### WRIST AUTOMATIC **BLOOD PRESSURE MONITOR**

**Operation Guide** 



### ATTENTION:

The operators must carefully read and completely understand the present manual before using the product.

### INDEX IMPORTANT INFORMATION CONTENTS AND DISPLAY INDICATORS INTENDED USE PACKAGE CONTENTS CONTRAINDICATION...... PRODUCT DESCRIPTION SPECIFICATIONS. SETUP AND OPERATING PROCEDURES.. Battery loading. Clock and date adjustment ...... Connecting the cuff to the monitor 4. Applying the cuff .. 5. Body posture during measurement...6. Taking your blood pressure reading... Displaying stored results ...... Deleting measurements from the memory Assessing high blood pressure for adults. 10. Technical alarm description.. 11. Troubleshooting (1). 12. Troubleshooting (2). MAINTENANCE. **EXPLANATION OF SYMBOLS ON UNIT**

# ELECTROMAGNETIC COMPATIBILITY INFORMATION ..... 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 (approx. 5 1/2"-7 11/16").

## **PACKAGE CONTENTS**

- 1 Blood Pressure Monitor With Attached Wrist Cuff • 1 Operation Guide
- 1 Plastic Bag

### **CONTRAINDICATION** It is inappropriate for people with serious arrhythmia to use

this Electronic Sphygmomanometer.

- **SPECIFICATIONS** Product name: Blood Pressure Monitor Model: KD-735
- Classification: Internally powered, Type BF applied part, IP22, No AP or APG,
  - Continuous operation.

    Machine size: Approx. 85mm x 64.5mm x28mm
  - (3 11/32" x 2 17/32" x 1 3/32") Cuff circumference:14cm 19.5cm (5 1/2" 7 11/16")
- Weight: Approx. 110g (3 7/8 oz.) (exclude batteries)
  Measuring method: Oscillometric method, automatic inflation and measure-
- Memory volume: 2x 60 times with time and date stamp 9. Power source: batteries: 2 ×1.5V SIZE AAA 10. Measurement range:

0-300 mmHg Cuff pressure: Systolic: 60-260 mmHg Diastolic: 40-199 mmHg Pulse rate: 40-180 beats/minute

11. Accuracy:

±3mmHg Pressure: Pulse rate

Less than 60: ±3bpm More than 60 (incl.): ±5%

12. Environmental temperature for operation:  $5^{\circ}C\sim40^{\circ}C$  ( $41^{\circ}F\sim104^{\circ}F$ )

13. Environmental humidity for operation: ≤90%RH

14. Environmental temperature for storage and transport: -20°C~55°C (-4°F~131°F)

Battery life: Approx 270 times
 All components belonging to the pressure measuring system, including accessories: Pump, Valve, LCD, Cuff, Sensor

- Read all of the information in the operation guide and any other literature in the box before operating the unit.
- The cuff should be placed at the same level as your heart.

- the blood circulation in your arm to recover. Prolonged over-inflation (cuff pressure exceed 300 mmHg or maintained above 15 mmHg for longer than

- Consult your physician if you have any doubt about below cases:

  1) The application of the cuff over a wound or inflammation disease 2) The application of the cuff on any limb where intravascular access
- 4) Simultaneously used with other monitoring medical equipments
- on the same limb;
- 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.
- tute, Electronic or automated sphygmomanometers.

  11. Information regarding potential electromagnetic or other interference be
- EQUIPMENT and the RF shielded room of an ME SYSTEM for magneticres-onance imaging, where the intensity of EM DISTURBANCES is high. 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 Sphygmomanometers can keep function, but the results may not be accurate, it's suggested that you consult with your physician for accurate assessment.

WLAN unit, microwave oven, etc. It can't be used near active HF SURGICAL

- There are 2 conditions under which the signal of IHB will be displayed:
- The coefficient of variation (CV) of pulse period >25%.
   The difference of adjacent pulse period≥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
- 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.
  Please do not share the cuff with other infective person to avoid 15. Please do no. cross-infection.
- 16. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules

Increase the separation between the equipment and receiver. Connect the equipment into an outlet on a circuit different from that to

Consult the dealer or an experienced radio/TV technician for help

17. This device complies with part 15 of the FCC Rules. Operation is subject to

18. Measurements are not possible in patients with a high frequency of arrhyth-

19. The device is not intended for use on neonates, children or pregnant women. (Clinical testing has not been conducted on neonates, children or pregnant

21. The device would not apply to the patients with poor peripheral circulation,

22. The device would not apply to the patients who use an artificial heart and

23. 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,

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

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

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

noticeably low blood pressure, or low body temperature (there will be low

20. Motion, trembling, shivering may affect the measurement reading.

the following two conditions: (1) This device may not cause harmful interfer-

ence, and (2) this device must accept any interference received, including

one or more of the following measures:
- Reorient or relocate the receiving antenna.

interference that may cause undesired operation.

which the receiver is connected.

blood flow to the measurement position).

lung (there will be no pulse)

24. The patient is an intended operator.

equipment.

