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Date: March 27 2020 Customer: Thermor Ltd Job Number: TH1011 Item Number: 3AL1-3E Designer: Alex Vranjesevic

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Colour Breakdown



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Instruction Manual Model: 3AL1-3E PREMIUM
Blood Pressure Monitor

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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** 

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### Premium Blood Pressure Monitor Instruction Manual

#### **Table of Contents**

### 1. Introduction

- 1.1 Features
- 1.2 Important Information
  - 1.2A Safety Information
  - 1.2B Care of the Device
  - 1.2C Comparing Readings to other Blood Pressure Devices
  - 1.2D Calibration
- 1.3 What Do Your Numbers Mean?
- 1.4 Normal Blood Pressure Values
- 1.5 Common Blood Pressure Questions and Answers

#### 2. Getting Started

- 2.1 About the 3AI 1-3F
- 2.2 About the LCD Screen
- 2.3 Inserting the Batteries
- 2.4 Using the AC/DC Power Adapter
- 2.5 Storing the Cuff

### 3. Using the Device

- 3.1 Setting Time, Date and Year
- 3.2 Select the User
- 3.3 Obtaining Accurate Measurements
  - 3.3A Tips on Taking Accurate Measurements
  - 3.3B Common Sources of Error
  - 3.3C Fitting the Wide Range Cuff
- 3.4 Measuring Your Blood Pressure
- 3.5 Pulse Arrythmia Detection
- 3.6 Determining Your "Real" Average Blood Pressure at Home
- 3.7 Blood Pressure Assessment Indicator
- 3.8 Medication Reminder
- 3.9 Viewing Previously Recorded Values
- 3.10 Clearing All Values
- 3.11 Discontinuing a Measurement

#### 4. Error Messages / Malfunctions

### 5. Care and Maintenance

#### 6. 5 Year Warranty

#### 7. Reference to Standards

### 8. Technical Specifications

UPC (For Reference Only)

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# 1. Introduction

Thank you for purchasing the BIOS Diagnostics™ Premium Blood Pressure Monitor. 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.

#### 1.1 Features

The 3AL1-3E is a fully automatic, digital, blood pressure measuring device with a unique fuzzy logic technology and a large LCD screen. It can store up to 99 blood pressure readings for each of the 2 users.

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

- PAD Pulse Arrythmia Detector technology displays pulse irregularities detected during a blood pressure
  reading. However, if the PAD symbol → → appears on a regular basis (e.g. several times a week with measurement
  taken daily), we advise you to consult your doctor.
- BP Assessment Indicator displays the range between which your blood pressure values lie.
- Medication Reminder allows you to program 2 daily alarms as a reminder to take medication or blood pressure.
- **Memory Feature** 2 users, 99 blood pressure readings each with time and date.

This device is easy to use and has been proven in clinical studies to provide excellent accuracy. Before using the 3AL1-3E, 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<sup>TM</sup> Premium Blood Pressure Monitor.

# 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.

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Item Number: 3AL1-3E Designer: Alex Vranjesevic

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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 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.

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### 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 patients 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 subjects 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 ones 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" number, 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

Blood pressure is too high when measuring at home and you have rested, the diastolic pressure is above 85 mmHg or the systolic blood pressure is over 135 mmHg. If you obtain readings in this range, consult your doctor immediately.

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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 " <b>Pre-hypertension</b> ": 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.

Adopted 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:**

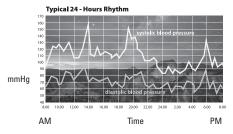
- \* Hypertension measured at home ≥ 135/85
- \* Hypertension measured at a physician's office ≥ 140/90
- \* Hypertension measured at a physician's office for a diabetic patient ≥ 130/80

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 significantly (50 mmHg to 60 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.



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### 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".

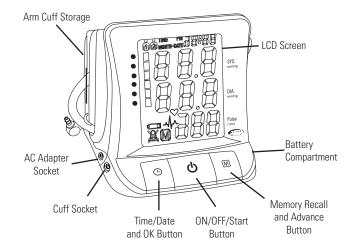
### c) Why should I monitor blood pressure at home?

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.

# 2. Getting Started

### 2.1 About the 3AL1-3E

This section describes the various components of the 3AL1-3E.



#### Upper arm cuff:

Wide range cuff for arm circumference 22 - 42 cm or 8.75" - 16.5".

