

REF 90734

  
pinkwave™

User's Manual

For use by qualified professionals only.



VISTA APEX

This manual must be read thoroughly and understood prior to using the PinkWave™ Curing Light.

**Procedure Pack Assembled by:**

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Tel.: +1-262-636-9755  
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Toll Free: +1-877-418-4782



**Rx ONLY**



**Emergo Europe**  
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91037-I-AP-ENG (14)

*A majority of major components are Made in Israel. Final construction performed in USA.*

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## IMPORTANT!

**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.

## INTRODUCTION

### Welcome to PinkWave™

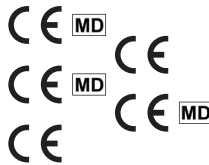
Congratulations on your decision to incorporate the PinkWave™ Curing Light into your practice. Vista Apex's PinkWave™ Curing Light uses multiple wavelengths (375-900nm) to cure mostly all polymerizable dental materials, making it one of the most versatile curing lights on the market. The PinkWave™ will greatly enhance the way you cure light cured dental materials, and is lightweight, easy to use, and most importantly clinically effective.

Our website, [vistaapex.com](http://vistaapex.com), provides information on new products, accessories, and educational assistance for you and your professional staff. If you have any questions regarding the use of the PinkWave™, please call our customer service department at 877-273-9123 (Toll Free).

### Contents of the PinkWave™ Curing Light Kit

The PinkWave™ Curing Light Kit is composed of the following:

- (1) Cordless handpiece
- (1) Charging base
- (100) Disposable barrier sleeves
- (5) Autoclavable Light Shields
- (1) Pack of 5 Anti-Roll Brackets
- (1) Charging cord
- (1) Battery pack
- (1) Instructions for Use
- (3) Protective Eyewear\* (*provided separately with each kit*)



**All Procedure Pack  
Components Manufactured by:**



**Inter-Med, Inc.**  
2200 South St.  
Racine, WI 53404 U.S.A.  
**Tel.:** +1-262-636-9755  
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[www.vistaapex.com](http://www.vistaapex.com)

**A majority of major  
components are Made in Israel.  
Final construction  
performed in USA.**

**NOTE:** All components are non-sterile.

\* *The PinkWave™ Paddle can be used instead of the Protective Eyewear provided with this kit.*

**NOTE:** 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.

## ***Intended Use / Indications for Use***

Source of illumination for curing photo-activated dental restorative materials and adhesives.

## **PINKWAVE™ SET-UP AND USE**

### ***Unpacking the Container***

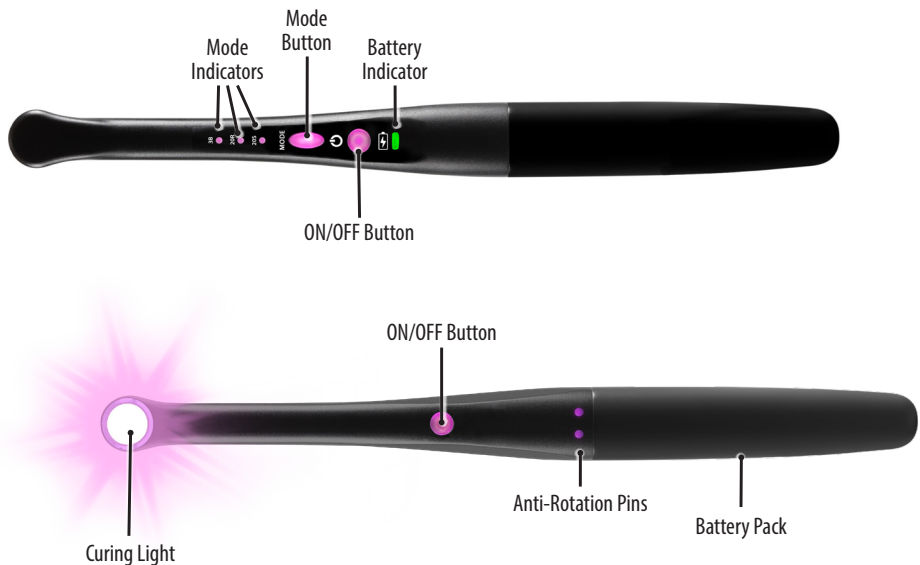
No special assistance is required to unpack and assemble the PinkWave™.

