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Vital Signs Monitor

User Manual

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Warning

1. Do not replace the battery without training, to avoid a series of dangerous situations such as battery over-heating, fire or explosion.
2. Do not calibrate it yourselves. The calibration is done before delivery. Please contact the manufacturer when calibration is needed.
3. The patient is the intended operator.
4. Do not disassemble or modify the device by yourselves.
5. For patients with a pacemaker, the heart rate monitor may count the pacemaker pulse when the heart is in cardiac arrest or arrhythmia. Please do not rely solely on the heart rate monitor to alarm.
6. Do not place the cuff over any wounds to avoid more serious injury.
7. Do not use the cuff on the limb with any implants or surgeries, otherwise it will cause harm to the patient due to the obstruction of blood flow.
8. The cuff should not be worn on the limb on the side of mastectomy or lymph node removal.
9. The compression of the cuff will cause any other monitoring equipment on the same limb to fail.
10. It is necessary to check whether the operation of the automatic sphygmomanometer will cause long-term damage to the patient's blood circulation.
11. Please contact your doctor immediately when you get an abnormal reading.
12. The device can only monitor one patient at a time.
13. The processing and reprocessing of thermometers, probes and accessories comply with the requirements of ISO 17664:2004 and ISO 14937:2009
14. Do not put the cuff or USB cable on the neck, to avoid any dangerous accidents and cause suffocation.
15. If the device has been in extreme heat or cold, place the device in an ambient environment of 20 degree Celsius for 2 hours before use.
16. Some materials on the equipment may cause sensitive reactions to some patients who are allergic to it. Please pay attention.

【Contraindications】

- 1.This device does not record the activity of an implantable cardiac pacemaker.People with implanted pacemakers should not use this device.
- 2.Patients should be cautious to use the device when suffering serious heart disease.
- 3.Do not use the blood pressure function with an injured arm.
- 4.Children or the people who cannot express their thoughts shall use the device under supervision.
- 5.Patients suffering from blood circulation disorders and blood diseases, please use it under the guidance of a doctor.

I COMPANY PROFILE

- 1.Company Name: Suzhou Melodicare Medical Technology Co., Ltd
Address: Room 301, Building F2, No.32 Hongxi road, Suzhou high-tech zone, Jiangsu province,China.
- 2.Contact: Email: info@minttihealth.com
Tel: +86 (0) 791-85230171
- 3.Website: www.minttihealth.com

II PRODUCT DESCRIPTION

1.Product Features

The unit has multi functions of measuring heart rate, body temperature, blood pressure and blood oxygen. The monitor works with your mobile device to test, track and share data.

Equipment application part: device and cuff.

2.Indications for Use

Intended Use:

- 1.The unit is intended for the use in measuring heart rate,ECG, body temperature, blood pressure and blood oxygen at home or monitoring of the hypertensives, fever patients and anoxic patients. It is intended to be used at home or healthcare facilities. And this device cannot be used in ICU.
- 2.Side effects: N/A
- 3.User profile (Patient profile):The device is intended to be used by lay persons, nurses, physicians who are able to read and understand English.
4. Do not use the device on body part with injury and skin infection.
- 5.Blood pressure measurement is intended to be used for person over 12 years old.
- 6.Body temperature measurement is intended to be used for person over 5 years old.
- 7.Heart Rate and SpO2 measurements are intended to be used for person over 6 years old.
- 8.The operator must be able to read English.
- 9.The ECG function of this device is not suitable for infants weighing less than 10kg.

3.Product Classification

According to the protection of the risk of electric shock, this product is classified as class II type equipment.

Type BF: Cuff; Type CF: ECG electrode, temperature probe, blood oxygen probe.

