Blood Pressure Monitor

Instruction Manual

Automatic Upper Arm Style
Model: BP126A

The user need to follow this instruction manual thoroughly for your safety. Please keep for future reference. For specific information about your own blood pressure, Consult your physician.

IFU-BP126A-EN-CB- V03
Issue date :2026-05-27

Catalogue

1 Introduction

Thank you for purchasing this blood pressure monitor. This blood pressure monitor uses the oscillometric method of blood pressure measurement.
The blood pressure monitor is intended for the fully automatic, non-invasive measurement of arterial blood pressure and pulse values on the upper arm.

1.1 Safety Instructions

This instruction manual provides you with important information about the Blood Pressure Monitor. To ensure the safe and proper use of this monitor, READ and UNDERSTAND all of the safety and operating instructions. If you do not understand these instructions or have any questions, contact your distributor before using this monitor. For specific information about your own blood pressure, consult with your physician.

1.2 Intended Use

This device is used to measure upper arm systolic blood pressure, diastolic blood pressure and pulse rate.

1.3 Intended users:

Personnel who can operate in accordance with the product user manual, including medical staff and patients.

1.4 Intended patient population

Suitable for adults.

1.5 Intended Use Environment:

The device is intended for use in home and professional healthcare environments.
Operation conditions 5~40℃ 15%~85%RH(non-condensing) 700 hPa~1060 hPa

1.6 Indications:

Monitor the blood pressure and pulse rate of adults.

1.7 Contraindications:

- Do not use this device with a defibrillator.
- Do not use this device during an MRI examination.
- Do not use the device in a flammable environment (ie, an oxygen-enriched environment).
- Do not immerse the device in water or other liquids. Do not use acetone or other volatile solutions to clean the device
- If you have had a mastectomy, please consult your doctor before using this monitor
- Do not use the monitor in a moving vehicle, such as a car or an airplane
- Avoid bathing, drinking alcohol or caffeine, smoking, exercising, and eating at least 30 minutes before the measurement

1.8 Expected clinical benefit:

Provide a blood pressure monitor with accuracy that meets regulatory requirements for users to measure blood pressure values.

1.9 Introduction to the working principle：

The pressure sensor captures varying cuff pressure and converts it into digital signals for the CPU. The embedded software processes the data via algorithms to determine systolic, diastolic blood pressure and pulse.

2 Important Safety Information

Read the Important Safety Information in this instruction manual before using this monitor. Follow this instruction manual thoroughly for your safety. Keep for future reference. For specific information about your own blood pressure, Consult with your physician.

2.1 Warning

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

- Before using the device, please ensure that you have read this manual thoroughly and fully understand corresponding precautions and risks.
- Do not use this device with a defibrillator.
- Do not use this device during MRI （magnetic resonance imaging）examination.
- Do not use the device in a combustible environment (i.e., oxygen-enriched environment).
- 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 dismantle the device, as this could cause damage or malfunctions or impede the operation of the device.
- Consult with your physician before using this monitor if you have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation; arterial sclerosis; poor perfusion; diabetes; pregnancy; pre-eclampsia or renal disease. NOTE that any of these conditions in addition to patient motion, trembling, or shivering may affect the measurement reading.
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Keep this device and its accessories out of reach of children and individuals who are unable to operate them properly, to prevent hazards such as ingestion of small parts (e.g., batteries) or entanglement with adapter cords and CUFF tubing. Children must not operate the device without supervision.
- 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.
- 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.
- Clean the device and cuff with a dry, soft cloth or a cloth dampened with

water and a neutral detergent. Never use alcohol, benzene, thinner or other harsh chemicals to clean the device or cuff.

