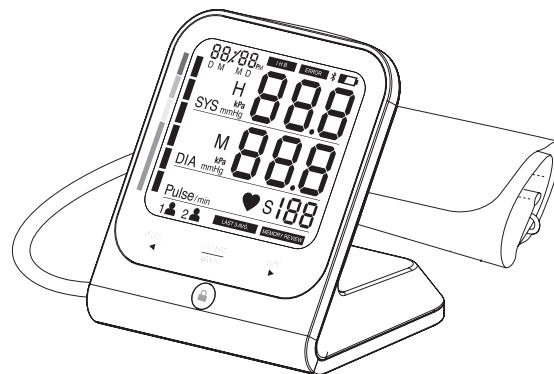


User Manual

Bluetooth Blood Pressure Monitor BPM100



EC REP Kinetik Medical Devices Ltd, NG90 6BH, UK

 Harvard Medical Devices Ltd, HK

BPM100 IB UK 20151029

- Please read the user manual carefully and thoroughly so as to ensure the safe usage of this product. Keep the manual for future reference.

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♥ Introduction

Thank you for buying your Kinetik Bluetooth Blood Pressure Monitor. Whether you have already been diagnosed with high blood pressure or want to track any changes to your blood pressure, you have taken the first step to a quick, easy and accurate device that will keep you and, if necessary, a doctor informed.

- **Accurate** – with irregular heartbeat detector to ensure correct measurement
- **Easy to use** – fully automatic, works at the push of a button.
- **Easy to read** – large LCD display.
- **Convenient** – pair via Bluetooth 4.0 with your phone or tablet to record readings
- **Suitable for two users**

Before you start, it is important that you read this manual carefully. Blood pressure testing is easy but to make sure you have the most accurate readings, it is important to follow the instructions. Please keep them in a safe place in case you need to refer back to them at a later date.












If you have any concerns about your blood pressure in anyway, we recommend you contact your doctor.

♥ Usage

The Kinetik Bluetooth Blood Pressure Monitor is intended for use in measuring blood pressure and heartbeat rate with arm circumference ranging from 22cm to 42cm (about 8¾"-16½"). It is intended for adult use only.

♥ Safety Information

The signs below will be in the user manual, labeling or other components. They are the requirement of standards and usage.

	Symbol for "THE OPERATION GUIDE MUST BE READ" (actual symbol colours are white on a blue background).		Symbol for "TYPE BF APPLIED PARTS"
	Symbol for "COMPLIES WITH MDD 93/42/EEC REQUIREMENTS"		Symbol for "ENVIRONMENT PROTECTION - Electrical waste products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice"
	Symbol for "MANUFACTURER"		
	Symbol for "SERIAL NUMBER"		
	Symbol for "DIRECT CURRENT"		Symbol for "Authorised Representative in the European Community"
	Symbol for "MANUFACTURE DATE"		Symbol for "Including RF transmitter"
IP21	Protection against ingress of water		Caution: These notes must be observed to prevent any damage to the device.

CAUTION

The device is not suitable for measuring the blood pressure of children. Ask your doctor before using it on older children.

The device is not suitable for use on pregnant women, patients with implanted, electronic devices, patients with pre-eclampsia, premature ventricular heartbeats, atrial fibrillation, peripheral, arterial disease and patients who have undergone intravascular therapy or arterio venous shunt or people who received a mastectomy. Please consult your doctor prior to using the unit if you are unsure.

Do not take any therapeutic measures on the basis of a self measurement. Never alter the dose of a medicine prescribed by a doctor. Consult your doctor if you have any question about your blood pressure.

Please keep the unit out of reach of infants, children or pets, since inhalation or swallowing of small parts is dangerous or even fatal.

⚠ CAUTION

This device is intended only for adult use only.

This device is intended for non-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than arm or for functions other than obtaining a blood pressure measurement.

If you experience discomfort during a measurement, such as pain in the arm or other complaints, press the START/STOP button to release the air immediately from the cuff. Loosen the cuff and remove it from your arm.

