

# WRIST BLOOD PRESSURE MONITOR

Use and maintenance book

**REF** **KD-7920 (GIMA 32773)**



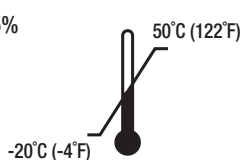
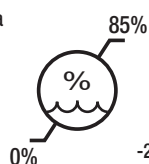
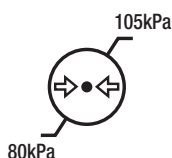
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IP22



CE 0197

# Wrist Blood Pressure Monitor

(ELECTRONIC SPHYGMOMANOMETER)

## OPERATION GUIDE

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## IMPORTANT INFORMATION

### NORMAL BLOOD PRESSURE FLUCTUATION

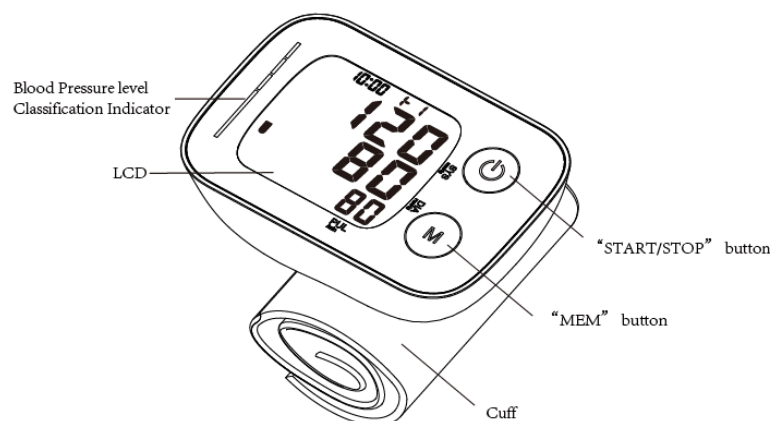
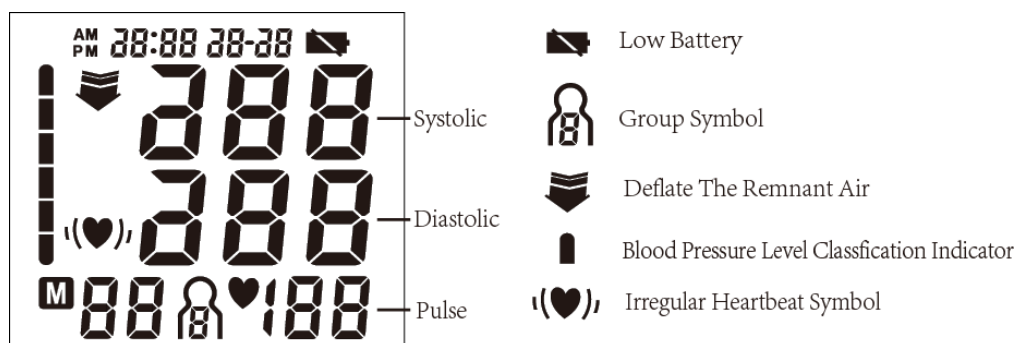
All physical activity, excitement, stress, eating, drinking, smoking, body posture and many other activities or factors (including taking a blood pressure measurement) will influence blood pressure value. Because of this, it is mostly unusual to obtain identical multiple blood pressure readings.

Blood pressure fluctuates continually ----- day and night. The highest value usually appears in the daytime and lowest one usually at midnight. Typically, the value begins to increase at around 3:00AM, and reaches to highest level in the daytime while most people are awake and active.

Considering the above information, it is recommended that you measure your blood pressure at approximately the same time each day.

Too frequent measurements may cause injury due to blood flow interference, please always relax a minimum of 1 to 1.5 minutes between measurements to allow the blood circulation in your arm to recover. It is rare that you obtain identical blood pressure readings each time.

### CONTENTS AND DISPLAY INDICATORS



*Note: The pictures in the manual are for reference only.*

## INTENDED USE

Fully Automatic Electronic Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. The cuff circumference is limited to 14cm ~ 19.5cm(5 1/2" ~ 7 11/16" ).

