



Fully Automatic Blood Pressure Monitor

User Manual

BPM4TL Series

Content

Medical Disclaimer	2
Intended Use	3
Additional Information on Blood Pressure	4 - 5
Precautions	6 - 7
Parts	8 - 10
Indicator & Classification of Blood Pressure	11
Setting up your Blood Pressure Monitor	12 - 13
Loading Batteries	12
Connecting the Cuff	13
Using your Blood Pressure Monitor	14 - 15
Measurement Procedure	14
Memory	15
Storage & Maintenance	16
Abnormality & Troubleshooting	17
Specifications	18
Explanation of symbols on Unit	19
Appendix	20 - 21
Blood Pressure Record Table	22

Medical Disclaimer

This manual and product are not meant as a substitute for advice provided by your doctor.

You are not to use the information contained herein, or this product for diagnosing or treating a health problem or prescribing any medication. If you have or suspect that you have a medical problem, promptly consult your healthcare provider.

Intended Use

This device uses the oscillometric method to automatically measure systolic and diastolic blood pressure as well as heart rate.

The measurement position is on the upper part of the left arm.

All values can be read out in one LCD panel.

The device is designed for home use and recommended for use by adults aged 18 years and older with upper arm circumference ranging from 9 inch ~ 13 inch (approx. 23 cm ~ 33 cm).

Additional Information on Blood Pressure

1. What is blood pressure?

Blood pressure is the measurement of the force of blood pushing against the walls of the arteries. Arterial blood pressure is constantly fluctuating during the course of the cardiac cycle. The highest pressure in the cycle is called the systolic blood pressure, and represents the pressure in the artery when the heart is beating. The lowest pressure is the diastolic blood pressure, and represents the pressure in the artery when the heart is at rest. Both the systolic and the diastolic pressure are necessary for a physician to evaluate the status of a patient's blood pressure. Many factors such as physical activity, anxiety or the time of day, can influence your blood pressure. Blood pressure is typically low in the mornings and increases from the afternoon to the evening. It is on average lower in the summer and higher in the winter.

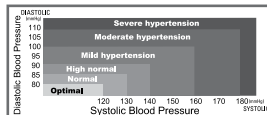
2. Why is it useful to measure blood pressure at home?

Having one's blood pressure measured by a doctor in a hospital or a clinic, is often associated with a phenomenon called "White Coat Hypertension" where the patient becomes nervous or anxious, thus raising his blood pressure. There are also numerous other factors that might cause your blood pressure to be raised at a specific time of day. This is why medical practitioners recommend home monitoring as it is important to get readings of blood pressure during different times of the day to really get an idea of your real blood pressure. Medical practitioners generally recommend the "Rule of 3", where you are encouraged to take your blood pressure three times in a row (at 3 ~ 5 minute interval), three times a day for three days. After three days you can average all the results and this will give you an accurate idea of what your blood pressure really is.

Additional Information on Blood Pressure

A. BHS (British Hypertension Society) blood pressure classifications:

Standards for assessment of high or low blood pressure without regard to age, have been established by the British Hypertension Society (BHS), as shown in the chart. However this chart is not exact for classification of blood pressure and it's intended to be used as a guide in understanding non-invasive blood pressure measurements. Please consult with your physician for proper diagnosis.



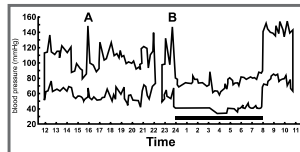
B. Variations in blood pressure:

Individual blood pressures vary greatly both on a daily and a seasonal basis. These variations are even more pronounced in hypertensive patients. Normally the blood pressure rises while at work and is at its lowest during sleeping period.

(hypertensive: a person who has high blood pressure symptoms.)

The graph right, illustrates the variations in blood pressure over a whole day with measurement taken every five minutes. The thick line represents sleep.

The rise in blood pressure at 4 PM (A in the graph) and 12 PM (B in the graph) corresponds to peak readings.



