

Ki-20 IMPLANT

manual



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You have required to read this manual carefully before operating this machine.
All products are medical devices.

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1. Overview

1-1. Indication

- It can be used at a wide range of dental procedures, including; canal treatment of endodontics and implant surgery. Such as drilling in to the tooth canal, general dentistry, and also removing carious material from the dentin. It's only for used by dental specialist.

1-2. Caution

- The federal law restricts this device to sale by or on the order of a dentist

1-3. Classification

- Protection against for electric shock

: Class I equipment

- Degree of protection against electric shock

: Type B applied part 

- Protection against harmful ingress of water.

① Equipment : Ordinary equipment

② Foot control (Ki-F20) / IPX8

- Equipment not suitable for use in the presence of a flammable anesthetic mixture with air, or oxygen or nitrous oxide.

- Mode of operation : Continuous operation



Caution

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

2. Precaution

Warning

- The KI-20 is designed for use by dental professionals only.
- Always consider the safety of the patient during operation.
- Read this user's manual thoroughly and understand completely of the functions of individual components before use.
- Make sure the product is in good working condition prior to use.
- A test run must be performed before operation to check that the product is working properly.
- If there is any abnormal condition including excessive vibration, noise, and heat while using the product, turn off the power immediately and contact your local dealer for repair.
- To prevent personal injury or product damage, it is necessary to check if the motor handpiece has been turned off before changing the file.
- Violent shocks, such as dropping the product, may cause product damage.
- Do not disassemble the motor handpiece.
- No modification of this equipment is allowed.
- Before cleaning the product, be sure to turn off the power, then wipe the Control Unit and Foot Control with a damp cloth, then with an alcohol-absorbed cloth.
- Do not use any organic solvent to clean the motor handpiece and control box.
- The electric motor generates significantly more power than traditional air turbines and air motors.
- Poorly maintained, worn, damaged, or misused handpieces may generate frictional heat capable of causing serious burn injuries to the patient.
- Handpieces must be properly maintained according to the specified maintenance schedule and inspected for signs of wear prior to each use.
- Transport and storage conditions.

	Temperature	Humidity	Atmospheric pressure
Use	0~35°C	10~75RH	500~1,060hpa
Store(transportation)	-20°C~40°C	0~90RH	700~1,060hpa

Caution

- For the follow up service and spare parts, please contact your local dealer.
- Ensure that the product is not exposed to dust, sulfur or salt.
- Use the recommended files only.

3. Components

3-1. Component Parts



①	Power cord	②	Control unit (Ki-20)	③	Irrigation tube (single use)
④	Y - tube (single use)	⑤	Tube holder	⑥	Coolant hanger
⑦	Foot control (Ki-F20)	⑧	Handpiece stand	⑨	E-type motor(Ki-MTO) & Motor cord
⑩	Foot hanger	⑪	Motor plug		

3-2. Component Assembly



4. Part Introduction

4-1. Control Unit



- ① Display panel
- ② LCD – Information
- ③ Rotation holder - Irrigation tube
- ④ Push button - Rotation holder open/close
- ⑤ Gear ratio button
- ⑥ Coolant button
- ⑦ Forward / Reverse button
- ⑧ Optic button
- ⑨ Memory button
- ⑩ Speed ⏴ ⏵ button
- ⑪ Torque ⏴ ⏵ button
- ⑫ Program ⏴ ⏵ button
- ⑬ Motor connector

4-2. Back Side of Control Unit



- ① Foot control connector
- ② Label - Specification
- ③ Power cord connector
- ④ Fuse box
- ⑤ Power switch (on/off)

4-3. LCD



- ① Program : Total 9 programs (can be saved in the memory)
- Program memory : Optic(on/off), Rpm, Gear ratio, Coolant, F/R, Torque.
- ② Optic (on/off)
- ③ Handpiece rpm range : 20~80,000rpm
The speed of the handpiece changes depends on the gear ratio (increase / decrease)
- ④ Gear Ratio : 1:1, 1:2, 20:1, 32:1 Total 4 gear ratio
- ⑤ Coolant : Total 4 steps (off -> 1step -> 2step -> 3step)

50ml/min	75ml/min	90ml/min

- ⑥ Forward / Reverse : Forward (F), Reverse (R)

- ⑦ Torque

20 : 1	32 : 1	1 : 1 / 1 : 2
5~70 Ncm	5~90 Ncm	No torque setting

- ⑧ Error code : Error code appears when following error occurs.