If you have questions or concerns, please visit [vistaapex.com](http://vistaapex.com) or call Vista Apex at 877-418-4782 (Toll Free).

Packaging should be inspected upon arrival for evidence of shipping damage. Damaged packaging may indicate the presence of an unsafe product and the product should not be used until carefully inspected. If the package or product is damaged, please contact Vista Apex at 877-418-4782 (Toll Free), as well as the delivery service to file a complaint.

### ***Introduction to the PinkWave™***

Please reference the image below to familiarize yourself with the PinkWave™.



## Attaching/Detaching the Battery Pack to the Handpiece

1. Insert the battery pack into the handpiece. Allow the threads to catch onto each other and then screw on clockwise.
2. When the battery pack and handpiece are correctly screwed in, the unit will beep multiple times.
3. **NOTE:** The battery pack is threaded and can only be inserted into the handpiece in one orientation! The battery pack should be easy to insert.



## Attaching and Removing the Barrier Sleeve

1. Insert the head of the PinkWave™ Curing Light into the opening on the bottom of the barrier sleeve.
2. Slide the barrier sleeve onto the PinkWave™ Curing Light to cover the entire device.
3. After use, peel off and dispose of the barrier sleeve.

**NOTE:** Only PinkWave™ Disposable Barrier Sleeves should be used on the PinkWave™ Curing Light. Barrier sleeves are for single use only.

## Using the Autoclavable Light Shields

1. Slide light shield over the barrier sleeve and head of PinkWave™.
2. Light shield opening should be facing the same way as the lens.
3. Light shield should be secured on the device and replicate the image below.



**NOTE: DO NOT** operate PinkWave™ without the Autoclavable Light Shield, and either the Vista Apex Protective Eyewear or PinkWave™ Paddle.

## Charging the Battery Pack

1. The PinkWave™ battery packs are partially charged when shipped. Before you turn on and start using the device, you must insert the battery pack into the handpiece and fully charge the battery pack before using it for the first time. The battery pack will be fully charged within three hours.
2. When the battery pack is charging, the light on the charging base will pulsate. Once charging is complete, the light on the charging base will stop pulsating and remain lit.



Pulsating  
Pink Light  
**CHARGING**



Solid  
Pink Light  
**FULLY  
CHARGED**

The handpiece is designed to display the battery state to the user via the battery indicator light.

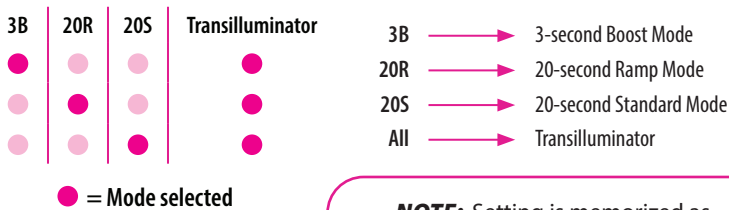
- When the battery pack is greater than 33% charged the indication lights will be solid **Green** during use.
- When the battery pack is less than 33% charged, the light will blink **Red** during use, indicating the handpiece needs to be charged as soon as possible. Once the blinking **Red** light comes on, you will have approximately 20 curing cycles left before light is completely dead.
- When the handpiece is not in use, the induction charging base securely stores and charges the PinkWave™ unit.

# PINKWAVE™ OPERATION

## Selecting Your Curing Mode

1. The curing modes are selected via the button on the top of the device.
2. Toggle through modes by pressing the mode button.
3. The current mode will light up bright pink when it has been selected. This setting will remain the default setting until a new setting is selected.
4. On standard and ramp mode, the light will beep once at 5 seconds, twice at 10 seconds and three times at 15 seconds.