Precautions

- * Do not use this manual and product as a substitute for advice, diagnosing or treating a health problem or prescribing any medication by your doctor. If you have a medical problem, promptly consult your healthcare provider.
 - * Read the Instruction Manual thoroughly before measuring and keep it at hand for your reference at any time.
 - * This device uses the oscillometric method to measure systolic and diastolic blood pressure as well as your heart rate. It's recommended for use by people over the age of 18 and not to be used on infants or children.
 - * The device is designed for home use and not suitable for clinical use.
-
- Do not take a measurement in a low (less than 50 °F/10 °C) and high (more than 104 °F/40 °C) temperature, nor in a place outside humidity ranges (15 % ~ 90 % R.H.), or you may get inaccurate readings.
 - Wait 30 ~ 45 minutes before measurement if you've just consumed caffeinated beverages or smoked cigarettes.
 - Rest at least 5 ~ 10 minutes before taking a measurement.
 - To allow your blood vessels to return to the condition prior to taking the measurement, please wait at least 3 ~ 5 minutes in between measurements. You may need to adjust the wait time according to your personal physiological situation.
 - We recommend you using the same arm (preferably the left arm) and measuring around the same time each day.
 - Sit down comfortably and place your elbow on the table with your feet flat on the floor. Please do not cross your legs during measurements.
 - Keep the device at heart level. Relax your hand with the palm facing up.
 - Perform measurements in a quiet and relaxed environment at room temperature.
 - Do not move or shake the device during a measurement. Please keep quiet and do not talk during measurements.

Precautions

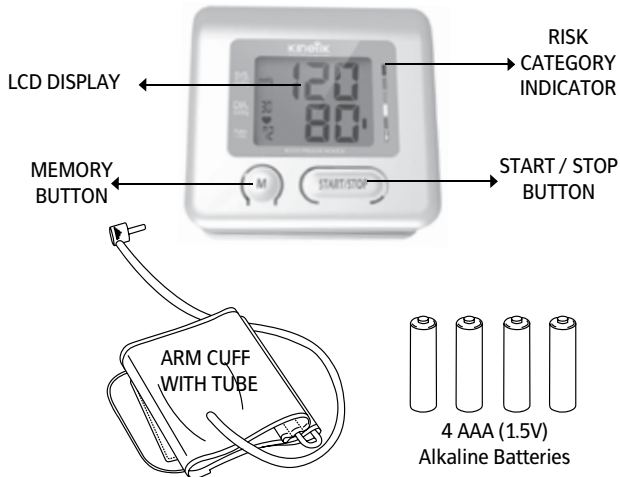
- Keep in mind that blood pressure naturally varies from time to time throughout the day and is affected by lots of different factors such as stress, eating, smoking, alcohol consumption, medication, and physical activity, etc. Normally the blood pressure rises while at work and is at its lowest during sleeping period.
- Blood pressure measurements should be interpreted by a physician or a trained health professional who is familiar with your medical history. Using the unit and recording the results regularly for your physician to interpret, you will keep your physician informed of the continuing changes in your blood pressure.
- If you have one of the circulatory problems such as arteriosclerosis, diabetes, liver disease, kidney disease, severe hypertension, peripheral circulation....., please consult your healthcare professional before using the device.
- This product is not suitable for people with arrhythmias and pregnant women.
- Blood pressure measurements taken with this device are equivalent to those obtained by a trained observer using the cuff / stethoscope auscultation method and are within the accuracy limits prescribed by the Standard of EN 1060-4.

ATTENTION :

1. Do not use the device on infants, children, or those who cannot express their own intention.
2. The device is equipped with sensitive electronic components. While measuring, avoid strong electrical or electromagnetic fields, e.g. mobile phones, microwave ovens, etc; or it may lead to temporary reading error or inaccuracy.
3. To avoid accidental strangulation, keep this product away from children and do not drape tube around neck.
4. Over use of a blood pressure monitor may result in blood flow interference, which is likely to cause uncomfortable sensations, such as temporary numbness to your arm. In general, these symptoms should not last long. However, if you do not recover after some time, please seek medical assistance.

