

iHealth™ Wireless Blood Pressure Wrist Monitor (BP7) OWNER'S MANUAL

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INTRODUCTION

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

PACKAGE CONTENTS

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

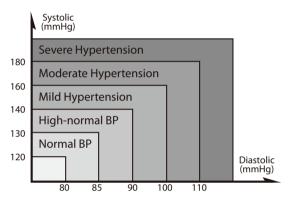
INTENDED USE

The iHealth Wireless Blood Pressure Wrist 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 wrist. The measurement range of the cuff circumference is 5.3" to 8.7" (13.5cm-22cm).

BLOOD PRESSURE CLASSIFICATION FOR ADULTS

The World Health Organization (WHO) has created the following guide for assessing high blood pressur e (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

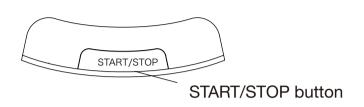
WHO/ISH Definitions and Classification of Blood Pressure Levels

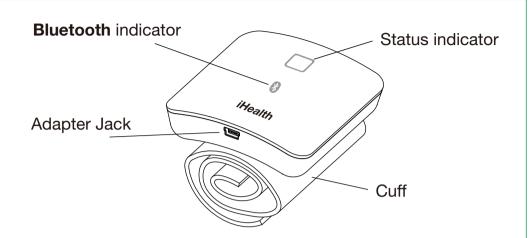
Note: This chart is not intended to provide a basis for any type of emergency condition or diagnosis based on the color scheme; this chart only depicts different classifications of blood pressure. Consult your physician for proper interpretation of blood pressure results.

CONTRAINDICATION

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

PARTS AND DISPLAY INDICATORS





SET UP REQUIREMENTS

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

iPod touch (5th generation)

iPod touch (4th generation)

iPod 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 App

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

Account Set Up and Registration

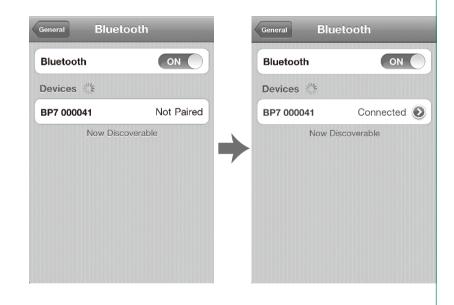
Follow the on-screen instructions to register and set up your personal account.

Charge Battery Prior First Time 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

- a. Apply the cuff or press the START/STOP button, the Bluetooth indicator will begin flashing.
- b. Turn **Bluetooth** "On" under the "Settings" Menu on the iOS device.
- c. Wait until the model name printed on the monitor, (i.e. "BP7 xxxxxxx") and "Not Paired appear in the **Bluetooth** menu, and select the model name "BP7 xxxxxxx" 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.



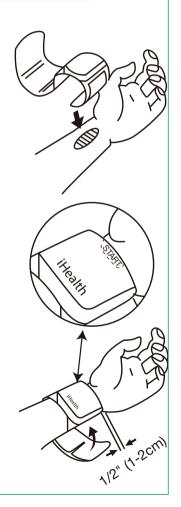
- d. Each subsequent time you use the monitor, "Not Connected" will be displayed next to BP7 xxxxxx" in the **Bluetooth** Menu.
- e. Please repeat these steps when you switch to another iOS device with the monitor.

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

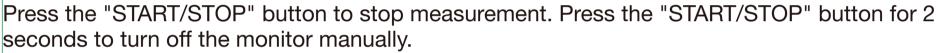
Blood pressure can be affected by the position of the cuff and your physiologic condition. It is very important that you keep your wrist at heart level.

- Be seated comfortably with your feet flat on the floor without crossing your legs. Stay still during measurement. Do not move your wrist, body, or the monitor.
- 2. Place your hand palm-side up in front of you and wrap the cuff around a bare wrist 1/2" (1-2cm) above the wrist joint. If the monitor is correctly placed, iHealth logo will be facing upright.
- 3. The middle of the cuff should be at the level of the right atrium of your heart.
- 4. It is advised to place the monitor's travel case under your arm for support and to keep your arm at optimal height for measurement.
- 5. Adjust the height of your wrist, the App will detect your wrist position and the measurement will start ONLY when the correct position is detected. Follow the on-screen instructions to begin measurement.



Remember to:

- Make sure that the appropriate cuff size is used; refer to the cuff circumference range in "SPECIFICATIONS".
- 2. Measure on the same wrist each time.
- 3. 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.
- 4. 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.



Auto Connect Option

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

Taking Measurements with Multiple iOS Devices

Turn off the Bluetooth on the last used iOS device if the Auto Connect option isenabled 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 instructions, 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 Wrist Monitor
- 2. Model: BP7
- 3. Classification: Internally powered; Type BF applied part; IPX0, No AP or APG; Continuous operation
- 4. Machine size: approx. 2.8"×2.9"×0.7" (72mm×74mm×17.6mm)
- 5. Cuff circumference: 5.3"- 8.7" (13.5cm-22cm), one size only
- 6. Weight: approx. 3.7oz(106g)(including 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

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- 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 wrist 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 Wrist 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.
- 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 Wrist 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 an 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%. Overcharging the battery may reduce its lifetime.

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.
- \triangle 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

PROBLEMA	POSSIBILE CAUSA	SOLUZIONE	
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	
<u></u>	Wrist or monitor was moved during test	Retest, make sure not to move your wrist 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	
Diaplay roads	The cuff position was not correct or it was not properly tightened.	Review the cuff application instructions and retest.	
Display reads an abnormal	Body posture was not correct during testing	Review body posture instructions and retest	
result	Speaking, moving wrist 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	Retest, make sure not to move your wrist or 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 service center.
- 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 open-close
 cycles of the closure.
- 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, 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.
- \triangle Battery replacement should only be performed by a qualified iHealth technician.

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To do otherwise will void your warranty and possibly damage your unit.

WARRANTY INFORMATION

The iHealth Wireless Blood Pressure Wrist 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 Wrist 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"

CE 0197 Symbol for "COMPILES WITH MDD93 /42/FFC REQUIDEMENTO" /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.

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Manufactured for iHealth Lab Inc.

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

+1-855-816-7705 <u>www.ihealthlabs.com</u>

Lotus Global Co., Ltd.

15 Alexandra Road, London UK, NW8 0DP

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



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 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 Wrist 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: Supplemen-

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Wireless Blood Pressure Wrist 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 Wrist Monitor is intended for use in the electromagnetic environment specified below.

The customer or the user of the Wireless Blood Pressure Wrist 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 cycle 70 % U _T (30 % dip in U _T) for 25 cycle $<5~\%~U_{T}(>95~\%~dip~in~U_{T})$ 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 cycle 70 % $U_{T}(30~\%~dip~in~U_{T})$ for 25 cycle $<5~\%~U_{T}(>95~\%~dip~in~U_{T})$ for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the monitor requires continued operation during power mains interruptions, it is recommended that the 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 Wrist Monitor is intended for use in the electromagnetic environment specified below.

The customer or the user of the Wireless Blood Pressure Wrist Monitor should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	I Electromagnetic environment - guidance	
			Portable and mobile RF communications equipment should be used no closer to any part of the 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, 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 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. b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/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 Wireless Blood Pressure Wrist Monitor

The Wireless Blood Pressure Wrist 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 Wrist 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	Separation di	stance according to frequency of tr m		
W W	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.