

Nature's Bond

Nature's Bond *Breast Pump Instructions For Use*

Model 603



www.devonmedicalproducts.com

1.866.446.0092

Indications for Use

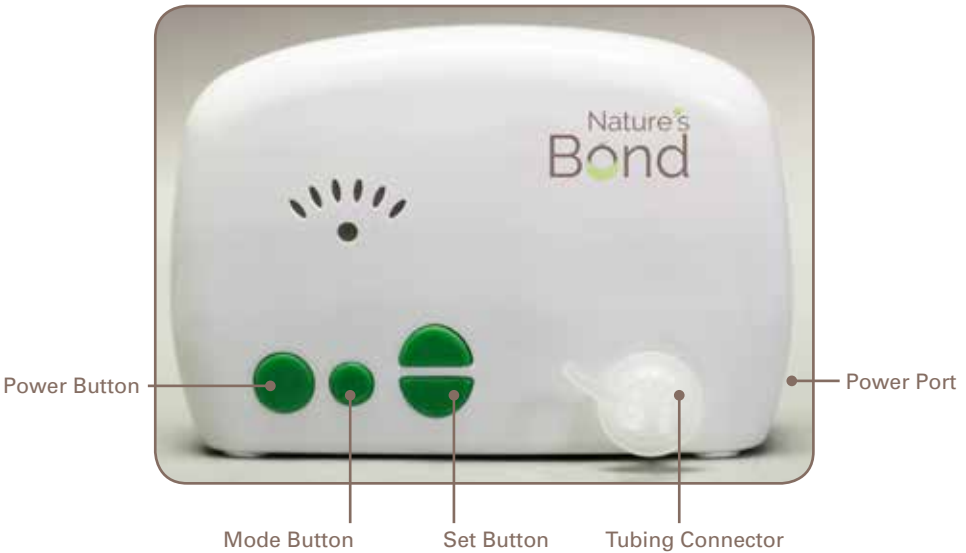
Nature's Bond breast pump is a single user device intended for lactating women to express and collect milk from their breasts to complement breast feeding.








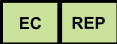








Description

Nature's Bond is a personal use electric breast pump that has two pumping modes and is capable of single and double pumping. **Nature's Bond** is to be used when the baby would normally be breast feeding, which is usually 2 - 3 times a day.

Accessories

- 2 80mm Breast Shields
- 2 74mm Breast Shields
- 4 Valves
- Carrying Bag
- 2 76mm Breast Shields
- 4 Caps
- Tubing
- 4 Bottles



	Warning/Caution: See instructions for use
	Dangerous Voltage Electrical shock hazard. Disconnect LINE CORD before servicing; refer servicing to qualified service personnel.
	Date Of Manufacture
	Type BF Applied Part
	Keep Dry
	Serial Number
	Manufacture Lot Number
	Authorized Representative in the European Community
	Class II Equipment
	Use By
	Manufacturer
	Catalog / Model Number
	ATTENTION: Consult ACCOMPANYING DOCUMENTS. This symbol is used to direct the user to refer to documentation for additional information regarding the system use or description.
	Protected against solid foreign objects of 12.5mm and greater and vertically falling water drops.
	Waste Electrical Goods Recycled
	Conforms to AAMI STD ES.60601-1, HA 60601-1-11, IEC STD 60601-1-6 Certified to CSA STD C22.2 No.60601-1, No. 60601-1-6, No. 60601-1-11



