Blood Pressure Monitor

Model: 2006-2B

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User manual

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Introduction

Thank you for purchasing this blood pressure monitor. This remarkable instrument is ideal for people who frequently monitor their own blood pressure because it's easy to use. Simply push of a button the monitor measures your blood pressure and pulse and displays the reading on a clear digital panel. Perfect for quick, easy readings at home, at work, almost anywhere!

The Monitor uses the oscillometric method of blood pressure measurement. This means the monitor detects your blood's movement through the artery in your arm and converts the movements into a digital reading. An oscillometric monitor does not need a stethoscope so the monitor is simple to use and measurements are easy to obtain.

Clinical research has proven a direct relationship between blood pressure in the wrist and blood pressure in the arm. Changes in wrist blood pressure reflect changes in arm blood pressure because the arteries in the wrist and the arm are connected each other. Frequently measuring the blood pressure will provide you and your doctor with an accurate indication of changes in your actual blood pressure.

Please read this user manual thoroughly before using the blood pressure monitor. For specific information on your own blood pressure, contact your physician.

Precaution before use

1. Do not confuse self-monitoring with self-diagnoses. Blood pressure measurements should only be interpreted by a health professional who is familiar with your medical history.
2. If you are taking medication, consult with your physician to determine the most appropriate time to measure your blood pressure. Never change a prescribed medication without first consulting with your physician.
3. For persons with irregular or unstable peripheral circulation problems due to diabetes, liver disease, hardening of the arteries, etc., there may be fluctuation in blood pressure values measured at the upper arm versus at the wrist.
4. This device is designed for adults to use if use this device on a child patient, old people or toddlers, consult with your physician or measure with relative aid.
5. Measurements may be impaired if this device is use near televisions, microwave ovens, X-ray mobile phone equipment or other devices with strong electrical fields. To prevent such interference, use the meter at a sufficient distance from such devices or turn them off.
6. This device is not suitable for disease diagnoses, urgent treatment, continuous monitoring during medical emergencies or operations.
7. Before using, should wash your hand.
8. If there is overmuch pressure or you feel uncomfortable, please press "POWER" button immediately for quick deflation
9. Five minutes should elapse before the first reading is taken.
10. If there are unexpected readings, you should seed an explanation from your physician.
11. Any reading may be affected by the measuring position, the patient's position, movement, or the patient's physical condition
12. Failure to use the cuff specified by use manual, or modified instrument may result in incorrect measurements.
13. If the device is stored in the lowest (-20℃) or highest temperature (55℃) environment and measured at the ambient temperature (20℃), it shall be placed in the environment for 15 minutes before the measurement.
14. Too frequent blood pressure measurements can lead to unnecessary stress and elevated blood pressure.
15. Measuring blood pressure in a wound can lead to incorrect measurements and bacterial infections.
16. Cuff may trigger lymphedema in the upper extremity when used on the arm for a mastectomy.
17. Pressure on the cuff can temporarily disable monitoring devices that are used at the same time on the same limb.
18. It is necessary to check whether the operation of the sphygmomanometer will have a long-term effect on the patient's blood circulation.
19. Continuous compression of the cuff by knotted hoses may result in incorrect measurements or damage to the patient's skin.
20. Contraindications: serious arteriosclerosis, cardiac pacemaker.
21. Patient is intended operator
22. Pregnant women and preeclampsia patients can’t use this device.
23. When worn on limbs with invasive devices or arteriovenous shunt devices, the cuff can cause injury to the patient.

24. There is no allergic reaction to the accessible material on the device;
25. Children are not allowed to operate the device and should not eat any falling parts;
26. Stop measurement immediately and cut off the power supply when the hose in the sleeve belt causes neck strangulation, so as to avoid damage to human body

Few words about blood pressure

Blood pressure is the force exerted on the walls of your blood vessels as blood flows through them.

Your heart is like a pump. When it contracts, or beats, it sends a surge of blood through the blood vessels and pressure increases. This is called your systolic pressure

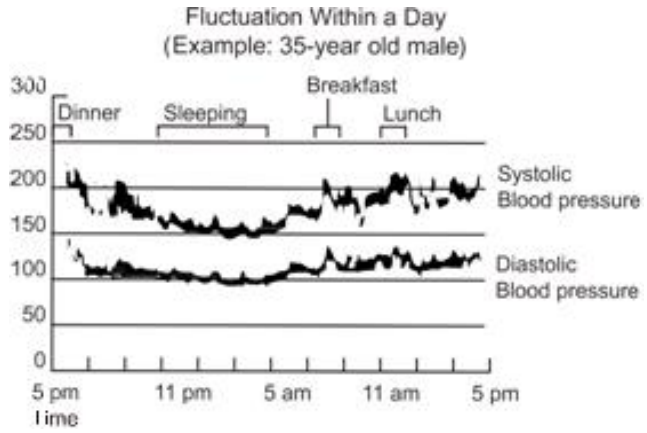
When your heart relaxes between beats, your blood pressure decreases. This is called your diastolic pressure.

