CMS50F User Manual

Pulse Oximeter

CONTEC Contec Medical Systems Co., Ltd.
Address:No.112 Qinhuang West Street, Economic &Technical Development Zone, Qinhuangdao, Hebei Province, PEOPLE' S REPUBLIC OF CHINA
Tel: +86-335-8015430
Fax:+86-335-8015588
Technical support:+86-335-8015431
E-mail:cms@contecmed.com.cn
Website:http://www.contecmed.com
CMS2.782.078ESS/1.1 1.4.01.01.822 2021.10

Instructions to User

Dear users, thank you very much for purchasing the Pulse Oximeter (hereinafter referred to as device).
It is a medical device, which can be used repeatedly.
The Manual describes, in accordance with the Pulse Oximeter's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.
Please read the User Manual carefully before using this product. The User Manual which describes the operating procedures should be followed strictly. 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.
Owing to the forthcoming renovation, the specific products you received may not be totally in accordance with the description of this User Manual. We would sincerely regret for that.
Our company has the final interpretation to this manual. The content of this manual is subject to change without prior notice.

Warnings:

Remind that it may cause serious consequences to tester, user or environment.

- Explosive hazard—DO NOT use the device in environment with inflammable gas such as anesthetic.
- DO NOT use the device while examining by MRI and CT, as the induced current may cause burn.
- Do not take the information displayed on the device as the sole basis for clinical diagnosis. The device is only used as an auxiliary means in diagnosis. And it must be used in conjunction with doctor's advice, clinical manifestations and symptoms.
- The maintenance to the device or replacement of the battery (non-detachable lithium battery) can only be performed by qualified service personnel specified by manufacturer, dangers (such as over-temperature, fire or explosion) may occur when replacing the battery by the personnel not fully trained. Users are not permitted to maintain or refit the device by themselves or replacement of the battery.
- Uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the microcirculation disturbance users. It is not recommended that the sensor is used on the same finger for more than 2 hours.
- For some special users who need a more careful inspection on the test site, please don't place the device on the edema or tender tissue.
- Please do not stare at the red and infrared light emitter (the infrared light is invisible) after turning on the device, including the maintenance staff, as it may be harmful to the eyes.
- The device contains silicone, PVC, TPU, TPE and ABS materials, whose biocompatibility has been tested in accordance with the requirements in ISO 10993-1, and it has passed the recommended biocompatibility test. The person who is allergic to silicone, PVC, TPU, TPE or ABS can not use this device.
- The disposal of scrap device, its accessories and packaging should follow the local laws and regulations, to avoid polluting to the local environment. And the packaging materials must be placed in the region where the children are out of reaching.
- The device can not be used with the equipment not specified in the Manual. Only the accessories appointed or recommended by the manufacturer can be used, otherwise it may cause injury to the tester and operator or damage to the device
- The SpO_2 probe accompanied is only suitable for using with the device. The device can only use the SpO_2 probe described in the Manual, so the operator has the responsibility to check the compatibility between the device and the SpO_2 probe before using, incompatible accessories may cause device performance degradation, device damage or user injury.
- Do not reprocess the accompanying SpO_2 probe.
- Check the device before use to make sure that there is no visible damage that may affect user's safety and device performance. When there is obvious damage, please replace the damaged parts before use.
- When the message "Sensor Off" or "Sensor Fault" appears on the screen, it indicates that the SpO_2 probe is disconnected or line fault occurs. Check the connection of the SpO_2 probe and whether there is damage for the probe, if necessary, please replace the probe to avoid risks. The probe fault will not result in a safety hazard.
- Functional testers can not be used to assess the accuracy of the SpO_2 probe and Pulse Oximeter.
- Some functional testers or patient simulators can be used to verify whether the device works normally, for example, INDEX-2LFE Simulator (software version: 3.00), please refer to the Manual for the detailed operation steps.
- Some functional testers or patient simulators can measure the accuracy of the device copied calibration curve, but they can not be used to evaluate the device accuracy.
- When using the device, please keep it away from the equipment which can generate strong electric field or strong magnetic field. Using the device in an inappropriate environment may cause interference to the surrounding radio equipment or affect its working.
- When storing the device, keep it away from children, pets and insects to avoid affecting its performance.
- Do not place the device in places exposed to direct sunlight, high temperature, humidity, dust, cotton wool or easy to splash water, to avoid affecting its performance.
- The measured accuracy will be affected by the interference of electrosurgical equipment.
- When several products are used on the same people simultaneously, danger may occur which is arisen from the overlap of leakage current.
- CO poisoning will appear excessive estimation, so it is not recommended to use the device
- This device is not intended for treatment.
- The intended operator of the device may be a user.
- Avoid maintaining the device during using
- Users should read the product manual carefully before use and operate according to the requirements