The figure below illustrates the light position based on the current mode.



**NOTE:** Setting is memorized as default until charged.

## Quick Curing Guide

	Standard Mode	Ramp Mode	Boost Mode
<b>Irradiance (mW/cm<sup>2</sup>)</b>	>1515	>1515	>1720
<b>Per 2 mm Layer</b>	One 10s cure	One 20s cure	One 3s cure
<b>Final Cure</b>	One 20s cure	One 20s cure	Two 3s cures

**NOTE:** Curing time may need to be adjusted due to composite, shade, depth of layer if over 2mm.

**NOTE:** These are default curing durations for the PinkWave™ Curing Light. Follow composite / dental material manufacturer's guidelines for required curing durations and irradiance values.

**NOTE:** Place the PinkWave™ Curing Light as close as possible to dental material. Irradiance rapidly decreases with increasing distance.

**NOTE:** Software will automatically turn the PinkWave™ handpiece off if left on for two continuous minutes in white light / transilluminator mode.

**NOTE:** Software does not allow for the handpiece to be used when in the charging base.

## **Transillumination Mode**

The transillumination mode can be executed by toggling through modes until all lights are illuminated and pressing the ON/OFF button. The transillumination light is turned off the same way, by pressing the ON/OFF button.

## **Disinfection / Sterilization**

The PinkWave™ Curing Light is provided non-sterile. There are not any special accessories needed to sterilize the PinkWave™ Curing Light parts. Follow detailed reprocessing instructions for cleaning and sterilizing the Light Shields and Anti-Roll Brackets.

ALWAYS use a single use disposable barrier sleeve on the PinkWave™ Curing Light and dispose of the single use disposable barrier sleeve after each patient. Do NOT reuse single use disposable barrier sleeves as that may result in patient cross contamination.

Clean the PinkWave™ Curing Light with an approved surface disinfectant solution such as a quaternary ammonium compound product that contains 20% alcohol or less. Wipe, do not spray, solution and follow the manufacturer's cleaning recommendations. Prevent liquids from entering openings on the unit.

**For Protective Eyewear:** Clean Protective Eyewear lens with water only. Use a soft cotton or microfiber cloth and gently pat lens dry. Do not use abrasive cleaning compounds, solvents, ammonia or alkaline cleaners.

**For PinkWave™ Paddle: DO NOT** autoclave the paddle. Autoclaving the paddle may cause damage. For cleaning the paddle in between patients, apply an appropriate medical grade surface disinfectant (e.g. Cavicide) to all surfaces of the paddle using a lint-free wipe per the disinfectant's instructions.

**NOTE: DO NOT** autoclave the handpiece, battery pack, charging base or PinkWave™ Paddle.



**CAUTION: DO NOT** immerse the unit or unit parts in solutions. Use of solutions other than those recommended may damage plastic parts and will void product warranty.



**CAUTION: DO NOT** use abrasive material such as scouring powder, organic solvents, or solvent-based cleaning fluids. In case of severe contamination, gently clean the device by using diluted alcohol.

Store the device in the box if it is not to be used for an extended period of time. Disassembly is not required when cleaning the handpiece and charging base.

## Infection Control Measures



**CAUTION:** To prevent cross-contamination, a disposable plastic sleeve must be used over the PinkWave™ with each use. A low-density polyethylene plastic disposable barrier covers the entire unit and provides a hermetically sealed barrier between the handpiece and patients. The disposable barrier limits patient-to-patient contamination. **Discard used barrier sleeves after each patient.**

