OIMv5

CE 0197

ISO 13485

For EU only

Note for Canadian Applications:

The device should be installed and operated in accordance with CAN/CSA-Z386-92: Laser Safety in Heath Care facilities.

TABLE OF CONTENTS

INTRODUCTION

The Picasso line of soft tissue dental lasers is designed for a wide variety of oral soft tissue and tooth 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.

Picasso | Picasso Lite lasers are intended for use by authorized dental professionals in oral soft tissue and tooth 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 a valuable addition to your practice. Please contact your authorized representative or AMD LASERS®, LLC if you have any questions or require assistance.

SAFETY

Precautions

Failure to comply with the precautions and warnings may lead to exposure to dangerous voltage levels or optical radiation sources. Please comply with all safety instructions and warnings.

CAUTION: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

CAUTION: These units have been designed and tested to meet the requirements of electromagnetic, electrostatic, and radio frequency interference testing. However, the possibility of electromagnetic or other interference may still exist.

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

Safety Instructions

Follow these safety instructions before and during treatments:

- All operatory entrances must be marked with an appropriate warning sign.
- Do not operate in the presence of explosive or flammable materials.
- All persons present in the operatory must wear protective eyewear.

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®, LLC.

- **Do not look directly into the beam or at specular reflections.**
- **Never direct or point the beam at anyone's eyes.**
- **Remove or cover all highly reflective items in the treatment area.**
- **Press STANDBY (Standby button) on the control panel before turning off unit.**
- **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 OFF (0) position and remove the key before leaving unit unattended.**

DANGER: DO NOT OPEN UNIT HOUSING AT ANYTIME. DANGER FROM HIGH VOLTAGE MAY EXIST AND WARRANTY IS VOIDED.

NOTE: Please be aware that metal/plastic cannula may become hot during use. Avoid contact of cannula with tissue.

Safety Features

Energy Monitor

Measures and verifies power output. Power deviations of more than 20% from the selected value will cause the display to show either error message “DIODE CALIBRATION”, or “LASER POWER” (Picasso Only).
The unit will not operate until the system is reset by pressing any key on the keypad. If error messages persist, please contact your authorized service representative or AMD LASERS®, LLC.

Circuit Breaker

Serves as a line switch to separate the unit from the main power supply (0 = OFF, I = ON)

System Monitor

The system monitors emergency stop switch, remote key, footswitch attachment, fiber attachment, and output power. An error in any one of these will stop the system.

Keyswitch

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

READY Button

Once the circuit breaker and keyswitch are set to the ON position, the 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.

Footswitch

Picasso | Picasso Lite will not emit laser energy 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. Do not use the Emergency Stop for normal stops.

Remote Interlock

This feature allows the device to be connected to the remote sensor, which will prevent its operation when triggered (i.e., by opening door). The remote interlock plug must be inserted for normal operation.

Functional Display

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

Safety Questions

Please direct any safety questions to an authorized representative or AMD LASERS®, LLC.

Safety Classification

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

- Laser Radiation – Class 4 (US classification)
- Type of protections against electrical shock – Class 1 (US classification)
- Degree of protection against electrical shock – Type B Applied Part
- Not protected against water ingress – Ordinary Equipment
- Not suitable for use in presence of flammable anesthetic mixture
- Operation Mode – Continuous Operation

EQUIPMENT DESCRIPTION

General

Components

- Delivery System (FIGURE 1)
- Console (FIGURE 2 and 3)

Handpiece used with strippable fiber

Multi-Tip Handpiece used with disposable tips

FIGURE 1

FIGURE 2

Item#	Item	Item Description
1	CONTROL PANEL	Displays and controls the parameters, such as power output, presets, aiming beam intensity, and speaker volume.
2	EMERGENCY STOP BUTTON	Disables the unit in the event of an emergency. Push once to disable Picasso | Picasso Lite. Push again to enable.
3	HANDPIECE AND TIPS	Handpiece and optional tips for a variety of operation
4	HANDPIECE HOLDER	Holds handpiece when not in use
5	FIBER SPOOL	Stores fiber
6	KEYSWITCH	Turns display of the unit ON and OFF
7	AC ADAPTER	Connects the unit and net power supply Input: 100-240 V 50-60Hz Output: 9V--3A
8	CIRCUIT BREAKER	Master ON/OFF switch
9	REMOTE INTERLOCK CONNECTOR	Connects interlock to the unit
10	FOOTSWITCH CONNECTOR	Connects footswitch to the unit
11	POWER SUPPLY CONNECTOR	Connects power supply to the unit
12	FIBER CONNECTOR	Connects fiber to the unit