## PACKAGE CONTENTS

- 1 Blood Pressure Monitor with attached wrist cuff
- 1 Operation Guide
- 1 Storage Case

## CONTRAINDICATION




It is inappropriate for people with serious arrhythmia to use this Electronic Sphygmomanometer.

## PRODUCT DESCRIPTION

Based on Oscillometric methodology and silicon integrated pressure sensor, blood pressure and pulse rate can be measured automatically and non-invasively. The LCD display will show blood pressure and pulse rate. The most recent 4×30 measurements can be stored in the memory with date and time stamp. The Electronic Sphygmomanometers corresponds to the below standards: IEC 60601-1 Edition 3.1 2012-08/EN 60601-1: 2006/A1: 2013 (Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance), IEC60601-1-2:2014/EN 60601-1-2:2015 (Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests), IEC80601-2-30:2018/EN 80601-2-30:2019 (Medical electrical equipment -- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers); EN 1060-3: 1997 + A2: 2009 (Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems); ISO81060-2 : 2013 (Non-Invasive Sphygmomanometers - Part 2: Clinical Validation Of Automated Measurement Type).





## SPECIFICATIONS

1. Product name: Wrist Blood Pressure Monitor
2. Model: KD-7920
3. Classification: Internally powered, Type BF applied part, IP22, No AP or APG, Continuous operation
4. Machine size: Approx. 89mm×60mm×31mm
5. Cuff circumference: 14cm ~ 19.5cm (5 1/2" ~ 7 11/16" )
6. Weight: Approx. 69g (2 7/16oz.) (exclude batteries and cuff)
7. Measuring method: Oscillometric method, automatic inflation and measurement
8. Memory volume: 4×30 times with time and date stamp
9. Power source: batteries: 2 ×1.5V  SIZE AAA
10. Measurement range:
  - Cuff pressure: 0-300mmHg
  - Systolic: 60-260mmHg
  - Diastolic: 40-199mmHg
  - Pulse rate: 40-180 beats/minute
11. Accuracy:
  - Pressure: ±3mmHg
  - Pulse rate: Less than 60: ±3bpm  
More than 60 (incl.) : ±5%
  - precision of the displayed values: 1mmHg
12. Environmental temperature for operation: 10°C ~ 40°C (50°F ~ 104°F)
13. Environmental humidity for operation: ≤85%RH
14. Environmental temperature for storage and transport: -20°C ~ 50°C (-4°F ~ 122°F)
15. Environmental humidity for storage and transport: ≤85%RH
16. Environmental pressure: 80kPa-105kPa
17. Battery life: Approx 200 times.
18. All components belonging to the pressure measuring system, including: Pump, Valve, LCD, Cuff, Sensor

Note: These specifications are subject to change without notice.

## NOTICE

1. Read all of the information in the operation guide and any other literature in the box before operating the unit.
2. Stay still, calm and rest for 5 minutes before blood pressure measurement.
3. The cuff should be placed at the same level as your heart.
4. During measurement, neither speak nor move your body and arm.
5. Measuring on same wrist for each measurement.
6. Please always relax at least 1 or 1.5 minutes between measurements to allow the blood circulation in your arm to recover. Prolonged over-inflation (cuff pressure exceed 300 mmHg or maintained above 15 mmHg for longer than 3 minutes) of the bladder may cause ecchymoma of your arm.

