

iHealth[®] Neo

Smart Blood Pressure Monitor

Tensiomètre connecté

Sfigmomanometro intelligente

Tensiómetro inteligente



Instruction For Use

Notice d'utilisation

Istruzioni per l'uso

Instrucciones de uso

iHealth®

Smart Blood Pressure Monitor (BP5S)

USER GUIDE

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INTRODUCTION

Thank you for selecting the iHealth Neo Smart Blood Pressure Monitor. The iHealth Neo Smart 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 devices to track and share vital blood pressure data.

PACKAGE CONTENTS

- 1 iHealth Neo Smart Blood Pressure Monitor
- 1 User Guide
- 1 Quick Start Guide
- 1 Charging Cable
- 1 Travel Bag

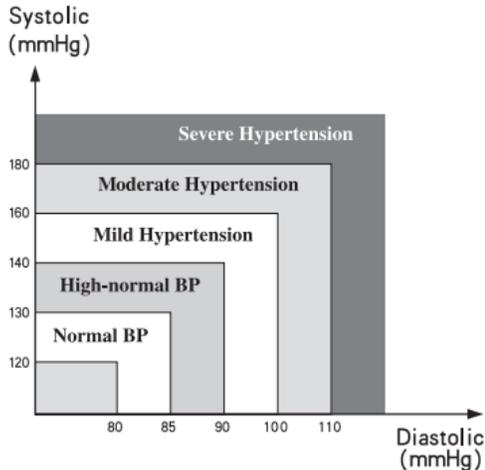
INTENDED USE

The iHealth Neo Smart 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 arm. The measurement range of the standard cuff circumference is 22cm-42cm (8.6" to 16.5").

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	≥ 110	RED

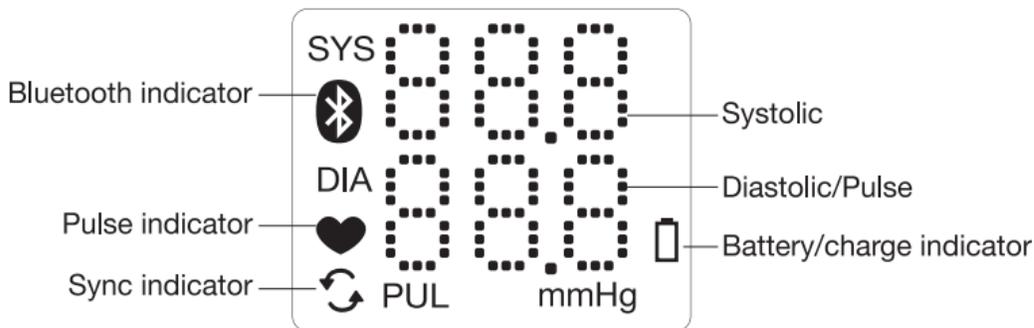
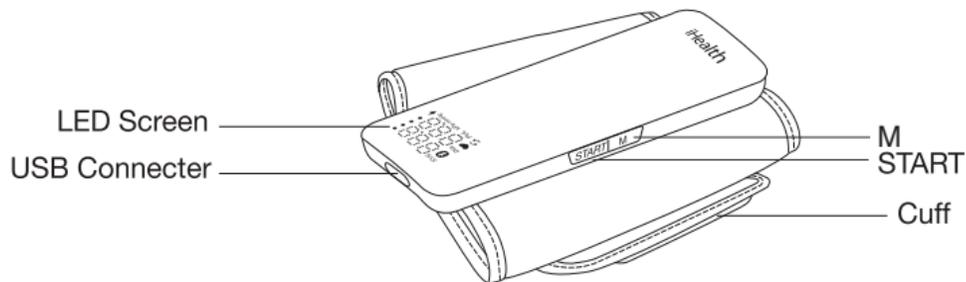
WHO/ISH Definitions and Classification of Blood Pressure Levels

