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iHealth®

www.iHealthLabs.eu

Art Ref: IB/iHealth-ABI 23/10/2015

START/STOP

• Wireless Blood Pressure Monitoring System
BP5(ABI)

• Système de suivi de Tension Artérielle connecté
BP5(ABI)

• Misuratore di Pressione Wireless
BP5(ABI)

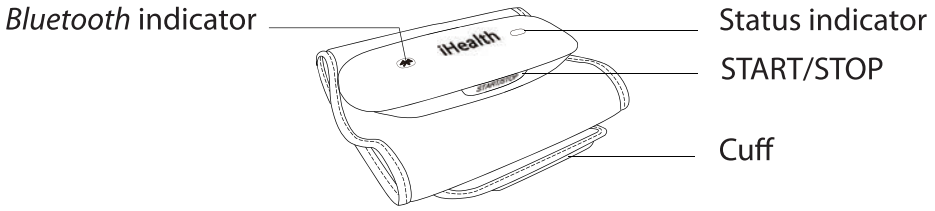
• Kabelloses Blutdruck-Monitoring-System
BP5(ABI)

• Sistema inalámbrico de control de la presión arterial
BP5(ABI)

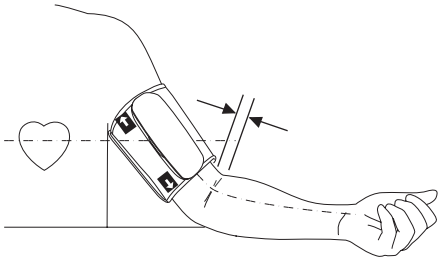
• Draadloos bloeddruk controlesysteem
BP5(ABI)

iHealth®

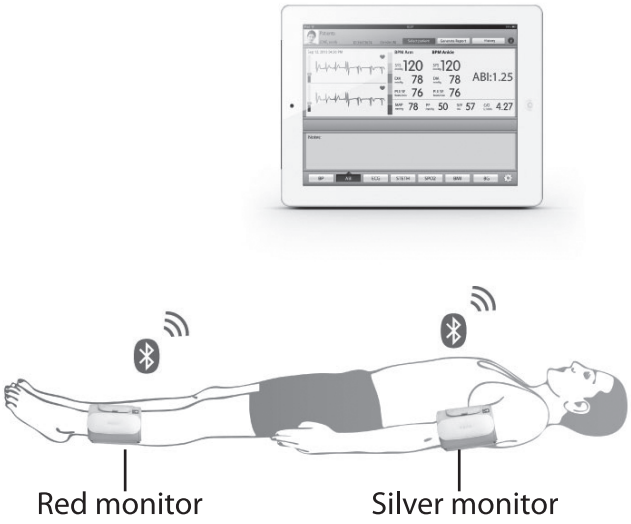
Device description



Position for blood pressure measurement



Position for Ankle Brachial Index measurement



The iHealth BP5 (ABI) is designed to be used with the following iPad models:

- iPad (3rd and 4th generation and above)
- iPad Mini

The iOS version of these devices should be V5.1 or higher.

Please read these instructions carefully **before** using the device.

This device has been developed by iHealth together with a team of medical specialists and engineers. We have taken the utmost care to manufacture a device that is user-friendly and clinically accurate. If you have any suggestions so that we can improve our products, please contact us at contact@ihealthlabs.eu.

This device bears the CE conformity mark. The quality of this wireless device has been verified and conforms to the provisions of the 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: Sup- plementary 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).

This device should give you years of excellent service. However, we recommend that you have the device tested for accuracy every 2 years or after any major mechanical impact (e.g. being dropped).

CONTENTS

THE IHEALTH QUALITY GUARANTEE

We guarantee all our devices for two years from date of purchase by the customer. During this guarantee period, iHealth assures free repair of internal faults or manufacturing errors. If you experience a problem with your device, please pack it carefully and send it to your local iHealth distributor.

Unfortunately, our guarantee does not cover parts subject to wear and tear, damage caused by dropping or impacts, by lack of maintenance, by faulty handling or the in- tervention of a third party, by natural disasters, by battery acid or by any prohibited decontamination or sterilization procedure.

