REF 408800

VISTA APEX

USER'S MANUAL

For use by qualified professionals only

phasor™

Patent# 10,589,829

This manual must be read thoroughly and understood prior to using the Phasor™ Composite Heating System.

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

CE

Rx ONLY

EC REP **Emergo Europe**
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

408800-I-V-77-ENG (6)

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 Vista Apex's Phasor™

Congratulations on your decision to incorporate the Phasor™ heated composite delivery system into your practice. This patent-pending device is the first of its kind, using NIR (near infrared) technology to rapidly warm highly filled composite compules. With the touch of a button, Phasor™ is able to heat composite material to 150°F in seconds, and maintain that temperature throughout the procedure.

Warming composite significantly lowers the viscosity of the material resulting in better adaptation, reduced voids and microleakage, and improved depth of cure. Materials remain highly sculptable, non-sticky, and easily shaped during manipulation.

Our website, www.vistaapex.com, also 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 Phasor™, please call our customer service department toll free at 877-418-4782.

Contents of the Phasor™ Kit

The Phasor™ is composed of the following:

- (1) Handpiece CE MD
- (3) Removable Nosecones CE MD
- (100) Barrier Sleeves CE MD
- (1) Stand
- (1) Power Supply CE
- (1) Device Maintenance Kit
- (1) Instructions for Use
- (1) Warranty Card

Power Supply:
GlobTek, Inc.
186 Veterans Drive
Northvale, NJ 07647 USA
Tel.: +1-201-784-1000

All Other Items:
Inter-Med, Inc.
2200 South St.
Racine, WI 53404 U.S.A.
Tel.: +1-262-636-9755

NOTE: ALL COMPONENTS ARE NON-STERILE

Intended Use / Indications for Use

Heating and dispensing of dental composite materials.

PHASOR™ SET-UP AND USE

Unpacking the Container

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

If you have questions or concerns, please visit www.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

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

LED Indicators

The composite gun is designed to display the battery state via the battery level indicator:

The LED light surrounding the ON/OFF button indicates current charge level (< 20% charged - **Red**, > 20% charged - **Green**).

It is advised to charge the battery when the indication lights are **Red**.

Charging the Battery

The Phasor™ battery is partially charged when shipped. To charge the battery, simply connect the micro-USB charger to the USB charging port on the device handle and plug the power adapter into a standard outlet.

During battery charging, the device activity indicator light will pulse.

Once charging is complete, the device activity indicator will remain blue.

When unplugged from the charger, the device activity indicator turns off and the device will enter a sleep mode.

PHASOR™ OPERATION

Inserting Composite

Snap a composite compule into the end of the device.
Position the compule so that the tip is directly under the LED lens.

- **Short Compules:** position forward
- **Long Compules:** position back

NOTE: The device will not operate in the absence of a composite compule.

CAUTION: Parts of the composite compule may become hot. Use caution and avoid touching the top of a hot composite compule.

Composite & Setting Compatibility

The chart below will list the ideal settings for most leading composite brands. Contact Vista Apex at 877-418-4782 (Toll Free) for additional assistance.

OPTIMAL Setting Compatible Setting DO NOT USE

COMPOSITE BRAND	SETTING 1	SETTING 2	SETTING 3	SETTING 4
3M®*				
DENTSPLY®*				
Ivoclar®*				
Kerr®*				
VOCO®*				
Coltene®*				
Kuraray®*				
GC®*				
Shofu®*				
Heraeus Kulzer®*				
Tokuyama®*				
Centrix®*				

*3M® is a registered trademark of 3M Company. Dentsply® is a registered trademark of DENTSPLY International. Ivoclar® is a registered trademark of IVOCLAR VIVADENT. Kerr® is a registered trademark of Kerr Corporation. VOCO® is a registered trademark of VOCO AMERICA, INC. Coltene® is a registered trademark of COLTENE/WHALEDENT, INC. Kuraray® is a registered trademark of KURARAY CO., LTD. GC® is a registered trademark of GC Corporation. Shofu® is a registered trademark of SHOFU, INC. Heraeus Kulzer® is a registered trademark of Heraeus Kulzer GmbH. Tokuyama® is a registered trademark of Tokuyama Corporation. Centrix® is a registered trademark of Centrix, Inc.

CAUTION: Do not deviate from the recommended settings.