1.Overview

Insert the finger when measuring, the device will directly display the SpO_2 value measured, it has a higher accuracy and repeatability.

1.1 Features

A. Easy to use.
B. Small in volume, light in weight, convenient to carry.
C. Low power consumption.

1.2 Intended purpose

The Pulse Oximeter can be used in measuring the pulse oxygen saturation and pulse rate through finger. The product is suitable for being used in family, hospital, oxygen bar, community healthcare, physical care in sports (It can be used before or after doing sports, and it is not recommended to use the device during the process of having sport) and etc.

1.3 Environment Requirements

Storage Environment
a) Temperature : -40℃~+60℃
b) Relative humidity : ≤95%
c) Atmospheric pressure : 500hPa~1060hPa
Operating Environment
a) Temperature: +10 ℃~ + 40 ℃
b) Relative Humidity : ≤75 %
c) Atmospheric pressure: 700hPa~1060hPa

1.4 Precautions

1.4.1 Attention
Point out conditions or practices that may cause damage to the device or other properties.

- Before using the device, make sure that it locates in normal working state and operating environment.
- In order to get a more accurate measurement, it should be used in a quiet and comfortable environment.
- When the device is carried from cold or hot environment to warm or humid environment, please do not use it immediately, wait four hours at least is recommended.
- If the device is splashed or coagulated by water, please stop operatin
- DO NOT operate the device with sharp things.
- High temperature, high pressure, gas sterilizing or immersion disinfection for the device is not permitted. Refer to User Manual in the relative chapter (6.1) for cleaning and disinfection. Please turn off the device before cleaning and disinfection.
- The device is suitable for children and adult.
- The device may not be suitable for all users, if you can't get a satisfactory result, please stop using it.
- Data averaging and signal processing have a delay in the upgrade of SpO_2 data values. When the data update period is less than 30 seconds, the time for obtaining dynamic average values will increase, which is arisen from signal degradation, low perfusion or other interference, it depends on the PR value.
- The device has 3-year service life, date of manufacture sees the label.
- The expected service life of the attached parts or accessories of the equipment is two year.
- If the shelf life is less than the expected service life, the shelf life of the attached parts or accessories of the equipment is two year.
- This device has the function of prompting, users can check on this function according to chapter 5.3.1 as a reference.
- The device has the function of limits prompting, when the measured data is beyond the highest or lowest limit, the device would start prompting automatically on the premise of the prompting function is on.
- The device has the function of prompting, this function can either be paused, or closed (default setting) for good. This function could be turned on through menu operation if you need. Please check the chapter 5.3.1 as a reference.
- The maximum temperature at the SpO_2 probe -tissue interface should be less than 41℃ which is measured by the temperature tester.
- During measuring, when abnormal conditions appear on the screen, please pull out your finger and reinsert it to measure again.
- If some unknown error appears during measuring, press "RESET" button to reset it.
- Do not contort or drag the wire of the device.
- The plethysmographic waveform is not normalized, as a signal inadequacy indicator, when it is not smooth and stable, the accuracy of the measured value may degrade. When it tends to be smooth and stable, the measured value read is the optimal and the waveform at this time is also the most standard.
- The device can not be used during charging.
- If necessary, please visit our official website to get the information about SpO_2 probe that can be used with this device.
- If the device or component is intended for single-use, then the repeated use of these parts will pose risks on the parameters and technical parameters of the equipment known to the manufacturer.
