iHealth®
Blood Pressure Monitor (BPM1AE)
OWNER'S MANUAL

Table of Contents

INTRODUCTION

Thank you for selecting the BPM1AE. The BPM1AE is a fully automatic arm cuff blood pressure monitor that uses the oscillometric principle to measure your blood pressure and pulse rate. The monitor can transmit your measurements to iHealth cloud when it connected with wifi.

PACKAGE CONTENTS

- 1 Blood Pressure Monitor
- 1 Owner's Manual
- 1 Cuff
- 1 Charging Cable

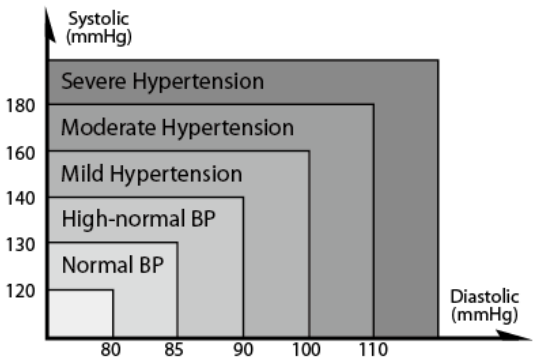
INTENDED USE

The BPM1AE(Electronic Sphygmomanometer) is intended for use in a professional setting or at home and is a non-invasive blood pressure measurement system. It is designed to measure the systolic and diastolic blood pressures and pulse rate of an adult individual by using a technique in which an inflatable cuff is wrapped around the upper arm. The measurement range of the cuff circumference is 8.6" to18.9' (22cm-48cm)

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

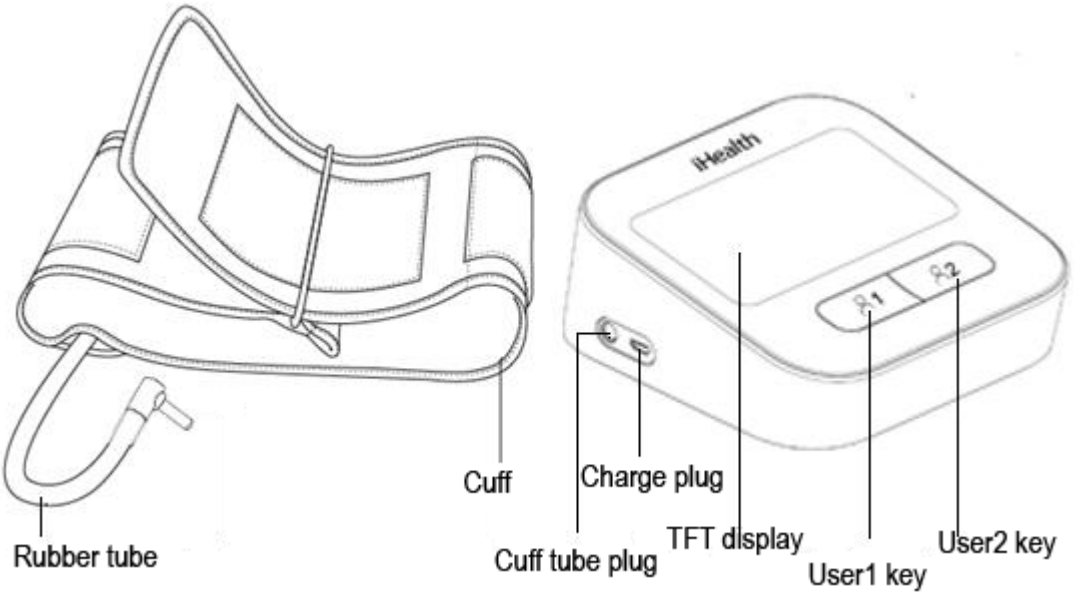
Note: This chart is not intended to provide a basis for any type of emergency condition or diagnosis based on the color scheme; this chart

only depicts different classifications of blood pressure. Consult your physician for proper interpretation of blood pressure results.