7. Consult your physician if you have any doubt about below cases:
  - 1) The application of the cuff over a wound or inflammation diseases;
  - 2) The application of the cuff on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present;
  - 3) The application of the cuff on the arm on the side of a mastectomy or lymph node clearance;
  - 4) Simultaneously used with other monitoring medical equipments on the same limb;
  - 5) Need to check the blood circulation of the user.
8.  This Electronic Sphygmomanometers is designed for adults and should never be used on infants or young children. Consult your physician or other health care professionals before use on older children.
9. Do not use this unit in a moving vehicle, This may result in erroneous measurement.
10. Blood pressure measurements determined by this monitor are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method, within the limits prescribed by the American National Standard Institute, Electronic or automated sphygmomanometers.
11. Information regarding potential electromagnetic or other interference between the blood pressure monitor and other devices together with advice regarding avoidance of such interference please see part ELECTROMAGNETIC COMPATIBILITY INFORMATION. It is suggested that the blood pressure monitor be kept 30 cm away from other wireless devices, such as WLAN unit, cell phone, microwave oven, etc. It can't be used near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magneticresonance imaging, where the intensity of EM DISTURBANCES is high.
12. If Irregular Heartbeat (IHB) brought by common arrhythmias is detected in the procedure of blood pressure measurement, a signal of  will be displayed. Under this condition, the Electronic Sphygmomanometer can keep function, but the results may not be accurate, it's suggested that you consult with your physician for accurate assessment.  
There are 2 conditions under which the signal of IHB will be displayed:
  - 1) The coefficient of variation (CV) of pulse period >25%.
  - 2) The difference of adjacent pulse period  $\geq 0.14s$ , and the number of such pulse takes more than 53 percentage of the total number of pulse.
13. Please do not use the cuff other than supplied by the manufacturer, otherwise it may bring biocompatible hazard and might result in measurement error.
14.  The monitor might not meet its performance specifications or cause safety hazard if stored or used outside the specified temperature and humidity ranges in specifications.
15.  Please do not share the cuff with other infective person to avoid cross-infection.
16. The device is not intended for use on neonates, children or pregnant women. (Clinical testing has not been conducted on neonates, children or pregnant women.)
17. Motion, trembling, shivering during measurement may affect the measurement reading.
18. The device would not apply to the patients with poor peripheral circulation, noticeably low blood pressure, or low body temperature (there will be low blood flow to the measurement position).
19. The device would not apply to the patients who use an artificial heart and lung (there will be no pulse).

20. Consult your physician before using the device for any of the following conditions:  
common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation,  
arterial sclerosis, poor perfusion, diabetes, pre-eclampsia, renal diseases.
21. The patient is an intended operator.
23. Attention that changes or modification not expressly approved by the party responsible for  
compliance could void the user's authority to operate the equipment.
24. Swallowing batteries and/or battery fluid can be extremely dangerous. Keep the batteries  
and the unit out of the reach of children and disabled persons.
25. If you are allergic to plastic/rubber, please don't use this device.
26. The essential performance of this medical device :
  - a. Limits of the error of the cuff pressure indication
  - b. Reproducibility of the blood pressure determination
  - c. Alarm

## SETUP AND OPERATING PROCEDURES


### 1. BATTERY LOADING


- a. Open battery cover at the back of the monitor.
- b. Load two "AAA" size batteries. Please pay attention to polarity.
- c. Close the battery cover.


When LCD shows battery symbol  , replace all batteries with new ones.

Rechargeable batteries are not suitable for this monitor.

Remove the batteries if the monitor will not be used for a month or more to avoid relevant  
damage of battery leakage.

 Avoid getting battery fluids in your eyes, if it happens, immediately rinse with plenty of  
clean water and contact a physician.

 The negative terminal of the battery needs to be compressed into the battery  
compartment properly after horizontal compression of the negative electrode. The battery  
is in contact with the spring.

 Make sure the battery cover is intact and not damaged before installing the battery.

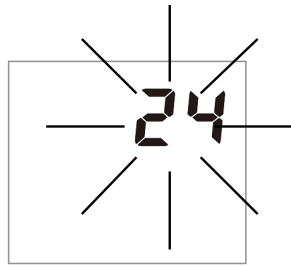


*The monitor, the batteries and the cuff, must be disposed of according to local  
regulations at the end of their usage.*

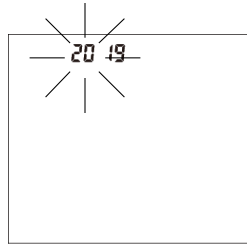
### 2. CLOCK AND DATE ADJUSTMENT

- a. At first the Blood Pressure Monitor is totally off, once you insert the battery, the  
Blood Pressure Monitor will enter Clock and Date Adjustment Mode.
- b. If the time of the device is already set and need to be changed, adjustment can be  
reached by pressing both the "START/STOP" and "MEM" button for 3 seconds  
in Standby Mode.
- c. In Clock and Date Adjustment Mode , the time format will blink at first , see  
picture2-1 .the default time format is 24h and the default clock and date is  
2019-1-1 1:00.
- d. Press the button "START/STOP" repeatedly, the year (first usage: default is 2019,

