PRODUCT GUIDE

Withings BPM Vision

EN (US)

WITHINGS

TABLE OF CONTENTS

ENGLISH

PRODUCT GUIDE - ENGLISH - US

Thank you for using BPM Vision.

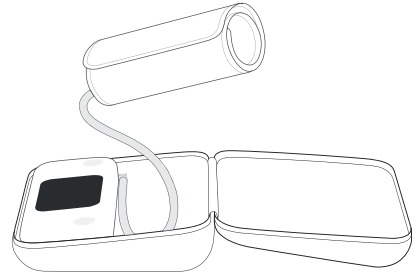
This guide explains how to use your BPM Vision.

It applies to users located in the United States of America.

BOX CONTENTS

Your BPM Vision box is composed of:

BPM Vision (provided with 22-42cm / 9-16.5'' cuff):



USB cable (for charging only):

Note: Use only power supply units compliant with IEC 60601-1 or IEC 62368-1 and authorized by the relevant NCBs for safe operation.

Quick start guide and product guide:

FIRST BLOOD PRESSURE MEASUREMENT

1. Sit comfortably with your legs uncrossed, keep your feet flat on the floor, with your arms and back properly supported. Remove all jewelry from your left arm. For long-sleeve shirts, roll the sleeve up without tightening it for a proper cuff placement on your bare arm.
   Rest for 5 minutes before the measurement.

   Do not take measurements right after a shower or bath, drinking alcohol or coffee, smoking, exercising or eating.

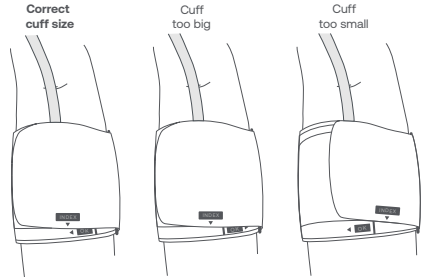
2. The cuff should be snug but not too tight. You should be able to insert one finger between the cuff and your arm. Align the Artery Indicator (Φ) with your main artery, according to the drawing on the cuff. The bottom edge of the arm cuff should be placed about 1'' / 2.5 cm above the bend of your elbow.

GET THE APPROPRIATE CUFF SIZE

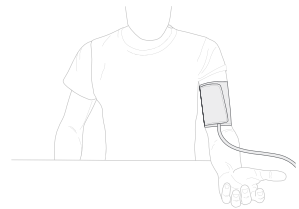
Check if your cuff fits: the “index” arrow printed on the inside of the cuff should point between the two “OK” bars.

If the cuff is too big: This device might not be adapted to your situation.

If the cuff is too small: Please visit Withings website and order a larger cuff. Plug the new cuff’s tube at the same spot as the other one. The measurement steps will remain the same with this new cuff.



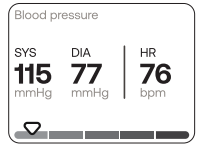
3. Place your left arm on a table with your hand palm facing up. Your arm should be resting comfortably on the table.



4 Short press the ON/OFF button to power on your BPM Vision. Press the middle button to launch a simple measurement. Do not speak or move during the measurement. At any time during a measurement, you can press the ON/OFF button to stop the arm cuff inflation.

You can also launch a 3-measurement series by selecting the option “Blood Pressure x3” while navigating the measurements menu.

5 After a successful measurement, your systolic blood pressure, diastolic blood pressure and heart rate will be displayed on the monitor screen.



6 If an error is returned during or after the measurement, please refer to the instructions displayed on screen. You can also find more detailed troubleshooting in page 14.

GET TO KNOW BPM VISION

RESULTS COLOR INDICATION: US/CANADA

(Blood pressure classifications can vary by geography. Read this paragraph if you are located in the US or Canada.)

