

User Manual

MediGenix Upper Arm Automatic Digital Blood Pressure Monitor BP-1209 (Ref: MGX-1209)



CE 0197

The product is in compliance with the requirements of MDD93/42/EEC
"0197" is the identification number of the Notified Body



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ESH

Clinically Validated by the European Society of Hypertension

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
Safety Notice

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Thank you for purchasing the MediGenix MGX-1209 Automatic Blood Pressure Monitor. The monitor unit has been manufactured using reliable circuitry and durable materials. Used properly, this blood pressure monitor will provide years of satisfactory service.

The MediGenix BP Monitor is intended for non-invasive measuring of an adult's systolic and diastolic blood pressure and pulse using the oscillometric method. The unit is designed for home or clinic use. Measurement position is on an adult's upper arm only. All values are shown on one LCD display.

Please read this User Manual before using the unit and retain it for future reference. Avoid risk and damage by following all warning precautions. Please consult your doctor for specific information about your blood pressure.

Icon Identification	
	Caution
	Mandatory
	Prohibited
	Type BF Equipment
	Instructions for Use MUST be consulted
	Serial Number
	Discard the used product according to local recycling regulations
	The product conforms with the requirements of the EC Directive MDD (93/42/EEC) for medical devices
	Manufacturer
	Authorised Representative in the European Community
	Keep dry
	Keep out of direct sunlight
	Manufacturing date

Safety Notice

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Caution

Individuals with serious circulation problems may experience discomfort. Consult your doctor prior to use.

Contact your doctor if test results regularly indicate abnormal readings. Do not attempt to self-treat these symptoms without consulting your doctor first.

The device is designed for its intended use only. Do not misuse in any way.


The device is not intended for infants or individuals who cannot express themselves.

Do not disassemble or attempt to repair.

Do not use mobile phones or other devices near the BP Monitor which generate strong electrical or electromagnetic fields, as they may cause incorrect readings due to being a source of interference.

Battery Precautions

Do not mix old and new batteries simultaneously.

Replace batteries when "Low Battery Indicator"  appears on screen.

Ensure battery polarity is correct.

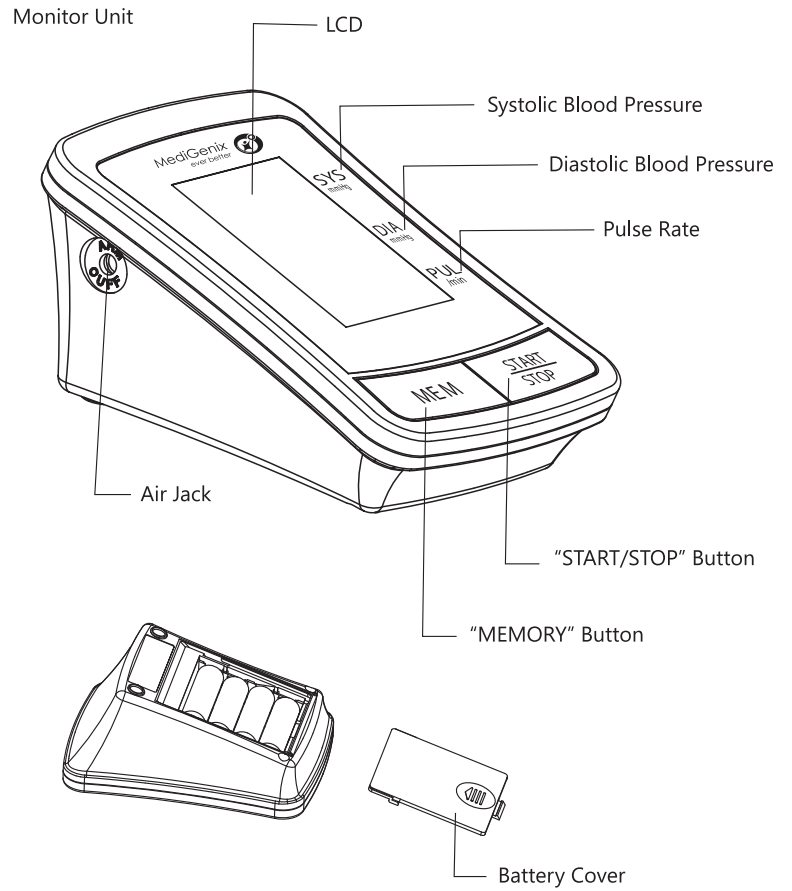
Do not mix battery types. Long-life alkaline batteries are recommended.