- If necessary, our company can provide some information (such as circuit diagrams, component lists, illustrations, etc.), so that the qualified technical personnel of the user can repair the device components designated by our company.
- The measured results will be influenced by the external colouring agent (such as nail polish, colouring agent or color skin care products, etc.), so don't use them on the test site.
- As to the fingers which are too cold or too thin or whose fingernail is too long, it may affect the measured results, so please insert the thicker finger such as thumb or middle finger deeply enough into the probe when measuring.
- The finger should be placed correctly (see Attached figure 4), as improper installation or improper contact position for sensor will influence the measurement.
- The light between the photoelectric receiving tube and the light-emitting tube of the device must pass through the subject's arteriole. Make sure the optical path is free from any optical obstacles like rubberized fabric, to avoid inaccurate results.
- Excessive ambient light may affect the measured results, such as surgical light (especially xenon light sources), bilirubin lamp, fluorescent lamp, infrared heater and direct sunlight, etc. In order to prevent interference from ambient light, make sure to place the sensor properly and cover the sensor with opaque material.
- Frequent movement (active or passive) of the subject or severe activity can affect the measured accuracy.
- The SpO_2 probe should not be placed on a limb with the blood pressure cuff, arterial ductus or intraluminal tube.
- The measured value may be inaccurate during defibrillation and in a short period after defibrillation, as it has not defibrillation function.
- The device has been calibrated before leaving factory.
- The device is calibrated to display functional oxygen saturation.
- The equipment connected with the Oximeter interface should comply with the requirements of IEC 60601-1.
- Please select medical power adapter to charge it, when connecting the special adapter with the socket, make sure there is no shelter near the socket and it is easy to plug and unplug, otherwise the power will not be cut off in time when necessary, causes damage.

1.4.2 Clinical restriction
A. As the measure is taken on the basis of arteriole pulse, substantial pulsating blood flow of subject is required. For a subject with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO_2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.
B. The measurement will be influenced by intravascular staining agents (such as indocyanine green or methylene blue), skin pigmentation.
C. The measured value may be normal seemingly for the tester who has anemia or dysfunctional hemoglobin(such as carboxyhaemoglobin (COHb), methaemoglobin (MetHb) and sulfhaemoglobin (SuHb)), but the tester may appear hypoxia, it is recommended to perform further assessment according the clinical situations and symptoms.
D. Pulse oxygen only has a reference meaning for anemia and toxic hypoxia, as some severe anemia users still show better pulse oxygen measured valued.
E. Contraindication:

a. The person who is allergic to silicone, PVC, TPU TPE or ABS can not use this device.
b. The damaged skin tissue can't be measured.
c. During cardiopulmonary resuscitation.
d. When the user is hypovolemic.
e. For assessing the adequacy of ventilatory support.
f. For detecting worsening lung function in users on a high concentration of oxygen.

1.5 Clinical indications

The Pulse Oximeter can be used in measuring the pulse oxygen saturation and pulse rate through finger.

2 Principle

Principle of the Oximeter is as follows: An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO_2) in glow & near-infrared zones. Operation principle of the device is: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning & Recording Technology, so that two beams of different wavelength of lights 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 screen through treatment in electronic circuits and microprocessor.

