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PROFESSIONAL MEDICAL PRODUCTS

PULSOXIMETRO DA POLSO
WRIST OXIMETER

Manuale d'uso - User manual

ATTENZIONE: *Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.*
ATTENTION: *The operators must carefully read and completely understand the present manual before using the product.*

REF 34340

Gima S.p.A.
Via Marconi, 1
20060 Gessate (MI) Italy
Made in China

CE 0476

M34340-IT-GB-Rev.5-12.23

Instructions to User

Wrist Oximeter is a precision measuring device, please read the manual very carefully before using this device.

Failure to follow these instructions may cause measuring abnormality or device damage.

Notes:

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

Instructions for Safe Operations

Check the device to make sure that there is no visible damage that may affect user's safety and measurement performance. When there is obvious damage, stop using the device.

Necessary servicing must be performed by qualified service engineers ONLY. Users are not permitted to maintain it by themselves.

The oximeter cannot be used together with the devices not specified in User Manual.

Cautions

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 testee is under MRI or CT scanning.

Warnings

For individual patients, there should be a more prudent inspecting in the placing process. The device can not be clipped on the edema and tender tissue. The light (the infrared light is invisible) emitted from the sensor is harmful to the eyes, so the user or even the service engineer should not stare at the light emitting components.

To dispose the device, the local law should be followed.

Attentions

Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.

The device should be kept out of the reach of children.

If the oximeter gets wet, please stop operating it.

When it is carried from cold environment to warm and humid environment, please do not use it immediately.

DO NOT operate the button on front panel with sharp materials.

High temperature or high pressure steam disinfection to the oximeter is not permitted. Refer to related chapter for instructions of cleaning and disinfection.

1 OVERVIEW
1.1 Appearance

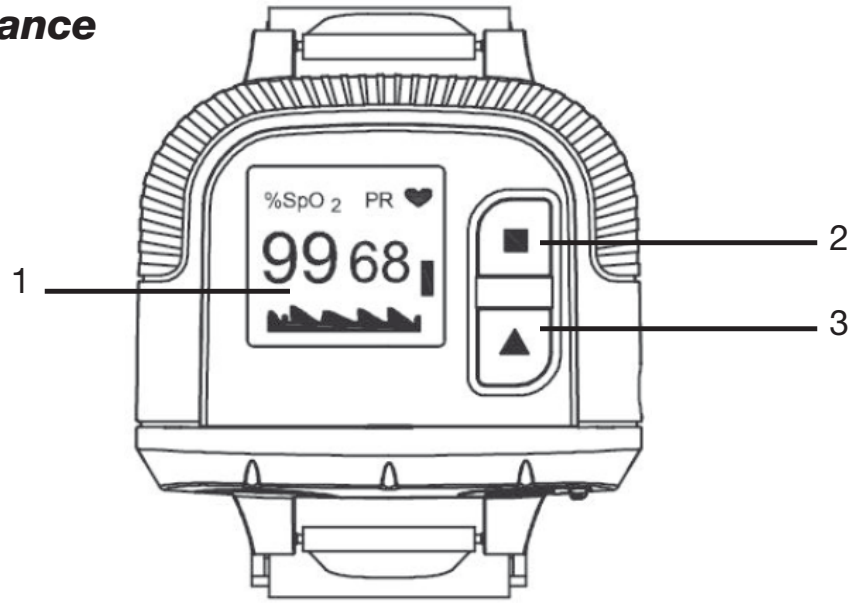

Figure 1 Front View

1. LCD screen
2. Set Key "■": shift display modes, confirm the operation etc.
3. Scroll Key "▲": Short Press to move display cursor, modify parameter values etc.
   Long Press to choose display always on or not which will be effective during measurement.

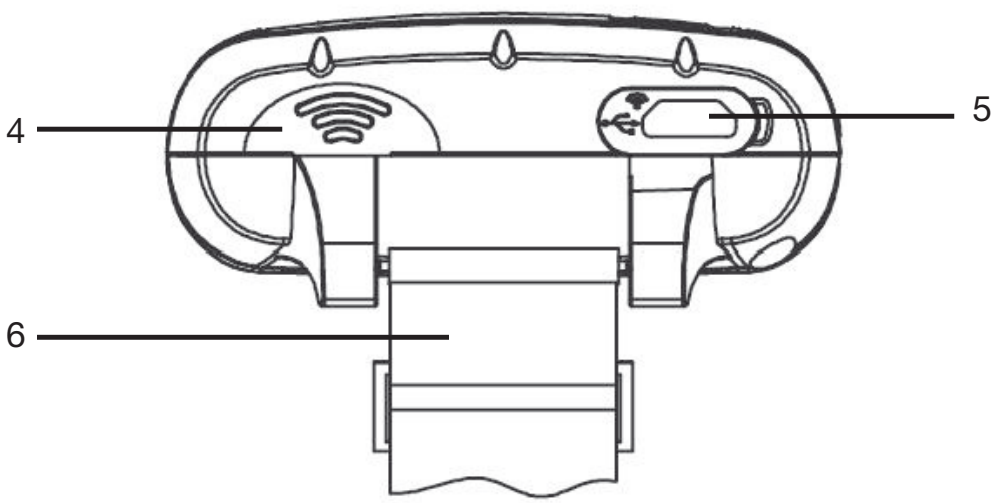

Figure 2 Frontal Side View

4. Buzzer
5. Data interface
6. Wristband

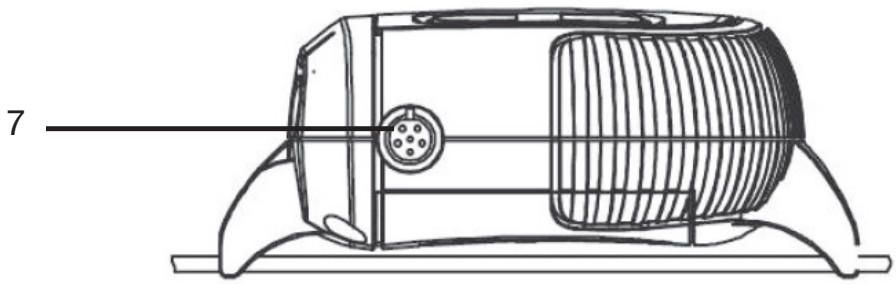

Figure 3 Right Side View

7. SpO_2 probe receptacle

1.2 Name and Model

Name: Wrist Oximeter
Model: 34340

1.3 Conformation

It comprises the main unit and SpO_2 probe.

