iHealth® Push

Wrist Blood Pressure Monitor

Tensiomètre au poignet

Monitor de presión arterial de muñeca

Instruction Manual

Manuel d'utilisation

Manual de instrucciones

EN

iHealth Push

Wrist Blood Pressure Monitor
(ELECTRONIC SPHYGMOMANOMETER)
Instruction Manual

INDEX

IMPORTANT INFORMATION
NORMAL BLOOD PRESSURE FLUCTUATION

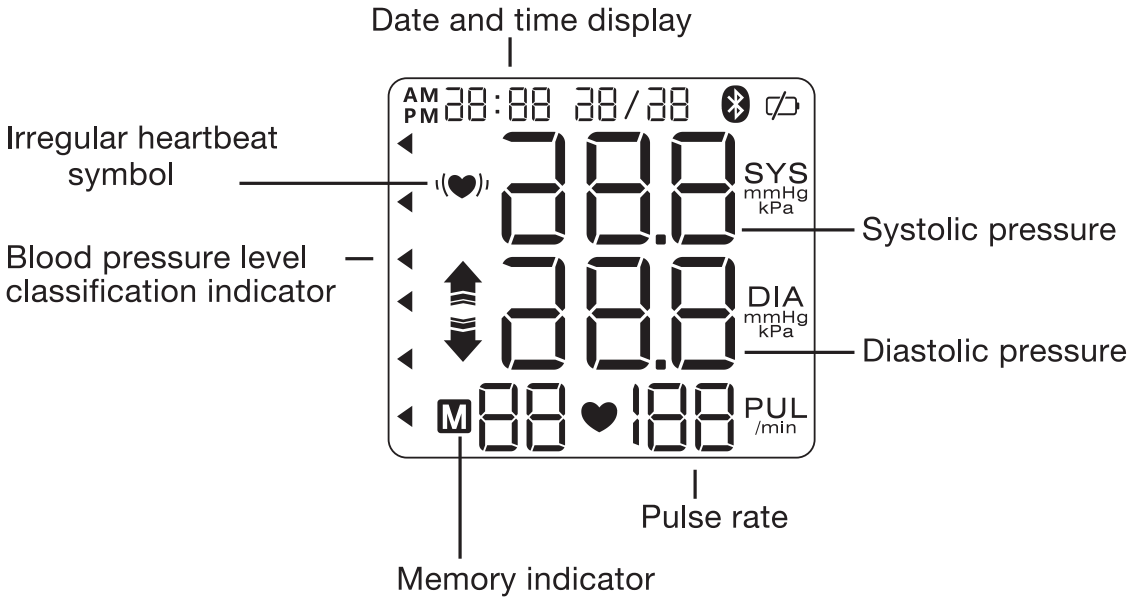
Blood pressure is affected by various factors, including excitement, stress, body position and physical activities such as eating, drinking, smoking or even taking a blood pressure measurement. As a result, it is unusual to obtain identical blood pressure readings multiple times.

Blood pressure constantly fluctuates throughout the day and night. Typically, the blood pressure continues to rise during the day and peaks while most people are awake and active. It then drops in the evening, reaching its lowest between midnight and 3 am while most people are sleeping.

Considering the above information, measuring your blood pressure at approximately the same time every day is recommended.

Taking measurements more often than necessary may cause an injury due to blood flow interference, so please always rest a minimum of 60 to 90 seconds between measurements to allow the blood circulation in your arm to recover.

