AMD LASERS®

Effective. Practical. Affordable. World Class Lasers.

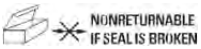
Operating Instructions Manual

PICASSO & PICASSO LITE

English - Version 8.1

PICASSO | PICASSO LITE OPERATING INSTRUCTIONS MANUAL

SYMBOL	DESCRIPTION
	Do Not Throw Away Consult with local laws with respect to medical equipment disposal.
	Laser Danger
	Do Not Autoclave
	Single Use Only
	Consult Instruction For Use
	Authorized Representative in the European Community
	Expiration Date
	Manufactured for AMD LASERS 7405 Westfield Blvd. Indianapolis, IN 46240 USA
	Fragile, handle with care
	Only Applicable for USA

SYMBOL	DESCRIPTION
	Type B Applied Part
	Warning Label
	Class II Equipment
	Must Read Manual Prior to Use
	Battery Direction
	Nonreturnable if Seal Is Broken
	Optical Fiber
	Manufactured Date
	Standby/Ready Button
	Protection Against Vertically Falling Drops of Water (e.g. Condensation)

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INTRODUCTION

The Picasso line of soft tissue dental lasers is designed for a wide variety of oral soft tissue and teeth whitening procedures. Picasso & Picasso Lite lasers utilize solid state diodes as a laser energy source. The energy is delivered to the operating area by means of a delivery system consisting of a flexible fiber connecting the laser source and the handpiece. The device is activated by means of a footswitch which may be wired or wireless.

Picasso & Picasso Lite lasers are intended for use by dentists, hygienists and/or authorized dental professionals on oral soft tissue as defined by the "Indications for Use". The Picasso Laser may also be used in teeth whitening procedures. The use of these devices requires proper clinical and technical training. This manual provides instructions for professionals that have completed the appropriate training.

When used and maintained properly, Picasso & Picasso Lite lasers will prove to be a valuable addition to your practice. Please contact your authorized representative or AMD LASERS® if you have any questions or require assistance.

SAFETY INFORMATION

SAFETY PRECAUTIONS

DANGER: LASER RADIATION – AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION!

WARNING: TO AVOID RISK OF ELECTRIC SHOCK, AC/DC ADAPTER MUST ONLY BE CONNECTED TO A PROPERLY GROUNDED POWER SOURCE!

The user should read and be thoroughly familiar with this manual before operating this dental diode laser. The equipment should be routinely inspected and maintained in accordance with the instructions given in the maintenance section of this manual. **Use of** controls or adjustments or performance or procedures other than those specified herein may result in hazardous radiation exposure. Unauthorized accessories not provided by the manufacturer may result in potential hazard.

All clinical procedures performed with Picasso & Picasso Lite must be subjected to the same clinical judgment and care as traditional techniques. Patient risk must always be considered and fully understood before clinical treatment. The clinician must completely understand the patient's medical history prior to treatment. Exercise caution for general medical conditions that might contraindicate a local procedure. Such conditions may include allergy to local or topical anesthetics, heart disease, lung disease, bleeding disorders, sleep apnea, or an immune system deficiency. Medical clearance from a patient's physician is advisable before treatment.

WARNING: Nominal Ocular Hazard Distance (NOHD) is 2 m from the distal end of the fiber.

Note: Laser equipment not in use should be protected against unauthorized use by removal of the key from the key switch.

Note: Opening this unit or adjusting components inside the unit will void the warranty since such actions may compromise the performance of the laser system.
Failure to comply with the stated precautions and warnings may lead to exposure to electrical shock and/or exposure to radiation sources. Please comply with all safety instructions and warnings.
Picasso and Picasso Lite have been tested and have been found to be compliant with the latest electrical safety standard (IEC60601-1 3rd Edition).

SAFETY INSTRUCTIONS

Follow these safety instructions before and during treatments:

- All operatory entrances must be marked with the appropriate danger warning sign.
- Do not operate the laser in the presence of explosive or flammable materials.
- Near infrared light (810 nm) from the laser can pass through the transparent components of the unprotected eye and is focused on the retina at the back of the eye. This can cause permanent retinal burns and blindness. Patients and operating room personnel should wear protective eyewear with an optical density (OD) of at least 5+ in the range of 800–820 nm during all procedures.

CAUTION: PERIODICALLY INSPECT EYEWEAR FOR PITTING AND CRACKING.

NOTE: For replacement, additional or prescription protective eyewear, please contact your authorized service representative or AMD LASERS®.

- Do not look directly into the beam or at specular reflections.
- Never direct or point the beam toward the eyes.
- Remove or cover all highly reflective items in the treatment area.
- Press STANDBY on the control panel before turning the unit off.
- Always press STANDBY on the control panel before exchanging handpieces or removing the fiber optic connector from the unit.
- Move the circuit breaker (located on rear panel) to the OFF (0) position, remove the key, and place it in a secure location before leaving the unit unattended.
- Remove all obstructions from the cooling vents on the device to ensure proper air flow and cooling of the device.

Safety Classification

The following safety classifications are applicable to the Picasso & Picasso Lite devices:

- Laser Radiation: Class 4 (US classification)
- Type of electrical shock protection: Class 1 (US classification)
- Degree of electrical shock protection: Type B Applied Part
- Laser not protected against water ingress: Ordinary Equipment
- Not suitable for use in the presence of flammable anesthetic mixtures
- Operation Mode: See Specifications

Safety Questions

Please direct safety questions to an authorized representative or directly to AMD LASERS.

SAFETY FEATURES

Circuit Breaker

Serves as a line switch to separate the unit from the main power supply: 0 = OFF, | = ON.

System Monitor

The system monitors the emergency stop switch, remote key, footswitch attachment, fiber attachment, and output power. Any detected error will stop the system.

Keyswitch

The unit can only be switched ON (key in horizontal position) with the proper key. Always turn the unit OFF (vertical position) and remove the key when not in use.

STANDBY/READY Button

Once the circuit breaker and keyswitch are set to the ON position, the STANDBY/READY button on the keypad must be pressed to enable the footswitch. One beep will sound to indicate that the system is ready for use. The STANDBY/READY button on the Picasso will turn green. For the Picasso Lite, the LED light will begin to blink.

Footswitch

No laser energy will be emitted until the user presses down on the footswitch.

Emergency Stop

Press the red Emergency Stop button to instantly turn off the unit. The button will be in the out position. To reset the Emergency Stop button, simply press again. The button will be in the pushed in position for normal operation. Only use the Emergency Stop for emergencies.

Remote Interlock

The remote interlock feature allows the user to connect the laser to an operatory door trigger to disable the laser when the door is opened. Please consult a qualified electrician to perform the proper wiring from the Remote Interlock Connector/Plug to the operatory door.
The remote interlock plug must be inserted for normal operation. If the laser is not connected to a remote interlock, an auxiliary connector, which bridges the connector contact pins, must be inserted into the Remote Interlock socket, located at the back of the unit. The connector is attached by pushing it into place. Removal is accomplished by sliding the portion of the connector closest to the laser housing away from the laser. The display will show the two dashes in the lowest position until the user has cleared the offending interlock violation (insertion of the supplied remote interlock plug and/or closing the door).

Audible and Visual Display

The laser will give an audible beep and flash a light within the ready button while the laser is firing. The audible sound may be adjusted or muted by the user. The visual display may not be turned off.

Functional Display
The Light Emitting Diode (LED) indicators on the front of the unit and control panel show the functional conditions of the system.

WIRELESS FOOT CONTROL COMPLIANCE

FC	Mod.: PICASSO	Frequency: 2.4G Hz
	FCC ID: YXI-PFCA	Voltage:1.5 Volts DC
	IC: 9348A-PFCA	1.5V AA Alkaline Batteries Only

FCC:

15.19 (a) (3):
This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: [1] this device may not cause harmful interference, and [2] this device must accept any interference received, including interference that may cause undesired operation.

15.21:
The user's manual or instruction manual for an intentional or unintentional radiator shall caution the user that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

15.105:
For a Class B digital device or peripheral, the instructions furnished the user shall include the following or similar statement, placed in a prominent location in the text of the manual.

NOTE:
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

IC: RSS-GEN:

7.1.2 Transmitter Antenna

WARNING: Do not modify this equipment without written authorization of the manufacturer.

Canada Only: This device should be installed and operated in accordance with CAN/CSA-Z386-92: Laser Safety in Health Care Facilities.
 User manuals for transmitters shall display the following notice in a conspicuous location: Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approval for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

7.1.3 User Manual

User manuals for license-exempt radio apparatus shall contain the following or equivalent notice in a conspicuous location in the user manual or alternatively on the device or both.
This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions:
[1] this device may not cause interference, and [2] this device must accept any interference, including interference that may cause undesired operation of the device.

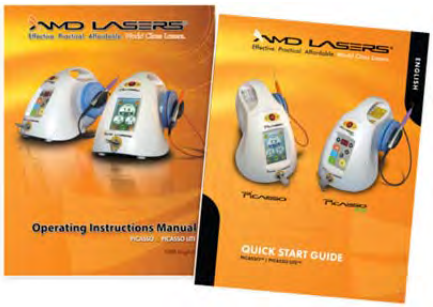
For Canadian Users only. A cable back up has been provided for the operation of the foot pedal as a wireless foot pedal is not currently available for use in Canada. Please be sure to connect the cable between the foot pedal and the “FS” socket on the back of the unit, verify that battery is removed, and then start your unit.

