

BLOOD PRESSURE MONITOR + KIT

THIS IS A TRADITIONAL PAPER MANUAL



FOR A BETTER INTRODUCTION, VISIT OUR ONLINE GUIDE

GREATERGOODS.COM/0602

We keep our digital guides up to date with helpful videos and FAQ's based on questions from our users. Follow the link to view setup information, activate your warranty, and contact customer support.

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| \triangle | Symbol for "CAUTION" - These notes must be observed to prevent any damage to the device. | | Symbol for "TYPE BF APPLIED PARTS" |
|-------------|--|------------|--|
| | | | Symbol for "THE OPERATION GUIDE MUST BE READ" |
| <u> </u> | Symbol for "MANUFACTURER" | (3) | |
| SN | Symbol for "SERIAL NUMBER" | X | Symbol for "ENVIRONMENT PROTECTION" - Waste electrical products should not be disposed |
| === | Symbol for "DIRECT CURRENT" | | of with household waste. Please recycle where facilities exist. Check |
| | Symbol for "MANUFACTURE DATE" | | with your local authority or retailer for recycling advice. |

Safety/Caution Information

↑ CAUTION -

- Consult your physician before measuring blood pressure, especially if you have any of the following conditions: hypertension, diabetes, arteriosclerosis, kidney or vascular disease, or any conditions affecting circulation.
- Do not change medication use or dosage based on measurement from this device.
 Take medication as prescribed by your physician. Only a physician is qualified to dianose and treat high blood pressure.
- · This device is not intended to be a diagnostic device.
- This device is intended for adult use only. Keep the unit out of reach of infants, children, or pets.
- This device is not intended for use on extremities other than the arm or for functions other than obtaining a blood pressure measurement. Do not use this device for any other purpose.
- Do not confuse self-monitoring with self-diagnosis. If you are taking medication, consult your physician to determine the most appropriate time to measure your blood pressure.
- If the cuff pressure exceeds 300 mmHg, the unit will automatically deflate.
 Should the cuff not deflate when pressures exceeds 300 mmHg, detach the cuff from the arm and press the START/STOP button to stop inflation.
- The equipment is not AP/APG equipment and not suitable for use in the presence of a flammable anesthetic mixture with air of with oxygen or nitrous oxide.
- · Do not touch battery output and the patient simultaneously.
- Avoid strong electromagnetic field radiated interference signals or electrical fast transient/burst signals.
- This device is contraindicated for any female who may be suspected of, or is pregnant.
 Besides provided inaccurate readings, the affects of this device on the fetus are unknown.
- This unit is not suitable for continuous monitoring during medical emergencies or operations.
- Do not disassemble or attempt to repair this device or any of its components. Doing so will void the warranty.
- Do not use this device near flammable gasses (anesthetic gas, oxygen, hydrogen) or when flammable liquids (alcohol) are present.
- Use only BALANCE™ authorized parts and accessories. Parts and accessories not approved for use with this device may damage the unit.

Introduction

Welcome to your new Balance Blood Pressure Monitor. We have designed this monitor to be as user-friendly as possible to ensure that you can use it with ease.

This model detects your blood pressure measurement by using the oscillometric method, which turns your blood pressure into a digital reading. With the oscillometric method, no stethoscope is needed. The model features blood pressure measurement, pulse rate measurement, two user modes, 60-entry memory storage per user, and a backlit LCD display for easy readability.

Please read the manual thoroughly before using this product.

OUR PROMISE

We're committed to creating 5-star products.

If we haven't delivered on our promise, please contact us.

For the best possible experience with your product,

please visit greatergoods.com/0602.

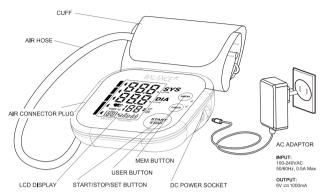


Device



| SYMBOL | DESCRIPTION | EXPLANATION |
|------------------|----------------------------------|--|
| SYS | Systolic blood pressure | High pressure result |
| DIA | Diastolic blood pressure | Low pressure result |
| ■ mmHg | mmHg (millimetres of mercury) | Measurement unit of blood pressure |
| Pu l /min | Pulse per minute | Beats per minute (BPM) |
| •22 | Irregular heartbeat | Blood pressure monitor is detecting an irregular heartbeat during measurement. |
| 1 | Grade | Displays grade of blood pressure |
| Lo+ | Low batteries | Batteries are low and need to be replaced |
| BB BB | Memory | The displayed measurement value is from the memory feature |
| ям 88:88 | Current time | Month/Day/Year – Hour/Minute |
| ▼ | Deflating | Cuff is deflating |
| USER 12 | User ID | Start measurement and save the results for USER 1 or USER 2 |

Device (cont.)