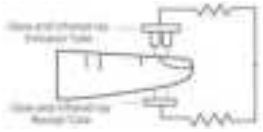

Figure 1. Operating principle

3 Functions

A. SpO_2 value display
B. PR value and bar graph display
C. Pulse waveform display
D. Low-battery indication: low-battery indication appears when the battery voltage is too low to work
E. Automatic standby function
F. display mode can be changed
G. Adjustable screen brightness
H. PR sound indication
I. Voice prompt for over-limit, sensor off /finger-out and low battery.
J. Memory function
K. The data can be uploaded to the terminal equipment by wired mode.
L. The data can be uploaded to the terminal equipment (Bluetooth wired equipment) by wireless mode.
M. With clock function
N. Charging function

4 Installation

4.1 Appearance

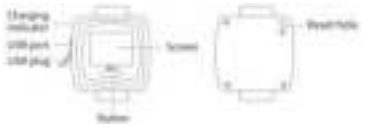

Figure 2 Appearance

USB interface: connect with USB cable or SpO_2 probe
Button: power on, pause sound prompt, display clock, enter menu, menu operation.
RESET hole: reset button inside of it, to reset the device.

4.2 Interface introduction

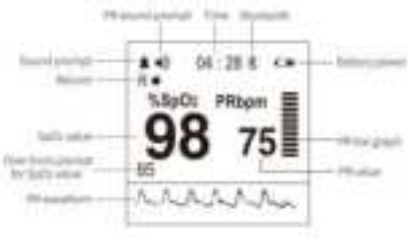

Figure 3 Measurement interface

4.3 SpO_2 probe installation

Open the USB plug of the device, then insert the SpO_2 probe interface into the USB port of the device.

4.4 Connection of USB cable

Open the USB plug of the device, insert the micro end of USB cable into the SpO_2 probe interface , the other end into computer or power adapter.

4.5 Structure and accessories

A. Structure: main unit, SpO_2 probe, USB cable, power adapter (optional) and Bluetooth adapter (optional).
B. Accessories: one SpO_2 probe, one USB cable, one power adapter (optional), one User Manual, Bluetooth adapter (optional).
Please check the device and accessories according to the list to avoid that the device can not work normally.
C.Software description
Software name: CMS50F embedded software
Software specification: no
Release version: 2.0
Naming rule for version: V <Major enhancive software upgrade>.<Minor enhancive software upgrade>.<Improvement software upgrade>
Involved algorithm: name: plethysmography; type: mature arithmetic
Purpose: be used to measure SpO_2, pulse rate, etc.
Clinical function: calculate SpO_2 and pulse rate values by collecting and processing the testee's pulse signal.

5 Operating

5.1 Measurement

A. Insert the finger into the probe as shown in Figure 4.

Figure 4 Sketch map for finger placement

(The appearance of actual probe may be different with the one shown as Figure 4, please refer to the actual probe.)
B.Press button to turn on the device, it displays the measurement interface.
C.Wait a few seconds, the device directly shows measurement result on the screen.
Note: when inserting the finger, the light emitting from the sensor must be directly irradiated to the side of the fingernail.
Note: during measuring, do not shake the finger and keep quiet, not move.

5.2Measurement interface

A.In sound prompt "ON" state, when the sound prompt occurs, short press the button to pause the sound prompt, and it will resume automatically after about 60s.
Sound prompt includes over-limit prompt, low-battery prompt, probe off or finger out prompt.
B.If you want to turn off the sound prompt permanently, please set it in menu.
If there is no sound prompt, short pressing the button will directly enter clock interface, press again to exit.

5.3 Menu operation

Under the measurement interface, long press the button to enter the main menu interface as shown in Figure 5, sound, record, clock,system and Bluetooth, etc. can be set, methods are as followings:

Figure 5 Main menu

Figure 6 Setting interface for sound prompt

5.3.1 Sound prompt setting

Under main menu, short press the button to select "Sound", then long press the button to enter its setting interface shown in Figure 6.
Short press the button to select the option to be adjusted, then long press the button to change the value.
"Direction": direction, "up": increase the value, "down": decrease the value
"SpO_2 HI": upper limit prompt for SpO_2 over-limit
"SpO_2 LO": lower limit prompt for SpO_2 over-limit
"PR HI": upper limit prompt for PR over-limit
"PR LO": lower limit prompt for PR over-limit
"Prompt Sound": prompt for over-limit, "off": close, "on": open.
"Pulse Sound": PR sound, "off": close, "on": open.
Lower limit can not exceed the upper limit, and the upper limit can not be lower than the lower limit when adjusting the values. SpO_2 range: 0 % ~ 100 %, PR range: 0 ~ 254 bpm
The values displayed in Figure 6 are the initial values of over-limit prompt.
After setting, short press the button to select "Exit", then long press the button to exit sound setting interface, and return to Main Menu interface.

