GIMA
PROFESSIONAL MEDICAL PRODUCTS

LEO BLOOD PRESSURE MONITOR

Use and maintenance book

***ATTENTION:** Operators must read and understand this manual completely before using the product.*

REF CONTEC08A (GIMA 32902)

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Chapter1 Functions and Purpose

1.1Description of functions:

The Sphygmomanometer apply to measure the non-invasive blood pressure and SpO_2 of human (adult, children, neonate), uses three-user mode, each user can store 100 items records of measurement results at most. Each record includes detailed measuring time, systolic pressure, diastolic pressure, average pressure, pulse rate and record number, etc. With 2.8 inch color LCD screen, clear interface, the function of data review is complete. User can implement ON/OFF, manual measuring, system setup, parameters change and other operations with seven buttons which are located on the front panel of the device.

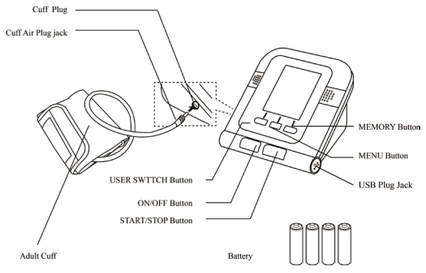
The Sphygmomanometer uses audible and visual prompt, when the battery power is low, the buzzer will intermittent buzzing and LCD screen displays "Low Power" to prompt user replace batteries. When the measurement data exceeds the set prompt limit, the font color of measurement results will change to red and the audible prompt will occur, user can open and close the prompt sound according to needs. With timing shutdown function, if there is no operation and SpO_2 measurement, the device will automatically turn off after 2 minutes. With USB interface, Users can send measurement results to PC. Refer to the help or explication of the related software for specific operation.

1.2Purpose:

In Europe,The Electronic Sphygmomanometer is applied to Blood Pressure (BP) measure and monitor for adult, pediatric, and neonatal. It has an optional SpO2 Measurement Function.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.In other areas,The Electronic Sphygmomanometer is intended to measure the systolic, diastolic and mean blood pressure as well as pulse rate via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm. It can be used on adult, pediatric and neonatal individuals.

Chapter2 Main Unit

The production is in the package. Open the package and confirm whether the production is whole.



Accessories:

Specification: limb circumference 22-32 cm (middle part of upper arm), please select suited cuff when measuring children or other limb circumference.

USB Data Line

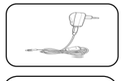
User Manual

Optional Accessories:

AC adapter

Input: voltage: AC 100 V~240 V frequency: 50 Hz/60 HZ Rated current: AC 150 mA

Output: DC5.0 V±0.2 V 1.0 A



SpO_2 probe: Integrated SpO_2 probe (This part is only suitable for European Union market)

A. SpO_2 measurement

Range:0 %~100 % Error: 70~100 %:±2 %;Below 70 %:unspecified Resolution: 1 %

Note: because SpO_2 probe measurements are statistically distributed, only about two-thirds of SpO_2 probe measurements can be expected to fall within ±Arms of the value measured by a CO-OXIMETER.

B. Pulse rate measurement

Range:30 bpm~250 bpm Error: ±2 bpm or ±2 %(select the larger) Resolution: 1bpm

C. Optical sensor: red light(wavelength: 660 nm, output power less than 6.65 mW) infrared light(wavelength: 880 nm, output power less than 6.75 mW). Optical sensors are light-emitting components that affect other medical devices that use this wavelength range. This information may be useful to clinicians who perform optical therapy.

D. Error 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 %; when measuring range is 30 bpm~100 bpm, pulse rate error is ±2 bpm; when measuring range is 100 bpm~250 bpm, pulse rate error is ±2 %.

Note:

◎The optional probe of the Sphygmomanometer is an integrated SpO_2 probe, the measuring part is integrated with the probe;

◎The service life of the integrated SpO_2 probe is three years.

Cuff:

Choose the right cuff based on the patient's upper arm circumference, there are several suitable cuffs(range of limb circumference, middle part of upper arm)

the range of limb circumference is 6-11 cm	the range of limb circumference is 10-19 cm
the range of limb circumference is 18-26 cm	the range of limb circumference is 22-30 cm
the range of limb circumference is 22-43 cm	the range of limb circumference is 32-43 cm

⚠ **Note** ⚠

- The cuff is a consumable. Calculate by measuring 6 times a day(3 times each morning and evening), the service life of the cuff is about 1 year.(using our experimental conditions)
- In order to correctly measure blood pressure, please replace the cuff in time.
- If the cuff leaks, please contact our company to buy a new one. The cuff purchased separately does not include the airway tube plug. When replacing, please do not throw the airway tube plug away, install it on the new cuff.

