VISTA I APEX

REF 407702

Instructions For Use

For use by qualified professionals only

ENDO ULTRA™

Patented

Ultrasonic Activation Kit

IMPORTANT!

Please read the entire manual before using this product for the first time.

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Rx ONLY

407704-I-V-ENG (10)

CONTENTS

Important!

Please read the entire manual before using this product for the first time.

Complete the enclosed warranty card and return electronically or through the mail.

FEATURES & BENEFITS

Science has shown that irrigants are more effective when they are electromechanically activated. Acoustic streaming and cavitation of intracanal irrigant has been shown to significantly enhance cleansing of difficult anatomy.

EndoUltra™ is the only device of its kind capable of generating the shear forces required to produce acoustic streaming and cavitation, improving debridement, disruption of biofilm in canal spaces, and penetration of irrigants into dentinal tubules resulting in significantly improved outcomes. The EndoUltra™ harnesses this sophisticated technology in a compact, cordless design.

EndoUltra™ disrupts biofilm and:

- Improves cleanliness
- Reduces bacteria levels
- Improves penetration of irrigants

EndoUltra™ Features

- Cordless ultrasonic operation
- Contra angle design for increased accessibility
- Activator tips
- LED light
- Rechargeable battery
- Handpiece sleeves

INDICATIONS FOR USE

EndoUltra™ is used in endodontic treatment by application of ultrasonic energy to intracanal solutions. The EndoUltra™ handpiece provides the necessary ultrasonic power to the tips, creating oscillation and vibration. EndoUltra™ is the only cordless activator unit capable of generating the tip frequency (40,000-50,000Hz) required to create sufficient acoustical streaming and cavitation necessary to effectively clean, penetrate, and remove vapor lock. A clean root canal system makes for better outcomes and reduces retreatment rate.

Contra-indications

The EndoUltra™ should not be used for any application outside of endodontic procedures.

Warnings

This system has been designed and manufactured to assure personal safety.

Please read all safety and operating instructions carefully before use. Handle system with care at all times.

Precautions

The EndoUltra™ should always be used with an EndoUltra™ protective barrier sleeve during every procedure.

WARNINGS & PRECAUTIONS

PLEASE NOTE! Prior to installation and start-up of the device, please read these instructions carefully. As with all technical devices, the proper function and safe operation of this device depend on the user's compliance with the standard safety procedures as well as the specific safety recommendations presented in these Operating Instructions.

1. **CAUTION:** Federal law restricts this device to sale by or on the order of a dental professional, or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device. The manufacturer assumes no liability for any damage arising from any other or improper use of this device.

2. The charger must be accessible at all times. Do not use the charger for any use other than charging of the EndoUltra handpiece. Disconnect the handpiece from the mains by unplugging the charger from the electrical outlet. Treating patients using the handpiece while it is still connected to the charger is prohibited for safety reasons. Device operation is possible only if the charger has been disconnected.

3. Use only the charger (AC adapter plug) which is provided with the device. The use of any other charger can result in damage to the battery.

4. The batteries are not user replaceable. When needed, the units should be returned to Vista Dental Products for replacement.
   Replacement of lithium batteries by inadequately trained personnel could result in a hazard.

5. Condensation resulting from the device being transferred from a cold to a warm environment may be a potential risk. Never begin operating the device until it has reached the ambient temperature.

6. There are no user-serviceable items in the handpiece or charger.
   No modification of this equipment is allowed.

7. Use only components and accessories listed in the Operating Instructions associated with the device. Failure to do so will void the warranty, may decrease the system performance, and may lead to unsafe operation.

8. In order to avoid electric shock, do not introduce any objects into the device or remove the device enclosure.

9. Should you have any reason to suspect the safety of the device to be compromised, the device must be taken out of operation and labeled accordingly to prevent third parties from inadvertently using a possibly defective device.

10. Keep solvents, flammable liquids, and sources of intense heat away from the device as they may damage the plastic housing of the device, the seals, or the operating buttons.

11. According to IEC 60601-1 / UL 60601-1, this device must not be used in the presence of flammable mixtures.

12. Do not allow any cleaning agents to enter the device during cleaning as they could cause an electrical short or a dangerous malfunction.

13. EndoUltra must not be used in patients or by users with heart pacemaker implants who have been advised to be cautious with regard to their exposure to small electrical devices.

14. Prior to each use of the device ensure that the EndoUltra and connected tip are producing sufficient ultrasonic agitation. If necessary, consult the "Operation" section of the manual to determine proper handpiece and tip operation.

