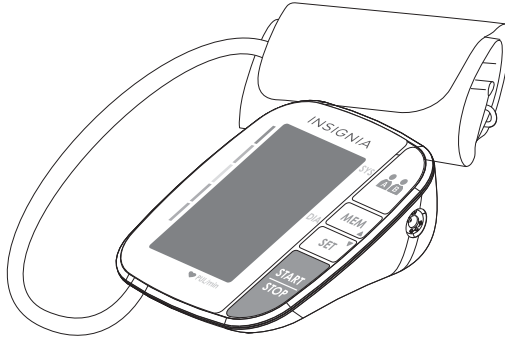
INSIGNIA™

USER GUIDE

Blood Pressure Monitor

NS-BPMW1



California Residents

WARNING: Reproductive harm - www.p65warnings.ca.gov

Before using your new product, please read these instructions to prevent any damage.

INSIGNIA™

Contents

Introduction

Congratulations on the purchase of your new Insignia Blood Pressure Monitor. Your blood pressure monitor features the latest in design and capabilities and will provide reliable and trouble-free performance.

Indications for use

This blood pressure monitor is a digital monitor intended for use in measuring blood pressure and heartbeat rate on persons with an arm circumference ranging from approximately 8.75" to 16.5" (22 cm to 42 cm). It is intended for adult use only.

Measurement principle

This product uses the Oscillometric Measuring method to detect blood pressure. Before every measurement, the unit establishes a "zero pressure" equivalent to the atmospheric pressure, then it begins inflating the arm cuff. Meanwhile, the unit detects pressure oscillations generated by beat-to-beat plusatile, which is used to determine the systolic and diastolic pressure and the pulse rate.

Important Safety Instructions

CAUTION

- This device is intended for adult use in homes only.
- The device is not suitable for use on neonatal patients, pregnant women, patients with implanted, electronic devices, patients with pre-eclampsia, premature ventricular beats, atrial fibrillation, peripheral, arterial disease and patients undergoing intravascular therapy or arterio-venous shunt, or people who received a mastectomy. Please consult your doctor prior to using the unit if you suffer from illnesses.
- The device is not suitable for measuring the blood pressure of children. Ask your doctor before using it on older children.

- The device is not intended for patient transport outside a healthcare facility.
- The device is not intended for public use.
- This device is intended for non-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the arm or for functions other than obtaining a blood pressure measurement.
- Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure. Do not begin or end medical treatment without asking a physician for treatment advice.
- If you are taking medication, consult your physician to determine the most appropriate time to measure your blood pressure. Never change a prescribed medication without consulting your physician.
- Do not take any therapeutic measures on the basis of a self measurement. Never alter the dose of a medicine prescribed by a doctor. Consult your doctor if you have any question about your blood pressure.
- When the device is used to measure patients who have common arrhythmias (such as atrial or ventricular premature beats or atrial fibrillation), the best result may occur with deviation. Please consult your physician about the result.
- Don't kink the connection tube during use. The cuff pressure may continuously increase which can prevent blood flow and result in harmful injury to the patient.
- When using this device, please pay attention to the following situation which may interrupt blood flow and influence blood circulation of the patient, thus cause harmful injury to the patient:
  - Connection tubing kinking.
  - Too frequent and consecutive multiple measurements.
  - The application of the cuff and its pressurization on any arm where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present.
  - Inflating the cuff on the side of a mastectomy.
- **WARNING**: Do not apply the cuff over a wound. It can cause further injury.
- Do not inflate the cuff on the same limb which other monitoring ME equipment is applied around simultaneously, because this could cause temporary loss of function of those simultaneously-used monitoring ME equipment.

