

SANTAMEDICAL

Wrist Type Blood Pressure Monitor

Model No.: BW-210



INSTRUCTION MANUAL

**PLEASE READ THIS INSTRUCTION MANUAL COMPLETELY
BEFORE OPERATING THIS UNIT.**

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Introduction

To achieve the maximum benefit from your blood pressure monitor, we recommend that you first consult with your physician or trained health care professional.

Thank you for purchasing an Blood Pressure Monitor. With proper care and use, your monitor will provide you with many years of reliable readings.

The method of measurement that your Automatic Monitor uses is called the oscillometric method. The monitor detects your blood's movement through the artery in your wrist and converts the movements into a digital reading. The oscillometric method does not require a stethoscope, making the monitor easy-to-use. The preformed cuff requires little effort to apply and is comfortable to wear. Clinical research has proven a direct relationship between blood pressure in the wrist and blood pressure in the arm. Because the arteries in the wrist and arm are connected, changes in wrist blood pressure reflect changes in arm blood pressure. Frequent wrist blood pressure measurements will provide you and your physician with an accurate indication of change in your true blood pressure.

People with severe hypertension, severe arteriosclerosis, or severe diabetes, should consult their physician about monitoring blood pressure at the arm.

Blood pressure readings determined with this device are equivalent to measurements obtained by a trained observer using the cuff/stethoscope auscultation method, within the limits prescribed by the National Standard for Electronic or Automated Sphygmomanometers.

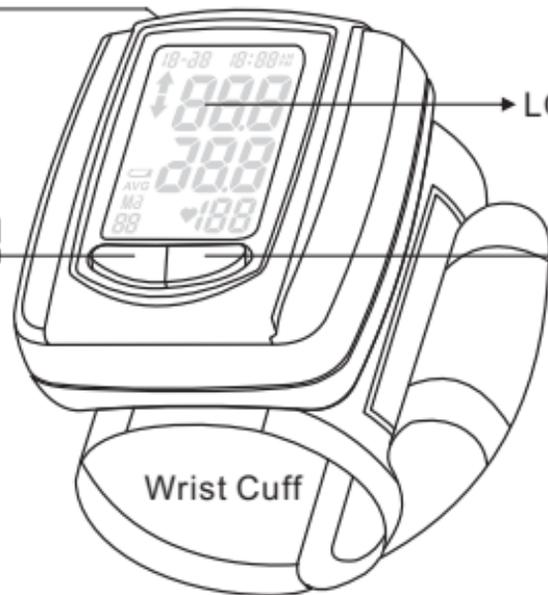
Important Information Before Use

1. Blood pressure measurements should only be interpreted by a physician or a trained health care professional who is familiar with your medical history. Through regular use of this device and recording of your measurements, you can keep your physician informed of the changes in your blood pressure.
2. Perform your measurement in a quiet place. You should be seated in a relaxed position.
3. Avoid smoking, eating, taking medication, alcohol consumption or physical activity 30 minutes prior to taking a reading. If you are exhibiting signs of stress, avoid taking your measurement until the feeling subsides.
4. Rest 15 minutes prior to taking a reading.
5. Remove any constrictive clothing or jewelry that may interfere with the cuff placement.
6. Keep the monitor stable during measurement to achieve an accurate reading. Remain still; do not talk during the measurement.
7. Record your daily blood pressure and pulse readings on a chart.
8. Take your readings at the same time, each day or as recommended by your physician to get an accurate indication of change in your true blood pressure.
9. Wait a minimum of 15 minutes between readings to allow for the blood vessels to return to normal. The wait time may vary depending on your individual physiological characteristics.
10. Although such cases are rare, for those with an extremely weak pulse or irregular pulse, errors may result which prevent proper measurement. If abnormal variations are noticed, consult with your physician or trained healthcare professional.
11. This device is intended for adult use. While taking a measurement, you can stop the inflation or deflation process of the cuff at any time by pressing the POWER button.

