Automatic Upper Arm Blood Pressure Monitor
(Model: BA-831X, BA-832X, BA-833X, BA-837X, BA-838X, BA-842X, BA-843X, BA-845X, BA-847X, BA-849X, BA-851X, BA-852X, BA-855X, BA-835, BA-836, BA-839, BA-840, BA-856)

User Manual
(Version: V1.0)

This manual is only used to operate this electronic device; the company will not bear the consequences caused by this instruction manual for other purposes and responsibilities.

Considering the needs of the technical improvement or file update, the company reserves the right to revise the content in these operating instructions for correction, and if the change does not involve the sold device safety without prior notice.

Due to technical update or the special requirements of users, under the condition of the instrument performance is not affected, the standard of some parts is different with this manual, please pay attention.

If your Device is not functioning properly, discontinue using your device and contact a customer service Specialist.

Content

Requirement of Use

Content on this page is indicated that careful attention to the operation steps should be paid when using our devices to avoid abnormal operation and the risk of personal injury.

Our company states that users must read the requirement of use before usage and operate the device according to the requirements of use. The company does not bear the duty of safety, reliability and performance guarantee if users do not operate the device as required and use, maintain, store the device according to the manual.

If any problems arise that may require service, contact a customer service Specialist immediately.

1. Safety and Regulatory

1.1 Introduction

Automatic Upper Arm Blood Pressure Monitor is designed to measure the systolic, diastolic and pulse rate of an individual by using a non-invasive technique which an inflatable cuff is wrapped around upper arm. Our method to define systolic and diastolic pressures is similar to the auscultatory method but using an electronic capacitive pressure sensor rather than stethoscope and mercury manometer. The sensor converts tiny alteration in cuff pressure to electrical signals; by analyzing those signals to define the systolic, diastolic and calculating pulse rate is a well-known technique in the market so called “oscillometric method”. The device also has low voltage indication, which will be triggered when the battery is low.

The product includes Bluetooth transmission functionality which can connect to APP and transfer data for APP, and the measuring data, including systolic diastolic pressures and pulse rate can be displayed on APP. The APP can control the device measuring when connecting device.

Carefully read all instructions and warnings before operating your Automatic Upper Arm Blood Pressure Monitor.

The Automatic Upper Arm Blood Pressure Monitor may be used solely for the purpose described in this manual.

1.2 Contraindications

For the following patients, they should not use the device:

- Contra-indicated for the NIBP measurement for analysis with heart disease (severe arrhythmia).
- Contra-indicated for the NIBP measurement at injured arm.
- A tendency toward internal Bleeding.
- People who allergic to the Nylon.

1.3 Adverse Reactions

You should stop using the device and should consult with your physicians if you experience adverse reactions from the device.

- Feel dizzy and vomit.
- Allergic reaction (like skin irritation or redness).

1.4 Warnings

1) Hypertension can’t be judged by the measured value through this product. The value is used for monitoring blood pressure.

2) Self-diagnosis of measurement results and self-treatment are dangerous. Contact your physician about the measured value.
3) Do not use the device on the injured arm or the arm under medical treatment.
4) Operate the device only as intended. Do not use the device for any other purpose.
5) Do not disassemble or attempt to repair the unit or components.
6) If battery fluid should get in your eyes, immediately rinse with plenty of clean water. Contact a physician immediately.
7) No modification of this equipment is allowed.
8) DO NOT wrap the arm cuff around an elbow in which a drip (intravenous infusion) is inserted or which is being used for blood transfusion as part of medical treatment. Doing so could result in an injury or a serious accident.
9) DO NOT use the device in the vicinity of flammable gases such as those used for anaesthesia. Doing so could ignite the gases and cause an explosion.
10) DO NOT use the device in enriched oxygen environments such as a hospital's hyperbaric chamber or oxygen tent. Doing so could ignite the oxygen and cause a fire.

1.5 Precautions

1) Do not subject the monitor and package to shocks, such as dropping it onto the floor.
2) This device is intended for use in measuring blood pressure and pulse rate in the adult population. Do not use this device on infants or persons who cannot express their intentions.
3) People with severe blood flow problems, or blood disorders, should consult a physician before using the device, as the arm cuff inflation can cause bruising.
4) Do not use this product on patients with severe arrhythmia, infants and people who can't express their intentions.
5) Dispose of the device, components and optional accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution.
6) 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 m away from the equipment.
7) Do not use the monitor if you find it is damaged or notice anything unusual.
8) If the cuff pressure feels abnormal or you experience any other irregularity while using the cuff, reduce the pressure immediately by pressing the "START/STOP" or "POWER" switch and then consult the sales outlet where you purchased the device.
9) Frequently repeated blood pressure measurements will not give accurate results. Allow an interval of about 3 minutes between measurements.
10) Measurement may not be possible for anyone with insufficient blood flow to the area where measurements will be taken or who suffers from a frequent irregular heartbeat. Consult your physician for advice on whether to use the device.
11) DO NOT wrap the cuff around an elbow.
12) If you use a cardiac pacemaker, consult your physician before using the device.
13) Blood pressure measurement may not be possible for anyone with common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation.
14) Be careful to strangulation due to cables and hoses, particularly due to excessive length keep unit out of the reach of young children/pets. The cord can cause strangulation.