5.3.2 Data storage

Under the main menu, short press the button to select "Record", then long press the button to enter the Record Menu interface as shown in Figure 7. It indicates that the device is storing when the red dot "R●" in measurement interface flickers.

Figure 7 Record menu interface

Short press the button to select the option to be adjusted, then long press the button to change the value.
"Mode": record mode selection, including: "Auto" and "Manual" mode. Under "Manual" mode, select to turn on / off memory by "Record".
Auto record: start recording after stable data appear, pull out the finger to finish recording a group of data (99 group of data at most), the total duration does not exceed 72 hours.
Manual record: store up to 24-hour data.
When the memory is full, it will display "Memory is full!", then it will enter the standby mode after several seconds. When exiting the standby mode, it will display "Memory is full!" to give user a prompt, press the button again to enter the measurement interface.
Note: under manual mode, when "Record" is "ON", the device will prompt to clear the data stored last time.
It will display "Recording" when there is no operation under record state for 30s, then it will enter energy saving mode after several seconds, long press the button to exit this mode; short press the button, it will display "Recording".
Note: under data recording state, after the display screen turns off automatically, in order to save power, pulse sound indication will turn off automatically.
"Seg": data segment.
After setting, short press the button to select "Exit", long press the button to exit record menu and return to main menu.
"Delete All": delete all records (auto record mode is shown as Figure 7).
Note: please upload data in time after recording, otherwise the data may be covered when the storage space is full.
Note: the historical data will be deleted once switching the record mode. Under recording state, the record mode can not be switched; under manual mode, the "Record" should be turned off before switching mode.

5.3.3 Clock setting

Under main menu, short press the button to select "Clock", long press the button to enter its sub-menu as shown in Figure 8.

Figure 8 Time setting interface

Figure 9 System menu interface

Short press the button to select the option to be adjusted, then long press the button to change the value. The device adopts 24-hour clock.
"set time": set the time, "yes": to set the time, "no": not set the time
"set year": set the year
"set month": set the month
"set day": set the day
"set hour": set the hour
"set minute": set the minute
After setting, short press the button to select "Exit", then long press the button to exit clock setting interface. If user changes the setting, current set time will be displayed, then press the button to return to the main menu; if the time is not set, it directly return to the main menu.

5.3.4 System setting and other options introduction

Under main menu, short press the button to select "System", then long press the button to enter the interface as shown in Figure 9.
Short press the button to select the option to be adjusted, then long press the button to change the value.
"Hard.Ver.": hardware version
"Soft.Ver.": software version
"ID": user name
"Demo": set the Demo mode, "on": turn on the Demo mode, "off": turn off the Demo mode.
"Sound Volume": set the sound volume, adjustable range: 1 ~ 3
"Brightness": set the screen brightness, adjustable range: 1 ~ 4

After setting, short press the button to select “Exit” ,then long press the button to exit the system menu and return to main menu.

5.3.5 Bluetooth setting

Under main menu, short press the button to select “Bluetooth” ,then long press the button to enter its selection interface as shown in Figure 10 and Figure 11. When the Bluetooth is “ON” ,if there is no data to be transmitted, the Bluelooih will turn off automatically after a few seconds.

Note: under data transmitting state by Bluetooth, the Bluetooth can not be turned off.

