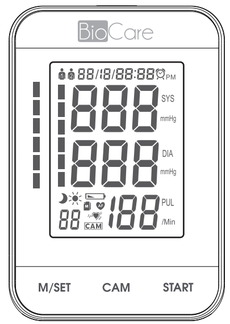
BioCare

Blood Pressure Monitoring System



Owner's Manual

Model : 3160A-3

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-3 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.

TEST PRINCIPLE

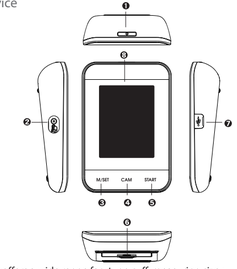
Blood pressure is measured non-invasively at the upper arm based on oscillometric method. If you have been diagnosed with a severe arrhythmia or irregular heartbeat, atrial or ventricular premature beats or atrial fibrillation, measurements made with this instrument should only be evaluated after consultation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

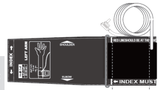
Device



1. O/I button
2. Cuff socket
3. M/SET Button
4. CAM 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.

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



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

DISPLAY SCREEN

1. Time Date
2. Alarm Clock
3. Systolic Pressure
4. Diastolic Pressure
5. Low battery Icon
6. Pulse Rate
7. AF Icon
8. CAM Mode
9. Heartbeat Icon
10. Irregular Heartbeat Detector
11. Memory Set
12. Memory Icon
13. Night Time Icon
14. Day Time Icon
15. Traffic Light Indicator
16. User Icon

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.

CAM technology – Clinically Accurate Measurement

CAM Technology - Clinically Accurate Measurement - provides you with the maximally accurate results of blood pressure measurement at home. Cardiologists recommend always take several repeated measurements and calculate their average values. The device in the CAM mode automatically takes 2 measurements in succession, analyzes the results and displays the ready values.

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 10 advice. The instrument does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

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).

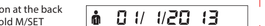
NOTE
- After the warning appears, device is blocked till the batteries have been replaced.
- Please use «AAA» 1.5V Batteries.
- If the blood-pressure monitor is left unused for long periods, please remove the batteries.

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.

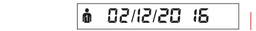
ENTER THE SETTING MODE

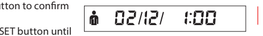
Insert batteries or press the O/I button at the back side of the device, then touch and hold M/SET button for 3 seconds until the "2013" flashes on the upper right corner.



SETTING THE DATE AND TIME

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





SETTING THE ALARM

This 3160 Series upper arm blood pressure monitor allows you to set 2 alarm clocks as a reminder to take medication or measurements.
a. Device in standby status, hold M/SET then hold CAM button. Release both buttons, "1" flashes on the screen, press M/SET button to toggle between alarm "1" and "2".
b. Touch CAM button, hour flashes, touch M/SET button to set the desired hours and touch CAM button for the next minute setting.

c. At the time of alarm, the meter beeps automatically. You can touch any button to silence it immediately.

How to switch off the alarm permanently : hold CAM button when the alarm number "1" or "2" is flashing, release as "On" is changed to "OFF" on the display

NOTE : The alarm times must be re-entered each time the batteries are replaced.

USER NUMBER SELECTION.

This 3160 Series system supports measurement for two users. Before measurement, make sure you set the unit for the intended user: device in standby status, hold START then M/SET button, till user icon switches to another one.

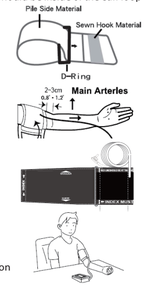
TESTING YOUR BLOOD PRESSURE

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.

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.



PROPER MEASUREMENT POSITION

Sit down for at least 10 minutes before measuring.
a. Place your elbow on a flat surface. Relax your hand with the palm facing up.
b. Make sure the cuff is about the same height as the location of your heart.
c. Press the O/I button to switch on the monitor.
d. Remain still and do not talk or move during the measurement.
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. Turn on the monitor by pressing the O/I button at the back side.

b. Touch START button, pump begins to inflate the cuff. The rising pressure in the cuff is shown on the display.

NOTE
In case the inflation pressure is not sufficient to determine measurement result, the monitor automatically re-inflates to a higher level.

c. Pressure in cuff increases to working pressure. Then pump stops and pressure falls.
d. The heart symbol " ♥ " starts to flash every heart beat once pulse is detected.
e. fter the measurement, systolic pressure, diastolic pressure, pulse rate and color bars classified from ESH (European Society of Hypertension) standards shows on the display.

f. If irregular heartbeat was detected during the measurement, LCD displays the "〰♥" icon to remind users of heartbeat irregularity. Please consult your doctor if it appears often.

