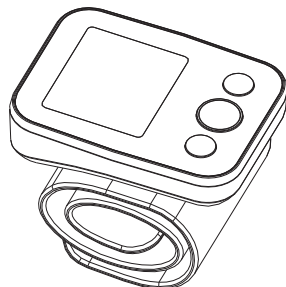


Owner's Manual

Wrist-type Fully Automatic Blood Pressure Monitor

Model BC43

Wrist Type



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Version: Z

Date of Issue: 2023.05

Contact Information

The lay operator or lay responsible or ganization should contact the manufacturer or the representative of manufacturer.
-for assistance,if needed,in setting up,using or maintaining the product,or
-to report unexpected operation or events.

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Safety Notice

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Thank you for purchasing the BC43 Blood Pressure Monitor. The unit has been constructed using reliable circuitry and durable materials. Used properly, this unit will provide yeas of satisfactory use.

Indications for use: The Wrist-type Fully Automatic Digital Blood Pressure monitors are intended to measure blood pressure (systolic and diastolic) and pulse rate of adults and adolescents over 12 years of age.
All functions can be used safely and values can be read out in one LCD DISPLAY. Measurement position is on adult upper wrist only.
The PATIENT is an intended OPERATOR.

Blood pressure measurement determined with this device are equivalent to those obtained by a trained observer using the cuff/ stethoscope auscultation method, within the limits prescribed by the Recognized Consensus Standard (IEC 80601-2-30) for electronic sphygmomanometers.

Precautions to Ensure Safe, Reliable Operation

1. Do not drop the unit. Protect it from sudden jars or shocks.
2. Do not insert foreign objects into any openings.
3. Do not attempt to disassemble the unit.
4. Do not crush the pressure cuff.
5. If the unit has been stored at temperatures below 0 °C, leave it in a warm place for about 15 minutes before using it. Otherwise, the cuff may not inflate properly.
6. If the unit has been stored at temperatures above 40 °C, leave it in a cool place for about 15 minutes before using it. Otherwise, the cuff may not inflate properly.
7. Do not store the unit in direct sunlight, high humidity or dust.
8. To avoid any possibility of accidental strangulation, keep this unit away from children and do not drape tubing around your neck.
9. Ensure that children do not use the instrument unsupervised; some parts are small enough to be swallowed.
10. Some may get a skin irritation from the cuff taking frequent readings over the course of the day, but this irritation typically goes away on its own after the monitor is removed.

Safety Notice

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Important Instructions Before Use

1. Do not confuse self-monitoring with self-diagnosis. Blood pressure measurements should only be interpreted by a health professional who is familiar with your medical history.
2. Contact your physician if test results regularly indicate abnormal readings.
3. If you are taking medication, consult with your physician to determine the most appropriate time to measure your blood pressure. NEVER change a prescribed medication without first consulting with your physician.
4. Individuals with serious circulation problems may experience discomfort. Consult your physician prior to use.
5. For persons with irregular or unstable circulation resulting from diabetes, liver disease, arteriosclerosis or other medical conditions, there may be variations in blood pressure values measured at the wrist versus at the upper arm. Monitoring the trends in your blood pressure taken at either the arm or the wrist is nevertheless useful and important.
6. People suffering from vascular constriction, liver disorders or diabetes, people with cardiac pacemakers or a weak pulse, and women who are pregnant should consult their physician before measuring their blood pressure themselves. Different values may be obtained due to their condition.
7. People suffering from arrhythmias such as atrial or ventricular premature beats or atrial fibrillation only use this blood pressure monitor in consultation with your doctor. In certain cases oscillometric measurement method can produce incorrect readings.
8. Too frequent measurements can cause injury to the patient due to blood flow interference.
9. The cuff should not be applied over a wound as this can cause further injury.

Safety Notice

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10. **DO NOT** attach the cuff to a limb being used for IV infusions or any other intravascular access, therapy or an arterio-venous (A-V) shunt. The cuff inflation can temporarily block blood flow, potentially causing harm to the patient.
11. The cuff should not be placed on the arm on the side of a mastectomy. In the case of a double mastectomy use the side of the least dominant arm.
12. Pressurization of the cuff can temporarily cause loss of function of simultaneously used monitoring equipment on the same limb.
13. A compressed or kinked connection hose may cause continuous cuff pressure resulting in blood flow interference and potentially harmful injury to the patient.
14. Check that operation of the unit does not result in prolonged impairment of the circulation of the patient.
15. Product is designed for its intended use only. Do not misuse in any way.
16. Product is not intended for infants or individuals who cannot express their intentions.
17. Prolonged over-inflation of the bladder may cause ecchymoma of your arm.
18. Do not disassemble the unit or wrist cuff. Do not attempt to repair.
19. Use only the approved wrist cuff for this unit. Use of other wrist cuffs may result in incorrect measurement results.
20. The system might produce incorrect readings if stored or used outside the manufacturer's specified temperature and humidity ranges. Make sure to store the blood pressure monitor, children, pets and pests are outside of accessible range.
21. Do not use the device near strong electrical or electromagnetic fields generated by cell phones or other devices, they may cause incorrect readings and interference or become interference source to the device.