15) Keep the device out of the reach of children/pets to avoid inhalation or swallowing of small parts.
16) Before every use, check the device. Do not use the device if it is damaged/degraded/loosened in any way. The continuous use of a damaged unit may cause injury, improper results, or serious danger.
17) No modification of this equipment is allowed. The private modification may cause device damage or result in injury.
18) When not in use, store the device in a dry room and protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on the storage case.
19) The main material of the case is ABS plastic and the main material of the cuff is Nylon. Be careful to the potential allergic reactions to these materials.
20) If you have any problems with this device, such as setting up, maintaining or using, please contact with service personnel of DONGGUAN E-TEST TECHNOLOGY CO., LTD. Don’t open or repair the device by yourself.
21) Please report to DONGGUAN E-TEST TECHNOLOGY CO., LTD. If any unexpected operation or events occur.
22) The patient is an intended operator.
23) Be careful regarding the effect of blood flow interference and resulting in harmful injury to the patient caused by continuous cuff pressure due to connection tubing kinking, please avoid connection tubing kinking.
24) Don't repeat blood pressure measurements frequently, too frequent measurements can cause injury to the patient due to blood flow interference.
25) Don't use the cuff over a wound, as this can cause further injury.
26) Don't use the cuff and its pressurization on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt is present because of temporary interference with blood flow and could result in injury to the patient.
27) Don't use the cuff and its pressurization on the arm on the side of a mastectomy or lymph node clearance which may result in injury to the patient.
28) Don't use the device when used monitoring EQUIPMENT, pressurization of the CUFF can temporarily cause loss of function of simultaneously used monitoring EQUIPMENT on the same limb which may result in injury to the patient.
29) Please check (for example, by observation of the limb concerned) that operation of the device does not result in prolonged impairment of the circulation of the blood of the patient.
30) Please use the device at the conditions suggested by the manufacturer, the performance of the AUTOMATED SPHYGMOMANOMETER can be affected by extremes of temperature, humidity, and altitude.
31) Please use accessories that are specified/authorized by manufacturer only. The use of unauthorized accessories may cause damage to the unit or danger to the operator/patient.

2. Device Description

2.1 General description

Automatic Upper Arm Blood Pressure Monitor is designed to measure the systolic, diastolic and pulse rate of an individual by using a non-invasive technique which an inflatable cuff is

wrapped around upper arm. Our method to define systolic and diastolic pressures is similar to the auscultatory method but using an electronic capacitive pressure sensor rather than stethoscope and mercury manometer. The sensor converts tiny alteration in cuff pressure to electrical signals; by analyzing those signals to define the systolic, diastolic and calculating pulse rate is a well-known technique in the market so called “oscillometric method”. The device also has low voltage indication, which will be triggered when the battery is low.
The product includes Bluetooth transmission functionality which can connect to APP and transfer data for APP, and the measuring data, including systolic diastolic pressures and pulse rate can be displayed on APP. The APP can control the device measuring when connecting device. All models are the same except the model name and color.

2.2 Intended for use/Indication for use

Automatic Upper Arm Blood Pressure Monitor is intended for use by medical professionals or at home to monitor and display diastolic, systolic blood pressure and pulse rate on adult each time, with the cuff around the left upper arm according to the instruction in the user's guide manual.

2.3 Essential Performance

The essential performance description of subject device:

– The measuring scope is equal to the RATED range for CUFF pressure which ranged 0 mmHg ~ 294 mmHg, with an accuracy of within ± 3 mmHg (± 0.4kPa).

- The device has a battery indicator on LCD screen, it can display the state of the power supply.

If the expected essential performance is lost or degraded due to EM disturbances, the operator should stop using the device immediately to avoid injury caused.

2.4 Cybersecurity

2.4.1 Description

- Network interface: BLE Bluetooth 5.1
- Intended use: Control measure and read measurement result
- Data type: Non-sensitive medical data (test results)
- Technical feature: Bidirectional data transmission based on BLE Bluetooth private profile, data transmission protocol is private protocol.

2.4.2 Ability

- Connectivity (CONN) : Device communication is based on BLE technology
- Physical protection (PLOK) : The device only reads data, but does not write data
- Data integrity and authenticity (IGAU) : The device only provides the ability to read data, but does not provide the ability to write data
- Data transmission confidentiality (TXCF) : adopts a private protocol, without related protocol documents, and cannot be analyzed.

2.5 Specification

Basic Specification	
Product name	Automatic Upper Arm Blood Pressure Monitor
Models	BA-831X, BA-832X, BA-833X, BA-837X, BA-838X, BA-842X, BA-843X, BA-845X, BA-847X, BA-849X, BA-851X, BA-852X, BA-855X, BA-835, BA-836, BA-839, BA-840, BA-856
Power Source(s)	6.0 VDC (1.5V alkaline battery x 4)
Measurement Principle	Oscillometry
Patient Population	Adult
Measurement Site of Body	Upper arm
Measuring Range	Pressure: 0~294mmHg Pulse: 40~199 beats/minute
Resolution	1 mmHg
Inflation and Deflation	Automatic
Memory Size	2 x 90 sets record
Method of Line Current Isolation	Type BF Applied Part
Accuracy	Pressure: ±3 mmHg Pulse: ±5%
Parameter of Bluetooth technology	
Wireless Protocol	Bluetooth Specification BLE Bluetooth 5.1
Transfer Power	0.001~0.5W
Frequency	2.4GHz~2.48GHz
Modulation	GFSK
Communication Distance Range	≤50m
Transmission of Alarm Signals	Yes
Can operate on the same network with other wireless products?	No
Security measures	Data Encryption, Channel Encryption
Quality of Service (QoS):	Data integrity: BER <0.3%, data with calibration
	Throughput: 100KBPS
	Accessibility: No
	Signal priorities: Pmin<30dbm
	App is designed to simplify operation and free hands. Do not do any background storage records, do not violate user privacy. The product can be opened and

	used only when the device is connected. When the product is started, the App can be opened to connect the device actively. The App can also be automatically disconnected when the device is shut down, and manually connected when the device is turned on again.
Intended wireless environment	Inhouse use
Additional Specification	
Operating Environment	Temperature: 5°C ~ 40°C Humidity: 10~90%RH Atmospheric Pressure:86 kPa~106 kPa
Storage Environment	Temperature: -20°C ~ +65°C Humidity: 10~95%RH Atmospheric Pressure:86 kPa~106 kPa
Electric Shock Protection	Internally powered equipment
Display	Blood Pressure (Systolic and Diastolic), Pulse, Date, Time, WHO BP Classification Indicating Bar, Low Battery Icon, Heart Icon, Memory Record Number
Inflation	Automatic
Deflation	Automatic
Software version	V250
Service Life	5 years

