

AccuMed

UPPER ARM BLOOD PRESSURE MONITOR



Instruction Manual

MODEL: ABP802

www.AccuMed.com

CE 0413

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INTRODUCTION

The Monitor uses the oscillometric method of blood pressure measurement.

Measurement Automatic Electronic Blood Pressure Monitor is intended for use by medical professionals or at home to monitor and display diastolic, systolic blood pressure, and pulse rate on adults each time, with an arm cuff around the left upper arm according to the instructions in the “ATTACHING THE ARM CUFF” section. The expected life of the product is 5 years.

The product complies with the electromagnetic compatibility requirement of EN60601-1-2 and safety standards of EN60601-1 and performance of EN1060-1. EN1060-3 as specified in EEC directive 93/42/EEC.

NOTES ON SAFETY


* The warning signs and sample icons shown here are listed for your safe and correct use of the unit, so as to prevent injuries or damages to the device.

* The icons and meanings are as follows:

Examples of signs





The  icon indicates prohibitions (what you should not do).

Matters involving actual prohibitions are indicated by text or pictures in or near .

The left icon refers to “general prohibition”.




The  icon indicates something that is compulsory (what must always be observed).

Matters involving actual compulsory actions are indicated by text or pictures in or near . The left icon refers to “general compulsion”.



The  icon indicates something can't be disassembled.

Matters involving actual compulsory actions are indicated by text or pictures in or near . The left icon refers to “general prohibition”.



Type BF Applied part







Attention and read before use



Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)



<p>Patient must follow doctor's instructions and should not perform self-judgment and self-treatment by the measuring result. Self-diagnosis on measured results and treatment are dangerous. The device should not be used to judge illness, first aid, and continuously monitor measuring. This device cannot be used for patient transport and surgical care. It can be used in household or fixed places only. Please press "on/off" button to stop work when you feel uncomfortable, or if the air is inflating abnormally without stopping.</p>	 Caution 
<p>Do not let a child below 12 years old and the people who can't express their intention use this. When it is used by the people of 12~18 years old, they should accompanied by an adult.</p>	
<p>Do not use the unit for purpose other than measuring blood pressure.</p>	
<p>Please do not use a mobile phone around the device. Please do not use the device around the magnetic field.</p>	
<p>Do not disassemble, repair, or remodel the main unit or the arm cuff of the blood pressure monitor. This will cause the unit to malfunction.</p>	

Requests from Manufacturer
<p>Make sure the connection tubing is not kinked before measuring to avoid any injury to patient.</p>
<p>For any patient, do not measure more than 3 times continuously. Wait for at least 5 minutes between any two measurements; otherwise it will cause extravasated blood.</p>
<p>Do not measure your blood pressure over 6 times each day.</p>
<p>Do not apply the cuff over a wound as this can cause further injury.</p>
<p>Do measure on the arm on the same side as a mastectomy, otherwise it could cause injury.</p>
<p>Observe the air pressure value on the LCD display.</p>
<p>When measuring, it should not exceed 299 mmHg, otherwise please press the "on/off" button to stop.</p>
<p>Do not use force to bend the arm cuff or the air tube.</p>
<p>Do not knock or drop the main unit.</p>
<p>Always use the accessories specified in the manual, the use of other parts not approved by the manufacturer may cause faults or injuries.</p>
<p>For service information, parts list, etc., please contact the dealer.</p>

ABOUT BLOOD PRESSURE

1. What is blood pressure?

Blood pressure is the force exerted by blood against the walls of the arteries. Systolic pressure occurs when the heart contracts. Diastolic pressure occurs when the heart expands.

Blood pressure is measured in millimeters of mercury (mmHg). One's natural blood pressure is represented by the fundamental pressure, which is measured first thing in the morning while one is still at rest and before eating.

2. What is hypertension and how is it controlled?

Hypertension, an abnormally high arterial blood pressure, if left unattended, can cause many health problems including stroke and heart attack.

Hypertension can be controlled by altering lifestyle, avoiding stress, and with medication under a doctor's supervision.

