WITHINGS BPM CONNECT PRO

Regulatory information

WITHINGS

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IMPORTANT NOTICE

Important safety information

Consult your doctor during pregnancy, or if you suffer from arrhythmia or arteriosclerosis. Please read this section carefully before using the BPM Connect Pro.

Instructions for use of BPM Connect Pro are described in the Onboarding Guide leaflet provided with this regulatory information leaflet

INTENDED USE

The BPM Connect Pro is a digital monitor intended for use in measuring blood pressure and heart rate. The device is intended to be used in a human adult population with an arm circumference of 9 inches to 17 inches (22 cm to 42 cm).

GENERAL SAFETY AND PRECAUTIONS

- Do not forcibly bend the arm cuff.
- Do not inflate the arm cuff when it is not wrapped around your arm.
- Do not apply strong shocks and vibrations to the blood pressure monitor or drop it.
- Do not take measurement after bathing, drinking alcohol, smoking, exercising or eating.
- Do not immerse the arm cuff in water.
- Do not use with a pacemaker, a defibrillator or other electric implant.
- Use on adults only.
- Do not use on children or pets.

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.

CAUTION

GENERAL USE
This blood pressure monitor is intended to be used in a home environment. Always consult your doctor. 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 such as common arrhythmias such as atrial or, ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, 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. 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 life or damage it. A damaged cuff or sensor may lead to incorrect measurements. The patient is an intended operator. Parts in contact with the skin: cuff. Measurements can be affected by extreme temperatures, humidity & altitude

- Do not leave the blood pressure monitor unattended with infants or people who cannot express their consent.
- Do not use the blood pressure monitor for any purpose other than measuring blood pressure.
- Do not disassemble the blood pressure monitor.
- Do not operate the blood pressure monitor in a moving vehicle (car, airplane).
- Do not use the device with the USB cable plugged in.

- Improper continuous pressure of cuff or too-frequent measurements may interfere with blood flow and result in injury to the user. Check to ensure that the use of the device does not result in prolonged impairment of your blood circulation.
- Do not apply the cuff over the user's arm if it has a wound or medical treatment, as this can cause further injury.
- Consult your physician before using this monitor if you have had a mastectomy.
- Use of the device can temporarily cause the loss of function of equipment that is used simultaneously on the same limb.
-When unexpected blood pressure reading is obtained, please contact the customer support.
-The continuous cuff pressure due to connection tubing kinking may cause the effect of blood flow interference and resulting harmful injury to the patient.

AFTER USE

CLEANING

- Do not use an alcohol-based or solvent agent to clean the device.
- Clean the device with a soft and dry cloth.
- The dirt on the cuff can be cleaned with a damp cloth and soap.
- Do not flush the device and cuff with a lot of water.
- Do not dismantle the device, disconnect the cuff, or try to repair it by yourself. If a problem occurs, please check with the distributor.
- Do not operate the device in a severe environment of extreme temperature, humidity, or direct sunshine.
- Do not shake the unit violently.
- Do not submerge the device or any of the components in water.
- Do not use the device after a strong shock, such as dropping the unit on the floor.

STORAGE

- Store the device and the components in a clean and safe location.
- If storage conditions are different from the usage conditions indicated in this document, please wait 30 minutes before 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. It is generally recommended to have the device inspected every 2 years to ensure proper functioning and accuracy. Do not use the device while doing maintenance steps.

TROUBLESHOOTING

PROBLEM	SOLUTIONS
The inflation action cannot be performed or the air pressure cannot rise	1. Check the cuff position, fasten the cuff correctly and remeasure blood pressure again. If the issue persists, please contact the customer service number of your 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

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SPECIFICATION & TECHNICAL DATA

Product description	Digital automatic blood pressure monitor
Model	WPM06
Blood pressure measurement method	Cuff oscillometric method
Cuff inflation	Automatic inflation with air pump at 6 mmHg/s
Pressure sensor	Gauge sensor
Measurement range (pressure)	Rated range of cuff pressure. 0 to 285 mmHg, DIA 40 to 130 mmHg, SYS 60 to 230 mmHg
Measurement range (pulse)	40 to 180 beats/min
Pressure sensor accuracy	Within +- 3 mmHg or 2% of reading
Accuracy (pulse)	Within +-5% of reading
Sensor	Semiconductor pressure sensor
Operating conditions	5 to 40°C, 15 to 90% RH, atmospheric 86Kpa-106kpa, altitude: 2000m
Storage and transport conditions	-20 to 60°C, 10 to 95% RH, atmospheric 86Kpa-106kpa, altitude: 2000m
Arm type	Use on left arm
Power source	5V 1A
Weight	Approx. 245g
Accessories	USB cable, Onboarding guide, Regulatory information leaflet
Product life	3 years
Wireless transmission	Wi-Fi, BLE, LTE Cat-m1
Typical operation time	6 months and 1000 cycles under normal use and good network coverage

SYMBOLS	DESCRIPTION
FC	Complies with FCC regulations
	Upper and lower limits of relative humidity
	Upper and lower limits of pressure
	Temperature range

SYMBOLS	DESCRIPTION
	Do not dispose of this product as unsorted municipal waste; take it to electronic recycling
	Follow instructions for use
	Direct current
	The CE labelling certifies thet the product complies with the essential requirements of Directive 2014/53/EU.
	RCM marking

CLASSIFICATION
Power by: Internally powered by a lithium ion battery
Applied Part level: Type BF (Body Floating)
IP Protection level: IP22
Mode of operation: Continuous Operation

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 Connect Pro, 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 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 its pressurization 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 instruction to use the product.