Remove batteries from the device when not in operation for more than 3 months.

Dispose of the batteries correctly observing local laws and regulations.

Unit Illustration

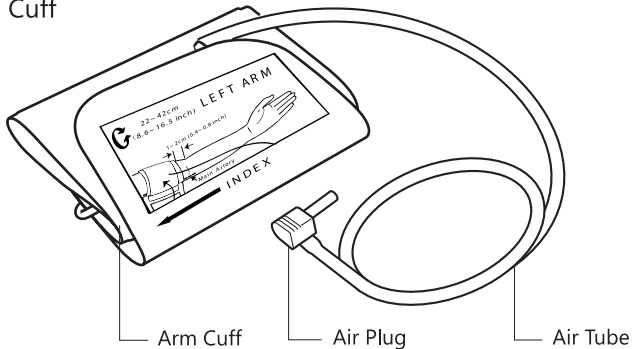
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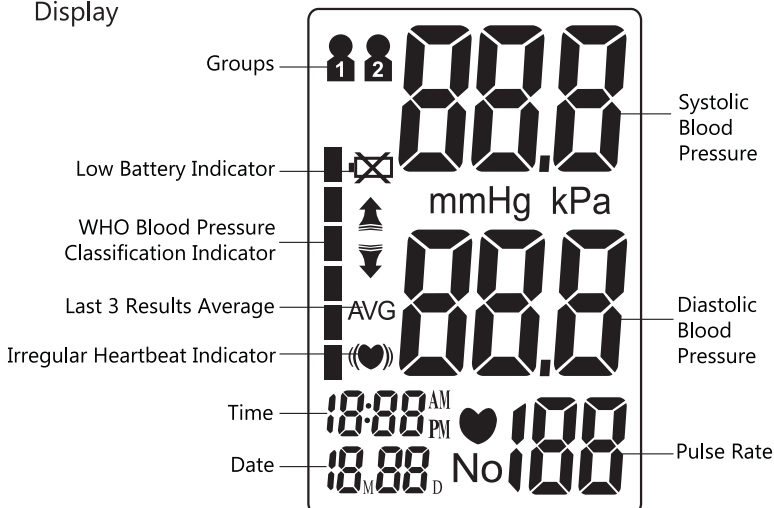
Unit Illustration

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Arm Cuff



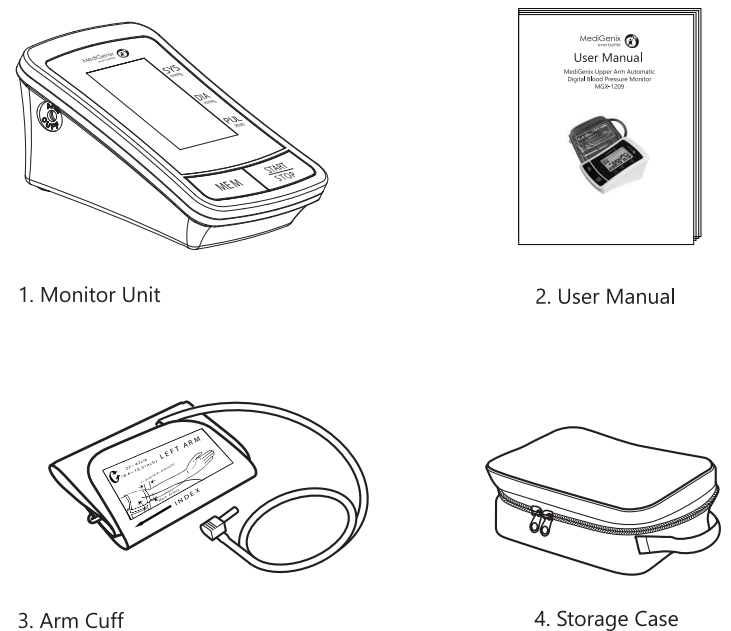
Display



Unit Illustration

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Contents



1. Avoid eating, exercising or bathing 30 minutes before testing.
2. Relax in a calm environment for 5 minutes before testing.
3. Do not stand whilst testing. Sit in a relaxed position with your arm resting in your lap or on a table in front of you.
4. Do not talk or move during measurement.
5. Do not test near strong electromagnetic interference such as microwave ovens or mobile phones.
6. Wait for at least 3 minutes before retesting.
7. Try to measure your blood pressure at the same time each day. First thing in the morning before you get up is best as you are relaxed and the conditions are the same each day. This will provide consistent results which can be compared to establish a trend.
8. Test comparisons should only be made when readings are made on the same arm, in the same position and at the same time of the day.
9. This blood pressure monitor is not recommended for people with severe arrhythmia.