Figure 10 Bluetooth “ON” interface

Figure 11 Bluetooth “OFF” interface

5.3.6 Shutdown

Under the main menu interface, short press the button to select “Power off” ,then long press the button to turn off the device.

5.3.7 Exit main menu

Under main menu, short press the button to select “Exit” ,then long press the button to exit the main menu and return to the measurement interface.

5.4 Data upload

5.4.1 Wired transmission

Connect the device to computer by the USB cable, upload the data after connecting with the PC software properly, refer to “Software operating instruction” for details.

Note: The PC software can be downloaded from our official website.

5.4.2 Bluetooth wired transmission

Turn on the device Bluetooth and the PC software to upload data, refer to “Software operating instruction” for details.

5.5 Charging

Power adapter can be selected to charge for the device.

It indicates that the device is charging when the indicator is orange, the charging is finished when the indicator turns to green.

5.6 Reset

Use a pointed and hard object (for example, a paper clip) to press the reset button inside of the RESET hole, to reset the device.

Maintenance, Transportation and Storage

6.1 Cleaning and Disinfecting

The device must be turned off before cleaning, and it should not be immersed into liquid. Please take out the internal battery before cleaning ,do not immerse it into liquid.

Use 75% alcohol to wipe the device enclosure, and use liquid soap or isopropanol to wipe the watchband for disinfection, nature dry or clean it with clean and soft cloth. Do not spray any liquid on the device directly, and avoid liquid penetrating into the device.

6.2 IVIainlcnance

A.Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect user’s safety and monitoring performance. It is recommended lhai the device should be inspected weekly at least. When there is obvious damage, stop using it.

B.Please clean and disinfect the device before/after using it according to the User Manual (6.1).

C.Plcasc charge the battery in lime when low battery appears.

D Recharge the battery soon after over-discharge, The device should be recharged every three months when it is not used for some time. It can extend the battery life following this guidance.

E.The device need not to be calibrated during maintenance.

6.3 Transportation and Storage

A. The packed device can be transported by ordinary conveyance or according io transport contract. During trail.sportalion, avoid strong shock, vibration and splashing with rain or snow, and it can not be transported mixed with toxic, harmful, [illegible] material.
B. The packed device should be stored in room with no corrosive gases and good vcnlilation. Temperature: -40°C~60°C; Humidity: <95

Troubleshooting

Trouble	Possible Reason	Solution
The values can not be displayed normally or stably	1.The finger is not properly positioned. 2.The finger is shaking or the user is moving. 3.The device is not used in environment required by the manual. 4.The device works abnormally.	1.Please insert the finger properly and measure again. 2.Lcl the user keep calm 3.Please use the device in normal [illegible] 4.Please contact ihe after-sales.
The device can not be turned on	1.Low battery or the battery is drained away. 2.The device works abnormally.	1.Please charge the battery. 2.Please contact the after-sales.
The display disappears suddenly.	1.The device enters into the energy saving mode. 2.Low battery. 3.The device works abnormally.	1.Please conlacl the after-sales. 2.Please charge the battery 3.Please conlacl the after-sales.
The device can not be used for full time after charge.	1.The battery is not charged fully. 2.The device works abnormally.	1.Please charge the battery. 2.Please contact the after-sales.
The battery can not be full charged even after 10 hours charging lime.	The battery works abnormally.	Please contact the after-sales.
The data can not be stored.	1.The device is not operated according lo the manual. 2.The device works abnormally.	1.Please operate the device according to the manual. 2.Please contact the after-sales.