Err 01	Micro motor is not connected.
Err 02	Foot control is not connected.
Err 03	Transformer is overheated.
Err 04	Coolant motor is overloaded.



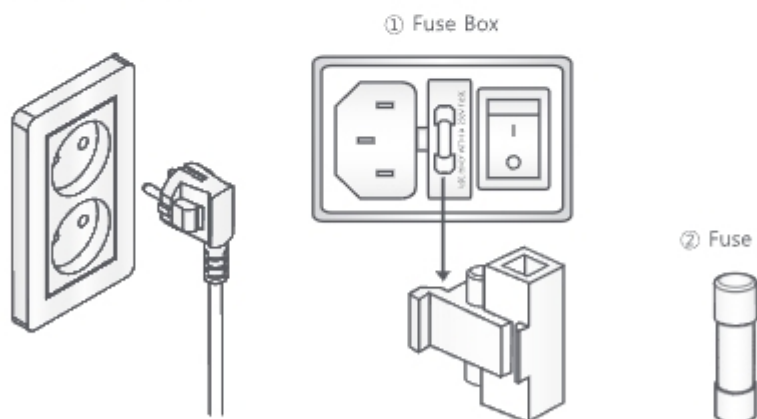
Special care must always be taken when handling the LCD panel.

4-4. Foot Control



- ① Foot hanger
- ② Coolant button (4 steps)
- ③ Program change button (9 Programs)
- ④ F/R change button - Changes the direction
- ⑤ Foot pedal - Micro motor speed control
- ⑥ Foot control connector

5. Main Power Input



- ① AC220~240V, 50/60Hz or AC100~120V, 50/60Hz
- ② 1.6AL (220~240V) or 3.15AL(100~120V)

⚠ Caution

- 1. To avoid electric shock, do not plug or unplug the power cord with wet hands.
- 2. The unit must be connected to the power with a suitable earth ground.

6. How to install

Caution

1. The control unit must be installed on a flat surface substantially, not interfered by peripheral devices. Avoid ventilation on the bottom plate of the control unit being blocked off.
2. The control unit must be used in a place where indoor temperature is maintained at a proper level. (0~35°C)
3. Do not use the unit in a dirty or very hot and humid place.

6-1. Connection



Motor Cord Connection

- Motor cord connector should be properly connected to the port which is located at the front fo the control unit by pushin it to the end until you hear a click sound.



Foot Control Connection

- Foot control cord connector is required to be properly connected to the foot control port in the back of the control unit.



Power Cord Connection

- Power cord connector is required to be properly connected to the port next to the power switch in the back of the control unit.

Caution

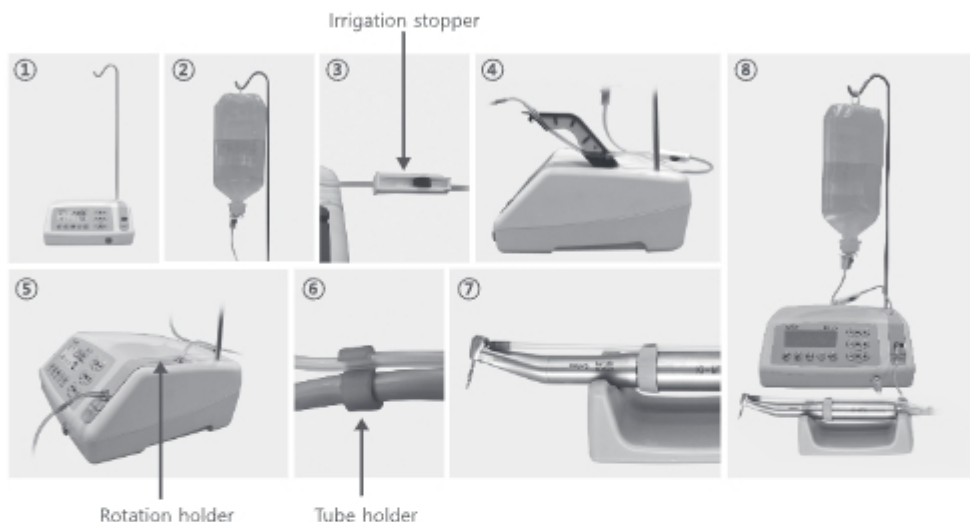
- Must check if all the cords are connected properly and safely before you plug in.