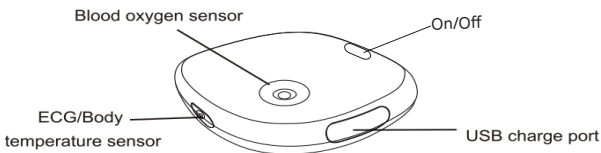
4.Operating Environment

Vital Signs Monitor operating environment as follows:

- a) Environment temperature: $+10^{\circ}\text{C} \sim +45^{\circ}\text{C}$
- b) Relative humidity: 10%~95%
- c) Barometric pressure: 86 kPa~106 kPa
- d) Ambient temperature test: when the ambient temperature is 25.5°C , temperature of the cuff is 27.1°C , the ECG metal plate is 27.2°C , and the blood oxygen probe is 26.1°C .
- e) When the ambient temperature is 40°C , temperature of the cuff is 41.6°C , the ECG metal plate is 41.7°C , and the blood oxygen probe is 40.6°C . At this time, the ECG application part exceeds 41°C , and the patient should use it without any skin damage, such as burns, scalds, or wounds. It is recommended that each use should not exceed 5 minutes.
- f) Supply voltage: $5\text{V} \pm 0.25\text{V}$; DC Power Supply 3.7V, Battery capacity:400mAh
- g) Communication protocol: Bluetooth 4.0; Bluetooth working frequency: 2.4000 ~ 2.4835GHz.

5.Structure and Components

The Vital Signs Monitor is made up of the main unit, arm cuff, USB charging cable and mobile APP



Note:

1. ECG electrodes part should not be placed near conductive materials such as magnets.
- 2.If the electrode and sensor of the device are loose or damaged, the corresponding function will not work properly, please contact our staff for return to the factory for repair.

6.Explanation of Symbols on Unit

	BF type application device		Scrap electrical equipment
	Warning sign		Please refer to user manual
	Serial Number	IP22	See below for explanation
	Lot number		Class II Anti-electronic type
	Manufacturer		European Representative
	CE mark		Production date
	Keep dry		Upward
	Fragile, handle with care		Keep from sunlight
	Recycle		Do not step on it with your feet
	CF type application device		DC mark

IP22:The first number 2: Protected against solid foreign objects of 12,5 mm Φ and greater. The second number: Protected against vertically falling water drops when enclosure tilted up to 15° . Vertically falling drops shall have no harmful effects when the enclosure is tilted at any angle up to 15° on either side of the vertical.

III PRODUCT SPECIFICATION

Model: Vision

Power voltage: DC3.7V

Size: 70mm*70mm*18.4mm

Weight: approximately 70g

Wireless communication: Bluetooth 4.0 operating frequency:
2.4000GHz-2.4835GHz

Blood pressure/heart rate

Measuring method: oscillometric method

Cuff perimeter: 22-35cm

Measuring range: Blood pressure 0-300mmHg

Systolic pressure: 60-260mmHg

Diastolic pressure: 40-199mmHg

Heart rate: 30-300bpm

Measuring error: blood pressure ± 3 mmHg Heart rate $\pm 5\%$

Blood oxygen

Measuring method: reflective Method Measuring range: 90%-99%

Measuring error: $\pm 2\%$

Temperature

Temperature measurement Measuring method: infra-red

Measuring part: forehead

Measuring range: 34°C - 43°C

Measuring error: 36-39°C $\pm 0.2^{\circ}\text{C}$

> 39°C or < 36°C $\pm 0.3^{\circ}\text{C}$

ECG measurement

Measurement mode: Single lead Input impedance: > 10M Ω

Input circuit current: < 0.1uA

Calibration voltage: 1mV ± 0.05 mV

Sensitivity tolerance: < 10%

50Hz interference suppression filter: > 20dB

Maximum input range: ± 4.7 mV

Polarization resistance voltage: ± 300 mV,

Amplitude variation < 10%

Frequency response: 0.5~40Hz

Overshoot: not more than 20%

Environmental humidity for storage and transport: -40°C - +55°C ,
 $\leq 93\%$ RH

Environmental pressure: 86-106kPa



Safety classification: this product should not be used under mixed gases of flammable anaesthetics and air mixture of oxygen or nitrous oxide environment.

IV SETUP AND OPERATING

PROCEDURES

Set up Requirements

The Vital Signs Monitor is designed to be used with the following required device:

- a) Bluetooth 4.0
- b) Android 5.0 system or newer, iOS 9.0 or newer system.

