Cod. 35100 OXY-50 Pulse Oximeter

User manual

This Manual is written and compiled in accordance with the council directive MDD93/42/EEC for medical devices and harmonized standards. In case of modifications and software upgrades, the information contained in this document is subject to change without notice.

The Manual describes, in accordance with the Pulse Oximeter's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.

Please read the User Manual carefully before using this product. The User Manual which describes the operating procedures should be followed strictly. Failure to follow the User Manual may cause measuring abnormality, equipment damage and human injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, human injury and equipment damage due to users' negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

Owing to the forthcoming renovation, the specific products you received may not be totally in accordance with the description of this User Manual. We would sincerely regret for that.

This product is medical device, which can be used repeatedly.

WARNING:

- **Uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the microcirculation barrier patients. It is recommended that the sensor should not be applied to the same finger for over 2 hours.**
- **For the special 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 is invisible) emitted from the device is harmful to the eyes, so the user and the maintenance man should not stare at the light.**
- **Testee can not use enamel or other makeup.**
- **Testee's fingernail can not be too long.**
- **Please refer to the correlative literature about the clinical restrictions and caution.**
- **This device is not intended for treatment.**

Contents

1. Safety

1.1. Instructions for safe operations

✧ 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 about cables and transducers. It is recommended that the device should be inspected once a week at least. When there is obvious damage, stop using the device.

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

✧ The oximeter cannot be used together with devices not specified in User's Manual. Only the accessory that appointed or recommendatory by manufacture can be used with this device.

✧ This product is calibrated before leaving factory.

1.2. Warning

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 measured by MRI and CT.

The person who is allergic to rubber can not use this device.

The disposal of scrap instrument and its accessories and packings (including battery, plastic bags, foams and paper boxes) should follow the local laws and regulations.

Please check the packing before use to make sure the device and accessories are totally in accordance with the packing list, or else the device may have the possibility of working abnormally.

Please choose the accessories and probe which are approved or manufactured by the manufacturer, or else it may damage the device.

The device can only be matched with the compatible probe.

Please don't measure this device with functional tester for the device's related information.

1.3. Attention

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

If the oximeter gets wet, please stop operating it.

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

DO NOT operate keys on front panel with sharp materials.

High temperature or high pressure steam disinfection of the oximeter is not permitted. Refer to User Manual in the relative chapter (7.1) for instructions of cleaning and disinfection.

Do not have the oximeter immerged in liquid. When it needs cleaning, please wipe its surface with medical alcohol by soft material. Do not spray any liquid on the device directly.

When cleaning the device with water, the temperature should be lower than 60 °C .

As to the fingers which are too thin or too cold, it would probably affect the normal measure of the patients' SpO_2 and pulse rate, please clip the thick finger such as thumb and middle finger deeply enough into the probe.

The pulse oximeter can be used to adult or infant. Whether the device is used to adult or infant, it depends on the probe selected.

🔔 The update period of data is less than 5 seconds, which is changeable according to different individual pulse rate.

🔔 Please read the measured value when the waveform on screen is equably and steady-going, This measured value is optimal value. And the waveform at the moment is the standard one.

🔔 If some abnormal conditions appear on the screen during test process, pull out the finger and reinsert to restore normal use.

🔔 The device has normal useful life for three years since the first electrified use.

🔔 This device has the function of alarming, users can check on this function according to chapter 6.1 as a reference.

🔔 The device has the function of limits alarming, when the measured data is beyond the highest or lowest limit, the device would start alarming automatically on the premise of the alarming function is on.

🔔 The device has the function of alarming, this function can either be paused, or closed (default setting) for good. This function could be turned on through menu operation if you need. Please check the chapter 6.1 as a reference.

🔔 The device may not work for all patients. If you are unable to achieve stable readings, discontinue use.

2. Overview

The pulse oxygen saturation is the percentage of HbO_2 in the total Hb in the blood, so-called the O_2 concentration in the blood. It is an important bio-parameter for the respiration. A number of diseases relating to respiratory system may cause the decrease of SpO_2 in the blood, furthermore, some other causes such as the malfunction of human body's self-adjustment, damages during surgery, and the injuries caused by some medical checkup would also lead to the difficulty of oxygen supply in human body, and the corresponding symptoms would appear as a consequence, such as vertigo, impotence, vomit etc. Serious symptoms might bring danger to human's life. Therefore, prompt information of patients' SpO_2 is of great help for the doctor to discover the potential danger, and is of great importance in the clinical medical field.

The Pulse Oximeter features in small volume, convenient operation and being portable. It is only necessary for patients to put one of his fingers into a probe for diagnosis, and a display screen will directly show the measured value of pulse oxygen saturation with the high veracity and repetition.