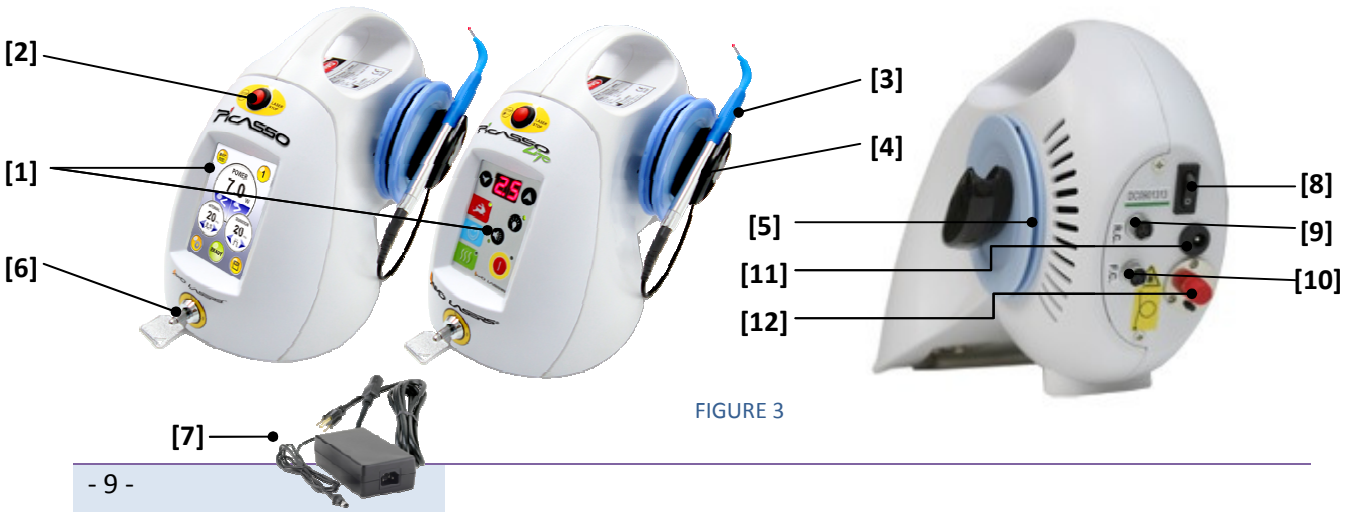


FIGURE 3

Picasso | Picasso Lite Setup

FIGURE 4

For Details refer to "Quick Start Guide" (Figure 4). See page 7 for identification of components.

1. Place unit in a clean, dry, and well ventilated area.
2. Verify circuit breaker is in OFF position.
3. Connect key into key switch. Verify it is in the OFF position.
4. Verify Emergency Stop button is disengaged (UP position).
5. Connect footswitch.
6. Connect remote interlock.
7. Connect power cord to power connector on unit and plug into wall outlet.
8. Connect fiber into fiber connection port.
9. Program Presets (see “Programming Presets”, page - 11 -).
10. Set up Delivery System handpiece and fiber (see page - 14 -).
11. See Operation Instructions on page - 17 -.

Control Panel Picasso

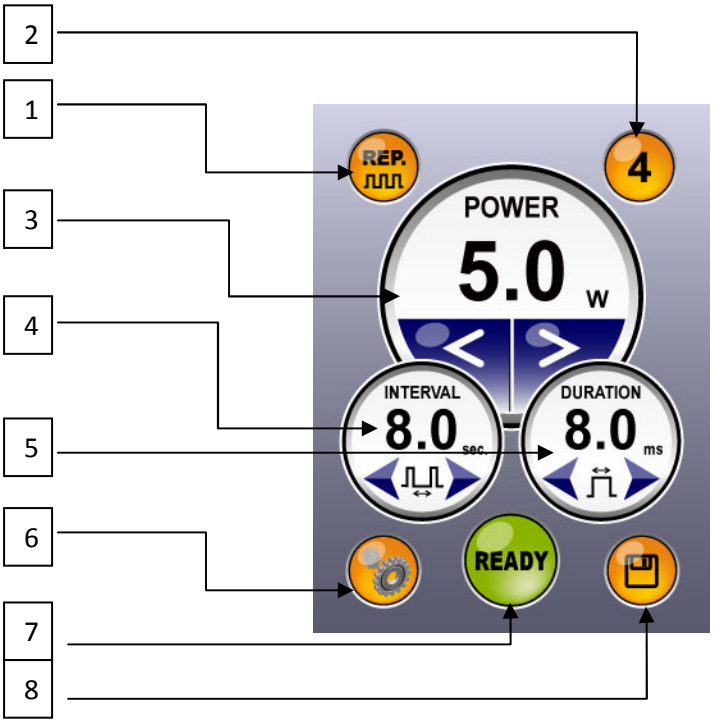


FIGURE 5

1. CONT/REP: Continuous 

or Repeating 

Modes
2. PRESETS: 1,2,3,4
3. POWER: 0.1-7W
4. INTERVAL: 20ms – 9.9 secs increments of .1ms
5. DURATION: 20 ms – 9.9 secs, setting increment is .1ms
6. SETTINGS: Language Selection | Aiming Beam Settings | Volume Settings

7. STANDBY/READY: 

Standby/ 

Ready button
8. SAVE: Save button

FIGURE 6

Language selection

Seven languages can be selected (Figure 6):

- English
- Spanish
- Portuguese
- Korean
- Japanese
- Russian
- Chinese

English is the default language.

