EVOLU®
electronics

Model: DBP-6177

GB

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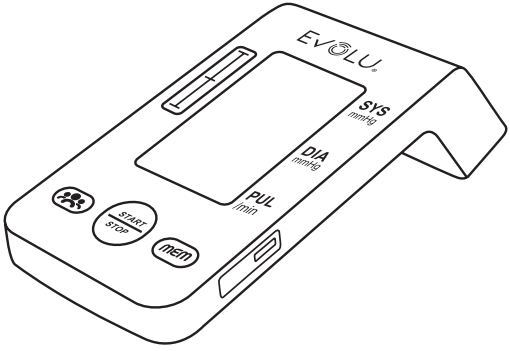


INSTRUCTION MANUAL
BLOOD PRESSURE MONITOR
AUTOMATIC

the best reason to take care of yourself

{YES, YOU}

TABLE OF CONTENTS

INTRODUCTION

Thank you for purchasing the DBP-6177 Blood Pressure Monitor. The device has been constructed using reliable circuitry and durable materials. Used properly, this device will provide years of satisfactory use.

This device is intended for non-invasive measuring an adult individual's systolic, diastolic blood pressure and heart rate using the oscillometric method. The device is not intended for use on infants and children. The device is designed for home or clinical use. All functions can be used safely andvalues can be read out in one LCD DISPLAY. Measurement position is on adult upper arm only.

Please read this manual thoroughly before using the device. Please retain this manual for future reference. For specific information about your blood pressure, please CONSULT YOUR DOCTOR.

To avoid risk and damage follow all warning precautions. Operate device only as intended. Read all instructions prior to use.

SAFETY NOTICE

WARNING SIGNS AND SYMBOLS USED

	Caution		Serial Number
	Mandatory		WEEE symbol. Discard the used product to the recycling collection point according to local regulations
	Prohibited		Manufacturer
	Type BF Equipment	EC REP	Authorized Representative in the European Community
	Instructions For Use MUST be Consulted		Keep Dry
	Manufacturing Date		Keep off Sunlight
	Do not litter!		Product can be recycled

CE 0197 CE mark. The product conforms to the requirements of the EC Directive MDD (93/42/EEC) on medical devices.

IP21 IP 21, Indoor Use Only
Protection against solid and liquid bodies penetration (protected against solid bodies over 12 mm; protected against access with a finger; protected against vertically falling water drops).

⚠ CAUTION

Individuals with serious circulation problems may experience discomfort. Consult your physician prior to use.
Contact your physician if test results regularly indicate abnormal readings. Do not attempt to self-treat these symptoms without consulting your physician first.

Product is designed for its intended use only. Do not misuse in any way.
Product is not intended for infants or individuals who cannot express their intentions.
Do not disassemble or attempt to repair.
Do not use cell phones and other devices, which generate strong electrical or electromagnetic fields, near the device, as they may cause incorrect readings and interference or become interference source to the device.
Only use a recommended AC adaptor double-insulated complying with EN 60601-1 and EN 60601-1-2 (see page 6). An unauthorized adaptor may cause fire and electric shock.

⚠ BATTERY PRECAUTIONS

Do not mix new and old batteries simultaneously.

Replace batteries when Low Battery Indicator " ⌧ " appears on screen.

Be sure battery polarity is correct.

Do not mix battery types. Long-life alkaline batteries are recommended.

Remove batteries from device when not in operation for more than 3 months.

Dispose batteries properly; observe local laws and regulations.

Important Instructions Before Use

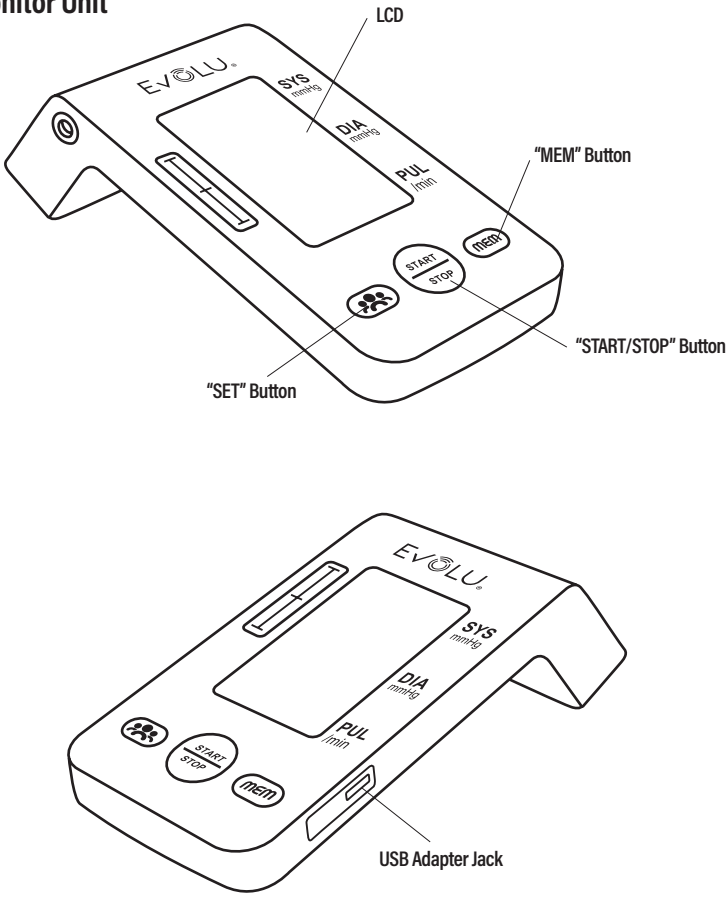
1. Do not confuse self-monitoring with self-diagnosis. Blood pressure measurements should only be interpreted by a health professional who is familiar with your medical history.
2. Contact your physician if test results regularly indicate abnormal readings.
3. If you are taking medication, consult with your physician to determine the most appropriate time to measure your blood pressure. NEVER change a prescribed medication without first consulting with your physician.
4. Individuals with serious circulation problems may experience discomfort. Consult your physician prior to use.
5. For persons with irregular or unstable circulation resulting from diabetes, liver disease, arteriosclerosis or other medical conditions, there may be variations in blood pressure values measured at the wrist versus at the upper arm. Monitoring the trends in your blood pressure taken at either the arm or the wrist is nevertheless useful and important.
6. People suffering from vascular constriction, liver disorders or diabetes, people with cardiac pacemakers or a weak pulse, and women who are pregnant should consult their physician before measuring their blood pressure themselves. Different values may be obtained due to their condition.
7. People suffering from arrhythmias such as atrial or ventricular premature beats or atrial fibrillation only use this blood pressure monitor in consultation with their doctor. In certain cases oscillometric measurement method can produce incorrect readings.
8. Too frequent measurements can cause injury to the patient due to blood flow interference.
9. The cuff should not be applied over a wound as this can cause further injury.
10. DO NOT attach the cuff to a limb being used for IV infusions or any other intravascular access, therapy or an arterio-venous (A-V) shunt. The cuff inflation can temporarily block blood flow, potentially causing harm to the patient.
11. The cuff should not be placed on the arm on the side of a mastectomy. In the case of a double mastectomy use the side of the least dominant arm.
12. Pressurization of the cuff can temporarily cause loss of function of simultaneously used monitoring equipment on the same limb.
13. A compressed or kinked connection hose may cause continuous cuff pressure resulting in blood flow interference and potentially harmful injury to the patient.
14. Check that operation of the device does not result in prolonged impairment of the circulation of the patient.
15. Product is designed for its intended use only. Do not misuse in any way.
16. Product is not intended for infants or individuals who cannot express their intentions.
17. Prolonged over-inflation of the bladder may cause ecchymoma of your arm.
18. Do not disassemble the unit device or arm cuff. Do not attempt to repair.
19. Use only the approved arm cuff for this device. Use of other arm cuffs may result in incorrect measurement results.