2.6 Device Components and Accessories

2.6.1 Main Unit

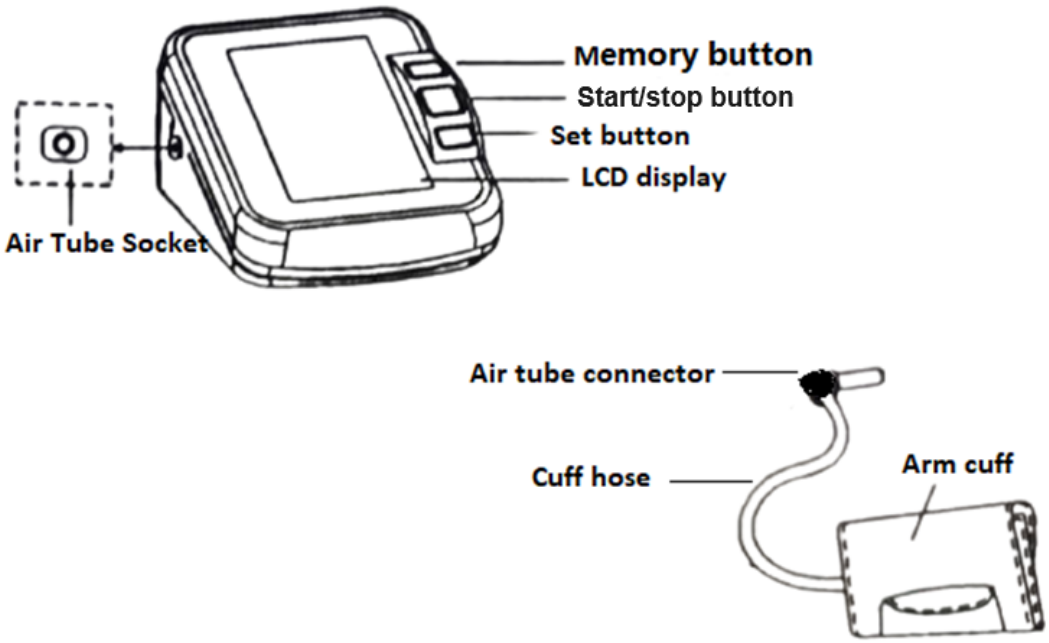

Figure 2.6.1-1 Appearance

2.6.2 LCD Display

The LCD screen is used to display measurement results and other related information, including: Time, Date, Systolic Blood Pressure, Diastolic Blood Pressure, Pulse, Memory Record Number, Heart Icon (Twinkle when measuring), low battery Icon, Blood Pressure Unit, Inflation/Deflation Indicator, and WHO BP Classification Indicating Bar.

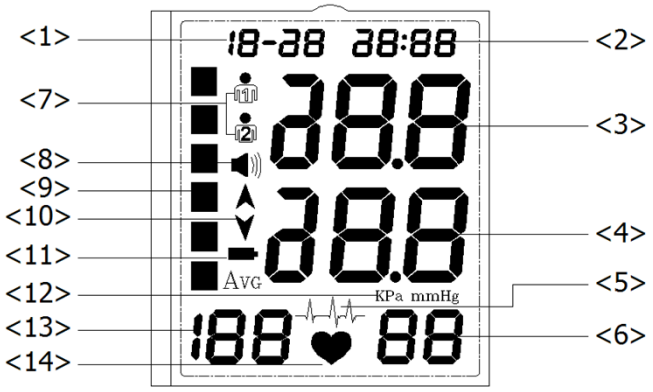

Figure 2.6.2-1 Display of LCD

Explanation for LCD display:

1) Date: Month - Day
2) Time: Hour - Minute
3) Systolic Blood Pressure (unit: mmHg)
4) Diastolic Blood Pressure (unit: mmHg)
5) Arrhythmia Detection Function
6) Memory Record Number

7) User indicator
8) Voice Function
9) WHO BP Classification Indicating Bar
10) Inflation/Deflation Indicator
11) Low Battery Icon
12) Blood Pressure Unit
13) Pulse (unit: beat/minute)
14) Heart Icon (Twinkle when measuring)

2.6.3 Accessories List

Before use, please check the components and accessories according to the following list, if anything is not in the package, please contact with manufacturer.

Accessories	Quantity
Main unit	1
Cuff	optional
Battery	4 x 1.5V AA batteries
User Manual	1

Note:

1) *Please replace the battery with the type specified by the manufacturer, or it could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.*

2) There are six sizes, you can select suitable size according to your arm circumference.

size A: 17-22cm (SMALL ADULT CUFF)

size B: 22-30cm (ADULT CUFF-1)

size C: 24-34cm (ADULT CUFF-2)

size D: 22-42cm (L-LARGE ADULT CUFF)

size E: 30-42cm (LARGE ADULT CUFF)

size F: 42-50cm (EXTRA LARGE ADULT CUFF)

3. Using Instructions

3.1 Preparation for use

3.1.1 Open packaging

The main unit and necessary accessories are in the box, please check according to the package list when you receive the product, and if there is any shortage, please call the customer service hotline for consultation.

