GIMA

PROFESSIONAL MEDICAL PRODUCTS

OXY 110 PULSE OXIMETER
OXYMÈTRE DE POULS OXY 110
PULSOXIMETRO OXY 110
PULSIOXÍMETRO OXY 110

Gima 34341

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MD CE 0123

M34341-M-Rev.7-07.26

Preface

Dear Customer,

Thank you for purchasing this quality product. Please read the manual very carefully before using this device. Failure to follow these instructions can cause measuring abnormality or damage to the Oximeter.

Version of the Manual: V1.0

Revision Date: May 15, 2026

Notes:

- The contents contained in this manual are subject to change without prior notice.
- Information furnished by **Creative** is believed to be accurate and reliable. However, no responsibility is assumed by **Creative** for its use, or any infringements of patents or other rights of third parties that may result from its use.

Safety information

Check the device to make sure that there is no visible damage that may affect user's safety and measurement performance. It is recommended that the device should be inspected minimally before each use. If there is obvious damage, stop using the device.

Necessary service must be performed only by qualified technicians. Users are not permitted to service this device.

The oximeter must not be used with the devices and accessories not specified in User Manual.

Warnings

- Explosive hazard—DO NOT use the oximeter in environment with inflammable gas such as some ignitable anesthetic agents.
- DO NOT use the oximeter while the Patient is under MRI or CT scanning. This device is NOT MRI Compatible.

Cautions

- Discomfort or pain may occur if using the sensor of this device continuously on the same location for a long time, especially for the patients with poor microcirculation. It is recommended that the Oximeter should not be applied to the same location for longer than 2 hours or less if any abnormal condition is found. Frequently check and re-position the Oximeter sensor.
- Misapplication of a SpO_2 probe with excessive pressure for prolonged periods can induce pressure injury.
- Place the SpO_2 probe on the finger/foot tightly will cause venous pulse and effect blood circulation, and lead to interstitial edema, hypoxia and

inaccurate measurement.

- Biocompatibility tests have been performed on all the applied parts; some exceptional allergic patients may still have anaphylaxis. Do not apply to those who have anaphylaxis.
- For the individual patients, there should be a more prudent inspecting in the placing process. The sensor cannot be placed on the edema and tender tissue.
- The local law should be followed when disposing of the expired device or its accessories.
- DO NOT operate in the environment where strong electro-magnetic interference exists, such as radiogram, television, radiophone, etc.
- Please pay attention to the SpO_2 probe cable while using to avoid strangulating patient.
- Degradation of sensors or electrodes (e.g., due to aging, contamination, or physical damage) or poor electrode contact (e.g., loosening, detachment) may lead to diminished signal quality, increased measurement error, unstable readings, or complete device failure. Regular inspection, cleaning, and replacement of sensors/electrodes in accordance with the manufacturer's recommendations are essential to maintain intended device performance.
- A functional tester is only intended to verify basic circuit continuity and functional response of a pulse oximeter. It must not be used to assess or confirm the clinical accuracy of SpO_2 or pulse rate measurements.
- The use of components not specified by the manufacturer or not certified

as compatible may result in degraded device performance.

Notes

- Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- If the Oximeter gets wet, please stop operating it and do not resume operation until it is dry and checked for correct operation. When it is carried from a cold environment to a warm and humid environment or vice versa, please do not use it immediately. Allow at least 15 minutes for the Oximeter to reach ambient temperature.
- DO NOT operate the button on the front panel with sharp materials or sharp point.
- DO NOT use high temperature or high-pressure steam disinfection on the oximeter and probes. Refer to related chapter for instructions regarding cleaning and disinfection.
- The intended use of this device is not for therapy purpose.
- The equipment is IP22 with protection against harmful solid foreign objects and ingress of liquid. So that means the equipment is protected against solid foreign objects of 12.5mm and greater, and protected against vertically falling water drops when enclosure tilted up to 15°.
- Please pay attention to the effects of lint, dust, light (including sunlight), etc.
- The device and all it parts and accessories should be kept out of the reach of pets, pests or children to avoid injury to them or causing damage to the device.

- This manual outlines product features for the most comprehensive configuration. Depending on your specific product model, some features described may not be included. Always refer to the actual product for precise functionality.
- If a password is required for data export, please consult your dealer or the manufacturer.
- Prtable and mobile RF communications equipment may affect the performance of the Oximeter.
- The oximeter is calibrated in the factory before sale, and there is no need for user to calibrate again.
- The device has no alarm system. So do not use the handheld pulse oximeter in situations where alarms are required. If the product is used in a situation where an alarm is required, there is a risk that the patient's abnormal status will not be obtained in a timely manner.

Contraindication

No known contraindications.

Declaration of Conformity

The manufacturer hereby declares that this device complies with the following standards:

IEC 60601-1: 2020 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance;

ISO 80601-2-61: 2017 - Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse Oximeter equipment.

And it also follows the provisions of the council Regulation (EU) 2017/745.

1 Overview

1.1 Appearance

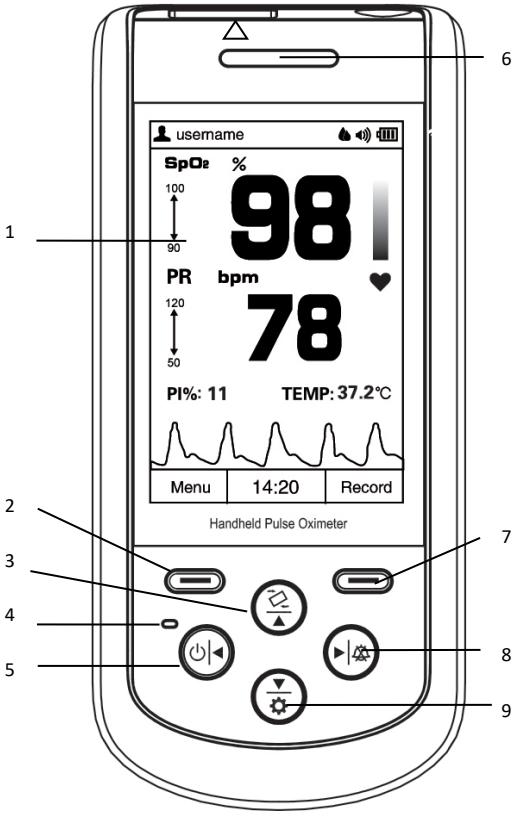
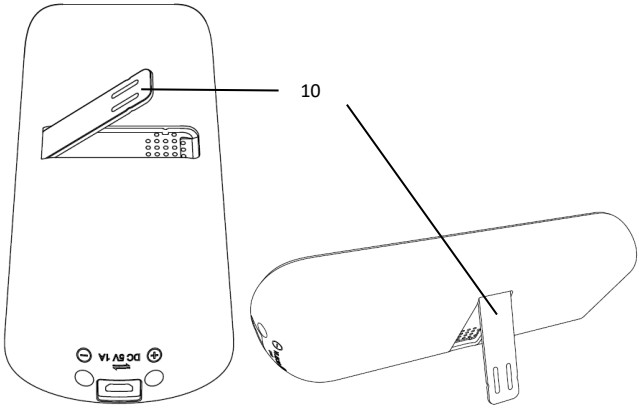


Figure 1.1 Front View



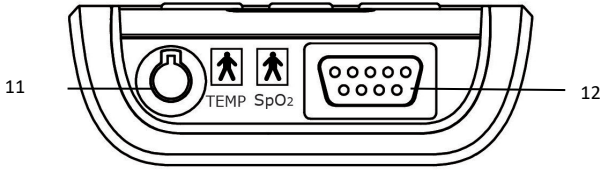


Figure 1.2 Upper-side view

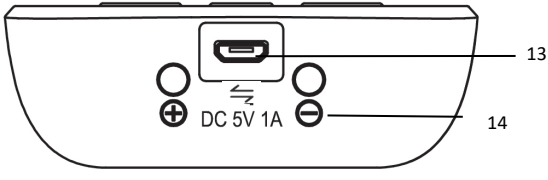


Figure 1.3 Bottom side view

1. **Display screen:** Display measurement result, trends and menus.

2. **(Menu/Confirm):** Short time press it to enter into menu screen, or to confirm the selection.

3.  **(Auto-rotate/Up):** On measuring screen, longtime pressing to enable or disable the automatic screen orientation (on horizontal or vertical direction); On menu or sub-menu screen, short time press it to move the cursor upwards or adjust the parameter value.

4. **(Power saving mode indicator)**: If the device is set as power saving mode, then the indicator lights up.

5.  **(Power/Left):** Power on/off the device by longtime pressing; On menu or sub-menu screen, short time press it to move the cursor left or adjust the parameter values.

6. **(Reminder indicator)**: If the probe is not well placed or disconnected, or the measured value exceeds the preset reminder limit value, then the reminder indicator will flash with orange color.

7. **(Record/Back):** Short time press it to enter into SpO_2 record list screen, or to back to the previous level of menu.