20. The system might produce incorrect readings if stored or used outside the manufacturer's specified temperature and humidity ranges.
21. Do not use the device near strong electrical or electromagnetic fields generated by cell phones or other devices, they may cause incorrect readings and interference or become interference source to the device. Do not use the device during patient transport outside healthcare facility for interference source existing as well.
22. Do not mix new and old batteries simultaneously
23. Replace batteries when Low Battery Indicator " " appears on screen. Replace both batteries at the same time.
24. Do not mix battery types. Long-life alkaline batteries are recommended.
25. Remove batteries from device when not in operation for more than 3 months.
26. Do not insert the batteries with their polarities incorrectly aligned.
27. Dispose batteries properly; observe local laws and regulations.
28. Only use a recommended AC adaptor double-insulated complying with EN 60601-1 and EN 60601-1-2. An unauthorized adapter may cause fire and electric shock.
29. Advising operator that Instruction manual/ Booklet must be consulted.
30. Essential performance:

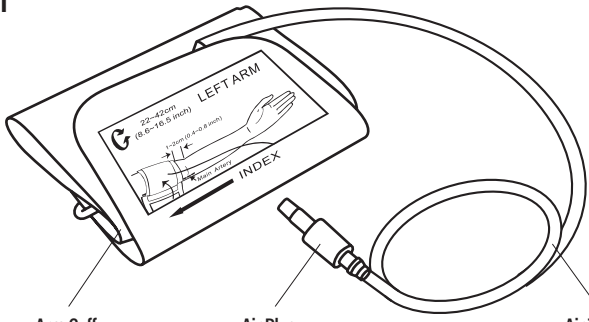
Electrosurgery interference recovery	Refer 202.6.2.101	IEC 80601-2-30
Limits of the error of the manometer	Refer 202.12.1.102	IEC 80601-2-30
Reproducibility of the BLOOD PRESSURE DETERMINATION	Refer 201.12.1.107	IEC 80601-2-30

