制作工艺：

封面：200g铜版纸覆哑膜彩印

内页：80g书写纸黑白双面印刷

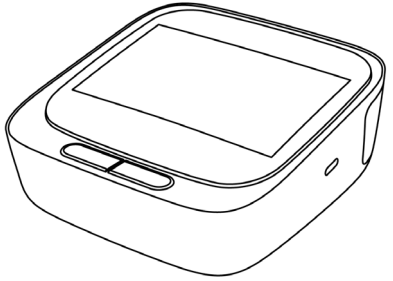
胶装

尺寸：95*140mm±1mm

注意不要压字
此页不印刷

LEPU MEDICAL

Blood Pressure Monitor + ECG



User Manual

English | Deutsch | Italiano | Español | Français

Contents

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 devices, accessories, detachable parts, and materials 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 6.
- When powered by internal battery, the contact time of cuff is 1min⩽t<10min.
- Biocompatibility tests have been performed on all the applied parts. But some exceptional allergic patients may still have anaphylaxis. Do not apply to those who have anaphylaxis.
- The conductive parts of electrodes and associated connectors for type BF applied parts, including neutral electrode, should not contact other conductive parts including earth.
- Prolonged continuous recording may increase the risk of undesirable changes in skin characteristics, such as irritation, reddening, blistering or burns.

- Please keep cables and hoses away from children. It can cause strangulation due to excessive length.
- Keep the device out of reach of pets, pests and children.
- Degraded or loosened electrodes can degrade performance or cause other problems, please always check the device before use and contact the manufacturer if you discover such conditions.
- If an inexperienced operator or inexperienced responsible party needs to obtain assistance in installing, using, or maintaining the ME equipment or ME system or to report unusual operation or events, please contact the manufacturer or the manufacturer's representative.

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 record data of single-channel electrocardiogram (ECG) from this device in combination with ambulatory ECG (Holter) analysis system (Al-ECG Tracker) can provide recommendations for atrial fibrillation, bradycardia, tachycardia, and sinus rhythm.

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 does not 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.

The device does not include analysis and diagnosis functions.

2.2 Contraindications

This device is contraindicated for use in ambulatory environments.

This device is contraindicated for use on aircraft.

This device is not intended for use in patients with cardiac pacemakers or other implantable devices.

2.3 About the Product

Product name: Blood Pressure Monitor + ECG

Product model: BP3F, BP3G, HDM3F, HDM3G

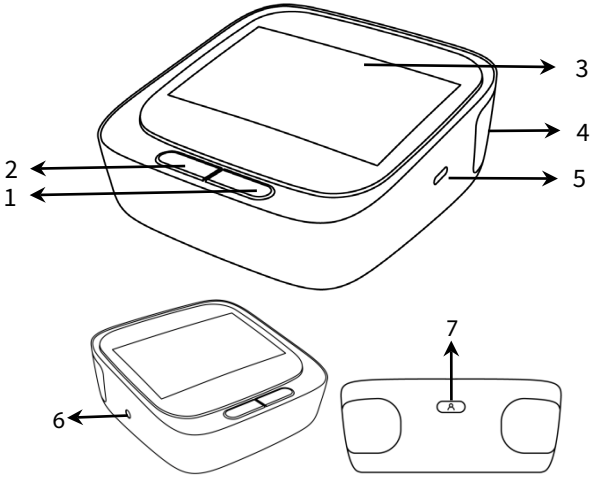
Difference between models is as the following form.

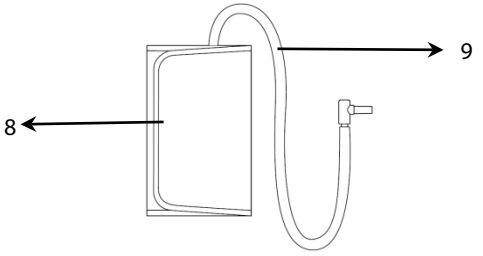
Model	BP	PR	ECG	HR	BT	Wifi	4G	Color
BP3F	●	●	●	●	●	●	×	White
BP3G	●	●	●	●	●	×	●	White
HDM3F	●	●	●	●	●	●	×	Black
HDM3G	●	●	●	●	●	×	●	Black

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

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.
   - Short press to stop measuring ECG.
   - Long press to turn off the screen.
2) Function button
   - Short press to start measuring ECG.
   - Press and hold for 2 seconds to review historical data.
3) Display screen
4) ECG electrodes

   Press and hold them while taking ECG measurements.
5) Cable connector
   - Connect with the charging cable.

