



REF 408800

USER'S MANUAL

For use by qualified professionals only

phasor™

(Patent Pending)



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



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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 Vista Dental'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.

The Vista Dental Products website, www.vista-dental.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
- (3) Removable Nosecones
- (1) Stand
- (1) Power Supply
- (3) Tooth Models
- (1) Device Maintenance Kit
- (1) Warranty Card

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

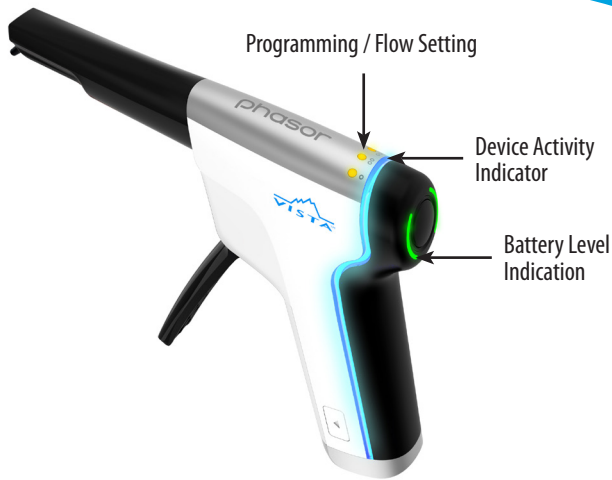
No special assistance is required to unpack and assemble the PHASOR™. If you have questions or concerns, please visit www.vista-dental.com or call Vista Dental Products at 877.418.4782 (Toll Free).

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 Dental Products 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.

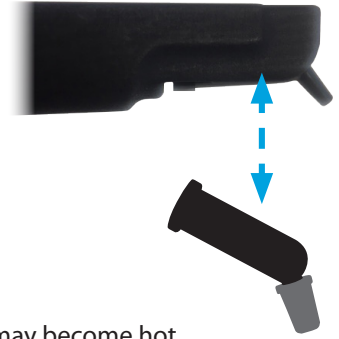
PHASOR™ Operation

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

For a complete list of compatible compules and their ideal setting visit www.vista-dental.com/phasor

■ OPTIMAL Setting

■ Compatible Setting

■ DO NOT USE

COMPOSITE BRAND	SETTING 1	SETTING 2	SETTING 3	SETTING 4
3M®*	Compatible	Compatible	Optimal	Do Not Use
DENTSPLY®*	Compatible	Compatible	Optimal	Do Not Use
Ivoclar®*	Compatible	Compatible	Optimal	Compatible
Kerr®*	Compatible	Optimal	Do Not Use	Do Not Use
VOCO®*	Compatible	Compatible	Compatible	Optimal
Coltene®*	Compatible	Optimal	Do Not Use	Do Not Use
Kuraray®*	Compatible	Compatible	Optimal	Compatible
GC®*	Compatible	Optimal	Do Not Use	Do Not Use
Shofu®	Optimal	Do Not Use	Do Not Use	Do Not Use
Heraeus Kulzer®*	Optimal	Do Not Use	Do Not Use	Do Not Use
Tokuyama®*	Compatible	Optimal	Do Not Use	Do Not Use



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. Never spray disinfectant directly onto the device.



CAUTION: Always use a protective barrier.

Black nosecone is removable and autoclavable.

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.

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.

DO NOT AUTOCLAVE HANDPIECE.

REMOVABLE NOSECONES CAN WITHSTAND AUTOCLAVE - (132°C / 0.22mPA for 3 minutes).



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.

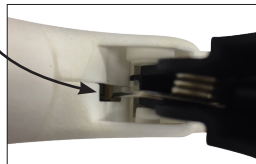


2. Rotate counterclockwise and remove the trigger bolt once loose.



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.



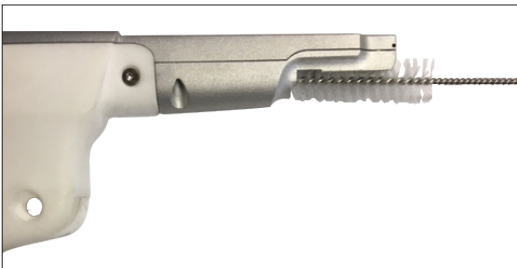
5. With the nosecone removed, clean the device with the provided brush.



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.



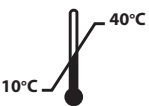



Remove the old battery and replace with the new battery, ensuring that +/- indicators are properly aligned as indicated on the battery door.

Troubleshooting Guide

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




















Problem	Possible Solution
Composite gun will not turn on	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 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 composites. 4. Check expiration date of composite.
Battery will not charge	<ol style="list-style-type: none"> 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 and verify the outlet is receiving power.
Composite compules are melting	<ol style="list-style-type: none"> 1. Adjust flow setting to low or universal ramp setting.

Technical Data

Technical Information	Phasor™ Composite Gun
Charger	Input: 100-240 VAC, 50-60 Hz
	Nominal Consumption: 6W max
	Manufacturer: GlobeTek 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
Operating Conditions	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.
	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
Relative Humidity: 30% - 90% (non condensing) 	
Atmospheric Pressure: 500hPa - 1400hPa 	

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 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		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 Dental Products 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 Dental Products shall not be liable for consequential or incidental damages. No person or distributor is authorized to modify the terms of this warranty.

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

Return Policy

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

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

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

Return Restocking Policy

30 days	15%
21-59 days	25%
60+ days	Not Returnable

Any equipment returned within 30 days from the date of the original shipment from Vista Dental Products 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 Dental Products 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 Dental Products 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 Dental Products within 10 days of receipt of goods.

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 electronic 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 3.0.

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.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles	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.


Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
	70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	
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 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	3 Vrms 150 kHz to 80 MHz	3V	$d = 0.35 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10V/m	$d = 0.35 \sqrt{P}$ 80 MHz to 800 MHz $d = 0.70 \sqrt{P}$ 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 3.0

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)		
	150kHz to 80MHz $d = 0.35 \sqrt{P}$	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 3.0

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

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