On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, open the cuff immediately. Prolonged high pressure (cuff pressure >300mmHg or constant pressure >15mmHg for more than 3 minutes) applied to the arm may lead to an echymosis.

Too frequent and consecutive measurements could cause disturbances in blood circulation and injuries.

Do not wrap the cuff on the same arm which other monitoring medical electrical equipment is applied simultaneously, this could cause temporary loss of function of those simultaneously-used monitoring medical electrical equipment.

Don't kink the connection tube during use, as the cuff pressure may continuously increase which can prevent blood flow and result in harmful injury to the PATIENT.

The equipment is not AP/APG equipment and not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

This unit is not suitable for continuous monitoring during medical emergencies or operations.

This device cannot be used with HF surgical equipment at the same time.

To avoid measurement errors, please avoid strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.

The operator shall not touch output of batteries/adaptor and the patient simultaneously.

The materials of the cuff have been tested and found to comply with requirements of ISO 10993-5:2009 and ISO 10993-10:2010. It will not cause any potential sensitization or irritation reaction. Never apply the cuff over damaged skin.

Do not use the unit in case of existing polyester resp. synthetic allergies.

Be careful to strangulation due to cables and hoses, particularly due to excessive length.

Do not connect the air hose to other medical equipment, as this could cause air to be pumped into intravascular systems or high pressure, what could lead to dangerous injuries.

Before use, make sure the device functions safely and is in proper working condition.

Please use the device under the environment which was provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced.

Please use ACCESSORIES and detachable parts specified/ authorised by the Manufacturer. This may cause damage to the unit or danger to the user/patients.

Please dispose of ACCESSORIES, detachable parts, and the medical electrical equipment according to the local guidelines.

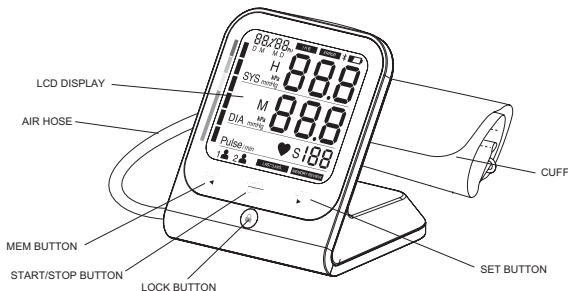
Please do not attempt to repair the unit yourself in the event of malfunctions. Only have repairs carried out by authorised service centres.

Please report to Manufacturer if any unexpected operation or events occur.

This Blood Pressure Monitor is calibrated at the time of manufacture. If the Blood Pressure Monitor is used according to the instructions, periodic re-calibration is not required.

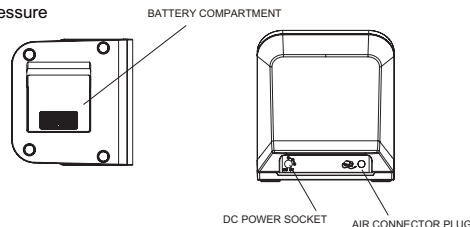
Please use a soft cloth to clean the whole unit. Don't use any abrasive or volatile cleaners.

♥ Monitor Components



Component list of pressure measuring system

- 1 Cuff
- 2 Air pipe
- 3 Pump
- 4 Valve



♥ List

1. Blood Pressure Monitor (BPM100)



3. 4×AAA batteries



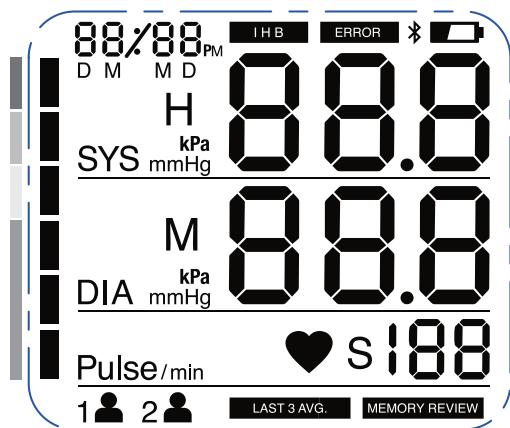
2. Cuff (Type BF applied part) (22cm~42cm)



(Please use Kinetik authorised cuff. For the size of the actual cuff please refer to the label on the attached cuff.)

