iHealth® Ease

Wireless Blood Pressure Monitor (BP3L)

User Guide

EN

INTRODUCTION

Thank you for selecting the iHealth Ease Wireless Blood Pressure Monitor. The iHealth Wireless Blood Pressure Monitor is a fully automatic arm cuff wireless blood Pressure monitor that uses the oscillometric principle to measure your blood pressure and pulse rate. The monitor works with your mobile device to measure, track and share vital blood pressure data.

PACKAGE CONTENTS

- 1 iHealth Wireless Blood Pressure Monitor
- 1 Blood Pressure Cuff
- 1 User Guide
- 1 Quick Start Guide
- 1 Charging Cable

INTENDED USE

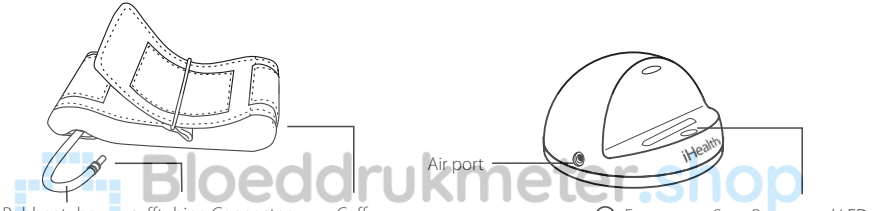
The iHealth Wireless Blood Pressure Monitor (Electronic Sphygmomanometer) is intended for use in a professional setting or at home and is a non-invasive blood pressure measurement system. It is designed to measure the systolic and diastolic blood pressures and pulse rate of an adult individual by using a technique in which an inflatable cuff is wrapped around the upper arm. The measurement range of the standard cuff circumference is 8-21/32" to 14-3/16" (22cm-36cm).

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

CONTRAINDICATION

⚠ It is not recommended for people with serious arrhythmia to use this wireless blood pressure monitor.

PARTS AND DISPLAY INDICATORS



SPECIFICATIONS

1. Product name: Wireless Blood Pressure Monitor
2. Model: BP3L
3. Classification: Internally powered; Type BF applied part; IPX0, No AP or APG; Continuous operation
4. Machine size: approx. 4.53"×4.53"×2.62" (115mm×115mm×66.5mm)
5. Cuff circumference: 8-21/32" to 14-3/16" (22cm - 36cm)
6. Weight: approx. 8.47oz (240g) (exclusive cuff);
7. Power: DC: 5.0V ⎓ 1A, Battery: 1×3.7V ⎓ Li-ion 2200mAh
8. Measurement range:
   Cuff pressure: 0 - 300 mmHg

Systolic: 60 - 260 mmHg
Diastolic: 40 - 199 mmHg
Pulse rate: 40 - 180 beats/minute

9. Accuracy:
   Pressure: ±3 mmHg
   Pulse rate: ±5%
10. Wireless communication:
    Bluetooth Smart
    Frequency Band: 2.402 - 2.480 GHz
11. Environmental temperature for operation: 10°C - 40°C (50°F - 104°F)
12. Environmental humidity for operation: ≤85% RH
13. Environmental temperature for storage and transport: -20°C - 55°C (-4°F - 131°F)
14. Environmental humidity for storage and transport: ≤85% RH
15. Environmental pressure: 80kPa - 105kPa
16. Battery life: more than 500 measurements on a full charge, the battery can maintain the performance characteristics for a minimum of 300 charge cycles
17. 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 User Guide and other provided instructions before operating the unit.
2. 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 arteriovenous (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.

3. Do not use this product in a moving vehicle as this may result in inaccurate measurements.
4. 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.
5. If you are using a smart phone to operate the device and a phone call comes in during the measurement, the measurement process will be terminated automatically. It is thus recommended that the phone be set in Airplane mode during measurement to avoid interrupting the measurement.
6. If an Irregular Heartbeat (IHB) is detected during the measurement procedure, the IHB symbol will be displayed. Under this condition, the Wireless 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 sets of circumstances:
   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.
7. Please do not use any cuff other than that supplied by the manufacturer as this may result in inaccurate measurements.
8. For information regarding potential electromagnetic or other interference between the Wireless Blood Pressure Monitor and other devices together with advice regarding avoidance of such interference, please see ELECTROMAGNETIC COMPATIBILITY INFORMATION. It is suggested that the Wireless Blood Pressure Monitor should be operated at least 10 meters away from electric or wireless devices (e.g. routers,

microwave oven, etc.)

9. If the blood pressure measurement (systolic or diastolic) is outside the rated range specified in part SPECIFICATIONS, the app will immediately display a technical alarm on the 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.
10. This device requires a medical AC adapter with an output of DC 5.0V that complies with IEC 60601-1/UL 60601-1 and IEC 60601-1-2 such as OH-1048A0501000U2 (input: 100-240V, 50/60Hz; output: DC 5V, 1.0A). Please note that the monitor jack size is USB Micro B. The USB jack should be used for charging only.

⚠ This 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.

⚠ 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.

BATTERY HANDLING AND USAGE

- When the monitor is connected to a mobile device, the battery percentage will be displayed in the mobile device app. If the battery charge is less than 25%, please charge the battery. The monitor will not work until the battery has enough power.
- When the monitor needs charging, please connect the monitor to a power source. The monitor will function normally work while charging.