Parts

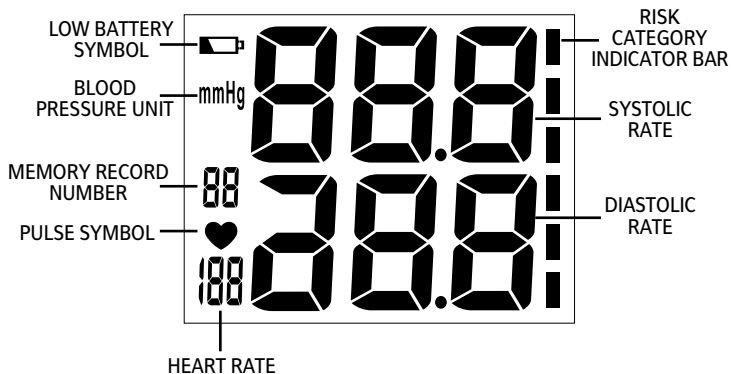
- Part names and product components






CAUTION :
Substitution of a component different from that supplied might result in measurement error.

Parts

- Unit display



Parts

SYMBOLS	Definitions
 Low Battery Symbol	<p>This symbol appears when the battery power is excessively low or the polarity reverses.</p> <p>→ We suggest you replace all batteries with new ones and make sure the +/- polarities are properly positioned.</p>
 Pulse Symbol	<p>Once pulse is detected, the symbol flashes with each pulse beat.</p> <p>→ Our suggestion: Please do not talk or move during measurements.</p>
 Risk Category Indicator Bar	<p>RCI bar arrowhead indicates the specific Risk Category that your measurement reading fits in.</p>

Indicator & Classification of Blood Pressure

Risk Category Indicator

The table below shows the different blood pressure classifications (Low to Severe hypertension) and corresponding colours. Please note that factors such as smoking, obesity and diabetes will affect your blood pressure. Always consult your physician or health care professional before starting a diet or exercise regime.


Classification of Blood Pressure Levels		Systolic (mmHg)	Diastolic (mmHg)	Corresponding Colour
Grade 3	Severe Hypertension	≥ 180	or ≥ 110	Dark Red
Grade 2	Moderate Hypertension	160 ~ 179	or 100 ~ 109	Light Red
Grade 1	Mild Hypertension	140 ~ 159	or 90 ~ 99	Orange
High-Normal		130 ~ 139	or 85 ~ 89	Yellow
Optimal & Normal		91 ~ 129	and 61 ~ 84	Green
Low		≤ 90	and ≤ 60	Yellow Down Arrow with Green Background

Note

- Low blood pressure, or hypotension, occurs when blood pressure during and after each heartbeat is much lower than usual. This means the heart, brain, and other parts of the body do not get enough blood. Symptoms may include blurry vision, confusion, dizziness, light-headedness, sleepiness and weakness. However, blood pressure that is borderline low for one person may be normal for another. Consequently, hypotension in a healthy person that does not cause any problems usually doesn't require treatment. If in doubt, seek advice from your physician or healthcare professional.
- The colour indicator and the colours used are designed to indicate the various classifications of blood pressure only. The use of red and orange colours should not be interpreted as a medical emergency.

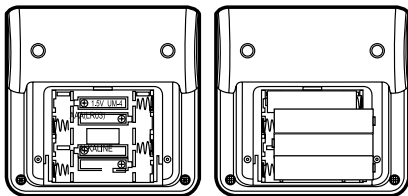
Setting up your Blood Pressure Monitor

Loading Batteries

When LOW BATTERY SYMBOL  appears on the display, or no reaction toward operation, please change batteries.

Replace all worn-out batteries with new ones and do not mix new and used batteries. Do not mix alkaline, standard (carbon-zinc) or rechargeable (cadmium) batteries either. Such action may shorten the battery life or cause the device to malfunction.

