iHealth® CardioMed

Ambulatory Blood Pressure Monitor (ABP100)

USER GUIDE

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Introduction to Ambulatory Blood Pressure Monitoring

Thank you for selecting the iHealth CardioMed Ambulatory Blood Pressure Monitoring. Ambulatory blood pressure monitoring (ABPM) is to allow subjects to wear an ambulatory blood pressure recording device for normal daily activities and sleep, the instrument will automatically set blood pressure measurements at intervals, recording 24h. Within the blood pressure data to provide valuable information to understand the level and trend of the patient's blood pressure fluctuations throughout the day.

Indication

The data obtained from ambulatory blood pressure monitors is accurate and useful for managing a wide variety of hypertensive situations including:

- Identifying white-coat hypertension phenomena
- Identifying masked hypertension phenomena
- Identifying abnormal 24-h BP patterns
  - Daytime hypertension
  - Siesta dipping / post-prandial hypotension
  - Nocturnal hypertension
  - Dipping status/isolated nocturnal hypertension
- Assessment of treatment
  - Assessing 24-h BP control
  - Identifying true resistant hypertension
- Assessing morning hypertension and morning BP surge
- Screening and follow up of obstructive sleep apnoea
- Assessing increased BP variability
- Assessing hypertension in the elderly
- Assessing hypertension in high-risk patients
- Identifying ambulatory hypotension
- Identifying BP patterns in Parkinson’s disease
- Assessing endocrine hypertension

Package Contents

* 1 iHealth CardioMed Ambulatory Blood Pressure Monitoring
* 2 Cuffs
* 1 User Guide
* 1 Quick Start Guide
* 1 Charging Cable

Intended Use

The iHealth CardioMed Ambulatory Blood Pressure Monitor is a non-invasive blood pressure measurement system that is intended to be worked with your mobile devices for the recording and displaying of up to 500 measurements of systolic and diastolic blood pressure and heart rate. It is intended for use as an aid or adjunct to diagnosis and treatment when it is necessary to measure an adult (> 12yrs.) patient's systolic and diastolic blood pressures over an extended period of time. The system is only for measurement, recording, and display. It makes no diagnoses.

Contraindication

- Measurements are not possible in patients with a high frequency of arrhythmias
- Do not apply the device to patients with sickle cell disease or patients who have or are expected to develop skin lesions.
- The device is not intended for use on pregnant women, neonates and children. The security and effectiveness of the device has not been validated on pregnant women, neonates and children.
- Do not apply the device to patients with coagulation disturbances.
- 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).

⚠Warning

- Read all of the information in the User Guide and other provided instructions before operating the unit.
- Consult your physician for any of the following situations:

  a) The application of the cuff on any limb with intravascular access or therapy, or an arteriovenous(A-V) shunt.

  b) The application of the cuff on the arm on the side of a mastectomy.

  c) Simultaneous use with other medical monitoring equipment on the same limb.
- Do not use this product in a moving vehicle as this may result in inaccurate measurements.
- If an Irregular Heartbeat (IHB) is detected during the measurement procedure, the IHB symbol will be displayed in the iHealth APP. Under this condition, the Blood Pressure Monitor can keep functioning, but the results may be inaccurate. Please consult your physician for accurate assessment.

  The IHB symbol will be displayed under 2 conditions:

  (1)The coefficient of variation (CV) of pulse period >25%.

  (2)The difference of adjacent pulse period is ≥0.14s and more than 53 percent of the total number of pulses readings falls within this definition.
- This product should not be used as a USB device.
- If the blood pressure measurement (systolic or diastolic) is outside the rated range specified inpart SPECIFICATIONS, the monitor will immediately display a technical alarm on the LED screen. In this case, repeat the measurement ensuring that the proper measurement procedures are followed and/or consult with your medical professional. The technical alarm is preset in the factory and cannot be adjusted or inactivated. This technical alarm is assigned as low priority according to IEC 60601-1-8. The technical alarm does not need to be reset.
- This device requires a medical AC adapter with an output of DC 5.0V that complies with IEC60601-1/UL 60601-1 and IEC 60601-1-2/EN 60601-1-2 such as FJ-SW328U0502000N(input:100-240V~, 50/60Hz, 0.4A Max; output: DC 5V, 2.0A). Please note that the monitor jack size is USB micro B. The USB jack should be used for charging only.
- Use of Charging Cable other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Please do not use any cuff other than that supplied by the manufacturer as this may result in inaccurate measurements.
- The device would not apply to the patients who use an artificial heart and lung (there will be no pulse)
- Consult your physician before using the device for any of the following conditions: common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, pre-eclampsia, renal diseases, secondary hypertension caused by other diseases.