Meaning of Symbols

Symbols	Meaning	Symbols	Meaning
©	Caution, consult accompanying documents	PRbpm	Pulse rate (bpm)
[illegible]	[illegible]	[illegible]	Pulse oxygen saturation (%)
[illegible]	Manufacturer	i	Fully charged
SN	Serial mimher	[illegible]	Use-by date

[illegible]	Recycling garbage WEEE (2012/19/EU)	[illegible]	USB
+	Battery anode	[illegible]	Battery cathode
IP22	It means this pulse [illegible] is protected against harmful effects of dripping water when tilled at 15° .	RST	RESET hole
[illegible]	Temperature limitation	[illegible]	Humidity limitation
o	Atmospheric pressure limitation	II	This way up
r	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	Close the sound prompt
[illegible]	Pause lhe sound prompt	O	Open the sound prompt
O-Ш	Menu/ Power button	dx	Close ihe PR sound
[illegible]	Recyclable	[illegible]	Open the PR sound
[illegible]	Bluetooth icon (Bluetooth wired device)	[illegible]	Manufaclure Dale
Sensor Off	The probe is disconnected.	Finger Out	The finger is not inserted.
R*	Recording	Sensor Fault	Probe failure
P/N	Material code	LOT	Batch No.
[illegible]	1. The finger clip falls off [illegible] 2. Probe error 3. Signal inadequacy indicator	[illegible]	Alarm inhibit

Note：Your device may not contain all the following symbols.

Specification

sPo2[see note 1]	
Display range	0%~99%
Measured range	0%~100%
Accuracy[see note 2]	70%~100%: ±2%; 0%~69%: unspecified.
Resolution	1%
PR	
Display range	30bpm 250bpra
Measured range	30bpm~250bpm
Accuracy[see note 3]	±2 bpm during the pulse rate range of 30 bpm 99 bpm and ±2% during the pulse rate range of 100 bpm ~ 250 bpm.
Resolution	1bpm
Accuracy under low perfusion[see note 4]	Low perfusion 0.4%: [illegible] PR: ±2 bpm during the pulse rate range of 30 bpm ~ 99 bpm and ±2% during the pulse rate range of 100 bpm 250 bpm.
Light interference	Under normal and ambient light conditions, the SpO2 deviation 1%
Pulse Intensity	Continuous bar-graph display, the higher display indicates the stronger pulse.
Upper and lower limit of measured values	
SpO2	0% 100%
PR	0 bpm ~ 254 bpm
Optical sensor [see note 5]	
Red light	Wavelength: about 660 nm, optical output power :< 6.65 mW
Infrared light	Wavelength: about 905 nm, optical output power: < 6.75 mW
Memory	Up to 99 group of data under auto mode, total duration does not exceed 72 hours. Up to 24-liour data under manual mode.
Safety class	Internally powered equipment, type BF applied pari
International Protection	IP22
Working voltage	DC 3.6 V ~ 4.2 V
Working current	< 100 mA
Power supply	A rechargeable lithium battery (3.7V) (The red wire on the battery denotes anode, the black wire on the battery denotes cathode.)
Battery life	Charge and discharge:no less than 500 times
Adapter specification	Output voltage: DC 5V Output current: 1000 mA
Dimensions and Weight	
Dimension	61 mm(L) ×56 mm(W) × 24 mm(H)
Weight	About 60 g (including a lithium battery)

Note 1: the claims of SpO_2 accuracy shall be supported by clinical study measurements taken over the full range. By artificial inducing, get the stable oxygen level to the range of 70 % to 100 % SpO 2;compare the SpO 2values collected by the secondary standard pulse oximeter equipment and the tested equipment at the same time, to form paired data, which was used for the accuracy analysis.(It is applicable for the probes equipped.

There are 12 healthy volunteers (male: 6, female: 6; age: 18~50; skin color: black: 2, light: 8, while: 2) data in the clinical report.

Note 2: because pulse oximeter equipment measurements are statistically distributed, only about two-thirds of pulse oximeter equipment measurements can be expected to fall within ±Amis of the value measured by a CO-OXIMETER.

Note 3: Patient simulator has been used to verify the pulse rate accuracy, it is stated as the root-mean-square difference between the PR measurement value and the value set by simulator.

Note 4: percentage modulation of infrared signal as the indication of pulsating signal strength, patieut simulator has been used to verify ils accuracy under conditions of low perfusion. SpO_2 and PR values are different due to low signal conditions, compare lhcm with the known SpO_2 and PR values of input signal.

