Fully Automatic Upper Arm

Blood Pressure Monitor

Model Number: B66T

USER'S MANUAL

CONTENTS

1. Introduction and Intended Use

This manual is for B66T models. It is a fully automatic digital blood pressure

measuring device for use by adults on the upper arm at home or in your doctor's/nurse's office. It enables very fast and reliable measurement of systolic and diastolic blood pressure as well as pulse through the oscillometric method. This device offers clinically proven accuracy and has been designed to be user friendly.

Before using, please read this instruction manual carefully and then keep it in a safe place. Please contact your doctor for further questions on the subject of blood pressure and its measurement.

Warning：Not suitable for neonatal and infants.

This device can not be used together with hf surgical equipment.

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.

• It is recommended that your physician review your procedure for using this device.

• Blood pressure readings obtained by this device should be verified before prescribing or making adjustments to any medications used to control hypertension. Under no circumstances should YOU alter the dosages of any drugs prescribed by your doctor.

• This monitor is intended for use by adults only. Consult with a physician before using this instrument on a child.

•In cases of irregular heartbeat (Arrhythmia), measurements made with this instrument should only be evaluated after consultation with your doctor.

• Familiarize yourself with the section titled "Important Information on Blood Pressure and its Measurement". It contains important information on the dynamics of blood pressure readings and will help you to obtain the best results.

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.

• Do not attempt to service or repair this device yourself. Should a malfunction occur, refer to local distributor or the manufacturer.

Warning：

1. Too frequent measurements can cause injury to the PATIENT due to blood flow interference
2. Don't place the cuff over wound part
3. Pressurization of the CUFF can temporarily cause loss of function of simultaneously used monitoring ME EQUIPMENT on the same limb

Contraindication

Use of this instrument on patients under dialysis therapy or on anticoagulant, antiplatelets, or steroids could cause internal bleeding.

1.2 Warnings and Precautions ⚠

Warning: Do not use cuffs, AC adapters or batteries other than those included with this product or replacement parts supplied by the manufacturer.
Warning: Do not use the batteries and the AC adapter to provide power at the same time.
Warning: This system may fail to yield specified measurement accuracy if operated or stored in temperature or humidity conditions outside the limits stated in the specifications section of this manual.
Warning: The separate ac adapter which is intended to connect USB interface of Blood Pressure Monitor has not been evaluated according to IEC 60601-1. The safety of the product shall be reappraised when it power supply by a separate ac adapter.
Warning: Remove the battery if the ME EQUIPMENT is not likely to be used for some time.
Warning: The user must check that the equipment functions safely and see that it is in proper working condition before being used.
Warning: No modification of this equipment is allowed.
Warning: The device is not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.
Warning: This equipment shall not be serviced or maintained while in use with the patient
Warning: 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.
Caution: To avoid any possibility of accidental strangulation, keep this unit away from children and do not drape tubing around your neck.
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.
Attention: Self-measurement means control, not diagnosis or treatment. Unusual values must always be discussed with your doctor. Under no circumstances should you alter the dosages of any drugs prescribed by your doctor.
Attention: The pulse display is not suitable for checking the frequency of heart pacemakers!
Attention: In cases of irregular heartbeat, measurements made with this instrument should only be evaluated after consultation with your doctor.
Note: To obtain the greatest accuracy from your blood pressure instrument, it is recommended that the instrument be used within the specified temperature and the relative humidity, please see the Technical Specifications
Note: The cuff is treated as the applied part.The user should contact the manufacturer for assistance, if needed, in setting up, using or maintaining the device.