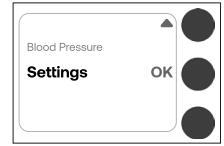
The Blood Pressure cursor on BPM Vision may indicate the following colors on the results color bar:

- **Green:** If your measurements indicate normal blood pressure.
- **Yellow:** If your measurements indicate elevated blood pressure.
- **Orange:** If your measurements indicate high blood pressure of stage 1.
- **Light Red:** If your measurements indicate high blood pressure of stage 2.
- **Dark Red:** If your measurements indicate that you are experiencing a hypertensive crisis. In this case, please contact your physician.

Note: As explained above, the result color indicator displayed on the device may vary depending on the classification guidelines of your region.

SETTINGS MENU

You can access the settings menu by navigating in the main menu and selecting “Settings” with the button in front of the “OK” command.



This menu is composed of the following features:

FACTORY RESET:
Factory resetting BPM Vision allows you to delete all of the data stored on it.

INFORMATION:
By selecting this item, you will have access to the serial number of the device or “MAC address”, the firmware version, and the battery level.

UPDATE:
This item allows you to launch a manual update of the device.

X3 DELAY (60):
This item allows you to choose the time between two measurements of the “Blood Pressure x3” mode. Default value is 60s.

BACK:
Select this item to exit the menu.

TROUBLESHOOTING

An empty battery icon will appear on the screen in case the device battery is too low. Please charge BPM Vision using the provided charging cable before taking a new measurement. You cannot use the device while it is charging.

This list will help you if you receive any of the following error messages:

Error code	Error description
ERROR 201	The cuff is not tight correctly. Please refer to the best practices for more information on how to position BPM Vision.
ERROR 202	Talk or movement has been detected during the measurement. Please try to take a new measurement and make sure you follow the best practices.
ERROR 203	No heart rate has been detected. Please try to take a new measurement and make sure you follow the best practices.
ERROR 204	Error calculating blood pressure. Please try to take a new measurement and make sure you follow the best practices.
ERROR 205	Heart rate measurements are outside of the 40-199 bpm range the BPM Vision is certified to measure. As such, a low heart rate can result in this error message.
ERROR 206	The measurement has been stopped manually.
ERROR 301	The cuff is not inflating correctly. Please try to take a new measurement and make sure you follow the guidelines.

ERROR 302	The cuff is not inflating. Please take a new measurement and make sure you follow the guidelines.
ERROR 303	BPM Vision failed to start a measurement. Please try to take a new measurement and make sure you follow the best practices.

If you receive any of the error messages listed below, please go visit https://program-support.withings.com

ERROR 100
ERROR 101
ERROR 102
ERROR 103
ERROR 104
ERROR 105
ERROR 108
ERROR 109
ERROR 221

Need more help?
Go visit: https://program-support.withings.com
Or contact: program-support@withings.com

REGULATORY INFORMATION

Please read this section carefully before using BPM Vision.

Important notice

Important safety information

Consult your doctor before using this monitor if you suffer from the following conditions: common arrhythmias such as atrial fibrillation or ventricular premature beats; arteriosclerosis; implantation with electrical devices; undergoing intravascular therapy; arteriovenous shunt; mastectomy; peripheral arterial disease; pregnancy; preeclampsia.

Intended use

The BPM Vision is a digital monitor intended for use in measuring blood pressure and pulse rate. The device is intended to be used in a human adult population (18 years old minimum) with an arm circumference of 8¾ to 16½ inches (22 to 42 cm) or 15¾ to 20½ inches (40 to 52 cm). It is intended for indoor use only.

Manufacturer:
GUANGDONG TRANSTEK MEDICAL
ELETRONICS CO., LTD.
Zone A, No.105, Dongli Road,
Torch Development District,
528437 Zhongshan, Guangdong, China

General safety and precaution

Interference may occur in the vicinity of equipment marked with the following symbol . 
If you have a pacemaker, defibrillator or other electric implant, please maintain a minimum distance of 6 inches or 15 cm between BPM Vision and your implanted device to mitigate the risk of electromagnetic interference.

In case of doubt, always consult your doctor prior to use.