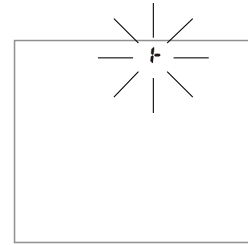
range is 2019~2099), month, day, hour and minute will blink in turn, see picture 2-2& 2-3 & 2-4 & 2-5 & 2-6. While the number is blinking, press the button “MEM” to increase the number, keep on pressing the button "MEM", the number will increase faster.



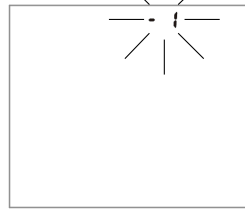
**Picture 2-1**



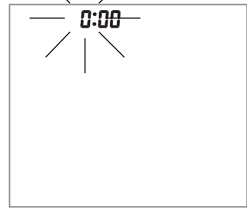
**Picture 2-2**



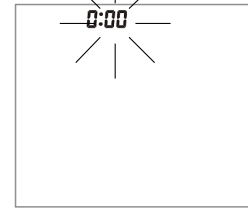
**Picture 2-3**



**Picture 2-4**



**Picture 2-5**



**Picture 2-6**

- e. During adjusting clock and date, the monitor will go back to Standby Mode automatically when no button will be pressed within 30 seconds.
- f. You can turn off the monitor by pressing “START/STOP” button when the minute is blinking, then the time and date is confirmed.

**Note:**

2.1 The clock format could be set by user.

2.2 Table 1 instructs the conversion relations between 24 hour format and 12 hour format.

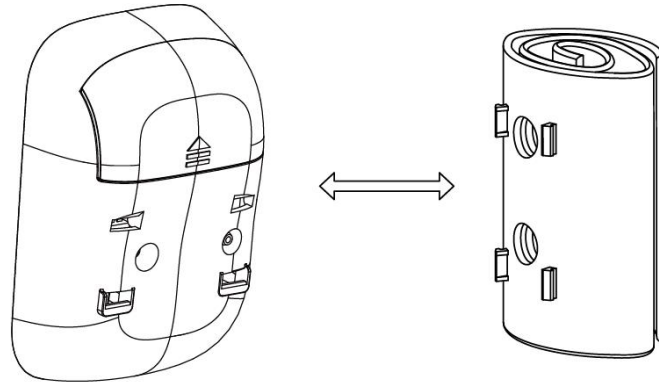
**Table 1**

24 hour format	12 hour format	24 hour format	12 hour format
0:00	12:00 AM	12:00	12:00 PM
1:00	1:00 AM	13:00	1:00 PM
2:00	2:00 AM	14:00	2:00 PM
3:00	3:00 AM	15:00	3:00 PM
4:00	4:00 AM	16:00	4:00 PM
5:00	5:00 AM	17:00	5:00 PM
6:00	6:00 AM	18:00	6:00 PM
7:00	7:00 AM	19:00	7:00 PM
8:00	8:00 AM	20:00	8:00 PM
9:00	9:00 AM	21:00	9:00 PM
10:00	10:00 AM	22:00	10:00 PM
11:00	11:00 AM	23:00	11:00 PM



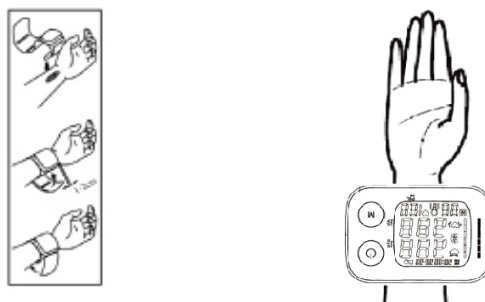
### 3. CONNECTING THE CUFF TO THE MONITOR

The cuff is attached to the monitor when it is packaged. Should the cuff become unattached, align the two plugs and four brackets of the cuff with the plug sockets and bracket sockets of the monitor and press the cuff to the monitor until the plugs and brackets are securely attached.