Specification

Dimensions For Main Unit:	185mm X 126mm X 57mm
Flow Rate; No Filter; Under Maximum Pressure:	≥7 L/min
Highest Negative Pressure At Stimulation Stage:	≤160mmHg
Highest Negative Pressure At Expression Stage:	≤210mmHg
Operating Cycle At Stimulation Stage:	Approx. 120 times/min
Operating Cycle At Expression Stage:	Approx. 60 times/min
AC Input Voltage Range:	100-240VAC
Operating Frequency:	47-63HZ
Input Current:	600mA, Max
Output Current:	2A, Max
Output Power:	18W
DC Output Voltage Range:	Adaptor: 12V+/-5% Battery: 1.5V x 6
Weight Of Main Unit:	Approx. 400g
Battery Specifications:	6 x 1.5 Vdc AA LR6 Battery
Environmental Conditions:	≤60dB(A)
Operating Atmospheric Pressure:	700hPa-1060hPa
Storage Conditions:	Temperature: -25°C-70°C Humidity: 0-93%
Operating Conditions:	Temperature: 5°C-40°C Humidity: 15%-93%



Warnings

Basic safety precautions should be taken when using electrical products, especially around children.

WARNING: If you are a mother who is infected with Hepatitis B, Hepatitis C or Human Immunodeficiency Virus (HIV), pumping breast milk will not reduce or remove the risk of transmitting the virus to your baby through your breast milk.

DANGER: To reduce risk of electrocution:

- The power adaptor is a part of the breast pump.
- Always unplug electrical products immediately after use.
- Do not use while bathing.
- Do not place or store product where it can be submerged in water.
- Do not reach for device once it has fallen in water. Immediately unplug from electrical outlet.
- Do not leave device unattended when plugged into an electrical outlet.
- Do not position the breast pump such that it is difficult to disconnect the adaptor plug from the main power supply.
- Remove batteries when Breast Pump is not likely to be used for some time because battery leakage could become a hazard.
- Close supervision is necessary when used near children or people with disabilities.
- Use product only for its intended use. Do not use attachments not recommended by the manufacturer.
- Keep cord away from heated surface.
- Never use while sleepy or drowsy.
- Never drop or insert objects into any opening or tubing.
- Do not use outdoors or operate where aerosol products are being used, or where oxygen is being administered.
- Always inspect power adaptor and batteries prior for use for damage and exposed wires. If damage is found, immediately discontinue use of power adaptor or batteries and contact Devon Medical Product's Customer Service.
- Do not use outdoors or operate during transportation.

WARNING: To avoid health risk and reduce the risk of injury:

- This product is intended for single user only and should not be shared between users.
- Do not drive while pumping.
- Never use while pregnant, as pumping can induce labor.
- Clean and sanitize all parts that come in contact with your breast and breast milk prior to first use.



Warnings (continued)

WARNING: To avoid health risk and reduce the risk of injury:

- Wash all parts that come in contact with your breast and breast milk after every use.
- Inspect all appropriate pump components before each use.
- Do NOT continue pumping for more than 2 consecutive pumping sessions if no results are achieved.
- Do not thaw frozen breast milk in a microwave or in a pan of boiling water.
- If tubing becomes moldy, discontinue use and replace tubing.
- If breast milk backup occurs, you must clean the tubing before your next pumping session.

WARNING: Can lead to minor injury:

- Do NOT wrap cord around adaptor body.
- Use only the power adaptor that comes with the Nature's Bond breast pump.
- Pump only with the breast pump in an upright position.
- Do NOT shorten tubing.
- Make sure the voltage of the power adaptor is compatible with the power source.
- Plug the power adaptor into the breast pump first, then into the power source.
- Do NOT use antibacterial or abrasive cleaners/detergents when cleaning breast pump or breast pump parts.
- Never put breast pump motor in water or sterilizer, as permanent damage can be caused to the device.
- Do not attempt to remove the breast shield from your breast while pumping. Turn the breast pump off and break the seal between your breast and breast shield with your finger, then remove the breast shield from your breast.
- If pumping is uncomfortable or causing pain, turn the unit off, break the seal between the breast and the breast shield with your finger and remove breast shield from your breast.
- If experiencing pain in the breast or nipple, discontinue pumping by shutting off the device or breaking the suction with your finger, even if you think the pump is not the source of the pain.

