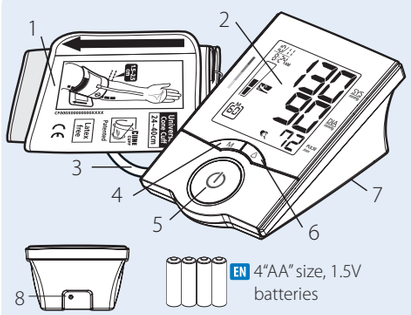
BION®

Automatic Upper Arm Blood Pressure Monitor


EN Instruction Manual

Model: MA801f

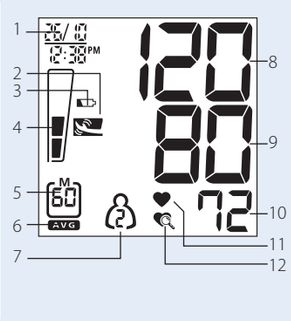
www.bionmedicalgroup.com



EN
1. Arm Cuff
2. LCD Display
3. Air Tube and Connector
4. Memory Key
5. ON/OFF/START key
6. User-Switching key
7. Battery Cover
8. AC Adaptor Jack

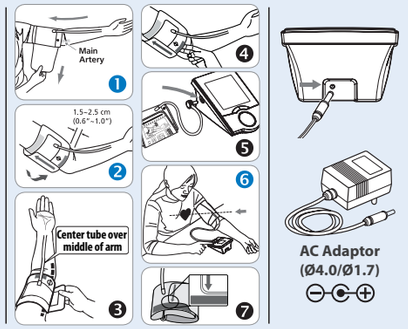


EN 4"AA" size, 1.5V batteries



EN
1. Date/Time Indicator
2. Movement Mark
3. Weak Battery Mark
4. Hypertension Risk Indicator
5. Memory/Date Mark
6. Memory Average Mark
7. Memory Zone
8. Systolic Pressure
9. Diastolic Pressure
10. Pulse Rate
11. Pulse Mark
12. Irregular Heartbeat Detector (IHB)

| Blood Pressure Standard (JNC7: 2003, unit: mmHg) | Systolic Pressure | | Diastolic Pressure |
|---|---|---|---|
| Normal | <120 | and | <80 |
| Suspected Hypertension | 120~139 | or | 80~89 |
| Suspected Stage 1 Hypertension | 140~159 | or | 90~99 |
| Suspected Stage 2 Hypertension | ≥160 | or | ≥100 |




## EN English

### Introduction

Blood pressure measurements determined with MA801f are equivalent to those obtained by a trained observer using cuff/stethoscope auscultation method, within the limits prescribed by the American National Standard, Electronic or Automated Sphygmomanometers. This unit is to be used by adult consumers in a home environment. Do not use this device on infants or neonates. MA801f is protected against manufacturing defects by an established International Warranty Program. For warranty information, you can contact the manufacturer, Rossmax International Ltd.

Attention: Consult the accompanying documents. Please read this manual carefully before use. For specific information on your own blood pressure, contact your physician. Please be sure to keep this manual.

### Real Fuzzy Measuring Technology

This unit uses the oscillometric method to detect your blood pressure. Before the cuff starts inflating, the device will establish a baseline cuff pressure equivalent to the air pressure. This unit will determine the appropriate inflation level based on pressure oscillations, followed by cuff deflation.

During the deflation, the device will detect the amplitude and slope of the pressure oscillations and thereby determine for you the systolic blood pressure, diastolic blood pressure, and pulse.

### Preliminary Remarks

This Blood Pressure Monitor complies with the European regulations and bears the CE mark "CE 0120". The quality of the device has been verified and conforms to the provisions of the EC council directive 93/42/EEC (Medical Device Directive), Annex I essential requirements and applied harmonized standards.

EN 1060-1: 1995/A2: 2009 Non-invasive sphygmomanometers - Part 1 - General requirements

EN 1060-3: 1997/A2: 2009 Non -invasive sphygmomanometers - Part 3 - Supplementary requirements for electro-mechanical blood pressure measuring systems

EN 1060-4: 2004 Non-invasive sphygmomanometers - Part 4: Test Procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers.

This blood pressure monitor was designed for long service time. To ensure accurate measurements, this monitor is recommended to be recalibrated every two years.

### Blood Pressure Standard

The National High Blood Pressure Education Program Coordinating Committee has developed a blood pressure standard, classifying blood pressure ranges into 4 stages. (Ref. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure-Complete Report JNC-7, 2003). This blood pressure classification are based on historical data, and may not be directly applicable to any particular patient. It is important that you consult with your physician regularly. Your physician will tell you your normal blood pressure range as well as the point at which you will be considered at risk. For reliable monitoring and reference of blood pressure, keeping long- term records is recommended. Please download the blood pressure log at our website www.rossmax.com.