6-2. Irrigation Tube Assembling

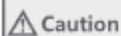
6-2-1. Purpose

- To make the saline solution flow and cool down the heat around the surgical operation area.

6-2-2. Installing the Irrigation Tube



- ① Mount the coolant hanger onto the control unit.
- ② Hang the saline bag on the coolant hanger and attach the irrigation tube to the saline bag.
- ③ Push the irrigation stopper to clamp the tube.
- ④ Push the push button in front of the control unit to open the rotation holder, and insert the irrigation tube.
- ⑤ Push down the rotation holder to close it.
- ⑥ Attach the tube holder on the motor cord and attach the irrigation tube onto the tube holder.
- ⑦ Connect the irrigation tube to the spray nozzle (internal/external).
(Please refer to 6-4 for more details of the handpiece)
- ⑧ Ensure that the irrigation tube is installed properly.
- ⑨ Ensure that the irrigation stopper is removed before use.



Caution

- If the pump operates while the tube is bent or the water does not come out, the tube may be broken or damaged.

6-3. Foot Control Assembling



- Assemble a foot hanger by pushing it into the holes in the back of foot control.

6-4. Handpiece Connection



Handpiece and E-type motor assembling

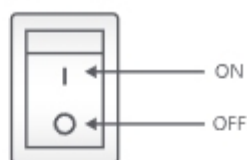
⚠ Caution

1. Turn off the power before assemble or disassemble the handpiece.
2. Make sure if the handpiece is securely connected to the motor before your operation.

7. Operation

- ① Check the power connector.
- ② Check the motor cord and handpiece connector.
- ③ Turn on the control unit.

Power Switch



7-1. Setting

Gear Ratio Change



1 : 1 → 1 : 2 → 20 : 1 → 32 : 1 → 1 : 1

Coolant Change



Off →  →  →  → Off

Forward / Reverse Change



Optic Change



Optic LED on & off

Torque Change



Torque can be adjusted by pushing the "torque" buttons.



Speed Change



Speed can be adjusted by pushing the "speed" buttons.



Program Save & Change



The setting for gear ratio, coolant, direction, optic, torque, and speed value can be saved by pressing the memory button for 1 second. (Settings will be saved as per the number that is displayed.)



You can save 9 different programs by changing the program numbers. Press program button to descend or ascend the program numbers. Select the program you prefer to use.

7-2 Setting - Foot Control

Coolant Change



Coolant Flow rate.

Off → → → → Off

Change the coolant flow rate by pressing the left button on the foot control.
Continue pressing the button to cycle through coolant flow rate options.

How to use



[Coolant Off]



[Pressing the left button]



[Coolant level 1]

If you press the left button in the foot control once, the coolant level will go up by one level.

Program Change



Change the program which you have saved on the control unit by pressing the middle button on the foot control.

The program number ascends from 1 to 9 by pressing the middle repeatedly.
To go backwards, press the middle button for 2 seconds, and then the program number will descend from 9 to 1 with repeated presses. A beep sound will be made each time the program number descends.

How to use



[Program #5 selected]



[Pressing the middle button]



[Program #6 selected]

Forward / Reverse Change



Change the direction by pressing right button on the foot control.

When the motor is on reverse mode, you will hear the beep sound every 2 seconds.

How to use



[Forward]



[Pressing the right button]



[Reverse]

If you press the right button on the foot control once, the handpiece direction will change from forward to reverse. By pressing it once again, it will change from reverse to forward.

Handpiece RPM Control



Change the speed of the handpiece by pressing the foot pedal.