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

CONTRAINDICATION

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

PARTS AND DISPLAY INDICATORS



SET UP REQUIREMENTS

Works with both iOS and Android devices: such as iPhone X/iPhone 8/Samsung Galaxy S6 Edge/SM-G9250/Samsung Galaxy Note3 Lite/Motorola Nexus 6

For a complete list of compatible devices, visit our support on page on www.ihealthlabs.eu

SET UP PROCEDURES

Download the Free iHealth MyVitals App

Prior to first use, download and install “iHealth MyVitals” from the App Store or Google Play Store. Follow the on-screen instructions to register and set up your personal account.

Access the iHealth Cloud Account

Your iHealth account also gives you access to the free and secure iHealth cloud service. Go to www.ihealthlabs.com and sign in with the same account.

Power on the Monitor

Press START button for at least 3 seconds until the LED screen display all characters to power on the monitor at the first use. If cannot power on the monitor normally, connect the monitor to a USB port using the charging cable provided until the charging indicator full and steady.

Activate the monitor

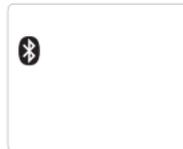
- Confirm that the “iHealth MyVitals” App had already been installed and login personal account. Scan the QR code can download the App if not downloaded.



- Choose “Neo (BP5S)” from the “Select New Device” page.



- c. The monitor cannot take measurements or view measurement history until activate. To active the monitor, press START or M button on the monitor, the monitor shows “000” and Bluetooth indicator flashing.
- d. Place the monitor near your smartphone, and follow the steps of the App to complete connecting.
- e. When a successful connection has been established, the Bluetooth indicator light will light up, means that the device had been activated successfully. Bluetooth can be connected directly without press any button when activated successfully.
- f. Now you can take blood pressure measurement without smartphone and upload data when Bluetooth is connecting.



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.



Apply the cuff

- Pull the cuff end through the metal loop, positioning it outward (away from your body).
- Place a bare arm through the cuff and position the cuff 1/2" (1-2cm) above the elbow joint.
- Tighten the cuff by pulling it towards your body, securing it closed with the Velcro fastener.
- While seated, place your hand, palm-side up, in front of you on a flat surface such as a desk or table.

When the left arm (blue arrow points down to the hand) is measured, position the monitor in the middle of your arm so that it is aligned with your middle finger.

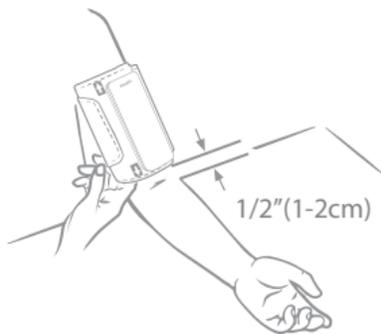
When the right arm (red arrow points down to the hand) is measured, position the monitor in the middle of your arm so that it is aligned with your middle finger.

- The cuff should fit comfortably, yet snugly around your arm. You should be able to insert one finger between your arm and the cuff.

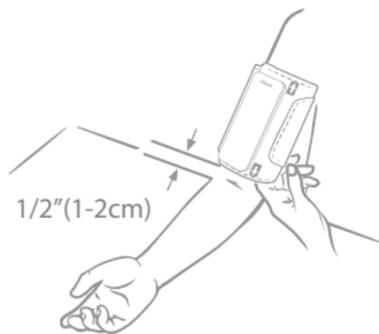
Remember to:

- Make sure that the appropriate cuff size is used; refer to the cuff circumference range in the Specifications section of this manual.
- Measure on the same arm each time.
- 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.
5. Keep the cuff clean. Cleaning the cuff after every 200 times of usage is recommended. If the cuff becomes dirty, clean it with a moistened cloth. Do not rinse the monitor or cuff with running water.



