# EN

## iHealth™ Wireless Blood Pressure Monitor (BP5) OWNER'S MANUAL

## **Table of Contents**

INTRODUCTION ·····	1
PACKAGE CONTENTS PACKAGE CONTENTS	1
INTENDED USE	1
BLOOD PRESSURE CLASSIFICATION FOR ADULTS	2
CONTRAINDICATION	2
PARTS AND DISPLAY INDICATORS	2
SET UP REQUIREMENTS SET UP PROCEDURES	3
SET UP PROCEDURES	4
MEASUREMENT PROCEDURES SPECIFICATIONS	5
SPECIFICATIONS	8
GENERAL SAFETY AND PRECAUTIONS	
BATTERY HANDLING AND USAGE	11
TROUBLESHOOTING CARE AND MAINTENANCE	13
CARE AND MAINTENANCE	14
EXPLANATION OF SYMBOLS	15
IMPORTANT INFORMATION REQUIRED BY THE FCC	
OTHER STANDARDS AND COMPLIANCES	18
ELECTROMAGNETIC COMPATIBILITY INFORMATION	19

## INTRODUCTION

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

#### PACKAGE CONTENTS

- 1 iHealth Wireless Blood Pressure Monitor
- 1 Owner's Manual
- 1 Quick Start Guide
- 1 Charging Cable
- 1 Travel Bag

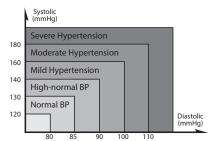
#### **INTENDED USE**

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 cuff circumference is 8.6" to 18.9"(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



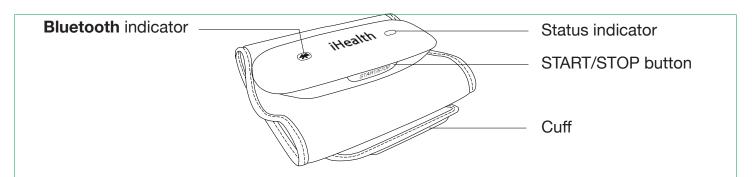
BLOOD PRESSURE CLASSIFICATION	SBP mmHg	DBP mmHg	COLOR INDICATOR		
Optimal	<120	<80	GREEN		
Normal	120-129	80-84	GREEN		
High-normal	130-139	85-89	GREEN		
Grade 1 Hypertension	140-159	90-99	YELLOW		
Grade 2 Hypertension	160-179	100-109	ORANGE		
Grade 3 Hypertension	≥180	≥100	RED		
WHO/ISH Definitions 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 Wireless Blood Pressure Monitor.

#### PARTS AND DISPLAY INDICATORS



## **SET UP REQUIREMENTS**

The iHealth Wireless Blood Pressure Monitor is designed to be used with the following iPod touch, iPhone and iPad models:

Pod touch (5th generation)

iPod touch (4th generation)

Pod touch (3rd generation)

iPhone 5

iPhone 4S

iPhone 4

iPhone 3GS

iPad (4th generation)

iPad (3rd generation)

iPad 2

iPad

iPad mini

The iOS version of these devices should be V5.0 or higher.

#### **SET UP PROCEDURES**

#### Download the Free iHealth MyVitals App

Prior to first use, download and install "iHealth MyVitals" from the App Store.

#### Account Set Up and Registration

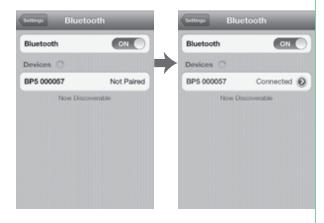
Follow the on-screen instructions to register and set up your personal account.

#### Charge Battery Before First Use

Connect the monitor to a USB port using the charging cable provided until the green indicator light stabilizes.

#### Connect to iOS Device via Bluetooth

- Apply the cuff or press the START/STOP button, the Bluetooth indicator will begin flashing.
- Turn Bluetooth "On" under the "Settings" menu on the iOS device.
- Wait until the model name printed on the monitor, (i.e. "BP5 xxxxxx") and "Not Paired" appear in the **Bluetooth** menu, and select the model name "BP5 xxxxxx" to pair and connect. The **Bluetooth** indicator will remain steady upon successful connection. When using the monitor for the first time, it may take up to 30 seconds for your iOS device to detect the **Bluetooth** signal.



Each subsequent time you use the monitor, "Not Connected" will be displayed next to "BP5 xxxxxxx" in the Bluetooth Menu.

Please repeat these steps when you switch to another iOS device with the monitor.

Monitor Status	Bluetooth Indicator
Waiting to connect	Flashing blue light
Connected and measuring	Steady blue light
Measurement completed and ready to disconnect	Gradually extinguishing light

#### 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**

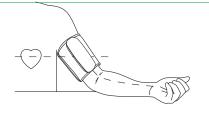
## Sitting Comfortably During Measurement

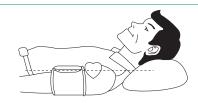
- a. Be seated with your feet flat on the floor without crossing your legs.
- b. Place your hand palm-side up in front of you on a flat surface such as a desk or a table.
- c. The middle of the cuff should be at the level of the right atrium of your heart.