To prevent hypertension or keep it under control:

- ❖ Do not smoke
- ❖ Exercise regularly
- ❖ Reduce salt and fat intake
- ❖ Have regular physical checkups
- ❖ Maintain proper weight

3. Why measure blood pressure at home?

Blood pressure measured at a clinic or doctor's office may cause apprehension and produce an elevated reading, 25 to 30 mmHg higher than that measured at home. Home measurement reduces the effects of outside influences on blood pressure readings, supplements the doctor's readings, and provides a more accurate, complete blood pressure history.

4. WHO blood pressure classification

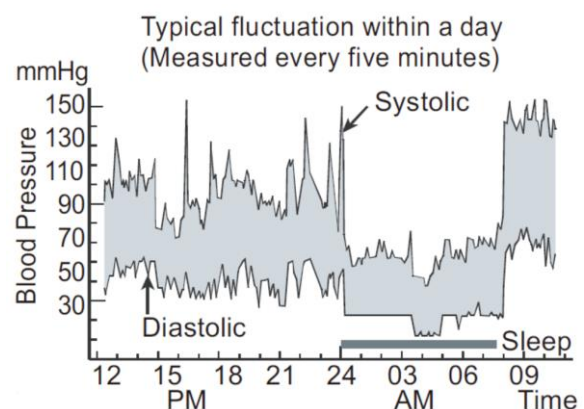
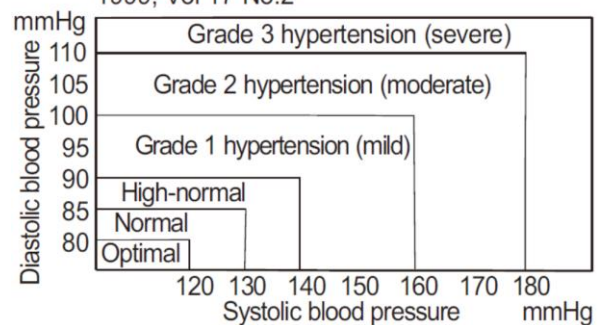
Standards for assessment of high blood pressure, without regard to age, have been established by the World Health Organization (WHO), and are shown in chart to the right.

5. Blood pressure variations

An individual's blood pressure varies greatly on a daily and seasonal basis. It may vary by 30 to 50 mmHg due to various conditions during the day. In hypertensive individuals, variations are even more pronounced.

Normally, the blood pressure rises while at work or play and falls to its lowest levels during sleep. So, do not be overly concerned by the results of one measurement.

Reference Material: Journal of Hypertension
1999, Vol 17 No.2



Take measurements at the same time every day using the procedure described in this manual to determine your normal blood pressure. Many readings give a more comprehensive blood pressure history. Be sure to note date and time when recording your blood pressure. Consult your doctor to interpret your blood pressure data.