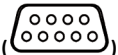
8.  (**Right/Sound**): On data recall screen, longtime press this key, then the delete dialog pops up; On measuring screen, longtime press it to disable or enable the global sound.

   On measuring screen, if the global sound is enabled, and reminder event occurs, then short time press it to perform audible reminder reset (that's to say, to reminder sound will be mute). When the current reminder event ends or a new type of reminder event occurs, then status of audible reminder reset will be ended (that's to say, the reminder sound will be generated again when an reminder event occurs). On menu or sub-menu screen, short time press it to move the cursor right or adjust the parameter values.

9.  **(Setting/Down):** On measuring screen, longtime pressing to enter into setting screen; On menu or sub-menu screen, short time press it to move the cursor downwards or adjust the parameter value.

10. **Support frame:** Support the device when switching to the horizontal direction.

11. **"TEMP"(**  **)**: Temperature Probe Connector.

12. **"SpO_2"(**  **)**: SpO_2 Probe Connector.

13. (): USB connector. Used for data uploading or charging.

14. (): DC power input contact shoes with polarity indication. Used for connecting external DC power input for charging the built-in rechargeable battery via the base.

1.2 Product Name and Model

Name: Handheld Pulse Oximeter

Model: SP-20, PC-66A

Model difference:

	SP-20	PC-66A
Color of silicone cover	Yellow	Blue

1.3 Structure

It consists of the main unit and SpO_2 probe.

(Note: with optional temperature prob, this Oximeter can make temperature measurement.)

1.4 Features

- ✧ It is lightweight, small in size and easy to carry
- ✧ Color LCD to display plethysmogram and parameters
- ✧ Measure SpO_2, Pulse Rate and Temperature simultaneously
- ✧ PI (Perfusion Index) display is available
- ✧ Up to 580 hours data storage for SpO_2 and PR and can be recalled
- ✧ 16 user IDs for marking data and can be added

- ✧ A built-on holder for convenient standing on desktop and display viewing
- ✧ Real-time battery status display and low battery voltage indication
- ✧ Auto power off is available
- ✧ Audible and visual reminder function is available
- ✧ Data uploading to PC for management (Optional)
- ✧ Power saving mode is available

1.5 Intended Use

This Handheld Pulse Oximeter is intended for measuring and recording the pulse rate, functional oxygen saturation (SpO_2), receive and display temperature (optional). It is applicable for spot-checking and/or continuous recording of SpO_2, pulse rate and temperature of adult, pediatric and neonate patients in clinical institutions and homes.

2 Power Supply

1. Internal power supply with built-in battery:

Built-in battery specification: 2000mAh lithium battery.

2. External power from the AC power adapter:

Use the power adapter provided by the manufacturer. Make sure the mains power supply meets the following specifications:

Input: a.c. 100-240V, frequency 50/60Hz 0.15A-0.0625A.

Output: d.c. 5V/1.2A.

Note: it's recommended to use the AC power adapter provided by the manufacturer.

3. The Base:

Input: Micro USB connector, 5VDC/1A

Output: Contact pins. 5VDC/1A

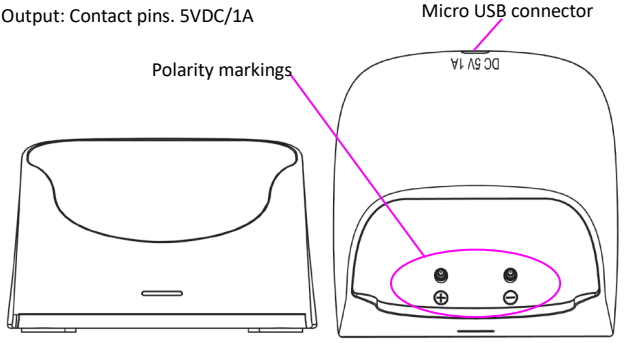


Figure 2.1A Base--front view Figure 2.1B Base--top view

Description:

The base is used to hold the oximeter, and also for charging the oximeter. You

can charge the oximeter by the following methods:

1) When the oximeter is held by the base, you can connect one end of the USB cable to the USB connector on the back of the base marked with “DC 5V/1A”, and the other end to the USB power source with output capacity of 5V DC/1A;

2) If the oximeter is not held by the base, then you can just connect one end of the USB cable to the USB connector on the device marked with "⇆", and the other end to the USB power source with output capacity of 5V DC/1A.

3) When connected to a computer using a USB cable, the device will enter data transfer mode by default . The charging mode is only entered when the AC adapter is used.

Notes:

1) During charging, if the oximeter is held by the base, please do not tilt the base backwards too much, or the USB cable and the USB connector may be damaged.

2) Put the device into the base properly, and pay attention to the polarity markings, as shown in figure 2.2.

Cautions

- Do not throw the battery into the water, liquid and fire.
- Keep the battery out of the reach of the child.
- Do not disassemble the battery.
- The local law should be followed when disposing of the expired device or its accessories in order to protect environment from being polluted.
- Please check or replace the lithium battery regularly.
- The external 5V DC output power supply device (computer or power adapter) connected to charging base or directly connected to the Oximeter must comply with standard IEC 60950 or IEC 60601-1. It’s

strongly recommended to use the power adapter provided by manufacturer for your safety!

- Do not place the oximeter in a place where it is difficult to disconnect the device.
- If the battery is damaged, please replace it with the same model lithium battery provided by the same manufacturer.
- Please unplug the SpO_2 probe and temperature probe while charging to prevent danger caused by children touching and playing by mistake.
- Do not measure temperature or SpO_2 while charging to avoid electric shock.

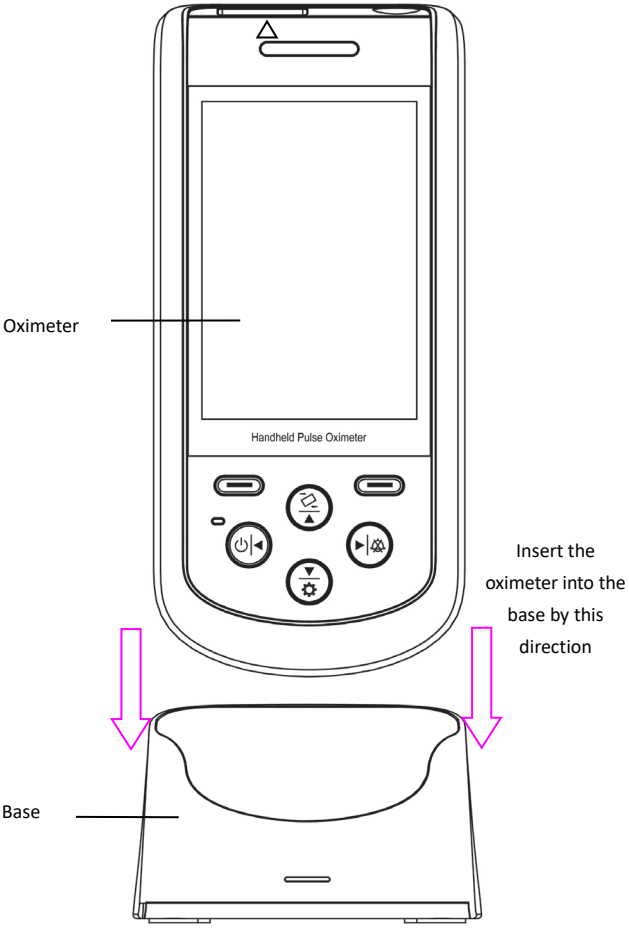


Figure 2.2 Connection between oximeter and base

3 Make Measurement

3.1 SpO_2 Measurement

This device can be equipped with five types of SpO_2 sensors:

- **KS-AC01/KS-AC02**
- **KS-AR01/KS-AR02**
- **KS-AYW02**
- **KS-ALW02**
- **KS-ALW02S**

3.1.1 Operation procedures for KS-AC01/KS-AC02

1. Connect the SpO_2 probe to the connector on the upper-side of the device marked with "SpO_2". (Note: When disconnecting the connector, be sure to hold the head of the connector firmly and pull).

2. The red blinking light inside the clip of the SpO_2 probe indicates a successful connection.

3. Insert one finger (index finger is preferred, the nail should be not too long) into the clip of the probe according to the finger mark, as shown in figure 3.1.1.

4. The device will begin to take the measurement, and the measured result will be displayed on the screen, as shown in figure 4.2.

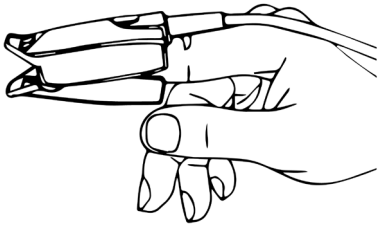


Figure 3.1.1

3.1.2 Operation procedures for KS-AYW02

The sole of the foot is the preferred measurement site.