Precaution

- This device is intended for indoor, home use and is not intended for self-use in public areas.
- This device is portable, but it is not intended for use during patient transport.
- Do not use the blood pressure monitor for any purpose other than measuring blood pressure.
- This device is not suitable for continuous monitoring during medical emergencies or operations.
- This device is intended for non-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the arm, or for any purpose other than obtaining a blood pressure measurement.
- This device is for adults. Do not use this device on neonates or infants. Do not use it on children and adolescents unless otherwise instructed by a medical professional.
- Consult with your physician before using this monitor if you suffer from the following conditions: common arrhythmias such as premature ventricular beats or atrial fibrillation; peripheral arterial disease; pregnancy; preeclampsia; implantation with electrical devices; undergoing intravascular therapy; arteriovenous shunt or mastectomy. Please note that any of these conditions may affect measurement readings, in addition to patient motion, trembling or shivering.
- Do not use this device for diagnosis or treatment of any health problems or diseases. Please consult with your physician first whether the blood pressure or pulse rate readings can be used as an input in determining clinical actions. Please note that clinical actions can only be determined by the physician, otherwise it may lead to delayed treatment or other dangerous situations.
- If you are taking medication, consult your physician to determine the proper time to measure your blood pressure.

- This device may be used only for the intended use described in this manual, the manufacturer shall have no liability for any incidental, consequential, or special damages caused by misuse or abuse.
- Please use the device under the environment which is provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced.
- The device may require up to 30 minutes to warm up / cool down from the minimum/ maximum storage temperature before it is ready for use.
- The blood pressure monitor, its adapter, and the cuff are suitable for use within the patient environment.
- Do not wash the cuff in a washing machine or dishwasher.
- Do not immerse the blood pressure monitor and the arm cuff in water.
- Do not allow the device to come into contact with cosmetics such as lotion or sunscreen.
- The device contains sensitive electronic components. To avoid measurement errors, avoid taking blood pressure measurements near a strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.
- Wireless communication equipment, such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies may cause interference that may affect the accuracy of measurements. A minimum distance of 1 foot (30 cm) should be kept from such devices during a measurement.
- Blood Pressure Monitor is intended for use by the patient.
- When an unexpected blood pressure reading is obtained, please contact the customer support.
- The patient is the intended operator.
- Withings BPM Vision is intended to be used by lay users.

Notice

You can use this device to take your own measurement, no third-party operator is required.
Adapter is specified as a part of ME EQUIPMENT. At the request of authorized service personnel, circuit diagrams, component part lists, descriptions and calibration procedures will be made available by the manufacturer or distributor. The expected lifetime of the cuff may vary by the frequency of washing, skin condition and storage state. Please report to the manufacturer and the competent authority of the Member State / the FDA in which you are established about any serious incident that has occurred in relation to this device.

Caution

- Do not attempt to repair the unit yourself if it malfunctions. Only have repairs carried out by authorized service centers.
- Do not apply strong shocks and vibrations to the blood pressure monitor or drop it.
- Do not use the device after a strong shock, such as dropping the unit on the floor.
- Do not inflate the arm cuff when it is not wrapped around your arm.
- Do not use the device while the USB cable is plugged in.
- It is recommended that the performance should be checked after repair, maintenance, by retesting the requirements in limits of the error of the cuff pressure indication and air leakage (testing at least at 50 mmHg and 200 mmHg). Please contact the manufacturer or distributor for authorized service personnel.
- Store your device, cuff and adapter in a clean and dry place, protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on it.
- Make sure the rubber tube of the cuff is not squeezed, stretched, or kinked during storage.
- Dispose of accessories, detachable parts, and the device according to the local guidelines.
- Do not interconnect this equipment with other equipment or use accessories, detachable parts, or materials not described in the instructions for use. use. Use of parts and components 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.

Warning

- Do not apply the cuff on an arm that has an intravenous drip or a blood transfusion attached.
- Do not kink, fold, stretch, compress, or otherwise deform the tube during measuring, as the cuff pressure might continuously increase, which could prevent blood flow and result in injury.
- Taking blood pressure measurements too frequently could disrupt blood circulation and cause injuries.
- Do not apply the cuff to areas of the body where skin is delicate or damaged. Check cuff site frequently for irritation.
- Do not place the cuff on the arm of a person whose arteries or veins are undergoing medical treatment, i.e. intra-vascular access or intra-vascular therapy or an arteriovenous (A-V) shunt, which could disrupt blood circulation and cause injuries.