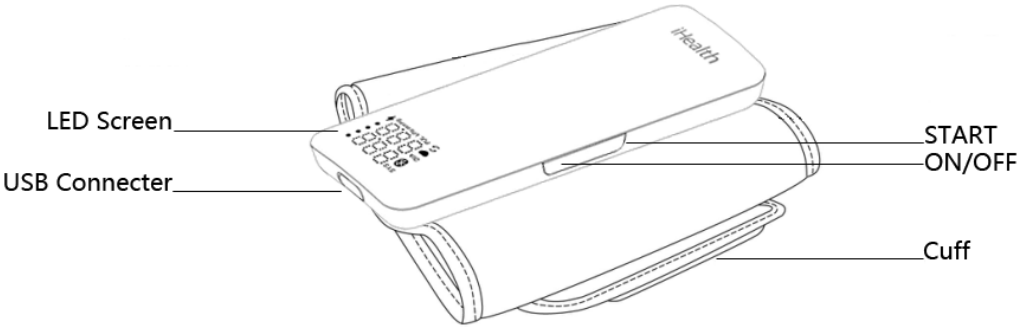
- Whether applying the device to confused, dazed, unconscious or otherwise incapable patients need to consult a physician. The device should be used only under supervision if the physician agrees.
- Whether applying the device to the patients with serious mobility impairments need to consult a physician. The device should be used only under supervision if the physician agrees.
- The device should not be exposed to strong electromagnetic fields, otherwise they may cause inaccurate results or malfunction.
- Do not use the device in combination with high-frequency(HF) surgical equipment.
- Do not use the device in the presence of flammable anaesthetics due to risk of explosion.
- The physician must be certain that, according to the health of the patient, the use of the device will not damage blood circulation in the arm.
- Do not attach the cuff to a limb being used for intravenous infusions. This may cause the infusion to be blocked and cause the patient harm.
- The cuff must not be placed on the area with dermatitis, open wounds and other contraindications. Please consult a physician for specific situation.

