MONET™

laser curing light

AMD LASERS®

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AMD LASERS®

DISCLAIMERS

Before operating this unit, read all instructions carefully. The manufacturer accepts no liability for any damage resulting from the improper use of this unit and/or for any purpose other than those covered by these instructions. In case of any questions or concerns, please feel free to contact us.

PRECAUTIONS

Do not use undo force against any of the lenses as this could dislodge them. This is a sealed unit and opening it will invalidate the warranty.

This product is specifically designed for use in dentistry and dental related applications for the polymerization of dental materials. This system must only be used by a dental professional that is appropriately licensed and trained to use polymerization light sources, according to the requirements of national and local regulations. This system should only be used in an enclosed dental operatory or similar medical facility.

Static Electricity- This unit may be susceptible to strong magnetic or static electric fields, which could disrupt the programming. If you suspect this has occurred, detach the battery, wait 15 seconds, then reattach the battery and try again.

Important Note: Do not autoclave the Monet® curing unit or immerse it in disinfectant or cleaning solutions. The Monet curing laser may be wiped with an appropriate disinfectant towelette or sprayed with a disinfectant and then wiped dry with a cloth.

Laser Inspection- This device creates an aiming beam effect, which is useful to determine if the laser is working.

Laser Safety- This curing light is a Class 4 laser device that emits laser energy at 450nm. This combination of power and wavelength creates particular risk to the eyes and skin. Ensure the distal end of the curing handpiece is placed in the oral cavity and over the area to be cured before the laser is activated. Always use the enclosed protective glasses. Each office should quickly develop and implement a laser safety program and identify a “Laser Safety Officer” to be responsible for the laser. The LSO’s duties include management of the laser and all accessories as well as training office personnel in all aspects of laser safety.

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US FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED DENTAL PROFESSIONAL.

USE AND SAFETY

ABOUT THIS MANUAL

A number of symbols are used both on the device and throughout this manual. It is important that you understand the meaning of each one, so that when encountered you will be familiar with the type of information that is being expressed.

ATTENTION: Important information is being presented. Refer to the Operator's Manual for more information.

HIGH INTENSITY LIGHT: Protect your eyes from the light generated by this product. High-intensity light could affect viable pulp tissue. Restrict exposure time to 3 seconds or less when <3mm of dentin remains over the pulp chamber.

RISK INFORMATION: Critical information is presented to avoid problems in performance or risk to you or the patient.

SHOCK HAZARD: Beware of electrical shock or injury.

CLASS II MEDICAL EQUIPMENT

TYPE B APPLIED PART

ELECTRONICS WASTE: Properly dispose of when use is discontinued.

INDICATIONS FOR USE

The Monet curing laser is indicated for light activated polymerization of dental materials such as composites, luting cements, adhesives, and sealants using visible light.

CONTRAINDICATIONS

- This device is not intended for cutting or ablating soft or hard tissues.
- DO NOT aim the distal end of the device at the eyes or skin.
- DO NOT use for more cycles than is necessary to achieve curing.
- Caution should be exercised when curing close to the pulp chamber as the laser energy and/or the composite polymerization may increase the temperature of the pulp and lead to pulpal necrosis.
- Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.
- Laser Radiation - Avoid exposure to the eyes or skin from direct or scattered radiation
- This product contains no user-serviceable components within the housing. Visible radiation may be present when the cover is removed. Do NOT open the laser housing under any circumstances.
- Eyewear that protects your eyes from wavelengths other than 450nm do not provide proper protection for use with this laser. Damage to the retina or cornea may be irreparable if exposed to direct, reflected or scattered radiation. Eyewear or filters commonly used with other types of curing lights may not offer sufficient protection. Only use eyewear indicated for the Monet curing laser. Always wear protective eyewear when operating the laser.
- Use of controls, or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
- Do not attempt to remove the cover from the laser housing for the purpose of repairing the laser. Serious Injury from an electrical shock or laser radiation could occur. Removing the cover on the laser will void the warranty.
- Treatments performed with this device are subject to the same clinical assessment as with traditional techniques. Consider the patient's medical history and risks prior to treatment. Patient conditions may exist that may contraindicate use of this device. Consult the patient's general physician if doubts exist.
- Avoid use in oxygen-enriched environments. If used, ensure anesthetic gases are cleared before using the Monet laser.
- Barrier sleeves are for one-time use only. They cannot be reprocessed and must not be used multiple times.