3.1.2 Check before use

1) Check the function of each component and whether it maintains good performance. All functions of the device can be safely used by the operator.

2) Check the appearance of the main unit and cuff, whether the battery is leaking, and whether the device can be turned on normally.

3) Should conduct periodic safety tests to ensure leakage current insulation.

3.1.3 Battery Loading

1) Open battery cover at the back of the machine. See Figure 3.1.3-1 and Figure 3.1.3-2.

2) Load 4 alkaline “AA” size batteries. Please pay attention to the polarity.

3) Close the battery cover.

Note：

1) *When LCD shows “Low Battery” icon it means you must change the batteries at once. See Figure 3.1.3-3 Rechargeable battery with a voltage of 1.2V is not suitable for this product.*

2) *Take out all the batteries if the device will be not used for a long time to avoid battery leakage and relevant damage.*

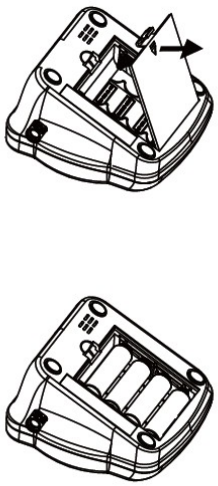

Figure 3.1.3-1

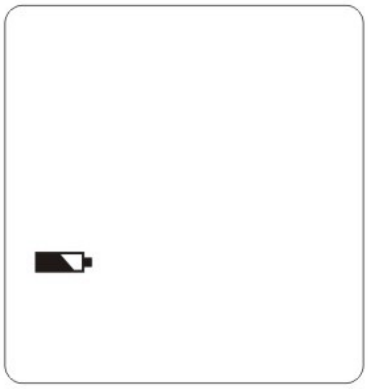

Figure 3.1.3-3

3.1.4 Install or remove the device with cuff

1) Take out the air tube from the cuff and insert the air tube connector into the air tube socket of main unit.

2) Pull out the air connector from the main unit, bend the air tube slightly and put it in the cuff.

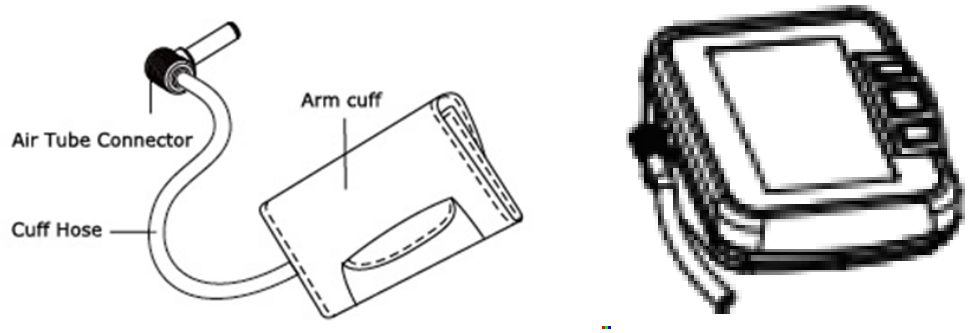

Figure 3.1.4-1

3.2 Operation

3.2.1 Set user

1) In sleep mode, press the “SET” button until only the user symbol 

or  appears on the LCD display.

2) Press “SET” button again to choose  or 
3) Press “START/STOP” button to confirm and the device will turn off simultaneously

3.2.2 Clock Adjusting

Long press the “SET” button and the individual figure will start blinking sequentially from month, date, hour to minute.

Press the “MEMORY” button to adjust, and press “SET” button to confirm then to go on the next setting.

Note:

- *Press “MEMORY” button once will cause the display to advance by one digit.*
- *After you change the batteries, you must readjust the date and time.*

3.2.3 Unit Change

1) For the unit change, you can select the mmHg or kPa; and the mmHg is definition unit.
2) When the device is turned off, press the button “START/STOP” for 10 seconds, then press “MEMORY”button to select mmHg or kPa.

3.2.4 Arm Cuff Connecting

Insert the end of the cuff through the D-Ring to make a loop. (Make sure that the Velcro stays outside when it is done.)

Ware the arm cuff with the hose downward. Pull the end of the cuff and secure it snugly with the Velcro.

Be sure to place the arm cuff on bare skin or thin-skinned cloth on arm, and place the cuff on the center of elbow then warp the arm cuff to keep a distance of 1 - 2 cm with the elbow. See Figure 3.2.4-1.

Note：

1) *Plug in the air tube connector to the monitor.*
2) *Before starting measurement, please sit comfortably with legs uncrossed, feet flat on the floor, back and arm supported.*
3) *Arm cuff connecting should make arm feel no much tension. Don't connect too tense (otherwise the measurement will be not precise).*
4) *Keep up the cuff to the right position that comes to the same height of heart.*
5) *When the cuff is dirty, detach it from the equipment, wash the cuff by hand with proper detergent and rinse it in the enough cold water, dry in air. Never iron it.*
6) *The patient relaxes as much as possible and not talk during the measurement procedure a recommendation that 5 min should elapse before the first reading is taken.*

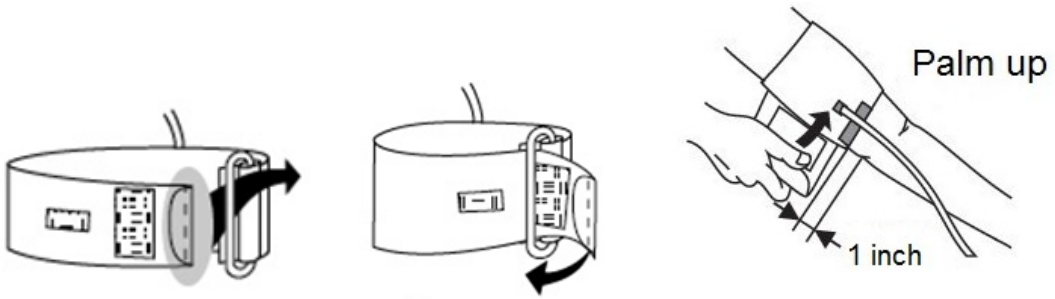

Figure 3.2.4-1

3.3 Measuring Process

3.3.1 Adjust your sitting posture

The following operating steps are needed to obtain accurate routine resting blood pressure values for the condition hypertension, including:

1) The patient position should be in normal use, including:
   a) comfortably seated,
   b) legs uncrossed,
   c) feet flat on the floor,
   d) back and arm supported, and
   e) middle of the cuff at the level of the right atrium of the heart;
2) The patient should be relaxed as much as possible and not talk during the measurement procedure;

Notes:

- *5 min should elapse before the first reading is taken.*
- *Measurements should be taken in a quiet place and you should be in a relaxed, seated position. Make sure that the room is not too hot or too cold.*
- *Avoid eating, drinking alcohol, smoking, or exercising for at least 30 minutes before taking a measurement.*
- *Do not move or talk during measurement.*

- *The following factors have an effect on the measurement, such as room temperature, environment, noise, speaking, cuff strapping, improper placement of sensors, body movement, and the place with electric fields.*
- *If there is clothing on your arm, please remove it.*
- *You can take a measurement on either your left or right arm. The blood pressure can differ between the right arm and left arm and therefore also the measured blood pressure values can be different. E-TEST recommends to always use the same arm for measurement. If the values between the two arms differ substantially, please check with your physician which arm to use for your measurement.*
- *It is not recommended for patients with weak pulse rate, upper gastrointestinal bleeding, extremely critical patients, severe arteriosclerosis, poor peripheral circulation especially those with severe diabetes resulting in peripheral vascular disease.*

3.3.2 Taking measurement

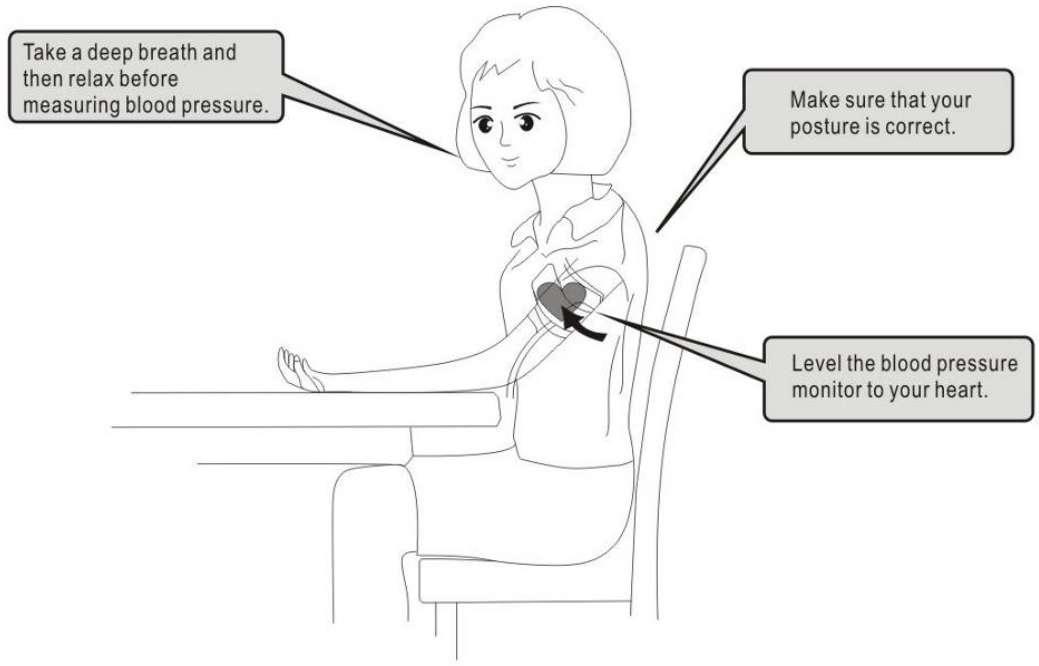

Figure 3.3.2-1 Measurement sitting posture

(1) After your body is in a comfortable position, press the “Start / Stop” button. The device will verify itself, and LCD will twinkle automatically.

After about two seconds, LCD shows one “00”. ***See Figure 3.3.2-3***

Then the machine begins to pressurize automatically.

(2) After measurement, the result of systolic, diastolic, pulse rate and level of WHO BP classification will be all displayed on LCD. The result will be automatically memorized by itself. ***See Figure 3.3.2-4***

(3) Press “Start/stop” button after measuring, the device will be turned off. The device will be automatically power off after 1 minute of none use.

Figure 3.3.2.-3

Figure 3.3.2-4

3.4 Memory function

The unit is designed to automatically stores up to 90 sets of measurement values (blood pressure and pulse rate) for each user (user 1 and user 2). When 90 sets of measurement values are stored, the oldest record is deleted to save the most recent values.

3.4.1 Reading memory results

1) Under the “Stop” condition, press button “MEMORY” and LCD displays the average of the last three measurements and “AVG” in the lower left corner.
2) Press the “MEMORY”button, LCD will show how many results it has, and then the latest result will be displayed, which is 01 for memory number. See **Figure 3.4.1-1.** Continuously press the “MEMORY” button; the memory number will increase by one.
3) Under the memory-displaying mode, it will be automatically power off after ten seconds of none use. Or you can press “Start/stop” button to shut down the device.
4) The voice function will speak out the displayed blood pressure and heart rate after each measurement finish when reading memory result.
5) If there is no memory, then LCD will show “00” for systolic, diastolic, and pulse rate, and show “00” for the number of memory. While press the “MEMORY” or “START/STOP”, the device will power off.

