GIMA
PROFESSIONAL MEDICAL PRODUCTS

DIGITAL BLOOD PRESSURE MONITOR

Use and maintenance book

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

REF **CONTEC08E (GIMA 49880)**

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Foreword

Please read the User Manual carefully before using this product. The User Manual which describes the operating procedures should be followed strictly. This manual detailed introduce the steps must be noted when using the product, operation which may result in abnormal, the risk may cause personal injury and product damage and other contents, refer to the chapters for details. Any anomalies or personal injury and device damage arising from use, maintain, store do not follow requirements of the User Manual, Our company is not responsible for the safety, reliability and performance guarantees! The manufacturer's warranty service does not cover such faults!

Our company has a factory record and user profile for each device, users enjoy free maintenance services for one year from the date of purchase. In order to facilitate us to provide you with a comprehensive and efficient maintenance service, please be sure to return the warranty card when you need repair service.

⚠**Note: Please read the User Manual carefully before using this product.**

Described in this User Manual is in accordance with practical situation of the product. In case of modifications and software upgrades, the information contained in this document is subject to change without notice.

The warning items

Before using this product, you should consider the safety and efficacy of the following described:

- Described each measurement results combined with clinical symptoms by qualified doctors.
- The reliability and operation of using this product whether meets the operation of this manual relate to the maintenance instructions.
- The intended operator of this product may be the patient.
- Do not perform maintenance and service while the device is in use.

⚠**Warning: Replace accessories which not provided by our company may lead to the occurrence of errors. Replace adapters, cuffs at will may result in wrong measurement results. Without our company or other approved maintenance organizations trained service personnel should not try to maintain the product.**

Responsibility of operator

- The operator must carefully read the User Manual before use this product, and strictly follow the operating procedure of the User Manual.
- Fully consider the security requirements during product design, but the operator should not ignore the observation for the patient and the state of machine.
- The operator has the responsibility to provide the use condition of the product to our company.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Responsibility for our company

- Our company have the responsibility to provide qualified product which conform to company standard of this product
- Our company will provide the circuit diagram, calibration method and other information at the request of the user to help the appropriate and qualified technicians to repair those parts designated by our company.
- Our company have the responsibility to complete product maintenance according to the contract.
- Our company have the responsibility to respond the requirements of user in time.
- In the following case, our company is responsible for the impact on the safety, reliability and performance of the device:

Assembly, addition, debugging, modification or repair are carried out by personnel approved by our company.

The electrical facilities in the room are in compliance with the relevant requirements and the device is used in accordance with the User Manual.

Chapter1 Functions and Purpose

1.1 Main Functions

- Measure blood pressure and store the measurement results.
- Data storage function, up to 199 records can be stored.
- With data review interface which is convenient for reviewing blood pressure parameter.
- The screen will prompt message when the power is low.
- When the measurement result can not be obtained due to some factors during the measurement, the device will display the corresponding error information.
- Measurement units: mmHg and kPa, which can be switched by the button.
- With automatic shutdown function, if there is no operation, the device will automatically turn off.
- Voice broadcast(optional for devices with voice function)

1.2 Intended Purpose

In Europe,The Electronic Sphygmomanometer can be used to measure NIBP of human body. The measured NIBP parameters can be recorded to provide reference for family members and relevant medical staff. It is applicable to adult and adolescent. It can be used in home and health institutions.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 individuals.

Chapter2 Safety Precautions:

In order to use it correctly, please read the "Safety Precautions" carefully before using it.

Operators do not need professional training, but should use this product after fully understanding the requirements in this manual.

To prevent users from suffering damage or loss due to improper use, please refer to "Safety Precautions" and use this product properly.

For safety reasons, be sure to comply with safety precautions.

⚠ **Note** ⚠

If not use correctly, it exists the possibility of damage for personnel and goods.

Good damage means the damage of house, property, domestic animal and pet.

⚠ **Contraindication** ⚠

Not found.

⚠ **Warning** ⚠

- You must not perform NIBP measurements on patients with sickle-cell disease or under any condition which the skin is damaged or expected to be damaged.
- For patients with severe disturbances of blood coagulation, whether automatically measure the blood pressure should be based on the clinical evaluation, because limb friction with the cuff may cause the risk of hematoma.
- For severe blood circulation disorder or arrhythmia patients, please use the device under the guidance of a doctor. If the arm is squeezed during measurement, it may cause acute internal hemorrhage or inaccurate measurement results.

