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CE 0123

Blood Pressure Monitor

Model Number: B11T

USER'S MANUAL

CONTENTS

1 Introduction and Intended Use

The device is a fully automatic digital blood pressure measuring device using oscillometric technique to measure systolic and diastolic blood pressure as well as the pulse for adults that ages are more than 12 years old by wrapping around the upper arm with cuff circumference ranging from 22cm to 42cm. The device can be used in medical facilities or at home, and only for indoor use.

Contraindication: The device is not used for patients under dialysis therapy or on anticoagulant, antiplatelets, or steroids.

The device is provide accurate blood pressure measurement values that are effective and suitable for clinical and home use.

Before using, please read this instruction manual carefully and then keep it in a safe place.

1.1 Remember...

• Only a health-care professional is qualified to interpret blood pressure measurements.
• This device is NOT intended to replace regular medical checkups.
• The device is not intended for use pregnant patient.The effectiveness has not been established in pregnant (including pre-eclamptic) patients.
•In cases of irregular heartbeat, measurements made with this instrument should only be evaluated after consultation with a physician.
• The products, including accessories, shall be processed in accordance with local regulations after reaching the life cycle.
• Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

1.2 Warnings and Precautions

Warning: Do not use the AC adapter if the unit or the power cord is damaged. Turn off the power and unplug the power cord immediately.
Warning: The device is not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.
Warning: If the patient is an intended operator, the functions of monitoring blood pressure and pulse rate can be safely used by patient. The routine clean and changing batteries can be performed by the patient.
Warning: The device provides a DC input port connected to external ac adapter. It is recommended that use the adapter specified by the manufacturer. The adapter should meet the following conditions: class II equipment, output voltage: DC 5V, current: ≥1A, and comply with IEC 60950, IEC 60601-1 or IEC 62368-1, provide at least two MOOP insulation between ac input and dc output. External adapter connected to medical electrical equipment through the DC input port must comply with the respective IEC or

ISO standards (e.g. IEC 60950 or IEC 62368-1 for data processing equipment). Further more all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3Ed. of IEC 60601-1, 60601-1-2, respectively). Anybody connecting external adapter to medical electrical equipment configurations a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.
Warning: Too frequent measurements can cause injury to the PATIENT due to blood flow interference.
Warning: Don't place the cuff over wound part.
Warning: Pressurization of the CUFF can temporarily cause loss of function of simultaneously used monitoring ME EQUIPMENT on the same limb.
Warning: Regularly checking the operation of the blood pressure monitor to ensure that it does not cause long-term damage to the patient's blood circulation.
Warning: Apply CUFF and its pressurization on the side of the patient's mastectomy or lymph node removal can cause injury.
Warning: To avoid any possibility of accidental strangulation, keep this device away from children and do not drape tubing around your neck.
Caution: The user must check that the equipment functions safely and see that it is in proper working condition before being used.
Caution: To avoid damaging the device, keep this unit away from children and pets.
Caution: The standard material used for the bladder and tubing is latex-free.
Caution: The device is intended to monitor, not to diagnose. Unusual values have to be always discussed with a physician. Under any circumstance, you should not alter the dosages of any drugs prescribed by a physician.
Caution: The device cannot be used to substitute the professional ECG monitor device for monitoring the frequency of heart beat.
Caution: This device can not be used together with HF surgical equipment.
Note: To obtain the greatest accuracy from your blood pressure monitor, it is recommended that the instrument be used within the specified temperature and the relative humidity, please see the Technical Specifications.
Note:The device can not be used in MRI environment.
Note: The cuff is defined as the applied part. The user should contact the manufacturer for assistance, if needed, replace, or maintaining the device.
Note: This device contains sensitive electronic components. Avoid strong electrical or electromagnetic fields in the direct vicinity of the device (e.g. mobile telephones, microwave ovens) during use. These can lead to erratic results.
Note: Do not attempt to service or repair this device yourself. Should a malfunction occur, refer to local distributor or the manufacturer.