To select another language, press  button. The system will then enter into the language selection display (Figure 5). Press desired language for 2 seconds, and the system will restart in the chosen language

AIMING BEAM brightness settings

To select the brightness for aiming beam, press  button. Press the  button to change the brightness settings.
5 steps: Off->Weakest->Weak->Strong ->Strongest

VOLUME settings

To select the volume of the unit, press the  button. Press the  button to change the volume settings.
5 steps: Mute->Quiet->Normal->Loud ->Very Loud

Setting Picasso

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.

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 and buttons (Figure 5, #4 and #5) to select desired interval and duration from 20ms to 9.9 sec.

STEP 2: Select desired preset 1-4 (Figure 5, #2)

STEP 3: POWER. Select desired power settings 0.1 – 7 watts using the and buttons (Figure 5, #3).

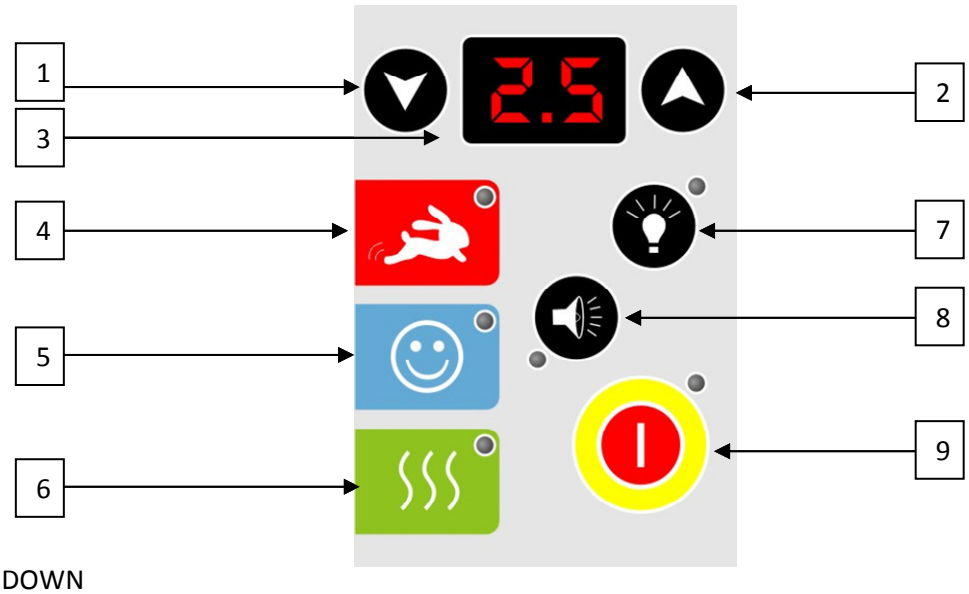
STEP 4: **INTERVAL / DURATION**. Select desired interval and duration (figure 5, #4 and #5) (available only on REP mode).

STEP 5: **SAVE**. Save desired settings by pushing the SAVE button for 2 seconds until the beep is heard (Figure 5, #8).

STEP 6: **READY**. Push **STANDBY** button (Figure 5, #7) to put unit into **READY** mode.
Press the footswitch to fire the laser.

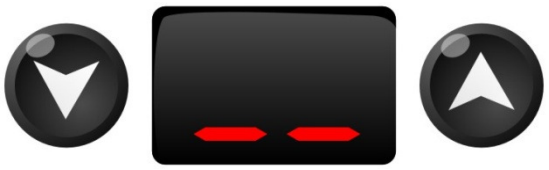
STEP 7: Repeat steps 1 through 6 to program additional presets.

Control Panel - Picasso Lite



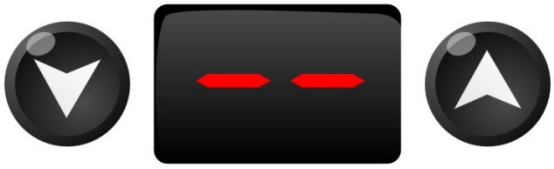
1. POWER DOWN
2. POWER UP
3. POWER DISPLAY
4. SPEED MODE
5. SUPER PULSE COMFORT MODE
6. DECONTAMINATION
7. AIMING BEAM SETTING: 3 steps: Off-> Low->High
8. VOLUME SETTING: 3 steps: Off-> Low->High
9. STANDBY / READY

TROUBLESHOOTING – PICASSO LITE



REMOTE INTERLOCK ERROR - Two horizontal lines on the bottom of the Power Display and a constant beeping sound indicate that the Remote Interlock is not in place, is inserted incorrectly, or that the Footswitch and Remote Interlock connections have been reversed.