Measurement Limitations

To different patient conditions, the oscillometric measurement has certain limitations. The measurement is in search of regular arterial pressure pulse. In those circumstances when the patient's condition makes it difficult to detect, the measurement becomes unreliable and measuring time increases. The user should be aware that the following conditions could interfere with the measurement, making the measurement unreliable or longer to derive. In some cases, the patient's condition will make a measurement impossible.

Patient Movement

Measurements will be unreliable or can not perform if the patient is moving, shivering or having convulsions. These motions may interfere with the detection of the arterial pressure pulses. In addition, the measurement time will be prolonged.

Cardiac Arrhythmia's

Measurements will be unreliable and may not be possible if the patient's cardiac arrhythmia has caused an irregular heartbeat. The measuring time thus will be prolonged.

Heart-lung Machine

Measurements will not be possible if the patient is connected to a heart-lung machine.

Pressure Changes

Measurements will be unreliable and may not be possible if the patient's blood pressure is changing rapidly over the period of time during which the arterial pressure pulses are being analyzed to obtain the measurement.

Severe Shock

If the patient is in severe shock or hypothermia, measurements will be unreliable since reduced blood flow to the peripheries will cause reduced pulsation of the arteries.

Heart Rate Extremes

Measurements can not be made at a heart rate of less than 40 bpm and greater than 240 bpm.

Round Patient

The thick fat layer of body will reduce the measurement accuracy, because the fat that come from the shock of arteries can not access the cuffs due to the damping

⚠ **Warning** ⚠

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

Please hand measurement results to the doctor who knows your health and accept diagnosis.

For Infant and the person who can't express oneself, please use the device under the guidance of a doctor.

Otherwise it may cause accident or dissension.

Please do not use for any other purpose except BP measurement.

Otherwise it may cause accident or holdback

Please use special cuff.

Otherwise it is possible that measurement result is incorrect.

Please do not keep the cuff in the over-inflated state for a long time.

Otherwise it may cause risk.

Please do not use air tube or power cable entangles patient's neck.

Otherwise it may cause strangulation.

Do not use the device in the case of there are flammable anesthetic gasses mixing with the air or nitrous oxide.

Otherwise it may cause risk.

If liquid splashes on the device or accessories, especially when liquids may enter the pipe or device, stop using and contact the service department.

Otherwise it may cause risk.

Dispose of the packaging material, observing the applicable waste control regulations and keeping it out of children's reach.

Otherwise it may cause harm to the environment or children.

Please use approved accessories for the device and check that the device and accessories are working properly and safely before use.

Otherwise the measurement result may be inaccurate or an accident may occur.

When the device is accidentally damp, it should be placed in a dry and ventilated place for a period of time to dissipate moisture.

Otherwise the device may be damaged due to moisture.

Do not store and transport the device outside the specified environment.

Otherwise it may cause measurement error.

It is recommended that you check if there is any damage on the device or the accessories regularly, if you find any damage, stop using it, and contact the biomedical engineer of the hospital or our Customer Service immediately. Do not disassemble, repair and modify the device without permission.

Otherwise it cannot be accurately measured.

This device can not be used on mobile transport platforms.

Otherwise it may cause measurement error.

This device can not be used on a tilted tabletop.

Otherwise there is a risk of falling.

Dispose of packaging materials, waste batteries and end-of-life products in accordance with local laws and regulations. The end-of-life products and materials are properly disposed of by the user in accordance with the authority's decree.

Replace accessories which not provided by our company may lead to the occurrence of errors.

Without our company or other approved maintenance organizations trained service personnel should not try to maintain the product.

This device can only be used for one test object at a time.

If the small parts on the device are inhaled or swallowed, please consult a doctor promptly.

The device and accessories are processed with allergenic materials. If you are allergic to it , stop using this product.

After pressing the power button, if the device has display fault such as white screen, blurred screen or no display content, please contact our company.

The device shall comply with the standard IEC 80601-2-30:Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers.

Do not use the device in a high-frequency electromagnetic environment,otherwise it may cause an abnormal error or shutdown. keep away from this environment,the device may return to normal.