Safety Notice

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22. The product contains a lithium battery, and do not discard the product in the fire or other environments that can easily cause a lithium battery to explode.
23. Dispose batteries properly; observe local laws and regulations.
24. Advising operator that Instruction manual/ Booklet must be consulted.
25. Only use a recommended class II AC Medical approved adaptor which comply with 2MOPP, and pass IEC 60601-1, IEC 60601-1-2(or FCC) standard . An unauthorized adaptor may cause fire and electric shock.
26. Do not use the device during transport vehicles for influencing measurement accuracy, such as patient transport in an ambulance or helicopter.
27. Contains small parts that may cause a choking hazard if swallowed by infants.
31. the blood pressure monitors equipped with bluetooth (BT) module is only transmit historical blood pressure (BP) from the subject device to a user-supplied digital device, and is not intended for active patient monitoring.
32. when the battery is being charged, the device should not be used to record blood pressure, for the sake of electrical safety.

WARNING SIGNS AND SYMBOLS USED	
	Keep off Sunlight
	Type BF Equipment
	Instructions For Use MUST be Consulted
	Discard the used product to the recycling collection point according to local regulations
IP 22	IP 22 indicate dustproof and waterproof grade. Number 2 indicate that Protected against solid foreign objects of 12.5 mm and greater; Number 2 indicate that Protection against vertically falling water drops when ENCLOSURE tilted up to 15°.
	Magnetic Resonance unsafe

Unit Illustration

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Federal Commulcation Commission (FCC) Interference Statement

1. 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. 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.
2. 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.
3. This equipment complies with radio frequency exposure limits set forth by the FCC for an uncontrolled environment.
4. This device must not be co-located or operating in conjunction with any other antenna or transmitter.

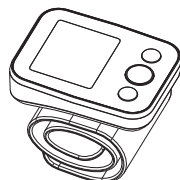
5. Essential performance:

Electrosurgery interference recovery	Refer 202.6.2.101 IEC 80601-2-30
Limits of the error of the manometer	Refer 202.12.1.102 IEC 80601-2-30
Reproducibility of the BLOOD PRESSURE DETERMINATION	Refer 201.12.1.107 IEC 80601-2-30

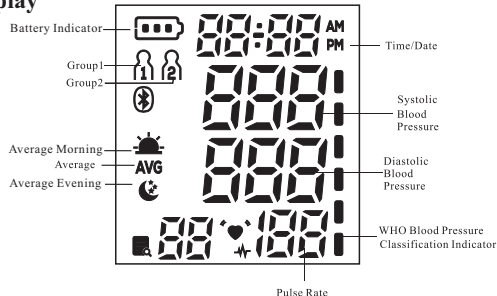
Unit Illustration

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Monitor Unit

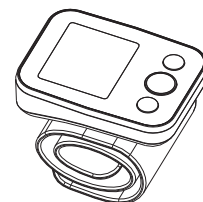


Display

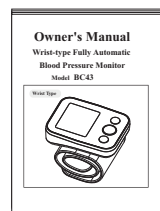


Contents

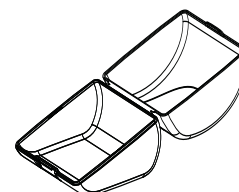
8



1. Monitor Unit



2. Owner's Manual



3. Plastic Storage Case

Important Testing Guidelines

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1. Avoid eating, exercising, and bathing for 30 minutes prior to testing.
2. Sit in a calm environment for at least 5 minutes prior to testing.
3. Do not stand while testing. Sit in a relaxed position while keeping your wrist level with your heart.
4. Avoid speaking or moving body parts while testing.
5. While testing, avoid strong electromagnetic interference such as microwave ovens and cell phones.
6. Wait 3 minutes or longer before re-testing.
7. Try to measure your blood pressure at the same time each day for consistency.
8. Test comparisons should only be made when monitor is used on the same wrist, in the same position, and at the same time of day.
9. This blood pressure monitor is not recommended for people with severe arrhythmia.
10. Do not use this blood pressure monitor if the device is damaged.