## Routine Maintenance

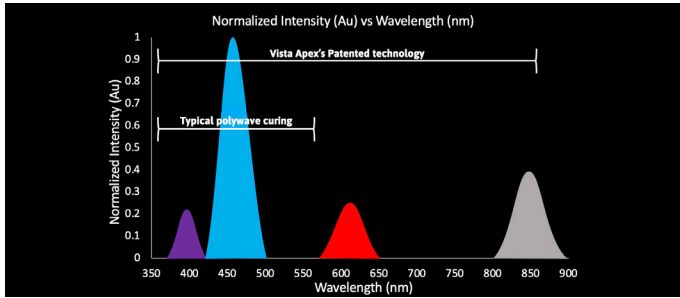







Periodically check the lens for cured dental resins. If necessary, carefully remove any adhered resin using a non-diamond dental hand instrument. The barrier sleeve helps keep dental materials from adhering to the surface of the lens.

## TROUBLESHOOTING GUIDE

If the suggested solutions do not rectify the problem, please call Vista Apex at 877-273-9123 (Toll Free).





















PROBLEM	POSSIBLE SOLUTION
<b>Light will not turn on</b>	<ol style="list-style-type: none"> <li>1. Check the unit's indication light. If red, place the handpiece on the charging base.</li> <li>2. Remove the battery pack and inspect for any defects if none are found reconnect the battery pack. A beep should be heard when the battery pack is inserted.</li> </ol>
<b>Light is not curing properly</b>	<ol style="list-style-type: none"> <li>1. Verify the unit provides adequate optical power using a radiometer.</li> <li>2. Verify that the appropriate curing mode is selected.</li> <li>3. With the handpiece turned off, and the battery pack removed, inspect the lens for residual cured composites/resins.</li> <li>4. Check expiration date of composite/resin.</li> </ol>
<b>Batteries will not charge</b>	<ol style="list-style-type: none"> <li>1. Remove the battery pack and inspect for any defects, if none are found reconnect the battery pack.</li> <li>2. Make sure the battery pack is properly connected to the handpiece.</li> <li>3. Make sure the charger is plugged in and verify the outlet is receiving power.</li> <li>4. Lights on charger should pulsate.</li> </ol>

# TECHNICAL DATA

TECHNICAL INFORMATION	PINKWAVE™ CORDLESS LED CURING LIGHT	
<b>Wavelength Range</b>	PinkWave™ optical power falls between 375-900nm (see graph below). <div data-bbox="274 423 958 719" style="text-align: center;">  </div>	
<b>Irradiance</b>	<b>Standard:</b> > 1515 mW/cm <sup>2</sup> , <b>Ramp:</b> > 1515 mW/cm <sup>2</sup> , <b>Boost:</b> > 1720 mW/cm <sup>2</sup> ,	
<b>Charger</b>	<b>Input:</b> 100-240 VAC, 50-60 Hz	<b>Nominal Consumption:</b> 6W max
	<b>Manufacturer:</b> Inter-Med, Inc.	<b>Model:</b> PinkWave™
	<b>Dimensions without adapter (DxH):</b> 87mm x 58mm	<b>Mass:</b> 175g
<b>Classification:</b> Protection class II, 		
<b>Handpiece</b>	<b>Battery:</b> 3.7 V nominal, 950mAh Li-ion	
	<b>Battery Pack Manufacturer:</b> HIBATT	<b>Battery Pack Model:</b> IMR14650
	<b>Dimensions (LxD):</b> 230mm x 20mm	<b>Mass:</b> 88g
	<b>Classification:</b> Type BF, 	
<b>Intermittent Operation:</b> The device has been designed solely for short-term operation. Typical operating time at room temperature (23°C): 3-20 sec (depending on mode) per layer of composite.		
<b>Operating Time:</b> Approximately 60 20-second cures.		
<b>Operating Conditions</b>	<b>Time to Charge Empty Battery Pack:</b> Approximately 3 hours	
	<b>Temperature:</b> 10°C - 40°C (59°F - 104°F) <div data-bbox="396 1222 481 1284" style="text-align: center;">  </div>	<b>Atmospheric Pressure:</b> 697hPa - 1013hPa <div data-bbox="724 1222 809 1284" style="text-align: center;">  </div>
<b>Transport and Storage Conditions</b>	<b>Temperature:</b> -20°C - 40°C (-4°F - 104°F) <div data-bbox="572 1320 657 1382" style="text-align: center;">  </div>	
	<b>Relative Humidity:</b> 30% - 90% (non condensing) <div data-bbox="380 1433 466 1495" style="text-align: center;">  </div>	<b>Atmospheric Pressure:</b> 500hPa - 1400hPa <div data-bbox="724 1433 809 1495" style="text-align: center;">  </div>