15. This device has been tested and found to comply with relevant EMC regulations and standards. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The device generates radio frequency energy and if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference with other devices, which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

    a. Reorient or relocate the receiving device.
    b. Increase the separation between the devices.
    c. Connect the device into an outlet on a circuit different from that to which the other device(s) are connected.
    d. Consult the manufacturer for help.

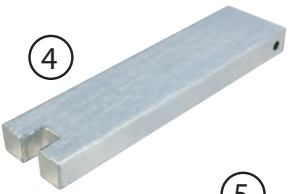
ADVERSE REACTIONS

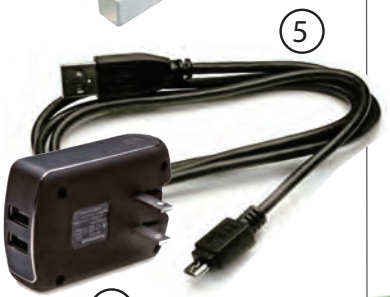
There are no known adverse reactions.

Symbols

SN	Serial Number		Consult instructions for use
	Manufacturer		Temperature Limitation
	Manufacturing Date		Humidity Limitation
	Class II Medical Electrical Equipment		Pressure Limitation
	Type BF Patient Applied Part	LOT	Batch Code / Lot Number
	Keep Dry	132°C	Autoclavable up to the temperature specified
REF	Part Number		Do not use if seal or packaging is compromised
	Warning / Caution	RxOnly	**CAUTION:** U.S. federal law restricts this device to sale by or on the order of a dental professional.
	Do not reuse		Do not throw in trash

SETTING UP THE EndoUltra™





COMPONENTS

Carefully unpack your new EndoUltra™ ultrasonic activator and confirm that all of the listed components and accessories are included:

1. EndoUltra™ handpiece with sleeve (1) *
2. Additional handpiece sleeves * (box of 2)
3. Activator tips (3) *
4. EndoUltra™ Wrench (1)
5. USB plug (1)
6. Wall charger (1)
7. Disposable Barrier Sleeves (100)

*All items are non-sterile

Charging the Unit

The EndoUltra™ runs on a lithium ion battery. An initial 4-hour burn-in charge is needed prior to first use.

Handpiece can be plugged in whenever not in use following initial 4-hour charge.

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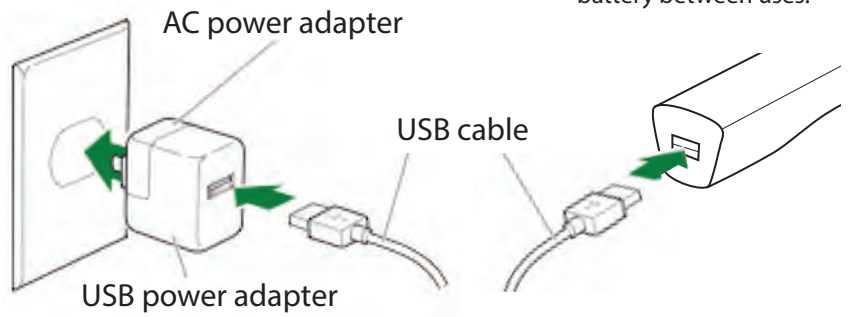
1. Connect USB cable to power adapter

Plug the power adapter into the wall outlet.

2. Connect the USB cable to the EndoUltra™ power connector.

Charge the handpiece battery between uses.



Monitor battery level indicator:

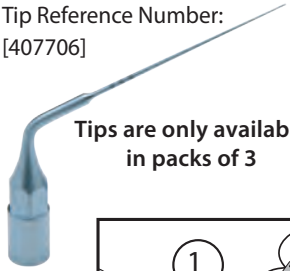
Full Charge Partial Charge Low Battery

When the indicator is red, plug unit in and bring it to a full charge.

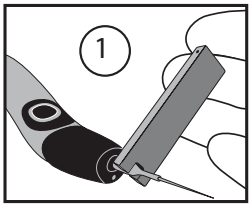
NOTE: Turn off the EndoUltra™ when not in use.

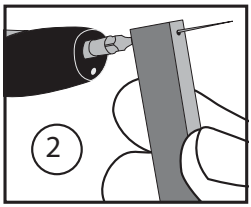
ENDO ULTRA™

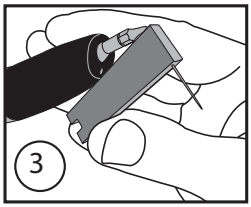
Tip Reference Number:
[407706]



Tips are only available in packs of 3







CAUTION:
Never screw or unscrew tip while the unit is activated.

