NuvōMed®
HEALTHY LIVING MADE SIMPLE.

BLOOD PRESSURE MONITOR WITH ATRIAL FIBRILLATION SCREENING

Item No.:AFIB-4/0148

Instruction Manual

Please read all instructions carefully before use and retain for future use

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KNOW YOUR DEVICE

Indication for Use

This device is for use by medical professional or home users. It is intended to measure the systolic and diastolic blood pressure of an adult individual by using a non-invasive technique, in which an inflatable cuff is wrapped around the upper arm.

Important Safety Information and Precautions

MEDICAL DISCLAIMER: This device and manual are not meant to be a substitute for advice provided by doctors or other medical professionals. Contact your physician for interpretation of measurements, or if you have or suspect you have a medical issue.

⚠ WARNING

- Contact your physician first if you suspect you have a medical issue.
- Not for use by children, pregnant women, or pre-eclamptic patients.
- If you suffer from arrhythmia, diabetes, blood circulation problems, or apoplexy, only use this device under a physician's care and instruction.
- Prolonged over-inflation of the monitor will result in harmful injury to the patient.
- Do not use this device over a wound, as this can cause further injury and harm.
- Too frequent measurements can cause harm and injury as a result of blood flow interference.
- This device may deliver improper results due to external interference, such as acceleration during transport or transport in general.
- Do not attempt to modify this device in any way.
- Store this device in a cool, dry place. Do not subject this device to extreme temperatures, humidity, or sunlight. This device might not meet performance specifications if stored or used outside the ranges specified in the "Specifications" section. Keep away from rain at all times.

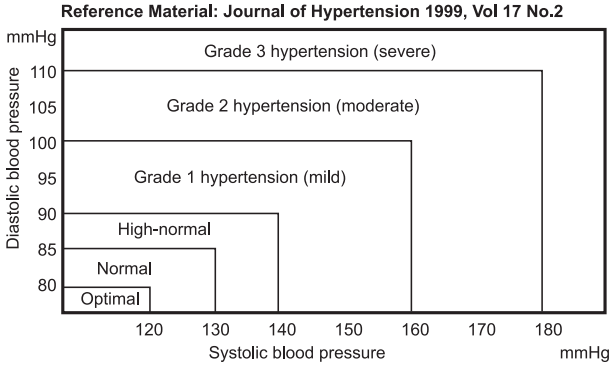
- Do not immerse this device in water or clean with cleaning products, alcohol, or solvents. Carefully follow cleaning instructions provided.
- Remove batteries if this device will not be used for a period of three or more months.
- Ensure that the device is used in the environment specified in the EMC declaration in this instruction manual, otherwise, the device may provide inaccurate results due to improper usage.
- Use of this device adjacent to or stacked with another device should be avoided because it could result in improper operation.
- This electrical medical equipment requires specific precautions regarding electromagnetic compatibility. For proper use, you must install and use the device according to the electromagnetic information.
- Do not use this device where flammable gases or liquids arepresent.
- Never drop the device.

Technical description is contained in the instruction manual.

Battery Warning

- Do not mix alkaline, stand (carbon-zinc) and rechargeable batteries (nickel hydride).
- Do not mix old and new batteries.
- Non-rechargeable batteries are not to be recharged.
- Exhausted batteries are to be removed.
- The supply terminals are not to be short-circuited.
- Only use batteries of the same or equivalent type.
- Batteries are to be inserted with the correct polarity (see diagram).

What is blood pressure?



Blood pressure is the force exerted by blood against the walls of the arteries. Systolic pressure occurs when the heart contracts. Diastolic pressure occurs when the heart expands. Blood pressure is measured in millimeters of mercury (mmHg). One's natural blood pressure is represented by the fundamental pressure, which is measured first thing in the morning while one is still at rest and before eating.

