Wrist Electronic Blood Pressure Monitor

Instruction Manual

Regulation information

FCC Caution:

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the 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.

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.

FCC RF Exposure Statement:

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

2. This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

CE Caution:

Risk of explosion if battery is replaced by an incorrect type. Dispose of used batteries according to the instructions.

Radio-frequency exposure:

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

Hereby, Shenzhen Urion Technology Co.,Ltd. declares that this product is in compliance with essential requirements and other relevant provisions of Directive 2014/53/EU. This product is allowed to be used in all EU member states.

Frequency bands	Maximum output power
BLE	-8.29 dBm (EIRP)

Copyright

Trademarks

Preface

Thank you for purchasing the wrist-type electronic blood pressure monitor.

In order to use this product safely and to avoid harm or loss due to improper use, please be sure to read this manual carefully and use it correctly before using the product.

After reading, please keep it in a safe place for future reference. A warranty card is included; please do not lose it.

*The illustrations in this manual are for reference only.

0.Safe to use

1.Failure to fully comply with the operations outlined in this manual may result in inaccurate measurement results.

2.Our company will not notify users of any changes to this manual.

3.The warning symbols and illustrations in this manual are intended to help you use this product safely and correctly, and to prevent injury to yourself and others.

4.Under no circumstances shall our company be held responsible for any issues, damages, or losses arising from calibration or maintenance of this system performed by individuals not authorized by our company.

5.This instruction contains warnings about potential foreseeable dangers, and a high level of vigilance should be maintained at all times for those dangers that are not stated.

Instructions for use and outer packaging symbols

Symbol	Explanation	Symbol	Explanation
	Caution		Type BF applied part
	Follow instructions for use		Non-ionizing electromagnetic radiation
	Batch code		Serial number
	Model number		Manufacturer
	Authorized Representative in the European Union		Country of manufacture
	MR unsafe		Direct current
	Unique device identifier		Medical Device
	This way up		Fragile, handle with care
	Keep dry		Indicates the temperature limits to which the medical device can be safely exposed
	Indicates the range of humidity to which the medical device can be safely exposed		Indicates the range of atmospheric pressure to which the medical device can be safely exposed
	CE Mark:conforms to essential requirements of EU MDR 2017/745		
	DISPOSAL:Do not dispose this product as unsorted municipal waste.Collection of such waste separately for special treatment is necessary.		
IP43	Safe waterproof and dustproof level, use in a relatively dry environment		

1. Notes

1. This blood pressure monitor is suitable for home use and is not recommended for use in public places as a public blood pressure monitor.
2. This device is not suitable for newborns or infants.
3. Long-term high blood pressure values are harmful to health, and consultation with a doctor and treatment are necessary. If abnormal values are detected, consult a doctor, but do not rely solely on a single measurement.
4. Please use the device in the environment as stated in this manual, otherwise, it may not measure correctly.
5. Blood pressure values can vary depending on your physical condition. Therefore, please measure your blood pressure in a quiet, relaxed environment.
6. Pregnant women should be extra cautious when measuring blood pressure, as their blood pressure fluctuations are more significant than in others.
7. Conditions such as common arrhythmia (e.g., premature atrial contractions, premature ventricular contractions, atrial fibrillation), arteriosclerosis, poor perfusion, diabetes, pregnancy, preeclampsia, kidney disease, trembling, or shaking may prevent this blood pressure monitor from delivering the claimed performance.
8. There may be risks when the cuff is excessively inflated for an extended period.
9. Do not tie the cuff too tightly. If the subject feels discomfort, immediately stop the measurement and rest for a few minutes before measuring again.
10. If taking medication that causes significant blood pressure fluctuations, consult a doctor promptly.
11. Replacing original parts with components not provided by the manufacturer may result in measurement errors.
12. Using the product in environments with excessively high or low temperatures, high humidity, or high altitudes may cause inaccurate measurements.
13. This product is not suitable for individuals with a pacemaker or other implanted devices.
14. Do not measure blood pressure frequently unless necessary, as it may hinder blood circulation.
15. Incorrect posture, state, or environment during measurement greatly affects results. Please strictly follow the instructions and guidelines in this manual during measurements.
16. Portable and wireless RF communication devices may interfere with this device. Do not place the

device near or in close contact with other devices, as this may cause increased radiation and reduced immunity to interference.

