

BIOS
Diagnostics™



Hypertension
CANADA

BLOOD PRESSURE MONITOR | With Atrial Fibrillation Screening

Instruction Manual
Model: 3MS1-4Y

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BIOS VP of Marketing - Mark Beaton accepts the 2017 Hypertension Canada Certificate of Excellence from Angelique Berg, CEO of Hypertension Canada

Trusted by Canadians for 3 Generations

At BIOS Diagnostics™, we are proud of our legacy in blood pressure monitoring in Canada. From the early 1930's to 1987 we manufactured "Tycos" brand professional blood pressure equipment for doctors and hospitals in Canada.

In the 1970's we pioneered the first blood pressure devices for monitoring at home, and in the 1980's we introduced digital technology in Canada. We haven't been counting, but we know that millions of our home-use monitors have been used by Canadians in the last 30 years.

All BIOS Diagnostics™ devices are developed in collaboration with physicians and clinically tested to prove their measurement accuracy. For more information on clinical tests and other BIOS medical products, visit our website at www.biosmedical.com.

If you have questions about this device or blood pressure monitoring at home, email us at support@biosmedical.com or call the **BIOS Medical Hotline 1-866-536-2289**.

Home Blood Pressure Monitor with Atrial Fibrillation Screening

Instruction Manual

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1. Introduction

Thank you for purchasing the BIOS Diagnostics™ Home Blood Pressure Monitor with Atrial Fibrillation Screening. Designed for convenient and easy operation, this device provides a simple, yet accurate method to measure your blood pressure.

Your blood pressure is an important parameter that can be used to monitor your health. This device enables you to monitor your blood pressure regularly, and maintain a record of your blood pressure measurements. You can then use this record to assist your physician in diagnosing and maintaining a healthy blood pressure level.

Indications for Use:

This blood pressure monitor (3MS1-4Y) is intended to measure the systolic/diastolic pressure, and pulse rate of an adult individual by using a non-invasive oscillometric technology. This device is designed to be portable, and used in both home and professional environments for every day blood pressure monitoring.

1.1 Features

The 3MS1-4Y is a fully automatic, digital, blood pressure measuring device with a unique fuzzy logic technology as well as patented MAM and AFIB technologies. It can store up to 200 blood pressure readings.

It provides a fast and reliable measurement of systolic and diastolic blood pressure as well as heart rate using the oscillometric measurement method.

AFIB detection is the world's leading digital blood pressure measurement technology for the early detection of atrial fibrillation (AFIB) and hypertension. These are the two top risk factors of heart disease and stroke which increase the risk of getting a stroke or heart disease in the future. It is important to detect AFIB and hypertension at an early stage, even though you may not experience any symptoms. Appropriate treatment can reduce your risk of suffering a stroke. For this reason, it is recommended that you visit your doctor when the device gives an AFIB signal during your blood pressure measurement. The AFIB algorithm has been clinically investigated by several prominent clinical investigators and showed that the device detects patients with AFIB at 97-100% certainty.^{1,2}

- **MAM - Averaging Mode technology** used in the device provides accurate measurements. Using three consecutive measurements, your result is calculated and displayed as a single averaged measurement on the display screen.
- **AFIB - Atrial Fibrillation Detector technology** icon is displayed when atrial fibrillation is detected during a blood pressure reading.
- **Blood Pressure Analyzer Software** allows you to download, record and chart your readings to accurately monitor your daily readings. The Blood Pressure software can be downloaded for free from www.biosmedical.com

1 Kearley K, Selwood M, Van den Bruel A, Thompson M, Mant D, Hobbs FR et al.: Triage tests for identifying atrial fibrillation in primary care: a diagnostic accuracy study comparing single-lead ECG and modified BP monitors. *BMJ Open* 2014; 4:e004565

2 Wiesel J, Arbesfeld B, Schechter D: Comparison of the Microlife blood pressure monitor with the Omron blood pressure monitor for detecting atrial fibrillation. *Am J Cardiol* 2014; 114:1046-1048

This powerful medical tool automatically stores all your blood pressure readings. By clicking the viewing options the user can review the readings in multiple forms including: by date, morning vs. evening readings, isolated systolic or diastolic or pulse. The automatic graph clearly shows your blood pressure history with highs and lows. Charts and graphs can even be printed or emailed to your doctor!

This device is easy to use and has been proven in clinical studies to provide excellent accuracy. Before using the 3MS1-4Y, read this instruction manual carefully and keep it in a safe place.

1.2 Important Information

Refer to the following sections to learn about important safety instructions and how to take care of the BIOS Diagnostics™ Home Blood Pressure Monitor with Atrial Fibrillation Screening.