What is hypertension and how is it controlled?
Hypertension, an abnormally high arterial blood pressure, if left unattended, can cause many health problems including stroke and heart attack. Hypertension can be controlled by altering one's lifestyle, avoiding stress, and with medication under a doctor's supervision. To prevent hypertension or to keep it under control:

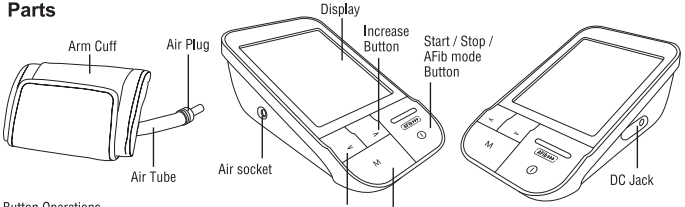
- Do not smoke
- Exercise regularly
- Reduce salt and fat intake
- Have regular physical checkups
- Maintain proper weight

Why measure blood pressure at home?
Blood pressure measured at a clinic or doctor's office may cause apprehension and can produce an elevated reading, 25 to 30mmHg higher than that measured at home. Home measurement reduces the effects of outside influences on blood pressure readings, supplements the doctor's readings and provides a more accurate, complete blood pressure history when used in conjunction to those provided by medical professionals.

World Health Organization (WHO) Blood Pressure Classification
Standards to assess high blood pressure, without regard to age, have been established by the World Health Organization (WHO), as shown in the chart above.

PREPARATION

Parts



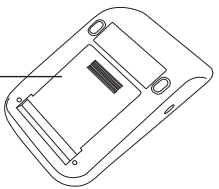
Button Operations

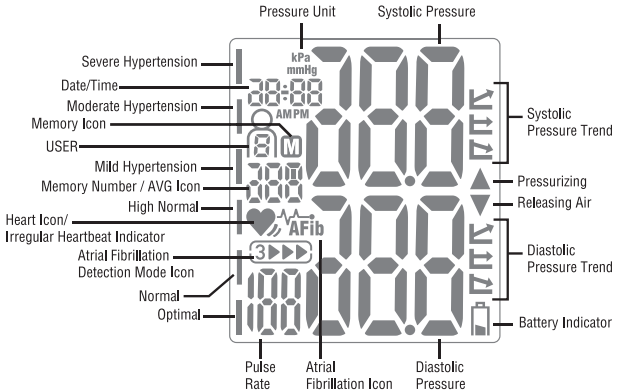
- Go to standby mode
  Press ⏻ button.

* The device goes to clock mode if idle for 1 min.

- Recalling average data
  Press [M] button.

- Select between different users
  (User 1 / User 2 / User 3 / User 4)
  Press [<] or [>] button

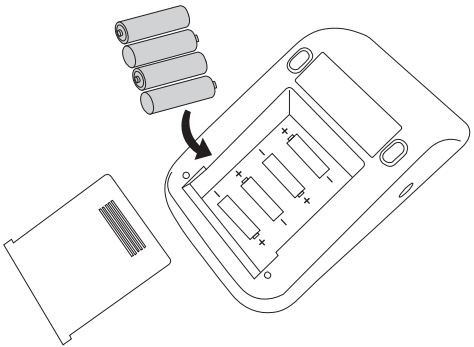




Set Up Your Device

Battery Installation:

1. Slide off the battery cover located on the bottom side of the unit (as shown in the figure).
2. Insert 4 x AAA alkaline batteries (not included).
3. Make sure the battery polarities (+) and (-) match the marking on the battery compartment.

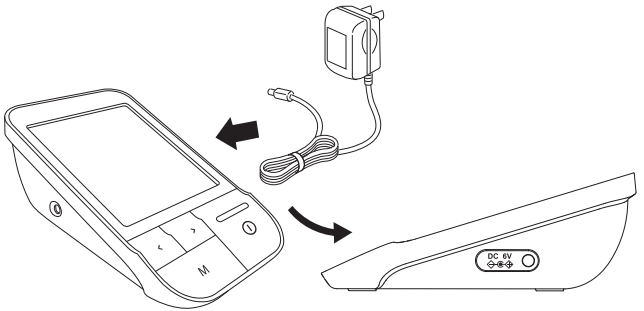


NOTE:

- Insert the batteries as shown in the battery compartment. If not, the device will not work or even be damaged.
- When battery power becomes weak, the battery icon and “E6” symbol will appear in the display. If this happens replace all batteries with new ones. Do not mix old and new batteries.
- Never use rechargeable batteries. This may damage the unit.
- Battery life may vary with ambient temperature and may be shorter at low temperature.

How to Use an Optional AC Adapter (accessory item sold separately):

1.Insert the AC adapter cord into the socket on the right side of the device.
2.Insert the AC adapter plug into the standard AC source outlet.
3.To remove the AC adapter, first disconnect the adapter plug from the AC outlet, then the adapter cord from the device.