1.4 Features

Wrist Oximeter can be used to measure and record the functional oxygen saturation (SpO_2) and pulse rate accurately. Simply put your finger into sensor, SpO_2 value and pulse rate value will be displayed on screen and stored in the device.

- It is light weight, small in size and easy to carry;
- Color OLED display;
- Perfusion index (PI) display is available;
- Automatic starts to measure SpO_2 and Pulse Rate (PR);
- Real-time clock display and setting;
- Over-limit alert by audible beep, visible display and vibration of the oximeter, the over limits can be adjustable;
- It is convenient for you to measure SpO_2 and pulse rate in long-term while sleeping or at other daily activity;
- Recording interval can be selected, up to 480 hours data memory;
- Applicable for longtime continuous measurement;
- PR trend curve and SpO_2 trend curve view
- Data storage and transmission to PC for view and analysis.

1.5 Intended Use

This Wrist Oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO_2). It is applicable for long-term measurement of adult's SpO_2 and pulse rate in home and clinics.

2 BATTERY INSTALLATION

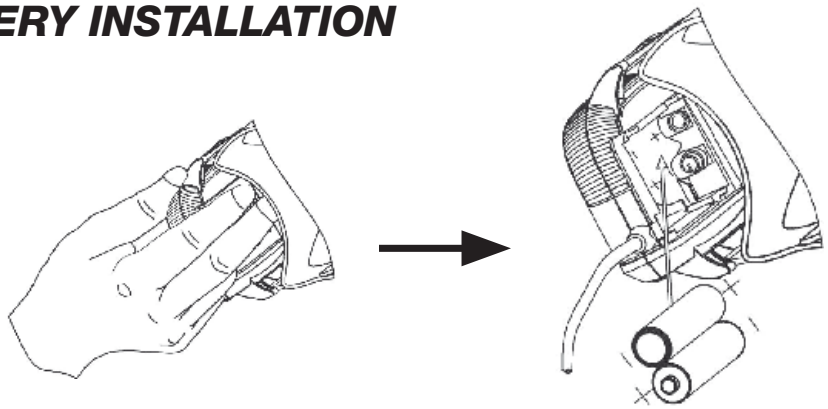

Figure 4 Battery Installation

1. Lift up the cloth covered on the battery cover. Then, use your index finger and middle finger to press against the battery cover. Meanwhile, slide it towards the side with SpO_2 probe (as shown in Figure 4).
2. Refer to Figure 4, insert two AAA size batteries into the battery compartment properly in the right direction.
3. Replace the cover.

Remark: After finishing battery installation, the oximeter will automatically power on and display software version number firstly.
Please take care when you insert the batteries, as the improper insertion may make the device not work.

3 OPERATION

NOTE for key button operation:
Long pressing: press a key down more than 1 second.
Short pressing: press a key down then let it go immediately (less than 1 second).
The following methods can activate the device while it is in standby status:

1. Short press Set Key "■" to activate the screen display.
2. Insert finger into the probe to activate the measurement and screen display automatically.
3. When USB data cable is connected between the device and PC, it will enter data uploading mode.

NOTE: If the calendar clock time has not been set, the device will enter the Time Settings screen while it powers up.
The device will enter standby status automatically if there is no key-press and no measuring signal in 20 seconds.
That is the only way to turn it off (i.e. at standby status).

