REF HCSM70S

SOFT-TOUCH FINGER PULSE OXIMETER

This manual describes the Pulse Oximeter's operation, features, functions, specifications, usage, repair, maintenance and storage; as well as warnings and safety procedures to protect the user and equipment.

INDICATIONS FOR USE

The Fingertip Pulse Oximeter is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate of adult, adolescent and child patients in hospitals, hospital-type facilities and homecare.

CONTRAINDICATIONS

This device is not intended for continuous monitoring.

PRECAUTIONS FOR USE

Please read the User Manual carefully before using this product. The User Manual describes operating procedures that should be strictly followed. Failure to follow the User Manual may cause measuring abnormality, equipment damage and human injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, human injury and equipment damage due to users' negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

This product is designed for ongoing, multiple-patient usage with an operating life of 5 years.
If you have any questions regarding to the use of this product, please call 1-800-MEDLINE.

CAUTIONS

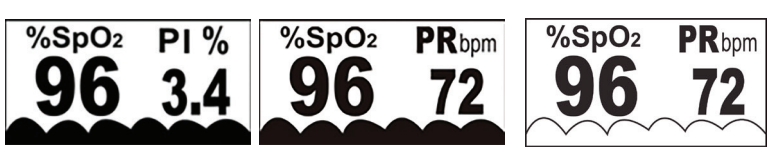
- Before use, carefully read the manual.
- Operation of the fingertip pulse oximeter may be affected by the use of an electrosurgical unit (ESU).
- The fingertip pulse oximeter must be able to measure the pulse properly to obtain an accurate SpO2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO2 measurement.
- Do not use the fingertip pulse oximeter in an MRI or CT environment.
- Do not use the fingertip pulse oximeter in situations where alarms are required. The device has no alarms. It is not for continuous monitoring.
- Do not use the fingertip pulse oximeter in an explosive atmosphere.
- 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.
- In order to ensure correct sensor alignment and skin integrity, the maximum application time at a single site for our device should be less than half an hour.
- Do not sterilize the device using autoclaving, ethylene oxide sterilizing, or immersing the device in liquid. The device is not intended for sterilization.
- Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
- This equipment complies with IEC 60601-1-2:2014 for electromagnetic compatibility for medical electrical equipment and/or systems. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device.
- Portable and mobile RF communications equipment can affect medical electrical equipment
- This equipment is not intended for use during patient transport outside the healthcare facility.
- This equipment should not be used adjacent to or stacked with other equipment.
- It may be unsafe to:
  —use accessories, detachable parts and materials not described in the instructions for use
  —interconnect this equipment with other equipment not described in the instructions for use
  —disassemble, repair or modify the equipment
- These materials that contact with the patient's skin contain medical silicone and ABS plastic enclosure are all pass the ISO10993-5 Tests for in vitro cytotoxicity and ISO10993-10 Tests for irritation and delayed-type hypersensitivity.
- Rx only: Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

PRODUCT FEATURES

1. Simple to operate and convenient to carry.
2. Small volume, light weight and low power consumption.
3. Dual color OLED displays SpO2, PR, PI (Perfusion Index), Pulse bar, and waveform.
4. Seven display modes
5. Level 1-10 adjustable brightness.
6. Two pcs AAA-size alkaline batteries; real-time battery status indication.
7. The device automatically shuts off after no operation in 8 seconds when "finger out" displays.
8. Multiple-patient reusability.

INSTRUCTIONS

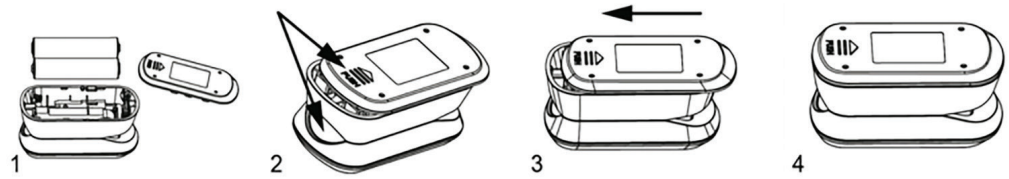
1. Install two AAA batteries according to the Battery Installation instructions.
2. Place one of your fingers into the rubber opening of the pulse oximeter.
3. Press the switch button one time on front panel to turn the pulse oximeter on.
4. Keep your hands still for the reading. Do not shake your finger during the test. It is recommended that you do not move your body while taking a reading.
5. Read the data from the display screen.
6. The display modes are as follows.



Notes:
- The pulse bar less than 30% indicates signal inadequacy and the displayed SpO2 or pulse rate value is potentially incorrect.
- If the screen displays "?", it means the signal is unstable, please keep your hands still and retry.
- PI means Perfusion Index.

