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VRN-I01/VRN-I02/VRN-I03/VRN-I06

Built-in Ultrasonic scaler

OPERATION MANUAL

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Rev.03/2020-C3

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1. SYMBOLS



Caution!
Read the operation
instruction



Class II equipment



Applied part, type B



Disposal



Manufacturer's logo



Manufacturer



Up



Serial number



Autoclavable



Storage temp



Keep dry



Storage Humidity



Fragile



Production date



Period of use



Refer to instruction manual/
booklet

2.DIRECTIONS AND INSTALLATION

The names of models VRN-I01,VRN-I02,VRN-I03 ,VRN-I06 described in this manual are referred to as "I01,I02 ,I03, I06 ".

2.1 INTRODUCTION

I01,I02,I03,I06 built-in ultrasonic scaler produced by URIT Medical Electronic Co.,Ltd., is mainly used for removing the calcul us and stains on teeth surface along with dental units and endo irrigation.

I01 is attached with a sealed handpiece, I02 is attached with a detachable handpiece,I03 is attached with a detachable LED handpiece.I06 is attached with a detachable LED Metal handle

2.2 COMPONENTS

2.2.1 The Packing List shows exactly what is included in your scaler.

2.2.2 Mainly Components

The device is composed of control circuit, a handpiece and scaling tips.

2.2.3 Applicable Scope

Installed in the dental unit, used for removing the calculus and stains on teeth surface.

2.3 TECHNICAL SPECIFICATIONS

- Power Supply: AC 24V(1 ± 10%),50/60Hz
- Input Power: ≤40VA
- Fuse Protector: T3AL 250V
- Tip Principal Oscillation Offset: 1 μ m (min),-50% deviation
100 μ m (max),+50% deviation
- Half-excursion Force:0.1N (min),-50% deviation
2N(max),+ 50% deviation
- Tip Vibration Frequency : 26kHz-33kHz
- Ultrasonic Output Power : 3W-20W
- Weight of Main Unit : 0.3kg
- Weight of Adapter : 0.2kg (optional)
- operating Mode : Continuous operating
- Electric shock Protection Type: Class equipment
- Electric Shock Protection Degree: Type B Applied Part
- Liquids Protection Degree: IPX 0
- Safety Degree of Usage in the presence of a Flammable Anaesthetic Mixture with air or with Oxygen or Nitrous Oxide: not suitable for being used in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide
- Working Condition: Environment Temp 5°C~40°C , Relative Humidity ≤80%

2.4 CONNECTION AND INSTALLATION

2.4.1 Connection and Installation

(The connection instruction is shown by a picture in the attachment.)

- Port 1 and Port 2 connect with electromagnetic valve;
- Port 3 and Port 4 connect with AC 24V from the inside of dental unit;
- Port 5 and Port 6 connect with gas control switch;
- Port 7 to Port 14 are free;
- Port 15 to Port 17 connect with potentiometer;
- Port 11 # is the control end of the root canal function.The main shaft of the power potentiometer is pushed in for the cleaning function and pulled out for the root canal rinse function (VRN-I02,VRN-I03,VRN-I06);

- Port 18 and Port 19 connect with the handpiece. (VRN-I01)
- Port 18 and Port 21 connect with the handpiece.(VRN-I02,VRN-I03,VRN-I06)

2.4.2 Notice

- The gas control switch, pneumatic water value and foot switch are equipped by the dental unit manufacturer or the user. The holes for installing the potentiometer and cable are drilled by the dental unit manufacturer, device supplier or the user.
- Keep enough space for dispersing heat of ultrasonic generator.
- Before turning on the device, turn the potentiometer knob to the minimum and the water control knob the maximum.
- The frequency of ultrasonic scaler is extremely high. Under normal working state of scaling tips, a light touch and a certain to-an-fro motion will eliminate the tartar without obvious heat.Overexertion and longtime lingering are forbidden.

3.FUNCTION AND OPERATION

3.1 WORKING PRINCIPLES

3.1.1 Instruction

Built-in Ultrasonic Scaler mainly consists of control circuit, hand piece and scaling tips. Its power and water are controlled by the foot switch and the handpiece holder of dental unit.