3.1 Taking Measurement

1. Insert the SpO_2 probe connector into the SpO_2 probe receptacle on the device properly.

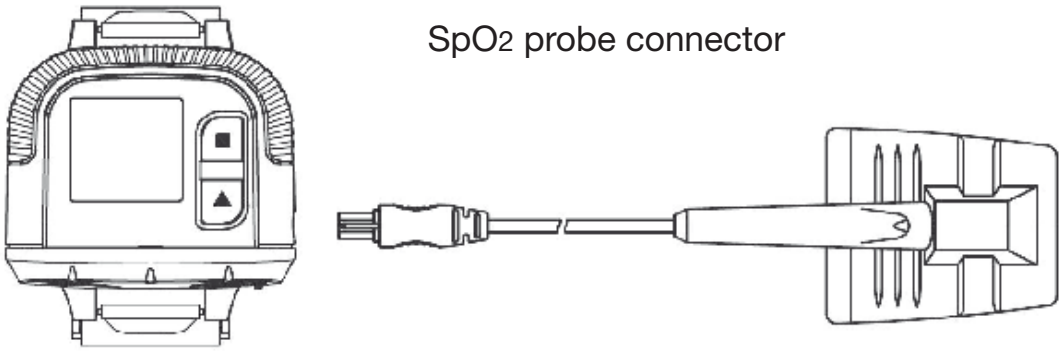

Figure 5 SpO_2 Probe Connection

2. Fix the oximeter on your left wrist (Figure 6);

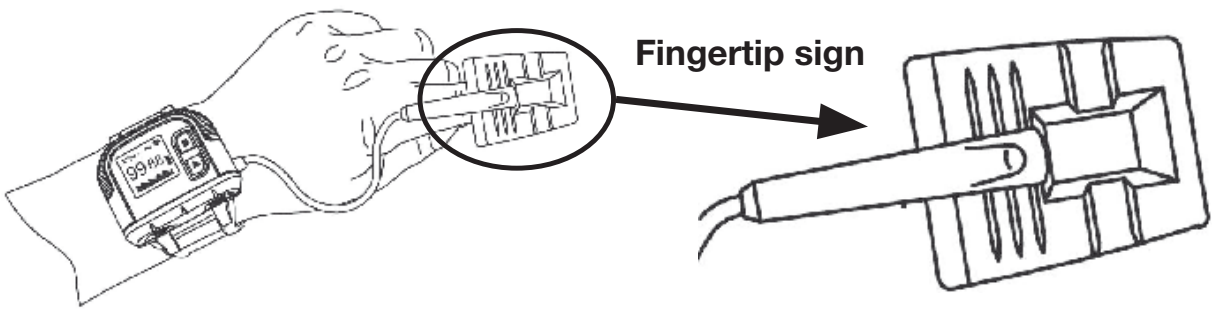

Figure 6 Placement Illustration

3. Then, hold the probe with its opening towards your index finger. The probe should be oriented in such a way that the sensor side with a finger tip icon is positioned on the top (Figure 6).
4. Next, insert your index finger into the probe until the fingernail tip rests against the stop at the end of the probe (Figure 7). Adjust the finger to be placed evenly on the middle base of the sensor (make sure the finger is in the right position). If the index finger cannot be positioned correctly, or is not available, other finger can be used.

Figure 7

Wrong Placement of the Probe:

Finger out Not deep enough

Figure 8

5. The oximeter will automatically start measurement in 2 seconds. Then the default screen will be displayed (Figure 9A). User can read the values and view the waveform from the display screen.

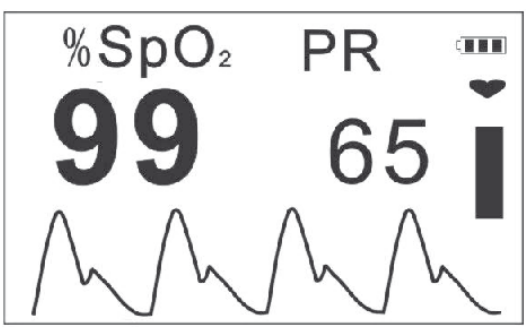

Figure 9A Default Screen Display

- **"SpO2"**: SpO2 label; "**99**": SpO2 value;
- **"PR"**: Pulse rate label; "**65**": Pulse rate value
- "♥": Pulse beat icon;
- "▭": Battery indicator;
- "▌": Pulsation bar-graph;
- The displayed waveform is plethysmogram.

Key Operations::

- Short press "■" key to switch display modes circularly, display screen will be switched among the three measure screens displays as shown in Figure 9A, Figure 9C and Figure 9D.

- Long press "▲" key: choose display always on or not which will be effective during measurement. If you choose display always on, the icon ("●") for "display always on" will appear on the screen as shown in Figure 9B.
- Short press "▲" key during measurement, the screen display direction can flip 180°.

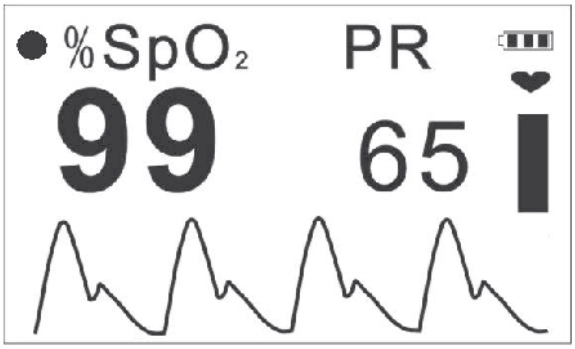

Figure 9B "Display Always On" is enabled

- "●": Icon for display always on, it indicates that the screen display is always on during measurement. If the icon is disappeared, it indicates that the screen display will be off after a period of displaying time during measurement for power saving.

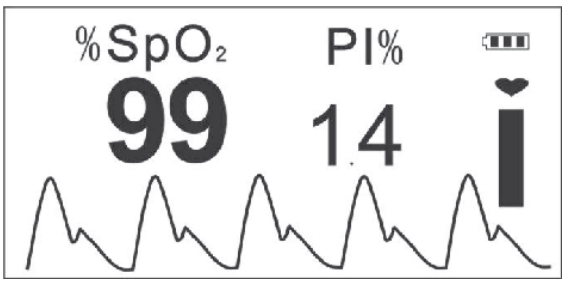

Figure 9C

- "**PI%**": Perfusion index label;

Figure 9D Real Time Clock

- "**12:30**": the current time.
- "**REC: 00:02:22**": the time period up to now in hh:mm:ss format for the current storing record since it was started. When finger is out, recording stops and here displays the time period for the last stored record. The time period will restart timing if a new piece of record is created once you insert finger into the probe to start another measurement.

Key Operations:

- Long press "■" key, menu screen will be displayed, refer to section 3.2 for details;

6. Prompt information

- During measurement, if you haven't inserted your finger into the probe or the probe is off, "Finger out " will be prompted on the screen.
- During measurement, if the probe is not connected to the oximeter, "No Signal!" will be prompted on the screen, as shown in Figure 10.

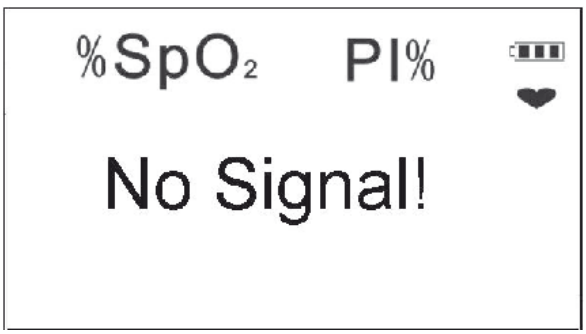

Figure 10 "No Signal" Indication

- During measurement, if the memory is full or the total number of the records reaches to 1024 pieces, the earliest record will be overwritten and the icon "" will appear on the screen for prompt, as shown in Figure 11.

