Instructions to User

Dear users, thank you for purchasing our Pulse Oximeter.

This Manual is written and compiled in accordance with the council directive MDD93/42/EEC for medical devices and harmonized standards. The information contained in this document is subject to change without notice.

The Manual describes, in accordance with the Pulse Oximeter's features and requirements, its features, functions, specifications, transportation methods, 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 lead to measurement abnormality, equipment malfunction and body injury. The manufacturer is NOT responsible for any safety, reliability, monitoring abnormality, malfunction and performance issues with regards to the equipment and/or any personal injuries that arise due to user's negligence to follow the manual's instructions.

As the device is undergoing constant revision and improvisation, the product(s) you received may not be in total accordance with the description of this User Manual. We sincerely regret for the inconvenience.

Caution: This device is not intended to diagnose or treat any medical condition or disease. It is intended for non-medical use in healthy people to monitor their pulse and blood oxygen levels during sports and/or aviation only. People who need SpO_2 and pulse rate measurements because of a medical condition should not use the device and should consult with

their physician.

WARNING:

- **Users might experience discomfort if the device is used continuously for a long period of time, especially for users suffering from poor microcirculation. It is recommended that the sensor should not be applied to the same finger for over 2 hours.**
- **The device should not be clipped on edema affected and/or tender tissue.**
- **The infrared light emitted from the device is invisible and can cause irreversible damage to the eyes, possibly leading to blindness. You should not stare at the light.**
- **Users should not use enamel or other makeup on the finger.**
- **User's fingernail should be kept neat and short for best result.**
- **Please refer to correlative literature about clinical restrictions of the device**
- **This device is not intended for medical treatment.**

Version 2.0

Issuing Date: May 2015

To download the latest manual or watch videos on how to use the CMS 50F, please visit http://www.innovogroups.com

CONTENTS

1 Safety

1.1 Safety Information

a) Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect patient's safety and/or monitoring performance of the device. The device should be inspected at least once a week. Stop using the device if physical damage is observed.

b) Maintenance must be performed by qualified service engineers ONLY. Users should not to maintain the device by themselves.

A. The oximeter should only be used with devices and/or accessories specified in this User's Manual.

B. This product is calibrated before leaving factory.

1.2 Warning

- Explosive hazard—DO NOT use the oximeter in environment with inflammable gas such as ignitable anesthetic agents.
- DO NOT use the oximeter while the user is undergoing MRI or CT scan.
- Do not remove the wristband while using the oximeter. Users who are allergic to the wristband should not use the pulse oximeter.
- The person who is allergic to rubber cannot use this device.
- The disposal of the device, accessories and packing material (including but not limited to battery, plastic bags, foams and paper boxes) should follow local laws and regulations.
- Please check that all the device and accessories listed in the packing list are accounted for before use.
- Please make sure that the accessories you use with the oximeter are approved by the manufacturer. Unapproved accessories may cause irreversible damage to the device.
- Please make sure that the battery chargers are in compliance

with the requirements of IEC 60601-1, or the device might be damaged.
Please do not use the device while charging.
The device should only be used with the Acc U Rate® SnugFit probe. Using the Contec CMS 50F probe might damage the oximeter.

1.3 Attention

Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
If the oximeter gets wet, stop operating it immediately.
When it is carried from cold environment to warm or humid environment, please do not use it immediately.
DO NOT operate keys on front panel with sharp materials.
High temperature or high pressure steam disinfection of the oximeter is not permitted. Refer to User Manual in the relative chapter (7.1) for instructions of cleaning and disinfection.
Do not immerse the oximeter in liquid. To clean it, please wipe its surface with medical alcohol with soft material. Do not spray any liquid on the device directly.
When cleaning the device with water, the temperature should be lower than 60°C.
The performance of the device is affected if the fingers are too small or cold. As such, please clip and insert the thumb or middle finger as deeply as possible into the probe.
The pulse oximeter can be used for adult or infant. However, a special probe is required for infant. Please contact the manufacturer for more details.
During measurement, the data is updated on average, every 5 seconds. However, this might change depending on individual.
Please read the measure value only when the amplitude of the waveform is equal and steady. At this point, the measured value

will be most accurate.