6) Connector
7) User switching key
   - Short press to enter the user switching screen.
   - When the system shuts off, long press to enter version screen.
   - Press again to switch users.
8) Cuff
9) Air hose

2.4 Symbols

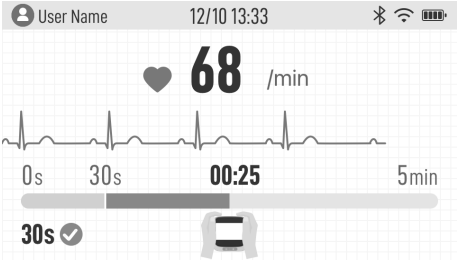
Symbol	Meaning
	Manufacturer
	Date of manufacture
	Serial number
	Unique device identifier
	Indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.

Symbol	Meaning
	Refer to instruction manual
	Type BF Applied Part
	MR unsafe
IP22	Indicates that the product is protected against solid foreign objects of 12,5 mm Ø and greater; and protected against vertically falling water drops when enclosure tilted up to 15°.
	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	Medical device
	Indicates that the product complies with the EU Medical Device Regulations (Regulation (EU) 2017/745)

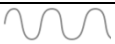
Symbol	Meaning
	Authorized representative in the European community
	UKCA marking
	UK Responsible Person
	Non-ionizing radiation
	Indicates that the marked item or its material is part of a recovery or recycling process.
	Our products and packaging can be recycled, don't throw them away! Find where to drop them off on the www.quefairedemesdechets.fr site (Only applicable for French market).
	Battery can be recycled, don’ t throw it away! (Only applicable for French market)
	Packaging can be recycled, don’ t throw it away! (Only applicable for French market)

2.5 Screen Display

Blood pressure measurement



ECG measurement

	ECG waveform demonstration
	Pulse wave
	Heartbeat symbol
	Bluetooth

	Wireless
	Battery status

2.6 Unpacking

Content of the kits:
The Main Unit;
A Cuff;
An Air Hose;
A Charging Cable;
A User Manual

3. Using the Product

Operating principles: It uses the oscillometric method to measure blood pressure.

Oscillometry method: The sphygmomanometer uses an air pump to inflate and pressurize the cuff, and use the inflatable cuff to compress the arteries, so that the arteries and blood vessels are in a state of complete obstruction. Then open the bleed valve to slowly decrease the pressure in the cuff. As the pressure in the cuff drops, the arteries are completely blocked-gradually open-fully open.

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.

The monitor works on very low power consumption, and a full charge usually lasts for months.

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

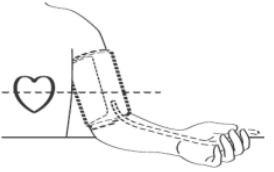
1) Wrap the cuff around the upper arm about 1 to 2 cm above the inside of the elbow, as shown.
2) Place the cuff directly against the skin, as clothing may cause a faint pulse and result in a measurement error.
3) Constriction of the upper arm, caused by rolling up a shirtsleeve, may prevent accurate 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) Press the Start/Stop button to access the main screen, then press it again to begin blood pressure measurement.
2) The monitor will automatically deflate the cuff slowly while taking measurements. A typical measurement takes about 30s.

3) 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 appears in the product. Otherwise, the measurement may be affected and the blood pressure readings may be inaccurate.

Note 2: The maximum temperature of the cuff in contact with the patient does not exceed 48°C and the skin surface contact duration should not exceed 1 hour.

3.2.5 Measuring Blood Pressure and ECG

1) Press the Start/Stop button to access the main screen, then press it again to begin blood pressure measurement.
2) 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)

3) The monitor will measure the blood pressure and ECG simultaneously.

4) 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 Start/Stop button to turn off the power after the measurement. Remove the cuff.

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.

- During the measurement, please remain as relaxed as possible and avoid any conversation.

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. (Or press the Start/Stop button to access the main screen, then press the Function button to start ECG recording.)
4) Wait for at least 30 seconds for measuring.