#### **Cuff connection:**

Insert the cuff connector 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.

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Colour Breakdown

Blood pressure classification

TIME

Systolic blood pressure (mmHg)

Diastolic blood pressure (mmHg)

Pulse rate (beats/minute)

### **Symbol Guide**

-√- Irregular heartbeat

M Memory

Muser number

Medication reminder

Heartbeat during measurement

■ Low battery

# 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.

# 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.





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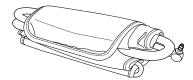


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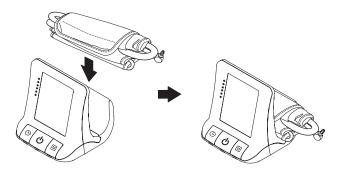
# 2.5 Storing the Cuff

The cuff used for measuring blood pressure is a delicate component of the device and should be stored carefully when not in use. The 3AL1-3E is designed such that the cuff can be stored along with the blood pressure monitor. Follow these steps to store the blood pressure cuff.

1. Roll up the upper arm cuff along with the inflating tube.



2. Push the folded cuff in the compartment at the back of the 3AL1-3E to store it safely.



# 3. Using the Device

This section describes how to get the maximum benefit from your 3AL1-3E blood pressure monitor. Follow the instructions carefully to get an accurate measurement of your blood pressure and pulse rate.

# 3.1 Setting the Time, Date and Year

When you insert the batteries for the first time (see "Inserting the batteries"), the 3AL1-3E prompts you to set the current date and time. You can also adjust the date and time at any time by pressing and holding down the ① button for over 3 seconds. Follow these steps to set the date and time:

When you replace the batteries, the LCD screen starts flashing the current year setting.
 Press the button repeatedly to adjust the year and then press the button to confirm the setting.





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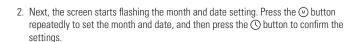
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Lastly, the screen starts flashing the hour and minute values. Press the button repeatedly to set the hour and minutes and then press the button to confirm the settings.



# 3.2 Select the User

This blood pressure monitor is designed to store 99 measurements for each of two users. Before taking a measurement, be certain that the correct user has been selected.

- a) Press and hold the ① button for 3 seconds until the user icon in the upper left corner of the LCD screen flashes.
- b) Press the (M) button to togale between users.
- c) Press the 🛈 button again to confirm your selection. You will need to press the 🔾 icon to cycle through each time and date settings until you are back in default mode.







# 3.3 Obtaining Accurate Measurements

Your blood pressure can vary based on numerous factors, physiological conditions, and your surroundings. Follow these quidelines 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.



Empty bladder (if necessary).



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



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



Do not speak while taking the measurement.



Take measurements on the non dominant arm.



Sit with legs uncrossed so as not to restrict blood flow



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



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

### 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.

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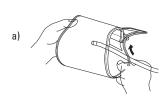
#### ATTENTION!

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 estimate of blood pressure variation patterns.

- 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 15 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

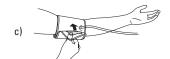
a) Put the end of the cuff (with fastener) through the metal ring, making the cuff a cylinder. (Ignore this step if your cuff is already set up.) Proper assembly allows the Velcro® to match up properly. Measure on your non-dominant arm, unless there is a >10 mmHg difference with the other arm, in which case use the arm with the higher pressure.



b) 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 small white arrow (Artery Mark) on the cuff should be over the brachial artery.



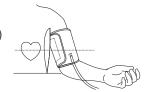
c) Pull the cuff and tighten it by attaching the Velcro® fastener.



d) The cuff should fit snugly around the bare 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.



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Item Number: 3AL1-3E
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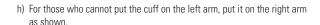


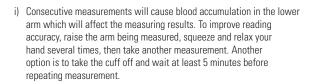


h)

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.





 i) 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.

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. A long beep sounds when the measurement is completed. The systolic and diastolic blood pressure values along with the pulse rate are displayed on the screen. The measurement is displayed for approximately 3 minutes.
- 2. Switch off the device by pressing the  $\bigcirc$  button to preserve the batteries. If no button is pressed for 3 minutes, the instrument switches the display off.



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# 3.5 PAD - Pulse Arrythmia Detection

This symbol  $\sqrt[\Lambda]{r}$  indicates that certain pulse irregularities were detected during the measurement. In this case, the result may deviate from your normal basal blood pressure — repeat the measurement. In most cases, this is no cause for concern.

However, if the PAD symbol appears on a regular basis (e.g. several times a week with measurement taken daily), we advise you to consult your doctor. Please show your doctor the following explanation:

### Information for the doctor on frequent appearance of the Pulse Arrythmia

### **Heartbeat Symbol**

This instrument is an oscillometric blood pressure monitor device that also analyzes pulse frequency during measurement. The instrument is clinically tested.

If pulse irregularities occur during measurement, the irregular heartbeat symbol is displayed after the measurement. If the symbol appears more frequently (e.g. several times per week on measurements performed daily) or if it suddenly appears more often than usual, we recommend the patient seek medical advice.

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

# 3.6 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.





# -)) PN

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.



# Project Type Instructions LIPC (For Reference Only)

Date: March 27 2020 Customer: Thermor Ltd Job Number: TH101 Item Number: 3AL1-3E Designer: Alex Vranjesevic

Design Update:

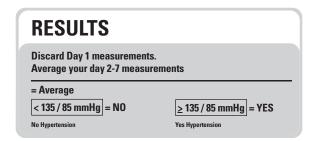
Reason For Project: New Item: New Branding: X

Artwork is not to be amended or scaled. If any changes are required please send through Thermor office v instructions, and we will amend here and resend artwork through. PLEASE RETURN WITH SIGNATURE

Revision: B







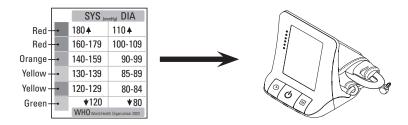
\*Note: If the result is "borderline" repeat the series for confirmation. This data can be used by a medical professional to make a diagnosis of hypertension.

### 3.7 Blood Pressure Assessment Indicator

The bars on the left hand edge 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 (vellow) or danger (red) range.

The classification is based on standards adopted from WHO (World Health Organization); which is recognized by Hypertension Canada (HC).

Refer to the chart below for details of the classification



The indicator bar raises according to your measurement.

- If your measurement has only one bar, your measurement is in the green zone, or "Normal" according to National Institute of Health (NIH) standards.
- If your measurement has two or three bars, it is in the yellow zone, or "Pre-Hypertension" according to NIH standards, or high normal according to the WHO classification.
- If your measurement has four bars, it is in the orange "Stage 1 Hypertension" zone.
- If your measurement has five bars, it is in the red "Stage 2 Hypertension" zone.
- If your measurement has six bars, it is in the red "Stage 3 Hypertension" zone.

UPC (For Reference Only)

Date: March 27 2020 Customer: Thermor Ltd Job Number: TH1011 Item Number: 3AL1-3E Designer: Alex Vranjesevic

Reason For Project: New Item: New Branding: X Design Update:

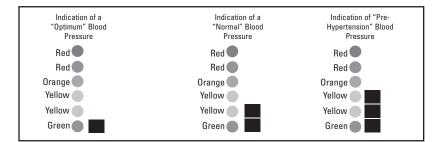
Artwork is not to be amended or scaled. If any changes are required please send through Thermor office with instructions, and we will amend here and resend artwork through. PLEASE RETURN WITH SIGNATURE

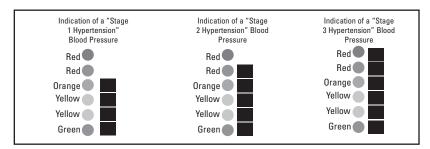
Revision: B



K

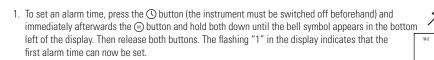
PM -3/15

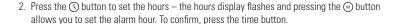


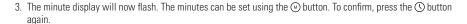


### 3.8 Medication Reminder

This instrument allows you to set two alarm times at which an alarm signal will then be triggered. This can be a useful aid, for instance as a reminder to take medication or to remind you to take your blood pressure at the same time each day.







4. The  $\bowtie$  symbol will now flash. Use the  $\circledcirc$  button to select whether the alarm time is to be active  $\bowtie$  or inactive  $\bowtie$ . To confirm, press the time button.