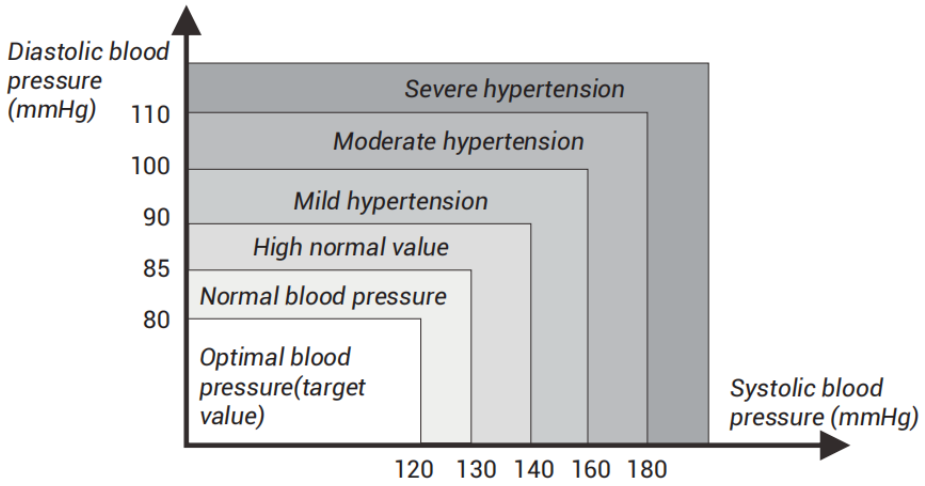
2 Important Information on Blood Pressure and its Measurement

2.1 How does high or low blood pressure arise?

Your level of blood pressure is determined in the circulatory center of the brain and adjusts to a variety of situations through feedback from the nervous system. To adjust blood pressure, the strength and speed of the heart (Pulse), as well as the width of circulatory blood vessels is altered.Blood vessel width is controlled by fine muscles in the blood vessel walls.
Your level of arterial blood pressure changes periodically during heart activity: During the “blood ejection” (Systole) the value is highest (systolic blood pressure value). At the end of the heart's “rest period” (Diastole) pressure is lowest (diastolic blood pressure value).

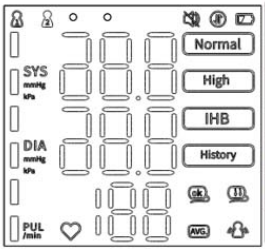
2.2 Which values are normal?

Please refer to the diagram below (Picture-01)



Picture-01

There are six grids in the display of device. Please refer to the Picture-01-01. Different grids represent different interval scales of
WHO.

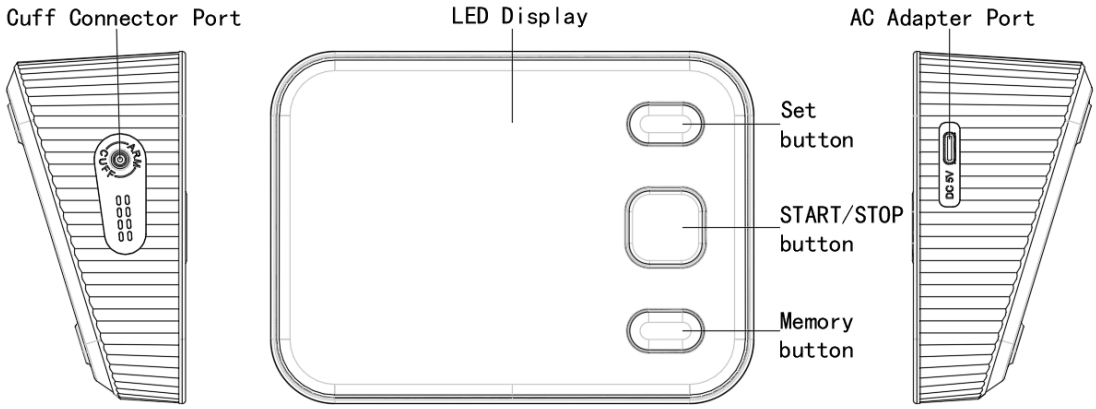


Blood pressure value	WHO grids in device	WHO Classification
DIA<80 & SYS <120	1	Optimal blood pressure
DIA<85 & SYS <130	2	Normal blood pressure
DIA<90 & SYS <140	3	High normal value
DIA<100 & SYS <160	4	Mild hypertension
DIA<110 & SYS <180	5	Moderate hypertension
DIA>=110 or SYS >=180	6	Severe hypertension