2.1. Features

A. Operation of the product is simple and convenient.

B. The product is small in volume, light in weight and convenient in carrying.

2.2. Major applications and scope of application

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

⚠ **The problem of overrating would emerge when the patient is suffering from toxicosis which caused by carbon monoxide, the device is not recommended to be used under this circumstance.**

2.3. Environment requirements

Storage Environment

a) Temperature: -40°C～+60°C

b) Relative humidity: 5%～95%

c) Atmospheric pressure: 500hPa～1060hPa

Operating Environment

a) Temperature: 10°C～40°C

b) Relative Humidity: 30%～75%

c) Atmospheric pressure: 700hPa～1060hPa

3. Principle

Principle of the Oximeter is as follows: An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO_2) in glow & near-infrared zones. Operation principle of the device is: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning & Recording Technology, so that two beams of different wavelength of lights can be focused onto human nail tip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on screen through treatment in electronic circuits and microprocessor.

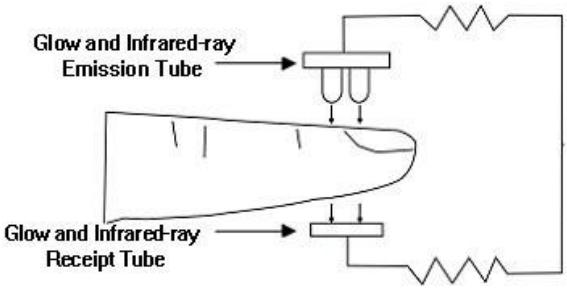


Figure 1.

4. Technical specifications

4.1. Main performance

A. SpO_2 value display

B. Pulse rate value display, bar graph display

C. Pulse waveform display

D. Low-voltage indication: low-voltage indicator appears before working abnormally which is due to low-voltage

E. Screen brightness can be changed

F. A pulse sound indication

G. With alarm function

H. With SpO_2 value and pulse rate value of storage, the stored data can be uploaded to computers

I. It can be connected with an external oximeter probe

J. Real-time data can be transmitted to computers

K. Review function

L. Clock function

4.2. Main Parameters

A. Measurement of SpO_2

Measuring range: 0%～100％

Accuracy:

When the SpO_2 measuring range is 70%～100％,the permission of absolute error is ±2％;

below 70% unspecified

B. Measurement of pulse rate

Measuring range: 30bpm～250bpm

Accuracy: ±2 bpm or ±2% (select larger)

C. Resolution

SpO_2: 1%, Pulse rate: 1bpm.

D. Measurement Performance in Weak Filling Condition:

SpO_2 and pulse rate can be shown correctly when pulse-filling ratio is 0.4%. SpO_2 error is ±4%, pulse rate error is ±2 bpm or ±2% (select larger).

E. Resistance to surrounding light:

The deviation between the value measured in the condition of man-made light or indoor natural light and that of darkroom is less than ±1%.

F. Power supply requirement: : 2.6 V DC ~ 3.6V DC.

G. Optical Sensor

Red light (wavelength is 660nm，6.65mW)

Infrared (wavelength is 880nm, 6.75mW)

H. Adjustable alarm range:

SpO_2：0%~100%

Pulse Rate: 0bpm~254bpm

5. Installation

5.1. View of the front panel

Figure 2. **Front View**

5.2. Underside View and Left View

Figure 3. **Underside View and Left View**

1、Probe jack : It is used to connect a SpO_2 sensor to measure the oxygen saturation and pulse rate.
2、USB port :It is used to connect a personal computer to export the trend data via a data line.

5.3. Battery and probe installation

A. Refer to Figure 4. and insert the two AA size batteries properly in the right direction.

Figure 4. **Batteries installation**

B. Replace the cover.
C. Inserting the SpO_2 probe of the pulse oximeter in the upper jack. (The probe is limited to be produced by our company; never replace it with the similar ones by other manufacturers).

⚠ **Please take care when you insert the batteries for the improper insertion may damage the device.**

⚠ **If the alarm function is on, the device will provide high-priority alarm signal when the**

battery is in low power status. Intermittent alarm will occur and the battery icon turns red in the state of flashing.

High priority indicating that immediate operator response is required.

5.3. Accessories

A. Dry battery(2AA)
B. A User Manual
C. A data line
D. A disk (PC software)
E. An adult-oximeter probe
An infant-oximeter probe

6. Operating Guide

6.1. Application method

A.

a) Put the suitable probe into the jack on the right side of the oximeter. (The probe is limited to be produced by our company; never replace it with the similar ones by other manufacturers).

b) Put the finger into the probe.

c) Press the "power on/off button" long , until the device turns on.
d) Do not shake the finger and keep the patient in a stable state during the process.
e) The data can be read directly from the screen on the measuring interface.