1.2A Safety Information

- Self-measurement means control, not diagnosis or treatment. Your values must always be discussed with your doctor or a physician who is familiar with your family history.
- If you are undergoing medical treatment and receiving medication, consult your doctor to determine the most appropriate time to measure your blood pressure. Never alter the dosages of any medication without direction from your doctor.
- Your blood pressure depends on several factors, such as age, gender, weight and physical condition. It also depends on the environment and your state of mind at the time of measurement. In general, your blood pressure is lower when you are asleep and higher when you are active. Your blood pressure may be higher when recorded at a hospital or a clinic and may be lower when measured in the relaxing comfort of your home. Due to these variations, we recommend that you record your blood pressure regularly at home as well as at your doctor's clinic.
- Try to record your blood pressure regularly at the same time of the day and under the same conditions. This will help your physician detect any extreme variations in your blood pressure and thus treat you accordingly.
- Morning Hypertension (> 135 / 85 mmHg): Recently, several studies have identified elevated cardiovascular risks (heart failure, stroke, angina) associated with "morning hypertension". There is a typical rise in blood pressure during the physiological changes from sleep to arising for the day.
- The ideal time to measure your blood pressure is in the morning just after you wake up, before breakfast and any physical activity, and in the absence of the urge to urinate. If this is not possible, try to take the measurements later in the morning, before you start any physical activity. Relax for a few minutes before you record your blood pressure.
- Your blood pressure increases or decreases under the following circumstances:

Blood pressure is higher than normal:

- When you are excited, nervous, or tense
- While taking a bath
- During and after exercise or strenuous physical activity
- When it is cold
- Within one hour after meals
- After drinking tea, coffee, or other caffeinated drinks

- After smoking tobacco
- When your bladder is full

Blood pressure is lower than normal:

- After consuming alcohol
- After taking a bath

- The pulse display is not suitable for checking the frequency of heart pacemakers.
- If you have been diagnosed with a severe arrhythmia or irregular heartbeat, vascular constriction, liver disorders, or diabetes, have a cardiac pacemaker, or are pregnant, measurements made with this instrument should only be evaluated after a consultation with your doctor.
- Take care while handling the batteries in the device. Incorrect usage may cause battery fluid leakage.

To prevent such accidents, refer to the following instructions:

- Insert batteries with the correct polarity.
- Turn off power after use. Remove and store the batteries if you are not planning to use the device for an extended period of time.
- Do not mix different types, brands, or size of batteries. This may cause damage to the product.
- Do not mix old and new batteries.
- Remove batteries and dispose of them according to the proper regulations in your area.
- Do not disassemble batteries or expose them to heat or fire.
- Do not short-circuit the batteries.
- Do not use rechargeable batteries.

1.2B Care of the Device

For prolonged life of your blood pressure monitor, note the following instructions:

- **Do not** drop or bang the unit. Prevent sudden jerks, jars, or shocks to the device to prevent damage.
- **Do not** insert any foreign objects in any device openings or vents.
- **Do not** disassemble the unit.
- If the unit has been stored at very low or freezing temperatures, allow to reach room temperature before using it.
- **Do not** store the unit in direct sunlight, high humidity, or in places with a lot of dust.
- Clean the device with a soft dry cloth. Do not use gasoline, thinner or similar solvents. Carefully remove spots on the cuff with a damp cloth and soap. Do not wash the cuff.
- **Do not** use the device if you think it is damaged or if anything appears unusual.
- Ensure that children do not use this device unsupervised; some parts are small enough to be swallowed.
- Using the unit in the immediate vicinity of mobile phones, microwave appliances or other devices with strong electromagnetic fields may result in impaired functioning.
- **Do not** use this device close to strong electromagnetic fields, such as mobile telephones or radio installations. Keep a distance from such devices when using this unit.

1.2C Comparing Readings to Other Blood Pressure Devices

Many questions arise when two blood pressure devices are compared in an effort to check accuracy. An accurate comparison requires repeatable measurements under the same conditions to “reference device” with known accuracy. Significant time is required to reduce naturally occurring blood pressure variability during the test. The subject should be seated comfortably with feet flat on the floor, and have rested for 5 minutes before the first reading to allow blood pressure levels to stabilize.

The patient's back, elbow and forearm should be supported, and the middle of the cuff should be at the level of the right atrium. There should be no talking or moving during the measurement and if comparing to an aneroid gauge or mercury column, observers should avoid parallax and be careful not to round measurements.

The most accurate way to compare devices is to take two readings at the same time. However, most people and doctor's offices do not have the equipment necessary to measure blood pressure from two devices simultaneously. To take sequential measurements properly requires a pair of initial measurements to determine the subject's blood pressure level: first with the reference equipment, followed by 60 seconds, then with the monitor-under-test. The actual accuracy test requires three pairs of measurements with 60 seconds between measurements. These measurements are averaged and a comparison can be made. Since most people tend to relax and their blood pressure falls with subsequent measurements, following this protocol reduces these natural changes in Blood Pressure levels. The standard technical error of both consumer and professional devices is normally ± 3 mmHg, so a discrepancy of 6 mmHg is acceptable even when the devices are working within their specifications.

Any comparisons without a known “reference device” and not following the procedures described above will yield unreliable results. In addition, to do an accuracy test properly the reference device must also be tested to a known reference to confirm its accuracy, prior to being used as the reference for comparisons.

1.2D Calibration

Digital blood pressure monitors do not require regular recalibration, unless the product has been dropped and internal parts have been damaged. If the unit turns on and does not display an error code, the product is working properly. In extremely rare cases, the cuff may have developed a pin-hole leak, or the gasket where the cuff connector enters the monitor may not have a proper seal; both of these leaking air issues will potentially cause errors in accuracy, but otherwise the product will work accurately without drifting out of calibration.

