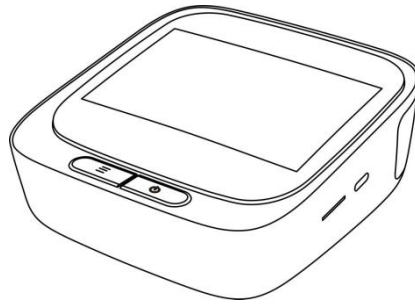


# User's Manual

## Blood Pressure Monitor + ECG



PN: 255-05970-01 Version:A

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# 1. The Basics

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

## 1.1 Safety

### Warnings and Cautionary Advice

- Before using the device, please ensure that you have read this manual thoroughly and fully understand corresponding precautions and risks.
- This device has been designed for practical use, but is not a substitute for a visit to the doctor.
- The data and results displayed on the device are for reference only and cannot be directly used for diagnostic interpretation or treatment.
- Do not use this device with a defibrillator.
- Never submerge the device in water or other liquids. Do not clean the device with acetone or other volatile solutions.
- Do not drop this device or subject it to strong impact.
- Do not place this device in pressure vessels or gas sterilization device.
- Do not disassemble and modify the device, as this could cause damage, malfunction or impede the operation of the device.
- Do not interconnect the device with other device not described in the Instruction for Use, as this could cause damage or malfunction.
- This device is not intended for use by people (including children) with restricted physical, sensory or mental skills or a lack of experience and/or a lack of knowledge, unless they are supervised by a person who has responsibility for their safety or they receive instructions from this person on how to use the device. Children should be supervised around the device to ensure they do not play with it.
- Do not use the device with persons with sensitive skin or allergies.
- Do not store the device in the following locations: locations in which the device is exposed to direct sunlight, high temperatures or levels of moisture, or heavy contamination; locations near to

sources of water or fire; or locations that are subject to strong electromagnetic influences.

- This device displays changes in the pulse rate and blood pressure etc. which may have various different causes. These may be harmless, but may also be triggered by illnesses or diseases of differing degree of severity. Please consult a medical specialist if you believe you may have an illness or disease.
- Vital signs measurements, such as those taken with this device, cannot identify all diseases. Regardless of the measurement taken using this device, you should consult your doctor immediately if you experience symptoms that could indicate acute disease.
- Do not self-diagnose or self-medicate on the basis of this device without consulting your doctor. In particular, do not start taking any new medication or change the type and/or dosage of any existing medication without prior approval.
- Avoid tightly folding the cuff or storing the hose tightly twisted for long periods, as such treatment may shorten the life of the components.
- The device and cuff are not water-resistant. Prevent rain, sweat and water from soiling the device and cuff.
- Sources of electromagnetic disturbance may affect this device (e.g. mobile telephones, microwave cookers, diathermy, lithotripsy, electrocautery, RFID, electromagnetic anti-theft systems, and metal detectors), please try to stay away from them when making measurements.
- To measure blood pressure, the arm must be squeezed by the cuff hard enough to temporarily stop blood flow through the artery. This may cause pain, numbness or a temporary red mark to the arm. This condition will appear especially when measurement is repeated successively. Any pain, numbness, or red marks will disappear with time.
- Too frequent measurements can cause injury to the patient due to blood flow interference.
- Consult your physician before using this monitor on an arm with an arterio-venous (A-V) shunt.
- Consult your physician before using this monitor if you have had a mastectomy or lymph node clearance.
- The pressurization of the CUFF can temporarily cause loss of function of simultaneously used monitoring device on the same