Solution: Verify that the Remote Interlock and Footswitch connectors haven't been reversed. Remove and re-insert the Remote Interlock.



FOOTSWITCH ERROR - Two horizontal lines in the middle of the Power Display and constant beeping sound indicate that Footswitch is not connected or that the connector is inserted incorrectly.

Solution: Connect the Footswitch.

POWER SETTINGS AND USE

CUTTTING AND COAGULATING SOFT TISSUE

Cutting and coagulating soft tissue procedures can be utilized with the standard handpiece and fiber and at a range between 0.5 WATTS to 2.5 WATTS on either REPEAT or CONTINUOUS MODES. Operator should try to use the least amount of power (WATTS) to achieve desired results.

TOOTH-WHITENING (Picasso only)

Tooth whitening should be performed on single teeth at a distance of 10 mm at 7.0 WATTS in the CONTINUOUS MODE for 9.9 seconds per tooth with the standard hand-piece and fiber (uninitiated), or as indicated with the directions for bleaching materials as indicated by the manufacturer.

Delivery System - Strippable Fiber

NOTE: The fiber optic cable, handpiece, and tips are shipped non-sterile.

The Delivery System consists of:

- Fiber Optic Assembly

NOTE: The standard fiber optic cable assembly is a 400µm fiber. Other sizes are available upon request.

- Handpiece
- Accessories: Adapter (To be used with Disposable/Bendable Tip)
- Picasso | Picasso Lite Handpiece Kit

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" (see page - 21 -). Fiber optic cable is not autoclavable unless labeled as "autoclavable."

Picasso | Picasso Lite Handpiece

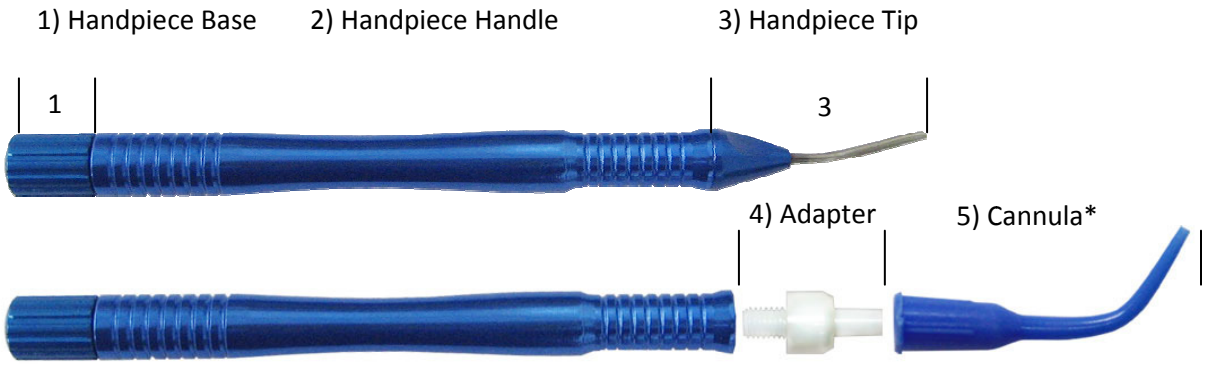


FIGURE 7

***** Customer supplied disposable tip (18 gauge or larger)

To connect handpiece to fiber optic assembly:

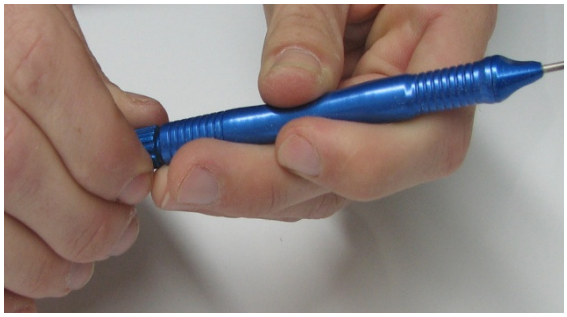


FIGURE 8

1. Loosen handpiece base (FIGURE 8)
2. Slide fiber through handpiece base, handle and tip
3. Approximately 3-4 inches (appx.7-10 cm) of fiber should protrude
4. Strip and cleave fiber (FIGURES 11 and 12) See directions Page - 15 -
5. Adjust to desired length
6. Gently tighten handpiece base to secure the fiber

Delivery System - Multi-Tip Handpiece

The delivery system used in conjunction with removable and disposable tips consists of the Multi-Tip Handpiece/fiber assembly (FIGURE 9):

FIGURE 9

The disposable tips (FIGURE 10) are for single use only. 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. To install a disposable tip, simply slide the tip over the handpiece until the tip is fully seated. The tip initiation procedure is the same as in the case of traditional fiber (refer to the Quick Start Guide).