When a doctor takes your blood pressure, he or she measures both your systolic and diastolic pressures and records them as numbers. For example, if your blood pressure reading is 126/76 (126 over 76), your systolic is 126 and your diastolic is 76. The numbers are calculated in millimetres of mercury and recorded as 126/76 mm Hg

These two numbers provide important information about your health. The more difficult it is for your blood to flow through your blood vessels, the higher both numbers will be. When blood pressure is consistently above normal it is called hypertension (High blood pressure).

Please consult your physician to determine if your blood pressure accurately reflects your actual blood pressure

Your blood pressure changes constantly. Blood pressure fluctuates from day to day and minute to minute according to your body's needs. For example, when you are exercising or angry your blood pressure increases, but when you are relaxing or sleeping your blood pressure decreases. These fluctuations are completely normal. This blood pressure monitor is especially helpful when tacking changes in your blood pressure because it travels anywhere and takes just seconds to use.



Factors that may cause the blood pressure to fluctuate

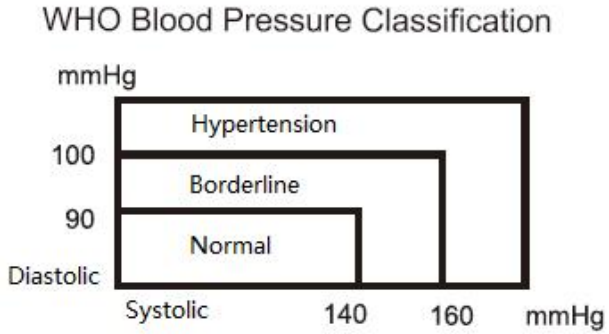
* Breathing
* Exercise
* Mental stress
* Worries
* Environmental and / or temperature change
* Eating
* Urination and bowel movement

* Talking * Taking a bath
* Drinking alcohol
* Smoking, etc.

Note: One or two readings will not provide a true indication of your normal blood pressure. It is very important to take regular, daily measurements and to keep accurate records. In partnership with your doctor, an accurate record of your blood pressure over a period of time can be a valuable aid in diagnosing and preventing potential health problems.

The World Health Organization (WHO) developed the following Blood Pressure Classification. This classification, however, is only a general guideline because blood pressure varies from person to person according to age, weight, and health status.

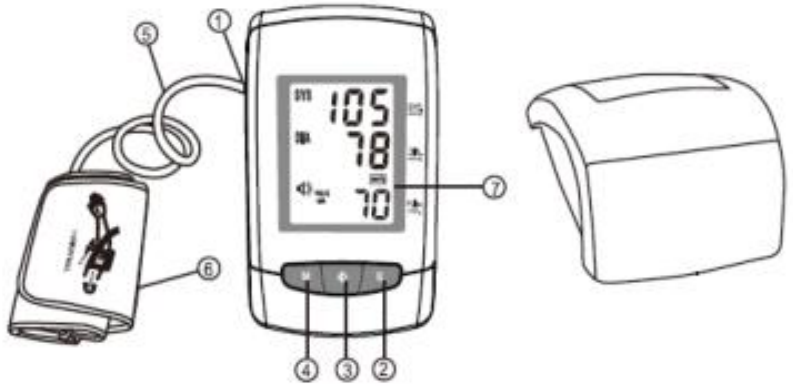
CONSULT YOUR PHYSICIAN TO DETERMINE YOUR NORMAL BLOOD PRESSURE.



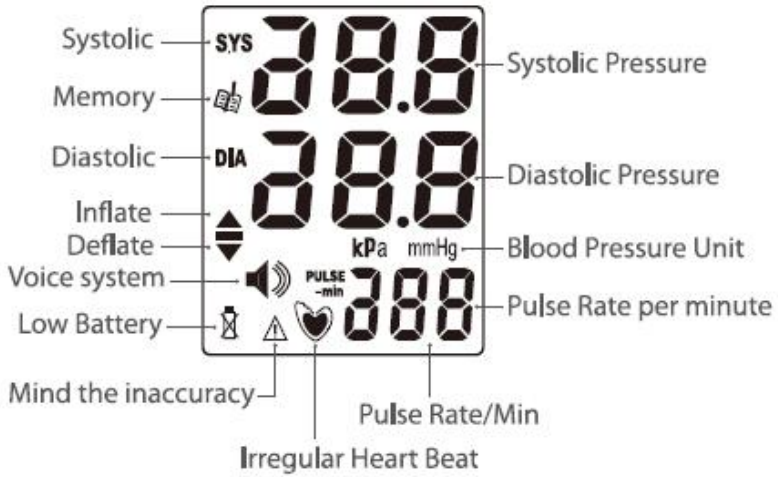
	Systolic (mmHg)	Diastolic (mmHg)
Normal	Less than 139	Less than 89
Borderline	140 to 159	90 to 99
Hypertension	More than 160	More than 100

