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.

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Rx ONLY

91037-I-AP-ENG(5)

pinkwave™

TABLE OF CONTENTS

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 (395 – 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.

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 877.418.4782 (Toll Free).

Contents of the PinkWave™ Kit

The PinkWave™ Curing Light Kit is composed of the following:
(1) Cordless handpiece
(1) Charging base
(100) Disposable barrier sleeves
(1) Instructions for Use
(5) Autoclavable light shields
(1) Charging cord
(1) Battery pack
(3) Protective Eyewear

NOTE: All components are non-sterile

Intended Use / Indications for Use

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

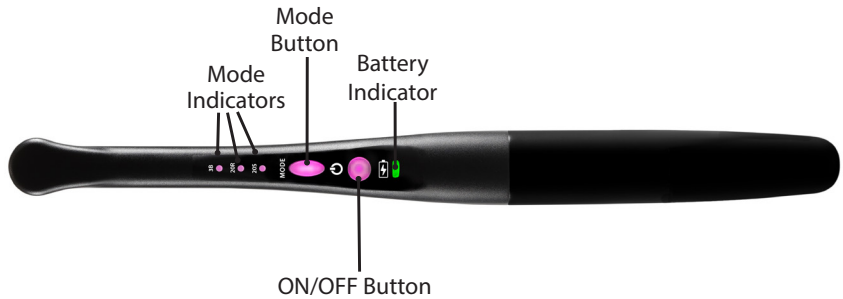
PinkWave™ Set-Up and Use

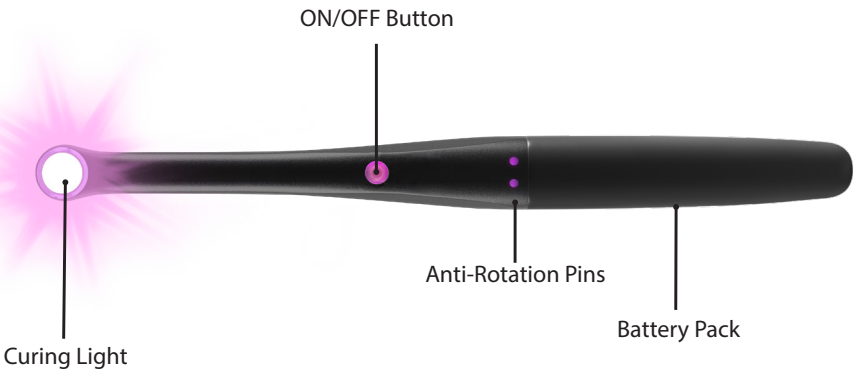
Unpacking the Container

No special assistance is required to unpack and assemble the PinkWave™.
If you have questions or concerns, please visit vistaapex.com 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 Dental Products 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! Do **NOT** try to screw the battery pack into the handpiece in the wrong 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: Barrier sleeves are for single use only.

NOTE: Only PinkWave™ Curing Light Barrier sleeves should be used on the PinkWave™ Curing Light.

Using the Autoclavable Light Shields

NOTE: DO NOT operate PinkWave™ without the light shield or protective eyewear.

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

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

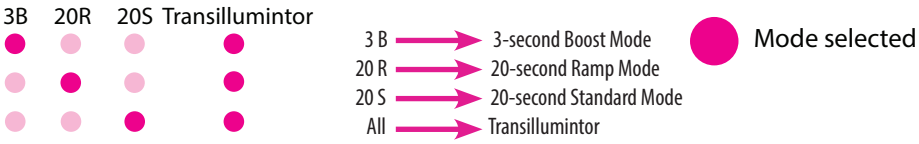
1. The curing modes are selected via the button on the top of the device.

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 changed

	Standard Mode	Ramp Mode	Boost Mode
Irradiance (mW/cm2)	>1515	>1515	>1720
Per 2 mm Layer	One 10s cure	One 20s cure	One 3s cure
Final Cure	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 and holding down 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.

Clean the PinkWave Curing Light, Protective Eyewear and Light Shields 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.
Note: The Light Shields can also be autoclaved. If you choose to autoclave The Light Shields, they should be autoclaved at 132˚C for 4 minutes. DO NOT autoclave the handpiece, battery pack, or charging base

DO NOT AUTOCLAVE PINKWAVE UNIT, BATTERY PACK OR CHARGING BASE.

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.

• **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 hand piece and patients. The disposable barrier limits patient-to-patient contamination. **Discard used barrier sleeves after each patient.**

Routine Maintenance

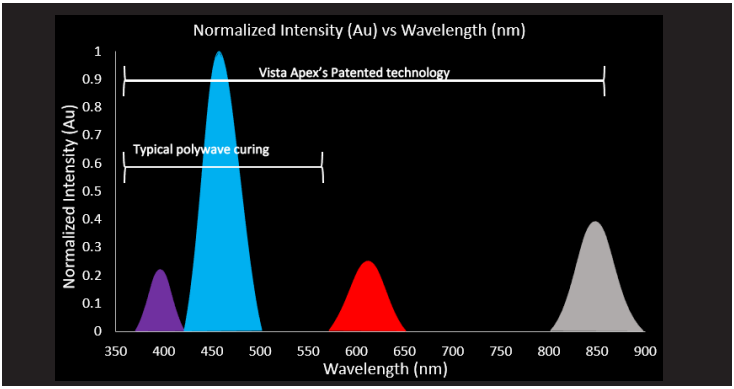
Periodically check the lens for cured dental resins. If necessary, carefully remove any adhered resin using a non-diamond dental hand instrument. The barrier sleeve helps keep dental materials from adhering to the surface of the lens.