## SYMBOL IDENTIFICATION

Description for additional symbols.

	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		Batch Code / Lot Number
	Keep Dry		European Representative
	Part Number		Do not use if seal or packaging is compromised.
	This symbol is a mandatory marking for devices entering the European market to indicate conformity with the essential health and safety requirements set out in European Regulations.		<b>CAUTION:</b> 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.
	Warning / Caution		Autoclavable up to the temperature specified.

## BATTERY PACK DISPOSAL

When disposing of electronic waste (ie. curing lights, charger, batteries and power supplies), follow local waste and recycling guidelines. Batteries contain toxic material and should not be disposed of in landfills or incinerators. Dispose of depleted batteries as directed by your local solid waste handling regulations.

To dispose of the battery pack, we recommend [www.call2recycle.com](http://www.call2recycle.com) (for North America) to locate a recycling facility near you.

## SAFETY NOTES, WARNINGS AND PRECAUTIONS

Read all instructions before operating this unit. The PinkWave™ LED Curing Light emits high intensity light waves and must only be used as indicated in this manual.

### **Safety Notes**

The PinkWave™ Curing Light is a medical device which is subject to IEC 60601-1 (EN 60601-1) and EMC directives IEC 60601-1-2 (EN 60601-1-2) Edition 4.0, as well as the 93/42/EEC Medical Device Directive. The curing light complies with the relevant EU regulations.

The curing light has been shipped from the manufacturer in a safe and technically sound condition. In order to maintain this condition and to ensure risk-free operation, the notes and regulations in these Instructions for Use have to be observed. To prevent damage to equipment and risks for patients, users and third parties, the following safety instructions have to be observed.



### **WARNING**

- The user should test the product before use to ensure proper functionality.
- The user should test the PinkWave™'s optical power using a radiometer prior to use.
- An irradiance value 800-1750 mW/cm<sup>2</sup> is acceptable for standard and ramp modes, and a value 1350-3300 mW/cm<sup>2</sup> is acceptable for boost mode.
- The irradiance value should be measured at 10s within a 20s cycle for standard and ramp modes.
- As with any heavily used medical device, the user needs to ensure a functional backup is readily available.
- **DO NOT** look directly into the light output. The Autoclavable Light Shield should always be used. Only Vista Apex provided Protective Eyewear or PinkWave™ Paddle should be used.
- **DO NOT** expose soft oral tissues at close proximity. Maintain a safe distance between the lens and the soft tissue.
- If using the PinkWave™ Curing Light in the Standard Mode and in close proximity of the gingival tissue, **DO NOT** expose tissue for more than 20 seconds.
- In Boost Power Mode, **DO NOT** expose soft oral tissue for more than 9 seconds (3 cycles).
- **DO NOT** autoclave the handpiece, battery pack or charging base.
- U.S. Federal law restricts the sale of this device by or on the order of a healthcare professional. Use of the device is restricted to qualified and trained personnel only in accordance with the instructions below. The manufacturer assumes no liability for any damage arising from any other or improper use of this device.