Blood Pressure Monitor Features

Date and Time
Button

MEMORY Recall
Button



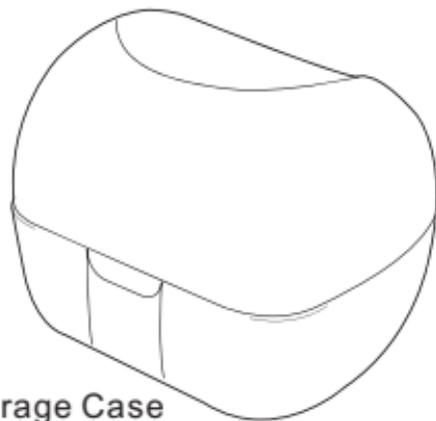
LCD Display

START/POWER
Button (on/off)

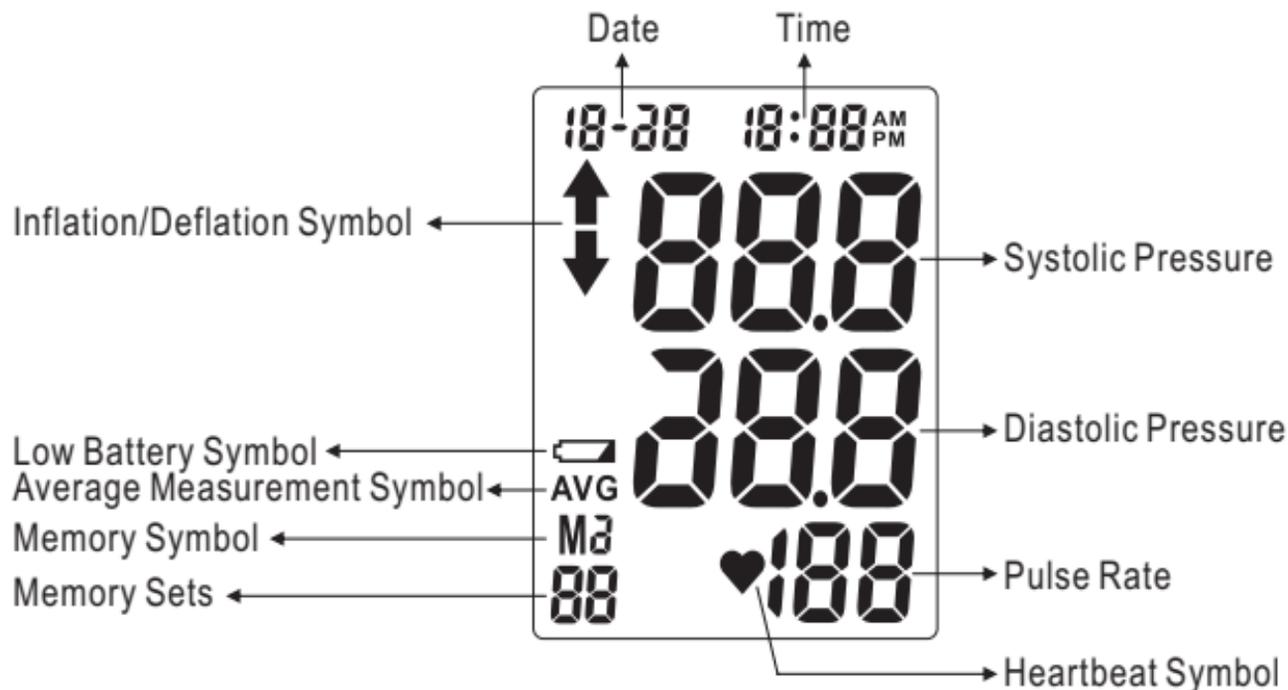
Wrist Cuff

3

Storage Case



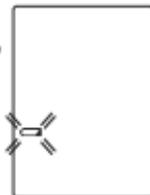
Description of LCD Display



Battery Installation

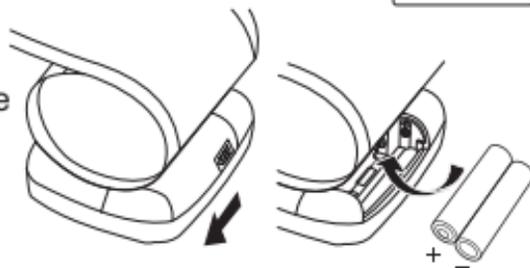
Low battery warning:

It is necessary to replace the batteries when the Low Battery symbol “” appears on the display, or when the display does not turn on after the POWER button is pressed.