4. User manual

♥ Understanding the Symbols on your Blood Pressure Monitor

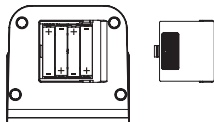


SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic blood pressure	High pressure result
DIA	Diastolic blood pressure	Low pressure result
Pulse/min	Pulse per minute	Beats per minute, BPM
LAST 3 AVG.	Average value	The average value of the latest three records
MEMORY REVIEW	Memory	The displayed measurement values from the memory.
kPa	kPa	Measurement Unit of the blood pressure (1kPa=7.5mmHg)
mmHg	mmHg	Measurement Unit of the blood pressure (1mmHg=0.133kPa)
Low battery	Low battery	Batteries are low and need to be replaced
I H B	Irregular heartbeat	Irregular heartbeat Detection
I	Grade	The grade of the blood pressure
88/88 PM D M M D	Current Time	Year/Month/Day(M/D or D/M), Hour/Minute
ERROR	Error	Error
H	Hour	The hour in the clock mode
M	Minute	The minute in the clock mode
S	Second	The second in the clock mode
♥	Heartbeat	Heartbeat detection during the measurement
1	User 1	Start measurement, save and transmit the measuring results for User 1
2	User 2	Start measurement, save and transmit the measuring results for User 2
Bluetooth icon	Bluetooth icon	The bluetooth icon blinks when the bluetooth is working


Before your first use, you will need to make sure the batteries are inserted correctly and the cuff is properly connected.

♥ Inserting the Batteries

1. Remove the battery cover on the back of the monitor.
2. Insert 4 x AAA batteries, making sure they are in the correct direction using the +/- symbols inside the battery compartment.
3. Replace the cover and make sure it is properly clicked shut.



Replace the batteries whenever:

- The **Lo +**  shows
- The display dims
- The display does not light up

♥ Connecting the Cuff

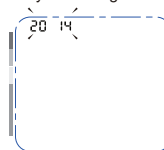
1. Insert the rubber tube connected to the cuff firmly into the air connector socket on the back of the monitor to ensure there is no air leakage.
2. Ensure that the end of the cuff is passed through the metal loop and the Velcro fastening is facing outwards. The cuff should be ready to use.

⚠ CAUTION

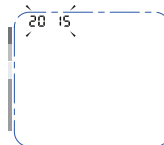
- Remove batteries if the device is not likely to be used for some time.
- The old batteries are harmful to the environment, do not dispose with other household waste.
- Remove the old batteries from the device and follow your local recycling guidelines.
- Do not dispose of batteries in fire. Batteries may explode or leak.

♥ Setting Date, Time, Measurement Unit and Clock Mode

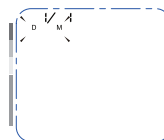
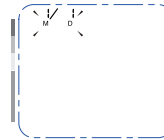
1. When the monitor is off, press the set button for three seconds to enter the mode for year setting.



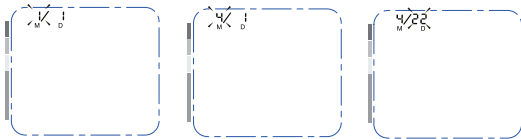
2. Press the MEM button to change the year. Each press will advance one year at a time.



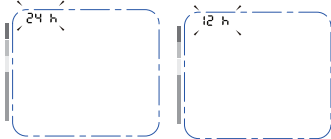
3. Once you have the correct year, press the set button again.
4. You will then move on to the day and month settings. Choose whether you want the date or month first i.e. D/M or M/D.



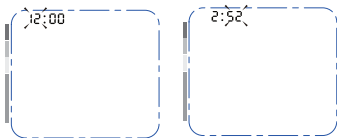
5. Then repeat steps 2 and 3 to set the correct date. When you have the correct date press the set button again.