The highest temperature of the enclosure may go up to 45 ℃, the contact time is less than 1 minute.

It is necessary to clean the device between uses on different patients.

2.1 Operation for power adapter(Separate Sale)

⚠ **Note** ⚠

The device can be powered by a power adapter that is a part of the medical electrical system.Be sure to use the dedicated medical grade power adapter of this device.

Otherwise it may cause trouble

Dedicated power adapter must use AC 100 V~240 V

Otherwise it may cause fire or electric shock.

When there is breakage of dedicated power adapter plug or wire, please do not use it.

Otherwise it may cause fire or electric shock.

Please do not plug or unplug the adapter on the socket with wet hands.

Otherwise it may cause electric shock or injury.

When using the power adapter to connect with the power socket, make sure the power socket is conveniently accessible, in order to timely disconnect from the power when emergency.

2.2 Operation for Battery

⚠ **Note** ⚠

Please use 4 "AA" size manganese or alkaline batteries, do not use batteries of other types.

Otherwise it may cause fire.

Do not mix old and new batteries and batteries of different types

Otherwise it may cause battery leakage, heat, rupture, and damage to Electronic Sphygmomanometer.

Please don't put wrong the positive and negative of battery. When the batteries power exhausts, replace with four new batteries at the same time.

Please take out the batteries when you do not use the device for a long time(3 months or more).

Otherwise it may cause battery leakage, heat, rupture, and damage to Electronic Sphygmomanometer.

If electrolyte of the batteries immodestly get in your eyes, immediately rinse with plenty of clean water.

It will cause blindness or other hazards, should immediately go to the nearest hospital for treatment.

If electrolyte of the batteries immodestly glues on the skin or the clothes, immediately rinse with plenty of clean water.

Otherwise it may hurt the skin.

Advice

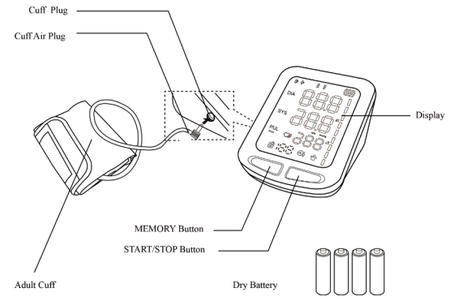
Do not strike or drop the device;

Do not inflate before the cuff wraps around the arm;

Do not inflect the cuff and the air tube forcibly.

Chapter3 Main Unit

All products are in the box. Open the box and confirm whether the product is whole.



3.1 Display

: Irregular pulse icon.Irregular pulse icon is displayed in the measurement results if the pulse internal is irregular during measuring,

: Movement icon.The "Movement" icon appears if patient moves and continue measuring may lead to inaccurate measurement.

: Cuff tied icon.The icon appears if Cuff tied properly.The icon disappears if not

: Memory Function icon.

/ : Voice icon.The voice function is enabled or not(optional for devices with Voice function)

3.2Accessories

Cuff **User Manual** **AC Adapter**

Cuff:

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

Separate Sale:

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

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** ⚠

It is recommended that the device should be inspected and calibrated (refer to Chapter 11 for details) once a year, as the aging of internal components (such as sensor) will degrade performance or cause other problems. 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.

Chapter4 External Interfaces

⚠ **Note** ⚠

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

① Cuff socket ② Power adapter socket

① is cuff identifier

② and represents different power adapter sockets, only one of them will appear on your product.

⚠ **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.

Chapter5 Battery/AC Adapter Installation

The production can use battery and AC adapter.

5.1 Battery Installation

① ②

① Open the battery compartment cover.

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

③ Close the battery compartment 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.

5.2 Usage of power adapter

1.Connect the sphygmomanometer and the power adapter. Plug the power adapter plug into the power adapter socket on the back of 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.

Chapter6 Button Functions

6.1 Description for button operation

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

- M Left button is "M" button, under "OFF" state, press this button to enter the review interface (refer to Chapter 8 for details.).
- START/STOP Right button is "START/STOP" button, under "OFF" state, press this button to enter measurement mode, inflate the cuff to measure blood pressure, press this button again to turn off the device.