Note: There is not an universally accepted definition of hypotension (low blood pressure), but a systolic pressure below 99 mmHg is usually regarded as hypotension

PRODUCT DESCRIPTION



1. Cuff Connector Jack
2. Setting Button
3. POWER Button
4. Memory Button
5. Air Tube (applied part)
6. Upper Arm Cuff (applied part)
7. LCD display



Install or replace batteries

When the battery symbol appears on the display or nothing is display while inflation during measurement, you should replace with new batteries.

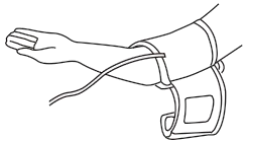
1. Press the snap hook on the battery cover to open it.
2. Insert four “AA” batteries in the correct polarity direction.
3. Replace the battery cover.
4. With the use of four alkaline “AA” batteries, you can measure approximately 250 times at room temperature of 22℃ and inflating to around 170 mmHg once a day. But the included batteries only for test purpose may not last as specified long period.
5. When the battery icon “ ” displays on the LCD, please replace four new batteries, please do not mix the new and old battery together.
6. If the unit will not be used for a long period, please take out all batteries to avoid liquid leakage damaging the unit.

Environment Protection – Waste electrical products should not disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice.

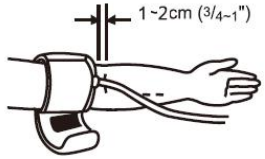
How to use the upper arm cuff

1. Pass the end of the cuff (with sewn-in rubber stopper) through the metal stirrup so that a loop is formed. The Velcro closer must be facing outwards. (Ignore this step if the cuff has already been prepared.)

2. Push the cuff over the left upper arm so that the tube points in the direction of the lower arm and palm.

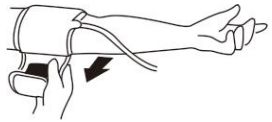


3. Lay the cuff on the arm as illustrated. Make certain that the lower edge of the cuff lies approximately 1 to 2 cm (3/4~1") above the elbow and that the rubber tube leaves the cuff on the inner side of the arm.

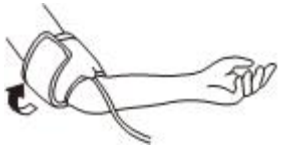


Important! The mark (about 2 cm long bar) must lie exactly over the artery which runs down the inner side of the arm.

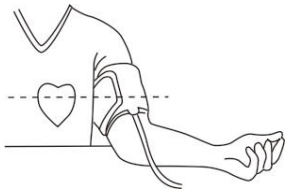
4. Tighten the free end of the cuff and close the cuff with the closer.



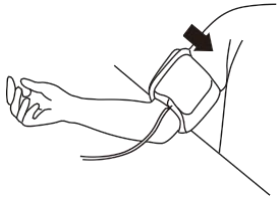
5. There must be no free space between the arm and the cuff as this would influence the result. Clothing must not restrict the arm. Any piece of clothing which does (e.g. a pullover) must be taken off.



6. Secure the cuff with the Velcro closer in such a way that it lies comfortably and is not too tight. Lay the arm on the table (palm upwards) so that the cuff is at the same height as the heart. Make sure that the tube is not kinked.



7. Remain seated quietly for two minutes before you begin the measurement.



Note:

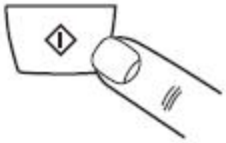
1. If it is not possible to fit the cuff to the left arm, it can also be placed on the right arm. However all measurements should be made using the same arm for better cross reference;
2. When measuring, the legs should not be crossed, feet flat on the ground, arms and back vertical.
3. When measuring, do not squeeze the hose of cuff, as this may cause injury or incorrect measurements.