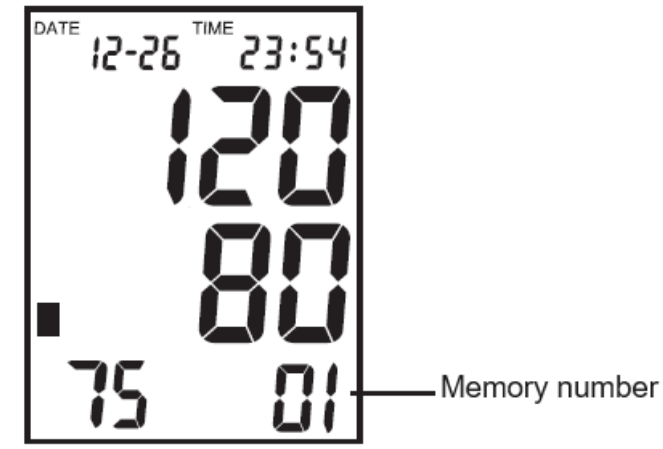

Figure 3.4.1-1

3.4.2 Delete for all memories

Under the mode of reading memories, holding on pressing “MEMORY” button for three seconds, all memories will be deleted.

If delete another user’s memories, change user under the “Stop” condition, then holding on pressing “MEMORY” button for three seconds.

3.5 Shut down

After measurement, press button “Start/stop” to turn off the device. The device will be automatically power off after 1 minute of none use.

3.6 Assessing High Blood Pressure for Adults

The follow standards for assessing high blood pressure (without regard to age or gender) have been established as a guideline according to WHO (World Health Organization) standard. See Figure 3.6.1. Please note that other risk factors (e.g. diabetes, obesity, smoking, etc.) need to be taken into consideration and may affect these figures. Consult with your physician for accurate assessment.

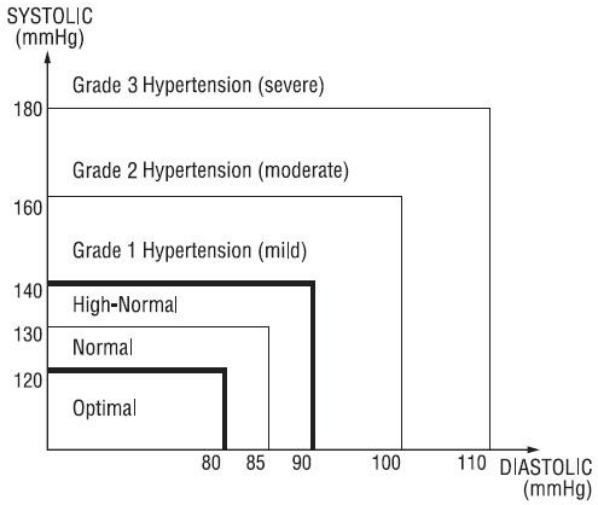

Figure 3.6.1-1

From the above figure, we can see the classification of blood pressure for adults is as below. The WHO BP Classification Indicating Bar would show out the blood pressure level by the length.

Blood Pressure Classification	**SBP (mmHg)**	**DBP (mmHg)**	**Length of WHO BP Classification Bar**
Optimal	<120	<80	1 grid
Normal	120-129	80-84	2 grids
High-Normal	130-139	85-89	3 grids
Stage 1 Hypertension	140-159	90-99	4 grids
Stage 2 Hypertension	160-179	100-109	5 grids
Stage 3 Hypertension	≧180	≧110	6 grids

Note:

1. The graph is not exact but may be used as a guide in understanding non-invasive blood pressure measurements. The device is intended for adult use only.
2. When measurement, please avoid compression or restriction of the connection tubing.
3. The device cannot be used with HF surgical equipment at the same time.
4. Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method, within the limits prescribed by the American National Standard, Manual, electronic, or automated sphygmomanometers.

3.7 Bluetooth function

If you purchase Bluetooth blood pressure monitor, please ask your distributor for instructions on how to use the APP or refer to the operations as below. You should ask for your distributor

for software package. After downloading and installing the Bluetooth APP, you can operate the device through the APP. After each measurement, the measurement results will be sent to the APP via Bluetooth connection.

The operations as follow:

(1) Open Bluetooth on mobile phone;
(2) Open “E-TEST” software;
(3) Press “START/STOP” button to turn on the device;
(4) Click “Scanning” to search device;
(5) Click the IP of searched device;
(6) APP interface displays “Connect success”;
(7) Put the cuff/arm at correct position; (refer to section 3.2.4 and 3.2.5)
(8) Click “START” to start measurement;
(9) After measurement, the results will be shown on APP;
(10) During measurement, you can click “STOP” to stop measurement;
(11) If you want to connect another device, click "Disconnect" to disconnect the original device or power off the original device and reconnect the other device.

Note:

(1) A device can only connect to one phone, and a phone can only connect to one device. When the device is connected, other phones will not be able to scan it.
(2) Before start measurement, you shall put the cuff/arm in the correct position and make sure your sit posture is correct.
(3) The software requires Android 5.1 above to install

4. Cleaning and Maintenance

4.1 Cleaning

(1) While cleaning, switch off the device and disconnect it from the power supply.
(2) Clean the monitor with soft and dry cloth.
(3) Carefully remove spots on the cuff with damp cloth and soapsuds.
(4) Don’t use detergent powder and other detergents.
(5) Don’t use gasoline, thinners or similar solvents.
(6) NEVER clean the blood pressure meter with thinners or benzene.
(7) Visually check whether the equipment is clean. If not, clean it again.