DEVICE ILLUSTRATION

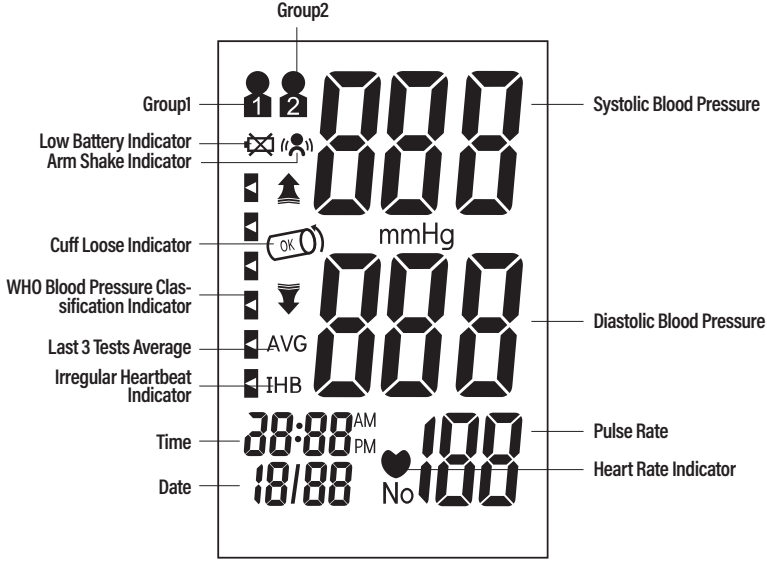
Monitor Unit



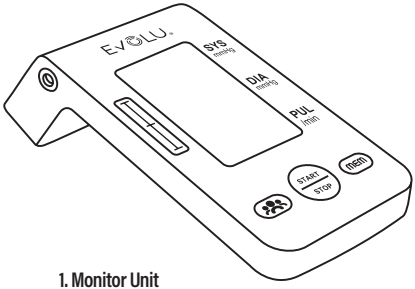
Arm Cuff



Display

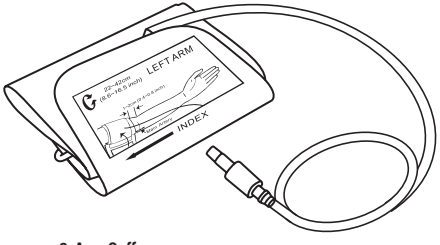


Contents

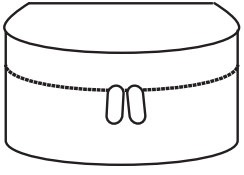


1. Monitor Unit

2. User Manual

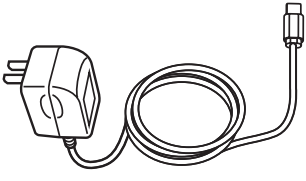


3. Arm Cuff



4. Storage Case

5. 3 new AAA alkaline batteries



6. 2MOPP Medical AC Adapter (DC 5.0 V,1000 mA)
(recommended, not provided)

IMPORTANT TESTING GUIDELINES

1. Avoid eating, exercising, and bathing for 30 minutes prior to testing.
2. Sit in a calm environment for at least 5 minutes prior to testing.
3. Do not stand while testing. Sit in a relaxed position while keeping your arm level with your heart.
4. Avoid speaking or moving body parts while testing.
5. While testing, avoid strong electromagnetic interference such as microwave ovens and cell phones.
6. Wait 3 minutes or longer before re-testing.
7. Try to measure your blood pressure consistency at the same time each day.
8. Test comparisons should only be made when device is used on the same arm, in the same position, and at the same time of day.
9. This blood pressure monitor is not recommended for people with severe arrhythmia.
10. Do not use this blood pressure monitor if the device is damaged.

QUICK START

1. Install batteries. (See Figure A)
2. Insert cuff air plug into the left side of monitor unit. (See Figure B)

Figure A

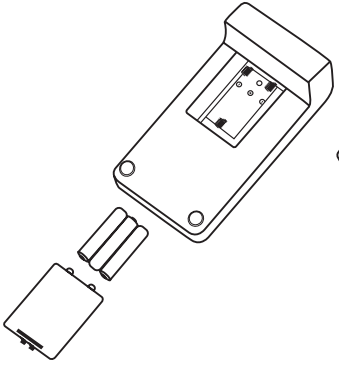
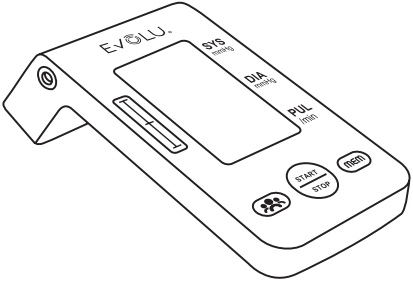
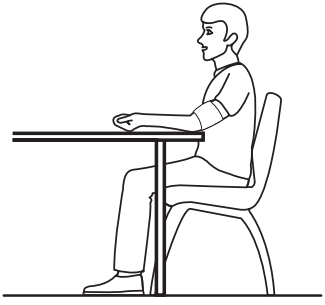


Figure B



3. Remove thick clothing from the arm area.
4. Rest for several minutes prior to testing. Sit down in a quiet place, preferably at a desk or table, with your arm resting on a firm surface and your feet flat on the floor. (See Figure C)

Figure C



5. Apply cuff to your left arm and keep level with your heart. Bottom of cuff should be placed approximately 1-2cm (0.4-0.8") above elbow joint. (See Figures D&E)

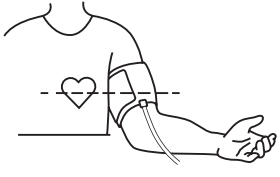


Figure D

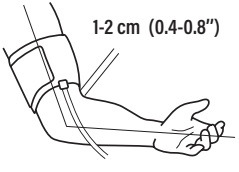
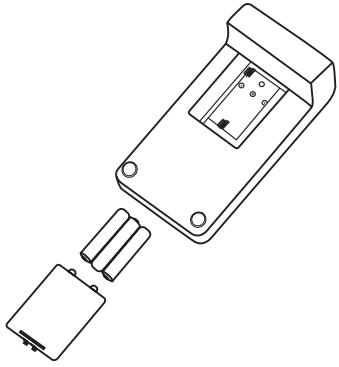


Figure E

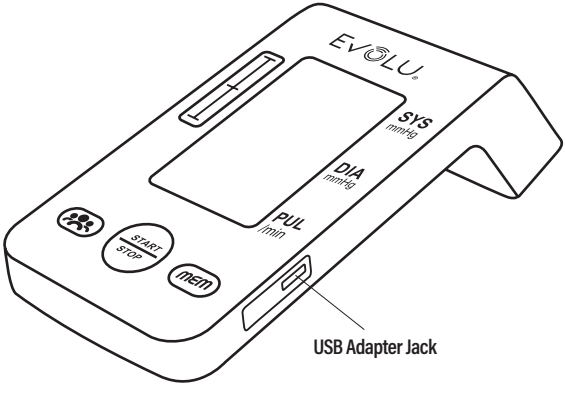
6. Press "START/STOP" Button to start testing.

DEVICE OPERATION
BATTERY INSTALLATION

Slide the battery cover off as indicated by the arrow.
Install 3 new AAA alkaline batteries according to polarity.
Close battery cover.



AC Adapter jack is on the back side of the monitor.
Medical AC adapter (DC 5.0 V, 1000 mA) can be used with the device (recommended, not provided). The adapter connect pin should be positive inside and negative outside with a 2.1mm coaxial joint. Do not use any other type of AC adapter as it may harm the device.



