

# Instruction for Use

## Arm Type Electronic Blood Pressure Monitor

**Model: BSX579B**

**\*Please thoroughly read the Instruction for Use before using the unit.**

**\*Please save this Instruction for Use for further reference**

**Version: A/0**

**Ref. No.: 8187M579B1**

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**Software Name: Electronic Blood pressure Monitor software**

**Software version: V1.0**

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## 2 PRODUCT INTRODUCTION

Thank you for purchasing the Arm Type Electronic Blood Pressure Monitor. The monitor is compact and easy-to-use at home, during travel and office. Perfect for people who frequently monitor their own blood pressure.

Your new Blood Pressure Monitor uses the oscillometric method of blood pressure measurement. This means the monitor detects your blood's movement through your brachial artery and converts the movements into a digital reading. No stethoscope, easy to use.



please read and follow all instructions and warnings before using this product. Save these instructions for future reference.

In this Instruction for Use, Arm Type Electronic Blood Pressure Monitor is often abbreviated to as “the monitor” or “the equipment”, or “the device”.

## 3 INTENDED USE

The Monitor is for use by medical professionals, operator or users at home and is a non-invasive blood pressure measurement system, intended to measure the high (systolic) and low (diastolic) blood pressures pulse rate of an adult individual by using a non-invasive technology wrapped around the Arm with Arm circumference ranging from 8 2/3 inches to 12 3/5 inches (22cm to 32 cm).

Rated ranges of Blood Pressure :0mmHg to 295mmHg (0kPa to 39.3kPa).

Rated ranges of Pulse rate: (40 to 180) beats/minute.

The product comes with the following components: Monitor, CUFF, Instruction for Use.

## 4 IMPORTANT INFORMATION

**To ensure a reliable reading follow these recommendations before taking a measurement:**

All physical activity, excitement, stress, eating, drinking, smoking, body posture and many other activities or factors (including taking a blood pressure measurement) will influence blood pressure value. Because of this, it is mostly unusual to obtain identical multiple blood pressure readings.

Blood pressure fluctuates continually (day and night). The highest value usually appears in the daytime and lowest one usually at midnight. Typically, the value begins to increase at around 3:00AM, and reaches to highest level in the daytime while most people are awake and active.

Considering the above information, it is recommended that you measure your blood pressure at a fixed time every day if needed.

Please always relax a minimum of 2 to 3 minutes between measurements to allow the blood circulation in your Arm to recover. It is rare that you obtain identical blood pressure readings each time.



### **Please pay attention to the following information before use:**

- Avoid the effect of blood flow interference and resulting harmful injury to the PATIENT caused by continuous the CUFF Pressure Mo due to connection tubing kinking;
- Too frequent measurements can cause injury to the PATINET due to blood flow interference;
- Avoid the application of the CUFF over a wound, as this can cause further injury;
- Avoid the application of 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 to blood flow and could result in injury to the PATIENT;
- Avoid the application of the CUFF and its pressurization on the Arm on the side of a mastectomy or lymph node clearance;
- Please pay attention to the information that pressurization of the CUFF can temporarily cause loss of function of simultaneously used monitoring ME EQUIPMENT on the same limb;
- Please pay attention to the necessity of checking (for example, by observation of the limb concerned) that operation of the Monitor does not result in prolonged impairment of the circulation of the blood of the PATIENT.
- A minimum of 2hrs required for the ME Equipment (this monitor) to warm from the minimum storage temperature (-20°C) between uses until the ME Equipment (this monitor) is ready for its Intended Use when the ambient temperature is 20 °C.
- A minimum of 2hrs required for the ME EQUIPMENT to cool from the maximum storage temperature (55 °C) between uses (4.2.2) until the ME EQUIPMENT is ready for its INTENDED USE when the ambient temperature is 20 °C.
- This product contains small parts that may cause a hazard if swallowed by infants, toddlers and children.
- Do not use this monitor on infants, toddlers, children or person who cannot express themselves.
- In order to keep the monitor clean, hygienic and working normal, do not contact with pets and pests.

The Monitor has different features to meet different user's need.

Please kindly read the Instruction for Use with the relevant Model Number you purchased and notice the difference between them.

Please read the Instruction for Use thoroughly before using this Monitor and please consult your physician for the specific information about your blood pressure.

Instruction for Use printed in English.

## 5 SAFETY INFORMATION

To assure the correct use of the product, basic safety measures should always be followed, including the warnings and cautions listed in this Instruction for Use.

SAFETY SYMBOLS USED IN THIS INSTRUCTION FOR USE	
 <b>WARNING</b>	Indicates a potentially hazardous situation Which, if not avoided, could result in death or serious injury.
 <b>CAUTION</b>	Indicates a potentially hazardous situation Which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property.