Slide the battery cover and insert 4 AAA alkaline batteries into the battery compartment as shown on the figure below. Make sure the polarities “+” and “-” ends are properly positioned.



ATTENTION :

- Batteries are hazardous waste. Do not dispose of them together with the household garbage. Please discard worn-out batteries to the recycling site according to local regulations.
- Keep the batteries away from children in case they choke on them.
- If the device is not to be used for over 2 months, please remove the batteries from its compartment for power-saving.

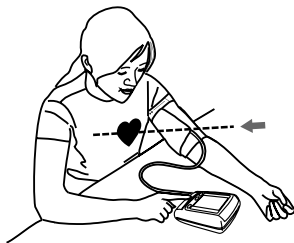
Setting up your Blood Pressure Monitor

Connecting the Cuff

- Press your brachial artery approximately 1 inch (2 ~ 3 cm) above the elbow on the inside of your left arm to determine where your strongest pulse is.
- Slide the end of arm cuff furthest from the tube through the metal ring to a loop. The smooth cloth should be on the inside of the cuff.
- If the cuff is located correctly, the velcro will be on the outside of the cuff and the metal ring will not touch your skin.
- Put left arm through the cuff loop. The bottom of the cuff should be approximately 1 inch (2 ~ 3 cm) above the inner elbow. The tube should lie over the brachial artery on the inner part of the arm.
- Pull the cuff so that the top and bottom edges are tightened around your arm.
- When the cuff is positioned properly, press the velcro firmly against the pile side of the cuff.
- Sit on a chair and lay your forearm on the table so that the cuff is at the same level as your heart.
- Relax your arm and turn your arm upward.
- Make sure there are no kinks in the air tube.

NOTE :

- Fit the cuff snugly, leaving enough space for 1 inch (2 ~ 3 cm) between the inner elbow and the lower edge of the cuff, or the measurement may not be accurate.
- This monitor comes with one size of arm cuff: 9" ~ 13" (23 ~ 33 cm).
- Do not wrap the cuff around any body part other than your arm.
- The device is not supposed to be used when your arm is wounded or injured.



Using your Blood Pressure Monitor

Measurement Procedure

• Switching on the monitor

- A. Switch on the monitor by pressing START/STOP button.
- B. All segments appear on the screen.

• Taking a measurement

- A. With the cuff wrapped around your arm, press START/STOP button to start measurement.
All display symbols appear on the screen for 2 seconds.

NOTE :

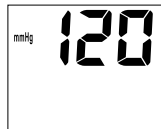
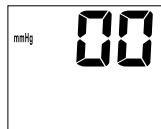
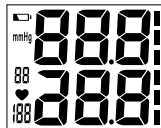
Do not inflate the cuff unless it is wrapped around your arm.

- B. After all symbols disappear, the display will show "00". The monitor is "Ready to Measure" and will automatically inflate to the level that is right for you.
- C. After the initial inflation of the cuff, the pressure will slowly decrease and when a pulse is detected, PULSE SYMBOL will start flashing.

NOTE :

- This monitor will re-inflate automatically if the system detects that your body requires more pressure for measurement.
- If you experience any pain during measurement, press the start/stop button to cancel the cuff inflation.
- To interrupt the measurement, press START/STOP button to switch to Standby Mode.

- D. When the measurement is finished, the systolic pressure, diastolic pressure, heart rate and corresponding Risk Category Indicator Bar will be displayed for about 1 minute.
- E. Without any operation for 1 minute, the device automatically shuts off.



Using your Blood Pressure Monitor

Memory

• Storing data

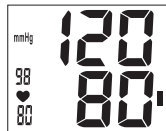
After each measurement, the systolic, diastolic pressure and heart rate will be automatically stored. The monitor can store up to 99 memory sets, and automatically replaces the oldest data with the most recent reading.