Reason For Project: New Item: New Branding: X Design Update:

Date: March 27 2020 Customer: Thermor Ltd Job Number: TH1011 Item Number: 3AL1-3E Designer: Alex Vranjesevic

Artwork is not to be amended or scaled. If any changes are required please send through Thermor office with instructions, and we will amend here and resend artwork through. PLEASE RETURN WITH SIGNATURE

Revision: B





# 3.9 Viewing Previously Recorded Values

The blood pressure monitor automatically stores your measurements with time and date. It can store up to 99 measurements for each of the 2 users. When more than 99 measurements are made, the oldest readings are deleted for that particular user to make space for the new ones.

To view the previously stored values, press the ② button. The last measurement is displayed. The date and time of the measurement are also displayed after the reading. Press the ③ button repeatedly to view all the measurements that are recorded on the device.

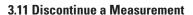






# 3.10 Clearing All Values

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



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



# 4. 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.	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.
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.

HI	Cuff pressure is over 300 mmHg.	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.

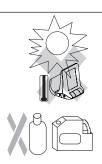
If problems occur when using the device the following points should be checked, and if necessary, the corresponding measures should be taken.

Malfunction	Remedy
The display remains empty when the device is switched on. The batteries are inserted.	Check batteries for correct polarity.     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.	Check the positioning of the cuff.     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 the daily development of the values and consult 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 BIOS Medical Blood Pressure Hotline: 1-866-536-2289

## 5. Care and Maintenance

- a) Do not expose the device to either extreme temperatures, humidity, dust or direct sunlight.
- b) The cuff contains a sensitive air-tight bubble. Handle this carefully and avoid all types of stress through twisting or buckling.
- c) Clean the device with a soft, dry cloth. Do not use gas, thinners or similar solvents. Spots on the cuff can be removed carefully with a damp cloth and soapsuds. The cuff with bladder must not be washed in a dishwasher, clothes washer, or submerged in water.



- d) Handle the tube carefully. Do not pull on it. Do not allow the tubing to kink and keep it away from sharp edges.
- e) Do not drop the monitor or treat it roughly in any way. Avoid strong vibrations.





- f) Never open the monitor. This invalidates the manufacturer's warranty.
- g) Batteries and electronic instruments must be disposed of in accordance with the locally applicable regulations, not with domestic waste.

## 6. 5 Year Warranty

BIOS Diagnostics™ blood pressure monitor has a 5 year warranty to be free of manufacturing defects for 5 years of the original owner. This warranty does not include the inflation system including the cuff and inflation bladder. The cuff is warranted for 2 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 person, who will make arrangements to have the device repaired 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 repair 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:

Repair 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 repair 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 repair and return shipping.

### 7. Reference to Standards

**Device standard:** Device corresponds to the requirements of the standard

for non-invasive blood pressure monitors:

AAMI/ANSI SP10 IEC 60601-1 IEC 60601-1-2 EN 1060-1 EN 1060-3 FN 1060-4

**Electromagnetic compatibility:**Device fulfills the stipulations of the International

standard IEC 60601-1-2

## 8. Technical Specifications

Weight: 570 g

**Size:** 134.94 (W) x 137.92 (L) x 145.9 (H) mm

**Storage temperature:**  $-20^{\circ}\text{C to }55^{\circ}\text{C}$  /  $-4^{\circ}\text{F to }131^{\circ}\text{F}$ 

**Humidity:** 15 to 90% relative humidity maximum

**Operation temperature:** 10°C to 40°C / 50°F to 104°F

**Display:** LCD-Display (Liquid Crystal Display)

Measuring method: Oscillometric
Pressure sensor: Capacitive

Measuring range:

**SYS/DIA**: 30 to 280 mmHa

**Pulse:** 40 to 200 beats per minute

**Cuff pressure display range:** 0 to 299 mmHg

**Memory:** Automatically stores the last 99 measurements for

2 users (total 198)

Measuring resolution: 1 mmHg

Accuracy: Pressure within ± 3 mmHg
Pulse ± 5% of the reading

**Power source:** 4 AA batteries, 1.5V

AC adapter 6V DC 600 mA

Accessories: Wide range cuff BD051 for arm circumference 22-42 cm

Technical alterations reserved



Follow Instructions for Use. This document provides important product operation and safety information. Please read this document thoroughly before using the device and keep for future reference.



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.



Not waterproof, please keep it dry.

BIOS I Medical

and Manufactured by / Fabriqué par :

Thermor Ltd.

16975 Lesue Street

Newamarket, on 13y 9a1

Manufachet, on 13y 9a1

Manufachet, on 13y 9a1

Wywy.biosmedical.com