2. Important Information on Blood Pressure and its Measurement

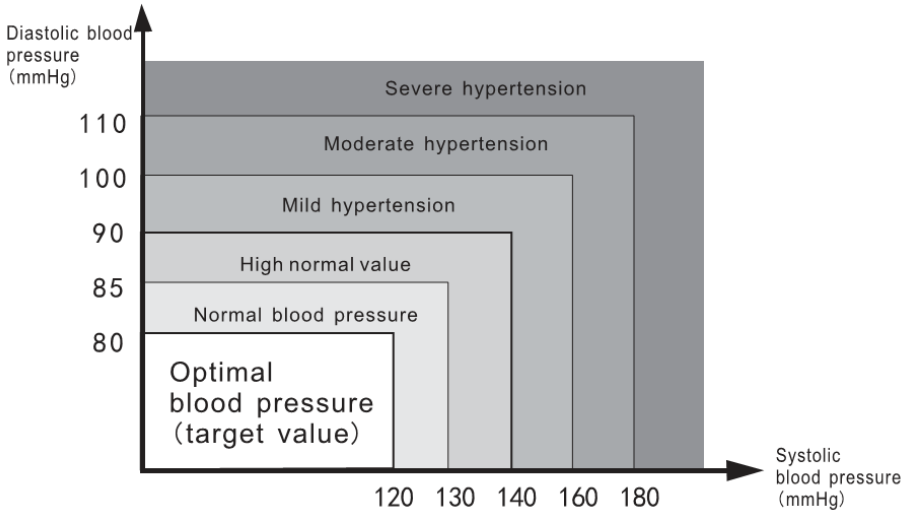
2.1. How does high or low blood pressure arise?

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).
Blood pressure values must lie within certain normal ranges in order to prevent particular diseases.

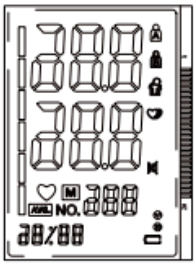
2.2. Which values are normal?

Please refer to the diagram below(Picture-01)



Picture-01

There are six grids in the display of device. Please refer to the picture-02. 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-02

Blood pressure is very high if your diastolic pressure is above 90 mmHg and/or your systolic blood pressure is over 160 mmHg, while at rest. In this case, please consult your physician immediately. Long-term values at this level endanger your health due to continual damage to the blood vessels in your body. If your systolic blood pressure values are between 140 mmHg

and 159mmHg and/or the diastolic blood pressure values between 90 mmHg and 99mmHg, consult your physician. Regular self-checks are necessary. If you have blood pressure values that are too low, (i.e., systolic values under 105mmHg and/or diastolic values under 60 mmHg), consult your physician. Even with normal blood pressure values, a regular self-check with your blood pressure monitor is recommended. You can detect possible changes in your values early and react appropriately. If you are undergoing medical treatment to control your blood pressure, keep a record of values along with time of day and date. Show these values to your physician. Never use the results of your measurements to independently alter the drug doses prescribed by your physician.

Further information

• If your values are mostly normal under resting conditions but exceptionally high under conditions of physical or psychological stress, it is possible that you are suffering from so-called “labile hypertension.” Consult your doctor.

• Correctly measured diastolic blood pressure values above 120mmHg require immediate medical treatment.

2.3. What can be done if regular high or low values are obtained?

1) Consult your doctor.

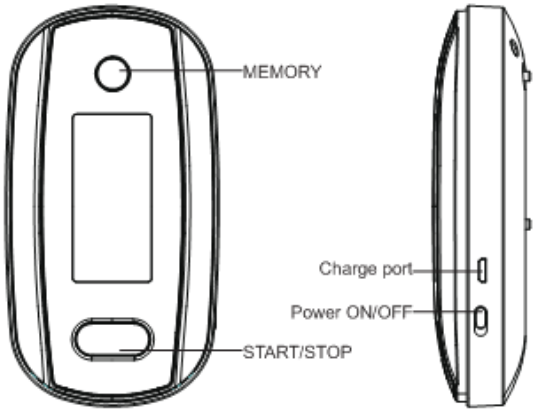
2) Increased blood pressure values (various forms of hypertension) are associated with considerable health risks over time. Arterial blood vessels in your body are endangered due to constriction caused by deposits in the vessel walls (Arteriosclerosis). A deficient supply of blood to important organs (heart, brain, muscles) can result from arteriosclerosis. Furthermore, the heart will become structurally damaged with increased blood pressure values.