# These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by







Picture 6

b. Then the monitor starts to seek zero pressure. See picture 6-1. The monitor inflates the cuff until sufficient pressure has built up for a meas-

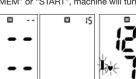
urement. Then the monitor slowly releases air from the cuff and carries out the measurement. Finally the blood pressure and pulse rate will be calculated and displayed on the LCD screen separately. Irregular heartbeat symbol (if any) will blink. See picture 6-2&6-3. The result will be automatically stored in the d. After measurement, the monitor will turn off automatically after 1 minute of

e. During measurement, you can press the "START" button to turn off the moni-

Note: Please consult a health care professional for interpretation of pres-

a. After measurement, you can review the results in the memory bank by pressing the "MEM" button. Alternatively, you can press "MEM" button in Clock Mode to display the stored results. If it no result stored, LCD will show dashes

memory bank, the LCD will





## 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 60 measurements can be stored in the memory with date and time stamp. The Electronic Sphygmomanometers corresponds to the below standards: IEC 60601-1Edition 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), IEC80601-2-30:2009+AMD1:2013/FN 80601-2-30:2010/A1:2015 (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).

- 15. Environmental humidity for storage and transport: ≤90% RH 16. Environmental pressure: 80kPa-105kPa

## Note: These specifications are subject to change without notice.

- Stay still, calm and rest for 5 minutes before blood pressure measurement.
- During measurement, neither speak nor move your body and arm. Measuring on same wrist for each measurement.
- Please always relax at least 1 or 1.5 minutes between measurements to allow
- - 3 minutes) of the bladder may cause ecchymoma of your wrist.
  - 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:

  - Need to check the blood circulation of the user.
- 9. Do not use this unit in a moving vehicle, This may result in erroneous meas
- 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 Insti-
- tween 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 at least 30 cm away from other wireless devices, such as

- 1. 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**

## a. Be seated with your feet flat on the floor, and don't cross

- 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

# 6. Taking your blood pressure reading

a. After applying the cuff and your body is in a comfortable position, press the "START" button. A beep is heard and all display characters are shown for selftest. See picture 6. Please contact the service center if segment is missing.

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no operation. Alternatively, you can press the "START" button to turn off the

7. Displaying stored results

as picture 7, while press the button "MEM" or "START", machine will turn off. If there are results in the

display the amount of the results in the memory bank. See picture 7-1.

Picture 7-1

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

with new ones.

SETUP AND OPERATING PROCEDURES Battery loading
 Open battery cover at the back of the monitor.

Load two "AAA" size batteries. Please pay attention to polarity. When LCD shows battery symbol replace all batteries

Rechargeable batteries are not suitable for this monitor

o 0 [ (+ AAA ] Avoid the battery fluid to get in your eyes. If it (+ AAA 1)

should get in your eyes, 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

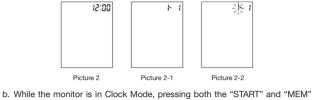
electrode. The battery is in contact with the spring.

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

The 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. Once you install the battery or turn off the monitor, it will enter Clock Mode, and LCD will display time and date by turns. See picture 2&2-1.



ute will blink in turn. While the number is blinking, press the button "MEM" to increase the number. Keep on pressing the button "MEM", the number will increase fast. You can turn off the monitor by pressing "START" button when the minute is

button simultaneously, a beep is heard and the month will blink at first. See picture 2-2. Press the button "START" repeatedly, the day, hour and min-

- blinking, then the time and date is confirmed. The monitor will turn off automatically after 1 minute of no operation, with the
- time and date unchanged.
  e. Once you change the batteries, you should readjust the time and date.

### The cuff is attached to the monitor when it is packaged. Should the cuff become unat-

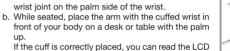
4. Applying the cuff

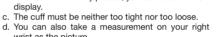
wrist as the picture

3. Connecting the cuff to the monitor

tached, 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.

a. Place the cuff around a bare wrist 1-2cm above the





- b. And then, the most recent result will be displayed with date and time stamp See picture7-2. Followed by, the blood pressure and pulse rate will be shown separately. Irregular heartbeat symbol (if any) will blink. See picture7-38.7-4.

  Press "MEM" button again to review the next result. See picture7-5. In this way, repeatedly pressing the MEM button displays the respective results measured previously.
- c. 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.

### **MAINTENANCE**

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- Do not drop this monitor or subject it to strong impact.
- Avoid high temperature and solarization. Do not immerse the monitor 2. 🔨
- in water as this will result in damage to the monitor. If this monitor is stored near freezing, allow it to acclimate to room
- temperature before use.