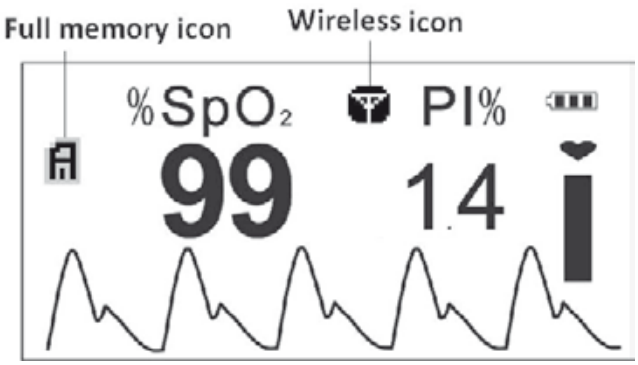

Figure 11 When Memory is Full

"": Wireless icon; If the wireless (bluetooth communication) function is enabled, the icon will be displayed on screen. Please refer to chapter 3.2.5 Wireless Setting.

Note: It is suggested that the data shall be uploaded to computer when memory is full, or the earliest record will be overwritten.

Working Mode

- The measurement will start automatically when the finger is inserted into the SpO_2 probe, so the data recording (SpO_2 and PR value) starts simultaneously as well. The display is as shown in Figure 9A.
- During measurement, if the icon "●" (for "display always on") is not shown on screen and no key button operation for 30 seconds, the screen display will be blank for power saving even when the measurement and data recording are still undergoing, but short pressing any key will activate the display for viewing the current measuring information again.
- If there is no signal and no key press to be detected (e.g. finger off) for 20 seconds, the device will be at standby status (i.e. blank screen and standby for measurement).
- When the device is at standby status, short pressing any key will activate the screen to default display screen, or once the finger is inserted in the SpO_2 probe, the measurement will start and screen display will be activated as well.

Note: During measurement, there is a green-dot flashing on the screen for indicating the measurement and data recording are undergoing when the display screen is blank, and if SpO_2 or/and PR values exceed the preset limit, it will activate the display and the value exceeded limit will flash.

3.2 Menu Operation

On display screen, long press "■", key menu screen will be displayed on the screen, as shown in Figure 12.

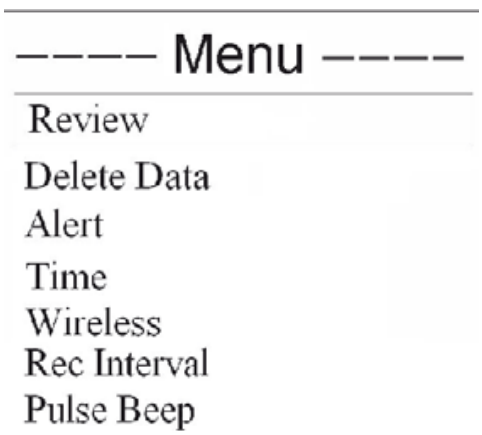

Figure 12 Menu Screen

- **Review:** view SpO_2 and pulse rate trend graph;
- **Delete Data:** delete all the records.
- **Alert:** set SpO_2 low limit, pulse rate high/low limit; and enable or disable the alert function.
- **Time:** set current date and time;
- **Wireless:** set or unset wireless function;
- **Rec Interval:** set the time interval to record SpO_2 and pulse rate data;
- **Pulse beep:** set the pulse beep, enable or disable it.

Operation Instructions:
- **Short press "▲" key**: shift cursor circularly;
- Short press **"■" key**: confirm the selection and enter into the corresponding screen;
- **Long press "■" key**: go back to the default screen display.

3.2.1 Trend Review

On menu screen, select "Review" and press "■" key to enter Trend Review screen, as shown in Figure 13.

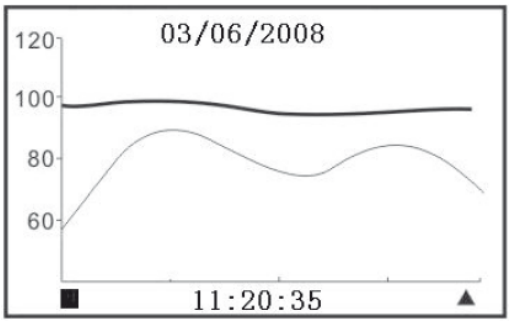

Figure 13 Trend Review Screen

- **"03/06/2008":** date of the measurement
- **"11:20:35":** start time of trend graph displayed on this screen;
- **"■▲":** Page scroll (backward/forward) button;
- **Curves in the middle area:**
  Green curve: indicate pulse rate trend curve;
  Orange curve: indicate SpO_2 trend curve;

Operation Instructions:
- Short press "▲" key: Page scroll forward;
- Short press "■" key: Page scroll backward;
- Long press "■" key: go back to the menu screen;

Note: when the display screen is menu screen or its submenu screen, the measurement will be interrupted.

3.2.2 Delete Data

On menu screen, select “Delete Data” and press “■” key to enter into Deletion Confirmation screen. Then, select “Yes” with “▲” key (short time press), after short pressing “■” key, all the records will be deleted.

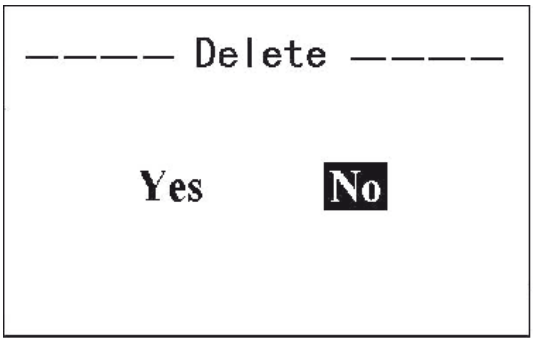

Figure 14 Delete Records

3.2.3 Over-limit Alert Settings

On menu screen, select “Alert” and press “■” key to enter Alert Limit Settings screen, as shown in Figure 15.

