iHealth® Push

Smart Blood Pressure Wrist Monitor

Tensiomètre poignet

Sfigmomanometro da polso

Tensiómetro de muñeca

Instruction For Use

Notice d’utilisation

Istruzioni per l'uso

Instrucciones de uso

EN

iHealth® Push

Wrist Blood Pressure Monitor
(ELECTRONIC SPHYGMOMANOMETER)
Instruction For Use

INDEX

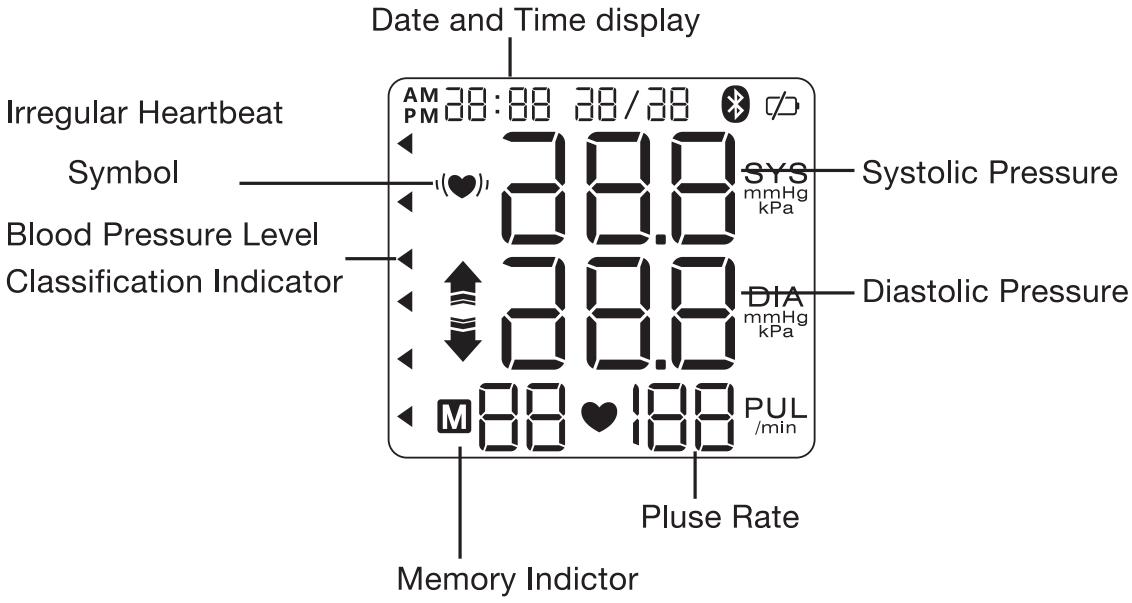
IMPORTANT INFORMATION
NORMAL BLOOD PRESSURE FLUCTUATION

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 min 30 sec 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