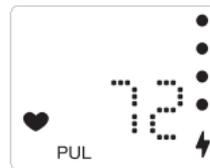
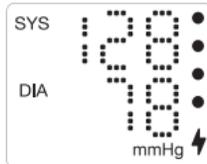
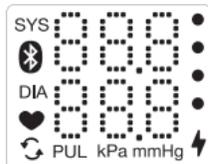
Left arm measurement



Right arm measurement

TAKING YOUR BLOOD PRESSURE READING

- a. Press the START button, the monitor will activate and all display characters are shown for self-test. You can check the LED screen display according to the right picture. Please contact the service center if symbol is missing.



- b. Then the cuff will be slowly inflated. The blood pressure and pulse will be measured during inflation. Inflation will stop as soon as the blood pressure and pulse rate have been calculated and displayed on the screen. The result will be automatically stored in the memory, and all results will be uploaded to the App automatically upon the next successful Bluetooth connection.
- c. During measurement, you can press the START button to turn off the monitor manually.
- d. After measurement, the monitor will turn off automatically after 60 seconds if no operation. Alternatively, you can press the START button to turn off the monitor manually.

Note: Please consult a health care professional for interpretation of pressure measurements.

BLUETOOTH FUNCTION

Connect to iOS/Android Device via Bluetooth

- a. Enable Bluetooth on your device.
- b. Launch the iHealth MyVitals App from your device.
- c. When a successful connection has been established, the Bluetooth indicator light will light up.
- d. When sync is processing, the sync indicator will flash, when sync is finished, The sync indicator lights up  for 2 seconds and then light off.



Bluetooth connected



Syncing



Sync finished

Note: The monitor will turn off Bluetooth function to save power under battery low status (when the monitor can no longer take blood pressure readings), and turn Bluetooth function on when charger is plugged in.

MEMORY FUNCTION

- a. Press the M button, the monitor will display the most recent measurement, display show systolic and diastolic, press M again could display the second recent measurement, and keep press the M button could view the last 10 measurements. Press START button could turn off the monitor.
- b. If the monitor has no memory, Press the M button, the device display “000” at both systolic and diastolic.



SPECIFICATIONS

1. Product name: iHealth Neo Smart Blood Pressure Monitor
2. Model: BP5S
3. Classification: Internally powered; Type BF applied part; IP22, No AP or APG; Continuous operation
4. Machine size: approx. 141.5 mm × 60.5 mm × 19 mm (5.57" × 2.38" × 0.75")
5. Cuff circumference: 22cm-42cm (8.66" to 16.54")
6. Weight: approx. 240g (8.47 oz) (including cuff)
7. Measuring method: Oscillometric method, automatic inflation and measurement
8. Memory volume: 200 times with time and date stamp
9. Power: DC:5.0V $\overline{=}$ 1.0A, Battery: 1*3.7V $\overline{=}$ Li-ion 950mAh
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: Less than 60: ± 3 bpm More than 60 (incl.): $\pm 5\%$
12. Wireless communication: Bluetooth V4.1 Class 2 Frequency Band: 2.400-2.4835 GHz
13. Environmental temperature for operation: 5°C-40°C (41°F -104°F)
14. Environmental humidity for operation: $\leq 85\%$ RH
15. Environmental temperature for storage and transport: -20°C-55°C (-4°F-131°F)
16. Environmental humidity for storage and transport: $\leq 90\%$ RH

17. Environmental pressure: 80kPa-105kPa
18. Battery life: more than 130 measurements on a full charge
19. The blood pressure measurement system includes accessories: pump, valve, cuff, LED screen and sensor.