- On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, open the cuff immediately. Prolonged high pressure (cuff pressure >300 mm Hg or constant pressure >15 mm Hg for more than three minutes) applied to the arm may lead to an ecchymosis.
- Please check that operation of the device does not result in prolonged impairment of the patient's blood circulation.
- When measuring, please avoid compression or restriction of the connection tubing.
- The device cannot be used with HF surgical equipment at the same time.
- The accompanying documents will disclose that the SPHYGMOMANOMETER was clinically investigated according to the requirements of ISO 81060-2:2013.
- To verify the calibration of the AUTOMATED SPHYGMOMANOMETER, please contact the manufacturer.
- This device is contraindicated for any female who may be or is pregnant. Besides providing inaccurate readings, the effects of this device on the fetus are unknown.
- Too frequent and consecutive measurements could cause disturbances in blood circulation and injuries.
- This unit is not suitable for continuous monitoring during medical emergencies or operations. Otherwise, the patient's arm and fingers will become anaesthetic, swollen, and even purple due to a lack of blood.
- When not in use, store the device in a dry room and protect it against extreme moisture, heat, lint, dust, and direct sunlight. Never place any heavy objects on the storage case.
- This device may be used only for the purpose described in these accompanying documents. The manufacturer cannot be held liable for damage caused by incorrect application.
- This device comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in these accompanying documents.
- The equipment is not AP/APG equipment and not suitable for use in the presence of a flammable anesthetic mixture with air of with oxygen or nitrous oxide.
- **Warning**: No servicing/maintenance while the ME equipment is in use.
- The patient is an intended operator.

- The patient can measure, transmit data, and change batteries under normal circumstances and maintain the device and its accessories according to the accompanying documents.
- To avoid measurement errors, please avoid strong electromagnetic fields, radiated interference signals, or electrical fast transient/burst signals.
- The blood pressure monitor and the cuff are suitable for use within the patient environment. If you are allergic to polyester, nylon, or plastic, please don't use this device.
- During use, the patient will be in contact with the cuff. The materials of the cuff have been tested and found to comply with requirements of ISO 10993-5:2009 and ISO 10993-10:2010. It will not cause any potential sensation or irritation reaction.
- Adapter is specified as a part of ME EQUIPMENT.
- If you experience discomfort during a measurement, such as pain in the arm or other complaints, press the **START/STOP** button to release the air immediately from the cuff. Loosen the cuff and remove it from your arm.
- If the cuff pressure reaches 40 kPa (300 mm Hg), the unit will automatically deflate. Should the cuff not deflate when pressure reaches 40 kPa (300 mm Hg), detach the cuff from the arm and press the **START/STOP** button to stop inflation.
- Before use, make sure that the device functions safely and is in proper working condition. Do not use the device if it is damaged in any way. The continuous use of a damaged unit may cause injury, improper results, or serious danger.
- Do not wash the cuff in a washing machine or dishwasher.
- The service life of the cuff may vary by the frequency of washing, skin condition, and storage state. The typical service life is 10,000 times.
- It is recommended that the performance should be checked every two years and after maintenance and repair, by retesting at least the requirements in limits of the error of the cuff pressure indication and air leakage (testing at least at 50 mm Hg and 200 mm Hg).
- Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines.
- Manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, etc., to assist to service personnel in parts repair.

- The plug/adapter plug pins insulates the device from the main supply. Do not position the device in a position where it is difficult to disconnect from the electrical outlet to safely terminate operation of ME equipment.
- The operator shall not touch output of batteries/adapter and the patient simultaneously.
- Cleaning: A dusty environment may affect the performance of the unit. Please use the soft cloth to clean the whole unit before and after use. Don't use any abrasive or volatile cleaners.
- The device doesn't need to be calibrated within two years of reliable service.
- If you have any problems with this device, such as setting up, maintaining, or using, please contact Insignia Customer Service. Don't open or repair the device by yourself in the event of malfunctions. The device must only be serviced, repaired, and opened by individuals at authorized sales/service centers.
- Please report to Insignia Customer Service if any unexpected operation or events occur.
- Keep the unit out of reach of infants, young children, or pets to avoid inhalation or swallowing of small parts. It is dangerous or even fatal.
- Be careful of strangulation due to cables and hoses, particularly due to excessive length.
- At least 30 min. required for ME equipment to warm from the minimum storage temperature between uses until it is ready for intended use. At least 30 min. required for ME equipment to cool from the maximum storage temperature between uses until it is ready for intended use.
- This equipment needs to be installed and put into service in accordance with the information provided in the accompanying documents.
- Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, and walkie-talkies can affect this equipment and should be kept at least distance "d" away from the equipment. The distance "d" is calculated by the MANUFACTURER from the 80 MHz to 5.8 GHz column of Table 4 and Table 9 of IEC 60601-1-2:2014, as appropriate.
- Please use ACCESSORIES and detachable parts specified/authorised by MANUFACTURER. Otherwise, it may cause damage to the unit or danger to the user/patients.