Picture-01-01

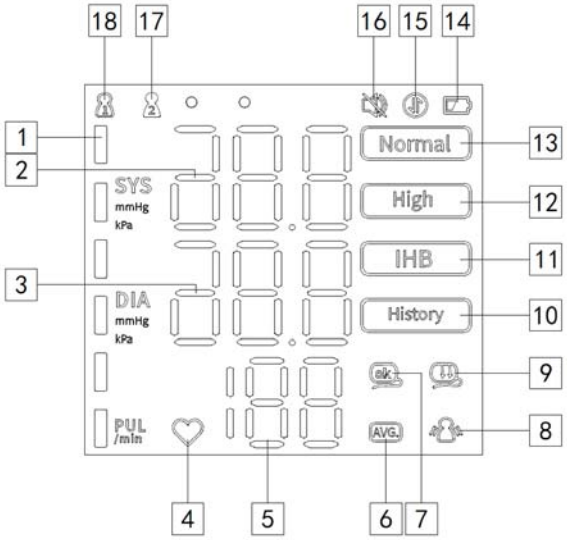
3 Components of Your Blood Pressure Monitor

3.1 Measuring unit



Picture-02

3.2 The symbols on the LED display



Picture-03

1.WHO function symbol 2. Systolic blood pressure
3.Diastolic blood pressure 4. Heartbeat symbol
5.Pulse display / Memory number 6. Average value symbol
7.Cuff wrap correct symbol 8. Misoperation error symbol
9. Cuff wrap error symbol 10. Historical records
11.Irregular heartbeat 12. High blood pressure
13. Normal blood pressure 14. Low battery symbol 15.
15.Bluetooth symbol 16. Mute symbol
17. USER 2 18. USER 1

3.3 Features of Model B11T

1.Double users: 2 x 120 sets memory 2.Cuff self-checking function
3. Irregular heartbeat checking 4. Average value function

5. Low battery display
6. WHO function
7. Auto power-off
8. External power adapter support
9.Volume adjustment
10.Bluetooth function
11. LED display

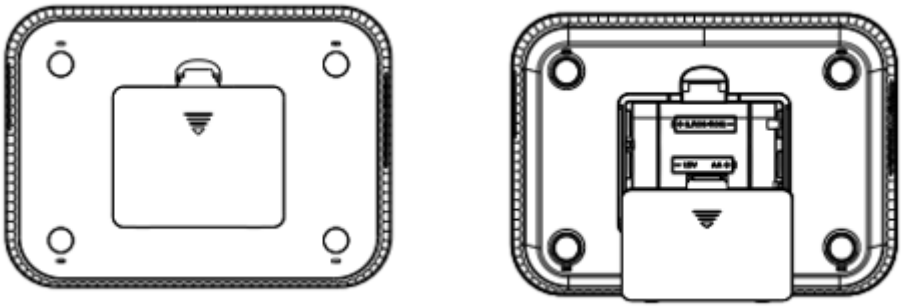
4 Using your Monitor for the First Time

4.1 Activating the pre-installed batteries

Battery Installation

Use only 1.5V "AA" alkaline batteries with this device.

1. Press the hook on the bottom of the battery cover and lift the cover off in the direction of the arrow (Picture-04).
2. Install 3 "AA" size batteries and make sure the + (positive) and - (negative) polarities match the polarities of the battery compartment, then close the battery cover.Make sure that the battery cover is securely in position.



Picture-04

Battery replacement

Low Battery Indicator

1. When the Low Battery Indicator appears on the display, turn the monitor off and remove all the batteries. Replace with 3 new batteries at the same time. Long-life alkaline batteries are recommended.
2. To prevent the damage of monitor from leaked battery fluid, please take out of battery if the monitor unused in a long time(generally more than 3 months). If battery fluid get in your eyes, immediately rinse with plenty of clean water. Contact a physician immediately.
3. Dispose of the device, components and optional accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution.

