



Foshan COXO Medical Instrument Co.,Ltd

BLDG 4, District A Guangdong New Light Source Industrial Base, South of Luocun Avenue Nanhai District Foshan 528226 Guangdong China



Lotus NL B.V.

Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
E-mail: peter@lotusnl.com

Foshan COXO Medical Instrument Co.,Ltd

TEL: 0086-757-66692058

FAX: 0086-757-81800058

E-mail: coxotec@163.com

Http: //www.coxotec.com

Ver: 2.2 Rev. Date: 2022-01-18

COXO[®]



CE 0197

Please read this Operation Manual carefully before use, and file for future reference.

High speed air turbine handpiece

Operation Manual

CX207/CX207-2

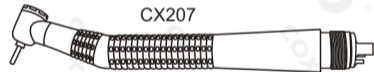
CX207-A/CX207-A-2

CX207-B/CX207-B-2

CX207-C/CX207-C-2/CX207-F

CX207-G/CX207-W/CX207-W-2

Introduction of Type



CX207



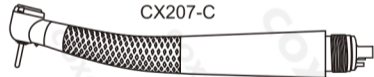
CX207-2



CX207-A



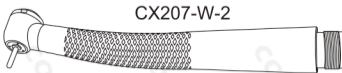
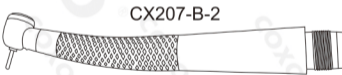
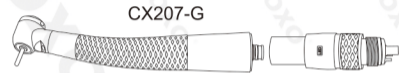
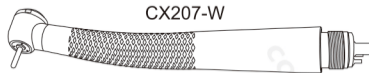
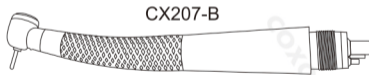
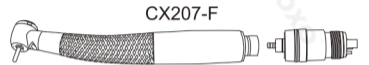
CX207-A-2



CX207-C



CX207-C-2



Auxiliary materials

Material introduced	Material code
Handpiece oil	244-1

Parts List:		
Host		1
Wrench		1
Cleaning wire		1
Quick Coupling		1
Operation Manual		1

⚠ Attention

- Read this Operation Manual before use to fully understand the product functions and file for future reference.
- When operating the product always consider the safety of the patient.
- This product does not consider patient's age (except infants), gender, weight or nationality.
- This product does not consider operator's age (mature person), height, weight, gender, or nationality.
- Users are responsible for the operational control, maintenance and continual inspection of this product.
- Do not allow any impact on to the product. Do not drop the product.
- Operators and all others in the area must wear eye protection and a mask when operating this handpiece.
- Should the product function abnormally, cease operation immediately and contact your Dealer.
- Depressing the Push Button while the handpiece is in operation may cause overheating, serious technical damage and possible premature handpiece failure. During operation avoid contact with any oral tissue that may cause the Push Button to be depressed while the handpiece is in operation.
- Do not use high acid water or sterilizing solutions to wipe, immerse or clean the product.
- The products are delivered in a non-sterile condition and must be autoclaved prior to use.
- Perform regular function and maintenance checks.
- If the product is not used for a long period check it is functioning correctly before using on a patient.
- To avoid clinical downtime it is recommended that a spare be kept on hand in case of a breakdown during surgery.

1. Technical Date

	CX207	CX207-2	CX207-A	CX207-A-2	CX207-B	CX207-B-2	CX207-C	CX207-C-2	CX207-F	CX207-G	CX207-W	CX207-W-2
Cartridge	Collet/Open	Collet	Open	Open	Open	Open	Open	Open	Collet/Open	Open	Open	Open
Chuck Type	Push button Wrench	Push button Wrench	Push button	Push button	Push button	Push button	Push button	Push button	Push button	Push button	Push button	Push button
Spray	1waySpray	1waySpray	1waySpray	1waySpray	1waySpray	1waySpray	1waySpray	1waySpray	3waySpray	3waySpray	3waySpray	3waySpray
Hole	4hole	2hole	4hole	2hole	4hole	2hole	4hole	2hole	2hole/4hole	6hole	4hole	2hole
Bulb	-	-	-	-	-	-	-	-	LED	LED	-	-
Voltage	-	-	-	-	-	-	-	-	-	2.9-3.2V	-	-
Rotation Speed	≥280, 000rpm											
Air flow rate	> 1.5L/min (at 200kPa)											
Rated torque	>0.0005N .m(6 hole and 4 hole at 0.28Mpa,2 hole at 0.22Mpa)											
Water	> 50mL/min (at 200kPa)											
Air Pressure	0.24~0.28Mpa (6 hole and 4 hole), 0.2~0.22Mpa (2 hole)											
Bur Type	ISO 1797-1 Type 3, diameter: 1.6mm, fitting length: min. 11mm, overall length: max. 23mm, working diameter: max. 2mm.											