Quick Start

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1. Before first use, please carefully check the packaging is complete, if not complete please contact the seller for replacement. Every time before use, please check the equipment for obvious damage, if there is equipment has been damaged, please use caution. In turn open the color box, asylum package (or receive bag), remove the blood pressure monitor, check whether the parts is complete, normal blood pressure monitor for power self-checking, if the battery power is insufficient, the screen shows "LO" error code, if the battery is normal, the device automatically after about 3 seconds time date set into the interface. After the setting, can enter the blood pressure measurement mode. (See Figure A)

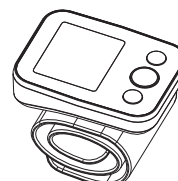


Figure A

2. Remove clothing from the wrist area . (See Figure B)
3. Rest for several minutes prior to testing. Wrap cuff around left wrist . (See Figure C)

Quick Start

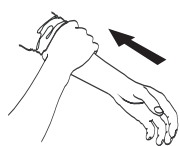


Figure B

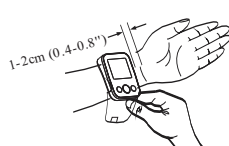


Figure C

4. Sit in a comfortable position and place wrist level with heart. (See Figure D)
5. Press "ON/OFF" button to start testing. (See Figure E)



Figure D



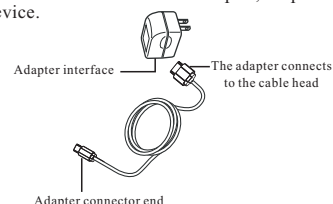
Figure E

Unit Operation

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Battery Installation

The device has a built-in lithium battery that must be recharged using a specific power adapter. When low battery indicator icon " " appears on the screen Please connect the power adapter to charge. When charging, The latest grid of the battery level symbol will flash until all grid numbers are displayed. Insert the adapter connector into the adapter interface, then insert the adapter into the socket, and then connect the adapter to the cable end. Insert the adapter interface on the device and press the on/off button to measure normally. (if this model has been packed) When you plug in the adapter, the screen power display changes, indicating that you are using the adapter for power. When the device is connected to an adapter, the power adapter is part of the entire device.



Note: Power supply is specified as part of ME EQUIPMENT. Do not use other non-standard adapters.

The above adapter parameters are as follows:

Input range: 100V-240V to 50/60Hz, 0.25A

Output range: 5.0V DC 1.0A, 5.0W

The interface at the adapter is USB-A port, and the interface at the device is USB-C port.

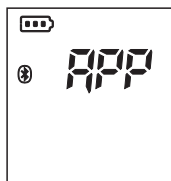
Unit Operation

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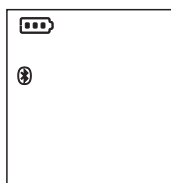
System Settings

1. Bluetooth connection

The device is turned on for the first time, and the screen displays as follows.



Click the button on the mobile device to enter pairing mode, and the Bluetooth icon on the screen will flash, as shown below. After pairing is completed, the device will automatically enter the time setting



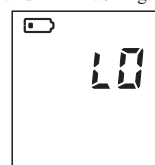
Unit Operation

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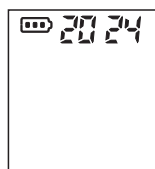
System Settings

1. Time/Date setting

First to electricity, battery installed, normal blood pressure monitor for power self-checking, if the battery power is insufficient, the screen shows "LO" error code and " " flashing.



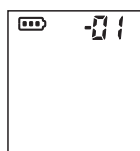
into the year set pattern, in the meantime, a flashing icon of the year is 0.5 seconds, press the button > year of increase, long press the key into the > can be adjusted quickly. Press the memory key to determine the current Settings year, the system default for year 2024.



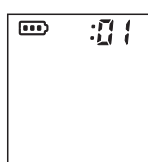
Unit Operation

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Determine the year after, enter in month setting mode, in the meantime, icon will display month scintillation a 0.5 seconds, press the keys into the > increase in plus, long press buttons or keys in > can be adjusted quickly. Press the open key to determine the current Settings in the system default for 1 month in September.



After the month of determining, into the day set patterns, in the meantime, display, 0.5 seconds icon will flash once, press the keys into the > plus the number of days, long press key into or > can quickly adjust the number of days. Press the open key to determine the date of the current setting, the system default date for no. 1.

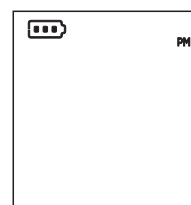
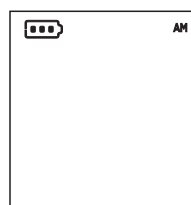


Unit Operation

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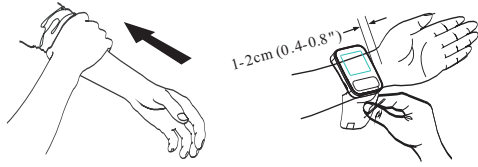
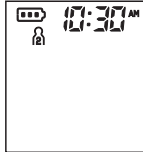
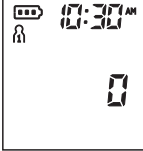
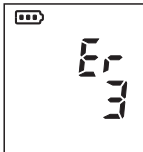
2. Time system setting

After determine the date, time set into the interface, in the meantime, according to time of 0.5 seconds icon will flash time, first set the hours, according to the first step in setting model to determine the time, if the first set is 12 h mode, the default time is 12:00 am, if the first step is 24 h mode, set the default time for 0:00, press the > button in the add hours, long press the key into the or > can quickly adjust hour, press the "Memory" key to determine the current setting hours.