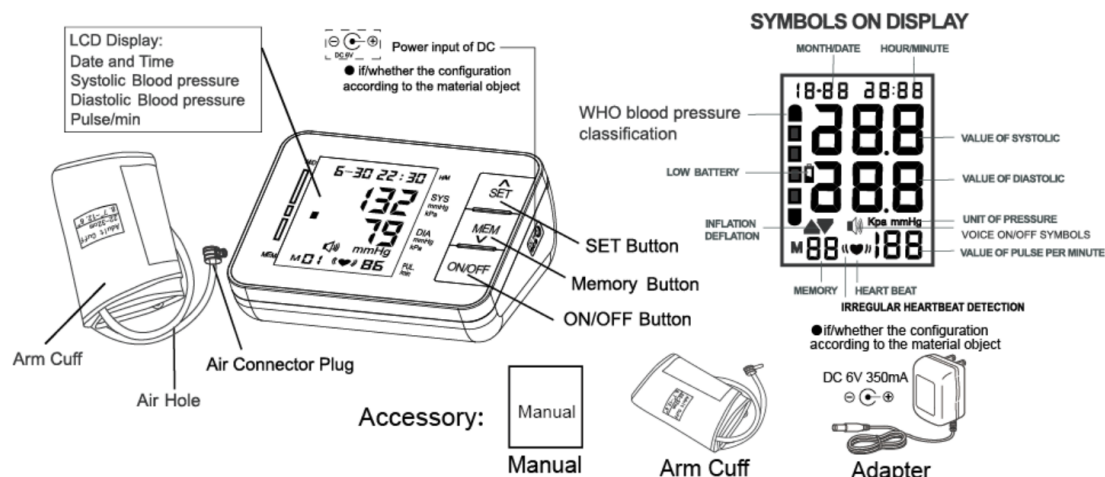
PRECAUTIONS BEFORE USE

1. If you are taking medication, consult with your doctor to determine the most appropriate time to measure your blood pressure. NEVER change a prescribed medication without first consulting with your doctor.
2. For people 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.
3. Measurements may be impaired if this device is used near televisions, microwave ovens, X-ray, mobile phone equipment, or other devices with strong electrical fields. To prevent such interference, use the monitor at a sufficient distance away from such devices or turn them off.
4. Before using, you should wash your hands.
5. Do not measure on the arm which is being used by monitoring ME Equipment. Otherwise it could cause loss of function.
6. Consult your doctor if unexpected readings are obtained. Also please refer to "TROUBLESHOOTING" section of the manual.
7. The reading is probably a little lower than measured in the hospital due to the steady mood at home.
8. Cuff pressure range is 0-299mmHg

FEATURES OF THE PRODUCT

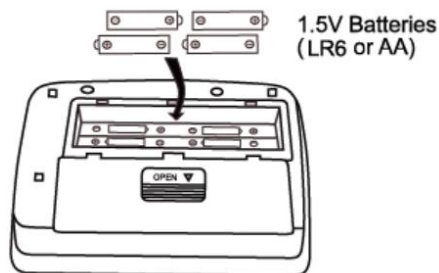
1. Memory can store 90 measurements.
2. Large and clear LCD display.
3. WHO blood pressure classification display.
4. Easy to use. Press a button to automatically measure and record the measurement values and measurement time.
5. Automatically turns off (within 1 minute) to save power.

PARTS IDENTIFICATION



INSERT OR REPLACE BATTERIES

1. Remove the battery cover.
2. Insert new batteries into the battery compartment as shown, taking care that the polarities (+) and (-) are correct.
3. Close the battery cover. Use only LR6, AA batteries.



Dispose of dead batteries to the authorized collecting party according to the regulation of each individual territory.

CAUTION

- ❖ Insert the batteries as shown in the battery compartment. If not, the device will not work.
- ❖ When (LOW BATTERY mark) blinks on the display, replace all batteries with new ones. Do not mix old and new batteries. It may shorten the battery life, or cause the device to malfunction.

(LOW BATTERY mark) does not appear when the batteries run out.

- ❖ Battery life varies with the ambient temperature and may be shorten at low temperatures.
- ❖ The batteries may leak and cause a malfunction.
- ❖ Use the specified batteries only. The batteries provided with the device are for testing monitor performance and may have a shorter life.
- ❖ Used batteries may leak and damage the main unit. Please observe the following points.

* If you are not going to use the unit for a long period of time (approximately three months or more), remove the batteries.

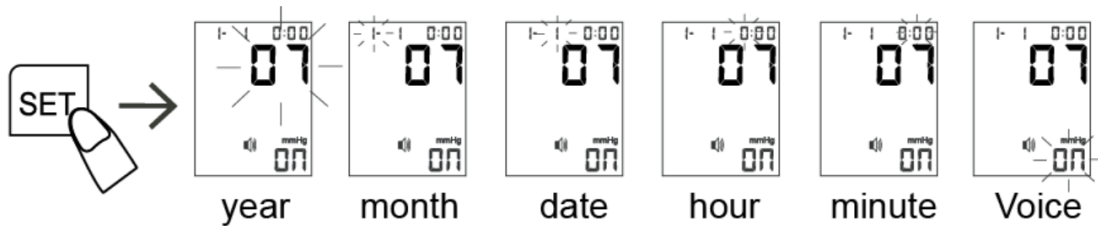
* Replace worn batteries with their polarities in the correct direction.