CONTENTS OF PICASSO & PICASSO LITE

#	ITEM	DESCRIPTION
1	Key Switch	Turns Display of the Unit ON & OFF
2	Control Panel	Displays & Controls the Parameters (e.g. Power Output, Presets, Aiming Beam & Intensity, & Speaker Volume)
3	Emergency Stop Button	Disables the Unit In the Event of an Emergency
4	Handle	For Transporting the Unit
5	Handpiece & Holder, Disposable Tip	Multi-Tip Handpiece/Fiber with Fiber Spool, Holder, & Disposable Tip
6	Fiber Spool	Stores Fiber
7	Wired Foot Control Connector Port	Connects Wired Foot Control to the Unit
8	Remote Interlock Port	Connects Interlock to the Unit
9	Circuit Breaker	Master ON/OFF Switch
10	Cooling Vents	Cooling Vents
11	AC Power Connector	Connects Power Supply to the Unit
12	Fiber Connector Port	Connects Fiber to the Unit
13	Operating Instructions Manual	Operating Instructions Manual
14	Quick Start Guide (QSG)	Quick Start Guide (QSG)
15	Transportation Box	Transportation Box (Picasso Only)
16	Wireless Foot Control Cable (Optional)	Optional Cable To Connect Wireless Foot Control Directly To the Device (Battery Must Be Removed)
17	Laser Eyewear Protective Goggles (3)	ANSI Z87, 800–820 nm, Optical Density (OD), includes Protective Case
18	Unit Keys	Used to Turn Machine Off/On
19	Wireless Foot Control	Wireless Foot Control Standard Picasso & Picasso Lite
20	AC Adapter	Connects the Unit & Net Power Supply Input: 100–240 V 50/60 Hz, Output: 9V, 5A AC/DC adapter is specified as a part of ME EQUIPMENT.
21	Power Cord	Power Cord
22	Articulating Paper	Sample of Paper to Be Used for Laser Tip Initiation
23	Remote Interlock	Remote Interlock
24	Training Certification DVDs	ICLE Training/Certification DVDs
25	Set-Up DVD	Set-Up DVD
26	Laser Danger Sign	Danger Sign for Operatory (Included at End of Manual)

MAIN UNITS: PICASSO | PICASSO LITE

FIGURE 1



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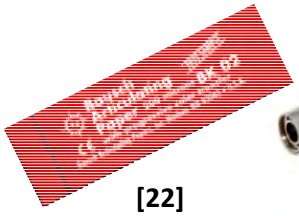

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[23]

[24] [25]

[26]

INDICATIONS FOR USE

Use of Picasso & Picasso Lite is generally indicated for incision, excision, vaporization, ablation and coagulation of oral soft tissues including the following:

- Gingival troughing for crown impression
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis and coagulation
- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy and frenotomy
- Implant recovery
- Incision and drainage of abscess
- Leukoplakia
- Operculectomy
- Oral papillectomies
- Pulpotomy
- Pulpotomy as an adjunct to root canal therapy
- Reduction of gingival hypertrophy
- Soft tissue crown lengthening
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa
- Vestibuloplasty

LASER PERIODONTAL PROCEDURES

- Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including: gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)
- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
- Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium

TEETH WHITENING INDICATIONS (PICASSO ONLY)

- Laser assisted whitening of teeth
- Light activation for whitening materials for teeth whitening

SET-UP INFORMATION

PICASSO & PICASSO LITE SET-UP

For details refer to Quick Start Guide. See FIGURE 1 for identification of components.

- Place unit in a clean, dry, and well-ventilated area.
- Verify circuit breaker is in OFF position.
- Insert key into key switch. Verify it is in the OFF position.
- Verify Emergency Stop button is disengaged (UP position).
- Connect footswitch.
- Connect remote interlock.
- Connect power cord to power connector on unit and plug into wall outlet.
- Insert fiber into Fiber Connection Port by first removing small white protective cap from the connector end of the fiber. Save the protective cap for future use and take care not to touch the end of the fiber. Next, attach the fiber to the Fiber Connection Port (FIGURE 12) by screwing the aluminum collar onto the Fiber Connection Port until the connection is “finger-tight.” If using strippable fiber, refer to the instructions provided with the fiber.
- Set up Delivery System Handpiece and Fiber (See FIGURE 9).

OPERATION INSTRUCTIONS

Turn ON Picasso & Picasso Lite

- Verify Red Emergency button (FIGURE 1, Item #3) is pushed in.
- Turn circuit breaker to ON position (FIGURE 1, Item #9).
- Rotate key clockwise to ON position.
- Select a PRESET or select a power level
- Press STANDBY/READY to place unit in READY Mode.
- Press foot control switch to fire laser and release to stop.

Turn OFF Picasso & Picasso Lite

- Press the STANDBY/READY button.
- Place handpiece back on handpiece holder.
- Switch circuit breaker to OFF position.
- Turn off and remove key from the unit, and place in a secure area.

CAUTION: VERIFY THAT THE FIBER OPTIC ASSEMBLY IS NOT TWISTED WHEN RETURNING THE HANDPIECE TO THE HOLDER. FIBER MAY BREAK IF IT IS TWISTED OR CRIMPED.

DO NOT LEAVE THE SYSTEM IN AN UNCONTROLLED ENVIRONMENT WHERE THE TEMPERATURE COULD DROP BELOW 41°F (5°C) (E.G. THE TRUNK OF A CAR). IF THIS OCCURS, ALLOW THE SYSTEM TO WARM UP TO ROOM TEMPERATURE FOR TEN TO FIFTEEN MINUTES BEFORE THE UNIT IS ACTIVATED.

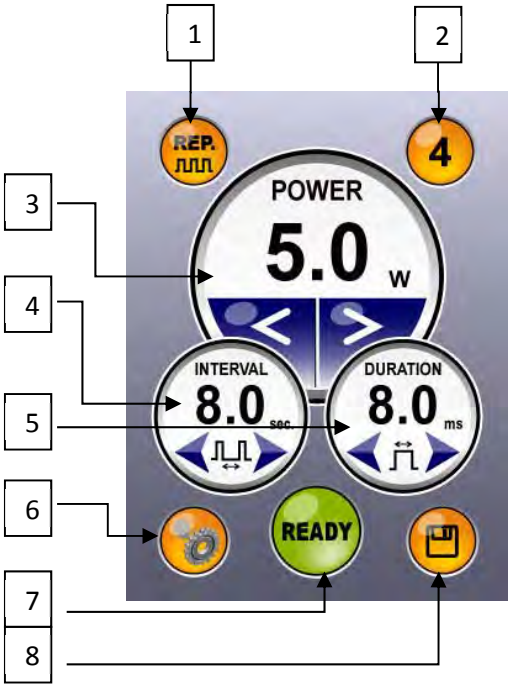
Warm-up Mode (Picasso Only)

If, during the self-diagnostic routine, the diode laser temperature is below 64°F (18°C), the system will go into warm-up mode. Follow these instructions:

- Press the STANDBY/READY button.
- Press and hold the footswitch.
- The STANDBY/READY light will flash and a beep will sound until the system is sufficiently warmed up. This may take up to two minutes. The handpiece should be left in the holder with the fiber pointing down.
- Hold the footswitch until the warm-up sequence stops.

NOTE: Always wear protective laser safety goggles during the warm-up, even while output power is negligible. The warm-up mode will not function at temperatures below 41°F (5°C). If the temperature of the unit drops below 41°F (5°C), the system should be left to warm up to room temperature for ten to fifteen minutes before the warm-up mode is activated.

CONTROL PANEL PICASSO



#	ITEM NAME	ITEM DESCRIPTION
1	Cont/Rep	CONT Continuous REP. or Repeating Modes
2	Presets	1 2 3 4
3	Power	0.5–7.0 W
4	Interval	20 ms–9.9 sec, increments of 10 ms
5	Duration	20 ms–9.9 sec, increments of 10 ms
6	Settings	Language Selection, Aiming Beam, & Volume Settings
7	Standby/Ready	STAND BY Standby READY or Ready Button
8	Save	Save Button

FIGURE 2

Programming Presets

STEP 1: Select desired type of laser operation mode: Continuous or Repeat.
Continuous Mode: In this mode, INTERVAL and DURATION are not available. POWER is able to be selected and saved as a preset.

Repeat Mode: In this mode, all the parameters (INTERVAL, DURATION, and POWER) can be adjusted and saved as a preset. Use the arrow buttons to select desired interval and duration from 20 ms to 9.9 sec.
STEP 2: Select desired preset 1–4.
STEP 3: POWER. Select desired power settings 0.5–7 W using the arrow buttons.
STEP 4: INTERVAL / DURATION. Select desired interval and duration, available only on REP mode.
STEP 5: SAVE. Save desired settings by pushing the SAVE button for 2 seconds until the beep is heard.
STEP 6: READY. Push STANDBY button to put unit into READY mode.
Press the footswitch to fire the laser.
STEP 7: Repeat steps 1–6 to program additional presets.