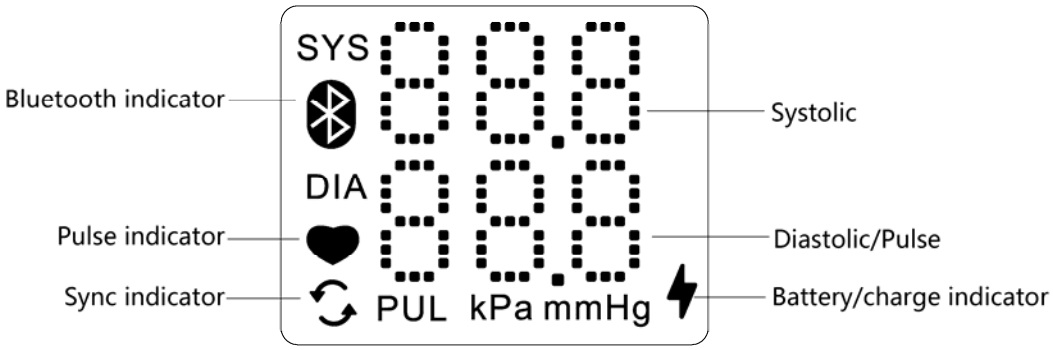
Caution

- Motion, trembling, shivering may affect the measurement reading.
- Blood pressure measurements determined by this product are equivalent to those obtained by professional healthcare practitioners using the cuff/stethoscope auscultation method within the limits prescribed by the American National Standard, Electronic or Automated Sphygmomanometer.
- 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 ELECTROMAGNETIC COMPATIBILITY INFORMATION. It is suggested that the blood pressure monitor be kept 10 meters away from other wireless devices, such as WLAN unit, microwave oven, etc.
- The results of blood pressure measurements may be influenced by: the patient's physical condition, cuff wrapping method, measuring posture, measuring environment etc. Strictly in accordance with product instructions to operate the device, otherwise it may lead to inaccurate results.
- It is recommended to apply the cuff to non-dominant arm. Choose the arm of the other side if there are blood pressure measurement contraindications(e.g. there are open wounds or amputation on the area where the cuff is wrapped) on the arm of one side. Please consult a physician for specific situation.
- Choose the appropriate cuff according to the arm circumference. The arm circumference outside the applicable scope of the cuff may lead to inaccurate results.
- Cuff wrapping method should be strictly in accordance with product instructions. Inappropriate cuff wrapping location, cuff wrapping too loose or too tight, and other factors may lead to inaccurate results.
- When the cuff is placed over thick clothing may result in inaccurate readings.
- Relax and be quiet during measurement, avoid talking and movement. Avoid flexing the muscles or moving the hand and fingers of the cuffed arm during the measurement.
- Do not use the device when it is exposed to mechanical vibration (e.g. in vehicles). Advise patient not to drive but if this is necessary to stop if possible during measurement.
- Please check measurement values by other methods (e.g. auscultation), if you suspect an value.
- To prevent electric shock hazard due to leakage current, only use the power supplies which are compliant with the technical specifications of the device.
- The equipment must never be connected to a printer, computer or other external equipment while still fitted to the patient.

- The physician should make the patient understand the whole measurement procedure and how to cope with the device. Instruct patient how to switch off the device and take off the cuff, in case of malfunctioning and other emergencies, such as repeated inflation.
- If the patient experience arm numbness or pain during the measurement, they should switch off the device immediately and take off the cuff.
- In some patients petechiae, haemorrhages or subcutaneous haematomas may occur. Please consult a physician for specific situation.
- Some patients may be allergic caused by the material of the cuff. Please consult a physician for specific situation.
- It is recommended that the patient record important events, such as take medicine(taking time, drug name, drug dose etc.), awake and asleep periods, any symptoms(pain, dizziness etc.), any events which may influence blood pressure values(after meals, taking a nap, smoking, watching matches, taking a car etc.).
- This product might not meet its performance specifications if stored or used outside the specified temperature and humidity ranges.
- Please do not share the cuff with any infectious person to avoid cross-infection.

PARTS AND DISPLAY INDICATORS





SPECIFICATIONS

1. Product name: iHealth CardioMed

2. Model: ABP100

3. Classification: Internally powered; Defibrillation-proof Type BF applied part; IP22, No AP or APG; Continuous operation

4. Machine size: approx. 5.57″x 2.38″x 0.75″ (141.5mm×60.5mm×19mm)

5. Cuff circumference: 8.66″ to 11.81″(22cm-30cm) and 11.81″ to 16.54″(30cm-42cm)

6. Weight: approx.3.54 oz(110g)(excluding cuff)

7.Measuring method: Oscillometric method, automatic inflation and measurement

8.Memory volume: 500 times with time and date stamp

9. Power: DC:5.0V ⎓ 2.0A, Battery: 1*3.7V ⎓ Li-ion 950mAh

10. Measurement range:

Cuff pressure: 0-300 mmHg

Systolic: 60-260 mmHg

Diastolic: 40-199 mmHg

Pulse rate: 40-180 beats/minute

11. Accuracy:

Pressure: ±3 mmHg

Pulse rate: ±5%

12.Wireless communication:

Bluetooth V4.0

Frequency Band: 2.400-2.4835 GHz

13. Environmental temperature for operation: 5°C-40°C(41°F -104°F)

14. Environmental humidity for operation: ≤85%RH

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

16. Environmental humidity for storage and transport: ≤90%RH

17. Environmental pressure: 80kPa-105kPa

18. Battery life: approx. 120 measurements on a full charge

19. The blood pressure measurement system includes accessories: pump, valve, cuff, LED screen and sensor.

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

SET UP REQUIREMENTS

The iHealth CardioMed Ambulatory Blood Pressure Monitor is designed to be used with the following iPad models:

iPad Air+

iPad mini+

iPad 3+

Please note that the compatible devices are subject to change. For the latest compatibility list, visitwww.ihealthlabs.com/support

