NatureSpirit®

Operation Manual CMS-50F-BLE

Pulse Oximeter



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Release date: 01/07/2019 Version: 1.0

Instructions

This manual provides the instructions necessary to operate Pulse Oximeter in accordance with its function and intended use. Ozbservance of this manual is a prerequisite for proper performance and correct operation, and ensures patient and operator safety.

Content of this manual is subject to change without prior notice. Issued date: 2019/01/07 Version: 1.0

Statement

The manufacturer is responsible for safety, reliability and performance of this product only in the condition that:

- All installation operations, expansions, changes, modifications and repairs of this product are conducted by manufacturer authorized personnel; and
- The electrical installation of the relevant room complies with the applicable national and local requirements; and
- This product is operated under strict observance of this manual.

Guarantee

Free service scope

■ The manufacturer provides free service to any product which conforms to the warranty regulations.

Chargeable service scope

■ The manufacturer's obligation or liability under his warranty does not include the service of any factitious damage, or misuse, or irresistible natural disaster, or delay resulting from the improper use or application of the product, or repairs by people other than the manufacturer authorized personnel.

Return Policy

In the event that it becomes necessary to return a unit to the manufacturer, please obtain a return authorization first. Please contact the manufacturer and provides the model number, serial number, and a brief description of the reason for return. Return shipments will not be accepted if the serial number is not clearly visible.

The customer is responsible for freight charges when this product is shipped to the manufacturer for service (including any relevant customs fees or other freight related charges).

Safety Information

WARNING:

It indicates a potential hazard situation or unsafe practice that if not avoided, could result in death or serious injury.

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

NOTE

It provides application tips or other useful information to ensure that you get the most you're your product.

WARNING

• The person who uses the pulse oximeter must receive adequate training before use.

- The pulse oximeter is intended only as adjunct in patient assessment.
 It must be used in conjunction with clinical signs and symptoms.
 It is not intended as a device used for treatment purposes.
- When using the pulse oximeter together with the electrical surgery equipment, the user should pay attention to and guarantee safety of the patient being measured.
- EXPLOSION HAZARD: Do not use the pulse oximeter in the presence of flammable anesthetics, explosive substances, vapors or liquids.
- Make sure not to use the pulse oximeter during MRI (magnetic resonance imaging) scanning or CT (Computed Tomography) environment because induced current could potentially cause burns.
- The pulse oximeter is without alarm function. Continuous monitoring for a long time is not suitable.
- No modification of the pulse oximeter is allowed. Maintenance should be operated by professional maintenance personnel who are approved by manufacturers.
- The pulse oximeter is commonly seal product. Keep its surface dry and clean, and prevent any liquid from infiltrating it.
- The pulse oximeter is precision and fragile. Avoid pressure, knock, strong vibration or other mechanical damage. Hold it carefully and lightly. If it is not in use, it should be appropriately placed.
- For disposal of pulse oximeter and accessories, follow local regulations or your hospital's policy regarding disposal of such pulse oximeter and accessories. Do not dispose randomly.
- Don't dismantle and replace the battery without authorization.
 When the battery is low or it has not been used for a long time, please charge the battery in time but protecting against overcharging.
- Please use the SpO2 sensor matching with the product or use the SpO2 sensor which the manufacturer has approved of it. The operator is responsible for checking the compatibility of the pulse oximeter, sensor and cable before use. And incompatible components can result in degrading performance. If there are signs of damage, please stop using.
- If the accessories are intended for single-use, please scrap according to relevant regulations after use. It is forbidden to re-use.
- A functional tester can't be used to assess the accuracy.
- Avoid static electricity, before using the pulse oximeter, confirmed direct or indirect static electricity of all the operators and patients who contact with the instrument.
- When in use, try to make the pulse oximeter keep away from radio receiver.
- If the pulse oximeter uses unspecified and without EMC test system configuration, it can enhance electromagnetic radiation or reduce anti-electromagnetic interference performance. Please use the specified configuration.
- Portable and mobile radio frequency communication equipment can affect the normal use of the pulse oximeter.
- The pulse oximeter should not be close to or stacked with other equipments, if you must be close to or stacked them in use, you should observed and verify that it can run normally with the configuration which it uses.