⚠ **Note** ⚠

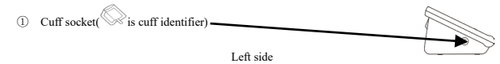
When the product and accessories described in this manual are about to exceed the period of use, they must be disposed according to relevant product handling specification. If you want to know more information, please contact our company or representative organization.

Chapter3 External Interfaces

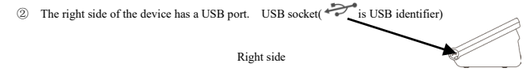
⚠ **Note** ⚠

When removing NIBP cuff, please take plug at the front of the windpipe to pull out.

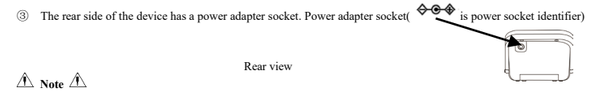
① Cuff socket(is cuff identifier)



② The right side of the device has a USB port. USB socket(is USB identifier)



③ The rear side of the device has a power adapter socket. Power adapter socket(is power socket identifier)

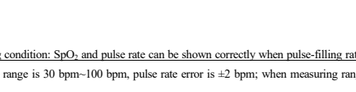


⚠ **Note** ⚠

All analog and digital equipment connected to this device must be certified to IEC standards(such as IEC60950: Information technology equipment-Safety and IEC60601-1: Medical electrical equipment-Safety), and all equipment should be connected to in accordance with the requirement of the valid version of the IEC60601-1 system standard. The person connecting the additional equipment to the signal input and output port is responsible for whether the system complies with the IEC60601-1 standard.

Chapter4 Battery/AC Adapter Installation

The product can use battery or AC adapter as power source.



4.1 Battery Installation

① Demount the battery cover in the direction of the arrow.

② Install "AA" batteries according to ⊕⊖ polarities.

③ Slide to close the battery cover.

Icon "▭": the batteries power will exhaust. Replace with four new batteries (the same sort) at the same time. Test while low power may cause data deviation and other problems.

Turn the unit off before replacing the batteries.

⚠ **Note** ⚠

When the battery reaches the end of its life, or if the battery is found to have odor, deformation, discoloration or distortion, stop using the battery and dispose of the used battery in accordance with local regulations, otherwise it will cause environmental pollution.

4.2 Usage of power adapter

1.Connect the sphygmomanometer and the power adapter. Insert the power adapter connector into the power adapter socket on the device

2.Please insert the power plug of the adapter into the AC 100 V~240 V socket.

⚠ **Note** ⚠

The device can be disconnected from the power supply network by unplugging the adapter plug.

When cut off the power supply, first cut off the connection of power socket and the regulated power supply, then cut off the connection of regulated power supply and the sphygmomanometer.

Please be sure to use dedicated medical grade power adapter.

⚠ **Note** ⚠

When regulated power supply and batteries are both used at the same time, the battery power will not be consumed.

Switch regulated power supply and battery as power supply when the device is off, otherwise, the device may shutdown due to power failure.

The device can be used normally after it is turned on ,without waiting for the device to be prepared.

Chapter5 Button Functions

All the operations to the Electronic Sphygmomanometer are through the buttons. The names of the buttons are above them. They are:

- 【**ON/OFF**】 ON/OFF button. Press this button to turn on/off the device.
- 【**START/STOP**】 Press it to inflate the cuff and start a blood pressure measurement. During measuring, press it to cancel the measurement and deflate the cuff.
- At all levels interface, the three buttons correspond respectively with the text prompts below the LCD screen, pressing any button will carry on the corresponding function, such as【UP】【MENU】【ENTER】【DOWN】 etc.

Chapter6 Setting the Date and Time

It is necessary to set date and time after power on.

The Electronic Sphygmomanometer can automatically stores measurement results with date and time.

If batteries power exhausts or removed, the time to stop.

At the moment, please reset date and time.

The Electronic Sphygmomanometer stores measure results of three users automatically, and up to 100 items for every user. If the date and time are set correctly, the date and time when measuring will be correct in the memory, otherwise it may not be correct.The results can be uploaded to PC via USB and processed with the PC software.

1、There are two modes of time setting:

(1) When using the Sphygmomanometer for the first time or after the Sphygmomanometer has been placed without power supply for a certain time(more than 3 minutes), after power on, there is a prompt of time error on the main interface, set date and time with 【UP】, 【DOWN】 and 【ENTER】 button.

(2) Press 【MENU】 button on the main interface to enter system menu, then enter 【SYSTEM TIME】 item, the current time will be displayed on the screen. Set date and time with 【UP】, 【DOWN】 and 【ENTER】 button.

2、After setting, select 【CONFIRM】 option and press 【ENTER】 button to confirm the setting value. If you do not want to change the time, select 【EXIT】 option and press 【ENTER】 button to return to the previous menu.

