MODEL KD-322

Semi Automatic Arm Cuff Blood Pressure Monitor

(ELECTRONIC SPHYGMOMANOMETER)

OPERATION GUIDE

INDEX

IMPORTANT INFORMATION

NORMAL BLOOD PRESSURE FLUCTUATION

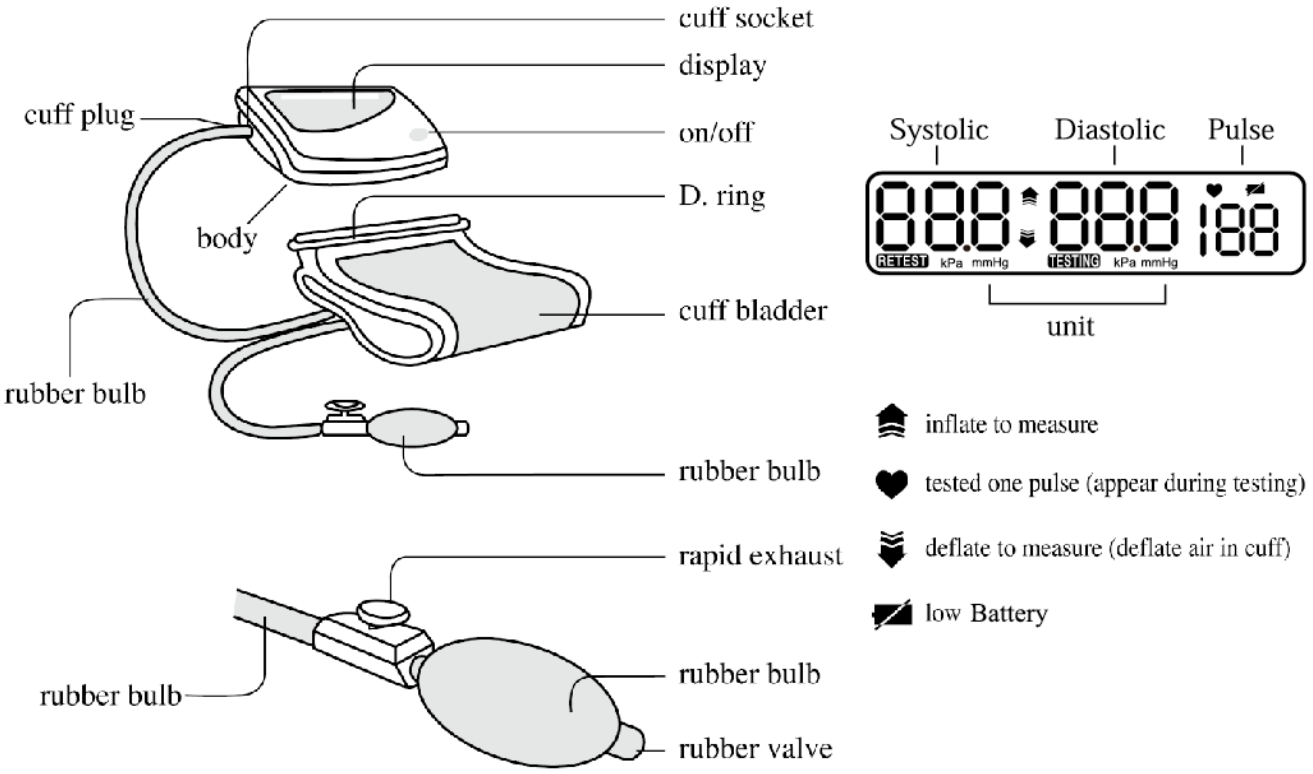
All physical activity, excitement, stress, eating, drinking, smoking, body posture and many other activities or factors (including taking a blood pressure measurement) will influence blood pressure value. Because of this, it is mostly unusual to obtain identical multiple blood pressure readings.

Blood pressure fluctuates continually ----- day and night. The highest value usually appears in the daytime and lowest one usually at midnight. Typically, the value begins to increase at around 3:00AM, and reaches to highest level in the daytime while most people are awake and active.