Activator Tips

- Tips feature convenient depth markers at 16mm, 17mm and 18mm
- Ultrasonic energy resonates down the entire length of the Activator tip.
- **Tip Frequency:**
  40-50 kHz (40,000 -50,000 cycles / second)

Tip Installation / Removal

1. Hand thread tip onto the handpiece.
2. Tighten with wrench until tip no longer spins
   NOTE: Do not over-tighten
3. Slide tip through wrench hole until it stops
   BEND TIP TO DESIRED ANGLE
   (70° - 90° for best results).

Reverse step (1) for tip removal

Activator tips are bendable to facilitate greater access. With continued use, the tip may wear at the bend joint; this will be easily visible and tip should then be replaced.

Estimated number of uses per tip: 20

NOTE:
Activator tips can be autoclaved prior to use. Tips can withstand autoclave at 132°C / 0.22mPA for 3 min.

Detailed manual cleaning and sterilization processes are available at: vista-dental.com

Additional Activator tips can be purchased from Vista Dental Products.
Call toll free 1-877-418-4782 or visit us at www.vista-dental.com

ENDO ULTRA™

HANDPIECE OPERATION

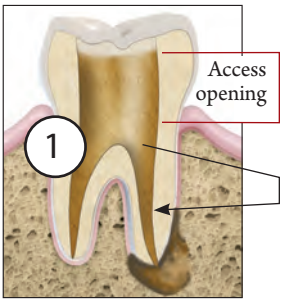
- Press ON / OFF button to activate unit (LED's will illuminate)
- Press ON / OFF button again to shut off.

NOTE: Turn off handpiece when not in use.

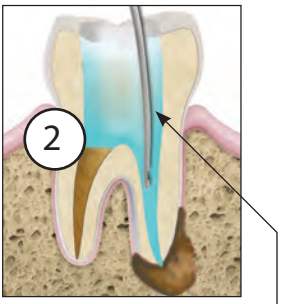
Technique Instructions:

1. Prepare canal to a fully tapered shape.
2. Irrigate as usual, filling the pulp chamber with specifically engineered irrigants (Chlor-XTRA™, SmearOFF™ or CHX-Plus™).
3. Thread Activator tip onto handpiece.
4. Tighten the tip with supplied flat wrench.
5. Press ON/OFF button again to activate tip.
6. Move Activator tip up and down using a small (2-3mm) vertical motion, maintaining a distance of 2mm from working length.
7. Activate intracanal solution for 30-60 seconds for optimal canal cleanliness.
8. Press ON/OFF button to turn OFF
9. Aspirate to remove any remaining debris from the canals.

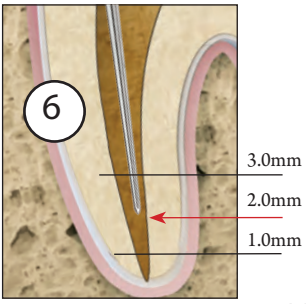
REPEAT THE ABOVE STEPS for each intracanal solution used.



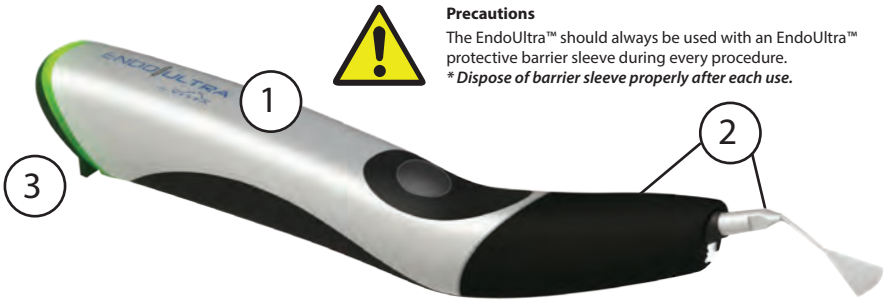
Pulp chamber and root canals cleaned and shaped



Irrigate chamber



MAINTENANCE / DISINFECTION:



Precautions

The EndoUltra™ should always be used with an EndoUltra™ protective barrier sleeve during every procedure.