17. This product may cause adverse events such as allergies during use. If discomfort occurs, stop using the device and consult a doctor.
18. Do not use this device in an environment with flammable anesthetic gases mixed with air or in environments with oxygen or nitrous oxide anesthetics.
19. When measuring, avoid electromagnetic interference above 3V/m. Potential sources of interference include microwave ovens, radiation, etc. The product should be kept away from high-frequency surgical equipment.
20. When disposing of this device and its accessories, please follow the national or regional laws and regulations.

2 Warnings and safety instructions

1） Do not wear this product during medical procedures (e.g. MRI).

2） Conditions such as diabetes, hyperlipidemia, and hypertension accelerate arteriosclerosis and may cause peripheral circulation disorders, which could affect the blood pressure measurement.

3） Individuals with blood circulation disorders or blood diseases may experience measurement errors when using this product.

4） Blood pressure measurement should not be performed on patients who have had vascular interventions, arteriovenous (A-V) shunts, or surgeries like mastectomy or lymph node dissection. Use of this product on these individuals could cause harm.

5） Frequent measurements may lead to injury due to disruption of blood flow.

6） Applying the cuff over a wound may cause further injury.

7） Cuff inflation may cause the malfunction of other monitoring devices used on the same limb simultaneously.

8） Check to ensure the blood pressure monitor is not causing long-term damage to the patient's blood circulation.

9） The following individuals should avoid blood pressure measurement or should only measure under a doctor's supervision:

- Individuals with tremor syndrome or those unable to bend their arms independently.
- Individuals with wounds or inflammation on the arm or wrist.

- Individuals undergoing intravenous infusions, blood transfusions, or those who have catheters in place.

- Patients using other monitoring medical devices.

3 Product Information

3.1 Intended Purpose

This device is intended for use by a person older than twelve (12) to measure the systolic, diastolic blood pressure and pulse rate at home and in medical institutions using the oscillometric method. The values obtained are for diagnostic reference only.

3.2 Contraindications

This product should not be used by individuals with allergies to the device.

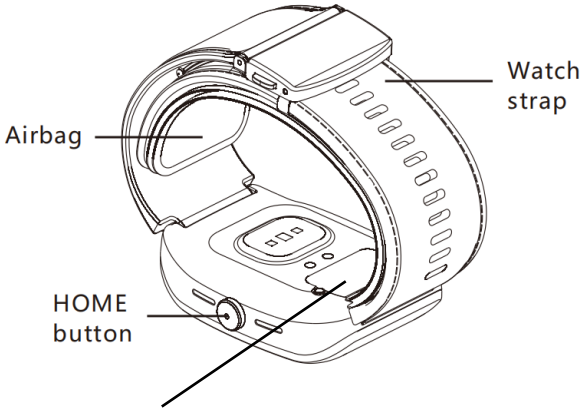
3.3. Specification

Description	Wrist Electronic Blood Pressure Monitor
Measurement method	Oscillometric method
Measurement site	Wrist
Measurable wrist circumference	15.0 cm～21.0 cm L size airbag: 16.1 cm ~ 20.0 cm
Measurement range	Pressure :0 ~300 mmHg (0 ~40kPa) SYS: 60 ~ 230 mmHg (8.0 ~ 30.7 kPa) DIA: 40 ~ 130 mmHg (5.3 ~ 17.3 kPa) Pulse rate: 40-180 beats/ min
Accuracy	Pressure:±3 mmHg (±0.4 kPa) or ±2% of the reading, whichever is greater Pulse rate:± 5%
Software name	Wrist Electronic Blood Pressure Monitor embedded software
Software release version	V1
Electrical safety classification	Internal power supply equipment (When using only the batteries),
Classification	Internally powered equipment; Type BF applied part; Protection against ingress of water or Particulate matter IP43; Not category AP/APG equipment; Mode of operation:Continuous operation
Power supply	Internal power supply: lithium battery DC 4.40V Battery voltage range: 3.5V-4.4V
Charger voltage and frequency	AC 110V-220V, 50Hz
Machine weight	90g
Screen	TFT

3.4 Structure and composition

This device consists of the main unit, cuff, and charger.