⚠ **Fingernails and the luminescent tube should be on the same side.**

⚠ **If the alarm function is on, the device will provide medium-priority alarm signal when probe or finger is out. Intermittent alarm will occur and the user interface presents "FINGER OUT".**
Medium priority indicating that prompt operator response is required.

B. Pause alarm:

a) Alarm including the alarm of measure data's going beyond the limits, the alarm of low-voltage, the alarm of probe or finger's out of position.
b) When alarm is on, press the "alarm pause button" can pause the alarm, it can renew alarm in about 60s, and if pressing the "alarm pause button" Again with in 60s, it can renew alarm .
c) If you want to turn off the alarm for good, you should enter the menu for operation.

C. Review Interface
a) On the measuring interface, press "up button" to enter the **Review Interface 1** directly, as shown in figure 5:

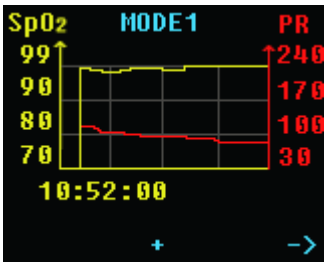


Figure 5. **Review Interface 1**

b) In review interface, press "menu button" to switch between **Review Interface 1** and **Review Interface 2**; press "Down button" to enter the review interface for next hour or last hour; In **Review Interface 1**, press "left button" or "right button" can move the trend graph for storage data, When the trend graph cannot be moved any more, the sign——"<-"or"->" shown under the LCD screen will disappear; in **Review Interface 2**, press "left button" or "right button" can move the arrow; Press "up button" to exit the review Interface.

c) In **Review Interface 1**, can observe the trend waveform composed by storage data, each screen can show storage data for 114 seconds, the yellow line shows the SpO_2 trend waveform, the red line shows the PR trend waveform, the time underside shows the starting time of dispalying the date in the screen, the middle "+" and "-" underside the screen means the operation direction of the "Down button". Press "right button", it will show "+" in the position, then press "Down button" to enter next hour; Press "left button", it will show "-" in the position, then press "Down button" to enter last hour.

d) The **Review Interface 2** shown based on **Review Interface 1**, the stored SpO_2 value and PR value in each second can be observed here, the underside date from left to right marks time, SpO_2 value, PR value. when the stored data exceeds the upper and lower limit setted by user, the relevant value will turn green.

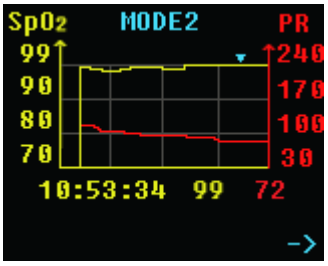


Figure 6. **Review Interface 2**

D. Clock interface

On the measuring interface, press the "right button" can enter the clock interface of figure 7. Press the "right button" again can return to the measuring interface.

Figure 7. **Clock interface**

E. Menu operations:

On the measuring interface, press the "menu button" can enter the menu of figure 8. Users can adjust the settings through the main menu, such as alarm, pulse sound indication, backlight, data storage, data transmission (with the use of data line), the specific method is as follows:

Figure 8. **Main Menu Interface**

a) Alarm setting

On the main menu interface, press the "up button" or "down button" to select "Alarm", then press the "left button" or “right button” to enter the alarm setting menu of figure 9:

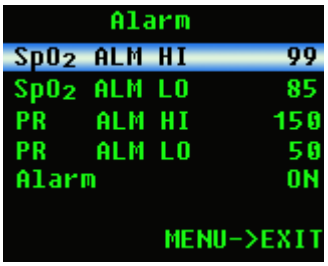


Figure 9. **Alarm Setting Menu**

a. The highest/lowest alarm limit setting

Press the "up button" or " down button "to choose the parameter to be adjusted, then press the "left button” or “right button" to change data. Each press of the "left button" or "right button", the data will raise or descend for one time accordingly.