- There are no luer lock connectors used in the construction of tubing. There is a possibility that they might be inadvertently connected to intravascular fluid systems, allowing air to be pumped into a blood vessel.
- Please use the device under the environment which was provided in the accompanying documents. Otherwise, the performance and lifetime of the device will be impacted and reduced.

Contraindications

- The device should not be used by any person who may be or is pregnant.
- The device is not suitable for use on patients with implanted electrical devices, such as cardiac pacemakers or defibrillators.

Safety information

The signs below might be in the user manual, labeling or other component. They are the requirement of standard and using.

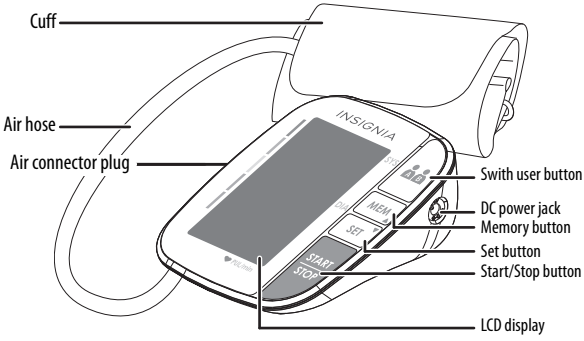
	Symbol for “THE OPERATION GUIDE MUST BE READ.”
	Symbol for “MANUFACTURER.”
	Symbol for “SERIAL NUMBER.”
	Symbol for “DIRECT CURRENT.”
	**Caution**: These notes must be observed to prevent any damage to the device.
	Symbol for “MANUFACTURE DATE.”
	Symbol for “TYPE BF APPLIED PARTS.”

	Symbol for “ENVIRONMENT PROTECTION - Electrical waste products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice.”
	Symbol for “RECYCLE.”

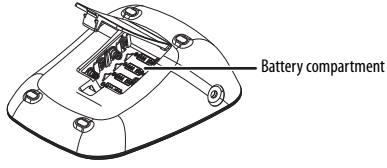
Features

- Blood Pressure Monitor
- Cuff
- AAA batteries (4)
- *User Guide*

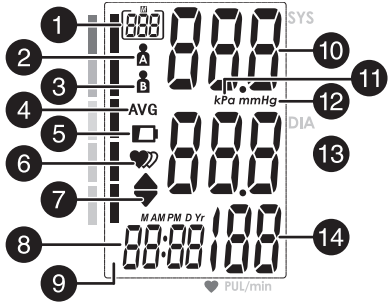
Front



Back



Display



#	ITEM	DESCRIPTION
1	Memory	Shows that the monitor is in the memory mode and which group of memory it is.
2	User A	Recording measurements for User A.
3	User B	Recording measurements for User B.
4	AVG Average value	The average value of the latest three records.
5	Low battery	Batteries are low and need to be replaced.
6	Heartbeat	Blood pressure monitor is detecting a heartbeat during measurement.
	Irregular heartbeat	Blood pressure monitor is detecting an irregular heartbeat during measurement.

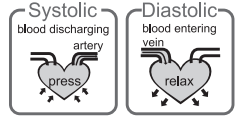
#	ITEM	DESCRIPTION
7	▲▼ Inflation/ Deflation	The cuff is ▲ inflating or ▼ deflating.
8	M AM PM D Yr 88:88 Current time	Shows the date (year, month, day) and time of measurements.
9	▌ Blood pressure level	Indicates the blood pressure level.
10	SYS Systolic blood pressure	Shows your heart's systolic pressure.
11	kPa kPa	Blood pressure is displayed in kilopascals (kPa).
12	mmHg mmHg	Blood pressure is displayed in millimeters of mercury (mmHg).
13	DIA Diastolic blood pressure	Shows your heart's diasoltic pressure.
14	♥ Pul/min Pulse display	Shows your pulse in beats per minute.

Learning about blood pressure

What are systolic pressure and diastolic pressure?

When ventricles contract and pump blood out of the heart, the blood pressure reaches its maximum value in the cycle. This is called *systolic pressure*.

When the ventricles relax, the blood pressure reaches its minimum value in the cycle. This is called *diastolic pressure*.



What is the standard blood pressure classification?