⚠ **Note** ⚠

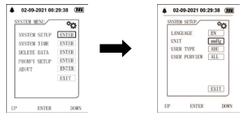
The range of year is from 2010 to 2099. When the year reaches 2099, pressing the 【UP】 button will return to 2010.

Chapter7 About Unit

There are two units: "mmHg" and "kPa".

The default is: "mmHg".

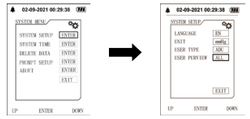
Enter the submenu 【SYSTEM SETUP】in the 【SYSTEM MENU】, then select【UNIT】option to switch units between "mmHg" and "kPa".



Chapter8 User Switch

The Electronic Sphygmomanometer stores the measure results of three users automatically, and up to 100 items for every user.

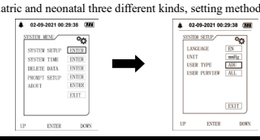
Press【USER】button in main interface to switch users. Or press【USER PURVIEW】item in 【SYSTEM SETUP】menu to switch users.



⚠ **Note** ⚠

When the【USER PURVIEW】is set to【ALL】, current user can be switched under main interface; when set to a certain user, it will not be able to switch under main interface.

User type can be set to adult, pediatric and neonatal three different kinds, setting method is as follows:



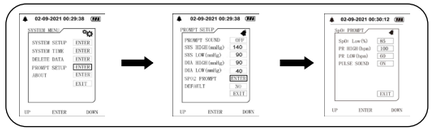
Chapter9 Over-limit Prompt Function

The Sphygmomanometer has two kinds of reminding methods:the technical parameter over-limit prompt and the physiological parameter over-limit prompt.

9.1 Physiological parameter over-limit prompt

The sphygmomanometer has the function of over-limit prompt, the user can press【MENU】button to enter system menu, select【PROMPT SETUP】option to enter its interface, then set the limit value of blood pressure. When the BP measurement result is higher than the high limit or lower than the low limit and the prompt is ON, the physiological prompt will occur; in【PROMPT SETUP】interface, select【SpO_2 PROMPT】option to enter its interface, when the SpO_2 measurement result is higher than the high limit or lower than the low limit and the prompt is ON, the physiological prompt will occur.

In the state of physiological prompt, press any button to cancel the prompt and it does not affect the next prompt; the prompt can be closed permanently with prompt switch of the prompt setup menu until the prompt switch be opened again.



9.2 Technical parameter over-limit prompt

When power is about to exhaust and prompt is ON, the prompt will occur. This prompt can not be canceled unless being closed or the power replaced.

⚠ Note ⚠Restore factory settings

If users want to restore the factory settings,select【DEFAULT】,then the data will be restored to the initial state.

Chapter10 The Usage Method of Sphygmomanometer

10.1 Accurate Measurement Way

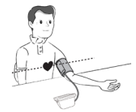
Measurement in quiet and relaxing state.

1.Adopt a comfortable sitting position, use back and arms to support the body.

2.Place your elbow on a table, the palm faces up and the body is relaxed.

3.The cuff is level with your heart.

4.Feet flat on the floor, and do not cross your legs.



⚠ **Advice** ⚠

Try to measure your blood pressure at the same time each day with the same arm and the same pose for consistency.

The high and low location of cuff will cause changes in measure results.

Do not touch the sphygmomanometer, cuff and windpipe during measure.

Measurements should be taken in a quiet place and the body relax.

Remain still 4~5 minutes before measurement.

Do not talk and movement during the measurement. Relax the body, do not let the muscle activity.

Wait 4~5 minutes between measurements.

Do not use precision instrument near the Sphygmomanometer.

⚠ **Warning** ⚠

When repeatedly measuring, the accurate blood pressure value may not be measured due to congestion in the arm. Please measure after the blood flow is smooth.

Repeated measurement for a long period of time, limbs rubbing with the cuff may be accompanied by purpura, ischemia and nerve damage. When measurement a patient, it is necessary to frequently check the color, warmth and sensitivity of the distal of the limb. Once any abnormalities are observed, place the cuff in another position or stop the blood pressure measurement immediately.

Please use the device at an environment of suitable temperature and humidity, otherwise it will cause measurement error.

Do not twist or wrap the airway tube. It can cause constant pressure in the cuff which can block blood flow and cause serious damage to the patient.

Do not use the cuff on the injured area, which will cause more serious damage to the area.

Do not use the cuff in the area where the treatment is being performed inside blood vessel or the arteriovenous connection. This may cause temporary blockage of blood flow and cause injury to the patient.

Do not use the cuff on the side of the mastectomy.

When using the cuff to pressurize, some of the body's functions may temporarily weaken. Do not use the measurement medical electrical equipment at the appropriate arm position.

Do not move during measurement, it will have a delayed effect on the patient's blood flow.