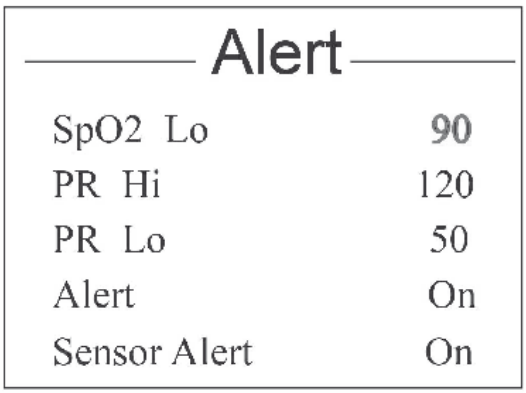

Figure 15 Over-limit Alert Settings

- **SpO2 Lo**: set SpO2 low limit; Setting range:85%~100%, default setting: 85%;
- **PR Lo:** set pulse rate low limit; Setting range:25bpm~99bpm, default setting: 50bpm;
- **PR Hi:** set pulse rate high limit; Setting range: 100bpm~250bpm, default setting: 120bpm;
- **Alert:** enable/disable the function of over-limit alert by audible beeping, visual display and vibration of the oximeter.

If select “ON”, when SpO_2 value or/and PR value exceeds its/their preset limits during measurement, the oximeter will beep and vibrate, and the numerical value exceeded limit will flash.

- Sensor alert: enable/disable the alert function. The factory default is “OFF”. If select “ON”, when probe off and/or finger out, the oximeter will beep and vibrate, then pressing any key will mute it and stop vibrating.

Operation Instructions:

- **Short press** “▲” shift cursor circularly;
- **Short press** “■” active the option;
- **Short press** “▲” **key:** increase numerical value one time;
- **Long press** “▲” **key:** increase numerical values continuously;
- **Short press** “■” **key:** confirm the selection;
- **Long press** “■” **key:** go back to the menu screen;

3.2.4 Time Settings

On menu screen, select “Time” and press “■” key to enter Time Settings screen, as shown in Figure 16.

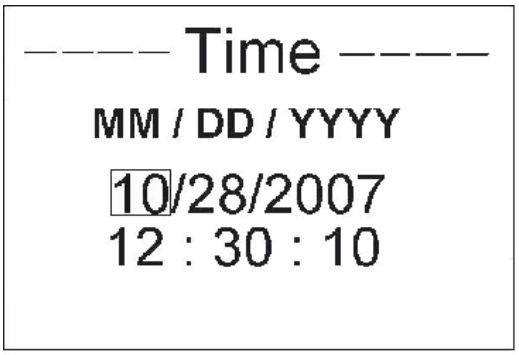

Figure 16 Date and Time Settings

- **Date format:** MM/DD/YYYY;
- **Time format:** hh:mm:ss;

Operation Instructions:

- **Short press** “▲” **key:** shift cursor circularly;
- **Short press** “■” **key:** active the option;
- **Short press** “▲” **key:** increase numerical value one time;
- **Long press** “▲” **key:** increase numerical value continuously;
- **Short press** “■” **key:** confirm the modification;
- **Long press** “■” **key:** go back to the menu screen;

3.2.5 Wireless Setting (Optional)

On menu screen, select “Wireless” and press “■” key to enter Wireless Setting screen, as shown in Figure 17.

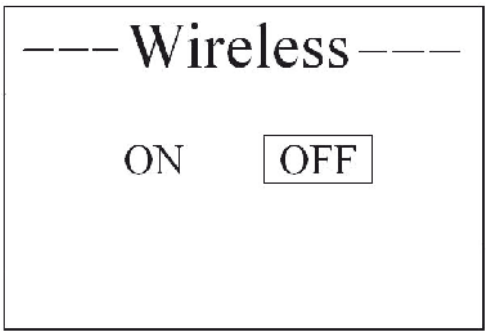

Figure 17 Wireless Setting Screen

Select “ON” or “OFF” with “▲” (key (short press), then short press “■” key to confirm the selection.

If you select “ON”, bluetooth communication will be enabled and the wireless icon displays on the screen.

Meanwhile the oximeter can communicate with the bluetooth enabled host device such as a smart phone which is running specific application software (APP) to receive the measured data (SpO_2, PR values and plethysmogram etc.). Please refer to the user manual of relative application software.

NOTE: Only the bluetooth protocol version 4.0 or later is supported.

3.2.6 Record Interval Settings

On menu screen, select “Rec Interval” and press “■” key to enter Record Interval Setting screen, as shown in Figure 18.

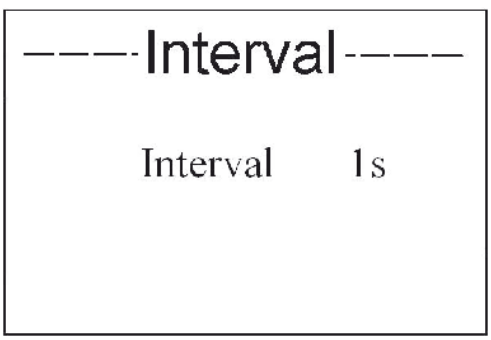

Figure 18 Record Interval Setting

Operation Instructions:

- **Short press** "■" **key:** active the option;
- **Short press** "▲" **key:** select record interval; three options: "1s", "4s" and "8s;
- **Short press** "■" **key:** confirm the selection;
- **Long press** "■" **key:** go back to the menu screen;

Note: The length of data record is constrained to at least 30 seconds, and the maximal length for one record is also limited to 60 hours (for 1 second interval), 240 hours (for 4 second interval) or 480 hours (for 8 second interval) respectively.

3.2.7 Pulse Beep Settings

On menu screen, select "Pulse beep" and press "■" key to enter Pulse Beep Setting screen, as shown in Figure 19.

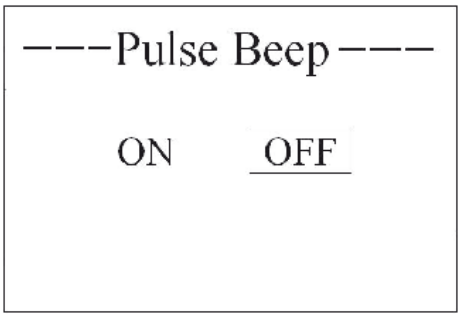

Figure 19 Pulse beep settings

The factory default is "OFF"; The latest setting status is that of you start the oximeter next time.