IMPORTANT:

- Plastic bottles and component parts become brittle when frozen and may break when dropped
- Bottles and component parts may become damaged if mishandled (dropped, over tightened, or knocked over)
- Take appropriate care in handling bottles and components
- Do not use the breast milk if bottles or components become damaged



Cleaning

Before using for the first time:

- Clean and sanitize the following parts before using your pump for the first time. Use drinking quality tap or bottled water for cleaning. Take apart and wash all parts that come in contact with the breast and breast milk immediately after use to avoid dry up of milk residues and to prevent growth of bacteria. Before each use, visually inspect the individual components for cracks, chips, tears, discoloration or deterioration. In the event that damage to the device is observed, please discontinue use until the parts have been replaced. Follow the cleaning and sanitizing instructions on the below list:
- Breast shield
- Breast shield connector
- Valve
- Breast milk bottles and lids

After each use:

Clean all parts that come in contact with your breast and breast milk.

1. Separate breast shields from breast shield connectors.
2. Twist and pull the valves off the breast shield connectors.
3. Rinse in cool water all separated parts that come in contact with breast and breast milk in order to remove breast milk residue.
4. Soak all separated parts in warm soapy water for 5 minutes.
5. Clean with a clean dish cloth or soft brush.
6. Rinse all separated parts with clear water.
7. Allow all parts to air dry in a clean area.
8. Store dry parts when not in use.

When using dishwasher:

1. Wash all separated parts on top rack of dishwasher.
2. Allow all breast pump parts to air dry in a clean area.
3. Store dry parts when not in use.

Sanitize daily:

1. Wash hands thoroughly.
2. Separate all parts that come in contact with your breast and breast milk.
3. Fill a pot with enough water to cover all parts.
4. Bring water to a boil.
5. Place parts in boiling water for 10 minutes.
6. Allow water to cool and gently remove parts from water with tongs.
7. Place parts on a clean surface.
8. Allow all parts to air dry.
9. Store dry parts when not in use. Do not store wet or damp parts.

Device and Tubing Cleaning:

1. Turn off breast pump.
2. Unplug breast pump from power source.
3. Remove tubing from the unit.
4. Remove tubing from the breast shield.
5. Rinse tubing in cool water.
6. Wash tubing in warm soapy water.
7. Rinse tubing with clear water.
8. Hang to air dry.
9. Wipe down the unit with a damp soft cloth.
10. To clean the bag, use a damp cloth to wipe the bag down after each use.



Assembly of Pump Kit

1. Wash hands before touching breast pump, kit and breasts, and avoid touching the inside of containers or lids.
2. Place the breast pump on a clean dry surface.
3. Securely attach breast shield to breast shield connector.
4. Push valves onto bottom of breast shield connectors.
5. Screw bottles onto breast shield connectors.
6. Insert tubing into the back of the breast shield connectors.
7. For double pumping, insert the free ends of the tubing onto both ports of the tubing connector on the device.
8. For Single Pumping, insert free end of tubing onto one port on the tubing connector on the device. Place the port cap over the unused port.
9. Correctly install 6 AA batteries into the battery enclosure located on the back of the device.
10. To use AC power, plug the power adaptor into the power jack on the device. Plug the power adaptor into a safe, proper electrical outlet.

Correctly fitting breast shields:

1. Properly fitting breast shields will ensure comfort and efficient milk expression. While some discomfort may be felt when first using a breast pump, it should not cause pain. Please contact a healthcare professional if you are unsure about breast shield sizing.
2. The nipple should be centered in the tunnel of the shield.
3. The nipple should move freely without rubbing when the pump is turned on.
4. Minimal or no part of the areola should be pulled into the tunnel when the pump is on.
5. You should see a gentle, rhythmic motion with the breast during each cycle.
6. After pumping, your breast should feel much less full with no areas of hardness.