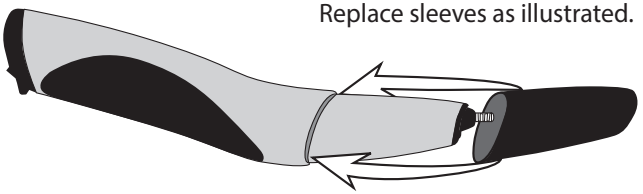
**** Dispose of barrier sleeve properly after each use.***

1. Clean EndoUltra™ handpiece with a simple disinfectant wipe before or after each use.

2. Remove Activator tip with EndoUltra™ wrench provided. Activator tips can be autoclaved prior to use. Tips and sleeves can withstand autoclave at 132°C / 0.22mPA for 3 min.

Detailed manual cleaning and sterilization processes are available at: vista-dental.com

Replace sleeves as illustrated.



3. Monitor battery level Indicator:

- Full Charge
- Partial Charge
- Low Battery

CAUTION:
Do not autoclave handpiece
Do not submerge handpiece in water

MAINTENANCE & CARE

Maintenance

The EndoUltra™ device is maintenance-free. No periodic maintenance is required. See the information contained in this chapter to secure problem-free operation.

Care of the Handpiece

Use only the charger included with the product. The use of other chargers may damage the battery cells or result in inadequate charge. Do not immerse the handpiece in water or incinerate. Please also observe the chapter on “Safety”.

Cleaning the Handpiece and Charger

Clean all the surfaces with a cloth lightly moistened with isopropyl alcohol.
To prevent cross contamination, single use EndoUltra™ Disposable Barrier Sleeves can be used on the handpiece.

⚠	The electronic components should not be autoclaved as it will damage the circuitry.
	Do not spray devices with any liquids as it may damage the circuitry and outer housing.
	Do not allow liquid to collect in the USB charger or USB receptacle on the rear of the handpiece or come in contact with the connectors as it may damage the circuitry and functionality.

Cleaning the 20/02 Tips

Activator tips can be autoclaved prior to use.
Tips can withstand autoclave at 132°C / 0.22mPA for 3 min.

Detailed manual cleaning and sterilization processes are available at: vista-dental.com

EndoUltra Disposable Barrier Sleeves

Dispose of the EndoUltra™ Disposable Barrier Sleeve properly after use. A new, unused barrier sleeve should always be used on every patient and should be replaced if it is torn or damaged during the examination procedure. Failure to do so may increase the risk of cross contamination between patients. The material of the barrier sleeve does not withstand high temperatures. Do not attempt to sterilize with autoclave, dry heat, or otherwise.

ACCESSORIES

EndoUltra™ Kit	407702
Handpiece Sleeves	407709
20/02 Activator Tips	407706
EndoUltra™ Wrench	407711
Disposable Barrier Sleeves	407719

DISPOSAL

Disposal of Unit

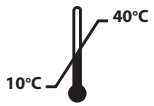
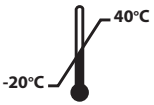
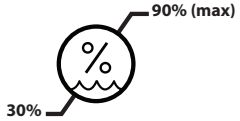
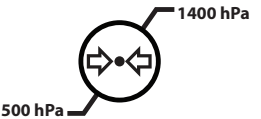
U.S. - Dispose of the system components in accordance with state and local laws.

EU - Dispose of in accordance with the Waste Electrical and Electronic Equipment Directive 2012/19/EU of the European Parliament and of the Council of the European Union.

Disposal of Accessories

Do not dispose EndoUltra™ accessories with household waste.
Follow your office protocol for disposal of regulated waste and management of sharps.

TECHNICAL DATA

Tip Materials	**File:** Stainless Steel 304 **Hub:** Aluminum 2024-T4 **Structural:** Epoxy Adhesive
Charger	**Input:** 100-240 V, 50-60 Hz
	Nominal Consumption: 0.5 A max
	Output: 5.0 V, 2.0 A max
	Manufacturer: TECH-POWER INT CO LTD
	Model: 71AN10W
	Dimensions without adaptor (LxWxH): 71AN10W
	Weight: 50g
	Classification: Protection class II, ⧈
Handpiece	**Input:** 5.0 V, 2.0 A max
	Battery: 3.7 V nominal, 800 mAh Li-ion, 2.96 Wh
	Battery Manufacturer: Ronda Battery Co.
	Battery Model: Li-ion 3.7 14500-800mAh
	Dimensions (LxWxH): 180mm, 26mm, 28mm
	Classification: Type BF,
	Intermittent Operation: The device has been designed solely for short-term operation. Typical operating time at room temperature (23°C): 1 min..
	Operating Time: ~1 hr fully charged
Charger and Handpiece	**Time to Charge Emply Battery:** Approx. 4 hr
	Operating Temperature: 10°C - 40°C (59°F - 104° F) 
	Relative Humidity: 30% - 90% (non condensing) 
	Atmospheric Pressure: 697hPa - 1013hPa 
Transport and Storage Conditions	**Operating Temperature:** -20°C – 40°C (-4°F – 104° F) 
	Relative Humidity: 30% - 90% (non condensing) 
	Atmospheric Pressure: 500hPa - 1400hPa 