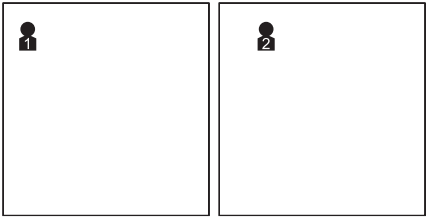
Note: Power supply is specified as part of ME EQUIPMENT.

SYSTEM SETTINGS

With power off, press "SET" button to activate System Settings. The Memory Group icon flashes

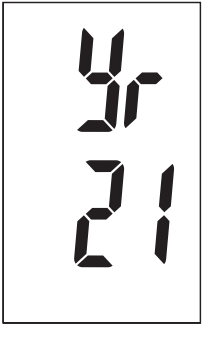
1. Select Memory Group

While in the System Setting mode, you may accumulate test results into 2 different groups. This allows multiple users to save individual test results (up to 150 memories per group.) Press " MEM " button to choose a group setting. Test results will automatically store in each selected group.



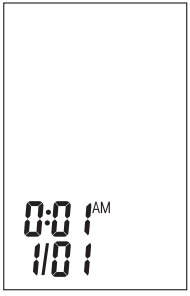
2. Time/Date setting

Press the "SET" button again to set the Year. Set the year first by adjusting the "MEM" button.



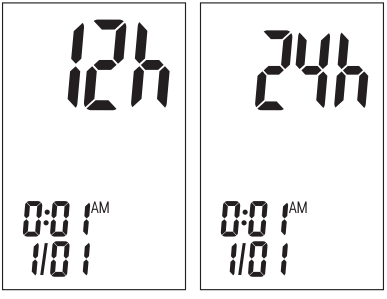
3. Time/Date setting

Press the "SET" button again to confirm the current month. Continue setting the date, hour, and minute in the same way.



4. Time formats

Press the "SET" button is pressed, and it will lock in your selection and continue in succession for 12/24 hours.



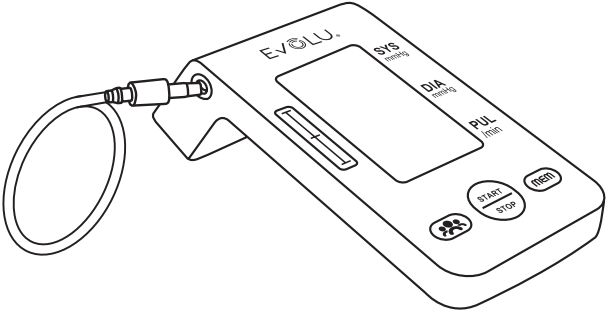
5. Saved Settings

While in any setting mode, press the "START/STOP" button to turn the device off. All information will be saved.

Note: If device is left on and not in use for 3 minutes, it will automatically save all information and shut off.

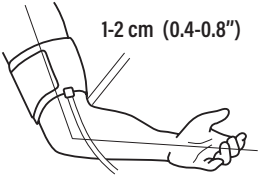
APPLYING THE ARM CUFF

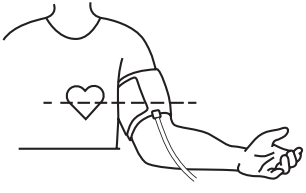
1. Firmly insert air plug into opening located on left side of monitor unit.



2. With sticky nylon section facing outward, insert end of cuff underneath metal ring of cuff.

3. Fasten cuff about 1-2cm (0.4-0.8") above the elbow joint. For best results apply cuff to bare arm and keep level with heart while testing.



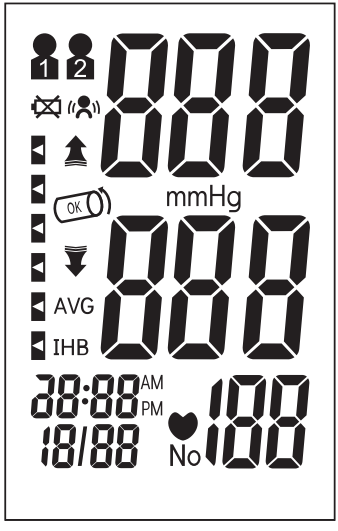


Note: Do not insert air plug into opening located on right side of monitor unit. This opening is designed for an optional power supply only.

TESTING

1. Power On

Press and hold "START/STOP" button to turn the device on. The LCD screen will appear for one second as device performs a quick diagnosis.



Note: Device will not function if residual air from previous testing is present in cuff. The LCD will flash " ▼ " device pressure is stabilized.

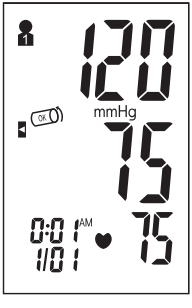
2. Testing

After cuff inflation, air will slowly rise as indicated by the corresponding cuff pressure value. A flashing " ♥ " will appear simultaneously on screen signaling heart beat detection.

Note: Keep relaxed during testing. Avoid speaking or moving body parts.

Result Display

The screen will display measurements for systolic and diastolic blood pressure. An indicator representing the current measurement will appear next to the corresponding WHO Classification.



Note: Refer to Page 24~25 for detail WHO Blood Pressure Classification Information.

Irregular Heartbeat Indicator

If the device detects an irregular heart rhythm two or more times during the measuring process, the Irregular Heartbeat Symbol " IHB "appears on screen along with measurement results. Irregular heartbeat rhythm is defined as rhythm that is either 25% slower or faster than the average rhythm detected while measuring systolic blood pressure and diastolic blood pressure. Consult your physician if the Irregular Heartbeat Symbol " IHB " frequently appears with your test results.