INTRODUCTION

The iHealth BP5(ABI) is a wireless cardiovascular monitoring system that measures or calculates blood pressure, but also a host of other cardiovascular vectors such as Ankle Brachial Index (ABI), Pulse Pressure (PP), Mean Arterial Pressure (MAP), Cardiac Output (CO) and Stroke Volume (SV). It gives a clear and comprehensive picture of a patient's cardiovascular health.

The iHealth BP5(ABI) technology makes it possible to take a clinically accurate and reliable measurement of all these parameters in under 3 minutes.

The monitoring system includes sensing devices that can be used in various combi- nations to take measurements of blood pressure or other parameters such as ABI. The iHealth BP5(ABI) is driven by the iHealth Pro App and is designed for use with the Apple iPad. It calculates ABI in real time and displays real-time pulse waves on the Apple iPad.

COMPONENTS

- 1 x upper arm blood pressure sensor
- 1 x ankle blood pressure sensor
- 1 x Instruction manual
- 2 x mini USB cables
- 1 x travel case

INSTALLING THE APP

Download the iHealth Pro App from the App Store and install it on your iPad. Use the search terms "iHealth Pro". Alternatively, you can find a direct link to download the App on www.iHealthLabs.eu/pro.

CHARGING THE BATTERIES

• First charge the device by connecting the mini-USB cables in the devices and con- necting them to a USB port. The monitors will not work until the batteries have enough power.

• When you charge the monitors, a small LED on the device will display different colors indicating the charge status.

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

LINKING THE MODULES TO YOUR iPad

• Once the devices are fully loaded, press the START/STOP button on the side of the devices. The *Bluetooth* Indicator Light on the devices will begin flashing.

• On your iPad, turn the *Bluetooth* "On" under the "Settings" Menu (Settings->*Bluetooth*->On).

• Wait until the model number printed on the side label of 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 Light will stop flashing once pairing is successful. When using the monitor for the first time, it may take up to 30 seconds for your iOS device to detect the *Bluetooth* signal. Repeat this procedure for both modules.

GETTING PREPARED FOR A BLOOD PRESSURE MEASUREMENT

Blood pressure measurements should ideally be taken when relaxed. When ready to take the reading, sit the patient down and position the cuff so that it is at the level of the heart.

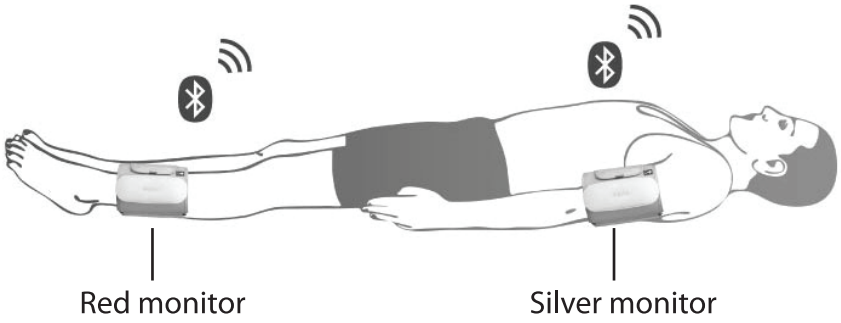
The blood pressure monitor should be at the level of the patient's heart to give accurate measurements. The cuff should fit snugly. It should wrap easily around the limb with some overlap. The edge of the cuff should be about one inch above the bend of the arm with the device over the brachial artery (locate the brachial artery by gently depressing your index and middle finger over the area and feeling for a pulse). There must be no free space between the arm and the cuff as it will influence the result. Clothing must not restrict the arm.

GETTING PREPARED FOR AN ANKLE-BRACHIAL INDEX MEASUREMENT

If you are measuring ABI (Ankle-Brachial Index), one cuff will be placed on the ankle (the one with the red lining and red casing) and the other on the upper arm (the one with the grey lining and the silver casing). In this case it is imperative that the patient be in a supine position (horizontal), so that the 2 cuffs are at the same level. The cuffs should fit snugly. They should wrap easily around the limbs with some overlap. For the ankle cuff the edge of the cuff should be positioned on the ankle with the device on the outside of the leg.