BATTERY HANDLING AND USAGE

- **Charge Battery before First Use**
  Connect the monitor to a USB port(Power: DC:5.0V ⎓ 2.0A) using the charging cable provided until the charging indicator steady.
- The battery charge will be displayed on the LED screen after each measurement. And when the monitor is connected to the iHealth APP, the battery charge will be displayed in the APP.
- The monitor will not work until the battery has enough power.
- When the monitor needs charging, please connect the monitor to a power source.
- You should charge the battery when the battery is less than 25% charged. Overcharging the battery may reduce its lifetime.

- When in charging mode, the charging status will be displayed on the LED screen. See the table below for details.

Monitor Status	Status Indicator
Charging	battery/charge symbol flashing slow
Fully charged	battery/charge symbol steady
Battery charge <25%	battery/charge symbol flashing fast
Battery low	battery/charge symbol flashing fast

⚠Do not change the battery. If the battery can no longer be charged, please contact Customer Service.

⚠Overcharging the battery may reduce its lifetime.

⚠Lithium battery replacement by inadequately trained personnel could result in a hazard such as a fire or explosion.

⚠Do not plug or unplug the power cord into the electrical outlet with wet hands. If the AC adapter is abnormal, please change the adapter.

⚠Do not use the monitor while charging.

⚠Do not use any other type of AC adapter as it may harm the monitor.

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

Note: *The battery has limited charge cycles and may eventually need to replaced by an iHealth service provider. Battery life and charge cycles vary by use and settings.*

SET UP PROCEDURES

Download the Free iHealth App

Prior to first use, scan QR code and download the iHealth App. Follow the on-screen instructions to register and set up your personal account.

Access the iHealth Cloud Account

Your iHealth account also gives you access to the secure iHealth cloud service.

Power on the Monitor

Connect the monitor to a USB port using the charging cable provided or press button at least 2 seconds until the LED screen displays all characters to power on the monitor at the first use.

ABPM SYNC AND SETUP

Bluetooth Function

The Bluetooth function is always on if the monitor has enough power. Only if the monitor is in low power status(not enough power to take blood pressure readings), the Bluetooth function will be turned off until the monitor has charged and have enough power.

Connect to iOS Device via Bluetooth

a. Enable Bluetooth on your iOS device.

b. Launch the iHealth App from your iOS device.

c. When a successful connection has been established, the Bluetooth indicator light will light up.

d. When sync is processing, the sync indicator will flash , when sync is finished, the sync indicator lights up for 2 seconds and then light off.

Bluetooth connected Syncing Syncing Sync finished

SYNC TIME AND SETTINGS

Automatic mode is disabled before automatic test parameters are set. Using APP to configuration automatic mode parameters. Time and date on the device will be automatically sync with your smart device when the Bluetooth connection is established.

MEASUREMENT PROCEDURES

Blood pressure can be affected by the position of the cuff and your physiologic condition. It is very important that the cuff should be placed at the same level as your heart.

Body Posture

Sitting Comfortably During Measurement

a. Relax and be quiet during measurement, avoid talking and movement.

b. When measuring in the standing position, let the cuffed arm hang relaxed, slightly away from the body.

c. When measuring in the sitting position, the arm should be supported at heart level.

d. Avoid flexing the muscles or moving the hand and fingers of the cuffed arm during the measurement

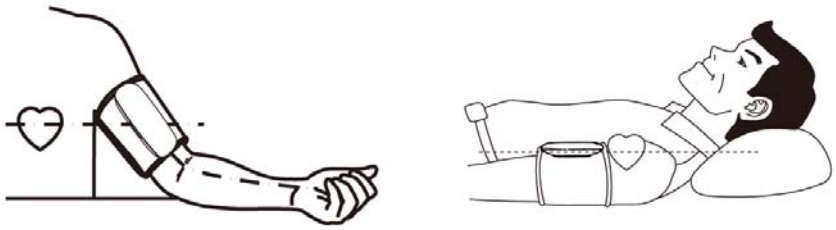
Lying Down During Measurement

a. Lie on your back.

b. Place your arm straight along your side with your hand palm-side up.