- 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 LED on the device will be displayed with different colors indicating the charging status. See the table below for details.

Monitor Status	**Status Indicator**
Charging	Flashing green light
Fully charged	Steady green light
Low battery	Flashing red light (for a few seconds)
Abnormal state	Steady red light

⚠ 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 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: Battery life and charge cycles vary by use and settings.

TROUBLESHOOTING

PROBLEM	POSSIBLE CAUSE	SOLUTION
Low Battery	Battery is less than 25%	Charge the battery
Display reads "ERROR"	Blood pressure is outside of measurement range	Re-test and contact your health professional if blood pressure measurement is still outside of normal range
	Arm or monitor was moved during test	Re-test, 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 application instructions and re-test
	The cuff was not properly applied	Review the cuff application instructions and re-test
Display reads an abnormal result	The cuff position was not correct or it was not properly tightened	Review the cuff application instructions and re-test
	Body posture was not correct during testing	Review body posture instructions and re-test
	Speaking, moving arm or body, being angry, excited or nervous during test	Re-test when calm; avoid speaking or moving during the test
Bluetooth connection unstable	*Bluetooth* connection unsuccessful, monitor is abnormal, or strong electromagnetic interference is present	Restart iOS/Android device. Reset monitor by pressing the ⏸ button . Make sure the monitor and iOS/Android device are away from other electrical equipment. Please see GENERAL SAFETY AND PRECAUTIONS
No response	Incorrect operation or strong electromagnetic interference	Press the ⏸ button to reset the device and reconnect the iOS/Android device to the monitor, re-launch app.

CARE AND MAINTENANCE

1. If this monitor is stored near freezing temperatures, allow it to return to room temperature before use.
2. If the monitor has not used for a long time, please be sure to fully charge it every month.
3. It is recommended that product performance be checked every 2 years or after each repair. Please contact the iHealth Customer Service Center to do so.
4. 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 by the iHealth technical department.
5. Clean the monitor with a dry, soft cloth or a moistened and well wrung soft cloth using water, diluted disinfectant alcohol, or diluted detergent.
6. 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.
7. The battery can maintain the performance characteristics for a minimum of 300 charge cycles.
8. 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.

⚠ 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 Wireless 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 Wireless 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 "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 "KEEP DRY"

 Symbol for "MANUFACTURER"

 Symbol for "DATE OF MANUFACTURE"

 Symbol for "WARNING"

SN Symbol for "SERIAL NUMBER"

EC REP Symbol for "EUROPEAN REPRESENTATIVE"

CE 0197 Symbol for "COMPILES WITH MDD93/42/EEC REQUIREMENTS"

iHealth is a trademark of iHealth Labs Inc.
"Made for iPod", "Made for iPhone", and "Made for iPad" mean that an electronic accessory has been designed to connect specifically to iPod, iPhone, or iPad, respectively, and has been certified by the developer to meet Apple performance standards. Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards. Please note that the use of this accessory with iPod, iPhone, or iPad may affect wireless performance. iPad, iPhone, and iPod touch are trademarks of Apple Inc., registered in the U.S. and other countries.

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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.

This product is approved in accordance to R&TTE directive transmitter.

Hereby, [iHealth Labs Inc.], declares that this [BP3L EASE] is in compliance with the essentialrequirements 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/certications

OTHER STANDARDS AND COMPLIANCES

The Wireless Blood Pressure Monitor corresponds to the following standards:
IEC 60601-1:2005 corr.1(2006)+corr.2(2007)/EN 60601-1： 2006/A11: 2011(Medical electrical equipment – Part 1: General requirements for safety);
IEC 60601-1-2:2007 /EN 60601-1-2:2007 /AC:2010 (Medical electrical equipment – Part 1: General requirements for safety; Collateral Standard-Electromagnetic compatibility - Requirements and tests);
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);
AAMI/ANSI 80601-2-30：2009/IEC 80601-2-30： 2009+Cor.2010(Medical electrical equipment –Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers).

ELECTROMAGNETIC COMPATIBILITY INFORMATION

Table 1

For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacture's declaration - electromagnetic emissions		
The BP3L is intended for use in the electromagnetic environment specified below. The customer or the user of the BP3L should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The BP3L uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The BP3L is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2

For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration - electromagnetic immunity			
The BP3L is intended for use in the electromagnetic environment specified below. The customer or the user of the BP3L should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3
For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration - electromagnetic immunity			
The BP3L is intended for use in the electromagnetic environment specified below. The customer or the user of the BP3L should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601test level**	**Compliance level**	**Electromagnetic environment - guidance**
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 A/m	Portable and mobile RF communications equipment should be used no closer to any part of the BP3L, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**: 80 MHz to 800 MHz $d=1.2\sqrt{P}$ 800 MHz to 2,5 GHz $d=2.3\sqrt{P}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined

			by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BP3L is used exceeds the applicable RF compliance level above, the BP3L should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BP3L.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Table 4

For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the BP3L

The BP3L is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BP3L can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment(transmitters) and the BP3L as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	$d=1.2\sqrt{p}$ **150 kHz to 80 MHz**	$d=1.2\sqrt{p}$ **80 MHz to 800 MHz**	$d=2.3\sqrt{p}$ **800 MHz to 2,5 GHz**
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.