Electromagnetic strength is influenced by the absorption and reflection of signals from structures, objects, and people.

The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 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, 7MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 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.

The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and the frequency range 80 MHz to 2,7 GHz are stipulated to decrease the chances of mobile/portable communications equipment causing interference if inadvertently brought into the measuring area.

Also, for this reason, an additional factor of 10/3 has been included in the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

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 stations, and TV broadcast stations cannot be accurately obtained through theoretical calculations alone.

An electromagnetic site survey should be considered to assess the electromagnetic environment of fixed RF transmitters. If the measured field strength in the AOJ-70 series Pulse Oximeter location exceeds the recommended RF compliance level above, the AOJ-70 series Pulse Oximeter should be re-evaluated to confirm it is properly functioning.

If abnormal operations are observed, corrective measures, such as re-orienting or relocating the AOJ-70 series Pulse Oximeter, may be necessary.
Over frequency ranges between 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Test Frequency (MHz)	Band (MHz)	Service a)	Modulation	Max. Power (W)	Distance	Immunity Test Level (V/m)

385	380-390	TETRA 400	Pulse modulation 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 modulation b) 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900,	Pulse modulat	2	0.3	28
870						

930		TETRA 800, iDEN 820, CDMA 850, LTE Band 5	ion b) 18 Hz			
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; 820, LTE Band 1,3,4,25; UMTS	Pulse modulation b) 217 Hz	2	0.3	28
1845						
1970						

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: The distance between the transmitting antenna and the ME-EQUIPMENT OR ME SYSTEM may be reduced to 1m, if applicable, to comply with the IMMUNITY TEST LEVEL. The 1m test distance complies with IEC 61000-4-3.

- For some services, only the uplink frequencies are included.
- The carrier shall be modulated using a 50% duty-cycle square wave signal.
- As an alternative to FM modulation, 50% pulse modulation at 18Hz may be used. However, it is essential to note that this alternative is ONLY a proxy and not the actual modulation.

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

The Pulse Oximeter is intended for use in electromagnetic environments, where radiated RF signals are controlled. The owner or wearer of this device can help prevent electromagnetic interference by keeping the minimum specified distance from portable and mobile RF communications equipment (transmitters) as calculated by the maximum power output of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to transmitter's frequency (m)		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E1}\right]\sqrt{p}$	**800 MHz 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 with power outputs not listed above, the recommended separation distance, d in meters (m), can be estimated through the equation applicable to the frequency of the transmitter - where P is the maximum power output rating of the transmitter in watts (W), according to the manufacturer of the transmitter.

NOTE:

→ At ranges between 80 MHz and 800 MHz, the higher frequency applies.

→ These guidelines may not apply in all situations. Electromagnetic strength is influenced by the absorption and reflection of signals from structures, objects, and people.

ERROR AND TROUBLESHOOTING (2)

ISSUE	POSSIBLE REASON	SOLUTION
The Oximeter fails to display the blood oxygen saturation level (SpO2) or pulse rate.	The finger is not correctly positioned (not placed between the sensor and the Light Emitting Diode).	Reposition the finger, ensuring it is placed right between the sensor and the Light Emitting Diode.
	The wearer's blood perfusion rate is too low.	Ensure there are no restrictions obstructing the wearer's blood flow.
The SpO2 or Pulse Rate value flickers.	The finger is not correctly positioned (not placed between the sensor and the Light Emitting Diode).	Reposition the finger, ensuring it is placed right between the sensor and the Light Emitting Diode.
	The finger is not stable, or the wearer is moving.	Ensure the wearer stays still during the measurement.

The Oximeter fails to power on.	The battery power is depleted.	Replace with new, powered batteries.
	The batteries are not correctly placed.	Reposition the batteries correctly according to the section “BATTERY INSTALLATION.”
	The oximeter is damaged.	Contact the distributor.
The screen suddenly goes off.	The oximeter goes off by default after 15 seconds of detecting no physiological signs.	This is normal. Simply turn on the oximeter again.
	The battery power is depleted.	Replace with new, powered batteries.

Note:

- There are no parts of this oximeter that the user or unauthorized technicians can service. Disassembly of this device should be done ONLY by qualified service personnel.
- Alternative, functional method(s) can be used to verify the accuracy of the obtained results.
- Do not spray, spill, or pour fluids on/into the oximeter, its accessories, connectors, switches, and opening. This might damage the device or reduce its measurement accuracy.

SYMBOLS

Symbol	Description
	Type BF Equipment
	Attention! Consult accompanying documents
% **SpO2**	Oxygen Saturation
♥ **/Min**	Pulse Rate

	Standard symbol for marking electrical devices according to Directive 200296/EC The device, accessories, and packaging should be disposed of correctly at the end of its shelf-life Kindly adhere to Local Ordinances and Regulations for guidance on the disposal of these materials Note: The Oximeter is subject to this regulation
	The device has NO alert system
	Caution! Consult accompanying documents

IP22	Protection requirement of Electrical Appliances according to the IEC60529
	Manufacturing Date
SN	Serial Number
RoHS	RoHS (Restriction of Hazardous Substances) certification mark
CE	CE certification mark

NOTE: The illustrations used in this manual may differ slightly from those on the actual product

Manual Version: 1.0
Revision Date: 2021/12

Pulse Oximeter