3) There are many different causes of high blood pressure. We differentiate between the common primary (essential) hypertension, and secondary hypertension. The latter group can be ascribed to specific organ malfunctions. Please consult your doctor for information about the possible origins of your own increased blood pressure values.

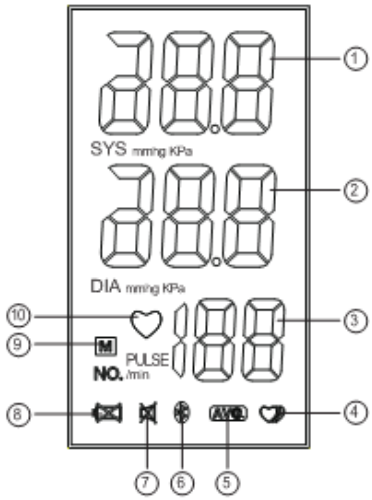
4) There are measures which you can take to reduce and even prevent high blood pressure.

3. Components of your blood pressure monitor

3.1. Measuring unit



Picture-03 Picture-04



Picture-05

3.2. The symbols on the LCD display

1. Systolic blood pressure 2. Diastolic blood pressure 3.Pulse display

4. Irregular heartbeat symbol 5.Average symbol 6. Bluetooth symbol

7. Mute symbol 8. Battery low symbol 9. Memory symbol

10. Heartbeat symbol

3.3. Features of Model B66T

1. Talking function 2.One user: 120 sets memory 3.Irregular heartbeat checking

4. Average value function 5. Battery display 6. Auto power-off

7. Built-in chargeable lithium battery 10.Volume adjustment 11. Date/time display

12. Cuff and main unit are integrated as one part 13. Bluetooth function

Note: Arm circumference should be measured with a measuring tape in the middle of the relaxed upper arm. Do not force cuff connection into the opening. Make sure the cuff connection is not pushed into the AC adapter port.

4. Using your Monitor for the First Time

4.1. Battery Power checking

The battery is built-in chargeable Lithium battery.

Press the “Power ON/OFF ” button, if the symbol is flickering and the device speaks “battery low power, please recharge it”. It means the battery power is low and need to be recharged. The power supply should be AC 5/1A.

When the symbol appears，it means the battery power is fully recharged. It can be used normally. If battery is not fully recharged， the symbol will flicker.

4.2. System Settings

After the battery is fully recharged, holding the START/STOP button more than 3 seconds to ON/OFF. Some functions can be set before use this monitor：

a. Start/Stop

Press the Start/Stop button one time. The device will start measurement. Press the Start/Stop button again, the measurement will stop.

b. Setting the Volume

Press and hold the START/STOP button, When display with SP is flashing, press memory button to switch volume 1, volume 2, volume 3 or OFF. Press START/STOP button to confirm.

c. Assessment of the memory record

Press memory button, it will seek for the memory record.

d. Delete record

When you checking the memory data, long press memory to delete existing user measurement data.

Note:

You can’t delete all measurement record from the monitor storage at one time, if you decide to delete the all record, please keep the record in another way, in case you need it some days later. Take the battery out won’t lead to a record missing.

5. Measurement Procedure

Note: You should always be seated and calm before and during measurement.

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).
• Always compare measurements taken at the same time of day, since blood pressure changes during the course of the day, as much as 20-40 mmHg.