The device need to be placed for 2 hours from the minimum storage temperature to being ready for its intended use.

The device need to be placed for 4 hours from the highest storage temperature to being ready for its intended use.

⚠ Note ⚠

The following conditions may also cause changes in the blood pressure measurement value.

Take the measurement in one hour after meal or after drinking alcohol, coffee or after smoking, exercise, bathing;

Using incorrect posture such as standing or lying down, etc;

The patient speak or move his body during measurement;

When measuring, the patient is nervous, excited, emotional instability;

The room temperature rise or fall sharply, or the environment of measurement often changes;

Measuring in a moving vehicle;

The high and low location of cuff will cause changes in measurement results;

Continuous measurement for a long time.

10.2 Applying the Cuff

Both left and right arm can be measured.

Bare your arm or cloth close-fitting clothing during measurement.

Carry out the operation in a room with comfortable temperature.

When measuring, take the thick clothes off instead of rolling up the sleeves.

In order to measure accurately, pay attention to applying the cuff properly (left arm).

① Insert the arm cuff air plug in the cuff socket of sphygmomanometer.

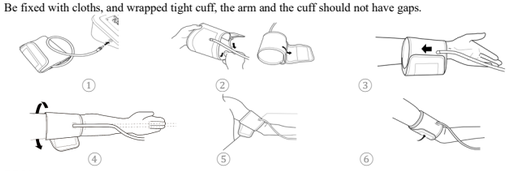
② Stretch cuff into a barrel for the arm can conformable enter into the barrel

③ Left arm penetrate through the cuff, the air tube of the cuff will pass the top of your palm.

④ Wrap the cuff to your upper arm. Make the air tube inside the forearm and aligned with your middle finger.

⑤ The bottom of the cuff should be approximately 2cm~3cm above your elbow.

⑥ Be fixed with cloths, and wrapped tight cuff, the arm and the cuff should not have gaps.



10.3 BP Measurement

The user can be set to three different types(adult, pediatric and newborn). Set it through the 【USER TYPE】 option in 【SYSTEM SETUP】 menu.

⚠ **Note** ⚠

When the patient is a newborn, please select the newborn mode and select the appropriate size of the cuff to measure, otherwise it may cause harm to the patient.

Errore. L'origine riferimento non è stata trovata. Press 【**START/STOP**】 button to start measurement.

During measurement, please keep correct pose and quiet state, do not move.

If you want to abort the measurement

Press【**START/STOP**】button, the device will stop inflating, and release the air from the cuff.

Errore. L'origine riferimento non è stata trovata. Confirm the Measurement Value

The measurement value can be stored automatically, using [memory function] (refer to Chapter11).

*Self-diagnosis and treatment using measured results may be dangerous. Follow the instructions of your physician.

⚠ Note ⚠

Wait at least 4-5 minutes between measurements

When repeatedly measuring, the accurate blood pressure value may not be measured due to congestion in the arm. Please measure after the blood flow is smooth.

- When some factors affect the measurement results in measurement process, error messages will appear on the screen, you can obviate the malfunction and restart a measurement.
- The minimum value of the patient's physiological signal is the minimum limit that the device can measure. The device may obtain inaccurate measurement results when it is operated below the minimum amplitude or minimum value of the patient's physiological signal.

Errore. L'origine riferimento non è stata trovata. In the state of the physiological parameter over-limit prompt is not triggered, press any button to carry on the corresponding button function; in audio prompt state, press any button (except 【ON/OFF】 button) to clear up the audio prompt.

④ Take off the cuff, press 【ON/OFF】 button to turn the device off.

Chapter11 Memory Function

The sphygmomanometer is designed to store the blood pressure, pulse rate values and the date and time when measured, which are up to 100 groups. If there have been stored 100 groups, the earliest results will be deleted when saving the 101 group of measurement results.

11.1 Review Memory Values

1. In the main interface (interface when starting-up), press【MEMORY】button to review the latest measured values in big-font with the serial number from 1 to 100.
2. Press【UP】/【DOWN】button to circularly switch the former measurement values.

*The right figure shows that there is no measurement result can be displayed.

3. Press【LIST】button to display the data list interface.
4. Press【TREND】 button to display trend interface.

End to display the measurement values:

Press【EXIT】button to return to the main interface or hold【ON/OFF】button to turn the device off.

11.2 Delete Memory Values

Users can delete all memory values of a user instead of separately delete one memory value.

1. Press【MENU】button to enter the system menu, select【DELETE DATA】option to enter its interface, select the user whose data to be deleted, after confirming again, all measurement results of the selected user will be deleted.
2. Finish Operation

Select 【EXIT】 to return to the previous menu, or hold【ON/OFF】button to turn the device off.