Selecting a Setting

Press & hold to enter programming mode.
This is indicated by flashing yellow lights.

Short press to toggle between settings.

1. ●○○ 3. ○○●
2. ○●○ 4. ●●●

Press & hold to exit.
Device will beep 3 times and shut off.

Your setting is now memorized as default.

Reference setting compatibility chart to determine the appropriate setting per composite brand.

CAUTION: Do not deviate from the recommended settings.

Start Heating Cycle

Short press to start/stop heating cycle.
The blue lights will flash while heating.

Setting 1-3: 45 seconds
Setting 4: 70 seconds

The blue lights will turn solid when heating cycle is complete.

The device will automatically shut off after 3 minutes of sustained heating.

Cleaning & Disinfection

The device may be wiped down with a standard disinfectant wipe. Quaternary ammonium compound products are recommended (containing 20% alcohol or less). Wipe, do not spray, solution onto the unit. Prevent liquids from entering openings on the composite gun unit. Never spray disinfectant directly onto the device.

CAUTION: Always use a protective barrier.

Follow detailed reprocessing instructions contained within this instructions for use for cleaning and sterilizing the black nosecone.

Between uses, check the lens to ensure it is clean. A dirty lens will decrease performance.

The Phasor™ is provided non-sterile. There are no special accessories needed to sterilize the Phasor™ heated composite delivery system.

DO NOT AUTOCLAVE HANDPIECE.

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.

Infection Control Measures

CAUTION: To prevent cross-contamination, a disposable plastic sleeve must be used over the Phasor™ with each use. A low-density polyethylene plastic disposable barrier covers the nose cone of 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

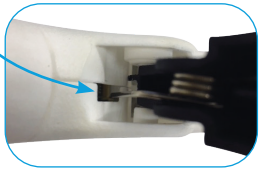
Between uses, check the lens to ensure it is clean.
A dirty lens will decrease performance.

1. Insert the hex key provided into the trigger bolt.

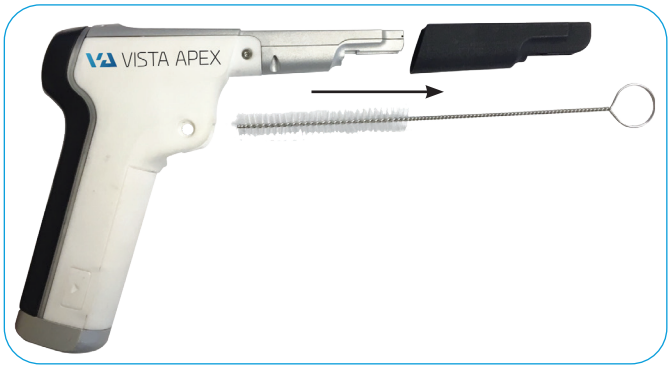
2. Rotate counterclockwise and remove the trigger bolt once loose.

3. Slide the trigger and spring assembly apart from the device.

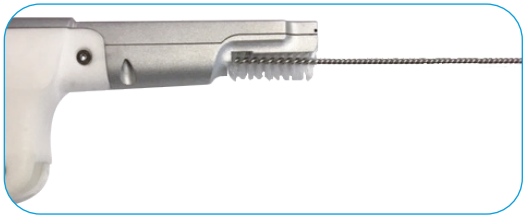
When reassembling, ensure spring is inserted into the small opening in the trigger space.



4. Tilt the device forward to allow the plunger to slide forward and be removed from the device.



5. With the nosecone removed, clean the device with the provided brush.



6. Thoroughly clean the plunger space and LED lens to remove any composite residue.

NOTE:

- Alcohol may be used as a cleaning solution.
- **DO NOT** insert the brush past the end of the bristles.

Battery Removal & Replacement

To remove battery compartment door, press the release button and separate from device by pulling.

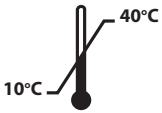
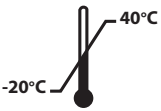
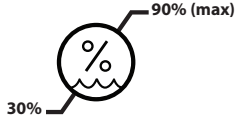
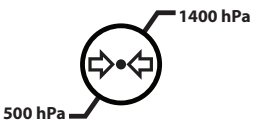
Remove the old battery and replace with the new battery, ensuring that +/- indicators are properly aligned as indicated on the battery door.

