REF 407702

VISTA APEX

# INSTRUCTIONS FOR USE

For use by qualified professionals only

# ENDOULTRA®

## Ultrasonic Activation Kit

Protected by many worldwide patents including US Patents #9,700,382, #10,213,272 and #11,648,083. Multiple patents pending.


**IMPORTANT!**

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

**Procedure Pack Assembled by:**
**Inter-Med, Inc.**
2200 South St.
Racine, WI 53404 U.S.A.
**Tel.:** +1-262-636-9755
**Fax:** +1-262-636-9760
**Toll Free:** +1-877-418-4782
**www.vistaapex.com**

**Rx ONLY**

407704-I-V-ENG (14)

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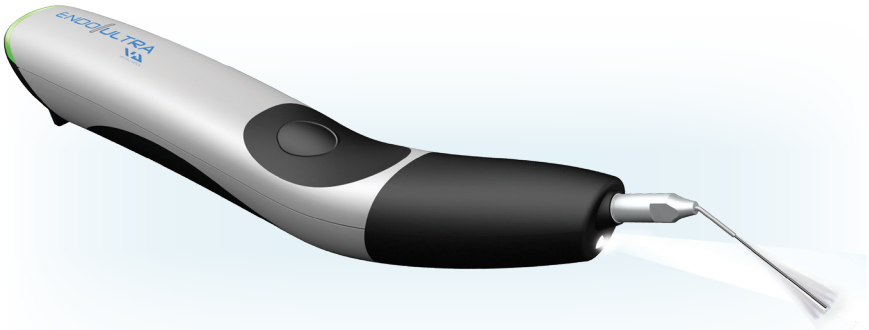
***IMPORTANT!***

Please read the entire manual before using this product for the first time.
Complete the enclosed warranty card and return electronically or by mail.




# INTRODUCTION

## *Welcome to EndoUltra®*

Congratulations on your decision to incorporate the best-in-class EndoUltra® Cordless Ultrasonic Activator into your dental practice!

Science has shown that irrigants are more effective when they are ultrasonically activated. Acoustic streaming and cavitation of intracanal irrigant has 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.

## *Indications for Use*

The EndoUltra® is used in endodontic treatment to facilitate canal debridement and cleanliness by application of ultrasonic energy to intracanal solutions after rotary instrumentation.

## *Intended Users & Target Patient Groups*

The EndoUltra® is intended to be used by trained dental professionals on patients undergoing endodontic therapy / treatment.

## *Contraindications*

The EndoUltra® should not be used for any application outside of activating irrigants during root canal 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® single use protective barrier sleeve during every procedure.

The EndoUltra tips have sharp, rigid ends. Use care to avoid contact with and damage to the root canal walls. Excessive force, improper angulation, or over-insertion may result in canal wall damage, which could allow irrigants to extrude into surrounding tissues and cause irritation or injury. Use the depth markings on the tip to verify proper insertion depth and positioning prior to activation.

## *Adverse Reactions*

There are no known adverse reactions.

# 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 Apex 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. Do NOT attempt to service the battery - the battery is NOT replaceable by the user. 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 solvants, 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.
16. According to the EU Medical Devices Regulation, users / patients are obliged to report serious events with a medical device to the manufacturer and to the competent authority of the country in which they occurred.
17. Reuse of single use barrier sleeves may result in patient to patient contamination, including the unintentional sharing of germs and disease. It is imperative that barrier sleeves are single use only and disposed of after each patient.
18. Handpiece sleeves and tips are reusable and should be cleaned and sterilized before first use and between patients. Follow detailed reprocessing instructions contained within these instructions. Handpiece sleeves and tips should be replaced immediately if visible wear is observed, or after 80 or 20 uses, respectively.