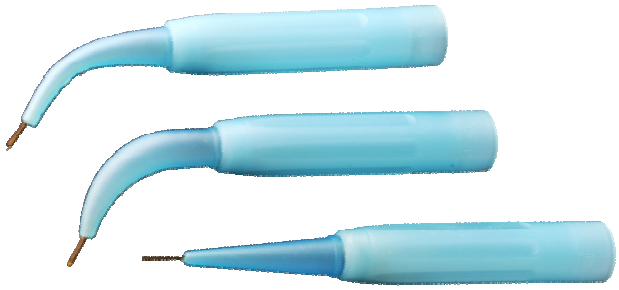


FIGURE 10

The Quadra Tip

The Quadra Tip (FIGURE 11) is used in conjunction with the Multi-Tip Handpiece. To use the Quadra Tip, simply slide it over the end of the Multi-Tip Handpiece. For instructions on bleaching, please refer to the application instructions supplied with the Bleaching Gel. Please note that the Quadra Tip is not autoclavable.

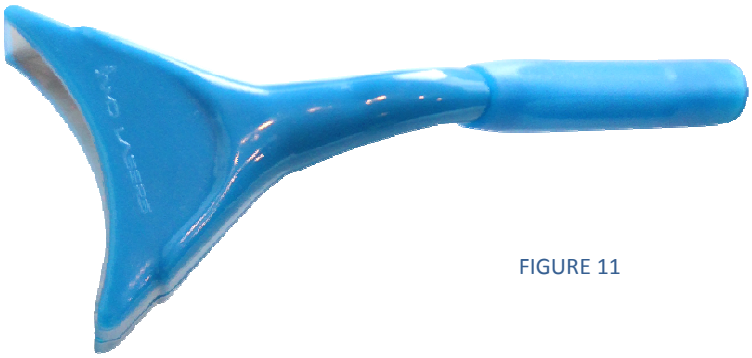


FIGURE 11

DIRECTIONS FOR STRIPPING AND CLEAVING PICASSO | PICASSO LITE FIBER

Picasso fiber should be cleave/scribed after each procedure.

To cleave/scribe the fiber:

1. Loosen the proximal end of the handpiece by unscrewing the handpiece base (Figure 8).
2. Push fiber optic cable into the base of the handpiece until fiber appears from the tip. Pull fiber approx. 3-4 inches (appx.7-10cm) out of the tip.
3. Select a fiber stripper that corresponds to the fiber diameter size.
4. Slide the black stop marker on the stripper to approximately 1 inch (25 mm). Insert fiber into the stripper until the end of the fiber touches the marker. Squeeze the stripper red 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 11).

FIGURE 11

5. Use the ceramic scribe to lightly scratch the end of the fiber. Place the fiber against a flat surface. Position the edge of the scribe approximately ¼ inch (0.6 cm) from the end of the fiber, and make a gentle scratch perpendicularly across the fiber (FIGURE 12), scribing (scratching) the surface at a 45 degree angle with the edge of the scribe. Make sure that the edge of the scribe is always perpendicular to the fiber during cleave/scribing (FIGURE 13).

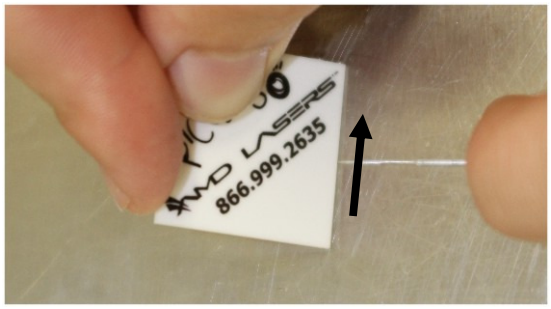


FIGURE 12

6. Hold the end of the fiber above the scribe 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.
7. Verify the scribe/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.
8. 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.

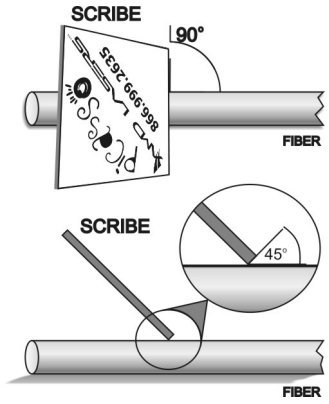


FIGURE 13

OPERATION INSTRUCTIONS

Turn ON Picasso

- Verify Red Emergency button (FIGURE 3, [2]) is depressed.
- Turn circuit breaker to ON position. See set-up page 9 for Circuit Breaker Location.
- Rotate key clockwise to ON position. The unit will turn on and begin a self-diagnostic routine for 4-5 seconds (FIGURE 14 – Picasso only).
- Select PRESET
- Press STAND-BY to place unit in READY Mode.
- Press foot control switch to fire laser and release to stop.