- limb.
- Consult your physician before using the monitor if you have severe blood flow problems or blood disorders as cuff inflation can cause bruising.
  - Please prevent that operation of the device results in prolonged impairment of the circulation of the blood of the patient.
  - Do not apply the cuff on an arm with another medical electrical equipment attached. The equipment may not function properly.
  - People who have a severe circulatory deficit in the arm must consult a doctor before using the device, to avoid medical problems.
  - Do not self-diagnose the measurement results and start treatment by yourself. Always consult your doctor for evaluation of the results and treatment.
  - Do not apply the cuff on an arm with an unhealed wound, as this can cause further injury.
  - Do not apply the cuff on an arm receiving an intravenous drip or blood transfusion. It may cause injury or accidents.
  - Remove tight-fitting or thick clothing from your arm while taking a measurement.
  - If the patients' arm is outside the specified circumference range that may result in incorrect measurement results.
  - The device is not intended for use with neonatal, pregnant, including pre-eclamptic, patients.
  - Do not use the device where flammable gases such as anesthetic gases are present. It may cause an explosion.
  - Do not use the device in the area of HF surgical equipment, MRI, or CT scanner, or in an oxygen rich environment.
  - The battery intended to be changed only by service personnel with the use of a tool, and replacement by inadequately trained personnel may result in damage or burn.
  - The patient is an intended operator.
  - Do not carry out the servicing and maintenance while the device is in use.
  - The patient can safely use all the functions of the device, and the patient can maintain the device by carefully reading Chapter 7.
  - When powered by internal battery, the contact time of cuff is

1min≤t<10min.

## 2. Introduction

### 2.1 Intended Use

The device is intended to measure blood pressure only, electrocardiogram (ECG) only or blood pressure and ECG simultaneously.

The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult population.

The device is intended to record, store, and transfer single-channel electrocardiogram(ECG), blood pressure and pulse rate.

The device is intended for use by healthcare professionals, and health-conscious individuals in a general household situation.

The device has not been tested and it is not intended for pediatric use.

The device no analysis by itself and is intended to be used with a compatible ambulatory ECG (holter) analysis system (AI-ECG Tracker) which will analyze the recorded data (used under the care of a physician).

The device data and the data analysis are then reviewed by a trained medical personnel for the purpose of forming a clinical diagnosis.

### 2.2 Contraindications

This device is contraindicated for use in ambulatory environments.

This device is contraindicated for use on aircraft.

### 2.3 About the Product

Product name: Blood Pressure Monitor + ECG

Note: BP3、BP3D、BP3K、HDM3、HDM3D、HDM3K without ECG

Product model: BP3, BP3D, BP3K, BP3F, BP3G, HDM3, HDM3D, HDM3K, HDM3F, HDM3G

The models difference is as the following form.

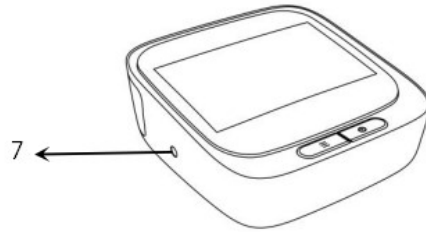
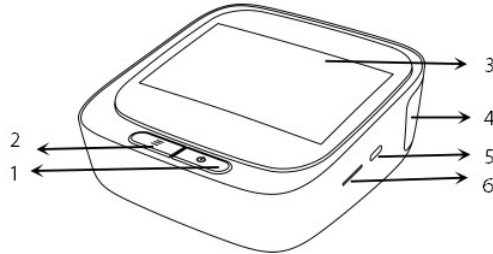
Model	BP	PR	ECG	HR	BT	Wifi	4G	Color
BP3	●	●	×	×	●	×	×	White
BP3D	●	●	×	×	●	●	×	White
BP3K	●	●	×	×	●	×	●	White
BP3F	●	●	●	●	●	●	×	White

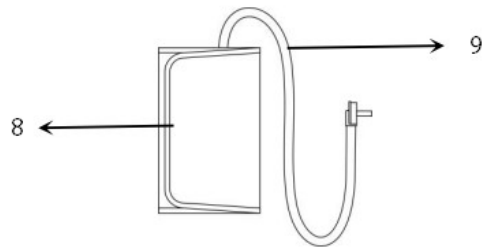
BP3G	●	●	●	●	●	×	●	White
HDM3	●	●	×	×	●	×	×	Black
HDM3D	●	●	×	×	●	●	×	Black
HDM3K	●	●	×	×	●	×	●	Black
HDM3F	●	●	●	●	●	●	×	Black
HDM3G	●	●	●	●	●	×	●	Black

Note 1: BP indicates Blood pressure; PR indicates Pulse rate; HR indicates Heart rate; BT indicates Blue tooth.