Replacing the Battery:

1. Press down on latch and lift the cover on the bottom of the monitor.
2. Insert or replace 2 x 1.5 V AAA batteries into the battery compartment, ensuring to match the indicated polarity symbols. Always use new batteries.
3. Replace the battery cover.



NOTE: Battery-operated

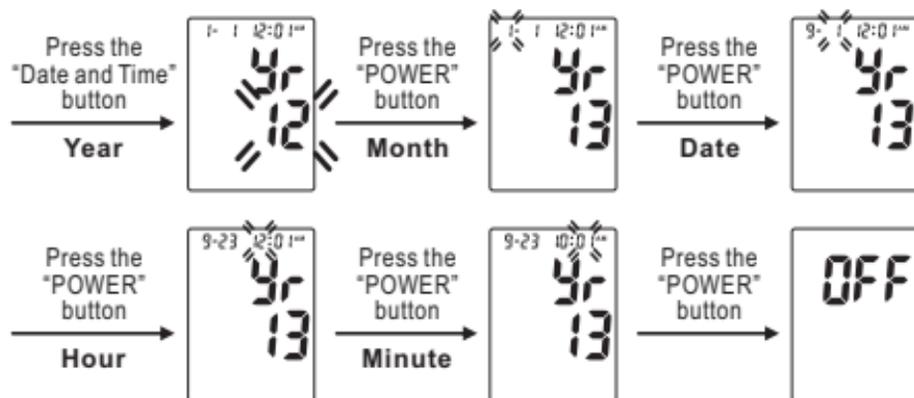
1. Please properly dispose of the batteries away from small children and heat.
2. It is recommended to remove the batteries if the unit will not be used for an extended period of time.
3. For long durations of non-operation, please remove all batteries from the device.
4. Batteries must be disposed of in accordance with local environmental and institutional policies.
5. Dispose of used batteries in accordance with the applicable legal regulations. Never dispose of batteries in the normal household waste.

Setting the Date and Time

It is necessary to set the date and time for the unit every time batteries are initially installed or replaced.

1. When the unit is off (a blank display screen) or after replacing batteries, press and release the "Date and Time" button; the "Year" will begin to flash on the display.
2. Press the "MEMORY" button to advance the display to the desired "Year", press "POWER" button to confirm the "Year".
3. Next, the "Month" will blink. Repeat steps 1 and 2 to set the "Month" and "Date", then "hour", then "Minute".

4. After setting the minute, the unit will automatically exit out of the date/time setting mode and briefly show the word OFF before shutting down.



Applying Your Cuff

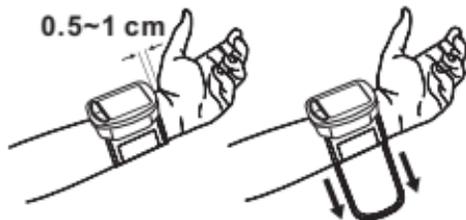
It is important to avoid smoking, eating, taking medication, alcohol consumption or physical activity 30 minutes prior to taking a reading. If for any reason you are unable to or should not use your left wrist, please modify the instructions for cuff application to your right wrist. Your physician can help you identify which wrist is best for you to take measurements from.



1. Remove any constrictive clothing or jewelry that may interfere with cuff placement.
2. Be seated at a table or desk with your feet flat on the floor.
3. Hold your wrist in front of you with your palm facing upward.
4. Apply the preformed cuff to your wrist so that the digital display face is positioned on the inside area of your wrist facing you.
5. Adjust the cuff 0.5~1 cm from the edge of the head of the ulna bone.
6. The cuff should fit comfortably, yet snugly around your wrist.