The chart on the right is the standard blood pressure classification published by American Heart Association (AHA):

BLOOD PRESSURE CATEGORY	SYSTOLIC MMHG (UPPER #)		DIASTOLIC MMHG (LOWER #)
Normal	Less than 120	and	Less than 80
Elevated	120–129	and	Less than 80
High blood pressure (hypertension) stage 1	130–139	or	80–89
High blood pressure (hypertension) stage 2	140 or higher	or	90 or higher
Hypertensive crisis (consult your doctor immediately)	Higher than 180	and/ or	Higher than 120
This chart reflects blood pressure categories defined by American Heart Association.			

CAUTION: Consult a physician if your measuring result falls outside the range. Only a physician can tell whether your blood pressure value has reached a dangerous point.

Irregular Heartbeat Detector

An irregular heartbeat is detected when a heartbeat rhythm varies while the device is measuring systolic pressure and diastolic pressure. During each measurement, the blood pressure monitor will keep a record of all the pulse intervals and calculate the average value of them.

If either of the following occur, the irregular heartbeat symbol will appear on the display with the measurement result:

- You have two or more pulse intervals and the difference between each interval and the average is more than the average value of ±25%

- You have four or more pulse intervals and the difference between each interval and the average is more than the average value of ±15%

CAUTION: The appearance of the irregular heartbeat symbol indicates that a pulse irregularity consistent with an irregular heartbeat was detected during measurement. Usually this is NOT a cause for concern. However, if the symbol appears often, seek medical advice. This monitor does not replace a cardiac examination but serves to detect pulse irregularities at an early stage.

Why does my blood pressure fluctuate throughout the day?

- Your blood pressure varies multiple times everyday. It is also affected by the way you tie your cuff and your measurement position, so take the measurement under the same conditions.
- Your blood pressure may vary more if you take a medication.
- Wait at least three minutes between measurements.

Why do I get a different blood pressure at home compared to the hospital?

Blood pressure varies throughout the day due to weather, emotions, exercise, and other factors. Also, there is a "white coat" effect, meaning blood pressure usually increases in clinical settings.

When you measure your blood pressure at home:

- Make sure that the cuff is attached correctly.
- Make sure that cuff is not too tight or too loose.
- Make sure that the cuff is attached to your upper arm.
- If you feel anxious, take two to three deep breaths before beginning. Relax for four to five minutes until you calm down.

Is the result the same if measuring on the right arm?

While it is okay to measure with either arm, we suggest you measure the same arm every time.

Setting up your blood pressure monitor

Powering your blood pressure monitor

Your blood pressure monitor can be powered with either batteries (included) or the AC adapter (not included).

CAUTION: For the best results and to protect your monitor, use the the correct batteries or a power adapter (not included).

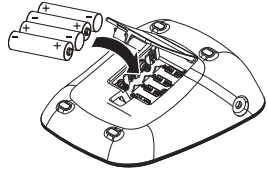
Installing the batteries

Replace the batteries whenever the low battery indicator (Lo + ▭) is shown or if the display is dim or doesn't light up.

CAUTION:

- Do not use new and used batteries together.
- Do not use different types of batteries together.
- Remove batteries if the device is not likely to be used for a long period of time.
- Remove the old batteries from the device following your local recycling guidelines.
- Do not dispose of the batteries in fire. Batteries may explode or leak.
- Worn batteries are harmful to the environment. Do not dispose with daily garbage.

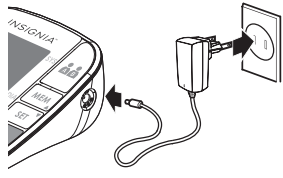
1. Squeeze the tab to open the battery cover.
2. Insert four AAA batteries. Make sure that the + and – symbols in the compartment match the batteries.



3. Close the battery cover.

Connecting an AC adapter (not included)

1. Make sure that your adapter meets the following requirements:
   - Input: AC 100–240 V, 50/60 Hz, 0.2 A max
     Output: 6 V, 1 A
2. Connect the AC adapter from the monitor's DC power jack to a power outlet.



Attaching the cuff to the monitor

Connect the cuff's air hose to the air connector plug on the side of the monitor.

Setting the date, time, and measurement units

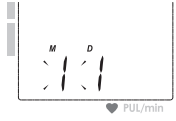
Set the clock before using your blood pressure monitor so that a time stamp can be assigned to each record in its memory.