3.1.2 Working Principles

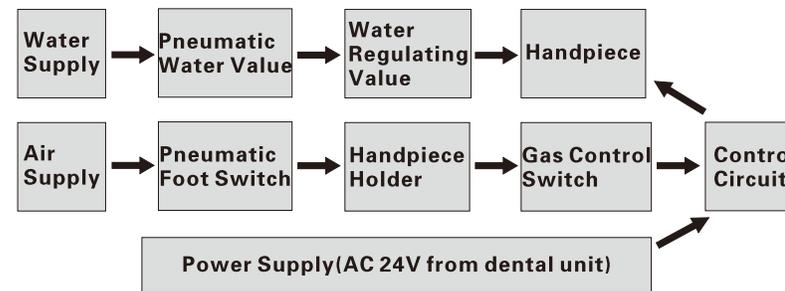


Figure 1

Pull the handpiece out of the Handpiece Holder, step on the Foot Switch, then the air is on. The air gets through the Gas Control Switch and turns on the scaler, the Water Regulating Value is opened at the same time.

3.2 PARTS INSTRUCTIONS

3.2.1 Usage Instruction of Wrench

When installing a scaling tip, insert the scaling tip into the hole of the wrench, hold the handpiece and turn the wrench clockwise till the tip stop. The scaling tips must be tightened up to get the best using effects.

When uninstalling a scaling tip, insert the scaling tip, hold the handpiece and turn the wrench anti-clockwise.



Figure 2

3.2.2 Usage Instruction of Main Parts of Sealed Handpiece



Figure 3

- Cap: Removable, can be screwed out to make the pole cleaned by disinfectant.
- Ruble Ring: Can be removed regularly and cleaned by disinfectant.
- Handpiece: Can not be autoclaved, can only be cleaned by disinfectant.
- Cable: connects the handpiece and water supply and power supply.

3.2.2 Usage Instruction of Main Parts of Detachable Handpiece

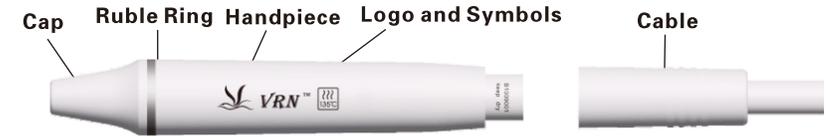
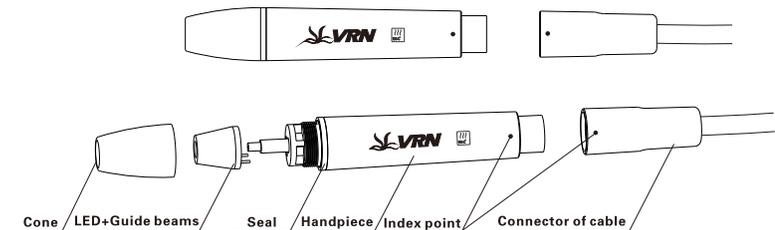


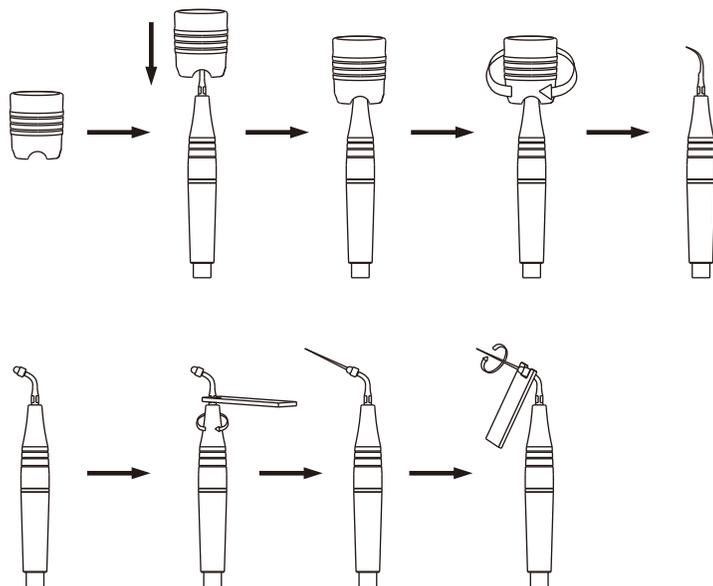
Figure 4

- Cap: Removable, can be screwed out to make the pole cleaned by disinfectant.
- Ruble Ring: Can be removed regularly and cleaned by disinfectant.
- Handpiece: Can be autoclaved.
- Logo and Symbols: Manufacturer's logo. Can be sterilized by high temperature (135°C) and high pressure (0.22 MPa).
- Cable: connects the handpiece and water supply and power supply.