CONTENTS AND DISPLAY INDICATORS

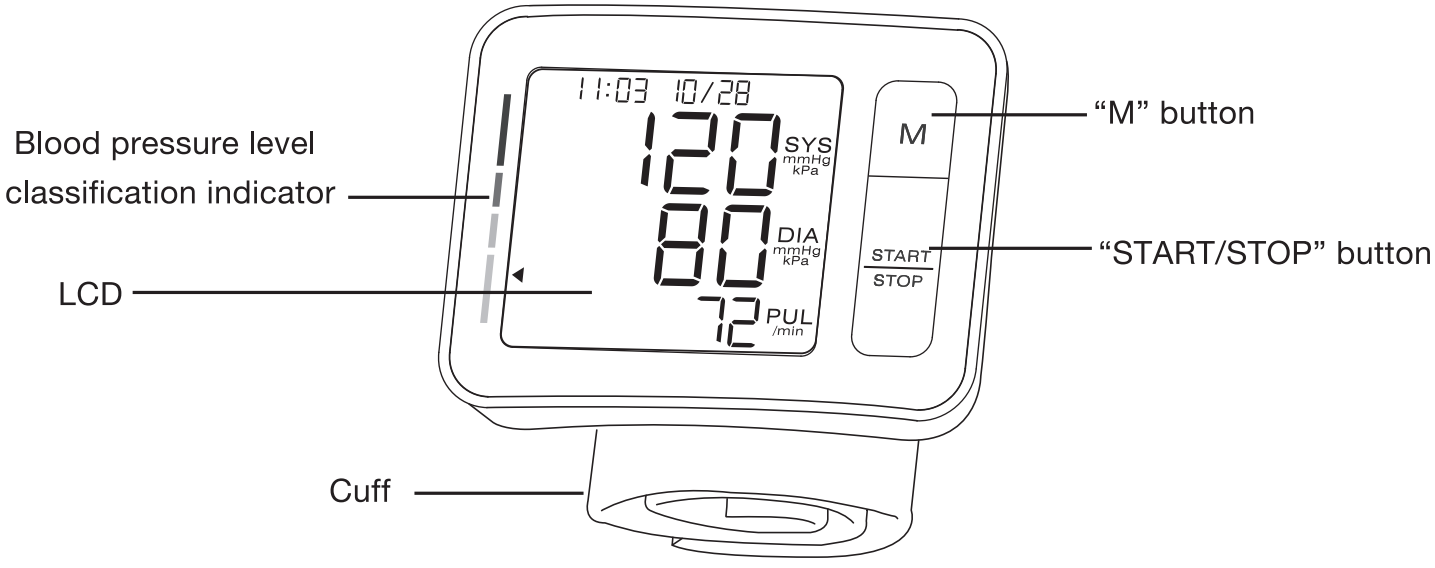


Bluetooth symbol

Low battery

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

Heartbeat indicator



INTENDED USE

iHealth Push Wrist Blood Pressure Monitor is for use by medical professionals or by individuals (patients) at home. It is a non-invasive blood pressure measurement system intended to measure the diastolic blood pressure, systolic blood pressure 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 5.5-7.7 in (14.0-19.5 cm).

BOX CONTENTS

- Wrist Blood Pressure Monitor
- Carrying Case
- 2 1.5V AAA Batteries
- Instruction Manual

CONTRAINDICATION

⚠ This Blood pressure monitor (Electronic Sphygmomanometer) is not suitable for people with severe arrhythmia to use.

PRODUCT DESCRIPTION

The iHealth Push Wrist Blood Pressure Monitor can measure both blood pressure and pulse rate automatically and non-invasively with the oscillometric method and integrated silicon pressure sensor. The LCD display will show blood pressure and pulse rate. The most recent 99 measurements can be stored on the device with date and time stamps.

MOBILE DEVICE COMPATIBILITY

The companion app for this blood pressure monitor works with iOS and Android devices with Bluetooth 4.0.
For a complete list of compatible devices, visit our support page at www.ihealthlabs.com

SPECIFICATIONS

1. Product name: iHealth Push Wrist Blood Pressure Monitor
2. Model: KD-723
3. Classification: Internally powered, Type BF applied part, IP22, No AP or APG, Continuous operation
4. Device dimensions: Approx. 3.1" × 2.4" × 0.9" (80 mm × 60 mm × 22mm) (not including the cuff)
5. Measurable wrist circumference: 5.5-7.7 in (14.0-19.5 cm)
6. Weight: Approx. 3.4 oz (96 g) (not including batteries)
7. Measurement method: Oscillometric method, automatic inflation and measurement
8. Memory: 99 readings with date and time stamps
9. Power source: Batteries: 2 ×1.5V⎓ SIZE AAA
10. Measurement ranges:
    Cuff pressure: 0-300mmHg
    Systolic: 60-260mmHg
    Diastolic: 40-199mmHg
    Pulse: 40-180 beats/minute

11. Accuracy:
    Pressure: ±3mmHg
    Pulse: ±5%
    Precision of the displayed values: 1mmHg
12. Operation conditions: 50°F to 104°F(10°C to 40°C), ≤85% RH, 80kPa-105kPa
13. Storage / Transport conditions: -4°F to 122°F(-20°C to 50°C) , ≤85% RH, 80kPa-105kPa
14. Battery life: Approx. 170 measurements
15. Wireless connection:
    Bluetooth Smart 4.0
    Frequency band: 2.400~2.4835GHz
16. The blood pressure measurement system includes accessories:
    Pump, Valve, LCD, Cuff, and Sensor.