A few suggestion before measurement

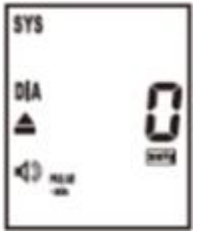
1. Avoid eating, smoking, and exercising for at least 30 minutes before taking a measurement. Also rest for at least 15 minutes before taking a reading.
2. Stress raises blood pressure. Avoid taking measurements during stressful times.
3. You would better apply the cuff on your left upper arm.
4. Measurement should be taken in a quiet place and you should be relaxed, seated position. Rest your left arm on a table.
5. Remain still and do not talk during the measurement.
6. Keep a record of your blood pressure and pulse for your doctor. Remember, a single measurement does not provide an accurate indication of your true blood pressure. You need to take and record several measurements over a period of time. Try to measure your blood pressure at the same time each day for consistency. Blood pressure measurements fluctuate considerably.
7. Wait 5-10 minutes between successive measurements. Waiting allows the engorged blood vessels to return to normal. You may require more rest time depending on your individual physical conditions.

How to measure blood pressure

1. Set up the cuff to your upper arm as previous section of "How to use the upper arm cuff".
2. Press the power button, The LCD display and the voice guiding the correct posture and measurement while the arm cuff start to inflate.



3. During the voice guiding the cuff is fully inflated, it will automatically start to deflate and the heart symbol will appear to indicate that measurement is in progress, once the symbol stop flashing and detect systolic, diastolic and pulse then the voice will announce the measure result.



When the monitor detects an irregular rhythm that varies by less than 25% from the average rhythm two or more times during the measurement, the Irregular Heartbeat Symbol will appear on the display with the measurement values, we recommend you consult your physician.

Remain still and do not talk during the measurement. Position your arm higher than the heart will get lower measure result, contrarily the measure result will get higher. This unit can intelligently adjust the cuff pressure and inflate to a higher pressure level when needed, so its normal when the unit re-inflate during one measurement.

Note:

- The value measured will be too low if you hold your cuff higher than heart level, or will be too high if you hold your cuff lower than heart level.
- The unit may store 10 measurements, if the data more than 10 records, it will delete the earliest data.
- During measurement do not speak or shake as which may affect the accuracy of the result.
- If you want to stop the measurement during measurement process, just press the power button to stop immediately.

Recalling memory

1. Press “M” button to turn on the device, then press “M” button until enter memory state like right figure.

2. Press “M” or “S” button to check the next measurement data.
3. If there is no memory, it will display “—” and then turn off in one second.

How to prevent a malfunction

1. Do not drop the device and avoid sudden jars or shocks.
2. Do not inset other objects into any holes.
3. Do not attempt to disassemble the unit.
4. Do not crush the pressure cuff.
5. If the unit has been stored at temperatures below 0°C, leave it in a warm place for 30 minutes before using it, otherwise, may get wrong measurement result.

Maintenance and repair

1. Do not wash or immerse the unit in water, use a soft and dry cloth to clean it.

2. Do not use the volatile liquids to clean the main unit or cuff.

3. Do not moisten the cuff, wash hands before measurement.

4. When the cuff dirty, Wipe on the surface of the cuff with a cloth moistened with a 70% dilution of isopropyl alcohol or a 80% or less dilution of disinfection ethanol (ethyl alcohol). Do not allow any liquids inside the cuff. If a liquid gets in the cuff, dry the inside well.

5. Precision components are used in the construction of this device. Extremes in temperature, humidity, direct sunlight, shock or dust should be avoided.

6. The disassemble arm cuff can be store in the storage box.

7. When the unit is on, press the “S” and “M” buttons together for 5 seconds, when “tst” displays, loose both buttons, the main program version will appear then enter to the static pressure testing mode, and “DIA” location shows “00”. (Only professional technician is qualified to operate).

Note: Do not maintain the equipment while it is in use.

Symbols information

	Type BF applied part
	Attention and read before use
	Indicates the medical device manufacturer
	Indicates the authorized representative in the European community
IP20	Degrees of protection provided by enclosures.
	Refer to instruction manual
	Please dispose of the device / battery / packing in accordance with the legal obligation in your area.
	Serial number
M	Memory key
S	Set key
	ON/OFF and measure key