Considering the above information, it is recommended that you measure your blood pressure at approximately the same time each day.

Too frequent measurements may cause injury due to blood flow interference, please always relax a minimum of 1 to 1.5 minutes between measurements to allow the blood circulation in your arm to recover. It is rare that you obtain identical blood pressure readings each time.

CONTENTS AND DISPLAY INDICATORS



INTENDED USE

Semi-Automatic Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-48cm (approx. 8 21/32” -18 29/32”).

CONTRAINDICATION

 It is inappropriate for people with serious arrhythmia to use this electronic blood pressure monitor.

PRODUCT DESCRIPTION

Based on Oscillometric methodology and silicon integrated pressure sensor, blood pressure and pulse rate can be measured automatically and non-invasively. The LCD display will show blood pressure and pulse rate. The Electronic Blood Pressure Monitor corresponds to the below standards: IEC 60601-1:2005/EN 60601-1:2006/AC:2010 (Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance), IEC60601-1-2:2007/EN 60601-1-2:2007 /AC:2010 (Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests), EN 1060-1: 1995 + A1: 2002 + A2: 2009 (Non-invasive sphygmomanometers - Part 1: General requirements), EN 1060-3: 1997 + A1: 2005 + A2: 2009 (Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems), ANSI/AAMI SP-10:2002+A1:2003+A2:2006.

SPECIFICATIONS

1. Product name: Blood Pressure Monitor
2. Model: KD-322
3. Classification: Internally powered, Type BF applied part,IPX0,No AP or APG,Continuous operation
4. Machine size: approx. 144mm×102mm×46mm (5 21/32" x 4 1/32" x 1 13/16")
5. Cuff circumference: 22cm-30cm(8 21/32" -11 13/16"), 30cm-42cm(11 13/16" -16 17/32") (Optional), 42cm-48cm(16 17/32" -18 29/32") (Optional)
6. Weight: approx. 162g (5 23/32oz.) (exclude batteries)
7. Measuring method: Oscillometric method, manual inflation and measurement
8. Power source: batteries:4 ×1.5V ⎓ SIZE AA
9. Measurement range:
   Cuff pressure: 0-300mmHg
   Systolic: 60-260mmHg
   Diastolic: 40-199mmHg
   Pulse rate: 40-180 beats/minute
10. Accuracy:
    Pressure: ±3mmHg
    Pulse rate: ±5%
11. Environmental temperature for operation: 5℃～40℃(41℉～104℉)
12. Environmental humidity for operation: ≤90%RH
13. Environmental temperature for storage and transport: -20℃～55℃(-4℉～131℉)
14. Environmental humidity for storage and transport: ≤90%RH
15. Environmental pressure: 80kPa-105kPa
16. Battery life: Approx. 540 times.
17. All components belonging to the pressure measuring system, including accessories: Pump, Valve, LCD, Cuff and Sensor.

Note: These specifications are subject to change without notice.

NOTICE

1. Read all of the information in the operation guide and any other literature in the box before operating the unit.
2. Stay still, calm and rest for 5 minutes before blood pressure measurement.
3. The cuff should be placed at the same level as your heart.
4. During measurement, neither speak nor move your body and arm.
5. Measuring on same arm for each measurement.
6. Please always relax at least 1 or 1.5 minutes between measurements to allow the blood circulation in your arm to recover. Prolonged over-inflation (cuff pressure exceed 300 mmHg or maintained above15 mmHg for longer than 3 minutes) of the bladder may cause ecchymoma of your arm.