5.2. Common sources of error:

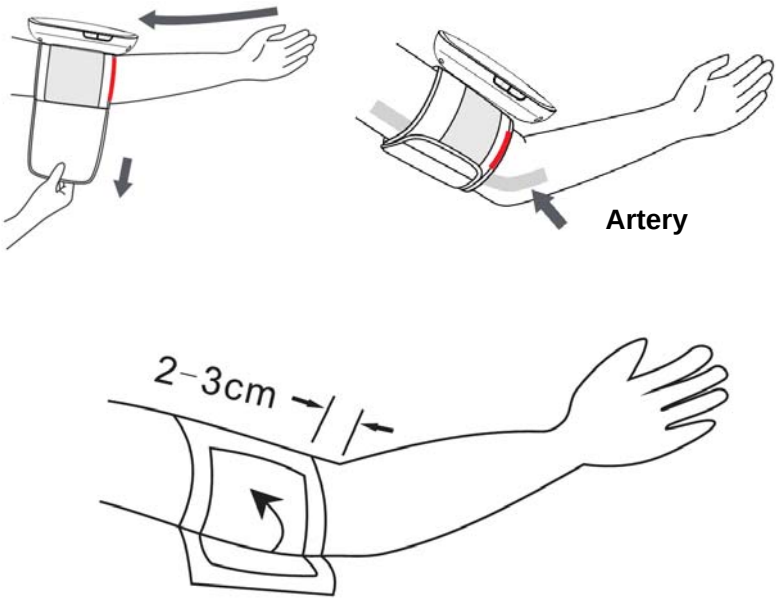
Note: Comparable blood pressure measurements always require the same conditions!
•Conditions should always be quiet.
•All efforts by the user to support the arm can increase blood pressure. Make sure you are in a comfortable, relaxed position and do not flex any of the muscles in the measurement arm during the measurement. Use a cushion for support if necessary.
• If the arm artery lies considerably lower or higher than the heart, an erroneously high or low blood pressure will be measured! Each 25-30cm difference in height between your heart and the cuff results in a measurement error of 10 mmHg!
Note: Only use approved cuffs!
• A loose cuff or a sideways protruding air pocket causes false measurement values.
• With repeated measurements, blood accumulates in the arm, which can lead to false results. Consecutive blood pressure measurements should be repeated after a 1 minute pause or after your arm has been held up in order to allow the accumulated blood to flow away. If you decide to take your Averaging Mode measurement again, be sure to wait at least one minute beforehand.

5.3. Fitting the Cuff

Please refer to picture-06
a) The cuff is pre-formed for easier use. Remove tight or bulky clothing from your upper arm.
b) 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 1/2” to 3/4” (1 to 2 cm) above the elbow. Important! The red mark on the edge of the cuff (Artery Mark) must lie over the artery which runs down the inner side of the arm.
c) To secure the cuff, wrap it around your arm and press the hook and loop closure together.
d) 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.
e) 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.

f)Remain seated quietly for at least two minutes before you begin the measurement.



Picture-06

5.4 Measure Procedure

Refer to picture 07

1. Sit comfortably in a chair with your feet flat on the floor.

2. 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:

1) Operate via the App on smart phone with Bluetooth

Install the App from Google play store or Apple app store. Open Bluetooth on smart phone, and then Turn on the App, the home interface will show up as picture App 01. Please refer the below steps tell how to remote control on the App:

a) Complete My Profile

Click the SET button on the top left corner as picture App 02, then select My Profile button to edit and save user information (male/female, name, age, height and weight) as picture App 03.

b) Setting Language

After setting My Profile, back to select and save the BM monitor Language as picture App 04.