CONTRAINDICATION

⚠It is not recommended for people with serious arrhythmia to use this Blood Pressure Monitor.

PARTS AND DISPLAY INDICATORS



SETUP AND OPERATING PROCEDURES

Download The Free iHealth App

Prior to first use, download and install the iHealth App from the App Store(iOS device) or Google Play(Android device). Use keyword search terms ”iHealth” , ”BPM1AE” or ”Blood Pressure Monitor”.

Set Wi-Fi

Step 1: Press and hold the user2 key for 10s, the monitor will display “Open MyVitals App, ready to connect”.

Step 2: Launch the App and set the Wi-Fi linking of BPM1AE with App guidance.

Step 3: If the monitor connects with router, the monitor will display ”Success at once, just a moment… ”.

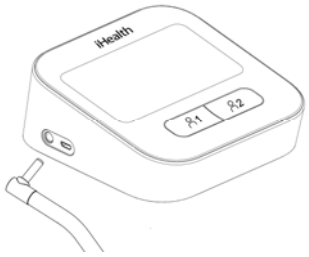
Step 4: If the monitor connects to cloud, the monitor will display “Wi-Fi setting is success, if the App reminder over time, please reopen the App”. Then Wi-Fi set done.

If Wi-FI set done, the monitor will connect to cloud at 2 hour intervals. If new version software release the monitor will updata automatic when it connect to cloud.
The monitor can sync clock with cloud automatic when it connect to cloud.

OPERATING PROCEDURES

Connecting The Cuff To The Monitor

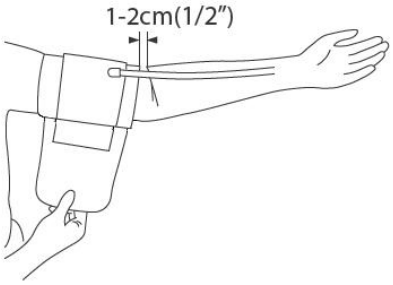
Insert the cuff tubing connector into the air port in the side of the monitor. Make sure that the connector is completely inserted to avoid air leakage during blood pressure measurements.



⚠ Avoid compression or restriction of the connection tubing during measurement, which may cause inflation error, or harmful injury due to continuous cuff pressure.

⚠ When the monitor in turn off mode, insert the cuff tubing connector the monitor will turn on.

Apply The Cuff



a. Pull the cuff end through the metal loop, positioning it outward (away from your body).
b. Place a bare arm through the cuff and position the cuff 1/2"(1-2 cm) above the elbow joint.
c. Tighten the cuff and close it 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. Position the rubber tube in the middle of your arm aligned with your middle finger.
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:

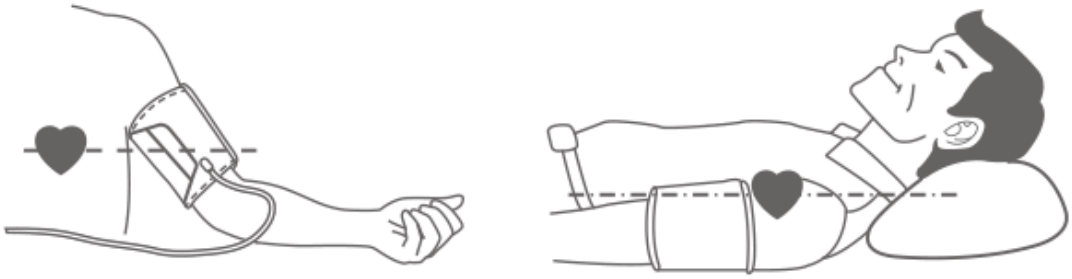
1. Make sure that the appropriate cuff size is used; refer to the cuff circumference range in "SPECIFICATIONS".
2. Measure on the same arm each time.
3. Stay still during measurement. Do not move your arm, body, or the monitor.