4.2 System Settings

Before making system settings, install the battery and turn on the power.Long press the 【SET】 button for about 3 seconds under the power off state until the user symbol flashes in the screen to enter the blood pressure monitor system setting.

The setting methods are as follows:

1. User setting: when the user symbol is flashing, short press the【MEM】button to select the user (1 or 2) whose measurement data need to be stored, and short press the 【SET】 button to confirm the next setting after selection.
2. Volume setting: When the screen display shows vol, there are OFF, 1, 2, 3 gears to

adjust the volume level, by short press 【MEM】 button to switch, when the low pressure position shows oFF for OFF, after selected, press【SET】button, for the next setup.
Note: After replacing the battery and powering up, it will enter the system setting interface directly to remind the user to make settings.

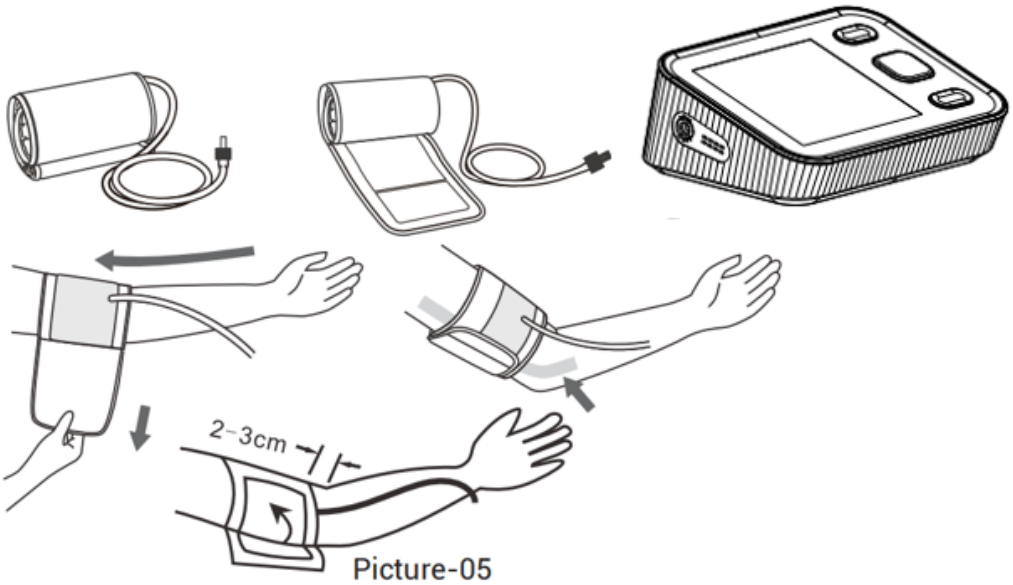
5 Measurement Procedure

5.1 Before measurement

• Avoid eating and smoking as well as all forms of exertion directly before measurement. These factors influence the measurement result. Find time to relax by sitting in an armchair in a quiet atmosphere for about ten minutes before taking a measurement.
• Remove any garment that fits closely to your upper arm.
• Always measure on the same arm (normally left).

5.2 Fitting the Cuff

Please refer to picture-05
1. Wrap the cuff around your upper left arm. The rubber tube should be on the inside of your arm extending downward to your hand. Make certain the cuff lies approximately 2 to 3 cm above the elbow. Important! The Φ on the edge of the cuff (Artery Mark) must lie over the artery which runs down the inner side of the arm.
2. To secure the cuff, wrap it around your arm and press the hook and loop closure together.
3. There should be little free space between your arm and the cuff. You should be able to fit 2 fingers between your arm and the cuff. Cuffs that don't fit properly result in false measurement values. Measure your arm circumference if you are not sure of proper fit.
4. Lay your arm on a table (palm upward) so the cuff is at the same height as your heart. Make sure the tube is not kinked.