NOMINAL OCULAR HAZARD DISTANCE

The NOHD is the distance beyond which the exposure during normal operation is not to exceed the appropriate Maximum Permissible Exposure (MPE). The NOHD for persons wearing safety glasses is shown in Table 1 below. The Nominal Hazard Zone (NHZ) is the area within which the laser source exposure levels exceed the MPE (which is the highest level of laser radiation to which a person may be exposed without hazardous effects or adverse biological changes in the eyes or skin). The outer limit of the NHZ is the NOHD.

APPROPRIATE EYE PROTECTION MUST BE WORN BY ALL INDIVIDUALS WITHIN THE NOMINAL HAZARD ZONE.

Source of Radiation	MPE (mW/cm²)	Divergence Angle (degrees)
Optic Tip (Direct)	1.00	0.015
Reflected from Tissue	1.00	N/A
NOHD		
	Optic Tip (Direct)	Reflected from Tissue
No Eyewear	27.3 ft (8.32m)	3.0 in (7.75cm)
With Eyewear (OD 4+)	0.33 in (0.8cm)	0.003 in (0.07mm)

Assumptions: Maximum Laser Power = 1.25 Watts, Direct viewing angle =0, Reflectance viewing angle =20°, Reflectance coefficient of tissue = 0.001

Table 1 - Nominal Ocular Hazard Distance (NOHD) for various viewing conditions while wearing eye protection.

LASER SAFETY PROGRAM

We recommend implementation of a Laser Safety Program appropriate for your dental office. The plan may include the following:

- Delegation of authority and responsibility for supervision and control of the laser to a designated Laser Safety Officer;
- Minimum training requirements for users of the laser;
- Security to restrict unauthorized use of the laser;
- Standard operating procedures to regulate the work environment in order to protect the patient and office staff from laser hazards.
- Ongoing reviews of laser safety procedures.

The safe use of a laser is the responsibility of the Laser Safety Officer (LSO) who can be a full or part-time employee, or the laser operator. It is their responsibility to train the staff, maintain records concerning training and the laser's performance, perform safety checks and prepare the laser for use on a daily basis. The LSO must keep records of any incidents that relate to the failure of the laser or any adverse effects related to laser therapy and report such incidents as prescribed by law. The LSO assures that a medical follow-up has been sought or has occurred following any adverse incident during treatment. The LSO is responsible for training of all office personnel who are involved with the laser preparation and use. Daily checks of the facility and equipment are also the LSO's responsibility. The LSO should test fire the laser each day prior to beginning each treatment procedure. For more information on the contents of a Laser Safety Plan, you can review ANSI Standard Z136.3 for Safe Use of Lasers in Health Care Facilities (US) or CAN/CSA-Z386-08 Laser Safety in Health Care Facilities(Canada).

LICENSING AND TRAINING

The safe use of the Monet curing laser is the responsibility of the entire dental team, the Laser Safety Officer appointed, and the dental office team. Protocols for the safe use of lasers have been developed by a combination of medical and dental professionals working in concert with educators at the university level, scientists and laser manufacturers. Usually, states or provinces do not have a specific licensure requirement for use of a laser by a dentist. Certain states and provinces, like Texas and Alberta, however, require the dental office to be certified and inspected prior to using a laser. The user is advised to check with the local Dental Association or State website to be aware of any specific requirements in your location. Some states require a hygienist to attend licensure training that includes both a lecture and hands-on training. Prior to using the laser, the hygiene applicants are required to pass a proficiency test for certification. These courses are usually taught by members of the Academy of Laser Dentistry who possess instructor credentials. Worker safety is the responsibility of the employer. ANSI standard Z136.1 (US) and CAN/CSA standard Z386-08 concerning Laser Safety in Health Care Facilities are sources for analyzing safety with respect to medical lasers. AMD Lasers recommends implementation of a Laser Safety Program for the safety of your patients and office staff in connection with the use of this laser curing light.