3. Saved Settings

While in any setting mode, press "ON/OFF" button to turn the unit off. All information will be saved.

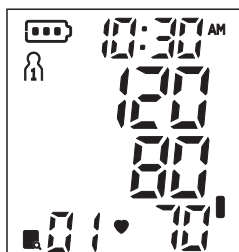
Unit Operation17 Note: If unit is left on and not in use for 1 minutes, it will automatically save all information and shut off. User memory group Settings This device has two memory group, each group has 120 memory value respectively. Determine the hours, minutes setting mode, enter in memory group setting mode,in the meantime, according to minutes 0.5 seconds icon will flash once,press the > button to switch memory groups. In sleep mode, press the “ON/OFF” button, the back of the screen lights up, and the current time, date and user memory group will be displayed after 2 seconds of full screen display.Memory group selection is completed, presses the button, switch machine, the measurement of blood pressure. When blood pressure within 30 seconds without operation, backlight closed, no operation within 60 seconds, enter a dormant state.  	Unit Operation18 Applying The Wrist Monitor Do not apply over clothing. If wearing a long sleeved shirt, be sure to roll sleeve back to forearm. Apply monitor to wrist as illustrated. Tighten cuff firmly as not to wiggle. 
Unit Operation19 Do not stand while testing. Sit in a comfortable position with back supported, feet flat on the floor with legs uncrossed. Place middle of the cuff at the level of the right atrium of the heart. 	Unit Operation20 Testing 1. Power On Under the main interface display, press the switch machine buttons, backlight automatically open.   2. Testing Blood pressure cuff pressure automatically, automatic stop, please keep quiet when measuring.If the cuff is not connected or cuff loose connection causes such as cuff pressure rise is unusual, the blood pressure cuff at start-up pump inflatable after a certain period of time, will stop the pump work, turn to wait for pressure, the screen shown above Err3. Please test cuff pneumatic connection state, can press "memory" button to enter to view memory or press the "start/stop" button to turn it off.
Unit Operation21    Note: in the process of the pressure must not be arbitrary shaking body, otherwise, the system will also to determine this for high blood pressure, and pressure again;	Unit Operation22 Blood pressure cuff pressure in the process of blood pressure measurement can be made. Armband internal pressure increases gradually, LCD real-time display the current pressure. When detected pulse, LCD screen flashing ♥ symbols, and display the current pressure corresponding to the heartbeat of cuff pressure value. Note: Do not speak, in the process of measuring twist arm, shaking body, etc., please keep quiet state.

Unit Operation

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4. Result Display

The screen will display measurements for systolic and diastolic blood pressure. A indicator representing the current measurement will appear next to the corresponding WHO Classification.



Note: Refer to Page 31~32 for detail WHO Blood Pressure Classification Information.

Unit Operation

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Irregular Heartbeat Indicator

If the monitor detects an irregular heart rhythm two or more times during the measuring process, the Irregular Heartbeat Symbol "♥" appears on screen along with measurement results. Irregular heartbeat rhythm is defined as rhythm that is either 25% slower or faster than the average rhythm detected while measuring systolic blood pressure and diastolic blood pressure. Consult your physician if the Irregular Heartbeat Symbol "♥" frequently appears with your test results.

Power Off

The "START/STOP" button can be pressed to turn off the unit in any mode. The unit can turn off the power itself about 1 minutes no operation in any mode.

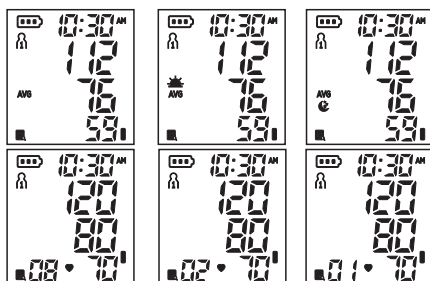
Safety Precaution: If pressure in arm cuff becomes too extreme while testing, press the "START/STOP" button to turn power off. The cuff pressure will rapidly dissipate once the unit is off.

Unit Operation

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Memory view and average view

In the main interface LCD screen all show self-checking, memory according to [memory] key value view, see the first is the average of the last seven days, and then the seven days before the measurement of mean and average in the afternoon in the morning, the last is the latest measurement data, and blood pressure by pressing enter key memory value view. According to the average switching, press V return on a liquid crystal display interface. On average, LCD shows average prompt "AVG", and display the corresponding average blood pressure classification information and classification identification on the morning of the afternoon.



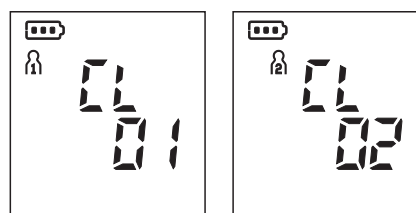
Unit Operation

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If you want to see other memory within the group, please user memory group set up in front of the boot, specific operation as shown in the "system Settings" in "User memory group Settings".