Connect the plug of the oxygen probe to the "SpO_2" interface on the top panel of the oximeter. Place the emitter and receiver along the edge of the foot near the little toe. Secure the probe to the foot using the foot wrap band, ensuring a snug but comfortable fit, and fasten it with the hook-and-loop fastener. After wrapping, ensure the emitter (round window) and receiver (square window) are in close contact with the skin, as shown in Figure 3.1.3.

If the finger is chosen as the measurement site, place the emitter and receiver on the top and bottom of the finger, then secure the probe to the finger using the wrap band and fasten it with the hook-and-loop fastener, as shown in Figure 3.1.4. The remaining steps are the same as for foot measurement.

Figure 3.1.2

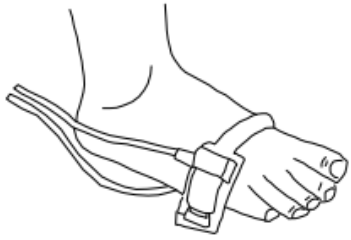


Figure 3.1.3

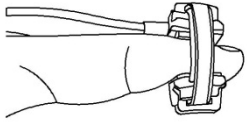


Figure 3.1.4

3.1.3 Measurement Steps for KS-AR01/KS-AR02

Connect the plug of the oxygen probe to the "SpO_2" interface on the top panel of the oximeter. Insert the patient's finger (preferably the index finger) into the probe as shown in Figure 3.1.5. The oximeter will begin measuring, and the measurement data will be displayed on the instrument screen.

Figure 3.1.5

3.1.4 Measurement Steps for KS-ALW02:

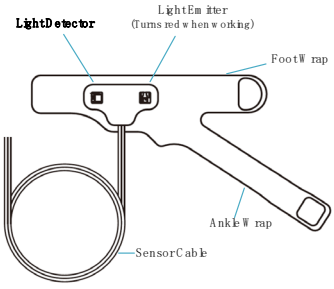


Figure 3.1.6

1. Choose the proper wrap based on weight.

Size	Weight
S	<8.6 lbs
M	8.6~18.7 lbs

2. For proper placement on either foot, place the sensors on the outside of the foot behind the pinky toe. Make sure the sensor touches the skin closely, then secure the foot wrap with Velcro (see Figure 3.6 and 3.7).

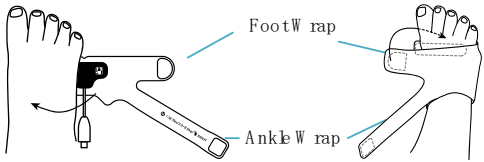


Figure 3.1.7

3. Use the ankle wrap to secure the sensor cable on the ankle or leg (see Figure 3.1.8). Do not over-tighten.

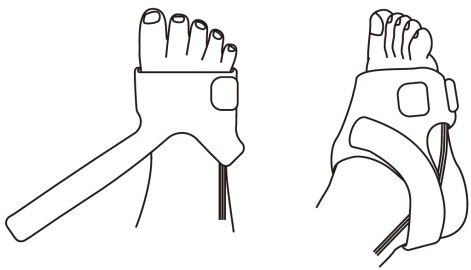


Figure 3.1.8

3.1.4 Measurement Steps for KS-ALW02S:

Connect the plug of the sensor to the "SpO_2" interface on the top panel of the oximeter. Select the wearing method and apply as shown in Figure 3.1.10. The pulse oximeter will begin measurement, and the data will display on the device

screen.

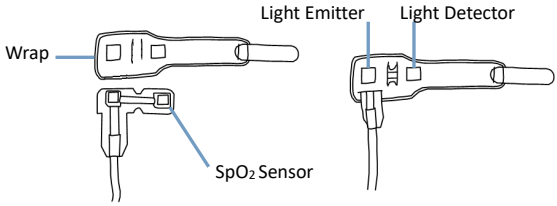


Figure 3.1.9

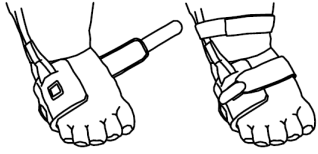


Figure 3.1.10

Safety instructions for SpO_2 measurement

- Long term use of the SpO_2 probe on the same place may result in discomfort or pain, especially for those with microcirculatory problems. It is recommended that the probe should NOT be applied to the same place for over two hours, change the measurement site periodically and when necessary.
- When the ambient temperature is over 35℃, please change the measuring site every two hours; when the ambient temperature is over 37℃, please do NOT use the SpO_2 sensor, as using in high temperatures can cause burns.

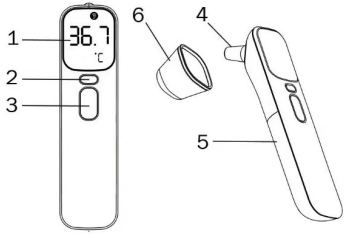
- Do NOT place the SpO_2 probe on a finger/foot with edema or fragile tissue.
- Do NOT put the SpO_2 probe and pressure cuff on the same limb, otherwise the blood pressure measurement may affect the SpO_2 measurement.
- The device is calibrated to display functional oxygen saturation.
- Do NOT allow the sensor cable to twist or bend.
- Check the SpO_2 sensor and cable before use. Do NOT use a damaged SpO_2 sensor.
- When the temperature of the SpO_2 sensor is abnormal, do not use it further.
- Remove nail polish or other cosmetic products from the fingernail.
- The fingernail should be of normal length.
- The SpO_2 sensor cannot be immersed into water, liquid or cleanser.
- The SpO_2 sensor can be repeatedly used. Please clean and disinfect before reuse.
- Connector with the label "SpO_2" can only be connected with SpO_2 probe, and connector with the label "TEMP" can only be connected with the temperature probe.

3.2 Temperature Measurement (optional)

The infrared thermometer is a delicate transducer. To operate please follow these steps and procedures. Failure to accurately operate may cause damage to the probe.

The infrared thermometer is as shown in figure 3.2.

Please place the infrared thermometer in a stable ambient temperature for 30 minutes before taking a measurement.



1. Display screen
2. Unit key (℃/℉)
3. Measuring key
4. Measuring tip of the ear thermometer probe
5. Battery cover
6. Temperature Probe Cover

Figure 3.2 The infrared thermometer

Mode of operation of the clinic thermometer: Adjusted mode

Note: The default mode is ear temperature measurement.

Operation procedure:

1. Connect the infrared thermometer to the connector on the upper side of device marked with "TEMP". Press the measuring key. When the LCD screen of the device displays "[redacted]", this indicates that the probe is successfully connected.
2. When the temperature unit "℃" on the screen of the probe is blinking, the user can begin to take the measurement.
3. Take off the probe cover and insert the tip of infrared thermometer into the earhole, Press the measuring key to start the measurement. A short beep means the measurement has finished and the result will be displayed on

the screen.

4. Press the unit key to switch between ℃ and ℉.

Note:

- Please refer to the IFU of the infrared thermometer for more information.
- If the infrared thermometer detects a hardware failure, a red screen will appear on the display screen and the probe will not enter into measuring mode. Press the measuring key to restart the measurement.
- The infrared thermometer will switch to stand by automatically if there is no operation for 1 minute. If a further measurement is needed, press the measuring key and repeat step 2 and step 3.
- Normal range of ear temperature: 35.8 ~ 38.0 ℃
- Each person has his/her own normal temperature value, and the normal temperature value also changes at different time within a day. Therefore, it's recommended to report your doctor not only the temperature value, but also the measuring position, if possible, you may provide your own normal temperature range to your doctor for reference.

Safety Instruction for Temperature Measurement

- This device meets requirements established in ISO 80601-2-56.
- Do NOT use the infrared thermometer when the subject temperature and ambient temperature are outside the operating ranges specified by the manufacturer.
- Performance of the device may be adversely affected when one or more of the following occur:

  A. Operation outside of the manufacturer specified subject temperature

range.

B. Operation outside of the manufacturer specified operating temperature and humidity ranges.

C. Storage outside of the manufacturer specified ambient temperature and humidity ranges.

D. Mechanical shock.

Manufacturer defined soiled or damaged infrared optical components.

- Do NOT take a measurement when the patient is moving.
- Patients with tympanites and otitis problems should NOT use this device.

4 Operation

4.1 Power on/off the Oximeter

- Long pressing"  " Power/Left key for 1~2 seconds, then the oximeter will be powered on. The oximeter will do self-test and then the software version and warning message "Professional attendance is required for continuous recording!" will be shown on the screen, as shown in figure 4.1 (refer to your oximeter for actual version).

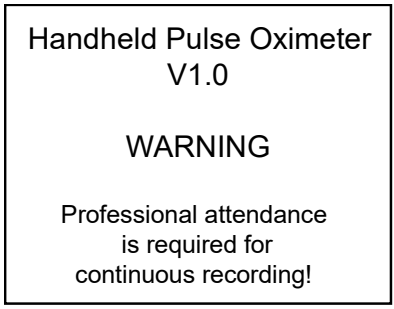


Figure 4.1

4.2 Default Display Screen

Press "⏻"power key for 2 seconds to start up the Oximeter, then the screen will display the default screen, as shown in Figure 4.2.