- During measuring, cuff will be inflated and squeezed the arm 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.
- People who have a severe circulatory deficit in the arm must consult a doctor before using the device, to avoid medical problems.
- Do not repair or maintain the equipment during use to avoid incorrect operation of the equipment and deviation or error of the measured value.
- After inflation, do not twist or knot the CUFF connection hose. Continuous pressure may interfere with blood flow, causing pain, numbness or temporary red marks on the arm due to pressure.
- Do not measure too frequently, which may cause pain and numbness to the user's arm due to obstructed blood flow.
- Do not use a cuff on an arm with a wound as it may cause further injury.
- When CUFF is applied to any limb and pressure is applied, the measurement can be stopped if the pressure temporarily interferes with the flow of blood and may cause numbness in the arm.
- Observe the measured arm during measurement, Immediately power off the device or disconnect the cuff connector to release air if persistent numbness or soreness occurs, to avoid prolonged impairment of limb blood circulation caused by cuff pressurization.
- people with physical, sensory or mental limitations, or those lacking relevant usage experience and knowledge. If such people need to use it, they must operate under the full supervision and usage guidance of the safety supervisor.
- Users with severe limb circulatory disorders should consult a doctor before using this device.
- Do not fold the cuff tubing during inflation. Excess cuff pressure may cause arm discomfort. The unit features automatic overpressure deflation. If the cuff remains pressurized and fails to deflate, power off the device via the power key or disconnect the cuff connector for rapid pressure release.
- Do not use this product with other medical monitoring devices on the same limb at the same time, as the CUFF inflation and compression process may cause temporary functional failure of the monitoring devices used on the same limb.

2.2 Caution

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property

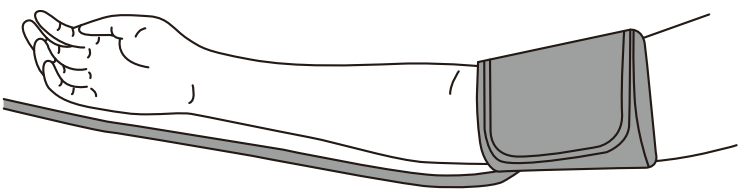
- Stop using this monitor and consult with your physician if you experience skin irritation or discomfort.
- If you have had a mastectomy or lymph node removal, talk to your doctor

before using this monitoring device.

- DO NOT use this monitor for any purpose other than measuring blood pressure.
- During measurement, make sure that no mobile device or any other electrical device that emit electromagnetic fields is within 30 cm of this monitor. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
- Avoid bathing, drinking alcohol or caffeine, smoking, exercising and eating for at least 30 minutes before taking a measurement.
- Rest for at least 5 minutes before taking a measurement.
- Remove tight-fitting or thick clothing from your arm while taking a measurement.
- Remain still and DO NOT talk while taking a measurement.
- ONLY use the arm cuff on persons whose arm circumference is within the specified range of the cuff.
- Ensure that this monitor has acclimated to room temperature before taking a measurement. Taking a measurement after an extreme temperature change could lead to an inaccurate reading. recommends waiting for approximately 2 hours for the monitor to warm up or cool down when the monitor is used in an environment within the temperature specified as operating conditions after it is stored either at the maximum or at the minimum storage temperature. For additional information on operating and storage/transport temperature, refer to chapter 11.
- Read and follow the “Correct Disposal of This Product”in chapter 10 when disposing of the device and any used accessories or optional parts.
- DO NOT insert batteries with their polarities incorrectly aligned.

2.3 General Precautions

- To stop a measurement, press the [START/STOP] button while taking a measurement.
- When you take a measurement on the right arm, the air tube should be at the side of your elbow. Be careful not to rest your arm on the air tube.



- Blood pressure may differ between the right and left arm, and may result in a different measurement value. Always use the same arm for measurements. If the values between both arms differ substantially, check with your physician on which arm to use for your measurements.