Language Selection

English is the default language. Nine other languages are available: Italian / French / Spanish / Portuguese / Korean / Japanese / Russian / Chinese / German
To select another language, press the SETTINGS button. The system will then enter into the language selection display. Press desired language for two seconds, and the system will restart in the chosen language.

AIMING BEAM brightness settings

To select the brightness for aiming beam, first press the SETTINGS button. Then press the  button to change the brightness settings. There are five levels for Picasso: Off / Weakest / Weak / Strong / Strongest.

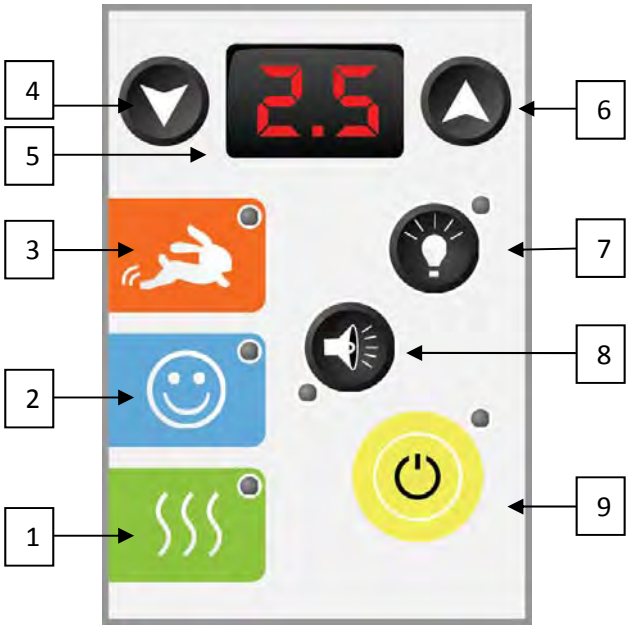
VOLUME settings

To select the volume, press the SETTINGS button. Then press the  button to change the volume settings. There are five levels: Mute / Quiet / Normal / Loud / Very Loud.

Custom Presets

The user is able to select POWER, INTERVAL, DURATION, CONT, or REP modes according to the operation. Pressing the SAVE button stores the selected parameters to PRESETS 1–4. The data is saved when the confirmation beep sound is heard. User can select the desired mode by selecting number 1–4.

CONTROL PANEL PICASSO LITE



#	ITEM NAME & DESCRIPTION
1	Hygiene: Aphthous Ulcers, Pulpotomies
2	Comfort Mode: Gingivectomies, Exposing Implants/Brackets/Teeth
3	Speed Mode: Surgery, Troughing, Frenectomies
4	Power Down
5	Power Display
6	Power Up
7	Aiming Beam Intensity: Off / Low / High
8	Volume Setting: Off / Low / High
9	Standby/Ready

FIGURE 3

Operating Picasso Lite

STEP 1: Insert Disposable Tip on the Multi-Tip Handpiece
STEP 2: Select Mode: Speed / Comfort / Hygiene
STEP 3: Select STANDBY/READY button and step on the foot control to activate the laser.

Programming Presets

Picasso Lite features three fully customizable presets:
Speed Mode: 1.8 W Continuous Mode
Comfort Mode: 1.8 W Gated (Repeat) Mode; 30 ms on/off
Hygiene Mode: 0.5 W Continuous Mode

Saving Presets

Each of the three default presets can be customized for power level, aiming beam intensity, and speaker volume. To change a preset from its default value, adjust power up or down to the desired level (0.5 W is the minimum setting). To adjust the brightness of the aiming beam, press the button; there are three levels: Off/Low/High. To adjust the volume, press the button; there are three levels:

Off/Low/High. Next, press and hold the desired preset button for four seconds until the power display cycles off and on. The new settings for the given preset have been saved.
Important: the unit only accepts one input at a time. It will perform based on the most recent input.

WIRELESS FOOT CONTROL

Instruction for Use

FIGURE 4

STEP 1: Place wireless foot control on the floor.
STEP 2: To open the cover, apply pressure to the right side of closed foot switch with your foot.
STEP 3: To operate the wireless foot control, apply pressure to enclosed foot switch with your foot. The green LED Indicator light glows to indicate that the foot switch is operating when you step on the pedal to fire laser.
STEP 4: To close the cover, push down sharply on arrow at front of cover with the ball of your foot.

Corded Connection Option for the FOOT CONTROL

Your wireless foot control has a corded connection option. This will allow you to use the foot control as a wired foot control if preferred. To use the corded connection, connect the optional foot control cable to the F.C. Port on the back of the foot control and to the back of your laser on the receptacle marked F.C. **You must remove the battery for wired operation**.

FIGURE 5

Corded Connection

FIGURE 6

Insert foot control cable in connection labeled F.C.

FIGURE 7

WARNINGS

DANGER: DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETIC MIXTURE WITH AIR, OXYGEN, OR NITROUS OXIDE.

DO NOT RE-USE DISPOSABLE OR SINGLE-USE ITEMS. FAILURE TO COMPLY MAY RESULT IN REINFECTION OR CROSS-INFECTION AND IS A HAZARD TO THE PATIENT.

DO NOT USE THIS UNIT IF YOU SUSPECT IT IS FUNCTIONING IMPROPERLY OR OTHER THAN DESCRIBED HEREIN.

Eyewear

Post appropriate warnings in operatories where the lasers are to be used, so that appropriate eyewear can be donned before the entry into the operatory. The doctor, patient, assistant, and any other persons in the operatory during laser procedures must wear the appropriate laser eyewear protection for the diode laser wavelength of 810 ± 10 nm with an optical density (OD) of at least +5. Class IV laser radiation is hazardous to the eye from the direct beam and diffuse reflections. It also represents a significant skin and fire hazard. Safety eyewear not designed to this specification is not suitable for use with Picasso lasers. Laser protective eyewear is available from your AMD LASERS representative.

Anesthesia

If anesthesia is required for treatment, closely monitor patients for signs of pain or discomfort. If such signs are present, adjust settings, apply anesthesia, or cease treatment, if necessary.

Adjacent Structures

Picasso and Picasso Lite are designed to remove soft tissue. Therefore, always be aware of adjacent structures and substructures during treatment and monitor them closely. Be extremely careful not to penetrate or ablate underlying or adjacent tissues. Do not direct laser energy toward hard tissues, such as tooth or bone. Directing laser toward amalgam, gold, metallic surfaces or reflective surfaces can result in laser beam reflection and/or scattered radiation.

Suction

Use high-speed suction as required to maintain a clear field of vision during treatment. Do not use Picasso and Picasso Lite if you cannot clearly see the treatment site. It is recommended that a smoke evacuator or in-line filter be used to capture the plume during the treatment of herpetic lesions, oral papillomas, and whenever possible. It is recommended that personnel wear a half face respirator/clinical mask with proper HEPA™ filtration. The plume should be regarded as a source of active biological material as it may contain viable tissue particulates.

Training

Only licensed professionals who are certified in Class 4 laser use and have read and understood this Operating Instructions Manual shall use this device. AMD LASERS® assumes no responsibility for parameters, techniques, methods, treatments, or results. Clinicians and/or operators must use their own clinical judgment and professionalism in determining all aspects of treatment, technique, proper power settings, interval, duration, etc. A six hour laser certification course is available from AMD LASERS prior to use.

Heat Generation

The end of the fiber optic cable, disposable tips, and non-disposable tips, cannulas, and the handpieces may become hot during use. Avoid unnecessary contact with tissue.

Disposable Tips

The disposable tips are designed and labeled for SINGLE USE only. These tips are not meant to be bent more than one time, and bent no more than 90°. They are designed to be bent once to the preferred angle, used on a single patient, and then disposed of properly. Bending the disposable tip more than once in an unintended manner is a risk to the fiber optic cable inside the cannula leading to potentially lowered power output. When the handpiece is not in use, place protective cap over the tip to prevent dust or contamination.
Additionally, bending the metal cannula in the Disposable Tip in an unintended manner can lead to a breakage resulting in a potential sharp point which could puncture the skin of the patient or office personnel. Care should be taken to not bend the metal cannula multiple times.

CAUTION: ALWAYS CHECK FOR PRESENCE OF THE AIMING BEAM BY SHINING THE TIP ONTO A NON-REFLECTIVE SURFACE BEFORE FIRING THE LASER. IF THE AIMING BEAM SETTING ON THE DEVICE IS NOT "OFF" AND YOU DO NOT SEE THE AIMING BEAM, DO NOT USE THE TIP. IT MAY BE BROKEN WHICH COULD RESULT IN HEATING OF THE METAL CANNULA POTENTIALLY CAUSING AN ACCIDENTAL BURN TO THE PATIENT.

PRECAUTIONS

AMD Picasso and Picasso Lite Diode Laser Systems are for Dental Use Only according to the Indications for Use in this OIM Version of the manual. The laser is to be used under the supervision of a Dental professional.
Laser tips, once initiated, are extremely HOT. Touching flammable surfaces with an initiated tip is not recommended.
Periodic cleaning of the tip during procedures is required to keep the efficiency of the heat transfer. If removing coagulum, use CaviCide™ or other equivalent solution following manufacturer's instructions. If using any product containing alcohol, make sure to allow tip to air dry fully prior to re-initiating the tip.
When placing the handpiece on the laser holder, make sure to have the tip pointing away from all plastic articles to avoid damage to the plastic and/or the tip.
Units can only accept one input at a time. Laser settings will reflect the last input from the user.