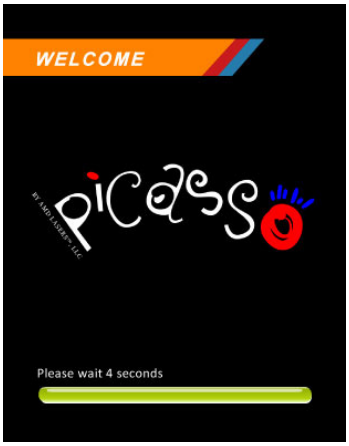


FIGURE 14

Turn OFF Picasso

- Press the STANDBY 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 fiber optic assembly is not twisted when returning the handpiece to the holder. Fiber may break if it is twisted.

Warm-up mode

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 the instructions on the display (Picasso only).

1. Press the READY button.
2. Press and hold the footswitch.
3. The LASER FIRING 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.
4. Hold the footswitch until the warm-up sequence stops.

NOTE: While output power is negligible, always wear protective glasses during the warm-up. The warm-up mode will not function at temperatures below 41°F (5°C), (Thermistor Error). Do not leave the system in an uncontrolled environment where the temperature might drop below 41°F (5°C) (i.e., the trunk of a car). If this happens, the system should be left to warm up to room temperature for ten to fifteen minutes before the warm-up mode is activated.

Picasso | Picasso Lite SPECIFICATIONS

General – Picasso | Picasso Lite

- Dimensions L x W x H -> 9.5'' x 6'' x 6.2'' (240 x 150 x 160mm)
- Weight 2.0 lbs (1 kg)

Electrical – Picasso | Picasso Lite

- Operating Voltage AC 110/230V ± 10%
- Current Rating 3A 1.5A
- Frequency 47-63Hz
- 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
- Pulse Duration 20 ms – 9.9 sec
- Pulse Interval 20 ms – 9.9 sec
- Delivery Fiber Diameter 200 - 1000µm
- Mode Multimode
- Max Output Power Range 7 Watts output 600µm or 400µm fiber ± 20%

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 Multimode
- Max Output Power Range 2.5 Watts output 200µm fiber ± 20%

Other Light Sources – Picasso | Picasso Lite

- Aiming Beam Diode Laser, max 5 mW, 630-670nm ± 20%

CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS

Contraindications

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.

Warnings

Eyewear

The doctor, patient, assistant, and any other persons in the operatory must wear appropriate laser eyewear protection for the diode laser wavelength of 810 ± 10 nm OD 5+.

Anesthesia

In soft tissue cases, anesthesia may not be required. Patients should be closely monitored for signs of pain or discomfort. If such signs are present, adjust settings, apply anesthesia, or cease treatment, if required.

Adjacent Structures

Picasso | Picasso Lite is designed to remove soft tissue. Therefore, always be aware of adjacent structures and substructures during procedures. Be extremely careful not to inadvertently 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 the laser beam reflecting.

Suction

Use high-speed suction as required to maintain a clear field of vision during treatment and/or during the treatment of herpetic lesions. Do not use Picasso | Picasso Lite if you cannot clearly see the treatment site. Mask with proper filtration should be utilized for the treatment of herpetic lesions.

Training

Only licensed professionals who are Certified in Class 4 laser use and have read and understood this Operating Instructions Manual should use this device. AMD LASERS®, LLC assumes no responsibility for parameters, techniques, methods, or results. Physicians must use their own clinical judgment and professionalism in determining all aspects of treatment, technique, proper power settings, interval, duration, etc.

CLINICAL APPLICATIONS

Introduction

To efficiently remove tissue, it is imperative to understand the nature of the Picasso | Picasso Lite. Picasso| Picasso Lite 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.

Indications of 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 impressions
- 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, including:

- Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including: gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility.)
- Laser soft tissue curettage
- 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

Tooth whitening Indications:

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

MAINTENANCE

Annual Maintenance

Picasso | Picasso Lite should be serviced annually by a qualified, trained, and certified technician.

Please contact your authorized representative or AMD LASERS®, LLC to discuss extended service contracts and annual maintenance options.

Daily Maintenance

Use a disinfectant to wipe down the front panel of Picasso | Picasso Lite system after each procedure. Do not use bleach or abrasive cleansers.

Contamination Control Procedures

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 unless labeled “autoclavable.”

Cleaning Instructions for Picasso | Picasso Lite Strippable Fiber Handpiece and the Fiber Optic Cable

FIGURE 15

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 | Picasso Lite Fiber Optic Delivery System.