The speed controls can be changed up to the maximum speed(rpm) of the handpiece.

How to use



[Pressing pedal]

Keep pressing the pedal to operate the motor.

7-3. Tips to Get Accustomed to Using the Foot Control

- ① Try to memorize which button serves each function.
- ② Practice numerous times until you do not make a mistake on using the foot control before using on the patient.
- ③ Contact your local dealer if you need training.
- ④ The foot hanger can help you to recognize the location of a button.



Caution

1. Make sure that the handpiece is not in operation before you turn off the control unit.
2. Make sure that you fully understand the functions of the foot control before use.

8. Error Message

- If an operational problem occurs, the display will show an error code allowing immediate problem diagnosis. When an error occurs, there will be a beep and an error code will appear on the LCD. The error code will display until the error is alleviated.

Error code	Status	Cause	Countermeasure
* Err 01 *	* Motor connection error.	<ul style="list-style-type: none"> * Motor cord failure. * E-type motor & motor cord connection error. 	<ul style="list-style-type: none"> * Handpiece connection may be loose. Securely reconnect the motor cord. When an error cannot be eliminated, request repair.
* Err 02 *	* Foot control abnormality.	<ul style="list-style-type: none"> * Foot control connection failure. 	<ul style="list-style-type: none"> * Check the connection state of the connector. If the error code is displayed even when the connector is normally connected, request repair.
* Err 03 *	* Control unit interior overheating error.	<ul style="list-style-type: none"> * Overheating by extended use under heavy load. * Operation of the control unit under an extremely high temperature. 	<ul style="list-style-type: none"> * Allow it to cool down before use. Since heat is sufficiently radiated, periphery of the main control unit should be well-ventilated wherever possible. When an error cannot be eliminated, request repair.
* Err 04 *	* Pump excess current.	<ul style="list-style-type: none"> * The irrigation tube is incorrectly fitted or the pump has failed. 	<ul style="list-style-type: none"> * Check the irrigation tube. If an error code is displayed even when the irrigation tube is normal, request repair.

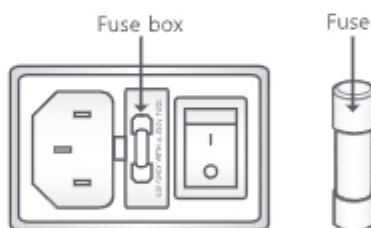
9. Troubleshooting

Symptom	Check point	Countermeasure
* Non-function of LCD display	* Plug status.	* Plug in the motor cord correctly.
	* Fuse status.	* Replace fuse.
	* Power switch status.	* Contact professional technician.
* Non-function of Foot control	* Foot control status.	* Plug in the foot control correctly.
* Heat problem	* Trouble of ball bearing.	* Contact professional technician.
* Strong vibration & noise	* Stained with foreign substance.	* Clean and sterilize the handpiece.
	* Trouble of ball bearing.	* Contact professional technician.

10. Maintenance

10-1. Fuse Replacement

- Check the fuse when the power does not turn on.
- Pull out the fuse box from the back of control unit when you check the fuse.



⚠ Caution - Must turn off the power and unplug the control unit before replacing the fuse.

10-2. Maintenance for Control Unit & Foot Control

- If the control unit, or foot control is stained with blood or saline solution, remove the AC electrical cord, wipe them with a damp cloth, then with an alcohol-absorbed cloth.

10-3. Maintenance of the Handpieces

- The handpieces must be sterilized before each use. Please refer to the user manual for more details.

11. Sterilization

- Following items are autoclavable.

Items	Note
<ul style="list-style-type: none"> * Handpiece * Nozzle clamp * Internal spray nozzle * Spray nozzle 	<p>* These are the parts that are included in the handpiece case. Please refer to the "User Manual for Handpiece" for more details.</p>
<ul style="list-style-type: none"> * E-type motor & Motor cord * Motor plug * Tube holder * Handpiece stand 	

- ① In case of foreign substances such as blood or saliva, we recommend you to clean them by using a piece of cloth or brush with alcohol.
- ② Inject the lubricated spray into the handpiece.
 - a. Do not use the spray on the E-type motor. It will damage the motor.
 - b. Attach the motor plug to the E-type motor.
- ③ Place in an sterilization pouch(or sterilization wrap) and seal it.
- ④ Recommended sterilization methods validate by Saeyang Microtech Co., Ltd.
- ⑤ Keep the handpiece in the sterilization pouch (or sterilization wrap) to keep it clean until you use it.