Chapter12 SpO_2 Measurement Function

(This chapter is only suitable for European Union market)

Precautions during SpO_2 Measurement:

⚠ **Note** ⚠

◎Make sure the nail covers the light. The probe cable should be on the backside of the hand. Improper probe placement or improper contact with the test site will influence the measurement.

◎SpO_2 value always displays in the fixed place.

◎The test site shall not use external coloring agent (such as nail polish, dyestuff or color skin care products, etc.), otherwise it will affect the measurement.

◎The fingers which are too cold or too thin may affect the measure accuracy, please insert the thicker finger such as thumb or middle finger deeply enough into the probe.

◎The SpO_2 probe is suitable for children and adults (not suitable for infants and newborns). The device may not applicable for all patients. If you are unable to achieve stable readings, stop using it.

◎Data averaging and signal processing will delay the SpO_2 displaying and data values transmitting. The update time of measurement data is less than 30 seconds, when signal attenuation, weak perfusion or other interference appears, it will result in time increasing of dynamic data averaging, which depends on the PR value.

◎The PLETH waveforms are not normalized, which is used as the indicator for signal incompleteness. So the accuracy of the measured values may decrease when the waveform does not tend to smooth and stable. When the waveform tends to smooth and stable, the reading is optimal value, and the waveform at the moment is the most standard one..

◎The temperature for the contact surface of the device with the body is less than 41℃, and this temperature value is measured by a temperature measuring device.

◎The device does not provide over-limit alarm function, so it is inapplicable for using in places where need such function.

◎The SpO_2 probe has been calibrated before leaving factory. It does not need to be calibrated during maintenance.

◎SpO_2 probe is calibrated to show functional oxygen saturation.

◎The SpO_2 probe and photoelectric receiving tube should be arranged in a way with the subject's arteriole in a position there between. Make sure the optical path is free from any optical obstacles like rubberized fabric, to avoid inaccurate measurement.

◎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.

◎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. SpO_2 and PR values are different due to low signal conditions, compare them with the known SpO_2 and PR values of input signal.

◎The claim for SpO_2 accuracy should be supported by clinical research measurements covering the entire spectrum. By artificially inducing to different stable oxygen levels, make it in the range of 70 % ～ 100 % of SpO_2. Use secondary standard SpO_2 measuring equipment for comparison to collect SpO_2 values together with the tested product, compose paired data groups for accuracy analysis.

◎Clinical report records data of 12 healthy volunteers, including 6 females and 6males. Volunteers' age ranges from 21 to 29. Skin color is distributed from dark to light, including 3 dark black skins, 2 medium black skins, 5 light skins, 2 white skins.

◎When using the device, please keep it away from the instruments that can generate strong electric or magnetic field. Use the device in an inappropriate environment may cause interference to the surrounding radio equipment or affect its working.

◎If necessary, please log on our company's official website to download the list of SpO_2 probes and extension cords that can be used in conjunction with this device.

⚠ **Warning** ⚠

◎Check if the cable of SpO_2 probe is in normal condition before measuring. After unplugging the SpO_2 probe cable from the socket, "SpO_2%" and "bmp" on the screen will disappear.

◎Do not use the SpO_2 probe once the package or the probe is found damaged. Instead, you shall return it to the vendor.

◎The supplied SpO_2 probe is only suitable for use with this device. This device can only use the SpO_2 probe described in this manual. It is the responsibility of the operator to check the compatibility of the device and the SpO_2 probe (and extension cable) before use. Incompatible accessories may result in device performance decreasing or cause injury to the patient.

◎SpO_2 probe is a medical product that can be used repeatedly.

◎The measured value may be normal seemingly for the testee who has anemia or dysfunctional hemoglobin (such as carboxyhaemoglobin (COHb), methaemoglobin (MetHb) and sulfhaemoglobin (SuHb)), but the testee may appear hypoxia, it is recommended to perform further assessment according the clinical situations and symptoms.

◎Pulse oxygen has only reference significance for anemia and toxic hypoxia, as some patients with severe anemia still show better pulse oxygen measurements.

◎Measurement accuracy can be affected by the interference of electrosurgical equipment.

◎Do not install the SpO_2 probe on an extremity with arterial catheter or receiving intravenous injection.

◎Do not perform SpO_2 measuring and NIBP measuring on same limb at one time, because obstruction of blood flow during NIBP measuring may adversely affect the reading of SpO_2 value.

◎Excessive movement (active or passive) of the subject or severe activity can affect the measurement accuracy.

◎Excessive ambient light may affect the measuring results, such as surgical light (especially xenon light sources), bilirubin lamp, fluorescent lamp, infrared heater and direct sunlight, etc. In order to prevent interference from ambient light, make sure to place the probe properly and cover the probe with opaque material.

◎The measured value may be inaccurate during defibrillation and in a short period after defibrillation, as the SpO_2 probe not have defibrillation-proof function.