1. When the monitor is off, press **SET**. The time is shown.
2. Press and hold **SET** again to change the year.

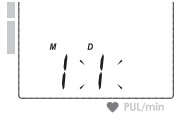
3 Press **MEM** repeatedly to change the year, then press SET to save your selection. Each press increases the year by one, cycling from 2018–2058.

4 When you get the right year, press **SET** to save the year. The display shows the date (month/day) settings.

5 Press **MEM** repeatedly to change the month, then press **SET** to save your selection. Each press increases the month by one, cycling from 1–12 (January–December).



6 Press **MEM** repeatedly to change the day, then press **SET** to save your selection. Each press increases the day by one, cycling from 1–31.



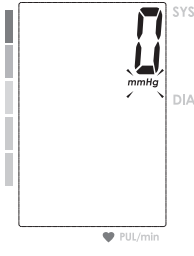
7 Press **MEM** repeatedly to change the time format, then press **SET** to save your selection. Each press switches between 12h and 24h.

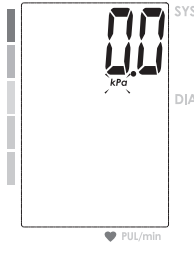
8 Press **MEM** repeatedly to change the hour, then press **SET** to save your selection. Each press increases the hour by one, cycling from 1–12 (if you selected 12h) or 0–23 (if you selected 24h).

9 Press **MEM** repeatedly to change the minutes, then press **SET** to save your selection. Each press increases the minutes by one, cycling from 00–59.

10 Press **MEM** repeatedly to change the blood pressure unit, then press **SET** to save your selection. Each press switches between mmHg and kPa.

The display shows "donE," all the date and time settings you made, then turns off.





Using your blood pressure monitor

Getting accurate measurements

Follow these tips for the most accurate readings (especially for people with hypertension):

- Rest for five minutes before the first measurement. Relax as much as possible and do not move and talk during the measurement.
- Keep the cuff at the same level as the right atrium of the heart.
- Sit comfortably with your feet flat on the ground. Do not cross your legs.
- Keep your back against the backrest of the chair.
- Wait at least three minutes between measurements. This allows your blood circulation to recover.
- For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, on the same arm, or as directed by a physician.

Measurements may be inaccurate if they are taken:

- Within one hour after eating or drinking.
- Immediately after tea, coffee, or smoking.
- Within 20 minutes after taking a bath.
- While talking or moving your fingers.
- In a very cold environment.
- When you need to discharge urine.

Attaching the cuff to your arm

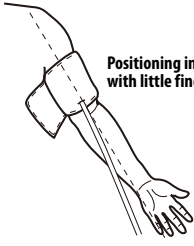
1. Remove all jewelry (such as watches and bracelets) from your left arm.

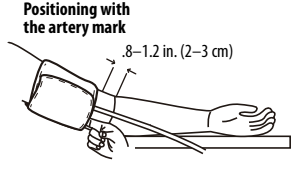
   Note: If your doctor has diagnosed you with poor circulation in your left arm, use your right arm.

2. Roll or push up your sleeve to expose the skin. Make sure that your sleeve is not too tight.
3. Hold your arm out with your palm facing up and attach the cuff to your upper arm. Make sure that the cuff is snug but not too tight. You should be able to insert one finger between the cuff and your arm.

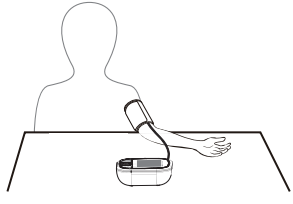
4 Position the tube off-center toward the inner side of your arm (in-line with the little finger).
OR
Position the artery mark (ϕ) over the main artery on the inside of your arm.

Note: To locate the main artery, press two fingers approximately .8 in. (2 cm) above the bend of your elbow on the inside of your left arm. Identify where the pulse can be felt the strongest. This is your main artery.





5 Sit upright in a chair and rest your arm on a table so the cuff is at the same level as your heart. Turn your palm upward. Take five or six deep breaths before starting measurements.



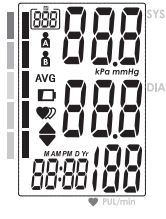
Taking your measurements

WARNING:
- This monitor is not suitable for measuring children.
- If you need to stop the cuff from inflating, press **START/STOP** to immediately release the air. Loosen the cuff and remove it from your arm.
- Read all "Important Safety Instructions" on page 3 before using this monitor.