Note:

- 1) 2 Hole of ISO 9168 Type 1; 4 Hole of ISO 9168 Type 2; 6 Hole of ISO 9168 Type 3.
- 2) Only use carbide cutters or diamond grinders that correspond to ISO 1797-1 type 3, are made of steel or hard metal.

2. User and Intended Use

- 2-1. Used by qualified professionals, only for dental treatment.
- 2-2. Intended Use: Removal of carious material, cavity and crown preparations, removal of flings, processing of tooth and restoration surfaces.

3. Connection & Disconnection of the Handpiece

3-1. Direct-Connect Type Connection

- 1) Insert the handpiece correctly into the hose connector and tighten the hose nut (Fig.1).
- 2) Make sure the handpiece is connected firmly to the hose.

3-2. Direct-Connect Type Disconnection

- Loosen the Hose Nut and remove from the Hose (Fig.2).

3-3. Quick Coupling Type Connection

- 1) The quick connector is inserted into the handpiece jack connections, push forward clamp quick connector;

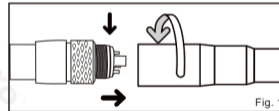


Fig. 1

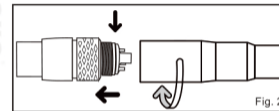


Fig. 2

- 2) Insert the handpiece to the coupling while pulling back the retention lock ring of the coupling. Release the retention lock ring.
- 3) Make sure the handpiece is firmly connected to the coupling.

3-4. Quick Coupling Type Disconnection

Pull back the Retention Lock Ring and remove the handpiece from the Coupling (Fig.3,4,5).

Warning:

- 1) Not in the operation procedure of loading remove high-speed air turbine handpieces.
- 2) Link hose according to the model of handpiece!
- 3) Must be firmly connected to use!
- 4) The maximum temperature produced by this equipment is not more than 60°C!
- 5) No more than 10 minutes of contact with the patient!
- 6) Our products can only be used in conjunction with equipment that complies with IEC 60601-1!

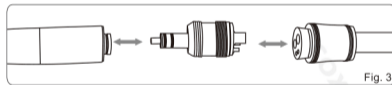


Fig. 3

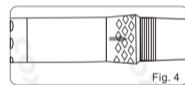


Fig. 4



Fig. 5

4. Insertion & Removal of the Bur

4-1. Push button

4-1-1. To Insert the Bur

- 1) Insert the bur until it is correctly seated in place (Fig.6).
- 2) Depress the Push Button and insert the bur into the chuck until it is secure then release the button.
- 3) Ensure that the bur is secure by gently pulling and pushing the bur WITHOUT depressing the Push Button.

4-1-2. To Remove the Bur

Depress the Push Button firmly and remove the bur.

Warning:

- 1) Remove the bur only after the handpiece has completely stopped rotating.
- 2) Use only good condition cut shank in line with Standard grinding bur.
- 3) Use of the process, do not press the button of high-speed air turbine handpieces.

This causes the button bur or grinder from overheating, there is risk of injury.

4-2. Wrench button

- 1) Pull back the needle retractor handle will be set in the head withdrawing device for handpiece;
- 2) Would remove the needle put on head, stuck a card shaft, and insert shaft policy rectangular holes,

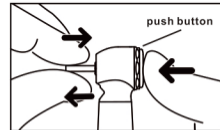


Fig. 6

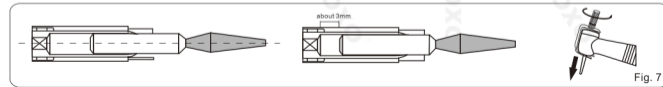
clockwise to take the needle, counterclockwise rotation of the lock pin;

3) Please confirm locking the lock pin. (Fig.7)

Warning:

1) Remove the bur only after the handpiece has completely stopped rotating.

2) Use only good condition cut shank in line with Standard grinding bur.



5. Clean Spraying Holes

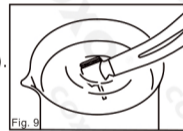
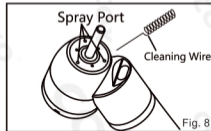
After the treatment of each patient, clean the head

1) Remove dirt and debris from the Clean Head Holes with the cleaning wire and brush (Fig.8).