- Place the cuff over the ankle so that the "up" label points in the direction of the patient's head and the "down" label points towards the patient's foot.
- Gently secure the cuff with the Velcro in such a way that it lies comfortably and is not too tight. There must be no free space between the ankle and the cuff as it will influence the result. Clothing must not restrict the ankle.

Once the devices are in place and connected to your iPad, simply start the iHealth Pro App and select "ABI". Press Start to take a measurement of your patient's ABI.



CHECK LIST FOR CORRECT MEASUREMENTS

- Instruct your patient not to use caffeine, tobacco, or alcohol for 30 minutes before a measurement.
- Before a measurement, ask the patient to sit in a chair and relax for 3-5 minutes, and not to talk.
- Put the cuff in the proper place respecting the "up" and "down" labels on the device.
- Make sure that the cuff is at heart level while doing a blood pressure measurement.
- Ensure that the patient is comfortable.

USING THE IHEALTH PRO APP

The iHealth Pro App is your gateway to a comprehensive picture of the cardio-vascular health of your patients. At any time, once a test has been performed, touch the result on the iPad for a pop-up explanation of the result.

ADDING A NEW PATIENT

To add a new patient to the database, tap the Patient icon on the App and select "Add". The Patient ID, Patient name and patient date of birth are fields that MUST be filled in. Though all other fields are optional, please note that certain predictive functions of the iHealth Pro App will not function unless they are filled in.

PATIENT ID

This field is a unique ID that identifies each particular patient. Patients can have identical names, but their IDs must be unique! This field is limited to 30 characters in length.

CHANGING MEASUREMENT UNITS

To change measurement units, tap the SETUP icon.

TAKING A MEASUREMENT

- Ensure that the device batteries are fully charged
- Ensure that your patient is sitting or lying in a comfortable, relaxed position.
- Press the "START/STOP" button at any time to stop measurement.

BLOOD PRESSURE

Position the blood pressure cuff with the silver casing on the arm of the patient. Select the blood pressure function in the App and touch the start button on the iPad.

ANKLE-BRACHIAL INDEX (ABI)

This mode takes simultaneous readings on two parts of the body and compares the two readings. From this, it calculates the ankle-brachial index, which is an indication of arterial blockages or of other peripheral arterial disease.

Position the blood pressure cuff with the silver casing on the arm and the blood pressure cuff with the red casing on the ankle of the patient. Select the ABI function in the App and touch the Start button on the iPad. Do not forget that an ABI measurement MUST be taken with the patient in horizontal position.

PRINTING A REPORT

All the information about the measurement that has just been taken can be printed in the form of a report, by visiting the "History" section and then "Generate Report" button. If you want to keep a hard copy of the report, we suggest you print it to a compatible printer after generating the PDF.

HISTORY SCREEN

The history screen allows you full access to all readings taken for a particular patient. On accessing this screen, the spreadsheet automatically displays all the readings for the patient whose name is displayed at the top of the screen.

WHAT IS SYSTOLIC AND DIASTOLIC PRESSURE?

Blood pressure is a measurement of how much force the blood exerts on the walls of the blood vessels. There are many different events occurring within the body as the heart pumps blood, known collectively as the cardiac cycle, and so blood pressure is measured at different points throughout this cycle.

Blood pressure is recorded in mmHg, or millimeters of mercury. The reading is taken with the patient seated and the arm slightly bent and at the same level as the heart. A cuff is wrapped around the arm an inch above the elbow, and an oscillometric sensor or auscultatory sensor (stethoscope) placed on the large brachial artery in the arm. The cuff is inflated to the point at which point blood flow is negligible. The cuff is then slowly deflated, and the level at which the patient's pulse can first be detected is recorded. This is the systolic blood pressure.

When the pulse is no longer detectable, a second number is recorded: the diastolic pressure, or the lowest amount of pressure in the arteries, occurring while the heart is at rest between beats. These two numbers are recorded as blood pressure - 110/70, for example. The systolic blood pressure reading is the first number, and the diastolic pressure the second.

Note: For ABI mode readings, the separate pressures for each reading are shown and the main number indicates the blood pressure of the patient at the level of the arm.