CAUTION: DIODE LASERS ARE ATTRACTED TO MELANIN AND HEMOGLOBIN. POWER LEVELS ARE INVERSELY RELATED TO THE AMOUNT OF PIGMENTATION AND VASCULARITY OF THE TARGETED TISSUE. AS PIGMENTATION VARIES FROM PATIENT TO PATIENT, START WITH THE LOWEST POWER SETTING AND INCREASE AS NEEDED TO ACCOMPLISH THE PROCEDURE IN TISSUES WHICH HAVE LOWER MELANIN AND VASCULAR CONTENT; USE ANESTHETIC AS NEEDED FOR PATIENT COMFORT.

STEP-BY-STEP INSTRUCTIONS

MULTI-TIP HANDPIECE WITH FIBER

The delivery system used in conjunction with removable and disposable tips consists of the Multi-Tip Handpiece/fiber assembly:

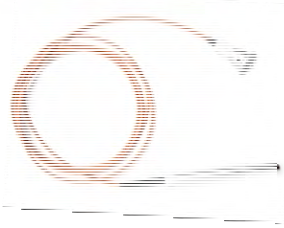
FIGURE 8

Fiber Spool

Multi-Tip Handpiece & Fiber

- Picasso (orange) / Picasso Lite (black)
- Length: 2 meters
- F.C. Connector and Handpiece
  NOTE: Tips are not autoclavable.

FIGURE 9



Handpiece and Fiber

Disposable Tips & Protective Cap

The advantage of a disposable tip over the traditional strippable and cleavable fiber is reduced set-up time since no stripping or cleaving of fiber is necessary. This accessory device is an “applied part” per IEC 60601-1.

CAUTION: THE DISPOSABLE TIPS (FIGURE 10), WHICH ARE THE APPLIED PARTS ARE FOR SINGLE USE ONLY AND MUST BE CLEANED PRIOR TO USE.

FIGURE 10

Disposable Tips

FIGURE 11

Protective Cap

Using Disposable Tips:

- Assorted bendable tips are available for use with both the Picasso and Picasso Lite Laser.
- Disposable tips are not sterile, and must be cleaned with a disinfectant wipe prior to use. If alcohol wipes are used, air dry prior to installing the tip on the Multi-Tip Handpiece and initiating the tip for use.
- Purple tips are 300 µm in size, available in 5 mm and 10 mm length.
- Orange tips are 400 µm in size, available in 5 mm and 10 mm length.
- Green tips are 200 µm in size, available in 20 mm length.
- **When using 200 µm and 300µm tips, you must set the power on your laser in accordance with the instructions provided inside the tip box.**
- **300 µm and 400 µm tips may be used according to the Picasso or Picasso Lite duty cycle up to 5 W. The 200 µm tips may not be used above 3W according to the established duty cycle. For any wattage, the surgical hand piece is also suitable. Only the Quadra tip can be used at wattages above 5W in the Picasso only for whitening purposes.**

CAUTION: USE A DISINFECTING WIPE, SUCH AS CAVIWIPES™ TO CLEAN THE DISPOSABLE TIP PRIOR TO USE.

To install a disposable tip, remove the blue protective cap (Figure 11) and slide the tip over the handpiece until the tip is fully seated.
You should hear and feel a slight 'click' when the tip snaps into place. To remove, pull gently on the tip and dispose of properly. The tip initiation procedure is the same as in the case of traditional fiber (refer to the Quick Start Guide).
These tips have a bendable steel cannula allowing the user to customize the angle of each tip for a specific application. The tip can be bent from 0° to a maximum of 90°. To bend the tip, pressure should be applied only in the middle of the metal cannula to form a smooth curve. See the Quick Start Guide for additional information.

CAUTION: DO NOT BEND THE TIP MORE THAN 90 DEGREES. DO NOT BEND THE TIP AT THE BASE OF THE CANNULA.

Bending the disposable tip more than once in an unintended manner is a risk to the fiber optic cable inside the cannula leading to potentially lowered power output.
After bending to the desired angle, the cannula should be visually inspected to ensure the tip is intact. Care should be taken to not bend the metal cannula multiple times.

CAUTION: ALWAYS CHECK FOR PRESENCE OF THE AIMING BEAM BY SHINING THE TIP ONTO A NON-REFLECTIVE SURFACE BEFORE FIRING THE LASER. IF THE AIMING BEAM SETTING ON THE DEVICE IS NOT "OFF" AND YOU DO NOT SEE THE AIMING BEAM, DO NOT USE THE TIP. IT MAY BE BROKEN WHICH COULD RESULT IN HEATING OF THE METAL CANNULA POTENTIALLY CAUSING AN ACCIDENTAL BURN TO THE PATIENT.

THE QUADRA TIP (PICASSO ONLY)

The Quadra Tip is used in conjunction with the Multi-Tip Handpiece for teeth whitening only. To use the Quadra Tip, remove the protective cap from the end of the Quadra Tip and slide it onto the Multi-Tip Handpiece (MTHP) until you hear a click.

FIGURE 12

NOTE: The AMD LASERS logo should face up on the adapter, and the notch on the adapter should align with the Quadra Tip peg.

The Quadra Tip is used 1–2 mm from the teeth once the bleach is placed on the teeth. Do not contact the patient with the Quadra Tip. Follow the instructions provided with the Whitening Gel.

CAUTION: THE QUADRA TIP IS NOT AUTOCLAVABLE AND SHOULD BE COLD DISINFECTED ONLY. IT IS NOT A DISPOSABLE. SINGLE-USE ITEM.

CLEANING INSTRUCTIONS FOR THE MULTI-TIP HANDPIECE AND QUADRA TIP

The use of CaviWipes™ Disinfectant and Cleaner is recommended for cleaning the Multi-tip Handpiece and Quadra Tip. Please follow the recommended instructions provided by the manufacturer for use and disposal.

STRIPPABLE FIBER WITH STANDARD HANDPIECE

FIGURE 13

Strippable Fiber

- 400 µm
- 3 meters in length
- FC connector

Fiber Spool

Cleaver

Autoclavable Handpiece (Removable)

400µm Stripper

NOTE: The fiber optic cable, handpiece, and tips are shipped non-sterile.
The Delivery System consists of the following:

- Fiber Optic Assembly
- Handpiece
- Accessories: Adapter (to be used with disposable cannula)
- Picasso and Picasso Lite Handpiece Kit

NOTE: The standard fiber optic cable assembly is a 400 µm fiber.

NOTE: The fiber optic cable, handpiece, and tips are reusable accessories that require cleaning and sterilization before and after each use. For instructions on cleaning and sterilization of the fiber optic cable, handpiece, and tips, refer to section “MAINTENANCE”. Fiber optic cable is not autoclavable unless labeled as “autoclavable”.

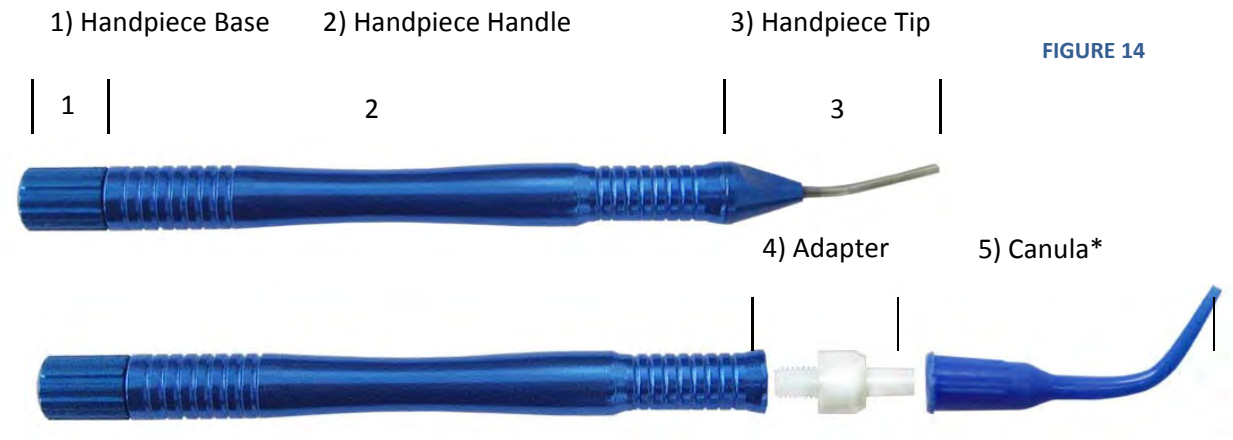


FIGURE 14

* Customer supplied disposable tip (18 gauge or larger)

To connect handpiece to fiber optic assembly:

1. Loosen handpiece base (FIGURE 15)
2. Slide fiber through handpiece base, handle, and tip
3. Approximately 3–4 in (~7–10 cm) of fiber should protrude
4. Strip and cleave fiber (FIGURES 16 and 17)
5. Adjust to desired length
6. Gently tighten handpiece base to secure the fiber

DIRECTIONS FOR STRIPPING AND CLEAVING PICASSO & PICASSO LITE FIBER

FIGURE 15

FIGURE 16

FIGURE 17

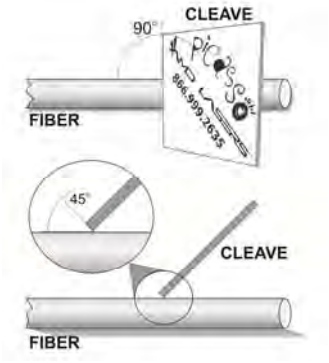


FIGURE 18

Strippable fiber should be stripped/cleaved after each procedure.