4. Stay still and calm for one to one and half minutes before taking a blood pressure measurement.
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.

Body Posture

Sitting Comfortably During Measurement

a. Be seated with your feet flat on the floor without crossing your legs.
b. Place your hand palm-side up in front of you on a flat surface such as a desk or table.
c. The middle of the cuff should be at the level of the right atrium of your heart.



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.

OPERATION INSTRUCTIONS

a. After applying the cuff and your body is in a comfortable position, press user1 key or user2 key the the monitor will turn on and display “While measuring, please relax”. Then the monitor starts to seek zero pressure. If the cuff doesn’t connect with the monitor, press any key the door temperature, outdoor tempetature(if Wi-Fi set done) ,the battery valume and clock(if Wi-Fi set done) will display on monitor for 3 seconds, Then the monitor will turn off automatically.
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 automatically be stored in the Memory bank of the monitor. If memory is stored

in the current memory group, the machine will show the difference between the current measurement results and the latest measurement. If the monitor connect to cloud, the measurements will be transmit to cloud automatically.

c. If the monitor connect to cloud and download the outdoor remind, press any key the monitor will display the outdoor remind, otherwise press any key the monitor will turn off.
d. After measurement, the monitor will turn off automatically after 1 minute of no operation.
e. During measurement, you can press the any key to turn off the monitor manually.

Important: Please consult a healthcare professional for interpretation of blood pressure measurements

SPECIFICATIONS

1. Product name: Blood Pressure Monitor
2. Model: BPM1AE
3. Classification: Internally powered, Type BF applied part, IP20, No AP or APG, Continuous operation
4. Machine size: approx. 4.7” x 4.6” x 2.0”(119mm × 118mm × 51mm)
5. Cuff circumference: 8.6’’-11.8’’(22cm-30cm), 11.8’’-16.5’’(30cm-42cm) (Optional), 16.5’’-18.9’’(42cm-48cm) (Optional)
6. Weight: approx. 12.3oz (350g) (excluding cuff)
7. Measuring method: Oscillometric method, automatic inflation and measurement
8. Memory volume: 2*1000 times with time and date stamp
9. Power: DC:5V⎓ 1.0A,

   Battery: 1*3.7V⎓Li-ion 2200mAh
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:
    Wi-Fi: IEEE802.b/g/n
13. Environmental temperature for operation: 10℃～40℃(50℉～104℉)
14. Environmental humidity for operation: ≤85%RH

15. Environmental temperature for storage and transport: -20℃～50℃(-4℉～122℉)
16. Environmental humidity for storage and transport: ≤85%RH
17. Environmental pressure: 80kPa-105kPa
18. Battery life: more than 180 measurements on a full charge
19. The blood pressure measurement system includes accessories, pump, valve, cuff, and sensor.

Note: These specifications are subject to change without notice.

GENERAL SAFETY AND PRECAUTIONS

1. Read all of the information in the Owner's Manual and other provided instructions 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 1.5 minutes between measurements to allow the blood circulation in your arm to recover. Prolonged over-inflation (cuff pressure exceed 300 mmHg or maintained above15 mmHg for longer than 3 minutes) of the bladder may cause ecchymoma of your arm.
7. Consult your physician for any of the following situations:
   a) The application of the cuff over a wound or inflamed area
   b) The application of the cuff on any limb with intravascular access or therapy, or an arterio-venous (A-V) shunt
   c) The application of the cuff on the arm on the side of a mastectomy
   d) Simultaneous use with other medical monitoring equipment on the same limb
   e) The blood circulation of the user needs to be checked
8. ⚠This Blood Pressure Monitor is designed for adults and should never be used on infants, young children, pregnant or pre-eclamptic patients. Consult your physician before use on children.
9. Do not use this product in a moving vehicle as this may result in inaccurate measurements.
10. 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.