1.3 What do your Numbers Mean?

Blood pressure is the pressure in your blood vessels while blood circulates throughout your body. High blood pressure or “Hypertension” is the pressure at which one's normal average blood pressure is considered too high and other health risks including: heart attack, stroke, dementia, kidney failure, heart disease and erectile dysfunction may occur. It is expressed as two numbers: systolic/diastolic 120 mmHg/80 mmHg (mmHg = millimeters of mercury). “Systolic” numbers refer to the pressure on the walls of your arteries while the heart is contracting and pushing blood. “Diastolic” pressure is the lower number when the heart is at rest and relaxed. A simple way to understand this is to picture a garden hose. When the tap is turned on, the immediate pressure on the walls of the hose is the “systolic” value, and when the tap is

turned off it is the “diastolic” number.

There are many different causes of high blood pressure. We differentiate between common primary (essential) hypertension, and secondary hypertension. The latter group can be ascribed to specific organic malfunctions. Please consult your doctor for information about the possible origins of your own increased blood pressure values.

1.4 Normal Blood Pressure Values

When rested, and measuring your blood pressure at home, measurements with diastolic pressure readings above 85 mmHg or systolic readings over 135 mmHg are considered high. If you obtain consistent readings in this range, consult your doctor immediately. High blood pressure values over time can damage blood vessels, vital organs such as the kidney, and your heart. With blood pressure values that are too low (i.e., systolic values under 105 mmHg or diastolic values under 60 mmHg), consult with your doctor.

Systolic	Diastolic	Comment
Below 120	Less than 80	This range is considered “ Normal ” and ideal
120 - 139	80 - 89	This range is considered “ Pre-hypertension ”. Discuss with your health care professional. Lifestyle modifications maybe required to avoid advancing into hypertension.
140 - 159	90 - 99	This is in the “ hypertension ” range. Discuss with your health care professional. Medication(s) and lifestyle modifications are typical treatments.
160 and higher	100 +	Discuss with your medical professional, medication(s) and lifestyle modifications are necessary to control your hypertension

Adapted From: Understanding and Managing your blood pressure; Hypertension Canada.

Note: A diagnosis of high blood pressure must be confirmed with a medical professional. A doctor should evaluate any unusual blood pressure readings. Additionally, lower targets may be appropriate for some populations such as African-Americans, the elderly, or patients with underlying issues such as diabetes mellitus or chronic kidney disease.

Important for Canadians:

*** Hypertension measured at home \geq 135/85**

*** Hypertension measured at a physician’s office \geq 140/90**

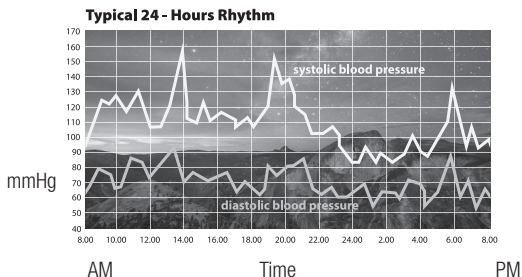
*** Hypertension measured at a physician’s office for a diabetic patient \geq 130/80**

For further information, see our website www.biosmedical.com.

1.5 Common Blood Pressure Questions and Answers

a) Why is my blood pressure reading always different?

Your blood pressure changes constantly. It is quite normal for blood pressure to fluctuate as much as 50 mmHg throughout the day. Blood pressure is normally lowest at night, but increases during waking hours when the stress and activities of everyday life are highest.



b) Why is the doctor's reading different from the reading taken at home?

Your blood pressure can vary due to the environment (temperature, nervous condition). When measuring blood pressure at the doctor's office, it is possible for blood pressure to increase due to anxiety and tension, this is known as "White Coat Hypertension". Home blood pressure monitoring has been known to predict health outcomes better than office blood pressure measurements.

c) Why should I monitor blood pressure at home?

One or two readings will not provide a true indication of your normal blood pressure. It is important to take regular, daily measurements and to keep records over a period of time. This information can be used to assist your physician in diagnosing and preventing potential health problems. Expert opinion suggests patients with normal blood pressure can benefit from one week of measuring every three months.

1.6 About MAM Technology

(Average Mode) technology is a new technology that enables optimum reliability in self-measurement of blood pressure.

An advanced measurement accuracy is achieved by the automatic analysis of three successive measurements, with short rest periods in between (see diagram 1).

This new technology provides reliable values for the doctor and can be used as the basis for reliable diagnostics and medication therapy for high blood pressure.

- Reliable patient self-measurement data for the doctor
- Safe hypertension diagnostic tool
- Reliable therapy control

1.6A Why Use MAM?