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

WARNINGS AND PRECAUTIONS

1. Read the instructions for use before using the device.
2. Stay still, calm, and rest for 5 minutes before taking a measurement.
3. Please always rest for at least 60 to 90 seconds between measurements to allow the blood circulation in your arm to recover. Prolonged over-inflation (cuff pressure exceeds 300 mmHg or maintained above 15 mmHg for more than 3 minutes) of the cuff may cause ecchymoma of your wrist.

4. Rest your arm so that the cuff is at the same level as your heart.
5. Do not speak or move during measurement.
6. Motion, trembling, and shivering may affect the measurement reading.
7. Use the same arm for each measurement.
8. Consult with your physician if you have any concerns about:
   1) Applying the cuff over a wound or inflammation disease;
   2) Applying the cuff on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present;
   3) Applying the cuff on the wrist on the side of a mastectomy;
   4) Using this monitor and other monitoring medical equipment on the same limb;
   5) The operation of the monitor resulting in prolonged impairment of the circulation of the blood.
9. ⚠ This blood pressure monitor is designed for adults and should never be used on infants or young children below the age of 12. Consult with your physician or other health care professionals before use on older children.
10. The device is not intended for use on infants, children, or pregnant women. (Clinical testing has not been conducted on infants, children, or pregnant women.)
11. Do not use this unit in a moving vehicle, as it may result in erroneous measurements.
12. 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 for electronic or automated sphygmomanometers.

13. For 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 section ELECTROMAGNETIC COMPATIBILITY INFORMATION. It is suggested that the wrist blood pressure monitor be kept 12 inches (30 cm) away from other wireless devices, such as a WLAN unit, cell phone, microwave oven, etc. This monitor cannot be used near active HF SURGICAL EQUIPMENT, and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.
14. If Irregular Heartbeat (IHB) brought by common arrhythmias is detected during measurement, a signal ((♥)) will be displayed. Under this condition, the blood pressure monitor can keep functioning, but the results may not be accurate. It is suggested that you consult with your physician for proper assessment. There are two 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 pulses takes more than 53 percent of the total number.
15. Please do not use any cuff other than those supplied by the manufacturer; otherwise, it may bring biocompatible hazards and result

in measurement error.

16. ⚠ Please do not share the cuff with other infective persons to avoid cross-infection.
17. ⚠ The monitor might not meet its performance specifications or cause a safety hazard if stored or used outside the specified temperature and humidity ranges in “SPECIFICATIONS.”
18. The device would not apply to 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 is not intended for use on patients who use an artificial heart and lung (there will be no pulse).
20. Consult with 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, and pre-eclampsia or renal diseases.
21. Measurements are not possible in patients with a high frequency of arrhythmias.
22. Swallowing batteries and/or battery fluid can be extremely dangerous. Keep the batteries and the unit out of the reach of children.
23. If you are allergic to plastic/rubber, please do not use this device.
24. The blood pressure monitor is not intended to be exposed to the Electromagnetic Interference (EMI) environment, MR please do not use the blood pressure monitor within the environment of the following device:

1) Magnetic Resonance Imaging (MRI)
2) Computerized Axial Tomography (CT)
3) Diathermy
4) Radio Frequency Identification (RFID)
5) Electromagnetic security systems such as metal detectors

OTHER STANDARDS AND COMPLIANCES

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)

SETUP AND OPERATING PROCEDURES

1. DOWNLOAD THE APP (Optional)

Prior to first use, download and install the iHealth Myvitals app from the App Store (iOS device) or Google Play (Android device). Use search term “Myvitals.”

2. INSTALLING BATTERIES

a. Open the battery cover on the back of the blood pressure monitor.
b. Insert two “AAA” batteries as indicated in the battery compartment.
c. Close the battery cover.

Note:

- *When the battery symbol shows on the display, replace batteries with new ones.*
- *Rechargeable batteries are not suitable for this blood pressure monitor.*
- *Remove the batteries if the blood pressure monitor will not be used for at least a month to avoid potential damage from battery leakage.*

⚠ Avoid getting the battery fluid in your eyes. If battery fluid gets in your eyes, immediately rinse with plenty of clean water and consult with your physician.