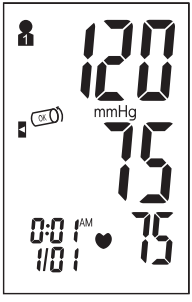
POWER OFF

The "START/STOP" button can be pressed to turn off the device in any mode. The device can turn off the power itself about 3 minutes no operation in any mode.

Safety Precaution: If pressure in arm cuff becomes too extreme while testing, press the "START/STOP " button to turn power off. The cuff pressure will rapidly dissipate once the device is off.

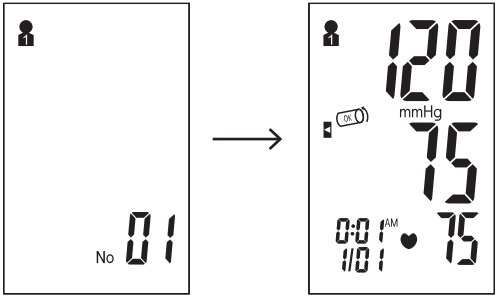
Last 3 Tests Average

With power off, press the "MEM" button to activate screen display. After the device performs a self-diagnosis, the screen will display the average test results from the last 3 readings of the last group used. The "AVG" symbol will appear along with the corresponding WHO Blood Pressure Indicator. The Memory Check mode can be accessed by pressing "MEM" button. To check the average results from other groups, select the desired group first prior to activating "SET" button in the off position. (See "Select Memory Group" on Page 13)



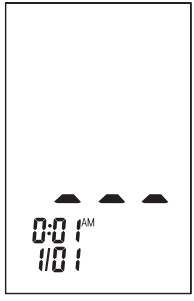
MEMORY CHECK

You may check past test results by using the "MEM" button. The most recent test result and oldest test result in memory can be viewed by pressing and holding the "MEM" button. Upon activating test results. you can press the "MEM" button to scroll through all test results stored in memory.



MEMORY DELETION

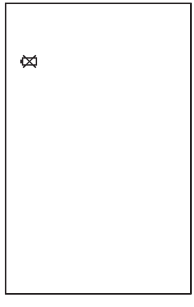
Memory for a selected group may be deleted while in Memory Check mode. Press and hold the "SET" button for approximately 3 seconds to delete all memory records from the selected group and then transfer into testing mode. Press the "START/STOP" button to turn the device off.



Note: Memory cannot be recovered once it has been deleted.

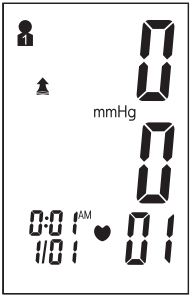
LOW BATTERY INDICATOR

The device will broadcast "Low Battery" when battery life is depleting and unable to inflate cuff for testing. The " " appears simultaneously for approximately 5 seconds prior to shutting off. Replace batteries at this time. No memory loss will occur throughout this process.



Static Pressure Measurement

In the power-down state, press and hold the "START/STOP" button, and then install the batteries. Until the LCD screen is full, release the "START/STOP" button. When the LCD screen displays the double zero, the blood-pressure meter is in a static state. Software version is displayed: 10 is a software version in the figure.



Note: Only Service personnel is permitted to access this mode, the mode is unavailable in normal use.

Arm Shake Indicator

If there is arm movement during the measurement, " " may be shown. Indicates that it may lead to abnormal accurate measurement results. At this time,the LCD will display " Err".

Cuff loose Indicator

When starting the measurement, " " will be displayed when the cuff is properly wound. When the cuff is too loose, " " will be displayed. At this time, please wear the cuff correctly and start measuring again.

TROUBLESHOOTING

Abnormal phenomenon	Cause analysis	Processing method
Abnormal sphygmomanometer	The armband is tied too tight or too loose, Or the arm strap is tied incorrectly	Roll the armband correctly
	Move the arm during measurement or Electronic sphygmomanometer	Stay quiet, keep your arm steady, and do not move the device
	Speaking, nervous or emotional during measurement	Instead of talking, please take deep breaths to calm your mood and relax your body
	Incorrect measurement posture	Adjust posture, see "Applying the Arm Cuff"
	There is interference in the charging process or improper operation in the measuring process	See operation Instructions

The following table shows the error signs that may occur during measurement, possible causes and handling methods. Please measure again using the correct method.

Error display	The cause of the problem	The solution
Er1	Can't detect high and low pressure	Please fasten the cuff before measuring
Er2	Cuff too loose or loose	Please fasten the cuff before measuring
Er3	Improper compression caused by arm or body movement	Hold the arm or body still and measure again
Er4	The pressure exceeds 300 mm Hg	Please fasten the cuff before measuring
Er5	The pressure exceeds 15 mm Hg for 3 minutes	Check whether the cuff is knotted or the vent valve is blocked. If the problem persists, contact the manufacturer
	Battery dead	Replace the battery or connect the power adapter (if any)

Note: If you cannot solve the abnormal situation by yourself, you can consult the distributor. It is forbidden to disassemble and repair without permission.

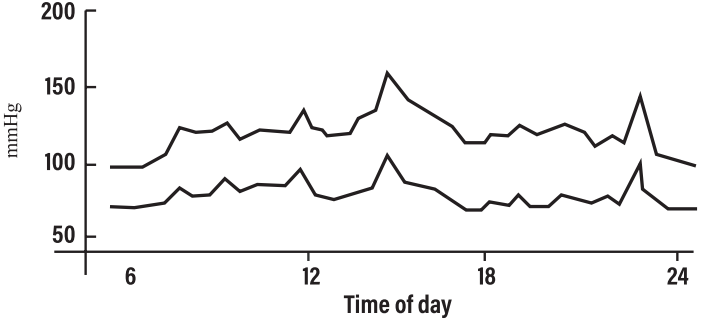
BLOOD PRESSURE INFORMATION

Blood Pressure

Blood pressure is the force of blood pushing against the walls of arteries. It is typically measured in millimeters of mercury (mmHg.) Systolic blood pressure is the maximum force exerted against blood vessel walls each time the heart beats. Diastolic blood pressure is the force exerted on blood vessels when the heart is resting between beats.
An individual's blood pressure frequently changes throughout the course of a day. Excitement and tension can cause blood pressure to rise, while drinking alcohol and bathing can lower blood pressure. Certain hormones like adrenaline (which your body releases under stress) can cause blood vessels to constrict, leading to a rise in blood pressure.