BATTERY INSTALLATION

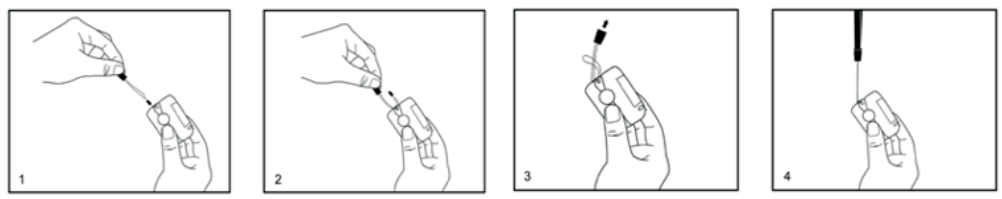
1. Slide the battery door cover horizontally along the arrow shown as the picture.
2. Install two AAA batteries into the battery compartment. Match the plus (+) and minus (-) signs in the compartment. If the polarities are not matched, damage may be caused to the oximeter.
3. Close the battery door cover.



Notes:
- Please remove the batteries if the pulse oximeter will not be used for long periods of time.
- Please replace the battery when the power indicator starts flickering.

LANYARD USE

1. Thread thinner end of the lanyard through the loop.
2. Thread thicker end of the lanyard through the threaded end before pulling it tightly.



Warnings!
- Keep the oximeter away from young children. Small items such as the battery door, battery, and lanyard are choking hazards.
- Do not hang the lanyard from the device's electrical wire.
- Please notice that the lanyard which is tied to the oximeter may cause strangulation due to excessive length.

MAINTENANCE AND STORAGE

1. Replace the batteries in a timely manner when low voltage lamp is lighted.
2. Clean surface of the fingertip oximeter before it is used in diagnosis for patients.
3. Remove the batteries if the oximeter is not operated for a long time.
4. It is best to store the product in -25~+70 and ≤93% humidity.
5 Keep in a dry place. Extreme moisture may affect oximeter lifetime and may cause damage.
6. Dispose of battery properly; follow any applicable local battery disposal laws.

Cleaning the fingertip pulse oximeter
Please use medical alcohol to clean the silicone that touches the finger inside of oximeter with a soft cloth dampened with 70% isopropyl alcohol. Also clean the finger being tested using alcohol before and after each test. Do not pour or spray liquids onto the oximeter, and do not allow any liquid to enter any openings in the device. Allow the oximeter to dry thoroughly before reuse. The fingertip pulse oximeter requires no routine calibration or maintenance other than replacement of batteries. **The use life of the device is five years when it is used for 15 measurements every day and 10 minutes per one measurement. Stop using and contact local service center if one of the following cases occurs:**
- An error in the Possible Problems and solutions is displayed on screen.
- The oximeter cannot be powered on in any case and not due to low battery power.
- There is a crack on the oximeter or damage to the display resulting in readings that cannot be identified; the spring fails to hold the device in place; or the key is unresponsive or unavailable.

Disinfecting
The applied parts touching the patient's body are required to be disinfected once after each use. The recommended disinfectants include: ethanol 70%, isopropanol 70%, glutaraldehyde-type 2% liquid disinfectants. Disinfection may cause damage to the equipment and is therefore not recommended for this pulse oximeter unless otherwise indicated in your hospital's servicing schedule. Clean the pulse oximeter before disinfecting it.
CAUTION: Never use EtO or formaldehyde for disinfection.

SPECIFICATIONS

1. Display Type
OLED display
2. SpO2
Display range: 0%~100%
Measurement range: 70%~100%
Accuracy: 70%~100%±2%; 0%~69% no definition
Resolution: 1%
3. Pulse Rate
Display range: 30bpm~250bpm

Measure range: 30bpm~250bpm
Accuracy: 30bpm~99bpm, ±2bpm; 100~250bpm, ±2%
Resolution: 1bpm

4. Perfusion Index

Display range: 0.1%~20.0%
Measure range: 0.2%~20.0%
Accuracy: 0.2%~1.0%, ±0.2digits; 1.1%~20.0%, ±20%
Resolution: 0.1%

5. Probe LED Specifications

Measuring Range	Wavelength	Radiant Power
RED	660±3nm	3.2mW
IR	905±10nm	2.4mW

6. Power Requirements

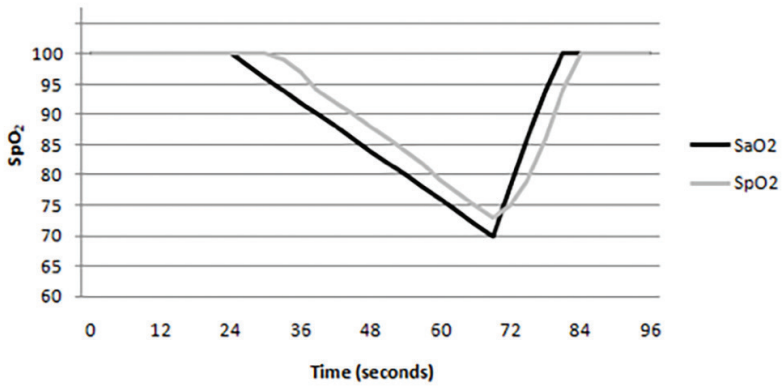
Two AAA alkaline Batteries
Power consumption: Less than 40mA
Battery Life: Two AAA 1.5V, 1200mAh alkaline batteries could be continuously operated as long as 24 hours.