### 4. APPLYING THE CUFF

- Place the cuff around a bare wrist 1-2cm above the wrist joint on the palm side of the wrist.
- While seated, place the arm with the cuffed wrist in front of your body on a desk or table with the palm up. If the cuff is correctly placed, you can read the LCD display. If you want to measure with the right wrist, you should invert the monitor and you will see the inverted blood pressure value.
- The cuff must be neither too tight nor too loose.
- You can also take a measurement on your right wrist as the picture.



#### Note:

- Please refer to the cuff circumference range in “SPECIFICATIONS” to make sure that the appropriate cuff is used.
- Measuring on same wrist each time.
- Do not move your arm, body, or the monitor during measurement.
- Stay quiet, calm for 5 minutes before blood pressure measurement.

- Please keep the cuff clean. Clean the cuff by wet soft cloth and mild detergent if the cuff becomes dirty. Do not remove the cuff from the monitor. Clean the cuff after the usage of every 200 times is recommended.
- Do not place the cuff around your wrist if the wrist has any inflammation, acute diseases, infections skin wounds.

## 5. BODY POSTURE DURING MEASUREMENT

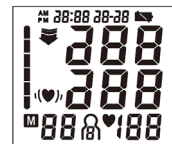
### Sitting Comfortably Measurement

- Be seated with your feet flat on the floor, and don't cross your legs.
- Place palm upside in front of you on a flat surface such as a desk or table.
- The middle of the cuff should be at the level of the right atrium of the heart.



## 6. TAKING YOUR BLOOD PRESSURE READING

- After applying the cuff and your body is in a comfortable position, press the "START/STOP" button. All display characters are shown for self-test. You can check the LCD display according to the right picture. Please contact the service center if segment is missing.



- Then the current memory bank (1, 2, 3 or 4) is displayed. Press "MEM" button to change over to other bank. Confirm your selection by pressing "START/STOP" button. The current bank can also be confirmed automatically after 5 seconds with no operation.
- Then the monitor inflates the cuff until sufficient pressure has built up for a measurement. Then the monitor slowly releases air from the cuff and carries out the measurement. Finally the blood pressure and pulse rate will be calculated and displayed on the LCD screen. The blood pressure classification indicator and Irregular heartbeat symbol (if any) will blink on the screen. The result will be automatically stored in the monitor.
- After measurement, the monitor will turn off automatically after 1 minute of no operation.
- During measurement, you can press the "START/STOP" button to turn off the monitor manually.



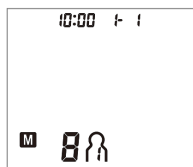
*Note: Please consult a health care professional for interpretation of pressure measurements.*

## 7. DISPLAYING STORED RESULTS

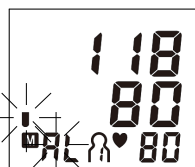
- In StandBy Mode, press "MEM" button, the monitor will display sign of current group. Press "MEM" button to switch group, press "START/STOP" to confirm current group. Then the amount of results in current user memory zone will be displayed. See picture 7. Then LCD will display the average value of all results in the current user memory zone. See picture 7-1. If no result stored in the current user memory zone,

LCD will display “0” for blood pressure and pulse rate. See picture 7-2.

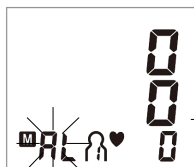
- b. Press “MEM” button, LCD will display the average value of all the results which is measured from 5 o’clock to 9 o’clock in last 7 days in the current user memory zone. See picture 7-3. If no result stored from 5 o’clock to 9 o’clock in last 7 days, LCD will display “0” for blood pressure and pulse rate. See picture 7-4.



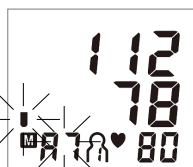
**Picture 7**



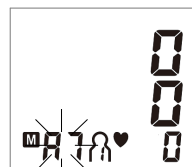
**Picture 7-1**



**Picture 7-2**

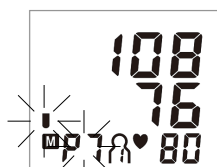


**Picture 7-3**

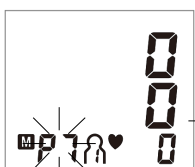


**Picture 7-4**

- c. Press “MEM” button again, LCD will display the average value of all the results which is measured from 18 o’clock to 20 o’clock in last 7 days in the current user memory zone. See picture 7-5. If no result stored from 18 o’clock to 20 o’clock in last 7 days, LCD will display “0” for blood pressure and pulse rate. See picture 7-6.