- Use only the charger that is provided with the device, cable type for this device is NEMA1-15 to IEC 320 C7 (non-polar). The use of any other charger can result in damage to the battery pack.
- 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.
- There are no user-serviceable items in this handpiece or charger. No modification of this equipment is allowed.
- In order to avoid electric shock, do not introduce any objects into the device or remove the device enclosure.
- 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. Safety may be compromised, e.g., if the device malfunctions or is noticeably damaged.
- 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.
- According to IEC 60601-1, this device must not be used in the presence of flammable mixtures.
- Do not allow any cleaning agents to enter the device during cleaning as they could cause an electrical short or a dangerous malfunction.
- Only Vista Apex may open the device housing and repair the device.
- UV emitted from this product. Eye or skin irritation may result from exposure. Use appropriate shielding.
- IR emitted from this product. Do not stare at operating lamp.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- Use only components and accessories listed in the instructions associated with the device. Failure to do so will void the warranty, may decrease the performance, and may lead to unsafe operation. Other cables may negatively affect EMC performance of the device.
- 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.

- PinkWave™ 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.
- 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:
  - Reorient or relocate the receiving device.  
Avoid stacking with other equipment.
  - Increase the separation between the devices.
  - Connect the device into an outlet on a circuit different from that to which the other device(s) are connected.
  - Consult the manufacturer for help.
- 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 PinkWave™, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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## OPERATING CONDITIONS AND SAFETY CONSIDERATION

### *Heat Generation*

The metal parts of the PinkWave™ Curing Light do not overheat to the point of discomfort or injury during standard operating durations (i.e. five consecutive standard mode, ramp mode or boost mode cures). However, care should be taken to allow the product to completely cool to room temperature between patients (approximately two minutes), to ensure overheating does not occur.



**CAUTION:** The PinkWave™ consists of high powered LEDs in the range of 375 – 900nm. The device's intended use is within the oral cavity and is to be used with the protective light shield.

## ***Safety Eyewear***

Please only use Vista Apex supplied Protective Eyewear or PinkWave™ Paddle.

Anyone with a history of retinopathy should consult their eye specialist before operating this unit. Use the PinkWave™ Curing Light extremely carefully and comply with all the necessary safety precautions (including wearing suitable, light filtering safety glasses).

Anyone who has had a cataract operation may be especially sensitive to light and should be advised against undergoing treatment with a PinkWave™ Curing Light unless adequate safety precautions are taken such as wearing suitable, light filtering safety glasses.

## ***Adverse Reactions***

There are no known adverse reactions.

## ***Contraindications***

Patients with a history of photosensitivity or photophobia or those using photosensitive medications (such as antimalarial drugs, chlorpromazine, St. John's wort, dimethyl-chlorotetracycline and 8-methoxypsoralen) are contraindicated for PinkWave™ Curing Light, and should not be exposed to the light emitting tip of the PinkWave™ Curing Light.

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# **VISTA APEX TERMS AND CONDITIONS OF WARRANTY**

The operator assumes all risk and liability for damages arising out of the improper use of the PinkWave™ Curing Light. In the event of a defect in material or workmanship, Vista Apex is limited, at its option, to replace of the defective product, a 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 PinkWave™ handpiece is warranted to be free from defects under normal usage conditions for 3 years of its date of delivery; the batteries for 1 year. 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(s) or 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 the product unless the return is authorized and shipped in accordance with the manufacturer's instructions. Contact the local representative of the distributor or if purchased directly from the manufacturer for shipping instructions, a return authorization number, and 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.

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## RETURN POLICY

<b>30 days</b>	15%
<b>31+59 days</b>	25%
<b>60+ days</b>	Not Returnable

Vista Apex will accept for return previously purchased merchandise which is suitable for resale or 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.

Equipment cannot be returned without written authorization from Vista Apex. Merchandise returned for credit must be received by Vista Apex within 30 days of the original invoice date.

### ***Return Stock Policy***

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- 60 days from the date of the original shipment from 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 the original shipment from Vista Apex will not be restockable for credit.