- Do not place the cuff on the arm on the same side of a mastectomy (especially when lymph nodes have been removed). It is recommended to take measurements on the unaffected side.
- Do not wrap the cuff on the same arm to which another monitoring device is applied. One or both devices could temporarily stop functioning if you try to use them at the same time.
- Please check (for example, by observation of the limb concerned) that the operation of the device does not result in prolonged impairment of patient blood circulation.
- On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, loosen and remove the cuff immediately. Prolonged high pressure applied to the arm (cuff pressure>300 mmHg or constant pressure >15 mmHg for more than 3 minutes) might lead to bruising and discolored skin.
- Do not use this device with high-frequency (HF) surgical equipment at the same time.
- This device is not used in conjunction with oxygen rich environments, not intended for use with flammable anesthetics, not intended for use in conjunction with flammable agents.
- Do not touch the output of the batteries/adapter and the user simultaneously.
- The power cord is considered the disconnect device for isolating this equipment from supply mains.
- Do not position the equipment so that it is difficult to reach or disconnect.
- Do not operate the device in a severe environment of extreme temperature, humidity, or direct sunshine.
- Do not use this device if you are allergic to polyester, nylon, or plastic.
- Only use accessories approved by the manufacturer. Using unapproved accessories might cause damage to the unit and injure users.
- If you experience discomfort during a measurement, such as pain in the arm or other complaints, press the Power button immediately to release the air from the cuff.
- Do not use the device while under maintenance, or being serviced.
- The air tube poses a risk of strangulation. Furthermore, the small parts of product and batteries present a choking hazard if swallowed. They should therefore always be kept away from infants/children.
- Sensor degradation or looseness may reduce performance of device or cause other problems.
- The device wil automatically turn off after 30 seconds if no user interraction is detected.
- This device is not designed for use in environments classified as Category AP or Category APG.

General use

This blood pressure monitor is intended to be used in a home environment and is not intended for self-use in public areas. It is intended for non-invasive measuring and monitoring of arterial blood pressure. The patient is an intended user or operator, as well as medical staff and lay persons. Measurements can be affected by extreme temperatures, humidity & altitude. BPM Vision has been clinically validated on the left arm. However, you can still measure your blood pressure by applying the cuff on your right arm, if your left arm cannot bear it. Self-diagnosis of measurement results and self-treatment are dangerous. People with severe blood flow problems or blood disorders should consult a doctor before using the blood pressure monitor. Cuff inflation can cause internal bleeding. Operational factors (common arrhythmias such as atrial fibrillation or ventricular premature beats; arteriosclerosis; implantation with electrical devices; undergoing intravascular therapy; arteriovenous shunt; mastectomy; diabetes; age; pregnancy; pre-eclampsia or renal disease; patient motion, trembling, shivering) can affect the performance of the automated sphygmomanometer and/or its blood pressure reading.
If you are taking medication, consult your physician to determine the proper time to measure your blood pressure.
This is a precision measuring device that may be understood by lay users, but should still be handled with care. Exposing the device to prolonged lint, dust or sunlight might reduce its lifetime or damage it. A damaged cuff or sensor may lead to incorrect measurements.
The USB port should only be used for recharging the device.
To recharge the battery, use the provided power cord (included) and a 5V 1A power supply unit (not included).
Parts in contact with the skin: cuff, tube.

Cleaning

In order to get the best performance, please follow the instructions below.

1. Cleaning Process:
Step 1: Make sure to switch off and unplug the device prior to cleaning.
Step 2: Use a soft cloth wetted with soapy water to clean the cuff first, and then use a soft cloth wetted with clear water to remove residual soap until there is no visible residual contaminants. Attention shall be paid to avoid liquid invasion into the cuff.
Step 3: Use a dry soft cloth to wipe the cuff, in order to remove residual moisture.