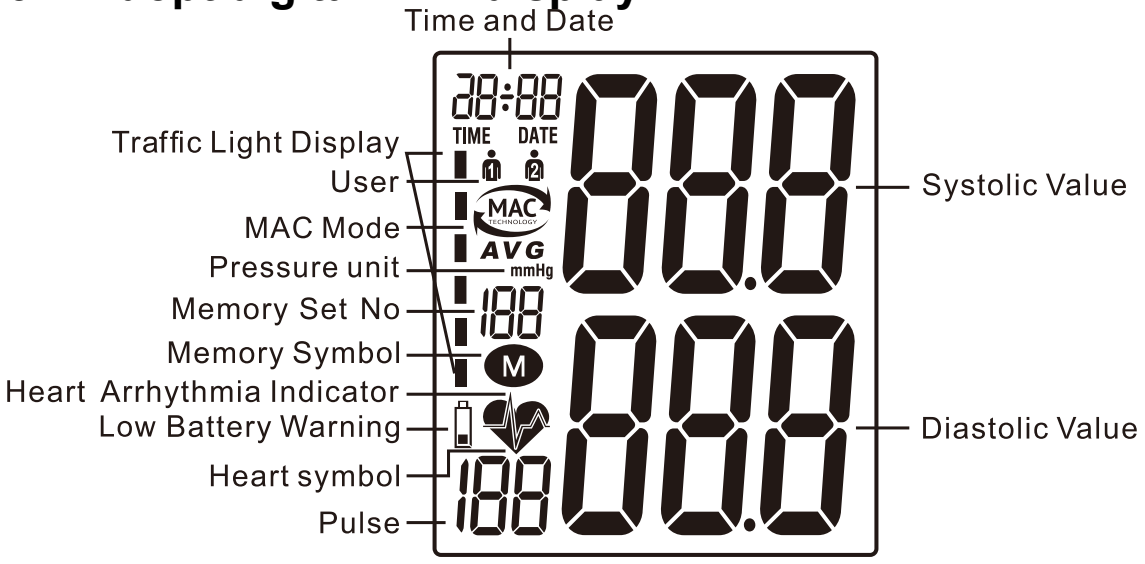
3 Know your device

3.1 Operating key：

– MEMORY Button: check memory and clear measurement values

- ON/OFF Button: Power on and measure start
- MAC MODE Button: Power on and measure start

3.2 Adopt digital LCD display



3.3 Common Functions:

1) Blood pressure and heart rate are measured
2) Memory storage and clearing functions
3) Date and time Settings

Note: The above basic normal functions can be safely used by the operator.

3.4 Functional Description

Low Battery Warning:

If the battery warning icon appears in the display, the batteries remain 20% power to warn user the batteries will be run out.

If the battery warning icon appears in the display, the batteries are empty and must be replaced by new ones

Attention! After the battery warning icon appears, the device is blocked until the batteries have been replaced.

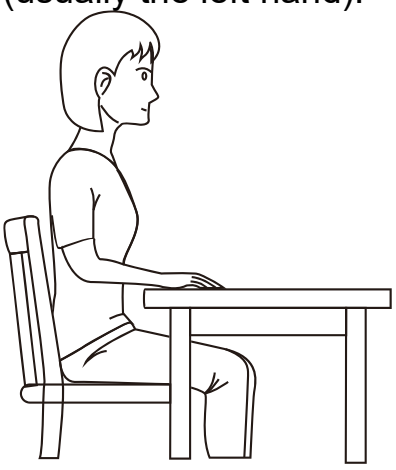
3.5 Preparing for a Measurement

30 min before measurement

Alcohol, diet, smoking, bathing, coffee, and any form of exercise should be avoided 30 minutes before the measurement. These factors can affect the results of your blood pressure measurement. Please sit down and relax in a quiet and comfortable environment for at least 10 minutes before the measurement.

5 minutes before the measurement

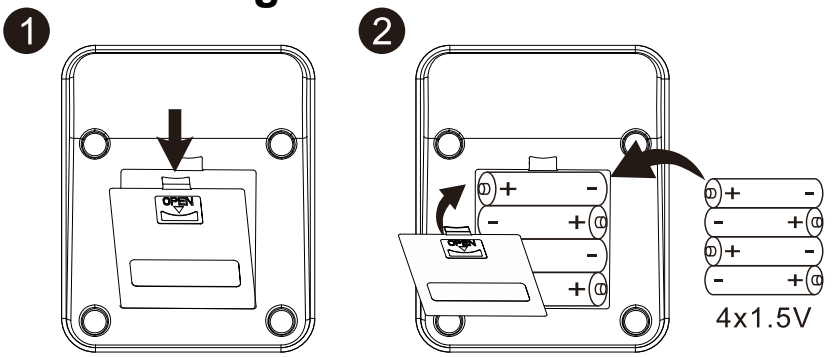
Sit still and relax, and always take each measurement on the same arm (usually the left hand).



4 Preparation before use

Please check the complete accessories before using this product.
Final assembly includes this battery installed (see section 4.1) and cuff wearing (see section 5.1)

4.1 Installing Batteries



1) Insert the batteries (4 x size AA 1.5V), thereby observing the indicated

polarity.