Picture-05

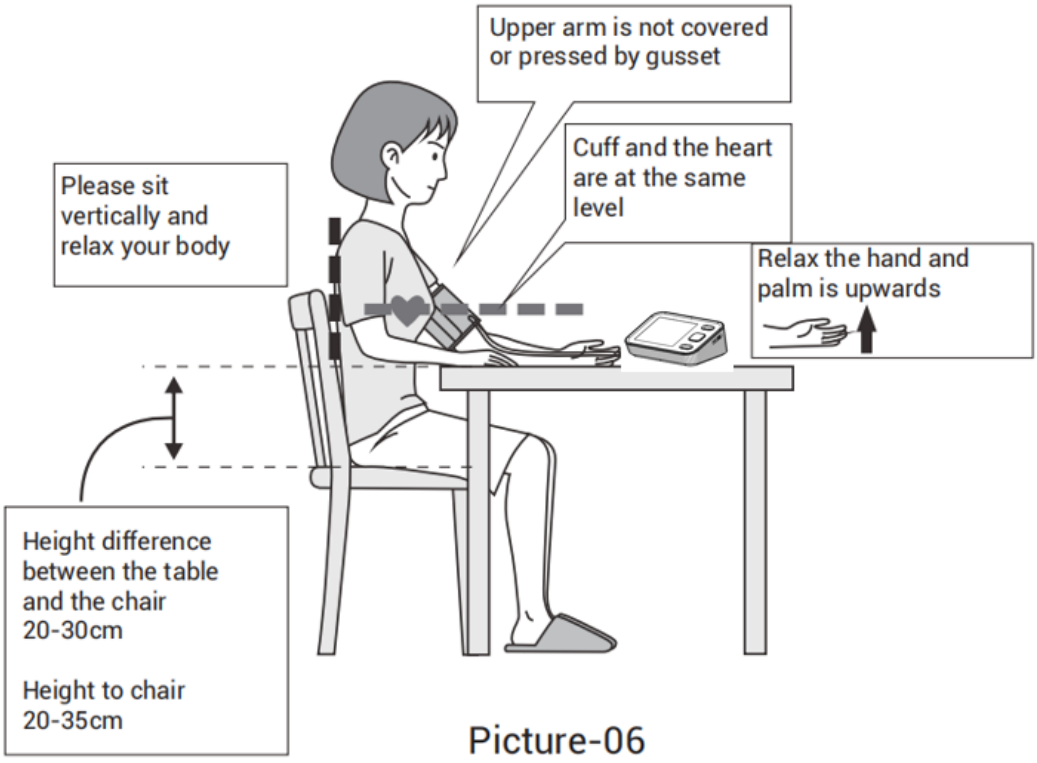
5.3 Measure Procedure

The device is designed to take measurements and store the measurement values in memory for two people using User ID 1 and User ID 2.

Refer to picture-06

1. Sit comfortably in a chair with your feet flat on the floor.
2. Select your User ID (1 or 2).
3. Stretch your arm forward on the desk and keep relaxing, make sure the palm of hand is upturned. Make sure arm is in correct position, to avoid body movement. Sit still and do not talk or move during the measurement.

After the cuff has been appropriately positioned on the arm and connected to the blood pressure monitor, the measurement can begin:



Picture-06

Operate via the App on smart phone with Bluetooth

1. Install the App from Google play store or Apple app store. Open Bluetooth on smart phone, and then turn on the App.
2. Bluetooth pairing

Turn on the device and the Bluetooth symbol (Ⓑ) will flash, Then operate bluetooth pairing according to the Settings on the APP, The Bluetooth symbol (Ⓑ) will stop flashing after the Bluetooth pairing is successful.

3. Bluetooth will be automatically searched and connected when it is powered on. After the Bluetooth connection is successful, the Bluetooth symbol (Ⓑ) will stop flashing and the measurement data will be uploaded to the APP.

Note:Devices that have been successfully paired will save the pairing information and do not need to be paired again.

It is recommended to connect the APP through Bluetooth before each measurement and then start the measurement.