3.2.3 Detachable handpiece connection(LED Handpiece)



3.2.4 Installation of tip and endochuck with wrench



4. MAINTENANCE AND DISINFECTION

4.1 STERILIZATION OF SCALING TIPS

Scaling tips can be cleaned by the ultrasound cleaner and sterilized by alcohol cotton or disinfected cloth, and also can be sterilized by high temperature and high pressure.

4.2 STERILIZATION OF WRENCH

The wrench can be cleaned by the ultrasound cleaner and sterilized by neutral non-corrosive disinfectant, and also can be sterilized by high temperature and high pressure.

4.3 STERILIZATION OF HANDPIECE

4.3.1 Sterilization of Sealed Handpiece (I01)

- The sealed handpiece can be sterilized by wiping with some disinfectant such as iodine, alcohol and glutaraldehyde
- During sterilizing the sealed handpiece, please notice whether the surface of the handpiece is damaged. Do not smear any protective oil on the surface of the handpiece.
- Do not soak the handpiece in any disinfectant.

4.3.2 Sterilization of Detachable Handpiece (I02 and I03,I06)

- Autoclaved by the high temperature and pressure:
 - 121°C, 1 bar (0.1 MPa), 20 minutes;
 - 135°C, 2.2 bar (0.22 MPa), 15 minutes.
- Pull out the handpiece and uninstall the scaling tips after each use.
- Pack the handpiece in sterile gauze or sterile bag before sterilization.
- Reuse the handpiece after it cool down naturally to avoid burning hands.
- Notice:
 - a) Before sterilization, empty the cleaning liquid in the handpiece with compressed air.
 - b) Be sure that the scaling tip has been uninstalled from the handpiece. It cannot be sterilized along with other spare parts.
 - c) Notice whether the surface of the handpiece is damaged during the treatment and sterilization. Do not smear any protective oil on the surface of the handpiece.
 - d) There are two waterproof O-rings at the end of handpiece. Please lubricate them with dental lube frequently, as sterilization and repeated pulling and inserting will reduce their life-span. Change a new one once it is damaged or worn excessively.
 - e) Sterilizable parts can be sterilized at least 250 times.
 - f) The following sterilizing methods are prohibited:
 - Put the handpiece into any liquid for boiling;
 - Soak the handpiece in any disinfectant.
 - Put the handpiece into oven or microwave oven for baking.

4.4 TROUBLE SHOOTING

FAULT	POSSIBLE CAUSES	SOLUTION
The scaling tip doesn't vibrate when stepping on the foot switch.	The plug is loose or wrong contact.	Connect as the shown picture.
	Handpiece connect with the cable irrelevantly.(I02)	Connect it again.
	Scaling tip is loose.	Fasten it by the wrench.
	The handpiece socket is too wet.(I02)	Dry it with hot wind.
	The handpiece is faulty	Send it back to the manufacturer or local agent dealer for repair.
The scaling tip vibrates, but no water flowing out.	Water supply of dental unit is off.	Examine the water supply of dental unit.
	The liquid pipe in the cable is blocked	Clean the liquid pipe with the multi-function syringe.
	The liquid way in the handpiece is blocked.	Clean the handpiece with the multi-function syringe.
The handpiece overheat.	Water shortage.	Turn up the water.
The water shortage.	The liquid pipe of dental unit is blocked.	Clean the water pipe.
	The liquid pipe in the cable is blocked.	Clean the liquid pipe with the multi-function syringe.
	The liquid way in the handpiece is blocked.	Clean the handpiece with the multi-function syringe.
	Insufficient water pressure	Enhance the water pressure.
The vibration becomes weak.	The tip loose.	Fasten the tip.
	The tip is faulty or worn down.	Change a new tip.
The potentiometer is out of order.	The potentiometer is faulty.	Change a new potentiometer.
Water leaks from the coupling between the handpiece and cable.	The water proof O-ring is damaged.	Change two new water proof O-ring.