TIME AND VOICE ON/OFF OF SYSTEM SETUP

1. Press "SET" key to turn on.
2. Press and hold "SET" key until the year number displays and flashes on LCD to enter the settings mode.
3. Press the "MEM" key to adjust the year, then press "SET" key again to save your setting and enter the month setting mode.
4. Press "MEM" key to adjust the month. Following the same steps to adjust date/hour/minute/(Voice on/off) until setting completed ("ON" is the



On, "OF" is the Off) Non-talking model does not have this function, or you may choose method No.2 to set the voice.



Method No.2 for voice setting: Please press and hold the "MEM" button when the device is in the shutdown state to enter the voice setting. Please press the "MEM" button again to choose "ON" or "OF". Press the "ON/OFF" button to quit.



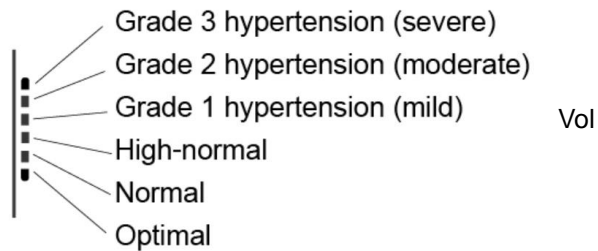
UNIT CONVERSION mmHg/kPa DISPLAY

The monitor has two kinds of blood pressure display units mm Hg(mmHg), kPa (kPa). (mmHg is the factory default). While the monitor is off, press and hold the ON/OFF button for 5 seconds. The monitor will boot up and measure showing the other unit. (If it was in mmHG it will change to kPa and vice versa.) Also the stored values will be shown in the new unit.



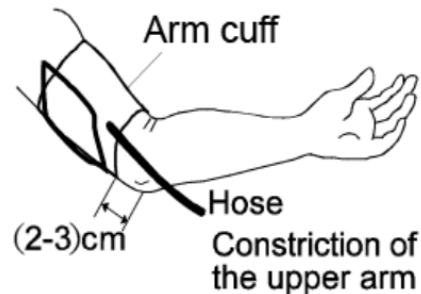
WHO BLOOD PRESSURE CLASSIFICATION DISPLAY

Diastolic blood pressure reference material: journal of hypertension 1999. 17 No.2



ATTACHING THE ARM CUFF

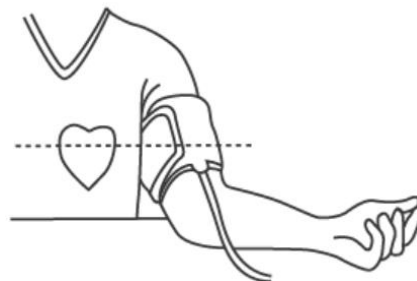
1. Wrap the arm cuff around the upper arm, about (2-3) cm above the elbow, as shown. Place the cuff directly on the skin, as clothing may cause a faint pulse, and result in a measurement error.
2. Constriction of the upper arm, caused by rolling up a shirtsleeve, may prevent accurate readings.
3. Secure the arm cuff with Velcro Strip in such a way that it lies comfortably and is not too tight. Lay the arm on the table (palm upwards) so that the arm cuff is at the same height as the heart. Make sure that the tube is not kinked.
4. Measure your arm circumference for cuff selection. Please refer to "SPECIFICATIONS" section.



HOW TO TAKE PROPER MEASUREMENTS

For the most accurate blood pressure measurement please adhere to the following guidelines:

- 1) Comfortably seated
- 2) Legs uncrossed
- 3) Feet flat on the floor.
- 4) Back and arm supported
- 5) Middle of the cuff at the same level as the heart



- Remain still and keep quiet during measurement.
- Relax as much as possible and not talk during the measurement process.
- Measure your blood pressure at about the same time every day.