- 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

## REPROCESSING INSTRUCTIONS

<b>Manufacturer:</b>	<b>Inter-Med, Inc.</b>
<b>Device:</b>	<b>PinkWave™ &amp; Accessories</b>
<b>WARNINGS</b>	<ul style="list-style-type: none"> <li>• Appropriate PPE (gloves, safety glasses, scrubs or lab coat) should be worn when reprocessing medical devices.</li> <li>• Electronic devices should never be submerged or soaked in any cleaning solution.</li> <li>• Electronic devices should never be autoclaved.</li> <li>• Do not disassemble electronic devices.</li> <li>• Do not use water on electronic devices.</li> <li>• Do not use abrasive cleaners.</li> <li>• Use neutral pH detergents during cleaning.</li> <li>• Do not use with commercial sterilization wraps or pouches with sterilization indicators that leave a stain.</li> <li>• For autoclavable products, do not sterilize with other products. Do not allow products to touch one another during autoclaving.</li> <li>• Reprocess products as soon as possible after use.</li> <li>• 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.</li> <li>• Reference should be made to the device's instructions for use / user manual for additional information which may be applicable to reprocessing.</li> </ul>
<b>Limitations on process:</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Vista Apex has validated the following number of reprocessing cycles for the products: <ul style="list-style-type: none"> <li>- PinkWave™ Silicone Shields &amp; Anti-Roll Brackets: 80 cycles</li> </ul> </li> </ul>

## REPROCESSING INSTRUCTIONS *(continued)*

<p><b>INSTRUCTIONS</b></p>	<ul style="list-style-type: none"> <li>• Following clinical use, immediately wipe clean any visible debris or contamination using a lint free cloth, which may be dampened with deionized water.</li> <li>• For non-electrical devices or accessories, the product should be immediately rinsed with water to remove debris.</li> <li>• 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.</li> <li>• If reprocessing cannot be performed immediately, maintain separation of soiled product from non-contaminated devices to avoid cross-contamination.</li> </ul>
<p><b>Preparation before cleaning:</b></p>	<ul style="list-style-type: none"> <li>• No disassembly is required for reprocessing. Do not attempt to disassemble product.</li> <li>• Remove any visible gross debris and wipe using a lint free cloth. For non-electronic devices or accessories, water may also be used.</li> </ul>
<p><b>Cleaning &amp; Disinfection:</b> <i>Automated</i></p>	<ul style="list-style-type: none"> <li>• 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.</li> </ul> <p><b>NOTE:</b> 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.</p>

## REPROCESSING INSTRUCTIONS *(continued)*

<p><b>Cleaning &amp; Disinfection:</b> <i>Manual</i></p>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• After 1-3 minutes of contact time, remove the disinfectant solution residue with a damp cloth. Use deionized water to dampen cloth. <ul style="list-style-type: none"> <li><b>NOTE:</b> 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.</li> <li><b>NOTE:</b> 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.</li> </ul> </li> </ul>
<p><b>Drying:</b></p>	<ul style="list-style-type: none"> <li>• Dry with gauze or lint-free cloth. Air dry until liquid is no longer present (approximately 30 minutes).</li> </ul>
<p><b>Maintenance, inspection and testing:</b></p>	<ul style="list-style-type: none"> <li>• 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.</li> </ul>
<p><b>Packaging:</b></p>	<ul style="list-style-type: none"> <li>• No special packaging is required for sterilization. <ul style="list-style-type: none"> <li><b>NOTE:</b> 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.</li> </ul> </li> </ul>

## REPROCESSING INSTRUCTIONS *(continued)*

<b>Sterilization:</b>	<ul style="list-style-type: none"><li>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).</li></ul> <p><b>NOTE:</b> Electronic devices should never be placed in autoclave. Do NOT autoclave electronic devices.</p>
<b>Storage:</b>	<ul style="list-style-type: none"><li>Store in a clean and dry location. Maintain separation of soiled from non-contaminated devices to avoid cross contamination.</li></ul>
<b>Additional information:</b>	No additional information needed for reprocessing.
<b>Manufacturer contact:</b>	<p><b>Inter-Med, Inc.</b> 2200 South Street Racine, WI 53404 USA +1-262-636-9755 info@vista-dental.com</p>

## APPENDIX – ELECTROMAGNETIC COMPATIBILITY AND SAFETY INFORMATION

The PinkWave™ Curing Light is tested according to IEC 60601-1-2, Edition 4.0. Medical electrical devices are subject to particular preventive action and must be installed and operated according to the EMC guidelines in the accompanying documents.