6. Finally, set the clock. You will need to choose if you would like to use 12 hour or 24 hour clock.

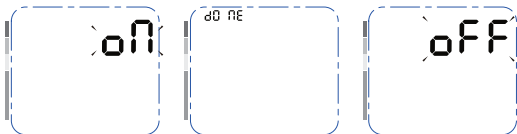


7. Then repeat steps 2 and 3 to set the correct time. When you have the correct time press the set button again.




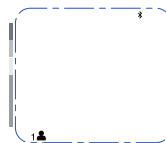
8. Repeat steps 2 and 3 to set the measurement unit.

9. Finally repeat steps 2 and 3 again and the display will show 'on'. When everything is set the display will say 'done' and the unit will turn off.

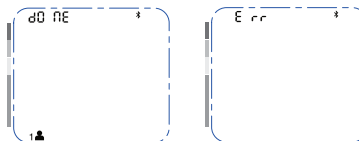


♥ Setting up the Bluetooth

1. Download the Kinetik Health app from the Android or Apple Store on to your phone or tablet.
2. Now, pair the Blood Pressure Monitor with your chosen device. You need to open the app on your device and then press the start/stop button on the monitor. The Bluetooth symbol  will flash to indicate pairing is in progress.



3. Select the correct user ID to connect up to the app. If pairing is successful the screen will display 'done'. If unsuccessful the screen will show 'Err' and you will need to start again.



4. After pairing is complete the monitor will turn off until you are ready to use it.

Bluetooth Module No.: AW2540MV1
RF Frequency Range: 2402 MHz to 2480 MHz
Output Power Range: -1 dBm
Supply Voltage: 2V-3.6 V
Transmitting Distance: 10 meters

♥ The First Time

Using the instructions below, take a measurement on both arms and record the results. This will determine which arm should be used for all your future measurements.

Take note of your reading on both arms. The arm which gives the higher systolic reading is the one that should be used for regular testing.

For example:

Left arm: 132 (systolic)

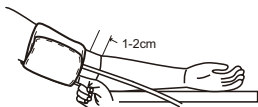
Right arm: 128 (systolic)

86 (diastolic)

84 (diastolic)

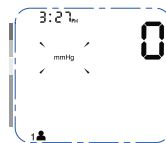
As the systolic is higher on the left arm reading this would be the one to always use in future.


1. Make sure you are sitting comfortably and have a table or other surface to rest your arm on. This is the ideal position to give the best results.
2. Place the cuff 1-2cm above the elbow joint on the correct arm, at the same height as your heart. It is best to test on a bare arm but measuring can be done over light clothing such as a shirt or blouse. If you have a weak pulse or tight clothing, it is recommended you test on a bare arm.



3. Place your arm on the table with the palm facing up and with the rubber tube running down the centre of the arm.
4. Take hold of the cuff end, making sure it is facing outwards and tighten it by pulling it through the metal loop and pressing the Velcro together to hold it in place. You should be able to fit two fingers under the cuff so that once it inflates it will not be too tight.
5. Switch the unit on by pressing the START/STOP button and measurement will start.

6. After an initial check, the LCD screen will display "0mmHg" and then the cuff will begin to inflate.



7. Once the cuff has automatically inflated, the LCD screen will display and save your results.
8. You can now release your cuff to reduce the pressure on your arm.
9. The device will start data transmission via the Bluetooth to your device – you will see the  flashing and the display will say 'done' when complete.

We understand that you might have some questions about taking your reading. Please review the questions section on page 18 for guidance.

♥ Understanding Your Measurement

Once your measurement is complete, the screen will display your systolic and diastolic pressure as well as your pulse rate. The screen will also give you an indication on the side scale to show if your blood pressure is too low, high or healthy.



Check your readings against the chart below to understand what they mean. If your systolic and diastolic readings fall into different categories, the higher value should be taken for classification. For example if your reading was 161/98 you would be classified as having moderate hypertension.

