

Model 0605

BALANCE ^g

WRIST BLOOD PRESSURE MONITOR MANUAL

CUSTOMER SUPPORT

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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/0605.



SAFETY INFORMATION



This device is intended for adult use only. This device is intended for non-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the wrist or for functions other than obtaining a blood pressure measurement. Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure. Do not begin or end medical treatment without asking a physician for treatment advice. If you are taking medication, consult your physician to determine the most appropriate time to measure your blood pressure. Never change a prescribed medication without consulting your physician.

If the cuff pressure exceeds 40 kPa (300 mmHg), the unit will automatically deflate. Should the cuff not deflate when pressures exceeds 40 kPa (300 mmHg), detach the cuff from the wrist 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 or with oxygen or nitrous oxide. This device cannot be used with HF surgical equipment at the same time. This device is not intended for patient transports outside a healthcare facility.

Please do not attempt to repair the unit yourself in the event of malfunctions. Only have repairs carried out by authorized service centers. Please report to manufacturer if any unexpected operation or events occur. Please use the soft cloth to clean the whole unit. Don't use any abrasive or volatile cleaners.

SAFETY INFORMATION (cont.)

The operator shall not touch output of batteries and the patients simultaneously. Do not use the monitor under the conditions of strong electromagnetic field (e.g. medical RF equipment) that radiates interference signal or electrical fast transient / burst signal. The user must check that the equipment functions safely and see that it is in proper working condition before being used. Please use ACCESSORIES and detachable parts specified / authorized by MANUFACTURER.

Otherwise, it may cause damage to the unit or danger to the user /patients. Manufacturer will make available on request circuit diagrams, component parts lists, etc. This unit is not suitable for continuous monitoring during medical emergencies or operations. Otherwise, the patient's wrist and fingers will become anesthetic, swollen, and even purple due to a lack of blood.

Please use the device under the environment which was provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced. During use, the patient will be in contact with the cuff.

This device will not cause any potential allergic reaction or contact injury. The device doesn't need to be calibrated with two years of reliable service. Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines. When the device was used to measure patients who have common arrhythmias, such as atrial or ventricular premature beats or atrial fibrillation, the best result may occur with deviation. Please consult your physician about the result. This device is contraindicated for any female subject who may be suspected of, or is pregnant. Besides providing inaccurate readings, the effects of this device on the fetus are unknown.

SAFETY INFORMATION (cont.)

The device has been evaluated clinically using manual cuff/stethoscope auscultation as the reference. Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff / stethoscope auscultatory method, within the limits prescribed by the American National Standard, manual, electronic, or automated sphygmomanometers.

The materials of the cuff have been tested and found to comply with requirements of ISO 10993-5:2009 and ISO 10993-10:2010.

INTRODUCTION / INDICATIONS FOR USE

The Balance Blood Pressure Monitor is intended for use in measuring blood pressure and heartbeat rate with wrist circumference ranging from 13.5 cm to 21.5 cm (about 5"-8½"). It is intended for adult indoor use only.

FEATURES:

Systolic blood pressure

Diastolic blood pressure

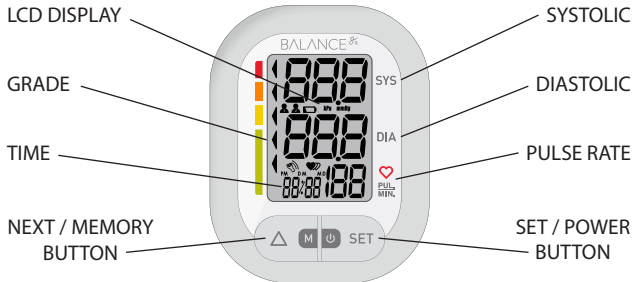
Pulse rate

60 records for each user










WARNING: No modification of this equipment is allowed.

MONITOR COMPONENTS



NOTE: While the monitor only has two buttons, each button has two functions. Throughout the manual, you will see the buttons referred to by the function being described in that step (e.g. Press and hold the “POWER” button to turn on then press the “SET” button to select your user and begin measuring).

SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic blood pressure	High pressure result
DIA	Diastolic blood pressure	Low pressure result
	Pulse per minute	Beats per minute (BPM)
	Shocking reminding	Shocking will result as inaccurate
kPa	kPa (kiloPascal)	Measurement unit of blood pressure
mmHg	mmHg (millimetres of mercury)	Measurement unit of blood pressure
	Irregular Heartbeat Detection	Irregular heartbeat
	Current time	Month / Day / Year – Hour / Minute
	Blood Pressure Grade	Displays grade of blood pressure
	User ID	Start measurement and save the results for USER 1 or USER 2
	Low batteries	Batteries are low and need to be replaced

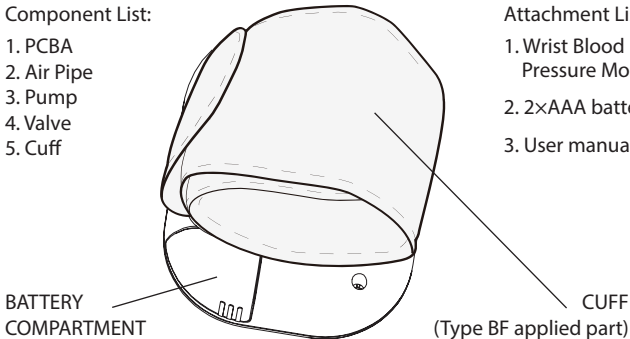
MONITOR COMPONENTS (cont.)