WHAT IS PULSE?

In medicine, a person's pulse is the throbbing of their arteries as an effect of the heartbeat. It can be felt at the neck, at the wrist and other places.

The term pulse is also used, although incorrectly, to denote the frequency of the heartbeat, usually measured in beats per minute. In most people, the pulse is an accurate measure of heart rate. Under certain circumstances, including arrhythmias, some of the heartbeats are ineffective and the aorta is not stretched enough to create a pal- pable pressure wave. The pulse is irregular and the heart rate can be (much) higher than the pulse rate.

A normal pulse rate for a healthy adult, while resting, can range from 60 to 100 beats per minute (BPM). During sleep, this can drop to as low as 40 BPM; during strenuous exercise, it can rise as high as 200-220 BPM. Generally, pulse rates are higher in younger persons. A resting heart rate for an infant is as high as or higher than an adult's pulse rate during strenuous exercise.

WHAT IS ANKLE-BRACHIAL INDEX (ABI)?

The Ankle-Brachial Index (ABI) is a comparison between the systolic levels of the arms and ankles. It is a fast, effective tool for screening for Peripheral Arterial Disease (PAD), a potentially life threatening disease.

The following table shows the range of possible readings:

ABI Value	**Indication**
0.96 or above	Generally normal
0.81 – 0.95	Mild disease
0.51 – 0.8	Moderate disease
0.31 – 0.50	Moderate to severe disease
0.30 or below	Severe disease

The ABI is calculated by dividing the ankle reading by the upper arm reading.

WHAT IS MEAN ARTERIAL PRESSURE?

The Mean Blood Pressure (MAP) is the average pressure forcing blood through the arteries. It is not the average of the systolic and diastolic blood pressure. It corresponds to a state of balance between the compressive and expansive forces acting on the ar- terial wall when there is no distension of the arterial wall, either outward or inward. MAP is an excellent way to evaluate the stress on the walls of the vessels. It is useful to quickly evaluate excessive load on the cardiovascular system.

The MAP is calculated as: diastolic + (0.412 x (systolic - diastolic))

WHAT IS PULSE PRESSURE?

Pulse pressure is the change in blood pressure seen during a contraction of the heart. Formally it is the systolic pressure minus the diastolic pressure. It is calculated as: Pulse Pressure = Systolic Pressure - Diastolic Pressure

Usually, the resting pulse pressure in healthy adults, sitting position, is about 40 mmHg. The pulse pressure increases with exercise due to increased stroke volume, healthy values being up to pulse pressures of about 100 mmHg. In healthy individuals the pulse pressure will typically return to normal within about 10 minutes.

If the usual resting pulse pressure is measured as less than 40 mmHg: If the pulse pressure is genuinely low, e.g. 25 mmHg or less, the cause may be low stroke volume, as in Congestive Heart Failure and/or shock. This interpretation is reinforced if the resting heart rate is relatively rapid, e.g. 100-120 (in normal sinus rhythm), reflecting increased sympathetic nervous system activity.

If the usual resting pulse pressure is consistently greater than 40 mmHg, e.g. 60 or 80 mmHg, the most likely basis is stiffness of the major arteries, aortic regurgitation (a leak in the aortic valve), an extra path for the blood to travel from the arteries to the veins, hyperthyroidism or some combination. A high resting pulse pressure is harmful and tends to accelerate the normal ageing of body organs, particularly the heart, the brain and kidneys.

WHAT IS STROKE VOLUME?

The stroke volume (SV) is the volume of blood ejected from a ventricle with each beat of the heart.

Its value is obtained by subtracting end-systolic volume (ESV) from the end-diastolic volume (EDV) for a given ventricle: SV = EDV - ESV

In a healthy 70kg man, the left ventricular EDV is 120 ml and the corresponding ESV is 50 ml, giving a stroke volume of 70 ml.

Stroke volume can also be approximated as: SV = Pulse Pressure x 1.7

WHAT IS CARDIAC OUTPUT?

Cardiac output is the volume of blood being pumped by the heart, in particular a ventricle in a minute. It is equal to the heart rate multiplied by the stroke volume.

