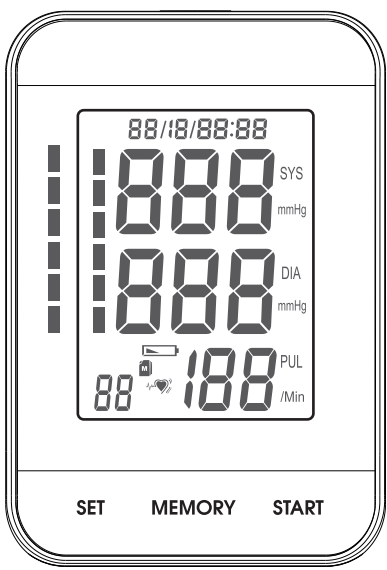




Blood Pressure Monitoring System



Owner's Manual Model : 3160A-1

Blood Pressure Owner's Manual

Dear 3160 System Owner :

Thank you for purchasing the Blood Pressure Monitoring System. This system is a fully automatic, digital blood-pressure measuring device for use on the upper arm, it enables very fast and reliable measurement of the systolic and diastolic blood-pressure as well as the pulse frequency by way of the oscillometric method of measuring.

This manual provides important information to help you operate this system correctly. Before using this product, please read the following contents thoroughly and carefully.

With the compact size and easy operation of this Blood Pressure Monitoring System, you can easily monitor your blood pressure by yourself at any time or place. In addition, this system can help you and your healthcare professionals to monitor and adjust your treatment plans, and keep your blood pressure under control. If you have other questions regarding this product, please contact the place of purchase.

- Type BF applied part.
- Read the instructions carefully before using this device.

IMPORTANT SAFETY PRECAUTIONS READ THIS BEFORE USE

1. Use this device **ONLY** for the intended use described in this manual.
2. Do **NOT** use accessories which are not specified by the manufacturer.
3. Do **NOT** use the device if it is not working properly or damaged.
4. Do **NOT** use the equipment where aerosol sprays are being used, or where oxygen is being administered.
5. Do **NOT** use under any circumstances on newborns.
6. This device does **NOT** serve as a cure for any symptoms or diseases. The data measured are for reference only. Always consult your doctor to have the results interpreted.
7. Keep the equipment and its flexible cord away from hot surfaces.
8. Do **NOT** apply the cuff to areas other than the place directed.
9. Do **NOT** remove plastic wrapping membrane to ensure the waterproof function.
10. Proper maintenance and periodically calibration are essential to the longevity of your device. If you are concerned about your accuracy of measurement, please contact local customer service for help.

KEEP THESE INSTRUCTIONS BEFORE YOU BEGIN

INTENDED USE

The 3160A-1 system is a system designed to measure the systolic and diastolic blood pressure and pulse rate by using a non-invasive technique in which an inflatable cuff is wrapped on the upper arm. It is intended for individuals age 18 and above for use at home and in clinical settings. The device is not to be used for the diagnosis of hypertension or for testing on newborns.

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TEST PRINCIPLE

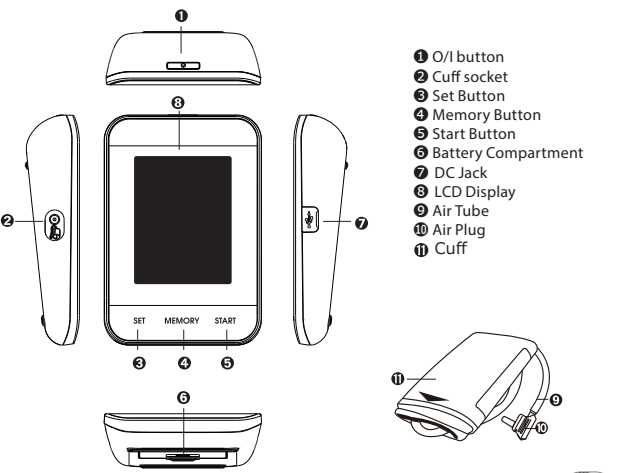
Blood pressure is measured non-invasively at the upper arm based on oscillometric method. If you have been diagnosed with a severe arrhythmia or irregular heartbeat, atrial or ventricular premature beats or atrial fibrillation, measurements made with this instrument should only be evaluated after consultation with the doctor or your healthcare professionals.