SAFETY EYEWEAR

While using the Monet curing laser, doctors, hygienists, auxiliary staff, patients, and anyone attending them in the operatory must wear the appropriate safety eyewear that has been designed for use with the 450nm wavelength. Never point the laser tip directly at the face, eyes or skin of anyone while emitting energy. The aiming beam is also capable of causing eye damage.

DANGER SIGNAGE

Each operatory where the Monet curing laser is used should have a “Laser in Use” sign placed at the operatory entrance when a procedure is in progress. This signage will help to reduce the risk of eye damage caused by inadvertent exposure to laser energy. Additional signs can be ordered through Customer Service.

LASER SECURITY

The laser should be protected against unauthorized use. This is best done by removing the battery pack from the unit, and storing the curing laser in a protected location.

EMERGENCY SHUTDOWN

In the event that laser emissions need to be terminated immediately, the following methods may be used:

- Detach the battery pack from the back of the unit.
- Press the activation switch on the unit.

REGULATORY COMPLIANCE

The Monet curing laser is designed to be compliant to the latest safety standards applicable to medical lasers in the US and Canada including IEC 60825-1:2014, IEC 60601-2-22:2007+A1:2012, AAMI/ANSI ES60601-1:2005+A1, CAN/CSA C22.2No. 60601-1:2014 and the Food and Drug Administration's Laser Performance Standard (21 CFR 1040.10 and 1040.11) except for deviations pursuant to Laser Notice 50, date June 24, 2007. Various labels are included on the laser as evidence of conformity to these requirements. The labels on the unit are required under these standards for safety purposes and should not be removed. Please review all labels prior to using the laser.

***** LABELS *****

WIRELESS INTERFERENCE

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. (Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense).

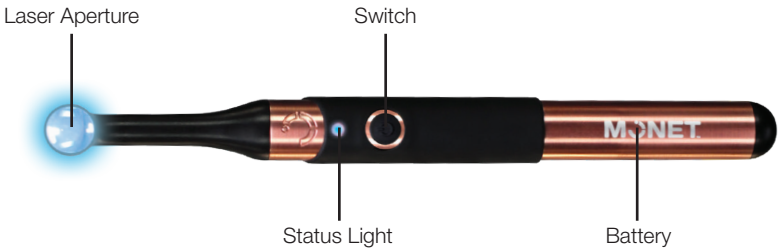
DESCRIPTION AND CONTROLS

KIT CONTENTS

1 - Monet Curing Laser Unit
2 - Rechargeable Batteries
3 - Laser Protective Glasses
1 - 50pk Disposable Barrier Sleeves
1 - Battery Charging Station
1 - Power Supply with Cord
1 - Laser Safety Sign
1 - Operator's Manual

FEATURES

The image below shows the features and controls of the Monet curing laser.



Laser Aperture - This is where the high-intensity light is emitted.

Status Light - The color and blinking pattern of this light indicates the present status of the unit.

Switch - This button is used to control the functions of the unit, including activating the high-intensity laser light.

Battery - The battery pack provides power for the unit. It can be detached and placed in the charging stand to recharge.

2 Charging Bays

SET-UP AND CHARGING

Take care when unpacking the contents of the kit. Before using the first time, make sure the battery is allowed to charge for at least 6 hours. Remove the charging stand from the packaging. Attach the connector of the power supply to the input port on the stand. Plug in the power cord to the wall outlet or to a surge protector (recommended). The power indicator light on the charging stand should illuminate. Place the charging stand on a flat, level surface. To charge a battery, rest the battery into the charging bay with the “bullseye” end of the battery facing down. The charging bay will show a green light when the battery is charging, and and the light will go out when the battery is fully charged. If you suspect the battery needs a charge but there is no light on the charging bay, make sure the correct end of the battery is facing down, and press down slightly to make sure the battery makes contact with the charger pins.