- If some abnormal conditions appear on the screen during test process, pull out the finger and reinsert to restore normal use.
- You should not use the device after three years.
- This device has a built-in alarm which will go off when the measured data is beyond the highest or lowest limit. Please check chapter 6.1 for more details.
- The device may not work for all patients. If you are unable to achieve stable readings, discontinue use.

2 Overview

SpO_2 stands for Peripheral capillary oxygen saturation. It is an estimation of the oxygen saturation level in your blood. Oxygen saturation is defined as the ratio of oxyhemoglobin to the total concentration of hemoglobin (i.e. Oxyhemoglobin + reduced hemoglobin) present in the blood. SpO_2 is an important bio-parameter. A number of diseases relating to the respiratory system may cause a decrease of SpO_2 in blood. Homeostasis failure and surgery complications may only lead to a reduction of oxygen supply to the human body. This could lead to vertigo, impotence, emesis and in severe hypoxia, coma and death. Therefore, prompt information of patients' SpO_2 is helpful to a doctor to anticipate potential danger and is of great importance in the clinical medical field.

The Pulse Oximeter feature herein is small, portable, non-invasive, easy to use and requires little power. The user only needs to insert a finger into the probe for SpO_2 and Pulse Rate measurement.

2.1 Features

1. The device is simple and easy to operate.
2. The product is small and portable.
3. Low power consumption.

2.2 Major Applications and Scope of Application

The Pulse Oximeter can be used to measure SpO_2 and pulse rate through a finger. The product is suitable for used at home, hospital, oxygen bar and community center. It can also be used during sports and/or aviation. However, the device is not recommended to be used when the user is exercising or physically active

⚠**The pulse oximeter might register a higher reading if the user is suffering from toxicosis caused by carbon monoxide. The device is not recommended to be used under such circumstance.**

2.3 Environment Requirements

Storage Environment

a) Temperature : -40°C to +60°C
b) Relative humidity : ≤95%
c) Atmospheric pressure : 500hPa~1060hPa

Operating Environment

a) Temperature: 10°C ~40°C
b) Relative Humidity : ≤75%
c) Atmospheric pressure: 700hPa~1060hPa

3 Principle

Oxygenated blood absorbs light at 660nm (red light), whereas deoxygenated blood absorbs light preferentially at 940nm (infra-red). Pulse oximeters consist of two light emitting diodes, at 600nm and 940nm, and two light collecting sensors, which measure the amount of red and infra-red light emerging from tissues traversed by the light rays. The relative absorption of light by oxyhemoglobin (HbO) and deoxyhemoglobin is then processed according to the Beer-Lambert's law and an oxygen saturation level is reported. The device directs its attention at pulsatile arterial blood and ignores local noise from the tissues. The result is a continuous qualitative measurement of the patients' oxyhemoglobin status. Oximeters deliver data about pulse rate, oxygen saturation (SpO_2) and cardiac output.

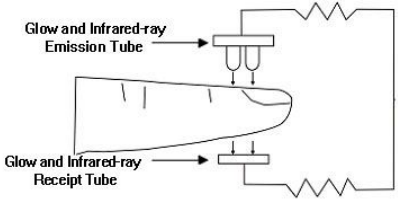


Figure 1.

The use of pulse oximeters is limited by a number of factors: Abnormal movement, such as occurs with agitated patients, will cause interference with SpO_2 measurement. Low blood flow, hypotension, vasoconstriction and hypothermia will reduce the pulsatility of capillary blood, and the pulse-oximeter will under-read or not read at all. Conversely, increased venous pulsation, such as tricuspid regurgitation, may be misread by the

pulse-oximeter as arterial blood, with a low resultant reading. Finally, it is generally accepted that the saturation percentage is unreliable on the steep part (around 60 mm Hg) of the oxyhemoglobin dissociation curve.

The Acc U Rate® SnugFit probe attempts to ameliorate some of the problems by

1) Fitting snugly without causing discomfort to the user's finger even under prolonged use. This allows reliable measurement of user's Pulse Rate and SpO_2 during sleep and/or exercise.