Troubleshooting Guide

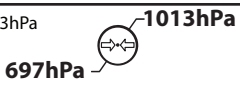
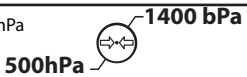
If the suggested solutions do not rectify the problem, please call Vista Apex 877.418.4782 (Toll Free).

Problem	Possible Solution
Light will not turn on	1. Check the unit's indication light. If red, place the handpiece on the charging base 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.
Light is not curing properly	1. Verify the unit provides adequate optical power using a radiometer 2. Verify that the appropriate curing mode is selected 3. With the handpiece turned off, and battery pack removed, inspect the lens for residual cured composites/resins 4. Check expiration date of composite/resin
Batteries will not charge	1. Remove the battery pack and inspect for any defects, if none are found reconnect the battery pack 2. Make sure the battery pack is properly connected to the handpiece 3. Make sure the charger is plugged in and verify the outlet is receiving power 4. Lights on charger should pulsate

Technical Data,

Technical Information	PinkWave™ Cordless LED Curing Light
Wavelength Range	PinkWave™ optical power falls between 395-900nm (see graph below). 

Technical Data, continued

Technical Information	PinkWave™ Cordless LED Curing Light
Irradiance	**Standard:** >1515mW/cm², **Ramp:** >1515mW/cm², **Boost:** >1720mW/cm²
Charger	**Input:** 100-240 VAC, 50-60 Hz
	Nominal Consumption: 6W max
	Manufacturer: Inter-Med, Inc.
	Model: PinkWave™
	Dimensions without adaptor (DxH): 87mm x 58mm
	Mass: 175g
	Classification: Protection class II, 
Handpiece	**Battery Pack:** 3.7 V nominal, 950mAh Li-ion
	Battery Manufacturer: HIBATT
	Dimensions (LxD): 230mm x 20mm, **Battery Model**: IMR 14650
	Mass: 88g
	Classification: Type BF, 
	Intermittent Operation: 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.
	Operating Time: Approximately 1 hr fully charged. Approximately 60 20 second cures.
Operating Conditions	**Time to Charge Emply Battery Pack:** Approx. 3 hrs.
	Temperature: 10°C - 40°C (59°F - 104° F) 
	Atmospheric Pressure: 697hPa-1013hPa 
Transport and Storage Conditions	**Temperature:** -20°C - 40°C (-4°F - 104° F) 
	Relative Humidity: 30%-90% (non-condensing) 
	Atmosperic Pressure: 500hPa-1400hPa 

Symbol Identification

Description for additional symbols.

SN	Serial Number		Follow instructions for use
	Manufacturer		Temperature Limitation
	Manufacturer Date		Humidity Limitation
	Protected Class II Electrical Insulation		Atmospheric Pressure Limitation
	Type BF Applied Part	LOT	Batch Code/ Lot number
	Keep dry	Rx ONLY	Prescription
REF	Part Number		Warning/Caution
	Do Not Dispose Of	132 °C	Autoclavable
	Single use		

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 (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 800-1750mW/cm^2 is acceptable for standard and ramp modes, and a value1350-3300mW/cm^2 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 and/or protective eyewear should always be used. Only Vista Apex provided safety glasses 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 insert fingers, instruments, or other objects into the rear of the handpiece when the battery pack is removed
- DO NOT autoclave the handpiece, battery pack, charging base.

CAUTION

- 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.

CAUTION

• 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 the 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.

WARNING

•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

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 395 – 900nm. The device's intended use is within the oral cavity and is to be used with the protective light shield.

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

• The PinkWave™ Curing Light is contraindicated in patients with a known history of hypersensitivity or allergy to any of the ingredients or their analogs.

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

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.

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 opertated 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 enviroment-guidance**
RF emissions CISPR 11	Group 1	PinkWave™ uses RF energy only for it interna function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic 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	± 2kV for power supply lines ± 1kV for input/output lines	±2kv for power supply lines	Mains power quality should be that of typical commercial or dental environment
Surge IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth		Mains power quality should be that of typical commercial or dental environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle		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.			

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic enviroment-guidance
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. **Recommended separation distance** $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{12}{V_2}]\sqrt{P}$ $d = [\frac{12}{E_1}]\sqrt{P}$ $d = [\frac{23}{E_1}]\sqrt{P}$ 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/m	
	3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz	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 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 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a - Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broad-cast 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 $d = [\frac{3,5}{V_1}]\sqrt{P}$	150 kHz to 80 MHz in ISM $d = [\frac{12}{V_2}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{12}{E_1}]\sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{23}{E_1}]\sqrt{P}$
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 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

REF 90734

VISTA | APEX

1-877-418-4782
www.vistaapex.com

*Internal test data
available upon request