  Do not attempt to disassemble this monitor.
- If you do not use the monitor for a long time, please remove the batteries. It is recommended the performance should be checked every 2 years or after repair. Please contact the service center.
  Clean the monitor with a dry, soft cloth or a soft cloth squeezed well after
- moistened with water, diluted disinfectant alcohol, or diluted detergent. 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.
- 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.

  10. 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 con-

# 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			

tacts skin) of the cuff by a soft cloth squeezed after moistened with Ethyl			
alcohol (75-90%), then dry the cuff by airing.  11. The monitor requires 6 hours to warm from the minimum storage temperature	1720	1700-1990	Pulse modulation 217Hz, 28V/m
between uses until the monitor is ready for its INTENDED USE when the	1845		
ambient temperature is 20 °C.  12. The monitor requires 6 hours to cool from the maximum storage temperature	1970		
between uses until the monitor is ready for its INTENDED USE when the	2450	2400-2570	Pulse modulation 217Hz, 28V/m

Table 3

## m 5240 5100-5800 Pulse modulation 217Hz, 9V/m 5500 5785

## 8. Deleting measurements from the memory

When any result is displaying, keeping on pressing button "MEM" for three seconds, all results in the current memory bank will be deleted after three "beep". LCD will show picture 8, Press the button "MEM" or "START", 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

Normal BF 100

SBP mmHg	<b>DBP</b> mmHg
<120	<80
120-129	80-84
130-139	85-89
140-159	90-99
160-179	100-109
≥180	≥110
	mmHg <120 120-129 130-139 140-159 160-179

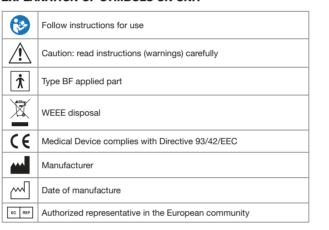
### 10. TECHNICAL ALARM DESCRIPTION

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 SPECIFICATIONS. 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 present in the factory

### **EXPLANATION OF SYMBOLS ON UNIT**

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



**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 Z specific recycling point for electric and electronic equipment. For further information on recycling points contact the local authorities, the local recycling center or the shop where the product was purchased. If the equipment is not disposed of correctly, fines or penalties may be applied in accordance with the national legislation and regulations.

**GIMA WARRANTY CONDITIONS**Congratulations for purchasing a GIMA product. This product meets high qualitative standards both as regards the material and the production. The warranty is valid for 12 months from the date of supply of GIMA.

During the period of validity of the warranty, GIMA will repair and/or replace free of charge all the defected parts due to production reasons. Labor costs and personnel traveling expenses and packaging not included. All components subject to wear are not included in the warranty.

The repair or replacement performed during the warranty period shall not extend the warranty. The warranty is void in the following cases: repairs performed by unauthorized personnel or with non-original spare parts, defects caused by negligence or incorrect use. GIMA cannot be held responsible for malfunctioning on electronic devices or software due to outside agents such as: voltage changes, electro-magnetic fields, radio interferences, etc.

The warranty is void if the above regulations are not observed and if the serial

code (if available) has been removed, cancelled or changed.

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

28 SN Serial number Covering Protection rate IP22 Keep in a cool, dry place Keep away from sunlight REF Product code LOT Lot number

The defected products must be returned only to the dealer the product was purchased from. Products sent to GIMA will be rejected.

# 12. Troubleshooting (2)

PROBLEM

No response when you press button

or load battery

PROBLEM	POSSIBLE CAUSE	SOLUTION
LCD shows low battery symbol	Low Battery	Change the batteries
LCD shows "Er 0"	Pressure system is unsta- ble 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	Apply the cuff correctly and try again
LCD shows "Er 4	Pneumatic system leak- age or cuff is too loose during inflation	

# **ELECTROMAGNETIC COMPATIBILITY INFORMATION** Table 1

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	

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

LCD shows "Er 5" Cuff pressure above Measure again after five minutes. If the monitor is still 300 mmHg abnormal, please contact the More than 3 minutes with cuff pressure above LCD shows "Er 6" local distributor or the factory 15 mmHg LCD shows "Er 7" EEPROM accessing error LCD shows "Fr 8" Device parameter checking error LCD shows "Er A Pressure sensor

SOLUTION

Take out batteries for five minutes, and then reinstall

all batteries

**POSSIBLE CAUSE** 

parameter error

interference

Incorrect operation or strong electromagnetic

### Table 2 **Enclosure Port**

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	

REF 32918 / KD-735

Imported and distributed by: Gima S.p.A. - Via Marconi. 1 20060 - Gessate (MI) Italy

REP



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