Device Operation

- Wash hands before touching breast pump, kit and breasts. Avoid touching the inside of containers or lids.
 - Always inspect breast shields, connectors, valves, and tubing prior to use for cleanliness.
 - If you experience pain or other symptoms while pumping, contact a healthcare professional.
 - Do not try to express with a vacuum that is too high and uncomfortable.
 - Make sure tubing is not kinked or pinched while pumping.
 - Contact your healthcare professional if you express on minimal milk or no milk or if expression is painful.
1. Center the assembled breast shields over your nipples.
 2. To begin pumping, press the "Power" button. When the device is powered on, a green LED will illuminate.
 3. The Nature's Bond has two pumping modes, Stimulation and Expression. A green LED will illuminate during Stimulation Mode, a blue LED will illuminate during Expression Mode.
 4. The two phases can be switched by pressing the "Mode" button. The pump will start in Stimulation Mode and beep after 2 minutes when it is time to switch to Expression Mode.
 5. Vacuum strength can be adjusted by pressing the "Up" and "Down" buttons. There are a total of 6 vacuum settings. Adjust accordingly to your comfort.
 6. The average duration of one pumping session is 20 minutes or when the bottle is fully filled, whichever comes first. Use a timer to keep track of the length of the session.

Device Operation (continued)

When the pumping session is over, unplug the tubing from the breast shields before setting down the bottles.

7. Close the bottle with a lid. Store appropriately.
8. Allow the pump to continue to run while you store the breast milk. This will allow any condensation that has formed to dry in the tubing.
9. Turn off breast pump.
10. Unplug from the power source.
11. Prior to storing your pump, remove the tubing.
12. Disassemble and clean per the Cleaning Instructions.
13. A solid yellow LED illuminating during treatment indicates “Low Battery.” After 2 minutes, the solid yellow LED will change to a flashing yellow LED. The system will shut down when the yellow LED flashes. In the event of a low battery, the device can be powered by plugging the AC adaptor into a proper, safe electrical outlet.

Storing Breast Milk

Breast Milk Storage Guidelines				
Room Temp	Cooler with Ice Pack	Refrigerator	Freezer	Thawed Breast Milk
4–6 hours at 66–78 °F (19–26 °C)	24 hours at 59 °F (15 °C)	3–8 days at 39 °F or lower (4 °C)	6–12 months 0 – 4 °F (-18 – -20 °C)	use within 24 hrs

References: www.BreastmilkGuidelines.com

Note: When storing breast milk in the refrigerator or freezer compartment, make sure to store away from the door in order to avoid fluctuations in temperature.

Preparing Breast Milk

- Thaw breast milk overnight in the refrigerator. Thawed breast milk is safe in the refrigerator for 24 hours. Do not refreeze thawed breast milk.
- Quickly thaw breast milk by holding the bottle under warm running water.
- Place the sealed bottle in a bowl of warm water for 20 minutes to bring it to body temperature.
- If you are adding expressed breast milk to a container of already frozen breast milk, make sure to add a lesser amount than the already frozen amount.

Feeding Breast Milk

It is recommended that breastfeeding is well established prior to bottle feeding your baby.

- Always inspect the bottle, nipple and other components immediately before and after each use. If nipple appears cracked or torn, discontinue use immediately.
- To prevent possible choking hazard, test strength of nipple by pulling on bulb portion of the nipple.
- Do not attempt to enlarge the nipple hole.
- Infants must not be bottle fed without adult supervision.
- Nipple should not be used as a pacifier.

Troubleshooting

Low or no suction:

- Check valve and tubing for chips or cracks. If flawed, replace valve or tubing respectively.
- Inspect breast shield and breast shield connector to make sure there are no cracks and they are securely attached to each other.
- Check all connections to ensure that they are tight and secure.

Will not power on:

- Check to make sure the outlet is proper and functioning.

Disposal

Medical equipment and devices should be disposed of in proper containers that meet Environmental Protection Agency standards. Check with local State Laws & Regulations to see what is required in your state or contact your local representatives.

Maintenance and Replacement Parts:

The **Nature's Bond** device contains no user serviceable parts inside: Opening or tampering with this device will void the warranty. In the event the **Nature's Bond** device requires repairs, it should be returned to the medical equipment company or to Devon Medical Products directly. Expected lifetime of the device is two years under normal use.