3.3 Upload Data

Before uploading the data to PC, please quit from the menu screen if you are doing the setup or trend view operation.

Before uploading, connect the USB data cable between the oximeter and PC.

- Do the following operations by the instruction in "Oximeter Data Manager User Manual", then the data uploading will be activated.
- Copy the data from the oximeter to PC (or other host device) as the oximeter will be mapped as a removable disk when it is connected to PC by USB data cable.

3.4 Low Battery Indication

If "▮" appears on the screen, it indicates that battery power is not enough, please change batteries. If you keep on using it, after a while the batteries are exhausted and the oximeter will be off

4 ADDITIONAL ADVICE FOR OPERATION

- The finger should be put properly and correctly.
- Avoid shaking finger as possible as you can during measurement;
- Do not put wet finger directly into sensor.
- Avoid placing the device on the same limb which is wrapped with a cuff for blood pressure measurement or during venous infusion.
- Do not let anything block the emitting light from device.
- Electrosurgical device interference may affect the measuring accuracy.
- Using enamel or other makeup on the nail may affect the measuring accuracy.
- If the first reading appears with poor waveform (irregular or not smooth), then the reading is unlikely true, the more stable value is expected by waiting for a while, or a restart is needed when necessary.

5 TECHNICAL SPECIFICATIONS

A. Display mode: Color OLED Display
B. Power supply requirement:
2 x LR03 (AAA) alkaline batteries or Ni-MH rechargeable batteries
Supply voltage: 3.0 VDC
Continues working time (display is off): >12hours
C. Operating current: ≤50mA
D. SpO_2 Parameter Specifications
Transducer: dual-wavelength LED
Measurement wavelength:
Red light: 663 nm, Infrared light: 890 nm.
Maximal optical output power: less than 1.5mW maximum average
Measuring range: 35~100%
Measuring accuracy:
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 9919.
E. Pulse Rate Parameter Specifications
Measuring range: 30bpm~240bpm
Accuracy: ±2bpm or ±2% (whichever is greater)
F. Preset limits:
SpO_2 Low limit setting: 85%
Pulse Rate limit setting range:
Upper limit: 120bpm
Lower limit: 50bpm

G. Update rate:
6 seconds moving average for SpO_2 and 8 beats average for Pulse Rate readings.
H. Perfusion Index Display
Range: 0.2%~20%
I. Performance under low perfusion condition
The accuracy of SpO_2 and PR measurement still meets the specification described above when the modulation amplitude is as low as 0.6%.
J. 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%.
K. Resistance to 50Hz /60Hz interference:
SpO_2 and PR are precise which have been tested by Fluke Biomedical Index 2 series SpO_2 simulator.
L. Dimensions: W 59mm×D 49mm×H 22mm
Net Weight: about 60g (not including batteries).
M. Classification
The type of protection against electric shock: Internally powered equipment.
The degree of protection against electric shock: Type BF applied part.
The degree of protection against harmful ingress of liquids: IPX2.
Electro-Magnetic Compatibility: Group I, Class B.

6 ACCESSORIES

- A data cable (optional)
- A Wristband
- A SpO_2 Probe
- Two batteries (AAA)
- A User Manual

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

7 REPAIR AND MAINTENANCE
7.1 Maintenance

The 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.

- Please change the batteries when the low-voltage indicator lightens.
- Please clean the surface of the device before using. Use cloth with alcohol to wipe the device first, and then let it dry in air or wipe it dry.
- Please take out the batteries if the oximeter will not be used for a long time.
- The recommended storage environment of the device: ambient temper-

ature: -20ºC ~60ºC, relative humidity 10%~95%, atmospheric pressure: 50kPa~107.4kPa

- 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 SpO_2 simulator, or it can be done by the local third party test house.

High-pressure sterilization cannot be used on the device.
Do not immerse the device in liquid.

7.2 Cleaning and Disinfecting Instruction

- Surface-clean sensor with a soft gauze by wetting with a solution such as 75% isopropyl alcohol, if low-level disinfection is required, use a 1:10 bleach solution. Then surface-clean with a damp cloth and dry with a piece of cloth.
- Clean the wristband with soapy water. Please detach the wristband from the oximeter firstly. (Refer to Appendix for detailed disassembly method).

Caution: Do not sterilize by irradiation steam, or ethylene oxide.
Do not use the sensor if it is damaged.

8 TROUBLESHOOTING

Trouble	Possible Reason	Solution
The SpO_2 and Pulse Rate display instable	1. The finger is not placed far enough inside.	1. Place the finger correctly inside and try again.
Can not turn on the device	1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3. The device is malfunctioning.	1. Change batteries. 2. Reinstall batteries. 3. Please contact the local service center.
Fragmental trend curve of SpO_2 and PR	1. Your finger is out of proper location in the probe. 2. Blood flow in the finger blocked. 3. Extreme movement.	1. Adjust your finger location properly. 2. Make sure there is no object may occlude the blood flow. 3. Extreme movement may cause invalid measuring result.

Trouble	Possible Reason	Solution
Always display "No Signal"	1. The probe is not connected to the oximeter properly. 2. The finger is not placed well. 3. The probe connector or the probe sensor is broken.	1. Connect the probe to the oximeter properly and try again. 2. Place the finger properly and try again. 3. Please contact the local service center.

9 APPENDIX

A - Common Knowledge for SpO_2 Measurement

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: $SpO_2 = HbO_2/ (HbO_2 + Hb)\times100\%$

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, hemoximeters report fractional oxygen saturation – a percentage of all measured hemoglobin, including dysfunctional hemoglobin, such as carboxyhemoglobin or metahemoglobin.

Clinical application of pulse oximeters: SpO_2 is an important physiological parameter to reflect the respiration and ventilation function, so SpO_2 measurement used in clinical becomes more popularly, such as monitoring the patient with serious respiratory disease, the patient under anesthesia during operation, premature 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 Factors affecting SpO_2 measuring 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.