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

Note: Blood pressure can be affected by the position of the cuff and your physiologic condition.



Fitting a Patient with the ABPM Cuff

a. Pull the cuff end through the metal loop, positioning it outward (away from your patient body).

b. Place a bare arm through the cuff and position the cuff 1/2"(1-2cm) above the elbow joint.

c. Tighten the cuff by pulling it towards your body, securing it closed with the Velcro fastener.

d. While seated, place your hand, palm-side up, in front of you on a flat surface such as a desk or table.

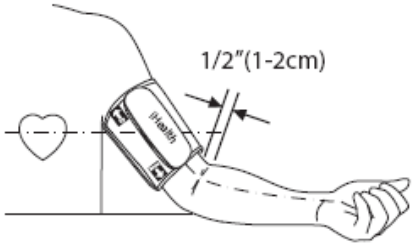
When the left arm is measured, position the monitor in the middle of your arm so that it is aligned with your middle finger.

When the right arm is measured, position the monitor in the middle of your arm so that it is aligned with your middle finger, the “up and down” position is opposite.

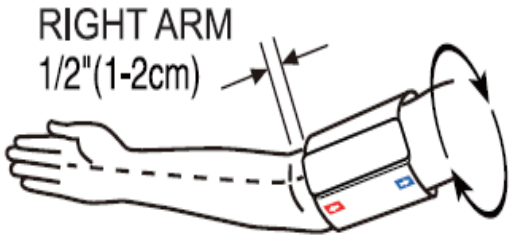
e. The cuff should fit comfortably, yet snugly around your arm. You should be able to insert one finger between your arm and the cuff.

Remember to:

1. Make sure that the appropriate cuff size is used; refer to the cuff circumference range in the Specifications section of this manual.
2. Measure on the same arm each time.
3. Stay still during measurement. Do not move your arm, body or the monitor.
4. Stay still and calm for one to one and half minutes before taking a blood pressure measurement. Prolonged over-inflation of the bladder may cause ecchymoma of your arm.
5. Keep the cuff clean. Cleaning the cuff after every 200 times of usage is recommended. If the cuff becomes dirty, clean it with a moistened cloth. Do not rinse the monitor or cuff with running water.



Left arm measurement



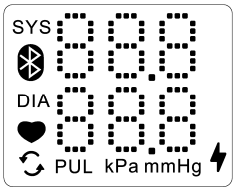
Right arm measurement

TAKING YOUR BLOOD PRESSURE READING

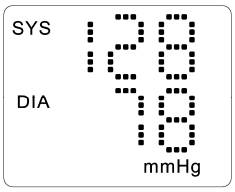
The iHealth CardioMed Ambulatory Blood Pressure Monitor has two measurement modes. Preparing your patient for the ABPM study is the most important step to achieving a successful test.

TAKING YOUR BLOOD PRESSURE READING MANUALLY

a. Long press the button, the monitor will activate and all display characters are shown for self-test. You can check the LED screen display according to the right picture. Please contact the service center if symbol is missing.

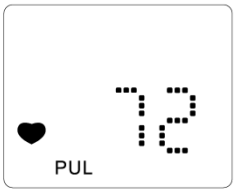


b. Then the cuff will be slowly inflated. The blood pressure and pulse will be measured during inflation. Inflation will stop as soon as the blood pressure and pulse rate have been calculated and displayed on the screen. The result will be automatically stored in the memory, and all results will be uploaded to the App automatically upon the next successful Bluetooth connection.



b. During measurement, you can press the button or button to turn off the monitor manually.

c. After measurement, the monitor will display SYS and DIA in first screen, and then display pulse rate in 2 seconds or press any button, and turn off display in 2 seconds or press any button.



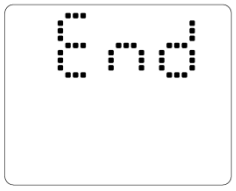
Note: Manual test readings taken before automatic mode is configured cannot be stored in memory.