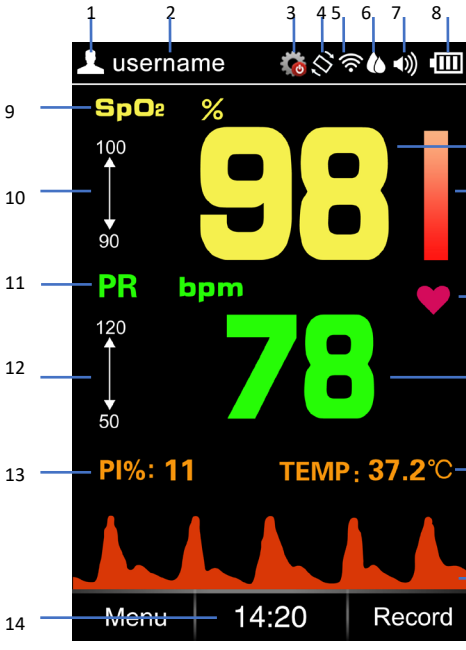


Figure 4.2A Default Display Screen---in vertical

1	Patient type	11	Pulse rate mark and unit
2	User ID	12	PR high/low limit setting value
3	Auto power off disable icon	13	Perfusion index
4	Auto-rotate icon	14	Current time

5	Wireless icon	15	SpO_2 value
6	Recording mode	16	Pulse strength bar-graph
7	Sound indicator	17	Pulse symbol
8	Battery indicator	18	Pulse rate value
9	SpO_2 mark	19	TEMP value
10	SpO_2 high/low limit setting value	20	Plethysmogram

Description:

- During measurement, if the probe is not placed properly, not connected or is off, then "Check Probe" message prompts and keeps blinking on the screen, and "bibibi..." reminder sound appears simultaneously. Reminder sound is sustaining for about 3 minutes, and if there is no any key operation in this period, then the device will power off automatically (if the auto power off function is enabled).

- During measurement, longtime pressing Auto-rotate/Up key "  ", then the Auto-rotate white icon "  " appears on the upper right corner of the screen, it means the auto rotation function is enabled, if you place this oximeter horizontally, then the display shows in horizontal, as shown in figure 4.2B.

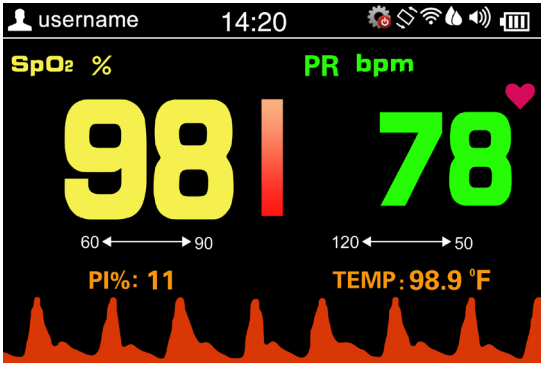


Figure 4.2B Default Display Screen---in horizontal

- Sound indicator "🔇" means that the global sound is disabled, the user can enable the global sound by longtime pressing "▶|🔔" key. Longtime pressing "▶|🔔" key again can disable the global sound, that's to say, the speaker is turned off at all, therefore, no pulse beep sound, no audible reminder and no key click sound.

- If the global sound is enabled by longtime pressing "▶|🔔" key, then during the measurement, over-limit reminder event or probe off event can activate the audible reminder. Refer to Section 6.2 for detailed reminder indication sound.

- If the memory is full, the corresponding memory full icon appears on the screen, "T" means temperature memory is full, "🩸" means

SpO_2 spot-check record memory is full, "  " means SpO_2 trend record memory is full. No display of the icon means the current corresponding storing space is not full. If the memory is full, the data storing will continue in such way the new record will overwrite the oldest record, so that it's recommended to upload the stored data into the computer in time.

4.3 Menu

On the default measuring screen, short time press "  " Menu/Confirm key for entering into main menu screen (as shown in Figure 4.3).

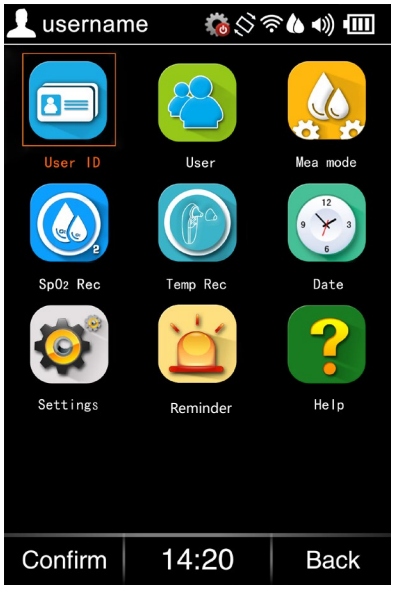


Figure 4.3 Main menu

There are 9 functional icons in main menu screen, press Up/Down/Left/Right key can move the cursor to make selection and press "▬" Menu/Confirm key again to confirm the selection.

- User ID: Add new or edit the current User ID.
- User: Select patient type, "Adult", "Pediatric" and “Neonate” for option.
- Recording mode: Select the data recording mode, "Spot-check Record" and "Trend Record" for option.
- SpO_2 record: Recall and review the records stored on the oximeter, two types of record for option: "Spot-check Record" and "Trend Record", see

Section 4.4 for details.

- TEMP Record: Review the temperature record list.
- Date: Set the time and date, see Section 4.3.6 for details.
- Settings: Set the system parameter, including brightness, sound volume, display language, power saving mode etc., see Section 4.3.7 for details.
- Reminder: Set the low reminder limit for SpO_2 and the high/low reminder limit for PR, see Section 4.3.8 for details.
- Help: To view the tips information of SpO_2 measurement and temperature measurement, see Section 4.3.9 for details.

4.3.1 User ID

On main menu screen, move the cursor on "User ID" and press Confirm key "( )", then the oximeter enters into User ID Setup screen, as shown in figure 4.4.

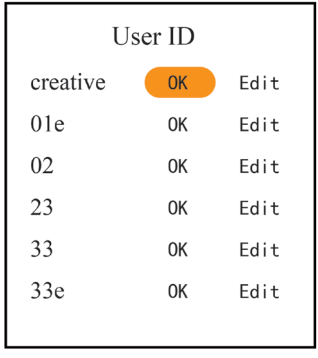


Figure 4.4A User ID setup screen

Move the cursor on "Edit" and press Confirm key "( )", when the cursor turns to blue, then the user can edit the User ID, and move the cursor on "OK" to confirm the edit, the edit screen is as shown in figure 4.4B.

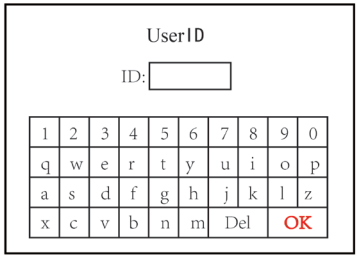


Figure 4.4B User ID edit screen

4.3.2 User

On main menu screen, move the cursor on "User" and press Confirm key "  ", then the oximeter enters into Patient type Setup screen, as shown in figure 4.5.

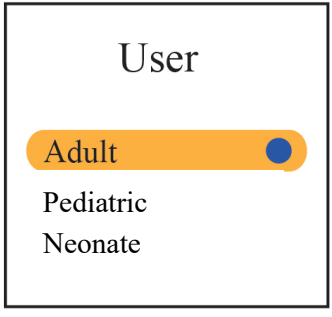


Figure 4.5 Patient type setup screen

4.3.3 Recording Mode

On main menu screen, move the cursor on "Recording Mode" and press Confirm key "  ", then the oximeter enters into Recording Mode Setup screen, as shown in figure 4.6.

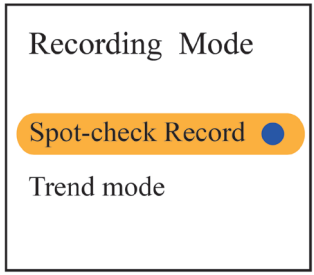


Figure 4.6 Recording mode setup screen

Note: When selecting “Spot-check Record” for data recording, the measuring time should last over 10 seconds to get one spot-check reading, or no reading value will not be recorded in Spot-check data record; When selecting “Trend Record”, the measuring time should exceed 30 seconds, or no one record will be recorded in Trend data record list.

4.3.4 SpO_2 Record

On main menu screen, move the cursor on "SpO_2 Record" and press Confirm key "( )", then the oximeter enters into SpO_2 record review method selecting screen, as shown in figure 4.7.

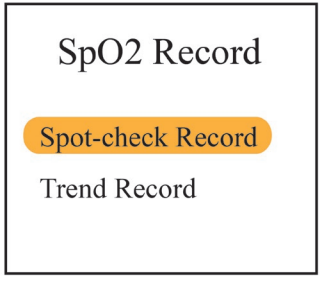


Figure 4.7 SpO_2 record review method selecting screen

Refer to Section 4.4 for details.