Charge the Battery

- a) Please charge the battery when the low battery warning appears in the APP.
- b) Please use the cable provided together with the unit to charge the battery.
- c) The oxygen LED indicator will flash when battery is being charged.
- d) The oxygen LED indicator will remain on when battery is fully charged.
- e) DO NOT use the unit when charging it.
- f)  The battery can only be replaced by maintenance personnel. It is warned that the replacement of the battery by personnel without adequate training will cause danger.
- g) Please use the adapter complying with IEC60601-1 standard to charge the device.
- h) Battery maintenance method:
 - Do not leave the device in a state where the battery power is too low for a long time, otherwise the lithium-ion battery will be damaged, and it should be charged occasionally.
 - Keep the device away from high temperature, otherwise it will affect the charging point of the battery.
 - The battery just can be replaced by the Maintenance personal only, otherwise it will cause danger.
- i) When the device is in different measurement functions, the battery usage time is different; however the battery cycle life is estimated to last more than 300 times of charging.
- j) Battery leakage may lead to unacceptable risks. Regular inspection or maintenance of the battery is required.

Turn on/off the Unit

- a) Turn on: long press the power button for 2s, the unit will gently vibrate. The power LED indicator is flashing blue light.
- b) Turn off: long press the power button for 2s, the unit will gently vibrate. The power indicator is dark.
- c) Connected and measuring: the power LED indicator is steady blue.

App Download

1. Search "MinttiVision" on Google Play or Apple Store, download and install MinttiVision APP

Connect the Device

Long press the power button to start the unit. Open the APP, the device will be automatically connected to the app. The unit is connected when the power LED indicator is steady blue. If the LED flashes, please click the Bluetooth icon to connect manually.

APP NOTICES

Make sure that the smartphone operation system is suitable before download the App.

Turn on the unit first then login to the App. Ensure your phone's bluetooth connection is switched on. This will automatically connect the unit to the APP.

Troubleshooting

PROBLEM	POSSIBLE CAUSE	SOLUTION
Can not download the APP	The smart phone does not conform with the requirements	Please check whether the smart phone's Bluetooth and operation system conforms with the requirements.
Can not be automatically connected	Incorrect operation	Turn on the unit first then login in the app, or connect manually
Can not be connected or find the unit	Low Bluetooth sensitivity	Re-login in the app or restarting the unit



Maybe should move up to the troubleshooting table.

Blood Pressure/ Heart Rate Measurement Instruction

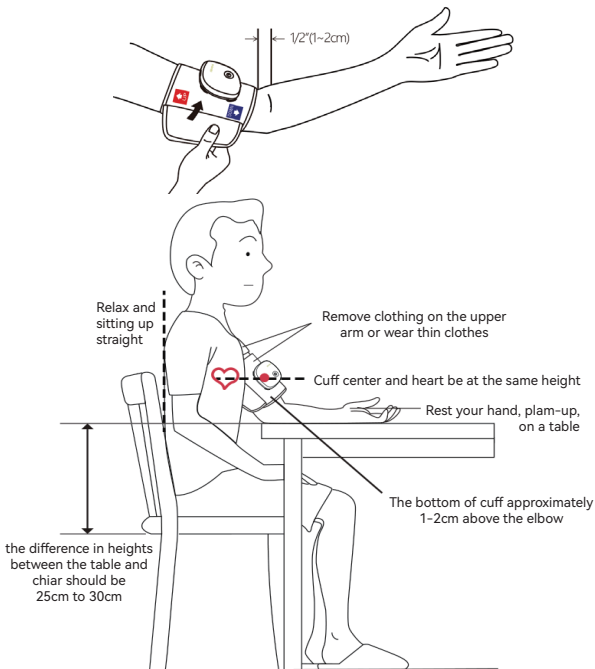
1. The working principle of blood pressure: The blood pressure function algorithm of this software is based on the third generation technology, adopting high-precision filtering algorithm to obtain systolic blood pressure, diastolic blood pressure, heart rate, composed of cuff, air pump, vent valve, blood pressure sensor and other devices. The air pump is used to inflate the cuff and the vent valve is used to quickly exhaust after the measurement is completed. The mobile phone sends a measurement command to BLE, and BLE receives the command from the mobile phone to control the working status of the air pump and the vent valve. The blood pressure sensor (MMR901) is used to collect the cuff pressure and transmit it to BLE via SPI. BLE will package the data and send it to the mobile phone according to the communication protocol.