2) Increasing the sensitivity of the sensor/receipt tube (See Figure 3) so that it can measure user's SpO_2 and Pulse Rate (PR) with precision even at low blood perfusion.

4) Blocking ambient light from reaching the sensor/receipt tube in (See Figure 1) that might affect the precision and reliability of the readings.

4 Technical Specifications

4.1 Main Performance

A. SpO_2 value display
B. Pulse rate value display, bar graph display
C. Pulse waveform display
D. Low-voltage indication: low-voltage indicator appears before working abnormally which is due to low-voltage
E. The display mode can be changed
F. Screen brightness can be changed
G. A pulse sound indication
H. With alarm function
I. Store 24 hours of SpO_2 value and pulse rate data which can be uploaded to computers for analysis
J. Uses an external oximeter probe to take measurement
K. Data can be transmitted to computers
L. With clock and alarm function
M. Wireless Transmission function (Bluetooth enabled model only)

4.2 Main Parameters

A. Measurement of SpO_2
Measuring range: 0%~100％
Accuracy:
When the range of SpO_2 is 70%~100％, the permissible error is ±2％;
Below 70% - unspecified.
B. Measurement of pulse rate
Measuring range: 30 bpm~250 bpm
Accuracy: ±2 bpm or ±2% (select larger)
C. Resolution
SpO_2 : ±1%, Pulse rate: ±1bpm.

D. Measurement Performance under low blood perfusion

The device can measure SpO_2 and pulse rate at blood perfusion level as low as 0.4%. However, SpO_2 error is increased to ±4%, and pulse rate error to ±2 bpm or ±2% (select larger).

E. Resistance to ambient light

The deviation between the values measured indoors or under man-made light and that of a darkroom is less than ±1%.

F. Power supply requirement: 3.6 V DC ~ 4.2V DC.

G. Optical Sensor

Red light (wavelength is 660nm,6.65mW)

Infrared (wavelength is 880nm, 6.75mW)

H. Adjustable alarm range

SpO_2 : 0%~100%

Pulse Rate: 0bpm~254bpm

5 Product Description

5.1 Front Panel View

Figure 2. Front view

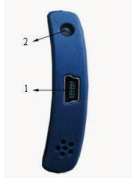


Figure 3. Left view

1. This USB port has multiple uses. It can be used to connect the SpO_2 probe/sensor, upload the data to a personal computer or to charge the lithium battery.
2. Charging indication light. When the device is charging, the indication light will be orange. When the battery status is full, the light turns to green.

5.2 Probe Connection

When connecting the Acc U Rate® SnugFit probe, make sure it is inserted properly and all the way into the pulse oximeter as shown

in Figure 4.

Figure 4.

5.3 Accessories

A. User Manual
B. Power adapter
C. USB Cable
D. Minidisc (PC software)
E. An adult-oximeter probe
An infant-oximeter probe (Purchase separately)

6 Operating Guide

6.1 Using the Device

A. Install the probe as outlined in Chapter 5.2. (Please do not use probes made by other manufacturers as the algorithm used by the watch will not work with them. Unapproved probes might also damage the oximeter)

B. Put the finger into the probe as shown in Figure 5 below.

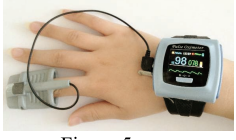


Figure 5.

C. Turn on the device by pushing the **button** on the panel for >1 second.

D. User should try to stay still as much as possible during measurement. Do not move the finger as this is the most common reason for inaccurate measurements.

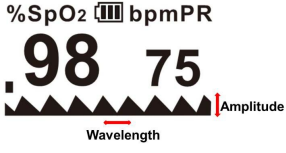


Figure 6.

E. Wait 10-30 seconds for the pulse oximeter to be optimized. The pulse oximeter is optimized when the plethysmograph gives a constant, stable reading. In other words, the wavelength and amplitude of each wave will be identical to the next (Figure 6).