Insert the battery into the opening of the laser unit. The battery should click into place. Remove a barrier sleeve from the pack and slide the sleeve over the aperture end of the unit.

This system uses high-energy rechargeable lithium ion batteries. This type of battery provides for long operation and meets the high demands of the laser device. Lithium batteries typically have a lifespan of 300 charging cycles and 100 curing cycles on a full charge, after which the charge level starts to decrease and the battery does not last as long as it used to. If you notice that the battery does not seem to last as long, even when the charging stand shows it is fully charged, it may be that the battery is worn out and needs replacing. Contact Customer Service to order a new one.

Proper care and storage must be made when handling these batteries. Failure to follow these important instructions may result in property damage or physical injury:

- Use only the power supply and charging stand provided with the Monet system. Use of other power supplies or chargers may overload the battery and result in explosion.
- Store the battery in a clean dry place at room temperature when not in use. DO NOT expose the battery to high temperatures or store near equipment that may generate heat.
- Use only a clean cloth or cotton swab moistened with distilled water or isopropyl alcohol if the “bullseye” end of the battery needs to be cleaned. Use of tap water or cleaning and disinfectant solutions may cause a short-circuit to occur on the battery contacts. DO NOT immerse the battery.
- Only use batteries specifically designed for the Monet laser. Use of any other battery, or attempts to alter the Monet battery, may result in physical harm or damage to the system.
- Ensure the charger is located and positioned so it is easy to disconnect the power supply from the charger if needed.
- Dispose of the battery responsibly, according to local regulations for the disposal of lithium batteries.

OPERATION

FUNCTIONS

Make sure a charged battery is attached to the unit and a barrier sleeve applied. Initially there will be no lights or functions with the light when the battery is first attached — this is normal. The table below describes the lights and functions of the unit.

STATUS	INDICATOR LIGHT	BEHAVIOR	NEXT ACTION
Sleep	None	The unit is in a low-power sleep mode.	Press the switch to 'wake up" the unit and go to Standby Status.
Standby	Solid Green	The unit is on.	Pressing the switch will enter the Ready Status. If no actions occur in 2 minutes, the unit will go to Sleep.
Ready	Blinking Blue-Green	At first the unit will beep three times. After the beeping, a low-level aiming beam will emit.	Pressing the switch will activate the high-intensity curing laser. If no action is taken within 30 seconds, the unit will go to Standby.
Emitting	Solid Blue	The unit will emit the high-intensity laser light for 3 seconds. An audible tone will sound during this time.	Pressing the switch will return the unit to the Ready Status. After 3 seconds of emissions, the unit will return to Ready.
Low Battery	Solid Yellow	The battery level is low and should be exchanged or recharged soon. The unit will beep every 10 seconds.	Finish up the current procedure, then place this battery in the charging stand to recharge.
High Temperature	Blinking Red	The unit been used excessively and is too hot.	Allow the unit to cool down. The red light will stop when it has cooled down enough.
Operating Error	Blinking White	An internal software or operating error has occurred.	Remove the battery, let the unit rest for 15 seconds, then reattach the battery and resume use. If this issue continues, contact Customer Service.

Energy from the Monet curing laser does travel through porcelain to cure underlying resin to a similar degree as that of a quality halogen or LED curing light. Unlike common halogen curing lights, the Monet curing laser does not generate wavelengths outside the range needed to cure most dental materials. Light outside of the initiators range is useless light and heat. Consequently, the depth of cure in the Monet laser is equivalent to that of quality halogen lights.