- Human blood pressure is not stable

1.6B Key Advantages

The technology provides reduction in:

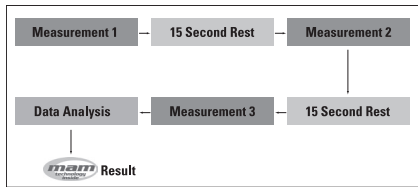
- Device scattering
- Insufficient rest prior to measurement
- Movement effects (i.e. coughing, talking, movement)
- Cuff positioning influences

1.6C Medical Benefits

- Improved accuracy

1.6D Measurement Sequence

- Single results are not displayed
- Due to the “Data Analysis” result, a 4th or 5th measurement may be applied. The following illustration provides a flow chart of the MAM Sequence



1.7 Important Facts About Atrial Fibrillation (AFIB)

1.7A What is Atrial Fibrillation (AFIB)?

Normally, your heart contracts and relaxes to a regular beat. Certain cells in your heart produce electrical signals that cause the heart to contract and pump blood. Atrial fibrillation occurs when rapid, disorganized electrical signals are present in the heart's two upper chambers, called the atria; causing them to contract quickly and irregularly (this is called fibrillation). Atrial fibrillation is the most common form of heart arrhythmia or irregular heart beat. You can live with atrial fibrillation, but it can lead to other rhythm problems, chronic fatigue, heart failure and - worst of all - a stroke. You will need a doctor to help you control the problem.

1.7B How Does AFIB Impact Family or Me?

One in every six strokes is AFIB-related. While individuals above the age of 65 are more likely to have AFIB, individuals as young as 40 can exhibit AFIB. Early diagnosis can help reduce the risk of a stroke.

1.7C AFIB detection provides a convenient way to screen for AFIB (only in MAM mode)

Knowing your blood pressure and knowing whether or not you or your family members have AFIB can help reduce the risk of stroke. AFIB detection provides a convenient way to screen for AFIB while taking your blood pressure.

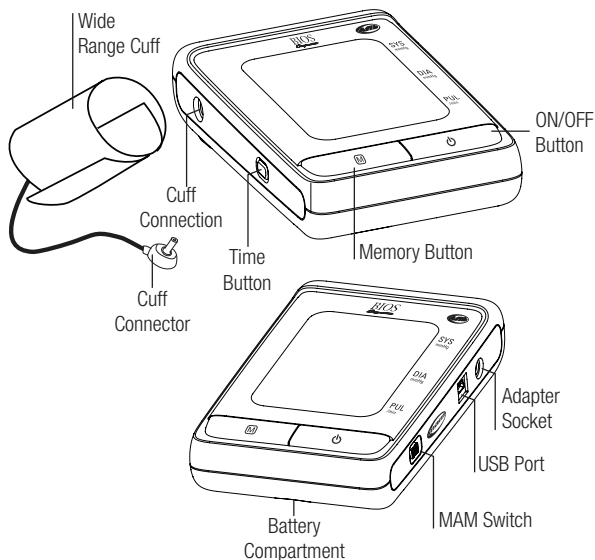
1.7D Risk Factors You Can Control

High blood pressure and AFIB are both considered «controllable» risk factors for strokes. Knowing your blood pressure and knowing whether or not you have AFIB is the first step in proactive stroke prevention.

2. Getting Started

2.1 About the 3MS1-4Y

a) This section describes the various components of the Blood Pressure Monitor.



b) Upper arm cuff:

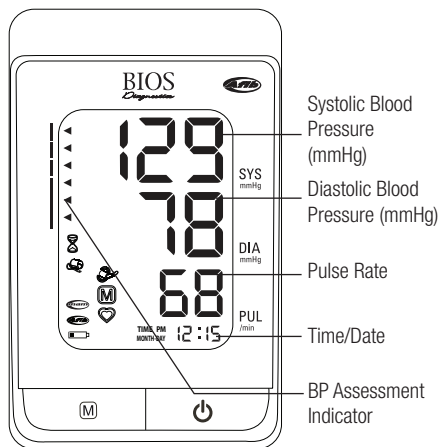
Type BD086 wide range cuff is for arm circumference 22-42 cm or 8.75" - 16.5".

Cuff connection:

Insert the cuff tube into the opening provided on the left side of the monitor as shown in the diagram.

2.2 About the LCD Screen

The LCD screen displays the systolic and diastolic blood pressure measurements along with your heart rate. It also displays previously recorded measurements and the date and time, when the appropriate button is pressed.



Symbol Guide



Atrial Fibrillation



MAM Averaging



Please wait in between measurements



Heartbeat during measurement



Memory



Low Battery



Cuff Check Indicator

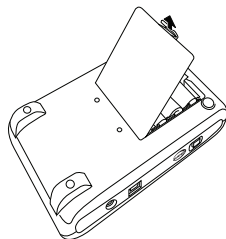


Arm Movement Indicator

2.3 Inserting the Batteries

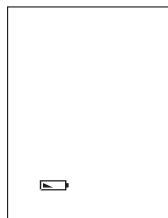
Follow these steps to insert the four "AA" batteries in the device.

1. Open the battery compartment cover in the direction shown.
2. Insert the four "AA" batteries with the correct polarity as indicated.
3. Replace the battery compartment cover.



Attention!

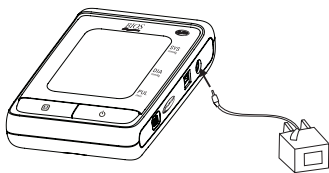
- After the battery warning appears, the device is blocked until the batteries have been replaced.
- Please use "AA" Long-Life or Alkaline 1.5V batteries.
- If the blood pressure monitor is left unused for long periods, please remove the batteries from the device.
- Do not mix old and new batteries. Do not mix alkaline, standard (carbon-zinc) or rechargeable batteries.