⚠ **If the alarm function is on, the device will provide medium-priority alarm signal when the data of SpO_2 or pulse rate is beyond the limit. Intermittent alarm will occur and the measurement shows in yellow.**
Medium priority indicating that prompt operator response is required.

b. The alarm state setting

Press the" up button" or " down button" to select "Alarm", then choose the alarm state (on/off) by pressing the "left button" o r" right button", choose “on” to turn on the alarms, and choose “off” to turn off the alarms for good.

c. Exit the Alarm settings

Press the "menu button" to exit the Alarm Settings Menu.

b) Pulse sound indication setting

On the main menu interface ,press the "up button" or "down button" to select “Pulse Sound”, then Press the "left button" Or "right button" to choose to have the Pulse Sound (heart beat) "on" or "off ".

c) Backlight adjustment

On the main menu interface, press the "up button" or "down button" to select" Brightness", then press the "left button" or "right button" to change the number in order to adjust the brightness of screen.

d) Data storage setting

This device has the ability to store 24 hours worth of data. It can store the measured pulse rate and SpO_2 value accurately, transfer the data to the computer, display the data and print reports (with the included SpO_2 Software - Green Heart)

a. On the main menu interface, press the "up button" or "down button" to select "Record", then press the "left button" or "right button" again to enter the dialog box of figure 10 or finger 11: if it is not in recording state, will come into figure 10; if it is in recording state, will come into figure 11.

Figure 10.

b. In the status shown in Figure 10, press "left button" or "right button" can change the setting of the item, then press "menu button" to exit the status in Figure 10, and perform setting. YES for starting recording, NO for do not recording.

c. In the status shown in Figure 11, press "left button" or "right button" can change the setting, press "menu button" will exit the Figure 11, and perform setting. YES for stopping recording, NO for continue recording.

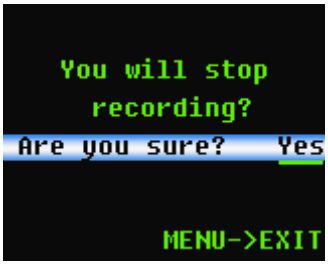


Figure 11.

d. If the data storage function is being turned on, when return to the measuring interface, a red "REC" sign and a flashing red dot would appear on screen, which means the device is in a state of storing.

e. In the state of storing, whatever interface the device is on (measuring interface, menu interface), the sign "Recording" would appear on the screen in 30 seconds, and then the screen will be automatically shut down. If pressing any button (power on/off excluded) at this moment, the sign "Recording" would appear on the screen, and then the screen will be automatically shut down again;

if pressing the "power on/off button", the device would return to the former interface.

f. If turning on the data storage function, the former data storage will be automatically removed.

g. In the state of data storing, after the screen is automatically shut down, the pulse sound indication would be off for saving power.

h. When the storage space is full, it displays “Memory is full” on the screen, and then shut down in a few seconds. But it will still display “Memory is full” by the next time you turn on the device on the purpose of warning the user, if press any button (power on/off excluded) again, it will enter the measuring interface.

e） Device ID

The user could modify device ID by software “SpO2 Assistant”.

f) Clock setting

On the main menu interface, press the "up button" or "down button" to select “Clock”, then enter the clock setting interface by Press the "left button" or "right button".

Figure 12. **Clock setting interface**

a. When entering the clock setting menu, the menu choice bar would be on the item of “set time”, and the state would always be “no” whenever it enters the clock setting menu on the purpose of avoiding unexpected changes of time due to improper operation. You can change the state by press the "left button" or "right button", choose “yes” to reset the time, choose “no” to forbid time resetting.

b. Press the "up button" or" down button" to select the parameter that you want to change, then adjust the data by press the "left button" or "right button".

c. Exit the clock setting menu directly by press the "menu button". If you have reset the time or date, when exiting the clock setting menu, firstly the renewed time and date would be displayed on the screen, then it returns to the main menu; if you didn’t reset the time and date , when exiting the clock setting menu, the device would return to the main menu directly.

g） Exit the main menu

On the main menu interface, press the "menu button" to exit the main menu.

E. PC software operation

Please connect the device with computer by the USB data line, then double click “SpO2 Assistant” icon to run the PC software. The functions such as uploading data and change device ID could be carried out by the software. Please refer to <SpO2 Assistant user manual> for details.

⚠ **If the users choose to turn on the synchronizing display function on computer, it would probably take several seconds for the data to appear on the computer screen. (If there is no data on the computer screen, unplug USB data line, then repeat step “E” again).**

6.2. Attention for operation

A. Please check the device before using, and confirm that it can work normally.

B. The finger should be in a proper position (see the attached illustration of figure 4 for reference), or else it may result in inaccurate measure.

C. The SpO_2 sensor and photoelectric receiving tube should be arranged in a way with the subject's arteriole in a position there between.

D. The SpO_2 sensor should not be used at a location or limb tied with arterial canal or blood pressure cuff or receiving intravenous injection.