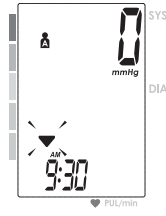
1 When the monitor is off, press the **START/STOP** to turn on the monitor. The monitor takes your measurements and saves the data for the selected user.

Note: You can select user A or B by pressing the user button during measurement or when in the memory mode.

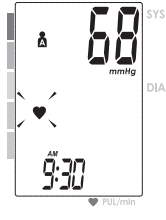
Monitor turns on



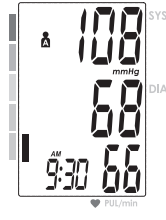
Adjusting the zero point



Inflating and measuring



Displays and saves measurement

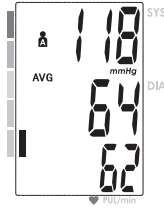


2 Press the **START/STOP** to turn off the monitor, or it will turn off within one minute.

Recalling records

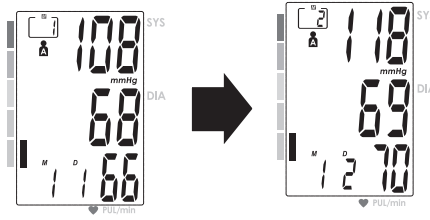
1 When the monitor is off, press **MEM**. The monitor cycles through the last three records. If there are less than three records, it will show the latest record instead.

> **Note**: The most recent record (1) is shown first. Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (for example, 2 becomes 3, and so on), and the last record (250) is dropped from the list.



2 If needed, press the user button to switch between User A or User B's records.

3 Press the **MEM** to move forward or **SET** to move backward through the records. Press and hold **MEM** to look over ten records quickly.



Deleting all records

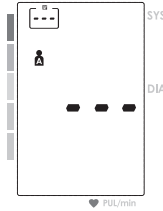
If you did not get the correct measurement, you can delete all records for the selected user. You cannot delete a single record.

1. When the monitor is off, press **MEM** to enter memory recall mode.
2. Press and hold **SET** for three seconds. "dEL ALL" and the user ID flash on the display.

3. Press **SET** to confirm that you want to delete all records. "dEL donE" and the user ID are shown, then the monitor turns off.

Note: If you don't want to delete the records, press **START/STOP**, then press **SET**.

4 When all records are deleted, the screen shows "- - -." Press **MEM** to return to the correct screen.



Maintaining your blood pressure monitor

In order to get the best performance:

- Store in a dry place and avoid the sunshine.
- Avoid intense shaking and collisions.
- Use a wet or dry cloth to remove dirt on the monitor.
- Avoid contact with water. Clean with a a dry cloth.
- Avoid dusty and unstable temperature environments.
- Do not attempt to clean the reusable cuff with water. Never immerse the cuff in water.
- Do not fold the cuff's tubing.
- Take the batteries out if the monitor won't be used for a long period of time.

Troubleshooting

PROBLEM	POSSIBLE SOLUTIONS
The display will not light up.	• The batteries may be low. Replace with new batteries. • Make sure that the batteries are inserted correctly. • Make sure that the AC adapter is securely connected to the blood pressure monitor and a working power outlet.

PROBLEM	POSSIBLE SOLUTIONS
The display says “out.”	• Your results are out of measurement range. Take a moment to relax. Refasten the cuff and measure again. If the problem persists, contact your physician.

Error messages

ERROR CODE	POSSIBLE PROBLEM/SOLUTION
“E 01” is shown.	The cuff is too tight or too loose. Refasten the cuff and measure again.
“E 02” is shown.	The monitor detected motion, talking, or the pulse is too poor while measuring. Relax for moment, then measure again.
“E 03” is shown.	The monitor doesn’t detect the pulse signal. Loosen or remove clothing on your arm, then measure again.
“E 04” is shown.	The measurement failed. Relax for a moment and then measure again.
“EExx” is shown. (“xx” is a number, such as 01, 02, etc. If this type of message is displayed, all are calibration errors.)	A calibration error occured. Retake the measurement. If the problem persists, contact customer service.
Display is dim or shows lo+.	Batteries are low. Replace the batteries.