6.2 Units setting

Under "OFF" state, press "M" button and "START/STOP" button simultaneously for 5 s to enter the setting interface, the default unit in this interface is "mmHg"; short press "M" button to switch the unit between "mmHg" and "kPa".

6.3 Volume setting (optional for devices with voice function)

■ Press "START/STOP" button again in the unit setting interface to enter the volume setting interface. Press "M" button to change the volume, the maximum volume is 4, and the minimum is 0 (silence).

■ After completing the setting, repeatedly press the "START/STOP" button to turn the device off.

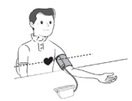
⚠ **Note** ⚠

■ The default unit of the device when leaving factory is mmHg.

Chapter7 The Usage Method of Sphygmomanometer

7.1 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, humidity and altitude 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.

7.2 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.

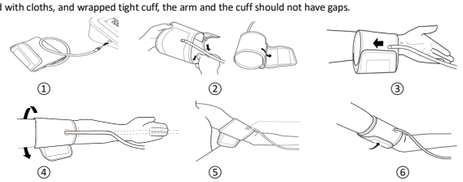
② Stretch cuff into a barrel for the arm can conformable enter into the barrel

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.



7.3 Measurement BP

① Under "OFF" state, press "START/STOP" button to start measuring.

During measurement, please keep correct pose and quiet state, the body could not move.The "Movement" icon appears if patient moves, and continue measuring may lead to inaccurate measurement.

If you want to abort the measurement

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

② Read the measurement result after the measurement is completed.

The measurement data will be displayed on the interface after the measurement is completed. If the measurement result is normal, the pressure bar at the right side is green. If the measurement result shows hypertension, red pressure bar will appear. The length of the pressure bar represents the difference between systolic blood pressure and diastolic blood pressure, the longer the pressure bar is, the larger the difference.

7.4 Confirm the Measurement Value

The World Health Organization has established globally accepted standards for the assessment of hypertension readings.(In the clinic environment)

Blood pressure level	Systolic pressure	Diastolic pressure
Normal	Pressure＜130mmHg	Pressure＜85mmHg
Normal Systolic Value	130mmHg≤Pressure≤139mmHg	85mmHg≤Pressure≤89mmHg
Mild Hypertension	140mmHg≤Pressure≤159mmHg	90mmHg≤Pressure≤99mmHg
Moderate Hypertension	160mmHg≤Pressure≤179mmHg	100mmHg≤Pressure≤109mmHg
Severe Hypertension/High Blood Pressure	180mmHg≤Pressure	110mmHg≤Pressure

*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 the screen displays Err, the measure can't be carried out correctly.
- Irregular pulse icon is displayed in the measurement results if the pulse internal is irregular during measuring, which may cause it is unable to take measurement correctly. Please keep quiet and remeasure. If the irregular pulse icon appears frequently, please consult a doctor.
- 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.

*The device will automatically turn off after five minutes in which there is no operation to the device, even if you forget to turn the power off.

Chapter8 Memory Function

The device can store NIBP values automatically, display up to 199 set of measurement results.

If 199 set of measurement data have been stored in current device, when saving the 200th set of data, the earliest set of data will be overwritten. If no measurement values, the memory values can be not numerated.

Memory function can not be used during measuring.

When there is no measurement values, "---" will display on the review interface.

8.1 Review the Memory Value

1.Under "OFF" state, press "M" button to display the average value of the latest three set of data, when the number of measurement data is less than three groups, it will supplement automatically. Continue to press "M" button in current interface to view all measurement records.

2.After the measurement is completed, press "M" button in the measurement result interface to display the average value of the latest three groups of data. continue to press "M" button in the current interface to view all measurement records.

8.2 Delete Memory Values

1.Users can delete all memory values of the current user instead of separately delete one memory value

2.Under the memory interface, press "M" button and "START/STOP" button simultaneously for more than 5 s, after "DEL" appears on the screen, all memory values will be deleted.

⚠ **Caution** ⚠

When querying the measurement records, please press "M" button continuously to query one by one.

Chapter9 Key and Symbols

Your device may not contain all the following symbols.