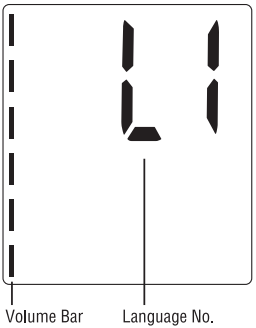


NOTE:
- Optional AC adapter should comply with the requirement of IEC 60601-1 standard.
- Use only the exclusive AC adapter specified by authorized dealers. Other AC adapter may vary in output voltage and polarities and may represent a risk on your life and damaging the device.
- When the AC adapter is in use, the device does not draw power from batteries.

Set Date / Time / Language / Volume

A. When new batteries are installed, “mmHg” will blink on the display.

1. Press the M key to confirm and then the numbers indicating ”YEAR” will start to blink.
2. Press < or > to set the current Year.
3. Press the M key to confirm and then the numbers indicating “MONTH” will start to blink.
4. Press < or > to set the current Month.
5. Press the M key to confirm and then the numbers indicating ”DAY” will start to blink.
6. Press < or > to set the current Day.
7. Press the M key to confirm and then the numbers indicating “HOUR” will start to blink.
8. Press < or > to set the current Hour.
9. Press the M key to confirm and then the numbers indicating “MINUTE” will start to blink.
10. Press < or > to set the current Minute.
11. Press the M key to confirm and then the numbers indicating language setting will start to blink.
12. Press < or > to select the desired language.
    (L0 - Mute / L1 - English / L2 - Spanish / L3 - Mandarin).
13. Press the M key to confirm and then volume bar will start to blink.
14. Press < or > to increase or decrease the volume.
15. Press the M key to confirm and then the settings will be completed.

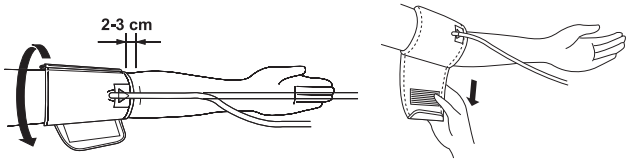


B. When device is in clock mode.

1. Press the ⏻ button or M key to activate standby mode.
2. Press and hold M key for about 3 seconds until “mmHg” blinks on the display.
3. Follow the same procedure above to set the Date / Time / Language / Volume.

INSTRUCTIONS FOR USE
How to Apply the Arm Cuff

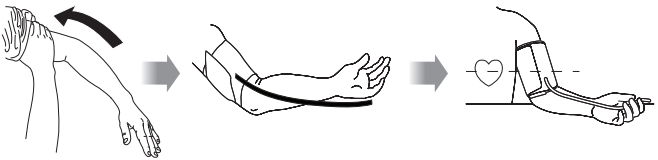
1. Pass the end of the cuff furthest from the tubing through the metal ring to form a loop. The smooth cloth should be the inside of the cuff loop.
2. Put your left arm through the cuff loop. The bottom of the cuff should be approximately 2 - 3 cm above the elbow. The white artery mark on the cuff should be lie over the brachial artery on the inside of the arm. The tube should run down the centre of arm and even with the middle finger. Do not place the arm cuff over heavy clothing (e.g. jacket or sweater sleeve) as the blood pressure monitor will not be able to take proper measurement. Blood circulation in the arm should not be restricted by tight clothing or other objects.
3. Pull the cuff so that the top and bottom edges are fitted evenly around your arm.



4. When the cuff is positioned correctly, press the sewn hook material firmly against the pile side of the cuff.
5. Make sure the cuff fits snugly around your arm. The cuff should make good contact with your skin.
6. If the cuff is assembled correctly, the sewn hook material will be on the outside of the cuff loop and the metal ring will not touch your skin.
7. Insert the cuff tubing into the socket on the left side of the unit. Make sure it is inserted firmly in the main unit that there are no kinks in the cuff tubing.

Before Measuring Your Blood Pressure

1. Apply the arm cuff following the instruction in “How to Apply the Arm Cuff”.
2. Rest at least for 5 minutes before each measurement. Otherwise, there may be erroneous result.
3. Sit down in a comfortable position, which your legs should be crossed, feet should be planted firmly on the floor, and your back should be upright (ideally supported by a chair). At the same time your arm should be supported on a flat surface where the cuff is level with your heart.
4. Relax your arm and turn your palm upward.
5. Relax, and keep still. Do not talk during the measurement as this may lead to inaccurate results being observed.