CURING BEHAVIOR

Although the power output of this unit is shown in the Specifications section of this manual, comparison of laser light output to that of halogen or LED curing light is not an apples-to-apples activity. Laser light behaves very differently from light emitted by a halogen or LED source. Most manufacturers of light-cured composites, adhesives, etc. report preferred curing times and light intensity based on halogen or LED light sources.

CAUTION - We highly recommend that you perform a test cure of your adhesive or composite on a mixing pad to understand how the material may cure. You may need to adjust curing times, and in the case of composites, the layer depth, to ensure a proper cure. Some materials may use initiators that might not interact well with the laser light emitted by the Monet curing laser and may cure very poorly.

APERTURE ATTACHMENTS

The Monet kit comes with aperture attachments that can be used to reduce the light output if needed. Such situations may include curing an initial or adaptive layer close to the pulp chamber, or tack curing. The table below shows the different aperture sizes, and the extent each one reduces the output intensity. NOTE: Apertures should not be considered a replacement for the barrier sleeve. When using an aperture, attach the aperture to the head, then place the barrier sleeve over the unit.

APERTURE SIZE	REDUCTION IN OUTPUT
2mm	89%
4mm	47.7%
6mm	24%
Intensity Attenuator	50%

EMERGENCY SHUTDOWN

In the event that laser emissions need to be terminated immediately, the following methods may be used:

- Detach the battery pack from the back of the unit.
- Press the activation switch on the unit.

CLEANING AND MAINTENANCE

CLEANING

The Monet curing laser is a state-of-the-art electronic device. To prevent unnecessary damage to the unit, the power supply, and the apertures, these care and cleaning guidelines must be followed.

The Monet unit is sealed so it can be surface cleaned and disinfected. The unit must be disinfected prior to first use and prior to use on the patient. Use only one of the disinfectant solutions listed below:

- Caviwipes
- Cavicide
- Opticide 3
- Lysol Disinfectant Cleaner
- Sporicidin Sterilizing and Disinfecting Solution
- MedSci 3% Glutaraldehyde
- Cidex PlusTM 28 Day Solution

Application is best done with a clean cloth moistened with the disinfectant solution. Apply the disinfectant so the surface of the Monet is visibly wet. Ensure the surface of the unit remains visibly wet for the contact time indicated in the instructions for use of the selected disinfectant solution. You may need to reapply the disinfectant solution multiple times until the indicated contact time is achieved. Once the unit has be treated with the disinfectant solution, allow the unit to fully dry before next use or before storing.

Avoid touching the emission lens to the dental materials. If dental materials become adhered to the lens, use a fingernail or plastic instrument to try and dislodge the material. If a metal tool is used, take special care not to scratch the lens.

DO NOT use harsh abrasives. DO NOT autoclave or otherwise sterilize these components. The protective glasses provided may be immersed in a water or alcohol-based solution but DO NOT autoclave or otherwise sterilize the glasses.

Ensure that any cleaning solutions have fully dried prior to using the Monet laser.

STORAGE

The laser unit should be stored in a secured location when not in use to prevent unauthorized access to or use of the laser device. Batteries should be stored in the charging station to ensure the battery performance is at an optimal level when needed. Best performance is realized when a battery is fully charged and then fully used up on a regular basis, therefore alternate the use of the two batteries. Avoid storing any of the Monet components where there is risk they could be knocked onto the floor.

CALIBRATION

The Monet system incorporates a closed-loop feedback monitor of the laser performance. This design provides consistent and reliable laser emissions during its lifespan. However, the emissions may change over time as the laser source gets older or the emission lens becomes fouled with adhered dental materials. We recommend that you arrange to have the unit sent in annually for a performance assessment and if necessary recalibration. It is not possible to calibrate the laser yourself. Third-party power output meters may be useful to monitor the change in output during the life of the unit, but should not be relied on as an absolute measurement of output intensity.

BATTERY REPLACEMENT

Lithium batteries typically have a lifespan of 300 charging cycles, after which the charge level starts to decrease. If you notice that the battery does not seem to last as long as expected, even when the charging stand shows it is fully charged, it may be that the battery is worn out and needs replacing. Contact Customer Service to order a new one.