# SYMBOL IDENTIFICATION

Description for additional 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 | | This symbol refers to the special disposal of electrical and electronic devices in EU countries. Please do not discard this device in household garbage. Check the proper means of disposal in your country at your community recycling, waste center or at your dealer. Take care to dispose of properly. |
| NON STERILE | Non-Sterile | | |

# SETTING UP THE ENDOULTRA®


## *Components*

Carefully unpack your new EndoUltra® Cordless Ultrasonic Activator and confirm that all of the listed components and accessories are included:

1. (1) EndoUltra® Handpiece with sleeve — MD
2. (2) Additional handpiece sleeves — MD
3. (3) Titanium activator tips – 20/02 — MD
4. (1) Tip wrench
5. (1) USB plug
6. (1) Wall charger
7. (100) Disposable barrier sleeves — MD

* All items are sold non-sterile. Handpiece sleeves and tips must be cleaned and sterilized prior to use following reprocessing instructions contained herein.

# ENDOULTRA® OPERATION

## *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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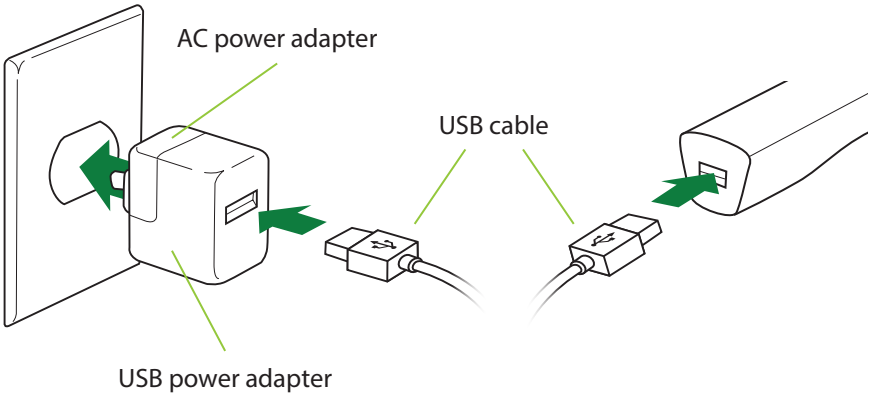
**1.** Connect USB cable to power adapter.

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 your battery charge level:**

● Full Charge ● Partial Charge ● Low Battery

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

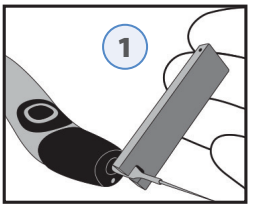
***NOTE:*** Turn off the EndoUltra® when not in use.

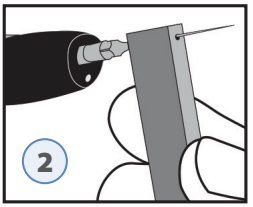
ENDO ULTRA®

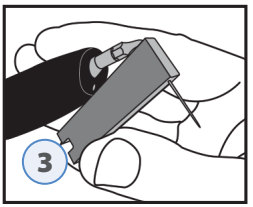
**Tips are only available in packs of 3**

**Call toll free 1-877-418-4782 or visit us at vistaapex.com to place your order.**

Product Reference #: 407706




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

   Reverse step 1 for tip removal

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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.

**Max number of uses per tip: 20**

***NOTE:*** Activator Tips must be cleaned and sterilized prior to use. Follow detailed reprocessing instructions contained herein.

## Handpiece Operation

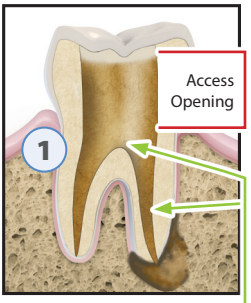
- Press ON/OFF button to activate unit (LEDs will illuminate).
- Press ON/OFF button again to shut off.

***NOTE:*** Turn off the EndoUltra® when not in use.

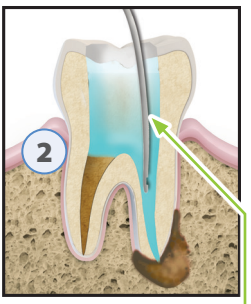
## Technique Instructions

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 tip 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.