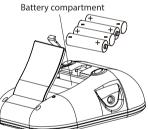
Installing and Replacing the Batteries

- 1. Open battery cover.
- **2.** Install the batteries by matching the correct polarity, as shown.
 - *Always use AAA batteries.
- 3. Close the cover.

Replace the batteries whenever $L_0 + \square$ shows, the display dims, or when the display does not light up.



- · Remove batteries if the device is not likely to be used for some time.
- The old battery is harmful to the environment. Do not dispose with other daily trash.
- · Remove the old battery from the device and follow your local recycling guidelines.
- Do not dispose of batteries in fire. Batteries may explode or leak.

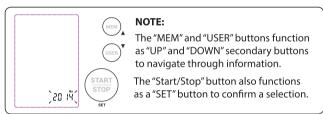


Setting Date, Time, and Measurement Unit

START

It is important to set the clock before using your blood pressure monitor, so that a time stamp can be assigned to each record that is stored in the memory.

- 1. When the display is off, hold the "Start/Stop" button for about 3 seconds to enter setup mode.
- 2. Press the "UP" arrow (MEM button) or the "DOWN" arrow (USER button) to change the year, then press the "SET" button to confirm the selection.



3. Once you select "SET," the next steps will appear on the screen as the following:

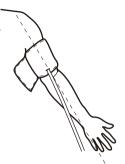


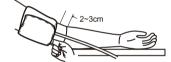
4. After setup is complete, the screen will display "done", show each of the entered settings, and turn off. The monitor is now ready to use.

Measurements

Fastening the Cuff

- Fasten the cuff on your upper arm, then position the tube off-center toward the inner side of the arm in line with the little finger.
- The cuff should be snug but not too tight. You should be able to insert one finger between the cuff and your arm.





3. Sit comfortably with your arm resting on a flat surface.

The middle of the cuff should be at the level of the right atrium of the heart. Before starting the measurement, sit comfortably with legs uncrossed, feet flat on the floor, back and arm supported.

IMPORTANT

- Resting for 5 minutes before measuring will give you the best reading.
- Wait at least 3 minutes between measurements. This allows your blood circulation to recover.
- For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, position of upper arm, or as directed by a physician.

Measurements (cont.)

Starting the Measurement

- With the monitor off, press the "Start/Stop" button to turn on the monitor.
- If necessary: Toggle which user you want to measure as by pressing the "USER" button
- **3.** Press the "Start/Stop" button again. The blood pressure monitor will begin the reading and finish the entire measurement.
- **4.** Press the "Start/Stop" button to power off, otherwise the monitor will automatically turn off within 1 minute of the reading.







· A CAUTION ·

- 1. When using this device, pay attention to the following situation, which may interrupt blood flow and influence blood circulation of the patient, thus causing injury to the patient: too frequent and consecutive measurements; the application of the cuff and its pressurization on any arm where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present; or inflating the cuff on the arm on the side of a mastectomy.
- 2. Do not apply the cuff over a wound, otherwise it can cause further injury.
- 3. Do not inflate the cuff on the same limb to which other monitoring ME EQUIPMENT is applied because this could cause temporary loss of function of the monitoring ME EQUIPMENT.
- **4.** Do not kink the connection tube. Otherwise, the cuff pressure may continuously increase, which can prevent blood flow and result in injury to the patient.

Memory

Recalling Records

- **1.** When the monitor is off, press the "MEM" button.
- If necessary: Toggle which user you want to view history for by pressing "USER."
- **3.** Press "MEM" once more, and the average value of the last three records show for that user.
- 4. Continue selecting entries or hold the "MEM" button to scroll through previous records quickly. Press the "USER" button to switch back and forth between users



Understanding Records

NOTE: The date and time of the record will show alternately.