Systolic measurement	Diastolic measurement	Your blood pressure category	Advice for you
Under 100	Under 60	Hypotension	Practice a healthy lifestyle. Consult your GP if you have symptoms of low blood pressure e.g. fainting
100-120	60-80	Ideal	Practice a healthy lifestyle.
120-129	80-84	Normal	Practice a healthy lifestyle.
130-139	85-89	High normal	Practice a healthy lifestyle.
140-159	90-99	Mild hypertension	Practice a healthy lifestyle. Re-measure your blood pressure monthly over next 3 months. If high levels (140/90) persist (e.g. 2 high readings on 2 separate occasions) consult your GP
160-179	100-109	Moderate hypertension	Practice a healthy lifestyle. Re-measure your blood pressure monthly over next 4 months. If high levels (160/100) persist (e.g. 2 high readings on 2 separate occasions) consult your GP.
180-219	110-119	Severe hypertension	Re-measure your blood pressure in a few days. If the high levels of 180/110 persist, consult your GP as soon as possible.
Over 220	Over 120	Very severe hypertension	We recommend you see your Doctor or healthcare professional as soon as possible.

Please be aware that blood pressure can fluctuate since it responds to minute changes in the body. It is unusual for it to continuously remain at exactly the same value, which is why it is recommended that the blood pressure be determined based on an average of multiple measurements over time. If you experience a higher than normal reading, do not panic as this can happen, relax and take a break for at least 10 minutes before measuring your blood pressure again.

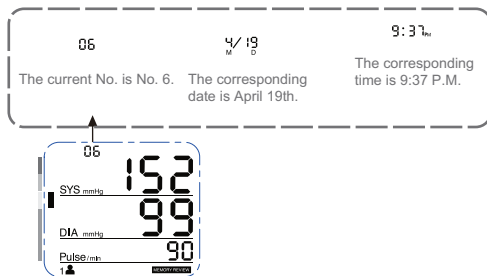
If your reading classifies you with any level of hypertension i.e. mild through to very severe, you should ask your doctor or pharmacist to assess you professionally at least once a year.

Low blood pressure (Hypotension) and high blood pressure (Hypertension) can only be diagnosed by a qualified healthcare professional, such as a doctor or pharmacist. If you have any concerns or questions, please contact your doctor or pharmacist.

♥ Recalling your Records

The most convenient way to see the record of your measurements is via the app but if you want to see them on the monitor itself this is also possible.

1. When the monitor is switched off press the 'Mem' button and this will show the average value of the last three readings.
2. Continue pressing the memory button until you arrive at the reading you want to see – the order number date and time will be displayed alternately.

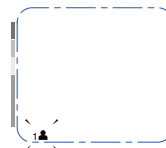


CAUTION

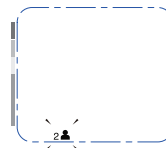
The most recent record (1) is shown first. Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (e.g., 2 becomes 3, and so on), and the last record (60) is dropped from the list.

♥ Setting up the Unit for a Second User

1. You can use the monitor to take measurements for two people. When the unit is switched off, press and hold the 'Mem' button to enter user setting mode. The user ID will flash.



2. To switch to the second user press the 'Mem' button again and the number 2 will flash alongside the user symbol. Press "SET" button to confirm your selection.



3. Make sure you only ever measure and record results using your chosen user number every time.

Tips: The maximum number of records is 60 for both User 1 and User 2.

♥ What is the difference between systolic and diastolic pressure?

Your heart is just like a pump which works all the time to make the blood flow through all blood vessels. Blood pressure measures the force on the wall of the blood vessels caused by the pressure of the blood.

Systolic pressure is the pressure of the blood when your heart beats to pump blood out.

Diastolic pressure is the pressure of the blood when your heart rests in between beats. This reflects how strongly your arteries are resisting blood flow.

♥ What is the benefit of the irregular heartbeat detector?

If you have an irregular heartbeat the monitor will not be able to give an accurate reading as there will be a variation in the overall heartbeat intervals. If the irregular heartbeat symbol appears this is usually not a cause for concern. Try re-testing for a more accurate result. However if the symbol does appear regularly, we recommend you consult your doctor.