• Recalling data

- A. Press M button to enter Memory Mode. The latest measurement (if any) appears in the first place.
- B. Press M button to read following measurements in sequence.
- C. To stop reading the memories, press START/STOP button to switch to Standby Mode.

• Erasing data

- A. Remove batteries from its compartment and put them back again. All stored data shall be deleted accordingly.
- B. To confirm the deletion, press M button and no data should appear.



Note: Once deleted, your data can NOT be restored.

Storage and Maintenance

• General Use

- * Do not in any way twist the cuff.
- * Do not press START/STOP button if the cuff is not wrapped around your upper arm.
- * Do not drop the product and avoid any strong impacts.

• Maintenance

- * Use a piece of cloth with water or mild cleansing agent to wipe the device and dry it immediately with a dry cloth.
- * Do not use detergent or any strong chemicals to clean the device.
- * Use only a dry cloth to wipe the cuff.
- * Do not attempt to disassemble or change any parts of the monitor, including arm cuff, substitution of a component different from that supplied might result in measurement error.
- * This blood pressure monitor is calibrated at the time of manufacture. If the blood pressure monitor is used according to the instruction, periodic recalibration is not required. If at any time you question the accuracy of the measurement, please contact the retailer immediately.

• Storage

- * If the device is not to be used for a long time, please remove the batteries from the device (leaking of battery acid can cause the device to malfunction).
- * Always store the unit in the storage case after use.
- * Do not place the device directly under sunlight, in high temperature, or in humid or dusty places.
- * Do not store the device in extremely low (less than $-4^{\circ}\text{F}/-20^{\circ}\text{C}$) and high (more than $158^{\circ}\text{F}/70^{\circ}\text{C}$) temperature, nor in a place its humidity exceeds 90% R.H.

Abnormality & Troubleshooting

SYMBOLS/SYMPTOMS	CONDITIONS/CAUSES	INDICATION/ CORRECTION
Unit does not turn on when START/STOP button is pushed.	Worn-out batteries.	Replace them with 4 new AAA alkaline batteries.
	Battery polarities have been positioned incorrectly.	Re-insert the batteries in the correct positions.
EE Measuring Error Symbol appears when blood pressure value displayed is excessively low or high.	Cuff has been placed incorrectly.	Wrap the cuff properly so that it is positioned correctly.
	Did you talk or move during measurement?	Measure again. Keep arm steady during measurement.
	Shaking of the arm with the cuff on.	
E1 Measuring Error Symbol	Air circuit abnormality.Cuff tube may not be plugged into monitor correctly.	Check cuff connection. Measure again.
E2 Measuring Error Symbol	Inflation pressure exceeding 300 mmHg.	Switch the unit off, then measure again.
E3 Measuring Error Symbol	Error determining measurement data.	Measure again.
Note: If "EP" appears on the display, just return the device to your local distributor or importer.		

Specifications

Model Number	BPM4TL
Measurement Method	Oscillometric
Measurement Range	Pressure: 0 ~ 300 mmHg Pulse: 40 ~ 199 Beats/Minute
Accuracy	Pressure: ± 3 mmHg Pulse: ± 5 % Max.
Inflation	Automatic Inflation (Air Pump)
Deflation	Automatic Air Release Control Valve
Display	Liquid Crystal Display
Memory	99 Memory Sets
Unit Dimensions	3.66 x 3.58 x 1.75 inch (L x W x H) 93 x 91 x 44.5 mm (L x W x H)
Unit Weight (Cuff & Batteries Excluded)	6.14 \pm 0.35 oz (173 \pm 10 g)
Cuff Size	23 ~ 33 cm (9 ~ 13 inch)
Storage/Transportation Environment	Temperature: -20 °C ~ 70 °C (-4 °F ~ 158 °F) Humidity: ≤ 90 % R.H.
Operation Environment	Temperature: 10 °C ~ 40 °C (50 °F ~ 104 °F) Humidity: 15 % ~ 90 % R.H.
Power Supply	AAA (1.5V) Alkaline Battery x 4
Battery Life	Approx. 300 measurements
Power-saving Mode	Without any operation for 1 minute, device automatically shuts off.
Accessories	4 AAA Alkaline Batteries, Arm Cuff with Tube, Instruction Manual, Pouch