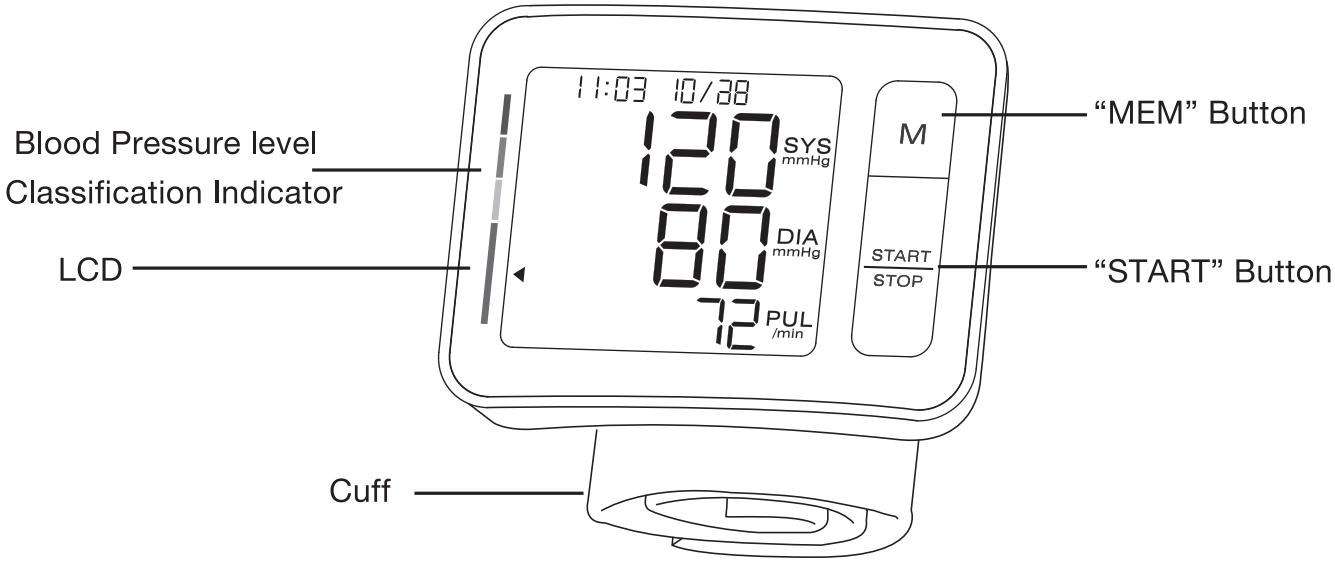


Bluetooth Symbol

Low Battery

Pressure in cuff is instable, or much remnant air in cuff

Heartbeat Indicator



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.

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 1×99 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/EN 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 + A1: 2002 + A2: 2009 (Non-invasive sphygmomanometers - Part 1: General requirements), EN 1060-3: 1997 + A1: 2005 + 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)

Mobile device compatibility

Works with both iOS and Android devices: such as iPhone 7/iPhone 7 Plus/Samsung Galaxy S6 Edge/SM-G9250/Samsung Galaxy Note3 Lite/Motorola Nexus 6

For a complete list of compatible devices, visit our support on page on www.ihealthlabs.eu

SPECIFICATIONS

1. Product name: Wrist Blood Pressure Monitor
2. Model: KD-723
3. Classification: Internally powered, Type BF applied part,IP22,No AP or APG, Continuous operation
4. Machine size: Approx. 80mm×60mm×22mm
5. Cuff circumference: 14cm ~ 19.5cm(5 1/2″~ 7 11/16″)
6. Weight: Approx. 96g (3 9/23oz.) (exclude batteries)

7. Measuring method: Oscillometric method, automatic inflation and measurement
8. Memory volume: 1×99 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: ±5%
12. Environmental temperature for operation: 10°C to 40°C (50°F to 104°F)
13. Environmental humidity for operation: ≤85%RH
14. Environmental temperature for storage and transport:
    -20°C to 50°C(-4°F to 122°F)
15. Environmental humidity for storage and transport: ≤85%RH
16. Environmental pressure: 80kPa-105kPa
17. Battery life: Approx 170 times.
18. Wireless Connection: *Bluetooth* Smart 4.0
    Frequency Band: 2.400~2.4835GHz
19. 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 instruction for use and ny 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 arm for each measurement.
6. Please always relax at least 1 or 1min 30sec between measurements to allow the blood circulation in your arm to recover. Prolonged over-inflation (cuff pressure exceeds 300 mmHg or maintained above15 mmHg for longer than 3 minutes) of the bladder may cause ecchymoma of your wrist.
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 wrist on the side of a mastectomy;
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.
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 Sphygmomanometers 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≥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 measure ment 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. 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. 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 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. This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
18. Measurements are not possible in patients with a high frequency of arrhythmias.
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 women.)

20. Motion, trembling, shivering may affect the measurement reading.
21. 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).
22. The device would not apply to the patients who use an artificial heart and lung (there will be no pulse)
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 venal diseases.
24. The patient is an intended operator.
25. Attention that changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
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.

SETUP AND OPERATING PROCEDURES

1. DOWNLOAD THE FREE APP

Prior to first use, download and install the iHealth Myvitals from the App

Store(iOS device) or Google Play(Android device). Use keyword search terms ”Myvitals”.

2. 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 the battery fluid to get in your eyes. If it should get in your eyes, immediately rinse with plenty of clean water and contact a physician.

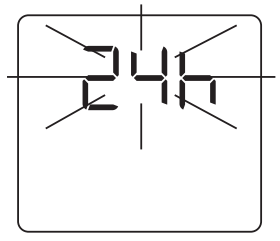
The monitor, the batteries and the cuff, must be disposed of according to local regulations at the end of their usage.