TROUBLESHOOTING

Problem	Possible Causes	Action
LED light does not illuminate	• Insufficient battery charge • Handpiece turned off	• Plug handpiece into USB wall charger (if after several minutes, charge indicator does not come on, the batter may be expired.) • Contact your distributor
Handpiece ON/OFF button does not work	• Insufficient battery charge • Handpiece turned off	• Plug handpiece into USB wall charger (if after several minutes, charge indicator does not come on, the battery may be expired.) • Contact your distributor
Battery does not recharge	• Power cord is not seated properly. Fully insert USB cord into unit and wall adapter • Handpiece turned off	• Verify power cord is properly seated in wall outlet • Verify USB power cord is seated properly in back of handpiece
EndoUltra™ tip will not activate, but LED light is ON	• Tip is not fully tightened • Activator tip may be bent improperly, fractured or not bent at all.	• Tighten tip with the wrench provided • Replace Activator tip and consult tip bending instructions
EndoUltra™ tip will not activate, and LED light is OFF	• Insufficient battery charge • Handpiece turned off	• Plug handpiece into USB wall charger (if after several minutes, charge indicator does not come on, the batter may be expired.) • Contact your distributor
Short Battery Life	• Battery is not fully charged. • Replacement battery needed.	• Bring device to full charge • Consult your distributor

VISTA DENTAL PRODUCTS TERMS AND CONDITIONS OF WARRANTY:

The operator assumes all risk and liability for damages arising out of the improper use of Vista's product. In the event of a defect in material or workmanship, Vista's liability is limited, at Vista's option, to replacement of the defective product, or part thereof, or reimbursement of the actual cost of the defective product. In order to take advantage of this limited warranty, the defective product must be returned to Vista.

The EndoUltra™ handpiece is warranted to be free from defects under normal usage conditions for 1 year from its date of delivery. There is no warranty, expressed or implied, on the EndoUltra™ Activator Tips. There is no warranty, expressed or implied, of merchantability or fitness. The manufacturer's sole obligation under this warranty is to opt to either repair or replace the defective part of the product. If service must be performed to correct a defect, then the manufacturer will provide the service at its factory according to the mutual agreement made in advance. The manufacturer and its distributors will not accept the return of product unless the return is authorized and shipped in accordance with the distributor's instructions. Contact the local representative of the distributor from which the product was purchased for shipping instructions, a return authorization number, and an ARS shipping label.

There is no warranty, remedy or condition, expressed or implied, except as provided herein. The warranty and remedies contained herein are made by the manufacturer to the first buyer for dental use and are in lieu of all other agreements (expressed or implied), liabilities or remedies for breach of warranty. Vista Dental Products shall not be liable for consequential or incidental damages. No person or distributor is authorized to modify the terms of this warranty.

This warranty is void if any defect is caused by conditions beyond the manufacturer's control, including acts of God, damage resulting from mishandling, neglect, misuse, improper maintenance, accident or alteration/repair by anyone other than the manufacturer. The buyer assumes all liability for any damage caused by improper use of the product. The manufacturer assumes no liability for the user's failure to follow the instructions contained in this manual.

RETURN POLICY

Vista Dental Products will accept for return previously purchased merchandise which is suitable for resale or that which was shipped in error by Vista Dental Products. Merchandise suitable for resale requires current labeling and unopened non-soiled packaging.

All returns must have prior approval and must be shipped "prepaid" along with a return authorization form and a copy of the original invoice. Any products returned that are discontinued, dated, damaged, or opened could be denied credit or assessed a higher return fee.

Merchandise returned for credit must be received by Vista Dental Products within 60 days of the original invoice date. Returns made within 30 days will be subject to a 15% restocking fee. Any returns made 31-60 days after the original invoice date will be subject to a 25% restocking fee.