1. Install batteries (see Figure A).
2. Insert the cuff air plug into the left side of the monitor unit (see Figure B).

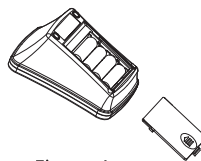


Figure A



Figure B

3. Remove clothing from your arm area.
4. Rest for at least 3 minutes before testing and do not eat or drink anything.
5. Sit down in a calm environment, preferably at a table, with your arm resting on a firm surface and both your feet flat on the floor (see Figure C).

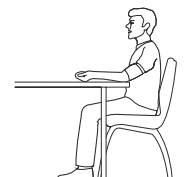


Figure C

6. Apply the cuff to your left arm with the tube situated as in Figure D below. The bottom of the cuff should be positioned approximately 1-2cm (0.4-0.8") above the elbow joint (see Figure E).

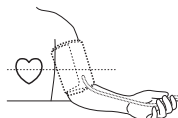


Figure D

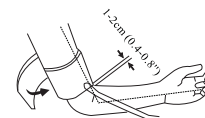
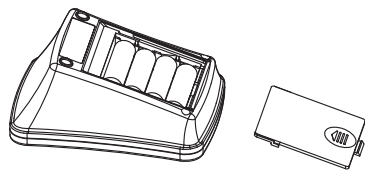


Figure E

7. Press the "START/STOP" button to start testing.

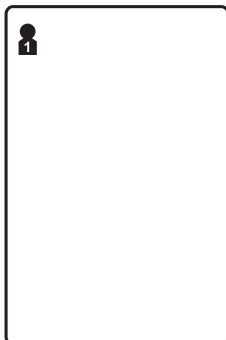
Battery Installation

Slide battery cover off as indicated by the arrow on the cover. Install 4 new AA alkaline batteries observing the correct polarity. Close the battery cover.



System Settings

1. Select Memory Group:
Hold down the "START/MEM" buttons together for 4 seconds to activate System Settings. A Memory Group icon will flash.
Push the "MEM" button to switch between group 1 and group 2.



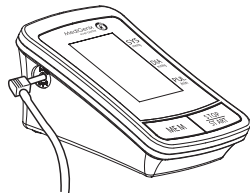
2. Time and Date Setting:
Push "START/MEM" buttons again to initiate time and date set up.
Push "MEM" to adjust values and "START/STOP" when satisfied to save the setting.
The next value will start flashing automatically. Repeat the process until all the settings are saved.



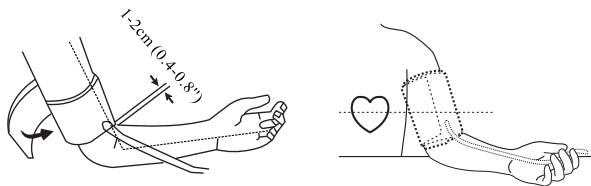
Note: if the unit is left on and is not used for 3 minutes, it will automatically save all information and switch off.

Applying the Arm Cuff

1. Firmly insert the air plug into the opening located on the left side of the monitor unit.




2. With the sticky velcro section facing outwards, insert the end of the cuff underneath the metal ring of the cuff.
3. Fasten the cuff about 1-2cm (0.4-0.8") above the elbow joint. For best results, apply the cuff to the bare arm. Keep it level with the heart while testing.



Testing


1. Power On:
Press and hold "START/STOP" button until a beep sounds. The LCD screen will appear for one second as the unit performs a quick diagnosis. A long tone indicates the unit is ready for testing.

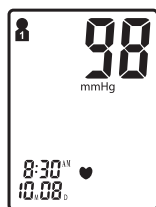


Note: The unit will not function if residual air from previous testing is present in the cuff. The LCD will flash  until the pressure is stabilized.

2. Pressurization:
Initial pressure is first pumped to 190mmHg. If the current user's systolic blood pressure is over 190mmHg, the unit will automatically re-inflate to the proper level.