Note 2: ● indicates that this function is available, × indicates that this function is not available.

Note 3: The model you purchased may not have all the above functions, please refer to the actual model purchased.





- 1) Start/Stop button
  - Power On/Off
  - Short press to Start/Stop measuring blood pressure.
- 2) Function button
  - Short press to start the ECG measurement.
  - Press and hold for 2 seconds to review historical data.
  - Short press to review historical data. (for models without ECG function)
- 3) Display screen
- 4) ECG electrodes
  - Press and hold them while taking ECG measurements.
- 5) Cable connector
  - Connect with the charging cable.
- 6) SIM card slot (only for certain models)
- 7) Connector
- 8) Cuff
- 9) Air hose

## 2.4 Essential performance













Measurement of blood pressure and ECG.

The maximum error of blood pressure does not exceed  $\pm 3\text{mmHg}$  ( $\pm 0.4\text{kPa}$ ).

The laboratory reproducibility of the blood pressure determination shall be less than or equal to  $3.0\text{mmHg}$  ( $0.4\text{kPa}$ ).



## 2.5 Symbols

Symbol	Meaning
	Manufacturer
	Date of manufacture
SN	Serial number
 0197	In conformity with Directive 93/42/EEC
IP22	Against ingress of solid foreign objects $\geq 12.5\text{mm}$ diameter, Against dripping (15° tilted)
	Follow operating instructions
	Application part type BF
	Warning
	MRI unsafe. Presents hazards in all MR environments as device contains strongly ferromagnetic materials.
	No alarm system
	Non-ionizing radiation
	European Representative
	Symbol for “ENVIRONMENT PROTECTION – Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice”.
	Medical device

## **2.5 Unpacking**

Main Unit;

Cuff;

Air Hose;

Charging Cable;

User Manual

## **3. Using the Product**

### **3.1 Charge the Battery**

Use the USB cable to charge the monitor. Connect the USB cable to a USB charger or to the PC. It takes 2-3 hours to fully charge. When the battery is fully charged, the indicator will be off.

The monitor works on very low power consumption, and a full charge usually lasts for months. A battery symbol, which indicates the battery status is displayed on the screen.

**Note:** The device cannot be used during charging, and if choosing a third party charging adaptor (Class II ), select one that complies with IEC60950 or IEC60601-1.

### **3.2 Blood Pressure Measurement**

#### **3.2.1 Before Taking Measurements**

To help ensure accurate measurements, follow these directions:

- Rest for at least 5 minutes before taking measurements.
- Stress raises blood pressure. Avoid taking measurements when stressed.
- Remove any tight-fitting clothing from your arm.
- A single measurement does not provide an accurate indication of your true blood pressure. You need to take and record several results over a period of time.
- Try to measure your blood pressure at the same time each day to maintain consistency.

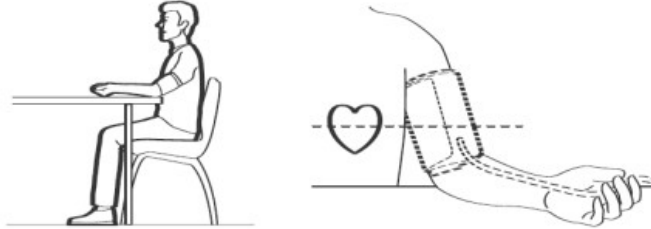
### 3.2.2 Applying the Arm Cuff

- 1) Wrap the cuff around the upper arm, about 1 to 2 cm above the inside of the elbow, as shown.
- 2) Place the cuff directly against the skin, as clothing may cause a faint pulse and result in a measurement error.
- 3) Constriction of the upper arm, caused by rolling up a shirtsleeve, may prevent accurate readings.
- 4) Confirm that the artery position mark is line up with the artery.

**Note:** Keep the host wear position aligned with the middle finger.

### 3.2.3 How to Sit Correctly

To take a measurement, you need to be relaxed and comfortably seated. Sit in a chair with your legs uncrossed and your feet flat on the floor. Place your arm on a table so the cuff is level with your heart.