◎The person who is allergic to silicone, PVC, TPU, TPE or ABS can not use this device.

◎For some special patients, it should be a more prudent inspecting in the measurement part. The probe can not be clipped on the edema and tender tissue.

◎Do not stare at the luminescent component directly when the device is turned on (infrared light is invisible), even if for maintenance purpose, or it may have bad influence to the eyes.

◎Uncomfortable or painful feeling may appear if using the SpO_2 probe ceaselessly, especially for the microcirculation barrier patients. It is recommended that the measurement should not be taken at the same position for over 2 hours. Continuous, long measurements may increase the risk of unwanted changes in the skin characteristics, such as exceptionally sensitive, reddish, blistering or oppressive necrosis, especially for neonates or the patients with perfusion disorder and change or immature skin form. It should be paid special attention to check the placement position of the probe according to the skin quality change, correct optical alignment and attachment method. Check the attachment position periodically and change it when the skin quality decreases. A more frequent check may be required due to the difference of patient's state.

◎Some models of functional tester or patient simulator can measure the accuracy of the device that reproduces the calibration curve, but it can not be used to evaluate the accuracy of this device.

◎Please refer to related medical literature for detailed clinical restrictions and contraindications,

◎This device is not used for treatment purpose.

◎Do not use the SpO_2 probe during MRI and CT scanning, as the induced current may cause burns.

◎When the device is ON, if power interrupt for more than 30s, the SpO_2 probe needs no operation after the power is restored, after the device is turned on, ensure that the SpO_2 probe can be used normally.

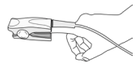
◎The probe can be used before/after sport, but not recommended to use during exercising.

◎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.

Chapter13 SpO_2 Measurement Method

(This chapter is only suitable for European Union market)

1) Attach the SpO_2 probe to the appropriate site of the patient finger as the following figure.



Place SpO_2 probe

2) Plug the connector of the SpO_2 probe cable into the USB socket in the lower right of the device. The main interface will switch to SpO_2 interface. This operation brings no affection to other functions.If no finger inserted into the probe or finger placement is improper, the SpO_2 interface displays finger-out prompt; when the probe cable is unplugged from the USB socket, the SpO_2 interface will display probe-off prompt, a few seconds later, it automatically return to the main interface.

3) The pulse sound can be set to on or off during measuring the SpO_2. The operation steps are: Press 【MENU】 to enter the system menu, select【POROMPT SETUP】to enter the setting interface, and select【SpO_2 PROMPT】to enter the SpO_2 prompt interface, in which you can set the pulse sound to on or off. Note: Please make sure the prompt switch is set to ON state before turning on the pulse sound. (set the prompt switch to on or off in the 【POROMPT SETUP】 interface)

⚠ **Note** ⚠

SpO_2 display range: 0 % ～ 100 %, PR display range: 30 bpm (beats/min) ～ 250 bpm (beats/min)

A SpO_2 probe fault may exist in the following situations, please stop using it and contact our after-sales service:

◎After reconnecting the probe cable with the USB port multiple times, the device main interface does not show any response;

◎When probe cable is connected normally and the finger properly placed in the probe, the SpO_2 interface still displays finger-out or probe-off prompt;

◎The SpO_2 interface prompts probe error;

Measurement Limitation

During operation, the accuracy of SpO_2 readings can be affected by:

- High-frequency electromagnetic interference such as interference from electrosurgical apparatus connected to the system.
- Intravenous dyestuff.
- Excessive patient movement.
- External light.
- Improper SpO_2 probe installation or incorrect contact position of the patient.
- Temperature of SpO_2 probe(optimal temperature range: 28°C ～ 40°C).
- Place the SpO_2 probe on an limb that has a blood pressure cuff, arterial catheter, or intravascular line.
- Concentrations of dysfunctional hemoglobin, such as carboxyhemoglobin(COHb) and methemoglobin(MetHb).
- SpO_2 is too low, Bad circular perfusion of the part being measured.
- Intravascular staining agents (such as indocyanine green or methylene blue), skin pigmentation.
- It is required to use SpO_2 probe which is provided by our company, contact with our sale department when necessary.