Wear protective latex gloves when handling the contaminated delivery system. To disconnect the delivery system, follow the instruction for delivery system assembly presented in the "Delivery System" section.

High-level Disinfection Instructions for the Fiber Optic Cable

- Transport the delivery system to a decontamination/sterilization work area.
- Take the fiber and strip 1 inch (25mm) 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 CAVICIDE and submerge approximately 12 inches (30cm) 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 disinfecting solution, please follow the manufacturer’s instructions.

Steam Sterilization for Picasso | 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:

- Place the handpiece and interchangeable tips inside a single wrap self-seal autoclave pouch.
- Remove autoclave tray and place pouch(s) 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)
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.

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 unit unless it is completely packaged inside of its shipping box. If you have any questions regarding transportation, please call your authorized representative or AMD LASERS®, LLC.

Storage

Picasso | Picasso Lite should be stored in a cool, dry place when not in use. Cover the unit when not in use for extended periods of time. Store the system in a place where it will not be accidentally hit.

Picasso | Picasso Lite are shipped inside a custom shipping box. Please save and store the box in a cool, dry place.

CALIBRATION

Picasso | Picasso Lite comes factory calibrated and certified for use. For accurate treatment results, the unit(s) should be calibrated every 12 months following the date of manufacture. Due to the potential for electrical shock, personal injury, or death; calibration should only be performed by authorized personnel. Improper calibration could lead to damage and failure to calibrate the laser. Calibration by anyone other than a certified AMD LASERS technician will void the warranty.

To schedule calibration of your unit, contact your authorized representative or AMD LASERS®, LLC at (866) 999-2635 or +1 (317) 202-9530 to obtain an RMA. Calibration generally takes 5 business days (excluding holidays). Calibration of AMD LASERS units is performed with an output watt meter and AMD LASERS calibration software.

EQUIPMENT NEEDED

1. PC with Windows XP or better and a serial (RS-232) port
2. Laser power/energy head unit such as an Ophir Model II P/N 7Z01550 or equivalent
3. 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
4. AMD LASERS Calibration Software
5. AMD LASERS Calibration Data Cable
6. #1 Philips Head Screw Driver.

Picasso

TURN LASER OFF and UNPLUG PRIOR TO CALBRATION PROCEDURE.
Remove front and side panel
1: Set up software, and connect laser to computer. Reconnect front and side panel.
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 fields to increase or decrease the output wattage to within +/- 20% of the desired setting.
4: When appropriate output power is reached, select “save”, and proceed to the next setting.
5: Repeat steps 2-4 above until all fields have been properly adjusted.

Picasso Lite

TURN LASER OFF AND UNPLUG PRIOR TO TESTING
Remove front panel
1: Move and place the short circuit test ring onto the test pin to enter calibration mode. Reconnect the front panel.
2: Turn laser “on” and fire the laser with the tip approx 1-2mm 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.

Calibration schedule

Dates:	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)

APPENDIX A – LABELS & DESCRIPTIONS

FIGURE 16

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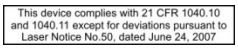
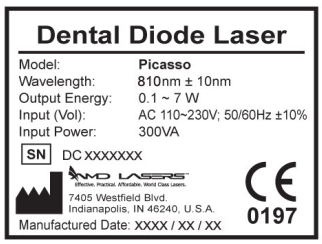


7



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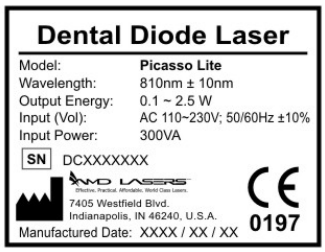

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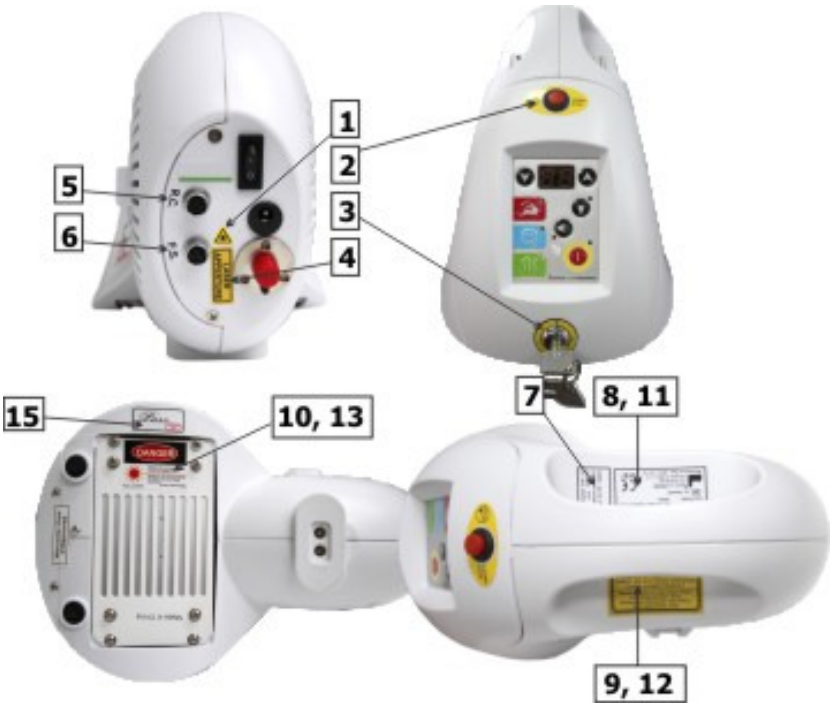
Label Positions