NOTE:

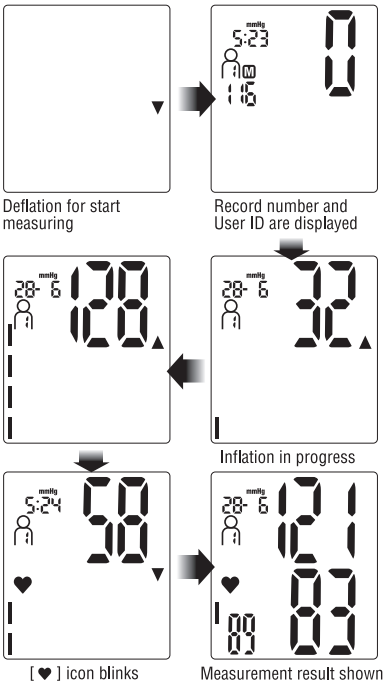
- This instrument is intended for use by adult only. Do not use this device on children, toddlers and infants.
- For reliable monitoring and reference of blood pressure, it is recommended to take measurements daily (at the same time of day).

- In order to obtain a resting condition blood pressure, do not eat, drink alcohol and caffeinated beverages, smoke, exercise or bath for at least 30 minutes before taking a measurement since your blood pressure varies from time to time depending on what you have eaten, drunk and what you have done.
- To minimize measurement variations due to physical activity, relax for five to ten minutes before taking a measurement. If you are experiencing emotional stress or go through significant muscular movement, the measurement results provided may be inaccurate.
- Stress raises blood pressure.
- You should not be physically tired or exhausted while taking a measurement.
- Perform measurements in a quiet and relaxed environment at room temperature.
- Remain relaxed, and do not speak during a measurement since this can affect the accuracy of the results.
- Always wait at least 5 minutes between measurement to allow the blood circulation in your arm to return to normal. You may need to increase the waiting time depending on your individual physiological characteristic.
- Should the device detect an abnormal condition, it stops the measurement and will display an error code E1/E2…/E6. Please see “TROUBLESHOOTING” for more details on how to remedy this.
- This device bases its measurements on your heartbeat. If you have a very weak on an irregular heartbeat, the device may have difficulty in determining your blood pressure. (An irregular heartbeat is defined as a heartbeat that varies by 25% from the average of all heartbeats during measurement.)
- Do not exert any kind of pressure on the hose during measurement, e.g. laying your arms or any other object on the hose. This could cause an incorrect measurement to be observed.

How to Measure Your Blood Pressure

1. Follow the instruction given in the section marked “Before Measuring Your Blood Pressure” to make yourself ready.
2. Press the ⏻ button to change the device from clock mode to standby mode.
3. Press < or > to select user memory. Select: 1, 2, 3 or 4. Confirm your selection by pressing the ⏻ button. Then press the ⏻ button to take a measurement.
   OR
   Press the ⏻ button twice to take a blood pressure measurement.
4. The cuff will start to inflate. It is normal for the cuff to feel very tight. A pressure bar indicator will be displayed during the measurement. See “PRESSURE BAR INDICATOR” for more details.
5. When inflation is complete, deflation starts automatically. Once the pulse is detected, the ♥ indicator will blink with each pulse beat, indicating that the measurement is in progress.
6. When the measurement is complete, the systolic and diastolic pressure and pulse rate are displayed and stored.

REMARK:
The backlight will remain on for around 45 seconds when the device is in use.

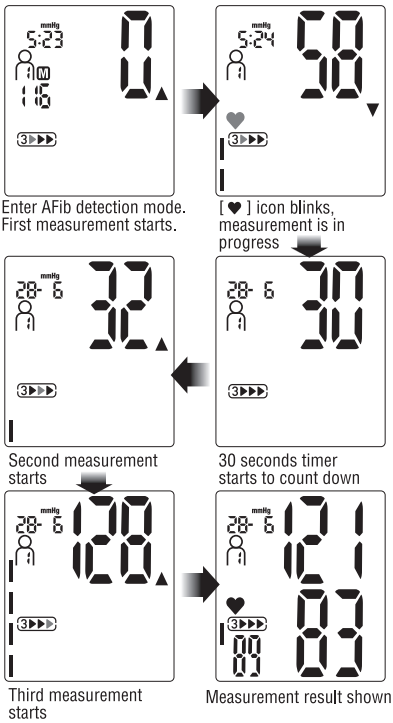


NOTE:
You can stop inflation by pressing the ⏻ button at any time.