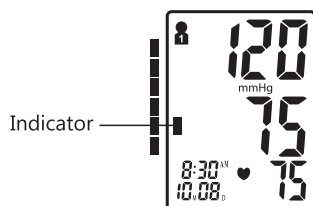


3. Testing:
After cuff inflation, air will slowly subside as indicated by the corresponding cuff pressure value. A flashing  will appear simultaneously on screen signaling heart beat detection.




Note: Relax and do not move or speak during testing.

4. Result Display:
Three short beeps sound when the testing is complete. The screen will display measurements for systolic and diastolic blood pressure and the pulse per minute. An indicator representing the current measurement will appear next to the corresponding WHO Classification.




Note: Refer to page 17 for detailed information on blood pressure.

Irregular Heartbeat Indicator:

If the monitor detects an irregular heart rhythm twice or more during the measuring process, the Irregular Heartbeat Symbol () will appear on screen together with the measurement results.


Irregular heartbeat rhythm is defined as rhythm that is either 25% slower or faster than the average rhythm detected whilst measuring systolic and diastolic blood pressure.

Consult your doctor if the Irregular Heartbeat Indicator () appears.

5. Storing Test Results:
Test results are automatically stored by date within the previously configured memory group. If the number of tests surpasses 60 memories per group, the most recent test results will show first thus eliminating the oldest readings.

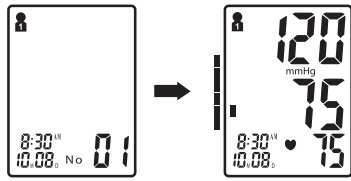
Power Off

The "START/STOP" button can be pressed to turn the unit off in any mode. The unit will switch itself off if it has not been operating in any mode for about 3 minutes.

 Safety Precaution: If the arm cuff pressure becomes too extreme whilst testing, simply press the "START/STOP" button to turn the unit off. The cuff pressure will rapidly deflate once the unit is off.

Memory Check

With power off, press and hold the "MEM" button to turn the unit on. The LCD will display the last measurement memory as NO:1 reading. Older test results in the memory can be viewed by pressing the "MEM" button repeatedly.



Memory Deletion

When in memory check mode, press "START/STOP" for about 3 seconds to delete all history results. The LCD screen will display "---" with beeping sounds. Press the "START/STOP" button to turn the unit off. Memory cannot be recovered once it has been deleted.

Last 3 Tests Average

With the power off, press the MEM button to activate the screen display. After the unit has performed a self-diagnosis, the screen will display the average of the last 3 test results of the last user group.

Low Battery Indicator

4 short warning beeps sound when the battery life is depleted and unable to inflate the cuff for testing. The appears simultaneously for approximately 5 seconds prior to switching off. Replace the batteries at this time. No memory loss will occur throughout this process.

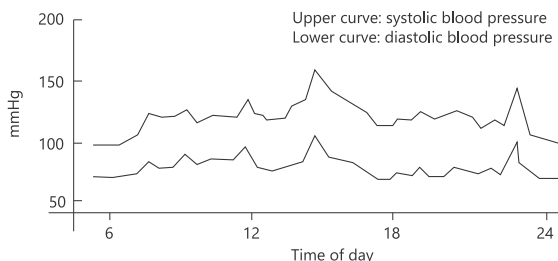
Blood Pressure

Blood pressure is the force of blood pushing against the walls of the arteries. It is typically measured in millimeters of mercury (mmHg). 120/80 is considered normal.

Systolic blood pressure is the maximum force exerted against blood vessel walls each time the heart beats and is the higher of the two readings (120). Diastolic blood pressure is the force exerted against blood vessel walls when the heart relaxes between beats and is the lower of the two readings (80).

Blood pressure frequently changes throughout the course of a day. Excitement or stress can cause blood pressure to rise whilst drinking alcohol or bathing can lower blood pressure. Certain hormones like adrenaline, which one's body releases when stressed, can cause blood vessels to constrict thus leading to a rise in blood pressure.

If one's blood pressure is too high it means the heart is working harder than it should. Like any muscle, if the heart is continuously working too hard it will grow thicker. The thickening of the heart muscle reduces the capacity of the heart chambers and so lowers the amount of blood the heart can pump out in a single beat. This means the heart has to beat faster to meet the oxygen supplies one's body is demanding and in so doing, perpetuates a dangerous cycle which can ultimately end in congestive heart failure.