1. Loosen the proximal end of the handpiece by unscrewing the handpiece base (FIGURE 15).
2. Push fiber optic cable into the base of the handpiece until fiber appears from the tip. Pull fiber approximately 3–4 inches (~7–10 cm) out of the tip.
3. Slide the black stop marker on the stripper to approximately 1 inch (2.5 cm). Insert fiber into the stripper until the end of the fiber touches the marker. Squeeze the red stripper handles pulling the stripper away from the handpiece in a smooth

motion to ensure that the fiber coating is cleanly removed. Grasp the fiber just above the handpiece with a firm grip (FIGURE 16).

4. Use the ceramic cleaver to lightly scratch the end of the fiber. Place the fiber against a flat surface. Position the edge of the cleaver approximately ¼ inch (0.6 cm) from the end of the fiber, and make a gentle scratch perpendicularly across the fiber (FIGURE 17), scribing (scratching) the surface at a 45° angle with the edge of the cleaver. Make sure that the edge of the cleaver is always perpendicular to the fiber during cleave/scribing (FIGURE 18).
5. Hold the end of the fiber above the cleaver between fingers and bend the end of the fiber until the end section breaks off. If the fiber end is removed properly, the fiber should be flat.
6. Verify the cleaver/cleave quality by aiming the fiber at a flat surface and observe the shape of the spot created by the visible aiming beam. If the visible spot is a full circle, then the power output is optimal. If the circle is distorted, repeat only the cleave/scribing procedure presented in steps 5 and 6 until you obtain a circular beam.
7. After the fiber is successfully cleaved, pull the fiber back through the handpiece, adjust the fiber end to desired length. Tighten the handpiece base. Ensure that the fiber is secure by pulling lightly on the fiber optic cable at the proximal end.
8. Wipe the completed handpiece and fiber with a clean wipe similar to CaviWipe™.

CONTAMINATION CONTROL PROCEDURES FOR THE STRIPPABLE FIBER AND SURGICAL HANDPIECE

The contamination control suggested for fiber optic cable, handpiece, and interchangeable tips is the system sterilization method. However, before sterilization, Picasso & Picasso Lite reusable accessories (handpiece, fiber optic cable, and interchangeable tips) should be carefully cleaned per the following procedure.

NOTE: Fiber optic cable is not autoclavable.

CLEANING INSTRUCTIONS FOR PICASSO & PICASSO LITE SURGICAL HANDPIECE & THE STRIPPABLE FIBER OPTIC CABLE

The cleaning process is intended to remove blood, protein, and other potential contaminants from the surface and crevices of reusable accessories. This process will also reduce the quantity of particles, microorganisms, and pyrogens present. Cleaning should be performed prior to sterilization and must be conducted only by qualified office personnel trained to perform the procedure and handle the Picasso and Picasso Lite Fiber Optic Delivery System.

Wear protective gloves when handling the contaminated delivery system. To disconnect the delivery system, follow the instructions for delivery system assembly presented in the section “Picasso & Picasso Lite set-up” under “Set-up Information”.

DISINFECTION INSTRUCTIONS FOR THE STRIPPABLE FIBER OPTIC CABLE

- Transport the delivery system to a decontamination/sterilization work area.
- Take the fiber and strip 1 inch (2.5 mm) off of the distal end of the fiber using the fiber cleaver. Make sure the part that has debris is removed entirely. Dispose of the contaminated fiber tip accordingly.

- Prepare a sterilizing and disinfecting solution of a CaviCide™ equivalent and submerge approximately 12 inches (30 cm) of the fiber's distal end into the solution for 5 minutes. For high level of disinfecting, immerse the fiber end for 30 minutes at 68°F (20°C).
- After this process is completed, thoroughly rinse and dry the fiber.
- For disposal of CaviCide™ equivalent disinfecting solution, please follow the manufacturer's instructions. CaviCide™ is not a product or trademark of AMD LASERS.

STEAM STERILIZATION FOR PICASSO AND PICASSO LITE SURGICAL HANDPIECE

Before sterilization, the handpiece must be cleaned and disassembled. For cleaning, follow the procedures previously described. To disassemble the handpiece from the fiber optic cable, carefully loosen the handpiece base and slide handpiece off of the fiber optic cable.
The process of thermal sterilization with saturated steam under pressure is carried out in an autoclave. To perform this procedure, follow these step-by-step instructions:

- Disassemble the handpiece, remove the rubber insert and store in a secure location for reassembly (do not autoclave the rubber insert).
- Place the handpiece and interchangeable tips inside a single wrap self-seal autoclave pouch.
- Remove autoclave tray and place pouch(es) on the tray.
- Place tray inside the autoclave chamber and set controls to the following values: Temperature: 250°F (121°C), Pressure:15 PSI (1 Bar), and Time Cycle: 20 minutes
- At the completion of the autoclave cycle, remove the tray and let the handpiece cool and dry.
- Attach the handpiece and the fiber optic cable to the unit for the next procedure.

CAUTION: DO NOT PLACE OR STACK OTHER DEVICES ON TOP OF THE FIBER OPTIC CABLE.

DISPOSAL OF USED FIBER TIPS, NON-WORKING FIBERS OR DISPOSABLE TIPS

Any portion of the fiber optic cable or disposable tip that comes in contact with a patient should be treated as a biohazard material and properly disposed of as governed by applicable laws and regulations.

CLINICAL APPLICATIONS

To efficiently remove tissue, it is imperative to understand the nature of the Picasso & Picasso Lite. Each laser operates unlike traditional devices. The techniques mentioned below must be practiced and perfected to ensure efficient operation. Please study this section carefully, practice on sample tissues, and attend a quality diode laser training seminar before using this device in a clinical situation. The Picasso line of soft tissue lasers are designed for a number of surgical and non-surgical procedures. (See "Indications for Use").
Only licensed professionals, who have successfully completed Picasso training and are certified in the use of Class IV lasers, have read and understand this manual, and know how to correctly operate the system, should use this device.
The use of the Picasso line of lasers can be used in a contact and non-contact modes. Surgery requires the initiation of distal 2–3 mm of fiber optic tip or fiber. Articulating paper is supplied with each laser for initiation. This initiation focuses laser energy to the tip.

Non-initiated tips are used in hygiene mode for the treatment of some ulcers and for other therapeutic reasons.

SOFT TISSUE SURGERY: CONTACT MODE

Cutting and coagulating soft tissue procedures can be utilized with either surgical handpiece or the multi-tip fiber handpiece and a disposable tip. The fiber tip or disposable tip must be initiated for cutting to occur. Operator should start with the lowest energy possible to achieve desired results. Disposable tips may not be used for procedures requiring more than 3.5 W.
Diode energy is highly absorbed by hemoglobin. The darker the pigment is the less energy is required to cut. Fibrous tissue requires more energy to cut. Most surgeries can be performed in the Speed or Comfort modes and a range between 0.5–2.5 W with either CONTINUOUS or PULSE MODES. Operator should try to use the least amount of power (WATTS) to achieve desired results.

When tissue builds up during a cutting procedure, remove the tissue using a clean gauze pad. Consult the accessories index for a complete listing of fibers and tips.
When procedure is complete, turn off the laser, appropriately dispose of the tip, clean handpiece with CaviCide™ or similar material, cover with protective cover, and place the handpiece in the holder.
Always clean and use a new tip prior to use.

DESCRIPTION OF LASER OPERATION MODES

Picasso and Picasso Lite have two modes of operation: CONTINUOUS and REPEAT (or PULSE) MODE. In CONTINUOUS mode, the laser will deliver output radiation at the power level specified by the user for as long as the foot switch is held down. In REPEAT / PULSE mode, the laser will deliver output radiation at the power level specified by the user and in a pulse format defined by the user for Picasso or 30 ms for Picasso Lite. In pulse mode, the wattage is reduced meaning that a setting on 1.0 W in pulse mode may produce only 0.5 W of energy at the tip. In this section, the operation of the laser is described.