E. Do not fix the SpO_2 sensor with adhesive or else it may result in venous pulsation and inaccurate measure of SpO_2 and pulse rate.

F. Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight and etc.

G. Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.

H. Testee can not use enamel or other makeup.

I. Please clean and disinfect the device after operating according to the User Manual (7.1).

6.3. Clinical restrictions

A. As the measure is taken on the basis of arteriole pulse, substantial pulsating blood flow of subject is required. For a subject with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO_2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.

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

C. The drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious error of SpO_2 measure.

D. As the SpO_2 value serves as a reference value for judgement of anemic anoxia and toxic anoxia, some patients with serious anemia may also report good SpO_2 measurement.

7. Maintain、transportation and storage

7.1. Cleaning and Disinfecting

Using medical alcohol to disinfect the device, nature dry or clean it with clean soft cloth.

7.2. Maintain

A. Please clean and disinfect the device before using according to the User Manual(7.1).

B. Please change the battery when the screen shows  .

C. Take out the battery if leave the equipment unused for long time.

D. The device needs to be calibrated once a year (or according to the calibrating program of hospital). It also can be performed at the state-appointed agent or just contact us for calibration.

7.3. Transportation and storage

A. The packed device can be transported by ordinary conveyance or according to transport contract. The device can not be transported mixed with toxic, harmful, corrosive material.

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

8. Troubleshooting

Trouble	Possible Reason	Solution
The SpO_2 and Pulse Rate can not be displayed normally	1. The finger is not properly positioned. 2. The patient's SpO_2 is too low to be detected.	1. Place the finger properly and try again. 2. Try again; Go to a hospital for a diagnosis if you are sure the device works all right.
The SpO_2 and Pulse Rate are not displayed stably	1. The finger is not placed inside deep enough. 2. The finger is shaking or the patient is moving.	1. Place the finger properly and try again. 2. Let the patient keep calm.
The device can not be turned on	1. The battery is drained away or almost drained away. 2.The battery is installed incorrectly. 3.The malfunction of the device.	1. Please change batteries. 2. Please Install the battery again. 3. Please contact the local service center.
The display is off suddenly	The battery is drained away or almost drained away .	Please change batteries.

9. Key of Symbols

Signal	Description
	Warning – See User Manual
%Spo_2	The pulse oxygen saturation(%)
PR	Pulse rate (bpm)
	Close the alarm sound indication
	Pause the alarm sound indication

	Open the alarm sound indication
	Close the pulse sound indication
	Open the pulse sound indication
	Fully charged battery
	Low battery
	Power on/off button
	Left button/Alarm pause button
	Menu button
	Right button
	Down button
	Up button
	USB
	Type BF
SN	Serial number
	1. The finger clip falls off (no finger inserted) 2. Probe error 3. Signal inadequacy indicator
IPX1	Ingress of liquids rank
	WEEE (2002/96/EC)

10. Function Specification

Information	Display Mode
The Pulse Oxygen Saturation（SpO_2）	2-digit digital OLED display
Pulse Rate（PR）	3-digit digital OLED display
Pulse Intensity (bar-graph)	bar-graph OLED display
SpO_2 Parameter Specification	
Measuring range	0%～100%, (the resolution is 1%).
Accuracy	70%～100%：±2% ,Below 70% unspecified.
Average value	Calculate the Average value in every 4 measure value. The deviation between average value and true value does not exceed 1%.
Pulse Parameter Specification	
Measuring range	30bpm～250bpm, (the resolution is 1bpm)
Accuracy	±2bpm or±2% (select larger)
Average pulse rate	Moving calculate the Average pulse rate every 4 cardio-beat's cycle. The deviation between average value and true value does not exceed 1%
Safety Type	Interior Battery，BFType
Pulse Intensity	
Range	Continuous bar-graph display, the higher display indicate the stronger pulse.
Battery Requirement	
Dry battery(2AA)	
Oximeter Probe	
Wavelength:660nm 880nm	
Dimensions and Weight	
Dimensions	110(L) × 60(W) × 23(H) mm

Weight	About 180g (with Dry battery(2AA))

Appendix 1

State	Alarm condition delay	Alarm signal generation delay
Low voltage alarm	1s	20ms
Spo_2 alarm	330ms	20ms
Pulse rate alarm	330ms	20ms
Probe error alarm	16ms	20ms

11. DISPOSAL

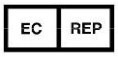
The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment. For further information on recycling points contact the local authorities, the local recycling center or the 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.

12. 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.

CE **0123**

 Contec Medical Systems Co., Ltd. - 066004 Qinhuangdao, Hebei Province - P.R.C.



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