Note: *These specifications are subject to change without notice.*

GENERAL SAFETY AND PRECAUTIONS

1. Read all of the information in the User Guide and other provided instructions before operating the unit.
2. Consult your physician for any of the following situations:
 - a) The application of the cuff over a wound or inflamed area.
 - b) The application of the cuff on any limb with intravascular access or therapy, or an arteriovenous(A-V) shunt.
 - c) The application of the cuff on the arm on the side of a mastectomy.
 - d) Simultaneous use with other medical monitoring equipment on the same limb.
 - e) The blood circulation of the user needs to be checked.
3. Do not use this product in a moving vehicle as this may result in inaccurate measurements.
4. Blood pressure measurements determined by this product are equivalent to those obtained by professional healthcare practitioners using the cuff/stethoscope auscultation method within the limits prescribed by the American National Standard, Electronic or Automated Sphygmomanometer.
5. If an Irregular Heartbeat (IHB) is detected during the measurement procedure, the IHB symbol will be displayed in the “iHealth MyVitals” APP. Under this condition, the Smart Blood Pressure Monitor can keep functioning, but the results may be inaccurate. Please consult your physician for accurate assessment.
The IHB symbol will be displayed under 2 conditions:

- 1) The coefficient of variation (CV) of pulse period $>25\%$.
- 2) The difference of adjacent pulse period is $\geq 0.14s$ and more than 53 percent of the total number of pulses readings falls within this definition.
6. Please do not use any cuff other than that supplied by the manufacturer as this may result in inaccurate measurements.
7. 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 blood pressure monitor be kept 10 meters away from other wireless devices, such as WLAN unit, cell phone, microwave oven, etc.
8. This product should not be used as a USB device.
9. If the blood pressure measurement (systolic or diastolic) is outside the rated range specified in part SPECIFICATIONS, the monitor will immediately display a technical alarm on the LED screen. In this case, repeat the measurement ensuring that the proper measurement procedures are followed and/or consult with your medical professional. The technical alarm is preset in the factory and cannot be adjusted or inactivated. This technical alarm is assigned as low priority according to IEC 60601-1-8. The technical alarm does not need to be reset.
10. This device requires a medical AC adapter with an output of DC 5.0V that complies with IEC60601-1/UL 60601-1 and IEC 60601-1-2/EN 60601-1-2 such as ASSA81a-050100 (input:100-240V, 50/60Hz, 0.45A; output: DC 5V, 1.0A). Please note that the monitor jack size is USB micro-B. The USB jack should be used for charging only.
11. Use of Charging Cable other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
12. Measurements are not possible in patients with a high frequency of arrhythmias.
13. The device is not intended for use on neonates, children or pregnant women. (Clinical testing

has not been conducted on neonates, children or pregnant women.)

14. Motion, trembling, shivering may affect the measurement reading.
15. The device would not apply to the patients with poor peripheral circulation, noticeably low blood pressure, or low body temperature (there will be low blood flow to the measurement position).
16. The device would not apply to the patients who use an artificial heart and lung (there will be no pulse)
17. Consult your physician before using the device for any of the following conditions: common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, pre-eclampsia, renal diseases.
18. The patient is an intended operator.
19. Swallowing batteries and/or battery fluid can be extremely dangerous. Keep the batteries and the unit out of the reach of children and disabled persons.
20. If you are allergic to plastic/rubber, please don't use this device.
21. Attention that changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

⚠ This Monitor is designed for adults and should never be used on infants, young children, pregnant or pre-eclamptic patients. Consult your physician before use on children.

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

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

BATTERY HANDLING AND USAGE

The battery charge will be displayed on the LED screen after each measurement. And when the monitor is connected to the “iHealth MyVitals” APP, the battery charge will be displayed in the APP. If the power is less than 25%, please charge the battery.

The monitor will not work until the battery has enough power.

- When the monitor needs charging, please connect the monitor to a power source.
- You should charge the battery when the battery is less than 25% charged. Overcharging the battery may reduce its lifetime.
- When in charging mode, the charging status will be displayed on the LED screen. See the table below for details.

Monitor Status	Status Indicator
Charging	battery/charge symbol flashing slowly
Fully charged	battery/charge symbol steady
Battery charge <25%	battery/charge symbol flashing fast
Battery low	battery/charge symbol flashing fast

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

⚠ Overcharging the battery may reduce its lifetime.