2.4 Using the AC Adapter


You may also operate this monitor using the included AC adapter (output 6V DC/600 mA with DIN plug). Use only the included AC adapter to avoid damaging the unit.

1. Ensure that the AC adapter and cable are not damaged.
2. Plug the adapter cable into the AC adapter port on the blood pressure monitor.
3. Plug the adapter into your electrical outlet. When the AC adapter is connected, no battery current is consumed



Note: No power is taken from the batteries while the AC adapter is connected to the monitor. If electrical power is interrupted, (e.g., by accidental removal of the AC adapter from the outlet) the monitor must be reset by removing the plug from the socket and reinserting the AC adapter connection.


Note: If using both batteries and adapter at the same time, make sure to unplug the adapter from the monitor first to ensure the time and date do not reset. If you unplug the adapter from the outlet the time and date will reset.








Functional check: Hold the  button down to test all the display elements. When functioning correctly all segments must appear.

3. Using the Device

This section describes how to get the maximum benefit from your 3MS1-4Y blood pressure monitor. Follow the instructions carefully to get an accurate measurement of your blood pressure and pulse rate.

3.1 Setting the Time and Date

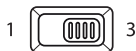
When you insert the batteries for the first time (see "Inserting the batteries"), the monitor prompts you to set the current date and time. You can also adjust the date and time by pressing and holding down the  button for over 3 seconds. Follow these steps to set the date and time settings:

1. When you press the  button for over 3 seconds, the year will start flashing. Press the  button to adjust the year and press the  button to confirm setting
2. Next, the screen starts flashing the month setting. Press the  button repeatedly to set the month and then press the  button to confirm the settings. Follow the same steps to set the date setting.
3. Lastly, the screen starts flashing the hour values. Press the  button repeatedly to set the hour and then press the  button to confirm the settings. Follow the same steps to set the minute values.




3.2 Measurement Mode Selection (MAM or Single)

Clinical studies demonstrate taking multiple blood pressure readings and calculating an “average” is more likely to determine your true blood pressure. Your premium blood pressure unit allows you to switch the unit to an Average Mode setting that automatically takes multiple readings!



Average Mode Slide Switch (MAM):

- If you would like to take an Average Mode measurement, move the slide switch to the right.
- Average Mode takes 3 measurements in succession and calculates the result and displays it as a single average measurement. A  symbol in the display indicates that the unit is set to the Average Mode.
- There will be 15 seconds resting time in-between each measurement. The unit will count down from 15 seconds. If one of the measurements causes an error message, it will be repeated one more time. If any additional error occurs the measurement will be discontinued and error code displayed.

Note: AFIB detection can only be done in MAM mode.



Single Mode

- If you would like to take a single mode measurement, please move the slide switch to the left.
- Single mode only has 1 measurement.

3.3 Obtaining Accurate Measurements

Your blood pressure can vary based on numerous factors, physiological conditions, and your surroundings. Follow these guidelines to obtain accurate and error-free measurements of your blood pressure and pulse rate.

3.3A Tips on Taking Accurate Measurements



In the morning before breakfast, 2 hours after dinner, before taking medication.



Avoid coffee and smoking within the hour, and no exercise 30 minutes before measuring.



Do not speak while taking the measurement.



Sit with legs uncrossed so as not to restrict blood flow.



Ensure that the cuff is level with the heart while the arm is supported on the table.



Empty bladder (if necessary).



Rest quietly for 5 minutes. Remain calm and quiet while the measurement is in process.



Take measurements on the non dominant arm.



Sit with back supported and measurement arm resting on a table. Sit with feet flat on the floor.

3.3B Common Sources of Error

All efforts by the patient to support the arm can increase the blood pressure. Make sure you are in a comfortable, relaxed position and do not activate any of the muscles in the measurement arm during the measurement. Use a cushion for support if necessary.

ATTENTION!

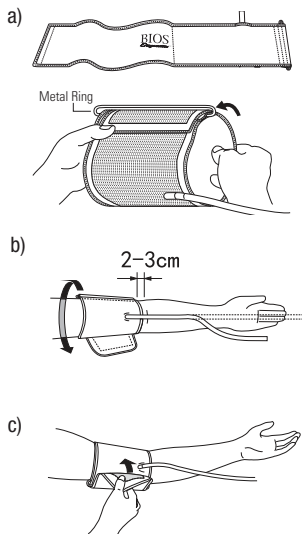
Comparable blood pressure measurements always require the same conditions with a peaceful and calm environment. Ensure that you take measurements under the same conditions to obtain an accurate and reliable readings.

- If the arm artery lies considerably lower or higher than the heart, an erroneous value of blood pressure is measured. Each 15 cm difference in height results in a measurement error of 10 mmHg.
- A loose cuff causes false measurement values.
- With repeated measurements, blood accumulates in the arm, which can lead to false results. Consecutive blood pressure measurements should be repeated after at least a 45 second pause or after the arm has been held up in order to allow the accumulated blood to flow away.

