

BLOOD PRESSURE MONITOR | Automatic AFIB

Instruction Manual
Model: BD410

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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**.

Blood Pressure Monitor - Automatic AFIB

Instruction Manual

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1. Introduction

Thank you for purchasing the BIOS Diagnostics™ Blood Pressure Monitor – Automatic AFIB. 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 (BD410) is intended to measure the systolic and diastolic pressure 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 BD410 is a fully automatic, digital, blood pressure measuring device with AFIB detection technology. It can store up to 960 blood pressure readings across 4 users.

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.

- **AFIB Detection Mode** - Using three consecutive measurements, your result is calculated and displayed as a single averaged measurement on the display screen. AFIB icon is displayed when atrial fibrillation is detected during a blood pressure reading.
- **Irregular Heartbeat Detection**
- **Averaging Features** - Averages the last 3 measurements, averages AM and PM readings
- **Systolic & Diastolic Trending** - Memory function displays upward, downward or stable trends
- **BP Assessment Indicator** - Displays the range between which your blood pressure values lie
- **Memory Feature** - 4 users, 240 blood pressure readings each, with time and date

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.

This device is easy to use and has been proven in clinical studies to provide excellent accuracy. Before using the BD410, 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™ Blood Pressure Monitor – Automatic AFIB.

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
- After taking a bath or using a hot tub
- 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
- While taking a bath or using a hot tub
- 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 " Optimal "
120-129	80-84	This range is considered " Normal ". Introduce/continue healthy lifestyle alterations to maintain healthy blood pressure.
130 - 139	85 - 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 above	100 and above	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**

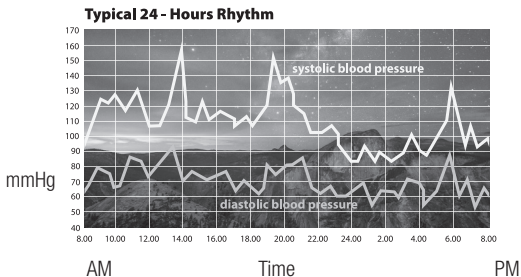
* **Hypertension measured at a physician's office for a diabetic patient \geq 130/80**

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 AFIB Detection Mode (Averaging Mode)

AFIB Detection Mode (Averaging Mode) is a 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.

This 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 AFIB Detection Mode?

- Human blood pressure is not stable

1.6B Key Advantages

The technology provides reduction in:

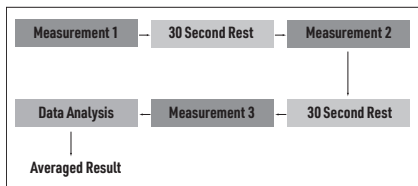
- Device scattering
- Insufficient rest prior to measurement
- Movement effects (i.e. coughing, talking, movement)
- Cuff positioning influences

1.6C Medical Benefits

- Improved accuracy

1.6D Measurement Sequence

- Single results are not displayed
- The following illustration provides a flow chart of the Averaging Sequence



1.7 Important Facts About Atrial Fibrillation (AFIB)

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.

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.

AFIB Detection Provides a Convenient Way to Screen for AFIB (only in AFIB Detection 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.

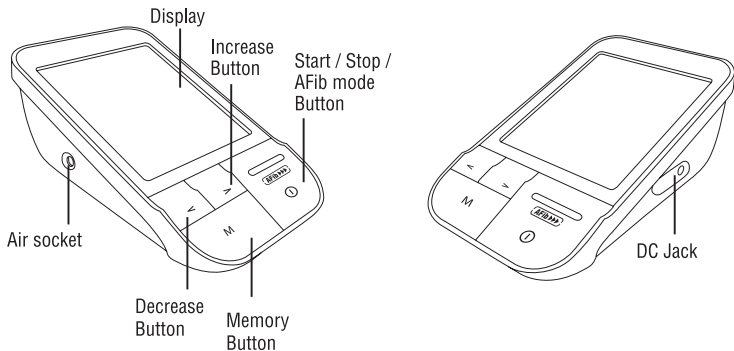
Risk Factors You Can Control

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

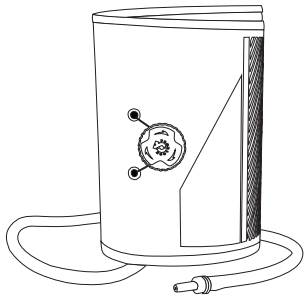
2.1 About the BD410

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



b) Upper arm cuffs:

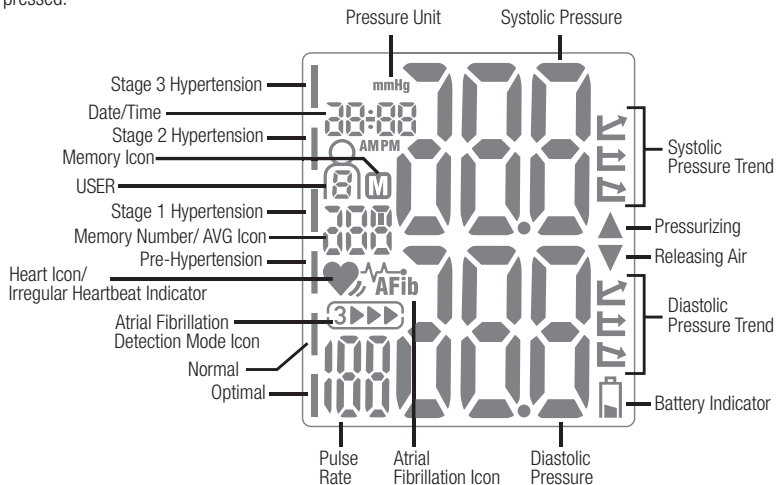
- BD41RC Easy-Fit Cuff (Wide Range) **(Included)**
Type BD41RC wide range cuff is for an arm circumference of 24-42 cm (9.4" - 16.5")



- BD41SC Soft Cuff (Standard Wide Range) **(Accessory Item Sold Separately)**
Type BD41SC wide range cuff is for an arm circumference of 22-44 cm (9" - 17")

2.2 About the LCD Screen

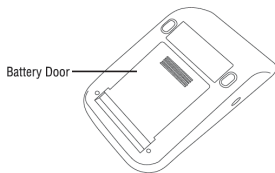
The LCD screen displays the systolic and diastolic blood pressure measurements along with your heart rate. It also displays previously recorded measurements and the date and time, when the appropriate button is pressed.



2.3 Inserting the Batteries (not included)


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

- Open the battery compartment cover in the direction shown.
- Insert the four "AAA" batteries with the correct polarity as indicated.
- Replace the battery compartment cover.



NOTE: When the batteries are removed from the device, the date/time will need to be reset.

Attention!

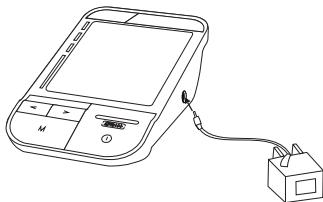
- When batteries are depleted the  icon, and "E6" will appear on the display. Batteries must be replaced.
- Please use "AAA" Long-Life or Alkaline 1.5V batteries.
- If the blood pressure monitor is left unused for long periods, please remove the batteries from the device.
- Do not mix old and new batteries. Do not mix alkaline, standard (carbon-zinc) or rechargeable batteries.



2.4 Using the AC Adapter

An AC adapter has been included with your device (output 6V DC/600mA). Use only the provided 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: When adapter is removed from the device, the date/time will need to be reset.

3. Using the Device

This section describes how to get the maximum benefit from your BD410 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

NOTE: You must set up Time and Date when installing new batteries, or connecting to a power supply.

1. After installing the new power source, use the [< / >] buttons to select the YEAR, confirm selection pressing the [M] button.
2. Repeat the same process to set the MONTH by using the [< / >] buttons, and the [M] button to confirm.
3. The same process is repeated to set the DATE. Use the [< / >] buttons to select, and the [M] button to confirm.
4. Finally, the TIME can be set. HOUR is selected first, then MINUTE using the [< / >] buttons to select, and the [M] button to confirm.

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- 1

3:00

NOTE: In order to change any setting you must repeat the process and confirm each setting by pushing the [M] button.

NOTE: When device is already connected to power, and in clock mode (sleep). Press and hold the [M] key for 3 seconds until the content on the display blinks. Follow the same procedure as above to set.

3.2 Selecting the User

1. Start by pressing the [⓪] to turn the device on.
2. Using the [←]/[→] buttons, select user 1, 2, 3, or 4. Confirm this selection by pressing the [⓪] button.

3.3 Measurement Mode Selection (Single or AFIB)

NOTE: The device is automatically set to Single measurement mode.