♥ What if I want to retest?

If you want to measure again, just press the start button. Leave at least three minutes between measurements to allow blood circulation to the arm to return to normal. Do not measure your blood pressure too many times in one session as it may cause discomfort in the arm.

♥ When is the best time to test my blood pressure?

Blood pressure fluctuates constantly during the day. Its value in the daytime is higher than in the evening with the lowest level being at midnight. The pressure begins to rise again at 3:00am and reaches its highest level any time during the day – so it is impossible to get a consistent reading. For this reason, please take your measurements at the same time of the day.

Relax for 10-20 minutes before taking a measurement and remain relaxed whilst measuring. Do not move or talk during measurement as this will affect the accuracy.

Measure one hour after eating and avoid measuring immediately after bathing.
Measure one hour after smoking or drinking alcohol/caffeine.

♥ Do I need to test at the same time, every time?

We recommend that measurements are taken at the same time, under the same conditions and in the same position each time because of the way your blood pressure constantly fluctuates depending on the time of day. This will help you to keep a more accurate record over time and reduce any possible variances to your readings.

♥ What if I get an error or abnormal reading?

Please see the troubleshooting guide at the end of this section.

♥ How can I delete the reading on the monitor?

If you are not happy with a reading and want to remove it from the memory, switch the monitor to the memory recall mode. Then hold the 'Mem' button for three seconds until the display flashes. The user number (1 or 2) will show along with 'del all'. Press the 'set' button to confirm deletion. The display will confirm 'done' and then turn off.



♥ What can I do to save battery power?

Any time the unit is accidentally turned on battery power will be used. To avoid this you can press the 'Lock' button – keep it pressed until the display says 'Off'. Holding the button again will turn the unit back on.

♥ How do I know when I need to change the batteries?

When the LCD screen displays 'low battery' new batteries must be inserted immediately to ensure accurate results. Do not mix old and new batteries or different types of batteries.

♥ Can I use rechargeable batteries?

No. You can only use standard batteries. Please dispose of batteries safely after use using your local battery recycling facility.

♥ Complied European Standards List

Risk management	ISO/EN 14971:2012 Medical devices — Application of risk management to medical devices
Labeling	EN 980 Symbols for use in the labelling of medical devices
User manual	EN 1041: 2008 Medical equipment manufacturers to provide information
General Requirements for Safety	EN 60601-1: 2006+A1:2013 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC/EN 60601-1-11: 2010 Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
Electromagnetic compatibility	IEC/EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
Performance requirements	EN ISO 81060-1:2012(new) Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type (ISO 81060-1:2007) EN 1060-3:1997+A2:2009 Non-invasive blood pressure Part 3: Supplementary requirements for electromechanical blood pressure measuring system
Clinical investigation	EN 1060-4: 2004 Automatic Blood Pressure Monitor overall system Interventional accuracy of the testing process
Usability	IEC/EN 60601-1-6: 2010 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability IEC/EN 62366: 2007 Medical devices - Application of usability engineering to medical devices
Software life-cycle processes	IEC/EN 62304:2006+AC: 2008 Medical device software - Software life cycle processes

♥ EMC Guidance

1) This equipment needs to be installed and put into service in accordance with the information provided in the user manual;

2) Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance $d=3,3\text{m}$ away from the equipment.

(Note: As indicated in Table 6 of IEC 60601-1-2:2007 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields $d=3, 3\text{m}$ at an IMMUNITY LEVEL of 3V/m)

♥ Practising a Healthy Lifestyle

Further information is available from NHS Choices at www.NHS.uk or your pharmacist or doctor to help you if you have high blood pressure. The best things you can do to promote healthy blood pressure are:

- Lose weight if you need to
- Exercise regularly
- Eat a healthy diet
- Reduce the amount of salt you eat
- Cut back if you drink too much alcohol
- Stop smoking
- Cut down on caffeine

♥ Cleaning and Maintenance

To clean the monitor, wipe with a dry cloth. Do not use polish or any liquids including water as this will damage the unit.