2) If the battery warning icon appears in the display, the batteries remain 20% power to warn user the batteries will be run out .
3) If the battery warning icon appears in the display, the batteries are empty and must be replaced by new ones

1) Attention! •After the battery warning icon appears, the device is blocked until the batteries have been replaced.
2) Please use «AA» Long-Life or Alkaline 1.5V Batteries. The use of 1.2V Accumulators is not recommended.
3) If the blood pressure monitor is left unused for long periods, please remove the batteries from the device.

4.2 Setting Date and Time

Please press the TIME button and the date will be shown in the display. Set user > year > month > day > hour > minute

- **Set user**

Press the MEMORY button for at least 3 seconds. The display now indicates the set user, during which the set user blink, To confirm, Click the MEMORY button to select User

- **Setting the time date**

1) Press the ON/OFF button for at least 3 seconds firstly , MAC will blink. Then press ON/OFF button again the display now indicates the set year, during which the four characters blink. The correct year can be entered by pressing the MEMORY button
2) Press the ON/OFF button again. The display now switches to the current date, during which the first character (month) blinks. The corresponding month can now be entered by pressing the MEMORY button.
3) Press the ON/OFF button again. The last two characters (day) are now blinking The corresponding day can now be entered by pressing the MEMORY button.
4) Press the ON/OFF button again. The display now switches to the current time, during which the first character (Hour) blinks The corresponding hour can now be entered by pressing the MEMORY button.
5) Press the ON/OFF button again. The last two characters (Minutes) now blink. The exact time can now be entered by pressing the MEMORY button
6) Once you have made your settings, press the ON/OFF button (TIME / DATE). The setting is confirmed and the clock starts running..

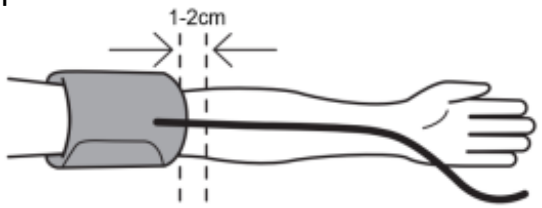
5 Use equipment

5.1 Applying the Arm Cuff

Attempt to carry out the measurements regularly at the same time of day, since the blood-pressure changes during the course of the day

1) Remove tight-fitting clothing or tight rolled up sleeve from your left upper arm. Do not place the arm cuff over thick clothes.
2) Insert the air plug into the air connector securely

3) The distance between cuff and elbow should be 1-2cm. Make sure do not press on the air tube.



Notes:

- When you take a measurement on the right arm, the air tube will be at the side of your elbow. Be careful not to rest your arm on the air tube.
- The blood pressure can differ between the right arm and the left arm, and the measured blood pressure values can be different, and recommends to always use the same arm for measurement. If the values between both arms differ substantially, please check with your physician which arm to use for your measurements.

5.2 Sitting Correctly

1) Sit comfortably with your back and arm supported
2) Place the arm cuff at the same level as your heart.
3) Keep feet flat, legs uncrossed, remain still and do not talk.
4) The sphygmomanometer is placed in a position that the user can normally operate, and the blood pressure reading displayed after the measurement is completed is not affected in any way..

5.3 Taking a Measurement

1) Press the ON/OFF button, the pump begins to inflate the cuff. In the display, the increasing cuff-pressure is continually displayed.
2) After reaching the inflation pressure, the pump stops and the pressure slowly falls away. The cuff-pressure is displayed during the measurement. When the device has detected the pulse, the heart symbol in the display begins to blink

3) When the measurement has been concluded, The measured systolic and diastolic blood-pressure values as well as the pulse frequency are now displayed. Example (Fig.): Systole 128, Diastole 70, Pulse 88

6) 

4) The measurement results are displayed, until you switch the device off or the device switches automatically off, to save the batteries.

5) When the measurement results are as follows:

- Measurement results display error provided, please follow the instructions in chapter 7 of Error Messages.
- If the measurement results are significantly deviated, please re-measure or consult your doctor.

5.4 Discontinuing a measurement

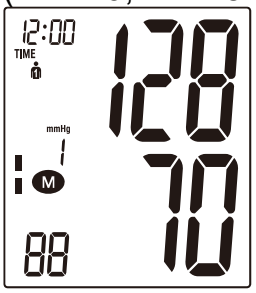
If it is necessary to interrupt a blood pressure measurement for any reason (e.g. the patient feels unwell), the “ON/OFF” power button can be pressed at any time. The device then immediately lowers the cuff-pressure automatically.