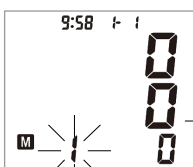
**Picture 7-5**



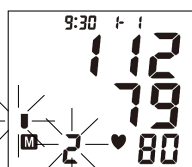
**Picture 7-6**



**Picture 7-7**



**Picture 7-8**



**Picture 7-9**

- d. Press “MEM” button again, the most recent result will be displayed with date and time stamp. See picture 7-7. Irregular heartbeat symbol (if any) and blood pressure classification indicator will blink at the same time. If the monitor has no result stored in the current user memory zone, the LCD will display “0” for blood pressure and pulse rate. See picture 7-8.
- e. Press “MEM” button again to review the next result. See picture 7-9. In this way, repeatedly pressing the “MEM” button displays the respective results measured previously.
- f. When reviewing the results, the monitor will turn off automatically after 1 minute of no operation. You can also press the “START/STOP” button to turn off the monitor manually.

*Note: When the monitor displaying the measurement, the classification color indicator can be shown different color according to the systolic pressure and diastolic pressure. Refer to the “ASSESSING HIGH BLOOD PRESSURE FOR ADULTS” section.*

## **8. DELETING MEASUREMENTS FROM THE MEMORY**

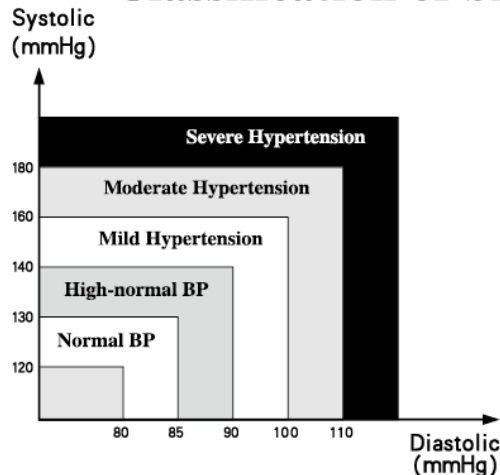
When any result is displaying, keeping on pressing button “MEM” for three seconds, all results in current bank will be deleted .

Press the button “START/STOP”, the monitor will turn off.

## 9. ASSESSING HIGH BLOOD PRESSURE FOR ADULTS

The following guidelines for assessing high blood pressure (without regard to age or gender) have been established by the World Health Organization (WHO). Please note that other factors (e.g. diabetes, obesity, smoking, etc.) need to be taken into consideration. Consult with your physician for accurate assessment, and never change your treatment by yourself.

### Classification of blood pressure for adults



WHO/ISH Definitions and Classification of Blood Pressure Levels

*Note: It is not intended to provide a basis of any type of rush toward emergency conditions/diagnosis based on the color scheme and that the color scheme is meant only to discriminate between the different levels of blood pressure.*

## 10. TECHNICAL ALARM DESCRIPTION

The monitor will show 'HI' or 'Lo' as technical alarm on LCD with no delay if the determined blood pressure (systolic or diastolic) is outside the rated range specified in part SPECIFICACIONES. In this case, you should consult a physician or check if your operation violated the instructions.

The technical alarm condition (outside the rated range) is preset in the factory and cannot be adjusted or inactivated. This alarm condition is assigned as low priority according to IEC 60601-1-8.


The technical alarm is non-latching and need no reset. The signal displayed on LCD will disappear automatically after about 8 seconds.

## 11. TROUBLESHOOTING (1)




PROBLEM	POSSIBLE CAUSE	SOLUTION
LCD Display shows abnormal result	The cuff position was not correct or it was not properly tightened	Apply the cuff correctly and try again.
	Body posture was not correct during testing	Review the "BODY POSTURE DURING MEASUREMENT" sections of the instructions and re-test.
	Speaking, arm or body movement, angry, excited or nervous during testing	Re-test when calm and without speaking or moving during the test.