⚠ The negative(-) side of the battery should be touching the spring.

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

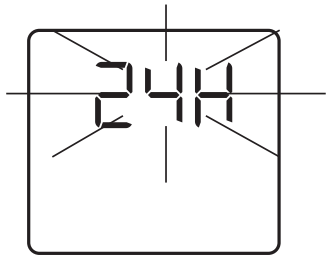
The monitor, the batteries, and the cuff, must be disposed of according to local regulations at the end of their usage.

3. SETTING THE DATE AND TIME

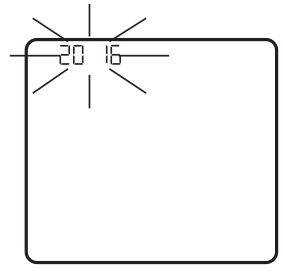
a. Once you insert the batteries, the time format will flash on the display (see picture 3-1), allowing you to adjust the date and time.

b. Press the “M” button to change the time format. If the monitor has no readings stored, the default time format is 24h, and the default date and time is 2016-1-1 12:00. Otherwise, the default time format, date and time remain the same from the most recent measurement.

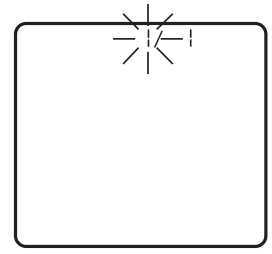
c. Press the “START/STOP” button, the year will flash (see picture 3-2). Then press the “M” button to increase the number. Keep pressing "M", the number will increase faster. Repeat the same steps to adjust the month, day, hour, and minute (see pictures 3-3, 3-4, 3-5 & 3-6).



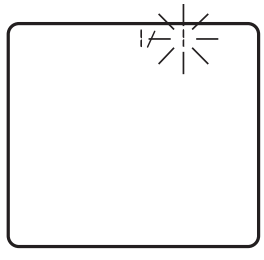
Picture 3-1



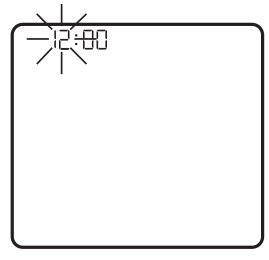
Picture 3-2



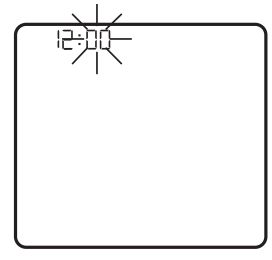
Picture 3-3



Picture 3-4



Picture 3-5



Picture 3-6

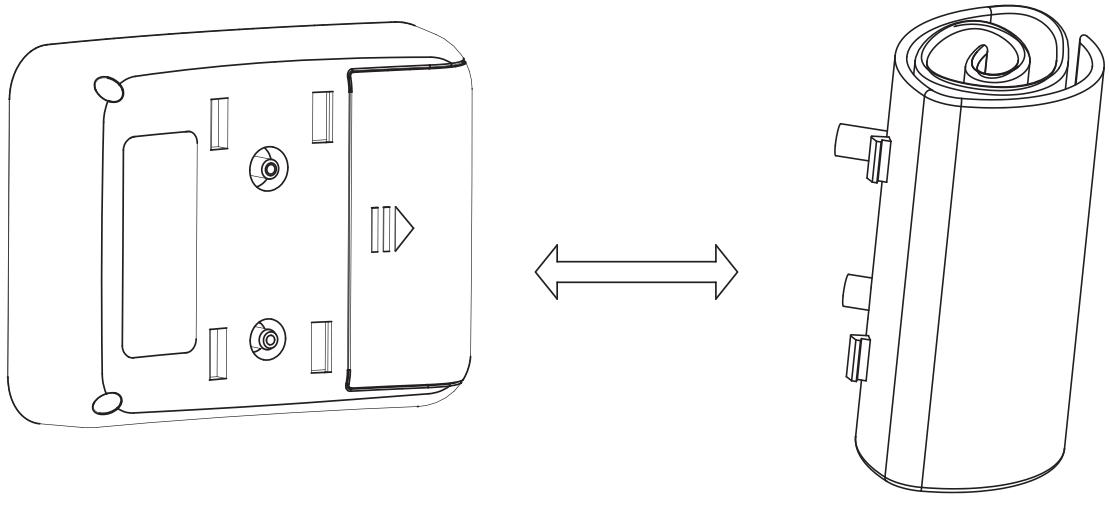
d. You can turn off the monitor by pressing the “START/STOP” button when the minute flashes, confirming the date and time.