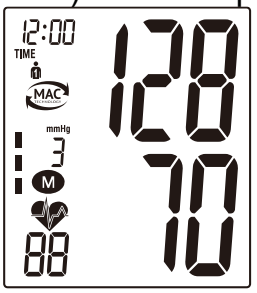
5.5 Using Memory Functions

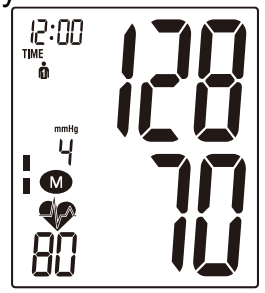
1) Reading memory:

Before using memory functions, select your user ID

The blood-pressure monitor automatically stores each of the last 120 measurement values. By pressing the MEMORY button, an average value of Average of the Latest 3 Readings and the further last 120 measurements (MR119,MR118…,MR1)can be displayed one after ther other

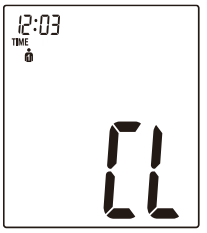






2) Deleting All Memories

Before you delete all readings stored in the memory, make sure you will not need refer to the readings at a later date. Keeping a written record is prudent and may provide additional information for your doctor’s visit. In order to delete all stored readings, depress the MEMORY button for at least 5 seconds, the display will show the symbol «CL» and then release the button. To permanently clear the memory, Press the MEMORY button while «CL» deletes stored readings.



6 Useful Information

What is Blood Pressure?

Blood pressure is a measure of the force of blood flowing against the walls of the arteries. Arterial blood pressure is constantly changing during the course of the heart’s cycle.

The highest pressure in the cycle is called the Systolic Blood Pressure; the

lowest is the Diastolic Blood Pressure. Both pressures, the Systolic and Diastolic, are necessary to enable a physician to evaluate the status of a patient's blood pressure.

Classification of hypertension:

These values are provided by the 2023 ESH Guidelines for the management
The BP category is defined by the highest level of BP, whether systolic or diastolic.
Isolated systolic or diastolic hypertension is graded 1, 2 or 3 according to SBP and DBP values in the ranges indicated. The same classification is used for adolescents ≧16 years old.

Category	Systolic (mmHg)	Diastolic (mmHg)
Optimal	<120	<80
Normal	120-129	80–84
High- Normal	130-139	85–89
Grade 1 hypertension	140–159	90–99
Grade 2 hypertension	160–179	100–109
Grade 3 hypertension	≧180	≧110
Isolated systolic hypertension	≧140	≦90
Isolated diastolic hypertension	≦140	≧90

7 Error Messages and Troubleshooting

If any of the below problems occur during measurement, check if there is any other electrical device is within 30 cm to the blood pressure monitor. If no but the problem still persists, please refer to the table below.

Error No.	Possible cause(s)
ERR 1	No pulse has been detected.
ERR 2	Unnatural pressure impulses influence the measurement result. Reason: The arm was moved during the Measurement (Artefact).
ERR 3	The inflation of the cuff takes too long. The cuff is not correctly seated.
ERR 5	The measured readings indicated an unacceptable difference between systolic and diastolic pressures. Take another reading following directions carefully. Contact you doctor if you continue to get unusual readings.
ERR 8	CUFF pressure >290 mmHg

Other possible malfunctions and their elimination

If problems occur when using the device, the following points should be checked and if necessary, the corresponding measures are to be taken:

Malfunction	Remedy
The display remains empty when the instrument is switched on although the batteries are in place.	1.Check batteries for correct polarity and if necessary insert correctly. 2.If the display is unusual, re-insert batteries or exchange them.
The device frequently fails to measure the blood pressure values, or the values measured are too low (too high).	Check the positioning of the cuff. Measure the blood-pressure again in peace and quiet as described in chapter 5.
Every measurement produces a different value although the instrument functions normally and the values displayed are normal	Please read the following information and the points listed in chapter 7 of Error Messages. Repeat the measurement. Please note: Blood pressure fluctuates continually so successive measurements will show some variability.
Blood pressure measured differs from those values measured by the doctor.	Record the daily development of the values and consult your doctor. Please note: Individuals visiting their doctor frequently experience anxiety which can result in a higher reading at the doctor than obtained at home under resting conditions.