The filtering algorithm is the core of the project, and the quality of the algorithm directly affects the accuracy of blood pressure. Three filtering algorithms are used to calculate blood pressure, which are limiting filtering, mean filtering and band-pass filtering.

2.The blood pressure and heart-rate measurement are easily influenced by the tester's (spacing) body gesture, cuff wearing way, physiologic condition and the surrounding environment; therefore please make

sure the middle of the cuff should be placed at the same level as your heart.

- 1) Stay calm and rest for at least 5 minutes before blood pressure measurement. Remove clothes from your arm or wear thin clothes to test.
- 2) Put the multifunctional Vital Signs Monitor to the cuff in a correct position, making sure that the bottom edge of the cuff is approximately 1 to 2 cm above the elbow, loosen or tighten it as long as it's comfortable.
- 3) Stay still and place the measuring arm on a table, palm-side up and relax so that the middle of the cuff is at the same level as your heart.
- 4) Select blood measurement on the APP and you can enter the page of blood measurement, press 'Start' to start measure; please keep calm when taking measurement.
- 5) Take the cuff off after completing the measurement



CAUTION

- Avoid eating, drinking, coffee, smoking, exercising and showering for at least 30 minutes before taking a measurement, please rest at least 5 minutes.
- Please ensure testing under a resting state, maintain emotional balance and make sure you do not need to urinate, and then take the measurement in a correct gesture.
- Always use the same arm for the measurement.
- Please stay calm during measurement. DO NOT move your body or arm. DO NOT measure under too cold, too hot or dramatically changing environments.
- DO NOT take the measurement in a the moving vehicle. This product can only be applied to arms, please do not use it on other body parts.
- DO NOT take continuous measurement on one arm. If multiple measurements are needed, wait at least 30 seconds before taking another measurement.
- Cannot be used in occasions where electrosurgical equipment is used.
- The pressure of arm cuff may cause paralysis to your arms, therefore children and the person with injured arm should use with caution.
- This arm cuff is specially designed, please do not remove or replace by yourself; if replacement is needed, please contact the factory.
- If there is a questionable reading, the measurement should be repeated.
- The expected service life of this cuff is more than 2000 times.
- Do not attempt to inflate your arm multiple times as the pressure exerted from the cuff can injure your arm.
- When common arrhythmia occurs (E.g. atrial and ventricular premature and atrial fibrillation), the measured value may be incorrect or unable to test.
- Young children or people who cannot express their thinking should not use this device, if yes this may cause accidents or disputes.
- The patients with blood circulation disorder or any blood diseases should use this monitor under guidance of doctor.
- The highly anxious patients are not advised to do self-test. The hypertension reference standard for this product complies with the family hypertension value $\geq 140/90$ mmHg of the 'guidelines for prevention and control of hypertension (2020 version)'.

Troubleshooting for blood pressure/heart rate

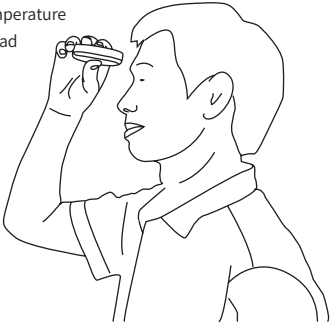
PROBLEM	POSSIBLE CAUSE	SOLUTION
Abnormal result (too low value)	The cuff position was not correct; speaking or body movement during testing; body posture was incorrect.	Review the body posture, apply the cuff correctly, and please stay calm during the process. For detailed operation, please consult the instruction.
Unable to inflate	Cuff leakage or incorrect device placement	Review the device position; please replace the cuff if there is a problem with cuff and contact the manufacture for a replacement.
Unable to test	Incorrect device placement or low battery	Check if the monitor is placed correctly and check the device battery. Please consult the instruction for detailed operation.