### OPERATING THE MONITOR

-  Consult your physician for specific information about your blood pressure. Self-diagnosis and treatment using measured results may be dangerous. Follow the instructions of your physician or licensed healthcare provider.
-  DO NOT adjust medication based on measurement results from the Monitor. Take medication as prescribed by your physician. Only a physician is qualified to diagnose and treat High Blood Pressure.
-  Users with upper limb defects should consult a doctor for permission before using.
-  During the measurement, if the CUFF is overinflated for a long time and the pressure is too high, the subject may feel uncomfortable. If the feeling is strong, please press the "START/STOP" button to relieve pressure or pull out the trachea plug, and take off the CUFF.
-  The monitor is not intended to be a diagnostic device.
-  If battery fluid should get in your eyes, immediately rinse with plenty of clean water. Contact a physician immediately.
-  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.
-  Those parts of the unit that shall not be serviced or maintained while in use with a patient.
-  Read all of the information in the Instruction for Use and other literature in the box before operating the unit.
-  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.
-  Operate the device only as intended. Do not use the device for any other purpose.
-  Dispose of the device, components optional accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution.
-  Do not use a cellular phone near the device. It may result in an operational failure.

 Use only BSX authorized parts and accessories. Parts and accessories not approved for use with the device may damage the unit.

 Use only the factory specified battery with this device.  
Do not use other types of battery. This may damage the unit.

 Measurements outside the cuff range are inaccurate and cannot be made, and may cause the cuff to fall off during inflation or other unpredictable events.

The  Monitor must be recharged every 6 months, otherwise the Limited warranty and the shelf life will end.

 When the monitor exceeds its service life, sensor and electrode degradation can lead to inaccurate measurement accuracy, or electrode looseness can lead to poor contact or other problems.

## RISK OF ELECTRICAL SHOCK

 Do not install or remove battery with wet hands.

## CARE AND MAINTENANCE

 Do not subject the monitor to strong shocks, such as dropping the unit on the floor.

 Do not submerge the device or any of the components in water.

 Store the unit and the components in a clean, safe location.

 Changes or modification not approved by BSX will void the user warranty. Do not disassemble or attempt to repair the unit or components.

 Changes or modification not approved by the manufacturer will void the user warranty. Do not disassemble or attempt to repair the unit or components. No modification of this equipment is allowed.

 If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

## 6 BEFORE TAKING A MEASUREMENT

To ensure a reliable reading follow these recommendations:

- 1) Avoid eating, drinking alcohol, smoking, exercising, and bathing for 30 min prior to taking a measurement. Rest for at least 15 min prior to taking the measurement.
- 2) Stress raises blood pressure, avoid taking measurements during stressful times.
- 3) Measurements should be taken in a quiet place.
- 4) Remove tight-fitting clothing from your Arm.
- 5) Sit on a chair with your feet flat on the floor. Rest your Arm on a table so that the CUFF is at the same level as your heart.
- 6) Remain still and do not talk during the measurement.
- 7) Wait 2 to 3 minutes between measurements, the wait time allows the arteries to return to the condition prior to taking the blood pressure measurement. You may need to increase the wait time depending on

your individual physiological characteristics.

- 8) Cleaning and disinfection of the unit following use to prevent PATIENT cross infection.

## 7 CONTRAINDICATION AND STATEMENT

### 7.1 Contraindication

It is inappropriate for people with serious arrhythmia to use the unit.

This device is only intended for use in measuring blood pressure and pulse rate in adult population. Do not use this unit for any other purpose.

The unit is not intended to be a diagnostic device. Self-diagnosis and treatment using measured results may be dangerous. Follow the instructions of your physician.

Patients with severe blood circulation disorders and blood diseases (need to be used under the guidance of a doctor).

Please do not use this device for people who cannot express their thoughts correctly, including infants and newborns.

### 7.2 Statement

- 1) The Monitor products manufactured by our company have passed clinical verification, and their safety and effectiveness are in line with the relevant national regulatory requirements.
- 2) The Monitor products manufactured by our company have been conducted contrast test with mercury column Blood Pressure Monitor, the blood pressure value measured by this equipment is equivalent to the measurement value of the auscultatory method and its error meets the specified requirements of IEC 80601-2-30:2009, which is within the acceptable range.

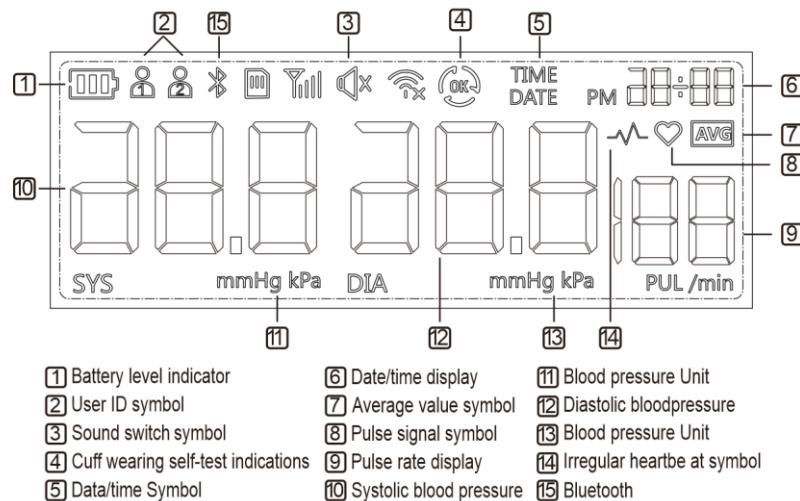
## 8 UNIT STRUCTURES & ACCESSORIES

### 8.1 The Main Unit



The above picture is only for reference. Please use the material object as standard.