3. CLOCK AND DATE ADJUSTMENT

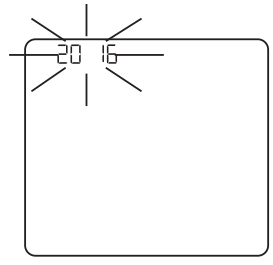
a. At first the Blood Pressure Monitor is totally off, once you insert the battery, the Blood Pressure Monitor will enter Clock and Date Adjustment Mode.
b. If the time of the device is already set and need to be changed, adjustment can be reached by pressing the “START/STOP” and “M” button for 3 seconds in Standby Mode.
c. In Clock and Date Adjustment Mode , the time format will blink at first , see picture3-1 .If the monitor has no result stored in the current user ,the

default time format is 24h (Europe Version) and the default clock and date is 2016-1-1 12:00, else the default time format, clock and date is same as the most recent result's.

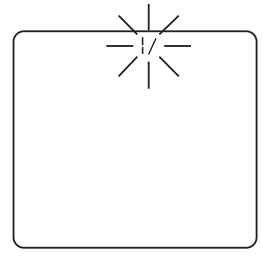
d. Press the button "START/STOP" repeatedly, the year (first usage: default is 2016, range is 2016~2099), month, day, hour and minute will blink in turn, see picture 3- 2& 3-3 & 3-4 & 3-5 & 3-6. While the number is blinking, press the button "M" to increase the number, keep on pressing the button "M", the number will increase faster.



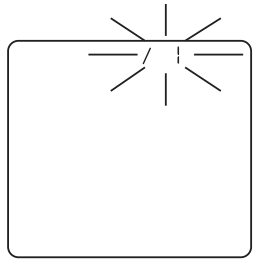
Picture 3-1



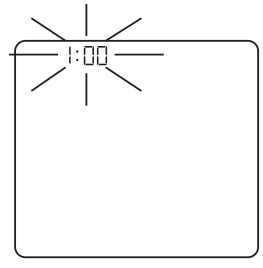
Picture 3-2



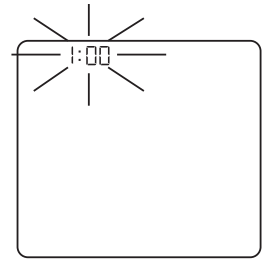
Picture 3-3



Picture 3-4



Picture 3-5



Picture 3-6

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: *3.1 The clock format could be set by user.*

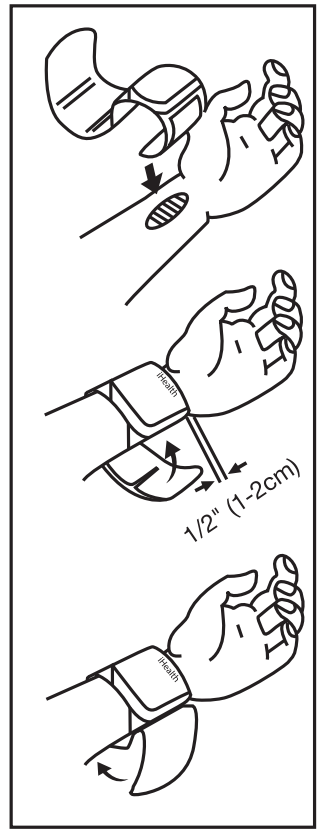
4. APPLYING THE CUFF

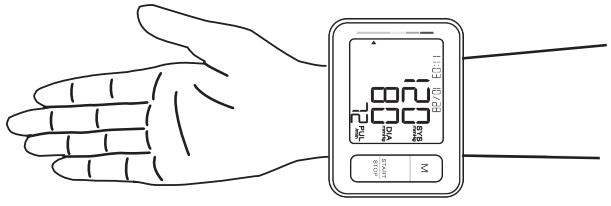
a. Place the cuff around a bare left wrist 1-2cm above the wrist joint on the palm side of the wrist.

b. 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.

c. The cuff must be neither too tight nor too loose.

d. You can also take a measurement on your right wrist as the picture 4.