Body Temperature Testing Guidance

- 1.Maintain the forehead dry and clean; align the monitor probe on the middle of forehead and above eyebrows with the monitor in the hand, the interval between monitor probe and forehead should be 1 to 2 cm.
- 2.Select “TEMPERATURE” on the APP then click “START” to measure.
- 3.Read the measuring value when the measurement is complete.
- 4.The measuring environment temperature should be > 16°C (60.8° F)
- 5.The temperature value is not displayed when beyond the display range.

The interval between monitor probe and forehead should be 1 to 2cm

Sensor of temperature
aim to forehead



 CAUTION

- Clean your forehead before measuring.
- Do not use temperature probe to directly touch your forehead skin.
- Please try to take measurement under a stable environment; do not measure in the direction of the Spacing or air-condition wind flow or places under direct sunlight.
- The measurement takes about 2 seconds.

It is normal to have temperature differences when you take multiple measurements of different body parts. The thermometer uses an adjustment algorithm which may cause a 0.2 degrees Celsius fluctuation when you take multiple measurements.

CAUTION(General)

1. 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.
2. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
3. 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 device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could occur.

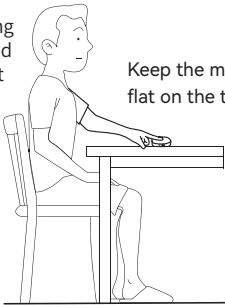
Troubleshooting

PROBLEM	POSSIBLE CAUSE	SOLUTION
Measured error	Sweat/oil/ dirt on forehead	Clean the forehead before measurement, stay dry and clean for the measuring part
	Measured distance was too far	The interval between monitor probe and forehead should be 1 to 2 cm according to the requirement

Blood Oxygen Measuring Guidance

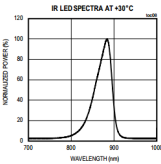
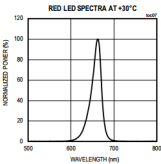
- 1.Place the multifunctional Vital Signs Monitor on the desk, stay still and calm, put the forefinger above the blood oxygen probe and use the finger pulp to touch the probe.
- 2.Select “Oximetry” on the APP and click “Start” to measure.
3. The uptake/upload of blood oxygen data is 4 seconds.

Adjust sitting position and keep quiet



Keep the minitor flat on the table

Put fingertip of forefinger on the oxygen detector



CAUTION

- The Vital Signs Monitor should be horizontally placed during the measurement.
- It's recommended to measure using the middle finger, with nails facing upwards.
- DO NOT move the finger during the measurement. There are some differences on the blood pressure, blood circulation, physiological features on different fingers, hence try to use the same finger to take measurements. The paralysis state caused by the continuous blood-pressure measurements can influence the blood circulation, which may affect the oximetry values, so do not measure the blood oxygen after finishing the blood pressure measurement.
- DO NOT use a finger that has nail polish on it for measurement.
- DO NOT take measurement under strong light.
- DO NOT measure after exercising.
- The temperature of the probe of the oximeter on the skin surface should not exceed 41°C . If it exceeds 41°C , special attention should be paid
- The measured blood-oxygen value may be incorrect if the tester's finger skin is too thick or has pigment deposition. If there are foreign matters between the probe and the measured parts, it may influence the result.
- The function tester cannot be used to evaluate the accuracy of the blood oxygen monitor.
- Cold fingertip skin or poor peripheral circulation caused by low temperature treatment or prolonged exposure to low-temperature environment can result in insufficient pulse signal, out of range measurements or inability to measure.
- The functional oxygen saturation displayed by the pulse oximetry device is calibrated.
- The waveform of this function module is not normalized.