Chapter14 Error Message

Error message will be displayed in the screen if there is something wrong when measuring. The causes and solutions are shown as follows:

Error Message	Causes	Solutions
Self-test failure System failure	Function abnormal	Please contact us
Loose cuff	Cuff is not connected correctly.	Correctly connect cuff (refer to Chapter 10)
Air leakage	Cuff plug fall off	Make sure the cuff plug is securely inserted in the windpipe (refer to Chapter 10)
Air pressure error	Air pressure error	Refer to the troubleshooting
Weak signal	The pulse signal is too weak or the cuff is loose.	Correctly connect cuff (refer to Chapter 10)
Overpressure	Cuff is blocked or squeezed	Correctly connect cuff (refer to Chapter 10)
Excessive movement Over range Saturated signal	The signal extent is too big owing to the arm or body moving or other reasons when measuring	Keep arm, body still, measure again
Time out	It takes too much time	

Chapter15 Troubleshooting

Abnormal Phenomenons	Causes	Solutions
BP measurement values too high or too low.	Cuff is not connected correctly.	Correctly connect cuff (refer to Chapter 10)
	Talk or move arms when measuring	Keep quiet and restart a measurement
	The turnup clothing presses the arm	Take off the clothing which presses the arm, and restart a measurement
No pressure	Cuff leakage	Buy a new cuff
	The cuff windpipe is not correctly connected with cuff	Correctly connect
	Cuff is not inflated	Stop using the device and contact us
Cuff deflates in short time	Loose cuff	Correctly apply cuff
It can not carry on measurement when press the measurement button		Switch on the power once again and restart a measurement
Power off suddenly when inflating	No use for a long time, the power of batteries can be exhausted owing to the changed temperature	Replace all four batteries with new ones.
Hold the on/off button but can not start the device	Power of batteries can be exhausted	Replace all four batteries with new ones.
	The battery polarities is reversed	Check the battery installation for proper placement of the battery polarities.
Cuff inflation start before press the measurement button or never stop inflating when measuring		Pull out the cuff to deflate. Stop using the device and contact us.
Cuff never deflation		Pull out the cuff to deflate. Stop using the device and contact us.
Air pressure error	No deflation or deflation error or inflation without stop	Pull out the cuff to deflate. Stop using the device and contact us.
	Others	Keep arm, body still, measure again.
No press value displayed or the value unchanged or change erratically when cuff inflated		Pull out the cuff to deflate. Stop using the device and contact us.
Other phenomenon		Switch on the power once again and restart an operation. Replace the batteries. If no, please contact us.

Chapter16 Keys and Symbols

Your device may not contain all the following symbols.

Signal	Description	Signal	Description
	Caution: read instructions (warnings) carefully		Follow instructions for use
SIS	Systolic pressure	DIA	Diastolic pressure
INFO	Information	PR	Pulse rate (bpm)
IP22	It means this pulse oximeter is protected against harmful effects of dripping water when tilted at 15° .	CEM	Electromagnetic compatibility
ADU	Adult	P/N	Material code of manufacturer
	Type BF applied parts		Recyclable
	Open the Prompt sound indication		Close the Prompt sound indication
LOT	Lot number		Expiration date
	This way up		Fragile, handle with care
	Keep in a cool, dry place		Atmospheric pressure limit
	Temperature limit		Humidity limit
	Manufacturer / Manufacture Date	UDI	Unique device identifier
	Batteries Power		Pulse rate (bpm)
	1.No NIBP data to review 2.An indicator of signal inadequacy		1.No Pulse rate 2.An indicator of signal inadequacy
	WEEE disposal	CE	Medical Device compliant with Directive 93/42/EEC
SN	Serial number		Class II applied
EC REP	Authorized representative in the European community		Interface for connecting cuff
MR	MR Unsafe,can not be used in MRI		Socket for power adapter
	No SpO_2 Alarms		Artery indicator label
MD	Medical device		Imported by
	Keep away from sunlight	REF	Product code

Chapter17 Maintenance, Cleaning and Keeping

***Please do obey the precautions and correct operating methods in this user manual. Otherwise, we will not responsible for any fault.**

⚠ **Warning** ⚠

Remove the batteries before cleaning. The accessories and main unit must be separated for cleaning.

Maintenance is not allowed during device using.

Do not squeeze the rubber tube on the cuff.

⚠ **Caution** ⚠

- High pressure disinfection to the device and accessories is not allowed.
- Do not let water or cleaning agent flow into the socket to avoid device damage.
- Do not soak the device and accessories in liquid.
- If any damage or deterioration of the device and accessories is found, please do not u

Maintenance:

- Clean the device and accessories regularly. It is recommended to clean them every one month.
- Before cleaning the device, remove batteries and disconnect it from the AC power. The accessories and main unit must be separated for cleaning. Do not maintain or repair the device during use.
- When cleaning the device, dip a clean cloth in isopropyl alcohol (70%), wring it out fully, and wipe the main unit, cuff and cuff windpipe separately for about 3 minutes, then use the other clean cloth moistened with distilled water, wring it out fully and respectively wipe the main unit, cuff and cuff windpipe for about 2 minutes. Repeat above 5 times until there is no obvious residual cleaning agent. Avoid isopropyl alcohol or water entering the main unit during cleaning. After cleaning, place the product in a dry and ventilated place to dry.
- Visual inspection to make sure the product is thoroughly cleaned. If any residue exists, please repeat the entire process described above.
- The device should be inspected and calibrated periodically (or obey the requirements of the hospital). It is available to inspect in the state specified inspection institution or by professional personal, or you can contact our company.Long press "USER" button in main interface for 5s to enter the calibration interface.