### Display Explanations

**EE / Measurement Error:** Make sure the L-plug is securely connected to the air socket and measure again quietly. Wrap the cuff correctly and keep arm steady during measurement. If the error keeps occurring, return the device to your local distributor or service center.

**E1 / Air Circuit Abnormality:** Make sure the L-Plug is securely connected to the air socket on the side of the unit and measure again quietly. If the errors still occur, return the device to your local distributor or service center for help.

**E2 / Pressure Exceeding 300 mmHg:** Switch the unit off and measure again quietly. If the error keeps occurring, return the device to your local distributor or service center.

**E3 / Data Error:** Remove the batteries, wait for 60 seconds, and reload. If the error keeps occurring, return the device to your local distributor or service center.

**Er / Exceeding Measurement Range:** Measure again quietly. If the error keeps occurring, return the device to your local distributor or service center.

### Movement Detector

The "Movement Detector" helps reminding the user to remain still and is indicating any body movement during measurement. The specified icon appears once a "body movement" has been detected during and after each measurement.

Note: It's highly recommended that you measure again if the icon appears.

### Guest Mode

This monitor has a non-stored single measurement function. Press the User-Switching key to select the memory zone of guest , and follow the Measurement Procedure to take a measurement correctly. When the measurement is completed, the measurement value will not be stored in memory zone.

### Hypertension Risk Indicator

The National High Blood Pressure Education Program Coordinating Committee has developed a blood pressure standard, classifying blood pressure ranges into 4 stages. This unit is equipped with innovative blood pressure risk indicator, which visually indicates the assumed risk level (normal / prehypertension / stage 1 hypertension / stage 2 hypertension ) of the result after each measurement.

### Irregular Heartbeat (IHB) Detector

This unit is equipped with an Irregular Heartbeat (IHB) Detector which allows those who have an irregular heartbeat to obtain accurate measurements alerting the user of the presence of an irregular heart beat during the measurement.

Note: It is strongly recommended that you consult your physician if the IHB icon ( ) appears often.

### Installing Batteries

1. Press down and lift the battery cover in the direction of the arrow to open the battery compartment.
2. Install or replace 4 "AA" sized batteries in the battery compartment according to the indications inside the compartment.
3. Replace the battery cover by clicking in the bottom hooks first, then push in the top end of the battery cover.
4. Replace the batteries in pairs. Remove batteries when unit is not in use for extended periods of time.

You need to replace the batteries when

⚠ 1. low battery icon appears on display.

2. the ON/OFF/START key is pressed and nothing appears on display.

Caution:

1. Batteries are hazardous waste. Do not dispose them together with the household garbage.
2. There are no user serviceable parts inside. Batteries or damage from old batteries are not covered by warranty.
3. Use exclusively brand batteries. Always replace with new batteries together. Use batteries of the same brand and same type.

### Applying the Cuff

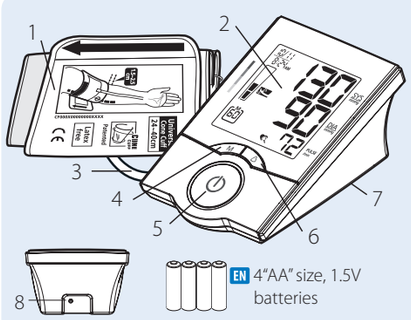
1. Unwrap the arm cuff, leaving the end of the cuff through the D-ring of the cuff.
2. Put your left arm through the cuff loop. The color strip indication should be positioned closer to you with the tube pointing in the direction of your arm (Fig. ①). Turn your left palm upward and place the edge of the arm cuff at approximately 1.5 to 2.5 cm above the inner side of the elbow joint (Fig. ②). Tighten the cuff by pulling the end of the cuff.
3. Center the tube over the middle of the arm. Press the hook and loop material together securely. Allow room for 2 fingers to fit between the cuff and your arm. Position the artery mark (Ø) over the main artery (on the inside of your arm) (Fig. ③,④). Note: Locate the main artery by pressing with 2 fingers approximately 2 cm above the bend of your elbow on the inside of your left arm. Identify where the pulse can be felt the strongest. This is your main artery.
4. Plug in the cuff connecting tube into the unit (Fig. ⑤).
5. Lay your arm on a table (palm upward) so the cuff is at the same height as your heart. Make sure the tube is not kinked (Fig. ⑥).
6. This cuff is suitable for your use if the arrow falls within the solid color line as shown on the right (Fig. ⑦). If the arrow falls outside the solid color line, you will need a cuff with other circumferences. Contact your local dealer for additional size cuffs.