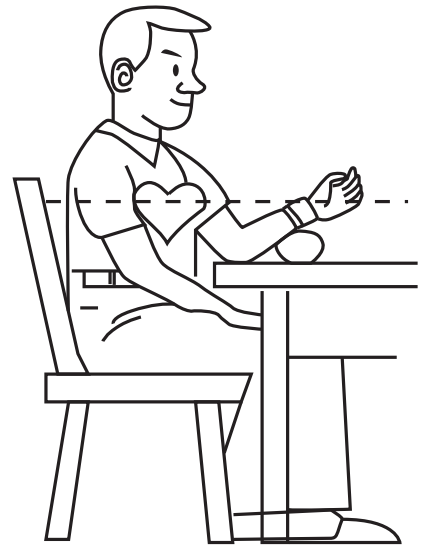
Picture 4 - Right wrist position

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 still, 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.

5. BODY POSTURE DURING MEASUREMENT

Sitting Comfortably Measurement



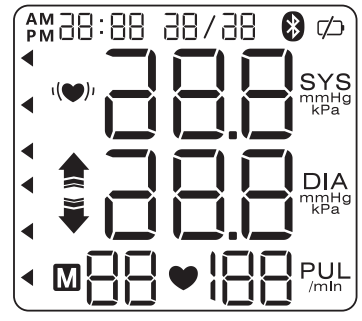
a. Be seated with your feet flat on the floor, and don't cross your legs.

b. Place palm upside in front of you on a flat surface such as a desk or table, with your elbow resting on a chair 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

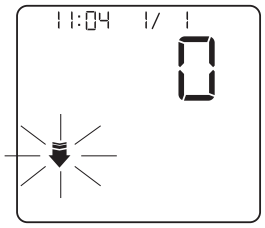
a. After applying the cuff and your body is in a comfortable position, press the "START/STOP" button. All display characters are shown for self-test. See picture 6. Please contact the service center if segment is missing.



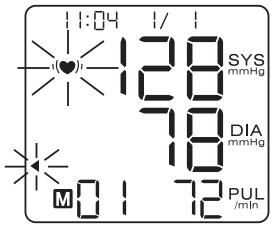
Picture 6

b. The monitor starts to seek zero pressure. See picture 6-1.

c. Then the cuff will be slowly inflated. The blood pressure and pulse will be measured during inflation. Inflation will stop as soon as the blood pressure and pulse rate have been calculated and displayed on the LCD. The irregular heartbeat symbol (if any) and blood pressure classification indicator will blink on the LCD, See picture 6-2. The result will automati cally be stored in the Memory bank of the monitor.



Picture 6-1



Picture 6-2

d. After measurement, the monitor will turn off automatically after 1 minute of no operation. Alternatively, you can press the “START/STOP” button to turn off the monitor manually.

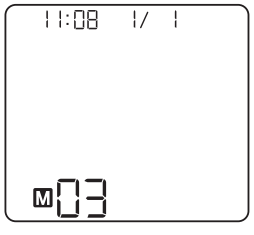
e. After measurement, the monitor display the result, you can press the “M” button to displaying stored results.

f. During measurement, you can press the “START/STOP” button to turn off the monitor manually.

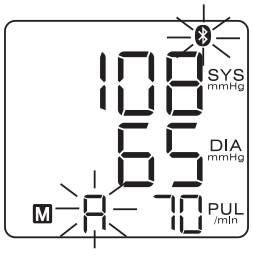
Note: *Please consult a health care professional for interpretation of pressure measurements.*

7. DISPLAYING STORED RESULTS

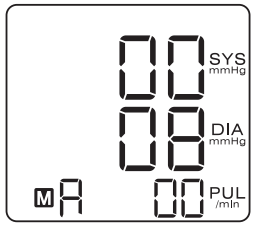
a. In Standby mode,press “M” button to display the stored results. The amount of results will be displayed. See picture 7-1. And then the LCD will display the average value of all results , See picture 7-2. If no result stored, LCD will show “00” as picture 7-3.



Picture 7-1

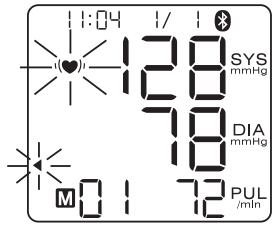


Picture 7-2

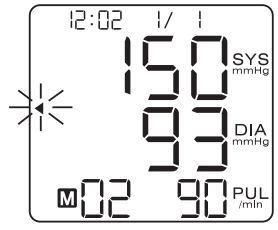


Picture 7-3

b. When the average is displayed, press the “M” button, the most recent result will be displayed. See picture 7-4. Followed by, the blood pressure and pulse rate will be shown separately. Irregular heartbeat symbol (if any) will blink. Press “M” button again to review the next result. See picture 7-5. The monitor will turn off if “M” button is pressed while displaying the last record.