Electromagnetic interference

The device contains sensitive electronic components. Avoid strong electromagnetic fields in the direct vicinity of the device (e.g. mobile phones, microwave ovens. Electrical interference can lead to temporary impairment of the measuring accuracy).

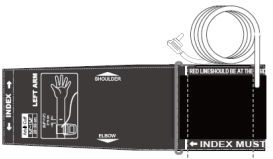
MONITOR OVERVIEW

Device



- 1 O/I button
- 2 Cuff socket
- 3 Set Button
- 4 Memory Button
- 5 Start Button
- 6 Battery Compartment
- 7 DC Jack
- 8 LCD Display
- 9 Air Tube
- 10 Air Plug
- 11 Cuff

3160 offers a wide range fan-type cuff, measuring size : 22~38cm, suitable for most of arm circumferences; Large cuff (measuring range 32~42cm) is available as special accessories.

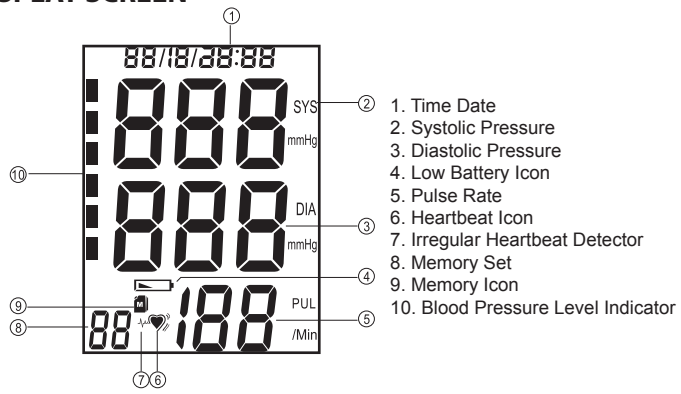


► The range index of cuff should fall into this range.

Do not use accessories or equipment which are not certified by manufacturer, they might increase emissions or decrease immunity of this system.

Blood Pressure Owner's Manual

DISPLAY SCREEN



- 1. Time Date
- 2. Systolic Pressure
- 3. Diastolic Pressure
- 4. Low Battery Icon
- 5. Pulse Rate
- 6. Heartbeat Icon
- 7. Irregular Heartbeat Detector
- 8. Memory Set
- 9. Memory Icon
- 10. Blood Pressure Level Indicator

ADVANTAGES OF AUTOMATIC BLOOD PRESSURE MONITOR

Blood Pressure Rate Indicator.

Blood pressure rate indicator is located along the left side in the display. The classification corresponds to ESH (European Society of Hypertension) ranges described in the table of the section «7.1. reference values».

After the measurement, there appears the color bars in the left part of the display: green zone - optimal blood pressure, yellow - elevated, orange - too high, red - dangerously high. This function helps you to self-orient in the measurement results.

Irregular Heartbeat Detection Advanced

IHB advanced is an oscillometric waveform technology which is more sensitive, but not specific, to identify varying rhythm symptom such as skipped heartbeats, abnormally rapid (Tachycardia), or slow (Bradycardia) pulse and Atrial Fibrillation occurring during the measurement, while regular IHB (Irregular Heart Beat) feature in the market is to detect a condition where the heartbeat rhythm varies by more than certain percentage from the average heartbeat detected during the measurement, If the symbol of IHB advanced appears on the display that means that certain abnormality in heart beat frequency was detected during the measurement. In this case, the result may deviate from your normal blood pressure - repeat the measurement. In most cases, this is no cause for concern. However, if the symbol appears on a regular basis (e.g. several times a week with measurements taken daily) we advise you to tell your doctor.

Please show your doctor the following explanation

Information for the doctor on frequent appearance of the Irregular Heartbeat Detector This instrument is an oscillometric blood pressure monitor that also analyses pulse frequency during measurement. The instrument is clinically tested. The symbol is displayed after the measurement, if pulse irregularities occur during measurement. If the symbol appears more frequently (e.g. several times per week on measurements performed daily) we recommend the patient to seek medical advice. The instrument does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

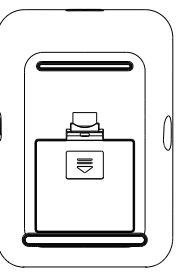
Blood Pressure Owner's Manual

SETTING THE MONITOR

Before using your monitor for the first time, check and update these settings. Make sure you complete the steps below and save the desired settings.