Note: The time is about 5s required for the device to warm from the minimum storage temperature between uses until the device is ready for its intended use when the ambient temperature is 20°C, and the time is about 5s required for the device to cool from the maximum storage temperature between uses until the device is ready for its intended use when the ambient temperature is 20°C.

### 3.2.4 Measuring Blood Pressure

- 1) Power on the blood pressure monitor.
- 2) Press the Start/Stop button to start taking blood pressure measurements.
- 3) The monitor will automatically deflate the cuff slowly while taking measurements. A typical measurement takes about 30s.
- 4) The readings will be displayed when the measurement is finished. You can press Start/Stop button again to stop the blood pressure

measurement.

**Note 1:** During the measurement, you should keep still and don't squeeze the cuff. Stop measuring when the pressure result appear in the product. Otherwise the measurement may be effected and the blood pressure readings may be inaccurate.

**Note 2:** Max. Temperature of the cuff in contact with the patient does not exceed 48°C, and skin surface contact, duration is less than 1 h.

### 3.2.5 Measuring Blood Pressure and ECG

- 1) Power on the blood pressure monitor.
- 2) Press the Start/Stop button to start taking blood pressure measurements.
- 3) Cover the electrodes on both sides of the monitor with your right and left hands, making sure that your fingers are in full contact with the electrodes. (See 3.3.2 for correct measuring position)
- 4) The monitor will measure the blood pressure and ECG simultaneously.
- 5) Readings of blood pressure and ECG will be displayed one by one when measurements are finished.

**Note:** Simultaneous measurement of blood pressure and ECG only supports the hand-to-hand ECG recording method.

### 3.2.6 After Measurement

The product will automatically release the cuff gas after the measurement is over.

Press the button to turn off the power after the measurement. Remove the cuff.

**Note:** The device has an automatic power shut-off function, which turns off the power automatically in two minute after measurement.

## 3.3 Recording ECG

### 3.3.1 Before Taking Measurements

To help ensure accurate measurements, follow these directions:

- Before using the ECG function, pay attention to the following points to obtain precise measurements.
- The ECG electrode must be positioned directly against the skin.
- If your skin or hands are dry, moisten them using a damp cloth before taking measurements.

- If the ECG electrodes are dirty, remove the dirt using a soft cloth or cotton swap dampened with disinfection alcohol.
- While taking measurements, do not touch your body with the hand with which you are taking measurements.
- Please note that there must be no skin to skin contact between your right and left hand. Otherwise, the measurements cannot be taken correctly.
- Stay still while taking measurements, do not speak and hold the device still. Movements of any kind will falsify measurements.
- If possible, take measurements when sitting and not when standing.
- Follow the text and voice guides on your phone to finish taking measurements.

### 3.3.2 Recording ECG

There are two methods to record ECG:



Hand to hand



Right hand to left Leg

To start an ECG Recording:

- 1) Put your right palm on the right side electrodes of the monitor.
  - 2) Place the left side electrodes to the body position that you desired to measure.
  - 3) Once the body parts are placed on the electrodes, press the **Function** button to start ECG recording.
  - 4) Wait for 30 seconds, the result readings will be displayed.
- To start recording ECG again, press the **Start/Stop** button to return to the Home screen, then press the **Function** button.

**Note:**

- The recording must take at least 30 seconds to complete, and to be analyzed by the detectors
- You can get different signal amplitudes from different methods. Use Lead II mode if the signal is too low in Lead I mode.

### 3.3.3 Turn on/off Heartbeat Sound

The buzzer beeps when a heartbeat is detected while recording ECG.

## 3.4 Reviewing History Records

You can review the history results and replay the recorded ECG waveform on the History screen.

Hold the **Function** button for 2 seconds to enter the History screen.

The last measurement results will be displayed by default.

For ECG recordings, the Heart Rate will be displayed first and then replayed over the 30-second ECG waveform.

To view the next records, press the **NEXT** button.

To exit the History screen, press the **HOME** button.

## 3.5 Turning On/Off Bluetooth

The product has built-in Bluetooth wireless connectivity, which enables exporting measured records to other device.