## 8.2 LCD Display Introductions



## 9 INSTALLATION AND USE

### 9.1 Battery level Introduction

In shutdown mode, Press the Start/Stop button/memory button/setting button, then enter into measuring pattern/recording pattern/setting pattern. When it displays, system will detect the battery level and will indicate the battery level on LCD display. Details are as follows:

1) Battery Level is full or enough:

Display the battery full icon (  ) or the battery icon (  ), user can take measurement and read the memory.

2) Battery Level is low:

Display power insufficiency icon (  ), then blood pressure can be measured and memory can be checked, but user should prepare battery timely.

3) When the battery is exhausted:

Display the exhausted icon (  ), It flashes 5 times and monitor will shut off immediately".

### 9.2 Using the device used to provide power

#### 1) To connect the External Power Equipment

- If you use AC adapter, please insert the AC Plug into the adapter Jack, then Please connect the DC output power plug of the adapter to the USB power port of the monitor.
- If you use other device used to provide power, please connect the DC output plug to the USB power port of the monitor.

#### 2) To disconnect the External Power Equipment

- If you use AC adapter, please hold the housing to remove the AC adapter from the electrical outlet, then remove the AC Adapter plug from the monitor.
- If you use other device used to provide power, please remove the DC plug from the USB power port of the monitor.

### 3) Battery Charge Indicator

The power insufficiency battery icon  or  will flicker to remind the user the monitor battery is under charging.

The Power fully battery icon  is fixed to display after the monitor battery is charged.

#### WARNING

Do not plug or unplug the power cord into the electrical outlet with wet hands.

The Blood Pressure Monitor cannot measure when charging.

#### CAUTION

Do not overload power outlets. Plug the device into appropriate voltage outlet.

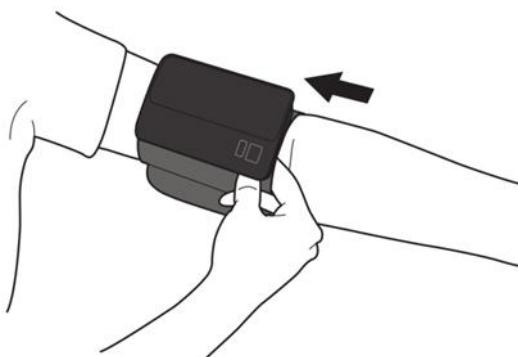
The device used to provide power must meet the requirements of IEC 60601-1.

The output of the device used to provide power should be 5V d.c.1A, connect port: USB power port (for power supply only, no data communication function).

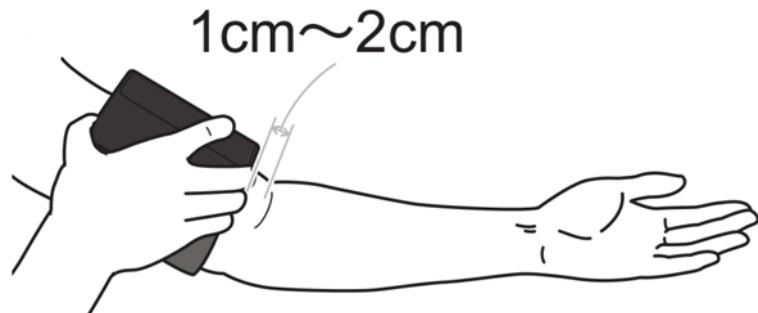
## 9.3 Blood Pressure Measurement Method

### 9.3.1 Applying the CUFF

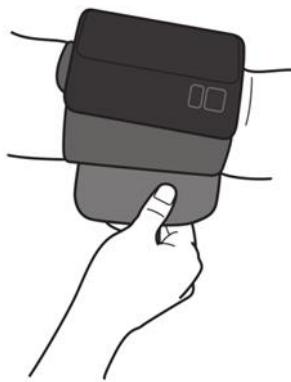
- 1) Make sure the air plug is securely inserted in the main unit.
- 2) Remove tight-fitting clothing from your upper arm.
- 3) Push open the CUFF into a tubular shape, until it is suitable for the arm to get in.



- 4) Place the CUFF around a bare Arm 2-3cm above the Arm joint on the palm side of the Arm.



- 5) Sit in a chair with your arms on the table in front of you, palms facing up, the display faces your eyes.



- 6) The CUFF must be neither too tight nor too loose, tightly wrap the cuff, and fix it with cloth buckle. Leave a finger gap between the arm and the cuff.
- 7) Adjust the upward direction of the machine body on the left upper arm.

**Note:**

Please refer to the CUFF circumference range in “PRODUCT SPECIFICATIONS” to make sure that the appropriate CUFF is used.

