

Set Real : set the year

“Set Month”: set the month
“Set Day”: set the day
“Set Hour”: set the hour
“Set Minute”: set the minute
Adjustable range for year: 2015 ~ 2045, month: 1 ~ 12, day: 1 ~ 30 (when there are 31 days in a month, it is 1 ~ 31), hour: 1 ~ 23, minute: 1 ~ 59.
After setting, press the “menu button” to exit clock menu, return to main menu.
5.5.4 System setting and other options introduction
Under main menu, press the “up button” or “down button” to select “System”, then press the “left button” or “right button” to enter the interface as shown in Figure 13.
Press the “up button” or “down button” to select the option to be adjusted, then press the “left button” or “right button” to change the value.
“Hard.Ver.”: hardware version
“Soft.Ver.”: software version
“ID”: user name
“Demo”: set the Demo mode, “on”: turn on the Demo mode, “off”: turn off the Demo mode.
“Sound Volume”: set the sound volume, adjustable range: 1 ~ 3
“Brightness”: set the screen brightness, adjustable range: 1 ~ 4
After setting, press the “menu button” to exit system setting menu, return to main menu.
5.5.5 Bluetooth setting (Bluetooth equipment)
Under main menu, press the “up button” or “down button” to select “Bluetooth”, then press the “left button” or “right button” to enter its selection interface as shown in Figure 14 and Figure 15 When the Bluetooth is “ON”, if no data is transmitted for some time, then the Bluetooth will be turned off automatically.
Under transmitting data by Bluetooth, the Bluetooth can not be turned off.



Figure 14. Bluetooth “ON” interface



Figure 15. Bluetooth “OFF” interface

5.5.6 Exit main menu
Under main menu, press the “menu button” to exit the main menu and return to the measurement interface.
5.6 Data upload
A. Wired transmission
Connect the device to the computer by the USB cable, upload the data after connecting the PC software. However, refer to “Software operating instruction” for details.
B. The PC software can be downloaded from our official website.
B. Bluetooth transmission (Bluetooth equipment)
Turn on the device Bluetooth and the PC software to upload data, refer to “Software operating instruction” for details.
5.7 Power off
Long press the “power on/off” button, until the device turns off.
When the device is in storing, it can’t be turned off.
6 Maintain, Transport and Storage
6.1 Cleaning and disinfection
The device must be turned off before cleaning, and it should not be immersed into liquid.
Please take out the internal battery before cleaning, do not immerse it into liquid.
Use 75% alcohol to wipe the device enclosure and the nail pad, nature dry or clean it with clean and soft cloth. Do not spray any liquid on the device directly, and avoid liquid penetrating into the device.
6.2 Maintenance
A. Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect patient’s safety and monitoring performance. It is recommended that the device should be inspected weekly at least. When there is obvious damage, stop using it.
B. Please clean and disinfect the device before/after using it according to the User Manual (6.1).
C. Please replace the batteries in time when low-battery appears.
D. Please take out the batteries if the device is not used for a long time.
E. The device need not to be calibrated during maintenance.
6.3 Transport and Storage
A. The packed device can be transported by ordinary conveyance or according to transport contract. During transportation, avoid strong shock, vibration and splashing with rain or snow, and it can not be transported mixed with toxic, harmful, corrosive material.
B. The packed device must be stored in room with no corrosive gases and good ventilation. Temperature: -40℃~+60℃; Relative humidity: ≤95%.

7 Troubleshooting

Trouble	Possible Reason	Solution
The values can not be displayed normally or stably.	1) The finger is not properly inserted.	1) Please insert the finger properly and measure again.
	2) The finger is shaking or the patient is moving.	2) Let the patient keep calm.
	3) The device is not used in environment required by the manual.	3) Please use the device in normal environment.
	4) The device works abnormally.	4) Please contact the after-sales.
The device can not be turned on	1) The battery is drained away or almost drained away.	1) Please change batteries.
	2) The battery is installed incorrectly.	2) Please Install the battery again.
	3) The device’s malfunction.	3) Please contact the local service center.
The display disappears suddenly.	1) The device enters into the energy saving mode.	1) Normal.
	2) Low battery.	2) Please change batteries.
	3) The device works abnormally.	3) Please contact the after-sales.
The data can not be stored.	1: The device is not operated according to the manual.	1: Please operate the device according to the manual.
	2: The device works abnormally.	2: Please contact the after-sales.