Troubleshooting

PROBLEM SYMPTOM	POSSIBLE CAUSE	SOLUTION
Data changed a lot in a short period	Measured way or body gesture was wrong	Re-measure according to the instruction
Unable to get measured results	Finger overexerted	Lightly press the middle finger on the device, do not overexert
	Finger is too thin	Use another finger to measure, ensure the finger is covering the blood-oxygen light during the process

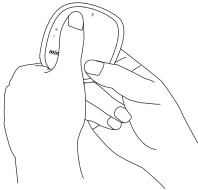
ECG Measuring Guidance

Basic Knowledge of ECG

Heart rate variability: means to monitor the autonomic nervous activity of the heart.

Instruction

1. The left thumb contacts the blood oxygen sensor. The hands don't touch each other.
2. Hold the device with your right hand while others touch the metal label on the back of the device. The power button faces the palm of the hand.
3. Press the “start” button on the APP to start measurement. The results will contents ECG diagram, heart rate, HRV and Breathing rate.



CAUTION

To avoid the external disturbance, please do the measurement in a quiet environment.

DO NOT do the measurement when the device is being charged. Please place two hands in correct position.

DO NOT perform the measurement with wet hands.

During the measurement, two hands DO NOT touch each other.

ECG measurement can get the results of Heart rate, HRV and Breathing rate at the same time.

ECG signal is extremely weak, so please sit still during the measurement.

In the process of measuring, keep steady DO NOT shake.

The test results are for reference only and need to be confirmed by the doctor.

Troubleshooting

PROBLEM	POSSIBLE CAUSE	SOLUTION
ECG diagram reverse	The position of two hands are reverse	Please correctly place both hands, according to instructions.

V MAINTENANCE

Maintenance under the following principles

1. Do not rinse the cuff with running water, clean the cuff with a dry and soft cloth if it is needed.
2. Do not use moistened cloth to wipe the Vital Signs Monitor because it is not waterproof.
3. Do not wipe the product with alcohol, gasoline, diluents.
4. This product is electronic product, including a battery, please do not put it close to fire source or heat source.
5. Every component of this product has been strictly tested by the manufacturer before leaving the factory, it is recommended to check the product once a year.
6. Do not disassemble or repair the product by yourself, if there is any problem with product quality or any doubts with measured results, please consult the customer service hotline.
7. It is recommended to calibrate the machine (at least once a year). Do not calibrate by yourself. Please contact the manufacturer or use the manufacturer's authorized service center to perform the calibration.

Storage under the following principles

1. Do not store the Vital Signs Monitor under the high temperature, humid, direct sunlight, dust, salty environment.
2. Do not store the monitor in a tilted position or on a surface which produces vibration and strike.
3. Do not store the monitor in a place with chemicals or corrosive gases.
4. Do not drop the monitor from high height.
5. Do not tightly fold the blood-pressure measurement cuff.

Repair under the following principles

1. Do not disassemble or repair the monitor by yourself, if there is any problem with product quality or any doubts with measured results, please consult the customer service hotline.
2. The cuff is specially designed, please contact the manufactured factory to repair or purchase if it is damaged, do not replace by yourself.

VI OBSOLETE EQUIPMENT MANAGEMENT



On the premise of the correct use of this product, the service life cycle of this product is 3 years. The cuff can be replaced if it is damaged. After correct use of 3 years, the device cannot be repaired and its safety performance cannot meet the requirement, then the device should be scrapped.

For the handling of the device, cuff, or waste battery, please refer to the local regulation. Please do not discard it casually.

Please confirm whether the equipment is in good condition before each use, for example, whether the surface of the equipment is flawed and scratched, and whether the equipment is damaged.

Unpack the package and check the equipment with the packing list to see whether the accessories are consistent with the list, whether they are damaged, and whether they are within the expected service life. If you have any questions, please contact the manufacturer or the agents.

VII QUALITY ASSURANCE

In terms of the unit, Minttihealth guarantee services as follows:

1. Products can be refunded, replaced or maintained free within 7 days after sale, under the usage of instruction sheet. Products can repaired for free within 1 year after sale in the precondition of non artificial damage.