Component List:

1. PCBA
2. Air Pipe
3. Pump
4. Valve
5. Cuff

Attachment List:


1. Wrist Blood Pressure Monitor
2. 2×AAA batteries
3. User manual

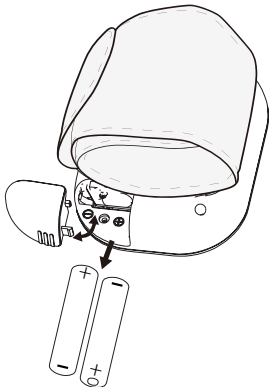


INSTALLING AND REPLACING THE BATTERIES

- Slide off the battery cover.
- Install the batteries by matching the correct polarity, as shown here. Always use the correct battery type (2 x AAA batteries).
- Replace the cover.

Replace the batteries whenever the following happen:

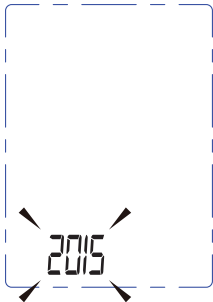
-  appears.
- The display dims.
- The display does not light up.



SETTING TIME, DATE, AND MEASUREMENT UNIT

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.
(year: 2014 - 2054 , time format: 24 H /12 H)

1. When the monitor is off, hold and press the "NEXT" button for about 3 seconds to enter into setting mode. The blinking numeral represents [YEAR].
2. Press the "NEXT" button to change the [YEAR]. Each press will increase the numeral by 1 in a cycling manner.



- 3.** When you find the right year, press the "SET" button to confirm your selection and it will turn to the next step.
- 4.** Repeat steps 2 and 3 to confirm [MONTH] and [DAY].
- 5.** Now the monitor is in time format setting. Repeat steps 2 and 3 to confirm the time format between 24 hours or 12 hours.
- 6.** Repeat steps 2 and 3 to confirm [HOUR] and [MINUTE].
- 7.** Repeat steps 2 and 3 to confirm the [MEASUREMENT UNIT].
- 8.** After confirming the measurement unit, the LCD will display all the settings you have done once again and then turn off.

FASTEN THE CUFF

1. Remove all accessories (watch, bracelet, etc.) from your wrist. If your physician has diagnosed you with poor circulation in one wrist, use the other one.
2. Roll or push up your sleeve to expose the skin.
3. Apply the cuff to your wrist with your palm facing up.
4. Position the edge of the cuff about 1-1.5 cm away from your palm.
5. Fasten the wrist cuff around your wrist, leaving no extra room between the cuff and your skin. If the cuff is too loose, the measurement will not be accurate. Rest for 5 minutes before measuring. Wait at least 3 minutes between measurements. This allows your blood circulation to recover.



NOTE: For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, on the same wrist, or as directed by a physician.

START THE MEASUREMENT

1. When the blood pressure monitor is off, press the "POWER" button to turn it on, the LCD will display the user ID first. Press the "NEXT" button to change the user ID between User 1 and User 2. Press the "SET" button to confirm, and it will finish the whole measurement for the selected user.
2. Press the "POWER" button to power off, otherwise the device will turn off within 1 minute.



LCD display



Adjust to zero



Inflating &
measuring



Display and save
the result.

Patients with Hypertension:

The middle of the cuff should be at the level of the right atrium of the heart. Before starting measurement, please sit comfortably with your legs uncrossed, feet flat on the floor, back and wrist supported. The patient must relax as much as possible and not talk during the measurement procedure. Sit comfortably with your tested wrist resting on a flat surface.

RECALLING RECORDS

1. When the monitor is off, press the "MEMORY" button to show the user selection screen. Use the "NEXT" button to switch between users. Use the "SET" button to select the user you want to view. This will display the average of the latest three measurements.

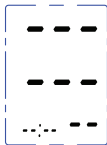
2. Press "NEXT" again, it will display the latest measurement of result, date, and time. Press the "NEXT" button again, it will display the next record, and so on. During the process of displaying the results, if there is no operation, the blood pressure monitor will turn off after one minute. Or you can press the "POWER" button to turn it off.