Therefore, if there are 70 beats per minute, and 70 ml blood is ejected with each beat of the heart, the cardiac output is 4900 ml/minute. This value is typical for an average adult at rest, although cardiac output may reach up to 30 liters/minute during extreme exercise.

APP UPDATES

Regular updates of the iHealth Pro App are available. Depending on the configuration of your iPad, this can be done automatically.

GENERAL SAFETY AND PRECAUTIONS

Read all of the information in the Owner's Manual and other provided instructions before operating the unit.

⚠ It is not advisable for people with serious arrhythmia to use this device.

⚠ Do not apply the cuff on the arm on the side of a mastectomy.

⚠ Do not use this product in a moving vehicle as this may result in inaccurate measurements.

⚠ Blood pressure measurements determined by this device are equivalent to those obtained by professional healthcare practitioners using the cuff/stethoscope auscul- tation method within the limits prescribed by the American National Standard, Elec- tronic or Automated Sphygmomanometer.

⚠ If an irregular heartbeat (IHB) is detected during the measurement procedure, the IHB symbol will be displayed. Under these conditions, the device will function, but the results may be inaccurate.

There are 2 conditions under which the signal of IHB will be displayed:

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

⚠ For information regarding potential electromagnetic or other interference between the blood pressure monitor and other devices, together with advice regarding avoidance of such interference, please see ELECTROMAGNETIC COMPATIBILITY INFORMATION. It is suggested that the device be kept 10 meters away from other wire- less devices, such as WLAN unit, microwave oven, etc.

⚠ This product is verified according to the auscultatory method. Please check Annex B of ANSI/AAMI SP-10:2002+A1:2003+A2:2006 for verification method details if needed.

⚠ If the determined blood pressure (systolic or diastolic) is outside the rated range specified in the SPECIFICATIONS, the App will immediately display a technical alarm. 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.

⚠ When the monitor is connected to an iOS device, the battery volume will be displayed on the iOS device. It is suggested that you charge the battery when the battery is less than 25%. The monitor will not work until the battery has enough power.

⚠ A medical AC adapter with an output of DC 5.0V and compliant with IEC 60601-1/UL 60601-1 and IEC 60601-1-2/EN 60601-1-2 is suitable for this monitor, such as ASP5-05010002EU (input: 100-240V, 50/60Hz, 200mA; output: DC 5V, 1.0A). Please note that the monitor jack size is USB mini B.

⚠ This product might not meet its performance specifications if stored or used outside the specified temperature and humidity ranges.

⚠ Please do not use the cuff with any infectious person to avoid cross-infection.

⚠ This device is designed for adults and should not be used on infants, young children, pregnant or pre-eclamptic patients.

⚠ Please do not use any other cuff than that supplied by the manufacturer as this may result in measurement errors and a biocompatible hazard.

BATTERY HANDLING AND USAGE

- When charging is needed, please connect the monitor to a power source.
- Do not change the battery. If the battery can no longer be charged, please contact the iHealth 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 USB cable with wet hands.
- Do not use any other type of AC adapter as it may harm the monitor.
- The monitors, cable, battery and cuff must be disposed of according to local regulations at the end of their usage.

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

SPECIFICATIONS

Product name:	iHealth BP5(ABI)
Classification:	Internally powered, Type BF applied part, IPX0, No AP or APG, Continuous operation

Device size:	145mm × 58mm × 30mm (per device)
Cuff circumference:	22-42cm
Weight:	Approx. 280g (including cuff) (per device)
Measuring method:	Oscillometric method, automatic inflation and measurement
Memory:	120 measurements with time and date
Power:	DC: 5.0V / 1.0A,
Battery:	3.7V Li-ion 400mAh
Measurement range:	Cuff pressure: 0-300 mmHg Systolic: 60-260 mmHg Diastolic: 40-199 mmHg
Pulse rate:	40-180 beats/minute
Accuracy:	Pressure: ±3 mmHg, Pulse rate: ±5%
Wireless communication:	*Bluetooth* V3.0 + EDR Class 2 SPP
Frequency Band:	2.402-2.480 GHz

Environmental temperature for operation: 5°C~40°C
Environmental humidity for operation: ≤90%RH
Environmental temperature for storage and transport: -20°C~55°C
Environmental humidity for storage and transport: ≤90%RH
Environmental pressure: 80kPa-105kPa
Battery life: more than 80 measurements on a full charge
The iHealth BP5(ABI) includes accessories: pump, valve, cuff, and sensor.
Note: These specifications are subject to change without notice.