Label descriptions

1. **Warning for Laser Aperture Port**
   Black on Yellow triangle shaped – located on back of unit next to the laser output port
2. **Emergency Laser Stop**
   Black on Yellow – located on the front of unit surrounding the emergency off red button
3. **Laser Off – 0, Laser On – I**
   Black on Yellow – located on the front of the unit surrounding the key switch
4. **Laser Aperture label**
   Black on Yellow– located on back of unit next to the laser output port
5. **Foot Switch**
   Black on White – located on the back of the unit next to the foot switch port and on the wireless foot switch next to the foot switch port
6. **Remote Control**
7. **CDRH Compliance label**
   Black on White – located on top of the unit

8, 11. Manufacturer label
Black on White – located on the top of the unit

9, 12. IEC, Exploratory label
Black on yellow – located on the top of the unit

10, 13. Laser Danger label
Red and black on white – located on the bottom of the unit

14. **Fragile Keep Dry**
   Located on both ends of the shipping box
15. **Quality Control Acceptance label**
   Black on White – located on the bottom of the unit

APPENDIX B – PARTS AND ACCESSORIES

Picasso | Picasso Lite DESCRIPTION

- Handpiece (s)
- Fiber Optic Assembly
    - Strippable fiber(s) or Multi-Tip Handpiece fiber for use with disposable tips
- Disposable tips (optional)
- Quadra Tip (optional)
- Laser Safety Glasses*
    - Prescription eyewear is available. Please contact your local authorized representative or AMD LASERS®, LLC for additional information.
- Key(s)
- Remote Interlock Plug
- Power Cord
- Footswitch
- Laser Radiation Danger Sign
- Quick Start Guide
- Set-up DVD
- Diode Laser Certification Training Information

APPENDIX C – (LIMITED WARRANTY)

AMD LASERS®, LLC warrants for a period of thirty-six (36) months for the Picasso and twenty-four (24) months for Picasso Lite from shipment to the original purchaser/user Picasso | Picasso Lite Laser system serial number _____. It is warranted to be free from 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 to the original purchaser/user of the equipment and only so long as the equipment is used in the country to which is was originally shipped by AMD LASERS®, LLC or by its authorized distributor. This warranty does not cover maintenance of parts that fail due to normal use, including, but not limited to, the fiber optic cable and handpiece. Warranty does not cover annual calibration of unit. Warranty is void if unit is not calibrated within 60 days of annual calibration date.

This warranty is null and void if the user attempts to service the equipment (other than performing the maintenance described in the Operator Manual) or if service is performed by persons who are not trained or authorized to do so by AMD LASERS®, LLC. If the unit is found to be defective within the period specified above after examination by an authorized service representative or AMD LASERS®, LLC and the failure was due to defective materials and/or workmanship, AMD LASERS®, LLC will repair, or, at its option, replace the defective parts without charge. AMD LASERS®, LLC 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®, LLC in providing service, AMD LASERS®, LLC is released of all liabilities with respect to the equipment. Disposable or consumable items are not covered by this warranty. The handpiece and fiber optic cable are warranted for 30 days against defects in workmanship and materials. AMD LASERS®, LLC 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.

THE EXPRESS WARRANTY ABOVE IS THE SOLE WARRANTY OBLIGATION OF AMD LASERS®, LLC 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 OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. AMD LASERS®, LLC IS NOT RESPONSIBLE FOR CONSEQUENTIAL DAMAGES ARISING OUT OF ANY DEFECT, IMPROPER USE, OR UNAUTHORIZED SERVICE OR REPAIR.

Prior to return of a unit, or any portion thereof, AMD LASERS®, LLC MUST be consulted to avoid unnecessary shipping. If return of the equipment is deemed necessary, a Return Authorized Number (RMA) will be assigned. This number must be recorded on the outside of the shipping container.

In order to receive warranty service, Picasso | Picasso Lite lasers must be shipped to AMD LASERS® in the original transportation case and proper shipping box with the foam packaging.

APPENDIX D – (LIMITED LIABILITY)

AMD LASERS®, LLC 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®, LLC MATERIALS.

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