2) Half fill a cup with clean water.

3) Rotate the handpiece and immerse half of the handpiece head in the cup of water (Fig.9).

4) Rotate then stop intermittently the handpiece 3 times for 2 to 3 seconds each time.



5) Wipe the headpiece dry.

*If the dirt could not be removed from the hole, clean it by brush.

6) Remove debris from the product. DO NOT use a wire brush.

7) Wipe clean with alcohol-immersed cotton swab or cloth.

6. Insertion & Removal of the Bur

6-1. Open Cartridge

1) Insert a test bur.

2) Locate the correct wrench tool on the head cap then turn the wrench counter clockwise to loosen the cap.

Remove the cap.

3) Use the bur to gently lever the cartridge, O-ring and washer out from the head.

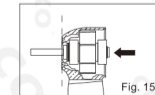
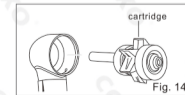
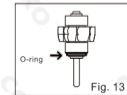
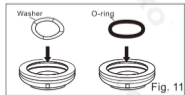
4) Remove the O-ring inside the head cap using a pointed tool then remove the washer located beneath the O-ring (Fig.10).

5) Attach a new washer and O-ring on the head cap (Fig.11).

6) Insert a new washer and O-ring into the head (Fig.12).

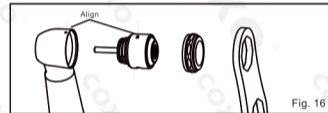
7) Make sure that the O-ring is correctly located on the cartridge (Fig.13).

- 8) Carefully insert the new cartridge into the head (Fig.14).
- 9) Completely insert the cartridge until the cartridge end face aligns with the end face of the handpiece head (Fig.15). If the cartridge cannot be inserted all the way, the washer or O-ring may be misaligned. In this case, remove the parts from the head and repeat the assembly from "6)".
- 10) Tighten the head cap with the correct head cap wrench.



6-2. Collect Cartridge

- 1) Mount a dummy bur in the chuck.
- 2) Remove the Head Cap using the supplied Head Cap Wrench.
- 3) Push the dummy bur to remove Cartridge.
- 4) Clean the head interior.



- 5) Align the Alignment Pin with the alignment slot and insert Cartridge.
- 6) Replace the Head Cap. (Fig. 16)

7. Lubrication

- 1) ① Direct-Connect Type: Remove the handpiece from the hose,
 - ② Quick Coupling Type: Disconnect the handle from the quick connector.
- 2) Remove the bur from the handpiece,
- 3) Mount the Tip Nozzle into the spray can port (Fig. 17)
- 4) Insert the Tip Nozzle into the Drive Air Prot of the handpiece. Hold the handpiece and spray for approximately 2-3 seconds. Apply lubricant until it expels from the handpiece head for at least 2 seconds (Fig. 18, 19).
- 5) Cartridge should be maintained, it is necessary to remember lubrication cleaning, place the residual impurities, rust bearings.

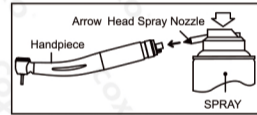


Fig. 17

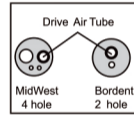


Fig. 18

⚠ Attention:

- 1) We recommend that the period of lubrication should be before each sterilization.
- 2) Before sterilization, please clean, disinfect and lubricate the high-speed air turbine handpieces!

8.Cleaning,Disinfection and Sterilization

Device:	High-speed air turbine handpiece
Advice:	Reprocessing procedures have only limited implication to this dental instrument. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. From the processing side there is no maximum number of allowable reprocessing. The device should no longer be reused in case of signs of material degradation. In case of damage the device should be reprocessed before sending back to the manufacturer for repair.
Reprocessing Instructions	
Preparation at the Point of Use:	Disconnect the handpiece from tube. Remove gross soiling of the instrument with cold water (<40°C) immediately after use. Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residuals which may influence the result of the reprocessing process. Store the instruments in a humid surrounding.