- Do not measure right after physical exercise or a bath. Take a rest for twenty or thirty minutes before taking the measurement.
- The reading could be affected by the following:
 Within in an hour after dinner, after having wine, coffee, red tea, sports, bathing; talking, being nervous, being in unsteady mood, bending forward, moving, room temperature dramatically changing during measuring; in moving vehicles, long continuous measuring.

HOW TO MEASURE BLOOD PRESSURE

1. Setup the arm cuff to your upper arm as previous section of “ATTACHING THE ARM CUFF”
2. Press the “ON/OFF” button, all icons appear for two seconds on DISPLAY, then switch to measurement, and displays “0” or the last measurement record.



3. To start the measurement, the cuff in the strap will automatically inflate. The mark (♥) will flash on LCD. When complete, the LCD will display measurement results.

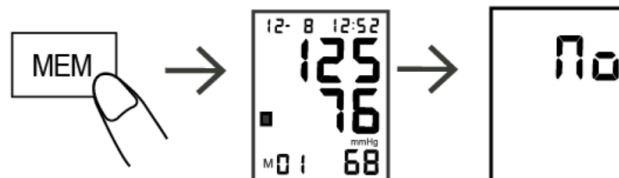


READ MEMORY

Press the “MEM” button to view the last measurement recorded. Press the “MEM” button again to go through older records. Press the “SET” button to go to more recent records. The number next to “M” on the screen indicates which record it is. The larger the number is, the older the record.

DELETE MEMORY

Press and hold the “MEM” button for 5 seconds to delete all of the records in memory. The LCD will display “No” after the records have been deleted.



CARE AND MAINTENANCE

To keep your digital blood pressure monitor in the best condition and protect the unit from damage, follow the directions listed below:

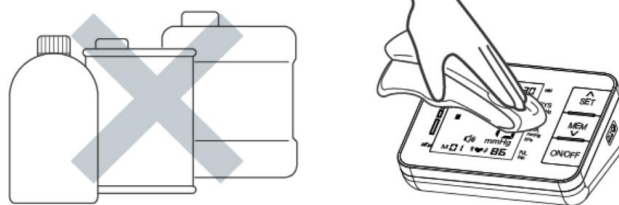
Keep the monitor in the storage case when not in use.

Do not fold the arm cuff too tightly.

The fabric fastener could touch the inner surface of the arm cuff and damage it.

Clean the monitor and cuff with a soft dry cloth.

Do not use any abrasive or volatile cleaners.



CAUTION

- * Do not submerge the device or any of the components in water.
- * Do not subject the monitor to extreme hot or cold temperatures, humidity, or direct sunlight.
- * Store the device and the components in a clean, safe location.
- * Do not subject the monitor to strong shocks, such as dropping the unit on the floor.
- * Remove the batteries if the unit will not be used for three months or longer. Always replace all the batteries with new ones at the same time.
 - ❖ This product is designed for use over an extended period of time; however, it is generally recommended that it be inspected and calibrated every two years to ensure proper function and performance.

SPECIFICATIONS

Measuring Method	Oscillometric Measurement
Indication	Digital LCD display
Measuring Range:	Pressure:(30~280)mmHg Pulse:(40~199)Beat/min
Accuracy:	Static Pressure: ± 3 mmHg Pulse: $\pm 5\%$
Memory:	90 Memories
Power supply:	4x1.5V Batteries (LR6 or AA) Using alkaline batteries will provide over 200 measurements.
Operating condition:	+5 °C ~+40 °C 15%RH~93%RH Atmospheric pressure: 70kPa~106kPa
storage condition:	-20 °C ~+55 °C 0%RH~93%RH Atmospheric pressure:50kPa~106kPa
Dimensions:	Approx.: 140(W)X110(H)X48(D)mm
Weight:	Approx.: 450g, excluding batteries
Classification	Type BF
Upper arm circumference	(22~32)cm
AC adapter	INPUT: 100-240V~ 50/60Hz, 0.3A OUTPUT: 6V 500mA

* Specifications may be changed without notice in the event of improvements being made.

