



BLOOD PRESSURE UNIT USER'S MANUAL

REF MDS4001

REF MDS4001LA

REF MDS4001PLUS

REF MDS4001LAT

REF MDS4001U

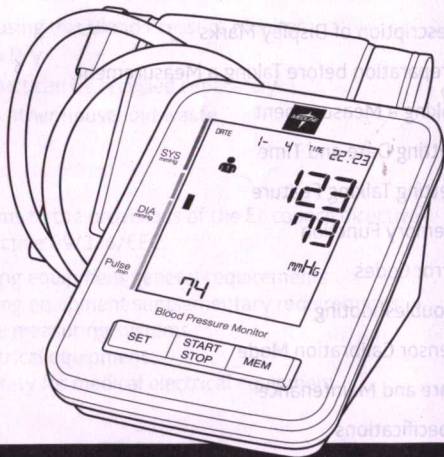


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IMPORTANT NOTES

1. Only a physician is qualified to interpret changes in your blood pressure. This device is not intended to replace regular medical examinations. It is recommended that your physician review your procedure for using this monitor. Never make adjustments to your medication unless recommended by your physician.
2. This Blood Pressure Monitor is intended for use by adults. Children should not use this monitor unless it is under the supervision of an adult.
3. Only use the cuff(s) included with this device or offered as approved accessories. Unapproved cuffs can affect measurement accuracy.
4. Please read the entire instructions carefully before using this Blood Pressure Monitor.
5. ⚠ Warning Symbol
6. ⚡ Type BF Symbol
7. □ Class II Symbol
8. ☂ Keep Dry
9. ♻ Product can be recycled separately from other household waste

MEASUREMENT ACCURACY

The quality of this device has been verified and conforms to the provisions of the Ec council directive 93/42/EEC on medical devices, as well as the EMC directive 89/336/EEC:

- | | |
|---------------------|--|
| EN 1061-1 | Non-invasive blood pressure measuring equipment general requirements |
| EN 1060-3 | Non-invasive blood pressure measuring equipment supplementary requirements for electro-mechanical blood pressure measuring systems |
| EN 60601-1 | Safety requirements for medical electrical equipment |
| EN 60601-1-2 | Electromagnetic compatibility and safety for medical electrical equipment |
| EN 14971 | Risk analysis for medical devices |

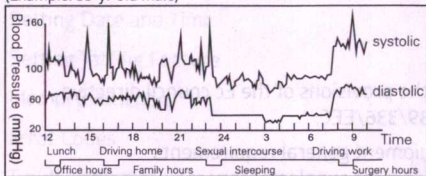
HELPFUL INFORMATION

What is Blood Pressure?

Blood pressure is the force that blood exerts on the arteries. This force is constantly changing as the heart beats. When the heart contracts, blood pressure reaches its highest value. This is called systolic blood pressure. When the heart relaxes between beats, the value of blood pressure is lower. This is called the diastolic blood pressure. The unit of measure for blood pressure is millimeter of mercury, abbreviated mmHg. For example, an individual's blood pressure may be measured as 120 mmHg (systolic) and 80 mmHg (diastolic). This would be spoken as "120 over 80" and written as "120/80". Remember that blood pressure varies throughout the day. Food intake, smoking, the time of day, stress, level of exercise and many other factors can affect it.

Typical Daily Blood Pressure Fluctuations

(Example: 35-yr old male)

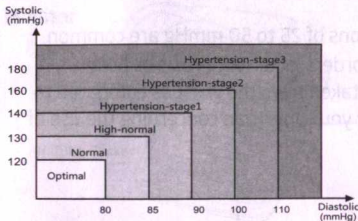


What is High Blood Pressure?

Hypertension, or high blood pressure, is a condition where an individual's blood pressure remains high over a long period of time. Consult with your physician with any questions or concerns you may have about hypertension.

Blood Pressure Classification

The World Health Organization (WHO) and the International Society of Hypertension (ISH)



Why is it Important to Measure Your Blood Pressure at Home?

Having your blood pressure taken at the doctor's office may cause you to become nervous, thus artificially raising your reading. Having the ability to take your blood pressure at home makes it easy to record a log of your daily readings. This will help you gain a greater understanding of your blood pressure reading and the factors that affect it. Be sure that you share your information with your physician.

Hints for Accurate Measurement

1. Relax and try to remain still for 5 to 10 minutes before a measurement.
2. Remove any clothing on the upper arm so that the cuff can be placed directly on the skin.
Constriction of the upper arm caused by rolling up a shirt sleeve may cause an inaccurate reading. Avoid this condition by completely removing the garment.
3. Refrain from eating, smoking and drinking (especially alcoholic beverages) before a measurement. These activities can affect your blood pressure.
4. Remember that blood pressure varies continuously throughout the day. Try to take your blood pressure at the same time each day.

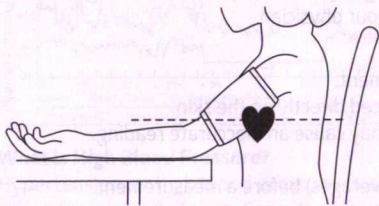
5. Do not be concerned with the results of one measurement. Many measurements, recorded over an extended period of time, will provide a better indication of your blood pressure.
6. Relax for 5 to 10 minutes before remeasuring your blood pressure.
7. Because many factors can affect your blood pressure, daily fluctuations of 25 to 50 mmHg are common.

Please note: Some individuals with hypertension, diabetes, kidney disorders, arteriosclerosis or poor circulation may see a significant difference in blood pressure readings taken from the wrist as compared to readings from the upper arm. It is recommended that you consult with your physician concerning the use of this monitor.

CORRECT METHOD OF MEASUREMENT

To obtain the most accurate blood pressure measurement, please follow these important directions:

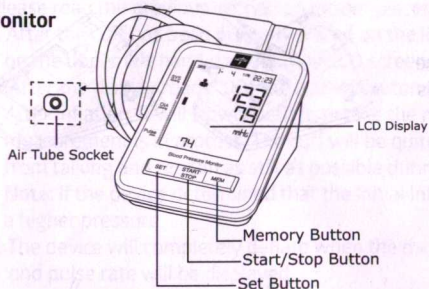
1. Be seated in a chair with back support.
2. Rest your left arm on a table so the cuff is at the same level as your heart.
3. Place both feet on the ground.



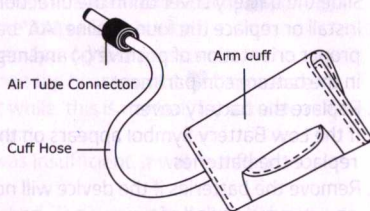
Important: The arm cuff must be at the same level as your heart or accurate measurement will not be possible. (Your heart is located slightly below your left armpit.)

PARTS IDENTIFICATION

Monitor



Accessories



DESCRIPTION OF DISPLAY MARKS

▲ Inflating

▼ Deflating

Er Measurement Error

♥ Measuring



Battery Display

*The battery indicator will reset when power resets. Please replace with new batteries when the battery indicator flashes.

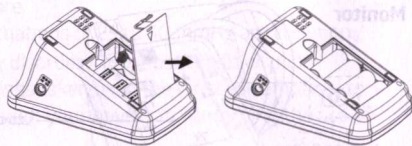


Arrhythmia Detection Function

PREPERATION BEFORE TAKING A MEASUREMENT

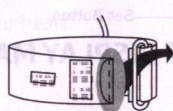
Battery Installation/Replacement

1. Slide the battery cover off in the direction of the arrow.
2. Install or replace the four alkaline "AA" batteries, noting the proper orientation of positive (+) and negative (-) terminals in the battery compartment.
3. Replace the battery cover.
4. If the Low Battery Symbol appears on the display, replace the batteries.
5. Remove the batteries if the device will not be used for an extended period of time.

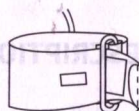


How to Apply the Arm Cuff

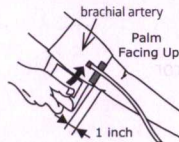
1. Insert the end of the cuff through the D-Ring to make a loop. (Make sure that the hook and loop closures stays outside when it is done.)
2. Wear the arm cuff with the hose downward. Pull the end of the cuff and secure it snugly with the hook and loop closures
3. Adjust the cuff so that the bottom edge is about 1 inch above the elbow on the inside of the arm. Make sure the colored area on the cuff covers the brachial artery.
4. Plug the air tube connector into the monitor.



Step 1



Step 2



Step 3





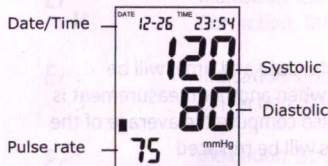
Step 4

Note: Batteries are hazardous waste.
Do not dispose with household garbage.

TAKING A MEASUREMENT

Please read the previous section on proper placement of the cuff and arm position.

1. After the cuff has been properly placed on the left arm, please press Set button and select [] or [] on the upper left hand corner of the LCD screen, and then press the Start | Stop button.
2. After the display reads "00" the cuff will automatically inflate to an appropriate pressure. After inflation, it will slowly deflate to take the measurement. When the heart mark " ♥ " appears a measurement is in process. The cuff will be quite snug for a short while, this is normal. Try to relax, refrain from talking and remain as still as possible during the measurement.
Note: If the device determined that the initial inflation pressure was insufficient, it will re-inflate to a higher pressure.
3. The device will completely deflate when the measurement is finished. The systolic and diastolic pressure and pulse rate will be displayed.



To end a measurement for any reason, just press the Start/Stop button to turn off the unit and release the cuff pressure. If during a measurement the power drops to an insufficient level, the device will end the measurement and display the low battery symbol. Please replace the batteries and repeat the measurement. If the device cannot detect your pulse, it will end the measurement attempt. Please wait a few minutes, make sure that the cuff is positioned properly and try again. The device will automatically shut off 1 minute after a measurement is finished. You can also press Start | Stop button to shut the device off.

SETTING DATE AND TIME

The device displays time and date on the LCD. They can be set according to the following method:

1. Make sure the machine is powered OFF, then hold the SET button for 5 seconds until digits on the screen start flashing.
2. Press the SET button to switch between month, date, hour and minute.
3. Press the MEM (Memory) button to advance the display selected by one digit at a time.

SETTING TALKING FEATURE

For the MDS4001LAT Talking Model, after the date and time settings are selected, the "SP" character will flash. Press the MEM (Memory) button to move from English, "SP 01", to Spanish, "SP 02", or to off, "SP OF".

MEMORY FUNCTION

Memory Input

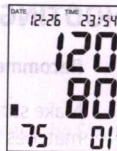
When a valid measurement is made, the result (systolic, diastolic, pulse rate, date and time) will be stored in the memory automatically as soon as the device is turned off or when another measurement is initiated. The device can store up to 90 readings for each of 2 users, and also compute the average of the latest 3 readings. When more than 90 readings are stored, the oldest ones will be replaced.

Memory Recall

By pressing Memory button, AVG will be shown in the lower left hand corner. AVG means the average of all recorded readings. Press the Memory button again and 01 will appear in the lower right hand corner, which is your latest reading in the memory. When you press Memory again, 02 will display which is the previous reading. When you press the Memory button repeatedly, the records will be displayed sequentially.

Memory Erase

Press memory button and hold it down more than 3 seconds to erase the readings of the selected records.



Memory frequency

ERROR CODES

Error Indicators

Possible Sources of Errors

Er
U

Indication: Incomplete inflation

Correction: Check if the cuff is firmly connected to the device.
If the Er message is still there, request a repair

Er
H

Indication: Cuff over-inflated and released automatically

Correction: Take a break, reposition the cuff and remeasure

Er
I

Indication: Could not obtain the pulse rate

Correction: Reposition the cuff and remeasure

Er
2

Indication: Strong electromagnetic interference (mobile phone or computer)

Correction: Relax, take a break and remeasure

Er
3

Indication: Irregular pulse rate or blood pressure

Correction: Relax, take a break and remeasure. If the pulse rate or blood pressure continues to be irregular, consult your doctor or health care professional

TROUBLESHOOTING

Problem

Recommended Method

No display

Make sure that the batteries are installed in the proper direction. (Polarity matches to the indication in the battery case.)

No measurement occurs

Check that the cuff is positioned properly, then repeat the measurement procedure.

Blood pressure readings are too high or too low

1. Check if your left arm is positioned properly.
2. Position your arm on a table so the cuff is at the same level as your heart.
3. Remain seated during the entire measurement period.
4. Refrain from hand and body movements during measurement.

Blood pressure readings are variable

Your blood pressure can fluctuate considerably throughout the day, all of the following factors can influence your blood pressure: emotional state, daily activities/exercise, smoking, drinking alcoholic beverages, eating, taking certain medications

SENSOR CALIBRATION MODE

The blood pressure device should only be calibrated by the manufacturer.

mmHg and kPa Transferring Instruction

If you want to change the measurement units, power off the device and then press the Start/Stop button for 10 seconds. Next press the "Memory" button and select mmHg or Kpa.

CARE AND MAINTENANCE

- Keep the device away from high temperatures, high humidity and direct sunlight.
- Keep sharp objects away from the cuff and tubing.
- Do not press the Start/Stop button without the cuff around your arm to avoid excess pressure build up that may damage the cuff.
- Use the device at a sufficient distance from devices with strong electrical fields, such as television, microwave ovens, X-ray equipment, etc.
- Do not subject the device to strong impact or drop it on the floor.
- Do not disassemble or modify the device or the cuff.
- Remove the batteries when the device is to be stored for extended periods of time.

Note: Removing the batteries will erase all readings in memory.

Use only a soft dry cloth to clean the unit. Do not use solvents or other petroleum-based cleaners.

SPECIFICATIONS

Manufacturer Model:	BA-803
Medline Item Numbers:	MDS4001, MDS4001LA, MDS4001PLUS, MDS4001LAT
Memory Function:	Storage and recall 2x90 measurements with average
Display:	LCD
Measuring Range:	Pressure: 0-280 mmHg Pulse: 40-199/minute
Sensor Accuracy:	Pressure: ± 3 mmHg Pulse: $\pm 5\%$
Inflation System:	Electro-pneumatic pump
Arm Size Ranges:	22-42 cm (8.6-16.5 inches)
Batteries:	1.5V alkaline (LR6/AA)X4
Automatic Power-off:	Approx. 1 minute after measurement
Reference Method for Clinical Trials:	Auscultatory measurement
Weight:	Approximately 420g(without batteries)
Operating Condition:	41°F ~ 104°F (5°C ~ 40°C) 10%~90%RH
Storage and Transport Condition:	-4°F ~ 149°F (-20°C ~ 65°C) 10%~95%RH
Standard Cited:	EN 1060-1 EN 60601-1-2 EN 1060-3 EN 14971 EN 60601-1

BLOOD PRESSURE LOG

Date	1/1	1/1	1/1					
Time	7:00	13:30	20:00					
mmHg	240							
	220							
	200							
	180							
	160							
	140							
	120	128	134	123				
	100							
	80	84	90	76				
	60							
Pulse	70	73	69					
Body Condition								