PICASSO

The following figure (Figure 19) identifies the various Modes of Operation for the Picasso device:

FIGURE 19

PRESET #	Continuous Mode (CONT)	Repeat Mode (REP)
1	 **SURGERY - CUT & COAG** INITIATED TIP 3.0 WATTS **WITH APPROPRIATE ANESTHESIA**	 **SURGERY - CUT & COAG - COMFORT SETTING** INITIATED TIP 2.0 WATTS 30 ms INTERVAL 30 ms DURATION
2	 **TROUGHING POSTERIOR** INITIATED TIP 2.2 WATTS **WITH APPROPRIATE ANESTHESIA**	 **PERIO TREATMENT** NON-INITIATED TIP 1.4 WATTS 20 ms INTERVAL 20 ms DURATION
3	 **TROUGHING ANTERIOR** INITIATED TIP 1.2 WATTS	 **APHTHOUS ULCER & HERPETIC LESION TREATMENT** NON-INITIATED TIP 0.8 WATTS 20 ms INTERVAL 20 ms DURATION
4	 **HYGIENE** NON-INITIATED TIP 0.5 WATTS	 **LASER WHITENING** 7 WATTS 1.5 sec INTERVAL 9.9 sec DURATION

PICASSO LITE

SPEED MODE

To select the SPEED MODE of operation, press the key marked with the rabbit symbol. In this mode, the preset from the factory is 1.8 W, continuous operation while the foot control is depressed. This is a continuous mode of operation. The only variable parameter is the output power. The user can increase and decrease power shown in watts by pressing the corresponding up/down arrow buttons.

To operate the laser in SPEED MODE, press the STANDBY/READY button. The laser will now deliver output radiation as long as the user holds the foot switch down. An audible signal will be sounded while the laser is active and the ready button will flash.
SPEED MODE output power can be changed at any time using the up/down arrow buttons. The user may lock this new parameter into the SPEED MODE setting by first selecting desired parameter for power and then by pushing and holding down the Speed button for approximately 5 seconds. The system will momentarily blink off and then on again symbolizing the new parameter has been set.

COMFORT MODE

To select the COMFORT MODE of operation, press the key marked with the HAPPY FACE symbol. In this mode, the preset from the factory is 1.8 W and 30 ms on time and 30 ms off time. This is a PULSED MODE of operation. The user can increase and decrease power shown in watts by pressing the corresponding up/down arrow buttons.
Once the user has selected the desired wattage, the unit may be enabled by pressing the STANDBY/READY button. After the STANDBY/READY button has been pressed, the user may operate the laser at this point by depressing the foot switch. The laser will respond by outputting radiation at the desired power level for a period of 30 ms. An audible signal will be sounded while the laser is active and the ready light will be flashing. At the end of the ON PULSE, the laser will pause for a period of 30 ms. After the OFF TIME has passed, the laser will repeat this pattern for as long as the foot switch is depressed. Laser treatment may be interrupted at any time by releasing the foot switch. To resume treatment, simply depress the foot switch.

HYGIENE MODE

To select the HYGIENE MODE of operation, press the key with the three wavy lines. This is a continuous mode of operation. In this mode, the laser is preset from the factory at 0.5 W. The only variable parameter is the output power. The user can increase power shown in watts by pressing the corresponding arrow buttons.
To operate the laser in HYGIENE MODE, press the STANDBY/READY button. The laser will deliver output radiation as long as the user holds the foot switch down. An audible signal will be sounded while the laser is active and the ready button will flash.
HYGIENE MODE output power can be changed at any time using the up/down arrow buttons. The user may lock this new parameter into the HYGIENE MODE setting by first selecting desired parameter for

power and then by pushing and holding down the HYGIENE button for approximately five seconds. The system will momentarily blink off and then on again symbolizing the new parameter has been set. The HYGIENE MODE can be used with a non-initiated tip for the treatment of ulcers.

PRODUCT SPECIFICATION

GENERAL

- Dimensions L x W x H — 9.5'' x 6'' x 6.2'' (240 mm x 150 mm x 160 mm)
- Weight: — 2.0 lbs (1 kg) ± 20%
- Working Environment: — Temperature 60°F/15°C–90°F/32°C, Humidity 25%–85% , Pressure 700 hpa–1060 hpa
- Storage: — Temperature 50°F/10°C–122°F/50°C, Humidity 25%–85% , Pressure 700 hpa–1060 hpa

ELECTRICAL

- Output Voltage: — +9.0 V DC
- Output Current: — 5.0 AMPS
- Output Power Range: — 45 Watts MAX
- External Fuses: — None
- Main Control: — Circuit Breaker
- On/Off Controls: — Keyswitch, Circuit Breaker, Emergency Stop
- Remote Interruption: — Remote Interlock Connector

LASER – PICASSO

- Laser Classification — IV (4)
- Medium — GaAlAs
- Wavelength — 810 ± 10 nm
- Power Accuracy — ± 20%
- Power Modes — Continuous, Repeat Pulse
- Adjustable Pulse Duration — 20 ms – 9.9 sec
- Pulse Interval — 20 ms – 9.9 sec
- Delivery Fiber — Diameter 400 µm
- Continuous Mode — Preset to 3.0 W continuous, adjustable from 0.5–7.0 W
- Repeat Mode — Preset to 2.0 W pulsed, 30 ms on time (duration), 30 ms off time (interval) Adjustable 0.5–7.0 W, 20 ms – 9.9 sec interval and duration

- Whitening Mode — Preset to 7.0 W, Repeating 9.9 sec duration, 1.5 sec interval
- Output Range — 0.5–7.0 W ± 20%
- Laser Operation Note: — 0.5–4.9 W Continuous Operations
  5.0–7.0 W Intermittent Operation 5 min on, 4 min off or in standby mode

OTHER LIGHT SOURCES

- Aiming Beam — 632 nm ± 20%, max 5 mW, Class 1 laser
- Medium — Laser Diode

LASER – PICASSO LITE

- Laser Classification — IV (4)
- Medium — GaAlAs
- Wavelength — 810 ± 10 nm
- Power Accuracy — ± 20%
- Power Modes — Continuous, Repeat Pulse
- Pulse Duration — 30 ms
- Pulse Interval — 30 ms
- Delivery Fiber Diameter — 200 µm
- Mode — Speed, Comfort, Hygiene
- Speed Mode — Preset to 1.8 W continuous
- Comfort Mode (interval) — Preset to 1.8 W pulsed, 30 ms on time (duration), 30 ms off time
- Hygiene Mode — 0.5 Watts, continuous
- Output Range — 0.5–2.5 W ± 20% output
- Laser Operation Note: — Intermittent operation 3 min on, 15 sec off or in standby mode.

INSTRUCTION FOR ACCESSORIES

INITIATING TIP

Focusing laser energy to the end of the fiber or tip is necessary for cutting and coagulation to occur. The better the initiation the more focused and concentrated laser energy becomes. A sample of articulating paper is included with each Picasso laser.

Select the SPEED or HYGIENE MODE preset and drag the tip onto the articulating paper while firing the laser.

A good ignition will cover 3–4 mm of the tip with a dark carbonization (Figure 20).

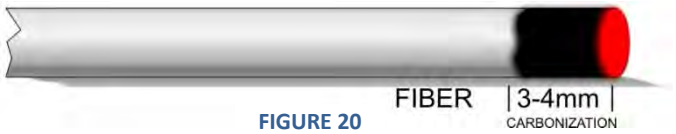


FIGURE 20

Articulating paper is flammable and precautions should be followed to prevent unintended combustion. Once initiated, do not touch the tip anywhere other than where cutting tissue is a desired treatment. For more information on initiation please consult the training DVDs included with your laser.

Initiating the tip of the Diode Laser is necessary for all procedures which require cutting or tissue removal.

Using provided or replacement articulating paper, rub the paper while firing the laser to cover 3–4 mm of the tip with carbonization.

Articulating paper is flammable. Please use and dispose of the articulating paper using fire proof collection bins in order to prevent accidental ignition of flammable materials. See Instructional video.

TEETH WHITENING (PICASSO ONLY)

Picasso teeth whitening should be performed only by trained personnel and as allowed by local, state and federal authorities. Picasso is designed for fast, efficient laser whitening with a unique laser adapter, the Quadra Tip. Most whitening is performed by first cleaning, pumicing the teeth, isolating the gingival and soft tissue mucosa with a liquid rubber dam, and applying the whitening manufacturer's bleach 1.5mm thick on the teeth. Picasso has a built in whitening mode (Preset #4 on the Picasso).

The Quadra Tip (FIGURE 21) does not make contact with the patient during the whitening procedure. Refer to the specific instructions supplied with your whitening kit.

To select the WHITENING operation, the user simply selects preset #4. This is a pulse mode of operation. In this mode, the mode is preset from the factory at 7.0 W continuously for 9.9 sec with a 1.5 sec off time. Releasing the foot control will interrupt the 9.9 sec cycle. The only variable parameter is the output power. To operate the laser in the WHITENING MODE press the STANDBY/READY button. The laser will now deliver output radiation as long as the user holds the foot switch down. An audible signal will be sounded while the laser is active and the ready button will flash.


FIGURE 21

The WHITENING MODE output power can be changed to a lower setting at any time using the up/down arrow buttons. The user may lock this new parameter into the WHITENING MODE setting by first selecting desired parameter for power and then by pushing and

holding down the button for approximately 5 sec. The system will momentarily blink off and then on again symbolizing the new parameter has been set. The Whitening procedure requires at least 5 W of power. Do not touch mucosa with the Quadra Tip during the whitening procedure.