Blood pressure measure

1. Press the【START|STOP】button to start Measure. The pump begins to inflate the cuff. In the display, the increasing cuff pressure is continually displayed.
2. After automatically reaching an individual pressure, the pump stops and the pressure falls. The cuff pressure is displayed during the measurement.
3. When the device has detected your pulse, the heart symbol in the display begins to blink.
4. When the measurement has been concluded, the measured systolic and diastolic blood pressure values, as well as the pulse will be displayed.
5. The measurement results are displayed until you switch the device off by pressing the 【START|STOP】 button. If no button is pressed for 60 seconds, the device switches off automatically.

Description of symbols during measurement

1.Cuff self-checking symbol ( )

The cuff correct symbol( ) will be displayed if the cuff position is correct, otherwise the wrong symbol( ) will be displayed. Please check again the cuff if the wrong symbol( ) is displayed.

2.Movement error symbol ( )

The Movement error symbol ( ) is displayed if you move your body during the measurement. Please remove the cuff, and wait 2-3 minutes. Reapply the cuff and take another measurement.

5.4. Irregular heartbeat Detector

This symbol( ) - indicates that pulse irregularities were detected during the measurement.

In this case, the result may deviate from your normal basal blood pressure repeat the measurement.

Information for the physician on frequent appearance of the Irregular Heartbeat Symbol.

This instrument is an oscillometric blood pressure monitor device that also analyzes pulse frequency during measurement. The instrument is clinically tested.

If pulse irregularities occur during measurement, the irregular heartbeat symbol is displayed after the measurement. If the symbol appears more frequently (e.g. several times per week on measurements performed daily) or if it suddenly appears more often than usual, we recommend the patient to seek medical advice. The instrument does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

5.5 Error Indicates

The following symbol will appear on the display when measuring abnormal:

SYMBOL	CAUSE	CORRECTION

No display appears	Weak battery or improper placement	Replace batteries with new ones. Check the battery installation for proper placement of the battery polarities.
Er1	Sensor abnormal	Please make sure the cuff pressure is drained and then measure again. If the error is still displayed, please send it to local distributor
Er2	Monitor could not detect pulse wave or cannot calculate the blood pressure data	Start the measurement again.If the error is still displayed, please send it to local distributor
Er3	Measurement results is abnormal or out the measurable range of blood pressure	Please keep quiet and measure again
Er4	Too loose cuff or air leakage	Tie the cuff correctly and make sure the air plug is properly inserted in the unit
Er5	The air tube is crimped or the cuff is tied too tight	Correct it and make the measurement again
Er6	The sensor is sensing great fluctuation in the pressure	Please keep quiet and don't move
Er7	The pressure that the sensor sensing is over the limit	Start the measurement again.If the error is still displayed, please send it to local distributor
Er8	The demarcation is incorrect or the device has not been demarcated	Please send back to the local distributor
HI	The pulse rate exceeds the upper limit (> 199 per minute)	Beyond the measurement range, normal reminder
LO	The pulse rate is less than the lower limit (< 40 per minute)	Beyond the measurement range, normal reminder

Trouble removal

Problem	Check	Cause and solutions
No power	Check the battery power	Replace new one
	Check the polarity position	Installation for proper placement of the batteries polarities
No inflation	Whether the plug insert	Insert into the air socket tightly
	Whether the plug broken or leak	Change a new cuff
Err and stop working	Whether move the arm when inflate	Keep the body peaceful

	Check if chatting when measured	Keep quite when measure
Cuff leak	Whether the cuff wrap too loose	Wrap the cuff tightly
	Whether the cuff broken	Change a new cuff
⚠ Please contact the distributor if you can't solve the problem, do not disassemble the unit by yourself!		

SYMBOL DESCRIPTIONS

The following symbols may appear in this manual, on the Digital Blood Pressure Monitor B11T, or on it's accessories. Some of the symbols represent standards and compliances associated with the Digital Blood Pressure Monitor B11T and its use.

Symbol	Explanation
	DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.
	CE Mark
	Authorized Representative in the European Community
IP21	The degree of avoid ingress of water or particulate matter into ME equipment.
	Date of manufacture
	Manufacturer
	Specifies serial number
	Type BF applied part
	Direct current
	Follow instructions for use
	MR unsafe
	Medical device
	Put up
	Fragile
	Afraid of the rain
	Fear of the sun
	Handle gently
	Temperature range
No Sterilize requirement	
Not category AP / APG equipment	
Mode of operation: continuous	

5.6 Memory

Each unit stores 120 sets measurements for 2 users, totally 240 sets (User 1 and 2).