### Measurement Procedures

Here are a few helpful tips to help you obtain more accurate readings:

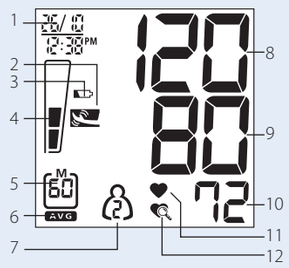
- Blood pressure changes with every heartbeat and is in constant fluctuation throughout the day.
- Blood pressure recording can be affected by the position of the user, his or her physiological condition and other factors. For greatest accuracy, wait one hour after exercising, bathing, eating, drinking beverages with alcohol or caffeine, or smoking to measure blood pressure.
- Before measurement, it's suggested that you sit quietly for at least 5 minutes as measurement taken during a relaxed state will have greater accuracy. You should not be physically tired or exhausted while taking a measurement.
- Do not take measurements if you are under stress or tension.
- During measurement, do not talk or move your arm or hand muscles.
- Take your blood pressure at normal body temperature. If you are feeling cold or hot, wait a while before taking a measurement.
- If the monitor is stored at very low temperature (near freezing), have it placed at a warm location for at least one hour before using it.
- Wait 5 minutes before taking the next measurement.

1. Press the User-Switching key to select memory zone 1, memory zone 2 or guest mode. After a memory zone is selected, press the ON/OFF/START key to reset the monitor so it can start measurement in the chosen memory zone.
2. Press the ON/OFF/START key. All digits will light up, checking the display functions. The checking procedure will be completed in 2 seconds.
3. After all symbols appear, the display will show a blinking "0".



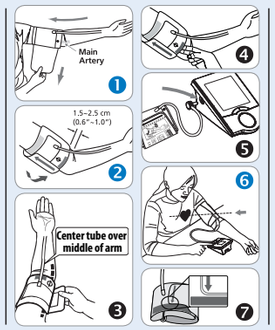

EN
1. Arm Cuff
2. LCD Display
3. Air Tube and Connector
4. Memory Key
5. ON/OFF/START key
6. User-Switching key
7. Battery Cover
8. AC Adaptor Jack

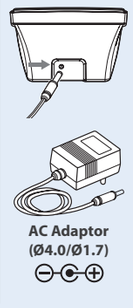
EN 4"AA" size, 1.5V batteries




EN
1. Date/Time Indicator
2. Movement Mark
3. Weak Battery Mark
4. Hypertension Risk Indicator
5. Memory/Date Mark
6. Memory Average Mark
7. Memory Zone
8. Systolic Pressure
9. Diastolic Pressure
10. Pulse Rate
11. Pulse Mark
12. Irregular Heartbeat Detector (IHB)

| Blood Pressure Standard (JNC7: 2003, unit: mmHg) | Systolic Pressure | | Diastolic Pressure |
|---|---|---|---|
| Normal | <120 | and | <80 |
| Suspected Hypertension | 120~139 | or | 80~89 |
| Suspected Stage 1 Hypertension | 140~159 | or | 90~99 |
| Suspected Stage 2 Hypertension | ≥160 | or | ≥100 |




The monitor is ready to measure and will automatically inflate the cuff slowly to start measurement.

4. When the measurement is completed, the cuff will exhaust the pressure inside. Systolic pressure, diastolic pressure and pulse will be shown simultaneously on the LCD screen. The measurement is then automatically stored into the pre-designated memory zone.

This monitor will re-inflate automatically to approximately 220 mmHg if the system detects that your body needs more pressure to measure your blood pressure.

Note: 1. This monitor automatically switches off approximately 1 minute after last key operation.

2. To interrupt the measurement, simply press the Memory or ON/OFF/START key; the cuff will deflate immediately.
3. During the measurement, do not talk or move your arm or hand muscles.

### Recalling Values from Memory

1. The monitor has two memory zones (1 and 2). Each zone can store up to 60 measurements.
2. To read memory values from a selected memory zone, use the User-Switching key to select a memory zone (1 or 2) from which you want to recall values. Press the Memory key. The first reading displayed is the average of the last 3 measurements stored in memory.
3. Continue to press the Memory key to view the last previously stored measurement. Every measurement comes with an assigned memory sequence number.

Note: The memory bank can store up to 60 readings per memory zone. When the number of readings exceeds 60, the oldest data will be replaced with the new record.

### Clearing Values from Memory

1. Press the User-Switching key to select memory zone 1 or memory zone 2.
2. Press and hold the Memory key for approximately 5 seconds, then the data in the memory zone can be erased automatically.