Picture 7-4



Picture 7-5

e. When displaying the stored results, the monitor will turn off automatically after 1 minute of no operation. You can also press the button “START/STOP” to turn off the monitor manually.

8. SYNCHRONIZING STORED RESULTS

a. In Standby Mode, press “M” button, the monitor will wait *Bluetooth* connect and *Bluetooth* symbol flashing. See picture 7-2. *Bluetooth* symbol will stop flashing when *Bluetooth* is connected. See picture 7-4.

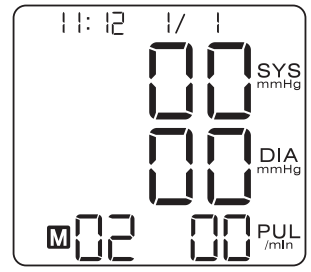
b. When *Bluetooth* symbol exists and not flashing button can’t work.

c. When *Bluetooth* is disconnected, 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.

d. After synchronizing stored results, all stroed results will be deleted automatically.

9. DELETING MEASUREMENTS FROM THE MEMORY

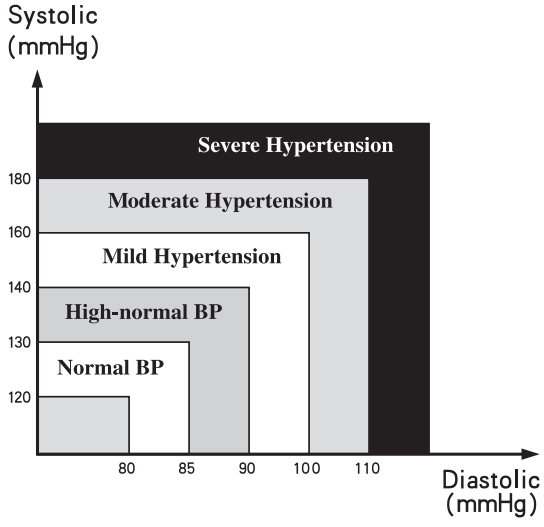
When any result is displaying, keeping on pressing button "M" for three seconds, all results will be deleted.
Press the button "START/STOP", the monitor will turn off.



10. 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



BLOOD PRESSURE CLASSIFICATION	SBP mmHg	DBP mmHg	COLOR INDICATOR
Optimal	<120	<80	GREEN
Normal	120-129	80-84	GREEN
High-Normal	130-139	85-89	GREEN
Grade 1 Hypertension	140-159	90-99	YELLOW
Grade 2 Hypertension	160-179	100-109	ORANGE
Grade 3 Hypertension	⩾180	⩾110	RED

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.*

11. 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.

12. 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.

13. 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	Apply the cuff correctly and try again
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”	EEPROM accessing 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.

A question? A difficulty? Please contact your support team:
For US/Canada: support@iHealthlabs.com or visit the section Support of https://ihealthlabs.com
For EU: support@ihealthlabs.eu or visit the section Assistance of https://ihealthlabs.eu or section Help in the application iHealth MyVitals.

MAINTENANCE

1. ⚠ Do not drop this monitor or subject it to strong impact.
2. ⚠ Avoid high temperature and direct sunlight. 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. If you do not use the monitor for a long time, please remove the batteries.
6. It is recommended the performance should be checked every 2 years or after repair. Please contact the service center.
7. Clean the monitor with a dry, soft cloth or a soft cloth squeezed well after moistened with water, diluted disinfectant alcohol, or diluted detergent.
8. 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 reparably can be supplied.
9. 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 clinic). 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.
11. 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.
12. 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
13. Not servicing/maintenance while the monitor is in use.

EXPLANATION OF SYMBOLS ON UNIT


Symbol for" THE OPERATION GUIDE MUST BE READ" (The sign background color: blue. The sign graphical symbol: white)


Symbol for "TYPE BF APPLIED PARTS" (The cuff is type BF applied part)


Symbol for "WARNING"


Symbol for "ENVIRONMENT PROTECTION – Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local Authority or retailer for recycling advice".