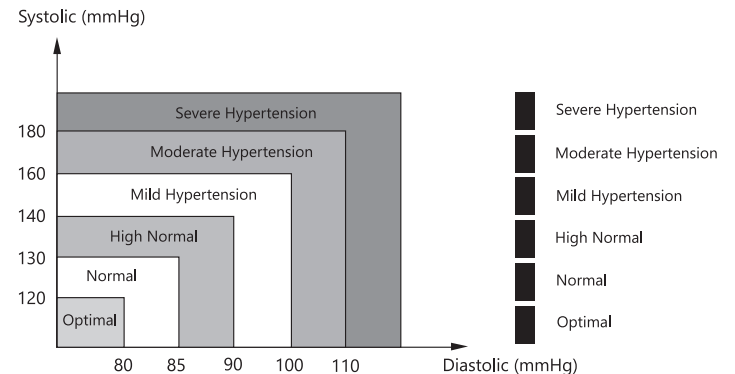
Example: fluctuations within a day (35 year old male)

Troubleshooting

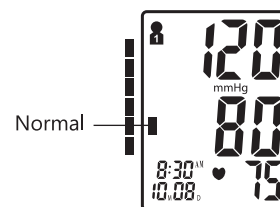
Problem	Possible Cause	Solution
Blood pressure results are not within the typical range.	Cuff is too tight or not properly positioned on the arm.	Firmly reposition the cuff approximately 1-2cm (1/2") above the elbow joint (see page 11).
	Inaccurate test results due to body movement or monitor movement.	Sit in a relaxed position with both feet flat on the floor and your left arm resting in your lap or on a table in front of you. Do not speak or move during testing. Ensure the monitor is not bumped or moved during testing.
"Err" is displayed.	Cuff fails to inflate properly.	Ensure air tube is properly fastened to the cuff and the monitor unit.
	Improper operation.	Read User Manual carefully and re-test properly.
	Pressurization is over 300mmHg.	Read User Manual carefully and re-test properly.

Health Reminder

Hypertension is a dangerous condition that can lead to multiple health problems including, but not limited to, heart failure, kidney failure and cerebral hemorrhaging. By maintaining a healthy, active lifestyle; by monitoring your blood pressure and having regular doctor visits; hypertension can be more effectively controlled especially when diagnosed in the early stages.



The WHO Blood Pressure Classification Indicator is based on established guidelines from the World Health Organisation.



Do not be alarmed if an abnormal reading occurs. A better indication of one's true blood pressure can be obtained by testing at the same time of the day for 3 days in a row - ideally first thing in the morning before getting out of bed.

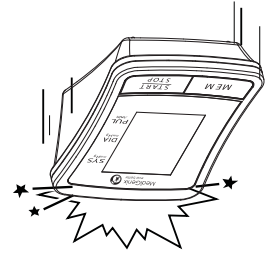
- Q: What is the difference between measuring blood pressure at home versus measuring blood pressure at the clinic or doctor?
 A: Readings taken in a clinical environment may be higher than usual due to the patient feeling anxious. This is known as White Coat Hypertension. Therefore readings taken at home at the same time each day are seen to give a more accurate account.

Note: Abnormal test results may be caused by:

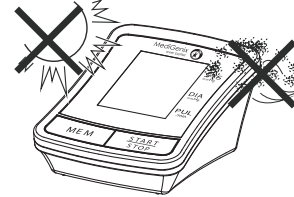
1. Improper cuff placement - ensure the cuff is snugly fitted and is not too tight nor too loose. The bottom of the cuff should be approximately 1-2cm (½") above the elbow joint.
2. Improper body position - ensure your body is kept in an upright position with your arm relaxed.
3. Feeling anxious or nervous - take 2 or 3 deep breaths and relax. Wait a few minutes and retest.
4. Moving or talking during measurement - do not move or talk during measurement. Breathe normally and relax.

- Q: What causes different readings?
 A: Blood pressure varies throughout the course of the day. Many factors may affect a person's blood pressure including diet, stress, cuff placement, levels of hydration.
- Q: Which arm should I apply the cuff to? What is the difference?
 A: Testing on the left arm may provide more accurate results as it is closest to the heart however either arm can be used. Ensure that when results are compared that the same arm has been used. Do not mix left and right arm results.
- Q: What is the best time of day for testing?
 A: Generally when you wake up in the morning before you get out of bed but otherwise any time of the day when you feel relaxed and stress free.