4.3.5 TEMP Record

On main menu screen, move the cursor on "TEMP Record" and press Confirm

key "[ ]", then the oximeter enters into temperature record list screen, as shown in figure 4.8.

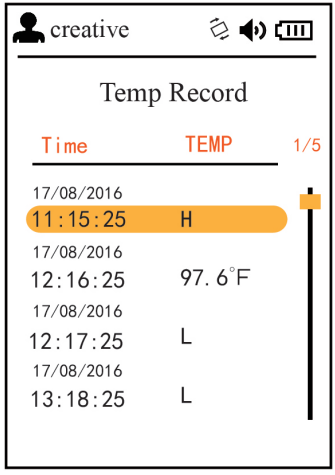


Figure 4.8 TEMP record list screen

4.3.6 Date

On main menu screen, move the cursor on "Date" and press Confirm key "[ ]", then the oximeter enters into date setup screen, as shown in figure 4.9.

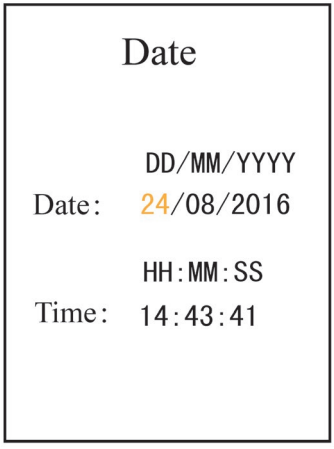


Figure 4.9 Date setup screen

Date setting procedure:

1) Move the cursor stays on the Year of the date, press Confirm key "▬" to active Year option, the cursor flashes on the Year of the date;

2) Press Up/Down key to adjust Year;

3) Press "▬" (Confirm) key to confirm and exit from date setting;

4) The procedures of adjusting Month, Day, Hour, Minute and Second value are the same with Year adjustment.

Date Format: DD-YY-MM; Time Format: HH:MM:SS

Note: The setting operations of other parameters (such as User ID, User, Auto Power Off, Power Saving etc.) are the same with date setting.

4.3.7 Settings

On main menu screen, move the cursor on "Settings" and press Confirm key "▬", then the oximeter enters into system setting screen, as shown in figure 4.10.

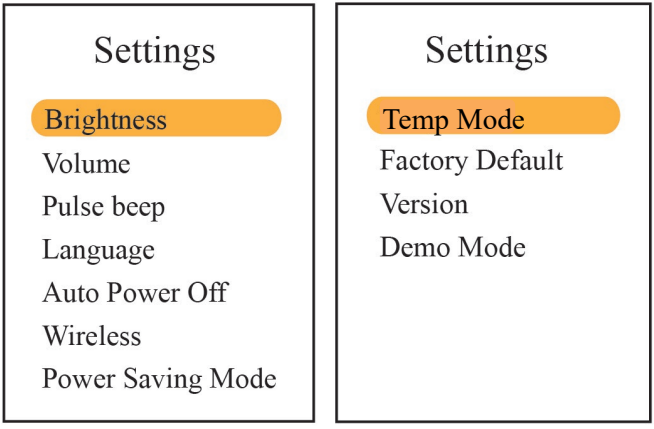


Figure 4.10 System setting screen

Description:

- Brightness: To set the brightness of backlight, 6 levels for optional, the factory default is level 3, as shown in figure 4.10A.
- Volume: To set the sound volume (including reminder sound, pulse beep sound and key click sound), 6 levels sound volume for optional, the factory default is level 3, as shown in figure 4.10B.
- Pulse beep: To turn on/off pulse beep, the factory default is “On”, as shown in figure 4.10C. If the global sound is enabled by longtime pressing “ ”key, and the pulse beep is set to “On” option, and when there is no over-limit event, then pulse beep sound can be heard during SpO_2 measurement.
- Language: This oximeter provides the display with two languages: English and Simplified Chinese, the factory default is "English", as shown in figure 4.10D.
- Auto power off: To turn on/off the Auto Power Off mode, the factory default is "On", as shown in figure 4.10E.
- Wireless: To turn on/off the wireless connection function, the factory default is "On", as shown in figure 4.10F.
- Power saving mode: To turn on/off the Power Saving mode, the factory

default is "On", as shown in figure 4.10G.

- TEMP unit: To set the temperature unit, "°C(Celsius)" and "°F(Fahrenheit)" for option, the factory default is "°F", as shown in figure 4.10H.
- Factory Default: Enter into the factory default setting, as shown in figure 4.10I.
- Version: For viewing version number of the software, as shown in figure 4.10J.
- Demo: Enter into the Demonstration mode, as shown in figure 4.10K.

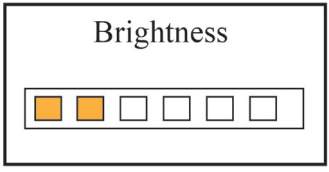


Figure 4.10A Brightness setup

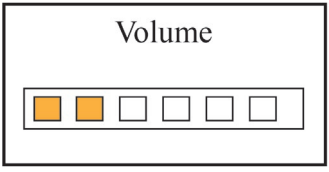


Figure 4.10B Volume setup

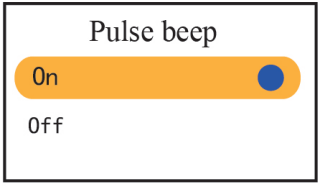


Figure 4.10C Pulse beep setup

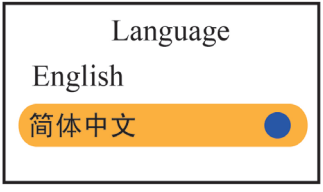


Figure 4.10D Language setup

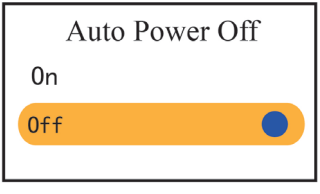


Figure 4.10E Auto Power OFF setup

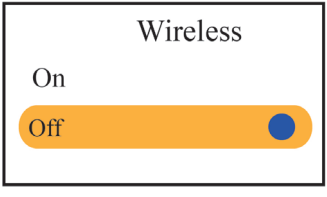


Figure 4.10F Wireless setup

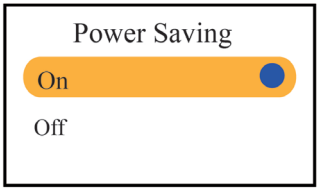


Figure 4.10G Power Saving setup

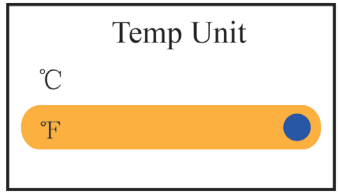


Figure 4.10I TEMP unit setup

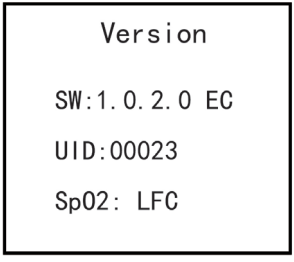


Figure 4.10H Version info

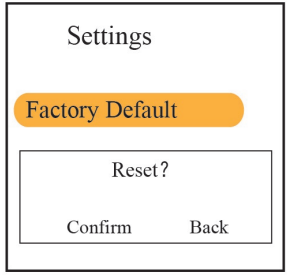


Figure 4.10J Default setting

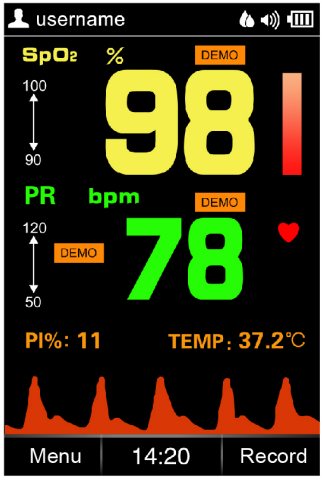


Figure 4.10K Demo mode

Notes:

- When the Auto Power Off is set to "On" option, if there is no key operation for 3 minutes, then the oximeter will power off automatically.
- When the Power Saving Mode is set to "On" option, during the measurement, if there is no key operation for 1 minute, the screen display will be dim for power saving. The display brightness will resume to normal condition by pressing any key.

4.3.8 Reminder

On main menu screen, move the cursor on "Reminder" and press Confirm key "( )", then the oximeter enters into reminder setting screen, as shown in figure 4.11.

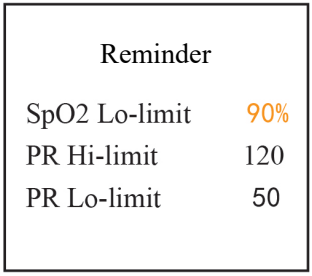


Figure 4.11 Reminder setting screen

- **SpO_2 Lo-Limit:** SpO_2 low limit setting; range: 50%~99%, the step is 1%. The factory default value is 90% for adult and 95% for pediatric and neonate.
- **PR Hi-Limit:** High limit setting of pulse rate; range: 100~240bpm. From 100 to 160, the step is 1bpm, and from 160 to 240, the step is 5bpm. The factory default value is 120bpm for adult and 160bpm for pediatric and neonate.
- **PR Lo-Limit:** Low limit setting of pulse rate; range: 30~99bpm, and the step is 1bpm. The factory default value is 50bpm for adult and 60bpm for pediatric and neonate.