Memory Deletion

In the condition of main interface, press the memory button, enter the average interface. Through user button to select the user, long press > and memory button 5 seconds for user delete memory value. Delete memories for all memory groups, long press > and memory button 15 seconds for user delete all memory value.



Note: Memory cannot be recovered once it has been deleted.

If you want to delete the other set of memories, please user memory group set up in front of the boot, specific operation as shown in the "system Settings" in "User memory group Settings";

Unit Operation

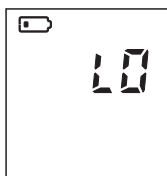
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Power Off

In any state, the boot can be fixed by press the "start/stop" button for 2 seconds to turn it off. If the device idle for 30 seconds, backlight closed, 60 seconds after the device has reached the "sleep" mode. Press any button except/key can be reactivated backlight. In the condition of error and low electricity, according to the key, open/equipment into "sleep" state immediately.

Low Battery Indicator

When measuring screen does not appear when the battery symbol, said the battery voltage is normal, sphygmomanometer can work normally. When the screen appear when measuring marks, said the battery voltage is low, please replace the battery, prevent blood pressure monitor can not work normally. Screen appears when measuring the flashing, and LCD screen will appear low voltage symbol "LO", sphygmomanometer automatic shutdown after about 5 s please immediately replace the battery, ensure the sphygmomanometer can normal use.

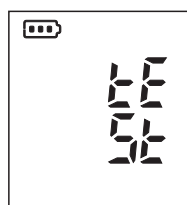


Unit Operation

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Static Pressure Measurement

While holding down the "ON/OFF" key, insert the "ON/OFF" until the "TEST" symbol is displayed on the screen. In this interface, press and hold the power button briefly to enter mode 1, where the interface displays as key detection. Press and hold the ">" key to enter the next static pressure mode, where static pressure status can be measured. In this mode, press and hold the ">" key briefly to enter version display, and press and hold the ">" key again to enter continuous measurement.



Note: Only Service personnel permitted to access to this mode, the mode unavailable in normal use.

Unit Operation

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Bluetooth requirements

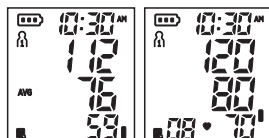
The monitor requires a device with:

- . Bluetooth 4.0 or later
- . Android 5.0 or later
- . IOS 9.0 or later

And works with:

- . iphone , iPod, iPad
- . Android Phones and Tablets

If the Bluetooth is turned on, the binding process will be automatically started to upload the internal memory data of the sphygmomanometer when the measurement is completed or the memory average is checked. In the data upload, BT symbol long display; After the transmission is complete, the BT symbol disappears. If there is no Bluetooth connection for more than 30 seconds, the device will report an error. The BT symbol will flash when the Bluetooth is not connected.



-Transfer your readings

1. As soon as your measurement is complete, open the app on your smart phone to transfer your readings.
2. You can view your blood pressure readings on the app.

Blood Pressure Information

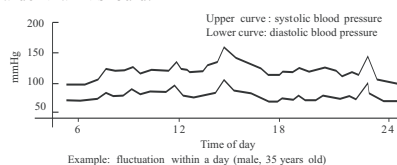
31

Blood Pressure

Blood pressure is the force of blood pushing against the walls of arteries. It is typically measured in millimeters of mercury (mmHg.) Systolic blood pressure is the maximum force exerted against blood vessel walls each time the heart beats. Diastolic blood pressure is the force exerted on blood vessels when the heart is resting between beats.

An individual's blood pressure frequently changes throughout the course of a day. Excitement and tension can cause blood pressure to rise, while drinking alcohol and bathing can lower blood pressure. Certain hormones like adrenaline (which your body releases under stress) can cause blood vessels to constrict, leading to a rise in blood pressure.

If these measuring numbers become too high, it means the heart is working harder than it should.

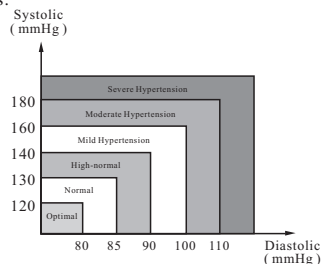


Blood Pressure Information

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Health Reminder

Hypertension is a dangerous disease that can affect the quality of life. It can lead to a lot of problems including heart failure, kidney failure, and cerebral hemorrhaging. By maintaining a healthy lifestyle and visiting your physician on a regular basis, hypertension and relative diseases are much easier to control when diagnosed in their early stages.



Note: Do not be alarmed if an abnormal reading occurs. A better indication of an individual's blood pressure occurs after 2-3 readings are taken at the same time each day over an extended period of time. Consult your physician if test results remain abnormal.