Step 4: Dry the cuff at a well-ventilated place after cleaning.

2. Disinfection Process:
Step 1: Make sure to switch off and unplug the device prior to disinfection.
Step 2: Use a soft cloth wetted with 70% isopropanol to disinfect the cuff for about 10 minutes. Attention shall be paid to avoid liquid invasion into the cuff.
Step 3: Use a clean dry cloth or towel to wipe off the disinfectant until there is no visible residue.
Step 4: Dry the cuff at a well-ventilated place after disinfection.

Suggestion:
Frequency of Cleaning and Disinfection:
For single patient multiple use, it's recommended to clean the device surface once a month or whenever it's necessary.
For multiple patient multiple use, it's recommended to clean the device every time before and after usage. Maintenance procedures shall be taken as per instruction.

Storage

- Store the device, cuff and adapter in a clean and dry location. Avoid exposure to extreme moisture, heat, lint, dust and direct sunlight. Do not place heavy objects on the device.
- Make sure the tube is not squeezed or stretched in storage.
- If storage conditions are different from the usage conditions indicated in this document, please move BPM Vision to a suitable location and wait 30 minutes before turning it on and taking a measurement.

Maintenance

If you cannot fix the problem using the troubleshooting instructions, request service from your dealer. The manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist the manufacturer's staff or authorized representative with repair. Do not use the device while doing maintenance steps. It is recommended to return to the original factory or service station every 2 years to
re-calibrate the device.

Troubleshooting

Problem	Solution
The inflation action cannot be performed or the air pressure cannot rise	Check the air connection and the cuff position, fasten the cuff correctly and remeasure blood pressure again. If the issue persists, please contact customer support by emailing program-support@withings.com or contact the health program in which you are enrolled.
Under normal circumstances, the measurement taken at home may differ from the measurement taken in a medical setting	1. The variation is due to the different environments 2. The blood pressure is changing according to the physiological or psychological status of the person being measured

Technical Specifications

Product description: Digital automatic blood pressure monitor
Model: WPM07
Reference: WPM07-08
Blood pressure measurement method: Cuff oscillometric method
Cuff inflation: Automatic inflation
Pressure sensor: Gauge sensor
Measurement range (pressure): Rated range of cuff pressure. 0 to 285 mmHg, diastolic 40 to 130 mmHg, systolic 60 to 230 mmHg
Measurement range (pulse): 40 to 199 beats/min
Pressure sensor accuracy: Within +- 3 mmHg or 2% of reading
Sensor: Semiconductor pressure sensor
Arm type: Use on left arm
Power source: 3.7V/2500mAh built-in rechargeable li-polymer battery. AC adapter powered mode: 5V-1A. Please use the AC adapter which is authorized by the manufacturer
Weight: 720g
Accessories: USB-C charging cable
Wireless transmission: BLE, Wi-Fi
Typical battery life: 1 year and 1000 cycles under normal use
Type of use/reuse: multiple patient multiple use

Operating conditions:
5 °C — 40 °C (41°F — 104°F)
15 % — 90 % non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa
70kPa — 106kPa
Max altitude: 2000 m
Storage and transport conditions:
-20 °C — 60 °C (-4°F — 140°F)
10 % — 93 % non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa
50kPa — 106kPa
Max altitude: 2000 m

Powered by: Internally powered by a lithium ion battery
Applied Part level: Type BF (Body Floating)
IP Protection level: IP22
Mode of operation: Continuous Operation
Dimensions: 230 x 190 x 70 mm
Device Classification: Battery Powered Mode: Internally Powered ME Equipment
AC Adaptor Powered Mode: Class II ME Equipment
Software version: 61

Service life: 3 years or 30,000 measurements (may vary based on usage conditions). Cuff: 10000 times.
Please be aware that the stated 3-year product life of Withings Blood Pressure Monitors represents a minimum lifespan under standard tested conditions. Withings products are designed to last: our Blood Pressure Monitors are manufactured with care, and are provided with continual over-the-air firmware updates to avoid obsolescence. This is why with proper care and usage, our health products are likely to serve you reliably for much longer than the minimum product life.