F. You may now read the SpO_2 and PR displayed on the OLED screen.

ATTENTION

⚠ **The Fingernails should be facing the LED lights and not the sensor**

⚠ **Make sure that your finger is put deep into the probe such that the fingertip is directly in between the LED sensor and the LED light source.**

⚠ **Make sure your finger is stationary in the probe while you are measuring your SpO_2 levels.**

⚠ **Excessive ambient infra-red light, especially for people who use the pulse oximeter in an overly bright lit room can interfere with the sensor.**

⚠ **Poor circulation can affect oximeter readings. Warm your hands and fingers before taking your measurements. Remember your pulse oximeter is measuring your SpO2 and PR based on your blood flow. If the blood flow in your finger drops below a certain level, the pulse oximeter will not be able to function.**

⚠ **If the alarm function is on, a medium-priority alarm will go off when the probe does not register a reading (like when the finger is out). User will hear an intermittent beeping sound and a "FINGER OUT" message will be displayed across the user interface. Medium priority alarms indicate that prompt operator response is required.**

The pulse oximeter is sensitive to the duration of the **button** (See Figure 2) being pressed. A short PUSH (<1 sec) or a long HOLD (>1 sec) of the **button** activates different functions of the pulse oximeter.

A. Change display direction

On the measuring interface, enter the clock interface by a short

PUSH to the **button**. PUSH the **button** again to change the display direction within 30 seconds.

B. Enter and exit the clock interface

1) The clock interface will automatically return to the measuring interface if no operations are registered within 30 seconds.

2) You may also press the **button** for about 10 seconds to enter the clock interface from the measuring interface. The device would return to the measuring interface again by pressing the **button** for about 10 seconds.

C. Pause alarm

1. The built in auditory and visual alarm will be activated if the oximeter is not place correctly on the finger, the battery is low or when your SpO_2 is beyond set limits. You may pause the alarm function by a PUSH to the **button**, but the alarm will be reactivated again in 60 seconds

2. If you do not want the alarm to go off, you must enter the operation menu to turn it off permanently (see below).

D. Menu operations

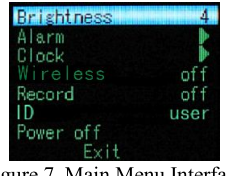


Figure 7. Main Menu Interface

When the device is in the measuring interface, HOLD the **button** in order to enter the operation menu shown in Figure 7. Users can adjust the backlight, alarm, clock, wireless transmission (option available only in Bluetooth enabled model), data storage, and power settings through the main menu. The specific operation methods are as follow:

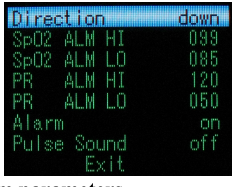
1) Backlight adjustment

In the main menu interface, PUSH **button** to select "Brightness". HOLD the **button** to adjust backlight brightness.

2) Alarm setting

In the main menu interface, PUSH **button** to select "Alarm". HOLD the power **button** to enter the alarm setting interface as shown in Figure 8:

Figure 8. Alarm Setting Menu



Adjusting the alarm parameters

PUSH the **button** to select "Direction", then HOLD the **button** to choose Up or Down. (This will be the direction the value of the SpO_2 and pulse rate limits will be adjusted)

To raise the SpO_2 and pulse rate limit, choose "Direction" as "up", then PUSH the **button** to highlight the parameter to be adjusted: SpO_2 high limit (SpO_2 ALM HI), SpO_2 low limit (SpO_2 ALM LO), Pulse rate high limit (PR ALM HI), Pulse rate low limit (PR ALM LO). HOLD the **button** to adjust the high limit to the desired value and release the **button** once the desired limit has been reached.

To lower the SpO_2 and pulse rate limit, choose "Direction" as "down", then PUSH the **button** to choose the parameter to be adjusted. HOLD the **button** to adjust the selected limit to the desired value and release the **button** once the desired limit has been reached.

⚠ **If the alarm function is on, the device will provide medium-priority alarm signal when the data of SpO_2 or pulse rate falls beyond set limit. Intermittent alarm will occur and the measurement will be displayed in yellow font.**

Medium priority indicating that prompt operator response is required.