INSERT BATTERIES

After you have unpacked your device, first insert the attached batteries (4 x size AAA 1.5V) with the indicated polarity. The battery compartment is located at the bottom side of the device (see illustration).



NOTE

- After the warning appears, device is blocked till the batteries have been replaced.
- Please use «AAA» 1.5V Batteries.
- If the blood-pressure monitor is left unused for long periods, please remove the batteries.

USE A MAINS ADAPTOR

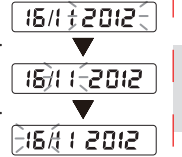
The 3160 Series Blood Pressure Monitor can be operated with a mains adapter (output 5 V DC / 600 mA).

- a. Connect the micro plug to the socket at the device right side.
- b. Plug the mains adapter (output 5 V DC / 600 mA) to a 100-240V electrical power socket

Setting the Date And Time

Insert batteries or press SET button, «2012» flashes on LCD.

- a. When the year flashes, press SET button until the correct year appears. Press MEMORY button to confirm and change to Month setting.
- b. When the month flashes, press SET button until the correct month appears. Press MEMORY button to confirm and change to date setting.
- c. Set the day, hour and minute in the same way as described above.



NOTE

If the meter is idle for 1.5 minutes during the setting mode, it will switch off automatically.

TESTING YOUR BLOOD PRESSURE

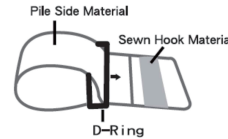
BEFORE MEASUREMENT

- Avoid caffeine, tea, alcohol and tobacco for at least 30 minutes before measurement
- Wait 30 minutes after exercising or bathing before measurement.
- Sit or lie down for at least 10 minutes before measurement.
- Do not measure when feeling anxious or tense.
- Take a 5-10 minutes break between measurements. This break can be longer if necessary, depending on your physical condition
- Keep the records for your doctor as reference.
- Blood pressure naturally varies between each arm. Always measure your blood pressure on the same upper arm.

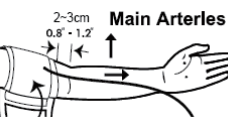
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FITTING THE CUFF PROPERLY

- a. Plug the cuff connector to the cuff socket on the device left side.

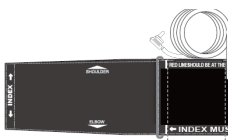


- b. Assemble the cuff as shown below. The smooth surface should be inside of the cuff loop and the metal D-ring should not touch your skin.



- c. Stretch your left (right) arm in front of you with your palm facing up. Slide and place the cuff onto your arm to let the air tube and artery mark region toward the lower arm.

Wrap and tighten the cuff above your elbow. The artery mark on the edge of the cuff should be approx. 0.8" to 1.2" (2 cm to 3 cm) above your elbow. Align the tube over the main arteries on the inside.



- d. Leave a little free space between the arm and the cuff : you should be able to fit two fingers between them. Remove all clothing covering or constricting the measurement arm.



- e. Press the hook material firmly against the pile material. The top and bottom edges of the cuff should be tightened evenly around your upper arm.

WARNING

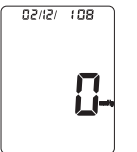
► If the cuff is relatively lower (higher) than the heart, the obtained blood pressure value could be higher (lower) than the actual value. A 15 cm difference in height may result in an error around 10 mmHg.

TAKING MEASUREMENTS

TAKING A SINGLE MEASUREMENT

Always apply the pressure cuff before turning on the monitor.

- a. Touch the Power button to turn the monitor on, press START button to begin. "0" displays on LCD which means device is under auto zero resetting.
- b. Pump starts to inflate and pressure in cuff increases to working pressure.



c. The heart symbol “♥” will show silently when pulse is detected during the inflation. When signal of pulse becomes strong, “♥” icon starts to flash.



d. After the measurement, the monitor displays the systolic pressure, diastolic pressure and pulse rate with a long beeper sounds. The reading is classified by color bar which divided according to WHO classification of blood pressure. If IHB is detected, LCD displays the Measurement with “♥” icon flashing 8 times to remind users of irregular heartbeat.