If these measuring numbers become too high, it means the heart is working harder than it should.

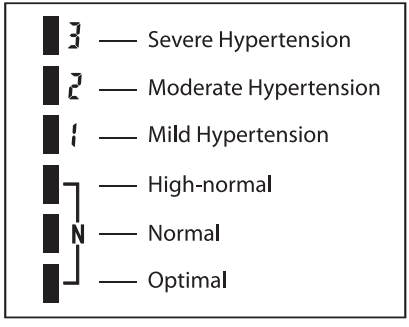
Upper curve: systolic blood pressure
Lower curve: diastolic blood pressure

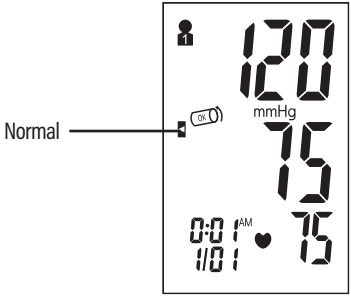


Example: fluctuations within a day (male, 35 years old)

WHO Blood Pressure Classification Indicator

The DBP-6177 is equipped with a classification indicator based on established guidelines from the World Health Organization. The chart below (marking on the monitor) indicates test results.

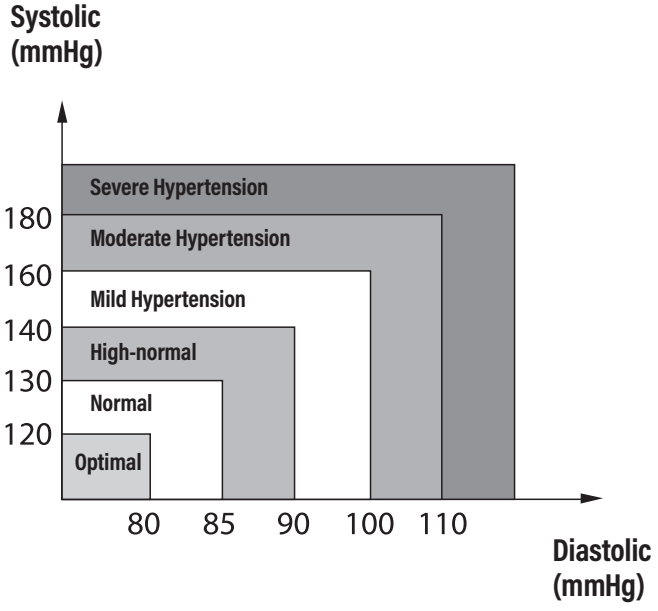




◂ : Blood Pressure Classification Indicator

Health Reminder

Hypertension is a dangerous disease that can affect the quality of life. It can lead to a lot of problems including heart failure, kidney failure, and cerebral hemorrhaging. By maintaining a healthy lifestyle and visiting your physician on a regular basis, hypertension and relative diseases are much easier to control when diagnosed in their early stages.



Note: Do not be alarmed if an abnormal reading occurs. A better indication of an individual's blood pressure occurs after 2-3 readings are taken at the same time each day over an extended period of time. Consult your physician if test results remain abnormal.

BLOOD PRESSURE Q&A

Q: What is the difference between measuring blood pressure at home or at a professional healthcare clinic?
A: Blood pressure readings taken at home are now seen to give a more accurate account as they better reflect your daily life. Readings can be elevated when taken in a clinical or medical environment. This is known as White Coat Hypertension and may be caused by feeling anxious or nervous.

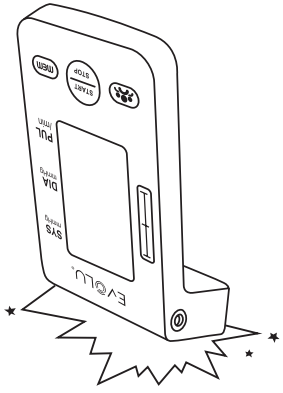
Note: Abnormal test results may be caused by:

1. **Improper cuff placement**
   Make sure cuff is snug-not too tight or too loose. Make sure bottom of the cuff is approximately 1-2cm (1/2") above the elbow joint.
2. **Improper body position**
   Make sure to keep your body in an upright position.
3. **Feeling anxious or nervous**
   Take 2-3 deep breaths, wait a few minutes and resume testing.

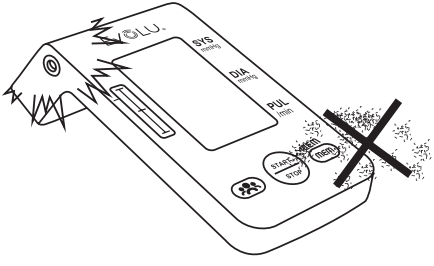
Q: What causes different readings?
A: Blood pressure varies throughout the course of a day. Many factors including diet, stress, cuff placement, etc. may affect an individual's blood pressure.
Q: Should I apply the cuff to the left or right arm? What is the difference?
A: Either arm can be used when testing, however, when comparing results, the same arm should be used. Testing on your left arm may provide more accurate results as it is located closer to your heart.
Q: What is the best time of day for testing?
A: Morning time or any time you feel relaxed and stress free.

MAINTENANCE

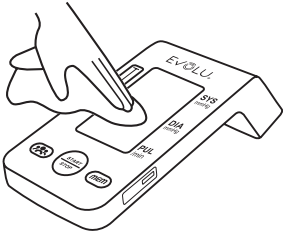
1. Avoid dropping, slamming, or throwing the device.