How to Measure Your Blood Pressure in Atrial Fibrillation (AFib) Detection Mode

1. Follow the instruction given in the section marked “Before Measuring Your Blood Pressure” to make yourself ready.
2. Press the ⏻ button to change the device from clock mode to standby mode.
3. Press < or > to select user memory. Select: 1, 2, 3 or 4. Confirm your selection by pressing the ⏻ button.
4. Press and hold the ⏻ button for 5 seconds to enter Atrial Fibrillation (AFib) detection mode. Release the ⏻ button when the AFib detection mode icon 3▶▶▶ is displayed.
5. A measurement will be given at the same time.
6. The first arrow of the AFib Detection Mode icon will blink. The cuff will then start to inflate. It is normal for the cuff to feel very tight. A pressure bar indicator will be displayed during measurement. See the section marked “PRESSURE BAR INDICATOR” for more details.
7. When inflation is complete, deflation will start automatically. Once the pulse is detected, the ♥ indicator will blink with each pulse beat, indicating that the measurement is in progress.
8. When the first measurement is complete, the cuff will automatically expel air from the cuff and deflate completely. At the same time, a 30 seconds timer will start to count down that allows user to rest and prepare for the next measurement.
9. The second measurement will then start. The second arrow of AFib Detection Mode icon will blink on. (Repeating steps 5, 6 and 7)
10. Then finally the Third measurement will start. The third arrow of AFib detection mode icon will blink on.
11. When the measurement is complete the average of the 3 measurement results will be displayed and stored.

REMARK:
The backlight will remain on for around 45 seconds while the deviceis in use.

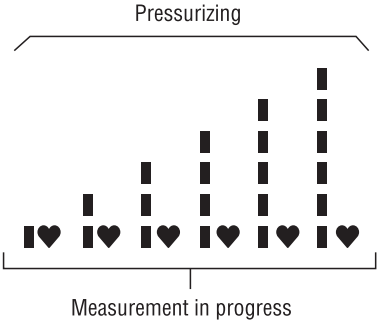


NOTE:

- The " ♥AFib " icon will be shown and the " AFib " symbol will blink if Atrial Fibrillation (AFib) is possibly detected.
- You can stop inflation by pressing the ⏻ button at any time.

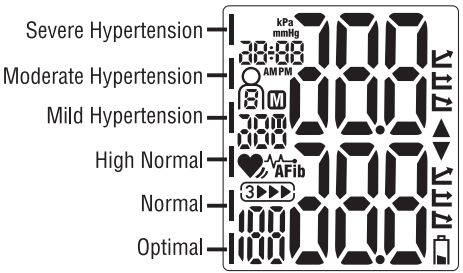
PRESSURE BAR INDICATOR

The indicator monitors the progress of pressing during measurement.



WORLD HEALTH ORGANIZTION (WHO) INDICATOR CLASSIFICATIONS

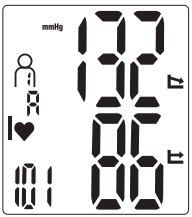
Each of the six segments of the bar indicator corresponds to the WHO blood pressure classification.

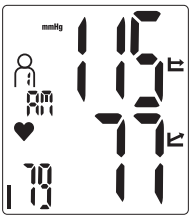


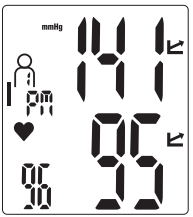
To Recall Average and Previous Measurement Data

This device has a memory capability to store the measurement readings for each user. Every time you complete the measurement, the device will automatically store the measurement result.

1. Press the M button in standby mode to enter the memory mode, the average blood pressure for the latest 3 measurements will then be displayed.
2. Press the > button to view the average data for the latest 7 days AM record (5:00 - 9:00 am).
3. Press the > button to view the average data for the latest 7 days PM record (6:00 - 8:00 pm).
4. Press the > button to view the latest measurement.
5. Continue to press the > button to cycle through past measurement records.
6. Press the < button to view previous measurement records.