Note:

(1) DO NOT bend the cuff or air hose excessively.
(2) DO NOT hard rub when clean the cuff. Take care not to get water into the air hose.

4.2 Maintenance

(1) DO NOT subject the unit to extreme temperatures, humidity, moisture or direct sunlight.
(2) Do not carry out repairs of any kind yourself. If a defect occurs, consult the distributor or customer services as mentioned on the package.
(3) DO NOT drop the blood pressure monitor or subject it to other shocks or vibration.
(4) Remove the batteries if the device will be left unused for a long period (More than 3 months).
(5) DO NOT attempt to disassemble the device.
(6) It is recommended that the performance should be checked every 2 years and after maintenance and repair, by retesting at least the requirements in limits of the error of the cuff pressure indication and Air leakage (testing at least at 50 mmHg and 200 mmHg).
(7) Replace only with the same or equivalent type recommended by the manufacturer. 4 x AA (1.5V) alkaline batteries are recommended.
(8) Do not splash water on the unit or allow liquids to get inside the unit.
(9) Do not remove the cuff lining in the arm cuff.
(10) Do not wash or moisten the cuff lining.

5. Storage

1) DO NOT store the blood pressure monitor in locations exposed to direct sunlight, high temperatures (over 65°C), low temperatures (below -20°C), high relative humidity (over 95%), low relative humidity (below 15%) or excessive amounts of dust.
2) DO NOT drop the blood pressure monitor or subject it to other shocks or vibrations.
3) Remove the batteries if the device will be left unused for a long period (More than 3 months).
4) DO NOT attempt to disassemble the device.
5) DO NOT bend the cuff or air hose excessively.
6) NEVER clean the blood pressure meter with thinners or benzene, as they may damage it.
7) DO NOT hard rub when cleaning the cuff. Take care not to get water into the air hose.
8) Removing the batteries will erase all readings in memory.
9) Use only a soft dry cloth to clean the unit. Do not use solvents or other petroleum-based cleaners.

6. Troubleshooting and Error indicators

6.1 Troubleshooting

Abnormality	Reason	Checkout
No display	Batteries are not in proper direction	Make sure that the batteries are installed in the proper direction. (Polarity matches to the indication in

		the battery case.)
Abnormal results	Cuff is not tightened properly or its position is incorrect.	Check that the cuff is positioned properly, over the measurement procedure again.
	The arm is moved during measuring.	Stay calm, arm remains steady. Do not move during measuring.
	Irregular heartbeat	You can test again for light irregular heartbeat patients. It is inappropriate for serious irregular heartbeat patients to use this device.
Blood pressure readings are too high or too low	Wrong position	Check if the arm is positioned properly Position your arm on a table, so the cuff is at the same level as your heart.
	Wrong position	Remain seated during the entire measurement period.
	Some interference in inflation or wrong operation during measuring	Refrain from hand and body movements during measurement
During the measurement, the unit stops output before the end time	The power is too low.	Change the batteries.
Disconnect	The Bluetooth of the phone is not turned on or the device is not turned on	Check that both are turned on.
	The device has been connected.	Check that the device has been connected. Or you can turn off the device and then reconnect.

6.2 Error indicators

Error indicators	**Possible sources of errors**
Er U	Indication: Incomplete inflation Correction: Check the cuff has been connected with device firmly, if same Er message indicated, request a repair
Er H	Indication: cuff over inflated and release automatically Correction: Take a break, and reposition the cuff and measure again

Er I	Indication: Could not obtain the pulse rate Correction: Reposition the cuff and measure again
Er 2	Indication: Strong Electromagnetic interference (Mobile phone and computer) Correction: Relax and take a break, and then measure again.
Er 3	Indication: irregular pulse rate or blood pressure Correction: Relax and take a break, and then measure again.

Note: If you cannot resolve the problem, you can contact factory or service agent.

7. Disposal

1) The device and accessories out of shelf life or use life should not be thrown randomly, these should be recycled by the manufacturer or you should contact its local authorities to determine the proper method of disposal of potentially bio-hazardous parts and accessories.
2) To dispose of packing materials, take appropriate actions in accordance with the rules and regulations in force in your area to prevent adverse ecological effects.
3) The expected service life for the device is 5 years.
4)  **DO NOT** dispose the batteries in domestic waste. Dispose of the batteries according to the local regulations dealing with the disposal of these special materials (e. g. to the collecting points).

8. Label & Symbols

Symbol	Explanation
CE 0123	It indicates that the product has passed the approval of the announcement agency No. 0123 (TÜV SÜD), and the product has been assessed by the manufacturer and deemed to meet EU safety, health and environmental protection requirements. It is required for products manufactured anywhere in the world that are then marketed in the EU.
	Indicates the medical device manufacturer.
EC REP	Indicates the authorized representative in the European Community/European Union.

	Indicates the date when the medical device was manufactured.
	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	TYPE BF APPLIED PART
	The symbol indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life.
	Medical Device
	Refer to instruction manual/booklet
IP20	It means the device could be protected against solid foreign objects of 12.5mm and greater, and there is no special protection for water or moisture.
	MR Unsafe: cannot be taken into the controlled access area of an MRI system. Devices not specifically designed to operate in magnetic resonance (MR) environment may cause injury to the patient.
	Indicates a medical device that can be broken or if not handled carefully
	Indicates a medical device that needs to be protected from moisture

9. ELECTROMAGNETIC COMPATIBILITY (EMC)

Before installing or using the device or system, keep an appropriate distance from radio frequency (RF) sources whenever possible. The sources include but not limit to:

- Radio and TV stations

- Portable and mobile RF communication devices (cell phones, two-way radios, base station, etc.)
- High-frequency surgical units, such as diathermy, electrocautery, argon beam coagulators, etc.
- X-ray, CT, or MRI devices

These devices are also possible sources of interference as they may emit higher levels of electromagnetic radiation.