Specifications

Dimensions (H × W × D)	**Blood pressure monitor**: 2.3 × 5.1 × 5.5 in. (5.9 × 13 × 14 cm)
Weight	.6 lbs (260 g)
Power supply	**Batteries**: 6VDC 4×AAA batteries **AC adapter**: Input: AC 100–240 V, 50/60 Hz, 0.2 A Max Output: 6 V, 1 A
Display mode	Digital LCD
Measurement mode	Oscillographic testing mode
Measurement range	**Rated cuff pressure**: 0 mmHg ~ 299 mmHg (0 kPa ~ 39.9 kPa) **Measurement pressure**: SYS: 60 mmHg ~ 230 mmHg (8.0 kPa ~ 30.7 kPa) DIA: 40 mmHg ~ 130 mmHg (5.3 kPa ~ 17.3 kPa) **Pulse value**: (40–199) beats/minute
Accuracy	**Pressure**: 41° ~ 104°F (5° ~ 40° C) within ±4 kPa (3 mmHg) **Pulse value**: ±5%
Operating conditions	**Temperature range**: 41° ~ 104° F (5° ~ 40° C) **Relative humidity range**: 15% to 90% (non-condensing, but not requiring a water vapor partial pressure greater than 50 hPa) **Atmospheric pressure range**: 700 hPa to 1060 hPa
Storage & transportation temperature	**Temperature**: -20° ~ 60° C **Relative humidity range**: . ≤93% (non-condensing, at a water vapor pressure up to 50 hPa)
Circumference of the upper arm	8.6–16.5 in. (22–42 cm)

Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP21 (The device is protected against solid foreign objects of .5 in. (12.5 mm) and greater and is protected against vertically falling water drops.)
Device classifications	**Battery mode**: Internally-powered ME equipment **AC adapter**: Class II ME equipment
Software version	A01

Legal notices

Compliance standards list

Risk management	• EN ISO 14971:2012 / ISO 14971:2007 Medical devices - Application of risk management to medical devices
Labeling	• EN ISO 15223-1:2016 / ISO 15223-1:2016 Medical devices. Symbols to be used with medical device labels, labeling and information to be supplied. Part 1 : General requirements
User manual	• EN 1041:2008+A1:2013 Information supplied by the manufacturer of medical devices

General requirements for safety	• EN 60601-1:2006+A1:2013/ IEC 60601-1:2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance • EN 60601-1-11:2015/ IEC 60601-1-11:2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
Electomagnetic compatibility	• EN 60601-1-2:2015/ IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
Performance requirements	• EN ISO 81060-1:2012 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type • EN 1060-3:1997+A2:2009 Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems • IEC 80601-2-30:2018 Medical electrical equipment- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
Clinical investigation	• EN 1060-4:2004 Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers • ISO 81060-2:2013 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type

Usability	• EN 60601-1-6:2010+A1:2015/IEC 60601-1-6:2010+A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability • IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
Software life-cycle processes	• EN 62304:2006/AC: 2008 / IEC 62304: 2006+A1:2015 Medical device software - Software life-cycle processes
Bio-compatibility	• ISO 10993-1:2009 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process • ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity • ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

EMC guidance

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments.

- **Warning**: Don't use near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
- **Warning**: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- **Warning**: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

- **Warning**: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 in. (30 cm) to any part of the equipment NS-BPMW1, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Technical description

1. All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.
2. Guidance and manufacturer's declaration – electromagnetic emissions and immunity.

Table 1

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS	
EMISSIONS TEST	**COMPLIANCE**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class [B]
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Comply

Table 2

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY		
IMMUNITY TEST	**IEC 60601-1-2 TEST LEVEL**	**COMPLIANCE LEVEL**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency
Surge IEC61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°.0% U_T; 1 cycle and 70% U_T; 25/30 cycles; Single phase: at 0°.0% UT; 250/300 cycle	0 % U_T; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°.0 % U_T; 1 cycle and 70% UT; 25/30 cycles; Single phase: at 0°.0 % U_T; 250/300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz/60 Hz	30 A/m 50 Hz/60 Hz

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY		
IMMUNITY TEST	**IEC 60601-1-2 TEST LEVEL**	**COMPLIANCE LEVEL**
Conduced RF IEC61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz
Note: U_T is the a.c. mains voltage prior to application of the test level.		