The alarm state setting

PUSH the **button** to select "Alarm". HOLD the **button** to set alarm on or off. Select "on" to turn on the alarms and "off" to turn off the alarms.

Pulse sound indication setting

PUSH the **button** to select "Pulse Sound". HOLD the **button** to set Pulse Sound (heart beat) alarm to "on" or "off".

Exit the Alarm settings

PUSH the **button** to select "EXIT". HOLD the **button** to exit the Alarm Settings Menu.

3) Clock setting

On the main menu interface, PUSH the **button** to select "Clock". HOLD the **button** to enter the clock setting interface.

Figure 9. Clock Setting Menu

A) When entering the clock setting menu, “Set time” will always be set to “NO” to prevent unexpected changes to the time as shown in Figure 9. If you want to change the time, HOLD the **button** to change “Set time” to “YES”.

B) PUSH the **button** to select the parameter that you want to change. HOLD the **button** to adjust the data.
C) PUSH the **button** to select "Exit". HOLD the **button** to exit the clock setting menu. If you have reset the time or date, when exiting the clock setting menu, the renewed time and date would be displayed on the screen before returning to the main menu; if you didn't reset the time and date, the device would return to the main menu directly when exiting the clock setting menu.
4) Wireless setting (This option will appear in Bluetooth enabled model only)
PUSH the **button** to select "Wireless". HOLD the **button** to turn on/off the Wireless function.
⚠**It is recommended to use the included 2.4GHZ wireless adapter which uses CSR as the main chip to transmit your data. Please do not unplug the USB cable or wireless adapter when the data is being transmitted between device and computer. When the data is being transmitted between the device and the computer, the user will not be able to alter "Wireless" settings. If the user still could not alter "Wireless" settings after completion of data transmission, please wait 30 seconds before trying again.**
5) Record - Data storage setting
This device has the ability to store 24 hours of data. The data can then be transferred to the computer for analysis via the included "SpO_2 Assistant" software. Please refer to <SpO_2 Assistant user manual> for instructions.
A. To record data, in the main menu interface, PUSH the **button** to select "Record", then HOLD the **button** to choose "Yes" to begin data recording. Select "No" if you want to turn off data recording.
B. The device will register the time of the recording

automatically.

C. If the data storage function is being turned on, a red "REC" sign and a flashing red dot would appear on the screen when returning to the measuring interface.

D. When the device is storing data, “Recording" would appear in the screen for 30 seconds irregardless of the interfaces the device might be in. The clock interface would then appear after several seconds and the screen automatically shut down. If you PUSH the **button** at this moment, "Recording" would appear on the screen again, and then the screen will be automatically shut down again; if a HOLD is applied to the **button**, the device would return to the former interface.

E. Turning on the data storage function will erase previous stored data

F. While recording, the pulse sound indication would be turned off after the screen is shut down to save power.

G. When the storage space is full, "Memory is full" will be displayed on the screen whenever you activate the device. No data will be recorded at this point. Please upload the data to the PC so that the space can be freed up to record new data. A PUSH to the **button** will trigger the pulse oximeter to enter into the measuring interface.

6) Device ID

Figure 10 Software Icon

The user can modify device ID by the “SpO_2 Assistant " software.

7) Power off

In the main menu interface, PUSH the **button** to select "Power off". PUSH the **button** again to shut down the device.

8) Exit the main menu

In the main menu interface, PUSH the **button** to select "Exit". PUSH the **button** again to exit the main menu.

E. Uploading Data

You may connect the device to the computer via USB or Bluetooth (in selected model only). To connect the pulse oximeter to the computer via Bluetooth, please make sure that you set the "wireless" option to "on" (See Wireless Setting above at page 16). **Please do NOT connect the pulse oximeter to the computer via "Add a Bluetooth device".** Please refer to the SpO_2 Assistant Manual on how to connect the pulse oximeter to the computer to upload data. If you prefer to watch a video on how to connect the pulse oximeter to the computer, please refer to http://innovogroups.com/products/cms50f.

⚠ **If the users choose to turn on the synchronizing display function on computer, it would probably take several seconds for the data to appear in the computer screen. (If no data is displayed, unplug the Wireless adapter or the USB cable and try again.)**

F. Charging the device

There are two ways to charge the device:

a) Connect the device to the computer with the USB cable

b) Connect the device to the power supply via the power adaptor.