3.5 Structure diagram and packing list



Air inlet and outlet (located at the junction of the watch body and the watch strap)

packing list:

Main Unit (including cuff and airbag) x1

Wrist Circumference Ruler x1

Manual (including warranty card) x1

Charging Base (including power cord) x1

Certificate × 1

4. Installation and use

4.1 Measurement principle

This device uses oscillometric technology to measure blood pressure, which is commonly known as the "oscillometric method." During the inflation of the cuff (airbag), the pressure fluctuation signals in the cuff are detected and analyzed by the pressure sensor to calculate systolic pressure, diastolic pressure, and pulse rate.

The device meets the requirements of IEC 80601-2-30 Part 2 for non-invasive blood pressure monitors.

This device is suitable for clinical patient blood pressure reference measurements but should not be used as a diagnostic tool.

According to the "Chinese Hypertension Prevention and Treatment Guidelines" (2018 revised edition), hypertension is defined as a systolic blood pressure (SBP) ≥ 140 mmHg and/or diastolic blood pressure (DBP) ≥ 90 mmHg.

Note: Low blood pressure is not yet precisely defined but is generally considered as systolic blood pressure below 100 mmHg.

4.2 Charging and starting up

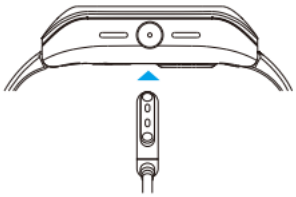
Charging: Align the magnetic charging base with the charging area on the back of the device. Connect the other end to the charger and plug it into a power source. The screen will display the charging status.

Power on: Press and hold the power button for 3 seconds to turn on the device.

Power off: When the device is on, press and hold the power button for 3 seconds to enter the power off screen.

Restart: If the device malfunctions, press and hold the power button for 10 seconds to restart.

Note: The device can automatically power on while charging, or you can press and hold the power button to turn it on manually. Charge the device after receiving the charging indicator.



•Please use the magnetic charger provided in the package for charging. Keep the device dry during charging.

•The magnetic charger consists of a charging head, charging cable, and charging base.

4.3 Measurement Operation Guide

Measurement Precautions

•The device cannot be used to measure blood pressure while charging.

•If discomfort occurs due to prolonged inflation of the cuff or any other reason during measurement, immediately release the air or stop the measurement.

•If the device inflates to 300 mmHg (40 kPa) or higher, immediately stop the measurement and release the air.

•Ask a qualified doctor to interpret your blood pressure measurement: age, weight and other medical conditions can cause slight differences in blood pressure. Do not make your own judgment on the measurement results.

•Correct the measuring posture: The measuring posture is very important for the accuracy of the measurement results.

-Please do not measure immediately after smoking, drinking alcohol or caffeinated drinks, bathing, or exercising. Wait at least 30 minutes before measuring.

-After urinating or defecating, please wait 10 minutes before measuring.

-Please do not measure within 2 hours after a meal.

-Do not measure in places that are too cold, too hot, or where the environment changes drastically.

-Do not measure while standing or lying down.

-Do not measure when any part of your body is under pressure.

-Do not measure in a moving vehicle.

-Please do not stretch or bend the strap and airbag with force.

-Try to rest for 5 minutes before measuring to make your body naturally relaxed. Avoid measuring when you are nervous.

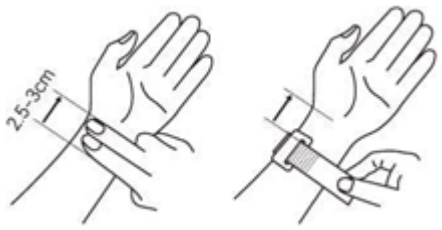
-Please measure in a quiet environment. Do not talk, bend your fingers, or move your body or arms during measurement.

-When measuring continuously, please wait 1 to 2 minutes before taking the next measurement. The waiting time allows the artery to return to the state before measuring the blood pressure.

4.4 Measurement operation process

4.4.1 Wearing a watch

Use a measuring tape to measure the circumference of your wrist. Measure at the point approximately two finger widths above the wrist's palm crease. Wrap the tape around your wrist, ensuring it is snug but not tight, and record the measurement (e.g., 16.0 cm).