Note:

- *When adjusting the date and time, the monitor will automatically go back to Standby Mode if no button is pressed within 30 seconds.*
- *If you need to reset the date and time, hold the “START/STOP” and “M” button for 3 seconds until the time format flashes. You will then be able to set the date and time as the above steps.*

4. 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.

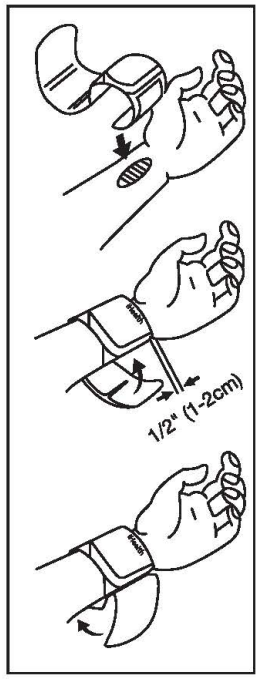


5. APPLYING THE CUFF

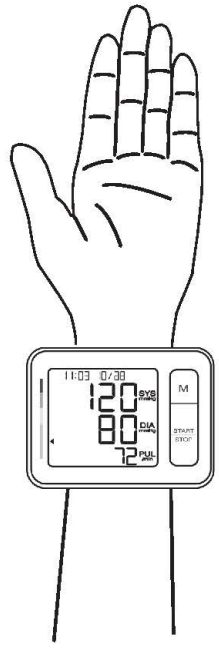
a. Apply the cuff around a bare wrist, leaving a clearance of ½ in (1-2 cm) between the cuff and the bottom of your palm.

b. While seated, place your elbow on the table to support your arm. Both your palm and monitor display should face upward. If the cuff is correctly applied, you should be able to see the LCD display as in picture 5-2 if you wear the cuff on your left wrist, or picture 5-3 if you wear the cuff on your right wrist.

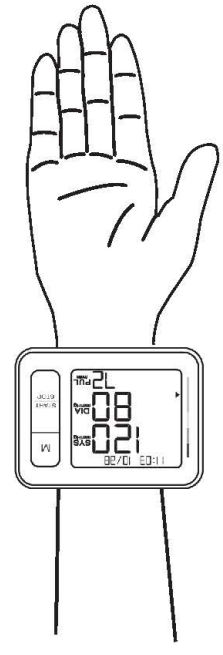
c. The cuff must be neither too tight nor too loose. You should be able to insert one finger between the cuff and your wrist.



Picture 5-1



Picture 5-2



Picture 5-3

Note:

- *Please refer to the measurable wrist circumference in "SPECIFICATIONS" to ensure cuff is suitable for use.*
- *Measure on the same wrist each time.*
- *Do not move your arm, body, or the monitor during measurement.*
- *Stay still, and rest for 5 minutes before taking the measurement.*
- *Please keep the cuff clean. Clean the cuff with a soft wet cloth and mild detergent if the cuff becomes dirty. Do not remove the cuff from the monitor. Cleaning the cuff after every 200 uses is recommended.*
- *Do not place the cuff around your wrist if your wrist has any inflammation, acute diseases, infections, or skin wounds.*

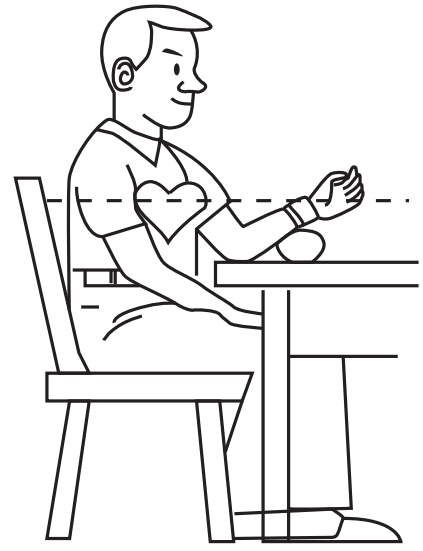
6. BODY POSTURE DURING MEASUREMENT

Sitting Correctly during Measurement

a. Sit with your feet flat on the floor. Do not cross your legs.

b. Place your elbow on a table, with your palm facing upward in front of you.

c. Your monitor should be approximately the same level as your heart. If the monitor is too high above or too low below your heart, your blood pressure will be artificially low or high.