If any other reasonable requirements, Minttihealth provides the repair service and technical services, but need to charge the cost accordingly.

2. Warranty time starts from the date on the purchasing invoice from manufacturer or authorized distributor.

This warranty shall not apply to the following situations:

1.The malfunction and damage caused by the other barriers (manmade factors or external device). The product malfunction caused by not following the instructions for use in accordance.

2.The damage caused by maintenance or dismounting without permission.

3.The malfunction caused by the fall and transportation failures after purchase.

4.The damage caused by factors beyond the control, fire, flood, abnormal voltage, other natural disaster and secondary product damage.

5.The damage under normal application but not in warranty time.

6.The products are purchased from unauthorized channels.

VIII ELECTROMAGNETIC COMPATIBILITY INFORMATION

If not following the below information, it will lead to the monitor's electromagnetic emission increases and/or immunity declines.

1.Special attention should be paid to the medical electrical device's EMC compatibility. The user should refer to the EMC compatibility information provided in the user manual to install and use the unit.

2.Mobile and convenient RF communication equipment will affect the medical electrical equipment.

3.Using the accessories, transducer and power cable outside of the ones specified by the manufacturer will lead to the same issue of here electromagnetic emission increases and immunity declines.

4.Do not use the unit beside other devices or stacked with other device.

If it is a must to be used beside other devices and or stacked with other device, should be care the unit closely to insure its normal operation.

5.Only use the replaceable electrical components and parts provided by Minttihealth.

Electromagnetic Emissions —The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the monitor should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions GB 4824	Group 1	The monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions GB 4824	Class B	The 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.
RF emissions GB 17625.1	Class A	
Voltage fluctuation Flicker emission GB 17625.1	Complies	

Electromagnetic Immunity—The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the MONITOR should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge(ESD) GB/T 17626.2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV ai	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 GB/T 17626.4	± 2 kV for power supply lines ± 1 kV I/O lines	± 2 kV for power supply lines NA, no I/O lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge GB/T 17626.5	± 2 kV for power supply lines ± 1 kV I/O lines	± 2 kV for power supply lines ± 1 kV I/O lines	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 GB/T 17626.11	<5 % U_T (>95 % dip in U_T) for 0.5cycle	<5 % U_T (>95 % dip in U_T) for 0.5cycle	Mains power quality should be that of a typical commercial or hospital environment.If the user of the Monitor requires continued operation during power mains interruptions, it is recommended that the Monitor be powered from an uninterruptible power supply or a battery.
	40 % U_T (60 % dip in U_T) for 5 cycles	40 % U_T (60 % dip in U_T) for 5 cycles	
	70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 mins	70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 mins	
Power frequency	3A/m	3A/m	Power frequency magnetic fields should be at levels.

Electromagnetic Immunity —The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the MONITOR should ensure that it is used in such an environment.

IMMUNITYtest	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF GB/T17626.6 Radiated RF GB/T17626.3	3 Vrms 150 kHzto 80 MHz 3 V/m 80 MHzto 2.5 GHz	3 V 3 V/m	Recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2 \sqrt{P}$ 150 kHz to 80 MHz $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol. 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a)Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MONITOR is used exceeds the applicable RF compliance level above, the MONITOR should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MONITOR. b)Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the Monitor.

The Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Wireless Blood Pressure Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MONITOR as recommended below, according to the maximum output power of the communications equipment.

Transmitter rated maximum output power(W)	Corresponding to the isolation distance of the transmitter at different frequencies(m)		
	150KHz to 80MHz $d=1.2\sqrt{P}$	80MHz to 800MHz $d=1.2\sqrt{P}$	800MHz to 2.5GHz $d=2.3\sqrt{P}$
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	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			

Package Contents

No.	Items	Num.
1	Vital Signs Monitor	1
2	Cuff	1
3	User manual	1
4	Warranty Card	1
5	QC Certificate	1
6	USB Line	1



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FCC Warning Statement: Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. 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.

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.

FCC Radiation Exposure Statement

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