5) Press the Start/Stop button or removing hands or leg and hand to finish measuring and data will be recorded.

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.
- The maximum temperature of the electrodes in contact with the patient does not exceed 48°C and the skin surface contact duration should not exceed 1 hour.

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.

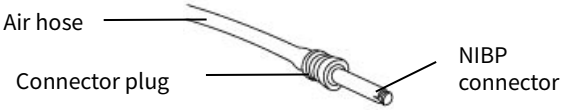
To view the previous record, press the **Function** button.

To exit the History screen, press the **Start/Stop** button.

3.5 Calibrating the Monitor

Operation procedure:

1) Take out the NIBP connector and connector plug and attach the NIBP connector with the connector plug on to one end of the air hose.

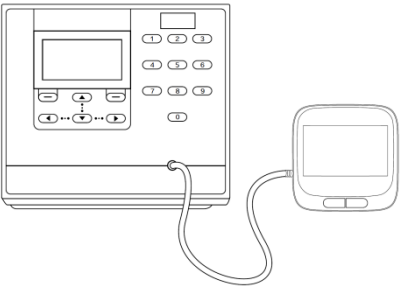


2) Prepare an air hose with a length of 0.5m to 1.0m and an inner and outer diameter of 4.0mm and 8.0mm respectively.

3) Select either of the following methods.

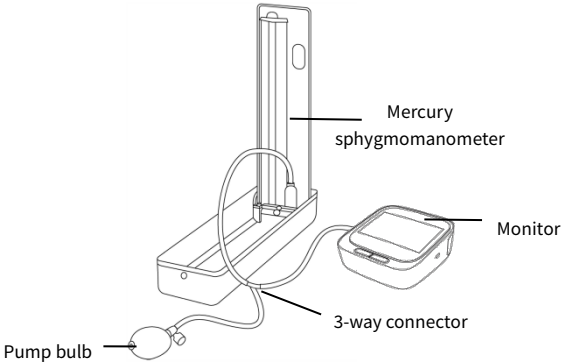
Method one:

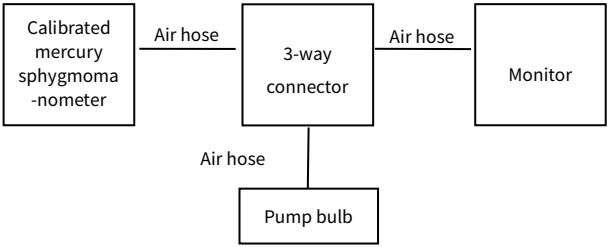
Connect one end of the air hose to the port on the noninvasive blood pressure simulator and the other end to the monitor.



Method two:

Connect one end of the air hose to the connector on the monitor, and the other end to the 3-way connector which connects a calibrated mercury sphygmomanometer and a pump bulb.





4) When the monitor is off-screen, press and hold the User switching key and Function button for 5s to enter the calibration mode.

5) Follow the on-screen instructions to proceed.

Note: This mode is for static pressure calibration and air leakage inspection of the monitor carried out by professional technicians only.

4. Trouble Shooting

Problem	Possible Cause	Recommended Action
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	Change to a

	support the Bluetooth 4.0 BLE	compatible phone.
The product doesn’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.

Error Code Interpreting

Error	Possible Cause	Recommended Action
Error 2	Measurement failed, excessive noise, abnormal result.	Measurement failed, please measure again.
Error 3	Measurement failed, weak signal, abnormal result.	Measurement failed, please measure again.
Error 4	Air leakage, pressure not exceeding 15mmHg in 15s, air leakage reported, abnormal result.	Please wear the cuff correctly and measure again.
Error 5	System error,	Measurement

Error	Possible Cause	Recommended Action
	abnormal result. Measurement interrupted by button operation.	failed, please measure again.
Error 8	Huge interference, stop measurement.	Do not move or talk during measurement, please measure again.
Error 10	Pressure greater than 15mmHg for more than 180s.	Measurement failed, please measure again.
	ECG recording time less than 30s.	Keep recording the ECG for at least 30s.
	Hands or leg and hand not in touch with ECG lead	Hold the ECG lead for at least 30s.