CARE AND MAINTENANCE

- If this monitor is stored near freezing temperatures, allow it to acclimate to room temperature before use.
- If the monitor is not used for a long time, please fully charge it before use.
- It is recommended that product performance be checked every 2 years or after each repair. Please contact the iHealth Customer Service for this.
- 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 qualified technical personnel to repair those parts of the equipment that are designated for repair can be supplied.
- Clean the monitor with a dry, soft cloth.
- The monitor can maintain the safety and performance characteristics for a minimum of 10,000 measurements or three years of usage, and the cuff can maintain the performance characteristics for a minimum of 10000 mea-

surements.

- The battery can maintain the performance characteristics for a minimum of 300 charge cycles.
- It is recommended that the cuff 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 device or subject it to strong impact.
- Avoid high temperature and direct sunlight. Do not immerse the device in water as this will result in damage to the monitor.
- Do not attempt to disassemble this device.
- Battery replacement should only be performed by a qualified iHealth technician.
- Cuff replacement should only be performed by a qualified iHealth technician.

EXPLANATION OF SYMBOLS

 Symbol for "TYPE BF APPLIED PARTS" (Cuff only)

 Symbol for "THE OPERATION GUIDE MUST BE READ"

 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 "COMPLIES WITH MDD93/42/EEC REQUIREMENTS"

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	Check that 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 properlyor pressure falls quickly during test	Review the cuff application instructions and retest
	Irregular heartbeat (arrhythmia)	It is inappropriate for people with arrhythmia to use this monitor.
	The cuff was not properly applied	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 application instructions and retest
	Body posture was not correct during testing	Review body posture instructions and retest
	Speaking or moving during test	Retest when calm; avoid speaking or movement during the test
Bluetooth connection unstable	Bluetooth connection unsuccessful, monitor is abnormal, or strong electromagnetic interfer-ence 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.
No response	Incorrect operation or strong electromagnetic interference.	Press the START/STOP button about 10 seconds to reset the device, re- launch app, and reconnect the iOS device to the monitor

iHealth is a trademark of iHealth Lab Inc.
“Made for iPad” mean that an electronic accessory has been designed to connect specifically to iPad 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 iPad may affect wireless performance.

iPad is a 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:

- This device may not cause harmful interference, and
- This device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by iHealthLabs Europe. 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 license-exempt RSS standard(s). Operation is subject to the following two conditions:

- This device may not cause interference, and
- 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, [Andon Health], declares that this [BP5-ABI] is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC. Directive 1999/5/EC declaration of conformity and all iHealth certification and regulatory documents can be downloaded on the following link : https://www.ihealthlabs.eu/support/certifications.

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.		
Emissions test	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	The Wireless Blood Pressure 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2

For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration - electro magnetic 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 % *Ur* (>95 % dip in *Ur*) for 0.5 cycles 40 % *Ur* (60 % dip in *Ur*) for 5 cycles 70 % *Ur* (30 % dip in *Ur*) for 25 cycles <5 % *Ur* (>95 % dip in *Ur*) for 5 s	<5 % *Ur* (>95 % dip in *Ur*) for 0.5 cycles 40 % *Ur* (60 % dip in *Ur*) for 5 cycles 70 % *Ur* (30 % dip in *Ur*) for 25 cycles <5 % *Ur* (>95 % dip in *Ur*) 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: UT 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 - electro magnetic 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 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	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 d =1.2√ P d =1.2 √P 80 MHz to 800 MHz d =2.3 √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, [1] should be less than the compliance level in each frequency range.[2] 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.

[1] 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 wireless blood pressure monitor is used exceeds the applicable RF compliance level above, the wireless blood pressure 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 wireless blood pressure monitor.
[2] 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 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 Wireless Blood Pressure 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 P	80 MHz to 800 MHz d =1.2 P	800 MHz to 2,5 GHz d =2.3 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.