NOTE: The record number, date, and time will display alternately.

DELETE THE RECORDS

You can delete all results of the selected user by following the steps below:

1. In the memory mode, press and hold the "SET" button for 3 seconds, the flash display "dEL" will show.
2. Press "NEXT" to toggle between YES and NO. Press "SET" to confirm selection. If YES is selected, the unit will delete the records and turn off.
3. If there is no record, this display will show:



MAINTENANCE

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

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.

STANDARD CLASSIFICATION

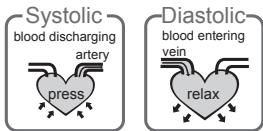
This chart reflects blood pressure categories defined by the American Heart Association.

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

Q: What is the difference between systolic pressure and diastolic pressure?

A: 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.



Q: Does it matter which wrist I use when measuring?

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

ABOUT BLOOD PRESSURE (cont.)

Q: Why does my blood pressure fluctuate throughout the day?

A: 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. Variations in pressure can also occur due to certain medicines being taken. Waiting at least 3 minutes between measurements is recommended.

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

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

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.




NOTE: 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.

BATTERY CAUTIONS

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

TROUBLESHOOTING

PROBLEM	SYMPTOM	CHECK THIS	SOLUTION
No power	Display will not light up.	Batteries are exhausted	Replace with new batteries
		Batteries are inserted incorrectly	Insert the batteries correctly
Low batteries	Display is dim or  icon is showing	Batteries are low	Replace with new batteries
Error message	E1 shows on screen	The inflation is too low	Refasten the cuff and then measure again
	E2 shows on screen	The cuff is not secure	Refasten the cuff and then measure again
	E3 shows on screen	Can't inflate the air during the process of measurement	Refasten the cuff and then measure again
	E4 shows on screen	The cuff is too tight	Refasten the cuff and then measure again

PROBLEM	SYMPTOM	CHECK THIS	SOLUTION
Error message	E5 shows on screen	The pressure of the cuff is excessive	Relax for a moment and then measure again
	E6 shows on screen	The voltage of the batteries is too low during inflation	Measure again. If E6 appears again, replace the batteries
	E10 or E11 shows on screen	The monitor detected motion while measuring	Relax for a moment and then measure again
	E20 shows on screen	Pulse not detected	Remove clothing covering the wrist or tighten the cuff and then measure again
	E21 shows on screen	Incorrect measurement	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: 2 AAA batteries (3V DC)

Display mode: Digital LCD V.A. 32mm × 45mm

Measurement mode: Oscillographic testing mode

Measurement range:

Rated cuff pressure: 0mmHg~300mmHg(0kPa ~ 40kPa)

Measurement pressure: SYS: 60mmHg~230mmHg (8.0kPa~30.7kPa)

DIA: 40mmHg~130mmHg (5.3kPa~17.3kPa)

Pulse value: (40 -199) beat / minute

Accuracy: Pressure:

5°C - 40°C within ± 0.4 kPa (3 mmHg)

Pulse value: $\pm 5\%$

Normal working condition:

Temperature: 5°C to 40°C

Relative humidity: $\leq 85\%$ RH

Atmospheric pressure: 86 kPa to 106 kPa

Storage & transportation condition:

Temperature: -20°C to 60°C

Relative humidity: 10% RH to 93% RH

Atmospheric pressure: 50 kPa to 106 kPa

Measurement perimeter of the wrist: About 5.3 in - 8.4 in

Net Weight: Approx. 105 g (Excluding the dry cells)

External dimensions: Approx. 3.4in x 2.6in x 0.9in (Exclude the cuff)

Mode of operation: Continuous operation

Degree of protection: Type BF applied part

Protection against ingress of water: IP22

Software version: V01

Device classification: Internally Powered ME Equipment

COMPLIED STANDARDS LIST

Risk management: ISO/EN 14971:2012 Medical devices — Application of risk management to medical devices

Labeling: ISO/EN 15223-1:2012 Medical devices. Symbols to be used with medical device labels, labeling, 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. IEC 60601-1-11 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Electromagnetic compatibility: IEC/EN 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. ANSI/AAMI SP10:2002/A2: 2008 Manual, electronic, or automated sphygmomanometers

Software life-cycle processes: IEC/EN 62304:2006+AC: 2008 Medical device software -Software life cycle processes

Usability: IEC 62366 Medical devices - Application of usability engineering to medical devices (IEC 62366:2007) IEC 60601-1-6 Medical electrical equipment - Part 1-6 : General requirements for basic safety and essential performance - collateral standard : Usability










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) This equipment needs to be installed and put into service in accordance with the information provided in the user manual.
- 2) 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 $d=3, 3\text{m}$ away 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 $d=3, 3\text{m}$ at an IMMUNITY LEVEL of 3V/m).

LABEL INFORMATION

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

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.

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