LIMITED WARRANTY

AMD Lasers guarantees that the purchased equipment/system will be free from manufacturing defects for the space of two (2) years from the date of original purchase by the end-user and shall be repaired/replaced at AMD Lasers's discretion. This warranty shall not cover damage or defect caused by misuse, accident, improper handling or actions contrary to those indicated in this manual, regardless of the date of purchase. This warranty does not cover postage or freight charges. This warranty does not apply to the external finish of the product or any of its components. AMD Lasers reserves the right to make changes in design or to modify such previously manufactured products. This warranty applies solely to the original purchaser and is not transferable.

TROUBLESHOOTING AND SERVICE

Please review the follow troubleshooting table first if a problem is encountered with the Monet laser system. Follow the actions indicated in the table to resolve any problems.

PROBLEM	ISSUE/CAUSES	SOLUTIONS
The unit does nothing when a battery is attached and I push the button.	The battery is not fully seated in the handle.	Press the battery into the handle to ensure it makes reliable contact.
	The battery is not charged.	Place the battery on the charging stand. If the indicator light for the bay is blinking, then the battery is charging and was likely too low to run the laser.
The unit's indicator is blinking red and beeping every 10 seconds.	The handle or head is getting hot. The unit has been used for too many consecutive cycles.	Allow the unit to cool down for at least 5 minutes.
Power output indicated on my output meter shows low.	Power meters from other curing light manufacturers should not be used with this product since the Monet is a laser.	If there is concern about the output intensity, contact Customer Service and arrange for a performance check and recalibration.
I put the unit into Ready Status, but when I pushed the button again it did not emit any light.	The unit may have gone back to Standby Status.	Make sure the indicator light is a blue-green color and the aiming beam is visible to ensure the unit is in Ready status.
	There may be a software error that has caused the unit to stop responding.	Detach the battery, wait 15 seconds, then reattach the battery. If this problem persists, contact Customer Service.
The unit's indicator is blinking white and beeping every 10 seconds.	A software error has occurred that prevents proper operation of the unit.	Detach the battery, wait 15 seconds, then reattach the battery. If this problem persists, contact Customer Service.

Should the laser fail to operate correctly, please contact AMD Lasers Customer Service at (866) 999-2635 or email at: support@amdlasers.com to obtain a Return Material Authorization (RMA) number for shipping purposes. No lasers will be accepted without an RMA. Please ensure that the RMA number is clearly marked on the box used to return the laser. It is recommended that you return your laser in its original packaging. Please clearly state the reasons for return. For service and repair purposes, AMD Lasers will provide on request circuit diagrams, parts lists, and repair information to qualified service personnel.

SPECIFICATIONS AND ACCESSORIES

Dimension	Length (w/ battery): 8.5 in (215mm) Diameter: 0.75 in (19mm)
Weight	90 grams
Laser Safety Classification (per IEC 60825)	Class 4
Wavelength of Light	450±5nm
Light Intensity at the Tip	2000–2400 mW/cm^2
Appropriate Protective Eyewear	420–460nm, OD 4+
Sleep Mode	After 2 minutes of inactivity.
Battery Charge Life	300 Cycles
Time to a Full Charge	5 Hours
Battery Type	Lithium Ion
Power Input, Monet Laser Unit	4.2 VDC @ 2.0 A
Power Input, Charging Stand	5 VDC @ 2.0 A
Power Input, Power Supply	100–240 VAC @ 50–60 Hz
Electrical Safety Classification	Class II
Equipment Classification	Type B Applied Part
Moisture Ingress Rating	IPX2
Mode of Operation	Non-Continuous (1 minute firing, 5 minutes resting basis)
Suitable Cables and Cords	Power Supply: 1.5m
Operating Temperature	15–30°C (60–86°F); Unit turns off automatically when the temperature at the wand tip reaches 48° C
Storage and Transport Conditions	0–40°C (32–104°F) 0–100% RH -1000 to + 9000 meters elevation