Based on the measured readings, it is recommended to refer to the table below to select the corresponding strap tightness scale.

Note: If the wrist circumference is out of range, it is not fully verified.,May affect the accuracy of blood pressure measurement.

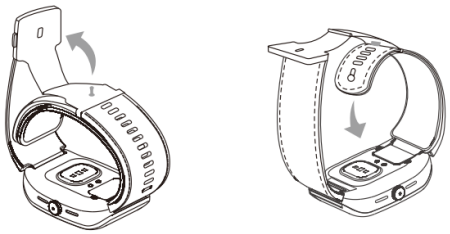
Adjusting the strap tightness

Wrist circumference (cm)	15.0-15.5	15.6-16.0	16.1-16.6	16.7-17.2	17.3-17.8	17.9-18.4	18.5-19.0	19.1-19.6	19.7-20.2	20.3-21.0
Watch strap hole position	7	8	9	10	11	12	13	14	15	16

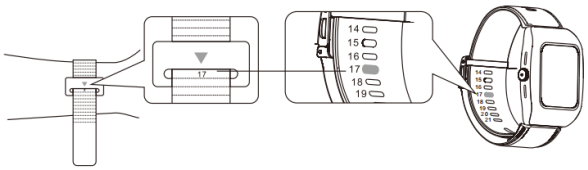
a. Open the watch buckle and airbag buckle

b. Select the watch strap scale according to the scale indicated when measuring with a ruler.

a.Open the watch buckle and airbag buckle.

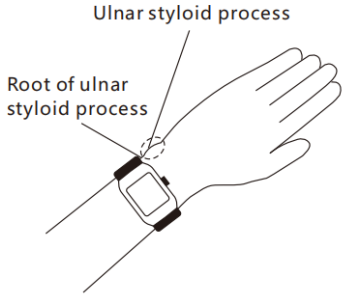


b.Select the watch strap scale according to the scale indicated when measuring with a ruler.



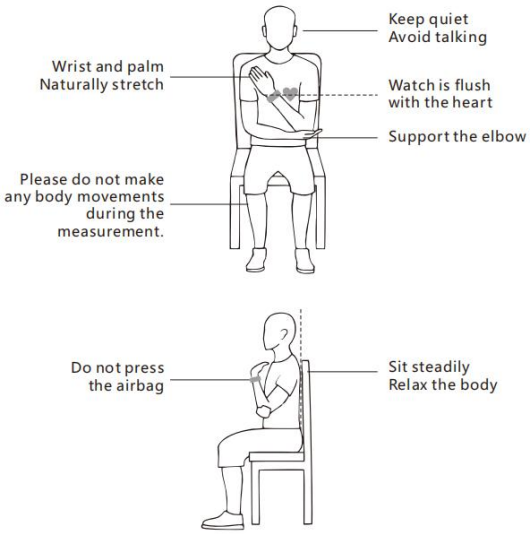
4.4.2 Wearing a watch

When wearing the device, position the main unit at the center of the back of your wrist. The edge of the main unit should be positioned just below the styloid process of the ulna, without pressing against it or being too far from it. The center of the display should be positioned approximately two finger widths above the wrist crease.



4.4.3 Measurement posture

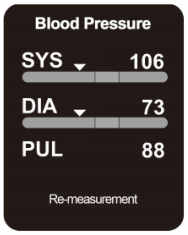
The measurement posture refers to the posture maintained from the start of the measurement until the device displays the measurement result. Actions that do not conform to the standard measurement posture may affect the measurement result.To ensure measurement accuracy, it is recommended to sit still for at least 5 minutes before measurement. The standard measurement posture includes: a. comfortable sitting posture, b. uncrossed legs, c. feet flat on the ground, d. back and arms supported, e. the midpoint of the cuff is at the same level as the heart.



* Your arms (especially your elbows) should not feel constricted by clothing, and the device should not be worn outside of clothing or pressed by clothing.