5. ACCESSORIES

5.1 ACCESSORIES OF I01

ITEMS	NAME	SPECIFICATIONS
1	Control Circuit(I01)	64mm × 75mm × 35mm
2	Handpiece and cable	/
3	Tips	5 pcs packed in 1 package
4	Potentiometer and flat cable	2KΩ
5	Potentiometer knob	/
6	Wrench	/
7	2/3 ways connector	/
8	Retainer ring	17mm × 15.4mm × 2mm
9	Pu Pipe(option)	/
10	PG head	/
11	Air control switch(option)	/

5.2 ACCESSORIES OF I02

ITEMS	NAME	SPECIFICATIONS
1	Control Circuit(I02)	64mm × 75mm × 35mm
2	Handpiece	/
3	Tips	5 pcs packed in 1 package
4	Detachable Cable	/
5	Potentiometer and flat cable	2KΩ
6	Potentiometer knob	/
7	Torque Wrench(option)	/
	Wrench(option)	/
8	2/3 ways connector	/
9	Retainer ring	17mm × 15.4mm × 2mm
10	Water proof O-rings	3.2mm × 1mm

ITEMS	NAME	SPECIFICATIONS
11	Endo Attachments(option)	/
12	Endo Wrench(option)	/
13	Pu Pipe(option)	/
14	PG Head	/
15	Air control switch(option)	/

5.3 ACCESSORIES OF I03

ITEMS	NAME	SPECIFICATIONS
1	Control Circuit(I02)	64mm × 75mm × 35mm
2	Handpiece	/
3	Tips	5 pcs packed in 1 package
4	LED detachable cable(I03)	/
5	Potentiometer and flat cable	2K Ω
6	Potentiometer knob	/
7	Torque Wrench	/
8	2/3 ways connector	/
9	Retainer ring	17mm × 15.4mm × 2mm
10	Water proof O-rings	3.2mm × 1mm
11	Endo Attachments	/
12	Endo Wrench	/
13	Pu Pipe(option)	/
14	PG Head	/
15	Air control switch(option)	/

NOTE: The exactly specifications of accessories are not been shown detailedly in this operation instrument. See the attached page and packing list for more information.

6. NOTES

6.1 NOTES OF USAGE

- Keep the device clean before and after operation.
- The handpiece, scaling tips and wrench must be sterilized before each use.
- Do not install or uninstall a scaling tip when stepping on the foot switch.
- The scaling tip must be fastened and there must be spray or drip coming out from the tip when operating.
- Change a new tip when it is damaged or worn down. Do not twist or rub the tip.
- Do not use impure water source and be sure not use normal brine instead of pure water source
- Be sure the tail of handpiece and the socket are dry before installing the handpiece (I02 and I03,I06).
- Do not pull the cable forcibly while operating in order to avoid the handpiece fall off from the socket (I02 and I03,I06).
- The threads of scaling tips which are produced by some other manufacturer might be coarse, rusty, collapsed or with different specification. They do not match the thread of our handpiece and will damage its thread beyond repair if force screwing down. Please always use the recommending scaling tips produced by URIT Medical Electronic Co.,Ltd .
- In order to avoid affecting the function of scaler, it is not allowed to dismantle the scaler. If you have any special requirement, please contact with us.

6.2 CONTRAINDICATION

- Hemophiliacs disable.
- Patients or dentists with cardiac pacemaker disable.
- Heart disease patients, pregnant women and infants should be cautious.

6.3 STORAGE AND MAINTENANCE

- This device should be handle with care, kept away from vibration and kept or installed in a cool, dry and ventilated place .
- Do not store the device along with any poisonous, mordant, flammable and explosive article .
- Storage humidity: ≤90%, storage temperature: -20℃~55℃.

- Please turn off the power if not use it. If not use for a long time, please turn the power and water on for 5 minutes once per month.

6.4 TRANSPORTATION

- Shock and vibration should be avoid in transport. Handle it with care and avoid to place upside down.
- Do not pack it with any hazardous articles in transport.
- Avoid the sun, rain or snow in transport.