Cycle Type	Pre-vacuum
Configuration	wrap
Temperature	132°C [270°F]
Exposure Time	4 minutes
Dry Time	30 minutes

Caution

1. E-type motor can be damaged from user's careless maintenance.
2. Make sure to remove any dirt before sterilize to prevent the product damage.
3. Irrigation tube is disposable. Do not re-use it.
4. Do not sterilize other than described above products.
It may be the cause of the quality problem.
5. Do not disassemble the E-Type motor & the motor cord.
- 6: The device consists the durability of at least 250 sterilization cycles.

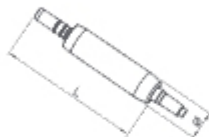
12. Specification

Control Unit



Model	KI-20
Power(Input)	AC 100~120V, 50/60Hz / AC 220~240V, 50/60Hz
Output	100VA
Weight	2,606g
Dimension	240(W) x 225(D) x 97(H)

E-Type Motor & Motor Cord



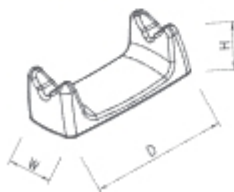
Model	KI-MTO
Weight	265g
Dimension	Φ22 x 117(L)
Max. Speed	40,000 RPM

Foot Control



Model	KI-F20
Weight	1,015g
Dimension	218(W) x 190(D) x 57(H)
Height including a coolant bar	165mm

Handpiece Stand



Weight	101g
Dimension	60(W) x 130(D) x 47(H)

13. Warranty

- We do not guarantee the quality in case of user's carelessness.

14. Electrical Specification

- The unit meets the collateral standards of electromagnetic compatibility - Requirements and tests EN 60601-1:2007(IEC 60601-1-2) the limits and methods of measurements of electromagnetic disturbance characteristics of industrial, scientific and medical radio frequency equipment EN 55011 Group 1, Class A, medical electrical equipment is subject in regard to the electromagnetic compatibility(EMC) and its special precautionary measure.
- The unit must in reference to the mentioned EMC-hints in the accompanying documents be installed and operated. Portable and mobile RF - communicating system (such as cell phones) can have influence to medical electrical equipment.
- Guidelines for the operator to use the Endo E Plus model device in electromagnetic environments.

Electromagnetic emissions		
The Ki-20 model device is intended for use in the electromagnetic environment specified below. The customer or the user of the Ki-20 model device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment
RF emissions CISPR 11	Group 1	The Ki-20 model device uses RF energy only for its internal function. Therefore, its RF missions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity


The Ki-20 Model device is intended for use in the electromagnetic environment specified below. The customer or the user of the Ki-20 Model device should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment
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 ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV common mode	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 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles 70 % <i>UT</i> (30 % dip in <i>UT</i>) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 5 s	<5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles 70 % <i>UT</i> (30 % dip in <i>UT</i>) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Ki-20 Model device requires continued operation during power mains interruptions, it is recommended that the Ki-20 Model device be powered from an uninterruptible power supply or a battery
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	If laser output distortion occurs, it may be necessary to position the Ki-20 Model device further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

NOTE *UT* is the a.c. mains voltage prior to application of the test level.

Electromagnetic immunity

The Ki-20 Model device is intended for use in the electromagnetic environment specified below. The customer or the user of the Ki-20 Model device should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Ki-20 Model device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2,3 \sqrt{P} \text{ 800 MHz to 2,5 GHz}$ <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,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

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 Ki-20 Model device is used exceeds the applicable RF compliance level above, the Ki-20 Model device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Ki-20 Model device.

^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 Ki-20 Model device

The Ki-20 Model device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Ki-20 Model device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Ki-20 Model device 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 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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