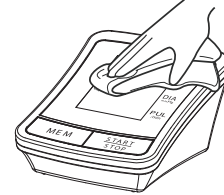
1. Avoid dropping, slamming or throwing the unit.



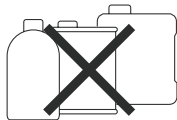
2. Avoid extreme temperatures. Do not expose the unit directly to sunshine.



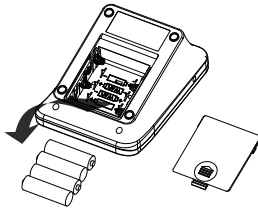
3. Use a soft cloth and mild detergent to gently wipe the unit clean. Use a damp cloth to wipe away excess detergent or dirt. Do not let liquid get into the unit.



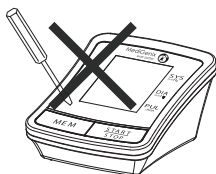
4. Cleaning the cuff: Do not soak the cuff in water! Apply a small amount of rubbing alcohol to a soft cloth to clean the cuff's surface. Use a damp cloth (water-based) to wipe clean afterwards. Allow the cuff to dry naturally at room temperature.
5. Do not use petrol, thinners or similar solvents.



6. Remove batteries when not in operation for an extended period of time.



7. Do not disassemble the unit.



8. Expected service life: approximately 3 years at 30 tests per day.

Product Description	Arm-Type Fully Automatic Digital Blood Pressure Monitor	
Model	MGX-1209	
Display	LCD Digital Display Size: 62.7 x 46.4mm (2.47" x 1.83")	
Measurement Method	Oscillometric Method	
Measurement Range	Pressure	0mmHg - 300mmHg
	Pulse	30 - 180 beats per minute
Measurement Accuracy	Pressure	±3mmHg
	Pulse	±5%
Pressurization	Automatic Pressurization	
Memory	2 x 60 Memories	
Functions	Irregular Heartbeat Detection WHO Classification Indicator Last 3 Results Average Low Battery Detection Automatic Power Off	
Power Source	4 AA batteries provided	
Battery Life	Approximately 2 months at 3 tests per day	
Unit Weight	Approximately 240g (excluding batteries)	
Unit Dimensions	Approximately 134 x 99 x 66mm (5.28" x 3.90" x 2.60") (LxWxH)	
Cuff Circumference	Approximately 135 x 485mm (WxL) Fits arm circumference 22 - 42cm (8.6 - 16.5 inch)	
Operating Environment	Temperature	5°C - 40°C (41°F - 104°F)
	Humidity	≤85%RH
Storage Environment	Temperature	-10°C - 55°C (14°F - 131°F)
	Humidity	<95%RH
Classification	Internal Powered Equipment, Type B Cuff is the Applied Part	

*Specifications are subject to change without notice

The MediGenix MGX-1209 Automatic Digital Blood Pressure Monitor complies with the European regulations and bears the CE mark "CE 0197". This blood pressure monitor also complies with mainly the following standards including, but not limited, to:

Safety standard:

EN 60601-1 Medical Electrical Equipment Part 1: General requirements for Safety EMC Standard;

EN 60601-1-2 Medical Electrical Equipment Part 1-2: General requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and tests performance standards;

EN 1060-1 Noninvasive Sphygmomanometers - General requirements;

EN 1060-3 Noninvasive Sphygmomanometers - Supplementary requirements for electromechanical blood pressure measuring systems;

EN 1060-4 Noninvasive Sphygmomanometers - Test procedures to determine the overall system accuracy of automated noninvasive sphygmomanometers.

ESH International Protocol 2010 clinically validated for BP-1209

Correct disposal of this product (Waste electrical & Electronic Equipment)



This marking shown on the product indicates that it should not be disposed of with other household waste at the end of its life. To prevent potential harm to the environment or human health, please separate this product from other types of wastes and recycle it responsibly. When disposing of this type of product, contact your local municipal office for details regarding how to dispose of this product at an environmentally safe recycling centre. This product should not be mixed with other commercial wastes for disposal. This product is free of hazardous materials.

The MediGenix MGX-1209 Automatic Digital Blood Pressure Monitor is covered by a 1 year product warranty from date of purchase. If the unit does not function properly due to defective components or poor workmanship, we will repair or replace it free of charge.

The warranty does not cover damages to the unit due to improper handling or accidental damage.

Please contact www.medigenix.co.uk for customer service and have your sales receipt to hand to validate your warranty.