1. Type of protection against electric shock: INTERNALLY POWERED EQUIPMENT.
2. Degree or protection against electric shock: TYPE BF APPLIED PART.
3. Mode of operation: CONTINUOUS OPERATION.
4. Equipment not suitable for category AP&APG equipment use in presence.

STATEMENT



The system might not meet its performance specifications if stored or used outside the temperature and humidity as mentioned below:

Operating conditions: +5 °C ~+40 °C 15%RH~93%RH 70kPa~106kPa

Storage conditions: -20 °C ~+55 °C 0%RH~93%RH

TROUBLESHOOTING

If you have trouble in 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 flashes.	No battery installation	Insert batteries
	Batteries are dead	Replace with new batteries
	The batteries are installed correctly	Insert battery in the correct polarities
Can't normally increase pressure	Check your arm cuff for any air leakage	Replace arm cuff with new one
Inflate pressure is too high		Re-measure or send back to dealer to re-calibrate pressure
Shaking while measuring	Hand or body shaking while measuring	Keeping static and correct gesture to measure again
 Battery icon on	Batteries have low power	Replace batteries and measure again
The systolic pressure value or diastolic pressure value too high	The arm cuff was held lower than your heart	Keep the correct position, remain still, and measure again
	The arm cuff was not attached properly	
	You moved your body or spoke while measuring	
The systolic pressure value or diastolic pressure value too low	The arm cuff was held higher than your heart	
	You moved your body or spoke while measuring	

ACCOMPANYING DOCUMENTS

A. Instructions for use

1. MODEL ABP802 needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS;
2. Portable and mobile RF communications equipment can affect MODEL ABP802.


B. Technical description

1. Warning that the use of accessories, transducers, and cables other than those specified with the exception of transducers and cables sold by the manufacturer of the MODEL ABP802 as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the MODEL ABP802.
2. Warning that the MODEL ABP802 should not be used adjacent to or stacked with other equipment

Guidance and manufacturer's declaration – electromagnetic emissions		
The MODEL ABP802 is intended for use in the electromagnetic environment specified below. The customer or the user of the MODEL ABP802 should assure that it is used in such an environment.		
Emissions	Compliance	Electromagnetic environment-- guidance
RF emissions CISPR 11	Group 1	The MODEL ABP802 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 MODEL ABP802 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	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The MODEL ABP802 is intended for use in the electromagnetic environment specified below. The customer or the user of the MODEL ABP802 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 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines and patient coupled lines	±2 kV for power supply lines and patient coupled lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) and neutral	±1 kV line(s) and neutral	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in U) T for 0,5 cycle 40 % UT (60 % dip in U) T for 5 cycles 70 % UT (30 % dip in U) T for 25 cycles <5 % UT	<5 % UT (>95 % dip in U) T for 0,5 cycle 40 % UT (60 % dip in U) T for 5 cycles 70 % UT (30 % dip in U) T for 25 cycles <5 % UT	Mains power quality should be that of a typical commercial or hospital environment. If a dip or an interruption of main power occurs, the current of the MODEL ABP802 may be dropped off from normal level, it may be necessary to use uninterruptible power supply or a battery.

	(>95 % dip in U) T for 5s	(>95 % dip in U) T for 5s	
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.
NOTE UT is the a.c. main voltage prior to application of the test level			

Guidance and manufacturer's declaration – electromagnetic immunity			
The MODEL ABP802 is intended for use in the electromagnetic environment specified below. The customer or the user of the MODEL ABP802 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment--guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the MODEL ABP802, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,3 \sqrt{P}$ 80 MHz to 2,5 MHz 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 meters (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 MODEL ABP802 is used exceeds the applicable RF compliance level above, the MODEL ABP802 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MODEL ABP802.

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

Recommended separation distances between portable and mobile RF communications equipment and the MODEL ABP802

The MODEL ABP802 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MODEL ABP802 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MODEL ABP802 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		
	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.