7. Consult your physician if you have any doubt about below cases:
   1) The application of the cuff over a wound or inflammation diseases;
   2) The application of the cuff on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present;
   3) The application of the cuff on the arm on the side of a mastectomy;
   4) Simultaneously used with other monitoring medical equipments on the same limb;
   5) Need to check the blood circulation of the user.
8. ⚠This Electronic Blood Pressure Monitor s is designed for adults and should never be used on infants or young children. Consult your physician or other health care professionals before use on older children.
9. Do not use this unit in a moving vehicle, This may result in erroneous measurement.
10. Blood pressure measurements determined by this monitor are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method, within the limits prescribed by the American National Standard Institute, Electronic or automated sphygmomanometers.
11. Information regarding potential electromagnetic or other interference between the blood pressure monitor and other devices together with advice regarding avoidance of such interference please see part ELECTROMAGNETIC COMPATIBILITY INFORMATION.
12. If Irregular Heartbeat (IHB) is detected in the procedure of blood pressure measurement, the electronic blood pressure monitors can keep function, but the results may not be accurate, it's suggested that you consult with your physician for accurate assessment.
13. Please do not use the cuff other than supplied by the manufacturer, otherwise it may bring biocompatible hazard and might result in measurement error.
14. ⚠The monitor might not meet its performance specifications or cause safety hazard if stored or used outside the specified temperature and humidity ranges in specifications.
15. ⚠Please do not share the cuff with other infective person to avoid cross-infection.
16. This blood pressure monitor is verified by auscultatory method. It is recommended that you check annex B of ANSI/AAMI SP-10:2002+A1:2003+A2:2006 for details of verification method if you need.
17. 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.

SETUP AND OPERATING PROCEDURES

1. BATTERY LOADING

a. Open battery cover at the back of the monitor.
b. Load four “AA” size batteries. Please pay attention to polarity.
c. Close the battery cover.

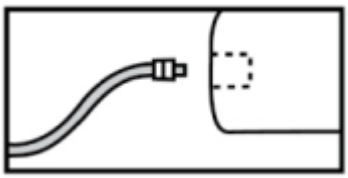
When LCD shows battery symbol , replace all batteries with new ones.
Rechargeable batteries are not suitable for this monitor.
Remove the batteries if the monitor will not be used for a month or more to avoid relevant damage of battery leakage.

⚠Avoid the battery fluid to get in your eyes. If it should get in your eyes, immediately rinse with plenty of clean water and contact a physician.

The monitor, the batteries and the cuff, must be disposed of according to local regulations at the end of their usage.

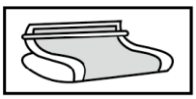
2. CONNECTING THE CUFF TO THE MONITOR

Insert the cuff tubing connector into the socket in the left side of the monitor. Make certain that the connector is completely inserted to avoid air leakage during blood pressure measurements.

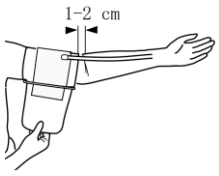


⚠ Avoid compression or restriction of the connection tubing during measurement，which may cause inflation error, or harmful injury due to continuous cuff pressure.

3. APPLYING THE CUFF



a. Pulling the cuff end through the medal loop (the cuff is packaged like this already), turn it outward (away from your body) and tighten it and close the Velcro fastener.
b. Place the cuff around a bare arm 1-2cm above the elbow joint.
c. While seated, place palm upside in front of you on a flat surface such as a desk or table. Position the air tube in the middle of your arm in line with your middle finger.
d. The cuff should fit comfortably, yet snugly around your arm. You should be able to insert one finger between your arm and the cuff.

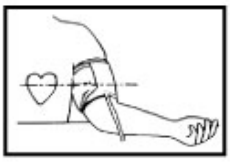


Note:

1. Please refer to the cuff circumference range in “SPECIFICATIONS” to make sure that the appropriate cuff is used.
2. Measuring on same arm each time.
3. Do not move your arm, body, or the monitor and do not move the rubber tube during measurement.
4. Stay quiet, calm for 5 minutes before blood pressure measurement.
5. Please keep the cuff clean. If the cuff becomes dirty, remove it from the monitor and clear it by hand in a mild detergent, then rinse it thoroughly in cold water. Never dry the cuff in clothes dryer or iron it. Clean the cuff after the usage of every 200 times is recommended.