Note: When the SpO_2 reading is lower than or equal to the preset reminder setting or the PR reading is higher than or equal to the preset high limit or the PR reading is lower than or equal to the preset low limit, then the over-limit reminder event will be activated, that's, the reminder sound "bibibibi..." occurs, and the corresponding reading(s) blinks. When measured on pediatric and neonate patients, if the SpO_2 reading is lower than or equal to the preset reminder setting for 10 seconds, then the reminder sound and blinking display will be activated.

4.3.9 Help

On main menu screen, move the cursor on "Help" and press Confirm key

"[ ]", then the oximeter help information screen, which shows SpO_2 and temperature measurement tips, as shown in figure 4.12.

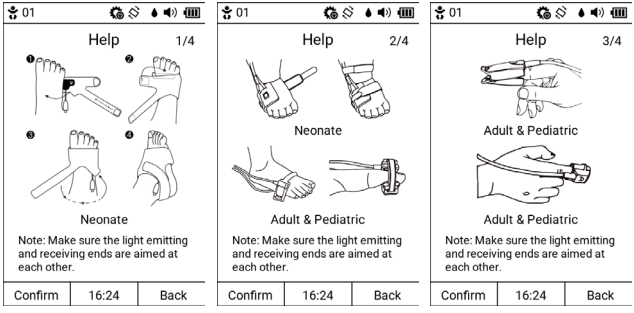


Figure 4.12 Help information---SpO_2 measurement

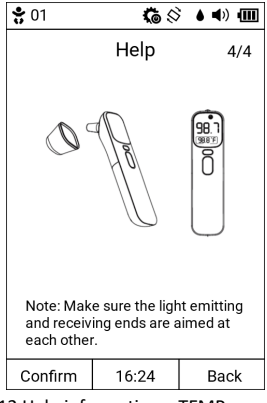


Figure 4.12 Help information---TEMP measurement

4.4 Record

4.4.1 Data Recall

On main default screen, short time press Record/Back key "[ ]" to enter into data recall screen, as shown in figure 4.13.

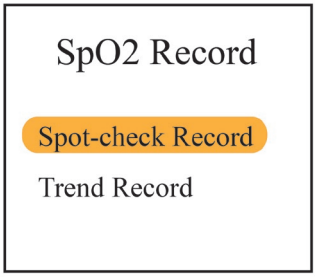


Figure 4.13 SpO_2 record

SpO_2 records include two types, Spot-check and Trend Record, Spot-check Record is a list showing the recording time, SpO_2 value and pulse rate value for each spot-checking event, as shown in figure 4.14.

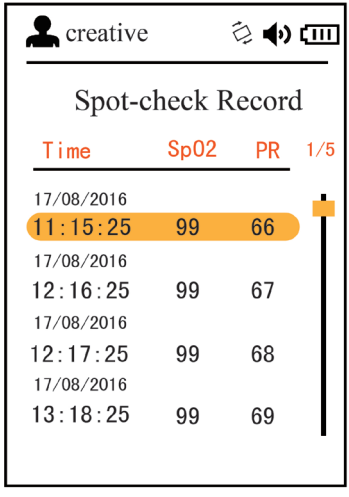


Figure 4.14 Spot-check Record list

If Trend Record is selected, then the screen shows a list of trend data record, and each record corresponds to a period of recording at a fixed time interval (1

second), as shown in figure 4.15, press Up/Down key ("  ") to select one record you need to review.

Select one record you need to review, and press Confirm key "  ", then the screen shows the corresponding User, User ID, and trend graph, as shown in figure 4.16.

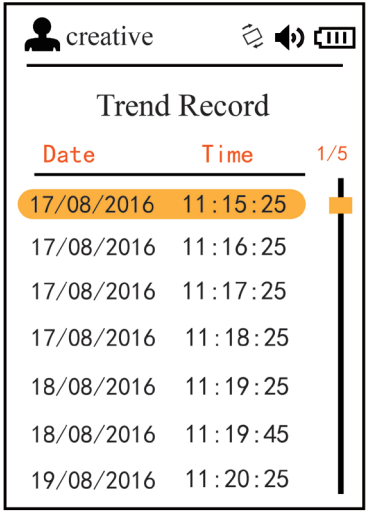


Figure 4.15 Trend record---List

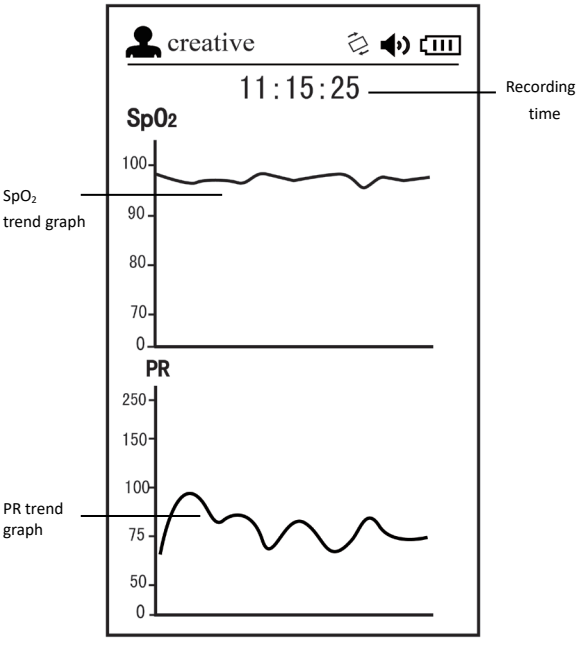


Figure 4.16 Trend record---Trend graph

4.4.2 Data Deletion

On the record list screen shown in figure 4.14 or 4.15, move the cursor on the record you want to delete, and longtime pressing Sound/Right key(" "), then a message “Are you sure to delete all?” prompts on the screen, as shown in figure 4.17.

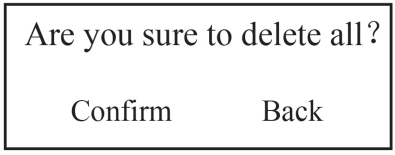


Figure 4.17 Delete records

At this time, short time press Menu/Confirm ("▬") key to confirm and delete the records. Or short time press Record/Back ("▬") key to return to record list screen.

4.4.3 Data Management

The device supports data export to PC.

You can also connect the device to Vihealth app, viewing measuring results on a mobile phone.

4.4.3.1 App Connection

Install the app on an Apple product or Android-powered device, including smart phones and tablets.

App name: ViHealth

iOS: App Store

Android: Google Play

Minimum system requirements: Android 8.0 and above, iOS 12 and above

DOWNLOAD ON THE App Store

GET IT ON Google Play

Or you can just scan the QR code below to download ViHealth.

1) Power on the device. Enter [Menu] screen and select [Settings]. Then set [Wireless] to “On”.
2) Tap [Add device now] on [Dashboard] interface or [Add device] on [Profile] interface to enter [Add your device] page, the app will search for available devices. Select your device and wait for connection.
3) Start a measurement by following tips on the device. You can view and

manage history records on the [History] interface.

5 Specifications

Safety Specifications

Type of protection against electric shock	Internally powered equipment
Degree of protection	Type BF applied parts
Degree of protection against harmful ingress of liquids	IP22
Electro-Magnetic Compatibility	Group I, Class B
Operation mode	Continuous operation

Physical Specifications

Dimensions	158 mm (L) × 73 mm (W) × 25 mm (H)
Net Weight	about 230g (including battery)
Display	3.5-inch color TFT LCD

Power Supply

Operating voltage	3.7V
Working current	≤200mA
Input power	<6VA
Continues working time	≤20 hours
Service life of internal power supply	Normal cycle charge/discharge times ⩾ 500 times

Environment Specifications

Operation	
Temperature	5°C ~40°C
Humidity	30%~80%(non-condensing)
Atmospheric pressure	70.0kPa~106.0kPa
Transportation and Storage	

Temperature	-20°C ~ 55°C
Humidity	10%~93%(non-condensing)
Atmospheric pressure	53.0kPa~106.0kPa
Transportation and Storage between Uses	
-25ºC without relative humidity control; and + 70ºC at a relative humidity up to 93% (non-condensing)	