Note 5: optical sensors as the light-emitting components, will affect other medical devices applied the wavelength range. The information may be useful for the clinicians who carry out the optical treatment.For example, photodynamic therapy operated by clinician.

Alarm

State	Prompt condition delay	Prompt signal generation delay
Low voltag eprompt	Is	20ms
SpO2 prompt	330ms	20ms
Pulse rate prompt	330ms	20ms
Probe error prompt	16ms	20ms

EMC

Tabic 1:

Guidance and manufacturer’s declaration –electromagnetic emission	
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The purchaser or Ihe user of the device should assure that it is used in such environment.	
Emission test	Compliance
RF emissions CISPR 11	Group 1

Table 2:

Guidance and manufacturer’s declaration-electromagnetic immunity		
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The purchaser or Ihe user of ihe Pulse Oximelcr should assure that it is used in such environment.		
Immunity test	IEC60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±15 kV air	±8kV contact ±15kV air
Power frequency (50 / 60Hz) magnetic field IEC 61000-4-8	30 A/m	30A/m

Table 3:

Guidance and manufacturer’s declaration – electromagnetic immunity		
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer the user of the Pulse Oximeter should assure that it is used in such environment.		
Immunity test	IEC 60601 test level	Compliance level
Radiated RF IEC61000-4-3	10 V/m 80 MHz~ 2.7 GHz	10 V/m80 MHz~ 2.7 GHz

NOTE 1 At 80 MHz and 800 MHz, 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.

a 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 Oximeter is used exceeds the applicable RF compliance level above, the Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Pulse Oximeter.

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

Table 4：

Guidance and manufacturer’s declaration - electromagnetic Immunity							
The [Code SI] 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							
	Test Frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Modulation b) (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
Radiated RF IEC610 00-4-3 (Test sped flea tions for ENCLOSURE PORT IMMUNITY to RF wireless commun ications equipme nt)	385	380 ~390	TETRA 400	Pulse modulation b) 18 Hz	K8	0.3	27
	450	430 ~470	GMRS 460, FRS 460	FMc) ± 5 kHz deviation 1 kHz sine	2	0.3	28
	710 745 780	704 ~787	LTE Band 13,17	Pulse modulation b) 217 Hz	02	0.3	9
	810 870 930	800 [illegible]	GSM 800/900, TETRA 800, iDEN 820. CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0.3	28
	1720 1845 1970	1700 ~1990	GSM 1800; CDMA 1900: GSM 1900; DECT; LTE Band 1, 3,4.25; UMTS	Pulse modulation b) 217 Hz	2	0.3	28
	2450	2400 ~2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0.3	28
	5240 5500 5785	5100 ~5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0.2	0.3	9

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

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 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced [illegible] separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be ailculated using the following equation:

$$E = \frac{M}{d}$$

Where P is the maximum power in W, d is the minimum separation distance in ra, and E is the IMMUNITY TEST LEVEL in V/m.

Warning

- Don’t near active HFSURGICAL EQUIPMENT and the KF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.
- 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.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.”
- 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 device including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Active medical devices are subject to special EMC precautions and they must be installed and used in accordance with these guidelines.

A Note：

- When the device is disturbed, the data measured may fluctuate ,please measure repeatedly or in another environment to ensure its accuracy.

Bluetooth Specification

Working frequency: 2402 MHz 2480 MHz
Modulation mode: GFSK
Transmitting power: -6 dBm, +4 dBm
Receiving sensitivity: -93 dBm

FCC Caution

§ 15.19 Labeling requirements.
This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

§ 15.21 Information to user.
Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

§ 15.105 Information to the user.
Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
-Reorient or relocate the receiving antenna.
-Increase the separation between the equipment and receiver.
-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
-Consult the dealer or an experienced radio/TV technician for help.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable/mobile exposure condition without restriction