FCC STATEMENT
FEDERAL COMMUNICATION COMMISSION INTERFERENCE STATEMENT

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 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.
FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.
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.
IMPORTANT NOTE:
RADIATION EXPOSURE STATEMENT:

The product complies with the US portable RF exposure limit set forth for an uncontrolled environment and are safe for intended operation as described in this manual. The further RF exposure reduction can be achieved if the product can be kept as far as possible from the user body or set the device to lower output power if such function is available.
This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter. Country Code selection feature to be disabled for products marketed to the US/CANADA. This equipment should be installed and operated with minimum distance 5mm (between the radiator & your body).

Industry Canada statement
This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

Regulatory information

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

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:

(1) L'appareil ne doit pas produire de brouillage;
(2) L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Caution:
The device for operation in the band 5150–5250 MHz is only for indoor use to reduce the potential for harmful interference to co-channel mobile satellite systems;

Avertissement:
les dispositifs fonctionnant dans la bande de 5150 à 5250MHz sont réservés uniquement pour une utilisation à l'intérieur afin de réduire les risques de brouillage préjudiciable aux systèmes de satellites mobiles utilisant les mêmes canaux;

Radiation Exposure Statement:
The product comply with the Canada portable RF exposure limit set forth for an uncontrolled environment and are safe for intended operation as described in this manual. The further RF exposure reduction can be achieved if the product can be kept as far as possible from the user body or set the device to lower output power if such function is available.

This equipment should be installed and operated with minimum distance 5mm between the radiator & your body.

Déclaration d'exposition aux radiations:
Le produit est conforme aux limites d'exposition pour les appareils portables RF pour les Etats-Unis et le Canada établies pour un environnement non contrôlé. Le produit est sûr pour un fonctionnement tel que décrit dans ce manuel. La réduction aux expositions RF peut être augmentée si l'appareil peut être conservé aussi loin que possible du corps de l'utilisateur ou que le dispositif est réglé sur la puissance de sortie la plus faible si une telle fonction est disponible.

Cet équipement doit être installé et utilisé avec un minimum de 5mm de distance entre le radiateur et votre corps.

IC: 11411A-WPM06
Contains: IC: 12732A-GM02SA

FCC ID: XNAWPM06
Contains FCC ID: 2AAGMGM02SA

EUROPE – EU DECLARATION OF CONFORMITY

Hereby, Withings declares that the radio equipment type of Withings BPM Connect Pro is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: withings.com/compliance.

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 cellular Smart Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the cellular 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 cellular 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	Not applicable	This cellular 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	Not applicable	

The cellular Smart Blood Pressure Monitor declaration electromagnetic immunity

This cellular Smart Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the cellular 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 RFIEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	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/ burstsIEC 61000-4-4	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): ±1 kV 100 kHz repetition frequency	The main power quality should be similar to 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% UT(95% dip in UT) for 0.5 cycle, -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 (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz and 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

DISPOSAL

Actuation of European directive 2012/19/EU, for reduction in use of dangerous substances in the elecrtic and electronic device and for garbage disposal. The symbol applied on the device or its packaging means that at the end of its useful life, the product not be disposed of with dometic waste.

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 retailer 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 device by the user, will be applied administrative endor-

sements in compliance with current standards. The device and its parts must be disposed of as appropriate, in accordance with national or regional regulations.

Version 1.0 April 2021

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 | 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. The use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the unit.

WARRANTY

Your BPM Connect Pro scale is guaranteed to be free of material and workmanship defects for a period of two (2) years from the date of receipt. This warranty does not apply to the cellular data transmission that requires a data plan subscribed by the entity that has provided you with this blood pressure monitor. Reference to standards

Europe – EU Declaration of Conformity -
This device complies with the essential requirements of the MDD (Medical Devices Directive) 93/42/EEC as amended by the 2007/47/EC. The declaration od conformity can be found at: withings.com/compliance.

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.

Software version: FW 181
Withings website
www.withings.com

MODE	Frequency band (MHz)	Maximum output power (dBm)
BT EDR	2402 -2480	1 dBm, 2.4G
BT LE	2412 - 2472	8dBm, 2.4G
LTE	1710 - 1785	23 dBm
LTE	880 - 915	23 dBm
LTE	832 - 862	23 dBm
LTE	703 - 748	23 dBm
WLAN	2400	20 dBm

Regulatory information

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CE **1282**

2021

Manufacturer:
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Ingress of water or particulate matter+33141460460

IP22 Ingress of water or particulate matter

Dry storage environment

FCC ID: XNAWPM06
Contains FCC ID: 2AAGMGM02SA

-20°C (4°F) 60°C (140°F)

Storage temperature

Complies with waste electrical and electronic equipment directive

Type BF Applied Part (cuff)

Read this manual before use

BC

California Energy Commission approval

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REG_WPM06_002

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Withings BPM Connect Pro

V1.1 - May 2021

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