Technical Specifications

SpO_2		
Transducer	Dual-wavelength LED sensor with wavelength	
	Red light	660±5 nm
	Infrared light	905±5 nm
	Maximal average optical output power	≤ 2mW
Display range	0~100%	
Measuring range	35~100%	
Measurement error	±2% for SpO_2 range from 70% to 100%; ±3% for SpO_2 range from 50% to 69%; not defined for SpO_2 below 50% *Note: The measurement error refers to the deviation obtained when using an SpO_2 simulator, where "%" represents the percentage of blood oxygen saturation.	
Measuring accuracy	Arms is not greater than 3% for SpO_2 range from 70% to 100%. *Note: Arms is defined as root-mean-square value of deviation according to ISO 80601-2-61.	
Pulse Rate		
Display and measuring range	20bpm~300bpm	
Accuracy	±2bpm or ±2% (whichever is greater)	
Temperature(optional)		
Measuring range	32.0℃~43.0℃	

Measuring accuracy	±0.2℃ for temperature range from 35.0℃ to 42.0℃, and ±0.3℃ for the rest
Response time	≤5s
Patient Group	Adult Pediatric and neonate
Measuring site	earhole
Deviation	≤0.1℃

Other Specifications

Perfusion Index Display	Range: 0.2%~20%
Frequency band	2.4GHz
Bluetooth working profile	BLE V5.0
Data Update	The update time for determining SpO_2 and PR value is 8 seconds, and the displaying update time is 1 second.
Resistance to interference of surrounding light	The difference between the SpO_2 value measured in the condition of indoor natural light and that of darkroom is less than ±1%

Compatible Device

Device name	Infrared Thermometer
Model	AOJ-200
Manufacturer	Shenzhen AOJ Medical Technology Co., Ltd.
CE Certification	CE0123, Certificate No. XXXXXXXXXX

6 Over-limit Indication

6.1 Limit settings

- SpO_2 low limit setting range: 50% ~ 99%.
- Pulse Rate limits setting range:

High: 100bpm--240bpm Low: 30bpm--99bpm

During the measurement, if the measured value exceeds the preset value, the

reminder beeping sound will be activated, the value that is over-limit will blink at the same time.

6.2 Over-limit indication sound mute setting

- During the measurement, if the global sound is enabled, then short time press"  " key to perform audible reminder reset (that's to say, the reminder sound will be mute, and icon "  " appears on the upper right corner of the screen), but the over-limited value still keeps blinking. when the current reminder event ends or a new type of reminder event occurs, then the status of audible reminder reset will be ended (that's to say, the reminder sound can be generated when a reminder event occurs, and icon "  " appears on the upper right corner of the screen).
- When the global sound is enables, then the longtime pressing "  " key can disable the global sound, and the sound icon becomes "". Longtime pressing "  " key again can enable the global sound. Note: "" means the speaker volume is set as 1 or 2 grid(s); "  " means the speaker volume is set as 3 or 4 grids; "  " means the speaker volume is set as 5 or 6 grids.
- During the measurement, if the probe is off or disconnected, the message "Check Probe" shows and keeps blinking on the display screen. The reminder sound starts (interval is 5 seconds). If the probe is still off and lasts for about 3 minutes, then the Oximeter will power off automatically.

7 Packing List

1. An Oximeter
2. A SpO_2 probe
3. User Manual
4. An oximeter rubber cover
5. A charging base
6. Power adapter
7. A temperature probe (optional)
8. Charging cable (optional)
9. A USB data cable (optional)
10. Carrying case(optional)

Notes:

1. The accessories are subject to change. See the package in your hand for detailed items and quantity.

2. All the parts of the device should NOT be replaced at will. If necessary, please use the components provided by the manufacture or those that are of the same model and standards as the accessories along with the device which are provided by the same factory. Otherwise, negative effects concerning safety and biocompatibility etc. may be caused.

3. This device can only connect with the manufacture nominated device.

8 Repair and Maintenance

8.1 Maintenance

The expected service life(not a warranty) of this device is 5 years. In order to ensure its long service life, please pay attention to the maintenance;

- If the battery is damaged, please contact your local sales representative or the manufacture.

- Please store the device carefully to avoid being damaged by pets, pests or children.
- Do not use the oximeter immediately when it is transferred from a cold environment to a warm, humid place.
- The oximeter is calibrated in the factory before sale, there is no need to calibrate it during its life cycle. However, if it is necessary to verify its accuracy routinely, the user can do the verification by means of SpO2 simulator, or it can be done by the local third-party test house.
- The maintenance of the instrument is limited to the qualified maintenance personnel designated by the manufacturer, and the user should not carry out maintenance without authorization. The manufacturer can provide maintenance manuals to the maintenance personnel, which contain circuit diagrams, component part lists, descriptions, calibration instructions and other relevant information required for maintenance.

8.2 Battery Maintenance

In order to extend the service life of the battery, the correct use and maintenance of the battery is necessary.

- Conduct regular inspections. If the internal battery is damaged, please contact the manufacturer in time to get it replaced with the same type and specification by qualified maintenance personnel. Users should not replace it by themselves.
- To prolong the battery service life, it is recommended to check and use the battery at least once a month.

- When the device is left unused for a long time, it should be charged 50% to 80% first with regular charging and maintenance every 3 months, so as to avoid a low power resulted from self-discharge, which may lead to irreversible loss of capacity.

8.3 Cleaning and Disinfecting Instruction

- Surface-clean the device with a soft cloth by wetting with a solution such as 75% alcohol.
- Then surface-clean by a dampened cloth and let it air dry or wipe it with a cloth.
- Please clean and disinfect the device after using to avoid cross infection.
- High-pressure disinfection cannot be used on the device.
- Do not immerse the device in liquid.

9 Troubleshooting

Trouble	Possible Reason	Solution
Unstable SpO_2 and Pulse Rate display	1. Probe misalignment. 2. The patient is moving.	1. Place the sensor correctly and try again. 2. Reduce patient movement.
Unable to measure temperature	Temperature probe is not connected properly	Reinsert the probe into the device
Device will not switch on	1. The batteries are drained or almost drained. 2. The device is malfunctioning.	1. Recharge battery. 2. Please contact the local service center.
No Display	1. The device will power off automatically when there is no signal and no operation for 1 minute. 2. The battery voltage is low.	1. Normal. 2. Recharge battery.
No Signal	1. Probe off or incorrect connection 2. Probe misalignment 3. Probe is damaged	1. Reconnect the probe 2. Place the sensor correctly 3. Replace a new probe

Appendix I Key of Symbols

Symbols on the screen

Symbol	Description
%SpO_2	The oxygen saturation
PI%	Perfusion Index
	Pulse rate (Unit: beats per minute)
	Pulse bar graph
	Low battery voltage
	Battery is full
	Reminder reset icon
	Speaker mute icon
	Speaker volume icon
	SpO_2 spot-check record memory full
	SpO_2 trend record memory full
	Temperature memory full
	Wireless transmission icon
	(Neonate/Pediatric/Adult) Patient type

Symbols on the device/packaging

Symbol	Description
SpO_2	SpO_2 probe connector
TEMP	Temperature probe connector
	Power/Left Key
	Right/ Sound Key
	Auto-rotate/Up Key
	Setting/Down Key
	Menu/Confirm key or Record/Back key
	Serial number
	CE mark (Indicates that the product complies with the EU Medical Device Regulations(Regulation (EU)2017/745)
	UKCA marking
	Medical device
	Unique device identification
	Authorized representative in the European Community
	UK Responsible Person
	Date of manufacture
	Manufacturer
	Type BF applied part

	Refer to user manual/booklet
	Indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling
IP22	Indicates that the product is protected against solid foreign objects of 12,5 mm Ø and greater; and protected against vertically falling water drops when enclosure tilted up to 15°
	No alarm system
	Non-ionizing electromagnetic radiation
	Caution
	General warning sign
	MR unsafe
	Fragile, handle with care
	Keep dry
	This way up
	Stacking limit by number
	Stacking limit by mass
	General symbol for recovery/recyclable
	Temperature limits

	Humidity limitation
	Atmospheric pressure limitation
	Our products and packaging can be recycled, don't throw them away! Find where to drop them off on the www.quefairedemesdechets.fr site (Only applicable for French market).
	Battery can be recycled, don’t throw it away! (Only applicable for French market)
	Packaging can be recycled, don’t throw it away! (Only applicable for French market)

Appendix II Accessories

Item	Model	Description	Manufacturer	Intended Users
SpO_2 Sensor	KS-AC01	D-PLUG	Shenzhen Creative Industry Co., Ltd.	Adult Pediatric
	KS-AC02	D-PLUG	Shenzhen Creative Industry Co., Ltd.	Pediatric
	KS-AR01	D-PLUG	Shenzhen Creative Industry Co., Ltd.	Adult Pediatric
	KS-AR02	D-PLUG	Shenzhen Creative Industry Co., Ltd.	Adult Pediatric
	KS-AYW02	D-PLUG	Shenzhen Creative Industry Co., Ltd.	Adult Pediatric
	KS-ALW02	D-PLUG	Shenzhen Creative Industry Co., Ltd.	Neonate
	KS-ALW02S	D-PLUG	Shenzhen Creative Industry Co., Ltd.	Neonate
Infrared Thermometer	AOJ-200	CE 0123	Shenzhen AOJ Medical Technology Co., Ltd.	Adult /Pediatric /Neonate
Power Adapter	LXCP12-005	European standard, 5V/1.2A	Shenzhen Longxc Power Supply Co., Ltd.	/
Charging Cable	Micro-USB	USB Power Cable	Shenzhen Ming Xiang Yu Technology Co., Ltd.	/
Charging base	/	/	Shenzhen Creative Industry Co., Ltd.	/
USB data cable	/	/	Shenzhen Creative Industry Co., Ltd.	/

Note: For specific details on accessories, please consult their individual instructions for use.