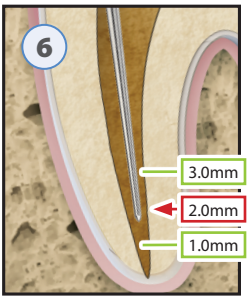
**REPEAT THE ABOVE STEPS** for each intracanal solution used.



Pulp chamber and root canals cleaned and shaped.



Irrigate chamber



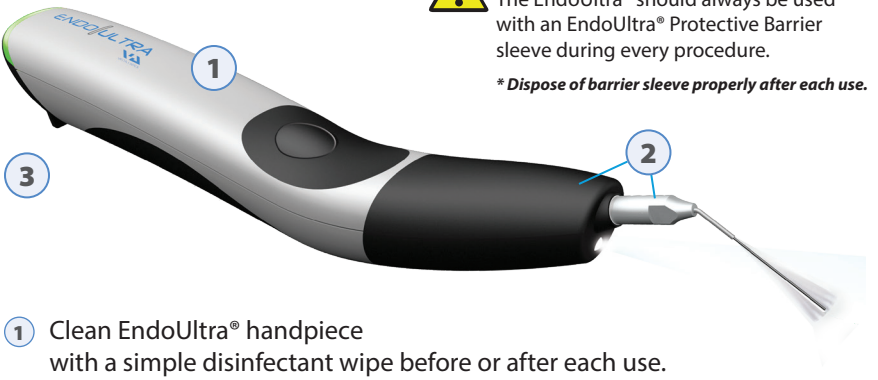
Insert Activator tip

# MAINTENANCE & CARE

## *Disinfection*

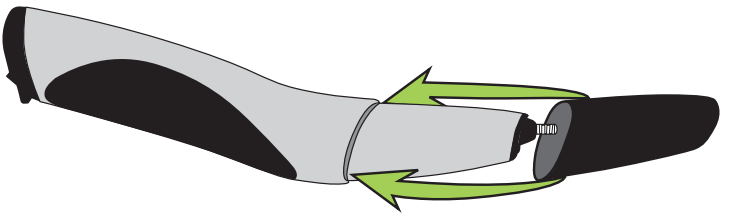
**PRECAUTIONS:**
The EndoUltra® should always be used with an EndoUltra® Protective Barrier sleeve during every procedure.

**** 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® Tip Wrench provided. Replace sleeve as illustrated.



***NOTE:*** Follow detailed reprocessing instructions contained within these instructions for reprocessing activator tips and handpiece sleeves.

3. Monitor your battery charge level:

● Full Charge ● Partial Charge ● Low Battery

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

## *Maintenance*

The EndoUltra® Cordless Ultrasonic Activator is maintenance-free.
No periodic maintenance is required.

## *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. Follow all precautions and warnings from this instructions for use.

## *Cleaning the Handpiece & Charger*

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

**CAUTION:**
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.

## *Reprocessing the 20/02 Tips & Handpiece Sleeves*

Tips and sleeves must be reprocessed in accordance with the reprocessing instructions contained within this instructions for use. Tips and sleeves must be reprocessed prior to initial use and between each use to minimize patient to patient cross contamination.

## *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

Order these accessories on our website (http://www.vistaapex.com), or check with your preferred dealer for product availability.

| Accessory | Manufacturer SKU |
|---|---|
| **Titanium Activator Tips** 3/pk, 20/02 | 407706 |
| **Replacement Nosecones** 2/pk | 407709 |
| **Disposable Protective Barriers** 100/pk | 407719 |
| **Tip Wrench** | 407711 |
| **Replacement USB Wall Adapter** (1) USB Wall Charger, (1) Micro USB Charging Cord | 4037 |
| **USB to Micro USB Adapter** | 4017 |

# DISPOSAL

**Disposal of Unit**

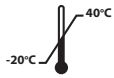
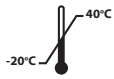
U.S. - Dispose of the system components in accordance with state and local laws.