### Guidance and Manufacturer's Declaration – Electromagnetic Emission

The following tables are guidelines according to the 4th edition of the medical standard IEC 60601-1-2.

The PinkWave™ Curing Light is intended for use in the electromagnetic environment specified below. The customer or the user of the PinkWave™ Curing Light should assure that it is used in such an environment.

EMISSION TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RF emissions CISPR 11	Group 1	PinkWave™ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electrical equipment.
RF emissions CISPR 11	Class B	PinkWave™ is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies	N/A
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	N/A

Table: According to IEC 60601-1-2, Edition 4.0

### Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The PinkWave™ Curing Light is intended for use in the electromagnetic environment specified below. The customer or the user of the PinkWave™ Curing Light 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	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electric fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines	Mains power quality should be that of typical commercial or dental environment.
Surge IEC 61000-4-5	± 1 kV line to line ± 2 kV line to earth		Mains power quality should be that of typical commercial or dental environment.


IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Voltage dips, short interruptions and voltage variations on power supply input line IEC 61000-4-11	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycles		Mains power quality should be that of typical commercial or dental environment. If the user of the PinkWave™ requires continued operation during power mains interruptions, it is recommended that the PinkWave™ be powered from an uninterruptible power supply or battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or dental environment.
Portable and mobile RF communications equipment should not be used closer to any part of PinkWave™, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Conducted RF IEC 61000-4-6	3V, 6V	3Vrms, 6V	Portable and mobile RF communications equipment should be used no closer to any part of the PinkWave™ Curing Light, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance</b> $d = \left[ \frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[ \frac{12}{V_2} \right] \sqrt{P}$ $d = \left[ \frac{12}{E_1} \right] \sqrt{P}$ $d = \left[ \frac{23}{E_1} \right] \sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. D Interference may occur in the vicinity of equipment marked with the following symbol:  
Radiated RF IEC 61000-4-3	3V/m  3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz  3V/m from 80MHz to 2.7GHz	3V/m  3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz  3V/m from 80MHz to 2.7GHz	

Table: According to IEC 60601-1-2, Edition 4.0

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

**NOTE:** At 80 MHz and 800 MHz, the higher frequency range applies.

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

**a** - Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered.

If the measured field strength in the location in which the PinkWave™ is used exceeds the applicable RF compliance level above, the PinkWave™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PinkWave™.

**b** - Over the frequency range 150 kHz to 80 MHz, field strength should be less than 10 V/m.

## Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the “PinkWave™ Curing Light”

The PinkWave™ is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PinkWave™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PinkWave™ Curing Light as recommended below, according to the maximum output power of the communication equipment. In general, portable RF communications equipment may degrade performance if used closer than 30 cm (12 inches).

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the “PinkWave™ Curing Light”				
Rated Maximum Output Power of Transmitter (W)	Separation Distance According To Frequency of Transmitter (m)			
	150 kHz to 80 MHz outside ISM bands $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	150 kHz to 80 MHz in ISM $d = \left[\frac{12}{V_2}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{12}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{23}{E_1}\right]\sqrt{P}$
0.01	0.12	0.2	0.4	1
0.1	0.37	0.64	1.3	2.6
1	1.17	2	4	8
10	3.7	6.4	13	26
100	11.7	20	40	80

Table: According to IEC 60601-1-2, Edition 4.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**NOTE:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

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*\*Internal test data  
available upon request*