Appendix III Common Knowledge

1 Meaning of SpO_2

SpO_2 is the saturation percentage of oxygen in the blood, so called O_2 concentration in the blood; it is defined by the percentage of oxyhemoglobin (HbO_2) in the total hemoglobin of the arterial blood. SpO_2 is an important physiological parameter to reflect the respiration function; it is calculated by the following method:

$$SpO_2 = HbO_2/ (HbO_2 + Hb) \times 100\%$$

HbO_2 are the oxyhemoglobins (oxygenized hemoglobin), Hb are those hemoglobins which release oxygen.

2 Principle of Measurement

Based on Lamber-Beer law, the light absorbance of a given substance is directly proportional with its density or concentration. When the light with certain wavelength emits on human tissue, the measured intensity of light after absorption, reflecting and attenuation in tissue can reflect the structure character of the tissue by which the light passes. Due to that oxygenated hemoglobin (HbO_2) and deoxygenated hemoglobin (Hb) have different absorption character in the spectrum range from red to infrared light (600nm~1000nm wavelength), by using these characteristics, SpO_2 can be determined. SpO_2 measured by this oximeter is the functional oxygen saturation -- a percentage of the hemoglobin that can transport oxygen. In contrast, hem oximeters report fractional oxygen saturation – a percentage of all measured hemoglobin, including dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin.

Clinical application of pulse oximeters: SpO_2 is an important physiological parameter to reflect the respiration and ventilation function, so SpO_2

monitoring used in clinical becomes more popularly, such as monitoring the patient with serious respiratory disease, the patient under anesthesia during operation, premature and pediatric and neonate. The status of SpO_2 can be determined in time by measurement and find the hypoxemia patient earlier, thereby preventing or reducing accidental death caused by hypoxia effectively.

3 Normal SpO_2 Range and Default Low Limit

In campagna area, healthy people's SpO_2 value is greater than 94%, so the values below 94% are determined as hypoxia. SpO_2<90% is considered as the default threshold for determining anoxia by most researchers, so SpO_2 low limit of the oximeter is set as 90% generally.

4 Factors affecting SpO_2 accuracy (interference reason)

✧ Intravascular dyes such as indocyanine green or methylene blue.

✧ Exposure to excessive illumination, such as surgical lamps, bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight.

✧ Vascular dyes or external used color-up product such as nail enamel or color skin care

✧ Excessive patient movement

✧ Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line

✧ Exposure to the chamber with High pressure oxygen

✧ There is an arterial occlusion proximal to the sensor

✧ Blood vessel contraction caused by peripheral vessel hyperkinesias or body temperature decreasing

5 Factors causing low SpO_2 value (pathology reason)

✧ Hypoxemia disease, functional lack of HbO2

✧ Pigmentation or abnormal oxyhemoglobin level

✧ Abnormal oxyhemoglobin variation

✧ Methemoglobin disease

✧ Sul hemoglobinemia or arterial occlusion exists near sensor

✧ Obvious venous pulsations

✧ Peripheral arterial pulsation becomes weak

✧ Peripheral blood supply is not enough

Appendix IV EMC Compliance

Warnings:

- The instrument conforms to the requirements of IEC60601- 1 - 2 , EN 60601-1-2, ISO 80601-2-61, EN ISO 80601-2-61 and EN/IEC 60601-1-1 standards for electromagnetic compatibility.
- The user shall install and use the EMC information provided in the random file.
- Portable and mobile RF communication equipment may affect the performance of the instrument, avoid strong electromagnetic interference when using, such as close to the mobile phone, microwave oven, etc .
- The guidance and manufacturer's declaration are detailed in the table below .
- The instrument should not be close to or stacked with other equipment. If it must to be close to or stacked, it should be observed and verified to be able to operate normally under its configuration.
- In addition to the cables sold by the instrument manufacturer as spare parts for internal components, the use of other accessories and cables may result in increased emission or reduced immunity.

Table 1

Guidance and manufacturer’s declaration-electromagnetic emission
The Handheld Pulse Oximeter is intended for use in the electromagnetic

<table>
<tr><td colspan="3">environment specified below. The customer or the user of the Handheld Pulse Oximeter should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment-guidance</td></tr>
<tr><td>Conducted emissions
CISPR 11</td><td rowspan="2">Group 1
Class B</td><td>The Handheld 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>Radiated emissions
CISPR 11</td><td rowspan="3">The Handheld Pulse Oximeter suitable for use in all establishments, including domestic establishments and those directly network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/flicker emissions
IEC61000-3-3</td><td>Complies</td></tr>
</table>

Table 2

<table>
<tr><td colspan="4">Guidance and manufacturer’s declaration-electromagnetic emission</td></tr>
<tr><td colspan="4">The Handheld Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Handheld Pulse Oximeter should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>IEC60601 test level</td><td>Compliance level</td><td>Electromagnetic environment -guidance</td></tr>
<tr><td>Electrostatic discharge(ESD)
IEC61000-4-2</td><td>±8 kV contact
±2 kV, ±4 kV, ±8 kV, ± 15 kV air</td><td>±8 kV contact
±2 kV, ±4 kV, ±8 kV, ± 15 kV air</td><td>Floors should be wood, concrete or ceramic tile. if floors are covered with synthetic material, the relative humidity should</td></tr>
</table>

			be at least 30%
Electrical fast transient/ burst IEC61000-4-4	±2kV for power Supply lines ±1kV for Input a.c. Power Ports	±2kV for power Supply lines ±1kV for Input a.c. Power Ports	N/A
Surge IEC 61000-4-5	±0.5 kV, 1kV line (s) to line(s) ±0.5 kV, ± 1 kV, ±2kV line(s) to earth	±0.5 kV, 1kV line (s) to line(s) ±0.5 kV, ± 1 kV, ±2kV line(s) to earth	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle <40% UT (60% dip in UT) for 5 cycles <70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	<5% UT (>95% dip in UT) for 0.5 cycle <40% UT (60% dip in UT) for 5 cycles <70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	N/A
Power frequency(50Hz/60Hz) magnetic field IEC61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or

			hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity			
The Handheld Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of The Handheld Pulse Oximeter should assure that it is used in such an electromagnetic environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment -guidance
Conducted RF IEC61000-4-6	0,15MHz–80MHz 3 V RMS outside the ISM band, 6 V RMS in the ISM	0,15MHz–80MHz 3 V RMS outside the ISM band, 6 V RMS in the ISM	Portable and mobile RF communications equipment should be used no closer to any part of The Handheld Pulse Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Radiated RF IEC61000-4-3	80 MHz to 2.7 GHz 3V/m	80 MHz to 2.7 GHz 3V/m	$d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz to 800MHz $d=2.3\sqrt{P}$ 800MHz to 2.5GHz 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 metres (m). b 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, and electromagnetic site survey should be considered. If the measured field strength in the location in which The Handheld Pulse Oximeter is used exceeds the applicable RF compliance level above, The Handheld Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as

re-orienting or relocating The Handheld Pulse Oximeter.

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

Table 4

Frequency Range and Level: RF wireless communication equipment			
Test Frequency (MHz)	Modulation	Minimum immunity Level (V/m)	immunity Level Applied (V/m)
385	**Pulse Modulation: 18 Hz	27	27
450	☒ *FM + 5 Hz deviation: 1 kHz sine ☐ **Pulse Modulation: 18 Hz	28	28
710 745 780	**Pulse Modulation: 217 Hz	9	9
810 870 930	**Pulse Modulation: 18 Hz	28	28
1720 1845 1970	**Pulse Modulation: 217 Hz	28	28
2450	**Pulse Modulation: 217 Hz	28	28
5240 5500 5785	**Pulse Modulation: 217 Hz	9	9

ATTENTION:

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.

Table 5

Recommended separation distances between portable and mobile RF communication the equipment

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

Rated maximum output power of transmitter W(Watts)	Separation distance according to frequency of transmitter M(Meters)		
	150kHz to 80MHz $d=1.2\sqrt{P}$	80MHz to 800MHz $d=1.2\sqrt{P}$	80MHz to 2,5GHz $d=2.3\sqrt{P}$
0,01	N/A	0.12	0.23
0,1	N/A	0.38	0.73
1	N/A	1.2	2.3
10	N/A	3.8	7.3
100	N/A	12	23

For transmitters rated at a maximum output power not listed above, the

recommended separation distance in metres (m) can be determined 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.