**NOTE**

- › If you press Power button during measurement, the monitor will be turned off.
- › If the pulse rate symbol is shown as “♥” instead of “♥”, this indicates that the monitor has detected an irregular heart beat.

MEMORY FUNCTION**Average of All Stored Memories**

Press MEMORY button, LCD shows a set of values averaged from all the stored memories of the selected user, accompanied by an icon «A».

**Viewing the Stored Values**

The device stores 90 most recent blood pressure test results along with respective dates and times in the monitor memory.

Reviewing Test Results

- Press MEMORY button, the single memory reading appears. Per the setting, the larger memory number indicates the newer record.
- Press MEMORY button again to display the next memory. Review all test results stored in the monitor.
- Delete the MEMORY With device in standby status, hold down SET button for 7 seconds until “CL” flashes on LCD, press SET button again to confirm with two short beeps and all memories removed.
- Exit the MEMORY Press START button and the monitor will turn off.

**NOTE**

The deleting operation will delete all the readings in memory, not only single reading.

MAINTENANCE**Battery**

Your monitor runs with four (4)1.5V AAA size alkaline batteries.

Low Battery Signal

The monitor will display the message below to alert you when the monitor power is getting low.

The symbol appears along with display messages: The monitor is functional and the result remains accurate, but it is time to change the batteries.

If the batteries are dead, the meter will turn it off immediately. The meter will not work till new batteries are inserted.

Replacing the Battery

To replace the batteries, make sure the monitor is turned off.

- Press the edge of the battery cover and lift it up to remove.
- Remove the old batteries and replace with four 1.5V AAA size alkaline batteries.
- Close the battery cover.

NOTE

- Replacing the batteries does not affect the test results stored in memory.
- As with all small batteries, these batteries should be kept away from small children. If swallowed, promptly seek medical assistance.
- Batteries might leak chemicals if unused for a long time. Remove the batteries if you are not going to use the device for an extended period (i.e., 3 months or more).
- Properly dispose of the batteries according to your local environmental regulations.

CARING FOR YOUR MONITOR

To avoid the monitor attracting dirt, dust or other contaminants, wash and dry your hands thoroughly before use.

Cleaning

- To clean the monitor exterior, wipe it with a cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft dry cloth. Do NOT flush with water.
- Do NOT use organic solvents to clean the monitor.
- Do NOT wash the pressure cuff.
- Do NOT iron the pressure cuff.

Monitor Storage

- Storage condition: -20°C to 55°C (-4°F to 131°F), below 95% relative humidity.
- Always store or transport the monitor in its original storage case.
- Avoid dropping or heavy impact.
- Avoid direct sunlight and high humidity.



No modifications of 3160A-1 Blood Pressure Monitoring System allowed by persons other than the manufacturer.

DETAILED INFORMATION**Reference Values**

Clinical studies show that adult diabetes is often accompanied by elevated blood pressure. People with diabetes can reduce their heart risk by managing their blood pressure along with diabetes treatment*4.

Monitoring your routine blood pressure trend helps you to know your body condition. Human blood pressure naturally increases after reaching middle age. This symptom is a result of continuous ageing of the blood vessels. Further causes include obesity, lack of exercise and cholesterol (LDL) adhering to the blood vessels. Rising blood pressure accelerates hardening of the arteries, and the body becomes more susceptible to apoplexy and coronary infarction. The recommended blood pressure range is as below :

Category	Systolic (mmHg)		Diastolic (mmHg)
Optimal	< 120	and	< 80
Normal*3	120–129	and/or	80–84
High normal	130–139	and/or	85–89
Grade 1 hypertension	140 – 159	and/or	90 – 99
Grade 2 hypertension	160–179	and/or	100–109
Grade 3 hypertension	≥ 180	and/or	≥ 110
Isolated systolic hypertension	≥ 140	and	< 90

Isolated systolic hypertension should be graded (1, 2, 3) according to systolic blood pressure values in the ranges indicated, provided that diastolic values are < 90mmHg.