Signal	Description	Signal	Description
⚠	Caution: read instructions (warnings) carefully		Follow instructions for use
SYS	Systolic pressure	DIA	Diastolic pressure
MAP	Mean blood pressure	PUL	Pulse rate (bpm)
IP20	Covering Protection rate	EMC	Electromagnetic compatibility
	Recyclable	P/N	Material code of manufacturer
LOT	Lot number		Use by date
	This way up		Fragile, handle with care
	Keep in a cool, dry place		Atmospheric pressure limit
	Temperature limit	%	Humidity limit
	Manufacturer		Date of manufacture
	Batteries Power	SN	Serial number
	Flating		Deflating
	WEEE disposal	CE	Medical Device compliant with Directive 93/42/EEC
	Class II applied		Type BF applied parts
EC REP	Authorized representative in the European community		Irregular pulse
	Socket for power adapter		Interface for connecting cuff
	Voice closed		Voice enabled
	Large movement during measurement	OK	Cuff tied properly
	Artery indicator label	MD	Medical device
MR	MR Unsafe, can not be used in MRI		Imported by
REF	Product code		

Chapter10 Error Message

When the high pressure position appears "Err" and the low pressure position appears the error number, the measurement is not normal.

Error Mark	Causes	Solutions
Err2 Err15	Function abnormal	Please contact us
Err4	① Incorrect battery installation ② Low battery or wrong battery type	① Correctly re-install the battery ② Replace new battery with correct type (see Chapter 5)
Err6 Err7 Err14	① Disconnection of cuff or cuff connection is loose, causing air leakage ② Cuff is wrapped loosely or is not wrapped, resulting in unable to reach the preset inflation value ③ Air leakage of cuff or internal device	① Correctly connect the cuff with the device (see Chapter 7) ② Correctly wear the cuff (see Chapter 7) ③ Please contact us
Err9	① Cuff is wrapped loosely or is not wrapped, resulting in sampled pulse signal is weak ② The pulse signal of the patient is weak	① Correctly wear the cuff (see Chapter 7) ② Measure again
Err12	① External pressure to the cuff during measurement leads to overpressure ② The airway or plug of the cuff is blocked, causing overpressure	① Do not squeeze the cuff or move your arm and body during measurement, and measure again ② Check the plug of the cuff and correctly connect the cuff with the device (see Chapter 7), and measure again
Err8 Err11 Err13	The signal changing is incorrect owing to the arm or body moving or other reasons when measuring	Keep the arm, body still, and measure again
Err10	The measurement result exceeds the limits owing to the arm or body moving or other reasons when measuring	
Err16	Measurement timeout caused by arm or body movement or other reasons during measuring	

Chapter11 Troubleshooting

Abnormal Phenomenons	Causes	Solutions
BP measurement values too high or too low.	Cuff is not connected correctly.	Correctly connect cuff.
	Talk or move arm in measurement	Keep quiet and restart a measurement.
	The turnup close oppress the arm	Take off the clothes, and restart a measurement
No pressure	Cuff leakage	Buy a new cuff.
	The cuff windpipe is not correctly connected with cuff	Correctly connect.
	Cuff not inflate	Contact us.
Cuff deflate in short time	Loose cuff	Correctly tangle cuff.
It can not carry on measurement ,even if press the measurement button		Return on the power and restart a measurement.
Abruptly turn the power off in adding pressure	No use for a long time, the 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	Batteries are worn	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		Stop using the device and contact us.
Cuff never deflation		Stop using the device and contact us.
Air pressure error	Deflation error	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 unaltered when cuff inflating		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.

Chapter12 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 use it.

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 shall be inspected and calibrated regularly (or according to inspection standard of hospital). The inspection can be carried out in appointed institutions, or by professional personnel or contact us for inspection.

■ In the units setting interface, press "START/STOP" button for 15s to enter the factory setting interface, in which the"CAL"is displayed, press the "M" button once to enter the static pressure interface, and keep pressing the "M" button for 15s 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.