⚠ Lithium battery replacement by inadequately trained personnel could result in a hazard such as a fire or explosion.

⚠ Do not plug or unplug the power cord into the electrical outlet with wet hands. If the AC adapter is abnormal, please change the adapter.

⚠ Do not use the monitor while charging.

⚠ Do not use any other type of AC adapter as it may harm the monitor.

 The monitor, cable, battery and cuff must be disposed of according to local regulations at the end of their usage.

Note: The battery has limited charge cycles and may eventually need to be replaced by an iHealth service provider. Battery life and charge cycles vary by use and settings.

TROUBLESHOOTING

PROBLEM	POSSIBLE CAUSE	SOLUTION
Low Battery	Battery do not have enough power	Charge the battery
LED display reads “Er0”	Pressure system is unstable before measurement	Retest, make sure not to move your arm or the monitor
LED display reads “Er1”	Fail to detect systolic pressure	
LED display reads “Er2”	Fail to detect diastolic pressure	
LED display reads “Er3”	Pneumatic system blocked or cuff is too tight during inflation	Apply the cuff correctly and try again
LED display reads “Er4”	Pneumatic system leakage or cuff is too loose during inflation	
LED display reads “Er5”	Cuff pressure above 300mmHg	Measure again after five minutes. If the monitor is still abnormal, please contact the local distributor or the factory.
LED display reads “Er6”	More than 160 seconds with cuff pressure above 15 mmHg	
LED display reads “Er7”	memory accessing error	
LED display reads “Er8”	Device parameter checking error	
LED display reads “ErA”	Pressure sensor parameter error	
LED display reads “  Er”	Bluetooth communicate error	Reset monitor by pressing the START button and holding for about 10 seconds, then connect the mobile device correctly and try again, If the monitor is still abnormal, please contact the local distributor or the factory.
LED 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, 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/Android device. Reset monitor by pressing the START/STOP button and holding for about 10 seconds. Make sure the monitor and iOS/Android device are away from other electrical equipment. Please see GENERALSAFETY AND PRECAUTIONS
No response when you press button	Incorrect operation or strong electromagnetic interference	Press the START/STOP button and hold for about 10 seconds to reset the device.

CARE AND MAINTENANCE

1. If this monitor is stored near freezing temperatures, allow it to return to room temperature before use.
2. If the monitor is not used for a long time, please be sure to fully charge it every month.
3. 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.
4. Clean the monitor with a dry, soft cloth or a moistened and well wrung soft cloth using water, diluted disinfectant alcohol, or diluted detergent.
5. 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.
6. The battery can maintain the performance characteristics for a minimum of 300 charge cycles.
7. It is recommended that if the cuff is used in a hospital or a clinic, it be disinfected twice a week. Wipe the inner side (the side that contacts skin) of the cuff with a soft cloth lightly moistened with Ethyl alcohol (75-90%). Then air-dry the cuff.
8. It is recommended that product performance be checked every 2 years or after each repair. Please contact the customer service.
9. The monitor requires 6 hours to warm from the minimum storage temperature between uses

until the monitor is ready for its INTENDED USE when the ambient temperature is 20 °C.
10. The monitor requires 6 hours to cool from the maximum storage temperature between uses until the monitor is ready for its INTENDED USE when the ambient temperature is 20 °C.

11. Not servicing/maintenance while the monitor is in use.

⚠ 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

iHealth Labs, Inc. ("iHealth") warrants the iHealth hardware (the "Product"), and only the Product, against defects in materials and workmanship under normal use for a period of one year (US) or two years (EU) from the date of purchase by the original purchaser ("Warranty Period"). Under this Limited Warranty, if a defect arises and a valid claim is received by iHealth within the Warranty Period regarding the Product, at its option and to the extent permitted by law, iHealth will either (1) repair the Product using new or refurbished replacement parts or (2) exchange the Product with a new or refurbished Product. In the event of a defect, to the extent permitted by law, these are the sole and exclusive remedies.