2. Avoid extreme temperatures. Do not expose device directly under sunshine.

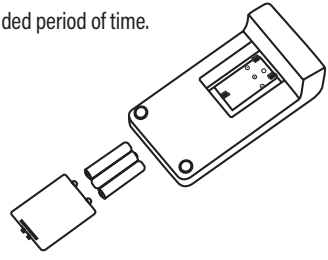


3. When cleaning the device, use a soft fabric and lightly wipe with mild detergent. Use a damp cloth to remove dirt and excess detergent.

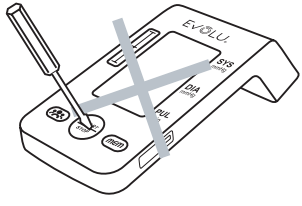


4. Cuff Cleaning: Do not soak cuff in water! Apply a small amount of rubbing alcohol to a soft cloth to clean cuff's surface. Use a damp cloth (water-based) to wipe clean. Allow cuff to dry naturally at room temperature. The cuff must be cleaned and disinfected before use between different users.
5. Do not use petrol, thinners or similar solvents.

6. Remove batteries when not in operation for an extended period of time.



7. Do not disassemble product.



8. It is recommended the performance should be checked every 2 years.
9. Expected service life: Approximately three years at 10 tests per day.
10. No service and maintenance should be performed during the use of the device. Maintenance of the device should only be performed by qualified technical service personnel.

Product inspection and calibration is carried out by accredited laboratory and is not a warranty service!
For service information, parts list etc., please contact the dealer.

SPECIFICATIONS

Product Description	Arm-type Fully Automatic Blood Pressure Monitor	
Model	DBP-6177	
Display	LCD Digital Display. Size: 66.4 mm x 43.1 mm (2.61" x 1.70")	
Measurement Method	Oscillometric Method	
Measurement Range	Systolic Pressure	60mmHg ~ 260mmHg
	Diastolic Pressure	30mmHg ~ 200mmHg
	Pressure	0mmHg ~ 299mmHg
	Pressure	±3mmHg
	Pulse	30 ~ 180 Beats/Minute
	Pulse	±5%
Pressurization	Automatic Pressurization	
Memory	2x150 Memories in Two Groups with Date and Time	
Function	Irregular Heartbeat Detection	
	WHO Classification Indicator	
	Last 3 Tests Average	
	Low Battery Detection	
	Automatic Power-Off	
Power Source	3 AAA batteries or Medical AC Adapter (DC 5.0 V, 1000 mA) (recommended, not provided)	
Battery Life	Approximately 2 months at 3 tests per day	
Device Weight	Approx. 155 g. (5.26 oz.) (excluding battery)	
Device Dimensions	Approx. 148.9 x 79.4 x 45.5mm (5.86"x 3.13"x1.79") (L x W x H)	
Cuff Circumference	Approx. 140 (W) x 568 (L) mm/ (Medium cuff: Fits arm circumference 22-42 cm)	

Operating Environment	Temperature	+10°C ~ +40°C; (50°F ~ 104°F)
	Humidity	15 % RH ~ 93 % RH;
	Pressure	800 hPa ~ 1060 hPa
Storage Environment	Temperature	-25°C ~ 55°C; (-13°F ~ 131°F)
	Humidity	≤ 93 % RH
Transport Environment	Temperature	-25°C ~ 55°C; (-13°F ~ 131°F)
	Humidity	≤ 93 % RH
Classification	Internal Powered Equipment, Type BF  , Cuff is the applied part.	
Ingress Protection Level	IP 21, Indoor Use Only	

Specifications are subject to change without notice.

This Blood Pressure Monitor complies with the European regulations and bears the CE mark"CE 0197"This blood pressure monitor also complies with mainly following standards (included but not limited):
Safety standard:
EN 60601-1 Medical electrical equipment part 1: General requirements for safety EMC standard: EN 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances – Requirements And Tests.
Performance standards:
IEC80601-2-30, Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers. EN 1060-3 Non-invasive sphygmomanometers - Supplementary requirements for electromechanical blood pressure measuring systems.
ISO 81060-2, non-invasive sphygmomanometers - part 2: clinical validation of automated measurement type.

ELECTROMAGNETIC COMPATIBILITY INFORMATION

The device satisfies the EMC requirements of the international standard IEC 60601-1-2.
The requirements are satisfied under the conditions described in the table below. The device is an electrical medical product and is subject to special precautionary measures with regard to EMC which must be published in the instructions for use. Portable and mobile HF communications equipment can affect the device. Use of the device in conjunction with non-approved accessories can affect the device negatively and alter the electromagnetic compatibility. The device should not be used directly adjacent to or between other electrical equipment.

Table 1

<table>
<tr><td colspan="3">Guidance and declaration of manufacturer-electromagnetic emissions</td></tr>
<tr><td colspan="3">The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment-guidance</td></tr>
<tr><td>Radiated emission CISPR 11</td><td>Group 1, class B.</td><td>The device uses RF energy only for its internal function. Therefore, its emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>Conducted emission CISPR 11</td><td>Group 1, class B.</td><td rowspan="3">The device 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.</td></tr>
<tr><td>Harmonic emissions IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Table 2

Guidance and declaration of manufacturer-electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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	± 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 %.
Electrostatic transient/burst IEC 61000-4-4	± 2 kV , 100kHz, for AC power port	± 2 kV , 100kHz, for AC power port	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5kV, ±1kV (differential mode)	±0.5kV, ±1kV (differential mode)	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	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital Group 1, environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m; 50Hz or 60Hz	30 A/m; 50Hz or 60Hz	Power frequency magnetic fields should be at levels characertic of a typical location in a typical commercial or hospital environment.