TAKING YOUR BLOOD PRESSURE READING AUTOMATICALLY

a. Long press the for at least 2 seconds to switch on or off the "Automatic Mode", the monitor shows current automatic mode on the LED screen. If the monitor has no automatic mode parameters, the monitor shows "- -" on the LED monitor. If the monitor has finished the automatic test, the monitor shows "END" on the LED monitor.

b. In the automatic mode, the LED screen is turned off by default. During the test, short press any button to turn on the LED screen and it will last to the end of this measurement.

c. When "Auto Mode" on ,while not in a measurement, short press any button to turn on the LED screen and the LED screen shows the last measurement result.



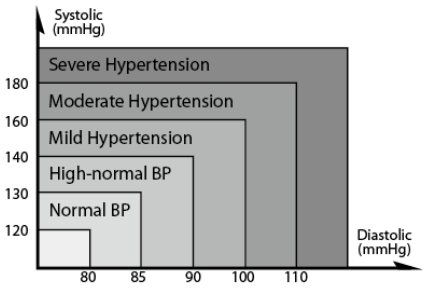
d. When "Auto Mode" on, the monitor will continue take measurements in the scheduled time, and after the monitor get enough readings, the monitor automatic stop taking readings.

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

BLOOD PRESSURE CLASSIFICATION FOR ADULTS

The World Health Organization (WHO) has created the following guide for assessing high blood pressure (without regard to age or gender). Please note that other factors (e.g. diabetes, obesity, smoking, etc.) also need to be considered. Consult with your physician for accurate assessment.

Classification of blood pressure for adults



BLOOD PRESSURE CLASSIFICATION	SBP mmHg	DBP mmHg
Optimal	<120	<80
Normal	120-129	80-84
High-normal	130-139	85-89
Grade 1 Hypertension	140-159	90-99
Grade 2 Hypertension	160-179	100-109
Grade 3 Hypertension	>=180	>=110

WHO/ISH Definitions and Classification of Blood Pressure Levels

Note: Consult your physician for proper interpretation of blood pressure results.

TROUBLESHOOTING

PROBLEM	POSSIBLE CAUSE	SOLUTION
Low Battery	Battery do not have enough power	Charge the battery
LED display reads “Er0”	Pressure system is unstable before measurement	Retest, make sure not to move your arm or the monitor

LED display reads “Er1”	Fail to detect systolic pressure	
LED display reads “Er2”	Fail to detect diastolic pressure	
LED display reads “Er3”	Pneumatic system blocked or cuff is too tight during inflation	Apply the cuff correctly and try again
LED display reads “Er4”	Pneumatic system leakage or cuff is too loose during inflation	
LED display reads “Er5”	Cuff pressure above 300mmHg	Measure again after five minutes. If the monitor is still abnormal, please contact the local distributor or the factory.
LED display reads “Er6”	More than 160 seconds with cuff pressure above 15 mmHg	
LED display reads “Er7”	memory accessing error	
LED display reads “Er8”	Device parameter checking error	
LED display reads “ErA”	Pressure sensor parameter error	
LED display reads “Er	**Bluetooth** communicate error	Reset monitor by pressing the button and holding for about 10 seconds, then connect the mobile device correctly and try again, If the monitor is still abnormal, please contact the local distributor or the factory.
LED display reads an abnormal result	The cuff position was not correct or it was not properly tightened	Review the cuff application instructions and retest
	Body posture was not correct during testing	Review body posture instructions and retest
	Speaking, moving arm or body, being angry, excited or nervous during test	Retest when calm; avoid speaking or movement during the test
Bluetooth connection unstable	**Bluetooth** connection unsuccessful, monitor is abnormal, or strong electromagnetic interference is present	Reset iOS device. Reset monitor by pressing the button and holding for about 10 seconds. Make sure the monitor and iOS device are away from other electrical equipment. Please see Warning
No response when you press button	Incorrect operation or strong electromagneticinterference	Press the button and hold

		for about 10seconds to reset the device.