Table 3

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY						
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment).						
TEST FREQUENCY (MHZ)	**BAND (MHZ)**	**SERVICE**	**MODULATION**	**MODULATION (W)**	**DISTANCE (M)**	**IMMUNITY TEST LEVEL (V/M)**
385	380–390	TETRA 400	Pulse modulation b) 18Hz	1.8	0.3	27
450	430–470	GMRS 460, FRS 460	FM c) ± 5kHz deviation 1kHz sine	2	0.3	28
710	704–787	LTE Band 13, 17	Pulse modulation b) 217Hz	0.2	0.3	9
745						
780						
810	800–960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18Hz	2	0.3	28
870						
930						
1720	1700–1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation b) 217Hz	2	0.3	28
1845						
1970						

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY						
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment).						
TEST FREQUENCY (MHZ)	**BAND (MHZ)**	**SERVICE**	**MODULATION**	**MODULATION (W)**	**DISTANCE (M)**	**IMMUNITY TEST LEVEL (V/M)**
2450	2400–2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100–5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

FCC Statement

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.

FCC Caution

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this 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 with the instructions, maybe 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 into an outlet on a circuit different form that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

ONE-YEAR LIMITED WARRANTY

Definitions:

The Distributor* of Insignia branded products warrants to you, the original purchaser of this new Insignia-branded product ("Product"), that the Product shall be free of defects in the original manufacturer of the material or workmanship for a period of one (1) year from the date of your purchase of the Product ("Warranty Period").

For this warranty to apply, your Product must be purchased in the United States or Canada from a Best Buy branded retail store or online at www.bestbuy.com or www.bestbuy.ca and is packaged with this warranty statement.

How long does the coverage last?

The Warranty Period lasts for 1 year (365 days) from the date you purchased the Product. Your purchase date is printed on the receipt you received with the Product.

What does this warranty cover?

During the Warranty Period, if the original manufacture of the material or workmanship of the Product is determined to be defective by an authorized Insignia repair center or store personnel, Insignia will (at its sole option): (1) repair the Product with new or rebuilt parts; or (2) replace the Product at no charge with new or rebuilt comparable products or parts. Products and parts replaced under this warranty become the property of Insignia and are not returned to you. If service of Products or parts are required after the Warranty Period expires, you must pay all labor and parts charges. This warranty lasts as long as you own your Insignia Product during the Warranty Period. Warranty coverage terminates if you sell or otherwise transfer the Product.

How to obtain warranty service?

If you purchased the Product at a Best Buy retail store location or from a Best Buy online website (www.bestbuy.com or www.bestbuy.ca), please take your original receipt and the Product to any Best Buy store. Make sure that you place the Product in its original packaging or packaging that provides the same amount of protection as the original packaging.

To obtain warranty service, in the United States and Canada call 1-877-467-4289. Call agents may diagnose and correct the issue over the phone.

Where is the warranty valid?

This warranty is valid only in the United States and Canada at Best Buy branded retail stores or websites to the original purchaser of the product in the county where the original purchase was made.

What does the warranty not cover?

This warranty does not cover:

- Customer instruction/education
- Installation
- Set up adjustments
- Cosmetic damage
- Damage due to weather, lightning, and other acts of God, such as power surges
- Accidental damage
- Misuse
- Abuse
- Negligence
- Commercial purposes/use, including but not limited to use in a place of business or in communal areas of a multiple dwelling condominium or apartment complex, or otherwise used in a place of other than a private home.
- Modification of any part of the Product, including the antenna
- Display panel damaged by static (non-moving) images applied for lengthy periods (burn-in).
- Damage due to incorrect operation or maintenance
- Connection to an incorrect voltage or power supply
- Attempted repair by any person not authorized by Insignia to service the Product
- Products sold "as is" or "with all faults"
- Consumables, including but not limited to batteries (i.e. AA, AAA, C etc.)
- Products where the factory applied serial number has been altered or removed
- Loss or Theft of this product or any part of the product
- Display panels containing up to three (3) pixel failures (dots that are dark or incorrectly illuminated) grouped in an area smaller than one tenth (1/10) of the display size or up to five (5) pixel failures throughout the display. (Pixel based displays may contain a limited number of pixels that may not function normally.)
- Failures or Damage caused by any contact including but not limited to liquids, gels or pastes.

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