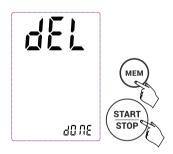


Memory (cont.)

Deleting Records

- **1.** When the monitor is off, press the "MEM" button.
- Select user, then hold down the "MEM" and "Start/Stop" buttons simultaneously.
- 3. When the "Del done" screen is presented, all the records have been erased. Then, the display will turn off.

WARNING: This deletes all records.



Tips/Maintenance

Tips for Measurement

It can cause inaccuracy if the measurement is taken under the following circumstances:

- · Measuring within 1 hour of eating or drinking
- · Measuring after tea, coffee, or smoking
- · Measuring within 20 minutes after taking a bath
- · Measuring when talking or moving your fingers
- · Measuring in a very cold environment
- · Measuring when needing to use the restroom

Maintenance

In order to get the best performance out of your monitor, please follow the below instructions:

- · Store monitor in a dry place
- Avoid contact with water; clean it with a dry cloth if needed
- · Do not attempt to clean the resizable cuff with water
- · Never submerge monitor or cuff in water

Indications for Use

The Balance Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and heartbeat rate for adults with an arm circumference ranging from 22cm to 42cm. It is intended for adult indoor use only.

About Blood Pressure

What is the difference between systolic pressure and diastolic pressure?

When ventricles contract and pump blood out of the heart, the blood pressure reaches its maximum value in the cycle, which is called systolic pressure. When the ventricles relax, the blood pressure reaches its minimum value in the cycle, which is called diastolic pressure.

What is the standard blood pressure classification?

The chart below is the standard blood pressure classification by the American Heart Association (AHA).



Blood discharging

| This chart reflects blood pressure categories defined by the American Heart Association. | | | |
|--|---------------------------|-----|----------------------------|
| Blood Pressure Category | Systolic mmHg (upper#) | | Diastolic mmHg (lower#) |
| Normal | less than 120 | and | less than 80 |
| Prehypertension | 120 – 139 | or | 80 – 89 |
| High Blood Pressure (Hypertension) Stage 1 | 140 – 159 | or | 90 – 99 |
| High Blood Pressure (Hypertension) Stage 2 | 160 or higher | or | 100 or higher |
| Hypertensive Crisis (Emergency care needed) | Higher than 180 | or | 110 or higher |

About Blood Pressure (cont.)

Why does my blood pressure fluctuate throughout the day?

- Individual blood pressure varies throughout the day. It is also affected by the way you fasten your cuff and your measurement position. Please make sure you measure your blood pressure under the same conditions each time you take a measurement.
- 2. Variations in the pressure can occur, due to certain medicines being taken.
- 3. Waiting at least 3 minutes between measurements is recommended.

Does it matter which arm I use when measuring?

It is acceptable to use either arm when measuring. However, to obtain the most consistent readings possible, it is suggested that you use the same arm each time you measure your blood pressure.

About Blood Pressure (cont.)

Why is the blood pressure I get from the hospital different from home?

Your blood pressure can vary throughout the day due to many factors such as weather, your emotions, exercise, etc.

When measuring your blood pressure at home, please check the following situations that could be causing a false measurement:

- · The cuff is too loose or too tight
- The cuff is not secured properly
- · Not placing the cuff correctly around the arm
- · If you feel anxious, nervous, or are not relaxed
- · Not resting your arm correctly
- · Measuring too quickly after a previous reading

Irregular Heartbeat Detector

This Blood Pressure Monitor is equipped with an intelligent function of Irregular Heartbeat Detector (IHB). During each measurement, this equipment records the heartbeat intervals and works out the standard deviation. If the calculated value is larger than or equal to 15, this equipment will light up the IHB symbol on the screen when displaying the results.