0.5~1 cm



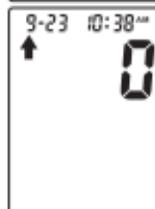
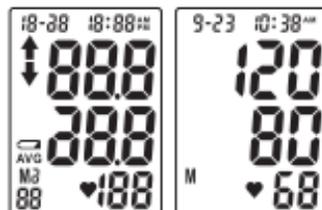
Refer to
instruction

Blood pressure naturally varies from one wrist to the other; therefore, measure your blood pressure on the same wrist to ensure comparability of the two readings.

Measurement of Pulse Rate and Blood Pressure

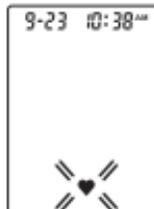
Please read the preceding portions of this manual prior to taking your first reading.

1. Rest your elbow on a solid surface with your palm facing upward. Elevate your wrist so that **the cuff is at the same level as your heart**. Relax your left hand.
2. Press the POWER button. This will turn the power on.
3. After the self-test, the values for the last reading will appear on the display.
4. The blood pressure monitor start to measure.
5. The cuff will automatically begin to inflate, with the display showing the increasing pressure in the cuff. As the pressure increases, an arrow pointing up will appear on the display.
6. When the inflation has reached optimum level, the display will begin to show the decreasing pressure; the screen will display an arrow pointing down while you feel the pressure of the cuff decrease.



Measurement of Pulse Rate and Blood Pressure

7. To detect the heartbeat, the heartbeat symbol will appear and continuous flashes on the LCD display.



8. Your blood pressure measurement and pulse will display simultaneously on the screen.



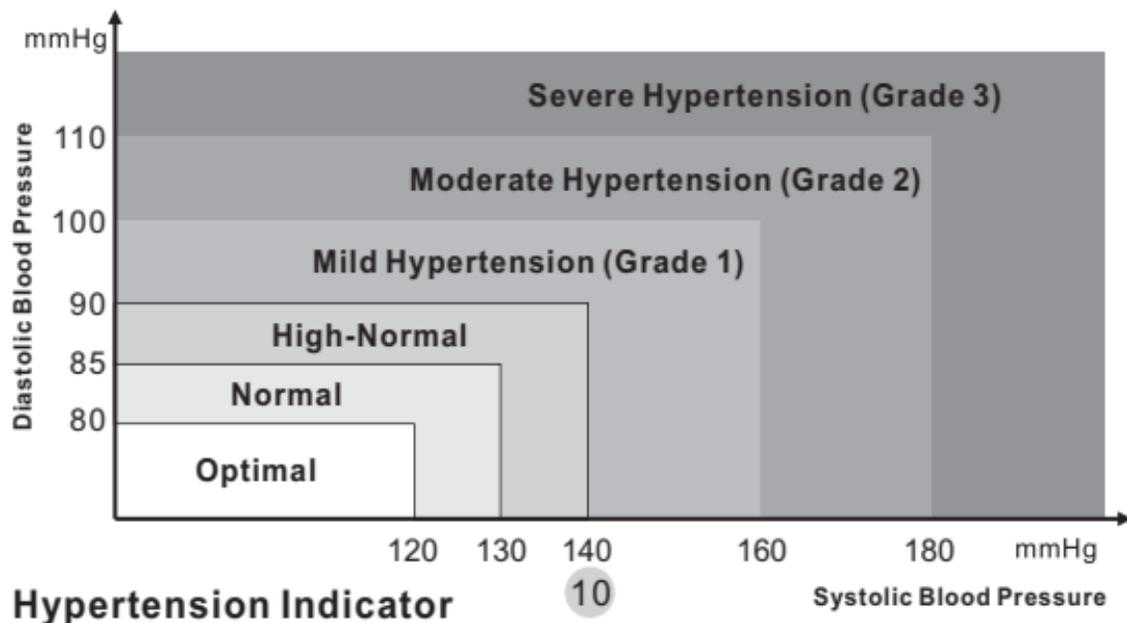
9. The Hypertension Indicator will indicate your reading range on the display separately.