Warranty Information

Devon Medical Products warrants its **Nature's Bond Breast Pump**, excluding accessories ("Breast Pump") to be free from defects in workmanship and materials for a period of one (1) year from the date Device is delivered to the original purchaser ("Breast Pump Warranty Period"). In addition, Devon Medical Products warrants its Breast Pump Accessories, (defined as bottles, caps, tubing sets, carrying case and breast shields) ("Accessories"), to be free from defects in workmanship and materials for a period of ninety (90) days from the date the Accessories are delivered to the original purchaser ("Accessories Warranty Period"). This Limited Warranty is extended only to the original purchaser (defined as the original purchaser from the distributor) and is non-transferable. Devon Medical Products' sole obligation under this Limited Warranty shall be, at its sole discretion, to repair or replace a Device which is defective in either workmanship or material. This is the sole remedy of the Purchaser. In addition, this Limited Warranty does not cover any Device which may have been damaged in transit or has been subject to misuse, neglect, or accident; or has been used in violation of Devon Medical Products' instructions, including, without limitation, the instructions contained in the Operation Manual.

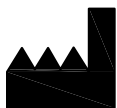
Warranty Information (continued)

THERE ARE NO WARRANTIES THAN THOSE EXPRESSLY STATED HEREIN.

TO THE EXTENT PERMITTED BY LAW, DEVON MEDICAL PRODUCTS DOES NOT MAKE ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE AS TO ANY PRODUCT OR DEVICE, WHETHER OR NOT THAT PRODUCT OR DEVICE IS COVERED BY ANY EXPRESS WARRANTY CONTAINED HEREIN.

IN NO EVENT SHALL DEVON MEDICAL PRODUCTS BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR INDIRECT DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS, USE OR TIME INCURRED BY PURCHASER OR END USER). IN ADDITION, DEVON MEDICAL PRODUCTS SHALL NOT BE LIABLE FOR ANY EXEMPLARY OR PUNITIVE DAMAGES.

Manufactured For



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Appendix 1

Important information regarding Electro Magnetic Compatibility (EMC)

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation. Medical devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the EN 60601-1-2: 2001+A1:2006 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices

Appendix 2

A. Instructions for use

1. **MODEL 603** 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 603**.

B. Technical description

1. **Warning:** 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 603** as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the **MODEL 603**.
2. **Warning:** the **MODEL 603** should not be used adjacent to or stacked with other equipment

3. Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The **MODEL 603** is intended for use in the electromagnetic environment specified below. The customer or the user of the **MODEL 603** should assure that it is used in such an environment

Emissions	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The MODEL 603 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 603 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 MODEL 603 is intended for use in the electromagnetic environment specified below. The customer or the user of the MODEL 603 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 dc lines	±2 kV for power supply lines and dc 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 ± 2 kV line(s) to earth	±1 kV line(s) and neutral ± 2 kV line(s) to earth	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 UT) for 0,5 cycle 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	<5 % UT (>95 % dip in UT) for 0,5 cycle 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	Mains power quality should be that of a typical commercial or hospital environment. If a dips or an interruption of mains power occurs, the current of the MODEL 603 may be dropped off from normal level, it may be necessary to use uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_r is the a.c. mains voltage prior to application if the test level.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The **MODEL 603** is intended for use in the electromagnetic environment specified below. The customer or the user of the **MODEL 603** 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 Hz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the MODEL 603, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance</p> <p>Recommended separation distance:</p> <p>$d = 1.2\sqrt{P}$</p> <p>$d = 1.2\sqrt{P}$ 80MHz to 800MHz</p> <p>$d = 2.3\sqrt{P}$ 800MHz to 2.5GHz</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 is 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). Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1: At 80 MHz, the higher the 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 603** is used exceeds the applicable RF compliance level above, the **MODEL 603** 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 603**.

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 603**

The **MODEL 603** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **MODEL 603** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **MODEL 603** as recommended below, according to the maximum output power of the communications equipment.

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

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

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

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

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