7. Environment Requirements

Operation Temperature: 5°C~40°C
Storage Temperature: -25°C~+70°C
Ambient Humidity: 15%~93% no condensation in operation; ≤93% no condensation in storage/transport
Atmosphere pressure: 70kPa~106kPa

8. Equipment Response Time

As shown in the following figure.
Response time of slower average is 8 seconds.



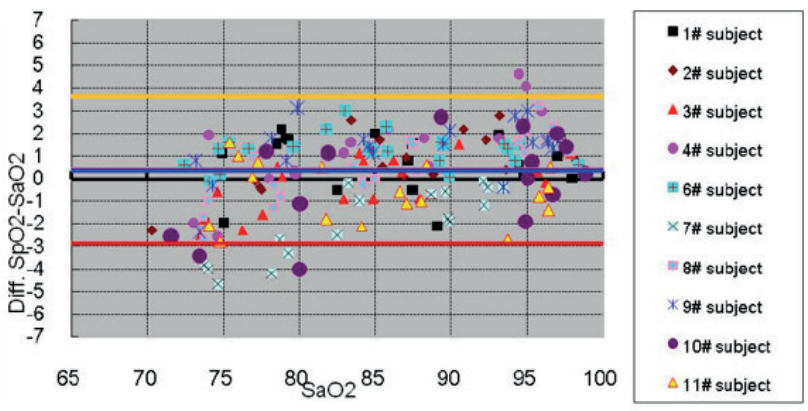
9. Equipment Response Time

According to the type of protection against electric shock: INTERNALLY POWERED EQUIPMENT;
According to the degree of protection against electric shock: TYPE BF APPLIED PART (The application part is rubber inside of the Pulse Oximeter);
According to the degree of protection against ingress of water: IP22
According to the mode of operation: CONTINUOUS OPERATION

CLINICAL SUMMARY STUDY

The following details are provided to disclose actual performance observed in the clinical validation study of healthy adult volunteers. The ARMS value analysis statement and Bland-Altman plot of data for HCSM70S is shown as following:

ARMS Value Analysis Statement			
Item	90--100	80--<90	70--<80
#pts	78	66	63
Bias	1.02	0.40	-0.48
ARMS	1.66	1.46	1.93



POSSIBLE PROBLEMS AND RESOLUTIONS

Problems	Possible causes	Solution
SpO2 or PR cannot be shown normally	1. Finger is not inserted correctly 2. Patient's SpO2 value is too low to be measured	1. Retry by inserting the finger 2. There is excessive illumination 3. Try some more times. If you can make sure no problem exists in the product, please go to a hospital timely for exact diagnosis
SpO2 or PR is shown unstably	1. Finger might not be inserted deep enough. 2. Excessive patient movement	1. Retry by inserting the finger 2. Be calm
The oximeter cannot be powered on	1. No battery or low power of battery 2. Batteries might be installed incorrectly 3. The oximeter might be damaged	1. Please replace batteries 2. Please reinstall the batteries 3. Please contact Medline customer service at 1-800-MEDLINE
Indication lamps are suddenly off	1. The product is automatically powered off when no signal is detected longer than 8 seconds 2. The battery power is too low to work	1. Normal 2. Replace the batteries
"Error 7" is displayed on screen	Err 7 means all the emission LED or reception diode is damaged	Please contact Medline customer service at 1-800-MEDLINE

SYMBOL DEFINITIONS

Symbol	Definition
	Type BF equipment (Refer to IEC 60601-1)
IP22	Protected against dripping water
PR bpm	Pulse rate (BPM)
	Attention
SpO2%	Oxygen saturation
	Low power indication
SpO2	No SpO2 Alarm
+70°C max, -25°C min, RH 93% non-condensing	Storage temperature and relative humidity
	Manufacturer's information
	Power Switch
SN	Serial No.
	Follow instruction for use
	Date of Manufacture
?	Indicate the signal is not stable
	Waste electrical and electronic equipment

BOX CONTENTS

1. Fingertip pulse oximeter
2. One lanyard
3. Two AAA batteries
4. One instruction manual

WARRANTY

Warranty Length: 1 year

www.medline.com
Manufactured in China for Medline Industries, Inc.
Three Lakes Drive, Northfield, IL 60093 USA.