10. The reading will automatically be stored in memory.

11. Select POWER to turn the unit off and conserve energy and battery life. The unit will automatically shut-off approximately 2 minutes.

World Health Organization (WHO)

The World Health Organization has established globally accepted standards for the assessment of high or low blood pressure readings. The below chart should be considered only as a guideline, always consult with your physician or health care professional to interpret your individual results.

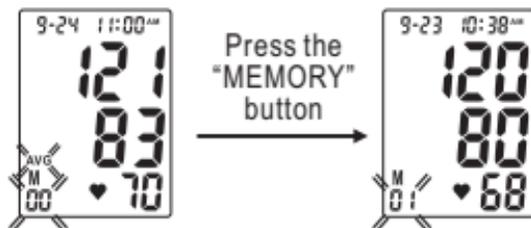


Memory Function

Recalling Measurements in Memory:

You can recall up to **60** total measurements in memory, plus an average of the last 3 stored measurements in memory to share with your physician or trained healthcare professional.

1. Press and release the “MEMORY” button. The unit will first display the average of the last 3 stored measurements.
2. Continue to press the “MEMORY” button to successively view the next previously stored measurements. Measurements will appear on the display from most current to oldest; the memory number will appear on the lower left corner.



3. All results for a given measurement will display, including measurement results, pulse rate, Hypertension Indicator, and date/time stamp.
4. When the number of readings exceeds **60**, the oldest data will be replaced with the new record.
5. Press the Power button to turn the monitor OFF at any time during review of the stored measurements.

Memory Function

Clearing Measurements from Memory:

From power display off, press and hold down the "MEMORY" button until the display shows CLr. This indicates that all measurements have been erased.



Troubleshooting

Problem	Probable Cause	Recommended Action
Nothing appears in the display even when the power is turned on.	Batteries are drained.	Replace all batteries with new ones.
	Battery are not correctly aligned with terminals.	Reinsert batteries in the correct position.
Low Battery Symbol appears.	Batteries are drained.	Replace all batteries with new ones.
	In colder temperatures batteries have weaker electrical charges.	Warm up the batteries, or use the device in a warmer setting.
Device operation time is inconsistent.	Different battery brands have different life spans.	Use Alkaline batteries and replace all batteries at the same time with same brand batteries.
No reading after measurement.	Batteries are drained.	Replace all batteries with new ones.
Suspicious blood pressure results.	Perhaps the cuff was improperly positioned.	Adjust patient and wrist cuff to measure.
	Blood pressure naturally varies throughout the day.	Rest a while, relax and measure again.
Suspicious heart rate results.	Bodily movement during device use.	Refrain from moving during measurement.
	Measurement shortly after exercise or exposure to the outdoors.	Do not take measurements after exercise or coming back from the outdoors.
Power switches off automatically.	System design.	Push the power button again, and then begin measure again.
During measuring, air re-inflates.	It could be a normal action if the user's blood pressure is higher than the initial pressure value, the device automatically pumps to a higher pressure by 40mmHg each time.	Relax, and try to take a measure again.
	The wrist cuff is not fastened properly.	Check that the wrist cuff is fastened properly and retake the measurement.

Error Codes

Err	Meaning	Corrective Action
Err 0	No pulse or detect pulses not enough.	Take off heavy clothes and retry again.
Err 1	Leakage in Cuff Pressure/Inflation too low.	The wrist cuff is not fastened properly. Re-apply the cuff, and take a measurement again.
Err 2	Pressure fault.	Rest a while, relax and retry again.
Err 3	Deflation fault.	The wrist cuff is not fastened properly. Re-apply the cuff, and take a measurement again.
Err	Memory error.	Take off batteries to reboot the device, then take another measurement.
	Low batteries.	Replace all batteries with new ones.