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

| TECHNICAL INFORMATION | ENDOULTRA® CORDLESS ULTRASONIC ACTIVATOR | | |
|---|---|---|---|
| **Tip Materials** | Titanium | | |
| **Charger** | **Input:** 90-264 V, 50-60 Hz | | |
| | **Nominal Consumption:** 0.5 A max | | |
| | **Output:** 5.0 V, 2.0 A max | | |
| | **Manufacturer:** GlobTek INC. | | |
| | **Model:** GTM46101-1005-USB | | |
| | **Dimensions without blade or cable (LxWxH):** 41mm x 71mm x 31.5mm | | |
| | **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 Pack Manufacturer:** Tenergy Battery Co | | |
| | **Battery Pack Model:** Li-ion 3.7 14500-800mAh | | |
| | **Dimensions (LxWxH):** 180mm x 26mm x 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 & Handpiece** | **Time to Charge Empty Battery:** Approximately 4 hrs. | | |
| | **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:** 10°C - 40°C (59°F - 104°F)   | **Relative Humidity:** 30% - 90% (non condensing)   | **Atmospheric Pressure:** 697hPa - 1013hPa   |

ENDO ULTRA®

# TROUBLESHOOTING GUIDE

If the suggested solutions do not rectify the problem, please call Vista Apex +1-877-418-4782 (Toll Free).

| PROBLEM | POSSIBLE CAUSES | ACTION |
|---|---|---|
| **LED light does not illuminate** | • *Insufficient battery charge.*<br>• *Handpiece turned off.* | • Plug handpiece into USB wall charger (if after several minutes, charger indicator does not come on, the battery may be expired).<br>• Contact your distributor. |
| **Handpiece ON/OFF button does not work** | • *Insufficient battery charge.*<br>• *Handpiece turned off.* | • Plug handpiece into USB wall charger (if after several minutes, charger indicator does not come on, the battery may be expired).<br>• Contact your distributor. |
| **Battery does not recharge** | • *Power cord is not seated properly. Fully insert USB cord into unit and wall adapter.*<br>• *Handpiece turned off.* | • Verify power cord is seated properly in wall outlet.<br>• 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.*<br>• *Activator tip may be bent improperly, fractured or not bent at all.* | • Tighten tip with the tip wrench provided.<br>• Replace Activator tip and consult tip bending instructions. |
| **EndoUltra® Tip will not activate, and LED light is OFF** | • *Insufficient battery charge.*<br>• *Handpiece turned off.* | • Plug handpiece into USB wall charger (if after several minutes, charger indicator does not come on, the battery may be expired).<br>• Contact your distributor. |
| **Short battery life** | • *Battery is not full charged.*<br>• *Replacement battery needed.* | • Bring device to full charge.<br>• Consult your distributor. |

# VISTA APEX TERMS & CONDITIONS OF WARRANTY

The operator assumes all risk and liability for damages arising out of the improper use of Vista Apex's product. In the event of a defect in material or workmanship, Vista Apex's liability is limited, at Vista Apex'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 Apex.

The EndoUltra® Cordless Ultrasonic Activator 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 Apex 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 Apex will accept for return previously purchased merchandise which is suitable for resale or that which was shipped in error by Vista Apex. 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 Apex 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.

| RESTOCKING POLICY | |
|---|---|
| **30 days** | 15% |
| **31-60 days** | 25% |
| **60+ days** | Not Returnable |

Equipment cannot be returned without written authorization from Vista Apex. Any equipment returned within 30 days from the date of the original shipment from Vista Apex 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 Apex 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 Apex 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 damage must be made to Vista Apex within 10 days of receipt of goods.

***Please complete enclosed warranty card and return electronically or by mail.***

# ADDITIONAL INFORMATION

## 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 device MUST NOT be used in the presence of flammable or potentially explosive gases or vapors that might catch fire and cause damage.

In case these materials have to be used let the vapors completely disperse before turning on the device.