- Please keep the CUFF clean. If the CUFF becomes dirty, please do not use water to clean or moisten the CUFF, and when necessary, absorbent cotton dipped with 75% medical alcohol can be used to wipe it gently, so as to conduct disinfection ( See clause “**MAINTENANCE , REPAIR AND CALIBRATION**” ).
- Never dry the CUFF in clothes dryer or iron it. Clean the CUFF after the usage of every 200 times is recommended.
- Do not place the CUFF around your Arm if the Arm has any inflammation, acute diseases, infections skin wounds.

**Warning:**

**1. Unclean CUFF may cause the following Risks:**

- Potential allergic reactions to accessible materials used in the ME EQUIPMENT;
- Contact injuries.

**2. Strangulation Risk due to cables and hoses, particularly due to excessive length.**

Follow the instructions of your physician or licensed healthcare provider.

## **9.4 Body Posture During Measurement**

**Body Posture during measurement as the right figure shown.**

**Sitting Measurement – Recommended Position**

- 1) Sit up right.
- 2) Place palm upside in front of you on a flat surface such as a desk or table, with your elbow resting on a chair or table.
- 3) The band should be at the same levels as your heart.

- 4) Placing your Arm on the monitor's plastic case as shown, in the picture to aid in maintaining a correct and still Arm position.



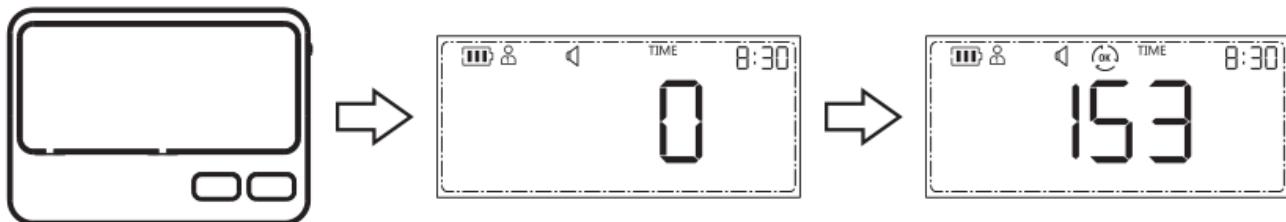
**Note:**

- 1) An explanation of the operating steps needed to obtain accurate routine resting BLOOD PRESSURE values for the condition hypertension, including:
  - PATIENT position in NORMAL USE, including
    - a) Comfortably seated;
    - b) Legs uncrossed;
    - c) Feet flat on the floor;
    - d) Place and rest the Arm with the cuff in front of you on the table with your palm facing up;
    - e) Back and Arms supported, and
    - f) Middle of the CUFF at the level of the right atrium of the heart;
  - A recommendation that the PATIENT relax as much as possible and not talk during the measurement PROCEDURE;
  - A recommendation that 5 min should elapse before the first reading is taken;
  - Measuring on same Arm each time;
  - OPERATOR position in NORMAL USE;
- 2) An explanation that any BLOOD PRESSURE reading can be affected by the measurement site, the position of the PATIENT (standing, sitting, lying down), exercise, or the PATIENT'S physiologic condition;
- 3) Details of the environmental or operational factors which can affect the performance of the BLOOD PRESSURE MONITOR and/or BLOOD PRESSURE reading (e.g. common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, age, pregnancy, pre-eclampsia, renal diseases, PATIENT motion,

trembling, shivering).

## 9.5 Blood pressure measurement

- 1) In the state of shutdown or standby, press the [Start/Stop] for starting up, it will start measurement automatically, and the CUFF will inflate automatically.

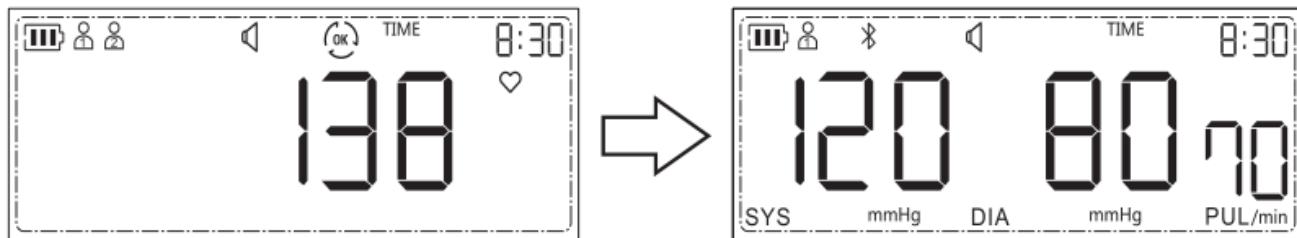


**Press Start/Stop button-----Start measuring-----Inflating**

\* When the CUFF starts to inflate, the Monitor will start to work automatically. In the process of inflation, the Monitor will also detect the pulse, so please do not move your Arm in the whole measurement process, and remain static throughout the process. The Arm will feel the CUFF extrusion, and this is a normal phenomenon of inflation.