7. AFTER SERVICE

- URIT Medical Electronic Co.,Ltd.is responsible for the saftry of the products only in the following two kinds of situations:
The maintaining, repairing and alterations were treated by our company or approved dealers.
The replaced spare parts are original from URIT Medical Electronic Co.,Ltd. and following the instructions to operate.
- Irreparable damage to the equipment caused by non–professional person dose not belong to free warranty.

8. DISPOSAL

This equipment dose not contain any poisonous and harmful substance. It can be disposed and destroyed according to the provisions of local authorities.

9. WARNING

The device is not suitable for use in the presence of flammable anesthetic mixtures with air orwith oxygen or nitrous oxide.

The device requires no calibration.

The device is not repairable and contains no user serviceable parts.

No modification of this equipment is allowed.(3rd Edition)

The user must check that the equipment functions safely and see that it is in proper working condition before being used.

The manufacturer does not require such preventive inspections by other persons.

10. EMC Declaration

Note :

1)URIT Medical Electronic Co.,Ltd.no express consent, any unauthorized changes or modifications to the device may cause electromagnetic compatibility of the device or other devices.

2)I01/I02/I03/I06 ultrasonic scaler de sign and test procedures related to electromagnetic compatibility.

10.1 Installation Cable Requirements

Cable Name	Cable Type	Cable length
Handle line	Unshielded parallel lines	2 Meter

10.2 The EMC key components

The product is a key component of EMC scaler chip motherboard, power adapter, or replace the use of non–attachment supporting the design, Cables, transducers,etc. will lead to EMC emission and immunity performance degradation. Do not replace machine parts.

10.3 Guidance and manufacturer's declaration – electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The [I01/I02/I03/I06] is intended for use in the electromagnetic environment specified below. The customer or the user of the [I01/I02/I03/I06] should assure that it is used in such an environment		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The [I01/I02/I03/I06] 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 [I01/I02/I03/I06] is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the [I01/I02/I03/I06] or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

10.3 Guidance and manufacturer's declaration – electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions			
The [I01/I02/I03/I06] is intended for use in the electromagnetic environment specified below. The customer or the user of the [I01/I02/I03/I06] 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	± 6KV contact ± 8KV air	± 6KV contact ± 8KV 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	± 2KV for power supply lines ± 1KV for input/output lines	± 2KV for power supply lines ± 1KV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	± 1KV line(s) to line(s) ± 2KV line(s) to earth	± 1KV line(s) to line(s) ± 2KV 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	<p>< 5% UT (> 95% dip in UT)for 0.5 cycle</p> <p>40% UT (60% dip in UT)for 5 cycle</p> <p>70% UT (30% dip in UT)for 25 cycle</p> <p>< 5% UT (> 95% dip in UT)for 5s</p>	<p>< 5% UT (> 95% dip in UT) for 0.5 cycle</p> <p>40% UT (60% dip in UT) for 5 cycle</p> <p>70% UT (30% dip in UT) for 25 cycle</p> <p>< 5% UT (> 95% dip in UT) for 5s</p>	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [I01/I02/I03/I06] requires continued operation during power mains interruptions, it is recommended the [I01/I02/I03/I06] be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/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. mains voltage prior to application of the test level.			

10.3 Guidance and manufacturer's declaration – electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions			
The [I01/I02/I03/I06] is intended for use in the electromagnetic environment specified below. The customer or the user of the [I01/I02/I03/I06] 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	3Vrms 150KHz~ 80MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of the [I01/I02/I03/I06], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3V/m 80MHz~ 2.5GHz	3V/m	<p>Recommended separation distance</p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.3\sqrt{P} \text{ 800 MHz to 2.5 GHz}$ <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, 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> 

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 [I01/I02/I03/I06] is used exceeds the applicable RF compliance level above, the [I01/I02/I03/I06] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [I01/I02/I03/I06].
 b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

10.6 Recommended separation distances between portable and mobile RF communications equipment and the [I01/I02/I03/I06]

Recommended separation distances between portable and mobile RF communications equipment and the [I01/I02/I03/I06]

The [I01/I02/I03/I06] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [I01/I02/I03/I06] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [I01/I02/I03/I06] 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		
	150KHz~80MHz	80MHz~800MHz	800MHz~2.5GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
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.