TROUBLESHOOTING GUIDE

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

PROBLEM	POSSIBLE SOLUTION
Composite gun will not turn on	1. Check the unit's battery indication light. If red or no light, charge the unit. 2. Remove the battery and check orientation. Reinsert into the device in proper orientation.
Composite gun is not heating	1. Verify the unit is charged. 2. Verify that an appropriate temperature is selected. 3. With the handpiece turned off, and battery removed, inspect the lens for residual composite. 4. Check expiration date of composite.
Battery will not charge	1. Inspect the USB charging port of any foreign objects that could interfere with a proper connection. 2. Remove the battery and check orientation. Reinsert into the device in proper orientation. 3. Make sure the battery is properly inserted in the handpiece. 4. Make sure the charger is plugged in and verify the outlet is receiving power.
Composite compules are melting	1. Adjust heat setting to lower setting and try again.

TECHNICAL DATA

TECHNICAL INFORMATION	PHASOR™ COMPOSITE GUN
Charger	**Input:** 100-240 VAC, 50-60 Hz
	Nominal Consumption: 6W max
	Manufacturer: GlobTek INC.
	Model: GTM46101-1005-USB
	Dimensions without blade or cable (LxWxH): 41mm x 71mm x 31.5mm
	Mass: 50g
	Classification: Protection class II, ⧈
Handpiece	**Battery:** 3.6 V nominal, 3000mAh Li-ion, 10.8 Wh
	Battery Pack Manufacturer: LG CHEM LTD.
	Battery Pack Model: LG-HG2-18650-INR
	Dimensions (LxWxH): 150mm x 120mm x 25mm
	Mass: 153g
	Classification: Type BF,
	Intermittent Operation: The device has been designed solely for short-term operation.
	Operating Time: Approximately 2 hrs. fully charged. Approximately 15 heat cycles on high setting.
Operating Conditions	**Time to Charge Empty Battery Pack:** Approximately 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)  **Atmospheric Pressure:** 500hPa - 1400hPa 

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	EC REP	European Representative
REF	Part Number		Do not use if seal or packaging is compromised
CE	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 Directives	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.
	Warning / Caution	132°C	Autoclavable up to the temperature specified

BATTERY DISPOSAL

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 in North America, we recommend www.call2recycle.com to locate a recycling facility near you.

SAFETY NOTES, WARNINGS AND PRECAUTIONS

Read all instructions before operating this unit. The Phasor™ heated composite delivery system emits high intensity light waves and must only be used as indicated in this manual.

The Phasor™ composite gun 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 composite gun complies with the relevant EU regulations.

The device 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 risk 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. Test each flow setting with the tooth models provided.
- As with any heavily used medical device, the user needs to ensure a functional backup is readily available.
- **DO NOT** keep or position near flammable materials, or materials that could combust.
- **DO NOT** look directly into the IR light output when the device is on.
- **DO NOT** insert fingers, instruments, or other objects into the handpiece when the battery pack is removed.
- **DO NOT** autoclave the handpiece, battery, charging cord or stand.
- **ONLY** heat composite starting at room temperature.
- **DO NOT** heat composite if it is already at an elevated temperature from use in the Phasor™ or other warming devices.
- **ONLY USE** replacement batteries provided by the manufacturer.
- **ONLY DISPENSE** composite after warming. Not intended to dispense composite at room temperature or below.

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 operation instructions. The manufacturer assumes no liability for any damage arising from any other or improper use of this device.
- Only use the charger which is provided with the device. The use of any other charger can result in damage to the device.
- 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.
- 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.
- 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.

OPERATING CONDITIONS AND SAFETY CONSIDERATION

Heat Generation

The Phasor™ heated composite delivery system has been designed not to overheat to the point of discomfort or injury during standard operating durations. However, care should be taken to allow the product to completely cool between uses (approximately two-three minutes), to ensure overheating does not occur.

Cool-Down

Phasor™ features a built in fan which will turn on automatically during operation. The fan will remain on after operation until the device reaches a lower temperature.

Adverse Reactions

There are no known adverse reactions.

Contraindications

Phasor™ should not be used for any application outside of composite restorations.

- **DO NOT** heat composite if it is already at an elevated temperature from use in the Phasor™ or other warming devices.
- **ONLY DISPENSE** composite after warming. Not intended to dispense composite at room temperature or below.