Single Mode:

- a) If you would like to take a Single Mode measurement, simply turn the device on using the [⓪] button, then press the [⓪] button again to start measurement.
- b) Single mode only takes 1 measurement, and will display your reading once the cuff has fully deflated.

AFIB Detection Mode:

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!

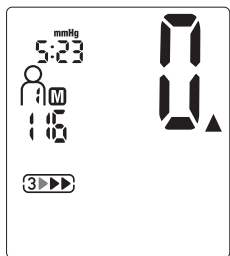
NOTE: Make sure your cuff is securely on your arm before entering into AFIB mode, as the first measurement is taken immediately

- a) If you would like to take an AFIB Detection Mode measurement, turn the device on using the [⓪] button.
Press and hold the [⓪] button for 5 seconds until you see the light on the button illuminate, and the [3▶▶▶] appear on the screen as the first measurement begins to be taken.
- b) Average Mode takes 3 measurements in succession and calculates the result and displays it as a single average measurement. A [3▶▶▶] symbol on the display indicates that the unit is set to the AFIB Detection averaging mode.
- c) There will be a 30 second resting time in-between each measurement. The unit will count down from 30 seconds.

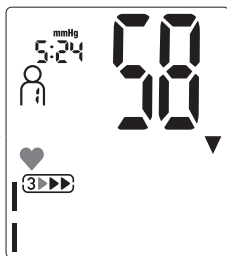
NOTE: If an error occurs during measurements in this mode, the device will return to stand-by mode, and no result will be displayed. Please ensure the cuff is correctly fitted, power source is strong, and try again.

NOTE: AFIB detection can only occur when in this mode.

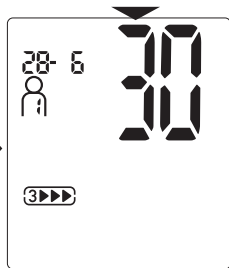
NOTE: If AFIB is detected during these readings the ♥^{AFIB} icon will be shown, and ♥^{AFIB} will blink.



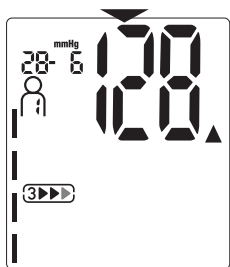
Enter AFIB Detection mode.
First measurement starts.



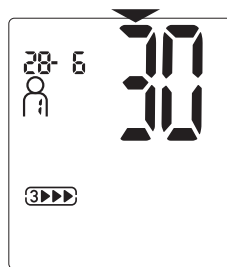
[♥] icon blinks.
Measurement #1 is in progress.



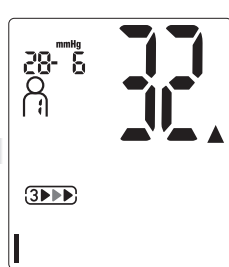
30 second timer starts
to count down.



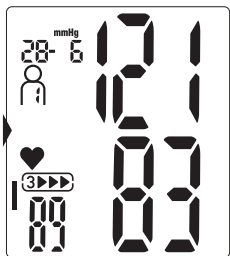
[♥] icon blinks.
Measurement #3 is
in progress.



30 second timer starts to
count down.



[♥] icon blinks.
Measurement #2 is in progress.



Averaged measurement
result is shown.

3.4 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.

3.4A 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.

3.4B 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 reading.

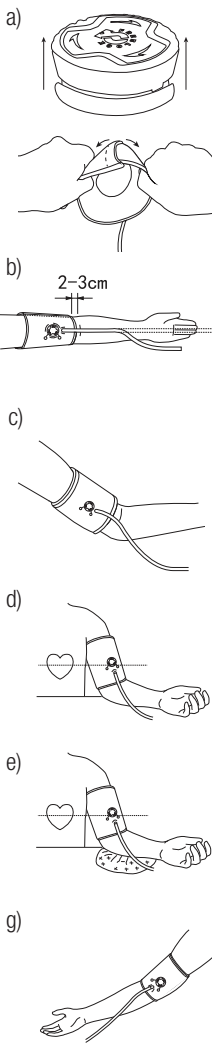
- If the arm artery lies considerably lower or higher than the heart, an erroneous value of blood pressure is measured. Each 15 cm difference in height results in a measurement error of 10 mmHg.
- A loose cuff causes false measurement values.
- With repeated measurements, blood accumulates in the arm, 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.