Equipment cannot be returned without written authorization from Vista Dental Products. Any equipment returned within 30 days from the date of the original shipment from Vista may not be assessed a restocking fee as long as the merchandise has current labeling and unopened non soiled packaging. Unopened equipment returned within 31 to 60 days from the date of the original shipment from Vista requires a restocking fee of 25% of the purchase price, including shipping and handling charges. Any equipment returned after 60 days from date of original shipment from Vista will not be restockable for credit. Installation, if required, must be initiated with an outside party, and is the sole responsibility of the customer.

- Special orders are not suitable for resale and therefore not returnable for credit.
- Claims for lost or damaged shipments should be filed immediately with the carrier.
- Claims for overage, shortage, and/or internal damages must be made to Vista Dental Products within 10 days of receipt of goods.

Complete enclosed warranty card and return electronically or through the mail.

tel: +1-262-636-9755 **toll free:** +1-877-418-4782 **fax:** +1-262-636-9760
www.vista-dental.com **www.endoultra.com**

EMC COMPATIBILITY

- EMC requirements have to be considered, and EndoUltra™ must be installed and used accordingly with the specific EMC information provided in the accompany documents.
- The device complies with the EMC (Electromagnetic Compatibility) according to IEC 60601-1-2. Radio transmitting equipment, cellular phones etc. shall not be used in close proximity of the unit as they could influence the performance of the system.
- Read carefully the indications relevant to the EMC in the dedicated appendix EMC COMPATIBILITY of this manual.

PROTECTION AGAINST EXPLOSIONS

The x-ray system MUST NOT be used in the presence of disinfectants, flammable or potentially explosive gases or vapors that might catch fire and cause damage.
In case these disinfectants have to be used let the vapors completely disperse before turning on the x-ray systems.

SYSTEM MODIFICATIONS OR UPGRADES

- Modifications or upgrades of the system can be carried out only if advised by Vista Dental Products and performed by authorized and qualified personnel, using ONLY genuine origi nal spare parts of Vista Dental Products.
- Vista Dental Products proscribes improper, unauthorized modifications or upgrades of the device, in order to avoid malfunctioning resulting in breakdowns and/or accident for patient, operator and equipment. Vista Dental Products assumes no responsibility and, consequently, declines all responsibility with respect to direct or indirect damages to people, the device or environment due to these reasons.
- Do not remove or attempt to remove the plastic covers of the device.
- It is strictly forbidden to attempt to repair electronic or mechanical parts by yourself.
- If you do not respect this warning you can compromise irreversibly the overall safety of the system and can be dangerous for operators, patients and environment.

Guidance and Manufacturer's Declaration

Below cables information are provided for EMC reference.

Cable	Max. cable length, Shielded/unshielded		Number	Cable classification
DC Power Line (USB Cable)	1.0m	Unshielded	1 Set	DC Power

Important information regarding Electro Magnetic Compatibility (EMC)

This electrical medical equipment needs special precautions regarding EMC and put into service according to the EMC information provided in the user manual; The equipment conforms to this IEC 60601-1-2:2014 standard for both immunity and emissions. Nevertheless, special precautions need to be observed:

➢ The equipment with no ESSENTIAL PERFORMANCE is intended used in Professional healthcare facility environment except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

➢ WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally".

➢ The use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

➢ WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."

➢ WARNING: If the use location is near (e.g. less than 1.5 km from) AM, FM or TV broadcast antennas, before using this equipment, it should be observed to verify that it is operating normally to assure that the equipment remains safe with regard to electromagnetic disturbances throughout the expected service life.

EMI Compliance Table (Table 1)

Table 1 - Emission

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class B	Professional healthcare facility environment
Harmonic distortion	IEC 61000-3-2 Class A	Professional healthcare facility environment
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	Professional healthcare facility environment

EMS Compliance Table (Table 2-5)

Table 2 - Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	3V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

Table 3 – Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

Table 4 – Input a.c. power Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrical fast transients/burst	IEC 61000-4-4	±2 kV 100kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	±0.5 kV, ±1 kV
Surges Line-to-ground	IEC 61000-4-5	±0.5 kV, ±1 kV, ±2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0.15MHz-80MHz 6V in ISM bands between 0.15MHz and 80MHz 80%AM at 1kHz
Voltage dips	IEC 61000-4-11	0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0% U_T, 250/300 cycles

Table 5 – Signal input/output parts Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0.15MHz-80MHz 6V in ISM bands between 0.15MHz and 80MHz 80%AM at 1kHz

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ULTRASONICS IN ENDODONTICS RESEARCH SOURCES

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NOTES

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