CAM MODE

(CLINICALLY ACCURATE MEASUREMENT)
Always apply the pressure cuff before turning on the monitor.
In CAM mode, 2 measurements (at 20 sec break) are automatically taken in succession and the result is then automatically analyzed and displayed. Because people's blood pressure constantly fluctuates, a result determined in this way is more reliable than the one produced by a single measurement.

a. Turn on the device by pressing the O/I button at the back side of the monitor.
b. Touch CAM button, pump begins to inflate the cuff. LCD display shows CAM icon and the rising pressure in the cuff.
c. Pressure in cuff increases to working pressure. Then pump stops and pressure falls.

NOTE
In case the inflation pressure is not sufficient to determine measurement result, the monitor automatically re-inflates to a higher level.

d. The heart symbol " ♥ " starts to flash every heart beat once pulse is detected.
e. After the 1st measurement, the monitor automatically starts the 2nd measurement after 20 sec countdown.
f. After the 2nd measurement, the device analyzes the1st and 2nd measurement values: if sys BP1- sys BP 2 >/= 15 mmHg, dia BP1 - dia BP2 >/= 10 mmHg, CAM mode will automatically start the 3rd measurement after another 20 sec countdown.

NOTE
In case the 1st and/or 2nd pulse rate </= 60, device willautomatically take 4 times measurement in succession.

g. The CAM measured systolic pressure, diastolic pressure, pulse rate and color bars classified from ESH(European Society of Hypertension) standards show on the display.
h. If irregular heartbeat was detected during the measurement, LCD displays the " 〰♥ " icon to remind users of heartbeat irregularity. Please consult your doctor if it appears often.
i. If LCD displays the " 〰♥ " icon quite often, please consult your doctor to check what kind of arrhythmias you may have. It is important for early diagnostic of atrial fibrillation.

MONITOR MEMORY

Press O/I button at the back side of the device, the monitor is turned on and stays standby.

AVERAGE OF ALL STORED MEMORIES
Touch M/SET button, LCD shows a set of values averaged from all the stored memories of the selected user, accompanied by an icon "A".

AVERAGE OF ALL STORED DAY-TIME MEMORIES
Press M/SET button again, LCD shows another set of values averaged from all the stored day-time (4:00~9:59) taken measurements, accompanied by an icon "A" and ☀ .

NOTE
Heart attack and stoke occurs more frequently in the morning. This feature averages the morning readings between 4:00 and 9:59AM to ident i fy morning hypertensions.

AVERAGE OF ALL STORED NIGHT-TIME MEMORIES
Press M/SET button once more, LCD shows the other set of values averaged from all the stored night-time (17:00~1:59) taken measurements, accompanied by an icon "A" and ☽ .

MEMORY RECALL
The device stores 90 most recent blood pressure test results along with respective dates and times in the monitor memory for each of two users.

Reviewing Test Results
a. Touch M/SET button again after you see the average of all stored night-time memories, the single memory reading appears.
b. Per the setting, the first reading you see is the last blood pressure result. Touch M/SET button again, the next measurement eg. M89, as well as the previous 88 measurements (M88, M87… M1) can be displayed one after the other.

NOTE ：CAM icon will show on LCD if the measurement is taken under CAM mode.

DELETE ALL STORED MEMORIES.
With device in standby status, hold down M/SET button for 14 seconds until "CL" flashes on LCD, press M/SET button again, all the stored memories inside is removed.
Before you delete all the readings stored in the memory, please make sure you will not need to use them any more at a later time.

DOWNLOADING RESULTS ONTO A COMPUTER

This device is able to be used with a personal computer running URIGHT Health Care Management System. All stored memory readings can be transferred to your computer via the attached micro USB cable.

a. Software installation Download the software from website, then click setup for installation of BioCare corproation.
b. Data Transmission Connect the monitor to your computer via micro USB cable, LCD immediately displays three lines to indicate successful connection and data transmission is now available.

NOTE
During the whole process of USB connection, the monitor is completely controlled by the software system.

MAINTENANCE

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.

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.
	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

1. 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.

2. 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.

3. 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.

4. 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	EC REP	Authorized representative in the European Community
	Manufacturer		Class II
SN	Serial number		Humidity limitation
	Caution, consult accompanying documents	IP21	Water-proof grade
	Type BF Equipment	CE 0197	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

CE 0197 -20°C 55°C 15% 95%

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