\* If the LCD appear an error code or error, please refer to the clause "**ERROR AND FAULT INSTRUCTIONS**" for troubleshooting.

- 2) Stop automatically after full inflation, and start to detect the pulse rate.



In the measuring process

End of the measurement

**Note:** This pictures in the measurement interface are only for reference.

- After the measurement is completed, the Monitor will display your blood pressure value and pulse rate number.
- If the monitor has stored results, the LCD will display the last one. If no result has been stored, “--” will appear on LCD.
- After the measurement is completed, take off the CUFF, press the [Start / Stop] button, and shut down manually.
- If no button is pressed, then the system will be shut down automatically after about 60 seconds.
- For the model with backlight, if no button is pressed, the backlight will be shut down automatically about 6 seconds later.

**Note:**

- a) Please consult a health care professional for interpretation of pressure measurements.
- b) The pictures in the measurement interface are only for reference.

## 10 FUNCTION SPECIFICATION

### 10.1 User Setting

- 1) In shutdown state, long press the "ON/OFF" (or name: START/STOP) key to enter user selection, press "MEM" to switch users.
- 2) Then press the "ON/OFF" (or name: START/STOP) key to enter the date setting and press the "MEM" key to set the year.
- 3) Then press the "ON/OFF" (or name: START/STOP) key, the month number flashes, and enter the setting month state, press the "MEM" key to set the month value.
- 4) Then press the "ON/OFF" (or name: START/STOP) key, the date number flashes, and enter the setting date state, press "MEM" key to set date value.
- 5) Then press the "ON/OFF" (or name: START/STOP) key, the "SY" icon flashes and enter the setting hourly system stat, press the memory key to set the day to 12 hours or 24 hours.
- 6) Then press the "ON/OFF" (or name: START/STOP) key, the number of hours flashes, enter the setting hour state. PM is displayed in the afternoon (if the system is set to 24 hours, PM Icon is not displayed in the afternoon), press "MEM" key to set the hour value.
- 7) Then press the [on/Off] (or START/STOP) key, the minute number flashes and enter the setting minute state. Press "MEM" key to set the value of minutes.
- 8) Then press the "ON/OFF" (or name: START/STOP) key, the unit flashes, and enter unit setting state, press the memory key to switch the unit of pressure (Unit of pressure: mmHg or kPa).
- 9) Then press the "ON/OFF" (or name: START/STOP) to enter the alarm clock setting state, AL and user number appear on the screen, and hour value flashes, press "MEM" key to set the hour value. then press "ON/OFF" (or: Start/Stop) key, the minute value flashes, press the "MEM" key to set the minute value.
- 10) Then press the "ON/OFF" (or name: START/STOP) key, the alarm switch flashes, press the "MEM" key to set whether to enable the alarm (OF means to turn off the alarm, ON means to enable the alarm). When the alarm rings, press any key to exit (note: each user can set the alarm separately).
- 11) Then press the "ON/OFF" (or name: START/STOP) key again, then shut down and save the setting result. Manual shutdown during the process or automatic shutdown without any action for 60(+/-5) seconds will save the Settings.

### 10.2 Voice Switch

Toggle the toggle switch on the shell side. Toggle to the "🔊" side to turn on the voice broadcast, and to the "🔇" side to turn off the voice broadcast.

## 10.3 Memory Deletion

In view of the memory, press and holding down the “MEM” button for about 2 to 5 seconds, and when the screen is fully displayed as “--”, then the memory is deleted.

Memory deletion is a one-time removal of all measurement data under all users.

## 10.4 Read the Memory

In the first time, press the “MEM” button, the “AVG” and “MR” icons are lighted, and display the average value of the first 3 times (when the number of the memory is greater than or equal to 3 groups);

In the second time, press the “MEM” button, “MR” icon is lighted, then the measurement records can be viewed, and long press the “MEM” button can quickly view the memory.

## 10.5 Memory Deletion

In power off mode, press and holding down the “MEM” button for about 5 seconds, and when the screen is fully displayed as “--”, then the memory is deleted.

Memory deletion is a one-time removal of all measurement data under all users.

## 10.6 Entering static pressure measurement method

- 1) Short press the “MEM” button, then press and hold down the “MEM” button & the “START/STOP” button for about 2s, Low pressure display area on the screen display the figure 0, and enter the static pressure measurement mode after releasing the button.
- 2) After entering the static pressure measurement mode, short press / long press “START/STOP” button can exit the static pressure measurement mode, and return to the time mode.

## 10.7 Bluetooth connection

Turn on the blood pressure monitor first.

Open the APP "Cloud blood Pressure" or the extended APP based on cloud blood pressure on the terminal.

Start the Bluetooth communication of the mobile phone, enter the APP measurement page, find the monitor and connect it.

Bind the straps according to the instructions and click "Start" button to measure.

The measurement results are displayed on the "Measurement" and "Record" pages.