MAINTENANCE

DENTAL LASER UNIT AND PLASTIC BARRIERS MAINTENANCE

This unit requires little operator maintenance. Wipe down the system with a cloth dampened with a mild antiseptic or cleaning solution–we recommend the use of CaviWipes™. Never use solvents or abrasive cleaners, which can damage the finish. Never pour or spray any liquid on or directly over the control console.
Protective plastic barriers can be used to protect the carrying handle, touch pad, handpieces, and goggles and are customer supplied.

ANNUAL MAINTENANCE

Picasso & Picasso Lite should be serviced annually by a qualified, AMD LASERS' trained technician. Please, contact your authorized representative or AMD LASERS® to discuss annual maintenance options. To maintain compliance with the applicable IEC and CDRH regulations, all systems must be checked and verified that they are functioning properly in the event the unit has been subjected to adverse environmental conditions such as fire, flood, mechanical abrasion, solvent spillage, etc.

Calibration is required to maintain your laser in good operating condition. By regulation, power is allowed to vary a total of +/- 20% from the established rated power. (21 CFR 1040.10).
If calibration shows a variation of more than +/- 20%, the laser needs to be returned to the AMD Laser Repair Center for repair.

The following safety checks shall be carried out:

- Verify all labels are firmly in place.
- Verify disconnection of the remote interlock causes the laser to return to and remain in STANDBY.
- Verify the display indicates LASER FIRING when the foot switch is depressed.
- Verify the audible signal is active when the foot switch is depressed and laser emission is present.
- Verify the laser goes into and remains in STANDBY when the fiber is removed from the laser aperture.

TRANSPORTATION

Picasso & Picasso Lite lasers are susceptible to misalignment if not handled properly. The unit should ALWAYS be handled carefully and never banged, jarred, jolted, dropped, or hit. Do not transport the laser unless it is completely packaged inside of its transportation box. Failure to properly package the laser can result in damage to the laser and accessories. When transporting or shipping your laser you

must always disconnect the keys, the AC Power Adapter, Remote Interlock, and fiber from the laser. Then, you must place the red protective cap on the Fiber Connector Port and replace the white and blue protective caps on the fiber. If you have any questions regarding transportation, please call your authorized representative or AMD LASERS®.

CALIBRATION PROCEDURE

The Picasso and Picasso Lite Dental Laser Units are factory calibrated. For accurate treatment results, the unit(s) should be calibrated every 12 months following the date of purchase. It is highly recommended that the customer contact AMD LASERS, rather than performing the calibration procedure outlined below. Performing these calibration procedures requires specialized equipment (see below) and technical expertise. Improper calibration could lead to instrument damage and failure to calibrate the laser.

DISCLAIMER: CALIBRATION BY ANYONE OTHER THAN A CERTIFIED AMD LASERS TECHNICIAN WILL VOID THE WARRANTY.

EQUIPMENT NEEDED:

- PC WITH WINDOWS XP OR BETTER AND A SERIAL (RS-232) PORT
- LASER POWER/ENERGY DISPLAY SUCH AS AN OPHIR MODEL II P/N 7Z01550 OR EQUIVALENT
- POWER/ENERGY METER FOR LOW POWER LASERS WITH 810 NM WAVELENGTH CAPABILITY AND ACCURACY BETTER THAN +/- 3%, SUCH AS AN OPHIR POWER METER P/N 7z02637 OR EQUIVALENT.
- AMD LASERS PROPRIETARY CALIBRATION SOFTWARE.
- AMD LASERS CALIBRATION DATA CABLE.
- #1 PHILLIPS SCREWDRIVER.

Note: Please contact AMD LASERS to obtain the Calibration software and required Date Cable.

PICASSO

WARNING: TURN LASER OFF AND UNPLUG PRIOR TO CALIBRATION PROCEDURE

REMOVE FRONT AND SIDE PANELS

1. SET UP SOFTWARE, AND CONNECT LASER TO COMPUTER. REPOSITION FRONT AND SIDE PANELS TO MINIMIZE POSSIBLE ELECTRICAL SHOCK.
2. TURN LASER "ON" AND FIRE THE LASER WITH THE FIBER TIP APPROXIMATELY 1–2 MM FROM THE POWER METER LASER HEAD.
3. ADJUST THE VALUES IN THE APPROPRIATE SOFTWARE CALIBRATION FIELDS TO INCREASE OR DECREASE THE OUTPUT WATTAGE TO WITHIN +/- 20% OF THE DESIRED POWER SETTING.
4. WHEN APPROPRIATE OUTPUT POWER IS REACHED, SELECT "SAVE" AND PROCEED TO THE NEXT SETTING.
5. REPEAT THIS PROCESS UNTIL ALL FIELDS HAVE BEEN PROPERLY ADJUSTED. ONCE CALIBRATION ACTIVITIES HAVE

BEEN COMPLETED, RE-ATTACH THE FRONT AND SIDE PANELS.

PICASSO LITE

WARNING: TURN LASER OFF AND UNPLUG PRIOR TO CALIBRATION PROCEDURE

REMOVE FRONT PANEL

1. MOVE AND PLACE THE JUMPER ONTO THE TEST PIN TO ENTER CALIBRATION MODE. REPOSITION THE FRONT PANEL TO MINIMIZE POSSIBLE ELECTRICAL SHOCK.
2. TURN LASER "ON" AND FIRE THE LASER WITH THE TIP APPROX. 1–2 MM FROM THE SURFACE OF THE POWER METER LASER HEAD.
3. ADJUST THE OUTPUT VALUES TO WITHIN +/- 20% OF THE DESIRED SETTING BY USING THE "LIGHT" BUTTON TO INCREASE AND THE "SOUND" BUTTON TO DECREASE.
4. DATA IS SAVED AUTOMATICALLY AFTER ADJUSTMENT.
5. REMOVE THE SHORT CIRCUIT TEST RING FROM THE TEST PIN WHEN CALIBRATION IS COMPLETE AND RE-ATTACH THE FRONT PANEL.

To schedule calibration of your unit, contact your authorized representative or AMD LASERS® at (866) 999-2635 to obtain an RMA.

CALIBRATION SCHEDULE

Authorized by:

Purchase Date ____//____// _____ _____

Calibration 1 ____//____// _____ _____
(12 months after purchase date)

Calibration 2 ____//____// _____ _____
(24 months after purchase date)

Calibration 3 ____//____// _____ _____
(36 months after purchase date)

Calibration 4____//____// _____ _____
(48 months after purchase date)

Calibration 5 ____//____// _____ _____
(60 months after purchase date)

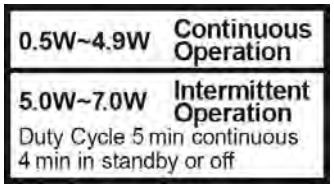
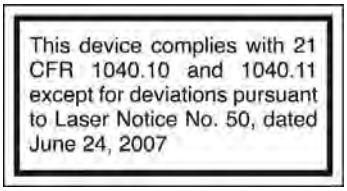
Calibration 6 ____//____// _____ _____
(72 months after purchase date)

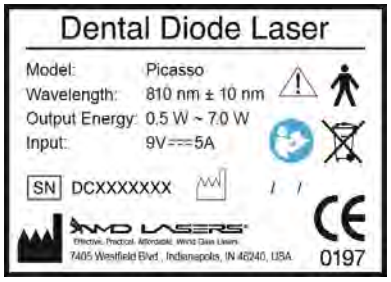
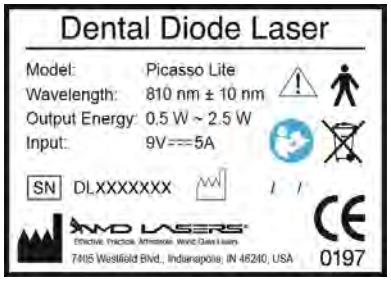
Contact AMD LASERS to be connected to the repair center closest to the laser location. Repair and maintenance centers are located worldwide.

ANNEX A: LABELS

FIGURE 22

ITEM	SYMBOL	DESCRIPTION
1	DC 9V, 5A	SPEC for DC Input
2	R.C.	Remote Control
3	F.S.	Foot Switch
4		Warning for Laser Aperture Port
5		Label for Optical Fiber (Picasso & Picasso Lite)
6		Laser Aperture Label
7		Emergency Laser Stop
8	PICASSO	Picasso Logo
9	PICASSO Lite	Picasso Lite Logo
10	AMD LASERS	AMD LASER Logo
11		Laser Key Switch

12		QC Pass Inspection Label
13		Laser Danger Label (Picasso) Note: Class IV May Be Expressed as Class 4
14		Laser Danger Label (Picasso Lite) Note: Class IV May Be Expressed as Class 4
15		Warranty Void if Removed Label
16A		Intermittent Operation Label (Picasso Lite)
16B		Intermittent Operation Label (Picasso)
17		CDRH Laser Notice 50 Compliance Label

18		Manufacture Label (Picasso)
19		Manufacturer Label (Picasso Lite)
20		Warning Label
21		IEC Explanatory Label (Picasso)
22		IEC Explanatory Label (Picasso Lite)

23		FCC and IC Identification Label The SN Starting with DL is for Picasso Lite. The SN Starting with DC is for Picasso Waterproof Mark for Foot Pedal
24		Warning Label for Foot Control
25		Battery Direction

AMD LASERS: TERMS AND CONDITIONS OF SALE

SHIPPING AND HANDLING

ALL DOMESTIC ORDERS WILL BE SHIPPED VIA STANDARD COURIER SERVICE, I.E. UPS. SHIPPING AND HANDLING WILL BE CALCULATED WHEN THE ORDER IS PROCESSED DEPENDING ON THE VALUE OF THE ORDER. STANDARD SHIPPING SERVICE IS UPS GROUND.