8 symbols

Symbols	Meaning	Symbols	Meaning
	Caution, consult accompanying documents		left button/prompt pause button
%SpO ₂	Pulse oxygen saturation (%)		Menu button
PRbpm	Pulse rate (bpm)		Right button/clock button
	Close the sound prompt		down button

	Pause the sound prompt		Up button/replay button
	Open the sound prompt		USB
	Close the pulse sound indication		Type BF applied part
	Open the pulse sound indication		Serial number
Finger Out	The finger is not inserted.	---	1. The finger clip falls off (no finger inserted) 2. Probe error 3.Signal inadequacy indicator
	The battery power is full		Two grid of the battery
	One grid of the battery		The lack of battery power.(Please change batteries in time for exact measuring)
	Alarm inhibit		Manufacturer
	Power on/off button		Manufacture Date
+	Battery anode		Battery cathode
	Temperature limitation		Atmospheric pressure limitation
	Humidity limitation		This way up
	Fragile, handle with care		Keep away from rain
IP22	It means this pulse oximeter is protected against harmful effects of dripping water when tilted at 15°		Recyclable
	Bluetooth: ON (Bluetooth equipment)		Recycling garbage WEEE (2012/19/EU)
REC	Recording		Use-by date
Sensor Off	The probe is disconnected.	Sensor Fault	Probe failure
P/N	Material code		Batch No.
EC REP	European Representative		This item is compliant with Directive 93/42/EEC of 14 June 1993 concerning medical devices; Including, at 21 march 2010, the amendments by Council Directive 2007/47/EC.

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

9 Specification

SpO ₂ [see note 1]	
Display range	0% ~ 100%
Measured range	0% ~ 100%
Accuracy [see note 2]	70%-100%: ±2%; 0%-69%: unspecified.
Resolution	1%
PR	
Display range	30 bpm ~ 250 bpm
Measured range	30 bpm ~ 250 bpm
Accuracy [see note 3]	±2 bpm during the pulse rate range of 30 bpm ~ 99 bpm and ±2% during the pulse rate range of 100 bpm ~ 250 bpm
Resolution	1 bpm
Accuracy under low perfusion [see note 4]	Low perfusion 0.4% SpO ₂ : ±4%; PR: ±2 bpm during the pulse rate range of 30 bpm ~ 99 bpm and ±2% during the pulse rate range of 100 bpm ~ 250 bpm.
Light interference	Under normal and ambient light conditions, the SpO ₂ deviation ≤ 1%
Pulse intensity	Continuous bar graph display, the higher display indicates the stronger pulse.
Upper and lower limit of measured values	
SpO ₂	0% ~ 100%
PR	0 bpm ~ 254 bpm
Optical sensor [see note 5]	
Red light	Wavelength: about 660 nm, optical output power: < 6.65 mW
Infrared light	Wavelength: about 905 nm, optical output power: < 6.75 mW
Memory	
Up to 99 group of data under auto mode, total duration does not exceed 72 hours.	
Up to 24-hour data under manual mode.	
Safety class	
Internally powered equipment, type BF applied part	
International Protection	
IP22	
Working voltage	
DC 2.6 V ~ 3.6 V	
Working current	
≤ 100 mA	
Power supply	
Dry battery (2AA)	
Operation time	
The device can continuously work for 20 hours when it was powered by two new batteries within the warranty period.	
Dimension and Weight	
Dimensions	
110(L) × 60(W) × 24(H) mm	
Weight	
About 120g (with Dry battery(2AA))	