Press the function button and hold it for 3 seconds to start Bluetooth mode.

Data can only be exported in Bluetooth mode. Pressing the Start/Stop button will exit Bluetooth mode.

## 4. Trouble Shooting

<b>Problem</b>	<b>Possible Cause</b>	<b>Recommended Action</b>
The product cannot be connected to the phone	The phone Bluetooth is OFF	Turn on the phone Bluetooth from the setting menu.
	The phone doesn't support the Bluetooth 4.0 BLE	Change to a compatible phone.

The product don't response to the button press.	The product is running in an unexpected status.	Reset the device by press and hold the button for 8s.
Cannot get blood pressure readings.	The measurement is interrupted by arm movement or unexpected bulb squeeze.	Keep arm still and don't squeeze the bulb during deflating-measure phase.
	There is an over-leakage of press	Check if the hose connection is loose.

## 5. Specifications

<b>Classifications</b>		
EC Directive	MDR, EU 2017/745	
	RED, 2014/53/EU	
Degree of protection against	Type BF	
<b>Environmental</b>		
<b>Item</b>	<b>Operating</b>	<b>Storage</b>
Temperature	5 to 45°C	-25 to 55°C
Relative humidity	10% to 95%	10% to 95%
Barometric	700 to 1060 hPa	700 to 1060 hPa
Degree of dust & water resistance	IP22	
Drop test	1.0 m	
<b>Physical</b>		
Size (main unit)	120*121.5*49 mm	
Weight (main unit)	< 500g	
Cuff size	22-42cm	

Wireless connectivity	Bluetooth 5.2 BLE Wifi 2.4G LTE CAT1
<b>Power Supply</b>	
Charge input	USB Type-C, DC 5V
Battery type	Rechargeable lithium-polymer battery
Charge time	2 hours
<b>Blood Pressure Measurements</b>	
Technology	Oscillometric Method
Pressure measurement range	0 – 300 mmHg
Pressure measurement accuracy	±3 mmHg
Pulse rate range	40 to 200 bpm
Pulse rate accuracy	±5%
Clinical accuracy	Meet IEC80601-2-30
<b>ECG Recording</b>	
Lead type	Integrated ECG electrodes
Lead set	Lead I, Lead II, Chest Lead
ECG length	30s-5min
Heart rate range	30 - 250 bpm
Heart rate accuracy	±2 bpm or ±2%, whichever is greater
Input impedance	≥10MΩ, 10Hz
Input dynamic range	10mV (peak-to-valley)
Common-Mode Rejection Ratio (CMRR)	≥60dB (for sinusoidal signals at the mains frequency) >45dB (for signals at twice the mains frequency)



ECG bandwidth	0.67 ~40 HZ
Gain Accuracy	Maximum amplitude error $\pm 10\%$
Heart Rate Calculation	Divide 1 minute by the number of squares between two R waves.
<b>Storage</b>	30 records
<b>Bluetooth RF</b>	
Frequency range	2.400GHz-2.483GHz
Wifi	
Frequency range	2.400GHz-2.483GHz
4G	
Frequency range	LTE-FDD B1/B3/B5/B7/B8/B20/B28
	LTE-TDD B38/B40/B41
Expected service life	5 years

## 6. Maintenance and Cleaning

### 6.1 Maintenance

To protect your device from damage, please observe the following:

- Store the device and the components in a clean, safe location.
- Do not wash the device and any components or immerse them in water.
- Do not disassemble or attempt to repair the device or components.
- Do not expose the device to extreme temperatures, humidity, dust or direct sunlight.
- The cuff contains a sensitive air-tight bubble. Handle this carefully and avoid all types of straining through twisting or buckling.
- Clean the device with a soft, dry cloth. Do not use petrol, thinners or similar solvent. Spots on the cuff can be removed carefully with a damp cloth and soapsuds. The cuff must not be washed!
- Do not drop the instrument or treat it roughly in any way. Avoid strong vibrations.
- Never open the device! Otherwise the manufacturer calibration becomes

invalid!