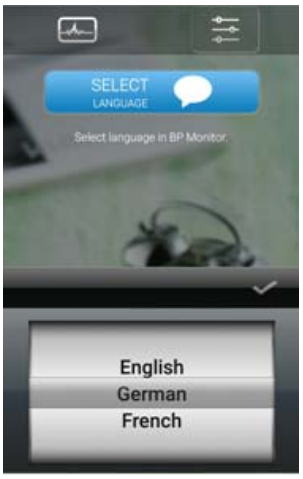
App 01

App 02

App 03

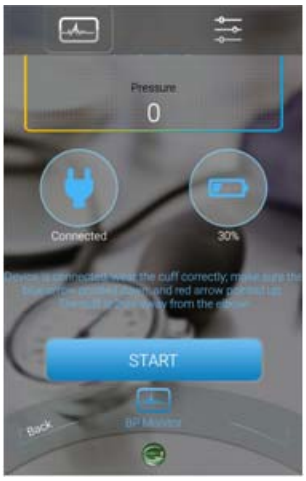
c) Connect Bluetooth

After the setting is finished, click the HOME button on the top right corner as picture App 01, then select Bluetooth Device button. A moment later, the device will be connected as picture App 05 and App 06.



App04

App05



App 06

d) Start the measurement

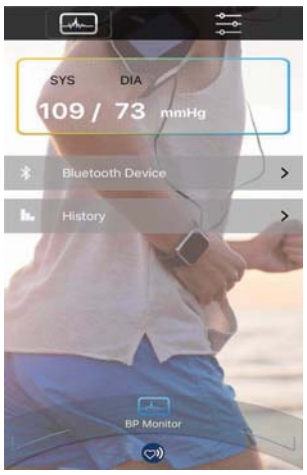
Once the Bluetooth is connected, click the “START” button on the App to start the testing as picture App 06. When measuring is done, the assessment will be voiced out and a interface about checking the result will show up as picture App 07 and App 08.

App 07

App 08

e) Checking the measurement

In the frame of home interface, it will show the last measurement as picture App 09. You can check the measurements with detail by clicking the History button as picture App 10 and app 11 .



App 09

App 10

App 11

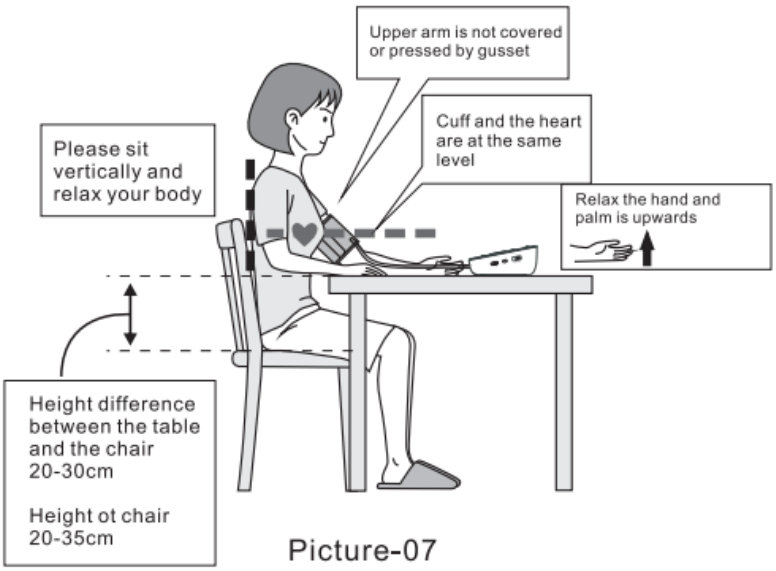
2) Operate on the device

Press the Stop/Start button as the power on (blue indictor is turned on). The pump begins to inflate the cuff. After automatically reaching an individual pressure, the pump stops and the pressure slowly falls. The device will speak out the result after the measurement is finished.

Recommended Use Methods:

1. Recommendation that the PATIENT relax as much as possible and not talk during the measurement PROCEDURE.
2. Recommendation that 5 min should elapse before the first reading is taken.

3. Any reading can be affected by the measurement site, the position of the PATIENT, exercise, or the PATIENT'S physiologic condition.
4. Performance of the AUTOMATED SPHYGMOMANOMETER can be affected by extremes of temperature, humidity and altitude.
5. To stop the inflation or measurement, push the START/STOP button. The monitor will stop inflating, start deflating, and will turn off.
6. After the monitor has detected your blood pressure and pulse rate, the cuff automatically deflates. Your blood pressure and pulse rate are displayed.
7. The monitor will automatically turn off after one minute.