To clean the cuff, you must disconnect from the monitor by removing the rubber tube from the socket. You can now clean by hand with warm, soapy water. Rinse thoroughly with cold water and towel dry. **Do not put in the washing machine, tumble dry or iron the cuff.**




♥ Warnings and Information

- Do not use this monitor if you suffer from atrial or ventricular premature heartbeats or atrial fibrillation.
- Not suitable for use on or by children.
- Do not drop this blood pressure monitor or subject it to strong impact.
- Avoid exposure to high temperatures, direct sunlight and contact with water.
- If the monitor is stored at temperatures below freezing, do not use immediately. Leave at room temperature for at least one hour before use.
- Do not attempt to disassemble the monitor. This will invalidate your warranty.
- Do not leave the batteries in the monitor if it is not in use for a long period of time.
- This blood pressure monitor is calibrated at the time of manufacture. If the blood pressure monitor is used according to the instructions, periodic recalibration is not required. If at any time you question the accuracy of the measurement, please contact your retailer immediately.

♥ Guarantee

This product is guaranteed for a period of one year from the date of purchase against mechanical and electrical manufacturing defects. In the unlikely event that you experience a problem, please return it to the retailer where you made the purchase, along with your receipt. Any attempted repairs by unauthorised persons will invalidate the guarantee. This does not affect your statutory rights.

This section includes a list of error messages and frequently asked questions for problems you may encounter with your blood pressure monitor. If the product is not operating as you think it should, check here first.

PROBLEM	SYMPTOM	CHECK	REMEDY
No power	Display will not light up.	Batteries are exhausted.	Replace with new batteries.
		Batteries are inserted incorrectly.	Insert the batteries correctly.
		AC adaptor is inserted incorrectly.	Insert the AC adaptor tightly.
Low batteries	Display is dim or shows:  + 	Batteries are low.	Replace with new batteries.
Error message	 + Err shows.	Data communication failed.	Check if the App/Bluetooth is on or not, try data transmission again.
	E 1 shows.	The cuff is not secure.	Refasten the cuff and then measure again.
	E 2 shows.	The cuff is very tight.	Refasten the cuff and then measure again.
	E 3 shows.	The pressure of the cuff is excess.	Relax for a moment and then measure again.
	E10 or E11 shows.	The monitor detected motion, talking or the pulse is too poor while measuring.	Relax for a moment and then measure again.
	E20 shows.	The measurement process does not detect the pulse signal.	Loosen the clothing on the arm and then measure again.
	E21 shows	The measurement failed.	Relax for a moment and then measure again.
	EExx, shows on the display.	A calibration error occurred.	Retake the measurement. If the problem persists, contact the retailer or our customer service department for further assistance.

Power supply	Battery powered mode: 6VDC 4×AAA batteries AC adaptor powered mode: 6V \pm 1A (Please only use the recommended AC adaptor model). (Not Included)
Display mode	Digital LCD V.A.84mm×73mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0mmHg~300mmHg(0kPa ~ 40kPa) Measurement pressure: SYS: 60mmHg~230mmHg (8.0kPa~30.7kPa) DIA: 40mmHg~130mmHg (5.3kPa~17.3kPa) Pulse value: (40-199)beat/minute
Accuracy	Pressure: 5℃~40℃ with \pm 0.4kPa(3mmHg) pulse value: \pm 5%
Normal working condition	Temperature: 5℃ to 40℃ Relative humidity: \leq 85%RH Atmospheric pressure: 86kPa to 106kPa
Storage & transportation condition	Temperature: -20℃~60℃ Relative Humidity: 10%RH~93%RH Atmospheric Pressure: 50kPa~106 kPa
Measurement perimeter of the upper arm	Approx 22cm~42cm
Net Weight	Approx.250g (Excluding the batteries and cuff)
External dimensions	Approx.107mm×103mm×118mm
Attachment	4×AAA batteries, user manual
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP21
Software Version	V01

WARNING: No modification of this equipment is allowed.