VISTA APEX TERMS AND CONDITIONS OF WARRANTY

The Phasor™ handpiece is warranted to be free from defects under normal usage conditions for one (1) year of its date of delivery; the batteries for one (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.

RETURN POLICY

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 RESTOCKING POLICY

30 days	15%
31-60 days	25%
60+ days	Not Returnable

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 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 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

Manufacturer:	**Inter-Med, Inc.**
Device:	**Phasor™ & Accessories**
WARNINGS	• Appropriate PPE (gloves, safety glasses, scrubs or lab coat) should be worn when reprocessing medical devices. • Electronic devices should never be submerged or soaked in any cleaning solution. • Electronic devices should never be autoclaved. • Do not disassemble electronic devices. • Do not use water on electronic devices. • Do not use abrasive cleaners. • Use neutral pH detergents during cleaning. • Do not use with commercial sterilization wraps or pouches with sterilization indicators that leave a stain. • For autoclavable products, do not sterilize with other products. Do not allow products to touch one another during autoclaving. • Reprocess products as soon as possible after use. • 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. • 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. • Vista Apex has validated the following number of reprocessing cycles for the products: - Phasor™ Nosecones: 20 cycles

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. • For non-electrical devices or accessories, the product should be immediately rinsed with water to remove debris. • 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. • 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. • 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: ***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. **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: ***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. • After 1-3 minutes of contact time, remove the disinfectant solution residue with a damp cloth. Use deionized water to dampen cloth. **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. **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. **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.

REPROCESSING INSTRUCTIONS *(continued)*

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). **NOTE:** Electronic devices should never be placed in autoclave. Do NOT autoclave electronic devices.
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.** 2200 South Street Racine, WI 53404 USA +1-262-636-9755 info@vista-dental.com

APPENDIX – ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY INFORMATION

The Phasor™ heated composite delivery system is tested according to IEC 60601-1-2, Edition 4.0.

Medical electrical devices are subject to particular preventive action according to EMC rules 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.

Phasor™ heated composite delivery system is intended for use in the electromagnetic environment specified below. The customer or the user of the Phasor™ heated composite delivery system should assure that it is used in such an environment.

EMISSION TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RF emissions CISPR 11	Group 1	Phasor™ 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	Phasor™ 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 Phasor™ heated composite delivery system is intended for use in the electromagnetic environment specified below. The customer or the user of the Phasor™ heated composite delivery system 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	± 6 kV contact ± 15 kV air	± 6 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	± 2 kV for power supply lines	Mains power quality should be that of typical commercial or dental environment.
Surge IEC 61000-4-4	± 1 kV line - line ± 2 kV line - earth	± 1 kV line - line No prot. 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	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of typical commercial or dental environment. If the user of the Phasor™ requires continued operation during power mains interruptions, it is recommended that the Phasor™ be powered from an uninterruptible power supply or battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or dental environment.
Portable and mobile RF communications equipment should not be used closer to any part of the Phasor™, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
			Recommended separation distance
Conducted RF IEC 61000-4-6	3Vrms 150 kHz to 80 MHz	3V	d = 0.35 √P
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10V/m	d = 0.35 √P 80 MHz to 800 MHz d = 0.70 √P 800 MHz to 2.5 GHz 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol: 

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 Phasor™ heated composite delivery system is used exceeds the applicable RF compliance level above, the Phasor™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Phasor™ heated composite delivery system.

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 "Phasor™ Heated Composite Delivery System"

The Phasor™ heated composite delivery system is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled.

The customer or the user of the Phasor™ heated composite delivery system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Phasor™ heated composite delivery system as recommended below, according to the maximum output power of the communication equipment.

Rated Maximum Output Power of Transmitter (W)	Separation Distance According To Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = 0.35 \sqrt{P}$	80 MHz to 800 MHz $d = 0.35 \sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7 \sqrt{P}$
0.01	0.035	0.12	0.23
0.1	0.11	0.38	0.73
1	0.35	1.2	2.3
10	1.1	3.8	7.3
100	3.5	12	23

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.

NOTES

phasor™

VISTA APEX

2200 South Street
Racine, WI 53404
1-877-418-4782
www.vistaapex.com

REF 408800