4. BODY POSTURE DURING MEASUREMENT

Sitting Comfortably Measurement



a. Be seated with your feet flat on the floor, and don’t cross your legs.
b. Place palm upside in front of you on a flat surface such as a desk or table
c. The middle of the cuff should be at the level of the right atrium of the heart.

5. TAKING YOUR BLOOD PRESSURE READING

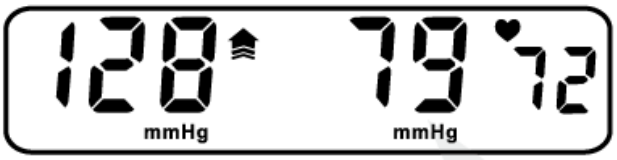
a. After applying the cuff and your body is in a comfortable position, press the “ON/OFF” button. A beep is heard and all display characters are shown for self-test.

b. After that, LCD will show “0” mmHg that indicate you can begin to inflate.

c. Please squeeze the bulb till the pressure is over your normal systolic pressure by 30mmHg, if you don’t know your normal systolic pressure, please squeeze the bulb till the pressure to 190mmHg.
d. Then the monitor slowly releases air from the cuff and carries out the measurement. Finally the blood pressure and pulse rate will be calculated and displayed on the LCD screen.

e. After reading the result, press the exhaust valve which is located in the front of the bulb to release the air.

f. When all the air is pushed out of the cuff, BPM will blink , then you can start measuring again.



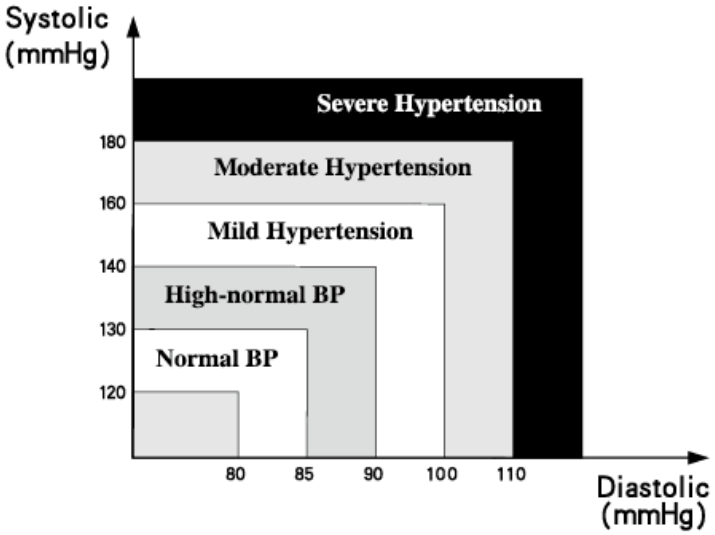
g. After measurement, the monitor will turn off automatically after 3 minutes of no operation. Alternatively, you can press the “ON/OFF” button to turn off the monitor manually.

h. During measurement, you can press the exhaust valve which is located in the front of the bulb to release the air.

Note: Please consult a health care professional for interpretation of pressure measurements.

6. ASSESSING HIGH BLOOD PRESSURE FOR ADULTS

The following guidelines for assessing high blood pressure (without regard to age or gender) have been established by the World Health Organization (WHO). Please note that other factors (e.g. diabetes, obesity, smoking, etc.) need to be taken into consideration. Consult with your physician for accurate assessment, and never change your treatment by yourself.



7. TROUBLESHOOTING (1)

PROBLEM	POSSIBLE CAUSE	SOLUTION
LCD Display shows battery symbol	Low Battery	Change all the batteries
LCD Display shows "EE"	Arm or blood pressure monitor was moved during testing	Re-test taking care to not move your arm or the blood pressure monitor
	The cuff does not inflate properly or pressure falls quickly during testing	Make certain the rubber tube is fully inserted into the blood pressure monitor
	Irregular heartbeat (arrhythmia)	It is inappropriate for people with serious arrhythmia to use this blood pressure monitor.