Source: The European Society of Hypertension and European Society of Cardiology Task Force Members. 2007 ESH-ESC Practice Guidelines for the Management of Arterial Hypertension. J Hypertens 2007; 25: 1751-1762.

*1 American Diabetes Association. The Diabetes-Heart Disease Link Surveying Altitudes Knowledge and Risk (2002)

SYSTEM TROUBLESHOOTING

If you follow the recommended action but the problem persists, or error messages other than the ones below appear, please call your local customer service. Do not attempt to repair by yourself and never try to disassemble the monitor under any circumstances.

Error Messages

MESSAGE	CAUSE	WHAT TO DO
	Inflation or pressure error	Refit cuff tightly and correctly. If error still remains, contact local customer service for help. Refit cuff tightly and correctly.
	Blood pressure measurement error	Relax and repeat the measurement. If error still remains, contact local customer service for help. Relax and repeat the measurement.

MESSAGE	CAUSE	WHAT TO DO
	Improper movement detected during measurement (Artifact).	Refit cuff tightly and correctly.
	No pulse detected	Relax and repeat the measurement. If error still remains, contact local customer service for help. Review the instructions and repeat the test.
	Problems with the monitor	If the monitor still does not work, please contact the local customer service for help.

Troubleshooting

- If no display appears after pressing Power button

POSSIBLE CAUSE	WHAT TO DO
Batteries exhausted.	Replace the batteries.
Batteries incorrectly installed or absent.	Check that the batteries are correctly installed.

- If the heart rate is higher/lower than user's average

POSSIBLE CAUSE	WHAT TO DO
Movement during measurement.	Repeat measurement.
Measurement taken just after exercise.	Rest at least 30 minutes beforehand.

- If the result is higher/lower than user's average measurement

POSSIBLE CAUSE	WHAT TO DO
May not be in correct position while measuring.	Adjust to the correct position to measure.
Blood pressure naturally varies from time to time.	Keep in mind for next measurement.

- If the cuff inflates again while measuring

POSSIBLE CAUSE	WHAT TO DO
Cuff is not fastened.	Fasten the cuff again.

If user's blood pressure is higher than the pressure the device has inflated, the device will automatically increase the pressure and start to inflate again. Stay relaxed and wait for the measurement.

SYMBOL INFORMATION

Symbol	Referent	Symbol	Referent
	Consult instructions for use		Authorized representative in the European Community
	Manufacturer		Class II
	Serial number		Humidity limitation
	Caution, consult accompanying documents		Water-proof grade
	Type BF Equipment		CE mark
	Dispose of in accordance with the requirements of your country.		

SPECIFICATIONS**System Performance**

Power source	Four 1.5V AAA alkaline batteries, 5V 0.6A mains adaptor
Size of monitor w/o cuff	138 (L) x 94 (W) x 33 (H) mm,
Weight	260g ± 5g with batteries
Cuff Size	M (medium) : 22-38cm / 8.7"~14.9"
Memory	Maximum 90 memory records
Power saving	Automatic power off if system idle 1.5 min.
System operating condition	10°C to 40°C (50°F to 104°F), 15-95% relative maximum humidity
Meter storage condition	-20°C to 55°C (-4°F to 131°F), 15-95% relative maximum humidity

Blood pressure measurement performance

Pressure range	20 - 280 mmHg
Heart rate range	40 - 200 beat per minute
Systolic Measurement Range	50 mmHg -250 mmHg
Diastolic Measurement Range	30 mmHg -180 mmHg
Pulse Rate Measurement Range	40 - 200 beats / minute
Maximum inflation pressure	280 mmHg
Accuracy of Pressure	±3 mmHg or ±2% of the reading
Accuracy of Pulse rate	±4% of the reading
Measurement unit	mmHg

This device has been tested to meet the electrical and safety requirements of:

- IEC/EN 60601-1,
 - IEC/EN 60601-1-2
- Reference to Standards :
- EN 1060-1 /-3, NIBP-requirements
 - IEC60601-1 General requirement for safety
 - IEC60601-1-2 Requirements for EMC
 - EN1060-4, NIBP clinical investigation
 - AAMI / ANSI / IEC 80601-2-30, ANSI/AAMI/ISO 81060-2, NIBP requirements



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