CARE AND MAINTENANCE

- Strictly in accordance with product instructions to maintain and clean the device.
- If this monitor is stored near freezing temperatures, allow it to return to room temperature before use.
- If the monitor is not used for a long time, please be sure to fully charge it every month.
- No monitor component needs to be maintained by the user. 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 the equipment which are designated for repair can be supplied.
- Clean the monitor with a dry, soft cloth or a moistened and well wrung soft cloth using water, diluted disinfectant alcohol, or diluted detergent.
- The monitor can maintain the safety and performance characteristics for a minimum of 30,000measurements or three years of usage, and the cuff integrity is maintained after 1,000 open-close cycles.
- The battery can maintain the performance characteristics for a minimum of 300 charge cycles.
- It is recommended that if the cuff is used in a hospital or a clinic, it be disinfected twice a week. Wipe the inner side (the side that contacts skin) of the cuff with a soft cloth lightly moistened with Ethyl alcohol (75-90%). Then air dry the cuff.
- It is recommended that product performance be checked every 2 years or after each repair. Please contact the customer service.
- Do not use the device if you think it is damaged or if anything appears unusual. Please refer your device to qualified service personnel of the manufacturers.
- The monitor requires 6 hours to warm or cool from the minimum storage temperature between uses until the monitor is ready for its INTENDED USE when the ambient temperature is 20 °C.
- It may lead to inaccurate results or equipment failure if the device is stored or used outside the specified temperature and humidity ranges.

⚠Do not drop this monitor or subject it to strong impact.

⚠Avoid high temperature and direct sunlight. Do not immerse the monitor in water as this will result in damage to the monitor.

⚠Do not attempt to disassemble this monitor.

⚠Battery replacement should only be performed by a qualified iHealth technician. To do otherwise will void your warranty and possibly damage your unit.

⚠Cuff replacement should only be performed by a qualified iHealth technician. To do otherwise will possibly damage your unit.

WARRANTY INFORMATION

The iHealth CardioMed Blood Pressure Monitor is warranted to be free from defects in materials and workmanship within one year from the date of purchase when used in accordance with the provided instructions. The warranty extends only to the end user. We will, at our option, repair or replace without charge the iHealth Next Blood Pressure Monitor covered by the warranty. Repair or replacement is our only responsibility and your only remedy under the warranty.

EXPLANATION OF SYMBOLS

 Symbol for "DEFIBRILLATION-PROOF TYPE BF APPLIED PARTS" (cuff only)

 Symbol for "THE OPERATION GUIDE MUST BE READ"

The sign background color: blue The sign graphical symbol: white

 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 "WARNING"

 Symbol for "MANUFACTURER"

 Symbol for "EUROPEAN REPRESENTATIVE"

 Symbol for "COMPILES WITH MDD93/42/EEC REQUIREMENTS"

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”

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Tel: 86-22-60526161

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 this device must accept any interference received, including interference that may cause undesired operation.

(2) Changes or modifications not expressly approved by iHealth Lab 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.

Please take attention that changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radioexempts de licence.

L'exploitation est autorisée aux deux conditions suivantes :

(1) l'appareil ne doit pas produire de brouillage, et

(2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut

fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada. Dans le but de réduire les risques de brouillage radioélectrique à l'intention des autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante.

Hereby, [ANDON HEALTH CO., LTD.] declares that the equipment type [ABP100] is incompliance with Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at the following internet address: www.ihealthlabs.eu

OTHER STANDARDS AND COMPLIANCES

The iHealth CardioMed Ambulatory Blood Pressure Monitor corresponds to the following 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);

IEC 60601-1-2:2014/EN 60601-1-2:2007/AC:2010(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 + 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).

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: <4dBm.

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 ±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

Table 3 – Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m

870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

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 100kHz 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	3V, 0.15MHz-80MHz 6V in ISM and amateur radio bands between 0.15MHz and 80MHz 80%AM at 1kHz
Voltage dips	IEC 61000-4-11	0% U_T; 0.5 cycle At 0º, 45º, 90º, 135º, 180º, 225º, 270º and 315º
		0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0º
Voltage interruptions	IEC 61000-4-11	0% U_T; 250/300 cycles

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