### Time Adjustment

1. To adjust the date/time in the monitor after installing or replaces batteries. The display will show a blinking number showing the date.
2. Change the date by pressing the Memory key, each press will increase the number. Press the ON/OFF/START key to confirm the entry and the screen will show a blinking number representing the month.
3. Change the month, the hour and the minute as described in Step 2 above, using the Memory key to change and the ON/OFF/START key to confirm the entries.
4. "0" will reappear as the Blood Pressure Monitor is ready for measurement again.

### Troubleshooting

If any abnormality will arise during use, please check the following points.

| Symptoms | Check Points | Correction |
|---|---|---|
| No display when the ON/OFF/START key is pressed | Have the batteries run down? | Replace them with four new batteries. |
| | Have the batteries' polarities been positioned incorrectly? | Re-insert the batteries in the correct positions. |
| EE mark shown on display or the blood pressure value is displayed excessively low (high) | Is the cuff placed correctly? | Wrap the cuff properly so that it is positioned correctly. |
| | Did you talk or move during measurement? | Measure again. Keep wrist steady during measurement. |
| | Did you vigorously shake the cuff during measurement? | |

Note: If the unit still does not work, return it to your dealer. Under no circumstance should you disassemble and repair the unit by yourself.

### Cautionary Notes

1. The unit contains high-precision assemblies. Therefore, avoid extreme temperatures, humidity, and direct sunlight. Avoid dropping or strongly shocking the main unit, and protect it from dust.
2. Clean the blood pressure monitor body and the cuff carefully with a slightly damp, soft cloth. Do not press. Do not wash the cuff or use chemical cleaner on it. Never use thinner, alcohol or petrol (gasoline) as cleaner.
3. Leaky batteries can damage the unit. Remove the batteries when the unit is not used for a long time.
4. The unit should not be operated by children so to avoid hazardous situations.
5. If the unit is stored near freezing, allow it to acclimate at room temperature before use.
6. This unit is not field serviceable. You should not use any tool to open the device nor should you attempt to adjust anything inside the device. If you have any problems, please contact the store or the doctor from whom you purchased this unit or please contact Rossmax International Ltd.
7. As a common issue for all blood pressure monitors using the oscillometric measurement function, the device may have difficulty in determining the proper blood pressure for users diagnosed with common arrhythmia (atrial or ventricular premature beats or atrial fibrillation), diabetes, poor circulation of blood, kidney problems, or for users suffered from stroke, or for unconscious users.
8. To stop operation at any time, press the ON/OFF/START key, and the air in the cuff will be rapidly exhausted.
9. Once the inflation reaches 300 mmHg, the unit will start deflating rapidly for safety reasons.
10. Please note that this is a home healthcare product only and it is not intended to serve as a substitute for the advice of a physician or medical professional.
11. Do not use this device for diagnosis or treatment of any health problem or disease. Measurement results are for reference only. Consult a healthcare professional for interpretation of pressure measurements. Contact your physician if you have or suspect any medical problem. Do not change your medications without the advice of your physician or healthcare professional.
12. Electromagnetic interference: The device contains sensitive electronic components. Avoid strong electrical or electromagnetic fields in the direct vicinity of the device (e.g. mobile telephones, microwave ovens). These may lead to temporary impairment of measurement accuracy.
13. Dispose of device, batteries, components and accessories according to local regulations.
14. This monitor may not meet its performance specification if stored or used outside temperature and humidity ranges specified in Specifications.

### Specifications

| | |
|---|---|
| Measurement Method | Oscillometric |
| Measurement Range | Pressure: 30~260 mmHg; Pulse: 40~199 beats/ minute |
| Pressure Sensor | Semi conductor |
| Accuracy | Pressure: ± 3mmHg; Pulse: ± 5% of reading |
| Inflation | Pump Driven |
| Deflation | Automatic Air Release Valve |
| Memory capacity | 60 memories for each zone x 2 zones |
| Auto-shut-off | 1 minute after last key operation |
| Operation Environment | 10°C~40°C (50°F~104°F); 40%~85% RH; 700~1060 hPa |
| Storage and Transportation Environment | -10°C~60°C (14°F~140°F); 10%~90% RH; 700~1060 hPa |
| DC Power Source | DC 6V four AA Batteries |
| AC Power Source | DC 6V, ≥600mA (Plug size: outer(-) is Ø4.0, inner(+) is Ø1.7) |
| Dimensions | 160 (L) X 111 (W) X 75 (H) mm |
| Weight | 310g (G.W.) (w/o Batteries) |
| Arm circumference | Adult: 24~40 cm (9.4"~15.7") |
| Limited Users | Adult users |
| | Type BF: Device and cuff are designed to provide special protection against electrical shocks. |
| IP Classification | IP21: Protection against harmful ingress of water and particulate matter |

*Specifications are subject to change without notice.