4.4.4 Click to measure

The device starts to pressurize automatically, and after the measurement is completed, the airbag automatically deflates, and the high pressure, low pressure, and pulse are displayed on the measurement result interface. (The high pressure in this manual refers to the systolic pressure, and the low pressure refers to the diastolic pressure).



4.4.5 Common Problems in Blood Pressure Measurement

Blood pressure cannot be measured or the reading is too high (low), and the blood pressure is different every time it is measured.

analyze:

❶Have you raised your hands to heart level?

❷Are the strap and airbags tight to the wrist?

❸Are your arms and shoulders tense?

❹Whether you are talking or moving your hands during measurement

Solution: Measure with the correct posture, wear the watch in the correct way, relax before measuring, and keep quiet and still during the measurement process. If you still cannot measure normally after repeated attempts, you should contact after-sales personnel.

4.5 Other functions

4.5.1Delete data function

All data will be cleared after the device is restored to factory settings.

4.5.2Measurement unit change

The factory setting unit is "mmHg". Swipe up on the blood pressure application interface and select the unit setting in the settings to change the unit.

4.5.3Entering static mode

If you need to enter the static pressure test mode, please contact the manufacturer. This function is mainly for professionals to enter the static pressure test mode of this equipment.

Warning: Ordinary users do not need to understand this function, and it is recommended not to perform this operation. The company is not responsible for any adverse consequences caused by improper operation.

5. Maintenance and care

5.1 Daily maintenance and use

To ensure the normal operation of the equipment and extend its service life, please pay attention to cleaning and maintenance of the equipment.

1. If there is dirt on the strap or airbag, please wipe it with a dry soft cotton cloth. If the dirt is difficult to remove, wipe it with a cloth dipped in water, wring it out thoroughly, and then wipe it dry with a dry cloth;

Note: The strap and airbag cannot be cleaned in a washing machine or dishwasher.

2. Do not clean or wet the airbag;

3. When cleaning the airbag, do not soak it in water directly; please prevent water, cotton wool and other foreign objects from entering the airbag body through the air nozzle;

4. During daily inspection, if you find any defects such as damage on the strap or airbag, please go to the after-sales service point designated by our company for repair;

5. Do not store the product in a place exposed to direct sunlight, moisture, high temperature, humidity, dust, or corrosive gases;

6. Keep the equipment and accessories clean to prevent foreign objects from blocking the air inlet and outlet, thereby affecting blood pressure measurement.

7. The accuracy of the blood pressure measurement pressure sensor of this device has been strictly tested and there is no need to calibrate it yourself. If you have any questions, please call the after-sales service hotline for consultation.

8. If the equipment fails due to your failure to comply with the above maintenance methods and the following storage precautions or other correct usage methods, the company will not bear the quality responsibility.

5.2 Operating Environment, Transport, and Storage Conditions

5.2.1 Operating Environment:

a) Temperature: 5°C ~ 40°C

b) Relative Humidity: 15% RH ~ 85% RH (no condensation)

c) Atmospheric Pressure: 70.0 kPa ~ 106.0 kPa

d) Altitude: ≤2000 m

5.2.2 Storage and Transport Conditions:

Temperature: -20°C ~ 55°C

Humidity: 10% RH ~ 93% RH (no condensation)

Atmospheric Pressure: 70.0 kPa ~ 106.0 kPa

5.2.3Storage environment

During transportation, avoid strong impacts, direct collisions, exposure to sunlight, or rain.

Avoid environments with direct sunlight, corrosive gases, or proximity to fire sources.

Warning:

Do not allow children or pets to swallow the device or its accessories, as this may cause injury or device failure or explosion.

5.3 Recalibration Recommendations

It is recommended that users send the product to a relevant metrological authority for recalibration regularly (every year or every six months).

5.4 Product Warranty Information

The blood pressure values measured by this device are equivalent to those measured using the auscultatory method, and the error complies with the requirements of IEC 80601-2-30 Part 2 for non-invasive blood pressure monitors.

This product has been clinically investigated according to the requirements of ISO 81060-2:2018 +Amd.1:2020+Amd.2:2024.

6. Exceptional Situation

The following table lists common malfunctions and corresponding troubleshooting methods that may occur during use. If any of these issues arise, refer to this table for resolution.