4 Factors causing low SpO_2 Measuring value (pathology reason)

- Hypoxemia disease, functional lack of HbO_2.
- Pigmentation or abnormal oxyhemoglobin level.
- Abnormal oxyhemoglobin variation.
- Methemoglobin disease.
- Sulfhemoglobinemia or arterial occlusion exists near sensor.
- Obvious venous pulsations.
- Peripheral arterial pulsation becomes weak.
- Peripheral blood supply is not enough.

B - Wristband Installation and Disassembly

Introduction

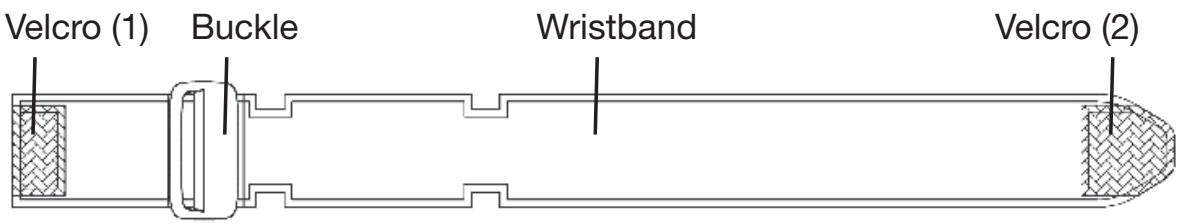

Fig. A

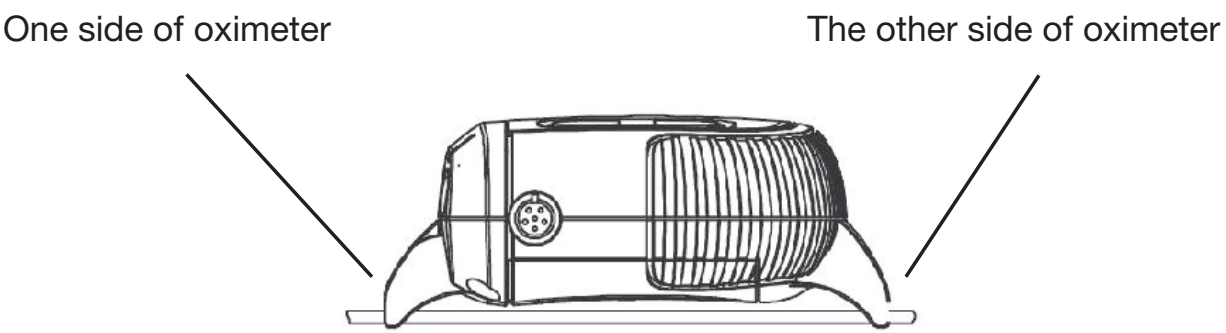

Fig. B Wrist oximeter

Installation Procedure

Step 1: Insert the wristband to the oximeter from one side to the other side, as shown in Fig. C.

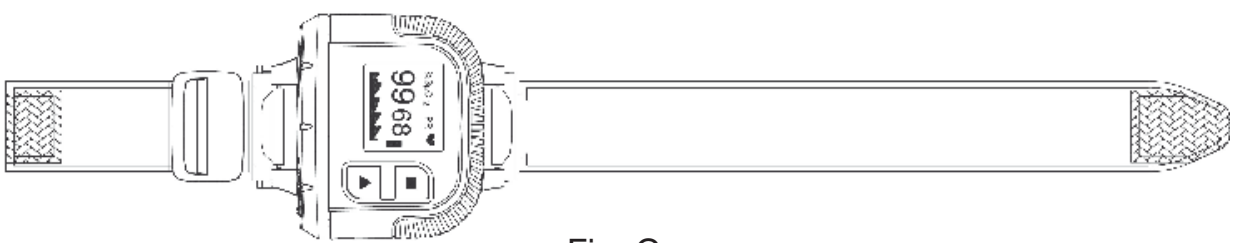

Fig. C

Step 2: Put the oximeter on the wrist, and stick the Velcro (1) to the inner side of wristband, press the wristband to make the Velcro (1) stick to the inner side of wristband firmly, as shown in Fig. D.

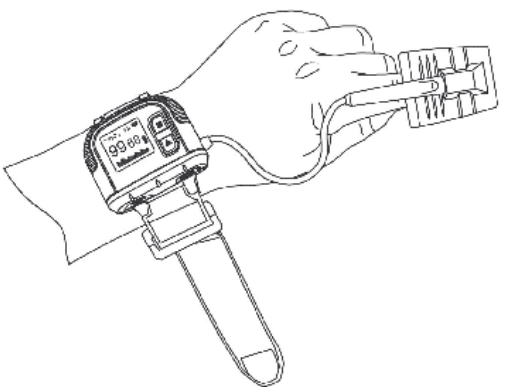

Fig. D

Step 3: Bring the wristband out from the buckle, and fold back the wristband, as shown in Fig. E. Then press the Velcro (2) to make it stick to the outer side of wristband firmly, as shown in Fig. F.

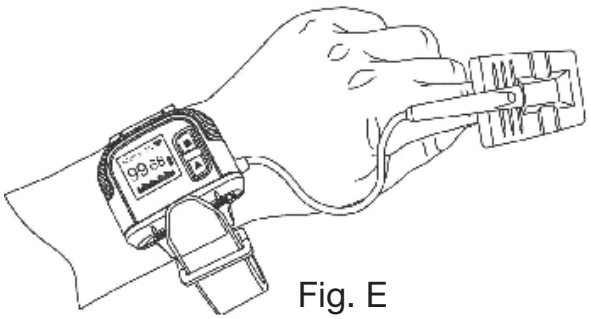

Fig. E

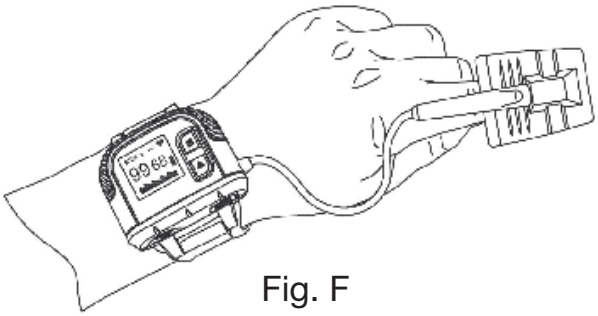

Fig. F

Disassembly: The process of wristband disassembly is similar to the installation method, but with reverse procedure.