Wireless Information

Mode	Frequency Band (MHz)	Maximum Output Power (dBm)
BLE	2402-2480	8 dBm
WLAN	2412-2484	20 dBm

Warning

- No modification of this equipment is allowed.
- Potential allergic reaction may occur due to skin irritation.
- Keep away from children, pets, and pests after each use.
- Strangulation may occur due to USB cable.
- Do not open/disassemble the product for battery replacement. When charging, the device will display the battery percentage if the user turns on the device.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Withings BPM Vision, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Activate the device at least once every three months to avoid battery leakage. Users must not allow SIP/SOPs and the patient to come into contact at the same time. In case of a serious incident that has occurred, please contact the manufacturer and local authorities immediately. Please contact the manufacturer when in need of assistance, setting up, using or maintaining the device or to report unexpected operation or events. Regarding the application of the cuff and itspressurization on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt is present because of temporary interference with blood flow and could result in injury to the patient. Any blood pressure reading can be affected by the measurement site, the position of the patient (standing, sitting, lying down), exercise, or the patient's physiologic condition. The performance of the automated sphygmomanometer can be affected by extremes of temperature, humidity, and altitude. Please follow the manufacturer instructions to use the product.

Federal Communication Commission Interference Statement

This device complies with Part 15 of the FCC Rules. 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.

This equipment 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 equipment 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 equipment 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.

CAUTION:

Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the equipment.

Federal Communication Commission Interference Statement

RF Exposure warning

This device meets the government's requirements for exposure to radio waves. This device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government.

The exposure standard employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6 W/kg.

Tests for SAR are conducted using standard operating positions accepted by the FCC with the EUT transmitting at the specified power level in different channels.

The FCC has granted an Equipment Authorization for this device with all reported SAR levels evaluated as in compliance with the FCC RF exposure guidelines. SAR information on this device is on file with the FCC and can be found under the Display Grant section of https://apps.fcc.gov/oetcf/eas/reports/GenericSearch.cfm after searching on FCC ID: XNAWPM07.

Caution

Declaration - Electromagnetic emissions and immunity for equipment and systems that are not life-supporting and are specified for use only in a shielded location.

Guidance and manufacturer's declaration-electromagnetic emissions

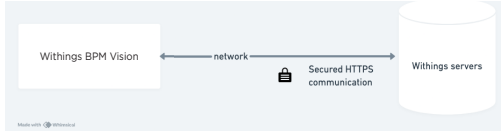
This Smart Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Smart Blood Pressure Monitor should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment – guidance
CE emissions CISPR11	Group 1	The Smart 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.
RE emissions CISPR11	Class B	
Harmonic emissions IEC 61000-3-2	N/A	This Smart 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.
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	N/A	

Safety and performance

Security
If needed, users can restore device configurations by following the factory reset procedure which is available through the Withings' Help Center.
You can subscribe to our status webpage (status.withings.io) in order to be notified if there is an incident or maintenance ongoing.
More information about how Withings protects your data can be found through the Withings' security web page (withings.com/us/en/data-security).
If you no longer use the device, we recommend you to perform a factory reset of your device in order to remove the personal data stored within the device.

Please find below an overview of the communication between your BPM Vision blood pressure monitor and Withings' servers.
Firmware updates:
Users can receive additional software updates automatically via Wi-Fi connectivity. If the device is configured in BLE (Bluetooth Low Energy), users will receive a notification via the Withings Application to update the firmware. Users are able to see the currently installed firmware in the settings menu of the device (accecible via the main menu). If the update of the device fails, the device remeains usable.