Table 2 (continued)

Guidance and declaration of manufacturer-electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Radiated RF EM fields IEC 61000-4-3	3V/m or 10 V/m 80MHz-2.7 Ghz 80%AM at 1kHz	3V/m or 10 V/m 80MHz-2.7 Ghz 80%AM at 1kHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. The recommended separation distance is 80 MHz to 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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
Conducted disturbances Induced by RF fields IEC 61000-4-6	3 V in 0.15 MHz- 80 MHz 6 V in ISM and/or amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1kHz	3 V in 0.15 MHz- 80 MHz 6 V in ISM and/or amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1kHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than th recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended seperation distance 80 MHz to 800 MHz 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be les than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

Table 3

Guidance and declaration of manufacturer-electromagnetic immunity

Nowadays, many RF wireless equipments have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. Arm-type Fully Automatic Digital Blood Pressure monitor has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and this medical equipment and/or systems as recommended below.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
2450	2400-2570	Bluetooth,WLAN, 802.11 b/g/n,RFID 2450,LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the device		
The device is intended for use in an electromagnetic environment in which radiated therefore disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device 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	
	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.7 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
100	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.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

ADDITIONAL NOTES

Important Instructions Before Use

1. **WARNING:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally
2. **WARNING:** PORTABLE RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of Arm- type Fully Automatic Digital Blood Pressure Monitor, including cables specified by the MANUFACTURER. 0therwise, degradation of the performance of this equipment could result.
3. The software identifier refer to the software evaluation report , and the file code is **JYRJ201231001.**
4. **Verify manometer pressure accuracy:**
   In the power-down state, press and hold the "START/STOP" button, and then install the batteries. Until the LCD screen is full, release the"START/STOP" button. When the LCD screen displays the double zero, the blood pressure meter is in a static state. At this point, 500ml gas capacity, calibrated standard pressure gauge, and manual pressure device can be connected to the sphygmomanometer through the sleeve interface of the sphygmomanometer, and manual pressure can be applied to the effective display range of the sphygmomanometer, and then the difference between the reading of the sphygmomanometer and that of the standard pressure gauge can be compared. This mode can be used to verify manometer pressure accuracy.
5. Contraindications:
   Product is not intended for infants or individuals who cannot express their intentions.
6. Intended Use:
   The digital blood pressure monitor is reusable for clinical and home use and are non-invasive blood pressure measurement system designed to measure the systolic and diastolic blood pressure and pulse rate of adolescents and adults individual by using a non-invasive technique, which is a well-known technique in the market called the "oscillometric method". The device can measure the systolic blood pressure, diastolic blood pressure, and pulse rate on the up-arm, and the device is reusable for clinical or home use.
7. The patient is the operator:
   the PATIENT is an intended OPERATOR.
   the PATIENT Do not carry out other maintenance operations except to replace the battery
8. **WARNING:** Do not modify this equipment without authorization of the manufacturer.
9. ESSENTIAL PERFORMANCE Maintenance advice:
   Pressure calibration will be carried out when this product leaves the factory. Patients can use the method described in the section "Verify Manometer Pressure Accuracy"to

verify the accuracy. If the accuracy deviation is large, please contact the manufacturer to recalibration.

10. Mechanical strength and resistance to heat. The resistance to heat will be retained by device during the EXPECTED SERVICE LIFE of the ME EQUIPMENT.
11. Do not place the blood pressure monitor and cuff at will. It will cause asphyxiation if the child swallows or twine around his neck.
12. The cuff and the case of the blood pressure monitor have been tested for biocompatibility and do not contain allergenic or harmful materials. Please stop using it if an allergy occurs during use.
13. **Warning:** Non-professionals do not modify the equipment, otherwise it will make the equipment measurement is not accurate."
14. **Warning:** Do not expose the equipment for a long time, otherwise it will reduce the performance of the equipment.
15. **Warning:** This device is not used for children and pets.
16. Clean: The equipment can be cleaned by lay operator according to the cleaning procedures in the instructions.
17. **Warning:** Do not use a damaged cuff for blood pressure measurement.
18. **Warning:** When measuring with the cuff, if the tester feels seriously uncomfortable, press the button of the blood pressure monitor to deflate the cuff, or remove the cuff directly from the arm.
19. **Warning:** If an unexpected reading occurs, the operator can take several more measurements and consult a doctor.
20. **Warning:** This equipment is used outside the specified environment, may damage the equipment, and may be inaccurate measurement.

Correct Disposal of This Product

(Waste Electrical & Electronic Equipment)

This marking shown on the product indicates that it should not be disposed with other household waste at the end of its life. To prevent potential harm to the environment or to human health, please separate this product from other types of wastes and recycle it responsibly. When disposing this type of product, contact the retailer where product was purchased or contact your local government office for details regarding how this item can be disposed in an environmentally safe recycling center.

Business users should contact their supplier and check the terms and conditions of the purchasing agreement. This product should not be mixed with other commercial wastes for disposal. This product is free of hazardous materials.

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feel better

CE 0197

REV.1/2023.02

WARRANTY CARD

Serial Nr. _____

Name of customer _____

Date of purchase _____

Contact number _____

Address _____

Sale company _____

Contact number _____

Address of sales company _____

The period of host free for warranty service is 2 years.
During the warranty period, we will decide to repair or replace damaged parts or accessories according to the case.
The warranty covers all parts of the blood pressure monitor except the cuff, adapter and batteries. The cuff, adapter and batteries are not covered by the warranty!

The following case does not include the warranty:
Damage caused by not correctly operating the product according to the manual.
Damage caused by accident.
The user disassembles and change the product without authorization.
No invoice, warranty card, the product serial being torn or can not identify.
Attention: please contact our distributor when the device needs maintenance. Please keep the packing of the product so that it could be used when returning the device to maintenance.
Product inspection and calibration are carried out by an accredited laboratory and are not a warranty service!