CAUTION

 Federal law restricts this device to sale by or on the order of a physician.

NOTE

 Important! Before use, carefully read this manual, all safety information and specifications.

Product Description

The CMS-50F-BLE Pulse Oximeter is wearable device with detachable SpO₂ sensor (BST09001S), and it has following features:

- Simple and convenient usage of product, simple one-touch operation.
- Small volume, light weight, convenient to carry.
- Lower consumption, original one 3.7V lithium battery can continuously work for 20 hour
- Low voltage reminder shows in screen when there's low battery, may influence the normal working.
- It will automatically power off when there's no signal generated.
- Daily maintenance and calibration are unnecessary.
- Rechargable.

Applicable people and scope

The pulse oximeter is suitable for monitoring adults and pediatric. It is used in the hospital's operation room, ICU, clinic section office, out-patient department, sickroom, emergency treatment. It can also be used in the recovery and health care organizations, the community medical treatments.

Intended Use

The pulse oximeter is reuse device and intended use for spot and

continuously checking of the pulse oxygen saturation and pulse rate for adult in clinic/home/sport environment. This medical device can be reused.

Contraindications

The pulse oximeter only applies to adults and pediatric, please don't use the product for children under the age of two, infant and necestal

Structure and Composition

The pulse oximeter is composed of a pulse oximeter and a SpO2 sensor.

Measurement Principle

An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of hemoglobio (Hb) and Oxyhemoglobio (HbO2) in glow and near-infrared zones. Operation principle of the instrument is Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm glow and 940nm near infrared light) can be focused onto human nail tip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on two groups of LEDs through process in electronic circuits and microprocessor.

Arterial oxygen saturation is measured by a method called pulse oximetry. It is a continuous, non-invasive method based on the different spectra absorption of hemoglobin and oxyhemoglobin (called spectrophotometer principle). It measures how much light, sent from light sources on the other side.

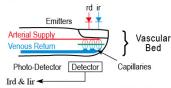


Diagram of Measurement Principle

Cleaning and Disinfection

CAUTION

- Never immerse or soak the pulse oximeter.
- Exercise caution during cleaning/disinfection to avoid wetting the pins.

 We accompany that the pulse extinct to be disinfected only recognity.
- We recommend that the pulse oximeter be disinfected only necessary to avoid long term damage to the pulse oximeter.
- Never use cleaning agents/disinfectants other than the recommended.
- Please shut off the power before clean the pulse oximeter. Never permit high-pressure and high-temperature disinfection of the pulse oximeter.
- Please clean and disinfect the SpO2 sensor (shell and silicone cushion) every time before and after you use the device as the following instruction.

Cleaning

- Clean the pulse oximeter/SpO₂ sensor with cotton or soft cloth moistened with water.
- After cleaning, wipe off the water with a soft cloth.
 Allow the pulse oximeter/SpO₂ sensor to air dry.

Disinfection

The recommended disinfectants: ethanol solution (70% Concentration); isopropanol solution (70% Concentration); or glutaraldehyde solution (2% Concentration).

- Clean the pulse oximeter/SpO₂ sensor as instructed above.
- 2. Disinfect the pulse oximeter/SpO₂ sensor with cotton or soft cloth moistened with one of the recommended disinfectants.
- After disinfection, be sure to wipe off the disinfectant left on the pulse oximeter/SpO₂ sensor with a soft cloth moistened with water.
- 4. Allow the pulse oximeter/SpO2 sensor to air dry.

Technical Specifications

1. Product specifications: Display mode: OLED

Size: 68 (H) × 58 (W) × 20(D) mm Weight: 50g (Do not contain sensor and Wrist strap)

2. Electrical specifications:

Working voltage: D.C. 3.4V~D.C.4.3V Battery type: one 3.7V lithium battery. Battery life: Charging cycle count is not less than 500 times. Power consumption: smaller than 50mA

Figure 2

3. SpO2:

Measurement range: 0~100%

Resolution: 1%

Accuracy: ±3% (70%~100%)

NOTE

 The method of confirming the blood oxygen measurement accuracy is to compare the oximetry measurement value with the value of blood gas analyzer.