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 ELECTROMAGNETIC COMPATIBILITY INFORMATION. It is suggested that the blood pressure monitor be kept 10 meters away from other wireless devices, such as WLAN unit, cell phone, microwave oven, etc.
12. If Irregular Heartbeat (IHB) is detected during the measurement procedure, the IHB symbol will be displayed. Under this condition, the Blood Pressure Monitor can keep functioning, but the results may be inaccurate. Please consult 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 percent of the total number of pulses.
13. Please do not use any other cuff other than that supplied by the manufacturer as this may result in measurement errors and a biocompatible hazard.
14. ⚠This product might not meet its performance specifications if stored or used outside the specified temperature and humidity ranges.
15. ⚠Please do not share the cuff with any infectious person to avoid cross-infection.
16. This product should not be used as a USB device.
17. If the determined blood pressure (systolic or diastolic) is outside the rated range specified in part SPECIFICATIONS, the app will immediately display a technical alarm on screen. In this case, consult a physician or ensure that proper measurement procedures are followed. 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 is non-latching and does not need to be reset.
18. A medical AC adapter with an output of DC 5.0V and complies with IEC 60601-1/UL 60601-1 and IEC 60601-1-2/EN 60601-1-2 is suitable for this monitor. Please note that the monitor jack size is USB micro-B.
19. 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.
20. Measurements are not possible in patients with a high frequency of arrhythmias.
21. 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.)
22. Motion, trembling, shivering may affect the measurement reading.

23. 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).
24. The device would not apply to the patients who use an artificial heart and lung (there will be no pulse)
25. 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, enal diseases.
26. The patient can be an intended operator.

BATTERY HANDLING AND USAGE

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

- When charging is needed, please connect the monitor to a power source. The monitor can work normally while charging.
- If the cuff doesn’t connect with the monitor, press any key the door temperature, outdoor tempetature(if Wi-Fi set done) ,the battery valume and clock(if Wi-Fi set done) will display on monitor. If the power is less than 20%(the battery valume indication only display a battery symbol), please charge the battery. The monitor will not work until the battery has enough power.
- When you charge the monitor, the monitor will display with different indicator indicating the charging status. See the table below for details.
- It is suggested that you charge the battery when the battery is less than 25%. 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 pull out the adapter when you are using the monitor.

⚠ 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.

Monitor Status	**Status Indicator**
Charging	dynamical battery symbol
Fully charged	full battery symbol
Low battery	empty battery symbol and reminder”Low battery unable to perform measurement, please recharge”

TECHNICAL ALARM DESCRIPTION

The monitor will show 'SYS or DIA beyond measurement range' or ' SYS or DIA below measurement range'' as technical alarm on screen 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 screen will disappear automatically after about 8 seconds.

TROUBLESHOOTING

PROBLEM	POSSIBLE CAUSE	SOLUTION
Low Battery	Battery is less than 20%	Charge the battery
Display reads “ERR xxx”	Blood pressure is outside of measurement range	Retest, make sure your blood pressure is within measurement range
	Arm or monitor was moved during test	Retest, make sure not to move your arm or the monitor
	The cuff does not inflate properly or pressure falls quickly during test	Review the cuff applizcation instructions and retest

	The cuff was not properly applied or the rubber tube was bent or pressed	Review the cuff application instructions and retest
Display reads an abnormal result	The cuff position was not correct or it was not properly tightened.	Review the cuff supplication 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
No response	Incorrect operation or strong electromagnetic interference	Press the user2 key about 10 seconds to reset the device, relaunch app, and reconnect the iOS device to the monitor