 Symbol for “MANUFACTURER”

CE 0197 Symbol for “COMPILES WITH MDD93/42/EEC REQUIREMENTS”

 Symbol for “DATE OF MANUFACTURE”

Symbol for “EUROPEAN REPRESENTATION”

Symbol for “SERIAL NUMBER”

IP22 The first characteristic numeral symbol for “Degrees of protection against access to hazardous parts and against solid foreign objects “. The second characteristic numeral symbol for “Degrees of protection against ingress of water”

WARRANTY INFORMATION

iHealth Labs, Inc. ("iHealth") warrants the iHealth hardware (the "Product"), and only the Product, against defects in materials and workmanship under normal use for a period of one year (US) or two years (EU) from the date of purchase by the original purchaser ("Warranty Period"). Under this Limited Warranty, if a defect arises and a valid claim is received by iHealth within the Warranty Period regarding the Product, at its option and to the extent permitted by law, iHealth will either (1) repair the Product using new or refurbished replacement parts or (2) exchange the Product with a new or refurbished Product. In the event of a defect, to the extent permitted by

law, these are the sole and exclusive remedies.

This warranty does not apply: (a) to consumable parts, such as the cuff or the battery that diminish over time, unless failure has occurred due to a defect in materials or workmanship; (b) to cosmetic damage, including but not limited to scratches, dents ; (c) to damage caused by accident, abuse, misuse, contact with liquid; (d) to damage caused by operating the iHealth product outside the user manual, the technical specifications or other iHealth product published guidelines; (e) to damage caused by service performed by anyone who is not a representative of iHealth or one of its representatives.

ANDON HEALTH CO., LTD.
No. 3 Jinping Street, Ya An Road, Nankai District, Tianjin 300190, China. Tel: 86-22-87611660

EC REP Lotus Global Co., Ltd.
1 Four Seasons Terrace West Drayton, Middlesex, London, UB7 9GG, United Kingdom
Tel: +0044-20-75868010 Fax: +0044-20-79006187

Distributed by

iHealthLabs Europe SAS 36 Rue de Ponthieu, 75008, Paris, France
www.ihealthlabs.eu E-mail: contact@ihealthlabs.eu

IMPORTANT INFORMATION REQUIRED BY THE RED

This product is approved in accordance to RED directive transmitter. interference
This product complies with Industry Canada. IC: RSS-210
IC NOTICE
This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions:
(1) this device may not cause interference, and
(2) this device must accept any interference, including interference that may cause undesired operation of the device.

iHealth is a trademark of iHealth Labs, Inc.
The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc and any use of such marks by iHealth Labs, Inc. is under license.
Other trademarks and trade names are those of their respective owners.

Hereby, [ANDON HEALTH CO., LTD.] declares that the equipment type[KD-723] is in compliance with Directive 2014/53/EU.
The full text of the EU declaration of conformity is available at the following internet address: https://ihealthlabs.eu/fr/content/189 -DoC-RED.

ELECTROMAGNETIC COMPATIBILITY INFORMATION

This product is applicable to the equipment and system requirements for

the purpose of receiving radio frequency energy for the purpose of the work, *Bluetooth* receive bandwidth 2M. This product can also be used to include RF transmitter equipment and system requirements and emission frequency of 2.4GHz ISM band, *Bluetooth* modulation types:GFSK, effective radiated power: < 20dBm

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

Table 2 - Enclosure Port

Phenomenon	**Basic EMC standard**	**Immunity test levels**
		Home Healthcare Environment
Electrostatic Discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM field	IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz

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 18 Hz, 27 V/m
450	430-470	FM, ± 5 kHz deviation, 1 kHz sine, 28 V/m
710	704-787	Pulse modulation 217 Hz, 9 V/m
745		
780		
810	800-960	Pulse modulation 18 Hz, 28 V/m
870		
930		
1720	1700-1990	Pulse modulation 217 Hz, 28 V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217 Hz, 28 V/m
5240	5100-5800	Pulse modulation 217 Hz, 9 V/m
5500		
5785		

Table 4 – Input A.C. power Port

Phenomenon	Basic EMC standard	Immunity test levels
		Home Healthcare Environment
Electrical fast transients/burst	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	± 0.5 kV, ± 1 kV
Surges Line-to-ground	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V, 0.15 MHz to 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Voltage dips	IEC 61000-4-11	0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0% U_T; 250/300 cycles