Blood Pressure Information

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Troubleshooting

Abnormal phenomenon	Cause analysis	Processing method
Abnormal sphygmomanometer	The armband is tied too tight or too loose, Or the arm strap is tied incorrectly.	Roll the armband correctly
	Move the arm during measurement of Electronic sphygmomanometer	Stay quiet, keep your arm steady, and do not move the monitor
	Speaking, nervous or emotional during measurement	Instead of talking, take deep breaths to calm your mood and relax your body
	Incorrect measurement posture	Adjust posture, see "Blood pressure gauge Wearing"
	There is interference in charging process or improper operation in measuring process	See operation Instructions.

The following table shows the error signs that may occur during measurement, possible causes and handling methods. Please measure again using the correct method

Error display	The cause of the problem	The solution
Er0	Production and development error	Please contact the manufacturer
Er1	Pulse rhythm error	Please fasten the cuff before measuring
Er2	Measurement range error	If the user can not resolve, please contact the manufacturer
Er3	Pneumatic System Error	Please fasten the cuff before measuring
Er4	Signal Error	Hold the arm or body still and measure again
Er5	Overinflation Error (>300mmHg)	Please fasten the cuff before measuring
Er6	System Error	Check whether the cuff is knotted or the vent valve is blocked. If the problem persists, contact the manufacturer
Er7	Bluetooth Error(Transmission Error)	Switch off the main unit, close the app, and deactivate and reactivate Bluetooth on your smartphone/tablet. Try to re-establish the connection.
Battery icon	Battery dead	Replace the battery or connect the power adapter (if any).

Note: If you cannot solve the abnormal situation by yourself, you can consult the manufacturer or the manufacturer's designated unit by phone. It is forbidden to disassemble and repair without permission. If necessary, professional maintenance personnel can ask the manufacturer for the list of components and circuit schematic diagram.

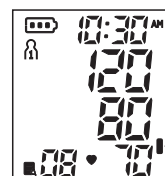
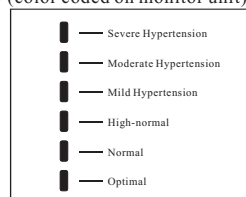
Blood Pressure Information

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WHO Blood Pressure Classification Indicator

The BC43 is equipped with a classification indicator based on established guidelines from the World Health Organization.

The chart below (color coded on monitor unit) indicates test results.



■ Blood Pressure Classification Indicator

Blood Pressure Q & A

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Q: What is the difference between measuring blood pressure at home or at a professional healthcare clinic?

A: Blood pressure readings taken at home are now seen to give a more accurate account as they better reflect your daily life. Readings can be elevated when taken in a clinical or medical environment. This is known as White Coat Hypertension and may be caused by feeling anxious or nervous.

Note: Abnormal test results may be caused by:

1. Improper cuff placement
Make sure cuff is snug-not too tight or too loose.
2. Improper body position
Make sure to keep your body in an upright position.
3. Feeling anxious or nervous
Take 2-3 deep breaths, wait a few minutes and resume testing.

Blood Pressure Q & A

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Q: What causes different readings?

A: Blood pressure varies throughout the course of a day. Many factors including diet, stress, cuff placement, etc. may affect an individual's blood pressure.

Q: Should I apply the cuff to the left or right wrist? What is the difference?

A: Either wrist can be used when testing, however, when comparing results, the same wrist should be used. Testing on your left wrist may provide more accurate results as it is located closer to your heart.

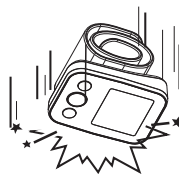
Q: What is the best time of day for testing?

A: Morning time or any time you feel relaxed and stress free.

Maintenance

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1. Avoid dropping, slamming, or throwing the unit.



2. Avoid extreme temperatures. Do not use outdoors.



Maintenance

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3. When cleaning the unit, use a soft fabric and lightly wipe with mild detergent. Use a damp cloth to remove dirt and excess detergent.



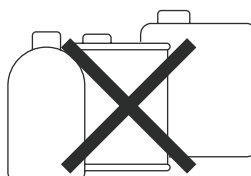
4. Cuff Cleaning: Do not soak cuff in water! Apply a small amount of rubbing alcohol to a soft cloth to clean cuff's surface. Use a damp cloth (water-based) to wipe clean. Allow cuff to dry naturally at room temperature. The cuff must be cleaned and disinfected before use between different users.



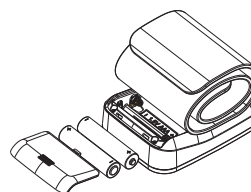
Maintenance

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5. Do not use petrol, thinners or similar solvents.



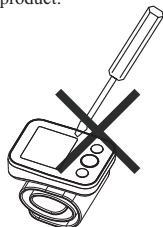
6. Remove batteries when not in operation for an extended period of time.



Maintenance

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7. Do not disassemble product.



