

# MUNET<sup>®</sup>

laser curing light





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## 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.

# R<sub>x</sub>

**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 a medical device utilized by a dental practitioner and is indicated for light activated polymerization of dental materials such as composites, luting cements, adhesives, and sealants using visible light.

## INTENDED PURPOSE/CLINICAL BENEFITS

The Monet Curing Laser is intended to deliver high-intensity light in the blue wavelengths to polymerize dental materials that have been placed in the mouth by a dental professional in conjunction with a dental procedure. This device facilitates placement of such tooth-colored resin materials that are esthetically and functionally acceptable as replacement tooth structure, aiding the patient in restoring mastication effectiveness, and preventing further damage and decay to the teeth.

## 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. Reprocessing may degrade or melt the material, preventing it from serving as a biohazard protection.
- USE CAUTION when treating patients who suffer from adverse photobiological reactions or sensitivities to high-intensity light, or patients who are undergoing chemotherapy or taking medications that induce heightened photosensitivity such as antibiotics like ciprofloxacin and doxycycline, antihistamines like diphenhydramine (Benadryl) and promethazine, and acne retinoids like Retin-A. The patient's primary physician should be consulted if there are questions.
- WARNING – Avoid directing the light towards gum or soft tissue.

## RESIDUAL RISKS

Although best practices have been applied to create a product that safely and effectively fulfills its purpose, some residual risks related to its use may be present that you should be aware of.

- Use only batteries designed for and provided with this device. Use of other batteries or power sources may result in an unexpected increase in light intensity.
- Usage of this device different what is explained in this manual may result in unforeseen hazards to your or the patient. Use this device as indicated in this manual.
- Use of this device in oxygen rich environments or in the presence of flammable gasses such as inhaled anesthetics may result in ignition of those gasses.
- Failure to use the single-use barrier sleeves or following the cleaning instructions contained in this manual may result in cross-contamination or infection of the patients.
- Transporting or shipping the device in packaging other than what it was initially provided in may result in damage to the device.
- The aperture attachments may become dislodged while the device is in the patient's mouth, allowing for the aperture to drop into the patient's mouth. Use of the barrier sleeve over the aperture captures the aperture if it should become detached.
- Use of the barrier sleeve helps preserve the clarity of the device optics. Contamination of the device optics with residual cured-on dental materials will reduce the light output of the device.

## 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/cm <sup>2</sup> ) | 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            | 28 ft (8.52m)             | 3.12 in (7.9cm)            |
| With Eyewear (OD 4+)  | 0.34 in (0.85cm)          | 0.003 in (0.07mm)          |

Assumptions: Maximum Laser Power = 2.0 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.

## SERIOUS INCIDENT

If a serious incident takes place that involved use of this device, such as eye exposure to laser energy, or a medical adverse event, please report this incident to the manufacturer as well as to the health agency, health ministry, or competent authority that has jurisdiction over your 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 56, dated February 21, 2023. 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            | 1 - 50pk Disposable Barrier Sleeves |
| 2 - Rechargeable Batteries             | 1 - Battery Charging Station        |
| 2 - Laser Protective Glasses           | 1 - Power Supply with Cord          |
| 1 - Laser Protective Glasses Insert    | 1 - Curing Guide                    |
| 1 - Laser Protective Handheld Paddle   | 1 - Laser Safety Sign               |
| 1 - Laser Protective Shield Attachment | 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.

**Shield** - Designed to slide onto the unit and provide protection against laser emissions. Ensure the shield is positioned between the laser source and your line of sight before laser emissions occur.

**Paddle** - Designed to be used with the unit and provide protection against laser emissions. Ensure the paddle is positioned between the laser source and your line of sight before laser emissions occur.



2 Charging Bays



Paddle



Shield

## SETUP 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 the battery, slide the battery down in the charging bay with the “bullseye” end of the battery facing down. The charging bay will show a red light when the battery is charging, and a green light 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 10 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 1 second. An audible tone will sound during this 1-second interval. | Pressing the switch will return the unit to the Ready Status. After 1 second of emission, 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.

It is recommended that you direct gentle dental unit air (air only, no water) at the restorative material if exposing the material for more than 3 seconds.

## 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
- Sodium hypochlorite 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 been 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 hereby warrants against defects in materials and workmanship of the following portions/aspects of the Monet curing laser along with its components and accessories (collectively referred to herein as Product):

- 24 months for the laser unit, charging stand, and external power supply;
- 6 months for the rechargeable battery pack;

This warranty shall be in effect as of the date of purchase only by the original end user of the respective items. This warranty shall include the cost of labor associated with addressing the defect in materials or workmanship.

This warranty does not include, cover, or apply to the following:

- All other accessories and single-use, consumable, or disposable accessories or aspects of the Product;
- The cost of freight/postage associated with movement of the Product for the purposes of fulfilling this warranty;
- Damage to the Product resulting from accident, misuse, alteration, or failure to follow the instructions contained within this document;
- Courtesy review, examination, or calibration of the Product not related to a declared defect;
- Ordinary wear to the Product consistent with natural aging, use and handling, and/or as a result of following the cleaning, care and maintenance instructions of this document;
- Damage incurred in transit due to failure to package the Product in its original factory packaging;

This warranty does not cover, and AMD Lasers is not liable for, any loss of revenue incurred due to the Product requiring replacement, repair, or servicing. The owner/user of the Product is required to read this document in full prior to use of the Product, and the owner/user accepts all liabilities and risks associated with use of the Product. This warranty is valid only to the original end-use purchase and is not transferrable.