Care and Maintenance

1. Clean the device and wrist cuff carefully only with a slightly moistened cloth.
2. Do not immerse the device in water. It may cause damage if water enters.
3. Do not use any gas, strong detergent, or solvents to clean the device, including the wrist cuff.
4. Disconnect the cuff and tubing from the monitor prior to storing.
5. Do not use any liquids on the monitor or cuff.
6. Use a soft, dry cloth to clean your monitor.
7. Do not store in direct sunlight, dust or excessive humidity.
8. Avoid extreme temperatures.
9. Do not disassemble the monitor or cuff.
10. Remove batteries if the monitor will not be used for an extensive period of time.

Applied Standards

This product conforms to the provisions of the EC directive MDD (93/42/EEC). The following standards apply to design and/or manufacture of the products:

- **EN 1060-1**
Non-invasive sphygmomanometers-Part 1 : General requirements
- **EN 1060-3**
Non-invasive sphygmomanometers-Part 3 : Supplementary requirements for electro-Mechanical blood pressure measuring system
- **EN 1060-4**
Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers
- **ANSI/AAMI Sp10**
Electronic or automated sphygmomanometers
- **ISO 14971**
Medical devices-Application of risk management to medical devices. The Classification according to IEC/EN 60601-1 sub-clause 5:
 - Internally powered equipment
 - IPX0
 - Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide
 - Continuous operation

 0197	TUV NO.
	Refer to instruction
	Type BP equipment (Cuff)
	The device shall be disposed in accordance with national laws after their useful lives
	Manufacturer's name and address
	

Technical Specification

- **Measuring range :** Blood Pressure : 30~280 mmHg
Pulse Rate : 40~199 beats/min
- **Calibration Accuracy:** Blood Pressure : ± 3 mmHg
Pulse rate : $\pm 4\%$ of reading
- **Operating environment :**
10°C~40°C (50°F~104°F) 
with relative humidity up to 85% (non condensing)
- **Storage/ Transportation environment :**
-20°C~+50°C (-4°F~+122°F) 
with relative humidity up to 85% (non condensing)
- **Power Source :** 2 x 1.5 V AAA batteries
- **Weight :** approx. 109g (exclude batteries)
- **Dimensions :** approx. 64mmX74mmX31mm (WXHxD)
- **Cuff circumference (M Size) :** approx. 12.5~21 cm

EMC Tables

Guidance and manufacturer's declaration-electromagnetic emissions

The **BW-210 Wrist Type Blood Pressure Monitor** is intended for use in the electromagnetic environment specified below. The customer or the user of the **BW-210 Wrist Type Blood Pressure Monitor** should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	The BW-210 Wrist Type Blood Pressure Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The BW-210 Wrist Type Blood Pressure Monitor 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.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

EMC Tables

Guidance and manufacturer's declaration-electromagnetic immunity

The **BW-210 Wrist Type Blood Pressure Monitor** is intended for use in the electromagnetic environment specified below. The customer or the user of the **BW-210 Wrist Type Blood Pressure Monitor** should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

EMC Tables

Guidance and manufacturer's declaration-electromagnetic immunity

The **BW-210 Wrist Type Blood Pressure Monitor** is intended for use in the electromagnetic environment specified below. The customer or the user of the **BW-210 Wrist Type Blood Pressure Monitor** should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of the BW-210 Wrist Type Blood Pressure Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3 \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p>

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **BW-210 Wrist Type Blood Pressure Monitor** is used exceeds the applicable RF compliance level above, the **BW-210 Wrist Type Blood Pressure Monitor** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **BW-210 Wrist Type Blood Pressure Monitor**.
- b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

EMC Tables

Recommended separation distances between portable and mobile RF communications equipment and the BW-210 Wrist Type Blood Pressure Monitor

The **BW-210 Wrist Type Blood Pressure Monitor** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **BW-210 Wrist Type Blood Pressure Monitor** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **BW-210 Wrist Type Blood Pressure Monitor** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=1.2 \sqrt{P}$	80 MHz to 800 MHz $d=1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d=2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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**Distributed by:
Gurin Products, LLC
2522 Chambers Road, Suite 100
Tustin, CA-92780**

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