Chapter13 NIBP Specification

Name	Electronic Sphygmomanometer
The degree of protection against ingress of water	IP20
Display	LED
Measurement Method	Oscillometric method
Working mode	Automatic
Operation mode	Continuous operation
Pressure Range	0~297 mmHg(0~39.6 kPa)
Overpressure protect	297±3 mmHg(39.6±0.4 kPa)
Measurement range	Pressure: SYS：30～270 mmHg(4～36 kPa) DIA：10～220 mmHg(1.3～29.3 kPa) Pulse: 40~240bpm
Inflation	160±5 mmHg(21.33±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	+5ºC~40 ºC 15%RH~85%RH(no condensation)
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 ºC~+55 ºC; Relative humidity: ≤95 %(no condensation)); 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 ºC, limb circumference is 270 mm, the measured blood pressure is normal, 4 "AA" alkaline batteries cab be used about 300 times.
Main Unit Dimensions	129*101*72 mm
Main 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 (Cuff)
Service life	The service life of the device is five years or 10000 times of BP measurement.
Date of manufacturer	See the label
Accessories	SStandard Configure: **Adult Cuff:** limb circumference 22-32 cm (upper arm center) **User Manual, four "AA" alkaline batteries** Optional Configure： **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 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 32-43 cm (middle part of upper arm) the range of limb circumference is 22-43 cm (middle part of upper arm)

Appendix

Table 1:

Guidance and manufacturer's declaration –electromagnetic emission	
The device is intended for use in the electromagnetic environment specified below. The purchaser or the user of the device should assure that it is used in such environment.	
Emission test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/flicker emissions IEC 61000-3-3	Applicable

Table 2:

Guidance and manufacturer's declaration-electromagnetic immunity		
The device is intended for use in the electromagnetic environment specified below. The purchaser or the user of the device should assure that it is used in such environment.		
Immunity test	IEC60601-1-2 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ± 15 kV air	±8kV contact ±15kV air
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ± 1 kV for input/output line	±2kV for power supply lines Not Applicable
Surge IEC 61000-4-5	±1 kV lines to lines ±2 kV lines to earth	±1 kV lines to lines Not Applicable
Voltage dips, short interruptions and voltage vatiations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 .cycle .At0°,45°,90°, 135°,180°,225°,270°and315°. 0 % UT; 1 cycle and 70 % UT ; 25/30 cycles ;Single phase:at 0°. 0 % UT ; 250/300 cycle	0 % UT; 0,5 .cycle .At0°,45°,90°, 135°,180°,225°,270°and315°. 0 % UT; 1 cycle and 70 % UT ; 25/30 cycles ;Single phase:at 0°. 0 % UT ; 250/300 cycle
Power frequency (50 / 60Hz) magnetic field IEC 61000-4-8	30 A/m	30A/m

Table 3:

Guidance and manufacturer's declaration – electromagnetic immunity		
The device is intended for use in the electromagnetic environment specified below. The customer the user of the device should assure that it is used in such environment.		
Immunity test	IEC60601-1-2 test level	Compliance level
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1kHz
Radiated RF IEC61000-4-3	10 V/m 80 MHz- 2.7 GHz 80% AM at 1kHz	10 V/m80 MHz- 2.7 GHz 80% AM at 1kHz

Table 4：

Guidance and manufacturer's declaration - electromagnetic Immunity							
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment							
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Maximum power(W)	Distance (m)	Immunity Test level (V/m)
	385	380–390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27
	450	430-470	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0,3	28
	710 745 780	704–787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9
	810 870 930	800–960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28
	1720 1845 1970	1700–1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4,25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28
	2450	2400–2570	Bluetooth,WLAN,802.11 b/g/n,RFID 2450,LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28
	5240 5500 5785	5100–5800	WLAN 802.11a/n	Pulse modulation b) 217 Hz	0,2	0,3	9
NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.							
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.							
The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: $E = \frac{6}{d}\sqrt{P}$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.							

Test Frequency	Modulation	IMMUNITY TEST LEVEL(A/m)
30 kHz a)	CW	8
134,2 kHz	Pulse Modulation 2,1 kHz b)	65 c)
13,56 MHz	Pulse Modulation 50 kHz b)	7,5 c)

a) This test applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEAL THCARE ENVIRONMENT.
b)The carrier shall be modulated using a 50% duty cycle square wave signal.
c)r.m.s.,before modulation is applied.

⚠ **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 device including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**
- **Active medical devices are subject to special EMC precautions and they must be installed and used in accordance with these guidelines.**

Note：

- **When the device is disturbed, the data measured may fluctuate, please measure repeatedly or in another environment to ensure its accuracy.**

The following cable types must be used to ensure that they comply with interference radiation and immunity standards:

Name	Length (m)	Shield
Power adapter cable	1.5	No

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