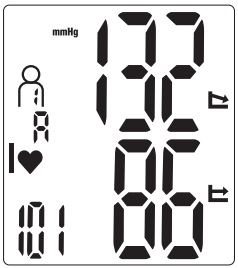






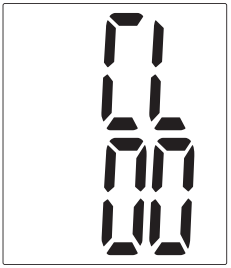
To Delete Measurement Data

1. Press the “M” button simultaneously when the device is showing the average of recent measurements or a single previous measurement data point (for that specific user selected user).
2. Press and hold < and > for 3 seconds until CL and 00 are shown.
3. All measurement data for the selected user will be deleted.



Press [M]

Press and hold
[<] and [>]
at the same time



All memories are cleared

WHAT IS AN IRREGULAR HEARTBEAT

This blood pressure monitor provides a blood pressure and pulse rate measurement even when an irregular heartbeat is occurring. An irregular heartbeat is defined as a heartbeat that varies by 25% from the average of all heartbeats during the blood pressure measurement. It is important that you are relaxed, remain still and do not talk during measurements.

WHAT IS ATRIAL FIBRILLATION

Atrial fibrillation is a quivering or irregular heartbeat (arrhythmia) that can lead to blood clots, stroke, heart failure and other-related complications.

DIFFERENCE BETWEEN AFIB AND IRREGULAR HEARTBEAT

The irregular heartbeat function detects irregularities in the pulse waves in one measurement. The AFib indicator function suggests the possibility of AFib when blood pressure is measured 3 consecutive times.

NOTE:

- We recommend you to contact your physician if you see this and AFib indicator frequently.
- The “irregular heartbeat” and “Atrial fibrillation” function do not replace a cardiac examination, but mat help to detect potential heart rate irregularities at an early stage. Always consult your physician to determine what will be the best course of action for your specific needs.
- The “irregular heartbeat” and “Atrial fibrillation” function are not designed for diagnosing or treating an arrhythmic disorder. Arrhythmia can only be ascertained by a licensed physician.

CARE AND MAINTENANCE

- For regular maintenance, this device only needs to be wiped gently with a soft, dry cloth. Never immerse this device or any components in water.
- Do not carry out repairs of any kind yourself. If a defect occurs, please contact your local authorized distributor. Use only authorized parts and accessories as recommended.

TROUBLESHOOTING

Nothing appears in the display, even when the power is turned on	Batteries are drained	Replace all batteries with new ones.
	Battery polarities are not in the correct position	Re-install the batteries with their negative and positive ends matching their indicated in the battery compartment.
	Loose in plug or contact with outlet (if AC adapter is used)	Check the wiring to make sure plug & outlet are properly secured.
ERROR code 1 (E1) appears	The cuff position is not correct.	Sit comfortably and still. Ensure that the cuff is at the same level as the heart.
ERROR code 2 (E2) appears	You moved your arm or body during measurement	Make sure you remain very still and quiet during the measurement.

ERROR code 3 (E3) appears	The cuff position is not fastened properly	Fasten the cuff correctly.
	The cuff may not be applied	Check whether tube connection of the cuff is secured to the unit properly.
ERROR code 4 (E4) appears	The unit does not measure	If you have a very weak or irregular heartbeat, the device may have difficulty in determining your blood pressure.
	There is a measuring Error	Sit comfortably and still. Fasten the cuff again carefully.
ERROR code 5 (E5) appears	Cuff over inflated	The measurement range is over 300 mmHg. It is recommended to see the doctor as soon as possible.
ERROR code 6 (E6) appears	Low battery	The battery power is too low to function. Replace the batteries with new one.
The monitor keeps reinflating	Circuit locked	Remove and reinsert the batteries and then proceed to take measurement again.

EMC DECLARATION

Guidance and manufacture's declaration - electromagnetic emission

This device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Conducted and radiated RF EMISSIONS	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	This device uses RF energy only for its internal function. Therefore, its RF energy emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Group B	This device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge IEC 61000-4-2	±8kV contact ±15kV air	±8kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Rated power frequency magnetic fields IEC 61000-4-8	50Hz: 30A/m 60Hz: 30A/m	50Hz: 30A/m 60Hz: 30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Conducted disturbances induced by RF fields IEC 61000-4-6	3Vrms 0.15MHz-80MHz 6Vrms in ISM and amateur radio bands between 0.15MHz and 80MHz 80% AM at 1KHz	3Vrms 0.15MHz-80MHz 6Vrms in ISM and amateur radio bands between 0.15MHz and 80MHz 80% AM at 1KHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{6}{E}\right]\sqrt{P}$ where P is the maximum output power rating of the transmitter in Watts (W), d is the minimum recommended separation distance in meters (m), and E is the immunity test level in V/m Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF EM fields IEC 61000-4-3	10V/m 80MHz-2.7GHz 80% AM at 1KHz	10V/m 80MHz-2.7GHz 80% AM at 1KHz	

