

(approx. 8-18.2").

#### PACKAGE CONTENTS 1 Blood Pressure Monitor

**Operation Guide** 

Stay quiet, calm for 5 minutes before blood pressure measurement. Please keep the cuff clean. If the cuff becomes dirty, remove it from the monitor and clear it by hand in a mild detergent, then rinse it thoroughly in cold water. Never dry the cuff in clothes dryer or iron it. Clean the cuff after the

usage of every 200 times is recommended. 6. Do not place the cuff around your arm if the arm has any inflammation, acute

16

17

18

13

television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or

- more of the following measures: Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
  Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help. 17. Measurements are not possible in patients with a high frequency of arrhythmias.

1 arm cuff 22-30cm (8-11") 1 Soft Storage Case 4x1.5 AAA batteries

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

6

renal diseases

equipment.

1. Battery loading

c. Close the battery cover.

relevant damage of battery leakage

23. The patient is an intended operator.

**SETUP AND OPERATING PROCEDURES** 

b. Load four "AAA" size batteries. Please pay attention to polarity.

a. Open battery cover at the back of the monitor.

# CONTRAINDICATION

**PRODUCT DESCRIPTION** 

Based on Oscillometric methodology and silicon integrated pressure sensor, blood pressure and pulse rate can be measured automatically and non-invasive-1. The LCD display will show blood pressure and pulse rate. The most recent 4X30 measurements can be stored in the memory with date and time stamp. The voice function will ease the operation. The Electronic Sphygmomanome-ters corresponds to the below standards: IEC 60601-1Edition 3.1 2012-08/ EN 60601-1:2006/A1:2013 (Medical electrical equipment -- Part 1: General re-quirements 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), IEC80601-2-30:2009+AMD1:2013/ EN IEC80601-2-30:2019 (Medical electrical equipment -Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers) EN 1060-1: 1995 + A2: 2009 (Non-invasive sphygmomanometers - Part 1: General requirements), 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)

- 18. 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.)
- 19. Motion, trembling, shivering may affect the measurement reading.
- 20. 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). 21. The device would not apply to the patients who use an artificial heart and
- lung (there will be no pulse)

22. Consult your physician before using the device for any of the following conditions: common arrhythmias such as atrial or ventricular premature beats or

24. Attention that changes or modification not expressly approved by the party

25. 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 26. If you are allergic to plastic/rubber, please don't use this device.

When LCD shows battery symbol UD, 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

responsible for compliance could void the user's authority to operate the

atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, pre-eclampsia,

#### diseases, infections skin wounds

during measurement.

#### 5. Body posture during measurement

## Sitting Comfortably Measurement

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



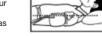
## Lying Down Measurement

12

- a. Lie on your back.
- b. Place your arm straight along your side with your palm upside.

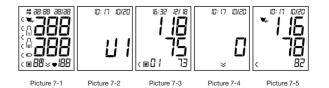


c. The cuff should be placed at the same level as your heart.



#### 6. Taking your blood pressure reading

a. After applying the cuff and your body is in a comfortable position, press the button. A beep is heard and all display characters are shown for selftest. See Picture 7-1. Please contact the service center if segment is missing



19

20

21

22

23

Indicato

green

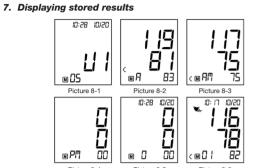
green

green

24

- b. Then the current memory bank (U1, U2, U3 or U4) is shown. See picture 7-2 Press "MEM" button to change over to other bank. Confirm your selection by pressing "START" button. The current bank can also be confirmed automatically after 5 seconds with no operation
- c. If the monitor has stored results, the LCD will momentarily display the most re cent one. If no result has been stored, zero will appear on LCD. See Picture 7-3. d. If the voice function is switched on, the monitor will speak out measurement tips.
- Then the monitor starts to seek zero pressure. See picture 7-4
- 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 c a l-culated 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. See Picture 7-5.
- g. After measurement, the monitor will turn off automatically after 1 minute of no operation. Alternatively, you can press the "START" button to turn off the monitor manually.
- h. During measurement, you can press the "START" button to turn off the monitor manually.