Note: Please detach the wristband from the oximeter before cleaning the wristband.

C - DOWNLOAD APP SOFTWARE ONTO SMART PHONES

Terminal devices such as Android/iOS smart phones can be used to receive data from the Oximeter in real-time, store the received data, and also review the stored data. To use this function, download the corresponding APP software onto the smart phone device.

Please follow the procedure to download:

1. Scan the QR Code image in below Figure.
2. When successfully scanned, a web link for downloading the APP software will be displayed.
3. Open the web link to download the APP software.
4. Install the software when successfully downloaded.

Note: For smart phone or Pad with iOS system (such as iPhone, iPad), you can also search the APP software on Apple App Store, then enter “Shenzhen Creative” into the search box. (if you use an iPad to search, please select “iPhone only” as well for searching.) Once the search results are listed, select the App name “@health” with icon 

, then download it from App software.

Key of Symbols

Symbol	Description
%SpO2	Pulse Oxygen Saturation
PI%	Perfusion Index
PR	Pulse Rate
	Wireless icon
	USB interface
	Pulse rate icon
	Low battery voltage
	Icon for display always on
	Full memory icon
SN	Serial number
	Date of manufacture
	Manufacturer

Symbol	Description
	Type BF applied part
	Follow instructions for use
	WEEE disposal
REF	Product code
CE	Medical Device complies with Directive 93/42/EEC
LOT	Lot number
	Caution: read instructions (warnings) carefully
	Keep in a cool, dry place
	Keep away from sunlight

***Disposal**: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment. For further information on recycling points contact the local authorities, the local recycling center or the shop where the product was purchased. If the equipment is not disposed of correctly, fines or penalties may be applied in accordance with the national legislation and regulations.*

GIMA WARRANTY CONDITIONS

Congratulations for purchasing a GIMA product. This product meets high qualitative standards both as regards the material and the production.
The warranty is valid for 12 months from the date of supply of GIMA.
During the period of validity of the warranty, GIMA will repair and/or replace free of charge all the defected parts due to production reasons.
Labor costs and personnel traveling expenses and packaging not included.
All components subject to wear are not included in the warranty.
The repair or replacement performed during the warranty period shall not extend the warranty. The warranty is void in the following cases: repairs performed by unauthorized personnel or with non-original spare parts, defects caused by negligence or incorrect use. GIMA cannot be held responsible for malfunctioning on electronic devices or software due to outside agents such as: voltage changes, electro-magnetic fields, radio interferences, etc. The warranty is void if the above regulations are not observed and if the serial code (if available) has been removed, cancelled or changed.
The defected products must be returned only to the dealer the product was purchased from. Products sent to GIMA will be rejected.

INFORMATION ON ELECTROMAGNETIC COMPATIBILITY
Electromagnetic compatibility
Levels of compliance with the EN 60601-1-2:2015 standard

- ESD immunity 15kV in air and 8kV on contact (EN 61000-4-2)
- Burst immunity 2kV/100kHz (EN 61000-4-4)
- Surge immunity (EN 61000-4-5): 1kV common/2kV differential
- Magnetic field (EN 61000-4-8): 30A/m
- Immunity to rf currents in the range 150kHz-80MHz (EN 61000-4-6) 3V modulation 80% 1kHz 6V modulation 80% 1kHz for the following frequency ranges: 6.765 MHz ÷ 6.795 MHz 13.553 MHz ÷13.567 MHz 26.957 MHz ÷ 27.283 MHz 40.66 MHz ÷ 40.70 MHz
- CISPR emissions 11 class B
- EN 61000-3-2 class A Harmonic currents
- PST, DT, DC Flickers

Immunity to RF fields (EN 61000-4-3):		
Field (V/m)	Frequency	Modulation
3	80MHz - 2700MHz	1kHz AM 80%
27	380MHz - 390MHz	18Hz PM 50%
28	430MHz - 470MHz	18Hz PM 50%
9	704MHz - 787MHz	217Hz PM 50%
28	800MHz - 960MHz	18Hz PM 50%
28	1700MHz - 1990MHz	217Hz PM 50%
28	2400MHz - 2570MHz	217Hz PM 50%
9	5100MHz - 5800MHz	217Hz PM 50%

Warnings:
Even if it complies with EN 60601-1-2, the medical device may interfere with other devices in the vicinity. The device should not be used next to or stacked with other equipment. Install the device away from other equipment which radiates high frequencies (short waves, microwaves, electrosurgical units,

mobile phones).
The device is designed to operate in an electromagnetic environment in which RF radiated disturbances are under control. The customer or the operator can help prevent electromagnetic interference by ensuring a minimum distance between mobile and portable RF communication devices (transmitters) and the medical device, as recommended below, in relation to the maximum output power of the radio communication devices

Rated maximum output power of transmitter (W)	Distance (m) of separation according to the frequency of the transmitter		
	from 150kHz to 80MHz $d = 1.2 \sqrt{P}$	from 80MHz to 800MHz $d = 1.2 \sqrt{P}$	from 800MHz to 2.5GHz $d = 2.3 \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters whose rated maximum output power is not listed above, the recommended separation distance d in metres (m) can be calculated using the equation applicable to the transmitter frequency, where P is the rated maximum power transmitter output in Watts (W) according to the transmitter manufacturer.

Notes:
(1) The highest frequency range must be applied at 80 MHz and 800 MHz
(2) These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and by the reflection from structures, objects and people.