Transportation:	Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.
Preparation for Decontamination:	The devices must be reprocessed in a disassembled state, as far as possible.
Pre-Cleaning:	Do a manual pre-cleaning, until the instrument are visually clean. Submerge the instruments in a cleaning solution and flush the lumens with a water jet pistol with cold tap water for at least 10 seconds. Clean the surface with a soft bristol brush.
Cleaning:	Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety. Automated Cleaning: Use a washer-disinfector meeting the requirements of the ISO 15883 series. Put the instrument into the machine on a tray. Connect the instrument with the WD by using suitable adapter and start the program:

	<ul style="list-style-type: none"> • 4 min pre-washing with cold water (<40°C) • emptying • 5 min washing with a mild alkaline cleaner at 55°C • emptying • 3 min neutralising with warm water (>40°C) • emptying • 5 min intermediate rinsing with warm water (>40°C) • emptying <p>The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weight).</p> <p>Note Acc. to EN ISO 17664 no manual reprocessing methods are required for these device. If a manual reprocessing method has to be used, please validate it prior to use.</p>
Disinfection:	<p>Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see EN 15883).</p> <p>A disinfection cycle of 5 min disinfection at 93°C has been validated for the device to achieve an A0 value of 3000.</p>

Drying:	<p>Automated Drying: Drying of outside of instrument through drying cycle of washer/ disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.</p>
Functional Testing, Maintenance:	<p>Visual inspection for cleanliness of the instruments and reassembling, if required. Functional testing according to instructions of use. If necessary, perform reprocessing process again until instrument is visibly clean.</p> <p>Before packaging and autoclaving, make sure that the handpiece has been maintained acc. to manufacturer's instruction.</p>
Packaging:	<p>Pack the instruments in an appropriate packaging material for sterilization. The packaging material and system refer to EN ISO 11607.</p>
Sterilization:	<p>Sterilization of instruments by applying a fractionated pre-vacuum steam sterilization process (according to EN 285 /EN 13060 /EN ISO 17665) under consideration of the respective country requirements.</p> <p>Minimum requirements: 3 min at 134°C (in EU: 5 min at 134°C)</p> <p>Maximum sterilization temperature: 137°C.</p> <p>Drying time:</p>

	<p>For steam sterilization, we recommend a drying time of 15 to 40 minutes. Choose a suitable drying time, depending on the autoclave and load. Refer to the autoclave's instructions for use.</p> <p>After sterilization:</p> <p>a. Remove the product from the autoclave.</p> <p>b. Let the product cool down at room temperature for at least 30 minutes. Do not use additional cooling. Check that the sterilization wraps or pouches are not damaged.</p> <p>Flash sterilization is not allowed on lumen instruments!</p>
Storage:	Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.
Reprocessing validation study information:	<p>The above-mentioned reprocessing process (cleaning, disinfection, sterilization) has been successfully validated. Refer to test reports:</p> <ul style="list-style-type: none"> - FOSHAN COXO_Cleaning Disinfection Validation Report - FOSHAN COXO_Sterilization Validation Report_Straight Handpiece, Air Motors - FOSHAN COXO_Sterilization Validation Report_High-speed air turbine handpiece
Additional Instructions: None	
It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.	

9.Environment conditions

Operating environment:

Ambient temperature: +5 °C-+40 °C
 Relative humidity: 20% - 80%RH
 Air pressure : 860hPa-1060hPa













Transportation and storage conditions:

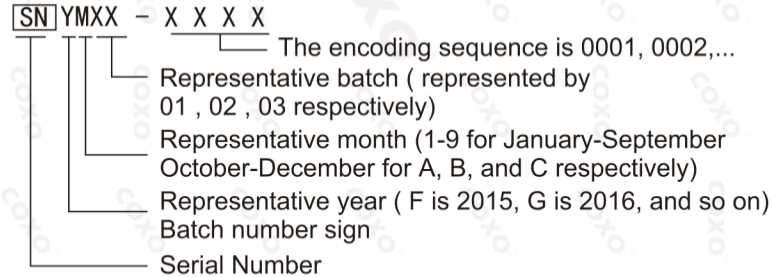
Ambient temperature: -10°C - +55°C
 Relative humidity: ≤93%RH
 Air pressure: 500hPa-1060hPa

10.Contraindications

1. Hemophilia patients should be used with caution.
2. The patient or doctor with a pacemaker is careful to use an electric motor to drive the handpiece.
3. Heart disease patients, pregnant women and children with caution.

11. Standar Symbols

	Warning		Autoclave		Thermo-Disinfector
	Attention, consult accompanying documents				Certified to MDD93/42/EEC
	Refer to Instruction Manual/Booklet				Type B applied part
	Serial number				Class II equipment
	Do not dispose of with domestic waste				Manufacturer
	Date Of Production				





12. Recycling and disposal

1. Recycling

COXO places special emphasis on environmental responsibility, and high-speed air turbine handpieces and packaging are designed to be as environmentally friendly as possible.