Note 1: the claims of SpO₂ accuracy shall be supported by clinical study measurements taken over the full range. By artificial inducing, get the stable oxygen level to the range of 70 % to 100 % SpO₂, compare the SpO₂ values collected by the secondary standard pulse oximeter equipment and the

tested equipment at the same time, to form paired data, which are used for the accuracy analysis. There are 12 healthy volunteers (male: 6, female: 6; age: 18~50; skin color: black: 2, light: 8, white: 2) data in the clinical report.
Note 2: because pulse oximeter measurement measurements are statistically distributed, only about two-thirds of pulse oximeter equipment measurements can be expected to fall within ±Arms of the value measured by a CO-OXIMETER.
Note 3: Patient simulator has been used to verify the pulse rate accuracy, it is stated as the root-mean-square difference between the PR measurement value and the value set by simulator.
Note 4: percentage modulation of infrared signal as the indication of pulsating signal strength, patient simulator has been used to verify its accuracy under conditions of low perfusion. SpO₂ and PR values are different due to low signal conditions, compare them with the known SpO₂ and PR values of input signal.
Note 5: optical sensors as the light-emitting components, will affect other medical devices applied the wavelength range. The information may be useful for the clinicians who carry out the optical treatment.For example, photodynamic therapy operated by clinician.

Appendix

State	Prompt contact delay	Prompt signal generation delay
Low voltage prompt	1s	20ms
SpO ₂ prompt	330ms	20ms
Pulse rate prompt	330ms	20ms
Probe error prompt	16ms	20ms

EMC

This equipment is suitable for professional healthcare facility environments and home healthcare environments.

Warning:

- Don't near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the this equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Note:

- this equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
 - The basic performance: SpO₂ measured range: 70% ~ 100%, absolute error: ±2%; PR measured range: 30 bpm ~ 250 bpm, accuracy:±2 bpm during the pulse rate range of 30 bpm ~ 99 bpm and ±2% during the pulse rate range of 100 bpm ~ 250 bpm.
 - When the device is disturbed, the data measured may fluctuate, please measure repeatedly or in another environment to ensure its accuracy.
 - Other devices may affect this device even though they meet the requirements of CISPR.
- Bluetooth Specification
Working frequency: 2402 MHz ~ 2480 MHz
Modulation mode: GFSK
Transmitting power: 0 dBm, +4 dBm
Receiving sensitivity: -93 dBm

Product configuration:

Serial number	name	Cable length
1	SpO ₂ probe	1.5m
2	USB cable	1m

Table 1

Guidance and Declaration - Electromagnetic Emissions		
Emissions test	Compliance	
Radiated RF EMISSIONS CISPR 11	Group 1	
Radiated RF EMISSIONS CISPR 11	Class B	
Harmonic distortion IEC 61000-3-2	Not applicable	
Voltage fluctuations and flicker IEC 61000-3-3	Not applicable	

Table 2

Guidance and Declaration - Electromagnetic Immunity		
Immunity Test	IEC 60601 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	Not applicable
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable
Voltage dips and Voltage interruptions IEC 61000-4-11	0 % U _n , 0.5 cycle, A0° , 45° , 90° , 135° , 180° , 225° , 270° and 315° , 0 % U _n ; 1 cycle and 70 % U _n ; 25/30 cycles; Single phase: at 0° . 0 % U _n ; 250/300 cycle	Not applicable
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	3 V 0.15MHz - 80 MHz 6 V in ISM and amateur radio bands between 0.15MHz to 80 MHz 80µA/M at 1kHz	Not applicable
Radiated RF IEC61000-4-3	10V/m 80 MHz-2.7GHz 80µA/M at 1kHz	10V/m 80 MHz-2.7GHz 80µA/M at 1kHz

NOTE: U_n is the a.c.mains voltage prior to application of the test level

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity						
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	IEC 60601-1-2 Test level (V/m)	Compliance level (V/m)
	385	380 - 390	TETRA 400	Pulse modulation b) 18 Hz	27	27
	450	430 - 470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	28	28
	710	704 - 787	LTE Band 13,17	Pulse modulation b) 217 Hz	9	9
	745					
	780					
	810	800~960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	28	28
	870					
	930					
	1720	1700~1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	28	28
	1845					
	1970					
2450	2400~2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	28	28	28
5240	5100~5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	9	9	9
5500						
5785						



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

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies