



User's Guide & Operation Instruction

Arterial Hardness & Blood Pressure Monitor



Model: V 201

How is your H-Value (degree of Arterial Hardness)?
We suggest you READ PAGES 3 to 5 TWICE in order to gain the most benefit from using this device.

Table of Contents

Indications for Use.....2

Important Notes.....2

Warning.....2

Caution.....2

Part one: User's Guide.....3

What is Arterial Hardness Indication and How to Interpret the Results Correctly?

 Monitoring Arterial Hardness.....4

Definitions.....4

Correct Steps & Procedure.....4

Classification: Arterial Hardness Indication.....5

 Monitoring Blood Pressure.....6

Definitions.....6

Classification: Blood Pressure.....7

Part Two: Operation Instruction.....8

 Hints for Accurate Measurement.....9

 Correct Posture of Measurement.....10

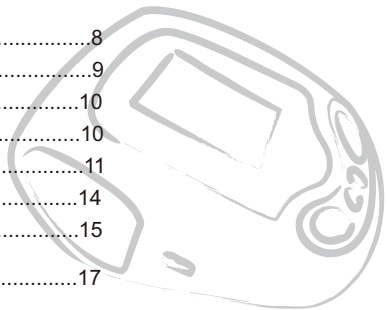
 Parts and Display Identification.....10

 Device Preparation.....11

 Taking a Measurement.....14

 Memory Function.....15

Part Three: Troubleshooting, Maintenance and other Information.....17



Indications for Use:

The device is a non-invasive monitor intended for use in measuring blood pressure and pulse rate in adult population.

The device also estimates the arterial compliance (elasticity of arterial wall) during measurement and gives an indication with readings.

The device is not intended to be a diagnostic device.

Important Notes

Please read the entire manual carefully before using this Arterial Hardness & Blood Pressure Monitor.

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 it is the advice of a physician.

- 5. ⚠ Warning Symbol
- 6. ♿ Type B Symbol
- 7. □ Class II Symbol

Warning

This device is intended for adult use. Do not allow children to play with this device.

Do not wrap the cuff around any parts of the body other than an adult's arm.

Substitution of a component different from that supplied might result in measurement error.

Caution

The H-Value technology requires 5 to 15 minutes rest before taking every measurement.

Part One:

User's Guide:

What is Arterial Hardness Indication and How to Interpret the Results Correctly?

Regular medical check-ups play an important role in your personal health management. We hope this Arterial Hardness Indication (H-Value) will motivate you to lead a healthier lifestyle, and it could also act as a reminder for you not to forget your regular check-up, or even seek an earlier appointment (e.g. If the average of H-Value constantly indicated 7-8 bars).

Besides measuring blood pressure and pulse, this device also estimates the compliance (elasticity) of your brachial artery during blood pressure measurement. This H-Value indication is a result of the measurement on brachial artery, which may or may not reflect the arterial hardness condition of the entire body.

Monitoring Arterial Hardness

Definitions

1. Arterial Hardness

Arterial hardness describes a biological change in the physical property of the arteries in particular the property of elasticity. If hardening of the arteries is not controlled, it can lead to further complications in the blood vessels of the heart and the brain. The harder your arteries are, the less elastic they are.

This unique technology has been given three different names as AHI (Arterial Hardness Indication) or ASI (Arterial Stiffness Indication) or H-Value (degree of arterial hardness)

2. Arteriosclerosis

Arteriosclerosis means a person's arteries have hardened to such a serious degree that a physician would diagnose it as a disease. Such disease may induce Stroke or Heart Attack, etc. The degree of Arteriosclerosis is difficult to diagnose since it progresses slowly and silently.

Caution: This device does not estimate Arteriosclerosis.

Correct Steps & Procedure

1. A single measurement of BP and H-Value reflects only the moment of measurement. similar to BP, the H-Value fluctuates due to emotion, stress, nervousness, temperature and some medications.

Daily fluctuation (2 to 5 bars) of H-Value is considerably normal.




2. The best use of this unique technology is to help you to monitor the current status and the future trend of your arterial hardness. **You must build a base of the AVERAGE of your H-Value by taking around 30 measurements.** When turning the power off, the LCD display will show the AVERAGE value from all the previous measurements (30 maximum). It helps to remind and motivate you to decrease (or at least to maintain) the AVERAGE number of bars, either by improving your lifestyle or consulting your doctor.

Caution: The H-Value technology requires the user to rest 5 to 15 minutes before taking a measurement. Users must relax and remain still during measurement in order to avoid a faulty blood pressure and/or H-Value reading.

Classification: Arterial Hardness Indication (H-Value)

The classifications provided in this manual are recommendations for reference only and are revised by their respective publishers from time to time. They are for reference only, and must not be used for self-diagnosis by patients. Any treatment or medication adjustment must be given by doctors only.

Caution: The classification is for Average Value only, not for individual measurement.

Arterial Hardness Indicator	Indication	Recommended Action
	Green zone means the elasticity of arteries appears to be good.	Keep doing what is healthy for your arteries
	Yellow zone indicates the arteries may be less elastic.	Consider modifying your lifestyle and diet to promote better arterial health.
	For constant red zone, the arteries appear to be even less elastic.	Don't forget your next medical check-up.

Definitions

1. 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 the millimeter of mercury, abbreviated mmHg.

Remember that blood pressure varies throughout the day. Food intakes, smoking, time of day, stress, level of exercise and many other factors can affect it.

2. Hypertension

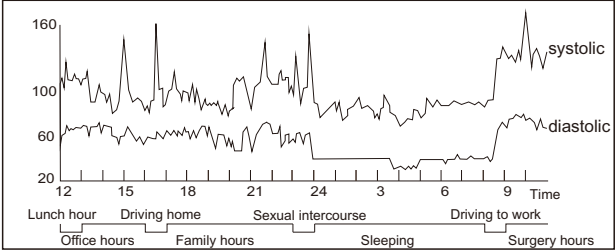
Hypertension, or high blood pressure, is a condition where an individual's blood pressure remains high over a long period of time. Untreated hypertension

can cause many serious medical problems.

3. Measurement Fluctuation

There are some physiological factors, which influence the measurement result such as, menstruation, cold, headache, feeling unwell, external injury, inflammation, aches and some medication (especially hypertension medication).

Typical daily blood pressure fluctuations
(Example: 35-year-old male)



Classification: Blood Pressure

The classifications provided in this manual are recommendation for reference only and are revised by their respective publishers from time to time. They are for reference only, and must not be used for self-diagnosis by patients. Any treatment or medication adjustment must be given by doctors only.

The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure has published the following chart to classify blood pressure.

Category	Systolic (mmHg)		Diastolic (mmHg)
Normal*	less than 120	and	less than 80
Pre-hypertension	120-139	or	80-89
Hypertension			
Stage 1	140-159	or	90-99
Stage 2	160 or higher	or	100 or higher

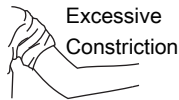
* Unusually low readings should be evaluated for clinical significance.
(From the Seventh Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure)

Part Two:

Operation Instruction

Hints for Accurate Measurement

1. **Rest 5 to 15 minutes before taking a measurement, and remain still during measuring.**
2. Remove any heavy clothing on the upper arm.
(Shirts are acceptable)
Constriction of the upper arm caused by rolling up a shirtsleeve may cause an inaccurate reading.
3. Refrain from eating, smoking, and drinking (especially alcoholic beverages) before a measurement. These activities can affect your blood pressure.
4. Do not be concerned with the results of just one measurement. Many measurements, recorded over a long period of time will provide a better indication of both your blood pressure and/or arterial hardness.
5. Please relax for at least 5 minutes before taking another measurement.

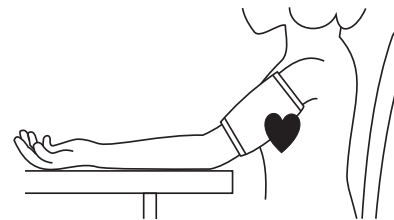


6. Many factors can affect your blood pressure and/or arterial hardness indication such as exercising, eating, talking, moving, nervousness, environment and temperature changes. Emotional stress can cause an increase in blood pressure, and/or the arterial hardness. Daily fluctuations of 25 to 50 mmHg or up to 3 bars are common for many people.
7. Remember that blood pressure and arterial hardness vary continuously throughout the day. Try to take your arterial hardness reading at the same time each day.

Correct Posture of Measurement

To obtain the most accurate blood pressure and H-Value measurement, please follow these important directions.

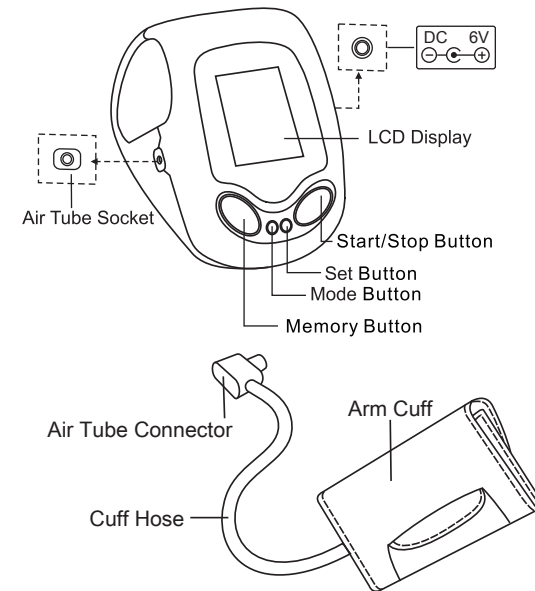
- Be seated in a chair with back support.
- Rest your arm on a table so the cuff is at the same level as your heart.
- Place both feet on the ground.



NOTE: 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.) If the cuff is 10 cm higher or lower than the heart, then the blood pressure will 8 mmHg lower or higher.







Parts and Display Identification

Parts Identification



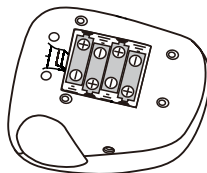
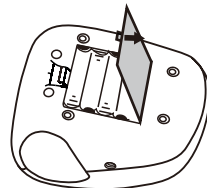
Caution: Substitution of a component different from that supplied might result in measurement error.

Description of LCD Display Marks

	Deflating
	Inflating
	Measuring
	Replace All (new) Batteries
	Blood Pressure Measurement Error
	Arterial Hardness Measurement Error

Battery Installation/ Replacement

1. Flip open the battery cover in the direction of the arrow.
2. Install or replace the four alkaline "AA" batteries, noting the proper orientation of positive (+) and negative (-) terminals of the batteries in the battery compartment.
3. Replace the battery cover.
4. If the Low Battery Symbol appears on the display, replace all batteries with new ones. Do not mix with any old battery, it will cause the new batteries to die very quickly.
5. Remove the batteries if the unit will not be used for an extended period of time.



NOTE: Batteries are hazardous waste.

Do not dispose with the household garbage.



NOTE: The following battery replacement procedure will help you keep the measurement memory, inflation level and the date/time setting.

1. **Replace one battery at a time. You have about 10 seconds for changing each battery before the memory and other settings are deleted.**
2. **Do not touch any button when changing the battery.**

1. After the batteries have been properly installed, "0:00" and "1 - 1" will appear as time and date respectively.
2. Press the Mode button repeatedly; the individual figure will start blinking sequentially from month, day, hour, then to minute.
3. After you have selected a desired column (month, day, hour or minute), indicated by the blinking digit, press the Adjust button to make adjustment to the current date and time.
4. After setting the correct date and time, press the Mode button or Start/ Stop button to exit the date/time setting mode.

NOTE: When the batteries are removed from the device, date/time needs to be set again.

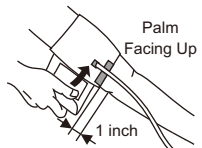
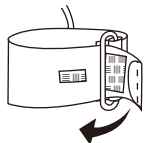
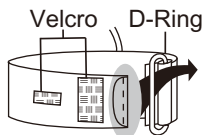
Setting Date and Time

For saving subsequent measurements with correct date and time, you have to set date and time after installation of batteries.

How to Apply the Arm Cuff

(Preferably on the left arm.)

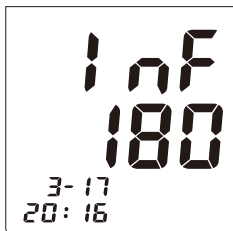
1. Insert the end of the cuff through the metal D-Ring to make a loop.
(Make sure that the Velcro stays outside when it is done.)
2. Wear the arm cuff with the hose downward. Pull the end of the cuff and secure it snugly with the Velcro.
3. Adjust the cuff that the bottom edge is about 1 inch above the elbow on the inside of the left arm. Please mind the red ribbon on the cuff covers the brachial artery.
4. Plug in the air tube connector tightly to the monitor.



Setting Inflation Level

Press Adjust button to select the proper inflation level. There are 3 preset levels : 180, 210 and 240 mmHg. Start taking measurement with the level 180 mmHg. If the setting is too low, the device will automatically re-inflate to a higher setting. If the device re-inflates every time you take a reading, you are advised to set the inflation level one level higher. It is not necessary to set inflation level every time you take a reading. If you do not change the inflation level, the unit will inflate to the level set previously.

By removing the batteries, the unit will reset the pressure setting to 180 mmHg

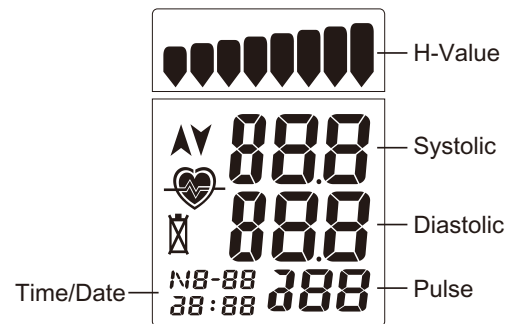


Taking a Measurement

Please review the previous sections on proper placement of the cuff and proper arm position.

1. After the cuff has been properly placed on either the right or left arm, press the Start/Stop button. All symbols on the LCD display will appear momentarily follow by inflation level.
2. After the display reads "0", the cuff will automatically inflate to the preset pressure, and will then begin to slowly deflate.

NOTE: If a downward arrow sign is displayed instead,



unplug the tube and press the cuff to force out remaining pressure. Plug the tube and continue.

3. The heart symbol will appear indicating that the measurement is in progress. The cuff will be quite snug for a short while; this is normal. Try to remain relaxed, refrain from talking, and be as still as possible during the measurement.
4. After a successful measurement, the unit deflates the cuff and displays the result on the LCD.

NOTE:

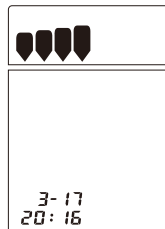
- To end a measurement for any reason, just press Start/Stop button to turn off the unit and the cuff pressure will be released.
- If during a measurement the power drops to an insufficient level, the unit will end the measurement and display the low battery symbol. Please replace the batteries (alkaline type).

Memory Function

- If the unit cannot detect your pulse, it will end the measurement attempt. It could be that the cuff was put on loosely. Relax for a few minutes, make sure that the cuff is put on properly, and try again.
- The unit will automatically shut off 3 minutes following a reading, or it can be turned off manually by pressing the Start/Stop button.

Arterial Hardness Indicator

After your first blood pressure reading, the unit displays your **arterial hardness average** in the Arterial Hardness Indicator section of the LCD display with current Date and Time when you turn off the unit. For more information on Arterial Hardness Indicator please refer to “Part One: User’s Guide,”



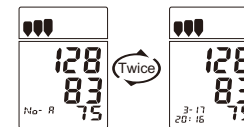
Memory Record

This unit has a memory feature. When a valid measurement is made, the data is stored in the memory automatically when the unit is turned off, automatically shuts off, or when another measurement is initiated.

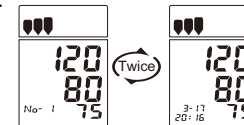
The unit is capable of storing 30 readings and computes the average from all the reading results in memory. When the 30 memories are full, the oldest records will be deleted as the new readings are being recorded, and the memory will maintain a moving average of the latest 30 readings.

Memory Recall

To recall your readings, press the Memory button. The average will be displayed first, indicated by "No-A" on the upper right hand corner. Two seconds later the Date/Time will be displayed. After alternatively displayed twice, the unit will exit memory mode and Return to Arterial Hardness Indicator display if the Memory button is not pressed again before it exits the memory mode.



Pressing the Memory button again and the memory number will appear in the upper right hand corner of the display. Again, after alternatively displayed twice, the unit will exit memory mode and return to the Arterial Hardness Indicator display if the Memory button is not pressed again before it exits the memory mode.



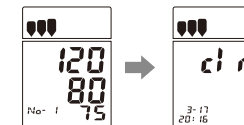
NOTE:

Smaller memory number represents newer entry. Up to 30 previous readings can be recalled. You may press the Start/Stop button at any time to exit memory mode and return to stand-by mode.

Memory Erase

If you let anyone else use this unit, that person's reading result will be stored. To prevent memory mix-up, you should erase that person's reading

record(s). To erase a record, press the Memory button to enter memory mode. Press it again to see No-1 shown on the display. Press and hold the Adjust button until you see "clr" appears on the display. The device will return to stand-by mode automatically, which is an indication that you have successfully erased the record. Repeat the same procedure if that person took more than one reading. No matter how many readings a person takes, you would always erase the record that display “No-1.” For example, if you took three readings, you would erase record “No-1” three times.






NOTE:



- When taking a measurement, the Memory button is inactive.
- When the batteries are removed from the device, all records of reading will be erased. If you want to keep the memory and other settings, please refer to the Battery Installation/Replacement section.

Part Three:

Troubleshooting, Maintenance and other Information

Error Indicators

Display	Possible causes of error	
	Indication:	Cuff pressure reaches 330 mmHg.
	Cause:	Twisted bladder inside of the cuff.
	Correction:	Make sure that the bladder lays flat within the cuff.
	Indication:	Display "Err", cuff pressure releases and "0" pressure display.
	Cause:	Excessive arm movement or talking during measurement.
	Correction:	Take the measurement again while keeping still.
	Indication:	Could not obtain pulse rate.
	Cause:	Cuff was loosely applied, extremely weak pulse or arrhythmia.
	Correction:	Reapply cuff and measure again.
	Indication:	Could not obtain pulse rate.
	Cause:	Cuff was loosely applied, extremely weak pulse or arrhythmia.
	Correction:	Reapply cuff and measure again.

	Indication:	Batteries are exhausted.
	Correction:	<p>Replace with four new alkaline "AA" batteries.</p> <p>NOTE: For safety and efficacy reason, this device requires high level of voltage to maintain operation. Therefore, the batteries deem unusable for this device still holds 2/3 of capacity. For environmental consideration, please try to use them for other devices that require less voltage, such as radio or devices without moving part (motor) before discarding them.</p> <p>To protect our environment, please do not discard batteries with household garbage. </p>

Troubleshooting

Problem	Recommended Action
Nothing appears in display	Make sure that the batteries are installed in the proper direction. (Polarity matches to the indications in the battery case.)
No measurement occurs	<ul style="list-style-type: none"> · Check that the cuff is positioned properly. · Go over the measurement procedure again.
Blood pressure reading is higher or lower than usual, or the readings fluctuate.	<ul style="list-style-type: none"> · Check if the cuff is positioned properly. · Rest your arm on a table so that the cuff is level with your heart during measurement. · Please read section on Measurement Fluctuation (Part One: User's Guide) and Correct Posture of Measurement (Part Two: Operation Instruction).

Care and Maintenance

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

NOTE: Removing the batteries will erase all readings in memory, and reset Date and Time.

- Use only a soft dry cloth to clean the unit. Do not use solvents or other petroleum-based cleaners.
- This device requires no recalibration unless it is dropped to the floor or other high impact situations.
- Circuit diagram and repairable part can be provided if it's necessary.

Sensor Calibration Mode

You need proper equipment to calibrate this device; therefore, do not attempt to do this by yourself. You may damage the unit. If by accident, you enter into the calibration mode by pressing the Memory button and the Start/Stop button at the same time, you will see two zeros appear in the LCD. Press the Start/Stop button to exit the calibration mode.

AC/DC Adaptor

If you would like to buy an AC/DC adaptor, please pay attention to the voltage and amp requirements stated in the Specification section.

Measurement Accuracy

The blood pressure measuring device bears the CE (conformity) label "CE 0044". The quality of the 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 1060-1

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

Specification

Model:	V201	
Measuring method:	Oscillometric	
Memory function:	Storage and recall of 30 measurements with average	
Display:	Digital LCD	
Measuring range:	Pressure: 20 - 280 mmHg	Pulse: 40 - 180 /minute
Sensor accuracy:	Pressure: ± 3 mmHg	
Inflation system:	Auto inflation with 3 Preset Pressure Levels (180 / 210 / 240mmHg)	
Deflation system:	Computer Controlled Linear Deflation / Exhaust Valve	
Arm size ranges:	22 - 33cm (9 - 13inches)	
Batteries / Adaptor:	a) 1.5V alkaline (LR6/AA) x 4	b) DC 6V 800mA
Automatic power-off:	Approx. 3 minutes after measurement	
Reference method for clinical trials:	Auscultatory measurement	
Weight:	Approx. 521 g (without batteries)	
Storage and transport condition:	-10°C ~ +60°C, 10% ~ 95% RH	
Operating condition:	+10°C ~ +40°C, 10% ~ 85% RH	
Standard cited	EN 1060-1 EN 1060-3 EN 14971	EN 60601-1 EN 60601-1-2



bio cuff™

Distributed by Bio Exams
www.bio-cuff.com