Picture-07

5.5. Irregular Heartbeat Detector

This symbol - indicates that certain pulse irregularities were detected during the measurement. In this case, the result may deviate from your normal basal blood pressure – repeat the measurement.

In most cases, this is no cause for concern. However, if the symbol appears on a regular basis (e.g. several times a week with measurements taken daily), we advise you to tell your doctor. Please show your doctor the following explanation:

Information for the doctor 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.

5.6 Error Indicates

SYMBOL	CAUSE	CORRECTION
No display appears	Weak battery or improper placement	Replace both batteries with new ones. Check the battery installation for proper placement of the battery polarities.
Er1	Sensor abnormal	Check if the pump is working or not. If it is working, then the problem is sensor abnormal. Please send it to the local distributor.
Er2	Monitor could not detect pulse wave or cannot calculate the blood pressure data	Check if the air releasing is too slow or not. If it is too slow, please check if there is any dust in the tube plug of the cuff and the cuff port in the device. If yes, please clean and start the measurement again. If no, please send the device back to the local distributor.
Er3	Measurement result is abnormal (SYS≦45mmHg, DIA≦24mmHg)	Occasionally-measure for one more time/ Always - send it to local distributor
Er4	Too loose cuff or air leakage (Cannot inflate to 30mmHg within 15s)	Tie the cuff correctly and make sure the air plug is properly inserted in the unit
Er 5	The air tube is crimped	Correct it and make the measurement again
Er 6	The sensor is sensing great fluctuation in the pressure	Please keep quiet and don’t move
Er 7	The pressure that the sensor sensing is over the limit	Please send back to the local distributor

Er 8	The demarcation is incorrect or the device has not been demarcated	Please send back to the local distributor

The above symbols will appear on the display when measuring abnormal

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 B66T, or on it's accessories. Some of the symbols represent standards and compliances associated with the Digital Blood Pressure Monitor B66T and its use.

EC REP — Authorized Representative in the European Community

CE 0123 — CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC.

Date of manufacture.

Manufacturer

SN — Specifies serial number

Type BF applied part

Direct current

DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.

Follow instructions for use

IP21 The degree of avoid ingress of water or particulate matter into ME equipment

5.7. Memory

At the end of a measurement, this monitor automatically stores each result with date and time. Each unit stores 120 sets measurements.

Viewing the stored values

Press MEM button, it will seek for the memory record.

5.8. 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.

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.

a) Do not expose the device to either extreme temperatures, humidity, dust or direct sunlight.

b) The cuff contains a sensitive air-tight bubble. Handle this cuff carefully and avoid all types of stress through twisting or buckling.

c) 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. The cuff with bladder must not be washed in a dishwasher, clothes washer, or submerged in water.

d) Handle the tube carefully. Do not pull on it. Do not allow the tubing to kink and keep it away from sharp edges.

e) Do not drop the monitor or treat it roughly in any way. Avoid strong vibrations.

f) Never open the monitor! This invalidates the manufacturer’s warranty.

g) Batteries and electronic instruments must be disposed of in accordance with the locally applicable regulations, not with domestic waste.

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

Your blood pressure monitor is guaranteed for 2 years against manufacturers' defects for the original purchaser only, from date of purchase. The warranty does not apply to damage caused by improper handling, accidents, professional use, not following the operating instructions or alterations made to the instrument by third parties.
Warranty only applies to the instrument. All accessories including the cuff are guaranteed for one year, USB charging cable is not included.
There are no user serviceable parts inside. Batteries or damage from old batteries is not covered by the warranty.
Note: According to international standards, your monitor should be checked for accuracy every year.

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 FCC 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.