## **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.

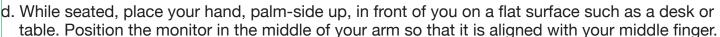




1/2" (1-2cm)

#### 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" (1-2cm) above the elbow joint.
- c. Tighten the cuff by pulling it towards your body, securing it closed with the Velcro fastener.



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.

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.

During measurement, press the "START/STOP" button to stop measurement. Press the "START/STOP" button for 2 seconds to turn off the monitor manually.

#### **Auto Connect Option**

Auto connect option allows the monitor to find the last used iOS device and re-establish the connection automatically. Auto connect option can be enabled in the App. (Device Setting -> Auto Connect -> On)

#### Taking Measurements with Mutiple iOS Devices

Turn off the Bluetooth of the last used iOS device if the Auto Connect option is enabled in your App, then follow the Set Up Instructions in the Quick Start Guide.

#### Measuring without an iOS Device

Enable the Offline Measurement function on the App.(Device Setting -> Offline Measurement -> On)Apply the cuff, follow the "Measurement Procedures", and then press the "START/STOP" button to begin measurement. All offline measurements will be uploaded to the App automatically upon the next successful Bluetooth connection.

For detailed operating instructions, please visit <u>www.ihealthlabs.com</u>.

**Note:** Physical activity including eating, drinking, and smoking as well as excitement, stress, and many other factors influence blood pressure results.

**ATTENTION:** You can stop the measurement process at any time by pressing and holding the "START/STOP" button for 2 seconds.

#### **SPECIFICATIONS**

- 1. Product name: Wireless Blood Pressure Monitor
- 2. Model: BP5
- 3. Classification: Internally powered, Type BF applied part, IPX0, No AP or APG, Continuous operation
- 4. Machine size: approx. 5.7" x 2.3" x 1.2"(145mm × 58mm × 30mm)
- 5. Cuff circumference: 8.6"-16.5"(22cm-42cm), 16.5"-18.9"(42cm-48cm) (XL size sold separately)
- 6. Weight: approx. 5.1oz (145g) (including cuff); approx.5.6oz(160g) (including XL cuff)
- 7. Measuring method: Oscillometric method, automatic inflation and measurement
- 8. Memory volume: 120 times with time and date stamp (off-line measurement only)
- 9. Power: DC: 5.0V === 1.0A, Battery: 1\*3.7V === Li-ion 400mAh
- 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** V3.0 + EDR Class 2 SPP Frequency Band: 2.402-2.480 GHz

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

- 14. Environmental humidity for operation: ≤90%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: more than 80 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. 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. when a call comes in during the measurement, the measurement process will be terminated

- automatically. It is recommended that the iOS device be set in Airplane mode during measurement to avoid strong magnetism interference.
- 6. If 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. There are 2 conditions under which the signal of IHB will be displayed:
  - a) The coefficient of variation (CV) of pulse period >25%.
  - b) 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.
- 7. 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.
- 8. 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.
- 9. This product should not be used as a USB device.
- 10. This product is verified by auscultatory method. It is recommended that you check Annex B of ANSI/AAMI SP-10:2002+A1:2003+A2:2006 for verification method details if needed.
- 11. 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.

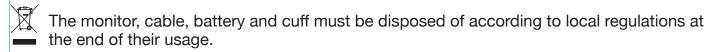
- 12. A medical AC adapter with an output of DC 5.0V and complies with IEC 60601-1/UL 60601-1 and IEC 60601-1-2/EN 60601-1-2 is suitable for this monitor, such as ASP5-05010002JU (input: 100-240V, 50/60Hz, 200mA; output: DC 5.0V, 1.0A). Please note that the monitor jack size is USB mini B.
- ⚠ This Wireless 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.
- ⚠ 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 the iOS device, the battery volume will be displayed on the iOS device. If the power is less than 25%, please charge the battery. The monitor will not work until the battery has enough power.
- When you charge the monitor, the LED will display with different colors indicating the charging status. See the table below for details.
- When charging is needed, please connect the monitor to a power source. The monitor can work normally while charging.
- It is suggested that you charge the battery when the battery is less than 25%.

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.
- ⚠ 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.