## SYSTEM MODIFICATIONS OR UPGRADES:

- Modifications or upgrades of the system can be carried out only by Inter-Med, Inc. and performed by authorized and qualified personnel, using ONLY genuine original spare parts of Inter-Med, Inc.. Device is NOT serviceable by operator.
- Inter-Med, Inc. concludes that improper, unauthorized modifications or upgrades of the device, are prohibited and may result in unintended malfunctions that may cause risks and danger to patients, operators, and/or equipment. Inter-Med, Inc. 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 this could result in endangering 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 30cm (12 inches) to any part of the equipment, including cables specified by the manufacturer. Othewise, degradation of the performance of this equipment will result.
- **WARNING:** If the use location is near (i.e. 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 Tables*

**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 fluctations and flicker | IEC 61000-3-3 Compliance | Professional healthcare facility environment |

**Table 2 -** Enclosure Port

| PHENOMENON | BASIC EMC STANDARD | IMMUNITY TEST LEVELS |
|---|---|---|
| | | PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT |
| Electrostatic discharge | IEC 61000-4-2 | ± 8 kV contact<br>± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air |
| Radiated RF EM field | IEC 61000-4-3 | 3 V/m<br>80 MHz-2.8 GHz<br>80% AM at 1 kHz |
| Proximity fields from RF wireless communications equipment | IEC 61000-4-3 | Refer to Table 3 |
| Rated power frequency magnetic fields | IEC 61000-4-8 | 30 A/m<br>50 Hz or 60 Hz |

**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 18 Hz, 27 V/m |
| 450 | 430-470 | FM, ±5 kHz deviation, 1 kHz sine, 28 V/m |
| 710 | 704-787 | Pulse modulation 217 Hz, 9 V/m |
| 745 | | |
| 780 | | |
| 810 | 800-960 | Pulse modulation 18 Hz, 28 V/m |
| 870 | | |
| 930 | | |
| 1720 | 1700-1990 | Pulse modulation 217 Hz, 28 V/m |
| 1845 | | |
| 1970 | | |
| 2450 | 2400-2570 | Pulse modulation 217 Hz, 28 V/m |
| 5240 | 5100-5800 | Pulse modulation 217 Hz, 9 V/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<br>100 kHz 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 | 3 V, 0.15 MHz-80 MHz<br>6 V in ISM bands between 0.15 MHz and 80 MHz<br>80% AM at 1 kHz |
| Voltage dips | IEC 61000-4-11 | 0% $U_T$; 0.5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° |
| | | 0% $U_T$; 0.5 cycle<br>and<br>70% $U_T$; 25/30 cycles<br>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 | 3 V, 0.15 MHz-80 MHz<br>6 V in ISM bands between 0.15 MHz and 80 MHz<br>80% AM at 1 kHz |

# REPROCESSING INSTRUCTIONS

| | |
|---|---|
| **Manufacturer:** | **Inter-Med, Inc.** |
| **Device:** | **EndoUltra® & Accessories** |
| **WARNINGS** | • Appropriate PPE (gloves, safety glasses, scrubs or lab coat) should be worn when reprocessing medical devices.<br>• Electronic devices should never be submerged or soaked in any cleaning solution.<br>• Electronic devices should never be autoclaved.<br>• Do not disassemble electronic devices.<br>• Do not use water on electronic devices.<br>• Do not use abrasive cleaners.<br>• Use neutral pH detergents during cleaning.<br>• Do not use with commercial sterilization wraps or pouches with sterilization indicators that leave a stain.<br>• For autoclavable products, do not sterilize with other products. Do not allow products to touch one another during autoclaving.<br>• Reprocess products as soon as possible after use.<br>• It is the user's responsibility to ensure that all reprocessing equipment used is properly validated, maintained, and calibrated in accordance with equipment specification and requirements.<br>• Reference should be made to the device's instructions for use / user manual for additional information which may be applicable to reprocessing. |
| **Limitations on process:** | • The products should be thoroughly inspected and tested for functionality after each reprocessing cycle. Devices should be replaced if any visible wear is seen, or if any noticeable decrease in product functionality is observed. Operator use and care will impact how long product will last. Contact Vista Apex with any questions.<br>• Vista Apex has validated the following number of reprocessing cycles for the products:<br>- EndoUltra® Handpiece Sleeves: 80 cycles<br>- EndoUltra® Tips: 20 cycles |