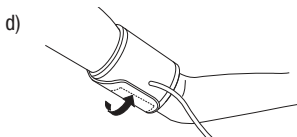
3.3C Fitting the Wide Range Cuff

NOTE: Visit www.biosmedical.com for a video that illustrates how to properly fit the cuff.

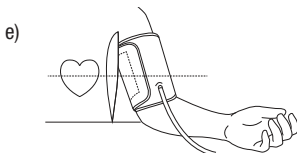
- Putting the cuff velcro side down on a table, the words on the cuff should be facing right side up. Put the end of the cuff (with fastener) through the metal ring, making the cuff a cylinder. (Ignore this step if your cuff is already set up.) Proper assembly allows the Velcro® to match up properly. Measure on your non-dominant arm, unless there is a >10 mmHg difference with the other arm, in which case use the arm with the higher pressure.
- Place the cuff around your bare arm. Make sure the bottom edge of the cuff is about 1" (2-3 cm) above the elbow joint. Adjust the cuff so that the rubber tubing under the cuff lies over the brachial artery, which runs on the inside of the arm (see Fig. b). The red material should be over the brachial artery.
- Pull the cuff and tighten it by attaching the Velcro® fastener. Measure on your non-dominant arm, unless there is a >10 mmHg difference with the other arm, in which case use the arm with the higher pressure.



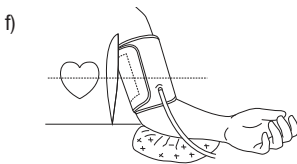
d) The cuff should fit snugly around the arm, but not too tight. You should be able to fit two fingers under the cuff. If the cuff is the wrong size, the device will not measure your blood pressure accurately. Contact the store, or BIOS Medical for other sized cuffs.



e) Place the arm on the table (palm facing upwards) so that the cuff is at the same level as the heart. Make sure there is no kink in the hose.

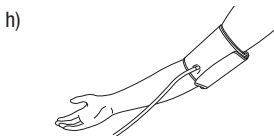


f) You can adjust the level of your arm by putting a cushion under your arm. Ideally the cuff should be at heart level.

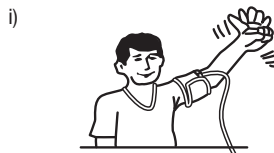


g) Remain seated in a comfortable room temperature for at least 5 minutes, then start the measurement.

h) For those who cannot put the cuff on the left arm, put it on the right arm as shown.



i) More than 6 consecutive measurements will cause blood accumulation in the lower arm which will affect the measuring results. To improve reading accuracy, raise the arm being measured, squeeze and relax your hand several times, then take another measurement. Another option is to take the cuff off and wait at least 5 minutes before repeating measurement.



j) If this device was stored in low temperature, it is necessary to leave it in room temperature for at least 1 hour, otherwise the measurement can be inaccurate.

Comment:



Continue to use the same arm for comparisons. It is not unusual for there to be a difference in blood pressure between arms. Initially, check BP on both arms. If one arm is 10mmHg higher, continue to measure on that arm.

Comparable blood pressure measurements always require the same conditions (Relax for several minutes before taking a measurement).

ATTENTION: Do not use a cuff other than the original cuff contained in this kit!



3.4 Measuring Your Blood Pressure

After following the guidelines described in the previous section and placing the cuff around your upper arm, you are now ready to measure your blood pressure. Follow these steps to record your measurement.

1. Press the  button to turn on the device and start measurement. The LCD screen is turned on. The cuff begins to inflate while the increasing cuff pressure is displayed on the screen. After the suitable inflation pressure is reached, the cuff stops inflating and the pressure gradually falls. When the measurement is complete, the systolic and diastolic blood pressure values along with the pulse rate are displayed on the screen. The measurement is displayed for approximately 1 minute.
2. Switch off the device by pressing the  button to preserve the batteries. If no button is pressed for 1 minute, the instrument switches the display off.


NOTE: The time will continuously be displayed on the screen.

3.5 Appearance of the Atrial Fibrillation Indicator (only in MAM mode)

This symbol  indicates that atrial fibrillation was detected during the measurement. If AFIB is present during blood pressure measurement, the AFIB Indicator is displayed. The AFIB  will flash 8 times rapidly once the measurement is complete and then stop flashing. In this case, the result may deviate from your normal blood pressure. It is highly recommended to take an additional measurement an hour later to increase the specificity of the detection. 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 visit your doctor. Please, provide the following explanation:

Information for the doctor on frequent appearance of the atrial fibrillation indicator

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 atrial fibrillation occurs 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 atrial fibrillation at an early stage.

- Sometimes the device will detect atrial fibrillation even when it is not there. This can happen if the arm moves during the reading or another rhythm problem is present. Keep the arm still during the reading. Visiting your doctor with this device may be necessary to check out any rhythm problems.
- This device may not detect atrial fibrillation in people with pacemakers or defibrillators.

3.6 BP Assessment Indicator

The bars on the left hand side of the display show you the range within which the indicated blood pressure values lies. Depending on the height of the bar, the readout value is either within the normal (green), borderline (yellow/orange) or danger (red) range.