Common faults	Troubleshooting
The device screen fails to illuminate.	Check if the device is turned off and press and hold the power button for 3 seconds to turn it on.
	Check if the device is out of battery and charge it accordingly.
	Press and hold the power button for 10 seconds to restart.
The device does not respond when the power button is pressed.	Check if the device is out of battery and charge it accordingly.
	Press and hold the power button for 10 seconds to restart.
	If the button is loose or shows no feedback when pressed, it may indicate a button module failure and requires factory replacement.
Unable to charge	Check for oxidation or contamination in the charging port that may cause poor contact, and clean thoroughly.
The touchscreen becomes laggy or unresponsive.	Clean the screen surface to avoid stains interfering with touch functionality.
	If neither of the above steps works, press and hold the power button for 10 seconds to restart.
Repeated measurement failures, or the measurement value is seriously low (or high)	Refer to Section 4.4.2 "Wearing a Watch" to verify the correct wearing method.
	Refer to Section 4.4.3 "Measurement Posture" to verify the correct measurement posture.
	Ensure blood pressure measurement is conducted in a quiet and relaxed state. It is recommended to perform several deep breaths before measurement to enhance relaxation.
Although the device is functioning properly, the measurement results vary each time.	Please carefully review the precautions listed under " Measurement Precautions". Attention: Blood pressure is dynamic, so differences in each measurement are inevitable.
The air pump is working, but the air pressure	Press and hold the power button for 10 seconds to restart.

does not rise or rises too slowly.	Check the airbag for damage or leaks. If leaks are found, return it to the manufacturer for repair.
	If it is damaged due to long usage, please buy a new product.

The following table describes potential error indicators and their causes during measurement. Please perform remeasurement using standardized procedures.

Error display		Cause of failure
Please adjust the wearing posture		Wearing Detection Failed.
Low power		Low battery.
“Fail” page with error code:	1	Abnormal pulse rate.
	2	Abnormal SBP.
	4	Abnormal DBP.
	32	Waveform fitting error.
	64	Insufficient waveform data.
	128	Overtime measurement error.

Warning: If the above conditions cannot be eliminated during use or other failures occur, please consult your local dealer!

7. Electromagnetic compatibility information

This product is designed and manufactured in accordance with the electromagnetic compatibility standards required for medical electrical equipment. This product complies with the requirements of the IEC60601-1-2 and IEC 80601-2-30:2018 standards.

Warning:

- Except for accessories sold by the manufacturer of this product as replacement parts for internal components, the use of accessories other than those specified may result in increased emissions or decreased immunity of the device or system.
- Don’t near active HF surgical equipment and the RF shield room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

- 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.
- Use of accessories 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.
- If use in the environment of strong electromagnetic source, the equipment will be affected. Do not use in imaging Settings, such as magnetic resonance imaging (MRI) and computed tomography (CT).

- Essential Performance is performance, the absence or degradation of which, would result in an unacceptable risk. The Essential Performance Functions of our device are Annex I of IEC 60601-1-2, EN 60601-1-2, IEC 80601-2-30:2018 (Subclause: 201.17&202) and EN IEC 80601-2-30:2019 (Subclause: 201.17&202).
- Even if other devices meet the emission requirements of the corresponding national standards, the blood pressure monitor may still be interfered with by other devices.

Guidelines and manufacturer's declaration

Guidance and manufacturer's declaration - electromagnetic emissions		
The product is intended to be used in the following specified electromagnetic environment, and the buyers or users of the device shall ensure that it is used in such electromagnetic environment:		
Launch test	Compliance	Electromagnetic environment - Guidelines
RF Emissions CISPR 11	Group 1	This product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are unlikely to cause any interference to nearby electronic equipment.
RF Emissions CISPR 11	Category B	This product is suitable for use in all establishments, including domestic and those directly connected to the public
Harmonic Emissions IEC 61000-3-2	Not applicable	

Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Not applicable	low-voltage power supply network that supplies buildings used for domestic purposes