The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heartbeat was detected during measurement. Usually this is NOT a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that the device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

Troubleshooting

| PROBLEM | SYMPTOM | CHECKTHIS | SOLUTION |
|------------------|--|---|--|
| | Display will not light up. | Batteries are exhausted | Replace with new batteries |
| No power | | Batteries are inserted incorrectly | Insert the batteries correctly |
| Low batteries | Display is dim or La + icon is showing | Batteries are low | Replace with new batteries |
| | E1 shows on screen | The cuff is not secure | Refasten the cuff and then measure again |
| | E2 shows on screen | The cuff is too tight | Readjust cuff to a comfortable fit and measure again |
| | E3 shows on screen | The pressure of the cuff is excessive | Relax for a moment and then measure again |
| Error message | E10 or E11 shows on screen | The monitor detected motion, talking, or the pulse is too poor while measuring | Relax for a moment and then measure again |
| message | E20 shows on screen | The measurement process does not detect the pulse signal | Loosen the clothing on the arm and then measure again |
| | E21 shows on screen | The measurement failed | Relax for a moment and then measure again |
| | EExx shows on screen | A calibration error occurred | Retake the measurement. If the problem persists, contact our customer service department for further assistance. |

Device Specifications

| Power supply | Battery powered mode: 6VDC 4×AAA batteries Adaptor powered mode: 6V AC Use recommended cord | | |
|--|---|--|--|
| Display mode | Digital LCD display with blue backlight V.A.60×40.5mm | | |
| Measurement mode | Oscillographic testing mode | | |
| Measurement range | Rated cuff pressure: 0mmHg~300mmHg Measurement pressure: (40mmHg-230mmHg) pulse value: (40-199) beat/minute | | |
| Accuracy | Pressure: 5°C-40°Cwithin± 3mmHg pulse value:±5% | | |
| Normal working condition | Temperature:5°C to 40°C Relative humidity ≤85% Atmospheric Pressure: 645mmHg ~ 795mmHg | | |
| Storage & transportation condition | Temperature:-20°C-60°C Relative Humidity 10%-93% Atmospheric Pressure: 375mmHg ~ 795mmHg | | |
| Measurement perimeter of the upper arm | About 22cm~42cm | | |
| Net Weight | Approx.175 g(Excluding the dry cells) | | |
| External dimensions | Approx.110×110×40mm | | |
| Attachment | 4×AAA batteries,user manual,storage bag AC adapter, insert card | | |
| Mode of operation | Continuous operation | | |
| Degree of protection | Type BF applied part | | |
| Protection against ingress of water | IP21 | | |
| Software Version | V01 | | |
| WARNING: No modifi | cation of this equipment is allowed. | | |

Standards List/FCC/EMC Guide

Complied Standards List

| Risk management | ISO 14971: 2007 Medical devices — Application of risk management to medical devices |
|---|--|
| Labeling | ISO 15223-1: 2012 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements |
| User manual | EN 1041: 2008 Medical equipment manufacturers to provide information |
| General Requirements For Safety | IEC 60601-1: 2005+A1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| Electromagnetic compatibility | IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard:Electromagnetic compatibility - Requirements and tests |
| Performance requirements and Clinical Investigation | IEC 80601-2-30:2009 Medical electrical equipment- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers ISO 81060-2:2009 Non-invasive sphygmomanometers Part 2: Clinical investigation of automated measurement type. |
| Software life-cycle processes | IEC 62304:2006 2008 Medical device software - Software life cycle processes |

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.

EMC Guidance

- 1. MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS.
- Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, and walkie-talkies can affect this equipment and should be kept at least a distance d=3, 3 ma way from the equipment.

(Note: As indicated in Table 6 of IEC 60601-1-2:2007 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields d=3, 3m at an IMMUNITY LEVEL of 3V/m)

Warranty

Warranty Information

Your Blood Pressure Monitor is warranted by the manufacturer against defects in materials and workmanship for two (2) years from the original purchaser from the date of purchase. Proof of purchase is required.

The warranty is void if the product has been subjected to mechanical damage or mistreatment, such as immersion. This warranty is in lieu of all other warranties, and limits the liability of the manufacturer. This warranty gives you certain legal rights and you may have other rights depending on which state the product was purchased in.

Manufactured by: Guangdong Transtek Medical Electronics Co., Ltd **Company:** Guangdong Transtek Medical Electronics Co., Ltd **Address:** Zone B, No.105, Dongli Road, Torch Development District, Zhongshan, 528437, Guangdong, China

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