***The contents of this manual and the specifications of the device covered by this manual are subject to change for improvement without notice.**

Explanation of symbols on Unit

This blood pressure monitor complies with the EC Directive and bears the CE mark. This blood pressure monitor also complies with mainly following standards (included but not limited):

Safety standard:

EN 60601-1 Medical electrical equipment part 1: General requirements for safety

EMC standard:

EN 60601-1-2 Medical electrical equipment part 1-2: General requirements for safety- Collateral standard: Electromagnetic compatibility- Requirements and tests

Performance standards:

EN 1060-1 Non-invasive sphygmomanometers - General requirements

EN 1060-3 Non-invasive sphygmomanometers - Supplementary requirements for electromechanical blood pressure measuring systems.

EN 1060-4 Non-invasive sphygmomanometers - Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers.



Important/Caution/Note! Read the operating instructions.



Follow instructions for use.



BF Classification:

- Internally powered equipment
- BF type applied part
- IPX0 - Not suitable for use in presence of flammable anesthetic mixture with air or with Oxygen or nitrous oxide
- Continuous operation with short-time loading



To avoid inaccurate results caused by electromagnetic interference between electrical and electronic equipments, do not use the device near a mobile phone or microwave oven.



Discard the used product to the recycling collection point according to local regulations.



Harvard Medical Devices Ltd.

Unit 1301, 13th Floor, Railway Plaza, 39 Chatham Road South, Tsimshatsui, Kowloon, Hong Kong.

Kinetik Medical Devices Ltd.

Mill Road, Rugby, Warwickshire, United Kingdom, CV21 1PR.

Appendix

● Guidance and manufacturer's declaration – electromagnetic emissions

The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	RF energy is used only to maintain device's operation. Therefore, its RF emissions are so low that it's not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not Applicable	

● Guidance and manufacturer's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:

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.

● Recommended separation distances between portable and mobile RF communication equipment and the device.

The device is intended for use in an electromagnetic environment where radiated RF disturbances are under control. User can help prevent electromagnetic interference by keeping the device at a minimum distance from portable and mobile RF communications equipment (transmitters). Below table details the maximum output power of transmitter:


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.

Appendix

● Guidance and manufacturer's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 Vrms</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>$d = 1.2 \sqrt{P}$</p> <p>$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 2.3 \sqrt{P}$ 80 MHz to 2.5 GHz</p> <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> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Blood Pressure Record Table

Date :		Time :		<input type="checkbox"/> Before <input type="checkbox"/> After	Meal
Systolic / Diastolic :				Pulse :	
Date :		Time :		<input type="checkbox"/> Before <input type="checkbox"/> After	Meal
Systolic / Diastolic :				Pulse :	
Date :		Time :		<input type="checkbox"/> Before <input type="checkbox"/> After	Meal
Systolic / Diastolic :				Pulse :	
Date :		Time :		<input type="checkbox"/> Before <input type="checkbox"/> After	Meal
Systolic / Diastolic :				Pulse :	
Date :		Time :		<input type="checkbox"/> Before <input type="checkbox"/> After	Meal
Systolic / Diastolic :				Pulse :	
Date :		Time :		<input type="checkbox"/> Before <input type="checkbox"/> After	Meal
Systolic / Diastolic :				Pulse :	
Date :		Time :		<input type="checkbox"/> Before <input type="checkbox"/> After	Meal
Systolic / Diastolic :				Pulse :	
Date :		Time :		<input type="checkbox"/> Before <input type="checkbox"/> After	Meal
Systolic / Diastolic :				Pulse :	
Date :		Time :		<input type="checkbox"/> Before <input type="checkbox"/> After	Meal
Systolic / Diastolic :				Pulse :	