When the device is charging, the indication light will be orange. When the battery is full, the light turns to green.

⚠ **If the alarm function is on, the device will display a high-priority alarm signal when the battery is in low power status. Intermittent alarm will occur and the battery icon turns red in the state of flashing.**

High priority alarm indicates that immediate operator response is required.

6.2 Cautions

A. Please check device before use to confirm that it is working normally. The SpO_2 and PR should be displayed correctly on the screen.

B. The finger should be place in between the LED lights and the sensor (see Figure 1 and 5 for reference), or it may result in inaccurate measurement.

C. The SpO_2 sensor should not be used on an arm with a blood pressure cuff or undergoing intravenous injection. It should not be used on the arterial canal too.

D. Do not fix the SpO_2 sensor with adhesive as it might lead to inaccurate measurement of the SpO_2 and pulse rate.

E. Excessive ambient light may affect measuring result although the Acc U Rate® SnugFit probe is designed to minimize such interference. Ambience light includes, but is not limited to fluorescent lamp, dual ruby light, infrared heater, direct sunlight and LED lights.

F. Strenuous activities or extreme electrosurgical interference may affect accuracy pf device.

G. User should not use enamel or other makeup to ensure accuracy.

H. Please clean and disinfect the device according to instructions outlined in Chapter 7.1 of the user manual.

6.3 Clinical Restrictions

A. As the accuracy of the device is based on the arteriole blood, an adequate amount of blood flow is required. The SpO_2 waveform (Plethysmography) will decrease for users with a weak

pulse due to shock, low body temperature, major bleeding, or use of vascular contracting drug. Under such circumstances, the measurement will be more sensitive to interference.

B. For users with a substantial amount of staining dilution drug such as methylene blue, indigo green and acid indigo blue, carbon monoxide hemoglobin (COHb), methionine (Me+Hb), thiosalicylic hemoglobin or icterus, the SpO_2 readings may be inaccurate.

C. Drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also affect the accuracy of SpO_2 measurement.

D. Patients with serious anemia may also report good SpO_2 measurement.

If you think that the above conditions apply to you, please consult a physician.

7 Maintenance, Transportation and Storage

7.1 Cleaning and Disinfecting

Use medical alcohol to disinfect the device. Let it air dry or clean it with clean soft cloth.

7.2 Maintenance

A. Please clean and disinfect the device as outline above.

B. Recharge the battery when the screen shows the empty battery icon.

C. The battery should be FULLY recharged before use if it has not been used for six months. This will extend the battery life significantly.

D. All units come pre-calibrated. You do not need to calibrate the oximeter.

7.3 Transportation and Storage

A. The device should not be transported with toxic, harmful, corrosive material.

B. The packed device should be stored in room with no corrosive gases and with good ventilation. Temperature: -40°C~60°C; Humidity: ≤95%

8 Troubleshooting

Trouble	Possible Reason	Solution
No SpO_2 and Pulse Rate is registered	1. The finger is not properly positioned. 2. The patient's blood perfusion is too low to be detected.	1. Make sure that the finger is inserted properly into the device. 2. Make sure nothing is restricting your blood flow (See Chapter 6.3).
The SpO_2 and Pulse Rate values displayed on the screen are erractic or lower than a spot check monitor	1. The finger is not placed deep enough into the probe. 2. The finger is moving.	1. Place the finger properly and try again. 2. Try to keep the patient stationary
The device cannot be turned on or the display turns off suddenly	1. The battery is drained. 2. The device has malfunctioned.	1. Please recharge the battery. 2. Please contact the local service center.
After a full charge, the battery is discharged after only a few hours of usage	1. The battery is not fully charged. 2. The battery has malfunctioned	1. Please recharged the battery. 2. Please contact the local service center.

The battery is not fully charged after 10 hrs.	1. The battery has malfunctioned	1. Please contact the local service center.