7. TAKING A BLOOD PRESSURE MEASUREMENT

a. After applying the cuff and making sure your body is in a proper position, press the “START/STOP” button, and all symbols will show on the display. See picture 7-1. Please contact customer service if some symbols are missing.

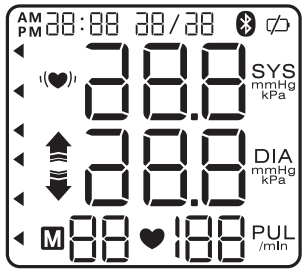
b. If the monitor has stored readings, the display will momentarily show the most recent one. See picture 7-2. If no readings have been stored, zero will appear on the display. See picture 7-3.

c. Please stay still so that the monitor can detect stable pressure within the cuff. The cuff will then start to inflate. See picture 7-4.

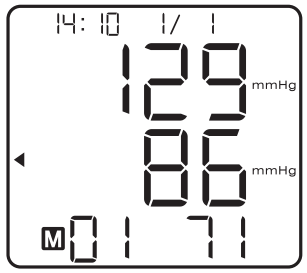
d. The blood pressure and pulse rate will be measured automatically during inflation. Inflation will stop as soon as the blood pressure and pulse rate have been calculated and displayed on the screen. The irregular heartbeat symbol (if applicable) and blood pressure classification indicator will flash on the display. See picture 7-5. The readings will automatically be stored on the monitor. You can press the “M” button to show the stored readings.

e. 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.

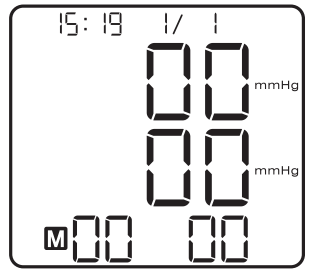
Note: *Please consult with a health care professional for interpretation of measurements.*



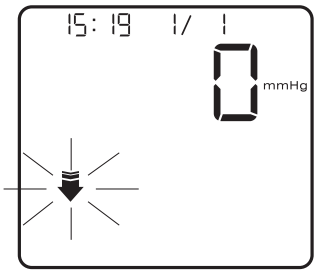
Picture 7-1



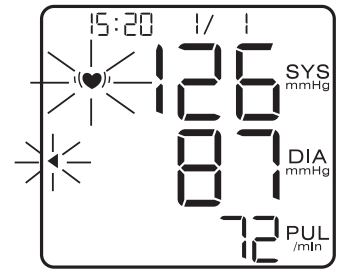
Picture 7-2



Picture 7-3



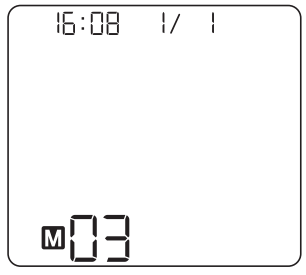
Picture 7-4



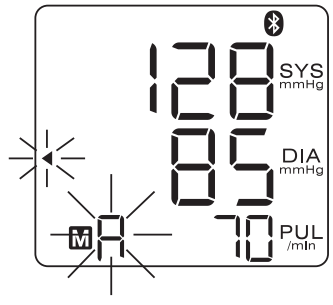
Picture 7-5

8. VIEWING STORED READINGS

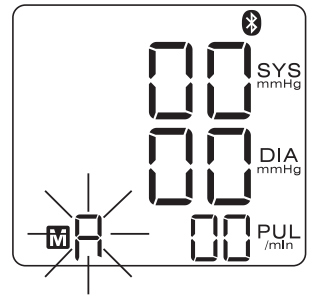
a. In Standby Mode, press the “M” button to display the stored readings. The number of readings will be displayed. See picture 8-1. Then, the display will show the average reading of all measurements. See picture 8-2. If no readings are stored, “00” will appear. See picture 8-3.