4. Pulse Rate:

Measurement range: 25~250bpm

Resolution: 1% Accuracy: ±2bpm 5. Low perfusion:

Range: 0.5%~20% SpO2 accuracy: ±3% (70%~100%) PR accuracy: 25~250bpm ±2bpm 6. Environment requirements:

Temperature: Operation: +5~+40°C

Transportation and storage: -10~+50°C

Humidity:

Operation: 15%~80% (noncondensing)

Transportation and storage: 10%~90% (noncondensing)

Atmospheric pressure: Operation: 860hPa~1060hPa

Transportation and storage: 700hPa~1060hPa

Packing List

The standard configuration				
Pulse oximeter	1pc			
SpO2 sensor	1pc			
Wrist strap	1pc			
Charging cable	1pc			
The operation manual	2pc			

Expected service life:

Pulse oximeter: 3 years SpO2 sensor: 2 years (expect the disposable SpO2 sensor)

Display Introduction



Figure 1

Directions for use

- 1. Insert the plug of the sensor into the slot of the pulse oximeter. (as shown in Figure 2.)
- (as shown in Figure 2.)

 2. Power on the pulse oximeter, monitoring interface appears on OLED display.(as shown in Figure 3.)
- 3. Installing the sensor on the appropriate part of the patient's body.

 (The correct placement as shown in Figure 4.)
- (The correct placement as shown in Figure 4.)

 4. Wait 10-15 seconds, data can be read from the screen.(The correct placement as shown in Figure 4.)

Display screen data refresh time for one second.

5. When the received signal is inadequacy, "
be displayed on the screen. (as shown in Figure 3.)





Figure





Figure 4

Figure 5

Operating button explanation

Power on and power off (as shown in Figure 4)
Power on: Press "POWER/FUNCTION" button, machine starts up

Power on: Press "POWER/FUNCTION" button, machine starts up and enter main menu.

Power off: Press "POWER/FUNCTION" button for 3 seconds, machine power off, or the sensor separated for 10 seconds, the machine automatically power off and the word "Bye bye" will be displayed on the screen (as shown in Figure 5).

Setting interface

Once the oximeter power on, press the "POWER/FUNCTION" button to switch to the Setting, and the factory setting as shown in Figure 6 & Finger 7.

"*" means the current line, short press to switch to the next line, and long press to set the current line.

"*" is now at Alarm Setup line (as shown in Figure6), then long press to switch to next interface(as shown in Figure7)

*** is now at Alarm Setup line (as shown in Figure6), then short press to switch to next line SpO2 Alm High line (as shown in Figure8), then long press to increase/decrease the Spo2 Value(as shown in Figure9). All the same for the other lines.

"*" at Line "+/-", it shows "+", that means, when setting the other line, data increase(Figure 6), otherwise, data decrease.

Setting range

Bluetooth: On/Off

Sp02 Alm High Range: 70-100% Sp02 Alm Low Range: 70-100% PR Alm High Range: 30-250bpm PR Alm Low Range: 30-250bpm Alarm: On/Off Beep: On/Off Volume: 1-5 Brightness: H/L/M

Exit to Main Interface: Short press to switch the "*" to "Exit", then Long press the button, the oximeter returns to the main interface; or 30s no operation, it returns to the main interface automatically.



Figure 8 Figure 9

The beep prompts in the condition as follows: Finger probe off: "didi", remind every 5s;

Blood oxygen out of setting: "dididididi", remind every 10s; Pulse Rate out of setting: "dididi", remind every 10s.

Charging steps

- Please do not use the measurement function when the battery charging.
- The charging connection and SpO₂ sensor connection share the same interface of device.
- 3. Unplug the SpO2 sensor from the device, and connect the charging cable with the interface of the device.
- 4. Connect the charging cable to the main power of USB port of PC/Cell Phone charger adapter and start charging.
- 5. The "Battery Indicator" on the screen will indicate the charging status, when the "Battery Indicator" showed full then the internal protective circuit will cut off charging automatically.

- Please disconnect charging cable from the main power or USB port of PC, when the "battery Indicator" showed full.
- 7. Charging complete.