5. Specifications

Classifications	
EC Directive	MDR, EU 2017/745
	RED, 2014/53/EU
Applied part	Type BF (cuff, electrode)
Maximum temperature of the applied part	Lower than +48°C

Environmental		
Item	**Operating**	**Storage**
Temperature	5 to 40°C	-25 to 70°C
Relative humidity (non-condensing)	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	
Physical		
Size (main unit)	120*121.5*49 mm	
Weight (main unit)	< 500 g	
Cuff size	22-42 cm	
Wireless connectivity	Bluetooth 5.2 BLE Wifi 2.4G LTE CAT1	
Power Supply		
Charge input	USB Type-C, DC 5V	
Battery type	Rechargeable lithium-polymer battery	
Charge time	2 hours	
Battery life	Normal cycle charge/discharge times ⩾ 200 times (Blood pressure measurement only + WiFi)	
Blood Pressure Measurements		
Technology	Oscillometric Method	
Pressure measurement range	0 – 298 mmHg	
Pressure measurement	±3 mmHg	

accuracy	
Diastolic blood pressure measurement range	40 - 150 mmHg
Systolic blood pressure measurement range	60 - 230 mmHg
Pulse rate range	40 - 200 bpm
Pulse rate accuracy	±5%
Clinical accuracy	Meet IEC80601-2-30
ECG Recording	
Lead type	Integrated ECG electrodes
Lead set	Lead I, Lead II
ECG length	30 s - 5 min
Heart rate range	30 - 250 bpm
Heart rate accuracy	±2 bpm or ±2%, whichever is greater
Input impedance	⩾10 MΩ, 10 Hz
Input dynamic range	10 mV (peak-to-valley)
Common-Mode Rejection Ratio (CMRR)	⩾60 dB (for sinusoidal signals at the mains frequency) >45 dB (for signals at twice the mains frequency)
ECG bandwidth	0.67 ~40 HZ
Gain Accuracy	Maximum amplitude error ±10%
Heart Rate Calculation	Divide 1 minute by the number of squares between two R waves.
Storage	30 records
Bluetooth RF	
Frequency range	2.400 GHz-2.483 GHz

Wifi	
Frequency range	2.400 GHz-2.483 GHz
Expected service life	Monitor: 5 years Cuff: 2 years Air Hose: 2 years
Information about AI-ECG Tracker	
Device name	AI-ECG Tracker
Model	S
Manufacturer	Shenzhen Carewell Electronics Co., Ltd.
CE Certification	CE0123, Certificate No.G1 0504400033

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!
- The manufacturer will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to service personnel in parts repair.
- The accuracy of this monitor has been carefully tested and is designed for a long service life.
- It is generally recommended to have the unit inspected every two years to ensure correct functioning and accuracy. Please consult your authorised Viatom dealer or the Viatom customer service at the address given on the packaging or attached literature.

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 the device and the arm cuff, and then let them air dry.
- Store them in a clean, safe location until re-use.

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 local laws and regulations.

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: 700mm; Outside Diameter: 7.5mm

8. Electromagnetic Compatibility

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

Essential performance:

Measurement of blood pressure and ECG.

The maximum error of blood pressure does not exceed ±3mmHg (±0.4kPa).

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

⚠ **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.

Guidance and manufacturer's declaration - electromagnetic emissions		
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.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
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	Class B	The Blood Pressure Monitor is

CISPR 11		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.
Harmonic emissions IEC61000-3-2	Not applicable	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Not applicable	

Guidance & Declaration — electromagnetic immunity			
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.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
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 U_T) for 25/30 cycles <5% U_T (>95% dip in U_T) for 5/6 sec	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 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_T is the a.c. mains voltage prior to application of the test level.			

Guidance & Declaration - Electromagnetic immunity			
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.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**

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 Pressure Monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Radiated RF IEC61000-4-3	10V/m 80MHz to 2.7 GHz 385MHz-5785 MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless Communication equipment (Refer to table 9 of IEC 60601-1-2:2014+A1:2020)	10 V/m 80MHz to 2.7 GHz 385MHz-5785 MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless Communication equipment (Refer to table 9 of IEC 60601-1-2:2014+A1:2020)	

PN: 256-000047-00 Version: V1.1 September, 2025

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