8. It is recommended the performance should be checked every 2 years.

9. Expected service life: Approximately three years at 10 tests per day.

10. No service and maintenance while it is in use and maintenance only be performed by service personnel. Service and maintenance require parts, repair, technical support will be provided.

Specifications

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Product Description	Wrist-type Fully Automatic Blood Pressure Monitor	
Model	BC43	
Display	LCD Digital Display Size: 40.7mm x 36mm (1.60" x 1.42")	
Measurement Method	Oscillometric Method	
Measurement Range	Systolic Pressure	60mmHg ~ 260mmHg
	Diastolic Pressure	40mmHg ~ 200mmHg
	Pressure	0mmHg ~ 299mmHg
	Pressure	± 3mmHg
	Pulse	40 ~ 199 Beats/Minute
	Pulse	± 5%
Pressurization	Automatic Pressurization	
Memory	2X50 Memories in Two Groups with Date and Time	
Function	Irregular Heartbeat Detection	
	WHO Classification Indicator	
	Record of all measurements	
	Average for the last 7 days	
	Afternoon average for the last 7 days	

Specifications

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Function	Low Battery Detection	
	Automatic Power-Off	
	LED Screen	
	Bluetooth	
Power Source	3.7V Lithium battery or DC 5V1A adapter(charge only)	
Battery Life	50 measurements	
Unit Weight	Approx.xxg (x.xx oz)	
Unit Dimensions	Approx. 82mm×61.6mm×24.4mm(L x W x H) (3.23" x 2.43" x 0.96")	
Cuff Circumference	Fits wrist circumference 13.5-21.5 cm(5.3"-8.5")	
Operating Environment	Temperature	10°C ~ 40°C (50°F~104°F)
	Humidity	< 90%RH,non-condensing
	Pressure	800hPa~1050hPa
Storage Environment	Temperature	-20°C~55°C (-4°F~131°F)
	Humidity	< 90%RH,non-condensing
Transport Environment	Temperature	-20°C~55°C (-4°F~131°F)
	Humidity	≤93% RH

Specifications

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Ingress Protection Rating	IP 22
Classification	Internal Powered Equipment Type BF 

Continued

Specifications are subject to change without notice.

This Blood Pressure Monitor complies with the European regulations and bears the CE mark“CE 0123”.This blood pressure monitor also complies with mainly following standards (included but not limited):

Safety standard:

EN 60601-1 Medical electrical equipment part 1: General requirements for safety EMC standard:

EN 60601-1-2 Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential

Performance -- Collateral Standard:

Electromagnetic Disturbances –Requirements And Tests.

Specifications

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Performance -- Collateral Standard:
Electromagnetic Disturbances –Requirements And Tests.
Performance standards:
IEC80601-2-30, Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.
EN 1060-3 Non-invasive sphygmomanometers - Supplementary requirements for electromechanical blood pressure measuring systems.
ISO 81060-2, non-invasive sphygmomanometers - part 2: clinical validation of automated measurement type.

Specifications

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The Blood Pressure Monitor is guaranteed for 2-year from the date of purchase. If the Blood Pressure Monitor does not function properly due to defective components or poor workmanship, we will repair or replace it freely. The warranty does not cover damages to your Blood Pressure Monitor due to improper handling. Please contact local retailer for details.

Contact Information

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Electromagnetic Compatibility Information

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The device satisfies the EMC requirements of the international standard IEC 60601-1-2. The requirements are satisfied under the conditions described in the table below. The device is an electrical medical product and is subject to special precautionary measures with regard to EMC which must be published in the instructions for use. Portable and mobile HF communications equipment can affect the device. Use of the unit in conjunction with non-approved accessories can affect the device negatively and alter the electromagnetic compatibility. The device should not be used directly adjacent to or between other electrical equipment.

Table 1

Guidance and declaration of manufacturer-electromagnetic emissions	
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.	
Emissions test	Compliance
Radiated emission CISPR 11	Group 1, ClassB

Electromagnetic Compatibility Information

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Table 2

Guidance and declaration of manufacturer-electromagnetic immunity		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
IMMUNITY test	IEC 60601 test level	Compliance level
Radiated RF EM fields IEC 61000-4-3	3V/m or 10 V/m 80MHz-2.7 GHz 80%AM at 1kHz (See table 3)	3V/m or 10 V/m 80MHz-2.7 GHz 80%AM at 1kHz (See table 3)
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m; 50Hz or 60Hz	30 A/m; 50Hz or 60Hz
Electrostatic- discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Proximity magnetic field IEC 61000-4-39	See Table 5	See Table 5

Electromagnetic Compatibility Information

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Table 3

Guidance and declaration of manufacturer-electromagnetic immunity						
Nowadays, many RF wireless equipments have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. Arm-type Fully Automatic Digital Blood Pressure Monitor has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014. The customer and/or user should keep a minimum distance between RF wireless communications equipment and this medical equipment and/or systems as recommended below.						
Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 15kHz	1.8	0.3	27
450	430-470	GMRK 400 FRS 400	100 kHz Frequency 1.3MHz, 500	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 8.20, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1900	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMLS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, IEEE 802.11 b/g/n, IEEE 802.11ac, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