Picture 8-1

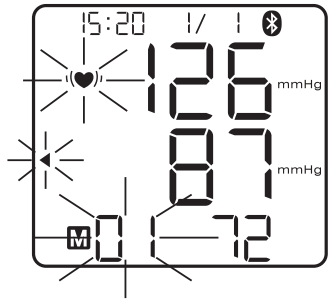


Picture 8-2

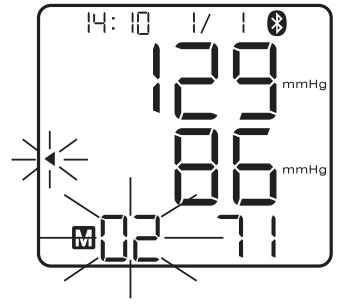


Picture 8-3

b. When the average reading is displayed, press the “M” button to display the most recent readings, see picture 8-4, including blood pressure and pulse rate. The irregular heartbeat symbol will flash, if applicable. Continue pressing the “M” button to view the next reading. See picture 8-5. If the “M” button is pressed again when you reach the last entry, the monitor will turn off.



Picture 8-4



Picture 8-5

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

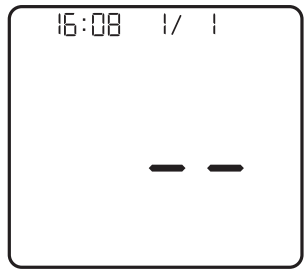
9. SYNCHRONIZING STORED RESULTS WITH APP

a. In Standby Mode, press the “M” button, the Bluetooth symbol will flash, indicating the monitor is ready for Bluetooth to connect. See picture 8-2.
b. The Bluetooth symbol will stop flashing and stay stable when Bluetooth is connected.
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 the stored results with the app, all stored results on the monitor will be removed automatically.

10. DELETING MEASUREMENTS FROM THE DEVICE

When a reading is displayed, holding the “M” button for three seconds will remove all the readings stored on the device. See picture 10.

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

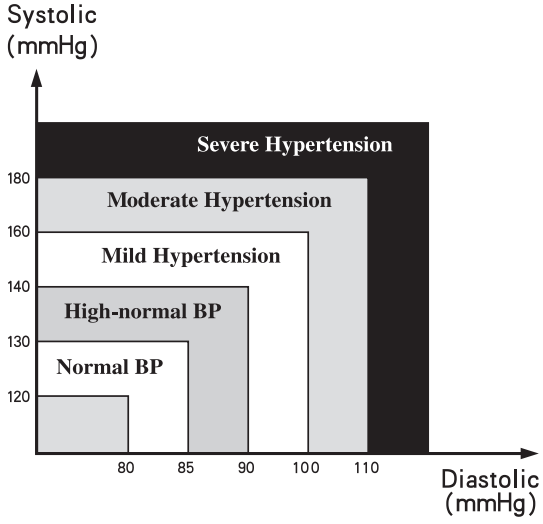


Picture 10

11. 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.) must be considered. Consult with your physician for accurate assessment. Never diagnose or treat yourself based on your readings.

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	YELLOW
Grade 1 Hypertension	140-159	90-99	RED
Grade 2 Hypertension	160-179	100-109	DARK RED
Grade 3 Hypertension	⩾180	⩾110	DARK RED

WHO/ISH Definitions and Classification of Blood Pressure Levels

Note: *It is not intended to provide a basis for any type of rush toward emergency conditions/diagnosis based on the color code. The color code is meant only to indicate different blood pressure levels.*

12. TECHNICAL ALARM DESCRIPTION

The monitor will show 'HI' or 'Lo' as a technical warning on the display immediately if the determined blood pressure (systolic or diastolic) is outside the rated range specified in the “SPECIFICATIONS” section. In this case, you should consult with a physician or check if you have followed the instructions.

The factory’s technical warning condition (outside the rated range) is preset and cannot be adjusted or deactivated. This warning condition is assigned as a low priority according to IEC 60601-1-8.

The technical warning is non-latching and does not require a reset. The signal displayed on the display will disappear automatically after about 8 seconds.

13. TROUBLESHOOTING (1)

PROBLEM	POSSIBLE CAUSE	SOLUTION
Display shows abnormal result	The cuff is not correctly placed, or it is not properly tightened.	Re-apply the cuff correctly and try again.
	Body posture is not correct during a measurement.	Review the “BODY POSTURE DURING MEASUREMENT” section of the instructions and take another measurement.
	You talk, move or get excited during a measurement.	Remain calm and do not talk or move during a measurement.
	Irregular heartbeat (arrhythmia) occurs.	It is not suitable for people with common arrhythmias to use this monitor.