NOTE:

- Data update period is less than 30 seconds.
- Don't put the SpO2 sensor on extremities with arterial catheter or venous syringe.
- It's the same as other medical equipment, should connect the cable carefully. And avoid patient is winded or suffocates. Electric surgical equipment cable can't entwine with sensor cable.
- Cover the sensor with opaque material under the condition of strong light. Failure to do so will result in inaccurate measurement.
- Try to keep the patient still (specially the arm) and avoid the measured site suffering excessive motion.
- Don't use the pulse oximeter to measure patients whose pulse rate is lower than 30bpm, which may cause incorrect results.
- Make sure no contamination or scar exists in the size where the SpO2 sensor is placed. Otherwise, the measured result may be incorrect because the signal received by the sensor is affected.
- When used on different patients, the pulse oximeter is prone to crossed contamination, which should be prevented and controlled by the user. Disinfection is recommended before using the pulse oximeter on other patients.
- 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 even 2 hours.
- Don't perform SpO2 monitoring and NIBP measurements on the same arm simultaneously. Obstruction of blood flow during NIBP measurements may adversely affect the reading of the SpO2 value.
- Testee's fingernail can't be too long. Otherwise the finger can't be inserted into the sensor to a suitable depth and the SpO2 measurements may be inaccurate.
- Make sure to place the SpO2 sensor on the finger in a correct direction. The LED part of the sensor should be at the backside of the patient hand and photodetector part at the inside. Make sure to insert the finger to suitable depth into the sensor so that the fingernail is just opposite to the light emitted from the sensor.
- The highest temperature of SpO₂ sensor contacts with patient's skin don't be allowed more than 41°C.
- Shock, anemia, hypothermia and the application of vasoconstriction drug may decrease arteria blood flow to an unmeasurable level.
- Pigment, or deep color (for example: nail polish, artificial nails, dye or pigmented cream) may cause inaccurate measurements.

Troubleshooting

Trouble	Possible reason	solution
The SpO2 and PR can't be displayed normally and the value disappeared.	The finger is not properly positioned. The patient's SpO ₂ is too low to be detected. The plug of sensor falls off.	Please the finger properly and try again. Try again; Go to a hospital for a diagnosis if you are sure the device works all right. Please insert the plug of sensor tight.
The SpO2 and PR display instable.	The finger is not placed inside enough. The finger is shaking or the testee is moving.	Place the finger properly and try again. Let the testee keep calm.
The device can't be powered on.	The batteries are drained or almost drained. The device's malfunction.	Recharge the battery. Please contact the manufacturer.
The screen is suddenly off.	The product is automatically powered off when no signal is detected longer than 10 seconds. Power quantity of the battery is exhausted.	Normal. Recharge the battery.

Symbol Meaning

Symbol	Meaning
	"CAUTIOUS"! Please refer to the operation manual.
†	Type BF Equipment.
X	The product does not contain alarm function.

Z	When the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling.
3	Information of manufacture, including name and address.
3	Date of manufacture.
\boxtimes	Service life.
SN	Serial Number.
LOT	Batch Code.
REF	Type Number.
IP22	The product is protected against harmful effects of dripping water per IEC 60529.

Appendix A EMC Declaration

Guidance and manufacturer's declaration - electromagnetic emissions - for all EQUIPMENT and SYSTEMS

The Pulse Oximeter is inte	ended for use in the elec	lectaration - electromagnetic emission tromagnetic environment specified below. The customer or it is used in such an environment.			
Emission test 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 CISPR11	Class B	The Pulse Oximeter is suitable for use in all establishments, including domestic establishments			
Harmonic emissions IEC 61000-3-2	Not applicable	and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.			
Voltage fluctuations/ flicker emissions IEC61000-3-3	Not applicable				

Guidance and manufacturer's declaration - electromagnetic immunity - for all EQUIPMENT and SYSTEMS Guidance and manufacturer's declaration electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 KV contact ±8 KV air	±6 KV contact ±8 KV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2KV for power supply lines	Not applicable	Not applicable
Surge IEC 61000-4-5	±1KV differential mode ±2KV common mode	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	C5% Ur (>95% dip in Ur) for 0.5 cycle 40% Ur (60% dip in Ur) for 5 cycles 70% Ur (20% dip in Ur) for 25 cycles <5% Ur (>95% dip in Ur) for 5 sec	Not applicable	Not applicable
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration - electromagnetic immunity for all EQUIPMENT and SYSTEMS that are not LIFE - SUPPORTING Guidance and manufacturer's declaration - electromagnetic immunity.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Public Obineter including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF	3 Vms	3 Vms	$d = \left[\frac{3.5}{v_1}\right] \sqrt{P}$
IEC 61000-4-6	150 kHz to 80 MHz		