If upon examination of the Product, within the timeframes specified above, the Product is found to be defective in materials or workmanship, AMD Lasers shall repair or replace at its discretion such defects in materials or workmanship and shall not charge the owner/user only for materials associated with such repair or replacement. AMD Lasers reserves the right to make changes in design or to modify the Product subsequent to its original manufacture. If upon examination the Product is found to be free of the claimed defects in materials or workmanship to which application under this warranty is lodged, the user/owner shall be charged for the labor necessary to perform the examination of the Product. This warranty is voided if anyone other than a AMD Lasers authorized service center performs service, calibration, or repair of the Product not described in this document.

In the event that the owner/user informs AMD Lasers of Product defects and the owner/user of the Product does not cooperate with AMD Lasers to accommodate repair, servicing, or replacement of the defects, this warranty shall be voided relative to such original defects and to all subsequent defects resulting from the continued presence of the original defects or continued use of the product with the original or new defects. Additionally, AMD Lasers is not liable for any death, injury, or property damage due to continued use of the Product with a defect present that is knowingly unaddressed by the owner/user. This warranty holds supremacy to any other agreement, guarantee or warranty, oral or written, expressed or implied, except such written agreements issued directly by the AMD Lasers and mutually entered into between the AMD Lasers and the ultimate owner/user of the Product.

## REPAIRS AND RETURNS

If you are not satisfied with the Monet, AMD Lasers extends the opportunity to obtain a full refund of the purchase price of the Product (not including fees, shipping, etc.) when ALL of the following conditions are met:

- The Product is returned to and arrives at AMD Lasers within 30 calendar days from the date of purchase;
- The Product is returned with all accessories and packaging originally shipped with the Product (minus consumables that may have been used); and
- All aspects of the Product, including accessories, documentation, and packaging are free from any damage;

If slight damages or a significant reduction in consumable items are identified, a refund may be provided for the purchase price discounted by 15% to cover reconditioning, replenishment of consumables, replacement of damaged items and restocking. If extensive damage is identified, the refund may be further discounted to offset the cost of damages.

Notwithstanding, no refund is offered if more than 30 days has passed since the date of purchase.

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.

## TROUBLESHOOTING

| 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 is red, the battery needs charging. If the light is green, the battery is fully charged. If there's no indicator light, make sure the charger is plugged in. |
| The unit's indicator is blinking red and beeping every 10 seconds.                              | The handle or head is getting hot.<br>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.  |

## SPECIFICATIONS AND ACCESSORIES

|   |  |
|---|--|
| Monet Curing Laser                          | Model: 001-00105   |
| Dimension                                   | Length (w/ battery): 8.5 in (215mm)<br>Diameter: 0.75 in (19mm)                                    |
| Weight                                      | 105 grams  |
| Laser Safety Classification (per IEC 60825) | Class 4  |
| Wavelength of Light                         | 450±5nm  |
| Light Intensity at the Tip                  | 2000–2400 mW/cm <sup>2</sup>   |
| Appropriate Protective Eyewear              | 420–460nm, OD 4+   |
| Sleep Mode                                  | After 10 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)<br>0–100% RH<br>-1000 to + 9000 meters elevation                                 |

| REPLACEABLE ACCESSORIES                           | 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 |
| Monet® Laser Protective Shield Attachment | 001-00118 |
| Monet® Laser Protective Handheld Paddle   | 001-00119 |
| Monet® Attenuator Caps (25PK)             | 001-00121 |
| Monet® Spacer Attachments (5PK)           | 001-00122 |
| Monet® Laser Protective Eyewear - Insert  | 002-00456 |

These accessories can be obtained from the same supplier/dealer from which you obtained your Monet Curing Laser, or may be ordered directly from the manufacturer.

## 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<br>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<br>CISPR 11                  | Class B       | --   |
| Harmonic Emissions<br>IEC 61000-3-2       | Not Available | --   |
| Voltage Fluctuations/Flicker<br>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)<br>IEC 61000-4-2   | ± 8 kV Contact<br>± 15 kV Air   | ± 8 kV Contact<br>± 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<br>IEC 61000-4-4   | ± 2 kV for Power Supply Lines<br>100 kHz repetition frequency   | ± 2 kV for Power Supply Lines<br>Not Applicable   | Main power quality should be that of a typical commercial or hospital environment.  |
| Surge<br>IEC 61000-4-5   | ± 1 kV differential mode<br>± 2 kV common mode  | ± 1 kV differential mode<br>± 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<br>IEC 61000-4-11 | 0% UT; 0.5 cycle at 45° increments<br>0% UT; 1 cycle and 70% UT; 25/30 cycles; Single phase at 0°<br>0% UT; 250/300 cycle | 0% UT; 0.5 cycle at 45° increments<br>0% UT; 1 cycle and 70% UT; 25/30 cycles; Single phase at 0°<br>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<br>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<br>IEC 61000-4-6 | 3 Vrms<br>0.15 to 80 MHz<br>6 Vrms in ISM bands<br>between 0.15 - 80 MHz<br>80% AM at 1 kHz<br>3 V/m | 3 Vrms           | Portable and mobile 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<br>IEC 61000-4-3  | 80 MHz to 2.7 GHz<br>80% AM at 1 kHz   | 3 V/m            | Recommended separation distance:<br>$d = [6/E1] \sqrt{P}$<br><br>...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).<br><br>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 theoretically 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 For:

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# MUNET<sup>®</sup>

laser curing light