

WRIST

BLOOD PRESSURE MONITOR

with BP Advisor™ Technology

BIOS
Diagnostics™



**INSTRUCTION
MANUAL**

Talking Wrist Blood Pressure Monitor

Instruction Manual

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1. Introduction

Thank you for purchasing the BIOS Diagnostics™ Talking Wrist Blood Pressure Monitor. Designed for convenience and easy operation, this device provides you with voice directions on how to take blood pressure correctly. It also announces your blood pressure reading, and lets you know how your systolic and diastolic numbers rate according to the World Health Organization (WHO) guidelines.

1.1 Features

- Voice prompt on how to take blood pressure correctly
- Announces and displays:
 - Systolic and diastolic pressure, and how they compare to WHO guidelines
 - Pulse rate
 - Mean arterial pressure
- Memory recalls 2 users, 60 measurements each
- Volume adjustment

Readings taken by the blood pressure monitor are equivalent to those obtained by a trained observer using the cuff and stethoscope method. Clinical performance were successfully done against ANSI/AAMI SP10 and international protocol, and The B.H.S. which has rated this product "recommended for clinical and home use", this is the highest grading available for blood pressure monitors. Please refer to BHS website http://www.bhsoc.org/bp_monitors/automatic_wrist.stm.

Before using the BD401, please read this instruction manual carefully and keep it in 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™ Talking Wrist 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.
- 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.

- Morning Hypertension (> 135 / 85 mm Hg): 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.
- This device is intended for adult use only.

2. About 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. Your blood pressure level is determined in the circulatory center of your brain. Your nervous system allows your body to adapt or alter blood pressure in response to different situations. Your body alters your pulse or heart rate and the width of blood vessels through changes in muscles in the walls of blood vessels.

Your blood pressure reading is highest when your heart pumps or ejects blood. This stage is called your systolic blood pressure.

Your blood pressure is lowest when the heart rests (in-between beats). This is called your diastolic blood pressure.

- 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. 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.
- It is critical to maintain blood pressure values within a “normal” range in order to prevent cardiovascular diseases. Increased blood pressure values (various forms of hypertension) have associated long and medium term health risks. These risks concern the arterial blood vessels of your body, which are endangered due to constriction caused by deposits in the vessel walls (arteriosclerosis). A deficient supply of blood to

important organs (heart, brain, muscles) can be the result. Furthermore, with long-term increased blood pressure values, the heart will become structurally damaged.

- There are many different causes of the appearance 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.

2.1 Normal Blood Pressure Values

Blood pressure is too high when, at rest, the diastolic pressure is above 90 mmHg or the systolic blood pressure is over 140 mmHg.

If you obtain 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.

Should the systolic blood pressure values lie between 140 mmHg and 160 mmHg or the diastolic blood pressure values lie between 90 mmHg and 95 mmHg, consult your doctor. Regular self-checks will be necessary.

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.

Even with normal blood pressure values, a regular self-check with your blood pressure monitor is recommended. This way you can detect possible changes in your values early and react appropriately.

Refer to the following table for classifying blood pressure values (units: mmHg) according to the World Health Organization (WHO):

Category	Systolic Blood Pressure	Diastolic Blood Pressure
Optimal	< 120	< 80
Normal	< 130	< 85
High Normal	130 - 139	85 - 89
Hypertension		
• Stage 1: Mild	140 - 159	90 - 99
• Stage 2: Moderate	160 - 179	100 - 109
• Stage 3: Severe	> 180	> 110
Isolated Systolic Hypertension	> 140	< 90

Further information

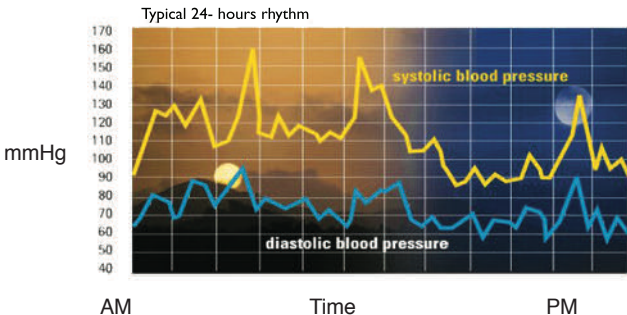
If your values are mostly “normal” under resting conditions but exceptionally high under conditions of physical or psychological stress, it is possible that you are suffering from so-called “labile hypertension”. In any case, please discuss the values with your doctor.

Correctly measured diastolic blood-pressure values above 120mmHg require immediate medical treatment.

2.2 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.



Your blood pressure also increases and 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

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.

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.

2.3 What is mean arterial pressure (MAP)?

The mean arterial pressure (MAP) is the average pressure that forces blood through the arteries. It is not the average of the systolic and diastolic blood pressure; rather, MAP corresponds to a state of balance between the compressive and expansive forces acting on the arterial wall when there is no distension outward or inward. MAP is an excellent way to evaluate the stress on the walls of your blood vessels, and can be used to evaluate excessive load on the cardiovascular system. Show your MAP history to your doctor to provide additional information that may help him or her understand your situation.

3.0 Getting Started

3.1 About the BD401



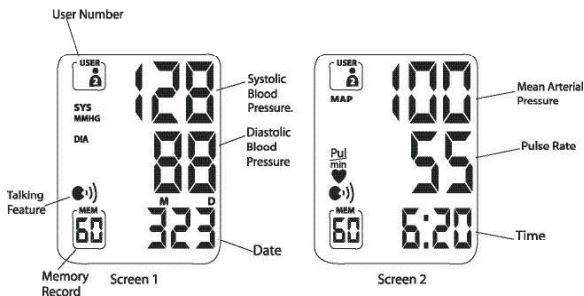
1. TALK / VOLUME BUTTON
2. LCD
3. ON / OFF BUTTON
4. SPEAKER
5. USER 1 / UP ARROW BUTTON
6. USER 2 / DOWN ARROW BUTTON
7. SET button



1. WRIST CUFF
2. BATTERY COMPARTMENT

3.2 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	DESCRIPTION	EXPLANATION
SYS	Systolic pressure	The highest blood pressure measured
DIA	Diastolic pressure	The lowest blood pressure measured
8888	Time (hour: minutes)	Current time
MAP	Mean arterial pressure	Average blood pressure measured (see "What is Mean Arterial Pressure (MAP)?" for more information)
	Pulse	Pulse rate per minute
	User	Shows which user profile (1 or 2 is being displayed)
	Memory	If "MEM" shows, the displayed measurement value is from the memory and not necessarily from the last reading.
	Weak battery	Batteries are low and need to be replaced
	Inflating	Unit is inflating with air to obtain the needed level of pressure
	Deflating	Wrist cuff air is exhausting or deflating

mmHg	Millimeter(s) of mercury	Measurement unit for blood pressure
kPa	Kilopascal	Measurement unit for blood pressure
	Voice activation	Voice announcing your blood pressure measured

3.3 Inserting The Batteries

Follow these steps to insert the two “AAA” batteries in the device.

1. Open the battery compartment cover in the direction shown.
2. Insert the two “AAA” batteries with the correct polarity as indicated.
3. Replace the battery compartment cover.



NOTE: Replace the batteries whenever the weak battery mark shows, the display is dim, or the display does not illuminate when the power is on. Replace all the batteries at the same time - it is dangerous to mix old and new batteries.

Contact your local waste disposal authority for instructions on how to dispose of used batteries. Used batteries can be harmful to the environment, and should not be thrown out with household trash.

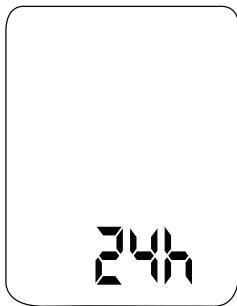
4. Using The Device

This section describes how to get the maximum benefit from your BD401 blood pressure monitor. Follow the instructions carefully to get an accurate measurement of your blood pressure and pulse rate.

4.1 Setting Date, Time, Language And Measurement Units

It is important to set the clock before using your blood pressure monitor, so that the correct time stamp can be assigned to each record that is stored in the memory.

1. When the unit is off, press and hold **SET** for 2 seconds to enter the setting mode.



2. The setting order is as follows: 12/24 hour format, hour, minute, year, month/day or day/month format, month, date, and measurement unit (kPa or mmHg), language (English or French).
3. Press  or  to increase / decrease a value or change the setting.
4. Press **SET** to accept the change and switch to the next setting.
5. When you are finished, press  to exit the setup menu.

4.2 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.

4.2A Before Measuring

- Avoid eating, smoking as well as all forms of exertion directly before the measurement. All these factors influence the measurement result. Relax by sitting in an armchair in a quiet atmosphere for about 5 minutes before the measurement
- Always take measurements on the same wrist (normally left) and in the same posture. Do not switch between right and left arms while recording your blood pressure as there may be a difference of up to 10mmHg pressure between the two wrist.
- Attempt to carry out the measurements regularly at the same time of day, since blood pressure changes during the course of the day. The ideal time to measure your blood pressure is in the morning after you wake up, before breakfast and physical activity, and in the absence of the urge to urinate.
- Rest for 5 minutes sitting quietly and release all the tension in your body especially the arm muscles before beginning with the measurement. Remain calm and quiet when the measurement is in process. Do not speak or move your arm (as well as other body) muscles during the process.
- 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.
- Do not lean backward or bend your wrist inward while taking a measurement.

4.2B Fitting the wrist

- a) Remove all accessories (watch, bracelet, etc.) from your left wrist. If your physician has diagnosed you with poor circulation in your left arm, use your right wrist.
- b) Roll or push up your sleeve to expose the skin.
- c) Apply the cuff to your left wrist with your palm facing up and the LCD display facing you.

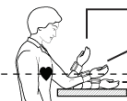


- d) Position the edge of the cuff about 0.4 inches (1cm) from the bottom of your palm.
- e) Fasten the wrist cuff around your wrist, leaving no extra room between the cuff and your skin. If the cuff is too loose, the measurement will not be accurate.

NOTE: Graphics may not exactly match product

4.2C Choose your measurement position

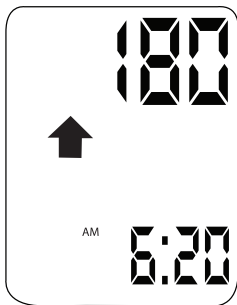
1. Choose the position from which you wish to measure - sitting or lying down.
2. Position your body so that your wrist is parallel with your heart, using the chart and illustrations below as a guide.

IF YOU ARE...	THEN...
Sitting down with an armrest	<p>Place your elbow on a table, using an object as a support under your forearm. Your wrist should be parallel with your heart with the palm facing up.</p>  <p>Measurement Reading becomes lower</p> <p>Correct measurement position</p> <p>Measurement Reading becomes higher</p>
Sitting down with no armrest	<p>Place your arm across your chest with the wrist parallel to your heart. Hold your elbow with the other hand.</p> 
Lying down	<p>Position your wrist on a support, cushion, or your thigh so that it is parallel with your heart with the palm facing up.</p> 

4.3 Measuring Your Blood Pressure

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

1. Relax your hand and press  to turn on the unit. A voice message will remind you to relax and remain still press again. The unit will then begin to inflate the wrist cuff. Once the pressure reaches 180 mmHg, it will slowly deflate until the measurement results show on the LCD.



NOTE: This unit can intelligently adjust the cuff pressure and inflate to a higher pressure level (>180 mmHg) when needed.

2. Your systolic and diastolic pressure readings will flash on the LCD, followed by MAP and pulse per minute readings every 2 seconds. At the same time, your measurement results and the blood pressure classification will also be announced.
3. To repeat the announcement, simply press **TALK / VOLUME**.
4. If you want to save the record to memory, press /▲ or /▼ and the results will be saved to User 1's or User 2's memory accordingly.
5. 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. The measurement is stored as the first (MEM 1) entry in the user record you selected; the last entry (MEM 60) is dropped, and all the entries in between move up 1 digit (e.g. 58 becomes 59, and so on).

4.4 Recalling Measurements Stored In Memory

To view a history of User 1's records, press /▲.

To view a history of User 2's records, press /▼.

The screen will alternate between displaying systolic pressure, diastolic pressure, and MAP/Pulse rate for that record.

NOTE:

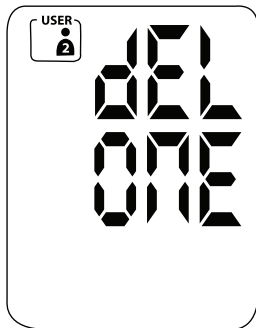
- The most recent record (1) is shown first. Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (e.g., 2 becomes 3, and so on), and the last record (60) is dropped from the list.
- Press the corresponding user button again (▲/▲ or ▼/▼) to see additional records.
- Press and hold the corresponding user button to auto-advance to additional records.
- The date and time of measurement are shown with each record.
- Memory records will be kept even when the batteries become exhausted and are replaced.

4.5 Deleting A Measurement Record From Memory

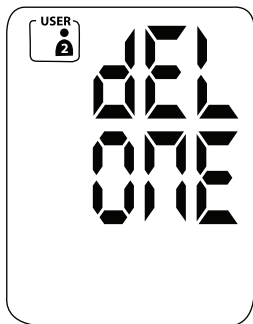
You have the option of deleting your latest measurement record or entire measurement history. This is useful if measurements have not been accurately recorded and need to be recorded again.

DELETING THE LATEST RECORD

1. Press ▲/▲ or ▼/▼ to recall the latest measurement record for User 1 or User 2.
2. Press and hold **SET** until the LCD shows "dEL ONE".



3. Press and hold **SET** for 2 seconds to delete the latest recorded measurement for User 1 or User 2. After you have confirmed deleting the latest record, the screen shows "dEL ONE".



4. If you decide to abort the delete action instead, press /▼ to go back to the main screen.

DELETING ALL RECORDS

1. Press /▲ or /▼ to recall the latest measurement record for User 1 or User 2.
2. Press and hold **SET** until the LCD shows "dEL ONE".
3. Press /▲ to show the option of deleting your entire measurement history; the LCD displays "DEL ALL".
4. Press and hold **SET** for 2 seconds to delete all measurement records. After you have confirmed deleting all records, the screen shows "dEL ONE".
5. If you decide to abort the delete action instead, press /▲ once OR press /▼ twice to go back to the main screen.

4.6 Discontinue A Measurement

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

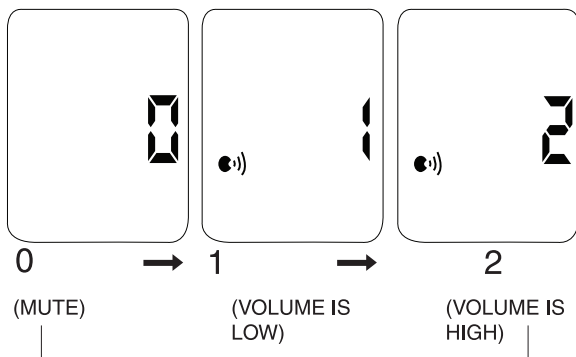
4.7 Voice Playback Of Blood Pressure Measurement

The features voice playback during and after blood pressure measurement results, as well as general instructions to help you prepare for taking measurements. When the unit has finished taking your measurement, your blood pressure readings, pulse and blood pressure classification are announced. If you want to repeat the announcement, simply press **TALK / VOLUME**. Anytime you recall a measurement record from memory, it will also be announced. Press **TALK / VOLUME** if you need to repeat the playback of any record.

VOLUME CONTROL

To adjust the volume level:

1. Press and hold **TALK / VOLUME** until volume level flashes on the LCD.
2. Press **TALK / VOLUME** to adjust volume level.



3. Press  when you have finished adjusting the volume.

NOTE: When volume level 0 is selected, the unit is on mute and you will not hear any voice messages announced.

5. Troubleshooting

This section includes a list of error messages and frequently asked questions for problems you may encounter with your blood pressure monitor. If the product is not operating as you think it should, check this list before arranging for servicing.

Problem	Symptom	Check This	Remedy
No power	Display is dim or will not light up	Batteries are exhausted	Replace with new batteries
Low batteries	 shows on the display	Batteries are low	Replace with new batteries
Error message	Err shows on the display.	A measurement error occurred	Relax for a moment and then measure again
	Err 1, 2, or 3 shows on the display	The wrist cuff is not secure	Refasten the cuff and then measure again
	Err 4 shows on the display	The monitor detected motion while measuring	Movement can affect the measurement. Relax for a moment and then measure again
	Err 5 shows on the display	Pressure is over 37.3kPa (280 mmHg)	Relax for a moment and then measure again

	Err 6 shows on the display	Deflation period was too long	Movement can affect the measurement. Relax for a moment and then measure again
	EExx shows on the display	A calibration error occurred	Retake the measurement. If the problem persists, contact the retailer or our customer service department for further assistance. Refer to the warranty for contact information and return instructions
Settings are wrong	Date and time are incorrect	The clock was not set or reset after installing new batteries	Reset the clock
	Measurement unit (kPa or mmHg) are incorrect	The measurement unit was not set or reset after installing new batteries	Reset the measurement unit
No user memory	Cannot find a record	The memory was not saved after taking a measurement	Retake the measurement. Press /▲ or /▼ to save the corresponding user's memory
		The record was stored to the wrong user memory	Press /▲ to view User 1's record. Press /▼ to view User 2's record

6. Care And Maintenance

- a) Do not expose the device to either extreme temperatures, high humidity, dust or direct sunlight. If the unit has been stored at very low or freezing temperature, allow to reach room temperature before using it.



- b) Clean the device with a soft, dry cloth. Do not use gas, thinners or similar solvents. Spots on the cuff and unit can be removed carefully with a slightly moistened cloth and soapsuds.



- c) Do not drop or bang the monitor or treat it roughly in any way. Prevent sudden jerks and shocks. Avoid strong vibrations.



- d) Never open the monitor. This invalidates the manufacturer's warranty.



- e) Batteries and electronic instruments must be disposed of in accordance with the locally applicable regulations, not with domestic waste.

- f) 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.

7. Lifetime Guarantee

BIOS Diagnostics™ blood pressure monitors have a lifetime 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.

If you have questions regarding the operation of your monitor call the **BIOS Diagnostics™ Blood Pressure 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:

Thermor Ltd.
Repair Department
16975 Leslie Street
Newmarket, ON L3Y 9A1
www.biosesactly.com
thermor@thermor-ins.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.

8. 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
EN1060-1
EN1060-3
EN1060-4

Electromagnetic compatibility:

Device fulfills the stipulations of the International standard IEC 60601-1-2

Readings taken by the blood pressure monitor are equivalent to those obtained by a trained observer using the cuff and stethoscope auscultation method. Clinical performance were successfully done against ANSI/AAMI SP10 and international protocol, and the B.H.S has rated this product "recommended for clinical and home use", this is the highest grading available for blood pressure monitors. please refer to BHS website http://www.bhsoc.org/bp_monitors/automatic_wrist.stm.

9. Technical Specifications

Weight:	6.3 oz (180g) without batteries
Size Height x Width x Depth:	3.5"(H) x 3.4"(W) x 1.2"(D) (90 x 86 x 30.8 mm)
Storage Temperature:	4°F to 140°F (-20°C to 60°C)
Humidity:	10% to 83% relative humidity
Operation Temperature:	50°F to 104°F (10°C to 40°C)
Display:	LCD Display (Liquid Crystal Display)
Measuring method:	Oscillometric / noninvasive
Measuring range:	
SYS/ DIA Pressure:	30 to 300 mmHg (4.0 to 40.0 kPa)
Pulse:	40 to 200 pulse/min
Accuracy:	
Pressure:	+/- 3 mmHg (+/- 0.4 kPa)
Pulse:	+/- 5%
Memory:	Maximum 60 records per user
Maximum number of users:	2
Cuff circumference:	5.3 to 7.7 inches (13.5 to 19.5 cm)
Power:	
Power source:	3V DC, 2 LR03 / AAA / UM4-size 1.5V batteries
Power save:	Auto power off after 1 minute of non-activity

9. Contacts for Support

Thermor Ltd.
16975 Leslie Street
Newmarket, ON L3Y 9A1
www.biosesactly.com

Toll Free Help Line: 1-866-536-2289

Email: thermor@thermor-ins.com

Made in China