2. Disposal of the handpieces

-  - Dispose of old equipment according to the laws, regulations and standards of your country (region).
-  - Ensure that all parts are free from contamination during disposal.

13. Trouble Shooting

Trouble	Possible cause	Solution
Big noise, low rotation speed, cutting force decrease or handpiece fail to running	Ball bearing damages	Replace ball bearing
Handpiece fail to spray mist	Spray hole blockage	Clean with probe
Handpiece water leakage	O-ring and washer aged	Replace aged parts
Normal noise but low rotation speed	Low air pressure	Adjust air pressure
Bur drop-off or fail to insert bur	Non standard bur or chucking system damages	Replace new bur or send it to maintaining center
Bur wobbling, low cutting force	O-ring or ball bearing damages	Replace spare parts

This product can be repaired by professional maintenance personnel on site, and accessories required for maintenance are purchased from COXO or distributors. Our service center can offer technical assistance to you.

14.Warranty

COXO grants the user a 12 months guarantee for its complete product range, except ball bearing (3 months guarantee) from the date of invoice issued, Maintenance over the term of guarantee will be at the customer's charge. COXO will not be responsible for damage or injury resulting from:

- excessive use
- improper manipulation of the product, or modification to product carried out by persons not authorized by COXO.
- fail to follow the instruction to install, operate and maintenance the handpiece.
- damage of chemical, electrical or electrolysis due to improper autoclaving and storing.
- improper working pressure.

15.Guidance and manufacturer's declaration--EMC

This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.

Attention:


- Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
- This unit has been thoroughly tested and inspected to assure proper performance and operation!
- This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacture's declaration – electromagnetic emission		
The High-speed air turbine handpieces is intended for use in the electromagnetic environment specified below. The customer or the user of the High-speed air turbine handpieces should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The High-speed air turbine handpieces use 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 emission CISPR 11	Class B	The High-speed air turbine handpieces is suitable for use in all establishment, including domestic establishments and those establishments directly connected to the public low-voltage power supply network with specific
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacture's declaration – electromagnetic immunity			
The High-speed air turbine handpieces is intended for use in the electromagnetic environment specified below. The customer or the user of the High-speed air turbine handpieces 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	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	Floors should be wood, concrete or ceramic tile. If floor 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	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5kV&±1kV differential mode ±0.5kV, ±1kV & ±2kV common mode	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	100% UT (100% dip in UT) for 0.5 cycle 100% UT (100% dip in UT) for 1 cycle 30% UT (70% dip in UT) for 25/30 cycles 100% UT (100% dip in UT) for 250/300 cycle	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the High-speed air turbine handpieces requires continued operation during power mains interruptions, it is recommended that the High-speed air turbine handpieces be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity			
The High-speed air turbine handpieces is intended for use in the electromagnetic environment specified below. The customer or the user of the High-speed air turbine handpieces should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz 6 Vrms in ISM band 3V/m 80 MHz to 2.7 GHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the High-speed air turbine handpieces, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2 \times \sqrt{P}$ $d=1.2 \times \sqrt{P}$ 80 MHz to 800 MHz $d=1.2 \times \sqrt{P}$ 800 MHz to 2.5 GHz

Radiated RF IEC 61000-4-3	385 MHz-5785 MHz test specification for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	385 MHz-5785 MHz test specification for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC60601-1-2:2014)	<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 meter (m). Field strength from fixed RF transmitters, determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE1 UT is the a.c. mains voltage prior to application of the test level.</p> <p>NOTE2 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE3 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

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 High-speed air turbine handpieces is used exceeds the applicable RF compliance level above, the High-speed air turbine handpieces should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the High-speed air turbine handpieces.

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 High-speed air turbine handpieces.

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter		
	150 kHz to 80 Mhz $d=1.2 \times \sqrt{P}$	80 Mhz to 800 MHz $d=1.2 \times \sqrt{P}$	80 MHz to 800 Mhz $d=2.3 \times \sqrt{P}$
0.01	Not applicable	0.12	0.23
0.1	Not applicable	0.38	0.73
1	Not applicable	1.2	2.3

10	Not applicable	3.8	7.3
100	Not applicable	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meter(m) can be estimated using the equipment 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

NOTE2 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE3 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.