	Irregular heartbeat (arrhythmia)	It is inappropriate for people with serious arrhythmia to use this Electronic Sphygmomanometer.
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## 12. TROUBLESHOOTING (2)















PROBLEM	POSSIBLE CAUSE	SOLUTION
LCD shows low battery symbol 	Low Battery	Change the batteries
LCD shows "Er 0"	Pressure system is unstable before measurement	Don't move and try again.
LCD shows "Er 1"	Fail to detect systolic pressure	
LCD shows "Er 2"	Fail to detect diastolic pressure	
LCD shows "Er 3"	Pneumatic system blocked or cuff is too tight during inflation	Connect the cuff correctly and try again. If the monitor is still abnormal, please contact the local distributor or the factory
LCD shows "Er 4"	Pneumatic system leakage or cuff is too loose during inflation	
LCD shows "Er 5"	Cuff pressure above 300mmHg	Measure again after five minutes. If the monitor is still abnormal, please contact the local distributor or the factory.
LCD shows "Er 6"	More than 3 minutes with cuff pressure above 15 mmHg	
LCD shows "Er 7"	Inner memory error	
LCD shows "Er 8"	Device parameter checking error	
LCD shows "Er A"	Pressure sensor parameter error	
No response when you press button or load battery.	Incorrect operation or strong electromagnetic interference.	Take out batteries for five minutes, and then reinstall all batteries.

## MAINTENANCE

1.  Do not drop this monitor or subject it to strong impact.
2.  Avoid high temperature and solarization. Do not immerse the monitor in water as this will result in damage to the monitor.
3. If this monitor is stored near freezing, allow it to acclimate to room temperature before use.
4.  Do not attempt to disassemble this monitor.
5. It is recommended the performance should be checked every 2 years or after repair. Please contact the service center.
6. Clean the monitor with a dry, soft cloth or a soft cloth squeezed well after moistened with water, diluted disinfectant alcohol, or diluted detergent.
7. No component can be maintained by user in the monitor. The circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are designated repairably can be supplied.
8. The monitor can maintain the safety and performance characteristics for a minimum of 10,000 measurements or three years, and the cuff integrity is maintained after 1,000 open–close cycles of the closure..
9. It is recommended the cuff should be disinfected 2 times every week if needed (For example, in hospital or in clinique). Wipe the inner side (the side contacts skin) of the cuff by a soft cloth squeezed after moistened with Ethyl alcohol (75-90%), then dry the cuff by airing.
10. The monitor requires 6 hours to warm from the minimum storage temperature between uses until the monitor is ready for its INTENDED USE when the ambient temperature is 20 °C.
11. The monitor requires 6 hours to cool from the maximum storage temperature between uses until the the monitor is ready for its INTENDED USE when the ambient temperature is 20 °C.
12. No servicing/maintenance while the monitor is in use .

### EXPLANATION OF SYMBOLS ON UNIT

	Imported by
	Caution: read instructions (warnings) carefully
	Type CF applied part, with defibrillation-proof function
	Serial number
	Manufacturer
	Date of manufacture
	Lot number

	Latex free
	Atmospheric pressure limit
	Temperature limit
	Humidity limit
	This way up
	Fragile, handle with care
	Keep in a cool, dry place
	Keep away from sunlight
	General warning label NOTE: Background color: yellow Triangular band: Black
	Medical Device compliant with Directive 93/42/EEC
	Authorized representative in the European community
	Follow instructions for use
	Product code
<b>IP22</b>	Covering Protection rate
	WEEE disposal

## ELECTROMAGNETIC COMPATIBILITY INFORMATION

**Table 1 - Emission**

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class B	Home healthcare environment

**Table 2 - Enclosure Port**

Phenomenon	Basic EMC standard	Immunity test levels
		Home Healthcare Environment

Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	10V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3

**Table 3 – Proximity fields from RF wireless communications equipment**

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		



*Disposal: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.*

#### **GIMA WARRANTY TERMS**

The Gima 12-month standard B2B warranty applies.