# 11 ERROR AND FAULT INSTRUCTIONS

## 11.1 Troubleshooting tips

PROBLEM	CAUSES AND SOLUTINS
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No power. No display appears on the unit.	Re-charge battery.
Measurement values appear too high or too low.	Blood pressure varies constantly. Many factors including stress, time of day, and how you wrap the CUFF, may affect your blood pressure, where you position your Arm, may affect your blood pressure. Review the sections "BLOOD PRESSURE MEASUREMENT METHOD".

## 11.2 Error indicators (Error Code)

SYMBOL	CAUSE	CORRECTION
Err1	Sensor abnormality	When measuring, avoid the environment (e.g. to magnetic fields, electromagnetic fields, external electrical influences etc.).
Err2	No pulse or blood pressure reading due to very weak artery pulse.	Remove CUFF. Wait 2-3 minutes and take another measurement. Repeat steps listed under the clause " <b>BLOOD PRESSURE MEASUREMENT METHOD</b> ". Inflate the CUFF 40mmHg higher than the previous inflation value.
	The CUFF is too loose	Apply the CUFF correctly. Refer. to the clause " <b>Applying the CUFF</b> "
	Clothing is interfering with the CUFF	Remove any closing interfering with the CUFF. Refer to the clause " <b>Applying the CUFF</b> "
Err4	Air plug disconnected	Insert the plug securely, refer to the clause " <b>Applying the CUFF</b> "
	Air cuff not applied correctly	Apply the CUFF correctly. Refer to the clause " <b>Applying the CUFF</b> "
	Air is leaking from the CUFF	Replace the CUFF with the new one.
	Others	Contact Customer Service.
Err5	Pipe bend causing air blockage	Apply the CUFF correctly. Refer to the clause " <b>Applying the CUFF</b> "
	connector blockage	Replace connector
	Others	Contact Customer Service
Err6	The interference is too large when in measurement	Repeat measurement. Remain still and do not talk during measurement. Refer to the clause " <b>BLOOD PRESSURE MEASUREMENT METHOD</b> ".

Err7	The CUFF Pressure Range was inflated above 295mmHg when inflating the CUFF manually.	Do not inflate the CUFF Pressure Range above 295mmHg (39.3kPa), Refer to the clause " <b>BLOOD PRESSURE MEASUREMENT METHOD</b> ".
Err8	The Systolic was measured out of the range	<ol style="list-style-type: none"> <li>1. Check whether the CUFF joint is loose.</li> <li>2. The SYSTOLIC Blood Pressure is over measurement range, please contact your doctor and follow his or her instructions.</li> </ol>
Err9	The Diastolic was measured out of the range.	<ol style="list-style-type: none"> <li>1. Check whether the CUFF joint is loose.</li> <li>2. The DIASTOLIC Blood Pressure is over measurement range, please contact your doctor and follow his or her instructions.</li> </ol>
	Battery is worn.	Please recharge in time.

**If the problem is still not resolved, please contact with the dealer or our customer service department, so as to obtain further assistance.**

## 12 NOTICE

- 1) The interval between two measurements shall be at least 2 to 3 minutes. The waiting between two measurements is mainly to get the artery back to the state before the blood pressure is measured.
- 2) When in repeated measurement, because the Arm blood flow may not be smooth, you may not measure the correct blood pressure. Please conduct measurement after the blood flow is smooth.
- 3) When the LCD display an Error code "Err", the measurement cannot be conducted correctly, please refer to the error and fault instructions in the next page.
- 4) When a measured person has an arrhythmia, the measurement value of blood pressure and pulse rate may not be accurate enough, so for patients with arrhythmia, it is advised to consult a doctor to make a professional diagnosis.
- 5) When the CUFF is too loose or too tight, it will affect the accuracy of measurement.
- 6) Measurement posture and physical condition, etc. will affect the measurement results. Please understand the knowledge of blood pressure, and eliminate all kinds of interference factors.
- 7) If the CUFF not provided by the manufacturer to replace the original one, it may lead to measurement error. Please do not use the CUFF other than supplied by the manufacturer.
- 8) Please do not use the blood pressure monitor with electrical appliances that emit electromagnetic interference, it may affect the accuracy.
- 9) The key component list of the machine includes main control chip, sensor, pump, electromagnetic valve, uniform speed air release valve and CUFF. Parts of the manufacturer's models and specifications specified in the list must be used; otherwise it may lead to problems of safety or accuracy.

- 10) The CUFF should be placed at the same level as your heart.
- 11) During measurement, neither speak nor move your body and Arm.
- 12) Use on same Arm for each measurement.
- 13) This Monitors is designed for adults and should never be used on infants or young children. Consult your physician or other health care professionals before use on older children.
- 14) Information regarding potential electromagnetic or other interference between the Monitor and other devices together with advice regarding avoidance of such interference please see part **ELECTROMAGNETIC COMPATIBILITY INFORMATION**.
- 15) The monitor might not meet its performance specifications or cause safety hazard if stored or used outside the specified temperature, humidity ranges and atmospheric pressure in specifications.
- 16) Please do not share the CUFF with other person to avoid cross-infection.
- 17) Please note that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- 18) When insert the pipe of CUFF, keep the air interface between the CUFF and the gas pipe of the host machine clean to prevent duct, clean cotton and other sundries form entering the pipe. The entry of debris into pipe may affect the measurement results or affect the measurement function, such as blocking the pipe.