8 Maintenance

Users can perform the following maintenance operations on the device, but pay attention to the precautions mentioned in each maintenance item.

8.1 Maintenance

To protect your monitor from damage, follow the directions below:
Changes or modifications not approved by the manufacturer will make the user warranty invalid.

Caution Pull out the cuff connector from the device, but don't pull out the tube from the cuff.

8.2 Storage

Properly store the blood pressure monitor main unit and all accessories when not in use..

1) Detach the cuff from the main unit.
2) Fold the air tube neatly and tuck it inside the cuff.
3) Place the main unit, cuff and other accessories into the dedicated storage case, or keep them in a clean, stable and safe area.

Caution!

- To disconnect the cuff connector, grip the plastic connector at the base of

the air tube. Do not pull the air tube directly.

- Do not bend the CUFF tube too much. At the same time, keep the CUFF away from sharp objects to prevent it from being scratched or punctured by sharp objects, which may cause air leakage.
- Do NOT store the device and accessories under the following conditions:
- When the device or accessories are wet.
- In areas with extreme temperature or humidity, direct sunlight, dust, or corrosive fumes such as bleach.
- In locations prone to vibration, impact or dropping.

8.3 Cleaning

Use a soft dry cloth or a soft cloth moistened with mild (neutral) detergent to clean your monitor and arm cuff, and then wipe them with a drycloth.

 The following operations are prohibited:

- Do not use any abrasive or volatile cleaners.
- Do not wash or immerse your monitor and arm cuff or other components in water.
- Do not use gasoline, thinners or similar solvents to clean your monitor and arm cuff or other components.

8.4 Battery replacement and maintenance:

1) When the device shows that the battery is low, please replace the battery in time.
2) When the device is not used for a long time (about 1 week), the battery should be taken out in time for separate storage.

Note: The installation of the battery is detailed in section 4.1 of this manual.

8.5 Calibration and Service

- The accuracy of this blood pressure 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 dealer or the Customer Service at the address given on the packaging or attached literature.

How to enter to test mode :

 This function is mainly for professionals to enter the pressure calibration mode of the electronic sphygmomanometer and check the pressure value of the electronic sphygmomanometer through a standard pressure meter Test methods :

- Press and hold “on/off button” while battery is installed , then “CA” and “0” will be displayed

8.6 Optional Medical Accessories

Arm cuff：22~32cm(M-size cuff) or 22~42cm (M-L size cuff)

9 Limited Warranty

Thank you for purchasing this product! Please use and maintain it as descirbed in the manual.

This product is guaranteed for 5 years from the date of purchase.
If you have any problems during the warranty period, please contact with the store where you buy it or our local distributor.

The following items will not be covered by the warranty service:
1) Repaired by the unauthorized person.
2) Product failure caused by private disassembly or modification.
3) Product failure caused by misuse or incorrect operation of the product.
4) The warranty do not cover the calibration service.
5) Product failure due to irresistible natural disasters.
6) Consumable accessories, such as batteries, packaging materials.
7) Products exceeded the warranty date .
Tips: Repairs or replacements during the warranty period will not result in any extension of the warranty period.

10 Correct Disposal of This Product

(Waste Electrical & Electronic Equipment)

This marking shown on the product or its packaging, indicates that it should not be disposed of, with other household wastes at the end of its working life.
To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this product from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources.
Household users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can return this item for environmentally safe recycling.
Business users should contact their supplier and check the terms and conditions of the purchase contract. This product should not be mixed with other commercial waste for disposal.

11 Technical specifications

Product description	Blood Pressure Monitor
Product category	Electronic Sphygmomanometers
Model	BP126A
Display	LCD digital display
Cuff pressure range	0 to 290mmHg