14. TROUBLESHOOTING (2)

PROBLEM	POSSIBLE CAUSE	SOLUTION
Display shows low battery symbol	Batteries are low.	Replace the batteries with new ones.
Display shows “Er 0”	Pressure system is unstable before measurement.	Do not move and try again.
Display shows “Er 1”	Systolic pressure is not detected.	
Display shows “Er 2”	Diastolic pressure is not detected.	
Display shows “Er 3”	Pneumatic system is blocked or cuff is too tight during inflation.	Apply the cuff correctly and try again.
Display shows “Er 4”	Air leak is detected in pneumatic system or cuff is too loose during inflation.	
Display shows “Er 5”	Cuff pressure is above 300mmHg.	Measure again after five minutes. If the monitor is still showing error message, please contact customer service.
Display shows “Er 6”	Cuff pressure is above 15 mmHg for over 3 minutes.	
Display shows “Er 7”	Memory accessing error is detected.	
Display shows “Er 8”	Device parameter checking error is detected.	
Display shows “Er A”	Pressure sensor parameter error is detected.	
No response when you press button or load battery.	Incorrect operation or strong electromagnetic interference occurs.	Remove batteries, wait for five minutes, and then reinstall batteries.

If you have any questions or difficulties using the device, do not hesitate to get in touch with the customer service team by contacting support@ihealthlabs.com or visiting the Support section at www.ihealthlabs.com

MAINTENANCE

1. ⚠ Do not drop this blood pressure monitor or subject it to strong impact.
2. ⚠ Avoid high temperatures and direct sunlight. Do not immerse the blood pressure monitor in water.
3. If this blood pressure monitor is stored near freezing temperatures, allow it to acclimate to room temperature before use.
4. 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 68 °F (20 °C).
5. 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 68 °F (20 °C).
6. ⚠ Do not attempt to disassemble or repair this blood pressure monitor.
7. ⚠ Do not service/maintain the monitor while it is in use.
8. Please remove the batteries if you are not using this blood pressure monitor for at least a month.
9. It is recommended that the performance of this blood pressure monitor should be checked every two years or after repair.

10. No component parts in the monitor can be maintained by the user. The circuit diagrams, component part lists, descriptions, calibration instructions, or other information can be supplied to assist the qualified technical personnel designated by the manufacturer to repair those parts of equipment.
11. The monitor can maintain the safety and performance characteristics for a minimum of 10,000 measurements or three years, whichever comes first. The cuff integrity is maintained after 1,000 open-close closure cycles.
12. Clean the monitor with a soft dry cloth or a soft cloth squeezed well after being moistened with water, diluted disinfectant alcohol, or diluted detergent.
13. The cuff should be disinfected twice weekly if needed (for example, in a hospital or clinic). Wipe the cuff's inner side (the side that contacts skin) with a soft cloth squeezed after moistening with Ethyl alcohol (75-90%), then dry the cuff by airing.

EXPLANATION OF SYMBOLS ON UNIT

THE OPERATION GUIDE MUST BE READ (The background color is blue. The graphical sign symbol is white.)

TYPE BF APPLIED PARTS (The cuff is type BF applied part.)

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.)

WARNING

MANUFACTURER

SERIAL NUMBER

CE 0197 COMPILES WITH MDD93/42/EEC REQUIREMENTS

COUNTRY OF MANUFACTURE (And date of manufacture if adjacent to date information.)

MAGNETIC RESONANCE(MR) UNSAFE

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

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www.ihealthlabs.com

IMPORTANT INFORMATION REQUIRED BY THE FCC

This device complies with Part 15 of the FCC Rules. Its 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.
Changes or modifications not expressly approved by iHealth Labs, Inc. would void the user's authority to operate the product.
Note: This product 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 product 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 product 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.

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.

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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.

ELECTROMAGNETIC COMPATIBILITY INFORMATION

This product applies to the equipment and system requirements to receive radio frequency energy for the work. Bluetooth receives 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, practical radiated power: < 20dBm

This medical device meets the following essential performance requirements:

a) Limits of the error of the cuff pressure indication

b) Reproducibility of the blood pressure determination

c) Alarm

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