Electromagnetic declaration of immunity of the Smart Blood Pressure Monitor
This Smart Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Smart Blood Pressure Monitor should ensure 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	3 Vrms 150kHz to 80MHz	N/A	N/A
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the equipment or system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Interference may occur in the vicinity of equipment marked with the following symbol.
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ±8 kV Air: ±2 kV, ±4 kV, ±8 kV, ±15 kV	Contact: ±8 kV Air: ±2 kV, ±4 kV, ±8 kV, ±15 kV	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 61000-4-8	2 kV for power supply lines 1 kV for input/output lines	N/A	The main power quality should be similar to that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV differential mode 2 kV common mode	line(s) to line(s): +/- 1kV 100kHz repetition frequency	The main power quality should be of the kind used in a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	-5% UT (95% dip in UT) for 0.5 cycles, -40% UT (60% dip in UT) for 5 cycles, -70% UT (30% dip in UT) for 25 cycles, -5% UT (95% dip in UT) for 5 sec	N/A	The main power quality should be that of a typical commercial or hospital environment. If the user of the equipment or system requires continued operation during power main interruptions, it is recommended that the equipment or system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	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. Main voltage prior to application of the test level.

RF Statement

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the following: Interference may occur in the vicinity of equipment marked with the following symbol.

Portable and mobile RF communication equipment (e.g. cell phones) can affect Medical Electrical Equipment.
The use of accessories and cables other than those specified may result in increased emissions or decreased immunity.
The device 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.

The device 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.
Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Use of accessories, transducers and cables 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.
The device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, which should be observed to verify normal operation in the configuration in which it will be used.
Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the following.
Portable and mobile RF communication equipment (e.g. cell phones) can affect Medical Electrical Equipment.

SAR
This product complies with EU requirements regarding restriction of exposure of persons to radio-frequency energy (RF) emitted by telecommunication and radio devices as it is designed and manufactured in such a way as not to exceed the exposure limits indicated by the European Union Commission. The permitted SAR limit for the general population is 2.0 W/Kg. This limit guarantees an ample safety margin that protects all persons regardless of age and health condition.

Essential performance:
Accuracy of measuring blood pressure and pulse rate

Measurement Range	Systolic pressure: 60-230 mmHg Diastolic pressure: 40-130 mmHg Pulse: 40-199 beats/minute
Rated Cuff Pressure	0-299 mmHg (0-39.9 kPa)
Accuracy	Static Pressure: 5°C-40°C within ±3mmHg Pulse value: ±5% Clinical validation: Mean difference within ±5mmHg; Standard deviation ≤8mmHg

Warning: Don't be near the active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. if such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
Warning: Use of accessories, transducers and cables 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.
Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Technical description:
1. all necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnelic disturbances for the expected lifetime.
2. Guidance and manufacturer's declaration -electromagnetic emissions and Immunity.

Warranty

Your BPM Vision blood pressure monitor is guaranteed to be free of material and workmanship defects for a period of two (2) years from the date of receipt.

Disposal

Actuation of European directive 2012/19/EU, for reduction in use of dangerous substances in the electric and electronic device and for garbage disposal.
At the end of the device's useful life, the user must deliver it to a collection center for electric and electronic garbage, or return it to the retail store when purchasing a new device. Disposing of the product separately prevents possible negative environmental and health consequences deriving from inadequate disposal. It also allows the recovery of materials it is composed of to save energy and resources and avoid negative effects to the environment and health. In case of abusive disposal of devices by the user, will be applied administrative endorsements in compliance with current standards. The device
and its parts must be disposed of as appropriate, in accordance with national or regional regulations.

Withings website: **www.withings.com**

Distributed by:
Withings Inc., 225 Franklin St,
Boston, MA 02110, USA

Equipment symbol description

Complies with FCC regulations
FCC ID: XNAWPM07


Upper and lower limits of relative humidity


Upper and lower limits of pressure


Temperature range


Follow instructions for use
Note: the background color of the symbol is blue.


Direct Current


Manufacturer:
GUANGDONG TRANSTEK MEDICAL ELETRONICS CO., LTD.
Zone A, No.105, Dongli Road, Torch Development District,
528437 Zhongshan, Guangdong, China


Reference


Date of manufacture


Ingress of water or particulate matter

Storage temperature


Type BF Applied Part (cuff)


Consult instructions for use or
consult electronic instructions for use


Caution is necessary when operating the device


Model number


MR Unsafe
To identify an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.

WITHINGS

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