Guidance and manufacturer's declaration - electromagnetic immunity			
This product is intended to be used in the following specified electromagnetic environment, and the buyers or users of the device shall ensure that it is used in such electromagnetic environment:			
Immunity test	IEC60601 test level	Comply with level	Electromagnetic environment - Guidelines
RF transmission IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz ～ 80 MHz 6 Vrms in ISM bans 3 V/m 80 MHz ～ 2.5 GHz	Not applicable 3 V/m 80 MHz～2.5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of this product, including cables, than the recommended separation distance calculated using the equation appropriate to the frequency of the transmitter. Recommended isolation distance $d=1.2\sqrt{P}$ d = 1.2 80 MHz to 800 MHz$\sqrt{P}$ d = 2.3 800 MHz～2.5GHz$\sqrt{P}$ Where: In the formula, P is the maximum rated output power of the transmitter (in watts W) provided by the transmitter manufacturer; d is the recommended isolation distance in meters (m). The field intensity of a stationary RF transmitter is determined by surveying the electromagnetic field [A], and at each frequency range [B] should be lower than the coincidence level. The interference may occur near devices marked with the following symbol. 
Note 1: The formula of higher frequency band should be adopted at 80MHz and 800MHz. Note2: This guideline may not be applicable to all cases, as the electromagnetic propagation is influenced			

by the absorption and reflection of buildings, objects, and human bodies.
A. The field strength of fixed transmitters, such as base stations for wireless (cellular/cordless) telephones and mobile ground radios, amateur radios, AM and FM radios, and television broadcasts etc., cannot be theoretically predicted with any accuracy. In order to evaluate the electromagnetic environment of fixed RF transmitter, the electromagnetic field survey should be conducted. If the measured field intensity of the site where the blood pressure monitor is used is higher than the RF conformance level of the above application, the device should be observed to verify its normal operation. If abnormal performance of the device is observed, the additional measures may be necessary, such as reorienting or re-positioning the electronic blood pressure monitor. B. The field intensity should be lower than 3 V/m in the whole frequency range of 150KHz ~ 80MHz.

Guidance and manufacturer's declaration - electromagnetic immunity			
This product is intended to be used in the following specified electromagnetic environment, and the buyers or users of the device shall ensure that it is used in such electromagnetic environment:			
Immunity Test	**IEC 60601 Test Level**	**Coincidence Level**	**Electromagnetic Environment - Guideline**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact discharge ±8 kV air discharge	± 6 kV contact discharge ±8 kV air discharge	The floor should be wood, concrete or ceramic tile. If the floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/ Burst IEC 61000-4-4	±2kV for power supply lines ±1 kV for Input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to ground	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT.) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles <5% UT (>95 % dip in UT) for 5/6 sec	Not applicable 3A/m	Mains power quality should be that of a typical commercial or hospital environment. If the user of the blood pressure monitor requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or

			a battery.
Power Frequency Magnetic Field (50/60Hz) IEC 61000-4-8	3 A/m	3 A/m	If this product does not work properly, it may be necessary to move it away from the source of the power frequency magnetic field or install magnetic shielding. The power frequency magnetic field in the intended installation location should be measured to ensure that it is sufficiently low.
Note：U_T refers to AC network voltage before the test voltage is applied.			

Recommended separation distances between portable and mobile RF communications equipment and the device			
This product is intended for use in an electromagnetic environment in which RF radiated disturbance is controlled. The purchaser or user of this product can prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and this product, depending on the maximum output power of the communication equipment.			
Transmitter maximum rated output power W	Isolation distance corresponding to different transmitter frequencies/m		
	150 kHz～80 MHz $d=1.2\sqrt{P}$	80 MHz～800 MHz $d=1.2\sqrt{P}$	800 MHz～2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3

100	12	12	twenty three
For transmitters with maximum rated output power not listed in the above table, the recommended isolation distance d, in meters (m), can be determined using the formula in the column corresponding to the transmitter frequency, where P is the maximum rated output power of the transmitter provided by the transmitter manufacturer, in watts (W). Note 1: At 80 MHz and 800 MHz, the formula for the higher frequency band should be used. NOTE 2 These guidelines may not be applicable in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Product Manufacturing Information

Product name: Wrist Electronic Blood Pressure Monitor

Model:U16H/U16L/U16P/U16W/U19M/U19R/U19S/U19T

Manufacturing Date/Product Batch/Serial Number: See the product label

Expected service life: 3 years.

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