3.4C Fitting the Easy Fit Cuff

- The Easy-Fit Cuff comes ready to use! In preparation for fitting the cuff to your arm size, you will want to start by loosening it. Holding the cuff so that the tubing is facing away from you, grab the adjustable dial and pull up until you hear a 'click'. When the dial is in this position, the cuff can easily be widened to its largest size. Do this by holding either side of the cuff, and pulling in opposite directions as shown in the image. Press the dial back in to prepare for individual sizing.
- Place the cuff around your bare arm. Using the adjustable dial (ensure the dial has been pushed back in) turn it clockwise to tighten the cuff to the desired fit. 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 of the cuff lies over the brachial artery, which runs on the inside of the arm (see Fig. b). The tube should be over the brachial artery.

NOTE: 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.

- 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.
- Place arm on to 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.
- You can adjust the level of your arm by putting a cushion under your arm. Ideally, the cuff should be at heart level.
- Remain seated in a comfortable room temperature space for at least 5 minutes, then start the measurement.
- For those who cannot put the cuff on the left arm, put it on the right arm as shown.



- h) 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.
- i) If this device was stored in low temperature, it is necessary to leave it in room temperature for at least 1 hour before use; otherwise the measurement may 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, or a cuff designed for this specific machine.

NOTE: If you have purchased the BD41SC wide range soft cuff please visit www.biosmedical.com for a video that illustrates proper fitting.

3.5 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; the LCD screen will turn on. Press [ⓘ] again and start measurement. 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. The cuff will fully deflate when the measurement is completed. The systolic and diastolic blood pressure values along with the pulse rate are displayed on the screen.

NOTE: See section 3.3 for instructions on how to select measurement mode.

2. When finished with the unit you can press the [ⓘ] button to force the unit into clock mode (sleep).

*The device will automatically go into clock mode (sleep) if idle for 2 minutes.

NOTE: In clock mode (sleep), the time will continuously be displayed on the screen.

3.6 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.

3.7 Appearance of the Atrial Fibrillation (AFIB) Indicator (only in AFIB

Detection mode)

This symbol [♥^{AFIB}] indicates that atrial fibrillation was detected during the measurement. If AFIB is present during blood pressure measurement, the AFIB Indicator is displayed. The AFIB symbol [♥^{AFIB}] will blink after the measurement is complete (if detected). 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 [♥^{AFIB}] symbol is displayed after the analysis if atrial fibrillation occurred 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.

3.8 BP Assessment Indicator

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

The classification is based on standards adopted from the WHO*

Refer to the chart below for details of the classification.




	SYS (mmHg)	DIA
Red	180 ▲	110 ▲
Orange	160-179	100-109
Yellow	140-159	90-99
Green	130-139	85-89
Green	120-129	80-84
Green	▼120	▼80

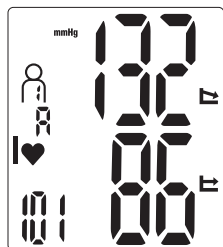
- If the bar lines up with the first or second green bar, your measurement is in the green zone, or "Normal".
- If the bar lines up with the third bar, it is still in the green zone, but is considered high normal pre-hypertension.
- If the bar lines up with the fourth bar, it is in the yellow "Stage 1 Hypertension" zone.
- If the bar lines up with the fifth bar, it is in the orange "Stage 2 Hypertension" zone.
- If the bar lines up with the sixth bar, it is in the red "Stage 3 Hypertension" zone.

3.9 Viewing Previous Measurement Values

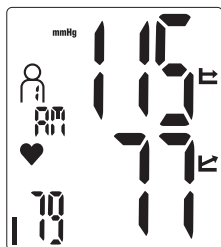
The blood pressure monitor automatically stores your measurements. It can store up to 240 measurements per user. When more than 240 measurements in a user's profile are present, the oldest readings are deleted to make space for the new ones.

- To view the previously stored values, in standby mode press the [M] button to enter the memory mode. The average blood pressure from the last 3 readings will be displayed first.
- Press the [>] button to view the averaged AM readings from the last 7 days (5:00 - 9:00 a.m.)
- Press the [>] button to view the averaged PM readings from the last 7 days (6:00 - 8:00 p.m.)
- Press the [>] button to view the most recent measurement record.
- Continue to press the [>] button to cycle through older measurements in the device.
- At any point, press the [<] button to view previous measurement records.

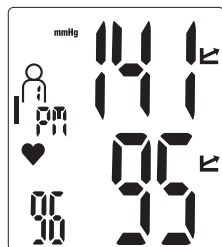
The memory function also shows systolic and diastolic trending (upwards , stable , or downwards ).