Specifications

Indication	Digital LCD display
Pressure display Range:	Pressure: 0-300 mmHg, Pulse rate: 40~195 Beat/min
Pressure display Accuracy:	Pressure: ±3mmHg; Pulse rate: ±5%
NIBP measurement range	SYS 60 to 260 mmHg DIA 30 to 195 mmHg Pulse rate 40 to 195 /min
NIBP accuracy	Maximum mean error within ±5mmHg Maximum standard deviation within 8mmHg
Pulse rate accuracy	Within ±5 % of reading
Inflation:	Electric Pump Inflation
Deflation:	Pressure Release Value
Memory:	50 sets
Power Source:	DC 6V, 4*AA (1.5V) battery
Battery Life:	Approx. 250 Charge-Discharge Cycles
Operating Environment Condition	5℃~40℃, RH≤80%, 700hPa~1060hPa
Storage Environment Condition	-20℃~55℃, RH≤93%, 500hPa~1060hPa
Outside Dimensions:	157mm(L)*96mm(D)*64mm(H)
Weight:	Approx. 495g (Apparatus and Battery)
Accessories	Cuff (fit arm size: 22~32cm, rated air pressure: 300mmHg , service life: 18 months), Instruction manual, Storage Pouch
Service life	5 years

Troubleshooting

If you have trouble while using the unit, please check the following points first.

ERROR DISPLAY	POSSIBLE CAUSE	HOW TO CORRECT
Nothing is displayed when you push the POWER button or "▬" battery icon flash	No battery installation	Insert batteries
	Battery worn out	Replace new batteries
	The polarities of batteries placed wrongly	Insert battery in the correct polarities
E1: The cuff Can't normally increase pressure	Check your cuff if any air leakage	Replace wrist cuff with new one
E0, E2, E7, E8, E9 Measurement failure	Cuff not properly adjust or placement, hand or body shaking.	Renew adjust cuff position and tightness, and keep hand still
E3. Inflate pressure too high		Re-measurement or send back dealer for re-calibrate pressure
E4: Have shaking while measurement	Hand or body shaking while measurement	Keeping static and correct gesture to measure again
E5: Automatically pressure release too fast	Cuff too tight	Readjust cuff and measure again
E6: Automatically pressure release too slow	Cuff too loose	
"▬" Battery icon on	Battery low power	Replace new battery, and measure again
The systolic pressure value or diastolic pressure value too high	1.The hand with the cuff was held lower than your heart	Keeping correct position and gesture to measure again
	2.The cuff was not attached properly	
	3.You moved your body or spoke during measurement	
The systolic pressure value or diastolic pressure value too low	1.The hand with the cuff was held higher than your heart	
	2.You moved your body or spoke during measurement.	

EMC statement

This device has been tested and homologated in accordance with EN 60601-1-2 for EMC. This does not guarantee in any way that the device will not be affected by electromagnetic interference. Avoid using the device in high electromagnetic environment.

Recommended separation distances between portable and mobile RF communications equipment and the 2006-2B Blood Pressure Monitor

The 2006-2B 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 2006-2B Blood Pressure Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 2006-2B 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 meters (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.

Guidance and manufacturer's declaration – electromagnetic emission

The 2006-2B Blood Pressure Monitor 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.

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The 2006-2B 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 emission CISPR 11	Class B	The 2006-2B 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/EN61000-3-2	Not applicable	
Voltage fluctuations /flicker emissions IEC/EN61000-3-3	Not applicable	

Guidance and manufacture's declaration–electromagnetic immunity

The 2006-2B Blood Pressure Monitor 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.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	± 8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC/EN61000-4-4	±2kV for power supply lines ±1kV for input/output lines	Not applicable	Not applicable
Surge IEC/EN61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	Not applicable
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC/EN61000-4-11	<5%UT(>95% dip in UT) for 0.5cycle 40%UT(60%dip in UT) for 5 cycles 70%UT(30%dip in UT) for 25 cycles <5%UT(>95% dip in UT) for 5s	Not applicable	Not applicable

Power frequency (50Hz/60Hz) magnetic field IEC61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacture's declaration – electromagnetic immunity			
The 2006-2B Blood Pressure Monitor 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.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC61000-4-6	3 Vrms 150 kHz ~ 80 MHz 6Vrmsc)in ISM bands between 0,15 MHz and 80 MHz	3 Vrms 150 kHz to 80 MHz 6Vrmsc)in ISM bands between 0,15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the 2006-2B Blood Pressure Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=1.2\sqrt{P}$ 150 kHz to 80 MHz $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.7 GHz
Radiated RF IEC61000-4-3	10V/m	10 V/m 80 MHz to	d=6 /E at RF wireless communications equipment bands (Portable RF communications
	80 MHz ~ 2.7 GHz	2.7 GHz	equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the 2006-2B Blood Pressure Monitor, including cables specified by the manufacturer). 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). 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 Interference may occur in the vicinity of equipment marked with the following symbol: 
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 2006-2B Blood Pressure Monitor is used exceeds the applicable RF compliance level above, the SD1Ultrasonic Doppler should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the 2006-2B Blood Pressure Monitor.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

c. The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz,21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

FCC Requirement

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

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.

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, 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 into 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.