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# REPROCESSING INSTRUCTIONS *(continued)*

| | |
|---|---|
| **INSTRUCTIONS** | • Following clinical use, immediately wipe clean any visible debris or contamination using a lint free cloth, which may be dampened with deionized water.<br>• For non-electrical devices or accessories, the product should be immediately rinsed with water to remove debris.<br>• For non-electrical devices or accessories, if reprocessing cannot be performed immediately, soak product in a mild, pH-neutral detergent until cleaning can be performed and maintain separation of soiled product from non-contaminated devices to avoid cross-contamination. DO NOT soak or submerge electronic devices.<br>• If reprocessing cannot be performed immediately, maintain separation of soiled product from non-contaminated devices to avoid cross-contamination. |
| **Preparation before cleaning:** | • No disassembly is required for reprocessing. Do not attempt to disassemble product.<br>• Remove any visible gross debris and wipe using a lint free cloth. For non-electronic devices or accessories, water may also be used. |
| **Cleaning & Disinfection:**<br>***Automated*** | • For non-electronic devices and accessories, it is recommended to use a washer-disinfector meeting the requirements of ISO 15883. Products should be positioned such that they do not make physical contact with other parts in the washer-disinfector. Use a neutral-pH based cleaning agent. There are no known constraints on pressures and temperatures.<br>**NOTE:** Electronic devices should never be placed in an automated washer-disinfector and should never be submerged or exposed to free flowing cleaning agents or water. |

# REPROCESSING INSTRUCTIONS *(continued)*

| | |
|---|---|
| **Cleaning & Disinfection:**<br>***Manual*** | • If cleaning and disinfecting the device manually, thoroughly wipe device using a single-use cloth dampened with a pH-neutral, aldehyde and alkylamine-free, alcohol-based, bactericidal, virucidal, fungicidal disinfectant solution (e.g. Alpet D2 Disinfectant or equivalent) following the manufacturer's instructions for use. Wipe device on all surfaces. Redampen cloth as needed.<br>• After 1-3 minutes of contact time, remove the disinfectant solution residue with a damp cloth. Use deionized water to dampen cloth.<br>**NOTE:** Any lumens, grooves, or fluid paths should be cleaned in an equivalent manner using an appropriately sized non-abrasive cleaning brush following the same steps above.<br>**NOTE:** Particular attention and care should be taken when cleaning around electronic connectors. When possible, disconnect the device from power (i.e. mains or battery). Do not stick any damp or wet material into any electronic connector or port. |
| **Drying:** | • Dry with gauze or lint-free cloth. Air dry until liquid is no longer present (approximately 30 minutes). |
| **Maintenance, inspection and testing:** | • Thoroughly inspect and test the product for functionality after each reprocessing cycle. Confirm product is free of debris and not damaged. Devices should be replaced if any visible wear is seen, or if any noticeable decrease in product functionality is observed. |
| **Packaging:** | • No special packaging is required for sterilization.<br>**NOTE:** Electronic devices should never be placed in autoclave. Do NOT autoclave electronic devices. Devices should be stored within the original package, or in a cool dry location, prior to subsequent use. |
| **Sterilization:** | • For non-electronic devices and accessories, moist heat sterilize in accordance with ISO 17665-1 at 132°C or 134°C, 0.22mPa for at least 3 minutes (20 minute dry time).<br>**NOTE:** Electronic devices should never be placed in autoclave. Do NOT autoclave electronic devices. |

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## REPROCESSING INSTRUCTIONS *(continued)*

| | |
|---|---|
| **Storage:** | • Store in a clean and dry location. Maintain separation of soiled from non-contaminated devices to avoid cross contamination. |
| **Additional information:** | No additional information needed for reprocessing. |
| **Manufacturer contact:** | **Inter-Med, Inc.**<br>2200 South Street<br>Racine, WI 53404 USA<br>+1-262-636-9755<br>info@vista-dental.com |

## NOTES

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