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

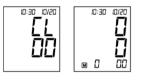


Picture 8-4 Picture 8-5 Picture 8-6

- a. In Standby Mode, press "MEM" button to display the stored results. The current memory bank will blink and the amount of results in this bank will be displayed. Press "START" button to change over to other bank. Confirm your selection by pressing "MEM" button. The current bank can also be confirmed automatically after 5 seconds with no operation. See picture 8-1.
- b. After selecting the memory bank, the LCD will display the average values in this bank. See picture 8-2. If no result stored, LCD will show zeros. See picture
- c. 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 8-3. 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.
- d. 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. 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 8-4. e. Then press the "MEM" button, the most recent result will be displayed. See picture 8-6. Followed by, the blood pressure and pulse rate will be shown separately. Irregular heartbeat symbol (if any) will blink. Press "MEM" button again to review the next result. In this way, repeatedly pressing the "MEM" button displays the respective results measured previously. If no result stored, LCD will show zeros. See picture 8-5.
- When displaying the stored results, the monitor will turn off automatically after 1 minute of no operation. You can also press the button "START" to turn off the monitor manually.

#### 8. Deleting measurements from the memory

When any result is displaying, keeping on pressing button "MEM" for three sec-onds, all results will be deleted. Press the button "MEM" or "START", the monitor will turn off

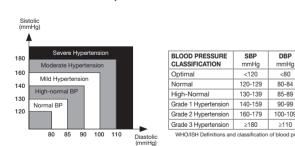


Picture 9-1 Picture 9-2

# 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 yourse

## Classification of blood pressure for adults



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 DUR- ING MEASUREMENT" sections of the instructions and re-test	
	Speaking, arm or body movement, an- gry, 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 Elec- tronic Sphygmomanometer	

# 12. Troubleshooting (2)

PROBLEM	POSSIBLE CAUSE	SOLUTION	
LCD Display shows battery symbol	Low Battery	Change the batteries	
LCD shows "Er 0"	Pressure system is unstable before measurement		
LCD shows "Er 1"	Fail to detect systolic pressure	Don't move and try again	
LCD shows "Er 2"	Fail to detect diastolic pressure		

			26
PROBLEM	POSSIBLE CAUSE	SOLUTION	]
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	
LCD shows "Er 4"	Pneumatic system leakage or cuff is too loose during inflation	abnormal, please contact the local distributor or the factory	
LCD shows "Er 5"	Cuff pressure above 300mmHg		1
LCD shows "Er 6"	More than 160 seconds with cuff pressure above 15 mmHg	Measure again after five minutes. If the monitor is still abnormal, please contact the local distributor or the factory	
LCD shows "Er 7"	Inner memory error		
LCD shows "Er 8"	Device parameter checking error		
LCD shows "Er A"	Pressure sensor parameter error	1	
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.  $\triangle$  Do not drop this monitor or subject it to strong impact.
- 2.  $\triangle$  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
- $\triangle$  Do not attempt to disassemble this monitor
- 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 dia-
- grams, 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.
- The monitor can maintain the safety and performance characteristics for a minimum of 10,000 measurements or three years, and the cuff integrity is 8. maintained after 1,000 open-close cycles of the closure. 9. It is recommended the cuff should be disinfected 2 times every week if need-
- ed (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 monitor is ready for its INTENDED USE when the ambient temperature is 20°C.

12. Not servicing/maintenance while the monitor is in use

# **EXPLANATION OF SYMBOLS ON UNIT**

8	Follow instructions for use	
Â	Caution: read instructions (warnings) carefully	
*	Type BF applied part	
X	WEEE disposal	
<b>C€</b> 0197	Medical Device complies with Directive 93/42/EEC	

	Manufacturer
~~	Date of manufacture
EC REP	Authorized representative in the European commu- nity
SN	Serial number
IP20	Covering Protection rate
111	

#### Table 2 **Enclosure Port**

25

27

28

29

30

-Rev.3-02.20

M32777-GB-

Phenomenon	Basic EMC	Immunity test levels Home Healthcare Environment	
	standard		
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	
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz	

31

32

#### Table 3 Proximity fields from RF wireless communications equipment

Test frequency	Band (MHz)	Immunity test levels
(MHz)		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		

			33
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

X 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.

35

36

34

Grade 2 Hypertension 160-179 100-109 orange Grade 3 Hypertension ≥180 ≥110 red

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

Ť	Keep in a cool, dry place
×	Keep away from sunlight
REF	Product code
LOT	Lot number

## 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 SPECIFICACIONS. 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

# **ELECTROMAGNETIC COMPATIBILITY INFORMATION**

#### Table 1 Emission

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class B	Home healthcare environment
Harmonic distortion	IEC 61000-3-2 Class A	Home healthcare environment
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	Home healthcare environment