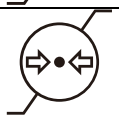
Blood pressure measurement range	SYS: 60 to 255 mmHg DIA : 30 to 199mmHg
Static accuracy	Pressure: ±3 mmHg
Pulse	Pulse measurement range ： 40 to 199 beats / min ±5% of display reading
Measurement method	Oscillometric , corresponding to Korotkoff method: Phase I : systolic , Phase V : diastolic
IP classification	IP20
Inflation	Automatic by electric pump
Deflation	Automatic pressure release valve
Applied part	 Type BF (arm cuff)
Power supply interface	⎓ 6V/0.6A
Mode of operation	Single automatic measurement
Power source:	Battery： 4x1.5V "AA" alkaline Batteries ; Or external power supply (DC 6V/0.6A);
Warranty	Monitor: 5 years
Operation conditions	Temperature:5°C ~40°C Humidity:15%RH ~85%RH(non-condensing) Atmospheric pressure:700 hPa~1060 hPa
Storage/transport conditions	Temperature:-10°C ~55°C Humidity:10%RH ~95%RH(non-condensing) Atmospheric pressure:500 hPa ~1060 hPa
Protection against electric shock	CLASS II and INTERNALLY POWERED
Dimensions :	Monitor:131× 92 × 60 ±1.0 mm
Weight :	Monitor: approximately 265 g (not including batteries) Arm cuff: approximately 109 g
Accessories:	**Cuff**: circumference 22~32cm(M-size cuff) or 22~42cm (M-L size cuff) ,
Contents	**device, cuff, user manual**
Memory	2 x 120 memories for 2 users (SYS, DIA, Pulse)

Note

1) These specifications are subject to change without notice.
2) IP classification is degrees of protection provided by enclosures in accordance with IEC 60529.
3) Users may purchase adapters on the market. Any adapter used with this device shall comply with EN 60601-1, EN 60601-1-2 and EN 60601-1-11.

12 Symbols Description

Symbols	Description	Symbols	Description
EU REP	Authorized representative		Applied part - Type BF

Symbols	Description	Symbols	Description
CE 0197	CE Marking of Conformity Announcement number institutions		Electrical and electronic equipment marks
LOT	Batch code		Refer to instruction manual/ booklet
IP20	Ingress protection degree provided by IEC 60529		General warning sign
	Date of manufacture		Caution
SN	Serial number		Manufacturer
MD	Medical device	UDI	Unique device Identifier(UDI)
	Direct current		Warning! Not suitable for children under 3 years old
REF	Catalogue number		Importer
	Humidity limitation		Temperature limit
	Atmospheric pressure limits		Distributor
	Fragile, handle with care		This way up
	Stacking limit by number		Keep dry
	Keep away from sunlight		

13 Guidance and Manufacturer’ s Declaration

Important information regarding Electro Magnetic Compatibility (EMC)
With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation. Medical devices should also not interfere with other devices. In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.
Our medical devices comply with IEC60601-1-2 in terms of immunity and emissions.

Guidance and manufacturer's declaration - electromagnetic emissions		
This product is suitable for electromagnetic environment as described below. Users should ensure that they are used in such an environment.		
Emission Test	Compliance	Electromagnetic Environment
RF emission CISPR 11	Group 1	All models use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	All models are suitable for used in all establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Compliance	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Compliance	

Guidance & Declaration — electromagnetic immunity			
This product is suitable for the following electromagnetic environment. Users should ensure that they are used in such an environment.			
Immunity test	IEC 60601 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 ±1 kV for Input/output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	±0.5 kV, ±1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11.	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles <5% UT (>95 % dip in UT) for 5/6 sec	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles <5% UT (>95 % dip in UT) for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the all models require continued operation during power mains interruptions, it is recommended that the all models be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	N/A	N/A
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance & Declaration - Electromagnetic immunity			
This product is suitable for use in the electromagnetic environment specified below. Users should ensure that they are used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	equipment should be used no closer to any part of all models, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	6 Vrms in ISM and amateur radio bands 10 V/m, 80 MHz 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)	N/A 10 V/m, 80 MHz 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)	Recommended separation distance d=[3,5/V1]×P1/2 d=1.2×P1/2 80 MHz to 800 MHz d=2.3×P1/2 800 MHz to 2.7 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 models are used exceeds the applicable RF compliance level above, the model AirMi 1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the models.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and all models

This product is suitable for controlling the electromagnetic environment of radiofrequency interference. Users can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication devices (transmitters)

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz d = 1.2×p1/2	80 MHz to 800 MHz d = 1.2×p1/2	800 MHz to 2.7 GHz d = 2.3×p1/2
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 estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz. the separation distance for 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.

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Incident Reporting Notice
Per EU MDR 2017/745 and equivalent rules, EU users and patients shall immediately report any serious incident related to product use to the manufacturer, its authorised representative and local competent authority of the EU Member State concerned.