## 6.2 Cleaning

The device can be repeatedly used. Please clean before reuse as follow:

- Clean the device with a soft, dry cloth with 70% alcohol.
- Do not use petrol, thinners or similar solvent.
- Clean the cuff carefully with cloth soaked 70% alcohol.
- The cuff must not be washed!
- Clean on the monitor and the arm cuff, and then let it air dry.

Note: The device is a non-sterile medical device and does not contain any sterile or degradable component thus the device is not subject to the shelf life requirements.

## 6.3 Disposal



Batteries and electronic instruments must be disposed of in accordance with the locally applicable regulations, not with domestic waste.

## 7. Accessories

Name	Model	Specification
Charging Cable	540-04595-00	Length: 1 m
Cuff	560-03388-00	Size: 530.2×135mm
Air Hose	260-05789-00	Length: 600mm; Outside Diameter: 7mm

## 8. Electromagnetic Compatibility

The device meets the requirements of EN 60601-1-2.

### **Warnings and Cautionary Advice**

- Using accessories other than those specified in this manual may result in increased electromagnetic emission or decreased electromagnetic immunity of the equipment.
- The device or its components should not be used adjacent to or stacked with other equipment.
- The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- Other devices may interfere with this device even though they meet the requirements of CISPR.
- When the inputted signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.
- Portable and mobile communication equipment may affect the performance of this device.
- Other devices that have RF transmitter or source may affect this device (e.g. cell phones, PDAs, and PCs with wireless function).
- If the essential performance is lost or degraded due to EM disturbances, the user is encouraged to reorient or relocate the device to stay away from sources of electromagnetic disturbance.

<b>Guidance and manufacturer's declaration - electromagnetic emissions</b>		
The Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Blood Pressure Monitor should assure that it is used in such an environment.		
<b>Emission test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
RF emissions CISPR 11	Group 1	The Blood Pressure Monitor use RF energy only for its internal function. Therefore, its RF emissions is very low and is not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Blood Pressure Monitor is suitable for use in all establishments, including

Harmonic emissions IEC61000-3-2	Not applicable	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	

<b>Guidance &amp; Declaration — electromagnetic immunity</b>			
The Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Blood Pressure Monitor should assure that it is used in such an environment.			
<b>Immunity test</b>	<b>IEC60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC 61000-4-4	±2kV for power supply lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV, ±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% $U_T$ (>95% dip in $U_T$ ) for 0.5 cycle  <5% $U_T$ (>95% dip in $U_T$ ) for 1 cycle  70% $U_T$ (30% dip in	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Electronic Stethoscope requires continued operation during power mains interruptions, it is recommended that

	U <sub>T</sub> ) for 25/30 cycles  <5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 5/6 sec		the Electronic Stethoscope be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields/ Proximity magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic fields IEC 61000-4-39	CW 8A/m for 30KHz Pluse modulation 2.1KHz, 65A/m for 134.2KHz Pluse modulation 50KHz,7.5A/ m for 13.56MHz	CW 8A/m for 30KHz Pluse modulation 2.1KHz, 65A/m for 134.2KHz Pluse modulation 50KHz,7.5A/ m for 13.56MHz	
Note: U <sub>T</sub> is the a.c. mains voltage prior to application of the test level.			

<b>Guidance &amp; Declaration - Electromagnetic immunity</b>			
The Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Blood Pressure Monitor should assure that they are used in such an environment.			
<b>Immunity test</b>	<b>IEC60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz  6 Vrms in ISM bands & amateur radio bands	Not applicable	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 Blood
Radiated RF IEC61000-4-3	10V/m 80MHz to 2.7 GHz  385MHz-5785MHz Test specifications	10 V/m 80MHz to 2.7 GHz  385MHz-5785MHz Test specifications	

	for ENCLOSURE PORT IMMUNITY to RF wireless Communication equipment (Refer to table 9 of IEC 60601-1-2:2014+A1:2020)	for ENCLOSURE PORT IMMUNITY to RF wireless Communication equipment (Refer to table 9 of IEC 60601-1-2:2014+A1:2020)	Pressure Monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
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**CE 0197**

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