AVG (average) of the last 3 readings is displayed. Trend indicators show the systolic and diastolic trends.



AM AVG (average) of latest 7 day morning measurements taken between 5:00 - 9:00 a.m.



PM AVG (average) of the latest 7 day evening measurements taken between 6:00 - 8:00 p.m.

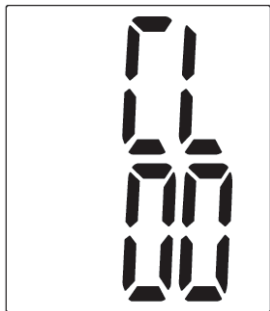
Note: See section 3.2 on how to select the user, to change user profile to view memory information.

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

3.10 Clearing Measurement Values

- Press the [M] button to enter into the user memory information.
- With a reading showing, press and hold down the [<] and [>] buttons simultaneously for approximately 7 seconds until [CL] and [00] are displayed on the screen
- All measurement data for the selected user has now been erased.

NOTE: If you only see [CL] and [--] displayed on the screen, it means the [<] and [>] buttons weren't held long enough. Follow the instructions above again.



3.11 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. Error Messages / Malfunctions

Error	Possible Cause	Remedy
E 1	Pulse is unable to be detected due to incorrect cuff positioning.	Ensure that the cuff is being worn correctly, and that you have your arm at the heart level.
E 2	Unnatural pressure impulses caused by arm movement during measurement.	Avoid unnecessary movement or talking. Rest and take another measurement.
E 3	Disruption during cuff inflation due to incorrect cuff positioning.	Ensure that the cuff is being worn correctly. Check that the cuff is correctly connected to the monitor.
E 4	Measurement error due to possible weak or irregular heartbeat.	Rest for few minutes, then try to take another measurement after re-fastening the cuff to ensure correct positioning.
E 5	The cuff has overinflated.	Ensure cuff sizing is correct for your arm size.
E 6	The battery in the device is low.	Switch to AC adapter if available, or replace the batteries before attempting another measurement.

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.
The device frequently fails to measure the blood pressure values, or the values measured are too low or too high.	<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.

Every measurement produces varying results although the instrument functions normally and the values displayed are normal.

Note that blood pressure fluctuates continuously; therefore measurements will show some variability.

Blood pressure values measured differ from those measured by the doctor.

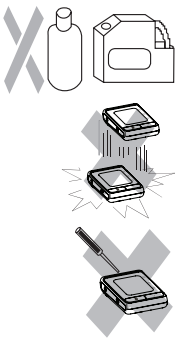
Record daily measurements for consultation with your doctor.

Note: Individuals visiting their doctor frequently experience anxiety which can result in a higher blood pressure reading than at home.

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

5. 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.



6. 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 1 year. 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.

7. Technical Specifications

Operating temperature:	5°C to 40°C / 41°F to 104°F 15 to 90 % relative maximum humidity
Storage temperature:	-25°C to 70°C / -13°F to 158°F Up to 90 % relative maximum humidity
Weight:	350g (including batteries)
Dimensions:	165 x 98 x 60 mm
Measuring procedure:	Non-invasive, Oscillometric
Measurement range:	Systolic Pressure: 60-260 mmHg Diastolic Pressure: 30-200 mmHg Pulse: 40-180 bpm
Cuff pressure display range:	30 mmHg – 250 mmHg
Resolution:	Pressure: 1 mmHg Pulse: 1 bpm
Static accuracy:	Pressure within ± 3 mmHg
Pulse accuracy:	± 5 % of the readout value
Voltage source:	Battery: 4 x 1.5V AAA batteries Adapter: DC 6V, 600 mA (output)
Battery Lifetime:	Approximately 300 measurements

Reference to standards:

EN ISO 13485:2016
EN ISO 81060-1:2012; ISO 81060-2:2013
EN 1060-3:1997+A2:2009
ISO 10993-5:2009; ISO 10993-10:2010
IEC 62304:2006+A1:2015
IEC 62366-1:2015
IEC 80601-2-30:2009+A1:2013
ISO 14971:2007
IEC 60601-1-2:2014; IEC 60601-1-11:2015; IEC 60601-1:2005+A1:2012; IEC 60601-1-6:2010+A1:2013



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.



IP21: Protected against solid foreign particles with a diameter of more than 12.5 mm. Provides protection against vertically falling drops of water or condensation.

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THERMOR LTD.
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NEWMARKET, ON L3Y 9A1
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