FCC COMPLIANCE

Caution: Changes or modifications to this device not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance to the Instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

SPECIFICATIONS

Display	LCD display
Measurement range	Systolic pressure: 50-250 mmHg, Diastolic pressure: 30-200 mmHg, Pulse: 40-180 beats/min
Accuracy	Pressure: +/-3 mmHg, Pulse: +/-5% of reading
Resolution	Pressure: 1 mmHg, Pulse: 1 beat/minute
Measurement method	Non-invasive, oscillometric method
Power source	4 x 1.5V AAA batteries (battery life 300 times)
Optional AC adapter	Input 100-240V, 50-60Hz, output 6V DC 600mA (output plug size is dia. 2.1x5.5mm, centred positive)
Operating temperature / humidity	+5°C to +40°C (23°F to 104°F), 15-90% RH maximum
Storage temperature / humidity	-25°C to +70°C (-13°F to 158°F), up to 90% RH maximum
Operation, storage and transport atmospheric pressure	700hPa to 1060hPa
Outer dimensions	Approx. 99 x 164 x 46mm (3.9 x 6.5 x 1.8 inches)
Arm circumference	22-44 cm (9-17 inches)
Accessories	Cuff, user manual, storage pouch
Classification	Application part Type BF

CALIBRATION AND SERVICE

The accuracy of this blood pressure monitor has been carefully tested and is designed for a long service life. It is generally recommended to have this device inspected and calibrated every 2 years to ensure correct functioning and accuracy. Please consult you authorized distributor.

Limited Warranty

This manufacturer's product warranty extends to the original consumer purchaser of the product. Neither the retailer nor any other company involved in the sale or promotion of this product is a co-warrantor of this manufacturer warranty.

WARRANTY DURATION: All materials and workmanship are warranted to the original consumer purchaser for a period of ninety (90) days from the original purchase date.

WARRANTY COVERAGE: This product is warranted against defective materials or workmanship. This warranty is void if the product has been damaged by accident, in shipment, unreasonable use, misuse, neglect, improper service, commercial use, repairs by unauthorized personnel or other causes not arising out of defects in materials or workmanship. This warranty doesn't cover the following which may be supplied with this product, including but not limited to; LCD Screens, glass parts, lenses, bulbs etc. This warranty is effective only if the product is purchased and operated in USA and Canada, and does not extend to any units which have been used in violation of written instructions furnished by manufacturer or to units which have been altered or modified or, to damaged products or parts thereof which have had the serial number removed, altered, defaced or rendered illegible.

WARRANTY DISCLAIMERS: This warranty is in lieu of all warranties expressed or implied and no representative or person is authorized to assume for manufacturer any other liability in connection with the sale of our products. There shall be no claims for defects or failure under any theory of tort, contractor commercial law including but not limited to, negligence, gross negligence, strict liability, breach of warranty and breach of contract. Under no circumstances will Manufacturer's / Distributor's maximum liability exceed the retail value of the product.

WARRANTY PERFORMANCE: During the above 90 day warranty period, a product with a defect will be either repaired or replaced with a reconditioned comparable model (at manufacturer's option). The repaired or replacement product will be in warranty for the balance of the 90 day warranty period and an additional one-month period. No charge will be applicable for such repair or replacement.

SERVICE AND REPAIR: If service is required for this product, you should first contact Nuvomed Inc Customer Service at info@nuvomed.us or by calling 1 (877) 612-5619, Monday to Friday 10am to 6pm EST.

NOTE: Manufacturer cannot assume responsibility for loss or damage during incoming shipment. As a precautionary measure, carefully package the product for shipment, and insure it with the carrier. Be sure to enclose the following details with the product: your full name, return address and daytime phone number, a note describing the problem you experienced, a copy of your sales receipt or other proof of purchase to determine warranty status. C.O.D. shipments cannot be accepted.

Distributed by:
Nuvomed Inc.
1400 Centre Circle, Downers Grove, IL 60515

Made in China