## **13 MAINTENANCE, REPAIR AND CALIBRATION**

- 1) When it is not in use, please keep the Monitor and its accessories in the packing box.
- 2) Avoid small material (example: lint, dust etc.) to enter the pipe and block the air pipe.
- 3) Do not store your monitor and other components:
  - a) If your monitor and other components are wet.
  - b) In locations exposed to extreme temperatures, humidity, direct sunlight, duct or corrosive vapors such as bleach.
  - c) In locations exposed to vibrations or shocks.
- 4) In order to prevent the Monitor from damage, please comply with the following items, otherwise, improper use will result in the loss of warranty services:
  - a) Because dust and direct sunlight reduces the life of the Equipment (include the Monitor and Cuff), Please do not place the Monitor and the CUFF in an environment of high temperature, unclean, damp, full of water vapor or direct sunlight. Please refer to the specification table for details. If stored and used outside the specified range of temperature and humidity, the system may not be able to achieve the claimed specifications.
  - b) Please do not firmly fold the CUFF or the air duct.
  - c) Please do not disassemble the Monitor.
  - d) Please do not allow the Monitor to be subjected to strong impact or vibration (for example, drop

the Monitor on the ground).

- e) Please do not use volatile liquid to clean the Monitor. Please use soft and dry cloth to clean the outer shell.
- f) Clean the monitor with a soft dry cloth. Do not use any abrasive or volatile to clean the monitor. Do not attempt to clean the CUFF.
- g) Please do not use water to clean or moisten the CUFF, and when necessary, absorbent cotton dipped with 75% medical alcohol can be used to wipe it gently, so as to conduct disinfection.
- h) Drop, collision and bending, etc. may reduce the performance of the battery; if the battery is found abnormal, such as packaging damaged and battery pack deformation, etc. do not use these batteries.



- i) The manufacturer will make available on request circuit diagrams, component part lists, descriptions.
- j) The patient can perform changing batteries.

- 5) Calibration instructions, or other information that will assist service personnel to repair those parts of the equipment that are designated by the manufacturer as repairable by service personnel.
- 6) The monitor can maintain the safety and performance characteristics for a minimum of 10,000 measurements.
- 7) For customer service: Shenzhen BSX Technology Electronics Co., Ltd.  
Warranty service, please refer to " LIMITED WARRANTY ".
- 8) Calibration:  
It is recommended the performance should be checked every 1 years or after repair. Please contact the service center.

## 14 CLEANING AND DISINFECTION

### 14.1 Cleaning

- 1) Turn off the power, dip the medical gauze in water, wring out and wipe the Monitor shell.

2) After cleaning, use dry medical gauze to remove water and dry thoroughly.

## 14.2 Disinfection

Clean the Monitor with medical gauze in 75% medical alcohol to wipe the Monitor shell and CUFF for disinfection, dry thoroughly and then store or for taking a measurement.

## 15 DISPOSAL TREATMENT STATEMENT

The product manufacturing date can be seen on the nameplate of the Monitor, and the product life is 5 years.

**WARNING:** Do not throw away batteries with uncontrolled daily waste.

**CAUTION:** Dispose of the device, components and optional accessories according With applicable national or regional regulations. Unlawful disposal may cause environmental pollution.

The marking in this manual that the batteries in this product should be disposed with household trash at the end of its working life. If the batteries are not disposed of properly, the substances included can cause harm to human health and the environment. Please follow environmental laws and guidelines for proper waste disposal.



## 16 DISPLAY SYMBOLS

Symbol	Title
	Manufacturer for Medical devices Health care - Medical equipment, to identify the manufacturer of a product.
	Date of manufacture: to indicate the date on which a product was manufactured.
	Use by date, To indicate that the device should not be used after the date accompanying the symbol.
	Catalogue number: to identify the manufacturer's catalogue number.
	Batch code : to identify the manufacturer's batch or lot code.
	Serial number: identify the manufacturer's serial number.

	TYPE BF APPLIED PART
	Waste electrical and electronic product recycling icon.
AP	Rating for ME EQUIPMENT or an ME EQUIPMENT part complying with specified requirements on construction, marking and documentation in order to protect against HAZARDS of ignition of flammable anaesthetic mixtures.
APG	Rating for ME EQUIPMENT or an ME EQUIPMENT part complying with specified requirements on construction, marking and documentation in order to protect against HAZARDS of ignition of flammable anaesthetic mixtures.
	Distribution packages shall not be exposed to sunlight.
	Contents of the distribution packages are fragile therefore it shall be handled with care.
	Distribution packages shall be kept away from rain and be kept in dry conditions.
	Distribution packages shall be stored, transported, and handled within temperature limits indicated.
	This is the correct upright position of the distribution packages for transport and/or storage.
	Maximum number of identical transport packages/items which may be stacked on the bottom package, where "5" is the limiting number.