This warranty does not apply: (a) to consumable parts, such as the cuff or the battery that diminish over time, unless failure has occurred due to a defect in materials or workmanship; (b) to cosmetic damage, including but not limited to scratches, dents ; (c) to damage caused by accident, abuse,

misuse, contact with liquid; (d) to damage caused by operating the iHealth product outside the user manual, the technical specifications or other iHealth product published guidelines; (e) to damage caused by service performed by anyone who is not a representative of iHealth or one of its representatives.

EXPLANATION OF SYMBOLS



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



Symbol for "WARNING"



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 "MANUFACTURER"



Symbol for "EUROPEAN REPRESENTATIVE"

CE 0197

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

IP22 The first characteristic numeral symbol for “Degrees of protection against access to hazardous parts and against solid foreign objects “. The second characteristic numeral symbol for “Degrees of protection against ingress of water”

iHealth is a trademark of iHealth Labs, Inc.

iPad, iPhone, and iPod touch are trademarks of Apple Inc., registered in the U.S. and other countries.

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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 this device must accept any interference received, including interference that may cause undesired operation.
- (2) 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 license-exempt RSS standard(s). Operation is subject to the following two conditions:

(1) This device may not cause interference, and this device must accept any interference, including interference that may cause undesired operation of the device.

The CE Mark applies to products regulated by certain European health, safety and environmental protection legislation. The CE Mark is obligatory for products it applies to: the manufacturer affixes the marking in order to be allowed to sell his product in the European market.

Hereby, [ANDON HEALTH CO., LTD] declares that the radio equipment type [BP5S] is in compliance with Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at the following internet address:
<https://ihealthlabs.eu/en/content/189-DoC-RED>

OTHER STANDARDS AND COMPLIANCES

The Wireless Blood Pressure Monitor corresponds to the following standards:

IEC 60601-1Edition 3.1 2012-08/EN 60601-1:2006/A1:2013 (Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance);

IEC 60601-1-2:2014/EN 60601-1-2:2015(Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests);

IEC80601-2-30:2009+AMD1: 2013/EN 80601-2-30:2010/A1: 2015(Medical electrical equipment

–Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers);
 EN 1060-1: 1995 + A2: 2009 (Non-invasive sphygmomanometers - Part 1: General requirements),;
 EN 1060-3: 1997 + A2: 2009 (Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems);
 ISO81060-2 : 2013, (Non-Invasive Sphygmomanometers - Part 2: Clinical Validation Of Automated Measurement Type).

ELECTROMAGNETIC COMPATIBILITY INFORMATION

This product is applicable to the equipment and system requirements for the purpose of receiving radio frequency energy for the purpose of the work, Bluetooth receive bandwidth 2M. This product can also be used to include RF transmitter equipment and system requirements and emission frequency of 2.4GHz ISM band, Bluetooth modulation types: GFSK, effective radiated power: < 20dBm.

Table 1 - Emission

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class B	Home healthcare environment
Harmonic distortion	IEC 61000-3-2 Class A	Home healthcare environment
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	Home healthcare environment

Table 2 - Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels
		Home Healthcare Environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	10V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

Table 3 – Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m

5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

Table 4 – Input a.c. power Port

Phenomenon	Basic EMC standard	Immunity test levels
		Home Healthcare Environment
Electrical fast transients/burst	IEC 61000-4-4	±2 kV 100kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	±0.5 kV, ±1 kV
Surges Line-to-ground	IEC 61000-4-5	±0.5 kV, ±1 kV, ±2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0.15MHz-80MHz 6V in ISM and amateur radio bands between 0.15MHz and 80MHz 80%AM at 1kHz
Voltage dips	IEC 61000-4-11	0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0% UT; 250/300 cycles