Measurements for each user are stored separately. Be certain that you are viewing the measurements for the correct user.

View the memory
With the unit off, press the【MEM】button. The monitor will display User ID and an average value of the last 3 times measurements stored in the unit.
(If measurements are less than 3 sets, directly display the first set)

Delete memory
In average value memory viewing mode,the average value symbol【AVG.】is being displayed, long press the【MEM】button for 3 seconds, then it will delete all measurements for the current user.
In single set memory viewing mode, long press the【MEM】button for 3 seconds , then it will delete only a set measurement being displayed.

5.7 Discontinuing a Measurement
If it is necessary to interrupt a blood pressure measurement for any reason (e.g the patient feels unwell), the Start/Stop button can be pressed at any time. The device then immediately lowers the cuff pressure automatically.

5.8 Using the AC Adapter
You may also operate this monitor using the AC adapter (output d.c. 5V 1A with Type-C connector).
1. Ensure that the AC adapter and cable are not damaged.
2. Plug the adapter cable into the AC adapter port on the right side of the blood pressure monitor.
3. Plug the adapter into your electrical outlet. When the AC adapter is connected, no battery current is consumed.

Note: No power is taken from the batteries while the AC adapter is connected to the monitor. If electrical power is interrupted,(e.g., by accidental removal of the AC adapter from the outlet) the monitor must be reset by removing the plug from the socket and reinserting the AC adapter connection.

6 Care and Maintenance

Wash hands after each time measurement.
If one device is used by different patients, wash hands before and after each use.
1. Do not expose the device to either extreme temperatures, humidity, dust or direct sunlight.
2. The cuff contains a sensitive air-tight bladder. Handle this cuff carefully and avoid all types of stress through twisting or buckling.
3. Clean the device with a soft, dry cloth. Do not use gas, thinners or similar solvents. Spots on the cuff can be removed carefully with a damp cloth and soapsuds, if necessary,

70% isopropanol can be used.The cuff with bladder must not be washed in a dishwasher, clothes washer, or submerged in water.
4. Handle the tube carefully. Do not pull on it. Do not allow the tubing to kink and keep it away from sharp edges.
5. Do not drop the monitor or treat it roughly in any way. Avoid strong vibrations.
6. Never open the monitor! This invalidates the manufacturer's warranty.
7. Batteries and electronic instruments must be disposed of in accordance with the locally applicable regulations, not with domestic waste.

6.1 Accuracy test

Sensitive measuring devices must be checked for accuracy from time to time. We recommend a periodical inspection of your unit by an authorized dealer every 1 year. Please turn to local distributor or the manufacturer.

7 Warranty/Service

Your blood pressure monitor is guaranteed for 2 year against manufacturers' defects for the original purchaser only, from date of purchase. The warranty does not apply to damage caused by improper handling, accidents, unprofessional use, not following the operating instructions or alterations made to the instrument by third parties.
Warranty only applies to the main device and its cuff. All other accessories are not covered by warranty.
There are no user serviceable parts inside. Batteries or damage from old batteries is not covered by the warranty.

8 Certifications

Device standard:
This device is manufactured to meet the blood pressure monitors:
IEC 80601-2-30 / IEC60601-1-11 / IEC60601-1
Electromagnetic compatibility:
Device fulfills the stipulations of the International standard IEC60601-1-2
The device was clinicallly investigated and the safety and efficacy is meet the requirement of ISO 81060-2. If you need to acquire a copy of the summary of the Clinical Investigation, please contact the manufacturer.