8. TROUBLESHOOTING (2)

PROBLEM	POSSIBLE CAUSE	SOLUTION
LCD Display shows "EE"	The cuff was not properly applied or the rubber tube was bent or pressed.	Review the cuff applying and testing sections of the instructions and re-test.
LCD Display shows abnormal result	The cuff position was not correct or it was not properly tightened	Apply the cuff correctly and try again
	Body posture was not correct during testing	Review the body posture and testing sections of the instructions and re-test.
	Speaking, arm or body movement, angry, excited or nervous during testing	Re-test when calm and without speaking or moving during the test
No response when you press button or load battery	Incorrect operation, or strong electromagnetic interference	Take out batteries for five minutes, and then reinstall all batteries.

MAINTENANCE

1. ⚠Do not drop this monitor or subject it to strong impact.
2. ⚠Avoid high temperature and solarization. Do not immerse the monitor in water as this will result in damage to the monitor.
3. If this monitor is stored near freezing, allow it to acclimate to room temperature before use.
4. ⚠Do not attempt to disassemble this monitor.
5. If you do not use the monitor for a long time, please remove the batteries.
6. It is recommended the performance should be checked every 2 years or after repair. Please contact the service center.
7. Clean the monitor with a dry, soft cloth or a soft cloth squeezed well after moistened with water, diluted disinfectant alcohol, or diluted detergent.
8. No component can be maintained by user in the monitor. The circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are designated repairably can be supplied.
9. The monitor can maintain the safety and performance characteristics for a minimum of 10,000 measurements or three years, and the cuff integrity is maintained after 1,000 open–close cycles of the closure.
10. It is recommended the cuff should be disinfected 2 times every week if needed (For example, in hospital or in clinique). Wipe the inner side (the side contacts skin) of the cuff by a soft cloth squeezed after moistened with Ethyl alcohol (75-90%), then dry the cuff by airing.

EXPLANATION OF SYMBOLS ON UNIT

 Symbol for" THE OPERATION GUIDE MUST BE READ"(The sign background colour: blue.The sign graphical symbol: white)

 Symbol for "WARNING"

 Symbol for "TYPE BF APPLIED PARTS" (The cuff is type BF applied part)

 Symbol for "ENVIRONMENT PROTECTION – Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local Authority or retailer for recycling advice".

 Symbol for "MANUFACTURER"

CE 0197 Symbol for "COMPILES WITH MDD93/42/EEC REQUIREMENTS"

 Symbol for "DATE OF MANUFACTURE"

Symbol for “EUROPEAN REPRESENTATION”

SN Symbol for “SERIAL NUMBER”

Symbol for “KEEP DRY”

WARRANTY INFORMATION

Only charge the cost of components and transport.

SERVICE CENTER

ANDON HEALTH CO., LTD.
No. 3 Jinping Street, Ya An Road, Nankai District, Tianjin 300190, China.
Tel: 86-22-60526081

Lotus Global Co., Ltd.
15 Alexandra Road, London UK, NW8 0DP
Tel: +0044-20-75868010 Fax: +0044-20-79006187

ELECTROMAGNETIC COMPATIBILITY INFORMATION

Table 1

For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacture’s declaration - electromagnetic emissions		
The KD-322 is intended for use in the electromagnetic environment specified below. The customer or the user of the KD-322 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The KD-322 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 KD-322 is suitable for use in all establishments other than domestic 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	

Table 2

For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer’s declaration - electromagnetic immunity

The KD-322 is intended for use in the electromagnetic environment specified below. The customer or the user of the KD-322 should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601test 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.

Table 3

For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration - electromagnetic immunity			
The KD-322 is intended for use in the electromagnetic environment specified below. The customer or the user of the KD-322 should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601test level**	**Compliance level**	**Electromagnetic environment - guidance**
Radiated RF	3 V/m 80 MHz to 2.5		Portable and mobile RF communications equipment should be used no closer to any part of the KD-322, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance：**

IEC 61000-4-3	GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz 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 KD-322 is used exceeds the applicable RF compliance level above, the KD-322 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the KD-322. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 4

For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the KD-322
The KD-322 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the KD-322 can help prevent

electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the KD-322 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 determined 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.