	WARNING. General warning sign, Indicates a potentially hazardous situation Which, if not avoided, could result in death or serious injury.
	CATION. Indicates a potentially hazardous situation Which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property.
	Refer to instruction manual/booklet, to signify that the instruction manual/ booklet must be read.
IP20	The IP code (or International Protection Rating, sometimes also interpreted as Ingress Protection Rating), First Digit:(2) Protected against access to hazardous parts with a finger. Second Digit :(2) Degrees of protection against water indicated by the second characteristic numeral: Non-protected.

## 17 PRODUCT SPECIFICATIONS

Item	Parameter
the intended purpose of the devices and their inherent risks	Class II a
Protection against electric shock	Internally powered, Type BF applied part (CUFF) Quasi-application section (LCD, Enclosure)
Protection against harmful ingress of water or particulate matter	IP20
ME Equipment and ME Systems intended for use with flammable anaesthetics	Not a category AP or APG equipment
ME Equipment and ME Systems used in conjunction with OXYGEN RICH ENVIRONMENTS	Not used in an oxygen rich environment

Mode of operation	Continuous operation
CUFF circumference	Approx. 220mm to 320mm
Weight	Approx. 370g (containing CUFF, Battery)
Physical Dimensions(mm) (Length*Width*Height)	Approx. 106 x 145 x 68.5
Measurement method	Oscillometric method
Pressure Range	Pressure: 0mmHg to 295mmHg (0kPa to 39.3kPa)
Measurement Range	Systolic pressure: (8.0~34.0) kPa, [(60~255) mmHg] Diastolic pressure: (4.0~26.0) kPa, [(30~195) mmHg] Pulse rate: (40 to 180) beats/minute
Accuracy	Blood pressure: $\pm 3$ mmHg ( $\pm 0.4$ kPa) of reading Pulse rate: $\pm 5\%$ of reading
Memory volume	Up to 99 reading with time and date stamp
Normal working environment	+5°C to +40°C, 15% to 85%RH; 80kPa to 106kPa
Storage and transportation environment	-20°C to +55°C; 10% to 93%RH; 70kPa to 106kPa
Voice function	Support voice broadcast
Automatic shutdown	Automatic shutdown after about 60 seconds without operation
Pressurization way	Intelligent control of air pump automatic pressurization
Quick exhaust mode	Intelligent control of automatic fast deflation
Pressure and Pulse detection	Resistive pressure sensor
Method(s) of sterilization	Need no sterilization
Battery service	Battery Life: About 300 times in charge. Battery recharge: Approx. 200 measurements with fully charged battery.
Power source	3.7V, 400mAh Lithium battery Input: 5.0V $\pm 1.0$ A
Lifetime	5 years
Shelf Life	Monitor: 5 years, Package: 1 year, battery: 2 years (The monitor must be recharged every 6 months, otherwise the shelf life will end).

If there is any performance improvement, the above specifications are subject to change without notice.

## 18 LIMITED WARRANTY (Warranty Card)

The Blood Pressure Monitor, excluding the Cuff, not including batteries, is warranted to be free from defects in materials and workmanship appearing within 5 years from the date of purchase when used in accordance with the instructions provided with the monitor. The Cuff is warranted to be free from defects in materials and workmanship appearing within one year from the date of purchase when the monitor is used in accordance with the instructions provided with the monitor. The above warranties extend only to the original retail purchaser.

We will, at our option, repair or replace without charge any unit or cuff covered by the above warranties. Repair or replacement is our only responsibility and your only remedy under the above warranties.

**Note:** The Monitor must be recharged every 6 months, otherwise the Limited warranty and the shelf life will end. The warranty of batteries is 6 months.

To obtain warranty service contact Customer Service by calling [redacted] for the address of the repair location and the return shipping and handling fee.

Enclose the Proof of Purchase. Include a letter, with your name, address, phone number, and description of the specific problem. Pack the product carefully to prevent damage in transit. Because of possible loss in transit, we recommend insuring the product with return receipt requested.

THE FOREGOING IS THE SOLE WARRANTY PROVIDED BY BSX IN CONNECTION WITH THIS PRODUCT, AND BSX HEREBY DISCLAIMS ANY OTHER WARRANTIES EXPRESS OR IMPLIED INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, IMPLIED WARRANTIES AND OTHER TERMS THAT MAY BE IMPOSED BY LAW, IF ANY, ARE LIMITED IN DURATION TO THE PERIOD OF THE ABOVE EXPRESS WARRANTY.

BSX SHALL NOT BE LIABLE FOR LOSS OF USE OR ANY OTHER SPECIAL, INCIDENTAL, CONSEQUENTIAL OR INDIRECT COSTS EXPENSES OR DAMAGES.

This warranty provides you with specific legal rights, and you may have other rights that vary by jurisdiction. Because of special local requirements, some of the above limitations and exclusions may not apply to you.

### **FCC Warning Statement**

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. 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.