	10		
adiated RF	3 V/m	3 V/m	$d = \left[\frac{3.5}{E_1}\right] \sqrt{P}$ 80 MHz to 800 MHz
C 61000-4-3	1000-4-3 80 MHz to 2.5 GHz		$d = \left[\frac{7}{E_1}\right] \sqrt{P}$ 800 MHz to 2.5 GHz
			Where P is the maximum output power rating of the transmitter is watts (Wil according to the transmitter manufacturer and d is the recommended separation distance in metars (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 the equipment marked with the following symbol:

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

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

- Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, analteur radio, AM and FM and bioradosts and TV broadosts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment use to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Pulse Obserted is used successful the applicable "Compliance level above, the Pulse Obserted is used successful the applicable" Compliance level above, the Pulse Obserted to be observed to verify normal operation. If above many the performance is observed, additional measures may be observed to verify normal operation. If above more than the pulse of the performance is observed, additional measures may be observed to the pulse of the performance in observed.
- be necessary, such as reorienting or relocating the Pulse Oximeter.

 b Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM -for EQUIPMENT or SYSTEM that are not LIFE - SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the Pulse Oximeter

The Puse Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of Pulse Oximeter can help prevent electromagnetic interference installating a minimum distance between portable and mobile RF communication equipment (transmittens) and the Pulse Oximeter as recommended below, according to the maximum output power of the communication equipment.

	Separation distance according to frequency of transmitter (m)				
Rated maximum output power of transmitter (W)	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right] \sqrt{P}$		
0.01	0.1167	0.1167	0.2333		
0.1	0.3689	0.3689	0.7379		
1	1 1.1667 1.1667		2.3333		
10	3.6893	3.6893	7.3786		
100	11.6667	11.6667	23.3333		

For transmitters rated af maximum output power not listed above, the recommended separation distance of in meters (m) can be estimated using the equation application to the frequency of the transmitter, where P is the transmitter of the transmitter of the transmitter maximum output power rating of the transmitter in waits (W) according to the transmitter manufacturer. NOTE 1 A 20 MHz and 800 MHz, the separation distance for the higher frequency range applies.

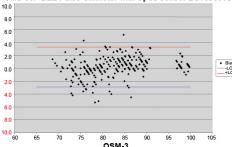
NOTE 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorbtion and reflection from structures, oblects and recognit.

Appendix B Graphical Plot of all sampled data points

CMS-50F-BLE Pulse Oximeter with SpO2 Sensor BST09001S

Hemoximeter Range	60-80	80-100	60-100	70-100	60-70	70-80	80-90	90-100
Mean	-0.18	0.46	0.23	0.23	0.23	-0.19	0.69	-0.09
Count	102	185	287	284	3	99	131	54
Missing Data	0	2	2	2	0	0	0	2
Standard Deviation	1.77	1.37	1.55	1.56	0.67	1.79	1.30	1.38
Standard Error	0.17	0.10	0.09	0.09	0.38	0.18	0.11	0.19
Upper LOA	3.35	3.16	3.29	3.31	N/A	3.39	3.27	2.62
Lower LOA	-3.72	-2.23	-2.83	-2.84	N/A	-3.78	-1.89	-2.79
Maximum	4.30	5.20	5.20	5.20	0.80	4.30	5.20	3.10
Minimum	-5.30	-5.10	-5.30	-5.30	-0.50	-5.30	-4.50	-5.10
Root Mean Square	1.77	1.44	1.56	1.57	0.59	1.79	1.47	1.37

CMS-50F-BLE Pulse Oximeter with SpO2 Sensor BST09001S



Simpro

Email: support@naturespiritproduct.com

TEL: 1-877-299-0356

2018 Primrose Dr, Irving, TX 75063