GOVERNING LAW, CONSENT TO JURISDICTION AND VENUE OF LITIGATION

THIS CONTRACT SHALL BE GOVERNED BY THE LAWS OF THE STATE OF INDIANA. ANY LITIGATION ARISING FROM A DISPUTE, ATTORNEYS' FEES, TRAVEL EXPENSES, COURT COSTS AND ANY OTHER RELATED EXPENSES ARE THE SOLE RESPONSIBILITY OF THE CUSTOMER. YOU HEREBY CONSENT TO PERSONAL JURISDICTION AND VENUE IN THE STATE OF INDIANA AND WAIVE ANY RIGHT TO TRANSFER VENUE. EACH PARTY WAIVES ANY RIGHT TO A TRIAL BY JURY.

ELECTRONIC SIGNATURES

YOU AGREE THAT AN ELECTRONIC COPY OF THIS CONTRACT OR SERVICE REPORT BEARING AUTHORIZED SIGNATURES MAY BE TREATED AS AN ORIGINAL.

RETURNS

ALL ORDERS MAY BE RETURNED WITHIN 30 DAYS OF SHIPMENT TO THE CUSTOMER. A 15% RESTOCKING FEE WILL BE CHARGED FOR ALL RETURNED ORDERS. ALL PRODUCT RETURNS MUST BE ACCOMPANIED BY A RETURN MATERIAL AUTHORIZATION (RMA) NUMBER ISSUED BY AMD LASERS WHICH CAN BE OBTAINED BY CALLING AMD LASERS AT (866) 999-2635. FOR LASER UNITS, THE TAMPER-EVIDENT TAPE

MUST BE INTACT FOR THE UNIT TO BE CONSIDERED RETURNABLE.IN SOME CASES, AMD LASERS WILL REPLACE AN ACCESSORY OR PART UNDER THE LIMITED WARRANTY, BUT WILL REQUIRE THE RETURN OF THE DEFECTIVE PART. A CREDIT CARD WILL BE NEEDED TO SECURE THE VALUE OF THE DEFECTIVE UNIT AND WILL BE CHARGED IF DEFECTIVE PART IS NOT RETURNED TO AMD LASERS IN A TIMELY MANNER

OR IF, UPON INSPECTION, AMD LASERS DETERMINES THAT THE RETURNED PRODUCT IS DEFECTIVE DUE TO MISUSE OR HANDLING AS OUTLINED IN THE LIMITED WARRANTY.

WARRANTY

AMD LASERS WARRANTS PICASSO OR PICASSO LITE FOR A PERIOD OF TWENTY-FOUR (24) MONTHS FROM THE SHIPMENT TO THE ORIGINAL PURCHASER/USER AGAINST DEFECTS IN MATERIAL AND WORKMANSHIP UNDER NORMAL USE AND SERVICE AND FIT FOR ORDINARY USE FOR WHICH DESIGNED, IF OPERATED BY A TRAINED AND COMPETENT OPERATOR AND IF PROPERLY SERVICED AND MAINTAINED. THIS LIMITED WARRANTY APPLIES ONLY SO LONG AS THE EQUIPMENT IS USED IN THE COUNTRY TO WHICH IT WAS ORIGINALLY SHIPPED BY AMD LASERS OR AUTHORIZED DISTRIBUTOR.

ALL RELATED ACCESSORIES USED IN CONJUNCTION WITH THE PRODUCTS INCLUDING BUT NOT LIMITED TO OPTICAL FIBER(S), HANDPIECE(S), QUADRA TIP, CLEAVER, AND STRIPPER, AND/OR PROTECTIVE EYEWEAR ARE WARRANTED FOR NINETY (90) DAYS AGAINST DEFECTS IN MATERIALS AND WORKMANSHIP. DISPOSABLE OR CONSUMABLE ITEMS (E.G. DISPOSABLE TIPS, WHITENING KITS, ETC.) ARE NOT COVERED BY THIS WARRANTY. THE LIMITED WARRANTY DOES NOT COVER ANY FEES OR COST ARISING FROM THE ANNUAL CALIBRATION OF THE UNIT.

THIS WARRANTY IS NULL AND VOID IF THE USER ATTEMPTS TO SERVICE THE EQUIPMENT (OTHER THAN PERFORMING THE MAINTENANCE DESCRIBED IN THE OPERATING INSTRUCTIONS MANUAL) OR IF SERVICE IS PERFORMED BY PERSONS WHO ARE NOT TRAINED OR AUTHORIZED TO DO SO BY AMD LASERS. IF THE UNIT IS FOUND TO BE DEFECTIVE WITHIN THE PERIOD SPECIFIED ABOVE AFTER EXAMINATION BY AN AUTHORIZED SERVICE REPRESENTATIVE OR AMD LASERS AND THE FAILURE WAS DUE TO DEFECTIVE MATERIALS AND/OR WORKMANSHIP, AMD LASERS WILL REPAIR, OR, AT ITS OPTION, REPLACE THE DEFECTIVE PARTS WITHOUT CHARGE. AMD LASERS RESERVES THE RIGHT TO MAKE SUCH AN EXAMINATION AND TO MAKE NECESSARY REPAIR/REPLACEMENT IN ITS OWN FACTORY, AT ANY AUTHORIZED REPAIR STATION, OR AT THE PURCHASER/USER'S PLACE OF INSTALLATION. IN THE EVENT THE USER DOES NOT COOPERATE WITH AMD LASERS IN PROVIDING SERVICE, YOU RELEASE AMD LASERS FROM ALL LIABILITIES WITH RESPECT TO WARRANTYING ANY EQUIPMENT OR ACCESSORIES. AMD

LASERS WILL NOT BE RESPONSIBLE OR OBLIGATED TO THE PURCHASER/USER FOR LOSS OF REVENUES INCURRED BY THE PURCHASER/USER DUE TO THE PRODUCT REQUIRING SERVICE.

IN ORDER TO RECEIVE WARRANTY SERVICE, PICASSO & PICASSO LITE LASERS MUST BE SHIPPED TO AMD LASERS IN ITS ORIGINAL TRANSPORTATION CASE AND PROPER SHIPPING BOX WITH FOAM PACKAGING. THE USER IS RESPONSIBLE FOR ALL SHIPPING COSTS. PLEASE REFER TO THE “RETURNS” SECTION OF THE TERMS AND CONDITIONS PRIOR TO SHIPPING ANY ITEMS TO AMD LASERS.

THE EXPRESS WARRANTY ABOVE IS THE SOLE WARRANTY OBLIGATION OF AMD LASERS AND REMEDY PROVIDED ABOVE IN LIEU OF ANY OTHER REMEDIES. THERE ARE NO OTHER AGREEMENTS, GUARANTEES OR WARRANTIES – ORAL OR WRITTEN, EXPRESSED OR IMPLIED – INCLUDING, WITHOUT LIMITATION, WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. AMD LASERS IS NOT RESPONSIBLE FOR CONSEQUENTIAL DAMAGES ARISING OUT OF ANY DEFECT, IMPROPER USE, OR UNAUTHORIZED SERVICE OR REPAIR. YOU ARE REQUIRED TO READ THE OPERATING INSTRUCTIONS MANUAL PRIOR TO USE OF THE PRODUCTS AND YOU ASSUME ALL RISKS AND LIABILITIES RESULTING FROM THE USE OF THE PRODUCTS.

OTHER

SALES TAX AND MEDICAL DEVICE EXCISE TAX MAY BE APPLICABLE DEPENDING ON APPLICABLE STATE AND LOCAL LAWS.

LIMITED LIABILITY

AMD LASERS® WILL NOT BE LIABLE FOR INCIDENTAL, CONSEQUENTIAL, INDIRECT, OR SPECIAL DAMAGES OF ANY KIND INCLUDING, BUT NOT LIMITED TO, DAMAGES FOR LOSS OF REVENUE, LOSS OF BUSINESS OR BUSINESS OPPORTUNITY, OR OTHER SIMILAR FINANCIAL LOSS ARISING OUT OF OR IN CONNECTION WITH THE PERFORMANCE, USE, OR INTERRUPTED USE OF THE “PICASSO” SYSTEM(S) OR ANY AMD LASERS® MATERIALS.

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EC REP

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DANGER

LASER RADIATION. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION.

Wavelength: 810 nm
Max Output Power: 7 W
Pulse Duration: 20 ms to 9.9 sec

EYE PROTECTION REQUIRED

NMD LASERS®

CLASS IV LASER PRODUCT

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DANGER

LASER RADIATION. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION.

Wavelength: 810 nm
Max Output Power: 2.5 W
Pulse Duration: 30 ms

EYE PROTECTION REQUIRED

NMD LASERS®

CLASS IV LASER PRODUCT

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Indianapolis, IN 46240 USA

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