**Note:** Battery life and charge cycles vary by use and settings.

PROBLEM	POSSIBLE CAUSE	SOLUTION
Low Battery	Battery is less than 25%	Charge the battery
	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
Display reads "ERROR"	The cuff does not inflate properly or pressure falls quickly during test	Review the cuff application instructions and retest
	Irregular heartbeat (arrhythmia)	It is inappropriate for people with serious arrhythmia to use this monitor. Check with physician
	The cuff was not properly applied	Review the cuff application instructions and retest
	The cuff position was not correct or it was not properly tightened	Review the cuff application instructions and retest
Display reads	Body posture was not correct during testing	Review body posture instructions and retest
an abnormal result	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 START/STOP button about 10s. Make sure the monitor and iOS device are away from other electrical equipment. Please see GENERAL SAFETY AND PRECAUTIONS
No response	Incorrect operation or strong electromagnetic interference	Press the START/STOP button about 10 seconds to reset the device, relaunch app, and reconnect the iOS device to the monitor

#### CARE AND MAINTENANCE

- If this monitor is stored near freezing temperatures, allow it to acclimate to room temperature before use.
- 2. If the monitor is not used for a long time, please 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 Customer Service.
- 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.
- 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.
- 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 openclose cycles of the closure.
- 7. The battery can maintain the performance characteristics for a minimum of 300 charge cycles.
- 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.
- ⚠ 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 "WARNING"



Symbol for "MANUFACTURER"

SN

Symbol for "SERIAL NUMBER"



Symbol for "EUROPEAN REPRESENTATIVE"

**C**€ 0197

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

iHealth is a trademark of iHealth Lab 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.

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

Manufactured for iHealth Lab Inc.

719 N. Shoreline Blvd., Mountain View, CA 94043, USA

+1-855-816-7705 www.ihealthlabs.com

EC REP

Lotus Global Co., Ltd.

REP 15 Alexandra Road, London UK, NW8 0DP

Tel: +0044-20-75868010 Fax: +0044-20-79006187



ANDON HEALTH CO., LTD.

No. 3 Jinping Street, YaAn 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 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.

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.

#### OTHER STANDARDS AND COMPLIANCES

The Wireless Blood Pressure Monitor corresponds to the following standards:

IEC 60601-1:2005 (Medical electrical equipment – Part 1: General requirements for safety);

IEC 60601-1-2:2007 (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);

ANSI/AAMI SP-10:2002+A1: 2003+A2:2006;

AAMI/ANSI 80601-2-30: 2009/IEC 80601-2-30: 2009+Cor.2010/EN 80601-2-30:2010(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 Wireless Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Wireless Blood Pressure Monitor should assure that it is used in such an environment.

<b>Emissions test</b>	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Wireless Blood Pressure Monitor 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	
Harmonic emissions IEC 61000-3-2	Class A	The MONITOR is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

# Table 2 For all ME EQUIPMENT and ME SYSTEMS

#### Guidance and manufacturer's declaration - electromagnetic immunity

The Wireless Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Wireless Blood Pressure Monitor 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 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$ <5 \% \ U_{T} \\ (>95 \% \ dip \ in \ U_{T}) \\ for \ 0.5 \ cycle \\ 40 \% \ U_{T} \\ (60 \% \ dip \ in \ U_{T}) \\ for \ 5 \ cycles \\ 70 \% \ U_{T} \\ (30 \% \ dip \ in \ U_{T}) \\ for \ 25 \ cycles \\ <5 \% \ U_{T} \\ (>95 \% \ dip \ in \ U_{T}) \ for \\ 5 \ s$	$<5 \% \ U_T$ (>95 % dip in $U_T$ ) for 0.5 cycle 40 % $U_T$ (60 % dip in $U_T$ ) for 5 cycles 70 % $U_T$ (30 % dip in $U_T$ ) for 25 cycles $<5 \% \ U_T$ (>95 % dip in $U_T$ ) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the wireless blood pressure monitor requires continued operation during power mains interruptions, it is recommended that the wireless blood pressure monitor be powered from an uninterruptible power supply or a battery.

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.
--	-------	-------	---

NOTE:  $U_T$  is the a.c. mains voltage prior to application of the test level.

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

#### Guidance and manufacturer's declaration - electromagnetic immunity

The Wireless Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Wireless Blood Pressure Monitor should assure that it is used in such an environment.

IMMUNITY test	IEC 60601test level	Compliance level	Electromagnetic environment - guidance	
			Portable and mobile RF communications equipment should be used no closer to any part of the wireless blood pressure monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  Recommended separation distance:	
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = $1.2\sqrt{P}$ 80 MHz to 800 MHz d = $2.3\sqrt{P}$ 800 MHz to 2.5 GHz 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, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup> Interference may occur in the vicinity of equipment marked with the following symbol:		
NOTE 1 At 80 MHz and 800 MHz NOTE 2 These guidelines may no from structures, objects	ot apply in all situations. Electro	applies. omagnetic propagation is affected by absorption and reflection		
<ul> <li>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 MONITOR is used exceeds the applicable RF compliance level above, the MONITOR should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MONITOR.</li> <li>b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</li> </ul>				

# iHealth™

# Wireless Blood Pressure Monitor

Tensiomètre sans fil Misuratore di pressione wireless Monitor de presión arterial inalámbrico Drahtloses blutdruckmessgerät

# OWNER'S MANUAL

MANUEL DE L'UTILISATEUR MANUALE D'ISTRUZIONI MANUAL DEL PROPIETARIO BEDIENUNGSANLEITUNG



#### 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 Wireless Blood Pressure Monitor

The Wireless Blood Pressure Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Wireless Blood Pressure Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MONITOR 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			
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$	
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.