The classification is based on standards adopted from ESH (European Society of Hypertension), AHA (American Heart Association) International Guidelines.

Refer to the chart below for details of the classification.



	SYS (mmHg)	DIA
Red	160▲	100▲
Orange	135-159	85-99
Yellow	130-134	80-84
Green	120-129	74-79
Green	110-119	67-73
Green	▼109	▼66

An arrow points to the indicator bar according to your measurement.

- If the arrow points to the first or second green bar, your measurement is in the green zone, or “Normal” according to the ESH/AHA classification.
- If the arrow points to the third bar, it is still in the green zone, but is considered high normal according to the ESH/AHA classification.
- If the arrow points to the fourth bar, it is in the yellow “Stage 1 Hypertension” zone.
- If the arrow points to the fifth bar, it is in the orange “Stage 2 Hypertension” zone.
- If the arrow points to the sixth bar, it is in the red “Stage 3 Hypertension” zone.






3.7 Viewing Previously Recorded Values

The blood pressure monitor automatically stores your measurements. It can store up to 200 measurements. When more than 200 measurements are made, the oldest readings are deleted to make space for the new ones.

To view the previously stored values, press the  button. The last measurement is displayed. The date and time of the measurement are also displayed after the reading. Press the  button repeatedly to view all the measurements that are recorded on the device.


Note: Blood pressure measurements are not stored when an error is encountered during measurement.

3.8 Clearing All Values

If you are sure that you want to permanently remove all stored values, hold down the  button (the instrument must have been switched off before hand) until the “” appears and then release the button. If you do not want to clear the values, press the  button. To permanently clear the memory, press the  button while “” is flashing. Individual values cannot be cleared.



3.9 Discontinuing a Measurement

If it is necessary to interrupt a blood pressure measurement for any reason (e.g. the patient feels unwell), the  button can be pressed at any time. The device then immediately lowers the cuff pressure automatically.

3.10 Determining Your “Real” Average Blood Pressure at Home

It is normal for blood pressure to vary significantly in the middle of the day when most people are busy with their daily tasks. Hypertension Canada recommends measuring in the morning and evening to avoid variability.

At the end of a measurement, this instrument automatically stores each result, including date and time.



AM

Take: 2 measurements, 1 minute apart

- Empty bladder (if necessary)
- In the morning before breakfast, before taking medication
- Sit with back supported and measurement arm resting on a table. Sit with feet flat on the floor.



PM

Take: 2 measurements, 1 minute apart

- Empty bladder (if necessary)
- 2 hours after dinner, before taking medication
- Sit with back supported and measurement arm resting on a table. Sit with feet flat on the floor.
- Avoid coffee and smoking within the hour, and no exercise 30 minutes before measuring.



RESULTS

Discard Day 1 measurements.
Average your day 2-7 measurements

= Average

$\leq 135 / 85$ mmHg

No Hypertension

$\geq 135 / 85$ mmHg = YES

Yes Hypertension

***Note: If the result is “borderline” repeat the series for confirmation. This data can be used by a medical professional to make a diagnosis of hypertension.**

4. Software Functions

This unit can be used in connection with your personal computer running the Blood Pressure Analyzer Software. The software will allow a capacity of monitoring 80 patients, each with 1000 data (Note: overuse will lower system efficiency). The memory data can be transferred to the computer by connecting the monitor via USB cable with your computer.

NOTE: The USB cable can be purchased at any electronics store. You will need USB cable Mini-B 5 pin. USB versions 1.0 or 2.0 will work on this device.

System Requirements:

This software is compatible with Microsoft® Windows® and Mac.

To download the software go to www.biosmedical.com. Go to the resource tab, select software downloads and download BIOS Diagnostics BP Analyzer+ Software (AFIB) for PC or MAC. Follow the directions to download the software.




Once installation is complete connect the monitor via USB cable with the PC. Three horizontal bars will appear on the display and last for 3 seconds.

The bars will then flash to indicate that the connection between computer and device is successfully made. As long as the cable is plugged in, the bars will keep flashing and the buttons are disabled.

During the connection, the device is completely controlled by the computer. Please refer to the ‘help’ file in the software for detailed instructions.

5. Error Messages / Malfunctions

If an error occurs during a measurement, a long beep followed by two short beeps is generated and the LCD display the corresponding error code.

Error	Possible Cause	Remedy
Err 1	No pulse has been detected or pulse signals are too weak	Ensure that the cuff is being worn correctly, and that you have your arm at the heart level.
Err 2 	Unnatural pressure impulses influence the measurement result. Reason: The arm was moved during the measurement.	Avoid unnecessary movement or talking.
Err 3 	The inflation of the cuff takes too long. The cuff is not correctly seated.	Ensure that the cuff is being worn correctly. Check that the cuff is correctly connected to the monitor.
Err 5	The difference between systolic pressure and diastolic pressure is too far away from acceptable and reasonable range.	Ensure that the cuff is being worn correctly and that you have been inactive for a sufficient time before making the measurement.
Err 6	Due to unstable conditions during measurements, it is not possible to calculate an average result.	Avoid unnecessary movement and talking.
	Low battery	Replace batteries.
H I	Cuff pressure is over 300 mmHg or pulse is over 200 beats per minute.	Ensure that the cuff is worn correctly and measure again. Avoid movement or talking when the cuff is being inflated.
LO	Pulse below 40 is detected.	Ensure that the cuff is worn correctly.