CARE AND 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 temperatures, allow it to acclimate to room temperature before use.
4. ⚠Do not attempt to disassemble this monitor.
5. If the monitor is not used for a long time, please sure to fully charge it every month.
6. It is recommended that product performance be checked every 2 years or after each repair. Please contact the service center.
7. 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.
8. Clean the monitor with a dry, soft cloth or a moistened and well wrung soft cloth using water, diluted disinfectant alcohol, or diluted detergent
9. The monitor can maintain the safety and performance characteristics for a minimum of 10,000 measurements or three years of usage,and the cuff integrity is maintained after 1,000 open-close cycles of the closure.
10. The battery can maintain the performance characteristics for a minimum of 300 charge cycles. Battery replacement should only be performed by a qualified iHealth technician. To do otherwise will void your warranty and possibly damage your unit.
11. Cuff replacement should only be performed by a qualified iHealth technician. To do otherwise will possibly damage your unit.
12. It is recommended that if the cuff is used, for example, 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.

WARRANTY INFORMATION

The 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 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 ”THE OPERATION GUIDE MUST BE READ”
The sign background color: blue.
The sign graphical symbol: white.

 Symbol for “WARNING”

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

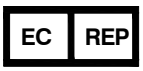
 Symbol for “ENVIRONMENT PROTECTION – Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice”.

 Symbol for “MANUFACTURER”

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

 Symbol for“ DATE OF MANUFACTURE”

 Symbol for “SERIAL NUMBER”

 Symbol for “EUROPEAN REPRESENTATIVE”

 Symbol for “KEEP DRY”

iHealth is a trademark of iHealth Labs Inc.

Manufactured for iHealth Labs Inc.
719 N. Shoreline Blvd., Mountain View, CA 94043, USA
1-855-816-7705
www.ihealthlabs.com

iHealthLabs Europe SARL
3 rue Tronchet, 75008, Paris, France
support@ihealthlabs.eu www.ihealthlabs.eu

ANDON HEALTH CO., LTD.
No. 3 Jinping Street, Ya An Road, Nankai District, Tianjin 300190, China

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 (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.

The SAR limit of USA (FCC) is 1.6 W/kg averaged over one gram of tissue. Device has also been tested against this SAR limit.

IC NOTICE

The SAR limit of Canada (IC) is 1.6 W/kg averaged over one gram of tissue. Device has also been tested against this SAR limit.

This Class B digital apparatus complies with Canadian ICES-003.
Cet appareil numérique de la classe B est conforme à la norme NMB-003 du Canada.

This product complies with Industry Canada. IC: RSS-247

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.
This product is approved in accordance to R&TTE directive transmitter. Hereby, [iHealth Labs Inc],declares that this BPM1AE is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC. Directive 1999/5/EC declaration of conformity can be downloaded on the following link:
https://www.ihealthlabs.eu/support/certifications

Ce produit est conforme à l'Industry Canada. IC: RSS-247
DECLARATION IC
Le présent appareil est conforme aux CNR d'Industrie Canada applicablesaux appareils ra dio exempts 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 br ouillage est susceptible d'en compromettre lefonctionnement.
Ce produit a été approuvé conformément au directives R&TTE de l'émetteur.
Par la présente, [iHealth Labs Inc.] déclare que l'appareil [BPM1AE] est conforme aux exigences essentielles et aux autres dispositions pertinentes de la directive 1999/5/CE. La déclaration de conformité, les documents réglementaires et certifications iHealth peuvent être consultés via ce lien : https://www.ihealthlabs.eu/support/certifications

OTHER STANDARDS AND COMPLIANCES

The Blood Pressure Monitor corresponds to the following standards:

IEC 60601-1:2005 +A1:2012(E)/EN 60601-1: 2006/A11: 2011 (Medical

electrical equipment -- Part 1: General requirements for basic safety and essential performance), IEC 60601-1-2:2014(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).

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, Wi-Fi receive bandwidth 22M. This product can also be used to include RF transmitter equipment and system requirements and

emission frequency of 2.4GHz ISM band, Wi-Fi modulation types: DBPSK/DQPSK/CCK (DSSS) BPSK/QPSK/16QAM/64QAM (OFDM) , 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 ±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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