⚠ **Advice** ⚠

- Do not use gasoline, volatile oil, diluent, etc. to wipe the device.
- Do not clean or wet the cuff.

Storage:

⚠ **Advice** ⚠

- Do not expose the device in direct sunlight for long time, otherwise the display screen maybe damaged.
- The basic performance and safety of the device are not affected by the dust or cotton wool in home environment, while the device shall not be placed where with high temperature, humidity or dusty.
- Aged cuff may result in inaccurate measurement, please replace the cuff periodically according to the user manual.
- To avoid device damage, keep the device out the reach of children and pets.
- Avoid the device close to extreme high temperature such as fireplace, otherwise the device performance may be affected.
- Do not store the device with chemical medicine or corrosive gas.
- Do not place the device where there is water.
- Do not place the device where with slope, vibration or impact
- Take the batteries out if the device is not to be used for three months or longer.

Chapter18 NIBP Specification

Name	Electronic Sphygmomanometer		
Display mode	2.8" color LCD Display		
The degree of protection against ingress of water	IP22		
Measurement method	Oscillometric method		
Working mode	Automatic		
Operation mode	Continuous operation		
Cuff pressure range	0-297 mmHg(0-39.6 kPa)		
Overpressure protection	adult mode	295±5 mmHg(39.33±0.67 kPa)	
	pediatric mode	240±5 mmHg(32±0.67 kPa)	
	neonatal mode	145±5 mmHg(19.33±0.67 kPa)	
Measurement Range	pressure	adult	SYS: 30~270 mmHg(4～36 kPa) DIA: 10~220 mmHg(1.3～29.3 kPa)
		pediatric	SYS: 30~235 mmHg(4～31.3 kPa) DIA: 10~195 mmHg(1.3～26 kPa)
		neonatal	SYS:30~135 mmHg(4～18 kPa) DIA: 10~100 mmHg(1.3～13.3 kPa)
	Pulse: 40~240 bpm		
Inflation	adult		160±5 mmHg(21.33±0.67 kPa)
	pediatric		120±5 mmHg(16±0.67 kPa)
	neonatal		70±5 mmHg(9.33±0.67 kPa)
Resolution	Pressure: 1mmHg(0.1 kPa)		
	Pulse: 1 bpm		
Accuracy	Static pressure: ±3 mmHg(±0.4 kPa)		
	Pulse: ±5 bpm or ±5% select larger		
Error	The BP value measured by the device is equivalent with the measurement value of Stethoscopy, perform clinical verification in accordance with the requirements in ISO 81060-2: 2013, whose error meets the followings: Maximum mean error: ±5 mmHg Maximum Standard deviation: 8 mmHg		
Operating temperature/ humidity	+5 ℃~40 ℃ 15 %RH~85 %RH(Non-condensing)		
Transport	Transport by general vehicle or according to the order contract, avoid pounded, shake and splash by rain and snow in transportation.		
Storage	Temperature: -20 ℃~+55 ℃; Relative humidity: ≤95 %; No corrosive gas and drafty.		
Atmospheric pressure	700 hPa~1060 hPa		
Power supply	4 "AA" alkaline batteries, AC Adapter(AC, 100 V-240 V, optional)		
Rated current	≤600 mA		
Battery life	When the temperature is 23 ℃, limb circumference is 270 mm, the measured blood pressure is normal, 4 "AA" alkaline batteries cab be used about 300 times.		
Dimensions	130(L)*110(W)*80(H) mm		
Unit Weight	300 gram(without batteries)		
Safety classification	Class II equipment (power supplied by power adapter)/Internally powered equipment (power supplied by batteries) Type BF applied part		
Service life	The service life of the device is five years or 10000 times of BP measurement.		
Date of manufacturer	See the label		
Accessories	Standard Configure: **Adult Cuff**: limb circumference 22-32 cm (upper arm center) **four "AA" alkaline batteries,User Manual** Optional Configure: **four "AA" alkaline batteries** **AC Adapter** Input: voltage: AC 100 V~240 V frequency: 50 Hz/60 H Rated current: AC 150 mA Output: DC 5.0 V±0.2 V 1.0 A **Power Adapter cable Cuff** the range of limb circumference is 6-11 cm (middle part of upper arm) the range of limb circumference is 10-19 cm (middle part of upper arm) the range of limb circumference is 18-26 cm (middle part of upper arm) the range of limb circumference is 22-30 cm (middle part of upper arm) the range of limb circumference is 22-43 cm (middle part of upper arm) the range of limb circumference is 32-43 cm (middle part of upper arm)		

***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

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