If problems occur when using the device the following points should be checked, and if necessary, the corresponding measures should be taken.

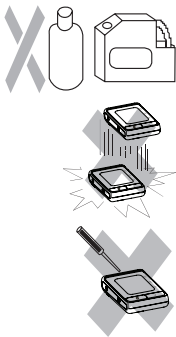
Malfunction	Remedy
The display remains empty when the device is switched on. The batteries are inserted.	<ol style="list-style-type: none"> 1. Check batteries for correct polarity. 2. If the display is unusual, re-insert the batteries or exchange them for new ones.
The pressure does not rise even though the pump is running.	Check the connection of the cuff tube and connect properly if necessary.

<p>The device frequently fails to measure the blood pressure values, or the values measured are too low or too high.</p>	<ol style="list-style-type: none"> 1. Check the positioning of the cuff. 2. Measure the blood pressure again, ensuring that you have remained motionless for a sufficient amount of time to ensure an accurate reading.
<p>Every measurement produces varying results although the instrument functions normally and the values displayed are normal.</p>	<p>Note that blood pressure fluctuates continuously; therefore measurements will show some variability.</p>
<p>Blood pressure values measured differ from those measured by the doctor.</p>	<p>Record daily measurements for consultation with your doctor.</p> <p>Note: Individuals visiting their doctor frequently experience anxiety which can result in a higher blood pressure reading than at home.</p>

For assistance call the BIOS Medical Hotline: 1-866-536-2289.

6. Care and Maintenance

- Do not expose the device to either extreme temperatures, humidity, dust or direct sunlight.
- The cuff contains a sensitive air-tight bubble. Handle this carefully and avoid all types of stress through twisting or buckling.
- Clean the device with a soft, dry cloth. Do not use gas, thinners or similar solvents. Dirt on the cuff should be removed with a damp cloth and soap. Do not put in the washing machine or dishwasher. Do not submerge in water.
- Handle the tube carefully. Do not pull on it. Do not allow the tubing to kink and keep it away from sharp edges.
- The monitor contains sensitive parts, and should be treated gently.
- Never open the monitor.** This invalidates the manufacturer's warranty.
- Batteries and electronic instruments must be disposed of in accordance with the locally applicable regulations, not with domestic waste.



7. Lifetime Limited Warranty

This BIOS Diagnostics™ Blood Pressure Monitor has a lifetime limited warranty to be free of manufacturing defects for the life of the original owner. This warranty does not include the inflation system including the cuff and inflation bladder. The cuff is warranted for two years. The warranty does not cover damage from misuse or tampering.

100% Satisfaction Guarantee

If at any time, you are not completely satisfied with the performance of this device, call our BIOS Medical Hotline and speak with a customer service representative, who will make arrangements to have the device tested or replaced to your full satisfaction.

If you have questions regarding the operation of your monitor call the

BIOS Medical Hotline: 1-866-536-2289.

Should correction be necessary, return the unit with all component pieces. Enclose proof of purchase and \$5.00 for return shipping and insurance. Ship the unit **prepaid** and insured (at owners option) to:

Thermor Ltd.

Returns Department

16975 Leslie Street

Newmarket, ON L3Y 9A1

www.biosmedical.com

Email: support@biosmedical.com

Please include your name, return address, phone number, and email address. Thermor will test or replace (at Thermor's option) free of charge any parts necessary to correct the defect in material or workmanship.

Please allow 10 days for return shipping.

8. Technical Specifications

Operating temperature:

10 to 40°C / 50 to 104°F

Storage temperature:

-20 to 55°C / -4 to 131°F

15 to 90 % relative maximum humidity

Weight:

560 g (including batteries)

Dimensions:

152 x 92 x 42 mm

Measuring procedure:

Oscillometric, Corresponding to Korotkoff method: Phase I systolic, Phase V diastolic

Measurement range:

20-280 mmHg - blood pressure

Cuff pressure display range:

0 - 299 mmHg

Resolution:

1 mmHg

Static accuracy:

Pressure within ± 3 mmHg

Pulse accuracy:

± 5 % of the readout value

Voltage source:

• 4 x 1.5 V batteries; size AA

• Main adapter DC 6V, 600 mA (optional)

Battery Lifetime:

Approximately 920 measurements

Reference to standards:

EN1060-1/-3

BHS Protocol; IEC 60601-1; IEC 60601-1-11, IEC 60601-1-2 (EMC),

IEC 80601-2-30

This device complies with the requirements of the Medical Device Directive 93/42/EEC.

Technical alterations reserved.



Read the instruction manual carefully before using this device, especially the safety instructions, and keep the instruction manual for future use.



Type BF applied part



Batteries and electronic devices must be disposed of in accordance with the locally applicable regulations, not with domestic waste.



IP20: Protected against solid foreign particles with a diameter of more than 12.5 mm, no protection against water.

BIOS | Medical

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THERMOR LTD.

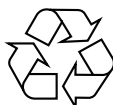
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