**EMC guidance and manufacturer's declaration**

Guidance and manufacturer's declaration-electromagnetic emissions

The MA801f is intended for use in the electromagnetic environment specified below. The customer or the user of the MA801f should assure that it is used in such an environment.

| Emission test | Compliance | Electromagnetic environment-guidance |
|---|---|---|
| RF emissions CISPR 11 | Group 1 | The MA801f uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class B | The MA801f is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/flicker emissions IEC 61000-3-3 | Compliance | |

Guidance and manufacturer's declaration-electromagnetic immunity.

The MA801f is intended for use in the electromagnetic environment specified below. The customer or the user of the MA801f should assure that it is used in such an environment.

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment-guidance |
|---|---|---|---|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 6 kV contact<br>± 8 kV air | ± 6 kV contact<br>± 8 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<br>± 1kV for input / output lines | ± 2kV for power supply lines<br>Not applicable | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1kV line(s) to line(s)<br>± 2kV line(s) to earth | ± 1kV differential mode<br>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% UT(>95% dip in UT) for 0,5 cycle<br>40% UT(60% dip in UT) for 5 cycles<br>70% UT(30% dip in UT) for 25 cycles<br><5% UT(>95% dip in UT) for 5 s | <5% UT(>95% dip in UT) for 0,5 cycle<br>40% UT(60% dip in UT) for 5 cycles<br>70% UT(30% dip in UT) for 25 cycles<br><5% UT(>95% dip in UT) for 5 s | Mains power quality should be that of a typical commercial or hospital environment. If the user of the MA801f requires continued operation during power mains interruptions, it is recommended that the MA801f be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment. |

NOTE: UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration-electromagnetic immunity

The MA801f is intended for use in the electromagnetic environment specified below. The customer or the user of the MA801f should assure that it is used in such and environment.

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment-guidance |
|---|---|---|---|
| Conducted RF IEC 61000-4-6 | 3 Vrms<br>150 KHz to 80 MHz | 3 Vrms | Portable and mobile RF communications equipment should be used no closer to any part of the MA801f including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:<br>d = 1,2 √P; d = 1,2 √P 80MHz to 800 MHz; d = 2,3 √P 800MHz to 2,5 GHz<br>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 metres (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: |
| Radiated RF IEC 61000-4-3 | 3 V/m<br>80MHz to 2,5 GHz | 3 V/m | |

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 MA801f is used exceeds the applicable RF compliance level above, the MA801f should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MA801f.
b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distance between portable and mobile RF communications equipment and the MA801f

The MA801f is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MA801f can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MA801f as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power of transmitter / W | Separation distance according to frequency of transmitter / m | | |
|---|---|---|---|
| | 150 kHz to 80 MHz / d=1,2√P | 80 MHz to 800 MHz / d=1,2√P | 800 MHz to 2,5 GHz / d=2,3√P |
| 0,01 | 0,12 | 0,12 | 0,23 |
| 0,1 | 0,38 | 0,38 | 0,73 |
| 1 | 1,2 | 1,2 | 2,3 |
| 10 | 3,8 | 3,8 | 7,3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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) according 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.

**Warranty Terms & Conditions (www.bionmedicalgroup.com/warranty)**

- Product is entitled to 5 years off-site warranty coverage against manufacturing defects from the date of purchase, **with the original invoice/receipt as proof of purchase**.
- This warranty does not cover damages or defects arising from accident, misuse, mishandling, improper installation, any manner of tampering, usage of wrong electrical supply/voltage, corrosion/fungus, rusting or stains, any unauthorized repair or modification to the product, act of god, fire, civil unrest and consequential damages.
- This warranty does not cover normal wear and tear, including, but not limited to, damages or leakage of blood pressure monitor cuffs.
- Batteries are not covered under this warranty.
- This warranty shall be null and void in the event that the serial number on the product has been altered or removed.

EN **WARNING:** The symbol on this product means that it's an electronic product and following the European directive 2012/19/EU the electronic products have to be dispose on your local recycling centre for safe treatment.

GMC Inc.
No. 686, Su Chu Rd., Chuzhou, Anhui, China
EC REP CMC Medical Devices& Drugs S.L.
C/Horacio Lengo No. 18, CP 29006, Málaga, Spain

ISO 13485 CE 0120
Bion_IB_MA801f(1)NAZ_EN_AH_ver1746
IWOMA801f000000XX