Electromagnetic Compatibility Information

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Table 4

Recommended separation distances between portable and mobile RF communications equipment and the device		
The device is intended for use in an electromagnetic environment in which radiated therefore disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.		
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m	
	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_{\text{L}}} \right] \sqrt{P}$	800 MHz to 2.7 GHz $d = \left[\frac{7}{E_{\text{L}}} \right] \sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
100	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.		
NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.		
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

Electromagnetic Compatibility Information

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Table 5

Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields		
Test frequency	Modulation	IMMUNITY TEST LEVEL(A/m)
30 kHz a)	CW	8
134.2kHz	Pulse Modulation α 2.1kHz	65α)
13.56MHz	Pulse Modulation α 50kHz	7.5 α)
a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT. b) The carrier shall be modulated using a 50% duty cycle square wave signal. c) r.m.s., before modulation is applied.		

Additional Notes

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Important Instructions Before Use

1. WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

2. WARNING: PORTABLE RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of Wrist-type Fully Automatic Digital Blood Pressure Monitor, including cables specified by the MANUFACTURER. Otherwise, degradation of the performance of this equipment could result.

3. The software identifier refer to the software evaluation report.

4. verify manometer pressure accuracy:

In the power down state, press and hold the " " button, and then install the batteries. Until the LCD screen is full, release the " " button.

When the LCD screen displays the double zero, the blood pressure meter is in static state. At this point, 500ml gas capacity, calibrated standard pressure gauge and manual pressure device can be connected to the sphygmomanometer through the sleeve interface of the sphygmomanometer, and manual pressure can be applied to the effective display range of the sphygmomanometer, and then the difference between the reading of the sphygmomanometer and that of the standard pressure gauge can be compared. This mode can be used to verify manometer pressure accuracy.

5. Contraindications:

Product is not intended for infants or individuals who cannot express their intentions.

6. Intended Use

The digital blood pressure monitor are reusable for clinical and home use and are non-invasive blood pressure measurement systems designed to measure the systolic and diastolic blood pressure and pulse rate of adolescents and adults individual by using a non-invasive technique, which is a well-known technique in the market called the "oscillometric method". it can measure the systolic blood pressure, diastolic blood pressure and pulse rate on up-arm, and the device is reusable for clinical or home use.

Additional Notes

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7. The patient is the operator:

the PATIENT is an intended OPERATOR.

the PATIENT Do not carry out other maintenance operations except to replace the battery.

8. WARNING:

Do not modify this equipment without authorization of the manufacturer.

9. ESSENTIAL PERFORMANCE Maintenance advice:

Pressure calibration will be carried out when this product leaves the factory. Patients can use the method described in the section "Verify Manometer Pressure Accuracy" to verify the accuracy. If the accuracy deviation is large, please contact the manufacturer to recalibration.

10. Mechanical strength and resistance to heat: The resistance to heat will be retained by device during the EXPECTED SERVICE LIFE of the ME EQUIPMENT.

11. Do not place the blood pressure monitor and cuff at will. It will cause asphyxiation if the child swallows or twine around his neck.

12. The cuff and the case of the blood pressure monitor have been tested for biocompatibility and do not contain allergenic or harmful materials. Please stop using it if allergy occurs during use.

13. Warning:

Non-professionals do not modify the equipment, otherwise it will make the equipment measurement is not accurate.

14. Warning:

Do not expose the equipment for a long time, otherwise it will reduce the performance of the equipment.

15. Warning:

This device is not used for children and pets

16. Clean:

The equipment can be cleaned by lay operator according to the cleaning procedures in the instructions

17. Warning:

Do not use a damaged cuff for blood pressure measurement.

18. Warning:

When measuring with the cuff, if the tester feels seriously uncomfortable, press the button of the blood pressure monitor to deflate the cuff, or remove the cuff directly from the arm.

Additional Notes

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19. Warning:

If an unexpected reading occurs, the operator can take several more measurements and consult a doctor.

20. Warning:

This equipment is used outside the specified environment, may damage the equipment, and may be inaccurate measurement.



Correct Disposal of This Product

(Waste Electrical & Electronic Equipment)

This marking shown on the product indicates that it should not be disposed with other household waste at the end of its life. To prevent potential harm to the environment or to human health, please separate this product from other types of wastes and recycle it responsibly. When disposing this type of product, contact the retailer where product was purchased or contact your local government office for details regarding how this item can be disposed in an environmentally safe recycling center. Business users should contact their supplier and check the terms and conditions of the purchasing agreement. This product should not be mixed with other commercial wastes for disposal. This product is free of hazardous materials.