9 Technical Specification

Model: B11T
Weight: 225g (Batteries and AC adapter are not included)
Display: 75*70mm LED Display

Size: 140(L)*102(W)*52(H)mm (±5mm)

Packaging list: 1×Main Device, 1×Cuff, 1×Users manual
Operating Conditions: Temperature: 5℃ to 40℃;Humidity: 15% to 90% RH;
Storage And Shipping Conditions:Temperature: -20℃~ +60℃;
Humidity:10%RH~93%RH;

Atmospheric pressure range: 70kPa~106kPa
Measuring method: Oscillometric
Pressure sensor: Resistive
Measuring range: DIA: 40-220mmHg; SYS: 60-260mmHg
Pulse: 40 to 199 per minute
Cuff pressure display range:0-295mmHg
Memory: Automatically stores the last 120 measurements for 2 users (total 240)
Measuring resolution: 1 mmHg
Accuracy: Pressure within ± 3 mmHg / pulse ± 5 % of the reading
Power source: a) 3*AA batteries, 4.5 V
b) AC adapter INPUT: 100-240V AC 50/60HZ OUTPUT: DC 5V 1A
Accessories: Wide range rigid cuff:22-42 cm
Users: Individuals age more than 12 years
IP classification: IP21
Automatically power off: 60 seconds
Expected service life of the device and accessories: 5 years

10 FCC Statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
(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 following measures:
—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.
Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.
This transmitter must not be co - located or operating in conjunction with any other

antenna or transmitter.
The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

11 EMC Declaration

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments and so on.
Warning: Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
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.
Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."
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 the Blood Pressure Monitor (B11T), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
If any: a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE).
If any: the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term “ESSENTIAL PERFORMANCE” need not be used).

Technical description
1.all necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.
2. Guidance and manufacturer's declaration -electromagnetic emissions and Immunity
Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	**Compliance**
RF emissions CISPR 11	Group 1

RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Applied

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	**IEC 60601-1-2** **Test level**	**Compliance 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
Electrical fast transient/burst IEC 61000-4-4	Power supply lines：±2 kV input/output lines：±1 kV 100 kHz repetition frequency	Power supply lines：±2 kV
Surge IEC 61000-4-5	line(s) to line(s)：±0.5 kV line(s) to earth：±2 kV line(s) to lines(s): ±1 kV	line(s) to line(s)：±0.5 kV line(s) to line(s)：±1 kV.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle At 0º, 45 º, 90 º, 135 º, 180 º, 225 º, 270 º and 315 º 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle	0% 0.5 cycle At 0º, 45 º, 90 º, 135 º, 180 º, 225 º, 270 º and 315 º 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz

Conduced RF IEC61000-4-6	150KHz to 80MHz： 3Vrms 6Vrms (ISM and amateur radio bands) 80% Am at 1kHz	150KHz to 80MHz： 3Vrms 6Vrms (ISM and amateur radio bands) 80% Am at 1kHz
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
Proximity magnetic fields IEC 61000-4-39	30 kHz: 8A/m 134.2 kHz: 65A/m 13.56 MHz: 7.5A/m	30 kHz: 8A/m 134.2 kHz: 65A/m 13.56 MHz: 7.5A/m
NOTE 1: U_T is the a.c. mians voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity					
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	**Test Frequency** (MHz)	**Band** [a] MHz)	**Service** [a]	**Modulation** (W)	**IMMUNITY TEST LEVEL** (V/m)
	385	380 to 390	TETRA 400	Pulse modulation [b] 18 Hz	27
	450	430 to 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	28
	710	704 to 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	9
	745				
	780				
	810	800 to 960	GSM 800/900, TETRA 800,	Pulse modulation [b]	28
	870				

	930		iDEN 820, CDMA 850, LTE Band 5	18 Hz	
	1720	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	28
	1845				
	1970				
	2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	28
	5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	9
	5500				
	5785				
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 % duty cycle square wave signal. c) As an alternative to FM modulation, the carrier may be pulse modulated using a 50 % duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.					

Table 4

Guidance and manufacturer's declaration - electromagnetic Immunity		
Test frequency	**Modulation**	**IMMUNITY TEST LEVEL (A/m)**
30 kHz [a]	CW	8
134,2 kHz	Pulse modulation [b] 2,1 kHz	65 [c]
13,56 MHz	Pulse modulation [b] 50 kHz	7.5 [c]

a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) r.m.s., before modulation is applied.