9 Symbols

Symbol	Description
	Refer to instruction manual/booklet
%SpO$_2$	Oxygen saturation (%)
PRbpm	Pulse rate (bpm)
	Full-voltage
	Low-voltage
	Alarm is deactivated
	Alarm paused
	Alarm is activated
	Bluetooth is enabled (option available in selected model only)
	Pulse sound deactivated

	Pulse sound activated
	menu **button**/power **button**/function **button**
	Type BF
SN	Serial number
	1. the finger clip falls off (no finger inserted) 2. Probe error 3. Signal inadequacy indicator
IP22	International Protection
	WEEE (2002/96/EC)

10 Function specification

Information	Display Mode
The Pulse Oxygen Saturation(SpO_2)	2-digit digital OLED display
Pulse Rate(PR)	3-digit digital OLED display
Pulse Intensity (bar-graph)	bar-graph OLED display
SpO_2 Parameter Specification	
Measuring range	0%~100%, (the resolution is 1%).
Accuracy	70%~100%:±2% , Below 70% unspecified.

Average value	Average value is derived from 4 previous values. The deviation between average and true value does not exceed 1%.
Pulse Parameter Specification	
Measuring range	30bpm~250bpm, (resolution = 1bpm)
Accuracy	±2bpm or±2% (select larger)
Average pulse rate	Average value is derived from 4 previous values. The deviation between average and true value does not exceed 1%.
Safety Type	Interior Battery, BF Type
Pulse Intensity	
Range	Continuous bar-graph display, higher amplitude indicates stronger pulse.
Battery Requirement	
Voltage 3.7 rechargeable lithium battery × 1	
Battery working life	
Charge and discharge no less than 500 times.	
Power Adapter	
Input Voltage	100 to 240V AC, 50/60 Hz
Output voltage	5V DC
Output current	1A
Wireless Module	

Transmit frequency	2.4GHz
Dimensions and Weight	
Dimensions	61(L) × 56(W) × 24 (H) mm
Weight	About 50g (with the lithium battery*1)

Appendix 1

State	Alarm condition delay	Alarm signal generation delay
Low voltage alarm	0.6s	20ms
SpO_2 alarm	400ms	20ms
Pulse rate alarm	400ms	20ms
Probe error alarm	400ms	20ms

Appendix 2

Guidance and manufacture's declaration – electromagnetic emissions for all EQUIPMENT and SYSTEMS

<table>
<tr><th colspan="3">Guidance and manufacture’s declaration – electromagnetic emission</th></tr>
<tr><td colspan="3">The CMS50F PLUS Pulse Oximeter is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The CMS50F PLUS 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.</td></tr>
<tr><td>RF emission CISPR 11</td><td>Class B</td><td rowspan="3">The CMS50F PLUS Pulse Oximeter is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for</td></tr>
<tr><td>Harmonic emissions IEC 61000-3-2</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuations flicker</td><td>Not applicable</td></tr>
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emissions IEC 61000-3-3		domestic purposes.

Guidance and manufacture's declaration – electromagnetic immunity –
for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The *CMS50F PLUS Pulse Oximeter* is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.			
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 ±6 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%. The manufacturer may recommend the ESD precautionary procedures to user.

Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacture's declaration – electromagnetic immunity –
for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration – electromagnetic immunity			
The *CMS50F PLUS Pulse Oximeter* is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V_{rms} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V_{rms} 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the *CMS50F PLUS Pulse Oximeter,* including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**

			$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (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 equipment marked with the following symbol: 

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 *CMS50F(W) PLUS Pulse Oximeter* is used exceeds the applicable RF compliance level above, the *CMS50F PLUS 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 *CMS50F PLUS Pulse Oximeter.*

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/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 *CMS50F PLUS Pulse Oximeter.*			
The *CMS50F PLUS Pulse Oximeter* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *CMS50F PLUS Pulse Oximeter* as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	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	**0.117**	**0.117**	**0.233**
0.1	**0.369**	**0.369**	**0.738**
1	**1.167**	**1.167**	**2.333**

10	**3.689**	**3.689**	**7.379**
100	**11.67**	**11.67**	**23.33**

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 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 absorption and reflection from structures, objects and people.