PRODUCT DESCRIPTION	PART NUMBER
Monet® Rechargeable Battery	001-00106
Monet® Laser Protective Glasses - Fitover	001-00107
Monet® Laser Protective Glasses - Sport	001-00108
Monet® Disposable Barrier Sleeve- REFILL (250 PK)	001-00109
Monet® Charging Stand	001-00110
Monet® Power Supply	001-00111
Monet® 2mm Beam Aperture (5PK)	001-00114
Monet® 4mm Beam Aperture (5PK)	001-00115
Monet® 6mm Beam Aperture (5PK)	001-00116
Monet® Intensity Attenuator (5PK)	001-00117

ELECTROMAGNETIC COMPATIBILITY

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The Monet® curing laser is intended for use in the electromagnetic environment specified below. The customer or user of the Monet laser should assure that it is set up and used in such an environment.

Emissions Test	Compliance	Notes
RF Emissions CISPR 11	Group 1	The Monet® curing laser 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	- -
Harmonic Emissions IEC 61000-3-2	Not Available	- -
Voltage Fluctuations/Flicker Emissions	Not Available	- -

The Monet® laser is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. Other portable and mobile RF communication equipment may still have an effect on the Monet laser. If the Monet laser is used adjacent to other equipment, test operate the Monet laser to ensure correct performance prior to use.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Monet® curing laser is intended for use in the electromagnetic environment specified below. The customer or user of the Monet laser 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 wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for Power Supply Lines 100 kHz repetition frequency	± 2 kV for Power Supply Lines Not Applicable	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5 cycle at 45° increments 0% UT; 1 cycle and 70% UT; 25/30 cycles; Single phase at 0° 0% UT; 250/300 cycle	0% UT; 0.5 cycle at 45° increments 0% UT; 1 cycle and 70% UT; 25/30 cycles; Single phase at 0° 0% UT; 250/300 cycle	Main power quality should be that of a typical commercial or hospital environment. If the user of the Monet® laser requires continued operation during power mains interruptions, it is recommended that the Monet unit be powered from an uninterrupted power supply or a battery.
(50/60 Hz) 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 hospital environment.

Note: UT is the AC mains voltage prior to application of the test level.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Monet® curing laser.

The Monet® curing laser is intended for use in an electromagnetic environment in which the radiated RF disturbances are controlled. The customer or the user of the Monet laser can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Monet laser as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	0.01	0.1	1	3	10	50	100
Minimum Distance (d)	0.2	0.6	2.0	3.5	6.3	14.1	20.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance in d in meters (m) can be estimated 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 1: At 80 MHz and 800 MHz, the separation distance for 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.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Monet® curing laser is intended for use in the electromagnetic environment specified below. The customer or the user of the Monet laser should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 0.15 to 80 MHz 6 Vrms in ISM bands between 0.15 - 80 MHz 80% AM at 1 kHz 3 V/m	3 Vrms	Portable and movie RF communications equipment should be used no closer to any part of the Monet® unit, including cables, than recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	80 MHz to 2.7 GHz 80% AM at 1 kHz	3 V/m	Recommended separation distance: $d = [6/E1] \sqrt{P}$ ...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 meters (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. Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1: At 80 MHz and 800 MHz, the separation distance for 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.

*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 theocratically with accuracy. To assess the electromagnetic environment due to the fixed RF compliance level above, the Monet® laser should be observed to verify normal operation. If abnormal performance is observed, additional measured may be necessary, such as reorienting or relocating the Monet® unit.
*Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

This product is in conformity with performance standards for laser products under 21 CFR 1040, except for conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1, as described in Laser Notice No. 56, dated May 8, 2019 and except with respect to those characteristics authorized by Variance Number 2020-V-2294 effective January 8, 2021.

Designed, Engineered,
and Assembled in the USA By:

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MONET™

laser curing light

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