WARNING:
EQUIPMENT MALFUNCTION OR INTERFERENCE
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.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Automatic Upper Arm Blood Pressure Monitor device or system, including cables specified by the manufacturer. Degradation of the performance of this equipment could result.

Use of accessories, transducers and cables other than those specified or provided by the DONGGUAN E-TEST TECHNOLOGY CO., LTD of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Magnetic and electric fields may interfere with the performance of the device or system. Make sure that all peripheral components operated in the vicinity of the device comply with the relevant EMC requirements. X-ray equipment, MRI devices, radio systems and so forth, are possible sources of interference because they may emit higher levels of electromagnetic radiation. Verify the performance of the system before use.

ESSENTIAL PERFORMANCE
The essential performance of the system may be lost or degraded because of electromagnetic disturbances. For expected degradations and instructions of the basic safety and essential performance maintenance in the case of electromagnetic disturbances, see the table below:

Essential Performance	**Degradation Caused by Electromagnetic**	**Essential Performance**

	Disturbances	**Maintenance**
The measuring scope is equal to the RATED range for CUFF pressure which ranged 0 mmHg ~ 294 mmHg, with an accuracy of within ± 3 mmHg (± 0.4kPa). - The device has a battery indicator on LCD screen, it can display the state of the power supply.	No degradation	Not Applicable

This device complies with Medical EMC Standard IEC 60601-1-2:2014/2020.

Guidance and manufacturer's declaration – electromagnetic emissions	
This equipment is intended for use in the electromagnetic environments specified below, and the purchasers or users shall ensure that it is used in these electromagnetic environments.	
Emissions	**Compliance**
RF emissions (Radiated) CISPR 11	Group 1 Class B
RF emissions (Conducted) CISPR 11	Not applicable
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable

Guidance and manufacturer's declaration – 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**	**Compliance**	**Environments**

	test level	**level**	
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	Professional healthcare facility and HOME HEALTHCARE environment
Electrical fast transient/burst (EFT) IEC 61000-4-4	±2 kV for power supply lines ±1 kV for signal lines	Not applicable	Not applicable
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	Not applicable	Not applicable
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 at 0° 70% UT, 25 / 30 cycle at 0° 70% UT, 25 / 30 cycle at 0° 0% UT, 250 / 300 cycle	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30A/m	Professional healthcare facility and HOME HEALTHCARE environment
Conducted RF IEC 61000-4-6	3 Vrms 0.15 MHz to 80MHz 6 Vrms in ISM bands between 0.15 MHz and 80MHz 6 Vrms in amateur radio bands between 0.15 MHz and 80MHz	Not applicable	Not applicable

Radiated RF IEC 61000-4-3	10 Vrms 80 MHz to 2.7GHz 80% AM at 1KHz	10 Vrms 80 MHz to 2.7GHz 80% AM at 1KHz	HOME HEALTHCARE environment
Proximity magnetic fields IEC 61000-4-39	30 kHz[7] / CW / 8A/m 134.2 kHz / Pulse modulation[8] 2.1KHz / 65A/m[9] 13.56MHz / Pulse modulation[8] 50 kHz / 7.5A/m[9]	Not available	Not available

NOTE

1. UT is the a.c. mains voltage prior to application of the test level ; 25 / 30 and 250 / 300 cycle means 25 / 250 for 50 Hz system and 30 / 300 for 60Hz system.
2. The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 4s0,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.
3. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot, theoretically, be predicted with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, consider conducting an electromagnetic site survey. If the measured field strength in the location the system is used exceeds the applicable RF compliance level listed in this table, observe the system to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system.
4. At 80 MHz and 800 MHz, the higher frequency range applies.
5. These guidelines may not apply in all situations. Electromagnetic propagation is affected by the reflection from structures, objects, and people.
6. 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.

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications

equipment

Test frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse modulation b) 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13,17	Pulse modulation b) 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18Hz	2	0.3	28
870						
930						
1 720	1 700-1 900	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217Hz	2	0.3	28
1 845						
1 970						
2 450	2 400-2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217Hz	2	0.3	28
5 240	5 100-5	WLAN 802.11a/n	Pulse	0.2	0.3	9

5 500 5 785	800		modulation [b] 217Hz			
NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.						
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50% pulse duty cycle square wave signal. c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.						

This device complies with part 15 of the FCC Rules. Operation is subject to the two conditions below:
(1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the measures below:
• Reorient or relocate the receiving antenna.
• Increase the separation between the equipment and receiver.
• Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
• Consult the dealer or an experienced radio/TV technician for help.

WARNING: Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment.

"Harmful interference" is defined in 47 CFR §2.1 by the FCC as follows: Interference which endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

RF Exposure:

This device has been evaluated and shown compliant with the FCC portable RF Exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter used in other systems.

10. Warranty Card

We hereby guarantee this product for a period of 180 days against defects and failure to perform as intended. This warranty is valid only if the product is used according to instruction provided in a non-commercial setting. We will repair the product as needed and if the product is not repairable, we will replace it at no charge within the warranty period.

For exchange or repair, please return the defective product along with a copy of receipt as proof of purchase to us or to the local dealer where product was purchased. Pack the product carefully to prevent damage in transit. Because of possible loss of product in transit, we recommend that you ensure the product and use a courier service with tracking number and return receipt.

Warranty List

Product Name:	Model:
Purchase date:	User's address:
Name:	Telephone:
Dealer:	Address:
Telephone:	
Description of the specific problem:	

11. Manufacturer Information

DONGGUAN E-TEST TECHNOLOGY CO., LTD.
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